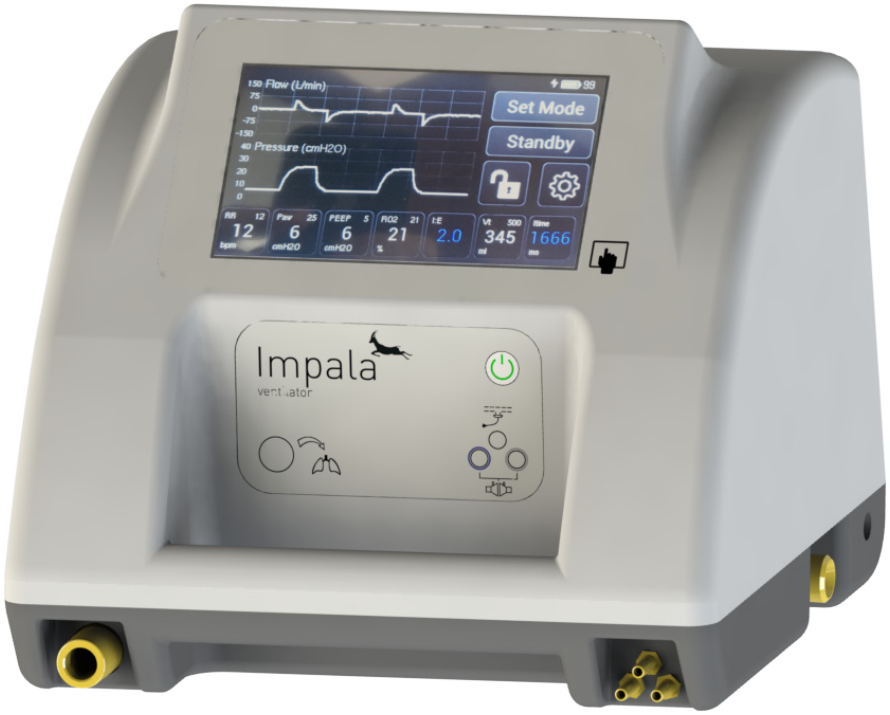
Impala
ventilator

MTTS



User Manual

MD Ventilator

UDI 111720644446

CE 2265

Effective date: July 2021
Issue Number: 01 Version: 05 EN
Issue Date: July 2021

www.mtts-asia.com

MTTS

Contents

Company Information

MEDICAL TECHNOLOGY TRANSFER AND SERVICES Co., LTD
House No. 26, Alley 41, An Duong Vuong Street, Tay Ho District, Hanoi City, Vietnam

Tel: +84 24 3766 6521
Fax: +84 24 3718 8050
Email: assistance@mtts-asia.com
www.mtts-asia.com

Logic s.r.l.
Via Antonio Pigafetta 1
34147 Trieste, Italy

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 Impala Ventilator is to be operated by qualified personnel only. This manual is a reference only that you should read, and understand before using the Impala ventilator on a patient to ensure particularly the safety considerations listed.
However, it is not intended to supersede your institution's protocol regarding the safe use of assisted ventilation.

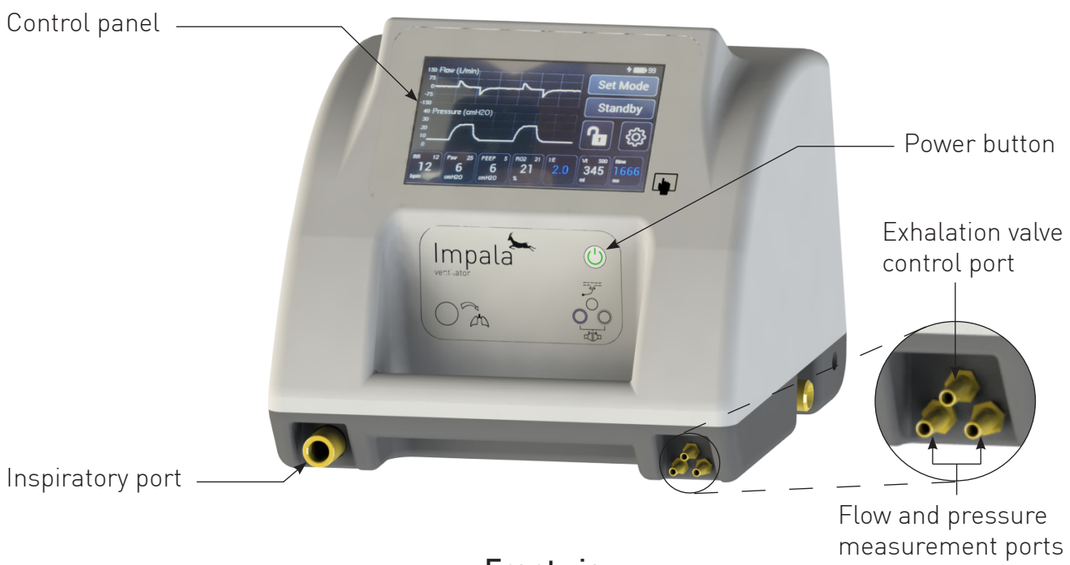
Device description:
The Impala Ventilator is an intensive-care ventilator that provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. The device contains a built-in pump to generate positive end-expiratory pressure (PEEP) and Peak Inspiratory Pressure (PIP) without necessity of any external air sources. An integrated blender and oxygen monitoring function also allows oxygen-rich (>21% O2) air with accurate fraction of inspired oxygen (FiO2) to be safely delivered to the patient. It may be used for both invasive and non-invasive ventilation.

Intended use:
The Impala Ventilator is indicated for the continuous or intermittent mechanical ventilation support of patients weighing at least 11 lb (5 kg) who require the following general types of ventilatory support, as prescribed by an attending doctor:
-Positive Pressure ventilation
-Assist/Control, SIMV, or CPAP modes of ventilation
-Breath types including Volume Control, Pressure Control, and Pressure Support

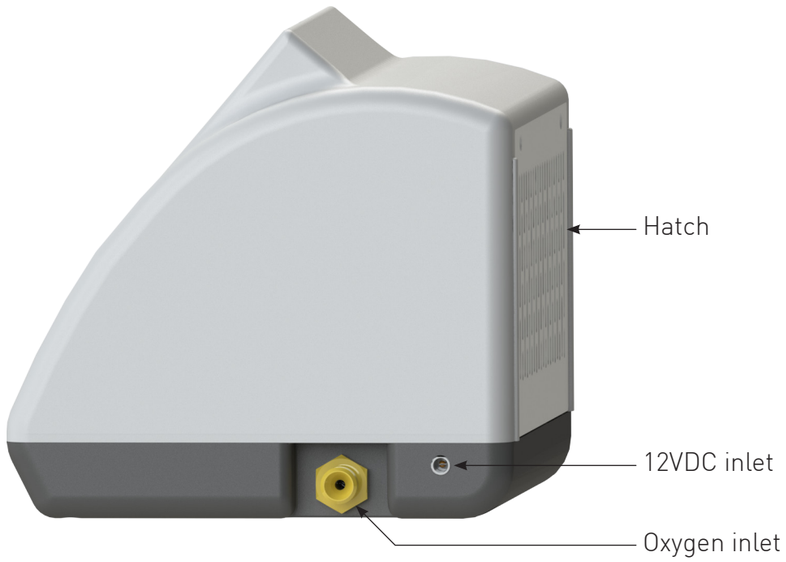
The Impala ventilator is intended for use by qualified, trained personnel under the direction of a doctor.

