INSUMOS MÉDICOS (II)

REPÚBLICA POPULAR CHINA 2020

BEIJING, 27 DE MARZO 2020

Embajada de la
República Argentina
República Popular China

Sección Comercial

Puntos destacados:

La Embajada argentina en Beijing –conjuntamente con los Consulados en Shanghái y Guangzhou- ha realizado las siguientes gestiones:

- Kit de testeo. El Ministerio de Salud de la Nación solicitó cotización del test RT-PCR de la empresa china BGI Genomics en una cantidad de 50.000 unidades. Precio unitario por test: US$ 15 (no incluye flete). Plazo de entrega: una semana. El transporte desde Argentina a China podría presentar una dificultad, ya que requiere refrigeración por la cantidad de horas de viaje. Se adjuntan especificaciones técnicas y certificaciones de la Unión Europea de calidad de la empresa. Asimismo, se remite nuevamente el presupuesto de diferentes kits de testeo, incorporando el mencionado test.

- Respiradores. ANMAT solicitó conocer las especificaciones técnicas de los respiradores cotizados en el informe anterior a fin de estudiar el cumplimiento de los estándares argentinos. Se adjunta información técnica de los nueve respiradores, cuyo stock se encuentra disponible al momento.

Test RT-PCR de la empresa BGI Genomics

El Test de Detección del COVID-19 "Real-Time Fluorescent RT-PCR" desarrollado por BGI Genomics, no sólo ha sido recomendado por la Comisión Nacional de Salud de la República Popular China, sino que también es el recomendado por el Ministerio de Salud de la Nación, atento a que los profesionales de la salud del Instituto Malbrán se encuentran capacitados para realizarlo.

- **Cantidad de Tests por Kit:** 50 unidades

- **Cotización por Kit:** US$ 700. **Este es un Precio Especial para Gobierno que nos brindó la empresa contactada.** El precio es EXW, es decir, el comprador se encarga del costo logístico.

- **Forma de Pago:** 100% al momento de realizar compra

- **Demora de Producción:** 1 (una) semana

- **Requisito de Transporte:** El envase se encuentra refrigerado con hielo seco, el cual sirve para algunas horas. Para un período extendido el transporte requiere refrigeración adicional para el kit.

- **Contacto con BGI Genomics:**

- **Ficha Técnica, Manual y Certificaciones:** Se adjuntan a continuación.

WE SEQUENCE, YOU DISCOVER

BGI

Real-Time Fluorescent RT-PCR Kit for 2019-nCoV Detection

Product Description

BGI's Real-Time Fluorescent RT-PCR kit for detecting the 2019 novel coronavirus (SARS-CoV-2) is a qualitative *in vitro* nucleic acid amplification assay designed for the ultra-sensitive and rapid investigation of SARS-CoV-2. The kit is intended for use in virology research only and is not intended for clinical diagnosis or patient management.

Features

- Samples to results within 3 hours
- Taqman Reverse Transcription PCR
- ORF1ab gene as domain target
- Human β–actin as internal control
- Manufacturing in ISO 13485 compliant and high-volume production facility
- Stringent QC with positive and blank controls

Benefits

- Highly sensitive – Superior limit of detection
- Highly specific – No cross-reactivity with other major human-related pathogens
- Fast – One-step duplex reaction with single target and internal control
- Easy to use – Pre-mixed primers, probes and enzymes
- Easy to interpret results – Analysis of one target with well defined controls

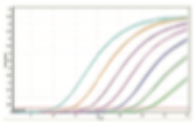
Specifications

- 50 reactions per kit
- Samples collected from throat swab or bronchoalveolar lavage fluid (BALF)
- Compatible with many major real-time PCR systems
- Limit of detection: 100 copies/mL
- Reagents stable under dark for 5 days at 2-8°C or 6 months at -18°C
- No cross-reactivity with human genome or 54 other human related pathogens

01
Add
Template RNA
+
Reaction Mix
+
Enzyme Mix

02
Run

03
Analyze



Samples to results in less than 3 hours

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Key Components

Component	Volume	Quantity	Description
2019-nCoV Reaction Mix	1mL/vial	1 vial	Reagents for amplification, probes and primers
2019-nCoV Enzyme Mix	80μL/vial	1 vial	Taq polymerase, reverse transcriptase and uracil-DNA glycosylase (UDG)
2019-nCoV Positive Control	750μL/vial	1 vial	Mix solution of pseudo-virus with target virus genes and internal reference
2019-nCoV Blank Control	750μL/vial	1 vial	DNase/RNase free water

Request for Information or Quotation

Contact your BGI account representative for more information including product pricing.
info@bgi.com
www.bgi.com

International Head Offices

BGI Americas

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Cambridge, MA 02142, U.S.A.
Tel: (617) 500-2741

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DK-2200 Copenhagen N, Denmark
Tel: (+45) 7026 0806

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16 Dai Fu Street,
Tai Po Industrial Estate,
New Territories,
Hong Kong China
Tel: +852 3610 3510

BGI Genomics BGI_Genomics

BGI
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Real-time fluorescent RT-PCR kit for detecting 2019-nCoV

【Generic product name】

Real-time fluorescent RT-PCR kit for detecting 2019-nCoV

【Package size】

50 tests/kit

【Intended use】

The kit is a qualitative in vitro nucleic acid amplification assay to detect the new coronavirus identified in China in 2019 using Reverse transcription PCR in specimen of nasopharyngeal swabs and Bronchoalveolar Lavage Fluid（BALF）from suspects.

In end of 2019, some pneumonia cases were reported in Wuhan, China and the pathogen was confirmed as a new strain of coronavirus . World Health organization has named the newly identified coronavirus as 2019-nCoV. Although more intensive researches must be conducted later to well understand the virus, in response to the emergency in disease control, simple and rapid kit is necessary to identify the virus timely and implement efficient interventions to contain the spread. The kit will qualitatively detect the nucleic acid of 2019-nCoV in specimen from suspects enabling to assess the infection situation of 2019-nCoV in suspects in clinical and public health practice.

【Principle of the procedures】

The kit is based on in vitro RT-PCR combining fluorescent probing. Primers and a sequence-specific fluorescence probes were designed tailored to high conservative region in 2019-nCoV genome. The probes are oligonucleotide attached fluorophores at the 5' end with FAM as reporter and 3' end with quencher. In a meantime, specific primers and probes were developed as internal reference with fluorophores VIC/HEX attached at 5' end as reporter. During the PCR procedures, the DNA polymerase cleaves the probe at the 5' end and separates the reporter dye from the quencher dye when the probes hybridize to the target DNA. This cleavage results in the fluorescent signal generated by the cleaved reporter dye, which is monitored real-time by the PCR detection system. Monitoring the fluorescence intensities during Real Time allows the qualitative detection of 2019-nCoV in specimens.

【Key contents】

Item（50 tests/kit）	Specification	Quantity	Description
2019-nCoV reaction Mix	1mL /vial	1 vial	Composed of reagent for amplification and probes and primers
2019-nCoV Enzyme Mix	80μL /vial	1 vial	Taq polymerase, Reverse transcriptase and UDG
2019-nCoV Positive control	750μL/vial	1 vial	Mix solution of recombinant plasmid of target virus genes and internal reference
2019-nCoV Blank control	750μL/vial	1 vial	DNase/RNase free water

Materials required but not provided

- Reagents：TIANamp Virus RNA extraction Kit (DP315-R) manufactured by TIANGEN, or QIAamp Viral RNA Mini Kit (52904) by QIAGEN
- 1.5 mL RNase/DNase-free microcentrifuge tube, RNase/DNase-free tips for pipettes, 0.2mL 8- tube strips for real-time PCR, Bench centrifuge, Vortex mixer.
- Notes：Components contained within a kit are intended to be used together. Do not mix components from different kit lots.

【Storage and shelf-life】

- The RT-PCR Kit should be stored at temperature lower than -18°C in dark. It is stable with self-life at 2-8°C for 5 days and at -18°C for 6 months. Unpacked kit should avoid repeated thaw-freeze cycle(4X)
- The PCR Kit can be transported at -18°C in dark stable for 5 days.

【Applicable instruments】

Applied Biosystems™ Real time PCR system 7500; SLAN-96P PCR system

【Specimen】

Sample collection

- Collect fresh specimen of Nasopharyngeal swabs, sputum and BALF from suspects.

- **Nasopharyngeal swabs**: Carefully take out the swab from package and quickly rotate it around two sides of fauces, throat and tonsil a few times applying pressure to collect as much secretions as possible. Avoid touching tongue. Break the swab stick and put the head into sampling solution in specimen tubes. Screw the tube cap tightly to ensure no leakage.

- **BALF:** Collect 3ml of unprocessed BALF in sterile, dry and clean DNase/RNase free Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film.

Storage

- The specimen should be kept in proper condition, at -18°C for not longer than 1 week and at-70℃ for not longer than 6 months.

- Frozen specimen should be thawed thoroughly while avoiding repeated thaw-freeze cycle.

Transportation

- The specimen should be shipped in low temperature condition using dry ice or ice bag.

【Laboratory procedures】（Please read the procedures carefully before your operation）

Sample processing

- The fresh specimen should be collected to ensure the qualified RNA in terms of quality and quantity for the assay. RNA should be extracted using Nucleic Acid extracting Kit in line with the manufacturer's instruction. The assay was validated by the recommended RNA extraction kits by TIANGEN （DP315-R）or QIAGEN（52904）.

- The extracted RNA should be tested immediately or stored at -70°C for test later.

Reagent preparation

- Take out all the kit contents and thaw them thoroughly at ambient temperature. Vortex and centrifuge briefly. The Enzyme Mix should be kept in ice continuously.
- Estimate the number of reactions (N) in the test, which includes the number of Blank control (1 tube), Positive control (1 tube), and specimens prepared. Prepare 8-tube strips for PCR based on the estimated N of reaction and develop the PCR mix as ingredients in following table. Pipette 20μL PCR Mix per tube into the 8-tube strips. Capped them fasten and transfer them to sample processing Area. The remaining reaction Mix and Enzyme Mix should be stored at -18°C immediately.

	2019-nCoV reaction Mix(μL)	2019-nCoV Enzyme Mix(μL)
PCR-Mix (μL)	18.5×N	1.5×N

Add sample

- Add 10 μL the extracted RNA of specimens, Blank control and Positive controls respectively into the 8-tube strips prefilled with PCR Mix. Capped them fasten and centrifuge them at 2000rpm for 10 seconds. Place the tubes into thermal cycler and record the exact location of controls and every specimen.

Real time PCR

- Set the fluorescent channels：Please refer to the manufacturer's instructions of thermocycler for detailed information on channel setting.

FAM channel (Reporter: FAM, Quencher: None) for RNA of 2019-nCoV; VIC/HEX channel (Reporter: VIC/HEX, Quencher: None) for internal reference; Reference Dye：None (only for ABI PCR system);
Sample Volume: 30.

- Configure PCR protocol

Step	Cycle	Temperature	Duration	Fluorescence measured(Y/N?)

1	1 cycle	50℃	20minutes	N
2	1 cycle	95℃	10minutes	N
3	40cycles	95℃	15 seconds	N
		60℃	30 seconds	Y

Data analysis

- Baseline and threshold for ABI7500 PCR system

Baseline starting point at 3 and ending at 15

The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, the blank control should be selected firstly and click off the Automatic standard curve by changing the option from "□√Auto"to "□Auto". Set the threshold manually just above the maximum
level of blank control curve (random noise curve) at FAM channel.

- Data from SLAN-96P PCR system

The starting and ending points of baseline should be set as 6 and 12 respectively.

The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, change the configuration of baseline optimization in basic parameter from automatic to manual. Then, manually set the threshold just above the maximum level of blank control curve (random noise curve) at FAM/ VIC(HEX).

Quality control

- Blank control: Ct values at FAM and VIC/HEX channels are 0 or no data available.
- Positive control：Standard curves at channel FAM and VIC/HEX channels are in S-shape with Ct values not higher than 32.
- Testing specimen: Standard curves at VIC/HEX channel is in S-shape with Ct not higher than 32.
- Above requirements should be met in a single test. Otherwise, the test is invalid. Please operate the retest strictly in line with the package insert.

【Threshold and reference range】

- Cut-off value of the kit was determined based on the Receiver Operator characteristic curve from testing clinical samples. Ct value for 2019-nCoV positive by the kit is not high than 38.

【Testing result interpretation】

- The specimen is positive of 2019-nCoV if standard curve at FAM channel is in s-shape with Ct value not higher than 38.
- The specimen is negative of 2019-nCoV if standard curve at FAM channel is not in s-shape with Ct at FAM as 0 or no data available while Ct at VIC/HEX not higher than 32.
- The specimen should be retested if standard curve at FAM is in S-shape with Ct higher than 38. The specimen can be reported on basis of retesting results as positive of 2019-nCoV for Ct higher than 38 and as negative of 2019-nCoV for standard curve not in S-shape and Ct of internal reference not higher than 32 at VIC/HEX.
- In case that standard curve at FAM is not in s-shape with Ct value as 0 or no data available, the specimen should be retested if Ct at VIC is higher than 32 or no data available.

【Limitation of the assay】

- The Results of the test is just for information in clinical practices to assess infection condition of patients combining with clinical presentations and other laboratory markers.
- The incorrect result can be caused by incorrect operations in sample collection, transportation or processing, very low concentration of target virus in the specimens, mutations within the viral genome covered by the kit's primers and/or probe, and unproved external interference factors, such as PCR inhibitor.

【Performance characteristics】

- The package is intact and liquid contents are clear, transparent and no sediments. All contents are in correct quantity as the package insert listed.
- Positive control is positive at both FAM and VIC/HEX channel in testing while blank control is negative at both channels.
- LOD of the kit is 100 copies/mL for detecting 2019-nCoV.
- A potential cross-reactivity of the RT-PCR Kit was tested and none of the tested pathogens have been reactive. The tested human coronavirus includes OC43,229E, HKU1 and NL63(HCoV-OC43, HCoV-229E, HCoV-HKU1, HCoV-NL63)

【Warning and precautions】

- FOR IN VITRO TEST ONLY. Please read the package insert carefully before your operation.The appropriate operations from specimen collection, storage and transportation, and laboratory test should be strictly manipulated in line with relevant regulations of biosafety and molecular laboratory management.
- The false positive or negative testing result can be led by poor quality of specimen, incorrect operations in sample collection, transportation or laboratory processing, or limitation of the technology. Operator should understand well the principles of the procedures and its limitation in performance in advance and avoid any potential mistakes intentionally.
- Separate laboratory areas are dedicated to performing predefined procedures of the assay.

  a) 1st Area：Preparation Area—Prepare testing reagent；

  b) 2nd Area：Sample processing—Process the specimen and controls；

  c) 3rd：Amplification Area—PCR conducted.

- All materials used in one area should always be remained in the area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected timely.
- All contents in the package are prepared dedicatedly for the intended testing purpose and validated. Replacing any of them will affect the testing performance of the kit. Components contained within a kit are intended to be used together. Do not mix components from different kit lots.
- Thaw all kit components thoroughly and centrifuge them briefly before starting an assay. Avoid repeated thaw-freeze cycle.
- 8-tube strips for real time PCR capped fasten and transferred to specimen processing area immediately after addition of Nucleic Acid reaction Mix.
- To prevent the contamination from exogenous RNA, sample addition should follow the sequence of negative control, specimen RNA and positive control. Filtered tips should be prepared and used separately in preparing reagent and sample addition.
- Ensure to pipette the samples exactly into the reaction mix in PCR tubes and avoid sticking the samples to the inside tube wall. The tubes should be capped fasten immediately after the addition.
- After the protocol of amplification is done, remove PCR tubes from the thermal cycler and discard them in a sealable plastic bag for autoclave and decontamination.
- Ensure no foam or bubbles present in the tubes when aliquoting nucleic acid Mix. All PCR tubes capped fasten before loading them into the thermal cycler to avoid any possible leakage and contamination.
- The workbench and lab supplies should be cleaned and disinfected regularly using 75% ethanol or UV light.
- All pipette tips and centrifuge tubes in the assay should be DNase/RNase-free. The used centrifuge tubes and pipette tips should be discarded in waste bin with Clorox (84) disinfectant and disposed with other laboratory wastes after decontamination.

【References】

[1] LU Rou-jian, ZHANG Ling-lin, TAN Wen-jie, ZHOU Wei-min, WANG Zhong, PENG Kun, RUAN Li. Development and Comparison

of Real-Time and Conventional RT-PCR Assay for Detection of Human Coronavirus NL63 and HKU1[J]. CHINESE JOURNAL OF VIROLOGY, 2008(4).

[2] NIU P, LU R, LAN J, LIU G, WANG W, TAN W. Development of Novel Multiplex Real-time RT-PCR Assays for Detection of MERS-CoV Infection[J]. CHINESE JOURNAL OF VIROLOGY, 2016(3).

[3] CHEN Yu-jing. Development of two-panel reactions of real-time PCR for detection of 18 types/subtypes of respiratory viruses[D]. 2015

【Manufacturer's information】

Manufacturing Site: BGI Biotechnology(Wuhan) Co.,Ltd

Site Address: Building B2, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East

Lake High-tech Development Zone, Wuhan, Hubei Province, PRC

Website：http://www.genomics.cn

【Release date of the user manual】

This manual was released on 2020-01.

