**Specificație tehnică completată**
**Ventilator pulmonar Adult, pediatric (caracteristici avansate) (110330)**
**Model: Hamilton-C6; Producător: HAMILTON Medical; Țara: Elveția**

| Specificarea tehnică deplină solicitată de către autoritatea contractantă | Specificarea tehnică deplină propusă de către autoritatea ofetantă |
|---|---|
| Ventilator pulmonar adult, pediatric (caracteristici avansate)<br>Cod 110330<br>Descriere Ventilatoarele mecanice oferă suport ventilator temporar sau permanent pentru pacienţii care nu pot respira pe cont propriu sau care au nevoie de asistenţă, menţinînd o ventilare adecvată.<br>Parametrul Specificația<br>Tip Mobil, pe suport cu rotile da<br>Tip pacient adult, pediatric da<br>Gama de control/setări Volum total 20-2,500 mL<br>Flux inspir 6-180 L/min<br>Presiune inspir 0-100 cm H2O<br>Rata respiratorie 0-100 rpm<br>Timp inspir 0.1 - 8 s.<br>Rata I:E 1:8 to 4:1<br>FiO2, % 21-100<br>Buton pentru respirație manuală da<br>PEEP/CPAP 0-50 cm H2O<br>Suport presiune 0-50 cm H2O<br>Inhalator da<br>Mecanism triger Presiune<br>Flux<br>Ajustarea presiunii pantă/rampă da<br>Funcția suspin da<br>Buton 100 % O2 da<br>Timpul maxim activ al butonului 100 % O2 2 min<br>Blocarea panoului de control da<br>Moduri de operare Modul<br>A/C A/C Volum respirator da<br>A/C presiune respiratorie da<br>Modul SIMV SIMV volum respirator da<br>SIMV presiune respiratorie da<br>Modul CPAP CPAP, CPAP/suport presiune (PS) da<br>Modul Apnea-backup da<br>Moduri combinate da<br>Ventilație neinvazivă da<br>Modul Bilevel/APRV da<br>Parametri monitorizați/afișați Presiunea inspiratorie maximă da<br>Presiunea medie în căile respiratorii da<br>Presiunea PEEP da<br>Volumul total da<br>Monitorizarea FiO2 da<br>Rata respiratorie da<br>Timp inspir da<br>Timp expir da<br>Rata I:E da<br>Volumul minutar spontan da<br>Alarme pacient FiO2 mare/mic da<br>Volum minutar mare/mic da<br>Presiune inspir mare/mică da<br>PIP mare da<br>PEEP mare da | Ventilator pulmonar adult, pediatric (caracteristici avansate) **DA**<br>Cod 110330<br>Descriere Ventilatoarele mecanice oferă suport ventilator temporar sau permanent pentru pacienţii care nu pot respira pe cont propriu sau care au nevoie de asistenţă, menţinînd o ventilare adecvată. **DA**<br>Parametrul Specificația<br>Tip Mobil, pe suport cu rotile **DA**<br>Tip pacient adult, pediatric **DA**<br>Gama de control/setări Volum total 20-2,000 mL **Da**<br>Flux inspir 6-180 L/min **DA maxim 260 L/min**<br>Presiune inspir 0-100 cm H2O **DA in modDuoPAP**<br>Rata respiratorie 0-**80** rpm **DA**<br>Timp inspir 0.1 - 12 s. **DA**<br>Rata I:E 1:9 to 4:1 **DA**<br>FiO2, % 21-100 **DA**<br>Buton pentru respirație manuală **DA**<br>PEEP/CPAP 0-50 cm H2O **DA**<br>Suport presiune 0-**100 cm H2O DA**<br>Inhalator **DA**<br>Mecanism triger Presiune **DA**<br>Flux **DA**<br>Ajustarea presiunii pantă/rampă **DA**<br>Funcția suspin **DA**<br>Buton 100 % O2 **DA**<br>Timpul maxim activ al butonului 100 % O2 2 min **DA**<br>Blocarea panoului de control **DA**<br>Moduri de operare<br>Modul A/C A/C Volum respirator **DA**<br>A/C presiune respiratorie **DA**<br>Modul SIMV SIMV volum respirator **DA**<br>SIMV presiune respiratorie **DA**<br>Modul CPAP CPAP, CPAP/suport presiune (PS) **DA**<br>Modul Apnea-backup **DA**<br>Moduri combinate **DA**<br>Ventilație neinvazivă **DA**<br>Modul Bilevel/APRV **DA**<br>Parametri monitorizați/afișați Presiunea inspiratorie maximă **DA**<br>Presiunea medie în căile respiratorii **DA**<br>Presiunea PEEP **DA**<br>Volumul total **DA**<br>Monitorizarea FiO2 **DA**<br>Rata respiratorie **DA**<br>Timp inspir **DA**<br>Timp expir **DA**<br>Rata I:E **DA**<br>Volumul minutar spontan **DA**<br>Alarme pacient FiO2 mare/mic **DA**<br>Volum minutar mare/mic **DA**<br>Presiune inspir mare/mică **DA**<br>PIP mare **DA**<br>PEEP mare **DA** |

| | |
|---|---|
| Lipsă PEEP da<br>Apnea da<br>Presiune/ocluzie continuă ridicată da<br>Inversare IE da<br>Circuit respirator deconectat da<br>Alarme echipament Lipsă alimentare gaz da<br>Lipsă alimentare electrică da<br>Baterie descărcată da<br>Eroare de sistem Sensor decalibrat, scurgere prin valve<br>Autodiagnostic da<br>Interfața Interfața cu dispozitivele exterioare da<br>Porturi pentru ieșirea datelor da<br>Port pentru alarmă la distanță da<br>Ieșire analogică da<br>Raportarea alarmelor și starea pacientului afișare pe display da<br>Transmiterea rapoartelor la imprimată da<br>Posibilitatea conectării în rețea centralizată da<br>Display LCD TFT da<br>Mărimea ≥ 15 inch<br>Touchscreen da<br>Compresor de aer Integrat în dispozitivului, tip turbină da<br>Alimentare Pneumatică Gazele comprimate aer, O2<br><br>Presiunea în rețea 3-6 atm<br>Electrică Rețea electrică 220 V, 50 Hz da<br>Baterie internă reîncărcabilă da<br>Timp operare baterie ≥ 1 h<br>Accesorii<br>Circuite respiratorii pediatrice tip reutilizabil 2 set.<br>adult tip reutilizabil 2 set.<br>Mască respiratorie pediatrice tip reutilizabil 1 set.<br>adult tip reutilizabil 1 set.<br>Umidificator Indicați modelul oferit model<br>Umidificator cu mentinerea temperaturi si umidificarea aerului în regim automa, Compatibil cu ventilatorul da<br>Minim două regimuri de funcționare: invaziv și neinvaziv da<br>Cameră de umidificare adult/pediatrice tip reutilizabil 1 buc.<br>Filtre antibacteriale pediatrice unică utilizare 100 buc.<br>adult unică utilizare 100 buc.<br>Senzor de debit adult/pediatrice tip reutilizabil 2 buc.<br><br>Plamăn de test adult tip reutilizabil 1 buc.<br>Suport pe rotile Indicați modelul oferit model<br><br>Min. 4 rotile da<br>Min. 2 roți cu frînă da<br>Braț articulat pentru fixarea furtunelor respiratorii da<br>Suport pentru fixarea/atașarea cablurilor electrice, furtunul aer, oxigen pentru transportare, depozitare da<br><br>Mîner pentru transportare da | Lipsă PEEP **DA**<br>Apnea **DA**<br>Presiune/ocluzie continuă ridicată **DA**<br>Inversare IE **DA**<br>Circuit respirator deconectat **DA**<br>Alarme echipament Lipsă alimentare gaz **DA**<br>Lipsă alimentare electrică **DA**<br>Baterie descărcată **DA**<br>Eroare de sistem Sensor decalibrat, scurgere prin valve **DA**<br>Autodiagnostic **DA**<br>Interfața Interfața cu dispozitivele exterioare **DA**<br>Porturi pentru ieșirea datelor **DA**<br>Port pentru alarmă la distanță **DA**<br>Ieșire analogică **DA**<br>Raportarea alarmelor și starea pacientului afișare pe display **DA**<br>Transmiterea rapoartelor la imprimată **DA**<br>Posibilitatea conectării în rețea centralizată **DA**<br>Display LCD TFT **DA**<br>Mărimea - 17 inch **DA**<br>Touchscreen **DA**<br>Compresor de aer Integrat în dispozitivului, tip turbină **DA**<br>Alimentare Pneumatică Gazele comprimate aer, O2 **DA**<br>Presiunea în rețea 3-6 atm **DA**<br>Electrică Rețea electrică 220 V, 50 Hz **DA**<br>Baterie internă reîncărcabilă **DA**<br>Timp operare baterie - 1,5 h **DA**<br>Accesorii<br>Circuite respiratorii pediatrice tip reutilizabil 2 set. **DA**<br>adult tip reutilizabil 2 set. **DA**<br>Mască respiratorie pediatrice tip reutilizabil 1 set. **DA**<br>adult tip reutilizabil 1 set. **DA**<br>Umidificator Indicați modelul oferit model **H-900 DA**<br>Umidificator cu mentinerea temperaturi si umidificarea aerului în regim automa, Compatibil cu ventilatorul **DA**<br>Minim două regimuri de funcționare: invaziv și neinvaziv **DA**<br>Cameră de umidificare adult/pediatrice tip reutilizabil 1 buc. **DA**<br>Filtre antibacteriale pediatrice unică utilizare 100 buc.<br>adult unică utilizare 100 buc. **DA**<br>Senzor de debit adult/pediatrice tip reutilizabil 2 buc. **DA**<br>Plamăn de test adult tip reutilizabil 1 buc. **DA**<br>Suport pe rotile Indicați modelul **este integrat in ventilator find ca parte componentă.**<br>Min. 4 rotile **DA**<br>Min. 2 roți cu frînă **DA**<br>Braț articulat pentru fixarea furtunelor respiratorii **DA**<br>Suport pentru fixarea/atașarea cablurilor electrice, furtunul aer, oxigen pentru transportare, depozitare **DA**<br>Mîner pentru transportare **DA** |

# Freigabedeckblatt zur handschriftlichen Freigabe von Hamilton Dokumenten

| | |
|---|---|
| Gültig für Dokument: | Declaration of Conformity |
| Nummer | DoC-CEDCL-H900_13 |
| Revision oder Version | 13 / -- |

**Dieses Freigabedokument ist zwingend dem Master-Exemplar beizulegen**

| Erstellt | Geprüft | | Freigegeben |
|---|---|---|---|
| Datum / Visum / Pers. Nr. | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | Datum / Visum / Pers. Nr. |
| 2020-12-14 22098 | Inhalt | 2020-12-14 [illegible] | 2020-12-14 A Weid/11GE |
| | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | |
| | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | |
| | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | |

* Wird zur Prüfung eine unbeteiligte Person (ohne direkte Projekt Beteiligung) hinzugezogen, ist diese mit „U" zu kennzeichnen.

HAMILTON MEDICAL
Intelligent Ventilation since 1983

# Declaration of Conformity

| | | |
|---|---|---|
| We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products | We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products | We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products |

**CEDCL-H900, Attachment on page 2**

| | | |
|---|---|---|
| meet the following EC directive (including all applicable amendments): | mit der folgenden EG-Richtlinie (einschliesslich aller zutreffenden Änderungen) übereinstimmt:<br><br>EC Medical Device Directive: 93/42/EEC, Annex II, Art. 3<br><br>All listed products are classified as class IIb. | sont en conformité avec le directive CE suivant (y compris leurs amendements, le cas échéant): |
| Please note, this EU Declaration of Conformity is issued under the sole responsibility of Hamilton Medical AG. | Bitte beachten Sie, dass diese EU Konformitätserklärung unter der alleinigen Verantwortung der Hamilton Medical AG ausgestellt wird. | Veuillez noter que cette déclaration de conformité UE est émise sous la seule responsabilité de Hamilton Medical AG. |

CE 0197

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany

Registration No: HD 60137935 0001

| **Validity:** | **Gültigkeit:** | **Validité:** |
|---|---|---|
| This declaration is valid for products manufactured in 2021. Lot numbers are traceable via manufacturing protocols. This declaration is valid in connection with the final inspection report. | Diese Konformitätserklärung gilt für Produkte, welche 2021. produziert werden. Die Losnummern sind über Fertigungsnachweise nachvollziehbar. Diese Konformitätserklärung ist gültig in Verbindung mit dem Endprüfprotokoll. | Cette déclaration est valable pour les produits fabriqués en 2021. Les numéros de lot peuvent être retracés par les preuves de production. Cette déclaration est valable associée au rapport d'inspection final. |

**Hamilton Medical AG**

Jens Hallek
CEO

Bonaduz, 04. JAN. 2021

DoC-CEDCL-H900_13

HAMILTON MEDICAL

Intelligent Ventilation since 1983

# CEDCL-H900 Attachment

| Product name | P/N | Basis UDI-DI / GTIN |
|---|---|---|
| HAMILTON-H900 | 950001 | 07630002801539 |
| | 950004 | 07630002801546 |
| | 950008 | 07630002801553 |

# Freigabedeckblatt zur handschriftlichen Freigabe von Hamilton Dokumenten

| | |
|---|---|
| Gültig für Dokument: | Declaration of Conformity |
| Nummer | DoC-CEDCL-HAM-C6_06 |
| Revision | 06 |
| oder | |
| Version | -- |

**Dieses Freigabedokument ist zwingend dem Master-Exemplar beizulegen**

| Erstellt | Geprüft | | Freigegeben |
|---|---|---|---|
| Datum / Visum / Pers. Nr. | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | Datum / Visum / Pers. Nr. |
| 2020-12-14 22098 | Inhalt | 2020-12-14 12378 | 2020-12-14 |
| | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | |
| | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | |
| | Geprüfter Aspekt | Datum / Visum / Pers. Nr. | |

* Wird zur Prüfung eine unbeteiligte Person (ohne direkte Projekt Beteiligung) hinzugezogen, ist diese mit „U“ zu kennzeichnen.

HAMILTON MEDICAL
Intelligent Ventilation since 1983

# Declaration of Conformity

| | | |
|---|---|---|
| We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products | Wir, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Schweiz, bestätigen, dass die folgenden Produkte | La société Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Suisse, confirme que les produits ci-dessous |

**CEDCL-HAM-C6, Attachment on page 2**

| | | |
|---|---|---|
| meet the following EC directive (including all applicable amendments): | mit der folgenden EG-Richtlinie (einschliesslich aller zutreffenden Änderungen) übereinstimmt: | sont en conformité avec le directive CE suivant (y compris leurs amendements, le cas échéant): |
| | EC Medical Device Directive: 93/42/EEC, Annex II, Art. 3<br><br>All listed products are classified as class IIb. | |
| Please note, this EU Declaration of Conformity is issued under the sole responsibility of Hamilton Medical AG. | Bitte beachten Sie, dass diese EU Konformitätserklärung unter der alleinigen Verantwortung der Hamilton Medical AG ausgestellt wird. | Veuillez noter que cette déclaration de conformité UE est émise sous la seule responsabilité de Hamilton Medical AG. |

CE 0197

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany

Registration No: HD 60137935 0001

| **Validity:** | **Gültigkeit:** | **Validité:** |
|---|---|---|
| This declaration is valid for products manufactured in 2021. Lot numbers are traceable via manufacturing protocols. This declaration is valid in connection with the final inspection report. | Diese Konformitätserklärung gilt für Produkte, welche 2021. produziert werden. Die Losnummern sind über Fertigungsnachweise nachvollziehbar. Diese Konformitätserklärung ist gültig in Verbindung mit dem Endprüfprotokoll. | Cette déclaration est valable pour les produits fabriqués en 2021. Les numéros de lot peuvent être retracés par les preuves de production. Cette déclaration est valable associée au rapport d'inspection final. |

**Hamilton Medical AG**

Jens Hallek
CEO

Bonaduz, 04. JAN. 2021

HAMILTON MEDICAL
Intelligent Ventilation since 1983

# CEDCL-HAM-C6 Attachment

| Product name | P/N | Basis UDI-DI / GTIN |
|---|---|---|
| HAMILTON-C6 | 160021 | 07630002808590 |

# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems

Replaces certificate, registration no.: HD 60137935 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

# EC Certificate

TÜVRheinland®

**Full Quality Assurance System**
**Directive 93/42/EEC on Medical Devices, Annex II excluding (4)**

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification includes the following manufacturing sites:

| No. | Location |
|---|---|
| /01 | Hamilton Medical AG<br>Via Crusch 8<br>7402 Bonaduz<br>Switzerland |
| /02 | Hamilton Medical AG<br>Parc Industrial Vial 10<br>7013 Domat/Ems<br>Switzerland |
| /03 | Hamilton Medical AG<br>Parc Industrial Vial 4<br>7013 Domat/Ems<br>Switzerland |

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Bevollmächtigter

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

# Certificate

TÜVRheinland®

**Quality Management System**
**EN ISO 13485:2016**

Registration No.: SX 1093044-1

Organization: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Scope: Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3348226-90
Effective date: 2021-05-19
Expiry date: 2023-07-08
Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierstelle

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

# Certificate

TÜVRheinland®

**Quality Management System**
**EN ISO 13485:2016**

Registration No.: SX 1093044-1

Organization: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification also covers the following locations:

| No. | Facility | Scope |
|---|---|---|
| /01 | c/o Hamilton Medical AG<br>Via Crusch 8<br>7402 Bonaduz<br>Switzerland | Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems |
| /02 | c/o Hamilton Medical AG<br>Parc Industrial Vial 10<br>7013 Domat/Ems<br>Switzerland | Manufacturing and servicing |
| /03 | c/o Hamilton Medical UK Ltd.<br>Unit 1 Forge Mills Park<br>Station Road<br>Coleshill<br>Birmingham<br>B46 1JH<br>United Kingdom | Distribution and servicing |
| /04 | c/o Hamilton Medical AG<br>Parc Industrial Vial 4<br>7013 Domat/Ems<br>Switzerland | Manufacturing of ventilator sensors and tubing systems |

Report No.: 3348226-90
Effective date: 2021-05-19
Expiry date: 2023-07-08
Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

# HAMILTON-C6

## Technical specifications for SW version 1.1.x

### Ventilation modes

| Mode form | Mode name | Mode | Adult/Ped | Neonatal |
|---|---|---|---|---|
| Volume-controlled, flow-controlled | (S)CMV | Breaths are volume controlled and mandatory, including patient triggered breaths. | ✓ | -- |
| | SIMV | Volume controlled mandatory breaths can be alternated with pressure-supported spontaneous breaths. | ✓ | -- |
| Volume-targeted, adaptive pressure-controlled | APVcmv / (S)CMV+ | Breaths are volume targeted and mandatory. | ✓ | ✓ |
| | APVsimv / SIMV+ | Volume-targeted mandatory breaths can be alternated with pressure-supported spontaneous breaths. | ✓ | ✓ |
| Pressure-controlled | PCV+ | All breaths, whether triggered by the patient or the ventilator, are pressure controlled and mandatory. | ✓ | ✓ |
| | P-SIMV+ | Mandatory breaths are pressure controlled. Mandatory breaths can be alternated with pressure-supported spontaneous breaths. | ✓ | ✓ |
| | DuoPAP | Mandatory breaths are pressure controlled. Spontaneous breaths can be triggered at both pressure levels. | ✓ | ✓ |
| | APRV | Spontaneous breaths can be continuously triggered. The pressure release between the levels contributes to ventilation. | ✓ | ✓ |
| | SPONT | Every breath is spontaneous, with or without pressure-supported spontaneous breaths. | ✓ | ✓ |
| Intelligent ventilation | ASV® | Operator sets %MinVol, PEEP, and Oxygen. Frequency, tidal volume, pressure, and I:E ratio are based on physiological input from the patient. | ✓ | -- |
| | INTELLiVENT®-ASV | Fully automated management of ventilation and oxygenation based on physiological input from the patient. The underlying mode is ASV. | O | -- |
| Noninvasive ventilation | NIV | Every breath is spontaneous. | ✓ | ✓ |
| | NIV-ST | Every breath is spontaneous as long as the patient is breathing above the set rate. A backup rate can be set for mandatory breaths. | ✓ | ✓ |
| | nCPAP-PS | Every breath is spontaneous as long as the patient is breathing above the set rate. A backup rate can be set for mandatory breaths. | -- | O |
| Oxygen therapy | HiFlowO2 | High flow oxygen therapy. No supported breaths. | O | O |

Standard: ✓ Option: O Not applicable: --

Swiss Quality

HAMILTON MEDICAL

Intelligent Ventilation since 1983

## Standard configuration and options (in alphabetical order)

| Functions | Adult / Ped | Neonatal |
|---|---|---|
| Capnography, mainstream (volumetric) and sidestream | O | O |
| Communication ports: Three COM ports, two USB ports, DVI, Nurse call | ✓ | ✓ |
| Communication protocols: for details see Connectivity brochure | ✓ | ✓ |
| Dynamic Lung (real-time visualization of the lungs) | ✓ | -- |
| Event log (up to 10,000 events with date and time stamp) | ✓ | ✓ |
| HAMILTON-H900 humidifier control via ventilator | O | O |
| Inspiratory and expiratory hold maneuver | ✓ | ✓ |
| IntelliCuff® cuff pressure controller control via ventilator | O | O |
| IntelliSync+ (inspiratory and expiratory trigger synchronization) | O | -- |
| IntelliTrig (leak compensation) | ✓ | ✓ |
| Languages (English, US English, Chinese, Croatian, Czech, Danish, Dutch, Finnish, French, German, Greek, Hungarian, Indonesian, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Spanish, Swedish, Turkish) | ✓ | ✓ |
| Manual breath / prolonged inspiration | ✓ | ✓ |
| Nebulization (Aerogen[5]) | O | O |
| Nebulization (pneumatic) | ✓ | -- |
| O2 enrichment | ✓ | ✓ |
| On-screen help | ✓ | ✓ |
| P/V Tool® Pro | O | O |
| Paramagnetic O2 sensor | O | O |
| Patient group | ✓ | O |
| Print screen | ✓ | ✓ |
| Screen lock | ✓ | ✓ |
| Second battery | O | O |
| SpO2 monitoring | O | O |
| Standby with timer | ✓ | ✓ |
| Suctioning tool | ✓ | ✓ |
| Transpulmonary pressure monitoring | ✓ | ✓ |
| TRC (tube resistance compensation) | ✓ | ✓ |
| Trends/Loops | ✓ | ✓ |
| Trigger, flow and pressure selectable | ✓ | ✓ |
| Vent Status (Visual representation of ventilator dependence) | ✓ | ✓ |

Standard: ✓ Option: O Not applicable: --

## Technical performance data (in alphabetical order)

| Description | Specification |
|---|---|
| Automatic expiratory base flow | Fixed at 6 l/min |
| Inspiratory pressure | 0 to 100 cmH2O |
| Maximum inspiratory flow | 260 l/min |
| Means of inspiratory triggering | Flow trigger control, pressure trigger control, or optional IntelliSync+ control |
| Means of expiratory triggering | Flow cycle (ETS), or optional IntelliSync+ control |
| Minimum expiratory time | 20% of cycle time; 0.2 to 0.8 s |
| O2 input flow | 80-150 l/min (at 2.8 bar/ 280 kPa / 41 psi input pressure) |
| Oxygen mixer accuracy | ± (Volume fraction of 2.5% + 2.5% of actual reading) |
| Preoperational checks | Tightness test, flow sensor/O2 sensor/CO2 sensor calibration |
| Tidal volume | Adult/Ped: 20 to 2000 ml<br>Neonatal: 2 to 300 ml |

## Standards and approvals

| | |
|---|---|
| Classification | Class IIb, continuously operating according to EC directive 93/42/EEC |
| Certification | EN 60601-1:2006/A1:2013, IEC 60601-1-2:2014, ANSI/AAMI ES60601-1:2005/(R)2012, ISO 80601-2-12:2011, CAN/CSA-C22.2 NO. 60601-1:14, EN ISO 5356-1:2015, ISO 80601-2-55:2011 |
| Declaration | The HAMILTON-C6 was developed in accordance with pertinent international standards and FDA guidelines. The ventilator is manufactured within an EN ISO 13485 and EN ISO 9001, Council Directive 93/42/EEC, Annex II, Article 3 certified quality management system. The ventilator meets the Essential Requirements of Council Directive 93/42/EEC, Annex I. |
| Electromagnetic compatibility | According to IEC 60601-1-2:2014 |
| Safety Class | Class I, Type B applied part (ventilator breathing system, VBS), type BF applied parts CO2 sensor including CO2 module connector, humidifier, Aerogen[5] system, nebulizer, and SpO2 sensor including SpO2 adapter, continuous operation according to IEC 60601-1 |

## Pneumatic specifications

| | | |
|---|---|---|
| O2 | Input pressure | 2.8 to 6 bar / 41 to 87 psi |
| | Connector | DISS (CGA 1240) or NIST |
| Air supply | | Integrated turbine with lifetime warranty |
| Inspiratory outlet (To patient port) | Connector | ISO 15 mm ID/22 mm OD conical |
| Expiratory outlet (From patient port) | Connector (on expiratory valve) | ISO 15 mm ID/22 mm OD conical |

## Electrical specifications

| | | |
|---|---|---|
| Input power | 100 to 240 VAC ±10%, 50/60 Hz | |
| Power consumption | 60 VA typical, 210 VA | |
| | (485 VA with humidifier) maximum | |
| Battery | Electrical specifications: | 14.4 V, 5.0 Ah, 72 Wh, 48 W typical, 288 W maximum |
| | Type: | Lithium-ion |
| | Normal operating time: | ≥ 90 min with one battery / ≥ 180 min with two batteries |

## Graphical patient data

| Graphic type/Tab name | Options |
|---|---|
| Waveforms | Pressure, Flow, Volume, Off, PCO2[1], FCO2[1], Plethysmogram[1], Ptrachea, Pes, Ptranspulm |
| Intelligent panels | Dynamic Lung[2], Vent Status, ASV Graph[3], SMPs (Secondary monitoring parameter) |
| Trends | 1-, 6-, 12-, 24-, or 72-h trend data for a selected parameter or combination of parameters |
| Loops | Pressure/Volume, Pressure/Flow, Volume/Flow, Volume/PCO2[1], Volume/FCO2[1], Pes/Volume, Ptranspulm/Volume |

## Alarms[4]

| Priority | Alarm |
|---|---|
| High priority | Apnea time (s), ExpMinVol high/low (l/min), Oxygen high/low (%), Pressure high/low (cmH2O), Flow sensor calibration needed, Exhalation obstructed, Disconnection, Oxygen supply failed |
| Medium priority | fTotal high/low (b/min), PetCO2 high/low (mmHg), Pressure limitation (cmH2O), Vt high/low (ml), SpO2 high/low, SpOC high/low, %leak, High PEEP, Loss of PEEP, Pulse high/low |
| Low priority | High SpO2, Loss of external power, Cuff leak |

1 CO2 + SpO2 option required | 2 For adult/pediatric patients only | 3 Only available in ASV mode | 4 For complete list of alarms see operation manual

## Control settings and ranges[5]

| Parameter (units) | Range Adult/Ped | Range Neonatal |
|---|---|---|
| Apnea backup | On, Off | On, Off |
| Cuff pressure (cmH2O) | 0 to 50 | 0 to 50 |
| Expiratory trigger sensitivity ETS (%) | 5 to 80 | 5 to 80 |
| Flow for HiFlowO2 therapy (l/min) | 2 to 80 | 2 to 12 |
| Flow pattern | Square, 50% decelerating, Sine, 100% decelerating | -- |
| Flow trigger (l/min) | 0.5 to 20, off | 0.1 to 5.0, off |
| Gender (sex) | Male, Female | -- |
| I:E | 1:9 to 4:1 | 1:9 to 4:1 |
| %MinVol (%) | 25 to 350 | -- |
| Nebulizer Duration (min) | 5 to 40, continuous | 5 to 40, continuous |
| Nebulizer Synchronisation | Inspiration, Exhalation, Insp. and Exh. | Inspiration, Exhalation, Insp. and Exh. |
| Oxygen (%) | 21 to 100 | 21 to 100 |
| P high (cmH2O) (only in DuoPAP and APRV) | 0 to 100 | 0 to 60 |
| P low (cmH2O) (only in APRV) | 0 to 50 | 0 to 25 |
| Pasvlimit (cmH2O) | 5 to 100 | -- |
| Pat. height (cm) (in) | 30 to 250 / 12 to 98 | -- |
| Pause (%) | 0 to 70 | -- |
| Pcontrol (cmH2O) | 5 to 100 | 3 to 60 |
| Peak flow (l/min) | 1 to 195 | -- |
| PEEP/CPAP (cmH2O) | 0 to 50 | 0 to 25 |
| Pinsp (cmH2O) | 3 to 100 | 0 to 60 |
| P-ramp (ms) | 0 to 2000 | 0 to 600 |
| Pressure trigger (cmH2O) | -0.1 to -15.0, off | -0.1 to -15.0, off |
| Psupport (cmH2O) | 0 to 100 | 0 to 60 |
| Rate (b/min) | 1 to 80 | 1 to 150 |
| Sigh | On, Off | -- |
| T high (s) (only in DuoPAP und APRV) | 0.1 to 40 | 0.1 to 40 |
| T low (s) (only in APRV) | 0.2 to 40 | 0.2 to 40 |
| TI (s) | 0.1 to 12 | 0.1 to 12 |
| TI max (s) | 0.5 to 3 | 0.25 to 3.0 |
| Tip (s) | 0 to 8 | -- |
| Tpause (s) | 0 to 30 | 0 to 30 |
| TRC compensation (%) | 0 to 100 | 0 to 100 |
| Vt (ml) | 20 to 2000 | 2 to 300 |
| Weight (kg) | -- | 0.2 to 30.0 |

5 Parameter settings and ranges can change depending on the mode

## Monitoring parameter

| Parameter (units) | | Description |
|---|---|---|
| Pressure | AutoPEEP (cmH2O) | Unintended positive end-expiratory pressure |
| | Paw (cmH2O) | Airway pressure |
| | ΔP (cmH2O) | Driving pressure |
| | PTP (cmH2O*s) | Inspiratory pressure time product |
| | Pcuff (cmH2O) | Cuff pressure |
| | Ptrans I (cmH2O) | The arithmetic mean value of Ptranspulm over the last 100 ms of the last inspiration. |
| | Ptrans E (cmH2O) | The arithmetic mean value of Ptranspulm over the last 100 ms of the last expiration. |
| | PEEP/CPAP (cmH2O) | PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure) |
| | Pinsp (cmH2O) | Inspiratory pressure |
| | Pmean (cmH2O) | Mean airway pressure |
| | Ppeak (cmH2O) | Peak airway pressure |
| | Pplateau (cmH2O) | Plateau or end-inspiratory pressure |
| | Pes min (cmH2O) | See PEEP. The pressure is measured through the Pes port instead of using airway pressure. |
| | Pes max (cmH2O) | See Ppeak. The pressure is measured through the Pes port instead of using airway pressure. |
| | Pes plateau (cmH2O) | See Pplateau. The pressure is measured through the Pes port instead of using airway pressure. |
| | Pes PTP (cmH2O) | See PTP. The pressure is measured through the Pes port instead of using airway pressure. |
| | Pes P0.1 (cmH2O) | See P0.1. The pressure is measured through the Pes port instead of using airway pressure. |
| Flow | Control Flow (l/min) | The set flow of gas to the patient. HiFlowO2 mode only. |
| | Insp Flow (l/min) | Peak inspiratory flow, spontaneous or mandatory |
| | Exp Flow (l/min) | Peak expiratory flow |
| Volume | ExpMinVol or MinVol NIV (l/min) | Expiratory minute volume |
| | MVSpont or MVSpont NIV (l/min) | Spontaneous expiratory minute volume |
| | VTE or VTE NIV (ml) | Expiratory tidal volume |
| | VTESpont (ml) | Spontaneous expiratory tidal volume |
| | VTI or VTI NIV (ml) | Inspiratory tidal volume |
| | Vt/IBW<br>Vt/Weight (ml/kg) | Tidal volume according to ideal body weight (IBW) for adult/ pediatric patients and according to the actual body weight for neonatal patients. |
| | VLeak (%) or MVLeak (l/min) | Leakage percent or total minute volume leakage |

## Monitoring parameter (continued)

| Parameter (units) | | Description |
|---|---|---|
| CO2 | FetCO2 (%) | Fractional end-tidal CO2 concentration |
| | PetCO2 (mmHg) | End-tidal CO2 pressure |
| | slopeCO2 (%CO2 / l) | Slope of the alveolar plateau in the PetCO2 curve, indicating the volume/flow status of the lungs |
| | Vtalv (ml) | Alveolar tidal ventilation |
| | V'alv (l/min) | Alveolar minute ventilation |
| | V'CO2 (ml/min) | CO2 elimination |
| | VDaw (ml) | Airway dead space |
| | VDaw/VTE (%) | Airway dead space fraction at the airway opening |
| | VeCO2 (ml) | Exhaled CO2 volume. |
| | ViCO2 (ml) | Inspired CO2 volume |
| SpO2 | SpO2 (%) | Oxygen saturation |
| | Pulse (1/min) | Pulse |
| | Plethysmogram | The waveform that visualizes the pulsating blood volume; it is delivered by the pulse oximeter. |
| | SpO2/FiO2 (%) | The SpO2/FiO2 ratio (%) is an approximation of the PaO2/FiO2 ratio, which, in contrast to PaO2/FiO2, can be calculated noninvasively and continuously. |
| | PI (%) | Perfusion index |
| | PVI (%) | Pleth variability index |
| | SpCO (ml/dl)[2] (%) | Carboxyhaemoglobin saturation |
| | SpMet (%) | Methaemoglobin saturation |
| | SpHb (g/dl) (mmol/l) | Total haemoglobin |
| | SpOC (ml/dl) | Oxygen content |
| Oxygen | Oxygen (%) | Oxygen concentration of the delivered gas |
| Time | I:E | Inspiratory:expiratory ratio |
| | fControl (b/min) | Mandatory breath frequency |
| | fSpont (b/min) | Spontaneous breathing frequency |
| | fTotal (b/min) | Total breathing frequency |
| | TI (s) | Inspiratory time |
| | TE (s) | Expiratory time |
| | Pause (s) | Inspiratory pause or plateau |
| Lung mechanics | Cstat (ml/cmH2O) | Static compliance |
| | P0.1 (cmH2O) | Airway occlusion pressure |
| | PTP (cmH2O*s) | Pressure time product |
| | RCexp (s) | Expiratory time constant |
| | Rinsp (cmH2O/(l/s)) | Inspiratory flow resistance |
| | RSB (1/(l*min)) | Rapid shallow breathing |




## Physical characteristics

| | |
|---|---|
| Weight | Monitor (interaction panel) 7.8 kg (17.2 lb), with shelf mount: 10.0 kg (22.0 lb)<br>Ventilation unit, shelf mount: 10.5 kg (23.15 lb)<br>46 kg (101 lb) with trolley, monitor, ventilation unit<br>The trolley can accommodate a maximum safe working load of 80 kg (176 lb) |
| Dimensions | See graphic above |
| Monitor | Type: Color TFT, Size: 1920 x 1200 pixels, 17 in (431.8 mm) diagonal |
| Monitor mounting options | VESA, pole mount, rail mount, handle mount |
| Trolley accessories | Basket, O2 cylinder holder (two bottles), HAMILTON-H900 mounting system, additional standard rail |

Manufacturer:

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 (0)58 610 10 20

info@hamilton-medical.com

**www.hamilton-medical.com**

689596.02

IEC IECEE CB SCHEME

Ref. Certif. No.

**DE 3 - 41071**

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

# CB TEST CERTIFICATE
# CERTIFICAT D'ESSAI OC

| | |
|---|---|
| Product | Humidifiers for medical use |
| Name and address of the applicant | **Hamilton Medical AG**<br>Via Crusch 8<br>7402 Bonaduz<br>SWITZERLAND |
| Name and address of the manufacturer | Hamilton Medical AG<br>Via Crusch 8, 7402 Bonaduz, SWITZERLAND |
| Name and address of the factory | Hamilton Medical AG<br>Parc Industrial Vial 10, 7013 Domat/Ems, SWITZERLAND |
| Ratings and principal characteristics | Rated Voltage: Ref: 950008 100 VAC (Japan)<br>Ref: 950004,110-127 VAC (USA)<br>Ref: 950001, 220-240 VAC (Europe)<br>Rated Frequency: 50/60 Hz<br>Rated Power Input: 260 VA (Japan)<br>293 VA (USA)<br>283 VA (Europe)<br>Protection Class: I<br>Type: BF<br>Protection against Ingress of water: IP21 |
| Trade mark (if any) | HAMILTON MEDICAL |
| Model/type Ref. | HAMILTON-H900, 950008, 950004, 950001 |
| Additional information (if necessary) | Certificate DE 3 – 40622 issued on 2016-10-05 is replaced by this certificate due to technical changes. Cl. 11.7, Biocompatibility and clause 17 EMC are excluded. IEC 62304:2006, IEC 62366:2007 and IEC 62366:2007/AMD1:2014 are also applied. |
| A sample of the product was tested and found to be in conformity with | IEC 60601-1:2005<br>IEC 60601-1:2005/AMD1:2012<br>IEC 60601-1-8:2006<br>IEC 60601-1-8:2006/AMD1:2012<br>IEC 60601-1-6:2010<br>IEC 60601-1-6:2010/AMD1:2013 |
| as shown in the Test Report Ref. No. which forms part of this certificate | 713145152 |

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

CB 058067 0078 Rev. 00
Date, 2019-01-11

( Paul Bielawski )

TÜV SÜD Product Service


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany


# HAMILTON-H900

Instructions for use
Gebrauchsanweisung
Instructions d'utilisation
Instrucciones de uso
Istruzioni per l'uso
Instruções de uso
Инструкции по эксплуатации
Kullanım talimatları
使用说明

**REF** 950001 (230 V) | 950004 (115 V) | 950008 (100 V)

Software version | Softwareversion | Version logicielle | Versión de software
Versioni software | Versão de software | Версия программного обеспечения
Yazılım sürümü | 软件版本 1.10x

624431/09 | 2021-01-11

CE 0197 EAC

HAMILTON MEDICAL
Intelligent Ventilation since 1983

# Instructions for use

## HAMILTON-H900

2021-01-11

624431/09

**Manufacturer**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz,
Switzerland
Phone: (+41) 58 610 10 20
Fax: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

**Distributor in USA**

Hamilton Medical, Inc.
4655 Aircenter Circle, Reno, NV
89502
Phone: (775) 858-3200
Toll-free: (800) 426-6331
Fax: (775) 856-5621
info@hamiltonmedical.com
www.hamilton-medical.com

# Table of Contents

# Preface

Be sure to read the documentation before using the device or accessories.

### Conventions used in this guide

In this manual:

- Button names are shown in a **bold** font.
- The graphics shown may not exactly match what you see in your environment.
- Not all features are available in all markets.

Safety messages are displayed as follows:

**⚠ WARNING**

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

**⚠ CAUTION**

*Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.*

***NOTICE***

Emphasizes information of particular importance.

In tables, safety messages are indicated as follows:

**⚠ WARNING!**

**⚠ CAUTION!**

**NOTICE!**

To download the latest version of this manual or other documents, visit the MyHamilton website:
https://www.hamilton-medical.com/MyHamilton

Hamilton Medical offers the Hamilton Medical College, which provides a variety of learning modules free of charge. To register, go to:
http://college.hamilton-medical.com/

**⚠ CAUTION**

*(USA only): Federal law restricts this device to sale by or on the order of a physician.*

### Intended use

The HAMILTON-H900 humidifier is intended for respiratory gas conditioning during invasive and noninvasive mechanical ventilation.

The device is intended for use in the hospital and institutional environment where health care professionals provide patient care.

The HAMILTON-H900 humidifier is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

# 1 Safety information

This section provides safety information related to setting up, operating, and servicing the humidifier.

**Carefully review all parts of this safety section before setting up and using the humidifier.**

**Be sure to review the Instructions for Use before using the humidifier.**

**Be sure to read the Instructions for Use provided with any devices and accessories used with the humidifier before use.**

If you have questions about any of the information in this manual, contact your Hamilton Medical representative or technical service personnel.

## 1.1 Electromagnetic susceptibility

**⚠ WARNING**

- **MR UNSAFE**. Keep away from magnetic resonance imaging (MRI) equipment. The HAMILTON-H900 poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
- Functioning of the humidifier may be impaired by the operation of high-frequency surgical equipment, microwaves, shortwaves, or strong magnetic fields in close proximity.
- To prevent increased emissions, decreased immunity, or interrupted operation of the HAMILTON-H900 humidifier or any accessories, use only accessories or cables that are expressly stated in this manual or in the Hamilton Medical e-catalog.
- Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (for example, IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1, clause 16).
- Anybody connecting additional equipment to medical electrical equipment configures a medical system and is, therefore, responsible that the system complies with the requirements for medical electrical systems. Note that local laws take priority over the above-specified requirements. If you have questions about how to proceed, consult your Hamilton Medical representative or technical service department.
- The humidifier is *not* protected against the effects of the discharge of a cardiac defibrillator.

***NOTICE***

- The HAMILTON-H900 humidifier requires special precautions regarding EMC (Electromagnetic Compatibility), and must be installed and put into service according to the EMC information provided in the *HAMILTON-H900 EMC Declarations*.
- Portable and mobile RF communications equipment can affect the HAMILTON-H900 humidifier.

## 1.2 Electrical power

**⚠ WARNING**

- To minimize the risk of electric shock, plug the humidifier power cord into an appropriate grounded power receptacle. It is the hospital's responsibility to ensure that the receptacle is properly grounded (earth).
- *Do not* use if the power cord is damaged.
- In case of incorrect voltage, power failure, or disconnection from the power supply, the humidifier emits an audible whistling sound. Turn the device off immediately and check for correct voltage.
- Ensure the correct voltage is used.

## 1.3 Fire and other hazards

**⚠ WARNING**

Do *not* use the humidifier in hazardous areas or with flammable gases.

## 1.4 General operation and setup

**⚠ WARNING**

- Before using the humidifier on the patient, verify that the breathing circuit is correctly connected to the ventilator as follows:

  – The blue inspiratory limb is connected to the *To patient* inspiratory port.

  – The white expiratory limb is connected to the *From patient* expiratory port.
- Use only parts and accessories specified in Section 8. Doing so ensures proper humidifier operation and prevents possible patient injury.
- Do not use the humidifier at an altitude above 4,000 meters or outside a temperature range of 10°C to 40°C. Using the humidifier above this altitude or outside of this temperature range can affect the quality of the therapy or injure the patient.
- Incorrect humidity or temperature settings can harm the patient.
- Do *not* use the humidifier during transfer of a ventilated patient outside the hospital.
- Turn ON the humidifier *after* turning on the ventilator.
- Turn OFF the humidifier *before* turning off the ventilator.
- Do not cover the humidifier IR measurement cells.
- Invasive (**INV**) mode must *only* be used with intubated and tracheostomized patients.
- Take additional precautions in case of allergic reactions.
- Regularly check the breathing circuit for condensation and drain it, if required.
- Device humidification performance may be negatively affected by the simultaneous use of a nebulizer.
- Do *not* touch the hot plate or the bottom of the water chamber. The surfaces can reach a temperature of over 85°C. These hot surfaces radiate heat.

**⚠ CAUTION**

- *Position the humidifier where the primary power supply can be easily disconnected.*
- *Use only parts and accessories specified in Section 8, and in the Hamilton Medical e-catalog, or that are specified as being compatible with the humidifier.*

  *Doing so ensures proper humidification, avoids degraded performance, and keeps your warranty in force.*
- *If the humidifier is turned Off then On, it will automatically start in Invasive (INV) mode unless configured differently.*
- *Check the breathing circuit set for damage prior to use. Discard the breathing circuit set if there is any sign of damage.*
- *The humidifier heating element and heater wires are automatically turned on when the water chamber and breathing circuits are correctly mounted, and the humidifier is turned on or is in Standby.*
- *If the ambient or gas inlet temperature, and/or flow rate is outside the recommended range, physiological humidity levels may not be achieved.*
- *The humidifier still may be powered, even if the display is not illuminated. See Table 1.*

***NOTICE***

- Before using a breathing circuit set on a patient, you must perform a tightness test. If this test fails, it may be repeated once. After two consecutive failed tests, the breathing set must be replaced by a new one.
- A fine, breath-dependent condensation (fogging) forming in the limb, flex tube, or flow sensor indicates that the humidity is properly set.
- All actions generate an audible sound.

## 1.5 Breathing circuits and water chamber

**⚠ WARNING**

- Failure to correctly connect the breathing circuit to the ventilator can injure the patient.
- To prevent accidental disconnection of the breathing circuit during use or transport, use only breathing circuits that comply with ISO 5367 or ISO 80601-2-74.
- Only fill the water chamber with sterile, demineralized water that meets the hospital's hygiene requirements.
- Do not tilt the water chamber.
- Do not fill any drug into the humidifier chamber.
- Ensure the water level does not exceed the maximum fill level.

***NOTICE***

- If the humidifier does not detect the breathing circuit, replace the components.
- The refill water should be no warmer than 37°C.
- Ensure that the water supply to the chamber is functioning properly.
- Ensure the humidifier is in Standby before disconnecting any components.

## 1.6 Humidifier and breathing circuit positioning

**⚠ WARNING**

- The humidifier must *always* be positioned below patient level.
- Do *not* operate the humidifier at an angle in excess of 10° relative to the floor.
- Be sure to route the breathing circuit without tension and without any kinks from the humidifier to the patient.
- Heated breathing limbs must *not* be placed directly on the patient's skin.
- If the humidifier is used adjacent to, or stacked on, other medical electrical equipment, verify the humidifier's normal operation in the configuration in which it will be used.
- Place the breathing circuit in such a way that liquid condensate cannot reach the patient.
- Attach breathing circuits or tubing clips appropriately to avoid mechanical forces on the ET tube.

***NOTICE***

- Check the stability of all connections prior to use.
- All limb connectors on the humidifier combine electrical connections with breathing circuit connectors. Ensure proper orientation of electrical contacts to match the connecting element on the humidifier.

## 1.7 Monitoring and alarms

***NOTICE***

- When an alarm is active, the display alternates between showing active alarm symbols and the current chamber exit temperature.
- Upon turning off the humidifier, the alarm loudness returns to the default value of 5.
- All technical alarms, detailed technical information, and maintenance procedures are described in the *HAMILTON-H900 Service Manual*.

## 1.8 Maintenance

**⚠ WARNING**

- Modifications to the humidifier are *not* permitted.
- *Always* disconnect the humidifier from electrical power before cleaning and disinfection to reduce the risk of electrical shock.

**⚠ CAUTION**

- *Handle used breathing circuits and water chambers as contaminated goods according to local laws and regulations or hospital internal procedures.*
- *To ensure proper servicing and to prevent possible physical injury, only Hamilton Medical authorized service personnel may service the humidifier using information provided in the HAMILTON-H900 Service Manual.*
- *Use only replacement parts supplied by Hamilton Medical.*

- *Do not attempt service procedures other than those specified in the HAMILTON-H900 Service Manual.*
- *Use only approved cleaning agents for cleaning and disinfection.*

***NOTICE***

- For specific information on cleaning, disinfecting, and sterilizing autoclavable (reusable) accessories and components, refer to the appropriate *Reprocessing Guide* and *Instructions for Use* provided with each part.
- (*USA only*) Use only EPA-registered cleaning agents for cleaning and disinfection.

# 2 Overview

This guide provides information about the set up and use of the HAMILTON-H900 humidifier.

The humidifier is designed for use with Hamilton Medical, as well as third-party, ventilators.

## 2.1 About the HAMILTON-H900 humidifier

The HAMILTON-H900 humidifier heats and humidifies respiratory gases for adult, pediatric, and neonatal patients.

It supports the following common respiratory modes:

- Invasive ventilation
- Noninvasive ventilation
- High flow oxygen therapy

The system comprises the humidifier housing, display, controls, water chamber, heater plate, and electrical connections for a heated breathing circuit.

It offers the following main features:

- Adjustable temperature and humidity controls
- Monitoring and alarm capabilities
- Integration of humidifier monitored data and controls with supported Hamilton Medical ventilators[1]

[1] Not available in all markets.

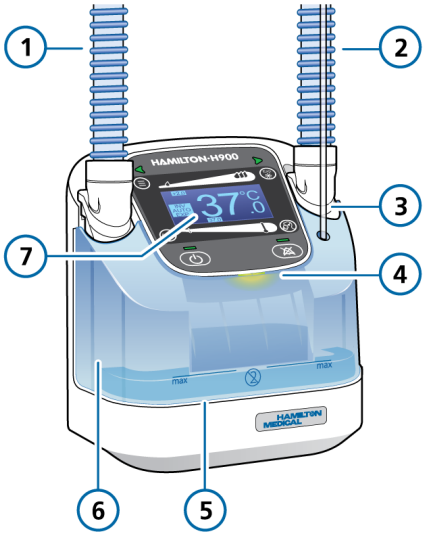
## 2.2 Physical descriptions

This section provides an overview of the humidifier and related breathing circuit sets.

### 2.2.1 About the humidifier

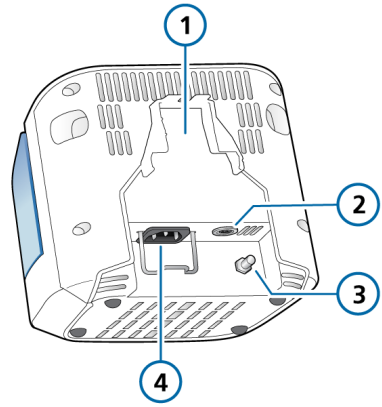
Figures 1 through 5 provide an overview of the humidifier.

Figure 1. HAMILTON-H900 humidifier, front view




| | | | |
|---|---|---|---|
| 1 | Ventilator inspiratory limb (blue) | 5 | Heater plate |
| 2 | Patient inspiratory limb (blue) | 6 | Water chamber |
| 3 | Water feed tube | 7 | Front panel and display |
| 4 | Visual alarm indicator | | |

Figure 2. HAMILTON-H900 humidifier, rear view




| | | | |
|---|---|---|---|
| 1 | Mounting bracket slot | 3 | Potential equalization terminal |
| 2 | RS-232 port | 4 | AC power socket |

### 2.2.2 About the main display

You can directly access all settings, modes, alarms, and controls from the main display during humidification.

Figures 3 through 5 illustrate the front panel controls, indicators, and display.

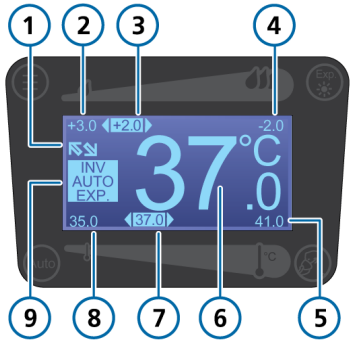
Figure 3. HAMILTON-H900 humidifier, front panel controls


| | | | |
|---|---|---|---|
| 1 | Temperature monitoring window button | 5 | Audio pause key |
| 2 | Temperature control sliders | 6 | Power/Standby key |
| 3 | Exp. temp increase button | 7 | Auto button |
| 4 | INV/NIV/HiFlow mode button | 8 | Display (see Figure 5) |

Figure 4. HAMILTON-H900 humidifier, front panel status indicators


| | | | |
|---|---|---|---|
| 1 | Limb connection status indicators | 3 | Power/Standby status indicator |
| 2 | Audio pause indicator | | |

Figure 5. HAMILTON-H900 humidifier, display




1 Ventilator connection enabled
2 Max. temperature gradient setting
3 Temperature gradient setting
4 Min. temperature gradient setting
5 Max. chamber exit temp setting
6 Current chamber exit temp
7 Chamber exit temp setting
8 Min. chamber exit temp setting
9 Active modes/ settings

*All of the elements on the display are shown for clarification purposes only; during operation, they may not all appear at the same time.*

### 2.2.3 About the humidifier breathing circuits

The HAMILTON-H900 humidifier supports a variety of single and dual limb breathing circuits for adult, pediatric, and neonatal patients.

For details, see your breathing circuit *Instructions for use*.

### 2.2.4 About the status indicators on the humidifier

Indicators on the front of the humidifier show important humidifier status information. See Figure 4.

Table 1. Status indicators

| Symbol | Description |
|---|---|
| **Power/Standby key with status indicator** | |
|  | *Green*: The humidifier is in operation. |
|  | *Orange*: The humidifier is in **Standby**. |
|  | *Blue*: The humidifier is turned off and connected to a power source. |
|  | *Unlit*: The humidifier is turned off and *not* connected to a power source. |
| **Limb connection status indicator** | |
|  | *Green*: The limb is connected correctly. |
|  | *Orange*: The humidifier is testing the limb connection. |
|  | *Red*: The limb connection is either faulty or a limb is not connected. |
| **Audio pause key with indicator** | |
|  | *Red*: Audio pause is active. |

## 2.3 Navigating windows and controls

This section describes how to use the humidifier buttons and sliders.

### 2.3.1 Using the control buttons

The buttons on the front panel (Figure 3) let you select modes, change settings, and see an overview of key temperature settings.

Table 2. Control buttons (see Figure 3)

| Button | Description |
|---|---|
|  | **Exp. temperature increase**<br>Increases the temperature in the expiratory limb. |
|  | **Auto**<br>Enables **Auto** mode.<br>See Section 4.2.2. |
|  | **INV/NIV/HiFlow operating modes**<br>Switches between **INV**, **NIV**, and **HiFlow** modes.<br>See Section 4.2. |
|  | **Temperature monitoring window**<br>Displays the current Y-piece temperature, chamber exit temperature, and temperature gradient values.<br>See Section 4.4. |

### 2.3.2 Using the sliders

In manual mode you can change the temperature settings using the control sliders (Figure 3).

Table 3. Temperature control sliders

| Slider | Description |
|---|---|
| **Temperature gradient slider** | |
|  | Adjusts the temperature difference between the chamber exit and the Y-piece.<br>See Section 4.3. |
| **Chamber exit temp slider** | |
|  | Adjusts the chamber exit temperature.<br>See Section 4.3. |

# 3 Preparing the humidifier for use

*Before proceeding, review the safety information in Section 1.*

Preparing the humidifier for use comprises the following steps:

- A one-time configuration of settings by a medical technician (see Table 4)
- For each new patient, humidifier setup tasks performed by medical caregivers (see Table 5)

Table 4. Configuration and setup by a medical technician

| To ... | See ... |
|---|---|
| *These one-time initial configuration tasks are completed by technical personnel.* | |
| Mount and position the humidifier | See the applicable *Installation Guide* for the ventilator or trolley |
| Configure the humidifier settings | Section 7 |
| *Optional*: Connect the humidifier to the RS-232 COM port of any supported Hamilton Medical ventilator | See the applicable *Operator's Manual* for the ventilator. |

Table 5. Configuration and setup by medical caregivers

| To ... | See ... |
|---|---|
| *The following tasks are performed by medical personnel caring for patients.* | |
| Connect to a power source | Section 3.1 |
| Connect the breathing circuit | Section 3.2 |
| Turn on the humidifier | Section 3.3 |
| Test the alarms | Section 3.4 |
| Specify humidifier settings | Section 3.5 |
| Connect the patient | Section 3.6 |

## 3.1 Connecting to a power source

Always check the reliability of the primary power outlet before plugging in the humidifier and the ventilator.

**To connect the humidifier to a power source**

- Connect the humidifier to an outlet that supplies AC power.[2]

## 3.2 Connecting the breathing circuit to the humidifier

Hamilton Medical provides a variety of breathing circuits for adult, pediatric, and neonatal patients.

For details, see the specific breathing circuit *Instructions for Use*.

## 3.3 Turning the humidifier on and off

When the humidifier is turned on, it automatically runs in the configured default mode.

Be sure to turn the ventilator on *before* turning on the humidifier.

**To turn on the humidifier**

- Press and hold  (**Power/Standby**) for approximately 3 seconds.

The humidifier runs a self-test. Once complete, the humidifier automatically starts in invasive (**INV**) mode unless configured differently.

[2] If using the humidifier with a supported Hamilton Medical ventilator, connect the humidifier power cable to the dedicated power socket on the ventilator.

**To turn off the humidifier**

- Press and hold  for approximately 3 seconds.

Be sure to turn the humidifier off *before* turning off the ventilator.

## 3.4 Testing the alarms

Before connecting a new patient to the humidifier, verify that the alarms operate correctly.

Ensure that the humidifier is turned on.

**To test the humidifier alarms**

1. Generate an alarm by removing the water chamber from the humidifier.
2. Verify that:
   – An acoustic alarm is audible
   – The visual alarm indicator is flashing (Figure 4)
   – The corresponding alarm symbol appears on the display (Table 9)

Resolve the alarm by re-inserting the water chamber into the humidifier, and verify that the alarm is reset.

## 3.5 Specifying humidifier settings

Select the humidification mode for your patient.[3] For details, see Section 4.2.

## 3.6 Connecting the patient

Connect the breathing circuit to the appropriate patient interface.

The humidifier is now set up and ready for use.

# 4 Working with the HAMILTON-H900 humidifier

Table 6. Operation overview

| For details about ... | See ... |
|---|---|
| Turning the humidifier on/off | Section 3.3 |
| Entering/exiting **Standby** | Section 4.1 |
| Accessing humidifier controls | Section 2.3 |
| Humidifier operating modes: **INV**, **NIV**, **HiFlow** | Section 4.2 |
| **Auto** and **Manual** settings | Section 4.2.2 |
| Changing humidity using temperature controls | Section 4.3 |
| Monitored humidifier parameters | Section 4.4 |
| Humidifier alarms | Section 5 |

## 4.1 Entering/exiting Standby

**⚠ CAUTION**

*In **Standby**, all settings are retained and the heat output is reduced.*

**Standby** is a waiting mode that lets you maintain current settings while the humidifier is not in operation.

When in **Standby**, the **Chamber exit temp** and **Temperature gradient** settings are reduced.[4] For details, see Section 9.7.

[3] When used with a Hamilton Medical ventilator that supports integrated operation, the humidifier matches the operating mode of the ventilator. For details, see your ventilator *Operator's Manual*.
[4] During nebulization, the **Temperature gradient** is *not* changed during **Standby**.

**To put the humidifier into Standby**

- Briefly press (Power/Standby).

  When in **Standby**, the display shows the elapsed time the humidifier has been in **Standby**. The **Power/Standby** indicator light is orange.

**To exit Standby and start humidification**

- Press .

  The humidifier resumes normal operation; the **Power/Standby** status indicator light is green.

## 4.2 About the humidifier operating modes

The HAMILTON-H900 offers the following operating modes: Invasive (**INV**), Noninvasive (**NIV**), and High flow oxygen therapy (**HiFlow**).

The operating mode selection determines the initial temperature settings, both at the water chamber exit (**Chamber exit temp**) and at the Y-piece (**Temperature gradient**), as well as the allowed temperature ranges for each of these controls.

These temperature ranges differ by patient group. See Table 18.

### 4.2.1 Changing modes

The humidifier automatically starts up in Invasive (**INV**) mode, unless configured differently in the custom default settings.

When changing to Invasive (**INV**) or Noninvasive (**NIV**) mode, the humidifier automatically sets the control settings to **Auto**.

**To change modes**

- Press (**Modes**) until the desired mode (**INV, NIV, HiFlow**) is displayed.

  The selected mode appears on the display.

Figure 6. INV mode (**1**) selected

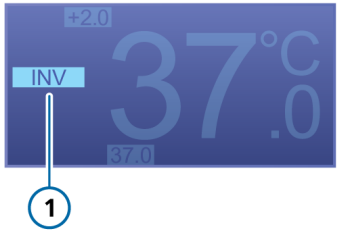



Figure 7. NIV mode (**1**) selected

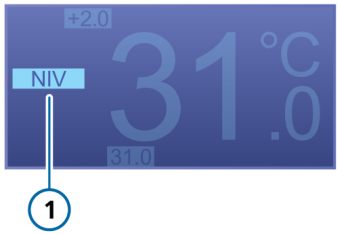
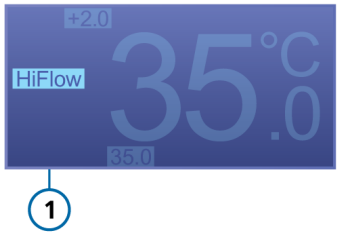



Figure 8. HiFlow mode (**1**) selected



### 4.2.2 Auto and manual control settings

You can use the humidifier in **Auto** mode, or you can manually adjust the settings. By default, the humidifier starts in **Auto** mode.

The **chamber exit temp** and **Temperature gradient** are set using either of the following methods:

- Loaded from the configured default settings (**Auto** mode)
- Set manually by the user

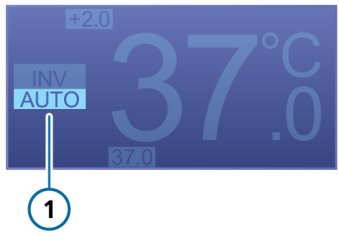
#### Automatic settings (Auto)

When set to **Auto**, the humidifier loads the configured default settings for the selected mode (see Section 7) and uses them to control the gas temperature.

At low ambient temperatures, the humidifier may automatically adjust the water chamber temperature.

When **Auto** mode is selected, the text **AUTO** appears on the main display.

Figure 9. Auto mode (**1**) selected

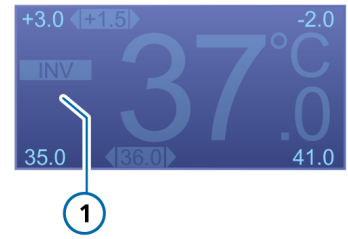



#### Manual settings

When you change the **Chamber exit temp** or **Temperature gradient** using the sliders, the humidifier switches to **Manual** mode. However, it still continues to automatically control the temperature to reach the specified settings.

When settings are changed manually, **Auto** no longer appears on the main display; the space is empty.

Figure 10. Manual mode (**1**) is in effect




#### 4.2.2.1 Enabling Auto mode

After manually changing either of the temperature settings, you can re-enable **Auto** mode.

#### To re-enable Auto mode

- Press Auto (**Auto**).

  Changing the operating mode to **INV** or **NIV** also automatically switches the humidifier to **Auto** mode.

## 4.3 Changing humidity using temperature controls

**NOTICE**

If the humidifier is in **Auto** mode, dragging either slider switches humidification to **Manual** mode.

**NOTICE**

In **HiFlow** mode, you cannot change the **Temperature gradient** using the slider. You can change the **Temperature gradient** to a new value in **Configuration**. See Section 7.

You can adjust the following controls on the humidifier[5]:

Table 7. Adjustable humidifier controls

| Control | Description |
|---|---|
| Chamber exit temp | Temperature at the water chamber exit.<br>The possible range of values for this control depends on the selected humidifier operating mode. For details, see Tables 16 and 18.<br>Higher values result in higher absolute humidity. |
| Temperature gradient | The difference between the temperature at the water chamber exit and at the Y-piece. |
| Exp. temp increase | When selected, the humidifier provides additional heat in the expiratory limb.[6] |

The maximum allowed temperature at the patient Y-piece is 42°C. The combination of the **Chamber exit temp** plus the **Temperature gradient** cannot exceed this limit. For example, if the **Temperature gradient** is set to 2°C, the highest possible setting for the **Chamber exit temp** is 40°C.

Furthermore, the **Temperature gradient** setting takes precedence over the **Chamber exit temp** setting. This means if a combination of settings would result in a Y-piece temperature greater than 42°C, then the **Temperature gradient** will remain unchanged, but the **Chamber exit temp** will be adjusted.

For example, if **Chamber exit temp** is set to 40°C, you can set **Temperature gradient** to 3°C even though the combination exceeds 42°C. Once the **Temperature gradient** setting is accepted, the **Chamber exit temp** value is automatically set to 39°C.

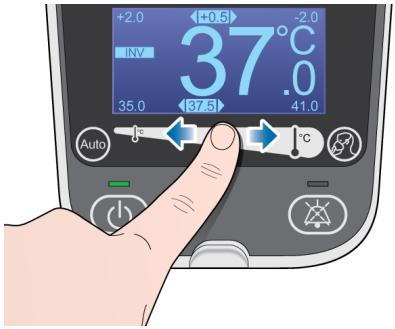
### To set the Chamber exit temperature

- Touch the **Chamber exit temp** slider at the current setting:
  - Drag left to decrease the chamber exit temperature
  - Drag right to increase the chamber exit temperature

The changes are confirmed by an audible beep and are applied immediately.

[5] When used with a Hamilton Medical ventilator that supports integrated humidifier control, you can also change the settings directly on the ventilator. For details, see your ventilator *Operator's Manual*.
[6] Single use, dual limb heated breathing circuits only.

Figure 11. Adjusting Chamber exit temperature




### To set a Chamber exit temperature > 39°C

To increase the **Chamber exit temp** above 39°C, the slider must be activated twice.

1. Touch the **Chamber exit temp** slider at the current setting and drag right to reach the limit of 39°C.
2. Touch and drag the slider again to set the chamber exit temperature above 39°C.

### To set the temperature gradient

- Touch the **Temperature gradient** slider at the current setting:

  – Drag right to decrease the temperature gradient

  – Drag left to increase the temperature gradient

The changes are confirmed by an audible beep and are applied immediately.

Figure 12. Adjusting Temperature gradient


For example, if the target Y-piece temperature is 39°C and the **Chamber exit temp** is set to 37°C, set the **Temperature gradient** to 2°C.

## 4.4 Monitoring humidification

Monitoring data is available in the **Temperature monitoring** window, which you can access at any time.[7]

The following parameters are monitored:

- Chamber exit temp
- Temperature gradient
- Y-piece temperature

[7] When used with a Hamilton Medical ventilator that supports integrated humidifier monitoring, humidifier data is shown on the ventilator display. For details, see your ventilator *Operator's Manual*.

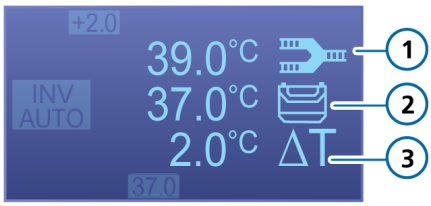
### 4.4.1 Displaying additional monitoring parameters

**To display the Temperature monitoring window**

- Press (Temperature monitoring window).

  The window closes after 30 seconds or when you press the button again.

Figure 13. Temperature monitoring window




| | | | |
|---|---|---|---|
| 1 | Current Y-piece temperature | 3 | Current Temperature gradient |
| 2 | Current chamber exit temp | | |

## 4.5 Day and Night display brightness settings

The humidifier display backlight supports two different display settings. Use these settings to set the brightness of the display.

**To switch between the Day and Night settings**

- Press and hold for 5 seconds.

To set the default day and night brightness, see Section 7.

# 5 Responding to humidifier alarms

Humidifier-related alarms notify you of conditions that require your attention. Alarms are indicated as follows:

- Graphically on the humidifier display
- With a sequence of 3 or 5 audible beeps
- The alarm lamp above the water chamber flashes
- When used with a Hamilton Medical ventilator that supports integrated humidifier monitoring, alarm messages are also indicated on the ventilator display.[8]

The alarms are categorized as high priority, medium priority, or technical fault, as described in Table 8.

See Table 9 for a complete list of alarms.

[8] Not available on all ventilators. See your ventilator *Operator's Manual*.

Table 8. Alarm indicators

| Alarm type | Alarm status indicator | Audio | Action required |
|---|---|---|---|
| High priority | Red, flashing<br>Alarm icon is shown on the display | A sequence of 5 beeps, repeated until the alarm is reset | The humidifier needs immediate attention. |
| Medium priority | Yellow, flashing<br>Alarm icon is shown on the display | A sequence of 3 beeps, repeated until the alarm is reset | The humidifier needs prompt attention. |
| Technical fault | Red, flashing<br>Technical fault (TF) number is shown on the display | A sequence of 3 beeps, repeated until the alarm is reset | • Record the technical fault (TF) number[9].<br>• Remove the humidifier from use.<br>• Have the humidifier serviced. |

[9] A list of all technical fault (TF) numbers is available in the *HAMILTON-H900 Service Manual*.

## 5.1 Temporarily silencing an alarm

One component of an alarm is the audible sound. With most alarms you can pause (silence) the alarm sound for two minutes at a time.

### To temporarily silence an alarm

- Press  (**Audio pause**) on the front of the humidifier.

  The audible humidifier alarm is muted for two minutes.

  Pressing the key a second time cancels the **Audio pause**.

The **Audio pause** backlight is continuously lit in red while an **Audio pause** is active.

When the time expires and the issue has not yet been resolved, the alarm sounds again.

## 5.2 Adjusting alarm loudness

**⚠ WARNING**

Be sure to set the auditory alarm loudness above the ambient sound level. Failure to do so can prevent you from hearing and recognizing alarm conditions.

You can set the loudness of the audible alarm.

By default, the loudness is set to 5. Upon turning off the humidifier, the alarm loudness is reset to the default value.

### To adjust the alarm loudness

1. If needed, press  (**Power/ Standby**) to put the humidifier into **Standby**.
2. Press  for 3 seconds.

   The display shows the current alarm loudness setting.
3. Adjust the alarm loudness using the **Chamber exit temp** slider (see Figure 3).

   The humidifier confirms your selection with a beep at the new loudness setting.
4. Press  to confirm your selection and return to normal operation.

## 5.3 Troubleshooting alarms

Table 9 lists the humidifier alarms, their graphical representation on the humidifier, a description, and suggested corrective actions.

Table 9. HAMILTON-H900 alarms

| Alarm | Alarm icon | Description | Action needed |
|---|---|---|---|
| **High priority** | | | |
| Humidifier tilt |  | Humidifier is dangerously inclined.<br>The humidifier is at a 10° angle or higher relative to the floor. | • Check the mounting of the humidifier.<br>• Check the ventilator trolley.<br>• Operate the humidifier at an angle less than 10° relative to the floor. |
| Temperature high |  | The gas temperature at the water chamber exit or at the Y-piece is above the set value. | • Check whether the breathing circuit is covered by the patient's bed covers.<br>• Check whether the breathing circuit or the humidifier chamber is directly exposed to sunlight.<br>• Replace the breathing circuit. |
| Water level high |  | The water level in the water chamber is above the maximum level mark. | • Empty humidifier chamber to reduce the water level.<br>• Replace the humidifier chamber.<br>• Operate the humidifier at an angle less than 10° relative to the floor. |
| Technical fault | Technical fault (TF) number is shown on the display | Technical fault due to humidifier malfunction. | • Check humidifier operation and all connections.<br>• Replace the humidifier and have it serviced.<br>• If a technical fault number is displayed, make a note of it and provide it when the humidifier is serviced. |

| Alarm | Alarm icon | Description | Action needed |
|---|---|---|---|
| **Medium priority** | | | |
| Temperature low |  | The gas temperature at the water chamber exit or at the Y-piece is below the set value. | • Wait until the system heats up completely (approx. 30 minutes).<br>• Check whether all settings are correct.<br>• Avoid direct air flow from air conditioning and the like to the humidifier and breathing circuit. |
| Water level low |  | The water level in the chamber is below the low level mark. | • Check water bottle and refill tubing.<br>• If the water bottle is empty, connect a new water bottle.<br>• Refill or exchange empty humidifier chamber.<br>• Operate the humidifier at an angle less than 10° relative to the floor. |
| Check water chamber |  | No chamber or incompatible water chamber is inserted. | Insert a new humidifier chamber and connect the breathing circuit. |
| Check left or right limb |  | The display and connection indicators show which limb is faulty.<br>• No limb or defective limb connected.<br>• No air flow.<br>• A limb is not properly connected.<br>• The WHITE humidifier expiratory limb is connected to the ventilator *To patient* inspiratory port. | • Insert or reseat the breathing circuit correctly.<br>• Replace the breathing circuit.<br>• Connect the BLUE humidifier inspiratory limb to the ventilator *To patient* inspiratory port.<br><br>When the connection indicator is:<br>*Green*: The limb is inserted correctly.<br>*Orange*: The humidifier is testing the connection.<br>*Red*: The connection is either faulty or nonexistent. |

# 6 Maintenance

*Before proceeding, review the safety information in Section 1.*

This section provides information about humidifier maintenance procedures and schedule, as well as cleaning and disinfection instructions.

All of the procedures in this section are to be performed by the operator.

For additional maintenance requirements, contact your Hamilton Medical service representative. Any documents referenced in this section are available on the MyHamilton website: https://www.hamilton-medical.com/MyHamilton

## 6.1 Cleaning, disinfection, and sterilization

Humidifier components must be regularly cleaned and disinfected, using the cleaning methods and solutions specific to the individual components.

It is important that you choose the appropriate method and materials when cleaning and disinfecting the humidifier and its components, not only to avoid damaging the equipment, but also to avoid cross-contamination.

Cleaning and disinfection information is presented as follows:

- Table 10 lists the applicable humidifier-related components, and indicates which cleaning and disinfection methods can be used for each one, the frequency with which the component must be cleaned/disinfected, and cleaning and disinfection agents.
- For breathing circuit sets and humidifier water chambers, see the *Instructions for use* or the *Reprocessing Guide*.

When working with the humidifier components, cleaning methods, and cleaning agents, keep the following in mind:

- Do *not* attempt decontamination procedures unless specified by Hamilton Medical.
- While we provide guidelines for agents and concentrations to use, if you have specific questions about the use of a particular cleaning or disinfection agent, contact the manufacturer of the agent.

Table 10. Humidifier cleaning and disinfection methods

| Part | Frequency | Cleaning/disinfection method | Cleaning agents |
|---|---|---|---|
| Humidifier exterior including:<br>• Housing<br>• Display<br>• Heater plate<br>• Power cables<br>• Mounting systems | After each patient use or as needed. | Wipe with a damp cloth using a registered and approved cleaning/disinfection solution. | Super Sani-Cloth germicidal wipes<br>CaviWipes |

## 6.2 Preventive maintenance

Preventive maintenance on your humidifier must be performed by Hamilton Medical authorized service personnel according to the instructions in the *HAMILTON-H900 Service Manual*.

# 7 Configuration

The humidifier is delivered with a default configuration of a variety of settings arranged by patient group.

You can change the following default settings in **Configuration** mode:

- **Chamber exit temperature**
- **Temperature gradient**
- Startup operating mode (**INV/NIV/HiFlow**)
- **Expiratory temperature increase** On/Off
- Backlight **Day/Night** brightness settings

## 7.1 Accessing Configuration mode

You can access **Configuration** mode when the humidifier is in **Standby**.

### To access configuration mode

1. If needed, press  to enter **Standby**.
2. Press and hold both  and  .

   Ensure that you press  first.

   The **Configuration** window appears after 5 seconds.

The humidifier is now in **Configuration** mode.

## 7.2 Changing configuration settings

Custom settings are persistent until you change them or restore factory settings.

In **Configuration** mode, the buttons on the humidifier front panel are used to navigate the views and make selections.

Table 11 describes how to page through **Configuration**, and how to change settings.

For an example of how to change a setting, see the procedure below on changing the default settings for **Temperature gradient**.

For a list of configuration settings, see Section 9.6.

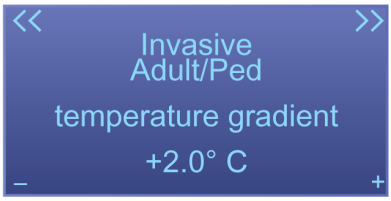
Table 11. Configuration mode navigation buttons

| Button | Description |
|---|---|
|  | Move forward through the views |
|  | Move backward through the views |
|  | Increase a value |
|  | Decrease a value |
|  | Save changes and exit **Configuration** mode |

**Example: Changing Temperature gradient**

**To change the default Invasive, Adult/Ped, Temperature gradient setting**

1. In **Configuration** mode, press Exp. until you see the view for the **Invasive, Adult/Ped, Temperature gradient**.




2. Press to increase the value or press Auto to decrease the value.
3. When finished, press to save the changes and exit **Configuration** mode.

## 7.3 Restoring the factory default settings

You can restore factory default settings at anytime.

**To restore the factory default settings**

1. In Configuration mode, repeatedly press Exp. until the **Reset all custom defaults** window appears.
2. Press Auto.

The factory default settings are restored.

# 8 Parts and accessories

This section lists the parts and accessories available for the HAMILTON-H900 humidifier.

For additional information, refer to the Hamilton Medical e-catalog on the Hamilton Medical website or contact your Hamilton Medical representative.

Table 12. Humidifier parts and accessories

| PN | Description |
|---|---|
| 260161 | HAMILTON-BC8022, breathing circuit set, dual limb, heated, with water chamber |
| 260186 | HAMILTON-BC4022, breathing circuit set, single limb, heated, with water chamber |
| 260185 | HAMILTON-BC8010, breathing circuit set, dual limb, heated, with water chamber and incubator extension |
| 260187 | HAMILTON-BC4010, breathing circuit set, single limb, heated, with water chamber and incubator extension |
| 260196 | HAMILTON-HC322, water chamber, single use |
| 260197 | HAMILTON-HC310, water chamber, single use |

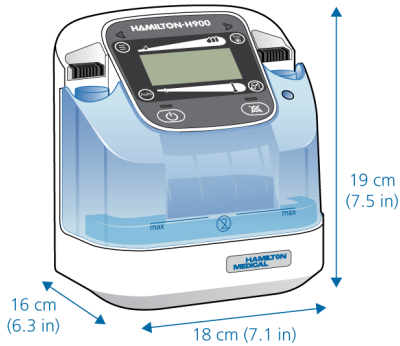
# 9 Specifications

## 9.1 Physical characteristics

Table 13. Physical characteristics

| Dimension | Specifications |
|---|---|
| Weight | Humidifier (with empty water chamber): 2.5 kg (5.5 lbs) |
| Dimensions | See Figure 14 |

Figure 14. HAMILTON-H900 dimensions



## 9.2 Environmental requirements

Table 14. Environmental requirements

| Environment | | Specifications |
|---|---|---|
| Temperature | Operation: | 10°C to 40°C |
| | Storage: | -20°C to 60°C |
| | | Recommended ambient temperature: 18°C to 26°C |
| Altitude | | Up to 4,000 m (13,123 ft) |
| Atmospheric pressure | Operation and storage: | 61 kPa to 106 kPa |
| Relative humidity | Operation: | 30% to 95%, noncondensing |
| | Storage: | 10% to 95%, noncondensing |
| Water protection | | IP21 |
| Gas input temperature | | 18°C to 31°C (recommended) |

## 9.3 Electrical specifications

Table 15. Electrical specifications

| Part number | Input power | Power consumption |
|---|---|---|
| 950001 (230 V) | 220 – 240 V<br>50/60 Hz | 283 VA |
| 950004 (115 V) | 110 – 127 V<br>50/60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50/60 Hz | 268 VA |
| Potential equalization | Terminal for the connection of a potential equalization conductor according to DIN 42801 | |

## 9.4 Control settings

Table 16. Control settings and ranges

| Parameter or setting (unit) | Mode | Range | Default | Resolution |
|---|---|---|---|---|
| Chamber exit temperature (°C) | INV | 35 to 41 | 37.0 | 0.5 |
| | NIV | 30 to 35 | 31.0 | 0.5 |
| | HiFlow | 33 to 37 | 35.0 | 2 |
| Temperature gradient (°C) | INV | -2 to 3 | Adult/Ped: 2<br>Neo: 3 | 0.5 |
| | NIV | -2 to 3 | Adult/Ped: 2<br>Neo: 3 | 0.5 |
| | HiFlow | -- | 2 | -- |
| Resulting max. airway temperature (Y-piece)[10] (°C) | INV | 33 to 42 | -- | -- |
| | NIV | 28 to 38 | -- | -- |
| | HiFlow | 35 to 39 | -- | -- |
| Expiratory temperature increase | All modes | On, Off | On | -- |
| Brightness setting for display | All modes | 1 to 5 | Day: 5<br>Night: 2 | 1 |

[10] Airway temperature is limited to 42°C by the humidifier.

## 9.5 Monitored parameters

Table 17. Monitored parameters, ranges, and accuracy

| Parameter (units) | Range | Accuracy |
|---|---|---|
| Chamber exit temp (°C) | 10 to 60 | 10 to 30: ±1<br>30 to 41: ±0.5<br>41 to 60: ±1 |
| Y-piece temperature (°C) | 28 to 43 | ± 0.5 |

## 9.6 Configuration

Table 18. Configuration specification

| Parameter | Mode | Configuration range | Default setting |
|---|---|---|---|
| Chamber exit temp (°C) | INV | 35 to 39 | 37.0 |
| | NIV | 30 to 35 | 31.0 |
| | HiFlow | 33, 35, 37 | 35.0 |
| Temperature gradient (°C) | INV | 0 to 3 | Adult/Ped: 2<br>Neo: 3 |
| | NIV | 0 to 3 | Adult/Ped: 2<br>Neo: 3 |
| | HiFlow | 0 to 3 | 2 |
| Startup mode | -- | Invasive, Noninvasive, HiFlow | Invasive |
| Brightness setting for display | All modes | 1 to 5 | Day: 5<br>Night: 2 |

## 9.7 Technical performance data

Table 19. Technical performance data

| Description | Specification | | |
|---|---|---|---|
| Flow rates[11] | Invasive: | Up to 60 l/min | |
| | Noninvasive: | Up to 120 l/min | |
| | HiFlow: | Up to 120 l/min | |
| Warm-up time | Less than 30 min | | |
| Humidity | At an ambient temperature of 18°C to 26°C: | | |
| | Invasive: | Temperature setting of 37 to 41°C | Minimum humidity: 33 mg H2O/l |
| | Noninvasive: | Temperature setting of 31 to 35°C | Minimum humidity: 12 mg H2O/l |
| | HiFlow: | Flow rate ≤ 60 l/min | Minimum humidity: 33 mg H2O/l |
| | | Flow rate > 60 l/min | Minimum humidity: 12 mg H2O/l |
| Standby heating specifications | Heated breathing circuits: | Y-piece limited to 30°C. | |
| Display | 3 in / 64 x 128 pixels, inverted dot matrix display (backlit) | | |
| Audio pause | 120 seconds | | |
| Alarm loudness[12] | Range = 1 to 8. Default = 5. | | |

[11] For minimal flow rates, see the breathing circuit *Instructions for use*.
[12] Volume at 1 meter distance from humidifier. A setting of 1 = 50 dB(A), 5 (default) = 60 dB(A), and 8 = 65 dB(A), with an accuracy of ±6 dB(A).

## 9.8 Essential performance

The temperatures applied to the respiratory gas and breathing circuit must be maintained within the specified settings, and must be monitored.

Should the temperature fall outside the specified limits, the humidifier must detect this fact and inform the user through an alarm.

## 9.9 Functional description of humidification system

The HAMILTON-H900 humidifier is designed to heat and humidify respiratory gases during mechanical ventilation. The respiratory gas is heated and humidified as it passes through a chamber that is partially filled with heated water.

The humidifier has two sensor-controlled heating systems:

- *Heater plate*. Heats the water in the water chamber.
- *Integrated breathing circuit heating system*. Heats the breathing limbs to prevent condensation.

The respiratory gas temperature is monitored at the chamber exit and in the breathing limb at the patient end.

## 9.10 Symbols used on device labels and packaging

| Symbol | Description |
|---|---|
|  | Follow the *Instructions for use* |
|  | Reference number |
|  | Serial number |
|  | Quantity |
|  | Manufacturer |
|  | Date of manufacture |
|  | Type BF applied part (classification of medical electrical equipment, type BF, as specified by IEC 60601-1) |
|  | Dispose according to Council Directive 2002/96/EC or WEEE (Waste Electrical and Electronic Equipment) |
|   | The TÜV NRTL mark with the indicators "C" and "US" means that the product complies with Canadian requirements and the requirements of US authorities for safety |
|  | Potential equalization |

| Symbol | Description |
|---|---|
|  | Warning: Hot surface.<br>The heater plate and the bottom of the chamber can reach a temperature of over 85°C. |
| CE 0197 | CE Marking of Conformity, seal of approval guaranteeing that the device is in conformance with the Council Directive 93/42/EEC concerning medical devices |
| IP21 | Protected against dripping water and solid particles larger than 12.5 mm |
| max | Filling level mark on water chamber |
|  | RS-232 serial interface for communication with Hamilton Medical ventilators |
|  | MR unsafe<br>The HAMILTON-H900 humidifier poses unacceptable risks to patient, medical staff, or other persons within the MR environment. |
|  | Chinese RoHS |
|  | Temperature probe<br>Marks the position of the temperature probe on the breathing circuit. |

## 9.11 Standards and approvals

The humidifier system meets relevant parts of the following standards, listed in Table 20.

Table 20. Standards and approvals, valid versions

| |
|---|
| IEC 60601-1:2005/A1:2012 |
| IEC 60601-1-2:2014 |
| IEC 60601-1-6:2010/A1:2013 |
| IEC 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| IEC 62304:2006/A1:2015 |
| IEC 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Disposal

The device must be disposed of according to your institution's protocols and Directive 2002/96/EC.

Breathing circuits and humidifier chambers must be disposed of according to the *Instructions for use* supplied with the breathing circuit sets.

## 9.13 Warranty

LIMITED WARRANTY

THE WARRANTY DESCRIBED IN THIS AGREEMENT IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. HOWEVER, IMPLIED WARRANTIES ARE NOT DISCLAIMED DURING THE PERIOD OF THIS LIMITED WARRANTY.

Hamilton Medical guarantees its products to be shipped free from defects in material and workmanship. The warranty does not include disposable items. Disposable items and consumable products are considered to be of single use or of limited use only and must be replaced regularly as required for proper operation of the product following the Operator's Manual.

Hamilton Medical shall have no obligations nor liabilities in connection with the product other than what is specified herein, including without limitation, obligations, and/ or liabilities for alleged negligence, or for strict liability. In no event shall the company be liable for incidental or consequential damages, either direct or contingent.

This Limited Warranty shall be void and not apply:

1. If the product has not been installed and connected by an authorized local representative of Hamilton Medical in accordance with the instructions furnished by Hamilton Medical and by a Hamilton Medical representative.
2. If no evidence is present that the occurrence of damage/repair happened within the certified warranty period.
3. If the serial number has been altered, effaced, or removed, and there is no bill of sale or evidence to verify the product's purchase date.
4. If the defects arise from misuse, negligence, or accidents or from repair, adjustment, modification, or replacement made outside Hamilton Medical's factories or other than an authorized service center or authorized service representative.
5. If the product has been modified, or in any nature altered without prior written authorization from Hamilton Medical.
6. If the product is or has been used in any way that is not specified under "Intended Use".
7. If the product has been used by anyone but properly trained personnel under the supervision of a physician.

Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty, but carry only the unexpired portion of the original Limited Warranty. The warranty of repaired and/or replaced components does not exceed the Limited Warranty of the device.

To obtain service under this Limited Warranty, claimant must promptly notify the country's sales partner of Hamilton Medical regarding the nature of the problem, serial number, and the date of purchase of the Product.

Except as stated above, Hamilton Medical shall not be liable for any damages, claims, or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages. Nor will Hamilton Medical be liable for any damages, claims, or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages resulting from misuse of the device or failure to comply with any of the provisions made in this manual.

### 9.13.1 Miscellaneous

The general terms and conditions of Hamilton Medical shall be applicable. This agreement shall be governed by, and construed in accordance with, the laws of Switzerland and may be enforced by either party under the jurisdiction of the court of Chur, Switzerland.

# Gebrauchsanweisung

## HAMILTON-H900

2021-01-11

624431/09

Dieses Dokument kann von der Hamilton Medical AG jederzeit ohne vorherige Ankündigung überarbeitet, ausgetauscht oder durch andere aktuellere Dokumente ersetzt werden. Stellen Sie sicher, dass Ihnen dieses Dokument in seiner aktuellsten Version vorliegt; für Fragen steht Ihnen die technische Support-Abteilung der Hamilton Medical AG, Schweiz, gerne zur Verfügung. Obwohl wir bei der Zusammenstellung der in diesem Handbuch enthaltenen Informationen größtmögliche Sorgfalt haben walten lassen, kann dies eine professionelle Beurteilung nicht ersetzen.

Die Hamilton Medical AG behält sich das Recht vor, unabhängig vom Inhalt dieses Handbuchs, ohne vorherige Ankündigung die beschriebenen Geräte (einschließlich der Software) zu ändern. Sofern nicht ausdrücklich schriftlich vereinbart, ist die Hamilton Medical AG nicht verpflichtet, dem Besitzer oder Bediener der im Handbuch beschriebenen Geräte (einschließlich der Software) Überarbeitungen, Aktualisierungen oder Änderungen mitzuteilen.

Die Geräte dürfen ausschließlich von entsprechend ausgebildeten Fachkräften bedient, gewartet und aufgerüstet werden. Die Hamilton Medical AG haftet in Bezug auf die Geräte lediglich im Rahmen der in diesem Handbuch aufgeführten eingeschränkten Garantiebedingungen.

Die Hamilton Medical AG haftet nicht für Verluste, Kosten, Auslagen, Unannehmlichkeiten oder Schäden, die möglicherweise durch den Missbrauch des Produktes oder die Verwendung nicht von der Hamilton Medical AG stammender Teile beim Austausch von Komponenten entstehen bzw. im Falle einer Änderung, Zerstörung oder Entfernung der Seriennummer.

Stellen Sie bei der Rücksendung an die Hamilton Medical AG sicher, dass Sie das Standardverfahren von Hamilton Medical für die Autorisierung der Rückgabe von Waren (Return Goods Authorization, RGA) einhalten. Bei der Entsorgung von Teilen sind alle gesetzlichen Bestimmungen hinsichtlich des Umweltschutzes zu befolgen.

Informationen zu von der Hamilton Medical AG verwendeten eigenen Warenzeichen und Warenzeichen von Dritten finden Sie unter: www.hamilton-medical.com/trademarks. Mit dem Symbol § gekennzeichnete Produkt- und/oder Firmennamen können Warenzeichen und/oder eingetragene Warenzeichen anderer Hersteller sein. Dazu gehören unter anderem: Aerogen§, Nihon Kohden§, Masimo§, Masimo SET§, Masimo rainbow SET§ und Capnostat§.

**Hersteller**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz,
Schweiz
Telefon:: (+41) 58 610 10 20
Fax: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Vorwort

Machen Sie sich vor der Verwendung des Gerätes oder Zubehörs unbedingt mit der Dokumentation vertraut.

### Konventionen in diesem Handbuch

In diesem Handbuch gelten folgende Konventionen:

- Die Namen von Schaltflächen sind in **Fettschrift** formatiert.
- Die verwendeten Grafiken entsprechen nicht unbedingt genau den Anzeigen in Ihrer Umgebung.
- Nicht alle Funktionen sind für alle Märkte verfügbar.

Sicherheitsmeldungen werden folgendermaßen angezeigt:

**⚠ WARNUNG**

Macht den Bediener auf Verletzungsrisiken, lebensgefährdende Situationen oder andere gravierende Nebenwirkungen aufmerksam, die durch den Gebrauch des Gerätes oder Bedienungsfehler ausgelöst werden können.

**⚠ VORSICHT**

*Macht den Bediener auf ein Problem aufmerksam, das beim Gebrauch des Gerätes aufgetreten oder durch einen Bedienungsfehler hervorgerufen sein könnte, z. B. eine Fehlfunktion, einen Ausfall oder eine Beschädigung des Gerätes oder anderer Produkte.*

***HINWEIS***

Hebt Informationen hervor, die besonders wichtig sind.

In Tabellen werden Sicherheitsmeldungen folgendermaßen angezeigt:

**⚠ WARNUNG!**

**⚠ VORSICHT!**

**HINWEIS!**

Die jüngste Version dieses Handbuchs sowie andere Dokumente können von der Webseite MyHamilton heruntergeladen werden:
https://www.hamilton-medical.com/MyHamilton

Über das Hamilton Medical College stellt Hamilton Medical eine Vielzahl an Lernmodulen kostenlos zur Verfügung. Hier können Sie sich registrieren:
http://college.hamilton-medical.com/

**⚠ VORSICHT**

*(Nur in den USA): In den USA darf das Gerät nur durch Ärzte oder auf ärztliche Anweisung hin verkauft werden.*

### Vorgesehener Verwendungszweck

Der HAMILTON-H900 Befeuchter ist für die Aufbereitung des Atemgases während der invasiven und nichtinvasiven maschinellen Beatmung vorgesehen.

Das Gerät ist zur Verwendung durch Pflegefachkräfte in Krankenhäusern und anderen Einrichtungen bestimmt.

Der HAMILTON-H900 Befeuchter ist ein Medizinprodukt, das innerhalb der Beschränkungen der angegebenen technischen Spezifikationen durch qualifiziertes, geschultes Personal verwendet werden muss, das unter der Aufsicht eines Arztes steht.

# 1 Sicherheitsinformationen

Dieser Abschnitt enthält Sicherheitsinformationen zur Einrichtung, Bedienung und Wartung des Befeuchters.

**Lesen Sie alle Teile dieses Abschnitts zur Sicherheit sorgfältig durch, bevor Sie den Befeuchter einrichten und verwenden.**

**Stellen Sie sicher, dass Sie vor dem Einsatz des Befeuchters die Gebrauchsanweisung lesen.**

**Lesen Sie unbedingt vor der Verwendung aller Geräte und Zubehörteile, die mit dem Befeuchter verwendet werden, die mitgelieferte Gebrauchsanweisung.**

Wenn Sie Fragen zu irgendwelchen Informationen in diesem Handbuch haben, wenden Sie sich an Ihren Ansprechpartner bei Hamilton Medical oder den technischen Kundendienst.

## 1.1 Elektromagnetische Verträglichkeit

**⚠ WARNUNG**

- **NICHT MR-SICHER**. Nicht in der Nähe von Magnetresonanztomographen (MRT) einsetzen. In der MR-Umgebung stellen sich durch den HAMILTON-H900 unzulässige Gefahren für den Patienten, das medizinische Fachpersonal und andere anwesende Personen.
- Die Funktion des Befeuchters kann durch den Betrieb von Instrumenten für die Hochfrequenzchirurgie, Mikrowellen, Kurzwellen oder starken Magnetfeldern im direkten Umfeld beeinträchtigt werden.
- Um erhöhte Emissionen, eine reduzierte Störfestigkeit und Betriebsunterbrechungen des HAMILTON-H900 Befeuchters oder eines Zusatzgerätes zu vermeiden, dürfen nur Zubehörteile und Kabel verwendet werden, die ausdrücklich in diesem Handbuch oder im Produktkatalog von Hamilton Medical aufgeführt werden.
- Zusätzliche Geräte, die mit den elektrischen medizintechnischen Geräten verbunden sind, müssen den entsprechenden IEC- oder ISO-Normen entsprechen (z. B. IEC 60950 für Datenverarbeitungssysteme). Außerdem sollten alle Konfigurationen den Anforderungen für elektrische medizintechnische Geräte entsprechen (siehe IEC 60601-1, Absatz 16).
- Jede Person, die zusätzliche Geräte an elektrische medizintechnische Geräte anschließt, konfiguriert ein medizintechnisches System und ist damit verantwortlich dafür, dass dieses System den Anforderungen für elektrische medizintechnische Systeme entspricht. Beachten Sie, dass lokale Gesetze Vorrang vor den oben genannten Anforderungen haben. Wenn Sie Fragen zur Vorgehensweise haben, wenden Sie sich an Ihren Ansprechpartner bei Hamilton Medical oder den technischen Kundendienst.
- Der Befeuchter ist gegen die Auswirkungen der Entladung eines Defibrillators *ungeschützt*.

***HINWEIS***

- Der HAMILTON-H900 Befeuchter erfordert besondere Vorsichtsmaßnahmen hinsichtlich der elektromagnetischen Verträglichkeit (EMV) und muss gemäß den EMV-Informationen in den *Erklärungen zur elektromagne-*

*tischen Verträglichkeit für den HAMILTON-H900* installiert und in Betrieb genommen werden.

- Tragbare und mobile HF-Telekommunikationsgeräte können sich auf den HAMILTON-H900 Befeuchter auswirken.

## 1.2 Stromversorgung

**⚠ WARNUNG**

- Stecken Sie den Netzstecker des Befeuchters in eine ordnungsgemäß geerdete Steckdose, um die Gefahr eines elektrischen Schlages zu minimieren. Es liegt im Verantwortungsbereich des Krankenhauses sicherzustellen, dass die Steckdose ordnungsgemäß geerdet ist (Schutzerdung).
- Verwenden Sie das Gerät *nicht*, wenn das Netzkabel beschädigt ist.
- Bei einer falschen Spannung, einem Stromausfall oder einer Unterbrechung der Verbindung zur Stromversorgung gibt der Befeuchter einen Pfeifton aus. Schalten Sie das Gerät sofort aus und überprüfen Sie, ob die richtige Spannung verwendet wird.
- Stellen Sie sicher, dass die korrekte Spannung verwendet wird.

## 1.3 Feuer und andere Gefahrenquellen

**⚠ WARNUNG**

Verwenden Sie den Befeuchter *nicht* in Gefahrenbereichen oder in Gegenwart entzündlicher Gase.

## 1.4 Allgemeines zu Betrieb und Einrichtung

**⚠ WARNUNG**

- Überprüfen Sie vor dem Einsatz des Befeuchters beim Patienten, dass das Beatmungsschlauchsystem wie folgt korrekt am Beatmungsgerät angeschlossen wurde:

  – Der blaue Inspirationsschenkel ist am Inspirationsanschluss *zum Patienten* angeschlossen.

  – Der weiße Exspirationsschenkel ist am Exspirationsanschluss *vom Patienten* angeschlossen.
- Verwenden Sie nur Komponenten und Zubehörteile, die in Abschnitt 8 angegeben sind. Dadurch wird eine ordnungsgemäße Funktion des Befeuchters sichergestellt und eine mögliche Verletzung des Patienten vermieden.
- Verwenden Sie den Befeuchter nicht auf einer Höhe von über 4000 Metern oder außerhalb eines Temperaturbereichs von 10 °C bis 40 °C. Wenn der Befeuchter über dieser Höhe bzw. außerhalb dieses Temperaturbereichs eingesetzt wird, kann das die Qualität der Therapie beeinträchtigen oder zu einer Verletzung des Patienten führen.
- Ungeeignete Feuchtigkeits- oder Temperatureinstellungen können den Patienten schädigen.
- Verwenden Sie den Befeuchter *nicht* während des Transports eines beatmeten Patienten außerhalb des Krankenhauses.
- Schalten Sie den Befeuchter erst EIN, *nachdem* das Beatmungsgerät eingeschaltet wurde.

- Schalten Sie den Befeuchter AUS, *bevor* das Beatmungsgerät ausgeschaltet wird.
- Decken Sie die IR-Messzellen des Befeuchters nicht ab.
- Der invasive Modus (**INV**) darf *nur* bei intubierten und tracheotomierten Patienten eingesetzt werden.
- Treffen Sie im Falle von allergischen Reaktionen zusätzliche Vorsichtsmaßnahmen.
- Überprüfen Sie das Beatmungsschlauchsystem regelmäßig auf Kondensatbildung und entfernen Sie Kondensat bei Bedarf.
- Die Befeuchtungsleistung des Gerätes kann durch die gleichzeitige Verwendung eines Verneblers negativ beeinflusst werden.
- Berühren Sie die Heizplatte und die Unterseite der Befeuchterkammer *nicht*. Die Oberflächen können eine Temperatur von über 85 °C erreichen. Diese heißen Oberflächen strahlen Wärme ab.

**⚠ VORSICHT**

- *Stellen Sie den Befeuchter so auf, dass eine problemlose Trennung von der Hauptstromversorgung möglich ist.*
- *Verwenden Sie nur Komponenten und Zubehörteile, die in Abschnitt 8 sowie im elektronischen Katalog von Hamilton Medical aufgeführt bzw. als mit diesem Befeuchter kompatibel ausgewiesen sind.*

  *Dadurch wird eine ordnungsgemäße Befeuchtung sichergestellt, eine Beeinträchtigung der Leistung wird verhindert und der Garantieanspruch bleibt erhalten.*
- *Wird der Befeuchter aus- und anschließend wieder eingeschaltet, startet er automatisch im invasiven Modus (**INV**), sofern keine andere Konfiguration festgelegt wurde.*
- *Untersuchen Sie das Beatmungsschlauchset vor dem Gebrauch auf Schäden. Entsorgen Sie das Beatmungsschlauchset, wenn es Anzeichen von Schäden aufweist.*
- *Das Heizelement des Befeuchters und die Schlauchheizungen werden automatisch eingeschaltet, wenn die Befeuchterkammer und die Beatmungsschlauchsysteme korrekt installiert sind und der Befeuchter eingeschaltet ist oder sich im **Standby**-Modus befindet.*
- *Wenn die Umgebungstemperatur oder die Temperatur am Gaseinlass und/oder die Flowrate außerhalb des empfohlenen Bereichs liegen, können die physiologischen Feuchtigkeitswerte möglicherweise nicht erreicht werden.*
- *Der Befeuchter kann trotzdem mit Strom versorgt werden, auch wenn der Bildschirm nicht beleuchtet ist. Informationen dazu finden Sie in Tabelle 1.*

***HINWEIS***

- Vor der Verwendung eines Beatmungsschlauchsets bei einem Patienten müssen Sie einen Dichtheitstest durchführen. Wird der Test nicht bestanden, kann er einmal wiederholt werden. Wenn der Test zweimal in Folge nicht bestanden wird, muss das Beatmungsschlauchset durch ein neues ersetzt werden.

