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R-5090340	212070722_allen_j_gerrard		Approve	Legal approves subject to the following: regulatory approval, as well as all products mentioned having obtained 510k and MS clearances; all product uses and applications being consistent with the applicable 510k and therefore being considered on-label; GEHC having support on file to substantiate all product claims made in this document and GEHC having permission on file to use all third party content featured in this document, as well as no protected health information being contained in any of the images in this document.	13 Aug 2012 15:28:52 GMT
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Periodic Review

There are no signatures or routes related to this business object.

Obsolescence Approval

There are no signatures or routes related to this business object.

* Printed versions are For Reference Only *

+ Indicates a task was reassigned from an original assignee

GE Healthcare

Carestation 30

Features

- GE Datex-Ohmeda family look and quality
- One or Two gases: O₂+ N₂O or Air (optional)
- 5.7-inch color ventilator display with waveforms and alarm message indicators
- Lightweight and compact for easy maneuverability
- One or two vap positions
- Dove tails for mounting accessories (optional)

Enhanced monitor integration capabilities

- Inspired oxygen monitoring (optional)
- SPO₂ monitoring with waveform (optional)

Advanced Ventilation

- Ventilation Modes:
 - VCV (Volume Control)
- WYSIWYG (What You Set Is What You Get) Tidal Volume setting
 - Compensation for breathing circuit compliance
 - Compensation for Fresh Gas Flow (optional)
- Pressure waveform for visual reference on a breath-by-breath basis
- Standby-mode



Revolutionary New Breathing Circuit

- Easy to clean, fully autoclavable, latex-free
- Easy removal-no tools required
- Quick Release for fast remove canister and refill soda lime
- Integrated design-less parts and connections helps reduce potential for leaks and misconnects
- One step bag/vent switch turns ventilator on/off
- Passive AGSS (optional)
- Auxiliary Comment Gas Outlet (optional)



Physical Specifications

Dimensions

Height: 148 cm/58 in

Width: 90 cm/35 in

Depth: 70 cm/28 in

Weight: 70 kg/220 lbs

Top shelf

Weight limit: 15 kg/33 lbs

Width: 40 cm/16 in

Depth: 30 cm/12 in

Work surface

Height: 74 cm/29 in

Size: 630 cm²/98 in²

Casters

12.5 cm/5 in, with brakes on the front casters

Drawers

20 cm x 30 cm x 30 cm/8 in x 12 in x 12 in

Ventilator display

5.7 inch TFT, 640 x 480

Ventilator Operating Specifications

Ventilation operating modes

VCV

Ventilator (VT) parameter ranges

Tidal volume range:
50 to 1500 mL

Incremental settings:
10 mL

Rate:
4 to 100 breaths per minute
(increments of 1 breath per minute)

Inspiratory/expiratory ratio:
2:1 to 1:8 (increments of 0.5)

Ventilator performance

Pressure range at inlet:
280 kPa to 600 kPa/ 41 psi to 87 psi

Peak gas flow:
63 L/min + fresh gas flow

Ventilator monitoring

Expiratory minute volume range: 0 to 63 L/min
Expiratory tidal volume range: 50 mL to 1500 mL
O₂ %: 15% to 100%

Peak pressure: -20 to 100 cmH₂O
Mean pressure: -20 to 100 cmH₂O

Ventilator accuracy

Delivery/monitoring accuracy

Volume delivery:
≥ 100 mL = better than 20%
< 100 mL = better than 20 mL

Volume monitoring:
≥ 100 mL = better than 20%
< 100 mL = better than 30 mL

Alarm settings

Tidal volume (TV_{exp}):
Low: 0 to 800 mL
High: 100 to 1800 mL

Inspired oxygen (FiO₂):
Low: 18 to 99%
High: 19 to 100%

Apnea alarm:
In Bag Mode, Apnea alarm happens under condition of no flow value, PAW fluctuates less than 2cmH₂O, and continue time exceeds 30 seconds.

Airway pressure (PAW):
Low: 4 to 20 cm H₂O
High: 5 to 100 cm H₂O

Sustained airway pressure:
Paw ≥ 10cmH₂O continuously for 10 seconds

Ventilator components

Flow transducer

Type: TVX Flow Transducer Cartridge
Dimensions: 22 mm OD and 15 mm ID/22 mm ID
Location: Expiratory Port

Oxygen Sensor

Type: Oxygen Sensor OOM102
Life Cycle: 15 Months

Anesthetic agent delivery

Vaporizers:
Tec 7 or V5

Number of positions:
2 or 1

Mounting:
Tool-free installation
Selectatec manifold interlocks or
Cagemount

Electrical specifications

Current leakage

100/120 V: < 500μA
220/240 V: < 500μA

Power and battery backup

Supply voltage:
100-120 Vac, 50/60 Hz

Power input:	220-240 Vac, 50/60 Hz	Provides a nominal minimum 22% concentration of oxygen in O ₂ /N ₂ O mixture
Backup power:	≤ 50 VA	
Battery type:	Demonstrated battery backup time under typical operating conditions is 360 minutes when fully charged	
Power cord:	Internal rechargeable sealed lead acid	
	Length: 5 m/16.4 ft	

Pneumatic specifications

Auxiliary common gas outlet

Connector: ISO 22 mm OD and 15 mm ID

Gas supply

Pipeline input range: 280 kPa to 600 kPa/41 psi to 87 psi

Pipeline connections: DISS - Male; DISS-Female; S90-116 (French Air Liquide); BSPP 3/8 (Scandinavian) or NIST (ISO 5359). All fittings available for O₂, Air, and N₂O

Cylinder input: Pin indexed in accordance with CGA-V-1; contains input filter and check valve
Note: Maximum 2 cylinders; all 2 inboard mounted.