Contraindications for Use:
No absolute contraindications exist to ventilator devices. The need for ventilator device is best made early on clinical grounds and depends on indication of doctor. A good rule of thumb is if the practitioner is thinking that mechanical ventilation is needed, then it probably is.The use of ventilator devices may subject patients to a variety of complications and adverse effects. Therfore, only professional operator can operate this device.

Overview



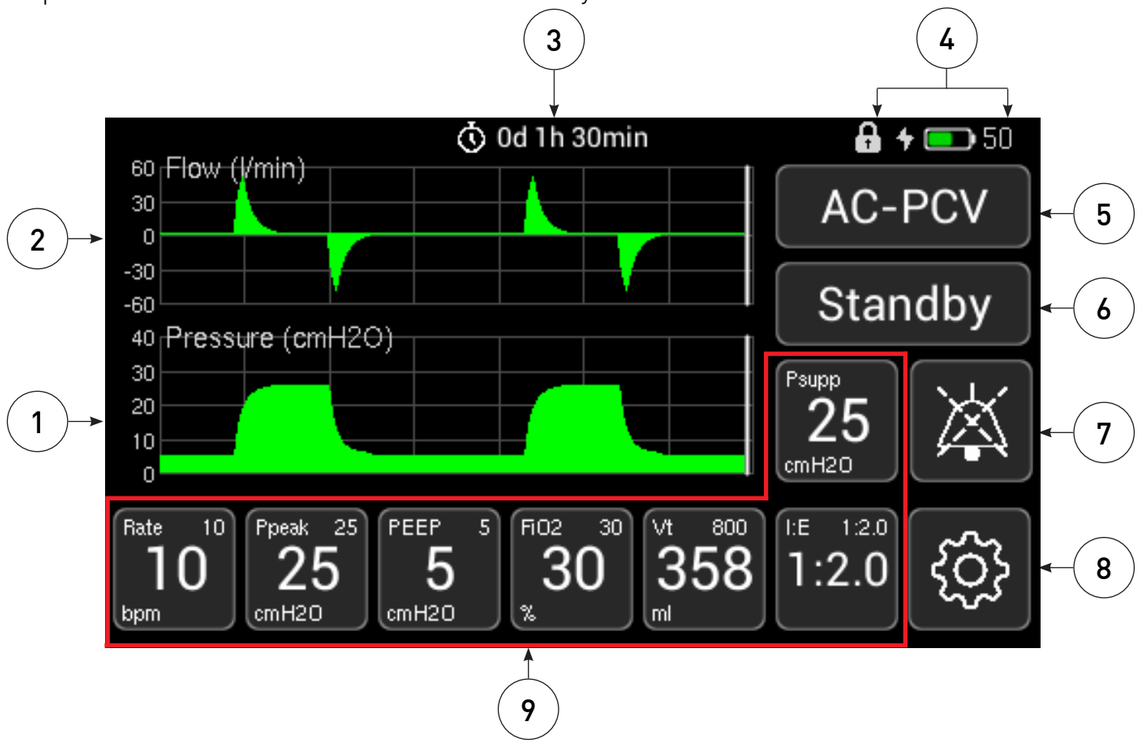
Front view



Side view

Control Panel

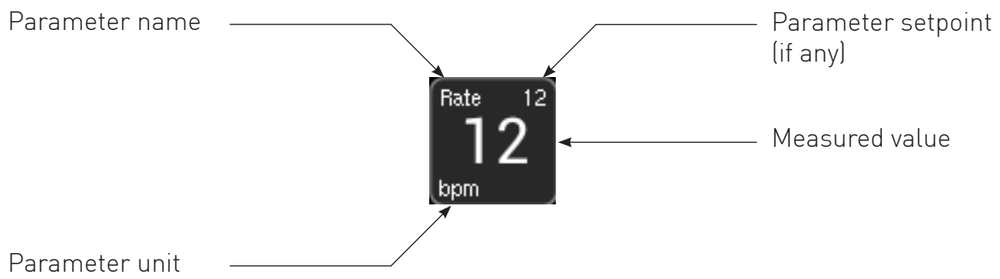
Impala Ventilator functions are controlled by touch screen.



1	**Pressure Graph**	Shows measured airway pressure as a function of time
2	**Flow Graph**	Shows the patient's flow waveforms as a function of time.
3	**Ventilation Timer**	Shows how long the patient has been ventilated
4	**Status Bar**	Shows infomation about locking, battery remaining capacity and charging conditions
5	**Ventilation Mode Button**	Shows the current ventilation mode. Touch this button to change mode.
6	**Standby Button**	Enable/Disable Standby mode.
7	**Alarm Silence Button**	Touch this button to mute auditory alarm for 2 minutes.
8	**Setting Button**	Touch this button to open/close Setting screen
9	**Ventilator Parameters**	Each button shows name, unit, measured value and/or setpoint of a ventilator's parameter. Details are depicted on the next page.

Ventilator parameter

Details of each ventilator parameter are showed in a button as below.



Following table describes frequently used parameters that are available on the main screen of each ventilation mode.

Ventilation mode	ISO 19223 code	Parameters on the main screen	Mode description	
			Mandatory breath	Spontaneous breath
AC-PCV	**A/C PC**	Ventilation rate, Peak/control pressure, PEEP, FiO2, Tidal volume, I:E ratio	Time-triggered , Time-cycled (normal) or volume-cycled (if tidal volume exceeds upper alarm limit), Pressure-controlled, Baseline: PEEP	Pressure- or flow-triggered, Time-cycled (normal) or volume-cycled (if tidal volume exceeds upper alarm limit), Pressure-controlled, Baseline: PEEP
AC-VCV	**A/C VC**	Ventilation rate, Peak pressure, PEEP, FiO2, Tidal volume, Peak inspiratory flow	Time-triggered, Volume-cycled (normal) or pressure-cycled (if Paw exceeds upper alarm limit) or time-cycled (if inspiration time exceeds 4/5 breath cycle), Flow-controlled, Baseline: PEEP	Pressure- or flow-triggered, Time-cycled or volume-cycled (if tidal volume exceeds upper alarm limit), Pressure-controlled, Baseline: PEEP
SIMV-PC	**SIMV-PC**	Ventilation rate, Peak/control pressure, PEEP, FiO2, Tidal volume, I:E ratio	Time-triggered, Time-cycled (normal) or volume-cycled (if tidal volume exceeds upper alarm limit), Pressure-controlled, Baseline: PEEP	(for synchronized breath) Pressure- or flow-triggered, Time-cycled (normal) or volume-cycled (if tidal volume exceeds upper alarm limit), Pressure-controlled, Baseline: PEEP
SIMV-VC	**SIMV-VC**	Ventilation rate, Peak pressure, PEEP, FiO2, Tidal volume, Peak inspiratory flow	Time-triggered, Volume-cycled (normal) or pressure-cycled (if Paw exceeds upper alarm limit) or time-cycled (if inspiratory time exceeds 4/5 breath cycle), Flow-controlled, Baseline: PEEP	(for synchronized breath) Pressure- or flow-triggered, Volume-cycled (normal) or pressure-cycled (if Paw exceeds upper alarm limit) or time-cycled (if inspiratory time exceeds 4/5 breath cycle), Flow-controlled, Baseline: PEEP