CE

Declaration of Conformity

Manufacturer: BGI Europe A/S
Address: Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark
Device: Real-time fluorescent RT-PCR kit for detecting 2019-nCoV
Catalogue number: MFG030010
Classification (IVDD, Annex II): Others
Conformity assessment route: ANNEX III

We herewith declare that the above mentioned product meets the provisions of the following EC Council Directives and Standards (IVDD 98/79/EC). All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

IVDD 98/79/EC: Council Directive 98/79/EC concerning in vitro diagnostic medical devices

Standard & Guideline:

No.	Standards No.	Standards Title
1.	MEDDEV 2.12.1: 2013 (Rev.8)	Guidelines on a medical device vigilance
2.	MEDDEV. 2.14/3 rev.1	IVD GUIDANCES: Supply of Instructions For Use (IFU) and other information for In-vitro Diagnostic (IVD) Medical Devices
3.	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4.	BS EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
5.	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
6.	EN ISO 18113-1:2011	vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
7.	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use IVD
8.	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9.	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
10.	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

Date CE mark was first affixed: 2020-02-24

华大基因
BGI

Signed by: General Manager Date: 2020.02.25

Embajada de la República Argentina
República Popular China

Cotización de Kits de testeo

No	Producto	Empresa	Demora resultado	Precio Unitario (US$ FOB)	Tiempo Referencial de Espera de Fabricación	Cantidad Mínima de Pedido	Requiere refrigreación para transporte	Contacto
1*	Real-Time Fluorescent RT-PCR	BGI Genomics	3 h	15.00	1 semana	5,000	Envase con hielo seco que sirve para 5 días max.	Terence Xiomg +8613693109371 terence.xiong@genomics.cn
2	COVID-19 IgM / IgG Detección rápida de oro coloidal	Sinopharm	Detección Rápida	3.70	menos de 100,000 kits en 7 días	5,000	No hace falta refrigeración. Temperatura de 4º a 30º C	Leticia +8613641179310 chehong@sinopharm.com
3	COVID-19 IgM / IgG Detección rápida de oro coloidal	Sinopharm	Detección Rápida	4.80	menos de 100,000 kits en 8 días	5,000	No hace falta refrigeración	Leticia +8613641179310 chehong@sinopharm.com
4	Real Time PCR Kit	SINOPHARM GENEODX.COM	1.5h	14.40	En Stock	1,000	Temperatura a -20°C (±5°C)	Sr. LIU Junyu, +8613786988757
5	Real Time PCR Kit	Shanghai ZJ Bio-Tech Co., Ltd	1.5h-2h	12.50	En Stock	1,000	Sin información	Sra. ZHU Lin (Julie), +8602134780595
6	Real Time PCR	BGI Genomics Co. Ltd.	3hs	15-20	En Stock	N/D	Envase con hielo seco que sirve para 5 días max.	Sr. Hugo Wu, +8618682190667 hugo.wu@bgi.com
7	Fluorescent PCR	DAAN Gene Co., Ltd. Of Sun Yat-sen University	3h	14.00	En Stock	50,000	Envase con hielo seco que sirve para 7 días max.	Sra. QIU Jinfen, +8613903059587

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8	Real Time PCR Kit	SANSURE BIOTECH INC.	2h	15.00	En Stock	N/D	Envase con hielo seco que sirve para 7 días max.	Sra. WEN Huilan (Carrie), +8615802606123
9	Real Time PCR Kit	Shanghai BioGerm Medical Technology Co., Ltd	80 min	11.50	En Stock	N/D	Temperatura a -20°C (±5°C)	Sr. MENG Kuibin, +86021-61984777 int. 882 / +8618515455125
10	SARS-CoV-2 Antibody Test	Guangzhou Wondfo Biotech Co., Ltd.	15 minutos	6.00	En Stock	2,000	Envase con hielo seco que sirve para 7 días max.	Sra. Paula Chen, +8613423623346 paula.chen@wondfo.com.cn
11	Colloidal gold	Innovita Biological Technology Co., Ltd.	15 min.	5.20	En stock	100,000	No hace falta refrigeración.	Alice XIN, +8618810557720
12	Multiple Real-Time PCR	Beijing Applied Biological Technologies Co., Ltd.	1,5horas	7.90	En Stock	50,000	Envase con hielo seco que sirve para 7 días max.	ZHANG Hui, +8618722218922
13	Reactivo fluorescente/IgG	Maccura Biotechnology Co., Ltd.	Reactivo fluorescente: 2 horas; IgG: 2,5 minutos	Reactivo fluorescente: US$ 13 IgG: US$ 4	En Stock	Depende del momento del pedido	Temperatura 30º a -10ºC	Johnny Chang, +862881731888 ext. 81659 13678022412 johny.chang@maccura.cn
14	IgG antibody	Vazyme Biotech Co., Ltd	10 min	A confirmar con pedido formal	En Stock	Depende del momento del pedido	Sin información	Sra. Deng Xiaoying, +8615895911434 dengxiaoying@vazyme.com
15	Test Kit para IgM+IgG antibody	Livzon Pharmaceutical Group Inc.	15 min	4.50	En Stock	Depende del momento del pedido	No hace falta refrigeración. Temperatura de 2º a 30º C	Sra. Wu Min (Myra), +86756-8132332 wumin@livzon.com.cn

1* Test y empresa con autorización de la Comisión Nacional de Salud de China y recomendado por el Ministerio de Salud de la Nación de Argentina

Información técnica de Respiradores

ANMAT solicitó conocer las especificaciones técnicas de los respiradores cotizados en el informe anterior a fin de estudiar el cumplimiento de los estándares argentinos.

Los respiradores especificados son los siguientes:

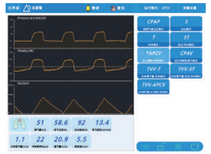
Empresa	Tipo de respirador
Curative Medical Technology (Beijing) Ltd.	ResMed CURATIVE GA ST40, Invasivo/No Invasivo
	ResMed CURATIVE FLOTONE ST30, No Invasivo
	Flexo, Dispositivo de conducto de aire presurizado positivo bi-nivel
Perlong Medical Equipment Co., Ltd.	PA 700B Respirador Médico
Datex-Ohmeda, Inc.	Carescape R860
Weinmann	VentiMotion 30
	VentiMotion Advanced
	VENTIlogic LS
	VENTIlogic plus

A continuación, se adjuntan especificaciones técnicas de cada tipo de respirador:

Utilize Strength to Defend Each Breathing

Guardian Angel for Respiratory Treatment

CURATIVE GA



Switch to an eye-catching interface with a high contrast at night
Secure patients' safety and serve better experience for use

A ***ResMed*** company

Technical parameters

Mode		
	Continuous positive airway pressure (CPAP)	
	Spontaneous (S)	
	Time (T)	
	Spontaneous/ Time (ST)	
	Assisted Pressure control (APCV)	
	Target tidal volume ventilation (TVV-T/ST/APCV)	
	Proportional assist ventilation (CPAV)-ST40P	
Setting		
	IPAP	4-40cmH_2O
	EPAP	4-25cmH_2O
	Inspiration slope	1-6 (100-600ms)
	Ramp	0-60min
	Inspiration time	0.2-4s
	Backup rate	4-60bpm
	Inspiration sensitivity	6 trigger sensitivities
	Expiration sensitivity	6 cycle sensitivities
	TVV target tidal volume	200-2000ml
	Oxygen concentration	21%-100%
	CPAV- assist proportion	1%-100% (ST 40P)
	CPAV- max tidal volume	200-2000ml (ST 40P)
Monitoring parameters		
	Minute ventilation volume	0-100L/min
	Tidal volume	0，30-3000ml
	Inspiration proportion	0-90%
	Inspiration rate	0-120bpm
	Leakage	0-200 L/min
	Peak expiratory pressure	0-50cmH_2O
General parameters		
	Oxygen input pressure range (High pressure port)	276- 600kPa (40-87psig)
	Weight (including batter)	8.4kg
	Volume	39cm × 35.5cm × 30.5cm

CE 0123

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CURATIVE

Embajada de la República Argentina
República Popular China

GA Ventilator

High-end Medical Non-invasive Ventilator

Silent and strong turbine, precise algorithm of ATT, air-oxygen mixer with high precision and a variety of ventilation modes, including proportional assist ventilation escort patients' every breath

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Powerful performance to ensure synchronicity

- Silent and strong turbine with a maximum flow rate of 280L/min and pressure 40cmH2O
- Equipped with adjustable air-oxygen mixer with oxygen concentration of 21%-100%
- Built-in smart lithium battery with 4-6 hours of super long standby
- ATT technology that can ensure synchronicity even under extreme situations like high respiratory rate and a huge amount of air leakage

Flexible and easy to use

- 12.1-inch color touch screen with an interface for operation and detection on the same page
- Comprehensive monitoring parameters with pressure, flow and volume waveform displayed synchronically
- Start-up self-test to ensure the stability and accuracy of each ventilation
- Manual selection between bright and soft interfaces makes it easier to detect the change of patient ventilation and provide better user experience

Complete modes suitable for different patients

- 9 modes of non-invasive ventilation
- CPAV mode (Proportional Assist Ventilation)
  During inhaling, the ventilator provides a pressure proportional to the size of the patient’s respiratory effort, which can be adjusted according to the patient's respiratory effort, to reduce the respiratory effort done by the patient and ensure synchronicity.
- TVV mode (ventilation), to ensure the capacity volume of ventilation.When the machine detects the patient’s breathing has not reached the set tidal volume, it will automatically raise the inspiratory pressure to reach the preset tidal volume, which can guarantee the stability of tidal volume even if the compliance or resistance changes.

Clinical universality, to meet the multi-department application needs

- Intensive care unit
- Respiratory department and other departments requiring assist ventilation
- Emergency department
- Patient transit

Floton™

Compact, Comfortable, Continues Sync

Embajada de la
República Argentina
República Popular China

Compact, Light and Quiet, the Floton BiLevel understands that every breath is different. Using advanced Adaptive Triggering Technology (ATT), Floton is designed to effortlessly synchronize with the natural breathing of the patient.

Bilevel Noninvasive Ventilator

ATT

ATT tracks every breath and monitors the different stages of the respiration cycle utilizing an Advanced Leak Calculation Algorithm that ensures reduced Work of Breathing (WOB) whilst providing the patient with effective and comfortable treatment.

Floton™ S20

BiLevel ventilation with Spontaneous (S) mode up to 20 cmH_2O

Floton™ ST20/ST25/ST30/ST33

BiLevel device with 5 modes of ventilation – S, T, ST, APCV and CPAP, inspiration pressure from 4cm H_2O to 33cm H_2O

SPECIFICATION

Dimensions	180 mm L×210 mmW ×105 mmH
Weight	1.6Kg (1.2Kg without humidifier)
IPAP range	4 –20 cmH_2O (ST20), 4 –25 cmH_2O (ST25) 4 –30 cmH_2O (ST30), 4 –33 cmH_2O (ST33)
EPAP range	4cm H_2O – 20cm H_2O
CPAP range	4cm H_2O – 20cm H_2O
Pressure accuracy	±(2% of the full scale reading + 4% of the actual read)
Ramp Time	0 – 60 min, 1min per step
Noise	<30dB(A)(at 10 cmH_2O/~1.0kPa)
Ventilation mode	CPAP/S/ST/T/APCV
BPM (Backup rate)	5 – 50 bmp
Inspiratory time ratio(I/T %)	10% - 80%
Rise Time (ISLP)	1 – 6
ISNS	1 – 6
AUTO	ON/OFF
Alarms	Power failure, Leak, Apnea, Pressure, Mask OFF, Low ventilation/Tidal volume
Monitoring parameters	IPAP, EPAP, VTidal , Vminute ,BPM(RR), Leak
Compliance Meter	1st on operation, 2nd on breathing detection
Protection against electric shock	Class II, EN 60601-1
Degree of protection against electric shock	Type B applied part
Protection against water ingress	Ordinary equipment, IPX1
Electromagnetic compliance	EN 60601-1-2
AC/DC adapter	Input: 100-240V, 50-60Hz, 2-1A; Output: DC24V , 2.5A
Operational Temperature	+5℃ ~ +35℃
Product certification	CE 0123
Operational relative humidity	10% ~ 93% (non-condensing)
Operational Atmospheric pressure	700hPa – 1060hPa
Transport/storage temperature	-20℃ ~ +55℃
Transport/storage relative humidity	10% ~ 93% (non-condensing)
Transport/storage Atmospheric pressure	500hPa – 1060hPa
Accessories (Optional)	Stand, Humidifier
Pressure control	At the mask

INNOVATIONS TO CURE

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CE 0123

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WWW.CURATIVEMEDICAL.COM

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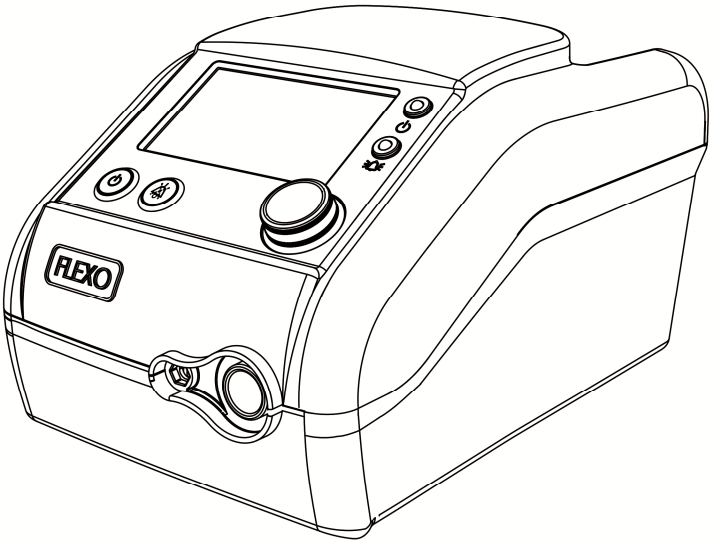
Flexo™

Bi-level Positive Airway Pressure Device

CE
0123



CURATIVE

TABLE OF CONTENTS

SYMBOL KEYS

Symbol	Description
	Attention! Consult accompanying documents
	Type B applied part
IPX1	Protection against water
	Class II Double insulated
	Direct and alternating current supply
	This device, its accessories and its packaging have to be disposed correctly at the end of the usage. Please follow Local Laws or Regulations for disposal
	Manufacturer
	Date of Manufacture
SN	Series Number
EC REP	Authorised representative in the European community
REF	Catalogue Number
CE 0123	European Declaration of Conformity

GLOSSARY

GLOSSARY Term	Meaning
IPAP	Inspiratory Positive Airway Pressure
EPAP	Expiratory Positive Airway Pressure
CPAP	Continuous Positive Airway Pressure
VT	Tidal Volume
ml	Milliliters, a unit of measure for volume in Flexo device
MV	Minute Ventilation
ITS	Inspiratory Time Set (Optional Spontaneous Ventilation Mode)
TI Set	Timed Inspiratory Set Menu for ITS (Inspiratory Time Set) Mode, an optional ventilation mode in S and ST Modes
TVV	Target Volume Ventilation (Optional Timed Ventilation Mode)
BPM	Breaths per minute
Leak	Leakage Volume per minute
Lpm	Liters per minute, a unit of measure for leak in Flexo device
ISLP	Inspiratory Slope, speed of rising pressure
ISNS	Inspiratory Sensitivity, the sensitivity of inspiration triggering
ESNS	Expiration Sensitivity, the sensitivity of expiration triggering
MODE	Mode of Operation
I/T%	Inspiratory Time % of Respiratory Cycle, similar to I:E Ratio, this shows the percentage of inspiration time in a respiration cycle, applicable with T, ST. APCV modes
RAMP	A mechanism of time-delayed Pressure Rise to Therapeutic Pressure, to improve patient comfort. RAMP Delay shall be defined by RAMP starting pressure and RAMP duration time. The user shall be able to adjust Starting Pressure and Duration.
AUTO	When the AUTOON feature is selected, the device shall begin to deliver CPAP therapy as soon as the system detects an inhaled breathe in the air pathway.

