Bio-Med Devices Inc.
TV-100 Operator's Manual

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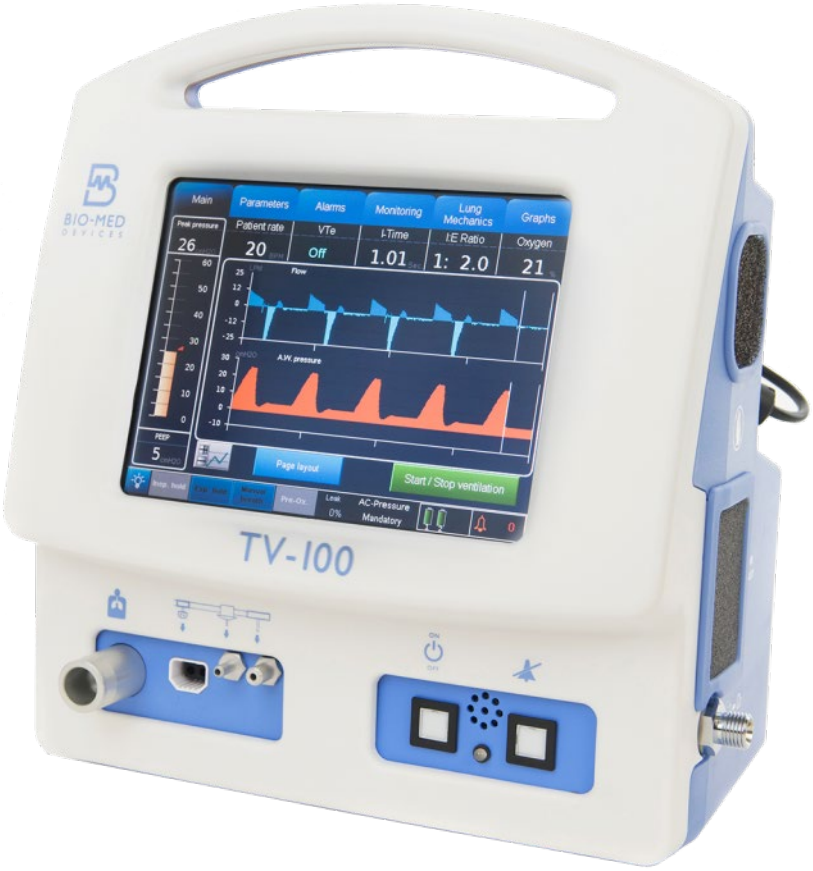

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I. Scope

This manual describes the features and operation of Bio-Med Devices Inc. TV-100 ventilator. To help ensure patient safety and proper performance of the TV-100, read and familiarize yourself with this manual before operating the TV-100.

II. Indications for Use / Intended Use

The TV-100 is intended for use by qualified medical personnel to provide intermittent to continuous ventilatory support to neonatal, pediatric, and adult patients. The TV-100 is intended for use in both invasive and non-invasive ventilation modes. The TV-100 is a transportable device, but can also be used in a fixed or permanently-installed installation. The TV-100 is intended for use in hospital including intra-hospital transport, pre-hospital, and air transport settings. The TV-100 is intended for use in ground / road ambulances and in air ambulances (both helicopters and fixed-wing aircraft).

CONTRAINDICATIONS

There are no direct contraindications for mechanical ventilation as it is a life-saving measure in a critically ill patient, and all patients should be offered the opportunity to benefit from this if needed. The only absolute contraindication for mechanical ventilation is if it is against the patient's stated wishes for artificial life-sustaining measures. The only relative contraindication is if non-invasive ventilation is available and its use is expected to resolve the need for mechanical ventilation. This should be started first as it has fewer complications than mechanical ventilation.[1]

III. Organization of this Manual

About this Manual

This section provides introductory information about the TV-100. This section includes scope, intended use, symbols, abbreviations, and safety information.

Chapter 1: Installation

This section provides information on unpacking, installing, and connecting the TV-100 ventilator; provides a list of the accessories included with the TV-100; provides information on the TV-100; and provides cleaning and sterilization information.

1. Ventilator Management, Andres L. Mora Carpio; Jorge I. Mora. StatPearls. https://www.ncbi.nlm.nih.gov/books/NBK448186

Chapter 2: Principles of Operation

This section provides a detailed description of the TV-100 principles of operation.

Chapter 3: User Interface

This section provides a detailed description of the TV-100 user interface.

Chapter 4: Performance Checkout Procedures

This section provides procedures to set up and test the TV-100 prior to patient use.

Chapter 5: Alarm Handling

This section provides a detailed description of how to recognize and respond to TV-100 alarm conditions.

Chapter 6: Troubleshooting

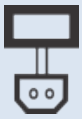
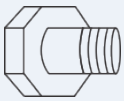
This section provides a top level troubleshooting guide for the TV-100.

Chapter 7: Specifications

This section provides TV-100 product specifications. This section also provides information on operating environment, physical and pneumatic characteristics of the unit, AC adapters and inverters, and EMC compatibility.

IV. Symbols

Symbol	Description
	Alarm Silence
	Type BF Equipment
	Manufacturer
	Date of Manufacture
	MR Unsafe
	Direct Current
	Warning
	Caution
	Notice
	Consult Accompanying Documents
	Follow Instructions for Use
	Power On / Off
	Must be disposed of in accordance with WEEE Directive. At the unit's "end of life", it may be returned to the manufacturer for proper reclamation.

Symbol	Description
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
EC REP	EC Representative
	Patient Output Connector
	Flow Sensor Connector
	Exhalation Valve Connector
	Airway Pressure Connector
	O_2 Connector
	Do Not Obstruct
	Product should be kept dry
CE 2797	The CE mark displayed on this product signifies that this device is in compliance with the European Medical Devices Regulation (2017/745). As a prerequisite for the CE mark, Bio-Med Devices operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (2797) pertains to Bio-Med's Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims.
	Humidity Limitation

Symbol	Description
	Temperature Limit
	Country of Origin & Manufacture
	Medical Device
	Unique Device Identifier
	Contains Hazardous Substances (see Section 7.4 Physical and Material Characteristics)

V. Abbreviations

Abbreviation	Definition
A/C	assist/control
AC	alternating current
Ah	amp-hour
BPH	breaths per hour
BPM	breaths per minute
C	degrees Celsius
CCW	counter-clockwise
cm	centimeter
cmH_2O	centimeters of water pressure
CPAP	continuous positive airway pressure
CW	clockwise
DARV	diaphragm actuated relief valve
dB	decibel
DC	direct current
E-Time, E, or EXP	expiratory time
ESD	electrostatic discharge
ESDS	electrostatic discharge sensitivity
Exh	exhalation
F	degrees Fahrenheit
Hz	hertz (cycles per second)
I:E Ratio	inspiratory to expiratory ratio
I-Time, I, or INSP	inspiratory time
kg	kilogram
kPa	kilopascal
L	liter
lbs	pounds
LCD	liquid crystal display

Abbreviation	Definition
LED	light emitting diode
LPM	liters per minute
mA	milliamp
mL	milliliter
mm	millimeter
MRI	magnetic resonance imaging
ms	millisecond
mV	millivolt
MV	minute volume
MVe	exhaled minute volume
N/A	not applicable
P_{aw}	pressure at the patient connector (airway pressure)
PCB	printed circuit board
PEEP	positive end expiratory pressure
PIP	peak inspiratory pressure
P/N	part number
PSI	pounds per square inch
SIMV	synchronized intermittent mandatory ventilation
Sec	second
SN	serial number
Te	expiratory time
Ti	inspiratory time
UI	user interface
VA	volt amp
VAC	volt alternating current
VDC	volt direct current
VER	software version
VT	tidal volume
VTe	exhaled tidal volume
W	watt

VI. Safety Statement

Bio-Med Devices, Inc. TV-100 ventilator performs in conformity with the specifications and descriptions contained in this manual, when operated in accordance with the information provided herein.

It is your responsibility to read and familiarize yourself with this manual before operating Bio-Med Devices, Inc. TV-100 ventilator. The TV-100 should only be used by qualified medical personnel. Attempting to use the TV-100 without a comprehensive understanding of its operation may result in patient injury.

Upon receipt of the TV-100, and periodically thereafter, complete the procedures detailed in Chapter 4: Ventilator Performance Checkout Procedures. While it is not necessary to perform a leak test, compliance test, or oxygen calibration prior to every use when using a Bio-Med Devices, Inc. circuit, the leak test can be performed if the user wants to verify the integrity of the circuit. If the TV-100 fails during a checkout procedure remove the TV-100 from use, contact Bio-Med Devices, Inc., and return the unit to be serviced by a qualified technician.

VII. Warnings, Cautions, and Notices

Document Conventions for Warnings, Cautions, and Notices

Warnings, cautions, and notices are presented in this manual in a format dissimilar to their surrounding text in order to clearly delineate the important information provided by these messages. An example of each message is presented below:

WARNING: When the ventilator is connected to a patient, qualified medical personnel should be present at all times, or within hearing range of the ventilator alarm system.

CAUTION: Touchscreen control buttons should be pressed by hand only. Care should be taken not to allow buttons to be contacted by sharp objects, as damage may result.

NOTICE: The batteries should be replaced at least every 2 years. Only use batteries supplied by Bio-Med Devices, Inc. part number PRT5567.

WARNINGS

- When the ventilator is connected to a patient, qualified medical personnel should be present at all times, or within hearing range of the ventilator alarm system. Failure to be in close proximity to the ventilator can contribute to a patient death or serious injury.
- In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death. In transport / EMS situations, the alternative life supporting method would usually be a manual resuscitator bag. For longer periods of usage time, e.g. in case of ventilator failure in a hospital setting, another ventilator should be used to replace the original ventilator.
- Only qualified medical personnel should operate the TV-100.
- The operating instructions provided in this manual are not intended as recommended clinical protocols.
- Do not attempt to ventilate a patient until thoroughly familiar with the operating instructions.
- Always test the TV-100 prior to use. Ventilate a test lung to verify proper operation prior to connecting the TV-100 to a patient.
- If the TV-100 fails a checkout procedure discontinue use, Bio-Med Devices, Inc. technical support should be contacted, and the TV-100 should be serviced by a qualified technician.
- If a ventilator malfunction should occur, Bio-Med Devices, Inc. technical support should be contacted, the TV-100 should be removed from use and serviced prior to use on another patient.
- Only qualified, trained, service technicians should attempt repairs and service when necessary. Serious personal injury and/or equipment damage can result if repairs are performed by unqualified personnel.
- If a system error persists after cycling power remove the TV-100 from use and contact Bio-Med Devices, Inc. technical support.

- Do not connect the TV-100 to a patient or ventilate a patient if there is any connection made to the USB dock. Do not make any connection to the USB dock while ventilating a patient.
- If the TV-100 is connected to a PC via the USB dock, starting TV-100 Utility while the TV-100 is powered on will turn off TV-100 power.
- Whenever an alarm condition exists it should be rectified immediately. Do not allow ventilation for an extended length of time with an alarm condition.
- Alarm limits set by alarm auto set may need to be adjusted manually. Verify that clinically appropriate alarm limits are set prior to connecting the TV-100 to a patient.
- VTe and MVe alarm limits are not set in alarm auto set functionality. Verify that clinically appropriate VTe and MVe alarm limits are set prior to connecting the TV-100 to a patient.
- It is imperative to verify that clinically appropriate alarm limits are fully operational following connection of the ventilator to a patient.
- The patient should not be left unattended after the alarm silence key is pressed as this will be followed by a period when the audible alarms are deactivated.
- The alarm port on the TV-100 should never be obstructed.
- In the event of an AC power failure, the TV-100 will automatically switch to battery operation and sound an alarm. The audible alarm may be silenced by pressing the alarm silence button, which will be flashing. On fully charged batteries, there will be approximately 7 hours of battery powered operation. No further lost external power alarm will sound until the low battery alarm. The low battery alarm may be temporarily silenced by pressing the alarm silence button. It is imperative to restore external power at this time to assure continued safe operation of the ventilator.
- Rapid blinking of the battery charge indicator LED indicates a problem charging; Bio-Med Devices, Inc. technical support should be contacted.
- It is extremely important that the pressure trigger control be carefully adjusted to assure proper operation in the SIMV and CPAP modes.
- In CPAP mode manual breaths will be delivered according to the set value of the backup breath. It is important that the backup ventilation parameters be carefully adjusted to assure proper operation of the manual breath feature.
- Under certain conditions in SIMV, with PEEP, even though the low peak pressure alarm is set correctly for assisted breaths there may be no low peak pressure alarm following a patient disconnect until the next delivered assisted breath. This period can be up to one minute. As an added precaution, set the low PEEP/CPAP and low exhaled tidal volume alarms so that they are appropriately operative.
- Always be certain that the maximum pressure limit is set correctly and is operative even when volume limiting to prevent possible inadvertent administration of high pressure. Increased pressure can be caused by blockage, changes in patient compliance or resistance, or system malfunction.
- In standby mode if the control pressure is set to a value greater than the peak pressure high alarm limit, then the TV-100 will set the high alarm limit 1 cmH_2O above the control pressure value.
- If the pressure at the patient connector exceeds the peak pressure high alarm limit, then the TV-100 will initiate pressure cycle to the set PEEP.

- Operation of the TV-100 in a contaminated environment can be hazardous to the patient.
- A patient filter should always be used in the patient breathing circuit to prevent cross contamination.
- Do not re-use disposable breathing circuits. Re-use of disposable (single-use) breathing circuits can result in contamination (patient infection) or circuit degradation (circuit can fall apart, develop holes, or exhibit polymer decay).
- Extreme care should be taken to assure that the patient circuit components are connected correctly. Improper connection can cause ventilator malfunction.
- The exhaled volume of the patient can differ from the measured exhaled volume due to leaks around the mask, or any other leaks in the breathing circuit.
- If CO_2 monitoring equipment is used with the ventilator for the measurement of expiratory carbon dioxide concentration, e.g., in the expiratory limb or at the patient connection port, it should be used in accordance with the standard BS EN ISO 80601-2-55 before being put into service.
- Do not apply tension to the flow sensor tubing. The flow sensor should not be in the patient circuit when not connected to the ventilator.
- Do not operate the TV-100 without batteries since it will fail to operate if the external power supply is disconnected.
- The TV-100 battery will require increased time to charge if the battery is depleted to less than 1% of charge capacity.
- The battery will not charge above 54 degrees Celsius (131 degrees Fahrenheit).
- Extended exposure to temperatures above 45 degrees Celsius can degrade battery performance and life.
- Breathing through the negative pressure relief valve requires greatly increased work of breathing and only air is provided. A situation in which the patient is breathing through this valve should be rectified immediately in order to prevent possible adverse effects to the patient.
- The TV-100 shall not be covered or positioned in such a way that the operation or performance of the TV-100 is adversely affected. Do not position the TV-100 in such a way that there is a risk of overheating. Do not block the gas intake port or emergency intake port.
- If the gas supply fails or there is a total electrical power failure, the patient may breathe atmospheric gas through the emergency intake port. This is, however, only a temporary emergency measure, which requires elevated inspiratory effort and it should be corrected immediately.
- Adding attachments or other components or sub assemblies to the ventilator breathing system can change the pressure gradient across the ventilator breathing system, and such changes to the ventilator breathing system can adversely affect the ventilator performance.
- 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.
- Nebulization or humidification can increase the resistance of breathing system filters, and the operator needs to monitor the breathing system filter frequently for increased resistance and blockage.

- When using nebulization or humidification, breathing system filters and heat-and-moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.
- The accuracy of the ventilator can be affected by the gas added by use of a nebulizer.
- The TV-100 should be used while it is in an upright position.
- Do not continue to use a ventilator which has been seriously impacted or abused.
- To avoid risk of electrical shock when using the TV-100 with AC power connected, this equipment must only be connected to a supply mains with protective earth.
- Because this is a CE marked device, the TV-100 must never be modified without prior expressed written consent from Bio-Med Devices, Inc.
- If using this ventilator in conjunction with a humidifier, a temperature monitor with alarm must be used if such a monitor is not a part of the base humidifier unit.
- Outside of the recommended pressure range for oxygen input of 40-90 PSI, the delivered oxygen concentration to the patient cannot be guaranteed to remain in specification, in which case an output delivered-oxygen limit alarm would sound. However, the dedicated alarm for low oxygen input pressure does not activate until the input pressure falls to 29 PSI, to forestall recurring nuisance alarms when hospital oxygen supplies are overtaxed facility-wide (e.g., in pandemic situations). Thus when the input pressure falls outside the range 29-90 PSI, the TV-100 will display an O_2 Pressure Inlet Out of Range alarm condition. The alarm condition should be corrected as quickly as possible.
- For units with the low pressure oxygen concentrator available as the oxygen source (not available in all regions), the required input pressure range includes 1-32 PSI. When the pressure falls outside that range, the TV-100 will display an O_2 Pressure Inlet Out of Range alarm condition. The alarm condition should be corrected as quickly as possible.
- This device is MR unsafe and not to be used in an MRI environment.
- Do not use in a hyperbaric chamber. Such use might impair ventilator function, possibly causing patient death or serious injury.
- The ventilator shall not be used with inlet gases, which are not specified for use (e.g. helium or mixtures with helium). Such use might cause the ventilator to not function correctly, leading to the risk of patient death or serious deterioration of health.
- The initial charge of the TV-100 battery will be 30% or less of the rated capacity in accordance with IATA transport safety guidelines. The battery should be charged fully prior to operating the TV-100 ventilator.
- Volume-limited ventilators should not be used on unattended patients.
- Avoid exposure to known sources of EMI (electromagnetic interference) with medical devices such as magnetic resonance imaging MRI systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors. Note that the presence of RFID devices may not be obvious.
- If the ventilator is dropped, it should be examined by qualified personnel for both external and internal damage. A complete checkout should be performed before returning the ventilator to service.

- It is the responsibility of the responsible user organization to ensure that the oxygen source is compatible with the *rated* range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use, as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.
- Do not use this ventilator in explosive environments. Such use might cause an explosion.
- Do not attempt to service or perform maintenance (except swapping a single battery) while the ventilator is in use.

CAUTIONS

- Only replace the battery pack with Bio-Med Devices, Inc. part number PRT5567. Do not substitute.
- The battery pack thermal fuse goes open circuit and non-resettable (rendering the battery non-functional) if the cell case temperature reaches 93 degrees Celsius (200 degrees Fahrenheit).
- When using an AC power source, only the power supply provided with the TV-100 is approved for use with this ventilator. Any other power supply may cause damage and/or unreliable operation.
- Any more comprehensive DC power supply than that which is supplied must be short circuit protected and must comply with all of the specifications as listed in Chapter 7: Specifications.
- When it is necessary to operate the TV-100 from an AC inverter, only inverters in compliance with NEMA standards should be used.
- Touchscreen control buttons should be pressed by hand only. Care should be taken not to allow buttons to be contacted by sharp objects, as damage may result.
- Do not place liquids on or near the TV-100. Liquid entering the unit can cause severe damage and malfunction.
- Do not position the equipment in such a way as to make it difficult to operate the disconnect device (applies to either end of power cord: the wall plug or the connector to the AC adapter).
- Antistatic or electrically conductive hoses or tubing should not be used with the TV-100.
- Under no circumstances should the TV-100 unit be gas sterilized, steam autoclaved, or submerged in liquid. The components of the unit are incompatible with these sterilization methods and severe damage can result.
- Moisture or dirt can affect the operation of the TV-100. Any input oxygen supply source must always be clean and dry; the oxygen should be “medical oxygen” per FDA terminology, that is, at least 99.0% pure. The oxygen also must contain < 37.5 milligrams of water per cubic meter of gas (mg/m^3) or < 50 ppm H_2O.
- When using a low pressure oxygen source option, the maximum attainable FiO_2 will be limited by the oxygen flow limits, the oxygen purity, and the MV_E.
- When utilizing an oxygen concentrator, the oxygen concentration may not be constant due to limitations in flow, pressure, purity and concentration of the supplied oxygen. The inspired oxygen concentration will vary, depending on the pressures, volumes, flows and circuit leak.
- Portable and mobile RF communications equipment can affect medical electronic equipment.

NOTICES

- In nCPAP/HFNC or HFNC mode on, pressure trigger and pressure support are inoperative. Additionally, peak pressure and PEEP read continuous pressure during CPAP mode.
- The maximum pressure should always be set higher than PEEP in order to achieve the PEEP setting.
- It is recommended that an external filter be used at all times in order to provide greater protection to the internal components of the TV-100.
- If a patient filter is not used there is a possibility of contamination with bodily fluids or expired gases during normal or single fault condition to the following components in the gas pathway: pressure relief valve assembly, oxygen sensor, mass flow sensor, main proportional valve, compressor assembly, and input manifold.
- If the ventilator is contaminated internally due to use without a patient filter, do not attempt to clean the internal components of the device. Instead, return the ventilator to the factory for evaluation.
- When using a patient filter connect it directly to the patient connector then connect the patient circuit.
- Due to the fact that O_2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed periodically (once a month) in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.
- The batteries should be replaced at least every 2 years. Only use batteries supplied by Bio-Med Devices, Inc., part number PRT5567.
- The TV-100 is capable of approximately 7 hours of operation with fully charged batteries under typical patient parameters.
- When running with two batteries installed, approximately 20 minutes of operation will remain after the second low battery alarm (charge below 10%) assuming properly maintained batteries in good condition.
- Prior to disposal of any component, with particular attention to the batteries and PCB, check with your local controlling authority for disposal regulations.
- Only you may make a claim against the carrier for damage occurring in shipment. Notify the carrier if any damage is observed.
- Non Bio-Med Devices, Inc. brand circuit compliance data is unknown, and volume compensation will be unavailable until the circuit compliance is measured.
- The TV-100 is equipped with automatic barometric pressure compensation for measured exhaled tidal volume.
- TV-100 components in contact with respiratory gases are shipped from the manufacturer clean, but not sterilized.
- Some portion of any oxygen supplied to the oxygen high pressure gas inlet is used as “fresh gas” (i.e. patient gas, gas supplied to the ventilator breathing system) if the delivered oxygen percentage is set above 21%.

- The possibility of hazards arising from errors in the software program is minimized via the use of the standards EN 62304 & ISO 14971 in design control.
- Negative pressure (subatmospheric) is not available with this ventilator during the expiratory phase.
- Any serious adverse incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the EU Member State (i.e., country) in which the user and/or patient is established.
- This ventilator can be used with closed suctioning.