Device Description

Ventilation mode	ISO 19223 code	Parameters on the main screen	Mode description	
			Mandatory breath	Spontaneous breath
PCV/PS	**S/T-vtPS/vtPC**	Ventilation rate, Peak/control pressure, PEEP, FiO2, Tidal volume, I:E ratio,	Time-triggered , Time-cycled (normal) or volume-cycled (if tidal volume exceeds upper alarm limit), Pressure-controlled, Baseline: PEEP	Pressure- or flow-triggered, Flow-cycled (normal) or volume-cycled (if tidal volume exceeds upper alarm limit) or time-cycled (if inspiratory time exceeds 4/5 breath cycle), Pressure-controlled, Baseline: PEEP
VCV/PS	**S/T-PS/VC**	Ventilation rate, Peak pressure, PEEP, FiO2, Tidal volume, Peak inspiratory	Time-triggered, Volume-cycled (normal) or pressure-cycled (if Paw exceeds upper alarm limit) or time-cycled (if inspiration time exceeds 4/5 breath cycle), Flow-controlled, Baseline: PEEP	Pressure- or flow-triggered, Flow-cycled (normal) or volume-cycled (if tidal volume exceeds upper alarm limit) or time-cycled (if inspiratory time exceeds 4/5 breath cycle), Pressure-controlled, Baseline: PEEP
CPAP	**CPAP**	Ventilation rate, Peak pressure, PEEP, FiO2, Tidal volume, Apnea time		Baseline: PEEP
BiPAP	**BPAP**	Ventilation rate, Peak pressure, PEEP, FiO2, Tidal volume, Apnea time, Support pressure (IPAP)		Pressure-controlled, Flow-cycled, Baseline: PEEP
HFNC	**-**	Peak pressure, FiO2, Peak inspiratory flow	Device provide continuously constant flow.	

Trigger window is 80% of the expiratory time. Synchronization window is 20% of the expiratory time.

Less frequently used parameters such as pressure trigger sensitivity or flow trigger sensitivity can be found in the Setting screen.

To adjust a parameter setpoint, touch its button.

Warnings

The Impala ventilator must be used only under the responsibility and on the prescription of a doctor/clinician.

The Impala ventilator must be used according to its intended use. Refer to Introduction section - page 5.

Be aware this manual describes how to respond to the ventilator, but does not tell you how to respond to the patient.

While the ventilator is in use, an alternative means of ventilation should always be available in the event of a ventilator problem. This is particularly true for ventilator-dependent patients. Supplementary observation, appropriate for the patient's condition, is also recommended.

The Impala ventilator is to be operated by qualified personnel only and use them for a ventilator-dependent patient. Make sure that they can already take suitable action in the event the ventilator identifies an alarming condition or experiences a problem This manual, accessory Directions for Use, all precautionary information, and specifications should be read before uses.

Explosion hazard. Do not use the Impala ventilator in the presence of flamable 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 (5°C to 40°C) or humidity range (0%RH to 95%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.

Ensure that the Locking key is activated so that some critical information of the ventilator is not modified

Warnings

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

The HMEF/ HEPA filter is not reusable, do not attempt to wash, clean, or reuse them.

To comply with the biosafety standards to reduce the risk of infection such as washing your hands thoroughly before and after handling the ventilator or its accessories. To clean the ventilator and its accessories regularly and systematically before and after each use and following any maintenance procedure to reduce the risks of infection.

To prevent possible patient injury, do not enter the diagnostic mode while a patient is connected to the ventilator. Verify that the patient is disconnected before proceeding.

Ensure that always verify all settings are set in accordance with the required prescription before starting ventilation. Avoid the patient to remain connected to the ventilator when ventilation is stopped, because a substantial quantity of exhalation gas, primary carbon dioxide, may be inhaled by the patient.

To prevent possible patient injury due to no annunciating alarms, verify the operation of any alarm device before use.

DO NOT reuse single-use bacteria filters, flow sensors, and other accessories. They must be discarded after single use. Reusing, disassembling, cleaning, disinfecting, or sterilizing a single-use part may compromise its functionality and system performance, leading to a possible operator or patient hazard. Performance is not guaranteed if an item labeled as single-use is reused.

An alternative means of ventilation shall be available whenever the ventilator is in use. If a fault is detected in the ventilator or its life-support functions are in doubt, disconnect the Impala Ventilator from the patient and immediately start ventilation with such a device.

Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health.

To reduce the risk of fire, use only breathing circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.

When using non-invasive ventilation, a CO_2 monitoring equipment in accordance with ISO 80601-2-55 should be used for the measurement of expiratory carbon dioxide concentration, the exhaled volume and exhaled CO_2 of the patient can differ from the measured exhaled volume and exhaled CO_2 due to leaks around the mask.

1. Content of the box

Impala set includes:

- Impala Control Unit with 12V adapter	VEN-10000	
- Oxygen Hose	VEN-10110	
- Mounting Shelf	VEN-10091	
- Breathing Circuit Support Arm	VEN-10092	
- Oxygen Hose Connector	CPD105XX	DISS, BS, JIS, SIS, DIN
- AC Cord	COR-1000X	EU, UK, US
- Stand Assembly Instructions	VEN-1101X	EN, FR, ES
- Reprocessing Guide	VEN-1102X	EN, FR, ES
- Quick Reference Guide	VEN-1103X	EN, FR, ES

Optional accessories:

- Humidifier	VEN-10055	
- Stand	VEN-10093	
- Test Lungs	VEN-10095	
- Brething Circuits:		
- Double Limb	VEN-1003X	Adult, Pediatric
- Single Limb*	VEN-1005X	Adult, Pediatric
- Patient's interface:		
- Silicon Mask	VEN-1006X	Size: 3,4,5
- Endotracheal Tube	VEN-1007X	Size: 5,6,7,8
- High Flow Nasal Cannula*	VEN-1008X	Size: S,M,L

*Requires Humidification

2. Stand assembly (optional)

A. Remove components from the box

x 1 Base

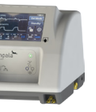
x 1 Stand

x 1 Basket

x 1 Device Holder

x 1 Oxygen Cylinder Holder

x 1 Supporting Arm



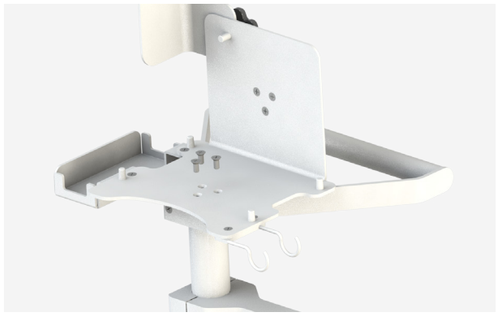
x 1 Impala Control Unit

x 3 Bolt M5x15 (Base)
x 2 Bolt M5x15 (Basket)
x 3 Bolt M5x10 (Device)
x 2 Bolt M10x30 (Oxygen)

