Specificație Completată

Mașină de anestezie (caracteristici de bază)

Model: CS 650/ Carestation 650 Producator: GE Healthcare; Tara: SUA/ China.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Mașină de anestezie (caracteristici de bază) Cod 110110 Descriere Mașina de anestezie este destinată să livreze, să monitorizeze gazele anestezice și să asigure respirația artificială a pacientului în timpul actului chirurgical Parametru Specificaţia Prize de gaz O2, Aer Display mașina de anestezie Color TFT sau LCD Debitmetre tipul Mecanice gaz O2, Air gama, L/min ≥ 0 – 15 Vaporizator tip vaporizator acceptate Izofluran da Sevofluran da Halothan da Enfluran da Desfluran da număr de vaporizatoare instalate la dipozitiv ≥ 1 unitate da Sevofluran da interlock da sistem de absorbție da Mecanisme de siguranță siguranța O2 acustică, vizuală siguranță de amestec hipoxic da Ventilator automat tip pacient Adult, Pediatric, Neonatal moduri de ventilație Manual/spontan, VCV, PCV, PS volumul Tidal, ml 20-1500 frecvența respirației/minut 5 - 100 fluxul inspirator, L/min ≥ 3-40 raportul I:E minim 4:1 la 1:4 pauză de inspirație da limita de presiune, cmH2O ajustabilă, ≥ 0-70 PEEP, cmH2O ≥ 0-30 Sistem de autodiagnostic testare la scurgeri, testarea circuitelor respiratorii, complianța, alimentarea cu gaz, verificarea tuturor sistemelor AGSS (sistem de evacuare a gazelor anestezice) da Sistem de management al consumului de agent anestezic da Parametri monitorizați și afișați pe display Presiunea de aer Alarmă de înaltă presiune da Alarma presiune subatmosferică da Continuarea alarma presiune da Presiune scăzută / apnee da Alte alarme de presiune da Volumul expirator / flux da Volumul minut, l/min da	Mașină de anestezie (caracteristici de bază) Cod 110110 Descriere Mașina de anestezie este destinată să livreze, să monitorizeze gazele anestezice și să asigure respirația artificială a pacientului în timpul actului chirurgical Parametru Specificaţia **DA** Prize de gaz O2, Aer **DA** Display mașina de anestezie Color TFT **display 15 inch tip touch screen DA** Debitmetre tipul **Electronice DA** gaz O2, Air **DA** gama, L/min ≥ 0 – 15 **DA Flow trigger 1 – 10 L/min Peak gas flow 120 L/min** Vaporizator tip vaporizator acceptate Izofluran **DA** Sevofluran **DA** Halothan **DA** Enfluran **DA** Desfluran **DA** număr de vaporizatoare instalate la dipozitiv - **2 unitate concomitant DA** **SevofluranDA la livrare va fi doar cu sevofluran** 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 5-1500 **DA** frecvența respirației/minut 4 – 100 **DA** fluxul inspirator, L/min ≥ 3-40 **DA** raportul I:E **2:1 la 1:8 DA** pauză de inspirație **DA** limita de presiune, cmH2O ajustabilă, 0-100 **DA** PEEP, cmH2O - 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 tip pasiva optional poate instalat de tip active.** Sistem de management al consumului de agent anestezic **DA** Parametri monitorizați și afișați pe display Presiunea de aer **DA** Alarmă de înaltă presiune **DA** 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	Concentrația de O2 Alarmă apnea **DA**
Timp de răspuns, sec <30	Timp de răspuns, sec <30 **DA**
Concentrația de CO2 Alarmă apnee da	Concentrația de CO2 Alarmă apnee **DA**
Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran	Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran **DA**
Auto indentificarea gazelor anestezice da	Auto indentificarea gazelor anestezice **DA**
Alarmă concentrare agent da	Alarmă concentrare agent **DA**
Determinarea și afișarea valorii MAC 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	Modulul de gaze încorporat la mașina de anestezie **DA** determină concentrațiile de gaze: O2, CO2, agenți anestezici **DA**
Celulă determinare O2 tip galvanică da	Celulă determinare O2 tip galvanică **DA**
Monitorul pentru afișarea funcțiilor vitale display Color TFT sau LCD da	Monitorul pentru afișarea funcțiilor vitale display Color TFT **DA diagonal 12 touch screen Model: B 125 , GE Helathcare**
monitor dedicat vizualizării funcțiilor vitale da	monitor dedicat vizualizării funcțiilor vitale **DA**
braț de fixare a monitorului din laterală pe mașină de anestezie da	braț de fixare a monitorului din laterală pe mașină de anestezie **DA**
baterie internă reîncărcabilă da	baterie internă reîncărcabilă **DA**
interfață de cominicare cu altele da	interfață de cominicare cu altele **DA**
Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă da	Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă **DA**
traseul ECG da	traseul ECG **DA**
analiza și măsurarea segmentui ST da	analiza și măsurarea segmentui ST **DA**
determinarea cel puțin 20 de aritmii da	determinarea cel puțin 20 de aritmii **DA**
Puls-oximetria (SpO2) fotopletismografia da	Puls-oximetria (SpO2) fotopletismografia **DA**
valoarea SpO2 da	valoarea SpO2 **DA**
indicile de perfuzie da	indicile de perfuzie **DA**
Tensiune sanguină neinvazivă (NIBP) da	Tensiune sanguină neinvazivă (NIBP) **DA**
Respirația (impendanța transtoracică) da	Respirația (impendanța transtoracică) **DA**
Temperatura da	Temperatura **DA**
Alarme prioritare 3	Alarme prioritare **3**
Tensiune de alimentare 220 V, 50 Hz	Tensiune de alimentare 220 V, 50 Hz **DA**
Prize auxiliare 220V ≥ 3 buc da	Prize auxiliare 220V ≥ 3 buc **DA fi livrat cu filtru de retea.**
Baterie internă reîncărcabilă da	Baterie internă reîncărcabilă **DA**
autonomie de lucru ≥ 1h da	autonomie de lucru ≥ 1h **DA pentru monitor B125**
Sertar pentru depozitare ≥ 3 buc da	Sertar pentru depozitare ≥ 3 buc **DA**
Presiune de alimentare cu gaze 3.0 - 6 bar	Presiune de alimentare cu gaze 3.0 - 6 bar bDA
Accesorii	Accesorii
Furtunul cu conector de conectare la sursa de aer comprimat 1 buc.	Furtunul cu conector de conectare la sursa de aer comprimat 1 buc. **DA DIN (hexagon)**
Furtunul cu conector de conectare la sursa de oxigen 1 buc.	Furtunul cu conector de conectare la sursa de oxigen 1 buc. **DA DIN (HEXAGON)**
Circuit de ventilare Adult, reutilizabil ≥ 2 set.	Circuit de ventilare Adult, reutilizabil - 2 set. **DA**
Plămîn de test Adult, reutilizabil ≥ 2 buc.	Plămîn de test Adult, reutilizabil - 2 buc. **DA**
Senzor de flux Reutilizabil ≥ 1 buc.	Senzor de flux Reutilizabil - 1 buc. **DA**
Filtru antibacterial Adult, unică utilizare ≥ 100 buc.	Filtru antibacterial Adult, unică utilizare - 100 buc. **DA**
Accesorii modul de gaz Adult ≥ 2 set.	Accesorii modul de gaz Adult - 2 set. **DA**
Cablu ECG Adult, reutilizabil 3 fire ≥ 1 buc.	Cablu ECG Adult, reutilizabil 3 fire - 1 buc. **DA**
Electrozi ECG Adult, unica utilizare ≥ 100 buc.	Electrozi ECG Adult, unica utilizare - 100 buc. **DA**
Senzor SpO2 Adult, reutilizabil ≥ 1 Buc.	Senzor SpO2 Adult, reutilizabil - 1 Buc. **DA**
Manșete NIBP Adult, reutilizabilă ≥ 2 buc.	Manșete NIBP Adult, reutilizabilă - 2 buc. **DA**
Adult mare, reutilizabilă ≥ 2 buc.	Adult mare, reutilizabilă - 2 buc. **DA**
Senzor de temperatură Adult, reutilizabil ≥ 1 buc.	Senzor de temperatură Adult, reutilizabil - 1 buc. **DA**

Specificație Completată

Mașină de anestezie (caracteristici medii)
Model: CS 650/ Carestation 650; Producator: GE Healthcare; Tara: SUA/ China.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă 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 Specificaţia Prize de gaz O2, Aer Display mașina de anestezie ≥12", color TFT sau LCD touch screen Debitmetre tipul electronice sau mecanic gaz O2, Air gama, L/min ≥ 0 – 15 Vaporizator tip vaporizator acceptate Izofluran da Sevofluran da Halothan da Enfluran da Desfluran da număr de vaporizatoare instalate la dipozitiv ≥ 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 ≥ 3-40 raportul I:E minim 4:1 la 1:4 pauză de inspirație da limita de presiune, cmH2O ajustabilă, ≥ 0-70 PEEP, cmH2O ≥ 0-30 Sistem de autodiagnostic testare la scurgeri, testarea circuitelor respiratorii, complianța, alimentarea cu gaz, verificarea tuturor sistemelor AGSS (sistem de evacuare a gazelor anestezice) da Sistem de management al consumului de agent anestezic da Circuitul pneumatic de ventilare a pacinetului cu funcție de incălzire a amestecului gazos da port auxiliar ieșire a amestecului gazos da Parametri monitorizați și afișați pe display Presiunea de aer Alarmă de înaltă presiune da Alarma presiune subatmosferică da Continuarea alarma presiune 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 Parametru Specificaţia **DA** Prize de gaz O2, Aer **DA** Display mașina de anestezie Color TFT **display 15 inch tip touch screen DA** Debitmetre tipul **Electronice DA** gaz O2, Air **DA** gama, L/min ≥ 0 – 15 **DA Flow trigger 1 – 10 L/min Peak gas flow 120 L/min** Vaporizator tip vaporizator acceptate Izofluran **DA** Sevofluran **DA** Halothan **DA** Enfluran **DA** Desfluran **DA** număr de vaporizatoare instalate la dipozitiv - **2 unitate concomitant DA** Izofloran **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 5-1500 **DA** frecvența respirației/minut 4 – 100 **DA** fluxul inspirator, L/min ≥ 3-40 **DA** raportul I:E **2:1 la 1:8 DA** pauză de inspirație **DA** limita de presiune, cmH2O ajustabilă, 0-100 **DA** PEEP, cmH2O - 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 tip pasiva optional poate instalat de tip active.** Sistem de management al consumului de agent anestezic **DA** Circuitul pneumatic de ventilare a pacinetului cu funcție de incălzire a amestecului gazos **DA** port auxiliar ieșire a amestecului gazos **DA** Parametri monitorizați și afișați pe display Presiunea de aer **DA** Alarmă de înaltă presiune **DA** Alarma presiune subatmosferică **DA** Continuarea alarma presiune **DA**

