

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 medii) Cod 110120 Descriere Mașina de anestezie este destinată să livreze, să monitorizeze gazele anestezice și să asigure respirația artificială a pacientului în timpul actului chirurgical Parametru Specificația Prize de gaz O₂, Aer Display mașina de anestezie $\geq 12"$, color TFT sau LCD touch screen Debitmetre tipul electronice sau mecanic gaz O₂, Air gama, L/min $\geq 0 - 15$ Vaporizator tip vaporizator acceptate Izofluran da Sevofluran da Halothan da Enfluran da Desfluran da număr de vaporizatoare instalate la dispozitiv ≥ 2 unități da Izofluran 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 $\geq 3-40$ raportul I:E minim 4:1 la 1:4 pauză de inspirație da limita de presiune, cmH₂O ajustabilă, $\geq 0-70$ PEEP, cmH₂O $\geq 0-30$ 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 Circuitul pneumatic de ventilare a pacientului cu funcție de încălzire a amestecului gazos da port auxiliar ieșire a amestecului gazos da 613688Parametri monitorizați și afișați pe display Presiunea de aer Alarmă de înaltă presiune da Alarma presiune subatmosferică da	Mașină de anestezie (caracteristici medii) Cod 110120 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 Specificația Prize de gaz O₂, Aer DA Display mașina de anestezie $\geq 12"$, color TFT sau LCD touch screen DA Debitmetre tipul electronice sau mecanic gaz O₂, Air DA gama, L/min $\geq 0 - 15$ DA Vaporizator tip vaporizator acceptate Izofluran da Sevofluran DA Halothan DA Enfluran DA a Desfluran DA număr de vaporizatoare instalate la dispozitiv ≥ 2 unități DA Izofluran 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 volumul Tidal, ml 20-1500 DA frecvența respirației/minut 5 – 100 DA fluxul inspirator, L/min $\geq 3-40$ raportul I:E minim 4:1 la 1:4 DA pauză de inspirație DA limita de presiune, cmH₂O ajustabilă, $\geq 0-70$ DA PEEP, cmH₂O $\geq 0-30$ DA 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 Circuitul pneumatic de ventilare a pacientului cu funcție de încălzire a amestecului gazos port auxiliar ieșire a amestecului gazos DA Parametri monitorizați și afișați pe display Presiunea de aer Alarmă de înaltă presiune DA