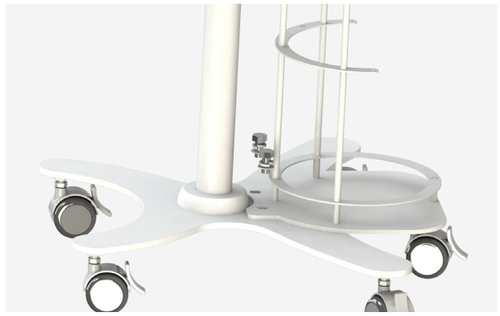
B. Attach Stand to Base

C. Attach Basket

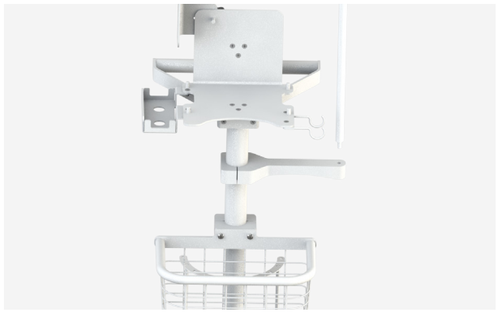
D. Attach Device Holder



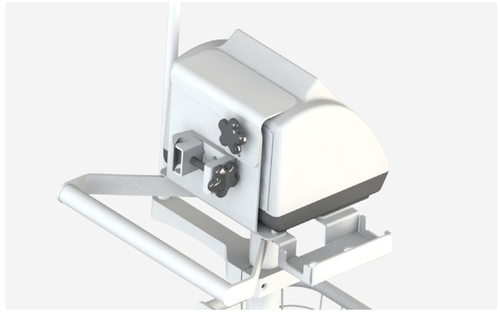
E. Attach Oxygen Cylinder Holder



F. Attach Supporting Arm

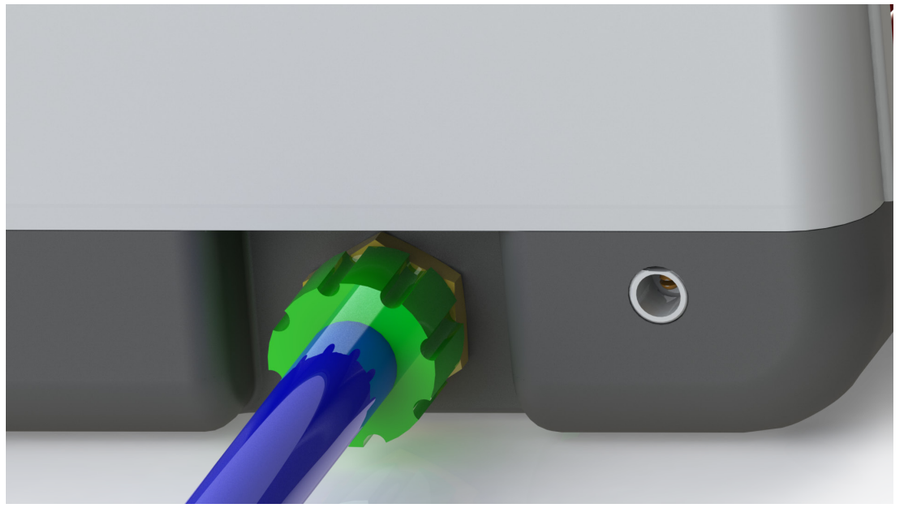


G. Attach Impala Control Unit



3. Gas hose

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



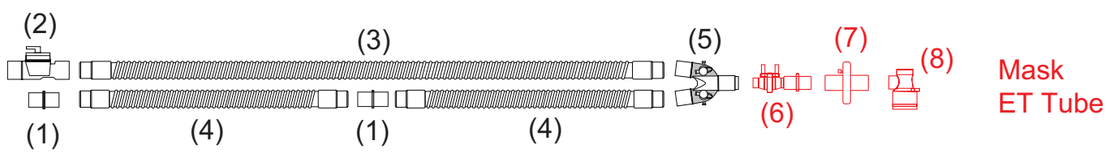
The gas sources must provide pressure within the range of 10 to 60 psi (0.7 to 4.1 bar). If the gas sources are outside of this range, the device may not be able to produce the desired %FiO2.

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

4. Breathing circuit (optional)

The device can work with both single-limb and double-limb (includes coaxial inspiratory/expiratory limb) breathing circuit.

A. DOUBLE LIMB CIRCUITS

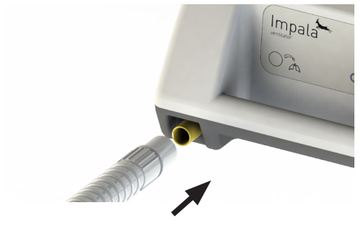


Item	Name
1	REUSABLE STRAIGHT CONNECTOR
2	REUSABLE EXHALATION VALVE
3	REUSABLE SILICONE CORRUGATE TUBE 120 CM
4	REUSABLE SILICONE CORRUGATE TUBE 60 CM
5	REUSABLE WYE CONNECTOR
6	DISPOSABLE FLOW SENSOR
7	DISPOSABLE HME FILTER
8	DISPOSABLE CATHETER MOUNT

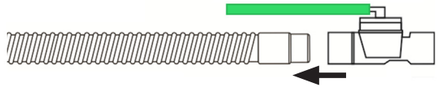
Reusable parts

Disposable parts

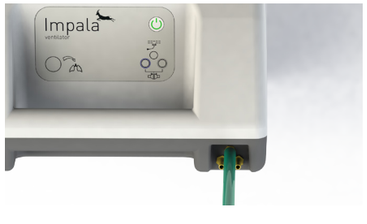
1. Attach straight connector (1) and inspiratory tube set (4+1+4) to the device



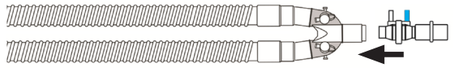
2. Insert exhalation valve (2) into the expiratory tube (3)



3. Attach exhalation valve control tube (2) to the port in front of the device

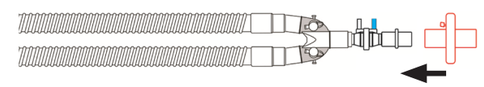


4. Connect expiratory tube (3) and inspiratory tupe set (4+1+4) witth the wye connector (5) and the flow sensor (6)



5. Connect flow sensor's (6) blue and clear tubes to the ports in front of the device

6. Connect the HME filter (7) and catheter mount (8) to the flow sensor (6)



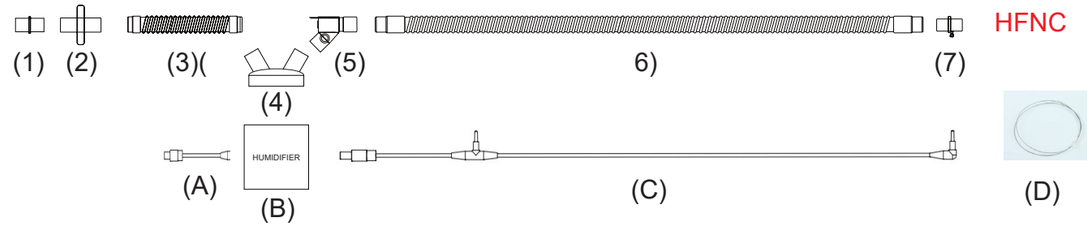
To prevent inaccurate readings, ensure the flow sensor tubing is not kinked.

