FLIGHT MEDICAL INNOVATIONS LTD.

FLIGHT 60 Ventilator

Operator's Manual

V60-00001-18 Rev.D

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CE 0483

Legal Notice

Disclaimer

FLIGHT MEDICAL INNOVATIONS LTD. (FLIGHT MEDICAL) provides this Operator's Manual in its commitment to help reduce patient risk and injury. However, this manual is not intended to in any way replace or substitute duty of care to a patient, professional responsibility, or professional judgment, nor is it intended to provide any warranty, promise, guarantee, assumption of risk or duty, release, or indemnity. Physicians shall at all times maintain responsibility for patient treatment and outcomes, and FLIGHT MEDICAL further assumes no liability for patient treatment or outcome or for physician's negligence, breach of duty of care, or malpractice.

The FLIGHT 60 Ventilator operator is solely responsible for selecting the appropriate level and method of patient monitoring.

Product modification or misuse can be dangerous. FLIGHT MEDICAL disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this ventilator with other products, whether supplied by FLIGHT MEDICAL or by other manufacturers, unless such a combination has been specifically endorsed by FLIGHT MEDICAL.

The design of FLIGHT 60 Ventilator, the Operator's and Service Manuals, and the labeling on the ventilator, take into consideration that the purchase and use of the equipment is restricted to trained professionals, and that certain inherent characteristics of the ventilator are known to the operator. Instructions, warnings, and caution statements are therefore limited to the specifics of the FLIGHT 60 Ventilator.

Federal law (US) restricts this device to sale by or on the order of a physician.

This Operator's Manual excludes references to various hazards which are obvious to medical professionals and operators of this equipment, to the consequences of product misuse, and to potential adverse effects in patients with abnormal conditions.

When the FLIGHT 60 Ventilator is used in homecare and subacute environments, only properly trained personnel should operate the ventilator. The FLIGHT 60 Ventilator is a restricted medical device designed for use by respiratory therapists or other properly trained and qualified personnel under the direction of a physician and in accordance with applicable state laws and regulations.

Transport of patients with the FLIGHT 60 Ventilator requires that medical staff have a good working knowledge of the ventilator's use and problem resolution. Proper emergency backup equipment must be immediately available during transport.

FLIGHT 60 Ventilator operators must recognize their responsibility for implementing safety monitoring mechanisms which supply appropriate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of means, such as electronic surveillance of equipment performance and patient condition. However, equipment surveillance should not replace direct observation of clinical signs.

The liability of FLIGHT MEDICAL is subject to and limited to the exclusive terms and conditions as set forth herein. Said liability is limited whether arising out of, or related to, the manufacture and sale of goods, their installation, demonstration, sales representation, use, performance, or otherwise. Any liability based upon product warranty is limited regardless of any fault attributable to FLIGHT MEDICAL and the nature of the action (including breach of warranty, negligence, and strict liability).

The written warranties are in lieu of all other warranties, expressed or implied, including, without limitation, warranties of merchantability, fitness for any purpose, or non-infringement.

FLIGHT MEDICAL shall not be liable for any special incidental or consequential damages incurred by the buyer to a third party. The buyer shall not be entitled to make liability recoveries from FLIGHT MEDICAL due to such situations.

Warranty

The FLIGHT 60 Ventilator warranty does not apply for/ in case of:

- Defects caused by misuse, mishandling, tampering, or by modifications not authorized by FLIGHT MEDICAL or its representatives.
- Rubber and plastic components and materials, which are guaranteed to be free of defects at time of delivery.

Any product which proves during the warranty period to be defective in workmanship or material, will be replaced, credited, or repaired. FLIGHT MEDICAL retains the discretion to select the most suitable of these options. FLIGHT MEDICAL is not responsible for deterioration, wear, or abuse. In all cases, FLIGHT MEDICAL will not be liable beyond the original selling price.

Application of this warranty is subject to the following conditions:

- FLIGHT MEDICAL or its authorized representatives must be promptly notified upon detection of the defective material or equipment.
- Defective material or equipment must be returned to FLIGHT MEDICAL or its authorized representative.
- Examination by FLIGHT MEDICAL or its authorized representatives must confirm that the defect is covered by the terms of this warranty.

The above is the sole warranty provided by FLIGHT MEDICAL. No other warranty, expressed or implied, is intended. Representatives of FLIGHT MEDICAL are not authorized to modify the terms of this warranty.

In no way does this or any of FLIGHT MEDICAL's policies, training materials, guidelines, or instructions create an obligation for FLIGHT MEDICAL to perform any services.

About this Document

This document contains information intended to ensure safe and effective use of the FLIGHT 60 Ventilator.

Chapters and Their Contents

Style Conventions

Convention	Used for
Verdana	Regular text.
Arial Bold	Names of menus, commands, buttons, and other elements of the user interface.
Arial Italics	Special terms, the first time they appear.
`Monospace`	Text entered by the user.
	**Notes,** which provide additional information intended to avoid inconveniences during operation. Notes also indicate important procedures to be followed.
 **CAUTION**	**Cautions**, which indicate possibility of equipment damage, if disregarded.
 **WARNING**	**Warnings**, which indicate possibility of personal injury to patient or others, if disregarded.

Table of Contents

1 Introduction

This Operator's Manual (V60-00001-18) contains information intended to ensure safe and effective use of the FLIGHT 60 Ventilator.

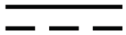
1.1 Intended Use

The FLIGHT 60 Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of individuals who require mechanical ventilation. Specifically, the FLIGHT 60 is applicable for adult and pediatric (i.e., infant, child and adolescent) patients, greater than or equal to 10kg (22 lbs).

The FLIGHT 60 Ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician; it is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications

1.2 Symbols

Symbol	Description
Front Panel	
	On/Off button
	Audio Paused
Rear Panel	
	Caution; consult accompanying documents
	Type BF applied part
	Temperature limitation
	Humidity limitation

Symbol	Description
	Atmospheric pressure limitation
	DC – Direct Current
	AC – Alternating Current
	USB – Universal Serial Bus
	LAN – Local Area Network

1.3 Overview

The FLIGHT 60 Ventilator is an electrically powered, microprocessor controlled ventilator with pressure support for spontaneous breathing. It can be pressure or time activated, volume or pressure limited, and time, pressure, or flow cycled. Backup ventilation is available, manual inflation is possible, and there is an emergency intake valve which allows the patient to pull ambient air into the patient circuit in the event of a complete loss of supply of gas pressure. Opening pressure is approximately –3 cmH2O (–3 mbar) during emergency intake.

The FLIGHT 60 Ventilator may be powered by external power (100-240 VAC or 12-15 VDC) or by its Li Ion internal batteries. Two internal Li Ion rechargeable batteries power the ventilator for up to 12 hours when fully charged.

The main component of the pneumatic system is an electrically controlled pump. This pump provides a compressed gas source so that no external air compressor is needed. Additionally, the exhalation valve is activated by an electrically controlled proportional solenoid.

Transport of patients with the FLIGHT 60 Ventilator requires that medical staff have a good working knowledge of the ventilator’s use and problem resolution. Proper emergency backup equipment must be immediately available during transport.

2 Safety Instructions

At all times, strictly follow this manual. The safe use of the FLIGHT 60 Ventilator requires full understanding of its operation, and adherence to the manual's instructions. The equipment is only to be used for the purpose specified in Section 1.1. Observe all of the WARNINGS and CAUTIONS posted in this manual, and on buttons found on the FLIGHT 60 Ventilator and associated accessories.

2.1 General Warnings


WARNING External power connection: To maintain grounding integrity when using AC power, only connect to hospital grade receptacles. Always disconnect the external power supply prior to servicing. There is a risk of explosion if used in the presence of flammable anesthetics.


WARNING All settings and adjustments in the different ventilation modes must be made in accordance with a physician's prescribed therapy.


WARNING Do not use electrically conductive patient circuits.


WARNING Always use a clean, disinfected patient circuit.


WARNING Always use an outlet filter or equivalent at the Airway Pressure Connector, to protect the internal transducers from moisture and other contaminants.


WARNING Always use appropriate monitors to ensure sufficient oxygenation and ventilation (such as pulse oximeter and/or capnograph) when the FLIGHT 60 Ventilator is in use on a patient.

WARNING The ventilator is ready for operation only when:

It is completely assembled.

The Quick Check Procedure, including the Exhalation Valve Calibration has been successfully completed.

WARNING Constant attention by qualified medical personnel is recommended whenever a patient is ventilated with the FLIGHT 60 Ventilator.

WARNING If a fault is detected in the ventilator and its life support functions are in doubt, immediately discontinue use; use an alternative method of ventilation until the fault has been corrected, and contact your provider or FLIGHT MEDICAL immediately.

WARNING Failure to identify and correct alarm violations may result in patient injury.

WARNING Ensure that the oxygen source is not empty before and during the use of the optional Air/Oxygen Entrainment Mixer or Oxygen Blending Bag Kit.

WARNING As Li-Ion batteries are charged and discharged over time, their ability to hold a charge is decreased with use. This can shorten the length of time the ventilator can function while on battery power.

WARNING The batteries should be replaced when the batteries no longer meet the needs of the user. This depends on a number of factors including settings and usage patterns.

WARNING When the FLIGHT 60 Ventilator is used for transport applications, ensure that the internal batteries are fully charged prior to use.


WARNING When the Battery Empty alarm sounds, only a limited amount of battery power remains, and an alternate power source should be found immediately.


WARNING Charge the batteries for a minimum of three hours before powering the ventilator from the batteries. This provides fully charged batteries.


WARNING During storage, charge the batteries for a minimum of three hours every 30 days. This provides charged batteries.


WARNING Always ensure that the green Ext. Power LED is illuminated after connecting the FLIGHT 60 Ventilator to an external AC or DC power source. If the LED is not illuminated, check all power connections and resolve any problems.


WARNING Always plug the FLIGHT 60 Ventilator into an AC power supply source when not in use, to ensure best battery performance.


WARNING The flow resistance of the air inlet filter, located on the right side of the ventilator, is likely to increase with repeated use. Ensure that the filter is changed regularly.


WARNING Only a FLIGHT MEDICAL approved patient circuit can be used with the FLIGHT 60 Ventilator.


WARNING Only a FLIGHT MEDICAL approved exhalation valve can be used with the FLIGHT 60 Ventilator.


WARNING Perform an exhalation valve calibration each time a circuit/exhalation valve is installed.


WARNING This FLIGHT 60 Ventilator has been tested and found to comply with EMC limits according to EN60601-1-1-2 standard class B. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving device.

Increase the distance between the equipment.

Connect the equipment into an outlet on a circuit different from that to which the device (s) is connected.

Consult the manufacturer for help.

2.2 Cautions


CAUTION Only use medical grade oxygen with the Air/Oxygen Entrainment Mixer or Oxygen Blending Bag Kit.


CAUTION Do not place liquid containers in the immediate vicinity or on top of the FLIGHT 60 Ventilator. Liquids that get into the ventilator can cause equipment malfunction and damage.


CAUTION An authorized FLIGHT MEDICAL factory-trained technician must do all service or repairs performed on the FLIGHT 60 Ventilator.


CAUTION Do not open the ventilator or perform service on an open unit while connected to external power.

Cautions

CAUTION Use standard antistatic techniques while working inside the ventilator or handling any electronic parts.

CAUTION Clean all external parts of the ventilator prior to servicing.

CAUTION Water in the oxygen supply can cause equipment malfunction and damage.

CAUTION Batteries contain Li-Ion. Do not discard them in an incinerator or force them open. Batteries should not be disposed of with normal waste.

Review FLIGHT 60 Ventilator Operator’s Manual before servicing the ventilator.

Use the tools and equipment specified in this manual to perform specific procedures.

3 Ventilator Description

3.1 Front Panel Features

The front panel contains the control buttons, visual indicators, display screen, and patient circuit connection.

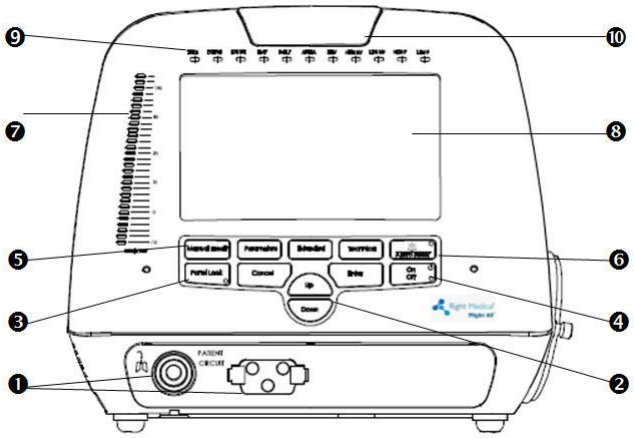


Figure 1 – Front Panel

Label	Name	Description
1	Patient Circuit Connector	Composed of a gas outlet and quick connector.
2	Up/Down button	Enables the user to scroll up and down the display controls.
3	Panel Lock button	Enables the user to lock the ventilator's control, preventing accidental changes. Pressing the button of a locked panel and then Enter, unlocks the panel.
4	On/Off button	Turns the ventilator on or off, to start or stop ventilation.
5	Manual Breath button	Delivers a user initiated manual inflation.
6	Audio Paused / Alarm Reset button	Toggle button. Pressing Audio Paused temporarily silences the audible alarm; pressing Alarm Reset clears latched alarm LEDs.
7	Pressure Gauge	The pressure gauge is a visual indicator of breath activity, which shows the dynamic movements of the breath pressures. When a breath is being delivered, the user can see the relative pressure and phase of the breath (inspiration or expiration). The pressure gauge is comprised of 29 LEDs. From -10 to +20 cmH2O, each notch equals 2 cmH2O; from 20 to 50 cmH2O, each notch equals 5 cmH2O; above 50 cmH2O, each notch equals 10 cmH2O.

Label	Name	Description
8	Display touch screen	Enables the user to modify the ventilation, alarm, and technical settings, and to view real time patient data, alarms, and logs.
9	LED Indicators	Inform the user of various events (see Section 3.1.1).
10	Primary Alarm LED	Flashes red to indicate that there is a high priority alarm.

3.1.1 LED Indicators

The LED indicators on the front panel inform the user of various events.

The following table describes the available LED indicators.

LED Indicator	Description
TRIG	Green LED indicates a patient's breathing effort.
EXT PWR	Green LED indicates that an external power source is being applied to the ventilator.
LOW BAT	Red LED indicates that detachable battery charge level has drop below 20%..
BAT	Orange LED indicates that the ventilator is powered on batteries.
FAULT	Red LED indicates a ventilator malfunction.
APNEA	Red LED indicates that the apnea alarm limit is being violated`
BUV	Red LED indicates that backup ventilation is active.
HIGH MV	Red LED indicates that the high minute volume alarm limit is being violated.
LOW MV	Red LED indicates that the low minute volume alarm limit is being violated.
HIGH P	Red LED indicates that the high peak airway pressure alarm limit is being violated.
LOW P	Red LED indicates that the low airway pressure alarm limit is being violated.

