Anexa nr.114.1
la Formularul Specificații tehnice
Servicii de mentenanta pentru ventilator Hamilton C1

Specificarea tehnică deplină solicitată, Standarde de referinţă	Specificarea tehnică ofertata
Lucrări necesare de întreținere a dispozitivului conform manualului de service și recomandării producătorului dispozitivului medical. 1. Obligatoriu se va prezenta lista lucrărilor de mentenanță și numărul de intervenții planificate de mentenanță de la producător, care urmeză să fie desfășurată. 2.Prezentarea listei detaliate cu costul fiecărei activități întreprinse. 3.Prezentarea listei cu prețul piese de schimb, kit de mentenanță care urmeză să fie inlocuite în procesul de mentenanță., Numărul de intervenții tehnice asupra dispozitivului medical conform recomandării producătorului dar nu mai puțin decât numărul de intervenții solicitate. Agentul economic v-a asigura lucrări de întreținere a dispozitivului medical solicitat și lucrări pentru toate dispozitivele aferente care sunt în legătură directă cu dispozitivul medical, sau accesorii. Înlăturarea tuturor defecțiunilor depistate, tehnice cât și cele de program. Intervenții de urgență Lucrări de diagnosticare, testare, reparație în cazul defecțiunilor minore neprevăzute (erori tehnice, calibrare, resetare). Intervenții de urgență cu reacționarea în maxim 24 ore de la notificarea defecțiunii, problemei, timpul intervenției telefonică maxim 1 oră, soluționarea problemei nu mai mult de 72 ore de la notificare. Chemarea inginerului companiei poate fi în formă scrisă cât și telefonică. Numărul de intervenții la solicitarea beneficiarului nelimitate pe tot parcursul contractului încheiat.	Lucrări necesare de întreținere a dispozitivului conform manualului de service și recomandării producătorului dispozitivului medical. • Procedura de mentenanță preventivă, pag.75 din manual Hamilton-C1 Prețul prezentat în Anexa 23 pentru o vizită include diagnosticarea, reparația în cazul în care nu este nevoie de piese adiționale și efectuarea procedurii de mentenanță efectuată anual conform manualului de service: 1. Inspecție vizuală 2. Inspecția sistemului respirator 3. Testarea bateriei 4. Testarea surselor de gaze medicale 5. Testarea senzorilor de flux 6. Testarea displayului 7. Calibrarea ventilatorului Analizatoare utilizate: 1. TSI-Flowmeter kit, 500084 2. Pressure controller setl, 500058 Kiturile de mentenanță se vor procura separat, în dependență de starea ventilatorului. Piesele de schimb necesare pentru înlocuire în caz de defecțiune, se vor achiziționa separat conform ofertei prezentate în urma diagnosticului. • Kit de mentenanță (Kitul nu este inclus in oferta de pret!) Cod | Configuratie | Interval de înlocuire

Intervenția trebuie să se soldeze cu dispozitivul reparat sau problema soluționată. Generarea din partea agentului economic a unui raport cu toate acțiunile de reparație, remediere interprinse și indicarea pieselor utilizate. **Controlul prin verificare a dispozitivelor medicale** Verificare stare aparat (să nu aibă lovituri, crăpături, starea şuruburilor şi prinderilor roţilor, etc.); Verificare parametrii tensiune de alimentare (tensiune, împământare, verificare întrerupători, etc.); Verificarea protecţiilor interne care asigură funcţionarea în condiţii de siguranţă ale aparatului; Verificare conectori şi cabluri; Măsurarea tensiunii din sursa de alimentare şi din bateria de back up; Măsurarea rezistenţelor diferitelor ansamble ale aparatului; Verificare şi curăţare filtre; Verificare şi curăţare ventilatoare de răcire; Verificare si calibrare ecran; Descărcare fişiere de logurişi erori; Verificare parametrii de protecție electrică conform EN 60601; Evaluarea parametrilor definitorii de performanță, prin examinare și testare; Verificarea îndeplinirii setului de criterii de acceptabilitate pentru dispozitivul medical (valori impuse, limite specificate, accesorii etc.). Verificarea și reglarea părților mecanice aflate în mișcare; Eliminarea jocurilor la părțile mecanice; Curățarea și gresarea părților mecanice aflate în mișcare; Curățarea plăcilor electronice (dacă este cazul), precum și a altor componente; Verificarea componentelor pneumatice (acolo unde este cazul).	<table><tr><td>161236</td><td>HEPA filter</td><td>Anual</td></tr><tr><td>161275</td><td>Dust filter for HEPA and fan Set of 5</td><td>Anual</td></tr><tr><td>160497</td><td>HPO inlet filter service kit</td><td>Anual</td></tr><tr><td>396200</td><td>O2 sensor</td><td>Anual</td></tr><tr><td>369108</td><td>Battery</td><td>La necesitate</td></tr></table> Se va reacționa în maxim 24 ore de la notificarea defecțiunii. problemei, timpul intervenției telefonică maxim 24 ore, soluționarea problemei nu mai mult de 72 ore de la notificare. Chemarea inginerului companiei poate fi în formă scrisă cât și telefonică. Intervenția trebuie să se soldeze cu dispozitivul reparat în cazul în care nu este nevoie de piese adiționale sau beneficiarul are piesa în stoc. În cazul în care este nevoie de piese adiționale, în urma diagnosticului se face ofertă de preț. În urma intervenției se generează un raport cu toate acțiunile de reparație, remediere interprinse și indicarea pieselor utilizate. **Controlul prin verificare a dispozitivelor medicale** ▪ Verificare stare aparat (să nu aibă lovituri, crăpături, starea şuruburilor şi prinderilor roţilor, etc.);**DA** ▪ Verificare parametrii tensiune de alimentare (tensiune, împământare, verificare întrerupători, etc.); **DA** ▪ Verificarea protecţiilor interne care asigură funcţionarea în condiţii de siguranţă ale aparatului; **DA** ▪ Verificare conectori şi cabluri; **DA** ▪ Măsurarea tensiunii din sursa de alimentare şi din bateria de back up; **DA** ▪ Măsurarea rezistenţelor diferitelor ansamble ale aparatului; **DA** ▪ Verificare şi curăţare filtre; **DA** ▪ Verificare şi curăţare ventilatoare de răcire; **DA** ▪ Verificare si calibrare ecran; **DA** ▪ Descărcare fişiere de logurişi erori; **DA** ▪ Verificare parametrii de protecție electrică conform EN 60601; **DA** ▪ Evaluarea parametrilor definitorii de performanță, prin examinare și testare; ▪ Verificarea îndeplinirii setului de criterii de acceptabilitate pentru dispozitivul medical (valori impuse, limite specificate, accesorii etc.). **DA** ▪ Verificarea și reglarea părților mecanice aflate în mișcare; **DA**

	▪ Eliminarea jocurilor la părțile mecanice; **DA** ▪ Curățarea și gresarea părților mecanice aflate în mișcare; **DA** ▪ Curățarea plăcilor electronice (dacă este cazul), precum și a altor componente; **DA** ▪ Verificarea componentelor pneumatice (acolo unde este cazul). **DA** ***Dacă producător nu prevede alte servicii asupra dispozitivului solicitat***

6

Preventive maintenance and testing

6.1 Introduction

⚠ WARNING

- To prevent transmission of disease, you must use personal protective equipment when handling contaminated bacterial filters, patient accessories or the ventilator. Refer to the HAMILTON-C1 Operator's Manual for instructions on sterilization.
- The device must be cleaned with disinfectant to prevent the spread of infection and germs.
- Used HEPA and air filters must be handled as contaminated. Follow all local, state, and federal regulations with respect to personal and environmental protection when disposing of used filters.

⚠ CAUTION

You must complete a service training course for the HAMILTON-C1 with Hamilton Medical or with a Hamilton Medical certified "Train-the-trainer" distributor before undertaking the maintenance and testing procedures described in this manual.

⚠ CAUTION

- *Observe all electrostatic discharge (ESD) hazard precautions.*
- *Make sure you observe all electrostatic discharge (ESD) hazard precautions before you disassemble the HAMILTON-C1 or handle any electronic components. This will help prevent possible damage to the electronic components.*

Preventive maintenance ensures that the unit is kept in optimal condition and that any defective parts are replaced before they can cause a loss of service. It also ensures that you have the latest software version.

You must perform the preventive maintenance schedule:

- after replacing a component;
- once a year or every 5000 operating hours, whichever comes first.

Hamilton Medical recommends updating the HAMILTON-C1 to the latest software version. Check the Hamilton Medical partner website (http://www.hamilton-medical.com).

The sequence of preventive maintenance steps are described in Chapter 6. Work methodically through each section.

Maintenance and testing is not complete until all steps are successfully performed.

6.1.1 Preventive maintenance sequence

Table 6-1. Preventive maintenance sequence

Step	Task	Where found	Time required
1.	Perform (or confirm it has been performed) the hospital's preventive maintenance.	Hospital preventive maintenance, refer to Section 6.2.	5-15 minutes
2.	Check if the latest software version is installed on the HAMILTON-C1 ventilator. Install the latest software if it is not installed.	Refer to Hamilton Medical's Partner-Net website (https://www.hamilton-medical.com/Partner-Net/) for the latest software version. Software version (Technical state): • For SW v2.x.x, see the Service Manual Section 8.2.6.1.2. • For SW v3.x.x, see the Service Manual Section 9.2.6.2.2.	10-15 minutes
3.	Perform the engineer's preventive maintenance.	Engineer's preventive maintenance, refer to Section 6.3.	10 minutes
4.	Perform components replacement if necessary.	Components removal/ assembly, refer to Section 11.	N/A
5.	Perform all calibrations and tests.	• For SW v2.x.x, see the Service Manual Chapter 8. • For SW v3.x.x, see the Service Manual Chapter 9.	40 minutes
6.	Perform the electrical safety tests.	Electrical safety tests, refer to Chapter 7.	30 minutes
7.	Perform the preoperational check.	HAMILTON-C1 Operator's Manual or local-language equivalent.	10 minutes

6.1.2 Items required for preventive maintenance

Consumable spare parts required:

- HEPA filter (PN 161236)
- Filter set (PN 161275). Each set contains 5 x dust filters and 5 x fan filters.
- O2 sensor (PN 396200) or O2 sensor (PN 10076708), Pb-Free
- O2 inlet filter kit (PN 160497)

In addition you must also have available:

- Blower module (for PN refer to Section 13.2.1)
- Lithium-ion battery (MSP369108)

For required tools, see Chapter 12.

For special tools, see Section 12.3.

For required test equipment , see Section 12.4.

NOTICE

For further information on the recommended spare parts list, download the *Recommended Spare Parts for Preventive Maintenance and Service* (PN 10103117) document from Hamilton Medical's Partner-Net website (https://www.hamilton-medical.com/Partner-Net/).

6.2 Hospital's preventive maintenance

The following table shows the maintenance tasks that hospital staff must perform. It is also available in the English version of the HAMILTON-C1 ventilator Operator's Manual.

Examine each HAMILTON-C1 ventilator for which you are responsible and verify that hospital staff are regularly performing these tasks. If necessary:

- perform the tasks yourself
- train the staff to perform these tasks.

Interval	System	Procedure
After each patient and according to hospital policy.	Breathing circuit (including mask, inspiratory filter, flow sensor, nebulizer jar, expiratory valve and membrane).	Replace with new, single use parts or with sterilized parts if that is hospital policy. Run the Tightness Test and the flow sensor calibration as shown in the HAMILTON-C1 ventilator Operator's Manual.
	Entire ventilator.	Run the pre-operational check as shown in the HAMILTON-C1 ventilator Operator's Manual.
Every 2 days or according to hospital policy.	Breathing circuit.	Empty any water from breathing tubes or water traps. Inspect parts for damage. Replace as necessary.
Every month (or more often, if required).	Air intake dust filter and fan filter set (5 pieces on the rear panel).	Check for dust and lint. If needed, clean or replace as shown in the HAMILTON-C1 ventilator Operator's Manual.
Every 6 months (while the ventilator is in storage)	Battery	Plug the ventilator into a mains power source and recharge the battery.

6.3 Engineer's preventive maintenance

The following table shows the maintenance tasks that the service engineer must perform.

Interval	System	Procedure
Yearly or every 5000 operating hours, whichever comes first	Ventilator	Carry out a visual inspection of the device: • Check that all marks, symbols, and labels related to safety are complete and legible • The ventilator is not damaged or dirty (nor are the cables) • All screws accessible from outside (e.g rear cover, filter cover, battery cap, communication board) are tight
	Trolley	The wheels and brakes are properly functioning. All screws are tight. Secure the screws with thread lock where required (e.g. rails, see Section 13.3.1).
	HEPA filter	Replace the HEPA filter as shown in the HAMILTON-C1 ventilator Operator's Manual.
	HPO inlet filter	Replace. See Section 11.11.
	Calibrations and tests	Perform all calibrations and tests in the service software. Refer to one of the following Chapters depending on the software version on the ventilator: • For SW v2.x.x, see Chapter 8. • For SW v3.x.x, see Chapter 9.
	General tests and checks	Perform all general tests and checks: • For SW v2.x.x, see Chapter 8.3. • For SW v3.x.x, see Chapter 9.3.
	Pre-operational checks	Perform the Pre-Operational Checks as shown in the HAMILTON-C1 ventilator *Operator's Manual*, under the Chapter, *Specifying ventilation settings*.
	Electrical safety tests	Perform all electrical safety tests. Refer to Chapter 7.
	Oxygen sensor	Replace if depleted as shown in the HAMILTON-C1 ventilator Operator's Manual. O2 sensor life specifications are approximate. The actual O2 sensor life depends on the operating environment. Operation at higher temperatures and higher oxygen concentrations will shorten O2 sensor life.
	Lithium-ion battery[4]	You much check the battery's state of health (SoH) during the yearly preventive maintenance: • Replace the lithium-ion battery when the battery's state of health (SoH) < 20%. (Battery replacement required message appears in the user mode) • Consider to replace lithium-ion battery when battery's state of health (SoH) < 40%. • Calibrate the battery when Error ≥ 5%. • For SW v2.x.x, see Section 8.2.6.4. • For SW v3.x.x, see Section 9.2.6.5. For further information on the battery's SoH, refer to Section 5.4.1.

[4] The expected service life of the battery is 3 years. To ensure correct function of the battery, you must follow the recommended preventive maintenance schedule.

Interval	System	Procedure
Yearly or every 5000 operating hours, whichever comes first	Blower module	You must check the **Blower timer** during the yearly preventive maintenance. • Replace the Blower Module when the Blower Timer has reached 100%. **NOTICE!** The Dynamic Lifetime Surveillance monitors the service life of the blower module. The blower service life message "Blower service required" is displayed in service software mode, typically after 8 years of a blower module in service. • The Blower Module must be replaced if the expected blower timer (ebt) is predicted to reach 100% in the next 6 months. Refer to the following Sections for details on the Blower Module: – To check the **Blower timer** on HAMILTON-C1 with SW v2.x.x, see Section 8.2.6.2.2. – To check the **Blower timer** on HAMILTON-C1 with SW v3.x.x, see Section 9.2.6.3.2. – To replace the Blower Module, see Section 11.20.

7

Electrical safety

7.1 Electrical safety overview

⚠ WARNING

- Electrical Safety Tests (IEC 62353) detailed in this section must be performed as part of, or as instructed in Section 6.3. In addition, IEC 62353 requires testing before initial start-up, after repair/service, or periodical/preventive maintenance.
- Disconnect the power cable of the device from the mains power supply if connected before you do the Electrical Safety Tests (IEC 62353) to prevent potential electrical hazards.
- You must do the electrical safety tests (IEC 62353) after a service or repair. This includes the following:
  – Installation or replacement of the communication board
  – Replacement of the power supply
  – Replacement of the control board or driver board
  – Removal of ground contacts from the HAMILTON-C1 ventilator
  – Preventive maintenance
  – Repair or service activity
  – Initial installation of the HAMILTON-C1 ventilator
  – Installation/removal of an electrical/electronic part or option board

Electrical safety test standard used by Hamilton Medical AG

Hamilton Medical AG performs a set of Electrical Safety Tests, as specified in IEC 60601-1 standard, on all the ventilator units that it manufactures.

Operator's responsibility: performing the electrical safety tests on the device

As stated in the WARNING above, it is a legal necessity that you do the *Electrical Safety Tests* as specified in IEC 62353 standard after performing the initial installation, preventive maintenance, repair/service or an adjustment on the HAMILTON-C1 ventilator.

The device operator is responsible for performing the electrical safety tests during the in-service or use phase of the HAMILTON-C1 ventilator.

For details on how to perform the electrical safety tests, see Section 7.5.

Country-specific regulations and test intervals

If IEC 62353 standard has not been adopted by your country, then you must follow your country's standard/norm for performing electrical safety tests on medical devices after installation, routine preventative maintenance, service, or repair.

You must observe the electrical safety tests intervals specified in the *Engineer's preventive maintenance*, Section 6.3 or observe the country-specific regulations regarding the electrical safety tests intervals or routine testing.

Connection to the mains power supply: rated supply frequency range (50 Hz / 60 Hz)

The *rated* supply frequency range for the HAMILTON-C1 ventilator is between 50-60 Hz. This means that the HAMILTON-C1 ventilator is designed to be connected to a mains power supply having a normal frequency between 50 Hz and 60 Hz.

The electrical safety tests must be conducted by applying a current-limited mains potential sinusoidal 50 Hz signal (60 Hz where this is the mains frequency in the country or region).

For further details on the electrical safety tests standards, refer to IEC 62353 and IEC 60601-1.

7.2 Electrical safety tests - IEC 62353 standard

You must perform the electrical safety tests as described in this section and as specified in IEC 62353 standard. In addition to the electrical safety tests described in this section, you can use an automated electrical safety testing devices, such as the Metron Safety Analyzer or RIGEL 288 Electrical Safety Tester. Observe the instructions of the Electrical Safety Tester/Analyser before use.

7.3 Specifications

Current in mA (RMS - Root Mean Square)	Setup for HAMILTON-C1 without communication board installed	Setup for HAMILTON-C1 with communication board installed
Setup	Refer to chapter 7.5	• with CO2 and SpO2: refer to chapter 7.6 • with CO2,SpO2 and humidifier: refer to chapter: 7.7
Equipment leakage (direct method)	0.1 mA	0.1 mA
Patient leakage current (direct method) AC	not applicable	5 mA

All measured values must be documented using the measurement process and are considered reference values.

Should the measured values obtained during the next maintenance cycle be within 90 to 100% of the permissible values, the reference values are to be used to evaluate the ventilators electrical safety.

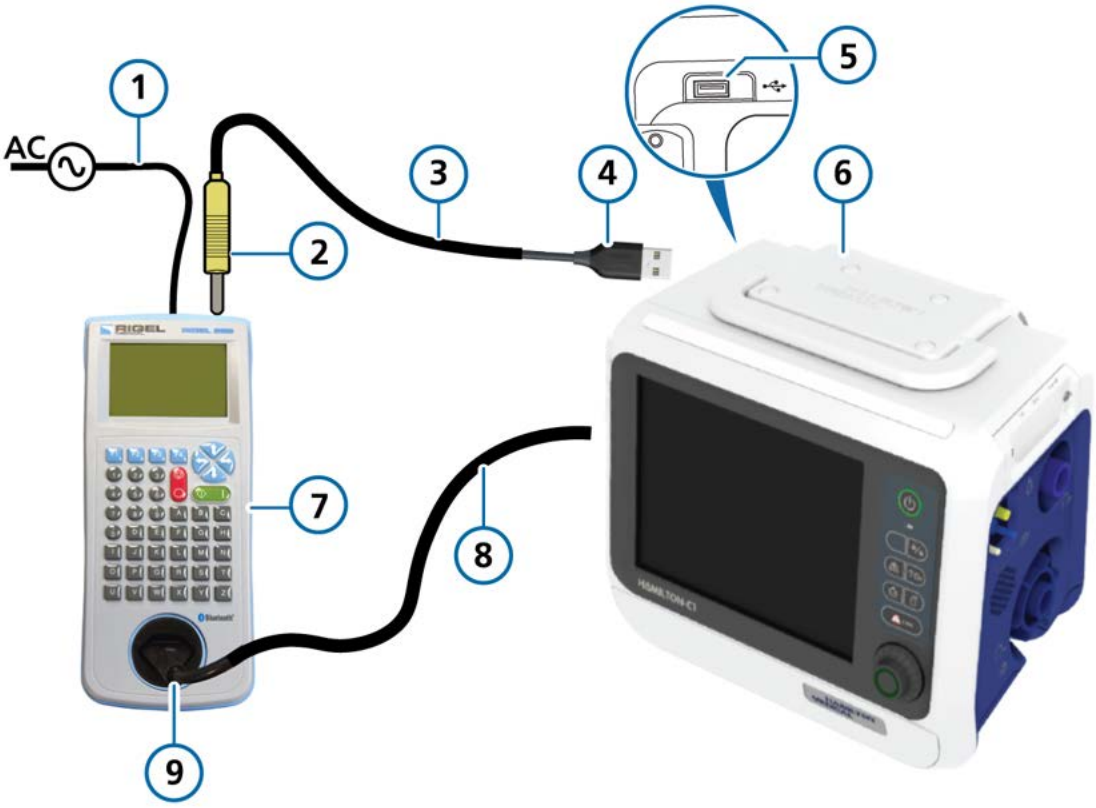
7.4 Device type

Per the IEC 62353 standard for medical devices, the HAMILTON-C1 is a Class II, Type BF device.

7.5 Setup for device without communication board installed

1. Connect the RIGEL 288 (7) power cable (1) to the AC mains power supply.
2. Connect the 4 mm Earth bond probe connector (2) of the electrical safety test cable (3) to the RIGEL 288, then connect the USB plug (4) to the USB port (5) on the HAMILTON-C1 ventilator (6).
3. Connect the HAMILTON-C1 ventilator (6) power cable (8) to the equipment under test (EUT) socket (9) on the RIGEL 288 (7).
4. Turn on the HAMILTON-C1 ventilator (6) in *Standby mode*.
5. Start the test sequence of the safety analyzer.

Figure 7-1. Electrical safety test: Setup for HAMILTON-C1 without communication board installed

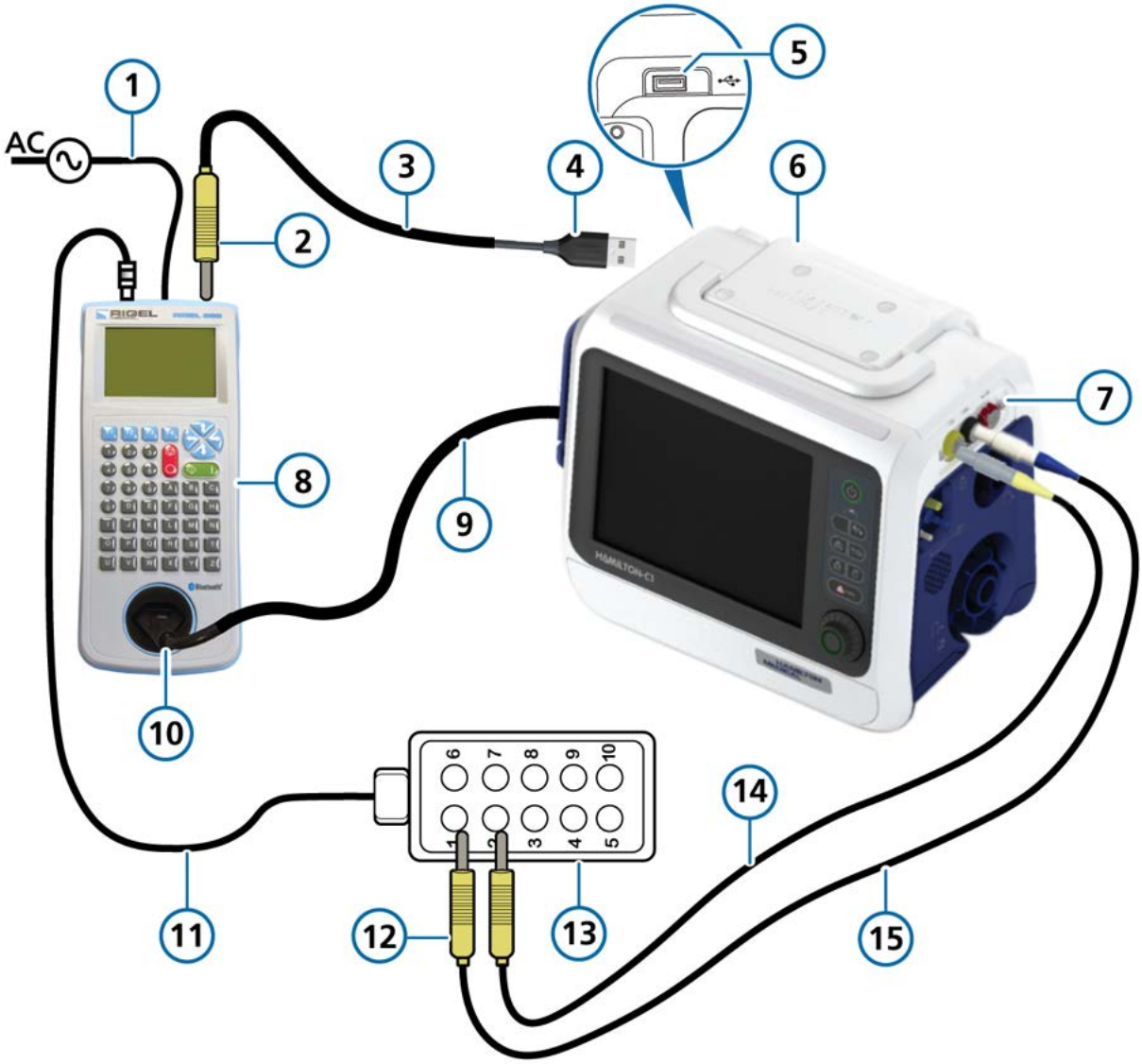


1	Electrical safety analyzer (RIGEL 288) power cable	6	HAMILTON-C1 ventilator
2	Electrical safety analyzer cable: 4 mm earth bond probe connector	7	Electrical safety analyzer (RIGEL 288)
3	Electrical safety analyzer cable (PN 161618)	8	HAMILTON-C1 ventilator power cable
4	Electrical safety analyzer cable: USB plug	9	Equipment under test (EUT) socket on (RIGEL 288)
5	HAMILTON-C1 ventilator USB port		

7.6 Setup for device with communication board installed (CO2 and SpO2)

1. Connect the RIGEL 288 (1) power cable (3) to the AC mains power supply.
2. Connect the 4 mm Earth bond probe connector (2) of the electrical safety test cable (3) to the RIGEL 288 (8), then connect the USB plug (3) to the USB port (5) on the HAMILTON-C1 ventilator.
3. Connect the HAMILTON-C1 ventilator (6) power cable (9) to the equipment under test (EUT) socket (10) on the RIGEL 288 (8).
4. Connect the AP-Box 331A700 (13) cable (11) to the RIGEL 288 (8).
5. Plug the connector (12) of the electrical safety test cable (15) for SpO2 option into the AP-Box 331A700 (13), then plug the connector on the other end of the cable into the SpO2 option port on the communication board (7).
6. Plug the connector of the electrical safety test cable (14) for CO2 option into the AP-Box 331A700 (13), then plug the connector on the other end of the cable into the CO2 option port on the communication board (7).
7. Turn on the HAMILTON-C1 ventilator (6) in *Standby mode*.
8. Start the test sequence of the safety analyzer.