The flow sensor's blue tube should always be toward the patient. Always attach the blue tube to the port marked with blue color.

B. SINGLE LIMB CIRCUITS

Single Limb circuits are intended for the use with humidifiers and High Flow Nasal Cannulas.

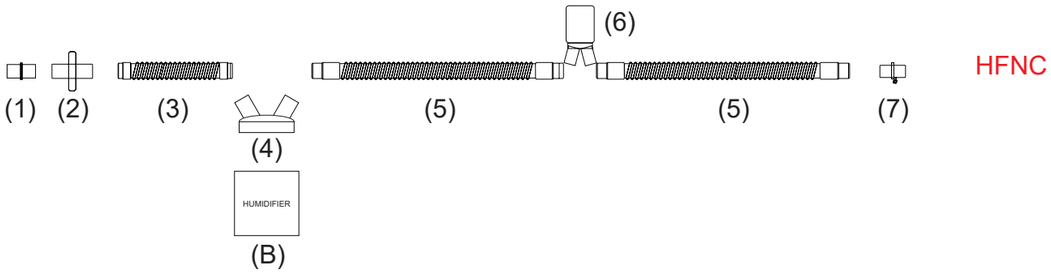
- SINGLE LIMB - HUMIDIFIED, HEATED



Item	Name
1	STRAIGHT CONNECTOR
2	BACTERIAL FILTER
3	SILICONE CORRUGATE TUBE 30 CM
4	HMIDIFIER CHAMBER
5	HEATER WIRE CONNECTOR
6	SILICONE CORRUGATE TUBE 120 CM
7	CONNECTOR WITH TEMP PORT

Item	Name
A	HEATER WIRE POWER CORD
B	HUMIDIFIER + GAS HEATER
C	TEMPERATURE SENSOR
D	HEATER WIRE DRAW LINE

- SINGLE LIMB - HUMIDIFIED, UNHEATED

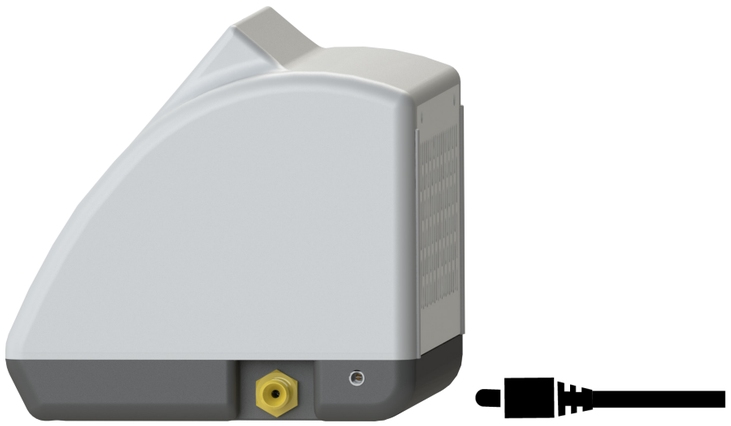


Item	Name
1	STRAIGHT CONNECTOR
2	BACTERIAL FILTER
3	SILICONE CORRUGATE TUBE 30 CM
4	HMIDIFIER CHAMBER
5	SILICONE CORRUGATE TUBE 60 CM
6	WATER TRAP
7	CONNECTOR WITH TEMP PORT

Item	Name
B	HUMIDIFIER

4. 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 and hold the Power Button to turn the device ON.

> ⚠ Only use power supply unit provided by MTTS.

> ℹ The device will start with the default STANDBY mode.

5. Use backup battery

The internal battery protects the device from failure of external power supply. When AC mains fail to provide power during ventilation, the ventilator power supply automatically switches to the internal backup battery without an interruption in ventilation. A power failure alarm sounds to signal the switchover. The alarm will continue sound until you silence the alarm. Silencing the alarm confirms operator notification of the power system change and resets the alarm.

The battery powers the ventilator until AC power is again adequate or until the battery is depleted.

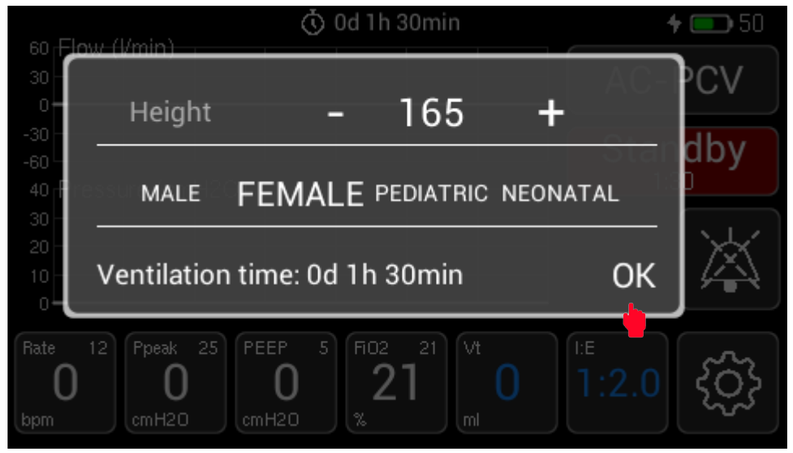
As a further safeguard, the device provides “low battery” and “empty battery” alarms when battery remaining capacity is less than 30% and 10%, respectively.

The battery powers the ventilator for typically 4 hours (for new, fully charged batteries with the device at default settings).

When the ventilator is connected to the AC mains power, the battery is charged, with or without the ventilator power being switched ON. If device is on, the charging symbol is displayed at the top right corner of the screen indicating the available the external power source.

Set patient information

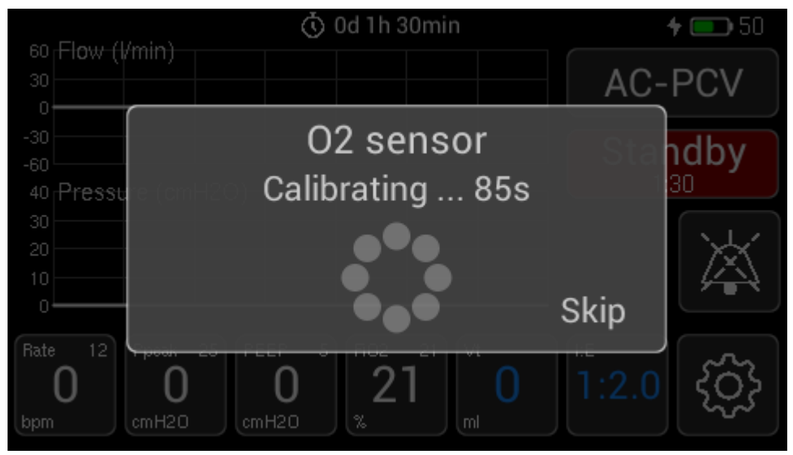
After turning on, a window automatically appears and shows information about the last patient. Touch OK to continue with the patient or change information to setup a new patient.



