Specificație Completată
Ventilator pulmonar adult, pediatric (caracteristici avansate)
Model: Hamilton-C6 Producător: HAMILTON Medical AG; Tara: ELVEȚIA.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Ventilator pulmonar adult, pediatric (caracteristici avansate) Cod 110330 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. Parametrul Specificația Tip Mobil, pe suport cu rotile da Tip pacient adult, pediatric da Gama de control/setări Volum total 20-2,500 mL Flux inspir 3-180 L/min Presiune inspir 0-100 cm H2O Rata respiratorie 0-100 rpm Timp inspir 0.1 - 8 s. Rata I:E 1:8 to 4:1 FiO2, % 21-100 Buton pentru respirație manuală da PEEP/CPAP 0-50 cm H2O Suport presiune 0-50 cm H2O Inhalator da Mecanism triger Presiune Flux Ajustarea presiunii pantă/rampă da Funcția suspin da Buton 100 % O2 da Timpul maxim activ al butonului 100 % O2 2 min Blocarea panoului de control da Moduri de operare Modul A/C A/C Volum respirator da A/C presiune respiratorie da Modul SIMV SIMV volum respirator da SIMV presiune respiratorie da Modul CPAP CPAP, CPAP/suport presiune (PS) da Modul Apnea-backup da Moduri combinate da Ventilație neinvazivă da Modul Bilevel/APRV da Parametri monitorizați/afișați Presiunea inspiratorie maximă da Presiunea medie în căile respiratorii da Presiunea PEEP da Volumul total da Monitorizarea FiO2 da Rata respiratorie da Timp inspir da Timp expir da Rata I:E da Volumul minutar spontan da Alarme pacient FiO2 mare/mic da Volum minutar mare/mic da	Ventilator pulmonar adult, pediatric (caracteristici avansate) **DA** Cod 110330 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** Parametrul Specificația Tip Mobil, pe suport cu rotile **DA** Tip pacient adult, pediatric **DA** Gama de control/setări Volum tital 20-2000 ml **DA** Flux inspator de vîrf (peak flow) 1 -195 L/min **DA** Presiune inspir, 3-100 cmH2O **DA** Rata respiratorie 1-80 rpm **DA** Timp inspir, **0.1 - 12s DA** Rata I:E 1:9 to 4:1 **DA** FiO2, % 21-100 **DA** Buton pentru respirație manuală **DA** PEEP/CPAP 0-50 cmH2O **DA** Suport presiune, 0-100 cmH2O **DA** Inhalator **DA** Mecanism triger Presiune **DA** Flux 0.5-20 L/min **DA** Ajustarea presiunii pantă/rampă **DA** Funcția suspin **DA** Buton 100 % O2 **DA** Timpul maxim activ al butonului 100 % O2 2 min **DA** Blocarea panoului de control **DA** Moduri de operare Modul A/C V-A/C Volum respirator **DA** A/C presiune respiratorie **DA** Modul SIMV V-SIMV volum respirator **DA** SIMV presiune respiratorie **DA** Modul CPAP CPAP, CPAP/suport presiune (PS **)DA** Modul Apnea-backup **DA** Moduri combinate **DA** Ventilație neinvazivă **DA** Modul Bileve/APRV **DA** Parametri monitorizați/afișați Presiunea inspiratorie maximă **DA** Presiunea medie în căile respiratorii **DA** Presiunea PEEP **DA** Volumul total **DA** FiO2 **DA** Rata respiratorie **DA** Timp inspir **DA** Timp expir **DA** Rata I:E **DA** Volumul minutar spontan **DA** Alarme pacient FiO2 mare/mic **DA** Volum minutar mare/mic **DA**

Presiune inspir mare/mică da	Presiune inspir mare/mică **DA**
PIP mare da	PIP mare **DA**
PEEP mare da	PEEP mare **DA**
Lipsă PEEP da	Lipsă PEEP da
Apnea da	Apnea **DA**
Presiune/ocluzie continuă ridicată da	Presiune/ocluzie continuă ridicată **DA**
Inversare IE da	Inversare IE da **DA**
Circuit respirator deconectat da	Circuit respirator deconectat **DA**
Alarme echipament Lipsă alimentare gaz da	Alarme echipament Lipsă alimentare gaz **DA**
Lipsă alimentare electrică da	Lipsă alimentare electrică **DA**
Baterie descărcată da	Baterie descărcată **DA**
Eroare de sistem	Eroare de sistem
Sensor decalibrat, scurgere prin valve	Sensor decalibrat, scurgere prin valve **DA**
Autodiagnostic da	Autodiagnostic **DA**
Interfața Interfața cu dispozitivele exterioare da	Interfața Interfața cu dispozitivele exterioare **DA**
Porturi pentru ieșirea datelor da	Porturi pentru ieșirea datelor **DA**
Port pentru alarmă la distanță da	Port pentru alarmă la distanță **DA**
Ieșire analogică da	Ieșire analogică **DA**
Raportarea alarmelor și starea pacientului afișare pe display da	Raportarea alarmelor și starea pacientului afișare pe display **DA**
Transmiterea rapoartelor la imprimată da	Transmiterea rapoartelor la imprimată **DA**
Posibilitatea conectării în rețea centralizată da	Posibilitatea conectării în rețea centralizată **DA**
Display LCD TFT da	Display LCD TFT **DA**
Mărimea ≥ 15 inch	Mărimea - **17 inch DA**
Touchscreen da	Touchscreen **DA**
Compresor de aer Integrat în dispozitivului, tip turbină da	Compresor de aer Integrat în dispozitivului, tip turbină **DA**
Alimentare Pneumatică Gazele comprimate aer, O2	Alimentare Pneumatică Gazele comprimate O2 **DA**
Presiunea în rețea 3-6 atm	Presiunea în rețea 3-6 atm **DA**
Electrică Rețea electrică 220 V, 50 Hz da	Electrică Rețea electrică 220 V, 50 Hz **DA**
Baterie internă reîncărcabilă da	Baterie internă reîncărcabilă **DA**
Timp operare baterie ≥ 1 h	Timp operare baterie - 1.5 h **DA**
Accesorii	Accesorii
Circuite respiratorii pediatrice tip reutilizabil 2 set.	Circuite respiratorii pediatrice tip reutilizabil 2 set. **DA**
adult tip reutilizabil 2 set.	adult tip reutilizabil 2 set. **DA**
Mască respiratorie pediatrice tip reutilizabil 1 set.	Mască respiratorie pediatrice tip reutilizabil 1 set. **DA**
adult tip reutilizabil 1 set.	adult tip reutilizabil 1 set. **DA**
Umidificator Indicați modelul oferit model	Umidificator Indicați modelul oferit model H-900 **DA**
Umidificator cu mentinerea temperaturi si umidificarea aerului în regim automa, Compatibil cu ventilatorul da	Umidificator cu mentinerea temperaturi si umidificarea aerului în regim automa, Compatibil cu ventilatorul **DA**
Minim două regimuri de funcționare: invaziv și neinvaziv da	Minim două regimuri de funcționare: invaziv și neinvaziv **DA**
Cameră de umidificare adult/pediatrice tip reutilizabil 1 buc.	Cameră de umidificare adult/pediatrice tip reutilizabil 1 buc. **DA**
Filtre antibacteriale pediatrice unică utilizare 100 buc.	Filtre antibacteriale pediatrice unică utilizare 100 buc. **DA**
adult unică utilizare 100 buc.	adult unică utilizare 100 buc. **DA**
Senzor de debit adult/pediatrice tip reutilizabil 2 buc.	Senzor de debit adult/pediatrice tip reutilizabil 2 buc. **DA**
Plămân de test adult tip reutilizabil 1 buc.	Plămân de test adult tip reutilizabil 1 buc. **DA**
Suport pe rotile Indicați modelul oferit model	Suport pe rotile Indicați modelul oferit model **Integrat in ventilator**
Min. 4 rotile da	Min. 4 rotile **DA**
Min. 2 roți cu frînă da	Min. 2 roți cu frînă **DA**
Braț articulat pentru fixarea furtunelor respiratorii da	Braț articulat pentru fixarea furtunelor respiratorii **DA**
Suport pentru fixarea/atașarea cablurilor electrice, furtunul aer, oxigen pentru transportare, depozitare da	Suport pentru fixarea/atașarea cablurilor electrice, furtunul aer, oxigen pentru transportare, depozitare **DA**
Mîner pentru transportare da	Mîner pentru transportare **DA**

