Anexa 22

Specificație tehnică completată

Model:Mașină de anestezie Carestation 650 cu monitor de pacient B105M,

Producător: GE Medical Systems, Datex-Ohmeda Inc, Țara: USA

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
Mașină de anestezie (caracteristici de bază) Cod 110110 Descriere Mașina de anestezie este destinată să livreze, să monitorizeze gazele anestezice și să asigure respirația artificială a pacientului în timpul actului chirurgical Parametru Specificaţia Prize de gaz O2, Aer Display mașina de anestezie Color TFT sau LCD Debitmetre tipul Mecanice gaz O2, Air gama, L/min ≥ 0 - 15 Vaporizator tip vaporizator acceptate Izofluran da Sevofluran da Halothan da Enfluran da Desfluran da număr de vaporizatoare instalate la dipozitiv ≥ 1 unitate da Sevofluran da interlock da sistem de absorbție da Mecanisme de siguranță siguranța O2 acustică, vizuală siguranță de amestec hipoxic da Ventilator automat tip pacient Adult, Pediatric, Neonatal moduri de ventilație Manual/spontan, VCV, PCV, PS volumul Tidal, ml 20-1500 frecvența respirației/minut 5 - 100 fluxul inspirator, L/min ≥ 3-40 raportul I:E minim 4:1 la 1:4 pauză de inspirație da limita de presiune, cmH2O ajustabilă, ≥ 0-70 PEEP, cmH2O ≥ 0-30 Sistem de autodiagnostic testare la scurgeri, testarea circuitelor respiratorii, complianța, alimentarea cu gaz, verificarea tuturor sistemelor AGSS (sistem de evacuare a gazelor anestezice) da Sistem de management al consumului de agent anestezic da Parametri monitorizați și afișați pe display Presiunea de aer Alarmă de înaltă presiune da Alarma presiune subatmosferică da Continuarea alarma presiune da Presiune scăzută / apnee da	Mașină de anestezie (caracteristici de bază) Cod 110110 Descriere Mașina de anestezie este destinată să livreze, să monitorizeze gazele anestezice și să asigure respirația artificială a pacientului în timpul actului chirurgical **DA** Parametru Specificaţia Prize de gaz O2, Aer **DA** Display mașina de anestezie Color TFT sau LCD **DA** Debitmetre tipul Mecanice **DA** gaz O2, Air **DA** gama, L/min ≥ 0 – 15 **DA** Vaporizator tip vaporizator acceptate Izofluran **DA** Sevofluran **DA** Halothan **DA** Enfluran **DA** Desfluran **DA** număr de vaporizatoare instalate la dipozitiv ≥ 1 unitate **DA** Sevofluran **DA** interlock **DA** sistem de absorbție **DA** Mecanisme de siguranță siguranța O2 acustică, vizuală siguranță de amestec hipoxic **DA** Ventilator automat tip pacient Adult, Pediatric, Neonatal **DA** moduri de ventilație Manual/spontan, VCV, PCV, PS **DA** volumul Tidal, ml 5-1500 **DA** frecvența respirației/minut 5 – 100 **DA** fluxul inspirator, L/min ≥ 3-40 **DA** raportul I:E minim 4:1 la 1:4 **DA 2:1 la 1:8** pauză de inspirație **DA** limita de presiune, cmH2O ajustabilă, ≥ 0-70 **DA** PEEP, cmH2O ≥ 0-30 **DA 4- 30** cmH2O Sistem de autodiagnostic testare la scurgeri, testarea circuitelor respiratorii, complianța, alimentarea cu gaz, verificarea tuturor sistemelor **DA** AGSS (sistem de evacuare a gazelor anestezice) **DA** Sistem de management al consumului de agent anestezic **DA** Parametri monitorizați și afișați pe display Presiunea de aer Alarmă de înaltă presiune **DA** Alarma presiune subatmosferică **DA**

Digitally signed by Chicu Natalia
Date: 2022.06.17 09:56:15 EEST
Reason: MoldSign Signature
Location: Moldova

Alte alarme de presiune da	Continuarea alarma presiune **DA**
Volumul expirator / flux da	Presiune scăzută / apnee **DA**
Volumul minut, l/min da	Alte alarme de presiune **DA**
Concentrația de O2 Alarmă apnea da	Volumul expirator / flux **DA**
Timp de răspuns, sec <30	Volumul minut, l/min **DA**
Concentrația de CO2 Alarmă apnee da	Concentrația de O2 Alarmă apnea **DA**
Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran	Timp de răspuns, sec <30 **DA**
Auto indentificarea gazelor anestezice da	Concentrația de CO2 Alarmă apnee **DA**
Alarmă concentrare agent da	Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran **DA**
Determinarea și afișarea valorii MAC da	Auto indentificarea gazelor anestezice **DA**
Modulul de gaze încorporat la mașina de anestezie da	Alarmă concentrare agent **DA**
determină concentrațiile de gaze: O2, CO2, agenți anestezici da	Determinarea și afișarea valorii MAC **DA**
Celulă determinare O2 tip galvanică da	Modulul de gaze încorporat la mașina de anestezie **DA**
Monitorul pentru afișarea funcțiilor vitale display	determină concentrațiile de gaze: O2, CO2, agenți anestezici **DA**
Color TFT sau LCD da	Celulă determinare O2 tip galvanică **DA**
monitor dedicat vizualizării funcțiilor vitale da	Monitorul pentru afișarea funcțiilor vitale display
braț de fixare a monitorului din laterală pe mașină de anestezie da	Color TFT sau LCD **DA**
baterie internă reîncărcabilă da	monitor dedicat vizualizării funcțiilor vitale **DA**
interfață de cominicare cu altele da	braț de fixare a monitorului din laterală pe mașină de anestezie **DA**
Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă da	baterie internă reîncărcabilă **DA**
traseul ECG da	interfață de cominicare cu altele **DA**
analiza și măsurarea segmentui ST da	Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă **DA**
determinarea cel puțin 20 de aritmii da	traseul ECG **DA**
Puls-oximetria (SpO2) fotopletismografia da	analiza și măsurarea segmentui ST **DA**
valoarea SpO2 da	determinarea cel puțin 20 de aritmii da
indicile de perfuzie da	Puls-oximetria (SpO2) fotopletismografia **DA**
Tensiune sanguină neinvazivă (NIBP) da	valoarea SpO2 **DA**
Respirația (impendanța transtoracică) da	indicile de perfuzie **DA**
Temperatura da	Tensiune sanguină neinvazivă (NIBP) **DA**
Alarme prioritare 3	Respirația (impendanța transtoracică) **DA**
Tensiune de alimentare 220 V, 50 Hz	Temperatura **DA**
Prize auxiliare 220V ≥ 3 buc da	Alarme prioritare 3
Baterie internă reîncărcabilă da	Tensiune de alimentare 220 V, 50 Hz **DA**
autonomie de lucru ≥ 1h da	Prize auxiliare 220V ≥ 3 buc **DA**
Sertar pentru depozitare ≥ 3 buc da	Baterie internă reîncărcabilă **DA**
Presiune de alimentare cu gaze 3.0 - 6 bar	autonomie de lucru ≥ 1h **DA**
Accesorii	Sertar pentru depozitare ≥ 3 buc **DA**
Furtunul cu conector de conectare la sursa de aer comprimat 1 buc.	Presiune de alimentare cu gaze 3.0 - 6 bar **DA**
Furtunul cu conector de conectare la sursa de oxigen 1 buc.	Accesorii
Circuit de ventilare Adult, reutilizabil ≥ 2 set.	Furtunul cu conector de conectare la sursa de aer comprimat 1 buc **DA**.
Plămîn de test Adult, reutilizabil ≥ 2 buc.	Furtunul cu conector de conectare la sursa de oxigen 1 buc. **DA**
Senzor de flux Reutilizabil ≥ 1 buc.	Circuit de ventilare Adult, reutilizabil ≥ 2 set. **DA**
Filtru antibacterial Adult, unică utilizare ≥ 100 buc.	Plămîn de test Adult, reutilizabil ≥ 2 buc. **DA**
Accesorii modul de gaz Adult ≥ 2 set.	Senzor de flux Reutilizabil ≥ 1 buc. **DA**
Cablu ECG Adult, reutilizabil 3 fire ≥ 1 buc.	Filtru antibacterial Adult, unică utilizare ≥ 100 buc. **DA**
Electrozi ECG Adult, unica utilizare ≥ 100 buc.	Accesorii modul de gaz Adult ≥ 2 set. **DA**
Senzor SpO2 Adult, reutilizabil ≥ 1 Buc.	Cablu ECG Adult, reutilizabil 3 fire ≥ 1 buc. **DA**

Anexa 22

Manșete NIBP Adult, reutilizabilă ≥ 2 buc. Adult mare, reutilizabilă ≥ 2 buc. Senzor de temperatură Adult, reutilizabil ≥ 1 buc.	Electrozi ECG Adult, unica utilizare ≥ 100 buc. **DA** Senzor SpO2 Adult, reutilizabil ≥ 1 Buc. **DA** Manșete NIBP Adult, reutilizabilă ≥ 2 buc. **DA** Adult mare, reutilizabilă ≥ 2 buc. **DA** Senzor de temperatură Adult, reutilizabil ≥ 1 buc. **DA**

GE Healthcare

Carestation™ 650

The Carestation 650 is a compact, versatile and easy to use anesthesia system designed to help clinicians deliver reliable anesthesia care to solve today's toughest challenges.

KEY FEATURES

- Elegant modern design in a slim, compact frame well suited for constrained environments
- Simple and easy to use 15" touchscreen ventilator display
- Intuitive CARESCAPE™ inspired user interface for the unified Carestation user experience
- Integrated CARESCAPE Respiratory Module
- Time saving tools to help streamline clinician workload
- Scalable software and hardware features: "build your own" Carestation
- ecoFLOW display option may help clinicians mitigate the risk of hypoxic mixtures while helping to reduce agent use by using low and minimum flows with continuous gas monitoring

VENTILATION

- Small, compact breathing system specifically designed for low flow anesthesia
- Fast gas kinetics for rapid wash-in and wash-out
- Digitally controlled flow valve ventilator supports all patient types from neonates to adults
- Advanced ventilation options including synchronized PCV-VG with pressure support (SIMV PCV-VG) and minimum rate ventilation (CPAP+PSV)
- Software enabled tools including Vital Capacity and Cycling Procedures to help automate repetitive tasks used during lung ventilation procedures
- Continual fresh gas flow with fresh gas flow compensation during mechanical ventilation

DESIGN

- Durable wheels, handles and central brake for mobility and stability
- Robust handles and mounting rails
- Easy to clean surfaces
- Movable display arm that rotates and tilts for ideal positioning
- Two vaporizer configuration
- Bi-level work surface illumination
- Absorbent canister designed for ease of use and long life
- Intelligent lighting that highlights active flow controls and auxiliary ports when in use

PHYSICAL SPECIFICATIONS

Product Description

Carestation 650 A1

Dimensions

Height:	135 cm/53.1 in
Width:	82.5 cm/32.4 in
Depth:	75 cm/29.5 in
Weight:	145 kg/320 lb*

Top shelf

Weight limit:	25 kg/55 lb
Width:	41.3 cm/16.3 in
Depth:	27.0 cm/10.6 in

Work surface

Height:	83.6 cm/32.9 in
Size:	1620 cm^2/251 in^2
Size: (with optional flip shelf)	2527 cm^2/392 in^2

Upper left Datex-Ohmeda (DO) dovetail

Dovetail length:	54 cm/21.3 in

Lower left Datex-Ohmeda (DO) dovetail

Dovetail length:	32 cm/12.6 in

Right Datex-Ohmeda (DO) dovetail

Dovetail length:	96.4 cm/38.0 in

Drawers (internal dimensions)

Height:	
Top and middle:	8.6 cm/3.4 in
Bottom:	13.3 cm/5.2 in
Width:	34 cm/13 in
Depth:	37 cm/14.6 in

Manual ventilation bag arm (optional)

Arm length:	39.8 cm/15.7 in
Bag arm height (adjustable):	53 cm/20.9 in 136 cm/53.5 in

Casters

Diameter:	12.5 cm/4.9 in
Brakes:	Central Brake

VENTILATOR OPERATING SPECIFICATIONS

Modes of ventilation – included

VCV (Volume Control) Mode with tidal volume compensation

Modes of ventilation – optional

PCV (Pressure Control Ventilation)

PCV-VG (Pressure Controlled Ventilation-Volume Guarantee)

SIMV (Synchronized Intermittent Mandatory Ventilation) (volume and pressure)

PSVPro™ (Pressure Support with Apnea backup)

CPAP+PSV (Pressure support mode)

SIMV PCV-VG

Advanced software options

Spirometry (included)

Auto alarm limits (included)

ecoFLOW

Pause Gas

Vital capacity and cycling

VCV Cardiac Bypass

** Excludes vaporizers, airway gas module, and patient monitor.*

Ventilator parameter ranges

Tidal volume range:	5 to 1500 mL (PCV modes 5 to 1500 mL) (Volume Control, PCV-VG and SIMV volume 20 to 1500 mL)
Incremental settings:	20 to 50 mL (increments of 1 mL) 50 to 100 mL (increments of 5 mL) 100 to 300 mL (increments of 10 mL) 300 to 1000 mL (increments of 25 mL) 1000 to 1500 mL (increments of 50 mL)
Minute volume range:	Less than 0.1 to 99.9 L/min
Pressure ($P_{inspired}$) range:	5 to 60 cmH_2O (increments of 1 cmH_2O) above set PEEP
Pressure (P_{max}) range:	12 to 100 cmH_2O (increments of 1 cmH_2O)
Pressure ($P_{support}$) range:	Off, 2 to 40 cmH_2O (increments of 1 cmH_2O)
Respiratory Rate:	4 to 100 breaths per minute for Volume Control and Pressure Control; 2 to 60 breaths per minute for SIMV, PSVPro and SIMV PCV-VG; 4 to 60 bpm for CPAP+PSV (increments of 1 breath per minute)
Inspiratory/ expiratory ratio:	2:1 to 1:8 (increments of 0.5) (VCV, PCV, PCV-VG)
Inspiratory time:	0.2 to 5.0 seconds (increments of 0.1 seconds) (SIMV, PSVPro and CPAP PSV)
Trigger window:	Off, 5 to 80% of Texp (SIMV, PSVPro) (increments of 5%)
Flow trigger:	1 to 10 L/min (increments of 0.5 L/min) 0.2 to 1 L/min (increments of 0.2 L/min)
Inspiration termination level:	5 to 75% (increments of 5%)
Inspiratory Pause range:	Off, 5-60% of Tinsp

Positive End Expiratory Pressure (PEEP)

Type:	Integrated, electronically controlled
Range:	OFF, 4 to 30 cmH_2O (increments of 1 cmH_2O)

Ventilator performance

Peak gas flow:	120 L/min + fresh gas flow
Flow valve range:	1 to 120 L/min
Flow compensation range:	100 mL/min to 15 L/min

VENTILATOR ACCURACY

Delivery/monitoring accuracy

Volume delivery:	> 210 mL = better than 7% ≤ 210 mL = better than 15 mL < 60 mL = better than 10 mL
Pressure delivery:	±10% or ±3 cmH_2O (larger of)
PEEP delivery:	±1.5 cmH_2O
Volume monitoring:	> 210 mL = better than 9% ≤ 210 mL = better than 18 mL < 60 mL = better than 10 mL
Pressure monitoring:	±5% or ±2.4 cmH_2O (larger of)

Alarm settings

Tidal volume (V_{TE}):	Low: OFF, 1 to 1500 mL High: 20 to 1600 mL, OFF
Minute volume (V_E):	Low: OFF, 0.1 to 10 L/min High: 0.5 to 30 L/min, OFF
Inspired oxygen (FiO_2):	Low: 18 to 99% High: 19 to 100%, OFF
Apnea alarm:	***Mechanical ventilation ON***: < 5 mL breath measured in 30 seconds ***Mechanical ventilation OFF:*** < 5 mL breath measured in 30 seconds
Low airway pressure:	4 cmH_2O above PEEP
High pressure:	12 to 100 cmH_2O (increments of 1 cmH_2O)
Sustained airway pressure:	***Mechanical ventilation ON:*** P_{max} < 30 cmH_2O, the sustained limit is 6 cmH_2O P_{max} 30 to 60 cmH_2O, the sustained limit is 20% of P_{max} P_{max} > 60 cmH_2O, the sustained limit is 12 cmH_2O ***PEEP and mechanical ventilation ON:*** Sustained limit increases by PEEP minus 2 cmH_2O ***Mechanical ventilation OFF:*** P_{max} 12 to 60 cmH_2O, the sustained limit is 50% of P_{max} P_{max} > 60 cmH_2O, the sustained limit is 30 cmH_2O
Subatmospheric pressure:	Paw < -10 cmH_2O
Audio pause countdown clock:	120 to 0 seconds

VENTILATOR COMPONENTS

Flow transducer

Type:	Variable orifice flow sensor (autoclavable)
Location:	Inspiratory outlet and expiratory inlet

Oxygen sensor

Type:	Optional galvanic fuel cell or paramagnetic with Airway Module option

Ventilator screen

Display size:	15 inch
Pixel format:	1024 x 768

Battery backup

Backup power:	Battery time is 90 minutes when fully charged, which supports full system functionality and ventilation.
Battery type:	Internal rechargeable sealed lead acid

Communication ports

RS-232C compatible serial interface

Ethernet

Datex-Ohmeda device interface solutions port

USB port

VGA Output

ANESTHETIC AGENT DELIVERY

Delivery

Vaporizers:	Tec™ 6 Plus, Tec 7, Tec 820, Tec 850
Number of positions:	2
Mounting:	Tool-free installation Selectatec™ manifold interlocks and isolates vaporizers

AIRWAY MODULES

General

Supported modules:	E-sCAiO, E-sCAiOV, N-CAiO
Size (HxWxD), excluding water trap:	113 x 38 x 205 mm/4.4 x 1.5 x 8.1 in
Weight:	0.7 kg/1.5 lb
Sampling rate:	120 mL/min ±20 mL

Automatic compensation for atmospheric pressure variation (495 to 795 mmHg) temperature and CO_2/N_2O and CO_2/O_2 collision broadening effect. Parameter display update interval typically breath-by-breath. Functional alarms for blocked sample line, D-fend check and D-fend replacement.