- Wenn sich im Schenkel, im flexiblen Schlauch oder im Flow-Sensor ein feines, atemabhängiges Kondensat (Nebel) bildet, ist die Feuchtigkeit optimal eingestellt.
- Bei allen Aktionen wird ein akustisches Signal ausgegeben.

## 1.5 Beatmungsschlauchsysteme und Befeuchterkammer

**⚠ WARNUNG**

- Bei unkorrektem Anschluss des Beatmungsschlauchsystems am Beatmungsgerät kann der Patient verletzt werden.
- Um eine versehentliche Diskonnektion des Beatmungsschlauchsystems während der Verwendung oder des Transports zu vermeiden, verwenden Sie ausschließlich Beatmungsschlauchsysteme, die die Anforderungen der Norm ISO 5367 oder ISO 80601-2-74 erfüllen.
- Befüllen Sie die Befeuchterkammer nur mit sterilem, entmineralisiertem Wasser, das die Hygieneanforderungen des Krankenhauses erfüllt.
- Neigen Sie die Befeuchterkammer nicht.
- Füllen Sie keine Medikamente in die Befeuchterkammer.
- Stellen Sie sicher, dass der Wasserstand nicht den maximalen Füllstand übersteigt.

***HINWEIS***

- Tauschen Sie die Komponenten aus, wenn der Befeuchter das Beatmungsschlauchsystem nicht erkennt.
- Das Wasser zum Nachfüllen darf maximal 37 °C warm sein.
- Stellen Sie sicher, dass die Wasserzufuhr zur Kammer ordnungsgemäß funktioniert.
- Stellen Sie sicher, dass sich der Befeuchter im **Standby**-Modus befindet, bevor Sie Komponenten trennen.

## 1.6 Positionierung des Befeuchters und des Beatmungsschlauchsystems

**⚠ WARNUNG**

- Der Befeuchter muss *stets* unter der Höhe des Patienten positioniert werden.
- Betreiben Sie den Befeuchter *nicht* in einem Winkel über 10° zum Boden.
- Stellen Sie sicher, dass das Beatmungsschlauchsystem spannungsfrei und ohne Knicke vom Befeuchter zum Patienten geführt wird.
- Beheizte Beatmungsschenkel dürfen *nicht* direkt auf der Haut des Patienten platziert werden.
- Sollte der Befeuchter in der Nähe von anderen medizinischen elektrischen Geräten betrieben oder darauf aufgestellt werden, überprüfen Sie den normalen Betrieb des Befeuchters in der zu verwendenden Konfiguration.
- Platzieren Sie das Beatmungsschlauchsystem so, dass kein flüssiges Kondensat zum Patienten gelangen kann.
- Befestigen Sie die Beatmungsschlauchsysteme oder Schlauchclips ordnungsgemäß, um eine mechanische Krafteinwirkung auf den ET-Tubus zu verhindern.

***HINWEIS***

- Überprüfen Sie die Stabilität aller Verbindungen vor der Verwendung.
- Alle Schenkelanschlüsse am Befeuchter kombinieren elektrische Anschlüsse mit Anschlüssen des Beatmungsschlauchsystems. Stellen Sie sicher, dass die elektrischen Kontakte korrekt ausgerichtet sind, so dass sie dem jeweiligen Anschlusselement am Befeuchter entsprechen.

## 1.7 Monitoring und Alarme

***HINWEIS***

- Wenn ein Alarm aktiv ist, zeigt der Bildschirm abwechselnd die aktiven Alarmsymbole und die aktuelle Temperatur am Kammerausgang an.
- Sobald der Befeuchter ausgeschaltet wird, wird die Alarmlautstärke auf den Standardwert 5 zurückgesetzt.
- Alle technischen Alarme, detaillierte technische Informationen sowie die Wartungsarbeiten sind im *Wartungshandbuch zum HAMILTON-H900* beschrieben.

## 1.8 Wartung

**⚠ WARNUNG**

- Änderungen am Befeuchter sind *nicht* zulässig.
- Trennen Sie den Befeuchter vor der Reinigung oder Desinfektion *stets* von der Stromquelle. Andernfalls besteht die Gefahr eines elektrischen Schlages.

**⚠ VORSICHT**

- *Gebrauchte Beatmungsschlauchsysteme und Befeuchterkammern sind gemäß den lokalen Gesetzen und Vorschriften oder den krankenhausinternen Verfahren als kontaminierte Produkte zu behandeln.*
- *Um eine den Vorschriften entsprechende Wartung zu gewährleisten und Verletzungen zu vermeiden, darf nur von Hamilton Medical autorisiertes Servicepersonal gemäß den Anweisungen im Wartungshandbuch zum HAMILTON-H900 Wartungsarbeiten am Befeuchter durchführen.*
- *Verwenden Sie ausschließlich Ersatzteile von Hamilton Medical.*
- *Führen Sie nur die ausdrücklich im Wartungshandbuch zum HAMILTON-H900 aufgeführten Wartungsmaßnahmen durch.*
- *Verwenden Sie nur die zulässigen Reinigungsmittel für die Reinigung und Desinfektion.*

***HINWEIS***

- Spezifische Angaben zur Reinigung, Desinfektion und Sterilisation autoklavierbarer (wiederverwendbarer) Zubehörteile und Komponenten finden Sie in der entsprechenden *Aufbereitungsvorschrift* sowie in der *Gebrauchsanweisung*, die der jeweiligen Komponente beiliegt.
- (*Nur in den USA*) Verwenden Sie ausschließlich von der EPA zugelassene Reinigungsmittel für die Reinigung und Desinfektion.

# 2 Überblick

Diese Anleitung stellt Informationen zur Einrichtung und Verwendung des HAMILTON-H900 Befeuchters bereit.

Der Befeuchter ist für den Einsatz mit Beatmungsgeräten von Hamilton Medical sowie von anderen Herstellern vorgesehen.

## 2.1 Informationen zum HAMILTON-H900 Befeuchter

Der HAMILTON-H900 Befeuchter beheizt und befeuchtet Atemgase für erwachsene, pädiatrische und neonatale Patienten.

Er unterstützt die folgenden gängigen Beatmungsmodi:

- Invasive Beatmung
- Nichtinvasive Beatmung
- High-Flow Sauerstofftherapie

Das System umfasst das Befeuchtergehäuse, den Bildschirm, die Bedienelemente, die Wasserkammer, die Heizplatte und die elektrischen Anschlüsse für ein beheiztes Beatmungsschlauchsystem.

Es bietet die folgenden grundlegenden Merkmale:

- Anpassbare Temperatur- und Feuchtigkeitsparameter
- Monitoring- und Alarmfunktionen
- Integration der vom Befeuchter überwachten Daten und Parameter bei unterstützten Beatmungsgeräten von Hamilton Medical[13]

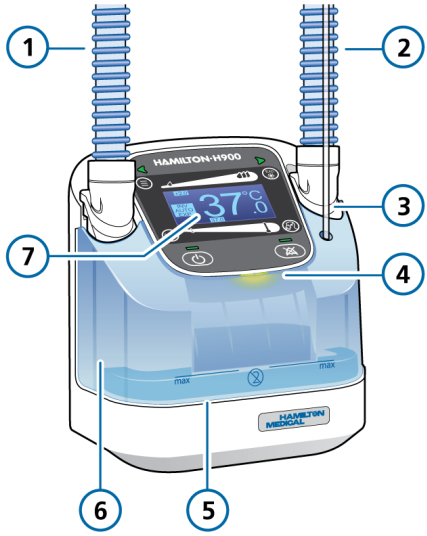
## 2.2 Gerätebeschreibungen

Dieser Abschnitt gibt einen Überblick über den Befeuchter und die zugehörigen Beatmungsschlauchsets.

### 2.2.1 Informationen zum Befeuchter

Die Abbildungen 1 bis 5 geben einen Überblick über den Befeuchter.

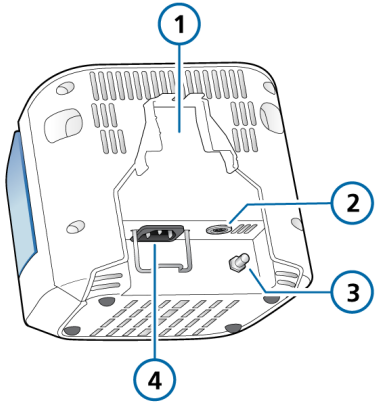
Abbildung 1. HAMILTON-H900 Befeuchter, Vorderansicht




| | | | |
|---|---|---|---|
| 1 | Inspirationsschenkel zum Beatmungsgerät (blau) | 5 | Heizplatte |
| 2 | Inspirationsschenkel zum Patienten (blau) | 6 | Befeuchterkammer |
| 3 | Wasserzufuhrschlauch | 7 | Bedienfeld und Bildschirm |
| 4 | Optische Alarmanzeige | | |

[13] Nicht für alle Märkte verfügbar.

Abbildung 2. HAMILTON-H900 Befeuchter, Rückansicht




| | | | |
|---|---|---|---|
| 1 | Aussparung für die Montagehalterung | 3 | Potenzialausgleichsanschluss |
| 2 | RS-232-Anschluss | 4 | Netzstrombuchse |

## 2.2.2 Informationen zum Hauptbildschirm

Vom Hauptbildschirm aus können Sie während der Befeuchtung direkt auf alle Einstellungen, Modi, Alarme und Parameter zugreifen.

Die Abbildungen 3 bis 5 zeigen die Bedienelemente und Anzeigen an der Vorderseite sowie den Bildschirm.

Abbildung 3. HAMILTON-H900 Befeuchter, Elemente am Bedienfeld


| | | | |
|---|---|---|---|
| 1 | Taste für Fenster zur Temperaturüberwachung | 5 | Taste „Audio anhalten“ |
| 2 | Schieberegler für Temperaturregelung | 6 | Taste „Hauptschalter/Standby“ |
| 3 | Taste für exsp. Temperaturerhöhung | 7 | Taste „Auto“ |
| 4 | Modustaste „INV“/„NIV“/„HiFlow“ | 8 | Bildschirm (siehe Abbildung 5) |

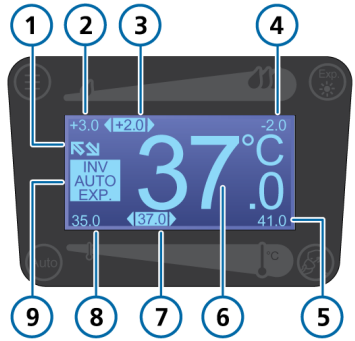
Abbildung 4. HAMILTON-H900 Befeuchter, Statusanzeigen am Bedienfeld


1 Statusanzeigen für Schenkelanschluss

2 Anzeige „Audio anhalten“

3 Statusanzeige „Hauptschalter/ Standby“

Abbildung 5. HAMILTON-H900 Befeuchter, Bildschirm




1 Verbindung zum Beatmungsgerät aktiviert

2 Max. Einstellung Temperaturgradient

3 Einstellung Temperaturgradient

4 Min. Einstellung Temperaturgradient

5 Max. Temperatureinstellung am Kammerausgang

6 Akt. Temperatur am Kammerausgang

7 Temperatureinstellung am Kammerausgang

8 Min. Temperatureinstellung am Kammerausgang

9 Aktive Modi/Einstellungen

*Alle Elemente auf dem Bildschirm sind nur zur Erläuterung abgebildet; während des Betriebs sind nicht immer alle gleichzeitig zu sehen.*

### 2.2.3 Informationen zu den Beatmungsschlauchsystemen des Befeuchters

Der HAMILTON-H900 Befeuchter unterstützt verschiedenste Beatmungsschlauchsysteme mit einem oder zwei Schenkeln für erwachsene, pädiatrische und neonatale Patienten.

Detaillierte Informationen dazu finden Sie in der *Gebrauchsanweisung* zu Ihrem Beatmungsschlauchsystem.

### 2.2.4 Informationen zu den Statusanzeigen am Befeuchter

Die Anzeigen an der Vorderseite des Befeuchters geben wichtige Informationen zum Befeuchterstatus an. Siehe Abbildung 4.

Tabelle 1. Statusanzeigen

| Symbol | Beschreibung |
|---|---|
| **Taste „Hauptschalter/Standby" mit Statusanzeige** | |
|  | *Grün*: Der Befeuchter ist in Betrieb. |
|  | *Orange*: Der Befeuchter befindet sich im **Standby**-Modus. |
|  | *Blau*: Der Befeuchter ist ausgeschaltet und mit einer Stromquelle verbunden. |
|  | *Aus*: Der Befeuchter ist ausgeschaltet und *nicht* mit einer Stromquelle verbunden. |
| **Statusanzeige für den Schenkelanschluss** | |
|  | *Grün*: Der Schenkel ist korrekt angeschlossen. |
|  | *Orange*: Der Befeuchter testet den Schenkelanschluss. |
|  | *Rot*: Entweder besteht ein Problem mit dem Schenkelanschluss oder ein Schenkel ist nicht angeschlossen. |
| **Taste „Audio anhalten" mit Anzeige** | |
|  | *Rot*: Die Funktion „Audio anhalten" ist aktiv. |

## 2.3 Navigieren durch die Fenster und Bedienelemente

In diesem Abschnitt wird die Verwendung der Tasten und Schieberegler des Befeuchters beschrieben.

### 2.3.1 Verwenden der Bedientasten

Mit den Tasten am Bedienfeld (Abbildung 3) können Sie Modi auswählen, Einstellungen ändern und sich einen Überblick über die wichtigsten Temperatureinstellungen verschaffen.

Tabelle 2. Bedientasten (siehe Abbildung 3)

| Taste | Beschreibung |
|---|---|
|  | **Exsp. Temperaturerhöhung**<br>Erhöht die Temperatur im Exspirationsschenkel. |
|  | **Auto**<br>Aktiviert den Modus **Auto**.<br>Informationen dazu finden Sie in Abschnitt 4.2.2. |
|  | **Betriebsmodi „INV"/„NIV"/„HiFlow"**<br>Schaltet zwischen den Modi **INV**, **NIV** und **HiFlow** um.<br>Informationen dazu finden Sie in Abschnitt 4.2. |

| Taste | Beschreibung |
|---|---|
| | **Fenster zur Temperaturüberwachung**<br>Zeigt die aktuellen Werte für die Temperatur am Y-Stück, die Temperatur am Kammerausgang sowie den Temperaturgradienten an.<br>Informationen dazu finden Sie in Abschnitt 4.4. |

### 2.3.2 Verwenden der Schieberegler

Im manuellen Modus können Sie die Temperatureinstellungen mithilfe der Schieberegler ändern (Abbildung 3).

Tabelle 3. Schieberegler für die Temperaturregelung

| Schieberegler | Beschreibung |
|---|---|
| **Schieberegler für den Temperaturgradienten** | |
|  | Passt den Temperaturunterschied zwischen dem Kammerausgang und dem Y-Stück an.<br>Informationen dazu finden Sie in Abschnitt 4.3. |
| **Schieberegler für die Temperatur am Kammerausgang** | |
|  | Passt die Temperatur am Kammerausgang an.<br>Informationen dazu finden Sie in Abschnitt 4.3. |

## 3 Vorbereiten des Befeuchters für den Einsatz

*Lesen Sie die Sicherheitsinformationen in Abschnitt 1, bevor Sie fortfahren.*

Um den Befeuchter für den Einsatz vorzubereiten, sind folgende Schritte erforderlich:

- Eine einmalige Konfiguration der Einstellungen durch einen Medizintechniker (siehe Tabelle 4)
- Einrichtung des Befeuchters durch medizinisches Pflegepersonal für jeden neuen Patienten (siehe Tabelle 5)

Tabelle 4. Konfiguration und Einrichtung durch einen Medizintechniker

| Schritt | Siehe ... |
|---|---|
| *Diese einmaligen Aufgaben für die Erstkonfiguration werden von einem Techniker durchgeführt.* | |
| Befeuchter installieren und positionieren | Siehe das jeweilige *Installationshandbuch* für das Beatmungsgerät oder das Fahrgestell |
| Befeuchtereinstellungen konfigurieren | Abschnitt 7 |
| *Optional*: Befeuchter am RS-232-COM-Anschluss eines beliebigen unterstützten Beatmungsgerätes von Hamilton Medical anschließen | Siehe das jeweilige *Bedienungshandbuch* für das Beatmungsgerät |

Tabelle 5. Konfiguration und Einrichtung durch medizinisches Pflegepersonal

| Schritt | Siehe ... |
|---|---|
| *Die folgenden Aufgaben werden von medizinischem Pflegepersonal durchgeführt.* | |
| An einer Stromquelle anschließen | Abschnitt 3.1 |
| Beatmungsschlauchsystem anschließen | Abschnitt 3.2 |
| Befeuchter einschalten | Abschnitt 3.3 |
| Alarme testen | Abschnitt 3.4 |
| Befeuchtereinstellungen festlegen | Abschnitt 3.5 |
| Patienten anschließen | Abschnitt 3.6 |

## 3.1 Anschließen an einer Stromquelle

Überprüfen Sie stets die Zuverlässigkeit des Hauptstromanschlusses, bevor Sie den Befeuchter und das Beatmungsgerät anschließen.

**So schließen Sie den Befeuchter an einer Stromquelle an:**

- Schließen Sie den Befeuchter an einer Steckdose an, die Wechselstrom bereitstellt.[14]

## 3.2 Anschließen des Beatmungsschlauchsystems am Befeuchter

Hamilton Medical bietet verschiedenste Beatmungsschlauchsysteme für erwachsene, pädiatrische und neonatale Patienten

Detaillierte Informationen dazu finden Sie in der *Gebrauchsanweisung* zum jeweiligen Beatmungsschlauchsystem.

## 3.3 Ein- und Ausschalten des Befeuchters

Wenn der Befeuchter eingeschaltet wird, läuft er automatisch im konfigurierten Standardmodus.

Achten Sie darauf, dass Sie erst das Beatmungsgerät einschalten, *bevor* Sie den Befeuchter einschalten.

**So schalten Sie den Befeuchter ein:**

- Halten Sie die Taste  (**Hauptschalter/Standby**) etwa 3 Sekunden lang gedrückt.

Der Befeuchter führt einen Selbsttest durch. Sobald dieser abgeschlossen ist, startet der Befeuchter automatisch im invasiven Modus (**INV**), sofern keine andere Konfiguration festgelegt wurde.

**So schalten Sie den Befeuchter aus:**

- Halten Sie die Taste  etwa 3 Sekunden lang gedrückt.

Achten Sie darauf, dass Sie erst den Befeuchter ausschalten, *bevor* Sie das Beatmungsgerät ausschalten.

[14] Wenn Sie den Befeuchter mit einem unterstützten Beatmungsgerät von Hamilton Medical verwenden, schließen Sie das Netzkabel des Befeuchters an der speziell dafür vorgesehenen Strombuchse am Beatmungsgerät an.

## 3.4 Testen der Alarme

Überprüfen Sie vor dem Anschluss eines neuen Patienten am Befeuchter die ordnungsgemäße Funktion der Alarme.

Stellen Sie sicher, dass der Befeuchter eingeschaltet ist.

**So testen Sie die Befeuchteralarme:**

1. Lösen Sie einen Alarm aus, indem Sie die Befeuchterkammer aus dem Befeuchter entfernen.
2. Stellen Sie sicher, dass:
   – ein akustischer Alarm zu hören ist
   – die optische Alarmanzeige blinkt (Abbildung 4)
   – das entsprechende Alarmsymbol auf dem Bildschirm angezeigt wird (Tabelle 9)

Beheben Sie den Alarm, indem Sie die Befeuchterkammer wieder in den Befeuchter einsetzen, und stellen Sie sicher, dass der Alarm aufgehoben wird.

## 3.5 Festlegen der Befeuchtereinstellungen

Wählen Sie den Beatmungsmodus für Ihren Patienten.[15] Detaillierte Informationen dazu finden Sie in Abschnitt 4.2.

## 3.6 Anschließen des Patienten

Schließen Sie das Beatmungsschlauchsystem am geeigneten Patientenanschluss an.

Der Befeuchter ist jetzt konfiguriert und einsatzbereit.

# 4 Arbeiten mit dem HAMILTON-H900 Befeuchter

Tabelle 6. Überblick über die Bedienung

| Informationen zu ... | Siehe ... |
|---|---|
| Ein-/Ausschalten des Befeuchters | Abschnitt 3.3 |
| Aufrufen/Beenden des **Standby**-Modus | Abschnitt 4.1 |
| Zugreifen auf die Parameter am Befeuchter | Abschnitt 2.3 |
| Betriebsmodi des Befeuchters: **INV**, **NIV**, **HiFlow** | Abschnitt 4.2 |
| Automatische (**Auto**) und **manuelle** Einstellungen | Abschnitt 4.2.2 |
| Ändern der Feuchtigkeit mithilfe der Temperaturparameter | Abschnitt 4.3 |
| Überwachte Befeuchterparameter | Abschnitt 4.4 |
| Befeuchteralarme | Abschnitt 5 |

## 4.1 Aufrufen/Beenden des Standby-Modus

**⚠ VORSICHT**

*Im **Standby**-Modus werden alle Einstellungen beibehalten und die Wärmeabgabe wird reduziert.*

Beim **Standby**-Betrieb handelt es sich um einen Ruhemodus, der es ermöglicht, die aktuellen Einstellungen beizubehalten, während der Befeuchter nicht in Betrieb ist.

[15] Bei Einsatz mit einem Beatmungsgerät von Hamilton Medical, das die integrierte Bedienung unterstützt, übernimmt der Befeuchter den Betriebsmodus des Beatmungsgerätes. Detaillierte Informationen dazu finden Sie im *Bedienungshandbuch* zu Ihrem Beatmungsgerät.

Im **Standby**-Modus werden die Einstellungen für die **Temperatur am Kammerausgang** und den **Temperaturgradienten** reduziert.[16] Detaillierte Informationen dazu finden Sie in Abschnitt 9.7.

**So aktivieren Sie den Standby-Modus am Befeuchter:**

- Drücken Sie kurz die Taste (**Hauptschalter/Standby**).

  Während des **Standby**-Modus wird auf dem Bildschirm die Zeit angezeigt, die verstrichen ist, seitdem sich der Befeuchter im **Standby**-Modus befindet. Die Anzeige **Hauptschalter/Standby** leuchtet orange.

**So beenden Sie den Standby-Modus und starten die Befeuchtung:**

- Drücken Sie die Taste .

  Der Befeuchter nimmt den normalen Betrieb wieder auf; die Statusanzeige **Hauptschalter/Standby** leuchtet grün.

## 4.2 Informationen zu den Betriebsmodi des Befeuchters

Der HAMILTON-H900 bietet die folgenden Betriebsmodi: invasiver Modus (**INV**), nichtinvasiver Modus (**NIV**) und High-Flow Sauerstofftherapie (**HiFlow**).

Die Auswahl des Betriebsmodus bestimmt die anfänglichen Temperatureinstellungen sowohl am Ausgang der Befeuchterkammer (**Temperatur am Kammerausgang**) als auch am Y-Stück (**Temperaturgradient**) sowie die zulässigen Temperaturbereiche für diese Parameter.

Diese Temperaturbereiche sind je nach Patientengruppe unterschiedlich. Informationen dazu finden Sie in Tabelle 18.

### 4.2.1 Wechseln zwischen den Modi

Der Befeuchter startet automatisch im invasiven Modus (**INV**), sofern keine andere Konfiguration in den benutzerdefinierten Standardeinstellungen festgelegt wurde.

Wenn zum invasiven Modus (**INV**) oder nichtinvasiven Modus (**NIV**) gewechselt wird, setzt der Befeuchter die Parametereinstellungen automatisch auf **Auto**.

**So wechseln Sie zwischen den Modi:**

- Drücken Sie die Taste (**Modi**), bis der gewünschte Modus (**INV**, **NIV**, **HiFlow**) angezeigt wird.

  Der gewählte Modus erscheint auf dem Bildschirm.

Abbildung 6. Modus „INV“ (**1**) ist ausgewählt

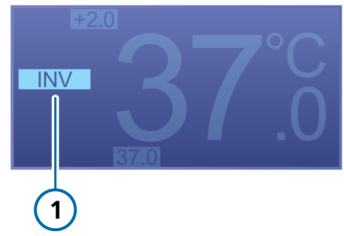
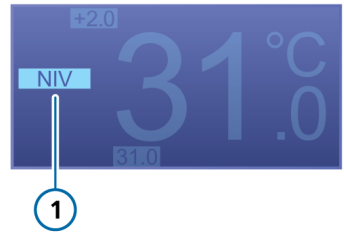
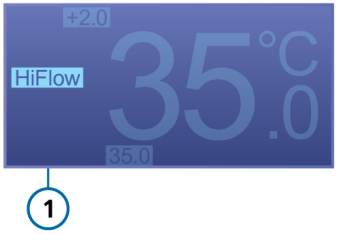



Abbildung 7. Modus „NIV“ (**1**) ist ausgewählt




[16] Während der Verneblung ändert sich die Einstellung für den **Temperaturgradienten** im **Standby**-Modus *nicht*.

Abbildung 8. Modus „HiFlow“ (**1**) ist ausgewählt




## 4.2.2 Automatische („Auto“) und manuelle Parametereinstellungen

Sie können den Befeuchter im Modus **Auto** verwenden oder die Einstellungen manuell anpassen. Standardmäßig startet der Befeuchter im Modus **Auto**.

Die Einstellungen für die **Temperatur am Kammerausgang** und den **Temperaturgradienten** können mit einer der folgenden Methoden festgelegt werden:

- Sie werden aus den konfigurierten Standardeinstellungen geladen (Modus **Auto**).
- Sie werden manuell vom Bediener festgelegt.

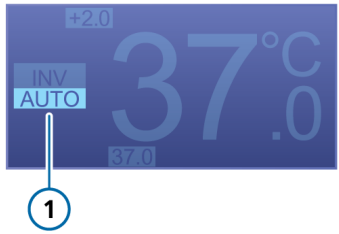
### Automatische Einstellungen („Auto“)

Wenn der Befeuchter auf **Auto** eingestellt wird, lädt er die konfigurierten Standardeinstellungen für den ausgewählten Modus (siehe Abschnitt 7) und verwendet diese zum Regeln der Gastemperatur.

Bei niedrigen Umgebungstemperaturen kann der Befeuchter die Temperatur der Befeuchterkammer automatisch anpassen.

Wenn der Modus **Auto** gewählt wird, erscheint der Text **AUTO** auf dem Hauptbildschirm.

Abbildung 9. Modus „Auto“ (**1**) ist ausgewählt

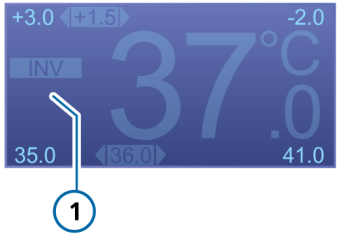



### Manuelle Einstellungen

Wenn Sie die Einstellung für die **Temperatur am Kammerausgang** oder den **Temperaturgradienten** mithilfe der Schieberegler ändern, wechselt der Befeuchter in den **manuellen** Modus. Allerdings regelt er die Temperatur weiterhin automatisch so, dass die festgelegten Einstellungen erreicht werden.

Wenn Einstellungen manuell geändert werden, wird der Text **Auto** nicht mehr auf dem Hauptbildschirm angezeigt; die entsprechende Stelle ist leer.

Abbildung 10. Manueller Modus (**1**) ist aktiv



#### 4.2.2.1 Aktivieren des Modus „Auto“

Nachdem eine der Temperatureinstellungen manuell geändert wurde, können Sie den Modus **Auto** wieder aktivieren.

**So aktivieren Sie den Modus „Auto“ wieder:**

- Drücken Sie die Taste Auto (**Auto**).

  Durch die Umstellung des Betriebsmodus auf **INV** oder **NIV** wechselt der Befeuchter ebenfalls automatisch in den Modus **Auto**.

## 4.3 Ändern der Feuchtigkeit mithilfe der Temperaturparameter

***HINWEIS***

Wenn sich der Befeuchter im Modus **Auto** befindet, wird die Befeuchtung durch Verschieben eines der Schieberegler auf den **manuellen** Modus umgestellt.

***HINWEIS***

Im Modus **HiFlow** können Sie die Einstellung für den **Temperaturgradienten** nicht mithilfe des Schiebereglers ändern. Sie können in der **Konfiguration** einen neuen Wert für den **Temperaturgradienten** festlegen. Informationen dazu finden Sie in Abschnitt 7.

Sie können folgende Parameter am Befeuchter anpassen[17]:

Tabelle 7. Einstellbare Parameter am Befeuchter

| Parameter | Beschreibung |
|---|---|
| Temperatur am Kammerausgang | Temperatur am Ausgang der Befeuchterkammer.<br>Der mögliche Wertebereich für diesen Parameter hängt vom Betriebsmodus ab, der für den Befeuchter ausgewählt ist. Detaillierte Informationen dazu finden Sie in den Tabellen 16 und 18.<br>Höhere Werte führen zu einer höheren absoluten Feuchtigkeit. |
| Temperaturgradient | Die Differenz zwischen der Temperatur am Ausgang der Befeuchterkammer und der Temperatur am Y-Stück. |
| Exsp. Temperaturerhöhung | Wenn dieser Parameter ausgewählt ist, erhöht der Befeuchter die Heizleistung im Exspirationsschenkel.[18] |

Die maximal zulässige Temperatur am Y-Stück des Patienten beträgt 42 °C. Die Summe aus der **Temperatur am Kammerausgang** und dem Wert für den **Temperaturgradienten** darf diesen Grenzwert nicht überschreiten. Wenn der **Temperaturgradient** beispielsweise auf 2 °C eingestellt wird, ist die höchste mögliche Einstellung für die **Temperatur am Kammerausgang** 40 °C.

[17] Bei Einsatz mit einem Beatmungsgerät von Hamilton Medical, das die integrierte Bedienung des Befeuchters unterstützt, können Sie die Einstellungen auch direkt am Beatmungsgerät ändern. Detaillierte Informationen dazu finden Sie im *Bedienungshandbuch* zu Ihrem Beatmungsgerät.

[18] Nur beheizte Beatmungsschlauchsysteme mit zwei Schenkeln für den Einmalgebrauch.

Außerdem hat die Einstellung für den **Temperaturgradienten** Vorrang vor der Einstellung für die **Temperatur am Kammerausgang**. Das heißt, wenn die Summe der Einstellungen am Y-Stück eine Temperatur von über 42 °C zur Folge hätte, bleibt die Einstellung für den **Temperaturgradienten** unverändert, aber die Einstellung für die **Temperatur am Kammerausgang** wird angepasst.

Wenn die **Temperatur am Kammerausgang** beispielsweise auf 40 °C eingestellt ist, können Sie für den **Temperaturgradienten** eine Einstellung von 3 °C wählen, obwohl die Summe 42 °C überschreitet. Sobald die Einstellung für den **Temperaturgradienten** übernommen wird, wird die **Temperatur am Kammerausgang** automatisch auf 39 °C zurückgesetzt.

### So legen Sie die Temperatur am Kammerausgang fest:

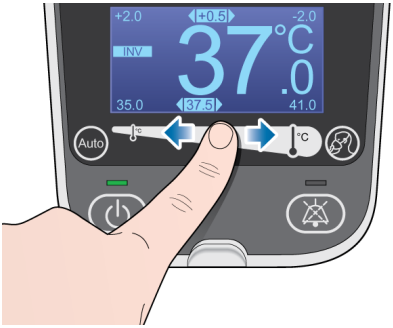
- Berühren Sie den Schieberegler für die **Temperatur am Kammerausgang** an der aktuellen Einstellung:

  – Ziehen Sie ihn nach links, um die Temperatur am Kammerausgang zu verringern.

  – Ziehen Sie ihn nach rechts, um die Temperatur am Kammerausgang zu erhöhen.

Die Änderungen werden durch einen akustischen Signalton bestätigt und sofort angewendet.

Abbildung 11. Anpassen der Temperatur am Kammerausgang




### So stellen Sie am Kammerausgang eine Temperatur von > 39 °C ein:

Um die **Temperatur am Kammerausgang** auf über 39 °C zu erhöhen, muss der Schieberegler zweimal aktiviert werden.

1. Berühren Sie den Schieberegler für die **Temperatur am Kammerausgang** an der aktuellen Einstellung und ziehen Sie ihn nach rechts, um den Grenzwert von 39 °C zu erreichen.
2. Berühren Sie den Schieberegler erneut und ziehen Sie ihn, um die Temperatur am Kammerausgang auf einen Wert über 39 °C einzustellen.

### So stellen Sie den Temperaturgradienten ein:

- Berühren Sie den Schieberegler für den **Temperaturgradienten** an der aktuellen Einstellung:

  – Ziehen Sie ihn nach rechts, um den Temperaturgradienten zu verringern.

  – Ziehen Sie ihn nach links, um den Temperaturgradienten zu erhöhen.

Die Änderungen werden durch einen akustischen Signalton bestätigt und sofort angewendet.

Abbildung 12. Einstellen des Temperaturgradienten


Wenn beispielsweise die Zieltemperatur am Y-Stück 39 °C beträgt und die **Temperatur am Kammerausgang** auf 37 °C eingestellt ist, wählen Sie für den **Temperaturgradienten** eine Einstellung von 2 °C.

## 4.4 Überwachung der Befeuchtung

Im Fenster zur **Temperaturüberwachung** sind Monitoring-Daten verfügbar, auf die Sie jederzeit zugreifen können.[19]

Die folgenden Parameter werden überwacht:

- Temperatur am Kammerausgang
- Temperaturgradient
- Temperatur am Y-Stück

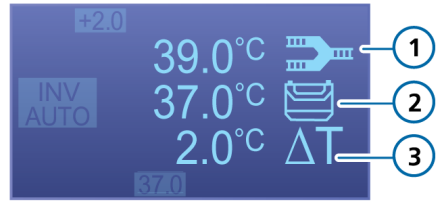
### 4.4.1 Anzeigen von zusätzlichen Monitoring-Parametern

**So zeigen Sie das Fenster zur Temperaturüberwachung an:**

- Drücken Sie die Taste (Fenster zur Temperaturüberwachung).

  Das Fenster wird automatisch nach 30 Sekunden bzw. nach erneutem Drücken der Taste geschlossen.

Abbildung 13. Fenster zur Temperaturüberwachung




| | | | |
|---|---|---|---|
| 1 | Akt. Temperatur am Y-Stück | 3 | Akt. Temperaturgradient |
| 2 | Akt. Temperatur am Kammerausgang | | |

## 4.5 Einstellungen für die Bildschirmhelligkeit für Tag und Nacht

Die Hintergrundbeleuchtung des Befeuchterbildschirms unterstützt zwei unterschiedliche Bildschirmeinstellungen. Legen Sie mit diesen Einstellungen die Bildschirmhelligkeit fest.

**So schalten Sie zwischen den Einstellungen für Tag und Nacht um:**

- Halten Sie die Taste 5 Sekunden lang gedrückt.

Informationen dazu, wie Sie die Standardhelligkeit für Tag und Nacht einstellen, finden Sie in Abschnitt 7.

[19] Bei Einsatz mit einem Beatmungsgerät von Hamilton Medical, das die integrierte Überwachung des Befeuchters unterstützt, werden Befeuchterdaten auf dem Bildschirm des Beatmungsgerätes angezeigt. Detaillierte Informationen dazu finden Sie im *Bedienungshandbuch* zu Ihrem Beatmungsgerät.

# 5 Umgang mit Befeuchteralarmen

Befeuchterbezogene Alarme informieren Sie über Zustände, die Ihre Aufmerksamkeit erfordern. Alarme werden folgendermaßen angezeigt:

- Grafisch auf dem Befeuchterbildschirm
- Mit einer Folge von 3 oder 5 akustischen Signaltönen
- Die Alarmleuchte über der Befeuchterkammer blinkt
- Bei Einsatz mit einem Beatmungsgerät von Hamilton Medical, das die integrierte Überwachung des Befeuchters unterstützt, werden Alarmmeldungen auch auf dem Bildschirm des Beatmungsgerätes angezeigt.[20]

Die Alarme werden wie in Tabelle 8 beschrieben in Alarme mit hoher und mittlerer Priorität sowie in technische Fehler unterteilt.

Eine vollständige Liste der Alarme finden Sie in Tabelle 9.

Tabelle 8. Alarmanzeigen

| Alarmtyp | Alarmstatusanzeige | Akustisches Signal | Erforderliche Maßnahme |
|---|---|---|---|
| Hohe Priorität | Rot, blinkend<br>Alarmsymbol wird auf dem Bildschirm angezeigt | Folge von 5 Pieptönen, die so lange wiederholt werden, bis der Alarm aufgehoben ist | Der Befeuchter erfordert Ihre sofortige Aufmerksamkeit. |
| Mittlere Priorität | Gelb, blinkend<br>Alarmsymbol wird auf dem Bildschirm angezeigt | Folge von 3 Pieptönen, die so lange wiederholt werden, bis der Alarm aufgehoben ist | Der Befeuchter erfordert umgehend Ihre Aufmerksamkeit. |
| Technischer Fehler | Rot, blinkend<br>Die Nummer des technischen Fehlers (TF) wird auf dem Bildschirm angezeigt | Folge von 3 Pieptönen, die so lange wiederholt werden, bis der Alarm aufgehoben ist | • Notieren Sie die Nummer des technischen Fehlers (TF)[21].<br>• Nehmen Sie den Befeuchter aus dem Einsatz.<br>• Lassen Sie den Befeuchter warten. |

[20] Nicht auf allen Beatmungsgeräten verfügbar. Informationen dazu finden Sie im *Bedienungshandbuch* zu Ihrem Beatmungsgerät.
[21] Eine Liste der Nummern aller technischen Fehler (TF) ist im *Wartungshandbuch zum HAMILTON-H900* enthalten.

## 5.1 Vorübergehende Unterdrückung eines Alarms

Der akustische Signalton ist eine Komponente eines Alarms. Bei den meisten Alarmen können Sie die Ausgabe des Alarmtons jeweils zwei Minuten lang anhalten (unterdrücken).

**So unterdrücken Sie einen Alarm vorübergehend:**

- Drücken Sie die Taste  (**Audio anhalten**) an der Vorderseite des Befeuchters.

  Der akustische Alarm des Befeuchters wird zwei Minuten lang stumm geschaltet.

  Durch erneutes Drücken der Taste wird die Funktion **Audio anhalten** deaktiviert.

Die Hintergrundbeleuchtung der Taste **Audio anhalten** leuchtet dauerhaft rot, während die Funktion **Audio anhalten** aktiv ist.

Wenn die Zeit abgelaufen ist und das Problem inzwischen nicht behoben wurde, ertönt der Alarm erneut.

## 5.2 Einstellen der Alarmlautstärke

**⚠ WARNUNG**

Stellen Sie die Alarmlautstärke so ein, dass der Lautstärkepegel über dem Geräuschpegel der Umgebung liegt. Andernfalls kann es vorkommen, dass Sie den Alarm nicht hören und Alarmzustände nicht erkennen.

Sie können die Lautstärke für akustische Alarme einstellen.

Standardmäßig ist die Lautstärke auf 5 eingestellt. Beim Ausschalten des Befeuchters wird die Alarmlautstärke auf den Standardwert zurückgesetzt.

**So stellen Sie die Alarmlautstärke ein:**

1. Drücken Sie ggf. die Taste  (**Hauptschalter/Standby**), um den **Standby**-Modus am Befeuchter zu aktivieren.
2. Halten Sie die Taste  3 Sekunden lang gedrückt.

   Auf dem Bildschirm wird die aktuelle Einstellung für die Alarmlautstärke angezeigt.
3. Stellen Sie die Alarmlautstärke mit dem Schieberegler für die **Temperatur am Kammerausgang** ein (siehe Abbildung 3).

   Der Befeuchter bestätigt Ihre Auswahl mit einem Piepton in der neuen Lautstärke.
4. Drücken Sie die Taste  , um Ihre Auswahl zu bestätigen und zum normalen Betrieb zurückzukehren.

## 5.3 Fehlerbehebung bei Alarmen

In Tabelle 9 werden die Befeuchteralarme, die zugehörige grafische Darstellung am Befeuchter, eine Beschreibung und die vorgeschlagenen Abhilfemaßnahmen aufgeführt.

Tabelle 9. HAMILTON-H900-Alarme

| Alarm | Alarmsymbol | Beschreibung | Maßnahme |
|---|---|---|---|
| **Hohe Priorität** | | | |
| Neigung des Befeuchters |  | Der Befeuchter ist gefährlich stark geneigt.<br>Der Befeuchter ist in einem Winkel von 10° oder darüber zum Boden aufgestellt. | • Prüfen Sie die Montage des Befeuchters.<br>• Prüfen Sie das Fahrgestell des Beatmungsgerätes.<br>• Betreiben Sie den Befeuchter in einem Winkel von weniger als 10° zum Boden. |
| Temperatur zu hoch |  | Die Gastemperatur am Ausgang der Befeuchterkammer oder am Y-Stück liegt über dem eingestellten Wert. | • Prüfen Sie, ob die Bettdecke des Patienten das Beatmungsschlauchsystem bedeckt.<br>• Prüfen Sie, ob das Beatmungsschlauchsystem oder die Befeuchterkammer direkter Sonneneinstrahlung ausgesetzt ist.<br>• Tauschen Sie das Beatmungsschlauchsystem aus. |
| Wasserstand zu hoch |  | Der Wasserstand in der Befeuchterkammer liegt über der Markierung für den maximalen Füllstand. | • Leeren Sie die Befeuchterkammer, um den Wasserstand zu senken.<br>• Tauschen Sie die Befeuchterkammer aus.<br>• Betreiben Sie den Befeuchter in einem Winkel von weniger als 10° zum Boden. |

| Alarm | Alarmsymbol | Beschreibung | Maßnahme |
|---|---|---|---|
| Technischer Fehler | Die Nummer des technischen Fehlers (TF) wird auf dem Bildschirm angezeigt | Technischer Fehler aufgrund einer Fehlfunktion des Befeuchters. | • Überprüfen Sie den Befeuchterbetrieb und alle Verbindungen.<br>• Tauschen Sie den Befeuchter aus und lassen Sie ihn warten.<br>• Wenn die Nummer für einen technischen Fehler angezeigt wird, notieren Sie sie und geben Sie sie an, wenn der Befeuchter gewartet wird. |
| **Mittlere Priorität** | | | |
| Temperatur zu niedrig |  | Die Gastemperatur am Ausgang der Befeuchterkammer oder am Y-Stück liegt unter dem eingestellten Wert. | • Warten Sie, bis das System vollständig aufgewärmt ist (etwa 30 Minuten).<br>• Prüfen Sie, ob alle Einstellungen korrekt sind.<br>• Vermeiden Sie einen direkten Luftstrom von der Klimaanlage oder einem ähnlichen Gerät auf den Befeuchter und das Beatmungsschlauchsystem. |
| Wasserstand zu niedrig |  | Der Wasserstand in der Befeuchterkammer liegt unter der Markierung für einen niedrigen Füllstand. | • Überprüfen Sie die Wasserflasche und füllen Sie die Schläuche wieder auf.<br>• Wenn die Wasserflasche leer ist, schließen Sie eine neue Wasserflasche an.<br>• Füllen Sie die leere Befeuchterkammer wieder auf oder tauschen Sie sie aus.<br>• Betreiben Sie den Befeuchter in einem Winkel von weniger als 10° zum Boden. |
| Befeuchterkammer prüfen |  | Es ist keine Kammer oder eine nicht kompatible Befeuchterkammer eingesetzt. | Setzen Sie eine neue Befeuchterkammer ein und schließen Sie das Beatmungsschlauchsystem an. |

| Alarm | Alarmsymbol | Beschreibung | Maßnahme |
|---|---|---|---|
| Linken oder rechten Schenkel prüfen |  | Der Bildschirm und die Anschlussanzeigen geben an, welcher Schenkel fehlerhaft ist.<br>• Es ist kein Schenkel oder ein defekter Schenkel angeschlossen.<br>• Kein Luftstrom.<br>• Ein Schenkel ist nicht ordnungsgemäß angeschlossen.<br>• Der WEISSE Exspirationsschenkel des Befeuchters ist am Inspirationsanschluss *zum Patienten* des Beatmungsgerätes angeschlossen. | • Setzen Sie das Beatmungsschlauchsystem (erneut) korrekt ein.<br>• Tauschen Sie das Beatmungsschlauchsystem aus.<br>• Schließen Sie den BLAUEN Inspirationsschenkel des Befeuchters am Inspirationsanschluss *zum Patienten* des Beatmungsgerätes an.<br>Die Farben der Anschlussanzeige bedeuten:<br>*Grün*: Der Schenkel ist korrekt eingesetzt.<br>*Orange*: Der Befeuchter testet den Anschluss.<br>*Rot*: Der Schenkel ist nicht korrekt angeschlossen oder nicht vorhanden. |

# 6 Wartung

*Lesen Sie die Sicherheitsinformationen in Abschnitt 1, bevor Sie fortfahren.*

Dieser Abschnitt enthält Informationen zu den Verfahren und zum Zeitplan für die Befeuchterwartung sowie Anweisungen für die Reinigung und Desinfektion.

Alle Verfahren, die in diesem Abschnitt beschrieben sind, müssen vom Bediener durchgeführt werden.

Informationen zu zusätzlichen Wartungsmaßnahmen erhalten Sie von Ihrem Servicebeauftragten von Hamilton Medical. Alle Dokumente, auf die in diesem Abschnitt verwiesen wird, sind auf der Website MyHamilton verfügbar: https://www.hamilton-medical.com/MyHamilton

## 6.1 Reinigung, Desinfektion und Sterilisation

Die Komponenten des Befeuchters müssen regelmäßig mithilfe der für die jeweiligen Komponenten spezifischen Reinigungsmethoden und -lösungen gereinigt und desinfiziert werden.

Es ist wichtig, dass Sie bei der Reinigung und Desinfektion des Befeuchters und seiner Komponenten die geeigneten Methoden und Materialien wählen, um nicht nur eine Beschädigung der Ausrüstung zu verhindern, sondern auch eine Kreuzkontamination zu vermeiden.

Die Informationen zur Reinigung und Desinfektion sind folgendermaßen aufbereitet:

- In Tabelle 10 werden die zutreffenden befeuchterbezogenen Komponenten aufgeführt. Außerdem ist darin angegeben, welche Reinigungs- und Desinfektionsmethoden verwendet werden können, wie häufig die Komponente zu reinigen/desinfizieren ist und welche Reinigungs- und Desinfektionsmittel dabei einzusetzen sind.
- Für Beatmungsschlauchsets und Befeuchterkammern lesen Sie die *Gebrauchsanweisung* oder die *Aufbereitungsvorschrift*.

Beachten Sie beim Umgang mit den Befeuchterkomponenten, den Reinigungsmethoden und den Reinigungsmitteln folgende Punkte:

- Führen Sie *nur* Dekontaminierungsverfahren aus, die explizit von Hamilton Medical genannt werden.
- Wir stellen zwar Richtlinien für die zu verwendenden Mittel und Konzentrationen bereit, bei spezifischen Fragen zur Verwendung eines bestimmten Reinigungs- oder Desinfektionsmittels sollten Sie sich jedoch an den jeweiligen Hersteller wenden.

Tabelle 10. Reinigungs- und Desinfektionsmethoden für den Befeuchter

| Komponente | Frequenz | Reinigungs-/Desinfektionsmethode | Reinigungsmittel |
|---|---|---|---|
| Oberflächen des Befeuchters, einschließlich:<br>• Gehäuse<br>• Bildschirm<br>• Heizplatte<br>• Netzkabel<br>• Befestigungssysteme | Nach jedem Einsatz bei einem Patienten oder nach Bedarf. | Wischen Sie die Komponenten mit einem Tuch ab, das mit einer zugelassenen und genehmigten Reinigungs-/Desinfektionslösung befeuchtet wurde. | Super Sani-Cloth keimtötende Desinfektionstücher<br>CaviWipes |

## 6.2 Vorbeugende Wartungsarbeiten

Vorbeugenden Wartungsarbeiten an Ihrem Befeuchter müssen von durch Hamilton Medical autorisiertes Servicepersonal gemäß den Anweisungen im *Wartungshandbuch zum HAMILTON-H900* durchgeführt werden.

# 7 Konfiguration

Der Befeuchter wird mit einer Standardkonfiguration für eine Reihe von Einstellungen geliefert, die nach Patientengruppe geordnet sind.

Sie können die folgenden Standardeinstellungen im **Konfigurationsmodus** ändern:

- **Temperatur am Kammerausgang**
- **Temperaturgradient**
- Betriebsmodus beim Gerätestart (**INV/NIV/HiFlow**)
- **Exsp. Temperaturerhöhung** Ein/Aus
- Helligkeitseinstellungen für die Hintergrundbeleuchtung für **Tag/Nacht**

## 7.1 Aufrufen des Konfigurationsmodus

Wenn sich der Befeuchter im **Standby**-Modus befindet, kann der **Konfigurationsmodus** aufgerufen werden.

**So rufen Sie den Konfigurationsmodus auf:**

1. Drücken Sie ggf. die Taste  , um den **Standby**-Modus aufzurufen.
2. Halten Sie die Tasten  und  gleichzeitig gedrückt.
   Achten Sie darauf, zuerst die Taste  zu drücken.
   Das **Konfigurationsfenster** erscheint nach 5 Sekunden.

Der Befeuchter befindet sich jetzt im **Konfigurationsmodus**.

## 7.2 Ändern der Konfigurationseinstellungen

Benutzerdefinierte Einstellungen werden dauerhaft gespeichert, bis Sie sie ändern oder die Werkseinstellungen wiederherstellen.

Im **Konfigurationsmodus** werden die Tasten am Bedienfeld des Befeuchters für die Navigation zwischen den Ansichten sowie für die Auswahl von Einstellungen verwendet.

In Tabelle 11 wird beschrieben, wie Sie durch die Ansichten der **Konfiguration** blättern und Einstellungen ändern.

Unten ist die Vorgehensweise beschrieben, wie die Standardeinstellungen für den Parameter **Temperaturgradient** geändert werden. Das können Sie als Beispiel dafür verwenden, wie Einstellungen geändert werden.

Eine Liste der Konfigurationseinstellungen finden Sie in Abschnitt 9.6.

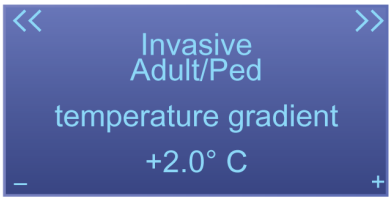
Tabelle 11. Tasten für die Navigation im Konfigurationsmodus

| Taste | Beschreibung |
|---|---|
|  | Vorwärts durch die Ansichten navigieren |
|  | Rückwärts durch die Ansichten navigieren |
|  | Einen Wert erhöhen |
|  | Einen Wert verringern |
|  | Änderungen speichern und den **Konfigurationsmodus** beenden |

**Beispiel: Ändern des Temperaturgradienten**

**So ändern Sie die Standardeinstellung für den Temperaturgradienten im invasiven Modus für Erwachsene/Pädiatrie:**

1. Drücken Sie im **Konfigurationsmodus** die Taste Exp., bis Sie die Ansicht mit folgendem Text sehen: **Invasive, Adult/Ped, Temperature gradient**.




2. Drücken Sie die Taste, um den Wert zu erhöhen, oder die Taste Auto, um den Wert zu verringern.
3. Drücken Sie abschließend die Taste, um die Änderungen zu speichern und den **Konfigurationsmodus** zu beenden.

## 7.3 Wiederherstellen der werksseitigen Standardeinstellungen

Sie können die werksseitigen Standardeinstellungen jederzeit wiederherstellen.

**So stellen Sie die werksseitigen Standardeinstellungen wieder her:**

1. Drücken Sie im Konfigurationsmodus wiederholt die Taste Exp., bis das Fenster **Reset all custom defaults** angezeigt wird.
2. Drücken Sie die Taste Auto.

Die werksseitigen Standardeinstellungen werden wiederhergestellt.

# 8 Komponenten und Zubehörteile

In diesem Abschnitt werden die Komponenten und Zubehörteile aufgeführt, die für den HAMILTON-H900 Befeuchter verfügbar sind.

Weitere Informationen finden Sie im elektronischen Katalog von Hamilton Medical, der auf der Website von Hamilton Medical verfügbar ist, bzw. erhalten Sie von Ihrem Ansprechpartner bei Hamilton Medical.

Tabelle 12. Komponenten und Zubehörteile für den Befeuchter

| PN | Beschreibung |
|---|---|
| 260161 | HAMILTON-BC8022, Beatmungsschlauchset, mit zwei Schenkeln, beheizt, mit Befeuchterkammer |
| 260186 | HAMILTON-BC4022, Beatmungsschlauchset, mit einem Schenkel, beheizt, mit Befeuchterkammer |
| 260185 | HAMILTON-BC8010, Beatmungsschlauchset, mit zwei Schenkeln, beheizt, mit Befeuchterkammer und Verlängerung für den Inkubator |
| 260187 | HAMILTON-BC4010, Beatmungsschlauchset, mit einem Schenkel, beheizt, mit Befeuchterkammer und Verlängerung für den Inkubator |
| 260196 | HAMILTON-HC322, Befeuchterkammer, für den Einmalgebrauch |
| 260197 | HAMILTON-HC310, Befeuchterkammer, für den Einmalgebrauch |

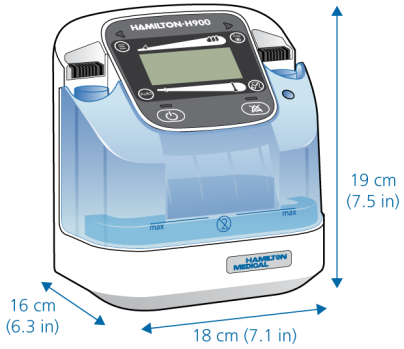
# 9 Spezifikationen

## 9.1 Maße und Gewichte

Tabelle 13. Maße und Gewichte

| Abmessung | Spezifikationen |
|---|---|
| Gewicht | Befeuchter (mit leerer Befeuchterkammer)<br>2,5 kg |
| Maße | Siehe Abbildung 14 |

Abbildung 14. HAMILTON-H900 – Maße



## 9.2 Standortanforderungen

Tabelle 14. Standortanforderungen

| Umgebung | | Spezifikationen |
|---|---|---|
| Temperatur | Betrieb: | 10 °C bis 40 °C |
| | Lagerung: | -20 °C bis 60 °C |
| | | Empfohlene Umgebungstemperatur: 18 °C bis 26 °C |
| Höhe über Meer | | Bis zu 4000 m |
| Luftdruck | Betrieb und Lagerung: | 61 kPa bis 106 kPa |
| Relative Luftfeuchtigkeit | Betrieb: | 30 % bis 95 %, nicht kondensierend |
| | Lagerung: | 10 % bis 95 %, nicht kondensierend |
| Wasserschutz | | IP21 |
| Gaseingangstemperatur | | 18 °C bis 31 °C (empfohlen) |

## 9.3 Elektrische Spezifikationen

Tabelle 15. Elektrische Spezifikationen

| Bestellnummer | Eingangsstrom | Leistungsaufnahme |
|---|---|---|
| 950001 (230 V) | 220–240 V<br>50/60 Hz | 283 VA |
| 950004 (115 V) | 110–127 V<br>50/60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50/60 Hz | 268 VA |
| Potenzialausgleich | Anschluss für einen Potenzialausgleichsleiter gemäß DIN 42801 | |

## 9.4 Parametereinstellungen

Tabelle 16. Parametereinstellungen und Bereiche

| Parameter oder Einstellung (Einheit) | Modus | Bereich | Standardeinstellung | Auflösung |
|---|---|---|---|---|
| Temperatur am Kammerausgang (°C) | INV | 35 bis 41 | 37,0 | 0,5 |
| | NIV | 30 bis 35 | 31,0 | 0,5 |
| | HiFlow | 33 bis 37 | 35,0 | 2 |
| Temperaturgradient (°C) | INV | -2 bis 3 | Erw./Päd.: 2<br>Neonaten: 3 | 0,5 |
| | NIV | -2 bis 3 | Erw./Päd.: 2<br>Neonaten: 3 | 0,5 |
| | HiFlow | -- | 2 | -- |
| Resultierende max. Atemwegstemperatur (Y-Stück)[22] (°C) | INV | 33 bis 42 | -- | -- |
| | NIV | 28 bis 38 | -- | -- |
| | HiFlow | 35 bis 39 | -- | -- |
| Exsp. Temperaturerhöhung | Alle Modi | Ein, Aus | Ein | -- |
| Helligkeitseinstellung für den Bildschirm | Alle Modi | 1 bis 5 | Tag: 5<br>Nacht: 2 | 1 |

[22] Die Atemwegstemperatur ist durch den Befeuchter auf 42 °C begrenzt.

## 9.5 Überwachte Parameter

Tabelle 17. Überwachte Parameter – Bereiche und Genauigkeit

| Parameter (Einheiten) | Bereich | Genauigkeit |
|---|---|---|
| Temperatur am Kammerausgang (°C) | 10 bis 60 | 10 bis 30: ± 1<br>30 bis 41: ± 0,5<br>41 bis 60: ± 1 |
| Temperatur am Y-Stück (°C) | 28 bis 43 | ± 0,5 |

## 9.6 Konfiguration

Tabelle 18. Konfiguration – Spezifikation

| Parameter | Modus | Konfigurationsbereich | Standardeinstellung |
|---|---|---|---|
| Temperatur am Kammerausgang (°C) | INV | 35 bis 39 | 37,0 |
| | NIV | 30 bis 35 | 31,0 |
| | HiFlow | 33, 35, 37 | 35,0 |
| Temperaturgradient (°C) | INV | 0 bis 3 | Erw./Päd.: 2<br>Neonaten: 3 |
| | NIV | 0 bis 3 | Erw./Päd.: 2<br>Neonaten: 3 |
| | HiFlow | 0 bis 3 | 2 |
| Modus beim Gerätestart | -- | Invasiv, nichtinvasiv, HiFlow | Invasiv |
| Helligkeitseinstellung für den Bildschirm | Alle Modi | 1 bis 5 | Tag: 5<br>Nacht: 2 |

## 9.7 Technische Leistungsdaten

Tabelle 19. Technische Leistungsdaten

| Beschreibung | Spezifikation | | |
|---|---|---|---|
| Flowraten[23] | Invasiv: | Bis zu 60 l/min | |
| | Nichtinvasiv: | Bis zu 120 l/min | |
| | HiFlow: | Bis zu 120 l/min | |
| Aufwärmzeit | Weniger als 30 Min. | | |
| Luftfeuchtigkeit | Bei einer Umgebungstemperatur von 18 °C bis 26 °C: | | |
| | Invasiv: | Temperatureinstellung von 37 °C bis 41 °C | Minimale Feuchtigkeit: 33 mg H2O/l |
| | Nichtinvasiv: | Temperatureinstellung von 31 °C bis 35 °C | Minimale Feuchtigkeit: 12 mg H2O/l |
| | HiFlow: | Flowrate ≤ 60 l/min | Minimale Feuchtigkeit: 33 mg H2O/l |
| | | Flowrate > 60 l/min | Minimale Feuchtigkeit: 12 mg H2O/l |
| Spezifikationen für die Heizleistung im Standby-Modus | Beheizte Beatmungsschlauchsysteme: | Y-Stück auf 30 °C begrenzt. | |
| Bildschirm | 3 Zoll/64 x 128 Pixel, inverse Punktmatrixanzeige (mit Hintergrundbeleuchtung) | | |
| Audio anhalten | 120 Sekunden | | |
| Alarmlautstärke[24] | Bereich = 1 bis 8. Standardeinstellung = 5. | | |

[23] Informationen zu den minimalen Flowraten finden Sie in der *Gebrauchsanweisung* zum Beatmungsschlauchsystem.
[24] Lautstärke in 1 Meter Abstand vom Befeuchter. Einstellung von 1 = 50 dB(A), 5 (Standardeinstellung) = 60 dB(A) und 8 = 65 dB(A), mit einer Genauigkeit von ± 6 dB(A).

## 9.8 Grundlegende Leistungsmerkmale

Die für das Atemgas und das Beatmungsschlauchsystem angewendeten Temperaturen müssen innerhalb der angegebenen Einstellungen aufrechterhalten und überwacht werden.

Wenn die Temperatur außerhalb der angegebenen Grenzwerte liegt, muss der Befeuchter diese Tatsache erkennen und den Bediener mit einem Alarm darüber informieren.

## 9.9 Funktionsbeschreibung des Befeuchtersystems

Der HAMILTON-H900 Befeuchter ist für die Beheizung und Befeuchtung der Atemgase während der maschinellen Beatmung vorgesehen. Das Atemgas wird beheizt und befeuchtet, während es eine teilweise mit beheiztem Wasser gefüllte Kammer passiert.

Der Befeuchter verfügt über zwei sensorgesteuerte Heizsysteme:

- *Heizplatte*. Beheizt das Wasser in der Befeuchterkammer.
- *Integriertes Heizsystem des Beatmungsschlauchsystems*. Beheizt die Beatmungsschenkel, um Kondensatbildung zu vermeiden.

Die Temperatur der Atemgase wird am Kammerausgang und im Beatmungsschenkel am Patientenende überwacht.

## 9.10 Symbole auf den Geräteaufklebern und Verpackungen

| Symbol | Beschreibung |
|---|---|
|  | *Gebrauchsanweisung* beachten |
|  | Referenznummer |
|  | Seriennummer |
|  | Menge |
|  | Hersteller |
|  | Herstellungsdatum |
|  | Anwendungsteil vom Typ BF (Klassifizierung der elektrischen medizintechnischen Geräte, Typ BF gemäß IEC 60601-1) |
|  | Entsorgung gemäß EU-Richtlinie 2002/96/EG oder WEEE (Elektro- und Elektronik-Altgeräte) |
|   | Das TÜV-NRTL-Zeichen mit den Zusätzen „C“ und „US“ besagt, dass das Produkt den Sicherheitsanforderungen der kanadischen sowie der US-amerikanischen Behörden entspricht. |
|  | Potenzialausgleich |

| Symbol | Beschreibung |
|---|---|
|  | Warnung: Heiße Oberfläche.<br>Die Heizplatte und die Unterseite der Kammer können Temperaturen von über 85 °C erreichen. |
| CE 0197 | CE-Konformitätskennzeichen: Genehmigungsplakette, mit der bestätigt wird, dass das Gerät der EU-Richtlinie 93/42/EWG – über Medizinprodukte – entspricht. |
| IP21 | Geschützt gegen Tropfwasser und Stoffpartikel ab einer Größe von 12,5 mm |
| max | Füllstandsmarkierung an der Befeuchterkammer |
|  | Serielle RS-232-Schnittstelle für den Datenaustausch mit Beatmungsgeräten von Hamilton Medical |
|  | Nicht MR-sicher<br>In der MR-Umgebung stellen sich durch den HAMILTON-H900 Befeuchter unzulässige Gefahren für den Patienten, das medizinische Fachpersonal und andere anwesende Personen. |
|  | RoHS für China |

| Symbol | Beschreibung |
|---|---|
|  | Temperatursensor<br>Zeigt die Position des Temperatursensors im Beatmungsschlauchsystem an. |

## 9.11 Normen und Zulassungen

Das Befeuchtersystem erfüllt die Anforderungen der relevanten Abschnitte folgender Normen, die in Tabelle 20 aufgeführt werden.

Tabelle 20. Normen und Zulassungen, gültige Versionen

| |
|---|
| IEC 60601-1:2005/A1:2012 |
| IEC 60601-1-2:2014 |
| IEC 60601-1-6:2010/A1:2013 |
| IEC 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| IEC 62304:2006/A1:2015 |
| IEC 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Entsorgung

Das Gerät muss gemäß den Richtlinien Ihres Krankenhauses und der Richtlinie 2002/96/EG entsorgt werden.

Beatmungsschlauchsysteme und Befeuchterkammern müssen gemäß der *Gebrauchsanweisung* entsorgt werden, die im Lieferumfang der Beatmungsschlauchsets enthalten ist.

## 9.13 Garantie

EINGESCHRÄNKTE GARANTIE

HIERMIT WIRD AUSDRÜCKLICH VEREINBART, DASS DIE HIER AUFGEFÜHRTEN GARANTIEBESTIMMUNGEN ALLE ANDEREN VEREINBARUNGEN ÄHNLICHEN INHALTS HINFÄLLIG WERDEN LASSEN. DER KÄUFER ERKLÄRT SICH EINVERSTANDEN, DASS KEINE GARANTIEN – WEDER IMPLIZIT NOCH EXPLIZIT – ÜBERNOMMEN WERDEN, DIE ÜBER DIE HIER VEREINBARTEN GARANTIEBESTIMMUNGEN HINAUSGEHEN. STILLSCHWEIGEND GETROFFENE GARANTIEVEREINBARUNGEN TRETEN JEDOCH WÄHREND DES DEFINIERTEN ZEITRAUMS MIT BESCHRÄNKTEN GARANTIELEISTUNG NICHT AUSSER KRAFT.

Hamilton Medical erklärt gegenüber dem Käufer, dass seine Produkte bei Auslieferung frei von Material- oder Produktionsfehlern sind. Verbrauchsmaterialien sind von der Garantie ausgeschlossen. Verbrauchsmaterialien und Einmalprodukte sind entweder für den Einweggebrauch bestimmt oder haben nur eine begrenzte Lebensdauer. Sie müssen regelmäßig gemäß dem Bedienungshandbuch ausgetauscht werden, damit das Produkt voll funktionsfähig bleibt.

Hamilton Medical kann nur im Rahmen der hier aufgeführten Garantievereinbarung haftbar gemacht werden und übernimmt keine zusätzlichen Verbindlichkeiten (z. B. Beschränkungen, Verbindlichkeiten oder Haftung für Fahrlässigkeit oder Haftung im engeren Sinne). Hamilton Medical haftet weder direkt noch pauschal für zufällig auftretende oder Folgeschäden.

Diese eingeschränkten Garantiebestimmungen erlöschen in den folgenden Fällen:

1. Wenn das Produkt nicht von einem autorisierten Vertreter von Hamilton Medical nach den von Hamilton Medical oder einem Vertreter bereitgestellten Anweisungen installiert und angeschlossen wurde.
2. Wenn nicht nachweisbar ist, dass der Schaden/die Reparatur innerhalb der Garantiezeit aufgetreten ist.
3. Wenn die Seriennummer manipuliert, unkenntlich gemacht oder entfernt wurde oder wenn kein Kaufbeleg vorhanden ist, aus dem das Datum des Erwerbs hervorgeht.
4. Wenn der Defekt als Folge von Bedienungsfehlern, Fahrlässigkeit oder Unfällen aufgetreten ist oder Reparaturen, Justierungen, Änderungen oder der Austausch von Komponenten nicht direkt von Hamilton Medical oder einem autorisierten Servicebeauftragten ausgeführt wurden.
5. Wenn das Produkt ohne vorherige schriftliche Genehmigung von Hamilton Medical modifiziert oder auf jegliche Art verändert wurde.
6. Wenn das Produkt auf eine Weise verwendet wird oder wurde, die nicht im Abschnitt „Vorgesehener Verwendungszweck“ angegeben ist.
7. Wenn das Produkt nicht von geschultem Personal bedient wurde, das unter der direkten Aufsicht eines Arztes steht.

Durch Reparaturen und/oder den Austausch von Komponenten innerhalb des eingeschränkten Garantiezeitraums wird dieser nicht verlängert. Die Garantie für reparierte und/oder ausgetauschte Komponenten gilt nicht länger als die Eingeschränkte Garantie des Gerätes.

Um eine Garantieleistung in Anspruch zu nehmen, ist es erforderlich, sofort Kontakt mit dem betreffenden Vertriebspartner von Hamilton Medical aufzunehmen und Informationen über die Art des aufgetretenen Problems, die Seriennummer und das Kaufdatum bereitzuhalten.

Mit Ausnahme der oben genannten Fälle kann Hamilton Medical nicht für Schäden, Ansprüche oder Verbindlichkeiten (einschließlich Fälle mit beschränkter Haftung, Verletzungsfolgen, Folgeschäden usw.) haftbar gemacht werden. Hamilton Medical kann auch nicht für Schäden, Ansprüche oder Verbindlichkeiten (einschließlich Fälle mit beschränkter Haftung, Verletzungsfolgen, Folgeschäden usw.) haftbar gemacht werden, die aus Bedienungsfehlern oder Nichtbeachtung von Anweisungen in diesem Handbuch resultieren.

### 9.13.1 Sonstiges

Die allgemeinen Geschäftsbedingungen von Hamilton Medical finden Anwendung. Diese Vereinbarung unterliegt den Gesetzen und der Rechtsprechung der Schweiz und kann von allen Parteien mit Gerichtsstand Chur, Schweiz, durchgesetzt werden.

# Instructions d'utilisation

## HAMILTON-H900

2021-01-11

624431/09

**Fabricant**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz,
Suisse
Téléphone: (+41) 58 610 10 20
Fax : (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Préface

Veuillez lire la documentation avant d'utiliser le dispositif ou les accessoires.

### Conventions utilisées dans le présent guide

Dans ce manuel :

- Les noms des boutons figurent en **gras**.
- Les graphiques figurant dans ce manuel peuvent ne pas refléter exactement ce qui s'affiche sur l'écran.
- Notez que toutes les fonctions ne sont pas disponibles dans tous les pays.

Des messages de sécurité s'affichent comme suit :

**⚠ AVERTISSEMENT**

Signale un danger pour la santé de l'utilisateur, voire un danger de mort ou d'autres réactions indésirables graves, associés à l'utilisation (bonne ou mauvaise) de l'appareil.

**⚠ PRÉCAUTION**

*Signale un problème potentiel lié à l'utilisation (bonne ou mauvaise) de l'appareil : dysfonctionnement ou panne de l'appareil, endommagement de l'appareil lui-même ou d'autres objets.*

***REMARQUE***

Met en valeur une information particulièrement importante.

Dans les tableaux, les messages de sécurité apparaissent comme suit :

**⚠ AVERTISSEMENT !**

**⚠ PRÉCAUTION !**

**REMARQUE !**

Pour télécharger la dernière version du présent manuel ou d'autres documents, consultez le site internet MyHamilton : https://www.hamilton-medical.com/MyHamilton

Hamilton Medical vous permet d'accéder au Hamilton Medical College, qui propose plusieurs modules d'e-learning gratuits. Pour vous inscrire, rendez-vous sur le site : http://college.hamilton-medical.com/

**⚠ PRÉCAUTION**

*(États-Unis uniquement) : conformément à la loi fédérale en vigueur aux États-Unis, seul un médecin peut assurer ou prescrire la vente de ce dispositif.*

### Usage prévu

L'humidificateur HAMILTON-H900 est destiné à conditionner le gaz respiratoire dans le cadre d'une ventilation mécanique invasive et non invasive.

Le dispositif est destiné au milieu hospitalier et aux établissements médicalisés.

L'humidificateur HAMILTON-H900 est un dispositif médical conçu pour être utilisé par du personnel qualifié et formé à cet effet, sous la supervision d'un médecin et dans les limites des caractéristiques techniques énoncées.

# 1 Informations relatives à la sécurité

Cette section fournit des informations de sécurité relatives à l'installation, à l'utilisation et à la maintenance de l'humidificateur.

**Lisez attentivement chaque partie de cette section relative à la sécurité avant d'installer et d'utiliser l'humidificateur.**

**Veuillez examiner les instructions d'utilisation avant d'utiliser l'humidificateur.**

**Veuillez lire les instructions d'utilisation fournies avec les périphériques et accessoires utilisés avec l'humidificateur avant toute utilisation.**

Si vous avez des questions sur les informations fournies dans le présent manuel, contactez votre représentant ou l'assistance technique Hamilton Medical.

## 1.1 Sensibilité électromagnétique

**⚠ AVERTISSEMENT**

- **MR UNSAFE**. Tenez-vous à distance de l'équipement d'imagerie par résonance magnétique (IRM). Le HAMILTON-H900 fait courir des risques inacceptables au patient, à l'équipe médicale ou à toute autre personne présente dans l'environnement IRM.
- Le fonctionnement de l'humidificateur peut être perturbé par le fonctionnement à proximité d'un équipement chirurgical haute fréquence, de micro-ondes, d'ondes courtes ou de champs magnétiques élevés.
- Pour éviter une augmentation des émissions, une diminution de l'immunité ou une interruption du fonctionnement de l'humidificateur HAMILTON-H900 ou de ses accessoires, vous devez utiliser uniquement les accessoires ou câbles expressément mentionnés dans ce manuel ou dans le catalogue de produits HAMILTON-H900.
- Le matériel supplémentaire raccordé à l'équipement électromédical doit être conforme aux normes CEI ou ISO correspondantes (par exemple, CEI 60950 pour les appareils de traitement des données). De plus, toutes les configurations doivent être conformes aux exigences relatives aux systèmes médicaux électriques (voir CEI 60601-1, clause 16).
- Toute personne qui raccorde un matériel supplémentaire à l'équipement électromédical intervient sur la configuration d'un système médical et est donc responsable de la conformité de l'ensemble aux exigences relatives aux systèmes médicaux électriques. Il faut également noter que les lois locales prévalent sur les exigences mentionnées ci-dessus. Si vous avez des questions sur la marche à suivre, contactez votre représentant ou l'assistance technique Hamilton Medical.
- L'humidificateur *n'est pas protégé* contre les décharges des défibrillateurs cardiaques.

***REMARQUE***

- L'humidificateur HAMILTON-H900 requiert des précautions spéciales relatives à la CEM (compatibilité électromagnétique) et doit être installé et mis en service conformément aux informations CEM fournies dans les *déclarations CEM du HAMILTON-H900*.
- Les appareils portables et mobiles à transmission radioélectrique peuvent perturber le fonctionnement de l'humidificateur HAMILTON-H900.

## 1.2 Alimentation électrique

**⚠ AVERTISSEMENT**

- Pour réduire le risque d'électrocution, branchez le cordon d'alimentation de l'humidificateur sur une prise de courant appropriée, mise à la terre. Il est de la responsabilité de l'hôpital de s'assurer que la prise est correctement mise à la terre.
- *N'utilisez pas* le produit si l'emballage est endommagé.
- En cas de tension de secteur incorrecte, de panne de courant ou de déconnexion de l'alimentation, l'humidificateur émet un sifflement audible. Éteignez immédiatement le dispositif et vérifiez que la tension d'alimentation est correcte.
- Vérifiez que la tension d'alimentation utilisée est correcte.

## 1.3 Incendie et autres risques

**⚠ AVERTISSEMENT**

*N'utilisez pas* l'humidificateur dans des zones dangereuses ou avec des gaz inflammables.

## 1.4 Fonctionnement général et configuration

**⚠ AVERTISSEMENT**

- Avant d'utiliser l'humidificateur sur le patient, vérifiez que le circuit respiratoire est correctement connecté au ventilateur, comme indiqué ci-dessous :

  – La branche inspiratoire bleue est connectée au port inspiratoire *Vers patient*.

  – La branche expiratoire blanche est connectée au port expiratoire *À partir du patient*.
- Utilisez uniquement les pièces et accessoires indiqués à la section 8. Vous assurez ainsi le bon fonctionnement de l'humidificateur tout en évitant tout risque de blessure du patient.
- N'utilisez pas l'humidificateur à une altitude supérieure à 4 000 mètres ou à une température non comprise entre 10 °C et 40 °C. L'utilisation de l'humidificateur au-dessus de cette altitude ou en dehors de cette plage de températures peut affecter la qualité de la thérapie ou entraîner une blessure pour le patient.
- Des réglages de température ou d'humidité inappropriés peuvent entraîner des blessures pour le patient.

- N'utilisez *pas* l'humidificateur pendant le transfert d'un patient ventilé à l'extérieur de l'hôpital.
- Allumez l'humidificateur *après* avoir allumé le ventilateur.
- Éteignez l'humidificateur *avant* d'éteindre le ventilateur.
- Ne couvrez pas les cellules de mesure IR de l'humidificateur.
- Le mode invasif (INV) doit *uniquement* être utilisé sur des patients intubés et trachéotomisés.
- Prenez des précautions supplémentaires en cas de réaction allergique.
- Vérifiez régulièrement la formation de condensation dans le circuit respiratoire et évacuez-la si nécessaire.
- Les performances d'humidification du dispositif peuvent être altérées par l'utilisation simultanée d'un nébuliseur.
- *Ne touchez pas* la plaque chaude ou le fond du réservoir d'eau. Les surfaces peuvent atteindre une température de plus de 85 °C. Ces surfaces chaudes génèrent de la chaleur.

**⚠ PRÉCAUTION**

- *Installez l'humidificateur à un endroit où la source d'alimentation principale est facile d'accès.*
- *Utilisez uniquement les pièces et accessoires spécifiés dans la section 8 et dans le catalogue en ligne de Hamilton Medical, ou les pièces spécifiées comme compatibles avec cet humidificateur.*

  *Le respect de cette consigne permet de garantir une humidification correcte et de préserver les performances ainsi que la validité de la garantie.*
- *Si l'humidificateur est éteint, puis allumé, il démarrera automatiquement en mode invasif (INV) sauf s'il est configuré différemment.*
- *Vérifiez que le kit de circuit respiratoire n'est pas endommagé avant toute utilisation. Jetez le kit de circuit respiratoire s'il semble endommagé.*
- *L'élément de chauffage de l'humidificateur et les fils chauffants sont automatiquement activés lorsque le réservoir d'eau et les circuits respiratoires sont correctement installés et que l'humidificateur est allumé ou en mode Standby.*
- *Si la température ambiante ou la température du gaz d'arrivée et/ou le débit se situent en dehors de la plage recommandée, les niveaux d'humidité physiologique peuvent ne pas être atteints.*
- *L'humidificateur peut toujours être allumé même si l'écran n'est pas éclairé. Voir tableau 1.*

***REMARQUE***

- Avant d'utiliser un kit de circuit respiratoire sur un patient, vous devez effectuer un test d'étanchéité. Le test peut être répété une fois en cas d'échec. Après deux échecs consécutifs, le kit du circuit respiratoire doit être remplacé par un nouveau kit.
- Lorsque le réglage de l'humidité est correct, une légère condensation issue de la respiration (brume) se forme dans la branche, le tuyau flexible ou le capteur de débit.
- Toutes les actions génèrent un bip sonore.

## 1.5 Circuits respiratoires et réservoir d'eau

**⚠ AVERTISSEMENT**

- Une mauvaise connexion du circuit respiratoire au ventilateur peut blesser le patient.
- Pour éviter tout débranchement accidentel du circuit respiratoire au cours de l'utilisation ou du transport, utilisez uniquement des circuits respiratoires conformes à la norme ISO 5367 ou ISO 80601-2-74.
- Remplissez le réservoir d'eau uniquement avec de l'eau stérile déminéralisée répondant aux exigences d'hygiène de l'hôpital.
- N'inclinez pas le réservoir d'eau.
- Ne remplissez pas le réservoir d'eau avec des médicaments.
- Vérifiez que le niveau d'eau ne dépasse pas le niveau de remplissage maximal.

***REMARQUE***

- Si l'humidificateur ne détecte pas le circuit respiratoire, remplacez les composants.
- L'eau de remplissage ne doit pas excéder une température de plus de 37 °C.
- Vérifiez que l'alimentation en eau du réservoir fonctionne correctement.
- Vérifiez que l'humidificateur est en mode **Veille** avant de déconnecter les composants.

## 1.6 Positionnement de l'humidificateur et du circuit respiratoire

**⚠ AVERTISSEMENT**

- L'humidificateur doit *toujours* être positionné en dessous du niveau du patient.
- Ne faites *pas* fonctionner l'humidificateur à un angle de plus de 10° par rapport au sol.
- Veillez à installer le circuit respiratoire sans créer de tension ni torsion entre l'humidificateur et le patient.
- Les branches respiratoires chauffantes *ne doivent pas* être mises en contact direct avec la peau du patient.
- Si l'humidificateur est utilisé à proximité d'un autre dispositif électromédical, ou bien s'il est posé dessus, vérifiez que l'humidificateur fonctionne normalement dans la configuration utilisée.
- Positionnez le circuit respiratoire de façon à ce que le condensat de liquide ne s'écoule pas vers le patient.
- Fixez les circuits respiratoires ou les clips de tubulures de manière à ne pas exercer de forces mécaniques sur la sonde d'intubation.

***REMARQUE***

- Vérifiez que tous les raccords sont stables avant toute utilisation.
- Tous les connecteurs des branches de l'humidificateur combinent des connexions électriques avec des connecteurs du circuit respiratoire. Vérifiez que les contacts électriques sont correctement orientés pour correspondre à l'élément de connexion de l'humidificateur.

## 1.7 Monitorage et alarmes

***REMARQUE***

- Lorsqu'une alarme est active, l'écran affiche en alternance les symboles d'alarme active et la température actuelle de sortie du réservoir.
- Lors de la mise hors tension de l'humidificateur, l'intensité de l'alarme sonore revient à la valeur par défaut de 5.
- Toutes les alarmes techniques, les informations techniques détaillées et les procédures de maintenance sont décrites dans le *Manuel de maintenance du HAMILTON-H900*.

## 1.8 Maintenance

**⚠ AVERTISSEMENT**

- Les modifications apportées à l'humidificateur *ne sont pas* autorisées.
- Vous devez *systématiquement* débrancher l'alimentation électrique de l'humidificateur avant de le nettoyer ou de le désinfecter pour réduire les risques de décharge électrique.

**⚠ PRÉCAUTION**

- *Manipulez les circuits respiratoires et les réservoirs d'eau usagés comme des produits contaminés, conformément à la législation et aux règlements locaux ou aux procédures internes de l'hôpital.*
- *Pour assurer le bon entretien de cet appareil et prévenir d'éventuelles blessures, seul du personnel agréé de Hamilton Medical peut se charger de la maintenance de l'humidificateur en se référant aux informations fournies dans le Manuel de maintenance du HAMILTON-H900.*
- *Utilisez uniquement des pièces de rechange fournies par Hamilton Medical.*
- *N'effectuez aucune procédure de maintenance qui n'est pas spécifiée dans le Manuel de maintenance du HAMILTON-H900.*
- *Utilisez uniquement des produits de nettoyage approuvés pour le nettoyage et la désinfection.*

***REMARQUE***

- Pour obtenir des informations spécifiques sur le nettoyage, la désinfection et la stérilisation à l'autoclave d'accessoires et de composants (réutilisables), reportez-vous au *Guide de retraitement* et aux *Instructions d'utilisation* fournis avec chaque composant.
- (*États-Unis uniquement*) Utilisez uniquement des produits de nettoyage homologués par l'EPA pour le nettoyage et la désinfection.

# 2 Présentation

Ce guide fournit des informations sur l'installation et l'utilisation de l'humidificateur HAMILTON-H900.

L'humidificateur est conçu pour être utilisé avec des ventilateurs Hamilton Medical et d'autres marques de fabricants.

## 2.1 À propos de l'humidificateur HAMILTON-H900

L'humidificateur HAMILTON-H900 chauffe et humidifie les gaz respiratoires pour la ventilation des adultes, des enfants et des nouveau-nés.

Il prend en charge les modes respiratoires courants suivants :

- Ventilation invasive
- Ventilation non invasive
- Thérapie d'oxygène à haut débit

Le système comprend le boîtier de l'humidificateur, l'écran, les réglages, le réservoir d'eau, la plaque chauffante et les connexions électriques d'un circuit respiratoire chauffant.

Il offre les fonctions principales suivantes :

- Réglages d'humidité et de température ajustables
- Fonctionnalités de monitorage et d'alarme
- Intégration des données et des réglages monitorés de l'humidificateur des ventilateurs Hamilton Medical pris en charge[25]

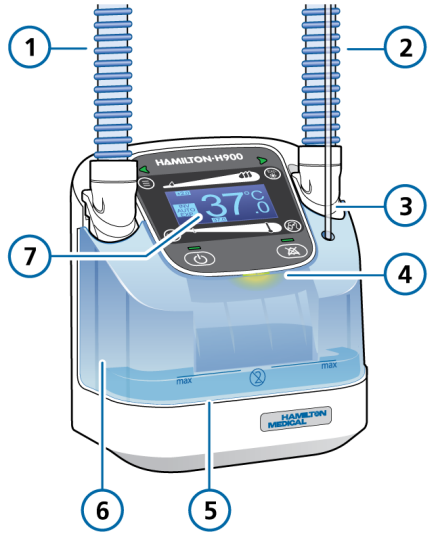
## 2.2 Caractéristiques physiques

Cette section fournit une présentation de l'humidificateur et des kits de circuit respiratoire associés.

### 2.2.1 À propos de l'humidificateur

Les figures 1 à 5 fournissent un aperçu du dispositif.

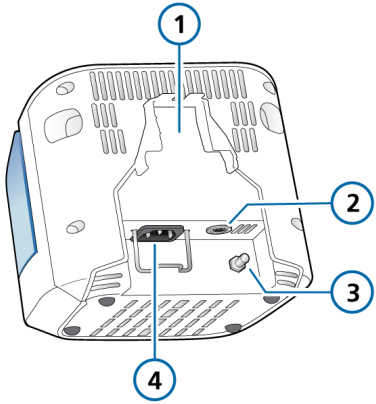
Figure 1. Humidificateur HAMILTON-H900, vue avant




| | | | |
|---|---|---|---|
| 1 | Branche inspiratoire du ventilateur (bleue) | 5 | Plaque chauffante |
| 2 | Branche inspiratoire côté patient (bleue) | 6 | Réservoir d'eau |
| 3 | Tuyau de remplissage d'eau | 7 | Panneau avant et écran |
| 4 | Indicateur visuel d'alarme | | |

[25] Non commercialisé dans certains pays.

Figure 2. Humidificateur HAMILTON-H900, vue arrière




| | | | |
|---|---|---|---|
| 1 | Fente pour support de montage | 3 | Borne d'équipotentiel |
| 2 | Port RS-232 | 4 | Prise d'alimentation CA |

## 2.2.2 À propos de l'écran principal

Tous les paramètres, modes, alarmes et réglages sont accessibles directement depuis l'écran principal pendant l'humidification.

Les figures 3 à 5 représentent les réglages, les voyants et l'écran du panneau avant.

Figure 3. Humidificateur HAMILTON-H900, réglages du panneau avant


| | | | |
|---|---|---|---|
| 1 | Bouton fenêtre de monitorage de temp | 5 | Touche pause audio |
| 2 | Curseurs contrôle temp | 6 | Touche M/A/Veille |
| 3 | Bouton d'augmentation de temp Exp. | 7 | Bouton Auto |
| 4 | Bouton du mode INV/NIV/HiFlow | 8 | Écran (voir figure 5) |

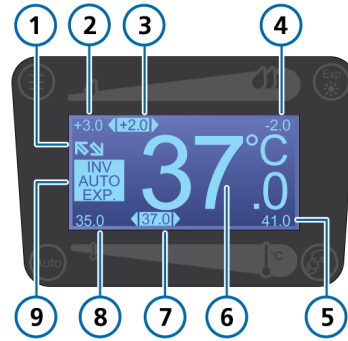
Figure 4. Humidificateur HAMILTON-H900, voyants d'état du panneau avant


1 Voyants d'état connexion des branches

2 Voyant Pause audio

3 Voyant d'état M/A/Veille

Figure 5. Humidificateur HAMILTON-H900, écran




1 Connexion du ventilateur activée

2 Réglage gradient maximal de temp

3 Réglage gradient de temp

4 Réglage gradient minimal de temp

5 Réglage temp maximale de sortie du réservoir

6 Temp actuelle de sortie du réservoir

7 Réglage temp de sortie du réservoir

8 Réglage temp minimale de sortie du réservoir

9 Modes/réglages actifs

*Tous les éléments de l'écran sont représentés à titre d'information uniquement. Pendant le fonctionnement, ils peuvent ne pas tous être visibles au même moment.*

### 2.2.3 À propos des circuits respiratoires de l'humidificateur

L'humidificateur HAMILTON-H900 prend en charge plusieurs circuits respiratoires à une ou deux branches pour adultes, enfants et nouveau-nés.

Pour plus de détails, reportez-vous aux *Instructions d'utilisation* de votre circuit respiratoire.

### 2.2.4 À propos des voyants d'état de l'humidificateur

Les voyants situés sur la face avant de l'humidificateur fournissent des informations importantes sur l'état du ventilateur. Reportez-vous à la figure 4.

Tableau 1. Voyants d'état

| Symbole | Description |
|---|---|
| **Touche M/A/Veille avec voyant d'état** | |
|  | *vert* : l'humidificateur fonctionne. |
|  | *orange* : l'humidificateur est en mode **Veille**. |
|  | *bleu* : l'humidificateur est éteint et raccordé à une source d'alimentation. |
|  | *éteint* : l'humidificateur est éteint et *non* raccordé à une source d'alimentation. |
| **Voyant d'état de la connexion des branches** | |
|  | *vert* : la branche est correctement connectée. |
|  | *orange* : l'humidificateur teste la connexion de la branche. |
|  | *rouge* : La connexion de la branche est défectueuse ou la branche n'est pas connectée. |
| **Touche de pause audio avec voyant** | |
|  | *rouge* : la pause audio est active. |

## 2.3 Navigation dans les fenêtres et les réglages

Cette section explique comment utiliser les boutons et les curseurs de l'humidificateur.

### 2.3.1 Utilisation des boutons de réglage

Les boutons du panneau avant (figure 3) vous permettent de sélectionner des modes, de changer des réglages et d'avoir un aperçu des réglages importants de température.

Tableau 2. Boutons de réglage (voir figure 3)

| Bouton | Description |
|---|---|
|  | **Augment température tuyau expiratoire**<br>Augmente la température dans la branche expiratoire. |
|  | **Auto**<br>Active le mode **Auto**.<br>Reportez-vous à la section 4.2.2. |
|  | **Modes de fonctionnement INV/NIV/HiFlow**<br>Alterne entre les modes **INV**, **NIV** et **HiFlow**.<br>Reportez-vous à la section 4.2. |
|  | **Fenêtre de monitorage de la température**<br>Affiche la température actuelle de la pièce en Y, la température de sortie du réservoir et les valeurs de gradient de température.<br>Reportez-vous à la section 4.4. |

### 2.3.2 Utilisation des curseurs

En mode manuel, vous pouvez changer les réglages de température à l'aide des curseurs de réglage (figure 3).

Tableau 3. Curseurs de contrôle de la température

| Curseur | Description |
|---|---|
| **Curseur de gradient de température** | |
|  | Ajuste la différence de température entre la sortie du réservoir et la pièce en Y.<br>Reportez-vous à la section 4.3. |
| **Curseur de température de sortie du réservoir** | |
|  | Ajuste la température de sortie du réservoir.<br>Reportez-vous à la section 4.3. |

## 3 Préparation de l'humidificateur avant utilisation

*Avant de poursuivre, lisez les informations relatives à la sécurité fournies à la section 1.*

La préparation de l'humidificateur en vue de son utilisation implique les étapes suivantes :

- Une configuration unique de réglages par un technicien médical (voir tableau 4)
- Pour chaque nouveau patient, opérations de configuration de l'humidificateur réalisées par du personnel soignant (voir tableau 5)

Tableau 4. Configuration et paramétrage par un technicien médical

| Pour ... | Voir ... |
|---|---|
| *Ces tâches ponctuelles de configuration initiale sont réalisées par du personnel qualifié techniquement.* | |
| Monter et positionner l'humidificateur | Voir le *Guide d'installation* correspondant du ventilateur ou du chariot |
| Configurer les réglages de l'humidificateur | Section 7 |
| *En option* : raccorder l'humidificateur au port RS-232 COM de n'importe quel ventilateur Hamilton Medical compatible | Voir le *Manuel de l'utilisateur* correspondant du ventilateur. |

Tableau 5. Configuration et paramétrage par du personnel soignant

| Pour ... | Voir ... |
|---|---|
| *Les tâches suivantes sont réalisées par le personnel médical s'occupant des patients.* | |
| Brancher le dispositif à une source d'alimentation | Section 3.1 |
| Connecter le circuit respiratoire | Section 3.2 |
| Mettre l'humidificateur sous tension | Section 3.3 |
| Tester les alarmes | Section 3.4 |
| Spécifier les réglages de l'humidificateur | Section 3.5 |
| Connecter le patient | Section 3.6 |

## 3.1 Connexion à une source d'alimentation

Vérifiez toujours la fiabilité de la prise d'alimentation principale avant de brancher l'humidificateur et le ventilateur.

**Pour brancher l'humidificateur à une source d'alimentation**

- Branchez l'humidificateur sur une prise alimentée en courant alternatif.[26]

## 3.2 Connexion du circuit respiratoire à l'humidificateur

Hamilton Medical fournit plusieurs circuits respiratoires pour adultes, enfants et nouveau-nés.

Pour plus de détails, reportez-vous aux *Instructions d'utilisation* du circuit respiratoire concerné.

## 3.3 Mise sous/hors tension de l'humidificateur

Lorsque l'humidificateur est sous tension, il fonctionne automatiquement dans le mode configuré par défaut.

Assurez-vous d'allumer le ventilateur *avant* d'allumer l'humidificateur.

**Pour mettre l'humidificateur sous tension**

- Appuyez sur la touche (M/A/Veille) et maintenez-la enfoncée pendant environ 3 secondes.

L'humidificateur effectue un auto-test. Une fois cette opération terminée, l'humidificateur démarre automatiquement en mode invasif (INV) sauf si la configuration a été modifiée.

**Pour mettre l'humidificateur hors tension**

- Appuyez sur la touche et maintenez-la enfoncée pendant environ 3 secondes.

Assurez-vous d'éteindre l'humidificateur *avant* d'éteindre le ventilateur.

## 3.4 Test des alarmes

Avant de relier un nouveau patient à l'humidificateur, vérifiez que les alarmes fonctionnent correctement.

Vérifiez que l'humidificateur est sous tension.

**Pour tester les alarmes de l'humidificateur**

1. Déclenchez une alarme en enlevant le réservoir d'eau de l'humidificateur.
2. Vérifiez les points suivants :
   – Une alarme sonore se fait entendre.
   – L'indicateur visuel d'alarme clignote (Figure 4)
   – Le symbole d'alarme correspondant apparaît à l'écran (Tableau 9)

Résolvez l'alarme en replaçant le réservoir d'eau dans l'humidificateur et vérifiez que l'alarme est réinitialisée.

[26] Si vous utilisez l'humidificateur avec un ventilateur Hamilton Medical compatible, branchez le câble d'alimentation de l'humidificateur à la prise d'alimentation dédiée du ventilateur.

## 3.5 Spécification des réglages de l'humidificateur

Sélectionnez le mode d'humidification pour votre patient.[27] Pour des détails, reportez-vous à la section 4.2.

## 3.6 Connexion du patient

Connectez le circuit respiratoire à l'interface patient appropriée.

L'humidificateur est désormais configuré et prêt à fonctionner.

# 4 Utilisation de l'humidificateur HAMILTON-H900

Tableau 6. Aperçu du fonctionnement

| Pour plus de détails sur ... | Voir ... |
|---|---|
| La mise sous/hors tension de l'humidificateur | Section 3.3 |
| Activer/quitter le mode **Veille** | Section 4.1 |
| Accès aux réglages de l'humidificateur | Section 2.3 |
| Modes de fonctionnement de l'humidificateur : **INV**, **NIV**, **HiFlow** | Section 4.2 |
| Réglages **Auto** et **Manuel** | Section 4.2.2 |
| Modification de l'humidité à l'aide des réglages de température | Section 4.3 |
| Paramètres monitorés de l'humidificateur | Section 4.4 |
| Alarmes relatives à l'humidificateur | Section 5 |

## 4.1 Activer/quitter le mode Veille

**⚠ PRÉCAUTION**

*En mode **Veille**, tous les réglages sont conservés et le débit de chaleur est diminué.*

Le mode **Veille** est un mode d'attente qui permet de conserver les réglages actuels alors que l'humidificateur ne fonctionne pas.

En mode **Veille**, les réglages pour la **température de sortie du réservoir** et le **gradient de température** sont diminués.[28] Pour des détails, reportez-vous à la section 9.7.

### Pour mettre l'humidificateur en mode Veille

- Appuyez brièvement sur la touche  (**M/A/Veille**).

  En mode **Veille**, l'écran affiche le temps pendant lequel l'humidificateur était en **Veille**. Le voyant **M/A/Veille** est orange.

### Pour quitter le mode Veille et démarrer l'humidification

- Appuyez sur  .

  L'humidificateur se remet à fonctionner normalement ; le voyant d'état **M/A/Veille** est vert.

[27] Lorsque l'humidificateur est utilisé avec un ventilateur Hamilton Medical qui prend en charge le fonctionnement intégré, l'humidificateur adopte le mode de fonctionnement du ventilateur. Pour plus de détails, reportez-vous au *Manuel de l'utilisateur* de votre ventilateur.

[28] Pendant la nébulisation, le **gradient de température** n'est *pas* modifié en mode **Veille**.

## 4.2 À propos des modes de fonctionnement de l'humidificateur

Le HAMILTON-H900 offre les modes de fonctionnement suivants : invasif (**INV**), non invasif (**NIV**) et thérapie d'oxygène à haut débit (**HiFlow**).

La sélection du mode de fonctionnement détermine les réglages de température de départ, à la fois au niveau de la sortie du réservoir d'eau (**température de sortie du réservoir**) et au niveau de la pièce en Y (**gradient de température**), ainsi que les plages de température autorisées pour chacun des réglages.

Ces plages de température varient en fonction du groupe de patients. Voir tableau 18.

### 4.2.1 Changement de modes

L'humidificateur démarre automatiquement en mode invasif (**INV**) sauf si vous avez configuré des réglages par défaut personnalisés.

Lorsque vous activez le mode invasif (**INV**) ou non invasif (**NIV**), l'humidificateur définit automatiquement les réglages sur **Auto**.

**Pour changer de modes**

- Appuyez sur (**Modes**) jusqu'à ce que le mode souhaité (**INV**, **NIV**, **HiFlow**) s'affiche.

  Le mode sélectionné apparaît à l'écran.

Figure 6. Mode INV (**1**) sélectionné

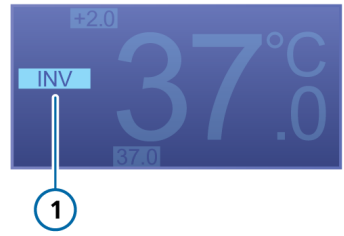



Figure 7. Mode NIV (**1**) sélectionné

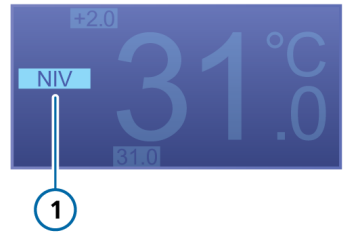
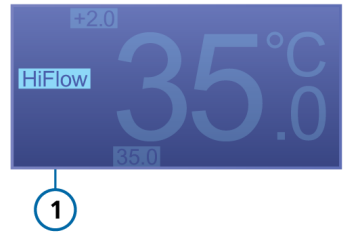



Figure 8. Mode HiFlow (**1**) sélectionné




### 4.2.2 Réglages des paramètres Auto et Manuel

Vous pouvez utiliser l'humidificateur en mode **Auto** ou vous pouvez ajuster manuellement les réglages. Par défaut, l'humidificateur démarre en mode **Auto**.

La **température de la sortie du réservoir** et le **gradient de température** sont réglés à l'aide de l'une des méthodes suivantes :

- Chargement à partir des réglages configurés par défaut (mode **Auto**)
- Réglage manuel par l'utilisateur

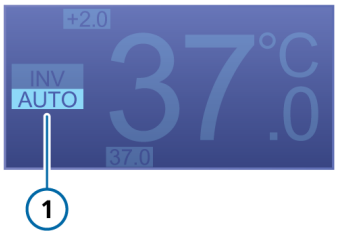
**Réglages automatiques (Auto)**

Lorsque le paramètre est réglé sur **Auto**, l'humidificateur charge les réglages configurés par défaut spécifiés pour le mode sélectionné (voir section 7) et les utilise pour contrôler la température du gaz.