NOTES ON USE IN EMS ENVIRONMENT

- Exposure to sunlight should not have any appreciable effect on the ventilator.
- When using the ventilator for extended periods of time in a high dust environment the external filter should be changed more frequently.

VIII. Contact Information

Authorized Representative in the European Community

Bio-Med Devices' Official Agent in Europe is:

Medicare Uitgeest BV
Westerwerf 10
1911JA Uitgeest
The Netherlands
NL

Telephone: +31 251 316358

Service

If service is required in the USA, the TV-100 must be properly packed and shipped pre-paid, directly or through your dealer, to the address below.

Bio-Med Devices, Inc.
61 Soundview Road
Guilford, CT 06437
USA
Toll Free Telephone: 800-224-6633

If service is required internationally, contact your local distributor for further instruction.

WARNING: Only qualified, trained, service technicians should attempt repairs and service when necessary. Serious personal injury and/or equipment damage can result if repairs are performed by unqualified personnel.

IX. Recommended Maintenance Schedule

Periodic preventative maintenance should be performed to insure continued proper operation of the TV-100 Ventilator. The frequency of preventative maintenance is determined by many factors, some of which are:

- Frequency & length of use
- Quality of compressed gas source(s)
- Environmental conditions

Timeline

The following is a list of routine maintenance procedures and maintenance schedule:

Interval	Recommended Procedures
Prior to each use	Check battery condition
Periodic	Performance check
Annual	Verify calibration **Recommend return to factory for this service**
Every 2 years	Major overhaul, cleaning and calibration Battery Replacement[1] **Recommend return to factory for this service**

1. Replace only with batteries supplied by Bio-Med Devices, Inc. P/N PRT5567. Do not substitute.

Chapter 1: Installation

1.1 Unpacking

Perform the following procedure after receiving the TV-100 shipping container:

1. Inspect the shipping container for any damage that may have occurred during shipment. Notify the carrier if any damage to the shipping container is observed.

NOTICE: Only you may make a claim against the carrier for damage occurring in shipment. Notify the carrier if any damage is observed.

2. Open the shipping container. Carefully remove the TV-100 ventilator and all accessories from the shipping container. Visually inspect the ventilator and accessories for any damage that may have occurred during shipping. Notify the carrier if any damage to the product is observed.

1.2 Accessories

The following is a list of basic accessories which can be used in conjunction with the TV-100 ventilator. Based on the options ordered, some of these will be included in the TV-100 shipping carton. Optional TV-100 accessories may be found on our website at www.biomeddevices.com, or by contacting Bio-Med Devices, Inc. customer support.

BMD Catalogue Number	Description
20011	Disposable Infant Breathing Circuit
80018	Disposable Adult Breathing Circuit
4409C	Disposable Infant Flow Sensor
4410	Disposable Pediatric/Adult Flow Sensor
1020	Adult Test Lung
1021	Infant Test Lung
4401	Disposable Patient Filter
1010	Oxygen High Pressure Supply Hose
5502	TV-100 Power Supply (with Power Cord)
5504	Unterminated Power Cord (Optional Accessory)
5501	TV-100 Operator's Manual
5508	Accessory Kit for TV-100

1.3 Cleaning and Sterilization

The TV-100 ventilator should be thoroughly cleaned and inspected following each patient use. Wipe the entire exterior of the unit using fresh Super Sani-Cloth germicidal disposable wipes, or equivalent. Thoroughly wet the surfaces of the unit. Use additional wipes as needed to ensure a continuous 3 minute contact time. During cleaning, power should be turned off and the plug-in power supply should be disconnected. Care should be taken not to allow cleaning agents to enter the unit as this could cause damage and subsequent malfunction.

CAUTION: Under no circumstances should the TV-100 unit be gas sterilized, steam autoclaved, or submerged in liquid. The components of the unit are incompatible with these sterilization methods and severe damage can result.

NOTICE: If the ventilator is contaminated internally due to use without a patient filter, do not attempt to clean the internal components of the device. Instead, return the ventilator to the factory for evaluation.

1.3.1 LCD Touchscreen Keypad

The touchscreen of the TV-100 is made of transparent plastic and may be damaged by chemical solvents and abrasive cleaners. Great care should be taken not to touch it with sharp objects, since it may be punctured, which could damage the touchscreen.

1.3.2 Patient Circuit

The complete patient circuit supplied with the TV-100 is disposable and intended for single use. The TV-100 may be used with Bio-Med Devices, Inc. reusable breathing circuits. Reusable breathing circuits may be found on our website at www.biomeddevices.com, or by contacting customer support.

WARNING: Do not re-use disposable breathing circuits. Re-use of disposable (single-use) breathing circuits can result in contamination (patient infection) or circuit degradation (circuit can fall apart, develop holes, or exhibit polymer decay).

1.4 Batteries

1.4.1 Battery Overview

Two rechargeable smart lithium ion batteries are supplied with the TV-100. Each battery has a typical voltage of 14.4 V and a typical capacity of 6600 mAh. Given normal storage and usage, the battery will deliver approximately 80 percent of its initial charge capacity after 300 charge/discharge cycles. Battery charge time is typically 3.5 to 4 hours. TV-100 batteries should be stored in a low humidity environment, free from corrosive gas, at a temperature variance of less than 21°C.

A small LCD on the battery displays the battery charge capacity. Each bar of the LCD represents 20% of the full charge capacity. The LCD displays 1 bar from 1%-20% charge capacity; 2 bars from 21%-40% charge capacity; 3 bars from 41%-60% charge capacity; 4 bars from 61%-80% charge capacity; and 5 bars from 81%-100% charge capacity. If the charge capacity of the battery falls below 1% then the LCD displays no bars.

Run the following test in order to determine the operating time of the batteries when they are nearing depletion. Set up the TV-100 with the patient circuit connected to a test lung. Run the TV-100 under typical patient parameters, without external power, until the second low battery alarm actuates (battery charge capacity below 10%). Note the time of this alarm. Continue running the TV-100 until the unit loses power. Note the time of the loss of power. The time elapsed from the first low battery alarm until the loss of power averaged 1 hour 43 minutes with properly maintained batteries in good condition. The time elapsed from the second low battery alarm until the loss of power should be approximately 20 minutes with properly maintained batteries in good condition.

TV-100 batteries run in parallel. This allows the user to swap out one of the batteries and still safely operate the TV-100 on battery power when the TV-100 is not connected to external power.

The battery compartment is located on the left side of the TV-100. The battery door opens towards the back of the unit by turning the locking mechanism counter clockwise (CCW).

The minimum operating time of the TV-100 on battery power is greater than 7 hours. The typical operating time is 8 hours 6 minutes. The minimum measured operating time on battery power was 7 hours 32 minutes, and the maximum measured operating time was 8 hours 43 minutes.

The operating conditions of the TV-100 used to measure these times are listed below:

- Patient type: Adult
- Mode: Volume-AC
- Tidal Volume: 700 mL
- Rate: 12 BPM
- Inspiratory Time: 1.5 seconds

NOTICE: The battery should be replaced at least every two years. Only use batteries supplied by Bio-Med Devices, Inc. P/N PRT5567. Do not substitute.

WARNING: The TV-100 battery will require increased time to charge if the battery is depleted to less than 1% of charge capacity.

WARNING: Never operate the TV-100 without batteries since it will fail to operate if the external power supply is disconnected.

WARNING: Extended exposure to temperatures above 45 degrees Celsius can degrade battery performance and life.

WARNING: The initial charge of the TV-100 battery will be 30% or less of the rated capacity in accordance with IATA transport safety guidelines. The battery should be charged fully prior to operating the TV-100 ventilator.

WARNING: If power supply loss and battery depletion causes ventilation to stop during patient use, an alternative means of ventilation must be used. In transport / EMS situations, the alternative life-supporting method would usually be a manual resuscitator bag. For longer periods of usage time, e.g. in case of ventilator failure in a hospital setting, another ventilator should be used to replace the original ventilator.

1.4.2 Battery Installation and Initial Charge

Perform the following procedure to install and charge the TV-100 batteries:

1. Push the battery retainer tab to the left/right and hold the retainer in place. The tab will obstruct the compartment into which you will not be installing the battery (See Figure 1.1 below).
2. Insert the battery into the battery compartment. The battery is keyed and the alignment notch on the battery must be properly aligned before insertion. Release the battery retainer tab (See Figure 1.1 below).
3. Repeat the above steps to install second battery.
4. Place the TV-100 within reach of a power outlet. Lock the AC adapter into AC adapter mount on the TV-100.
5. Plug the AC adapter into the TV-100 external power connector. The plug is keyed and the alignment notch on both connectors must be aligned before engaging (See Figure 1.2 below). Rotate the collar on the plug clockwise to lock the AC adapter plug in place.
6. Plug the power cord into the AC adapter then plug power cord into the power outlet.
7. Once plugged in the battery charge indicator will begin to blink slowly, indicating the TV-100 is charging. Charge the unit until the battery charge indicator stops blinking and remains solidly lit. This indicates the batteries are fully charged.

WARNING: Rapid blinking of the battery charge indicator LED indicates a problem charging; Bio-Med Devices, Inc. technical support should be contacted.

WARNING: The initial charge of the TV-100 battery will be 30% or less of the rated capacity in accordance with IATA transport safety guidelines. The battery should be charged fully prior to operating the TV-100 ventilator.

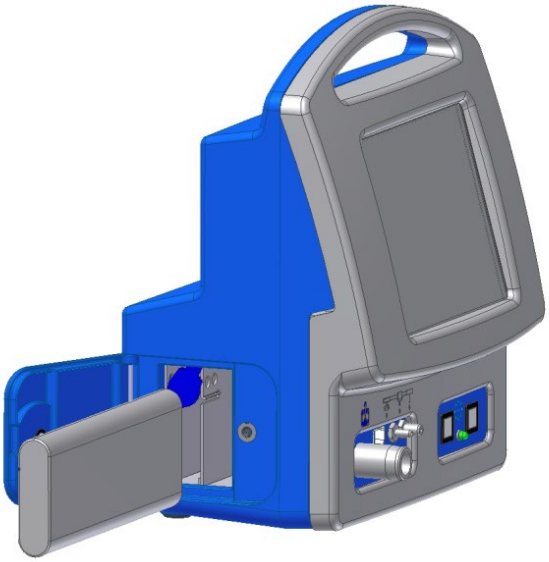


Figure 1.1: Battery Installation

Figure 1.2: External Power Connector

1.5 Patient Circuit Connection

The patient circuit is made up of external components that route gas from the TV-100 to the patient. The breathing circuit will differ depending on the patient. Bio-Med Devices, Inc. adult disposable breathing circuit (BMD P/N 80011) is illustrated below.

WARNING: A patient filter should always be used in the patient circuit to prevent cross contamination. Do not re-use disposable breathing circuits.

NOTICE: When using a patient filter connect it directly to the patient connector then connect the patient circuit.

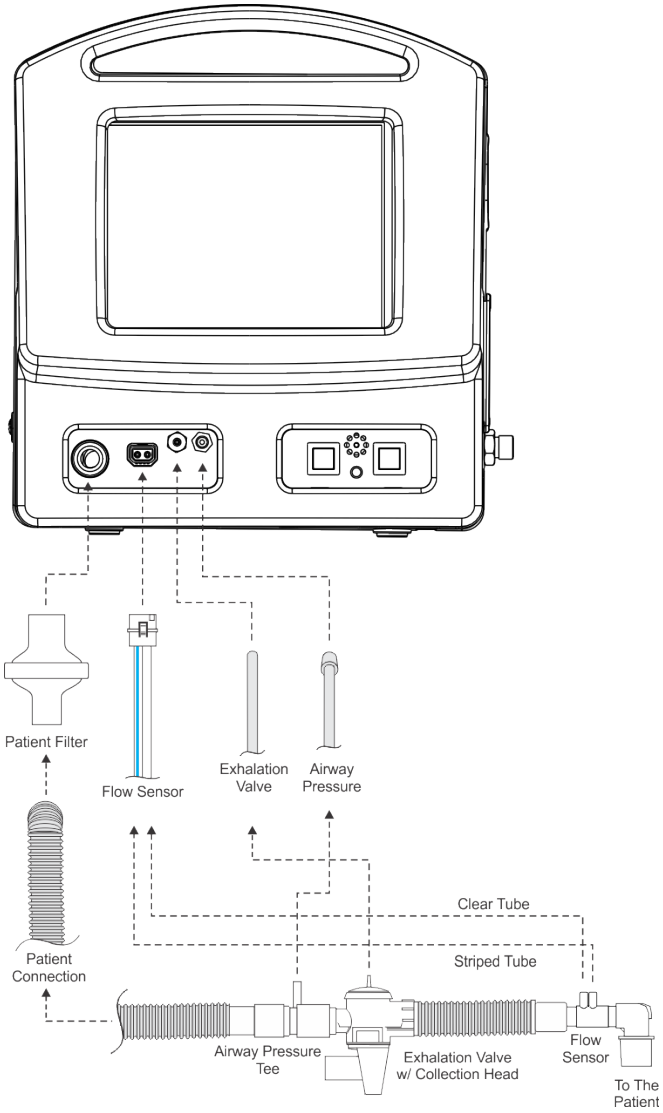


Figure 1.3: Patient Circuit Setup

1.6 USB Dock / Software Update Connection

The USB interface is to be used only by a qualified service technician. For more information on the USB dock / software update connection refer to the TV-100 service manual.

WARNING: Do not connect the TV-100 to a patient or ventilate a patient if there is any connection made to the USB dock. Do not make any connection to the USB dock while ventilating a patient.

WARNING: If the TV-100 is connected to a PC via the USB dock, starting TV-100 Utility while the TV-100 is powered on will turn off TV-100 power.

1.7 Training Recommendations

Upon receipt of the TV-100 ventilator, the qualified medical professional should at a minimum read this manual in its entirety, and follow their own facility's training guidelines for new equipment. Bio-Med Devices also recommends further video training, available at www.biomeddevices.com. Training should be refreshed annually at a minimum, if the medical professional is not a regular user of the TV-100 ventilator.

Chapter 2: Principles of Operation

2.1 General Overview

This section details the operational theory of the Bio-Med Devices, Inc. TV-100 ventilator. The TV-100 is designed to be a compact, lightweight, microprocessor controlled ventilator which allows for precise ventilatory control. The TV-100 is easy to mount in an ambulance or to a transport incubator, and it is easy to transport via its built in handle and mounting bracket. The TV-100 features an internal compressor which allows the TV-100 to operate without the need for external pressurized air supply; however an external oxygen supply may be connected to blend with the air from the internal compressor. To further simplify use there are minimal ventilation controls. The TV-100 user interface (UI) is a touchscreen color LCD with full VGA resolution.

At power on, the TV-100 will perform a power on self-test. The power on self-test checks all microprocessors, all pressure and flow sensors, all valves, and memory. If the power on self-test fails the TV-100 will display a warning popup with alarm message.

The TV-100 utilizes various filtering and smoothing techniques. The TV-100 has an airway pressure sensor, an atmospheric pressure sensor, an oxygen pressure sensor, two differential pressure sensors for flow sensor flow, a mass flow sensor, and an oxygen sensor. All TV-100 sensors are read every 5 milliseconds.

Airway pressure sensor readings are processed through an algorithm that removes noise spikes of less than 5 milliseconds duration by replacing the spike sample with the average of the samples before and after it. The airway pressure reading is then further processed using an exponentially-weighted, moving-average filter. The filtered readings are then used to calculate all the patient pressure-related parameters such as Airway Pressure, Peak Pressure, Peak Inspiratory Pressure, Mean Pressure, IPAP, PEEP, CPAP, and EPAP. The displayed Airway Pressure waveform is updated every 50 milliseconds. Peak Inspiratory Pressure is the highest Airway Pressure value during inspiration. Peak Pressure is the highest Airway Pressure value during a breath. Mean pressure is the average Airway Pressure during a breath. The measured PEEP/CPAP/EPAP value is the average of the last 8 Airway Pressure values for adult and pediatric patients, and the average of the last 4 Airway Pressure values for neonatal patients.

Oxygen inlet pressure and atmospheric pressure sensor readings are processed using an exponentially-weighted, moving-average filter with the same time constants as the airway pressure filter.

Pneumotach flow sensor readings are first converted from a differential pressure reading to a flow value. The flow value is corrected for oxygen percentage and actual temperature and pressure. The corrected flow value is processed through an algorithm that removes noise spikes of less than 5 milliseconds duration by replacing the spike sample with the average of the samples before and after it. The corrected flow value is then further processed using an exponentially-weighted, moving-average filter with the same time constants as the airway pressure filter.

Any parameters which are dependent on a flow sensor are unavailable unless a flow sensor is present in the patient circuit.

To detect a Flow Trigger, the last three flow sensor values are compared to a running average of the expiratory flow sensor.

The Mass Flow Sensor readings are corrected for oxygen percentage and actual temperature and pressure. No filtering is performed on the mass flow value.

The oxygen sensor reading is processed using an exponentially-weighted, moving-average filter. During ventilation, the displayed oxygen percentage value is averaged over one breath period. The Oxygen Calibration procedure waits for the measured oxygen percentage to be stable for 30 seconds before recording the calibration value.

The circuit resistance test uses 5 second averages of the airway pressure and mass flow values to calculate the circuit resistance.

Rate is averaged over five breaths. If rate changes more than 50 percent then the rate begins to recalculate with the current breath. The next breath will be the average of the previous two breaths.

Exhaled minute volume uses a running average of the last five breaths.

The TV-100 will provide leak compensation for PEEP/CPAP/EPAP in all modes and attempt to achieve the set operating point in pressure targeted modes. During exhalation, PEEP/CPAP/EPAP is maintained by controlling the Main Proportional Valve and the exhalation valve. When the measured PEEP/CPAP/EPAP drops below its set point, the Main Proportional Valve and exhalation valve adjust to maintain the set parameters. During inspiration in Pressure-AC, PRVC-AC, and NIV modes, the compressor motor speed will increase to supply additional flow, as needed, to maintain the set Pressure Control or IPAP value. During inspiration in Volume-AC mode, the compressor motor speed will increase to maintain the set Tidal Volume. In this way, the flow increases to compensate for the leak. The flow compensation can maintain the set pressure for various leaks depending on the set targets and the leak magnitude, up to leaks of 100 liters per minute. The amount of inspiratory flow can be set when using nCPAP/HFNC in neonates and HFNC in pediatric and adults. This allows the use of various high flow therapy devices.

2.2 Phases of Breath

2.2.1 Inspiration

Inspiration is the phase of a breath where air is flowing into the patient's lungs. The TV-100 supplies this flow during normal ventilator operation. The flow waveform depends on the breath type and the control method (i.e., volume control, pressure control). Flow and pressure cycling causes the end of inspiration and initiates the expiration phase of a breath. In the event of a ventilator malfunction that stops flow to the patient, the TV-100 provides a vacuum relief valve to permit the patient to inhale atmospheric air.

2.2.2 Expiration

Expiration is the phase of a breath where air is flowing out of the patient's lungs. During normal ventilator operation, expiration is directed to atmosphere through an expiration valve in the patient

circuit. Flow and pressure triggering causes the end of expiration and initiates the inspiration phase of a breath. In the event of a ventilator malfunction which stops active cycling of the expiration valve, the valve will default to the open position to permit the patient to exhale.

2.3 Breath Types

2.3.1 Assisted Breath

An assisted breath is initiated by the patient and controlled by the TV-100. The inspiratory phase of an assisted breath is either volume or pressure controlled. During the expiratory phase, the TV-100 permits the patient to exhale freely until the set baseline pressure level is reached. Expiration lasts until the patient triggers another breath, or the TV-100 triggers a breath according to the set rate.

2.3.2 Mandatory Breath

A mandatory breath is initiated and controlled by the TV-100. The inspiratory phase of a mandatory breath is either volume or pressure controlled. During the expiratory phase, the TV-100 permits the patient to exhale freely until the set baseline pressure level is reached. Expiration lasts until the patient triggers another breath, or the TV-100 triggers a breath according to the set rate.

2.3.3 Manual Breath

A manual breath is initiated by the clinician and controlled by the TV-100. The inspiratory phase of a manual breath is either volume or pressure controlled. During the expiratory phase, the TV-100 permits the patient to exhale freely until the set baseline pressure level is reached. Expiration lasts until the patient triggers another breath, or the TV-100 triggers a breath according to the set rate. To prevent breath stacking, the Manual Breath button is only available during the expiratory phase, and only after the minimum expiratory time has elapsed.

2.3.4 Sigh Breath

Sigh breath is available for adult and pediatric TV-100 patient types. A sigh breath can be either an assisted or a mandatory breath. When using volume control, a sigh breath will deliver 30 percent more volume than the previously delivered breath. The inspiratory phase of the sigh breath is limited to 3 seconds, limited to the peak airway pressure high alarm limit, and limited to the maximum allowable volume for the set patient type. These limits may result in the TV-100 delivering a sigh breath with less than a 30 percent increase in volume. When using pressure control, a sigh breath will deliver an additional 10 cmH_2O pressure above the peak pressure of the previous breath. The TV-100 will limit this pressure to the high pressure alarm limit. Sigh breaths are delivered as follows: the first breath after sigh is activated will be a sigh breath. Subsequent sigh breaths will be delivered every fifty breaths (regardless of breath type) or every seven minutes, whichever comes first.

2.3.5 Spontaneous Breath

A spontaneous breath is initiated and controlled by the patient. The inspiratory phase of a spontaneous breath may be pressure supported; otherwise, the TV-100 supplies enough flow to maintain the baseline pressure level for the duration of the inspiratory phase. Inspiration is terminated by pressure if the pressure rises, signifying an expiratory maneuver by the patient, or when the flow has decreased below a set minimum rate when flow cycle is enabled. The maximum length of time for the Inspiratory phase of the spontaneous breath is equal to 2 times the SET inspiratory time or 3.0 seconds (if the inspiratory time is set to 1.5 seconds or longer). In the Peds/Adult CPAP Mode the maximum allowable inspiratory time is 3.0 seconds. During the expiratory phase, the TV-100 permits the patient to exhale freely above the set baseline pressure level. Expiration lasts until the patient triggers another breath, or the TV-100 triggers a breath according to the set rate.

2.4 Ventilation Controls

2.4.1 Volume Control

Volume control applies to TV-100 controlled breaths. In a volume controlled breath the TV-100 delivers the set tidal volume to the patient on each breath. If the clinician sets inspiratory time (I-Time), the TV-100 will calculate the peak flow required to deliver the set tidal volume in the set I-Time. Figure 2.1 below illustrates a TV-100 volume control waveform.