The patient height is used to calculate ideal body weight (IBW) and estimate initial tidal volume with a factor of 6 ml/kg.
Adult male: IBW (kg) = 0.9079 x Patient height (cm) - 88.022
Adult female: IBW (kg) = 0.9049 x Patient height (cm) - 92.006

Calibrate oxygen sensor

Oxygen sensor is automatically calibrated. The process takes 90 seconds to complete. The display shows the calibration progress.



Perform tightness test

The tightness test will begin after flow sensor calibration completes. The ventilator is gradually pressurized to 50 cmH2O. Any leak in the breating circuit will result in the test failure.

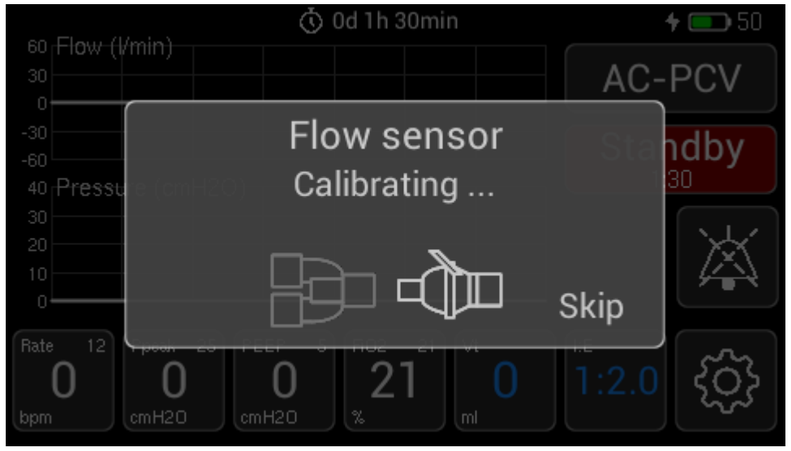
⚠ A finger covered with an alcohol pad may be used to occlude the patient connection during testing.

- Ensure another source of ventilatory support is available during the calibration and testing. The patient must be disconnected from ventilator during the calibration and testing processes.
- To cancel the calibration or testing process while in progress, touch Skip button on the screen.
- If calibration is skipped, the device starts ventilating but measurements can be inaccurate.
- Flow sensor and HME filter can be removed during oxygen sensor calibration process.

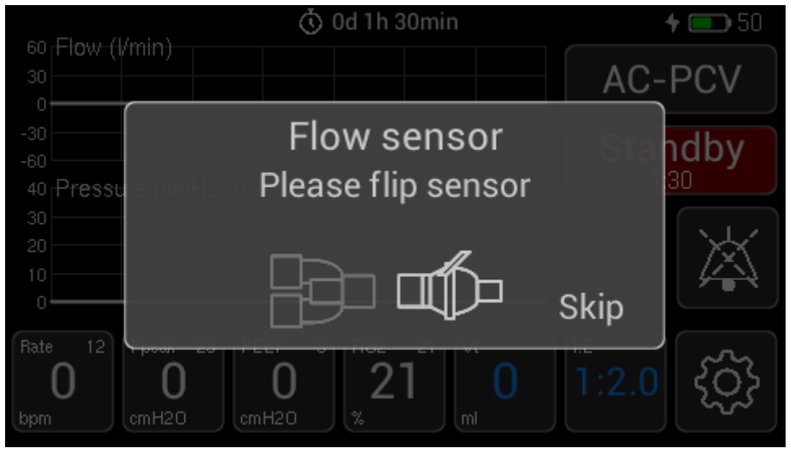
Calibrate flow sensor

After oxygen sensor calibration complete, the flow sensor will be calibrated with instructions shown on display. The operator will need to flip the sensor during calibration process.

> Flow sensor calibration is not performed when the single limb breathing circuits are used. The process is cancelled by pressing the button or after 15 seconds of no activity.

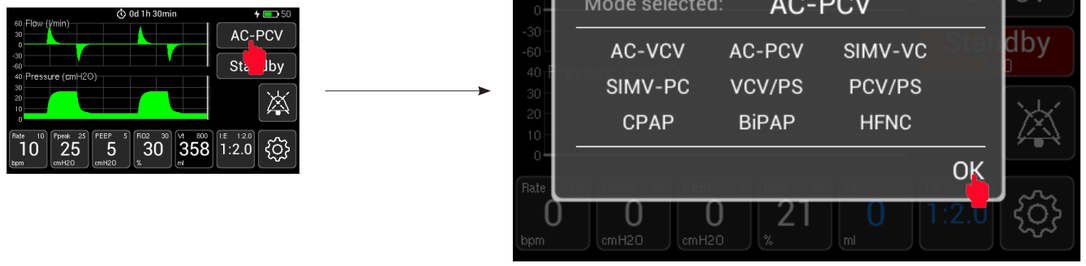


The operator will be asked to flip the sensor during calibration process.



Set ventilation mode

Touch ventilation Mode button to open Mode selection window. On this window, select desired ventilation mode and touch OK.



> When changing the mode during ventilation, significant transitions of pressure, flow, or cycling rate might occur, depending on the difference between the modes. Before setting the new mode, first ensure that the settings between the different modes are compatible. This reduces the risk of discomfort and harm to the patient

Adjust parameters

Touch the parameter to open its window for adjustment. On this window, touch '+' or '-' to increase or decrease the parameter setpoint. Some preset values are also given on the window for quick selection. Touch OK to return to the main screen.

Refer to Ventilator Parameter section for available parameters in each ventilation mode.

Start/Stop ventilation

After selecting ventilation mode and all neccessary parameters are set, ventilation can be started by touching Standby button. Touching Standby during ventilation will put the device in Standby mode and stop ventilation. A timer in the standby button starts counting up to show how long the patient has not been ventilated.

Red color of the standby button indicates that the device is in Standby mode.

Setting screen

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

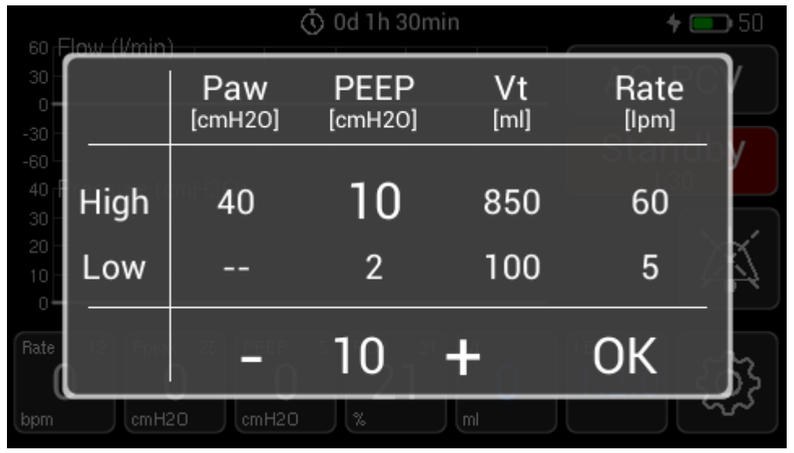
Following features are available on the Setting screen:

- Go to the Device information screen
- Calibrate oxygen sensor and flow sensor
- Set alarm limits
- Check system tightness
- Adjust less frequenly used parameters
- Adjust alarm sound loudness

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

Set alarm limits

To set alarm limits, touch the 'Alarm' button on the Setting screen. Select desired alarm limit and adjust its value. Touch OK to return to the Setting screen.