Non-disturbing gases:

Ethanol, acetone, isopropanol, methane, nitrogen, nitric oxide, carbonmonoxide, water vapor, freon R134A (for CO_2, O_2 and N_2O):

Maximum effect on readings:	CO_2 < 0.2 vol %; O_2, N_2O < 2 vol %, AA < 0.15 vol%

Carbon dioxide (CO_2)

$EtCO_2$:	End-tidal CO_2 concentration
$FiCO_2$:	Inspired CO_2 concentration

CO_2 waveform

Measurement range:	0 to 15% (0 to 15 kPa, 0 to 113 mmHg)
Accuracy:	±0.2 vol % + 2 % of reading

Datex-Ohmeda infrared sensor

Adjustable low and high alarm limits for $EtCO_2$ and $FiCO_2$

Respiration rate (RR)

Measurement range:	4 to 100 breaths/min
Detection criteria:	1% variation in CO_2

Adjustable low and high alarm limits for respiration rate; alarm for apnea

Patient Oxygen (O_2)

FiO_2:	Inspired O_2 concentration
EtO_2:	End-tidal O_2 concentration
FiO_2-EtO_2:	Inspired-expired difference

O_2 Measurement

Measurement range:	0 to 100%
Accuracy:	±1 vol % +2 % of reading

Datex-Ohmeda differential paramagnetic sensor

Adjustable low and high alarm limits for FiO_2 and EtO_2; alarm for FiO_2 < 18%

Nitrous Oxide (N_2O)

Measurement range: 0 to 100%
Accuracy: ±2 vol % +2 % of reading

Anesthetic Agent (AA)

Halothane, Isoflurane, Enflurane
Measurement range: 0 to 6%
Accuracy: ±(0.15 vol% +5% of reading)

Sevoflurane
Measurement range: 0 to 8%
Accuracy: ±(0.15 vol% +5% of reading)

Desflurane
Measurement range: 0 to 20%
Accuracy: ±(0.15 vol% +5% of reading)

Waveform displayed
MAC value displayed (Airway Gas Option modules)
MACage value displayed (CARESCAPE modules)
Identification threshold: 0.15 vol%**
Agent mixture detection
Adjustable high and low alarm limits for EtAA, FiAA

Patient Spirometry™

Pressure-volume loop
Pressure-flow loop
Flow-volume loop
Airway pressure and flow waveforms
Adjustable low and high alarm limits for P_{peak}, $PEEP_{tot}$ and MV_{exp}
Alarms for MV_{exp} << MV_{insp} and for MV_{exp} low. Detection through D-lite™ or Pedi-lite™ flow sensor and gas sampler with following specifications:

CARESCAPE Airway Modules

	D-lite(+)	Pedi-lite(+)
Respiration rate:	4 to 35 breaths/min	4 to 70 breaths/min
Tidal volume		
Measurement range:	150 to 2000 mL	5 to 300 mL
Accuracy**:	±6% or 30 mL	±6% or 4 mL
Minute volume		
Measurement range:	2 to 20 L/min	0.1 to 5 L/min
Airway pressure		
Measurement range:	-20 to +100 cmH_2O	
Accuracy**:	±1 cmH_2O	
Display units:	cmH_2O, mmHg, kPa, mbar, hPa	
Flow		
Measurement range:	-100 to 100 L/min	-25 to 25 L/min
I:E		
Measurement range:	1:4.5 to 2:1	
Compliance		
Measurement range:	4 to 100 mL/cmH_2O	1 to 100 mL/cmH_2O
Airway resistance		
Measurement range:	0 to 200 $cmH_2O/L/s$	

Sensor specifications

	D-lite/ D-lite(+)	Pedi-lite/ Pedi-lite(+)
Dead Space:	9.5 mL	2.5 mL
Resistance		
at 30 L/min:	0.5 cmH_2O	
at 10 L/min:		1.0 cmH_2O

ELECTRICAL SPECIFICATIONS

Current leakage

100/120 V: < 300µA
220/240 V: < 500µA

Power

Power input: 100-120 Vac, 50/60 Hz
220-240 Vac, 50/60 Hz
120/220-240 Vac ± 10%, 50-60 Hz

Power cord:
- Length: 5 m/16.4 ft
- Rating: 10A @ 220-240 Vac or
  15A @ 100-120 Vac
  10A @ 120/220-240 Vac

Inlet modules

100/120 V:
- Without outlets: 2A
- With outlets: 10A

220/240 V:
- Without outlets: 2A
- With outlets: 8A

Outlet modules (optional)

100/120 V:
3 outlets on side, 1-3A, individual breakers, isolation transformer (optional)

220/240 V:
3 outlets on side, 1-2A, 2-1A, individual breakers, isolation transformer (optional)

120/220-240 V:
No outlets

***Typical value*

PNEUMATIC SPECIFICATIONS

Auxiliary O_2 (optional)

Connection:	7-10 mm hose barb port
O_2 concentration range:	100% O_2
Flow range:	0 to >10 L/min

Auxiliary O_2+Air (optional)

Connection:	7-10 mm hose barb port
O_2 concentration range:	100% O_2 only, or 21% to 100% O_2 with Air
Flow range:	
for O_2 and Air:	0 and 100 mL/min to 15 L/min

Auxiliary common gas outlet (optional)

Connector:	ISO 22 mm OD and 15 mm ID

Gas supply

Pipeline input range:	280 kPa to 600 kPa (41 psig to 87 psig)
Pipeline connections:	DISS-male, DISS-female, AS4059, S90-116, or NIST
	All fittings available for O_2, N_2O, and Air, and contain pipeline filter and check valve.
	Secondary O_2 pipeline inlet available.
Cylinder input:	Pin indexed in accordance with CGA-V-1 or DIN-477 (nut and gland); contains input filter and check valve.
	Large cylinder kit available for O_2 and N_2O (with DIN-477).

Note: *Maximum 3 cylinders*

Primary regulator diaphragm minimum burst pressure:	2758 kPa/400 psig
Primary regulator nominal output:	≤ 345 kPa/50 psig Pin indexed cylinder connections ≤ 414 kPa/60 psig DIN-477 cylinder connections

O_2 controls

Method:	N_2O shut off with loss of O_2 pressure
Supply failure alarm:	< 252 kPa (36.55 psig)
O_2 flush:	Range: 25 to 75 L/min

Fresh gas

Flow range:	
for O_2 and Air:	0 and 100 mL/min to 15 L/min (minimal flow capable)
for N_2O:	0 and 100 mL/min to 10 L/min
Pneumatic Total Flow Tube:	1 to 10 L/min
Measurement accuracy	
for O_2, Air and N_2O:	±6% of measured value, or ±25 mL/min (larger of)
for Total Flow tube:	±5% of full scale (larger of) at 100% O_2
O_2 concentration range:	21% to 100% when Air is available
O_2 Cell accuracy:	±2.5% plus 2.5% of reading
Compensation:	Temperature and atmospheric pressure compensated to standard conditions of 20°C and 101.3 kPa
Hypoxic guard:	Mechanical Link-25: Provides a nominal minimum 25% concentration of oxygen in O_2/N_2O mixture.

Materials

All materials in contact with patient breathing gases are not made from natural rubber latex.

ENVIRONMENTAL SPECIFICATIONS

System operation

Temperature:	10° to 40°C (50° to 104°F)
Humidity:	15 to 95% relative humidity (non-condensing)
Altitude:	-440 to 3565 m (500 to 800 mmHg) -440 to 4000 m (without Airway Module) (475 to 800 mmHg)

System storage

Temperature:	-25° to 60°C (-13° to 140°F)
Humidity:	15 to 95% relative humidity (non-condensing)
Altitude:	-440 to 4880 m (425 to 800 mmHg)
Oxygen cell storage:	-15° to 50°C (5° to 122°F) 10 to 95% relative humidity 500 to 800 mmHg

Electromagnetic compatibility

Immunity:	Complies with all applicable requirements of EN 60601-1-2
Emissions:	CISPR 11 group 1 class A
Standard compliance:	AAMI ES60601-1, CSA C22.2 #601.1, EN/IEC 60601-1, ISO 80601-2-13
European Notified Body CE Mark:	CE0197

BREATHING CIRCUIT SPECIFICATIONS

Carbon dioxide absorbent canister

Absorbent capacity:	Reusable canister 1370 mL/1150 g Disposable canister 1440 mL/1200 g

Ports and connectors

Exhalation:	22 mm OD ISO 15 mm ID taper
Inhalation:	22 mm OD ISO 15 mm ID taper
Bag port:	22 mm OD (15 mm ID), ROW 22 mm ID, Australia

Bag-to-Ventilator switch

Type:	Bi-stable
Control:	Controls ventilator and direction of breathing gas within the circuit

Integrated Adjustable Pressure Limiting (APL) valve

Range:	0.5 to 70 cmH_2O
Tactile knob indication at:	30 cmH_2O and above
Adjustment range of rotation:	0.5 to 30 cmH_2O (0 to 230°) 30 to 70 cmH_2O (230 to 330°)

Materials

All materials in contact with exhaled patient gases are autoclavable, except O_2 cell, and Airway Modules.
All materials in contact with patient gas are not made from natural rubber latex.

Breathing circuit parameters

Compliance:

Bag mode:	1.81 mL/cmH_2O (filled disposable absorber canister) 1.74 mL/cmH_2O (filled reusable absorber canister)
Mechanical mode:	Automatically compensates for compression losses within the absorber and bellows assembly
Volume:	2006 mL Ventilator side 500 mL Bag side 1000 mL Reusable canister 1000 mL Disposable canister

Expiratory resistance in bag mode:

Flow rate	***P_{exp} Absorber canister Installed***	***P_{exp} Absorber canister Removed***
5 L/min	0.57 cmH_2O	0.57 cmH_2O
30 L/min	2.47 cmH_2O	2.47 cmH_2O
60 L/min	5.60 cmH_2O	5.60 cmH_2O

Note: *Values include patient circuit tubing and wye piece (0.65 cmH_2O at 60 L/min)*

Anesthetic gas scavenging

AGSS Type	***Hospital extract system required***	***Machine connection***
High vacuum, low flow:	High vacuum 36 +/- 3 L/min @ 12 inHg (305 mmHg)	SIS evac
High vacuum, low flow:	High vacuum 25- 30 L/min @ 12 inHg (305 mmHg)	DISS evac
Low vacuum, high flow:	Low vacuum 50 to 80 L/min ISO 1H	BSI 30 mm threaded
Low vacuum, low flow:	Low vacuum 25 to 50 L/min ISO 1L	12.7 mm hose barb, 25 mm hose barb, or 30 mm ISO taper
Passive:	Passive system with air break	30 mm/1.2 in M ISO taper

Product may not be available in all countries and regions.
Contact a GE Healthcare Representative for more information.
Please visit www.gehealthcare.com

GE Healthcare
PO Box 7550
Madison, WI 53707-7550
USA

Always refer to complete instruction manual before use.

This document applies to Carestation 650 A1.

DOC1649438 Rev7

Non-USA

GE Healthcare

Datex·Ohmeda

EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC, Annex II and of the directive 2011/65/EU)

We

Manufacturer
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
PO Box 7550
Madison, WI 53707-7550 USA

EU Authorized Representative
GE Healthcare Finland Oy
Kuortaneenkatu 2
Helsinki, Finland
FI-00510

Manufacturing Site
GE Medical Systems (China) Co., Ltd.
19 Changjiang Road
Wuxi, Jiangsu, PR China 214028

Declare under our sole responsibility that the class IIb devices:

Carestation 650

Version: A1 REF: 1012-9650-000

Carestation 650c

Version: A1 REF: 1012-9655-000

Carestation 620

Version: A1 REF: 1012-9620-000

GMDN Code: 37710, UMDNS Code: 10-134

Classification rule (93/42/EC Annex IX): Class IIb, Rule 11

To which this declaration relates is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it. In addition, the product is in conformity with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as assessed by the manufacturer).

This conformity is based on the following elements:

- Information included in the documents:
  Technical Documentation Ref: DOC1659791, of the product to which this declaration relates.
- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nuremberg, Germany, Notified Body # 0197, Certificate N° HD 60098566 0001 valid until 9 June 2016.
- List of harmonized standards applied for CE marking is located in the Technical Documentation file for this product.

Monica Morrison
Regulatory Affairs Director

16 JUN 2015
Madison, USA, Day Month -Year

This EC declaration of conformity is the initial revision. Reference of the Declaration: DOC1659800

CERTIFICATE

This is to certify that the company

GE Healthcare Finland Oy

Kuortaneenkatu 2
00510 Helsinki
Finland

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design, manufacture, sales, marketing and service operation and distribution of patient monitoring system and related accessories, anaesthesia machine and ventilator acccessories and clinical information system devices. Final configuration, manufacturing and distribution of cardiology products.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	548099 MDSAP16
Certificate unique ID	170771008
Effective date	2020-10-04
Expiry date	2023-10-03
Frankfurt am Main	2020-10-04

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

Annex to certificate
Certificate registration No.: 548099 MDSAP16
Certificate unique ID: 170771008
Effective date: 2020-10-04

GE Healthcare Finland Oy

Kuortaneenkatu 2
00510 Helsinki
Finland

Audited site	DUNS No., site scope and country-specific requirements
GE Healthcare Finland Oy Kuortaneenkatu 2 00510 Helsinki Finland	Design, manufacture, sales, marketing and service operation of patient monitoring system and related accessories, anaesthesia machine and ventilator acccessories and clinical information system devices. Final configuration, manufacturing and distribution of cardiology products. **-AUS(a), BRA, CND, JPN, USA (a,b,c,d)** **DUNS No.: 401966697**
GE Healthcare Finland Oy Viestikatu 7 70600 Kuopio Finland	Design, manufacture, sales, marketing and service operation of clinical information system devices. **-AUS(a), BRA, CND, JPN, USA (a,b,c,d)** **DUNS No.: 401966697**

Annex to certificate
Certificate registration No.: 548099 MDSAP16
Certificate unique ID: 170771008
Effective date: 2020-10-04

GE Healthcare Finland Oy

Kuortaneenkatu 2
00510 Helsinki
Finland

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821

EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745,

ROHS directive 2011/65/EU and Radio Equipment Directive 2014/53/EU.

We:

Manufacturer	EU Authorized Representative
GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226, USA	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France

Manufacturing Site

GE Medical systems (China) Co., Ltd
No. 19, ChangJiang Road, WuXi National Hi-tech Development Zone
Jiangsu, P.R. China 214028

Declare under our sole responsibility that the device:

B125P/B105P/B125M/B105M/B155M Patient Monitor

Basic UDI-DI: 8406821BUG00102GM

Identification number:

B105P	6160000-001
B125P	6160000-002
B105M	6160000-003
B125M	6160000-004
B155M	6160000-005

SIGNATURE:

18 NOV 2020

Monica Morrison
Executive - Regulatory Affairs
Washington, DC USA

Date

Reference of the Declaration: DOC2430297

Intended Purpose: Vital Signs Monitoring Instrument
GMDN Code and Description: 33586 Patient monitor, multiparameter

EMDN Code and Description: Z120302 Vital Signs Monitoring Instruments

Class: IIb

Classification rule (Annex VIII): Rule 10

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it and with the requirements of the RoHS directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This conformity is based on the following elements:

- Technical Documentation reference: DOC2430158, of the product to which this declaration relates.
- EC certificate No. HZ 2214580-1:
  - Conformity assessment procedure followed: Annex IX, Chapters I, III
  - Delivered by TÜV Rheinland LGA Products GmbH (0197)

We, manufacturer, declare under our sole responsibility that:

B125P/B105P/B125M/B105M/B155M Patient Monitor equipped with B1x5-01 WLAN module

To which this declaration relates is in conformity with the requirements of the Radio Equipment Directive 2014/53/EU which applies to it.

This conformity is based on the following elements:

- The device conforms to the Directive 2014/53/EU through Annex II-Internal Production Control
- The list of harmonized standards applied is located in the Technical File for this product.

SIGNATURE:

18 NOV 2020

Monica Morrison Date
Executive - Regulatory Affairs
Washington, DC USA

Reference of the Declaration: DOC2430297

EC Certificate

EU Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 2214580-1
Manufacturer:	**GE Medical Systems Information Technologies, Inc.** 9900 Innovation Drive Wauwatosa, WI 53226 USA
EUDAMED Single Registration No.:	N/A
Products:	Class IIa- Z120503 ELECTROCARDIOGRAPHS Class IIb -Z120302 VITAL SIGNS MONITORING INSTRUMENTS
Authorised representative(s):	**GE Medical Systems SCS** 283 Rue de la Miniere, 78530 BUC France

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2020-11-17

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	234158038-30
Effective date:	2020-11-17
Expiry date:	2025-10-30
Issue date:	2020-11-17

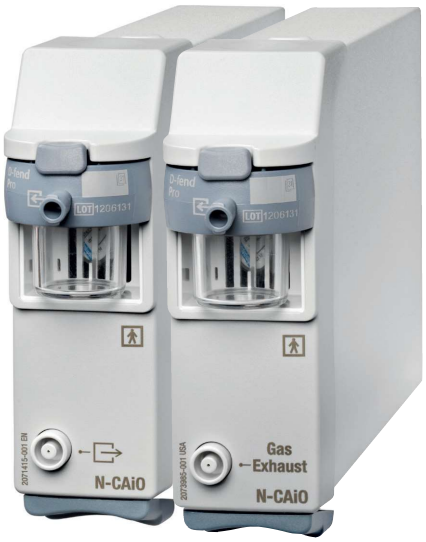
TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

GE Healthcare



Airway Gas Option, N-CAiO

Essential anesthesia monitoring for adult, pediatric and neonatal anesthesia applications.

With the B40 Patient Monitor, the airway gas module, N-CAiO, supports respiratory monitoring in the Operating Room.

Features

- Airway gases measured by the sidestream method
- Et and Fi values updated breath by breath
- Fast oxygen measurement for accurate EtO_2 and FiO_2 values
- Automatic identification of the anesthetic agent in use
- Light, compact size with low power consumption
- Variety of GE-validated gas sampling accessories for monitoring application-specific needs

Clinical measurements

- CO_2 and N_2O – GE infrared technology:
  Inspired and end-tidal values, CO_2 waveform and respiration rate
- Respiration rate – calculated from the CO_2 waveform
- Anesthetic agents – GE infrared technology
  - Measures and identifies all five agents halothane, enflurane, isoflurane, sevoflurane and desflurane
  - MAC (Minimum Alveolar Concentration)
- Patient oxygen – GE paramagnetic oxygen (O_2) technology:
  Inspired, end-tidal and Fi-Et difference, waveform

Technical specifications

General

When monitoring neonatal or other patients that have high respiration rate or low tidal volume these modules shall be used within the limits of respiration rates and tidal volumes to ensure specified measurement accuracy.

Sampling flow	120 ±20 ml/min

Size and fit of gas sampling accessories may impact measured gas concentration values at low tidal volumes. Always ensure use of appropriate accessories according to patient and application.

Automatic compensation for atmospheric pressure variation (660-1060 mbar), temperature and CO_2, O_2, N_2O, agent cross effect compensation. Parameter display update interval typically breath-by-breath.

