Model:Mașină de anestezie Carestation 650, cu monitor de pacient B155M
Producător: GE Medical Systems, Datex-Ohmeda Inc, Țara: USA

Mașină de anestezie (caracteristici avansate)				
Cod	**110130**			
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 cerută**	**Specificația propusă**
Prize de gaz			O2, Aer	Da
Display mașina de anestezie			≥15", color TFT sau LCD	Da 15 "
			touch screen	Da
Debitmetre	**tipul**		electronice	Da
	gaz		O2, Air	Da
	gama, L/min		≥ 0 - 15	Da
Vaporizator	**tip vaporizator acceptate**	**Izofluran**	da	Da
		Sevofluran	da	Da
		Halothan	da	Da
		Enfluran	da	Da
		Desfluran	da	Da
	număr de vaporizatoare instalate la dispozitiv	**≥ 2 unități**	da	Da
		Izofluran	da	Da
		Sevofluran	da	Da
	interlock		da	Da
	sistem de absorbție		da	Da
Mecanisme de siguranță	**siguranța O2**		acustică, vizuală	Da
	siguranță de amestec hipoxic		da	Da
Ventilator automat	**tip pacient**		Adult, Pediatric, Neonatal	Da
	moduri de ventilație		Manual/spontan, VCV, PCV, SIMV, PS	Da
	mecanism electronic de amestec agazelor (mixer)		da	Da
	volumul Tidal, ml		20-1500	Da 1- 1500 ml
	frecvența respirației/minut		5 - 100	Da
	fluxul inspirator, L/min		≥ 3-40	Da
	raportul I:E		minim 4:1 la 1:8	Da **2:1 la 1:8**
	pauză de inspirație		da	Da
	limita de presiune, cmH2O		ajustabilă, ≥ 0-70	Da
	PEEP, cmH2O		≥ 0-30	Da
	Sistem de autodiagnostic		testare la scurgeri, testarea circuitelor respiratorii, complianța, alimentarea cugaz, verificarea tuturor sistemelor	Da
AGSS (sistem de evacuare a gazelor anestezice)			da	Da
Sistem de management al consumului de agent anestezic			da	Da
Posibilitate de a schimba tipul gazului principal din meniu			da	Da

Circuitul pneumatic de ventilare a pacientului	**amestecului gazos**			
	port auxiliar ieșire a amestecului gazos		da	Da
Parametri monitorizați și afișați pe display	**Presiunea de aer**	**Alarmă de înaltă presiune**	da	Da
		Alarma presiune sub atmosferică	da	Da
		Continua rea alarma presiune	da	Da
		Presiune scăzută / apnee	da	Da
		Alte alarme de presiune	da	Da
	Volumul expirator / flux		da	Da
	Volumul minut, l/min		da	Da
	Concentrația de O2	**Alarmă apneea**	da	Da
		Timp de răspuns, sec	<30	Da
	Concentrația de CO2	**alarmă apnee**	da	Da
	Monitorizare agent	**Tipul de agenți**	Halothan, isofluran, sevofluran, Enfluran, Desfluran	Da
		Auto identifica rea gazelor anestezic e	da	Da
		Alarmă concentrare agent	da	Da
		Determinar ea șiafișarea valorii MAC	da	Da
	spirometria		da	Da
Modulul de gaze	**încorporat la mașina de anestezie**		da	Da
	determină concentrațiile de gaze: O2,CO2, agenți anestezici		da	Da
	Celulă determinare O2 tip paramagnetic		da	Da
Monitorul	**display**	**≥15", color TFT sau LCD**	da	Da
		touch screen	da	Da
	monitor dedicat vizualizării funcțiilor		da	Da