Locked Mode	Locked Mode is a state where the features and parameters of the Flexo device cannot be changed unless the device is unlocked. This prevents accidental changes to be made while the device is functioning.
Unlocked Mode	Unlocked Mode is a state where the features and parameters of the Flexo device can be changed freely.
CURE TIME	Cure Time is a resettable timer that can track the amount of time the device is used by a patient. For example, it can be reset after the device is used by one patient, to begin to track the amount of time the Flexo device is used by new patient.
LowMV	Low minute ventilation alarm
LowVT	Low tidal volume alarm
Power Fail	System Alarm indicating a Power Failure Condition
MASKOFF	System Alarm indicating a mask-removed Condition
HiPRES	High pressure alarm, for airway pressure that is 3 cm H_2O higher than the IPAP setting for a time period longer than 1 second
APNEA	Apnea alarm
MINIT	Minimum Inspiration Time
Stand by Mode	Power is connected to the system, display is active, motor is not running

1 WARNINGS AND CAUTIONS

WARNINGS:

- The device cannot be used while mobile unless it is connected with a Curative Medical approved portable power cable.
- The device is not designed for life support.
- Do not use the device in the presence of nitrous oxide or flammable anesthetic mixtures in combination with oxygen or air.
- In the event that the device noise level becomes higher than normal, the device-output of air becomes too hot, the device has an abnormal smell or if any part of the device becomes broken, stop using it immediately and contact an authorized dealer.
- The device can only be switched off completely when the power supply is disconnected from the wall socket.
- Make sure the exhalation opening in the mask or swivel is open so that the exhaled air containing CO_2 can escape.
- It is important to minimize CO_2 re-breathing when using non-invasive ventilation. If the device is turned off, avoid wearing the mask for more than 3 minutes to minimize re-breathing. While the device is in use, maintain sufficient airflow at low pressure settings so that it can efficiently remove the exhaled gas (CO_2) and minimize re-breathing by the patient.
- The air inlet of the device should never be covered.
- To avoid electric shock:
    - Do not use the device if the device casing or cables are damaged.
    - Do not use the device if it has been dropped in water.
    - Keep device away from water.
    - Before cleaning the device, pull the power plug out of the socket.
- If the patient experiences mucous membrane dryness in the nose and pharynx, frontal sinus trouble, earache, a running nose or skin sensitivity etc. you should consult your physician immediately.
- Operation of the device may be adversely affected by:
    - Electromagnetic fields exceeding the level of 3V/m or Electrostatic Discharge greater or equal to 8kV in the test conditions of EN 60601-1-2
    - The operation of high frequency (diathermy) equipment.
    - Defibrillators, or short wave therapy equipment
    - Radiation (e.g., X-ray, CT)
    - Magnetic fields (e.g., MRI).
    - Do not sterilize the device with high pressured steam

CAUTIONS:

- The device must be used exclusively under the prescription of a physician.
- Do not use the device before the recommended therapeutic pressure is prescribed by a physician.
- To prevent water entering the breathing circuit connection on the mask, the device must always be positioned below the head.
- Use caution when the device is operating at room temperatures above 35°C. If the device is used when temperature is above 35°C then the temperature of the airflow may be excessively warm, which may cause thermal irritation or injury to the patient's airway.
- Make sure the Flexo device kept away from any heating or cooling equipment (e.g., air vents, radiant heaters or air conditioners). Also make sure that loose bedding, curtains do not block the filter intake of the device. Air must flow freely around the device for the system to work properly.
- Before carrying or packing the device you must empty the humidifier of water
- Check the alarm function regularly, and if the device has not been used for a long time please check the power failure alarm before use. If the Power failure alarm does not work contact your dealer.
- If the device has recently been placed in a very hot or very cold environment, we recommend waiting for 2 hours to allow temperature to normalize before switching the device on.
- The device should be operated at temperatures between 5°C and 35°C.

2 LIABILITY

The manufacturer shall not be held liable for any damages in case of:

- Tampering, modifying, adding expansion features or repair by persons who have not been authorized by the manufacturer.
- Using accessory or spare parts that are not recommended by Curative Medical Devices gmbh, or not officially registered by the user.
- Using the device in a way that was not instructed in this manual.

3 Introduction

3.1 Intended use

Flexo Bi-level positive airway pressure therapy device is used to provide non-invasive ventilatory support of mechanical ventilation for

- Patients who are independent and spontaneously breathing
- Patients with respiratory insufficiency and sleep breathing disorders

It can provide both a stable continuous positive airway pressure and a bi-level positive airway pressure. It is not a life support ventilator.

The therapeutic pressure is prescribed by a physician according to patients' condition.

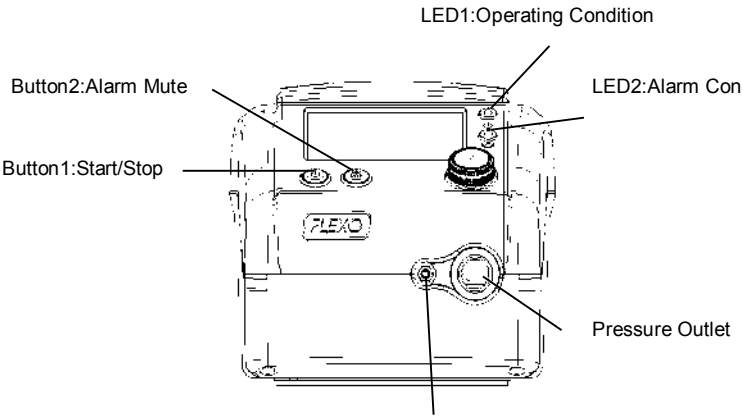
3.2 Contraindications

The use of positive airway pressure device may be contraindicated if the patient suffers from the following pre existing conditions:

- Pneumothorax
- Pneumomediastinum (Air in mediastinum)
- Cerebrospinal fluid leakage
- Pneumocephalus
- Extremely low blood pressure or shock
- Confusion or coma resulting in the patient not been able to co-operate with or accept the mask
- Excessive secretions in the airway as well as not coughing effectively and weak voluntary breathing.

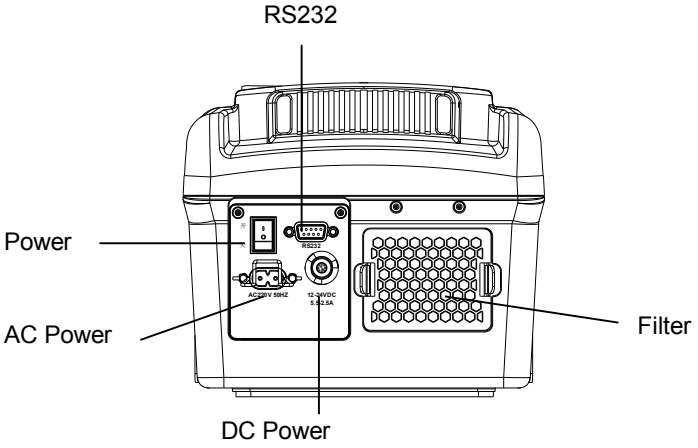
3.3 Description of the Flexo device

3.3.1 Front view of Flexo device



See Section Control Panel and Monitor Display Layout for details on use and function.

3.3.2 Rear view of Flexo device



Attention: The data transmission interface is only used during production or service when transmitting data to RS232 or the USB of a PC.
Equipment connected to the analog or digital interfaces must comply with the respective IEC standards (e.g. IEC 950 for data processing equipment

and IEC 60601-1 for medical equipment). All configurations shall comply with the current version of the standard for SYSTEMS IEC 60601-1. If you are in doubt consult the technical service department or your local representative. RS232 port is only for technical use.

3.3.3 Accessories and parts

- 1 Flexo Bi-level Positive Airway Pressure Device
- 1 AC Power cord
- 1 or more Filter-pack
- 1 Flexible Hose with the pressure sampling tube

3.3.4 Connecting the system

- Check whether the device is damaged and if any accessories or parts are missing.
- Put the device on a stable and even surface. Make sure the air inlet in the back of the device is not blocked.
- Connect the power supply cord to the device.
- Connect the two ends of the hose to the device's air outlet and mask separately.
- Connect the pressure sampling tube to the pressure sampling port in the device.

4 Operating the device

4.1 Connecting power to the device

1. Plug the device into a powered wall outlet.
2. Turn the device onto standby using the switch at the back of the device. The switch shall be in the "ON" position.
3. The Power light on the device will display green when the Flexo is "ON".
4. When the device is on standby the monitor display is visible.
5. Adjust the settings of the device according to the patient's requirements using the Control Knob.

4.2 First time use of the device

During the first time use, the Flexo device will enter into ST Mode and ready for use. The Table, Default Settings List, shows the values that are considered default in Flexo. Allow 5 to 10 seconds for the machine to start up before it enters the default ST mode.

Default Settings List (See Operating Mode Section for Details regarding Parameters)

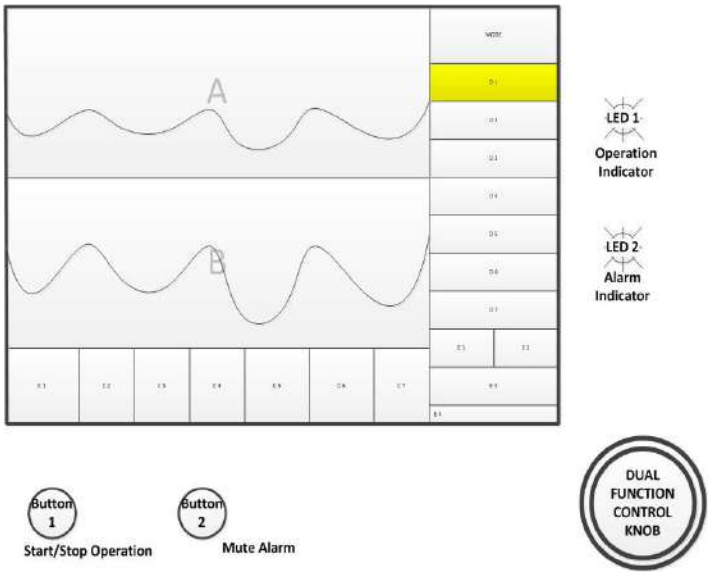
Default Operating Mode		ST, Spontaneous with Timed Back Up Mode	
Setting Parameters	IPAP	IPAP	14.0 cm H_2O
	EPAP	EPAP	4.0 cm H_2O
	BPM	Breathes Per Minute	12 BPM
	I/T%	Inspiratory Phase Percentage	33%
	ISLP	Inspiratory Slope Adjustment	3
	ISNS	Inspiratory Sensitivity Adjustment	3
	ESNS	Expiratory Sensitivity Adjustment	3
Optional Setting	ITS	Min IT	0.2 sec
		Max IT	4.0 sec
	TVV	Tidal Volume Ventilation	OFF
Alarm	HIGH IP	High Inspiratory Pressure Alarm	OFF
	APNEA	Apnea Alarm	OFF
	LOW VT	Low Tidal Volume Alarm	OFF
	LOW MV	Low Minute Volume Alarm	OFF
	HIGH LEAK	High Leak Alarm	OFF
	LOW LEAK	Low Leak Alarm	OFF

4.3 Routine use of the device

Flexo makes operation efficient during routine use by going directly into Monitor Screen of the operating mode of the last session. The Flexo device will recall these values after the device completes its start up process. The start up process usually takes 5 to 10 seconds.

All settings from the last session of use are retained in Flexo, including the Locked or Unlocked State. For specific information on Locked and Unlocked State, please see the later section on “LOCKING AND UNLOCKING THE SETTINGS”.

4.4 Control panel and monitor display



Object	Object Name	Details
Display	Flexo LCD	Displays all Flexo Information, Modes and Parameters
LED1	Operation Indicator	Lights up when Flexo device is in operation
LED2	Alarm Indicator	Lights up when Flexo device alarm condition is met
Button 1	Start/Stop Operation	Begins and ends selected therapy
Button 2	Alarm Mute	Mutes alarm buzzer for 15 seconds
Control Knob	Dual Function Control Knob	Turn to change selection Depress to select function

To change Operating Modes from this monitor screen, please review the following sections:

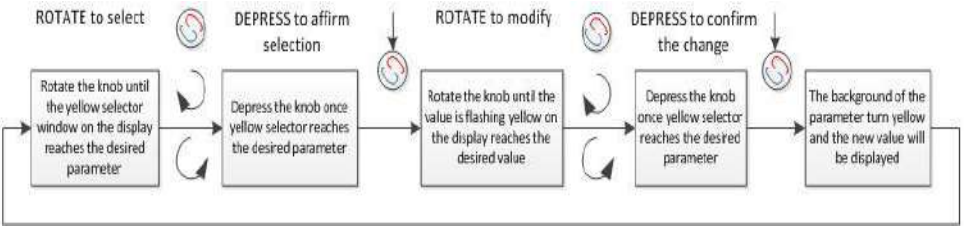
- GENERAL USE OF FLEXO CONTROL KNOB
- DISPLAY LAYOUT, OPERATING MODES AND PARAMETERS

4.5 Main menu display

Title	Object Name	Relevant Section in User Manual
MONITOR	Access to the Operating Modes Monitor Screen	See section 4.7 on Main Menu from Monitor Screen
ALARM	Access to the Alarm Set Menu	See section 4.9 on Alarm Screen
DEFAULT	Access function to reset all settings to default values	See section 4.12 on Default Screen
OTHER	Access to CURE TIME Counter and Password Controls	See sections 4.10 and 4.11 on Other Screen and Password Screen

4.6 General use of the control knob in the device

This is a general rule for operating the Flexo device and applies to all mode selections and parameter changes on the device.



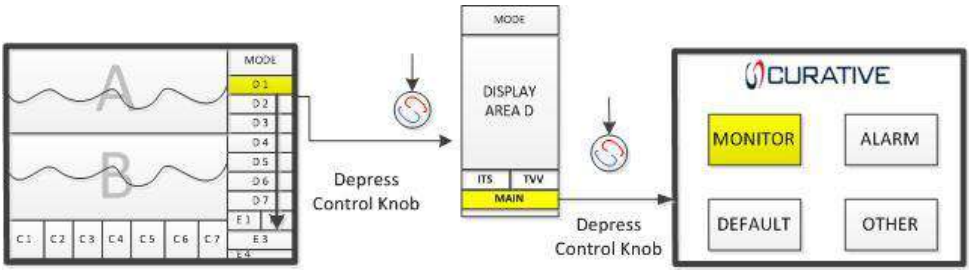
- Rotate to Select: The background of the parameter is active when it appears in yellow color. Rotate the Control Knob as the parameters are activated in sequence.
- Depress to Affirm: By depressing the Control Knob one time, the value of the active parameter will flash in yellow. This means the value can now be changed.

- Rotate to Modify: Rotate the Control Knob of the active selection until the value desired is reached. As the value changes, it continues to flash.
- Depress to Confirm: Depress the Control Knob to accept the new value selected. Once the new value is accepted, the background of the parameter will return to yellow.
- Rotate the dial to move to the next parameter to be changed, if desired.

Note that when the parameter is not longer active, it will appear in the same background color as the rest of the display.

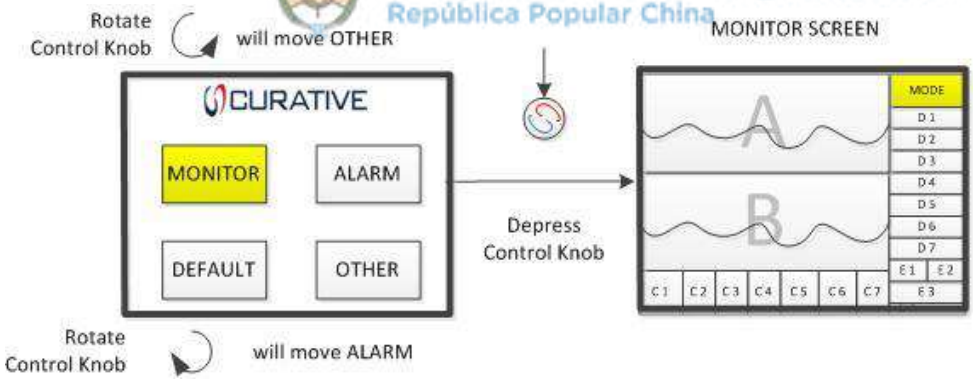
4.7 Main menu from monitor screen

In order to access the Alarm, Default and Other settings, place the yellow selection window to MAIN in the Display Area D.



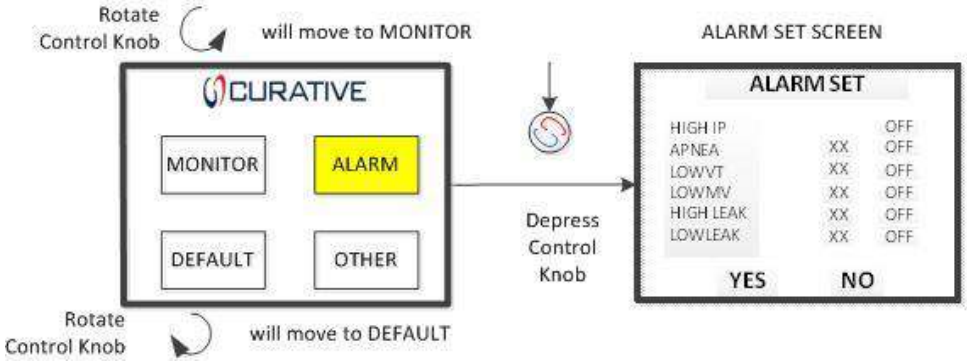
This allows us to navigate back to the main menu. Main menu can access all four main functions of the FLEXO device.

4.8 Monitor screen



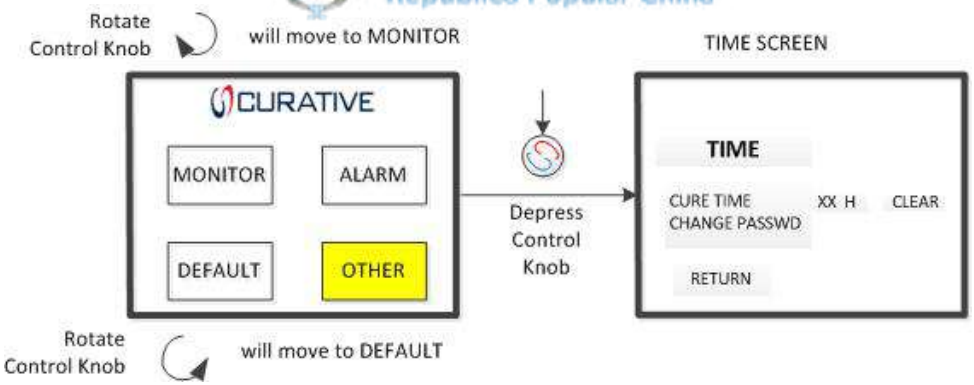
Use this screen flow to access the operating modes of the Flexo device. See section on Monitor Screen Layout for details.

