

# CARESCAPE Respiratory Modules E-sCO(V), E-sCAiO(V), E-sCAiO(V)E, E-sCOVX, E-sCAiOVX

Monitoring respiratory and ventilatory parameters for adult, pediatric and neonatal patients in anesthesia and critical care applications



This family of compact respiratory modules is designed to support respiratory monitoring in anesthesia and critical care areas. Depending on the module type, host device software version and the clinical application, they provide measurements of airway gases, anesthetic agents with agent identification, Patient Spirometry and Gas Exchange.

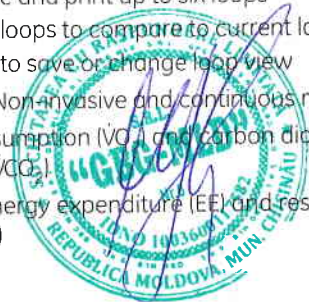
## Features

- Airway gases measured by the sidestream method
- Eight module versions available to meet the needs of various care areas
- All parameter values sampled proximal at the patient's airway with a single gas sampling line, D-lite(+)\* or Pedi-lite(+) flow sensor, along with an additional Spirometry tube
- Et and Fi values updated breath by breath
- Fast oxygen measurement for accurate EtO<sub>2</sub> and FiO<sub>2</sub> values
- Automatic identification of anesthetic agents
- Detects end inspiratory and end expiratory occlusions automatically and displays values for Statis Plat, Static PEEPi+e and Static Compliance
- Calculated balance gas value for estimating the N<sub>2</sub>-concentration
- Very compact size, low weight and low power consumption

## Clinical measurements

- CO<sub>2</sub> and N<sub>2</sub>O – GE infrared technology: Inspired and end-tidal values, CO<sub>2</sub> waveform and respiration rate

- Respiration rate – calculated from the CO<sub>2</sub> waveform
- Anesthetic agents – GE infrared technology
  - Measures and identifies all five agents and two agent mixtures: halothane, enflurane, isoflurane, sevoflurane and desflurane
  - MAC (Minimum Alveolar Concentration)
  - MACage with age, temperature and ambient pressure compensation
- Patient oxygen – GE paramagnetic oxygen (O<sub>2</sub>) technology: Inspired, end-tidal and Fi-Et difference, waveform
- Patient Spirometry – Designed to measure true patient values independent of the ventilator with GE-patented D-lite(+) and Pedi-lite(+) flow sensors and gas samplers at the patient airway
  - Numerical values for airway pressure, minute and tidal volumes, compliance, airway resistance and I:E ratio values, and flow and airway pressure waveforms
  - Continuous measurement of intrinsic, extrinsic and total PEEP
  - Pressure-volume and flow-volume loops
  - Ability to store and print up to six loops
  - Recall saved loops to compare to current loop
  - Module keys to save or change loop view
- Gas exchange - Non-invasive and continuous measurement
  - Oxygen consumption (VO<sub>2</sub>) and Carbon dioxide production (VCO<sub>2</sub>)
  - Values for energy expenditure (EE) and respiratory quotient (RQ)



## Technical specifications

### General

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

Sampling flow 120 ± 20 ml/min

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

Automatic compensation for atmospheric pressure variation (660-1060 mbar), temperature and CO<sub>2</sub>, O<sub>2</sub>, N<sub>2</sub>O, agent cross effect compensation. Parameter display update interval typically breath-by-breath.

Functional alarms for

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

### Letters in the module name stand for

s = Single-width module

C = CO<sub>2</sub> and N<sub>2</sub>O

Ai = Anesthetic agents and agent identification

O = Patient O<sub>2</sub>

V = Patient Spirometry

E = End-tidal control support with Aisys\* CS<sup>2</sup>

X = Gas Exchange metabolics  $\dot{V}O_2$ ,  $\dot{V}CO_2$ , RQ and EE

### Non-disturbing gases

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

### Carbon dioxide (CO<sub>2</sub>)

GE infrared absorption sensor technology

CO<sub>2</sub> waveform

EtCO <sub>2</sub>	End-tidal CO <sub>2</sub> concentration
FiCO <sub>2</sub>	Inspired CO <sub>2</sub> concentration
Measurement range	0 to 15 vol% (0 to 15 kPa, 0 to 113 mmHg)
Accuracy	±(0.2 vol% + 2% of reading)
Rise time	< 260 ms