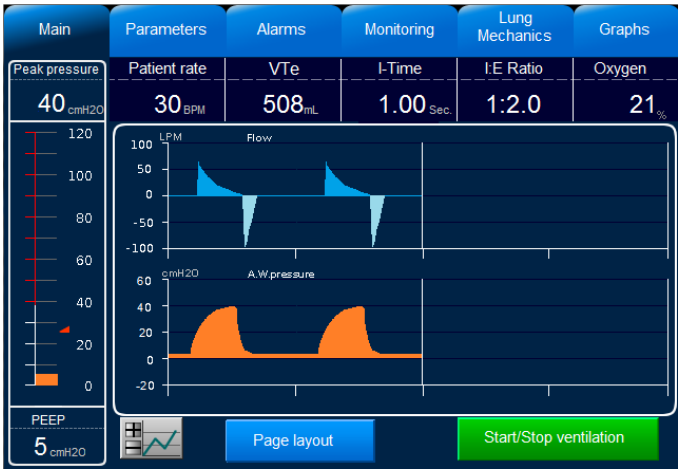


Figure 2.1: Volume Control Waveform

2.4.2 Pressure Control

Pressure control applies to TV-100 controlled breaths. In a pressure controlled breath the TV-100 delivers a decelerating flow to produce the set inspiratory rise time and establish the set pressure within the set I-Time. The TV-100 delivers flow as needed to maintain the set pressure for the duration of the inspiratory phase. The set pressure will be referenced to PEEP. Figure 2.2 below illustrates a TV-100 pressure control waveform, as well as patient triggered breaths.

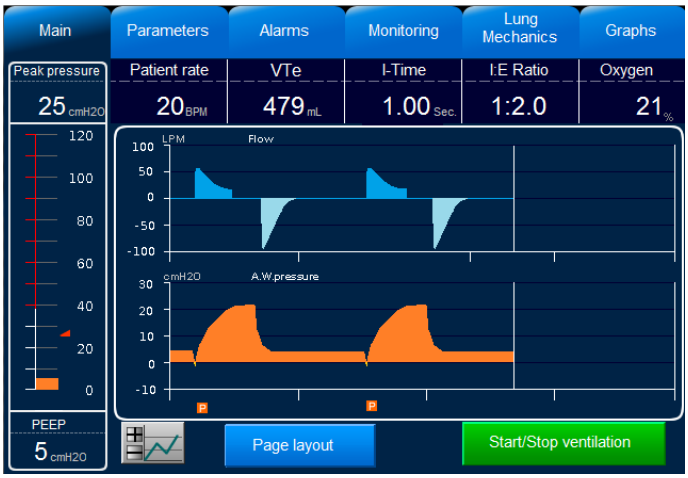


Figure 2.2: Pressure Control Waveform

2.4.2.1 Inspiratory Rise Time (I-Rise Time)

The TV-100 Pressure Control ventilation modes establish the ventilation target airway pressure and maintain that target pressure during the inspiratory phase. The speed at which the target airway pressure is attained, known as inspiratory rise time, or I-Rise time, is dependent on: the set pressure control; PEEP; compliance and resistance of the patient and the airway; and the flow rate delivered by the ventilator. The flow rate for particular pressure control and PEEP settings is adjustable using the I-Rise time setting on the Parameters screen of Pressure Control modes. The I-Rise time setting is a relative index and can be set from 1 to 9. The default value is 9 and corresponds to the lowest flow rate the ventilator would use for a particular Pressure Control setting, PEEP setting, and system resistance and compliance. It is important for the user to set the I-Rise properly because an overly high flow rate may result in peak inspiratory pressures exceeding the desired target for a small number of breaths upon initial ventilation.

2.4.2.1.1 Inspiratory Rise Time for Pediatric and Adult Patients

For pediatric and adult patient settings, I-Rise time controls the flow rate as follows. Upon initiating ventilation in a Pressure Control ventilation mode, the TV-100 delivers a test breath. Based on the results of the test breath, the TV-100 sets the compressor motor speed and valve settings to deliver a Pressure Control breath with a rise time approximating 33% of the set inspiratory time. The TV-100 has a fixed maximum compressor motor speed of approximately 32,000 rpm. If the default I-Rise time setting of 9 was used, the current compressor motor speed is measured as the baseline, and subtracted from

the maximum compressor motor speed. The difference is divided by 8, resulting in a compressor motor speed increment. This increment will be added to the baseline compressor motor speed each time the I-Rise time setting is decreased by 1. The faster motor speed results in a higher flow rate resulting in a faster I-Rise time. For example, in a hypothetical patient, the Pressure Control was set to 16 cmH_2O, PEEP to 4 cmH_2O, I-time to 1 second and rate to 15 bpm, and the I-Rise time was set to 9. Upon ventilation, the ventilator delivered a stable breath to the patient with a peak inspiratory pressure of 20 cmH_2O at a rate of 15 bpm and the I-rise time was measure at 0.33 seconds, i.e., it took 0.33 seconds from trigger to reach the Pressure Control setting of 16 cmH_2O on top of the PEEP of 5 cmH_2O. It was found that the motor speed was 10,000 rpm as the baseline in this particular case. Subtracting 10,000 rpm from the maximum motor speed of 32,000 rpm and dividing by 8 gives 2,750 rpm for every incremental change in the I-Rise time setting. In summary for this example, the TV-100 would operate as follows:

I-Rise Time Setting	Compressor Motor Speed, rpm
9	10,000
8	12,750
7	15,500
6	18,250
5	21,000
4	23,750
3	26,500
2	29,250
1	32,000

2.4.2.1.2 Inspiratory Rise Time for Neonate Patients

For neonate patient settings, the system limits the range of motor speeds to a span of 4,800 rpm. This prevents high flow rates to the neonate patient that might result in overpressure conditions in the initial breaths. Thus, for an example in which an I-Rise time of 9 resulted in a base compressor motor speed of 10,000 rpm as above, the maximum motor speed achieved with the I-Rise time set to 1 would be 14,800. Over the range of I-Rise time settings from 1 to 9. This example would result in the following compressor motor speeds:

I-Rise Time Setting	Compressor Motor Speed, rpm
9	10,000
8	10,600
7	11,200
6	11,800
5	12,400
4	13,000
3	13,600
2	14,200
1	14,800

2.4.3 Pressure Support

Pressure support applies only to spontaneous breaths. In a pressure supported breath the TV-100 delivers flow sufficient to produce the set inspiratory rise time and establish the set pressure support level above PEEP. The TV-100 then delivers flow in a decelerating pattern to maintain the set pressure support level for the duration of the inspiratory phase. Inspiration will be terminated when 2 times the set Inspiratory time has been reached or if the patient begins to exhale prior to the above criteria being met, pressure will rise above the pressure support level and the TV-100 will pressure cycle. If enabled, when the flow has decreased below the set flow control threshold the TV-100 will flow cycle.

2.5 Ventilation Modes

2.5.1 A/C Mode (Assist/Control)

Assist/Control mode provides controlled or assist controlled ventilation. If the patient triggers inspiration, the TV-100 senses the negative pressure or flow created by the inspiratory effort and initiates an assisted breath. If the patient fails to trigger inspiration, the TV-100 provides controlled breaths as determined by the clinician.

A/C mode allows the clinician to choose between volume or pressure control for the delivered assisted, mandatory, and manual breaths. The clinician will then be able to set rate, I-Time, PEEP level, and pressure and/or flow trigger sensitivities.

In this mode the clinician may initiate an expiratory hold to measure the patient's AutoPEEP level, and an inspiratory hold to measure the plateau pressure and static lung compliance of the patient. Inspiratory hold is only available in volume control modes. There is no apnea functionality in this mode, because the minimum rate ensures that an apneic period cannot occur.

2.5.2 CPAP Mode (Continuous Positive Airway Pressure)

CPAP mode is available to intubated pediatric and adult patient types. In CPAP mode the TV-100 delivers a minimum continuous pressure during ventilation as well as manual or spontaneous breaths.

When the TV-100 detects a patient's inspiratory effort, the ventilator will deliver flow to the patient for up to 3.0 seconds. The patient can terminate this flow any time prior to 3.0 seconds by a pressure cycle. If flow cycle is enabled, the breath can be cycled by a set flow cycle level. If a manual breath is given by pressing the manual breath button, flow will be delivered to the patient at whatever inspiratory time is set in any other mandatory ventilation mode. In the event a new patient was selected at startup, the pediatric and adult inspiratory times will be the default values of 0.75 seconds and 1.0 seconds respectively.

If pressure support is enabled, pressure support breaths will be triggered by the patient's inspiratory effort. Pressure support breaths are triggered by the flow sensor; or if there is no flow sensor present, via the airway pressure line. If the TV-100 determines the patient has not initiated a breath within the apnea delay time interval, the TV-100 will begin apnea ventilation and the apnea alarm will actuate.

CPAP mode allows the clinician to choose between volume or pressure control for the delivered manual breaths. The clinician will then be able to adjust the associated parameters for the selected breath type. The clinician is also able to set CPAP level and trigger sensitivities. In CPAP mode rate alarms are enabled and the rate is displayed.

In CPAP mode flow cycle is available. Delivered flow is based on the mass flow sensor measured values. The displayed flow is based on the flow sensor measurement; or if there is no flow sensor present, flow is not displayed.

WARNING: It is extremely important that the pressure trigger control be carefully adjusted to assure proper operation in the CPAP mode.

WARNING: Under certain conditions in CPAP mode, in particular with high flows and low CPAP pressures, if the low peak pressure alarm is set so that no false alarms occur, this alarm may be inoperative if a patient disconnect occurs. It is extremely important to have the low PEEP/CPAP and low exhaled tidal volume alarms set correctly.

WARNING: In CPAP mode manual breaths will be delivered according to the set value of the backup breath. It is important that the backup ventilation parameters be carefully adjusted to assure proper operation of the manual breath feature.

2.5.3 NIV Mode (Non-invasive Ventilation)

In NIV mode the TV-100 delivers manual, mandatory, or spontaneous breaths. NIV mode allows the clinician to set the IPAP/EPAP levels to be applied to spontaneous breaths. IPAP is referenced to zero, not to EPAP/PEEP. The clinician may also set trigger sensitivities by flow if a flow sensor is present in the patient circuit, or via airway pressure line. The clinician will be able to set rate, I-Time, IPAP, EPAP, trigger levels, and apnea delay time. The clinician can provide CPAP in NIV mode by setting the IPAP and EPAP values to the same level.

If the apnea delay interval is exceeded due to a rate set lower than the apnea delay time and there is no patient triggered breath during that time, then the TV-100 will detect apnea. The TV-100 will ventilate per the configured apnea backup settings and the apnea alarm will actuate. The apnea backup feature can be disabled by turning off backup rate.

Patient triggered breaths that occur at a rate greater than the rate set by the clinician will be spontaneous breaths at the set IPAP level, and the inspiratory time will proceed until the breath is pressure cycled, flow cycled (if enabled), or when 2 times the set Inspiratory Time has expired (whichever comes first). If the patient fails to trigger inspiration before the end of the expiration phase of any breath, the TV-100 will deliver a controlled breath for the duration of the set inspiratory time. If the rate is set to zero and apnea backup is disabled, then there is no defined expiratory phase and the TV-100 will not deliver a controlled breath. If a rate is set in NIV Mode, because you are expecting the patient to have a spontaneous respiratory effort, the rate should be set to a level lower than the actual patient's rate. The patient will have more control of the breath, from both a triggering aspect as well as when to terminate the breath.

NIV mode is available to all non-intubated TV-100 patient types. In NIV mode breaths should be delivered via a non-vented mask, or nasal prongs using a dual limb circuit. NIV mode works with Bio-Med Devices, Inc. standard dual limb circuits as well as with non-vented masks.

2.5.4 SIMV Mode (Synchronized Intermittent Mandatory Ventilation)

In SIMV mode the TV-100 delivers manual, mandatory, assisted, or spontaneous breaths. The assisted breath period represents the minimum time between assisted breaths, and will be determined by the set rate. The first patient triggered breath in SIMV mode will be an assisted breath. Patient triggered breaths that occur before the assisted breath period has elapsed will be spontaneous breaths. The first patient triggered breath that occurs after the assisted breath period has elapsed will be an assisted breath. If the patient fails to trigger the ventilator before the end of the expiration phase of any breath a mandatory breath will be delivered to the patient.

The clinician chooses between either volume control or pressure control for the mandatory, manual, and assisted breaths. The clinician adjusts the associated parameter(s) for the selected control method. The clinician is able to set the pressure support level to be applied to spontaneous breaths. The clinician is able to set rate, I-Time, PEEP level, and trigger sensitivities. The clinician is able to initiate an expiratory hold to measure the patient's AutoPEEP level. The clinician is able to initiate an inspiratory hold to measure the plateau pressure and static lung compliance of the patient. Apnea detection is required in SIMV mode.

When pressure support is enabled, the ventilator will deliver flow sufficient to produce the set inspiratory rise time and establish the set pressure support level above PEEP. When the airway pressure reaches the set pressure support level the exhalation valve will open.

Volume-SIMV and Pressure-SIMV both allow apnea detection by setting the Apnea delay time. The Backup tidal volume (Backup pressure control for Pressure-SIMV) and the Backup rate may be set. In

order for the apnea period to be detected and the backup ventilation to be engaged, the apnea delay time must be set to a level less than the resulting cycle time dictated by the set mandatory rate. For example, if the SIMV rate is 10 bpm, and the apnea delay time is less than 6 seconds, and no spontaneous breaths are detected within the apnea delay time, apnea will be detected since the ventilator will not deliver mandatory breaths sooner than the apnea delay time; conversely, if the SIMV rate is 10 bpm, and the apnea delay time is greater than 6 seconds, apnea will never be detected since the ventilator will deliver mandatory breaths sooner than the 6 second apnea delay time.

WARNING: It is extremely important that the pressure trigger control be carefully adjusted to assure proper operation in SIMV mode.

WARNING: Under certain conditions in SIMV, with PEEP, even though the low peak pressure alarm is set correctly for assisted breaths there may be no low peak pressure alarm following a patient disconnect until the next delivered assisted breath. This period can be up to one minute. As an added precaution, set the low PEEP/CPAP and low exhaled tidal volume alarms so that they are operative.

2.5.5 PRVC-AC Mode (Pressure Regulated Volume Control – Assist Control)

The TV-100 PRVC-AC ventilation mode delivers a set volume to the patient with a pressure controlled breath, a breath with a decelerating flow. In this mode, the ventilator responds to changes in the system compliance in a controlled fashion to safely ensure the target volume is achieved. Spontaneous breaths can be triggered by either pressure or flow triggers. Controlled breaths are triggered based on the set ventilation rate. If flow cycle is turned on, the TV-100 will cycle the breath based on a flow cycle threshold; otherwise, the TV-100 will cycle on the set I-time.

Upon the start of ventilation, the TV-100 will deliver a volume controlled test breath, approximating the target tidal volume, to determine the system compliance. Once an initial Pressure Control value is calculated based on the measurements obtained from the test breath, the TV-100 will begin to deliver pressure controlled breaths.

If the system compliance decreases during ventilation the TV-100 will increase the target pressure to continue to ensure delivery of the target volume. To do this in a safe manner, the pressure will not increase by more than 3 cmH_2O per breath (1 cmH_2O per breath for neonate patients). The pressure will continue to be increased until the target tidal volume is achieved. Similarly, if the system compliance increases, TV-100 will decrease the target pressure to continue to ensure delivery of the target volume. The TV-100 will alarm 5 cmH_2O below the peak pressure high alarm setting, and display a warning popup notifying the user: PRVC pressure limit reached. This popup will repeat every 30 seconds if the condition still persists. This will allow the user to make a decision on whether to raise the High Peak Pressure alarm limit, or decrease the target tidal volume. A High Peak Pressure alarm will occur when the High Peak Pressure limit is reached, and will also limit the pressure at that point.

2.5.6 nCPAP/HFNC (High Flow Nasal Cannula) Mode

nCPAP/HFNC Mode is a non-invasive mode available to neonatal patient types and pediatric/adult patient types. HFNC Mode is available for pediatric/adult patient types. The mode is displayed as nCPAP/HFNC for neonatal patient types, and is displayed as HFNC for pediatric/adult patient types. In neonatal patient types nCPAP/HFNC mode allows the clinician to choose and set either a flow (LPM) or a pressure (cmH_2O) to be delivered continuously to the patient.

> NOTE: When using the pressure variable in nCPAP/HFNC mode for neonatal patient type, a standard patient circuit with exhalation valve and pressure line should be used. When the Flow variable is selected in nCPAP/HFNC mode, only the patient tubing should be connected to the output on the vent. The exhalation valve should not be connected.

In pediatric/adult patient types, HFNC mode allows the clinician to choose and set only flow (LPM) to be delivered continuously to the patient. The clinician is then able to adjust the selected control variable. The clinician may also adjust the oxygen concentration in nCPAP/HFNC if an oxygen source is connected to the ventilator. There are no triggers and no cycles in nCPAP/HFNC. Pressure is limited to the set high peak pressure alarm limit, if active. When ventilating neonatal patients with nCPAP/HFNC ventilation mode, there are many possible configurations at the patient interface. Some inherently provide a leak allowing for constant flow, others do not. To ensure a proper delivery of the set oxygen level, the TV-100 will open the exhalation valve on the patient circuit every five seconds. This ensures the oxygen level will not increase substantially beyond the set point in cases when there is no flow due to the absence of any leak. To further ensure level concentrations of oxygen delivery, it is recommended that a leak adapter be added to the exhalation side of the patient circuit. The displayed flow is based on the internal mass flow sensor. In nCPAP/HFNC mode the Lung Mechanics Page and Graphs Page will be inaccessible.

nCPAP/HFNC mode allows the clinician to connect tubing via an adapter to supply a resuscitation bag, or to supply flow to a nasal cannula. For neonatal patient types, in order to connect the tubing the clinician should connect a 4.5mm endotracheal tube adapter to the patient output on the ventilator. The clinician can set the desired flow by choosing Flow in setup, then adjusting the set flow.

> NOTE: The particular cannula or tubing size may restrict the flow rate to a specific maximum level. A larger bore tubing may need to be connected to allow the flow desired.

The clinician may also set oxygen concentration if an oxygen source is connected to the ventilator. This allows the clinician to manually ventilate the patient prior to intubation.

2.5.7 Apnea Detection

The TV-100 provides the clinician with apnea detection functionality. Apnea detection functionality is turned on when the clinician selects a ventilation mode that requires apnea detection (e.g., SIMV, NIV, and CPAP). The apnea period is set on the Alarms page. The apnea rate and apnea control method are set on the Parameters page. If apnea detection is disabled then apnea parameters will be inaccessible by

the clinician. Apnea Backup can only be disabled in NIV Mode. There is no rate setting in CPAP Mode. In SIMV Modes the Set Rate and the Apnea delay setting may preclude backup ventilation from occurring. Regardless of apnea detection functionality being disabled rate may never be set to zero (rate can be turned off in NIV Mode). The apnea alarm will open a popup message that the clinician must acknowledge.

2.5.8 Standby Mode

In standby mode the TV-100 allows the clinician to set up ventilation controls prior to connecting the TV-100 to the patient. During standby mode, ventilation will not be performed and TV-100 parameters may be changed. In order to enable standby mode the clinician must select the Start/Stop Ventilation button. The clinician must acknowledge the decision to enter standby mode by selecting the Stop Ventilation button on the popup message.

In standby mode the TV-100 will save circuit and compensation information generated prior to, or while in, standby mode. In order to disable standby mode the clinician must select the Start/Stop Ventilation button. The clinician must acknowledge the decision to start ventilation by pressing the Start Ventilation button on the popup message.

2.6 Oxygen Delivery

2.6.1 Oxygen Controls

Oxygen controls are displayed on the Parameters Page. If the unit is enabled with the low pressure oxygen source (not available in all regions), the TV-100 will display two selections: “Oxygen” and “Oxygen Source”. If the unit is not enabled with the low pressure oxygen source (not available in all regions), there will be only one oxygen control labeled “Oxygen”.

2.6.2 Oxygen Source

If the unit is enabled with the low pressure oxygen source (not available in all regions), pressing the “Oxygen Source” button provides two selections: “High Pressure” and “Concentrator”.

2.6.2.1 High Pressure Oxygen Source

If the selected oxygen source is High Pressure, the connected oxygen source must be medical grade oxygen at a pressure of 29 to 90 PSI. Prior to initiating ventilation, the TV-100 measures the pressure at the oxygen input connector on the right side of the unit.

Outside of the recommended pressure range for oxygen input of 40-90 PSI, the delivered oxygen concentration to the patient cannot be guaranteed to remain in specification, in which case an output delivered-oxygen limit alarm would sound. However, the dedicated alarm for low oxygen input pressure does not activate until the input pressure falls to 29 PSI, to forestall recurring nuisance alarms when hospital oxygen supplies are overtaxed facility-wide (e.g., in pandemic situations). Thus when the input pressure falls outside the range 29-90 PSI, the TV-100 will display an O_2 Pressure Inlet Out of Range alarm condition. The alarm condition should be corrected as quickly as possible.

2.6.2.2 Oxygen Concentrator

If the selected oxygen source is Concentrator for units with the low pressure oxygen concentrator available (not available in all regions), the required input pressure range includes 1 to 32 PSI. When the pressure falls outside that range, the TV-100 will display an O_2 Pressure Inlet Out of Range alarm condition. Outside of this specified range, the delivered oxygen concentration cannot be guaranteed to remain in specification. The alarm condition should be corrected as quickly as possible.

CAUTION: When utilizing an oxygen concentrator, the oxygen concentration may not be constant due to limitations in flow, pressure, purity and concentration of the supplied oxygen. The inspired oxygen concentration will vary, depending on the pressures, volumes, flows and circuit leak.

Limitations in oxygen flow delivered by an oxygen concentrator may result in lower than expected delivered oxygen concentration. The maximum minute volume, MV_{EMax}, that can be delivered given a target $_{FiO2}$ can be calculated for a given 100% input oxygen flow as follows: $MV_{EMax}(\mathrm{L}) = \frac{\text{Input Oxygen Flow (LPM)}}{FiO_2}$ given the input oxygen flow is 100% oxygen. If the input oxygen flow is less than 100% oxygen, the MV_{EMax} must be reduced proportionately.

2.6.3 Oxygen

The Oxygen button is used to select the percentage of oxygen the unit will deliver. If the oxygen input pressure is not within the specified range, the Oxygen button will not be active, and will be displayed in gray.