Freigabedeckblatt zur handschriftlichen Freigabe von Hamilton Dokumenten

Gültig für Dokument:	Declaration of Conformity
Nummer	DoC-CEDCL-H900Acc_17
Revision	17
oder	
Version	--

Dieses Freigabedokument ist zwingend dem Master-Exemplar beizulegen

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

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-H900Acc, 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

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:

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.

Gültigkeit:

Diese Konformitätserklärung gilt für Produkte, welche 2021. produziert werden. Die Losnummern sind über Fertigungsnachweise nachvollziehbar. Diese Konformitätserklärung ist gültig in Verbindung mit dem Endprüfprotokoll.

Validité:

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-H900Acc_17

HAMILTON MEDICAL

Intelligent Ventilation since 1983

CEDCL-H900Acc Attachment

Product name	P/N	Basis UDI-DI / GTIN
HAMILTON-BC8022	260161	07630002801560
HAMILTON-BC4022	260186	07630002804189
HAMILTON-BC8010	260185	07630002800846
HAMILTON-BC4010	260187	07630002801416
HAMILTON-BC8022-A	260188	07630002805568
HAMILTON-BC8010-A	260189	07630002807197

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 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

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60137935 0001

Report No.: 21213508 015

Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products:
Ventilators and ventilator systems

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60136804 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2019-07-09

Date: 2019-04-02

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60137935 0001
Report No.: 21213508 015

Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Additional site:

Hamilton Medical AG
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler

Date: 2019-07-09

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 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 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) Ventilation unit, shelf mount: 10.5 kg (23.15 lb) 46 kg (101 lb) with trolley, monitor, ventilation unit 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:

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HAMILTON-H900

Technical specifications for software v1.10x

Operating modes

Manual and auto mode	For invasive and noninvasive ventilation, and high flow oxygen therapy (HiFlow).

Control settings

Parameter	Mode	Range	Default	Resolution
Chamber exit temperature	Invasive	35°C to 41°C	37°C	0.5°C
	Noninvasive	30°C to 35°C	31°C	0.5°C
	HiFlow	33°C to 37°C	35°C	1°C
Temperature gradient	Invasive	-2°C to 3°C	Adult/Ped: 2°C Neo: 3°C	0.5°C
	Noninvasive	-2°C to 3°C	Adult/Ped: 2°C Neo: 3°C	0.5°C
	HiFlow	--	2°C	--
Resulting airway temperature (Y-piece)[1]	Invasive	33°C to 42°C	--	--
	Noninvasive	28°C to 38°C	--	--
	HiFlow	35°C to 39°C	--	--

Monitoring

Parameter	Temperature	Accuracy
Chamber exit temperature	10°C to 60°C / 30°C to 41°C	±1°C / ±0.5°C
Y-piece temperature	28°C to 43°C	±0.5°C

1 Airway temperature is limited by the humidifier software to 42°C

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Alarms

High priority	Temperature too high, water level too high, humidifier dangerously inclined
Medium priority	No humidifier chamber inserted or defective chamber, no limb or defective limb connected, a limb is not properly connected, low temperature, low water level
Additional	Visual alarm light, on-screen alarms
Audio pause	120 s
Alarm loudness	For medium- and high-priority alarms at 1 m distance from humidifier: A setting of 1 = 50 db(A), 5 = 60 db(A), and 8 = 65 db(A), with an accuracy of ±6 db(A).

Performance

Description	Specifications		
Flow rates	Invasive	Up to 60 l/min	
	Noninvasive	Up to 120 l/min	
	HiFlow	Up to 100 l/min	
Warm-up time	Less than 30 minutes		
Humidity	At an ambient temperature of 18°C to 26°C:		
	Invasive	Temperature setting of 37°C to 41°C	Minimum humidity 33 mg H2O/l
	Noninvasive	Temperature setting of 31°C 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	Limited to 30°C on Y-piece		

Electrical characteristics

Input voltage	220 – 240 V / 110 – 127 V / 100 V
Frequency	50 / 60 Hz
Maximum power	283 VA (230 V version) / 293 VA (115 V version) / 260 VA (100 V version)
Potential equalization	Terminal for the connection of a potential equalization conductor according to DIN 42801
Connectors[2]	Interface RS-232 connection only with a Hamilton Medical ventilator

2 Not available in all markets

Standards and approvals

Classification	Class I (in accordance to IEC 60601-1), Class IIb (in accordance with MDD/MDR)
Certification	IEC 60601-1:2012, IEC 60601:2007, ISO 8185:2007, ISO 5356-1:2015, ISO 80601-2-74:2017
Applied parts	Heated breathing circuit tubes (Type BF)

Environments

Temperature	10°C to 40°C (operation), -20°C to 60°C (storage) Recommended ambient temperature: 18°C to 26°C
Relative humidity	30 to 95% noncondensing (operating) / 10 to 95% noncondensing (storage)
Altitude	Up to 4,000 m (13,123 ft) / 61 kPa to 106 kPa atmospheric pressure
Gas input temperature	18°C to 31°C (recommended)
Ingress Protection (IP)	IP 21

Physical dimensions

Dimensions (W×D×H)	18 cm (7.1 in) × 16 cm (6.3 in) × 19 cm (7.5 in)
Weight	2.5 kg (5.5 lb)
Display	3 in / 64 × 128 pixels, inverted dot matrix display (backlit)

Manufacturer:

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INTELLiVENT-ASV

Operator's Manual

HAMILTON-C6

REF 160770, 160771, 160772, 160768, 160769

Software version 1.x.x

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HAMILTON MEDICAL

Intelligent Ventilation since 1983

Operator's Manual

INTELLiVENT-ASV

2021-02-25

624954/02

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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

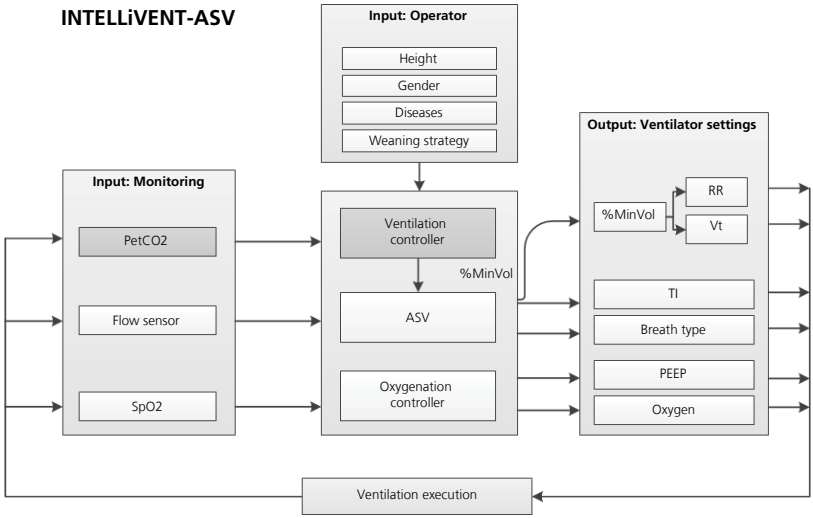
1.1 Overview

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* • Pulse oximetry documentation • 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