4.9 Alarm screen



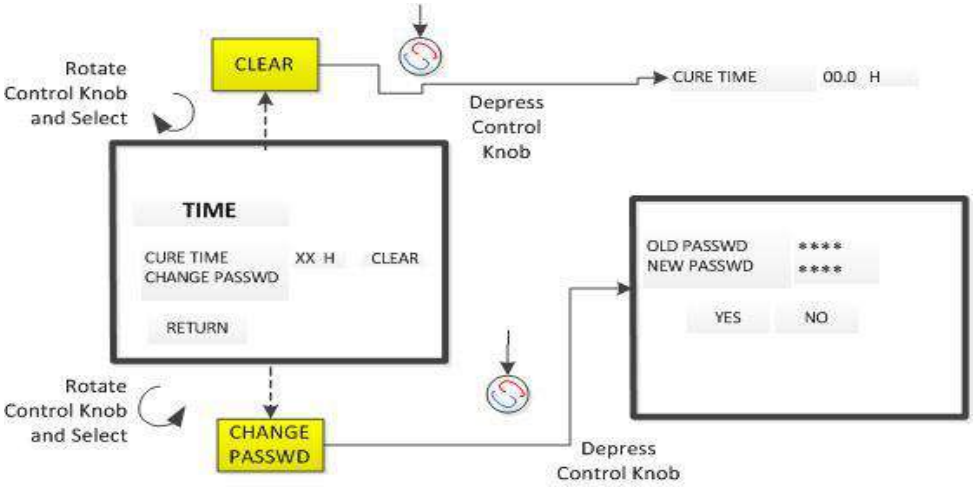
Use this screen flow to access the alarm settings menu of the Flexo device. See section regarding Alarm Settings for details.

4.10 Other screen



Use this screen flow to access the Time Menu and Password settings of the Flexo device.

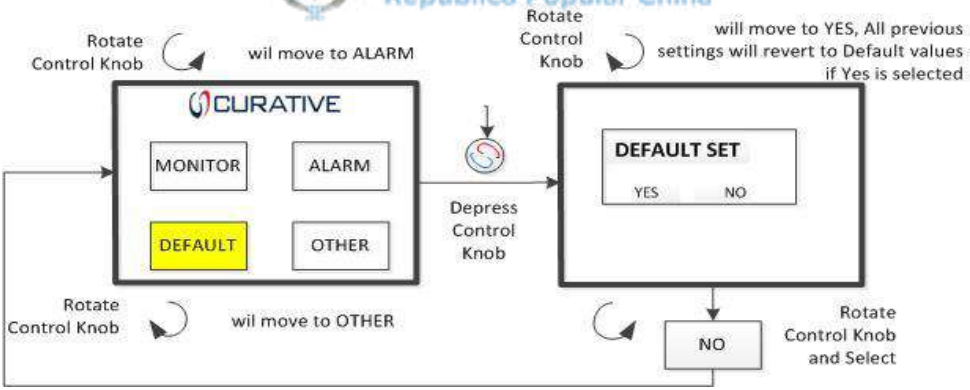
4.11 Password screen



Use this screen flow to access the Time Menu and Password settings of the Flexo device.

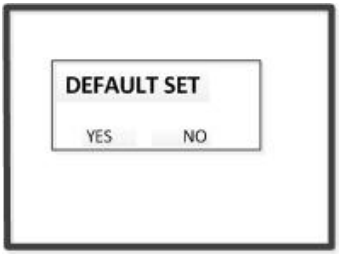
Selecting affirms the changes, selecting cancels the setting changes.

4.12 Default screen



Use this screen flow to access the Default Menu of the Flexo device. If is selected for DEFAULT SET, see Section on Default Values for details. Selecting cancels the default setting change requested.

4.13 Default Set Screen Detail



You can return the Flexo to the default setting through the Main menu.
Use the Control Knob to select or .
By selecting YES, the system will erase all previously set values and return to the default values.

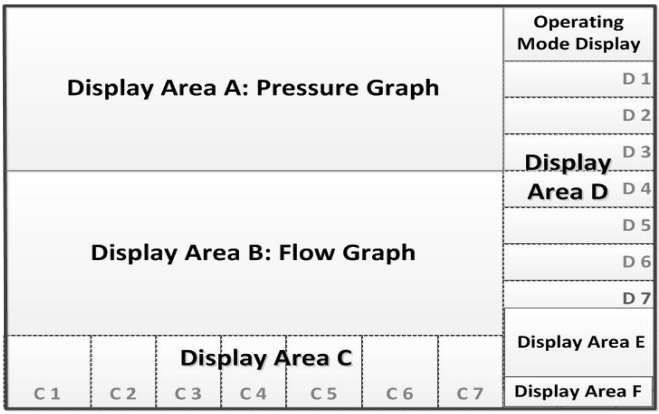
Please refer to the Default Settings listed in the section “FIRST TIME USE OF THE FLEXO DEVICE”.

5 Monitor display layout, operating modes and parameters

5.1 Monitor screen display layout

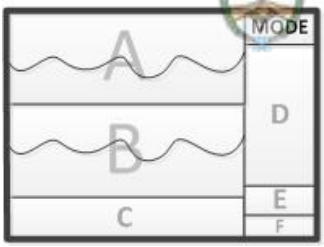
This is a general layout screen of the Flexo Display in the Monitor Function. While the illustration does not reflect the actual settings, it serves to show the partitions of different information being displayed.

For a list of available settings in each operating mode, see the relevant section for the specific Operating Mode.



Display Area	Object Name	Details
A	Pressure Graph	Pressure versus Time Display (in cm H_2O, 12 seconds time basis)
B	Flow Graph	Flow versus Time Display (lpm, 12 seconds time basis)
C	Patient Parameters	Patient Parameters calculated during operation
D	Operating Mode Settings	Settings available in Operating Mode
E	Special Options Settings	Additional Options in Operating Mode
F	System Status Displays	System Status Display • Padlock Icon, showing Lock-out status • Alarm Description • Alarm Star Icon, showing Alarm status

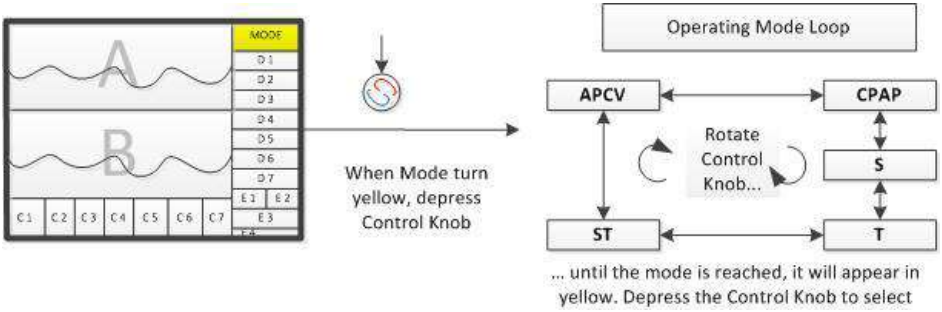
5.2 Operating modes



For each Operating Mode listed below, Flexo lists the settings available on the Clinical Settings Area on the right-most column of the display. Each mode has basic settings. Certain modes have additional settings that are available. This section details the all possible settings available for each of these modes.

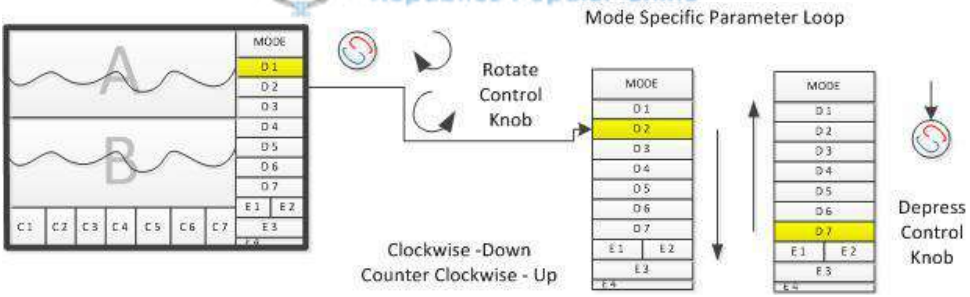
Mode	Therapy Description
S	Spontaneous Mode Bi-Level Airway Pressure
T	Timed Mode Bi-Level Airway Pressure
ST	Spontaneous Mode Bi-Level Airway Pressure with Timed Mode Back-up
APCV	Assisted Pressure Control Ventilation Mode Bi-Level Airway Pressure
CPAP	Constant Positive Airway Pressure

5.2.1 Changing operating modes



When the setting parameter is active, the background appears in yellow color. Rotate the Control Knob and follow the General Use of Flexo Control Knob until the desired selection is on a yellow background. Depress and rotate the Control Knob until the new value is available. Depress the Control Knob to accept the new value selected.

5.2.2 Changing settings and parameters in operating modes

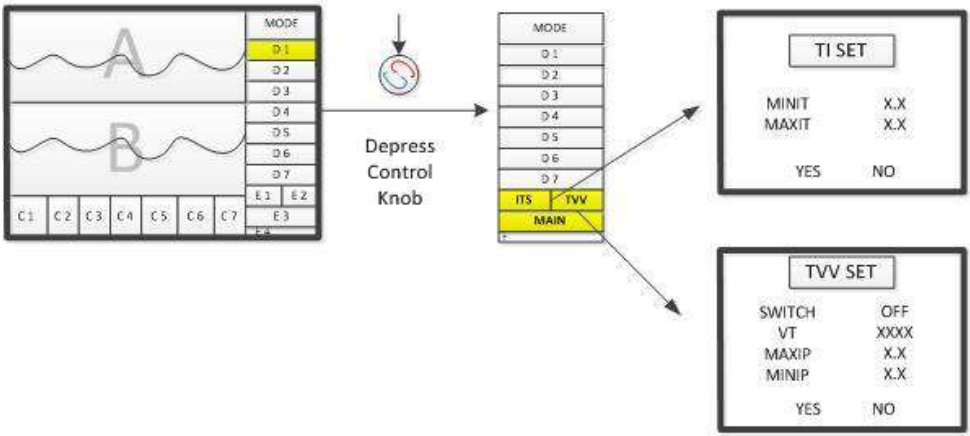


The method to change settings in Operating Mode also compiles with the general rule for using the Flexo Control Knob.

- Rotate the Control Knob to select the desired parameter
- Depress the Control Knob to affirm the selection
- Rotate the Control Knob to modify the selected parameter
- Depress the Control Knob to confirm the change

See the section on “General Use of the Control Knob in the Flexo Device” for details.

5.2.3 Changing optional settings in operating modes



Use this screen flow to access the Optional Settings Menu of the Flexo device. See the section on Optional Ventilation Modes for details.

Selecting affirms the changes, selecting cancels the setting changes.

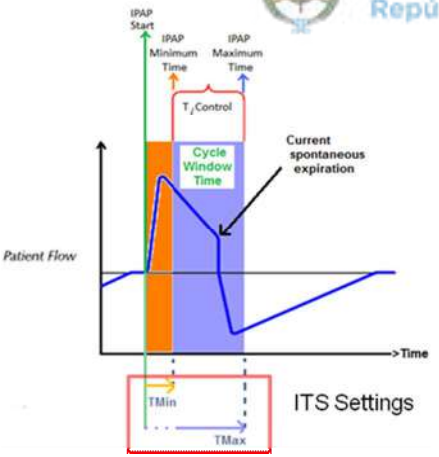
5.3 Ventilation options within certain operating modes

On the Flexo device, there are two additional options that can enhance the clinical ease and flexibility of the mechanical ventilation.

- Ventilation based on ITS, or Inspiratory Time Set, can be activated in S and ST modes*
- Ventilation based on TVV, or Tidal Volume Ventilation, can be activated in S， ST， APCV and T modes

* Note that ITS settings are accessible but not active in operating modes not mentioned here.

5.3.1 Inspiratory Time Set (ITS) Option



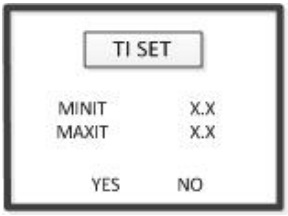
Inspiratory Time Set (ITS) allows the clinician to define the time patient spends in Inspiratory phase. It can be activated in S and ST modes. There are several ways to utilize ITS Mode:

(1) Ensure the patient takes in a minimum breath duration, or,

(2) Allow the physician to prolong IPAP phase in order to decrease chaotic breathing by patient,

This mode can be useful for patients who exhibiting shallow breathing or may be highly anxious.

ITS Option is Set Using the TI SET Menu



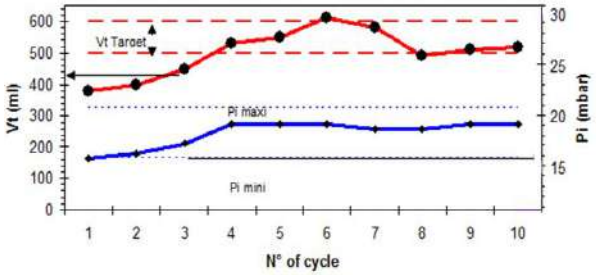
The setting for ITS are as follows

- MINIT: 0.2 to 4.0 seconds, in 0.1 second steps
- MAXIT: MINIT to 4 seconds, in 0.1 second steps

Selecting affirms the changes to the parameters, selecting cancels the setting changes.

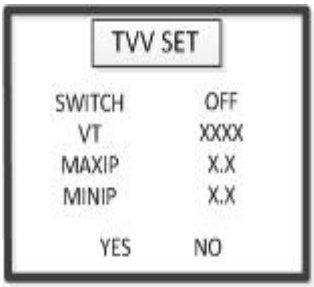
5.3.2 Target Volume Ventilation (TVV) Option

TVV allows the clinician to define a tidal volume value which the patient should receive. Along with a band of IPAP range, as defined by MAXIP and MINIP, the device will deliver the intended tidal volume in all operating modes.



The graphic on the left shows a set goal for the patient TV of 500 ml. The setting of MAXIP = 30 cm H_2O and a MINIP = 21 cm H_2O.

TVV Option is Set Using the TVV Menu



The settings for TVV are as follows

- SWITCH: ON/OFF
- VT: 50 to 2500 ml, in 50 ml
- MAXIP: MINIP to 30 cm H_2O, in 0.5 cm H_2O steps
- MINIP: 4 cm H_2O to MAXIP, in 0.5 cm H_2O steps

To switch the feature or by selecting the SWITCH feature. After making changes to the parameters, select affirm those settings, selecting to cancel the setting changes.

5.4 Locking and unlocking the settings

The Flexo device can be locked to prevent accidental changing of the settings on the device. First, rotate the Control Knob to Area F of the Display in Monitor Screen. The open padlock icon in Area F should be in a yellow background. This shows that it is active. By depressing and holding the Control Knob for three seconds, the padlock should appear closed.

In this state, the device will not allow any settings to be changed when the control knob is accidentally touched. The closed padlock icon in the Area F of the Monitor Screen will remain closed after the device is switched off. As long as power is connected to the Flexo device, the settings in locked mode are retained.

The device can be unlocked by depressing the Control Knob again for three seconds. The yellow padlock icon in the Area F of the Monitor Screen will appear unlocked.

5.5 Primary operating modes of Flexo device

- **Spontaneous Mode: S Mode**

  The inspiration and expiration phase is dependent on patient's spontaneous breathing. During the inspiration phase the device delivers at the preset IPAP pressure and during expiration phase the device delivers at the preset EPAP pressure.

Operating Mode	S TAG	Spontaneous Mode Bi-Level Breathing Therapy Summary	 Range
Available Setting Parameters	IPAP	IPAP	4 to 30 cm H_2O with ST30 4 to 25 cm H_2O with ST25 4 to 20 cm H_2O with ST20
	EPAP	EPAP	4 to 20 cm H_2O
	ISLP	Inspiratory Slope Adjustment	1 to 6; 1 = fast rise; 6 = slow rise
	ISNS	Inspiratory Sensitivity Adjustment	1 to 6; 1 = most-; 6 = least-; sensitive
	ESNS	Exhalation Sensitivity Adjustment	1 to 6; 1 = most-; 6 = least-; sensitive
	RAMP	RAMP Time Delay for pressure to be raised from the pressure setting to the therapy setting	0 to 60 minutes
	AUTO	Start therapy by breathe detection	ON or OFF
Options	ITS	Inspiratory Time Set	MIN IT= 0.2 to MAX IT seconds MAX IT= MINIT to 4.0 seconds
	TVV	Tidal Volume Ventilation	TV Setting 50 to 2500 ml MAX IP = MINIP to 30 cm H_2O MIN IP = 4 to MAX IP

- **Timed Mode: T Mode**

  The inspiration and expiration phase is dependent on the settings of the device. The patients breathing will be controlled by the BPM (Breaths per minute) and I/T% (percentage of inspiration time over a respiration cycle) set.

  The pressure will be switched automatically at a rate determined by BPM and I/T%.

Operating Mode	**T**	**Timed Mode Bi-Level Breathing Therapy**	
	TAG	**Summary**	**Range**
Available Setting Parameters	IPAP	IPAP	4 to 30 cm H_2O with ST30 4 to 25 cm H_2O with ST25 4 to 20 cm H_2O with ST20
	EPAP	EPAP	4 to 20 cm H_2O
	ISLP	Inspiratory Slope Adjustment	1 to 6; 1 = fast rise; 6 = slow rise
	BPM	Breathes Per Minute	4 to 60 Breathes
	I/T%	Inspiratory Phase Percentage	10% to 80%
Options	TVV	Tidal Volume Ventilation	TV Setting 50 to 2500 ml MAX IP = MINIP to 30 cm H_2O MIN IP = 4 to 30 cm H_2O

Note that ITS Option is accessible in T mode but any settings in ITS Option are not active in T mode.