Presiune scăzută / apnee da	Presiune scăzută / apnee **DA**
Alte alarme de presiune da	Alte alarme de presiune **DA**
Volumul expirator / flux da	Volumul expirator / flux **DA**
Volumul minut, l/min da	Volumul minut, l/min **DA**
Concentrația de O2 Alarmă apnea da	Concentrația de O2 Alarmă apnea **DA**
Timp de răspuns, sec <30	Timp de răspuns, sec <30 **DA**
Concentrația de CO2 Alarmă apnee da	Concentrația de CO2 Alarmă apnee **DA**
Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran	Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran **DA**
Auto indentificarea gazelor anestezice da	Auto indentificarea gazelor anestezice **DA**
Alarmă concentrare agent da	Alarmă concentrare agent **DA**
Determinarea și afișarea valorii MAC da	Determinarea și afișarea valorii MAC **DA**
Modulul de gaze încorporat la mașina de anestezie da	Modulul de gaze încorporat la mașina de anestezie **DA**
determină concentrațiile de gaze: O2, CO2, agenți anestezici da	determină concentrațiile de gaze: O2, CO2, agenți anestezici **DA**
Celulă determinare O2 tip paramagnetică/ galvanică da	Celulă determinare O2 tip galvanică **DA**
Monitorul pentru afișarea funcțiilor vitale display ≥ 12 inch, color TFT sau LCD da	Monitorul pentru afișarea funcțiilor vitale display Color TFT **DA diagonal 12 inch Model: B 125 , GE Helathcare**
touch screen da	**Touch screen DA**
monitor dedicat vizualizării funcțiilor vitale da	monitor dedicat vizualizării funcțiilor vitale **DA**
braț de fixare a monitorului din laterală pe mașină de anestezie da	braț de fixare a monitorului din laterală pe mașină de anestezie **DA**
imprimantă termică încorporată da	imprimată termică încorporată **DA**
baterie internă reîncărcabilă da	baterie internă reîncărcabilă **DA**
Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă da	Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă **DA**
traseul ECG da	traseul ECG **DA**
analiza și măsurarea segmentui ST da	analiza și măsurarea segmentui ST **DA**
determinarea cel puțin 20 de aritmii da	determinarea cel puțin 20 de aritmii **DA**
Puls-oximetria (SpO2) fotopletismografia da	Puls-oximetria (SpO2) fotopletismografia **DA**
valoarea SpO2 da	valoarea SpO2 **DA**
indicile de perfuzie da	indicile de perfuzie **DA**
Tensiune sanguină neinvazivă (NIBP) da	Tensiune sanguină neinvazivă (NIBP) **DA**
Respirația (impendanța transtoracică) da	Respirația (impendanța transtoracică) **DA**
Temperatura da	Temperatura **DA**
Tensiune sanguină invazivă (IBP) da	Tensiune sanguină invazivă (IBP) **DA**
Alarme prioritare 3	Alarme prioritare **3**
Tensiune de alimentare 220 V, 50 Hz	Tensiune de alimentare 220 V, 50 Hz **DA**
Prize auxiliare 220 V ≥ 3 buc da	Prize auxiliare 220V ≥ 3 buc **DA fi livrat cu filtru de retea.**
Baterie internă reîncărcabilă da	Baterie internă reîncărcabilă **DA**
autonomie de lucru ≥2h da	autonomie de lucru ≥ 2h **DA pentru monitor**
Sertar pentru depozitare ≥ 3 buc da	Sertar pentru depozitare -3 buc **DA**
Frînă centralizată pentru fixarea aparatului da	Frînă centralizată pentru fixarea aparatului **DA**
Presiune de alimentare cu gaze 3.0 - 6 bar	Presiune de alimentare cu gaze 3.0 - 6 bar **DA**
Accesorii	Accesorii
Furtunul cu conector de conectare la sursa de aer comprimat 1 buc.	Furtunul cu conector de conectare la sursa de aer comprimat 1 buc. **DA DIN (hexagon)**
Furtunul cu conector de conectare la sursa de oxigen 1 buc.	Furtunul cu conector de conectare la sursa de oxigen 1 buc. **DA DIN (HEXAGON)**
Circuit de ventilare Adult, reutilizabil ≥ 2 set.	Circuit de ventilare Adult, reutilizabil - 2 set. **DA**
Plămîn de test Adult, reutilizabil ≥ 2 buc.	Plămîn de test Adult, reutilizabil - 2 buc. **DA**
Senzor de flux Reutilizabil ≥ 2 buc.	Senzor de flux Reutilizabil - 2 buc. **DA**
Filtru antibacterial Adult, unică utilizare ≥ 200 buc.	Filtru antibacterial Adult, unică utilizare - 200 buc. **DA**
Accesorii modul de gaz Adult ≥ 2 set.	Accesorii modul de gaz Adult - 2 set. **DA**
Cablu ECG Adult, reutilizabil 5 fire ≥ 1 buc.	Cablu ECG Adult, reutilizabil 5 fire - 1 buc **DA**
Cablu ECG Adult, reutilizabil 3 fire ≥ 1 buc.	Cablu ECG Adult, reutilizabil 3 fire - 1 buc. **DA**
Electrozi ECG Adult, unica utilizare ≥ 100 buc.	Electrozi ECG Adult, unica utilizare - 100 buc. **DA**

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.	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**

Specificație Completată
Mașină de anestezie (caracteristici avansate)
Model: CS 650/ Carestation 650; Producător: GE Healthcare; Tara: SUA/ China.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
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 Specificaţia Prize de gaz O2, Aer Display mașina de anestezie ≥15", color TFT sau LCD touch screen Debitmetre tipul electronice gaz O2, Air gama, L/min ≥ 0 – 15 Vaporizator tip vaporizator acceptate Izofluran da Sevofluran da Halothan da Enfluran da Desfluran da număr de vaporizatoare instalate la dipozitiv ≥ 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, SIMV, PS mecanism electronic de amestec a gazelor (mixer) da volumul Tidal, ml 20-1500 frecvența respirației/minut 5 - 100 fluxul inspirator, L/min ≥ 3-40 raportul I:E minim 4:1 la 1:8 pauză de inspirație da limita de presiune, cmH2O ajustabilă, ≥ 0-70 PEEP, cmH2O ≥ 0-30 Sistem de autodiagnostic testare la scurgeri, testarea circuitelor respiratorii, complianța, alimentarea cu gaz, verificarea tuturor sistemelor AGSS (sistem de evacuare a gazelor anestezice) da Sistem de management al consumului de agent anestezic da Posibilitate de a schimba tipul gazului principal din meniu da Circuitul pneumatic de ventilare a pacinetului cu funcție de incălzire a amestecului gazos da port auxiliar ieșire a amestecului gazos da Parametri monitorizați și afișați pe display Presiunea de aer Alarmă de înaltă presiune da	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 Specificaţia **DA** Prize de gaz O2, Aer **DA** Display mașina de anestezie Color TFT **display 15 inch tip touch screen DA** Debitmetre tipul **Electronice DA** gaz O2, Air **DA** gama, L/min ≥ 0 – 15 **DA Flow trigger 1 – 10 L/min Peak gas flow 120 L/min** Vaporizator tip vaporizator acceptate Izofluran **DA** Sevofluran **DA** Halothan **DA** Enfluran **DA** Desfluran **DA** număr de vaporizatoare instalate la dipozitiv - **2 unitate concomitant DA** Izofloran **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, SIMV, PS mecanism electronic de amestec a gazelor (mixer) **DA** volumul Tidal, ml 5-1500 **DA** frecvența respirației/minut 4 – 100 **DA** fluxul inspirator, L/min ≥ 3-40 **DA** raportul I:E **2:1 la 1:8 DA** pauză de inspirație **DA** limita de presiune, cmH2O ajustabilă, 0-100 **DA** PEEP, cmH2O - 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 tip pasiva optional poate instalat de tip active.** Sistem de management al consumului de agent anestezic **DA** Posibilitate de a schimba tipul gazului principal din meniu **DA** Circuitul pneumatic de ventilare a pacinetului cu funcție de incălzire a amestecului gazos **DA** port auxiliar ieșire a amestecului gazos **DA** Parametri monitorizați și afișați pe display Presiunea de aer **DA** Alarmă de înaltă presiune **DA**