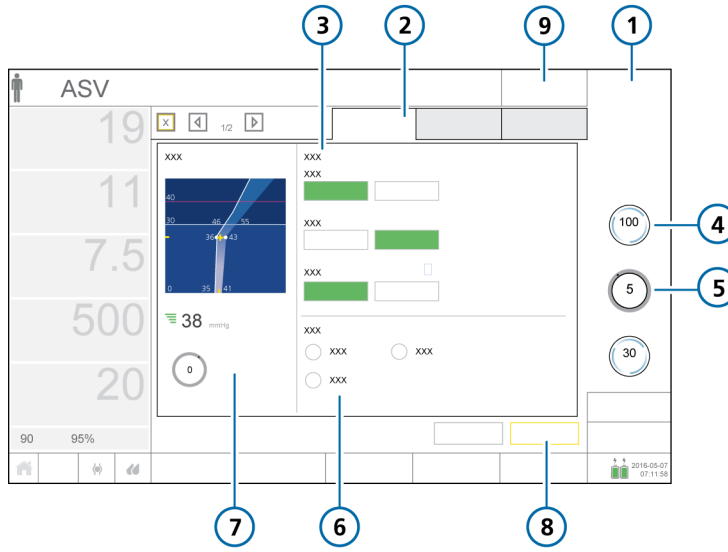
- Automated management of *all* controls is disabled if the patient weighs < 7 kg.
- Automated management of %MinVol is disabled when the CO2 sensor is disabled.
- Automated management of PEEP is disabled when:
  – Either the Chronic Hypercapnia or Brain Injury patient condition is selected. If Chronic 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.

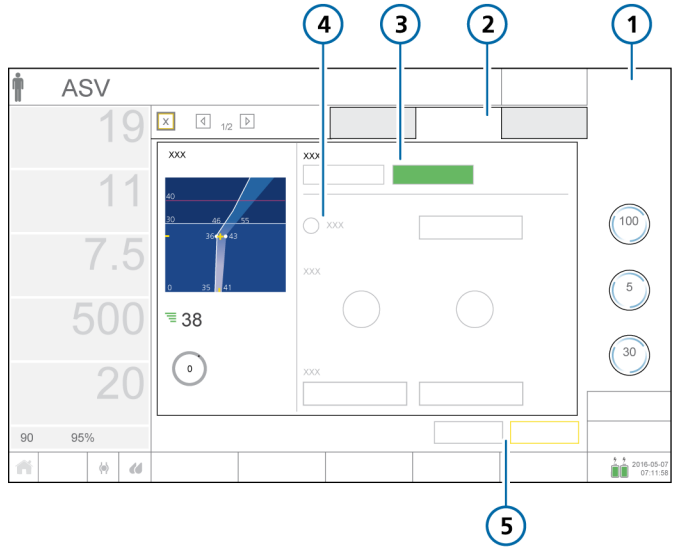
7. If displayed, touch **Continue** to accept the settings and proceed to the next step.

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:

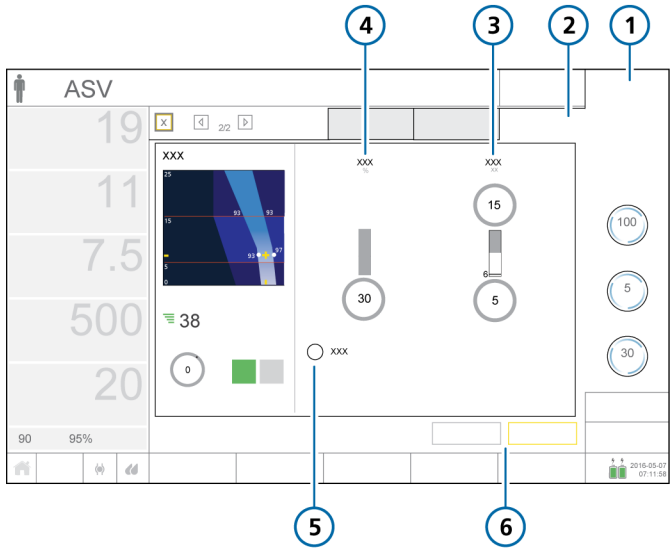
- Set the minimum Oxygen level (between 21% and 30%)
- Set an upper and/or lower PEEP limit
- Enable/disable auto-recruitment

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. The minimum difference allowed between the low and high limit is 2 cmH2O. 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. To enable auto-recruitment, touch the checkbox to select it. When auto-recruitment is enabled, the text **auto-recruitment** is displayed on the Oxygenation map and horizon (views 1 and 2). 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*.

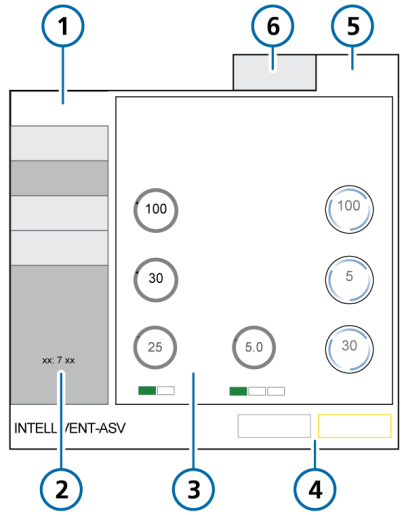
5. Touch the **Patient** tab to review patient data (height, gender), to ensure the correct **IBW** is calculated.

   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

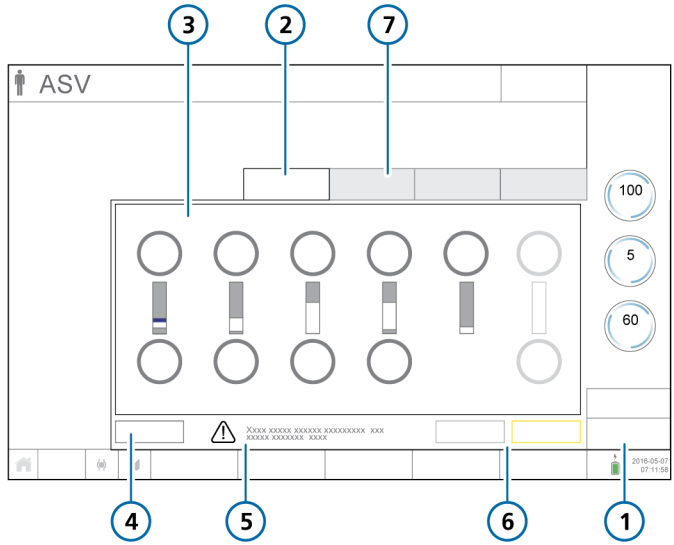
You can suppress the physiological PetCO2 and SpO2 alarms for 2 minutes by pressing the Audio Pause key, in the same manner as other alarms on the ventilator. For details, see the chapter, *Responding to alarms*, in your ventilator *Operator's Manual*.

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.