funcțiilor vitale				
	braț de fixare a monitorului din laterală pe mașină de anestezie		da	Da
	imprimantă termică încorporată		da	Da
	baterie internă reîncărcabilă		da	Da
	interfață de comunicare cu altele		da	Da
Modulele Hemodinamce incluse	**Electrocardio-grama (ECG)**	**frecvența cardiacă**	da	Da
		traseul ECG	da	Da
		analiza și măsurarea segmentul ST	da	Da
		determin area cel puțin 20 de aritmii	da	Da
	Puls-oximetria (SpO2)	**fotopletismo grafia**	da	Da
		valoarea SpO2	da	Da
		indicele de perfuzie	da	Da
	Tensiune sanguină ne invazivă (NIBP)		da	Da
	Respirația (impedanța trans toracică)		da	Da
	Temperatura pe 2 canale		da	Da
	Tensiune sanguină invazivă (IBP) pe 2 canale		da	Da
	Modul de monitorizare BIS (bi-spectralindex) sau modul de monitorizarea obiectiva a profunzimii blocului neuro-muscular intra anestezic (TOF/ NMT)		da	Da
Alarme prioritare			3	Da
Tensiune de alimentare			220 V, 50 Hz	Da
Prize auxiliare 220 v ≥ 3 buc			da	Da
Baterie internă	**reîncărcabilă**		da	Da
	autonomie de lucru ≥2h		da	Da
Sertar pentru depozitare ≥ 3 buc			da	Da
Frână centralizată pentru fixarea aparatului			da	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
Plămân de test	**Adult, reutilizabil**		≥ 2 buc.	Da
Senzor de flux	**Reutilizabil**		≥ 2 buc.	Da
Filtru antibacterian	**Adult, unică utilizare**		≥ 200 buc.	Da

de gaz			
Cablu ECG	**Adult, reutilizabil 5 fire**	≥ 2 buc.	Da
Senzor 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**	≥ 2 buc.	Da
Cablu de interconectare senzor IBP	**Adult, reutilizabil**	≥ 1 buc.	Da
Senzor IBP	**Adult, unica utilizare**	≥ 10 buc.	Da
Accesorii necesare de funcționare a modululuiBIS sau TOF/ NMT	**Accesorii pentru Adult**	≥ 5 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
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USA

Always refer to complete instruction manual before use.

This document applies to Carestation 650 A1.

DOC1649438 Rev7

Non-USA

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.

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

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

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3030 Ohmeda Drive
PO Box 7550
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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

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This conformity is based on the following elements:

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- List of harmonized standards applied for CE marking is located in the Technical Documentation file for this product.

Monica Morrison
Regulatory Affairs Director

6 MAY 2016
Madison, USA, Day Month -Year

This EC declaration of conformity is superceeds the 16 June 2015 revision. Reference of the Declaration: DOC1659800

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

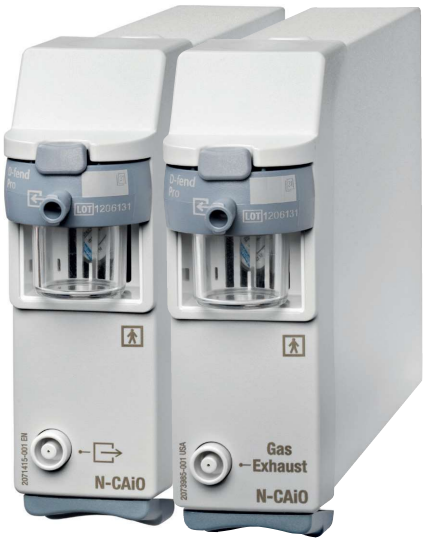
TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

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.

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Milwaukee, WI 53223
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00510 Helsinki
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GE Healthcare
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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

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
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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
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Lionel DREUX
Certification Director

GE Healthcare

Quick Guide

Neuromuscular Transmission

What is neuromuscular transmission?

Neuromuscular transmission (NMT) is the transfer of an impulse between a nerve and a muscle in the neuromuscular junction. NMT can be blocked by neuromuscular blocking agents – drugs which cause transient muscle relaxation and prevent the patient from moving and breathing spontaneously.