Si la température ambiante est basse, l'humidificateur peut régler automatiquement la température du réservoir d'eau.

Lorsque le mode **Auto** est sélectionné, le texte **AUTO** apparaît sur l'écran principal.

Figure 9. Mode Auto (**1**) sélectionné

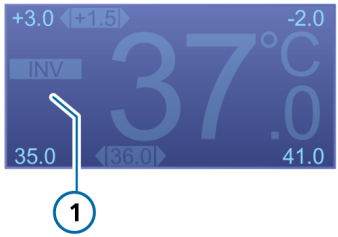



**Réglages manuels**

Si vous modifiez la **température de sortie du réservoir** ou le **gradient de température** à l'aide des curseurs, l'humidificateur passe en mode **Manuel**. Cependant, il continue toujours à contrôler automatiquement la température pour atteindre les réglages spécifiés.

Lorsque les réglages sont changés manuellement, **Auto** n'apparaît plus sur l'écran principal ; la zone est vide.

Figure 10. Mode manuel (**1**) actif




### 4.2.2.1 Activation du mode Auto

Après avoir changé manuellement les réglages de température, vous pouvez réactiver le mode **Auto**.

**Pour réactiver le mode Auto**

- Appuyez sur Auto (**Auto**).
  Activer le mode de fonctionnement **INV** ou **NIV** a également pour effet d'activer automatiquement le mode **Auto** de l'humidificateur.

## 4.3 Modification de l'humidité à l'aide des réglages de température

***REMARQUE***

Si l'humidificateur est en mode **Auto**, le changement des curseurs a pour effet d'activer le mode **Manuel** de l'humidification.

***REMARQUE***

En mode **HiFlow**, il est impossible de changer le **gradient de température** à l'aide du curseur. Vous pouvez régler le **gradient de température** sur une nouvelle valeur dans la **configuration**. Reportez-vous à la section 7.

Vous pouvez ajuster les réglages suivants sur l'humidificateur[29] :

Tableau 7. Réglages de l'humidificateur ajustables

| Réglage | Description |
|---|---|
| Température de sortie du réservoir | Température à la sortie du réservoir d'eau.<br>La plage de valeurs possibles pour ce réglage dépend du mode de fonctionnement de l'humidificateur sélectionné : Pour plus de détails, reportez-vous aux tableaux 16 et 18.<br>Des valeurs supérieures entraînent une humidité supérieure absolue. |
| Gradient de température | Différence entre la température à la sortie du réservoir d'eau et au niveau de la pièce en Y. |
| Exp. Augmentation temp | Lorsque ce réglage est sélectionné, l'humidificateur fournit une chaleur supplémentaire dans la branche expiratoire.[30] |

La température maximale autorisée au niveau de la pièce en Y du patient est de 42 °C. La combinaison des valeurs pour la **température de sortie du réservoir** et le **gradient de température** ne peut pas dépasser cette limite. Par exemple, si le **gradient de température** est réglé sur 2 °C, le réglage le plus élevé possible pour la **température de sortie du réservoir** est 40 °C.

En outre, le réglage du **gradient de température** prévaut sur le réglage de la **température de sortie du réservoir**. Cela signifie que si une combinaison de réglages produisait une température au niveau de la pièce en Y supérieure à 42 °C, alors le **gradient de température** resterait inchangé mais le réglage de la **température de sortie du réservoir** serait ajusté.

Par exemple, si le réglage de la **température de sortie du réservoir** est défini sur 40 °C, vous pouvez régler le **gradient de température** sur 3 °C même si la combinaison dépasse 42 °C. Une fois le réglage du **gradient de température** accepté, le réglage de la **température de sortie du réservoir** est automatiquement réinitialisé sur 39 °C.

### Pour régler la température de sortie du réservoir

- Appuyez sur le curseur de la **température de sortie du réservoir** au niveau du réglage actuel :

  – Faites glisser le curseur vers la gauche pour diminuer la température de sortie du réservoir.

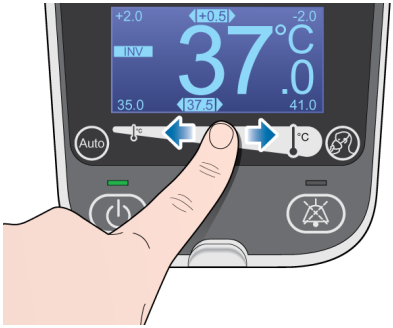
  – Faites glisser le curseur vers la droite pour augmenter la température de sortie du réservoir.

Les changements sont confirmés par un bip sonore et sont appliqués immédiatement.

[29] Lorsque l'humidificateur est utilisé avec un ventilateur Hamilton Medical qui prend en charge le contrôle de l'humidificateur intégré, vous pouvez également modifier les réglages directement sur le ventilateur. Pour plus de détails, reportez-vous au *Manuel de l'utilisateur* de votre ventilateur.

[30] Circuits respiratoires chauffants à deux branches, à usage unique exclusivement.

Figure 11. Réglage de la température de sortie du réservoir




### Pour régler une température de sortie du réservoir > 39 °C

Pour augmenter la **température de sortie du réservoir** au-dessus de 39 °C, le curseur doit être activé deux fois.

1. Appuyez sur le curseur de la **température de sortie du réservoir** au niveau du réglage actuel et faites glisser le curseur vers la droite pour atteindre la limite de 39 °C.
2. Appuyez et faites glisser de nouveau le curseur pour régler la température de sortie du réservoir au-dessus de 39 °C.

### Pour régler le gradient de température

- Appuyez sur le curseur du **gradient de température** au niveau du réglage actuel :

  – Faites glisser le curseur vers la droite pour diminuer le gradient de température.

  – Faites glisser le curseur vers la gauche pour augmenter le gradient de température.

Les changements sont confirmés par un bip sonore et sont appliqués immédiatement.

Figure 12. Réglage du gradient de température


Par exemple, si la température cible de la pièce en Y est de 39 °C et que le réglage de la **température de sortie du réservoir** est défini sur 37 °C, réglez le **gradient de température** sur 2 °C.

## 4.4 Monitorage de l'humidification

Les données de monitorage sont disponibles dans la fenêtre de **Monitorage de la température**, accessible à tout moment.[31]

Les paramètres suivants sont monitorés :

- Température de sortie du réservoir
- Gradient de température
- Température au niveau de la pièce en Y

[31] Lorsque l'humidificateur est utilisé avec un ventilateur Hamilton Medical qui prend en charge le monitorage de l'humidificateur intégré, les données de l'humidificateur apparaissent sur l'écran du ventilateur. Pour plus de détails, reportez-vous au *Manuel de l'utilisateur* de votre ventilateur.

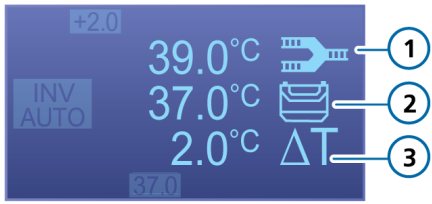
### 4.4.1 Affichage de paramètres de monitorage supplémentaires

**Pour afficher la fenêtre de monitorage de la température**

- Appuyez sur (**Fenêtre de monitorage de la température**).

  La fenêtre se ferme après 30 secondes ou si la touche est de nouveau activée.

Figure 13. Fenêtre de monitorage de la température




| | | | |
|---|---|---|---|
| 1 | Temp actuelle de pièce en Y | 3 | Gradient de temp actuel |
| 2 | Temp actuelle de sortie du réservoir | | |

## 4.5 Réglages de la luminosité de l'écran Jour et Nuit

Le rétroéclairage de l'écran de l'humidificateur prend en charge deux réglages d'écran différents. Utilisez ces réglages pour définir la luminosité de l'écran.

**Pour alterner entre les réglages Jour et Nuit**

- Appuyez sur la touche et maintenez-la enfoncée pendant 5 secondes.

Pour régler la luminosité par défaut du jour et de la nuit, voir section 7.

# 5 Réponses aux alarmes de l'humidificateur

Les alarmes associées à l'humidificateur vous préviennent des conditions qui requièrent votre attention. Les alarmes sont indiquées comme suit :

- Graphiquement sur l'écran de l'humidificateur.
- Avec une série de 3 ou 5 bips sonores.
- La zone lumineuse d'alarme au-dessus du réservoir d'eau clignote.
- Lorsque l'humidificateur est utilisé avec un ventilateur Hamilton Medical qui prend en charge le monitorage de l'humidificateur intégré, les messages d'alarme apparaissent également sur l'écran du ventilateur.[32]

Les alarmes sont répertoriées comme étant de priorité absolue, de priorité moyenne ou de défaut technique, comme indiqué dans le tableau 8.

Reportez-vous au tableau 9 pour une liste exhaustive des alarmes.

[32] Non disponible sur tous les ventilateurs. Reportez-vous au *Manuel de l'utilisateur* de votre ventilateur.

Tableau 8. Voyants d'alarme

| Type d'alarmes | Voyant d'état d'alarme | Indications sonores | Action requise |
|---|---|---|---|
| Priorité absolue | Rouge, clignotant<br>Icône d'alarme affichée à l'écran | Séquence de 5 bips, répétée jusqu'à ce que l'alarme soit réinitialisée | L'humidificateur requiert une attention immédiate. |
| Priorité moyenne | Jaune, clignotant<br>Icône d'alarme affichée à l'écran | Séquence de 3 bips, répétée jusqu'à ce que l'alarme soit réinitialisée | L'humidificateur requiert une attention rapide. |
| Défaut technique | Rouge, clignotant<br>Une référence de panne technique apparaît sur l'écran | Séquence de 3 bips, répétée jusqu'à ce que l'alarme soit réinitialisée | • Consignez la référence de panne technique[33].<br>• Mettez l'humidificateur hors service.<br>• Faites réparer l'humidificateur. |

[33] Une liste de toutes les références de panne technique est disponible dans le *Manuel de maintenance du HAMILTON-H900*.

## 5.1 Neutralisation temporaire d'une alarme

L'un des composants d'une alarme est la tonalité sonore. Avec la plupart des alarmes, vous pouvez mettre en pause (neutraliser) la sonnerie pendant deux minutes à chaque fois.

### Pour neutraliser temporairement une alarme

- Appuyez sur (**Pause audio**) sur la face avant de l'humidificateur.

  L'alarme sonore de l'humidificateur est neutralisée pendant deux minutes.

  Appuyez une deuxième fois sur la touche pour annuler la **Pause audio**.

Le rétroéclairage de la touche **Pause audio** est toujours allumé en rouge lorsqu'une **Pause audio** est active.

Une fois la durée écoulée, si le problème n'est pas résolu, l'alarme retentit de nouveau.

## 5.2 Réglage de l'intensité de l'alarme

**⚠ AVERTISSEMENT**

Assurez-vous de régler le volume sonore de l'alarme au-dessus du niveau sonore ambiant. Il est important de respecter cette consigne pour être sûr d'entendre une alarme le cas échéant.

Vous pouvez régler le volume de l'alarme sonore.

Le volume est réglé par défaut sur 5. Lors de la mise hors tension de l'humidificateur, l'intensité de l'alarme sonore est réinitialisée à la valeur par défaut.

### Pour régler l'intensité de l'alarme sonore

1. Si nécessaire, appuyez sur (**M/A/Veille**) pour mettre l'humidificateur en **Veille**.
2. Appuyez sur pendant 3 secondes.

   L'écran affiche le réglage actuel de l'intensité de l'alarme sonore.
3. Réglez l'intensité de l'alarme sonore à l'aide du curseur de la **température de sortie du réservoir** (voir figure 3).

   L'humidificateur confirme le choix du nouveau réglage d'intensité par un bip.
4. Appuyez sur pour confirmer votre choix et reprendre le fonctionnement normal.

## 5.3 Dépannage des alarmes

Le tableau 9 répertorie les alarmes de l'humidificateur, leur représentation graphique sur l'humidificateur, une description et des suggestions d'actions correctives.

Tableau 9. Alarmes du HAMILTON-H900

| Alarme | Icône d'alarme | Description | Action requise |
|---|---|---|---|
| **Priorité absolue** | | | |
| Inclinaison humidificateur |  | L'humidificateur est dangereusement incliné.<br>L'humidificateur est positionné à un angle supérieur ou égal à 10° par rapport au sol. | • Vérifier l'installation de l'humidificateur.<br>• Vérifier le chariot du ventilateur.<br>• Utiliser l'humidificateur à un angle inférieur à 10° par rapport au sol. |
| Température haute |  | La température du gaz au niveau de la sortie du réservoir d'eau ou de la pièce en Y est supérieure à la valeur définie. | • S'assurer que le circuit respiratoire ne soi pas recouvert par les couvertures du lit du patient.<br>• S'assurer que le circuit respiratoire ou le réservoir de l'humidificateur ne soit pas exposé(e) à la lumière directe du soleil.<br>• Remplacer le circuit respiratoire. |
| Niveau d'eau élevé |  | Le niveau d'eau du réservoir d'eau est supérieur au niveau de remplissage maximal. | • Vider le réservoir de l'humidificateur pour réduire le niveau d'eau.<br>• Replacer le réservoir de l'humidificateur.<br>• Utiliser l'humidificateur à un angle inférieur à 10° par rapport au sol. |

| Alarme | Icône d'alarme | Description | Action requise |
|---|---|---|---|
| Défaut technique | Une référence de panne technique apparaît sur l'écran | Panne technique due à un dysfonctionnement de l'humidificateur. | • Contrôlez le fonctionnement de l'humidificateur et toutes les connexions.<br>• Remplacez l'humidificateur et faites-le réparer.<br>• Si une référence de défaut technique s'affiche, prenez-en note et indiquez cette référence lorsque vous ferez réparer l'humidificateur. |
| **Priorité moyenne** | | | |
| Température basse |  | La température du gaz au niveau de la sortie du réservoir d'eau ou de la pièce en Y est inférieure à la valeur définie. | • Attendre la fin du préchauffage du système (30 minutes environ).<br>• Vérifier que tous les réglages sont corrects.<br>• Éviter d'exposer directement l'humidificateur et le circuit respiratoire aux courants d'air, etc. |
| Niveau d'eau faible |  | Le niveau d'eau du réservoir d'eau est inférieur au niveau de remplissage minimal. | • Vérifier la bouteille d'eau et remplir la tubulure.<br>• Si la bouteille d'eau est vide, installer une nouvelle bouteille d'eau.<br>• Remplir ou remplacer le réservoir de l'humidificateur.<br>• Utiliser l'humidificateur à un angle inférieur à 10° par rapport au sol. |
| Vérifier le réservoir d'eau |  | Réservoir d'eau manquant ou réservoir installé non compatible. | Insérer un nouveau réservoir de l'humidificateur et raccorder le circuit respiratoire. |

| Alarme | Icône d'alarme | Description | Action requise |
|---|---|---|---|
| Vérifier la branche gauche ou droite |  | L'écran et les voyants du raccord indiquent quelle branche est défectueuse.<br>• Branche non raccordée ou défectueuse.<br>• Aucun débit d'air.<br>• Une branche est mal connectée.<br>• La branche expiratoire BLANCHE de l'humidificateur est connectée au port inspiratoire du ventilateur *Vers patient*. | • Insérer ou réinstaller correctement le circuit respiratoire.<br>• Remplacer le circuit respiratoire.<br>• Connecter la branche inspiratoire BLEUE de l'humidificateur au port inspiratoire du ventilateur *Vers patient*.<br>Si le voyant du raccord est :<br>*vert* : la branche est correctement installée ;<br>*orange* : l'humidificateur teste la connexion ;<br>*rouge* : la connexion est défectueuse ou inexistante. |

# 6 Maintenance

*Avant de poursuivre, lisez les informations relatives à la sécurité fournies à la section 1.*

Cette section fournit des informations sur les procédures et le calendrier de maintenance de l'humidificateur, ainsi que des instructions de nettoyage et de désinfection.

Toutes les procédures décrites dans cette section sont censées être effectuées par l'utilisateur.

Pour toute opération de maintenance supplémentaire, contactez un technicien de Hamilton Medical. Tous les documents mentionnés dans cette section sont disponibles sur le site internet MyHamilton : **https://www.hamilton-medical.com/MyHamilton**

## 6.1 Nettoyage, désinfection et stérilisation

Les composants de l'humidificateur doivent être régulièrement nettoyés et désinfectés, à l'aide de méthodes et de solutions de nettoyage spécifiques à chaque composant.

Il est important de choisir la méthode et les produits appropriés pour nettoyer et désinfecter l'humidificateur et ses composants, non seulement pour éviter d'endommager l'équipement mais également pour éviter toute contamination croisée.

Les informations de nettoyage et de désinfection sont présentées comme suit :

- Le tableau 10 répertorie les composants relatifs à l'humidificateur et indique quelles méthodes de nettoyage et de désinfection peuvent être utilisées pour chacun d'eux, la fréquence à laquelle le composant doit être nettoyé/désinfecté et les produits de nettoyage et de désinfection.
- Pour les kits de circuit respiratoire et les réservoirs d'eau, voir les *Instructions d'utilisation* ou le *Guide de retraitement*.

Lorsque vous utilisez les composants de l'humidificateur, les méthodes de nettoyage et les produits de nettoyage, gardez ceci à l'esprit :

- N'essayez *pas* d'utiliser d'autres procédures de décontamination que celles qui sont spécifiées par Hamilton Medical.
- Bien que nous fournissions des recommandations pour les produits et les concentrations à utiliser, si vous avez des questions spécifiques sur l'utilisation d'un produit de nettoyage ou de désinfection particulier, contactez le fabricant de ce produit.

Tableau 10. Méthodes de nettoyage et de désinfection de l'humidificateur

| Pièce | Fréquence | Méthode de nettoyage/désinfection | Produits de nettoyage |
|---|---|---|---|
| Extérieur de l'humidificateur, y compris :<br>• Boîtier<br>• Écran<br>• Plaque chauffante<br>• Câbles d'alimentation<br>• Systèmes de montage | Après chaque utilisation sur un patient ou si besoin. | Essuyer à l'aide d'un chiffon imbibé d'une solution approuvée et homologuée de nettoyage/désinfection. | Lingettes désinfectantes Super Sani-Cloth<br>CaviWipes |

## 6.2 Maintenance préventive

La maintenance préventive de votre humidificateur doit être effectuée par un technicien agréé Hamilton Medical, conformément aux instructions du *Manuel de maintenance du HAMILTON-H900*.

# 7 Configuration

L'humidificateur est livré avec une configuration par défaut de plusieurs réglages organisés par groupe de patient.

Vous pouvez modifier les réglages par défaut suivants en mode de **configuration** :

- **Température de sortie du réservoir**
- **Gradient de température**
- Mode de fonctionnement au démarrage (**INV/NIV/HiFlow**)
- **Augmentation de la température expiratoire** Marche/Arrêt
- Réglages de la luminosité **Jour/Nuit** du rétroéclairage

## 7.1 Accès au mode de configuration

Vous pouvez accéder au mode de **configuration** lorsque l'humidificateur est en mode **Veille**.

### Pour accéder au mode de configuration

1. Si besoin, appuyez sur  pour activer le mode **Veille**.
2. Appuyez sur les deux touches  et  et maintenez-les enfoncées.

   Veillez à bien appuyer sur la touche  en premier.

   La fenêtre de **configuration** apparaît après 5 secondes.

L'humidificateur est désormais en mode de **configuration**.

## 7.2 Modification des réglages de configuration

Les réglages personnalisés restent actifs jusqu'à leur modification ou la restauration des réglages d'usine.

En mode de **configuration**, les boutons situés sur le panneau avant de l'humidificateur permettent de naviguer entre les vues et de faire des sélections.

Le tableau 11 décrit comment naviguer dans le mode de **configuration** et changer les réglages.

Par exemple, pour modifier un réglage, reportez-vous à la procédure ci-dessous relative au changement des réglages par défaut du **gradient de température**.

Pour obtenir une liste des réglages de configuration, voir section 9.6.

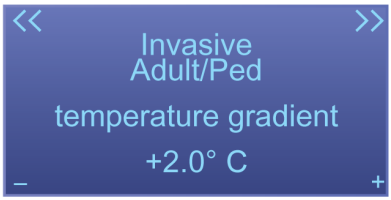
Tableau 11. Boutons de navigation du mode de configuration

| Bouton | Description |
|---|---|
|  | Avancer d'une vue |
|  | Reculer d'une vue |
|  | Augmenter une valeur |
|  | Diminuer une valeur |
|  | Enregistrer les modifications et quitter le mode de **configuration** |

**Exemple : changement du gradient de température**

**Pour changer le réglage par défaut pour le gradient de température dans le mode invasif, Adulte/Enfant**

1. En mode de **configuration**, appuyez sur Exp. jusqu'à l'affichage de **Invasive, Adult/Ped, Temperature gradient**.




2. Appuyez sur pour augmenter la valeur ou sur Auto pour diminuer la valeur.
3. Une fois terminé, appuyez sur pour enregistrer les modifications et quitter le mode de **configuration**.

## 7.3 Restauration des réglages d'usine par défaut

Vous pouvez restaurer les réglages d'usine par défaut à tout moment.

**Pour restaurer les réglages d'usine par défaut**

1. En mode de configuration, appuyez de façon répétée sur Exp. jusqu'à ce que la fenêtre **Reset all custom defaults** apparaisse.
2. Appuyez sur Auto.

Les réglages d'usine par défaut sont restaurés.

# 8 Pièces et accessoires

Cette section répertorie les pièces et accessoires disponibles pour l'humidificateur HAMILTON-H900.

Pour plus d'informations, reportez-vous au catalogue en ligne du site internet de Hamilton Medical ou contactez votre représentant Hamilton Medical.

Tableau 12. Pièces et accessoires de l'humidificateur

| Réf. | Description |
|---|---|
| 260161 | HAMILTON-BC8022, kit de circuit respiratoire à deux branches, chauffant, avec réservoir d'eau |
| 260186 | HAMILTON-BC4022, kit de circuit respiratoire à une branche, chauffant, avec réservoir d'eau |
| 260185 | HAMILTON-BC8010, kit de circuit respiratoire à deux branches, chauffant, avec réservoir d'eau et rallonge pour couveuse |
| 260187 | HAMILTON-BC4010, kit de circuit respiratoire à une branche, chauffant, avec réservoir d'eau et rallonge pour couveuse |
| 260196 | HAMILTON-HC322, réservoir d'eau, à usage unique |
| 260197 | HAMILTON-HC310, réservoir d'eau, à usage unique |

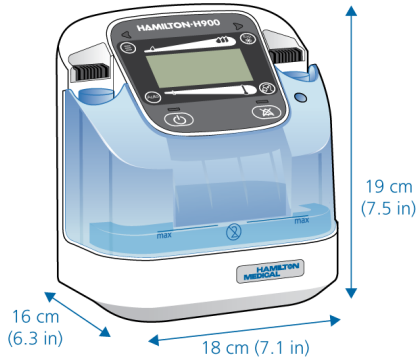
# 9 Spécifications

## 9.1 Caractéristiques physiques

Tableau 13. Caractéristiques physiques

| Dimension | Spécifications |
|---|---|
| Poids | Humidificateur (avec réservoir d'eau vide) : 2,5 kg |
| Dimensions | Voir figure 14 |

Figure 14. Dimensions du HAMILTON-H900



## 9.2 Conditions environnementales requises

Tableau 14. Conditions environnementales requises

| Environnement | | Spécifications |
|---|---|---|
| Température | Fonctionnement : | 10 à 40 °C |
| | Stockage : | -20 à 60 °C |
| | | Température ambiante recommandée : 18 à 26 °C |
| Altitude | | Max. 4 000 m |
| Pression atmosphérique | Fonctionnement et stockage : | 61 kPa à 106 kPa |
| Humidité relative | Fonctionnement : | 30 à 95%, sans condensation |
| | Stockage : | 10 à 95 %, sans condensation |
| Protection contre les projections de liquide | | IP21 |
| Température d'arrivée du gaz | | 18 à 31 °C (recommandé) |

## 9.3 Spécifications électriques

Tableau 15. Spécifications électriques

| Référence | Alimentation d'entrée | Consommation électrique |
|---|---|---|
| 950001 (230 V) | 220 - 240 V<br>50/60 Hz | 283 VA |
| 950004 (115 V) | 110 - 127 V<br>50/60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50/60 Hz | 268 VA |
| Équipotentiel | Borne pour le branchement du conducteur équipotentiel conformément à la norme DIN 42801 | |

## 9.4 Réglages

Tableau 16. Réglages des paramètres et plages

| Paramètre ou réglage (unité) | Mode | Plage | Par défaut | Résolution |
|---|---|---|---|---|
| Température de sortie du réservoir (°C) | INV | 35 à 41 | 37,0 | 0,5 |
| | NIV | 30 à 35 | 31,0 | 0,5 |
| | HiFlow | 33 à 37 | 35,0 | 2 |
| Gradient de température (°C) | INV | -2 à 3 | Adulte/Enf. : 2<br>Néonatal : 3 | 0,5 |
| | NIV | -2 à 3 | Adulte/Enf. : 2<br>Néonatal : 3 | 0,5 |
| | HiFlow | -- | 2 | -- |
| Température max. résultante des voies aériennes (pièce en Y)[34] (°C) | INV | 33 à 42 | -- | -- |
| | NIV | 28 à 38 | -- | -- |
| | HiFlow | 35 à 39 | -- | -- |
| Augmentation de la température expiratoire | Tous les modes | Activé, désactivé | Activé | -- |
| Réglage de la luminosité de l'écran | Tous les modes | 1 à 5 | Jour : 5<br>Nuit : 2 | 1 |

[34] Température des voies aériennes limitée à 42 °C par l'humidificateur.

## 9.5 Paramètres monitorés

Tableau 17. Paramètres contrôlés, plages et précision

| Paramètre (unités) | Plage | Précision |
|---|---|---|
| Température de sortie du réservoir (°C) | 10 à 60 | 10 à 30 : ± 1<br>30 à 41 : ± 0,5<br>41 à 60 : ± 1 |
| Température au niveau de la pièce en Y (°C) | 28 à 43 | ± 0,5 |

## 9.6 Configuration

Tableau 18. Caractéristique de configuration

| Paramètre | Mode | Plage de configuration | Réglage par défaut |
|---|---|---|---|
| Température de sortie du réservoir (°C) | INV | 35 à 39 | 37,0 |
| | NIV | 30 à 35 | 31,0 |
| | HiFlow | 33, 35, 37 | 35,0 |
| Gradient de température (°C) | INV | 0 à 3 | Adulte/Enf. : 2<br>Néonatal : 3 |
| | NIV | 0 à 3 | Adulte/Enf. : 2<br>Néonatal : 3 |
| | HiFlow | 0 à 3 | 2 |
| Mode au démarrage | -- | Invasif, Non invasif, HiFlow | Invasif |
| Réglage de la luminosité de l'écran | Tous les modes | 1 à 5 | Jour : 5<br>Nuit : 2 |

## 9.7 Données de performances techniques

Tableau 19. Données de performances techniques

| Description | Spécification | | |
|---|---|---|---|
| Vitesses de débit[35] | Invasif : | Jusqu'à 60 l/min | |
| | Non invasif : | Jusqu'à 120 l/min | |
| | HiFlow : | Jusqu'à 120 l/min | |
| Temps de préchauffage | Moins de 30 min | | |
| Humidité | Á une température ambiante comprise entre 18 et 26 °C : | | |
| | Invasif : | Réglage de température entre 37 et 41 °C | Humidité minimale : 33 mg H2O/l |
| | Non invasif : | Réglage de température entre 31 et 35°C | Humidité minimale : 12 mg H2O/l |
| | HiFlow : | Débit ≤ 60 l/min | Humidité minimale : 33 mg H2O/l |
| | | Débit > 60 l/min | Humidité minimale : 12 mg H2O/l |
| Spécifications de chauffage en Veille | Circuits respiratoires chauffants : | Pièce en Y limitée à 30 °C. | |
| Écran | 3 pouces/64 x 128 pixels, affichage à matrice de points inversée (rétroéclairage) | | |
| Pause audio | 120 secondes | | |
| Intensité de l'alarme sonore[36] | Plage = 1 à 8. Par défaut = 5. | | |

[35] Pour connaître les débits minimaux, reportez-vous aux *Instructions d'utilisation* du circuit respiratoire.
[36] Volume à 1 mètre de distance de l'humidificateur. Une valeur de 1 = 50 dB(A), 5 (par défaut) = 60 dB(A) et 8 = 65 dB(A), avec une précision de ± 6 dB(A).

## 9.8 Performances principales

Les températures appliquées au gaz respiratoire et au circuit respiratoire doivent être maintenues dans la plage de réglages spécifiés et surveillées.

Si la température dépasse les limites spécifiées, l'humidificateur doit détecter ce problème et en informer l'utilisateur à l'aide d'une alarme.

## 9.9 Description fonctionnelle du système de l'humidification

L'humidificateur HAMILTON-H900 est conçu pour chauffer et humidifier les gaz respiratoires pendant la ventilation mécanique. Le gaz respiratoire est chauffé et humidifié pendant son passage dans un réservoir partiellement rempli d'eau chauffée.

L'humidificateur comporte deux systèmes de chauffage contrôlés par capteur :

- *Plaque chauffante*. Chauffe l'eau du réservoir d'eau.
- *Système de chauffage du circuit respiratoire intégré*. Chauffe les branches respiratoires pour éviter la condensation.

La température du gaz respiratoire est contrôlée à la sortie du réservoir et dans la branche respiratoire côté patient.

## 9.10 Symboles utilisés sur les étiquettes et l'emballage du dispositif

| Symbole | Description |
|---|---|
|  | Respecter les *Instructions d'utilisation* |
|  | Numéro de référence |
|  | Numéro de série |
|  | Quantité |
|  | Fabricant |
|  | Date de fabrication |
|  | Pièce appliquée Type BF (Équipement médical électrique de type BF selon la norme IEC 60601-1) |
|  | Mise au rebut en conformité avec la Directive du Conseil 2002/96/CE relative aux déchets d'équipements électriques ou électroniques (DEEE) |
|   | Le symbole TÜV NRTL accompagné des indicateurs «C» et «US» signifie que le produit est conforme aux exigences canadiennes et aux exigences des autorités américaines en matière de sécurité. |

| Symbole | Description |
|---|---|
|  | Équipotentiel |
|  | Avertissement : surface chaude.<br>La plaque chauffante et le fond du réservoir peuvent atteindre une température supérieure à 85 °C. |
| CE 0197 | Marquage de conformité CE, sceau d'approbation garantissant que le dispositif est conforme à la Directive du Conseil 93/42/CEE concernant les appareils médicaux |
| IP21 | Protégé contre les chutes verticales de gouttes d'eau et les particules solides de plus de 12,5 mm |
| max | Repère du niveau de remplissage sur le réservoir d'eau |
|  | Interface série RS-232 pour la communication avec les ventilateurs de la marque Hamilton Medical |
|  | MR unsafe<br>L'humidificateur HAMILTON-H900 fait courir des risques inacceptables au patient, à l'équipe médicale ou à toute autre personne présente dans l'environnement IRM. |

| Symbole | Description |
|---|---|
|  | RoHS chinoise |
|  | Capteur de température<br>Indique la position de la sonde de température sur le circuit respiratoire. |

## 9.11 Normes et homologations

Le système d'humidificateur est conforme aux parties pertinentes des normes suivantes, répertoriées dans le tableau 20.

Tableau 20. Normes et homologations : versions valides

| |
|---|
| CEI 60601-1:2005/A1:2012 |
| CEI 60601-1-2:2014 |
| CEI 60601-1-6:2010/A1:2013 |
| CEI 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| CEI 62304:2006/A1:2015 |
| CEI 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Mise au rebut

Le dispositif doit être mis au rebut conformément aux protocoles de votre établissement et à la Directive 2002/96/CE.

Les circuits respiratoires et les réservoirs d'eau de l'humidificateur doivent être mis au rebut conformément aux *Instructions d'utilisation* fournies avec les kits de circuits respiratoires.

## 9.13 Garantie

GARANTIE LIMITÉE

LA GARANTIE DÉCRITE DANS CET ACCORD REMPLACE TOUTE AUTRE GARANTIE, EXPRESSE OU IMPLICITE, INCLUANT LES GARANTIES IMPLICITES DE VALEUR COMMERCIALE ET D'APTITUDE À UN OBJECTIF PARTICULIER. TOUTEFOIS, LES GARANTIES IMPLICITES NE SONT PAS DÉNIÉES PENDANT CETTE PÉRIODE DE GARANTIE LIMITÉE.

Hamilton Medical garantit que ses produits livrés sont exempts de défaut de matériau et de fabrication. La garantie ne couvre pas les éléments jetables. Les éléments jetables et les consommables sont considérés être seulement à usage unique ou limité ; ils doivent être remplacés régulièrement pour garantir un bon fonctionnement du produit, conformément aux instructions du Manuel de l'utilisateur.

Hamilton Medical n'aura aucune obligation ou responsabilité à l'égard du produit autre que celles spécifiées dans ce document, y compris sans s'y limiter : les obligations et/ou responsabilités liées à une négligence alléguée ou à une responsabilité inconditionnelle. En aucun cas, la société ne sera responsable de dommages fortuits ou indirects, directs ou conditionnels.

Cette Garantie limitée sera nulle et ne s'appliquera pas :

1. Si le produit n'a pas été installé et raccordé par un représentant local agréé de Hamilton Medical et conformément aux instructions fournies par Hamilton Medical et un représentant de Hamilton Medical.
2. En cas d'absence de preuve attestant de la survenue du dommage ou de la réparation pendant la période de garantie limitée certifiée.
3. En cas de modification, effacement ou retrait du numéro de série et d'absence de bordereau de vente ou autre document permettant de vérifier la date d'achat du produit.
4. Si les défauts proviennent de mauvaise utilisation, de négligence ou d'accidents ou de réparation, d'ajustement, de modification ou de remplacement effectué hors des usines de Hamilton Medical ou par une autre entité qu'un centre de SAV agréé ou un représentant du SAV agréé.
5. Si le produit a fait l'objet d'une modification quelconque sans l'autorisation écrite préalable de Hamilton Medical.
6. Si le produit est ou a été utilisé d'une façon quelconque non spécifiée à la section « Usage prévu ».
7. Si le produit a été utilisé par une autre personne que le personnel dûment formé sous la supervision d'un médecin.

Les remplacements et/ou les réparations fournis au titre de cette Garantie limitée ne bénéficient pas d'une nouvelle garantie, mais seulement de la partie non échue de la Garantie limitée d'origine. La garantie des composants réparés et/ou remplacés ne dépasse pas la Garantie limitée de l'appareil.

Pour bénéficier de cette Garantie limitée, le demandeur doit notifier rapidement au partenaire commercial de Hamilton Medical de son pays : la nature du problème, le numéro de série et la date d'achat du Produit.

À l'exception de ce qui est mentionné ci-dessus, Hamilton Medical ne saurait être responsable d'un quelconque dommage, d'une quelconque plainte ou responsabilité incluant, sans toutefois s'y limiter, les dommages corporels ou les dommages fortuits, indirects ou spéciaux. Hamilton Medical ne saurait être responsable d'un quelconque dommage, d'une quelconque plainte ou responsabilité incluant, sans toutefois s'y limiter, les dommages corporels ou les dommages fortuits, indirects ou spéciaux résultant d'une mauvaise utilisation du dispositif ou du non-respect des instructions fournies dans le présent manuel.

### 9.13.1 Divers

Les conditions générales de Hamilton Medical s'appliquent. Cet accord est gouverné par et interprété conformément aux lois de Suisse et peut être appliqué par chacune des parties sous la juridiction de la cour de Chur, en Suisse.

# Instrucciones de uso

## HAMILTON-H900

2021-01-11

624431/09

**Fabricante**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz,
Suiza
Teléfono: (+41) 58 610 10 20
Fax: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Tabla de contenido

# Introducción

Lea la documentación antes de usar el dispositivo o los accesorios.

### Convenciones de esta guía

En este manual:

- Los nombres de los botones aparecen en **negrita**.
- Es posible que los gráficos que se muestran en este manual no coincidan exactamente con lo que vea en su propio entorno.
- No todas las opciones están disponibles en todos los mercados.

Los mensajes de seguridad se muestran de la siguiente forma:

**⚠ ADVERTENCIA**

Alerta al usuario sobre la posibilidad de que se produzca una lesión, la muerte u otras reacciones adversas graves relacionadas con el uso inadecuado o abuso del dispositivo.

**⚠ PRECAUCIÓN**

*Alerta al usuario sobre la posibilidad de que se produzca un problema en el dispositivo relacionado con el uso o un uso inadecuado, como puede ser un mal funcionamiento, un fallo o un daño en el equipo u otra propiedad.*

***AVISO***

Resalta la información que tiene una importancia especial.

En las tablas, los mensajes de seguridad se muestran de la siguiente forma:

**⚠ ADVERTENCIA**

**⚠ PRECAUCIÓN**

**AVISO**

Para descargar la última versión de este manual u otros documentos, visite el sitio web MyHamilton:
**https://www.hamilton-medical.com/MyHamilton**

Hamilton Medical pone a su disposición Hamilton Medical College, donde encontrará diversos módulos de aprendizaje de forma gratuita. Para registrarse, acceda a:
**http://college.hamilton-medical.com/**

**⚠ PRECAUCIÓN**

*(Solo en EE. UU.): la legislación federal estipula que este dispositivo puede ser adquirido solo por un médico o por petición del mismo.*

### Uso previsto

El humidificador HAMILTON-H900 está diseñado para el acondicionamiento de gas respiratorio durante la ventilación mecánica invasiva y no invasiva.

El dispositivo está diseñado para su uso en un entorno hospitalario y de centros sanitarios en el que los profesionales de la salud proporcionan cuidados a los pacientes.

El humidificador HAMILTON-H900 es un producto sanitario diseñado para personal debidamente formado y cualificado que lo utilice bajo la supervisión de un médico y en función de las características técnicas especificadas.

# 1 Información de seguridad

En este apartado, se proporciona información de seguridad relacionada con la instalación, el funcionamiento y el mantenimiento del humidificador.

**Revise cuidadosamente todas las piezas de este apartado de seguridad antes de instalar y utilizar el humidificador.**

**Asegúrese de revisar las instrucciones de uso antes de utilizar el humidificador.**

**Lea las instrucciones de uso suministradas con los dispositivos y accesorios del humidificador antes de utilizarlos.**

Si tiene dudas sobre cualquier información incluida en este manual, póngase en contacto con su representante de Hamilton Medical o el personal del servicio técnico.

## 1.1 Susceptibilidad electromagnética

**⚠ ADVERTENCIA**

- **MR UNSAFE**. Mantener alejado de equipos de resonancia magnética (RM). El HAMILTON-H900 supone riesgos inaceptables para el paciente, el personal médico u otras personas que se encuentren en el entorno de RM.
- El funcionamiento del humidificador puede verse alterado por equipos quirúrgicos de alta frecuencia, microondas, ondas cortas o campos magnéticos intensos que operen cerca de este.
- Para evitar que aumenten las emisiones, disminuya la inmunidad o se interrumpa el funcionamiento del humidificador HAMILTON-H900 o de cualquier accesorio, utilice solamente los accesorios y los cables indicados expresamente en este manual o en el catálogo electrónico en línea de Hamilton Medical.
- Los equipos adicionales conectados a los equipos electromédicos deben cumplir las normas CEI o ISO pertinentes (por ejemplo, CEI 60950 para el equipo de tratamiento de datos). Además, todas las configuraciones deben cumplir los requisitos establecidos para los sistemas electromédicos (consulte la norma CEI 60601-1, cláusula 16).
- Cualquier persona que conecte un equipo adicional a un equipo electromédico está configurando un sistema médico y, por lo tanto, es responsable de que este cumpla los requisitos de los sistemas electromédicos. Tenga en cuenta que las normativas locales tienen prioridad con respecto a los requisitos mencionados anteriormente. Si tiene dudas sobre la manera de proceder, consulte con el representante de Hamilton Medical o el departamento de servicio técnico.
- El humidificador *no* está protegido contra los efectos de la descarga de un desfibrilador cardiaco.

***AVISO***

- Es necesario tomar medidas de precaución especiales respecto a la compatibilidad electromagnética del humidificador HAMILTON-H900, que debe instalarse y ponerse en servicio conforme a la información de CEM que se indica en las *Declaraciones de compatibilidad electromagnética del HAMILTON-H900*.
- Los equipos de comunicaciones de radiofrecuencia portátiles y móviles pueden afectar al humidificador HAMILTON-H900.

## 1.2 Alimentación eléctrica

**⚠ ADVERTENCIA**

- Para reducir a un mínimo el riesgo de descarga eléctrica, conecte el cable de alimentación del humidificador a una toma adecuada con toma de tierra. Es responsabilidad del hospital garantizar que la toma de corriente está correctamente conectada a tierra.
- *No* lo utilice si el cable de alimentación está dañado.
- En caso de tensión incorrecta, fallo de alimentación o desconexión de la fuente de alimentación, el humidificador emite un pitido. Apague el dispositivo inmediatamente y compruebe si la tensión es correcta.
- Asegúrese de que se utiliza la tensión de alimentación correcta.

## 1.3 Riesgo de incendio y otros peligros

**⚠ ADVERTENCIA**

*No* utilice el humidificador en zonas peligrosas ni con gases inflamables.

## 1.4 Ajustes y funcionamiento generales

**⚠ ADVERTENCIA**

- Antes de utilizar el humidificador con el paciente, compruebe que el circuito respiratorio está conectado correctamente con el respirador, como sigue:

  – La rama inspiratoria azul está conectada con el puerto inspiratorio *hacia el paciente*.

  – La rama espiratoria blanca está conectada con el puerto espiratorio *desde el paciente*.
- Utilice solo las piezas y los accesorios que se especifican en el apartado 8. De este modo, se garantizará un funcionamiento correcto del humidificador y se evitarán posibles lesiones al paciente.
- No use el humidificador a una altitud superior a los 4000 metros ni fuera del rango de temperatura de 10 °C a 40 °C. Si utiliza el humidificador a una altitud superior o fuera de este rango de temperatura, la calidad del tratamiento podría verse afectada o el paciente podría sufrir lesiones.
- Un ajuste incorrecto de la humidificación o la temperatura puede provocar daños al paciente.
- *No* utilice el humidificador durante el transporte extrahospitalario de un paciente con respiración asistida.
- Encienda el humidificador *después* de encender el respirador.
- Apague el humidificador *antes* de apagar el respirador.
- No cubra las celdas de medición IR del humidificador.
- El modo invasivo (INV) *solo* debe utilizarse en pacientes intubados o traqueotomizados.
- En caso de reacción alérgica, tome medidas de precaución adicionales.
- Compruebe habitualmente el circuito respiratorio para verificar si existe condensación y, en caso necesario, séquelo.
- El uso simultáneo de un nebulizador puede afectar de manera negativa a la humidificación del dispositivo.
- *No* toque la placa calefactora ni la parte inferior de la cámara de agua.

Estas superficies pueden alcanzar temperaturas superiores a 85 °C e irradian calor.

**⚠ PRECAUCIÓN**

- *Coloque el humidificador en un lugar que permita fácilmente la desconexión de la fuente de alimentación principal.*
- *Utilice solo las piezas y los accesorios que se especifican en el apartado 8 y en el catálogo electrónico en línea de Hamilton Medical, o aquellos que se identifiquen como compatibles con este humidificador.*

  *De este modo, se garantiza un funcionamiento correcto de la humidificación, se evita una reducción del rendimiento y se mantiene la vigencia de la garantía.*
- *Si se apaga y se enciende el humidificador, este se iniciará automáticamente en modo invasivo (**INV**) a menos que se configure de otro modo.*
- *Compruebe si el equipo respiratorio presenta daños antes de utilizarlo. En caso de visualizar algún daño, deseche el equipo respiratorio.*
- *El elemento calefactor del humidificador y los cables calefactores se encienden de manera automática cuando se monta correctamente la cámara de agua y los circuitos respiratorios y se enciende el humidificador o este se encuentra en **Standby**.*
- *Si la temperatura ambiente o la temperatura del gas de entrada o bien el flujo se encuentran fuera del intervalo recomendado, pueden no alcanzarse los niveles de humedad fisiológica.*
- *El humidificador puede seguir recibiendo alimentación, aunque la pantalla no esté iluminada. Consulte la tabla 1.*

***AVISO***

- Antes de utilizar el equipo respiratorio en un paciente, debe realizar una prueba de estanqueidad. En caso de fallo, puede repetirse una vez. Si la prueba falla dos veces, debe cambiarse el equipo respiratorio por uno nuevo.
- La formación de una condensación fina con la respiración (empañamiento) en la rama, tubo flexible o sensor de flujo indica que el ajuste de humedad es el adecuado.
- Todas las acciones generan un pitido.

## 1.5 Circuitos respiratorios y cámara de agua

**⚠ ADVERTENCIA**

- Si el circuito respiratorio no se conecta correctamente con el respiratorio, el paciente puede resultar herido.
- Para evitar una desconexión accidental del circuito respiratorio durante el uso o el transporte, utilice únicamente circuitos respiratorios que cumplan las normas ISO 5367 o ISO 80601-2-74.
- La cámara de agua solo debe llenarse con agua estéril y desmineralizada que cumpla los requisitos de higiene del hospital.
- No incline la cámara de agua.
- No rellene la cámara del humidificador con ningún fármaco.
- Asegúrese de que el nivel de agua no supere el nivel de llenado máximo.

**AVISO**

- Si el humidificador no detecta el circuito respiratorio, sustituya los componentes.
- El agua de recarga no debe superar los 37 °C.
- Asegúrese de que el suministro de agua de la cámara funciona correctamente.
- Asegúrese de que el humidificador está en modo **Standby** antes de desconectar los componentes.

## 1.6 Colocación del humidificador y el circuito respiratorio

**⚠ ADVERTENCIA**

- El humidificador *siempre* debe colocarse por debajo del nivel del paciente.
- El humidificador *no* debe funcionar en un ángulo superior a 10° con el suelo.
- Asegúrese de que no se produzcan dobleces ni tensión en el circuito respiratorio al conectarlo del humidificador al paciente.
- Las ramas respiratorias con calefacción *no* deben colocarse directamente sobre la piel del paciente.
- Si el humidificador se utiliza cerca de otros equipos electromédicos o apilado sobre ellos, compruebe que este funciona correctamente en la configuración en la que se va a utilizar.
- Coloque el circuito respiratorio de forma que la condensación de fluidos no pueda llegar al paciente.
- Conecte los circuitos respiratorios o los soportes de los tubos correctamente para evitar que se produzcan fuerzas mecánicas en el tubo ET.

**AVISO**

- Compruebe la fijación de todas las conexiones antes de utilizar el dispositivo.
- Todos los conectores de las ramas del humidificador combinan conexiones eléctricas con conectores del circuito respiratorio. Asegúrese de que orienta correctamente los contactos eléctricos de manera que coincidan con el elemento de conexión del humidificador.

## 1.7 Monitorización y alarmas

**AVISO**

- Cuando hay una alarma activa, la pantalla alterna la visualización de los símbolos de la alarma activa y la temperatura actual de la salida de la cámara.
- Al apagar el humidificador, el volumen de la alarma vuelve al valor predeterminado de 5.
- Todas las alarmas de fallo técnico, la información técnica detallada y los procedimientos de mantenimiento se describen en el *manual de servicio técnico de HAMILTON-H900*.

## 1.8 Mantenimiento

**⚠ ADVERTENCIA**

- *No* se permite realizar modificaciones en el humidificador.
- Para reducir el riesgo de descarga eléctrica, desconecte *siempre* el humidificador de la red de alimentación antes de limpiarlo y desinfectarlo.

**⚠ PRECAUCIÓN**

- *Manipule los circuitos respiratorios y las cámaras de agua usados como productos contaminados según la normativa y legislación locales o los procedimientos internos del hospital.*
- *Para garantizar un servicio adecuado de reparación y evitar la posibilidad de daños físicos, únicamente el personal autorizado de Hamilton Medical podrá proporcionar servicio técnico al humidificador siguiendo las instrucciones del manual de servicio técnico de HAMILTON-H900.*
- *Utilice únicamente las piezas de repuesto que suministra Hamilton Medical.*
- *No intente realizar procedimientos de servicio técnico distintos de los especificados en el manual de servicio técnico de HAMILTON-H900.*
- *Utilice únicamente productos de limpieza aprobados para la limpieza y desinfección.*

***AVISO***

- Si desea información específica sobre la limpieza, la desinfección y la esterilización en autoclave de accesorios y componentes (reutilizables), consulte la *guía de reprocesamiento* y las *instrucciones de uso* que se suministran con cada componente.
- (*Solo en EE. UU.*) Utilice únicamente productos de limpieza aprobados con registro EPA para la limpieza y desinfección.

# 2 Visión general

En esta guía, se proporciona información sobre la instalación y el uso del humidificador HAMILTON-H900.

El humidificador está diseñado para utilizarse con respiradores de Hamilton Medical y de terceros.

## 2.1 Acerca del humidificador HAMILTON-H900

El humidificador HAMILTON-H900 calienta y humidifica los gases respiratorios para pacientes adultos, pediátricos y neonatos.

Admite los siguientes modos respiratorios comunes:

- Ventilación invasiva
- Ventilación no invasiva
- Terapia con flujo alto de oxígeno

El sistema consta de una carcasa, pantalla, controles, cámara de agua, placa calefactora y conexiones eléctricas del humidificador para un circuito respiratorio con calefacción.

Ofrece las siguientes características principales:

- Controles de humedad y temperatura regulables
- Opciones de monitorización y alarma
- Integración de los datos y controles monitorizados del humidificador con respiradores compatibles de Hamilton Medical[37]

[37] No disponible en todos los mercados.

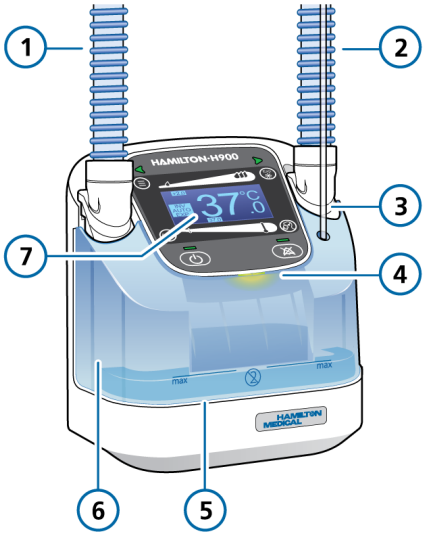
## 2.2 Descripciones físicas

En este apartado, se proporciona una descripción general del humidificador y los equipos respiratorios relacionados.

### 2.2.1 Acerca del humidificador

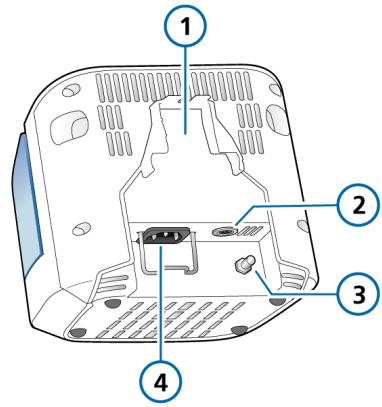
Las figuras 1 y 5 proporcionan una visión general del humidificador.

Figura 1. Humidificador HAMILTON-H900, vista frontal




| | | | |
|---|---|---|---|
| 1 | Rama inspiratoria del respirador (azul) | 5 | Placa calefactora |
| 2 | Rama inspiratoria del paciente (azul) | 6 | Cámara de agua |
| 3 | Vía de suministro de agua | 7 | Pantalla y panel frontal |
| 4 | Indicador visual de alarmas | | |

Figura 2. Humidificador HAMILTON-H900, vista posterior




| | | | |
|---|---|---|---|
| 1 | Ranura del soporte de montaje | 3 | Terminal de ecualización de potencial |
| 2 | Puerto RS-232 | 4 | Toma de corriente alterna |

### 2.2.2 Acerca de la pantalla principal

Puede acceder directamente a todos los ajustes, modos, alarmas y controles desde la pantalla principal durante la humidificación.

Las figuras 3–5 ilustran los controles del panel frontal, los indicadores y la pantalla.

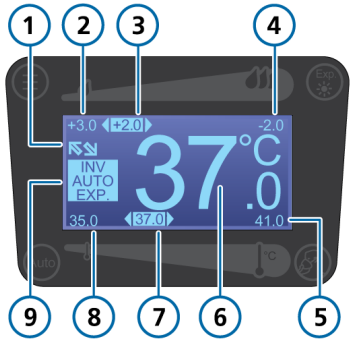
Figura 3. Humidificador HAMILTON-H900, controles del panel frontal


| | | | |
|---|---|---|---|
| 1 | Botón de ventana de monitorización de temp. | 5 | Tecla Pausar sonido |
| 2 | Controles deslizantes de temp. | 6 | Tecla Encendido/ Standby |
| 3 | Botón Aumento Temp. Esp. | 7 | Botón Auto |
| 4 | Botón de modos INV/NIV/HiFlow | 8 | Pantalla (consulte la figura 5) |

Figura 4. Humidificador HAMILTON-H900, indicadores de estado del panel frontal


| | | | |
|---|---|---|---|
| 1 | Indicadores estado de conexión de ramas | 3 | Indicador estado Encendido/ Standby |
| 2 | Indicador Pausar sonido | | |

Figura 5. Humidificador HAMILTON-H900, pantalla




1 Conexión respirador activada
2 Ajuste gradiente de temp. máx.
3 Ajuste gradiente temp.
4 Ajuste gradiente de temp. mín.
5 Ajuste temp. de salida mín. de cámara
6 Temp. actual en salida de cámara
7 Ajuste temp. en salida de cámara
8 Ajuste temp. salida mín. de cámara
9 Modos/ajustes activos

*Todos los elementos de la pantalla se muestran únicamente por motivos aclaratorios; durante el funcionamiento, puede que no aparezcan todos al mismo tiempo.*

### 2.2.3 Acerca de los circuitos respiratorios del humidificador

El humidificador HAMILTON-H900 es compatible con diversos circuitos respiratorios de una o dos ramas para pacientes adultos, pediátricos y neonatos.

Si desea información detallada, consulte las *instrucciones de uso* del circuito respiratorio.

### 2.2.4 Acerca de los indicadores de estado del humidificador

Los indicadores de la parte delantera del humidificador muestran información importante sobre el estado del humidificador. Consulte la figura 4.

Tabla 1. Indicadores de estado

| Símbolo | Descripción |
|---|---|
| **Tecla Encendido/Standby con indicador de estado** | |
|  | *verde*: el humidificador está en funcionamiento. |
|  | *naranja*: el humidificador está en modo **Standby**. |
|  | *azul*: el humidificador está apagado y conectado a una fuente de alimentación. |
|  | *apagado*: el humidificador está apagado y *sin* conexión a ninguna fuente de alimentación. |
| **Indicador de estado de conexión de las ramas** | |
|  | *verde*: la rama está conectada correctamente. |
|  | *naranja*: el humidificador está probando la conexión de la rama. |
|  | *rojo*: la conexión de la rama está defectuosa o la rama no está conectada. |
| **Tecla de pausa de sonido con indicador** | |
|  | *rojo*: la pausa de audio está activa. |

## 2.3 Desplazamiento por las ventanas y los controles

En este apartado se describe cómo utilizar los botones y controles deslizantes del humidificador.

### 2.3.1 Uso de los botones de control

Los botones del panel frontal (figura 3) le permiten seleccionar los modos, cambiar los ajustes y ver una descripción general de los ajustes de temperatura claves.

Tabla 2. Botones de control (consulte la figura 3)

| Botón | Descripción |
|---|---|
|  | **Aumento temperatura espiratoria**<br>Aumenta la temperatura en la rama espiratoria. |
|  | **Auto**<br>Activa el modo Auto.<br>Consulte el apartado 4.2.2. |
|  | **Modos de funcionamiento INV/NIV/HiFlow**<br>Alterna entre los modos INV, NIV y HiFlow.<br>Consulte el apartado 4.2. |
|  | **Ventana de monitorización de la temperatura**<br>Muestra la temperatura actual en la pieza en Y, la temperatura en la salida de la cámara y los valores del gradiente de temperatura.<br>Consulte el apartado 4.4. |

### 2.3.2 Uso de los controles deslizantes

En modo manual, puede cambiar los ajustes de temperatura mediante los controles deslizantes (figura 3).

Tabla 3. Controles deslizantes de temperatura

| Control deslizante | Descripción |
|---|---|
| **Control deslizante del gradiente de temperatura** | |
|  | Ajusta la diferencia de temperatura entre la salida de la cámara y la pieza en Y.<br>Consulte el apartado 4.3. |
| **Control deslizante de temperatura en la salida de la cámara** | |
|  | Ajusta la temperatura en la salida de la cámara.<br>Consulte el apartado 4.3. |

# 3 Preparación del humidificador para su uso

*Antes de continuar, revise la información de seguridad en el apartado 1.*

Los preparativos del humidificador para su uso constan de los siguientes pasos:

- Configuración puntual de los ajustes realizada por un técnico en medicina (consulte la tabla 4)
- Tareas de configuración del humidificador para cada nuevo paciente llevadas a cabo por los profesionales sanitarios (consulte la tabla 5)

Tabla 4. Configuración e instalación realizadas por un técnico en medicina

| Para... | Consulte... |
|---|---|
| *Estas tareas de configuración inicial solo son necesarias una vez y las realiza el servicio técnico.* | |
| Montar y colocar el humidificador | Consulte la *guía de instalación* correspondiente del respirador o carro |
| Configurar los ajustes del humidificador | Apartado 7 |
| *Opcional*: Conectar el humidificador al puerto RS-232 COM de cualquier respirador compatible de Hamilton Medical | Consulte el *manual del operador* correspondiente del respirador. |

Tabla 5. Configuración e instalación realizadas por profesionales sanitarios

| Para... | Consulte... |
|---|---|
| *Las siguientes tareas las realiza el personal médico al cuidado de los pacientes.* | |
| Conectar a la fuente de alimentación | Apartado 3.1 |
| Conexión del circuito respiratorio | Apartado 3.2 |
| Encender el humidificador | Apartado 3.3 |
| Probar las alarmas | Apartado 3.4 |
| Especificar los ajustes del humidificador | Apartado 3.5 |
| Conectar al paciente | Apartado 3.6 |

## 3.1 Conexión a la fuente de alimentación

Compruebe siempre la fiabilidad de la toma de alimentación principal antes de enchufar el humidificador y el respirador.

### Para conectar el humidificador a una fuente de alimentación

- Conecte el humidificador a una toma eléctrica que suministre energía de CA.[38]

## 3.2 Conexión del circuito respiratorio al humidificador

Hamilton Medical ofrece diversos circuitos respiratorios para pacientes adultos, pediátricos y neonatos.

Si desea información detallada, consulte las *instrucciones de uso* específicas del circuito respiratorio.

## 3.3 Encendido y apagado del humidificador

Al encender el humidificador, se pone en funcionamiento automáticamente en el modo configurado de forma predeterminada.

Asegúrese de encender el respirador *antes* de encender el humidificador.

### Para encender el humidificador

- Mantenga pulsado  (**Encendido/Standby**) durante 3 segundos aproximadamente.

[38] Si utiliza el humidificador con un respirador compatible de Hamilton Medical, conecte el cable de alimentación del humidificador a la toma de corriente pertinente del respirador.

El humidificador realizará una autocomprobación. Una vez terminada, el humidificador se iniciará automáticamente en modo invasivo (**INV**) a menos que se configure de otro modo.

**Para apagar el humidificador**

- Mantenga pulsado  durante 3 segundos aproximadamente.

Asegúrese de apagar el humidificador *antes* de apagar el respirador.

## 3.4 Comprobación de las alarmas

Antes de conectar un paciente nuevo al humidificador, compruebe que las alarmas funcionan correctamente.

Asegúrese de que el humidificador está encendido.

**Para probar las alarmas del humidificador**

1. Genere una alarma extrayendo la cámara de agua del humidificador.
2. Compruebe que:
   – se oye una alarma
   – el indicador visual de alarma se ilumina de manera intermitente (figura 4)
   – aparece el símbolo de alarma correspondiente en la pantalla (tabla 9)

Resuelva la condición de alarma volviendo a insertar la cámara de agua en el humidificador y compruebe que la alarma se restablece.

## 3.5 Especificación de los ajustes del humidificador

Seleccione el modo de humidificación para su paciente.[39] Si desea más información, consulte el apartado 4.2.

## 3.6 Conexión del paciente

Conecte el circuito respiratorio a la interfaz adecuada del paciente.

Ahora el humidificador está instalado y listo para su uso.

# 4 Trabajo con el humidificador HAMILTON-H900

Tabla 6. Visión general del funcionamiento

| Si desea más información sobre... | Consulte... |
|---|---|
| Encendido y apagado del humidificador | Apartado 3.3 |
| Entrada y salida del modo **Standby** | Apartado 4.1 |
| Acceso a los controles del humidificador | Apartado 2.3 |
| Modos de funcionamiento del humidificador: **INV**, **NIV**, **HiFlow** | Apartado 4.2 |
| Ajustes **Auto** y **Manual** | Apartado 4.2.2 |
| Cambio de la humedad usando controles de temperatura | Apartado 4.3 |
| Parámetros monitorizados del humidificador | Apartado 4.4 |
| Alarmas del humidificador | Apartado 5 |

[39] Cuando se utiliza con un respirador de Hamilton Medical que admite el funcionamiento integrado, el modo de funcionamiento del humidificador coincide con el del respirador. Si desea más información, consulte el *manual del operador* del respirador.

## 4.1 Entrada y salida del modo Standby

**⚠ PRECAUCIÓN**

*En **Standby**, todos los ajustes se mantienen y la emisión de calor se reduce.*

**Standby** es un modo de espera que permite mantener los ajustes actuales mientras el humidificador no esté en funcionamiento.

Cuando está en modo **Standby**, los ajustes para la **temperatura en la salida de la cámara** y el **gradiente de temperatura** disminuyen.[40] Si desea más información, consulte el apartado 9.7.

### Para que el humidificador pase a modo Standby

- Pulse brevemente  (**Encendido/Standby**).

  En el modo **Standby**, la pantalla muestra el tiempo transcurrido con el humidificador en este modo. La luz del indicador **Encendido/Standby** es de color naranja.

### Para finalizar el modo Standby e iniciar la ventilación

- Pulse  .

  El humidificador reanuda su funcionamiento normal; la luz del indicador de estado **Encendido/Standby** es de color verde.

## 4.2 Acerca de los modos de funcionamiento del humidificador

El HAMILTON-H900 ofrece los siguientes modos de funcionamiento: invasivo (**INV**), no invasivo (**NIV**) y terapia con flujo alto de oxígeno (**HiFlow**).

La selección del modo de funcionamiento determina los ajustes de temperatura iniciales, tanto en la salida de la cámara de agua (**temperatura en la salida de la cámara**) como en la pieza en Y (**gradiente de temperatura**), y en los rangos de temperatura permitidos para cada uno de estos controles.

Estos rangos de temperatura difieren por grupo de pacientes. Consulte la tabla 18.

### 4.2.1 Cambio de los modos

El humidificador arranca automáticamente en modo invasivo (**INV**), a menos que se configure de otro modo en los ajustes personalizados de los valores predeterminados.

Al cambiar al modo invasivo (**INV**) o no invasivo (**NIV**), el humidificador establece automáticamente los ajustes de control en **Auto**.

### Para cambiar los modos

- Pulse  (**Modos**) hasta que aparezca el modo deseado (**INV, NIV o HiFlow**).

  El modo seleccionado aparece en la pantalla.

[40] Durante la nebulización, el **gradiente de temperatura** *no* cambia en modo **Standby**.

Figura 6. Modo INV (**1**) seleccionado

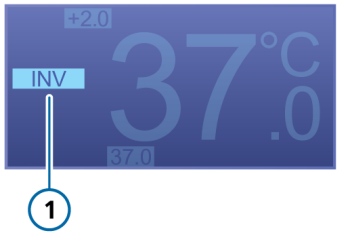



Figura 7. Modo NIV (**1**) seleccionado

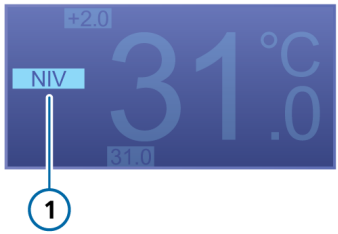
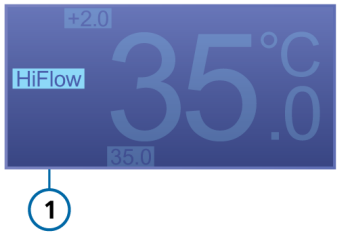



Figura 8. Modo HiFlow (**1**) seleccionado




### 4.2.2 Ajustes de control Auto y Manual

Puede utilizar el humidificador en modo **Auto**, o bien puede ajustar la configuración manualmente. De forma predeterminada, el humidificador empieza en modo **Auto**.

Los ajustes para la **temperatura en la salida de la cámara** y el **gradiente de temperatura** se establecen utilizando cualquier de los métodos siguientes:

- Carga desde los ajustes predeterminados configurados (modo **Auto**)
- Ajustado manualmente por el usuario

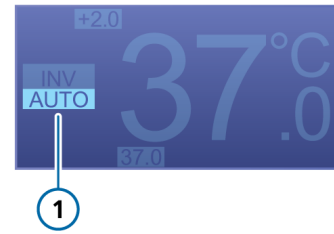
#### Ajuste automático (Auto)

Cuando se configura en **Auto**, el humidificador carga los ajustes configurados de forma predeterminada para el modo seleccionado (consulte el apartado 7) y los usa para controlar la temperatura del gas.

A temperaturas ambiente bajas, el humidificador puede ajustar automáticamente la temperatura de la cámara de agua.

Al seleccionar el modo **Auto**, aparece el texto **AUTO** en la pantalla principal.

Figura 9. Modo Auto (**1**) seleccionado

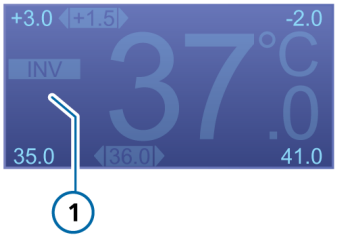



#### Ajustes manuales

Al cambiar la **temperatura en la salida de la cámara** o el **gradiente de temperatura** mediante los controles deslizantes, el humidificador cambia al modo **Manual**. Sin embargo, continúa controlando automáticamente la temperatura para alcanzar los ajustes especificados.

Cuando los ajustes se cambian manualmente, el modo **Auto** deja de aparecer en la pantalla principal; el espacio está vacío.

Figura 10. El modo Manual (**1**) se aplica




### 4.2.2.1 Activación del modo Auto

Después de cambiar manualmente cualquiera de los ajustes de temperatura, puede volver a activar el modo **Auto**.

**Para volver a activar el modo Auto**

- Pulse Auto (**Auto**).

  Cambiar el modo de funcionamiento a **INV** o **NIV** también cambia automáticamente el humidificador al modo **Auto**.

## 4.3 Cambio de la humedad usando controles de temperatura

***AVISO***

Si el humidificador está en modo **Auto**, arrastrar cualquier control deslizante cambia la humidificación al modo **Manual**.

***AVISO***

En el modo **HiFlow**, no puede cambiar el **gradiente de temperatura** mediante el control deslizante. Puede cambiar el valor del **gradiente de temperatura** en la **configuración**. Consulte el apartado 7.

Ajuste los siguientes controles en el humidificador[41]:

Tabla 7. Controles del humidificador ajustables

| Control | Descripción |
|---|---|
| Temperatura en la salida de la cámara | La temperatura en la salida de la cámara de agua.<br>El intervalo de valores posibles para este control depende del modo de funcionamiento seleccionado del humidificador. Si desea más información, consulte las tablas 16 y 18.<br>Los valores más altos dan como resultado un valor absoluto de humedad superior. |
| Gradiente de temperatura | La diferencia entre la temperatura en la salida de la cámara de agua y en la pieza en Y. |
| Aumento Temp. Esp. | El humidificador proporciona calor adicional en la rama espiratoria cuando se selecciona.[42] |

La temperatura máxima permitida de la pieza en Y del paciente es 42 °C. La combinación de los valores de la **temperatura en la salida de la cámara** y el **gradiente de temperatura** no puede superar este límite. Por ejemplo, si el **gradiente de temperatura** se define en 2 °C, el mayor ajuste posible para la **temperatura en la salida de la cámara** será 40 °C.

Además, el ajuste del **gradiente de temperatura** tiene prioridad con respecto al ajuste de la **temperatura en la salida de la cámara**. Esto quiere decir que, si se produce una combinación de ajustes en los que la temperatura de la pieza en Y es

[41] Si se usa con un respirador de Hamilton Medical compatible con el control integrado del humidificador, podrá modificar los ajustes directamente en el respirador. Si desea más información, consulte el *manual del operador* del respirador.
[42] Solo circuitos respiratorios de un solo uso con calefacción en las dos ramas.

superior a 42 °C, el ajuste del **gradiente de temperatura** no se modificará, pero sí se ajustará el valor de la **temperatura en la salida de la cámara**.

Por ejemplo, si la **temperatura en la salida de la cámara** se define como 40 °C, puede ajustar el **gradiente de temperatura** a 3 °C aunque la combinación supere los 42 °C. Una vez que se acepte el ajuste del **gradiente de temperatura**, el valor de la **temperatura en la salida de la cámara** se ajustará automáticamente a 39 °C.

### Para definir la temperatura en la salida de la cámara

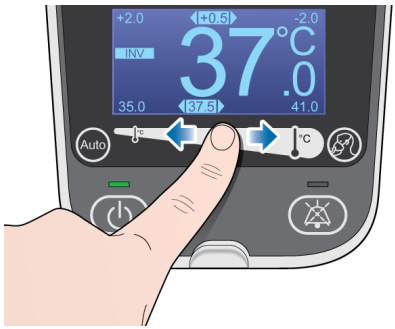
- Toque el control deslizante de la **temperatura en la salida de la cámara** en el ajuste actual:

  – Arrastre a la izquierda para reducir la temperatura en la salida de la cámara

  – Arrastre a la derecha para aumentar la temperatura en la salida de la cámara

Los cambios se confirman mediante un pitido y se aplican de forma inmediata.

Figura 11. Ajuste de la temperatura en la salida de la cámara




### Para definir una temperatura en la salida de la cámara >39 °C

Para aumentar la **temperatura en la salida de la cámara** por encima de 39 °C, hay que activar dos veces el control deslizante.

1. Toque el control deslizante de la **temperatura en la salida de la cámara** en el ajuste actual y arrástrelo a la derecha para alcanzar el límite de 39 °C.
2. Toque y arrastre de nuevo el control deslizante para definir la temperatura en la salida de la cámara por encima de 39 °C.

### Para definir el gradiente de temperatura establecido

- Toque el control deslizante del **gradiente de temperatura** en el ajuste actual:

  – Arrastre a la derecha para reducir el gradiente de temperatura

  – Arrastre a la izquierda para aumentar el gradiente de temperatura

Los cambios se confirman mediante un pitido y se aplican de forma inmediata.

Figura 12. Ajustar el gradiente de temperatura


Por ejemplo, si la temperatura de la pieza en Y objetivo es de 39 °C y la **temperatura en la salida de la cámara** se define como 37 °C, defina el **gradiente de temperatura** como 2 °C.

## 4.4 Monitorización de la humidificación

Los datos de monitorización están disponibles en la ventana de **monitorización de la temperatura**, a la que se puede acceder en cualquier momento.[43]

Se monitorizan los parámetros siguientes:

- Temperatura en la salida de la cámara
- Gradiente de temperatura
- Temperatura en la pieza en Y

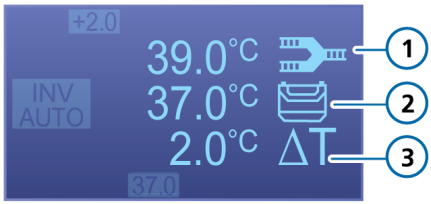
### 4.4.1 Visualización de parámetros de monitorización adicionales

**Para mostrar la ventana de monitorización de la temperatura**

- Pulse (Ventana de monitorización de la temperatura).

  La ventana se cierra una vez transcurridos 30 segundos o al pulsar el botón de nuevo.

Figura 13. Ventana de monitorización de la temperatura




| | | | |
|---|---|---|---|
| 1 | Temp. actual pieza en Y | 3 | Gradiente temp. actual |
| 2 | Temp. actual en salida de cámara | | |

## 4.5 Ajustes de brillo de pantalla día y noche

La retroiluminación de la pantalla del humidificador acepta dos ajustes de visualización diferentes. Utilice estos ajustes para definir el brillo de la pantalla.

**Para alternar entre los ajustes de día y noche**

- Mantenga pulsado durante 5 segundos.

Para establecer el brillo predeterminado de día y noche, consulte el apartado 7.

# 5 Respuesta ante alarmas del humidificador

Las alarmas del humidificador informan sobre estados que requieren su atención. Las alarmas se muestran de la siguiente forma:

- Gráficamente, en la pantalla del humidificador
- Mediante una secuencia de 3 o 5 pitidos
- La señal luminosa de alarma sobre la cámara de agua parpadea
- Si se usa con un respirador de Hamilton Medical compatible con la monitorización integrada del humidificador, los mensajes de alarma también se mostrarán en la pantalla del respirador.[44]

Las alarmas se clasifican como de prioridad alta, prioridad media o alarma general, tal y como se describe en la tabla 8.

[43] Si se usa con un respirador de Hamilton Medical compatible con la monitorización integrada del humidificador, los datos del humidificador se mostrarán en la pantalla del respirador. Si desea más información, consulte el *manual del operador* del respirador.
[44] No disponible en todos los respiradores. Consulte el *manual del operador* del respirador.

Consulte la tabla 9 para ver una lista completa de las alarmas.

Tabla 8. Indicadores de alarmas

| Tipo de alarma | Indicador de estado de alarma | Sonido | Acción necesaria |
|---|---|---|---|
| Prioridad alta | Roja intermitente<br>El icono de alarma se muestra en la pantalla. | Se repite una secuencia de 5 pitidos hasta que se restablece la alarma. | El humidificador requiere atención inmediata. |
| Prioridad media | Amarilla intermitente<br>El icono de alarma se muestra en la pantalla. | Se repite una secuencia de 3 pitidos hasta que se restablece la alarma. | El humidificador requiere atención rápida. |
| Alarma general | Roja intermitente<br>En la pantalla aparece un número de fallo técnico (TF). | Se repite una secuencia de 3 pitidos hasta que se restablece la alarma. | • Registre el número de alarma general (TF)[45].<br>• Retire el humidificador del uso clínico.<br>• Póngase en contacto con el servicio técnico. |

[45] En el *manual de servicio técnico de HAMILTON-H900*, figura una lista de todas las alarmas generales (TF).

## 5.1 Silencio temporal de una alarma

Un componente de una alarma es el sonido audible. En la mayoría de las alarmas se puede hacer una pausa en el sonido (silenciarla) durante dos minutos cada vez.

### Para silenciar una alarma temporalmente

- Pulse  (**Pausar sonido**) en la parte frontal del humidificador.

  La alarma acústica del humidificador se silencia durante dos minutos.

  Al pulsar la tecla de nuevo, se cancela la **pausa de sonido**.

La retroiluminación de la opción **Pausar sonido** se ilumina continuamente en rojo cuando la **pausa de sonido** está activada.

Si el tiempo termina y el problema no se ha resuelto, la alarma suena de nuevo.

## 5.2 Ajuste del volumen de la alarma

**⚠ ADVERTENCIA**

Asegúrese de fijar el volumen de las alarmas acústicas por encima del volumen del ruido del entorno. De lo contrario, no oirá ni reconocerá los estados de alarma.

El volumen de la alarma acústica se puede definir.

El volumen se fija de manera predeterminada en 5. Al apagar el humidificador, el volumen de la alarma se restablece al valor predeterminado.

### Para ajustar el volumen de las alarmas

1. Si lo necesita, pulse  (**Encendido/Standby**) para poner el humidificador en modo **Standby**.
2. Pulse  durante 3 segundos.

   En la pantalla aparecerá el ajuste del volumen actual de las alarmas.
3. Ajuste el volumen de la alarma mediante el control deslizante de la **temperatura en la salida de la cámara** (consulte la figura 3).

   El humidificador confirmará su selección mediante un pitido con el nuevo ajuste de volumen.
4. Pulse  para confirmar la selección y volver al funcionamiento normal.

## 5.3 Solución de problemas con las alarmas

En la tabla 9, se enumeran las alarmas del humidificador, su representación gráfica en el humidificador, una descripción y las medidas correctivas recomendadas.

Tabla 9. Alarmas de HAMILTON-H900

| Alarma | Icono de alarma | Descripción | Acción necesaria |
|---|---|---|---|
| **Prioridad alta** | | | |
| Humidificador inclinado |  | El humidificador tiene una inclinación peligrosa.<br>El humidificador está en un ángulo de 10° o más con respecto al suelo. | • Compruebe el montaje del humidificador.<br>• Compruebe el carro del respirador.<br>• Utilice el humidificador en un ángulo inferior a 10° con respecto al suelo. |
| Temperatura alta |  | La temperatura del gas en la salida de la cámara de agua o en la pieza en Y está por encima del valor establecido. | • Compruebe si el circuito respiratorio está cubierto con las mantas de la cama del paciente.<br>• Compruebe si el circuito respiratorio o la cámara de agua están expuestos a la luz solar directa.<br>• Cambie el circuito respiratorio. |
| Alarma de nivel de agua |  | El nivel de agua en la cámara de agua es superior a la marca de nivel máximo. | • Vacíe la cámara del humidificador para reducir el nivel del agua.<br>• Cambie la cámara del humidificador.<br>• Utilice el humidificador en un ángulo inferior a 10° con respecto al suelo. |
| Alarma general | En la pantalla aparece un número de fallo técnico (TF). | Alarma general debido a un fallo en el funcionamiento del humidificador. | • Verifique el funcionamiento del humidificador y todas las conexiones.<br>• Cambie el humidificador y póngase en contacto con el servicio técnico.<br>• Si se muestra un número de fallo técnico, anótelo y especifíqueselo al servicio técnico cuando vaya a reparar el humidificador. |

| Alarma | Icono de alarma | Descripción | Acción necesaria |
|---|---|---|---|
| **Prioridad media** | | | |
| Temperatura baja |  | La temperatura del gas en la salida de la cámara de agua o en la pieza en Y está por debajo del valor establecido. | • Espere hasta que el sistema se caliente por completo (aprox. 30 minutos).<br>• Compruebe si son correctos todos los ajustes.<br>• Evite que los flujos de aire, por ejemplo del aire acondicionado y similares, se dirijan directamente al humidificador y al circuito respiratorio. |
| Nivel de agua bajo |  | El nivel de agua en la cámara de agua es inferior a la marca de nivel mínimo. | • Compruebe la botella de agua y rellene el tubo.<br>• Si la botella de agua está vacía, conecte una nueva.<br>• Rellene o cambie la cámara del humidificador vacía.<br>• Utilice el humidificador en un ángulo inferior a 10° con respecto al suelo. |
| Comprobar cámara de agua |  | No hay cámara o se ha instalado una cámara de agua incompatible. | Inserte una cámara de agua nueva y conecte el circuito respiratorio. |

| Alarma | Icono de alarma | Descripción | Acción necesaria |
|---|---|---|---|
| Comprobar rama izquierda o derecha |  | La pantalla y los indicadores de conexión muestran qué rama está defectuosa.<br>• Sin rama o rama conectada defectuosa.<br>• Sin flujo de aire.<br>• Una rama no está correctamente conectada.<br>• La rama espiratoria BLANCA del humidificador está conectada al puerto inspiratorio *hacia el paciente* del respirador. | • Inserte o vuelva a colocar el circuito respiratorio correctamente.<br>• Cambie el circuito respiratorio.<br>• Conecte la rama inspiratoria AZUL del humidificador al puerto inspiratorio *hacia el paciente* del respirador.<br><br>Cuando el indicador de conexión se ilumina en:<br>*Verde*: significa que la rama está insertada correctamente<br>*Naranja*: significa que el humidificador está probando la conexión<br>*Rojo*: significa que la conexión es defectuosa o no existe |

# 6 Mantenimiento

*Antes de continuar, revise la información de seguridad en el apartado 1.*

Este apartado ofrece información sobre los procedimientos y los plazos de mantenimiento del humidificador, así como instrucciones para su limpieza y desinfección.

El operador debe realizar todos los procedimientos que se describen en este apartado.

Si desea conocer procedimientos de mantenimiento adicionales, póngase en contacto con el representante del servicio técnico de Hamilton Medical. Los documentos mencionados en este apartado están disponibles en el sitio web MyHamilton: https://www.hamilton-medical.com/MyHamilton

## 6.1 Limpieza, desinfección y esterilización

Los componentes del humidificador deben limpiarse y desinfectarse de forma periódica a través de los métodos y las soluciones de limpieza específicos para cada componente.

Es importante que seleccione el método y los materiales apropiados al limpiar y desinfectar el humidificador y sus componentes, no solo para evitar dañar el equipo, sino también para evitar la contaminación cruzada.

La información sobre limpieza y desinfección se presenta de la siguiente forma:

- En la tabla 10, se muestra una lista de los componentes relativos al humidificador y se indica qué métodos de limpieza y desinfección se pueden emplear para cada uno, la frecuencia con la que se deben limpiar/desinfectar los componentes, así como los agentes de limpieza y desinfección.
- Para obtener información sobre los equipos respiratorios y las cámaras de agua del humidificador, consulte las *instrucciones de uso* o la *guía de reprocesamiento*.

Al trabajar con los componentes del humidificador, así como al emplear los métodos y los agentes de limpieza correspondientes, tenga en cuenta lo siguiente:

- *No* realice ningún procedimiento de descontaminación que no haya recomendado Hamilton Medical.
- Aunque ofrecemos directrices sobre los agentes y las concentraciones, si tiene dudas específicas sobre el uso de un producto de limpieza o desinfectante en particular, póngase en contacto con el fabricante.

Tabla 10. Métodos de limpieza y desinfección del humidificador

| Pieza | Frecuencia | Método de limpieza/desinfección | Productos de limpieza |
|---|---|---|---|
| Humidificador exterior, incluidos estos elementos:<br>• Carcasa<br>• Pantalla<br>• Placa calefactora<br>• Cables de alimentación<br>• Sistemas de instalación | Tras su uso en cada paciente o según sea necesario. | Lavar con un paño humedecido con una solución de limpieza/desinfección aprobada y registrada. | Paños germicidas Super Sani-Cloth<br>CaviWipes |

## 6.2 Mantenimiento preventivo

El mantenimiento preventivo del humidificador debe realizarlo personal del servicio técnico autorizado de Hamilton Medical, que actuará de acuerdo con las instrucciones del *manual de servicio técnico de HAMILTON-H900*.

# 7 Configuración

El humidificador se entrega con una configuración predeterminada de diversos ajustes organizados por grupo de pacientes.

En el modo de **configuración**, puede modificar los ajustes predeterminados siguientes:

- **Temperatura en la salida de la cámara**
- **Gradiente de temperatura**
- Modo de funcionamiento inicial (**INV/NIV/HiFlow**)
- **Aumento de la temperatura espiratoria** (activado o desactivado)
- Ajustes de brillo de **Día/Noche** de la retroiluminación

## 7.1 Acceso al modo de configuración

Al modo de **configuración** se accede con el humidificador en **Standby**.

**Para acceder al modo de configuración**

1. Si lo necesita, pulse  para acceder a **Standby**.
2. Mantenga pulsadas las teclas  y  .

   Asegúrese de que pulsa la tecla  en primer lugar.

   Tras 5 segundos, aparece la ventana de **configuración**.

El humidificador se encuentra ahora en modo de **configuración**.

## 7.2 Cambio de los ajustes de configuración

Los ajustes personalizados se mantendrán hasta que los cambie o restablezca los ajustes de fábrica.

En el modo de **configuración**, los botones del panel frontal del humidificador se emplean para navegar entre las vistas y realizar selecciones.

En la tabla 11, se describe cómo echar un vistazo al modo de **configuración** y cómo cambiar los ajustes.

Para obtener un ejemplo de cómo cambiar un ajuste, consulte el procedimiento que se describe a continuación sobre el cambio de los ajustes predeterminados del **gradiente de temperatura**.

Para ver la lista de ajustes de configuración, consulte el apartado 9.6.

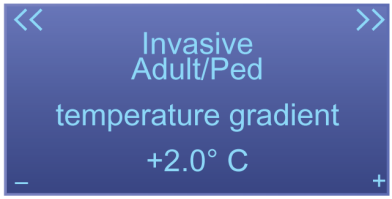
Tabla 11. Botones de navegación del modo de configuración

| Botón | Descripción |
|---|---|
|  | Desplazamiento hacia delante por las vistas |
|  | Desplazamiento hacia atrás por las vistas |
|  | Aumento de un valor |
|  | Reducción de un valor |
|  | Almacenamiento de los cambios y salida del modo de **configuración** |

**Ejemplo: cambio del gradiente de temperatura**

**Para cambiar el ajuste predeterminado del gradiente de temperatura en el modo invasivo, adulto/ped.**

1. En el modo de **configuración**, pulse Exp. hasta que visualice **Invasive, Adult/Ped, Temperature gradient**.




2. Pulse para aumentar el valor o pulse Auto para reducirlo.
3. Cuando haya finalizado, pulse para guardar los cambios y salir del modo de **configuración**.

## 7.3 Restauración de los ajustes predeterminados de fábrica

Puede restaurar los ajustes predeterminados de fábrica en cualquier momento.

**Para restaurar los ajustes predeterminados de fábrica**

1. En el modo de configuración, pulse varias veces Exp. hasta que aparezca la ventana **Reset all custom defaults**.
2. Pulse Auto.

Se restauran los ajustes predeterminados de fábrica.

# 8 Piezas y accesorios

En este apartado, se enumeran las piezas y accesorios disponibles para el humidificador HAMILTON-H900.

Para obtener información adicional, consulte el catálogo electrónico de Hamilton Medical en el sitio web de Hamilton Medical o póngase en contacto con el representante de Hamilton Medical.

Tabla 12. Piezas y accesorios del humidificador

| PN | Descripción |
|---|---|
| 260161 | HAMILTON-BC8022, equipo respiratorio de dos ramas con calefacción y cámara de agua |
| 260186 | HAMILTON-BC4022, equipo respiratorio de una rama, con calefacción y cámara de agua |
| 260185 | HAMILTON-BC8010, equipo respiratorio de dos ramas con calefacción, cámara de agua y ampliación de incubadora |
| 260187 | HAMILTON-BC4010, equipo respiratorio de una rama con calefacción, cámara de agua y ampliación de incubadora |
| 260196 | HAMILTON-HC322, cámara de agua, desechable |
| 260197 | HAMILTON-HC310, cámara de agua, desechable |

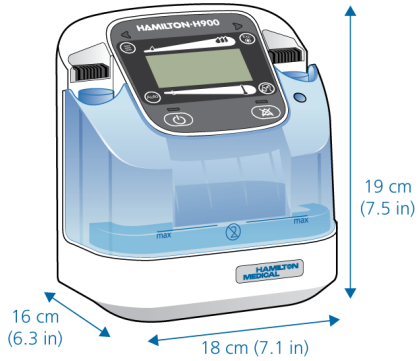
# 9 Especificaciones

## 9.1 Características físicas

Tabla 13. Características físicas

| Dimensiones | Especificaciones |
|---|---|
| Peso | Humidificador (con cámara de agua vacía): 2,5 kg |
| Dimensiones | Consulte la figura 14 |

Figura 14. Dimensiones del HAMILTON-H900



## 9.2 Requisitos medioambientales

Tabla 14. Requisitos medioambientales

| Entorno | | Especificaciones |
|---|---|---|
| Temperatura | Funcionamiento: | de 10 °C a 40 °C |
| | Almacenamiento: | de -20 °C a 60 °C |
| | | Temperatura ambiente recomendada: de 18 °C a 26 °C |
| Altitud | | Hasta 4000 m |
| Presión atmosférica | Funcionamiento y almacenamiento: | de 61 kPa a 106 kPa |
| Humedad relativa | Funcionamiento: | del 30 al 95%, sin condensación |
| | Almacenamiento: | del 10 al 95%, sin condensación |
| Protección contra el agua | | IP21 |
| Temperatura de entrada del gas | | de 18 °C a 31 °C (recomendado) |

## 9.3 Especificaciones eléctricas

Tabla 15. Especificaciones eléctricas

| Número de pieza | Alimentación de entrada | Consumo de energía |
|---|---|---|
| 950001 (230 V) | de 220 a 240 V<br>50/60 Hz | 283 VA |
| 950004 (115 V) | de 110 a 127 V<br>50/60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50/60 Hz | 268 VA |
| Ecualización de potencial | Terminal para la conexión de un conductor de ecualización de potencial de acuerdo con la norma DIN 42801 | |

## 9.4 Ajustes de control

Tabla 16. Ajustes de control e intervalos

| Parámetro o ajuste (unidades) | Modo | Intervalo | Valor predeterminado | Resolución |
|---|---|---|---|---|
| Temperatura en la salida de la cámara (°C) | INV | De 35 a 41 | 37,0 | 0,5 |
| | NIV | De 30 a 35 | 31,0 | 0,5 |
| | HiFlow | De 33 a 37 | 35,0 | 2 |
| Gradiente de temperatura (°C) | INV | De -2 a 3 | Adulto/Ped.: 2<br>Neonatal: 3 | 0,5 |
| | NIV | De -2 a 3 | Adulto/Ped.: 2<br>Neonatal: 3 | 0,5 |
| | HiFlow | -- | 2 | -- |
| Temperatura máxima de la vía aérea resultante (pieza en Y)[46] (°C) | INV | De 33 a 42 | -- | -- |
| | NIV | De 28 a 38 | -- | -- |
| | HiFlow | De 35 a 39 | -- | -- |
| Aumento de la temperatura espiratoria | Todos los modos | Encendido, apagado | Encendido | -- |
| Ajuste de brillo para la pantalla | Todos los modos | De 1 a 5 | Día: 5<br>Noche: 2 | 1 |

[46] La temperatura de la vía aérea está limitada por el humidificador a 42 °C.

## 9.5 Parámetros monitorizados

Tabla 17. Parámetros monitorizados, intervalos y precisión

| Parámetros (unidades) | Intervalo | Precisión |
|---|---|---|
| Temperatura en la salida de la cámara (°C) | De 10 a 60 | De 10 a 30: ± 1<br>De 30 a 41: ± 0,5<br>De 41 a 60: ± 1 |
| Temperatura en la pieza en Y (°C) | De 28 a 43 | ± 0,5 |

## 9.6 Configuración

Tabla 18. Especificación de configuración

| Parámetro | Modo | Intervalo de configuración | Ajuste predeterminado |
|---|---|---|---|
| Temperatura en la salida de la cámara (°C) | INV | De 35 a 39 | 37,0 |
| | NIV | De 30 a 35 | 31,0 |
| | HiFlow | 33, 35, 37 | 35,0 |
| Gradiente de temperatura (°C) | INV | De 0 a 3 | Adulto/Ped.: 2<br>Neonatal: 3 |
| | NIV | De 0 a 3 | Adulto/Ped.: 2<br>Neonatal: 3 |
| | HiFlow | De 0 a 3 | 2 |
| Modo inicial | -- | Invasivo, no invasivo, HiFlow | Invasivo |
| Ajuste de brillo para la pantalla | Todos los modos | De 1 a 5 | Día: 5<br>Noche: 2 |

## 9.7 Datos técnicos de rendimiento

Tabla 19. Datos técnicos de rendimiento

| Descripción | Especificación | | |
|---|---|---|---|
| Magnitudes de flujo[47] | Invasivo: | hasta 60 l/min | |
| | No invasivo: | hasta 120 l/min | |
| | HiFlow: | hasta 120 l/min | |
| Tiempo de calentamiento | Menos de 30 min | | |
| Humedad | A una temperatura ambiente de entre 18 y 26 °C: | | |
| | Invasivo: | Ajuste de temperatura de entre 37 y 41 °C | Humedad mínima: 33 mg H2O/l |
| | No invasivo: | Ajuste de temperatura de entre 31 y 35 °C | Humedad mínima: 12 mg H2O/l |
| | HiFlow: | Frecuencia de flujo ≤60 l/min | Humedad mínima: 33 mg H2O/l |
| | | Frecuencia de flujo >60 l/min | Humedad mínima: 12 mg H2O/l |
| Especificaciones de calentamiento en Standby | Circuitos respiratorios con calefacción: | Pieza en Y limitada a 30 °C. | |
| Pantalla | 3 pulgadas / 64 x 128 píxeles, pantalla de matriz de puntos invertida (con retroiluminación) | | |
| Pausar sonido | 120 segundos | | |
| Volumen de las alarmas[48] | Intervalo = 1-8. Predeterminado = 5. | | |

[47] Si desea información sobre los intervalos de flujo mínimo, consulte las *instrucciones de uso* del circuito respiratorio.
[48] Volumen a 1 m de distancia del humidificador. Un ajuste de 1 = 50 dB(A), 5 (predeterminado) = 60 dB(A) y 8 = 65 dB(A), con precisión de ±6 dB(A).

## 9.8 Rendimiento básico

Las temperaturas aplicadas al gas respiratorio y al circuito respiratorio deben mantenerse dentro de los ajustes especificados, y deben monitorizarse.

Si la temperatura rebasa los límites establecidos, el humidificador debe detectarlo e informar al usuario mediante una alarma.

## 9.9 Descripción funcional del sistema de humidificación

El humidificador HAMILTON-H900 está diseñado para añadir humedad y calentar los gases respiratorios durante la ventilación mecánica. El gas respiratorio se calienta y humidifica a medida que pasa por una cámara que está parcialmente llena con agua calentada.

El humidificador tiene dos sistemas de calefacción controlados mediante sensores:

- *Placa calefactora*. Calienta el agua de la cámara de agua.
- *Sistema de calefacción del circuito respiratorio integrado*. Calienta las ramas respiratorias para evitar la condensación.

La temperatura del gas respiratorio se monitoriza en la salida de la cámara y en la rama respiratoria del extremo del paciente.

## 9.10 Símbolos utilizados en el paquete y las etiquetas del dispositivo

| Símbolo | Descripción |
|---|---|
|  | Siga las *instrucciones de uso* |
|  | Número de referencia |
|  | Número de serie |
|  | Cantidad |
|  | Fabricante |
|  | Fecha de fabricación |
|  | Pieza aplicada Tipo BF (clasificación de equipo electromédico, tipo BF, tal como se especifica en la norma CEI 60601-1) |
|  | Deseche el equipo de acuerdo con la Directiva del Consejo 2002/96/CE o RAEE (residuos de aparatos eléctricos y electrónicos) |
|  | La marca TÜV NRTL con las indicaciones "C" y "US" señala que el producto cumple los requisitos de seguridad de las autoridades competentes canadienses y estadounidenses, respectivamente. |

| Símbolo | Descripción |
|---|---|
|  | Ecualización de potencial |
|  | Advertencia: Superficie caliente.<br>La placa calefactora y la parte inferior de la cámara pueden alcanzar temperaturas superiores a 85 °C. |
| CE 0197 | Marca CE de conformidad, sello de garantía de aprobación que garantiza que el dispositivo cumple la Directiva 93/42/CEE del Consejo, relativa a los productos sanitarios. |
| IP21 | Protección contra las salpicaduras de agua y las partículas sólidas de más de 12,5 mm. |
| max | Marca de nivel de llenado en la cámara de agua |
|  | Interfaz en serie RS-232 para la comunicación con los respiradores de Hamilton Medical |
|  | MR no seguro<br>El HAMILTON-H900 supone riesgos inaceptables para el paciente, el personal médico u otras personas que se encuentren en el entorno de RM. |

| Símbolo | Descripción |
|---|---|
|  | RoHS chino |
|  | Sensor de temperatura<br>Indica la ubicación del sensor de temperatura en el circuito respiratorio. |

## 9.11 Normas y aprobaciones

El sistema del humidificador cumple los apartados pertinentes de las siguientes normas que se indican en la tabla 20.

Tabla 20. Normas y autorizaciones, versiones válidas

| |
|---|
| CEI 60601-1:2005/A1:2012 |
| CEI 60601-1-2:2014 |
| CEI 60601-1-6:2010/A1:2013 |
| CEI 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| CEI 62304:2006/A1:2015 |
| CEI 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Eliminación

El dispositivo debe eliminarse conforme a los protocolos de su centro sanitario y a la Directiva 2002/96/CE.

Los circuitos respiratorios y las cámaras de humidificador deben eliminarse conforme a las *instrucciones de uso* proporcionadas con los equipos respiratorios.

## 9.13 Garantía

GARANTÍA LIMITADA

LA GARANTÍA DESCRITA EN ESTE ACUERDO SUSTITUYE A CUALQUIER OTRA GARANTÍA EXPLÍCITA O IMPLÍCITA, INCLUIDAS LAS GARANTÍAS IMPLÍCITAS DE COMERCIALIZACIÓN Y ADECUACIÓN PARA UN FIN PARTICULAR. EN CUALQUIER CASO, NO SE RENUNCIA A LAS GARANTÍAS IMPLÍCITAS DURANTE EL PERÍODO DE ESTA GARANTÍA LIMITADA.

Hamilton Medical garantiza que todos sus productos se envían libres de cualquier defecto de material o de fabricación. La garantía no incluye los elementos desechables. Los elementos desechables se consideran de un solo uso o de uso limitado y solo deben ser sustituidos cuando sea preciso para que el producto funcione adecuadamente, según las instrucciones del manual del operador.

Considerando que Hamilton Medical no tendrá obligaciones ni responsabilidades relacionadas con el producto que no sean las especificadas en el presente, incluidas, entre otras, las obligaciones o las responsabilidades causadas por negligencia o por responsabilidad estricta. En ningún caso la empresa será responsable de daños incidentales o consecuentes, ya sean directos o derivados.

La presente garantía quedará anulada en los casos siguientes:

1. Si el producto no lo ha instalado ni conectado un representante local autorizado de Hamilton Medical según las instrucciones que proporciona Hamilton Medical y el representante de Hamilton Medical.
2. Si no existen pruebas de que la producción del daño o la reparación haya tenido lugar durante el período certificado de garantía.
3. Si se ha modificado, borrado o retirado el número de serie y no hay factura de compra ni ninguna otra prueba que demuestre la fecha en la que se adquirió el equipo.
4. Si los defectos han derivado del mal uso, la negligencia, de un accidente o de una reparación, un ajuste, una modificación o una sustitución que se haya realizado fuera de las fábricas de Hamilton Medical o fuera de los centros de servicio técnico o representantes autorizados.
5. Si el producto ha sido modificado o alterado de alguna forma sin una autorización previa y por escrito de Hamilton Medical.
6. Si el producto se utiliza o se ha utilizado de alguna manera distinta a las especificadas en el capítulo "Uso previsto".
7. Si utiliza el producto alguna persona distinta del personal que ha recibido la formación adecuada bajo la supervisión de un médico.

Las reparaciones y sustituciones que se realicen de acuerdo con esta garantía limitada no tienen una nueva garantía, sino que tienen únicamente la parte no expirada de la garantía limitada original. La garantía de los componentes reparados o sustituidos no supera la garantía limitada del dispositivo.

Para poder obtener servicio de mantenimiento que cubra esta garantía limitada, el solicitante debe ponerse en contacto de inmediato con el representante comercial de Hamilton Medical e informarle de la naturaleza del problema, así como del número de serie y la fecha de compra del producto.

A excepción de los mencionados, Hamilton Medical no será responsable de ningún daño o reclamación, incluidos, entre otros, lesiones personales o daños incidentales, consecuentes o especiales. Hamilton Medical tampoco será responsable de ningún daño o reclamación, incluidos, entre otros, lesiones personales o daños accidentales, consecuentes o especiales derivados de un uso inapropiado del dispositivo o de la infracción de alguna de las disposiciones de este manual.

### 9.13.1 Miscelánea

Se aplican los términos y condiciones generales de Hamilton Medical. Este contrato se regirá y se interpretará de acuerdo con la legislación de Suiza y puede ser aplicado por cualquiera de las partes bajo la jurisdicción de los tribunales de Chur, Suiza.

# Istruzioni per l'uso

## HAMILTON-H900

2021-01-11

624431/09

**Produttore**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz
Svizzera
Telefono: (+41) 58 610 10 20
Fax: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Prefazione

Assicurarsi di leggere la documentazione prima dell'utilizzo del dispositivo o degli accessori.

### Convenzioni utilizzate in questa guida

In questo manuale:

- I nomi di tasti sono riportati in **grassetto**.
- I grafici raffigurati possono non corrispondere esattamente a quelli visualizzati nell'ambiente in uso.
- Non tutte le funzionalità sono disponibili in tutti i mercati.

