MTTS

Beluga
resuscitator

User Manual

MD Resuscitator

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MTTS

Contents

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EC REP

Introduction

WARNING - a warning statement refers to the conditions when the possibility of injury to the patient or user exists if a procedure is not followed correctly.

NOTE - a note statement provides additional information intended to clarify points, procedures or instructions.

This user manual is intended for health care professionals.

The Beluga Resuscitator is to be operated by qualified personnel only. This manual, accessory Directions for Use, all precautionary information, and specifications should be read before use.

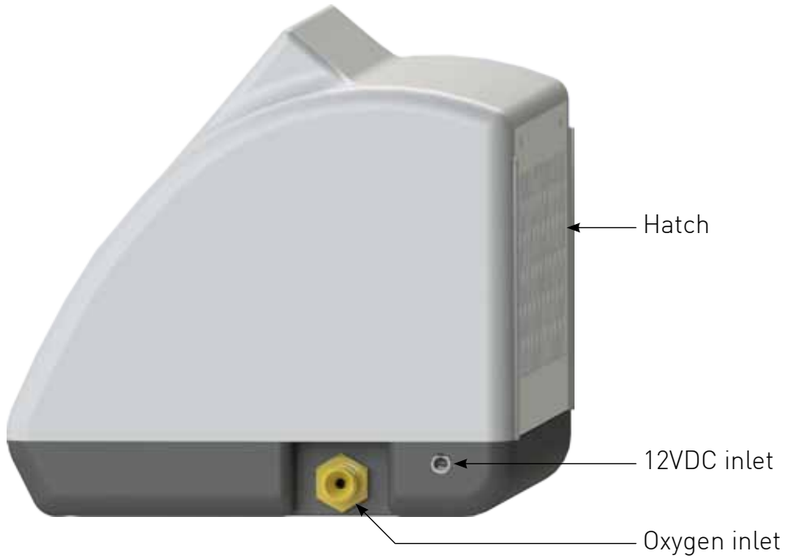
Device description:
Beluga Resuscitator is a standalone T-piece resuscitator intended to provide positive pressure ventilation during resuscitation of infants. The device contains a built-in pump to generate positive end-expiratory pressure (PEEP) and Peak Inspiratory Pressure (PIP) without the necessity of any external air sources. An integrated blender and oxygen monitoring function also allow oxygen-rich (>21% O2) air with an accurate fraction of inspired oxygen (FiO2) to be safely delivered to the patient.

Intended use:
Beluga Resuscitator is an infant resuscitator intended to provide assisted respiratory breaths to newborn babies in delivery suites, nurseries and neonatal intensive care units.

Contraindications for use:
The need for resuscitator device is best made early on clinical grounds and depends on indication of doctor. There are some contraindications exist to resuscitator devices: Meconium stained baby depressed at birth; Congenital diaphragmatic hernia

Overview

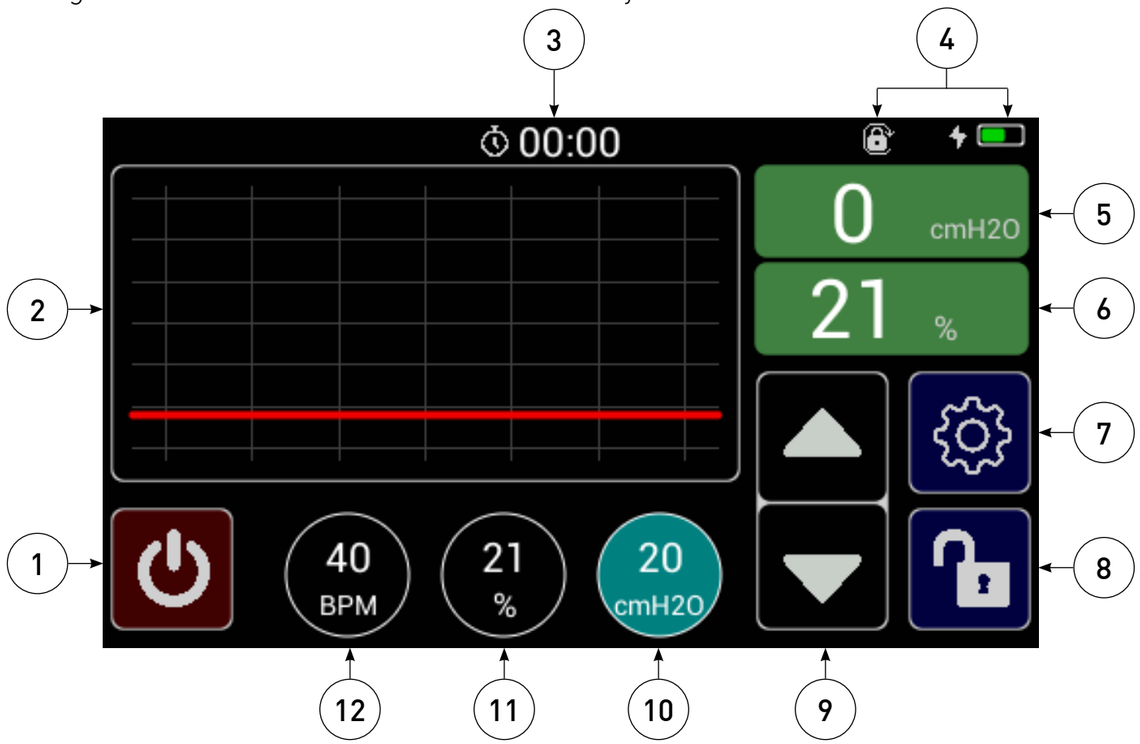
Front view



Side view

Control Panel

Beluga Resuscitator functions are controlled by touch screen.