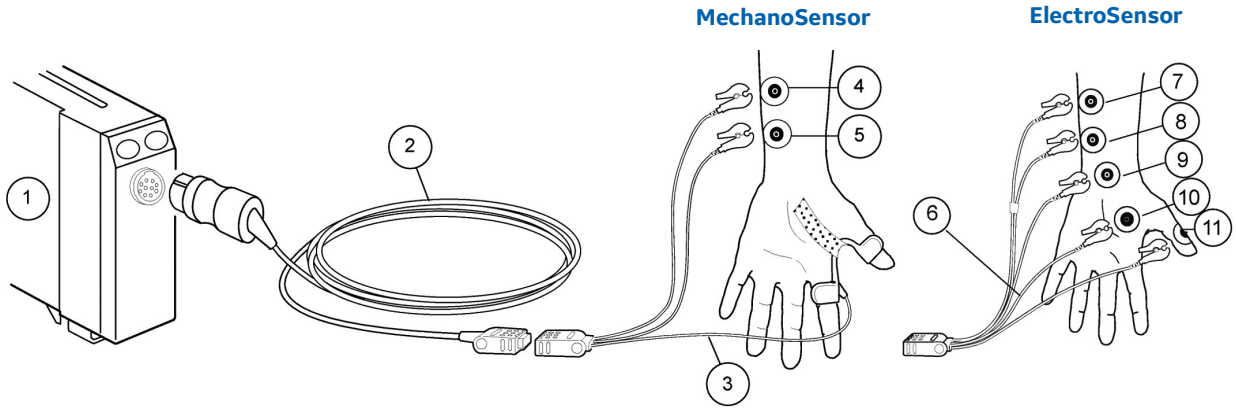
Muscle relaxation is used during general anesthesia to enable endotracheal intubation and to provide the surgeon with optimal working conditions. In critical care, muscle relaxation is used during mechanical ventilation to minimize the patient's work of breathing and to improve oxygenation.

How is the NMT block measured?

The level of neuromuscular block is routinely measured by stimulating a peripheral nerve, usually in the hand and by subjectively evaluating the muscle response either visually or tactilely with a device. Evidence suggests that despite use of subjective neuromuscular monitoring techniques, a large percentage of patients arrive to the PACU with residual paralysis.[1]

By comparison, GEHC offers the NMT module, which provides quantitative, automatic measurements of muscle response to stimulus and consequentially, the level of block. This objective measurement can be used to safely time extubation and avoid the occurrence of residual paralysis.

GE Healthcare offers two different sensor types for the NMT module. The innovative MechanoSensor measures the motion of the thumb with a piezoelectric sensor, which converts the physical motion to an electrical signal and quantifies the evoked mechanical response. The MechanoSensor sensor is available in adult and pediatric sizes. The ElectronSensor directly measures the electrical activity of the muscle with recording electrodes, quantifying the response to nerve stimulation. The ElectroSensor can be used on the patient's hand or foot in both adult and pediatric patients.



NMT measurement setup with MechanoSensor based on kinemyography (KMG) for routine clinical NMT monitoring. Use a narrow tape to secure MechanoSensor securely on the patient's hand. Traditional electromyography (EMG) measurement with ElectroSensor.

1. Module with NMT measurement capability
2. NMT sensor cable
3. MechanoSensor or Pediatric MechanoSensor lead wire set
4. Electrode, white lead connection site for nerve stimulation
5. Electrode, brown lead connection site for nerve stimulation
6. ElectroSensor leadwire set
7. White stimulating electrode
8. Brown stim ulating electrode
9. Electrode, black lead connection site, ground
10. Electrode, green lead connection site, recording muscle-contraction effect
11. Electrode, red lead connection site, recording muscle-contraction effect

[1] Murphy GS, Brull SJ. Residual neuromuscular block: Lessons unlearned. Part 1: Definitions, incidence, adverse psychological effects of residual neuromuscular block. Anesth Analg 2010;111:120-128

Starting nerve stimulus

Start the NMT measurement by defining a patient specific reference with a supramaximal stimulus current for the unrelaxed patient before administering neuromuscular blocking agents. This will ensure reliable measurements are achieved during all levels of neuromuscular blockade. Thereafter module automatically maintains the optimum current throughout the procedure.

For reliable NMT measurement use GE validated NMT electrodes to provide large conductive surface.