To set the desired oxygen level, press the Oxygen button. A pop-up screen will appear with a green outline on the right side that displays the target oxygen value. Set the desired target oxygen value either by using the numeric keypad or the up or down arrows. Once the desired value is entered, press “OK”. The high and low alarm limits can also be set from this pop-up window by selecting the high alarm or low alarm with a touch. The active cell will be outlined in green when selected and the value can be set using the numeric keypad or the up and down arrows.

3.1 Physical Interface

3.1.1 Case Overview

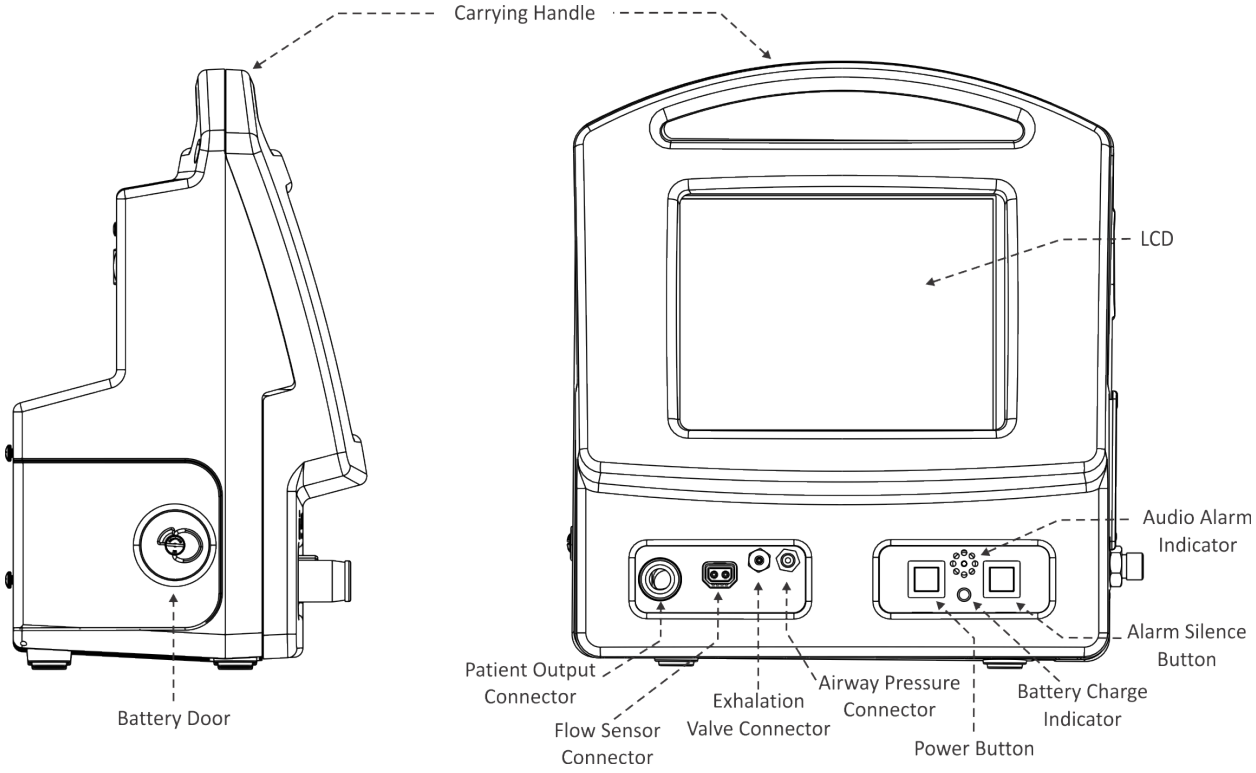


Figure 3.1: TV-100 Case Left & Front View

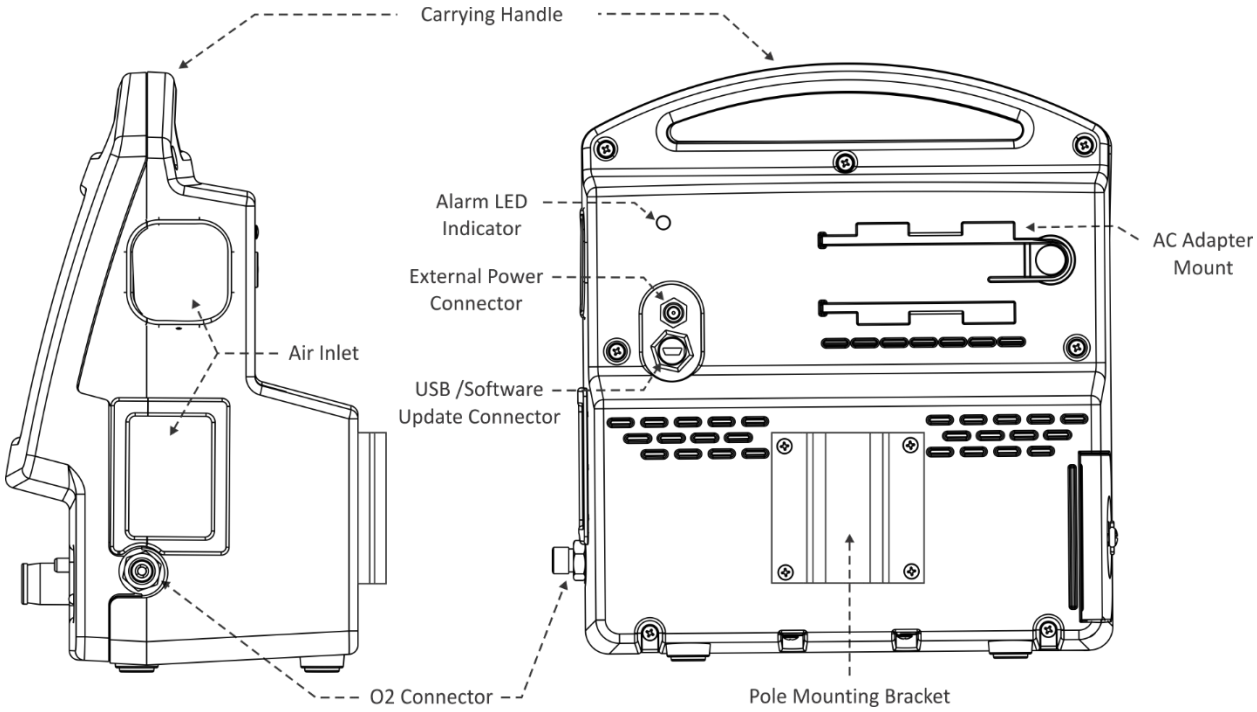


Figure 3.2: TV-100 Case Right & Back View

WARNING: The TV-100 shall not be covered or positioned in such a way that the operation or performance of the TV-100 is adversely affected. Do not position the TV-100 in such a way that there is a risk of overheating. Do not block the gas intake port or emergency intake port.

3.2 Graphical User Interface (GUI)

The TV-100 graphical user interface (GUI) is designed for simplicity of navigation and use. The TV-100 LCD touchscreen is 8.4" measured diagonally. The following sections will guide you through the various menus and features of the TV-100 GUI.

Pages are the interface through which you, the user, interact with the TV-100. Pages share a design similarity for ease of navigation. When a new page loads, the change is made clear to you by animating objects and modifying colors to create visual differentiation from previous pages.

The TV-100 uses a simple color code, so that you can tell from a glance what information is being displayed. The TV-100 displays teal colored numbers when the number is set by the user, white colored numbers when the number is measured by the TV-100, and orange colored numbers when the numbers are alarm values set by the user.

The TV-100 displays buttons as follows. Blue colored buttons will load new screens, green colored buttons indicate to the user that the button will cause a parameter to change and affect ventilation, yellow colored buttons indicate to the user that the button is used for cancellation or returning to a previous screen, and red colored buttons are used only for warning confirmations.

3.2.1 Startup

Figure 3.3: Splash Screen & Loading Pages

The splash page is the first page you will see. The splash page is black with the Bio-Med Devices, Inc. logo centered on the page. The loading page will display after the splash page.

The loading page is black with a blue progress bar centered at the bottom of the page. The progress bar represents the TV-100 processor communications and will fill as communications are successfully completed.

WARNING: If a system error persists after cycling power remove the TV-100 from use and contact Bio-Med Devices, Inc. technical support.

The system title page will load directly from the loading page. The system title page displays the device name, and the software version number centered in the page. The copyright message is displayed at the bottom of this page.

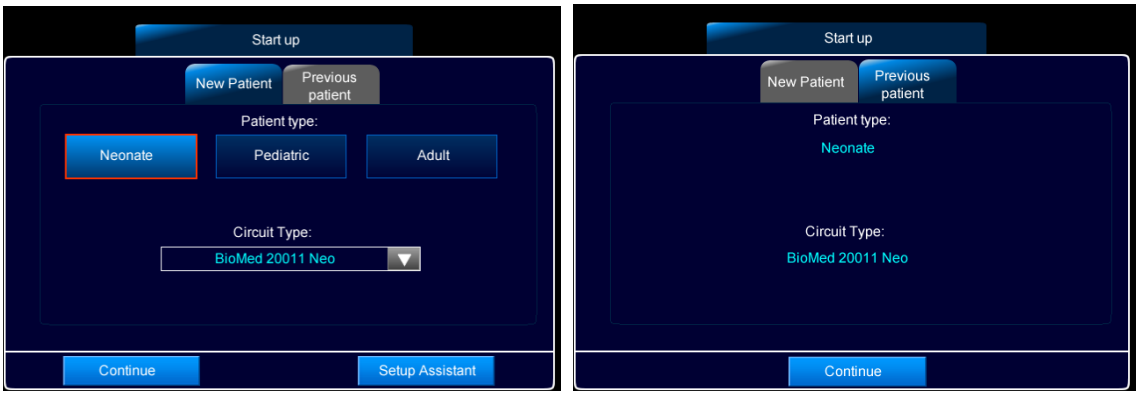


Figure 3.4: Startup Page

The startup page will load directly from the system title page and is comprised of two tabs. The startup page allows you to begin ventilation on a new patient, or to continue ventilation from previous patient parameter settings.

The new patient tab allows the user to select the patient type, the circuit type, and to continue to the main page or to start the setup assistant. The Continue button and Setup Assistant button will be inactive and will be displayed in gray until the user selects patient type. The user may choose Neonate, Pediatric, and Adult from patient type.

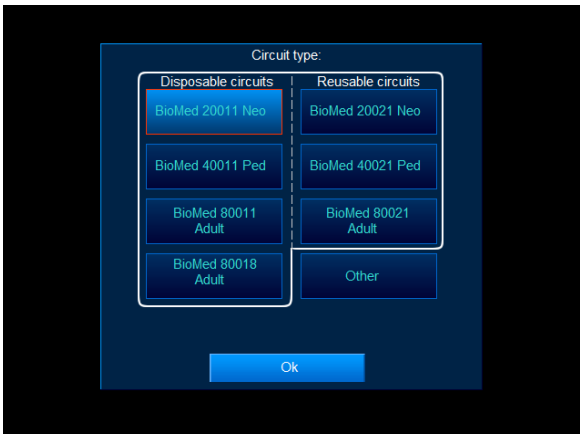


Figure 3.5: Select Circuit Popup

Pressing the Circuit type button will load the select circuit popup. This popup allows you to select circuit type. The TV-100 stores compliance data for Bio-Med Devices, Inc. brand circuits in memory. This selection includes both disposable and reusable circuit types, as well as types for neonate, pediatric and adult patients. Upon choosing neonatal, pediatric or adult patient type, the respective Bio-Med Devices, Inc. disposable circuit model P/N 20011 (neonatal), P/N 40011 (pediatric) or P/N 80018 (adult) will be selected. If the user needs to select a different circuit (or reusable circuit) the circuit drop down menu

will allow a selection to be made. If the selected circuit is incompatible with the selected patient type then the message “Patient/Circuit mismatch” will appear below the Circuit type button and the Continue button will be unavailable until the selection is fixed. If the user selects the Other button, the message “Measure compliance for volume compensation” will be displayed above the OK button on the select circuit popup.

NOTE: At this point the user should proceed to the TOOLS Menu and perform a Leak Test followed by a Compliance Test. If the incorrect pneumotach (flow sensor) is installed for the patient size selected, the user will not be able to proceed until the proper flow sensor is installed, or it is removed altogether.

The previous patient tab (Refer to Figure 3.4) allows the user to quickly and easily resume ventilation of a patient using the most recent patient parameters stored in memory. This menu displays the patient type and circuit type used in previous ventilation, as well as the Continue button. When the user selects the Continue button the TV-100 will display the parameters page. You cannot make changes to the patient parameters displayed in the previous patient tab.

NOTICE: Non Bio-Med Devices, Inc. brand circuit compliance data is unknown, and volume compensation will be unavailable until the circuit compliance is measured.

If you wish to make changes to the patient parameters select the Setup Assistant button. If you select neonate or pediatric patient type, the TV-100 will display the advanced setup page (basic setup is inaccessible for these patient types). If you select adult patient type, the TV-100 will give you the choice to select either basic setup or advanced setup.

If you press the Continue button the TV-100 will display the parameters page, allowing you to set patient parameters and begin ventilation. It is important to verify the patient type is compatibly matched to all patient parameters before ventilation.

3.2.2 Setup Assistant

The setup assistant is a user friendly guide to help set TV-100 patient parameters.

Figure 3.6: Setup Assistant Page

The main setup assistant page is displayed above. This page will be displayed whenever you enter the setup assistant. If the patient type is neonate or pediatric only advanced setup will be available, and the TV-100 will open the advanced setup page automatically. If the patient type is adult the user can select either the Basic Setup button or the Advanced Setup button.

3.2.2.1 Basic Setup

The basic setup page allows you to set general parameters for quick ventilation of a patient.

Figure 3.7: Basic Setup Page

The user is prompted with a page to select the gender and height of the patient. Height is adjustable with an up button and down button. The Back button will return you to the main setup assistant page. If you press the Continue button the TV-100 will load the parameters page.

The TV-100 will set the following parameters in basic setup assistant:

- Mode: Volume-AC
- Tidal Volume: 7 mL per kg, utilizing ideal body weight formula[1]

- PEEP: 5 cmH_2O
- Set Rate: 12 BPM
- I-Time: 1.00 Sec.
- Pressure Trigger: 2.0 cmH_2O
- Flow Trigger: 10 cmH_2O
- Sigh Breath: Off

1. Ideal body weight formula
   a. Male: 50 kg + 2.3 kg per inch over 5 feet (60 inches)
   b. Female: 45.5 kg + 2.3 kg per inch over 5 feet (60 inches)
2. If oxygen is connected the clinician will need to set the oxygen percentage

3.2.2.2 Advanced Setup

The advanced setup page gives you full control of TV-100 parameters. Advanced setup allows you to enter each parameter in a step by step method.

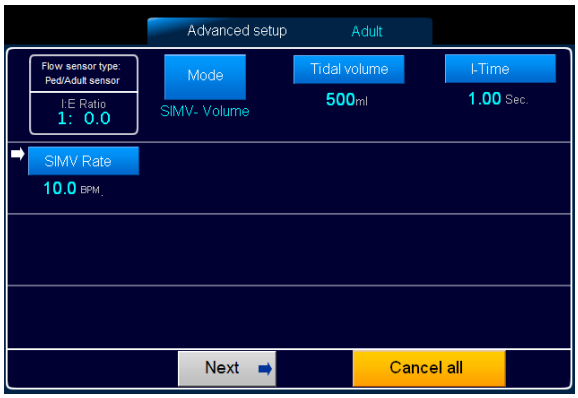


Figure 3.8: Advanced Setup Page

The advanced setup page is displayed above. The selected patient type is displayed on the top tab to the right of the page name. The flow sensor type and I:E ratio are displayed in the top left corner of the page.

Ventilation mode will be the first parameter you set. After setting the ventilation mode each applicable parameter of the selected mode will appear in a series for the user to set. After setting a parameter the next parameter will be displayed to the right of the previously set parameter. The TV-100 will display an animated arrow to point the user to the next parameter to be set. The user can accept the displayed parameter value by pressing the NEXT button. The user may also open the popup menu for that parameter and change it accordingly.

At any time, the user may readjust a set parameter. Adjusting a parameter will return the series to that parameter.

Once the user has entered all applicable parameters, the Continue button will appear. Pressing the Continue button will load the parameters page. Pressing the Cancel All button will return the user to the previous page.

3.2.3 Popup Menus

Popup menus are used to display messages, set patient parameters, calibrate and test the TV-100, and to display and acknowledge alarms. Popup menus appear superimposed over the current page. The current page will dim so that the popup is easy to navigate and read.

There are four types of popup menus: warning popup, option popup, numeric parameter popup, and message popup.

3.2.3.1 Warning Popup

The warning popup is used to display alarms that are not related to patient parameters, as well as other ventilator messages. The shutdown popup is an example of a warning popup unrelated to alarms. A list of current alarm conditions is listed on the alarm popup. The alarm popup closes when you acknowledge the alarm conditions listed by pressing the close button or the alarm silence button.

3.2.3.1.1 Shutdown Popup

The shutdown popup is an example of a warning popup. The shutdown popup is used to verify the user wishes to power off the TV-100. The TV-100 will display the shutdown popup when the user presses and holds the power button for two (2) seconds. If the user presses the Power off button the TV-100 will power off. If the user presses the Cancel button the TV-100 will close the shutdown popup and return to normal operation.

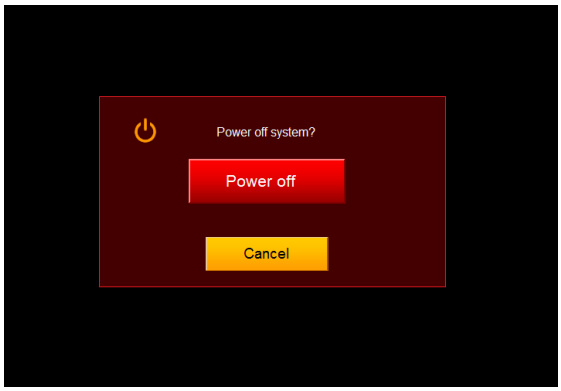


Figure 3.9: Shutdown Popup

3.2.3.2 Option Popup

The option popup presents you with selectable option buttons which will change ventilator parameters or conditions. The sigh breath popup is an example of an option popup. The sigh breath popup displays two option buttons used for turning on and turning off sigh breath.

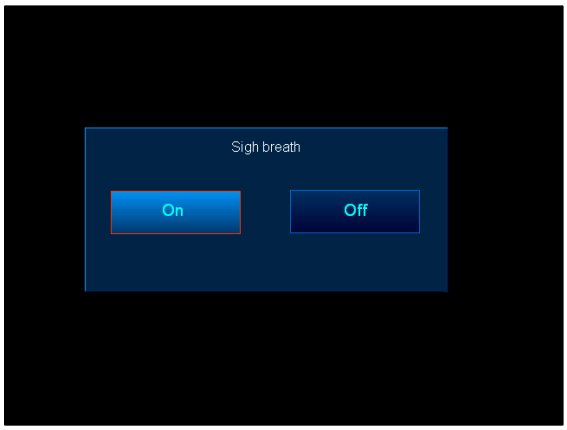


Figure 3.10: Sigh Breath Popup

3.2.3.3 Numeric Parameter Popup

Numeric parameter popup menus are used for setting ventilation parameters with numeric values.

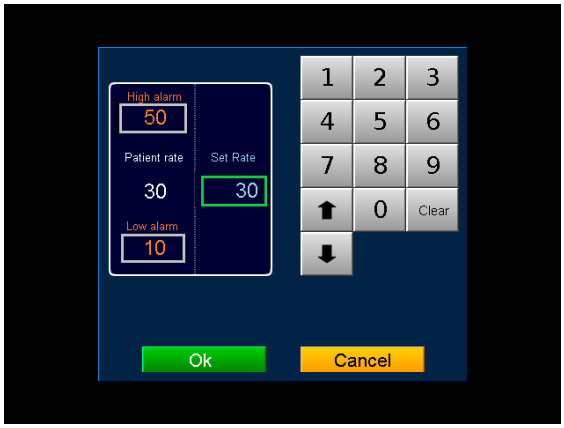


Figure 3.11: Numeric Parameter Popup With Settable Value

When the TV-100 displays a numeric parameter popup with a settable value and settable alarm limits, the popup will display the following elements: a box with the measured value on the left, the set value on the right, the high alarm limit above the measured value, and the low alarm limit below the measured value. If you press the set value, low alarm limit, or high alarm limit the TV-100 will highlight the box surrounding that value and make the set value adjustable.

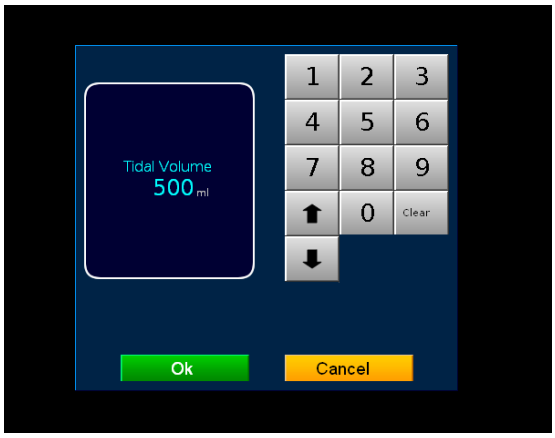


Figure 3.12: Numeric Parameter Popup With Settable Value & No Alarm Limits

When the TV-100 displays a numeric parameter popup with a settable value, without alarm limits, the popup will display the following elements: a box containing the set value. Pressing the set value will highlight the box surrounding that value and make the set value adjustable.

Figure 3.13: Numeric Parameter Popup With Settable Alarm Limits

When the TV-100 displays a numeric parameter popup with settable alarm limits but without a settable value, the popup will display the following elements: a box containing the measured value, the high alarm limit above the measured value, and the low alarm limit below the measured value. Pressing the low alarm limit value or high alarm limit value will highlight the box surrounding that value and make it adjustable. The high alarm and low alarm limits will blink red when the measured value violates either limit.

The numeric key pad is used for entering numeric values, increasing or decreasing values, as well as turning values on and off. The TV-100 will automatically apply decimal places to applicable values as you type them into the key pad.