Adjustable low and high alarm limits for EtCO<sub>2</sub> or FiCO<sub>2</sub>

### Respiration rate (RR)

Measurement range	4 to 100 breaths/min
Detection criteria	1 vol% change in CO <sub>2</sub> level
Alarm note sent to host device if no breath detected in 20 seconds	

### Patient oxygen (O<sub>2</sub>)

GE differential paramagnetic sensor

O<sub>2</sub> waveform

FiO <sub>2</sub>	Inspired O <sub>2</sub> concentration
EtO <sub>2</sub>	End-tidal O <sub>2</sub> concentration
FiO <sub>2</sub> -EtO <sub>2</sub>	Inspired-expired difference
Measurement range	0 to 100 vol%
Accuracy	±(1 vol% + 2% of reading)
Rise time	< 260 ms

### Nitrous oxide (N<sub>2</sub>O)

GE infrared absorption sensor

FiN <sub>2</sub> O	Inspired N <sub>2</sub> O concentration
EtN <sub>2</sub> O	End-tidal N <sub>2</sub> O concentration
Measurement range	0 to 100 vol%
Accuracy	±(2 vol% + 2% of reading) N <sub>2</sub> O ≤ 85%

Note: N<sub>2</sub>O is only displayed with CARESCAPE\* ANE and PACU software

### Anesthetic agent (AA)

GE infrared absorption sensor

Anesthetic agent waveform

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

MAC or MACage value options for hosts

Agent mixture detection

Measurement range

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

### Agent identification

Identification threshold	0.15 vol%
Detection time	< 20 sec



## Patient Spirometry

Pressure-volume loop, flow-volume loop, airway pressure and flow waveforms updated breath by breath

Adjustable low and high alarm limits for Ppeak, PEEPtot and MVexp

Messages for MVexp << MVinsp and for low volumes

Through selection of D-lite or Pedi-lite gas sampling and flow sensor from menu, the following specifications apply:

	D-lite(+)	Pedi-lite(+)
<i>Respiration rate</i>	4 to 35 breaths/min	4 to 70 breaths/min
<i>Tidal volume</i>		
Measurement range	150 to 2000 ml	5 to 300 ml
Accuracy	±6% or 30 ml	±6% or 4 ml
<i>Minute volume</i>		
Measurement range	2 to 20 l/min	0.1 to 5 l/min
<i>Airway pressure</i>		
Measurement range	-20 to +100 cmH <sub>2</sub> O	-20 to +100 cmH <sub>2</sub> O
Accuracy	±1 cmH <sub>2</sub> O	±1 cmH <sub>2</sub> O
Display units	cmH <sub>2</sub> O, mmHg, kPa, mbar, hPa	
<i>Flow</i>		
Measurement range	-100 to +100 l/min	-25 to +25 l/min
<i>tE</i>		
Measurement range	1:4.5 to 2:1	1:4.5 to 2:1
<i>Compliance</i>		
Measurement range	4 to 100 ml/cmH <sub>2</sub> O	1 to 100 ml/cmH <sub>2</sub> O
<i>Airway resistance</i>		
Measurement range	0 to 200 cmH <sub>2</sub> O/l/s	0 to 200 cmH <sub>2</sub> O/l/s

The presence of xenon or helium in the breathing circuit causes incorrect measurement values.

## Sensor specifications

	D-lite(+)	Pedi-lite(+)
Dead space	9.5 ml	2.5 ml

## Gas Exchange and metabolics†

$\dot{V}O_2$	Oxygen consumption
$\dot{V}CO_2$	Carbon dioxide production
Measurement range	20 to 999 ml/min
$\dot{V}CO_2$ and $\dot{V}O_2$ Accuracy	Valid for respiration rates 4 to 35 breaths/min (adult), 8 to 35 breaths/min (pediatric) FiO <sub>2</sub> <65 vol%: ±10% or 10 ml, whichever is greater FiO <sub>2</sub> 65...85 vol%: ±15% or 15 ml, whichever is greater

CARESCAPE monitors B850 and B650 calculate and display Energy expenditure (EE) and Respiratory Quotient (RQ).