3.2 Back Panel Features

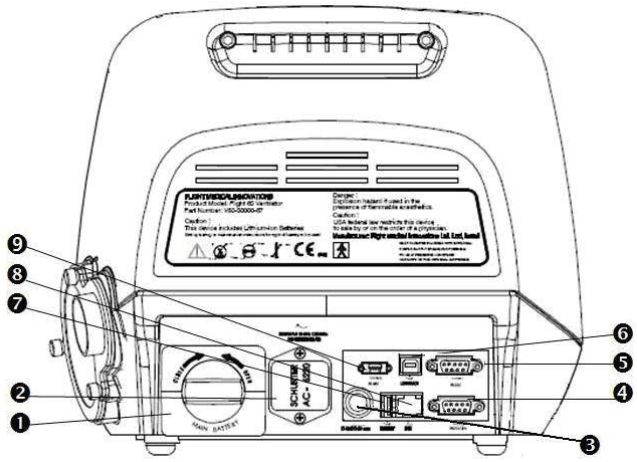


Figure 2 – Back Panel

WARNING To ensure proper grounding and prevent possible shock hazards, this device should only be connected to grounded power receptacles.

WARNING HOME CAREGIVERS: External power in the home environment must support min. 100 to max. 240 V AC, and must have a grounded receptacle.

Label	Name	Description
1	Detachable Battery	
2	AC Connector with Fuses	100 – 240 V AC, 50 – 60 Hz, Fuses 2x8A (time lag)
3	DC Connector	12 – 15 V DC
4	RS-232 Serial Port (COM2)	Remote alarm connector (Normally Open and Normally Closed options).
5	RS-232 Serial Port (COM1)	Online output of events and error messages to the PC, using a dedicated PCS2 protocol; for authorized and qualified service technicians only.
6	USB B type	PC connector: USB port for downloading the main application from the PC using a dedicated PCS2 protocol; for authorized and qualified service technicians only.
7	USB A type	USB port for uploading LOG files to an external memory stick; for authorized and qualified service technicians only.

Label	Name	Description
8	LAN (RJ45)	LAN for network logging (currently not available).
9	Mini RS-485 (COM3)	For connecting FLIGHT MEDICAL peripherals. For future use.

3.3 Left Side Panel Features

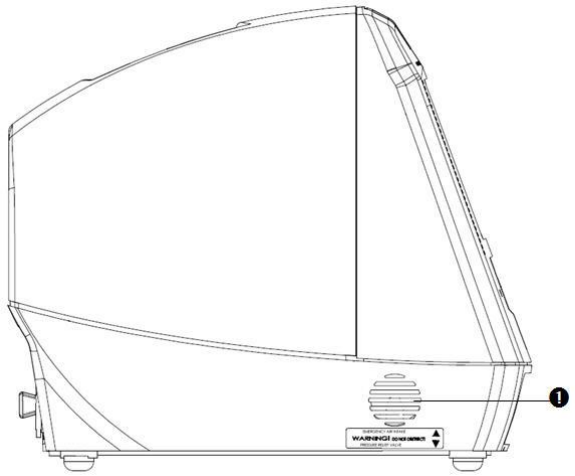


Figure 3 – Left Side Panel

Label	Name	Description
1	Emergency Air Intake	Enables the patient to pull ambient air into the patient circuit in the event of a complete system failure. The Air Intake opening pressure is approximately -3 cmH2O (-3 mbar).

WARNING Do not obstruct the Emergency Air Intake! Any impediment can result in patient suffocation.

WARNING HOME CAREGIVERS: Should a complete failure of the ventilator occur, the Emergency Air Intake allows the patient to breathe from room air through the intake valve. Blockage of the valve can result in suffocation.

3.4 Right Side Panel Features

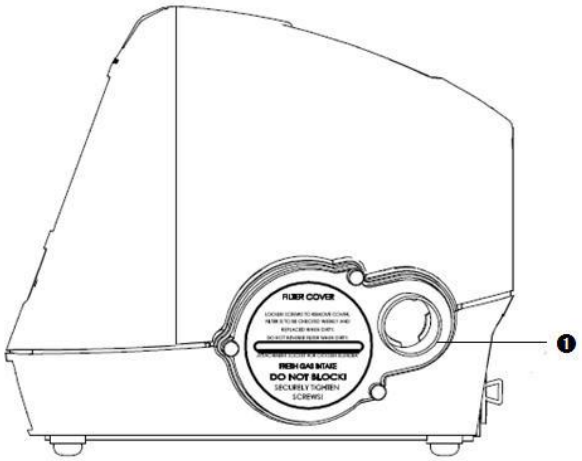


Figure 4 - Right Side Panel

Label	Name	Description
1	Fresh Gas Intake and Filter Cover	Environmental air enters through this 30 mm ID Fresh Gas Intake. The air inlet particle filter is placed behind the Filter Cover to protect the patient as well as the ventilator's piston system from dirt and particles. The Fresh Gas Intake also serves as the attachment socket for the optional FLIGHT 60 Ventilator Air/Oxygen Entrainment Mixer or Oxygen Blending Bag.

WARNING Do not block the Fresh Gas Intake.

3.5 LCD Screens

The LCD screen of the FLIGHT 60 Ventilator is divided into three sections:

- Alarm and power management area – the top section of the screen (see Section 3.5.1).
- Patient monitoring area – the middle section of the screen (see Section 3.5.2).
- Control area – the bottom part of the screen; it can display the main parameters, extended parameters, or technical parameters (see Section 3.5.3).

3.5.1 Alarm and Power Management Area

The Alarm and Power Management area displays the following:

- Alarms and Cautions – Left side of this area. Up to three alarms (alarm messages) and/or cautions are displayed, according to their priority.
- Battery icons – Right side of this area. Battery icons show:
  - Battery capacity (%)
  - Color – Green battery icon indicates that there is sufficient capacity; orange indicates low capacity.
  - Arrows – Up arrows on the battery icon indicate that batteries are charging; down arrows indicate that the batteries are depleted.

3.5.2 Patient Monitoring Area

Patient monitoring parameters are displayed at all times on the Parameters, Extended, and Technical screens, to ensure continuous monitoring of the patient during ventilation.

The following table describes the patient monitoring parameters.

Name	Description	Range	Resolution	Updated
P Peak	Peak Inspiratory Pressure	0 to 99 cmH2O	1 cmH2O	Breath by breath
P base	Baseline airway pressure at the end of expiration	0 to 99 cmH2O	1 cmH2O	Breath by breath
P mean	Mean airway pressure	0 to 99 cmH2O	1 cmH2O	10 seconds rolling average
Vte	Expiratory Tidal Volume	0 to 9.99 L	10 ml	Breath by breath
Vti	Inspiratory Tidal Volume	0 to 9.99 L	10 ml	Breath by breath
MVe	Expiratory Minute Volume	0 to 99.9 L/min	1 L/min	10 seconds rolling average
MVi	Inspiratory Minute Volume	0 to 99.9 L/min	1 L/min	10 seconds rolling average
Actual f	Total number of patient or time activated breaths	99 b/min	1 b/min	Breath by breath
I:E	I:E Ratio	1:99 to 3:1		
	Note: I:E Ratio is determined by the f and Ti settings. If the expiratory time is longer than the inspiratory time, the display format is 1:X.X. If the expiratory time is shorter than Ti, the display format is X.X:1.			

Name	Description	Range	Resolution	Updated
PIF	Peak Inspiratory Flow	6 to 100 L/min	1 L/min	Breath by breath
FiO2	Fraction of Inspired Oxygen	21% to 100% O2	1%	Every 10 seconds

3.5.3 Control Area

Parameters Screen

Pressing the Parameters button switches over to the main settings screen. This is the default screen in standby and ventilation mode. The display always switches back automatically to Parameters from the Extended or Technical settings display.

Figure 5 – Parameters Settings

Button	Description
Ptrig	Used to determine the pressure trigger level (trigger sensitivity) in terms of how far the airway pressure must drop below the set baseline pressure in order for a patient's spontaneous efforts to be detected. Range: -0.1 to -9.9 cmH2O/mbar Resolution: 0.1 cmH2O/mbar
PEEP	Used to establish a baseline positive airway pressure in the patient circuit during the exhalation phase. Range: 0, 3 to 30 cmH2O/mbar Resolution: 1 cmH2O/mbar

Button	Description
PSV	Used to determine the level of support in pressure during inspiration, for patient triggered spontaneous breaths. Range: 0 to 60 cmH2O/mbar Resolution: 1 cmH2O/mbar
f	Used to set the frequency of breaths. In ACMV mode, it determines the number of time-triggered breaths; in SIMV mode, it determines the total number of mandatory breaths. Range: 1 to 99 b/min Resolution: 1 b/min
FLOW	Used to set the mandatory flow (volume control). This control button appears only if FLOW is selected in the Ti/FLOW control button on the extended parameters screen. Otherwise, the Ti button appears (see button below). Range: 6 to 100 L/min Resolution: 1 L/min
Ti	Used to set the inspiratory time for mandatory breaths (volume or pressure control). This control button appears only if Ti is selected in the Ti/FLOW control button on the extended parameters screen. Otherwise, the FLOW button appears (see above button). Range: 0.1 to 3.0 seconds Resolution: 0.1 seconds
VCV	Used to set the mandatory tidal volume for the VCV submode. Range: 0.1 to 2.2 L Resolution: 0.01 L
PCV	Used to set the target pressure for the PCV submode. Range: 5 to 60 cmH2O/mbar Resolution: 1 cmH2O/mbar
LOW P	Used to set the minimum allowed pressure of a mandatory breath. Range: 3 to 98 cmH2O/mbar Resolution: 1 cmH2O/mbar
HIGH P	Used to set the maximum allowed pressure value of a mandatory breath. Range: 4 to 99 cmH2O/mbar Resolution: 1 cmH2O/mbar

Button	Description
LOW MV	Used to set the minimum Minute Volume allowed for a patient. Range: 0.0 to High MV – 1 Resolution: 0.1 L
HIGH MV	Used to set the maximum Minute Volume allowed for a patient. Range: Low MV + 1.0 to 50 Resolution: 0.1 L
MODE	Used to select the ventilator mode. Available options: **ACMV** (Assist/Control Mandatory Ventilation) **SIMV** (Synchronized Intermittent Mandatory Ventilation) **SPONT** (Spontaneous Ventilation)
PCV/VCV	Used to select the ventilator submode. Available options: **PCV** (pressure control ventilation) **VCV** (volume control ventilation)

Extended Screen

Pressing the Extended button switches over to the extended settings screen.

Figure 6 – Extended Settings

Button	Description
Buzzer	Used to set the alarm buzzer volume. Available options: **HIGH** and **LOW**

Button	Description
PowerSave	Used to activate/deactivate the power saving system in the AC and DC supply. When activated, the screen turns Off and the pressure gauge displays one LED only to indicate the peak pressure.
Waveform	Used to select the type of waveform: **Square** - the flow stays constant during the inspiratory phase **Descend** - the flow descends linearly until the final flow (at the end of inspiration) and is 50% of the peak flow. (Peak flow is calculated based on the tidal volume and inspiratory time.) This option is enabled only in VCV mode.
Apnea Interval	Used to set the maximum allowed time of apnea.
Ti/Flow ctl.	Used to specify whether the Inspiratory Time or the Flow criteria will stay constant during Volume Controlled management.
Rise Profile	Used to set the rise level that the system will deliver. Available levels are **1** (the fastest) to **5** (the slowest). This option is enabled only in PCV and PSV modes.
PSV Flow Term	Used to set the expiratory trigger from 10% to 70% of the peak flow. This option is enabled only in PSV mode.
PSV Ti	Used to control and limit the inspiratory time in Pressure Support Ventilation from 0.1 to 3 seconds.
FiO2	Used to activate or deactivate O2 enrichment monitoring. Activating FiO2 displays the FiO2 value on the screen; deactivating it turns the display off.
FiO2 Low	Used to define the low value of oxygen in the ventilator air mixture that sets off the alarm. The low value can be set to any value between OFF (min value 21%) and FiO2 High minus 10. Enabled only when FiO2 is activated (ON).
FiO2 High	Used to define the high value of oxygen in the ventilator air mixture that sets off the alarm. The high value can be set to any value between FiO2 Low plus 10 to OFF (max value 100%). Enabled only when FiO2 is activated (ON).

Technical Screen

Pressing the Technical button switches over to the technical settings screen.

Figure 7 – Technical Settings

Button	Description
Press Units	Used to determine in which units the pressure is displayed on the ventilator. Available options: **cmH2O** and **mbar**
LOW P Spont	Used to activate/deactivate the low-pressure alarm in SPONT mode.
Language	Used to select the display language of the ventilator.
Show Info	Used to display the following system information: **Unit Serial Number**, **Software Version**, **Compressor Serial Number**, **Hour Meter**, and **Next Service**.
Valve CAL	Used to enter the patient circuit exhalation valve calibration process.
Set Load	Used to load a ventilation configuration that has been predefined in the ventilator.
Set Save	Used to save a ventilation configuration in the ventilator, for later use; up to five configurations can be saved.
Set Clock	Used to set the system time and date, for logging purposes.
Show Log Alarm	Used to display the alarms that have occurred, by date, time, and type.
Show Log Change	Used to display the changes that have been made to the ventilator states, modes, and settings. These changes are displayed by date, time, type, and values.
Goto More…	Used to access the advanced technical menu. This function is available to authorized and qualified service technicians. Please refer to the Service Manual.

3.6 Accessories

3.6.1 Air/Oxygen Entrainment Mixer

The Air/Oxygen Entrainment Mixer is used to blend atmospheric air with medical grade oxygen at a precise ratio. A control knob allows for incremental adjustment from 21% to 100% FIO2. The high pressure oxygen hose has a standard female DISS 1240 connection. The Mixer attaches to the Fresh Gas Intake of the FLIGHT 60 Ventilator on the Filter Cover, located on the right side of the ventilator.

Pneumatic Requirements: Oxygen 35-90 psig (2.4 to 6.2 Bar)

Figure 8 - High Pressure Oxygen Mixer

3.6.2 Oxygen Blending Bag Kit

The Oxygen Blending Bag Kit is used to blend atmospheric air with a low flow (0 to 10 L/min) medical grade oxygen source. The Oxygen Blending Bag Kit attaches to the Fresh Gas Intake on the Filter Cover, located on the right side of the ventilator. This system allows the user to ventilate patients with oxygen enriched gas from 21% to 100% FiO2.

Pneumatic Requirements: Oxygen 0-10 L/min

Figure 9 - Low Pressure Oxygen Blending Bag

4 Installation

4.1 Introduction

Familiarize yourself with the instructions in this section prior to ventilator's installation. Following all of the listed steps is essential for ensuring the safest possible operation of the ventilator. Use the information in this section in conjunction with established hospital protocols and homecare dealer instructions.


WARNING Only properly trained personnel should install the ventilator.

4.2 Removing the Ventilator Parts from the Box

Before installing the ventilator, familiarize yourself with the various components. Remove all of the items from the shipping box and inspect each part and component for completeness and verify that there is no shipping damage.

The complete assembly consists of the following parts:

- FLIGHT 60 Ventilator
- Operator's Manual
- AC Power Cord
- Patient Circuit – Single Patient Use
- Air Inlet Filter (pk. Of five filters)
- Detachable Battery (Main)
- Integral Battery (Secondary)

4.3 Mounting the Ventilator

➔ **To mount the ventilator:**

1. Mount the ventilator on a stable surface (e.g., bedside table or the Roll Stand Assembly).

2. To mount the ventilator on the Roll Stand Assembly, follow the instructions provided with the assembly; position the ventilator on a pedestal mount and then secure it using the screws provided.