1	**Power Button**	Touch and hold this button to turn off the device
2	**Realtime Pressure Graph**	Plots measured pressure in realtime The graph will be expand in look screen
3	**Timer**	Displays Procedure Timers
4	**Status Bar**	Displays Infomation about locking, battery charging conditions
5	**Pressure Measurement**	Displays Measured Pressure
6	**FiO2 Measurement**	Displays Measured FiO2
7	**Setting Button**	Touch this button to enter Setting screen
8	**Lock Button**	Touch this button to lock the screen
9	**Up and Down Buttons**	Touch and hold these buttons to adjust a setpoint. The setpoint can be selected by touching but 10, 11, or 12

Device Description

10	**PIP Setpoint**	Touch this button to select PIP setpoint
11	**FiO2 Setpoint**	Touch this button to select FiO2 setpoint
12	**Ventilation Rate Setpoint**	Touch this button to select Ventilation rate setpoint

Devices starts with PIP setpoint of 0 cmH2O. When selected, it is automatically set to 20 cmH2O.

When PIP setpoint step size is set greater than 1, touching and holding the Up/Down buttons will only increase/decrease the value once.

Warnings

The Beluga Resuscitator is to be operated by qualified personnel only. This manual,accessory Directions for Use, all precautionary information, and specifications should be read before use.

Explosion hazard. Do not use the Beluga Resuscitator in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

Do not modify this equipment without authorization of the manufacturer.

Using the device outside of the specified ambient temperature range (19°C to 37°C) or humidity range (30%RH to 90%RH) can compromise performance.

Do not operate the device if any of the components appear to be damaged or broken. Damaged or broken components should be discarded and replaced.

Do not position the device in a location that reduces its ventilation.

Do not block any of the air vents on the back of the device.

The presence of electro-surgical devices, shortwave or microwave equipment near this device could lead to electrical interference that would negatively affect the function of the device.

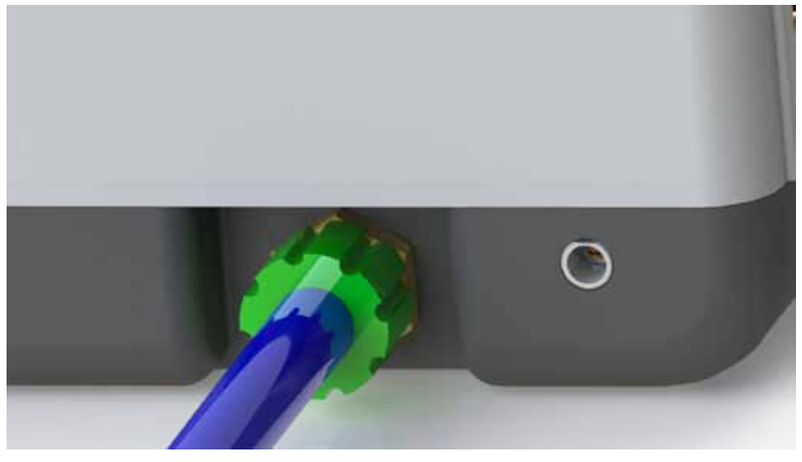
Using tubing or other breathing circuit components without cleaning or disinfection between patients can result in infections.

The device should only be used with tubing, cables and connectors specified in this user manual. Use of components not specified in this user manual can result in serious injury to the patient or operator or damage to the device.

1. Attach the T-piece circuit, gas hose

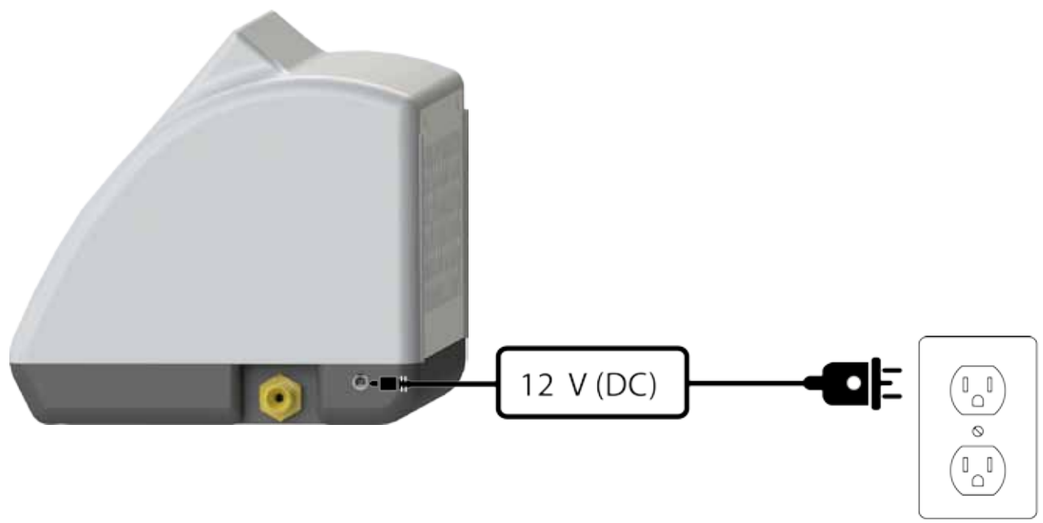
A. Attach the T-piece circuit to the mixed gas outlet in the front of the device.