EE‡	Energy expenditure
Display range	0 to 6000 kcal/d or 0 to 25120 kJ/d
RQ‡	Respiratory Quotient ( $\dot{V}CO_2/\dot{V}O_2$ )
Display range	0.6 to 1.3

The presence of xenon, N<sub>2</sub>O or helium in the breathing circuit causes incorrect measurement values.

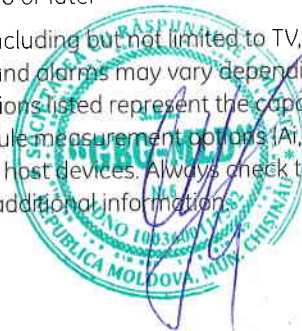
† Measurement not applicable for neonatal patients

‡ Calculated by host device. For more information on other host devices, refer to their user documentation.

## System compatibility

- CARESCAPE Monitor B850
- CARESCAPE Monitor B650
- CARESCAPE Monitor B450
- B40 Patient Monitor (2060600-002)
- Aisys CS<sup>2</sup>
- Avance\* CS<sup>2</sup>
- S/5 Anesthesia Monitor, software version L-ANE06(A) 24.1 or later
- S/5 Critical Care Monitor, software version L-ICU06(A) 24.1 or later
- S/5 Compact Anesthesia Monitor, software version L-CANE05(A) 19.6 or later
- S/5 Compact Critical Care Monitor, software version L-CICU05(A) 19.6 or later

Displayed data (including but not limited to TV, MV, RR, Raw and N<sub>2</sub>O) trends and alarms may vary depending on the host device. Specifications listed represent the capabilities of the modules. All module measurement options (Ar, V, X) may not be available in all host devices. Always check the host device's User Manual for additional information.





## Environmental specifications

### Operating conditions

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

### Storage conditions

Temperature	-25 to 60°C (-13 to 140°F)
Relative humidity	10 to 90%, non-condensing
Ambient pressure	500 to 1060 mbar

## Physical specifications

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

## Imagination at work

### About GE Healthcare

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.

GE Healthcare Finland Oy  
Kuortaneenkatu 2  
00510 Helsinki, Finland  
Europe

[www.gehealthcare.com](http://www.gehealthcare.com)



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## EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4  
Full Quality Assurance System  
Medical Devices

Registration No.: HD 60116081 0001

Report No.: 15094929 004

**Manufacturer:** GE Medical Systems  
(China) Co., Ltd.  
No. 19, Changjiang Road  
Wuxi National Hi-Tech Dev.Zone  
214028 Jiangsu  
China

**Products:** Medical Devices  
  
(see attachment for products and additional sites included)  
  
Replaces Approval, Registration No.: HD 60110059 0001

**Expiry Date:** 2021-05-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2017-01-03

**Date:** 2017-01-03

Notified Body

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg

Attachment to  
Certificate

Registration No.: HD 60116081 0001  
Report No.: 15094929 004

Manufacturer: GE Medical Systems  
(China) Co., Ltd.  
No. 19, Changjiang Road  
Wuxi National Hi-Tech Dev.Zone  
214028 Jiangsu  
China

Products:

- Ultrasound Diagnostic Systems and Probes
- Anesthesia Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC  
9900 Innovation Drive, Wauwatosa, WI 53226, USA

Manufacture of Ultrasound Diagnostic Systems

GE Medical Systems (China) Co., Ltd.  
No.22, Gao Lang East Road, Wuxi National Hi-Tech  
Development Zone, Jiangsu 214028, P.R.China

Subject: Ultrasound Diagnostic Systems

Notified Body

Date: 2017-01-03

X. Ren



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TÜVRheinland

TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg

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Attachment to  
Certificate

Registration No.: HD 60116081 0001  
Report No.: 15094929 005

Client:  
GE Medical Systems  
(China) Co., Ltd.  
No. 19, Changjiang Road  
Wuxi National Hi-Tech Dev.Zone  
214028 Jiangsu  
China

Producer:

- Ultrasound Diagnostic Systems and Probes  
- Analytical Devices
- Bone Densitometry Systems
- ECG Module

Sites included:

GE Medical Systems Ultrasound & Primary Care (High End) Division  
1000 Innovation Drive, Wauwatosa, WI 53226, USA

GE Medical Systems (China) Co., Ltd.  
No.22, Gao Lang East Road, Wuxi National Hi-Tech  
Development Zone, Jiangsu 214028, P.R.China

Date: 2017-12-20