4.4 Installing the Detachable Battery

➔ **To install the detachable battery:**

1. Insert the detachable battery into the ventilator.
2. Plug Turn the lock dial clockwise, in the direction of the CLOSE arrow, until it is firmly locked.

Figure 10 – Installing the Detachable Battery

4.5 Plugging in the Power Cord (for AC)

➔ **To plug in the power cord:**

1. Plug the AC power cord into the power entry connector.
2. Plug the ventilator's electric cord into a properly grounded outlet.

   The ventilator is now in STANDBY mode. The EXT PWR LED is illuminated, and the batteries begin recharging.

Figure 11 – Plugging in the Power Cord

4.6 Attaching the Patient Circuit

The following procedure describes how to attach a patient circuit to the ventilator. When the complete circuit is changed.

➔ **To attach the single limb patient circuit:**

1. Attach the quick connector to its socket on the front panel and tightly secure.
2. Attach the 22 mm ID patient circuit to the Gas Output on the front panel.
3. If using with an HME, attach the HME to the flow orifice.

Figure 12 - Patient Circuit (Quick Connector)

Figure 13 - Patient Circuit (22 mm Tube)

➔ **To attach the dual limb patient circuit:**

1. Attach the quick connector to its socket on the front panel and tightly secure.
2. Attach the 22 mm ID inspiratory limb to the Gas Output on the front panel.
3. If using with an HME, attach the HME to the flow orifice.
4. Place the exhalation valve diaphragm inside the exhalation valve base with its holding tip facing forward.
5. Press the exhalation valve cover to its base. Rotate the exhalation valve cover 1/4 turn clockwise to secure it into place. Verify the secure pin in place.
6. Attach the 22 mm ID expiratory limb to the exhalation valve on the front panel.
7. To detach the exhalation valve cover, press the pin and rotate the exhalation valve cover 1/4 turn counter clockwise

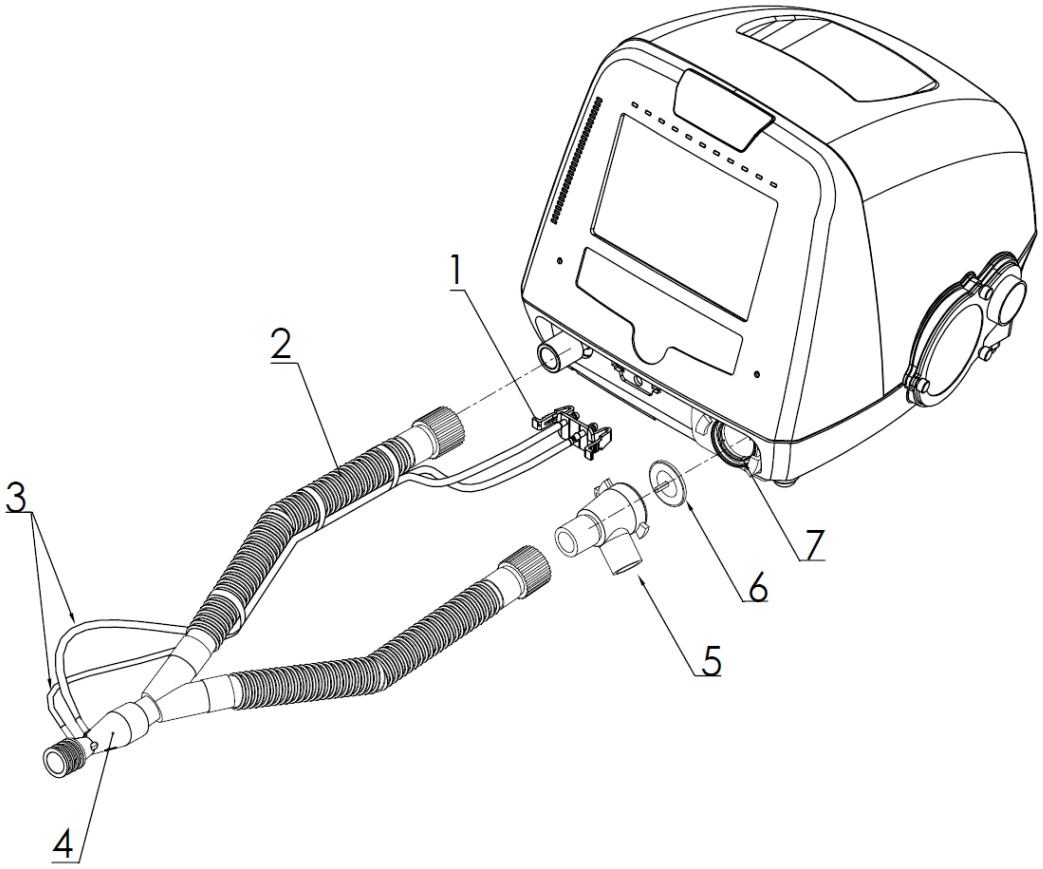


Figure 14 – Dual Limb Patient Circuit

1. Quick Connector
2. Inspiratory Limb
3. Flow Transducer Lines
4. Flow Orifice
5. Exhalation Valve Cover
6. Exhalation Valve Diaphragm
7. Exhalation Valve Base

CAUTION Single use Exhalation Valve Diaphragm is intended for use for a maximum of 7 days.

4.7 Installing Oxygen Accessories

Two optional oxygen accessories can be attached to the FLIGHT 60 Ventilator:

- The Air/Oxygen Entrainment Mixer

- The Oxygen Blending Bag Kit


WARNING Ensure that the oxygen source is not empty before and during the use of Air/Oxygen Entrainment Mixer or Oxygen Blending Bag Kit.

4.7.1 The Air/Oxygen Entrainment Mixer

An optional Air/Oxygen Entrainment Mixer (p/n V13-00010-60) is designed for use with the FLIGHT 60 Ventilator. It is used to blend atmospheric air with pressurized medical grade oxygen at a precise ratio. The standard oxygen inlet connection is DISS 1240.

The Air/Oxygen Entrainment Mixer specifications are described in the following table.

Feature	Specification
Flow Range	Up to 100 L/min
FIO2	21% to 100%
Accuracy	±8% (at flows: 10-100 L/min)
Input Pressure – Oxygen	35-90 psig/240-620 kPa


WARNING The oxygen concentration to the patient should be monitored. Set the FiO2 alarm limit to ±10% from the set oxygen concentration. Perform O2 sensor calibration after replacing the sensor.


WARNING The Air/Oxygen Entrainment Mixer is designed to operate with a hospital grade O2 supply.


No oxygen is delivered through the Air/Oxygen Entrainment Mixer while the FLIGHT 60 Ventilator is in Standby or Settings mode.

Figure 15 - Air/Oxygen Entrainment Mixer

Installing the Air/Oxygen Entrainment Mixer

The Air/Oxygen Entrainment Mixer attaches into the inlet port on the Filter Cover, located on the right side of the ventilator.

WARNING Make sure to monitor the state of the air inlet filter, and when necessary replace it to ensure that it is clean when using the Mixer.

Before attaching the Air/Oxygen Entrainment Mixer, make sure that the three hold-down screws on the Filter Cover are tight. If the screws are not tight, ambient air may enter the FLIGHT 60 Ventilator from around the inlet cover. This may change the oxygen enrichment level delivered to the patient when the Mixer is in use.

➔ **To Install the Air/Oxygen Entrainment Mixer:**

1. Unscrew the three thumb screws on the Filter Cover from the ventilator housing.
2. Remove the Filter Cover and inspect the filter. Replace the filter, if it is dirty.
3. Reattach the Filter Cover, ensuring that the three thumb screws are tight.

Figure 16 – Inspect Filter

4. With the oxygen hose facing toward the front of the ventilator, press the 30 mm OD outlet of the Mixer into the Attachment Socket (Fresh Gas Intake port) of the FLIGHT 60 Ventilator Filter Cover. Rotate the mixer 1/4 turn clockwise to secure it into place.
5. Connect the oxygen hose DISS fitting to the oxygen supply and secure the fitting.
6. Open the supply pressure valve slowly and listen to verify that there is no hiss, indicative of a leak. Do not use the oxygen mixer with a leak in the system.
7. Set the entrainment mixer dial to the desired concentration.

WARNING Ensure that the oxygen supply is enabled prior to powering on the FLIGHT 60 Ventilator and after the Air/Oxygen Entrainment Mixer is secured in place. Otherwise, stress to the internal pump will occur and gas delivery to the patient will be compromised.

Figure 17 - Air/Oxygen Entrainment Mixer Installation

4.7.2 The Oxygen Blending Bag Kit

The Oxygen Blending Bag Kit is designed for use with the FLIGHT 60 Ventilator. The Oxygen Blending Bag Kit (p/n V17-00001-67) allows the operator to ventilate patients with oxygen enriched gas of up to 100% oxygen.

The Oxygen Blending Bag is not a calibrated mixing device. The level of oxygen enrichment achieved is affected by these variables: minute volume, oxygen supply flow, and the presence or absence of PEEP.

After identifying the level of oxygen enrichment that the patient needs, use the graphs in Figure 20 and Figure 21 to estimate how many liters per minute of oxygen are needed for the minute volume delivered to the patient. Verify FiO2 delivery with the oxygen monitor.

WARNING The Oxygen Blending Bag Kit is designed to operate with a hospital grade O2 supply. The flow rate of the supply to the oxygen blending bag should not exceed 10 L/min flow.

WARNING Using an oxygen concentrator as the oxygen supply source may affect the level of oxygen enrichment, as in most cases oxygen concentrators do not supply 100% oxygen. Use the FLIGHT 60 Ventilator oxygen monitor to verify FiO2 delivery.

WARNING Any change in settings or any change in patient assisted breathing patterns that alters the delivered minute volume, will alter the level of oxygen enrichment.

Figure 18 - Oxygen Blending Bag Kit

Installing the Oxygen Blending Bag Kit

The Oxygen Blending Bag Kit attaches into the Fresh Gas Intake port on the Filter Cover, located on the right side of the FLIGHT 60 Ventilator.

The following materials are required for Installation:

- Hospital grade oxygen source
- Oxygen 50 psig regulator/flow meter (0-10 L/min) assembly with small-bore connector
- A suitable length of oxygen supply tubing

➔ **To install the Oxygen Blending Bag Kit:**

1. Remove the three thumb screws from the Filter Cover.
2. Remove the Filter Cover and inspect the filter. Replace the filter, if it is dirty.
3. Reattach the Filter Cover, ensuring that the three thumb screws are tight.

Before attaching the Oxygen Blending Bag, make sure that the three hold-down screws on the Filter Cover are tight. If the screws are not tight, ambient air may enter the FLIGHT 60 Ventilator from around the inlet cover. This may change the oxygen enrichment level delivered to the patient when the Oxygen Blending Bag is in use.

4. Press the 30 mm OD outlet of the Oxygen Blending Bag Kit into the Fresh Gas Intake port of the FLIGHT 60 Ventilator Filter Cover.
5. Attach the oxygen supply tubing to the oxygen flow meter and to the small-bore connector of the Oxygen Blending Bag Kit.

WARNING Keep the oxygen supply tubing (and cylinder) away from traffic areas.

6. Tug lightly on both ends of the tubing to verify that it is secure.
7. Adjust the oxygen flow meter to the appropriate liter-flow to obtain the desired level of oxygen enrichment.
8. Monitor regularly the patient's inspiratory minute volume and delivered FiO2, and adjust the oxygen liter flow as necessary to maintain the prescribed level of oxygen enrichment.

Figure 19 - Oxygen Blending Bag Kit Installation

Disassembling and Cleaning the Oxygen Blending Bag Kit

For information on disassembly and cleaning, see the instructions included with the Blending Bag Kit or see Chapter 7.

Monitoring the Oxygen Supply Flow in the Oxygen Blending Bag

The following graphs can be used to determine the required oxygen supply flow for the patient. There are two graphs – the first one is for when there is no PEEP; the second is for when PEEP is added.

The oxygen supply flow of the Oxygen Blending Bag Kit is determined according to the desired percent of oxygen enrichment as well as the minute volume of the patient.

CAUTION The oxygen blending bag is not a calibrated oxygen mixing device. It requires the use of oxygen monitoring, to verify the level of oxygen enrichment. The information in these graphs should be used as a reference only.

➔ **To use the graphs:**

1. Select the appropriate graph, based on whether you are ventilating with or without PEEP.
2. Select the Desired % of Oxygen Enrichment listed at the bottom of the graph.
3. Follow your selection up vertically until it meets with the line that is equal to the minute volume of the patient (i.e. flow 10 L/min).

The patient's delivered minute volume can be read from the display.

4. Move horizontally to the left and identify the estimated oxygen supply flow (L/min) needed.
5. Set the flow meter to the oxygen supply flow indicated.

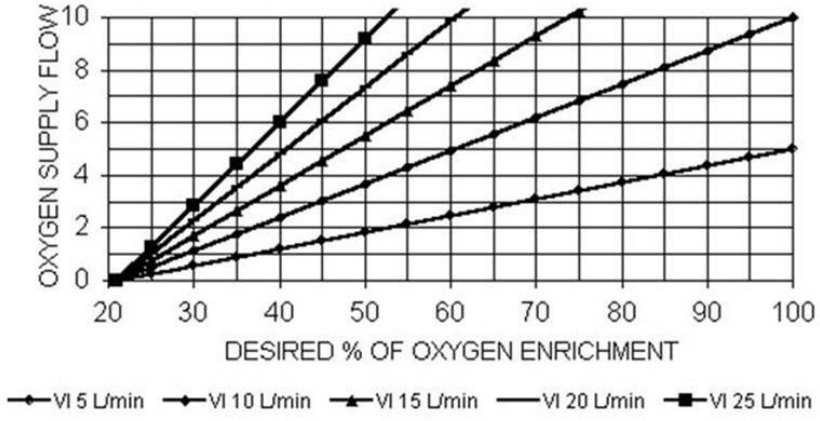


Figure 20 - Oxygen Supply Flow for Desired % of Oxygen Enrichment – Without PEEP

When PEEP is added, it changes the mixing of oxygen with air. Use the chart in Figure 20 when the patient is ventilated without PEEP; use the chart in Figure 21 in the presence of PEEP. Data in the chart in Figure 21 are taken at an I:E ratio of 1:2. Different I:E ratios may slightly affect the Desired % of Oxygen Enrichment when PEEP is in use.