- **CPAP Mode**

  In CPAP mode the device will output the set pressure constantly.

Operating Mode	**CPAP**	**CPAP Therapy**	
	TAG	**Summary**	**Range**
Available Setting Parameters	CPAP	CPAP	4 to 20 cm H_2O
	RAMP	RAMP Time Delay for pressure to be raised from the pressure setting to the therapy setting	0 to 60 minutes
	AUTO	Start therapy by breathe detection	ON or OFF

- **Spontaneous- Timed Mode: ST Mode**

  ST mode includes 2 patterns, when the patient is able to breathe spontaneously, the device works as S mode; however, when the patient is unable to breathe spontaneously or the patient's breath slows to a rate less than the preset backup rate (BPM), the device will switch to T mode.

  For optional modes, ITS settings are activated only when the patient is breathing spontaneously. When the device detects that the patient's breathing is less than the preset backup rate, the ITS settings will no longer active as the device enters T mode.

Operating Mode	**ST**	**Spontaneous Breathing Mode with Timed Back-up**	
	TAG	**Summary**	**Range**
Available Setting Parameters	IPAP	IPAP	4 to 30 cm H_2O with ST30 4 to 25 cm H_2O with ST25 4 to 20 cm H_2O with ST20
	EPAP	EPAP	4 to 20 cm H_2O
	BPM	Breathes Per Minute	4 to 60 Breathes
	I/T%	Inspiratory Phase Percentage	10 to 80%
	ISLP	Inspiratory Slope Adjustment	1 to 6; 1 = fast-; 6 = slow- rise
	ISNS	Inspiratory Sensitivity Adjustment	1 to 6; 1 = most-; 6 = least-; sensitive
	ESNS	Expiratory Sensitivity Adjustment	1 to 6; 1 = most-; 6 = least-; sensitive
Options	ITS	Inspiratory Time Set	MIN IT = 0.2 to 4.0 seconds MAX IT= MINIT to 4.0 seconds
	TVV	Tidal Volume Ventilation	TV Setting 50 to 2500 ml MAX IP = MINIP to 30 cm H2O MIN IP = 4 to 30 cm H2O

Note that ITS Option is available in ST mode but ITS Option will not be active when T mode is activated in ST mode.

- **Pressure control Mode: APCV(Assisted pressure control ventilation)**

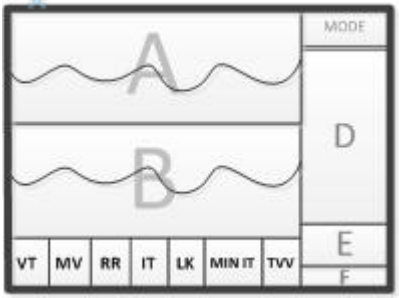
  APCV mode is similar to the ST mode, except that all breaths in a controlled cycle. The APCV mode is a pressure-limited, device-or-patient triggered, time-cycled mode. Therefore, the inspiratory pressure may be triggered by the patient or by the therapy device, but IPAP will be pressure-limited with a set cycle time determined by the inspiratory time control (I/T %).

Operating Mode	**APCV** TAG	**Assisted Pressure Control Ventilation** Summary	**Range**
Available Setting Parameters	IPAP	IPAP	4 to 30 cm H_2O with ST30 4 to 25 cm H_2O with ST25 4 to 20 cm H_2O with ST20
	EPAP	EPAP	4 to 20 cm H_2O
	BPM	Breathes Per Minute	4 to 60 Breathes
	I/T%	Inspiratory Phase Percentage	10 to 80%
	ISLP	Inspiratory Slope Adjustment	1 to 6; 1 = fast rise; 6 = slow rise
	ISNS	Inspiratory Sensitivity Adjustment*	1 to 6; 1 = most-; 6 = least-; sensitive
	ESNS	Expiratory Sensitivity Adjustment*	1 to 6; 1 = most-; 6 = least-; sensitive
Options	TVV	Tidal Volume Ventilation	TV Setting 50 to 2500 ml MAX IP = MINIP to 30 cm H2O MIN IP = 4 to 30 cm H2O

Note that ITS Option is accessible in APCV mode but any settings in ITS Option are not active in APCV mode.

* ISNS and ESNS settings are not active in APCV mode.

6 Patient parameter display

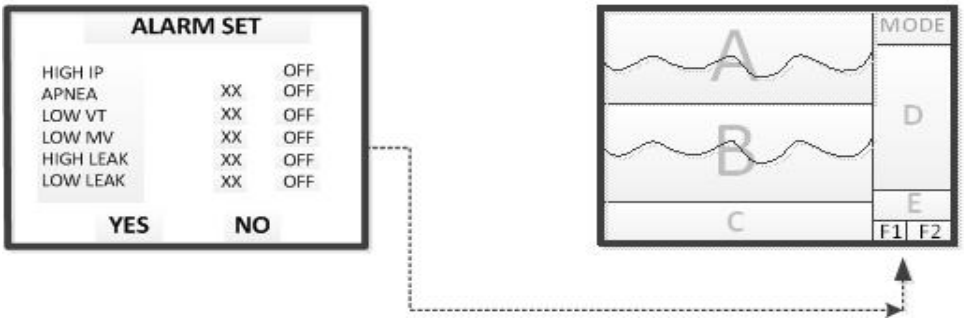


The bottom left region of the display shows the patient parameters as it is monitored by the device is shown in the table below.

VT	MV	RR	IT	LK	MINIT	TVV
Tidal Volume	**Minute Volume**	**Respiratory Rate**	**Inspiratory Time**	**Leak**	**Minimum inspiratory time**	**Target Volume Ventilation**
50 to 3000 ml, ±20%	0 to 99.9 lpm, ±20%	1 to 99 BPM, ± 2 BPM	0.2 to 4.0 sec, ±20%	0 to 99.9 lpm, ±10%	0.2 to 4.0 sec, ±20%	On or Off

7 Alarm settings, appearance and handling on Flexo

The Alarm Set Menu is an option on the Main Menu. Alarm Set Screen is where changes to the settings can be initiated. If an alarm condition applies, the Area F of the Monitor screen will display Alarm Description and a flashing Alarm Star Icon and accompanied by an audible tone and the LED 2 (Alarm LED) will light up.



Once alarm condition no longer exists, the audible tone will stop and the yellow LED2 (Alarm LED) will disappear. The Area F of the Monitor screen will cease to display Alarm Description and the Alarm Star Icon will no longer flash.

7.1 Alarm summary table

TAG	Description	Range and Options
MASKOFF	Patient Circuit Disconnect	System Alarm
HiPRESS	High Inspiratory Pressure Alarm	3 cm H_2O > IPAP setting in 1 sec
APNEA	Apnea Alarm	5 to 60 sec, 5 sec / step
LOW VT	Low Tidal Volume Alarm	50 to 3000 ml, 50 ml / step
LOW MV	Low Minute Volume Alarm	1 to 99 lpm, 1 lpm / step
HIGLEAK	High Leak Alarm	LOWLEAK to 200 lpm, 1 lpm / step
LOWLEAK	Low Leak Alarm	1 lpm to HIGHLEAK, 1 lpm / step

The table above shows the Alarm Settings that are available in the Flexo product. The list arranged in order of priority. To set an alarm, use the control dial to select which alarm is used and then turn or .

7.2 Alarm prioritization

According to the priority listed in the previous section, alarms in the Flexo device are arranged in this order, with Maskoff is the highest priority and LowLeak is the lowest

priority. The Alarm description shows the highest priority alarm rather than the most recent alarm.

If two alarms occur within the same period of time, the alarm of higher priority will displayed in Area F in place of the alarm of lower priority.

See the Section on “MUTE ALARM BUTTON” for further refinement of the alarm priorization.

7.3 Mute alarm button

While an alarm is sounded, the alarm can be muted for 15 seconds by depressing Button2 (Mute Alarm button). Note that after the alarm mute button is depressed, any subsequent (new) alarm(s) will also be muted.

The LED2 (Alarm button) will continue to light up if the alarm condition applies. The Alarm Description and Alarm Star Icon will continue to flash in Area F of the Monitor screen.

If an alarm activation is muted and is followed by an alarm of higher priority, the alarm buzzer will sound to signal the new alarm condition. The description of an alarm of higher priority will display in place of an alarm of lower priority in Area F of the Monitor Display.

7.4 Maskoff alarm

In all operating modes, when the system detects patient air circuit is disconnected, the mask off alarm will sound. This is a system level alarm cannot be turned off.

In CPAP mode, with AUTO parameter selected in ON, the Flexo device will stop when the system detects that the patient air circuit is disconnected. In this case, the maskoff alarm will not sound.

7.5 High Pressure alarm (HIPRES)

The high-pressure alarm is activated when the airway pressure is 3 cm H_2O higher than the IPAP setting for more than 1 second. This alarm can be turned or .

7.6 Apnea alarm (APNEA)

The apnea alarm detects pauses in spontaneous breathing. The alarm is activated when the time between spontaneous breaths exceeds the Apnea alarm setting. The alarm setting range is from 5 to 60 seconds, 5 second per step.

The alarm is terminated as soon as the Flexo device detects a spontaneous breath in the patient circuit. This alarm can be turned or .

7.7 Low tidal volume alarm (LOWVT)

The low tidal volume alarm is activated when the calculated tidal volume ≤ the alarm setting. The alarm setting range is from 50 to 3000ml, 50 ml per step.

The alarm is terminated when the calculated tidal volume is greater than the alarm setting or by pressing the Alarm Mute Button. This alarm can be turned or .

7.8 Low minute ventilation alarm (LOWMV)

The low minute ventilation alarm detects when a user is not receiving the specified volume of air per minute. The alarm is activated when the calculated minute ventilation ≤ the alarm setting. The alarm setting range is from 1 to 99 lpm, 1 lpm per step.

The alarm is terminated when the calculated minute ventilation is greater than the alarm setting or by pressing the Alarm key. This alarm can be turned or .

7.9 High leakage (HIGH LEAK)

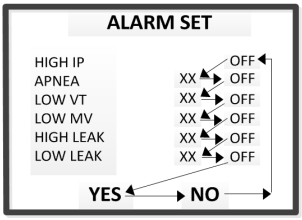
Alarm for High Leakage can be set from the value of the LOW LEAK setting upto 200 lpm, in 1 lpm per step. This alarm can be turned or .

7.10 Low leakage (LOW LEAK)

Alarm for Low leakage can be set from 1 lpm to the value of the HIGH LEAK value, 1 lpm per step. This alarm can be turned or .

7.11 Alarm set display

Below shows the method of selecting and changing the Alarm Settings on the Flexo device.



- On the ALARM SET Screen shown on the left diagram, the yellow selection window can be moved by rotating the Flexo Control Knob.
- When the yellow selection window falls on the parameter, depress the control knob one time.
- Then rotate the control knob and the value will be changed. A clockwise rotation increases the value. A counter-clockwise rotation decreases the value.
- Refer to the General Use of Flexo Control Knob for details on how to change parameters.

7.12 Checking the power failure alarm

Switch the device on and keep running for at least 10 seconds. If the power cord is unplugged or the power is switched off at the socket the alarm should sound. Check whether the alarm lasts long enough (~ 30sec). When the device is switched on the alarm should stop automatically. Please check the alarm at least once a month. This alarm does not show in the Alarm Status Area of the display and it is a system level alarm cannot be turned off.

If the mains power is disconnected, the power failure alarm will sound. The alarm is stop after the power is resupplied to the device will return to the stand-by mode. If the Start/Stop button is pressed, the device will restart with operating mode and settings of the most recent session.

8 Functions Summary of the device

8.1 Inspiratory time percentage setting

Inspiratory time percentage (I/T%) of the total respiratory cycle as inspiratory ratio.

When the Flexo is in T, ST or APCV mode the inspiratory ratio can be set. The range can be set between 10 to 80%, adjusted in intervals of 1%.

8.2 Respiratory rate (BPM)

In T, ST or APCV mode, the frequency of breathing can be set. Frequency setting range of 4 to 60 breathes per minute, adjusting in 1bpm interval.

8.3 RAMP

In CPAP and S mode, when this function is selected the device will start delivering 4 cmH_2O air pressure first before increasing the pressure steadily to the set pressure within the set time. This function is to allow the patient to fall asleep more comfortably. This soft start function is particularly helpful for patients who are not accustomed to continuous positive airway pressure therapy. The pressure delay time range is between 0 - 60 minutes with pressure steps every minute.

8.4 Automatic mode

In the CPAP mode, if "Automatic" (ON) mode is selected then when the mask is breathed into the Flexo will automatically begin to provide therapy. When you remove the mask within 15 seconds, the Flexo will automatically shut down. In this mode, if the Pressure Hose or Breathing mask are disconnected, the Flexo will automatically shut down.

9 Cleaning and maintenance

9.1 Cleaning the Flexo

WARNING! To avoid electrical shock unplug the Flexo power cord before cleaning the device

WARNING! Do not immerse the device in liquid or allow any liquid to enter the enclosure, inlet filter, or any other openings

1. To clean the exterior of the device use a dampened cloth and a mild detergent. Allow the device to dry completely before plugging in the power cord.
2. The mask and tubing should be cleaned daily. For details on cleaning your mask and accessories refer to the cleaning instructions packaged with the accessories.

9.2 Cleaning the Patient Air Circuit

The Curative Medical Patient Air Circuit consists of a pressure hose and a pressure sampling tube.

1. Clean the exterior of the device use a dampened cloth and a mild detergent
2. Do not rinse the interior of the air circuit as this may allow water to enter the device.

If your patient air circuit needs replacing, make sure the replacement approved by Curative Medical Devices gmbh.

WARNING! Ensure the patient air circuit is dry before use.

9.3 Cleaning the Filter

The fine filter is in the filter cassette at the back of the device. Take it out and change it with a new one every week. Never use the device without a filter. Dirty inlet filters may cause high operating temperatures that may affect device performance. Regularly examine the inlet filters for cleanliness. If there is a lot of dust or smoke in the environment change the filter more frequently.

Ensure that you buy your filters from a vendor endorsed by the manufacturer.

WARNING! Ensure the filter is dry. A damp or wet filter may damage the device**.**

WARNING! Ensure the device is powered off before changing the filter.

10 Troubleshooting and Service

10.1 Troubleshooting

- Different problems that may be encountered, their causes and solutions are detailed below.
- If your dealer cannot resolve the problems, please consult your physician or contact our service center

Problem	Cause	Solution
Low output pressure	Air leak is detected by the device.	Check that the pressure sampling tube is not occluded. If necessary, clean the pressure sample tube thoroughly. After cleaning, assure it is dried properly.
		Check all connections to reduce leakage. Re-seat mask and adjust headgear to reduce leakage around mask.
Discomfort due to high pressure.	When pressure is over 13cmH_2O(~1.3kPa), some patients will feel discomfort. However, this pressure may be needed for effective therapy.	You may take up to 4 weeks to be accustomed to higher pressures. When using the device, breathe through nose with mouth closed and keep calm. If you continue to experience discomfort consult your physician.
Symptoms of sleep apnea syndrome appears again. (like day time sleepiness)	When your weight is increased, your nose is blocked or you drink etc, you need higher pressures.	Consult your physician.
Air is too warm	Dirty filter	Change filter
	Air inlet blocked	Check air inlet
	The device is too close to wall, curtains or other objects, which hinders air	Take away the device to keep it over 20cm from wall, drapery or bedding that may hinder free

	circulation	airflow around the inlet.
No air flow	Water in the pressure tube	Dry the pressure sampling tube thoroughly
	Motor malfunction	Check motor by contacting your distributor
Low air flow	Ramp function is active	Decrease or deactivate RAMP setting
	Air inlet blocked	Check air inlet
	Settings and air let appear to be normal	Check that the Pressure Sampling Tube is not properly connected
Motor always operates at maximum speed	The pressure tube is not connected or it is blocked	Check the pressure sampling tube
	Leakage inside device, leaks out of the seams	Contact our service center
When turned on, the device doesn't work	The device is in automatic operation (AUTO ON)	Set the device to manual operation (AUTO OFF) in CPAP
	No electric supply	Check whether Flexo power cable is securely and properly connected to the device
		Check main electricity supply (at wall outlet) is active.
	Internal component failure	Check internal component status by contacting your distributor
Motor works normally but the output pressure is lower than the set pressure	Patient air circuit is not correctly connected with the device	Check whether connection is correct and firm
	Air leakage through mask or patient hose	Contact your distributor or our service center
Only low output pressure	Dirty filter or air outlet blocked	Change filter, check air outlet
	Therapeutic pressure readjusted	Consult your physician
	RAMP function active in CPAP mode	If necessary, cancel RAMP function or change the settings

		of RAMP and try again
Too noisy	Patient hose has been disconnected or connected incorrectly	Check for loose connections and reconnect securely.
	Leakage through mask or patient hose	Check patient hose and refit the mask to decrease leak
	Not air tight between humidifier and device	Check all pressure connections to the device for leaks

10.2 Service

- Service of the Flexo should only be performed by Curative Medical Devices gmbh authorized.
- To maintain the device's useful life, the user must review and understand the Flexo's safety information in the "Warnings and Cautions" Section, as well as the instructions in the Section titled, "Cleaning and Maintenance".