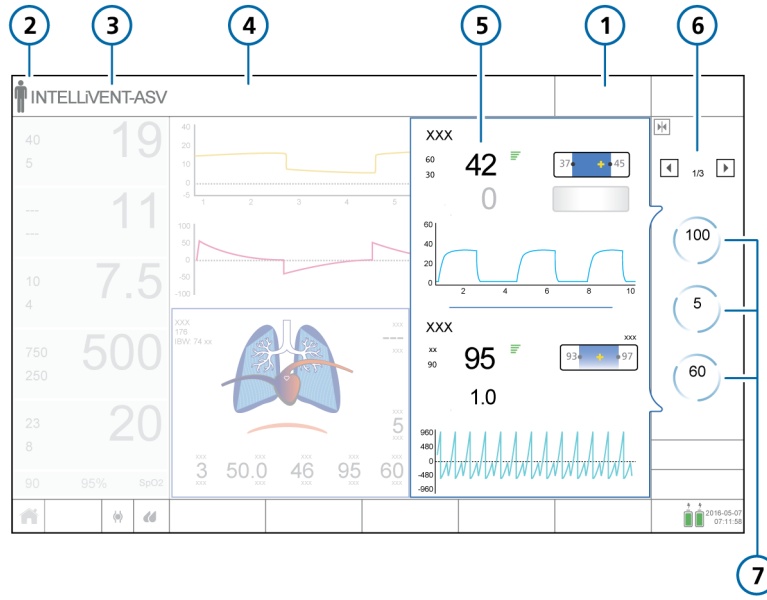
1.4.9 Adjusting settings during active ventilation

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

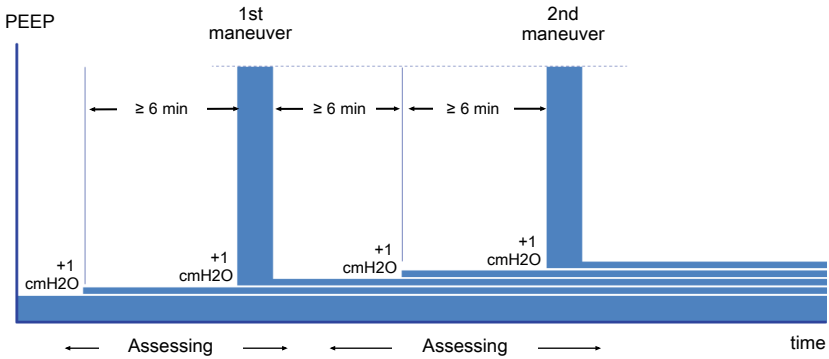
- In the INTELLiVENT-ASV Settings > More window, touch the Auto-recruitment checkbox. See Figure 1-4.

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

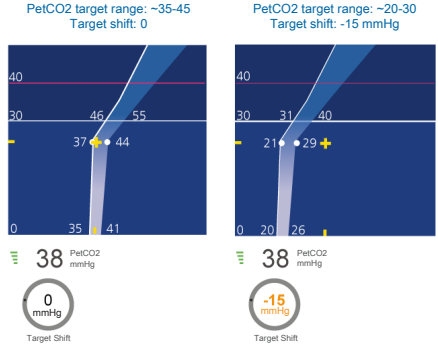
Assume the following patient conditions apply:

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

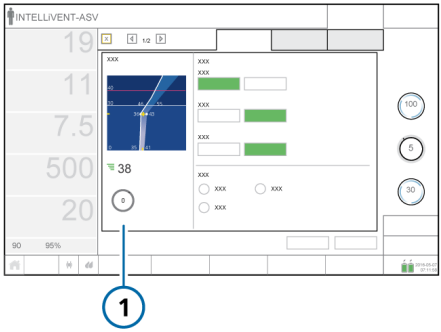
PetCO2 target shift limits	
All patient conditions	-20 mmHg to 10 mmHg

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. Target shift is 0; there is no change to the target range values.
	Yellow text. Target shift is between ±1 and ±5.
	Orange text. 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.

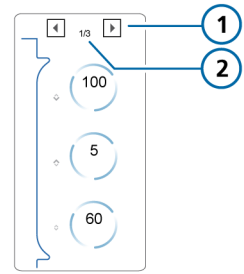
Most of these windows are displayed as a series of views that you can cycle through during ventilation.

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. The map is shown: • In the INTELLiVENT-ASV Settings window, in view 1 • During active ventilation in view 2	Section 1.5.2 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. For an active patient, the spontaneous breathing rate is displayed (fSpont). The horizon is shown during active ventilation in view 1.	Section 1.5.3
Oxygenation maps	Two maps are available: • The PEEP/SpO2 view shows the current patient SpO2 value and the target range in relation to PEEP, together with the set limits. • The FiO2/PEEP view shows the patient's current combination of Oxygen/PEEP values, together with the set limits. The selected map is shown: • In the INTELLiVENT-ASV Settings window, in view 2 • During active ventilation in view 2	Section 1.5.4 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. 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. A plethysmogram is shown: • During active ventilation in views 1 and 3 • As a waveform on the main display, if selected	Section 1.5.6
Capnogram	Provides a real-time CO2 waveform. A capnogram is shown: • During active ventilation in views 1 and 3 • 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

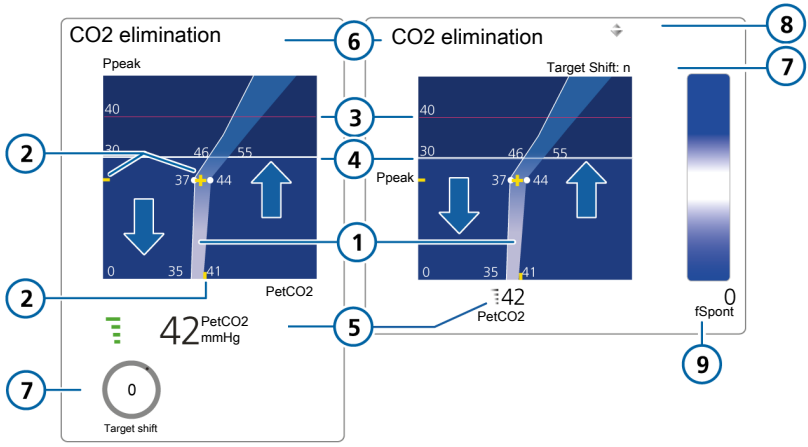
NOTICE

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

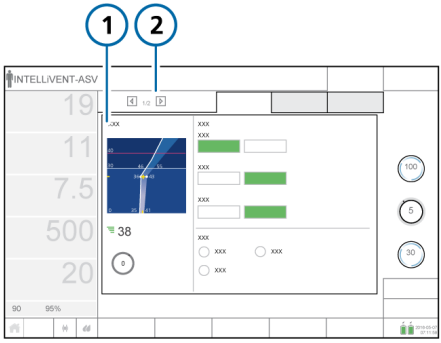
1. To open the INTELLiVENT-ASV Settings window, touch the **Target** button at the top right of the display, or touch an automated controller.