I messaggi relativi alla sicurezza sono visualizzati come segue:

**⚠ AVVERTENZA**

Avvisa l'operatore della possibilità di lesioni, decesso o altre reazioni avverse gravi associate all'utilizzo o all'uso improprio del dispositivo.

**⚠ ATTENZIONE**

*Avvisa l'operatore della possibilità di problemi associati all'utilizzo o all'uso improprio del dispositivo, quali malfunzionamento, guasto, danni al dispositivo o ad altri oggetti.*

***AVVISO***

Sottolinea le informazioni di particolare importanza.

Nelle tabelle, i messaggi relativi alla sicurezza sono indicati come segue:

**⚠ AVVERTENZA!**

**⚠ ATTENZIONE!**

**AVVISO!**

Per scaricare l'ultima versione di questo manuale o altri documenti, visitare la pagina MyHamilton del sito Web all'indirizzo:
https://www.hamilton-medical.com/MyHamilton

Hamilton Medical offre Hamilton Medical College, in cui sono forniti gratuitamente svariati moduli formativi. Per registrarsi, visitare il sito Web all'indirizzo:
http://college.hamilton-medical.com/

**⚠ ATTENZIONE**

*(Solo per gli Stati Uniti): la legge federale limita la vendita di questo dispositivo da parte di un medico o su prescrizione medica.*

### Uso previsto

L'umidificatore HAMILTON-H900 è destinato al condizionamento di gas respiratori durante la ventilazione meccanica invasiva e non invasiva.

Il dispositivo è destinato all'uso nell'ambiente ospedaliero in cui i professionisti sanitari forniscono l'assistenza al paziente.

L'umidificatore HAMILTON-H900 è un dispositivo medicale destinato a essere utilizzato da personale esperto e qualificato sotto la direzione di un medico e nei limiti delle specifiche tecniche indicate.

# 1 Informazioni sulla sicurezza

Questa sezione fornisce informazioni sulla sicurezza relative alla configurazione, all'utilizzo e alla manutenzione dell'umidificatore.

**Esaminare attentamente e interamente questa sezione sulla sicurezza prima di configurare e utilizzare l'umidificatore.**

**Prima di utilizzare l'umidificatore, non dimenticare di riesaminarne le Istruzioni per l'uso.**

**Prima dell'uso, assicurarsi di leggere le Istruzioni per l'uso fornite con i dispositivi e gli accessori utilizzati con l'umidificatore.**

In caso di domande sulle informazioni riportate in questo manuale, contattare il rappresentante o il personale dell'assistenza tecnica Hamilton Medical.

## 1.1 Suscettività elettromagnetica

**⚠ AVVERTENZA**

- **MR UNSAFE** (Non sicuro per la risonanza magnetica). Tenere lontano da attrezzature per risonanza magnetica nucleare (RMN). HAMILTON-H900 presenta dei rischi inaccettabili per il paziente, il personale medico o altre persone all'interno dell'ambiente di risonanza magnetica.
- Il funzionamento dell'umidificatore può essere compromesso in prossimità di apparecchiature chirurgiche ad alta frequenza in funzione, microonde, onde corte o campi magnetici forti.
- Per evitare un aumento delle emissioni elettromagnetiche, una riduzione dell'immunità elettromagnetica o interruzioni del funzionamento dell'umidificatore HAMILTON-H900 o di qualsiasi accessorio, utilizzare solo accessori e cavi espressamente indicati nel presente manuale o nel catalogo dei prodotti di HAMILTON-H900.
- Qualunque dispositivo supplementare connesso ad apparecchiature elettromedicali deve essere conforme agli standard IEC o ISO applicabili (per esempio, IEC 60950 per apparecchiature di elaborazione dei dati). Inoltre, tutte le configurazioni devono rispettare i requisiti stabiliti per i sistemi elettromedicali (vedere IEC 60601-1, clausola 16).
- Chiunque connetta un dispositivo supplementare a un'apparecchiatura elettromedicale configura un sistema medicale ed è, pertanto, responsabile della conformità di quest'ultimo ai requisiti per i sistemi elettromedicali. Le leggi locali hanno la priorità rispetto ai requisiti sopra menzionati. In caso di domande su come procedere, consultare il rappresentante o l'assistenza tecnica Hamilton Medical.
- L'umidificatore *non* è protetto contro gli effetti della scarica di un defibrillatore cardiaco.

***AVVISO***

- L'umidificatore HAMILTON-H900 necessita di speciali precauzioni relativamente alla EMC (compatibilità elettromagnetica) e deve essere installato e messo in servizio secondo le informazioni EMC fornite nelle *Dichiarazioni EMC per l'HAMILTON-H900*.
- Le apparecchiature di comunicazione RF mobili e portatili possono influire sull'umidificatore HAMILTON-H900.

## 1.2 Alimentazione elettrica

**⚠ AVVERTENZA**

- Per ridurre il rischio di scosse elettriche, collegare il cavo di alimentazione dell'umidificatore ad una presa appropriata di collegamento all'alimentazione dotata di messa a terra. È responsabilità dell'ospedale assicurarsi che la presa di collegamento sia dotata di messa a terra adeguata.
- *Non* utilizzare se il cavo di alimentazione è danneggiato.
- In caso di alimentazione con tensione non corretta, interruzione dell'alimentazione o scollegamento dall'alimentazione, l'umidificatore emette un fischio. Spegnere immediatamente il dispositivo e verificare che la tensione utilizzata sia corretta.
- Assicurarsi di utilizzare la tensione di alimentazione corretta.

## 1.3 Incendio e altri rischi

**⚠ AVVERTENZA**

*Non* usare l'umidificatore in aree pericolose o con gas infiammabili.

## 1.4 Funzionamento generale e impostazione

**⚠ AVVERTENZA**

- Prima di utilizzare l'umidificatore sul paziente, verificare che il circuito paziente sia connesso correttamente al ventilatore, come descritto di seguito:

  – La branca inspiratoria blu è connessa alla porta inspiratoria *Al paziente*.

  – La branca inspiratoria bianca è connessa alla porta espiratoria *Dal paziente*.
- Utilizzare solo i componenti e gli accessori specificati nella sezione 8. In questo modo si ha la certezza che l'umidificatore funzioni correttamente e si evita il rischio di potenziali lesioni al paziente.
- Non utilizzare l'umidificatore ad altitudini superiori ai 4000 metri o a temperature al di fuori dell'intervallo che va da 10 °C a 40 °C. Se si utilizza l'umidificatore ad altitudini superiori o a temperature al di fuori dell'intervallo specificato, la qualità della terapia può essere compromessa e il paziente può subire lesioni.
- Un'impostazione non corretta dell'umidità o della temperatura può risultare dannosa per il paziente.
- *Non* utilizzare l'umidificatore durante il trasferimento di un paziente ventilato al di fuori dell'ospedale.
- Accendere l'umidificatore *dopo* aver acceso il ventilatore.
- Spegnere l'umidificatore *prima* di spegnere il ventilatore.
- Non coprire le celle di misurazione IR dell'umidificatore.

- La modalità invasiva (INV) deve essere utilizzata *soltanto* con pazienti intubati e tracheostomizzati.
- Prendere precauzioni aggiuntive nel caso di reazioni allergiche.
- Controllare regolarmente se è presente condensa nel circuito paziente e, se necessario, drenarlo.
- L'uso simultaneo di un nebulizzatore può influire negativamente sulla capacità di umidificazione del dispositivo.
- *Non* toccare la piastra calda o il fondo della camera dell'acqua. La temperatura delle superfici può superare gli 85 °C. Queste superfici calde irradiano calore.

**⚠ ATTENZIONE**

- *Posizionare l'umidificatore in una posizione in cui sia possibile disconnetterlo facilmente dall'alimentazione principale.*
- *Impiegare solo i componenti e gli accessori specificati nella Sezione 8 e nel catalogo dei prodotti di Hamilton Medical o che sono specificati come compatibili con questo umidificatore.*

  *In questo modo si garantisce un'umidificazione corretta, si evita il deterioramento delle prestazioni e si mantiene la validità della garanzia.*
- *Se si spegne e si riaccende l'umidificatore, esso si avvia automaticamente in modalità invasiva (INV) a meno che sia configurato diversamente.*
- *Prima dell'uso, controllare che il set circuito paziente non sia danneggiato. Eliminare il set circuito paziente se risulta danneggiato.*
- *L'elemento riscaldante e i fili di riscaldamento dell'umidificatore sono automaticamente accesi quando la camera dell'acqua e i circuiti paziente sono montati correttamente e l'umidificatore è acceso o nella modalità **Standby**.*
- *Se la temperatura ambiente o la temperatura del gas in ingresso e/o la velocità del flusso sono al di fuori dell'intervallo raccomandato, i livelli di umidità fisiologica possono non essere raggiunti.*
- *L'umidificatore può essere alimentato anche se il display non è illuminato. Vedere la Tabella 1.*

***AVVISO***

- Prima di utilizzare un set circuito paziente su un paziente, effettuare il test di tenuta. Se questo test ha esito negativo, può essere ripetuto una volta. Dopo due test consecutivi con esito negativo, il set circuito paziente deve essere sostituito con uno nuovo.
- La formazione, nella branca, nel tubo flessibile o nel sensore di flusso, di una condensa sottile (annebbiamento) dovuta alla respirazione indica che l'umidità è impostata correttamente.
- Tutte le azioni generano un segnale acustico.

## 1.5 Circuiti paziente e camera dell'acqua

**⚠ AVVERTENZA**

- La connessione errata del circuito paziente al ventilatore può provocare lesioni al paziente.
- Per evitare la disconnessione accidentale del circuito paziente durante l'utilizzo o il trasporto, utilizzare solo circuiti paziente conformi alla norma ISO 5367 o ISO 80601-2-74.
- Riempire la camera dell'acqua solo con acqua sterile, demineralizzata, che soddisfa i requisiti igienici dell'ospedale.
- Non inclinare la camera dell'acqua.
- Non inserire alcun farmaco nella camera dell'umidificatore.
- Verificare che il livello dell'acqua non superi il livello di riempimento massimo.

***AVVISO***

- Se l'umidificatore non rileva il circuito paziente, sostituirne i componenti.
- La temperatura dell'acqua di riempimento non deve essere superiore a 37 °C.
- Assicurarsi che il rifornimento di acqua alla camera stia funzionando correttamente.
- Assicurarsi che l'umidificatore sia in **Standby** prima di disconnettere i componenti.

## 1.6 Posizionamento di circuito paziente e umidificatore

**⚠ AVVERTENZA**

- L'umidificatore deve *sempre* essere posizionato al di sotto del livello del paziente.
- *Non* utilizzare l'umidificatore a un angolo superiore a 10° rispetto al pavimento.
- Accertarsi di far passare il circuito paziente, senza tirarlo eccessivamente né attorcigliarlo, dall'umidificatore al paziente.
- Le branche riscaldate del circuito paziente *non* devono essere posizionate direttamente sulla pelle del paziente.
- Se l'umidificatore viene utilizzato nelle vicinanze di altre apparecchiature elettromedicali o posizionato sopra di esse, verificarne il normale funzionamento nella configurazione da utilizzare.
- Posizionare il circuito paziente in modo che la condensa liquida non raggiunga il paziente.
- Collegare in modo appropriato i circuiti paziente o le clip per il fissaggio dei tubi al fine di evitare che vengano esercitate forze meccaniche sul tubo ET.

**AVVISO**

- Prima dell'uso, controllare la stabilità di tutti i collegamenti.
- Tutti i connettori per le branche del circuito presenti sull'umidificatore combinano i collegamenti elettrici con i connettori del circuito paziente. Assicurarsi che i contatti elettrici siano orientati correttamente in modo che corrispondano all'elemento di collegamento sull'umidificatore.

## 1.7 Monitoraggio e allarmi

**AVVISO**

- Quando un allarme è attivo, sul display la visualizzazione dei simboli degli allarmi attivi si alterna a quella della temperatura corrente in corrispondenza dell'uscita della camera.
- Dopo lo spegnimento dell'umidificatore, l'intensità dell'allarme ritorna al valore predefinito 5.
- Tutti gli allarmi di tipo tecnico, le informazioni tecniche dettagliate e le procedure di manutenzione sono descritti nel *Manuale tecnico di HAMILTON-H900*.

## 1.8 Manutenzione

**⚠ AVVERTENZA**

- *Non* è permesso apportare modifiche all'umidificatore.
- Per ridurre il rischio di scosse elettriche, prima di eseguire la pulizia e la disinfezione, disconnettere *sempre* l'umidificatore dall'alimentazione elettrica.

**⚠ ATTENZIONE**

- *Maneggiare i circuiti paziente e le camere dell'acqua usati come articoli contaminati secondo le leggi e le normative locali o le procedure interne dell'ospedale.*
- *Per garantire interventi appropriati ed evitare possibili lesioni, la manutenzione dell'umidificatore può essere eseguita solo da personale tecnico autorizzato da Hamilton Medical utilizzando le informazioni fornite nel Manuale tecnico di HAMILTON-H900.*
- *Impiegare esclusivamente i ricambi forniti da Hamilton Medical.*
- *Non tentare di eseguire procedure di manutenzione diverse da quelle specificate nel Manuale tecnico di HAMILTON-H900.*
- *Per la pulizia e la disinfezione, utilizzare solo agenti detergenti approvati.*

**AVVISO**

- Per informazioni specifiche sulla pulizia, la disinfezione e la sterilizzazione di accessori e componenti (riutilizzabili) autoclavabili, fare riferimento alla *Guida alla risterilizzazione* e alle *Istruzioni per l'uso* appropriate, fornite per ciascun componente.
- (*Solo per gli Stati Uniti*) per la pulizia e la disinfezione, utilizzare solo agenti detergenti approvati dall'EPA.

# 2 Panoramica

Questa guida fornisce informazioni sulla configurazione e sull'utilizzo dell'umidificatore HAMILTON-H900.

L'umidificatore è progettato per essere utilizzato sia con ventilatori Hamilton Medical, sia con ventilatori di terze parti.

## 2.1 Informazioni sull'umidificatore HAMILTON-H900

L'umidificatore HAMILTON-H900 riscalda e umidifica i gas respiratori per pazienti adulti, pediatrici e neonatali.

Il dispositivo supporta le seguenti modalità respiratorie di uso comune:

- Ventilazione invasiva
- Ventilazione non invasiva
- Terapia con ossigeno ad alto flusso

Il sistema è costituito da: involucro esterno dell'umidificatore, display, comandi, camera dell'acqua, piastra riscaldante e collegamenti elettrici per un circuito paziente riscaldato.

Consente di utilizzare le seguenti funzioni principali:

- Comandi regolabili per la temperatura e l'umidità
- Capacità di monitoraggio e allarmi
- Integrazione dei comandi e dei dati monitorati dell'umidificatore nei ventilatori Hamilton Medical supportati[49]

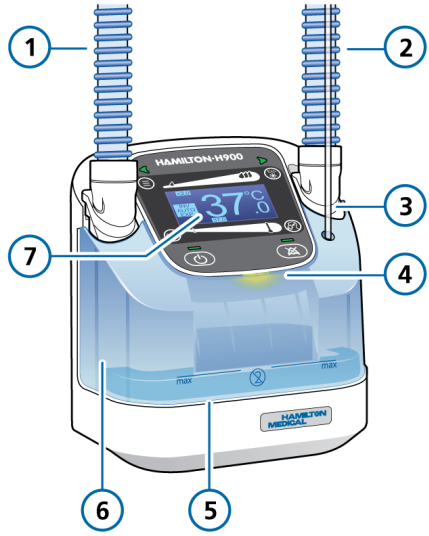
## 2.2 Descrizioni fisiche

Questa sezione fornisce una panoramica dell'umidificatore e dei relativi set circuito paziente.

### 2.2.1 Informazioni sull'umidificatore

Le Figure da 1 a 5 forniscono una panoramica dell'umidificatore.

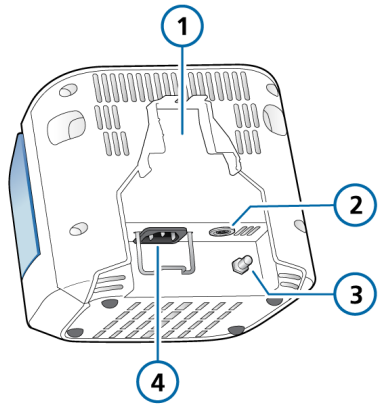
Figura 1. Umidificatore HAMILTON-H900, vista frontale




| | | | |
|---|---|---|---|
| 1 | Branca inspiratoria ventilatore (azzurra) | 5 | Piastra riscaldante |
| 2 | Branca inspiratoria paziente (azzurra) | 6 | Camera dell'acqua |
| 3 | Tubo di erogazione acqua | 7 | Pannello anteriore e display |
| 4 | Indicatore di allarme visivo | | |

[49] Non disponibile in tutti i mercati.

Figura 2. Umidificatore HAMILTON-H900, vista posteriore




| | | | |
|---|---|---|---|
| 1 | Alloggiamento staffa di montaggio | 3 | Terminale equipotenziale |
| 2 | Porta RS-232 | 4 | Presa dell'alimentazione CA |

Figura 3. Umidificatore HAMILTON-H900, comandi sul pannello anteriore


| | | | |
|---|---|---|---|
| 1 | Pulsante per finestra di monitoraggio della temp. | 5 | Tasto Pausa allarme acustico |
| 2 | Dispositivi scorrimento per controllo della temp. | 6 | Tasto Accensione/ Standby |
| 3 | Pulsante Temp. Esp. Aumentata | 7 | Tasto Auto |
| 4 | Pulsante modalità INV/NIV/HiFlow | 8 | Display (vedere la Figura 5) |

### 2.2.2 Informazioni sulla visualizzazione principale

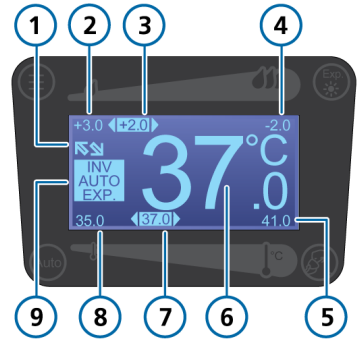
Durante l'umidificazione, è possibile accedere direttamente alla totalità di impostazioni, modalità, allarmi e comandi dal display principale.

Le figure da 3 a 5 illustrano i comandi, gli indicatori e il display presenti sul pannello anteriore.

Figura 4. Umidificatore HAMILTON-H900, indicatori di stato sul pannello anteriore


| | | | |
|---|---|---|---|
| 1 | Indicatori stato della connessione branche | 3 | Indicatore stato Accensione/ Standby |
| 2 | Indicatore Pausa allarme acustico | | |

Figura 5. Display dell'umidificatore HAMILTON-H900




| | | | |
|---|---|---|---|
| 1 | Connessione ventilatore attivata | 6 | Temp. corrente all'uscita della camera |
| 2 | Impost. gradiente di temp. max. | 7 | Impost. temp. all'uscita della camera |
| 3 | Impost. gradiente di temp. | 8 | Impost. temp. min. all'uscita della camera |
| 4 | Impost. gradiente di temp. min. | 9 | Modalità/impostazioni attive |
| 5 | Impost. temp. max. all'uscita della camera | | |

*Sono qui mostrati tutti gli elementi presenti sul display unicamente a scopo illustrativo; durante l'utilizzo è possibile che gli elementi non siano tutti visualizzati contemporaneamente.*

### 2.2.3 Informazioni sui circuiti paziente dell'umidificatore

L'umidificatore HAMILTON-H900 supporta diversi circuiti paziente a branca singola e doppia per pazienti adulti, pediatrici e neonatali.

Per maggiori dettagli, vedere le *Istruzioni per l'uso* del circuito paziente utilizzato.

### 2.2.4 Informazioni sugli indicatori di stato presenti sull'umidificatore

Gli indicatori sul pannello frontale dell'umidificatore mostrano informazioni importanti sullo stato dell'umidificatore. Vedere la Figura 4.

Tabella 1. Indicatori di stato

| Simbolo | Descrizione |
|---|---|
| **Tasto di Accensione/Standby con indicatore di stato** | |
|  | *verde*: l'umidificatore è in funzione. |
|  | *arancione*: l'umidificatore è in Standby. |
|  | *blu*: l'umidificatore è spento e collegato a una fonte di alimentazione. |
|  | *spento*: l'umidificatore è spento e *non* collegato a una fonte di alimentazione. |
| **Indicatore di stato della connessione delle branche** | |
|  | *verde*: la branca è connessa correttamente. |
|  | *arancione*: l'umidificatore sta verificando la connessione della branca. |
|  | *rosso*: la connessione della branca è difettosa oppure non vi è alcuna branca collegata. |
| **Tasto Pausa allarme acustico con indicatore** | |
|  | *rosso*: la pausa allarme acustico è attiva. |

## 2.3 Utilizzo delle finestre e dei comandi

Questa sezione spiega come utilizzare i pulsanti e i dispositivi di scorrimento presenti sull'umidificatore.

### 2.3.1 Utilizzo dei pulsanti di comando

I pulsanti presenti sul pannello anteriore (Figura 3) consentono di selezionare le modalità, modificare le impostazioni e visualizzare una panoramica delle principali impostazioni della temperatura.

Tabella 2. Pulsanti di comando (vedere la Figura 3)

| Pulsante | Descrizione |
|---|---|
|  | **Temperatura esp. aumentata**<br>Aumenta la temperatura nella branca espiratoria. |
|  | **Auto**<br>Attiva la modalità Auto.<br>Vedere la Sezione 4.2.2. |
|  | **Modalità operative INV/NIV/ HiFlow**<br>Passa da una modalità all'altra: INV, NIV e HiFlow.<br>Vedere la Sezione 4.2. |
|  | **Finestra di monitoraggio della temperatura**<br>Visualizza i valori attuali della temperatura in corrispondenza del raccordo a Y, di quella all'uscita della camera e del gradiente di temperatura.<br>Vedere la Sezione 4.4. |

### 2.3.2 Utilizzo dei dispositivi di scorrimento

In modalità manuale è possibile modificare le impostazioni della temperatura utilizzando i comandi a dispositivo di scorrimento (Figura 3).

Tabella 3. Dispositivi di scorrimento per il controllo della temperatura

| Dispositivo di scorrimento | Descrizione |
|---|---|
| **Dispositivo di scorrimento del gradiente di temperatura** | |
|  | Regola la differenza di temperatura tra l'uscita della camera e il raccordo a Y.<br>Vedere la Sezione 4.3. |
| **Dispositivo di scorrimento della temperatura all'uscita della camera** | |
|  | Regola la temperatura in corrispondenza dell'uscita della camera.<br>Vedere la Sezione 4.3. |

## 3 Preparazione dell'umidificatore per l'uso

*Prima di procedere, rivedere le informazioni sulla sicurezza riportate nella Sezione 1.*

La preparazione dell'umidificatore per l'uso comprende i seguenti passaggi:

- La configurazione delle impostazioni da parte di un tecnico del settore medico, da eseguire una sola volta (vedere la Tabella 4)
- Per ogni nuovo paziente, le attività di impostazione effettuate dagli operatori sanitari (vedere la Tabella 5)

Tabella 4. Configurazione e impostazione da parte di un tecnico del settore medico

| Per... | Vedere... |
|---|---|
| *Queste attività di configurazione iniziali vengono completate una sola volta dal personale tecnico.* | |
| Montaggio e posizionamento dell'umidificatore | Vedere la *Guida di installazione* relevante relativa al ventilatore o al carrello |
| Configurazione delle impostazioni dell'umidificatore | Sezione 7 |
| *Opzionale*: collegamento dell'umidificatore alla porta COM RS-232 di qualsiasi ventilatore Hamilton Medical supportato | Vedere il *Manuale operatore* rilevante del ventilatore |

Tabella 5. Configurazione e impostazione da parte degli operatori sanitari

| Per... | Vedere... |
|---|---|
| *Le attività seguenti vengono effettuate dal personale medico che si occupa dei pazienti.* | |
| Connettere a una fonte di alimentazione | Sezione 3.1 |
| Connettere il circuito paziente | Sezione 3.2 |
| Accendere l'umidificatore | Sezione 3.3 |
| Eseguire il test degli allarmi | Sezione 3.4 |
| Specificare le impostazioni dell'umidificatore | Sezione 3.5 |
| Connettere il paziente | Sezione 3.6 |

## 3.1 Connessione a una fonte di alimentazione

Controllare sempre l'affidabilità della presa di alimentazione principale prima di collegare l'umidificatore e il ventilatore all'alimentazione.

### Per connettere l'umidificatore a una fonte di alimentazione

- Connettere l'umidificatore a una presa elettrica che fornisca corrente alternata.[50]

## 3.2 Connessione del set circuito paziente all'umidificatore

Hamilton Medical fornisce diversi circuiti paziente per pazienti adulti, pediatrici e neonatali.

Per maggiori dettagli, vedere le *Istruzioni per l'uso* dello specifico circuito paziente utilizzato.

## 3.3 Accensione e spegnimento dell'umidificatore

Quando l'umidificatore viene acceso, si avvia automaticamente nella modalità configurata come predefinita.

Prestare attenzione ad accendere il ventilatore *prima* di accendere l'umidificatore.

### Per accendere l'umidificatore

- Premere e tenere premuto  (**Accensione/Standby**) per circa 3 secondi.

L'umidificatore eseguirà un auto-test. Terminato il test, l'umidificatore si avvia automaticamente in modalità invasiva (**INV**), a meno che sia configurato diversamente.

### Per spegnere l'umidificatore

- Premere e tenere premuto  per circa 3 secondi.

Prestare attenzione a spegnere l'umidificatore *prima* di spegnere il ventilatore.

[50] Se si utilizza l'umidificatore insieme a un ventilatore Hamilton Medical supportato, collegare il cavo di alimentazione dell'umidificatore nell'apposita presa di alimentazione presente sul ventilatore.

## 3.4 Esecuzione del test degli allarmi

Prima di connettere un nuovo paziente all'umidificatore, verificare che gli allarmi funzionino correttamente.

Verificare che l'umidificatore sia acceso.

**Per verificare il funzionamento degli allarmi dell'umidificatore**

1. Generare un allarme rimuovendo la camera dell'acqua dall'umidificatore.
2. Verificare che:
   – Si senta un allarme acustico
   – L'indicatore di allarme visivo stia lampeggiando (Figura 4)
   – Il simbolo dell'allarme corrispondente venga visualizzato sul display (Tabella 9)

Eliminare la condizione di allarme reinserendo la camera dell'acqua nell'umidificatore e verificare che l'allarme venga reimpostato.

## 3.5 Specificazione delle impostazioni dell'umidificatore

Selezionare la modalità di umidificazione opportuna per il paziente.[51] Per maggiori dettagli, vedere la Sezione 4.2.

## 3.6 Connessione del paziente

Connettere il circuito paziente all'interfaccia paziente appropriata.

L'umidificatore è ora configurato e pronto per l'uso.

# 4 Utilizzo dell'umidificatore HAMILTON-H900

Tabella 6. Panoramica del funzionamento

| Per maggior dettagli su... | Vedere... |
|---|---|
| Accensione/spegnimento dell'umidificatore | Sezione 3.3 |
| Attivazione/disattivazione della modalità **Standby** | Sezione 4.1 |
| Accesso ai comandi dell'umidificatore | Sezione 2.3 |
| Modalità operative dell'umidificatore **INV**, **NIV**, **HiFlow** | Sezione 4.2 |
| Impostazioni **Auto** e **Manuale** | Sezione 4.2.2 |
| Modifica dell'umidità utilizzando i comandi della temperatura | Sezione 4.3 |
| Parametri dell'umidificatore monitorati | Sezione 4.4 |
| Allarmi dell'umidificatore | Sezione 5 |

## 4.1 Attivazione/disattivazione della modalità Standby

**⚠ ATTENZIONE**

*Nella modalità **Standby**, tutte le impostazioni sono mantenute e l'uscita di calore è ridotta.*

La modalità **Standby** è una modalità di attesa che consente di mantenere le impostazioni correnti quando l'umidificatore non viene utilizzato.

[51] Se lo si utilizza con un ventilatore Hamilton Medical che supporta il funzionamento integrato, l'umidificatore utilizza la stessa modalità operativa del ventilatore. Per maggiori dettagli, vedere il *Manuale operatore* del ventilatore.

Quando è attiva la modalità **Standby**, i valori impostati per la **temperatura in corrispondenza dell'uscita della camera** e il **gradiente di temperatura** vengono diminuiti.[52] Per maggiori dettagli, vedere la Sezione 9.7.

**Per mettere l'umidificatore in Standby**

- Premere brevemente (**Accensione/Standby**).

  Quando è attiva la modalità **Standby**, il display mostra il tempo trascorso in **Standby**. La spia dell'indicatore di **Accensione/Standby** è arancione.

**Per disattivare la modalità Standby e iniziare l'umidificazione**

- Premere .

  L'umidificatore riprende a funzionare normalmente, la spia dell'indicatore dello stato di **Accensione/Standby** è verde.

## 4.2 Informazioni sulle modalità operative dell'umidificatore

L'HAMILTON-H900 consente di utilizzare le seguenti modalità operative: invasiva (**INV**), non invasiva (**NIV**) e terapia con ossigeno ad alto flusso (**HiFlow**).

La selezione della modalità operativa determina le impostazioni iniziali per la temperatura, sia in corrispondenza dell'uscita della camera dell'acqua (**temperatura in corrispondenza dell'uscita della camera**) che del raccordo a Y (**gradiente di temperatura**), nonché gli intervalli di temperatura consentiti per ciascuno di questi comandi.

Questi intervalli di temperatura sono diversi per i vari gruppi di pazienti. Vedere la Tabella 18.

### 4.2.1 Modifica della modalità

L'umidificatore si avvia automaticamente in modalità invasiva (**INV**), a meno che non sia configurato in modo differente nelle impostazioni predefinite personalizzate.

Quando si passa dalla modalità invasiva (**INV**) a quella non invasiva (**NIV**) o viceversa, l'umidificatore imposta automaticamente le impostazioni dei comandi su **Auto**.

**Per modificare la modalità**

- Premere (**Modalità**) finché non viene visualizzata la modalità desiderata (**INV**, **NIV**, **HiFlow**).

  La modalità selezionata viene visualizzata sul display.

Figura 6. Modalità INV (**1**) selezionata

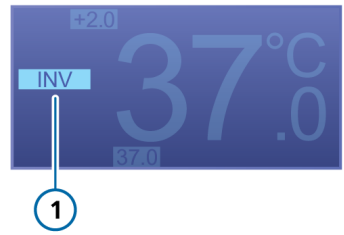
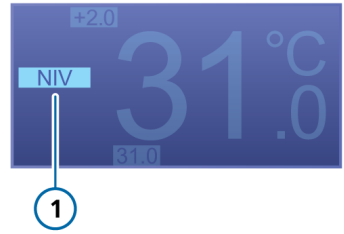



Figura 7. Modalità NIV (**1**) selezionata




[52] Durante la nebulizzazione, il **gradiente di temperatura** *non* viene modificato quando è attiva la modalità **Standby**.

Figura 8. Modalità HiFlow (**1**) selezionata

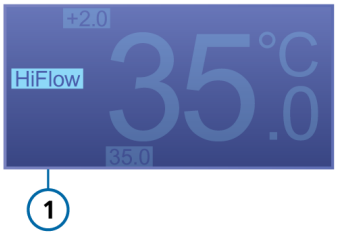
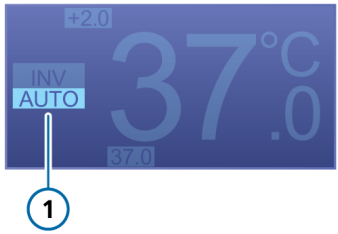



Figura 9. Modalità Auto (**1**) selezionata




### 4.2.2 Impostazioni dei comandi Auto e Manuale

È possibile utilizzare l'umidificatore in modalità **Auto**, oppure regolare le impostazioni manualmente. Per impostazione predefinita, l'umidificatore si avvia in modalità **Auto**.

La **temperatura in corrispondenza dell'uscita della camera** e il **gradiente di temperatura** si impostano utilizzando uno dei seguenti metodi:

- Valori caricati dalle impostazioni predefinite configurate (modalità **Auto**)
- Impostazioni manuali dell'utente

#### Impostazioni automatiche (Auto)

Quando è impostato su **Auto**, l'umidificatore carica le impostazioni predefinite configurate per la modalità selezionata (vedere la Sezione 7) e le utilizza per controllare la temperatura dei gas.

Se la temperatura ambiente è bassa, l'umidificatore può regolare automaticamente la temperatura della camera dell'acqua.

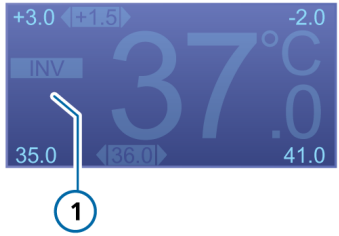
Quando la modalità **Auto** è selezionata, sul display principale viene visualizzato il testo **AUTO**.

#### Impostazioni manuali

Quando si modifica la **temperatura in corrispondenza dell'uscita della camera** o il **gradiente di temperatura** utilizzando i dispositivi di scorrimento, l'umidificatore passa alla modalità **Manuale**. Tuttavia, l'umidificatore continua a controllare automaticamente le temperature per raggiungere le impostazioni specificate.

Se si modificano le impostazioni manualmente, il testo **Auto** non viene più visualizzato nel display e lo spazio che occupava resta vuoto.

Figura 10. Modalità Manuale (**1**) attiva



#### 4.2.2.1 Attivazione della modalità Auto

Dopo aver modificato manualmente una qualunque impostazione per la temperatura, è possibile riattivare la modalità **Auto**.

**Per riattivare la modalità Auto**

- Premere (Auto) (**Auto**).

  Anche se si passa alla modalità operativa **INV** o **NIV** l'umidificatore passa automaticamente in modalità **Auto**.

## 4.3 Modifica dell'umidità utilizzando i comandi della temperatura

***AVVISO***

Se l'umidificatore è in modalità **Auto**, spostando un qualsiasi dispositivo di scorrimento si passa all'umidificazione in modalità **Manuale**.

***AVVISO***

Se la modalità **HiFlow** è attiva, non è possibile modificare il **gradiente di temperatura** utilizzando il dispositivo di scorrimento. È possibile modificare il **gradiente di temperatura** assegnando un nuovo valore al parametro nella modalità di **configurazione**. Vedere la Sezione 7.

È possibile regolare i seguenti comandi sull'umidificatore[53]:

Tabella 7. Comandi dell'umidificatore disponibili

| Comando | Descrizione |
|---|---|
| Temperatura in corrispondenza dell'uscita della camera | Temperatura in corrispondenza dell'uscita della camera dell'acqua.<br>Il possibile range di valori per questo comando dipende dalla modalità operativa selezionata per l'umidificatore. Per maggiori dettagli, vedere le Tabelle 16 e 18.<br>Valori più alti determinano un'umidità assoluta più elevata. |
| Gradiente di temperatura | La differenza tra la temperatura in corrispondenza dell'uscita della camera dell'acqua e quella sul raccordo a Y. |
| Aumento della temperatura di espirazione | Quando è selezionato, l'umidificatore fornisce riscaldamento aggiuntivo nella branca espiratoria.[54] |

La temperatura massima consentita in corrispondenza del raccordo a Y del paziente è 42 °C. La somma dei valori della **temperatura in corrispondenza dell'uscita della camera** e del **gradiente di temperatura** non può superare questo limite. Per esempio, se il **gradiente di temperatura** è impostato su 2 °C, l'impostazione massima possibile per la **temperatura in corrispondenza dell'uscita della camera** è 40 °C.

[53] Se si utilizza l'umidificatore con un ventilatore Hamilton Medical che ne supporta il controllo integrato, è anche possibile modificare le impostazioni direttamente sul ventilatore. Per maggiori dettagli, vedere il *Manuale operatore* del ventilatore.
[54] Solo circuiti paziente riscaldati a branca doppia e monouso.

Inoltre, il valore impostato per il **gradiente di temperatura** ha la priorità rispetto al valore impostato per la **temperatura in corrispondenza dell'uscita della camera**. Ciò significa che se una combinazione di valori impostati genera una temperatura in corrispondenza del raccordo a Y maggiore di 42 °C, il **gradiente di temperatura** resta invariato mentre la **temperatura in corrispondenza dell'uscita della camera** viene modificata di conseguenza.

Per esempio, se la **temperatura in corrispondenza dell'uscita della camera** è impostata su 40 °C, è possibile impostare il **gradiente di temperatura** su 3 °C anche se la somma dei due valori supera i 42 °C. Una volta accettata l'impostazione del **gradiente di temperatura**, il valore della **temperatura in corrispondenza dell'uscita della camera** viene reimpostato automaticamente su 39 °C.

### Per regolare la temperatura in corrispondenza dell'uscita della camera

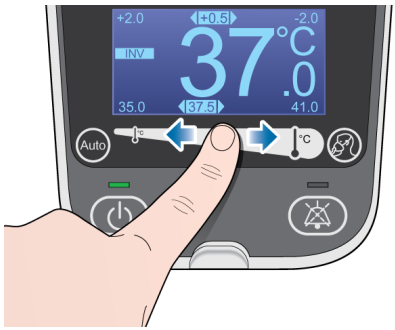
- Toccare il dispositivo di scorrimento della **temperatura in corrispondenza dell'uscita della camera** posizionato sul valore attualmente impostato:

  – Trascinarlo verso sinistra per ridurre la temperatura in corrispondenza dell'uscita della camera

  – Trascinarlo verso destra per aumentare la temperatura in corrispondenza dell'uscita della camera

Le modifiche vengono confermate da un segnale acustico e vengono applicate immediatamente.

Figura 11. Regolazione della temperatura in corrispondenza dell'uscita della camera




### Per impostare una temperatura in corrispondenza dell'uscita della camera > 39 °C

Per aumentare la **temperatura in corrispondenza dell'uscita della camera** oltre i 39 °C, occorre attivare il dispositivo di scorrimento due volte.

1. Toccare il dispositivo di scorrimento della **temperatura in corrispondenza dell'uscita della camera** posizionato sul valore attualmente impostato e trascinarlo verso destra fino a raggiungere il limite di 39 °C.
2. Toccare e trascinare nuovamente il dispositivo di scorrimento per impostare la temperatura in corrispondenza dell'uscita della camera su un valore superiore a 39 °C.

### Per impostare il gradiente di temperatura

- Toccare il dispositivo di scorrimento del **gradiente di temperatura** posizionato sul valore attualmente impostato:

  – Trascinarlo verso destra per ridurre il gradiente di temperatura

  – Trascinarlo verso sinistra per aumentare il gradiente di temperatura

Le modifiche vengono confermate da un segnale acustico e vengono applicate immediatamente.

Figura 12. Regolazione del gradiente di temperatura


Per esempio, se la temperatura da raggiungere in corrispondenza del raccordo a Y è 39 °C e la **temperatura in corrispondenza dell'uscita della camera** è impostata su 37 °C impostare il **gradiente di temperatura** su 2 °C.

## 4.4 Monitoraggio dell'umidificazione

I dati di monitoraggio sono disponibili nella finestra di **monitoraggio della temperatura**, accessibile in ogni momento.[55]

Vengono monitorati i parametri seguenti:

- Temperatura in corrispondenza dell'uscita della camera
- Gradiente di temperatura
- Temperatura in corrispondenza del raccordo a Y

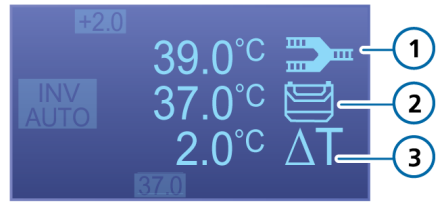
### 4.4.1 Visualizzazione dei parametri di monitoraggio aggiuntivi

**Per visualizzare la finestra di monitoraggio della temperatura**

- Premere (**finestra di monitoraggio della temperatura**).

  La finestra si chiude dopo 30 secondi o quando si preme nuovamente il pulsante.

Figura 13. Finestra di monitoraggio della temperatura




| | | | |
|---|---|---|---|
| 1 | Temp. corrente al raccordo a Y | 3 | Gradiente di temp. corrente |
| 2 | Temp. corrente all'uscita della camera | | |

[55] Se si utilizza l'umidificatore con un ventilatore Hamilton Medical che supporta il monitoraggio integrato dei due dispositivi, i dati dell'umidificatore vengono visualizzati sul display del ventilatore. Per maggiori dettagli, vedere il *Manuale operatore* del ventilatore.

## 4.5 Impostazioni della luminosità del display Giorno e Notte

La retroilluminazione del display dell'umidificatore risponde a due diverse impostazioni del display. Utilizzare tali impostazioni per impostare la luminosità del display.

**Per passare dall'impostazione Giorno all'impostazione Notte e viceversa**

- Premere e tenere premuto per 5 secondi.

Per determinare l'impostazione predefinita per la luminosità diurna e notturna, vedere la Sezione 7.

# 5 Risposta agli allarmi dell'umidificatore

Gli allarmi relativi all'umidificatore notificano all'operatore le condizioni per cui è richiesta attenzione. Gli allarmi sono indicati come segue:

- Graficamente sul display dell'umidificatore
- Con una sequenza di 3 o 5 segnali acustici
- Con la lampada di allarme sopra alla camera dell'acqua lampeggiante
- Se si utilizza l'umidificatore con un ventilatore Hamilton Medical che supporta il monitoraggio integrato dei due dispositivi, i messaggi di allarme vengono visualizzati anche sul display del ventilatore.[56]

Gli allarmi sono classificati nelle categorie alta priorità, media priorità o guasto tecnico, come indicato nella Tabella 8.

Vedere la Tabella 9 per un elenco completo degli allarmi.

[56] Non disponibile su tutti i ventilatori. Vedere il *Manuale operatore* del ventilatore.

Tabella 8. Indicatori di allarme

| Tipo di allarme | Indicatore di stato di allarme | Segnale acustico | Intervento richiesto |
|---|---|---|---|
| Priorità alta | Rosso, lampeggiante<br>Icona di allarme visualizzata sul display | Una sequenza di 5 beep, ripetuta fino alla reimpostazione dell'allarme | Il problema richiede un intervento immediato. |
| Priorità media | Giallo, lampeggiante<br>Icona di allarme visualizzata sul display | Una sequenza di 3 beep, ripetuta fino alla reimpostazione dell'allarme | Il problema richiede un rapido intervento. |
| Guasto tecnico | Rosso, lampeggiante<br>Sul display viene visualizzato un numero del guasto tecnico (TF). | Una sequenza di 3 beep, ripetuta fino alla reimpostazione dell'allarme | • Annotare il numero del guasto tecnico (TF) [57].<br>• Non utilizzare l'umidificatore.<br>• Richiedere un intervento tecnico sull'umidificatore. |

[57] L'elenco completo dei numeri di guasto tecnico (TF) è disponibile nel *Manuale tecnico di HAMILTON-H900*.

## 5.1 Tacitazione temporanea di un allarme

Il suono acustico è una componente di un allarme. Con la maggior parte degli allarmi, è possibile sospendere (tacitare) il suono dell'allarme acustico per due minuti alla volta.

### Per tacitare temporaneamente un allarme

- Premere  (**Pausa allarme acustico**) sul lato anteriore dell'umidificatore.

  L'allarme acustico dell'umidificatore viene tacitato per due minuti.

  Se si preme il tasto una seconda volta, la **Pausa allarme acustico** viene annullata.

La retroilluminazione del tasto **Pausa allarme acustico** è accesa con luce fissa rossa quando una **Pausa allarme acustico è attivata**.

Terminato il tempo senza aver risolto il problema, l'allarme suona di nuovo.

## 5.2 Regolazione dell'intensità dell'allarme

**⚠ AVVERTENZA**

Assicurarsi di impostare l'intensità degli allarmi acustici al di sopra del livello acustico ambientale. La mancata esecuzione di tale operazione può impedire di sentire e riconoscere le condizioni di allarme.

È possibile impostare l'intensità dell'allarme acustico.

Per impostazione predefinita, l'intensità è impostata su 5. Dopo lo spegnimento dell'umidificatore, l'intensità dell'allarme ritorna al valore predefinito.

### Per regolare l'intensità dell'allarme

1. Se necessario, premere  (**Accensione/Standby**) per mettere l'umidificatore in **Standby**.
2. Premere  per 3 secondi.

   Il display mostra l'impostazione corrente dell'intensità dell'allarme.
3. Regolare l'intensità dell'allarme utilizzando il dispositivo di scorrimento della **temperatura in corrispondenza dell'uscita della camera** (vedere la Figura 3).

   L'umidificatore conferma la nuova selezione emettendo un segnale acustico con la nuova intensità.
4. Premere  per confermare la selezione e tornare al normale funzionamento.

## 5.3 Identificazione e correzione degli allarmi

Nella Tabella 9 sono elencati gli allarmi dell'umidificatore, la loro rappresentazione grafica sull'umidificatore, la relativa descrizione e le azioni correttive suggerite.

Tabella 9. Allarmi di HAMILTON-H900

| Allarme | Icona di allarme | Descrizione | Intervento richiesto |
|---|---|---|---|
| **Priorità alta** | | | |
| Umidificatore inclinato |  | Inclinazione pericolosa dell'umidificatore.<br>L'umidificatore è posizionato a un angolo di 10° o superiore rispetto al pavimento. | • Verificare che l'umidificatore sia montato correttamente.<br>• Controllare il carrello del ventilatore.<br>• Utilizzare l'umidificatore con un'inclinazione rispetto al pavimento di al massimo 10°. |
| Temperatura alta |  | La temperatura del gas in corrispondenza dell'uscita della camera o sul raccordo a Y è al di sopra del valore impostato. | • Verificare se il circuito paziente è coperto dalle coperte del letto del paziente.<br>• Verificare se il circuito paziente o la camera dell'umidificatore è direttamente esposta alla luce del sole.<br>• Sostituire il circuito paziente. |
| Livello dell'acqua alto |  | Il livello dell'acqua nella camera dell'acqua è al di sopra del contrassegno di livello massimo. | • Svuotare la camera dell'umidificatore per ridurre il livello dell'acqua.<br>• Sostituire la camera dell'umidificatore.<br>• Utilizzare l'umidificatore con un'inclinazione rispetto al pavimento di al massimo 10°. |

| Allarme | Icona di allarme | Descrizione | Intervento richiesto |
|---|---|---|---|
| Guasto tecnico | Sul display viene visualizzato un numero del guasto tecnico (TF). | Guasto tecnico dovuto a un malfunzionamento dell'umidificatore. | • Controllare il funzionamento dell'umidificatore e tutte le connessioni.<br>• Sostituire l'umidificatore e richiedere un intervento tecnico.<br>• Se viene visualizzato un numero di guasto tecnico, annotarlo e fornirlo al momento dell'intervento tecnico sull'umidificatore. |
| **Priorità media** | | | |
| Temperatura bassa |  | La temperatura del gas in corrispondenza dell'uscita della camera dell'acqua o sul raccordo a Y è al di sotto del valore impostato. | • Attendere finché il sistema non si riscalda completamente (circa 30 minuti).<br>• Verificare che tutte le impostazioni siano corrette.<br>• Evitare il flusso d'aria diretta dal condizionamento dell'aria ecc. all'umidificatore e al circuito paziente. |
| Livello dell'acqua basso |  | Il livello dell'acqua nella camera è al di sotto del contrassegno di livello basso. | • Controllare il flacone dell'acqua e riempire il circuito.<br>• Se il flacone dell'acqua è vuoto, collegarne uno nuovo.<br>• Riempire o cambiare la camera dell'umidificatore vuota.<br>• Utilizzare l'umidificatore con un'inclinazione rispetto al pavimento di al massimo 10°. |
| Controllare la camera dell'acqua |  | Nessuna camera o camera dell'acqua non compatibile inserita. | Inserire una nuova camera dell'umidificatore e collegare il circuito paziente. |

| Allarme | Icona di allarme | Descrizione | Intervento richiesto |
|---|---|---|---|
| Controllare la branca sinistra o quella destra |  | Il display e gli indicatori di connessione indicano quale branca è difettosa.<br>• Branca non connessa o difettosa.<br>• Nessun flusso d'aria.<br>• Una branca del circuito non è connessa correttamente.<br>• La branca espiratoria BIANCA dell'umidificatore è connessa alla porta inspiratoria *Al paziente* del ventilatore. | • Inserire o riposizionare correttamente il circuito paziente.<br>• Sostituire il circuito paziente.<br>• Connettere la branca espiratoria AZZURRA dell'umidificatore alla porta inspiratoria *Al paziente* del ventilatore.<br><br>Quando l'indicatore di collegamento è:<br>*Verde*: la branca è inserita correttamente.<br>*Arancione*: l'umidificatore sta verificando il collegamento.<br>*Rosso*: il collegamento è difettoso o inesistente. |

# 6 Manutenzione

*Prima di procedere, rivedere le informazioni sulla sicurezza riportate nella Sezione 1.*

Questa sezione fornisce alcune informazioni sulle procedure e il programma di manutenzione dell'umidificatore, oltre a istruzioni su pulizia e disinfezione.

Tutte le procedure descritte in questa sezione devono essere eseguite dall'operatore.

Per ulteriori requisiti di manutenzione, contattare il rappresentante dell'assistenza tecnica Hamilton Medical. Tutti i documenti citati in questa sezione sono disponibili sul sito Web MyHamilton: https://www.hamilton-medical.com/MyHamilton

## 6.1 Pulizia, disinfezione e sterilizzazione

Pulire e disinfettare regolarmente i componenti dell'umidificatore utilizzando metodi di pulizia e soluzioni detergenti specifici per i singoli componenti.

È importante scegliere il metodo e i materiali appropriati per la pulizia e la disinfezione dell'umidificatore e dei suoi componenti, non solo per evitare di danneggiare l'apparecchiatura ma anche per evitare contaminazioni crociate.

Le informazioni sulla pulizia e la disinfezione sono presentate come segue:

- Nella Tabella 10 sono elencati i componenti rilevanti relativi all'umidificatore e sono indicati i metodi di pulizia e disinfezione che possono essere utilizzati per ciascuno di essi, la frequenza con cui occorre pulire/disinfettare ogni componente e gli agenti da utilizzare per la pulizia e la disinfezione.
- Per i set circuito paziente e le camere dell'acqua dell'umidificatore, vedere le *Istruzioni per l'uso* o la *Guida alla risterilizzazione*.

Quando si opera sui componenti dell'umidificatore utilizzando metodi di pulizia e agenti di pulizia, ricordare quanto segue:

- *Non* tentare procedure di decontaminazione, a meno che non diversamente specificato da Hamilton Medical.
- Anche se Hamilton Medical fornisce alcune linee guida relative agli agenti e alle concentrazioni da utilizzare, in caso di domande specifiche relative all'utilizzo di un particolare agente di pulizia o di disinfezione, contattare il produttore dell'agente.

Tabella 10. Metodi di pulizia e disinfezione dell'umidificatore

| Componente | Frequenza | Metodo di pulizia/ disinfezione | Agenti di pulizia |
|---|---|---|---|
| Parte esterna dell'umidificatore, comprendente:<br>• Involucro esterno<br>• Display<br>• Piastra riscaldante<br>• Cavi di alimentazione<br>• Sistemi di montaggio | Dopo ogni utilizzo sul paziente o secondo necessità. | Strofinare con un panno inumidito con una soluzione di pulizia/disinfezione approvata e registrata. | Salviette germicide Super Sani-Cloth<br>CaviWipes |

## 6.2 Manutenzione preventiva

La manutenzione preventiva dell'umidificatore deve essere eseguita da personale tecnico autorizzato da Hamilton Medical, secondo le istruzioni fornite nel *Manuale tecnico di HAMILTON-H900*.

# 7 Configurazione

L'umidificatore viene consegnato con una configurazione predefinita per diverse impostazioni, raggruppate per gruppo pazienti.

È possibile modificare le impostazioni predefinite seguenti nella modalità di **configurazione**:

- **Temperatura in corrispondenza dell'uscita della camera**
- **Gradiente di temperatura**
- Modalità operativa all'avvio (**INV/NIV/HiFlow**)
- Attivazione/disattivazione **Aumento della temperatura di espirazione**
- Impostazioni luminosità retroilluminazione **Giorno/Notte**

## 7.1 Accesso alla modalità di configurazione

È possibile accedere alla modalità **di configurazione** quando l'umidificatore è in modalità **Standby**.

**Per accedere alla modalità di configurazione**

1. Se necessario, premere  per attivare la modalità **Standby**.
2. Premere e tenere premuti contemporaneamente  e  .

   Prestare attenzione a premere  per primo.

   Dopo 5 secondi, si apre la finestra di **configurazione**.

L'umidificatore è ora in modalità di **configurazione**.

## 7.2 Modifica delle impostazioni di configurazione

Le impostazioni personalizzate restano attive finché non vengono modificate o finché non vengono ripristinate le impostazioni di fabbrica.

Nella modalità di **configurazione**, si utilizzano i pulsanti presenti sul pannello anteriore dell'umidificatore per spostarsi da una vista all'altra e per effettuare le selezioni desiderate.

La Tabella 11 illustra come muoversi tra le pagine di **configurazione** e come modificare le impostazioni.

Per un esempio di modifica di un'impostazione, vedere la procedura descritta di seguito relativa alla modifica delle impostazioni predefinite per il **gradiente di temperatura**.

Per l'elenco delle impostazioni di configurazione, vedere la Sezione 9.6.

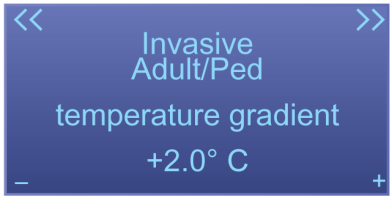
Tabella 11. Pulsanti di navigazione della modalità di configurazione

| Pulsante | Descrizione |
|---|---|
|  | Spostamento in avanti da una vista all'altra |
|  | Spostamento indietro da una vista all'altra |
|  | Aumento di un valore |
|  | Diminuzione di un valore |
|  | Salvataggio delle modifiche e chiusura della modalità di **configurazione** |

**Esempio: modifica del gradiente di temperatura**

**Per modificare l'impostazione predefinita del gradiente di temperatura per la modalità invasiva e il gruppo Adulto/Ped.**

1. Nella modalità di **configurazione**, premere Exp. finché non si visualizza la vista relativa a **Invasive, Adult/Ped, Temperature gradient**




2. Premere per aumentare il valore o premere Auto per diminuirlo.
3. Al termine, premere per salvare le modifiche e chiudere la modalità di **configurazione**.

## 7.3 Ripristino delle impostazioni di fabbrica predefinite

È possibile ripristinare le impostazioni di fabbrica in qualunque momento.

**Per ripristinare le impostazioni di fabbrica predefinite**

1. Nella modalità di configurazione, premere ripetutamente Exp. finché non si visualizza la finestra di **Reset all custom defaults**.
2. Premere Auto.

Vengono ripristinate le impostazioni predefinite di fabbrica.

# 8 Componenti e accessori

In questa sezione sono elencati i componenti e gli accessori disponibili per l'umidificatore HAMILTON-H900.

Per informazioni aggiuntive, consultare il catalogo dei prodotti di Hamilton Medical o contattare il rappresentante Hamilton Medical.

Tabella 12. Componenti e accessori dell'umidificatore

| PN | Descrizione |
|---|---|
| 260161 | HAMILTON-BC8022, set circuito paziente, branca doppia, riscaldato, con camera dell'acqua |
| 260186 | HAMILTON-BC4022, set circuito paziente, branca singola, riscaldato, con camera dell'acqua |
| 260185 | HAMILTON-BC8010, set circuito paziente, branca doppia, riscaldato, con camera dell'acqua e prolunga per incubatrice |
| 260187 | HAMILTON-BC4010, set circuito paziente, branca singola, riscaldato, con camera dell'acqua e prolunga per incubatrice |
| 260196 | HAMILTON-HC322, camera dell'acqua, monouso |
| 260197 | HAMILTON-HC310, camera dell'acqua, monouso |

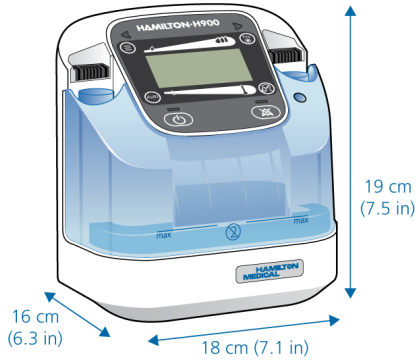
# 9 Specifiche

## 9.1 Caratteristiche fisiche

Tabella 13. Caratteristiche fisiche

| Dimensione | Specifiche |
|---|---|
| Peso | Umidificatore (con camera dell'acqua vuota): 2,5 kg |
| Dimensioni | Vedere la Figura 14 |

Figura 14. Dimensioni di HAMILTON-H900



## 9.2 Requisiti ambientali

Tabella 14. Requisiti ambientali

| Ambiente | | Specifiche |
|---|---|---|
| Temperatura | Operativa: | da 10 °C a 40 °C |
| | Stoccaggio: | da -20 °C a 60 °C |
| | | Temperatura ambiente consigliata: da 18 °C a 26 °C |
| Altitudine | | Fino a 4.000 m |
| Pressione atmosferica | Operativa e di stoccaggio: | da 61 kPa a 106 kPa |
| Umidità relativa | Operativa: | dal 30% al 95%, senza condensa |
| | Stoccaggio: | dal 10% al 95%, senza condensa |
| Grado di protezione contro l'ingresso di acqua | | IP21 |
| Temperatura di ingresso del gas | | Da 18 °C a 31 °C (consigliata) |

## 9.3 Specifiche elettriche

Tabella 15. Specifiche elettriche

| Codice articolo | Alimentazione | Consumo elettrico |
|---|---|---|
| 950001 (230 V) | Da 220 a 240 V<br>50/60 Hz | 283 VA |
| 950004 (115 V) | Da 110 a 127 V<br>50/60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50/60 Hz | 268 VA |
| Equipotenziale | Terminale per il collegamento di un conduttore equipotenziale secondo la normativa DIN 42801 | |

## 9.4 Impostazioni dei comandi

Tabella 16. Impostazioni e range dei comandi

| Parametro o impostazione (unità) | Modalità | Range | Impostazione predefinita | Risoluzione |
|---|---|---|---|---|
| Temperatura in corrispondenza dell'uscita della camera (°C) | INV | Da 35 a 41 | 37,0 | 0,5 |
| | NIV | Da 30 a 35 | 31,0 | 0,5 |
| | HiFlow | Da 33 a 37 | 35,0 | 2 |
| Gradiente di temperatura (°C) | INV | Da -2 a 3 | Adulto/Ped.: 2<br>Neonatale: 3 | 0,5 |
| | NIV | Da -2 a 3 | Adulto/Ped.: 2<br>Neonatale: 3 | 0,5 |
| | HiFlow | -- | 2 | -- |
| Temperatura risultante max. delle vie aeree (raccordo a Y)[58] (°C). | INV | Da 33 a 42 | -- | -- |
| | NIV | Da 28 a 38 | -- | -- |
| | HiFlow | Da 35 a 39 | -- | -- |
| Aumento della temperatura di espirazione | Tutte le modalità | On, Off | On | -- |
| Impostazione della luminosità del display | Tutte le modalità | Da 1 a 5 | Giorno: 5<br>Notte: 2 | 1 |

## 9.5 Parametri monitorizzati

Tabella 17. Parametri monitorizzati, range e accuratezza

| Parametro (unità di misura) | Range | Accuratezza |
|---|---|---|
| Temperatura in corrispondenza dell'uscita della camera (°C) | Da 10 a 60 | Da 10 a 30: ±1<br>Da 30 a 41: ±0,5<br>Da 41 a 60: ±1 |
| Temperatura in corrispondenza del raccordo a Y (°C) | Da 28 a 43 | ±0,5 |

[58] La temperatura delle vie aeree è limitata a 42 °C dall'umidificatore.

## 9.6 Configurazione

Tabella 18. Specifiche di configurazione

| Parametro | Modalità | Range di configurazione | Impostazione predefinita |
|---|---|---|---|
| Temperatura in corrispondenza dell'uscita della camera (°C) | INV | Da 35 a 39 | 37,0 |
| | NIV | Da 30 a 35 | 31,0 |
| | HiFlow | 33, 35, 37 | 35,0 |
| Gradiente di temperatura (°C) | INV | Da 0 a 3 | Adulto/Ped.: 2<br>Neonatale: 3 |
| | NIV | Da 0 a 3 | Adulto/Ped.: 2<br>Neonatale: 3 |
| | HiFlow | Da 0 a 3 | 2 |
| Modalità di avvio | -- | Invasiva, non invasiva, HiFlow | Invasiva |
| Impostazione della luminosità del display | Tutte le modalità | Da 1 a 5 | Giorno: 5<br>Notte: 2 |

## 9.7 Dati tecnici sulle prestazioni

Tabella 19. Dati tecnici sulle prestazioni

| Descrizione | Specifica | | |
|---|---|---|---|
| Flussi[59] | Invasiva: | Fino a 60 l/min | |
| | Non invasiva: | Fino a 120 l/min | |
| | HiFlow: | Fino a 120 l/min | |
| Tempo di riscaldamento | Meno di 30 minuti | | |
| Umidità | A una temperatura ambiente tra 18 °C e 26 °C: | | |
| | Invasiva: | Impostazione della temperatura fra 37 °C e 41 °C | Umidità minima: 33 mg H2O/l |

[59] Per conoscere i flussi minimi, vedere le *Istruzioni per l'uso* del circuito paziente.

| Descrizione | Specifica | | |
|---|---|---|---|
| Umidità | Non invasiva: | Impostazione della temperatura fra 31 °C e 35°C | Umidità minima: 12 mg H2O/l |
| | HiFlow: | Flusso ≤ 60 l/min | Umidità minima: 33 mg H2O/l |
| | | Flusso > 60 l/min | Umidità minima: 12 mg H2O/l |
| Specifiche per il riscaldamento in Standby | Circuiti paziente riscaldati: | Temperatura in corrispondenza del raccordo a Y limitata a 30 °C | |
| Display | 3 pollici / 64 x 128 pixel, display a matrice di punti inversa (retroilluminato) | | |
| Pausa allarme acustico | 120 secondi | | |
| Intensità dell'allarme[60] | Intervallo = da 1 a 8. Valore predefinito = 5 | | |

## 9.8 Prestazioni essenziali

Le temperature applicate al gas respiratorio e ai circuiti paziente devono essere monitorate e mantenute entro le impostazioni specificate.

Se la temperatura supera i limiti specificati, l'umidificatore deve rilevare l'evento e informare l'utente mediante un allarme.

## 9.9 Descrizione funzionale del sistema di umidificazione

L'umidificatore HAMILTON-H900 è progettato per riscaldare e umidificare i gas respiratori durante la ventilazione meccanica. Il gas respiratorio viene riscaldato e umidificato passando attraverso una camera parzialmente riempita di acqua riscaldata.

L'umidificatore comprende due sistemi di riscaldamento controllati mediante sensori.

- *Piastra riscaldante*: riscalda l'acqua nella camera dell'acqua.
- *Sistema di riscaldamento per circuito paziente integrato*: riscalda le branche del circuito paziente per evitare la formazione di condensa.

La temperatura del gas respiratorio viene monitorata in corrispondenza dell'uscita della camera e all'estremità della branca del circuito lato paziente.

[60] Volume a 1 metro di distanza dall'umidificatore. Un'impostazione di 1 = 50 dB(A), 5 (predefinita) = 60 dB(A) e 8 = 65 dB(A), con un'accuratezza pari a ±6 dB(A).

## 9.10 Simboli presenti sulle etichette e sulla confezione del dispositivo

| Simbolo | Descrizione |
|---|---|
|  | Seguire le *Istruzioni per l'uso* |
| REF | Numero di riferimento |
| SN | Numero di serie |
| QTY | Quantità |
|  | Produttore |
|  | Data di fabbricazione |
|  | Parte applicata di tipo BF (classificazione degli apparecchi elettromedicali: tipo BF, secondo le specifiche della normativa IEC 60601-1) |
|  | Smaltire secondo le disposizioni della Direttiva del Consiglio Europeo 2002/96/CE o WEEE (Waste Electrical and Electronic Equipment, rifiuti di apparecchiature elettriche ed elettroniche) |
|  | Il marchio TÜV NRTL con gli indicatori "C" e "US" indica che il prodotto è conforme ai requisiti di sicurezza stabiliti dalle autorità canadesi e statunitensi |

| Simbolo | Descrizione |
|---|---|
|  | Equipotenziale |
|  | Avvertenza: superficie calda.<br>La piastra riscaldante e la parte inferiore della camera possono raggiungere una temperatura superiore a 85 °C. |
| CE 0197 | Marchio di Conformità CE: marchio di approvazione che garantisce la conformità dell'apparecchio alla Direttiva del Consiglio Europeo 93/42/CEE sui dispositivi medici |
| IP21 | Protetto dalla caduta verticale di gocce d'acqua e dalla penetrazione di corpi solidi di dimensioni superiori a 12,5 mm. |
| max | Simbolo del livello di riempimento sulla camera dell'acqua |
|  | Interfaccia seriale RS-232 per la comunicazione con i ventilatori Hamilton Medical |
|  | MR unsafe (Non sicuro per la risonanza magnetica)<br>L'umidificatore HAMILTON-H900 presenta dei rischi inaccettabili per il paziente, il personale medico o altre persone all'interno dell'ambiente di risonanza magnetica. |

| Simbolo | Descrizione |
|---|---|
|  | RoHS cinese |
|  | Sonda termica<br>Segna la posizione della sonda termica sul circuito paziente. |

## 9.11 Standard e approvazioni

Il sistema di umidificazione è conforme alle parti applicabili dei seguenti standard, elencati nella Tabella 20.

Tabella 20. Standard e approvazioni, versioni valide

| |
|---|
| IEC 60601-1:2005/A1:2012 |
| IEC 60601-1-2:2014 |
| IEC 60601-1-6:2010/A1:2013 |
| IEC 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| IEC 62304:2006/A1:2015 |
| IEC 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Smaltimento

Il dispositivo deve essere smaltito secondo i protocolli ospedalieri e la direttiva 2002/96/CE.

I circuiti paziente e le camere dell'umidificatore devono essere smaltiti secondo le *Istruzioni per l'uso* fornite con i set circuito paziente.

## 9.13 Garanzia

GARANZIA LIMITATA

LA GARANZIA DESCRITTA IN QUESTO CONTRATTO SOSTITUISCE QUALSIASI ALTRA GARANZIA, ESPRESSA O IMPLICITA, IVI INCLUSA QUALSIASI GARANZIA DI COMMERCIABILITÀ E IDONEITÀ PER SCOPI PARTICOLARI. IL PRODUTTORE SI ASSUME LA RESPONSABILITÀ DELLE GARANZIE IMPLICITE PER LA DURATA DELLA PRESENTE GARANZIA LIMITATA.

Hamilton Medical garantisce che i propri prodotti vengono forniti privi di difetti di materiale e lavorazione. La presente garanzia non copre gli elementi monouso. Gli elementi monouso e i prodotti di consumo devono essere utilizzati una sola volta o un numero limitato di volte e devono essere sostituiti regolarmente per garantire il corretto funzionamento del prodotto, secondo il Manuale operatore.

A eccezione di quelle specificate in questa garanzia, Hamilton Medical non riconosce alcuna responsabilità relativamente al prodotto, fra cui, senza alcun limite, obblighi e/o responsabilità per presunta negligenza, o per responsabilità assoluta. In nessun caso la società potrà essere ritenuta responsabile di danni incidentali o consequenziali, diretti o contingenti.

La presente garanzia limitata è da considerarsi nulla e non può essere applicata nei seguenti casi:

1. Se l'installazione e la connessione del prodotto non sono state eseguite da un rappresentante locale autorizzato di Hamilton Medical secondo le istruzioni fornite da Hamilton Medical o da un rappresentante di Hamilton Medical.

2. Se non è possibile dimostrare che il danno si è verificato o la riparazione è stata eseguita nel periodo coperto dalla garanzia.
3. Se il numero di serie è stato modificato, cancellato o eliminato, e in assenza di fattura o documento che indichi la data di acquisto del prodotto.
4. Se i difetti sono dovuti all'utilizzo improprio, negligenza o incidenti, oppure a riparazioni, modifiche, cambiamenti o sostituzioni effettuati da personale non autorizzato (queste operazioni devono essere eseguite negli impianti Hamilton Medical o da un centro di assistenza tecnica autorizzato, o da un rappresentante dell'assistenza tecnica autorizzato).
5. Se il prodotto è stato in qualsiasi modo modificato senza la previa autorizzazione scritta di Hamilton Medical.
6. Se il prodotto è o è stato utilizzato in qualsiasi modo non specificato nella sezione "Uso previsto".
7. Se il prodotto non è stato utilizzato da personale appositamente addestrato sotto la supervisione di un medico.

Le sostituzioni e/o le riparazioni effettuate in base alla presente garanzia limitata non sono coperte da nuova garanzia, ma vengono incluse nel periodo rimanente della garanzia limitata originale. La garanzia dei componenti riparati e/o sostituiti non supera la garanzia limitata del dispositivo.

Per ottenere l'assistenza tecnica prevista dalla presente garanzia limitata, il ricorrente deve informare prontamente il rivenditore Hamilton Medical nel proprio Paese, fornendo i seguenti dati: tipo di problema, numero di serie e data di acquisto del prodotto.

A eccezione dei casi elencati, Hamilton Medical non è responsabile di danni, rivendicazioni o responsabilità fra cui, ma non esclusivamente, lesioni personali fisiche oppure danni incidentali, consequenziali o speciali. Hamilton Medical non è neppure responsabile di danni, rivendicazioni o responsabilità fra cui, ma non esclusivamente, lesioni personali fisiche, incidentali, consequenziali o danni speciali derivanti dall'uso improprio del dispositivo o dalla mancata osservanza di qualsivoglia disposizione presente in questo manuale.

### 9.13.1 Varie

Saranno applicabili i termini e le condizioni generali di Hamilton Medical. Il presente accordo sarà governato dalle leggi della Svizzera e interpretato conformemente a esse, e potrà essere applicato da entrambe le parti sotto la giurisdizione del tribunale di Chur, Svizzera.

# Instruções de uso

## HAMILTON-H900

2021-01-11

624431/09

**Fabricante**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz,
Suíça
Telefone: (+41) 58 610 10 20
Fax: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Prefácio

Certifique-se de que lê a documentação antes de usar o dispositivo ou acessórios.

### Convenções usadas neste guia

Neste manual:

- Os nomes dos botões são indicados a **negrito**.
- Os gráficos mostrados podem não corresponder exatamente ao que está visualizando em sua tela.
- Alguns recursos não estão disponíveis em todos os mercados.

As mensagens de segurança são exibidas da seguinte forma:

**⚠ AVISO**

Alerta o usuário da possibilidade de lesão, morte ou outras reações adversas graves associadas ao uso ou uso incorreto do dispositivo.

**⚠ ADVERTÊNCIA**

*Alerta o usuário da possibilidade de um problema com o dispositivo associado ao seu uso ou uso incorreto, como mau funcionamento do dispositivo, falha do dispositivo, danos ao dispositivo ou danos à outra propriedade.*

***ATENÇÃO***

Enfatiza informações de particular importância.

Nas tabelas, as mensagens de segurança são indicadas da seguinte forma:

**⚠ AVISO!**

**⚠ ADVERTÊNCIA!**

**ATENÇÃO!**

Para descarregar a versão mais recente deste manual ou outros documentos, visite o website MyHamilton: https://www.hamilton-medical.com/MyHamilton

A Hamilton Medical coloca ao seu dispor o Hamilton Medical College, que proporciona uma variedade de módulos de formação gratuitos. Para se registrar, visite http://college.hamilton-medical.com/

**⚠ ADVERTÊNCIA**

*(Somente EUA): Segundo as leis federais, este dispositivo só pode ser vendido por um médico ou por ordem de um médico.*

### Uso pretendido

O umidificador HAMILTON-H900 destina-se ao condicionamento de gases respiratórios durante a ventilação mecânica invasiva e não invasiva.

O dispositivo foi projetado para uso no ambiente institucional e hospitalar onde profissionais de cuidados de saúde forneçam cuidados aos pacientes.

O umidificador HAMILTON-H900 é um dispositivo médico e deve ser utilizado por indivíduos treinados e qualificados, sob orientação de um médico e respeitando os limites das especificações técnicas apresentadas.

# 1 Informação de segurança

Esta seção fornece informação de segurança relacionada com a configuração, operação e manutenção do umidificador.

**Verifique cuidadosamente todas as partes desta seção de segurança antes de configurar e usar o umidificador.**

**Certifique-se de que verifica as Instruções de uso antes de usar o umidificador.**

**Certifique-se de que lê as Instruções de uso fornecidas com os dispositivos e acessórios usados em conjunto com o umidificador antes de usá-los.**

Se tiver questões sobre qualquer informação contida no presente manual, contate seu representante ou a equipe de assistência técnica Hamilton Medical.

## 1.1 Suscetibilidade eletromagnética

**⚠ AVISO**

- **RM INSEGURA**. Mantenha-se afastado de equipamentos de imagem por ressonância magnética (IRM). O HAMILTON-H900 representa riscos inaceitáveis para o paciente, a equipe médica ou qualquer outra pessoa no ambiente de RM.
- O funcionamento do umidificador pode ser afetado pela operação de equipamento cirúrgico de alta frequência, microondas, ondas curtas ou fortes campos magnéticos na proximidade.
- Para evitar maiores emissões, menor imunidade ou interrupção do funcionamento do umidificador HAMILTON-H900 ou de quaisquer acessórios, utilize apenas os acessórios ou cabos mencionados explicitamente neste manual ou no catálogo de produtos HAMILTON-H900.
- Todos os equipamentos conectados a dispositivos eletromédicos devem atender às normas IEC ou ISO cabíveis (por exemplo, IEC 60950 para equipamentos de processamento de dados). Além disso, todas as configurações devem atender às exigências para sistemas eletromédicos (ver IEC 60601-1, cláusula 16).
- Qualquer indivíduo que conectar outros equipamentos a um equipamento eletromédico estará configurando um sistema médico e, portanto, será responsável por garantir que o sistema atende aos requisitos cabíveis para dispositivos eletromédicos. Note que a legislação local tem prioridade sobre as exigências descritas acima. Se tiver questões sobre como proceder, consulte seu representante ou o departamento de assistência técnica da Hamilton Medical.
- O umidificador *não* está protegido contra os efeitos de descarga de um desfibrilador cardíaco.

***ATENÇÃO***

- O umidificador HAMILTON-H900 requer precauções especiais em relação à CEM (compatibilidade eletromagnética), e deve ser instalado e colocado em funcionamento de acordo com a informação sobre a CEM que está disponível nas *diretrizes relativas à CEM para o umidificador HAMILTON-H900*.
- Equipamentos de comunicação por RF móveis ou portáteis podem interferir com o umidificador HAMILTON-H900.

## 1.2 Energia elétrica

**⚠ AVISO**

- Para minimizar o risco de choque elétrico, conecte o cabo de energia do umidificador em um receptáculo de energia aterrado apropriado. É da responsabilidade do hospital garantir que o receptáculo está corretamente aterrado (terra).
- *Não* utilize se o cabo de energia estiver danificado.
- Se a voltagem estiver incorreta, existir queda de energia ou desconexão da rede elétrica, o umidificador emite um som sibilante sonoro. Desligue imediatamente o dispositivo e assegure a voltagem correta.
- Assegure que é usada a voltagem correta.

## 1.3 Incêndio e outros riscos

**⚠ AVISO**

*Não* use o umidificador em áreas perigosas ou com gases inflamáveis.

## 1.4 Informações gerais sobre a operação e configuração

**⚠ AVISO**

- Antes de usar o umidificador no paciente, garanta que o circuito de respiração está conectado ao respirador corretamente da seguinte forma:

  – A alça inspiratória azul está conectada à porta inspiratória *Para o paciente*.

  – A alça expiratória branca está conectada à porta expiratória *Do paciente*.
- Use somente peças e acessórios especificados na Seção 8. Isso garante a operação correta do umidificador e evita possíveis lesões ao paciente.
- Não utilize o umidificador a uma altitude acima dos 4.000 metros ou fora de uma gama de temperatura de 10 °C a 40 °C. Utilizar o umidificador acima desta altitude ou fora desta gama de temperatura pode interferir na qualidade do tratamento ou lesionar o paciente.
- Configurações de temperatura ou umidade incorretas podem ter consequências para o paciente.
- *Não* utilize o umidificador durante a transferência de um paciente em ventilação fora do hospital.
- LIGUE o umidificador *após* ligar o respirador.
- DESLIGUE o umidificador *antes* de desligar o respirador.
- Não cubra as células de medição por infravermelhos do umidificador.
- O modo invasivo (**INV**) *só* pode ser usado com pacientes entubados e traqueostomizados.
- Tome precauções adicionais em caso de reações alérgicas.
- Verifique regularmente o circuito de respiração quanto a condensação e drene-o se necessário.
- O desempenho do umidificador do dispositivo pode ser afetado pela utilização simultânea de um nebulizador.
- *Não* toque a placa quente ou o fundo da câmara de água. As superfícies podem atingir uma temperatura superior a 85 °C. Estas superfícies quentes irradiam calor.

**⚠ ADVERTÊNCIA**

- *Coloque o umidificador em um local que permita a fácil desconexão da fonte de energia principal.*
- *Utilize apenas peças e acessórios especificados no Seção 8 e no catálogo de produtos HAMILTON-H900, ou os que são especificados como compatíveis com este umidificador.*

  *Isso garante que o umidificador funciona corretamente, evita a degradação do desempenho e mantém a garantia vigente.*
- *Se o umidificador for desligado e, em seguida, ligado, ele irá iniciar automaticamente no modo Invasivo (INV), exceto se estiver configurado de outra forma.*
- *Verifique o kit de respiração quanto a danos antes do uso. Descarte o kit de respiração se houver qualquer sinal de danos.*
- *O elemento de aquecimento do umidificador e os fios aquecedores são automaticamente ligados quando a câmara de água e os circuitos de respiração são corretamente montados, e o umidificador está ligado ou em modo **Em Espera**.*
- *Se a temperatura ambiente ou a temperatura do gás de admissão e/ou a taxa de fluxo se encontrar fora do intervalo recomendado, pode não ser possível alcançar os níveis de umidade fisiológica.*
- *O umidificador ainda pode estar energizado, mesmo que a tela não esteja iluminada. Consulte a Tabela 1.*

***ATENÇÃO***

- Antes de usar um kit de respiração em um paciente, você tem que executar um teste de vazamento. Se esse teste falhar, ele poderá ser repetido uma vez. Se o teste falhar após duas tentativas consecutivas, o kit de respiração deverá ser substituído por um novo.
- A formação de uma ligeira condensação dependente da respiração (névoa) na alça, tubo flexível ou sensor fluxo indica que a umidade está corretamente configurada.
- Todas as ações emitem um som.

## 1.5 Circuitos de respiração e câmara de água

**⚠ AVISO**

- A falha em conectar corretamente o circuito de respiração ao respirador pode lesionar o paciente.
- Para evitar a desconexão acidental do circuito de respiração durante o uso ou transporte, use somente circuitos de respiração que cumprem a norma ISO 5367 ou ISO 80601-2-74.
- Abasteça a câmara de água somente com água estéril, desmineralizada e em conformidade com as exigências do hospital em termos de higiene.
- Não incline a câmara de água.
- Não encha nenhum medicamento na câmara do umidificador.
- Certifique-se de que o nível de água não excede o nível máximo de enchimento.

***ATENÇÃO***

- Se o umidificador não detectar o circuito de respiração, substitua os componentes.
- A água de abastecimento não deverá estar a uma temperatura superior a 37 °C.
- Assegure que o fornecimento de água para a câmara está em perfeito estado de funcionamento.
- Certifique-se de que o umidificador é colocado no modo **Em Espera** antes de desconectar quaisquer componentes.

## 1.6 Posicionamento do umidificador e do circuito de respiração

**⚠ AVISO**

- O umidificador deverá estar *sempre* posicionado abaixo do nível do paciente.
- *Não* opere o umidificador a um ângulo superior a 10° relativamente ao chão.
- Certifique-se de que encaminha o circuito de respiração do umidificador para o paciente sem tensão nem dobras.
- As alças de respiração aquecidas *não* devem ser colocadas diretamente sobre a pele do paciente.
- Se o umidificador for utilizado ao lado ou sobre outro equipamento eletromédico, verifique se ele funciona normalmente na configuração em que será utilizado.
- Coloque o circuito de respiração de modo que o condensado do líquido não alcance o paciente.
- Fixe os circuitos de respiração ou os clipes de tubos de forma adequada para evitar forças mecânicas no tubo ET.

***ATENÇÃO***

- Verifique a estabilidade de todas as conexões antes do uso.
- Todos os conectores da alça no umidificador combinam conexões elétricas com conectores do circuito de respiração. Assegure a orientação adequada dos contatos elétricos para que correspondam ao elemento de conexão no umidificador.

## 1.7 Monitoração e alarmes

***ATENÇÃO***

- Quando um alarme estiver ativo, a tela alterna entre exibir os símbolos dos alarmes ativos e a temperatura atual da saída da câmara.
- Ao desligar o umidificador, a sonoridade dos alarmes regressa ao valor padrão de 5.
- Todos os alarmes técnicos, informação técnica detalhada e os procedimentos de manutenção estão descritos no *Manual de manutenção do HAMILTON-H900*.

## 1.8 Manutenção

**⚠ AVISO**

- *Não* são permitidas modificações ao umidificador.
- Desconecte *sempre* o umidificador da energia elétrica antes de limpar e desinfetar para reduzir o risco de choque elétrico.

**⚠ ADVERTÊNCIA**

- *Manuseie os circuitos de respiração e a câmara de água usados como produtos contaminados de acordo com as leis e regulamentos locais ou os procedimentos internos do hospital.*
- *Para garantir uma boa manutenção e evitar possíveis lesões físicas, a manutenção do umidificador deve ser feita apenas pela equipe de manutenção autorizada da Hamilton Medical, usando as informações fornecidas no Manual de manutenção do HAMILTON-H900.*
- *Use somente peças de reposição fornecidas pela Hamilton Medical.*
- *Não tente fazer procedimentos de manutenção diferentes dos descritos no Manual de manutenção do HAMILTON-H900.*
- *Utilize somente agentes de limpeza aprovados para a limpeza e desinfecção.*

***ATENÇÃO***

- Para obter informações específicas sobre a limpeza, desinfecção e esterilização de acessórios e componentes autoclaváveis (reutilizáveis), consulte o respectivo *Guia de reprocessamento* e as *Instruções de uso* anexadas a cada peça.
- (*Somente EUA*) Utilize somente agentes de limpeza registrados na EPA para a limpeza e desinfecção.

# 2 Visão geral

Este guia fornece informações sobre a configuração e o uso do umidificador HAMILTON-H900.

O umidificador foi concebido para ser utilizado com respiradores Hamilton Medical, bem como respiradores de terceiros.

## 2.1 Acerca do umidificador HAMILTON-H900

O umidificador HAMILTON-H900 aquece e umidifica gases respiratórios para pacientes adultos, pediátricos e neonatais.

Este suporta os seguintes modos respiratórios comuns:

- Ventilação invasiva
- Ventilação não invasiva
- Tratamento de oxigênio de alto fluxo

O sistema inclui o invólucro do umidificador, tela, controles, câmara de água, placa aquecedora e conexões elétricas para um circuito de respiração aquecido.

Este oferece os seguintes recursos principais:

- Controles de umidade e temperatura ajustáveis
- Recursos de alarme e monitoração
- Integração de controles e dados monitorados do umidificador com respiradores Hamilton Medical suportados[61]

[61] Não disponível em todos os mercados.

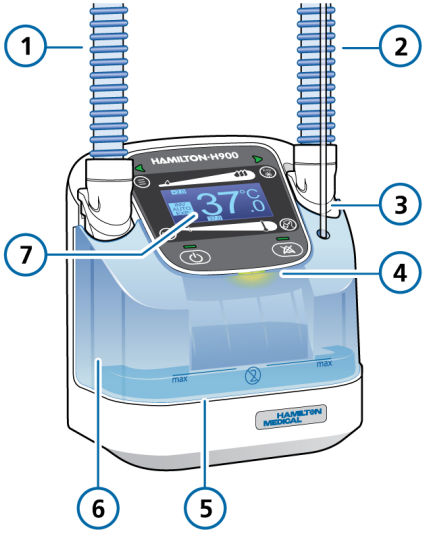
## 2.2 Descrições físicas

Esta seção dá uma visão geral do umidificador e kits de respiração relacionados.

### 2.2.1 Acerca do umidificador

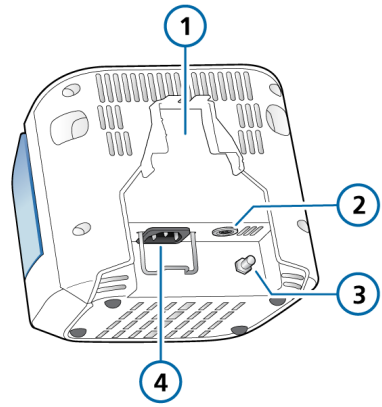
As Figuras 1 a 5 fornecem uma visão geral do umidificador.

Figura 1. Umidificador HAMILTON-H900, vista frontal




| | | | |
|---|---|---|---|
| 1 | Alça inspiratória do respirador (azul) | 5 | Placa aquecedora |
| 2 | Alça inspiratória do paciente (azul) | 6 | Câmara de água |
| 3 | Tubo de alimentação de água | 7 | Painel frontal e tela |
| 4 | Indicador de alarme visual | | |

Figura 2. Umidificador HAMILTON-H900, vista traseira




| | | | |
|---|---|---|---|
| 1 | Encaixe do suporte de montagem | 3 | Terminal de equalização potencial |
| 2 | Porta RS-232 | 4 | Tomada elétrica CA |

### 2.2.2 Acerca da tela principal

Você pode acessar diretamente todas as configurações, modos, alarmes e controles a partir da tela principal durante a umidificação.

As Figuras 3 até 5 ilustram a tela, indicadores e controles do painel frontal.

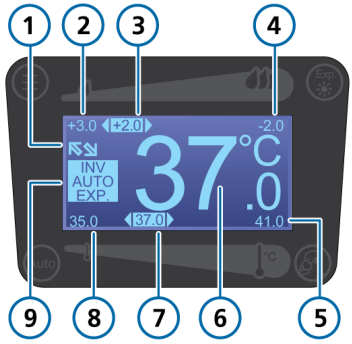
Figura 3. Umidificador HAMILTON-H900, controles do painel frontal


| | | | |
|---|---|---|---|
| 1 | Botão da janela Monitoração de temp. | 5 | Tecla Pausar áudio |
| 2 | Controles deslizantes da temp. | 6 | Tecla Energia/Em Espera |
| 3 | Botão Aum. da temp. exp. | 7 | Botão Auto |
| 4 | Botão do modo INV/NIV/HiFlow | 8 | Tela (consulte a Figura 5) |

Figura 4. Umidificador HAMILTON-H900, indicadores de estado do painel frontal


| | | | |
|---|---|---|---|
| 1 | Indicadores de estado da conexão à alça | 3 | Indicador de estado Energia/Em Espera |
| 2 | Indicador de Pausar áudio | | |

Figura 5. Umidificador HAMILTON-H900, tela




1 Conexão do respirador ativada
2 Configuração do gradiente máx. de temp.
3 Configuração do gradiente de temp.
4 Configuração do gradiente mín. de temp.
5 Configuração da temp. máx. da saída da câmara
6 Temp. atual da saída da câmara
7 Configuração da temp. da saída da câmara
8 Configuração da temp. mín. da saída da câmara
9 Configurações/ modos ativos

*Todos os elementos na tela são exibidos somente para fins ilustrativos; durante a operação, os mesmos podem não surgir todos ao mesmo tempo.*

### 2.2.3 Acerca dos circuitos de respiração do umidificador

O umidificador HAMILTON-H900 suporta uma variedade de circuitos de respiração de alça dupla e única para pacientes adultos, pediátricos e neonatais.

Para obter informações detalhadas, consulte as *Instruções de uso* do seu circuito de respiração.

### 2.2.4 Acerca dos indicadores de estado no umidificador

Os indicadores na frente do umidificador indicam informações importantes sobre o estado do umidificador. Consulte a Figura 4.

Tabela 1. Indicadores de estado

| Símbolo | Descrição |
|---|---|
| **Tecla Energia/Em Espera com indicador de estado** | |
|  | *Verde*: O umidificador está em funcionamento. |
|  | *Laranja*: O umidificador está Em Espera. |
|  | *Azul*: O umidificador está desligado e conectado a uma fonte de energia. |
|  | *Apagado*: O umidificador está desligado e *não* está conectado a uma fonte de energia. |
| **Indicador de estado da conexão à alça** | |
|  | *Verde*: A alça está conectada corretamente. |
|  | *Laranja*: O umidificador está testando a conexão à alça. |
|  | *Vermelho*: A conexão à alça está defeituosa ou uma alça não está conectada. |
| **Tecla Pausar áudio com indicador** | |
|  | *Vermelho*: Pausar áudio está ativo. |

## 2.3 Controles e janelas de navegação

Esta seção descreve como usar os cursores e botões do umidificador.

### 2.3.1 Usar os botões de controle

Os botões no painel frontal (Figura 3) permitem que você selecione modos, altere configurações e visualize uma visão geral das principais configurações de temperatura.

Tabela 2. Botões de controle (consulte a Figura 3)

| Botão | Descrição |
|---|---|
|  | **Aumento temperatura expiração**<br>Aumenta a temperatura na alça expiratória. |
|  | **Auto**<br>Ativa o modo **Auto**.<br>Consulte a Seção 4.2.2. |
|  | **Modos operacionais INV/NIV/HiFlow**<br>Comuta entre os modos **INV**, **NIV** e **HiFlow**.<br>Consulte a Seção 4.2. |
|  | **Janela Monitoração da temperatura**<br>Exibe a temperatura atual da peça em "Y", temperatura da saída da câmara e valores do gradiente de temperatura.<br>Consulte a Seção 4.4. |

### 2.3.2 Usar os cursores

No modo manual, você pode alterar as configurações de temperatura usando os controles deslizantes (Figura 3).

Tabela 3. Controles deslizantes da temperatura

| Cursor | Descrição |
|---|---|
| **Cursor do gradiente de temperatura** | |
|  | Ajusta a diferença de temperatura entre a saída da câmara e a peça em "Y".<br>Consulte a Seção 4.3. |
| **Cursor da temperatura da saída da câmara** | |
|  | Ajusta a temperatura da saída da câmara.<br>Consulte a Seção 4.3. |

# 3 Preparação do umidificador para uso

*Antes de continuar, revise as informações de segurança na Seção 1.*

A preparação do umidificador para uso inclui as seguintes etapas:

- Uma configuração dos ajustes única por um técnico de medicina (consulte a Tabela 4)
- Para cada paciente novo, as tarefas de configuração do umidificador devem ser executadas por prestadores de cuidados médicos (consulte a Tabela 5)

Tabela 4. Configuração e instalação por um técnico de medicina

| Para ... | Ver ... |
|---|---|
| *Estas tarefas de configuração iniciais únicas são da responsabilidade do pessoal técnico.* | |
| Montar e posicionar o umidificador | Consulte o *Guia de instalação* aplicável para o respirador ou carrinho |
| Configurar os ajustes do umidificador | Seção 7 |
| *Opcional*: conectar o umidificador à porta COM RS-232 para qualquer respirador Hamilton Medical suportado | Consulte o *Manual do operador* aplicável para o respirador. |

Tabela 5. Configuração e instalação por prestadores de cuidados médicos

| Para ... | Ver ... |
|---|---|
| *As tarefas seguintes são executadas pelo pessoal médico que está encarregue do paciente.* | |
| Conectar a uma fonte de energia | Seção 3.1 |
| Conectar o circuito de respiração | Seção 3.2 |
| Ligar o umidificador | Seção 3.3 |
| Testar os alarmes | Seção 3.4 |
| Especificar as configurações do umidificador | Seção 3.5 |
| Conectar o paciente | Seção 3.6 |

## 3.1 Conectar a uma fonte de energia

Verifique sempre se o suprimento da fonte de energia principal é confiável antes de ligar o umidificador e o respirador.

### Para conectar o umidificador a uma fonte de energia

- Conecte o umidificador a uma tomada de CA.[62]

## 3.2 Conectar o circuito de respiração ao umidificador

A Hamilton Medical oferece uma variedade de circuitos de respiração para pacientes adultos, pediátricos e neonatais.

Para obter informações detalhadas, consulte as *Instruções de uso* específicas do circuito de respiração.

## 3.3 Ligar e desligar o umidificador

Quando o umidificador é ligado, ele trabalha automaticamente no modo padrão configurado.

Certifique-se de que liga o respirador *antes* de ligar o umidificador.

### Para ligar o umidificador

- Pressione e mantenha pressionado  (**Energia/Em Espera**) por aproximadamente 3 segundos.

Um autoteste será iniciado. Assim que estiver concluído, o umidificador inicia automaticamente em modo invasivo (**INV**), exceto se estiver configurado de outra forma.

[62] Se estiver usando o umidificador com um respirador Hamilton Medical suportado, conecte o cabo de energia do umidificador à tomada elétrica dedicada, no respirador.

**Para desligar o umidificador**

- Pressione e mantenha pressionado  por aproximadamente 3 segundos.

Certifique-se de que desliga o umidificador *antes* de desligar o respirador.

## 3.4 Testar os alarmes

Antes de conectar um novo paciente ao umidificador, verifique se os alarmes funcionam corretamente.

Certifique-se de que o umidificador está ligado.

**Para testar os alarmes do umidificador**

1. Emita um alarme removendo a câmara de água do umidificador.
2. Verifique se:
   – É possível ouvir um alarme sonoro
   – O indicador de alarme visual está intermitente (Figura 4)
   – O símbolo de alarme correspondente surge na tela (Tabela 9)

Resolva o alarme voltando a inserir a câmara de água no umidificador e verifique se o alarme é reposto.

## 3.5 Especificar as configurações do umidificador

Selecione o modo de umidificação para seu paciente.[63] Para obter informações detalhadas, consulte a Seção 4.2.

## 3.6 Conectar o paciente

Conecte o circuito de respiração à interface do paciente adequada.

O umidificador está agora configurado e pronto para uso.

# 4 Trabalhar com o umidificador HAMILTON-H900

Tabela 6. Visão geral da operação

| Para informações detalhadas sobre ... | Ver ... |
|---|---|
| Ligar/desligar o umidificador | Seção 3.3 |
| Entrar/sair de **Em Espera** | Seção 4.1 |
| Acessar aos controles do umidificador | Seção 2.3 |
| Modos operacionais do umidificador: **INV**, **NIV**, **HiFlow** | Seção 4.2 |
| Configurações **Auto** e **Manual** | Seção 4.2.2 |
| Alterar a umidade usando controles de temperatura | Seção 4.3 |
| Parâmetros monitorados do umidificador | Seção 4.4 |
| Alarmes do umidificador | Seção 5 |

[63] Quando for usado com um respirador Hamilton Medical que suporta a operação integrada, o umidificador corresponde ao modo operacional do respirador. Para obter informações detalhadas, consulte o *Manual do operador* do seu respirador.

## 4.1 Entrar/sair de Em Espera

**⚠ ADVERTÊNCIA**

*Em modo **Em Espera**, todas as configurações são retidas e a saída de calor é reduzida.*

**Em Espera** é um modo de espera que permite preservar as configurações atuais enquanto o umidificador não estiver em funcionamento.

Quando estiver no modo **Em Espera**, as configurações para a **temperatura da saída da câmara** e o **gradiente de temperatura** são reduzidas.[64] Para obter informações detalhadas, consulte a Seção 9.7.

### Para colocar o umidificador Em Espera

- Pressione brevemente (**Energia/Em Espera**).

  Durante o modo **Em Espera**, a tela exibe o tempo decorrido em que o umidificador esteve **Em Espera**. A luz do indicador **Energia/Em Espera** está laranja.

### Para sair do modo Em Espera e iniciar a umidificação

- Pressione .

  O umidificador retoma a operação normal; a luz do indicador de estado **Energia/Em Espera** está verde.

## 4.2 Acerca dos modos operacionais do umidificador

O HAMILTON-H900 oferece os seguintes modos operacionais: Invasivo (**INV**), Não invasivo (**NIV**) e tratamento de oxigênio de alto fluxo (**HiFlow**).

A seleção do modo operacional determina as configurações iniciais de temperatura na saída da câmara de água (**saída da câmara**) e na peça em "Y" (**gradiente de temperatura**), bem como as gamas de temperatura permitidas para cada um destes controles.

Estas gamas de temperatura diferem consoante o grupo de pacientes. Consulte a Tabela 18.

### 4.2.1 Alterar os modos

O umidificador inicia automaticamente no modo invasivo (**INV**), exceto se os ajustes forem personalizados.

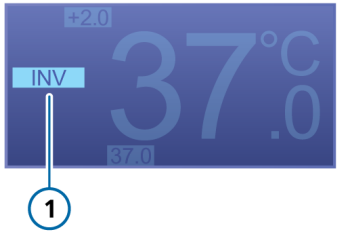
Ao mudar para o modo invasivo (**INV**) ou não invasivo (**NIV**), o umidificador define automaticamente as configurações de controle para **Auto**.

### Para alterar os modos

- Pressione (**Modos**) até ser exibido o modo desejado (**INV**, **NIV**, **HiFlow**).

  O modo selecionado surge na tela.

Figura 6. Modo INV (**1**) selecionado




[64] Durante a nebulização, o **gradiente de temperatura** *não* é alterado durante o modo **Em Espera**.

Figura 7. Modo NIV (**1**) selecionado

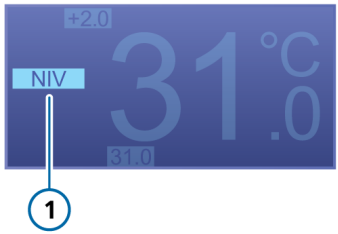
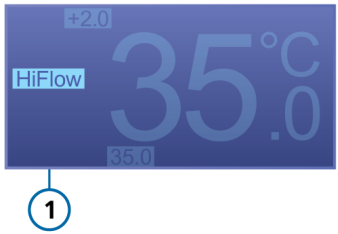



Figura 8. Modo HiFlow (**1**) selecionado




### 4.2.2 Configurações de controle Auto e Manual

Você pode usar o umidificador no modo **Auto** ou pode ajustar manualmente as configurações. Por defeito, o umidificador inicia no modo **Auto**.

A **temperatura da saída da câmara** e o **gradiente de temperatura** são definidos usando qualquer um dos seguintes métodos:

- Carregado a partir das configurações padrão ajustadas (modo **Auto**)
- Definido manualmente pelo usuário

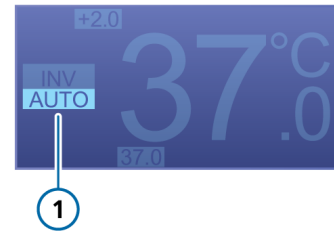
#### Configurações automáticas (Auto)

Quando programado para **Auto**, o umidificador carrega as respectivas configurações padrão especificadas para o modo selecionado (consulte a Seção 7) usa-os para controlar a temperatura do gás.

A baixas temperaturas ambiente, o umidificador poderá ajustar automaticamente a temperatura da câmara de água.

Quando o modo **Auto** estiver selecionado, o texto **AUTO** surge na tela principal.

Figura 9. Modo Auto (**1**) selecionado

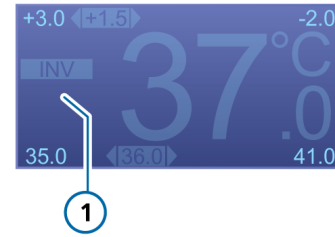



#### Configurações manuais

Quando você altera a **temperatura da saída da câmara** ou o **gradiente de temperatura** usando os cursores, o umidificador comuta para o modo **Manual**. Contudo, ele ainda continua controlando automaticamente a temperatura para alcançar as configurações especificadas.

Quando as configurações são alteradas manualmente, **Auto** deixa de surgir na tela principal; o espaço está vazio.

Figura 10. O modo Manual (**1**) está ativo



#### 4.2.2.1 Ativação do modo Auto

Após alterar manualmente qualquer uma das configurações de temperatura, você pode voltar a ativar o modo **Auto**.

**Para voltar a ativar o modo Auto**

- Pressione Auto (**Auto**).

  A alteração do modo operacional para **INV** ou **NIV** também comuta automaticamente o umidificador para o modo **Auto**.