Figure 7-2. Electrical safety test: Setup for HAMILTON-C1 with communication board installed (CO2 and SpO2)



1	Electrical safety analyzer (RIGEL 288) power cable	9	HAMILTON-C1 ventilator power cable
2	Electrical safety analyzer cable: 4 mm earth bond probe connector	10	Equipment under test (EUT) socket on (RIGEL 288)
3	Electrical safety analyzer cable (PN 161618)	11	Connector for AP-Box 331A700 to RIGEL 288
4	Electrical safety analyzer cable: USB plug	12	Electrical safety test cable plug for communication board option
5	USB port on HAMILTON-C1 ventilator	13	AP-Box 331A700 (10-way applied part, adapter box)
6	HAMILTON-C1 ventilator	14	Electrical safety test cable CO2 option (PN 159171)
7	HAMILTON-C1 ventilator communication board: • CO2, RS232, and Nurse Call (PN 161520) • CO2, SpO2, and RS232 (PN 161636)	15	Electrical safety test cable SPO2 option (PN 159681)
8	Electrical safety analyzer (RIGEL 288)		

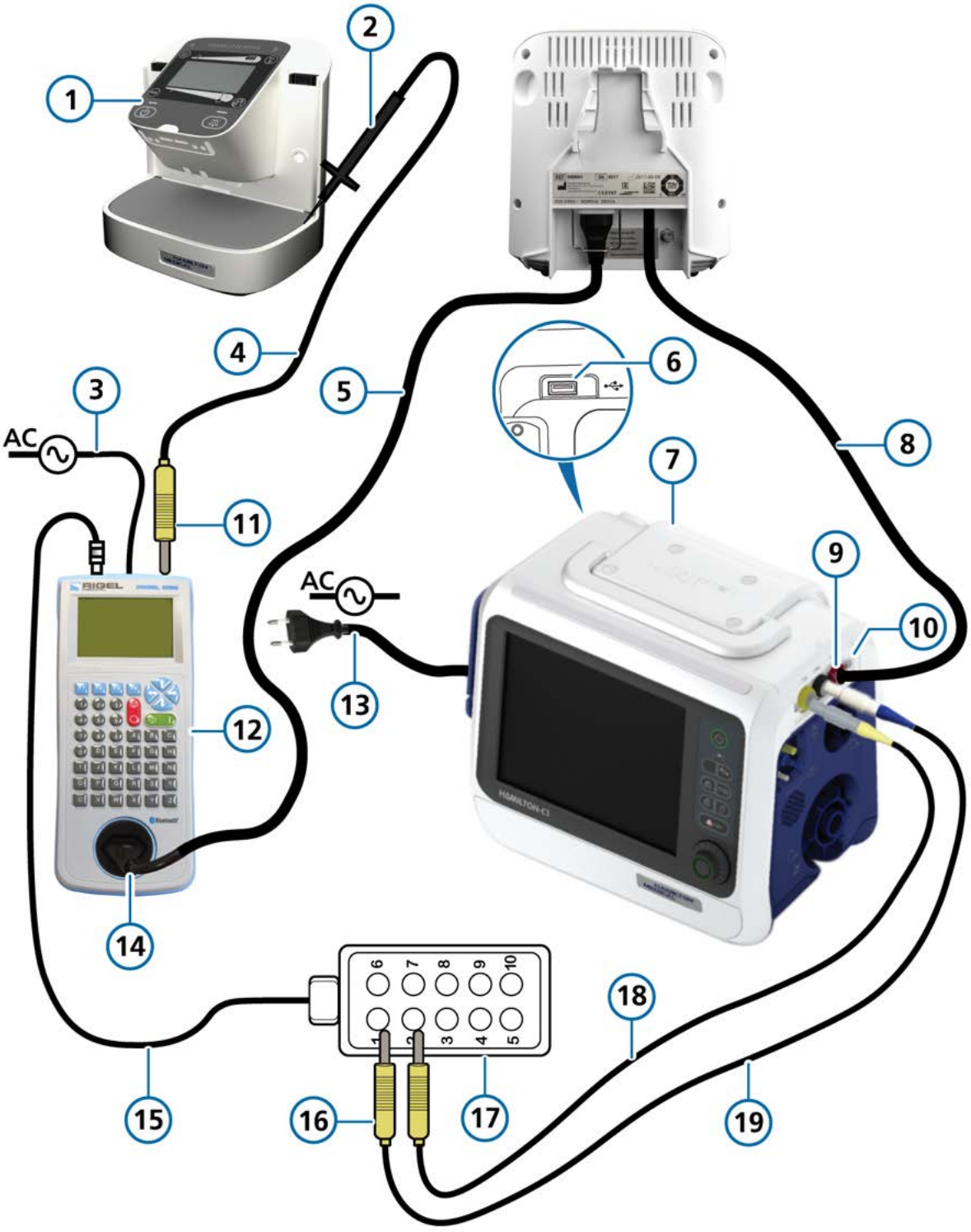
7.7 Setup for device with communication board installed (CO2, SpO2 and humidifier)

The electrical safety test for both **Class I** and **Class II systems** must be performed, as described in Sections 7.7.1 and 7.7.2.

7.7.1 Class I system under test

1. Perform the electrical safety test on the HAMILTON-H900. Refer to the *HAMILTON-H900 Service Manual (PN 624466), Electrical Safety Chapter*.
2. Connect the RIGEL 288 (12) power cable (3) to the AC mains power supply.
3. Connect the 4 mm Earth bond probe connector (11) of the electrical safety test cable (4) to the RIGEL 288 (12), then connect the probe (2) on the other end of the cable to the HAMILTON-H900 humidifier (1) heater plate slot.
4. Connect the HAMILTON-H900 humidifier (1) power cable (5) to the equipment under test (EUT) socket (14) on the RIGEL 288 (12).
5. Connect the communication cable (8) of the HAMILTON-H900 (1) to the COM port (9) on the communication board (10).
6. Connect the AP-Box 331A700 (17) cable (15) to the RIGEL 288 (12).
7. Plug the connector (10) of the electrical safety test cable (19) for SpO2 option into the AP-Box 331A700 (17), then plug the connector on the other end of the cable into the SpO2 option port on the communication board (10).
8. Plug the connector of the electrical safety test cable (18) for CO2 option into the AP-Box 331A700 (17), then plug the connector on the other end of the cable into the CO2 option port on the communication board (10).
9. Connect the HAMILTON-C1 ventilator (7) to the AC mains power supply.
10. Turn on the HAMILTON-C1 ventilator (7) in *Standby mode*.
11. Start the test sequence of the safety analyzer.

Figure 7-3. Electrical safety test for Class I device: Setup for HAMILTON-C1 with communication board (CO2, SpO2 and humidifier) installed

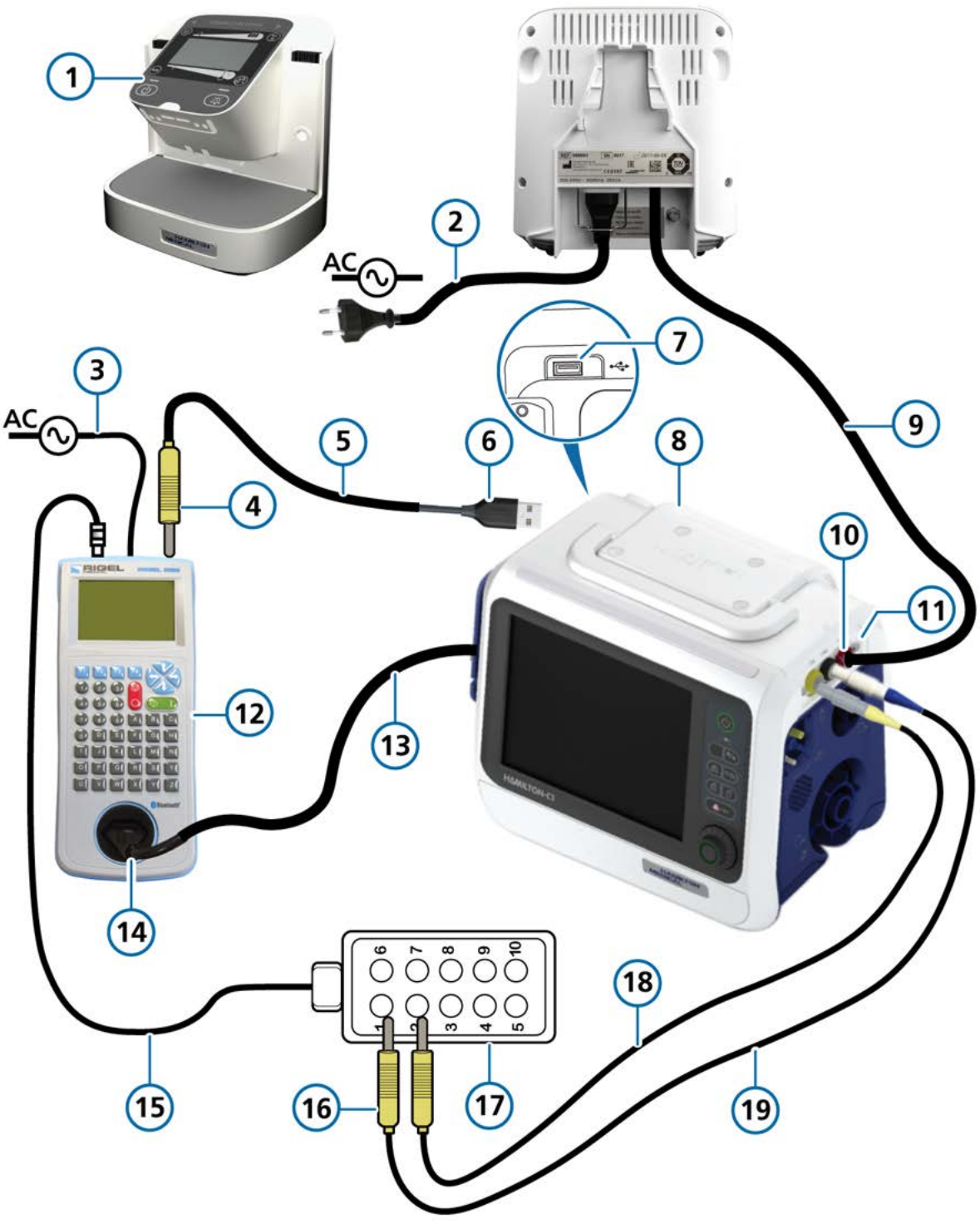


1	HAMILTON-H900 humidifier	11	Electrical safety analyzer cable: 4 mm earth bond probe connector
2	Probe connector	12	Electrical safety analyzer (RIGEL 288)
3	Electrical safety analyzer (RIGEL 288) power cable	13	HAMILTON-C1 ventilator power cable
4	Electrical safety analyzer cable	14	Equipment under test (EUT) socket on (RIGEL 288)
5	HAMILTON-H900 humidifier power cable	15	Connector for AP-Box 331A700 to RIGEL 288
6	HAMILTON-C1 ventilator USB port	16	Electrical safety test cable plug for communication board option
7	HAMILTON-C1 ventilator	17	AP-Box 331A700 (10-way applied part, adapter box)
8	HAMILTON-H900 communication cable (PN 950473 or PN 10077038)	18	Electrical safety test cable CO2 option (PN 159171)
9	HAMILTON-H900 (1) COM port	19	Electrical safety test cable for SpO2 option (PN 159681)
10	HAMILTON-C1 ventilator communication board: • CO2, RS232, and Nurse Call (PN 161537) • CO2, SpO2, and RS232 (PN 161635 / PN 161990) • H900 interface board: CO2, COM , and SPO2 (PN 10076964)		

7.7.2 Class II system under test

1. Connect the RIGEL 288 (12) power cable (3) to the AC mains power supply.
2. Connect the 4 mm Earth bond probe connector (5) of the electrical safety test cable (5) to the RIGEL 288, then connect the USB plug (6) to the USB port (7) on the HAMILTON-C1 ventilator (8).
3. Connect the communication cable (9) of the HAMILTON-H900 (1) to COM port (10) on th communication board (11).
4. Connect the HAMILTON-H900 humidifier (1) power cable (2) to the AC mains power supply.
5. Connect the HAMILTON-C1 ventilator (8) power cable (13) to the equipment under test (EUT) socket (14) on the RIGEL 288 (12).
6. Connect the AP-Box 331A700 (17) cable (15) to the RIGEL 288 (12).
7. Plug the connector (16) of the electrical safety test cable (19) for SpO2 option into the AP-Box 331A700 (17), then plug the connector on the other end of the cable into the SpO2 option port on the communication board (11).
8. Plug the connector of the electrical safety test cable (18) for CO2 option into the AP-Box 331A700 (17), then plug the connector on the other end of the cable into the CO2 option port on the communication board (11).
9. Turn on the HAMILTON-C1 ventilator (8) in *Standby mode*.
10. Start the test sequence of the safety analyzer.

Figure 7-4. Electrical safety test for Class II device: Setup for type BF (communication board CO2 and SpO2 and humidifier installed)



1	HAMILTON-H900 humidifier	11	HAMILTON-C1 ventilator communication board: • CO2, RS232, and Nurse Call (PN 161520) • CO2, SpO2, and RS232 (PN 161636) • CO2, SpO2, Humidifier/COM1 (PN 10076964)
2	HAMILTON-H900 humidifier power cable	12	Electrical safety analyzer (RIGEL 288)
3	Electrical safety analyzer (RIGEL 288) power cable	13	HAMILTON-C1 ventilator power cable
4	Electrical safety analyzer cable: 4 mm earth bond probe connector	14	Equipment under test (EUT) socket on (RIGEL 288)
5	Electrical safety analyzer cable (PN 161618)	15	Connector for AP-Box 331A700 to RIGEL 288
6	Electrical safety analyzer cable: USB plug	16	Electrical safety test cable plug for communication board option
7	HAMILTON-C1 ventilator USB port	17	AP-Box 331A700 (10-way applied part, adapter box)
8	HAMILTON-C1 ventilator	18	Electrical safety test cable CO2 option (PN 159171)
9	HAMILTON-H900 communication cable (PN 950473 or PN 10077038)	19	Electrical safety test cable for SpO2 option (PN 159681)
10	HAMILTON-H900 COM port		

8

Software version 2.x.x

8.1 Introduction

⚠ WARNING

- Read the preventive maintenance and testing Chapter 6, before performing any of the tests or calibrations in this Chapter.
- When servicing the ventilator, it is important that the ventilator is serviced on its stand or on a suitable workbench.
- If one of the tests indicates that you must replace a part, do so immediately and update the technical state (see Section 8.2.6.1.3) and then repeat all tests and calibrations. See contents in this section.

⚠ WARNING

- To prevent patient or ventilator contamination, always use a bacterial filter between the HAMILTON-C1 ventilator and the inspiratory limb of the patient breathing circuit.
- For troubleshooting see knowledge base.
- Record all results on the ventilator test report (see Chapter 17).
- Confirm that the technical state is up-to-date and the ventilator has been restarted after the technical state modifications (see Section 8.2.6.1.3).

⚠ CAUTION

- *Make sure you install the applicable mandatory backup battery or batteries in the battery compartment of the HAMILTON-C1 ventilator.*
- *Make sure you operate the HAMILTON-C1 ventilator in ventilation mode to warm up the ventilator for at least 20 minutes before you start the calibrations and tests in service software mode.*

NOTICE

- The battery status information, that is, DC symbol shown in the service software screenshots is for illustrative purposes only.
- The service software version 3.x.x is applicable to HAMILTON-C1 with SN > SN6000 only.

This section describes each of the units comprising the HAMILTON-C1 ventilator Service Software.

Before starting, ensure that you are familiar with typographic conventions (see Section 1.2) and expressions (see Section 1.3).

The ventilator test report form is the standard form to be used and must be completed each time the tests and calibrations are performed. If there is not a suitable form, you can photocopy and use the form (see Chapter 17).

8.2 Service software 2.x.x

This section provides information on the following:

- Functions of the service software
- Structure of the service software
- Service software calibrations and tests.

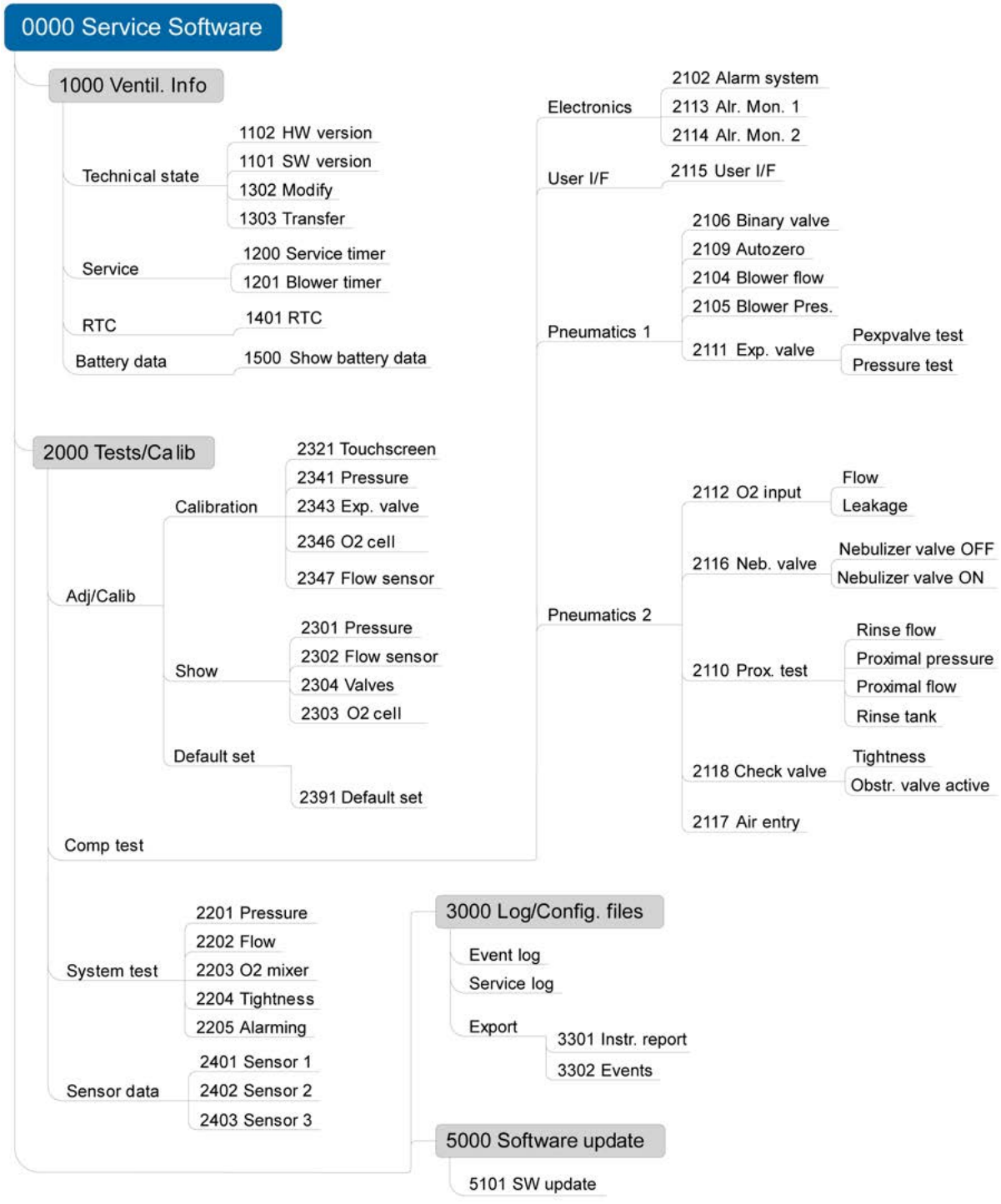
8.2.1 Functions of the service software

The operator can use the HAMILTON-C1 service software menu options to do the following:

- Display information on the device hardware and software revisions and versions.
- Check the correct operation of the device hardware and software.
- Calibrate and test the hardware of the device.
- View and export the *Event log*, *Service log* and *Instrument report*.
- Update/upgrade the device software

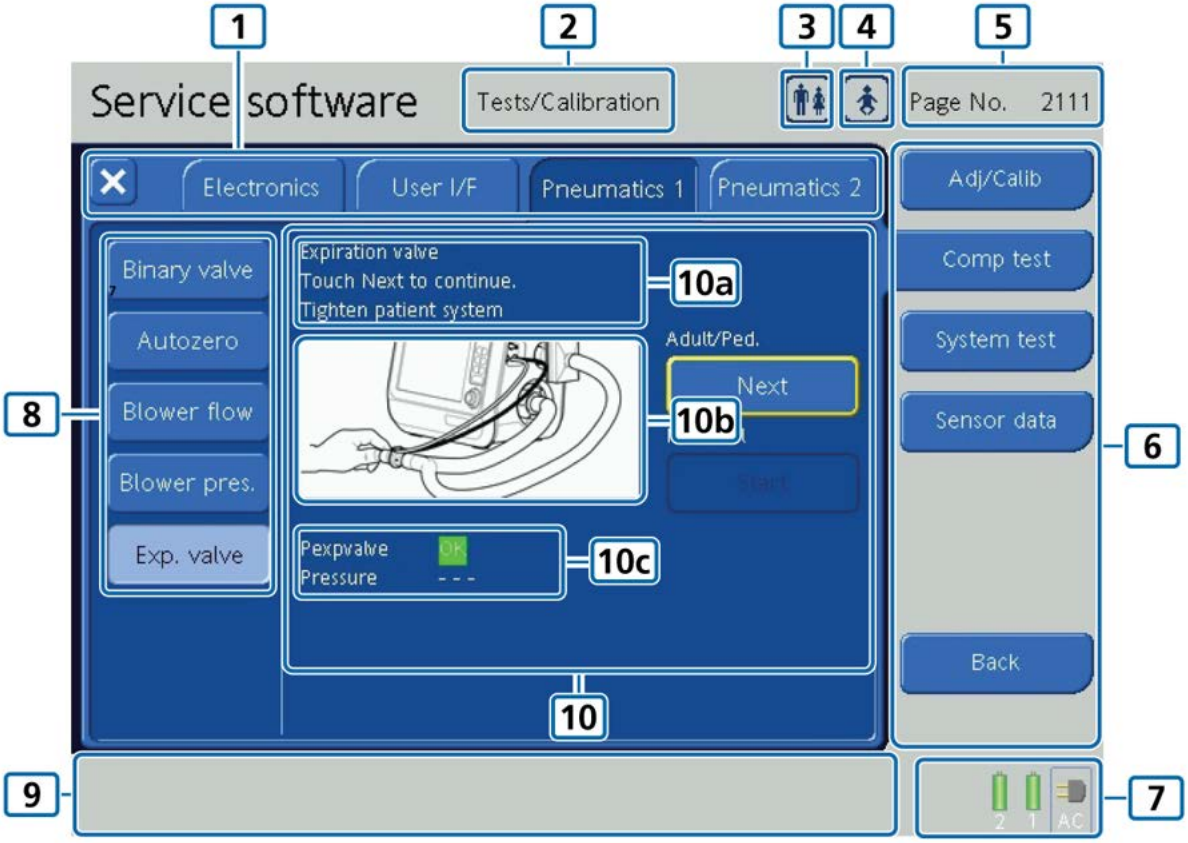
8.2.2 Structure of the service software

Figure 8-1. Service software structure SW v2.2.x



8.2.3 Service software screen layout

Figure 8-2. Service software screen layout



1	Menu tab layer 2: Optional test tabs	6	Menu tab layer 1: Adjustment/Calibration, Component test, System test, and Sensor data tabs
2	Header window	7	Power (AC/DC) status, date, and time window
3	Patient group button for Adult/Paediatric configuration: Calibrations and tests	8	Menu tab layer 3: Optional test tabs
4	Patient group button for Neonate configuration: Calibrations and tests	9	Alarm information window
5	Service software page number	10	Test configuration window: • 10a. Test window information/dialog • 10b. Test configuration illustration/graphic window • 10c. Test status and results indication

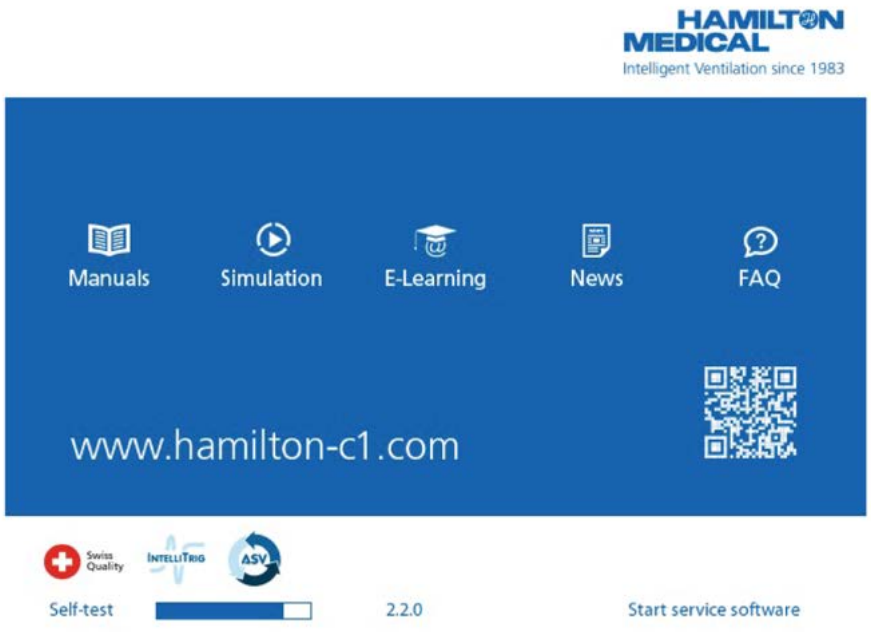
Icon / Button	Status	Description
	Adult/Ped. option installed only. Adult/Ped. mode is selected for calibration and tests.	HAMILTON-C1 < SN6000
	Adult/Ped. configuration selected for calibration and tests.	HAMILTON-C1 > SN6000
	Neonatal configuration selected for calibration and tests.	HAMILTON-C1 > SN6000
	Calibration / test is in progress	HAMILTON-C1 > SN6000

8.2.4 Starting the service software

1. The bar indicates the progress of the start-up self-test procedure. The starting of the service software is shown on the main screen.
2. Press the **ON** (1) button located on the ventilator front panel, then press and hold the Manual Breath (4) and the **100% O2** (3) buttons at the same time until the two corresponding green LEDs (2) light up.

Figure 8-3. Starting the HAMILTON-C1 ventilator in service software mode

Figure 8-4. Starting the service software

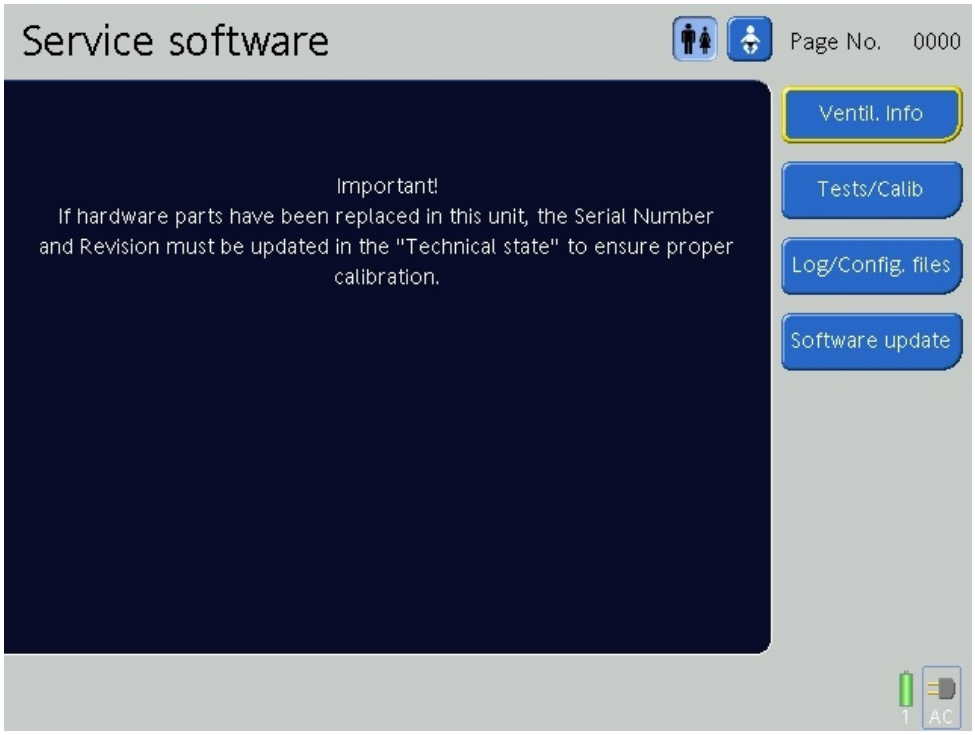


The start-up of the ventilator consists mainly of:

- System self check (RAM, ROM test, checksum) boot procedure
- Starting the operating system
- Starting and verifying technical state (Device Part Number, HW Components)
- Starting all SW processes
- Initializing the digital periphery:
  - Compatibility check of the FPGA on the ESM
  - EEPROMs checksum test
  - I/O PORTs
  - Serial interfaces
  - Network interface
- Switching on the power voltages (for the valves and the blower)
- Initializing the power periphery (enabling valves and blower)
- Instrument self-test:
  - Checking the SW version, and if a newer version was installed -> performing migration
  - Detecting the device's configuration, modules and options
  - Checking the HW versions
  - Checking the RTC (if it has been reset due to power loss)
  - Loading the calibration values from the EEPROMs
  - Testing the sensors (values within range calibration values)
  - Testing the valves (on / off)
  - Testing the blower (short run)
  - Testing the lamps (on / off)
  - Testing the speaker (on / off feed back)
  - Testing the buzzer (on / off feed back)
- Entering the ventilation start window or the service software

When the service software self-test has finished, the main service software screen is displayed.

Figure 8-5. Main service software screen (Page No. 0000)



8.2.5 Print screen

The print screen function saves a JPG file of the current ventilator screen to a USB memory drive.

To create a screen shot

1. Insert a USB memory drive into the USB port.

2. Press the Print screen key  while the desired display is shown.

The device saves the image to the memory drive. The green indicator next to the key is lit while the device saves the image.

The filename takes this format:

screenshot_yyyymmdd_HHMMSS.jpg

where:

yyyy is the year

mm is the month

dd is the day

HH is the hour (in 24-hour format)

MM is the minute

ss is the second.

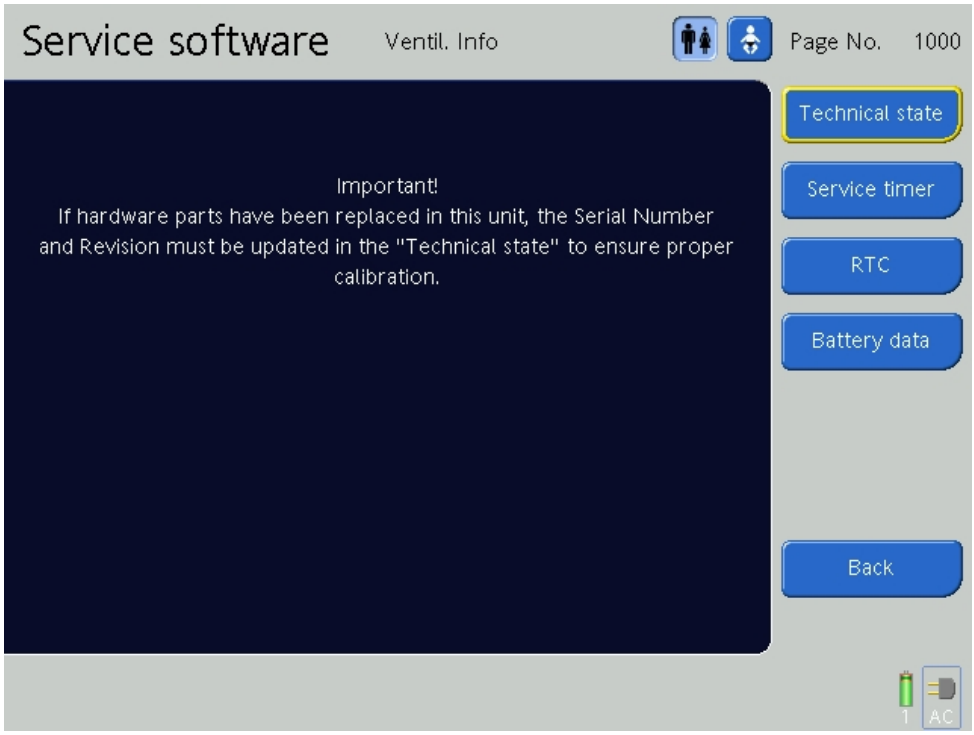
NOTICE

Specification for the USB memory stick:
USB memory stick - Hamilton Medical PN 396376
File system: FAT or FAT32
Unpartitioned memory
No operating system or security software installed

8.2.6 Ventilator info screens (Page No. 1000)

From the main service software screen, press the **Ventil. Info** button.