There will be an Ok button and a Cancel button at the bottom of the numeric parameter popup. When you press the Cancel button the TV-100 will close the numeric parameter popup, cancelling any changes you have made. When you press the OK button the TV-100 will check the entered values, then the TV-100 will apply those values and close the numeric parameter popup. When you press the OK button and the entered value is above or below its applicable range the TV-100 will display “Out of range”. The TV-100 will also display an arrow pointing to the invalid value. You must correct the entered value before beginning ventilation.

Figure 3.14: Confirmation Popup for Value Changes over 30 Percent

The TV-100 will display a confirmation message when a value is changed by 30 percent or more of the original value. You must acknowledge a change of this amount before the TV-100 will apply the set value.

3.2.3.4 Message Popup

The message popup is a small rectangular popup that displays a message with white text. The TV-100 will display a message popup to inform the user about a notification or a reminder.

3.2.4 Status Bar

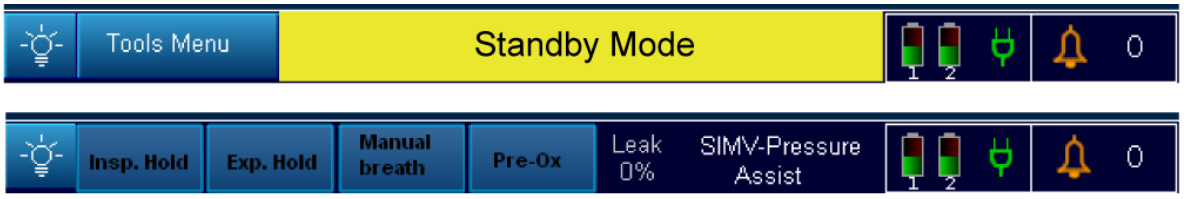


Figure 3.15: Status Bar in Standby Mode & Status Bar in Ventilation

The status bar is an easily accessible menu of buttons displayed at the bottom of all full pages. The status bar allows you to access the tools menu page, deliver a manual breath, initiate or cancel preoxygenation, adjust the backlight, and perform inspiratory and expiratory hold. The status bar also displays ventilator indicators such as breath type, ventilation mode, alarm silence indicator and timer, external power supply icon, and battery status.

When the TV-100 is in standby mode, the status bar will display the message: Standby Mode. Standby Mode is displayed in large text with a flashing yellow background. Standby Mode replaces the Manual breath, inspiratory hold (Insp. Hold), expiratory hold (Exp. Hold), and preoxygenation (Pre-Ox) buttons, which are only accessible during ventilation. The status bar also displays the Tools Menu button. When you press the Tools Menu button the TV-100 will load the tools menu page.

If you are in a ventilation mode which precludes any of the buttons on the Status Bar from use, then that button will be inactive.

3.2.4.1 Backlight Adjust Button

The Backlight Adjust button is located on the far left of the status bar. This button displays a light bulb icon and controls backlight brightness. When you press this button the TV-100 will cycle through the different backlight brightness presets and adjust the display accordingly. These presets are 100% brightness, 75% brightness, 50% brightness, and 25% brightness. The default backlight brightness preset is 100% brightness.

3.2.4.2 Inspiratory and Expiratory Hold Buttons

The inspiratory hold (Insp. Hold) button will initiate an inspiratory hold. Inspiratory hold is available in all modes except nCPAP/HFNC Mode. The minimum inspiratory hold will be 0.5 seconds for adult and pediatric patient types. The minimum inspiratory hold will be 0.3 seconds for neonatal patient type. If the Insp. Hold button is pressed and released while the vent is in an expiratory phase, the minimum Insp. Hold length will be added to the next control or assist breath. Inspiratory hold will not be applied to a pressure support breath if it occurs first. The Insp. Hold button will be greyed out and inactive for 20 seconds, starting at the beginning of exhalation following the Insp. Hold. The user may extend inspiratory hold for up to 15 seconds if they continue to press the Insp. Hold button. The 15 second timer will start with the inspiratory phase of the next control or assist breath. The ventilator will automatically cycle into expiration either when the button is released, or when 15 seconds have elapsed

from the beginning of inspiration. If the Insp. Hold button is released at any time prior to the end of the next control or assist breath, then the minimum inspiratory hold will be applied.

The expiratory hold (Exp. Hold) button will initiate an expiratory hold. Expiratory hold will be 1.0 second for adult and pediatric patient types. Expiratory hold will be 0.5 seconds for neonatal patient type. Expiratory hold is not adjustable. The user may initiate an expiratory hold to measure the patient's AutoPEEP level, and an inspiratory hold to measure the plateau pressure and static lung compliance of the patient.

When the inspiratory hold button is pressed in a volume mode, the static compliance and plateau pressure will be displayed for 10 seconds on the Lung Mechanics Page. When the expiratory hold button is pressed the auto peep value will be calculated and displayed for 10 seconds on the Lung Mechanics Page.

3.2.4.3 Manual Breath Button

The Manual Breath button initiates a manual breath. The manual breath will be delivered according to parameters set by the user. The Manual Breath button is only accessible during ventilation.

3.2.4.4 Preoxygenation Button

The preoxygenation (Pre-Ox) button initiates or cancels the preoxygenation function. If the TV-100 does not detect a connected oxygen source greater than or equal to 29 PSI the Pre-Ox button will be inactive and will be displayed in gray. For pediatric and adult patients, when the user presses the preoxygenation button the TV-100 will deliver 100% oxygen to the patient for a 60 second period. For neonatal patients, when the user presses the preoxygenation button the TV-100 will deliver oxygen at a concentration 10% above the current set oxygen level to the patient for a 60 second period. During this 60 second period the Pre-Ox button will be highlighted to indicate preoxygenation is active. After the 60 second period preoxygenation will terminate automatically, and the Pre-Ox button will return to its normal appearance. The user may manually stop preoxygenation by pressing the Pre-Ox button while preoxygenation is active.

3.2.4.5 Leak Display

The leak display is an indicator of delivered tidal volume with respect to leak. The leak display measures the difference between delivered tidal volume and exhaled tidal volume. Leak display is dependent on a flow sensor being present in the patient circuit. If a flow sensor is not present leak display will be inactive.

3.2.4.6 Ventilation Mode and Delivered Breath Displays

The ventilation mode and delivered breath displays indicate the current ventilation mode, as well as the type of breath the TV-100 is delivering to the patient. There will be no delivered breath display when the TV-100 is not delivering a breath.

3.2.4.7 Battery Icon Display

The battery icons are vertical bar icons that display the charge status of the batteries. Below the battery icons are numerals to distinguish the batteries (1 & 2). The batteries are represented by green bars proportional to the charge remaining in the batteries. When the batteries are discharged they are represented by red bars. When the TV-100 detects a battery is not present that bar icon will be black with a red X symbol. When the TV-100 detects a battery is charging the numeral below the bar icon will toggle from the numeral to a lightning bolt icon.

3.2.4.8 External Power Supply Icon Display

The external power supply icon display is a power plug icon located to the right of the battery icon display. This icon is displayed when the TV-100 is connected to external power. When the TV-100 is running solely on battery power there will be no external power supply icon displayed on the status bar.

3.2.4.9 Alarm Silence/Alarm Inhibition and Alarm Time Displays

When you initiate an alarm silence or alarm inhibition the alarm indicator will display the type of alarm silence/alarm inhibition. The TV-100 will display four types of alarm indicators. These indicators are displayed below and represent, in order: alarms normal, alarms silenced, alarms inhibited, and alarms off.

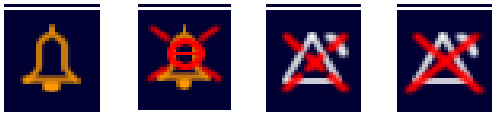


Figure 3.16: Alarm Silence/Alarm Inhibition Indicators

The alarm timer indicator displays the amount of time, in seconds, remaining while alarms are silenced or inhibited. Alarms will be silenced or inhibited for 120 seconds.

3.2.5 Main Page

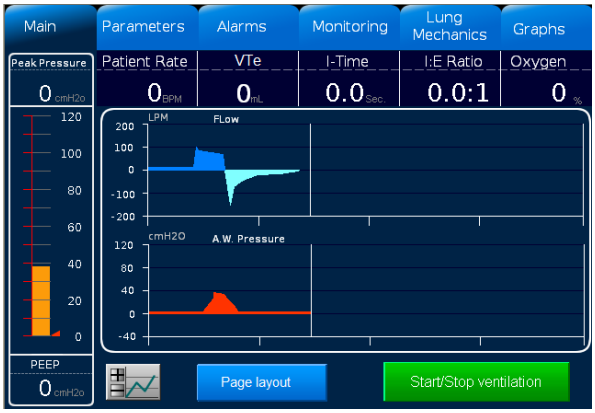


Figure 3.17: Main Page

The main page displays various TV-100 ventilator parameters. The main page allows the user to easily start or stop ventilation. The main page contains the following:

3.2.5.1 Pressure Bar Graph

This vertical bar graph is displayed on the left of the screen and displays airway pressure. The color of the bar is orange when displaying values above zero. The color of the bar is yellow when displaying values below zero. The numeric labeling of the graph is dependent on the pressure range set by the user. If the pressure range is 0-60 cmH_2O then the bar graph will display the range in steps of 10 cmH_2O. If the pressure range is 0-120 cmH_2O then the bar graph will display the range in steps of 20 cmH_2O. There is a peak pressure display above the pressure bar and a PEEP pressure display below the pressure bar.

3.2.5.2 Measured Parameters

The measured parameters are located at the top of the main page. Measured parameters display real time measurements of ventilator parameters. These parameters are not selectable from the main page. These parameters include: Patient Rate, exhaled tidal volume (VTe), inspiratory time (I-Time), I:E Ratio, and Oxygen.

3.2.5.3 Waveform Display

The waveform display is located in the middle of the main page. The waveform display is a real time measurement of ventilator parameters. The waveform display utilizes color coded icons to indicate the difference between a pressure trigger and a flow trigger. An orange icon will be displayed to indicate pressure trigger. A blue icon will be displayed to indicate flow trigger. If you press the Waveform Scale button located at the left bottom corner of the page you can adjust the x-axis and y-axis of the displayed waveforms. When you press the Waveform Scale button it will display buttons labeled “+” (plus) and “-” (minus) next to each waveform. Plus and minus buttons will also replace the Waveform Scale button. The plus button will enlarge the applicable waveform, while the minus button will reduce the applicable waveform. The plus and minus buttons which replace the Waveform Scale button will adjust the

waveform x-axis in a manner similar to the y-axis. When you adjust either the x-axis or the y-axis of the waveform display the TV-100 will reload the waveform display.

3.2.5.3.1 Page Layout Popup

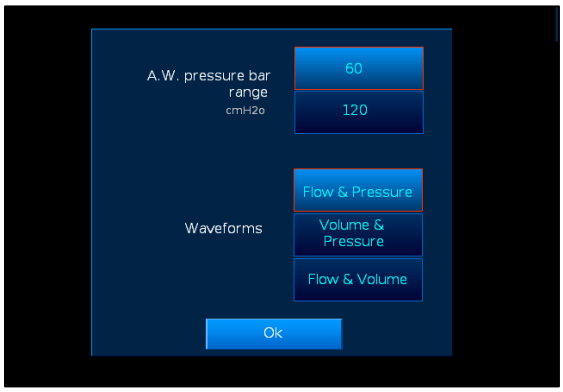


Figure 3.18: Page Layout Popup

When you press the Page Layout button the TV-100 will display the popup above. You can choose between three different pairs of parameters to display on the main page. These pairs are: Flow & Pressure, Volume & Pressure, and Flow & Volume. When you select a new pair of parameters the TV-100 will reload the waveform display with those parameters. You can also change the airway pressure bar graph range in this popup. The settable y-axis for the pressure bar graph is 60 or 120 cmH_2O.

3.2.5.4 Start/Stop Ventilation Button

Figure 3.19: Start/Stop Ventilation Popup

The Start/Stop Ventilation button is used to start or to stop ventilation. When you press this button during ventilation a popup will display asking you to confirm your choice. Once you press the button labeled “Stop Ventilation” the TV-100 will enter standby mode. When you press this button during standby mode, the button will load a popup asking you to confirm your choice. Once you press the button labeled “Start Ventilation” the TV-100 will begin ventilation.

3.2.6 Parameters

Figure 3.20: Parameters Page

The parameters page allows you to adjust all settable patient parameters as well as change ventilation modes. Some buttons on the parameters page will be mutually exclusive. Settable patient parameters will vary depending on the selected mode.

3.2.6.1 Patient Type Display

The patient type display is located at the top of the parameters page, and displays the selected patient type. You can set the patient type to: Neonate, Pediatric, or Adult. The patient type can only be set from the startup page.

3.2.6.2 Flow Sensor Display

The flow sensor display is located to the right of the patient type at the top of the parameters page, and displays the selected flow sensor type. If no flow sensor is connected this field will display “No Flow Sensor”. If a flow sensor is connected this field will display the name and type of flow sensor connected.

3.2.6.3 I:E Ratio Display

The I:E ratio display is located at the top of the page to the right of the flow sensor display. This field will display the I:E ratio.

3.2.6.4 Mode Select Button

The mode select button is located below the patient type, flow sensor, and I:E ratio displays. The mode select button is used to select a ventilation mode and is labeled "Mode". Pressing the mode select button will display the mode selection popup.

Figure 3.21: Mode Selection Popup (Pediatric/Adult Patient)

The mode selection popup allows you to set the ventilation mode. TV-100 ventilation modes are listed below:

- Volume-AC
- Volume-SIMV
- PRVC-AC
- Pressure-AC
- Pressure-SIMV
- NIV
- nCPAP / HFNC
    - nCPAP / HFNC (Neonatal)
    - HFNC (Pediatric/Adult)
- CPAP (Pediatric/Adult only)
    - CPAP-Volume Backup
    - CPAP-Pressure Backup

For more information on TV-100 ventilation modes and ventilation controls refer to Chapter 2.4 Ventilation Controls, and Chapter 2.5 Ventilation Modes.

When you press the Ok button the TV-100 will set the selected mode and close the selection popup. If you press the Cancel button the TV-100 will disregard the mode change and close the selection popup.

3.2.6.4.1 Verifying New Mode Selection

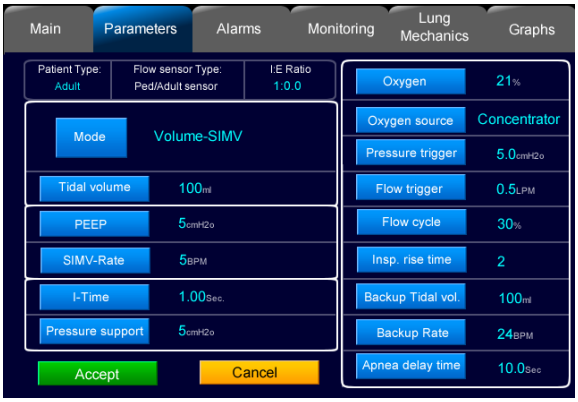


Figure 3.22: New Mode Verification Parameters Page

If you adjust mode during ventilation the mode selection popup will close and the TV-100 will load the new mode verification parameters page. The parameters page will display the available parameters for the newly selected mode. The TV-100 will continue to ventilate while the user adjusts parameters for the newly selected mode. During new mode verification the page navigation tabs will be inactive and will be displayed in gray.

If you press the Accept button the newly selected ventilation mode will become the active ventilation mode and the TV-100 will display the main page. If you press the Cancel button the selected ventilation mode and all parameter changes will be disregarded, and the TV-100 will remain in the current ventilation mode.

3.2.6.5 Exit Apnea Button

When the TV-100 initiates apnea functionality, a yellow button labeled “Exit Apnea mode” will be displayed to the right of the Start/Stop ventilation button. If the user presses the Exit Apnea button, then the TV-100 will stop apnea ventilation and return the ventilator to the previous ventilation mode.

3.2.6.6 Settable Patient Parameter Buttons

Settable patient parameter buttons are blue buttons labeled with the names of the settable parameters. The TV-100 displays the current set value to the right of the settable patient parameter button. If a patient parameter is unavailable, then the settable patient parameter button will be inactive and will be displayed in gray. If the user presses a settable patient parameter button, then the TV-100 will open the numeric parameter popup for the selected patient parameter.

For more information on numeric parameter popup menus refer to Chapter 3 Section 3.2.3.3 Numeric Parameter Popup.

Settable patient parameters are listed below. Parameter availability is described where applicable:

- Tidal Volume: available in Volume-AC and Volume-SIMV
- Backup Tidal Volume: available in Volume-SIMV and CPAP Volume

- Set Rate: available in Volume-AC, Pressure-AC, PRVC-AC, and NIV
- Backup Rate: available in Volume-SIMV, Pressure-SIMV, NIV, CPAP Volume, and CPAP Pressure
- SIMV Rate: available in Volume-SIMV and Pressure-SIMV
- PEEP: available in Volume-AC, Volume-SIMV, Pressure-AC, and Pressure-SIMV, and PRVC-AC
- CPAP: available in CPAP Volume and CPAP Pressure
- EPAP: available in NIV
- IPAP: available in NIV
- Inspiratory time (I-Time): available in Volume-AC, Volume-SIMV, PRVC-AC, Pressure-AC, Pressure-SIMV, and NIV
- Backup I-Time: available in CPAP Volume, and CPAP Pressure
- Pressure Control: available in Pressure-AC and Pressure-SIMV
- Pressure Support: available in Volume-SIMV, Pressure-SIMV, CPAP Volume, and CPAP Pressure
- Backup Pressure Control: available in Pressure-SIMV, NIV, and CPAP Pressure
- Oxygen: available in all modes, available only if the TV-100 detects a connected O_2 source greater than or equal to 29 PSI and less than 90 PSI for high pressure oxygen source; or greater than or equal to 1 PSI and less than 32 PSI for concentrator oxygen source.
- Flow Trigger: available only if the TV-100 detects a flow sensor, not available in nCPAP/HFNC
- Flow Cycle: available in Volume-SIMV, PRVC-AC, Pressure-AC, Pressure-SIMV, NIV, CPAP Volume, and CPAP Pressure
- Inspiratory Rise Time (I-Rise Time): available in Pressure-AC and Pressure-SIMV
- Pressure Trigger: available in Volume-AC, Volume-SIMV, PRVC-AC, Pressure-AC, Pressure-SIMV, NIV, CPAP Volume, and CPAP Pressure
- Apnea Delay: available in Volume-SIMV, Pressure-SIMV, NIV, CPAP Volume and CPAP Pressure
- Sigh Breath: available in Volume-AC, PRVC-AC, Pressure-AC, available to pediatric and adult patient types
- Flow: only available in nCPAP / HFNC

3.2.7 Alarms Page

Figure 3.23: Alarms Page

The alarms page displays graphical representations of patient parameter ranges with alarm limits. Each parameter displays a vertical bar graph which represents that parameters total range. Each parameter displays the unit of measurement for that range at the top of the graph. If an alarm parameter is turned off the alarm page will display the message “Off” in place of a graph. When an alarm condition occurs the alarming limit will blink red. The alarm limit will blink until the alarm condition has been corrected (Refer to Figure 3.24 to the right).

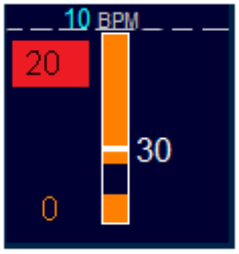


Figure 3.24

Apnea delay time is adjusted on the alarms page. To adjust apnea delay time press the Apnea delay time button. The TV-100 will load a numeric value popup where you can make adjustments to apnea delay time and confirm these changes. For more information on apnea functionality refer to Chapter 2 Section 2.5.7 Apnea Detection.

Parameters that have a settable value and also have settable alarm limits include: Patient Rate, Oxygen, PEEP/CPAP/EPAP, and IPAP. These parameters display the high alarm limit, the measured value, the low alarm limit, and the set value. The bar graph is divided into two colors. Alarm ranges are orange while non alarm ranges are dark blue. A white horizontal line travels along the bar graph representing the measured value of the parameter.

Above each graph is a blue button labeled with the parameter name. If you press this button a numeric parameter popup will load allowing you to adjust the set value.

Parameters that have a settable alarm limit but do not have a settable value include: exhaled tidal volume (VTe), exhaled minute volume (MVe), Peak pressure, and Mean pressure. These parameters display the high alarm limit, the measured value, and the low alarm limit. The bar graph is divided into two colors. Alarm ranges are orange while non alarm ranges are dark blue. A white horizontal line travels along the bar graph representing the measured value of the parameter.

3.2.7.1 Alarm Auto Set

The Alarm auto set button is located at the top of the alarms page. The Alarm auto set button is only available during ventilation. During standby mode the Alarm auto set button will be inactive and will be displayed in gray. The Alarm auto set button is only available when the TV-100 achieves set parameters and the breathing pattern is determined to be stable. The TV-100 determines the breathing pattern is stable by detecting there are no large changes in pressure/volume levels over a period of delivered breaths. If you press the Alarm auto set button the TV-100 will load the alarm auto set popup.

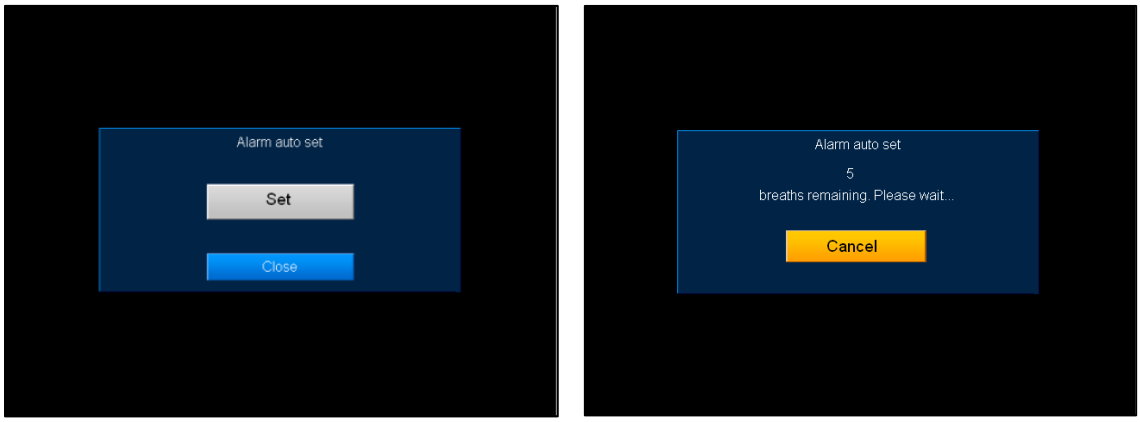


Figure 3.25: Alarm Auto Set Popup

When you press the Set button, the TV-100 will begin to set the alarms. The TV-100 will take five sample breaths then calculate the necessary values to balance alarm limits.