Alarma presiune subatmosferică da	Alarma presiune subatmosferică **DA**
Continuarea alarma presiune da	Continuarea alarma presiune **DA**
Presiune scăzută / apnee da	Presiune scăzută / apnee **DA**
Alte alarme de presiune da	Alte alarme de presiune **DA**
Volumul expirator / flux da	Volumul expirator / flux **DA**
Volumul minut, l/min da	Volumul minut, l/min **DA**
Concentrația de O2 Alarmă apnea da	Concentrația de O2 Alarmă apnea **DA**
Timp de răspuns, sec <30	Timp de răspuns, sec <30 **DA**
Concentrația de CO2 alarmă apnee da	Concentrația de CO2 Alarmă apnee **DA**
Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran	Monitorizare agent Tipul de agenți Halothan, isofluran, sevofluran, Enfluran, Desfluran **DA**
Auto indentificarea gazelor anestezice da	Auto indentificarea gazelor anestezice **DA**
Alarmă concentrare agent da	Alarmă concentrare agent **DA**
Determinarea și afișarea valorii MAC da	Determinarea și afișarea valorii MAC **DA**
spirometria da	Spirometrie **DA**
Modulul de gaze încorporat la mașina de anestezie da	Modulul de gaze încorporat la mașina de anestezie **DA**
determină concentrațiile de gaze: O2, CO2, agenți anestezici da	determină concentrațiile de gaze: O2, CO2, agenți anestezici **DA**
Celulă determinare O2 tip paramagnetic da	Celulă determinare O2 tip galvanică **DA**
Monitorul pentru afișarea funcțiilor vitale display ≥15", color TFT sau LCD da	Monitorul pentru afișarea funcțiilor vitale display Color TFT **DA diagonal 15 inch Model: B650 , GE Helathcare**
touch screen da	**Touch screen DA**
monitor dedicat vizualizării funcțiilor vitale da	monitor dedicat vizualizării funcțiilor vitale **DA**
braț de fixare a monitorului din laterală pe mașină de anestezie da	braț de fixare a monitorului din laterală pe mașină de anestezie **DA**
imprimantă termică încorporată da	imprimato termica incorporate **DA**
baterie internă reîncărcabilă da	baterie internă reîncărcabilă **DA**
interfață de cominicare cu altele da	interfață de cominicare cu altele **DA**
Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă da	Modulele hemodinamice incluse Electro-cardio-grama (ECG) frecvența cardiacă **DA**
traseul ECG da	traseul ECG **DA**
analiza și măsurarea segmentui ST da	analiza și măsurarea segmentui ST **DA**
determinarea cel puțin 20 de aritmii da	determinarea cel puțin 20 de aritmii **DA**
Puls-oximetria (SpO2) fotopletismografia da	Puls-oximetria (SpO2) fotopletismografia **DA**
valoarea SpO2 da	valoarea SpO2 **DA**
indicile de perfuzie da	indicile de perfuzie **DA**
Tensiune sanguină neinvazivă (NIBP) da	Tensiune sanguină neinvazivă (NIBP) **DA**
Respirația (impendanța transtoracică) da	Respirația (impendanța transtoracică) **DA**
Temperatura pe 2 canale da	Temperatura **DA**
Tensiune sanguină invazivă (IBP) pe 2 canale da	Tensiune sanguină invazivă (IBP) pe 2 canale **DA**
Modul de monitorizare BIS (bispectral index) sau modul de monitorizarea obiectiva a profunzimii blocului neuro-muscular intraanestezic (TOF/ NMT) da	Modul de monitorizare BIS (bispectral index) sau modul de monitorizarea obiectiva a profunzimii blocului neuro-muscular intraanestezic (TOF/ NMT) **DA**
Alarme prioritare 3	Alarme prioritare **3**
Tensiune de alimentare 220 V, 50 Hz	Tensiune de alimentare 220 V, 50 Hz **DA**
Prize auxiliare 220 v ≥ 3 buc da	Prize auxiliare 220V ≥ 3 buc **DA fi livrat cu filtru de retea.**
Baterie internă reîncărcabilă da	Baterie internă reîncărcabilă **DA**
autonomie de lucru ≥2h da	autonomie de lucru - 1- 2 h depinde de configuratie **DA pentru monitor**
Sertar pentru depozitare ≥ 3 buc da	Sertar pentru depozitare ≥ 3 buc **DA**
Frînă centralizată pentru fixarea aparatului da	Frînă centralizată pentru fixarea aparatului **DA**
Presiune de alimentare cu gaze 3.0 - 6 bar	Presiune de alimentare cu gaze 3.0 - 6 bar **DA**
Accesorii	Accesorii
Furtunul cu conector de conectare la sursa de aer comprimat 1 buc.	Furtunul cu conector de conectare la sursa de aer comprimat 1 buc. **DA DIN (hexagon)**
Furtunul cu conector de conectare la sursa de oxigen 1 buc.	Furtunul cu conector de conectare la sursa de oxigen 1 buc. **DA DIN (HEXAGON)**

Circuit de ventilare Adult, reutilizabil ≥ 2 set.	Circuit de ventilare Adult, reutilizabil - 2 set. **DA**
Plămîn de test Adult, reutilizabil ≥ 2 buc.	Plămîn de test Adult, reutilizabil - 2 buc. **DA**
Senzor de flux Reutilizabil ≥ 2 buc.	Senzor de flux Reutilizabil - 2 buc. **DA**
Filtru antibacterial Adult, unică utilizare ≥ 200 buc.	Filtru antibacterial Adult, unică utilizare - 200 buc. **DA**
Accesorii modul de gaz Adult ≥ 2 set.	Accesorii modul de gaz Adult - 2 set. **DA**
Cablu ECG Adult, reutilizabil 5 fire ≥ 2 buc.	Cablu ECG Adult, reutilizabil 5 fire - 1 buc **DA**
Senzor ECG Adult, unica utilizare ≥ 100 buc.	Sensor Electrozi ECG Adult, unica utilizare - 100 buc. **DA**
Senzor SpO2 Adult, reutilizabil ≥ 2 Buc.	Senzor SpO2 Adult, reutilizabil - 2 Buc. **DA**
Manșete NIBP Adult, reutilizabilă ≥ 2 buc.	Manșete NIBP Adult, reutilizabilă - 2 buc. **DA**
Adult mare, reutilizabilă ≥ 2 buc.	Adult mare, reutilizabilă - 2 buc. **DA**
Senzor de temperatură Adult, reutilizabil ≥ 2 buc.	Senzor de temperatură Adult, reutilizabil - 2 buc. **DA**
Cablu de interconectare senzor IBP Adult, reutilizabil ≥ 1 buc.	Cablu de interconectare senzor IBP Adult, reutilizabil -1 buc. bDA
Senzor IBP Adult, unica utilizare ≥ 10 buc.	Senzor IBP Adult, unica utilizare 10 buc. **DA**
Accesorii necesare de functionare a modulului BIS sau TOF/ NMT Accesorii pentru Adult ≥ 5 buc.	Accesorii necesare de functionare a modulului BIS sau TOF/ NMT Accesorii pentru Adult - 5 buc. **DA**

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

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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

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Lionel DREUX
Certification Director

GE Healthcare

B105 and B125

Patient Monitors

Simple. Flexible. Reliable.

gehealthcare.com

Presenting GE Healthcare's **B105** and **B125** Patient Monitors

The B1X5 Patient Monitors are **simple, flexible,** and **reliable** monitors — delivering parameter technology that you can trust.

With constant improvement in medical technologies, the need for better quality healthcare is on the rise. However, care providers continue to face a wide range of operational and clinical challenges that often get in the way of accurate diagnoses.

That is why we at GE Healthcare go the extra mile to provide a holistic solution that transforms your monitoring capabilities and your performance.

Designed with clinicians for clinicians, the B105 and B125 Patient Monitors are engineered from the ground-up to meet your clinical requirements. These advanced Patient Monitors are equipped with parameter technologies and dependable features that empower you to monitor and diagnose with greater confidence.

Simple and intuitive
for your busy staff

Flexible
for your diverse care area and acuity needs

Reliable and robust
technology for challenging work environments

Clinical **performance** you can **trust**

With over 40 years of innovation in parameter technology, GE Healthcare has been at the forefront of continuous research and development to build solutions that help you in your daily work. Our diversified monitoring portfolio features cutting-edge products equipped with advanced technologies such as:

DINAMAP™ SuperSTAT™ NIBP

Proven NIBP technology, utilizing GE-patented “smart cuff” pressure control to improve measurement time, patient comfort, and artifact rejection, all while retaining the classic DINAMAP accuracy.

EK Pro arrhythmia algorithm

Simultaneous four-lead analysis helps optimize the detection and analysis of arrhythmias, helping ensure no cardiac event goes unnoticed. The algorithm helps distinguish noise and artifacts from true beats, reduces false alarms, and enables uninterrupted ECG monitoring even in the event of a single electrode failure.

TruSignal™ SpO_2

Ability to reject motion artifacts and detection even at low perfusion.

$EtCO_2$

CO_2 side stream measurement done at the patient’s airway.

1975	First bedside capnometer
1976	DINAMAP NIBP invented, earns 50 patents over its lifecycle
1980	First 12SL: ECG Analysis
1982	NeuroMuscular Transmission monitoring
1983	Anesthesia monitoring with automatic AA indentification
1984	First simultaneous multi-lead arrhythmia analysis (EK-Pro)
	First to place ST-segment monitoring capabilities in a surgical patient monitor
1985	First paramagnetic O_2 measurement
1986	Continuous metabolic measurement
1991	Patient Spirometry (D-lite™)
1993	12-lead ECG on a bedside monitor
1996	12-lead ST trending on a bedside
1999	4-channel EEG/AEP on a bedside module
2003	Introduction of Entropy™
2004	EK-Pro arrhythmia analysis to include P-wave recognition and A Fib detection
2009	Surgical Pleth Index (SPI)*
2012	Miniaturized respiratory gas module
2017	B105 and B125 Patient Monitors

*SPI is not cleared by US FDA.

All technologies may not be available in all markets. All technologies may not be available in B1X5 monitors.

Simplicity you can **trust**

With improved workflow and efficient operations, you can now elevate your monitoring capabilities to the next level.

Simple and efficient workflow

Designed with an intuitive and clever user-interface, these Patient Monitors allow you to lower training time and enhance monitoring capabilities with:

- Seven pre-configured workflow settings for simple set-up
- Auto-snapshot of most critical alarms
- Alarm reporting options for better alarm management and instant care in cases of arrhythmia, high/low blood pressure, and ECG-lead detachment
- Convenient screen lock button for easy cleaning, maintenance, and intra-hospital transport

Simple user-interface

Designed to facilitate improved operations, the Patient Monitors' intuitive user-interface allows for continuous monitoring with:

- Capacitive touchscreen for fast response and enhanced user experience
- Uninterrupted display of primary ECG-lead waveform and other vital signs across settings
- Choice of numerical or continuous waveform monitoring
- Large numeric mode that enables critical parameter visibility even up to 4 meters

Flexible clinical abilities

The B105 and B125 Patient Monitors equip you with clinical versatility across different care areas with features such as:

- ST Segment and full Arrhythmia analysis, SpO_2, NIBP, IBP, RR, ECG, $EtCO_2$
- Additional parameter slot for upgradability and scalability for changing clinical needs

Flexible operations

Advanced technologies allowing you to continuously monitor almost anywhere in the hospital in various situations and workflows.

- Wireless connectivity for enhanced mobility across the hospital
- Centralized alarm management through GE CARESCAPE™ Central Station
- EMR connectivity through HL7® outbound protocol
- Optional thermal printer and additional screen for flexible usage

Flexible connectivity

The B105 and B125 Patient Monitors can seamlessly connect with GE Healthcare CARESCAPE network environment to give you the complete picture on a single robust platform.