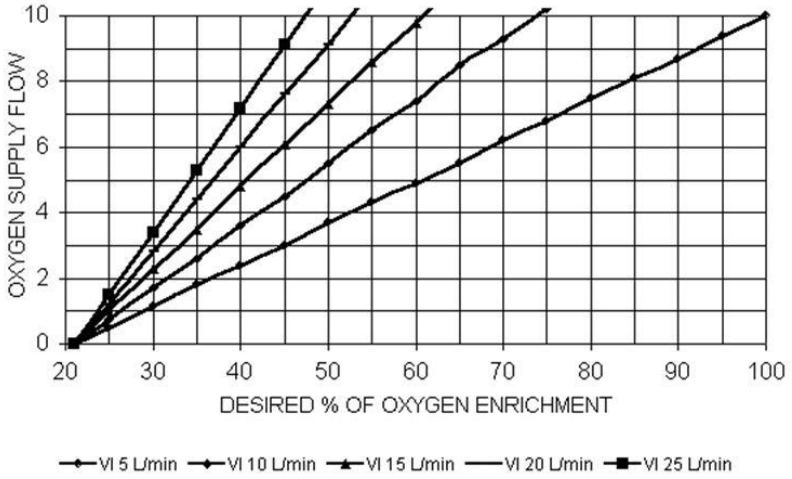


Figure 21 - Oxygen Supply Flow for Desired % of Oxygen Enrichment with PEEP

5 Using the Ventilator

Familiarize yourself with the instructions in this section prior to ventilating patients with the FLIGHT 60 Ventilator. Following all of the listed steps is essential for ensuring the safest possible operation of the ventilator. Use the information in this section in conjunction with established hospital protocols and homecare dealer instructions.


WARNING Only properly trained personnel should operate the ventilator. The FLIGHT 60 Ventilator is a restricted medical device designed for use by Respiratory Therapists or other properly trained and qualified personnel under the direction of a physician and in accordance with applicable state laws and regulations.

5.1 Basic Operation

5.1.1 Powering On the Ventilator


CAUTION Review all of the General Warnings and Cautions in Chapter 2 prior to using the ventilator.

The FLIGHT 60 Ventilator can be used either with an AC (external) or DC (internal batteries) power source.


Before using the ventilator, **either with AC or DC** power source, ensure that the internal batteries are fully charged.

➔ **To turn on the ventilator:**

1. Press the **On/Off** button.

   The ventilator performs a brief self-test to ensure proper microprocessor function. During the self-test, verify that all indicator LEDS illuminate.

   The display activates and the ventilator purges, to clean the set of flow transducer tubes and the flow orifice while alarm buzzer emits a single beep.

   Following the self-test, the ventilator enters SETTINGS mode; in this mode, all settings are available and the display screen is activated. In SETTINGS mode, you can adjust the ventilation parameters; however, the FLIGHT 60 Ventilator does not ventilate and the On indicator does not illuminate.

5.1.2 Turning Off the Ventilator

➔ **To shut down the ventilator:**

1. On the ventilator front panel, press the On/Off button.

   The system pops up a message: "Are you sure you want to shut down? To shut down, press the On/Off button for 3 seconds ".

   The On/Off button LED blinks to indicate another 3-second press is expected.

2. Press the On/Off button for three seconds, within five seconds of receiving the pop-up message.

   The Ventilator shuts down, and the LED turns off.

   You can press the Silence button to mute the audible alarm.

When operating with a battery, the ventilator turns itself off automatically after the system has been in SETTINGS mode for five minutes, and during this time no keys have been touched.

5.1.3 Navigating Between Screens

Navigation between screens is performed using the keypad buttons: **Parameters**, **Extended**, and **Technical**.

Ventilation can be turned On and Off from the Parameters screen only.

5.1.4 Setting Control Values

Each of the three screens (Parameters, Extended, and Technical) has a set of control buttons. You can adjust the values of the control buttons in any of the three screens in a similar fashion.

➔ **To adjust control values:**

1. Select the parameter by pressing the relevant control button (for example: *f*, Ti, or P trig).

   The control button's color changes from gray to orange, indicating that its value is enabling for adjustment.

2. Adjust the numeric value using the **Up/Down** buttons.
3. Accept the value by doing one of the following:

   - Press the selected button again (restores the button's color to gray).

- Press **Enter**.
- Press another control button to select a new parameter for adjustment.
- Wait five seconds without making a change.

Default and Saved Values

When the device is brought up for the first time, it uses a set of default values for all of its parameters and settings. After changing the settings, the new values are saved in the system's nonvolatile memory for further usage. The newly set values persist until the device is reset (by a certified technician only); this means that stopping the device, turning it off, or disconnecting it from all power sources does not affect the parameter values.

5.1.5 Delivering a Manual Breath

Pressing the **Manual Breath** button delivers an operator initiated manual inflation. However, the Manual Breath button does not initiate an inflation, if the patient is currently in the inspiratory phase of a breath, or if the airway pressure is > 5 cmH2O (mbar) above the set PEEP level. Manual Breath delivers the set flow rate (in Volume Control) or the set target pressure (in Pressure Control); however, inspiratory time is controlled by the user.

During Manual Breath, the breath is terminated if any of the following occurs:

- The Manual Breath button is released.
- The High Pressure alarm is violated.
- Three seconds have elapsed.

Manual Breath is only available in ACMV and SIMV modes.

Manual Breath may be prematurely cycled off in the first several breaths in Pressure Control, when the initial flow has not yet been optimized.

5.1.6 Locking the Panel

➔ **To lock the panel:**

1. Press the **Panel Lock** button twice within five seconds.

The LED turns on. All buttons are disabled for adjustment, except for the Audio Paused/Alarm Reset button.

➔ **To unlock the panel:**

1. Press the **Panel Lock** button once and then press the **Enter** button.

   The Panel Lock button is deactivated.

5.1.7 Canceling Parameter Adjustments

To reject adjustments of parameters, limits, and controls, press the **CANCEL** button before the setting button is fixated (button's color changes from orange to gray).

5.1.8 Accepting Parameter Adjustments

To accept adjustments of parameters, limits, and controls, press the **ENTER** button.

5.1.9 Changing Parameter Value (Up/Down Button)

The Up/Down control buttons are used for parameter adjustment. Select the desired parameter by tapping its touch button once. Press the **Up** control button to increase the parameter value, or the **Down** control button to decrease the parameter value.

5.2 Setting the Main Parameters

5.2.1 Mode of Operation

The **MODE** control button enables you to switch the ventilator between the following operational modes:

- **ACMV** (Assist/Control Mandatory Ventilation)
- **SIMV** (Synchronized Intermittent Mandatory Ventilation)
- **SPONT** (Spontaneous Ventilation)

ACMV Mode

In ACMV mode, time activated (mandatory) breaths are delivered in accordance with the *f* setting. Patients can trigger mandatory breaths in addition to, or in place of, time activated (mandatory) breaths, if the effort that they generate causes airway pressure to meet the Ptrig setting. Each such patient effort results in a mandatory breath. The breath can be volume or pressure controlled. PEEP may be added. Tidal volume is determined by the target pressure, Ti, patient respiratory mechanics in Pressure Control, and by the tidal volume setting in Volume Control.

As with all FLIGHT 60 Ventilator operating modes, Backup Ventilation is activated if the Apnea alarm limit is violated.

In **A/CMV** mode, the **PSV**, **PSV Flow Term** and **PSV Ti** control buttons are not utilized and are therefore darkened. However, they remain adjustable.

SIMV Mode (Synchronized Intermittent Mandatory Ventilation)

In SIMV mode, patients receive a fixed number of volume or pressure controlled mandatory breaths (time or patient activated) and may breathe spontaneously between mandatory breaths, with or without pressure support (PSV). See Figure 22 for a schematic illustration. PEEP may be added.

The first patient triggered breath in any mandatory breath interval is a patient triggered mandatory breath. The patient has the rest of the interval to breathe spontaneously. If the patient does not trigger the ventilator, and one complete mandatory breath interval has elapsed, a time triggered mandatory breath is delivered.

A mandatory breath lockout interval is activated whenever the patient triggers a mandatory breath. This limits the number of mandatory breaths (time triggered or patient triggered) that the patient receives in 60 seconds, to the *f* (b/min) setting.

As with all FLIGHT 60 Ventilator operating modes, Backup Ventilation is activated if the Apnea alarm limit is violated.

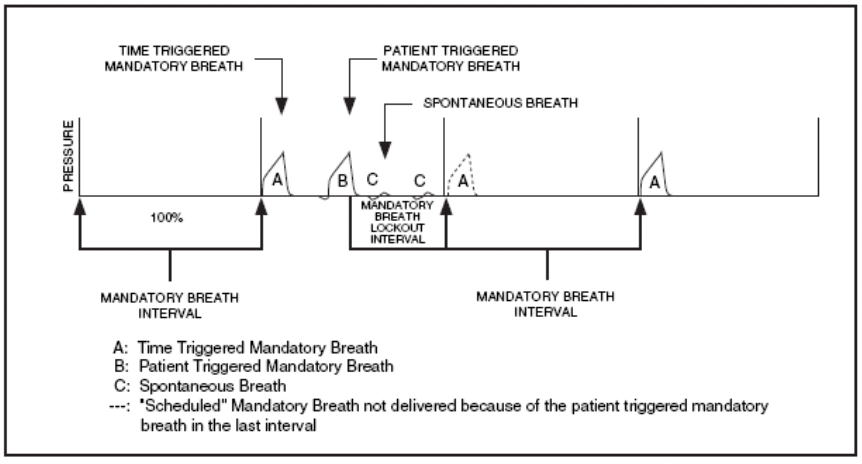


Figure 22 - Synchronized Intermittent Mandatory Ventilation (SIMV)

SPONT Mode (Spontaneous Ventilation)

In SPONT mode, mandatory breaths are not delivered. However, the caregiver can adjust both PEEP/CPAP and pressure support (PSV) levels. The patient has control over each breath.

When PEEP/CPAP is set above 0, the ventilator mode is CPAP (without PSV) or Bi-level Positive Airway Pressure (with PSV). Ensure that Ptrig is set so that the FLIGHT 60 Ventilator detects all spontaneous patient efforts.

Entries for tidal volume, *f* and Ti are all inactive in SPONT mode. However, users can preset these parameters for future ACMV or SIMV operation.

As with all FLIGHT 60 Ventilator operating modes, Backup Ventilation is activated if the Apnea alarm limit is violated.

In **SPONT** mode, the ***f*, Ti, PCV, VCV, Waveform**, and **Ti/Flow ctl** control buttons are not utilized and are therefore darkened. However, they remain adjustable.

➔ **To set the mode of operation:**

1. Tap the **MODE** control button.

   The available operating modes appear.

Figure 23 – Operating Modes

2. Tap the desired mode.

   The selected mode is displayed on the Mode control button.

5.2.2 Submode of Operation (VCV/PCV)

In ACMV and SIMV modes, the ventilator can work in either of two submodes:

- Volume Control (VCV) – ventilator volume controls mandatory breaths.
- Pressure Control (PCV) – ventilator pressure controls mandatory breaths.

In either case, all breaths delivered to the patient, whether time (ventilator initiated) or patient-triggered, are the same.

In **SPONT** mode, the **PCV/VCV** button is not utilized and is therefore darkened; however, the value can be preset.

Volume Control Ventilation (VCV)

The user can define which parameter will remain constant when changing the VCV – Flow or Ti. Once the parameter is selected, its value can be adjusted; then, any change of volume modifies the other parameter.

The system supports two modes of flow waveform:

- Square – the flow is constant during the inspiratory phase.
- Descending – the flow decreases gradually during the inspiratory phase.

Make sure that the mandatory flow setting is adequate to meet patient flow demands.

In **ACMV VCV** mode, the **Rise Profile** control button is not utilized and are therefore darkened. However, it remains adjustable.

The VCV mode delivers volume controlled breaths as the mandatory breaths. The user can set the volume and select whether the Ti or the Flow will adjust to fit the set volume. The user can define which parameter will remain constant when changing the VCV – Flow or Ti. Once the parameter is selected, its value can be adjusted; then, any change to the volume will modify the other parameter.

The tidal volume delivered to the patient is limited by the minimal and maximal flow of the system.

If the Volume Control setting causes the flow rate to reach the maximum or minimum level of the flow specification, adjustment of Volume Control ceases, and a setting limitation message appears in a pop-up window.

When Volume Control is first initiated, it may take five or six breaths to reach the volume setting.

➔ **To set the VCV submode of operation:**

1. Tap the **PCV/VCV** control button.

   The PCV and VCV submodes are displayed.

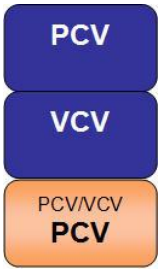


Figure 24 – Available Submodes

2. Tap the **VCV** option.

   VCV appears on the VCV/PCV button.

   The **VCV** control button appears on the Parameters screen, with its predefined numerical value.

Figure 25 – The VCV Control Button (Tidal Volume)

Mandatory Tidal Volume

During Volume Control ventilation, tidal volume can be set for mandatory breaths. If a volume setting is changed while the ventilator is operating, the change takes place in increments over a series of breaths.

When a large change is made to the volume setting, it may take five or six breaths to reach the volume setting.

➔ **To set the target volume:**

1. Tap the **VCV** control button (see Figure 25).
2. Adjust the VCV value (tidal volume), using the **Up/Down** button.

Pressure Control Ventilation (PCV)

The FLIGHT 60 Ventilator targets and maintains patient airway pressure at the set pressure control level throughout inspiration. Breath termination occurs when either of the following conditions exists:

- The set Ti elapses.
- The Peak inspiratory pressure exceeds the Pressure Control setting by 8 cmH2O (mbar).

Maximum airway pressure never exceeds the user set High pressure alarm limit setting.

The target airway pressure for pressure controlled mandatory breaths in ACMV and SIMV is the display setting above ambient pressure; not above PEEP.

In **PCV** mode, the **Waveform**, and **Ti/Flow ctl** control buttons are not utilized and are therefore darkened. However, they remain adjustable.

Both time and patient triggered mandatory breaths can be delivered in ACMV and SIMV Pressure Control operation. During SIMV Pressure Control operation, patients can breathe spontaneously between mandatory breaths with or without pressure support.

When disconnecting the patient circuit during PCV/PSV ventilation, such as for suctioning, the flow may increase in order to compensate for the low pressure. After reconnecting the patient circuit, the flow automatically readjusts to meet the patient's demand.

The PCV mode delivers pressure controlled breaths as the mandatory breaths.

When Pressure Control is first initiated or the setting is changed, the first few breaths may cycle off early until the rise profile is optimized. If early cycling off continues, reevaluate the patient circuit configuration and lengthen the tubing as necessary.

The minimum target airway pressure is 5 cmH2O/mbar above the set baseline pressure (PEEP).

➔ **To set the PCV submode of operation:**

1. Tap the **PCV/VCV** control button.

   The PCV and VCV submodes are displayed.

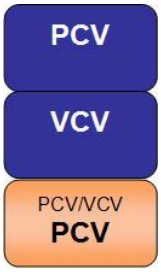


Figure 26 – Available Submodes

2. Tap the **PCV** option to select it.

   PCV appears on the PCV/VCV button.

   The **PCV** control button appears on the Parameters screen, with its predefined numerical value.

Figure 27 – The PCV Control Button (Target Pressure)

Target Pressure

➔ **To set the target pressure:**

1. Tap the **PCV** control button (see Figure 27).
2. Adjust the PCV value (the target pressure), using the **Up/Down** button.

5.2.3 Inspiratory Time (Ti) / Flow

Flow shares a numeric display button with **Ti**. You can switch between Ti and Flow, using the **Ti/Flow ctl** button on the Extended screen. When **Flow** is displayed on the button, **Ti** is displayed on the monitoring display.

The Ti setting determines the inspiratory time for mandatory breaths (volume or pressure control).

The Flow setting determines the flow of mandatory volume breaths.