Functional alarms for

- Low gas sampling flow
- Blocked sample line
- Blocked sample gas outflow
- Disconnected water trap
- Blocked water trap

Letters in the module name stand for

C = CO_2 and N_2O

Ai = Anesthetic agents with single agent identification

O = Patient O_2

Non-disturbing gases

- Ethanol, acetone, isopropanol, methane, nitrogen, nitric oxide, carbon monoxide, water vapor and freon R134A (for CO_2, O_2 and N_2O).
- Maximum effect of non-disturbing gases on readings: O_2 & N_2O <2vol%, CO_2 < 0.2 vol%, AA < 0.15 vol%.

Carbon dioxide (CO_2)

GE infrared absorption sensor technology

CO_2 waveform

$EtCO_2$	End-tidal CO_2 concentration
$FiCO_2$	Inspired CO_2 concentration
Measurement range	0 to 15 vol% (0 to 15 kPa, 0 to 113 mmHg)
Accuracy	±(0.2 vol% + 2% of reading)
Rise time	<260 ms

Adjustable low and high alarm limits for $EtCO_2$ or $FiCO_2$

Respiration rate (RR)

Measurement range	4 to 100 breaths/min
Detection criteria	1 vol% change in CO_2 level

Alarm note sent to host device if no breath detected in 20 seconds

Patient oxygen (O_2)

GE differential paramagnetic sensor

O_2 waveform

FiO_2	Inspired O_2 concentration
EtO_2	End-tidal O_2 concentration
FiO_2-EtO_2	Inspired-expired difference
Measurement range	0 to 100 vol%
Accuracy	±(1 vol% + 2% of reading)
Rise time	<260 ms

Nitrous oxide (N_2O)

GE infrared absorption sensor

FiN_2O	Inspired N_2O concentration
EtN_2O	End-tidal N_2O concentration
Measurement range	0 to 100 vol%
Accuracy	±(2 vol% + 2% of reading) $N_2O \leq 85\%$

Anesthetic agent (AA)

GE infrared absorption sensor

Anesthetic agent waveform, if requested by host device

FiAA	Inspired anesthetic agent concentration
EtAA	End-tidal anesthetic agent concentration

MAC value options for hosts

Measurement range

Sevoflurane	0 to 8 vol%
Desflurane	0 to 20 vol%
Isoflurane, enflurane, halothane	0 to 6 vol%
Accuracy	±(0.15 vol% + 5% of reading)

Agent identification

Identification threshold	0.15 vol%
Detection time	<20 sec

System compatibility

- B40 Patient Monitor, (2060600-002)

Environmental specifications

Operating conditions

Temperature	10 to 40°C (50 to 104°F)
Relative humidity	10 to 98% non-condensing
Ambient pressure	660 to 1060 mbar

Storage conditions

Temperature	-25 to 60°C (-13 to 140°F)
Relative humidity	10 to 90% non-condensing

Physical specifications

Dimensions (H x W x D), excluding water trap	11.3 x 3.8 x 20.5 cm (4.4 x 1.5 x 8.1 in)
Weight	0.7 kg (1.5 lb)

About GE Healthcare

GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services help our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

GE Healthcare
8200 W. Tower Ave.
Milwaukee, WI 53223
USA

www.gehealthcare.com

GE Healthcare Finland Oy
Kuortaneenkatu 2
00510 Helsinki
Finland

GE Healthcare
3/F Building # 1,
GE Technology Park
1 Hua Tuo Road
Shanghai 201203
China

imagination at work

DOC1379111 5/13

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 60146867 0001

Organization: GE Medical Systems
Information Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226
USA

Scope: Design, Development, and Manufacture of Patient Monitoring Systems, Cardiology ECG Recording and Analysis Systems, Invasive Cardiology Equipment Systems and Medical Software

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

Report No.: 32090997.003

Effective date: 2020-08-12

Expiry date: 2023-03-11

Issue date: 2020-08-12

TÜV Rheinland LGA Products GmbH
TÜVRheinland®

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

Balazs Bozsik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Simple. Smart. Agile.

Carestation™ 600 Series:
reliable and agile anaesthesia solution
with smart tools to help simplify your daily work
and manage non-ordinary events

Carestation 600 Series

Carestation 620/650/650c (A1)

Imagination at work

Patient Safety is at the hearth of everything we do[6]

PATIENT SAFETY IN ANAESTHESIOLOGY

European Society of Anaesthesiology ESA

It's estimated that more than 400,000 people die each year due to preventable medical errors[1]

Many of these errors are technology-related[1]

Human factor play a large part in the delivery of safe care to patients[2]

Multiple patient safety organizations work actively with surgical, nursing and clinical partners to reliably provide and improve safety in patient care[3,4].

The industry plays a key role in developing, manufacturing and supplying new equipment for enhanced patient care. Anesthesiology has been the leading specialty in medicine for the development of patient safety . There are still other areas to improve through research & innovation[4,5] .

GE is an historical partner of the ESA Patient Safety initiative since the Helsinki declaration.

Our commitment is to contribute to Patient Safety by focusing on clinical innovation and simplifying user experience[6]

GE ESA PARTNER

1 ECRI report 2014
https://www.ecri.org/press/Pages/2014-Top-10-Health-Technology-Hazards-Report.aspx
2 Best practice & research clinical RJ Glavin, Anaesthesiology 2011
3 ReasonJ: Human Error. Cambridge , Cambridge University press 1990
4 Helsinki declaration - Eurpean journal of anesthesiology ; 2010; 27
5 Gaba DM: Anaesthesiology as a model for patient safet in health care . BMJ 2000;320:785-8

[6]Didier Deltort, VP & GM Monitoring Solutions, Life Care Solutions, HealthCare Systems at GE Healthcare: ESA 2013 e-News
http://barcelonanews.fb.ma.addemar.com/c32/e0/hc4ec6/index.html#a1
http://newsroom.gehealthcare.com/ge-healthcare-joins-industry-hospital-leaders-in-patient-safety-commitment/

Simplifying anaesthesia daily tasks
Easy to use. Easy to learn.

Intuitive screen navigation

15” touch controls

Fast and responsive
Flat menus, drop down lists
Multiple pathways to access menus

Quick vent modes set up (<3 s)

Contextual menus
Procedures, Alarms

Fully flexible layouts and configurations
Patient/User profiles , Spirometry,
ecoFLOW* Display Option etc..

Customized for specific procedures

Intuitive and fast access to essential OR tasks

*available on Carestation 650 or 650c

Unified User Interfaces

Carestation 600 Series features a **unified** user interface for **ventilator and CARESCAPE™ patient monitors** to flatten and simplify the learning curve

Consistent:

- ✓ Flat menus structures
- ✓ Highly configurable user/patient profiles
- ✓ Similar contextual menus to quickly address OR tasks

Flattening the learning curve to ensure effective reaction to non ordinary events

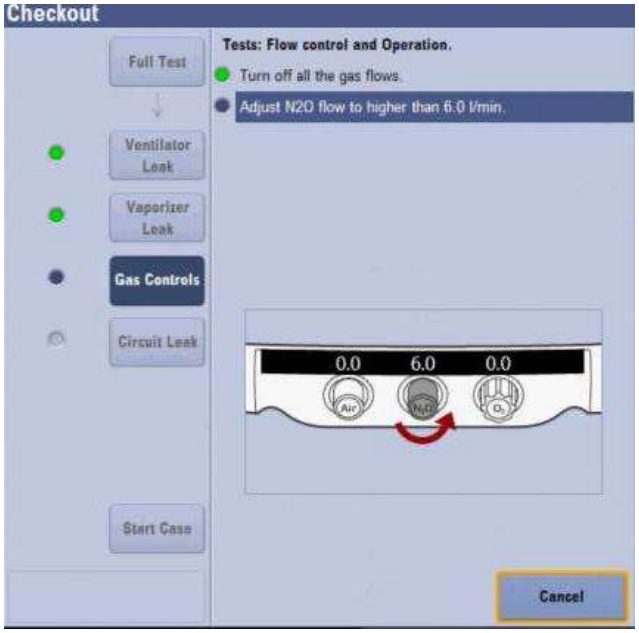
Primary controls within a reach

Tactile controls are comfortably within reach
to speed up operations and help eliminate stretching and awkward positions.

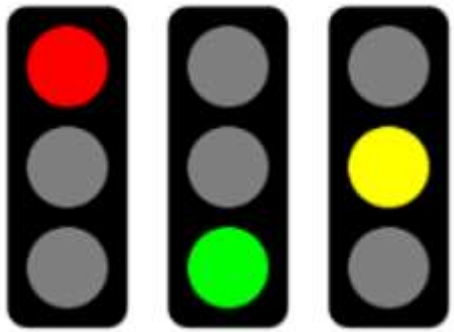
APL valve Manual/Auto switch front located for repetitive and fast machine interactions. Optimized ergonomics of ACGO, Auxiliary O2, O2 flush.

Rotating and tilting display arm for enhanced visualization in every working space and light conditions.

Fast, Interactive system check



- Fast => less than 3 minutes with final report
- Assistance with clear images and color coded icons
- Comprehensive test for operational confidence (Vent leaks , Vap leaks, Circuit leaks, Gas controls)
- Personalized (up to 4 four check steps can be customized by site to match clinical workflow)



Breathing circuit: quick disassembly & cleaning

Step 1: remove CO2 absorber

Step 2: unlatch breathing circuit

Step 3: remove breathing circuit

- Designed to facilitate rapid removal and assembly – tools free
- Built in humidity collector (Condenser)
- Built in CO2 absorber bypass (EZ- Change)
- Autoclavable highly durable flow sensors
- Humidity free flow sensors
- Minimal n° of components
- Easy to manage cleaning cassette
- Comprehensive cleaning quick guides

JB30399XE Not approved in all markets. Not cleared or approved by the US FDA. Not for sale in the United States. Carestation 620/650/650c (A1)

Intelligent tools to give more confidence in daily work.

- Intelligent illuminated controls
- Clear Active case/Standby notification
- Exceptional alarm management
- Pause gas flow*
- Electronic scavenging detector
- ACGO smart control

Smart

JB30399XE Not approved in all markets. Not cleared or approved by the US FDA. Not for sale in the United States. Carestation 620/650/650c (A1)

*available on Carestation 650 or 650c

Intelligent guidance to help prevent faults

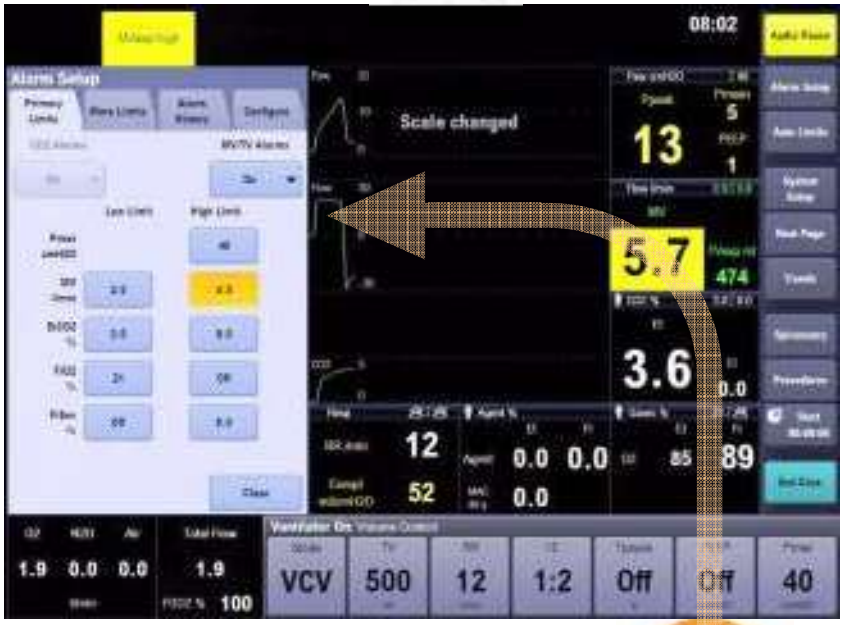
Case notifications

- Clear Standby notification reinforcing machine status
- Automatic case activation when switch is moved to ventilation mode

Illuminated guidance

- Lights turn on automatically on the active flow controls guiding the user - machine interaction
- Visible reinforcement on the ventilation screen to highlight flow status whenever auxiliary ports are in use

Easy Alarm Management



Auto alarm limits*

To help reduce clinician alarm fatigue and avoid false alarms during mechanical ventilation,

Auto Alarm Limits software automatically manages upper and lower limit alarms for EtCO2 , MV, TV in real time on a case-by-case basis for tailored patient care

*available on Carestation 650 or 650c

TUNNELING ALARMS

One-touch alarm response

Menu opens and highlights parameter causing alarm. Change with a simple twist and click of comwheel

Priority Limits Tab

Selection of top 4 parameters grouped into a specific tab to facilitate the adjustment of their low/high limits

Pause Gas Procedure*

Advancing the temporary circuit disconnects maneuver.

One button temporarily stops all gas flows and suspends alarms, agent delivery and ventilation so you can:

- Place all your focus on the patient by minimizing user-machine interactions
- Protecting medical staff from hazard agent delivery
- Helping to preserve patient gas mixture and minimize gas mixture dilution

"Flow Paused" indication and countdown time clearly displayed on screen. Press "restart" or tap screen to resume.

Scavenging detector

Avoiding possible and unwanted exposure to scavenged flow thanks to an alarm that will be triggered when the scavenging flow will be out of range**

*available on Carestation 650 or 650c

**only available with active scavenging systems

Smart ACGO to help prevent faults and misconnects

- ACGO has a cover. When ACGO is active the cover cannot be closed. Indicator that the auxiliary port is in use. Once ACGO switch is turned on a light will indicate the active flow port
- Visible reinforcement that ACGO is active is provided on the ventilation screen to highlight flow status whenever ACGO port is in use
- When the AGCO is disabled the cover will be closed preventing possible misconnection of the patient circuit

Optimizing your workspace with modern design

The right fit for any OR

Convenient mobility

Adaptable to your needs

High quality look & feel

agile

The right fit for any OR

Carestation 650c Pendant

Carestation 650c Wall Mount

Carestation 650 Trolley

- Carestation 600 series can flex up or down to suit the needs of any environment
- Pendant and Wall mount solutions have a modern transport equipment to facilitate serviceability and repositioning

Convenient Mobility

Compact and light weight

Central Brake*

Caster Guards*

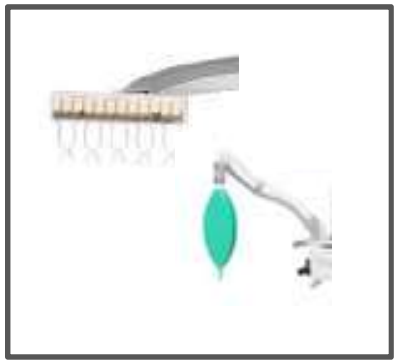
- Compact design and several supporting handles for a smooth transport
- Central brake to quickly secure machine positioning
- In built cable pusher/caster guards to protect patient cables during machine repositioning

* Available on Carestation 650

Enriched by details to better serve your needs

Flexible Monitor Mounting*

Handles and supports*



Cable/circuit management arms

Metal work surfaces*

CARESCAPE respiratory module

Flip desk

Cabinet Design*

3rd cylinder option

Disposable or reusable canister

Premium built **look and feel**.
Delivering on
- ✓ Quality
- ✓ Reliability

JB30399XE Not approved in all markets. Not cleared or approved by the US FDA. Not for sale in the United States. Carestation 620/650/650c (A1)

* Available on Carestation 650 and 650c

Carestation 600 Series

Reliability

Dependable performance. Uptime confidence.

17,000,000+ SOFTWARE ACTIONS STRESS TEST

EQUAL TO: **~2,900 years** of 8 cases/day

1,000,000,000+ FLOW VALVE CYCLES

EQUAL TO: **~30+ years** (if cycled 1/sec)

STABILITY AND TIP TESTING UNDER HARSH CONDITIONS

WEIGHT TEST EQUAL TO: **~2 Orca Whales** ~17k lbs/7900 kg to failure

220,000+ HARDWARE & SOFTWARE REBOOT CYCLES

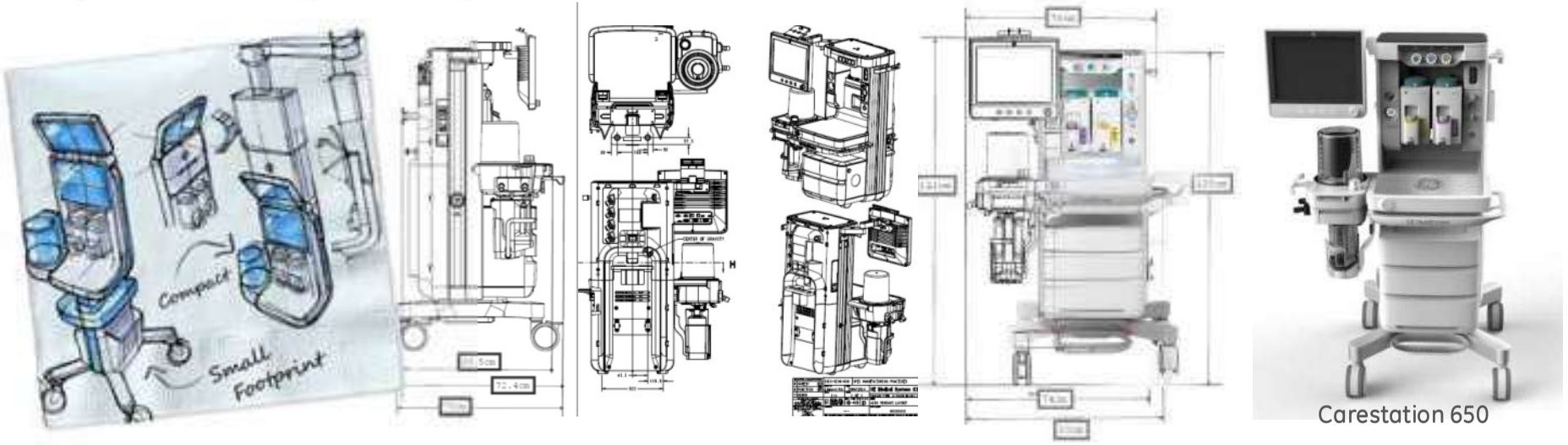
EQUAL TO: **~600 years** of daily reboots

19,000 hours of reliability and endurance testing – equal to over 450,000 simulated cases.

GE internal verification and validation report 2015 (DOC1677887)

Designing a Carestation for today's challenges

Engineered for dependability. Designed to delight.