- Flexibility to share parameter modules and accessories across GE Patient Monitors*
- Flexibility to view parameters nearly anywhere, anytime**

Flexibility you can **trust**

With flexible operations and versatile clinical capabilities, you can now deliver optimal care almost anytime and anywhere.

* CARESCAPE, B20, and B40 Patient Monitor **Via Mobile Care Web Viewer

Reliability you can **trust**

With reliable monitoring capabilities, maintenance, and service, you can provide the high standard of care that your patient needs.

Reliable technology

Built with proven technologies that facilitate better performance and greater data security, the B105 and B125 Patient Monitors help you collect accurate patient information with low risk of security breaches. Now, care with confidence with the support of:

- Upgraded cyber security by implementing WPA-Enterprise and WPA2-Enterprise for better data protection
- Latched alarm system for dependable monitoring
- Fast roaming across wireless networks within the hospital for data security
- Capacitive touchscreen tested for up to one million operations

Reliable performance

Designed to enable excellent monitoring even in harsh conditions, this range of Patient Monitors allows you to capture and store critical information while providing excellent care with:

- Three-hour battery life to enable uninterrupted monitoring
- Stable performance even in tough environmental conditions (+5°C to +40°C)
- Advanced platform that records and stores up to 168 hours of monitoring activity across all parameters
- Advanced algorithm for accurate analyses of up to 16 types of arrhythmia including A Fib

Reliable service

The B105 and B125 Patient Monitors are an extension of our mission to serve customers when and where they need us. You can now rely on our support for queries or on-site assistance with dependable service for consistent and optimal performance.

GE Healthcare B105 and B125 Patient Monitors — a holistic solution that transforms your monitoring capabilities and your performance.

Accurately and reliably monitor clinical parameters

Easily cater to diverse care areas and acuity needs

Conveniently operate an intuitive solution

Effortlessly learn the functionalities without extensive training

Accurately monitor and diagnose

Imagination at work

Product may not be available in all countries and regions. Full product technical specification is available upon request. Contact a GE Healthcare Representative for more information. Please visit www.gehealthcare.com/promotional-locations.

Data subject to change.

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JB47001XX 3/16

B125 Patient Monitor

Simple. Flexible. Reliable.

The B125 patient monitor from GE Healthcare delivers clinical performance you can trust. It is simple and intuitive for busy caregivers, flexible for diverse care areas and acuity needs, and reliable for challenging work environments.

Parameter excellence

The B125 Monitor is designed with advanced parameter technologies for accurate and reliable patient monitoring:

- EK-Pro arrhythmia analysis
- DINAMAP™ SuperSTAT non-invasive blood pressure
- TruSignal™ enhanced SpO_2 saturation monitoring. Also available with Nellcor® OxiMax® SpO_2 or Masimo® SET® SpO_2 algorithms
- GE $EtCO_2$ sidestream measurement
- Comprehensive package for neonatal[1] measurements

Simple & intuitive user interface

The B125 Monitor makes it easy to acquire, monitor and interpret patient data to support timely decision-making:

- Seven pre-configured workflow settings
- Choice of numerical or continuous waveform monitoring
- Big numeric view capability
- Capacitive touch screen

Flexible for diverse care areas & acuity needs

Designed with advanced technologies to support connectivity & operations across hospital enterprise.

- Connectivity to GE CARESCAPE™ networks and Mobile Care Web Viewer
- Flexibility to share parameter modules and accessories across other GE monitors
- Advanced applications such as ST Segment and Full Arrhythmia

Robust & reliable

Its rugged & robust design stands up to harsh environments and the everyday wear-and-tear of busy care areas.

- Upgraded cyber security
- Stable performance in tough environmental conditions
- 75 cm height drop test for main unit
- Three hour battery

[1] Impedance respiration is intended for use with only adult and pediatric patients in United States, Argentina, Guam, Puerto Rico, Saint Croix and Saint Thomas. CO_2 measurement through E-miniC Module is intended for use with patients weighing over 5kg (11 lb) only.

Technical specifications

Display

Size	12.1 in (diagonal)
Resolution:	1280 x 800 pixels (WVGA)
Number of waveforms	Up to 6
Display layout and colors	User-configurable
Controls	Capacitive Touch screen & Trim Knob™ control and hard keys (standard)

Parameters and modules

Parameters	Modules[2]
ECG	Configured hemodynamic module
Resp	
SpO_2	
NIBP	
Temp	
2 channel InvBP	
Sidestream CO_2	E-miniC

ECG

Leads available	3-lead configuration: I, II, III 5-lead configuration: I, II, III, aVR, aVL, aVF and V
Sweep speed	12.5, 25 or 50 mm/s
Gain range	0.5x, 1x, 2x and 4x
Heart rate accuracy	30 to 300 bpm, ±5% or ±5 bpm, whichever is greater

Bandwidth

50/60 Hz power supply	Monitor: 0.5 to 40 Hz ST: 0.05 to 40 Hz Diagnostic: 0.05 to 145 Hz
Pacemaker detection	Range: 2 to 700 mV Pulse width: 0.5 to 2 ms
Arrhythmia analysis	Asystole, V Fib / V Tach, V Tach, VT>2 R on T, V Brady, Couplet, Bigeminy, Accelerated Ventricular arrhythmia, Multifocal PVCs, A Fib, Missing beat, Pause, Tachy, Brady, Trigeminy
ST segment analysis	Numeric range: -9 to +9 mm (-0.9 to +0.9 mV) Accuracy: ±0.2 mm or ±10%, whichever is greater, within the measurement range of -8 to 8 mm Numeric resolution: 0.1 mm (0.01 mV) ST Trends: Up to 168h

Impedance respiration[3]

Range	Adult/pediatric: 4 to 120 resp/min Neonate[3]: 4 to 180 resp/min
Accuracy	±5% or ±5 resp/min, whichever is greater
Gain range	0.1 to 5 cm/Ohm

SpO_2

TruSignal SpO_2

Measurement range

Pulse oximetry	1 to 100%
Pulse rate	30 to 250 bpm

Measurement accuracy

Saturation	Without motion-adult/pediatric Finger sensor: 70 to 100% ±2% Without motion-neonate[3]: 70 to 100% ±3% With motion-adult/pediatric/neonate[3]: 70 to 100% ±3% Low perfusion-adult/pediatric: 70 to 100% ±3% (1~69% unspecified)
Pulse Rate	Without motion: ±2 bpm (Adult/Pediatric/Neonatal[3])

[2] Refer to B125 User's Manual for more information.

[3] Impedance respiration is intended for use with only adult and pediatric patients in United States, Argentina, Guam, Puerto Rico, Saint Croix and Saint Thomas. CO_2 measurement through E-miniC Module is intended for use with patients weighing over 5kg (11 lb) only.

Nellcor OxiMax

Measurement range

Pulse oximetry	1 to 100%
Pulse rate	20 to 250 bpm

Measurement accuracy

Saturation	Adult: 70 to 100% ±2% Neo: 70 to 100% ±3% Low perfusion: 70 to 100% ±2% 0~69% unspecified
Pulse Rate	±3 bpm

Masimo SET

Measurement range

Pulse oximetry	1 to 100%
Pulse rate	25 to 240 bpm

Measurement accuracy

Saturation	Without motion-adult/pediatric: 70 to 100% ±2% Without motion-neonate[4]: 70 to 100% ±3% With motion-adult/pediatric/ neonate6: 70 to 100% ±3% Low perfusion: 70 to 100% ±2% (0~69% unspecified)
Pulse rate	Without motion: ±3 bpm With motion: ±5 bpm

NIBP

Measurement technique	Oscillometric with step deflation
Modes	Manual, automatic and stat

NIBP Measurement ranges

Systolic	Adult/Pediatric: 30 to 290 mmHg Neonate[4]: 30 to 140 mmHg
MAP	Adult/Pediatric: 20 to 260 mmHg Neonate[4]: 20 to 125 mmHg
Diastolic	Adult/Pediatric: 10 to 220 mmHg Neonate[4]: 10 to 110 mmHg
Accuracy	Meets AAMI ISO81060-2 and IEC 80601-2-30
Default initial inflation pressure	Adult/Pediatric: 135 ±15 mmHg Neonate[4]: 100 ±15 mmHg
Maximum determination time	Adult/Pediatric: 2 min Neonate[4]: 85 s
Over pressure monitor	Adult/Pediatric: 294 ±6 to 330 mmHg Neonate[4]: 147 ±3 to 165 mmHg

Invasive blood pressure

Measurement range	-40 to 320 mmHg (-5.3 to 42.7 kPa)
Measurement accuracy	±5% or ±2 mmHg, whichever is greater
Frequency response	4 to 22 Hz
Transducer sensitivity	5 µV/V/mmHg

Temperature

Numerical display	T1, T2, T2-T1
Measurement range	10 to 45°C (50 to 113°F)
Measurement accuracy	±0.1°C without probe
Display resolution	0.1°C
Probe	YSI probes recommended by GE Healthcare

Networking

Compatibility	CARESCAPE Network
Wi-Fi connectivity[5]	IEEE 802.11a/b/g/n
Wi-Fi security[5]	WPA-Personal; WPA2-Personal; WPA-Enterprise; WPA2-Enterprise
Connectivity to EMR	HL7® outbound protocol direct through the CARESCAPE Gateway

I/O connectors

RS-232 computer serial output, Defibrillation synch, Nurse call, USB port, additional display connector

Mounting

GCX compatible

Integrated carrying handle

[4] Impedance respiration is intended for use with only adult and pediatric patients in United States, Argentina, Guam, Puerto Rico, Saint Croix and Saint Thomas. CO_2 measurement through E-miniC Module is intended for use with patients weighing over 5kg (11 lb) only.

[5] Available in registered regions only.