   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



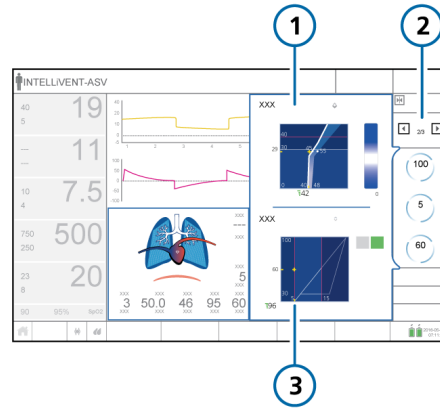
1	Ventilation map	2	View arrows and current view number

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

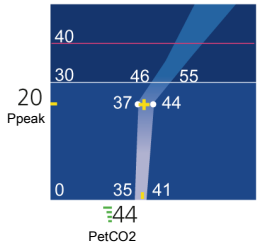


1	Ventilation map	3	Oxygenation map
2	View arrows and current view number		

1.5.2.2 About the PetCO2 target zone

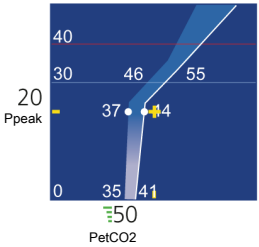
At a very basic level, the ventilation controller attempts to keep the patient in the target zone as described here.

The Ventilation map provides examples of each situation: PetCO2 is within, above, or below the target zone.



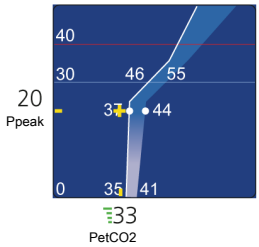
Patient symbol within the PetCO2 target zone

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

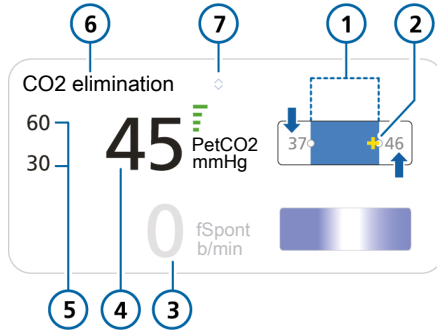
When the patient symbol is to the left of the target zone (in the decrease zone, PetCO2 is too low), the %MinVol setting decreases.

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**).

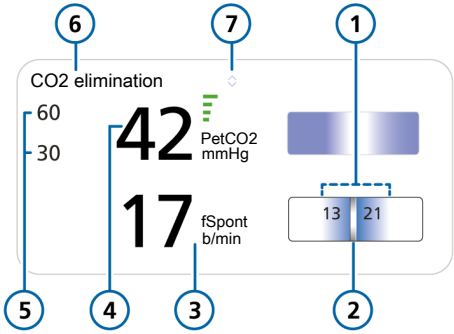
Figure 1-15. Ventilation horizon, passive patient



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

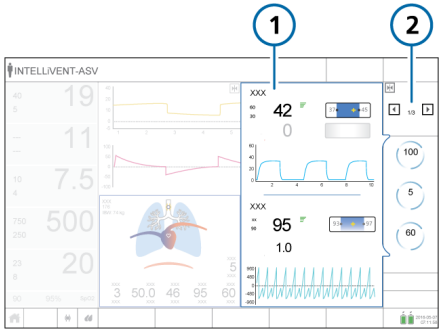


1	Spontaneous breathing target zone, showing upper and lower boundaries	5	Upper and lower **PetCO2** alarm limits
2	Patient symbol (floater) showing current value	6	Horizon title: CO2 elimination
3	Current measured **fSpont** value	7	When **%MinVol** is increasing (^) or decreasing (v), the appropriate 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**.

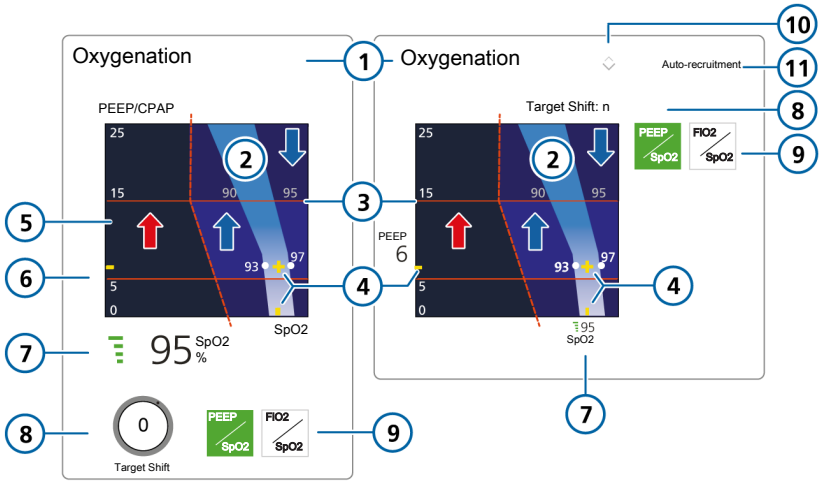
The *FiO2/PEEP* schema shows **Oxygen** on the y-axis and **PEEP** on the x-axis. The yellow cross is the patient symbol denoting the patient's current measured combination of **Oxygen/PEEP** values. The triangular **PEEP/Oxygen** curve shows the target treatment levels, depending on whether treatment 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*)

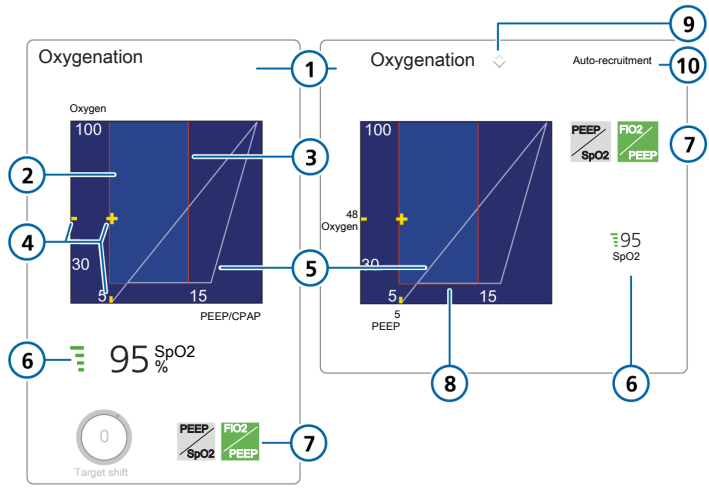
9 Oxygenation map selection button: PEEP/SpO2

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.

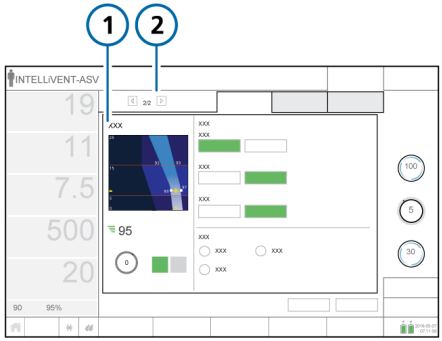
   The Settings window opens, with the **Auto** tab selected.

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.

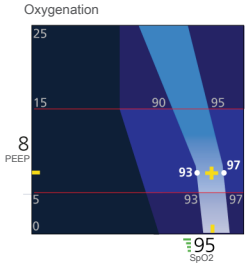
2. To display the FiO2/PEEP map, touch the **FiO2/PEEP** button.

   To display the PEEP/SpO2 map, touch the **PEEP/SpO2** button.

1.5.4.2 About the SpO2 target zone

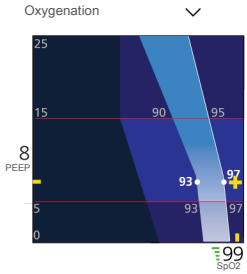
At a very basic level, the oxygenation controller attempts to keep the patient in the target zone as described here.

The PEEP/SpO2 (left) and FiO2/PEEP (right) maps below provide examples of each situation: SpO2 is within, above, or below the target zone.