Primary regulator diaphragm minimum burst pressure: 2758 kPa/400 psig

Primary regulator nominal output: Pin indexed: The primary regulator is set to pressure less than 345 kPa (50 psi).

O₂ controls

Method: Proportionate decrease of N₂O with reduction in O₂ Pressure

Supply failure alarm range: ≤0.22Mpa continuously for 3 seconds

O₂ flush: Range: 25 to 75 L/min

Flowmeters

O₂ ranges: 0.1 to 1.0 L/min and 1.0 to 10.0 L/min

N₂O ranges: 0.1 to 1.0 L/min and 1.0 to 10.0 L/min

Air range: 0.1 to 1.0 L/min and 1.0 to 10.0 L/min

Hypoxic guard system

Type: Mechanical gear

Range:

Environmental specifications

System operation

Temperature: 10° to 40°C/50°F to 104°F

Humidity: 15 to 95% relative humidity

Altitude: -440m to 3565m

System storage

Temperature: -25°C to 65°C/-13°F to 149°F

Humidity: 15 to 95% relative humidity

Altitude: -440m to 5860m

Electromagnetic compatibility

Immunity: Complies with all requirements of EN/IEC

Emissions: CISPR 11 group I class B

Approvals: EN/IEC 60601-1-2

Breathing circuit specifications

Operational modes

Breathing circuit is circle mode only

Carbon dioxide absorbent canister

Absorbent capacity: 1450 mL

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

Pressure gauge

Scale range:

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 to 70 cm H₂O

Tactile knob indication at: 30 cm H₂O and above

Adjustment range of rotation: 0 to 30 cm H₂O (0 to 230°)

30 to 70 cm H₂O (230 to 330°)

≤ 15 seconds

Materials

All materials in contact with exhaled patient gases are autoclavable, except flow sensor and O₂ cell.

All materials in contact with patient gas are free of natural rubber latex.

Breathing circuit parameters

Compliance:

Bag Mode		Vent Mode	
Internal Compliance	Internal Compliance	Internal Compliance	Internal Compliance
(ml/cmH ₂ O)	(ml/30cmH ₂ O)	(ml/cmH ₂ O)	(ml/30cmH ₂ O)
1.45	44	1.3	39

Breathing system resistance in bag mode*:

Bag mode*	Flow (L/min)	Resistance (kPa)	Resistance (cmH ₂ O)
	5	0.03	0.3
	30	0.17	1.7
	60	0.56	5.6

*Values include patient circuit tubing and Y-piece 0.15 kPa (0.20 psi) expiratory resistance at 1 L/s. Patient circuit tubing and breathing system configurations may affect resistance.

Anesthetic gas scavenging

Passive scavenging

Negative pressure relief:
0.3 cmH₂O

Outlet connector:
30 mm male taper ISO

Accuracy:

30 to 250 bpm: ± 2 digits or ± 2%, whichever is greater, (without clinical motion)

30 to 250 bpm: ± 5 digits (during clinical motion)

30 to 250 bpm: ± 3 digits (during clinical low perfusion)

251 to 300 bpm unspecified

Alarm for SpO₂ module on CS30 machine

1. "SpO₂ no valid data" alarm: the board does not provide SpO₂ or pulse rate values.
2. "SpO₂ board removed" alarm: the communication between the board and the host stops
3. "SpO₂ probe off" alarm : Sensor is off patient (see SENSOR_OFF)
4. "Check SpO₂ Probe" alarm: Sensor placement is poor or plethysmographic waveform amplitude is too low to calculate SpO₂ or pulse rate values (see SENSOR_SITE)
5. "No SpO₂ Probe" alarm: No sensor plugged in (see NO_SENSOR)
6. "SpO₂ Faulty Probe" alarm: Probe hardware error (see PROBE_FAULT)

Integrated Pulse Oximetry specifications

SpO₂

Declared range:
70 to 100%

Displayed range:
0 to 100%

First reading, full accuracy:
≤ 10 seconds

Accuracy:
70 to 100% ± 2 digits (without clinical motion)
70 to 100% ± 3 digits (during clinical motion)
70 to 100% ± 2 digits (during low perfusion)
Below 70% unspecified

Pulse rate

Displayed range:
30 to 300 beats per minute (bpm)

First reading, full accuracy:

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Data Sheet

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Date	Revision	Description	Author
2012-Aug-03	1.0	Initial released	Zhang Feng Frank
2012-Aug-09	2.0	<ol style="list-style-type: none"> 1. Top shelf weight limit 25kg, changed to 15kg. 2. Pressure waveforms sweep speed 20Hz, no report to support this number. (delete this item from Data Sheet) 3. Support failure alarm range 230kPa to 250kPa, sounds at maximum volume every 10 seconds, changed to <=0.22Mpa continuously for 3 seconds. 4. Hypoxic guard system provides a nominal minimum 25%, changed to 22%. 5. Operation humidity 10%-95%, changed to 15%-95%. 6. Volume monitoring: < 100 mL = better than 20 mL , changed to < 100 mL = better than 30 mL 7. © 2010 General Electric Company - All Rights Reserved. Changed to © 2012 General Electric Company - All Rights Reserved. 	Zhang Feng Frank



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