Figure 8-6. The ventilator info screen



On the ventilator info screen are the:

- Technical state button
- Service timer button
- Real time clock (RTC) button
- Battery data button
- Back button (return to the main menu)

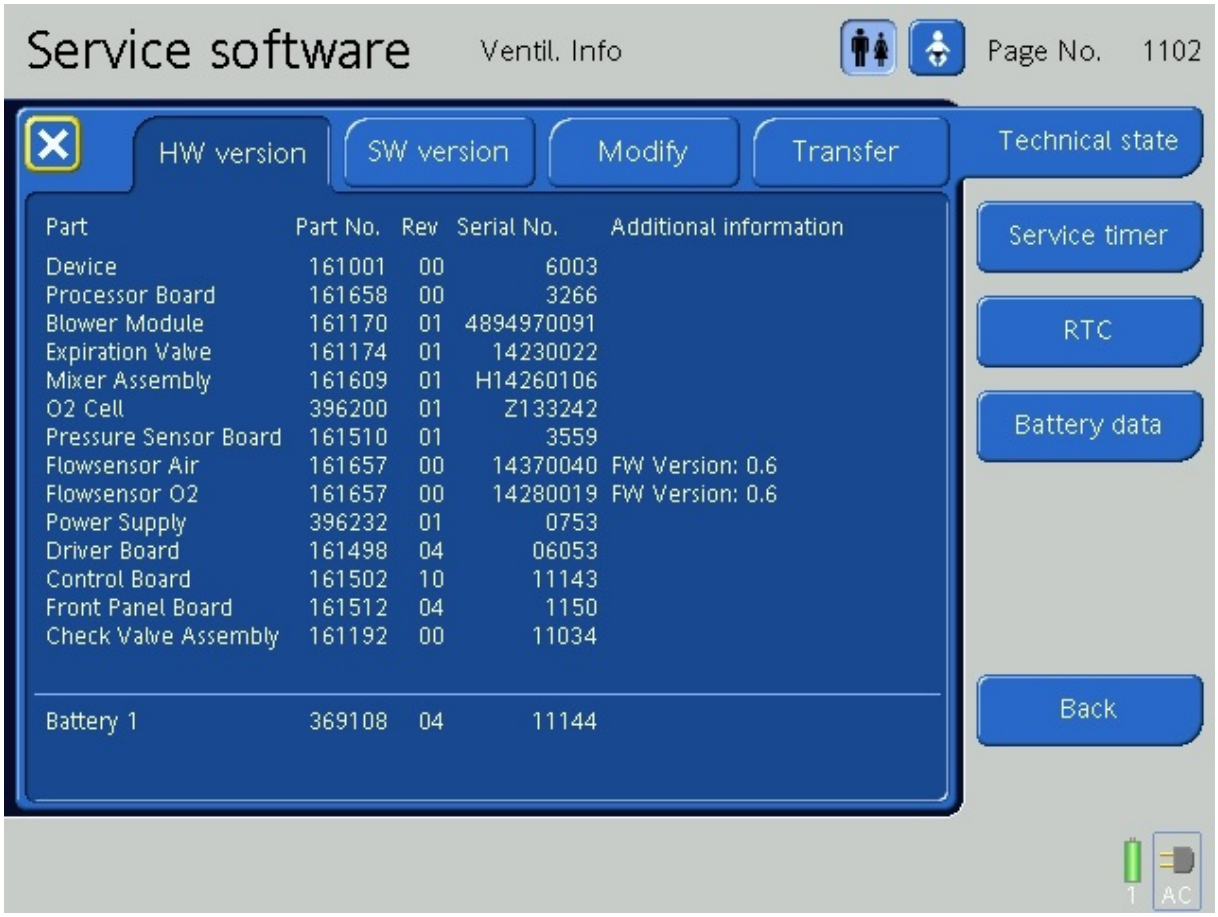
8.2.6.1 Technical state

Touch the **Technical state** button to enter the technical state window. Information about the **Hardware (HW) version**, **Software (SW) version**, **Modify**, and **Transfer** can accessed in the **Technical state** window.

8.2.6.1.1 HW version (Page No. 1102)

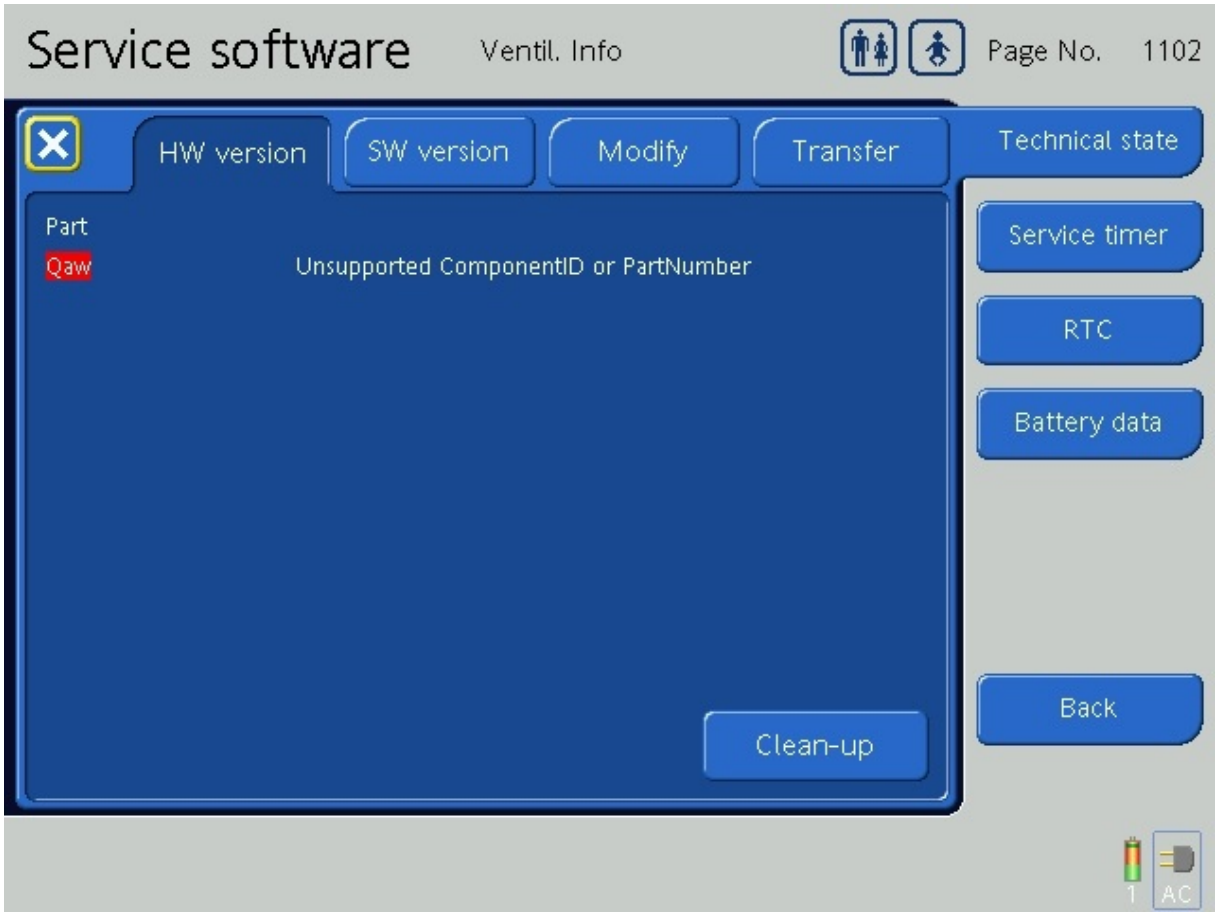
1. Touch the **HW version** tab (if not already selected). The **HW version** tab displays the device name, part number, revision, serial number and timing information.
2. The information of the following components will be updated automatically from the HAMILTON-C1 ventilator during start-up:
   - Battery 1
   - Control board
   - Processor board (ESM-board)
   - Driver board
   - Pressure sensor board
   - Front panel board
   - Flow sensor AIR (Qvent)
   - Flow sensor O2 (QO2)
   - O2 sensor
   - Communication board
3. Record the hardware version information on the ventilator test report (see Chapter Ventilator test report).

Figure 8-7. HW version (Page No. 1102)



1. In case the technical state is corrupt, or after upgrading from SW version 1.x to 2.x, the **Clean-up** button will appear.
2. Touch the **Clean-up** button to restore the structure of the technical state.

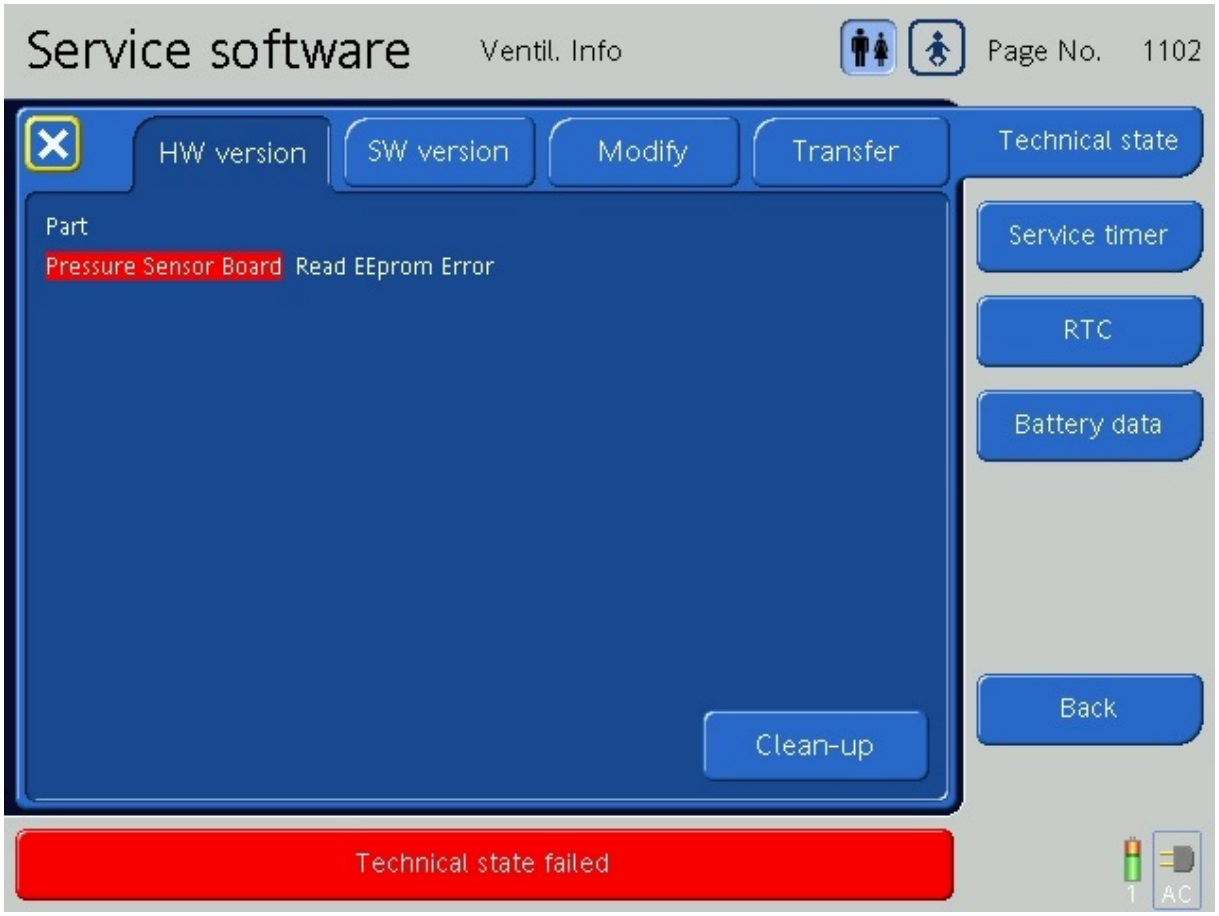
Figure 8-8. Clean-up button (Page No. 1102)



1. In case the technical state cannot be read out from the EEPROM of a component or after a control board replacement, the unit will fail in self-test and alarm with "Technical state failed". Other Technical faults will appear as after effect.
2. The HW version will display the part[5] which causes the problem, highlighted in red. If the communication bus to the EEPROM is interrupted, the first part of the communication will be displayed. This part is not absolutely the problem causing part. Check the cable connection and replace the defective component if necessary. The **Clean-up** button also appears but has no function in this case.

[5] Except the Flow sensor AIR and O2 as well as the O2 sensor. If one of these three components cannot be read, the part will not be listed in the HW version tab. After clean-up make sure all part numbers are selected correctly and the revision number as well as the serial number has been entered.

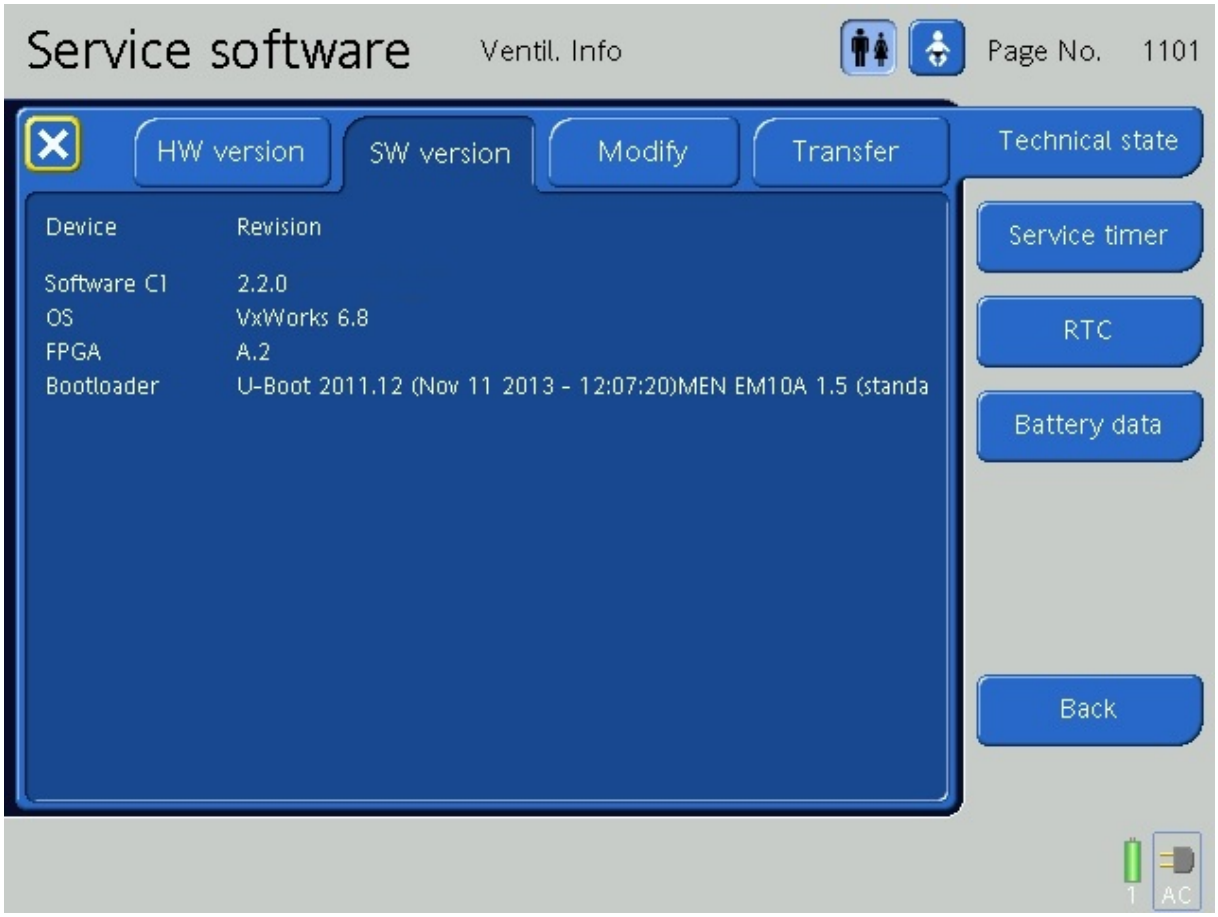
Figure 8-9. EEprom read error (Page No. 1102)



8.2.6.1.2 SW version (Page No. 1101)

1. Touch the **Technical state** button to enter the technical state section.
2. Touch the **SW version** tab. The software version tab displays the device names and revisions of the operating software.
3. Record the software version information of the HAMILTON-C1 ventilator on the Test Report (see Chapter 17).

Figure 8-10. SW version (Page No. 1101)



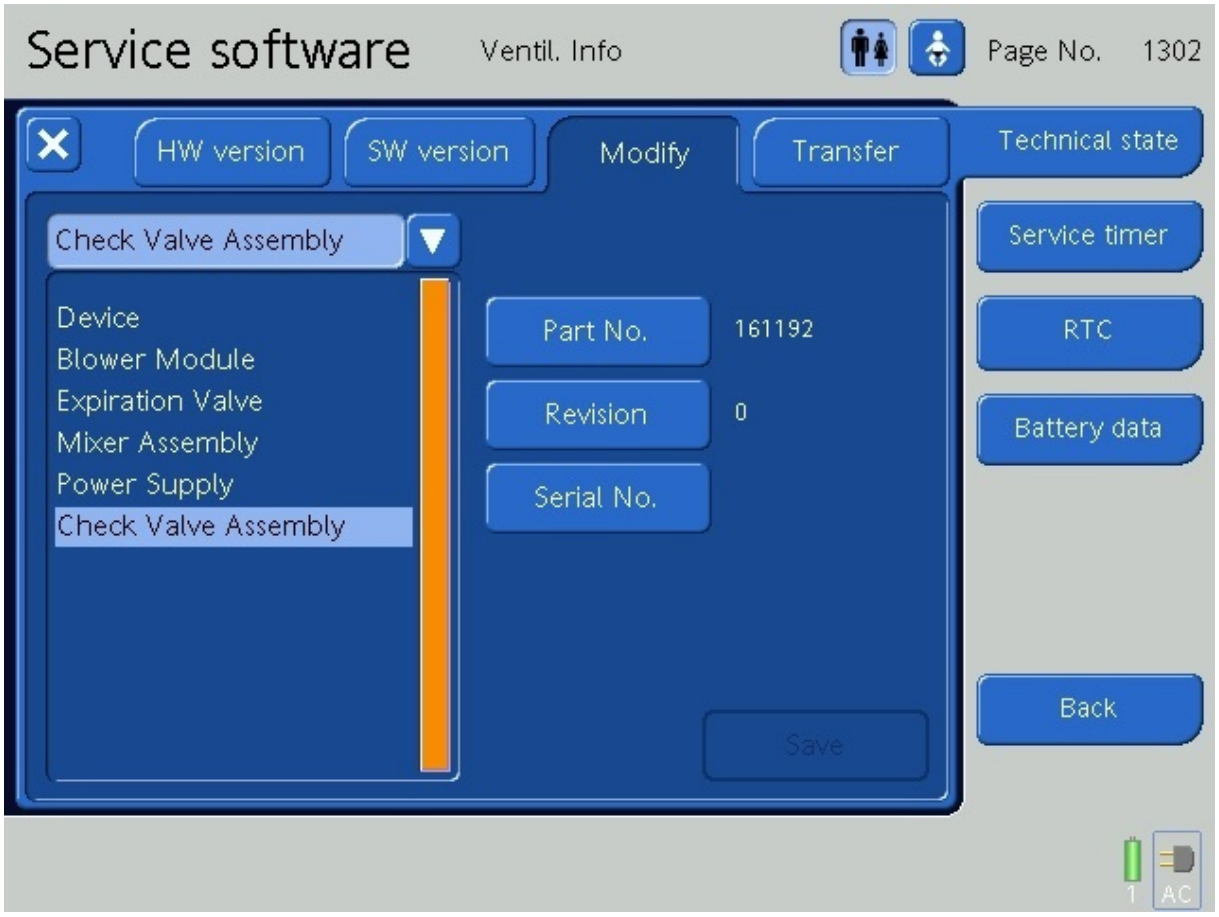
8.2.6.1.3 Modify (Page No. 1302)

⚠ CAUTION

- *You must update the technical state when you replace a part listed in the Modify window. Restart the HAMILTON-C1 before you perform the service software tests and calibrations.*
- *Make sure to select the correct part number. Cross check with the label / installation guide of the spare part.*
- *A change of the serial number of the blower module will reset the blower timer.*

1. The modify tab allows updating information when a part has been replaced. Touch the **Modify** button. Select the hardware component to be modified.

Figure 8-11. Modify technical state (Page No. 1302)



2. To change the serial or revision number touch the corresponding button and enter the number(s). Proceed with **Confirm**. When finished press the **Save** button.

3. To change the part number touch the **Part No.** button and select the correct number.

Figure 8-12. Modify technical state info (Page No. 1302)

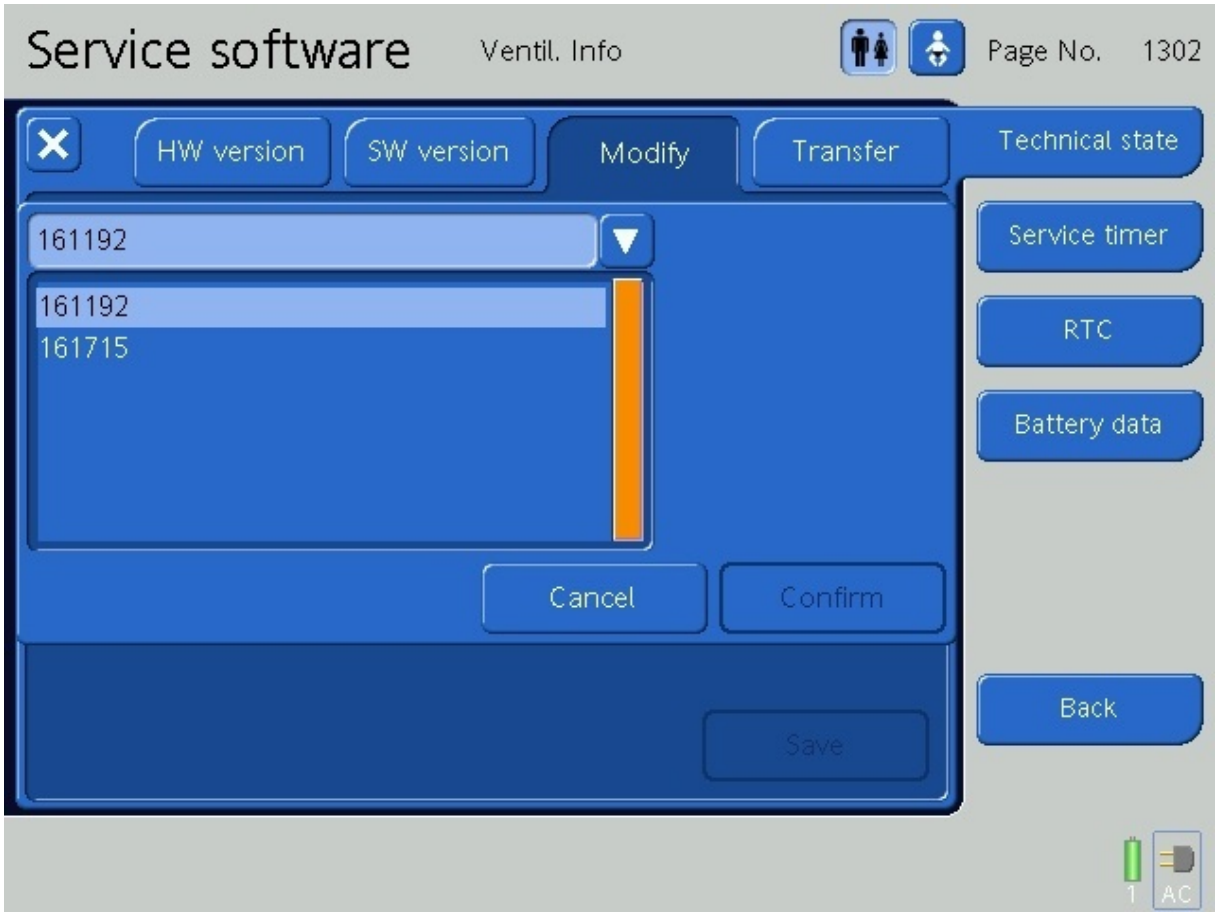


Table 8-1. Selectable part numbers, technical state (Page No. 1302)

Component	Part No.	Applicable to	Remarks
Device	161001	HAMILTON-C1	Part No. can only be set with the installation of a new control board
	161003	HAMILTON-C1 (JPN)	
Blower Module	161170	MSP161170	Blower type D
	161151 (SW v ≥ SW v2.2.7)	MSP161151	Blower type H **NOTICE!** Blower module 'type H' requires a driver board with Rev. No. ≥ Rev. 06.
	161025 (SW v ≥ SW v2.2.7)	N/A	Blower type J (PN 10103804) **NOTICE!** Blower module 'type J' requires a driver board with Rev. No. ≥ Rev. 06.
Expiration valve	161174	MSP161174	HAMILTON-C1 with SN < SN6000
		MSP161265	HAMILTON-C1 with SN > SN6000
Mixer Assembly	161171 or 161178	MSP161171	HAMILTON-C1 < SN6000 MSP161171 and MSP161178 are no longer available.
	161179	MSP161179	HAMILTON-C1 with SN < SN6000
	161609	MSP161609	HAMILTON-C1 with SN > SN6000
Power Supply	396232	MSP396232	
Check Valve Assembly	161243	MSP161243	HAMILTON-C1 with SN < SN6000
	161192	MSP161192	HAMILTON-C1 with SN > SN6000

Reset the blower timer after blower module replacement

⚠ CAUTION

The blower timer (Blower %) must be reset only after a replacement of the blower module.

For SW v ≥ v2.2.4:

1. To change the **Serial No.** of the blower module: touch the **Serial No.** button, then select the applicable blower module serial number.

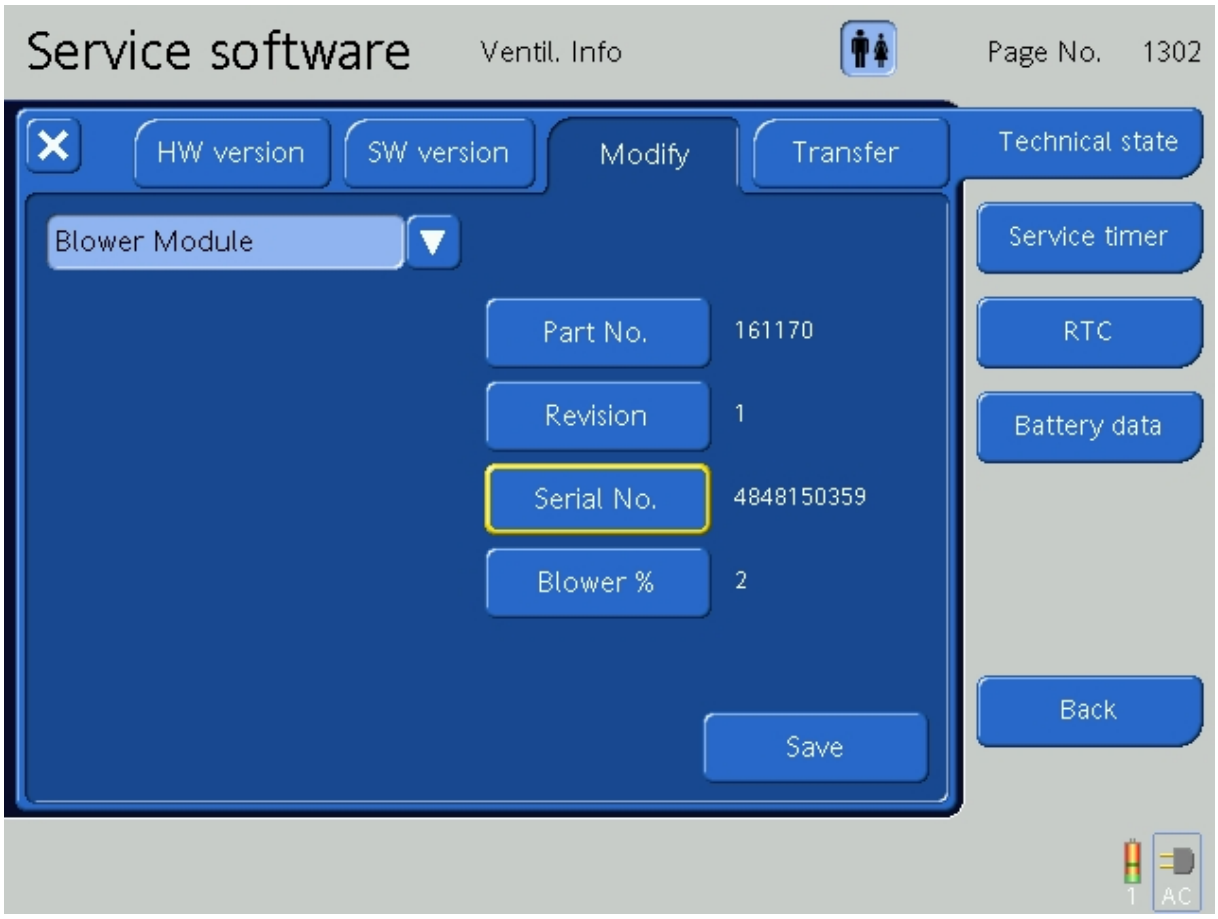
2. Touch the **Confirm** button to apply the selected blower module **Serial No**. The **Blower %** button appears.