The TV-100 will calculate the following parameters for the alarm auto set. The TV-100 will apply the calculated high and low alarm limits.

Parameter	High Alarm (Adjusted Above Measured Value)	Low Alarm (Adjusted Below Measured Value)
Patient rate	+40%	-40%
Peak pressure	+6 cmH_2O	-30%
PEEP/CPAP/EPAP	+3 cmH_2O	-3 cmH_2O (OFF if value is 0)
IPAP	+3 cmH_2O	-3 cmH_2O
Oxygen	+20%	-20%
Mean Pressure	+40%	-40%

WARNING: VTe and MVe alarm limits are not set in alarm auto set functionality. Verify that clinically appropriate VTe and MVe alarm limits are set prior to connecting the TV-100 to a patient.

WARNING: Alarm limits set by alarm auto set may need to be adjusted manually. Verify that clinically appropriate alarm limits are set prior to connecting the TV-100 to a patient.

3.2.7.2 Event Log

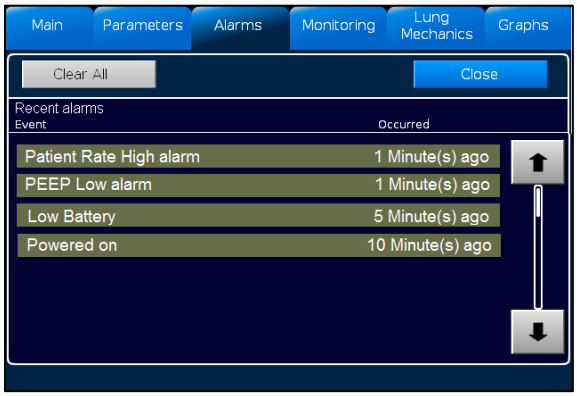


Figure 3.26: Event Log Page

The event log page is accessed by pressing the Event log button at the top of the alarms page. The event log page displays up to the 32 most recent ventilator events as well as the elapsed time since that the event occurred. The Clear all button will clear the list of events. The Close button will close the event log page and the TV-100 will reload the alarms page. Turning the TV-100 power off will clear the event log.

3.2.7.3 Alarms Page during Patient Parameter Alarm

When an alarm condition occurs, the TV-100 will initiate an audible and visual indication of the alarm. The TV-100 will blink the alarm parameter that is out of limit on the alarms page, the physical alarm button will blink, and the TV-100 will sound an audible alarm. When a patient parameter alarm condition occurs and the user is not on the alarms page, the alarms tab will blink and will be displayed in red.

For more information on alarm handling refer to Chapter 5: Alarm Handling.

3.2.8 Monitoring Page

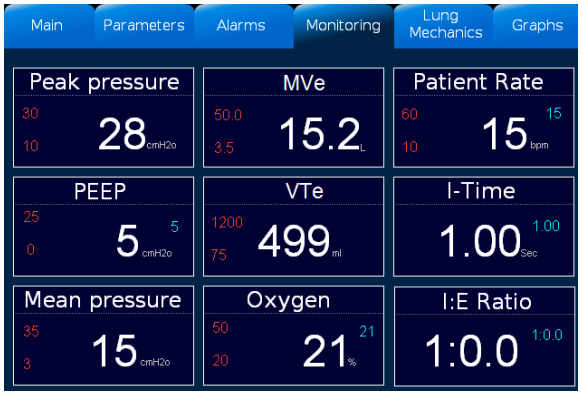


Figure 3.27: Monitoring Page

The monitoring page displays current ventilation parameters. The monitoring page is neatly arranged, and displays values in bold text. This allows you to easily monitor ventilation parameters from a distance of up to 15 feet.

> NOTE: 7 of these 9 measured values are displayed on the Main Page (only MVe and Mean Pressure are not displayed on the Main Page)

Monitoring page display parameters include Peak pressure, Exhaled minute volume (MVe), Patient Rate, PEEP/CPAP/EPAP, Exhaled tidal volume (VTe), I-Time, Mean pressure, Oxygen, and I: E Ratio. These parameter displays include the measured value, alarm limits if available, and the set value if available. If a parameter is in an alarm condition the exceeded alarm limit(s) will blink red.

3.2.9 Lung Mechanics Page

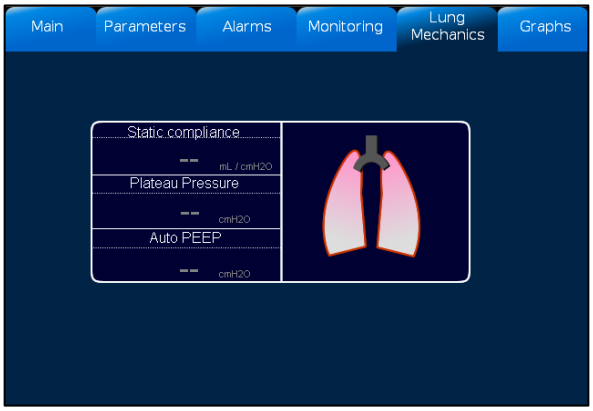


Figure 3.28: Lung Mechanics Page

The lung mechanics page displays an animated lung graphic as well as patient parameters related to lung mechanics.

The animated lung represents the patient's lung movement. The lungs expand as the patient's lung volume increases and contract while the patient's lung volume decreases. The trachea is used to animate the direction of air flow in the lung. A blue arrow pointing downwards appears on the trachea when air is flowing into the patient's lung. A blue arrow pointing upwards appears on the trachea when air is flowing out of the patient's lung.

The patient parameter displays the following parameters: Static lung compliance, Plateau Pressure, and Auto PEEP. These parameters will initially display double dashes.

Static compliance and Plateau Pressure will display their measured numeric value only after the user performs an inspiratory hold in the volume modes of ventilation. After 10 seconds, the numeric value will be removed from the lung mechanics page and will be replaced with double dashes. Auto PEEP will display its measured numeric value only after the user performs an expiratory hold. After 10 seconds, the numeric value will be removed from the lung mechanics page and will be replaced with double dashes.

3.2.10 Graphs Page

The Graphs page displays waveforms and loops. This page is subdivided into three different tabs: Waveforms, Volume/Pressure loop, and Flow/Volume loop. A scale button located below these tabs is used to adjust the value scale (y-axis) and time scale (x-axis) of the graph displayed on the page. Inspiratory and expiratory hold buttons are located below the scale button.

3.2.10.1 Waveforms Tab

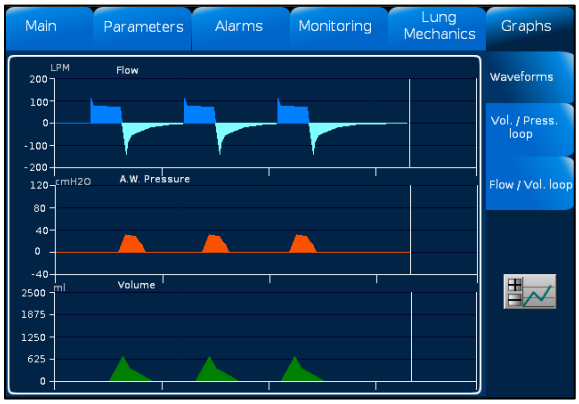


Figure 3.29: Graphs Page Waveform Tab

The waveforms tab displays three waveforms and a scale button to adjust the time and waveform range.

The flow waveform measures flow in liters per minute (LPM). The waveform is light blue for all values above zero and teal for all values below zero. Flow range is -200 to 200 LPM. The scale ranges for the flow wave are: -200 to 200, -100 to 100, -50 to 50, and -25 to 25.

The airway pressure waveform measures pressure in cmH_2O. The waveform is light brown for all values above zero and yellow brown for all values below zero. Airway pressure range is -40 to 120 cmH_2O. The scale ranges for the pressure wave are: -40 to 120, -20 to 60, -10 to 30, and -5 to 15.

The volume waveform measures volume in milliliters (mL). The waveform is green. Volume range is 0 to 2500 mL. The scale ranges for the volume wave are: 0 to 2500, 0 to 1000, 0 to 500, 0 to 100, and 0 to 25.

3.2.10.2 Volume/Pressure Loop Tab

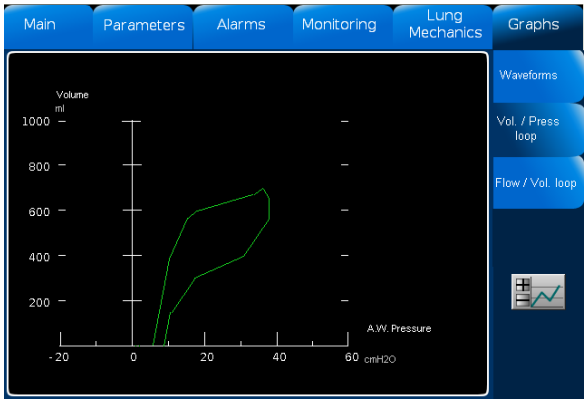


Figure 3.30: Graphs Page
Volume/Pressure Loop Tab

The volume/pressure loop displays a line plotting graph. The y-axis of this graph represents volume and the x-axis of this graph represents the airway pressure. Volume range is 0 to 2500 mL. Airway pressure range is -20 to 120 cmH_2O. The graph is updated as the breath is taking place and displays as a green loop. The scale ranges for the A.W. Pressure axis are adjustable from a maximum of -40 to 120 cmH_2O to a minimum of -5 to 15 cmH_2O. The scale ranges for the Volume axis are adjustable from a maximum of 0 to 2500 mL to a minimum of 0 to 10 mL.

3.2.10.3 Flow/Volume Loop Tab

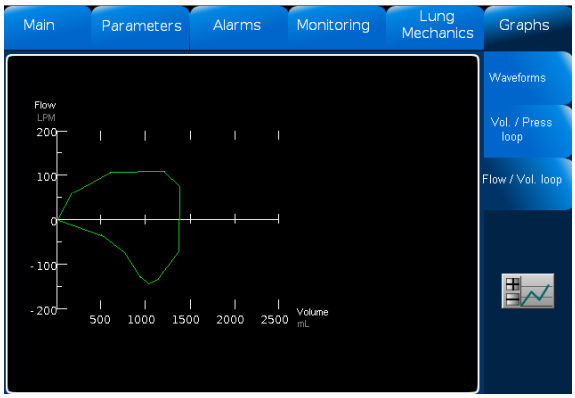


Figure 3.31: Graphs Page
Flow/Volume Loop Tab

The flow/volume loop displays a line plotting graph. The y-axis of this graph represents flow (LPM) and the x-axis of this graph represents volume. Flow range is -200 to 200 LPM. Volume range is 0 to 2500 mL. The graph is updated as the breath is taking place and displays as a green loop. The scale ranges for the Volume axis are adjustable from a maximum of 0 to 2500 mL to a minimum of 0 to 10 mL. The scale ranges for the Flow axis are adjustable from a maximum of -200 to 200 LPM to a minimum of -5 to 5 LPM.

3.2.11 Tools Page

Figure 3.32: Tools Page

The tools menu page allows you to configure, adjust, and test ventilation features. To access the tools menu page press the Tools Menu button on the status bar. The tools page is accessible only when the TV-100 is in standby mode. All alarm functionalities will be disabled when the tools menu page is active.

In a column on the right side of the tools page the TV-100 displays a summary of product information. This information includes: the company logo, the device name "TV-100", software version, copyright date, serial number, hours used, and last service date.

The tools menu page displays the following selectable buttons:

- Oxygen calibration
- Leak test
- Compliance measurement
- Resistance measurement
- Audio & Alarm test
- Touchscreen calibration
- System Language
- System tools

The system tools page is password protected and is accessible only to authorized personnel. The other buttons on the tools page will be used to perform various tests and calibrations to help ensure proper performance of the TV-100. These buttons are described in greater detail in Chapter 4: Performance Checkout Procedures.

3.2.11.1 System Language Popup

The system language popup is used to set the display language for the TV-100. The system language selection popup displays an option button for each language with the name of the language as the button label. Language buttons are labeled with that language's native spelling. The current language is highlighted. When you select a new language you must confirm the choice by pressing the Close button at the bottom of the popup.

The available system languages are:

- English
- French
- Spanish
- German
- Italian
- Portuguese
- Norwegian
- Polish
- Chinese
- Russian

Chapter 4: Performance Checkout Procedures

4.1 General Overview

WARNING: If the TV-100 fails during a checkout procedure discontinue use, Bio-Med Devices, Inc. technical support should be contacted, and the TV-100 should be serviced by a qualified technician.

The checkout procedures described in this chapter help to ensure the TV-100 ventilator is operating properly.

The tools menu page allows you to configure, adjust, and test ventilation features. The tools menu page is the starting point for each of the procedures described in this chapter. To access the tools menu page press the Tools Menu button on the status bar. The tools page is accessible only when the TV-100 is in standby mode. All alarm functionalities will be disabled when the tools menu page is active.

Figure 4.1: Tools Menu Page

4.2 Touchscreen Calibration

Press the Touchscreen Calibration button on the tools page (Refer to Figure 4.1).

To calibrate the touchscreen you must touch the top left corner of the page, followed by the bottom right corner of the page, and finally the center of the page. Follow the screen prompts to touch the center of the targets. To ensure accurate calibration you may be asked to repeat the calibration process. Once the calibration is complete, the TV-100 will close touchscreen calibration and will reload the tools page.

4.3 Oxygen Calibration

Press the Oxygen Calibration button on the tools page (Refer to Figure 4.1).

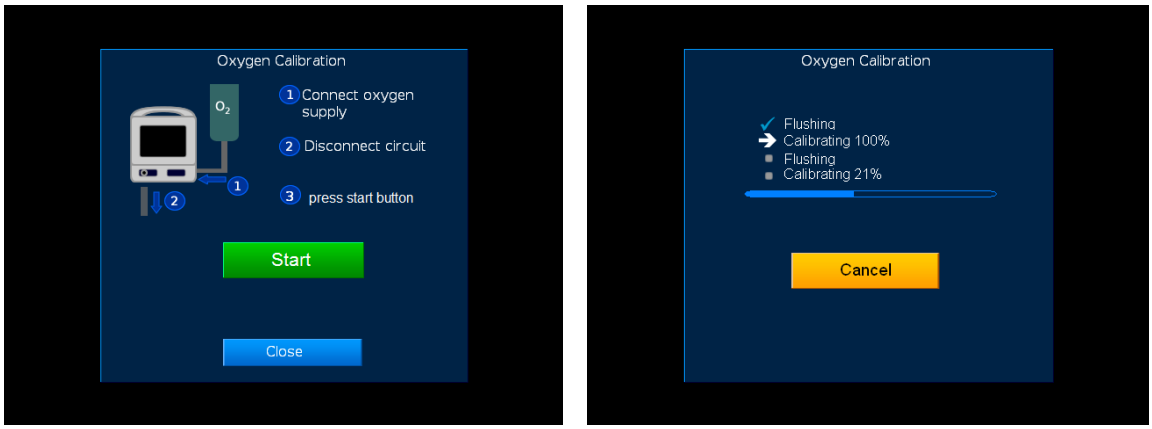


Figure 4.2: Oxygen Calibration

Connect an external 100% medical grade oxygen supply to the O_2 supply fitting on the right side of the TV-100. Disconnect the patient circuit, if connected, from the TV-100 then press the Start button. If the TV-100 does not detect an oxygen source, the Start button will be disabled.

As the TV-100 performs the calibration, a bar representing the calibration progress will fill as each step is successfully completed. If you cancel the calibration the TV-100 will reload the oxygen calibration popup.

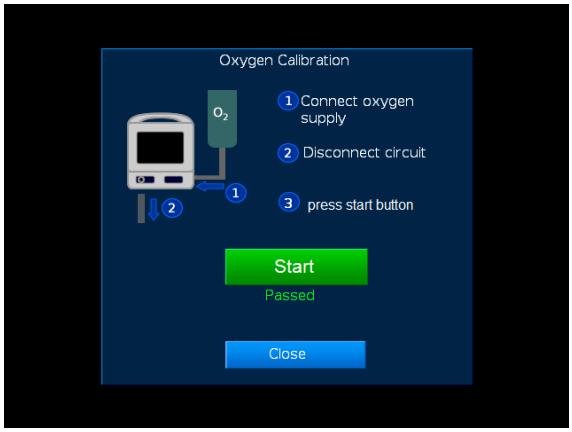


Figure 4.3: Oxygen Calibration

When calibration is complete, the TV-100 will reload the oxygen calibration popup and the test result will be displayed below the Calibrate button: “Passed” or “Failed”.

NOTICE: Due to the fact that O_2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed periodically (once a month) in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

4.4 Leak Test

Press the Leak Test button on the tools page (Refer to Figure 4.1).

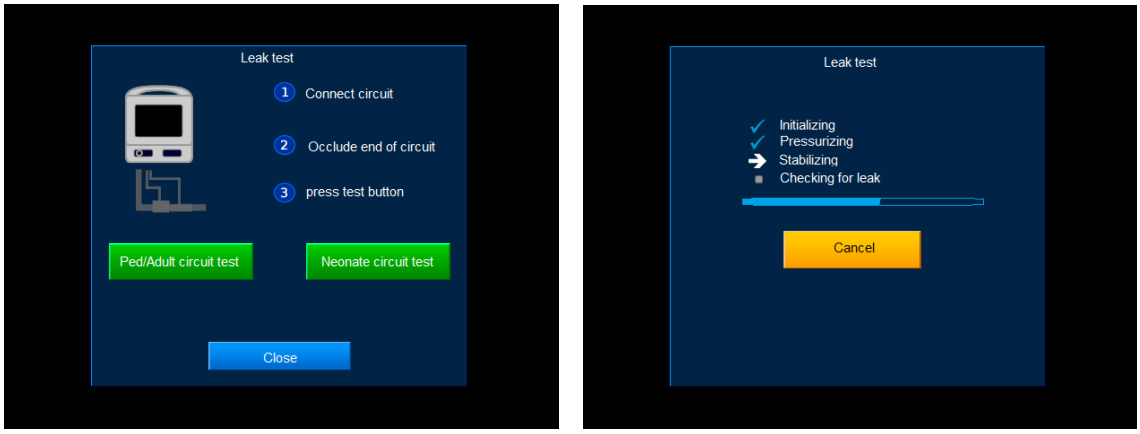


Figure 4.4: Leak Test

Connect the patient circuit to the TV-100. Make sure that the patient circuit is connected properly. Occlude the end of the patient circuit. Press the test button for the appropriate patient type. The test buttons are labeled: “Ped/Adult circuit test” and “Neonate circuit test”.

The pediatric/adult test detects if flow is greater than 200 mL/min at 50 cmH_2O pressure. The neonatal test detects if flow is greater than 50 mL/min at 20 cmH_2O pressure. If the detected flow is less than the values above the leak test will pass. If the detected flow is greater than the values above the leak test will fail.

As the TV-100 performs the calibration, a bar representing the test progress fills as each step is successfully completed. If you cancel the test the TV-100 will reload the leak test popup.

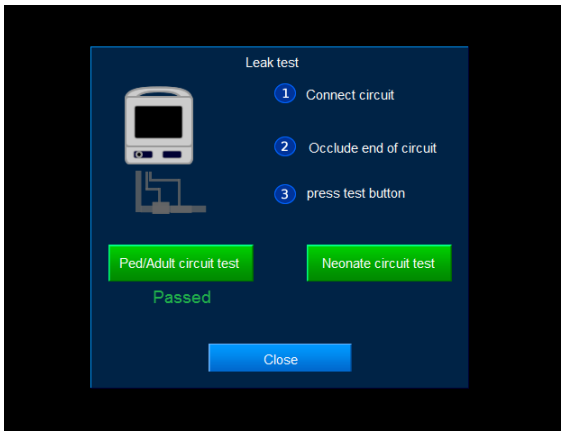


Figure 4.5: Leak Test

When the test is complete, the TV-100 will reload the leak test popup and the test result will be displayed below the Leak Test button: “Passed” or “Failed”.

If the leak test fails, check the patient circuit and all connections then restart the test procedure. If the leak test passes, the compliance measurement will become active and accessible from the tools page.

4.5 Compliance Measurement

Press the Compliance Measurement button on the Tools page (Refer to Figure 4.1).

Compliance measurement calculates the static compliance of the connected patient circuit. When using a Bio-Med Devices, Inc. brand circuit the compliance measurement is stored in memory and the compliance measurement should not be calibrated.

NOTICE: Non Bio-Med Devices, Inc. brand circuit compliance data is unknown, and volume compensation will be unavailable until the circuit compliance is measured.

Compliance measurement is accessible after the leak test has been performed and passed. If the TV-100 has not passed the leak test the TV-100 will display the message “Leak test must pass first” and the Calibrate button will be inactive. The compliance measurement popup is illustrated below (Figure 4.6).

Figure 4.6: Compliance Measurement

Press the Calibrate button to begin the measurement. As the TV-100 performs the measurement, a bar representing the measurement progress fills as the measurement is successfully completed. If you cancel the measurement then the TV-100 will reload the compliance measurement popup.

When calibration is complete, the TV-100 will reload the compliance measurement page. If the compliance measurement passes, the TV-100 will display “Passed” above the compliance factor value. If the compliance measurement fails, the TV-100 will display “Failed”.