## 4.3 Alterar a umidade usando controles de temperatura

***ATENÇÃO***

Se o umidificador estiver no modo **Auto**, arrastar qualquer um dos cursores comuta a umidificação para o modo **Manual**.

***ATENÇÃO***

No modo **HiFlow**, você não pode alterar o **gradiente de temperatura** usando o cursor. Você pode alterar o **gradiente de temperatura** para um novo valor em **configuração**. Consulte a Seção 7.

Você pode ajustar os seguintes controles no umidificador[65]:

Tabela 7. Controles ajustáveis do umidificador

| Controle | Descrição |
|---|---|
| Temperatura da saída da câmara | Temperatura na saída da câmara de água.<br>O intervalo de valores possível para este controle depende do modo operacional selecionado do umidificador. Para obter informações detalhadas, consulte as Tabelas 16 e 18.<br>Valores mais altos resultam em mais umidade absoluta. |
| Gradiente de temperatura | A diferença entre a temperatura na saída da câmara de água e na peça em "Y". |
| Aumento da temperatura expiração | Quando selecionado, o umidificador fornece aquecimento adicional na alça expiratória.[66] |

A temperatura máxima permitida no paciente (peça em "Y") é 42 °C. A combinação da **temperatura da saída da câmara** mais o **gradiente de temperatura** não pode exceder este limite. Por exemplo, se o **gradiente de temperatura** estiver programado para 2 °C, a configuração máxima possível para **temperatura da saída da câmara** é 40 °C.

Além disso, a configuração **gradiente de temperatura** prevalece sobre a configuração **temperatura da saída da câmara**. Isto significa que se uma combinação de configurações resultar em uma temperatura da

[65] Quando for usado com um respirador Hamilton Medical que suporta o controle do umidificador integrado, você também pode alterar as configurações diretamente no respirador. Para obter informações detalhadas, consulte o *Manual do operador* do seu respirador.

[66] Somente circuitos de respiração aquecidos de alça dupla e de uso único.

peça em "Y" superior a 42 °C, o **gradiente de temperatura** permanecerá inalterado, mas a **temperatura da saída da câmara** será ajustada.

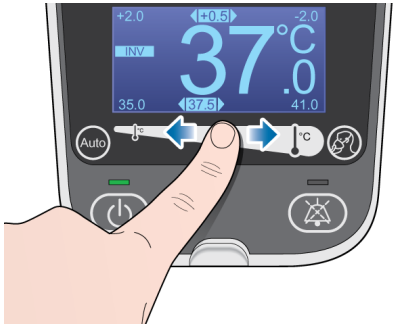
Por exemplo, se a **temperatura da saída da câmara** estiver programada para 40 °C, você pode programar o **gradiente de temperatura** para 3 °C apesar de a combinação exceder 42 °C. Assim que a configuração **gradiente de temperatura** for aceita, o valor de **temperatura da saída da câmara** é automaticamente definido para 39 °C.

### Para definir a temperatura da saída da câmara

- Toque no cursor **temperatura da saída da câmara** na configuração atual:
  - – Arraste para a esquerda para diminuir a temperatura da saída da câmara
  - – Arraste para a direita para aumentar a temperatura da saída da câmara

As alterações são confirmadas por um bipe acústico e são aplicadas imediatamente.

Figura 11. Ajuste da temperatura da saída da câmara




### Para definir a temperatura da saída da câmara > 39 °C

Para aumentar a **temperatura da saída da câmara** acima de 39 °C, o cursor tem que ser ativado duas vezes.

1. Toque no cursor **temperatura da saída da câmara** na configuração atual e arraste para a direita para alcançar o limite de 39 °C.
2. Toque no cursor e arraste-o novamente para definir a temperatura da saída da câmara acima de 39 °C.

### Para definir o gradiente de temperatura

- Toque no cursor **gradiente de temperatura** na configuração atual:
  - – Arraste para a direita para diminuir o gradiente de temperatura
  - – Arraste para a esquerda para aumentar o gradiente de temperatura

As alterações são confirmadas por um bipe acústico e são aplicadas imediatamente.

Figura 12. Ajuste do gradiente de temperatura


Por exemplo, se a temperatura alvo da peça em "Y" for 39 °C e a **temperatura da saída da câmara** estiver definida para 37 °C, defina o **gradiente de temperatura** para 2 °C.

## 4.4 Monitorar a umidificação

Os dados de monitoração estão disponíveis na janela **Monitoração da temperatura**, a qual você pode acessar a qualquer altura.[67]

São monitorados os seguintes parâmetros:

- Temperatura da saída da câmara
- Gradiente de temperatura
- Temperatura da peça em "Y"

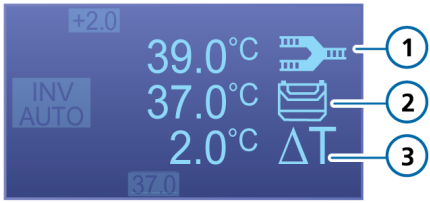
### 4.4.1 Exibir parâmetros de monitoração adicionais

**Para exibir a janela Monitoração da temperatura**

- Pressione (Janela Monitoração da temperatura).

  A janela fecha após 30 segundos ou quando você pressionar novamente o botão.

Figura 13. Janela Monitoração da temperatura




| | | | |
|---|---|---|---|
| 1 | Temperatura atual da peça em "Y" | 3 | Gradiente de temperatura atual |
| 2 | Temp. atual da saída da câmara | | |

## 4.5 Configurações de brilho da tela para Dia e Noite

A luz de fundo da tela do umidificador suporte duas configurações de tela diferentes. Use estas configurações para definir o brilho da tela.

**Para comutar entre as configurações de Dia e Noite**

- Pressione e mantenha pressionado por 5 segundos.

Para definir o brilho de dia e noite padrão, consulte a Seção 7.

[67] Quando for usada com um respirador Hamilton Medical que suporta a monitoração do umidificador integrada, os dados do umidificador são exibidos na tela do umidificador. Para obter informações detalhadas, consulte o *Manual do operador* do seu respirador.

# 5 Responder aos alarmes do umidificador

Os alarmes relacionados ao umidificador notificam-no relativamente a condições que requerem a sua atenção. Os alarmes são indicados da seguinte forma:

- Graficamente, na tela do umidificador
- Com uma sequência de 3 ou 5 bipes acústicos
- A lâmpada de alarme em cima da câmara de água pisca
- Quando forem usados com um respirador Hamilton Medical que suporta a monitoração do umidificador integrada, as mensagens de alarme também são indicadas na tela do umidificador.[68]

Os alarmes estão categorizados como de alta prioridade, prioridade média ou falha técnica, conforme descrito na Tabela 8.

Consulte a Tabela 9 para obter uma lista completa de alarmes.

Tabela 8. Indicadores de alarme

| Tipo de alarme | Indicador de estado do alarme | Áudio | Ação necessária |
|---|---|---|---|
| Alta prioridade | Vermelho, intermitente<br>O ícone de alarme é exibido na tela | Sequência de 5 bipes, repetida até o alarme ser desligado | O umidificador requer atenção imediata. |
| Prioridade média | Amarelo, intermitente<br>O ícone de alarme é exibido na tela | Sequência de 3 bipes, repetida até o alarme ser desligado | O umidificador requer atenção imediata. |
| Falha técnica | Vermelho, intermitente<br>É exibido um código de falha técnica (TF) na tela | Sequência de 3 bipes, repetida até o alarme ser desligado | • Registre o código de falha técnica (TF)[69].<br>• Deixe de usar o umidificador.<br>• Mande o umidificador para a assistência técnica. |

[68] Não disponível em todos os respiradores. Consulte o *Manual do operador* do seu respirador.
[69] Está disponível uma lista de todos os códigos de falhas técnicas TF) no *Manual de manutenção do HAMILTON-H900*.

## 5.1 Silenciar um alarme temporariamente

Um dos componentes de um alarme é o som. Na maioria dos alarmes, você pode pausar (silenciar) o alarme sonoro por dois minutos de cada vez.

### Para silenciar um alarme temporariamente

- Pressione (**Pausar áudio**) na frente do umidificador.

  O alarme sonoro do umidificador é silenciado por dois minutos.

  Pressionar a tecla uma segunda vez cancela **Pausar áudio**.

A luz de fundo de **Pausar áudio** acenderá continuamente a vermelho enquanto **Pausar áudio** estiver ativo.

Se o tempo expirar e o problema não tiver sido resolvido, o alarme volta a soar.

## 5.2 Ajustar a sonoridade dos alarmes

**⚠ AVISO**

Certifique-se que a sonoridade do alarme sonoro está acima do nível de som ambiente. Caso contrário, você pode não ouvir nem detectar as condições de alarme.

Você pode definir a sonoridade do alarme sonoro.

Por padrão, a sonoridade é definida para 5. Ao desligar o umidificador, a sonoridade dos alarmes é reposta para o valor padrão.

### Para ajustar a sonoridade dos alarmes

1. Se necessário, pressione (**Energia/Em Espera**) para colocar o umidificador **Em Espera**.
2. Pressione por 3 segundos.

   A tela exibe o ajuste atual de sonoridade dos alarmes.
3. Ajuste a sonoridade dos alarmes usando o cursor de **temperatura da saída da câmara** (consulte a Figura 3).

   O umidificador confirma sua seleção com um bipe no novo ajuste da sonoridade.
4. Pressione para confirmar a sua seleção e regressar à operação normal.

## 5.3 Solução de problemas de alarme

A Tabela 9 lista os alarmes do umidificador, sua representação gráfica no umidificador, uma descrição e ações corretivas sugeridas.

Tabela 9. Alarmes de HAMILTON-H900

| Alarme | Ícone de alarme | Descrição | Medida necessária |
|---|---|---|---|
| **Alta prioridade** | | | |
| Umidificador inclinado |  | Umidificador com inclinação perigosa.<br>O umidificador está em um ângulo igual ou superior a 10° relativamente ao chão. | • Verifique a montagem do umidificador.<br>• Verifique o carrinho do umidificador.<br>• Opere o umidificador a um ângulo inferior a 10° relativamente ao chão. |
| Alta temperatura |  | A temperatura do gás na saída da câmara de água ou na peça em "Y" está acima do valor ajustado. | • Verifique se o circuito de respiração está coberto pela cobertura da cama do paciente.<br>• Verifique se o circuito de respiração ou a câmara do umidificador estão expostos à luz solar direta.<br>• Substitua o circuito de respiração. |
| Nível de água alto |  | O nível de água na câmara de água está acima da marca de nível máximo. | • Esvazie a câmara do umidificador para reduzir o nível da água.<br>• Substitua a câmara do umidificador.<br>• Opere o umidificador a um ângulo inferior a 10° relativamente ao chão. |

| Alarme | Ícone de alarme | Descrição | Medida necessária |
|---|---|---|---|
| Falha técnica | É exibido um código de falha técnica (TF) na tela | Falha técnica devido a falha do umidificador. | • Verifique a operação do umidificador e todas as conexões.<br>• Substitua o umidificador e mande para a assistência técnica.<br>• Se for exibido um número de falha técnica, anote-o e indique-o quando mandar o umidificador para a assistência técnica. |
| **Prioridade média** | | | |
| Temperatura baixa |  | A temperatura do gás na saída da câmara de água ou na peça em "Y" está abaixo do valor ajustado. | • Aguarde até o sistema aquecer completamente (aprox. 30 minutos).<br>• Verifique se todas as configurações estão corretas.<br>• Evite o fluxo de ar direto do ar condicionado e semelhantes no umidificador e no circuito de respiração. |
| Nível de água baixo |  | O nível de água na câmara está abaixo da marca de nível mínimo. | • Verifique frasco de água e reabasteça os tubos.<br>• Se o frasco de água estiver vazio, conecte um novo frasco da água.<br>• Reabasteça ou substitua a câmara do umidificador vazia.<br>• Opere o umidificador a um ângulo inferior a 10° relativamente ao chão. |
| Verifique a câmara de água |  | Nenhuma câmara ou câmara de água incompatível está inserida. | Insira uma nova câmara do umidificador e conecte o circuito de respiração. |

| Alarme | Ícone de alarme | Descrição | Medida necessária |
|---|---|---|---|
| Verifique a alça esquerda ou direita |  | A tela e os indicadores de conexão exibem qual a alça defeituosa.<br>• Nenhuma alça ou alça defeituosa conectada.<br>• Nenhum fluxo de ar.<br>• Uma alça não está corretamente conectada.<br>• A alça expiratória BRANCA do umidificador está conectada à porta inspiratória do respirador *Para o paciente*. | • Insira ou reinstale corretamente o circuito de respiração.<br>• Substitua o circuito de respiração.<br>• Conecte a alça inspiratória AZUL do umidificador à porta inspiratória do respirador *Para o paciente*.<br><br>Quando o indicador de conexão está a:<br>*Verde*: a alça está inserida corretamente.<br>*Laranja*: o umidificador está testando a conexão.<br>*Vermelho*: a conexão está defeituosa ou não existe. |

# 6 Manutenção

*Antes de continuar, revise as informações de segurança na Seção 1.*

Esta seção fornece informações sobre a agenda e procedimentos de manutenção do umidificador, bem como instruções de limpeza e desinfecção.

Todos os procedimentos nesta seção devem ser executados pelo operador.

Para obter requisitos adicionais de manutenção, entre em contato com o seu representante Hamilton Medical. Quaisquer documentos referenciados nesta seção estão disponíveis no website MyHamilton: https://www.hamilton-medical.com/MyHamilton

## 6.1 Limpeza, desinfecção e esterilização

Os componentes do umidificador têm que ser regularmente limpos e desinfetados, usando soluções e métodos para a limpeza específicos para os componentes individuais.

É importante que você escolha os materiais e método apropriados durante a limpeza e desinfecção do umidificador e dos seus componentes, não somente para evitar danos no equipamento, como também para evitar a contaminação cruzada.

As informações de limpeza e desinfecção são apresentadas da seguinte forma:

- A Tabela 10 lista os componentes aplicáveis relacionados ao umidificador e indica quais os métodos para a limpeza e desinfecção que podem ser usados para cada um, a frequência com que cada componente tem que ser limpo/desinfetado e os agentes de limpeza e desinfecção.
- Para kits de respiração e câmaras de água dos umidificadores, consulte as *Instruções de uso* ou o *Guia de reprocessamento*.

Ao trabalhar com os componentes do umidificador, métodos para a limpeza e agentes de limpeza, tenha em consideração o seguinte:

- *Não* utilize procedimentos de descontaminação que não tenham sido especificados pela Hamilton Medical.
- Embora forneçamos instruções relativas aos agentes e concentrações a usar, se quiser colocar questões específicas sobre a utilização de um determinado agente de limpeza ou desinfecção, contate o fabricante do agente.

Tabela 10. Métodos para a limpeza e desinfecção do umidificador

| Peça | Frequência | Método para a limpeza/desinfecção | Agentes de limpeza |
|---|---|---|---|
| Parte externa do umidificador, incluindo:<br>• Invólucro<br>• Ecrã<br>• Placa aquecedora<br>• Cabos elétricos<br>• Sistemas de montagem | Após utilizar em cada paciente ou conforme necessário. | Limpe com um pano umedecido usando uma solução de limpeza/desinfecção registrada e aprovada. | Toalhetes germicidas Super Sani-Cloth<br>CaviWipes |

## 6.2 Manutenção preventiva

Deve ser efetuada uma manutenção preventiva no seu umidificador pela equipe de manutenção autorizada da Hamilton Medical e de acordo com as instruções no *Manual de manutenção do HAMILTON-H900*.

# 7 Configuração

O umidificador é fornecido com uma configuração padrão de uma variedade de ajustes, organizados por grupo de pacientes.

Você pode alterar as seguintes configurações padrão no modo **configuração**:

- **Temperatura da saída da câmara**
- **Gradiente de temperatura**
- Modo operacional de inicialização (**INV/NIV/HiFlow**)
- **Aumento da temperatura expiratória** Lig/Desl
- Configurações de brilho de luz de fundo **Dia/Noite**

## 7.1 Acessar o modo configuração

Você pode aceder ao modo **configuração** quando o umidificador está no modo **Em Espera**.

### Para aceder ao modo de configuração

1. Se necessário, pressione  para entrar no modo **Em Espera**.
2. Pressione e mantenha pressionados  e  .

   Certifique-se de que pressiona  primeiro.

   A janela de **configuração** surge após 5 segundos.

O umidificador está agora no modo **configuração**.

## 7.2 Alterar as configurações

As configurações personalizadas são persistentes até você alterá-las ou restaurar as configurações de fábrica.

No modo **configuração**, os botões no painel frontal do umidificador são usados para navegar pelas vistas e selecionar.

A Tabela 11 descreve como navegar pela **configuração** e como alterar configurações.

Para obter um exemplo de como alterar uma configuração, consulte o procedimento abaixo sobre como alterar as configurações padrão para o **gradiente de temperatura**.

Para obter uma lista de configurações, consulte a Seção 9.6.

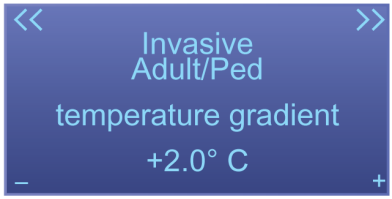
Tabela 11. Botões de navegação do modo configuração

| Botão | Descrição |
|---|---|
|  | Mova para a frente através das vistas |
|  | Mova para trás através das vistas |
|  | Aumente um valor |
|  | Diminua um valor |
|  | Salve as alterações e saia do modo **configuração** |

**Exemplo: Alteração do gradiente de temperatura**

**Para alterar a configuração padrão de gradiente de temperatura, invasivo, Adulto/Ped**

1. No modo **configuração**, pressione Exp. até visualizar a vista para o **Invasive, Adult/Ped, Temperature gradient**.




2. Pressione para aumentar o valor ou pressione Auto para diminuir o valor.
3. Quando terminar, pressione para salvar as alterações e sair do modo **configuração**.

## 7.3 Restaurar as configurações de fábrica

Você pode restaurar as configurações de fábrica a qualquer altura.

**Para restaurar as configurações de fábrica**

1. No modo configuração, pressione repetidamente Exp. até surgir a janela **Reset all custom defaults**.
2. Pressione Auto.

As configurações de fábrica estão restauradas.

# 8 Peças e acessórios

Esta seção lista as peças e acessórios disponíveis para o umidificador HAMILTON-H900.

Para mais informações, consulte o catálogo de produtos Hamilton Medical no website da Hamilton Medical ou contate seu representante Hamilton Medical.

Tabela 12. Peças e acessórios do umidificador

| PN | Descrição |
|---|---|
| 260161 | HAMILTON-BC8022, kit de respiração, alça dupla, aquecido, com câmara de água |
| 260186 | HAMILTON-BC4022, kit de respiração, alça única, aquecido, com câmara de água |
| 260185 | HAMILTON-BC8010, kit de respiração, alça dupla, aquecido, com câmara de água e extensão da incubadora |
| 260187 | HAMILTON-BC4010, kit de respiração, alça única, aquecido, com câmara de água e extensão da incubadora |
| 260196 | HAMILTON-HC322, câmara de água, uso único |
| 260197 | HAMILTON-HC310, câmara de água, uso único |

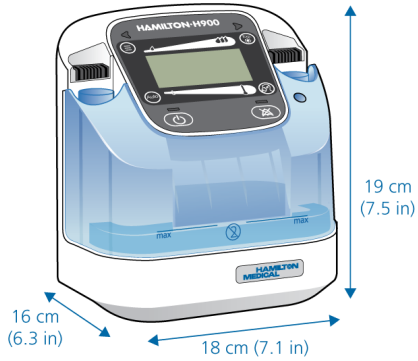
# 9 Especificações

## 9.1 Características físicas

Tabela 13. Características físicas

| Dimensão | Especificações |
|---|---|
| Peso | Umidificador (com câmara de água vazia): 2,5 kg |
| Dimensões | Ver Figura 14 |

Figura 14. Dimensões do HAMILTON-H900



## 9.2 Especificações ambientais

Tabela 14. Especificações ambientais

| Ambiente | | Especificações |
|---|---|---|
| Temperatura | Operação: | 10 °C a 40 °C |
| | Armazenamento: | -20 °C a 60 °C |
| | | Temperatura ambiente recomendada: 18 °C a 26 °C |
| Altitude | | Até 4.000 m |
| Pressão atmosférica | Operação e armazenamento: | 61 kPa a 106 kPa |
| Umidade relativa | Operação: | 30% a 95%, sem condensação |
| | Armazenamento: | 10% a 95%, sem condensação |
| Proteção da água | | IP21 |
| Temperatura da entrada de gás | | 18 °C a 31 °C (recomendada) |

## 9.3 Especificações elétricas

Tabela 15. Especificações elétricas

| Nº. p/pedido | Entrada de energia | Consumo de energia |
|---|---|---|
| 950001 (230 V) | 220 - 240 V<br>50/60 Hz | 283 VA |
| 950004 (115 V) | 110 - 127 V<br>50/60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50/60 Hz | 268 VA |
| Equalização potencial | Terminal para a conexão de um condutor de equalização de potencial de acordo com a DIN 42801 | |

## 9.4 Configurações de controle

Tabela 16. Configurações e intervalos de controle

| Parâmetro ou configuração (unidade) | Modo | Intervalo | Padrão | Resolução |
|---|---|---|---|---|
| Temperatura da saída da câmara (°C) | INV | 35 a 41 | 37,0 | 0,5 |
| | NIV | 30 a 35 | 31,0 | 0,5 |
| | HiFlow | 33 a 37 | 35,0 | 2 |
| Gradiente de temperatura (°C) | INV | -2 a 3 | Adulto/Ped: 2<br>Neonatal: 3 | 0,5 |
| | NIV | -2 a 3 | Adulto/Ped: 2<br>Neonatal: 3 | 0,5 |
| | HiFlow | -- | 2 | -- |
| Temperatura máx. resultante das vias aéreas (peça em "Y")[70] (°C) | INV | 33 a 42 | -- | -- |
| | NIV | 28 a 38 | -- | -- |
| | HiFlow | 35 a 39 | -- | -- |
| Aumento da temperatura expiratória | Todos os modos | Lig, Desl. | Liga | -- |
| Configuração Brilho para tela | Todos os modos | 1 a 5 | Dia: 5<br>Noite: 2 | 1 |

[70] A temperatura das vias aéreas está limitada a 42 °C pelo umidificador.

## 9.5 Parâmetros monitorados

Tabela 17. Parâmetros monitorados, intervalos e precisão

| Parâmetro (unidades) | Intervalo | Precisão |
|---|---|---|
| Temperatura da saída da câmara (°C) | 10 a 60 | 10 a 30: ±1<br>30 a 41: ±0,5<br>41 a 60: ±1 |
| Temperatura da peça em "Y" (°C) | 28 a 43 | ± 0,5 |

## 9.6 Configuração

Tabela 18. Especificação das configurações

| Parâmetro | Modo | Intervalo de configuração | Configuração padrão |
|---|---|---|---|
| Temperatura da saída da câmara (°C) | INV | 35 a 39 | 37,0 |
| | NIV | 30 a 35 | 31,0 |
| | HiFlow | 33, 35, 37 | 35,0 |
| Gradiente de temperatura (°C) | INV | 0 a 3 | Adulto/Ped: 2<br>Neonatal: 3 |
| | NIV | 0 a 3 | Adulto/Ped: 2<br>Neonatal: 3 |
| | HiFlow | 0 a 3 | 2 |
| Modo de inicialização | -- | Modo invasivo, não invasivo, HiFlow | Invasivo |
| Configuração Brilho para tela | Todos os modos | 1 a 5 | Dia: 5<br>Noite: 2 |

## 9.7 Dados técnicos de desempenho

Tabela 19. Dados técnicos de desempenho

| Descrição | Especificação | | |
|---|---|---|---|
| Fluxo[71] | Invasivo: | Até 60 l/min | |
| | Não invasivo: | Até 120 l/min | |
| | HiFlow: | Até 120 l/min | |
| Tempo de aquecimento | Inferior a 30 min | | |
| Umidade | A uma temperatura ambiente de 18 °C a 26 °C: | | |
| | Invasivo: | Configuração de temperatura de 37 °C a 41 °C | Umidade mínima: 33 mg H2O/l |
| | Não invasivo: | Configuração de temperatura de 31 °C a 35 °C | Umidade mínima: 12 mg H2O/l |
| | HiFlow: | Fluxo ≤ 60 l/min | Umidade mínima: 33 mg H2O/l |
| | | Fluxo > 60 l/min | Umidade mínima: 12 mg H2O/l |
| Especificações do aquecimento no modo Em Espera | Circuitos de respiração aquecidos: | Peça em "Y" limitada a 30 °C. | |
| Ecrã | 3 pol. / 64 x 128 píxeis, tela de matriz de pontos invertida (luz de fundo) | | |
| Pausar áudio | 120 segundos | | |
| Sonoridade dos alarmes[72] | Gama = 1 a 8. Padrão = 5. | | |

[71] Para taxas de fluxo mínimas, consulte as *Instruções de uso* do circuito de respiração.
[72] Volume a uma distância de 1 metro do umidificador. Uma configuração de 1 = 50 dB(A), 5 (padrão) = 60 dB(A) e 8 = 65 dB(A), com uma precisão de ±6 dB(A).

## 9.8 Desempenho essencial

As temperaturas aplicadas ao gás respiratório e ao circuito de respiração têm que ser mantidas dentro das configurações especificadas e têm que ser monitoradas.

Se a temperatura ultrapassar os limites especificados, o umidificador tem que detectar este fato e informar o usuário através de um alarme.

## 9.9 Descrição funcional do sistema do umidificador

O umidificador HAMILTON-H900 foi projetado para aquecer e umidificar os gases respiratórios durante a ventilação mecânica. O gás respiratório é aquecido e umidificado enquanto passa pela câmara, que está parcialmente preenchida com água aquecida.

O umidificador tem dois sistemas de aquecimento controlados por sensor:

- *Placa aquecedora*. Aquece a água na câmara de água.
- *Sistema de aquecimento do circuito de respiração integrado*. Aquece as alças respiratórias para prevenir a condensação.

A temperatura do gás respiratório é monitorada na saída da câmara e na alça respiratória na extremidade do paciente.

## 9.10 Símbolos utilizados na rotulagem e embalagem do dispositivo

| Símbolo | Descrição |
|---|---|
|  | Siga as *Instruções de uso* |
|  | Número de referência |
|  | Número de série |
|  | Quantidade |
|  | Fabricante |
|  | Data de fabricação |
|  | Peça aplicada tipo BF (classificação de equipamento eletromédico segundo a IEC 60601-1: tipo BF) |
|  | Descarte de acordo com Diretiva do Conselho 2002/96/CE ou a norma WEEE (Waste Electrical and Electronic Equipment) |
|  | A marca TÜV NRTL com os indicadores "C" e "US" significa que o produto atende às normas de segurança dos EUA e do Canadá |
|  | Equalização potencial |

| Símbolo | Descrição |
|---|---|
|  | Aviso: superfície quente.<br>A placa aquecedora e o fundo da câmara podem atingir uma temperatura superior a 85 °C. |
| CE 0197 | Marca de Conformidade CE. Selo de aprovação que indica que este dispositivo atende à Diretiva 93/42/CEE sobre dispositivos médicos |
| IP21 | Protegido contra salpicos de água e partículas sólidas superiores a 12,5 mm |
| max | Marca do nível de enchimento na câmara de água |
|  | Interface de série RS-232 para comunicação com respiradores Hamilton Medical |
|  | RM insegura<br>O umidificador HAMILTON-H900 representa riscos inaceitáveis para o paciente, a equipe médica ou qualquer outra pessoa no ambiente de RM. |
|  | RoHS chinesa |
|  | Sonda de temperatura<br>Indica a localização da sonda de temperatura no circuito de respiração. |

## 9.11 Padrões e aprovações

O sistema do umidificador atende aos itens cabíveis das seguintes normas listadas na Tabela 20.

Tabela 20. Normas e aprovações, versões válidas

| |
|---|
| IEC 60601-1:2005/A1:2012 |
| IEC 60601-1-2:2014 |
| IEC 60601-1-6:2010/A1:2013 |
| IEC 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| IEC 62304:2006/A1:2015 |
| IEC 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Descarte

O dispositivo deverá ser descartado de acordo com a Diretiva 2002/96/CE e conforme os protocoles da sua instituição.

Os circuitos de respiração e câmaras de água deverão ser descartados de acordo com as *Instruções de uso* fornecidas com os kits de respiração.

## 9.13 Garantia

GARANTIA LIMITADA

A GARANTIA ESPECIFICADA NESTE CONTRATO SUPERA QUAISQUER OUTRAS GARANTIAS, EXPRESSAS OU IMPLÍCITAS, INCLUINDO AS GARANTIAS IMPLÍCITAS DE UTILIDADE COMERCIAL OU ADEQUAÇÃO A UM PROPÓSITO ESPECÍFICO. ENTRETANTO, AS GARANTIAS IMPLÍCITAS NÃO SERÃO ANULADAS DURANTE O PERÍODO DE VIGÊNCIA DESTA GARANTIA LIMITADA.

A Hamilton Medical garante que seus produtos estarão livres de defeitos em materiais ou de fabricação no momento em que forem enviados. A garantia não cobre itens descartáveis. Os itens descartáveis e produtos consumíveis são considerados itens de uso único ou de uso limitado e devem ser trocados regularmente, conforme necessário para operação correta do produto, conforme descrito no Manual do operador.

A Hamilton Medical não assumirá compromissos ou responsabilidades relacionadas com o produto além das especificadas aqui, incluindo, entre outras, obrigações e/ou responsabilidade por alegações de negligência ou responsabilidade exclusiva pelo produto. A empresa não assumirá, em nenhuma situação, responsabilidade por danos incidentais ou consequenciais, diretos ou contingentes.

Esta Garantia Limitada será nula e não se aplicará nas seguintes situações:

1. se o produto não for instalado e conectado por um representante local autorizado da Hamilton Medical de acordo com as instruções da Hamilton Medical e por um representante da Hamilton Medical;
2. se não forem apresentadas evidências de que o dano ou o reparo ocorreu no período da garantia;
3. se o número de série tiver sido adulterado, apagado ou retirado e não houver faturas comerciais ou outras evidências que permitam verificar a data de compra do produto;
4. em caso de defeitos causados por uso incorreto, negligência ou acidentes causados por reparos, ajustes, modificações ou trocas de componentes realizados fora das fábricas da Hamilton Medical ou por outros indivíduos que não um serviço de assistência técnica autorizado ou um representante do mesmo;
5. se o produto for modificado ou tiver sua natureza alterada sem consentimento prévio por escrito da Hamilton Medical;
6. se o produto for ou tiver sido utilizado de um modo que não o especificado em "Uso pretendido";
7. se o produto tiver sido usado por pessoas não adequadamente treinadas sob a supervisão de um médico.

A realização de trocas de componentes e/ou reparos nos termos desta Garantia Limitada não implicam em uma nova garantia e serão seguidos somente pela porção ainda não vencida da Garantia Limitada inicial. A garantia dos componentes reparados e/ou trocados não deverá superar a Garantia Limitada do dispositivo.

Para obter assistência nos termos desta Garantia Limitada, o solicitante deverá notificar oportunamente o representante de vendas da Hamilton Medical e informar a natureza do problema, o número de série e a data de compra do produto.

Exceto conforme indicado acima, a Hamilton Medical não assumirá nenhuma responsabilidade em caso de danos, reivindicações ou culpa, incluindo, entre outros, lesões corporais ou danos incidentais, consequenciais ou específicos. A Hamilton Medical não assumirá igualmente qualquer responsabilidade em caso de danos, reivindicações ou culpa, incluindo, entre outros, lesões corporais ou danos incidentais, consequenciais ou específicos resultantes do uso indevido do dispositivo ou falha em cumprir qualquer uma das disposições deste manual.

### 9.13.1 Disposições adicionais

Os termos e condições da Hamilton Medical estarão em vigor. Este contrato será regido e interpretado de acordo com as leis da Suíça e poderá ser invocado por qualquer uma das partes sob o foro do tribunal de Chur, na Suíça.

# Инструкции по эксплуатации

## HAMILTON-H900

2021-01-11

624431/09

**Производитель**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz,
Switzerland (Швейцария)
Тел.: (+41) 58 610 10 20
Факс: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Содержание

# Введение

Прежде чем использовать аппарат или его принадлежности, обязательно ознакомьтесь с соответствующей документацией.

### Условные обозначения в этом руководстве

Далее указано, какие условные обозначения используются в этом руководстве.

- Названия кнопок выделены **жирным** шрифтом.
- Изображения дисплея могут отличаться от фактических.
- В некоторых странах могут быть доступны не все функции.

Далее объясняются значения примечаний по безопасности.

**⚠ ПРЕДУПРЕЖДЕНИЕ**

Указывает на риск получения травм, возможный летальный исход или другие серьезные побочные реакции, связанные с использованием устройства или нарушением правил его эксплуатации.

**⚠ ВНИМАНИЕ**

*Указывает на риск возникновения проблемы, вызванной использованием или неправильным применением устройства, в частности его неисправности либо сбоя, а также повреждения этого устройства или другого имущества.*

***ПРЕДОСТЕРЕЖЕНИЕ***

Служит для обозначения особо важной информации.

Далее показано, как выглядят примечания по безопасности в таблицах.

**⚠ ПРЕДУПРЕЖДЕНИЕ!**

**⚠ ВНИМАНИЕ!**

**ПРЕДОСТЕРЕЖЕНИЕ!**

Последнюю версию данного руководства, а также другие документы можно загрузить с веб-сайта MyHamilton: https://www.hamilton-medical.com/MyHamilton

Hamilton Medical College предлагает различные бесплатные учебные модули. Зарегистрироваться можно на странице http://college.hamilton-medical.com/

**⚠ ВНИМАНИЕ**

*Только для США: федеральное законодательство разрешает продажу устройства только врачам или по их заказу.*

## Назначение

Увлажнитель HAMILTON-H900 предназначен для регулировки температуры и влажности дыхательных газовых смесей во время инвазивной и неинвазивной механической вентиляции легких.

Устройство предназначено для использования в медицинских и специальных учреждениях, уход за пациентами в которых осуществляется квалифицированным медицинским персоналом.

Увлажнитель HAMILTON-H900 – это медицинское устройство, предназначенное для использования квалифицированным персоналом, который прошел надлежащее обучение, под руководством врача и с соблюдением указанных технических характеристик.

# 1 Правила техники безопасности

В этом разделе приведены инструкции по технике безопасности, связанные с установкой, использованием и техническим обслуживанием увлажнителя.

**Перед установкой и использованием увлажнителя внимательно ознакомьтесь с содержанием всех глав раздела по технике безопасности.**

**Прежде чем использовать увлажнитель, обязательно прочтите Инструкции по эксплуатации.**

**Внимательно ознакомьтесь с инструкциями по эксплуатации всех устройств и принадлежностей, используемых с увлажнителем.**

Если у вас возникнут вопросы касательно любых сведений в этом руководстве, свяжитесь с представителем компании Hamilton Medical или специалистами по техническому обслуживанию.

## 1.1 Электромагнитная восприимчивость

**⚠ ПРЕДУПРЕЖДЕНИЕ**

- **НЕБЕЗОПАСЕН ДЛЯ МРТ**. Не приближайтесь к оборудованию для магнитно-резонансной томографии (МРТ). В условиях магнитного резонанса увлажнитель HAMILTON-H900 представляет опасность для пациента, медицинских работников и других людей.
- Если увлажнитель расположен возле высокочастотных хирургических приборов или в радиусе действия микроволн, коротких волн либо сильного магнитного поля, он может работать неправильно.
- Во избежание увеличения интенсивности излучения, снижения иммунитета, сбоев в работе увлажнителя HAMILTON-H900 или каких-либо принадлежностей используйте только кабели и принадлежности, указанные в данном руководстве либо электронном онлайн-каталоге Hamilton Medical.
- Дополнительные устройства, подключаемые к медицинскому электрооборудованию, должны отвечать требованиям соответствующих стандартов МЭК или ISO (например, МЭК 60950 «Оборудование информационных технологий»). Кроме этого, все конфигурации должны отвечать требованиям к медицинским электрическим системам (стандарт МЭК 60601-1, пункт 16).
- Лица, выполняющие подключение дополнительных устройств к медицинскому электрооборудованию, осуществляют конфигурацию системы, поэтому несут ответственность за ее соответствие требованиям к медицинским электрическим системам. Помните, что местное законодательство является приоритетным по отношению к указанным выше требованиям. По вопросам касательно дальнейших действий обращайтесь к представителю компании Hamilton Medical или в отдел технической поддержки.
- В увлажнителе *не* предусмотрена защита от воздействия разряда при проведении электрической дефибрилляции.

**ПРЕДОСТЕРЕЖЕНИЕ**

- При установке и вводе устройства в эксплуатацию необходимо соблюдать особые меры предосторожности касательно ЭМС (электромагнитной совместимости), изложенные в *Заявлениях об ЭМС для увлажнителя* HAMILTON-H900.
- Переносное и мобильное радиочастотное оборудование для передачи данных может повлиять на работу увлажнителя HAMILTON-H900.

## 1.2 Электропитание

**⚠ ПРЕДУПРЕЖДЕНИЕ**

- Чтобы свести к минимуму риск поражения электрическим током, подключайте шнур питания увлажнителя к заземленной в соответствии с предъявляемыми требованиями электрической розетке. Ответственность за заземление розетки несет медицинское учреждение.
- *Не* использовать при повреждении шнура питания.
- В случае несоответствия требованиям к напряжению, перебоев питания или отсоединения от питающей сети увлажнитель издает свистящий звук. Незамедлительно выключите устройство и проверьте напряжение питающей сети.
- Убедитесь, что напряжение питающей сети соответствует требованиям.

## 1.3 Опасность возникновения пожара и другие риски

**⚠ ПРЕДУПРЕЖДЕНИЕ**

*Не* используйте увлажнитель в опасных местах и зонах с легковоспламеняющимися газами.

## 1.4 Общие сведения касательно установки и эксплуатации

**⚠ ПРЕДУПРЕЖДЕНИЕ**

- Прежде чем использовать увлажнитель для пациента, убедитесь, что дыхательный контур правильно подключен к аппарату ИВЛ .

  – Синий патрубок вдоха подсоединен к порту вдоха *к пациенту*.

  – Белый патрубок выдоха подсоединен к порту выдоха *от пациента*.
- Используйте только детали и принадлежности, указанные в разделе 8. Это позволит обеспечить надлежащую работу увлажнителя и предотвратить возможное травмирование пациента.
- Не используйте увлажнитель на высоте более 4000 м или вне пределов температурного диапазона от 10 °C до 40 °C. Это может привести к ухудшению качества терапии или травмированию пациента.
- Неправильные настройки уровня влажности или температуры могут привести к ухудшению состояния пациента.

- *Не* используйте увлажнитель во время транспортировки вентилируемого пациента за пределами медицинского учреждения.
- Включайте увлажнитель, только *после* запуска аппарата ИВЛ.
- Отключайте увлажнитель, *прежде чем* выключить аппарат ИВЛ.
- Не закрывайте ячейки для ИК-спектроскопии.
- Инвазивную вентиляцию (INV) можно применять *только* для интубированных пациентов и пациентов с трахеостомой.
- Соблюдайте дополнительные меры предосторожности на случай аллергической реакции.
- Регулярно проверяйте дыхательный контур на наличие конденсата и при необходимости сливайте воду.
- Эффективность увлажнения устройством может снижаться, если параллельно используется небулайзер.
- *Не* прикасайтесь к горячей пластине и нижней части водной камеры. Температура этих поверхностей может превышать 85 °C, и они излучают тепловую энергию.

**⚠ ВНИМАНИЕ**

- *Установите увлажнитель таким образом, чтобы его можно было легко отключить от основного источника питания.*
- *Используйте только детали и принадлежности, указанные в разделе 8, электронном каталоге Hamilton Medical или списке совместимых с увлажнителем продуктов.*

*Это позволит обеспечить надлежащую работу увлажнителя, избежать снижения его эффективности, а также сохранить право на гарантийное обслуживание.*

- *Если увлажнитель выключить, а затем включить, он автоматически запустится в режиме инвазивной вентиляции (INV) при условии, что настройки не изменялись.*
- *Прежде чем использовать комплект дыхательного контура, осмотрите его и убедитесь в отсутствии повреждений. При наличии таковых утилизируйте комплект.*
- *Нагревательный элемент увлажнителя и провода-нагреватели автоматически включаются, если водная камера и дыхательные контуры правильно подсоединены, а увлажнитель включен или находится в ждущем режиме.*
- *Если температура окружающей среды, подаваемой газовой смеси и/или скорость потока не соответствуют рекомендованной, устройство может не обеспечить необходимый уровень влажности.*
- *Питание может поступать в увлажнитель, даже если экран не светится. См. таблицу 1.*

***ПРЕДОСТЕРЕЖЕНИЕ***

- Прежде чем использовать комплект дыхательного контура, выполните проверку на герметичность. Если результаты проверки неудовлетворительны, ее можно повторить еще раз. Если и вторая попытка даст отрицательный результат, комплект дыхательного контура следует заменить.

- Нормальная конденсация (запотевание) в патрубке, гибкой трубке или датчике потока, образующаяся вследствие дыхательной деятельности пациента, свидетельствует об использовании правильных настроек увлажнения.
- Все действия сопровождаются звуковым сигналом.

## 1.5 Дыхательные контуры и водная камера

**⚠ ПРЕДУПРЕЖДЕНИЕ**

- Неправильное подсоединение дыхательного контура может привести к травмированию пациента.
- Чтобы предотвратить случайное отсоединение дыхательного контура во время использования или транспортировки, используйте только дыхательные контуры, которые соответствуют стандарту ISO 5367 или ISO 80601-2-74.
- Наполняйте водную камеру только стерильной, деминерализованной водой, которая соответствует санитарно-гигиеническим требованиям медицинского учреждения.
- Не наклоняйте водную камеру.
- Не добавляйте в камеру какие-либо жидкие лекарственные формы.
- Убедитесь, что уровень воды не превышает обозначенный максимум.

***ПРЕДОСТЕРЕЖЕНИЕ***

- Если увлажнитель не обнаруживает дыхательный контур, замените его компоненты.
- Температура воды, доливаемой в резервуар, не должна превышать 37 °C.
- Убедитесь, что вода подается в камеру надлежащим образом.
- Прежде чем отсоединять компоненты, убедитесь, что на устройстве активирован ждущий режим.

## 1.6 Размещение увлажнителя и дыхательного контура

**⚠ ПРЕДУПРЕЖДЕНИЕ**

- *Всегда* размещайте увлажнитель ниже уровня расположения пациента.
- *Не* используйте увлажнитель, если угол его наклона превышает 10°.
- Убедитесь, что подсоединенный дыхательный контур со стороны увлажнителя или пациента не натянут и не согнут.
- Нагреваемые дыхательные патрубки *не* должны непосредственно соприкасаться с кожей пациента.
- Если увлажнитель устанавливается на другое устройство или рядом с ним, убедитесь, что в планируемой конфигурации увлажнитель функционирует нормально.

- Располагайте его так, чтобы конденсат не поступал к пациенту.
- Дыхательные контуры или удерживающие зажимы трубок следует подсоединять так, чтобы исключить механическое воздействие на ЭТ-трубку.

*ПРЕДОСТЕРЕЖЕНИЕ*

- Прежде чем использовать комплект, проверьте надежность всех соединений.
- Все коннекторы для присоединения патрубков на увлажнителе содержат электрические контакты и разъемы дыхательного контура. Убедитесь, что электрические контакты правильно расположены: они должны соответствовать соединительному элементу увлажнителя.

## 1.7 Мониторинг и сигналы тревоги

*ПРЕДОСТЕРЕЖЕНИЕ*

- В случае срабатывания тревоги на экране поочередно отображается значок активной тревоги и текущая температура на выходе из камеры.
- После выключения увлажнителя для громкости звукового сигнала восстанавливается значение по умолчанию 5.
- Описания всех тревог о технических неисправностях и процедур обслуживания, а также подробные технические сведения приведены в *Руководстве по обслуживанию HAMILTON-H900*.

## 1.8 Техническое обслуживание

**⚠ ПРЕДУПРЕЖДЕНИЕ**

- *Запрещается* вносить изменения в конструкцию увлажнителя.
- *Всегда* отсоединяйте увлажнитель от источника питания перед очисткой и дезинфекцией, чтобы снизить риск поражения электрическим током.

**⚠ ВНИМАНИЕ**

- *Обращайтесь с использованными дыхательными контурами и водными камерами как с загрязненными предметами, соблюдая местные законы и нормы, а также внутренние процедуры медицинского учреждения.*
- *С целью соблюдения надлежащих процедур и во избежание травмирования работы по техническому обслуживанию увлажнителя должны выполняться квалифицированным персоналом компании Hamilton Medical с соблюдением инструкций, указанных в Руководстве по обслуживанию HAMILTON-H900.*
- *Для замены используйте только компоненты, предоставленные компанией Hamilton Medical.*
- *Запрещается проведение процедур технического обслуживания, не указанных в Руководстве по обслуживанию HAMILTON-H900.*
- *Используйте для очистки и дезинфекции только одобренные средства.*

***ПРЕДОСТЕРЕЖЕНИЕ***

- Подробная информация об очистке, дезинфекции и стерилизации автоклавируемых (многоразовых) принадлежностей и компонентов приведена в прилагаемых к ним документах «*Руководство по повторной обработке*» и «*Инструкции по эксплуатации*».
- *Примечание для США.* Запрещается использование средств для очистки и дезинфекции, не прошедших регистрацию в Агентстве по охране окружающей среды США (EPA).

# 2 Обзор

В этом руководстве содержатся сведения о настройке и использовании увлажнителя HAMILTON-H900.

Увлажнитель предназначен для использования с аппаратами ИВЛ от компании Hamilton Medical, а также других производителей.

## 2.1 Обзор увлажнителя HAMILTON-H900

Увлажнитель HAMILTON-H900 обеспечивает увлажнение и нагрев респираторной газовой смеси для проведения терапии у взрослых, педиатрических и неонатальных пациентов.

Устройство поддерживает указанные ниже обычные режимы вентиляции.

- Инвазивная вентиляция
- Неинвазивная вентиляция
- Кислородная терапия с высокой скоростью потока

Система состоит из корпуса увлажнителя, экрана, органов управления, водяной камеры, нагревательной пластины и электрических контактов для подключения нагреваемого дыхательного контура.

Ниже приведены основные функции системы.

- Регулируемые настройки температуры и влажности
- Мониторинг и управление тревогами
- Интеграция данных мониторинга и настроек параметров с поддерживаемыми аппаратами ИВЛ Hamilton Medical [73]

## 2.2 Физические характеристики

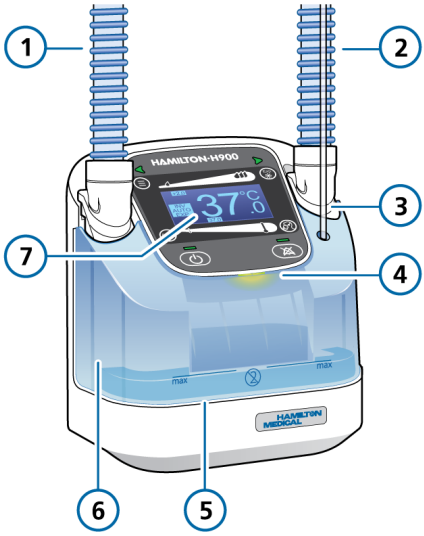
В этом разделе приведено описание увлажнителя и подключаемых к нему комплектов дыхательных контуров.

[73] Эта функция доступна не во всех странах.

### 2.2.1 Обзор увлажнителя

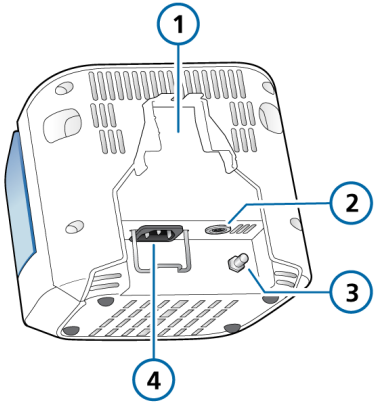
На рисунках с 1 по 5 изображен увлажнитель.

Рисунок 1. Увлажнитель HAMILTON-H900. Вид спереди




| | | | |
|---|---|---|---|
| 1 | Патрубок вдоха со стороны аппарата ИВЛ (синий) | 5 | Нагревательная пластина |
| 2 | Патрубок вдоха со стороны пациента (синий) | 6 | Водяная камера |
| 3 | Трубка для подачи воды | 7 | Передняя панель и экран |
| 4 | Визуальный индикатор тревоги | | |

Рисунок 2. Увлажнитель HAMILTON-H900. Вид сзади




| | | | |
|---|---|---|---|
| 1 | Паз для монтажного кронштейна | 3 | Зажим выравнивания потенциалов |
| 2 | Разъем RS-232 | 4 | Разъем питания от источника переменного тока |

### 2.2.2 Обзор главного экрана

Во время работы увлажнителя с главного экрана можно получить прямой доступ ко всем настройкам, режимам, сигналам тревоги и элементам управления.

На рисунках с 3 по 5 показаны элементы управления на передней панели, индикаторы и экран.

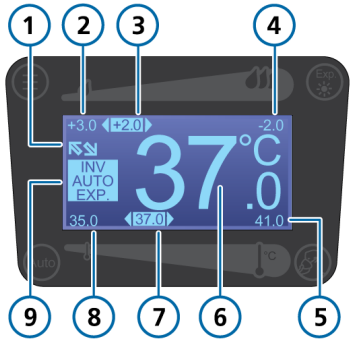
Рисунок 3. Увлажнитель HAMILTON-H900. Элементы управления на передней панели


| | | | |
|---|---|---|---|
| 1 | Кнопка окна мониторинга температуры | 5 | Кнопка временного отключения звуковой сигнализации |
| 2 | Ползунки регулировки температуры | 6 | Кнопка питания / ждущего режима |
| 3 | Кнопка увеличения температуры в патрубке выдоха | 7 | Кнопка «Авто» |
| 4 | Кнопка режимов INV/NIV/HiFlow | 8 | Экран (см. рис. 5) |

Рисунок 4. Увлажнитель HAMILTON-H900. Индикаторы состояния на передней панели


| | | | |
|---|---|---|---|
| 1 | Индикаторы подключения патрубков | 3 | Индикатор питания / ждущего режима |
| 2 | Индикатор временного отключения звуковой сигнализации | | |

Рисунок 5. Увлажнитель HAMILTON-H900. Экран




1 Подключение к аппарату ИВЛ

2 Макс. значение температурного градиента

3 Значение температурного градиента

4 Мин. значение температурного градиента

5 Макс. значение температуры на выходе из камеры

6 Текущая температура на выходе из камеры

7 Значение температуры на выходе из камеры

8 Мин. значение температуры на выходе из камеры

9 Активированные режимы/параметры

*Все элементы на экране могут не показываться одновременно в процессе работы. Изображение использовано только с целью объяснения.*

### 2.2.3 Обзор дыхательных контуров, подключаемых к увлажнителю

Увлажнитель HAMILTON-H900 поддерживает различные дыхательные контуры с одним и двумя патрубками для проведения терапии у взрослых, педиатрических и неонатальных пациентов.

Подробные сведения см. в *Инструкциях по эксплуатации* дыхательного контура.

### 2.2.4 Обзор индикаторов состояния на увлажнителе

Индикаторы на передней панели увлажнителя отображают важную информацию о его состоянии. См. рисунок 4.

Таблица 1. Индикаторы состояния

| Значок | Описание |
|---|---|
| **Кнопка питания / ждущего режима с индикатором состояния** | |
|  | *Зеленый:* увлажнитель работает. |
|  | *Оранжевый:* увлажнитель в ждущем режиме. |
|  | *Синий:* увлажнитель не работает и подключен к источнику питания. |
|  | *Не горит:* увлажнитель не работает и *не* подключен к источнику питания. |

| Значок | Описание |
|---|---|
| **Индикатор подключения патрубков** | |
| | *Зеленый:* патрубок подключен правильно. |
| | *Оранжевый:* увлажнитель проверяет соединение. |
| | *Красный:* патрубок подключен неправильно или не подключен. |
| **Кнопка временного отключения звуковой сигнализации с индикатором** | |
| | *Красный:* звуковая сигнализация временно отключена. |

## 2.3 Переход между окнами и параметрами

В этом разделе приведены инструкции по использованию кнопок и ползунков увлажнителя.

### 2.3.1 Использование кнопок управления

С помощью кнопок на передней панели (рис. 3) можно выбирать режимы, изменять настройки и просматривать основные параметры температуры.

Таблица 2. Кнопки управления (см. рисунок 3)

| Кнопка | Описание |
|---|---|
| Exp. | **Повышение температуры на выдохе**<br>Увеличение температуры в патрубке выдоха. |
| Auto | **Авто**<br>Включение режима Auto.<br>См. раздел 4.2.2. |
| | **Режим работы INV/NIV/HiFlow**<br>Переключение между режимами вентиляции INV, NIV и HiFlow.<br>См. раздел 4.2. |
| | **Окно мониторинга температуры**<br>Отображение значений текущей температуры в У-образном коннекторе, на выходе из камеры, а также температурного градиента.<br>См. раздел 4.4. |

### 2.3.2 Использование ползунков

В ручном режиме можно изменять настройки температуры с помощью ползунков управления (рис. 3).

Таблица 3. Ползунки регулировки температуры

| Ползунок | Описание |
|---|---|
| **Ползунок для настройки температурного градиента** | |
|  | Регулирует разницу температур на выходе из водной камеры и со стороны У-образного коннектора.<br>См. раздел 4.3. |
| **Ползунок для регулировки температуры на выходе из камеры** | |
|  | Регулирует температуру на выходе из камеры.<br>См. раздел 4.3. |

Таблица 4. Конфигурация параметров, выполняемая техническим персоналом

| Действие | См. |
|---|---|
| *Описанная ниже начальная конфигурация выполняется техническим персоналом один раз.* | |
| Установите увлажнитель и зафиксируйте его положение | См. соответствующее *Руководство по установке* аппарата ИВЛ или тележки |
| Выполните конфигурацию параметров увлажнителя | Раздел 7 |
| *Дополнительно*: подключите увлажнитель к порту RS-232 COM любого совместимого аппарата ИВЛ Hamilton Medical. | См. соответствующее *Руководство пользователя* аппарата ИВЛ |

# 3 Подготовка увлажнителя к эксплуатации

*Прежде чем продолжить, ознакомьтесь с правилами техники безопасности в разделе 1.*

Чтобы подготовить увлажнитель к эксплуатации включает приведенные ниже этапы.

- Начальная конфигурация параметров техническим персоналом компании (см. таблицу 4)
- Для каждого нового пациента настройки параметров увлажнителя выполняются медицинским персоналом (см. таблицу 5)

Таблица 5. Конфигурация параметров, выполняемая медицинским персоналом

| Действие | См. |
|---|---|
| *Приведенные далее действия выполняются медицинским персоналом, который осуществляет уход за пациентами.* | |
| Подключите аппарат к источнику питания. | Раздел 3.1 |
| Подключите дыхательный контур | Раздел 3.2 |
| Включите увлажнитель | Раздел 3.3 |
| Выполните тестирование тревог | Раздел 3.4 |
| Выберите настройки увлажнителя | Раздел 3.5 |
| Подключите пациента | Раздел 3.6 |

## 3.1 Подключение к источнику питания

Всегда проверяйте исправность розетки основного источника питания, прежде чем подключать увлажнитель и аппарат ИВЛ.

### Подключение увлажнителя к источнику питания

- Подключите увлажнитель к розетке сети переменного тока.[74]

## 3.2 Подключение дыхательного контура к увлажнителю

Hamilton Medical предлагает различные дыхательные контуры для проведения терапии у взрослых, педиатрических и неонатальных пациентов.

Подробные сведения см. в соответствующих *Инструкциях по эксплуатации* дыхательного контура.

## 3.3 Включение и выключение увлажнителя

Увлажнитель автоматически запускается в настроенном режиме по умолчанию.

*Прежде чем* активировать увлажнитель, убедитесь, что аппарат ИВЛ включен.

### Включение увлажнителя

- Нажмите кнопку питания / ждущего режима и удерживайте ее 3 секунды.

Увлажнитель начнет самотестирование. Если настройки не изменялись, увлажнитель автоматически запускается в режиме инвазивной вентиляции (INV).

### Выключение увлажнителя

- Нажмите кнопку и удерживайте ее 3 секунды.

*Прежде чем* выключить аппарат ИВЛ, убедитесь, что питание увлажнителя отключено.

## 3.4 Тестирования тревог

Прежде чем подключить увлажнитель к новому пациенту, проверьте работу системы тревог.

Убедитесь, что увлажнитель включен.

### Проверка работы системы тревог увлажнителя

1. Спровоцируйте срабатывание тревоги, отсоединив водную камеру.
2. Убедитесь, что:
   – срабатывает звуковой сигнал;
   – мигает визуальный индикатор тревоги (см. рисунок 4);
   – соответствующий значок тревоги отображается на экране (см. таблицу 9).

Устраните причину срабатывания тревоги, подсоединив водную камеру в увлажнитель, и убедитесь, что тревога отключилась.

[74] Подключите кабель питания увлажнителя к специальному разъему на аппарате ИВЛ (при использовании совместимого аппарата ИВЛ Hamilton Medical).

## 3.5 Выбор настроек увлажнителя

Установите режим увлажнения для пациента.[75] Подробные сведения приведены в разделе 4.2.

## 3.6 Подсоединение системы к пациенту

Подключите дыхательный контур к соответствующему интерфейсу пациента.

Теперь увлажнитель настроен и готов к использованию.

# 4 Использование увлажнителя HAMILTON-H900

Таблица 6. Обзор правил эксплуатации

| Подробные сведения | См. |
|---|---|
| Включение и выключение увлажнителя | Раздел 3.3 |
| Включение и выключение ждущего режима | Раздел 4.1 |
| Просмотр параметров увлажнителя | Раздел 2.3 |
| Режимы работы увлажнителя: INV, NIV, HiFlow | Раздел 4.2 |
| Автоматические и задаваемые вручную параметры | Раздел 4.2.2 |
| Изменение показателя влажности с помощью параметров температуры | Раздел 4.3 |
| Мониторируемые параметры увлажнителя | Раздел 4.4 |
| Связанные с увлажнителем тревоги | Раздел 5 |

## 4.1 Включение и выключение ждущего режима

**⚠ ВНИМАНИЕ**

*В ждущем режиме все настройки сохраняются, а тепловыделение сокращается.*

Ждущей режим – это режим, в котором сохраняются установленные текущие настройки, когда увлажнитель не работает.

Во время Реж. ожид. значения температуры на выходе из водной камеры и температурного градиента снижаются.[76] Подробные сведения приведены в разделе 9.7.

### Включение ждущего режима

- Нажмите и сразу отпустите кнопку питания / ждущего режима  .

  В ждущем режиме с момента его активации на дисплее отображается отсчет времени. Горит индикатор кнопки питания / ждущего режима оранжевого цвета.

[75] При использовании с аппаратами ИВЛ Hamilton Medical, которые поддерживают интеграцию устройств, увлажнитель переключается в режим, активированный на данном аппарате. Подробные сведения приведены в *Руководстве пользователя* аппарата ИВЛ.

[76] При выполнении ингаляционной терапии температурный градиент *не* изменяется в ждущем режиме.

### Переход из ждущего режима в режим работы

- Нажмите кнопку  .

  Увлажнитель перейдет в режим нормальной работы и загорится зеленый индикатор состояния кнопки питания / ждущего режима.

## 4.2 Рабочие режимы увлажнителя

Рабочие режимы, доступные в увлажнителе HAMILTON-H900: инвазивный (INV), неинвазивный (NIV), а также кислородная терапия с высокой скоростью потока (HiFlow).

Выбором рабочего режима определяются начальные настройки температуры на выходе из водной камеры и со стороны У-образного коннектора (температурный градиент), а также диапазоны допустимых температур для этих параметров.

Эти диапазоны отличаются в зависимости от группы пациентов. См. таблицу 18.

### 4.2.1 Изменение режимов

Если настройки по умолчанию не изменялись, увлажнитель автоматически запускается в режиме инвазивной вентиляции (INV).

При переходе увлажнителя в режим инвазивной (INV) или неинвазивной (NIV) вентиляции, для контролируемых параметров автоматически включается режим Auto.

### Как изменить режим

- Нажимайте кнопку выбора режимов  , пока не появится необходимый (INV, NIV, HiFlow).

  Значок выбранного режима отобразится на дисплее.

Рисунок 6. Выбрана инвазивная вентиляция (**1**)

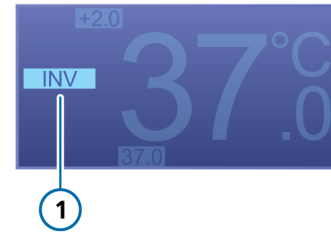



Рисунок 7. Выбрана неинвазивная вентиляция (**1**)

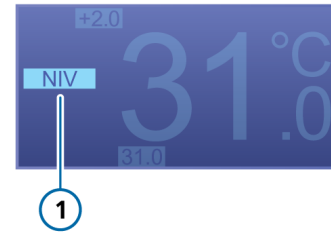
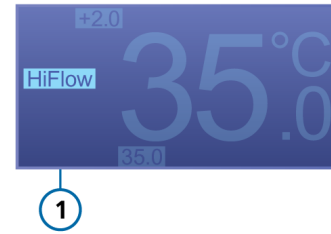



Рисунок 8. Выбран режим HiFlow (**1**)



### 4.2.2 Автоматические и задаваемые вручную контролируемые параметры

Увлажнитель можно запустить в автоматическом режиме Auto или задать параметры вручную. При запуске устройства режимом по умолчанию является автоматический, Auto.

Значения температуры на выходе из камеры и температурного градиента можно установить при помощи одного из указанных ниже способов.

- Загрузить как сконфигурированные настройки по умолчанию (режим Auto).
- Задать вручную.

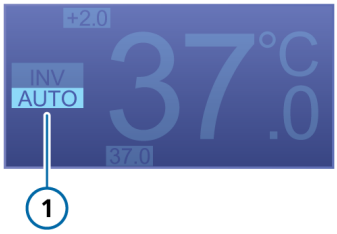
#### Автоматическая настройка (режим «Авто»)

В режиме Auto увлажнитель загружает заданные для соответствующего режима настройки по умолчанию (см. раздел 7) и использует их для контроля температуры газовой смеси.

При низких температурах окружающей среды увлажнитель может автоматически регулировать температуру в водной камере.

При активации режима Auto на главном экране отображается надпись AUTO.

Рисунок 9. Выбран автоматический режим (**1**)

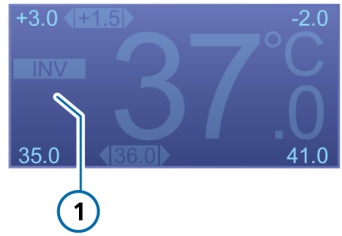



#### Ручная настройка

Чтобы изменить значение температуры на выходе из камеры или температурного градиента с помощью ползунков, необходимо перейти в ручной режим. Однако увлажнитель и в дальнейшем будет автоматически регулировать температуру, чтобы достичь заданных значений.

Если изменение параметров происходит в ручном режиме, надпись AUTO не отображается – область на главном экране остается незанятой.

Рисунок 10. Активирован ручной режим (**1**)




#### 4.2.2.1 Включение автоматического режима

После изменения параметров температуры вручную можно повторно включить режим Auto.

#### Повторное включение автоматического режима

- Нажмите кнопку включения режима Auto (Auto).

  При смене режима вентиляции с INV на NIV и наоборот автоматически применяется конфигурация Auto.

## 4.3 Изменение показателя влажности с помощью параметров температуры

***ПРЕДОСТЕРЕЖЕНИЕ***

При изменении положения любого ползунка в режиме Auto увлажнитель переключается в ручной.

***ПРЕДОСТЕРЕЖЕНИЕ***

Нельзя изменить значение температурного градиента в режиме HiFlow с помощью ползунков. Задать новое значение температурного градиента можно в окне конфигурации. См. раздел 7.

Далее указаны параметры, значения которых можно корректировать на увлажнителе [77].

Таблица 7. Регулируемые параметры увлажнителя

| Параметр | Описание |
|---|---|
| Температура на выходе из камеры | Температура на выходе из водной камеры.<br>Допустимый диапазон температур для этого параметра зависит от выбранного режима увлажнителя: Подробные сведения см. в таблицах 16 и 18.<br>Чем выше значения, тем больше показатель абсолютной влажности. |
| Температурный градиент | Разница температур на выходе из водной камеры и со стороны У-образного коннектора. |
| Увелич. Темп. | Если выбран этот параметр, увлажнитель повышает температуру в патрубке выдоха для уменьшения конденсации.[78] |

Максимальная допустимая температура со стороны пациента (в У-образном коннекторе) составляет 42 °C. Сумма значений, заданных для температуры на выходе из камеры и температурного градиента, не должна превышать это ограничение. Например, если для температурного градиента выбрано значение 2 °C, максимальное значение для температуры на выходе из камеры составляет 40 °C.

Кроме того, значение температурного градиента приоритетнее значения температуры на выходе из камеры. Поэтому если сумма значений температур в У-образном коннекторе превысит 42 °C, то будет изменено значение температуры на выходе из камеры, а не температурного градиента.

Например, если для температуры на выходе из камеры выбрать значение 40 °C, температурный градиент можно установить на 3 °C, хотя сумма значений будет превышать 42 °C. После применения значения температурного градиента, значение температура на выходе из камеры будет автоматически изменено на 39 °C.

[77] При использовании с аппаратом ИВЛ Hamilton Medical со встроенными средствами управления увлажнителем изменять настройки можно также непосредственно на данном аппарате ИВЛ. Подробные сведения приведены в *Руководстве пользователя* аппарата ИВЛ.

[78] Использование одноразовое и только с нагреваемыми дыхательными контурами с двумя патрубками.

### Регулировка температуры на выходе из камеры

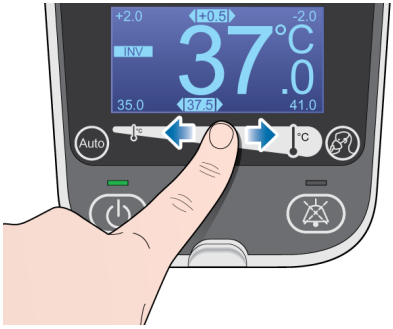
- Коснитесь текущего значения температуры на выходе из камеры и перетяните ползунок:

  – влево, чтобы уменьшить температуру на выходе из камеры;

  – вправо, чтобы увеличить температуру на выходе из камеры.

Изменения применяются сразу и подтверждаются звуковым сигналом.

Рисунок 11. Регулировка температуры на выходе из камеры




### Установка температуры на выходе из камеры > 39 °C

Чтобы установить значение температуры на выходе из камеры выше 39 °C, необходимо дважды переместить ползунок.

1. Коснитесь текущего значения и переместите ползунок температуры на выходе из камеры вправо, чтобы достичь граничного значения 39 °C.
2. Снова коснитесь ползунка и переместите за значение 39 °C.

### Установка температурного градиента

- Коснитесь текущего значения температурного градиента и перетяните ползунок:

  – вправо, чтобы уменьшить температурный градиент;

  – влево, чтобы увеличить температурный градиент.

Изменения применяются сразу и подтверждаются звуковым сигналом.

Рисунок 12. Регулировка температурного градиента


Например, чтобы достичь температуры со стороны У-образного коннектора 39 °C при установленном значении температуры на выходе из камеры 37 °C, необходимо задать температурный градиент 2 °C.

## 4.4 Мониторинг параметров увлажнителя

Данные мониторинга доступны в окне мониторинга температуры, в которое можно перейти в любое время.[79]

[79] При использовании с аппаратом ИВЛ Hamilton Medical со встроенными средствами мониторинга работы увлажнителя данные с него отображаются на экране аппарата ИВЛ. Подробные сведения приведены в *Руководстве пользователя* аппарата ИВЛ.

Мониторируемые параметры указаны ниже.

- Температура на выходе из камеры
- Температурный градиент
- Температура со стороны У-образного коннектора

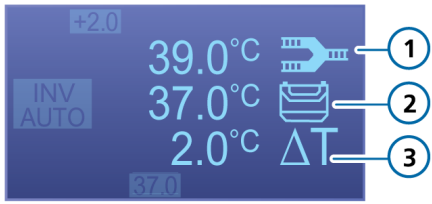
### 4.4.1 Отображение дополнительных мониторируемых параметров

#### Отображение окна мониторинга температуры

- Нажмите кнопку (окно мониторинга температуры).

  Окно закроется через 30 секунд или после повторного нажатия кнопки.

Рисунок 13. Окно мониторинга температуры




| | | | |
|---|---|---|---|
| 1 | Текущая температура со стороны У-образного коннектора | 3 | Текущий температурный градиент |
| 2 | Текущая температура на выходе из камеры | | |

## 4.5 Дневной и ночной режим яркости экрана

Дисплей увлажнителя поддерживает два различных режима подсветки. С их помощью можно регулировать яркость дисплея.

#### Переключение между дневным и ночным режимом

- Нажмите кнопку и удерживайте ее не менее 5 секунд.

Чтобы установить значение яркости по умолчанию для дневного или ночного режима, см. раздел 7.

# 5 Реагирование на тревоги, связанные с работой увлажнителя

Тревоги, связанные с работой увлажнителя, свидетельствуют о возникновении условий, на которые необходимо обратить внимание. Ниже приведены способы индикации тревог.

- Сообщение на экране увлажнителя.
- Подача 3 или 5 последовательных звуковых сигналов.
- Мигание сигнальной лампы над водяной камерой.
- При использовании с аппаратом ИВЛ Hamilton Medical со встроенными средствами мониторинга работы увлажнителя сообщения о тревогах также отображаются на экране аппарата ИВЛ.[80]

Все сообщения подразделяются на три категории: тревоги с высокой и средней приоритетностью, а также аппаратные ошибки (см. таблицу 8).

Чтобы ознакомиться с полным списком тревог, см. таблицу 9.

Таблица 8. Индикаторы тревог

| Тип тревоги | Индикатор состояния тревоги | Звуковой сигнал | Необходимое действие |
|---|---|---|---|
| Высокая приоритетность | Красный, мигает<br>На экране отображается значок тревоги | 5 последовательных звуковых сигналов, повторяются до отключения тревоги | Проблема, связанная с работой увлажнителя, требует неотложного решения. |
| Средняя приоритетность | Желтый, мигает<br>На экране отображается значок тревоги | 3 последовательных звуковых сигналов, повторяются до отключения тревоги | Проблема, связанная с работой увлажнителя, требует оперативного решения. |
| Аппаратная ошибка | Красный, мигает<br>На экране отображается номер аппаратной ошибки (TF). | 3 последовательных звуковых сигналов, повторяются до отключения тревоги | • Запишите номер аппаратной ошибки (TF)[81].<br>• Прекратите использовать увлажнитель.<br>• Передайте увлажнитель на техническое обслуживание. |

[80] Доступно не во всех аппаратах ИВЛ. См. *Руководство пользователя* аппарата ИВЛ.
[81] См. список номеров аппаратных ошибок (TF) в *Руководстве по обслуживанию HAMILTON-H900*.

## 5.1 Временное отключение звукового сигнала тревоги

Сообщения о тревогах сопровождаются звуковым сигналом. Для большинства тревог звуковой сигнал отключается на две минуты.

### Временное отключение звукового сигнала тревоги

- Нажмите кнопку временного отключения звуковой сигнализации  на передней панели увлажнителя.

  Звуковая сигнализация тревоги отключится на две минуты.

  Повторное нажатие кнопки отменяет временное отключение звуковой сигнализации.

При отключении звуковой сигнализации кнопка временного отключения звуковой сигнализации непрерывно подсвечивается красным.

Если время до повторной активации звуковой сигнализации истекло, а проблема еще не устранена, звуковой сигнал тревоги срабатывает повторно.

## 5.2 Регулировка громкости сигнала тревоги

**⚠ ПРЕДУПРЕЖДЕНИЕ**

Установленная громкость звукового сигнала должна превышать уровень внешних шумов. В противном случае вы не сможете услышать сигналы тревог и определить причины их срабатывания.

Громкость звукового сигнала тревоги можно регулировать.

По умолчанию для параметра «Громкость» установлено значение 5. Значение по умолчанию для громкости звукового сигнала тревоги восстанавливается после выключения увлажнителя.

### Регулировка громкости сигнала тревоги

1. При необходимости нажмите кнопку питания / ждущего режима  , чтобы перевести увлажнитель в ждущий режим.
2. Нажмите кнопку  и удерживайте ее 3 секунды.

   На экране появится текущее значение громкости звукового сигнала тревоги.
3. Отрегулируйте громкость сигнала тревоги с помощью ползунка температуры на выходе из камеры (см. рисунок 3).

   В подтверждение выбранного значения сработает звуковой сигнал установленной громкости.
4. Наймите кнопку  , чтобы подтвердить выбор и продолжайте работу в обычном режиме.

## 5.3 Устранение причин срабатывания тревог

В таблице 9 приводится список связанных с увлажнителем тревог, их графическое представление на устройстве, а также описание и предлагаемые меры по устранению причин срабатывания.

Таблица 9. тревоги HAMILTON-H900

| Тревога | Значок тревоги | Описание | Необходимое действие |
|---|---|---|---|
| **Высокая приоритетность** | | | |
| Увлажнитель: наклон |  | Опасный угол наклона увлажнителя.<br>Увлажнитель наклонен на 10° или больше относительно пола. | • Проверьте крепление увлажнителя.<br>• Проверьте положение тележки для аппарата ИВЛ.<br>• Установите увлажнитель под углом не более 10° относительно пола. |
| Температура высокая |  | Температура газовой смеси на выходе из водной камеры или со стороны У-образного коннектора превышает заданное значение. | • Убедитесь, что дыхательный контур на кушетке пациента не накрыт одеялом.<br>• Проверьте, защищены ли дыхательный контур и водная камера от попадания прямого солнечного света.<br>• Замените дыхательный контур. |
| Высота уровня воды |  | Уровень воды в камере превышает обозначенный максимальный. | • Слейте немного воды из камеры увлажнителя.<br>• Замените камеру увлажнителя.<br>• Установите увлажнитель под углом не более 10° относительно пола. |

| Тревога | Значок тревоги | Описание | Необходимое действие |
|---|---|---|---|
| Аппаратная ошибка | На экране отображается номер аппаратной ошибки (TF). | Сообщение об аппаратной ошибке, обусловленной неисправностью увлажнителя. | • Проверьте увлажнитель и все соединения.<br>• Замените увлажнитель и передайте его на техническое обслуживание.<br>• Если отображается код аппаратной ошибки, запишите его и предоставьте специалисту по техническому обслуживанию. |
| **Средняя приоритетность** | | | |
| Низкая температура |  | Температура газовой смеси на выходе из водной камеры или со стороны У-образного коннектора ниже заданного значения. | • Подождите, пока система полностью прогреется (до 30 минут).<br>• Проверьте все настройки.<br>• Убедитесь, что на увлажнитель и дыхательный контур не попадают прямые воздушные потоки из систем кондиционирования воздуха и т. п. |
| Низкий уровень воды |  | Уровень воды в камере ниже обозначенного минимального. | • Проверьте состояние бутылки с водой и при необходимости заполните ее.<br>• Если бутылка с водой пуста, подключите новую.<br>• Наполните камеру увлажнителя водой или замените ее.<br>• Установите увлажнитель под углом не более 10° относительно пола. |

| Тревога | Значок тревоги | Описание | Необходимое действие |
|---|---|---|---|
| Проверьте водную камеру |  | Отсутствует или установлена несовместимая водная камера. | Вставьте новую камеру увлажнителя и подключите дыхательный контур. |
| Проверьте патрубки (справа и слева) |  | На место неисправности указывает информация на экране, а также индикаторы подключения.<br>• Отсутствует патрубок или подключен неисправный.<br>• Отсутствует поток воздуха.<br>• Патрубок подключен неправильно.<br>• БЕЛЫЙ патрубок выдоха со стороны увлажнителя подсоединен к порту вдоха *к пациенту* на аппарате ИВЛ. | • Подсоедините дыхательный контур надлежащим образом.<br>• Замените дыхательный контур.<br>• Подсоедините СИНИЙ патрубок вдоха со стороны увлажнителя к порту вдоха *к пациенту* на аппарате ИВЛ.<br><br>Цвет индикатора соединения<br>*Зеленый:* патрубок присоединен правильно.<br>*Оранжевый:* увлажнитель проверяет соединение.<br>*Красный:* соединение неправильное или отсутствует. |

# 6 Техническое обслуживание

*Прежде чем продолжить, ознакомьтесь с правилами техники безопасности в разделе 1.*

В этом разделе описываются процедуры технического обслуживания увлажнителя и периодичность их проведения, а также приведены инструкции по его очистке и дезинфекции.

Все описанные в этом разделе процедуры должен выполнять оператор.

За дополнительными требованиями касательно технического обслуживания обращайтесь к представителю сервисной службы компании Hamilton Medical. С указанными в этом разделе документами можно ознакомиться на веб-сайте MyHamilton: https://www.hamilton-medical.com/MyHamilton

## 6.1 Очистка, дезинфекция и стерилизация

Компоненты увлажнителя необходимо регулярно чистить и дезинфицировать с применением специализированных методов и чистящих средств.

Для очистки и дезинфекции увлажнителя и его компонентов важно выбрать подходящие метод и материалы. Это предотвратит возможное повреждение оборудования и перекрестное заражение.

Информация об очистке и дезинфекции представлена в таблицах ниже.

- В таблице 10 приведен список используемых с увлажнителем компонентов. Для каждого компонента указан метод очистки или дезинфекции, частота проведения данной процедуры, а также рекомендуемые чистящие и дезинфицирующие средства.
- Информацию о комплектах дыхательного контура и водяных камерах см. в *Инструкциях по эксплуатации* и *Руководстве по повторной обработке*.

Применяя методы очистки и чистящие средства при обслуживании компонентов увлажнителя, учтите указанное ниже.

- *Запрещается* выполнять процедуры по дезинфекции, непредусмотренные компанией Hamilton Medical.
- Мы предоставляем информацию о рекомендуемых чистящих средствах и концентрациях растворов. Если у вас возникнут дополнительные вопросы касательно использования конкретного чистящего или дезинфицирующего средства, обратитесь к соответствующему производителю.

Таблица 10. Методы очистки и дезинфекции увлажнителя

| Деталь | Частота тока | Метод очистки/ дезинфекции | Чистящие средства |
|---|---|---|---|
| Наружные компоненты увлажнителя<br>• Корпус<br>• Экран<br>• Нагревательная пластина<br>• Кабели питания<br>• Крепежные системы | Каждый раз после использования для проведения терапии у пациента или при необходимости. | Протереть влажной тканью, смоченной в растворе зарегистрированного и одобренного чистящего или дезинфицирующего средства. | Бактерицидные салфетки Super Sani-Cloth<br>CaviWipes |

## 6.2 Профилактическое обслуживание

Профилактический осмотр увлажнителя должен выполняться квалифицированным персоналом по техническому обслуживанию компании Hamilton Medical с соблюдением инструкций, указанных в *Руководстве по обслуживанию HAMILTON-H900*.

# 7 Конфигурация

Увлажнитель поставляется с различными конфигурациями настроек по умолчанию, которые используются для разных групп пациентов.

В режиме конфигурации можно изменить указанные ниже настройки по умолчанию.

- Температура на выходе из камеры
- Температурный градиент
- Режим работы при запуске (INV/NIV/HiFlow)
- Включение/выключение функции повышения температуры на выдохе
- Яркость экрана в дневном/ночном режиме

## 7.1 Доступ к режиму «Конфиг-ция»

В режим конфигурации можно перейти из ждущего режима.

**Доступ к режиму «Конфиг-ция»**

1. Нажмите кнопку , чтобы войти в ждущий режим (если необходимо).
2. Нажмите и удерживайте кнопки и Auto.
   Первой необходимо нажать кнопку .
   Окно конфигурации откроется через 5 секунд.

Теперь увлажнитель работает в режиме конфигурации.

## 7.2 Изменение настроек конфигурации

Выбранные пользователем параметры сохраняются до тех пор, пока не будут внесены изменения или восстановлены заводские настройки.

В режиме конфигурации кнопки на передней панели увлажнителя используются для выбора элементов и навигации между режимами просмотра.

В таблице 11 приведены инструкции по навигации между разделами окна конфигурации и изменению параметров.

В качестве примера ознакомьтесь с процедурой изменения настроек по умолчанию для температурного градиента ниже.

Список параметров конфигурации см. в разделе 9.6.

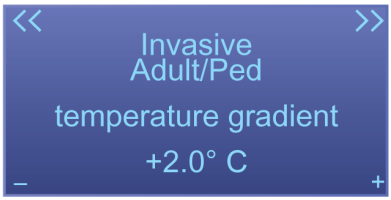
Таблица 11. Навигационные кнопки режима конфигурации

| Кнопка | Описание |
|---|---|
|  | Переход вперед между разделами |
|  | Переход назад между разделами |
|  | Увеличение значения |
|  | Уменьшение значения |
|  | Сохранение изменений и выход из режима конфигурации |

### Пример: Изменение температурного градиента

#### Изменение настроек по умолчанию температурного градиента при инвазивной ИВЛ взрослых/педиатрических пациентов

1. В режиме конфигурации нажимайте кнопку Exp., пока не появится окно настройки температурного градиента при инвазивной ИВЛ взрослых/педиатрических пациентов Invasive, Adult/Ped, Temperature gradient.




2. Чтобы увеличить значение, нажмите кнопку, чтобы уменьшить – Auto.
3. После внесения всех необходимых изменений нажмите кнопку, чтобы их сохранить и выйти из режима конфигурации.

## 7.3 Восстановление заводских настроек по умолчанию

Заводские настройки по умолчанию можно восстановить в любое время.

#### Восстановление заводских настроек по умолчанию

1. В режиме конфигурации последовательно нажимайте кнопку Exp., пока не откроется раздел сброса пользовательских настроек по умолчанию Reset all custom defaults.
2. Нажмите кнопку Auto.

Заводские настройки по умолчанию восстановятся.

# 8 Детали и принадлежности

В этом разделе указаны детали и принадлежности, которые можно приобрести для увлажнителя HAMILTON-H900.

Дополнительную информацию можно найти в электронном каталоге на вебсайте Hamilton Medical или получить у представителя компании.

Таблица 12. Детали и принадлежности увлажнителя

| PN | Описание |
|---|---|
| 260161 | Комплект нагреваемого дыхательного контура HAMILTON-BC8022 с двумя патрубками и водной камерой |
| 260186 | Комплект нагреваемого дыхательного контура HAMILTON-BC4022 с одним патрубком и водной камерой |
| 260185 | Комплект нагреваемого дыхательного контура HAMILTON-BC8010 с двумя патрубками, водной камерой и удлинителем для использования в кувезах |
| 260187 | Комплект нагреваемого дыхательного контура HAMILTON-BC4010 с одним патрубком, водной камерой и удлинителем для использования в кувезах |
| 260196 | Одноразовая водная камера HAMILTON-HC322 |
| 260197 | Одноразовая водная камера HAMILTON-HC310 |

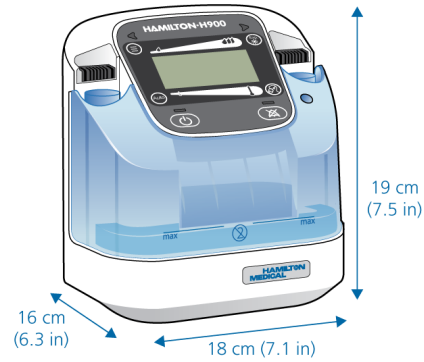
# 9 Технические характеристики

## 9.1 Физические характеристики

Таблица 13. Физические характеристики

| Параметр | Технические характеристики |
|---|---|
| Масса | Увлажнитель (с незаполненной водной камерой): 2,5 кг |
| Габариты | См. рисунок 14 |

Рисунок 14. Габариты увлажнителя HAMILTON-H900



## 9.2 Требования к условиям окружающей среды

Таблица 14. Требования к условиям окружающей среды

| Среда | | Технические характеристики |
|---|---|---|
| Температура | Эксплуатация: | 10–40 °C |
| | Хранение: | –20–60 °C |
| | | Рекомендованная температура окружающей среды: 18–26 °C |
| Высота | | До 4000 м |
| Атмосферное давление | При работе и хранении: | 61–106 кПа |
| Относительная влажность | Эксплуатация: | 30–95% (без конденсации) |
| | Хранение: | 10–95% (без конденсации) |
| Защита от попадания воды | | IP21 |
| Температура газовой смеси на входе | | 18–31 °C (рекомендовано) |

## 9.3 Электрические характеристики

Таблица 15. Электрические характеристики

| Номер детали | Входная мощность | Потребляемая мощность |
|---|---|---|
| 950001 (230 В) | 220–240 В<br>50 / 60 Гц | 283 В·А |
| 950004 (115 В) | 110–127 В<br>50 / 60 Гц | 293 В·А |
| 950008 (100 В) | 100 В<br>50 / 60 Гц | 268 В·А |
| Выравнивание потенциалов | Зажим для подключения проводника выравнивания потенциалов (согласно DIN 42801) | |

## 9.4 Контролируемые параметры

Таблица 16. Контролируемые параметры и их диапазоны

| Параметр или настройка (единицы измерения) | Режим | Диапазон | По умолчанию | Разрешение |
|---|---|---|---|---|
| Температура на выходе из камеры (°C) | INV | 35–41 | 37,0 | 0,5 |
| | NIV | 30–35 | 31,0 | 0,5 |
| | HiFlow | 33–37 | 35,0 | 2 |
| Температурный градиент (°C) | INV | –2–3 | Взрос./Пед.: 2<br>Младенец: 3 | 0,5 |
| | NIV | –2–3 | Взрос./Пед.: 2<br>Младенец: 3 | 0,5 |
| | HiFlow | -- | 2 | -- |
| Итоговая максимальная температура в дыхательных путях (У-образный коннектор)[82] (°C) | INV | 33–42 | -- | -- |
| | NIV | 28–38 | -- | -- |
| | HiFlow | 35–39 | -- | -- |
| Повышение температуры на выдохе | Все режимы | Вкл., Выкл. | Вкл. | -- |
| Настройка яркости экрана | Все режимы | 1–5 | День: 5<br>Ночь: 2 | 1 |

[82] Согласно настройкам увлажнителя максимальная температура в дыхательных путях составляет 42 °C.

## 9.5 Мониторируемые параметры

Таблица 17. Диапазоны и погрешности мониторируемых параметров

| Параметр (единицы измерения) | Диапазон | Точность |
|---|---|---|
| Температура на выходе из камеры (°C) | 10–60 | 10–30: ±1<br>30–41: ±0,5<br>41–60: ±1 |
| Температура со стороны У-образного коннектора (°C) | 28–43 | ±0,5 |

## 9.6 Конфигурация

Таблица 18. Спецификации конфигурации

| Параметр | Режим | Варианты конфигурации | Значение по умолчанию |
|---|---|---|---|
| Температура на выходе из камеры (°C) | INV | 35–39 | 37,0 |
| | NIV | 30–35 | 31,0 |
| | HiFlow | 33, 35, 37 | 35,0 |
| Температурный градиент (°C) | INV | 0–3 | Взрос./Пед.: 2<br>Младенец: 3 |
| | NIV | 0–3 | Взрос./Пед.: 2<br>Младенец: 3 |
| | HiFlow | 0–3 | 2 |
| Режим при запуске | -- | Инвазивная вентиляция, неинвазивная вентиляция, HiFlow | Инвазивные |
| Настройка яркости экрана | Все режимы | 1–5 | День: 5<br>Ночь: 2 |

## 9.7 Данные о технической производительности

Таблица 19. Данные о технической производительности

| Описание | Технические характеристики | | |
|---|---|---|---|
| Скорость потоков[83] | Инвазивная вентиляция: | До 60 л/мин | |
| | Неинвазивная вентиляция: | До 120 л/мин | |
| | HiFlow: | До 120 л/мин | |
| Время прогрева | Менее 30 мин | | |
| Влажность | При температуре окружающей среды 18–26 °C | | |
| | Инвазивная вентиляция: | При заданных значениях температуры 37–41 °C | Минимальный уровень влажности: 33 мг H2O/л |
| | Неинвазивная вентиляция: | При заданных значениях температуры 31–35 °C | Минимальный уровень влажности: 12 мг H2O/л |
| | HiFlow: | Скорость потока : ≤ 60 л/мин | Минимальный уровень влажности: 33 мг H2O/л |
| | | Скорость потока : > 60 л/мин | Минимальный уровень влажности: 12 мг H2O/л |
| Характеристики подогрева в ждущем режиме | Нагреваемые дыхательные контуры: | Ограничение в 30 °C в У-образном коннекторе | |
| Экран | 3 дюйма, 64 x 128 пикселей, инвертированный точечно-матричный дисплей (с задней подсветкой) | | |
| Временное отключение звуковой сигнализации | 120 с | | |
| Громкость сигнала тревоги[84] | Диапазон = 1–8. По умолчанию = 5. | | |

[83] Информацию о минимальных скоростях потока см. в *Инструкциях по эксплуатации* дыхательного контура.
[84] Громкость на расстоянии 1 м от увлажнителя. Уровень 1 = 50 дБ(A), 5 (по умолчанию) = 60 дБ(A), 8 = 65 дБ(A), погрешность ±6 дБ(A).

## 9.8 Базовая производительность

Температуру респираторной газовой смеси и дыхательных контуров следует контролировать и поддерживать в диапазоне заданных значений.

Если значение температуры находится вне пределов установленного диапазона, в увлажнителе срабатывает тревога, оповещающая пользователя о проблеме.

## 9.9 Функциональное описание системы увлажнителя

Увлажнитель HAMILTON-H900 предназначен для подогрева и увлажнения дыхательных газовых смесей во время механической вентиляции легких. Дыхательная газовая смесь нагревается и увлажняется, проходя через камеру, которая частично заполнена нагретой водой.

Увлажнитель использует две системы подогрева, которые контролируются датчиками.

- *Нагревательная пластина*. Нагревает воду в камере.
- *Встроенная нагревательная система дыхательного контура*. Нагревает дыхательные патрубки для предотвращения конденсации.

Температура респираторной газовой смеси проверяется на выходе из камеры и в дыхательном патрубке со стороны пациента.

## 9.10 Обозначения, используемые на наклейках устройства и упаковке

| Значок | Описание |
|---|---|
|  | Следуйте *инструкциям по эксплуатации* |
|  | Идентификационный номер |
|  | Серийный номер |
|  | Количество |
|  | Производитель |
|  | Дата выпуска |
|  | Рабочая часть аппарата (изделие типа BF), находящаяся в непосредственном контакте с пациентом; тип BF согласно классификации по стандарту МЭК 60601-1 для медицинского электрооборудования. |
|  | Утилизировать в соответствии с Директивой 2002/96/EC или Директивой WEEE («Отходы электрического и электронного оборудования»). |

| Значок | Описание |
|---|---|
|  | Знак TÜV NRTL с обозначениями C и US указывает, что продукт соответствует требованиям к безопасности, установленным уполномоченными органами в Канаде и США соответственно. |
|  | Выравнивание потенциалов |
|  | Предупреждение: горячая поверхность.<br>Нагревательная пластина и нижняя часть камеры могут нагреваться до температуры свыше 85 °C. |
| CE 0197 | Маркировка CE – знак, означающий соответствие изделия требованиям Европейского Союза, а именно Директиве 93/42/ЕЭС «О медицинском оборудовании». |
| IP21 | Защита от попадания капель воды и твердых частиц размером больше 12,5 мм |
| max | Отметка уровня заполнения водной камеры |
|  | Последовательный интерфейс RS-232 для обмена данными с аппаратами ИВЛ Hamilton Medical |

| Значок | Описание |
|---|---|
|  | Небезопасен для МРТ<br>В условиях магнитного резонанса увлажнитель HAMILTON-H900 представляет опасность для пациента, медицинских работников и других людей. |
|  | Правила ограничения содержания вредных веществ (Китай) |
|  | Температурный зонд<br>Указывает положение температурного зонда в дыхательном контуре. |

## 9.11 Стандарты и утверждения

Система увлажнителя отвечает разделам стандартов, приведенных в таблице 20.

Таблица 20. Стандарты и утверждения, действующие версии

| |
|---|
| МЭК 60601-1:2005/A1:2012 |
| МЭК 60601-1-2:2014 |
| МЭК 60601-1-6:2010/A1:2013 |
| МЭК 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| МЭК 62304:2006/A1:2015 |
| МЭК 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Утилизация

Устройство необходимо утилизировать согласно протоколам, действующим в учреждении, а также в соответствии с положениями Директивы 2002/96/EC.

Дыхательные контуры и водные камеры следует утилизировать в соответствии с *Инструкциями по эксплуатации* из комплекта поставки дыхательного контура.

## 9.13 Гарантия

ОГРАНИЧЕННАЯ ГАРАНТИЯ

ОПИСАННАЯ В ДАННОМ СОГЛАШЕНИИ ГАРАНТИЯ ЗАМЕНЯЕТ ЛЮБЫЕ ДРУГИЕ ГАРАНТИЙНЫЕ ОБЯЗАТЕЛЬСТВА, ЯВНО ВЫРАЖЕННЫЕ ИЛИ ПОДРАЗУМЕВАЕМЫЕ, ВКЛЮЧАЯ КОСВЕННЫЕ ГАРАНТИИ ТОВАРНОГО КАЧЕСТВА ИЛИ ПРИГОДНОСТИ ДЛЯ ИСПОЛЬЗОВАНИЯ ПО НАЗНАЧЕНИЮ. ОДНАКО В ТЕЧЕНИЕ СРОКА ДЕЙСТВИЯ ЭТОЙ ОГРАНИЧЕННОЙ ГАРАНТИИ ОТКАЗ ОТ ПОДРАЗУМЕВАЕМЫХ ГАРАНТИЙ НЕ ДОПУСКАЕТСЯ.

Компания Hamilton Medical гарантирует отсутствие дефектов в поставляемых изделиях, а именно материальных и производственных дефектов. Гарантия не покрывает предметы однократного использования. Предметы однократного использования и расходные материалы рассматриваются исключительно как изделия разового или ограниченного пользования и должны регулярно заменяться согласно указанным в этом руководстве требованиям для надлежащей работы аппарата.

Компания Hamilton Medical не несет никаких обязательств или ответственности относительно продукта, кроме указанных в тексте этой гарантии, включая, помимо прочего, обязательства и (или) ответственность в случае возможной небрежности либо безусловные обязательства. Ни при каких обстоятельствах компания не несет ответственность за побочные или косвенные убытки, как прямые, так и условные.

Эта ограниченная гарантия недействительна и не применяется в приведенных ниже случаях.

1. Изделие не было установлено и подключено уполномоченным региональным представителем компании Hamilton Medical в соответствии с инструкциями, предоставленным компанией Hamilton Medical или ее представителем.
2. Нет доказательств того, что повреждение возникло или ремонт был выполнен на протяжении предусмотренного гарантийного периода.
3. Серийный номер изделия был изменен, стерт или удален, и отсутствует чек на проданный товар либо другое подтверждение, с помощью которого можно установить дату приобретения изделия.
4. Причиной повреждений является неправильное использование, невнимательность, несчастный случай, а также ремонт, регулировка, модификация или замена компонентов, выполненные за пределами заводов компании Hamilton Medical либо другим сервисным центром или представителем, не авторизованным ею.

5. В изделие были внесены модификации или были изменены какие-либо его свойства без предварительного письменного разрешения от компании Hamilton Medical.
6. Продукт используется или ранее использовался любым способом, не указанным в разделе «Назначение устройства».
7. Продукт использовался неквалифицированным, не прошедшим соответствующее обучение персоналом и не под наблюдением врача.

Замена и/или ремонт, выполненный в течение срока действия этой ограниченной гарантии, не подразумевают выдачу новой гарантии, а включают только неистекший срок оригинальной. Гарантия на отремонтированные и/или замененные компоненты не имеет приоритета над ограниченной гарантией на устройство.

Чтобы пройти обслуживание по данной ограниченной гарантии, лицо, предъявляющее требование, должно сразу сообщить региональному партнеру компании Hamilton Medical по продажам суть проблемы, серийный номер и дату приобретения изделия.

За исключением указанного выше, компания Hamilton Medical не несет ответственности касательно каких-либо заявлений о повреждениях, претензий или требований, включая, без ограничений, телесные повреждения либо случайные, косвенные или особые повреждения. Компания Hamilton Medical не несет ответственность за возникновение каких-либо повреждений и претензий или выполнение обязательств, включая (но не ограничиваясь этим) телесные повреждения или случайные, косвенные либо фактические убытки, которые возникают вследствие ненадлежащей эксплуатации устройства или несоблюдения положений, приведенных в этом руководстве.

### 9.13.1 Другое

В других случаях применяются общие положения и условия соглашения с компанией Hamilton Medical. Данное соглашение должно регулироваться и толковаться в соответствии с законодательством Швейцарии и может приводиться в исполнение любой из сторон под юрисдикцией суда города Чур, Швейцария.

# Kullanım talimatları

## HAMILTON-H900

2021-01-11

624431/09

Bu belge, Hamilton Medical AG tarafından, önceden haber verilmeksizin istenildiği zaman gözden geçirilebilir, yenisiyle değiştirilebilir veya geçersiz kılınarak yerine başka belgeler kullanılabilir. Bu belgenin geçerli en güncel sürümünün elinizde olduğundan emin olun; bu hususta şüpheniz varsa, Hamilton Medical AG, İsviçre teknik destek departmanı ile iletişime geçin. İşbu belgede öne sürülen bilgilerin doğru olduğuna inanılsa da bu, konunun uzmanı olan kişilerin kanaatinin kullanılmasının yerini alamaz.

Bu belgedeki hiçbir bilgi, Hamilton Medical AG'nin işbu belgede tanımlanan ekipmanı (yazılım dahil) önceden haber vermeksizin gözden geçirme veya başka şekillerde değiştirme ya da modifiye etme hakkını herhangi bir şekilde sınırlandıramaz ve kısıtlayamaz. Aksi yönde açık, yazılı bir anlaşmanın olmadığı durumlarda, Hamilton Medical AG'nin, ilgili ekipmanın (yazılım dahil) sahibine ya da kullanıcısına karşı, işbu belgede belirtilen türden bir revizyon, değişiklik veya modifikasyon ile ilgili olarak kanıt gösterme yükümlülüğü yoktur.

Bu ekipman, yalnızca eğitimli uzman kişiler tarafından kullanılmalı, ekipmanın bakımı veya bir üst modele yükseltilme işlemi yine bu kişiler tarafından yapılmalıdır. Hamilton Medical AG'nin cihazla ve cihazın kullanımıyla ilişkili tek yükümlülüğü, bu kılavuzda yer alan Sınırlı Garanti bölümünde ifade edildiği şekildedir.

Hamilton Medical AG, herhangi bir kayıp, masraf, harcama, uygunsuz durum veya ürünün hatalı kullanımı nedeniyle ya da parçalar yenileriyle değiştirilirken Hamilton Medical AG'ye ait olmayan parçaların kullanılması veya seri numaralarının değiştirilmesi, silinmesi ya da çıkarılması halinde oluşabilecek hiçbir zarardan mükellef değildir.

Parçaları Hamilton Medical AG'ye iade ederken standart Hamilton Medical iade edilen mallar için yetkilendirme (RGA) prosedürünü uyguladığınızdan emin olun. Parçaların imha edilme işlemi çevreyi korumaya yönelik tüm yerel, resmi ve federal yönetmeliklere uygun olarak yapılmalıdır.

Hamilton Medical AG tarafından kullanılan tüm tescilli markalar ve üçüncü parti markaları için bkz. www.hamilton-medical.com/trademarks. [§] sembolü ile işaretli ürün ve/veya şirket isimleri, ilgili ürün sahiplerinin ticari ve/veya tescilli ticari markaları olabilir. Bu ürünlere şunlar dahildir, ancak tüm ürünler bunlarla sınırlı değildir: Aerogen[§], Nihon Kohden[§], Masimo[§], Masimo SET[§], Masimo rainbow SET[§] ve Capnostat[§].

**Üretici**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz,
İsviçre
Telefon:: (+41) 58 610 10 20
Faks: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Önsöz

Cihazı veya aksesuarları kullanmadan önce belgeleri okuduğunuzdan emin olun.