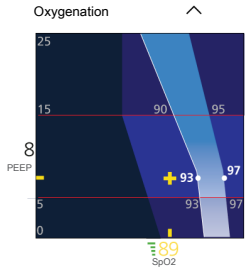
Patient symbol within the SpO2 target zone

When the patient symbol is within the target zone, **Oxygen** is fine tuned to get the patient to the middle of the target range.



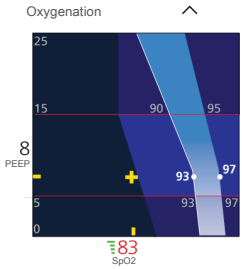
Patient symbol above the target zone

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.



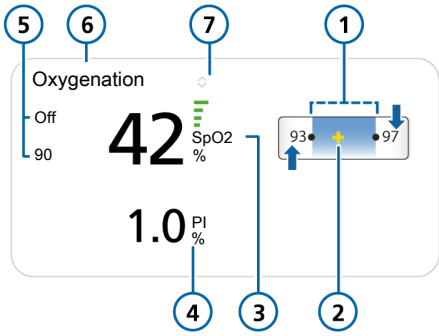
Patient symbol below the SpO2 target zone, in the Emergency zone

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

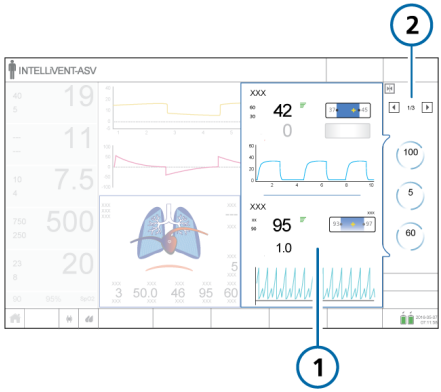


1	Target zone, showing upper and lower boundaries	5	Upper and lower **SpO2** alarm limits
2	Yellow patient symbol (cross) showing current patient value	6	Horizon title: Oxygenation
3	Current **SpO2** value and quality index	7	When **PEEP** or **Oxygen** is increasing (^) or decreasing (v), the appropriate 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.

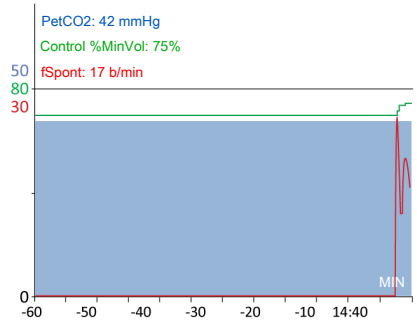
During active ventilation with INTELLiVENT-ASV, the plethysmogram is displayed together with the Oxygenation horizon, as well as with the SBT history window. For details about selecting the plethysmogram as a waveform on the ventilator main display, see the *Pulse Oximetry Instructions for Use*.

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]

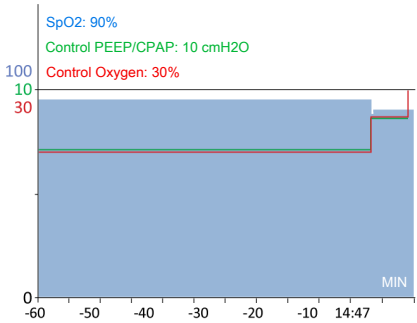
[7] Note that the graphs provided here do not represent actual data, they just illustrate how the different parameters are represented.

Ventilation controller trend graph



The Ventilation controller trend graph provides data for the following parameters: PetCO2, Control %MinVol, and fSpont.

Oxygenation controller trend graph

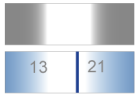


The Oxygenation controller trend graph provides data for the following parameters: SpO2, Control PEEP/CPAP, and Control Oxygen.

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. 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. 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. 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. 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 *Medium priority.*	Oxygenation controller set **Oxygen** to 100% due to low **SpO2** saturation. **SpO2** is, or was, in the emergency zone. **To resolve** • Check patient condition. • Open and close the alarm buffer to reset the alarm (even if the alarm situation changes).
Oscillation Oxygen *Medium priority.*	Large variations in **Oxygen** in a short time period. **To resolve** • Check patient condition. • Set **Oxygen** to **Manual**.
Oscillation PEEP/CPAP *Medium priority.*	Large variations in **PEEP** in a short time period. **To resolve** • Check patient condition. • Set **PEEP** to **Manual**.
Oscillation %MinVol *Medium priority.*	Large variations in **%MinVol** in a short time period. **To resolve** • Check patient condition. • Set **%MinVol** to **Manual**.

Alarm/Priority	Definition/Corrective action
Oxygenation adjustment off *Medium priority.*	Oxygenation controller is frozen due to poor or absent SpO2 signal. **To resolve** • Check pulse oximeter connections. • Set PEEP and/or Oxygen to Manual.
Oxygen controller at limit *Low priority.*	PEEP and/or Oxygen are at defined limit and cannot be increased. **To resolve** • Check patient condition. • Verify limit settings. • Set PEEP and/or Oxygen to Manual.
Oxygen control limit exceeded *Medium priority.*	Oxygen exceeds the limit defined by the Oxygen message alarm (Alarms window). **To resolve** • Check patient condition. • Open and close the alarm buffer to reset the alarm (even if the alarm situation changes).
Oxygen supply failed *Medium priority.*	Oxygen source flow lower than expected. **To resolve** • Check patient condition. • Check oxygen supply, change supply if necessary. • Check oxygen supply for leaks. • Provide alternative ventilation until issue is resolved.
Recruitment in progress *Low priority.*	Notification about ongoing recruitment maneuver. Check patient condition.
Ventilation adjustment OFF *Medium priority.*	Ventilation controller is frozen when any of the following conditions occurs for longer than 30 seconds: • Poor or absent CO2 signal • fSpont > 60 b/min (> 40 kg IBW) • fSpont > 100 b/min (≤ 40 kg IBW) **To resolve** • Check patient condition. • Check CO2 connections. • Set %MinVol to Manual.

Alarm/Priority	Definition/Corrective action
Ventilation controller at limit *Low priority.*	%MinVol is at defined limit (200%) and cannot be increased. **To resolve** • Check patient condition. • 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. 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 When Quick Wean is enabled: ASV target Rate + 3
Upper limit of range	ASV target Rate + d d = %MinVol * k where k = 0.1 Quick Wean disabled k = 0.15 Quick Wean enabled

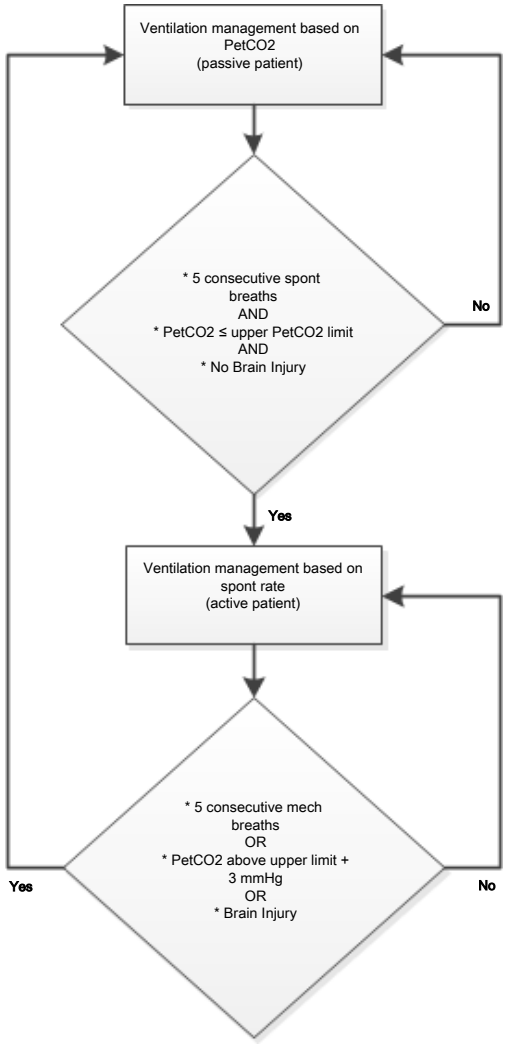
While the patient is active, the patient's spontaneous rate is detected by the flow sensor. The PetCO2 value is only used in the background for additional safety to avoid excessive values.