3. Touch the **Blower %** button and enter the blower timer % value of installed blower module. Proceed with **Confirm**. When finished press the **Save** button.

For SW v < v2.2.4:

Change the Serial No. of the blower module and touch **Confirm**. The blower timer will be reset to 0.

Figure 8-13. Blower timer reset (Page No. 1302): Blower %



8.2.6.1.4 Transfer (Page No. 1303)

⚠ CAUTION

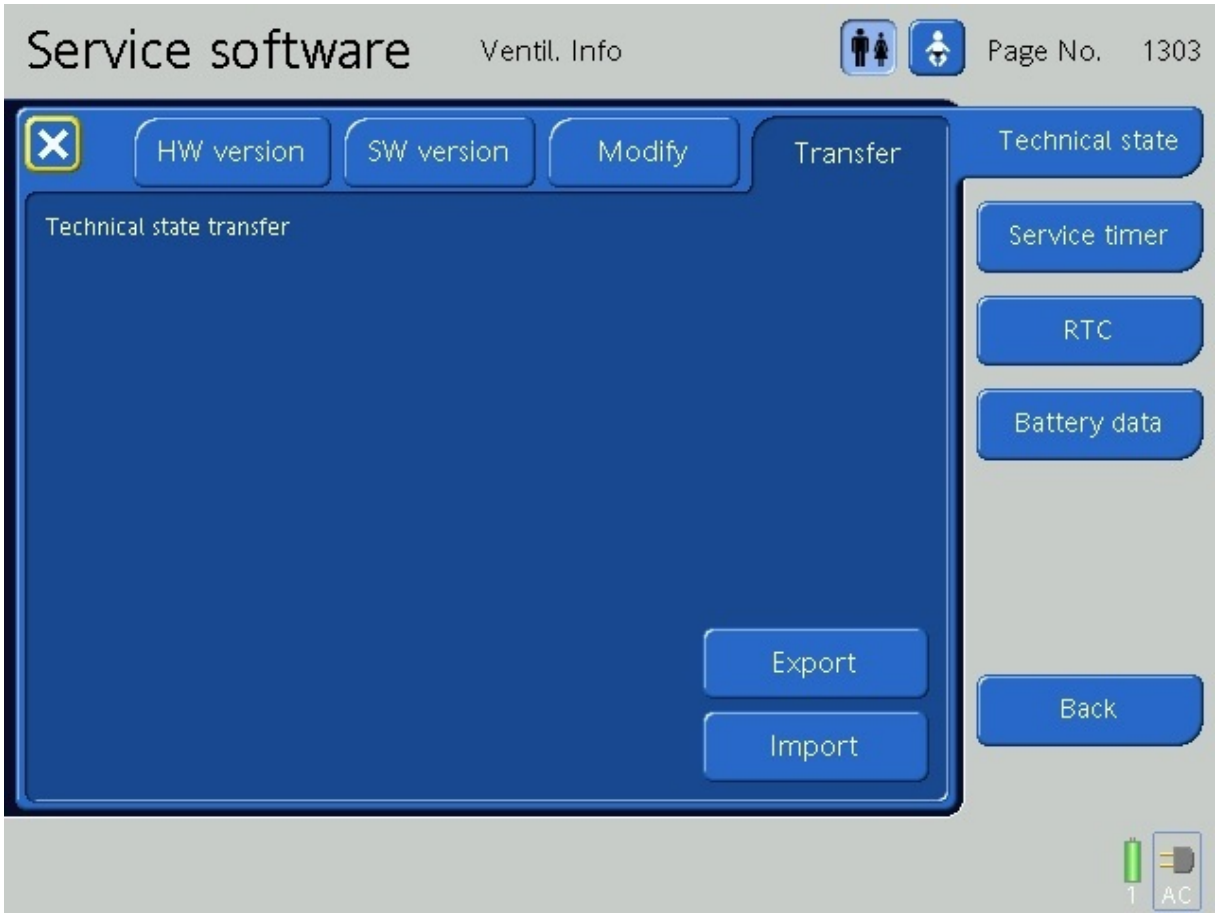
Technical state exported with software version 1.x.x cannot be imported in software version 2.x.x or higher.

NOTICE

- **For SW v < v2.2.4**:
  If the Serial No. of the Blower module in the technical state differs from the one in the import file, the blower timer will be reset to 0 after import. The blower timer can no longer be reset back again.
- **For SW v ≥ v2.2.4:**
  If the Serial No. of the Blower module in the technical state differs from the one in the import file, the blower timer remains unchanged after import.

The technical state can be exported and imported to/from the USB flash drive. Make sure the USB flash drive is connected to the ventilator, then touch the corresponding button.

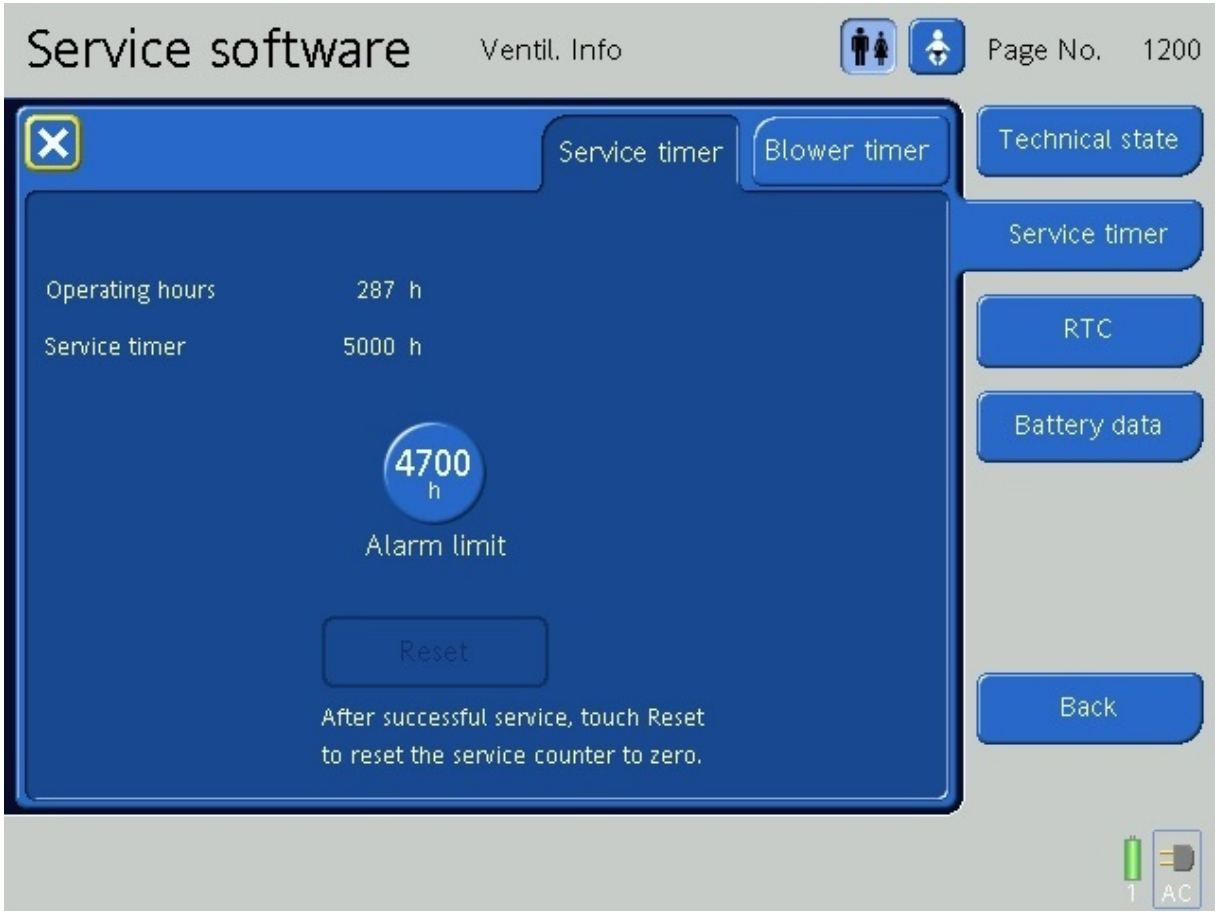
Figure 8-14. Transfer (Page No. 1303): Export / Import the technical state of the device



8.2.6.2 Service timer

1. Touch the **Service timer** tab to view the total **Operating hours** of the ventilator.

Figure 8-15. Service timer (Page No. 1200)

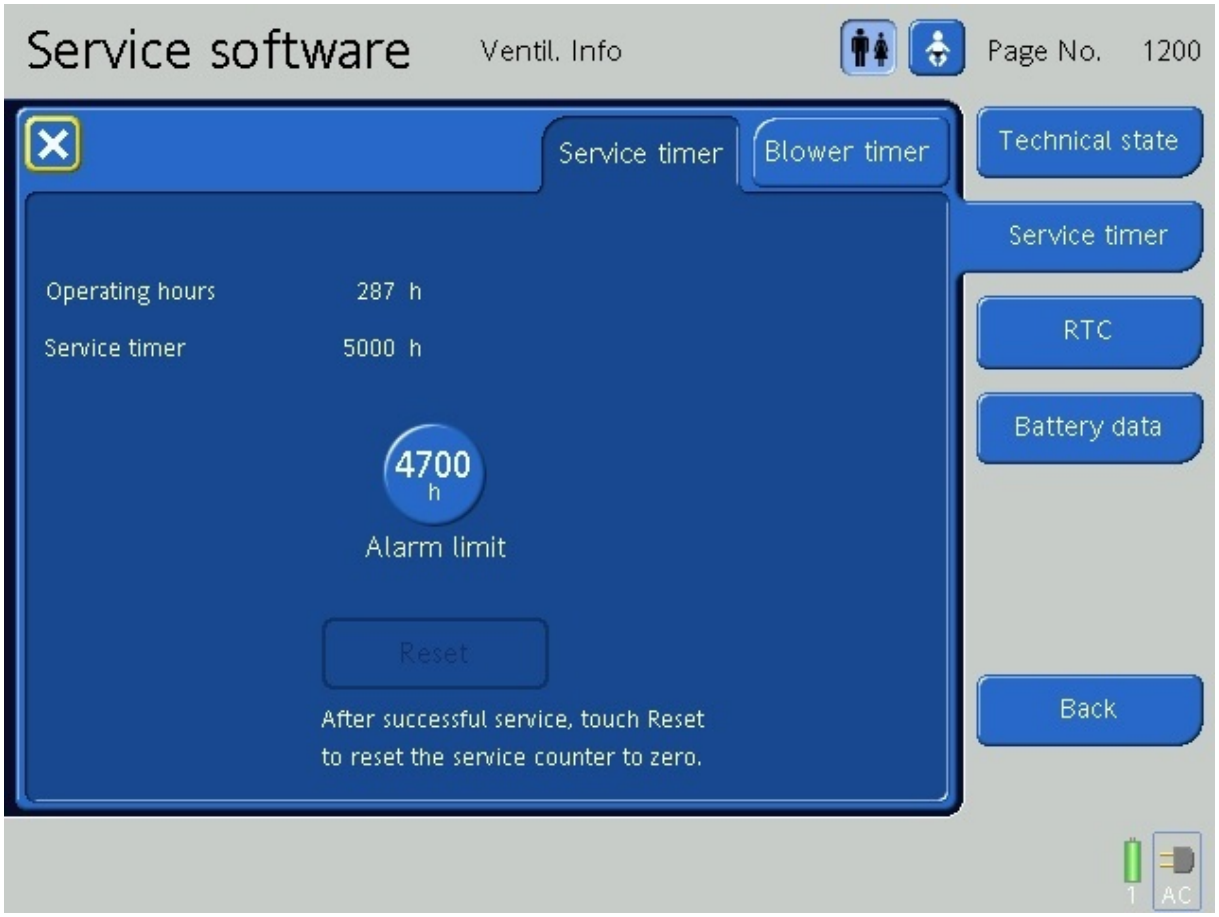


8.2.6.2.1 Service timer (Page No. 1200)

On the **Service timer** tab, the total operating hours are displayed and the service timer hours are displayed since the last time the service timer was previously reset.

The **Alarm limit** button allows to set the number of hours between service intervals to be changed.

Figure 8-16. Service timer (Page No. 1200)



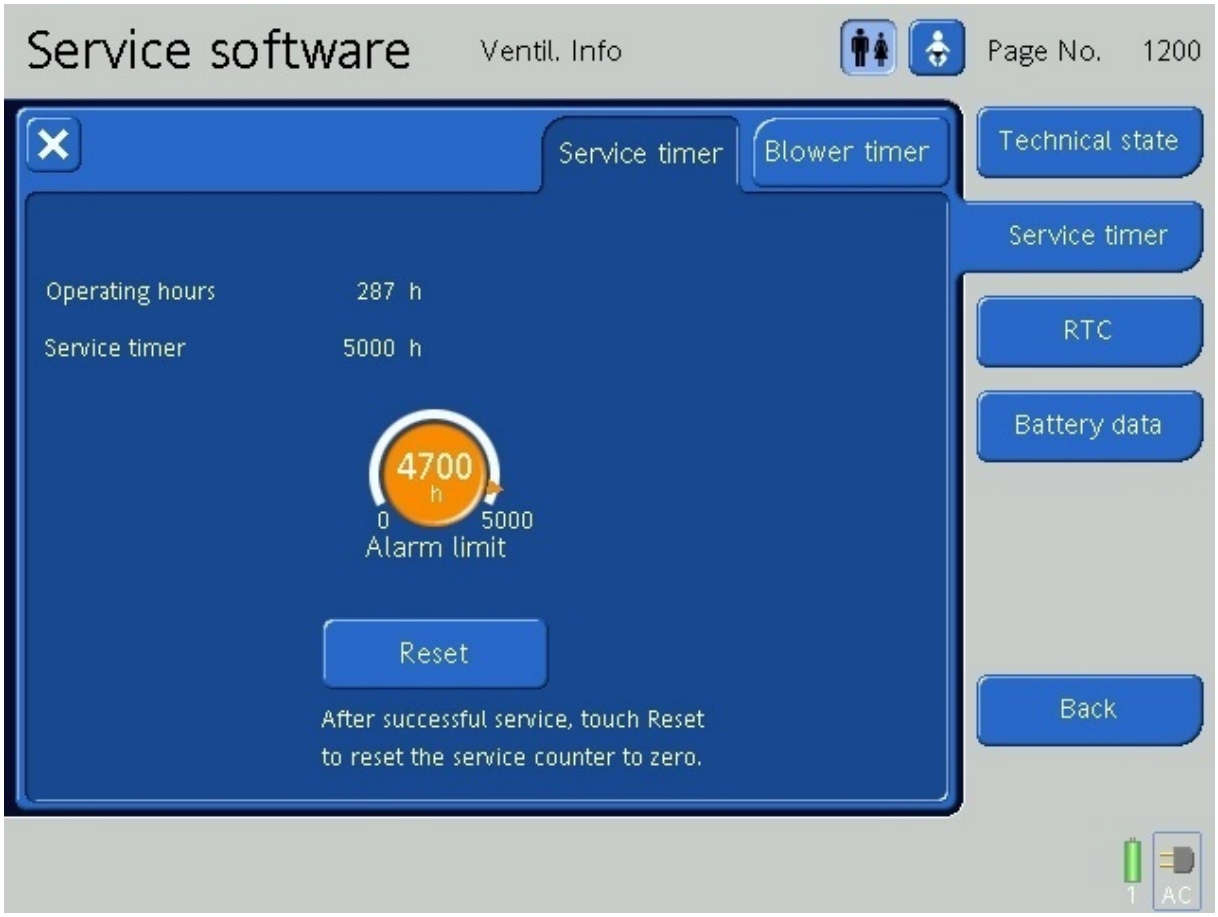
After successful service, the service timer can be reset.

To reset the counter:

1. Touch the **Alarm limit** button and change the alarm limit by rotating the P&T knob.
2. Confirm by touching the **Alarm limit** button or by pressing the P&T knob.

4. Reset the service counter by touching the **Reset** button.

Figure 8-17. Reset service timer (Page No. 1200)



8.2.6.2.2 Blower timer (Page No. 1201)

1. Touch the **Blower timer** tab. On the **Blower timer** tab, the total blower operation time is displayed in percentage. The expected operation time (100%) is calculated based on the operating hours, temperature and rotation speed of the blower.

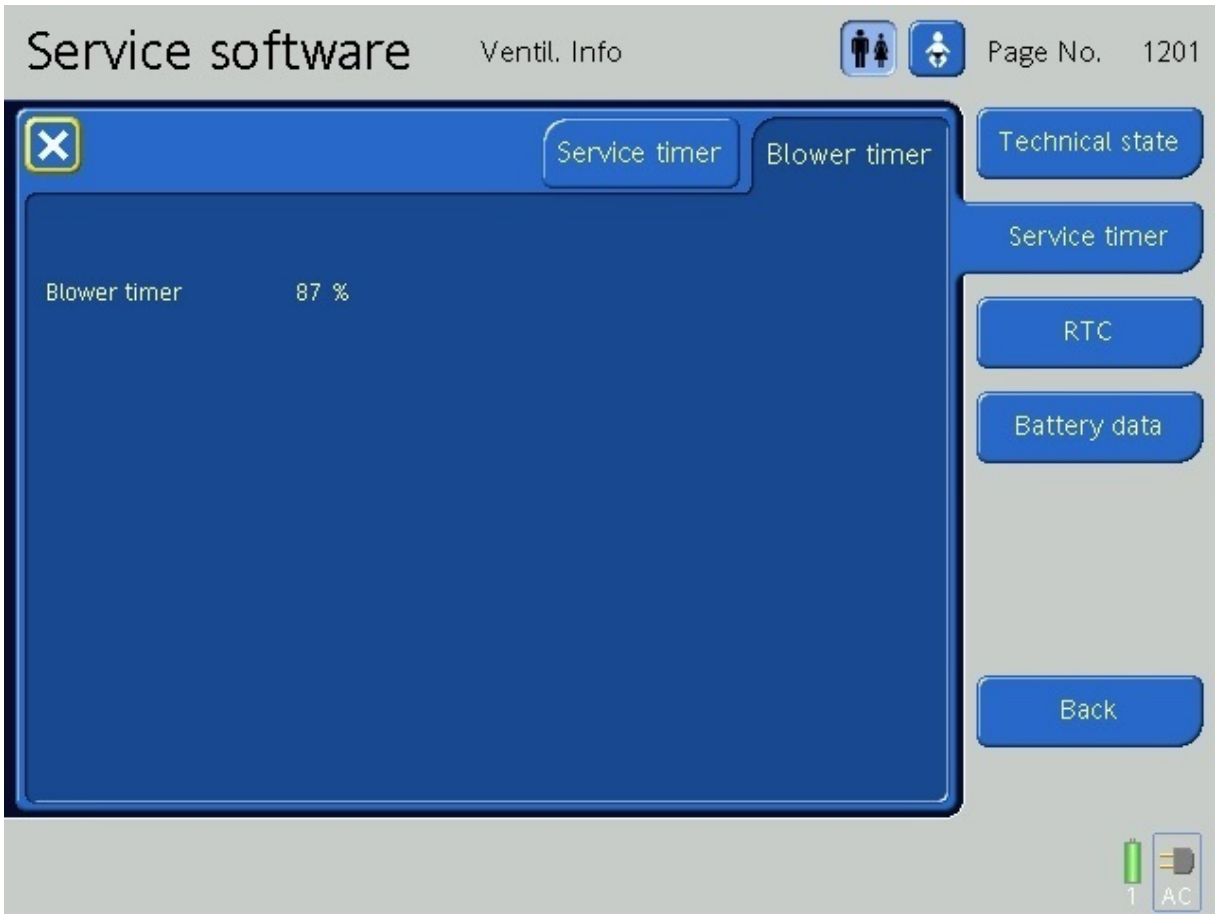
2. Replace the blower when the blower timer ≥ 100%. Also replace the blower when the prediction of the blower timer in the next 6 months reaches 100%. See prediction calculation help in the table below.

Table 8-2. Prediction of the blower timer in 6 months:

$ebt = bt + \left(\frac{bt}{y \times 2}\right)$	Where: ebt = expected blower timer in 6 months [%] bt = current blower timer [%] y = number of years since the installation of the blower [Year(s)]

3. After replacement of the blower module, enter the serial number and revision number of the blower in the technical state and reset the blower timer (see Section 8.2.6.1.3).

Figure 8-18. Blower timer

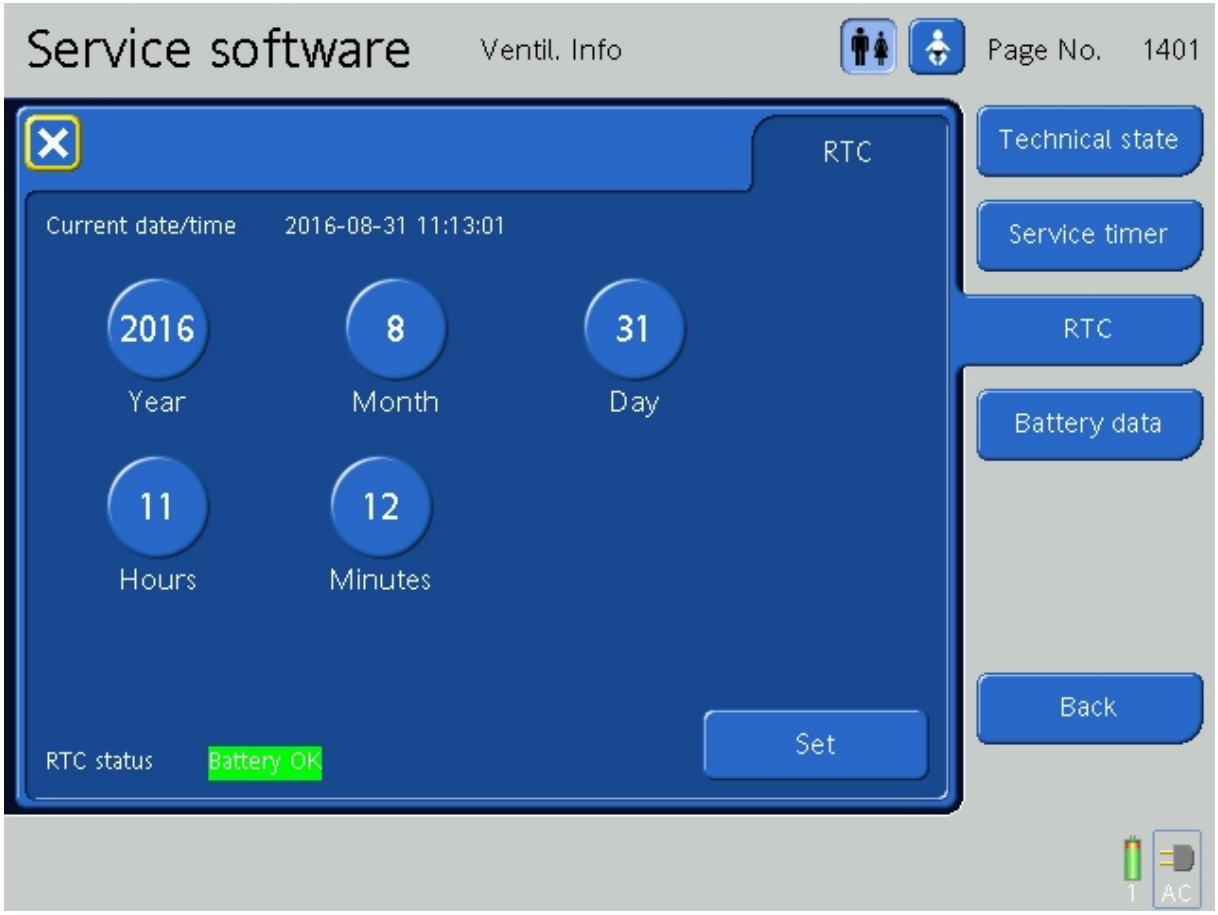


8.2.6.3 RTC (Real time clock) (Page No. 1401)

Check the current date and time and adjust if necessary:

1. Select the value that needs to be adjusted by touching the corresponding button on the screen or by using the P&T knob until the desired button is highlighted.
2. Change the number displayed by rotating the P&T knob.
3. Confirm by touching the corresponding button on the screen again or pressing the P&T knob.
4. Touch the **Set** button to set the values.
5. Check the RTC status for "Battery OK" .

Figure 8-19. Real time clock (Page No. 1401)



8.2.6.4 Battery data (Page No. 1500)

1. Touch the **Battery data** button to display the battery data.
2. Check the state of health (SoH) of the battery.
3. Replace the battery when the state of health (SoH) is < 20%
4. Consider to replace the battery when:
   - the state of health (SoH) is < 40%, depending on the way of use.
   - the cell voltages are permanently asymmetrical (cell voltage difference more than 100 mV).
5. Calibrate the battery if Error ≥ 5%.
6. Record the battery data on the ventilator test report (see Chapter Ventilator test report).

Also refer to Section 5.4.1.

NOTICE

Information about Cell voltage 4

The battery with Part No. 369108 only contains 3 cells; therefore, **Cell voltage 4** displays "-" .

Figure 8-20. Example of battery with a good SoH. A battery replacement is not required.