Continuarea alarma presiune da Presiune scăzută / apnee da Alte alarme de presiune da Volumul expirator / flux da Volumul minut, l/min da Concentrația de O2 Alarmă apnea da Timp de răspuns, sec <30 Concentrația de CO2 Alarmă apnee da Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran Auto indentificarea gazelor anestezice da Alarmă concentrare agent da Determinarea și afișarea valorii MAC da Modulul de gaze încorporat la mașina de anestezie da determină concentrațiile de gaze: O2, CO2, agenți anestezici da Celulă determinare O2 tip paramagnetică/ galvanică da Monitorul pentru afișarea funcțiilor vitale display ≥ 12 inch, color TFT sau LCD da touch screen da monitor dedicat vizualizării funcțiilor vitale da braț de fixare a monitorului din laterală pe mașină de anestezie da imprimantă termică încorporată da baterie internă reîncărcabilă da Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă da traseul ECG da analiza și măsurarea segmentui ST da determinarea cel puțin 20 de aritmii da Puls-oximetria (SpO2) fotopletismografia da valoarea SpO2 da indicile de perfuzie da Tensiune sanguină neinvazivă (NIBP) da Respirația (impedanța transtoracică) da Temperatura da Tensiune sanguină invazivă (IBP) da Alarme prioritare 3 Tensiune de alimentare 220 V, 50 Hz Prize auxiliare 220 V ≥ 3 buc da Baterie internă reîncărcabilă da autonomie de lucru ≥ 2h da Sertar pentru depozitare ≥ 3 buc da Frână centralizată pentru fixarea aparatului da Presiune de alimentare cu gaze 3.0 - 6 bar Accesorii Furtunul cu conector de conectare la sursa de aer comprimat 1 buc. Furtunul cu conector de conectare la sursa de oxigen 1 buc. Circuit de ventilare Adult, reutilizabil ≥ 2 set. Plămîn de test Adult, reutilizabil ≥ 2 buc. Senzor de flux Reutilizabil ≥ 2 buc. Filtru antibacterial Adult, unică utilizare ≥ 200 buc. Accesorii modul de gaz Adult ≥ 2 set. Cablu ECG Adult, reutilizabil 5 fire ≥ 1 buc.	Alarma presiune subatmosferică DA Continuarea alarma presiune DA Presiune scăzută / apnee DA Alte alarme de presiune DA Volumul expirator / flux DA Volumul minut, l/min DA Concentrația de O2 Alarmă apnea DA Timp de răspuns, sec <30 DA Concentrația de CO2 Alarmă apnee DA Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran Auto indentificarea gazelor anestezice DA Alarmă concentrare agent DA Determinarea și afișarea valorii MAC DA Modulul de gaze încorporat la mașina de anestezie DA determină concentrațiile de gaze: O2, CO2, agenți anestezici d DA Celulă determinare O2 tip paramagnetică/ galvanică da Monitorul pentru afișarea funcțiilor vitale display ≥ 12 inch, color TFT sau LCD DA touch screen DA monitor dedicat vizualizării funcțiilor vitale da braț de fixare a monitorului din laterală pe mașină de anestezie DA imprimantă termică încorporată DA baterie internă reîncărcabilă DA Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă DA traseul ECG DA analiza și măsurarea segmentui ST DA determinarea cel puțin 20 de aritmii DA Puls-oximetria (SpO2) fotopletismografia DA valoarea SpO2 DA indicile de perfuzie DA Tensiune sanguină neinvazivă (NIBP) DA Respirația (impedanța transtoracică) DA Temperatura DA Tensiune sanguină invazivă (IBP) DA Alarme prioritare 3 DA Tensiune de alimentare 220 V, 50 Hz DA Prize auxiliare 220 V ≥ 3 buc d DA Baterie internă reîncărcabilă DA autonomie de lucru ≥ 2h DA Sertar pentru depozitare ≥ 3 buc DA Frână centralizată pentru fixarea aparatului da Presiune de alimentare cu gaze 3.0 - 6 bar DA Accesorii Furtunul cu conector de conectare la sursa de aer comprimat 1 buc. DA Furtunul cu conector de conectare la sursa de oxigen 1 buc. DA Circuit de ventilare Adult, reutilizabil ≥ 2 set. DA Plămîn de test Adult, reutilizabil ≥ 2 buc. DA Senzor de flux Reutilizabil ≥ 2 buc. DA Filtru antibacterial Adult, unică utilizare ≥ 200 buc. DA
--	--

Anexa 1

Cablu ECG Adult, reutilizabil 3 fire ≥ 1 buc. Electrozi ECG Adult, unica utilizare ≥ 100 buc. Senzor SpO2 Adult, reutilizabil ≥ 2 buc. Manșete NIBP Adult, reutilizabilă ≥ 2 buc. Adult mare, reutilizabilă ≥ 2 buc. Senzor de temperatură Adult, reutilizabil ≥ 1 buc. Cablu de interconectare senzor IBP Adult, reutilizabil ≥ 1 buc. Senzor IBP Adult, unica utilizare ≥ 5 buc	Accesorii modul de gaz Adult ≥ 2 set. DA Cablu ECG Adult, reutilizabil 5 fire ≥ 1 buc. DA Cablu ECG Adult, reutilizabil 3 fire ≥ 1 buc. DA Electrozi ECG Adult, unica utilizare ≥ 100 buc. DA Senzor SpO2 Adult, reutilizabil ≥ 2 buc. DA Manșete NIBP Adult, reutilizabilă ≥ 2 buc. DA Adult mare, reutilizabilă ≥ 2 buc. DA Senzor de temperatură Adult, reutilizabil ≥ 1 buc. DA Cablu de interconectare senzor IBP Adult, reutilizabil ≥ 1 buc. DA Senzor IBP Adult, unica utilizare ≥ 5 buc DA
---	---

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:	2527 cm ² /392 in ² (with optional flip shelf)

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)