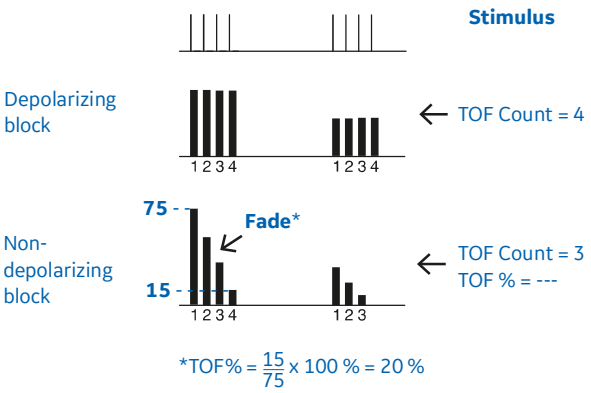
Train-of-four (TOF) is used as the default stimulation mode with four stimuli at 0.5 second intervals causing muscles to contract.

Quantitative muscle response

The muscle response can be quantified with different parameters depending on the type and the level of neuromuscular block.

TOF Count is the number of detected muscle responses. **Train-of-four ratio (TOF%)** is the ratio of the fourth muscle response to the first one. TOF% indicates fade in non-depolarizing block. Once the TOF Count drops below four responses or T1% is less than 10%, the TOF% is not shown.

When depolarizing agents are used, no fade occurs, and the height of the four responses indicates the level of block.



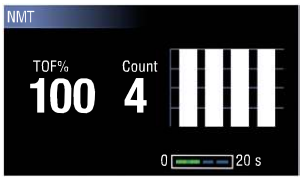
*TOF% = $\frac{15}{75}$ x 100 % = 20 %

When no responses are detected to TOF stimulation, the **post tetanic count** (PTC) is the only way to measure the neuromuscular block. A tetanic stimulation (50 Hz) is generated for five seconds and post-tetanic responses to single twitch stimulation are counted. The larger the PTC, i.e., the number of detected responses, the sooner the normal TOF responses return. PTC is rarely used in critical care.

Light			Medium			Deep		
100	TOF%	20	4	Count	0	10	PTC	0

Relaxometer illustrates the level of neuromuscular blockade

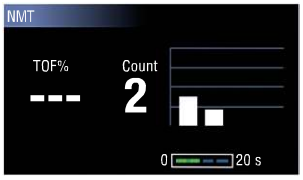
Monitoring of neuromuscular block in five steps



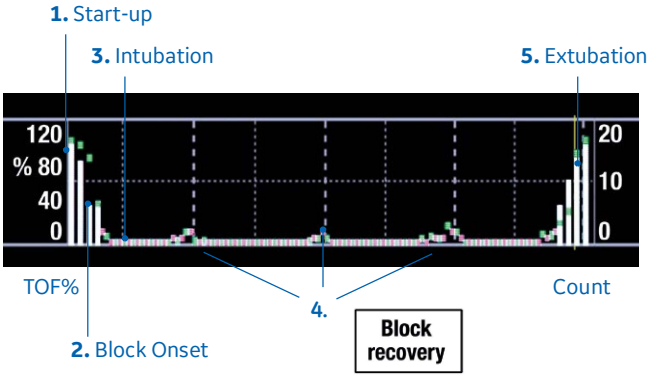
1. Properly secure the sensor of choice (as depicted on page 1). Press measurement start-up. The monitor will start the measurement by setting the stimulus current automatically and by performing a reference measurement. Depolarizing relaxants result in an equal drop in all four responses, without fade.

2. Non-depolarizing relaxants cause a fade in the responses, indicated by a lower TOF% and a slope in the bar graph.

3. Neuromuscular block can be used to facilitate endotracheal intubation. The physician can use the time when all responses disappear (i.e., TOF Count is 0) as a guide to determine when to intubate.



4. During surgery and in critical care, TOF Count is used to maintain steady optimal level of neuromuscular block. When TOF Count exceeds a level set by the user, the GE monitor will give a “Block recovery” message.



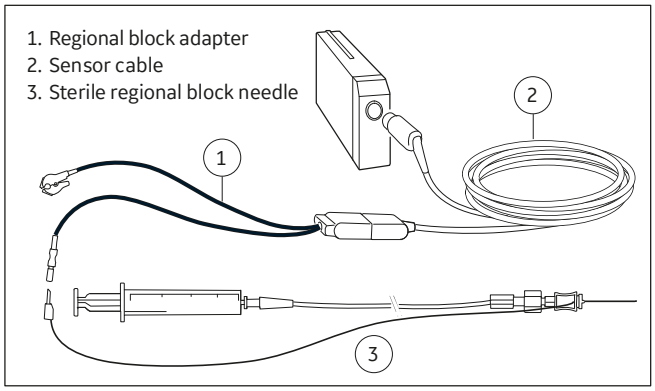
5. Antagonists, if used, should not be given before TOF count rises to 4. For safer extubation, TOF% should be higher than 90.