11 Specifications

Flexo	
Pressure range	ST30 4cm H_2O (~0.4kPa) to 30 cm H_2O (~3.0kPa) ST25 4cm H_2O (~0.4kPa) to 25 cm H_2O (~2.5kPa) ST20 4cm H_2O (~0.4kPa) to 20 cm H_2O (~2.0kPa)
Pressure variance (Tested in accordance to ISO-17510-1: 2007, Test Annex CC)	IPAP ±(2% of the full scale reading + 4% of the actual reading) EPAP ±(2% of the full scale reading + 4% of the actual reading) CPAP ±(2% of the full scale reading + 4% of the actual reading)
Ramp time	0-60min, in 1min./step, ±20%
Noise: (10 cm H_2O/~1.0kPa)	<45dB (A)
Dimensions	300mm(L)×200mm(H)×170mm(W)
Weight	2.75Kg
AC power	AC Input 100-240V 2.1A 50-60Hz
DC power	DC Input 12-24V, 2.5 to 5.5A
Protection again electric shock	Class II
Degree of protection against electric shock	Type B Applied Part
Degree of protection against harmful ingress of water	Ordinary Equipment, IPX1
Electromagnetic Compatibility	Flexo device meets the requirements of EN 60601-1-2.

*Pressure Variance as measured by method described in ISO-17510-1 Annex BB, Pressure Accuracy In Normal Use.

Operation	
Temperature	+5°C ～ +35°C
Relative humidity	10%％～ 95%(non-condensing)
Atmosphere pressure	700hPa ～ 1060hPa

Transport or storage	
Temperature	-20°C ～ +55°C

Relative humidity	10% ～ 95%(non-condensing)
Atmosphere pressure	500hPa ～ 1060hPa

PARAMETERS, Function	ADJUSTABLE AND CALCULATED Description	Range, Adjustment Steps and Accuracy
IPAP	Inspiratory Positive Airway Pressure	4 to 30cm H_2O with ST30 [0.5 cm H_2O per step] 4 to 25cm H_2O with ST25 [0.5 cm H_2O per step] 4 to 20cm H_2O with ST20 [0.5 cm H_2O per step] (see Pressure Variance for accuracy information)
EPAP	Expiratory Positive Airway Pressure	4 to 20cmH_2O [0.5 cmH_2O per step] (see Pressure Variance for accuracy information)
CPAP	Continuous Positive Airway Pressure	4 to 20cmH_2O [0.5 cmH_2O per step] (see Pressure Variance for accuracy information)
MODE	Operation mode	S, T, ST, APCV,CPAP
ISLP	Speed of rising pressure	1 to 6, 1 per step, from 40 ms to 400 ms, time taken to reach 80%*(time from EPAP to IPAP), ±20%
ISNS	Sensitivity of inspiration triggering	1 to 6, 1 per step, 1 to 12 lpm (2 cc up to 12 cc) 1 = 1 lpm to 6 = 12 lpm, ±20%
ESNS	Sensitivity of expiration triggering	1 to 6, 1 per step, 1 = 60%-, to 6 = 10%-, maximum peak flow, ±20%
BPM	Breaths per minute	4 to 60, 1 bpm per step, ± 2 bpm
MV	Minute Ventilation	0 to 99.9 lpm, ± 20%
IT	Inspiration Time	0.2 to 4.0 second, ± 20%
Leak	Leakage Volume per minute	0 to 99.9 lpm, ± 10%

I/T%	Inspiratory Time as a percent of the respiration cycle	10% to 80%, 1% per step, ±20%
VT	Tidal Volume Value in TVV Mode	50 to 2500 ml, 50 ml per step, ±20%
MAXIT	Maximum Inspiration Time Value in ITS Mode	0.2 to 4.0 s, .1 s per step ±20%
MINIT	Minimum Inspiration Time Value in ITS Mode	0.2 to 4.0 s, .1 s per step ±20%
RAMP	Ramp Time (CPAP and S)	0 to 60 min, 1min per step, ±20%
AUTO	Automatic start by breathe detection (CPAP and S)	ON/OFF
HiPRES	High pressure alarm	ON/OFF
APNEA	Apnea alarm	5s to 60s, 5s per step
LowMV	Low minute ventilation alarm	1 to 99 L/m, 1 lpm per step
LowVT	Low tidal volume alarm	50 to 3000 ml, 50 ml per step
HIGHLK	High Leak alarm	1 to 200 lpm, 1 lpm per step
LOWLK	Low Leak alarm	1 to 200 lpm, 1 lpm per step
POWERFAIL	Power Failure alarm	System Alarm, Always On
MASKOFF	Mask Off alarm	System Alarm, Always On

DISPLAYED PARAMETERS Function	Description	Range/Measurement
VT	Tidal Volume	50 to 3000 ml, ±20%
MV	Minute Ventilation	0 to 99.9 lpm, ± 20%
RR	Respiratory Rate	1 to 99 bpm, ± 2 bpm
IT	Inspiration Time	0.2 to 4.0 sec, ± 20%
LK	Leakage Volume per minute	0 to 99.9 lpm, ± 10%
MINIT	Minimum inspiratory time	0.2 to 4.0 sec, ± 20%

12 Quality warranty

Every Flexo device meets all the technical statements in the user manual and all accessories and spare parts are complete. According to the regulations, the warranty of the device is two years from the day of purchase.

Within 7 days of purchase, if there is any deficiency in function and workmanship you can return the device, exchange it or get it repaired with free of charge.

We are not responsible for:

- Damage by misuse, abuse or accident.
- Damage caused by water getting into the device due to misuse is not covered the under warranty.
- Do not open the device without our permission or the warranty will become void.
- When returning the device for any reason you must pay for accessories and spare parts.
- Dispose discarded items or the device according to your country's law or return it to our company.

13 Electric magnetic information

Guidance and manufacturers declaration of electromagnetic immunity for equipment and systems that are not life supporting

Attention! Please use Flexo Bi-level sleep apnea breathing therapy and ventilatory support device according to electric magnetic information in list.

The Flexo is intended for use in the electromagnetic environment specified below. The user of the Flexo should ensure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Flexo uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Flexo is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations	Complies	

/ flicker emissions IEC 61000-3-3		

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±4 kV air ±8 kV air	±6 KV contact ±4 kV air ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Flexo requires continued operation during power mains interruptions, it is recommended that the Flexo be powered from an uninterruptible power supply or a battery.

	cycles <5% UT (>95% dip in UT) for 5 sec	cycles <5% UT (>95% dip in UT)] for 5 sec	
Power frequency (50/60Hz) Magnetic field IEC-61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at normal levels typical of a location in a commercial or hospital environment.
NOTE: UT is the A/C mains voltage prior to application of the test level.			

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment including cables should not be used close to any part of the Flexo other than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the Flexo is used exceeds the applicable RF compliance level above, the Flexo should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as, re-adjusting or relocating the Flexo.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Flexo

The Flexo is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the Flexo can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF

communications equipment (transmitters) and the Flexo as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.39	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

14 Disclaimer of warranty and limitation of Flexo

Curative medical devices gmbh (Curative) guarantees the highest possible care in the manufacture of its products. However, it has to be observed that due to the difference of the patients under medical treatment, no product under all circumstances is always absolutely effective. Curative has no influence in the application of the product, in the

diagnosis of the doctor and the application of the product out of its premises. Curative cannot guarantee either the intended effectiveness or the application of the product without any complications. Therefore, Curative medical devices gmbh does not undertake a responsibility for any damages and costs. Curative will only replace those products showing a defect which Curative is responsible for. Members of Curative are not allowed to change the conditions mentioned before, to extend liability or to assume any additional product-related obligations. Product subject to change. There is no express or implied warranty, including without limitation of any implied warranty of merchantability or fitness for a particular purpose, on Curative products described in this publication. Under no circumstances shall Curative be liable for any direct, incidental, or consequential damages other than as expressly provided by specific law. No person has the authority to bind Curative to any representation or warranty except as specifically set forth herein.

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Curative will not be responsible for any direct, incidental, or consequential damages resulting from re-use of the product.

IFU-21027121 R07

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CURATIVE

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Tel: +33 (0) 426100200
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E-mail: EC-REP@resmed.com

General Specifications

Patient type	Adult & pediatric patients
Dimensions (H x W x D)	115 cm x 65 cm x 50 cm
Weight	42 kg
Power	220-240 V, 50-60 Hz (well grounded)
Backup power	At least 30 minutes, nominally between 2 to 4 hours
Display	10.4 inch TFT display

Ventilator

Tidal volume	Adjustable range: 50-1500 ml, Display range: 0-2000 ml
Respiratory rate	1-99 bpm
Inspiratory pressure limit	10-60 cmH2O
Ventilation modes	Manual, Spontaneous, Standby, Assist/Control (A/C), Intermittent Positive Pressure Ventilation (IPPV), Synchronized Intermittent Positive Pressure Ventilation (SIPPV), Intermittent Mandatory Ventilation (IMV), Synchronized Intermittent Mandatory Ventilation (SIMV)
Minute volume	≥ 18 L/min BTPS
Trigger Sensitivity	Pressure: -10-10 cmH2O
SIMV Rate	1-20 bpm
Inspiration/Expiration ratio (I:E)	4:1-1:4
Inspiratory time	0.1-2.0 s
PEEP	0-10 cmH2O
Oxygen & AIR inlet pressure range	280-600 kPa
O2 concentration	45-100 %
SIGH	1-8 per 100 breaths (tidal volume set at 1.5 x)

Humidifier

Humidifier	9 level adjustable nebulization

Other Specifications

Monitoring	Tidal volume, minute volume, control frequency, spontaneous respiration rate, airway pressure, I:E, inhalation & exhalation status, Inspiratory trigger, inhaled oxygen concentration, PEEP, airway resistance, lung compliance & more
Alarm	Audible and/or visual alarms for ventilation volume, tidal volume, oxygen concentration, asphyxia, airway pressure, intubation disconnection, low oxygen, power failure & more, also features a alarm query function

Professional Medical Equipment Exporter & Manufacturer

ABOUT US

Founded in 2003 & headquartered in Nanjing, Perlong Medical is one of the largest exporter & manufacturer of medical equipment in China. We specialize in providing a one stop solution for medical equipment needs and helping our clients improve their procurement programs.

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Perlong Medical Equipment Co., Ltd.

PA 700B MEDICAL VENTILATOR

Superior Ventilation From Experience

Support

Diligency

Proficiency

Designed for resiptorary care

Looking for high-caliber mechanical ventilation that delivers competent responsive respiration thearpy, that doesn't break the bank?

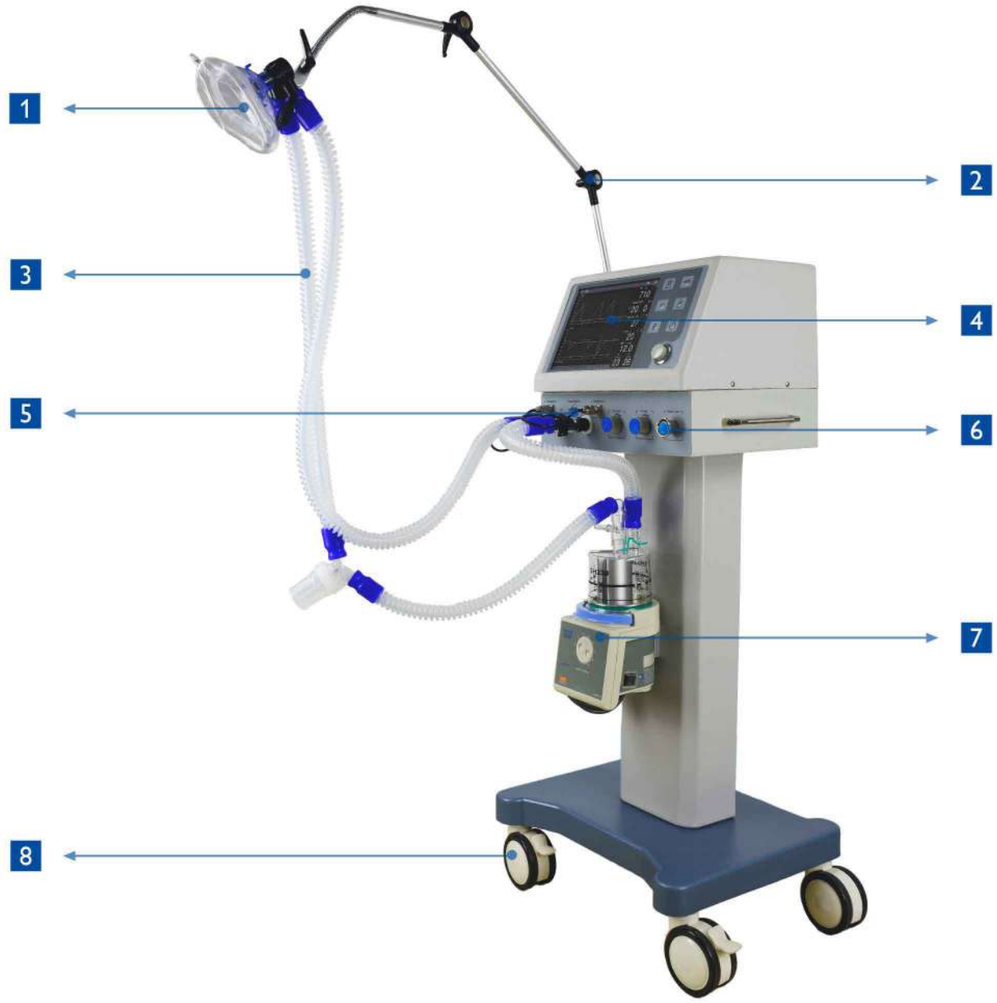
At Perlong, we recognize the crucial role that mechanical ventilation plays in the complex world of modern healthcare. We understand there are numerous challenges ranging from raising patient throughput, medicinal shortages, cost overruns and the need to keep abreast of developments in an evolving discipline.

Therefore, in order to meet these challenges, the modern mechanical ventilator requires more than simple functionality, it needs to be able to precisely deliver what the patient needs. Therefore, finding the right solution that strikes the right balance between reliability & appropotieness demands both experience and expertise.

With over a decade of experience designing, developing and manufacturing anesthesia ventilation equipment, Perlong has that expertise, we understand your challenges and we created the PA 700B medical ventilator to provide you with the perfect medium between service and security.

Promoting Excellence Through Design

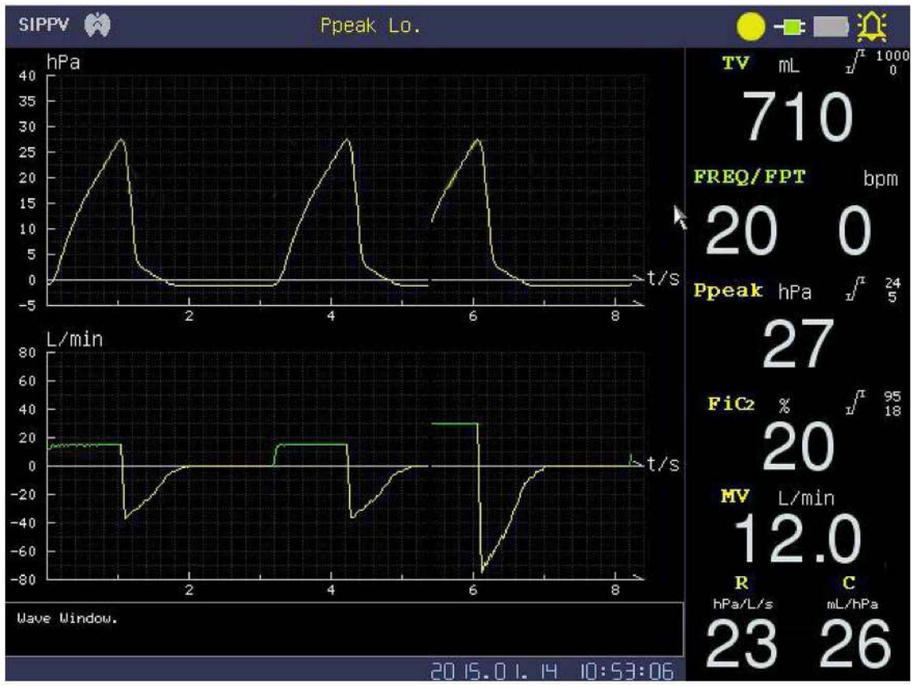
Built from nonhazardous environmentally friendly material, the precisely constructed and elegantly designed PA 700B provides an ergonomic and easily movable mechanical ventilator that requires only the bare minimum of operating space.



1. Lightweight reusable clear breathing mask
2. 3 section articulated adjustable support arm
3. Flexible easy-to-secure breathing circuit
4. Built-in high visibility 10.4 inch TFT color display
5. Quick response infrared flow sensors
6. Oxygen flush release
7. 9 level adjustible humidifer
8. Swivel wheels with caster contact brakes

Comprehension At A Glance

The built-in 10.4 inch TFT color display offers a simple and convenient method for users to view detailed relevant patient status information in a timely and easily accessible manner.



I Real time status indication

In the medical environment, its often critical to stay abreast of changes and developments in information. This is why we created a display system for the PA 700B, that succinctly and clearly provides real time notifications on the status of the patient, the alarms, the ventilation process, as well as the ventilator itself.