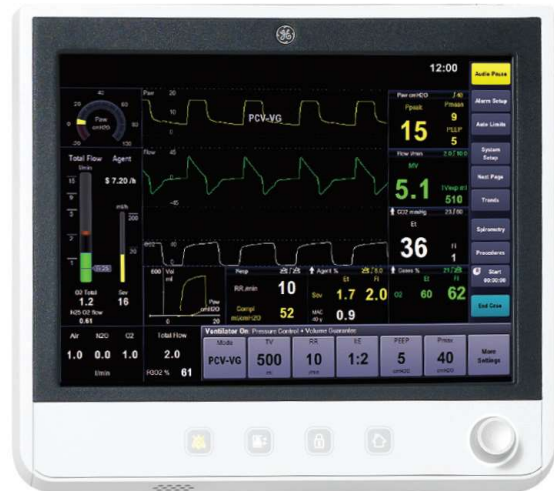
Height:	
Top and middle:	8.6 cm/3.4 in
Bottom:	13.3 cm/5.2 in
Width:	34 cm/13 in
Depth:	37 cm/14.6 in

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

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 ₂ O (increments of 1 cmH ₂ O) above set PEEP
Pressure (P_{max}) range:	12 to 100 cmH ₂ O (increments of 1 cmH ₂ O)
Pressure (P_{support}) range:	Off, 2 to 40 cmH ₂ O (increments of 1 cmH ₂ O)
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 ₂ O (increments of 1 cmH ₂ O)

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 ₂ O (larger of)
PEEP delivery:	±1.5 cmH ₂ O
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 ₂ O (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 ₂ O above PEEP
High pressure:	12 to 100 cmH ₂ O (increments of 1 cmH ₂ O)
Sustained airway pressure:	Mechanical ventilation ON: $P_{\text{max}} < 30 \text{ cmH}_2\text{O}$, the sustained limit is 6 cmH ₂ O $P_{\text{max}} 30 \text{ to } 60 \text{ cmH}_2\text{O}$, the sustained limit is 20% of P_{max} $P_{\text{max}} > 60 \text{ cmH}_2\text{O}$, the sustained limit is 12 cmH ₂ O PEEP and mechanical ventilation ON: Sustained limit increases by PEEP minus 2 cmH ₂ O Mechanical ventilation OFF: $P_{\text{max}} 12 \text{ to } 60 \text{ cmH}_2\text{O}$, the sustained limit is 50% of P_{max} $P_{\text{max}} > 60 \text{ cmH}_2\text{O}$, the sustained limit is 30 cmH ₂ O
Subatmospheric pressure:	$P_{\text{aw}} < -10 \text{ cmH}_2\text{O}$
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 ₂ O 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 CO₂, O₂ and N₂O):

Maximum effect on readings:	CO ₂ < 0.2 vol %; O ₂ , N ₂ O < 2 vol %, AA < 0.15 vol%
-----------------------------	--

Carbon dioxide (CO₂)

EtCO ₂ :	End-tidal CO ₂ concentration
FiCO ₂ :	Inspired CO ₂ concentration

CO₂ 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 (O₂)

FiO ₂ :	Inspired O ₂ concentration
EtO ₂ :	End-tidal O ₂ concentration
FiO ₂ -EtO ₂ :	Inspired-expired difference

O₂ 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 (N₂O)

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 ₂ O
Accuracy**:	±1 cmH ₂ O
Display units:	cmH ₂ O, 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 ₂ O	1 to 100 mL/cmH ₂ O
--------------------	--------------------------------	--------------------------------

Airway resistance

Measurement range:	0 to 200 cmH ₂ O/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 ₂ O	
at 10 L/min:		1.0 cmH ₂ O

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, 2-2A, 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 O₂ (optional)

Connection:	7-10 mm hose barb port
O ₂ concentration range:	100% O ₂
Flow range:	0 to >10 L/min

Auxiliary O₂+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 ₂ O, 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); con- tains input filter and check valve. Large cylinder kit available for O ₂ and N ₂ O (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

O₂ controls

Method:	N ₂ O 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 ₂ O:	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 ₂ O:	±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 pres- sure compensated to standard con- ditions of 20°C and 101.3 kPa
Hypoxic guard:	Mechanical Link-25: Provides a nominal minimum 25% concentration of oxygen in O ₂ /N ₂ O 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 cmH₂O
Tactile knob indication at: 30 cmH₂O and above
Adjustment range of rotation: 0.5 to 30 cmH₂O (0 to 230°)
30 to 70 cmH₂O (230 to 330°)

Materials

All materials in contact with exhaled patient gases are autoclavable, except O₂ 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/cmH₂O
(filled disposable absorber canister)
1.74 mL/cmH₂O
(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:

	<i>P_{exp}</i> Absorber canister Installed	<i>P_{exp}</i> Absorber canister Removed
Flow rate		
5 L/min	0.57 cmH ₂ O	0.57 cmH ₂ O
30 L/min	2.47 cmH ₂ O	2.47 cmH ₂ O
60 L/min	5.60 cmH ₂ O	5.60 cmH ₂ O

Note: Values include patient circuit tubing and wye piece (0.65 cmH₂O 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.