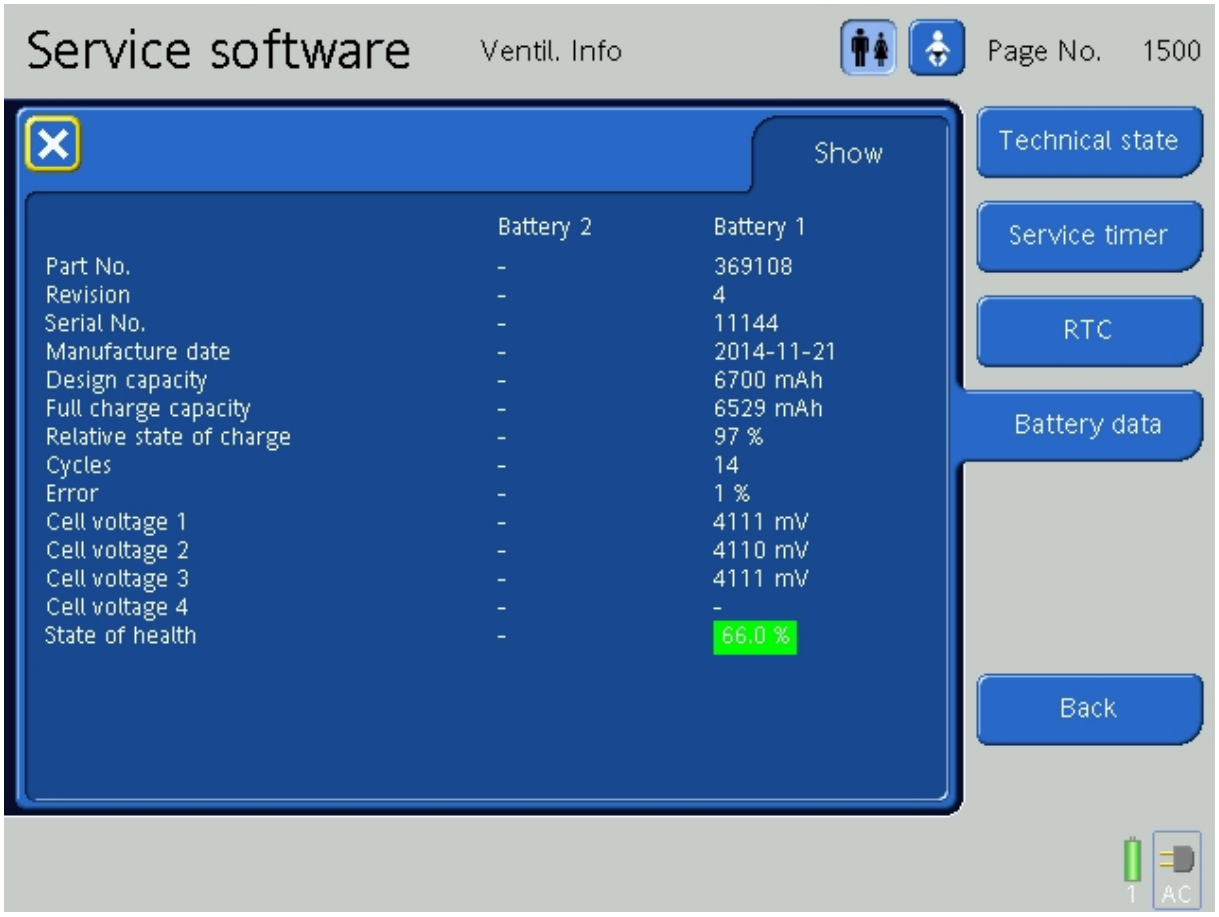
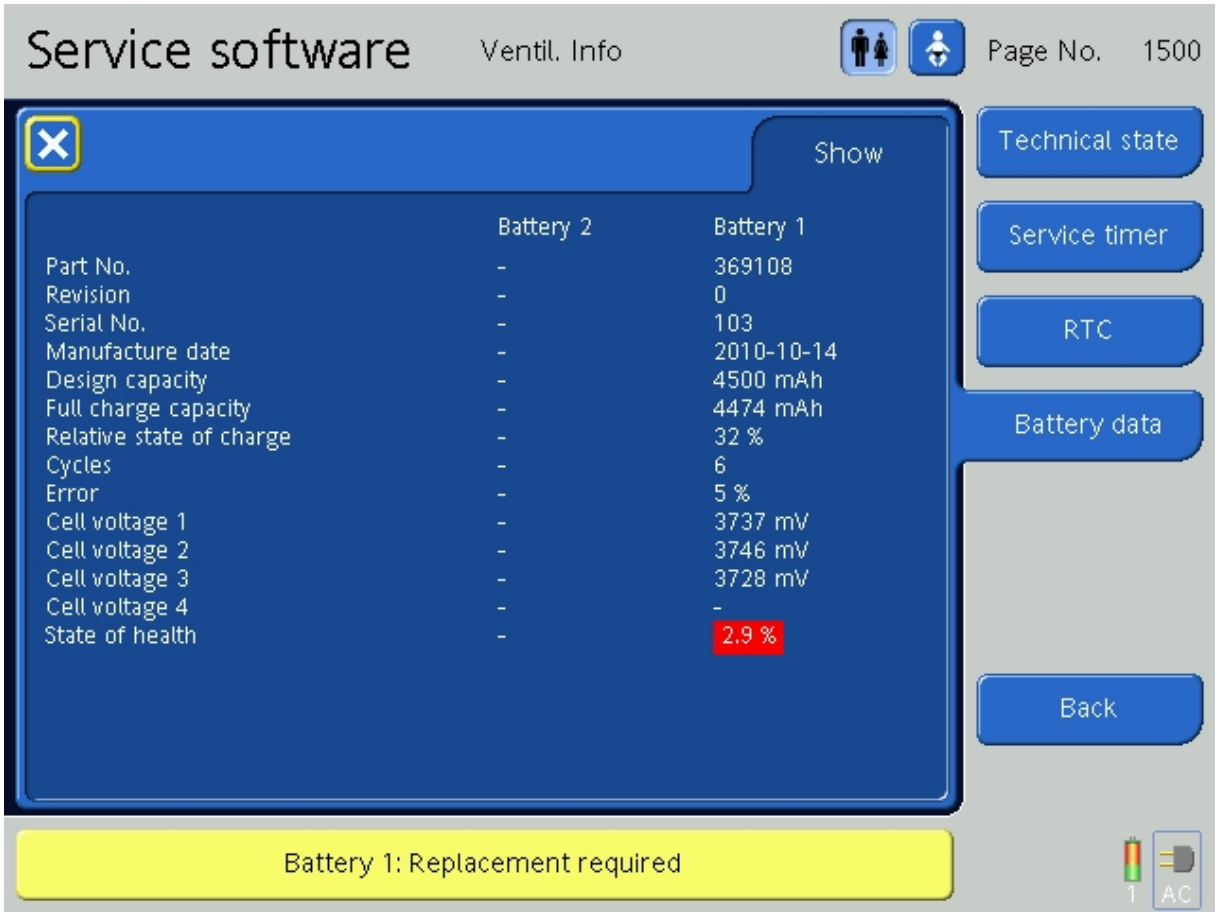


Figure 8-21. Example of an older battery with a bad SoH. This battery must be replaced.



8.2.7 Adjustment / calibration (ADULT/PED.)

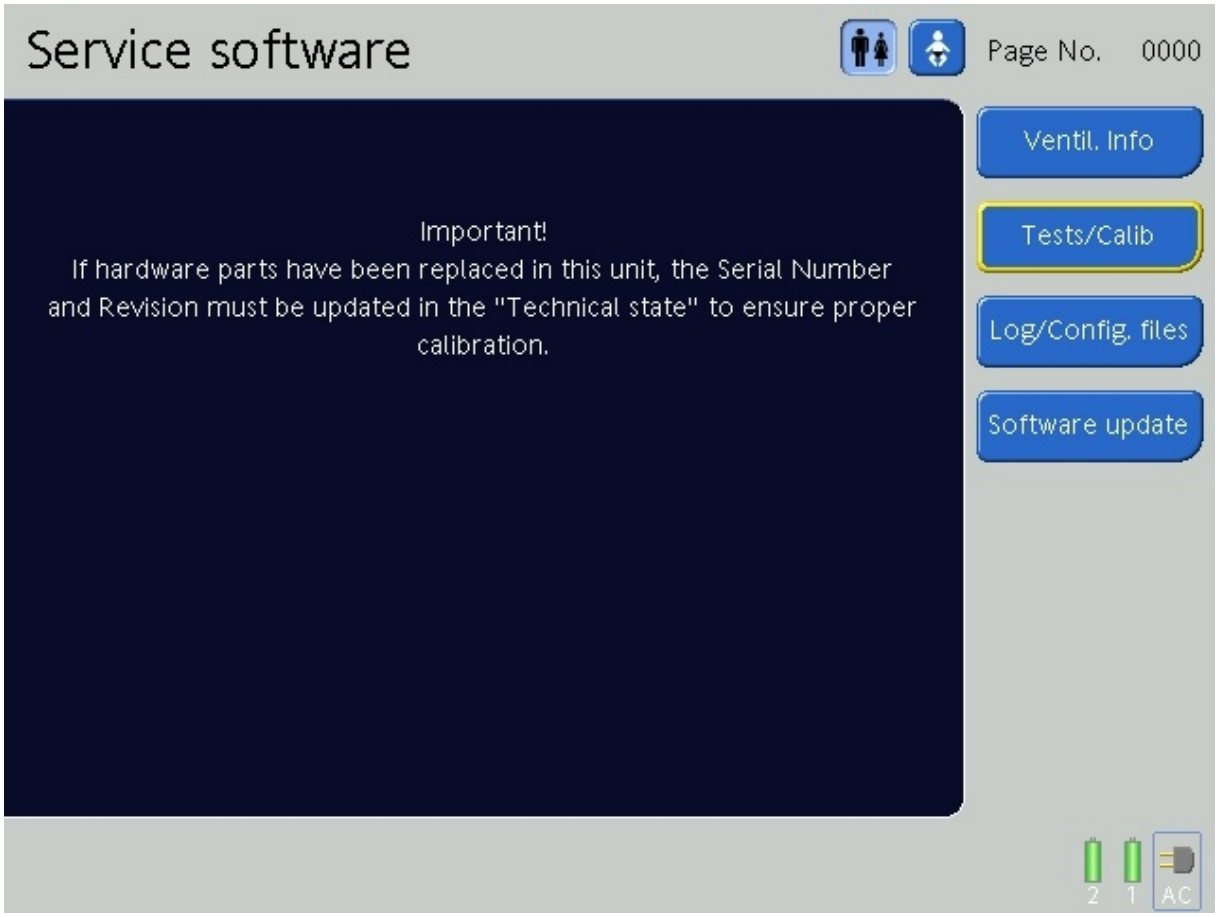
8.2.7.1 Overview adjustment/calibration (ADULT/PED.)

Adjustment/ Calibration	Description	Component adjusted/ calibrated
Adj/Calib > Calibration > Touchscreen (Page No. 2321) (see Section 8.2.7.4)	Allows calibrating the coordinates of the touch controller. (4–Point calibration)	• Touchscreen
Adj/Calib > Calibration > Pressure (Page No. 2341) (see Section 8.2.7.5)	Allows to adjust the pressure sensor gain using an external pressure measurement as reference.	Pressure sensor: • Pvent_control • Pvent_monitor • Paw
Adj/Calib > Calibration > Exp. valve (Page No. 2343) (see Section 8.2.7.6)	The expiratory valve assembly contains a voltage controlled linear valve (Expiratory proportional valve). The opening point of the valve depends on the contained spring. The goal of the expiratory valve calibration is to find the opening voltage of the valve, which we call offset voltage. The offset voltage also depends on which expiratory valve is used (Adult/Ped. or Neonatal). Test sequence: A constant pressure is exerted on the inspiration outlet. The voltage on the expiratory valve is adjusted until the flow (3 l/min) through the expiratory valve is in the required range. The calibration is done with a lower and a higher pressure. The calibration reaches an end as soon as both, the high and the low offset are within a defined tolerance. At the end the average value of voltage offset high and low is stored and used by the software.	Expiratory proportional valve: • with Adult / Ped. expiratory valve
Adj/Calib > Calibration > O2 cell (Page No. 2346) (see Section 8.2.7.7)	The O2 cell calibration is separated into two parts: • Offset calibration: Calibrates the offset voltage of the amplifier circuit (Control Board). • Gain calibration: During this two-minutes calibration of the oxygen cell, the ventilator delivers an increased oxygen concentration (if oxygen is connected in the high pressure mode) or 21% oxygen (if oxygen is connected in the low pressure mode or disconnected). It tests the cell and resets the calibration points specific to the cell in use.	• O2 cell
Adj/Calib > Calibration > flow sensor (Page No. 2347) (see Section 8.2.7.8)	This calibration checks and resets the calibration point specific to the flow sensor in use. The flow sensor is calibrated in both directions.	External flow sensor Qaw: • Adult/Ped. flow sensor

8.2.7.2 Test / calibration screens (Page No. 2000)

From the Main Service Software Screen, touch the **Tests/Calib** button.

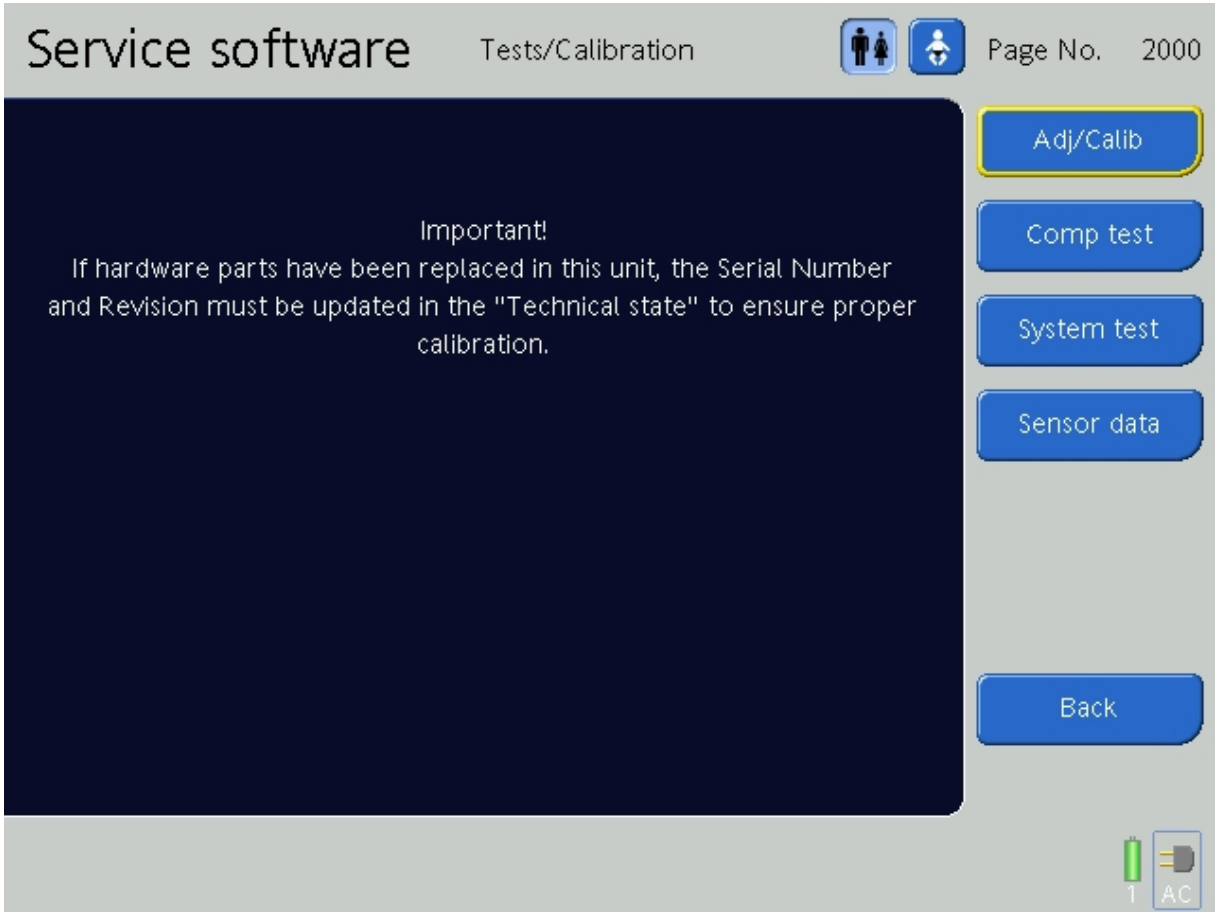
Figure 8-22. The Main Service Software Screen



The Tests/Calibration screen gives access to the following submenu:

- Adjustment / Calibration button (Adj/Calib)
- Component Test button (Comp test)
- System Test button
- Sensor Data button
- Back button

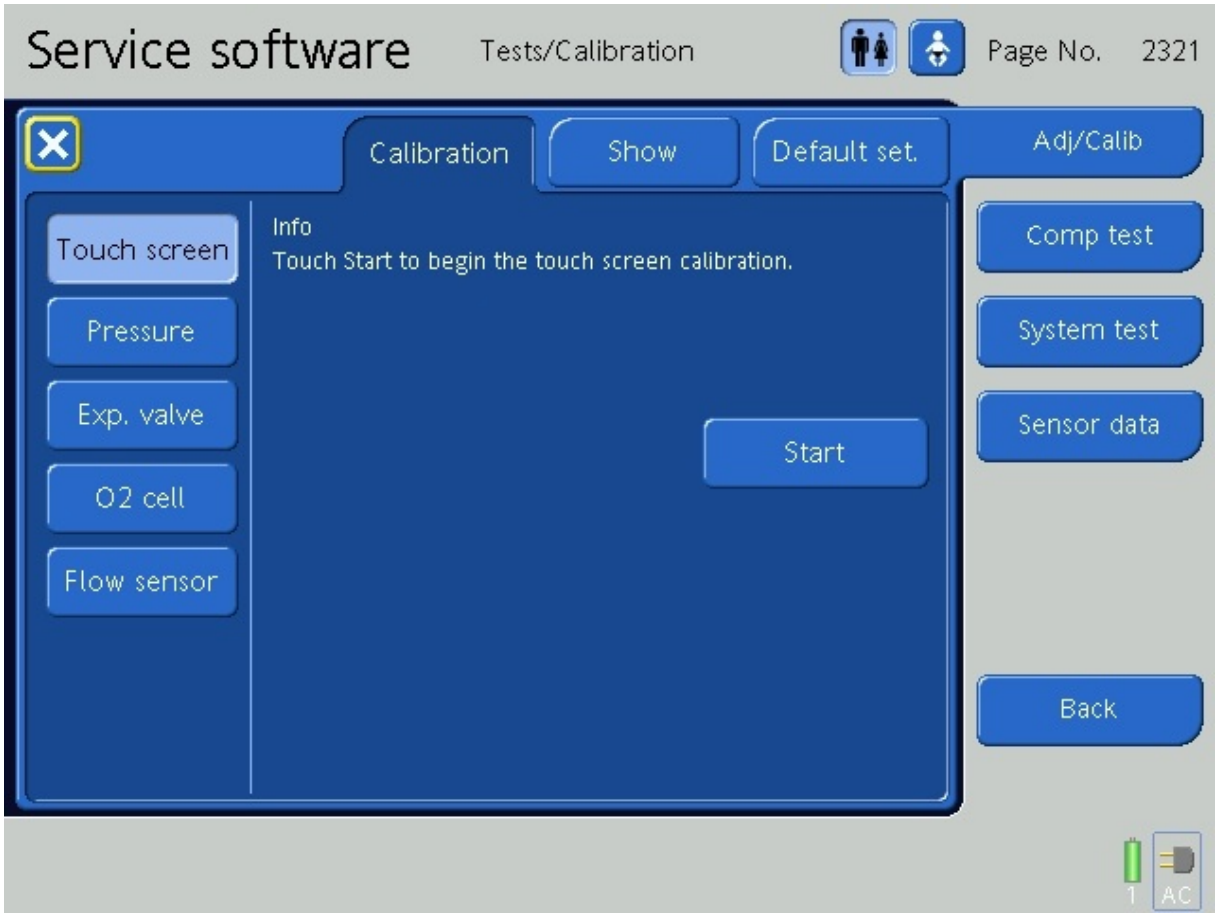
Figure 8-23. Tests / calibrations (Page 2000)



8.2.7.3 Calibration tab

Touch the **Calibration** tab to enter the calibration section.

Figure 8-24. The Calibration Tab



8.2.7.4 Touchscreen calibration (Page No. 2321)

1. Touch the **Touchscreen** button to enter the touchscreen calibration. Touch the Start button, then follow the screen prompts to touch the cursor when it appears in the corners and center of the screen.