Carestation 650

Based on input from customers, we invited the GE Global Design team to help us reimagine the anesthesia system to tackle today's challenges. They delivered on this and so much more with a design that will write the next chapter in GE's already iconic 100 year history of anesthesia innovation. Carestation 600 series marries elegant and functional design with digital technologies that anticipate future user demands — instilling confidence in an uncertain and evolving healthcare environment.

GE OFFERS A GLOBAL NETWORK OF PERIOP EXPERTISE

★★★★★
Award winning design expertise from GE Global Design Group†

Ventilation expertise GE/Datex-Ohmeda is known for

Patient Monitoring and Parameter Expertise

†GE Healthcare Global design team has won over 10 Design awards from the International Design Excellence Award (IDEA)

Advanced Software Options

ecoFLOW*
Low Flow, High Impact

Decision support tool helping to mitigate the risk of hypoxic delivery and avoid excess Fresh Gas Flow (FGF) delivery.

Patient
Helps your patient care by continuously monitoring the precise flow rates required to maintain target inspired oxygen concentrations

Economical
Anaesthetic agents are the biggest ongoing expense associated with anaesthesia units. The ecoFLOW option offers cost savings through more efficient utilization of inhaled anaesthetics

Ecological
By choosing a low flow practice, the environmental impact of anaesthetic vapours and gases can be minimized to help reduce the impact of these greenhouse gases

JB30399XE Not approved in all markets. Not cleared or approved by the US FDA. Not for sale in the United States. Carestation 620/650/650c (A1)

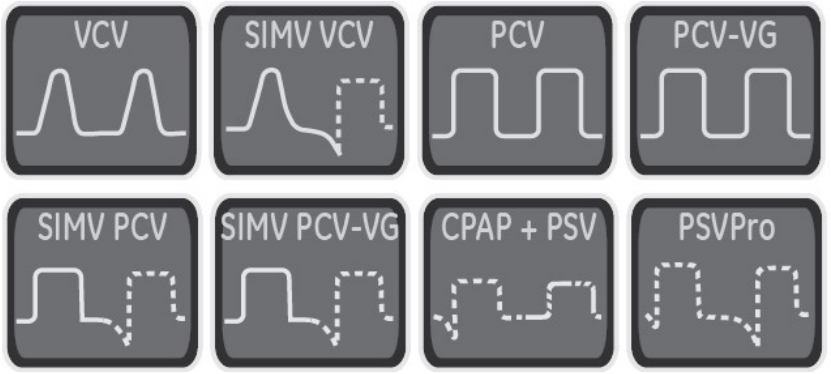
* Available on Carestation 650 and 650c

Lung Protection
Advanced ventilation & automated maneuvers

Vital Capacity Procedure*: Automated bag "squeeze and hold" procedure

Cycling Procedure*: Programmable steps for increasing and decreasing PEEP levels

- Compliance Measurement
- Trending
- Spirometry
- Full set of Ventilation modes
- From neonates to adult



JB30399XE Not approved in all markets. Not cleared or approved by the US FDA. Not for sale in the United States. Carestation 620/650/650c (A1)

* Available on Carestation 650 and 650c

Disclaimer

Data subject to change.
Marketing Communications GE Medical Systems
Société en Commandite Simple au capital de 85.418.040 euros
283, rue de la Minière, 78533 Buc Cedex France
RCS Versailles B 315 013 359

JB30399XE Not approved in all markets. Not cleared or approved by the US FDA. Not for sale in the United States. Carestation 620/650/650c (A1)

ATTESTATION / *CERTIFICATE* **N° 7550 rev. 22**
Délivrée à Paris le 17 mai 2021
Issued in Paris on May 17th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité */ Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 DIRECTIVE 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Catégorie du(des) dispositif(s) */ Device(s) category*

Equipements de cardiologie et systèmes de surveillance de patients
Systèmes de surveillance clinique et systèmes de télémétrie médicale
Baie de cathétérisme et/ou d'électrophysiologie
Moniteurs cardiaques et leurs accessoires
Moniteurs de surveillance patient
Systèmes d'électrocardiographie et de surveillance de patients

Cardiology equipment and patient monitoring systems
Clinical Monitoring Systems and Medical Telemetry Systems
Catheterization and/or Electrophysiology lab System
Cardiology monitors and accessories
Patient monitors
Electrocardiographs and patient monitoring systems

Voir document complémentaire GMED */ See GMED additional document*
n° 38313

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P602818, P601202, le système d'assurance qualité – pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P602818, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification.

Début de validité / *Effective date :* **June 8th, 2021 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

GMED_b2p3_new2020-V0-04-

GMED – 7550 rev. 22
Renouvelle le certificat 7550-21

Ce document complémentaire GMED n° 38313 rev. 1 atteste de la validité du certificat CE N° 7550 rev. 22 au regard des informations listées ci-dessous.

This GMED additional document n° 38313 rev. 1 attests to the validity of EC certificate N° 7550 rev. 22 with regard to the information listed below.

Fabricant / *Manufacturer:*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Patient monitor, Central unit	**Central Station (CSCS)**	**IIb**
Patient monitor module, multiparameter	**Patient Data Module (PDM)**	**IIb**
Patient monitor, multiparameter	**B20**	**IIb**
Patient monitor, multiparameter	**B40**	**IIb**
Patient Monitor, multiparameter	**B105**	**IIb**
Patient Monitor, multiparameter	**B125**	**IIb**
Patient Monitor, multiparameter	**CARESCAPE ONE**	**IIb**
Transportable physiologic monitoring system	**V100**	**IIb**
Telemetry system, electrocardiograph	**ApexPro Telemetry System**	**IIb**
Clinical monitoring systems	**Unity Network ID**	**IIb**
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	**MacLab**	**IIb**
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	**CardioLab**	**IIb**
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	**ComboLab**	**IIb**

GMED 0459

GMED - 38313 rev. 1
Renouvelle le document n° 38313 rev. 0

GMED SAS GMED SAS

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Electrocardiograph, Holter analyzer	**Mars**	**IIa**
Electrocardiograph, Holter analyzer	**Mars SP4**	**IIa**
Information system software, application program, cardiology	**MUSE – SW Only**	**IIa**
Information system software, application program, cardiology	**CV Web**	**IIa**
ECG Acquisition module	**CAM 14V2**	**IIa**
ECG Acquisition module	**CAM HD**	**IIa**
Interpretive multichannel electrocardiograph	**MAC 2000**	**IIa**
Interpretive multichannel electrocardiograph	**MAC 600**	**IIa**
Interpretive multichannel electrocardiograph	**MAC VU360**	**IIa**
Stress exercise monitoring system, cardiac	**Case**	**IIa**
Stress exercise monitoring system, cardiac	**Cardiosoft / CS**	**IIa**
Stress exercise monitoring system, cardiac	**Cardiosoft / CS WIN8**	**IIa**
Electrocardiograph, Electrodes	**KISS**	**IIa**

Site couvert et Activités / *Location and Activities*

Site / *Location*	**Activités** / *Activities*
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC **8200 WEST TOWER AVENUE** **MILWAUKEE, WISCONSIN 53223 - USA**	**Siège social – responsable de la mise sur le marché** **Conception, fabrication et contrôle final** *Headquarters – legal manufacturer* *Design, manufacture and final control*

GMED | **0459**

GMED - 38313 rev. 1
Renouvelle le document n° 38313 rev. 0

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC, Annex II
and of the directive 2011/65/EU

We

Manufacturer
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
PO Box 7550
Madison, WI 53707-7550 USA

EU Authorized Representative
GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France

Declare under our sole responsibility that the device:

Tec 820, Tec 850

Ref: 1177-9820-ISO, 1177-9820-SEV, 1177-9850-ISO, 1177-9850-SEV

GMDN Code: Isoflurane vaporizer - 36890; Sevoflurane vaporizer - 36980

GMDN Description: A device used to vaporize the anaesthetic agent isoflurane or sevoflurane and deliver a controlled amount of the agent to a patient being prepared for surgery. The device is usually mounted to an anaesthesia system or ventilator.

UDI-DI (GTIN) code: 1177-9820-ISO: 00840682124744; 1177-9820-SEV: 00840682124720; 1177-9850-ISO: 00840682124751; 1177-9850-SEV: 00840682124737

Classification rule (93/42/EEC Annex IX): 11 Class IIb

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
  - Technical Documentation/DHF Ref./ réf: DOC2019683, of the product to which this declaration relates
  - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431, Neuremberg, Germany, Notified Body #0197, Certificate N° HD 60109676 0001, valid until 19 April 2021
  - harmonized standards applied on the product to which this declaration relates
- For the directive 2011/65/EU (RoHS)
  - Technical Documentation/DHF Ref./ réf: DOC1977840 and DOC1979675, of the product to which this declaration relates

Monica Morrison
Regulatory Affairs Director

22 AUG 2017
Madison, WI USA

This EC declaration of conformity is the first issue.

Tec 820/850 Vaporizer

Technical Reference Manual

Table of Contents

1 Introduction

In this section

1.1 General information

1.1.1 Technical competence

The procedures described in this Technical Reference Manual should be performed by trained and authorized personnel only. Maintenance should only be undertaken by a competent, trained individual having experience in the repair of devices of this nature. No repairs should ever be undertaken or attempted by anyone not having such qualifications.

Replace damaged parts with components manufactured or sold by GE Healthcare. Then test the unit to ascertain that it complies with the manufacturer’s published specifications.

Read completely through each step in every procedure before starting the procedure; any exceptions may result in a failure to properly and safely complete the attempted procedure.

1.1.2 Important

The information contained in this Technical Reference Manual pertains only to those models of products which are marketed by GE Healthcare as of the effective date of this manual or the latest revision thereof. This Technical Reference Manual was prepared for exclusive use by GE Healthcare service personnel in light of their training and experience as well as the availability to them of parts, proper tools and test equipment. Consequently, GE Healthcare provides this Technical Reference Manual to its customers purely as a business convenience and for the customer's general information only without warranty of the results with respect to any application of such information. Furthermore, because of the wide variety of circumstances under which maintenance and repair activities may be performed and the unique nature of each individual's own experience, capacity, and qualifications, the fact that customer has received such information from GE Healthcare does not imply in any way that GE Healthcare deems said individual to be qualified to perform any such maintenance or repair service. Moreover, it should not be assumed that every acceptable test and safety procedure or method, precaution, tool, equipment or device is referred to within, or that abnormal or unusual circumstances, may not warrant or suggest different or additional procedures or requirements.

This manual is subject to periodic review, update and revision. Customers are cautioned to obtain and consult the latest revision before undertaking any service of the equipment.

Note This manual provides essential information for service, for more details on safe operation, transport, temperature, storage, barometric pressure and other specifications, please refer to the User's Reference Manual of this device.

Note Servicing of this product in accordance with this Technical Reference Manual should never be undertaken in the absence of proper tools, test equipment

and the most recent revision to this service manual which is clearly and thoroughly understood.

Note Servicing and/or Repair procedures for this Product must be performed by personnel trained and authorized by manufacturer.

WARNING Do not modify this equipment without authorization from the manufacturer. Unauthorized modifications could result in damage to the equipment and/or cause patient injury.

If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

WARNING

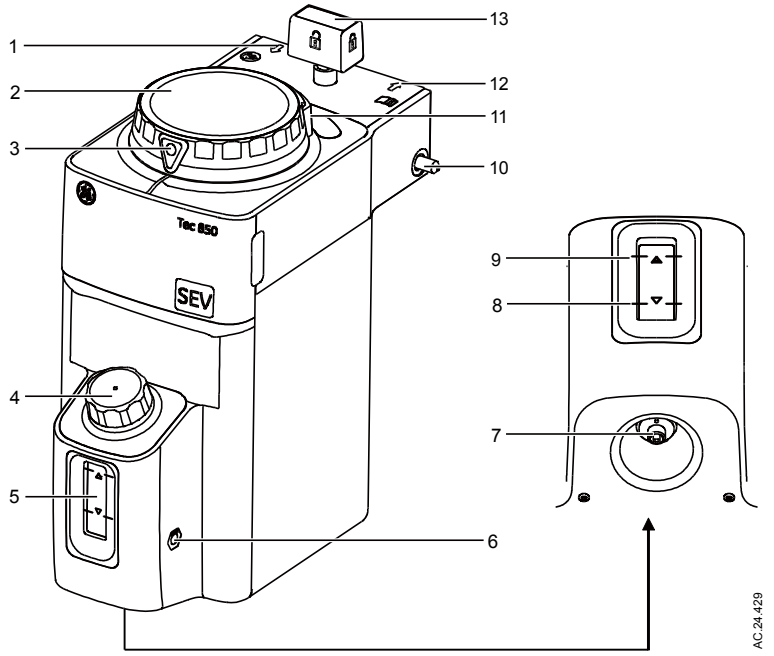
- Use this equipment only with the specified nonflammable anesthetic agents.
- Do not use lubricants that contain oil or grease. They may burn or explode in high O2 concentrations.
- Do not tilt the vaporizer. If the vaporizer has been tilted or inverted, incorrect agent output may occur.
- National Institute for Occupational Safety and Health (NIOSH) or equivalent recommendations for air exchange should be considered in any use environment.

1.2 Introduction

The Tec 820/850 vaporizer is designed for use in continuous flow techniques of inhalation anesthesia. Each vaporizer is agent specific and is clearly labeled for the intended agent.
The vaporizer is temperature, flow and pressure compensated so that its output remains relatively stable despite cooling due to evaporation, variations at inlet flow and fluctuating pressures. The vaporizer is designed to be used on Selectatec manifolds but the interlock system is designed to function on Selectatec Series Mounted Manifolds only.
Refer to the User's Reference Manual of the vaporizer for instruction on the handling, transportation, storage, mounting and operating procedures.

1.2.1 Elements of the vaporizer

Be familiar with the elements of the vaporizer before reading instructions in the subsequent sections of this manual.



1. Gas inlet into vaporizer
2. Control dial
3. Off mark
4. Filler cap (filling port under filler cap)
5. Agent level indicator
6. Drain plug
7. Drain nozzle
8. Minimum level line
9. Maximum level line
10. Interlock pin
11. Release button
12. Gas outlet out of vaporizer
13. Locking lever

Figure 1-1 • Vaporizer elements

1.3 Symbols used on the equipment

Symbols replace words on the equipment or in product manuals.

Warnings and cautions tell you about dangerous conditions that can occur if you do not follow all instructions in this manual.

Warnings tell about a condition that can cause injury to the operator or the patient.

Cautions tell about a condition that can cause damage to the equipment.

Read and follow all warnings and cautions.

1.3.1 Symbols associated with standards

Symbol	Title	Standard reference number	Description
	Locking, general	IEC 60417-5569	IEC 60417: Graphical symbols for use on equipment
	Unlocking	IEC 60417-5570	IEC 60417: Graphical symbols for use on equipment
	"OFF" (power)	IEC 60417-5008	IEC 60417: Graphical symbols for use on equipment
	Serial number	ISO 700-2498	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Catalog number	ISO 7000-2493	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Refer to instruction manual/booklet (blue background)	ISO 7010-M002	ISO 7010: Graphical symbols - Safety colors and safety signs - Registered safety signs
	Operating instructions	ISO 7010-1641	ISO 7000: Graphical symbols for use on equipment - Registered symbols

	MR conditional	ASTM F2503 Clause 7.3.2	ASTM F2503: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
	Manufacturer	ISO 7000-3082	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Date of manufacture	ISO 7000-2497	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Keep dry	ISO 7000-0626	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Humidity limitation	ISO 7000-2620	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Temperature limit	ISO 7000-0632	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Fragile, handle with care	ISO 7000-0621	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Protect from heat and radioactive sources	ISO 7000-0615	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	General symbol for recovery/recyclable	ISO 7000-1135	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Atmospheric pressure limitation	ISO 7000-2621	ISO 7000: Graphical symbols for use on equipment - Registered symbols
	Authorized representative in the European Community	ISO 15223-1 5.1.2	ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1:General requirements

1.3.2 Symbols not associated with standards

	Gas inlet into vaporizer		Gas outlet out of vaporizer
	Maximum line		Minimum line
	Graphical representation to identify objects with evaluated conformity within SBAC.		GOST R Russian certification
	Caution: federal law prohibits dispensing without prescription		Unique device identifier
	Ukraine national conformity		Eurasian conformity
	CE conformity mark Systems with this mark agree with the European Council Directive (93/42/EEC) for Medical Devices when they are used as specified in their User's Reference manuals. The xxxx is the certification number of the Notified Body used by Datex-Ohmeda's Quality Systems.		

1.4 Abbreviations

Abbreviations	Definition
CO2	Carbon dioxide
ISO	Isoflurane
O2	Oxygen
SEV	Sevoflurane
FRU	Field Replaceable Unit
RH	Relative humidity
SBAC	Brazilian System on Conformity Assessment

2 Theory of Operation

In this section

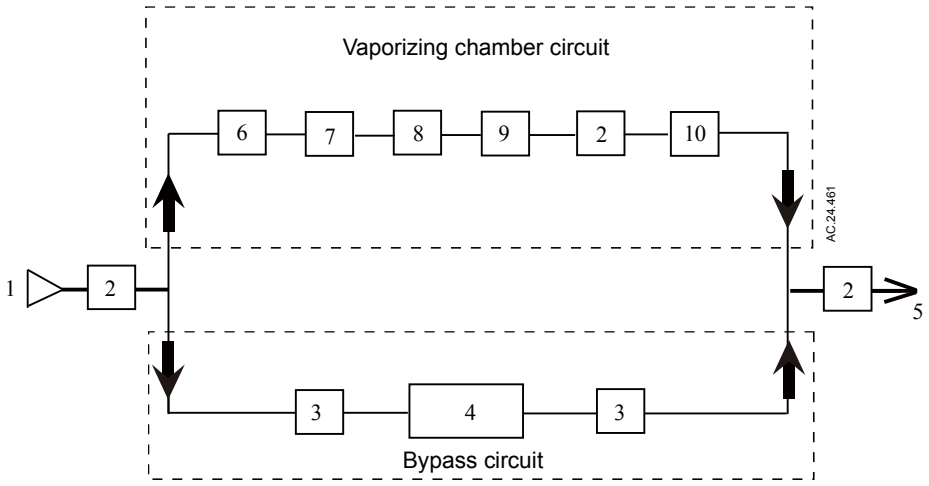
2.1 Delivery of gas/agent vapor

2.1.1 Overview

The output concentration of the Tec 820/850 vaporizer is regulated by the "variable flow-split" method described in the following text and shown in the figures (Figure 2-1 and Figure 2-2).