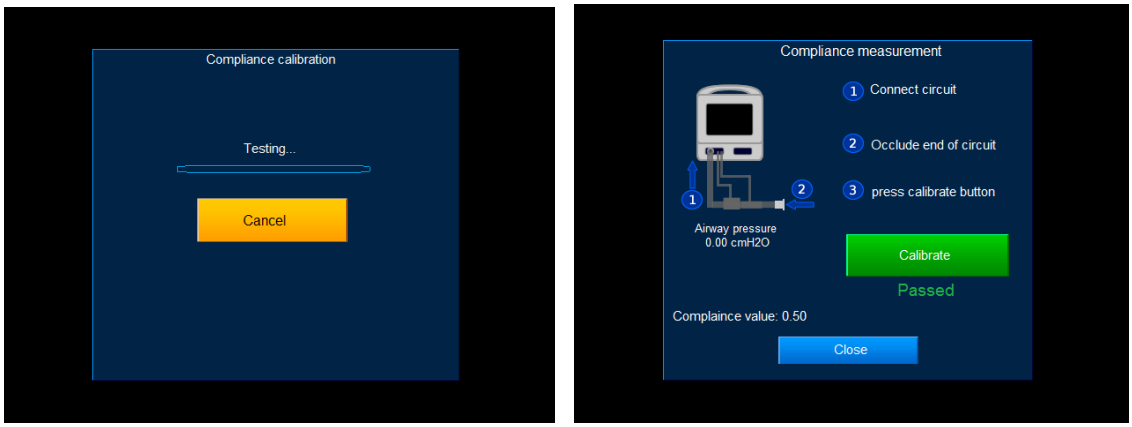


Figure 4.7: Compliance Measurement

4.6 Audio & Alarm Test

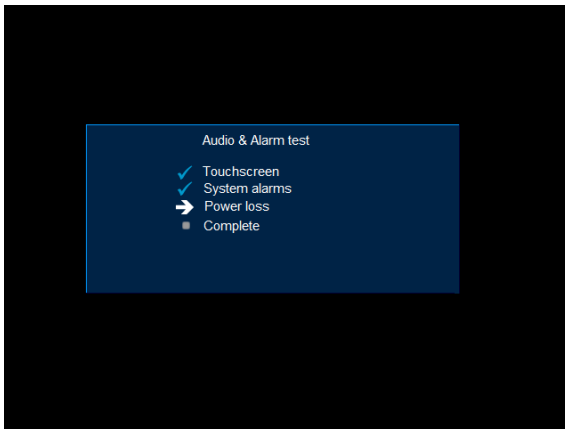


Figure 4.8: Audio & Alarm Test

The Audio & Alarm test will verify that the TV-100 audio alarm indicator is in proper working condition.

Press the Audio & Alarm Test button on the tools page (Refer to Figure 4.1).

The TV-100 will display the audio & alarm test popup and begin the test. During the test 3 audible tones will sound. Each tone will last for 3 seconds with a 2 second pause between tones. As the TV-100 performs the test, a check mark will be displayed next to each functioning alarm processor. There is no cancel button for this test. If the TV-100 emits all 3 audible tones, then the test has passed. If the TV-100 does not emit 3 audible tones, then the test has failed. When the test is complete, the audio & alarm popup will close and the TV-100 will reload the tools page.

4.7 Resistance Measurement

Press the Resistance Measurement button on the Tools page (Refer to Figure 4.1).

The resistance measurement is used to measure the pressure differential across the patient circuit with a specific flow through the patient circuit.

The resistance measurement popup is illustrated below (Refer to Figure 4.9). Press the button for the appropriate patient type circuit to begin the measurement. The buttons are labeled: “Ped/Adult circuit” and “Neonate circuit”.

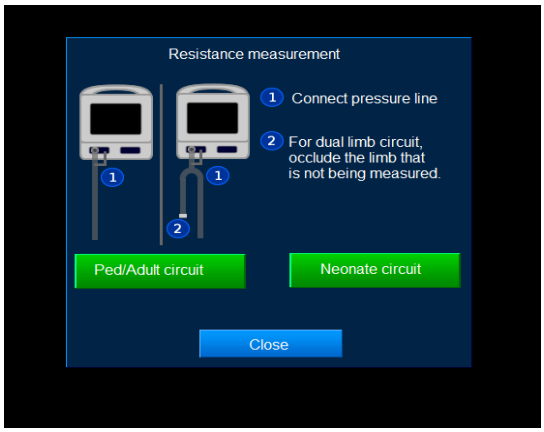


Figure 4.9: Resistance Measurement

Connect the resistance measurement adapter (BMD Catalogue # 5503) to the TV-100 patient output connector. Connect the pressure line from the adapter to the TV-100 airway pressure connector. Connect the circuit in reverse to the TV-100, with the patient end of the circuit connected to the resistance measurement adapter. Occlude the pressure line from the circuit.

If measuring a single limb circuit do not occlude the end of the circuit. If measuring a dual limb circuit connect the patient end of the circuit to the TV-100. Occlude the limb of the circuit that will not be measured. To measure the resistance of the inspiratory limb occlude the expiratory limb and vice versa.

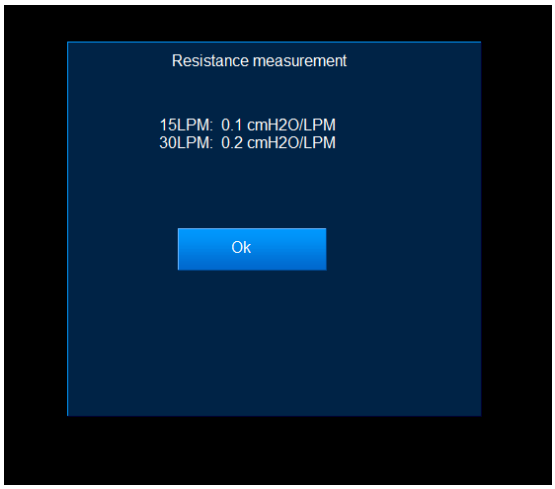


Figure 4.10: Resistance Values

After the measurement the TV-100 will display the resistance values for the patient circuit. For neonate circuits two resistance values will be displayed. These measurement values will be for flows of 15 LPM and 30 LPM. For pediatric and adult patient circuits four resistance values will be displayed. These measurement values will be for flows of 30 LPM, 60 LPM, 120 LPM, and 160 LPM. An example of neonate resistance values is illustrated above (Refer to Figure 4.10). If the resistance measurement fails, the TV-100 will display “Failed”.

Chapter 5: Alarm Handling

5.1 General Overview

This chapter describes how to recognize, acknowledge, and correct ventilator alarm conditions. Refer to Chapter 3 Section 3.2.7 Alarms Page for more information on how to set and monitor alarm parameters in the TV-100 GUI.

When an alarm condition occurs, the TV-100 will initiate an audible and visual indication of the alarm. The TV-100 will blink the alarm parameter that is out of limit on the alarms page, the physical alarm button will blink, and the TV-100 will sound an audible alarm. The clinician can switch to the Alarms page to view details of the alarm. In the event of a non-patient parameter related alarm, the TV-100 will display a warning popup. The warning popup will have the same flashing characteristics as those on the alarms page.

Before connecting the TV-100 to a patient verify alarm functionality. To verify patient parameter limit alarm conditions, set the patient parameter outside the alarm limit and verify the TV-100 alarm actuates. To verify warning popup alarm conditions generate the specific condition(s) which will cause the TV-100 to alarm (refer to Chapter 5 Section 5.5.3 Warning Popup for more information). For example, to verify Lost External Power unplug the AC power cord from the TV-100 and confirm the lost external power warning popup is displayed and the TV-100 begins to alarm.

5.2 High Priority Alarms

High priority alarm conditions occur when a mechanical, electrical, or software failure may render the TV-100 inoperable. High priority alarms are indicated by flashing the alarm button red at a frequency of 2.0 Hz with a 50% duty cycle and by an audible alarm with characteristics as given in EN 60601-1-8 for high priority alarms. Any alarm condition that presents a serious danger to the patient will also be classified as a high priority alarm. In a power failure or power off condition, the Alarm Silence button and audible alarm indicators will continue to operate for as long as three minutes following loss of power. High priority alarms are colored red. High priority alarms include:

- Apnea event
- Battery disconnect
- Low battery
- Component failure
- Patient parameter above or below its set alarm limits
- Patient or breathing circuit disconnect

5.3 Medium Priority Alarms

Medium priority alarms signal a condition that requires immediate attention from the user. Medium priority alarms are indicated by flashing the alarm button red at a frequency of 0.5Hz with a 50% duty cycle and by an audible alarm with characteristics as given in EN 60601-1-8 for medium priority alarms. In addition, the portion of the LCD representing the alarming parameter will flash red at a frequency of 0.5Hz with a duty cycle of 50%. Medium priority alarms are canceled automatically if the condition causing the alarm is rectified. If more than one alarm occurs simultaneously, each will be represented visually. Medium priority alarms are colored yellow. Medium priority alarms include:

- Parameter defaulted (TV-100 detects and automatically corrects an invalid value)
- Low O_2 supply pressure
- Loss of external power supply / power source
- Flow sensor disconnect / wrong flow sensor

5.4 Alarm Silence and Alarm Inhibition

Alarms may only be silenced or inhibited if you press the physical alarm button located on the front of the TV-100. The alarm button is labeled in Chapter 3 Section 3.1.1 Case Overview.

5.4.1 Alarm Silence

When you press the alarm button during an active alarm condition, the TV-100 will silence the alarm for 120 seconds. If you press the alarm button again during the 120 second period the TV-100 will cancel the alarm silence.

During the alarm silence period there will be no audible indication of the alarm condition. All visual alarm indications will function as normal during alarm silence. Alarm silence will be canceled if a new alarm condition occurs during the 120 second alarm silence period, and the TV-100 will sound an audible alarm.

5.4.2 Alarm Inhibition

Pressing the alarm button when there are no active alarms will inhibit all alarms for 120 seconds. Pressing the alarm button again during the 120 second inhibition period will cancel the alarm inhibition.

During the alarm inhibition period there will be no audible indication of alarm conditions. Visual alarm indications will function as normal during alarm inhibition, however warning popup messages will not be displayed. Alarm inhibition, prevents all alarms (current and newly occurring) from sounding. Alarm inhibition can only be canceled when the inhibition period expires or by pressing the physical alarm button.

5.5 Displaying Alarms

5.5.1 Patient Parameter Alarms

Patient parameter alarms are displayed on the alarms page. Refer to Chapter 3 Section 3.2.7 Alarms Page for more information on how the TV-100 displays patient parameter alarms.

5.5.2 Alarms Tab

Figure 5.1: Alarms Tab

The TV-100 will blink the alarms tab red to indicate the alarm condition. The alarms tab will have the same flashing characteristics as those on the alarms page.

5.5.3 Warning Popup

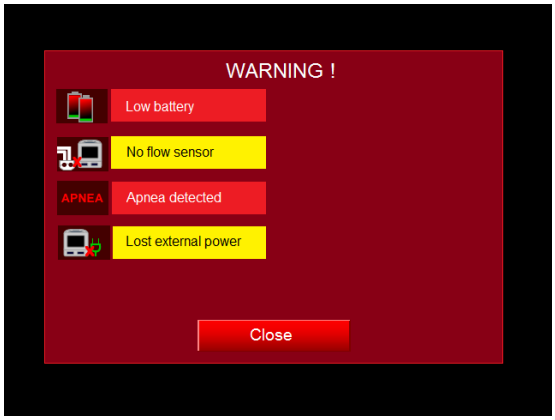


Figure 5.2: Warning Popup

The warning popup displays all non-patient parameter TV-100 alarms. High priority alarms will be displayed with a red background and white text. Medium priority alarms will be displayed with a yellow background and black text.

5.5.3.1 Warning Popup Alarm Icons

Low Battery (High priority alarm): Low battery alarm is displayed when the combined charge level of the batteries is below 20%. Low battery alarm is displayed again when the charge level drops below 10%. Below 10% charge the battery icon display background, the alarm silence button, and the alarm LED indicator will continue to flash red until the alarm condition is corrected.

Lost External Power (Medium priority alarm): Lost external power is displayed when the external power source is removed from the TV-100.

Battery Unplugged (High priority alarm): Battery unplugged is displayed when a battery is unplugged from the TV-100.

No Flow Sensor (Medium priority alarm): No Flow sensor is displayed when the flow sensor is unplugged from the TV-100.

Flow Sensor Mismatch (Medium priority alarm): Flow sensor mismatch is displayed when the selected circuit is incompatible with the selected patient type, e.g., a Neonate flow sensor is plugged in while the selected patient type is Adult or Pediatric.

Unsupported Sensor (Medium priority alarm): Unsupported sensor is displayed when a flow sensor is plugged in but not recognized by the TV-100.

A Parameter Defaulted (Medium priority alarm): A Parameter defaulted is displayed when the TV-100 detects and automatically corrects a numeric setting that has an invalid value due to error or data corruption. These numeric settings include all settable parameters, all settable alarm values, and patient height.

Apnea Detected (High priority alarm): Apnea detected is displayed when the TV-100 switches to backup mode.

Power On Test Failure (High priority alarm): The power on test failure is displayed when the TV-100 performs a hardware and software test after power up with an unsuccessful result. An error code is displayed along with the message.

O_2 Pressure Inlet Out of Range (High priority alarm): O_2 pressure inlet out of range is displayed when the TV-100 detects the pressure from the oxygen supply inlet has dropped below or risen above the TV-100 specified range.

PRVC Pressure limited (High priority alarm): PRVC pressure limited is displayed when the measured airway pressure is within 5 cmH_2O of the peak high alarm setting.

Obstruction Detected (High priority alarm): When the TV-100 detects an obstruction the unit will stop ventilation and display the obstruction detected high priority alarm. The unit will display the text: Obstruction detected, remove obstruction, press start ventilation to continue. The user should acknowledge the obstruction detected condition, close the warning popup and correct the alarm condition, which will restart ventilation. If 15 seconds elapses from the detection of the obstruction and there is no acknowledgment of the alarm condition, then ventilation will restart. If the obstruction has not resolved, the obstruction alarm will again stop ventilation for 15 seconds or acknowledgement of the alarm condition, whichever comes first.

To test this alarm is functional the user should connect a patient circuit with test lung to the TV-100, and then occlude the patient circuit exhalation valve.

5.6 Alarm Parameter Ranges and Alarm Limits

Parameter	Range		Unit of Measurement	Resolution	Affected by Auto Set	Can be Turned Off
	Neonatal	Ped/Adult				
Peak Pressure Low	1 - 64	3 - 104	cmH_2O	1	Yes	No[1]
Peak Pressure High	4 - 65	4 - 105	cmH_2O	1	Yes	No
Rate Low	0 - 159	0 - 109	BPM	1	Yes	No
Rate High	1 - 160	1 - 110	BPM	1	Yes	No
VTe Low	0 - 124	50 - 3199	mL	1	No	Yes
VTe High	3 - 125	51 - 3200	mL	1	No	Yes
MVe Low	0.0 - 44.9	0.0 - 99.9	L	0.1	No	Yes
MVe High	0.1 – 45.0	0.1 - 100.0	L	0.1	No	Yes
PEEP Low	0 - 24	0 - 34	cmH_2O	1	Yes	Yes
PEEP High	1 - 30	1 - 40	cmH_2O	1	Yes	No
CPAP Low	N/A	0 - 34	cmH_2O	1	Yes	Yes
CPAP High	1 - 30	1 - 40	cmH_2O	1	Yes	No
EPAP Low	0 - 24	0 - 34	cmH_2O	1	Yes	Yes
EPAP High	1 - 30	1 - 40	cmH_2O	1	Yes	No
Mean Low	0 - 79	0 - 104	cmH_2O	1	Yes	Yes
Mean High	1 - 80	1 - 105	cmH_2O	1	Yes	No
O_2 Low	18 - 100	18 - 100	%	1	Yes	No
O_2 High	19 - 105	19 - 105	%	1	Yes	No

1. Peak Pressure Low alarm defaults to off in nCPAP/HFNC mode

5.7 Default Alarm Values

Parameter & (Unit of Measurement)	Mode	Neonatal Value		Pediatric Value		Adult Value	
		High	Low	High	Low	High	Low
Rate (BPM)	Volume-AC	70	20	40	10	40	10
	Volume-SIMV	70	20	40	10	40	8
	PRVC-AC	70	20	40	10	40	10
	Pressure-AC	70	20	40	10	40	10
	Pressure-SIMV	70	20	40	10	40	8
	NIV	70	20	40	10	40	10
	nCPAP/HFNC						
	CPAP Volume-Backup			40	10	40	10
	CPAP Pressure-Backup			40	10	40	10
Oxygen (%)	Volume-AC	100	19	100	19	100	19
	Volume-SIMV	100	19	100	19	100	19
	PRVC-AC	100	19	100	19	100	19
	Pressure-AC	100	19	100	19	100	19
	Pressure-SIMV	100	19	100	19	100	19
	NIV	100	19	100	19	100	19
	nCPAP/HFNC	100	19	100	19	100	19
	CPAP Volume-Backup	100	19	100	19	100	19
	CPAP Pressure-Backup	100	19	100	19	100	19
PEEP/EPAP/CPAP (cmH_2O)	Volume-AC	10	OFF	10	OFF	10	OFF
	Volume-SIMV	10	OFF	10	OFF	10	OFF
	PRVC-AC	10	OFF	10	OFF	10	OFF
	Pressure-AC	10	OFF	10	OFF	10	OFF

	Pressure-SIMV	10	OFF	10	OFF	10	OFF
	NIV						
	nCPAP/HFNC	10	OFF	10	OFF	10	OFF
	CPAP Volume-Backup			10	OFF	10	OFF
	CPAP Pressure-Backup			10	OFF	10	OFF
IPAP (cmH_2O)	Volume-AC						
	Volume-SIMV						
	PRVC-AC						
	Pressure-AC						
	Pressure-SIMV						
	NIV	28	2	28	2	30	2
	nCPAP/HFNC						
	CPAP Volume-Backup						
	CPAP Pressure-Backup						
Vte (mL)	Volume-AC	100	0	400	50	650	300
	Volume-SIMV	100	0	400	50	650	300
	PRVC-AC	100	0	400	50	650	300
	Pressure-AC	100	0	400	50	650	300
	Pressure-SIMV	100	0	400	50	650	300
	NIV	100	0	400	50	650	300
	nCPAP/HFNC						
	CPAP Volume-Backup			400	50	650	300
	CPAP Pressure-Backup			400	50	650	300
Mve (L)	Volume-AC	3.0	0	12	1	30	2
	Volume-SIMV	3.0	0	12	1	30	2

	PRVC-AC	3.0	0	12	1	30	2
	Pressure-AC	3.0	0	12	1	30	2
	Pressure-SIMV	3.0	0	12	1	30	2
	NIV	3.0	0	12	1	30	2
	nCPAP/HFNC						
	CPAP Volume-Backup			12	1	30	2
	CPAP Pressure-Backup			12	1	30	2
Peak Pressure (cmH_2O)	Volume-AC	30	10	35	10	35	10
	Volume-SIMV	30	10	35	10	35	10
	PRVC-AC	30	10	35	10	35	10
	Pressure-AC	30	10	35	10	35	10
	Pressure-SIMV	30	10	35	10	35	10
	NIV	30	10	35	10	35	10
	nCPAP/HFNC	30	OFF	30	OFF	35	OFF
	CPAP Volume-Backup			35	10	35	10
	CPAP Pressure-Backup			35	10	35	10
Mean Pressure (cmH_2O)	Volume-AC	16	4	18	4	27	4
	Volume-SIMV	16	4	18	4	27	4
	PRVC-AC	16	4	18	4	27	4
	Pressure-AC	16	4	18	4	27	4
	Pressure-SIMV	16	4	18	4	27	4
	NIV	16	4	18	4	27	4
	nCPAP/HFNC	OFF	OFF	OFF	OFF	OFF	OFF
	CPAP Volume-Backup			18	4	27	4
	CPAP Pressure-Backup			18	4	27	4

Symptom	Possible Cause	Corrective Action
Audible alarm with no visible indication	Hardware failure Software failure	Contact Bio-Med Devices, Inc. technical support
Continuous audible tone	Hardware failure	Contact Bio-Med Devices, Inc. technical support
Auto cycling of the TV-100	Pressure trigger or Flow trigger parameters too low (sensitive) Hardware failure	Increase pressure trigger parameter Contact Bio-Med Devices, Inc. technical support
Battery will not charge / external power connected	Defective battery	Replace battery
External power failure alarm	Loss of external power Defective AC adapter	Contact Bio-Med Devices, Inc. technical support
Low battery audible / visual alarm	Low battery	Recharge battery
No battery operation	No battery charge Defective battery	Recharge battery Replace battery
No display	Defective LCD Hardware Failure	Contact Bio-Med Devices, Inc. technical support
No exhaled tidal volume reading	Flow sensor disconnected Software failure	Reconnect the flow sensor Contact Bio-Med Devices, Inc. technical support
O_2 not correctly calibrating / calibrated	O_2 sensor failure Calibration procedure not followed correctly	Contact Bio-Med Devices, Inc. technical support Recalibrate O_2 sensor
Peak Pressure high limit alarm	Peak pressure parameter too low Blockage in airway or tubing	Increase peak pressure parameter Remove blockage from airway
Pneumatic reading inaccurate	Flow sensor failure Leak in patient circuit	Replace the flow sensor Check circuit connections
Ventilator Failure	Hardware failure	Contact Bio-Med Devices, Inc. technical support
No power off alarm	Hardware Failure	Contact Bio-Med Devices, Inc. technical support

7.1 Specifications

Parameter	Neonatal Range & Unit of Measurement	Pediatric/Adult Range & Unit of Measurement	Resolution of Display	Accuracy
Rate	5 – 150 BPM	5 – 100 BPM	1	±10%
SIMV Rate	1 – 50 BPM	1 – 50 BPM	0.1	±10%
Tidal Volume	2 – 100 mL	75 – 2500 mL	1	±10%
MVe	0 – 45 L	0 – 100 L	0.1	±15%
VTe	2 – 125 mL	50 – 2500 mL	1	±15%
Flow	0.1 – 30 LPM	0.1 – 180 LPM	0.1	±10%
Base Flow	2.5 LPM	6 LPM	N/A	N/A
Flow Cycle	5 – 70 %	5 – 70 %	1	±15%
Flow Trigger	0.5 – 30.0 LPM	0.5 – 30.0 LPM	0.1 Neonatal; 0.5 Ped/Adult	N/A
CPAP	N/A	0 – 35 cmH_2O	1	±5% or ±1 cmH_2O
PEEP	0 – 25 cmH_2O	0 – 35 cmH_2O	1	±5% or ±1 cmH_2O
EPAP	0 – 25 cmH_2O	0 – 35 cmH_2O	1	±5% or ±1 cmH_2O
IPAP	3 – 40 cmH_2O	3 – 40 cmH_2O	1	±5% or ±1 cmH_2O
Peak Pressure (PIP)	0 – 60 cmH_2O	0 – 99 cmH_2O	1	±3% FS
Pressure Control	0 – 59 cmH_2O	0 – 99 cmH_2O	1	±5% or ±1 cmH_2O
Pressure Support	1 – 60 cmH_2O	1 – 60 cmH_2O	1	±5% or ±1 cmH_2O
Pressure Trigger	-0.2 to -10.0 cmH_2O	-0.2 to -10.0 cmH_2O	0.1	±10%
Plateau Pressure	60 cmH_2O	100 cmH_2O	1	±5% or ±1 cmH_2O
Oxygen	21 – 100 %	21 – 100 %	1	±5% FS
I-Time	0.1 – 3.0 seconds	0.1 – 3.0 seconds	0.05	N/A
E-Time	0 – 100 seconds	0 – 100 seconds	0.1	N/A
I:E Ratio	3.0:1 – 1:99.0	3.0:1 – 1:99.0	N/A	N/A
Apnea Delay Time	5 – 60 seconds	5 – 60 seconds	5	N/A