The Flow and Ti values are related to each other. Therefore, if the Ti setting causes the flow rate to reach the maximum or minimum level of the flow specification, you cannot further change the Ti numeric value, and a setting limitation message appears in a popup window.

The flow can be adjusted indirectly by changing the tidal volume (Volume Control) or Ti settings.

In **SPONT** mode, the **Ti**/**Flow** button is not utilized and is therefore darkened; however, its value can be preset.

Inspiratory Time

➔ **To set the inspiratory time:**

1. Tap the **Ti** control button.
2. Adjust the Ti value, using the **Up/Down** button.

Figure 28 – Setting the Inspiratory Time

If the selected Ti setting results in an inverse I:E Ratio, the system displays an "Inverse I:E" message in the Message popup window. After you receive this warning message, you can continue increasing the Ti value up to an I:E Ratio of 3:1.

If the Ti setting causes the flow rate to reach the maximum or minimum level of the flow specification, you cannot further adjust the Ti numeric value, and a setting limitation message appears in a popup window.

Flow Rate

➔ **To set the mandatory flow:**

1. Tap the **Flow** control button.
2. Adjust the Flow value, using the **Up/Down** button.

Figure 29 – Setting the Mandatory Flow

5.2.4 Frequency of Breaths (*f*)

In the ACMV mode, the *f* (frequency) setting determines the minimum number of time-triggered mandatory breaths; in the SIMV mode, it determines the total number of mandatory breaths. The frequency or rate value is displayed on the *f* button.

In **SPONT** mode, the *f* button is not utilized and is therefore darkened; however, its value can be preset.

➔ **To set the frequency of breaths:**

1. Tap the ***f*** control button.
2. Adjust the *f* value, using the **Up/Down** button.

Figure 30 – Setting the Frequency of Breaths

If the selected *f* setting results in an inverse I:E Ratio, the system displays an "Inverse I:E" message in the Message popup window, to alert you of this. After you receive this warning message, you can continue increasing the *f* value up to an I:E Ratio of 3:1.

5.2.5 Pressure Trigger Level (Ptrig)

The Ptrig setting determines trigger sensitivity in terms of how far the airway pressure must drop below the set baseline pressure for a patient's spontaneous efforts to be detected. The Ptrig LED indicator illuminates each time the airway pressure reaches the set Ptrig level. The blinking Ptrig LED is referred to as the Patient Effort Indicator. The Pressure Trigger Level is displayed in the Ptrig button, and can be changed.

➔ **To set the Ptrig value:**

1. Tap the **Ptrig** button.
2. Adjust the Ptrig value, using the **Up/Down** button.

Figure 31 – Setting the Pressure Trigger Level

It is recommended to set Ptrig as close to -0.1 cmH2O as possible without auto triggering, in order to maximize triggering synchrony.

5.2.6 Positive End Expiratory Pressure (PEEP)

The PEEP setting establishes a baseline positive airway pressure in the patient circuit during the exhalation phase. The set PEEP value is displayed in the PEEP button.

In Pressure Control ventilation, PEEP cannot be set higher than 5 cmH2O/mbar below the Pressure Control setting.

The value of PEEP plus PSV cannot exceed 60 cmH2O/mbar.

Rapid decrease of the PEEP value may cause HIGH PBASE alarm.

➔ **To set the PEEP value:**

1. Tap the **PEEP** button.
2. Adjust the PEEP value, using the **Up/Down** button.

Figure 32 – Setting the Positive End Expiratory Pressure Level

5.2.7 Pressure Support Ventilation (PSV)

PSV (pressure support Ventilation) functions during patient triggered spontaneous breaths in SIMV and SPONT modes only. During each spontaneous breath, the ventilator supports the patient by elevating the airway pressure to the PSV + PEEP level.

Breaths are terminated when any of the following conditions exists:

- The flow to the patient drops to the set % of that breath's peak flow.
- The target airway pressure is exceeded by 3 cmH2O (mbar).
- The PSV Ti has elapsed.

Maximum airway pressure never exceeds the High Pressure alarm limit setting.

In ACMV mode, the **PSV** button is not utilized and is therefore darkened; however, the value can be preset.

➔ **To set the pressure support level:**

1. Tap the **PSV** control button.
2. Adjust the PSV value, using the **Up/Down** button.

Figure 33 – Setting the Pressure Control Level

The value of PEEP plus PSV cannot exceed 60 cmH2O/mbar.

5.2.8 Lower and Upper Pressure Limits (Low P, High P)

The Low P and High P values determine the lower and upper limit, respectively, for the pressure of a mandatory breath.

The LOW P SPONT control button in the Technical screen enables selecting whether or not the pressure of spontaneous breaths is also to be checked (see Section 5.4.3).

➔ **To set the Low P value:**

1. Tap the **Low P** control button.
2. Adjust the Low P value, using the **Up/Down** button.

Figure 34 – Setting the Low Pressure Limit

If the system detects that the pressure does not reach the Low P settings for three consecutive mandatory breaths, the Low Pressure alarm is activated. This alarm becomes passive when even one of the mandatory breaths reaches the requested level.

The Low P value can be between PEEP + 3 and High P – 1. Low P adjusts when PEEP is increased.

➔ **To set the High P value:**

1. Tap the **High P** control button.
2. Adjust the High P value, using the **Up/Down** button.

Figure 35 – Setting the High Pressure Alarm Limit

If the system detects that the pressure of a mandatory breath exceeds the High P limit, the High Pressure alarm is activated and the pressure is relieved to the room air.

5.2.9 Lower and Upper Minute Volume Alarm Limits (Low MV, High MV)

The Low MV and High MV values determine the upper and lower alarm limit, respectively, of the patient's minute volume (Vt x *f*). It is recommended to set the minute volume with a range of values that enable the patient to be ventilated safely and comfortably.

Low MV

➔ **To set the Low MV value:**

1. Tap the **Low MV** control button.
2. Adjust the Low MV value, using the **Up/Down** button.

Figure 36 – Setting the Low Minute Volume Alarm Limit

If the patient inspiratory or expiratory minute volume drops below the Low MV set value, an alarm sounds and a message is displayed.

High MV

➔ **To set the High MV value:**

1. Tap the **High MV** control button.
2. Adjust the High MV value, using the **Up/Down** button.

Figure 37 – Setting the High Minute Volume Alarm Limit

If the patient inspiratory or expiratory minute volume exceeds the High MV set value, an alarm sounds and a message is displayed on the screen.

5.2.10 Settings Limitation Pop-Up Messages

When an adjustment that you make to a parameter setting causes the parameter to reach software defined limitations, the system notifies you by displaying a Limitation pop-up message.

The following table lists the Limitation pop-up messages, and how they are activated.

Message	Activation
PEEP Limited by HIGH P Setting	PEEP reached High P – 4.
PEEP Limited by PCV	PEEP reached PCV – 5.
PEEP Limited by PSUP	PEEP reached 60 – PSV.
PSV limited by PEEP	PSV reached 60 – PEEP.
Reached Max I:E	Ti/Flow or *f* reached a value that caused the I:E ratio to reach its max range 3:1.
INVERSE I:E	Ti or *f* reached a value that inversed the I:E ratio.
LOW P Limited by HIGH P	LOW P reached HIGH P – 1.

Message	Activation
LOW P Limited by PEEP	LOW P reached PEEP + 3.
PCV Limited by PEEP	PCV reached PEEP + 5.
Reached Max Flow	Increasing VCV or Decreasing Ti caused the Flow to reach its max possible value.
Reached Min Flow	Decreasing VCV or increasing Ti caused the Flow to reach its min possible value.
HIGH P Limited by LOW P	HIGH P reached LOW P + 1.
HIGH MV Limited by LOW MV	HIGH MV reached LOW MV + 1.
LOW MV Limited by HIGH MV	LOW MV reached HIGH MV – 1.
Reached Max Ti	Increasing VCV or Decreasing Flow caused Ti to reach its max possible value.
Reached Min Ti	Decreasing VCV or increasing Flow caused Ti to reach its min possible value.
LOW O2 limited by HIGH O2 Setting	LOW O2 reached HIGH O2 – 10.
HIGH O2 Limited by LOW O2 Setting	HIGH O2 reached LOW O2 + 10.

5.3 Setting the Extended Parameters

5.3.1 Alarm Buzzer Volume

You can set the volume of the alarm buzzer.

➔ **To set the alarm buzzer volume:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **Buzzer** control button.

   The control button turns orange, and a pop-up list displays the two unit options: **LOW** and **HIGH**.

3. Tap the control button to select **LOW**; or **HIGH**.

   The selected volume is displayed on the control button.

5.3.2 Activating/Deactivating Power Saving

You can activate or deactivate the power saving system in the AC and DC supply. When activated, the system waits five minutes. If during that time none of the

control buttons were touched or alarms were set off the screen turns Off and the pressure gauge displays one LED only to indicate the peak pressure.

➔ **To activate/deactivate the power saving system:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **PowerSave** control button.

   The control button turns orange, and a pop-up list displays the two options: **ON** and **OFF**.

3. To activate the power saving system, tap the control button to select **ON**; to deactivate the power saving system, tap the control button to select **OFF**.

   Your selection (ON or OFF) is displayed on the control button.

5.3.3 Waveform Type

The Waveform parameter can be set in VCV mode only.

There are two types of waveform:

- **Square** - the flow stays constant during the inspiratory phase.
- **Descend** –the flow descends linearly until the final flow (at the end of inspiration), and is 50% of the peak flow.

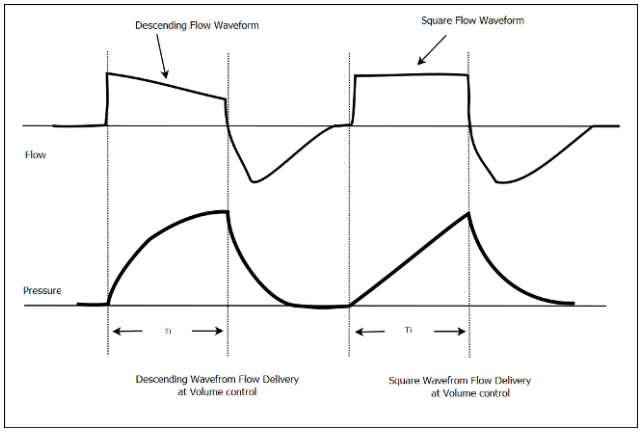


Figure 38 – Waveform Types

➔ **To set the waveform type:**

1. On the ventilator front panel, press the **Extended** button.

The Extended parameters are displayed on the ventilator screen.

2. Tap the **Waveform** control button.

   The control button turns orange, and a pop-up list displays the two options: **Square** and **Descend**.

3. Tap the control button to select **Square** or **Descend**.

   Your selection is displayed on the control button.

5.3.4 Inspiratory Time / Flow Control (TI / Flow ctl.)

You can determine the criteria that will remain constant during Volume Controlled management: Inspiratory Time or Flow criteria.

In ACMV/SIMV PCV modes, the Ti/Flow ctl button is not utilized and is therefore darkened. However, it remains adjustable.

➔ **To set the criteria that will remain constant for Volume Controlled Management:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **Ti/Flow ctl.** control button.

   The control button turns orange, and a pop-up list displays the available options: **Ti** and **Flow**.

3. Tap the control button to select **Ti** or **Flow**.

   Your selection is displayed on the control button.

5.3.5 Rise Profile

The system can deliver five different levels of rise times, ranging from 1 (the fastest) to 5 (the slowest).

You can set the rise time levels in PCV and PSV modes only.

Set the initial Rise Profile to level 3 and then adjust it according to the patient comfort.

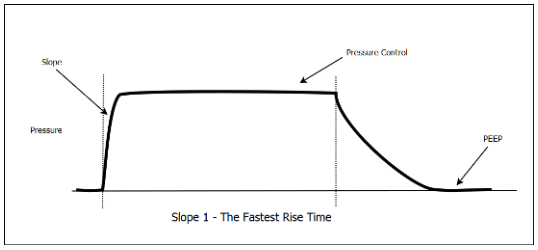


Figure 39 – The Fastest Rise Profile (Level 1)

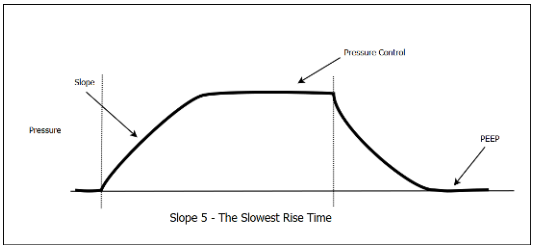


Figure 40 – The Slowest Rise Time (Level 5)

➔ **To set the rise profile level:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **Rise Profile** control button.

   The control button turns orange.

3. Press the **Up/Down** button soft key to increase/decrease the level, until you reach the desired rise profile level.

   The selected rise profile level is displayed on the control button.

5.3.6 Pressure Support Flow Termination (PSV Flow Term)

The PSV flow threshold is used to determine the end of a pressure support breath. You can set the PSV Flow Term from 10% to 70% of the peak flow.

In ACMV and SIMV VCV mode, the **PSV Flow Term** button is not utilized and is therefore darkened. However, it remains adjustable.

➔ **To set the flow threshold:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **PSV Flow Term** control button.

   The control button turns orange.

3. Press the **Up/Down** button soft key to increase/decrease the threshold in steps of 5, until you reach the desired flow threshold.

   The selected flow threshold is displayed on the control button.

5.3.7 Pressure Support Ventilation Inspiratory Time (PSV Ti)

You can control and limit the inspiratory time in Pressure Support Ventilation from 0.1 to 3 seconds. Tap the button on the screen, and then increase/decrease the value using the Up/Down soft key.

In ACMV, SIMV VCV mode, the **PSV Ti** button is not utilized and is therefore darkened. However, it remains adjustable.

➔ **To set the flow threshold:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **PSV Ti** control button.

   The control button turns orange.

3. Press the **Up/Down** button soft key to increase/decrease the PSV inspiratory time; it can be a value between 0.1 and 3 seconds.

   The selected PSV inspiratory time is displayed on the control button.

5.3.8 Activating/Deactivating the O2 Enrichment Monitor (FiO2)

You can activate or deactivate O2 enrichment monitoring. Activating FiO2 displays the FiO2 value on the screen; deactivating it turns the display off.

➔ **To activate O2 enrichment monitoring:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **FiO2** control button.

   The control button turns orange, and a pop-up list displays the available options: **ON** or **OFF**.

3. To activate monitoring tap the button **ON**; to deactivate monitoring tap the button **OFF**.

High and Low Levels for the Oxygen Alarm (FiO2 Low and FiO2 High)

The system sets off an alarm when there is a low and/or a high level of oxygen in the ventilator air mixture. You can define the low value and/or high value of oxygen that sets off the alarm. The low value can be set to any value between OFF (min value 21%) and FiO2 High minus 10. The high value can be set to any value between FiO2 Low plus 10 to OFF (max value 100%).

You can set the low and high levels for setting off the alarm, only if FiO2 monitoring is enabled.

➔ **To define the low level of oxygen that sets off the alarm:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **FiO2 Low** control button.

   The control button turns orange.

3. Press the **Up/Down** button soft key to increase/decrease the value of the low level of oxygen that will set off the alarm.

   The selected low level is displayed on the button.

➔ **To define the high level of oxygen that sets off the alarm:**

1. On the ventilator front panel, press the **Extended** button.

   The Extended parameters are displayed on the ventilator screen.