Paper Recorder

Method	Thermal dot array
Horizontal resolutions	24 dots/mm (600 dpi)
Vertical resolution	8 dots/mm (200 dpi)
Waveforms	Selectable 1, 2, or 3 waveforms
Numerics	HR, SpO_2, NIBP, IBP1, IBP2, $EtCO_2$/$FiCO_2$, T1, T2, Resp
Graphical trend printout	HR, ST, IBP1, IBP2, NIBP, SpO_2, Pleth, CO_2, Resp, T1+T2
Paper width	50 mm, printing width 48 mm
Paper speed	6.25, 12.5, 25 mm/s

Performance specifications

Alarms

Priority	High, Medium, Low and Message
Notification	Audible and visual
Setting	Default and individual
Visual alarm notification	Red, yellow, cyan Audio silence message General alarm message
Audio pause	2 min
Adjustment	Adjustment page

Trends

Graphical	All parameters, selectable time scales from 20 min to 168h
Numerical	All parameters, sampling according to time setting or after NIBP determination
Snapshot	Up to 200 snapshots Manual or alarm triggered
OCRG trend[6]	Real time or snapshot Neonate mode only
Trend cursor	In graphical trend

Environmental specifications

Operating conditions

Temperature	5 to 40°C (41 to 104°F)
Relative humidity	20 to 90% noncondensing
Atmospheric pressure	700 to 1060 hPa (525 to 795 mmHg)

Storage and transport conditions

Temperature	-20 to 60°C (-4 to 140°F)
Relative humidity	10 to 90% noncondensing
Atmospheric pressure	700 to 1060 hPa (525 to 795 mmHg)

Power specifications

AC input	100 to 240V ±10%, 50/60 Hz, 150VA
Protection	Class I
Battery	Exchangeable lithium-ion, 1 pcs max
Charging time	< 4 h to 90% capacity
Run time	> 3 h

Physical specifications

Dimensions (H x W x D)	Without extension rack: 280 x 317 x 150 mm (11.0 x 12.5 x 5.9 in)
Weight	4.3 kg (9.5 lb) w battery
Ingress protection	IPX1

Certifications

IEC 60601-1 passed

CE marking according to Council Directive 93/42/EEC concerning medical devices amended by 2007/47/EC

[6] Neonate Resp is not available for USA and 510k required countries.

Imagination at work

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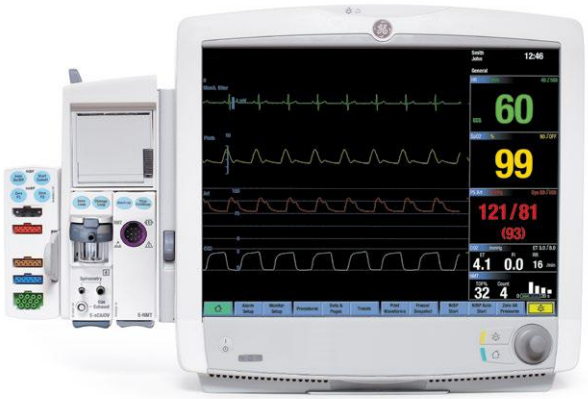
DOC1937971 Rev. 3 4/17

GE Healthcare

CARESCAPE Monitor B650

Efficiency built in.



The CARESCAPE™ Monitor B650 can help you manage your patient flow by getting you the right clinical information, when and where you need it. Its intuitive design makes it easy to use for all staff experience levels, and upgradeability protects your long-term system investments.

Providing clinical excellence, dependable data continuity and integration

- Combines the best of Marquette™ Electronics and Datex-Ohmeda™ legacies into one platform
- Delta pressure (SPV and PPV) monitoring capability may help the clinician in guiding fluid management
- CARESCAPE Patient Data Module provides consistent hemodynamic measurement during intra-hospital transport and also transfers trend data
- Innovative algorithms aid in accurate diagnoses, including GE EK-Pro, GE DINAMAP™ non-invasive blood pressure, and 12 SL™ diagnostic ECG with direct 2-way MUSE™ ECG communication
- Comprehensive respiratory monitoring ranging from standard CO_2 to optional gas exchange and metabolic monitoring
- Various parameters can help you assess the adequacy of anesthesia in the OR, and give insight to patients' readiness for ventilator weaning in the ICU
- Connectivity with the CARESCAPE Gateway enables communications to EMR systems through standard HL7® protocol
- Combination monitoring capability enables mobile patients to be monitored

Compact, flexible, intuitive design

- Pages & Profiles functionality with dedicated software for OR, PACU, ICU, NICU and ED care areas can increase flexibility and workflow efficiency by configuring monitors to unit standards and patient populations
- User-controlled views, from eight to 14 waveforms with overlays and insets, allow for flexibility and customization, based on caregivers' and patients' needs
- Exceptional alarm functionality, including Auto View on Alarm which automatically shares clinically significant alarms within and across care units, also provides flexibility in setting alarm limits and priorities which may help optimize your workflow and reduce alarm fatigue
- Integrated USB ports allow for a keyboard, mouse, barcode readers and other data entry device attachment
- Compact design with pivoting frame fits ergonomically into different environments and allows for customizing with multiparameter modules and other options

Protecting long-term investments

- Backwards compatible with many existing Marquette Electronics and Datex-Ohmeda components
- Structured upgrade programs can lower costs of ownership
- Remote service through InSite™ ExC provides updates and predictive maintenance

Technical specifications

Display

Size	15 in (diagonal)
Type	Active matrix color TFT LCD
Resolution	1024 x 768 pixels (XGA)
Number of traces	8 individual, up to 14 with overlays and insets
Sweep speed	0.625, 6.25, 12.5, 25, 50 mm/sec
Configuration	Automatic configuration according to parameter availability. Manual configuration with up to 8 user-configurable profiles for care-specific configurations, and up to 6 user-configurable display pages for each profile

Controls

Touch screen	Resistive technology
Keys	3 standard hard keys: ON/Standby, Home, Pause Audio Alarm 11 additional touchscreen keys: Trends, Monitor Setup, Data & Pages, Alarm Setup, Procedures, Print Waveforms, Freeze/ Snapshot, NIBP Auto, NIBP Start/ stop, Parameters, Zero All Pressures
Remote control	Ordered separately

Pivoting module frame

Features	Can be pivoted to a locked closed position, locked to an open 45° angle, or locked to a 90° open position. Support for CARESCAPE Patient Data Module or Patient Side Module
Options	Two optional E-module slots and optional recorder

Parameters and modules

Parameters	Patient Side Module (E-PSM, E-PSMP)	CARESCAPE Patient Data Module (PDM)
ECG	3, 5, 6 and 10 leadwires	3, 5, 6 and 10 leadwires
SpO_2	GE SpO_2	Masimo SET®, Nellcor OxiMax®
NIBP	GE	GE DINAMAP SuperSTAT algorithm
InvBP	0 or 2	0 or 4
Temp	2	2, Optional with C.O.
Cardiac output	-	Optional with temperature

Parameters	E-Modules[1]
Multi parameter modules	
InvBP & Temp	E-P[2], E-PP[2], E-PT
SvO_2 & C.O.	E-COP, E-COPSv
Single parameter modules	
SpO_2	E-NSATX, E-MASIMO
NMT	E-NMT
CCO	E-PiCCO
EEG	E-EEG
BIS	E-BIS
Entropy™	E-ENTROPY
Respiratory modules	
Sidestream CO_2	E-miniC
Sidestream CO_2 & O_2	Single-width[3]: E-sCO, E-sCOV
Sidestream CO_2, O_2, Agents & N_2O	Single-width[3]: E-sCAiO, E-sCAiOV, E-sCAiOE, E-sCAiOVE, E-sCAiOVX
Patient Spirometry	Single-width[3]: E-sCOV, E-sCOVX, E-sCAiOV, E-sCAiOVE, E-sCAiOVX
Gas exchange or metabolics	E-sCOVX, E-sCAiOVX

Parameter modules are ordered separately.

NOTE: For a complete list of compatible devices, please refer to the CARESCAPE Modular Monitors Supplemental Information Manual Software version 2.

1 Acronyms for the parameters measured are as follows: P=invasive pressure; R=respiration rate, E=ECG; S=SpO_2; T=temperature; N=NIBP; C=CO_2 and N_2O; Ai=anesthetic agents and nitrous oxide with agent identification; O=O2; V=Patient Spirometry; X=gas exchange; s=single-width

2 Module measures invasive blood pressure only

3 Displayed data (including but not limited to TV, MV, RR, Raw and N_2O) trends and alarms may vary depending on the host device. Specifications listed represent the capabilities of the modules. Always check the host device's User Manual for additional information.

Software version and options

Main software	ESP v2 Care-area specific software packages to optimize workflows: OR, PACU, ICU, ED, NICU
Other software options	Extended software options specific to each main software package

Upgradable with the CARESCAPE Upgrade Program

Networking

Compatibility	CARESCAPE Network with peer-to-peer communication S/5 Network with iCentral v5.1
Features	Centralized viewing and remote alarm management with bed-to-bed viewing and AVOA functionality
Network type	LAN, WLAN (optional)
WLAN communication protocol (optional)	IEEE 802.11a/b/g

I/O connectors

Ethernet	1 RJ45 for monitor network 3 optional RJ45 for HIS, service and Unity Network™ ID
E-Port	1 optional DB9F, for CARESCAPE Patient Data Module
Display	1 DVI out (VGA with adapter)
USB port	2 USB 2.0 2 optional USB 2.0

Mounting

GCX compatible

FM quick-mount compatible

Integrated carrying handle

Paper recorder (optional, built-in)

Method	Thermal dot array
Horizontal resolutions	24 dots/mm (600 dpi) @ 25 mm/sec
Vertical resolution	8 dots/mm (200 dpi)
Number of waveform channels	Four
Paper width	50 mm (2 in)
Paper length	30 m (100 ft)
Paper speed	1, 5, 10, 12.5 25 and 50 mm/sec

Performance specifications

Alarms

Categories	Patient status and system status
Priority	High, Medium, Low, Escalating and Informational In accordance with IEC 60601-1-8
Notification	Audible and visual
Setting	Default and individual
Visual alarm notification	Red, yellow, cyan
Audio pause	2 or 5 minutes
Volume	79 dB(A) (max) measured at 1m, high priority alarm

Power specifications

Power supply

Universal input voltage range	100 to 240 Vac +/-10%, 50/60 Hz
Power consumption	140 VA (max)
Protection class	Class I
Grounding	Hospital grade
Cooling	Natural convection – no fans

Battery (optional)

Type	Exchangeable Lithium-Ion
Number of batteries	1
Voltage	11.1 V (nominal)
Capacity	6.21Ah (typical)
Charge time (to 90% of full capacity)	2 to 3 hours, depending on configuration
Run time	1 to 2 hours, depending on configuration
Battery life	150 cycles to 80% capacity

Environmental specifications

Operating conditions

Temperature	10°C to 35°C (50°F to 95°F)
Relative humidity	10% to 90% non-condensing

Storage conditions

Temperature	-20°C to 60°C (-4°F to 140°F)
Relative humidity	10% to 90% non-condensing

Physical specifications

Dimensions (H x W x D)	36 x 37 x 22 cm (14.2 x 14.6 x 8.67 in)
Weight	9.8 kg (21.6 lb) without modules (incl. battery, recorder, E-module frame)
Patient Side Module	+ 0.6 kg (1.3 lb)
CARESCAPE Patient Data Module	+ 1.1 to 1.3 kg (2.4 to 2.9 lb)
E-modules	+ 0.3 to 1.6 kg (0.6 to 3.5 lb)

Warranty

One year.