B. Attach the compressed oxygen source to the CGA 1240 oxygen inlet.



2. Plug in and power up

A. The connector plugs into the side of the device and then directly into the power outlet in the wall.



B. Press the Power Button to turn the device ON.

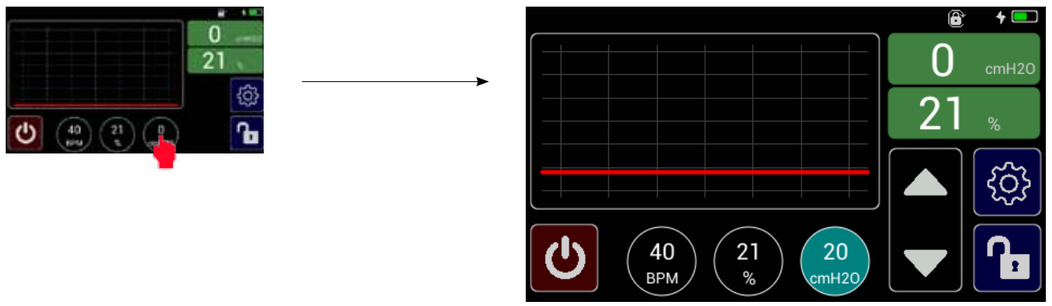
⚠ Only use T-piece circuit and power supply unit provided by MTTS.

ℹ The gas sources must provide pressure within the range of 10 to 60 psi (0.7 to 4.1 bar). If the gas sources are outside of this range, the device may not be able to produce the desired %FiO2.

ℹ Attaching the compressed oxygen will not waste any oxygen. The machine will not use any compressed oxygen until you increase the FiO2 setpoint.

Start the device

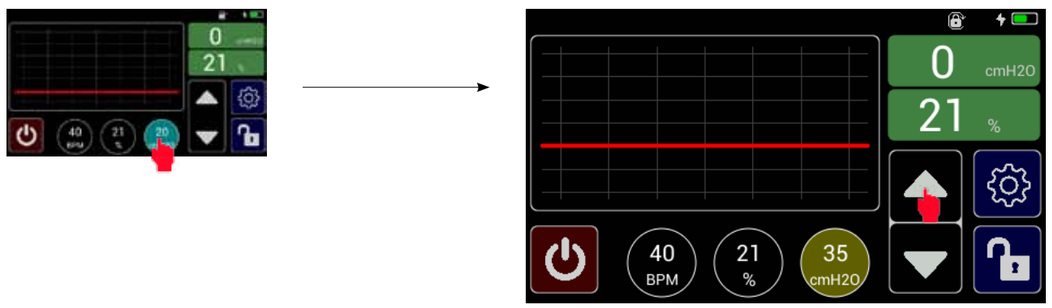
Touch PIP Setpoint to start the device.



The device will start immediately with default PIP Setpoint of 20 cmH2O.

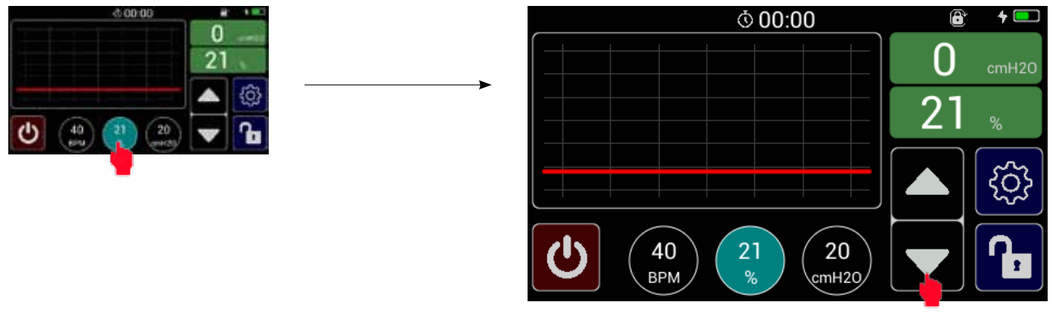
Adjust parameters

A. PIP
Select PIP setpoint circle, then touch and hold Up/Down button to adjust PIP.

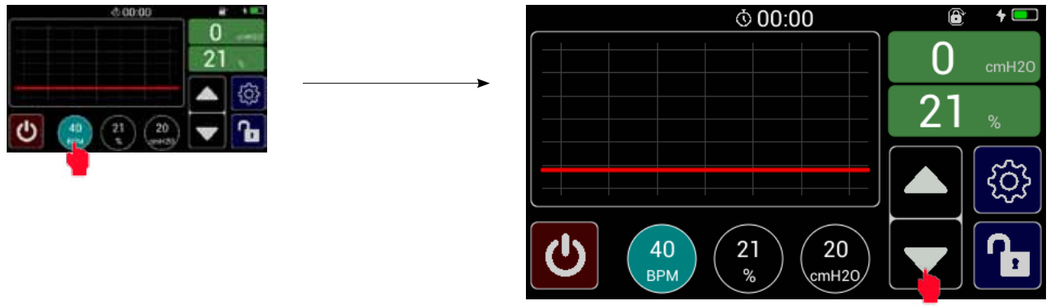


The red horizontal level will move up/down according to the change.