Screen lock/unlock

The Screen Lock/Unlock function prevents inadvertent touch screen entries. To lock or unlock the screen, press and hold Lock/Unlock keys.

Turn the device off

Press and hold the Power button to turn the device off.

The Impala Ventilator will generate visual and audible alarm signals to notify you of alarm conditions detected.
An alarm condition is indicated by:

- Audible alarm tone
- Visual alarm indicator (flashing parameter button and power button)

Alarm silence

Audible alarms may be suspended, while visual alarms may not. The alarm silence button is used to temporarily silence audible alarms for 2 minutes. When this button is pressed, its color turns red indicating audible alarms are silenced. The alarm sounds are can be restored by press the button again.

Alarm system test

In order to verify the operation of auditory and visual alarms, perform the following procedure:
1. On the main screen, disconnect flow sensor and start ventilation
2. Check pressure audible alarm sounds
All the alarms are considered HIGH PRIORITY (ref. IEC 60601-1-8).

List of alarms

Alarm	Cause/Ventilator Response	Corrective Action
Power failure	AC mains fail to provide power	Silence the alarm to continue with internal back up battery.
Low battery / empty battery	The AC (mains) power source cut-off and internal battery capacity is less than 30%	Reconnect the device to an external power supply.
Obstruction	Airway obstruction The alarm condition delay does not exceed 1 second	Check patient's trachea and clear the obstruction. If the filter or exhalation valve is obstructed, replace it.
Disconnection	Patient circuit disconnected The alarm condition delay does not exceed 1 second.	Clean, unblock, and/or re-connect the patient circuit

Alarm	Cause/Ventilator Response	Corrective Action
Apnea (CPAP/BiPAP modes)	Adjustment of apnea time too low	Have physician determine if ventilator settings are appropriate for the patient.
	Adjustment of the inspiratory sensitivity level too high	
	Patient stops breathing	
High pressure	Adjustment of upper airway pressure (Paw) alarm limit too low (only for A/C VC, SIMV VC modes)	Note: Always consult the clinical before changing PEEP, FiO2, pressure, volume or rate settings. Increase the alarm limit
	Airway obstruction	Check patient's trachea and clear the obstruction. If the filter is obstructed, replace the filter
	Coughing or other high-flow exhalation efforts	Treat patient's cough. Silence the alarm, if necessary
	Patient inspiratory resistance or compliance changes	Have physician determine if ventilator settings are appropriate for the patient.
High rate	Adjustment of upper rate alarm limit too low	Readjust the alarm limit
	Adjustment of the inspiratory sensitivity level too low	Adjust trigger sensitivity according to the patient
	Patient hyperventilating	Silence the alarm and call for a medical team if the symptoms persist
		Check for auto-cycling and adjust inspiratory sensitivity, manage leaks or drain condensation from patient circuit
	Defective flow sensor	Have a qualified technician replace the defective component(s) and call your customer service representative
Low rate	Adjustment of lower rate alarm limit too high	Readjust the alarm limit
	Adjustment of the inspiratory sensitivity level too high	Adjust trigger sensitivity according to the patient
	Defective flow sensor	Have a qualified technician replace the defective component(s) and call your customer service representative

Alarm system

Alarm	Cause/Ventilator Response	Corrective Action
High volume	Adjustment of the upper tidal volume (Vt) alarm limit too low	Note: Always consult the clinical before changing PEEP, FiO2, pressure, volume or rate settings. Modify the alarm limit.
	Flow sensor not calibrated properly	Calibrate the flow sensor
Low volume	Adjustment of the upper tidal volume (Vt) alarm limit too high or adjustment of the pressure level not enough to reach the volume required	Modify the alarm limit or the pressure level according to the physician's prescription
	Patient circuit obstructed or disconnected	Clean, unblock, and/or re-connect the patient circuit
	Flow sensor not calibrated properly	Calibrate the flow sensor
Low FiO2	Not enough oxygen	Check oxygen source. Replace oxygen tank if it's empty.
	Oxygen sensor not calibrated properly	Calibrate the oxygen sensor
High FiO2	Oxygen sensor not calibrated properly	Calibrate the oxygen sensor

Cleaning

The reusable breathing circuit includes parts that must be completely disassembled and decontaminated before use. These parts includes breathing tubes, mask, flow sensor, exhalation valve, straight and wye connectors. These parts are not manufactured by MTTS, please comply with the original manufacturers' guidlines.

- Comply with hospital, local and national guidelines for product cleaning frequencies.
- Ensure oxygen supply is turned off and disconnected from Impala Ventilator before performing cleaning procedures.
- 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 Impala Ventilator is immersed in any cleaning liquid or cleaning solution.
- Do not use abrasive cleaning solutions.
- Ensure all Impala Ventilator parts and accessories are checked before returning the device to service.

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.

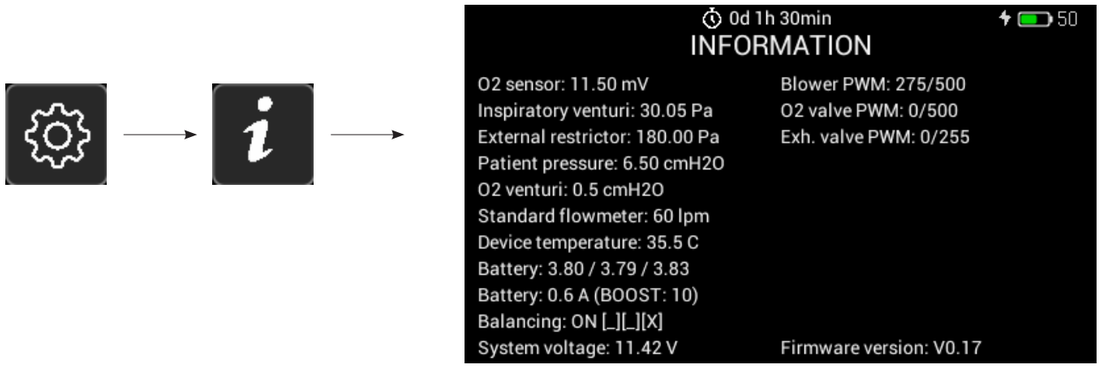
Please contact an authorised MTTS representative for further assistance with any servicing or maintenance requirement.

The Impala Ventilator 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.