Nerve location for regional block

The NMT module can also be used to locate the nerve to be blocked in regional anesthesia.

A regional block needle is stimulated with small, repeated 2.0 mA stimuli while the nerve is approached. Each nerve stimulus should result in muscle contraction. The closer the needle is to the motor nerve, the lower the current is needed to give a response. When even a small stimulus current (e.g., < 0.5mA) results in a visible muscle contraction, the optimum site has been located and local anesthetic can be injected.

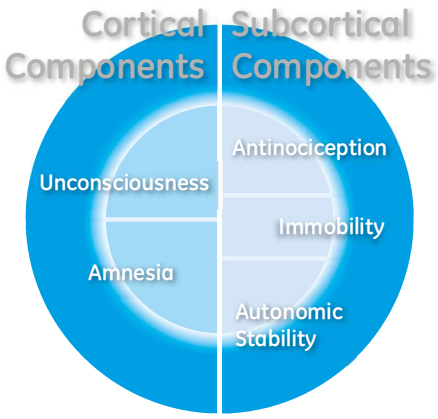
This method helps clinicians find the optimum site of the regional nerve to be blocked and, thus, optimizes the bolus of the anesthetic to be injected. The correct location also protects the patient against mechanical nerve and vessel lesions.



Adequacy of Anesthesia

Adequacy of Anesthesia consists of several interrelated components as depicted below.

One of the objectives of general anesthesia is **immobility**, i.e., the assurance that the patient does not move. Often neuromuscular blocking agents are used to achieve this goal. Anesthetic agents prolong and amplify the effects of neuromuscular blocking agents, therefore, it is recommended to use quantitative NMT monitoring when anesthetic agents are used together with neuromuscular blockade. NMT is an important part of adequacy of anesthesia monitoring and, when combined with other parameters such as the Entropy and hemodynamic measurements, it helps to achieve a more complete picture of the patient's status.



Why use the NMT module?

Automatic and hands-free

Neuromuscular block measurements with the NMT module are easy. Simply attach the sensor and push the Start-up key.

The module will set the supramaximal current and automatically cycle according to the user-defined measurement interval.

Optimal dosage during anesthesia and in critical care

Quantitative NMT monitoring gives a clear picture of the individual dosage needs of the patient and facilitates optimal and cost-effective administration of neuromuscular blocking drugs.

Optimized recovery

Monitoring the level of neuromuscular block enables follow-up and prediction of recovery and helps in correct timing of the antagonists, which may decrease the incidence of residual paralysis.

Enhanced patient safety

Objective, quantitative monitoring is the only means to safely indicate recovery of neuromuscular block (TOF%>90%).[1, 2] Therefore, utilizing the NMT module can help decrease the incidence of residual paralysis and the associated respiratory complications.

Fast patient throughput

Patients that arrive to the PACU with residual paralysis (TOF%<90) stay on average 90 minutes longer.[3] Using NMT to guide extubation times can support shorter length of stay.

Integrated information

When the NMT measurement is integrated in a monitoring system, the measured values are displayed, trended and automatically documented together with all the other monitored parameters.

Additional resources

For white papers, guides and other instructive materials about our clinical measurements, technologies and applications, please visit **http://clinicalview.gehealthcare.com/**

[1] ATOTW 290 – Residual Neuromuscular Blockade, 26/08/2013

[2] Lars I. Eriksson, M.D., Ph.D., Evidence-based Practice and Neuromuscular Monitoring: It's Time for Routine Quantitative Assessment. Anesthesiology 5 2003, Vol.98, 1037-1039.

[3] Butterly A, Bitner EA, George E, Sandberg WS, Eikermann M, Schmidt U. Postoperative residual curarization from intermediate-acting neuromuscular blocking agents delays recovery room discharge. Br J Anaesth. 2010; 105: 304-309.