Imagination at work

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GE Healthcare

CARESCAPE Monitor B650
Connecting intelligence and care.

Accurate, efficient monitoring every step of the way.

Patient status can change quickly. You need monitoring accuracy and efficiency that can keep up. Whether your patients are in the ICU, OR, CCU, PACU, or NICU, the CARESCAPE* Monitor B650 provides accurate and convenient access to critical data to help you make more informed care decisions.

Clinical excellence where you need it most.

Better data enables better outcomes. The CARESCAPE Monitor B650 supports clinical excellence with proven, comprehensive GE Healthcare parameters, including dual $Sp0_2$, continuous metabolics, and Patient Spirometry. The system also supports cardiac diagnostic excellence with two-way communication with the MUSE* ECG management system, and GE's unique Adequacy of Anesthesia concept for tailored anesthesia.

Flexible alarm options help support smart workflow and a more restful patient environment, with alarm management settings that can be customized to meet specific care area needs.

Flexibility at every point of care.

The CARESCAPE Monitor B650 provides seamless integration with GE anesthesia devices, allowing remote on/off function to begin monitoring at the anesthesia station. Combination monitoring with ApexPro* telemetry allows early mobility of patients to help reduce length of stay. The monitor can accommodate two single-width E-modules, as well as a multi-parameter module for comprehensive, customized monitoring.

Throughout care, full data continuity with the CARESCAPE Patient Data Module supports patient mobility with uninterrupted flow of clinical intelligence virtually anywhere. The system also gives you the flexibility of seamlessly capturing patient data directly into HIS/EMR. The wireless operating option supports data connectivity wherever it is needed.

For more information about the CARESCAPE Monitor B650 and the entire portfolio of CARESCAPE modular monitors, please contact your GE Healthcare representative.

Designed to help you focus on patients.
The CARESCAPE Monitor B650 delivers data via a configurable, user-friendly 15-inch display. The pivotal frame allows full access to the patient, with better cable management as patients transition from high to low acuity. So, at any stage of care, you can focus on the patient instead of the technology.

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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imagination at work

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GE Healthcare

Simple. Smart. Agile.

Carestation™ 650

Carestation 650 is a reliable and agile anaesthesia solution with smart tools to help simplify your daily work and manage non-ordinary events.

Simple.

Ease of use, easy to learn.

Carestation 650 intelligently packages and connects monitoring devices, innovative parameters and advanced ventilation tools in a single, integrated system. A rotating clinical staff in a fast paced OR requires minimal product training in order to focus more time on the patient. Perioperative care is increasingly complex with more sick patients, requiring more tasks to accomplish in the same time and with the same resources in a highly regulated environment.

Carestation 650 is simply familiar and helps you to reduce part of this complexity with comfort.

"Reducing reliance on human beings by standardizing and simplifying clinical processes with decision support and technology is a powerful way to increasing process reliability.[1]

Intuitive Navigation

15 " screen with quick touch controls. Direct access to operations without menu overlap. Highly configurable screen. Simple access to specific OR tasks re-grouped in a dedicated menu.

Unified User Interface

Carestation 650 features a unified CARESCAPE user interface between ventilator and patient monitors to flatten the learning curve and help reduce the risk of errors.

APL and switch

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

Interactive system check

The daily checkout process is as simple and quick as it is thorough. It is interactive with traffic light step-by-step on screen guidance.

Breathing circuit cassette

Breathing circuit that can be quickly dismantled without the use of tools. Minimal components to clean, to meet high hygienic standards.

A clinical study shows that inadequate alarms, improvised oxygen delivery systems and misdiagnosis or treatment of breathing circuit events can contribute to severe patient injuries.[2]

Smart.

Intelligent tools to give you more confidence in your daily work.

The industry role is fundamental to help prevent device misuse. GE is committed to building innovative anaesthesia solutions that balance user interface design with intelligent tools to help clinicians prevent misuse and medical errors. The best way to demonstrate effectiveness in preventing errors is to not let them happen.

Carestation 650 offers smart tools to simplify daily work and help ensure effective reactions to non-ordinary events. When seconds count, active mechanisms can help clinicians better manage non-ordinary events.

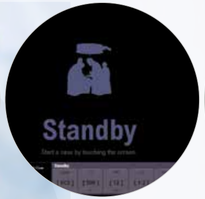
Clinical alarm with inadequate configuration practices is the TOP Health Technology Hazards on the 2014 annual report published by ECRI Institute. Several death and severe patients harm may be prevented with more effective alarm management.[3]

Easy alarm management

Direct access to favourite Primary Alarms limits. Auto Alarm Limits software may help reduce alarm fatigue, allowing you to quickly review and accept tailored CO2 and MV/TV alarm limits real-time within a case.

Intelligent lighting controls

Automatic lightning on all flow controls provide information on the active ones. A clear indicator on the next step to follow can help avoid incorrect maneuvers.



Clear active case notifications

Automatic patient case activation when switching from manual to automatic ventilation. Visible and clear stand-by screen notification.

ACGO protective mechanism

ACGO port has a protective lid to avoid misconnection. By switching on the ACGO, a dedicated screen is automatically activated to visually reinforce which port is in use. This visible alert will remain until the ACGO is on.

Pause Gas flow

A workflow solution that simplifies temporary circuit disconnects. One button temporarily stops all gas flows and suspends alarms, agent delivery and ventilation for up to one minute allowing you to focus on the patient.

Scavenging alert

An alarm with a notification on the screen alerts the staff when scavenging gas flow is out of range. It will help detect incorrect gas evacuation.

Making environment less complicated can offset some of the potential hazards to patient outcome.[4]

Agile.

Optimizing the workspace.

Designed with essential flexibility in mind, the Carestation 650 features cutting-edge technology and head-turning design in a compact and transport-friendly system that can go where you need it.

In the operating theater world that keeps getting smaller Carestation 650 precisely meets the space constraints needed to stay nice and roomy. It is all about configuring the Carestation to fit your space and meet your team's needs comfortably.

Wall mount system
(Carestation 650c)

Pendant system
(Carestation 650c)

Flexible patient monitor mountings

Multiple choices of patient monitors mounting within rotating and tilting display arm to allow optimized visualization

Variety of customizable supports

Bars and supports for additional devices and accessories to keep lines and cables tidy in place.

Workspace optimization

Great work surfaces, additional flip desk. Ample drawers. Bi-level surface illumination.

Convenient mobility

Central brake and back wheels brakes to ensure stability. In built cable pusher to protect patient cables.

Flexible options that grow...

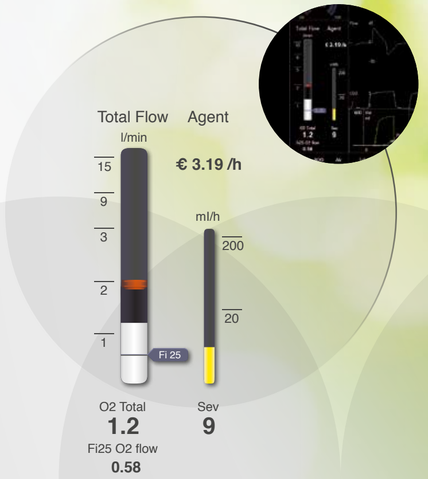
Low flow. High impact.

ecoFLOW

Clinicians skilled in the practice of low and minimal flow anesthesia delivery understand that sometimes less is more. That's why we developed ecoFLOW, an efficient anesthesia delivery technology that provides visual guidance to help you maintain the desired inspired oxygen concentration and identify unnecessarily high fresh gas flow rates.

ecoFLOW technology

A new way to look at flow tubes to help you ensure your inspired oxygen target settings are achieved.
The illustration shows flows above the Fi25 target as potential waste gas or excess to the patient's consumption. Whenever fresh gas flow exceeds the patient's requirement, gases enter the scavenging system and, ultimately, contaminate the atmosphere.



A true eco system. Economical and ecological.

Anesthetic agents are not only costly, but scientific evidence suggests that excess inhaled agents released into the atmosphere have the potential to affect the environment.[5] Offered on the Carestation 650, ecoFLOW may have a positive impact on the environment when agent waste gases are reduced.

Patient

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

Economical

Anesthetic agents are the biggest ongoing expense associated with anesthesia units. The ecoFLOW option offers cost savings through more efficient utilization of inhaled anesthetics.[6]

Ecological

By choosing a low flow practice, the environmental impact of anesthetic vapors and gases can be minimized to help reduce the impact of these greenhouse gases.

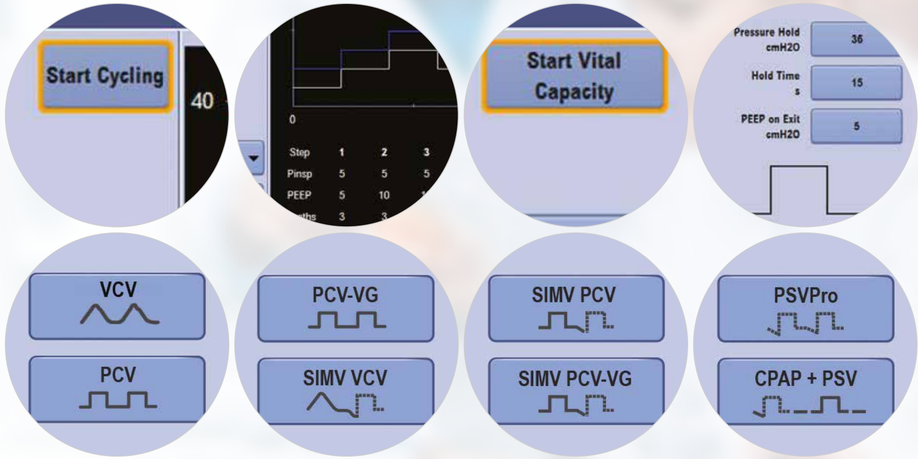
... with you as your needs change

Lung Protection

Software-enabled tools help simplify your workload. Vital Capacity and Cycling Procedures help automate repetitive tasks used during lung ventilation procedures.