II Intuitive UI display

The trimmed down intuitive user interface of the PA 700B designed with accessibility and convenience in mind, allows users to effortlessly toggle between patient parameters, system settings, Pressure-Time, Flow-Time, Pressure-Volume and Flow-Volume waveforms at the touch of a button.

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ICU quality ventilation

The PA 700B adapts Perlong Medical's patented ventilator technology to deliver versatile proven high quality ventilation performance.

VENTILATION MODES:

- Intermittent Positive Pressure Ventilation
  - Standard & synchronized
- Intermittent Mandatory Ventilation
  - Precise rapid breath rescheduling
  - Standard & synchronized
- Continuous Spontaneous Ventilation
  - Completely unassisted & patient driven
- Standby Ventilation
  - Simple trouble-free disconnection
- Assist/Control Ventilation
  - Steady dependable tidal cycling
- And More

Features You Can Relay On

3 section support arm

Mounted robust fully adjustable articulated support arm devised to provide greater stability and improved conviencence.

Adjustable SH 330 humdifer

Adjustable 9 level professional medical humidifier, ensures smoother and more consistent gas nebulization.

Compact versatile design

The ergonomic lightweight frame and compact design choices allows for greater effectiveness & utility.

Accessories & Other Components

Aside from it's core components, the PA 700B also features an automated startup self-checking function, can reflexively convert to backup power mode during outages and comes equipped with an automatic self-calibrating sensor as well as an imported respiratory control valve for added efficiency.

Gas Connecting Tubes

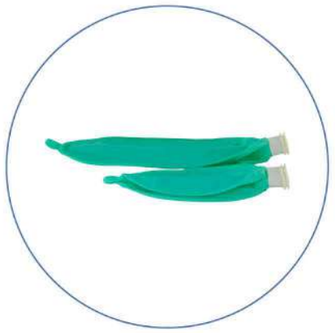
Sturdy easily identifiable color coded gas connecting tubes.

Infrared Flow Sensor

Promotes more reliable, stable and rapid gas flow response times.

Gas Pressure Regulators

Industry standard cylinder style brass gas pressure regulators.



Manual Breathing Bag

Robust rubber reservoir bag, available in adult, pediatric & neonatal sizes.

Clear Breathing Masks

Comfortable lightweight reusable breathing masks, available in all sizes.

Breathing Circuit Tubes

Reusable breathing circuit tubes, available in adult and pediatric lengths.

The PA 700B also includes a broad selection of other accessories for you to choose from:

- Battery
- Power cords
- Disposable breathing masks
- Disposable circuit tubes
- Swivel wheel with brakes
- Swivel wheel without brakes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2015

Datex-Ohmeda, Inc.
Trishia Mercier
Regulatory Affairs Leader
PO Box 7550
Madison, WI 53707

Re: K142679

Trade/Device Name: CARESCAPE R860
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, continuous, facility use
Class: II
Product Code: CBK
Dated: May 12, 2015
Received: May 13, 2015

Dear Ms. Mercier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142679

Device Name
CARESCAPE R860

Indications for Use *(Describe)*

The CARESCAPE R860 ventilator is designed to provide mechanical ventilation or support to neonatal, pediatric, and adult patients weighing 0.25 kg and above. The CARESCAPE R860 ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator that includes integrated monitoring of FiO2, airway pressure, flow, and volume.

Additional respiratory gas monitoring capabilities are supported through the use of optional GE patient monitoring modules.

Not all features are available for all patient types or product configurations.
The CARESCAPE R860 ventilator is not a pulmonary function calculation device.

The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	September 17, 2014
Submitter:	GE Healthcare Datex-Ohmeda, Inc. 3030 Ohmeda Drive P.O. Box 7550 Madison, WI 53707-7550 USA
Primary Contact Person:	Trishia Mercier Regulatory Affairs Leader Telephone: (608) 709-3260 Fax: (608) 646-6488 Email: Trishia.Mercier@ge.com
Secondary Contact Person:	Monica Morrison Regulatory Affairs Director Telephone: (608) 709-3439 Fax: (608) 646-7464 Email: Monica.Morrison@ge.com
Device Trade Name:	CARESCAPE R860
Common/Usual Name:	Ventilator, Continuous
Classification Names: Product Code: Regulation Number:	Ventilator, continuous, facility use CBK 21 CFR 868.5895
Predicate Device(s):	GE Datex-Ohmeda Engström Carestation, Engström Pro K111116 Maquet Servo-I Ventilator K123149
Intended Use:	The CARESCAPE R860 ventilator is designed to provide mechanical ventilation or support to neonatal, pediatric, and adult patients weighing 0.25 kg and above. The CARESCAPE R860 ventilator is a microprocessor based, electronically controlled, pneumatically driven ventilator that includes integrated monitoring of FiO2, airway pressure, flow, and volume. Additional respiratory gas monitoring capabilities are supported through the use of optional GE patient monitoring

	modules. Not all features are available for all patient types or product configurations. The CARESCAPE R860 ventilator is not a pulmonary function calculation device. The system is designed for facility use, including within-facility transport, and should only be used under the orders of a clinician.

Device Description:

The CARESCAPE R860 is a flexible, adaptable, intuitive critical care ventilator. Touchscreen capability allows the user to quickly and easily access patient information and procedures. A wide selection of performance options gives the user full control of the system configuration. The CARESCAPE R860 features patient monitoring, patient ventilation, and the capability of interfacing with central information management systems.

The CARESCAPE R860 is designed to provide mechanical ventilation for adult, pediatric and neonatal patient types weighing 0.25 kg and above, and having degrees of pulmonary impairment varying from minor to severe.

The CARESCAPE R860 introduces a new user interface with touch screen capabilities. Icons represent configurable views of past (historical trends), present (patient status), and possible future patient needs through clinical decision support, including Spontaneous Breathing Trial to evaluate a patient's ability to breath spontaneously for a limited, specified duration of time.

This ventilator comes with standard ventilation modes as well as purchasable ventilation modes and clinical decision support features.

Standard ventilation modes:

- A/C VC (Assist Control Volume Control)
- A/C PC (Assist Control Pressure Control)
- A/C PRVC (Assist Control Pressure Regulated Volume Control)
- SIMV VC (Synchronized Intermittent Mandatory Ventilation Volume Control)
- SIMV PC (Synchronized Intermittent Mandatory Ventilation Pressure Control)
- CPAP/PS (Continuous Positive Airway Pressure/Pressure Support)
- SBT (Spontaneous Breathing Trial)

Purchasable ventilation modes:

- nCPAP (nasal Continuous Positive Airway Pressure)
- SIMV PRVC (Synchronized Intermittent Mandatory Ventilation Pressure Regulated Volume Control)

- BiLevel
- BiLevel VG (BiLevel airway pressure ventilation Volume Guaranteed)
- VS (Volume Support)
- NIV (Non-Invasive Ventilation)
- APRV (Airway Pressure Release Ventilation)

Additional features:

- FRC (Functional Residual Capacity)
- SpiroDynamics

The CARESCAPE R860 is based on the Engström Carestation feature set and contains similar performance characteristics to the Engström family of ventilators.

The CARESCAPE R860 is a microprocessor-based, pneumatically controlled, data driven ventilator which includes integrated FiO2, airway pressure, spirometry and volume monitoring and an Aerogen Aeroneb nebulizer control board. The ventilator consists of two main components: the display and the ventilator unit. The display allows the user to interface with the system through a resistive touch screen and Trim Knob with keys. The CARESCAPE R860 also includes an optional module bay which allows the integration of various Datex-Ohmeda patient monitoring modules with the ventilator.

The user interface for control of nebulization is provided via the ventilator display unit. The standard nebulizer board is provided with the CARESCAPE R860. Users have the option to configure the system to use an external pneumatic nebulizer in place of the standard nebulizer.

Optional accessories common to the CARESCAPE R860 and the predicate Engström family of ventilators include a trolley/cart, integrated air compressor, support arm, humidifier and water trap mounting brackets. Additional optional accessories include airway modules, intratracheal pressure sensor, auxiliary electrical outlets, adjustable mounting rail, nebulizer and components, and module bay.

The optional medical air compressor is intended for use as an accessory to provide a dry, filtered, breathable compressed air supply. The compressor is installed in the base of the ventilator cart. The compressor is powered from AC mains only. A source of compressed oxygen is required to be connected to ventilator equipped with the optional compressor. The use of an integrated air compressor was first cleared on the predicate Engström Carestation and Engström Pro in K050597.

Optional functionality includes integrated respiratory gas monitoring, capabilities to measure SpiroDynamics via a GE supplied intratracheal pressure sensor in patients using sized 6.5 tracheal tubes and larger, and calculation of functional residual capacity of mechanically ventilated patients using Nitrogen Wash In/Wash Out method. The integrated respiratory gas monitoring is provided via the Datex-Ohmeda Gas Modules, E-CO, E-COV, E-COVX, E-CAiO, E-CAiOV, E-CAiOVX (K051092), E-MiniC module (K052582), or E-sCO, E-sCOV, E-sCAiO, E-sCAiOV (K123195) which are physically

integrated into the CARESCAPE R860, receive electronic power from the CARESCAPE R860 and communicate measured values to the CARESCAPE R860 for display on the system display unit.

Summary of the Technological Characteristics of the Device:

The CARESCAPE R860 is based on the Engström Carestation feature set and contains similar performance characteristics to the Engström family of ventilators. Changes include the addition of an upgraded display, new graphical user interface, added accessories and upgraded software. The CARESCAPE R860 is designed to be compliant with ANSI/AAMI ES60601-1:2005 (R 2012), Medical electrical equipment, Part 1: General requirements for basic safety and essential performance and the relevant collateral standards. There are no changes to the intended use or fundamental scientific technology of the ventilator.

Summary of Non-Clinical Testing for the Device:

The CARESCAPE R860 ventilator has been thoroughly tested through verification of specifications and validation, including software validation, to ensure the product is substantially equivalent to the predicate Engstrom Carestation. Verification of compliance with applicable standards has also been completed. The following quality assurance measures were applied during the development of the CARESCAPE R860 system:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Testing on unit level
- Integration testing
- Performance Testing (Verification)
- Safety Testing (Verification)
- Simulated Use/User Requirements Testing (Validation)
- Standards Compliance – the list of standards to which the CARESCAPE R860 complies is listed below:
    - ANSI/AAMI ES60601-1:2005 (R 2012
    - IEC 60601-1-2:2007 + 2010 Interpretation
        - Includes additional testing applicable to RFID frequency ranges of 125 kHz/134 kHz, 13.56 MHz, 902-915 MHz and 2.4 GHz
    - IEC 60601-1-6: 2010
    - IEC 60601-1-8: 2006
    - ISO 80601-2-12:2011 + Technical Corrigendum 1

- IEC 62366:2008
- ISO 5356-1
- IEC 62304

Extensive non-clinical testing was performed to establish substantial equivalence of the CARESCAPE R860. Verification and validation testing was performed according to pre-determined acceptance criteria, which concluded that the CARESCAPE R860 is substantially equivalent to the predicate Engström Carestation.

Summary of Clinical Testing for the Device:

The CARESCAPE R860 ventilator incorporates modifications to the predicate Engstrom Carestation. These modifications did not require clinical testing. The changes made were completely evaluated by non-clinical tests to verify and validate the substantial equivalence of the ventilator.

Summary of Changes:

The following is an overview of the differences between the proposed CARESCAPE R860 and the predicate Engström Carestation:

- Upgraded 15 inch LCD and Tough Screen
- Simplified graphic User Interface for the features that exist in 7.x, but with a simplified hierarchy, designed for ease of use
- Updated the names of the ventilation modes
- Added Volume Support for Adult and Pediatric patients
- Updated accessories list, including addition of a new optional compressor, the EVair compressor, Inspiratory Safety Guard, Accessory Rail and updated gas monitoring modules from GE
- Visual differentiation of the neonatal patient type from the adult and pediatric patient type. Labeling will more clearly designate the neonatal patient type from the adult and pediatric
- Updated User Requirements Manual and Technical Reference Manual which reflect the new user interface
- Compliant with ANSI/AAMI ES60601-1:2005 (R 2012), Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

Determination of Substantial Equivalence:

Datex-Ohmeda, Inc., doing business as GE Healthcare, considers the CARESCAPE R860 to be as safe and as effective, and performance is substantially equivalent to as the predicate device, the Engström Carestation. The summary above demonstrates that there are no new questions of safety or effectiveness for the CARESCAPE R860.

VENTI*motion* 30

Convincing Effectiveness

WEINMANN
medical technology

VENTI*motion* 30

is now even more versatile.

Operating convenience

- Intuitive navigation with rotary dial and direct access to the most important ventilation parameters
- Softstart
- Numeric and graphic display of ventilation parameters
- Compatible with accessories for the VENTI product line

Safety

- Visual and acoustic alarms
- Optional back-up power supply provided by external rechargeable battery VENTI*power* for up to seven hours of operation
- High flow of up to 300 liters/min for pressure constancy and leakage compensation.
- Weinmann Hygiene Concept complies with hygiene guidelines issued by Robert-Koch Institute.

More therapy comfort and convenience with our innovative features

Volume compensation

Optimum safety and stability of tidal volume. Three different speeds can be set for an increase in tidal volume. Volume compensation automatically switches to precise regulation upon reaching a corridor around the targeted volume in order to achieve the most precise setting for targeted volume.

Expiratory ramp

The expiratory ramp is the temporary splint applied to the airways at the start of expiration to counteract an expiratory collapse. The expiratory flow remains higher on average, allowing the volume to be exhaled and the respiratory position to be lowered.

With humidifier VENTI*click* and oxygen valve VENTI-O_2 plus

With VENTI*power*

In the transport bag

1

2

3

4

Accessories

1 VENTI*click* – WM 24365
Adaptable humidifier without extra power supply and tubes

2 VENTI*power* – WM 27630
Optional external battery guarantees several hours of device operation

3 VENTI-O_2 plus – WM 27200
Adaptive oxygen valve without additional connection tube: no adverse effect on trigger and volume compensation from oxygen feed up to 15 l/min

4 WEINMANN*support* – WM 93305
PC software with converter cable USB-RS 485 (WM 93321) for setting and analysis

Our complete range of therapy solutions, accessories and mask systems is at: **weinmann.de**

Technical data for VENTI*motion* 30

CE 0197 Certified Quality Management System meeting EC directive 93/42/EEC Annex II (EN ISO 13485)

Product class as per 93/42/EEC:	II a
Dimensions (W x H x D):	230 x 120 x 280 mm
Weight:	approx. 3.7 kg
Temperature range	
■ Operation:	+5 °C to +35 °C
■ Storage:	-40 °C to +70 °C
Air pressure range:	600 – 1100 hPa (allows operation up to altitude of 4000 meters) automatic altitude adjustment
Electric connection:	115 – 230 V AC, 50 – 60 Hz tolerance -20 % +10 %
Current consumption at:	**230 V** **115 V**
■ Operation:	0.17 A 0.3 A
■ Standby:	0.050 A 0.108 A
Classification as per EN 60601-1	
■ Type of protection from electric shock:	protection class II
■ Degree of protection from electric shock:	type BF
Electromagnetic compatibility as per EN 60601-1-2	
■ Radio interference suppression:	EN 55011
■ Radio interference immunity:	EN 61000-3-2, EN 61000-3-3, EN 61000-4-2 to 6, EN 61000-4-8, EN 61000-4-11
Mean sound pressure level/ Operation as per EN ISO 17510 at a distance of 1 m from device in patient position:	at 20 hPa: about 32 dB (A) at 15 hPa: about 30 dB (A)# at 12 hPa: about 28 dB (A)# at 10 hPa: about 26 dB (A)# at 7 hPa: about 24 dB (A)
Sound pressure level for alarm:	**about 62 dB (A)**
IPAP pressure range:	6 to 30 hPa
EPAP pressure range:	4 to 20 hPa
CPAP pressure range:	4 to 20 hPa
Pressure accuracy:	±0.6 hPa
Increment:	0.2 hPa (1 hPa ≈ 1 cm H_2O)
Minimum stable limit pressure (PLS_{min}) (min. pressure in event of fault):	≥ 0 hPa
Maximum stable limit pressure (PLS_{max}) (max. pressure in event of fault):	≤ 60 hPa

Ventilation modes:	CPAP, ST, T
Respiratory frequency:	6 to 45 l/min
Accuracy:	±0,5 l/min
Increment:	1 l/min
I:E ratio:	
■ Inspiration time:	15% to 67% of respiratory period
■ Increment:	1%
■ Accuracy:	±1 %
Trigger level:	can be set at six levels, separate for inspiration and expiration, expiration trigger can be deactivated for ST mode
Pressure increase/pressure decrease speed:	can be set at six levels
Accuracy Volume measurement:	at 23 °C: ±15 %
Flow at max. motor speed at 0 hPa:	285 l/min ±15 l/min
Flow at max. motor speed with bacteria filter at 0 hPa:	270 l/min ±15 l/min
Heating of respiratory air as per HMV:	2.5 °C
Pressure constancy measured as per DIN EN ISO 17510 in CPAP mode:	at 20 hPa: Δp ≤ 1 hPa at 14 hPa: Δp ≤ 1 hPa at 10 hPa: Δp ≤ 1 hPa at 7 hPa: Δp ≤ 0,5 hPa
Fine filter filtration degree up to 2 µm:	≥ 99.7 %
Fine filter service life:	1000 hours with normal ambient air
Allowed humidity for operation and for storage:	≤ 95 % rel. humidity (no condensation)
System resistance with air flow of 60 l/min at patient connection	
VENTImotion 30 with tube system WM 24130 and Silentflow WM 23600:	0,20 $\frac{kPa \cdot s}{l}$
VENTIclick WM 24365 and bacteria filter WM 24148, VENTImotion 30 with O_2 tube system WM 23737:	0,31 $\frac{kPa \cdot s}{l}$

Embajada de la
República Argentina
República Popular China

Weinmann Geräte für Medizin GmbH + Co. KG develops, produces and markets diagnostic and therapeutic solutions for sleep medicine and ventilation.