© 2019 General Electric Company – All rights reserved.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE representative for the most current information. GE, the GE Monogram, Carestation, CARESCAPE, PSVPro, Tec, Selectatec, Patient Spirometry, D-lite and Pedi-lite are trademarks of the General Electric Company. GE Healthcare, a division of General Electric Company. GE Medical Systems, Inc., doing business as GE Healthcare.

Datex-Ohmeda, Inc. a General Electric Company.

This document applies to Carestation 650 A1.

DOC1649438 Rev7

Non-USA



B105M/B125M/B155M

Monitoare pentru pacienți

Vă alimentăm performanța.



Monitoare 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 SpO₂: GE TruSignal™, Masimo SET® sau Nellcor™ OxiMax
- GE EtCO₂ 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 ore¹
- Testat cu standardul EMC Ediția a 4-a
- Rezistent la apă cu standardele IP22

gehealthcare.com

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

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 ₂ O în flux secundar	E-sCO
Sidestream CO ₂ , O ₂ , agenți și N ₂ O în flux secundar	E-sCAiO, N-CAiO
Debit cardiac + InvBP 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
Alarmer de aritmii	
Alarmer letale	Asistolă, fibrilație ventriculară/tahicardie ventriculară, tahicardie ventriculară
Alarmer de RC	Bradicardie, Tahicardie

Alarmer ventriculare	VT>2, R pe T, bradicardie ventriculară, Cuplete, Bigeminie, Ventricular accelerat, Trigeminie, PVC-uri multifocale
Alarmer 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 CO₂ prin intermediul Modulului E-miniC este destinată 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) Tehnologia APOD (Adaptive Probe Off Detection)	Da 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

Calculare

SPV (Variația presiunii sistolice)	SBPmax – SBPmin (unde SBP este tensiunea arterială sistolică)
PPV (Variația presiunii pulsului)	$(PP_{max} - PP_{min}) / [(PP_{max} + PP_{min}) / 2]$ 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	Alarmer 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	leșire 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 ₂ O, 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

Alarmer

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 ₂ O 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 Clasa I
Protecție	
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

Este posibil ca produsul să nu fie disponibil în toate țările și regiunile. Specificațiile tehnice complete ale produsului sunt disponibile la cerere. Contactați un reprezentant GE Healthcare pentru mai multe informații. Vă rugăm intrați pe www.gehealthcare.com/promotional-locations. Datele pot fi modificate.
© 2020 General Electric Company.

GE, monograma GE, CARESCAPE, D-lite+, Pedi-lite sunt mărci comerciale ale General Electric Company.

Masimo și SET sunt mărci comerciale ale Masimo Corporation. Nellcor și OxiMax sunt mărci comerciale ale unei companii Medtronic. HL7 este o marcă comercială înregistrată a Health Level Seven (HL7), Inc. Linux este marca comercială înregistrată a Linus Torvalds în SUA și în alte țări. Toate celelalte mărci comerciale ale terților sunt proprietatea deținătorilor respectivi.

Reproducerea sub orice formă este interzisă fără permisiunea scrisă prealabilă a GE. Este interzisă utilizarea oricărei informații din acest material pentru a diagnostica sau trata orice boală sau afecțiune. Cititorii trebuie să consulte un profesionist din domeniul sănătății.

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.



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

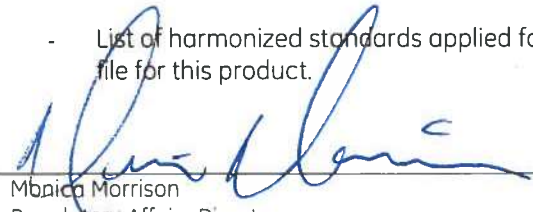
GMDN Code: 37710, UMDNS Code: 10-134

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



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 accessories 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



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.

Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



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 accessories 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



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:

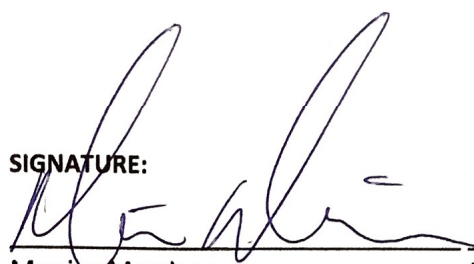
B125P/B105P/B125M/B105M/B155M Patient Monitor equipped with B1x5-01 WLAN module

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:



Date

Monica Morrison

Executive - Regulatory Affairs

Washington, DC USA

EC Certificate

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



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



Songin
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.



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

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)



Patient Safety is at the hearth of everything we do⁶

PATIENT SAFETY IN ANAESTHESIOLOGY



It's estimated that more than 400,000 people die each year due to preventable medical errors¹

Many of these errors are technology-related¹

Human factor play a large part in the delivery of safe care to patients²

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. Anaesthesiology 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 experience⁶

¹ ECRI report 2014

² <https://www.ecri.org/press/Pages/2014-Top-10-Health-Technology-Hazards-Report.aspx>

³ Best practice & research clinical RJ Glavin, Anaesthesiology 2011

⁴ Reason J: Human Error. Cambridge University press 1990

⁵ Helsinki declaration - European journal of anaesthesiology; 2010; 27

⁶ Gaba DM: Anaesthesiology as a model for patient safety 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/>



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)

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



Intuitive screen navigation

Unified User Interfaces

Primary controls within a reach

Fast interactive system check

Quick dismantling breathing circuit

Simple



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)

Intuitive screen navigation

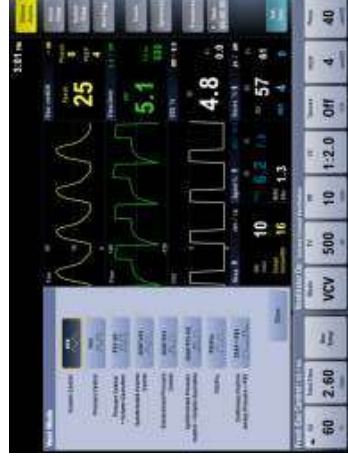
15" touch controls



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



*available on Carestation 650 or 650c

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)

Intuitive and fast access to essential OR tasks

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



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)

Primary controls within a reach

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



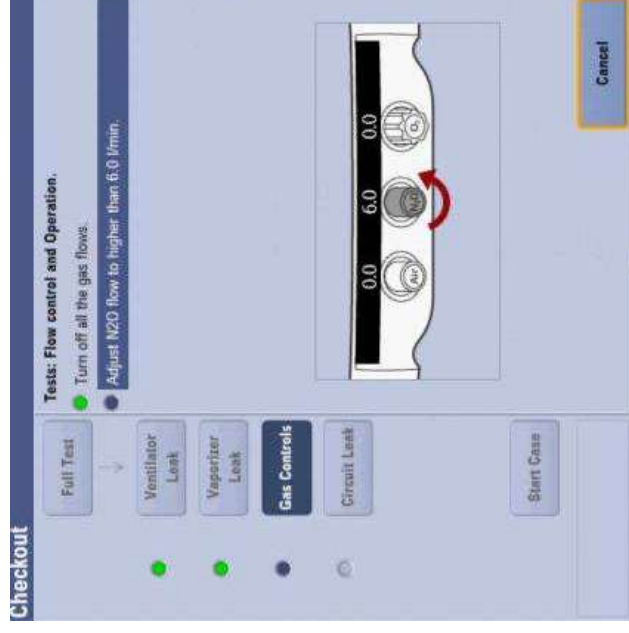
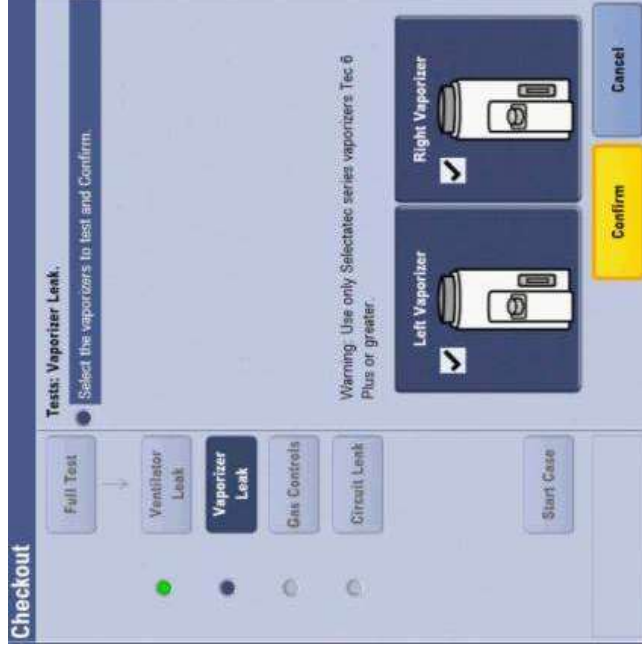
APL valve Manual/Auto switch front located for repetitive and fast machine interactions. Optimized ergonomics of ACGO, Auxiliary O2, O2 flush.