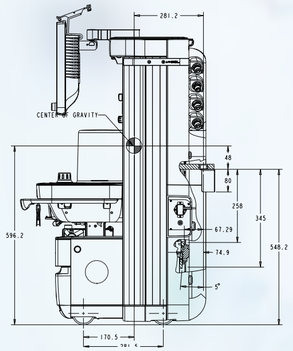
Advanced ventilation – neonate to adult

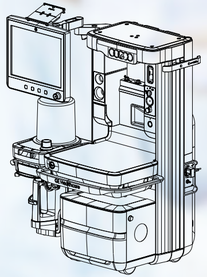
Healthcare is more complex than ever and your anesthesia system needs to adapt to suit a wide range of patients. Our electronic flow valve technology offers precise flow sensor sensitivity for volumes as low as 5 mL in PCV mode to help you deliver with confidence.

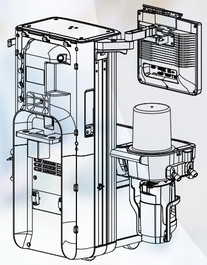


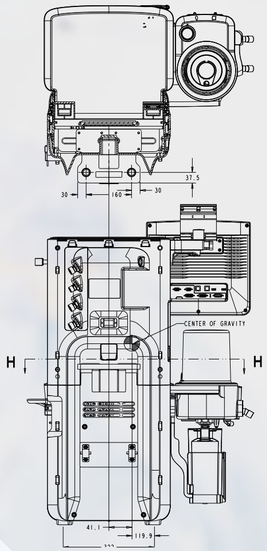
Leveraging expertise of the GE Perioperative Global Design team to anticipate future demands

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 650 marries elegant and functional design with digital technologies that anticipate future user demands — instilling confidence in an uncertain and evolving healthcare environment.









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

Ventilation expertise from GE Global Anesthesia

Patient Monitoring and Parameter Expertise

Reliable.

Making better possible for over a century.

20,000 Hours of reliability and endurance testing – equal to over 8 million simulated cases[7].

500,000+ Hardware component cycles

17,000,000+ Software actions stress test

-60° to +120° C Extreme temperature testing

Rigorous interference and shock testing

Stability and tip testing under harsh conditions

Industry-leading Lean Six Sigma manufacturing

120,000,000+ Flow sensor tests

1,000,000,000+ Flow valve cycles

250,000+ Hardware and software reboot cycles

Every single detail of the Carestation 650 has been in the center of rigorous engineering actions for development and verification. This has involved systematic design rigor, reviews, and the implementation of reliability growth methods like stressing and testing software and hardware to emulate extreme operational conditions.

1 Essentials of Patient Safety, European Society of Anaesthesiology (ESA 2013) http://html.esahq.org/patientsafetykit/resources/downloads/01_Basics/Essentials-of-Patient-Safety-Ch-Vincent.

2 Mehta SP, Eisenkraft JB, Posner KL, Domino KB, Patient injuries from anesthesia gas delivery equipment: a closed claims update. Anesthesiology. 2013 Oct;119(4):788-95. doi: 10.1097/ALN.0b013e3182a10b5e.

3 ECRI report 2014.

4 Ronnie J. Glavin, "Best Practice & Research Clinical Anaesthesiology 2011 193-206.

5 There are several online resources available to learn more about the environmental impact of anesthetic agents including:

General Anesthetic Gases and the Global Environment (author Yumiko Ishizawa, M.D., MPH, Ph.D.) Anesth. Analg. September, 2010

Global Warming Potential of Inhaled Anesthetics: Application to Clinical Use

(authors: Susan M. Ryan, M.D., Ph.D., and Claus J. Nielsen, CSc) International Society for Anaesthetic Pharmacology July 2010 www.anesthesia-anelgesia.org

6 ECRI Institute Healthcare Product Comparison: Anesthesia Units. 2011.

7 GE internal verification and validation testing report 2015. DOC1677887.

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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.

GE Imagination at work

Not approved in all markets. Not cleared or approved by the US FDA.
Not for sale in the United States.

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JB31805XE

This document applies to Carestation 650 A1 and Carestation 650c A1

Carestation™ 650

Simple. Smart. Agile.

Carestation 650 is a reliable and agile anaesthesia solution with smart tools to help simplify your daily work and manage non-ordinary events.

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

Not 510K cleared. Not available for sale in the United States

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:	1930 cm^2/299 in^2
Size: (with optional flip shelf)	2950 cm^2/471 in^2

Upper left Datex-Ohmeda (DO) dovetail

Dovetail length:	54 cm/21.3 in

Lower left Datex-Ohmeda (DO) dovetail

Dovetail length:	28 cm/11.0 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, patient monitor and wall mount bracket.*

Not 510K cleared. Not available for sale in the United States

Ventilator parameter ranges

Tidal volume range:	5 to 1500ml (PCV modes 5 to 1500ml) (Volume Control, PCV-VG and SIMV volume 20 to 1500ml)
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:	Demonstrated 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
Number of positions:	2
Mounting:	Tool-free installation Selectatec™ manifold interlocks and isolates vaporizers

Airway Modules

General

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%

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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: 1A
- With outlets: 5A

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

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***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)

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
Approvals:	AAMI ES60601-1, CSA C22.2 #601.1, EN/IEC 60601-1, ISO 80601-2-13
European Notified Body CE Mark:	CE0197

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Breathing Circuit Specifications

Carbon dioxide absorbent canister

Absorbent capacity:	Reusable canister 1370 mL/1150 g Disposable canister 1437 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 1004 mL Reusable canister 985 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 L/min @ 12 in Hg (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 55 to 65 L/min	BSI 30 mm threaded
Low vacuum, low flow:	36 L/min	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

Imagination at work

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Datex-Ohmeda, Inc. a General Electric Company.

This document applies to Carestation 650 A1

DOC1649438 Rev3 11/15

Attachment 1 to the Certificate number: VTT-C-11340-01-1004-543-15

Manufacturer:	GE Healthcare Finland Oy Kuortaneenkatu 2, FI-00510 Helsinki Finland
Activity and product category:	Design, manufacture and final inspection of patient monitoring systems and related accessories, anaesthesia machine and ventilator related accessories
Products:	The certificate covers the following products:

Patient monitors and software

Name	*Description*	*Class*	*GMDN*
CARESCAPE Monitor B450	Patient monitor	IIb	33586
CARESCAPE Monitor B450-LI	Patient monitor	IIb	33586
CARESCAPE Monitor B650	Patient monitor	IIb	33586
CARESCAPE Monitor B650-LI	Patient monitor	IIb	33586
CARESCAPE Monitor B850	Patient monitor	IIb	33586
CARESCAPE Monitor B850-LI	Patient monitor	IIb	33586
CARESCAPE B850, version MBC303	Patient monitor	IIb	33586
F7-01 Frame	Module Frame	IIb	36757
F5-01 Frame	Module Frame	IIb	36757
BX50 ESP V2 Software Upgrade	Patient monitor software	IIb	59378
Surgical Pleth Index Software License	Haemodynamic patient monitoring system application software	IIb	42407
B20i	Patient monitor	IIb	33586
B40i	Patient monitor	IIb	33586
S/5 Network and iCentral	Patient monitoring system central station monitor	IIb	38470

VTT EXPERT SERVICES OY VTT EXPERT SERVICES LTD

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.

Attachment 1 to the Certificate number: VTT-C-11340-01-1004-543-15

	Mobile Care Software License	Patient monitoring system central station monitor	IIb	38470
	Navigator Applications Suite	Anaesthesia workstation application software	IIb	42428
Date:	Valid from: 23rd February 2018			
	Tuomas Toivonen		Anniina Mäkelä	

This attachment 1 supersedes the previous attachment 1 signed 21st July 2016

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.

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FINAS
Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer:	GE Healthcare Finland Oy Kuortaneenkatu 2 FI-00510 Helsinki FINLAND
Coverage of Certificate:	Design, manufacture and final inspection
Product category:	Patient monitoring systems and related accessories, anaesthesia software
Valid until:	27th May 2024

The manufacturer´s quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 6th September 2019

EUROFINS EXPERT SERVICES OY

Tuomas Toivonen

Anniina Mäkelä

Certificate no.

C-01-1004-698-19

Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

EC DECLARATION OF CONFORMITY

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

We

Manufacturer

GE Healthcare Finland Oy
Kuortaneenkatu 2
FI-00510 Helsinki, Finland

Declare under our sole responsibility that the class IIb device:

Product Description	Catalog Designation
CARESCAPE Bx50 V3 U-SW	5514034-01

GMDN Code: 59378
An individual software application program or group of programs intended to provide clinical management information for a patient being monitored by a single-patient physiologic monitoring system. It provides the ability to continually detect, measure, and display multiple physiological parameters associated with a single-patient, typically bedside or in an acute care setting. It typically includes visible and/or audible signal/alarm features and monitored parameters such as electrocardiogram (ECG), blood pressure, heart rate, temperature, cardiac output. A basic set of application programs and routines are included with the system that can be upgraded to add new system capabilities.

Classification rule (93/42/EC Annex IX): 10

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it.

This conformity is based on the following elements:

Information included in the documents:

- Technical Documentation Ref.: CARESCAPE Bx50 V3 U-SW Technical File DOC2361050 of the product to which this declaration relates, for design, verification and manufacturing of the device.
- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by Eurofins Expert Services (Notified Body no. 0537) on 6th September 2019 / Certificate no. C-01-1004-698-19
- List of standards applied for CE marking as in Appendix 1

Helsinki, 12 March 2020

Rauno Ruoho
Regulatory Affairs Director

This EC Declaration of Conformity is initial revision.