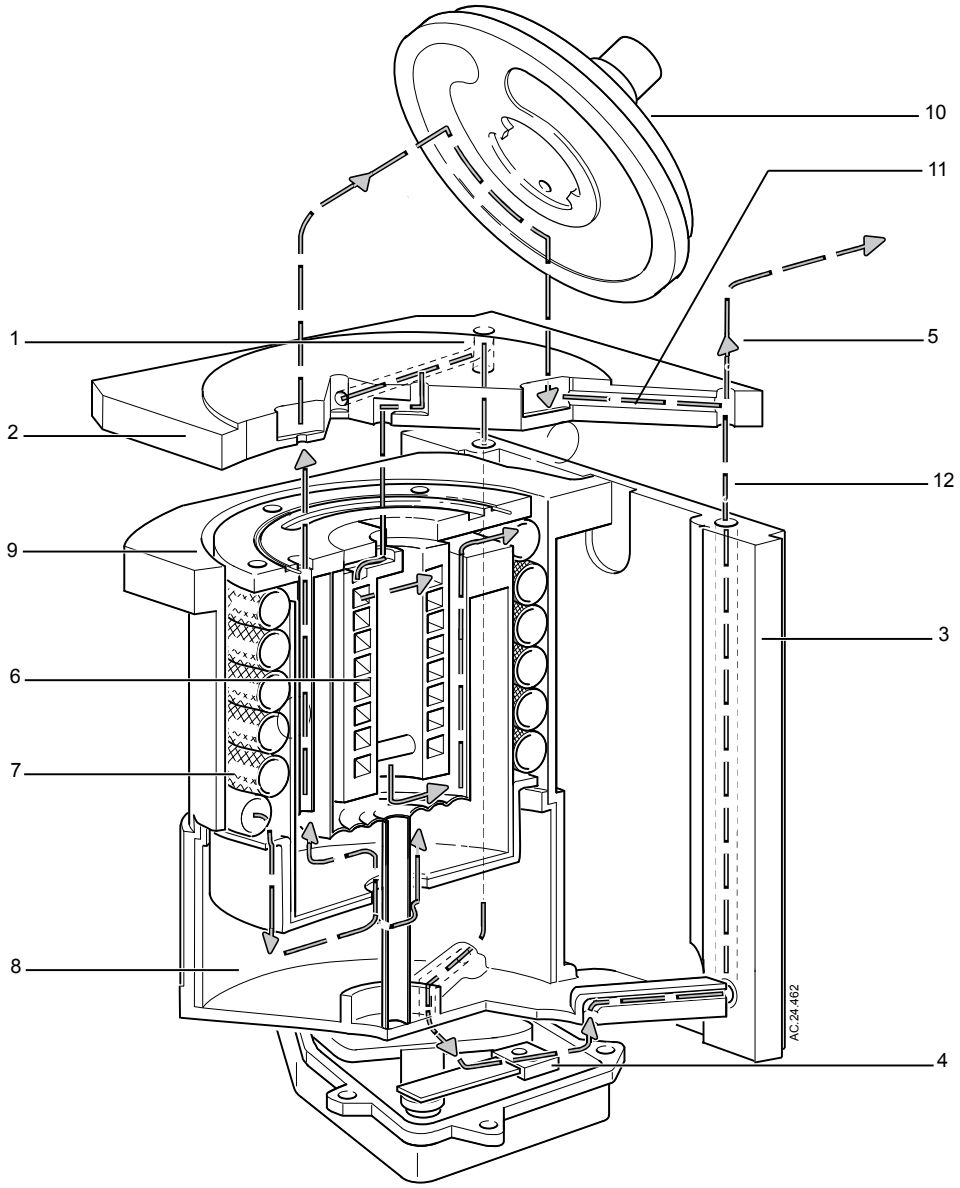
A total flow of fresh gas from upstream enters the vaporizer where it is split into two streams. One stream flows into the fresh gas bypass circuit and the other stream flows through the vaporizing chamber where it is saturated with the vapor of the liquid anesthetic agent.

Both gas paths have methods to regulate the flow to achieve desired total output agent concentration. Before exiting the vaporizer through the gas outlet, the split gas streams are joined. The combined total flow then flows out from the vaporizer via the Selectatec circuitry to the anesthesia gas delivery system.



1. Vaporizer gas inlet
2. Sump cover
3. Gas transfer manifold
4. Thermostat
5. Vaporizer gas outlet
6. IPPV (Intermittent Positive Pressure Ventilation) compensating assembly
7. Wick assembly
8. Vaporizing chamber
9. Sump assembly
10. Rotary valve assembly

Figure 2-1 • Circuit overview diagram



1. Vaporizer gas inlet
2. Sump cover
3. Gas transfer manifold
4. Thermostat Fresh gas bypass
5. Combined fresh gas and saturated gas out
6. IPPV compensating assembly
7. Wick assembly
8. Vaporizing chamber
9. Sump assembly
10. Rotary valve assembly
11. Saturated fresh gas with anesthetic vapor
12. Fresh gas from bypass circuit

Figure 2-2 • Vaporizer gas flow diagram

2.1.2 Vaporizing chamber circuit

Refer to Figure 2-1 and Figure 2-2 in "*2.1.1 Overview*".

The fresh gas flow through the vaporizing chamber (8) flows across the sump cover (2) where it is diverted through the central cavity of the rotary valve assembly (10) and back through the Intermittent Positive Pressure Ventilation (IPPV) compensating assembly (6).

Gas flows from the IPPV assembly down through the tubular wick assembly (7) where it picks up anesthetic vapor and then flows across the base of the vaporizing chamber above the liquid agent.

From the base of the vaporizing chamber the gas mixture flows through the sump cover to the curved vapor control channel of the rotary valve assembly (10) and then back into the sump cover (2) where it combines with the fresh gas from the bypass circuit.

The combined total flow then flows out (5) from the vaporizer to the anesthesia breathing system.

2.1.3 Bypass circuit

Refer to Figure 2-1 and Figure 2-2.

The bypass circuit includes the gas transfer manifold (3) with restrictor and a thermostat assembly (4) that is located at the base of the vaporizer.

The fresh gas flows through the bypass circuit vertically downwards across the sump base through the thermostat and back up the gas transfer manifold to the common gas outlet. Before reaching the thermostat, the fresh gas flows through a restrictor integrated in the gas transfer manifold to decrease the turbulence effect.

The bimetallic strip inside the thermostat deflects according to its temperature to control the resistance offered to the flow of gas through it. This deflection changes the relative proportions of gas flowing through the bypass and vaporizing chamber circuits.

2.2 Main functional components

2.2.1 Interlock mechanism

The vaporizer contains an interlock system which should make sure that:

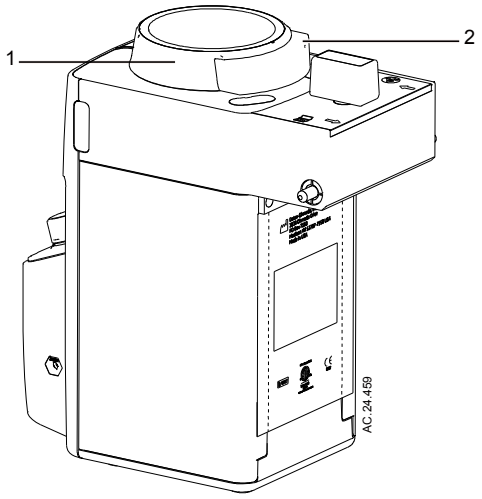
- The vaporizer is locked onto the manifold before the dial can be turned on.
- Only one vaporizer at a time can be turned on.
- The gas flow enters only the vaporizer that is turned on.
- Any unwanted trace vapor is minimized once the vaporizer is turned off.

When a locked vaporizer is turned on, the rods of the locked vaporizer extend from the sides, preventing the adjacent vaporizer from being turned on at the same time.

2.2.2 Control Dial

The Control Dial (1) with a concentration scale calibrated in % of anesthetic agent vapor per total volume (% V/V) is used to set the desired concentration of the anesthetic agent.

A Dial Release (2) is incorporated in the dial assembly to prevent accidental displacement of the Control Dial from the off position. To select a setting, it is necessary to depress the Dial Release and simultaneously rotate the Control Dial counter-clockwise.

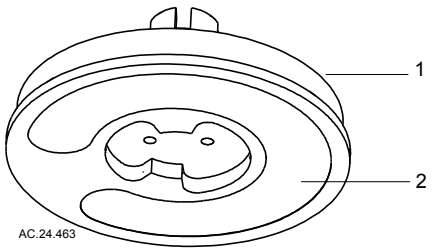


The vaporizer must be locked onto the manifold before turning the Control Dial on. Fresh gas does not flow through the vaporizer until the vaporizer is turned on.

2.2.3 Rotary valve assembly

Flow through the vaporizing chamber is determined by the position of the rotary valve assembly (1) which has a curved vapor control channel (2) machined on its surface. Depth of the curved vapor control channel is gradually changed from one side to the other side. Depth of the channel at certain position determines the orifice size for gas flow from vaporizer chamber.

The rotary valve assembly is actuated by turning the Control Dial.

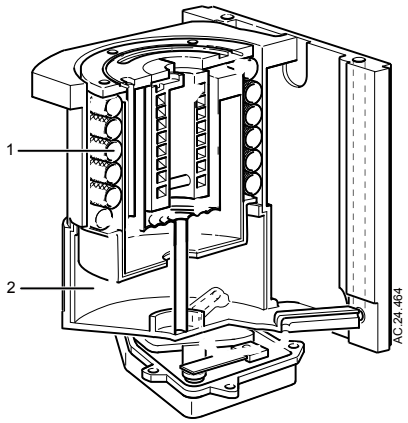


2.2.4 Sump assembly

The sump assembly comprises a vaporizing chamber (1) which stores the liquid anesthetic and also acts as an evaporator for the stored anesthetic.

It is designed to saturate the gas entering the sump with anesthetic agent vapor.

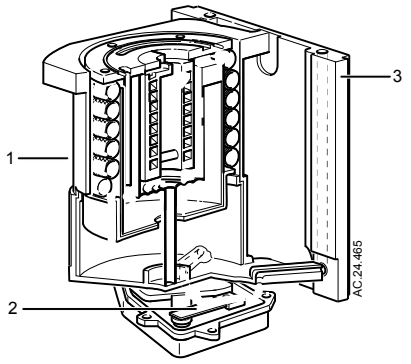
Full saturation of the gas flowing through the vaporization chamber is achieved by passing the gas stream over a large surface area of the wick (2). A wick skirt extends from the top of spiral wick (2) to the bottom of the vaporizing chamber (1). The bottom part of the wick skirt is soaked in liquid anesthetic agent and maintains steady evaporation of agent in the wick.



2.2.5 Thermostat and gas transfer manifold

The thermostat (2) is located under sump assembly (1). As liquid agent evaporates, the temperature in the sump drops. Ambient temperature changes also impact the temperature inside the sump. The bimetallic strip thermostat responds to these changes in temperature and adjusts the split between bypass flow and vaporizing chamber flow, maintaining a steady agent output.

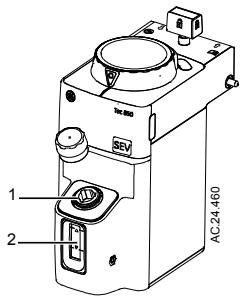
The gas transfer manifold (3) provides the gas transfer channel for the fresh gas flowing through the thermostat. A restrictor integrated in the gas transfer manifold regulates the gas flow before reaching the thermostat.



2.2.6 Filling the vaporizer

The filling port (1) provides an interface between the external agent container and the internal parts of the vaporizer. Different filling ports have different keying and sealing features, designed to prevent users from accidentally filling the sump from an incorrect container. The filling port is mounted on the filler body which in turn is mounted on the sump. A cap protects the system when it is not being filled. The cap should be attached and tightened at all times. The anesthetic agent level can be observed through the agent level indicator (2).

Refer to User's Reference Manual for detailed information about the filling adapters and operation steps.



3 Checkout Procedures

In this section

3.1 Visual inspection procedures

3.1.1 Physical cosmetic defects check

1. Inspect the surfaces of the vaporizer, verify there are no physical defects, including signs of damage or abuse such as cracks and dents.
2. Verify that there are no cosmetic defects including illegible Control Dial markings, missing, illegible, or incorrect required labels.

   If the unit requires cosmetic repair, refer to Section 6.2 for available service parts.

CAUTION Do not attempt to use a vaporizer that has been dropped until appropriate testing of the device is done to ensure it is working to specification. See User's Reference Manual for maintenance instructions. If used without proper testing, the device may perform erratically and patient injury may occur or the user may be exposed to anesthetic agent by a leak.

3.1.2 Serial number / Dial visual inspection

1. Verify the serial number is present on both the product label on the back of the unit and on the dial. Make sure both serial numbers match and are legible.
2. If the serial numbers are not legible or the two serial numbers do not match, stop using the vaporizer.

3.2 Low pressure leak test

This manual only describes the common procedures of the vaporizer negative low pressure leak test; some test procedure could vary on different anesthesia machines. For more details on this test, please refer to the Technical Reference Manual of the anesthesia machine on which this vaporizer is installed.

The leak test can be completed either as a system test following the anesthesia machine checkout procedure or using a squeeze bulb as described below.

1. Test the leak test device.

   - Place your thumb on the inlet of the leak test device. Push hard for a good seal.
   - Squeeze the bulb to remove all air from the bulb.
   - If the bulb completely inflates in less than 60 seconds, replace the leak test device.

2. Place the vaporizer on the anesthesia machine; depress the locking lever and turn clockwise to lock the vaporizer onto the manifold.
3. Refer to the anesthesia machine Technical Reference Manual and perform below steps:

   - Connect the test device to the anesthesia machine.
   - Test the anesthesia machine for low pressure leaks (with all vaporizers turned off) and verify the anesthesia machine passes the low pressure leak test.

4. Test the vaporizer for low pressure leaks:

   - Depress the Dial Release and turn the Control Dial to 1%.
   - Turn all flow controls fully clockwise (closed). Do not over tighten.
   - Squeeze the bulb repeatedly until it is empty.
   - If the bulb completely inflates in 30 seconds or less, there is a leak in the vaporizer.
   - Repeat the test for concentration settings 3%, 5%, and 8% (if applicable).

5. Remove the test device from the machine.

WARNING Agent mixtures from the low-pressure leak test stay in the system. Always flush the system with O2 after the low pressure leak test (1 l/min for one minute).

Turn off all vaporizers at the end of the low-pressure leak test.

6. Flush the system with O2. Refer to the anesthesia machine Technical Reference Manual for details.
7. If the test fails, refer to General Troubleshooting section for detailed actions.

3.3 Vaporizer back pressure test

1. Mount the vaporizer onto the Selectatec manifold of the anesthesia machine.
2. Lock the vaporizer onto the manifold.
3. Set the O2 flow to 6 l/min.
4. Make sure that the O2 flow stays constant.
5. Depress the vaporizer dial release and slowly adjust the vaporizer concentration from Off to 1%. Pause at each graduation and observe the O2 flow.
6. The O2 flow must not decrease more than 1 l/min through the full range.

   If the O2 flow decreases more than 1 l/min, the vaporizer is malfunctioning.
7. Turn the dial to the Off position.

3.4 Vaporizer efficacy test

1. Mount the vaporizer to the Selectatec manifold of the anesthesia machine.
2. Lock the vaporizer onto the manifold.
3. Set the O2 flow to 5±0.5 l/min.
4. Ensure that the fresh gas output is connected to a gas scavenging system.
5. Ensure that the vaporizer is filled with anesthetic level between the min and max lines.
6. Measure the concentration at the fresh gas outlet using an agent monitor calibrated to measure the specific agent.
7. Turn the Control Dial to each setting listed in below table. Wait and allow the readings to stabilize after each setting.

Isoflurane Vaporizer (5% Dial)						
	Tec 850 Vaporizer		Tec 820 Vaporizer		ISO 8835-4 (for reference)	
Dial Setting (Vol%)	Min Vol%	Max Vol%	Min Vol%	Max Vol%	Min Vol%	Max Vol%
1	0.75	1.25	0.75	1.25	0.75	1.37
3	2.55	3.45	2.40	3.60	2.40	3.90
5	4.25	5.75	4.00	6.00	4.00	6.50

Sevoflurane Vaporizer (8% Dial)						
	Tec 850 Vaporizer		Tec 820 Vaporizer		ISO 8835-4 (for reference)	
Dial Setting (Vol%)	Min Vol%	Max Vol%	Min Vol%	Max Vol%	Min Vol%	Max Vol%
1	0.60	1.40	0.60	1.60	0.60	1.60
3	2.55	3.45	2.40	3.60	2.40	3.90
5	4.25	5.75	4.00	6.00	4.00	6.50
8	6.80	9.20	6.40	9.60	6.40	10.40

8. For each setting, observe the reading on the agent monitor and check whether the vaporizer output is within the specification listed in above table.

Note Take into account measurement accuracy of the agent monitor and environmental effects as described in User's Reference Manual.

4 Troubleshooting

In this section

4.1 General troubleshooting

WARNING Any troubleshooting and service to the vaporizer must be performed by GE Healthcare trained and authorized personnel.

Faults	Possible Cause	Action
Locking lever cannot turn after installing on a manifold	Vaporizer is incorrectly installed on the manifold.	Observe the checklist in the User's Reference Manual for correct installation of the vaporizer.
	Interlock mechanism failure	1. Remove the vaporizer from the manifold. 2. Press and turn the locking lever to verify the mechanism works. If the mechanism does not work when not installed on the manifold, stop use and send the unit to GE Healthcare authorized service center for repair.
Dial Release cannot be depressed	The anesthesia machine manifold Dzus spring fails	If vaporizer is correctly installed and the lock lever mechanism works, the issues is on the anesthesia machine manifold. To confirm this, use another vaporizer slot on the manifold or test the vaporizer on another anesthesia machine. Refer to anesthesia machine service manual for service instructions.
	Vaporizer is not locked on the manifold	Lock the vaporizer on the manifold. A locked symbol on the Lock Lever is facing the user when vaporizer is locked on the manifold.
	Another vaporizer is turned on	Verify that all other vaporizers on the manifold are in OFF position. They can still be locked on the manifold.
	Interlock mechanism failure	1. Remove the unit from the manifold. 2. Press and turn the Lock Lever. 3. Press the Dial Release and observe the interlock pins. If the pins protrude outwards, the mechanism works. Reinstall the vaporizer and attempt again. If the pins do not move or the action does not feel smooth, stop using the unit and send it to GE Healthcare authorized service center for repair.