Imagination at work

JB43409XX(2) 7/17

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

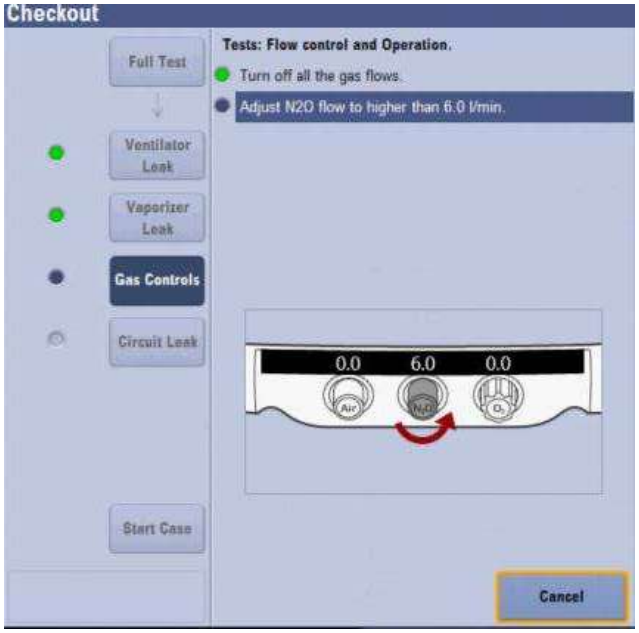
Primary controls within a reach

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

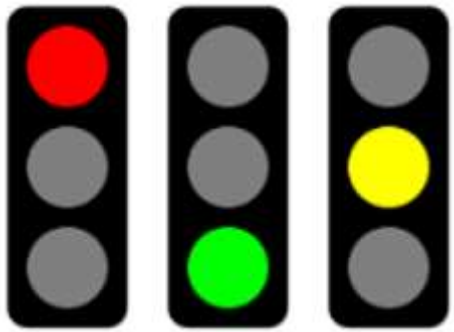
APL valve Manual/Auto switch front located for repetitive and fast machine interactions. Optimized ergonomics of ACGO, Auxiliary O2, O2 flush.

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

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*available on Carestation 650 or 650c

Intelligent guidance to help prevent faults

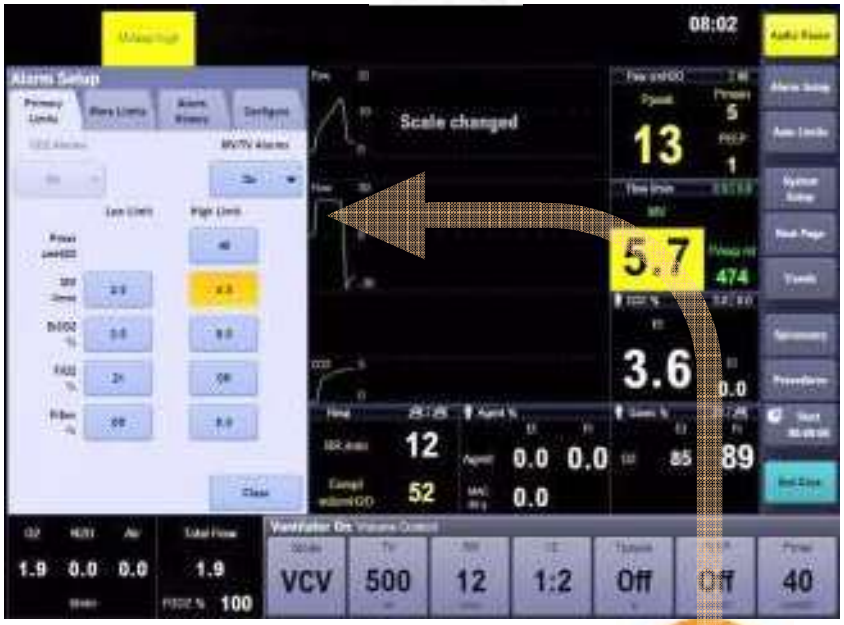
Case notifications

- 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*

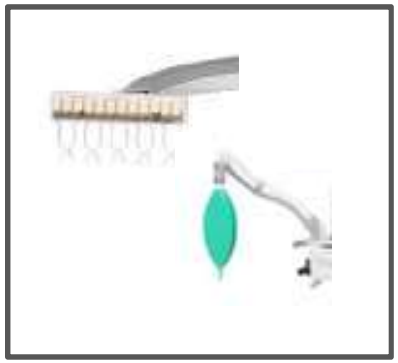
- Compact design and several supporting handles for a smooth transport
- Central brake to quickly secure machine positioning
- In built cable pusher/caster guards to protect patient cables during machine repositioning