Appendix 1

Relevant Standards
IEC 62304: 2006 + A1: 2015: Medical device software – Software life cycle processes
IEC 60601-1-6: 2010, A1: 2013: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 62366-1: 2015: Medical devices - Application of usability engineering to medical devices
IEC 60601-1-8: 2006 + A1: 2012: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-25:2011: Medical Electrical Equipment Part 25: Particular Requirements for the Safety and essential performance of Electrocardiographs
IEC 60601-2-26:2012: Medical electrical equipment - Part 2-26: Particular requirements for the safety and essential performance of electroencephalographs
IEC 60601-2-27: 2011: Medical electrical equipment - Part 2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30: 2009, A1: 2013: Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-34:2011: Medical Electrical Equipment - Part 2-34: Particular Requirements for the basic safety and essential performance, of Invasive Blood Pressure Monitoring Equipment
IEC 60601-2-40:2016: Medical Electrical Equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
IEC 60601-2-49:2011: Medical electrical equipment - Part 2-49: Particular requirements for the safety essential performance of multifunction patient monitoring equipment
ISO 80601-2-55: 2011: Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.
ISO 80601-2-56: 2009: Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
ISO 80601-2-61: 2011: Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
EN 1041:2008, A1:2013: Information supplied by the manufacturer of medical devices
EN ISO 14971:2012 Medical devices — Application of risk management to medical devices

GE Healthcare

EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC, Annex II)
(Following the provisions of the RoHS directive 2011/65/EU, Articles 7, 13 and Annex VI)

We

Manufacturer:
GE Healthcare Finland Oy
Kuortaneenkatu 2
00510 Helsinki
Finland

Declare under our sole responsibility that the class IIb device:

CARESCAPE Monitor B650

A unit that, utilizing built-in functions, modules or other equipment, collects several monitoring parameters and displays these by the bed/patient. A bedside unit can be coupled up to a central unit, but can operate independently. The monitoring parameters can be, e.g. electrocardiogram (ECG), blood pressure, temperature, cardiac output or respiration gases.

REF: 2068487-001

GMDN Code: 33586

Classification rule (93/42/EC Annex IX) 10

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 RoHS Directive 2011/65/EU, Article 4.

This conformity is based on the following elements:

Information included in the documents:

- Technical Documentation Ref.: CARESCAPE Monitor B650 Technical File (DOC1271276)
- EC Certificate: Approval of full quality assurance system (Annex II of the medical devices directive 93/42/EEC) delivered by VTT Expert Services Ltd (Notified Body no. 0537) on 08 May 2015 / Certificate N° VTT-C-11340-01-1004-543-15
- List of standards applied for CE marking as in Appendix 1

Helsinki, 17 June 2015

Rauno Ruoho
Regulatory Affairs Director

This EC declaration of conformity is the fourth version for this product and replaces the previous dated 04-June-2015. This EC declaration of conformity is applicable to production units with serial number SEW14257957HA and later and serial numbers

SEW14010122HA	SEW14019943HA	SEW14019952HA	SEW14019962HA	SEW14019976HA
SEW14010123HA	SEW14019944HA	SEW14019954HA	SEW14019963HA	SEW14019977HA
SEW14010124HA	SEW14019945HA	SEW14019955HA	SEW14019964HA	SEW14019978HA
SEW14010125HA	SEW14019946HA	SEW14019956HA	SEW14019967HA	SEW14019979HA
SEW14010126HA	SEW14019947HA	SEW14019957HA	SEW14019968HA	SEW14019980HA
SEW14010127HA	SEW14019948HA	SEW14019958HA	SEW14019969HA	SEW14019981HA
SEW14010128HA	SEW14019949HA	SEW14019959HA	SEW14019971HA	SEW14019982HA
SEW14010129HA	SEW14019950HA	SEW14019960HA	SEW14019973HA	
SEW14010130HA	SEW14019951HA	SEW14019961HA	SEW14019975HA	

Relevant Standards
EN 60601-1:1990+ A1:1993 + A2:1995 + A13:1996: Medical electrical equipment — Part 1: General requirements for safety
EN 60601-1-1:2001: Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-2:2001 + A1:2006: Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests
EN 60601-1-4:1996 + A1:1999: Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems
EN 60601-1-6:2007 +AC:2010: Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability
EN 60601-1-8:2007+AC:2010: Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-2-10:2000 + A1:2001: Medical electrical equipment — Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
EN 60601-2-25 + A1:1995: Medical electrical equipment — Part 2-25: Particular requirements for the safety of electrocardiographic
EN 60601-2-26:2003: Medical electrical equipment — Part 2-26: Particular requirements for the safety of electroencephalographs
EN 60601-2-27+AC:2006: Medical electrical equipment — Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
EN 60601-2-30:2000: Medical electrical equipment — Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
EN 60601-2-34:2000: Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
EN 60601-2-40:1998 Medical electrical equipment — Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
EN 60601-2-49:2001: Medical electrical equipment — Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
EN 60601-2-51:2003 Medical electrical equipment — Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
EN 1060-1:1995 + A2:2009: Non-invasive sphygmomanometers — Part 1: General requirements EN 1060-3:1997 + A2:2009: Non-invasive sphygmomanometers — Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems Except for: Clause 7.9 failed by PDM module: Testing performed in accordance with EN 1060-4
EN ISO 9919:2009: Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
EN 12470-4:2000 + A1:2009 Clinical thermometers — Part 4: Performance of electrical thermometers for continuous measurement Except for: Clause 6.3 b) Temperature measurement error with single use probes exceeded maximum permissible error. Clause 6.4 The response time of the Esophageal stethoscope with temperature probe exceeds 150s for the probe sizes 18F and 24F.
EN ISO 21647:2009: Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN ISO 14971:2012 Medical devices — Application of risk management to medical devices (ISO 14971:2007(E))
EN 1041:2008: Information supplied by the manufacturer of medical devices
EN 980:2008 Symbols for use in the labeling of medical devices
EN 62366:2008 Medical Devices- Application of usability to medical devices
EN 62304:2006 Medical device software – Software life cycle processes

Tec 820 Vaporizer

Combining clinical performance with ergonomic design

The agent specific Tec™ 820 Vaporizer from GE Healthcare delivers isoflurane and sevoflurane effectively and efficiently. Each Tec 820 presents an improved ergonomic design, with consistent agent delivery and reliability while reducing total cost of ownership

Features

- Tec 820 agent specific vaporizers are designed to deliver isoflurane and sevoflurane anesthetic agents
- Provides output consistent with the dial setting throughout the clinical flow range
- Easy to turn dial and fine graduations help control agent delivery
- Enhanced design with consistent, reliable operation over the product life
- Tec 820 vaporizer supports the Easy-Fil agent filling mechanism
- Improved ergonomics and contemporary design complements GE Healthcare's anesthesia systems
- Attaches to GE Healthcare interlocking Selectatec™ manifold
- No planned factory service needed
- Three-year warranty

gehealthcare.com

Clinical performance

- Tec 820 Vaporizers are designed to provide consistent output throughout the clinical flow range from 200 ml/min to 15 l/min. Models are available for isoflurane and sevoflurane
- Tec 820 Vaporizers are equipped with a large diameter control dial with graduations up to 5% V/V (isoflurane models) or 8% V/V (sevoflurane models)
- The easy turning dials and small graduations on the Tec 820 Vaporizer help you fine tune anesthetic delivery over the full range of dial settings and flow rates

Enhanced ergonomics

- The ergonomic dial release on the Tec 820 Vaporizer allows either left or right hand operation
- Wide, centered liquid level indicator provides a clear indication of the fill level of the vaporizer
- Easy to turn dial with enhanced readability

Lower overall ownership costs

- The Tec 820 Vaporizer has no planned factory service, which helps lower the total cost of ownership and eliminate the logistical challenges associated with the return of vaporizers to the factory. For complete user maintenance requirements, refer to the User Reference Manual
- The Tec 820 Vaporizer comes with a three-year warranty

Reliability, convenience, and operating excellence

- Tec 820 is compatible with modern agent filling systems that simplify filling and help minimize agent leaks while filling
- To minimize filling frequency, the Tec 820 Vaporizer can hold up to 300 ml of anesthetic agent
- The Tec 820 Vaporizer can be mounted on GE Healthcare anesthesia systems equipped with the Selectatec manifold without tools and without taking the anesthesia system out of service
- The Tec 820 Vaporizer also interlocks in series with GE Healthcare Tec 7 and Tec 6 Plus Vaporizers
- The non-spill system in the Tec 820 Vaporizer limits movement of liquid agent if the vaporizer is tilted or inverted, protecting internal components and helping maintain output within clinically acceptable limits

Easy-Fil helps simplify agent filling

Tec 820 agent specific vaporizers

Physical specifications

Dimensions

Height:	25 cm
Depth:	22 cm
Width:	11 cm
Weight:	7 kg dry

Agent capacity

Total capacity:	300 ml
Capacity between min/max fill marks:	170 ml
Wick system capacity:	75 ml approximately

Pneumatics specifications

Calibration and flow resistance

Calibration:	Calibration of all models is done at 21°C using O_2 as carrier gas, 5 l/min fresh gas flow, at sea-level ambient pressure
Isoflurane models:	Control dial calibrated up to 5% V/V. The control dial is marked in steps of 0.25% up to 1% and in steps of 0.5% between 1% and 5%.
Sevoflurane models:	Control dial calibrated up to 8% V/V. Control dial is marked in steps of 0.25% up to 1% and in steps of 0.5% between 1% and 8%.
Flow resistance:	OFF: Isolated, no resistance from vaporizer ON: 5 l/min O_2: <20 cmH_2O

Accuracy

Isoflurane models:	±0.25% of delivered agent or ±20% of control dial setting (whichever is greater)
Sevoflurane models:	+0.6/-0.4% of delivered agent or ±20% of control dial setting (whichever is greater)
Fresh gas flow:	200 ml/min to 15 l/min

Environmental specifications

Operation

Temperature:	15°C to 35°C
Humidity:	15% to 95% relative humidity (non-condensing)
Ambient pressure:	500-800 mmHg

Storage and Transport

Temperature:	-25°C to 60°C
Humidity:	15% to 95% relative humidity (non-condensing)
Ambient pressure:	400-800 mmHg

Service

Planned factory service free

MRI Safety Information

MR Conditional

Agent filling systems

Isoflurane models: Easy-Fil™
Sevoflurane models: Easy-Fil

Note: may not be available in all regions

Warranty

Warranted to be free from functional defects in materials and workmanship for a period of three years from the date of original delivery.

Agent color coded Easy-Fil adapters

GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter – great people and technologies taking on tough challenges.

From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

Imagination at work

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