### Bu kılavuzda kullanılan adlandırmalar

Bu kılavuzda:

- Düğme isimleri **koyu** yazı tipiyle gösterilmiştir.
- Gösterilen grafikler kendi kullanımınızda gördüğünüz nesnelerin tam olarak aynısı olmayabilir.
- Özelliklerin tümü bütün pazarlarda mevcut değildir.

Güvenlik mesajları aşağıdaki şekilde gösterilmektedir:

**⚠ UYARI**

Cihazın kullanımı veya hatalı kullanımı ile ilişkili yaralanma, ölüm ya da diğer ciddi advers reaksiyonların oluşma olasılığı hususunda kullanıcıyı uyarır.

**⚠ DİKKAT**

*Cihazın hatalı şekilde çalışması, arızalanması, hasar görmesi veya diğer aksesuarların zarar görmesi gibi cihazın kullanımı veya hatalı kullanımı ile ilişkili cihazla ilgili bir sorunun oluşma olasılığı hususunda kullanıcıyı uyarır.*

***NOT***

Büyük önem taşıyan bilgilerin altını çizer.

Tablolarda güvenlik mesajları aşağıdaki şekilde gösterilmiştir:

**⚠ UYARI!**

**⚠ DİKKAT!**

**NOT!**

Bu kılavuzun veya diğer belgelerin en son sürümünü indirmek için MyHamilton web sitesini ziyaret edin:
https://www.hamilton-medical.com/MyHamilton

Hamilton Medical, çeşitli öğrenme modüllerini ücretsiz olarak sunan Hamilton Medical College'i sunar. Kayıt olmak için şu adrese gidin:
http://college.hamilton-medical.com/

**⚠ DİKKAT**

*(Sadece ABD): Bu ürünün hekimin kendisi tarafından ya da siparişi üzerine satılması, Federal yasa tarafından sınırlandırılmıştır.*

### Kullanım amacı

HAMILTON-H900 nemlendirici, invazif ve noninvazif mekanik ventilasyon sırasındaki respiratuvar gaz denetimi için kullanılır.

Cihaz, sağlık profesyonellerinin hasta bakımı sağladığı hastaneler ve kurumsal ortamlarda kullanılmak üzere tasarlanmıştır.

HAMILTON-H900 nemlendirici, hekim nezaretindeki deneyimli ve eğitimli personel tarafından ve belirtilen teknik spesifikasyonlar dahilinde kullanılan tıbbi bir cihazdır.

# 1 Güvenlik bilgileri

Bu kısım, nemlendiricinin kurulması, çalıştırılması ve bakımı ile ilgili güvenlik bilgilerini sağlar.

**Nemlendiriciyi kurmadan ve kullanmadan önce bu güvenlik bölümünün tüm kısımlarını dikkatli şekilde gözden geçirin.**

**Nemlendiriciyi kullanmadan önce Kullanım Talimatlarını gözden geçirdiğinizden emin olun.**

**Nemlendirici ile birlikte kullanılan cihaz ve aksesuarlarla verilen Kullanım Talimatlarını kullanmadan önce okuduğunuzdan emin olun.**

Bu kılavuzda yer alan bilgilerle ilgili sorularınız varsa, Hamilton Medical temsilciniz ya da teknik servis personeli ile iletişime geçin.

## 1.1 Elektromanyetik duyarlılık

**⚠ UYARI**

- **MR TEHLİKESİ**. Manyetik rezonans görüntüleme (MRI) ekipmanına yaklaşmayın. HAMILTON-H900, MR ortamında hastalar, tıbbi personel ve diğer kişiler için kabul edilemez riskler doğurur.
- Yüksek frekanslı cerrahi cihaz, mikrodalga veya kısa dalgaların kullanılması ya da civardaki güçlü manyetik alanlar nemlendiricinin işleyişine zarar verebilir.
- Emisyon artışı ve bağışıklık azalmasını önlemek veya HAMILTON-H900 nemlendirici veya herhangi bir aksesuarının kesintisiz çalışmasını sağlamak için yalnızca bu kılavuzda ya da Hamilton Medical e-kataloğunda açıkça belirtilen aksesuar ya da kabloları kullanın.
- Tıbbi elektrikli ekipmana bağlı ek ekipman (örn. veri işleme ekipmanı için IEC 60950) ilgili IEC veya ISO standartlarına uygun olmalıdır. Ayrıca, tüm yapılandırmalar tıbbi elektrik sistem gerekliliklerine uymak zorundadır (IEC 60601-1, madde 16).
- Elektrikli tıbbi cihaza ilave cihaz bağlayan herkes bir tıbbi sistem yapılandırıyor demektir ve dolayısıyla sistemin, tıbbi sistemlerin gerekliliklerine uyumlu olmasıyla ilgili sorumluluk kişiye aittir. Yerel yasaların yukarıda belirtilen gereksinimlere göre önceliği olduğunu dikkate alın. Nasıl devam edeceğiniz konusunda sorularınız varsa, Hamilton Medical temsilcinize ya da teknik servis departmanınıza başvurun.
- Nemlendiricinin, kardiyak defibrilatörün deşarj etkilerine karşı bir koruması *bulunmamaktadır*.

***NOT***

- HAMILTON-H900 nemlendirici, EMC (Elektromanyetik Uyumluluk) ile ilgili özel önlemlerin alınmasını gerektirir ve kurulumu ve kullanımının, *HAMILTON-H900 EMC Beyanlarında* verilen EMC bilgilerine uygun şekilde yapılması gerekir.
- Taşınabilir özelliğe sahip HAMILTON-H900 nemlendirici mobil RF iletişim ekipmanlarından etkilenebilir.

## 1.2 Elektrik gücü

**⚠ UYARI**

- Elektrik çarpması riskini en aza indirmek için nemlendirici güç kablosunu uygun şekilde topraklanmış bir güç prizine takın. Prizin uygun şekilde topraklanmasını (toprak) sağlamak hastanenin sorumluluğundadır.
- Güç kablosu hasar görmüşse *kullanmayın*.
- Yanlış voltaj kullanıldığında, elektrik kesintisinde veya ana şebeke kaynağı bağlantısı kesildiğinde, nemlendirici işitilebilir bir ıslık sesi yayar. Cihazı derhal kapatın ve doğru voltajın kullanılıp kullanılmadığına bakın.
- Doğru voltajın kullanıldığından emin olun.

## 1.3 Yangın ve diğer tehlikeler

**⚠ UYARI**

Nemlendiriciyi tehlikeli alanlarda veya yanıcı gazlarla birlikte *kullanmayın*.

## 1.4 Genel çalıştırma ve kurulum

**⚠ UYARI**

- Nemlendiriciyi hastada kullanmadan önce solunum devresinin ventilatöre aşağıda gösterildiği gibi doğru şekilde bağlandığını doğrulayın:

  – Mavi inspiratuvar parça *Hastaya giden* inspiratuvar portuna bağlanır.

  – Beyaz ekspiratuvar parça *Hastadan gelen* ekspiratuvar portuna bağlanır.
- Yalnızca 8. kısımda belirtilen parça ve aksesuarları kullanın. Böylece nemlendiricinin düzgün şekilde çalışması sağlanır ve hastada olabilecek yaralanma önlenir.
- Nemlendiriciyi 4.000 metreden fazla rakımda veya 10°C ila 40°C arası bir sıcaklık dışında kullanmayın. Nemlendiriciyi bu rakımın üstünde veya bu sıcaklık aralığının dışında kullanmak tedavinin kalitesini etkileyebilir ya da hastayı yaralayabilir.
- Yanlış nem veya sıcaklık ayarları hastaya zarar verebilir.
- Nemlendiriciyi, ventilasyon sistemine bağlı bir hastanın hastane dışına transferi sırasında *kullanmayın*.
- Ventilatörü açtıktan *sonra* nemlendiriciyi AÇIN.
- Ventilatörü kapatmadan *önce* nemlendiriciyi KAPATIN.
- Nemlendirici IR ölçüm ünitelerinin üzerini örtmeyin.
- İnvaziv (INV) mod, *yalnızca* entübe edilen ve trakeotomi uygulanan hastalarda kullanılmalıdır.
- Alerjik reaksiyonların oluşması halinde ilave önlemler alın.
- Solunum devresini yoğuşmaya karşı düzenli olarak kontrol edin ve gerektiğinde boşaltın.
- Cihazın nemlendirme performansı eşzamanlı olarak bir nebulizatör kullanıldığında olumsuz etkilenebilir.
- Sıcak plakaya veya su haznesinin alt kısmına *dokunmayın*. Yüzeylerdeki sıcaklık 85°C'ye ulaşabilir. Bu sıcak yüzeyler ısı yayar.

**⚠ DİKKAT**

- *Nemlendiriciyi, ana güç kaynağı bağlantısının kolayca kesilebileceği şekilde konumlandırın.*
- *Yalnızca 8. kısımda ve Hamilton Medical e-kataloğunda belirtilen ya da nemlendirici ile uyumlu olarak belirtilen parça ve aksesuarları kullanın.*

  *Bu durum, uygun nemlendirme sağlar, düşük performansı önler ve garantinizin geçerli kalmasını sağlar.*
- *Nemlendirici kapatılıp açılırsa, farklı şekilde yapılandırılmadığı sürece otomatik olarak İnvaziv **(INV)** modunda başlayacaktır.*
- *Kullanmadan önce solunum devresi setinde hasar olup olmadığını gözden geçirin. Herhangi bir hasar belirtisi varsa solunum devresi setini atın.*
- *Nemlendirici ısıtma ögesi ve ısıtma kabloları, su haznesi ve solunum devreleri düzgün şekilde monte edildiyse, nemlendirici çalışır durumdaysa veya **Bekleme** modundaysa otomatik olarak çalışır.*
- *Ortam sıcaklığı veya gaz giriş sıcaklığı ve/veya akış hızı önerilen aralık dışındaysa, fizyolojik nem seviyeleri elde edilemeyebilir.*
- *Ekranda ışık olmasa bile nemlendiricide hala güç olabilir. Bkz. tablo 1.*

***NOT***

- Bir hastada kurulu bir solunum devresi setini kullanmadan önce, bir kaçak testi yapmalısınız. Bu test başarısız olursa işlem bir kez daha tekrarlanabilir. Art arda iki başarısız testten sonra solunum seti yenisiyle değiştirilmelidir.
- Parça, esnek tüp veya akış sensöründe oluşan az miktarda ve nefesten bağımsız yoğuşma (buğulanma) nemin düzgün ayarlandığı anlamına gelir.
- Tüm eylemler işitilebilir bir ses üretir.

## 1.5 Solunum devreleri ve su haznesi

**⚠ UYARI**

- Solunum devresinin ventilatöre doğru şekilde bağlanmaması hastanın yaralanmasına neden olabilir.
- Solunum devresi bağlantısının kullanım veya taşıma esnasında kazara yerinden çıkmasını önlemek için yalnız ISO 5367 veya ISO 80601-2-74 uyumlu solunum devrelerini kullanın.
- Su haznesini yalnızca hastanenin hijyen gerekliliklerini karşılayan steril, minerallerden arındırılmış suyla doldurun.
- Su haznesini eğmeyin.
- Nemlendirici haznesine herhangi bir ilaç doldurmayın.
- Su seviyesinin maksimum dolum seviyesini aşmadığından emin olun.

***NOT***

- Nemlendirici solunum devresini algılamazsa bileşenleri değiştirin.
- Takviye edilen su 37°C'den sıcak olmamalıdır.
- Hazneye giden su kaynağının düzgün şekilde çalıştığından emin olun.
- Bileşenleri sökmeden önce nemlendiricinin **Bekleme** modunda olduğundan emin olun.

## 1.6 Nemlendirici ve solunum devresinin konumlandırılması

**⚠ UYARI**

- Nemlendirici *daima* hastanın bulunduğu seviyenin altında konumlandırılmalıdır.
- Nemlendiriciyi zemine göre 10°'nin üzerindeki açılarda *çalıştırmayın*.
- Solunum devresini, nemlendiriciden hastaya giden devrede hiçbir gerilim ve kıvrılma oluşmayacak şekilde yerleştirin.
- Isınan solunum parçaları doğrudan hastanın cildi üzerine *yerleştirilmemelidir*.
- Nemlendirici diğer medikal elektrikli cihazlara yakın ya da istiflenmiş şekilde kullanılırsa, kullanılacağı konfigürasyonda nemlendiricinin normal çalışmasını doğrulayın.
- Solunum devresini sıvı yoğuşmasının hastaya ulaşamayacağı şekilde yerleştirin.
- ET tüpü üzerinde mekanik kuvvet oluşmaması için, solunum devrelerini veya tüp klipslerini uygun şekilde takın.

***NOT***

- Kullanımdan önce tüm bağlantıların sağlam olup olmadığını kontrol edin.
- Nemlendirici üzerindeki tüm parça konektörleri, elektrik bağlantılarını solunum devresi konektörleriyle birleştirir. Elektrik temas noktalarını, nemlendirici üzerindeki bağlantı ögesiyle doğru eşleşecekleri şekilde yerleştirin.

## 1.7 İzleme ve alarmlar

***NOT***

- Bir alarm etkinken, ekran, etkin alarm sembollerini gösteren ekran ile mevcut hazne çıkış sıcaklığı ekranı arasında geçiş yapar.
- Nemlendiriciyi kapattıktan sonra, alarm ses seviyesi 5 varsayılan değerine döner.
- Tüm teknik alarmlar, ayrıntılı teknik bilgiler ve bakım prosedürleri *HAMILTON-H900 Bakım Kılavuzu*'nda tanımlanmıştır.

## 1.8 Bakım

**⚠ UYARI**

- Nemlendiricide herhangi bir değişiklik yapılmasına izin *verilmemektedir*.
- Elektrik çarpması riskini azaltmak için temizlik ve dezenfeksiyondan önce *daima* nemlendiricinin elektrik bağlantısını kesin.

**⚠ DİKKAT**

- *Kullanılmış solunum devreleri ve su haznelerine, yerel kanun ve düzenlemeler veya hastane içi prosedürlerine uygun olarak kontamine malzeme muamelesi yapın.*
- *Uygun servis hizmeti vermek ve olası fiziksel yaralanmaları önlemek için nemlendiricinin bakımı yalnızca Hamilton Medical tarafından yetkilendirilen servis personeli tarafından bu HAMILTON-H900 Bakım Kılavuzu'nda verilen bilgiler kullanılarak yapılabilir.*
- *Yalnızca Hamilton Medical tarafından tedarik edilen yedek parçaları kullanın.*

- *HAMILTON-H900 Bakım Kılavuzu'nda belirtilenler dışında herhangi bir bakım prosedürünü uygulamayın.*
- *Temizlik ve dezenfeksiyon için sadece onaylanmış temizlik maddelerini kullanın.*

**NOT**

- Otoklavlanabilir (yeniden kullanılabilir) aksesuarların ve bileşenlerin temizliği, dezenfeksiyonu ve sterilizasyonu hakkında özel bilgi almak için, her parça ile birlikte verilen uygun *Tekrar İşleme Kılavuzu* ve *Kullanım Talimatları*'na bakın.
- (*Sadece ABD*) Temizlik ve dezenfeksiyon için sadece EPA tescilli temizlik maddelerini kullanın.

# 2 Genel bakış

Bu kılavuz, HAMİLTON-H900 nemlendiricinin kurulumu ve kullanımı hakkında bilgi sağlar.

Nemlendirici, Hamilton Medical ve üçüncü taraf ventilatörler ile kullanılmak üzere tasarlanmıştır.

## 2.1 HAMILTON-H900 nemlendirici hakkında

HAMILTON-H900 nemlendirici yetişkin, pediatrik ve neonatal hastalar için solunum gazlarını ısıtır ve nemlendirir.

Aşağıdaki ortak solunum modlarını destekler:

- İnvaziv ventilasyon
- Noninvaziv ventilasyon
- Yüksek akışlı oksijen tedavisi

Sistem; ısıtmalı bir solunum devresi için nemlendirici muhafazası, ekran, kontroller, su haznesi, ısıtıcı plaka ve elektrik bağlantılarını içerir.

Aşağıdaki ana özellikleri sunar:

- Ayarlanabilir sıcaklık ve nem kontrolleri
- İzleme ve alarm kaabiliyetleri
- Desteklenen Hamilton Medical ventilatörler ile nemlendirici izlenen veri ve kontrollerinin entegrasyonu[85]

## 2.2 Fiziksel açıklamalar

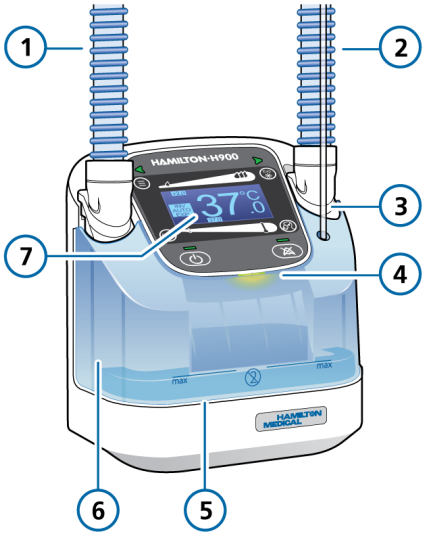
Bu kısımda, nemlendirici ve ilgili solunum devresi setlerine genel bir bakış sağlar.

[85] Bütün pazarlarda mevcut değil.

### 2.2.1 Nemlendirici hakkında

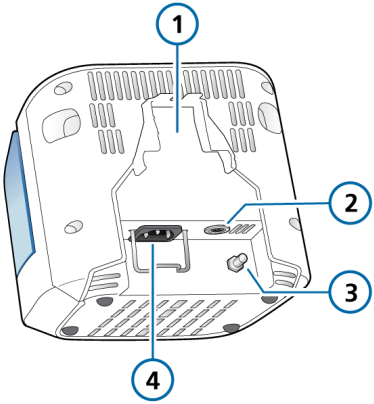
1 ile 5 arasındaki şekiller nemlendiriciye genel bir bakış sağlar.

Şekil 1. HAMILTON-H900 nemlendirici, önden görünüm




| | | | |
|---|---|---|---|
| 1 | Ventilatör inspiratuvar parça (mavi) | 5 | Isıtıcı plaka |
| 2 | Hasta inspiratuvar parça (mavi) | 6 | Su haznesi |
| 3 | Su besleme tüpü | 7 | Ön panel ve ekran |
| 4 | Görsel alarm göstergesi | | |

Şekil 2. HAMILTON-H900 nemlendirici, arkadan görünüm




| | | | |
|---|---|---|---|
| 1 | Bağlantı parçası yuvası | 3 | Potansiyel eşitleme terminali |
| 2 | RS-232 portu | 4 | AC prizi |

### 2.2.2 Ana ekran hakkında

Nemlendirme sırasında ana ekrandan tüm ayarlara, modlara, alarmlara ve kontrollere doğrudan erişebilirsiniz.

3 ile 5 arasındaki şekiller ön panel kontrollerini, göstergeleri ve ekranı gösterir.

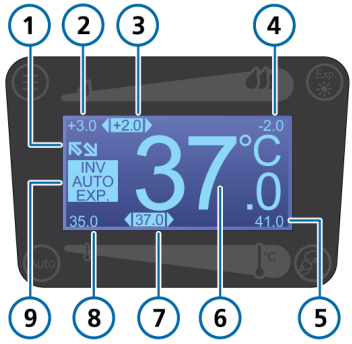
Şekil 3. HAMILTON-H900 nemlendirici, ön panel kontrolleri


| | | | |
|---|---|---|---|
| 1 | Sıcaklık izleme penceresi düğmesi | 5 | Sesi duraklat tuşu |
| 2 | Sıcaklık kontrolü kaydırıcıları | 6 | Güç/Bekleme tuşu |
| 3 | Exp. ısı artışı düğmesi | 7 | Auto düğmesi |
| 4 | INV/NIV/HiFlow modu düğmesi | 8 | Ekran (bkz. şekil 5) |

Şekil 4. HAMILTON-H900 nemlendirici, ön panel durum göstergeleri


| | | | |
|---|---|---|---|
| 1 | Parça bağlantı durumu göstergeleri | 3 | Güç/Bekleme durumu göstergesi |
| 2 | Sesi duraklat göstergesi | | |

Şekil 5. HAMILTON-H900 nemlendirici, ekran




1 Ventilatör bağlantısı etkin
2 Maks. sıcaklık derece ayarı
3 Sıcaklık derecesi ayarı
4 Min. sıcaklık derece ayarı
5 Maks. hazne çıkış sıcaklığı ayarı
6 Mevcut hazne çıkış sıcaklığı
7 Hazne çıkış sıcaklığı ayarı
8 Min. hazne çıkış sıcaklığı ayarı
9 Etkin modlar/ayarlar

*Ekrandaki tüm öğeler yalnızca açıklama amacıyla gösterilmiş olup çalışma sırasında hepsi aynı anda görünmeyebilir.*

### 2.2.3 Nemlendirici solunum devreleri hakkında

HAMILTON-H900 nemlendirici yetişkin, pediatrik ve neonatal hastalar için çeşitli tek ve çift parçalı solunum devrelerini destekler.

Daha fazla bilgi için, solunum devrenizin *Kullanım talimatları*'na bakın.

### 2.2.4 Nemlendiricideki durum göstergeleri hakkında

Nemlendiricinin önündeki göstergeler önemli nemlendirici durum bilgilerini gösterir. Bkz. şekil 4.

Tablo 1. Durum göstergeleri

| Sembol | Açıklama |
|---|---|
| **Durum göstergeli Güç/Bekleme tuşu** | |
|  | *Yeşil*: Nemlendirici çalışmakta. |
|  | *Turuncu*: Nemlendirici **Bekleme** konumunda. |
|  | *Mavi*: Nemlendirici kapalı ve bir güç kaynağına bağlı. |
|  | *Yanmaz*: Nemlendirici kapalı ve bir güç kaynağına bağlı *değil*. |
| **Parça bağlantı durumu göstergesi** | |
|  | *Yeşil*: Parça doğru şekilde bağlanmış. |
|  | *Turuncu*: Nemlendirici parça bağlantısını test ediyor. |
|  | *Kırmızı*: Parça bağlantısı arızalı veya bir parça bağlı değil. |
| **Göstergeli ses duraklatma tuşu** | |
|  | *Kırmızı*: Ses duraklatma aktif. |

## 2.3 Pencerelerde ve kontrollerde gezinme

Bu kısımda, nemlendirici düğme ve kaydırıcılarının nasıl kullanılacağı açıklanır.

### 2.3.1 Kontrol düğmelerinin kullanımı

Ön paneldeki düğmeler (şekil 3) modları seçmenize, ayarları değiştirmenize ve önemli sıcaklık ayarlarını genel olarak görmenize olanak tanır.

Tablo 2. Kontrol düğmeleri (bkz. şekil 3)

| Düğme | Açıklama |
|---|---|
|  | **Exp. ısı artışı**<br>Ekspiratuvar parçasındaki sıcaklığı artırır. |
|  | **Oto**<br>**Oto** modunu etkinleştirir.<br>Bkz. kısım 4.2.2. |
|  | **INV/NIV/HiFlow çalışma modları**<br>**INV**, **NIV** ve **HiFlow** modları arasında geçiş yapar.<br>Bkz. kısım 4.2. |
|  | **Sıcaklık izleme penceresi**<br>Geçerli Y parça sıcaklığını, hazne çıkış sıcaklığını ve sıcaklık derecesi değerlerini görüntüler.<br>Bkz. kısım 4.4. |

### 2.3.2 Kaydırıcıların kullanımı

Manuel modda, kontrol kaydırıcılarını kullanarak sıcaklık ayarlarını değiştirebilirsiniz (şekil 3).

Tablo 3. Sıcaklık kontrolü kaydırıcıları

| Kaydırıcı | Açıklama |
|---|---|
| **Sıcaklık derece kaydırıcısı** | |
|  | Hazne çıkışı ile Y parçası arasındaki sıcaklık farkını ayarlar.<br>Bkz. kısım 4.3. |
| **Hazne çıkış sıcaklığı kaydırıcısı** | |
|  | Hazne çıkış sıcaklığını ayarlar.<br>Bkz. kısım 4.3. |

# 3 Nemlendiricinin kullanım için hazırlanması

*Devam etmeden önce, kısım 1'deki güvenlik bilgilerini gözden geçirin.*

Nemlendiricinin kullanıma hazırlanması aşağıdaki adımları içerir:

- Bir tıbbi teknisyen tarafından ayarların tek seferlik konfigürasyonu (bkz. tablo 4)
- Her yeni hasta için, hasta bakıcılar tarafından gerçekleştirilen nemlendirici kurulum görevleri (bkz. tablo 5)

Tablo 4. Bir tıbbi teknisyen tarafından konfigürasyon ve kurulum

| Şuraya gidin ... | Bkz. |
|---|---|
| *Tek seferlik başlangıç konfigürasyonu görevleri teknik personel tarafından tamamlanacaktır.* | |
| Nemlendiriciyi monte edin ve konumlandırın | Ventilatör veya araba için geçerli *Kurulum Kılavuzu*'na bakın |
| Nemlendirici ayarlarını yapın | Kısım 7 |
| *İsteğe bağlı*: Nemlendiriciyi, desteklenen Hamilton Medical Ventilatörün RS-232 COM portuna bağlayın | Ventilatör için geçerli *Kullanım Kılavuzu*'na bakın. |

Tablo 5. Hasta bakıcılar tarafından konfigürasyon ve kurulum

| Şuraya gidin ... | Bkz. |
|---|---|
| *Aşağıdaki görevler hastalara bakım veren tıbbi personel tarafından gerçekleştirilecektir.* | |
| Bir güç kaynağına bağlamak için | Kısım 3.1 |
| Solunum devresini bağlamak için | Kısım 3.2 |
| Nemlendiriciyi açın | Kısım 3.3 |
| Alarmları test edin | Kısım 3.4 |
| Nemlendirici ayarlarını belirleyin | Kısım 3.5 |
| Hastayı bağlayın | Kısım 3.6 |

## 3.1 Bir güç kaynağına bağlanması

Nemlendirici ve ventilatörü prize takmadan önce daima ana güç prizinin güvenilirliğini kontrol edin.

**Nemlendiriciyi bir güç kaynağına bağlamak için**

- Nemlendiriciyi AC güç sağlayan bir prize bağlayın.[86]

## 3.2 Solunum devresinin nemlendiriciye bağlanması

Hamilton Medical yetişkin, pediatrik ve neonatal hastalar için çeşitli solunum devreleri sağlar.

Daha fazla bilgi için, spesifik solunum devresi *Kullanım Talimatları*'na bakın.

## 3.3 Nemlendiriciyi açma ve kapatma

Nemlendirici açıkken, otomatik olarak yapılandırılan varsayılan modda çalışır.

Nemlendiriciyi açmadan *önce* ventilatörü mutlaka açın.

**Nemlendiriciyi açmak için**

- Yaklaşık 3 saniye  (**Güç/Bekleme**) düğmesini basılı tutun.

Nemlendirici bir otomatik test gerçekleştirir. Tamamlandıktan sonra, nemlendirici farklı yapılandırılmadıkça otomatik olarak invaziv (**INV**) modunda başlar.

[86] Desteklenen bir Hamilton Medical ventilatör nemlendirici kullanıyorsanız, nemlendirici güç kablosunu ventilatörün özel güç prizine bağlayın.

**Nemlendiriciyi kapatmak için**

- Yaklaşık 3 saniye  düğmesini basılı tutun.

Ventilatörü kapatmadan *önce* nemlendiriciyi kapattığınızdan emin olun.

## 3.4 Alarmların test edilmesi

Yeni bir hastayı nemlendiriciye bağlamadan önce, alarmların doğru çalıştığını doğrulayın.

Nemlendiricinin açık olduğundan emin olun.

**Nemlendirici alarmlarını test etmek için**

1. Su haznesini nemlendiriciden çıkararak bir alarm üretin.
2. Şunları doğrulayın:
   – Akustik alarm seslidir
   – Görsel alarm göstergesi yanıp sönüyor (şekil 4)
   – İlgili alarm sembolü ekranda görülüyor (tablo 9)

Su haznesini nemlendiriciye yeniden takarak alarma neden olan durumu ortadan kaldırın ve alarmın sıfırlandığını doğrulayın.

## 3.5 Nemlendirici ayarlarının belirlenmesi

Hastanız için nemlendirme modunu seçin.[87] Daha fazla bilgi için bkz. Kısım 4.2.

## 3.6 Hastanın bağlanması

Solunum devresini uygun hasta arayüzüne bağlayın.

Nemlendirici şimdi kurulu durumda ve kullanıma hazırdır.

# 4 HAMILTON-H900 nemlendirici ile çalışmak

Tablo 6. Çalışmaya genel bakış

| ... hakkında daha fazla bilgi için | Bkz. |
|---|---|
| Nemlendiriciyi açma/kapama | Kısım 3.3 |
| **Bekleme**'ye giriş/**Bekleme**den çıkış | Kısım 4.1 |
| Nemlendirici kontrollerine erişim | Kısım 2.3 |
| Nemlendirici çalışma modları: **INV**, **NIV**, **HiFlow** | Kısım 4.2 |
| **Otomatik** ve **manuel** ayarları | Kısım 4.2.2 |
| Sıcaklık kontrolleri kullanılarak nemin değiştirilmesi | Kısım 4.3 |
| İzlenen nemlendirici parametreleri | Kısım 4.4 |
| Nemlendirici alarmları | Kısım 5 |

[87] Entegre çalışmayı destekleyen bir Hamilton Medical ventilatör ile kullanıldığında, nemlendirici ventilatörün çalışma moduyla eşleşir. Daha fazla bilgi için ventilatör *Kullanıcı Kılavuzu*'nuza bakınız.

## 4.1 Beklemeye giriş/Beklemeden çıkış

**⚠ DİKKAT**

*Bekleme modunda, tüm ayarlar korunur ve ısı çıkışı azaltılır.*

**Bekleme**, nemlendirici çalışmazken mevcut ayarları korumanıza izin veren bir bekleme modudur.

**Bekleme** modundayken, **Hazne çıkış sıcaklığı** ve **Sıcaklık derecesi** ayarları azaltılır.[88] Daha fazla bilgi için bkz. Kısım 9.7.

### Nemlendiriciyi Bekleme moduna almak için

- Kısa süre ⏻ (**Güç/Bekleme**) seçeneğine basın.

  **Bekleme** konumundayken, ekran nemlendiricinin **Bekleme** modunda geçirdiği süreyi gösterir. **Güç/Bekleme** göstergesi ışığı turuncudur.

### Bekleme konumundan çıkmak ve nemlendirmeye başlamak için

- ⏻ öğesine basın.

  Nemlendirici normal çalışmaya devam eder; **Güç/Bekleme** durum göstergesi ışığı yeşil yanar.

## 4.2 Nemlendirici çalışma modları hakkında

HAMILTON-H900 aşağıdaki çalışma modlarını sunar: İnvaziv (**INV**), Noninvaziv (**NIV**) ve yüksek akışlı oksijen tedavisi (**HiFlow**).

Çalışma modunun seçimi, su haznesi çıkışı (**Hazne çıkış sıcaklığı**) ve Y parçasındaki (**Sıcaklık derecesi**) başlangıç sıcaklık ayarlarını, ayrıca bu kontrollerin her biri için izin verilen sıcaklık aralıklarını belirler.

Bu sıcaklık aralıkları hasta grubuna göre farklılık gösterir. Bkz. tablo 18.

### 4.2.1 Modların değiştirilmesi

Nemlendirici özel varsayılan ayarlarda farklı bir şekilde yapılandırılmadıkça, otomatik olarak İnvaziv (**INV**) modda başlar.

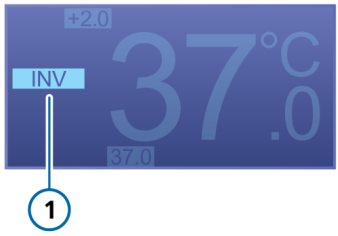
İnvaziv (**INV**) veya Noninvaziv (**NIV**) moduna değiştirildiğinde, nemlendirici kontrol ayarlarını otomatik olarak **Auto** (Oto) olarak ayarlar.

### Modları değiştirmek için

- İstenilen mod (**INV**, **NIV**, **HiFlow**) görüntülenene kadar ⚙ (**Modlar**) öğesine basın.

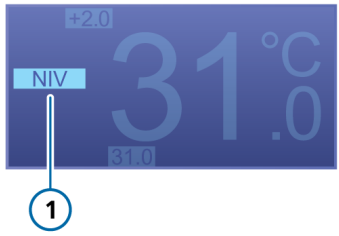
  Seçili mod ekranda görünür.

Şekil 6. INV modu (**1**) seçili

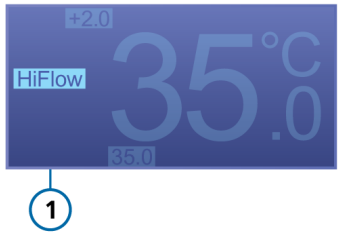



[88] Nebulizasyon yapılırken, **Bekleme** sırasında **Sıcaklık derecesi** *değiştirilmez*.

Şekil 7. NIV modu (**1**) seçili




Şekil 8. HiFlow modu (**1**) seçili




### 4.2.2 Otomatik ve manuel kontrol ayarları

Nemlendiriciyi **Oto** modunda kullanabilir veya ayarları manuel olarak belirleyebilirsiniz. Varsayılan olarak, nemlendirici **Oto** modunda başlar.

**Hazne çıkış sıcaklığı** ve **Sıcaklık derecesi** aşağıdaki yöntemlerden biri kullanılarak ayarlanır:

- Yapılandırılan varsayılan ayarlardan yüklenir (**Oto** modu)
- Kullanıcı tarafından manuel ayarlanır

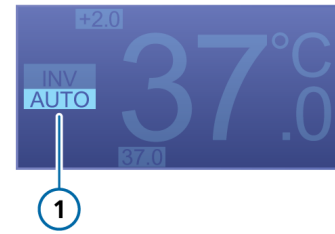
#### Otomatik ayarlar (Oto)

**Auto** (Oto) olarak ayarlandığında, nemlendirici seçili olan mod (bkz. kısım 7) için belirlenen varsayılan ayarları yükler ve bunları gaz sıcaklığını kontrol etmek için kullanır.

Düşük ortam sıcaklıklarında, nemlendirici su haznesi sıcaklığını otomatik olarak ayarlayabilir.

**Oto** modu seçildiğinde, **AUTO** (Oto) metni ana ekranda görünür.

Şekil 9. Oto mod (**1**) seçili

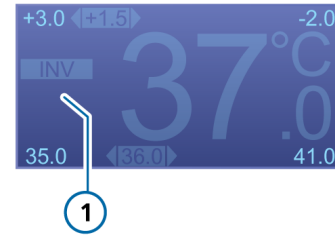



#### Manuel ayarlar

Kaydırıcıları kullanarak **Hazne çıkış sıcaklığı** veya **Sıcaklık derecesini** değiştirdiğinizde, nemlendirici **manuel** moda geçer. Ancak, belirtilen ayarlara ulaşmak için sıcaklığı da otomatik olarak denetlemeye devam eder.

Ayarlar manuel olarak değiştirildiğinde, **Auto** (Oto) artık ana ekranda görünmez; alan boştur.

Şekil 10. Manuel mod (**1**) etkindir



#### 4.2.2.1 Oto modu etkinleştirme

Sıcaklık ayarlarından birini manuel olarak değiştirdikten sonra **Oto** modunu yeniden etkinleştirebilirsiniz.

**Oto modu yeniden etkinleştirme**

- (Auto) (**Oto**) düğmesine basın.

  Çalışma modunu **INV** veya **NIV** olarak değiştirmek de nemlendiricinin otomatik olarak **Oto** moduna geçmesini sağlar.

## 4.3 Sıcaklık kontrolleri kullanılarak nemin değiştirilmesi

***NOT***

Nemlendirici **Oto** modundaysa, her iki kaydırıcının sürüklenmesi, nemlendirmeyi **manuel** moda değiştirir.

***NOT***

**HiFlow** modunda, kaydırıcıyı kullanarak **Sıcaklık derecesini** değiştiremezsiniz. **Konfigürasyon** içinde **Sıcaklık derecesini** yeni bir değerle değiştirebilirsiniz. Bkz. kısım 7.

Aşağıdaki kontrolleri nemlendirici üzerinde ayarlayabilirsiniz[89]:

Tablo 7. Ayarlanabilir nemlendirici kontrolleri

| Kontrol | Açıklama |
|---|---|
| Hazne çıkış sıcaklığı | Su haznesi çıkışındaki sıcaklık.<br>Bu kontrol için olası değer aralığı seçilen nemlendirici çalışma moduna bağlıdır. Daha fazla bilgi için, bkz. tablo 16 ve 18.<br>Daha yüksek değerler daha yüksek mutlak neme yol açar. |
| Sıcaklık derecesi | Su haznesi çıkışı ve Y parçasındaki sıcaklık arasındaki fark. |
| Exp. ısı artışı | Seçildiğinde, nemlendirici ekspiratuvar parçada ek ısı sağlar.[90] |

Hastada (Y parçası) izin verilen maksimum sıcaklık 42°C'dir. **Hazne çıkış sıcaklığı** artı **Sıcaklık derecesi** kombinasyonu bu limiti aşamaz. Örneğin, **Sıcaklık derecesi** 2°C'ye ayarlıysa, **Hazne çıkış sıcaklığı** için olası en yüksek ayar 40°C'dir.

Ayrıca, **Sıcaklık derecesi** ayarı **Hazne çıkış sıcaklığı** ayarından daha önceliklidir. Bu durum, ayarların bir kombinasyonunun 42°C'den büyük bir Y parçası sıcaklığına neden olması durumunda, **Sıcaklık derecesi** ayarının değişmeden kalacağı, ancak **Hazne çıkış sıcaklığı** ayarının değiştirileceği anlamına gelir.

Örneğin, **Hazne çıkış sıcaklığı** 40°C'ye ayarlıysa, kombinasyon 42°C'yi aşsa bile **Sıcaklık derecesi** değerini 3°C'ye ayarlayabilirsiniz. **Sıcaklık derecesi** ayarı kabul edildikten sonra, **Hazne çıkış sıcaklığı** değeri otomatik olarak 39°C'ye ayarlanır.

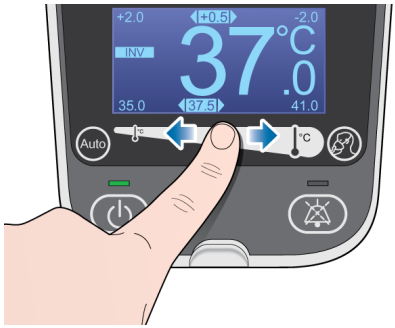
[89] Entegre nemlendirici kontrolünü destekleyen bir Hamilton Medical ventilatör ile kullanıldığında, ayarları doğrudan ventilatörün üzerinden de değiştirebilirsiniz. Daha fazla bilgi için ventilatör *Kullanıcı Kılavuzu*'nuza bakınız.
[90] Yalnızca tek kullanımlık, çift parça ısıtmalı solunum devreleri.

### Hazne çıkış sıcaklığını ayarlamak için

- Mevcut ayarda **Hazne çıkış sıcaklığı** kaydırıcısına dokunun:
  - – Hazne çıkış sıcaklığını azaltmak için sola sürükleyin
  - – Hazne çıkış sıcaklığını artırmak için sağa sürükleyin

Değişiklikler sesli bir bip sesi ile onaylanır ve anında uygulanır.

Şekil 11. Hazne çıkış sıcaklığının ayarlanması




### Hazne çıkış sıcaklığını > 39°C olarak ayarlamak için

**Hazne çıkış sıcaklığını** 39°C'nin üzerine çıkarmak için kaydırıcı iki kez etkinleştirilmelidir.

1. Mevcut ayarda **Hazne çıkış sıcaklığı** kaydırıcısına dokunun ve 39°C limitine ulaşmak için sağa sürükleyin.
2. Hazne çıkış sıcaklığını 39°C'nin üzerine çıkarmak için kaydırıcıya tekrar dokunun ve sürükleyin.

### Sıcaklık derecesini ayarlamak için

- Mevcut ayarda **Sıcaklık derecesi** kaydırıcısına dokunun:
  - – Sıcaklık derecesini azaltmak için sağa sürükleyin
  - – Sıcaklık derecesini artırmak için sola sürükleyin

Değişiklikler sesli bir bip sesi ile onaylanır ve anında uygulanır.

Şekil 12. Sıcaklık derecesini ayarlama


Örneğin, hedef Y parçası sıcaklığı 39°C ise ve **Hazne çıkış sıcaklığı** 37°C olarak ayarlanmışsa, **Sıcaklık derecesini** 2°C'ye ayarlayın.

## 4.4 Nemlendirmenin izlenmesi

İzleme verileri, istediğiniz zaman erişebileceğiniz **Sıcaklık izleme penceresinde** mevcuttur.[91]

Aşağıdaki parametreler izlenir:

- Hazne çıkış sıcaklığı
- Sıcaklık derecesi
- Y parçası sıcaklığı

[91] Entegre nemlendirici izlemeyi destekleyen bir Hamilton Medical ventilatör ile kullanıldığında, ventilatör ekranında nemlendirici verileri gösterilir. Daha fazla bilgi için ventilatör *Kullanıcı Kılavuzu*'nuza bakınız.

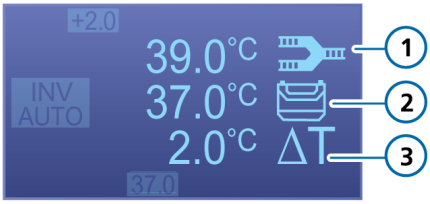
### 4.4.1 İlave izleme parametrelerinin görüntülenmesi

**Sıcaklık izleme penceresini görüntülemek için**

- ☰ öğesine (**Sıcaklık izleme penceresi**) basın.

  Pencere 30 saniye sonra veya düğmeye tekrar bastığınızda kapanır.

Şekil 13. Sıcaklık izleme penceresi




| | | | |
|---|---|---|---|
| 1 | Geçerli Y parçası sıcaklığı | 3 | Geçerli sıcaklık derecesi |
| 2 | Mevcut hazne çıkış sıcaklığı | | |

## 4.5 Gündüz ve Gece ekran parlaklık ayarları

Nemlendirici ekranı arka ışığı iki farklı ekran ayarını destekler. Ekranın parlaklığını ayarlamak için bu ayarları kullanın.

**Gündüz ve Gece ayarları arasında geçiş yapmak için**

- 5 saniye ☰ düğmesini basılı tutun.

Varsayılan gün ve gece parlaklığını ayarlamak için bkz. kısım 7.

# 5 Nemlendirici alarmlarına yanıt verilmesi

Nemlendirici ile ilgili alarmlar dikkatinizi gerektiren koşulları size bildirir. Alarmlar aşağıdaki gibi gösterilir:

- Nemlendirici ekranında grafiksel olarak
- Sırayla 3 veya 5 duyulabilir bip sesi ile
- Su haznesinin üstündeki alarm lambası yanıp söner
- Entegre nemlendirici izlemeyi destekleyen bir Hamilton Medical ventilatör ile kullanıldığında, ventilatör ekranında alarm mesajları da gösterilir.[92]

Alarmlar tablo 8'de açıklandığı gibi yüksek öncelikli, orta öncelikli veya teknik arıza olarak sınıflandırılır.

Alarmların tam listesi için, tablo 9'a bakın.

Tablo 8. Alarm göstergeleri

| Alarm tipi | Alarm durumu göstergesi | Ses | Eylem gerekli |
|---|---|---|---|
| Yüksek öncelikli | Kırmızı, yanıp sönüyor<br>Alarm simgesi ekranda gösterilir | 5 bip dizisi; alarm sıfırlanıncaya kadar tekrarlanır | Nemlendiriciye acilen bakılması gerekir. |
| Orta öncelikli | Sarı, yanıp sönüyor<br>Alarm simgesi ekranda gösterilir | 3 bip dizisi; alarm sıfırlanıncaya kadar tekrarlanır | Nemlendiriciye derhal müdahale gerekir. |
| Teknik arıza | Kırmızı, yanıp sönüyor<br>Teknik arıza (TF) numarası ekranda gösterilir | 3 bip dizisi; alarm sıfırlanıncaya kadar tekrarlanır | • Teknik arıza (TF) numarasını kaydedin[93].<br>• Nemlendiriciyi kullanımdan alın.<br>• Nemlendiriciye bakım yaptırın. |

[92] Tüm ventilatörlerde mevcut değildir. Ventilatör *Kullanıcı Kılavuzu*'nuza bakın.
[93] Tüm teknik arıza (TF) numaralarının bir listesi *HAMILTON-H900 Bakım Kılavuzu*'nda mevcuttur.

## 5.1 Bir alarmın geçici olarak susturulması

Alarmın bir bileşeni duyulabilir bir sestir. Çoğu alarmda, alarm sesini bir seferde iki dakika boyunca duraklatabilirsiniz (susturabilirsiniz).

### Bir alarmı geçici olarak susturmak için

- Nemlendiricinin önündeki  (**Ses duraklatma**) düğmesine basın.

  Sesli nemlendirici alarmı iki dakika boyunca kapatılır.

  Tuşa ikinci kez basıldığında **Ses duraklatma** iptal edilir.

Bir **Ses duraklatma** aktif olduğunda, **Ses duraklatma** arka ışığı sürekli kırmızı olarak yanar.

Süre dolduğunda ve sorun henüz çözülmediyse, alarm tekrar çalar.

## 5.2 Alarm ses seviyesinin ayarlanması

**⚠ UYARI**

Sesli alarm şiddetini, mutlaka ortam ses seviyesinin üstüne ayarlayın. Aksi taktirde, alarm durumları duyulamaz ve tanınamaz.

Sesli alarmın şiddetini ayarlayabilirsiniz.

Varsayılan olarak, ses seviyesi 5 olarak ayarlanır. Nemlendiriciyi kapattıktan sonra, alarm ses seviyesi varsayılan değerine sıfırlanır.

### Alarm şiddetini ayarlamak için

1. Gerekirse, nemlendiriciyi **Bekleme**'ye sokmak için  (**Güç/Bekleme**) düğmesine basın.
2. 3 saniye  öğesine basın.

   Ekranda mevcut alarm ses seviyesi ayarı görüntülenir.
3. **Hazne çıkış sıcaklığı** kaydırıcısını kullanarak alarm ses seviyesini ayarlayın (bkz. şekil 3).

   Nemlendirici, yeni ses seviyesi ayarında bir bip sesiyle seçiminizi onaylar.
4. Seçiminizi onaylamak ve normal çalışmaya geri dönmek için  düğmesine basın.

## 5.3 Sorun giderme alarmları

Tablo 9 nemlendirici alarmları, nemlendirici üzerindeki grafik gösterimlerini, bir açıklamayı ve önerilen düzeltici eylemleri listeler.

Tablo 9. HAMILTON-H900 alarmları

| Alarm | Alarm simgesi | Açıklama | Eylem gerekli |
|---|---|---|---|
| **Yüksek öncelikli** | | | |
| Nemlendirici eğik |  | Nemlendirici tehlikeli şekilde eğilmiş.<br>Nemlendirici zemine göre 10° veya daha büyük bir açıda konumlandırılmıştır. | • Nemlendiricinin montaj durumunu kontrol edin.<br>• Ventilatör arabasını kontrol edin.<br>• Nemlendiriciyi zemine göre 10°den daha az bir açıyla çalıştırın. |
| Yüksek ısı |  | Su haznesi çıkışı veya Y parçasındaki gaz sıcaklığı ayarlanan değerin üzerindedir. | • Solunum devresinin hastanın yatak örtüsüyle örtülüp örtülmediğini kontrol edin.<br>• Solunum devresinin veya nemlendirici haznesinin doğrudan güneş ışığına maruz kalıp kalmadığını kontrol edin.<br>• Solunum devresini değiştirin. |
| Su seviyesi yüksek |  | Su haznesindeki su seviyesi maksimum seviye işaretinin üstündedir. | • Su seviyesini azaltmak için nemlendirici haznesini boşaltın.<br>• Nemlendirici haznesini yenisiyle değiştirin.<br>• Nemlendiriciyi zemine göre 10°den daha az bir açıyla çalıştırın. |
| Teknik arıza | Teknik arıza (TF) numarası ekranda gösterilir | Nemlendirici arızası nedeniyle teknik arıza. | • Nemlendiricinin çalıştığını ve tüm bağlantılarını kontrol edin.<br>• Nemlendiriciyi değiştirin ve bakıma gönderin.<br>• Bir teknik arıza numarası görüntüleniyorsa, bunu kaydedin ve nemlendiricide bakım sırasında bunu verin. |

| Alarm | Alarm simgesi | Açıklama | Eylem gerekli |
|---|---|---|---|
| **Orta öncelikli** | | | |
| Sıcaklık düşük |  | Su haznesi çıkışı veya Y parçasındaki gaz sıcaklığı ayarlanan değerin altındadır. | • Sistem tamamen ısınana kadar bekleyin (yaklaşık 30 dakika).<br>• Tüm ayarların doğru olup olmadığını kontrol edin.<br>• Havalandırmadan ve benzeri bir yerden, nemlendiriciye ve solunum devresine doğrudan gelen hava akışını engelleyin. |
| Su seviyesi düşük |  | Haznedeki su seviyesi düşük seviye işaretinin altındadır. | • Su şişesini ve takviye tüp düzeneğini kontrol edin.<br>• Su şişesi boşsa, yeni bir su şişesi takın.<br>• Boş nemlendirici haznesini tekrar doldurun veya değiştirin.<br>• Nemlendiriciyi zemine göre 10°den daha az bir açıyla çalıştırın. |
| Su haznesini kontrol edin |  | Hazne yok veya uyumsuz su haznesi yerleştirilmiş. | Yeni bir nemlendirici haznesi yerleştirin ve solunum devresini bağlayın. |

| Alarm | Alarm simgesi | Açıklama | Eylem gerekli |
|---|---|---|---|
| Sol veya sağ parçayı kontrol edin |  | Ekran ve bağlantı göstergeleri hangi parçanın arızalı olduğunu gösterir.<br>• Parça yok veya arızalı parça bağlanmış.<br>• Hava akışı yok.<br>• Bir parça uygun şekilde bağlanmamış.<br>• BEYAZ nemlendirici ekspiratuvar parça, ventilatörün *Hastaya giden* inspiratuvar portuna bağlanır. | • Solunum devresini düzgün bir şekilde takın veya yerine tekrar oturtun.<br>• Solunum devresini değiştirin.<br>• MAVİ nemlendirici inspiratuvar parçasını ventilatörün *Hastaya giden* inspiratuvar portuna bağlayın.<br><br>Bağlantı göstergesi:<br>*Yeşil*: Parça doğru şekilde bağlanmış.<br>*Turuncu*: Nemlendirici bağlantıyı test ediyor.<br>*Kırmızı*: Bağlantı arızalı veya mevcut değil. |

# 6 Bakım

*Devam etmeden önce, kısım 1'deki güvenlik bilgilerini gözden geçirin.*

Bu kısımda, nemlendiricinin bakım prosedürleri ve takviminin yanı sıra temizlik ve dezenfeksiyon talimatları hakkında bilgi verilmektedir.

Bu kısımda tüm prosedürler operatör tarafından gerçekleştirilecektir.

Ek bakım gereklilikleri için Hamilton Medical servis temsilciniz ile iletişime geçin. Bu kısımda atıfta bulunulan belgeler MyHamilton web sitesinde bulunabilir: **https://www.hamilton-medical.com/MyHamilton**

## 6.1 Temizlik, dezenfeksiyon ve sterilizasyon

Nemlendirici bileşenleri, her bir bileşene özgü temizleme yöntemleri ve çözeltileri kullanılarak düzenli olarak temizlenmeli ve dezenfekte edilmelidir.

Nemlendiriciyi ve bileşenlerini temizlerken ve dezenfekte ederken, yalnızca ekipmana zarar vermemek için değil, aynı zamanda çapraz kontaminasyonu önlemek için de uygun yöntemi ve malzemeleri seçmeniz önemlidir.

Temizlik ve dezenfeksiyon bilgileri aşağıdaki gibi sunulmuştur:

- Tablo 10 geçerli nemlendiriciyle ilgili bileşenleri listeler ve her biri için hangi temizleme ve dezenfeksiyon yöntemlerinin kullanılabileceğini, bileşenin hangi sıklıkta temizlenmesi/dezenfekte edilmesi gerektiğini ve hangi temizleme ve dezenfeksiyon maddelerinin kullanılacağını gösterir.
- Solunum devresi setleri ve nemlendirici su hazneleri için *Kullanım talimatları*'na veya *Tekrar İşleme Kılavuzu*'na bakın.

Nemlendirici bileşenleri, temizleme yöntemleri ve temizlik maddeleri ile çalışırken aşağıdakileri göz önünde bulundurun:

- Hamilton Medical tarafından belirtilmedikçe dekontaminasyon prosedürlerini *denemeyin*.
- Kullanılacak maddeler ve konsantrasyonlar için talimatlar sağlamakla birlikte, belirli bir temizlik veya dezenfeksiyon maddesinin kullanımı hakkında sorularınız varsa, maddenin üreticisi ile iletişime geçin.

Tablo 10. Nemlendirici temizleme ve dezenfeksiyon yöntemleri

| Parça | Frekans | Temizleme/dezenfeksiyon yöntemi | Temizlik maddeleri |
|---|---|---|---|
| Şunlar dahil nemlendiricinin dışı:<br>• Yuva<br>• Ekran<br>• Isıtıcı plaka<br>• Güç kabloları<br>• Montaj sistemleri | Her hasta kullanımından sonra veya gerektiğinde. | Tescilli ve onaylı bir temizleme/dezenfeksiyon çözeltisi kullanarak nemli bir bezle silin. | Super Sani-Cloth antiseptik bezler<br>CaviWipes |

## 6.2 Koruyucu bakım

Nemlendiricinizin koruyucu bakımı Hamilton Medical yetkili servis personeli tarafından *HAMILTON-H900 Bakım Kılavuzu*'ndaki talimatlara uygun olarak yapılmalıdır.

# 7 Konfigürasyon

Nemlendirici, hasta grubu tarafından düzenlenen çeşitli ayarların varsayılan konfigürasyonu ile teslim edilir.

**Konfigürasyon** modunda aşağıdaki varsayılan ayarları değiştirebilirsiniz:

- **Hazne çıkış sıcaklığı**
- **Sıcaklık derecesi**
- Başlangıç çalışma modu (**INV/NIV/HiFlow**)
- **Ekspiratuvar sıcaklığı artırma** Açık/Kapalı
- Arka ışık **Gündüz/Gece** parlaklık ayarları

## 7.1 Konfigürasyon moduna erişme

**Konfigürasyon** moduna nemlendirici **Bekleme** modundayken erişebilirsiniz.

**Konfigürasyon moduna erişmek için**

1. Gerekirse, **Bekleme** moduna girmek için  üzerine basın.
2.  ve  üzerine basılı tutun.

   Önce  üzerine bastığınızdan emin olun.

   **Konfigürasyon** penceresi 5 saniye sonra görüntülenir.

Nemlendirici artık **Konfigürasyon** modundadır.

## 7.2 Konfigürasyon ayarlarının değiştirilmesi

Özel ayarlar, siz bunları değiştirene veya fabrika ayarlarını geri yükleyene kadar kalıcıdır.

**Konfigürasyon** modunda, görünümlerde gezinmek ve seçimler yapmak için nemlendirici ön panelindeki düğmeler kullanılır.

Tablo 11 **Konfigürasyon** modunda nasıl gezileceğini ve ayarların nasıl değiştirileceğini açıklar.

Bir ayarın nasıl değiştirileceğine ilişkin bir örnek için, **Sıcaklık derecesinin** varsayılan ayarlarını değiştirme konusundaki aşağıdaki prosedüre bakın.

Konfigürasyon ayarlarının bir listesi için bkz. kısım 9.6.

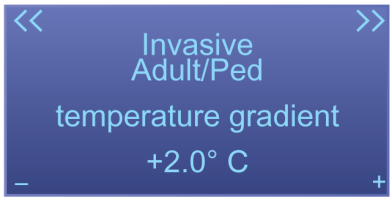
Tablo 11. Konfigürasyon modu gezinti düğmeleri

| Düğme | Açıklama |
|---|---|
|  | Görünümlerde ileri git |
|  | Görünümlerde geri git |
|  | Bir değeri artır |
|  | Bir değeri azalt |
|  | Değişiklikleri kaydet ve **Konfigürasyon** modundan çık |

**Örnek: Sıcaklık derecesini değiştirme**

**Varsayılan İnvaziv, Yetişkin/Ped, Sıcaklık derecesi ayarını değiştirmek için**

1. **Konfigürasyon** modunda, **Invasive, Adult/Ped, Temperature gradient** (İnvaziv, Yetişkin/Ped, Sıcaklık derecesi) görünümünü görene kadar Exp. öğesine basın.




2. Değeri artırmak için öğesine, azaltmak için Auto öğesine basın.
3. İşlem tamamlandığında, değişiklikleri kaydetmek için öğesine basın ve **Konfigürasyon** modundan çıkın.

## 7.3 Varsayılan fabrika ayarlarına geri döndürme

İstediğiniz zaman varsayılan fabrika ayarlarına geri döndürebilirsiniz.

**Varsayılan fabrika ayarlarına geri döndürmek için**

1. Konfigürasyon modunda, **Reset all custom defaults** (Tüm özel varsayılanları resetle) penceresi görünene kadar Exp. öğesine art arda basın.
2. Auto öğesine basın.

Fabrika varsayılan ayarlarına geri döndürüldü.

# 8 Parçalar ve aksesuarlar

Bu kısımda HAMILTON-H900 nemlendirici için mevcut parça ve aksesuarlar listelenmiştir.

Daha fazla bilgi için, Hamilton Medical web sitesindeki elektronik kataloğa bakın veya Hamilton Medical temsilciniz ile iletişime geçin.

Tablo 12. Nemlendirici parçaları ve aksesuarları

| PN | Açıklama |
|---|---|
| 260161 | HAMILTON-BC8022, su haznesi olan, çift parçalı, ısıtmalı solunum devresi seti |
| 260186 | HAMILTON-BC4022, su haznesi olan, tek parçalı, ısıtmalı solunum devresi seti |
| 260185 | HAMILTON-BC8010, su haznesi ve inkübatör uzatması olan, çift parçalı, ısıtmalı solunum devresi seti |
| 260187 | HAMILTON-BC4010, su haznesi ve inkübatör uzatması olan, tek parçalı, ısıtmalı solunum devresi seti |
| 260196 | HAMILTON-HC322, su haznesi, tek kullanımlık |
| 260197 | HAMILTON-HC310, su haznesi, tek kullanımlık |

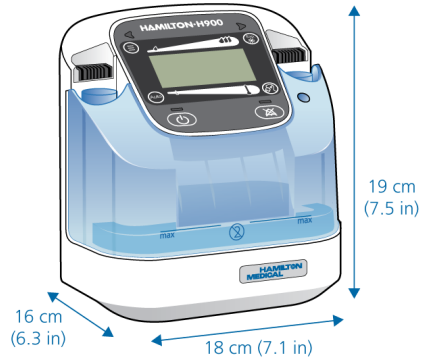
# 9 Spesifikasyonlar

## 9.1 Fiziksel özellikler

Tablo 13. Fiziksel özellikler

| Boyut | Spesifikasyonlar |
|---|---|
| Ağırlık | Nemlendirici (boş su haznesi): 2,5 kg |
| Boyutlar | Bkz. şekil 14. |

Şekil 14. HAMILTON-H900 boyutları



## 9.2 Çevresel gereklilikler

Tablo 14. Çevresel gereklilikler

| Çevre | | Spesifikasyonlar |
|---|---|---|
| Sıcaklık | Çalışma: | 10°C ila 40°C |
| | Saklama: | -20°C ila 60°C |
| | | Önerilen ortam sıcaklığı: 18°C ila 26°C |
| Yükseklik | | En fazla 4.000 m |
| Atmosfer basıncı | Çalışma ve saklama: | 61 kPa ila 106 kPa |
| Bağıl nem | Çalışma: | %30 ila %95, yoğuşmasız |
| | Saklama: | %10 ila %95, yoğuşmasız |
| Su koruması | | IP21 |
| Gaz giriş sıcaklığı | | 18°C ila 31°C (önerilen) |

## 9.3 Elektriksel spesifikasyonlar

Tablo 15. Elektriksel spesifikasyonlar

| Parça numarası | Giriş gücü | Güç tüketimi |
|---|---|---|
| 950001 (230 V) | 220 – 240 V<br>50/60 Hz | 283 VA |
| 950004 (115 V) | 110 – 127 V<br>50/60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50/60 Hz | 268 VA |
| Potansiyel eşitleme | DIN 42801'e uygun bir potansiyel eşitleme kondüktörü bağlantısı için terminal | |

## 9.4 Kontrol ayarları

Tablo 16. Kontrol ayarları ve aralıkları

| Parametre veya ayar (birim) | Mod | Aralık | Varsayılan | Çözüm |
|---|---|---|---|---|
| Hazne çıkış sıcaklığı (°C) | INV | 35 ila 41 | 37,0 | 0,5 |
| | NIV | 30 ila 35 | 31,0 | 0,5 |
| | HiFlow | 33 ila 37 | 35,0 | 2 |
| Sıcaklık derecesi (°C) | INV | -2 ila 3 | Yetişkin/Ped: 2<br>Neo: 3 | 0,5 |
| | NIV | -2 ila 3 | Yetişkin/Ped: 2<br>Neo: 3 | 0,5 |
| | HiFlow | -- | 2 | -- |
| Ortaya çıkan maks. havayolu sıcaklığı (Y parçası)[94] (°C) | INV | 33 ila 42 | -- | -- |
| | NIV | 28 ila 38 | -- | -- |
| | HiFlow | 35 ila 39 | -- | -- |
| Ekspiratuvar sıcaklığı artırma | Tüm modlar | Açık, Kapalı | Açık | -- |
| Ekran için parlaklık ayarı | Tüm modlar | 1 ila 5 | Gündüz: 5<br>Gece: 2 | 1 |

[94] Havayolu sıcaklığı nemlendirici tarafından 42°C'ye sınırlandırılmıştır.

## 9.5 İzlenen parametreler

Tablo 17. İzlenen parametreler, aralıklar ve doğruluk

| Parametre (birim) | Aralık | Doğruluk |
|---|---|---|
| Hazne çıkış sıcakl. (°C) | 10 ila 60 | 10 ila 30: ±1<br>30 ila 41: ±0,5<br>41 ila 60: ±1 |
| Y parçası sıcaklığı (°C) | 28 ila 43 | ± 0,5 |

## 9.6 Konfigürasyon

Tablo 18. Konfigürasyon spesifikasyonu

| Parametre | Mod | Konfigürasyon aralığı | Varsayılan ayar |
|---|---|---|---|
| Hazne çıkış sıcakl. (°C) | INV | 35 ila 39 | 37,0 |
| | NIV | 30 ila 35 | 31,0 |
| | HiFlow | 33, 35, 37 | 35,0 |
| Sıcaklık derecesi (°C) | INV | 0 ila 3 | Yetişkin/Ped: 2<br>Neo: 3 |
| | NIV | 0 ila 3 | Yetişkin/Ped: 2<br>Neo: 3 |
| | HiFlow | 0 ila 3 | 2 |
| Başlangıç modu | -- | İnvaziv, noninvaziv, HiFlow | İnvaziv |
| Ekran için parlaklık ayarı | Tüm modlar | 1 ila 5 | Gündüz: 5<br>Gece: 2 |

## 9.7 Teknik performans verileri

Tablo 19. Teknik performans verileri

| Açıklama | Spesifikasyon | | |
|---|---|---|---|
| Akış hızları[95] | İnvaziv: | 60 l/dak'ya kadar | |
| | Noninvaziv: | 120 l/dak'ya kadar | |
| | HiFlow: | 120 l/dak'ya kadar | |
| Isınma süresi | 30 dak'dan az | | |
| Nem | 18°C ila 26°C ortam sıcaklığında: | | |
| | İnvaziv: | 37°C ila 41°C'lik sıcaklık ayarı | En düşük nem değeri: 33 mg H2O/l |
| | Noninvaziv: | 31°C ila 35°C'lik sıcaklık ayarı | En düşük nem değeri: 12 mg H2O/l |
| | HiFlow: | Akış hızı ≤ 60 l/dak | En düşük nem değeri: 33 mg H2O/l |
| | | Akış hızı > 60 l/dak | En düşük nem değeri: 12 mg H2O/l |
| Bekleme ısıtma spesifikasyonları | Isıtılan solunum devreleri: | Y parçası 30°C'ye sınırlı. | |
| Ekran | 3 giriş / 64 x 128 piksel, ters nokta vuruşlu ekran (arkadan aydınlatmalı) | | |
| Sesi duraklat | 120 saniye | | |
| Alarm şiddeti[96] | Aralık = 1 - 8. Varsayılan = 5. | | |

## 9.8 Temel performans

Solunum gazı ve solunum devresine uygulanan sıcaklıklar belirli ayarlarla korunmalı ve izlenmelidir.

Sıcaklık belirtilen limitlerin dışında kalırsa, nemlendirici bunu tespit etmeli ve bir alarm ile kullanıcıyı bilgilendirmelidir.

[95] Asgari akış hızları için solunum devresi *kullanım talimatlarına* bakın.
[96] Nemlendiriciden 1 metre mesafede hacim. 1 = 50 dB(A), 5 (varsayılan) = 60 dB(A) ve 8 = 65 dB(A) ayarları, ±6 dB(A) doğruluk ile.

## 9.9 Nemlendirici sisteminin fonksiyonel tanımı

HAMILTON-H900 nemlendirici mekanik ventilasyon sırasında respiratuvar gazları ısıtmak ve nemlendirmek için tasarlanmıştır. Respiratuvar gaz ısıtılmış suyla kısmen doldurulan bir hazneden geçerken ısıtılır ve nemlendirilir.

Nemlendirici iki adet sensör kontrollü ısıtma sistemine sahiptir:

- *Isıtma plakası*. Su haznesindeki suyu ısıtır.
- *Entegre solunum devresi ısıtma sistemi*. Yoğuşmayı önlemek için solunum parçalarını ısıtır.

Respiratuvar gaz sıcaklığı hazne çıkışında ve hasta ucundaki solunum parçasında izlenir.

## 9.10 Cihaz etiketleri ve paketlerde kullanılan semboller

| Sembol | Açıklama |
|---|---|
|  | *Kullanım talimatlarını* izleyin |
| REF | Referans numarası |
| SN | Seri numarası |
| QTY | Miktar |
|  | Üretici |
|  | Üretim tarihi |

| Sembol | Açıklama |
|---|---|
|  | Tip BF uygulanan parça (IEC 60601-1 tarafından belirlenen tıbbi elektrikli ekipman sınıflandırılması) |
|  | Konsey Direktifi 2002/96/EC veya WEEE'ye (Atık Elektrikli ve Elektronik Cihazlar) uygun olarak imha edin |
|  | "C" ve "US" göstergelerine sahip TÜV NRTL işareti, ürünün Kanada gerekliliklerine ve ABD makamlarının güvenlik gerekliliklerine uygun olduğu anlamına gelir |
|  | Potansiyel eşitleme |
|  | Uyarı: Sıcak yüzey.<br>Isıtma plakası ve haznenin altı 85°C üzeri bir sıcaklığa erişebilir. |
| CE 0197 | CE Uygunluk İşareti; cihazın tıbbi cihazlarla ilgili 93/42/EEC sayılı Konsey Direktifine uygun olduğunu garanti eden onay mührü |
| IP21 | Su damlacıklarına ve 12,5 mm'den büyük katı parçacıklara karşı korumalıdır |
| max | Su haznesi üzerindeki dolum seviyesi işareti |
|  | Hamilton Medical ventilatörlerle bağlantı için RS-232 seri bağlantı arayüzü |

| Sembol | Açıklama |
|---|---|
|  | MR tehlikesi<br>HAMILTON-H900 nemlendirici, MR ortamında hastalar, tıbbi personel ve diğer kişiler için kabul edilemez riskler doğurur. |
|  | Çince RoHS |
|  | Sıcaklık probu<br>Sıcaklık probunun solunum devresi üzerindeki konumunu gösterir. |

## 9.11 Standartlar ve onaylar

Nemlendirici sistemi, tablo 20'de listelenen aşağıdaki standartların ilgili parçalarına uygundur.

Tablo 20. Standartlar ve onaylar, geçerli sürümler

| |
|---|
| IEC 60601-1:2005/A1:2012 |
| IEC 60601-1-2:2014 |
| IEC 60601-1-6:2010/A1:2013 |
| IEC 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| IEC 62304:2006/A1:2015 |
| IEC 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 Elden çıkarma

Cihaz, kurumunuzun protokollerine ve Direktif 2002/96/EC'ye uygun olarak elden çıkarılmalıdır.

Solunum devreleri ve nemlendirici hazneleri, solunum devresi setleriyle birlikte verilen *Kullanım talimatlarına* uygun olarak elden çıkarılmalıdır.

## 9.13 Garanti

SINIRLI GARANTİ

BU SÖZLEŞMEDE TANIMLANAN GARANTİ, TİCARİ ELVERİŞLİLİĞE YA DA ÖZEL BİR AMACA UYGUNLUĞA DAİR HER TÜRLÜ ÖRTÜLÜ GARANTİ DE DAHİL OLMAK ÜZERE, AÇIK VEYA ÖRTÜLÜ DİĞER GARANTİLERDEN HERHANGİ BİRİNİN VE TÜMÜNÜN YERİNE GEÇER. ANCAK, ÖRTÜLÜ GARANTİLERDEN BU SINIRLI GARANTİ SÜRESİNCE FERAGAT EDİLMEZ.

Hamilton Medical, ürünlerinin malzeme ve işçilik bakımından hiçbir kusur içermeksizin gönderileceğini garanti eder. Garanti atılabilir parçaları içermemektedir. Atılabilir parçalar ve sarf malzemeleri tek kullanımlık veya yalnızca sınırlı kullanıma uygun ürünler olarak kabul edilir ve bunların, Kullanıcı Kılavuzuna uygun şekilde, ürünün düzgün şekilde çalışabilmesi adına düzenli aralıklarla değiştirilmeleri gerekir.

Hamilton Medical, ürünle ilgili olarak, işbu belgede tanımlanan, iddia edilen ihmalkarlığa veya kusursuz sorumluluğa dair yükümlülükler ve/veya sorumluluklar dahil olmak ancak bunlarla sınırlı olmamak kaydıyla, hiçbir yükümlülük ve sorumluluk üstlenmeyecektir. Şirket, ister doğrudan

isterse koşullara bağlı şekilde, kaza eseri veya dolaylı olarak oluşan zararlarla ilgili hiçbir sorumluluğu kabul etmez.

Bu Sınırlı Garanti aşağıdaki durumlarda hükümsüz ve geçersiz olacaktır:

1. Ürün, bir yetkili yerel Hamilton Medical temsilcisi tarafından, Hamilton Medical ve bir Hamilton Medical temsilcisi tarafından sağlanan talimatlara uygun olacak şekilde kurulmamış ve bağlanmamışsa.
2. Hasarın/tamirin, onaylı garanti süresi içerisinde gerçekleştiğine dair hiçbir kanıt yoksa.
3. Seri numarası değiştirilmiş, silinmiş veya çıkarılmışsa ve ürünün satın alınma tarihini doğrulayacak hiçbir fatura veya kanıt yoksa.
4. Arızalar; hatalı kullanım, ihmalkarlık veya kazalar nedeniyle ya da Hamilton Medical fabrikalarının dışında gerçekleştirilen veya yetkili servis hizmeti veren merkez ya da yetkili servis temsilcisi tarafından gerçekleştirilmeyen tamir, ayarlama, modifikasyon veya parça değiştirme işlemleri sonucunda oluşmuşsa.
5. Ürün, Hamilton Medical'den önceden yazılı izin alınmadan modifiye edilmiş veya herhangi bir şekilde değiştirilmişse.
6. Ürün, "Kullanım amacı" bölümünde belirtilmeyen herhangi bir şekilde kullanılıyorsa veya kullanılmışsa.
7. Ürün, bir hekimin gözetimi altında uygun eğitim almış personel dışında herhangi biri tarafından kullanılmışsa.

Bu Sınırlı Garanti çerçevesinde yapılan parça değişiklikleri ve/veya tamirler yeni bir garanti niteliği taşımaz ve yalnızca orijinal Sınırlı Garantinin süresi geçmemiş bölümüne ilişkindir. Tamir edilen ve/veya değiştirilen bileşenlerin garantisi cihazın Sınırlı Garanti süresini aşmaz.

Bu Sınırlı Garanti çerçevesinde hizmet almak için, talep sahibi Hamilton Medical'in ilgili ülkedeki satış ortağını, sorunun mahiyeti, seri numarası ve Ürünün satın alınma tarihi konularında hemen bilgilendirmelidir.

Hamilton Medical yukarıda ifade edilenler haricinde; vücut yaralanmaları veya kaza eseri ya da dolaylı olarak oluşan veya özel hasarlar dahil olmak ancak bunlarla sınırlı olmamak kaydıyla, hiçbir zarar, istem veya sorumluluk kabul etmeyecektir. Ayrıca Hamilton Medical; vücut yaralanmaları veya kaza eseri ya da dolaylı olarak oluşan veya özel hasarlar dahil olmak ancak bunlarla sınırlı olmamak kaydıyla, cihazın hatalı kullanımı veya bu kılavuzdaki hükümlerin herhangi biriyle uyuşmazlık yaşanması durumunda oluşacak hiçbir zarar, istem veya sorumluluktan da mükellef değildir.

### 9.13.1 Diğer

Hamilton Medical'in genel hüküm ve koşulları geçerli olacaktır. Bu anlaşma, İsviçre yasalarına uygun olarak düzenlenecek ve yorumlanacak ve Chur, İsviçre mahkemesinin yetkisi altında taraflardan herhangi biri tarafından uygulanabilecektir.

# 使用说明

## HAMILTON-H900

2021-01-11

624431/09

**制造商**

Hamilton Medical AG 瑞士哈美顿医疗公司
Via Crusch 8，CH-7402 Bonaduz，
瑞士
电话：（+41）58 610 10 20
传真：(+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# 目录

# 前言

在使用该设备或附件之前务必阅读本文档。

### 本指南中使用的规约

在本手册中：

- 按钮名称以**粗体**字显示。
- 所示的图表显示内容可能与您在自己的环境中看到的内容并不完全一致。
- 并非所有市场均提供所有功能。

安全信息按如下显示：

**⚠ 警告**

警告使用者因为使用或者误用本设备可能发生的伤害、死亡或者其他严重不良反应。

**⚠ 小心**

*警告使用者因为使用或者误用本设备可能发生的故障，例如呼吸机故障、呼吸机无反应、呼吸机损坏或者其他性能故障。*

***注意***

强调特别重要的信息。

在表格中，安全信息按如下显示：

**⚠ 警告！**

**⚠ 小心！**

**注意！**

需要下载本手册或其他文档的最新版本，请访问 MyHamilton 网站：
https://www.hamilton-medical.com/MyHamilton

Hamilton Medical 哈美顿医疗公司设有 Hamilton Medical 瑞士哈美顿医疗公司网络学院，其提供各种免费学习课程。若要注册，请转至：
http://college.hamilton-medical.com/

**⚠ 小心**

*（仅限美国）：联邦法律规定此设备只能由医生或遵照医嘱进行销售。*

### 预期用途

HAMILTON-H900 湿化器适用于有创和无创机械通气时呼吸气体的调节。

设备预期用于医院和医务人员提供病人护理的机构环境。

HAMILTON-H900 湿化器是一种供具备相应资质且训练有素的人员使用的医疗设备，使用该设备时应在医生的指导下，并不超出其规定的技术规范范围。

# 1 安全须知

本节提供湿化器设置、运行和服务相关的安全信息。

**在设置和使用湿化器前小心阅读本安全章节的所有内容。**

**在使用湿化器前务必阅读使用说明。**

**在使用与湿化器配合使用的任何设备和附件之前务必阅读附带的使用说明。**

如果您对本手册的任何信息有疑问，请联系 Hamilton Medical 哈美顿医疗公司代表或技术服务部门。

## 1.1 电磁敏感度

**⚠ 警告**

- **MR 不安全。**请远离磁共振成像（MRI）设备。HAMILTON-H900 对 MR 环境中的病人、医务人员或其它人员会造成不可接受的风险。
- 湿化器附近高频手术设备的运转、微波、短波或强磁场可能会影响到设备的功能。
- 为防止增加排放、降低免疫力或者中断 HAMILTON-H900 湿化器或任何附件的运转，请仅使用本手册或 Hamilton Medical 哈美顿医疗公司电子产品目录中明确规定的附件或线缆。
- 连接到医疗电气设备的其他设备必须符合相应的 IEC 或 ISO 标准（例如，适用于数据处理设备的 IEC 60950）。此外，所有配置应该符合医疗电气系统的相关规定（请参阅 IEC 60601-1 第 16 款）。
- 任何将其他设备连接到医疗电气设备并进行医疗系统配置的人员也要负责确保系统符合医疗电气系统的相关规定。请注意，当地法律优先于上述规定。如果您有关于如何使用的疑问，请咨询 Hamilton Medical 哈美顿医疗公司代表或技术服务部门。
- 心脏除颤器进行放电时，湿化器得*不*到保护。

***注意***

- HAMILTON-H900 湿化器需要采取电磁兼容性 (EMC) 方面的特殊防范措施，并需要根据 *HAMILTON-H900 EMC 声明*提供的 EMC 信息进行安装和使用。
- 便携式移动射频通讯设备会影响 HAMILTON-H900 湿化器。

## 1.2 电源

**⚠ 警告**

- 为了将触电的危险降到最低，将湿化器插头插入适当接地的电源插座。医院负责确保插座适当接地。
- 如果电源线损坏，*请勿*使用。
- 如果电压不正确、电源故障或电源断开，湿化器会发出鸣笛声。立即关闭设备，并检查电压是否正确。
- 确保使用了正确的电压。

## 1.3 火灾和其他危险

**⚠ 警告**

切*勿*在危险场所或存在易燃性气体的场所使用湿化器。

## 1.4 一般操作和设置

**⚠ 警告**

- 在将湿化器用于病人之前，按照下列说明验证呼吸管路是否正确连接到呼吸机：
  – 蓝色吸气肢连接到*至病人*吸气端口。
  – 白色呼气肢连接到*自病人*呼气端口。
- 请仅使用第 8 节中指定的配件和附件。以此确保湿化器适当运转并预防可能的病人损伤。
- 请勿在海拔 4000 米以上或温度 10°C 至 40°C 范围以外的地方使用湿化器。这样可能会影响治疗质量或伤害病人。
- 不正确的湿度设置或温度设置会伤害病人。
- 在医院外转运机械通气病人时切*勿*使用湿化器。
- 打开呼吸机*后*再打开湿化器。
- 关闭呼吸机*前*先关闭湿化器。
- 不要遮盖湿化器的 IR 测量单元。
- 有创 (INV) 模式*只*能用于气管插管和气管切开的病人。
- 如果病人出现过敏反应，请采取额外的预防措施。
- 定期检查呼吸管路有无冷凝水，并根据需要排干。
- 同时使用雾化器可能使设备的湿化性能受到负面影响。
- 请*勿*接触热板或水箱底部。其表面温度可超过 85℃。这些热表面会辐射热量。

**⚠ 小心**

- *请将湿化器安装在可轻易断开主电源的位置。*
- *请仅使用第 8 节中及 Hamilton Medical 哈美顿医疗公司电子产品目录中指定的配件和附件，或者使用指明与湿化器兼容的配件和附件。*
  *这样可以确保湿化正确无误，避免降低性能，并提供有效保修。*
- *如果湿化器关闭后打开，其将在有创 (INV) 模式下自动启动，除非进行不同配置。*
- *使用前检查呼吸装置是否有损坏。如果有任何损坏迹象，请丢弃呼吸装置。*
- *当水箱和呼吸管路已正确安装，并且湿化器处于开启状态或待机状态时，湿化器的加热元件和加热丝会自动开启。*
- *如果环境或入口气体温度和/或流速超出推荐范围，可能无法达到生理湿度水平。*
- *即使显示器不亮，湿化器仍可能处于通电状态。请参阅表 1。*

***注意***

- 给病人使用呼吸装置前，必须进行气密性测试。如果测试失败，可以重复一次。如果连续两次测试失败，则必须更换新的呼吸装置。
- 肢管中、柔性管道中或流量传感器中形成微细的随呼吸变化的水汽凝结（雾化）表示湿度设置适当。
- 所有操作都会发出提示音。

## 1.5 呼吸管路和水箱

**⚠ 警告**

- 呼吸管路未正确连接至呼吸机可伤害病人。
- 为预防在使用或转运过程中呼吸管路意外脱落，请仅使用符合 ISO 5367 或 ISO 80601-2-74 标准要求的呼吸管路。
- 水箱只能灌注符合医院卫生要求的无菌软化水。
- 请勿使水箱倾斜。
- 请勿将任何药物注入湿化器水箱。
- 确保水位不超过最高水位。

***注意***

- 如果湿化器未检测到呼吸管路，请更换组件。
- 注水温度不应超过 37°C。
- 请确保水箱的水供应正常。
- 确保湿化器在断开任何组件之前处于待机状态。

## 1.6 湿化器和呼吸管路定位

**⚠ 警告**

- 湿化器*必须始终*位于病人身体平面下方。
- 湿化器倾斜角度超过 10° 时（相对于地板），切*勿*开机运行。
- 确保从湿化器至病人的呼吸管路无张力及任何扭结。
- 加热肢管*不能*直接放置在病人皮肤上。
- 如果在其他医疗电气设备附近使用或堆叠使用湿化器，请验证湿化器在其将使用的配置中可以正常运行。
- 适当放置呼吸管路，以避免冷凝水影响病人。
- 请正确连接呼吸管路或管道夹以避免对气管内插管产生机械力。

***注意***

- 使用前请检查所有连接的稳定性。
- 湿化器上的所有肢管接头将电气连接与呼吸管路接头结合在一起。请确保电触头的方向正确，以匹配湿化器上的连接元件。

## 1.7 监测和报警

***注意***

- 当报警激活时，主动报警符号和当前水箱出口温度会交替显示。
- 关闭湿化器后，报警音量将回复到默认值 5。
- 所有技术报警,详细的技术信息和维护规程如 *HAMILTON-H900 维修手册*中所述。

## 1.8 维护

**⚠ 警告**

- *不*允许改装湿化器。
- 在清洁和消毒之前请*务必*断开湿化器电源，以减少触电的危险。

**⚠ 小心**

- *根据当地的法律法规或医院的内部规定，将使用过的呼吸管路和水箱作为污染物品处理。*
- *为确保进行正确维修和防止可能造成的身体伤害，只能由 Hamilton Medical 哈美顿医疗公司授权的维修人员利用 HAMILTON-H900 维修手册中提供的信息维修湿化器。*
- *仅使用 Hamilton Medical 哈美顿医疗公司提供的替换零件。*
- *不要尝试 HAMILTON-H900 维修手册中没有说明的维修程序。*
- *仅使用批准的清洁剂进行清洁和消毒。*

***注意***

- 有关耐热压处理（可重复使用）的附件和组件的清洁、消毒和灭菌，请参考各部分提供的*再处理指南*和*使用说明*。
- （*仅限美国*）仅使用 EPA 认证的清洁剂进行清洁和消毒。

# 2 概述

本指南提供有关 HAMILTON-H900 湿化器设置和使用的信息。

该湿化器旨在与 Hamilton Medical 哈美顿医疗公司以及第三方呼吸机配合使用。

## 2.1 关于 HAMILTON-H900 湿化器

HAMILTON-H900 湿化器加热和湿化成人、儿童和新生儿病人用呼吸气体。

其支持下列常用呼吸模式：

- 有创通气
- 无创通气
- 高流量氧疗

该系统由湿化器外壳、屏幕、控制、水箱、加热板及加热的呼吸管路用电气连接组成。

其提供下列主要功能：

- 可调节温度和湿度控制
- 监测和报警能力
- 湿化器监控的数据和控制与所支持的 Hamilton Medical 哈美顿医疗公司呼吸机集成[97]

[97] 并非在所有市场均有提供。

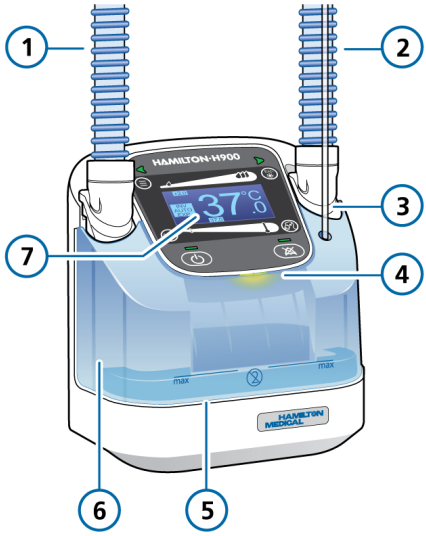
## 2.2 物理描述

本节对湿化器及相关的呼吸装置进行了概述。

### 2.2.1 关于湿化器

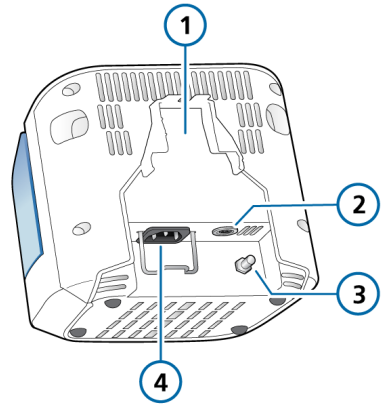
图 1 至 5 对湿化器进行了概述。

图 1. HAMILTON-H900 湿化器，前视图




| | | | |
|---|---|---|---|
| 1 | 呼吸机吸气肢（蓝色） | 5 | 加热板 |
| 2 | 病人吸气肢（蓝色） | 6 | 水箱 |
| 3 | 供水管 | 7 | 前面板和屏幕 |
| 4 | 可视报警指示灯 | | |

图 2. HAMILTON-H900 湿化器，后视图




| | | | |
|---|---|---|---|
| 1 | 安装支架槽 | 3 | 等电位端子 |
| 2 | RS-232 端口 | 4 | 交流电插座 |

### 2.2.2 关于主屏幕

您可以在湿化过程中从主屏幕直接访问所有设置、模式、报警和控制。

图 3 至 5 显示前面板控制、指示灯和屏幕。

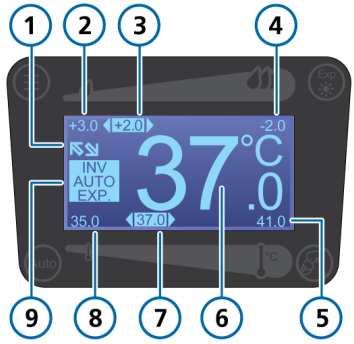
图 3. HAMILTON-H900 湿化器，前面板控制


| | | | |
|---|---|---|---|
| 1 | 温度监测窗口按钮 | 5 | 音频暂停键 |
| 2 | 温度控制滑动条 | 6 | 电源/待机键 |
| 3 | 呼气肢温度增加按钮 | 7 | 自动按钮 |
| 4 | INV/NIV/HiFlow 模式按钮 | 8 | 屏幕（参阅图 5） |

图 4. HAMILTON-H900 湿化器，前面板状态指示灯


| | | | |
|---|---|---|---|
| 1 | 肢管连接状态指示灯 | 3 | 电源/待机状态指示灯 |
| 2 | 音频暂停指示灯 | | |

图 5. HAMILTON-H900 湿化器，屏幕




1 呼吸机连接启用
2 最大温度梯度设置
3 温度梯度设置
4 最小温度梯度设置
5 最大水箱出口温度设置
6 水箱出口当前温度
7 水箱出口温度设置
8 最小水箱出口温度设置
9 激活模式/设置

*屏幕上显示的所有元件仅用于解释；在运行过程中，它们不会同时全部出现。*

### 2.2.3 关于湿化器呼吸管路

HAMILTON-H900 湿化器支持各种单肢和双肢成人、儿童及新生儿病人用呼吸管路。

欲了解详细信息，请参阅呼吸管路*使用说明*。

### 2.2.4 关于湿化器上的状态指示灯

湿化器正面的指示灯显示重要的湿化器状态信息。请参阅图 4。

表 1. 状态指示灯

| 符号 | 说明 |
|---|---|
| **带有状态指示灯的电源/待机键** | |
|  | *绿色*：湿化器在运行中。 |
|  | *橙色*：湿化器处于待机状态。 |
|  | *蓝色*：湿化器关闭，但已连接电源。 |
|  | *未亮起*：湿化器关闭，而且未连接电源。 |
| **肢管连接状态指示灯** | |
|  | *绿色*：肢管已正确连接。 |
|  | *橙色*：湿化器正在检测肢管连接。 |
|  | *红色*：肢管连接错误或肢管未连接。 |
| **带有指示灯的音频暂停键** | |
|  | *红色*：音频暂停激活。 |

## 2.3 导航窗口和控件

本节描述如何使用湿化器按钮和滑动条。

### 2.3.1 使用控制按钮

您可以通过前面板上的按钮（图 3）选择模式，更改设置，以及查看重要温度设置的概要。

表 2. 控制按钮（参阅图 3）

| 按钮 | 说明 |
|---|---|
|  | **升高呼气温度**<br>使呼气肢温度增加。 |
|  | **自动**<br>启用自动模式。<br>请参阅第 4.2.2 节。 |
|  | **INV/NIV/HiFlow 运行模式**<br>在 INV、NIV 和 HiFlow 模式之间切换。<br>请参阅第 4.2 节。 |
|  | **温度监测窗口**<br>显示目前的 Y 形管温度、水箱出口温度及温度梯度值。<br>请参阅第 4.4 节。 |

### 2.3.2 使用滑动条

在手动模式下，您可以使用控制滑动条更改温度设置（图 3）。

表 3. 温度控制滑动条

| 滑动条 | 说明 |
|---|---|
| **温度梯度滑动条** | |
|  | 调节水箱出口与 Y 形管之间的温度差。<br>请参阅第 4.3 节。 |
| **水箱出口温度滑动条** | |
|  | 调节水箱出口温度。<br>请参阅第 4.3 节。 |

# 3 湿化器用前准备

*开始操作前，请阅读第 1 节中的安全信息。*

湿化器用前准备包含以下步骤：

- 由医疗技术人员进行一次性设置配置（参阅表 4）
- 对于每个新病人，由医护人员执行湿化器设置任务（参阅表 5）

表 4. 由医疗技术人员进行配置和设置

| 操作..... | 请参阅..... |
|---|---|
| *这些一次性初始配置操作由技术人员完成。* | |
| 安装和放置湿化器 | 参阅适用的呼吸机或台车*安装指南* |
| 配置湿化器设置 | 第 7 节 |
| *选配*：将湿化器连接至任何支持的 Hamilton Medical 哈美顿医疗公司呼吸机的 RS-232 COM 端口 | 请参阅适用的呼吸机*操作手册*。 |

表 5. 由医护人员进行配置和设置

| 操作..... | 请参阅..... |
|---|---|
| *以下操作由病人医护人员完成。* | |
| 连接至电源 | 第 3.1 节 |
| 连接呼吸管路 | 第 3.2 节 |
| 打开湿化器 | 第 3.3 节 |
| 测试报警 | 第 3.4 节 |
| 指定湿化器设置 | 第 3.5 节 |
| 连接病人 | 第 3.6 节 |

## 3.1 连接至电源

插入湿化器和呼吸机电源插头之前请务必检查主电源插座的可靠性。

### 将湿化器连接到电源

- 将湿化器连接到交流电源插座。[98]

## 3.2 将呼吸管路连接到湿化器

Hamilton Medical 哈美顿医疗公司提供各种成人、儿童及新生儿病人用呼吸管路。

欲了解详细信息，请参阅特定的呼吸管路*使用说明*。

## 3.3 打开和关闭湿化器

湿化器在打开后会自动在所设的默认模式下运行。

确保在打开湿化器*前*先开启呼吸机。

### 打开湿化器

- 按住  （电源/待机键）并持续约 3 秒。

湿化器将运行自检。自检完成后，湿化器在有创 (INV) 模式下自动启动，除非配置了不同的设置。

### 关闭湿化器

- 按住  并持续约 3 秒。

确保在关闭呼吸机*前*先关闭湿化器。

## 3.4 测试报警

给新病人使用湿化器之前，请验证报警是否正常工作。

确保湿化器已打开。

### 测试湿化器报警

1. 从湿化器上拆下水箱，触发报警。
2. 验证：
   - 可以听到报警声音
   - 可视报警指示灯闪烁（图 4）
   - 相应的报警符号出现在屏幕上（表 9）

将水箱重新插入湿化器，解决报警状况，然后验证报警是否重置。

## 3.5 指定湿化器设置

为病人选择湿化模式。[99]有关详细信息，请参阅第 4.2 节。

## 3.6 连接病人

将呼吸管路连接到适当的病人连接界面。

湿化器现在已设置好并可以使用了。

[98] 如果湿化器与所支持的 Hamilton Medical 哈美顿医疗公司呼吸机配合使用，请将湿化器电源线连接到呼吸机上专门的电源插座。
[99] 与支持集成操作的 Hamilton Medical 哈美顿医疗公司呼吸机配套使用时，湿化器匹配呼吸机的操作模式。欲了解详情，请参阅呼吸机*操作手册*。

# 4 使用 HAMILTON-H900 湿化器

表 6. 操作概述

| 欲了解关于以下内容的详细信息... | 请参阅..... |
|---|---|
| 开启湿化器开关 | 第 3.3 节 |
| 进入/退出待机 | 第 4.1 节 |
| 访问湿化器控件 | 第 2.3 节 |
| 湿化器操作模式：INV, NIV, HiFlow | 第 4.2 节 |
| 自动和手动设置 | 第 4.2.2 节 |
| 使用温度控件更改湿度 | 第 4.3 节 |
| 监测的湿化器参数 | 第 4.4 节 |
| 湿化器报警 | 第 5 节 |

## 4.1 进入/退出待机

**⚠ 小心**

*在待机状态下，将保存所有设置并减少热量输出。*

待机是一种等待模式，允许您在湿化器不运行的情况下保持当前设置。

在待机时，水箱出口温度和温度梯度设置减少。[100]有关详细信息，请参阅第 9.7 节。

### 使湿化器进入待机模式

- 短按  （电源/待机键）。
  在待机时，该屏幕显示湿化器待机运行时间。电源/待机指示灯呈橙色。

### 退出待机状态并开始湿化

- 按  。
  湿化器恢复正常运行；电源/待机状态指示灯呈绿色。

## 4.2 关于湿化器操作模式

HAMILTON-H900 提供下列操作模式：有创(INV)、无创(NIV)和高流量氧疗(HiFlow)。

此操作模式选择决定了水箱出口（水箱出口温度）和 Y 形管（温度梯度）的初始温度设置以及上述控件的允许温度范围。

这些温度范围根据病人组有所不同。请参阅表 18。

### 4.2.1 更改模式

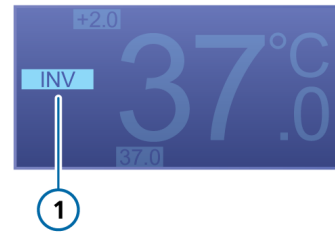
湿化器在有创(INV)模式下会自动启动，除非在自定义默认设置中配置了不同的设置。

当从有创(INV)更改为无创(NIV)模式时，湿化器自动将控制设置设为自动。

### 更改模式

- 按  （模式），直至显示所需的模式(INV, NIV, HiFlow)。
  所选择的模式出现在屏幕上。

图 6. 选择 INV 模式 (**1**)




[100] 在雾化过程中，温度梯度在待机时不会更改。

图 7. 选择 NIV 模式 (**1**)

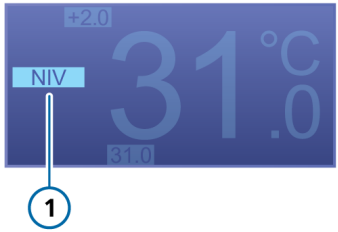
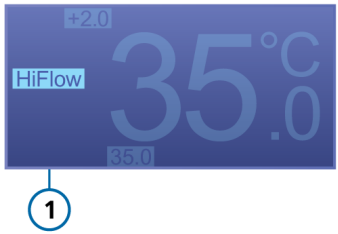



图 8. 选择 HiFlow 模式 (**1**)




### 4.2.2 自动和手动控制设置

您可以在自动模式下使用湿化器，或者您可以手动调节设置。在默认情况下，湿化器在自动模式下启动。

使用任一下列方法设置水箱出口温度和温度梯度：

- 从所设的默认设置中加载（自动模式）
- 由用户手动设置

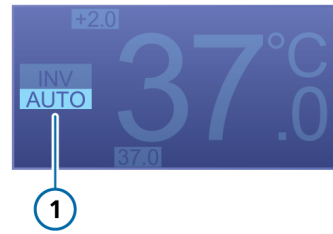
#### 自动设置（自动）

当设置为自动时，湿化器加载为所选模式配置的默认设置（请参阅第 7 节），并使用它们控制气体温度。

在低环境温度下，湿化器可能会自动调节水箱温度。

在选择自动模式时，主屏幕上显示“AUTO”。

图 9. 选择自动模式(**1**)

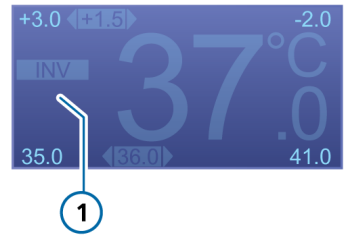



#### 手动设置

当使用滑动条更改水箱出口温度或温度梯度时，湿化器切换至手动模式。但其仍继续自动控制温度，以达到指定设置。

当手动更改设置时，主屏幕上不再显示“AUTO”；此处为空。

图 10. 手动模式(**1**)在使用中




#### 4.2.2.1 启用“自动”模式

在手动更改任一温度设置后，您可以重新启用自动模式。

#### 重新启用自动模式

- 按 Auto（自动）。
  将操作模式更改为 INV 或 NIV 也会使湿化器自动切换至自动模式。

## 4.3 使用温度控件更改湿度

**注意**

如果湿化器在自动模式下，拖动任一滑动条会使湿化切换至手动模式。

**注意**

在 HiFlow 模式下，您无法使用滑动条更改温度梯度。您可以在配置中将温度梯度更改为一个新的值。请参阅第 7 节。

您可以在湿化器上调整下列控件[101]：

表 7. 可调整的湿化器控件

| 控制 | 说明 |
|---|---|
| 水箱出口温度 | 水箱出口温度。<br>此控制数值的可能范围视所选湿化器操作模式而定。有关详细信息，请参阅表 16 和 18。<br>数值越高，绝对湿度越高。 |
| 温度梯度 | 水箱出口和 Y 形管之间的温度差。 |
| 呼气肢加温 | 若选择，湿化器可在呼气肢内提供额外热量。[102] |

最大允许病人 Y 形管温度是 42°C。水箱出口温度与温度梯度之和不能超过此限值。例如，如果温度梯度设置为 2°C，则水箱出口温度的最高可设值为 40°C。

此外，梯度温度设置优先于水箱出口温度设置。这意味着如果设置之和会使 Y 形管温度大于 42°C，则温度梯度将维持不变，但水箱出口温度将进行调节。

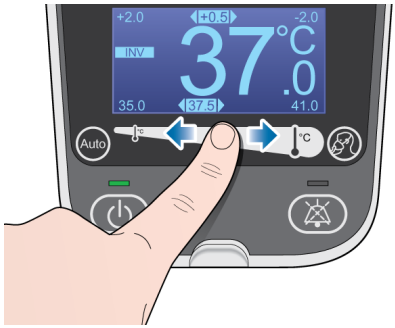
例如：如果水箱出口温度设置为 40°C，则可以将温度梯度设置为 3°C，即使两者之和超过 42°C。一旦温度梯度设置被接受，水箱出口温度值即自动重置为 39°C。

### 设置水箱出口温度

- 触摸当前设置下的水箱出口温度滑动条：
  - 向左拖动，降低水箱出口温度
  - 向右拖动，升高水箱出口温度

变更通过“哔哔”声确认，并立即应用。

图 11. 调节水箱出口温度




### 设置水箱出口温度 > 39°C

欲升高水箱出口温度 39°C 以上，必须激活滑动条两次。

1. 触摸当前设置下的水箱出口温度滑动条，然后向右拖动，达到限值 39°C。
2. 再次触摸和拖动滑动条，设置水箱出口温度 39°C 以上。

[101] 与支持集成湿化器控制的 Hamilton Medical 哈美顿医疗公司呼吸机配套使用时，您也可以直接更改呼吸机上的设置。欲了解详情，请参阅呼吸机*操作手册*。
[102] 仅用于一次性、双肢加热呼吸管路。