B. FiO2
Select FiO2 Setpoint circle, then touch Up/Down button to adjust FiO2.



C. Ventilation Rate (VR)
Select VR Setpoint circle, then touch Up/Down button to adjust VR.



Ventilation rate is used by metronome only.

Metronome can be disabled in Setting panel.

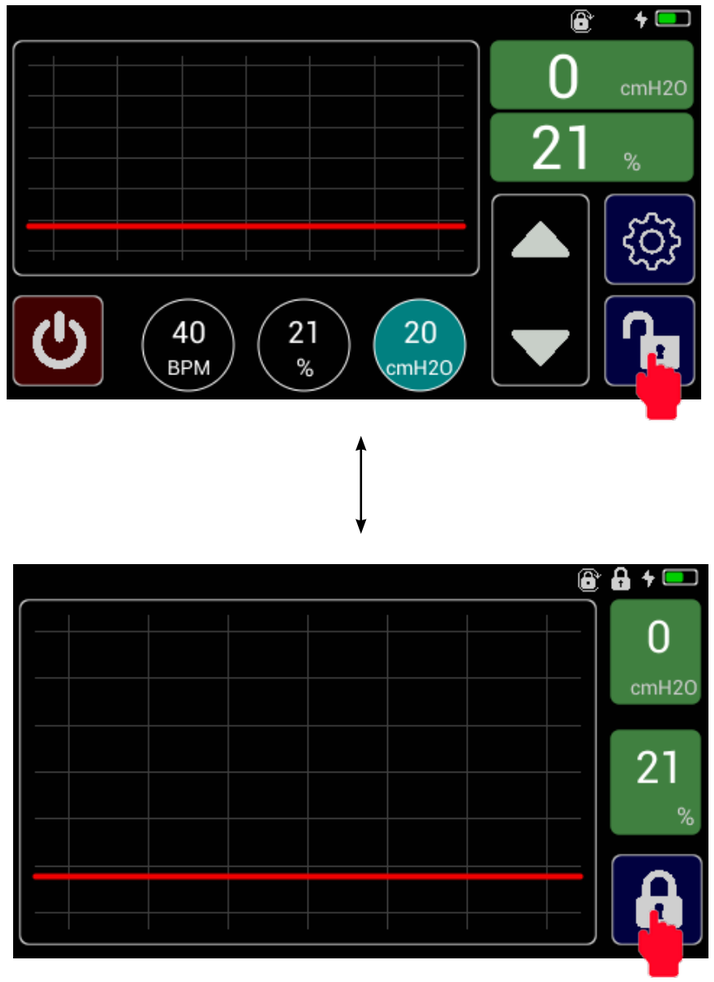
Resuscitate patient

A. Fit T-piece to resuscitation mask and place over the baby's mouth and/or nose.

B. Resuscitate by placing and removing thumb over the PEEP cap to allow inspiration and expiration.

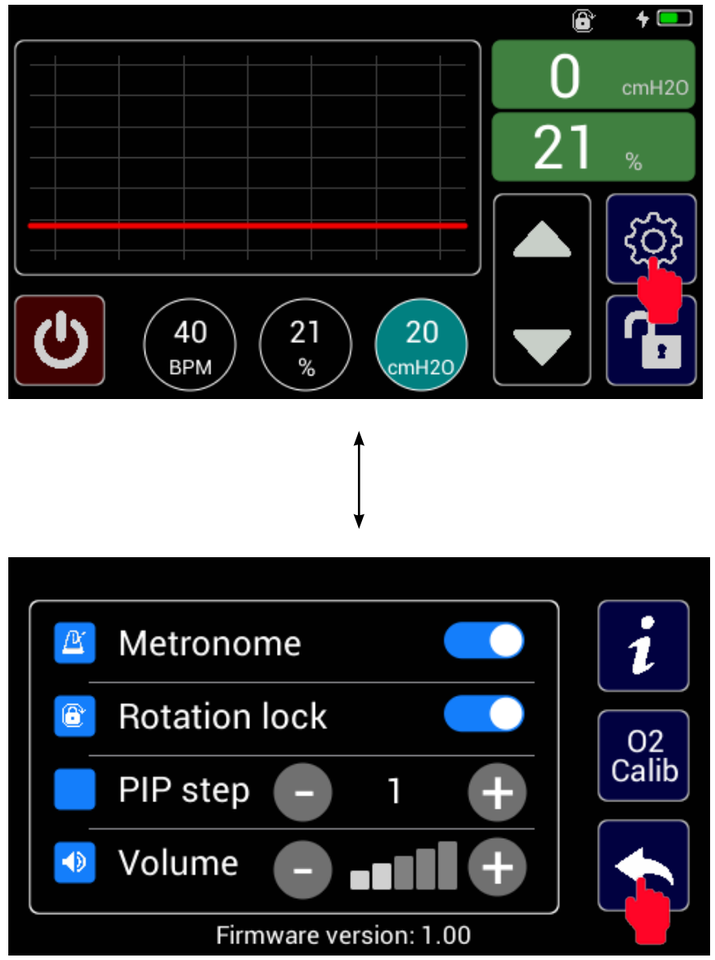
Lock/unlock the screen

The screen can be locked by touch and hold the lock button. On the locked screen, all setpoints will disapear and the graph will expand. To unlock the screen, touch and hold the unlock button.