Faults	Possible Cause	Action
Liquid leaks	Bottle adapter not tightened or has a damaged seal.	Verify that all seals are in place and have not been damaged. Re-tighten the adapter to the agent container. Test another agent container and adapter.
	Drain plug is open	If leak occurs independent of filling, verify the drain plug is tightened.
	Foreign objects in the filler	Verify filler is clear of foreign objects. Use a small tool to remove any foreign objects. Check for leaks before attempting to re-fill.
	Agent level indicator or internal parts damaged	Stop use and send the vaporizer to GE Healthcare authorized service center to repair. Note local regulations for shipping containers with anesthetic agent.
Low pressure leak test fails	Cap is loose	Ensure the cap is tightened to fit snugly (~1 Nm).
	Cap seal damaged	Visually inspect sealing surfaces on cap and filler. Clean if necessary, tighten the cap, and re-do the leak test. Replace the cap according to the instructions in this manual.
	Manifold o-rings damaged	1. Remove the vaporizer from the manifold. 2. Visually inspect the manifold o-rings and replace as necessary. Note: Replacement o-rings are supplied with each new vaporizer and are also available from the manufacturer. 3. Retest.
	Drain plug is not properly tightened.	Verify the drain plug is appropriately tightened.
	Concentration control system leak.	Install the G-flange kit per instructions in this manual.

Faults	Possible Cause	Action
Incorrect agent output	System leaks	Verify the anesthesia system passes leak test.
	Agent measurement system is inaccurate	Calibrate the measurement system and redo the test.
	Agent measurement system is not precise enough	Take into account the accuracy of the measurement equipment used.
	Measurement conditions differ from calibration conditions.	Check that the measurement environment is similar to the calibration environment and effects of variables (in the User's Reference Manual) are appropriately considered.
	Bypass flow temperature compensation system damaged.	Verify the system has no visible signs of dropping or other physical abuse. If the physical appearance is normal and the unit consistently fails efficacy test, stop using the unit.
	Internal control parts damaged or worn	If the unit consistently fails the efficacy test even after accounting for differences in measurement equipment and environment, stop using the unit.

WARNING Liquid anesthetic agent leaks may contaminate the room air with dangerous agent concentrations. Handle units with liquid agent leaks according to the local safety practices.

Depressing the Dial Release when the vaporizer is not locked on a manifold may cause trace concentrations of agent vapor to escape to surrounding room air.

5 Repair Procedures

In this section

5.1 Service procedures

WARNING This manual and all its associated documentation must be studied thoroughly before any attempt is made to set up, operate, maintain or service any part of the Tec 820/850 vaporizer. Failure to do so may result in patient injury.

The vaporizer must only be serviced by technicians fully trained and authorized by GE Healthcare.

Handle the vaporizer with care.

Do not tilt the vaporizer if it contains anesthetic agent.

Do not carry the vaporizer by the control dial. Use two hands to grasp the vaporizer body.

Wear necessary PPE (Personal Protect Equipment) when servicing the vaporizer. Wearing safety shoes is a must to avoid injury in case the vaporizer is dropped.

CAUTION Do not use force to remove the vaporizer from the manifold.

Turn the Vaporizer dial to OFF when it is not in use.

Note If laying the vaporizer on its front or side during service, make sure that the surface will not scratch the vaporizer.

Follow below sequences to perform the service procedures:

1. Drain and dry the vaporizer before starting disassembly if the vaporizer contains anesthetic agent and cannot be kept upright during repair.
2. Remove the vaporizer from the anesthesia machine.
3. Inspect the serial number (SN) information
4. Inspect damage and wear.
5. Replace damaged parts or other parts as necessary.
6. Fill the vaporizer with proper agent.
7. Reinstall the vaporizer to anesthesia machine and perform related checkout procedure to the whole system.

Note Refer to the User's Reference Manual for the filling and installation procedures.

5.1.1 Draining and drying the vaporizer

Anesthetic agent must be drained from the vaporizer before transport or extended storage of the vaporizer. Drain the vaporizer only in a properly ventilated area.

Draining

WARNING Do not drain the agent into any container other than a properly labeled disposal container. The container must be safe to use with liquid anesthetic agents and comply with hospital and local regulations. Do not reuse drained anesthetic agent because of the risk of drug contamination.

1. Remove the vaporizer from the Selectatec manifold and move it to a properly ventilated location.
2. Ensure the control dial is in off position.
3. Remove the cap from the vaporizer filler.
4. Place an empty container under the drain nozzle. To drain a full vaporizer, the container volume should exceed 250 ml. On Quik-Fil™ variants, screw the agent bottle onto the drain nozzle.
5. Use the supplied tool or equivalent 3 mm hex wrench tool to open the drain plug.
6. Drain the vaporizer until empty.
7. Tighten the drain plug.
8. Replace and tighten the filler cap.

Drying

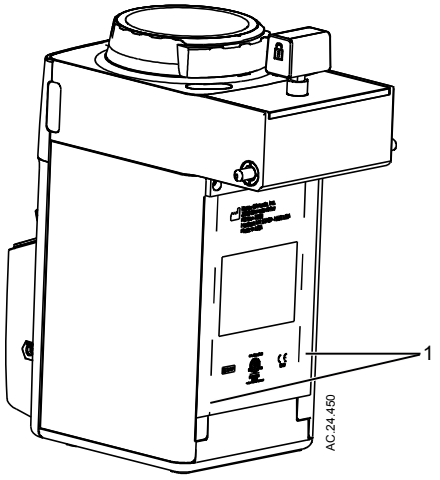
Drained vaporizer can still contain agent in the vaporizer wick. To ensure all agent is removed from the wick, use the following procedure.

1. Mount the vaporizer (not connected to a patient).
2. Turn the vaporizer to the highest setting.
3. Run a high flow of air (for example, 8 l/min) through the vaporizer until an agent monitor reads 0%.

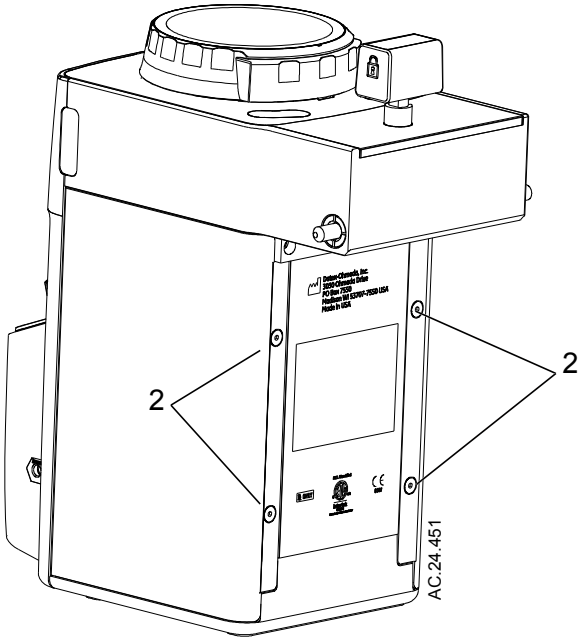
5.2 Replacing the Side Plates

1. Drain the vaporizer. Refer to the User's Reference Manual for the draining procedure.
2. If the two strips (1) are connected with the product label, cut the strips off along the vertical perforated lines.
3. Remove both strips to expose the screws beneath.

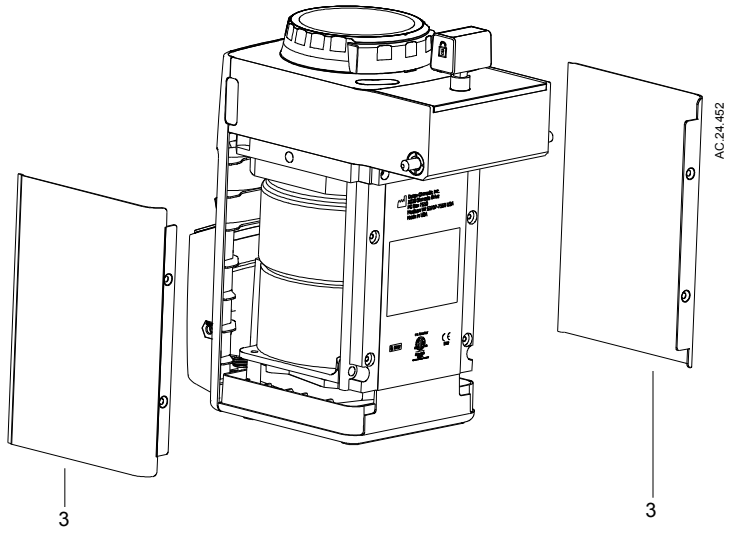
Note Replacement label strips are included in the Side Plate kit.



4. Use T10 Torx driver, remove the four screws (2) that hold the Side Plates to the vaporizer body.



5. Use a screwdriver to pry the Side Plates (3) loose and remove the them (3).

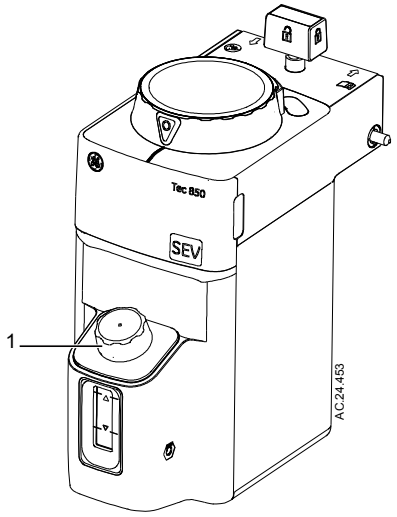


6. Align and insert new Side Plates into the groove of the Front Cover.
7. Re-install the four screws and torque to 0.6 Nm.
8. Affix the labels, included in the Side Plate kit, to the back of the vaporizer to cover the screws.

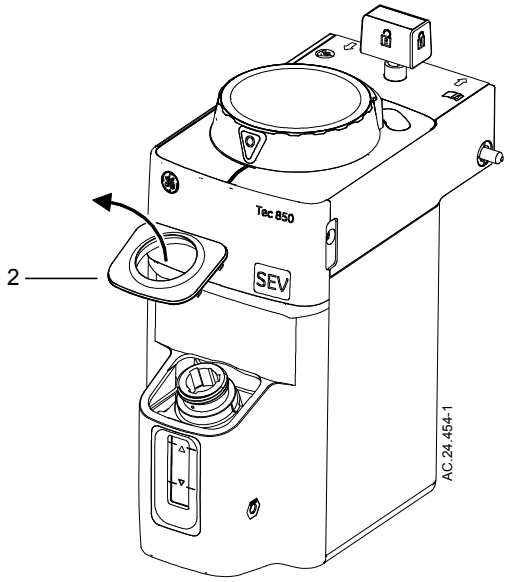
5.3 Replacing the Front Cover

CAUTION There are multiple Front Cover kits available. Before installing the new Front Cover kit, check for the correct agent description before removing the old Front Cover.

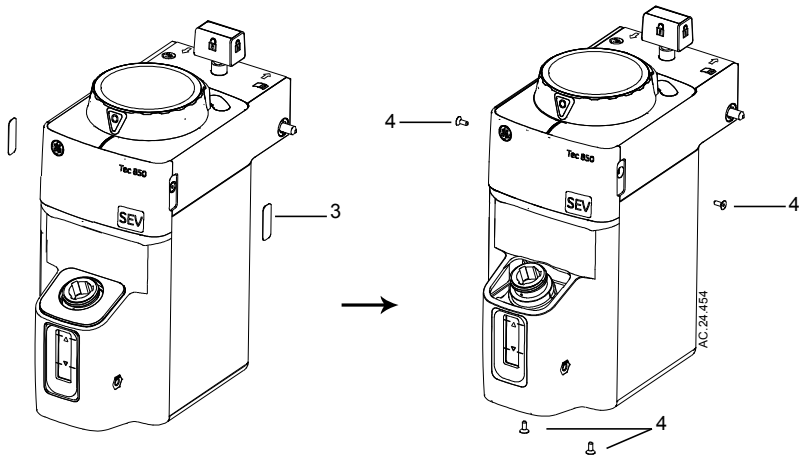
1. Drain the vaporizer. Refer to the User's Reference Manual for the detailed draining procedure.
2. Open the Filler Cap (1) and remove it from the filling port.



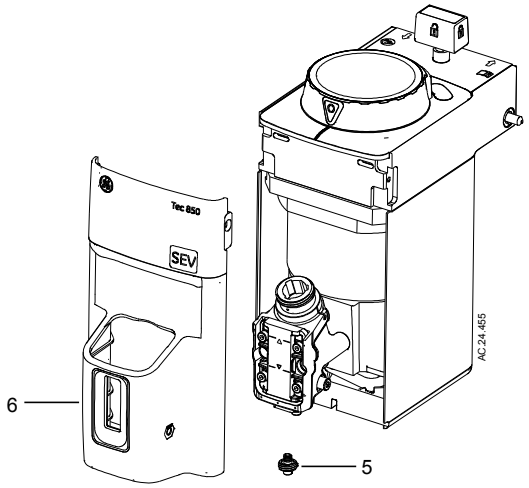
3. Insert a screwdriver between the Snap-On Cover and the filling port to pry off the Snap-On Cover (2).



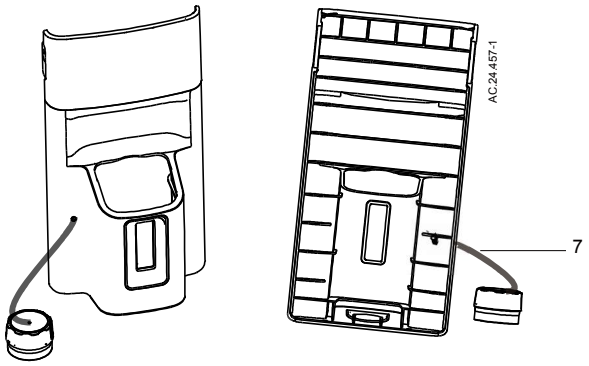
4. Remove the two ear labels (3) that cover the two screws on the upper sides of the vaporizer. Use a T10 Torx driver to remove the four screws (4) that hold the Front Cover to the vaporizer body. Two screws are located under ear labels and two are on the bottom of the vaporizer.



5. Remove the drain nozzle (5) with a 4 mm Hex wrench.
6. Remove the Front Cover (6).



7. Open the knot at the end of the Filler Cap tether (7) and remove it from the old Front Cover. Attach the tether to the new Front Cover by making a knot at the end.



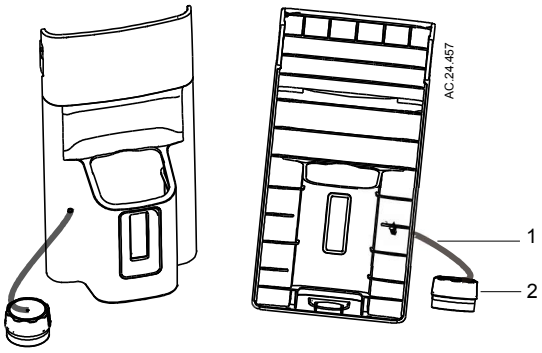
8. Install the Front Cover.
9. Ensure the Side Plates are positioned inside the Front Cover.
10. Install the four screws and torque to 0.6 Nm
11. Install the Drain Nozzle using 4 mm Hex and torque to 2 Nm.
12. Install the ear labels.

Note Use the new ear labels included in the Front Cover kit.

13. Re-install the Snap-On Cover.
14. Re-install the Filler Cap.

5.4 Replacing the Filler Cap

1. Drain the vaporizer. Refer to the User's Reference Manual for the detailed draining procedure.
2. Remove the Front Cover together with the Filler Cap. See "*5.3 Replacing the Front Cover*" for details.
3. Cut the Filler Cap tether (1) to remove the Filler Cap (2) from the Front Cover.

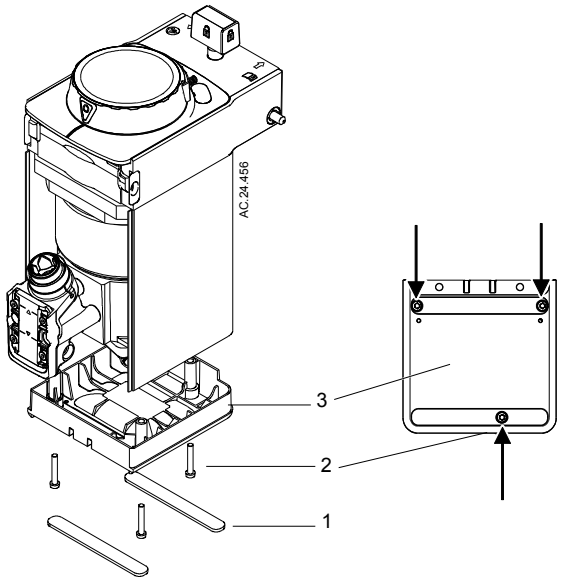


4. Thread the tether of the new Filler Cap through the hole of the Front Cover, make a knot at the end of the tether.
5. Install the Front Cover with the new Filler Cap to the vaporizer body. Refer to "*5.3 Replacing the Front Cover*".

CAUTION Verify the color ring on the Filler Cap matches the drug designation on the Front Cover.

5.5 Replacing the Base Cover

1. Drain the vaporizer. Refer to the User's Reference Manual for the detailed draining procedure.
2. Remove the Front Cover together with the Filler Cap. Refer to "*5.3 Replacing the Front Cover*" for detailed instructions on how to remove the Front Cover.
3. Place the vaporizer on its back to remove the Base Cover:



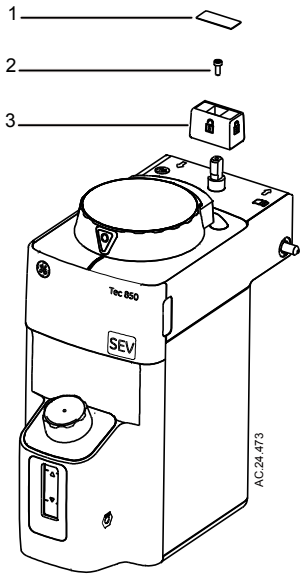
   - Remove and discard the two rubber pads (1). Replacement rubber pads are in the kit.
   - Use a T15 Torx driver to remove the three screws (2) that hold the Base Cover to the vaporizer body.
   - Remove the Base Cover (3).

Note Use new ear labels and rubber pads included in the Base Cover service kit for reassembling.

4. Install the new Base Cover. Torque the screws to 2.0 Nm.
5. Install the Front Cover according to the step 8 to step 13 in section "*5.3 Replacing the Front Cover*".