* 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

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* 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

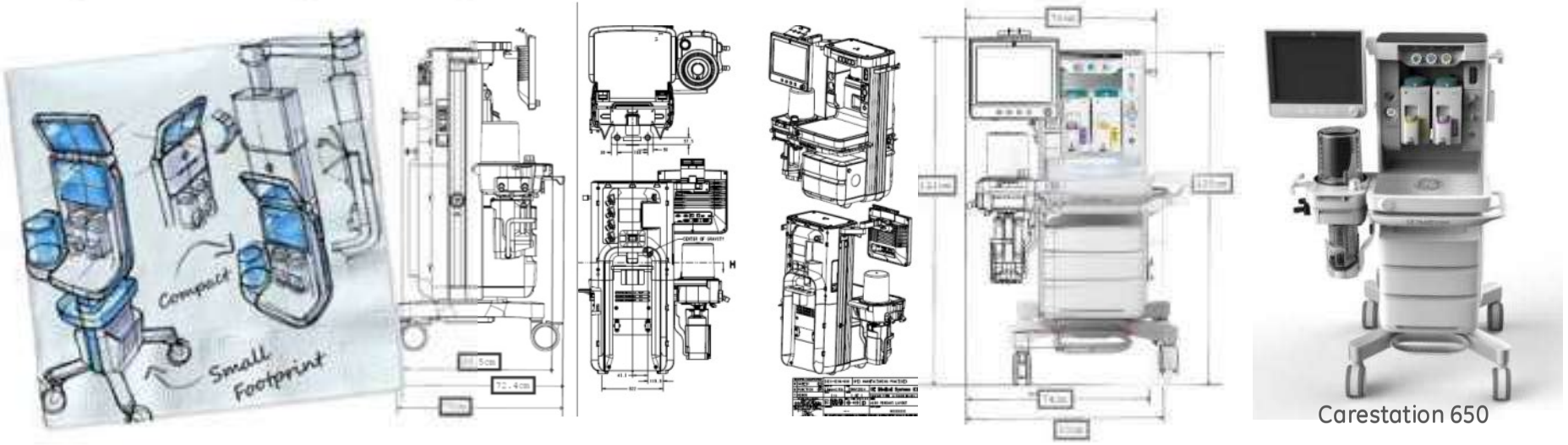
EQUAL TO: **~600 years** of daily reboots

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

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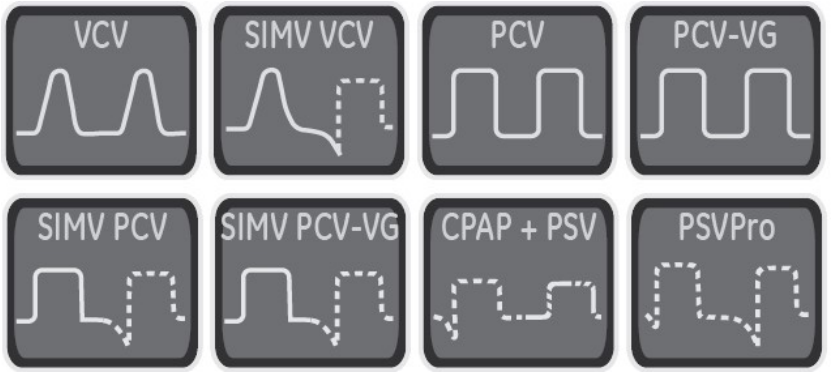
* Available on Carestation 650 and 650c

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



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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

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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.

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Monica Morrison
Regulatory Affairs Director

22 AUG 2017
Madison, WI USA

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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

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

b155m

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Co
DM000316370	MONITOR DE PACIENT		B155M	6160000-005	SUA	GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC	INTERMED S.R.L.	Rg04-000185	10-08-2021	