Figure 8-25. Start touch screen calibration

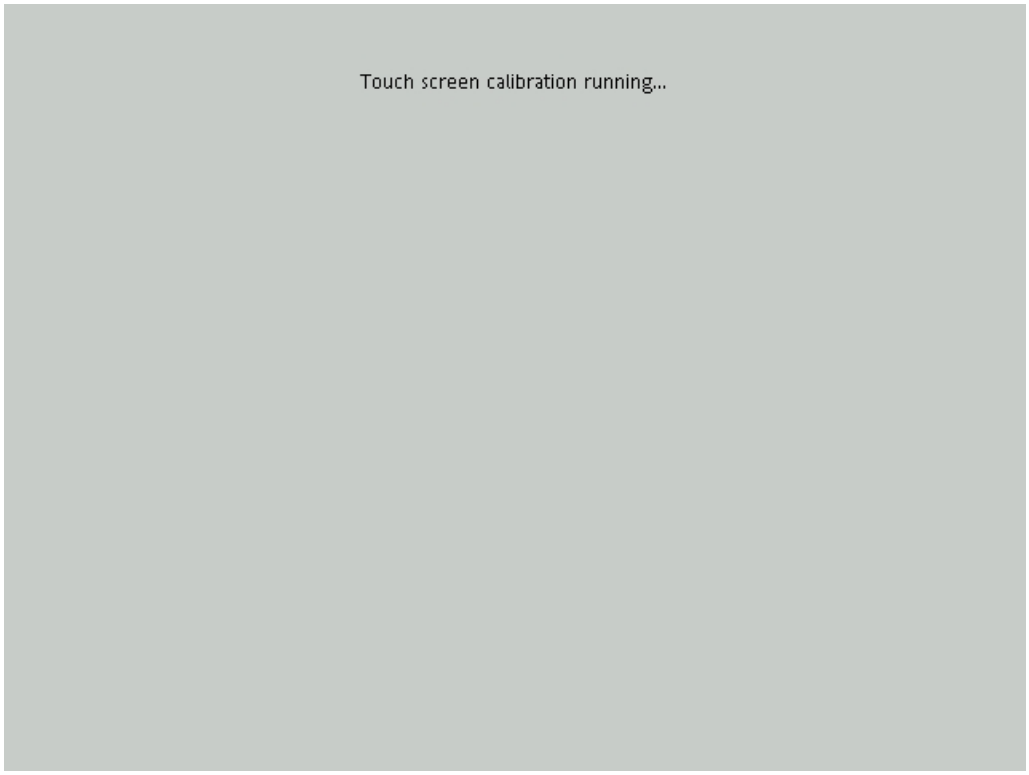


Figure 8-26. Touch the cross located on the top left of the screen

Figure 8-27. Touch the cross located on the top right of the screen

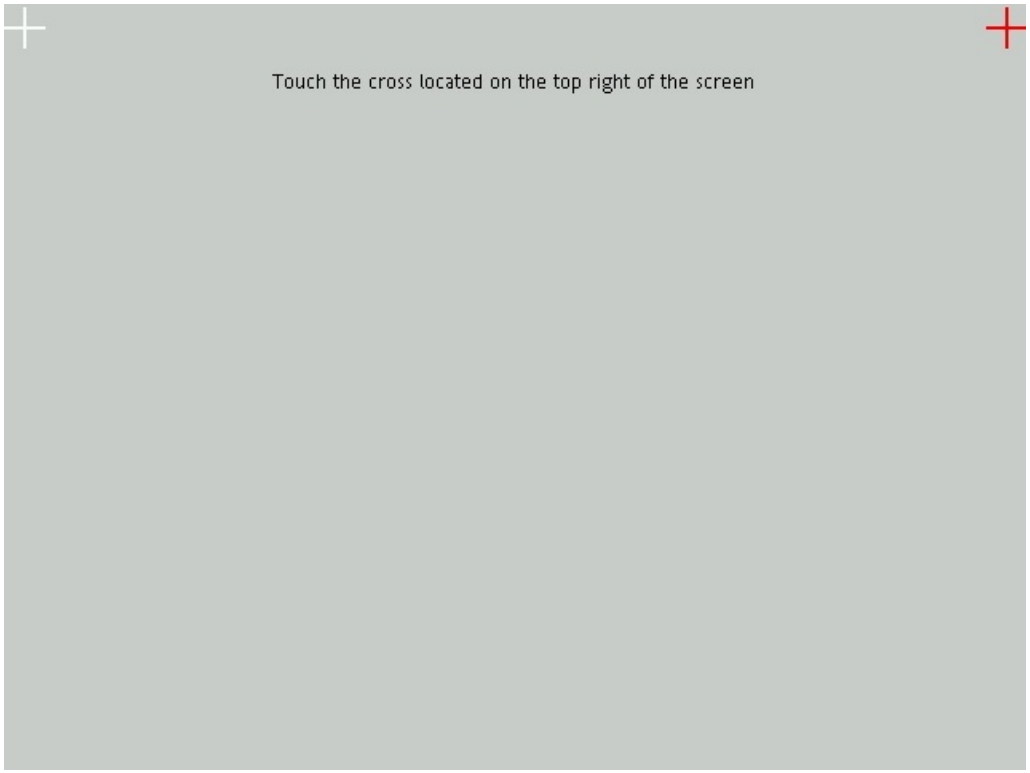


Figure 8-28. Touch the cross located on the bottom right of the screen

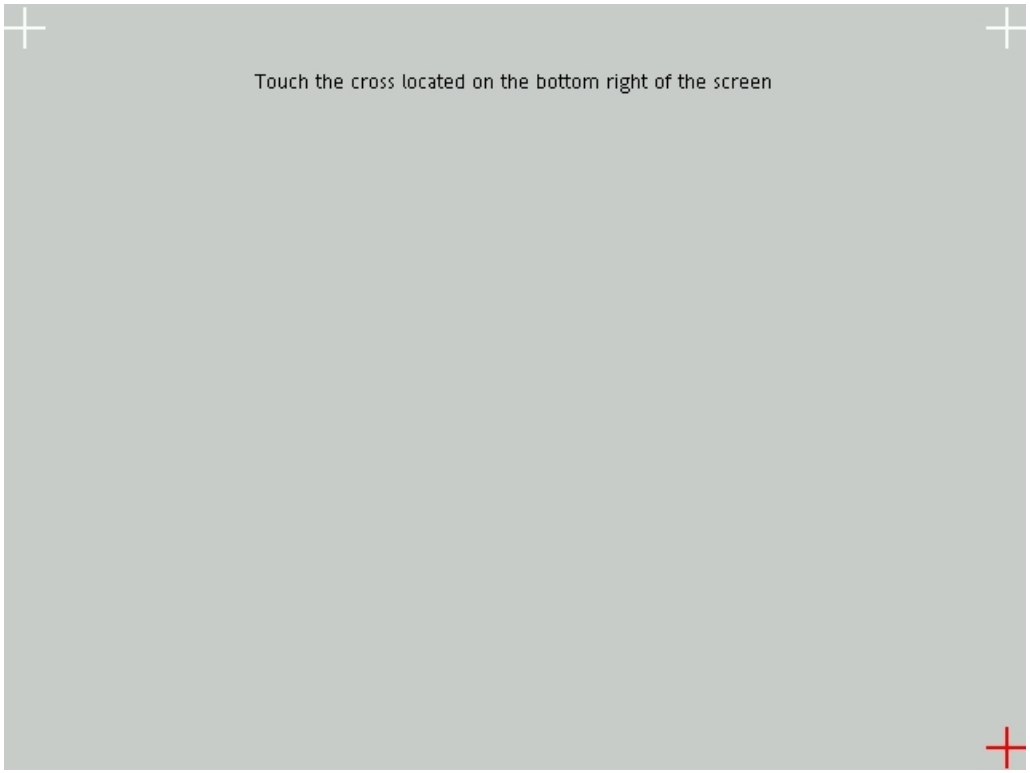


Figure 8-29. Touch the cross located on the bottom left of the screen

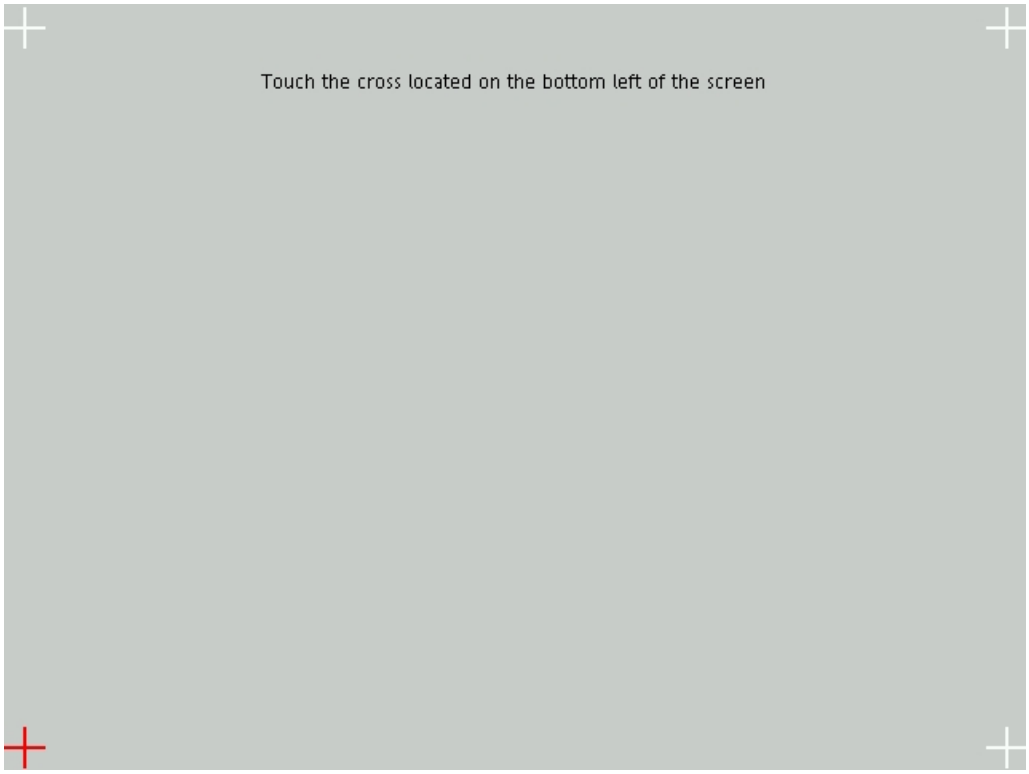


Figure 8-30. Touch the test touchscreen

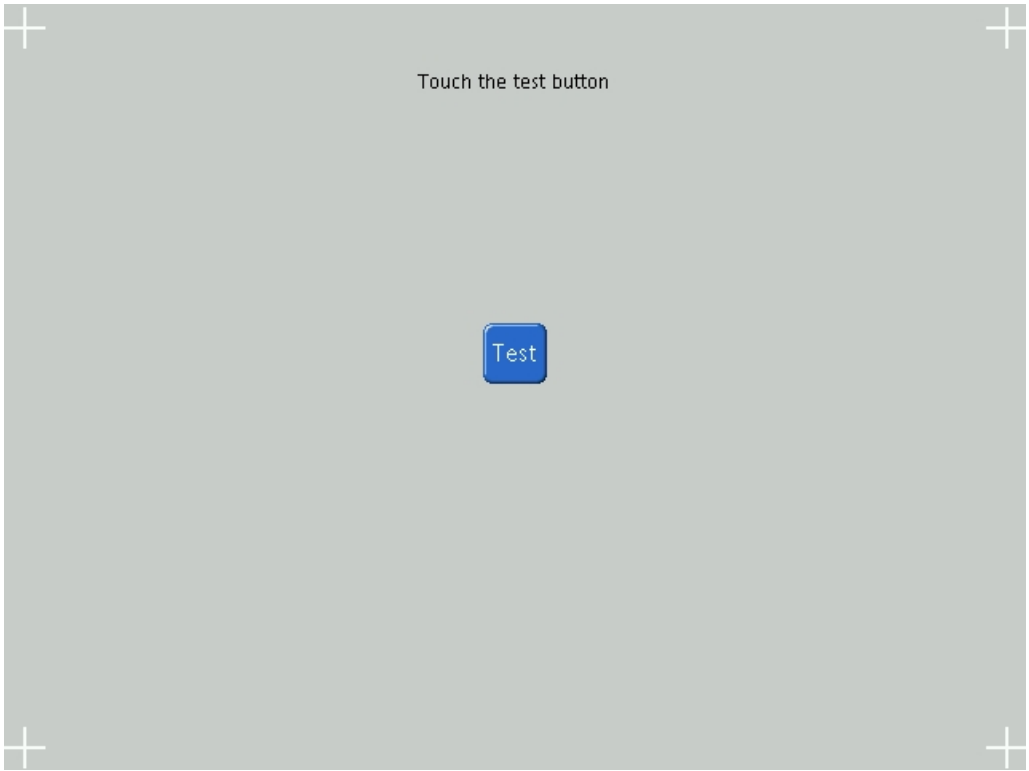
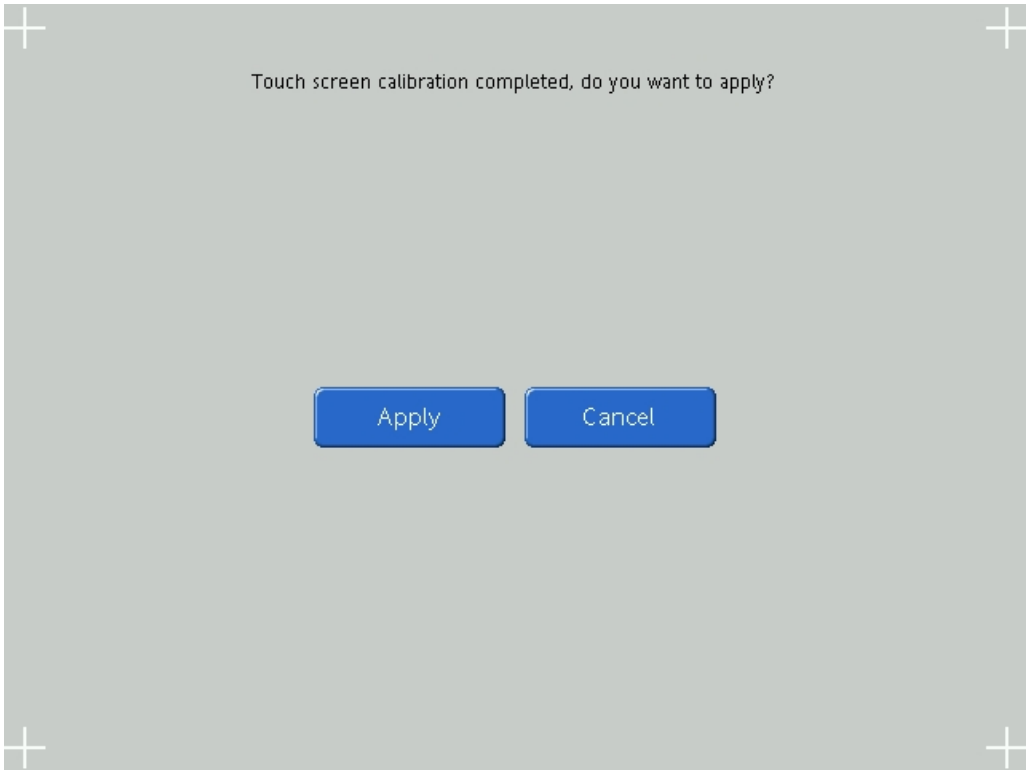
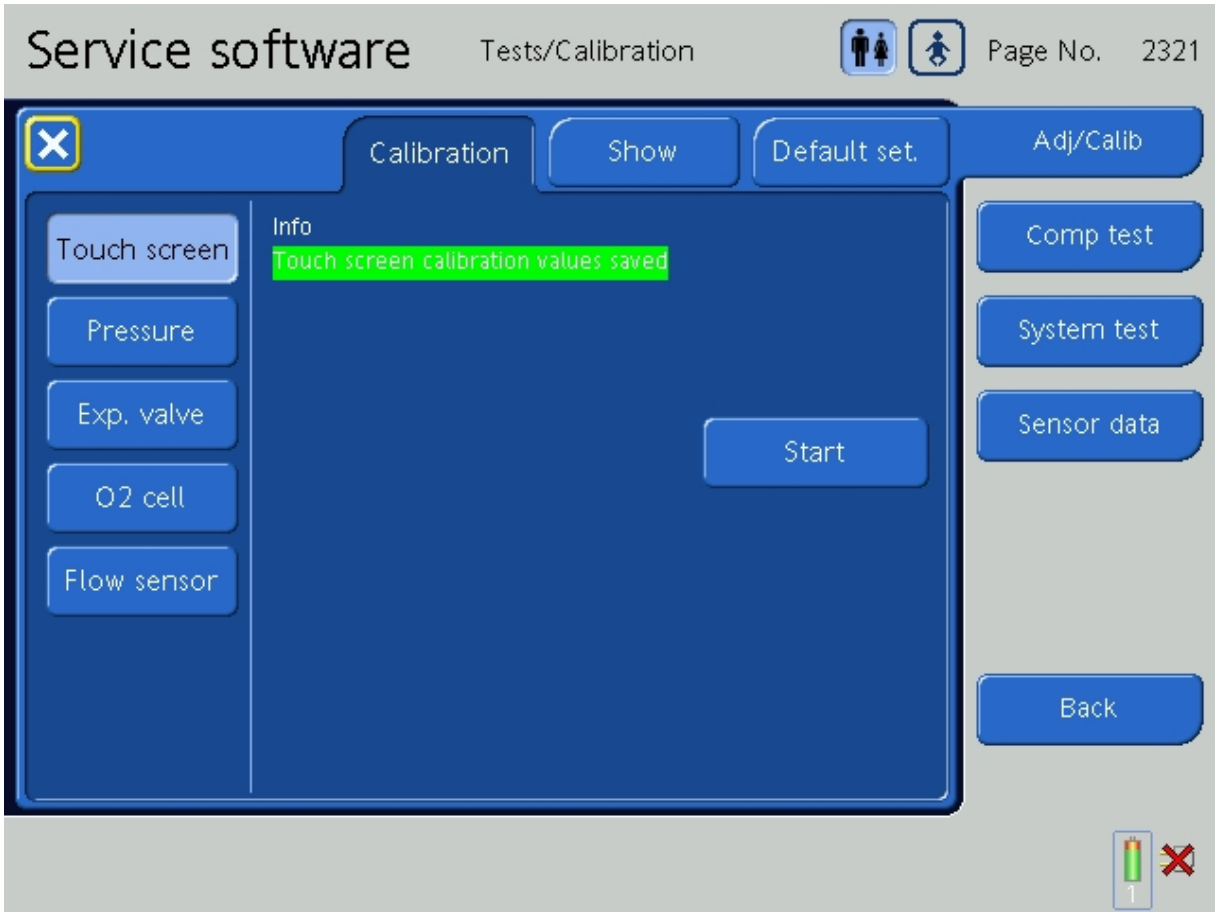


Figure 8-31. Apply new touchscreen calibration values



2. The Info message **Touch screen calibration values saved** confirms the completion of the touch screen calibration.

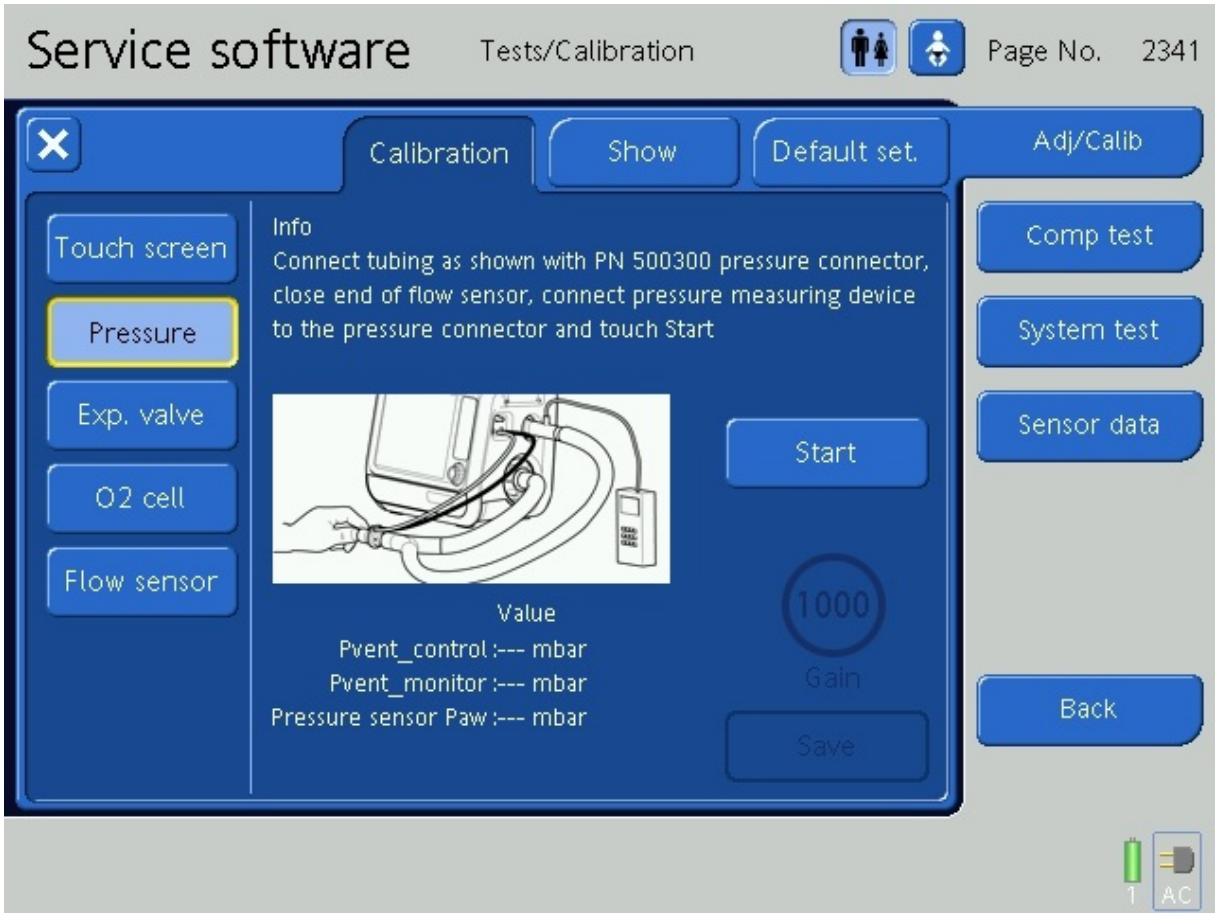
Figure 8-32. Touchscreen calibration values saved



8.2.7.5 Pressure adjustment (Page No. 2341)

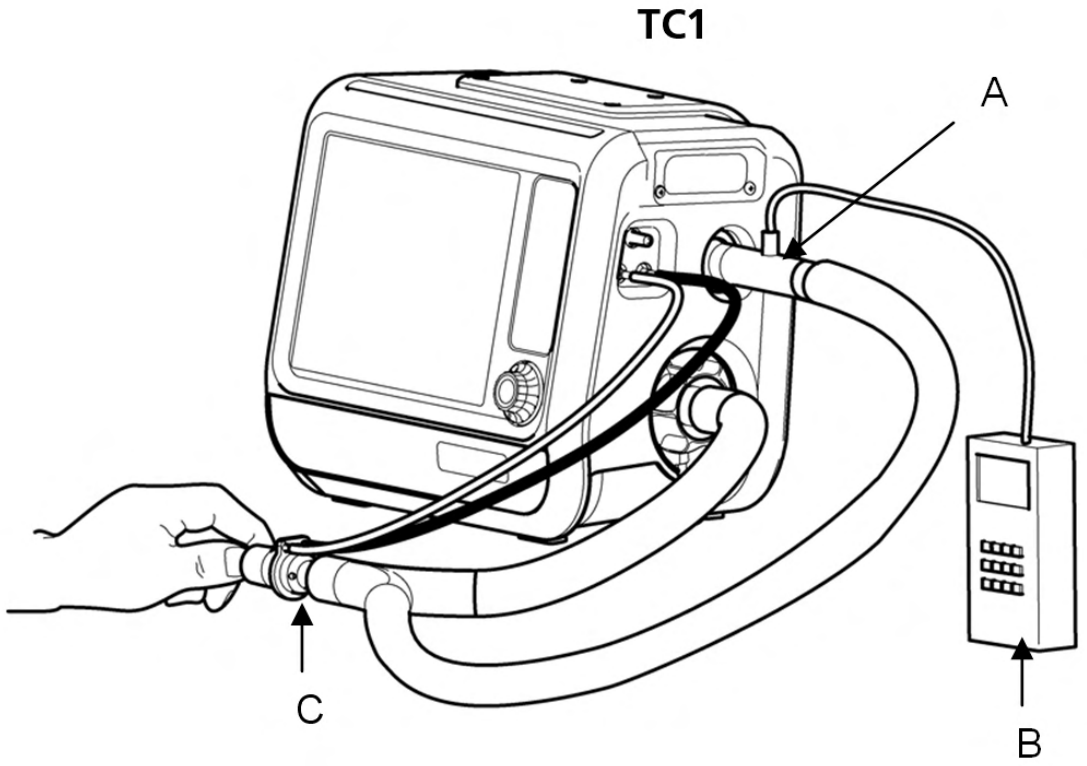
1. Touch the **Pressure** button to enter the pressure calibration.

Figure 8-33. Pressure calibration



2. Set up test configuration 1.

Figure 8-34. Test configuration 1: Pressure calibration



A	Pressure connector (PN 500300)	C	Close the flow sensor outlet
B	External pressure gauge		

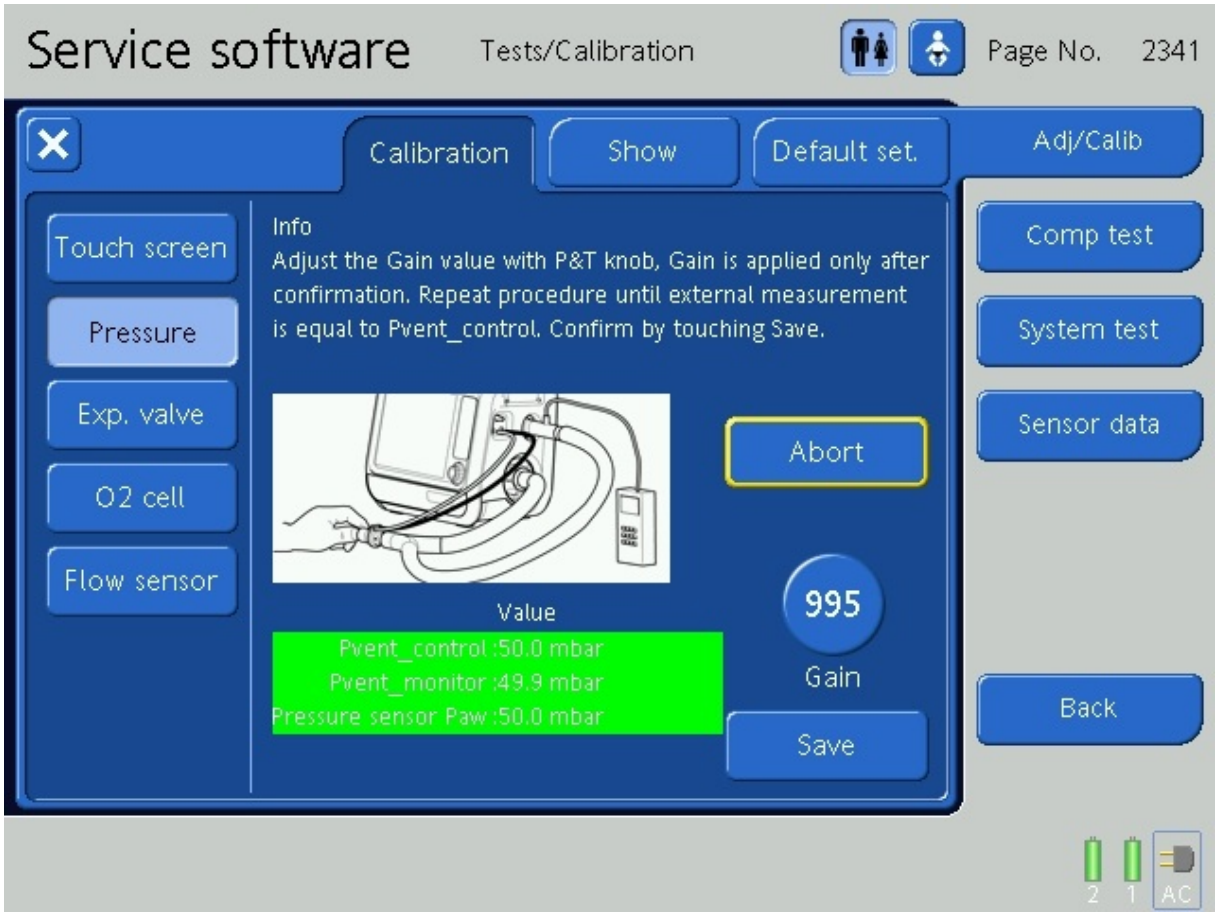
3. To begin with the adjustment touch the **Start** button.

4. Touch the **Gain** button and adjust the **Gain** value by rotating the P&T knob. Confirm by pressing the P&T knob.

5. Adjust the **Gain** until the external pressure gauge shows **50 mbar**, +/- 0.5 mbar (51 cmH2O, +/- 0.5 cmH2O).

6.Touch the **Save** button to store the gain value after completion.

Figure 8-35. Gain value adjustment



8.2.7.6 Expiratory valve calibration (Page No. 2343)

1. Touch the **Exp. valve** button to enter the expiratory valve calibration.

2. Select adult mode: touch the adult  icon in the window header.

3. Set up test configuration 2 and make sure the adult expiratory valve cover is installed.

Figure 8-36. Adult expiratory valve calibration (Page No. 2343)

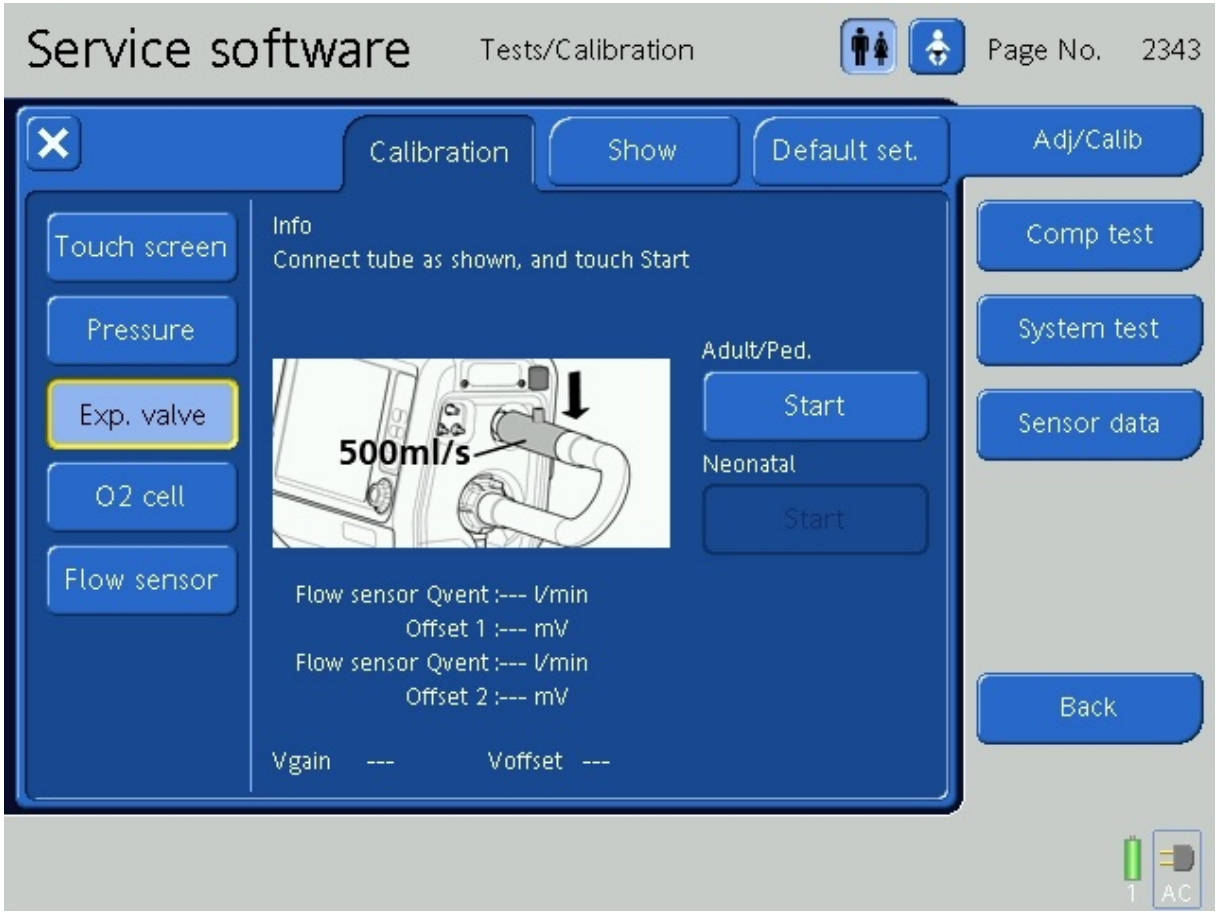
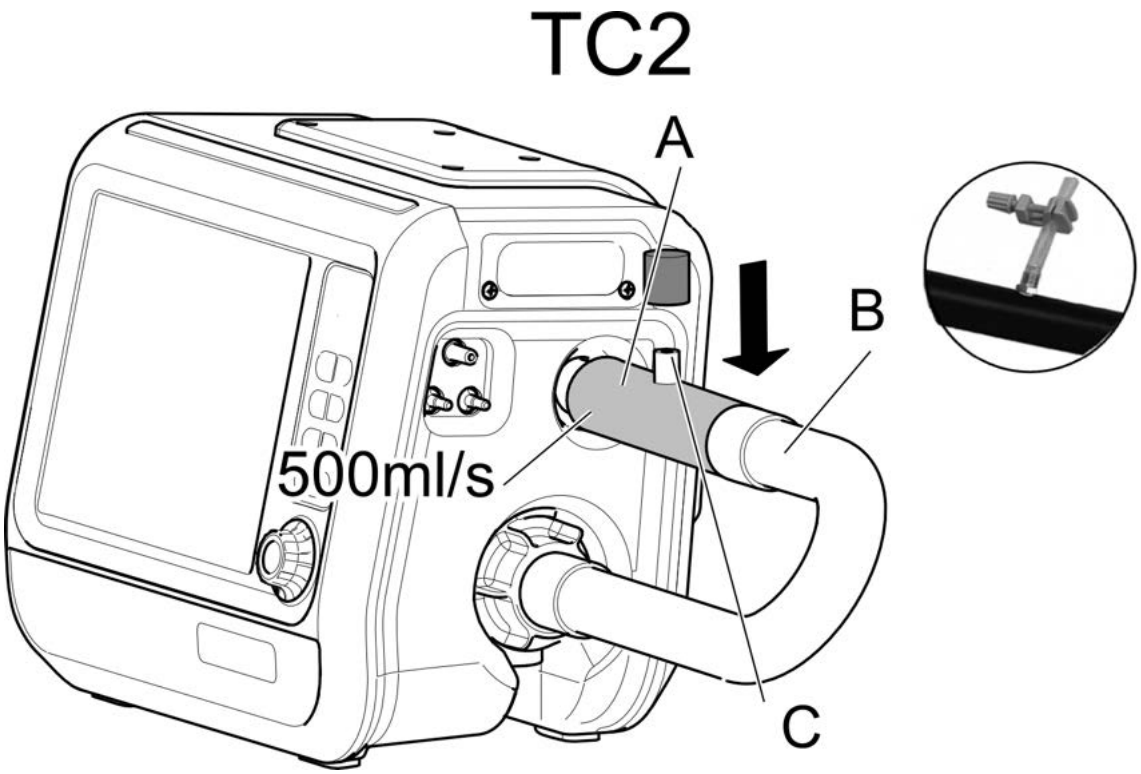


Figure 8-37. Test configuration 2



A	Orifice tube 500 ml/s (PN 500290)	C	Close the orifice tube connector (e.g. use a clamp PN 279812, see Figure Test configuration 2)
B	Silicone tube ID 22 mm, OD 30 cm (PN 260100)		

4. Touch the **Start** button (Adult/Ped.) to begin with the calibration. The calibration runs automatically, as indicated by the flow sensor Qvent, Offset 1 and Offset 2 values changing during the calibration process.

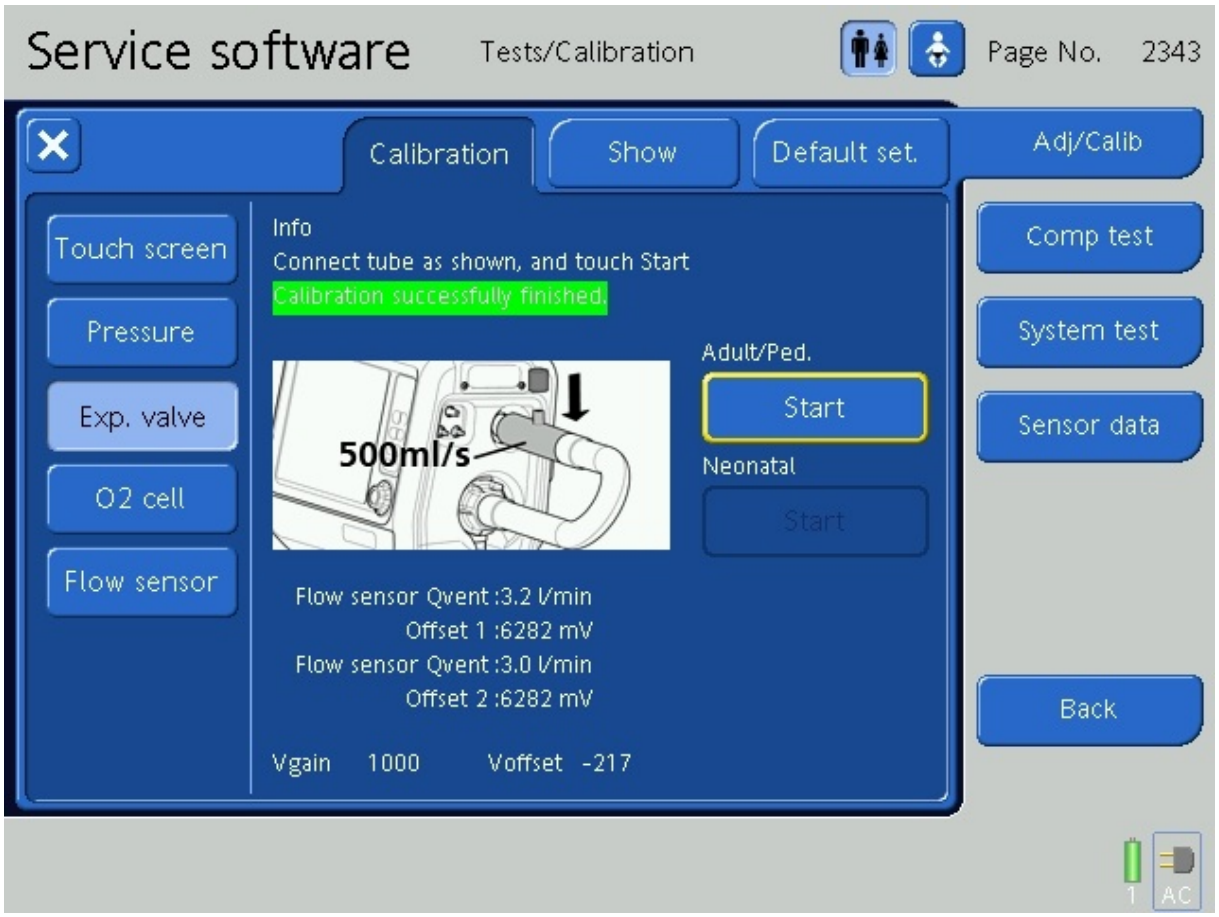
NOTICE

Due to the sensitivity of the system the orifice tube 500ml/s is used in order to have a defined resistance. The calibration can take a few minutes.

Vgain is not used and remains set to 1000.

Vgain and **Voffset** values are shown as soon as the calibration is successfully completed.

Figure 8-38. Adult/Ped. expiratory valve calibration



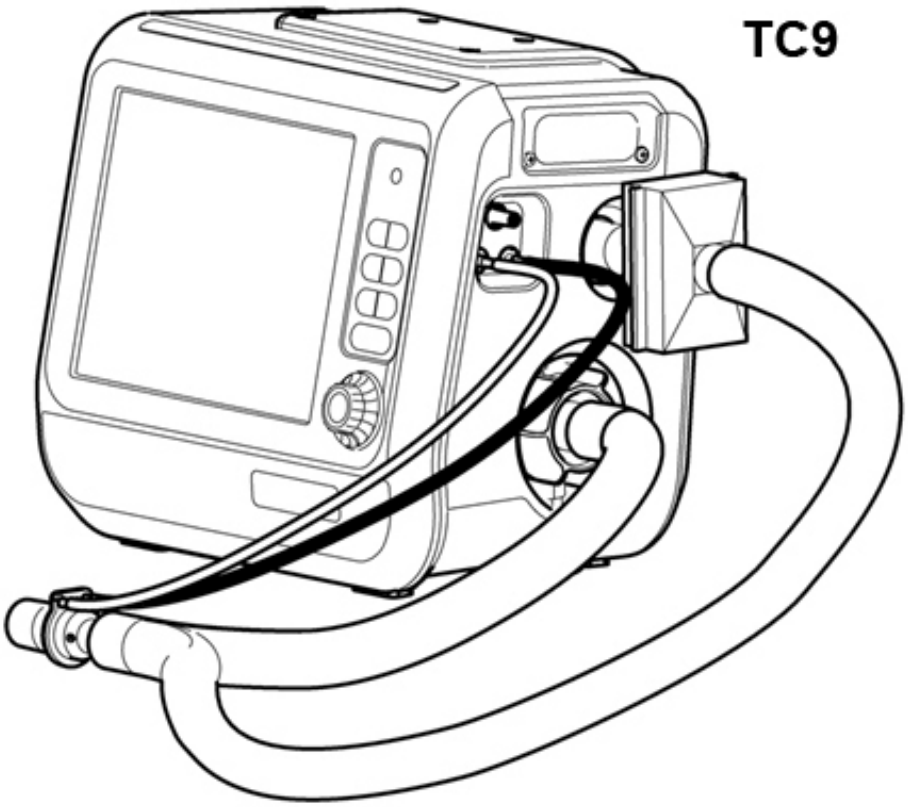
8.2.7.7 O2 cell calibration (Page No. 2346)

1. Set up test configuration 9 and connect the HAMILTON-C1 to high pressure O2 (if available).

NOTICE

If the high-pressure source oxygen concentration is less than 99% (or you are unsure of the exact concentration delivered), disconnect the high-pressure oxygen gas hose before starting calibration.