Products from the Hamburg-based, family-owned company are tailored exactly to the needs of patients and experts. Before market launch, every product goes through a certified validation process in research and development, procurement, production and quality management.

Weinmann, a Löwenstein Group company since 2013, is among the Top 3 in many of its demanding international markets, thanks to ideas, experience and innovation. Thanks too to the decades of trust that Weinmann's partners around the world have placed in our proven products Made in Germany.

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A Company in the Löwenstein Group

WEINMANN medical technology

1

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Accessories

1 **VENTI*click* – WM 24365**
Adaptable humidifier without extra power supply and tubes

2 **VENTI*power* – WM 27630**
Optional external battery guarantees several hours of device operation

3 **VENTI-O_2 plus – WM 27200**
Adaptive oxygen valve without additional connection tube: no adverse effect on trigger and volume compensation from oxygen feed up to 15 l/min

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Technical data for VENTI*motion advance*

CE 0197 Certified Quality Management System meeting EC directive 93/42/EEC Annex II (EN ISO 13485)

Product class as per 93/42/EEC:	II a
Dimensions (W x H x D):	230 x 120 x 280 mm
Weight:	approx. 3.7 kg
Temperature range	
■ Operation:	+5 °C to +35 °C
■ Storage:	-40 °C to +70 °C
Air pressure range:	600 – 1100 hPa (allows operation up to altitude of 4000 meters) automatic altitude adjustment
Electric connection:	115 – 230 V AC, 50 – 60 Hz tolerance -20 % +10 %
Current consumption at:	**230 V** **115 V**
■ Operation:	0.17 A 0.3 A
■ Standby:	0.050 A 0.108 A
Classification as per EN 60601-1	
■ Type of protection from electric shock:	protection class II
■ Degree of protection from electric shock:	type BF
Electromagnetic compatibility as per EN 60601-1-2	
■ Radio interference suppression:	EN 55011
■ Radio interference immunity:	EN 61000-3-2, EN 61000-3-3, EN 61000-4-2 to 6, EN 61000-4-8, EN 61000-4-11
Mean sound pressure level/ Operation as per EN ISO 17510 at a distance of 1 m from device in patient position:	at 20 hPa: about 32 dB (A) at 15 hPa: about 30 dB (A)# at 12 hPa: about 28 dB (A)# at 10 hPa: about 26 dB (A)# at 7 hPa: about 24 dB (A)
Sound pressure level for alarm:	about 62 dB (A)
IPAP pressure range:	6 to 40 hPa
EPAP pressure range:	4 to 20 hPa
CPAP pressure range:	4 to 20 hPa
Pressure accuracy:	±0.6 hPa
Increment:	0.2 hPa (1 hPa ≈ 1 cm H_2O)
Minimum stable limit pressure (PLS_{min}) (min. pressure in event of fault):	≥ 0 hPa
Maximum stable limit pressure (PLS_{max}) (max. pressure in event of fault):	≤ 60 hPa

Ventilation modes:	CPAP, ST, T, TA
Respiratory frequency:	6 to 45 l/min
Accuracy:	±0,5 l/min
Increment:	1 l/min
I:E ratio:	
■ Inspiration time:	15% to 67% of respiratory period
■ Increment:	1%
■ Accuracy:	±1 %
Trigger level:	can be set at six levels, separate for inspiration and expiration, expiration trigger can be deactivated for ST mode
Pressure increase/pressure decrease speed:	can be set at six levels
Accuracy Volume measurement:	at 23 °C: ±15 %
Flow at max. motor speed at 0 hPa:	285 l/min ±15 l/min
Flow at max. motor speed with bacteria filter at 0 hPa:	270 l/min ±15 l/min
Heating of respiratory air as per HMV:	2.5 °C
Pressure constancy measured as per DIN EN ISO 17510 in CPAP mode:	at 20 hPa: Δp ≤ 1 hPa at 14 hPa: Δp ≤ 1 hPa at 10 hPa: Δp ≤ 1 hPa at 7 hPa: Δp ≤ 0,5 hPa
Fine filter filtration degree up to 2 µm:	≥ 99.7 %
Fine filter service life:	1000 hours with normal ambient air
Allowed humidity for operation and for storage:	≤ 95 % rel. humidity (no condensation)
System resistance with air flow of 60 l/min at patient connection	
VENTI*motion* advance with tube system WM 24130 and Silentflow WM 23600:	0,20 $\frac{kPa \cdot s}{l}$
VENTI*click* WM 24365 and bacteria filter WM 24148, VENTI*motion* advance with O_2 tube system WM 23737:	0,31 $\frac{kPa \cdot s}{l}$

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partner for life

WEINMANN medical technology

VENTI*motion* advance

Convincing Effectiveness

WEINMANN medical technology

VENTI*logic* LS
VENTI*logic* plus

100% mobility and reliability in IV and NIV

LÖWENSTEIN
medical

VENTI*logic* LS
VENTI*logic* plus

Your requirements for reliability and mobility are our benchmark.

VENTI*logic* LS and VENTI*logic* plus offer you a high degree of reliability and versatility every day at all times. Their practice-oriented monitoring and mobility concepts are supplemented by unique ventilation functions.

VENTI*logic* LS and VENTI*logic* plus have leakage and single patient circuits. In addition VENTIlogic LS offers a double patient circuit system with patient valve and volume-controlled ventilation modes (VCV, aVCV).

Single patient circuit with patient valve

Double patient circuit with patient valve (only VENTI*logic* LS)

Areas of use

- For treatment of adults and children starting with 50 ml tidal volume and 5 kg body weight
- Invasive and non-invasive ventilation
- In hospital and at home
- Stationary and mobile

Use of several replaceable batteries allows unlimited independent operation.

Our concept assures more freedom

VENTI*logic* LS and VENTI*logic* plus are equipped with two options for mouthpiece ventilation, namely pressure-controlled (MPVp) and volume-controlled (MPVv). Both are available in all circuit systems. Mouthpiece ventilation gives the patient maximum freedom and independence in his therpay. The three ventilation program settings allow an ideal combination of daytime mouthpiece ventilation with night-time ventialtion means. The mobility concept ensures safety and reliability in the delivery of required ventilation.

- Mobile use for intra-hospital transfers: With 9 hours of battery power (internal rechargeable battery and optional replaceable battery* have a capacity of 4.5 hours each), the devices can adapt to any change of location.
- Mobile use at home: VENTI*logic* LS and VENTI*logic* plus give your patients freedom of movement.
- Sure in an unsure situation: Leakage is reliably compensated for in volume and pressure controlled modes.** The high-performance blower ensures continuous patient care in mobile use and difficult ventilation situations, even with imprecise fit of patient interface.

Special shock resistance

Shock and vibration resistance were specially tested against recognized standards to ensure device's compliance with demands in mobile hospital and domestic surroundings. (Shock test as per IEC 60068-2-27 and Vibration test as per IEC 60068-2-64).

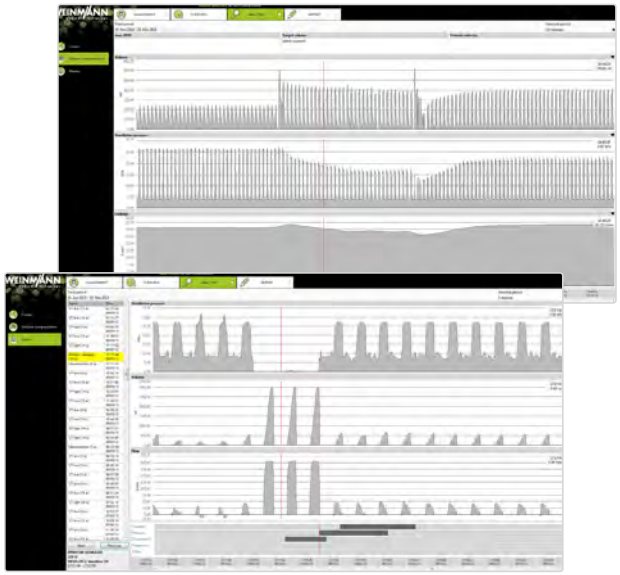
* The operating range of the rechargeable battery depends on the settings of the ventilation parameters and on the battery's age and charge level.
The internal battery may be used only as an emergency source of power and not as a continuous primary source.

** Reliable leakage compensation in volume-controlled

Our monitoring concept ensures safe and reliable therapy

The comprehensive and clear monitoring concept provides the best support of your treatment:

- Intuitive operation for fast check of ventilation settings
- Simple and direct monitoring of oxygen saturation and pulse with the SpO_2 module.
- Unique alarm management (highly visible, large alarm window) for top safety: You can concentrate completely on therapy without any stress.
- VENTI*views*: PC software for Löwenstein Medical ventilators reads out, displays, analyzes, archives and generates reports on patient and compliance data and their clinical application:
  - Focus on ventilation requirements
  - Process-oriented operation matches procedures in hospital



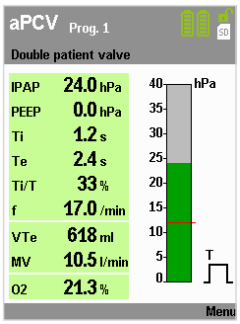
VENTI*views*
(Software)

The fast and simple way to ideal therapy settings – with innovative features by Löwenstein Medical

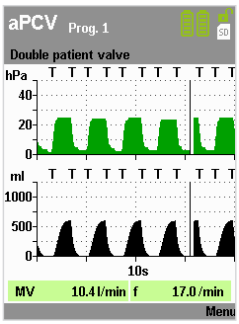
- Doctors can configure three storable ventilation programs for patients who need varying degrees of ventilation support. With the simple press of a key, the doctor, nurse or patient can select the individual programs to satisfy the patient's needs.
- LIAM (Lung Insufflation Assist Maneuver): the integrated cough support is easy to use and requires no change of masks. The patient himself or a nurse can activate the function.
- Volume compensation: Function to guarantee a pre-set target volume. The speed can be set in three levels.

Particularly suitable for COPD patients

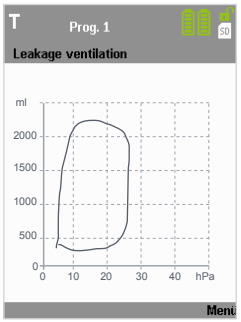
- AirTrap Control: Exhalation pressure relief to prevent dynamic hyperinflation. Thanks to AirTrap Control, VENTI*logic* LS and VENTI*logic* plus automatically regulate pressure to a frequency and expiration time ideal for the patient. The titration process is thereby significantly simplified.
- Trigger lockout: Effective protection from false triggering and trigger artefacts at higher trigger sensitivity. The fast way to perfectly synchronized ventilation.
- Expiratory pressure ramp: Temporary pneumatic splint in airways at the start of expiration to counteract expiratory collapse of airways.
  The expiratory flow remains larger on average, the volume can be exhaled more easily and respiratory position can be lowered.



Fast and simple
monitoring of ventilation settings



Pressure and volume curves
with auto-scaling function



Pressure/volume loop with
auto-scaling axes

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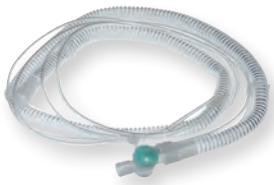

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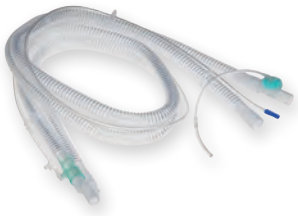

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Accessories

1 Replaceable battery
WM 27919

2 Bacteria filter (for leakage circuit)
WM 24148

3 Bacteria filter (for valve ventilation) Teleflex Iso-Gard
WM 27591

4 Bacteria filter (for valve system)
WM 24476

5 O_2 measurement set
WM 15732
consists of:
- O_2 sensor connection line – WM 27792
- O_2 sensor – WM 27128
- O_2 sensor T-piece – WM 27143

6 VENTI*remote* alarm (10 m)
WM 27745 (10 m)
WM 27755 (30 m)

7 SpO_2module
WM 27280

8 Adapter for automobile
WM 24616

9 Analogbox D/A
WM 27560

10 Leakage circuit
WM 24130 (can be disinfected)
WM 24120 (can be sterilized)

11 Single patient circuit with patient valve
WM 27181

12 Double patient circuit with patient valve
WM 27182

13 Water-resistant transport bag
WM 27976
for mobile usage of VENTI*logic* LS and VENTI*logic* plus

Set, mouthpiece ventilation (not shown)
WM 27647

Test adapter, packed (not shown)
WM 27140

VENTI*views* (not shown), PC-Software
WM 27870

Connection cable for nurse call
WM 27780 (10 m)
WM 27790 (30 m)

CE 0197

Technical data

Product class as per directive 93/42/EEC:	II b
Dimensions (W x H x D):	240 x 153 x 340 mm
Weight	
• without replaceable battery:	about 5.9 kg
• with replaceable battery:	about 6.5 kg
Temperature range	
• Operation:	+5 °C to +35 °C
• Storage:	-40 °C to +70 °C
Air pressure range:	600 – 1100 hPa (below 700 hPa leakage is to be kept low because the device may not be able to compensate for high ventilation pressures)
Electrical connections:	110 – 230 V AC, 50 – 60 Hz Tolerance -20%, +10%
Power consumption at	230 V 110 V
• Operation:	0,35 A 0,8 A
• Standby:	0,05 A 0,13 A
Maximum power consumption:	120 W
Switching capacity Remote alarm connection:	60 V DC/2A; 42 V AC/2A
Battery capacity*)	
• internal rechargeable battery:	4.5 hours
• replaceable/rechargeable battery:	4.5 hours
*) The capacity depends on the ventilation parameter settings and the battery's age and state of charge.	
Classification as per EN 60601-1	
• Protection from electric shock:	Protection class II
• Degree of protection from electric shock:	Type BF
Time required to charge battery:	
• Charge via ventilator:	about 6 hours per battery
Leakage modes in both devices:	CPAP, S, ST, T, MPVp, MPVv
Valve ventilation modes in both devices:	PSV, PCV, aPCV, SIMV, MPVp, MPVv
and only VENTI*logic* LS:	VCV, aVCV
Special therapeutic functions:	
• AirTrap Control	• LIAM
• Trigger lockout	• Volume compensation
• Expiratory pressure ramp	• Mouthpiece ventilation
• three ventilation programs	
Electromagnetic Compatibility	
• Radio interference suppression:	EN 55011
• Radio interference resistance:	EN 61000-3-2, EN 61000-3-3, EN 61000-4-2 to 6, EN 61000-4-8, EN 61000-4-11
Mean sound level / operation as per EN ISO 17510 with 1 m distance between device and patient position:	about 28 dB(A) at 10 hPa
Sound level about 69 dB(A) as per of alarm:	EN 60601-1-8
IPAP pressure range:	6 to 40 hPa (leakage circuit) 4 to 40 hPa (valve system)
PEEP/EPAP pressure range:	4 to 20 hPa (leakage circuit) 0 to 20 hPa (valve system)
CPAP pressure range:	4 to 20 hPa (leakage circuit)
Pressure accuracy:	to 35 hPa ± 0.8 hPa from 35 hPa ± 1.5 hPa
Increment:	0.2 hPa (1 hPa = 1 mbar ≈ 1 cm H_2O)
Tidal volume:	50 – 3000 ml
Minimum pressure limit stability (PLSmin) (min. pressure in case of device failure):	≥ 0 hPa
Maximum pressure limit stability (PLSmax) (max. pressure in case of device failure):	≤ 60 hPa
Respiratory rate:	5 to 45 bpm
Accuracy:	± 0.2 bpm
Increment:	0.5 bpm
I:E-ratio	
• Inspiration time:	15% to 67% of breathing period
• Increment:	1%
• Accuracy:	±1%
Trigger level:	adjustable in 8 stages for inspiration and 14 stages for exhalation (from 5 % to 95 % of maximum flow), can be switched off for exhalation in ST mode
Pressure increase speed:	Can be set in 6 levels
Pressure decrease speed	
• Leakage system:	Can be set in 6 levels
• Valve system:	One permanently set level
Accuracy Volume measurement:	at 23 °C: ±20 %, at least 25 ml
Max. allowable flow with oxygen feed:	15 l / at ≤ 1000 hPa
Max. heating of respiratory air at 35°C ambient temperature:	41 °C
Pressure constancy measured as per DIN EN ISO 17510 in CPAP mode:	< 10 hPa: Δp ≤ 0.5 hPa > 10 hPa: Δp ≤ 1.0 hPa
Fine filter separation level to 2 µm:	≤ 99.7%
Fine filter service life:	1000 hours in normal ambient air
Allowable humidity operation and storage:	≤ 95% rF (no condensation)
Flow at max. speed at 0 hPa:	
• Leakage ventilation:	350 l/min
• Single patient circuit with patient valve:	345 l/min
• Double patient circuit with patient valve (only VENTI*logic* LS):	345 l/min
Tolerance:	± 15 l/min

p10122en1711

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