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 *and* • 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 *and* • 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 *and* • The patient's **Rate** value is within the target range	No change in **%MinVol**. 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. 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. 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 Gray (or blue), red, or orange bars 	• The **%MinVol** control is a solid red circle; it is frozen. • The **Ventilation adjustment OFF** alarm is generated. • 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 Green bars 	• The **%MinVol** control is a blue rotating circle. • The alarm is reset. • 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

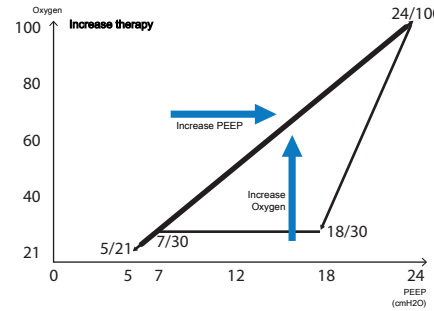
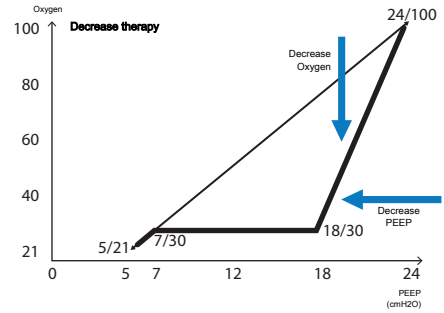


Figure 1-24. Decrease of oxygenation support, Open Lung concept



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 • Increasing **Oxygen** support
Decrease **Oxygen** stepwise	Decreases Oxygen by 5% of current **Oxygen** value every **60 seconds**	• **Oxygen** automatically managed • Decreasing **Oxygen** support
Increase **PEEP** stepwise	Increases **PEEP** by 1 cmH2O every **6 minutes**	• **PEEP** automatically managed • Increasing **PEEP** support
Decrease **PEEP** stepwise	Decreases **PEEP** by 1 cmH2O every **6 minutes**	• **PEEP** automatically managed • Decreasing **PEEP** support
Decrease **PEEP** stepwise quickly	**Exception:** Decreases **PEEP** by 1 cmH2O quickly every **30 seconds**	• **PEEP** automatically managed • **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 Gray (or blue), red, or orange bars 	• The **PEEP** and **Oxygen** controls are solid red circles; they are frozen. • The **Oxygenation adjustment OFF** alarm is generated. • The ventilator uses the same oxygenation rules as when in ASV mode. For details, see your ventilator *Operator's Manual*. • Automatic emergency increase of oxygen management is *inactive* (Section 1.8.2).
SpO2 signal is available and reliable Green bars 	• The **PEEP** and **Oxygen** controls are blue rotating circles. • The alarm is reset. • Automated oxygenation management resumes. • 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 • The Chronic Hypercapnia or Brain injury patient condition is selected • SpO2 monitoring is disabled	PEEP is set to Manual
Oxygen • Oxygen monitoring (O2 sensor) is disabled • 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 (set to Automatic)	The device does the following: • Shifts the PetCO2 range to the right by up to +5 mmHg, depending on pressure, to support spontaneous breathing. • 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%. • The system continuously monitors the patient against weaning criteria (Section 2.4). 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. • The system continuously monitors the patient against weaning criteria. • When defined criteria are met, automatically initiates an SBT. • All of the related parameters are configurable, and some can be fine tuned during ventilation. • You can manually start an SBT any time the patient is active. See Section 1.4.5.
Automated SBTs disabled	This is the default setting. • The system continuously monitors the patient against weaning criteria. • 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%. • All of the related parameters are configurable, and some can be fine-tuned during ventilation. • 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. 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. 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. 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. 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%. 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. 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. If the upper limit is reached during an SBT, the SBT is stopped.
Rate (b/min)	Respiratory rate. Number of breaths per minute. 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. 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. 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. 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. Only applies when automated SBTs are enabled.
Time between 2 SBTs (min)	Defines the minimum length of time that must pass between two SBTs. 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. 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). 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

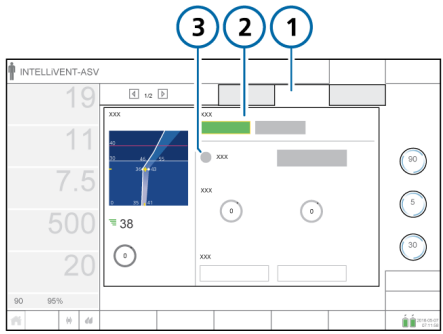
2.3 Enabling/disabling and setting up automated SBTs

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



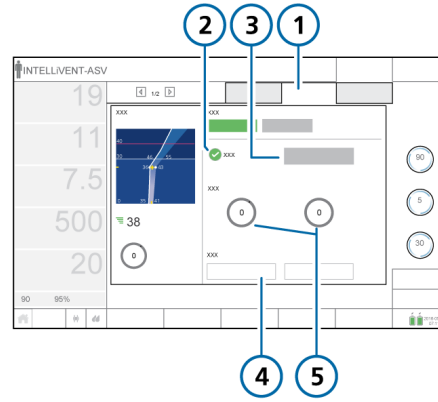
1	Quick Wean	3	Automatic SBT (*not* selected)
2	Automatic		

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.

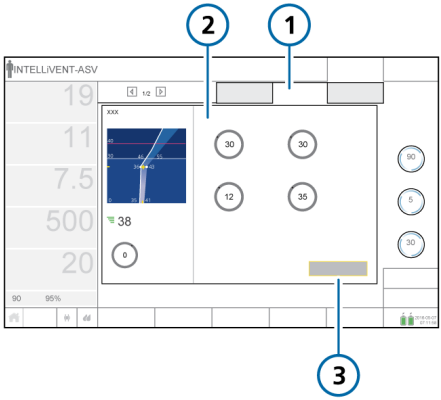
6. Touch **Close** to accept the settings and return to the Quick Wean window.

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

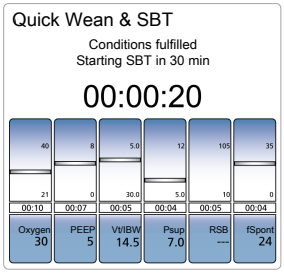
SBT setting	Description
Automatic SBT	Select checkbox to enable automatic SBTs when specified clinical conditions are met.
SBT settings	Touch to display additional SBT-related settings.
SBT time range	Hours between which an SBT can be started. Even if clinical conditions match the specified SBT starting criteria, if the start time for the SBT is outside of the range specified here, the SBT will not take place. 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. The system: • Adjusts **%MinVol** to the configured setting • Adjusts PEEP to the configured setting (if automatically controlled) • Displays the SBT history window • Displays the Quick Wean & SBT status window
Stop SBT	Select to immediately stop an ongoing SBT. 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. 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. 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.