2. Tap the **FiO2 High** control button.

   The control button turns orange.

3. Press the **Up/Down** button soft key to increase/decrease the value of the high level of oxygen that will set off the alarm.

   The selected high level is displayed on the button.

5.3.9 Apnea

You can set the Apnea alarm limit; this can be between 10 and 60 seconds.

➔ **To define the Apnea alarm limit:**

1. On the ventilator front panel, press the **Extended** button.

The Extended parameters are displayed on the ventilator screen.

2. Tap the **Apnea** control button.

   The control button turns orange.

3. Press the **Up/Down** button soft key to increase/decrease the value of the Apnea.

   The selected value is displayed on the button.

If the patient Apnea time is longer than the set value, the Apnea alarm sets off and the Backup Ventilation (BUV) is activated.

Backup Ventilation is functional in all modes.

Backup Ventilation in ACMV and SIMV Modes

In ACMV and SIMV modes, *f* is automatically increased to 1.5 times the set frequency, subject to a minimum of 15 and a maximum of 99 b/min or a 3:1 I:E ratio. If the I:E ratio is higher than 3:1, *f* is calculated as the set frequency divided by45.

Backup Ventilation in SPONT Mode

In SPONT mode, the mode automatically changes from SPONT to SIMV, Pressure Controlled Ventilation (PCV), mandatory breath frequency (*f*) = 15 b/min, peak inspiratory pressure = 15 cmH2O/mbar above set PEEP, and inspiratory time (Ti) = 1.0 sec.

Cancellation of Backup Ventilation

BUV mode ends in either of the following cases:

- Patient Cancelled – There are two patient-triggered breaths during the APNEA interval time.
- User Cancelled – By pressing **Alarm Reset** to stop the BUV alarm.

In both cases, the BUV audible alarm stops, the corresponding LED indicator is latched, and the ventilator immediately returns to the user-selected settings before APNEA BUV was triggered.

Pressing the **Alarm Reset** button to stop the BUV alarm does not cancel other alarms.

Backup Ventilation is not active for the Apnea preset time after the user resets the BUV alarm.

5.4 Setting the Technical Parameters

5.4.1 System Language

You can select the language of the ventilator display.

➔ **To set the system language:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Language** control button.

   The control button turns orange, and a pop-up list displays the available languages.

3. Tap the control button to select the desired language.

   Your selection is displayed on the control button.

5.4.2 Pressure Units Display (Press Units)

You can display the pressure in either cmH2O or mbar units.

➔ **To set the pressure units for display:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Press Units** control button.

   The control button turns orange, and a pop-up list displays the two unit options: **cmH2O** and **mbar**.

3. Tap the control button to select **cmH2O** unit or **mbar** unit.

   The selected unit is displayed on the control button.

5.4.3 Activating/Deactivating the SPONT Mode Low Pressure Alarm (LOW P Spont)

In SPONT mode, you can activate/deactivate the low-pressure alarm.

➔ **To deactivate the low pressure alarm:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **LOW P Spont** control button.

   The control button turns orange, and a pop-up list displays the two options: **ON** and **OFF**.

3. Tap ON to activate the alarm; tap OFF to deactivate the alarm.

   Your selection (ON or OFF) is displayed on the control button.

5.4.4 Displaying the System Information

You can display the following system information on the ventilator screen: **Unit Serial Number**, **Software Version**, **Compressor Serial Number**, **Hour Meter**, and **Next Service**.

➔ **To display system information:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Show INFO** control button.

   The system information is displayed on the screen.

5.4.5 Performing Exhalation Valve Calibration

Each time an exhalation valve is replaced by another, such as when the complete circuit is changed, it must be recalibrated before it is used. After calibration is finished, you should adjust patient settings appropriately.

➔ **To calibrate the exhalation valve:**

1. Connect the patient circuit (the side which is attached to the patient) to an adult (500 ml) test lung.
2. Press the **On/Off** button once to enter Settings mode.
3. Press the **Technical** button once, and then tap the **Valve Cal** button.

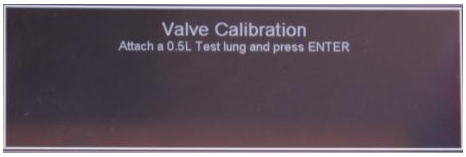


Figure 41 – Valve Calibration Screen

4. Press **Enter** and follow the instructions on the display.

The FLIGHT 60 Ventilator starts the exhalation valve calibration and the ventilator automatically tests the exhalation valve.

- If it passes the test, the message "Cal Completed" is displayed.
- If the test fails, the message "Cal Failed" is displayed. Check the integrity of the circuit, connections, and test lung, and then reinitiate calibration.

5. When calibration is finished, remove the test lung and press **Enter** or **Cancel** to exit.

WARNING Inadequate ventilation may result if the exhalation valve is not calibrated properly. If the circuit/exhalation valve fails the calibration procedure, try another circuit/exhalation valve or use an alternate method of ventilation.

CAUTION Some disposable patient circuit/exhalation valve assemblies are not compatible with the FLIGHT 60 Ventilator due to the requirements of the ventilator's pressure management system. If your disposable circuit fails consistently, switch to a FLIGHT MEDICAL approved, reusable (single patient) FLIGHT 60 Ventilator patient circuit / exhalation valve assembly to ensure that the FLIGHT 60 Ventilator performs to specification.

HOME CAREGIVERS: It is common practice to have two patient circuits available in homecare environments to ensure that a clean circuit is always available for regularly scheduled circuit changes. The exhalation valve in each circuit must be calibrated before being put into use.

5.4.6 Storing/Loading a Ventilation Configuration

After you configure the ventilator for a particular patient, you can store the configuration on the ventilator for later use. It is possible to store up to five configurations.

➔ **To store the ventilation configuration:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Set Save** control button.

   The patient configuration is saved.

You can load a predefined ventilation configuration, instead of configuring the ventilator from scratch.

➔ **To load a predefined ventilation configuration:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Set Load** control button.

   The control button turns orange, and a pop-up list with the numbers of the saved configurations appears.

3. Tap the control button that corresponds to the number of the saved configuration. For example, to load configuration 2, tap the control button with the number 2.

   The selected configuration is loaded onto the ventilator.

5.4.7 System Clock

You can set the system time and date, for logging purposes.

➔ **To set the time and date:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Set Clock** control button.

   The time and date setting screen is open.

3. To set the Time tap the required button Hour / Minute / Second, press the Up/Down button until you reach the desired value, and then press **Enter**.

   To set the Date tap the required button Day / Month / Year, press the Up/Down button until you reach the desired value, and then press **Enter**.

   The time and date are set.

5.4.8 Displaying the Alarms/Changes Log

Alarms that occur, are logged in the system, by date, time, and type. You can display the log of alarms, and browse through it.

➔ **To display the log of alarms:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Show Log Alarm** control button.

   The log of alarms is displayed on the ventilator screen.

You can scroll through the list of alarms, using the **Up/Down** button.

When prompted, you can clear the log from the screen by confirmation. The code is 1315✓.

Changes to the ventilator are logged by date, time, type, and values. You can browse through the log, to see changes that have been made to the ventilator states, modes, and settings.

➔ **To display the log of ventilator changes:**

1. On the ventilator front panel, press the **Technical** button.

   The Technical parameters are displayed on the ventilator screen.

2. Tap the **Show Log Change** control button.

   The log of changes is displayed on the ventilator screen.

   You can scroll through the list of ventilator changes, using the **Up/Down** button.

When prompted, you can clear the log from the screen by confirmation. The code is 1315✓.

5.4.9 Accessing the Advanced Technical Menu

Only authorized and qualified service technicians can access the advanced technical menu. Refer to the Service Manual.

5.5 Initiating Ventilation

After setting all the required parameters, checking all alarm limit and control settings to ensure that they are appropriate for the patient to be ventilated, and performing exhalation valve calibration, you can initiate ventilation.

➔ **To begin ventilation:**

1. On the ventilator front panel, press the **On/Off** button for three seconds.

   The system emits a small noise while it purges, to clean the set of flow transducer tubes and the orifice. The system then starts ventilating. The On/Off button LED is illuminated in Green to indicate that the system is working.

2. Connect the ventilator patient circuit to the patient interface.

3. Reassess HIGH Pressure and LOW Pressure alarm settings, and adjust them to appropriate levels.
4. Verify that the Ptrig indicator blinks each time the patient initiates a spontaneous inspiratory effort. Readjust Ptrig as necessary.
5. Reassess the HIGH MV and LOW MV alarm settings and adjust to the appropriate levels.

5.6 Monitoring the Patient

After initiating ventilation, it is important that you closely monitor the patient for at least 10 minutes to ensure that the patient is receiving adequate ventilation. Patient monitoring parameters are displayed at all times on all three screens, to ensure continuous monitoring of the patient during ventilation.

The patient monitoring parameters are listed in Section 3.5.2.

6 Ventilator Alarms

The FLIGHT 60 Ventilator comes with an intelligent alarm system, which warns you of problems with the ventilator. An alarm occurs when there is a risk to the patient. A caution occurs when there is an undesirable situation which does not pose immediate risk to the patient.

The FLIGHT 60 Ventilator alarm system includes variable and automatic alarms (ventilation and technical).

These alarms can either be audible or visual.

This chapter describes:

- Audible Alarm and Caution Signals (see Section 6.1)
- Visual Alarm and Caution Signals (see Section 6.2)
- Alarm and Caution Specifications of the variable and automatic alarms (see Section 6.3)
- Silencing Audible Alarms (see Section 6.4)
- Resetting Alarms (see Section 6.5)
- Setting Up a Remote Alarm (see Section 6.6)

6.1 Audible Alarm and Caution Signals

The system distinguishes between a caution and an alarm by emitting sounds of different lengths and frequencies of repetition, as follows:

- **Alarms**: the audible alarm sounds twice a pattern of three tones, pause and two more tunes. The pattern repeats as long as the alarm cause remains active.
- **Cautions**: the audible alarm sounds a pattern of three tones. The pattern repeats itself as long as the caution cause remains active.

The caregiver can adjust the sound level of the alarm to high or low.

6.2 Visual Alarm and Caution Signals

The visual alarm and caution system is composed of:

- One major visual alarm signal – Flashing red to indicate that there are alarms in the system.
- An Alarm Message display

If multiple alarms occur at the same time, the three most important alarms or cautions are displayed according to their internal priority, Left to right from the highest to the lowest priority - alarms are displayed in red; cautions in yellow. Every time a new alarm/caution is activated, the system recalculates the correct order of the alarms and displays the three most important ones

- Indicator LEDS - Few alarms are supported by red LED indicators, which are synchronized with the major visual alarm signal. They include: FAULT, APNEA, BUV, HIGH MV, LOW MV, HIGH P, and LOW P. When the alarms are active, their corresponding LEDS are flashing. When an alarm becomes passive (inactive), its corresponding LED turns stable (latched).

CAUTION FAULT LED indicates unrecoverable internal system failure. Ventilate the patient with an alternate means of ventilation. Make note of the message in the alarm display area and the alarm log. Contact your provider or FLIGHT MEDICAL.

6.3 Alarm and Caution Specifications

This section describes the specifications for the FLIGHT 60 Ventilator:

- Variable ventilation alarms
- Automatic ventilation alarms
- Automatic technical alarms
- Cautions

6.3.1 Variable Ventilation Alarms

Alarm	Range	Activation
HIGH PRESSURE	4 to 99 cmH2O	When the airway pressure reaches the high pressure alarm limit setting
LOW PRESSURE	3 to 98 cmH2O	When the airway pressure remains below the low pressure alarm limit setting for three consecutive mandatory breaths or three consecutive mandatory and spontaneous breaths when LOW P Spont is active

Alarm	Range	Activation
LOW MV INS LOW MV EXH	0.0 to 50.0 L/min	When the inspiratory or expiratory minute volume falls below the Low Minute Volume alarm setting
HIGH MV INS HIGH MV EXH	1.0 to 50.0 L/min	When the inspiratory or expiratory minute volume exceeds the High Minute Volume alarm setting
FiO2 LOW	21% to 90% O2	When the delivered O2 falls below the FiO2 Low alarm setting
FiO2 HIGH	31% to 99% O2	When the delivered O2 exceeds the FiO2 High alarm setting
APNEA	10 to 60 sec	When no breaths have been delivered for a period longer than the preset apnea time of 10 to 60 seconds

6.3.2 Automatic Ventilation Alarms

Alarm	Activation
LOW PBASE	When the PEEP value is less than the set value by more than 3 cmH2O for more than three seconds (depends on stable PEEP for the pervious 5 consecutive breaths)
HIGH PBASE	When the PEEP value is higher than the set value by more than 8 cmH2O for more than three seconds (depends on stable PEEP for the pervious 5 consecutive breaths)
PROX LINE	When the outlet pressure is significantly higher than the patient pressure.
OCCLUSION	When the pressure does not drop to less than PEEP + 15 within three seconds, although the safety solenoid is open
BUV	When Apnea is detected
PCV NOT REACHED	When the pressure does not reach 50% of the set level for three consecutive breaths

6.3.3 Automatic Technical Alarms

Alarm	Activation
EMPTY BAT	When less than 50% of the integral (secondary) battery and less than 20% of the detachable (main) battery charge remains
CAL O2 SENSORS	When the O2 sensor returns an invalid value
MOTOR FAULT	When the motor does not work properly
MOTOR POWER LOW	When the motor power is insufficient
PRESS SENSOR	When the patient pressure is significantly higher than the outlet pressure
POWER FAULT	When electrical circuit fails

Alarm	Activation
MEMORY FAULT	When the NVRAM does not work properly
CHECK SETTING	When the self test finds that settings parameters are out of range
Main BAT CHARGER	When the detachable (main) battery charger does not start working
Main BAT V. HIGH	When the detachable (main) battery voltage is higher than 18 V
Main BAT V. LOW	When the detachable (main) battery voltage is lower than 11 V
Main BAT TEMP HIGH	When the detachable (main) battery temperature is higher than 60 °C
Main BAT GAUGE	When there is no communication with the battery CPU
Main BAT VOLTAGE	When the detachable (main) battery voltage is different than the gauge voltage
Sec BAT CHARGER	When the integral (secondary) battery charger does not start working
Sec BAT V. HIGH	When the integral (secondary) battery voltage is higher than 18 V
Sec BAT V. LOW	When the integral (secondary) battery voltage is lower than 11 V
Sec BAT TEMP HIGH	When the integral (secondary) battery temperature is higher than 60 °C
Sec BAT GAUGE	When there is no communication with the battery CPU
Sec BAT VOLTAGE	When the integral (secondary) battery voltage is different than the gauge voltage

When an alarm message is generated, it is recorded in the alarms log with its accurate time and date.

6.3.4 Cautions

Caution	Activation
Power Switchover	When the device is disconnected from the AC power supply and starts using the internal battery
Battery LOW	When less than 20% of the detachable (main) battery and more than 50% of the integral (secondary) battery charge remain

The cautions are of lower priority than any alarm.

6.4 Silencing Audible Alarms

You can silence all active alarms and cautions for 60 seconds.

➔ **To silence audible alarms and cautions:**

1. On the ventilator front panel, press the **Audio Paused** button.

   The system enters pre-silence mode. The Audio Paused indicator is illuminated, and all alarms (except for the Fault Alarm) are silenced for 60 seconds.