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

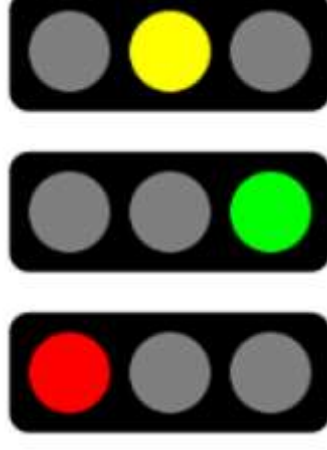


JB30399XE Not approved in all markets. Not cleared or approved by the US FDA. Not for sale in the United States. Carestation 620/650/650c (A1)

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



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



ALARMS

TUNNELING

One-touch alarm response
Menu opens and highlights parameter causing alarm. Change with a simple twist and click of commwheel

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

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



Pause Gas Procedure* (II)

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

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)

**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 ACGO is disabled the cover will be closed preventing possible misconnection of the patient circuit



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)

Optimizing your workspace with modern design

The right fit for any OR
Convenient mobility
Adaptable to your needs
High quality look & feel

agile



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

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



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)

Convenient Mobility



Compact and light weight



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



Central Brake*



Caster Guards*



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

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.

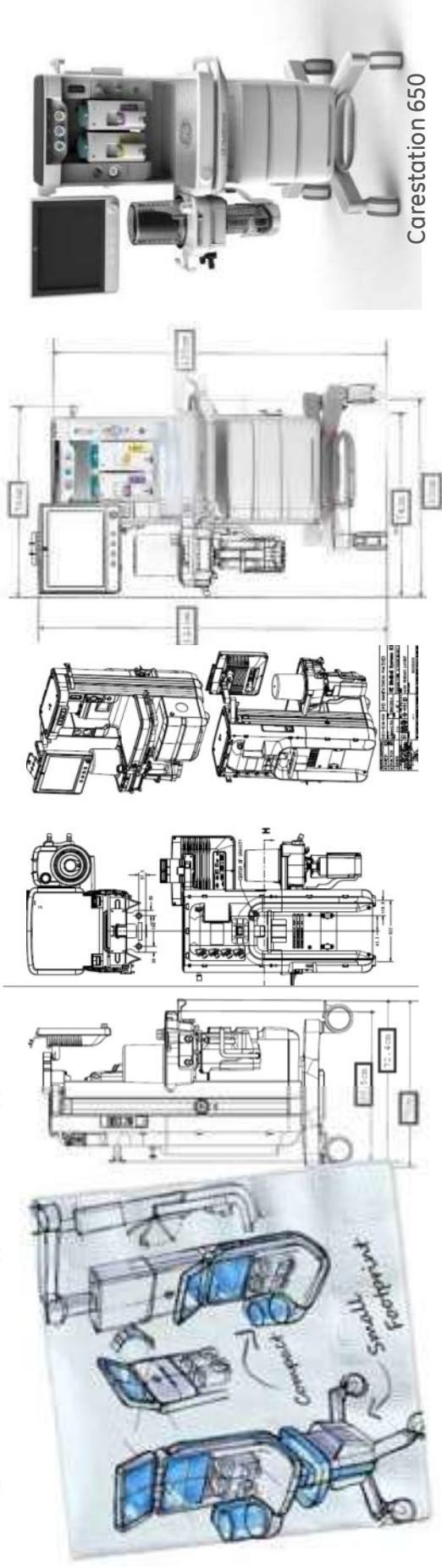
GE internal verification and
validation report 2015 (DOC1677887)

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)

Carestation 600 Series

Designing a Carestation for today's challenges

Engineered for dependability. Designed to delight.