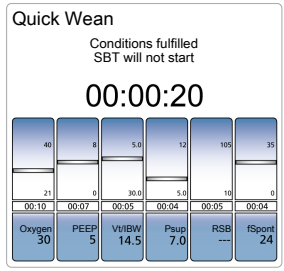
2.4 Conditions for starting weaning activities

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	 • The device shows the status *Conditions fulfilled, starting SBT in XX min* in the Quick Wean & SBT Status window, and starts a timer. • 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. 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. 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	 The device shows the status *Conditions fulfilled, SBT will not start* in the Quick Wean Status window. 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. 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 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 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 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 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 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: • The text *Conditions fulfilled/Starting SBT in XX time period*. • 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: • The text *Conditions fulfilled/SBT will not start*. • A timer (HH:MM:SS) showing how long the patient values have been within the target ranges.
SBT is in progress	Displays: • The text *SBT running* • A timer (HH:MM:SS) showing how long the SBT has been running • Pulsing green bars above and below the floats for parameters that are within the defined thresholds Parameters that are out of range do not show the green bar.

2.4.4.2 SBT history window

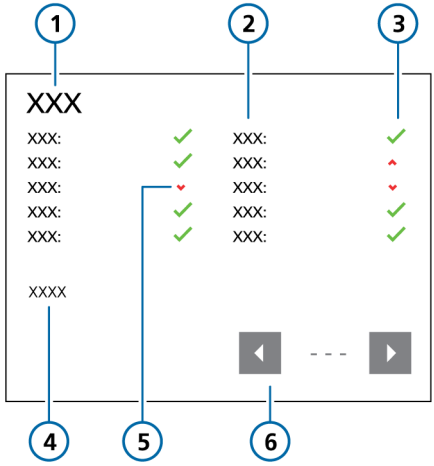
The SBT history window, available in view 3 of the INTELLiVENT-ASV views, displays an overview of all of the key ventilation parameters.

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: • Rate inc% • PetCO2 inc (absolute increase in PetCO2) 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). 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 Set in the To start SBT window. 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 Set the upper limit that **PEEP** cannot exceed during an SBT.	Patients > 40 kg: > 8 Patients ≤ 40 kg: > 6
PetCO2 (mmHg)	Used indirectly together with **PetCO2 inc** as *To stop SBT* criteria. 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 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 Set the upper limit that **Psupport** cannot exceed during the SBT.	> 12
Rate (b/min)	INTELLiVENT-ASV Settings > Quick Wean/SBT Settings window Set the upper limit that **Rate** cannot exceed during SBT.	Patients > 30 kg: > 35 Patients ≤ 30 kg: > 45

Parameter (unit)	Where set/how used	Default *To stop SBT* value
Rate inc	Configuration > Modes > SBT > To stop SBT window 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 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 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 *Medium priority.*	The SBT was stopped. For possible reasons, see Section 2.6. Dismiss the alarm as described in Section 2.8.
SBT successfully fulfilled *Medium priority.*	The SBT was ended because **Max. duration** was reached. Dismiss the alarm as described in Section 2.8.
SBT stopped after HHH hours MM minutes	How long the SBT ran before being stopped. 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. 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. 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. 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. 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. 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:** Patients > 40 kg: ≤ 8 Patients ≤ 40 kg: ≤ 6 **To stop SBT:** Patients > 40 kg: > 8 Patients ≤ 40 kg: > 6 **During SBT:** **PEEP** is set to 5 by default.	**Displayed in:** • INTELLiVENT-ASV main display in **PEEP** control • Quick Wean & SBT status window • SBT history window • Monitoring window **Set in:** • Configuration > Modes > SBT > To start SBT • Configuration > Modes > SBT > SBT settings	**To start SBT:** 5–10 **PEEP during SBT:** 0–5
PetCO2 (mmHg)	**To stop SBT:** PetCO2 > (upper limit INTELLiVENT-ASV PetCO2 target range + 3 mmHg)	**Displayed in:** • Patients ≤ 40 kg: Quick Wean status panel • SBT history window • Ventilation horizon and map • Monitoring > CO2 window • Dynamic Lung panel 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:** > 8 increase	Not displayed. **Set in:** Configuration > Modes > SBT > To stop SBT	4–20
Psupport max (cmH2O)	**To start SBT:** ≤ 12 **To stop SBT:** > 12	**Displayed in:** • INTELLiVENT-ASV Settings > Quick Wean/SBT settings window • SBT history window **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 **To stop SBT:** > 105	**Displayed in:** • Patients > 40 kg: Quick Wean & SBT status panel • SBT history window The **RSB** parameter is only used for patients weighing > 40 kg. This value is not configured.	105
Rate (b/min)	**To start SBT:** Patients > 30 kg: ≤ 35 Patients ≤ 30 kg: ≤ 45 **To stop SBT:** Patients > 30 kg: > 35 Patients ≤ 30 kg: > 45	**Displayed in:** • Quick Wean & SBT status window (as **fSpont**) • SBT history window (as **fSpont**) • INTELLiVENT-ASV Settings > Quick Wean/SBT settings window **Set in:** INTELLiVENT-ASV Settings > Quick Wean/SBT settings window	25–65
Rate inc (%)	**To stop SBT:** > 50% increase over the average rate established just prior to the start of the SBT	**Displayed in:** SBT history window **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. **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 **To stop SBT:** Below the INTELLiVENT-ASV SpO2 target range minus 2%	**Displayed in:** • Oxygenation horizon and map (views 1, 2, 3) • Monitoring > SpO2 window • SBT history window • Dynamic Lung panel • Main window under MMP list 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 Patients ≤ 40 kg: 60 s **To stop SBT:** Patients > 40 kg: 180 s Patients ≤ 40 kg: 30 s	**Displayed and configured in:** • Configuration > Modes > SBT > To start SBT • Configuration > Modes > SBT > To stop SBT	10–300
	For the following parameters, the **Tolerance time** setting is predefined (regardless of the Configuration settings): • **%fSpont**: must be 100% for a minimum of 60 seconds • 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 **To stop SBT:** < 5 ml/kg	**Displayed in:** • Quick Wean & SBT status window • SBT history window • Monitoring window **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) 70 to 200 (automatic)
Oxygen (%)	21 to 100 (manual and automatic)
PEEP (cmH2O)	0 to 50 (manual) 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*. INTELLiVENT-ASV can only be used for patients weighing more than 7 kg.
MinVol (target) (l/min)	Target **MinVol** is calculated as: **IBW x NormMinVent x %MinVol/100** 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 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. Default: 30%
Maximum Oxygen	100%
PEEP limits	Low: 5 to 22 (Default: 5) 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

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

Certificate Holder: **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
Switzerland

including the locations according to annex

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

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2017-07-09 until 2020-07-08.

2020-02-06 (Change)

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Certificate Registr. No. **01 100 1710001**

No.	Location	Scope
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development and distribution of ventilators and ventilator systems
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing of ventilators and ventilator systems
/03	Hamilton Medical UK Ltd. Unit 1 Forge Mills Park Station Road Coleshill Birmingham B46 1JH United Kingdom	Distribution and servicing of ventilators and ventilator systems

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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 Via Crusch 8, 7402 Bonaduz, Switzerland
	Representative Name/Position 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 #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 #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:			

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	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 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:			

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Device Model	**Software Revision**		**Software Release Date**
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	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:			