Figure 8-39. Test configuration 9



2. Touch the **O2 cell** button to enter the O2 cell calibration.

⚠ CAUTION

Do not disconnect the O2 sensor for the offset calibration.

3. To start the **Offset** calibration touch the **Start** button. The result is indicated with **OK/NOT OK**.

4. The O2 cell **Gain** calibration starts automatically after the Offset calibration is completed. The progress bar shows the current state.

Figure 8-40. O2 Cell calibration (Offset) with high-pressure oxygen

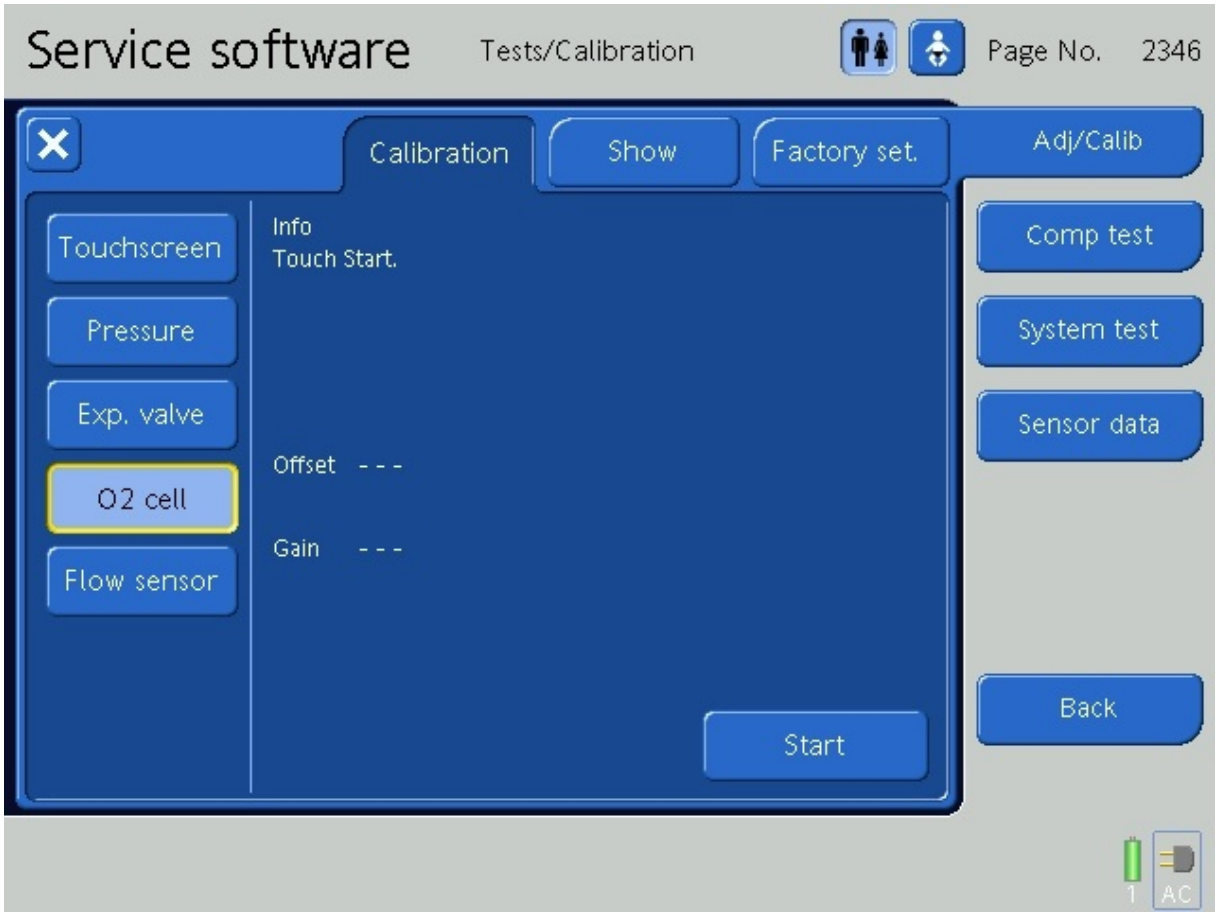
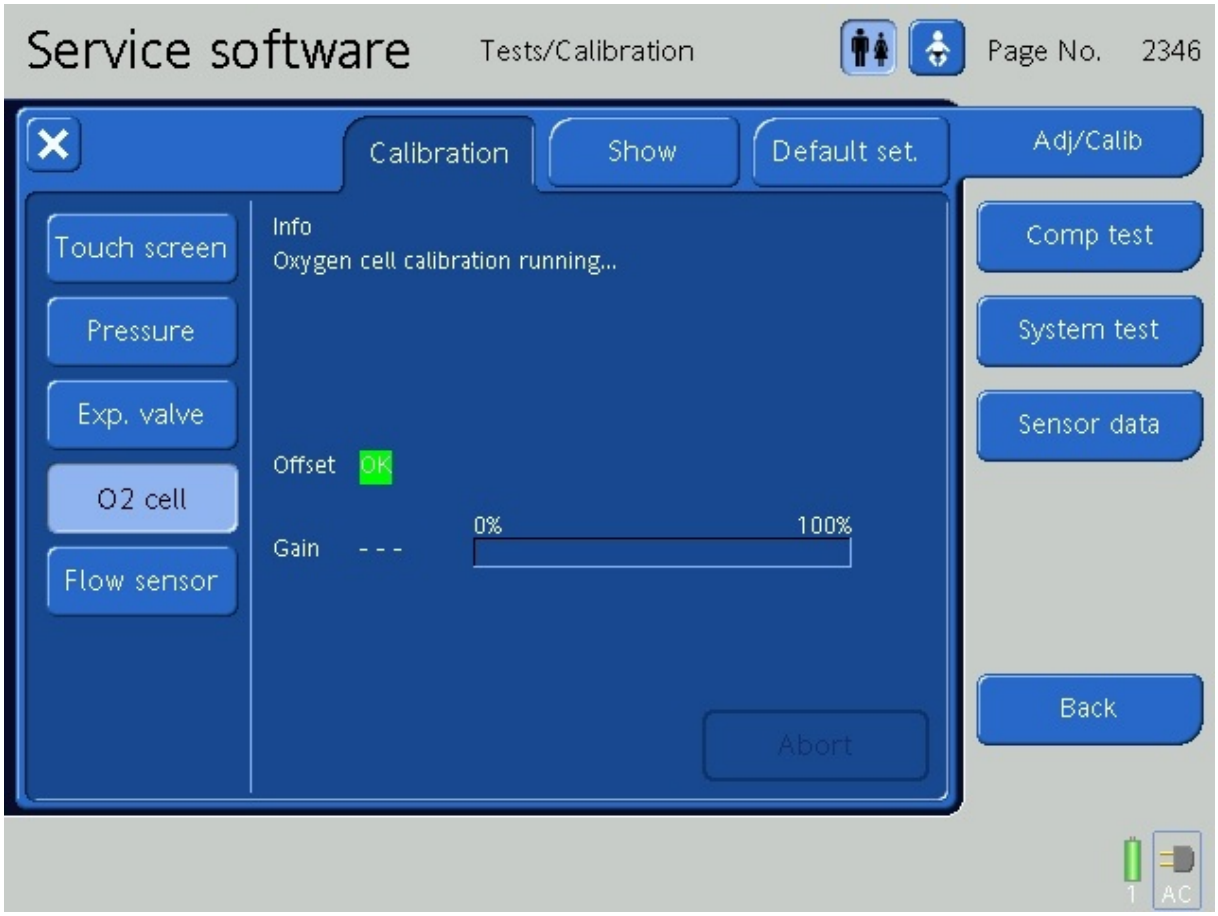


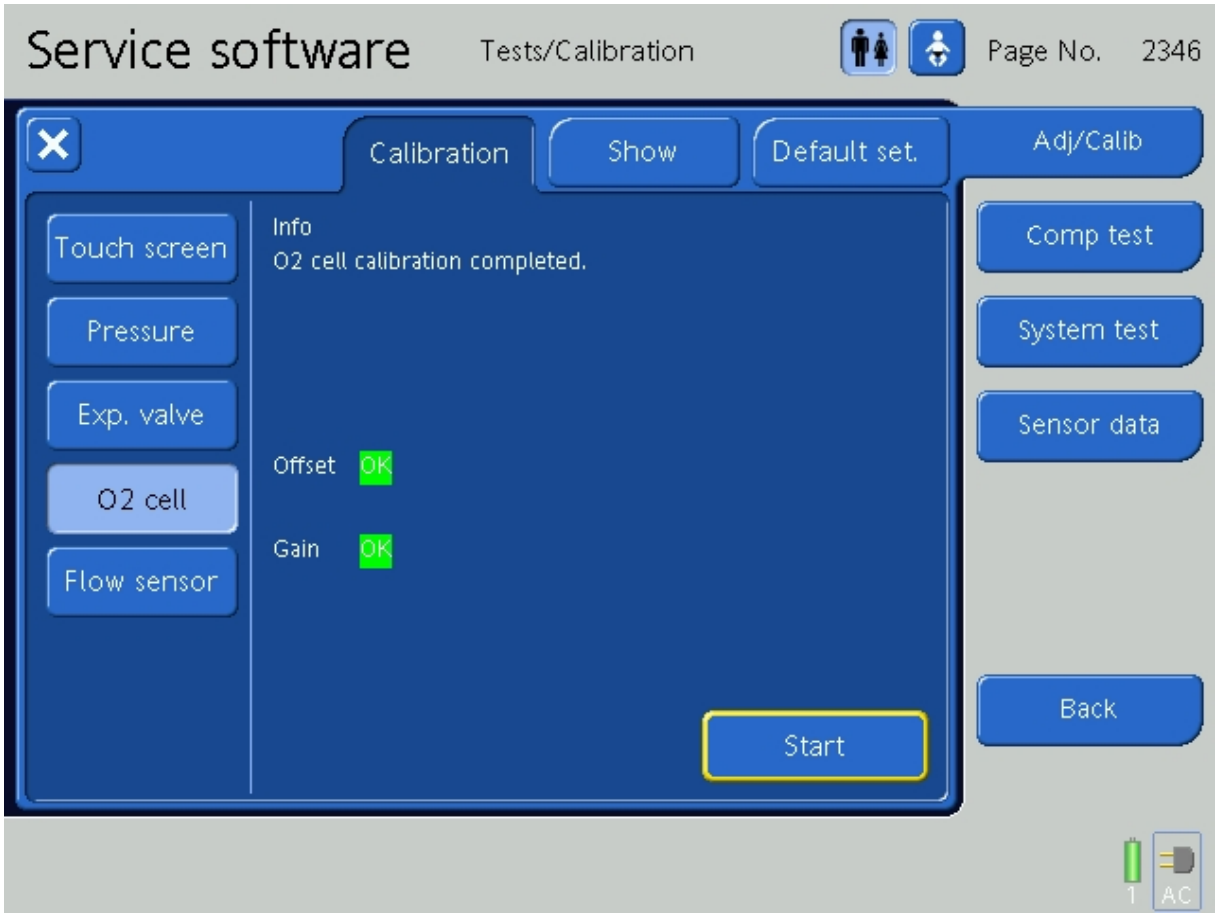
Figure 8-41. O2 cell calibration (Gain)



NOTICE

The gain calibration takes approx. 2 minutes. The result is indicated with **OK/NOT OK** and the completion is displayed with the Info message.

Figure 8-42. O2 Cell calibration completed



8.2.7.8 Flow sensor calibration (Page No. 2347)

1. Touch the **Flow sensor** button to enter the flow sensor calibration.

2. Select the adult mode: touch the adult  icon in the window header.

3. Connect the HAMILTON-C1 with the adult breathing circuit (Test configuration 9).

Figure 8-43. Adult/Ped. flow sensor calibration (Page No. 2347)

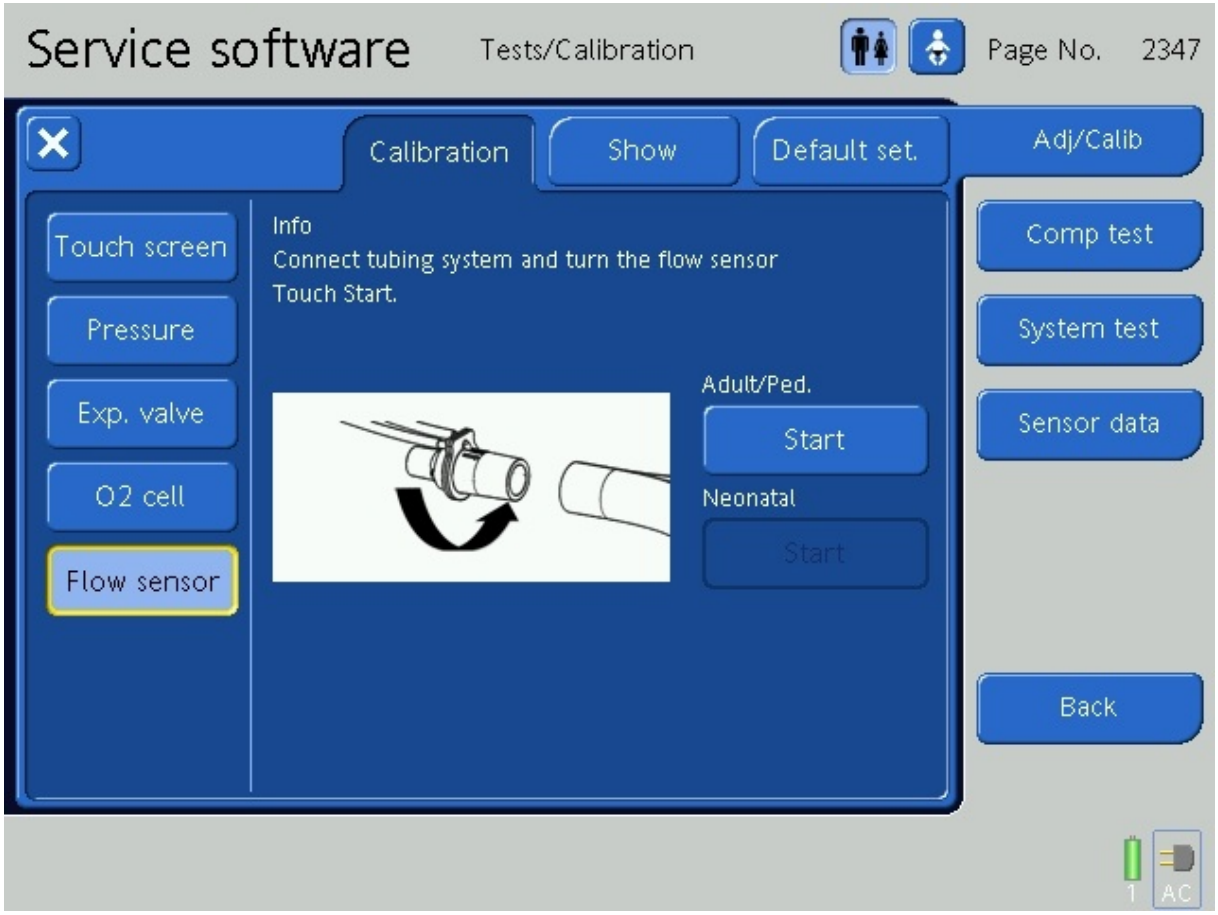
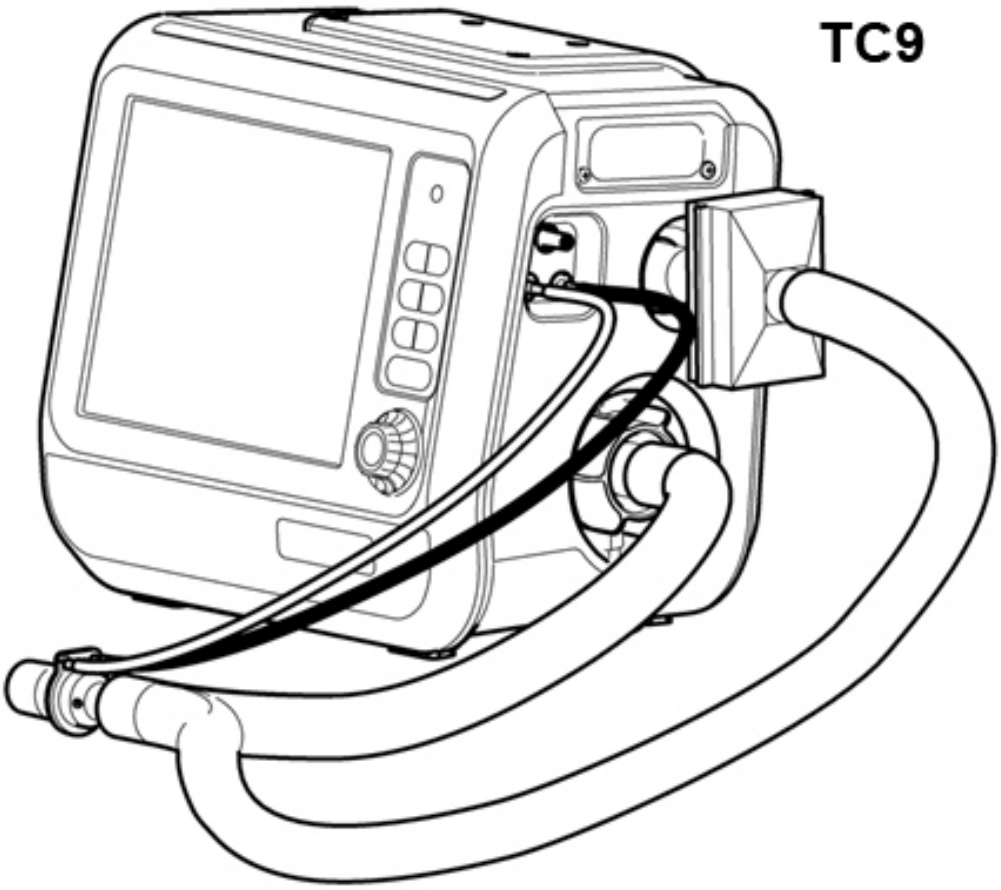
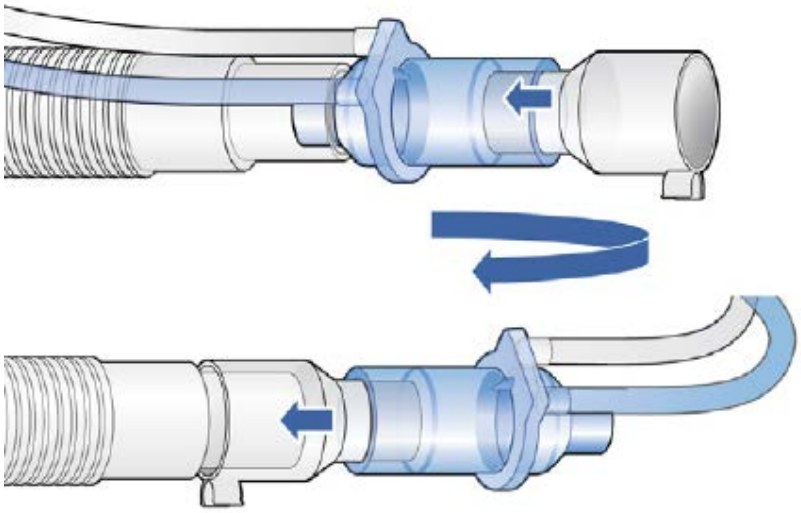


Figure 8-44. Test Configuration 9



4. **Turn** the flow sensor before you start the calibration.

Figure 8-45. Adult/Ped. flow sensor



5. Start the Adult/Ped. flow sensor calibration by touching the **Start** button.

6. **Flow sensor calib started** will be displayed.

7. **Turn** or flip back the flow sensor when instruction is given and proceed by touching the **Next** button.

Flow sensor calibration successful will be shown on the display after the calibration.

Figure 8-46. Flow sensor calibration

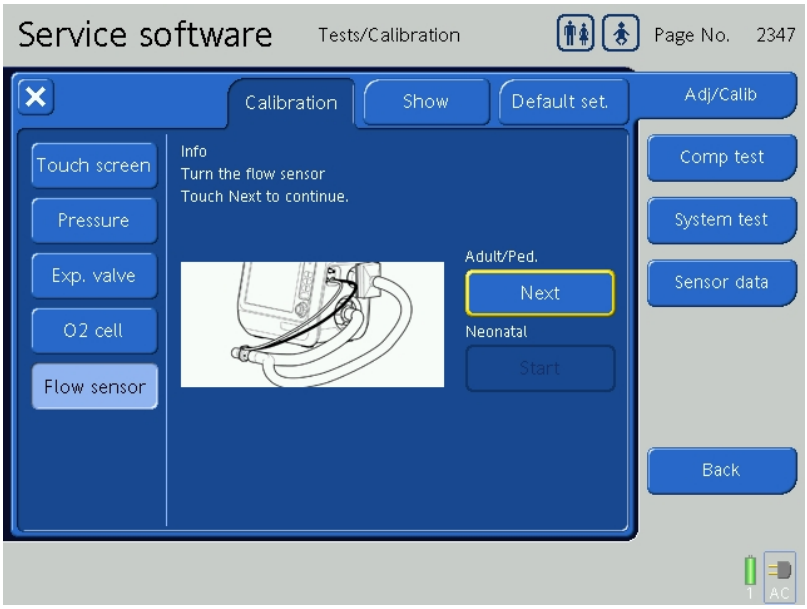
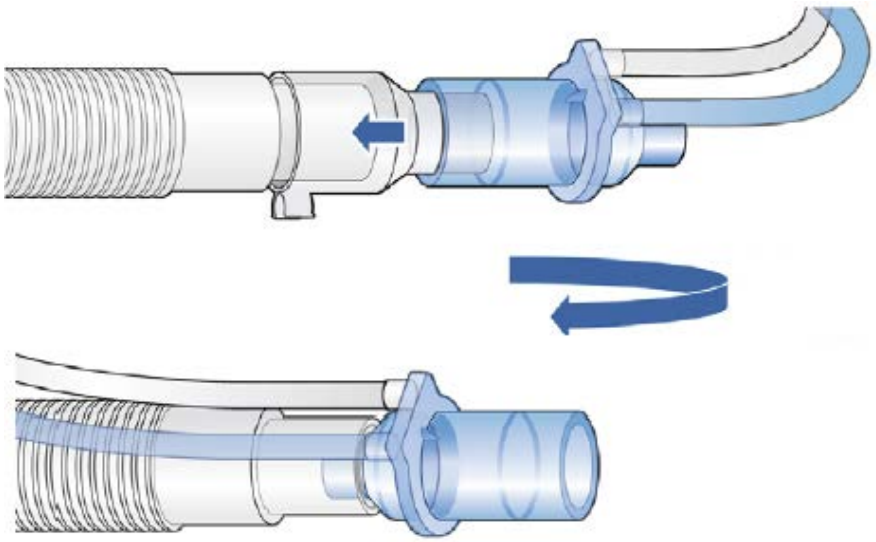


Figure 8-47. Turn Adult/Ped. flow sensor



8.2.7.9 Calibration/adjustment values (Page No.2301-2304)

1. Touch the **Show** tab to display the calibration values.

Pressure sensor (Page No. 2301)

2. Touch the **Pressure** button to display the offset and gain values of the pressure sensors (Pvent_control, Pvent_monitor and Paw).

Flow sensor (Page No. 2302)

3. Touch the **flow sensor** button to display the inspiratory flow and expiratory flow values at different pressures. To display the adult/ped. or the neonatal valve calibration values touch the corresponding button in the window header.

⚠ CAUTION

The system saves only one set of flow sensor calibration values. For example, if the last flow sensor calibration was done with an adult/ped. flow sensor and a new flow sensor calibration will be performed with neonatal flow sensor, the adult/ped. calibration values will be overwritten by the neonatal values.

Valves (Page No. 2304)

4. Touch the **Valves** button to display the offset and gain values of the expiratory valve. To display the adult/ped. or the neonatal valve calibration values touch the corresponding button in the window header.

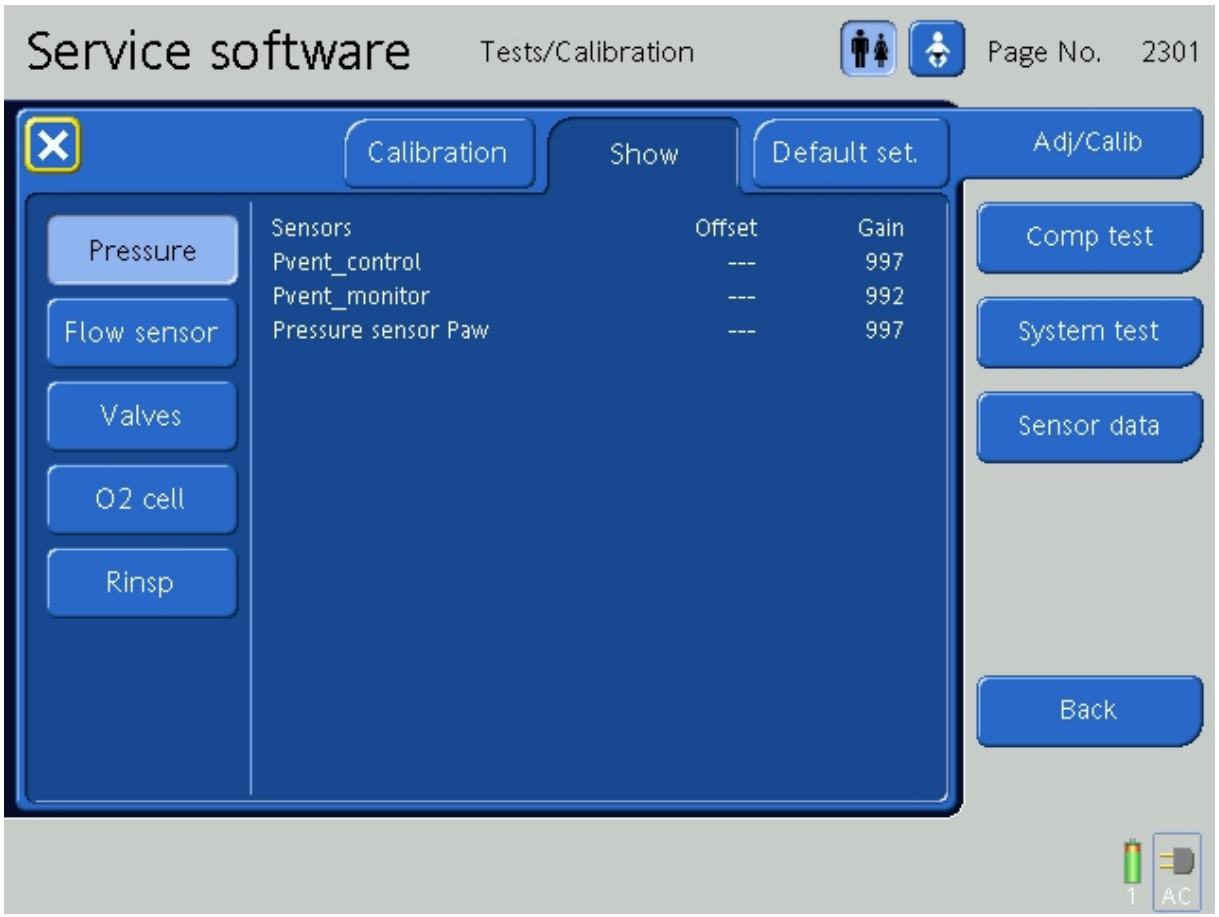
O2 cell (Page No. 2303)

5. Touch the **O2 cell** button to display the offset and gain values of the O2 cell. **O2 cell Gain level, normal range of values is from 600 to 1600.** These values are included in the instrument report export (see Section 8.2.13.3)

Rinsp (Page No. 2305)

6. Touch the **Rinsp** button to display the calibration values of the inspiratory tube resistance.

Figure 8-48. Calibration/Adjustment values



8.2.7.10 Default settings (Page No. 2391)

⚠ CAUTION

If calibration is not possible due to a corrupted calibration file, set to default settings. Repeat all calibrations and tests.

1. Touch the **Default set.** tab.
2. Touch the **Set** button.
3. To reset the flow sensor calibration values only touch the **Flow sensor** button. To reset all calibration values touch the **All** button.
4. Touch the **Confirm** button to reset to the default settings.