Carestation 650

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

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.



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)

†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



✓ Compliance Measurement

✓ Trending

✓ Spirometry

✓ Full set of Ventilation modes

✓ From neonates to adult



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



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

© 2015 General Electric Company – All rights reserved.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

Contact your GE representative for the most current information.

™ GE, GE Monogram, Carestation, CARESCAPE are trademarks of General Electric Company.

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)

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 EtO₂ and FiO₂ 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

- CO₂ and N₂O – GE infrared technology:
Inspired and end-tidal values, CO₂ waveform and respiration rate
- Respiration rate – calculated from the CO₂ 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 (O₂) 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 CO₂, O₂, N₂O, 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 = CO₂ and N₂O

Ai = Anesthetic agents with single agent identification

O = Patient O₂

Non-disturbing gases

- Ethanol, acetone, isopropanol, methane, nitrogen, nitric oxide, carbon monoxide, water vapor and freon R134A (for CO₂, O₂ and N₂O).
- Maximum effect of non-disturbing gases on readings: O₂ & N₂O <2vol%, CO₂ < 0.2 vol%, AA < 0.15 vol%.

Carbon dioxide (CO₂)

GE infrared absorption sensor technology

CO₂ 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 EtCO₂ or FiCO₂

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 (O₂)

GE differential paramagnetic sensor

O₂ 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 (N₂O)

GE infrared absorption sensor

FiN ₂ O	Inspired N ₂ O concentration
EtN ₂ O	End-tidal N ₂ O concentration
Measurement range	0 to 100 vol%
Accuracy	±(2 vol% + 2% of reading) N ₂ O ≤ 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)

© 2013 General Electric Company – All rights reserved.
GE and GE Monogram are trademarks of General Electric Company.

General Electric Company reserves the right to make changes in specification and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE representative for the most current information

Always refer to the user manual that accompanies the monitor/module.

GE Healthcare Finland Oy, a General Electric company, doing business as GE Healthcare.

GE Healthcare, a division of General Electric Company

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

Certificate



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

TÜVRheinland

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



Bal Balazs

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

B105M ge medical

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
DM000316368	MONITOR DE PACIENT		B105M	6160000-003	SUA	GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC	INTERMED S.R.L.	Rg04-000185	10-08-2021

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

carestation 650									
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
DM000136947	UNITATE DE ANESTEZIE, MOBILĂ		CARESTATION 650C, VERSION A1	1012-9655-000	SUA	DATEX-OHMEDA, INC.	INTERMED S.R.L.	A07.PS-01.Rg04-188	16-07-2018
DM000136946	UNITATE DE ANESTEZIE, MOBILĂ		CARESTATION 650, VERSION A1	1012-9650-000	SUA	DATEX-OHMEDA, INC.	INTERMED S.R.L.	A07.PS-01.Rg04-188	16-07-2018



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.

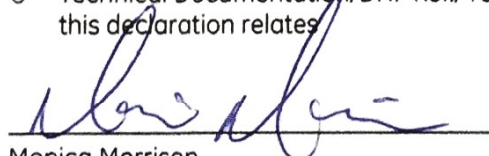
UDI-DI (GTIN) code: 1177-9820-ISO: 00840682124744; 1177-9820-SEV: 00840682124720;
1177-9850-ISO: 00840682124751; 1177-9850-SEV: 00840682124737

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.

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.

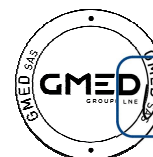
GMED certifies that, on the basis of the results contained in the file referenced P602818, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

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 – 7550 rev. 22
Renouvelle le certificat 7550-21

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459

Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

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

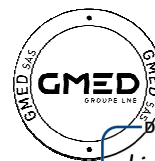
Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
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



DocuSigned by:

Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

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

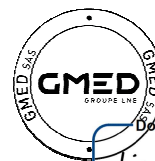
Site couvert et Activités / Location and Activities

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 <i>Headquarters – legal manufacturer Design, manufacture and final control</i>

GMED **0459**

GMED - 38313 rev. 1

Renouvelle le document n° 38313 rev. 0



DocuSigned by:

Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director