**设置温度梯度**

- 触摸当前设置下的温度梯度滑动条：
  – 向右拖动，降低温度梯度
  – 向左拖动，升高温度梯度

变更通过“哔哔”声确认，并立即应用。

图 12. 调节温度梯度


例如，如果目标 Y 形管温度设置为 39°C 及水箱出口温度为 37°C，则温度梯度设为 2°C。

## 4.4 监测湿化

可随时访问温度监测窗口，获取监测数据。[103]

监测下列参数：

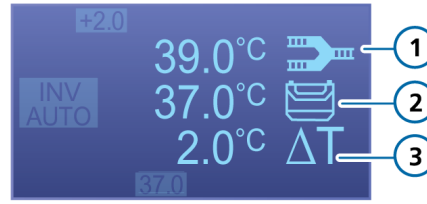
- 水箱出口温度
- 温度梯度
- Y 形管温度

### 4.4.1 显示其他监测参数

**显示温度监测窗口**

- 按 (温度监测窗口)。
  30 秒后，或当您再次按下该按钮时，此窗口会关闭。

图 13. 温度监测窗口




1 当前 Y 形管温度
2 水箱出口当前温度
3 当前温度梯度

## 4.5 日间和夜间显示亮度设置

湿化器屏幕背光支持两种不同的显示设置。使用这些设置设定屏幕的亮度。

**在日间和夜间设置之间切换**

- 按住 并持续 5 秒。

欲设置默认的日间和夜间亮度，请参阅第 7 节。

[103] 与支持集成湿化器监测的 Hamilton Medical 哈美顿医疗公司呼吸机配套使用时，湿化器数据显示在呼吸机屏幕上。欲了解详情，请参阅呼吸机*操作手册*。

# 5 对湿化器报警做出响应

湿化器相关报警告知您需要注意的状况。报警显示如下：

- 在湿化器屏幕上以图表形式
- 连续 3 或 5 个“哔哔”声
- 水箱上的报警灯闪烁
- 与支持集成湿化器监测的 Hamilton Medical 哈美顿医疗公司呼吸机配套使用时，报警消息也显示在呼吸机屏幕上。[104]

报警可按照表 8 中的说明分为高优先级、中优先级或技术故障。

请参阅表 9 了解完整的报警清单。

表 8. 报警指示灯

| 报警类型 | 报警状态指示灯 | 声音 | 所需措施 |
|---|---|---|---|
| 高优先级 | 红色，闪烁<br>报警图标显示在屏幕上 | 连续 5 个提示音，一直重复到报警重置为止 | 湿化器需要立即处理。 |
| 中优先级 | 黄色，闪烁<br>报警图标显示在屏幕上 | 连续 3 个提示音，一直重复到报警重置为止 | 湿化器需要尽快处理。 |
| 技术故障 | 红色，闪烁<br>技术故障 (TF) 编号会显示在屏幕上 | 连续 3 个提示音，一直重复到报警重置为止 | • 记录技术故障 (TF) 编号[105]。<br>• 停止湿化器的使用。<br>• 维修湿化器。 |

[104] 并非在所有呼吸机上均有提供。请参阅呼吸机*操作手册*。
[105] 在 *HAMILTON-H900 维修手册*中提供所有技术故障 (TF) 编号的清单。

## 5.1 暂时消除报警音

声音报警音响是一个报警组件。对于大多数报警，您可以一次暂停报警音（静音）2 分钟。

### 暂时消除报警音

- 按下湿化器前面的  （音频暂停）。

  湿化器报警声将静音 2 分钟。

  再次按下该按键，将取消音频暂停。

当音频暂停被激活时，音频暂停键背光灯会持续亮为红色。

当时限已到，而故障仍未解除时，报警声会再次响起。

## 5.2 调整报警音量

**⚠ 警告**

请确保将声音报警音量设置为大于周围环境声音水平。否则您可能听不见报警声，也不能察觉报警情况。

您可以设置声音报警的音量。

默认的音量设置为 5。关闭湿化器后，报警音量将被重置为默认值。

### 调节报警音量

1. 如果需要，按  （电源/待机键），使湿化器进入待机模式。
2. 按  并持续 3 秒。

   屏幕将显示当前报警音量设置。
3. 使用水箱出口温度滑动条调节报警音量（参阅图 3）。

   湿化器将以新的音量设置发出一声“哔”以确认您的选择。
4. 按  确认您的选择，然后返回正常操作。

## 5.3 故障排除报警

表 9 列示了湿化器报警，以及其在湿化器上的图形表示、描述和建议的纠正措施。

表 9. HAMILTON-H900 报警

| 报警 | 报警图标 | 说明 | 所需措施 |
|---|---|---|---|
| **高优先级** | | | |
| 湿化器倾斜 |  | 湿化器危险倾斜。<br>以 10° 或以上的角度（相对于地板）运行湿化器。 | • 检查湿化器的安装。<br>• 检查呼吸机台车。<br>• 以 10° 以下的角度（相对于地板）运行湿化器。 |
| 温度高 |  | 水箱出口或 Y 形管气体温度高于所设值。 | • 检查呼吸管路是否被病床的被子盖住。<br>• 检查呼吸管路或湿化器水箱是否直接暴露于阳光下。<br>• 更换呼吸管路。 |
| 高水位 |  | 水箱水位高于最高水位。 | • 排空湿化器水箱以降低水位。<br>• 更换湿化器水箱。<br>• 以 10° 以下的角度（相对于地板）运行湿化器。 |
| 技术故障 | 技术故障 (TF) 编号会显示在屏幕上 | 因湿化器故障导致的技术故障。 | • 检查湿化器运行状况及所有连接。<br>• 更换湿化器并进行维修。<br>• 如果显示技术故障编号，请记录该编号，并在维修湿化器时提供。 |

| 报警 | 报警图标 | 说明 | 所需措施 |
|---|---|---|---|
| **中优先级** | | | |
| 温度过低 |  | 水箱出口或 Y 形管气体温度低于所设值。 | • 等待系统完全加热（约 30 分钟）。<br>• 检查所有设置是否正确。<br>• 避免来自空调等设备的直接气流吹向湿化器和呼吸管路。 |
| 水位过低 |  | 水箱水位低于最低水位。 | • 检查储水瓶和注水管道。<br>• 如储水瓶已空，请连接新的储水瓶。<br>• 重新注水或更换空的湿化器水箱。<br>• 以 10° 以下的角度（相对于地板）运行湿化器。 |
| 检查水箱 |  | 未插入水箱或插入的水箱不兼容。 | 插入一个新的湿化器水箱，并连接呼吸管路。 |
| 检查左肢或右肢 |  | 屏幕和连接指示灯会显示是哪个肢出现故障。<br>• 无肢管连接或肢管连接异常。<br>• 无气流。<br>• 肢管未正确连接。<br>• 将白色湿化器呼气肢连接至呼吸机*至病人*吸气端口。 | • 插入或重新正确连接呼吸管路。<br>• 更换呼吸管路。<br>• 将蓝色湿化器吸气肢连接至呼吸机*至病人*吸气端口。<br><br>当连接指示灯为：<br>*绿色*：肢管已正确插入。<br>*橙色*：湿化器正在检测连接。<br>*红色*：连接故障或未连接。 |

# 6 维护

*开始操作前，请阅读第 1 节中的安全信息。*

本节提供了湿化器维护规程和计划有关的信息，以及清洁和消毒说明。

应由操作人员执行本节中的所有规程。

有关其它维护要求，请联系 Hamilton Medical 哈美顿医疗公司服务代表。有关本节的任何文件可在 MyHamilton 网站上找到：https://www.hamilton-medical.com/MyHamilton

## 6.1 清洁、消毒及灭菌

湿化器组件必须使用各个组件特定的清洁方法和清洁剂定期进行清洁和消毒。

您应选择适当的方法和材料对湿化器及其组件进行清洁和消毒，这一点非常重要，不仅可避免损坏设备，还可避免交叉污染。

清洁和消毒信息如下：

- 表 10 列示了适用的湿化器相关组件，并显示每个组件可使用哪种清洁和消毒方法，组件的清洁/消毒频率，以及清洁剂和消毒剂。
- 关于呼吸装置和湿化器水箱，请参阅*使用说明*或*再处理指南*。

在使用湿化器组件、清洁方法和清洁剂时，请记住下列注意事项：

- 请*勿*尝试使用非 Hamilton Medical 哈美顿医疗公司指定的清洁方式进行操作。
- 当我们提供应使用的清洁/消毒剂和浓度时，如果您对特殊清洁或消毒剂的使用存在任何疑问，请联系其制造商。

表 10. 湿化器清洁和消毒方法

| 配件 | 频率 | 清洁/消毒方法 | 清洁剂 |
| --- | --- | --- | --- |
| 湿化器外部包括：<br>• 外壳<br>• 屏幕<br>• 加热板<br>• 电源线<br>• 安装系统 | 每次病人使用后或根据需要。 | 用湿布和经认证和批准的清洁/消毒剂擦拭。 | Super Sani-Cloth 杀菌湿巾<br>CaviWipes |

## 6.2 预防性维护

对湿化器进行预防性维护必须由 Hamilton Medical 哈美顿医疗公司授权的维修工程师根据 *HAMILTON-H900 维修手册*中的说明执行。

# 7 配置

湿化器以按病人组安排的各种设置的默认配置进行输送。

您可以在配置模式下更改下列默认设置：

- 水箱出口温度
- 温度梯度
- 启动操作模式(INV/NIV/HiFlow)
- 升高呼气温度开/关
- 背光日间/夜间亮度设置

## 7.1 访问配置模式

您可在湿化器处于待机状态下访问配置模式。

**访问配置模式**

1. 如果需要，按 进入待机模式。
2. 同时按住 和 Auto。
   确保首先按下 。
   配置窗口在 5 秒后出现。

湿化器现在处于配置模式。

## 7.2 更改配置设置

自定义设置是永久性的，直至您更改它们或恢复出厂设置。

在配置模式下，可使用湿化器前面板上的按钮导航视图和进行选择。

表 11 描述了如何翻页配置，以及如何更改设置。

如何更改设置举例，请参阅下面更改温度梯度默认设置有关的程序。

欲了解配置设置列表，请参阅第 9.6 节。

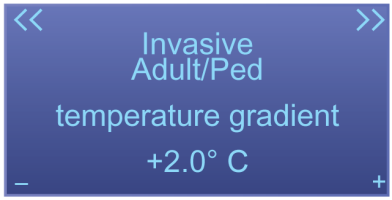
表 11. 配置模式导航按钮

| 按钮 | 说明 |
| --- | --- |
| Exp. | 向前浏览视图 |
| | 向后浏览视图 |
| | 增加一个值 |
| Auto | 减少一个值 |
| | 保存更改并退出配置模式 |

**示例：更改温度梯度**

**更改默认的有创、成人/儿童、温度梯度设置**

1. 在配置模式下，按 Exp.，直至看到 Invasive、Adult/Ped、Temperature gradient 的视图




2. 按 使该值增加，或按 Auto 使该值减少。
3. 结束后，按 保存变更并退出配置模式。

## 7.3 恢复出厂默认设置

您可以随时恢复出厂默认设置。

**恢复出厂默认设置**

1. 在配置模式下，重复按 Exp. 直至“Reset all custom defaults”窗口出现。
2. 按 Auto。

出厂默认设置已恢复。

# 8 配件和附件

本节列出了 HAMILTON-H900 湿化器可用的配件和附件。

有关其他信息，请参阅 Hamilton Medical 瑞士哈美顿医疗公司网站上的电子产品目录或联系 Hamilton Medical 哈美顿医疗公司的代表。

表 12. 湿化器配件和附件

| PN | 说明 |
|---|---|
| 260161 | HAMILTON-BC8022，呼吸装置，双肢，加热，带有水箱 |
| 260186 | HAMILTON-BC4022，呼吸装置，单肢，加热，带有水箱 |
| 260185 | HAMILTON-BC8010，呼吸装置，双肢，加热，带有水箱和保温箱延长管 |
| 260187 | HAMILTON-BC4010，呼吸装置，单肢，加热，带有水箱和保温箱延长管 |
| 260196 | HAMILTON-HC322，水箱，一次性使用 |
| 260197 | HAMILTON-HC310，水箱，一次性使用 |

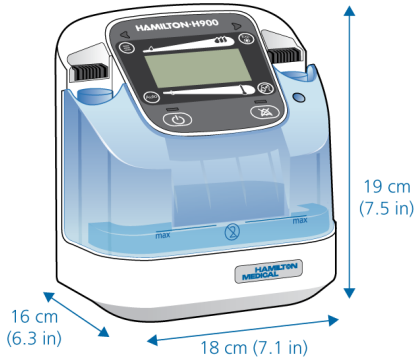
# 9 技术要求

## 9.1 物理特性

表 13. 物理特性

| 尺寸 | 技术要求 |
|---|---|
| 重量 | 湿化器（带有空水箱）：2.5 kg（5.5 磅） |
| 尺寸 | 请参阅图 14 |

图 14. HAMILTON-H900 尺寸



## 9.2 环境要求

表 14. 环境要求

| 环境 | | 技术要求 |
|---|---|---|
| 温度 | 操作： | 10°C 至 40°C |
| | 储存： | -20°C 至 60°C |
| | | 推荐环境温度：18°C 至 26°C |
| 海拔 | | 高达 4000 m（13,123 英尺） |
| 气压 | 运行和储存： | 61 kPa 至 106 kPa |
| 相对湿度 | 操作： | 30% 至 95%，非冷凝 |
| | 储存： | 10% 至 95%，非冷凝 |
| 防水等级 | | IP21 |
| 输入气体温度 | | 18°C 至 31°C（建议） |

## 9.3 电气技术要求

表 15. 电气技术要求

| 部件号 | 输入电源 | 功耗 |
|---|---|---|
| 950001 (230 V) | 220 至 240 V<br>50 / 60 Hz | 283 VA |
| 950004 (115 V) | 110 至 127 V<br>50 / 60 Hz | 293 VA |
| 950008 (100 V) | 100 V<br>50 / 60 Hz | 268 VA |
| 电位均衡 | 按照 DIN 42801 用于连接等电位导体的端子 | |

## 9.4 控制设置

表 16. 控制设置和范围

| 参数或设置 (单位) | 模式 | 范围 | 默认值 | 分辨率 |
|---|---|---|---|---|
| 水箱出口温度 (°C) | INV | 35 至 41 | 37.0 | 0.5 |
| | NIV | 30 至 35 | 31.0 | 0.5 |
| | HiFlow | 33 至 37 | 35.0 | 2 |
| 温度梯度 (°C) | INV | -2 至 3 | 成人/儿童：2<br>新生儿：3 | 0.5 |
| | NIV | -2 至 3 | 成人/儿童：2<br>新生儿：3 | 0.5 |
| | HiFlow | -- | 2 | -- |
| 产生最高气道温度（Y 形管）[106] (°C) | INV | 33 至 42 | -- | -- |
| | NIV | 28 至 38 | -- | -- |
| | HiFlow | 35 至 39 | -- | -- |
| 升高呼气温度 | 所有模式 | 开、关 | 开 | -- |
| 显示亮度设置 | 所有模式 | 1 至 5 | 日间：5<br>夜间：2 | 1 |

[106] 气道温度通过湿化器限定至 42°C。

## 9.5 监测参数

表 17. 监测参数、范围和准确度

| 参数 (单位) | 范围 | 准确度 |
| --- | --- | --- |
| 水箱出口温度<br>(°C) | 10 至 60 | 10 至 30：±1<br>30 至 41：±0.5<br>41 至 60：±1 |
| Y 形管温度<br>(°C) | 28 至 43 | ± 0.5 |

## 9.6 配置

表 18. 配置技术要求

| 参数 | 模式 | 配置范围 | 默认设置 |
| --- | --- | --- | --- |
| 水箱出口温度<br>(°C) | INV | 35 至 39 | 37.0 |
| | NIV | 30 至 35 | 31.0 |
| | HiFlow | 33, 35, 37 | 35.0 |
| 温度梯度<br>(°C) | INV | 0 至 3 | 成人/儿童：2<br>新生儿：3 |
| | NIV | 0 至 3 | 成人/儿童：2<br>新生儿：3 |
| | HiFlow | 0 至 3 | 2 |
| 启动模式 | -- | 有创、无创、HiFlow | 有创 |
| 显示亮度设置 | 所有模式 | 1 至 5 | 日间：5<br>夜间：2 |

## 9.7 技术性能数据

表 19. 技术性能数据

| 说明 | 技术要求 | | |
|---|---|---|---|
| 流速[107] | 有创： | 最高 60 l/min | |
| | 无创： | 最高 120 l/min | |
| | HiFlow： | 最高 120 l/min | |
| 预热时间 | 少于 30 分钟 | | |
| 湿度 | 在环境温度 18°C 至 26°C 下： | | |
| | 有创： | 温度设置 37°C 至 41°C | 最小湿度：33 mg H2O/l |
| | 无创： | 温度设置 31°C 至 35°C | 最小湿度：12 mg H2O/l |
| | HiFlow： | 流速 ≤ 60 l/min | 最小湿度：33 mg H2O/l |
| | | 流速 > 60 l/min | 最小湿度：12 mg H2O/l |
| 待机加热技术要求 | 加热呼吸管路： | Y 形管限定至 30°C。 | |
| 屏幕 | 7.6 厘米（3 英寸） / 64 x 128 像素，倒点阵屏幕（背光） | | |
| 音频暂停 | 120 秒 | | |
| 报警音量[108] | 范围 = 1 至 8。默认 = 5。 | | |

## 9.8 基本性能

应用于呼吸气体和呼吸管路的温度必须维持在指定设置范围以内，而且必须进行监测。

如果温度超出指定的限值，湿化器必须检测到此情况，并通过报警通知用户。

[107] 欲了解最小流速，请参阅呼吸管路*使用说明*。
[108] 距湿化器 1 m 时的音量。设置数值对应的分贝数：1 = 50 dB(A)、5（默认）= 60 dB(A) 和 8 = 65 dB(A)，准确度为 ±6 dB(A)。

## 9.9 湿化系统功能说明

HAMILTON-H900 湿化器适用于在机械通气期间加热和湿化呼吸气体。呼吸气体在通过部分注入热水的水箱时被加热和湿化。

湿化器拥有两个传感器控制的加热系统：

- *加热板*。加热水箱中的水。
- *集成呼吸管路加热系统*。加热呼吸肢管以预防凝结。

在水箱出口和病人端呼吸肢管中监测呼吸气体的温度。

## 9.10 设备标签和包装上使用的符号

| 符号 | 说明 |
|---|---|
|  | 请按照*说明使用* |
| REF | 参考号 |
| SN | 序列号 |
| QTY | 数量 |
|  | 制造商 |
|  | 出厂日期 |
|  | BF 类应用配件（医疗电气设备的分类，BF 类，依照 IEC 60601-1 标准规定） |
|  | 根据欧洲理事会 2002/96/EC 指令或 WEEE（电子电器废弃物）进行废弃处置 |

| 符号 | 说明 |
|---|---|
|  | 带指示符 "C" 和 "US" 的 TÜV NRTL 标记表示产品符合加拿大和美国安全局的相关规定 |
|  | 电位均衡 |
|  | 警告：热表面。<br>加热板和水箱底部温度可超过 85°C。 |
| CE 0197 | 符合性 CE 标志。该认证标志保证了该呼吸机符合有关医疗设备的欧洲理事会第 93/42/EEC 号指令。 |
| IP21 | 防滴水，并且可防止大于 12.5 mm 的固体颗粒进入设备内 |
| max | 水箱上的水位标识 |
|  | RS-232 通信串行接口连接 Hamilton Medical 哈美顿医疗公司呼吸机 |
|  | MR 不安全<br>HAMILTON-H900 湿化器对 MR 环境中的病人、医务人员或其它人员会造成不可接受的风险。 |
|  | 中文 RoHS |
|  | 温度探头<br>在呼吸管路上标示出温度探头的位置。 |

## 9.11 标准和认证

湿化器系统符合下列标准中的相关内容，如表 20 中所列。

表 20. 标准和认证，有效版本

| |
|---|
| IEC 60601-1:2005/A1:2012 |
| IEC 60601-1-2:2014 |
| IEC 60601-1-6:2010/A1:2013 |
| IEC 60601-1-8:2006/A1:2012 |
| ISO 80601-2-74:2017 |
| EN ISO 5356-1:2015 |
| EN ISO 5367:2014 |
| IEC 62304:2006/A1:2015 |
| IEC 62366-1:2015 |
| ISO 13485:2016 |

## 9.12 废物处理

该设备必须根据机构规定和第 2002/96/EC 号指令进行处置。

呼吸管路和湿化器水箱必须根据随呼吸装置一起提供的*使用说明*进行处置。

## 9.13 保修

有限保修

在此份协议中所描述的保修，是代替任何及其它所有已经表明或默认的保修，包括针对某种特定目的的营销性和适合性的默认保修。但在本有限保修期内，公司将对默示保修负责。

Hamilton Medical 哈美顿医疗公司保证其产品在交付时无材料和工艺上的缺陷。该保修不包括一次性产品。一次性产品和耗材产品只能使用一次或有限次数，必须遵循本操作手册并根据需要定期更换才能确保产品正常工作。

对于此处指定的产品之外的其他产品，Hamilton Medical 哈美顿医疗公司没有任何相关义务或责任，包括但不限于对宣称的过失或严格责任的义务和/或责任。在任何情况下，对于意外或间接损害，不管是直接的还是偶然发生的，公司概不负责。

在下列情况下，本有限保修无效并且不适用：

1. 产品并非由 Hamilton Medical 哈美顿医疗公司授权的当地代表根据 Hamilton Medical 哈美顿医疗公司及其代表提供的说明进行安装和连接。
2. 没有证据表明损坏/维修是在保修的保质期内发生的。
3. 机身编号已被更改、涂抹或揭掉，并且没有发票或证据可以确定产品的购买日期。
4. 缺陷是由以下原因造成的：误用、过失或事故，或者在 Hamilton Medical 哈美顿医疗公司的工厂外或并非由授权的服务中心或服务代表进行维修、调整、改装或更换。
5. 未经 Hamilton Medical 哈美顿医疗公司事先书面授权即修改或在任何方面更改产品。
6. 产品（曾）用于规定"预定用途"以外的其他用途。
7. 如果本品曾由除适当培训的人员在医生的监督下外的任何人士使用。

根据本有效保修提供的更换和/或维修服务不会享受新的保修，只能享受原始有限保修中未到期的部分。对维修和/或更换的组件的保修不会超过设备的有限保修。

要根据本有效保修享受服务，要求方必须立即向所在国家/地区的 Hamilton Medical 哈美顿医疗公司销售合作伙伴提供有关问题性质、序列号和产品购买日期的信息。

除上述规定外，对于任何损害、索赔或责任，包括但不限于人身伤害或意外的、间接的或特殊的损害，Hamilton Medical 哈

美顿医疗公司概不负责。对于误用器械或不遵守本手册中的任何条款导致的任何损害、索赔或责任，包括但不限于人身伤害或意外的、间接的或特殊的损害，Hamilton Medical 哈美顿医疗公司亦概不负责。

### 9.13.1 其他事项

Hamilton Medical 哈美顿医疗公司的一般条款和条件同样适用。本协议由瑞士法律管辖并根据瑞士法律解释，可以由任一方在瑞士库尔法院的管辖之下强制执行。

For more information:
www.hamilton-medical.com

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz, Switzerland
☎ +41 (0)58 610 10 20
info@hamilton-medical.com
**www.hamilton-medical.com**

EC REP
medin Innovations GmbH
Adam-Geisler-Strasse 1
DE – 82140 Olching


# INTELLiVENT-ASV

## Operator's Manual

## HAMILTON-C6

**REF** 160770, 160771, 160772, 160768, 160769

Software version 1.x.x

624954/02 | 2021-02-25

HAMILTON MEDICAL

Intelligent Ventilation since 1983

# Operator's Manual

## INTELLiVENT-ASV

2021-02-25

624954/02

This document may be revised, replaced, or made obsolete by other documents by Hamilton Medical AG at any time and without notice. Ensure that you have the most current applicable version of this document; if in doubt, contact the technical support department of Hamilton Medical AG, Switzerland. While the information set forth herein is believed to be accurate, it is not a substitute for the exercise of professional judgment.

Nothing in this document shall limit or restrict in any way Hamilton Medical AG's right to revise or otherwise change or modify the equipment (including its software) described herein, without notice. In the absence of an express, written agreement to the contrary, Hamilton Medical AG has no obligation to furnish any such revisions, changes, or modifications to the owner or user of the equipment (including software) described herein.

The equipment must be operated, serviced, or upgraded only by trained professionals. Hamilton Medical AG's sole responsibility with respect to the equipment and its use is as stated in the limited warranty provided in the device *Operator's Manual*.

Hamilton Medical AG shall not be liable for any loss, cost, expense, inconvenience, or damage that may arise out of misuse of the product, or if non-Hamilton Medical AG parts were used when replacing parts, or if serial numbers were amended, deleted, or removed.

If returning parts to Hamilton Medical AG, be sure to use the standard Hamilton Medical returned goods authorization (RGA) procedure. Disposal of parts shall follow all local, state, and federal regulation with respect to environmental protection.

For all proprietary as well as third-party trademarks used by Hamilton Medical AG, see **www.hamilton-medical.com/trademarks**. Product and/or company names marked with a § may be the trademarks and/or registered trademarks of their respective owners, including but not limited to Aerogen§, Nihon Kohden§, Masimo§, Respironics§.

**Manufacturer**

Hamilton Medical AG
Via Crusch 8, CH-7402 Bonaduz, Switzerland
Phone: (+41) 58 610 10 20
Fax: (+41) 58 610 00 20
info@hamilton-medical.com
www.hamilton-medical.com

# Table of Contents

### About this guide

This guide describes the features and functions of INTELLiVENT-ASV for HAMILTON-C6, and is designed for use with the following documentation:

- Your ventilator *Operator's Manual*
- *Pulse oximetry Instructions for use* for your ventilator
- *INTELLiVENT-ASV Quick Guide*

### Conventions used in this guide

In this manual:

- Button and tab names are shown in a **bold** font.
- The notation *XX* > *XX* shows the sequence of buttons/tabs to touch to open the associated window.

  For example, the text *Open the System* > *Settings window* means touch the **System** button, then touch the **Settings** tab.
- The graphics shown in this manual may not exactly match what you see in your environment.
- Pressure is indicated in cmH2O, length in cm, and temperature in degrees Celsius (°C). The units of measure for pressure and length are configurable.
- **PI** and **PVI** are only available only with a Masimo SET† pulse oximeter.

Safety messages are displayed as follows:

**⚠ WARNING**

A WARNING alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

**⚠ CAUTION**

*A CAUTION alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.*

***NOTICE***

A NOTICE emphasizes information of particular importance.

In tables, safety messages are indicated as follows:

**⚠ WARNING!**

**⚠ CAUTION!**

**NOTICE!**

In our manuals, we refer to *active* and *passive* patients.

- An *active* patient is one who is making inspiratory efforts.
  Active breathing is identified as the occurrence of at least five (5) consecutive spontaneous breaths. Spontaneous breaths are those for which inspiration is both patient triggered and patient cycled.
  In addition to spontaneous breaths as described, an active patient must also meet the requirements described in Section 1.7.3.

- A *passive* patient is one who is not making inspiratory efforts.
  Passive breathing is identified as the occurrence of at least five (5) consecutive mandatory breaths. In general, mandatory breaths are those for which inspiration is either machine triggered or machine cycled. In INTELLiVENT-ASV, mandatory inspirations are both machine triggered and machine cycled. In addition to mandatory breaths as described, a passive patient must also meet the requirements described in Section 1.7.3.

# 1 INTELLiVENT-ASV

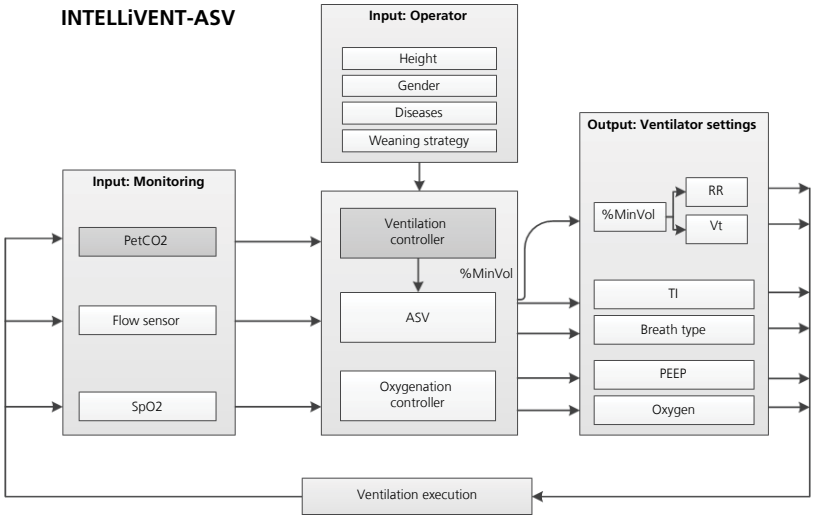
## 1.1 Overview

INTELLiVENT-ASV is an advanced ventilation mode, based on the proven Adaptive Support Ventilation (ASV) mode, to automatically regulate CO2 elimination and oxygenation for both passive and active patients, based on both physiologic data from the patient and clinician-set targets.

With this mode, the clinician sets targets for **PetCO2** and **SpO2** for the patient. INTELLiVENT-ASV then automates management of the controls for CO2 elimination (**%MinVol**), and oxygenation (**PEEP** and **Oxygen**) based on these targets and on the physiologic input from the patient (**PetCO2** and **SpO2**).

INTELLiVENT-ASV continuously monitors patient conditions and automatically and safely adjusts parameters to keep the patient within target ranges, with minimal clinician interaction, from intubation until extubation.

Figure 1-1. INTELLiVENT-ASV workflow



For detailed information about how INTELLiVENT-ASV regulates these parameters, see:

- Section 1.7, Management of minute volume
- Section 1.8, Management of PEEP and Oxygen
- For details on the ASV mode, see your ventilator *Operator's Manual*

When enabled, INTELLiVENT-ASV offers automated recruitment maneuvers and can also help promote early weaning using Quick Wean.

Before using INTELLiVENT-ASV, be sure to review the indications and contraindications for use, as well as all safety-related messages.

## 1.2 Indications and contraindications for use

### Indications for use

***NOTICE***

- Use the INTELLiVENT-ASV for adult and pediatric patients only.
- Use INTELLiVENT-ASV for intubated patients only.
- Be sure you are familiar with the use of the CO2 and SpO2 sensors. See your ventilator *Operator's Manual*, the *Pulse Oximetry Instructions for Use*, and documentation provided with the sensors.

INTELLiVENT-ASV is designed for use with all adult and pediatric patients weighing 7 kg or more. It is not available for neonatal applications. INTELLiVENT-ASV can be used in the hospital and during primary and secondary transport.

### Contraindications for use

**⚠ WARNING**

Do *not* use the INTELLiVENT-ASV automatic **PEEP/Oxygen** adjustment if dyshemoglobin is expected or clearly evidenced, or if the difference between SaO2 and SpO2 is greater than 5%[1].

**⚠ CAUTION**

*Do NOT use SpO2 measurement and automated PEEP/Oxygen adjustments with patients having intravenous dyes.*

Do NOT use INTELLiVENT-ASV if:

- The patient weight is under 7 kg
- There is airway leakage
- The INTELLiVENT-ASV target ranges for **PetCO2** and **SpO2** cannot be set according to your hospital protocol or to the patient's condition

[1] You can compensate for differences between SaO2/SpO2 and PaCO2/PetCO2 up to set limits. For details, see information about Target shift.

## 1.3 Preparing for ventilation with INTELLiVENT-ASV

**⚠ WARNING**

- Additional ventilator-independent patient monitoring (for example, bedside vital monitoring or a blood gas analyzer) must be used during INTELLiVENT-ASV ventilation. Check PaCO2 against displayed **PetCO2**, and SaO2 against **SpO2**.
- The physician is responsible for final decisions.

Preparing for ventilation with INTELLiVENT-ASV comprises the following steps.

Table 1-1. Preparing for ventilation with INTELLiVENT-ASV, overview

| To ... | See ... |
|---|---|
| Set up and enable the CO2 and SpO2 sensors | • Ventilator *Operator's Manual*<br>• Pulse oximetry documentation<br>• CO2 documentation |
| Prepare the ventilator for operation, including performing the preoperational check | Ventilator *Operator's Manual* |
| Connect the patient | Ventilator *Operator's Manual* |
| Specify and confirm INTELLiVENT-ASV settings | Section 1.4 |
| Start ventilation and monitor the patient | Ventilator *Operator's Manual* |

## 1.4 Specifying INTELLiVENT-ASV settings

Once the ventilator is prepared for use and all tests are successfully completed, you are ready to set up INTELLiVENT-ASV for use.

You use the INTELLiVENT-ASV Settings window to specify patient data and automation choices, in addition to other options.

Navigating the window differs depending on whether you are setting up INTELLiVENT-ASV for the first time for the current patient or you are adjusting settings during active INTELLiVENT-ASV ventilation.

- When you first select the INTELLiVENT-ASV mode, you are guided through the setup process to enter patient information and adjust the INTELLiVENT-ASV settings as required for the patient.

  The setup process then prompts you to fine-tune any control settings, and review and adjust alarm limits. You are prompted to confirm the settings on each window.

- When displayed:
  - Touching the **Back** button returns you to the previously displayed window.
  - Touching the **X** or **Cancel** buttons, or doing nothing for 1 minute, closes the INTELLiVENT-ASV Settings window and returns you to the previously selected mode.

- During active ventilation, you can access the INTELLiVENT-ASV Settings window at any time to make further adjustments. All of the tabs in the window are available and function the same way as during initial setup, except

that there are no **Back/Cancel/Continue/Confirm** buttons. Changes are applied as soon as you make them.

You can also adjust control settings and alarm limits at any time, same as with any other ventilation mode.

Specifying INTELLiVENT-ASV settings comprises the following steps.

Table 1-2. Specifying INTELLiVENT-ASV settings

| | See... |
|---|---|
| Verify the patient settings in the Standby window. | Section 1.4.1 |
| Select the INTELLiVENT-ASV mode. | Section 1.4.2 |
| Select ventilation and oxygenation automation options. | Section 1.4.3 |
| Select the patient condition, if needed. | Section 1.4.4 |
| Select Quick Wean/SBT options. | Section 1.4.5 |
| Specify additional settings (minimum **Oxygen** limit, upper and lower **PEEP** limits, and auto-recruitment). | Section 1.4.6 |
| Review and adjust control settings. | Section 1.4.7 |
| Review and adjust alarm limits. | Section 1.4.8 |
| Adjust settings during active ventilation, if needed. | Section 1.4.9 |

## 1.4.1 Specifying patient data

***NOTICE***

When coming from Standby and **Last patient** is selected, the last-used settings are active, including patient height and gender, alarm limits, and control settings.

**To specify patient data**

- In the Standby window, choose the correct patient group, gender, and height.

  If needed, you can adjust these settings during ventilation in the Controls > Patient window.

Be sure this data is accurate. It is used to calculate the patient's IBW, which is used by the INTELLiVENT-ASV controllers to regulate ventilation parameters.

You can fine-tune the settings at a later time, if needed.

For additional information, see the ventilator *Operator's Manual*.

### 1.4.1.1 Notes about exiting Standby

When starting ventilation from standby with a new patient selected and activating INTELLiVENT-ASV, the controllers (**%MinVol**, **PEEP**, and **Oxygen**) are set to default settings.

If you select **Last Patient** in the Standby window and start ventilating the patient, the system assumes the same settings that were in place before entering standby.

### 1.4.2 Selecting the INTELLiVENT-ASV mode

INTELLiVENT-ASV is an option in the ventilator Modes window.

**To select the INTELLiVENT-ASV mode**

1. Do either of the following:
   – Touch the mode name at the top left of the display.
   – Touch the **Modes** button at the top right of the display.
2. Touch the **INTELLiVENT-ASV** button.
3. Touch **Confirm**.

The INTELLiVENT-ASV Settings window (Figure 1-2) opens, displaying the **Auto** tab.

You can now select INTELLiVENT-ASV options.

### 1.4.3 Selecting ventilation/ oxygenation automation options

***NOTICE***

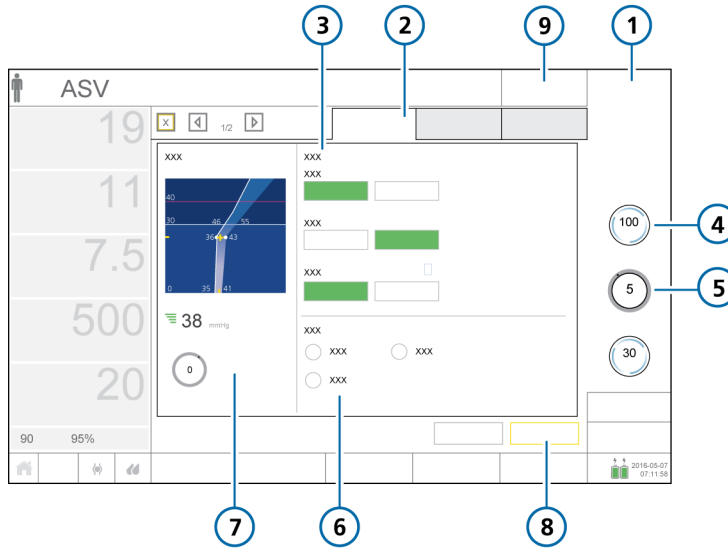
- Automated management of *all* controls is disabled if the patient weighs < 7 kg.
- Automated management of %MinVol is disabled when the CO2 sensor is disabled.
- Automated management of PEEP is disabled when:
  – Either the Chronic Hypercapnia or Brain Injury patient condition is selected. If Chronic Hypercapnia and ARDS are *both* selected, PEEP management can be automated.
  – The SpO2 sensor is disabled
- Automated management of Oxygen is disabled when:
  – The SpO2 sensor is disabled
  – The O2 cell is disabled

Use the INTELLiVENT-ASV Settings > Auto window to specify:

- Whether adjustments of one or more of the following controls should be performed automatically by the device or manually by the clinician: %MinVol, PEEP, and Oxygen

  Sections 1.7 and 1.8 in this guide provide detailed information about how INTELLiVENT-ASV regulates these controls automatically.
- A patient condition (ARDS, Chronic Hypercapnia, or Brain injury)
- Shift the PetCO2 and/or SpO2 target zones, if needed

Figure 1-2. INTELLiVENT-ASV Settings window, Auto tab




| | | | |
|---|---|---|---|
| 1 | Modes button | 6 | Patient condition options |
| 2 | Auto tab | 7 | Map panel showing either a Ventilation map (labeled CO2 elimination) in view 1 or an Oxygenation map in view 2 |
| 3 | Controller settings: Automatic, Manual buttons for %MinVol, PEEP, Oxygen | 8 | Cancel/Continue buttons (if displayed) |
| 4 | Automated management indicator and parameter value | 9 | Target button (to access the INTELLiVENT-ASV Settings window) |
| 5 | Manual management indicator and parameter value | | |

### To set automation options for INTELLiVENT-ASV

✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 2.

1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button at the top right of the display, or touch an automated controller.

The Settings window opens, with the **Auto** tab selected, where you define automation settings and any applicable patient condition.

2. For each of the controls, %MinVol, PEEP, and Oxygen, choose whether management is performed by the device or by the operator:

   – Touch Automatic to have INTELLiVENT-ASV regulate the control.

   When you select Automatic for a given control, the appropriate map is displayed on the left: setting %MinVol to Automatic displays the ventilation map, and setting PEEP or Oxygen to Automatic displays the Oxygenation PEEP/SpO2 map.

   – When Oxygen is set to Automatic, you can set an absolute lower limit that the controller will not fall below.

   When PEEP is set to Automatic, you can set absolute upper and lower limits for the controller. You set these limits in the INTELLiVENT-ASV Settings > More window.

   – When set to Manual, the device makes no adjustments to the control; it is operator controlled. This is the default setting.

3. Review the control settings on the right and, if desired, make any adjustments.

4. Continue to *Selecting patient conditions* if your patient has chronic hypercapnia, ARDS, or a brain injury.

   If you are not setting any patient condition, continue to the next step.

5. If displayed, touch **Continue** to accept the settings and proceed to the next step.

### 1.4.4 Selecting patient conditions

The patient condition options affect some default CO2 elimination and oxygenation startup values and target settings. During initialization, settings are dynamically updated in real-time as you change the patient condition, and are reflected in the control values shown on the right side of the display as well as in the target zone of the associated Ventilation or Oxygenation map.

**To specify patient conditions**

✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 2.

1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button at the top right of the display, or touch an automated controller.

   The Settings window opens, with the **Auto** tab selected.

2. Before proceeding, be sure to read the safety information related to selecting patient conditions, in Section 1.4.10.1.

3. *Only* if the patient has any special conditions, select one or more of the following entries: ARDS, Chronic Hypercapnia, Brain injury.

   Selecting an entry changes the startup settings and targets for ventilation and/or oxygenation, and may affect whether regulation of PEEP can be automated. See Table 1-5.

   The Maps panel (Section 1.5.1) on the left shows the CO2 elimination and oxygenation targets based on the patient condition selections you make.

4. Carefully review the **PetCO2** target range shown in the Ventilation map, and the **SpO2** target range shown in the Oxygenation map.

   If needed, make adjustments using the **Target Shift** control (Section 1.4.10.3).

5. Review the control settings on the right and, if desired, make any adjustments.

6. Set automation options, as needed, if you haven not already done so.

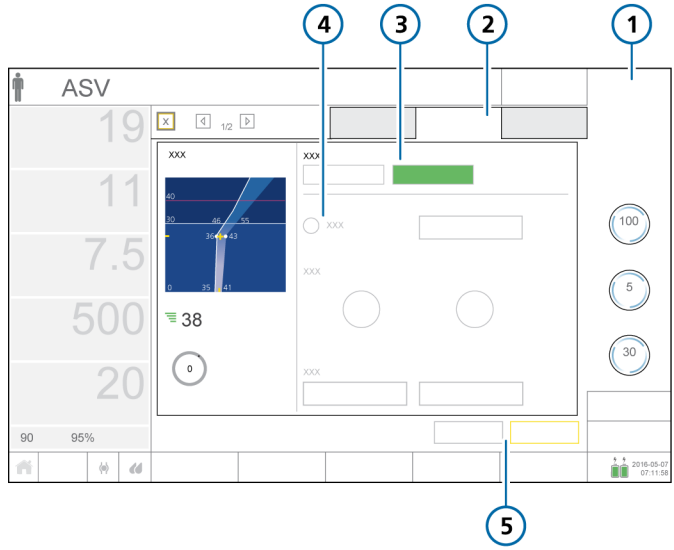
7. If displayed, touch **Continue** to accept the settings and proceed to the next step.

## 1.4.5 Selecting Quick Wean and SBT options

Quick Wean is not available if the patient condition selected in INTELLiVENT-ASV is **Brain injury**.

Use the INTELLiVENT-ASV Settings > Quick Wean window to specify Quick Wean and spontaneous breathing trial (SBT) settings, if desired.

Figure 1-3. INTELLiVENT-ASV Settings window, Quick Wean tab




| | | | |
|---|---|---|---|
| 1 | Modes button | 4 | Automatic SBT checkbox (unavailable when Quick Wean is disabled) |
| 2 | Quick Wean | 5 | Back/Continue buttons (if displayed) |
| 3 | Disabled (default) | | |

**To enable/disable Quick Wean and automated SBTs**

✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 3.

1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button at the top right of the display, or touch an automated controller.

   The Settings window opens, with the **Auto** tab selected.

2. To display Quick Wean/SBT options, touch the **Quick Wean** tab (Figure 1-3).

3. Select whether to enable Quick Wean.

   By default, Quick Wean is disabled.

   To enable Quick Wean, touch the **Automatic** button. The target range of acceptable CO2 values is permanently shifted up to +5 mmHg to the right, depending on pressure, while Quick Wean is enabled. For details, see Chapter 2.

   In addition, the Automatic SBT checkbox becomes available.

4. To enable automated SBTs and specify options, see Section 2.3.

   Otherwise, continue to the next step.

5. If displayed, touch **Continue** to accept the settings and proceed to the next step.

## 1.4.6 Specifying additional settings

The INTELLiVENT-ASV Settings > More window provides access to additional INTELLiVENT-ASV options:

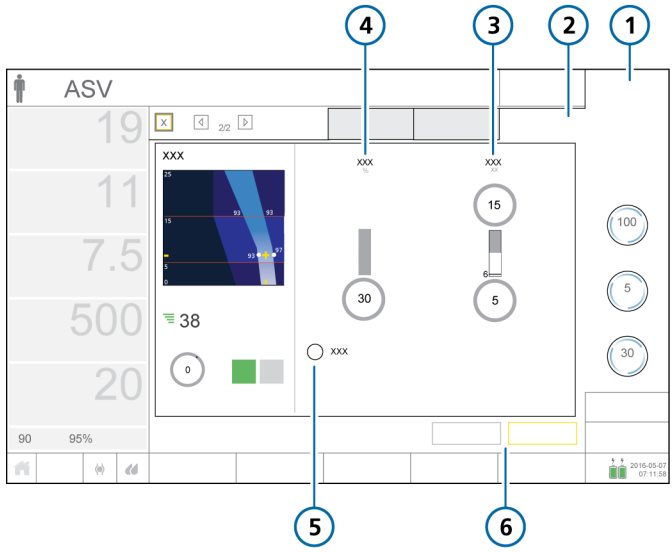
- Set the minimum Oxygen level (between 21% and 30%)
- Set an upper and/or lower PEEP limit
- Enable/disable auto-recruitment

The Oxygenation map is automatically displayed when you open the More window.

Table 1-3. More tab settings

| Setting | Description |
|---|---|
| Oxygen limit | When the Oxygen control is set to Automatic, you can set an absolute lower limit that the Oxygen controller cannot fall below. The limit can be set between 21% and 30%. See Section 1.4.10.4. |
| PEEP limit control | When the PEEP control is set to Automatic, you can set an absolute upper limit that the PEEP controller cannot exceed, as well as an absolute lower limit that it cannot fall below.<br>The minimum difference allowed between the low and high limit is 2 cmH2O.<br>See Section 1.4.10.5. |
| Auto-recruitment | When the PEEP control is set to Automatic, you can enable automatic recruitment. For details, see Section 1.4.10.2.<br>To enable auto-recruitment, touch the checkbox to select it.<br>When auto-recruitment is enabled, the text **auto-recruitment** is displayed on the Oxygenation map and horizon (views 1 and 2).<br>By default, auto-recruitment is disabled. |

Figure 1-4. INTELLiVENT-ASV Settings window, More tab




| | | | |
|---|---|---|---|
| 1 | Modes button | 4 | Oxygen limit |
| 2 | More | 5 | Auto-recruitment |
| 3 | PEEP limit control | 6 | Back/Confirm buttons (if displayed) |

### To set minimum oxygen limit, PEEP limit, and auto-recruitment options

✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 3.

1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button at the top right of the display, or touch an automated controller.

   The Settings window opens, with the **Auto** tab selected.

2. Touch the **More** tab (Figure 1-4).
3. Set options as specified in Table 1-3.
4. If displayed, touch **Confirm** to accept the settings and proceed to the next step, reviewing and adjusting control settings.

## 1.4.7 Adjusting control settings

As with other modes, you can adjust parameter settings for INTELLiVENT-ASV. The controls are the same as in ASV.

During initial setup of INTELLiVENT-ASV, the Controls > Basic window opens automatically after you touch **Confirm** in the INTELLiVENT-ASV Settings > More window.

### To adjust INTELLiVENT-ASV control settings

✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 2.

1. To open the Controls window, touch the **Controls** button at the bottom right of the display.

   The contents of the **Basic** tab are displayed by default.

2. Adjust any settings as needed.
3. Touch the **More** tab to enable or disable **Sigh**, as needed.
4. Touch the **TRC** tab to adjust any settings as needed.

   For details on tube resistance compensation, see your ventilator *Operator's Manual*.

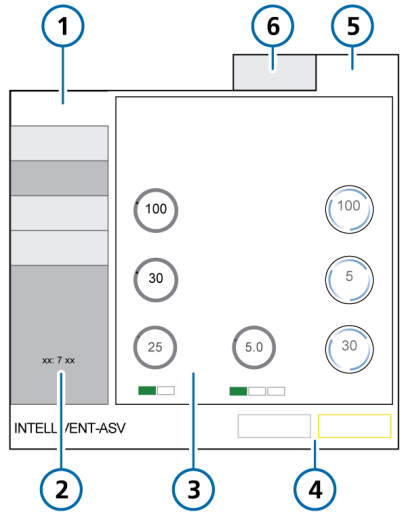
5. Touch the **Patient** tab to review patient data (height, gender), to ensure the correct **IBW** is calculated.

   You can also access the Patient window by touching the patient icon at the top left of the display.

   For details, see your ventilator *Operator's Manual*.

6. If displayed, touch **Confirm** to accept the settings and proceed to the next step, reviewing and adjusting alarm limits.

Figure 1-5. INTELLiVENT-ASV Controls window, Basic tab




| | | | |
|---|---|---|---|
| 1 | Basic | 4 | Cancel/Confirm buttons (if displayed) |
| 2 | Current minute volume | 5 | Modes |
| 3 | Control settings: **P-ramp**, **Pasvlimit**, **ETS**, **Trigger**, **%MinVol**, **PEEP**, **Oxygen** | 6 | Target |

## 1.4.8 Adjusting alarm limits

**⚠ WARNING**

- Set all alarms to clinically acceptable values, especially **Pressure**, **ExpMinVol**, **SpO2**, and **PetCO2**.
- To prevent patient injury, periodically review all alarm settings.

**NOTICE**

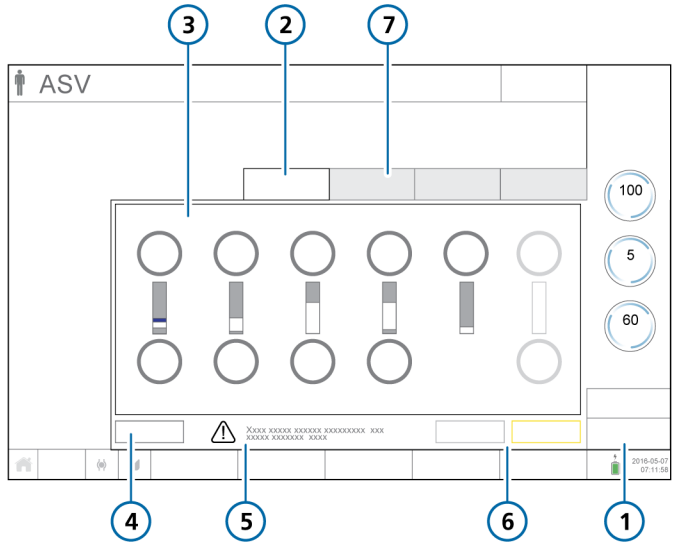
You can suppress the physiological PetCO2 and SpO2 alarms for 2 minutes by pressing the Audio Pause key, in the same manner as other alarms on the ventilator. For details, see the chapter, *Responding to alarms*, in your ventilator *Operator's Manual*.

As with other modes, you can adjust alarm limits for INTELLiVENT-ASV. The Limits 1 window contains the general alarm settings, as well as the Oxygen level notification control. The Limits 2 window contains the PetCO2- and SpO2-related alarm settings.

For additional information:

- For details about Oxygen level notification, see Section 1.4.10.6.
- For troubleshooting, see Section 1.6.
- For detailed information about alarms, including default settings and ranges, see your ventilator *Operator's Manual* and the *Pulse Oximetry Instructions for Use*.

Figure 1-6. Setting alarm limits




| | | | |
|---|---|---|---|
| 1 | Alarms | 5 | Safety notice |
| 2 | Limits 1 | 6 | Back/Continue buttons (if displayed) |
| 3 | Alarm limit controls | 7 | Limits 2 |
| 4 | Auto button | | |

**To adjust INTELLiVENT-ASV alarm limits**

✓ If you just selected the INTELLiVENT-ASV mode and are going through the initial setup process, start with step 2.

1. To open the Alarms window, touch the **Alarms** button at the bottom right of the display.

   The contents of the **Limits 1** tab are displayed by default.

2. Adjust any limits as needed.

3. Touch the **Limits 2** tab to review and adjust additional alarm limits.

4. To set alarm limits automatically, touch the **Auto** button.

   Selecting **Auto** automatically sets alarm limits around the current monitoring parameter values, except for the following alarm limits: Apnea, Vt, SpO2, Pulse, and PI. These alarm limits remain unchanged, and must be set manually to the desired level.

5. If displayed, touch **Confirm** to accept the settings and proceed to the next step.

INTELLiVENT-ASV setup is now complete.

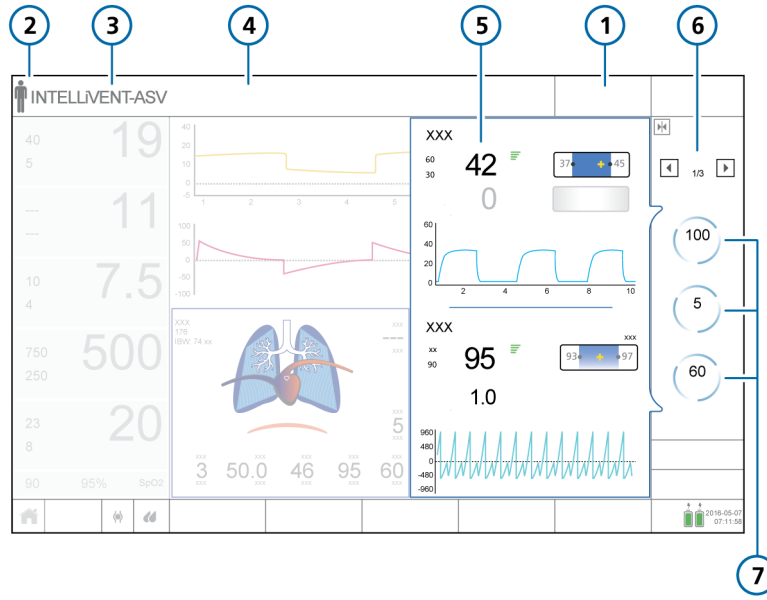
### 1.4.9 Adjusting settings during active ventilation

During active ventilation, you can adjust INTELLiVENT-ASV settings at any time. You can also review the Ventilation/Oxygenation maps and horizons, guides, plethysmogram, capnogram, and Quick Wean-related views (when enabled).

All of the tabs in the INTELLiVENT-ASV Settings window are available and function the same way as during initial setup, except that there are no **Cancel/Back**, **Continue/Confirm** buttons. Changes are applied as soon as you make them.

You can also adjust control settings and alarm limits at any time, same as with any other ventilation mode. For details, refer to your ventilator *Operator's Manual*.

Figure 1-7. Active ventilation with INTELLiVENT-ASV




| | | | |
|---|---|---|---|
| 1 | Touch **Target** to open the INTELLiVENT-ASV Settings window | 5 | Ventilation and Oxygenation horizons, with capnogram and plethysmogram |
| 2 | Touch the patient icon to open the Patient window | 6 | View navigation buttons and number |
| 3 | Touch the mode name or the **Mode** button to open the Modes window | 7 | Controls managed by INTELLiVENT-ASV |
| 4 | Alarm message bar | | |

### To display the INTELLiVENT-ASV Settings window

1. At any time during ventilation with INTELLiVENT-ASV, touch the **Target** button at the top right of the display, or touch one of the automated controllers.

   The INTELLiVENT-ASV Settings window opens, with the **Auto** tab selected (Figure 1-2).

2. Make changes as desired on any of the tabs.
3. To review or change control settings, touch the **Controls** button and make changes as needed.
4. To review or change alarm settings, touch the **Alarms** button and make changes as needed.

## 1.4.10 About INTELLiVENT-ASV settings

The following sections provide details about the following features:

| Settings | See ... |
|---|---|
| Patient conditions | Section 1.4.10.1 |
| Auto-recruitment maneuvers | Section 1.4.10.2 |
| Target shift | Section 1.4.10.3 |
| PEEP limit | Section 1.4.10.5 |
| Oxygen limit | Section 1.4.10.4 |
| Oxygen level notification (**Oxygen msg %**) | Section 1.4.10.6 |

### 1.4.10.1 About patient conditions

**⚠ CAUTION**

- *Select the Chronic Hypercapnia and/or ARDS patient condition only if the patient has one of these conditions; in case of doubt, do NOT select either of these options.*
- *Always select Brain injury if you are sure that the patient has this condition. If the patient suffers from a brain injury but the Brain injury option is not selected, increased CO2 levels and high cranial pressure might result. Carefully monitor intracranial pressure when available.*
- *If **Brain Injury** is selected but the patient is to be ventilated normally, the patient will be slightly hyperventilated and increased peak pressures might occur.*

***NOTICE***

- If **Brain injury** is selected, the ventilation controller (**%MinVol**) regulates in accordance with the measured **PetCO2** signal even if the patient is breathing spontaneously.
- The **Brain injury** target range has the highest priority of all patient conditions.
- If either the **Chronic Hypercapnia** or **Brain injury** patient condition is selected, management of **PEEP** cannot be automated; you must manually set the desired **PEEP** level. If **Chronic Hypercapnia** and **ARDS** are *both* selected, PEEP management can be automated.

Patient conditions are used in INTELLiVENT-ASV to determine:

- Startup settings to use for **%MinVol**, **PEEP**, and **Oxygen**
- Whether **PEEP** can be automated or must be manually controlled
- **PetCO2** and **SpO2** target ranges
- **%MinVol** for active patients, based on **fSpont** or **PetCO2** (if **Brain Injury** selected)

For details about selecting patient conditions, see Section 1.4.4.

Table 1-4 lists the patient conditions available in the INTELLiVENT-ASV Settings window. For patients with mixed conditions, you can select more than one option.

Table 1-4. Patient conditions in INTELLiVENT-ASV

| Patient condition | Description |
|---|---|
| Normal patient | No condition selected |
| ARDS | Acute respiratory distress syndrome, which presents as an acute, severe injury to most segments of the lung |
| Chronic Hypercapnia | For patients with chronically high arterial CO2 values, usually as a result of obstruction in airways due to chronic bronchitis, emphysema, or both |
| Mixed (ARDS and Chronic Hypercapnia) | For patients with both listed conditions |
| Brain Injury | Patients with brain injuries with whom it is critical to maintain CO2 under strict control to keep intracranial pressures at safe levels, and to keep oxygenation within a normal range |

Table 1-5 provides an overview of the values set for startup and during ventilation. Startup values all depend on the selected patient condition(s).

In all cases, Quick Wean and auto-recruitment are disabled at startup.

Table 1-5. Patient conditions and startup values for ventilation

| | Ventilation | Oxygenation | |
|---|---|---|---|
| Patient condition | %MinVol startup value (%) | Oxygen startup value (%) | PEEP startup value (cmH2O)[2] |
| Normal | 100 | 60 | 5 |
| ARDS | 120 | 100 | 8 |
| Chronic Hypercapnia | 100 | 60 | Manually controlled |
| ARDS + Chronic Hypercapnia | 120 | 100 | 8 |
| Brain Injury | 100 | 60 | Manually controlled |

[2] Control of settings not explicitly marked as *Manual* can be automated.

### 1.4.10.2 Automatic recruitment maneuvers

**⚠ CAUTION**

*Check for pneumothorax and potential susceptibility to pneumothorax before ventilating the patient. Automatic PEEP adjustment during recruitment maneuvers can lead to an increase in ventilation pressure levels.*

Automatic recruitment is a strategy for re-expanding collapsed lung tissue, and then maintaining higher PEEP to prevent subsequent "de-recruitment". To recruit collapsed lung tissue, sufficient pressure must be imposed to exceed the critical opening pressure of the affected lung.

Automatic recruitment in INTELLiVENT-ASV, called *auto-recruitment*, is an optional function designed to reopen collapsed lung units in severely hypoxemic patients, such as those with ARDS.

The ventilator automatically performs a recruitment maneuver when a second consecutive PEEP increase is required *and* the following conditions are met:

- PEEP controller is set to Automatic
- Auto-recruitment is enabled
- The patient is *not* breathing spontaneously; that is, the patient is passive
- Monitored SpO2 is below the target range (that is, the patient is hypoxemic)
- The ventilator has made two consecutive PEEP increases, according to the automated PEEP regulation rules
- The set maximum PEEP has not been reached

When these conditions are met, the ventilator performs a recruitment maneuver. PEEP is increased to 40 cmH2O and held for 20 seconds; PEEP is then decreased to the appropriate setting according to the automated PEEP regulation rules.

Auto-recruitment maneuvers occur after two consecutive automatic increases of PEEP of 1 cmH2O. This means the recruitment maneuver cycle occurs no more often than once every 12 minutes. As soon as a recruitment maneuver is performed, the device generates a Recruitment manuever in progress message.

Note that use of the P/V Tool also counts as a recruitment maneuver.

By default, auto-recruitment is disabled, and must be manually enabled for use.

**To enable or disable auto-recruitment**

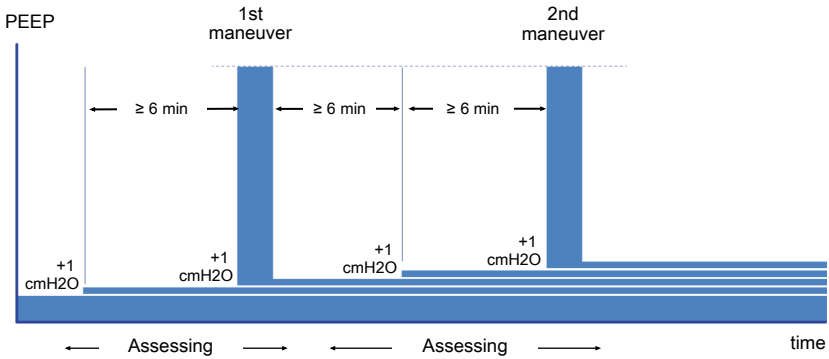
- In the INTELLiVENT-ASV Settings > More window, touch the Auto-recruitment checkbox. See Figure 1-4.

When auto-recruitment is enabled, the text **auto-recruitment** is displayed on the Oxygenation maps and horizon.

**Important:**

- During the recruitment maneuver, all patient alarms are suppressed.
- The maneuver is canceled if a flow sensor failure or any pneumatic disconnection is detected.
- No recruitment maneuver takes place if any of the following occurs:
  - PEEP is manually changed
  - The patient is active

Figure 1-8. Recruitment maneuver cycle




### 1.4.10.3 Target shift

**⚠ CAUTION**

- *Regularly check the patient after specifying a **PetCO2** or **SpO2** target shift to verify that the range is still appropriate for the current patient condition.*
- *Changing the target range and NOT monitoring the patient's progress can increase risk of hyper- or hypoventilation or hyper- or hypoxemia.*

INTELLiVENT-ASV uses **PetCO2** and **SpO2** as monitoring inputs for regulation of ventilation and oxygenation, and works to keep the patient within the target range for these values.

These target ranges are shown in the Ventilation and Oxygenation maps and horizons. INTELLiVENT-ASV adjusts ventilation and oxygenation controls to bring the patient to the middle of the set range.

In general, **PetCO2** and **SpO2** values represent a reliable index of CO2 partial pressure in the arterial blood (**PaCO2**) and partial pressure of dissolved oxygen in the arterial blood (**PaO2**), respectively (measured using blood gas analysis (BGA)). To get the most accurate approximation of PaCO2, the second highest **PetCO2** value out of 8 breaths is used.

Under normal conditions, **PaCO2** is approximately 3-5 mmHg higher than **PetCO2** — the difference between the values is referred to as the *PaCO2-PetCO2 gradient*. Under special clinical conditions (such as shunt), the PaCO2-PetCO2 gradient can increase, requiring adjustment of the ventilation targets.

The **Target Shift** control allows you to move the **PetCO2** and **SpO2** target ranges to the left (lower values) or to the right (higher values), within the limits defined in Tables 1-6 and 1-7. INTELLiVENT-ASV always tries to bring patient values to the middle of the specified range.

When determining the appropriate PetCO2 target range for your patient, keep the following considerations in mind (described in more detail with examples):

- Is the displayed PetCO2 target range appropriate for your patient?
- Is the PaCO2-PetCO2 gradient outside of the physiologic normal range?

### Is the displayed PetCO2 target range appropriate for your patient?

Check whether one of the patient conditions applies to your patient. If so, select the condition. If the range is still inadequate for your patient, use the **Target Shift** control to adjust the target range as needed to set the appropriate limits.

### Example

If INTELLiVENT-ASV sets the PetCO2 target range to 40–50 mmHg and:

- The ideal PetCO2 target for the patient is *50 mmHg*, consider setting the Target Shift to +5 to move the target range 5 mmHg to the right, to 45–55 mmHg.
- The ideal PetCO2 target for the patient is *30 mmHg*, consider setting the Target Shift to -15 to move the target range 15 mmHg to the left, to 25–35 mmHg.

### Is the PaCO2-PetCO2 gradient outside of the physiologic normal range?

If the difference between the two is greater than 3-5 mmHg, consider adjusting the PetCO2 target range to achieve the desired PaCO2 value.

### Example

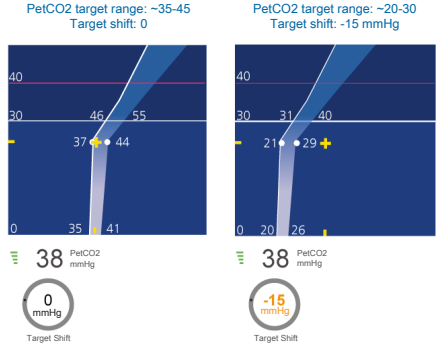
Assume the following patient conditions apply:

Measured PetCO2 = 38 mmHg[3]
PaCO2 from the BGA = 60 mmHg
Target PaCO2 = 40-50 mmHg

The PaCO2-PetCO2 gradient at 17 mmHg[4] is well outside the normal range.

In this case, consider setting the Target Shift to -15[5] to move the PetCO2 target range 15 mmHg to the left, for a target range between 20 and 30 mmHg.

Figure 1-9. Target shift example




INTELLiVENT-ASV makes adjustments to try to get the patient's PetCO2 values to the middle of the target range, which in this case should result in PaCO2 values within the desired 40 to 50 mmHg target PaCO2.

You can adjust the SpO2 target range in the same manner.

[3] PetCO2 is in the middle of the target range.
[4] 60 – 38 – 5 = 17
[5] 60 (current PaCO2 from BGA) – 45 (middle of target PaCO2 range) = 15 shift to the left

Table 1-6. PetCO2 target shift limits

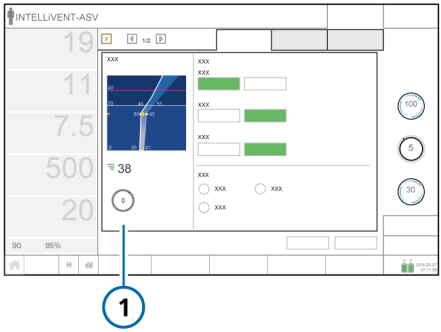
| PetCO2 target shift limits | |
|---|---|
| All patient conditions | -20 mmHg to 10 mmHg |

Table 1-7. SpO2 target shift limits based on patient condition

| SpO2 target shift limits[6] | |
|---|---|
| Normal | -5% to +4% |
| ARDS | -2% to +4% |
| Chronic Hypercapnia | -2% to +5% |
| Mixed (Chronic Hypercapnia + ARDS) | -2% to +5% |
| Brain Injury | -2% to +2% |

The **Target Shift** control is located in the Ventilation and Oxygenation map panel on the left side of the INTELLiVENT-ASV Settings window.

Figure 1-10. Target Shift control (1)




### To shift the target zone to the left or to the right

1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button or an automated controller.
2. Display the appropriate map: Ventilation (PetCO2 target range) or Oxygenation (SpO2 target range) using the View arrows in the INTELLiVENT-ASV Settings window.
3. Touch the **Target Shift** control and adjust the target range limits; then accept the value.

   - Setting the value to a positive number shifts the target range to the right, targeting a higher PetCO2 or SpO2.

   - Setting the value to a negative number shifts the target range to the left, targeting a lower PetCO2 or SpO2.

   - To shift the PetCO2 target range to a value beyond ±5 mmHg, set the value now to +5 or -5, as needed.
4. To shift the PetCO2 target range beyond ±5 mmHg, touch the **Target Shift** control again and set the value as desired; then accept the value.

The change is applied immediately and is visible in the associated Ventilation or Oxygenation map. During ventilation, the applied target shift is displayed on the associated map.

The PetCO2 **Target Shift** value and text is displayed in different colors depending on the setting.

[6] If a change in patient condition would cause the existing limit to be exceeded, the target shift is automatically reduced to comply with the new conditions.

Table 1-8. Target shift display

| Target Shift control | Text color and description |
|---|---|
|  | Black text.<br>Target shift is 0; there is no change to the target range values. |
|  | Yellow text.<br>Target shift is between ±1 and ±5. |
|  | Orange text.<br>Target shift is greater than ±5. |

### 1.4.10.4 Minimum Oxygen limit

When the **Oxygen** controller is set to **Automatic**, you can set an absolute lower limit for Oxygen; Oxygen will not fall below this limit.

**To set the minimum Oxygen limit**

- In the INTELLiVENT-ASV Settings > More window, set the limit to any value between 21% and 30%.

The default setting is 30%.

### 1.4.10.5 PEEP limit

When the PEEP controller is set to **Automatic**, the **PEEP limit** control allows you to define an absolute high limit that the PEEP controller cannot exceed. If enabled, you can also specify an absolute low limit for **PEEP**; **PEEP** will not fall below this limit, listed in Table 1-9.

Note that the minimum difference between the low and high limit is 2 cmH2O.

Table 1-9. PEEP limit control settings

| PEEP limit control range (cmH2O) | Default (cmH2O) |
|---|---|
| Low: 5 to 22 | Low: 5 |
| High: 7 to 24 | High: 15 |

If the patient condition **Chronic Hypercapnia** or **Brain injury** is selected, you set **PEEP** manually.

**To set PEEP limits**

- In the INTELLiVENT-ASV Settings > More window, set the desired high and/or low PEEP limits. See Figure 1-4.

### 1.4.10.6 Oxygen level notification

When the **Oxygen** controller is set to **Automatic**, you can specify an oxygen level that, when exceeded, generates a medium-priority alarm message that is displayed in the message bar.

The Oxygen message control is only a notification tool; it *does not* affect the percentage of delivered oxygen.

This threshold is set using the **Oxygen msg** control in the Alarms > Limits 2 window. See Section 1.4.8.

## 1.5 Monitoring INTELLiVENT-ASV

**⚠ CAUTION**

*Check the patient's condition periodically to assess readiness for weaning.*

***NOTICE***

- If the **PetCO2** signal is NOT reliable, the automated **%MinVol** controller freezes after 30 seconds. See Section 1.7.4.
- If the **SpO2** signal is NOT reliable, the automated **PEEP** and **Oxygen** controls freeze after 30 seconds. See Section 1.8.4.

INTELLiVENT-ASV provides easy access to numerical and graphical monitoring data. Data is shown on the main display in the Monitoring window, in the various graphic panels (trends, Dynamic Lung, Vent Status, plethysmogram, capnogram), and in the INTELLiVENT-ASV-specific windows, including the Ventilation/Oxygenation maps and horizon graphs.

Note that trend graphs for **PetCO2**- and **SpO2**-related parameters, as well as for the ventilation and oxygenation controller settings are also available. For details, see Section 1.5.7.

The following sections provide details about the Ventilation and Oxygenation maps and horizon graphs. For details about the Quick Wean-related views, see Chapter 2.

For details about other ventilator graphics and displays (for example, the Dynamic Lung, Vent Status panel, waveforms, and the Monitoring window), see your ventilator *Operator's Manual*.

### 1.5.1 About the INTELLiVENT-ASV windows and views

INTELLiVENT-ASV provides a graphical overview of CO2 elimination (ventilation) and oxygenation, as well as other INTELLiVENT-related data on the main display in specialized windows.

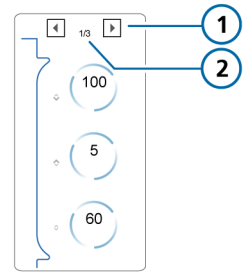
Most of these windows are displayed as a series of views that you can cycle through during ventilation.

**To display view windows**

- Touch the left or right view navigation button to cycle through the views.

The view number is displayed between the buttons.

Figure 1-11. Displaying INTELLiVENT-ASV views




1 View navigation buttons 2 View number

The following table describes the INTELLiVENT-ASV windows, as well as where they are displayed.

Table 1-10. INTELLiVENT-ASV views, overview

| View | Description | See ... |
|---|---|---|
| Ventilation map | Shows the current patient PetCO2 value and target range in relation to Ppeak, together with the set limits.<br>The map is shown:<br>• In the INTELLiVENT-ASV Settings window, in view 1<br>• During active ventilation in view 2 | Section 1.5.2<br>For details about the rules used to regulate CO2 elimination, see Section 1.7. |
| Ventilation horizon | For a passive patient, shows a zoom into the map at the current PetCO2 value and target range.<br>For an active patient, the spontaneous breathing rate is displayed (fSpont).<br>The horizon is shown during active ventilation in view 1. | Section 1.5.3 |
| Oxygenation maps | Two maps are available:<br>• The PEEP/SpO2 view shows the current patient SpO2 value and the target range in relation to PEEP, together with the set limits.<br>• The FiO2/PEEP view shows the patient's current combination of Oxygen/PEEP values, together with the set limits.<br>The selected map is shown:<br>• In the INTELLiVENT-ASV Settings window, in view 2<br>• During active ventilation in view 2 | Section 1.5.4<br>For details about the rules used to regulate oxygenation, see Section 1.8. |
| Oxygenation horizon | Shows a zoom into the map at the current SpO2 value and target range.<br>The horizon is shown during active ventilation in view 1. | Section 1.5.5 |

| View | Description | See ... |
|---|---|---|
| Plethysmogram | Provides a real-time waveform that represents the pulsating blood volume.<br>A plethysmogram is shown:<br>• During active ventilation in views 1 and 3<br>• As a waveform on the main display, if selected | Section 1.5.6 |
| Capnogram | Provides a real-time CO2 waveform.<br>A capnogram is shown:<br>• During active ventilation in views 1 and 3<br>• As a waveform on the main display, if selected | Section 1.5.6 |
| **Quick Wean related** | | |
| Quick Wean, Quick Wean & SBT status | Shows the status for SBT- and weaning-related parameters. | Section 2.4.4.1 |
| SBT history | The SBT history panel is shown during active ventilation in view 3. | Section 2.4.4.2 |

## 1.5.2 About the Ventilation (CO2 elimination) map

The INTELLiVENT-ASV ventilation controller monitors end-tidal CO2 (**PetCO2**), and uses this data to adjust **%MinVol** to regulate CO2 elimination, according to the detailed rules and conditions described in Section 1.7.

The INTELLiVENT-ASV ventilation controller uses a predefined end-tidal CO2 target schema with peak pressure (**Ppeak**) on the y-axis and **PetCO2** on the x-axis. Peak pressure is the sum of **PEEP** and the inspiratory pressure set by the controller.

This schema is called the *Ventilation* map. In the map, the yellow cross is the patient symbol denoting the patient's current measured **PetCO2** value at the current peak pressure. The boomerang shaped area of the graph is the target range, which denotes a range of values at a given peak pressure.

### 1.5.2.1 Reviewing the Ventilation map

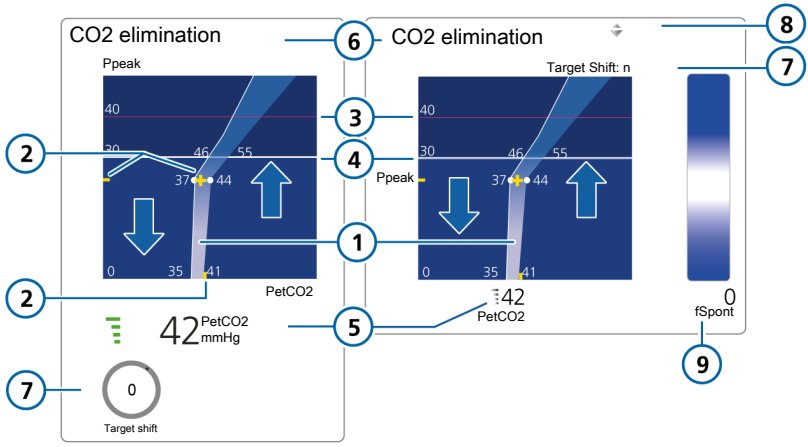
***NOTICE***

The maximum **Ppeak** value that can be shown on the Ventilation map is 50 cmH2O, so in some cases, the map may not show the patient symbol. INTELLiVENT-ASV is running, however.

The Ventilation map is available in two locations:

- INTELLiVENT-ASV Settings window, in view 1
- During active ventilation with INTELLiVENT-ASV, in view 2

Figure 1-12. Ventilation map, INTELLiVENT-ASV Settings window (left), main display during active ventilation (right)




1 Target zone

2 Yellow patient symbol (cross) and current patient values

3 High pressure alarm limit

4 Pressure limitation: Pasvlimit

5 Current measured **PetCO2** value and quality index

6 Map title: CO2 elimination

7 Target Shift. When set, the map in view 2 shows the setting (*Target Shift: n* > or *Target Shift: < n*)

8 When **%MinVol** is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, **%MinVol** is in target zone.

9 For active patient: target range and current **fSpont** value

*The blue arrows are for clarification purposes only; they do not appear on the display. Up arrow:* Increase zone (**PetCO2** too high, increase **%MinVol**); *Down arrow:* Decrease zone (**PetCO2** too low, decrease **%MinVol**).

### To display the Ventilation map in the INTELLiVENT-ASV Settings window

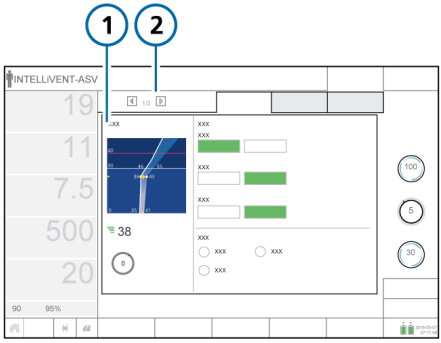
1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button at the top right of the display, or touch an automated controller.

   The Settings window opens, with the **Auto** tab selected.

2. If the Ventilation (CO2 elimination) map is not already displayed, touch the left view navigation arrow at the top left of the window to display view 1.

The panel shows the Ventilation map, measured PetCO2 value, and the **Target Shift** control.

Figure 1-13. Ventilation map, INTELLiVENT-ASV Settings window



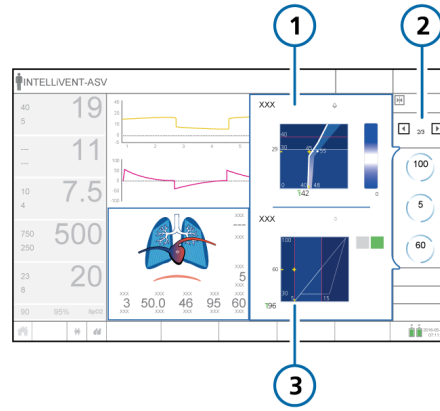

| | | | |
|---|---|---|---|
| 1 | Ventilation map | 2 | View arrows and current view number |

### To display the Ventilation map while INTELLiVENT-ASV is running

- If it is not already displayed, touch the view navigation arrows at the right of the display or swipe right on the display until view 2 is displayed.

View 2 shows the Ventilation map and measured PetCO2 value.

Figure 1-14. Ventilation map, in main display during active ventilation

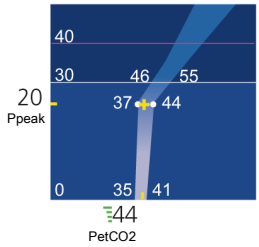



| | | | |
|---|---|---|---|
| 1 | Ventilation map | 3 | Oxygenation map |
| 2 | View arrows and current view number | | |

### 1.5.2.2 About the PetCO2 target zone

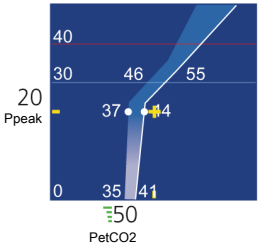
At a very basic level, the ventilation controller attempts to keep the patient in the target zone as described here.

The Ventilation map provides examples of each situation: PetCO2 is within, above, or below the target zone.



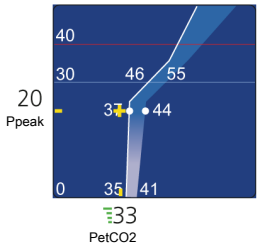

**Patient symbol within the PetCO2 target zone**

When the patient symbol is within the target zone, the %MinVol is fine tuned to get the patient to the middle of the target range.




**Patient symbol above the PetCO2 target zone**

When the patient symbol is to the right of the target zone (in the increase zone, PetCO2 is too high), the %MinVol setting increases.




**Patient symbol below the PetCO2 target zone**

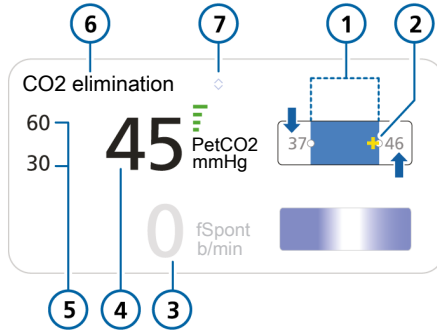
When the patient symbol is to the left of the target zone (in the decrease zone, PetCO2 is too low), the %MinVol setting decreases.

### 1.5.3 About the Ventilation horizon

For a passive patient, the Ventilation horizon shows a simplified view of the same data as the Ventilation map, together with the upper and lower **PetCO2** alarm limits.

When the patient is active, the horizon shows spontaneous breathing activity (**fSpont**).

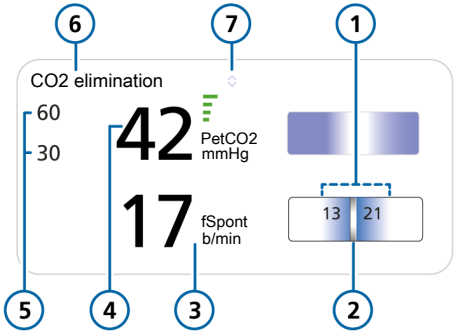
Figure 1-15. Ventilation horizon, passive patient




| | | | |
|---|---|---|---|
| 1 | Target zone, showing upper and lower boundaries | 5 | Upper and lower **PetCO2** alarm limits |
| 2 | Patient symbol (yellow) showing current value | 6 | Horizon title: CO2 elimination |
| 3 | **fSpont** value (0) | 7 | When **%MinVol** is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, **%MinVol** is in the target zone. |
| 4 | Current measured **PetCO2** value and quality index | | |

*The blue arrows are for clarification purposes only; they do not appear on the display. Up arrow:* Increase zone (**PetCO2** too high, increase **%MinVol**); *Down arrow:* Decrease zone (**PetCO2** too low, decrease **%MinVol**).

Figure 1-16. Ventilation horizon, active patient

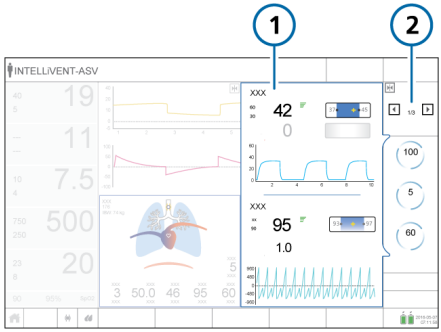



| | | | |
|---|---|---|---|
| 1 | Spontaneous breathing target zone, showing upper and lower boundaries | 5 | Upper and lower **PetCO2** alarm limits |
| 2 | Patient symbol (floater) showing current value | 6 | Horizon title: CO2 elimination |
| 3 | Current measured **fSpont** value | 7 | When **%MinVol** is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, **%MinVol** is in the target zone. |
| 4 | Current measured **PetCO2** value and quality index | | |

The appropriate Ventilation horizon (for active or passive patient) is shown on the main display during active ventilation, in view 1.

For details about the rules governing automated **%MinVol** adjustments, see Section 1.7.

Figure 1-17. Ventilation horizon, during active ventilation




| | | | |
|---|---|---|---|
| 1 | Ventilation horizon | 2 | View arrows and current view number |

## 1.5.4 About the Oxygenation maps

The INTELLiVENT-ASV oxygenation controller monitors SpO2, and uses this data to adjust **PEEP** and **Oxygen** to regulate oxygenation, according to the detailed rules and conditions described in Section 1.8.

We use the term *treatment* to refer to the joint effect of **PEEP** and **Oxygen**:

- *Increasing treatment* refers to changes to **PEEP** and/or **Oxygen** that cause SpO2 to increase. The controller makes these changes based on ARDSnet guidelines.
- *Decreasing treatment* refers to changes in these control values that cause SpO2 to decrease. The controller makes these changes based on the Open Lung concept.

The INTELLiVENT-ASV oxygenation controller uses two predefined schemas, referred to as the *Oxygenation* maps.

The *PEEP/SpO2 target* schema shows **PEEP** on the y-axis and **SpO2** on the x-axis. The yellow cross is the patient symbol denoting the patient's current measured **SpO2** value at the current **PEEP**. The boomerang shaped area of the graph is the target zone, which denotes a range of **SpO2** values at a given **PEEP**.

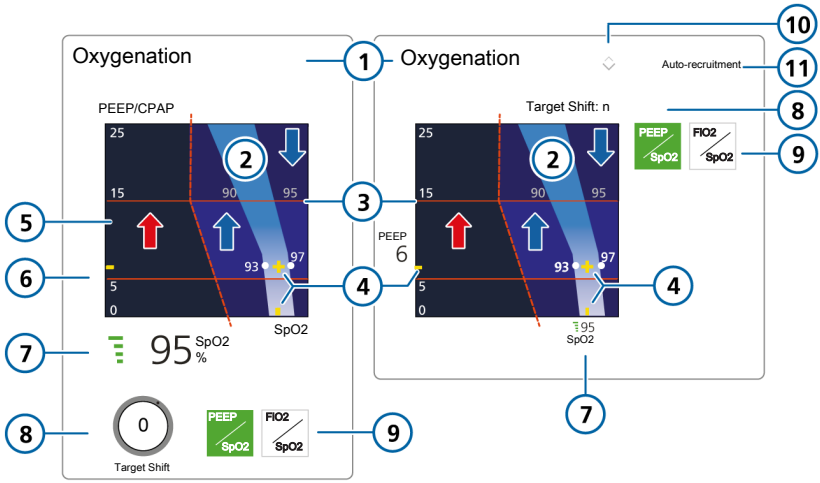
The *FiO2/PEEP* schema shows **Oxygen** on the y-axis and **PEEP** on the x-axis. The yellow cross is the patient symbol denoting the patient's current measured combination of **Oxygen/PEEP** values. The triangular **PEEP/Oxygen** curve shows the target treatment levels, depending on whether treatment remains unchanged, increases, or decreases.

### 1.5.4.1 Reviewing the Oxygenation maps

The Oxygenation maps (PEEP/SpO2 and FiO2/PEEP) are available in two locations:

- INTELLiVENT-ASV Settings window, in view 2
- During active ventilation with INTELLiVENT-ASV, on the main display in view 2

Figure 1-18. Oxygenation map, PEEP/SpO2, in INTELLiVENT-ASV Settings window (left), main display during active ventilation (right)




1 Map title: Oxygenation

2 Target zone

3 Upper PEEP limit

4 Yellow patient symbol (cross) and current patient values

5 Dark blue emergency zone

6 Lower PEEP limit

7 Current measured **SpO2** value and quality index

8 Target Shift. When set, the map in the main display shows the setting (*Target Shift: n* > or *Target Shift: < n*)

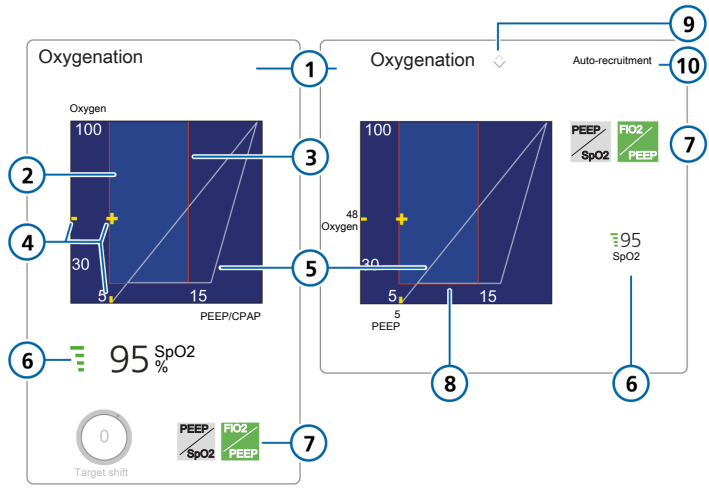
9 Oxygenation map selection button: PEEP/SpO2

10 When **PEEP** or **Oxygen** is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, **SpO2** is in target zone.

11 When auto-recruitment is enabled, text is displayed on the map

*The red/blue arrows and dotted line are for clarification purposes only; they do not appear on the display. Blue up arrow:* Increase treatment zone. *Blue down arrow:* Decrease treatment zone. *Red arrow:* Emergency increase zone (dark blue area), **Oxygen** set to 100%.

Figure 1-19. Oxygenation map, FiO2/PEEP, in INTELLiVENT-ASV Settings window (left), main diplay during active ventilation (right)




| | | | |
|---|---|---|---|
| 1 | Map title: Oxygenation | 6 | Current measured **SpO2** value and quality index |
| 2 | Lower **PEEP** limit | 7 | Oxygenation map selection button: FiO2/PEEP |
| 3 | Upper **PEEP** limit | 8 | Lower **Oxygen** limit |
| 4 | Yellow patient symbol (cross) and current patient values | 9 | When **PEEP** or **Oxygen** is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, **SpO2** is in target zone. |
| 5 | PEEP/Oxygen curve | 10 | When auto-recruitment is enabled, text is displayed on the map |

### To display the Oxygenation map in the INTELLiVENT-ASV Settings window

1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button at the top right of the display, or touch an automated controller.

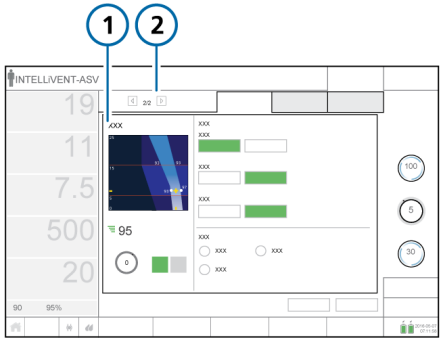
   The Settings window opens, with the **Auto** tab selected.

2. If the Oxygenation panel is not already displayed, touch the right view navigation arrow at the top left of the window to display View 2.

   The panel shows the PEEP/SpO2 Oxygenation map, measured **SpO2** value, and the **Target Shift** control.

3. To display the FiO2/PEEP map, touch the **FiO2/PEEP** button.

Figure 1-20. Oxygenation map, INTELLiVENT-ASV Settings window




| | | | |
|---|---|---|---|
| 1 | Oxygenation map | 2 | View arrows and current view number |

### To display the Oxygenation maps while INTELLiVENT-ASV is running

1. If it is not already displayed, touch the view navigation arrows at the right of the display until view 2 is displayed.

   View 2 shows the Oxygenation map and the measured **SpO2** value. See Figure 1-14.

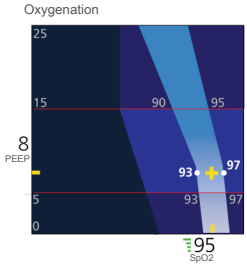
2. To display the FiO2/PEEP map, touch the **FiO2/PEEP** button.

   To display the PEEP/SpO2 map, touch the **PEEP/SpO2** button.

## 1.5.4.2 About the SpO2 target zone

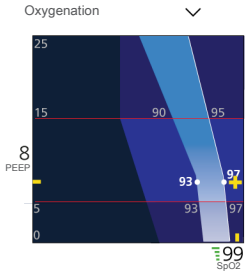
At a very basic level, the oxygenation controller attempts to keep the patient in the target zone as described here.

The PEEP/SpO2 (left) and FiO2/PEEP (right) maps below provide examples of each situation: SpO2 is within, above, or below the target zone.



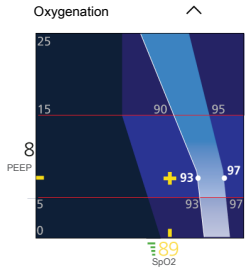

**Patient symbol within the SpO2 target zone**

When the patient symbol is within the target zone, **Oxygen** is fine tuned to get the patient to the middle of the target range.



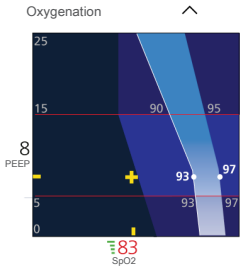

**Patient symbol above the target zone**

When the patient symbol is to the right of the target zone (in the *decrease zone*, indicating that the treatment is more than sufficient), the treatment is decreased. The down arrow above the map indicates a treatment decrease is occurring.




**Patient symbol below the SpO2 target zone**

When the patient symbol is to the left of the target zone (in the *increase zone*, indicating oxygenation is inadequate), the treatment is increased. The up arrow above the map indicates a treatment increase is occurring. As a result of being below the target zone, a medium-priority alarm is generated; the parameter is shown in the associated color.



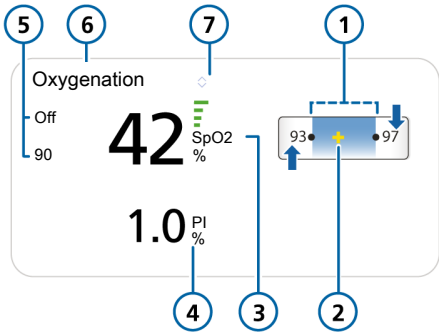

**Patient symbol below the SpO2 target zone, in the Emergency zone**

If the patient symbol is to the far left of the target zone in the dark blue *emergency zone* indicating hypoxemia, **Oxygen** is immediately increased to 100%. The up arrow above the map indicates a treatment increase is occurring. As a result of being below the target zone, a high-priority alarm is generated; the parameter is shown in the associated color.

## 1.5.5 About the Oxygenation horizon

The Oxygenation horizon shows a simplified view of the same data as the SpO2/PEEP Oxygenation map, together with the upper and lower *SpO2* alarm limits. With a Masimo SET SpO2 sensor, the horizon also shows the measured perfusion index (**PI**).

Figure 1-21. Oxygenation horizon

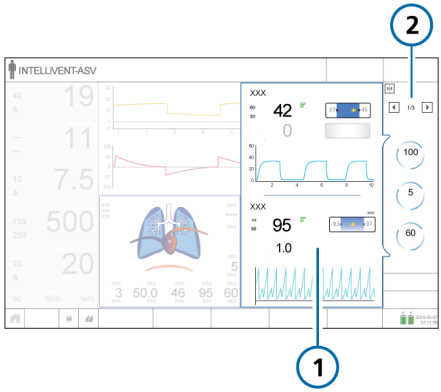



| | | | |
|---|---|---|---|
| 1 | Target zone, showing upper and lower boundaries | 5 | Upper and lower **SpO2** alarm limits |
| 2 | Yellow patient symbol (cross) showing current patient value | 6 | Horizon title: Oxygenation |
| 3 | Current **SpO2** value and quality index | 7 | When **PEEP** or **Oxygen** is increasing (^) or decreasing (v), the appropriate indicator appears. When the arrows are the same size, **SpO2** is in the target zone. |
| 4 | Current **PI** value *(Masimo SpO2 sensor only)* | | |

*The blue arrows are for clarification purposes only; they do not appear on the display. Up arrow:* Increase treatment zone; *Down arrow:* Decrease treatment zone.

The Oxygenation horizon is shown on the main display during active ventilation in view 1.

Figure 1-22. Oxygenation horizon during active ventilation




| | | | |
|---|---|---|---|
| 1 | Oxygenation horizon | 2 | View arrows and current view number |

## 1.5.6 About the plethysmogram and capnogram

A CO2 capnogram and SpO2 plethysmogram are available as part of the INTELLiVENT-ASV standard views. You can also display them as individual waveforms, in the same manner as other waveforms on the main display.

The time scale displayed is the same as for other waveforms. See your ventilator *Operator's Manual* for details.

### About the capnogram

A capnogram is a waveform that represents CO2 levels throughout a breath cycle.

During active ventilation with INTELLiVENT-ASV, the capnogram is displayed together with the Ventilation horizon, as well as with the SBT history window. For details about selecting the capnogram as a waveform on the ventilator main display, see your ventilator *Operator's Manual*.

### About the plethysmogram

A plethysmogram is a waveform that represents the pulsating blood volume; it is generated by the pulse oximeter.

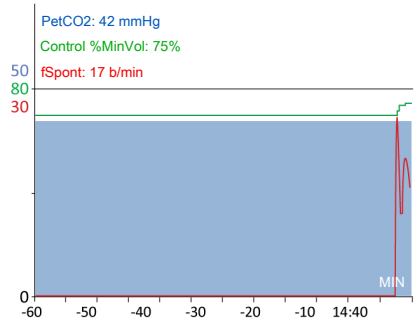
During active ventilation with INTELLiVENT-ASV, the plethysmogram is displayed together with the Oxygenation horizon, as well as with the SBT history window. For details about selecting the plethysmogram as a waveform on the ventilator main display, see the *Pulse Oximetry Instructions for Use*.

## 1.5.7 About trends

In addition to the trend data available for monitored parameters, you can also trend the actions of the ventilation and oxygenation controllers when using INTELLiVENT-ASV. The same time periods are available as for other parameters, namely, 1-, 6-, 12-, 24-, or 72-h trends. Each parameter is represented by a different color, as indicated in the graph legend.[7]

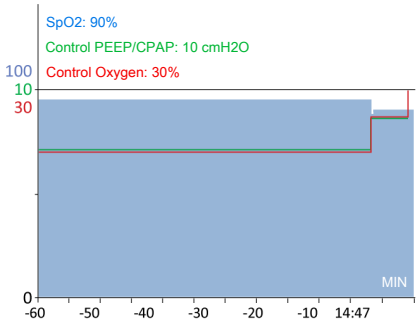
[7] Note that the graphs provided here do not represent actual data, they just illustrate how the different parameters are represented.

### Ventilation controller trend graph




The Ventilation controller trend graph provides data for the following parameters: PetCO2, Control %MinVol, and fSpont.

### Oxygenation controller trend graph

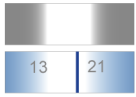



The Oxygenation controller trend graph provides data for the following parameters: SpO2, Control PEEP/CPAP, and Control Oxygen.

## 1.5.8 INTELLiVENT-ASV symbols

The following table describes important symbols and controls used with INTELLiVENT-ASV.

Table 1-11. INTELLiVENT-ASV-related symbols and controls

| Symbol | Color | Description |
|---|---|---|
|  | White | View selection.<br>In the INTELLiVENT-ASV Settings window, two views are available; the view navigation arrows change the view between the Ventilation (view 1) and Oxygenation (view 2) panels.<br>During active ventilation, three views are available; the view navigation arrows change the view between those described in Section 1.5.1. |
|  | Yellow | Patient symbol. Indicates the current condition of the patient in the graph. |
|  | Gray (or blue) (4 bars), Red (1 bar), Orange (2 bars) | Quality index showing unreliable signal quality. Sensor values are not usable or sensor not enabled or connected.<br>When this occurs, the related controller freezes and an alarm is generated indicating the automatic management is turned OFF. |
|  | Green (3 or 4 bars) | Quality index showing stable acceptable signal quality. The data from the sensor is highly stable and reliable. |
|  | White | Measured **PetCO2** sensor value and quality index. |
|  | PetCO2 horizon is greyed out; fSpont horizon is active | When the **PetCO2** horizon is greyed out, the patient is breathing spontaneously. The **fSpont** horizon is active.<br>When the **fSpont** horizon is greyed out, the patient meets the passive criteria. The **PetCO2** horizon above it is active. |
|  | White | The **fSpont** measurement is displayed when spontaneous breathing is detected by the flow sensor and used as physiologic input. |

| Symbol | Color | Description |
|---|---|---|
|  | Red | Critical SpO2 value. SpO2 is below the set lower alarm limit. |
|  | Black or white | Dashes indicate that no sensor value can be detected. |
|  | White | Increase arrow, next to the horizon name and to the left of the automated controllers. Indicates that treatment must be increased. |
|  | White | Decrease arrow, next to the horizon name and to the left of the automated controllers. Indicates that treatment must be decreased. |
|  | Blue | Value is stable, in range. Displayed next to the horizon name and to the left of the automated controllers. |
|  | White | Time to increase. Counts down the time to the next increase of the control. |
|  | White | Time to decrease. Counts down the time to the next decrease of the control. |
|  | White | Recruitment symbol. Indicates that a recruitment maneuver will be performed after the next PEEP increase. Counts down the time to maneuver. |
|  | White | Recruitment in progress. Message displayed, and count-down timer indicating duration of maneuver. Located close to the PEEP controller. |
|  | Gray circle | Manual management. Indicates that the operator must manage the control. |
|  | Blue circle rotating clockwise | Automatic management. Indicates that INTELLiVENT-ASV is managing the patient and treatment has been increased (comets moving clockwise). A faster rotation provides a visual indication of ongoing or recent changes. |

| Symbol | Color | Description |
|---|---|---|
|  | Blue circle rotating counter-clockwise | Automatic management. Indicates that INTELLiVENT-ASV is managing the patient and treatment has been decreased (comets moving counter-clockwise). A faster rotation gives a visual indication of ongoing or recent changes. |
|  | Red circle | No automatic management – controller is in a frozen state. A sensor value may be absent. |
|  | Green circle | Oxygen enrichment in progress. For details, see your ventilator *Operator's Manual*. |

## 1.6 Troubleshooting alarms

**⚠ CAUTION**

*You can suppress audible CO2 and SpO2 alarms for 2 minutes by pressing the* **Audio Pause** *key.*

***NOTICE***

When the device is in Standby, all SpO2-related alarms are suppressed.