Setting screen

Setting screen allows some features of the device to be configured. To enter Setting screen, touch Setting button on the unlocked screen. To return the unlocked screen, touch the Return button on the Setting screen.



Following features are available on the Setting screen:

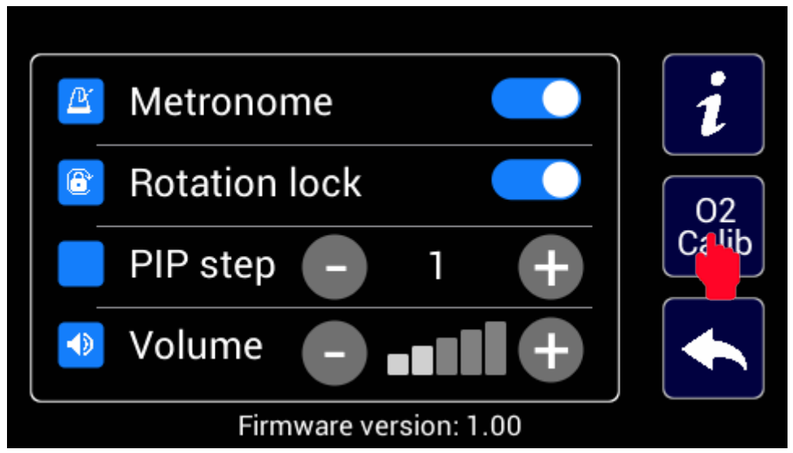
- Calibrate oxygen sensor
- Goto the Device information screen

- Enable/disable metronome
- Lock/unlock autorotate function
- Adjust PIP step size
- Adjust alarm volume

> The Setting screen and available features may vary depending on the software version.

Calibrate oxygen sensor

To calibrate oxygen sensor, touch the 'O2 Calib' button on the Setting screen. The process will take 1-2 minutes to complete. After calibration, the FiO2 reading should be 21%.

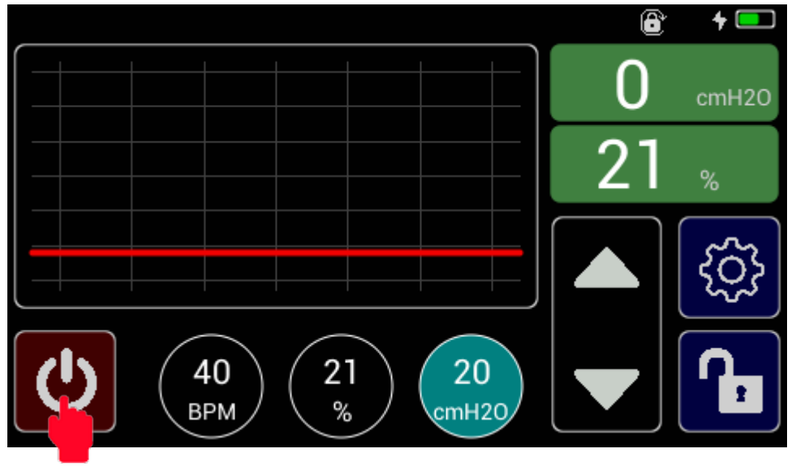


> Disconnect oxygen source before calibration.

> Oxygen sensor must be calibrated at least every 3 months. It is recommended to calibrate the sensor before each use.

Turning off the device

The device can be turned off by Power button either on the screen or in front of the device. Press and hold the button for 1.5 second.



Alarm system

General

List of alarms:

Alarm	Cause	Effect
HIGH PRESSURE 	Measured pressure higher than the PIP setpoint by 4 cmH2O	Device adjusts pressure by itself
	Pressure >14 cmH2O for longer than 5 seconds	No effect
HIGH FiO2 	Measured FiO2 higher than the setpoint by 6 %FiO2	Device controls oxygen valve to regulate FiO2
PRESSURE SENSOR FAILURE 	Pressure sensor disconnected or faulty	No effect
OXYGEN SENSOR FAILURE 	Oxygen sensor disconnected or faulty	Oxygen valve closed
LOW BATTERY 	Battery remaining capacity is low	No effect

Alarm system test

All the alarms listed above are conisdered MEDIUM PRIORITY (ref. IEC 60601-1-8).

In order to verify the operation of auditory and visual alarms, perform the following procedure:
1. On the unlocked screen, set PIP to 20 cmH2O
2. Occlude the mixed gas outlet for 10 seconds.
3. Check pressure audible alarm sounds

Cleaning

- Comply with hospital, local and national guidelines for product cleaning frequencies.
- Ensure oxygen supply is turned off and disconnected from Beluga Ventialator before performing cleaning procedures.
- Cleaning shall be performed at ambient condictions.
- Before cleaning, remove and discard all used disposable products using recommended method of disposal.
- Dust all surfaces with clean damp soft cloth.
- Clean all plastic surfaces with mild detergent solution (maximum 2% in water).
- Dry all the surfaces after cleaning with a clean soft cloth or paper towel.
- Ensure that no part of Beluga Resuscitator is immersed in any cleaning liquid or cleaning solution.
- Do not use abrasive cleaning solutions.
- Ensure all Beluga Resuscitator parts and accessories are checked before returning the device to service.