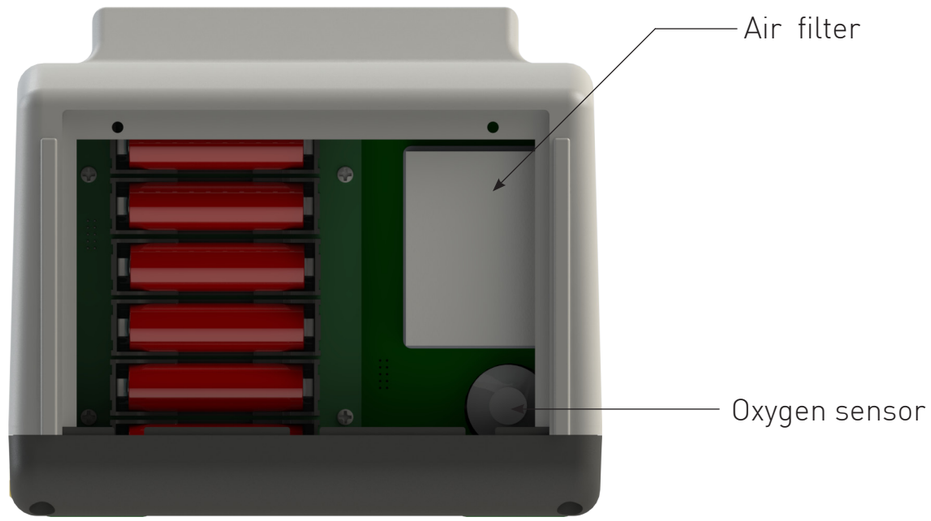
Device information screen

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.



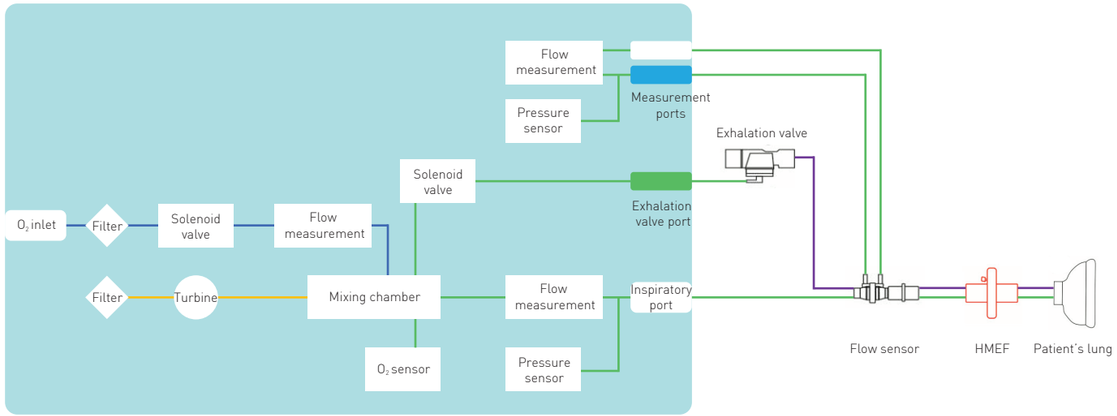
Air filter and oxygen sensor replacement

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.



Maintenance

Pneumatic diagram



- Inspiratory gas
- Expiratory gas
- O_2
- Ambient air

Specifications

Performance Specifications

Type of mechanical ventilation device	:	Invasive
Intended use	:	All patients that need help ventilation
Ventilation modes	:	AC-VCV, AC-PCV, SIMV-PC, SIMV-VC, VCV/PS, PCV/PS, CPAP, BiPAP
Required accessories	:	Disposable HMEF, Exhalation valve, flow sensor, breathing circuit (reusable or disposable)
I:E ratio	:	1:9 - 4:1
Trigger	:	Time triggering: 60/Rate (s) Pressure triggering: 0.1-10 (cmH_2O) Flow triggering: 0.1-15 (l/min)

Physical Specifications

Dimensions (HxWxD)	overall	:	20 cm x 22cm x 20 cm
Total unit mass			3 kg
Alarms	High Priority Audible	:	5 pulse burst, followed by 0.5 second delay, followed by 5 pulse burst, followed by 3 second delay
	High Priority Visual Alarm	:	Red flashing at 1.5 Hz
	Medium Priority Audible	:	3 pulse burst, followed by 2.5 second delay
	Medium Priority Visual	:	Yellow flashing at 0.5 Hz
Internal pump	Alarm Volume	:	>50 dBA at 1m, adjustable
	Type	:	Blower, 12VDC
Ingress Protection	Maximum limited pressure	:	75 cmH_2O
	IP21	:	(dripping water)

Control setting Specifications

Positive End Expiratory Pressure (PEEP)	:	0-25 cmH_2O
Peak Inspiratory Pressure (PIP)	:	0-60 cmH_2O
Fraction of Inspired Oxygen (FiO2)	:	21-100%, response time < 30 s
Frequency (Respiratory rate)	:	2-60 bpm
Support pressure	:	0-60 cmH_2O
Tidal volume (Vt)	:	25-2000 ml

Monitoring parameters Specifications

Positive End Expiratory Pressure (PEEP)	:	± (2+(4%)) cmH_2O, moving average over the last 40 milliseconds
Peak Inspiratory Pressure (PIP)	:	± (2+(4%)) cmH_2O, moving average over the last 40 milliseconds
Frequency (Respiratory rate)	:	±1 bpm
Fraction of Inspired Oxygen (FiO2)	:	±(2.5 + 2.5 %) $\%FiO_2$, moving average of FiO_2 over the last breath
Tidal volume (Vt)	:	± (4+(15%)) ml

Specifications

Electrical Specifications

Power characteristics Off-the-shelf external power supply		60W, 100-240VAC, 47/63Hz 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 Capacity	11.1V Li-ion 6 cells, 6000mAh

Environmental Specifications

Operating	Ambient temperature +5°C to +40°C Humidity: 0% to 95% RH non condensing Atmospheric Pressure: 70-106kPa
Transport and storage	Ambient temperature 0°C to +50°C Humidity: 0% to 95% 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
ISO 80601-2-12:2020
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:

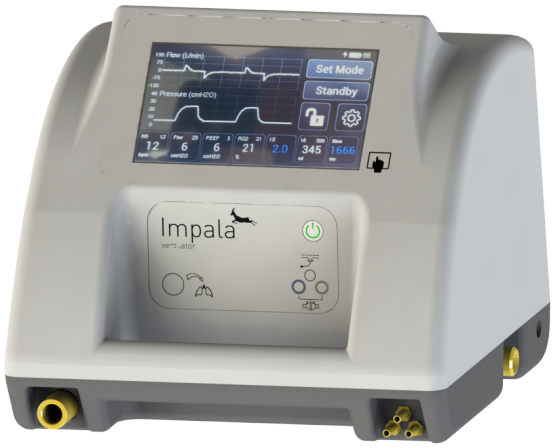
- Locate and contact your nearest MTTS service provider via MTTS website:
  http://www.mtts-asia.com/support/
- Call the Technical Support Centre:
  +84 24 3766 6521

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

MEDICAL TECHNOLOGY TRANSFER AND SERVICES Co., LTD
House No. 26, Alley 41, An Duong Vuong Street, Tay Ho District, Hanoi City, Vietnam

Tel: +84 24 3766 6521
Fax: +84 24 3718 8050
Email: assistance@mtts-asia.com
www.mtts-asia.com



EC REP

Logic s.r.l.
Via Antonio Pigafetta 1
34147 Trieste, Italy