Figure 8-49. Default settings (Page No. 2391)

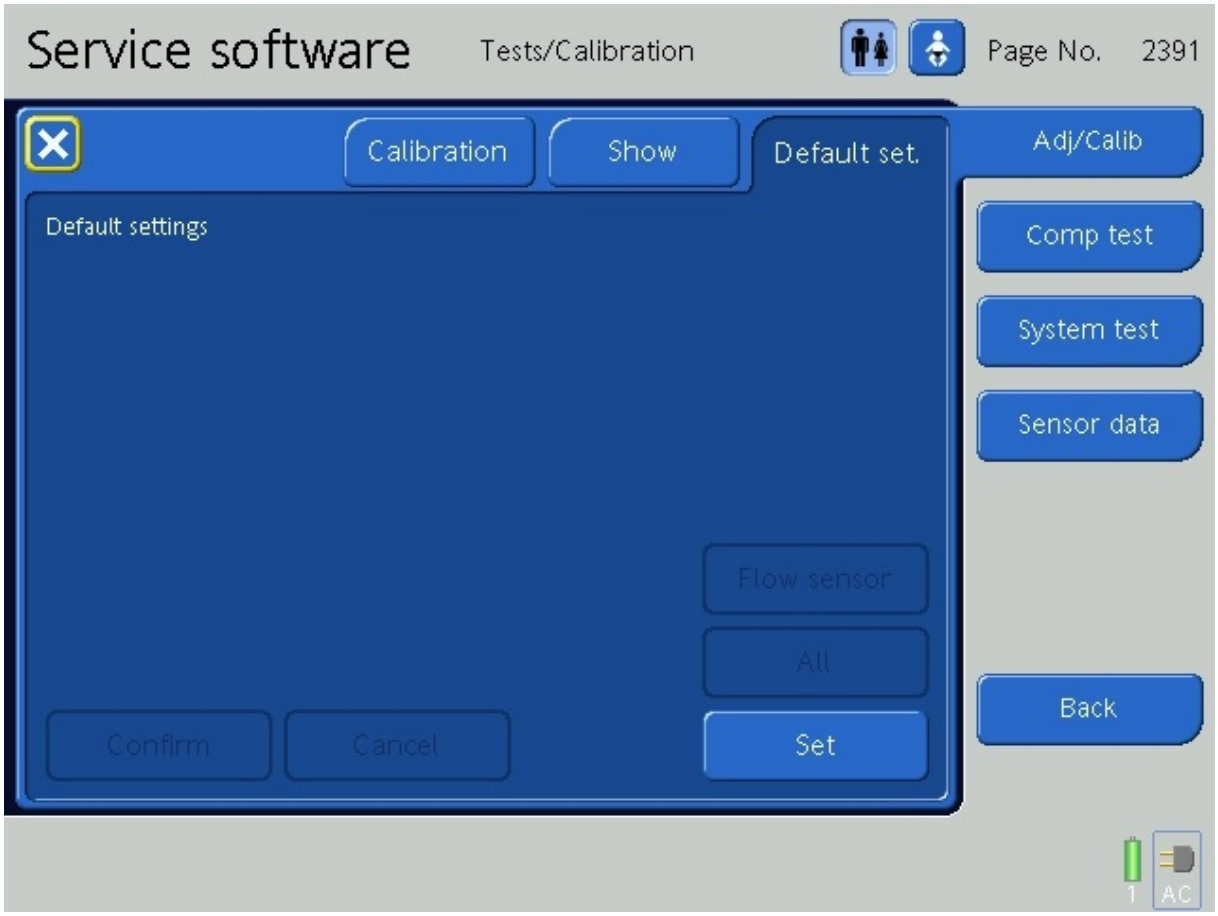


Figure 8-50. Set flow sensor or all calibration values to default

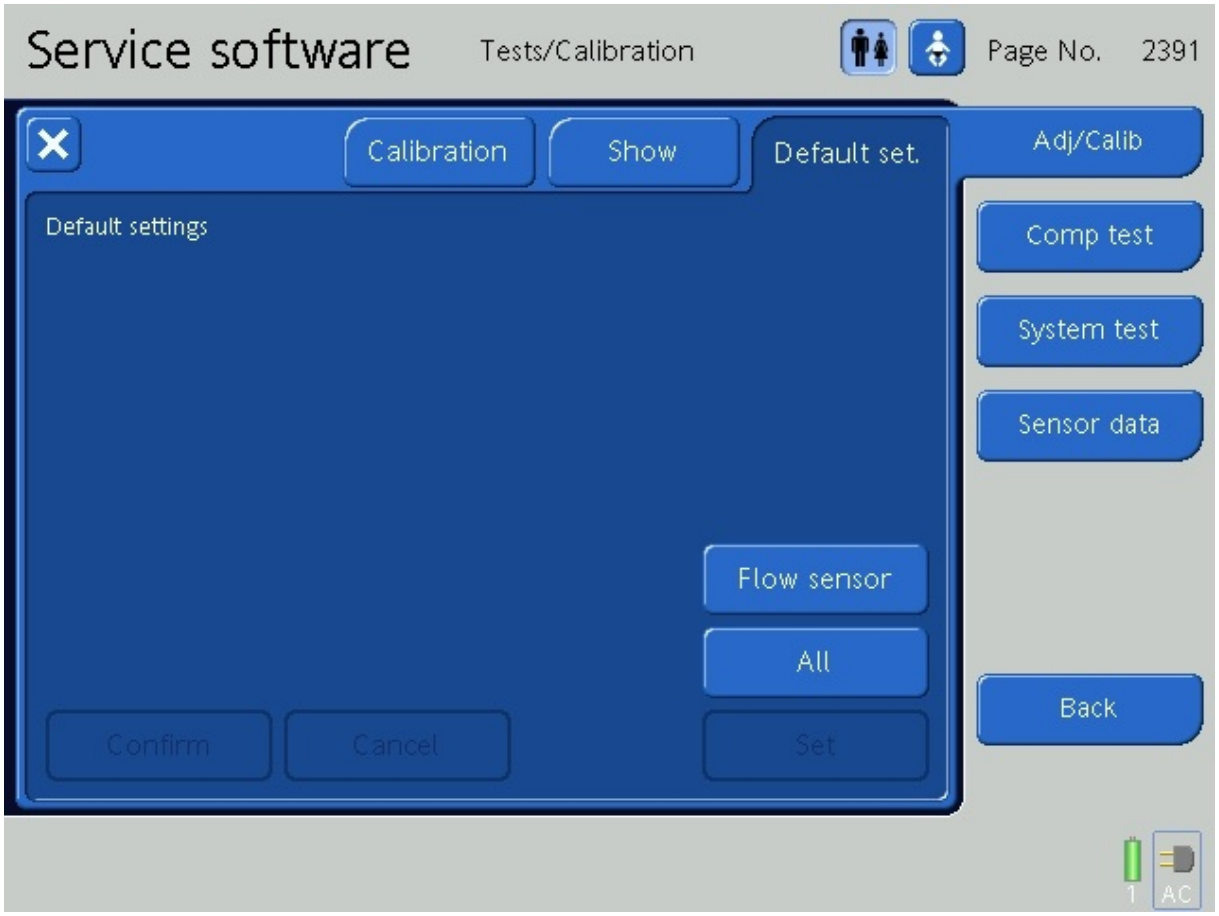


Figure 8-51. Confirm setting to default

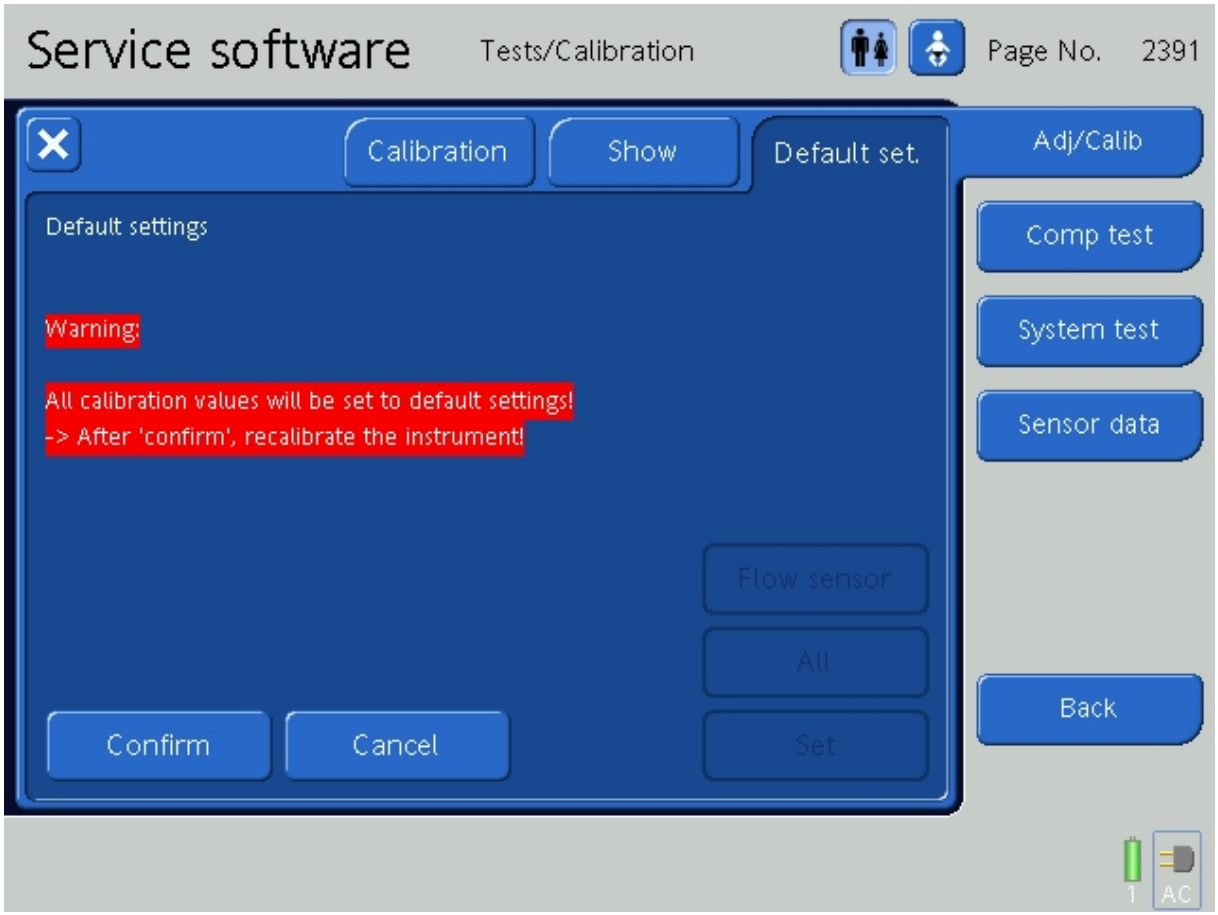
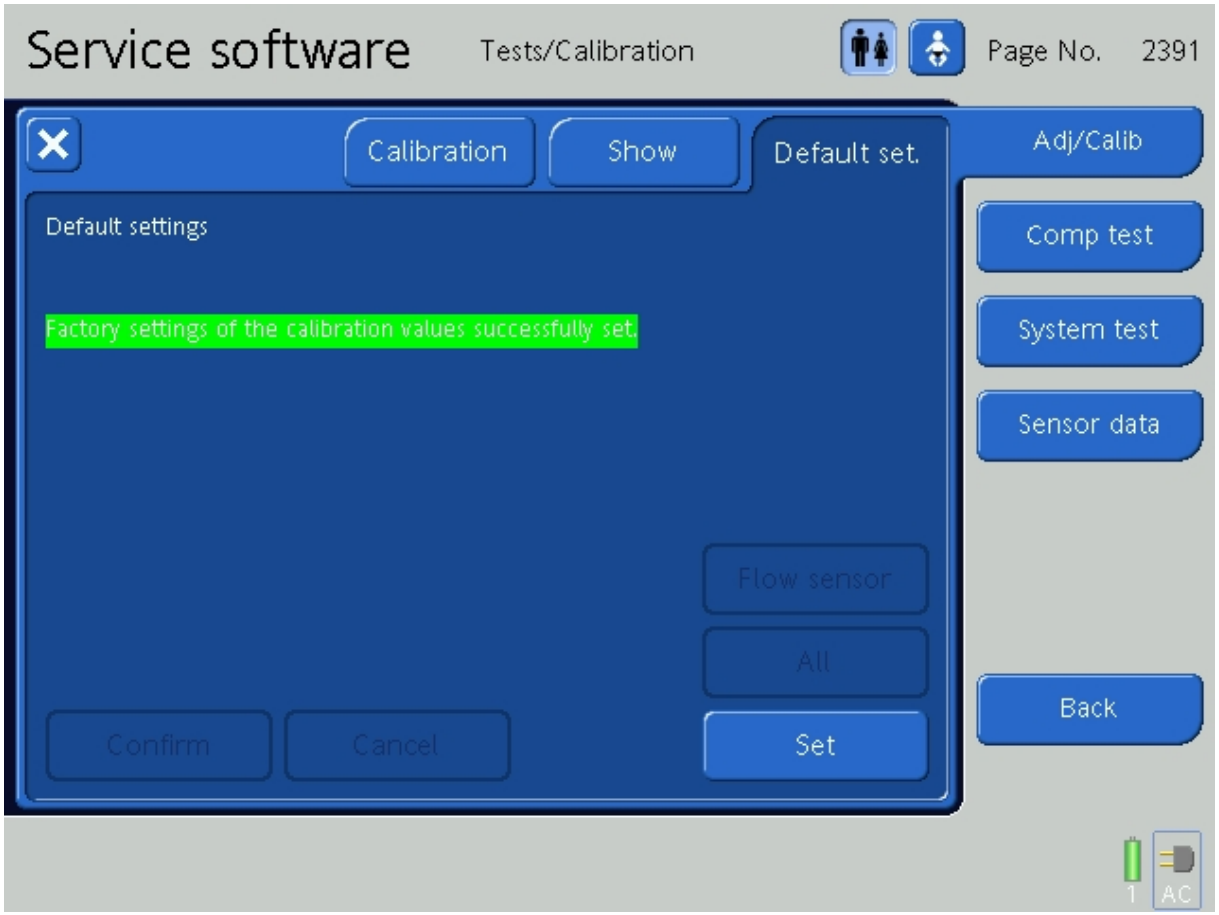


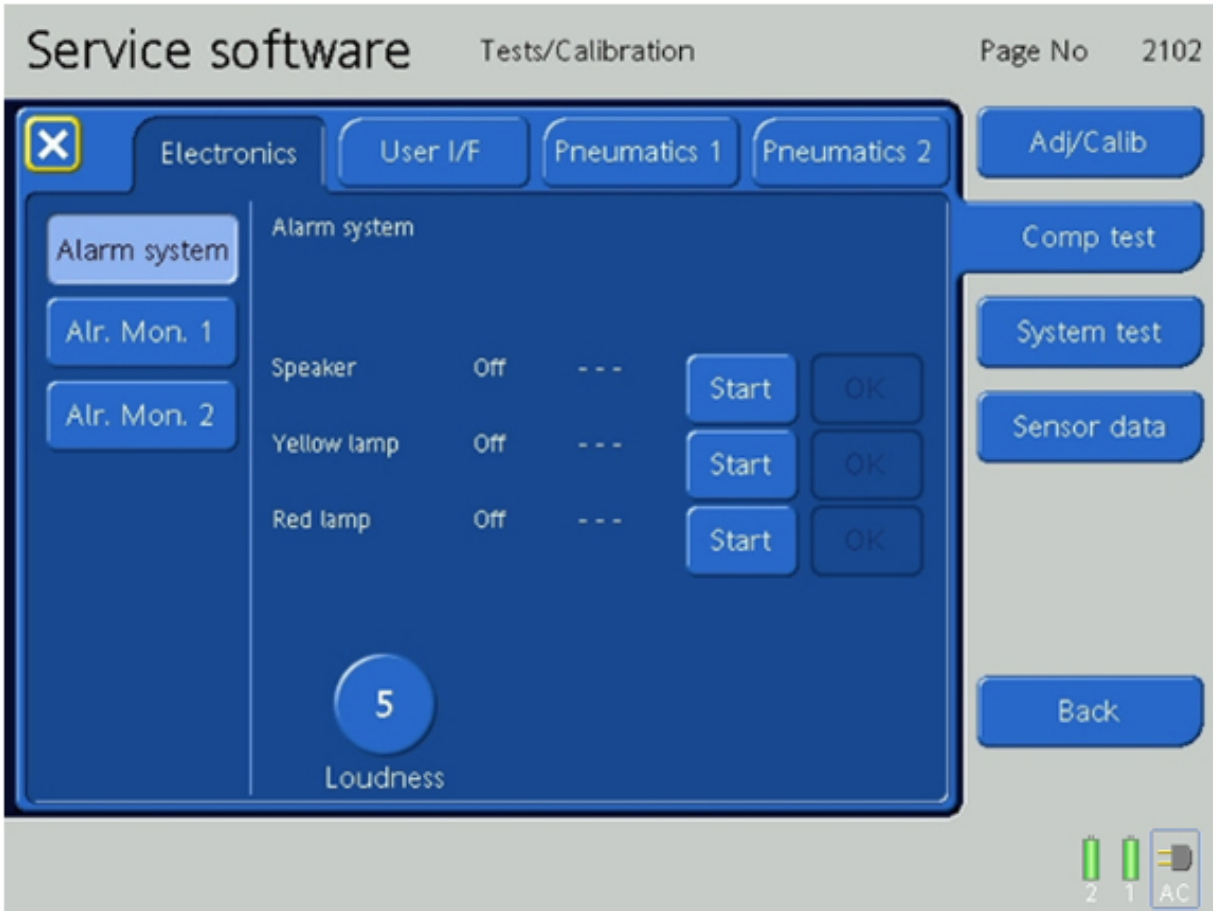
Figure 8-52. Default settings successfully set



8.2.8 Component test (ADULT/PED.)

1. Select **Comp test** tab to enter the component test section.

Figure 8-53. Component test



8.2.8.1 Overview component test (ADULT/PED.)

Component Tests	Description	Component tested
Electronics > Alarm system (Page No. 2102) (see Section 8.2.8.2.1)	This test allows activating the components related to the alarm system, it also tests the loudness levels. The test result needs to be confirmed manually.	• Loudspeaker • Alarm lamp lights red or yellow, depending on the alarm
Electronics > Alarm Mon. 1 (Page No. 2113) (see Section 8.2.8.2.2)	(Steps 1 - 6) These tests diagnose the alarm monitoring system components. (Steps 7 - 8) Testing the Ambient state. This test consists of setting the blower to achieve a certain pressure and a certain flow for 5s, afterwards the instrument will be switched to Ambient state causing the blower to stop. The flow sensor AIR (Qvent) is used to ensure the blower has stopped. The Ambient state has activated the alarm silence LED and the buzzer. The test result needs to be confirmed manually. (Steps 9 - 10) This test checks the alarm in case of fan failure. It requires stopping the fan mechanically with the help of a Torx T10 by inserting it through the hole extra made for this test. The hole is a guide allowing to stop the fan without touching its propeller.	• Alarm silence button and LED • Ambient state • Buzzer • Fan
Electronics > Alarm Mon. 2 (Page No. 2114) (see Section 8.2.8.2.3)	This test activates the software watchdog. The test result has to be confirmed manually. Afterwards the ventilator needs to be restarted.	• Watchdog (software tasks)
User I/F > (Page No. 2115) (see Section 8.2.8.3)	With this test the user interface related components can be activated in order to check the interaction of the hardkeys with the GUI, hardkey combination can also be tested. Dimming the screen and alarm lamp is tested using the day/night button. The P&T knob has 16 steps. The test is to see that all 16 steps register with the ventilator.	• P&T knob • Hardkeys + LED's • Backlight (day/night brightness)
Pneumatics 1 > Binary valve (Page No. 2106) (see Section 8.2.8.4.1)	This test checks the auto zero valves during operation and autozeroing sequence. A constant pressure is applied. Both status, "running" and "autozero", are tested for the following valves: Pvent_monitor, PFlowsensor.	Auto zero valves of : • Pvent_monitor • Pflowsensor
Tests/Calib > Comp test > Pneumatics 1 > Autozero (Page No. 2109) (see Section 8.2.8.4.2)	The test is repeating the autozero sequence 5 times under a defined pressure.	Auto zero of: • Pressure sensor Paw • Flow sensor Qaw • Pvent_monitor • Pvent_control
Tests/Calib > Comp test > Pneumatics 1 > Blower flow (Page No. 2104) (see Section 8.2.8.4.3)	Several flows (ml/s) will be set as target to the blower and the achieved blower speed in rpm measured by a Hall sensor should be within the defined tolerance.	Blower
Tests/Calib > Comp test > Pneumatics 1 > Blower pressure (Page No. 2105) (see Section 8.2.8.4.4)	Several pressures are set as target to the blower and the achieved pressure measured by the pressure sensor Pvent_monitor should be within the given tolerance.	Blower

Component Tests	Description	Component tested
Tests/Calib > Comp test > Pneumatics 1 > Exp. valve (Page No. 2111) (see Section 8.2.8.4.5)	This test checks the expiratory valve, pressure sensors, and the expiratory proportional valve. - Pexpvalve test: While the patient system is tightened and the expiratory proportional valve is fully closed, the Pressure Sensors Pexpvalve and Pvent_control will be compared and have to be equal. Afterwards the expiratory proportional valve will be opened and the pressure sensor Pexpvalve must measure zero. -Pressure test: Several pressures are set as target to the blower and expiratory valve with a defined base flow. The pressures are measured by Paw and have to be within the defined tolerance.	• Expiratory valve adult/ped. • Pressure sensor Pexp-valve • Expiratory proportional valve
Tests/Calib > Comp test > Pneumatics 2 > O2 input (Page No. 2112) (see Section 8.2.8.5.1)	For this test the ventilator needs to be connected to high pressure oxygen. Several flows will be set as target to the O2 mixer valve. The oxygen flow is measured by the internal flow sensor QO2 and has to be within a certain tolerance. In a second test the leakage is tested.	O2 mixer assembly
Tests/Calib > Comp test > Pneumatics 2 > Neb. valve (Page No. 2116) (see Section 8.2.8.5.2)	For this test the ventilator needs to be connected to high pressure oxygen. In this test the proximal flow sensor is used to measure the generated flow when the nebulizer valve is in closed or open state. The test results are successful if the measured Qaw is within the defined tolerances.	Nebulizer valve
Tests/Calib > Comp test > Pneumatics 2 > Prox. Test (Page No. 2110) (see Section 8.2.8.5.3)	This test consists of four parts: - Rinse flow test: This test requires checking the rinse flow manually by immersing the 2 flow tubes in a glass of water as depicted. The number of bubbles has to be approximately equal on each outlet. The blower is set to a constant pressure and the rinse flow valve is open in 5–seconds-breath cycles in order to provide the rinse flow tank with gas. The test result needs to be confirmed manually. - Proximal pressure: This test allows checking the proximal pressure of the external flow sensor. Two different pressures are applied consecutively by the blower through the inspiratory port. The achieved pressure is measured by the pressure sensor Paw and has to be within the tolerance. - Proximal flow: A certain flow is set as target to the blower, controlled by the internal flow sensor Qvent. The flow through the proximal flow sensor is measured by the internal differential pressure sensor Qaw and has to be within a certain tolerance. - Rinse tank: This test checks the tightness of the Rinse flow tank. A defined pressure will be applied from the blower while the inspiratory port is blocked manually. The rinse flow valve is open in order to fill the tank for a few seconds. Afterwards the rinse flow valve is closed and the pressure in the rinse flow tank should remain the same for a certain time. The pressure is then tested by the pressure sensor Paw. It has to be within the defined tolerance.	• Rinse flow • Pressure sensor Paw • Proximal flow sensor Qaw • Rinse flow valve • Rinse flow tank
Tests/Calib > Comp test > Pneumatics 2 > Check valve (Page No. 2118) (see Section 8.2.8.5.4)	(HAMILTON-C1 < SN6000) This test pressures up the test lung to a certain pressure. Afterwards the flow sensor Qaw measures if there is a certain flow flowing backwards into the system ensuring the check valve works properly.	• Check valve and bypass

Component Tests	Description	Component tested
Tests/Calib > Comp test > Pneumatics 2 > Check valve (Page No. 2118) (see Section 8.2.8.5.4)	(HAMILTON-C1 > SN6000) - Tightness This test pressures up the test lung to a certain pressure. Afterwards the flow sensor Qaw measures if the check valve assembly is tight. - Obstr. valve active This test pressures up the test lung to a certain pressure. Afterwards the obstruction valve will be opened. The flow sensor Qaw measures if the pressure can be released within a defined time frame.	• Check valve and obstruction valve (Release valve)
Tests/Calib > Comp test > Pneumatics 2 > Air entry (Page No. 2117) (see Section 8.2.8.5.5)	This test allows to check the filter pressure sensor Pfilter with and without an obstructed filter.	• HEPA filter • Pressure sensor Pfilter

8.2.8.2 Electronics

1. Select the **Electronics** tab (if not already selected).

8.2.8.2.1 Alarm system (Page No. 2102)

1. Touch the **Electronics** tab to enter the tests of the alarm system. Touch the **Alarm system** to enter the test window for the speaker and alarm lamp.

Speaker test

2. Touch the **Start** button and confirm with **OK/NOT OK** if the loudspeaker is audible.

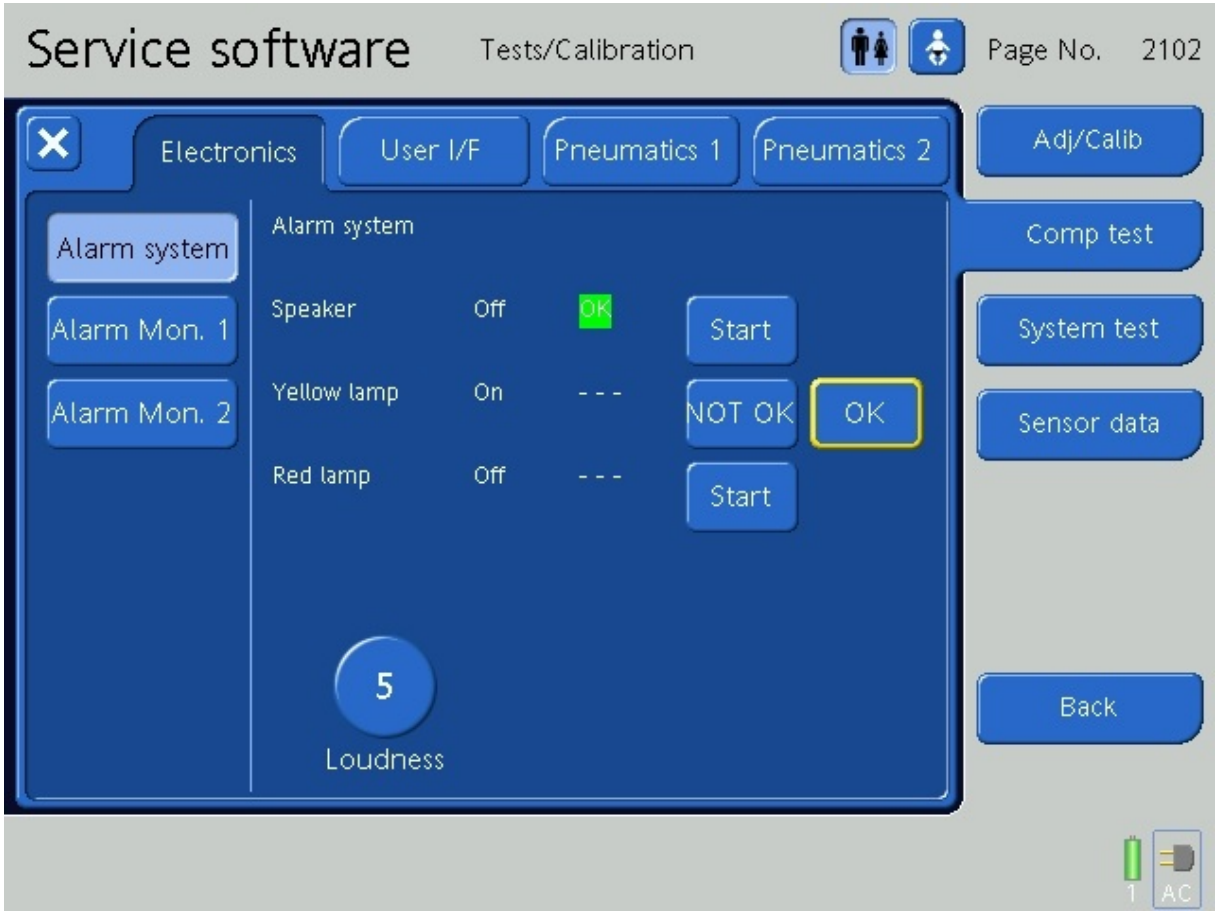
Yellow lamp

3. Touch the **Start** button and confirm with **OK/NOT OK** if the yellow lamp is ON.

Red lamp (Control Board Rev. < 09)

4. Touch the **Start** button and confirm with **OK/NOT OK** if the red lamp and the alarm silence LED are ON

Figure 8-54. Alarm System (Page No. 2102, (1/2))



Red lamp (Control Board Rev. ≥ 09)

5. Touch the **Start** button and confirm with **OK/NOT OK** if the red lamp and the alarm silence LED are blinking.

6. Use the **Loudness** button to set and check the loudness range 1–10. Check if there is no distorted sound in the loudness range 1–10.

NOTICE

This loudness setting also sets the loudness for the System test Alarming.

To check the alarm sound on High-, Medium-, Low-Prio Alarm on loudness range 1–10, set the loudness and perform the System test Alarming (see Section 8.2.9.6).

Figure 8-55. Alarm System (Page No. 2102, (2/2))