You can cancel the pre-silence mode before 60 seconds are up, by pressing the **Audio Paused** button once again.

6.5 Resetting Alarms

When the cause for the alarm is no longer present, alarms become inactive (passive); they stabilize (latch) their corresponding LEDs (they stop blinking). You can clear the color from all passive LEDs.

➔ **To reset alarms:**

1. On the ventilator front panel, press the **Alarm Reset** button.

   The latched LED indicators are released.

6.6 Setting Up a Remote Alarm

The remote alarm feature enables monitoring device alarms from a distant station. When connected to a remote alarm system, all visible and audible alarms on the device are transmitted as an electronic signal to the remote alarm station. Other conditions, such as system shutdown (or power down) can also be detected by the remote alarm system.

The FLIGHT 60 device can be connected to a third party remote alarm system in several configurations. In order to connect the device to a remote alarm system, a special cable must be fitted to the system and integration must be conducted between the device and the remote alarm system.

Before attempting any connection, contact your provider or FLIGHT MEDICAL. Technical Support, and request the FLIGHT 60 Remote Alarm Technical spec.

The design, implementation, installation, and testing of the cable are the sole responsibility of the integrator, and must be done in accordance with the FLIGHT-60 Remote Alarm Technical spec, in order to ensure the proper functioning of the system and alarm.

7 Cleaning and Maintenance

7.1 Cleaning and Disinfecting

The FLIGHT 60 Ventilator and associated patient circuits are shipped in clean but not sterile condition. Reusable (single patient) patient circuits should be disinfected before reapplying to the patient.

Use the information in this section in conjunction with hospital policy, physician prescription, or Homecare Dealer instructions.

7.1.1 FLIGHT 60 Ventilator

Wipe clean the FLIGHT 60 Ventilator between patients, and once a week while in use.

➔ **To clean the ventilator:**

1. Wipe clean the exterior (besides the screen) of the ventilator and all parts not in direct contact with patients, using a cloth that has been dampened with a medical detergent or alcohol-based cleaning solution.
2. Clean the front panel display (the screen) using a lint free damp cloth dampened with LCD cleaner solution.
3. Air dry.

CAUTION Do not apply the cleaning solution directly on the screen.

CAUTION On the front panel display or ventilator housing, do not use agents that contain acetone, toluene, halogenated hydrocarbons, or strong alkaline.

CAUTION Never autoclave or EtO sterilize the FLIGHT 60 Ventilator and its accessories. These processes will damage the FLIGHT 60 Ventilator and accessories, rendering them unusable.

7.1.2 FLIGHT 60 Ventilator Accessories

All accessories should be thoroughly cleaned, rinsed, and air dried prior to disinfecting. Examine all accessories for excessive wear or damage. Discard and replace if necessary.

Oxygen Blending Bag Kit

➔ **To disassemble the Oxygen Blending Bag Kit:**

1. Remove the Oxygen Blending Bag Kit from the FLIGHT 60 Ventilator air inlet.
2. Disconnect the oxygen tubing and slide the rubber bag off its fitting.

➔ **To clean the Oxygen Blending Bag Kit:**

1. Wash the outside of the rubber bag and the plastic parts (without taking them apart) using a mild cleanser, warm water, and a soft brush.
2. Rinse thoroughly with sterile, distilled water, removing all traces of the cleanser.
3. Shake off excess water and place all parts on a clean towel to air dry. (Do not heat or blow dry.)


CAUTION Avoid touching the rubber valves, which are inserted in the plastic body. Do not attempt to clean the inside of the rubber bag; keep it dry.

➔ **To disinfect the Oxygen Blending Bag Kit:**

1. Soak the plastic and metal parts in either of the following solutions:
   - One part 5% Acetic Acid (white vinegar) and two parts sterile, distilled water for 30 minutes (for home use only)
   - Glutaraldehyde solution (Cidex [2%]) for two hours
2. Rinse with sterile, distilled water, removing all traces of the cleanser.
3. Air dry.


Do not soak the rubber bag. Use a soft cloth to wipe the external surface with either solution. Rinse with distilled water and air dry.

Reusable (Single Patient) Patient Circuits

The patient circuit includes 22mm ID breathing tube, exhalation valve and flow sensing kit (flow orifice, quick connector and triplet 2.75mm ID tubes).


CAUTION FLIGHT MEDICAL patient circuits are supplied non-sterile.

Clean and disinfect patient circuits once weekly while in use. Always use a clean, disinfected exhalation valve when the patient circuit is reassembled for patient use.

Examine the patient circuit for excessive wear or damage. Discard and replace, if necessary. To avoid degradation of the reusable (single patient) patient circuit components, do not exceed 20 cleaning cycles or half a year of usage (whichever occurs first).

HOME CAREGIVERS: In the home environment, it is important to always use a clean, disinfected patient circuit. The objective of cleaning circuits is to render the surfaces free of pathogens.

➔ **To disassemble the patient circuit:**

1. Remove the entire circuit from the ventilator.
2. Remove the exhalation valve and flow sensing kit.
3. Disassemble the circuit to expose all surfaces for cleaning.

CAUTION The FLIGHT MEDICAL patient circuit is manufactured from a Polyester Elastomer, high-temperature material and incorporates a silicone rubber cuff. To avoid damage to the circuit, attach and detach the circuit by handling only the silicone cuffs. Do not pull or twist the circuit.

If you are using a FLIGHT MEDICAL patient circuit, refer to the cleaning and disinfecting directions below. If you are using another manufacturer's patient circuit approved by FLIGHT MEDICAL, refer to the manufacturer's instructions for cleaning.

➔ **To clean the patient circuit:**

1. Use a low flow of running water or air to clear tubing and passages of organic matter.
2. Bathe for a minimum of 10 minutes using mild detergent or liquid cleanser.
3. Wash all components of the patient circuit with a soft brush.
4. Rinse thoroughly with sterile, distilled water, removing all traces of the cleanser.
5. Shake off excess water, and place all parts on a clean towel to air dry. (Do not heat or blow dry.)

➔ To disinfect the patient circuit components:

1. Soak plastic and metal parts in any of the following solutions:
   - One part 5% Acetic Acid (white vinegar) and two parts sterile, distilled water for two hours (for home use only)
   - Glutaraldehyde solution (Cidex [2%]) for two hours
2. Rinse with sterile, distilled water, removing all traces of the cleanser.

3. Air dry.

CAUTION Patient circuit components should NOT come in contact with the following solutions, because they may cause disintegration of the tubing: Hypochlorite, Phenol (>5%), Inorganic Acids, Formaldehyde, Ketone, Chlorinated Hydrocarbons, and Aromatic Hydrocarbons.

CAUTION Patient circuits should be inspected after disinfecting to check for deterioration. If the circuit is damaged or shows excessive wear, replace with a new circuit.

Reusable (Single Patient) Exhalation Valve

Clean and disinfect the Exhalation Valve twice weekly, while in use.

Figure 42 - Exhalation Valve Assembly

➔ **To dissasemble the exhalation valve:**

1. Remove the exhalation valve from the patient circuit (see Figure 42).
2. Rotate counterclockwise the top cap of the exhalation valve and lift it off.
3. Lift out the valve drive line fitting, and separate it from the diaphragm (see Figure 43).

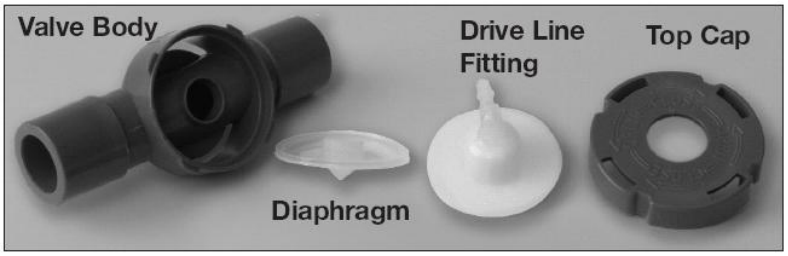


Figure 43 - Exhalation Valve Disassembled Parts

➔ **To clean the exhalation valve:**

1. Use a low flow of running water or air to clear tubing and passages of organic matter.
2. Wash the exhalation valve with a soft brush.
3. Rinse thoroughly with sterile, distilled water.
4. Shake off excess water, and place it on a clean towel to air dry. (Do not heat or blow dry.)

➔ **To disinfect the exhalation valve:**

1. Soak plastic and metal parts in any of the following solutions:
   - One part 5% Acetic Acid (white vinegar) and two parts sterile, distilled water for two hours (for home use only); Then, rinse with sterile distilled water.
   - Glutaraldehyde solution (Cidex [2%]) for two hours; Then, rinse with sterile, distilled water.
   - Boiling distilled water; boil the water for 15 minutes, making sure that water covers the valve at all times. Allow the water to cool and then drain (for home use only)
2. Air dry.

After the exhalation valve is dry, reassemble it according to the following procedure, to ensure proper ventilator operation.

➔ **To reassemble the exhalation valve:**

1. Carefully seat the diaphragm so that it lies flat on the white plastic drive line fitting and snaps on around the edge completely.
2. Place the fitting/diaphragm assembly in the valve body, with the drive line fitting lined in the opposite direction of the patient and/or the arrow sign.
3. Carefully place the cap over the fitting/diaphragm assembly and turn the cap clockwise until it comes up against the stop.
4. Perform an exhalation valve calibration to ensure proper operation of the ventilator.

Do not try to turn the drive line fitting after securing the cap. This may cause the diaphragm to become wrinkled or unseated and affect ventilator performance.

FLIGHT 60 Ventilator Air Inlet Particle Filter


WARNING NEVER operate the FLIGHT 60 Ventilator without a clean inlet particle filter in place.


WARNING NEVER reverse the inlet particle filter when it is dirty.

The air inlet particle filter, located on the right side of the ventilator behind the Filter Cover, keeps dirt and particles out of the ventilator's piston system. As the filter becomes dirty, it can reduce the volume of air drawn into the ventilator.

Check the inlet filter weekly. Replace it with a new filter when the majority of the filter surface area has changed from a clean white to dirty brown color. Inlet filters are not reusable.


After replacing the filter, make sure that the three hold down screws on the Filter Cover are secure. If the screws are not tight, ambient air may enter the FLIGHT 60 Ventilator from around the inlet cover.


HOME CAREGIVERS: When the FLIGHT 60 Ventilator is used in a homecare environment, the filter may become dirty more frequently and therefore must be inspected and/or changed more often.

7.2 Maintenance

7.2.1 Preventive Maintenance

It is recommended to take the following measures to maintain the FLIGHT 60 Ventilator:

- Check the Air Inlet Filter (located behind the Filter Cover) weekly. Replace it when the majority of the filter surface area has changed from a clean white to dirty brown color. Air Inlet Filters are not reusable.


HOME CAREGIVERS: When the FLIGHT 60 Ventilator is used in homecare environments, the filter may become dirty more frequently and therefore, it must be inspected and/or changed more often.


WARNING NEVER reverse the inlet particle filter when it is dirty.

- Inspect the FLIGHT 60 Ventilator power cord on a regular basis, for signs of a broken or frayed power cord.
- Inspect the exhalation valve and flow orifice to verify that there are no cracks or damaged surfaces.
- Wipe down the surface of the ventilator housing regularly to remove any dust that might accumulate.

If service is required, contact your provider.

7.2.2 Internal Battery Maintenance

It is recommended that if the batteries are no longer meet the time requirements of the user, they should be replaced.

To preserve the internal batteries' life:

- Whenever possible, plug the FLIGHT 60 Ventilator into the external power source to charge the batteries.
- Use the Auto Lighter Cable accessory to power the FLIGHT 60 Ventilator when traveling by automobile.

7.2.3 15,000 Hour Maintenance

A comprehensive maintenance should be performed after 15,000 hours of operation. The 15,000 hour maintenance includes replacement of the pump assembly.

Contact your provider or FLIGHT MEDICAL for detailed information on the 15,000 hour maintenance (see Section 8.5 for contact information).


HOME CAREGIVERS: Do not attempt to open or perform any service procedures on the FLIGHT 60 Ventilator. Only FLIGHT MEDICAL trained technicians are authorized to service the ventilator. Contact your Homecare Dealer or FLIGHT MEDICAL .

7.3 General Warnings

- Preventive maintenance work, repairs, and service may only be performed by FLIGHT MEDICAL trained or factory-authorized personnel.
- Always follow accepted hospital procedures or physician instructions for handling equipment contaminated with body fluids.
- The ventilator and its accessories must be thoroughly cleaned and disinfected after each patient use. Perform all cleaning and disinfection of external parts and accessories in accordance with established hospital procedures, physician prescription, or Homecare Dealer instructions.
- Certain components of the ventilator, such as the exhalation valve and the front panel, consist of materials that are sensitive to some organic solvents used for cleaning and disinfection (such as phenols, halogen releasing compounds, oxygen releasing compounds, and strong organic acids). Exposure to such substances may cause damage that is not immediately recognizable.
- The reusable (single patient) patient circuit including the exhalation valve and flow sensing kit and other parts that come in direct contact with the patient should be periodically disinfected while in use.

8 Troubleshooting

8.1 Introduction

The FLIGHT 60 Ventilator is used in life-support situations. As such, it is essential that all individuals using the FLIGHT 60 Ventilator, including clinicians and support staff, have a thorough understanding of its operation. This should include a working knowledge of the ventilator's pneumatic and electronic systems.

The following practical troubleshooting section is provided as a training resource for individuals learning how to use the FLIGHT 60 Ventilator, and as a reference tool for those already familiar with its use and operation. It should be noted that this outline is not all inclusive, and is intended only as a guide.

HOME CAREGIVERS: Contact your Homecare Dealer, physician, or FLIGHT MEDICAL if you have questions or concerns about the performance of the FLIGHT 60 Ventilator.

WARNING Only properly trained personnel should operate the ventilator. The FLIGHT 60 Ventilator is a restricted medical device designed for use by Respiratory Therapists or other properly trained and qualified personnel under the direction of a physician and in accordance with applicable state laws and regulations.

8.2 Alarms

Problem	Potential Cause	Suggested Action
Apnea Alarm	Patient did not trigger a breath for the preset Apnea interval (10 to 60 seconds).	Reevaluate the patient and ventilator settings and provide increased ventilatory support, as needed.
	Patient efforts are not detected. Trigger level set improperly.	Use Ptrig to adjust the trigger level closer to the baseline pressure (0 cmH2O) so that patient efforts are detected (indicated by the Ptrig LED illuminating green).
Prox Line Alarm	Humidity in the proximal line.	The ventilator purges every 5 minutes, to clean the tubes. Verify the alarm ceased after the ventilator purge.