The reusable resuscitation circuit includes a number of parts that must be completely disassembled and sterilized before use. These parts include:

Component	Recommended sterialization method
Silicone tube	Autoclaving
PEEP valve	Low-temperature plasma sterilization OR soak disinfection with 1:500 chlorine-containing disinfectant
Mask	Autoclaving

Only qualified personnel should carry out service and maintenance procedures.

After the maintenance is completed, ensure the equipment is functioning correctly in accordance with the published performance specifications.

Ensure only approved replacement parts are used during service and maintenance procedures.

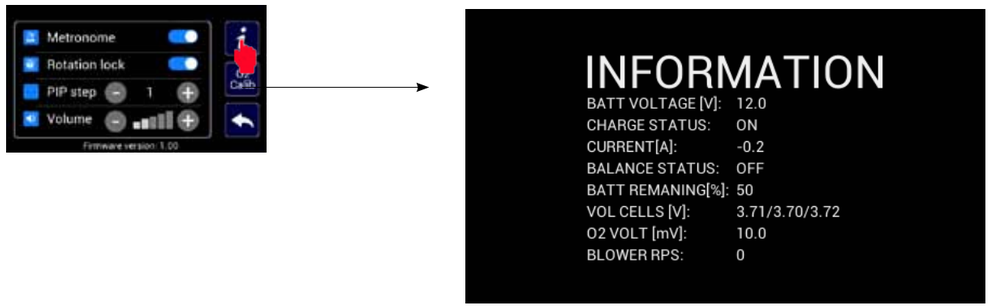
Please contact an authorised MTTS representative for further assistance with any servicing or maintenance requirement.

The Beluga Resuscitator includes a number of parts that must be replaced or serviced during the lifetime of the device. These parts include:

Component	Approx. Duration of Use	Maintenance Information
Air filter	6 months	Clean or replace.
Oxygen sensor	18 months	Replace if it is fauty or FiO2 control is not accurate after calibration.

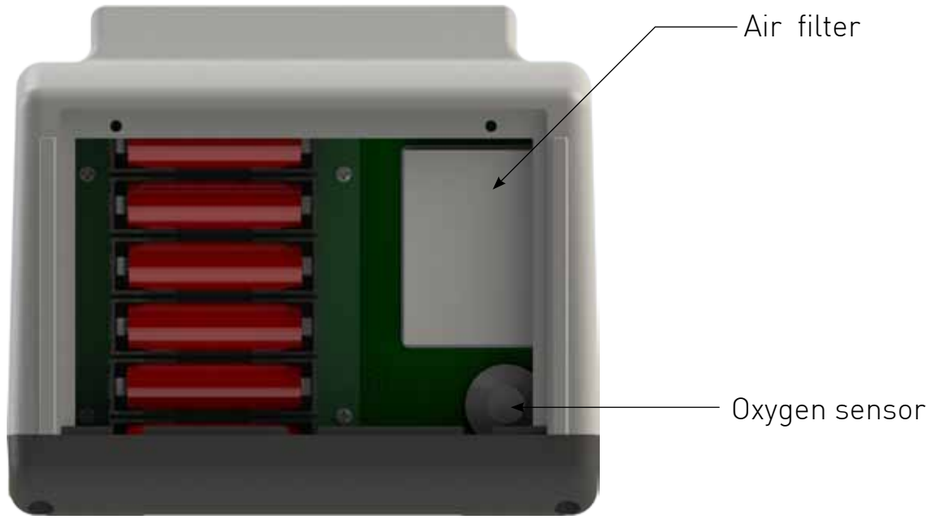
Device information screen

To better understand the device performance, device information should be checked before opening the device. From Setting screen, touch the Info button to see this information.



Air filter and oxygen sensor replacement

To access air filter and oxygen sensor, open the back hatch with a Philips head screwdriver. Gently take the filter/sensor out and replace with the new one.



Specifications

Performance Specifications

Control Settings

Set PIP	Default	20 cmH2O
	Range	5 - 45 cmH2O
Set FiO_2	Default	21 %FiO_2
	Range	21 - 100 %FiO_2
Set Ventilation rate	Default	Disabled
	Range	30 - 60 BPM

Displays

Measured pressure display	Accuracy	±1 cmH2O
	Range	0 - 100 cmH2O
Measured FiO_2 display	Accuracy	±5 %FiO_2
	Range	21 - 100 %FiO_2

Physical Specifications

Dimensions (HxWxD)	overall	20 cm x 22cm x 20 cm
Total unit mass		2.5 kg
Alarms	Medium Priority Audible	3 pulse burst, followed by 2.5 second delay
	Medium Priority Visual	Yellow flashing at 0.5 Hz
	Alarm Volume	Adjustable
Internal pump	Type	Blower, 12VDC

Electrical Specifications

Power characteristics		60W, 100-240VAC, 47/63Hz
Off-the-shelf external power supply		International medical safety approvals (ANSI/AAMI/EN 60601-1, UL/TUV) Class I construction is standard (ground required) 100k hours MTBF Energy Star Efficiency Level V compliant RoHS 3 compliant Over voltage / over current protection
Battery	Type	11.1V Li-ion
	Capacity	6 cells, 6000mAh