1. All values are expressed under ATPD conditions (ambient temperature & pressure dry)
2. MVe accuracy ±20% in PRVC-AC mode

- Alarm sound pressure level: 71 dB(A) ± 9 dB(A) at 1 meter

7.1.1 Default Parameter Values

Parameter	Mode	Neonatal Value & Unit of Measurement	Pediatric Value & Unit of Measurement	Adult Value & Unit of Measurement
Tidal Volume	Volume-AC	9 mL	200 mL	500 mL
	Volume-SIMV	9 mL	200 mL	500 mL
	PRVC-AC	9 mL	200 mL	500 mL
	Pressure-AC			
	Pressure-SIMV			
	NIV			
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup			
Pressure Control	Volume-AC			
	Volume-SIMV			
	PRVC-AC			
	Pressure-AC	16 cmH_2O	20 cmH_2O	20 cmH_2O
	Pressure-SIMV	16 cmH_2O	20 cmH_2O	20 cmH_2O
	NIV			
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup			
IPAP	Volume-AC			
	Volume-SIMV			
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV			
	NIV	18 cmH_2O	18 cmH_2O	20 cmH_2O
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup			
PEEP/CPAP	Volume-AC	4 cmH_2O	5 cmH_2O	5 cmH_2O
	Volume-SIMV	4 cmH_2O	5 cmH_2O	5 cmH_2O
	PRVC-AC	4 cmH_2O	5 cmH_2O	5 cmH_2O
	Pressure-AC	4 cmH_2O	5 cmH_2O	5 cmH_2O
	Pressure-SIMV	4 cmH_2O	5 cmH_2O	5 cmH_2O
	NIV			

	nCPAP/HFNC	4 cmH_2O		
	CPAP Vol-Backup		5 cmH_2O	5 cmH_2O
	CPAP Pres-Backup		5 cmH_2O	5 cmH_2O
EPAP	Volume-AC			
	Volume-SIMV			
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV			
	NIV	4 cmH_2O	5 cmH_2O	5 cmH_2O
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup			
Rate/SIMV Rate	Volume-AC	30 BPM	15 BPM	12 BPM
	Volume-SIMV	30 BPM	15 BPM	10 BPM
	PRVC-AC	30 BPM	15 BPM	12 BPM
	Pressure-AC	30 BPM	15 BPM	12 BPM
	Pressure-SIMV	30 BPM	15 BPM	10 BPM
	NIV	30 BPM	15 BPM	12 BPM
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup			
Inspiratory Time	Volume-AC	0.35 seconds	0.75 seconds	1 second
	Volume-SIMV	0.35 seconds	0.75 seconds	1 second
	PRVC-AC	0.35 seconds	0.75 seconds	1 second
	Pressure-AC	0.35 seconds	0.75 seconds	1 second
	Pressure-SIMV	0.35 seconds	0.75 seconds	1 second
	NIV	0.35 seconds	0.75 seconds	1 second
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup			
Pressure Support	Volume-AC			
	Volume-SIMV	OFF (10 cmH_2O)	OFF (10 cmH_2O)	OFF (10 cmH_2O)
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV	OFF (10 cmH_2O)	OFF (10 cmH_2O)	OFF (10 cmH_2O)
	NIV			
	nCPAP/HFNC			
	CPAP Vol-Backup		OFF (10 cmH_2O)	OFF (10 cmH_2O)
	CPAP Pres-Backup		OFF (10 cmH_2O)	OFF (10 cmH_2O)

Flow	Volume-AC			
	Volume-SIMV			
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV			
	NIV			
	nCPAP/HFNC	4 lpm	12 lpm	15 lpm
	CPAP Vol-Backup			
	CPAP Pres-Backup			
Oxygen	Volume-AC	21 %	21 %	21 %
	Volume-SIMV	21 %	21 %	21 %
	PRVC-AC	21 %	21 %	21 %
	Pressure-AC	21 %	21 %	21 %
	Pressure-SIMV	21 %	21 %	21 %
	NIV	21 %	21 %	21 %
	nCPAP/HFNC	21 %	21 %	21 %
	CPAP Vol-Backup	21 %	21 %	21 %
	CPAP Pres-Backup	21 %	21 %	21 %
Pressure Trigger	Volume-AC	1.0 cmH_2O	2.0 cmH_2O	2.0 cmH_2O
	Volume-SIMV	1.0 cmH_2O	2.0 cmH_2O	2.0 cmH_2O
	PRVC-AC	1.0 cmH_2O	2.0 cmH_2O	2.0 cmH_2O
	Pressure-AC	1.0 cmH_2O	2.0 cmH_2O	2.0 cmH_2O
	Pressure-SIMV	1.0 cmH_2O	2.0 cmH_2O	2.0 cmH_2O
	NIV	1.0 cmH_2O	2.0 cmH_2O	2.0 cmH_2O
	nCPAP/HFNC			
	CPAP Vol-Backup		2.0 cmH_2O	2.0 cmH_2O
	CPAP Pres-Backup		2.0 cmH_2O	2.0 cmH_2O
Flow Trigger	Volume-AC	1.0 lpm	2.0 lpm	2.0 lpm
	Volume-SIMV	1.0 lpm	2.0 lpm	2.0 lpm
	PRVC-AC	1.0 lpm	2.0 lpm	2.0 lpm
	Pressure-AC	1.0 lpm	2.0 lpm	2.0 lpm
	Pressure-SIMV	1.0 lpm	2.0 lpm	2.0 lpm
	NIV	1.0 lpm	2.0 lpm	2.0 lpm
	nCPAP/HFNC			
	CPAP Vol-Backup		OFF (2.0 lpm)	OFF (2.0 lpm)
	CPAP Pres-Backup		OFF (2.0 lpm)	OFF (2.0 lpm)
Flow Cycle	Volume-AC			
	Volume-SIMV	OFF (5 lpm)	OFF (5 lpm)	OFF (5 lpm)
	PRVC-AC	OFF (5 lpm)	OFF (5 lpm)	OFF (5 lpm)

	Pressure-AC	OFF (5 lpm)	OFF (5 lpm)	OFF (5 lpm)
	Pressure-SIMV	OFF (5 lpm)	OFF (5 lpm)	OFF (5 lpm)
	NIV	OFF (5 lpm)	OFF (5 lpm)	OFF (5 lpm)
	nCPAP/HFNC			
	CPAP Vol-Backup		OFF (5 lpm)	OFF (5 lpm)
	CPAP Pres-Backup		OFF (5 lpm)	OFF (5 lpm)
I-Rise	Volume-AC			
	Volume-SIMV			
	PRVC-AC			
	Pressure-AC	9	9	9
	Pressure-SIMV	9	9	9
	NIV			
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup			
Backup Tidal Volume	Volume-AC			
	Volume-SIMV	9 mL	200 mL	500 mL
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV			
	NIV			
	nCPAP/HFNC			
	CPAP Vol-Backup		200 mL	500 mL
	CPAP Pres-Backup			
Backup Pressure Control	Volume-AC			
	Volume-SIMV			
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV	16 cmH_2O	20 cmH_2O	25 cmH_2O
	NIV	16 cmH_2O	20 cmH_2O	25 cmH_2O
	nCPAP/HFNC			
	CPAP Vol-Backup			
	CPAP Pres-Backup		20 cmH_2O	25 cmH_2O
Backup Rate	Volume-AC			
	Volume-SIMV	30 BPM	15 BPM	12 BPM
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV	30 BPM	15 BPM	12 BPM
	NIV	30 BPM	15 BPM	12 BPM

	nCPAP/HFNC			
	CPAP Vol-Backup		15 BPM	12 BPM
	CPAP Pres-Backup		15 BPM	12 BPM
Apnea Delay	Volume-AC			
	Volume-SIMV	5 seconds	15 seconds	15 seconds
	PRVC-AC			
	Pressure-AC			
	Pressure-SIMV	5 seconds	15 seconds	15 seconds
	NIV	5 seconds	15 seconds	15 seconds
	nCPAP/HFNC			
	CPAP Vol-Backup		15 seconds	15 seconds
	CPAP Pres-Backup		15 seconds	15 seconds

7.2 Operating and Storage / Shipping Environment

Parameter	Range & Unit of Measurement
Operating Temperature	32° – 104° F (0° – 40° C)
Storage / Shipping Temperature	14° – 122° F (-10° – 50° C)[1]
Operating Relative Humidity	10 – 95 % relative, non condensing
Storage / Shipping Relative Humidity	0 – 95 %
Operating Atmospheric Pressure	10 – 16 PSI (70 – 110 kPa)
Storage / Shipping Atmospheric Pressure	8.3 – 16 PSI (57.2 – 110 kPa)

1. The ventilator will take 32 minutes to stabilize from 50° C to 40° C.
   The ventilator will take 1 hour and 57 minutes to stabilize from -10° C to 0° C.

7.3 Electrical Specifications

Parameter	Range & Unit of Measurement
Input Voltage (DC)	12 – 30 VDC
Input Voltage (AC)	100 – 240 VAC

7.4 Physical and Material Characteristics

Parameter	Measurement
Height	12.8" (32.5 cm)
Width	11.9" (30.2 cm)
Depth	7.6" (19.3 cm)
Weight	15.6 lbs (7.1 kg)

Individual internal components of this device contain the following IARC group 1 material of note, with content % per sub-part (not of the entire device) greater than 0.1% by weight:
Lead (only alloyed in brass and always < 4% by weight content of each individual brass sub-part)

No special precautions are necessary on the part of the user (or patient). This includes use for potentially vulnerable populations such as children and pregnant or breast-feeding women, to whom accrue no known residual risks of the presence of brass in respiratory equipment. Brass has been a standard construction material in respiratory devices for decades, and has a specific exemption under the RoHS directive.

7.5 Pneumatic Characteristics

- Outside of the recommended pressure range for oxygen input of 40-90 PSI, the delivered oxygen concentration to the patient cannot be guaranteed to remain in specification, in which case an output delivered-oxygen limit alarm would sound. However, the dedicated alarm for low oxygen input pressure does not activate until the input pressure falls to 29 PSI, to forestall recurring nuisance alarms when hospital oxygen supplies are overtaxed facility-wide (e.g., in pandemic situations). Thus when the input pressure falls outside the range 29-90 PSI, the TV-100 will display an O_2 Pressure Inlet Out of Range alarm condition. The alarm condition should be corrected as quickly as possible.
- For units with the low pressure oxygen concentrator available as the oxygen source (not available in all regions), the required input pressure range includes 1-32 PSI. When the pressure falls outside that range, the TV-100 will display an O_2 Pressure Inlet Out of Range alarm condition. Outside of this specified range, the delivered oxygen concentration cannot be guaranteed to remain in specification. The alarm condition should be corrected as quickly as possible.
- Neonatal relief valve actuates at 60 cmH_2O
- Pediatric/Adult relief valve actuates at 100 cmH_2O
- The TV-100 initiates pressure cycle at 105 cmH_2O to set PEEP low alarm limit pressure
- Patient filter resistance to flow 0.6 cmH_2O at 30 LPM, dead space 69 mL, and bacterial/viral filtration 99.99%.
- Compressor air input filtered by dual 70 PPI (pores per inch) 0.5" thick filters.
- Oxygen response times for 21 – 90% oxygen settings are:

Delivered volume (mL)	500	150	30
Breath Rate(BPM)	10	20	30
I/E ratio	1:2	1:2	1:2
Resistance (cmH_2O/l/sec)	5	20	50
Circuit type	80011	40011	20011
Time, base flow on (min:sec) [1]	0:40	0:42	1:36
Time, base flow off (min:sec) [1]	0:48	0:40	1:25

1. Per BS EN ISO 80601-2-12 (201.12.1.104) test method

- Breathing circuit resistances are:

Breathing circuit model	Flow case (LPM)	Inspiratory Resistance (cmH_2O/LPM)	Expiratory Resistance (cmH_2O/LPM)
20011	5	0.03	0.06
40011	30	0.04	0.08
80011	60	0.01	0.04
80018	60	0.01	0.08

- Ventilation mode code cross reference:

TV-100 Mode Name	ISO 19223 Mode Group / Code
A/C (Assist/Control)	1b
CPAP	4b
NIV	1b
SIMV	2b
PRVC-AC	1b
nCPAP/HFNC	4
Apnea Detection	N/A
Standby Mode	N/A

7.6 EN 60601-1 Safety Ratings

- Class I grounded power supply
- Type BF
- IP Rating IP44 (First number 4 indicates protection against ingress by objects > 1 mm in size. Second number 4 indicates that water splashing against the enclosure from any direction shall have no harmful effect.)
- Continuous operation
- Not suitable for use with AP or APG (flammable anesthetic mixtures)

7.7 AC Adapters and Inverters

This section explains some of the requirements for connecting a Bio-Med Devices, Inc. TV-100 ventilator to an AC adapter. It is important that the correct AC adapter be used and if a TV-100 is to be used in a vehicle with an AC generating device (inverter), it must comply with certain requirements.

7.7.1 Land Operation

When using an AC adapter to either run the TV-100 or to charge the batteries, only the AC adapter supplied by Bio-Med Devices, Inc. should be used.

This AC adapter has been thoroughly tested for proper operation with the TV-100 to make sure that all standards are met. This includes all of the applicable standards for safety, EMI/RFI, power surges, and leakage.

Although other forms and brands of AC adapters may operate the TV-100, there is no guarantee of system reliability or conformance to required standards.

Should an emergency arise and it becomes necessary to operate the TV-100 without the Bio-Med Devices, Inc. supplied AC adapter, use only an AC adapter that is approved for medical use and complies with all applicable standards. It must produce filtered DC voltage ranging between 12 and 30 volts DC and be rated for continuous 5.0 amps with peak surge current of 15 amps for 5 mSec.

Should a TV-100 fail to operate or charge from an AC adapter, both the TV-100 and the AC adapter should be returned together to Bio-Med Devices, Inc. for evaluation.

7.7.2 Air Operation – Fixed or Rotary Wing Aircraft

The aircraft industry is constantly making technical advancements in the areas of composite material construction and weight reduction of installed equipment. Unfortunately, this can conflict with the safe operation of some electronic medical equipment. Composite materials do not work well as a grounding agent for electronic equipment. The weight reduction techniques used in AC inverters often create unsafe conditions when operating electronic medical equipment.

The TV-100 is designed to operate from an external power source delivering 12 to 30 volts DC at a continuous current of 5.0 amps with peak surge current of 15 amps for 5 mSec.

It is best to operate the TV-100 from the aircraft's 24-volt DC battery source, rather than an AC inverter. To ensure the best “grounding” between the TV-100 and the aircraft metal frame, connect the TV-100 directly to the 24-volt DC power bus through appropriate fusing. This will keep extraneous interference and current leakage to a minimum.

7.7.3 Inverter Operation

If it is necessary to operate the TV-100 from an AC inverter, similar to KGS Electronics brands, only those inverters in compliance with NEMA standards should be used. Inverters with “split winding” output transformers should not be used with the TV-100 and supplied AC adapter.

The inverter output must be configured like standard household or industrial wiring, where the black wire is “hot”, the white wire is “neutral”, and the green wire is “ground”. The neutral and ground wires should be connected together at one point of the frame so that there is no voltage between them, and there should be 115 volts AC between the hot and neutral wires.

The inverter receptacles must be of the standard three-prong configuration to utilize the hospital-grade cord of the Bio-Med Devices, Inc. supplied AC adapter. This will keep voltage surges, spurious noise and leakages to a minimum.

Any other type of AC/DC power supply or AC adapter, such as open frame devices, medically approved or not, is not recommended by Bio-Med Devices, Inc.

7.8 EMC Compatibility

7.8.1 Additional Guidance and Manufacturer's Declaration – Electromagnetic Emissions/Immunity

The TV-100 is compliant with relevant EMC requirements only when used with these cables and transducers:

- Bio-Med Devices' part # ESEN012 internal pressure transducer
- Bio-Med Devices' part # ESEN013 internal pressure transducer
- Bio-Med Devices' part # ESEN014 internal pressure transducer
- Bio-Med Devices' part # ESEN015 internal pressure transducer
- Bio-Med Devices' part # ESEN016 internal flow transducer
- Bio-Med Devices' part # ESEN017 internal pressure transducer
- Bio-Med Devices' part # A0066 internal oxygen cell cable 10" long (tip to tip)
- Bio-Med Devices' part # 5502 external power supply/charger with 6' intrinsic output cable and 8' IEC-320 input cable. Note: The TV-100 is compliant when run on its charged battery alone, but if it is run with the charger plugged in, the charger must be as specified above.
- Bio-Med Devices' part # EOVE011 touchscreen, tails extending 2" (includes header length)
- Bio-Med Devices' part # PRT5511 flat-ribbon cable extending 3" (for LCD)

7.8.1.1 Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in the following documentation.

7.8.1.2 Cables, Accessories or Transducers

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

7.8.1.3 Other Equipment

The TV-100 should not be used immediately adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the TV-100 should be observed to verify normal operation in the configuration in which it will be used.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TV-100, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Avoid exposure to known sources of EMI (electromagnetic interference) with medical devices such as magnetic resonance imaging MRI systems, diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors. Note that the presence of RFID devices may not be obvious.

7.8.1.4 Essential Performance

The TV-100 continues to function normally when exposed to the immunity testing described below.

- There was no change in operating mode
- There were no changes in delivered volume greater than 10% for individual breaths or averaged over one minute
- There was no cessation of operation
- There were no noises on pressure waveforms that would interfere with diagnosis or monitoring
- There was no unintended operation
- There was no change in default settings, programmable parameters or settings
- There were no hardware faults or component failures

Guidance and manufacturer's declaration – electromagnetic emissions		
The TV-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the TV-100 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The TV-100 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 emissions CISPR 11	Class B	The TV-100 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.
Harmonics emissions IEC 61000-3-2	Class A	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity		
The TV-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the TV-100 should assure that it is used in such an environment.		
Immunity test	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-2, 4, 8 kV contact +/-2, 4, 8, and 15 kV air	Floors should be wood, concrete or ceramic tile. If floors 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 +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line to line +/- 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TV-100 requires continued operation during power mains interruptions, it is recommended that the TV-100 be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.		

Electromagnetic Immunity		
The TV-100 is intended for use in the electromagnetic environment specified below. The customer or the user of the TV-100 should assure that it is used in such an environment.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 V rms i 10 V/m	The TV-100 is suitable for the electromagnetic environment of typical commercial or hospital settings.

The TV-100 was also tested for radiated immunity to RF wireless communication equipment at the test levels below.

Frequency (Hz)	Modulation	Level V/m
385	Pulse, 18 Hz, 50% DC	27
450	FM, 1 kHz Sine, ±5 Hz Deviation	28
710, 745, 780	Pulse, 217 Hz, 50% DC	9
810, 870, 930	Pulse, 18 Hz, 50% DC	28
1720, 1845, 1970	Pulse, 217 Hz, 50% DC	28
2450		28
5240, 5500, 5785		9

7.9 Device Lifetime & End-of-Life Disposal

The estimated device lifetime of this ventilator is ten years. This figure is based upon MTBF analysis of components. This does not mean that the ventilator must be removed from service at exactly ten years

of age; most parts will be replaceable in factory service. If the device ceases to function in specification, it should be returned to the factory for evaluation. Significant adverse usage events (e.g., unreasonable impact) might render the device beyond justifiable repair, for safety or financial reasons. Cease to reuse this device if out-of-spec operation is detected, or if physical signs of serious damage are noted (e.g., a cracked display, or fluid ingress inside the case).

To decommission the TV-100 Ventilator, the user may send it back to Bio-Med Devices for proper disposal and recycling of all applicable components. If this is not practical, the user may disassemble the device and recycle components using local recycling resources. It is recommended to separate out the brass, aluminum, other metals, circuit boards, wire harnesses, and batteries for respective recycling. The batteries are Lithium-Ion type. Please consider these potential hazards before attempting disassembly of the TV-100:

7.9.1 Disassembly Hazards (for service or EOL device disposal)

- Once the back case (A0018) is removed, the front case (A0021) is exposed. The copper finger strips (EGAS004 & EGAS005) installed around the edges of the front case can cut fingers and hands when handling the assembly.
- When replacing / removing the oxygen sensor, the area surrounding the sensor is covered by sharp metal edges of the bottom chassis (MBRA082) and is also close to the copper finger strips (EGAS004 & EGAS005) which can scratch and cut up fingers if not careful.
- When separating the front case (A0021) and the chassis assembly (A0020), sharp edges and corners on the battery box (A0043) can cause cuts and scratches. Careful handling of these parts should be taken in order to avoid severe scratches and cuts.
- Sharp corners and rugged edges on the front chassis (MBRA082) can also cause cuts and scratches.
- Sharp corners on the brackets (MBRA090 & MBRA091) can scratch and cut.
- Test points on the main board (EPCBA25) and the power board (EPCBA20) are exposed, so there is a possibility of getting pricked by the exposed header connectors. During cable and tube handling, one might contact any of these exposed headers.
- The connector ends on the charger board (EPCBA23) are sharp and exposed; these can be easily touched or brushed up against.
- The motor (MMOT001) and exhalation valve control module (PVAL057 - EVCM) can get hot enough for someone to get burned (assuming the device is disassembled immediately after usage, which is not advisable).
- The batteries may retain some stored energy, so the metal contacts should not be touched. These contacts should be covered with electrical tape after removing the batteries from the TV-100.

Addendum A

Additional Information per IEC 60601-1 & 60601-1-8 Standards

Device Shutdown Procedure: Press and hold down the power button until the unit displays the shutdown pop-up (2 seconds). Press the power off button to shut down the TV-100. Press the alarm button to silence the audible alarm.

In the event of power interruption or loss user set alarm limits will not be lost.

For interruptions of less than or equal to 30 seconds, the alarm settings before the power loss will be restored automatically.

The default manufacturer alarm settings are not accessible to users.

Expected device service life: 10 years

For schematics, component part lists, descriptions, test instructions, or other information that will assist service personnel to repair those parts of the TV-100 that are designated by Bio-Med Devices, Inc. as repairable by service personnel, please reference the TV-100 service supplement.