5.6 Replacing the Locking Lever

1. Use a small flat-blade screwdriver to pry off the label (1) from the Locking Lever.



2. Using a T10 Torx driver to remove the Locking Lever screw (2).
3. Remove the Locking Lever (3).

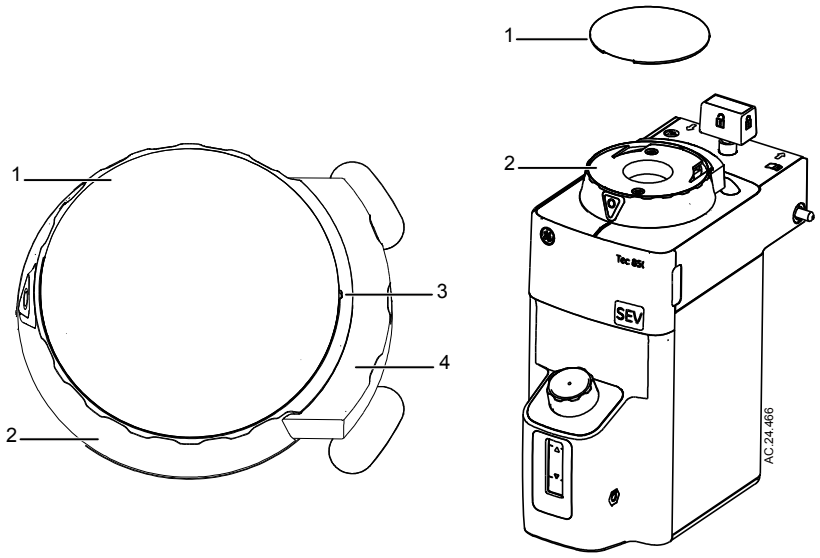
Note Use the new screw and label included in the service kit for reassembling.

4. Install the new Locking Lever in the reverse order as removed. Torque the screws to 1.0 Nm.

Note Ensure the side of the Locking Lever with "Unlock" symbol is facing toward the vaporizer dial.

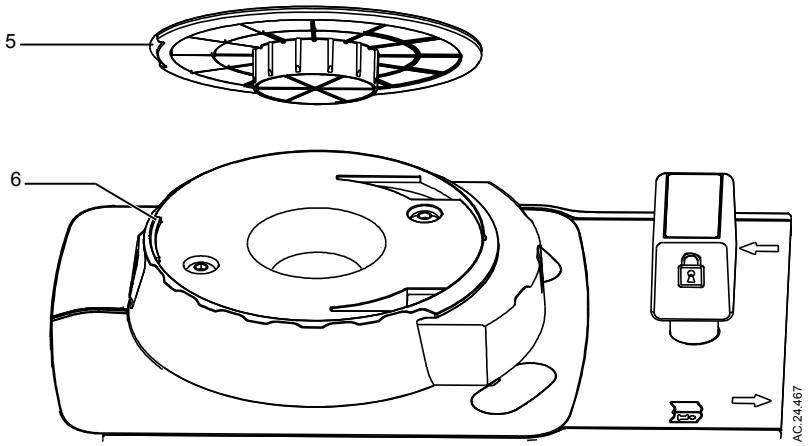
5.7 Replacing the Dial Crown

1. Remove the Dial Crown (1) from the Control Dial assembly (2). Notice the small slot (3) next to the Dial Release. Insert a thin needle-like tool into the slot and pry off the Dial Crown.



Note Verify that the drug color ring on the new Dial Crown matches the model of the vaporizer.

2. Align the groove (5) in the Dial Crown with the lug (6) on the Control Dial. Install the new Dial Crown onto the Control Dial.

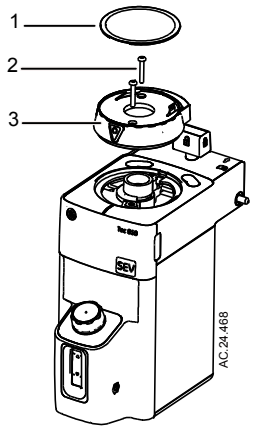


5.8 Replacing the Top Plate and the Top Plate Lable

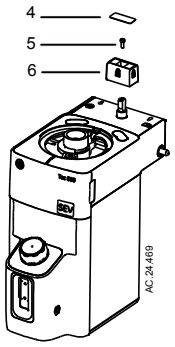
Note Keep the vaporizer in an upright position while performing the Top Plate replacement procedure. Tipping it could result in the interlock to become misaligned.

1. Remove the Control Dial assembly:
   - Remove the Dial Crown (1). Refer to "*5.7 Replacing the Dial Crown*" for details.
   - Use a 2.5 mm Hex wrench to remove the two screws (2) that hold the Control Dial to the vaporizer body.
   - Remove the Control Dial assembly (3).

Note Gently depress the Dial Release to lift the Control Dial.



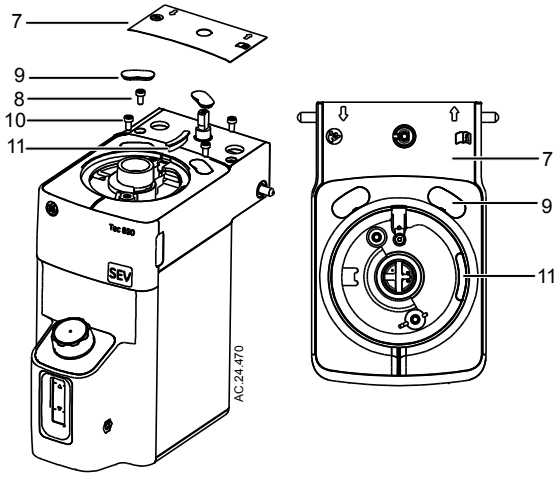
2. Remove the Locking Lever (refer to "*5.6 Replacing the Locking Lever*"):
   - Remove the label (4) on the Locking Lever.
   - Use a T10 Torx driver to remove the screw (5) that fixes the Locking Lever to the shaft.
   - Remove the Locking Lever (6).



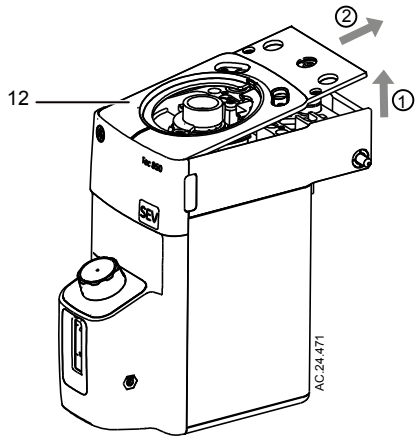
3. Remove the labels and mounting screws.

   - Remove the cover label (7). The cover label can be discarded as the kit includes new label.
   - Use a T15 Torx driver to remove the two screws (8) under the cover label.
   - Remove the two plastic covers (9) by prying them off with a needle type tool.
   - Use a T15 Torx driver to remove the two screws (10) under the two plastic covers.
   - Take out the Stop Insert (11) from the Top Plate.

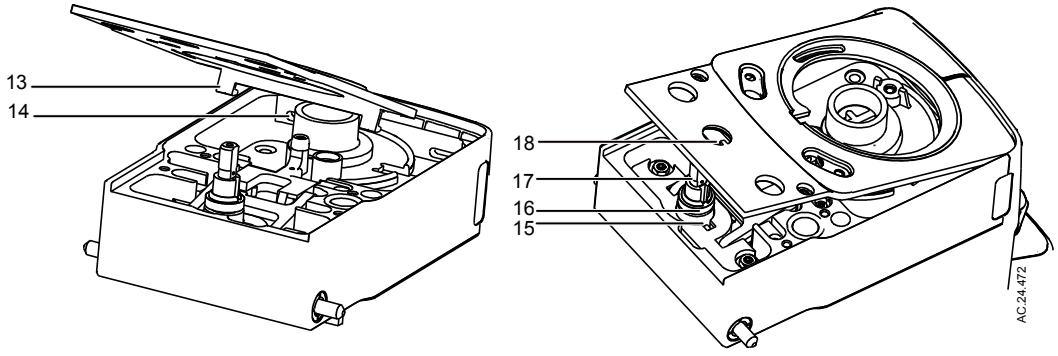
Note The Stop Insert and Control Dial are a calibrated pair. Ensure these components are always kept together. If parts from another vaporizer are installed, vaporizer output will be affected.



4. First slightly tilt the rear end of the Top Plate (12) , then remove the Top Plate as indicated.



5. In case the Top Plate Bushing (16) remains stuck to the Top Plate during its removal, remove the bushing from the Top Plate and place it back on the Locking Shaft (15).
6. Install the new Top Plate to the vaporizer.
   - Insert the two hooks (13) of the Top Plate into the two holes (14) in the vaporizer body.
   - Ensure the bushing (16) is on the spindle (17). Make sure the grooves are aligned.
   - Align the tab (18) with the grooves in the spindle and the bushing, then push the Top Plate down to install it.
   - Secure the Top Plate with screws and torque the screws to 2.0 Nm.



7. Refer to steps 2 through 4 and reassemble the vaporizer in the reverse order. Secure the Locking Lever with the screw and torque it to 1.0 Nm.

Note Use new labels and plastic covers included in the service part kit for reassembling.

8. Test the vaporizer after the replacement operation:
   - Verify that the dial serial number on the Control Dial matches the serial number on the product label.

- Verify that the Control Dial can be turned to, but does not exceed, the maximum dial setting.

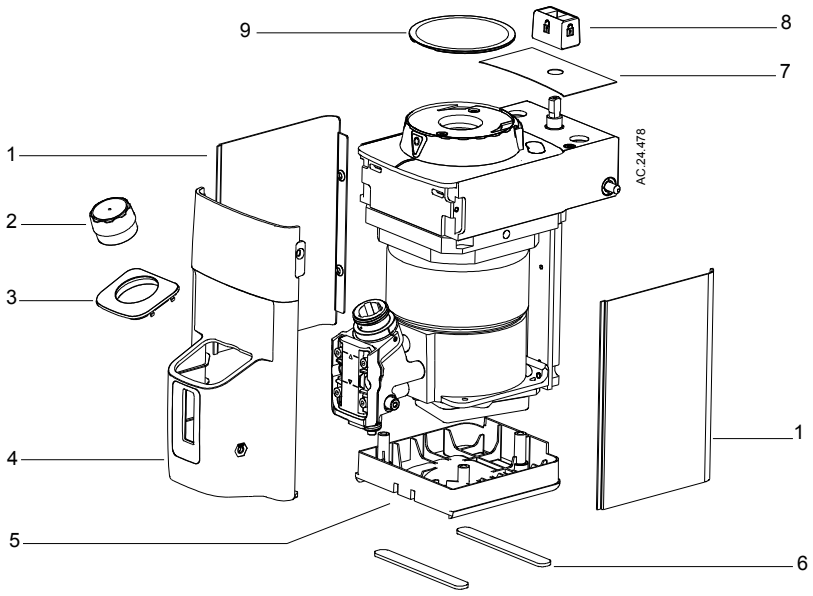
6 Illustrated Parts

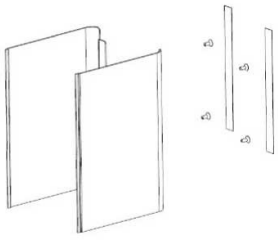
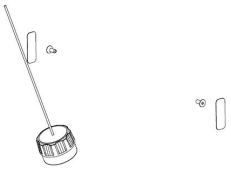
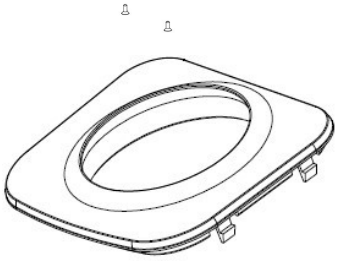
In this section

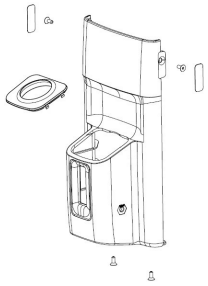
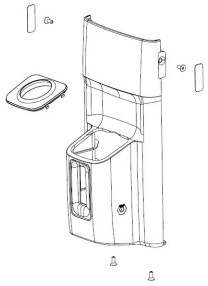
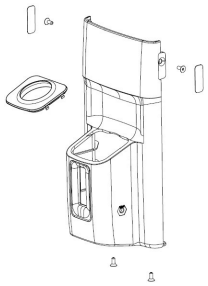
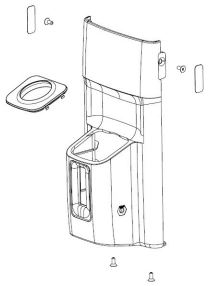
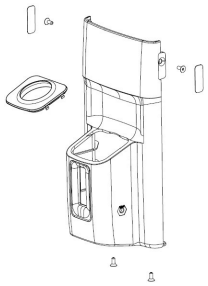
6.1 Service tools

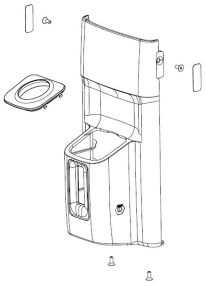
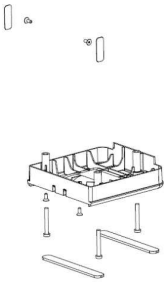
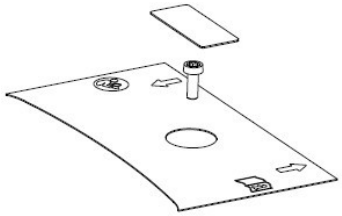
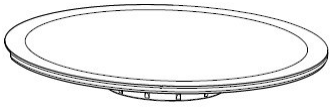
Item	Description	Stock Number
1	Low pressure leak test device (Squeeze bulb)	0309-1319-800
2	3-mm Hex wrench	Obtain locally
3	4-mm Hex wrench	Obtain locally
4	Agent monitor	Obtain locally
5	T10 Torx driver	Obtain locally
6	T15 Torx driver	Obtain locally
7	Torque wrench	Obtain locally

6.2 Service parts

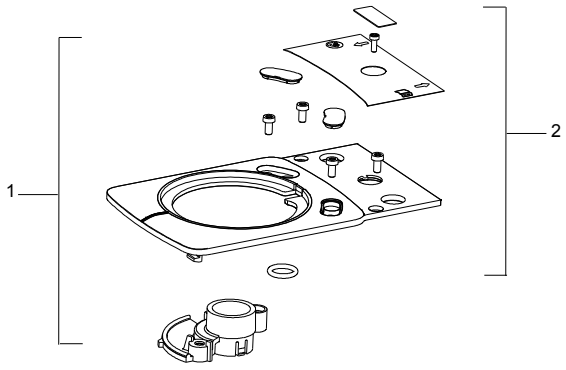


Item	Kit illustration	Description	Stock Number	Qty
1		Side Plate Kit	M7204003-S	
		- Side Plate		(2)
		- Screw, M3×8		(4)
		- Blank Strip Label		(2)
2		SEV Filler Cap Kit	M7206006-S	
		- Cap Assembly, SEV		
		- Screw, M3×8		(4)
		- Ear Label		(2)
2		ISO Filler Cap Kit	M7206007-S	
		- Cap Assembly, ISO		
		- Screw, M3×8		(4)
		- Ear Label		(2)
3		Snap-on Cover, SEV	M7204005-S	
3		Snap-on Cover, ISO	M7204006-S	

Item	Kit illustration	Description	Stock Number	Qty
4		Front Cover Kit, SEV Tec 850	M7204004-S	
		- Front Cover, SEV Tec 850		
		- Screw, M3×8		(4)
		- Ear Label		(2)
		- Snap-on Cover, SEV		
4		Front Cover Kit, SEV Tec 820	M7204009-S	
		- Front Cover, SEV Tec 820		
		- Screw, M3×8		(4)
		- Ear Label		(2)
		- Snap-on Cover, SEV		
4		Front Cover Kit, ISO Tec 850	M7204008-S	
		- Front Cover, ISO Tec 850		
		- Screw, M3×8		(4)
		- Ear Label		(2)
		- Snap-on Cover, ISO		
4		Front Cover Kit, ISO Tec 820	M7204010-S	
		- Front Cover, ISO Tec 820		
		- Screw, M3×8		(4)
		- Ear Label		(2)
		- Snap-on Cover, ISO		
4		Front Cover Kit, SEV 850, Baxter SAFE-T-SEAL	M7204015-S	
		- Front Cover, SEV Tec 850		
		- Screw, M3×8		(4)
		- Ear Label		(2)
		- Snap-on Cover, SEV		
		- Label, Baxter SAFE-T-SEAL Label	M7205007-S	

Item	Kit illustration	Description	Stock Number	Qty
4		Front Cover Kit, SEV 850, Piramal Fill	M7204016-S	
		- Front Cover, SEV Tec 850		
		- Screw, M3×8		(4)
		- Ear Label		(2)
		- Snap-on Cover, SEV		
		- Piramal Fill Label	M7205008-S	
5		Base Cover Kit	M7204001-S	
		- Base Cover		
		- Screw, M4×30		(3)
		- Rubber Pad		(2)
		- Screw, M3×8		(4)
		- Ear Label		(2)
6		Rubber Pad (including 2 pads)	M7204007-S	
7		Top Plate Label Kit	M7205003-S	
		- Top Plate Label		
		- Locking Lever Label		
		- Screw, M3×12		
8		Locking Lever Kit	M7203006-S	
		Locking Lever		
		Screw, M3×12		
		Locking Lever Label		
9		Dial crown, SEV	M7203004-S	
9		Dial crown, ISO	M7203014-S	
-	-	Ear Label	M7205004-S	(2)

6.3 Service parts (Cont.)



Item	Description	Stock Number	Qty
1	G-Flange Seal Kit	2074919-001-S	
	- G-Flange Seal		
	- O-ring		
	- Top Plate		
	- Top Plate Plug		(2)
	- Top Plate Label		
	- Screw, M4×8		(4)
	- Screw, M3×12		
	- Locking Lever Label		
2	Top Plate Kit	M7203001-S	
	- O-ring		
	- Top Plate		
	- Top Plate Plug		(2)
	- Top Plate Label		
	- Screw, M4×8		(4)
	- Screw, M3×12		
	- Locking Lever Label		
-	Top Plate Plug	M7203008-S	(2)

Index

Tec 820/850 Vaporizer
Technical Reference Manual
English
2094230-001
07 2017 Rev E

B105M/B125M/B155M

Monitoare pentru pacienți

Vă alimentăm performanța.

Monitoarele pentru pacienți B105M/B125M/B155M oferă performanțe clinice premium în toate zonele de îngrijire. Aceste monitoare scalabile, precise, integrate, cu design intuitiv, sunt disponibile având afișaje cu ecran tactil de 10, 12 sau 15 inch.

Capabilități avansate

Gama de monitoare B1x5M se poate implementa perfect într-o varietate de setări de îngrijire:

- ECG EK-Pro v14 cu 4 derivații pentru analiza simultană a aritmiei
- Măsurarea neinvazivă a tensiunii arteriale DINAMAP™ SuperSTAT
- Alegerea tehnologiilor de SpO_2: GE TruSignal™, Masimo SET® sau Nellcor™ OxiMax
- GE $EtCO_2$ pentru măsurarea fluxului lateral, a agenților anestezici și a debitului cardiac
- Monitorizare* Entropy™ pentru monitorizarea stării creierului
- NMT pentru blocarea transmisiei neuromusculare și monitorizarea inversărilor
- Conectivitate la rețelele GE CARESCAPE™
- Flexibilitate pentru partajarea modulelor de parametri și a accesoriilor cu monitoarele CARESCAPE

*Pentru pacienți cu vârsta peste 2 ani.