Specifications

Environmental Specifications

Operating	Ambient temperature +18°C to +35°C Humidity: 0% to 90% RH non condensing Atmospheric Pressure: 70-106kPa
Transport and storage	Ambient temperature 0°C to +50°C Humidity: 0% to 90% RH non condensing Atmospheric Pressure: 70-106kPa
Exclusions	None

Standards for Reference

EN ISO 13485:2016
EN ISO 14971:2012
EN 60601-1:2006/A1:2013
EN 60601-1-2:2015
EN 60601-1-6:2010
EN 60601-1-8:2007/A11:2017
MEDDEV 2.12-1 Rev. 8
MEDDEV. 2.7.1 Rev. 4
MEDDEV. 2.12-2 Rev. 2

Explanation of Symbols

This statement provides important information or highlights information that may be easily overlooked.

This statement is a warning. Not following this statement could result in injury to the patient or operator, or damage to the device.

CE 2265 CE Marking with Notified Body Number.

Do not disassemble the device unless you are an MTTS trained technician or have been instructed to by qualified personnel.

Refer to the user manual before operating this device.

Refer to the user manual before operating this device.

This device contains electronic parts. Do not dispose of it with normal waste. Dispose of it according to local guidelines for disposal of eletronics. Dispose according to the WEEE directive in the European Union.

MD Medical device

UDI Unique identification number

Website where a user can obtain additional information on the medical product

EC REP Name and address of European Authorized Representative.

Device manufacturer.

Date of manufacture.

SN Serial number.

Keep out of direct sunlight.

Power supply polarity

12V DC 5A 12 Volt, Direct Current, 5 Ampere

Warranty Policy

General Terms

This MTTS Limited Warranty gives you, the customer, express limited warranty rights from MTTS, the manufacturer for the duration specified on the Warranty Card. Please refer to the MTTS Website for an extensive description of your limited warranty entitlements. In addition, you may also have other legal rights under applicable law or special written agreement with MTTS.

MTTS MAKES NO OTHER EXPRESS WARRANTY OR CONDITION WHETHER WRITTEN OR ORAL AND MTTS EXPRESSLY DISCLAIMS ALL WARRANTIES AND CONDITIONS NOT STATED IN THIS LIMITED WARRANTY. TO THE EXTENT ALLOWED BY LOCAL LAW OF JURISDICTIONS OUTSIDE VIETNAM, MTTS DISCLAIMS ALL IMPLIED WARRANTIES OR CONDITIONS, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. FOR ALL TRANSACTIONS OCCURRING IN VIETNAM ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY, SATISFACTORY QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE IS LIMITED TO THE DURATION OF THE EXPRESS WARRANTY SET FORTH ABOVE. SOME COUNTRIES DO NOT ALLOW A LIMITATION ON HOW LONG AN IMPLIED WARRANTY LASTS OR THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR CONSUMER PRODUCTS. IN SUCH COUNTRIES, SOME EXCLUSIONS OR LIMITATIONS OF THIS LIMITED WARRANTY MAY NOT APPLY TO YOU. FOR CONSUMER TRANSACTION, THE LIMITED WARRANTY TERMS CONTAINED IN THIS STATEMENT, EXCEPT TO THE EXTENT LAWFULLY PERMITTED, DO NOT EXCLUDE, RESTRICT, OR MODIFY BUT ARE IN ADDITION TO THE MANDATORY STATUTORY RIGHTS APPLICABLE TO THE SALE OF THIS PRODUCT TO YOU.

This Limited Warranty is applicable in all countries and may be enforced in any country or region where MTTS or its authorized service providers offer warranty service for the same product model number (subject to the terms and conditions set forth in this Limited Warranty)

Under this Limited Warranty, products purchased in one country or region may be transferred to another country or region where MTTS or its authorized service providers offer warranty service for the same product model number. Warranty terms, service availability, and service response times may vary from country or region to country or region. Standard warranty service response time is subject to change due to local parts availability. If so, your MTTS authorized service provider can provide you with details. MTTS will not alter form, fit, or function of this MTTS product to make it operate in a country for which it was never intended to function for legal or regulatory reasons. MTTS is not responsible for any tariffs or duties that may be incurred in transferring the products.

MTTS guarantees that the product that you have purchased or leased from MTTS is free from defects in materials or workmanship under normal use during Limited Warranty Period. The Limited Warranty Period starts on the date of purchase or lease from MTTS, or from the date MTTS completes installation. Your dated sales or delivery receipt, showing the date of purchase of the product, is your proof of the purchase or lease date. You may be required to provide proof or purchase or lease as a condition of receiving warranty service. You are entitled to hardware warranty service according to the terms and conditions of this document if a repair to your MTTS product is required within the Limited Warranty Period.

Unless otherwise stated, and to the extent permitted by local law, new MTTS product may be manufactured using new materials and used materials equivalent to new in performance and reliability. MTTS may repair or replace MTTS products (a) with new or previously used products or parts equivalent to new in performance and reliability, or (b) with equivalent products to an original product that has been discontinued. Replacement parts are warranted to be free from defects in material or workmanship for ninety (90) days or, for the reminder of Limited Warranty Period of the MTTS product they are replacing or in which they are installed, whichever is longer.