The following table provides trouble-shooting information for alarms related to INTELLiVENT-ASV.

For information about working with alarms, including resetting them, see your ventilator *Operator's Manual* and SpO2-related documentation.

For the following alarm types, see the listed documentation:

- *Quick Wean/SBT-related alarms*, see Section 2.8.
- *SpO2-related alarms*, see the *Pulse oximetry Instructions for use*.
- *PetCO2-related alarms*, see your ventilator *Operator's Manual*.

Table 1-12. INTELLiVENT-ASV alarms, priority, and corrective actions

| Alarm/Priority | Definition/Corrective action |
|---|---|
| FiO2 set to 100% due to low SpO2<br>*Medium priority.* | Oxygenation controller set **Oxygen** to 100% due to low **SpO2** saturation. **SpO2** is, or was, in the emergency zone.<br>**To resolve**<br>• Check patient condition.<br>• Open and close the alarm buffer to reset the alarm (even if the alarm situation changes). |
| Oscillation Oxygen<br>*Medium priority.* | Large variations in **Oxygen** in a short time period.<br>**To resolve**<br>• Check patient condition.<br>• Set **Oxygen** to **Manual**. |
| Oscillation PEEP/CPAP<br>*Medium priority.* | Large variations in **PEEP** in a short time period.<br>**To resolve**<br>• Check patient condition.<br>• Set **PEEP** to **Manual**. |
| Oscillation %MinVol<br>*Medium priority.* | Large variations in **%MinVol** in a short time period.<br>**To resolve**<br>• Check patient condition.<br>• Set **%MinVol** to **Manual**. |

| Alarm/Priority | Definition/Corrective action |
|---|---|
| Oxygenation adjustment off<br>*Medium priority.* | Oxygenation controller is frozen due to poor or absent SpO2 signal.<br>**To resolve**<br>• Check pulse oximeter connections.<br>• Set PEEP and/or Oxygen to Manual. |
| Oxygen controller at limit<br>*Low priority.* | PEEP and/or Oxygen are at defined limit and cannot be increased.<br>**To resolve**<br>• Check patient condition.<br>• Verify limit settings.<br>• Set PEEP and/or Oxygen to Manual. |
| Oxygen control limit exceeded<br>*Medium priority.* | Oxygen exceeds the limit defined by the Oxygen message alarm (Alarms window).<br>**To resolve**<br>• Check patient condition.<br>• Open and close the alarm buffer to reset the alarm (even if the alarm situation changes). |
| Oxygen supply failed<br>*Medium priority.* | Oxygen source flow lower than expected.<br>**To resolve**<br>• Check patient condition.<br>• Check oxygen supply, change supply if necessary.<br>• Check oxygen supply for leaks.<br>• Provide alternative ventilation until issue is resolved. |
| Recruitment in progress<br>*Low priority.* | Notification about ongoing recruitment maneuver.<br>Check patient condition. |
| Ventilation adjustment OFF<br>*Medium priority.* | Ventilation controller is frozen when any of the following conditions occurs for longer than 30 seconds:<br>• Poor or absent CO2 signal<br>• fSpont > 60 b/min (> 40 kg IBW)<br>• fSpont > 100 b/min (≤ 40 kg IBW)<br>**To resolve**<br>• Check patient condition.<br>• Check CO2 connections.<br>• Set %MinVol to Manual. |

| Alarm/Priority | Definition/Corrective action |
|---|---|
| Ventilation controller at limit<br>*Low priority.* | %MinVol is at defined limit (200%) and cannot be increased.<br>**To resolve**<br>• Check patient condition.<br>• Set %MinVol to Manual. |

## 1.7 Management of minute volume (%MinVol)

**⚠ WARNING**

Regularly inspect CO2 adapters/sensors. Patient secretions and/or condensation in airway adapters can lead to an incorrect PetCO2 reading.

**⚠ CAUTION**

*Do NOT use the sidestream CO2 sensor with automatic management of %MinVol.*

Ventilation (%MinVol) management operates in two modes: Automatic and Manual.

### Automatic minute volume management

When automated, the INTELLiVENT-ASV ventilation controller uses the following data to set the minute volume (%MinVol):

- The controller uses different inputs to control the target minute volume, depending on whether the patient is passive or active
  - **Passive patient.** The controller uses the measured end-tidal CO2 partial pressure, PetCO2, as described in Section 1.7.1.
  - **Active patient.** The controller uses the difference between the targeted and actual respiratory rate, as described in Section 1.7.2.

  For details on how the automated controller manages the transition between spontaneous breathing and passive activity, see Section 1.7.3.
- All ASV safety limits are active for prevention of Apnea, baro- and volutrauma, auto-PEEP, and dead-space ventilation, including the tidal volume (Vt) limit of 1.5 x (upper Vt alarm limit).
- The target PetCO2 that is set depends on:
  - The patient's treatment level (peak inspiratory pressure)
  - Operator-set patient condition (Section 1.4.10.1)
  - Operator-set PetCO2 target shift (Section 1.4.10.3)
  - Whether Quick Wean is enabled (Section 2.2)
- The acceptable spontaneous breathing rate is calculated using the information in Table 1-15.

The %MinVol limits that are in force during automatic minute volume management are listed in Table 1-13.

As soon as the upper limit for the automatic management of **%MinVol** is reached, a **Ventilation controller at limit message** is generated.

Table 1-13. %MinVol limits for automatic minute volume management

| | |
|---|---|
| **Minimum %MinVol** | |
| **PetCO2** available | 70 |
| **PetCO2** not available | 100 (automatic control suspended) |
| **Maximum %MinVol** | |
| **PetCO2** available | 200 |
| **PetCO2** not available | 200 (automatic control suspended) |

### Manual minute volume management

In manual mode, you keep the CO2 elimination within the target range by adjusting **%MinVol**, based on the **PetCO2** monitoring values and on clinical practice.

## 1.7.1 Management of %MinVol, passive patient

When the patient is passive, the ventilator adjusts the target minute ventilation based on the **PetCO2** value of the patient.

End-tidal CO2 partial pressure (**PetCO2**), available when the CO2 sensor is connected, is the maximum partial pressure of CO2 exhaled during a breath, just before the start of inspiration. This represents the final portion of air that was involved in the exchange of gases in the alveolar area, and is, generally, a reliable index of CO2 partial pressure in the arterial blood.

Under normal conditions, PaCO2 is approximately 3-5 mmHg higher than **PetCO2** — the difference between the values is referred to as the *PaCO2-PetCO2 gradient*. Under special clinical conditions (including ventilation/perfusion mismatch, such as shunt), the PaCO2-PetCO2 gradient can increase, requiring adjustment of the ventilation targets (using the **Target Shift** control). For details, see Section 1.4.10.3.

To get the most accurate approximation of PaCO2, the second highest **PetCO2** value out of 8 breaths is used.

The **PetCO2** target range depends on:

- Operator-set patient condition (Section 1.4.10.1)
- Operator-set **PetCO2** target shift (Section 1.4.10.3)
- Current level of ventilator support (**Ppeak**)

Within these ranges, and based on the **PetCO2** response from the patient, **%MinVol** is adjusted as described in the following table.

Table 1-14. Automated management of %MinVol, passive patient

| When these conditions apply ... | %MinVol change |
|---|---|
| **PetCO2** is above the upper limit of acceptable values | **%MinVol** increase |
| **PetCO2** is below the lower limit of acceptable values | **%MinVol** decrease |
| **PetCO2** is within the target range | Minor **%MinVol** changes |

| When these conditions apply ... | %MinVol change |
|---|---|
| PetCO2 measurement is invalid or unreliable for at least 30 seconds | %MinVol control is frozen.<br>The Ventilation adjustment OFF alarm is generated. |

## 1.7.2 Management of %MinVol, active patient

When a patient is active, spontaneously triggering the breaths, the ventilator adjusts the target minute ventilation based on the spontaneous breathing rate of the patient.

The acceptable range for the spontaneous breathing rate is determined as follows:

Table 1-15. Spontaneous breathing rate range calculation

| | |
|---|---|
| Lower limit of range | ASV target Rate + 2<br>When Quick Wean is enabled:<br>ASV target Rate + 3 |
| Upper limit of range | ASV target Rate + d<br>d = %MinVol * k<br>where<br>k = 0.1<br>Quick Wean disabled<br>k = 0.15<br>Quick Wean enabled |

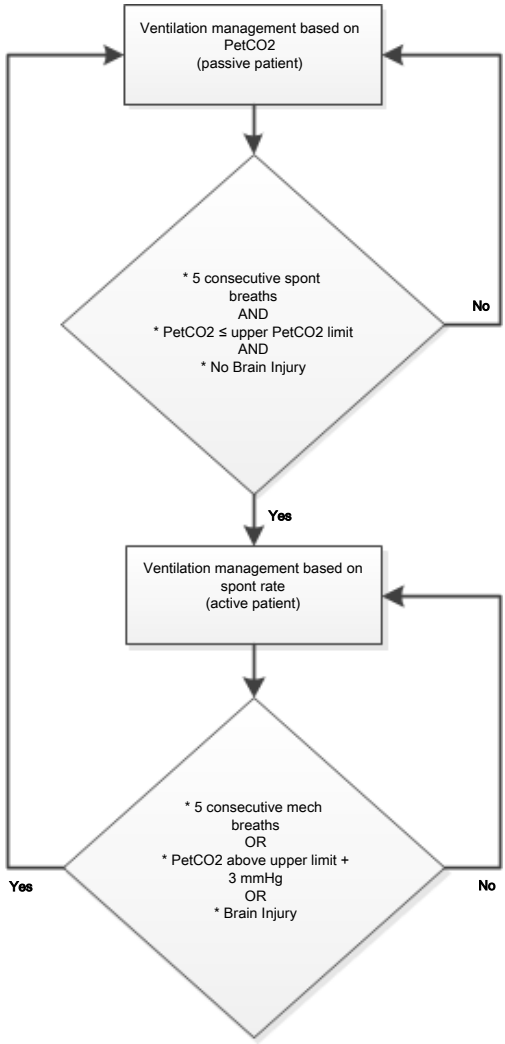
While the patient is active, the patient's spontaneous rate is detected by the flow sensor. The PetCO2 value is only used in the background for additional safety to avoid excessive values.

The rules listed in the following table apply to automated control of %MinVol for an active patient, and refer to the transition rules specified in Section 1.7.3.

Table 1-16. Automated management of %MinVol, active patient

| When these conditions apply ... | %MinVol change |
|---|---|
| • The patient complies with the rules in Section 1.7.3<br>*and*<br>• The patient's **Rate** is above the upper limit of the acceptable spontaneous rate (danger of patient fatigue) | **%MinVol** increase |
| • The patient complies with the rules in Section 1.7.3<br>*and*<br>• The patient's **Rate** is below the lower limit of the acceptable spontaneous rate | **%MinVol** decrease |
| • The patient complies with the rules in Section 1.7.3<br>*and*<br>• The patient's **Rate** value is within the target range | No change in **%MinVol**.<br>If Quick Wean is enabled, see Section 2.4.1 for details. |
| The patient's **PetCO2** is invalid for more than 30 seconds | **%MinVol** control is frozen.<br>The **Ventilation adjustment OFF** alarm is generated. |
| The patient's spontaneous rate is invalid (> 60 b/min (for patients > 40 kg **IBW**), > 100 b/min (for patients ≤ 40 kg **IBW**)) for more than 30 seconds | **%MinVol** control is frozen.<br>The **Ventilation adjustment OFF** alarm is generated. |

## 1.7.3 Rules for transitioning between active and passive states



### Passive patient

For a passive patient, the controller starts adjusting the %MinVol based on PetCO2 when ANY of the following are true:

- Five consecutive mechanical breaths occur *or*
- The PetCO2 value exceeds the upper limit by at least 3 mmHg *or*
- The Brain Injury patient condition is selected

In this case, the %MinVol is adjusted on the PetCO2 input.

When a reliable PetCO2 measurement is not available (Table 1-18), the ventilation controller suspends automated management, and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

### Active patient

For an active patient, the ventilation controller starts adjusting the %MinVol based on the Rate when ALL of the following are true:

- Five consecutive patient-triggered breaths occur *and*
- The PetCO2 value is below the upper limit *and*
- The Brain Injury patient condition is NOT selected

The controller continuously checks the passive patient rule (above) since it uses Rate as input criteria.

If the passive patient rule does not apply, the controller continues to adjust the %MinVol based on the spontaneous breathing rate of the patient.

If the patient's spontaneous rate is invalid[8] for more than 30 seconds, the ventilation controller suspends automated management and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

When a reliable PetCO2 measurement is not available (Table 1-18), the ventilation controller suspends automated management, and the %MinVol control is frozen. The Ventilation adjustment OFF alarm is generated.

[8] fSpont > 60 b/min (> 40 kg IBW) or fSpont > 100 b/min (≤ 40 kg IBW)

## 1.7.4 Important notes about ventilation management

When ventilating with INTELLiVENT-ASV, pay particular attention to important notes in the following areas:

Table 1-17. Important notes about ventilation management

| For ... | See ... |
|---|---|
| Signal quality and ventilation | Section 1.7.4.1 |
| Actions that temporarily halt automatic ventilation management | Section 1.7.4.2 |
| PetCO2 is not available | Section 1.7.4.3 |
| Disconnection or flow sensor failure resolved in 5 min or less | Section 1.7.4.4 |
| Disconnection or flow sensor failure resolved in more than 5 min | Section 1.7.4.5 |
| Returning to active ventilation from standby | Section 1.7.4.6 |

### 1.7.4.1 Signal quality and ventilation management

The following table summarizes INTELLiVENT-ASV operation depending on the quality of the **PetCO2** signal.

Table 1-18. PetCO2 signal quality and automated ventilation management

| Signal reliability and quality index | These conditions apply ... |
|---|---|
| **PetCO2** signal is unavailable or of poor quality for more than 30 seconds<br>Gray (or blue), red, or orange bars<br>  | • The **%MinVol** control is a solid red circle; it is frozen.<br>• The **Ventilation adjustment OFF** alarm is generated.<br>• The minute volume adjustment works as it does in ASV, with a constant minute ventilation equal to the last valid automatic **%MinVol** setting. For details, see your ventilator *Operator's Manual*. |
| **PetCO2** signal is available and reliable<br>Green bars<br>  | • The **%MinVol** control is a blue rotating circle.<br>• The alarm is reset.<br>• Automated ventilation management resumes. |

### 1.7.4.2 Actions that temporarily halt automatic ventilation management

Automated ventilation management pauses during the following actions:

- ASV is not operating in normal mode (see your ventilator *Operator's Manual*)
- Disconnection
- Flow sensor calibration
- Tightness test
- Suctioning
- P/V Tool maneuver
- Inspiratory/expiratory hold maneuver
- Auto-recruitment

In some cases, the controller remains displayed with a blue rotating circle, and when the action is completed, it resumes automated management with the last-used setting.

### 1.7.4.3 PetCO2 is not available

When a quality **PetCO2** measurement is not available (for example, the sensor is disabled or the signal quality is poor), the minute volume adjustment works the same as with ASV, with a constant minute ventilation (**%MinVol**) setting equal to the last valid automatic **%MinVol** value (frozen state).

- The ventilation controller display changes from blue to red.
- The alarm, **Ventilation adjustment OFF**, is generated. INTELLiVENT-ASV works like ASV with constant minute ventilation.

If this occurs when **%MinVol** is between 70% and 99%, the **%MinVol** is set to 100 and ventilation continues with **%MinVol** at 100% once a valid **PetCO2** measurement is again available.

When **PetCO2** is again available, the alarm is cleared and the minute volume adjustment switches back to fully automatic mode.

- The controller changes from red to a blue rotating circle again.
- **%MinVol** is adjusted automatically.

### 1.7.4.4 Disconnection or flow sensor failure resolved in 5 minutes or less

When a disconnection or flow sensor failure situation is resolved in 5 minutes or less, the device:

- The **%MinVol** management adjustment pauses for 10 breaths.
- The ASV adjustment (**Pinsp** and ASV target rate) pauses for 4 breaths after reconnection.
- If the adjustment is in its initialization phase, it remains there for at least 3 more breaths.

For details, see your ventilator *Operator's Manual*.

#### 1.7.4.5 Disconnection or flow sensor failure resolved in more than 5 minutes

When a disconnection or flow sensor failure is resolved in more than 5 minutes:

- The ventilation controller adjustment pauses for 2 minutes.
- The ASV adjustment re-initializes. If the adjustment is in its initialization phase, it remains there for at least 3 more breaths.

#### 1.7.4.6 Starting active ventilation from Standby

When starting ventilation with a new patient selected and INTELLiVENT-ASV activated, the %MinVol adjustment initializes with the default settings.

If Last Patient was selected, the system assumes the patient settings, in addition to the %MinVol values from the last patient.

In the event the PetCO2 quality index is below 50, the %MinVol control changes from a blue rotating circle to a red non-pulsing circle. Ventilation management does not start.

When the PetCO2 quality index is above 50, ventilation management starts in automatic mode. The %MinVol control is a blue rotating circle.

## 1.8 Management of PEEP and Oxygen

As INTELLiVENT-ASV relies on the measurements provided by the SpO2 sensor, be sure to carefully review the safety messages provided in this guide, as well as those provided in the *Pulse oximetry Instructions for use*.

***NOTICE***

- The emergency increase of oxygen rules remain in place for all cases as long as the Oxygen control is set to Automatic.
- The oxygenation controller can only adjust the Oxygen between 21% and 100%.
- When the minimum Oxygen limit is set > 21%, a red line indicating the limit appears on the Oxygenation maps.
- Outside of performing an SBT, the PEEP controller can only operate between 5 and 24 cmH2O.
- If the PEEP control is automated, the set PEEP high and low limit controls are activated. The Oxygenation maps show two red lines, one showing the upper PEEP limit and one showing the lower.

Oxygenation (PEEP/Oxygen) management operates in two modes: Automatic and Manual.

### Automatic oxygenation (PEEP and Oxygen) management

Automated PEEP/Oxygen management sets the **Oxygen** and **PEEP** values according to the following inputs, which determine the expected **SpO2** range for the patient:

- Measured oxygen saturation (**SpO2**)
- Operator-set patient condition (Section 1.4.10.1)
- Operator-set Target Shift (Section 1.4.10.3)

The lung-protective rules for oxygenation management, used during automated PEEP/Oxygen management, are based on the ARDSnet guidance when increasing the therapy, and the Open Lung concept when decreasing the treatment. See Section 1.8.1.

### Manual oxygenation management

In manual mode, you keep the **SpO2** within the target range by adjusting **PEEP** and/or **Oxygen**, based on the **SpO2** monitoring values and on clinical practice.

## 1.8.1 Management of PEEP/Oxygen for all patients

Using the SpO2 signal retrieved from the pulse oximeter, the system calculates the difference between the current and the target **SpO2** value. This calculation, together with the operator's input, is used to determine the treatment action.

Automated PEEP/Oxygen management comprises two steps:

- The operator's input and the actual treatment (**PEEP**) define the **SpO2** target range. The ranges differ based on patient conditions (Section 1.4.10.1).

  The SpO2 signal and the **SpO2** target range are used to define the treatment action (increase, decrease, no change of treatment).

- The system decides, depending on the actual combination of PEEP and Oxygen on the PEEP/Oxygen curve, whether PEEP and/or Oxygen are increased.

  The relationship between **PEEP** and **Oxygen** is based on the ARDSnet guidance for increasing therapy (Figure 1-23, the target path is the bold line) and the Open Lung concept for decreasing therapy (Figure 1-24, the target path are the bold lines).

Figure 1-23. Increase of oxygenation support, ARDSnet guidance

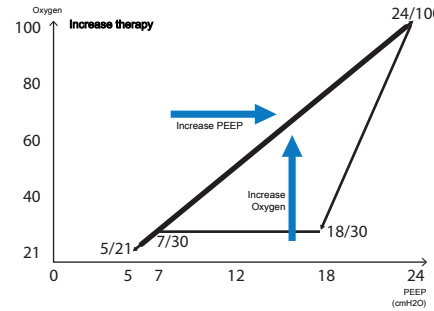
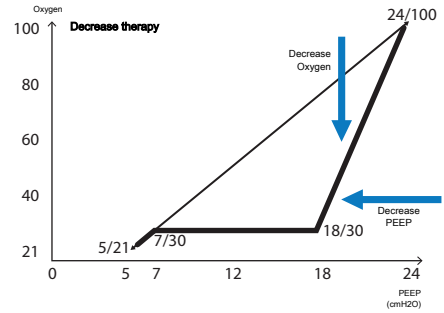



Figure 1-24. Decrease of oxygenation support, Open Lung concept



The device adjusts PEEP and Oxygen, which affect the oxygenation of the patient. Section 1.8.3 provides an overview of the controllers' actions depending on the measured SpO2 value.

## 1.8.2 Emergency increase of Oxygen

When Oxygen is set to Automatic, the device provides a safety feature that continuously monitors the patient's SpO2 to avoid dangerous desaturation. Upon detecting an inadequate SpO2 level, the device reacts immediately to deliver 100% Oxygen to the patient.

The safety feature is activated when the physiologic SpO2 value of the patient falls below the lowest acceptable value, thus triggering the 100% Oxygen response. The FiO2 set to 100% due to low SpO2 alarm is generated.

## 1.8.3 Oxygenation management rules

The automated oxygenation controller adjusts PEEP and Oxygen as described here.

### SpO2 is in range (within the target zone limits) and the Oxygen setting is above the PEEP/Oxygen curve

The controller *decreases Oxygen support* as long as all of the following conditions are met:

- SpO2 remains in range
- Oxygen was last increased over 10 minutes ago
- There is no change in PEEP

### SpO2 is too low (below the lower SpO2 target zone limit)

The controller *increases oxygenation support*.

| Position of patient symbol in the FiO2/PEEP map, relative to the ARDSnet curve | |
|---|---|
| Above the curve | The controller changes PEEP stepwise to the PEEP/Oxygen curve. |
| On the curve | The controller increases PEEP and Oxygen stepwise at the same time to follow the curve. |
| Below the curve | The controller increases Oxygen stepwise to the curve. |

### SpO2 is critically low (in the Emergency zone)

The controller *performs an emergency Oxygen increase*.

The Oxygen control displays the value 100%. See Section 1.8.2.

### SpO2 measurement is unavailable

The controller *is frozen*.

The PEEP and Oxygen controls are frozen, displayed as solid red circles, and the Oxygenation adjustment OFF alarm is generated. Oxygenation management is no longer automated.

**SpO2 is high, above the target zone limit**

The controller *decreases oxygenation support*.

| Position of patient symbol in the FiO2/PEEP map, relative to the Open Lung curve | |
|---|---|
| Above the curve | The controller decreases **Oxygen** stepwise to the PEEP/Oxygen curve. |
| On the curve | The controller first decreases **Oxygen**, then **PEEP** to follow the curve. |
| Below the curve | The controller automatically decreases **PEEP** stepwise to the curve. |

### 1.8.3.1 How the controller adjusts Oxygen and PEEP

***NOTICE***

If an upper PEEP limit is specified, the controller will not exceed the limit.

If a lower PEEP and/or Oxygen limit is specified, the controller will not go below the limit.

The following table describes the rules the controller follows to adjust the oxygenation parameters.

Table 1-19. Increase/decrease increments of Oxygen and PEEP by automated oxygenation controller[9]

| Oxygenation management | Action | Takes place when ... |
|---|---|---|
| Increase **Oxygen** stepwise | Increases Oxygen by 10% of current **Oxygen** value every **30 seconds** | • **Oxygen** automatically managed<br>• Increasing **Oxygen** support |
| Decrease **Oxygen** stepwise | Decreases Oxygen by 5% of current **Oxygen** value every **60 seconds** | • **Oxygen** automatically managed<br>• Decreasing **Oxygen** support |
| Increase **PEEP** stepwise | Increases **PEEP** by 1 cmH2O every **6 minutes** | • **PEEP** automatically managed<br>• Increasing **PEEP** support |
| Decrease **PEEP** stepwise | Decreases **PEEP** by 1 cmH2O every **6 minutes** | • **PEEP** automatically managed<br>• Decreasing **PEEP** support |
| Decrease **PEEP** stepwise quickly | **Exception:** Decreases **PEEP** by 1 cmH2O quickly every **30 seconds** | • **PEEP** automatically managed<br>• **PEEP** is above the upper **PEEP** limit (if **PEEP** was set manually above the limit |

[9] When the **PEEP** and/or **Oxygen** control setting is manually changed and then control is again set to **Automatic**, these rules still apply. The time interval starts from the time of the last manual change.

## 1.8.4 Important notes about oxygenation management

When ventilating with INTELLiVENT-ASV, pay particular attention to important notes in the following areas:

Table 1-20. Important notes about oxygenation management

| For ... | See ... |
|---|---|
| Signal quality and oxygenation management | Section 1.8.4.1 |
| Actions that temporarily halt automatic oxygenation management | Section 1.8.4.2 |
| Oxygen level notification | Section 1.8.4.3 |
| Returning to active ventilation from standby | Section 1.8.4.4 |

### 1.8.4.1 Signal quality and oxygenation

The following table summarizes INTELLiVENT-ASV operation depending on the quality of the **SpO2** signal.

Note that the controllers may also be frozen as a result of various **SpO2**- and **Oxygen**-related alarms.

The automatic emergency increase of **Oxygen** is inactive when **Oxygen** is controlled manually.

Table 1-21. SpO2 signal quality and automated oxygenation management

| Signal reliability and quality index | These conditions apply ... |
|---|---|
| **SpO2** signal is unavailable or of poor quality for more than 30 seconds<br>Gray (or blue), red, or orange bars<br>  | • The **PEEP** and **Oxygen** controls are solid red circles; they are frozen.<br>• The **Oxygenation adjustment OFF** alarm is generated.<br>• The ventilator uses the same oxygenation rules as when in ASV mode. For details, see your ventilator *Operator's Manual*.<br>• Automatic emergency increase of oxygen management is *inactive* (Section 1.8.2). |
| **SpO2** signal is available and reliable<br>Green bars<br>  | • The **PEEP** and **Oxygen** controls are blue rotating circles.<br>• The alarm is reset.<br>• Automated oxygenation management resumes.<br>• Automatic emergency increase of oxygen management is *active* (Section 1.8.2) |

#### 1.8.4.2 Actions that temporarily halt automatic oxygenation

Automated oxygenation management pauses during the following actions:

- Disconnection
- Oxygen enrichment
- Flow sensor calibration
- Tightness test
- Suctioning
- Oxygen cell calibration
- Oxygen supply failure
- P/V Tool maneuver
- Inspiratory/Expiratory hold maneuver
- Auto-recruitment

In some cases, the controller remains displayed with a blue rotating circle, and when the action is completed, it resumes automated management with the last-used setting.

#### 1.8.4.3 Oxygen level notification

When the automatic oxygenation controller is active, you can set the ventilator to display a message if the **Oxygen** concentration exceeds a specific limit that you specify. If the notification threshold is reached, an alarm is generated and the message **Oxygen limit exceeded** is displayed. See Section 1.4.10.6.

#### 1.8.4.4 Starting active ventilation from Standby

When starting ventilation with a new patient selected and INTELLiVENT-ASV activated, the **PEEP** and **Oxygen** adjustments initialize with the default settings.

If **Last Patient** was selected, the system assumes the patient settings, in addition to the **PEEP** and **Oxygen** values from the last patient.

## 1.9 Manual control of ventilation and oxygenation

With INTELLiVENT-ASV, you can manage minute volume (**%MinVol**), **Oxygen**, and/or **PEEP** automatically or manually.

In some cases, automated management is not available, as described in the following sections.

### 1.9.1 Manual control of ventilation

When **%MinVol** is controlled manually, the device uses the same rules as when in ASV mode. For details, see your ventilator *Operator's Manual*.

Table 1-22. Conditions for manual control of %MinVol

| When these conditions are met ... | This control must be adjusted MANUALLY by the operator |
|---|---|
| CO2 monitoring is disabled | **%MinVol** is set to **Manual** |

For control to be automated, you must manually set %MinVol to Automatic in the INTELLiVENT-ASV Settings window.

### 1.9.2 Manual control of oxygenation

You must control PEEP and/or Oxygen manually when any of the conditions listed in the following table occur.

Table 1-23. Conditions for manual control of PEEP and/or Oxygen

| When these conditions are met ... | This control must be adjusted MANUALLY by the operator |
|---|---|
| **PEEP**<br>• The Chronic Hypercapnia or Brain injury patient condition is selected<br>• SpO2 monitoring is disabled | PEEP is set to Manual |
| **Oxygen**<br>• Oxygen monitoring (O2 sensor) is disabled<br>• SpO2 monitoring is disabled | Oxygen is set to Manual |

When PEEP or Oxygen is controlled manually, the device uses the same rules as when in ASV mode. For details, see your ventilator *Operator's Manual*.

For control to be automated, you must manually set the desired controls to Automatic in the INTELLiVENT-ASV Settings window.

## 1.10 Assessing results

After the calculated targets are reached, the ventilation management results need to be assessed. Use the monitored parameters for this purpose. To assess respiratory acid-base status, it is recommended that arterial blood gases be measured to monitor the minute volume adjustment.

# 2
# Quick Wean

## 2.1 Overview

**⚠ WARNING**

Additional ventilator-independent patient monitoring (for example, bedside vital monitoring or a blood gas analyzer) must be used during INTELLiVENT-ASV ventilation. Check PaCO2 against displayed **PetCO2**, and SaO2 against **SpO2**.

**⚠ CAUTION**

*The responsibility for final decisions regarding weaning and extubation rests solely with the physician/operator. Additional criteria not provided by the ventilator have to be taken into account.*

Quick Wean is integrated into INTELLiVENT-ASV, and when activated, provides continuous dynamic monitoring and control of patient conditions to evaluate the patient's potential readiness for extubation. Together with the clinician and the patient, Quick Wean is part of a complex care cycle that has as its goal a respiratorily healthy, spontaneously breathing patient.

Weaning from a ventilator is a difficult process that comprises training, evaluation, and testing. A widely accepted and commonly used method is to decrease ventilatory support and, if possible, perform spontaneous breathing trials (SBTs) to evaluate the patient's muscle activity and endurance.

An SBT is a diagnostic tool that can help determine whether the patient is ready to be removed from ventilator support and can breathe on their own. It is known that the use of a protocolized standard process is beneficial in regard to patient safety and outcomes. Note that in INTELLiVENT-ASV, automated SBTs are disabled until explicitly enabled.

### 2.1.1 About Quick Wean use and modes

Quick Wean offers two modes of use: with and without automated SBTs. For details on enabling or disabling these options, see Section 2.3.

Table 2-1. Quick Wean modes of use

| Quick Wean mode | Description |
|---|---|
| Quick Wean disabled | Default setting. No continuous monitoring against defined weaning criteria occurs. |
| Quick Wean enabled<br>(set to Automatic) | The device does the following:<br>• Shifts the PetCO2 range to the right by up to +5 mmHg, depending on pressure, to support spontaneous breathing.<br>• When the patient is active (Section 1.7.2), the device gradually reduces %MinVol. As long as these conditions are met, the %MinVol is decreased to and/or maintained at 70%.<br>• The system continuously monitors the patient against weaning criteria (Section 2.4).<br><br>Two SBT-related options are then available: automated SBTs enabled or disabled. |
| Automated SBTs enabled | This option offers all the benefits of providing standardized, protocolized care.<br>• The system continuously monitors the patient against weaning criteria.<br>• When defined criteria are met, automatically initiates an SBT.<br>• All of the related parameters are configurable, and some can be fine tuned during ventilation.<br>• You can manually start an SBT any time the patient is active.<br><br>See Section 1.4.5. |
| Automated SBTs disabled | This is the default setting.<br>• The system continuously monitors the patient against weaning criteria.<br>• As long as the patient is breathing spontaneously and the patient's rate is below the upper limit of the target range, the %MinVol is decreased to and/or maintained at 70%.<br>• All of the related parameters are configurable, and some can be fine-tuned during ventilation.<br>• You can manually start an SBT any time the patient is active. |

### 2.1.2 Key terms

The following table describes some key terms for Quick Wean.

Table 2-2. Key terms and parameters for Quick Wean

| Term/Parameter | Description |
|---|---|
| SBT | *Spontaneous breathing trial.* Diagnostic test to help determine whether patients are ready to be removed from ventilator support and can breathe on their own. |
| Automated SBT | When enabled, the device performs an SBT when specified criteria are met. By default, disabled. |
| *To start SBT* group of parameters | A list of parameters that must all be within a predefined range for a specific amount of time for the patient to be considered ready for an SBT.<br>This set of parameters and values is referred to as the *To start SBT criteria*. |
| *To stop SBT* group of parameters | A list of parameters that are monitored during an SBT, to determine whether to stop the SBT. If any of the values is outside the predefined range for a specified period of time, an ongoing SBT is stopped.<br>This set of parameters and values is referred to as the *To stop SBT criteria*. |
| fSpont / %fSpont | fSpont is the absolute number of spontaneous breaths taken. %fSpont is the percentage of spontaneous breaths to total breaths taken.<br>The Quick Wean panel shows fSpont; the SBT history panel shows %fSpont. |
| Max. duration (min) | Defines the length of time the SBT can run. If the patient conditions continue to stay within defined thresholds, the SBT ends after the time specified by this parameter.<br>Only applies during an SBT. |
| %MinVol (%) | When Quick Wean is enabled, as long as the patient is active and the patient's rate is below the upper limit of the target range (Section 1.7.2), the device gradually reduces %MinVol to 70%.<br>When SBTs are enabled and an SBT starts, %MinVol is reduced to a default value of 25%. |
| Oxygen (%) | Inspired oxygen. |

| Term/Parameter | Description |
|---|---|
| **PEEP** (cmH2O) | Positive end-expiratory pressure. Airway pressure at the end of exhalation. |
| **PetCO2** (mmHg) | End-tidal CO2 pressure. |
| **PetCO2 inc** (mmHg) | The absolute increase in **PetCO2** (relative to an average calculated prior to the start of the SBT) that is permitted during an SBT.<br>Only applies during an SBT. |
| **Psupport max** (cmH2O) | The maximum pressure support allowed before starting an SBT, and an absolute upper limit that it cannot exceed during the SBT.<br>If the upper limit is reached during an SBT, the SBT is stopped. |
| **Rate** (b/min) | Respiratory rate. Number of breaths per minute.<br>Defines the maximum rate allowed before an SBT can take place, as well as an absolute upper limit that cannot be exceeded during an SBT.<br>If the upper limit is reached during an SBT, the SBT is stopped. |
| SBT time range | Defines the hours between which an SBT can be started.<br>Even if the *To start SBT* criteria are met, the SBT will not take place until the current time of day is inside the specified range, if criteria are still met.<br>If an SBT is in progress when the time is out of range, the SBT continues until it is completed. |
| **SpO2** (%) | Measurement of oxygen saturation in the blood. |
| **Time before starting SBT** (min) | Defines the length of time that patient conditions must stay within the *To start SBT* limits before an SBT can start.<br>Only applies when automated SBTs are enabled. |
| **Time between 2 SBTs** (min) | Defines the minimum length of time that must pass between two SBTs.<br>Only applies when automated SBTs are enabled. |
| **Tolerance time** (s) | The length of time a parameter value can be out of range without affecting the countdown to an SBT or an ongoing SBT.<br>If any one parameter is out of range for longer than this time period, the countdown timer is reset or an ongoing SBT is stopped. |
| **Vt/IBW** (ml/kg) | Tidal volume per kilogram of ideal body weight. |

| Term/Parameter | Description |
|---|---|
| RSB (1 /(l*min)) | Rapid shallow breathing index. The total breathing frequency (fTotal) divided by the exhaled tidal volume (VTE).<br>The RSB parameter is only used for patients weighing > 40 kg. For patients weighing less, the PetCO2 parameter is used. |

## 2.2 Quick Wean in clinical use

This section provides a brief overview of the Quick Wean clinical workflow, key parameters, and indications for use.

### 2.2.1 Quick Wean workflow

Upon enabling Quick Wean, the device does the following:

- Shifts the PetCO2 range to the right by up to +5 mmHg, depending on pressure, to support spontaneous breathing.
- As long as the patient is active (Section 1.7.2), the device gradually reduces %MinVol to 70%.

  As long as these conditions are met, the %MinVol is decreased to and/or maintained at 70%.

  The device adjusts %MinVol as follows:
  - If %MinVol is already at 70%, the device does nothing.
  - If %MinVol is above 70%, the device decreases %MinVol to 70% in steps of no more than 1% per breath.
- If the patient is passive (Section 1.7.1), INTELLiVENT-ASV continues ventilating the patient. When the conditions are again met, the ventilator repeats the %MinVol reduction process described above.

Note that the up to +5 mmHg PetCO2 target zone shift remains in place as long as Quick Wean is enabled.

### 2.2.2 About the Quick Wean parameters

Quick Wean monitors a large set of parameters to support weaning. Default settings for these parameters are consensus based, and, if modified, are generally set once and then used as the defaults.

Some of settings can be modified during ventilation; others are defined in Configuration. Further, some parameters are calculated and are not user modifiable.

Parameters are grouped into the following basic categories:

- *To start SBT* parameters that are monitored to determine whether an SBT can be started
- *SBT settings* parameters that determine the settings for an SBT
- *To stop SBT* parameters that are monitored to determine whether to stop an ongoing SBT

For details about the Quick Wean/SBT parameters, see Section 2.10, which lists where each one is set and monitored, and value ranges.

### 2.2.3 Indications for use

**NOTICE**

Quick Wean is not available if the patient condition selected in INTELLiVENT-ASV is **Brain injury**.

Quick Wean can be enabled at any time during ventilation. Conducting an SBT, however, is only possible when:

- The patient is active
- Quick Wean is enabled

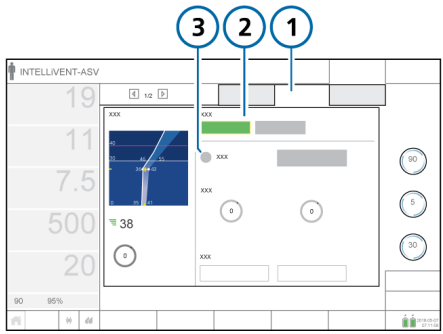
## 2.3 Enabling/disabling and setting up automated SBTs

Quick Wean must be enabled to automate SBTs. For details about enabling Quick Wean, see Section 1.4.5.

#### To enable/disable automated SBTs

1. Ensure Quick Wean is enabled in the INTELLiVENT-ASV Settings > Quick Wean window.

Figure 2-1. INTELLiVENT-ASV Settings > Quick Wean window, Quick Wean enabled



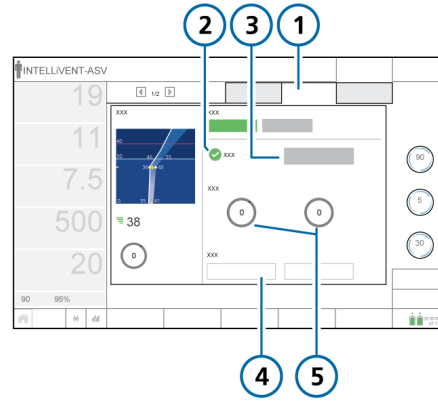

| | | | |
|---|---|---|---|
| 1 | Quick Wean | 3 | Automatic SBT (*not* selected) |
| 2 | Automatic | | |

2. Select whether to enable SBTs.

   By default, automated SBTs are disabled.

   To enable SBTs, touch the **Automatic SBT** checkbox. A checkmark indicates SBTs are enabled. The **SBT settings** button also becomes available.

Figure 2-2. INTELLiVENT-ASV Settings > Quick Wean window, SBTs enabled




| | | | |
|---|---|---|---|
| 1 | Quick Wean | 4 | Manually Start/ Stop SBT buttons |
| 2 | Automatic SBT, selected | 5 | Automatic SBT time range |
| 3 | SBT settings button available | | |

3. Using the **SBT Time range** controls, set the time period during which automatic SBTs can be performed. By default, they can be performed between 8 am and 8 pm.

   For details about the SBT time range, see Table 2-3.

4. If SBTs are enabled, touch the **SBT settings** button to access additional controls.

   These values can be modified during ventilation and in Standby, as appropriate.

   The Quick Wean tab changes to *SBT settings*, and the contents of the window change to show SBT-related options.

5. Set SBT options as desired. Table 2-3 describes these controls.

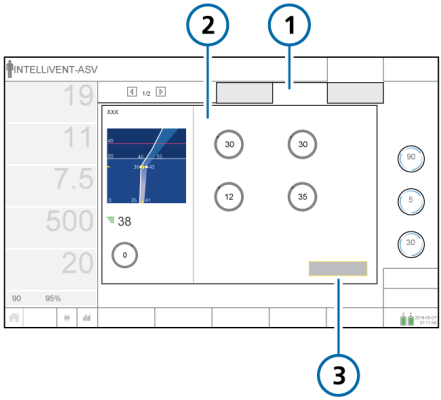
6. Touch **Close** to accept the settings and return to the Quick Wean window.

7. If displayed, touch **Continue** to accept the settings and proceed to the next step.

   Touching the **Back** button returns you to the Auto window.

   Touching the **X** button or doing nothing for 1 minute closes the window and returns you to the previously selected mode.

Figure 2-3. INTELLiVENT-ASV Settings > SBT Settings window




1 SBT settings

2 SBT controls: Time before starting SBT, Time between 2 SBTs, Psupport max, Rate

3 Close

Table 2-3. SBT settings, available during ventilation

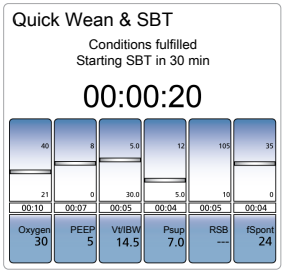
| SBT setting | Description |
|---|---|
| Automatic SBT | Select checkbox to enable automatic SBTs when specified clinical conditions are met. |
| SBT settings | Touch to display additional SBT-related settings. |
| SBT time range | Hours between which an SBT can be started.<br>Even if clinical conditions match the specified SBT starting criteria, if the start time for the SBT is outside of the range specified here, the SBT will not take place.<br>To allow automated SBTs to start at any time, set both controls to the same time. |
| Manually start/stop SBT | Manually start/stop an SBT. Only available when the patient is active and the patient's **Rate** is below the upper limit of the target range. |
| Start SBT | Touch to immediately start an SBT.<br>The system:<br>• Adjusts **%MinVol** to the configured setting<br>• Adjusts PEEP to the configured setting (if automatically controlled)<br>• Displays the SBT history window<br>• Displays the Quick Wean & SBT status window |
| Stop SBT | Select to immediately stop an ongoing SBT.<br>The system returns to the previous INTELLiVENT-ASV settings and monitors patient conditions for the next possible SBT. |
| Time before starting SBT (min) | Length of time that *To start SBT* parameters must remain within specified limits before an SBT can start.<br>See Section 2.4.2). |
| Time between 2 SBTs (min) | The minimum length of time after an automated SBT is executed before another automated SBT can be started. |
| Psupport max (cmH2O) | The maximum pressure support allowed before starting an SBT, and an absolute upper limit that it cannot exceed during an SBT.<br>Shown as the upper **Pinsp** limit in the Quick Wean & SBT Status window. |
| Rate (b/min) | The maximum rate allowed before starting an SBT, and an absolute upper limit that it cannot exceed during an SBT. |

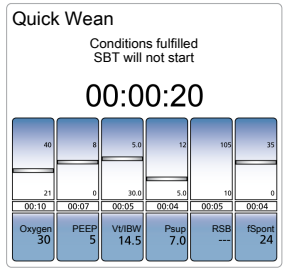
## 2.4 Conditions for starting weaning activities

Quick Wean continuously monitors the patient's condition against a set of criteria that must be met for weaning activities to be possible. They are referred to as the *To start SBT parameters* or *To start SBT criteria*.

1. When Quick Wean is enabled, the device starts monitoring *To start SBT* parameters.
2. When all of the following conditions are met, the steps listed in Table 2-4 occur, depending on whether automated SBTs are enabled:
   - The patient is active
   - The *To start SBT* criteria are met

Table 2-4. Device actions when To start SBT criteria are met

| When *To start SBT* criteria are met and ... | Quick Wean/Quick Wean & SBT Status window (see Section 2.4.4) |
|---|---|
| Automated SBTs are enabled |  <br>• The device shows the status *Conditions fulfilled, starting SBT in XX min* in the Quick Wean & SBT Status window, and starts a timer.<br>• The measured values for each of the *To start SBT* parameters must remain within the defined ranges for the length of time specified in the **Time before starting SBT** parameter.<br><br>Note that any of the *To start SBT* parameters can be out of range for up to the time specified by the **Tolerance time** parameter without affecting the countdown.<br><br>For example, with a **Tolerance time** of 30 seconds, any parameter can be out of range for up to 30 seconds with no effect. If a parameter value remains out of range for 31 or more seconds, the process resets. |

| When *To start SBT* criteria are met and ... | Quick Wean/Quick Wean & SBT Status window (see Section 2.4.4) |
|---|---|
| Automated SBTs are disabled |  <br>The device shows the status *Conditions fulfilled, SBT will not start* in the Quick Wean Status window.<br>Note that any of the *To start SBT* parameters can be out of range for up to the time specified by the **Tolerance time** parameter without affecting this status.<br>For example, with a **Tolerance time** of 30 seconds, any parameter can be out of range for up to 30 seconds with no effect. If a parameter value remains out of range for 31 or more seconds, the *Conditions fulfilled* status is removed, and the device continues to monitor the patient's condition. |

You can also manually start an SBT. See Section 2.5.1.

## 2.4.1 About %MinVol calculations

When Quick Wean is enabled, once the patient is active and the patient's **Rate** is within the target range as described in Section 1.7.2, the device decreases **%MinVol** stepwise to 70%.

The device adjusts **%MinVol** as follows:

Table 2-5. %MinVol adjustments

| Patient status | Quick Wean status | The device ... |
|---|---|---|
| Active, **Rate** within target range | Quick Wean enabled | Decreases **%MinVol** to 70% |
| | Quick Wean disabled | No **%MinVol** change |
| Active, **Rate** out of range | Quick Wean enabled or disabled | INTELLiVENT-ASV **%MinVol** management |

### 2.4.2 Parameters used to determine weaning readiness (To start SBT group)

***NOTICE***

In the Quick Wean & SBT Status panel, the **RSB** parameter is shown only for patients weighing > 40 kg. For patients weighing ≤ 40 kg, the **PetCO2** parameter is shown instead.

The following parameters are monitored to determine the patient's readiness for weaning activities. They are monitored regardless of whether automated SBTs are enabled or disabled.

For the definition of a parameter, see Section 2.1.2. For parameter ranges and other details, see Section 2.10.

Some parameters use different thresholds depending on the patient weight. Where applicable, these differences are marked.

Table 2-6. Quick Wean To start SBT criteria

| Parameter (unit) | Where set/how used | Default *To start SBT* value |
|---|---|---|
| %fSpont | Not configurable | 100% during **Time before starting SBT** |
| Oxygen (%) | Configuration > Modes > SBT > To start SBT window | ≤ 40 |
| PEEP (cmH2O) | Configuration > Modes > SBT > To start SBT window | Patients > 40 kg: ≤ 8<br>Patients ≤ 40 kg: ≤ 6 |
| Psupport max (cmH2O) | INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | ≤ 12 |
| Rate (b/min) | INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | Patients > 30 kg: ≤ 35<br>Patients ≤ 30 kg: ≤ 45 |
| RSB (1/(l*min)) | Not configurable | ≤ 105 |
| SpO2 (%) | Not configurable | In INTELLiVENT-ASV normal/high range (within or above target zone) |
| Vt/IBW (ml/kg) | Configuration > Modes > SBT > To start SBT window | ≥ 5 |
| Time before starting SBT (min) | INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | 30 |

| Parameter (unit) | Where set/how used | Default *To start SBT* value |
|---|---|---|
| Time between 2 SBTs (min) | INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | 30 |
| SBT Time range (hh:mm) | INTELLiVENT-ASV Settings > Quick Wean window<br>To allow automated SBTs to start at any time, set both controls to the same time. | Between 8:00 and 20:00 (8 am to 8 pm) |
| Tolerance time (s) | Configuration > Modes > SBT > To start SBT window<br>If any one parameter (listed in this table) is out of range for longer than this time period, the count-down timer is reset. | Patients > 40 kg: 180<br>Patients ≤ 40 kg: 60 |

The default values for most of these parameters are set in Configuration (Section 2.9). A few of the parameters can be modified during ventilation in the INTELLiVENT-ASV Settings window, as described in Section 2.4.3.

### 2.4.3 User-modifiable SBT parameters, INTELLiVENT-ASV Settings window

The INTELLiVENT-ASV Settings > Quick Wean/SBT settings windows provide access to the SBT-related parameters that you can adjust during ventilation, if needed. You do not have to put the ventilator into Standby to make changes. Changes are implemented immediately, and the system starts making adjustments, if needed.

The time-related parameters (**Time before starting SBT**, **Time between 2 SBTs**, and **SBT time range**) are only effective when automated SBTs are enabled. You can adjust the other parameters in this window at any time.

When Quick Wean is enabled, the system monitors the non-time-related parameters to help determine whether to start an SBT, and once an SBT is taking place, whether to stop an ongoing SBT. These values are used in addition to the *To start SBT* parameters and *To stop SBT* parameters specified during configuration.

**To access SBT settings**

See Section 2.3.

### 2.4.4 Monitoring progress

When Quick Wean is enabled, two additional monitoring windows are available:

- Quick Wean or Quick Wean & SBT Status window
- SBT history window (view 3)

### 2.4.4.1 Quick Wean/Quick Wean & SBT Status window

Like the ventilation Vent Status window, the Quick Wean/Quick Wean & SBT Status window uses floating indicators moving up and down within the columns to show the values for SBT- and weaning-related parameters. The data is updated every breath.

To help you quickly determine the SBT status (automatic or not), the window name changes as follows:

- When automatic SBTs are disabled, the window is labeled *Quick Wean*.
- When automatic SBTs are enabled, the window is labeled *Quick Wean & SBT*.

The content of the window changes depending on which phase the device is in.

Table 2-7. Quick Wean/Quick Wean & SBT Status window

| When ... | Quick Wean/Quick Wean & SBT Status window ... |
|---|---|
| Quick Wean is enabled | Displays the text *Verifying conditions*. |
| *To start SBT* conditions are met | Displays:<br>• The text *Conditions fulfilled/Starting SBT in XX time period*.<br>• Displays a timer (HH:MM:SS) showing how long the patient values have been within the target ranges. |
| *To start SBT* conditions are met | Displays:<br>• The text *Conditions fulfilled/SBT will not start*.<br>• A timer (HH:MM:SS) showing how long the patient values have been within the target ranges. |
| SBT is in progress | Displays:<br>• The text *SBT running*<br>• A timer (HH:MM:SS) showing how long the SBT has been running<br>• Pulsing green bars above and below the floats for parameters that are within the defined thresholds<br>Parameters that are out of range do not show the green bar. |

### 2.4.4.2 SBT history window

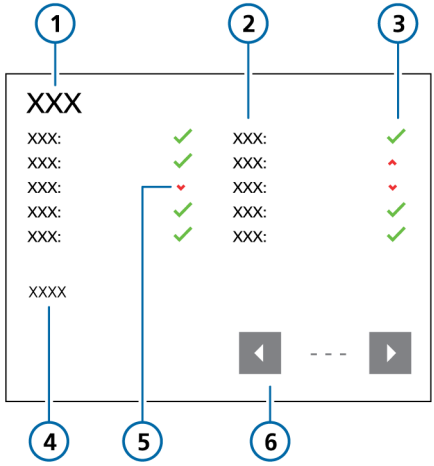
The SBT history window, available in view 3 of the INTELLiVENT-ASV views, displays an overview of all of the key ventilation parameters.

A green checkmark indicates that the parameter is within acceptable limits. A red up or down arrow indicates a parameter value that is out of the acceptable range.

During an active SBT, the window displays the start time and date, as well as the status message, *SBT running*. When an SBT is ended, the window displays information about how the previous SBT ended (successfully completed (*fulfilled*) or stopped prematurely (*stopped*).

The History (arrow) buttons at the bottom of the window allow you to scroll through previous SBT data.

Figure 2-4. SBT history window




| | | | |
|---|---|---|---|
| 1 | Panel title: SBT history | 4 | SBT status, time started |
| 2 | Weaning parameters | 5 | Value out of range (red up arrow: too high; red down arrow: too low) |
| 3 | Value in range (green checkmark) | 6 | View previous SBT data |

### To display the SBT history window

- Touch the view buttons until the SBT history window is displayed.

## 2.5 Conducting an SBT

SBTs can be started manually (Section 2.5.1) or automatically.

To start an automated SBT, all of the following conditions must be met:

- The patient must be active
- Automated SBTs are enabled
- Patient conditions must be within target ranges for all of the *To start SBT* criteria, for the time specified in the **Time before starting SBT** setting
- Enough time has passed since the last SBT (**Time between 2 SBTs** setting), if applicable
- The current time is within the allowed range (**SBT Time Range** setting)

If all conditions are met, the system starts an SBT.

The following changes occur.

Table 2-8. System changes when conducting an SBT

| System changes | For details, see ... |
|---|---|
| The Quick Wean & SBT status window displays pulsing green bars for parameters within the defined thresholds, and starts a timer. | Section 2.4.4.1 |
| The SBT history window shows the time the SBT started. | Section 2.4.4.2 |

| System changes | For details, see ... |
|---|---|
| Additional parameters are used during the SBT:<br>• Rate inc%<br>• PetCO2 inc (absolute increase in PetCO2)<br><br>Rate inc% and PetCO2 inc values are used as *To stop SBT* criteria. The limits are set in Configuration. | Section 2.5.2 |
| The system changes the settings for %MinVol and PEEP, if needed, to those specified in Configuration (Configuration > Modes > SBT settings window).<br>Note that PEEP settings are changed only if PEEP management is automated. | Section 2.9.1 |

## 2.5.1 Manually starting/stopping an SBT

You can manually start an SBT any time the patient is breathing spontaneously. The Start SBT button becomes available in the INTELLiVENT-ASV Settings > Quick Wean window.

### To manually start an SBT

1. Touch the **Target** button to access the INTELLiVENT-ASV Settings window.
2. Touch the **Quick Wean** tab.
   Note that the **Start SBT** button is enabled only when the patient is breathing spontaneously.
3. Touch the **Start SBT** button.

The system immediately starts an SBT by reducing %MinVol and PEEP (when management is automated) to the configured settings. For details on what the device does, see Table 2-8.

The SBT continues until it successfully completes or it is stopped. See Section 2.6.

The SBT history window displays the start time of the SBT, with the text, *SBT manually started*. It also provides the end time, with a short description of how the SBT ended: *SBT successfully fulfilled* (completed the specified time), *SBT stopped* (stopped ahead of time due to parameter value(s) being out of range, or *SBT manually stopped*.

### To manually stop an SBT

- In the INTELLiVENT-ASV Settings > Quick Wean window, touch the **Stop SBT** button.

The SBT history window records the time the SBT was stopped, and shows the text, *SBT manually stopped*.

The system returns to the previous INTELLiVENT-ASV settings and starts monitoring patient conditions for the next possible SBT.

## 2.5.2 PetCO2 increases

***NOTICE***

PetCO2 inc is used as part of *To stop SBT* criteria; it is not displayed.

During an SBT, the system uses the PetCO2 increase as a *To stop SBT* criterion. You set a maximum allowed value in the *To stop SBT* window in Configuration.

The changes in PetCO2 can give an indication of whether the patient is experiencing increased work of breathing (WOB). The system monitors the PetCO2 increase, as well as the measured PetCO2 value against the defined target range. For details about how the controller uses this data, see Section 1.7.2.

### 2.5.3 Monitoring breath rate increases

**NOTICE**

Rate inc % is only monitored during an SBT.

During an SBT, the breathing rate increase (Rate inc %), in percent, is also monitored.

The changes in this value can provide an indication of whether the patient is experiencing increased work of breathing (WOB) during an SBT. The rate increase is measured every minute by taking the current value and calculating the percent change from an average rate established just prior to the start of the SBT.

The parameter is displayed in the Monitoring 1 window, as main monitoring parameters (MMP) (configurable), secondary monitoring parameters (SMPs) in the Monitoring window, trend graphs, and in the SBT history window.

## 2.6 Conditions for stopping an SBT

**NOTICE**

The maximum length of time a disconnection is allowed is 1 minute, regardless of the Tolerance time setting.

If an SBT is stopped due to disconnection (whether inadvertent or for suctioning), the ventilator continues with the previous INTELLiVENT-ASV settings.

The SBT window displays the message SBT stopped manually.

During an SBT, the device monitors the *To stop SBT* parameters and other settings to determine whether to stop the SBT.

An SBT (automated or manual) is stopped if any of the following conditions is met:

- If a *To stop SBT* parameter is out of range for longer than the time interval specified in the Tolerance time parameter, the SBT is stopped, and an alarm, SBT aborted, is generated.
- Quick Wean is disabled in the INTELLiVENT-ASV Settings window.
- The device is placed into standby.
- The %MinVol is manually changed.
- The ventilation mode is changed.
- A P/V Tool maneuver is performed.
- The patient becomes passive (no longer meets the active criteria).
- The measured SpO2 value meets the criteria for a rapid therapy escalation.
- A disconnection > 1 minute occurs.

The following table lists the *To stop SBT* parameters and the default threshold values.

Some of the *To stop SBT* parameters are not explicitly set. Rather, they are either calculated, or you set the *To start/during SBT* value, and a value outside of this setting becomes the *To stop SBT* criterion.

For the definition of a parameter, see Section 2.1.2. For parameter ranges and other details, see Section 2.10.

Table 2-9. Quick Wean To stop SBT criteria

| Parameter (unit) | Where set/how used | Default *To stop SBT* value |
|---|---|---|
| Oxygen (%) | Configuration > Modes > SBT > To start SBT window<br>Set in the To start SBT window.<br>The **Oxygen** setting to end an SBT is always the **Oxygen** setting in the To start SBT window + 10. | > 50 |
| PEEP (cmH2O) | Configuration > Modes > SBT > To start SBT window<br>Set the upper limit that **PEEP** cannot exceed during an SBT. | Patients > 40 kg: > 8<br>Patients ≤ 40 kg: > 6 |
| PetCO2 (mmHg) | Used indirectly together with **PetCO2 inc** as *To stop SBT* criteria.<br>For additional details, see Section 1.7.2. | If **PetCO2** > (upper limit INTELLiVENT-ASV PetCO2 target range + 3 mmHg), an ongoing SBT is stopped immediately. |
| PetCO2 inc (mmHg) | Configuration > Modes > SBT > To stop SBT window<br>End-tidal CO2 pressure increase compared to the values before the SBT. Only applies during an SBT. | > 8 mmHg |
| Psupport max (cmH2O) | INTELLiVENT-ASV Settings > Quick Wean/SBT settings window<br>Set the upper limit that **Psupport** cannot exceed during the SBT. | > 12 |
| Rate (b/min) | INTELLiVENT-ASV Settings > Quick Wean/SBT Settings window<br>Set the upper limit that **Rate** cannot exceed during SBT. | Patients > 30 kg: > 35<br>Patients ≤ 30 kg: > 45 |

| Parameter (unit) | Where set/how used | Default *To stop SBT* value |
|---|---|---|
| Rate inc | Configuration > Modes > SBT > To stop SBT window<br>Percentage increase in respiratory rate as a result of the SBT. Only applies during an SBT. | > 50% increase over the average rate established just prior to the SBT |
| RSB (1/(l*min)) | Not configurable. | > 105 |
| SpO2 (%) | Not configurable. | < (INTELLiVENT-ASV-set SpO2 target range) |
| Vt/IBW (ml/kg) | Configuration > Modes > SBT > To start SBT window<br>Here you specify the minimum**Vt/IBW** setting allowed during an SBT. | < 5 |
| Tolerance time (s) | Configuration > Modes > SBT > To stop SBT window | Patients > 40 kg: 180<br>Patients ≤ 40 kg: 30 |
| Max. duration (min) | Configuration > Modes > SBT > To stop SBT window | 30 |

## 2.7 Conditions for successfully completing an SBT

During an SBT, the device monitors parameters against the *To stop SBT* threshold values. If parameters remain in range for the duration set for the SBT (specified by the **Max. duration** parameter), the SBT is ended and marked as **SBT successfully fulfilled**. An **SBT Fulfilled** alarm is generated.

When an SBT is fulfilled, the device:

- Returns to the previous INTELLiVENT-ASV settings
- Returns **%MinVol** and **PEEP** (when automated) to the value prior to the start of the SBT
- Starts monitoring patient conditions against the *To start SBT* thresholds (Section 2.4), and the **Time between 2 SBTs** time.

## 2.8 About Quick Wean alarms and messages

Quick Wean provides a set of alarms and messages related to weaning activities, including SBTs. Messages are written to the Event log. Alarms and messages are displayed in the following locations:

- Alarm message bar
- Event log
- SBT history window

### To review and dismiss an alarm

▸ Do any of the following:

– Touch the message to open the Alarms > Buffer window. Review the message, then close the window.

– Touch the red I-icon and view the alarm log.

– Open the Alarms > Buffer window and review the alarm message, then close the window.

To review help information for the alarm, touch the alarm entry in the buffer. A short description is displayed.

The following table provides an overview of the Quick Wean-related alarms and messages. For detailed information about system alarms, see your ventilator *Operator's Manual*.

Table 2-10. Quick Wean alarms and messages

| Alarm message | Description |
|---|---|
| SBT aborted<br>*Medium priority.* | The SBT was stopped. For possible reasons, see Section 2.6.<br>Dismiss the alarm as described in Section 2.8. |
| SBT successfully fulfilled<br>*Medium priority.* | The SBT was ended because **Max. duration** was reached.<br>Dismiss the alarm as described in Section 2.8. |
| SBT stopped after HHH hours MM minutes | How long the SBT ran before being stopped.<br>Shown in SBT history window and Event log. |
| SBT started at YYYY-MM-DD HHH hours MM minutes | When an SBT starts automatically, this message records the time.<br>Shown in SBT history window and Event log. |
| SBT fulfilled after HHH hours MM minutes | When SBT ends successfully, this message records the time. The time is equal to the **Max. duration** value.<br>Shown in SBT history window. |
| SBT manually started at YYYY-MM-DD HHH hours MM minutes | When an SBT is manually started by selecting the **Start SBT** button, this message records the time.<br>Shown in SBT history window. |

| Alarm message | Description |
|---|---|
| SBT manually stopped after HHH hours MM minutes | When an SBT is manually ended by selecting the **Stop SBT** button, this message records for how long the SBT ran.<br>Shown in SBT history window and Event log. |
| Too high (red up arrow) and Too low (red down arrow) indicators | When a parameter's value goes above the allowed range, a red up arrow is displayed next to the parameter in the SBT history window.<br>When a parameter's value is below the allowed range, a red down arrow is displayed. |
| Within range (green checkmark) indicator | When a parameter's value is within the specified range, a green checkmark is displayed. |

## 2.9 Configuring Quick Wean and SBTs

You configure Quick Wean using the Configuration screens, in Standby mode. These settings cannot be modified while ventilating a patient.

While the default parameter values are all based on the currently available literature, you can change the settings if you prefer to use a different protocol.

The system monitors patient conditions against these parameter thresholds to determine whether the patient is ready for weaning activities, what adjustments to make when an SBT begins, and whether to stop the weaning activities.

For details on putting the ventilator into Standby and accessing Configuration mode, refer to the ventilator *Operator's Manual*.

Some settings are based on the patient's weight: patients weighing > 40 kg and those weighing ≤ 40 kg. For the list of default values, see Table 2-12.

### 2.9.1 Adjusting default SBT values in Configuration

The default SBT control settings are defined in the following locations:

- In Configuration mode, in the Modes > SBT windows: To start SBT, SBT settings, and To stop SBT
- In the INTELLiVENT-ASV Settings > Quick Wean/SBT settings window (Section 2.3)

The SBT configuration windows provide access to the following controls:

Table 2-11. SBT default settings configuration windows

| Configuration window | Controls |
|---|---|
| To start SBT | Patient conditions are monitored against the limits defined here for the listed parameters to determine when they are ready for an SBT: **PEEP**, **Oxygen**, **Vt/IBW**, **Tolerance time** |
| SBT settings | When an SBT begins, the device adjusts **PEEP** (when automated) and **%MinVol** to the values specified here. |
| To stop SBT | During an SBT, patient conditions are monitored against the limits defined here for the listed parameters to determine whether to stop the SBT: **Rate inc**, **PetCO2 inc**, **Tolerance time**, **Max. duration** |

Each of these windows is divided into two groups: the controls on the top half apply to patients weighing > 40 kg; the controls on the bottom half apply to patients weighing ≤ 40 kg.

You can change the default settings to match your institution's protocol, if needed.

**To change the default *To start SBT*, *SBT*, and/or *To stop SBT* settings in Configuration**

1. Without a patient connected, put the ventilator into Standby.
2. Access the Configuration screens, and on the left side, touch **Modes**, then touch **SBT**.

   The **SBT** tabs appear, with the *To start SBT* parameters displayed by default.
3. In the To start SBT window, review and adjust the threshold values for starting an SBT for the following parameters: PEEP, Oxygen, Vt/IBW, and Tolerance time.

   For details about the parameters, see Table 2-6.
4. Touch the **SBT settings** tab to review and adjust the starting PEEP and %MinVol values for an SBT.

   When conditions to start an SBT are met, the device adjusts these parameters to the values set here for the duration of the SBT.
5. Touch the **To stop SBT** tab to review and adjust the threshold values for stopping an SBT for the following parameters: Rate inc, PetCO2 inc, Tolerance time, and Max. duration.

   For details about the parameters, see Table 2-9.
6. To reset the values to the factory defaults, touch the **Use factory settings** button, and when prompted to confirm, touch **Yes**.

   Touch **No** to cancel the reset.

   All of the controls on all three SBT windows are reset to the factory default settings.
7. Touch the **Back** button to return to the main Configuration window.
8. When finished, exit Configuration mode.

## 2.9.2 Restoring factory default settings

**To return the SBT parameter values to factory defaults**

1. Open the Configuration > Modes > SBT window.
2. Touch the **Use factory settings** button.

   All of the controls on all three SBT windows are reset to the factory default settings.

   Note that this does not affect the SBT parameters that are set in the INTELLiVENT-ASV Settings window. Those parameter defaults are configured in individual Quick Setups.

## 2.10 Quick Wean parameter specifications

The following table is a comprehensive list of all of the Quick Wean-related parameters.

For the definition of a parameter, see Section 2.1.2.

Note that references to the Quick Wean status window apply to both *Quick Wean* and *Quick Wean & SBT*.

Table 2-12. Quick Wean parameters

| Parameter | Default values | Where displayed/Where set | Range |
|---|---|---|---|
| %fSpont (%) | **To start SBT:** 100% | **Displayed in:** SBT history window **Set in:** N/A (calculated value) | -- |
| fSpont | -- | **Displayed in:** • Quick Wean & SBT status window • SBT history window • Monitoring window **Set in:** N/A | -- |
| Max. duration (min) | By default, set to 30 minutes OFF means that there is no limit to how long the SBT can run. | **Displayed and set in:** Configuration > Modes > SBT > To stop SBT | OFF, 20–240 |
| %MinVol (%) | **Quick Wean enabled:** 70 **During SBT:** 25 | **Displayed in:** INTELLiVENT-ASV main display in the **%MinVol** control **Set in:** Configuration > Modes > SBT > SBT settings | **%MinVol during SBT:** 25–70 |
| Oxygen (%) | **To start SBT:** ≤ 40 **To stop SBT:** > 50 The buttons are interdependent: The *To start SBT* setting is always 10 below the *To stop SBT* setting. | **Displayed in:** • INTELLiVENT-ASV main display in the **Oxygen** control • Quick Wean & SBT status window • SBT history window • Monitoring window **Set in:** Configuration > Modes > SBT >To start SBT | **To start SBT:** 30–50 **To stop SBT:** 40–60 |

| Parameter | Default values | Where displayed/Where set | Range |
|---|---|---|---|
| PEEP (cmH2O) | **To start SBT:**<br>Patients > 40 kg: ≤ 8<br>Patients ≤ 40 kg: ≤ 6<br>**To stop SBT:**<br>Patients > 40 kg: > 8<br>Patients ≤ 40 kg: > 6<br>**During SBT:**<br>**PEEP** is set to 5 by default. | **Displayed in:**<br>• INTELLiVENT-ASV main display in **PEEP** control<br>• Quick Wean & SBT status window<br>• SBT history window<br>• Monitoring window<br>**Set in:**<br>• Configuration > Modes > SBT > To start SBT<br>• Configuration > Modes > SBT > SBT settings | **To start SBT:**<br>5–10<br>**PEEP during SBT:**<br>0–5 |
| PetCO2 (mmHg) | **To stop SBT:**<br>PetCO2 > (upper limit INTELLiVENT-ASV PetCO2 target range + 3 mmHg) | **Displayed in:**<br>• Patients ≤ 40 kg: Quick Wean status panel<br>• SBT history window<br>• Ventilation horizon and map<br>• Monitoring > CO2 window<br>• Dynamic Lung panel<br>This value is not configured. You can, however, shift the target range, if needed. See Section 1.4.10.3. | Depends on PetCO2 target range |
| PetCO2 inc (mmHg) | **To stop SBT:**<br>> 8 increase | Not displayed.<br>**Set in:** Configuration > Modes > SBT > To stop SBT | 4–20 |
| Psupport max (cmH2O) | **To start SBT:**<br>≤ 12<br>**To stop SBT:**<br>> 12 | **Displayed in:**<br>• INTELLiVENT-ASV Settings > Quick Wean/SBT settings window<br>• SBT history window<br>**Set in:** INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | 6–25 |

| Parameter | Default values | Where displayed/Where set | Range |
|---|---|---|---|
| RSB (1 /(l*min)) | **To start SBT:** ≤ 105<br>**To stop SBT:** > 105 | **Displayed in:**<br>• Patients > 40 kg: Quick Wean & SBT status panel<br>• SBT history window<br>The **RSB** parameter is only used for patients weighing > 40 kg.<br>This value is not configured. | 105 |
| Rate (b/min) | **To start SBT:**<br>Patients > 30 kg: ≤ 35<br>Patients ≤ 30 kg: ≤ 45<br>**To stop SBT:**<br>Patients > 30 kg: > 35<br>Patients ≤ 30 kg: > 45 | **Displayed in:**<br>• Quick Wean & SBT status window (as **fSpont**)<br>• SBT history window (as **fSpont**)<br>• INTELLiVENT-ASV Settings > Quick Wean/SBT settings window<br>**Set in:** INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | 25–65 |
| Rate inc (%) | **To stop SBT:**<br>> 50% increase over the average rate established just prior to the start of the SBT | **Displayed in:**<br>SBT history window<br>**Set in:** Configuration > Modes > SBT > To stop SBT | 20–100 |
| SBT time range | To allow SBTs at any time, set both controls to the same time.<br>**Default:** Between 8:00 and 20:00. | **Displayed and set in:** INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | HH:MM |

| Parameter | Default values | Where displayed/Where set | Range |
|---|---|---|---|
| SpO2 (%) | **To start SBT:** Within or above the INTELLiVENT-ASV SpO2 target range<br>**To stop SBT:** Below the INTELLiVENT-ASV SpO2 target range minus 2% | **Displayed in:**<br>• Oxygenation horizon and map (views 1, 2, 3)<br>• Monitoring > SpO2 window<br>• SBT history window<br>• Dynamic Lung panel<br>• Main window under MMP list<br>This value is not configured. You can, however, shift the target range, if needed. See Section 1.4.10.3. | Depends on the SpO2 target range |
| Time before starting SBT (min) | By default, set to 30 minutes | **Displayed and set in:** INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | 10–120 |
| Time between 2 SBTs (min) | **To start next SBT:** By default, 30 minutes | **Displayed and set in:** INTELLiVENT-ASV Settings > Quick Wean/SBT settings window | 30–240 |
| Tolerance time (s) | **To start SBT:** Patients > 40 kg: 180 s<br>Patients ≤ 40 kg: 60 s<br>**To stop SBT:** Patients > 40 kg: 180 s<br>Patients ≤ 40 kg: 30 s | **Displayed and configured in:**<br>• Configuration > Modes > SBT > To start SBT<br>• Configuration > Modes > SBT > To stop SBT | 10–300 |
| | For the following parameters, the **Tolerance time** setting is predefined (regardless of the Configuration settings):<br>• **%fSpont**: must be 100% for a minimum of 60 seconds<br>• For patients ≤ 40 kg, the **Tolerance Time** for **Rate** and **Vt/IBW** is 180 seconds | | |
| Vt/IBW (ml/ kg) | **To start SBT:** ≥ 5 ml/kg<br>**To stop SBT:** < 5 ml/kg | **Displayed in:**<br>• Quick Wean & SBT status window<br>• SBT history window<br>• Monitoring window<br>**Set in:** Configuration > Modes > SBT > To start SBT | 3–6 |

# 3 Specifications

## 3.1 Intended use

The INTELLiVENT-ASV software is an option for the HAMILTON-C6 ventilator, and is, for all legal purposes, subject to the Intended Use as stated in the current ventilator *Operator's Manual*.

## 3.2 Technical data

The following table provides technical data related to INTELLiVENT-ASV.

Table 3-1. INTELLiVENT-ASV technical data

| **Operator settings** | |
|---|---|
| **Patient height** (cm) | 30 to 250 (adult, pediatric) |
| **%MinVol** (%) | 25 to 350 (manual)<br>70 to 200 (automatic) |
| **Oxygen** (%) | 21 to 100 (manual and automatic) |
| **PEEP** (cmH2O) | 0 to 50 (manual)<br>5 to 24 (automatic) |

| **Internal calculations** | |
|---|---|
| Ideal body weight, **IBW** (kg) | Calculation based on patient height and gender. For details, see your ventilator *Operator's Manual*.<br>INTELLiVENT-ASV can only be used for patients weighing more than 7 kg. |
| **MinVol** (target) (l/min) | Target **MinVol** is calculated as:<br>**IBW x NormMinVent x %MinVol/100**<br>where *NormMinVent* (l/kg/min) is the normal minute ventilation (not valid for pediatric patients < 30 kg). For details, see your ventilator *Operator's Manual*. |
| ASV target respiratory rate (b/min) | Calculated as described in Section 1.7.2. |
| **Vdaw** (ml/kg) | Calculation of the dead space: **IBW x 2.2** |
| **Vt** (target) | **MinVol/f** (target) |

| Monitoring | |
|---|---|
| Values (numerical) | PetCO2 target range, depending on patient condition and treatment (Ppeak); SpO2 target range, depending on patient condition and treatment (PEEP) |
| Current ventilation settings | ExpMinVol, fTotal, fControl, Ppeak (Pinsp + PEEP), Oxygen, PEEP |
| Patient status | fSpont, PetCO2, SpO2 |
| Graphics | f (target)/Vt, PetCO2/target, PEEP/O2, PEEP/SpO2 |
| Trend parameters | Ventilation control, Oxygenation control |

| Performance specifications, Ventilation controller | |
|---|---|
| Settling time | < 5 minutes |
| Response time (90% of steady state) | < 5 minutes (typical) |
| (Rel./command) Overshoot/ undershoot | < 20% |
| Steady state deviation | 5% |
| Maximum change of %MinVol per breath | 1% |

| Performance specifications, Oxygenation controller | | |
|---|---|---|
| | **Oxygen** | **PEEP** |
| Settling time | The settling time depends on the patient condition relative to the **SpO2** target, as defined by the appropriate approach (ARDSnet or Open Lung concept) for the current treatment. Note that if **SpO2** enters the emergency zone, the system immediately sets **Oxygen** to 100%. | 6 minutes |
| Response time (90% of steady state) | N/A, only target range for **SpO2** specified | 6 minutes |
| Rel/Command overshoot | none | N/A, **SpO2** of some patients does not respond at all to **PEEP** changes. In this case, **Oxygen** is also changed if it is set to **Automatic**. |
| Command overshoot | none | N/A, **SpO2** of some patients does not respond at all to **PEEP** changes. Upper **PEEP** limit, 24 cmH2O, user can set lower limit. |
| Steady state deviation | N/A, only target range for SpO2 specified | N/A, only target range for **SpO2** specified |
| Tracking error | N/A | N/A, only target range for **SpO2** specified |
| Maximum change | Decrease: 5% of current **Oxygen** setting every 60 s<br>Increase: 10% of current **Oxygen** setting every 30 s | 1 cmH2O every 6 min |

| Lung-protective ventilation, Ventilation controller | |
|---|---|
| Minimum %MinVol | 70% (100% if no PetCO2 is available) |
| Maximum %MinVol | 200% |

| Lung-protective ventilation, Oxygenation controller | |
|---|---|
| Minimum Oxygen | 21% or 30%, depending on what is selected in the Oxygen limit control in the INTELLiVENT-ASV Settings > More window.<br>Default: 30% |
| Maximum Oxygen | 100% |
| PEEP limits | Low: 5 to 22 (Default: 5)<br>High: 7 to 24 (Default: 15) |

## 3.3 Data logging

Breath-by-breath data representing the actual values of these listed monitoring values and settings are saved by the ventilation unit of the processor.

Table 3-2. Data log inputs

| Saved parameters | Unit |
|---|---|
| Date | N/A |
| Time | N/A |
| ARDS | N/A |
| Chronic hypercapnia | N/A |
| Brain injury | N/A |
| Quick Wean | N/A |
| Controller ventilation | N/A |
| Controller oxygenation | N/A |
| Controller PEEP | N/A |
| Recruitment passive | N/A |
| Recruitment running | N/A |
| fSpont | N/A |
| PEEP limit | cmH2O |
| %MinVol | % |
| ExpMinVol | l/min |
| RRIMV | breaths per min |
| RRtot | breaths per min |
| RRtarget | breaths per min |
| fSpont | breaths per min |
| Ti | s |
| Pinsp | cmH2O |
| SpO2 | % |
| PetCO2 | mmHg |
| Oxygen | % |
| PEEP/CPAP | cmH2O |
| Pulse | bpm (beats per minute) |
| QI-SpO2 | % |
| VtTarget | ml |
| RCexp | s |

The memory reserved for breath-by-breath data allows storage of at least 10 days of recording. The data is saved breath-by-breath, but at most one time per second.

Data is exported using the test software. Refer to the ventilator *Service Manual*.

## 3.4 References

References are available on the Hamilton Medical website, **www.hamilton-medical.com**.

**active patient**
An active patient is one who is making inspiratory efforts. Active breathing is identified as the occurrence of at least five (5) consecutive spontaneous breaths. Spontaneous breaths are those for which inspiration is both patient triggered and patient cycled. In addition to spontaneous breaths as described, an active patient must also meet the requirements described in the rules for transitioning between active and passive states.

**alarm buffer**
Contains information on recent alarm occurrences

**ARDS**
Acute respiratory distress syndrome, which presents as an acute, severe injury to most segments of the lung

**brain injury**
Patients with brain injuries with whom it is critical to maintain CO2 under strict control to keep intracranial pressures at safe levels, and to keep oxygenation within a normal range

**chronic hypercapnia**
For patients with chronically high arterial CO2 values, usually as a result of obstruction in airways due to chronic bronchitis, emphysema, or both

**IBW**
Ideal body weight; a calculated value for adult and pediatric patients based on the patient's gender and height; used as the basis for the initial settings of various parameters

**Oxygen**
Oxygen (FiO2) concentration of the delivered gas, a control setting, monitored parameter.

**Oxygenation controller**
Automated PEEP and Oxygen controller, available in INTELLiVENT-ASV

**PaCO2-PetCO2 gradient**
The difference between the PaCO2 measured in the blood (using blood gas analysis) and the PetCO2 measured using a noninvasive CO2 sensor. Under normal conditions, PaCO2 is approximately 3-5 mmHg higher than PetCO2.

**passive patient**
A passive patient is one who is not making inspiratory efforts. Passive breathing is identified as the occurrence of at least five (5) consecutive mandatory breaths. In general, mandatory breaths are those for which inspiration is either machine triggered or machine cycled. In INTELLiVENT-ASV, mandatory inspirations are both machine triggered and machine cycled. In addition to mandatory breaths as described, a passive patient must also meet the requirements described in the rules for transitioning between active and passive status.

**PEEP/CPAP**
PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure), a control setting and monitored parameter. PEEP and CPAP are constant pressures applied during both the inspiratory and expiratory phases.

**Plethysmogram**
The waveform that visualizes the pulsating blood volume; it is delivered by the pulse oximeter.

**SpO2**
Oxygen saturation.

**Ventilation controller**
Automated %MinVol controller, available in INTELLiVENT-ASV. The controller uses different inputs to control the target minute volume, depending on whether the patient is passive or active.

## Icons



## A



## B



## C



## D



## F



## I



## M

## O



## P



## Q



## R



## S

## T



## V

For more information:
www.hamilton-medical.com

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz, Switzerland
☎ +41 (0)58 610 10 20
info@hamilton-medical.com
**www.hamilton-medical.com**

EC REP
medin Innovations GmbH
Adam-Geisler-Strasse 1
DE – 82140 Olching

## Manufacturer Disclosure Statement for Medical Device Security – MDS$^2$

### DEVICE DESCRIPTION

| Device Category | Manufacturer | Document ID | Document Release Date |
|---|---|---|---|
| Ventilator | Hamilton Medical AG | HAM_MDS | 11.05.2020 |

| Device Model | Software Revision | Software Release Date |
|---|---|---|
| HAMILTON-C6 | SW 1.1.4 | 08.07.2019 |

| | Company Name | Manufacturer Contact Information |
|---|---|---|
| Manufacturer or Representative Contact Information | Hamilton Medical AG | Hamilton Medical AG<br>Via Crusch 8, 7402 Bonaduz, Switzerland |
| | Representative Name/Position<br>Annemarie Weideli / Team Leader RA | |

**Intended use** of **device** in network-connected environment:

The HAMILTON-C6 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

The HAMILTON-C6 cannot be connected to a network and/or the internet. There is an RS232 point to point connection possibility for outgoing data only (no bi-directional communication).

### MANAGEMENT OF PRIVATE DATA

| | Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form. | Yes, No, N/A, or See Note | Note # |
|---|---|---|---|
| A | Can this **device** display, transmit, or maintain **private data** (including **electronic Protected Health Information** [ePHI])? | Yes | |
| B | Types of **private data** elements that can be maintained by the **device**: | | |
| B.1 | Demographic (e.g., name, address, location, unique identification number)? | No | |
| B.2 | Medical record (e.g., medical record #, account #, test or treatment date, **device** identification number)? | Yes | 1 |
| B.3 | Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)? | Yes | 2 |
| B.4 | Open, unstructured text entered by **device user/operator**? | No | |
| B.5 | **Biometric data**? | No | |
| B.6 | Personal financial information? | No | |
| C | Maintaining **private data** - Can the **device**: | | |
| C.1 | Maintain **private data** temporarily in volatile memory (i.e., until cleared by power-off or reset)? | Yes | |
| C.2 | Store **private data** persistently on local media? | Yes | 3 |
| C.3 | Import/export **private data** with other systems? | Yes | 4 |
| C.4 | Maintain **private data** during power service interruptions? | Yes | 3 |
| D | Mechanisms used for the transmitting, importing/exporting of **private data** – Can the **device**: | | |
| D.1 | Display private data (e.g., video display, etc.)? | Yes | |
| D.2 | Generate hardcopy reports or images containing **private data**? | Yes | 5 |
| D.3 | Retrieve **private data** from or record **private data** to **removable media** (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)? | Yes | 6 |
| D.4 | Transmit/receive or import/export **private data** via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)? | Yes | 4 |
| D.5 | Transmit/receive **private data** via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)? | No | |
| D.6 | Transmit/receive **private data** via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)? | No | |
| D.7 | Import **private data** via scanning? | No | |
| D.8 | Other? | No | |

Management of Private Data notes: #1 Device Serial Number; #2 Height, Weight, Patient Type (Adult, Pediatric, Neonatal), Gender; #3 Event Log; #4 RS232 Communication Protocols; #5 Screen Shot / DVI; #6 USB

| Device Category | Manufacturer | Document ID | Document Release Date |
|---|---|---|---|
| Ventilator | Hamilton Medical AG | HAM_MDS | 43962 |
| **Device Model** | **Software Revision** | | **Software Release Date** |
| HAMILTON-C6 | SW 1.1.4 | | 43654 |

## SECURITY CAPABILITIES

| | Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form. | Yes, No, N/A, or See Note | Note # |
|---|---|---|---|
| **1** | **AUTOMATIC LOGOFF (ALOF)** | | |
| | The **device**'s ability to prevent access and misuse by unauthorized **users** if **device** is left idle for a period of time. | | |
| 1-1 | Can the **device** be configured to force reauthorization of logged-in **user**(s) after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)? | No | 1 |
| 1-1.1 | Is the length of inactivity time before auto-logoff/screen lock **user** or administrator configurable? (Indicate time [fixed or configurable range] in notes.) | N/A | __ |
| 1-1.2 | Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the **user**? | N/A | __ |
| ALOF notes: | #1 During emergency situations immediate access must be guaranteed | | |
| **2** | **AUDIT CONTROLS (AUDT)** | | |
| | The ability to reliably audit activity on the **device**. | | |
| 2-1 | Can the **medical device** create an **audit trail**? | Yes | __ |
| 2-2 | Indicate which of the following events are recorded in the audit log: | | |
| 2-2.1 | Login/logout | No | __ |
| 2-2.2 | Display/presentation of data | No | __ |
| 2-2.3 | Creation/modification/deletion of data | Yes | 1 |
| 2-2.4 | Import/export of data from **removable media** | No | __ |
| 2-2.5 | Receipt/transmission of data from/to external (e.g., network) connection | No | __ |
| 2-2.5.1 | **Remote service** activity | No | __ |
| 2-2.6 | Other events? (describe in the notes section) | Yes | 2 |
| 2-3 | Indicate what information is used to identify individual events recorded in the audit log: | | |
| 2-3.1 | **User** ID | No | __ |
| 2-3.2 | Date/time | Yes | __ |
| AUDT notes: | #1 Modification of controls<br>#2 Alams, Technical Events | | |
| **3** | **AUTHORIZATION (AUTH)** | | |
| | The ability of the device to determine the authorization of users. | | |
| 3-1 | Can the **device** prevent access to unauthorized **users** through **user** login requirements or other mechanism? | No | 1 |
| 3-2 | Can **users** be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular **users**, power **users**, administrators, etc.)? | No | __ |
| 3-3 | Can the **device** owner/**operator** obtain unrestricted administrative privileges (e.g., access operating system or application via local root or admin account)? | No | __ |
| AUTH notes: | #1 During emergency situations immediate access must be guaranteed | | |

| Device Category | Manufacturer | Document ID | Document Release Date |
|---|---|---|---|
| Ventilator | Hamilton Medical AG | HAM_MDS | 43962 |
| **Device Model** | **Software Revision** | | **Software Release Date** |
| HAMILTON-C6 | SW 1.1.4 | | 43654 |

| | Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form. | Yes, No, N/A, or See Note | Note # |
|---|---|---|---|
| **4** | **CONFIGURATION OF SECURITY FEATURES (CNFS)** | | |
| | The ability to configure/re-configure **device security capabilities** to meet **users'** needs. | | |
| 4-1 | Can the **device** owner/operator reconfigure product **security capabilities**? | No | |
| CNFS notes: | | | |
| **5** | **CYBER SECURITY PRODUCT UPGRADES (CSUP)** | | |
| | The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade **device**'s security patches. | | |
| 5-1 | Can relevant OS and **device** security patches be applied to the **device** as they become available? | Yes | 1 |
| 5-1.1 | Can security patches or other software be installed remotely? | No | 2 |
| CSUP notes: | #1 Device Software Update<br>#2 Can only be done by a certified service technician | | |
| **6** | **HEALTH DATA DE-IDENTIFICATION (DIDT)** | | |
| | The ability of the **device** to directly remove information that allows identification of a person. | | |
| 6-1 | Does the **device** provide an integral capability to de-identify **private data**? | No | |
| DIDT notes: | | | |
| **7** | **DATA BACKUP AND DISASTER RECOVERY (DTBK)** | | |
| | The ability to recover after damage or destruction of **device** data, hardware, or software. | | |
| 7-1 | Does the **device** have an integral data backup capability (i.e., backup to remote storage or **removable media** such as tape, disk)? | No | |
| DTBK notes: | | | |
| **8** | **EMERGENCY ACCESS (EMRG)** | | |
| | The ability of **device users** to access **private data** in case of an emergency situation that requires immediate access to stored **private data**. | | |
| 8-1 | Does the **device** incorporate an **emergency access** ("break-glass") feature? | Yes | |
| EMRG notes: | | | |
| **9** | **HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)** | | |
| | How the **device** ensures that data processed by the **device** has not been altered or destroyed in an unauthorized manner and is from the originator. | | |
| 9-1 | Does the **device** ensure the integrity of stored data with implicit or explicit error detection/correction technology? | Yes | |
| IGAU notes: | | | |

| Device Category | Manufacturer | Document ID | Document Release Date |
|---|---|---|---|
| Ventilator | Hamilton Medical AG | HAM_MDS | 43962 |
| **Device Model** | **Software Revision** | | **Software Release Date** |
| HAMILTON-C6 | SW 1.1.4 | | 43654 |

| | Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form. | Yes, No, N/A, or See Note | Note # |
|---|---|---|---|
| **10** | **MALWARE DETECTION/PROTECTION (MLDP)** | | |
| | The ability of the **device** to effectively prevent, detect and remove malicious software (**malware**). | | |
| 10-1 | Does the **device** support the use of **anti-malware** software (or other **anti-malware** mechanism)? | No | 1 |
| 10-1.1 | Can the **user** independently re-configure **anti-malware** settings? | N/A | __ |
| 10-1.2 | Does notification of **malware** detection occur in the **device user** interface? | N/A | __ |
| 10-1.3 | Can only manufacturer-authorized persons repair systems when **malware** has been detected? | N/A | __ |
| 10-2 | Can the device owner install or update **anti-virus software**? | No | __ |
| 10-3 | Can the device owner/**operator** (technically/physically) update virus definitions on manufacturer-installed **anti-virus software**? | N/A | __ |
| MLDP notes: | #1 Standalone device and embedded operating system | | |
| **11** | **NODE AUTHENTICATION (NAUT)** | | |
| | The ability of the **device** to authenticate communication partners/nodes. | | |
| 11-1 | Does the **device** provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information? | No | __ |
| NAUT notes: | Serial number provided over RS232 protocols<br>No possibility to receive data from external device (unidirectional protocol) | | |
| **12** | **PERSON AUTHENTICATION (PAUT)** | | |
| | Ability of the **device** to authenticate **users** | | |
| 12-1 | Does the **device** support **user/operator**-specific username(s) and password(s) for at least one **user**? | No | __ |
| 12-1.1 | Does the device support unique **user/operator**-specific IDs and passwords for multiple users? | N/A | __ |
| 12-2 | Can the **device** be configured to authenticate **users** through an external authentication service (e.g., MS Active Directory, NDS, LDAP, etc.)? | No | 1 |
| 12-3 | Can the **device** be configured to lock out a **user** after a certain number of unsuccessful logon attempts? | No | __ |
| 12-4 | Can default passwords be changed at/prior to installation? | No | __ |
| 12-5 | Are any shared **user** IDs used in this system? | No | __ |
| 12-6 | Can the **device** be configured to enforce creation of **user** account passwords that meet established complexity rules? | No | __ |
| 12-7 | Can the **device** be configured so that account passwords expire periodically? | No | __ |
| PAUT notes: | #1 Standalone device not connected to network | | |
| **13** | **PHYSICAL LOCKS (PLOK)** | | |
| | Physical locks can prevent unauthorized **users** with physical access to the **device** from compromising the integrity and confidentiality of **private data** stored on the **device** or on **removable media**. | | |
| 13-1 | Are all **device** components maintaining **private data** (other than **removable media**) physically secure (i.e., cannot remove without tools)? | Yes | __ |
| PLOK notes: | | | |

| Device Category | Manufacturer | Document ID | Document Release Date |
|---|---|---|---|
| Ventilator | Hamilton Medical AG | HAM_MDS | 43962 |
| **Device Model** | **Software Revision** | | **Software Release Date** |
| HAMILTON-C6 | SW 1.1.4 | | 43654 |

| | Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form. | Yes, No, N/A, or See Note | Note # |
|---|---|---|---|
| **14** | **ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)** | | |
| | Manufacturer's plans for security support of 3rd party components within **device** life cycle. | | |
| 14-1 | In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s). | See Note | 1 |
| 14-2 | Is a list of other third party applications provided by the manufacturer available? | Yes | __ |
| RDMP notes: | #1 VxWorks Version 6.X | | |
| **15** | **SYSTEM AND APPLICATION HARDENING (SAHD)** | | |
| | The **device**'s resistance to cyber attacks and **malware**. | | |
| 15-1 | Does the **device** employ any hardening measures? Please indicate in the notes the level of conformance to any industry-recognized hardening standards. | Yes | 1 |
| 15-2 | Does the **device** employ any mechanism (e.g., release-specific hash key, checksums, etc.) to ensure the installed program/update is the manufacturer-authorized program or software update? | Yes | 4 |
| 15-3 | Does the **device** have external communication capability (e.g., network, modem, etc.)? | Yes | 2 |
| 15-4 | Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)? | No | 5 |
| 15-5 | Are all accounts which are not required for the **intended use** of the **device** disabled or deleted, for both **users** and applications? | N/A | __ |
| 15-6 | Are all shared resources (e.g., file shares) which are not required for the **intended use** of the **device**, disabled? | Yes | __ |
| 15-7 | Are all communication ports which are not required for the **intended use** of the **device** closed/disabled? | Yes | 3 |
| 15-8 | Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the **intended use** of the **device** deleted/disabled? | Yes | __ |
| 15-9 | Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the **intended use** of the **device** deleted/disabled? | Yes | __ |
| 15-10 | Can the **device** boot from uncontrolled or **removable media** (i.e., a source other than an internal drive or memory component)? | No | __ |
| 15-11 | Can software or hardware not authorized by the **device** manufacturer be installed on the device without the use of tools? | No | __ |
| SAHD notes: | #1 Security Patches, White Listing of Software Processes (Software Update); #2 RS232 Point to Point Communication #3 Ethernet Interface disabled; #4 Checksum and digitaly singed package; #5 The used File System doesn't support file-level access controls | | |
| **16** | **SECURITY GUIDANCE (SGUD)** | | |
| | The availability of security guidance for **operator** and administrator of the system and manufacturer sales and service. | | |
| 16-1 | Are security-related features documented for the **device user**? | No | __ |
| 16-2 | Are instructions available for **device**/media sanitization (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data)? | No | __ |
| SGUD notes: | | | |

| Device Category | Manufacturer | Document ID | Document Release Date |
|---|---|---|---|
| Ventilator | Hamilton Medical AG | HAM_MDS | 43962 |
| **Device Model** | **Software Revision** | | **Software Release Date** |
| HAMILTON-C6 | SW 1.1.4 | | 43654 |

| | Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form. | Yes, No, N/A, or See Note | Note # |
|---|---|---|---|
| **17** | **HEALTH DATA STORAGE CONFIDENTIALITY (STCF)** | | |
| | The ability of the **device** to ensure unauthorized access does not compromise the integrity and confidentiality of **private data** stored on **device** or **removable media**. | | |
| 17-1 | Can the **device** encrypt data at rest? | No | __ |
| STCF notes: | | | |
| **18** | **TRANSMISSION CONFIDENTIALITY (TXCF)** | | |
| | The ability of the **device** to ensure the confidentiality of transmitted **private data**. | | |
| 18-1 | Can **private data** be transmitted only via a point-to-point dedicated cable? | Yes | __ |
| 18-2 | Is **private data** encrypted prior to transmission via a network or **removable media**? (If yes, indicate in the notes which encryption standard is implemented.) | No | __ |
| 18-3 | Is **private data** transmission restricted to a fixed list of network destinations? | N/A | 1 |
| | #1 Standalone device not connected to network | | |
| TXCF notes: | | | |
| **19** | **TRANSMISSION INTEGRITY (TXIG)** | | |
| | The ability of the **device** to ensure the integrity of transmitted **private data**. | | |
| 19-1 | Does the **device** support any mechanism intended to ensure data is not modified during transmission? (If yes, describe in the notes section how this is achieved.) | Yes | 1 |
| | #1 Polling protocol (parity bit, limited range of ASCII characters) / Block Protocol (CRC) | | |
| TXIG notes: | | | |
| **20** | **OTHER SECURITY CONSIDERATIONS (OTHR)** | | |
| | Additional security considerations/notes regarding **medical device** security. | | |
| 20-1 | Can the **device** be serviced remotely? | No | __ |
| 20-2 | Can the **device** restrict remote access to/from specified devices or **users** or network locations (e.g., specific IP addresses)? | No | __ |
| 20-2.1 | Can the **device** be configured to require the local **user** to accept or initiate remote access? | No | __ |
| OTHR notes: | | | |

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD America

# CERTIFICATE

**No. U8 058067 0079 Rev. 00**

**Holder of Certificate:** **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
SWITZERLAND

**Production Facility(ies):** 102325

**Certification Mark:**

**Product:** **Humidifiers for medical use**

**Model(s):** **HAMILTON-H900**

**Parameters:**

| | |
|---|---|
| Rated Input Voltage: | Ref.:950004 110-127 VAC |
| Rated Frequency: | 50/60 Hz |
| Rated Input Power: | 293 VA |
| Protection against ingress of water: | IP21 |
| Protection Class: | I |
| Applied Part Type: | BF |

Remarks:
The certificate is valid for USA and Canada.
Other countries might have other requirements, which were not part of this certification.

**Tested according to:** CAN/CSA-22.2 No. 60601-1:14
ANSI/AAMI ES60601-1:2005/(R)2012

The product was voluntarily tested according to the relevant safety requirements noted above. It can be marked with the certification mark above. The mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing and Certification Regulations". TÜV SÜD America Inc. is an OSHA recognized NRTL and a Standards Council of Canada accredited certification body.

**Test report no.:** 713145152

**Date,** 2019-01-10

( Paul Bielawski )


TÜV SÜD America Inc. • 10 Centennial Drive • Peabody • MA 01960 • USA

TÜV®

A4 / 07.17

**Zertifiziervertrag**
Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierordnung von TÜV SÜD Product Service.
Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

**Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:**
- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben

und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

---

**Certification contract**
Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations.
On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

**Requirements for the validity of the certificate in principle:**
- Validity of the quoted test standard(s)

In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

---

**认证合约**

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

**维持证书有效性的原则要求：**
- 认证所依据标准的有效性

此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
- 生产场地通过定期的监督

---

**認証契約**

認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

**認証書の有効性に関する原則的な要求事項**
- 引用している試験規格が有効である

さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
- 定期的な工場監査を実施している

---

**Contrato de certificação**
A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD.
Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

**Requisitos para a validade do certificado (em princípio):**
- Validade da(s) norma(s) de ensaio(s) referenciada(s).

Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
- Auditoria de monitoração realizada regularmente.