Model intuitiv. Flux de lucru neîntrerupt.

- 12 forme de undă pentru a vizualiza simultan toate formele de undă ale parametrilor necesari
- Comunicare Bed to Bed și funcționalitate Automatic view on alarm (AVOA) pentru a revizui datele de monitorizare la distanță ale pacientului
- Funcționalitate circulantă pentru tranziția perfectă a monitorului de la un pat la altul în cadrul rețelei CARESCAPE
- Platforma de serviciu la distanță InSite™ pentru depanare la distanță
- Scorul Național de Avertizare Timpurie (NEWS) pentru o intervenție la timp

Robust pentru sarcini solicitante. Sigur într-o lume cibernetică.

- Respectă indicațiile FDA privind securitatea cibernetică a dispozitivelor medicale
- Un filtru ECG oferă o performanță sporită a semnalului în zonele zgomotoase
- Cu baterie de mare capacitate: >4 ore[1]
- Testat cu standardul EMC Ediția a 4-a
- Rezistent la apă cu standardele IP22

[1] În funcție de configurație, cu configurație tipică ECG, timp ciclu NIBP 15 min, SpO2, luminozitatea afișajului 70%.

gehealthcare.com

Versiune de software VSP 3.0

Specificații tehnice

Afișaj

Dimensiune	B155M: 15,6 in (diagonală) B125M: 12,1 in (diagonală) B105M: 10,1 in (diagonală)
Rezoluție	B155M: 1366x768 (HD) B125M / B105M: 1280x800 (WXGA)
Număr forme de undă	până la 12
Afișarea și culorile ecranului	configurabile de utilizator
Controale	Ecran tactil capacitiv și Trim Knob™

Parametri și module

Parametri	Module[2]
ECG	Modul hemodinamic integrat
Resp	
SpO_2	
NIBP	
Temp	
InvBP cu 2 canale	
CO_2 în flux secundar	E-miniC[3]
Entropie	E-Entropie[4]
CO_2, O_2 și N_2O în flux secundar	E-sCO
Sidestream CO_2, O_2, agenți și N2O în flux secundar	E-sCAiO, N-CAiO
Debit cardiac + InvIBP cu 1 canal	E-COP5
Transmisia neuromusculară	E-NMT

ECG

Derivații disponibile	configurație cu 3 derivații: I, II, III configurație cu 5 derivații: I, II, III, aVR, aVL, aVF și V configurație cu 10 derivații: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 și V6
Viteza de baleiaj	12,5, 25 sau 50 mm/s
Interval amplificare	0.5x, 1x, 2x și 4x
Precizia ritmului cardiac	20 la 300 bpm, ±5% sau ±5 bpm, oricare este mai mare

Lățimea de bandă

Filtru ECG	Monitor: 0,5 la 40 Hz ST: 0,05 la 40 Hz Diagnostic: 0,05 la 145 Hz Moderat: 0,5-20 Hz
Detectare stimulator cardiac	Interval voltaj: 2 la 700 mV Lățime puls: 0,5 la 2 ms

Alarme de aritmii

Alarme letale	Asistolă, fibrilație ventriculară/tahicardie ventriculară, tahicardie ventriculară
Alarme de RC	Bradicardie, Tahicardie
Alarme ventriculare	VT>2, R pe T, bradicardie ventriculară, Cuplete, Bigeminie, Ventricular accelerat, Trigeminie, PVC-uri multifocale
Alarme atriale	Fibrilație atrială, lipsă puls, pauză, neregulat, tahicardie SV
Alarmă PVC	PVC-uri frecvente, SVC-uri frecvente

Analiza segmentului ST

Interval numeric	-9 la +9 mm (-0,9 la +0,9 mV)
Acuratețe	±0,2 mm sau ±10%, oricare dintre acestea este mai mare, în intervalul de măsurare de la -8 la 8 mm
Rezoluție numerică	0,1 mm (0,01 mV)

Impedanță respirație

Interval	Adult/pediatric: 4 la 120 respirații/min Nou-născuți: 4 la 180 respirații/min
Acuratețe	±5% sau ±5 respirații/min, oricare este mai mare
Interval amplificare	0,1 la 5 cm/Ohm

SpO_2

TruSignal SpO_2

Interval măsurare	
Pulsoximetrie	1 la 100%
Puls	30 la 250 bpm
IP (Index circulație sangvină)	0 la 32
Acuratețe măsurare	
Saturație	Fără mișcare-adult/pediatric Senzor de deget: 70 la 100% ±2% Fără mișcare-nou-născuți: 70 la 100% ±3% Cu mișcare-adult/pediatric/nou-născuți: 70 la 100% ±3% Circulație sangvină scăzută-adult/pediatric: 70 la 100% ±3% (<70% nespecificat)
Puls	fără mișcare: ±2 bpm (Adult/Pediatric/Nou-născuți)

Nellcor OxiMax

Interval măsurare	
Pulsoximetrie	1 la 100%
Puls	20 la 250 bpm
Acuratețe măsurare	
Saturație	Adulți: 70 la 100% ±2% Nou-născuți: 70 la 100% ±3% Circulație sangvină scăzută: 70 la 100% ±2% <70% nespecificat
Puls	±3 bpm

[2] Consultați Manualul de utilizare B105M/B125M/B155M pentru mai multe informații.
[3] Măsurarea CO_2 prin intermediul Modulului E-miniC este destinat utilizării numai la pacienții cu o greutate de peste 5 kg (11 lb).
[4] Modulul E-Entropy va fi utilizat doar la pacienții cu vârsta peste 2 ani.
[5] E-COP nu este destinat utilizării la pacienții nou-născuți.

Masimo SET

Interval măsurare

Pulsoximetrie	1 la 100%
Puls	25 la 240 bpm

Acuratețe măsurare

Saturație	Fără mișcare-adult/pediatric: 70 la 100% ±2% Fără mișcare-nou-născuți: 70 la 100% ±3% Cu mișcare-adult/pediatric/nou-născuți: 70 la 100% ±3% Circulație sangvină scăzută: 70 la 100% ±2% (<70% nespecificat)
Puls	fără mișcare: ±3 bpm Cu mișcare: ±5 bpm
IP (Index circulație sangvină)	Da
Tehnologia APOD (Adaptive Probe Off Detection)	Da

NIBP

Tehnică de măsurare	Oscilometrică cu deflație în trepte
Moduri de măsurare	Manuală, Automată (cu timpul ciclului de serie personalizat) și STAT
Timpi automați ciclu 30 min, 1 oră, 1,5 ore și 2 ore	Personalizat, 1, 2, 3, 4, 5, 10, 15, 20,

Intervale măsurare NIBP

Sistolic	Adult/pediatric: 30 la 290 mmHg Nou-născuți: 30 la 140 mmHg
MAP	Adult/Pediatric: 20 la 260 mmHg Nou-născuți: 20 la 125 mmHg
Diastolic	Adult/pediatric: 10 la 220 mmHg Nou-născuți: 10 la 110 mmHg

Acuratețe clinică

Diferență medie	±5 mmHg
Deviație standard	≤ 8 mmHg
Standard raportare	ANSI/AAMI ISO81060-2 și IEC 80601-2-30

Caracteristici de siguranță

Presiunea inițială de umflare implicită	Adult/Pediatric: 135 ±15 mmHg Nou-născuți: 100 ±15 mmHg
Timp maxim de determinare	Adult/Pediatric: 2 min Nou-născuți: 85 s
Monitor supra-presiune	Adult/Pediatric: 300 ±6 la 330 mmHg Nou-născuți: 150 ±3 la 165 mmHg

Puls din NIBP

Interval Măsurare	30 bpm la 250 bpm
Acuratețe	±5% sau ±5 bpm (oricare este mai mare)

Măsurarea invazivă a tensiunii arteriale

Din măsurătorile hemodinamice integrate

Interval măsurare	-40 to 320 mmHg (-5,3 la 42,7 kPa)
Acuratețe măsurare	±4% sau ±2 mmHg, oricare este mai mare
Răspuns frecvență	4 la 22 Hz
Sensibilitate transductor	5µV/V/mmHg
Interval puls (PR)	30 la 250

Din modulul E-COP

Interval măsurare	-30 to 320 mmHg (-4,0 la 42,7 kPa)
Acuratețe măsurare	±4% sau ±4 mmHg, oricare este mai mare
Răspuns frecvență	4 la 22 Hz
Sensibilitate transductor	5µV/V/mmHg
Interval puls (PR)	30 la 250

Calcule

SPV (Variația presiunii sistolice)	SBPmax – SBPmin (unde SBP este tensiunea arterială sistolică)
PPV (Variația presiunii pulsului)	(PPmax – PPmin)/[(PPmax + PPmin)/2] x 100 (unde PP este presiunea pulsului)

Temperatură

Afișaj numeric	T1, T2, Tsânge

Din măsurătorile hemodinamice integrate (T1, T2)

Interval măsurare	10 to 45 °C (50 to 113 °F)
Acuratețe măsurare	±0,1 °C fără sondă ±0,2 °C cu sondă de la 25 la 45 °C ±0,3 °C cu sondă de la 10 la 25 °C (fără a include 25 °C)
Afișaj resolution	0,1 °C

Din modulul E-COP (Tsânge)

Interval măsurare	17,5 la 43 °C (63,5 la 109,4 °F)
Acuratețe măsurare	±0,5 °C (17,5 °C la 30,9 °C) ±0,3°C (31°C la 43,0°C)
Afișaj resolution	0,1 °C

Arhitectura rețelei

Rețea fizică N/W	1000BaseT
Wireless	Wi-Fi IEEE 802.11a/b/g/n, roaming rapid

Servicii de networking

Outbound HL7®	Conectivitate directă la EMR sau la terțe sisteme pentru trenduri numerice
CARESCAPE (Unity) CARESCAPE Gateway	Conectivitate la CIS / HIS prin Alte aplicații de networking
Serviciu la distanță	Diagnoza la distanță a dispozitivului prin serverul InSite™ RSvP

Aplicații de networking CARESCAPE (Unity)

Fereastră Bed to Bed*

Date afișate	Forme de undă și valori numerice de la șase parametri, o alarmă la distanță și informații de la distanță despre pat
Paturi la distanță la 40 de paturi	Alarme de monitorizare pentru până
Monitorizat	Vizualizarea unui pat din 1023 paturi

AVOA (Auto View of Remote beds in alarm)*

Informații despre mesajul de alarmă la distanță	Numele unității și al patului, mesaj de alarmă, alarmare mai mult de 1 pat
Notificare de alarmă configurabilă	Mesaj, Vizualizare automată, Vizualizare automată întotdeauna

Rotire

Funcționalitate	Rotire între unități și paturi; Adăugarea de noi unități și paturi; Selectarea imprimantei

Periferice I/O

Conectori standard

Port Ethernet / WIFI	Suportă HL7 and CARESCAPE Unity N/W
Port USB 2.0	Jurnale serviciu descărcare
Setări de importare/exportare	
Trenduri numerice de export	
	Instalare software, firmware și e-manuale
Port HDMI	Suportă afișarea clonelor secundare B155M: 1366 x 768 pixeli B125M/B105M: 1280 x 800 pixeli
Port serial RS232	Exportă datele trendurilor o/p și alarmele către iCollect doar prin intermediul protocolului DRI

Conectori non-standard

Conector asistent medical	se conectează la sistemul de asistență medicală al spitalului
Conector sincronizare defibrilator	Ieșire sincronizare defibrilator Conector recorder Imprimantă termică autonomă B1X5-REC Recorder
Cadru B1X5-F2	al doilea cadru pentru conector suplimentar pentru module

Securitatea rețelelor și a datelor

Certificat Wi-Fi	CE, FCC
Autentificare Wi-Fi	Support WPA-Personal; WPA2-Personal; WPA-Enterprise; WPA2- Enterprise
Criptare date WIFI	Suport WPA/WPA2 cu TKIP și AES CCMP
Conexiune LAN / WLAN	Suportă IEEE 802.1X bazat pe port Control acces rețea (NAC)
Schimb de fișiere prin USB	Toate funcțiile USB sunt protejate prin parolă Export criptat de tendințe numerice, setări de utilizator și jurnale de servicii prin USB

Montare

Mâner de transport integrat compatibil cu GCX

Imprimantă termică locală

Metodă	Matrice de puncte termice
Rezoluții orizontale	24 puncte/mm (600 dpi)
Rezoluție verticală	8 puncte/mm (200 dpi)
Forme de undă	Selectabile 1, 2 sau 3 forme de undă
Tipărire trenduri numerice	HR, Pleth, NIBP, IBP1, IBP2, T1, T2, Et/FiCO_2, RR, Pleth, C.O., C.I., REF, SPV, PPV, IBP4, Tblood, RE, SE, BSR, NMT Count, O_2, N_2O, AA, BAL, MAC
Lățime hârtie	50 mm, lățime de imprimare 48 mm
Viteză hârtie	5, 10, 12,5 și 25mm/s, configurabilă de utilizator
Imprimantă la distanță	Suportă atât imprimantă laser, cât și imprimantă termică (cu stația centrală CARESCAPE)

Rack pentru module (integrat)

Slot pentru un singur modul

Cadru secundar B1X5-F2 (opțional)

Al doilea cadru suplimentar pentru până la două module

*Compatibil numai cu monitoarele de pacienți B155M / B125(M/P) / B105(M/P) VSP3.0

Specificații de performanță

Alarme

Prioritate	Prioritate reglabilă: Ridicată, medie, scăzută și informare Control local și de la distanță din stația centrală
Detectare alarmă	Asistolă, fibrilație ventriculară/tahicardie ventriculară, tahicardie ventriculară, Bradicardie, FiO_2 scăzut, EtO_2 scăzut și FiN_2O ridicat
Configurabilitate alarmă	Definiți intervalul ratei pentru tahicardie ventriculară și criteriile de durată pentru o alarmă durabilă privind tahicardie ventriculară
Alarmă	tahicardie ventriculară
Notificare	Sonoră și vizuală
Ton alarmă	IEC, General, ISO, ISO2
Setare	Implicită și individuală
Notificare alarmă vizuală	roșu, galben, cyan Mesaj audio silențios Mesaj general de alarmă
Reglarea limitei de alarmă	Control local și de la distanță din stația centrală
Temporizator pauză audio	2 min
Imprimare automată a alarmei	până la 23 alarme

Trenduri

Grafice	Toți parametrii, scale de timp selectabile de la 20 min la 168h (7 zile)
Numerice	Toți parametrii, cu 168 de ore (7 zile) de eșantionare a datelor de trend în funcție de setarea timpului sau după determinarea NIBP, CO și PCWP
Instantaneu	Până la 200 instantanee Declanșat manual sau prin alarmă Instantanee de evenimente cu formă de undă (pe stația centrală CARESCAPE)
Trend OxyCRG	Doar mod nou-născuți Vizualizare în timp real sau instantaneu Stochează până la 70 instantanee OxyCRG Durata instantaneului cu 6 minute înainte și 2 minute după evenimentul OxyCRG
Cursor trend	În trendul grafic

Divulgare completă

Filă/pagină: toate ECG, Hemo

Toate vizualizările ECG	ECG I, II, III, aVR, aVL, aVF, formele de undă V1, V2, V3, V4, V5 și V6
Vizualizare Hemo	ECG II, IBP1, IBP2, IBP4, SpO_2 și formele de undă Resp
Parametri suportați	ECG, SpO_2, IBP și RESP

Viteza de baleiaj a revizuirii formelor de undă configurabilă
Stocare 72 de ore cu toate datele despre forma de undă
Legătură integrată cu istoricul alarmelor
Revizuirea divulgare completă cu privire la alarma specifică
Revizuirea divulgare completă cu privire la timpul specific

EWS (Scor de alarmare timpurie)

Protocol	Scorul național de avertizare timpurie (NEWS) 2
Parametri	HR/PR Puls, tensiunea arterială sistolică, LOC (nivel de conștiință), TEMP, SpO_2, Rată Resp și Aer sau Oxigen

Istoric cu valori detaliate ale parametrilor și sub-scoruri

Scorul total EWS pe ecranul principal cu codare color și marcaje de timp

Răspunsul clinic și scorurile parametrilor individuali cu culori pe o fereastră dedicată

Revizuire risc clinic EWS și îndrumările EWS

Specificații de mediu

Condiții de funcționare

Temperatură	5 la 40°C (41 la 104°F)
Umiditate relativă	15 la 90% fără condens
Presiune atmosferică	700 la 1060 hPa (525 la 795 mmHg)

Condiții de depozitare și transport

Temperatură	-20 la 60°C (-4 la 140°F)
Umiditate relativă	10 la 90% fără condens
Presiune atmosferică	700 la 1060 hPa (525 la 795 mmHg)

Specificații de putere

Intrare AC	100 la 240 V ±10%, 50/60 Hz
Consum de energie	Monitor ≤150 VA Cadru secundar B1X5-F2 ≤50 VA
Protecție	Clasa I
Acumulator	1, litiu-ion de mare capacitate
Timp încărcare	< 4 ore la 90% din capacitate
Timp funcționare	>4,0 ore pentru B155M / B125M >4,5 ore pentru B105M cu configurație tipică: ECG, timp ciclu NIBP 15 min, SpO_2, luminozitatea afișajului 70%

Specificații fizice

Monitor

Dimensiuni (î x l x A)	B155M: 305 x 405 x 175 mm B125M: 280 x 312 x 175 mm B105M: 275 x 265 x 175 mm
Greutate (cu acumulator și fără module)	B155M: ≤ 5,2 kg (11,5 lb) B125M: ≤ 4,2 kg (9,3 lb) B105M: ≤ 3,8 kg (8,4 lb)
Protecție infiltrare	IP22

Cadru secundar B1X5-F2

Dimensiuni (î x l x A)	160 x 132 X 266 mm cu plăcuță de montaj
Greutate	1,4 kg (30,9 lb) u plăcuță de montaj

Certificări

IEC 60601-1 admis

Marcaj CE conform Regulamentului UE privind dispozitivele medicale (UE) 2017/745

Marcaj UL

Certificări CB

Sistem

Sistem de operare	Linux®
Sistem de răcire	Convecție naturală, fără ventilator în interior pentru răcire

B125M, B105M, B155M JB00262XE

2020-09-21

Versiunea de software VSP3.0 pentru monitoarele de pacienți B105M/B125M/B155M nu sunt disponibile pe toate piețele și nu sunt confirmare 510k.