Warranty Policy

MTTS will, at its sole discretion, repair or replace any components or product that manifests a defect in materials or workmanship during the Limited Warranty Period. All component parts removed under this Limited Warranty become the property of MTTS. In the unlikely event that your MTTS product has recurring failures, MTTS at its sole discretion, may elect to provide you with (a) a replacement unit selected by MTTS that is the same or equivalent to your MTTS product in performance or (b) to give you a refund of your purchase price or lease payments (less interests) instead of a replacement. This is your exclusive remedy for defective products.

Exclusions

MTTS DOES NOT WARRANT THAT THE OPERATION OF THIS PRODUCT WILL BE UNINTERRUPTED OR ERROR-FREE. MTTS IS NOT RESPONSIBLE FOR DAMAGE THAT OCCURS AS RESULT OF YOUR FAILURE TO FOLLOW THE INSTRUCTIONS INTENDED FOR THE PRODUCT.

This Limited Warranty does not apply to expendable or consumable parts and does not extend to any product from which the serial number has been removed or that gas been damaged or rendered defective (a) as a result of accident, misuse, abuse, contamination, improper or inadequate maintenance or calibration (if required) or other external causes; (b) by operation outside the usage parameters stated in the user documentation shipped with the product; (c) by software, interfacing, parts or supplies not supplier by MTTS; (d) improper site preparation or maintenance; (e) virus infection; (f) loss or damage in transit ; or (g) by modification or service by anyone other than (i) MTTS personnel, (ii) an MTTS authorized service provider, or (iii) your own installation of end-user replaceable MTTS or MTTS approved parts if available for your MTTS product in the servicing country or region.

Limitation of Liability

IF YOUR MTTS PRODUCT FAILS TO WORK AS WARRANTED ABOVE, THE MAXIMUM LIABILITY OF MTTS UNDER THIS LIMITED WARRANTY IS EXPRESSLY LIMITED TO THE LESSER OF THE PRICE YOU HAVE PAID FOR THE PRODUCT OR THE COSTS OF REPAIR OR REPLACEMENT OF ANY HARDWARE COMPONENTS THAT MALFUNCTION IN CONDITIONS OF NORMAL USE.

EXCEPT AS INDICATED ABOVE, IN NO EVENT WILL MTTS BE LIABLE FOR ANY DAMAGES CAUSED BY THE PRODUCT OR THE FAILURE OF THE PRODUCT TO PERFORM, INCLUDING ANY LOST PROFITS OR SAVINGS OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. MTTS IS NOT LIABLE FOR ANY CLAIM MADE BY A THIRD PARTY OR MADE BY YOU FOR A THIRD PARTY.

THIS LIMITATION OF LIABILITY APPLIES WHETHER DAMAGES ARE SOUGHT, OR CLAIM MADE, UNDER THIS LIMITED WARRANTY OR AS A TORT CLAIM (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY), A CONTRACT CLAIM, OR ANY OTHER CLAIM. THIS LIMITATION LIABILITY CANNOT BE WAIVED OR AMENDED BY ANY PERSON. THIS LIMITATION OF LIABILITY WILL BE EFFECTIVE EVEN IF YOU HAVE ADVISED MTTS OF THE POSSIBILITY OF ANY SUCH DAMAGES. THIS LIMITATION OF LIABILITY, HOWEVER, WILL NOT APPLY TO CLAIMS FOR PERSONAL INJURY.

THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS. YOU MAY ALSO HAVE OTHER RIGHTS THAT MAY VARY FROM COUNTRY TO COUNTRY. YOU ARE ADVISED TO CONSULT APPLICABLE COUNTRY LAWS FOR A FULL DETERMINATION OF YOUR RIGHTS.

Warranty Policy

Limited Warranty Period

The Limited Warranty Period for this MTTS product is a specified, fixed period commencing of the date of purchase and specified on the Warranty Card. The date on your sales receipt is the date of purchase unless MTTS or your reseller informs you otherwise in writing.

Customer Responsibilities

In order to avoid the risk of charges for issues not covered by your limited warranty (issues that are not due to defects in materials and workmanship on MTTS product), you will be asked to assist MTTS as follows:

- Verify configurations, load most recent firmware, install software patches, run MTTS diagnostics and utilities;
- Implement temporary procedures or workarounds provided by MTTS while MTTS works on permanent solution;
- Cooperate with MTTS in attempting to resolve the problem using online chat, email, or telephone. This may involve performing routine diagnostic procedures, installing additional software updates or patches;
- Perform additional tasks as defined within each type of warranty service provided by MTTS and any other actions that MTTS may reasonably request in order to best perform the warranty support

CUSTOMER IS RESPONSIBLE FOR DELIVERING THE PRODUCT (AND ALL COSTS INVOLVED) FROM HIS LOCATION TO THE MTTS AUTHORIZED SERVICE POINT.

Contacting MTTS

If your MTTS product fails during the Limited Warranty Period and the suggestions in the product documentation do not solve the problem, you can receive support by doing one of the following:

- Locate and contact your nearest MTTS service provider via MTTS website:
  http://www.mtts-asia.com/support/
- Call the Technical Support Centre:
  +84 24 3766 6521

Before calling MTTS or an MTTS authorized service provider please have the following information available:

- Product serial number and model name
- Applicable error messages
- Detailed questions

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