Problem	Potential Cause	Suggested Action
	Proximal line disconnected or kinked.	Reconnect the proximal line or unkink the line.
	Circuit is disconnected from the patient.	Reconnect the circuit to the patient.
	Quick connector is loosened.	Secure the quick connector.
	Pressure transducer is improperly calibrated or defective.	Call FLIGHT MEDICAL.
Empty Battery Alarm	Detachable and Integral batteries charge is depleted and the ventilator shutdown will occur shortly.	Immediately connect the FLIGHT 60 Ventilator to external AC or DC power.
Power Switch Over Caution	External power cord is disconnected.	Reinsert the power cord.
	External power source failure	Use the batteries. Recharge the batteries when AC is available.
High Pressure Alarm	Increased patient resistance or decreased patient compliance.	Evaluate the patient. The patient may need suctioning, aerosol therapy, etc.
	Increased patient circuit resistance.	Check for obstructions (kinked tubes, water in tubing, occluded filters, etc.)
	Control/alarm parameters have changed.	Reevaluate settings.
	High Pressure alarm set incorrectly.	Readjust High Pressure alarm, if appropriate. Notify physician as necessary.
High Pbase alarm	Airway pressure remains above the Low Pressure alarm setting at the beginning of inspiration. Indicates an occlusion in the circuit/exhalation valve or that the proximal pressure line or exhalation drive line is pinched.	Unblock the occluded area. Recalibrate the exhalation valve.
	High breath rate (insufficient time to exhale).	Evaluate patient and make necessary adjustments to ventilation parameters.
	Ventilator auto triggering from leak or improper Ptrig setting.	Fix the leak and readjust Ptrig as needed.
	Rapid decreasing of the PEEP value.	Gradually decrease the PEEP.
High MV alarm	Increased spontaneous patient breathing.	Evaluate the patient. Adjust the High MV alarm setting, if needed.

Problem	Potential Cause	Suggested Action
	Increase in trachea/airway leak.	Evaluate the leak, look for normal wake-sleep trends, and set alarms appropriately.
	Increased minute volume due to ventilator auto triggering from leak	Check circuit for leak and correct. Perform leak check (exhalation valve calibration) on patient circuit.
	Increased minute volume due to ventilator auto triggering from Ptrig setting too low (most common with single use exhalation valve).	Reevaluate/readjust Ptrig setting (especially after circuit change).
	Increased minute volume due to ventilator auto triggering from loose quick connector.	Secure the quick connector.
	Increased minute volume due to ventilator auto triggering from circuit disconnected for airway care or by accident.	Reconnect the circuit securely. Push Audio Paused when reconnecting after airway care (to allow one minute for stabilization).
Low Battery Caution	Less than 20% of the detachable battery operation remains.	Plug the power cord into an external power source to charge.
Low Pressure Alarm	Decreased patient resistance or increased patient compliance.	Evaluate the patient. Adjust the ventilation settings and/or Low Pressure alarm, as needed.
	Leak or disconnect in the patient circuit.	Verify that connections are tight and leak free.
	Low Pressure alarm set incorrectly.	Readjust Low Pressure alarm, if appropriate. Notify physician as necessary.
Low Pbase Alarm	Baseline pressure is below set PEEP due to airway or circuit leak, or fluid pooled in tubing.	Verify that all circuit connections are secure and leak free, and that all fluid is cleared from the tubing.
Low MV Alarm/ Apnea Alarm	Patient efforts are not detected. The trigger level (Ptrig) is set improperly.	Perform a leak check on the patient circuit (exhalation valve calibration), secure the circuit connections, and evaluate the Ptrig setting. Detected patient efforts are indicated by the Ptrig LED illuminating green.
	The Low MV alarm is set above the delivered mandatory minute volume.	Readjust Low MV alarm setting level.

Problem	Potential Cause	Suggested Action
	Patient needs suctioning or airway occlusion (pressure control / pressure support).	Suction and evaluate patient.
	Patient is breathing slowly or is not breathing.	Evaluate patient.
	Apnea interval is too short.	Evaluate the patient. Adjust the Apnea alarm.
	Nebulizer treatment inline during pressure control / pressure support.	Adjust the Low MV alarm during nebulizer treatment.
Occlusion Alarm	Exhalation valve is blocked or line is kinked.	Check the exhalation valve line. Replace the exhalation valve assembly. Then, recalibrate the exhalation valve.
	High breath rate.	Change to lower rate, evaluate patient.
PCV Not Reached Alarm	Gross leak in the patient circuit.	Check all patient circuit connections.
	Target pressure setting requires a flow rate that is beyond the FLIGHT 60 Ventilator's maximal flow capability.	Reevaluate the ventilator settings and strategy.
Fault Alarm Led	Unrecoverable internal system failure.	Ventilate the patient with an alternate means of ventilation. Make note of the message in the alarm display area. Call FLIGHT MEDICAL
Check Setting Alarm	Non volatile storage inconsistency.	Verify which ventilation control is out of range and correct its value.

8.3 General/Clinical

Problem	Potential Cause	Suggested Action
Alarm volume too loud or too quiet.	Unintended setting.	To toggle between loud and quiet, push the buzzer button and choose from the list.

Problem	Potential Cause	Suggested Action
Batteries depleted too fast; not lasting up to 12 hours	Batteries are not fully charged.	Charge the batteries to their full charge level. Batteries charge in three hours from AC. Check the charge level by viewing the main and secondary battery icon level on the display. Extend the battery use time by plugging into AC when available. Suggestion: Optional accessory, Automobile 12V power cord can be used to plug the ventilator into the automobile cigarette lighter. Ensure that the green Ext. Power LED is illuminated when connected to an external AC or DC power source (it can take up to one minute). If the LED is not illuminated, check the connections and resolve any problems.
	Power Save is OFF. This decreases battery use time by 20% to 30%.	Enter Extended Setup and turn Power Save ON.
	Batteries are not in optimal condition or need to be replaced.	As the battery ages, the Low Battery caution occurs sooner. When this begins to infringe on the required battery time, the batteries should be replaced.
CO2 rises Child's CO2 rises dramatically when put on the ventilator	Too much dead space (re breathing) in the patient circuit. (On a single-limb circuit, the tubing on the patient side of the exhalation valve is dead space.)	On small patients, avoid using any tubing between the flow orifice and the patient. If extension tubing is a must, it should be as small as 15 mm ID and shorter than 50 mm. Note: The patient circuit tubing should always be 22 mm ID, even on small children.

Problem	Potential Cause	Suggested Action
Circuit disconnect / no alarm sounds Patient circuit is disconnected from the patient, but there is no alarm.	Low Pressure alarm is not appropriately set.	Set the Low Pressure alarm to ensure that it sounds when the patient circuit is disconnected. After setting up the patient and stabilizing the ventilation, remove the circuit from the patient at the airway and observe the peak airway pressure that develops with the next breath. Reconnect the patient and set the Low Pressure alarm above this pressure.
	High/Low Minute Volume alarm limits are not appropriately set.	Set High/Low alarms to bracket patient minute volume.
Exhalation Valve Cal Fails (Cal Failed) Reusable (single patient) or single use exhalation valve	A leak in the system.	a. Check all circuit connections. b. Check that the test lung is leak-free and that it is ≤ 1 L in size. c. Check that the exhalation valve drive line is secured. d. Use your thumb (covered with a clean gauze pad or equivalent) instead of a test lung, to occlude circuit during calibration. e. If using a reusable (single patient) exhalation valve, ensure that the diaphragm is seated properly. f. Try a different exhalation valve. NOTE: After taking corrective action, repeat Exhalation Valve Calibration procedure.
	Exhalation valve in use is not compatible with ventilator.	Use an exhalation valve that is approved for use with the FLIGHT 60 Ventilator.
Exhalation Valve Honks Exhalation valve makes honking noise	Low compliance / high resistance of circuit system.	Make sure that the patient circuit is 22 mm ID (regardless of patient size).
	The single use exhalation valve in use is not compatible with the ventilator.	Use an exhalation valve that is approved for use with the FLIGHT 60 Ventilator.

Problem	Potential Cause	Suggested Action
External Power Not Working After plugging into an external AC or DC outlet, Ext. Power indicator does not light after one minute.	Power cord is not plugged far enough into the ventilator outlet.	Check that the power cord is pushed in all the way.
	AC outlet has no power.	Check for power in the AC outlet or use another AC outlet with power.
	DC Auto lighter outlet is not active with engine off.	Make sure that the auto lighter outlet is active with the engine off, or turn the engine on.
Frequency is 1.5 Times Set Value Ventilator sounds alarm and the respiratory frequency is 1.5 times the original set value.	Ventilator is in Backup Ventilation in response to the Apnea Alarm being violated.	Backup Ventilation will stop, and the respiratory frequency will return to normal when the patient will triggered two spontaneous breaths within the preset Apnea interval or the user press the Alarm Reset button to stop the Backup Ventilation alarm.
Manual Inflation Button Breath terminates and High Pressure alarm is violated.	High Pressure alarm setting reached during Manual inflation.	If a higher inflation pressure is needed, increase the High Pressure alarm limit setting to a safe but appropriate level. Otherwise, decrease the flow rate or manual inflation time.
Manual Inflation Button Cannot generate adequate rise in pressure.	Mandatory flow is set too low.	Evaluate ventilation settings. If appropriate, decrease the inspiratory time to increase the flow.
	Gross leak in patient circuit.	Check/secure all patient circuit connections.
	Faulty exhalation valve.	Replace the exhalation valve.
	Pressure Control mode.	Assess Pressure Control setting.
PEEP Control Baseline pressure during exhalation continues to slowly decrease.	Faulty exhalation valve.	Replace the exhalation valve.
	Leak in the patient circuit.	Perform a leak check (exhalation valve calibration) and eliminate any leaks found.
	Leak around ET (Endotracheal) tube/ patient interface.	Check ET tube/patient interface.
PEEP Control Monitored Pbase is less than set PEEP.	Leak in patient circuit, endotracheal tube cuff, patient interface, or other.	Find and correct the leak.
	Uncalibrated exhalation valve.	Calibrate exhalation valve per instructions.
	Faulty exhalation valve.	Replace the exhalation valve.

Problem	Potential Cause	Suggested Action
Pressure reading Pressure does not return to zero when PEEP is set to zero.	Patient circuit resistance is caused by an occluded filter or exhalation valve, pooled water, or lodged secretions which prevent the free exit of patient exhalation.	Temporarily disconnect the patient circuit from the ventilator GAS OUTPUT outlet. If the pressure reading returns to zero, the cause of the elevated baseline pressure is circuit resistance. Check for (and empty) water in the patient circuit. Check for (and replace) the clogged filter or heat moisture exchanger in the patient circuit. Check for (and clean) an exhalation valve that has become clogged with medications or patient secretions. Ensure that the expiratory drive line is not kinked.
Pressure reading Baseline pressure (PEEP) is fluctuating.	Water in patient circuit tubing.	Drain tubing.
	Leak in patient circuit.	Perform exhalation valve calibration, check/eliminate any leaks found.
	Leak in the exhalation valve.	Replace the exhalation valve.
	Bounce/rebound from test lung.	Use a test lung with better physiological performance.
Pressure Not Rising Ventilator sounds like it is delivering breaths; however, the pressure is not rising during the breath.	Massive leak in the patient circuit.	Locate the leak and fix it.
	Exhalation valve diaphragm has become unseated.	Replace the exhalation valve / patient circuit.
Trigger Problem Patient cannot trigger the ventilator.	Inappropriate Ptrig setting.	Adjust the Ptrig towards "-0.1" until the ventilator autotriggers, then slowly increase the Ptrig setting until the autotriggering stops.
	Baseline pressure increased inadvertently due to *f*, Ti, Volume control, or Pressure control change.	Check the ventilation settings; readjust if necessary.
	Baseline pressure increased inadvertently due to incomplete exhalation.	Check the ventilation settings; readjust if necessary.

Problem	Potential Cause	Suggested Action
	Patient lacks any spontaneous effort or has very weak effort.	Evaluate the patient.
Trigger Problem Ventilator auto-triggering	Ptrig is not set properly.	Readjust Ptrig level.
	Leak in patient circuit, exhalation valve, or expiratory drive line.	Check/secure the circuit connections. Change the exhalation valve.
Trigger Problem Patient double-triggers the ventilator.	In volume control, the flow is set inappropriately low.	Check the flow setting in the display. If it is too low for patient need, decrease the inspiratory time (Ti) setting until the flow is set appropriately.
	Pressure support is set too low for patient need.	Reevaluate the pressure support setting.
Ventilator Makes Noise When Air/Oxygen Mixer Is Connected FLIGHT 60 Ventilator makes a loud noise when using the Air Oxygen Entrainment Mixer connected to a gas cylinder.	Cylinder is turned off or empty.	Check that the cylinder is turned on and that it is not empty.
Ventilator Pistons Move Between Breaths Ventilator sounds like the dual micro pistons continue to move between breaths.	The FLIGHT 60 Ventilator generates a 7.5 L/min of continuous flow in between breaths when PEEP is > 0 cmH2O.	Ventilator is operating correctly.
Water in Breathing Circuit Tubing	Room temperature is cooler than the heated, humidified breathing gas in the circuit. When the gas in the circuit cools, water precipitates out.	a. Place water trap inline with the patient circuit and empty it regularly. c. Use a heated wire circuit.

8.4 Air/Oxygen Entrainment Mixture

Problem	Potential Cause	Suggested Action
Monitored FiO2 is lower than set FiO2 by > 8%, when using Air Oxygen	Appropriate mixer retaining bracket and screw is missing.	Contact your provider or FLIGHT MEDICAL to obtain an appropriate retaining bracket and screw.

Problem	Potential Cause	Suggested Action
Entrainment Mixer.	Filter cover is loose.	Tighten the filter cover.
	Filter cover needs to be replaced.	Contact your provider or FLIGHT MEDICAL to obtain a replacement filter cover.
Mixer makes a pronounced clicking sound during normal operation.	Oxygen source gas pressure is low.	Check that the oxygen source gas is 50 psig.
	Oxygen source regulator is oscillating.	Check the oxygen source regulator. If the noise continues, Contact your provider or FLIGHT MEDICAL.
Oxygen leaks out of Mixer when connected to 50 psig oxygen gas source.	Mixer diaphragm is leaking.	Contact your provider or FLIGHT MEDICAL.

8.5 Contact Information

Address further questions or problems to one of the FLIGHT MEDICAL offices.

FLIGHT MEDICAL INNOVATIONS Ltd.
Address: 13 Hamelacha St., Lod 71520, ISRAEL
Tel: +972-8-923-5111
Fax: +972-8-923-6111
Email: info@flight-medical.com
Website: www.flight-medical.com

European Authorized Representative
Obelis s.a
Address: Boulevard Général Wahis 53 1030 Brussels, BELGIUM
Tel: +32 2 7325954
Fax: +32 2 7326003
Email: mail@obelis.net

9 Ventilator Quick Check Procedure

9.1 Introduction

Upon initial setup of the ventilator, verify proper ventilator operation by performing the Quick Check Procedure.

This procedure is intended to assist qualified operators to establish a routine program for verifying proper FLIGHT 60 Ventilator operation. Perform this procedure each time the ventilator is prepared for clinical use.

Repeat the Quick Check Procedure each time the ventilator is placed on a new patient or the patient circuit/exhalation valve is changed.

Before performing the test, you must perform a pretest inspection, and set up the ventilator for the test.

The Quick Check Procedure includes the following tests:

- Checking the power management
- Checking the alarms
- Checking the monitored parameters

HOME CAREGIVERS: This procedure should be performed by your Homecare equipment provider, prior to delivery of the FLIGHT 60 Ventilator, to verify proper operation. It can also be performed in the homecare environment to ensure proper setup and function of the ventilator.

WARNING Do not use the FLIGHT 60 Ventilator if it fails this procedure.

9.1.1 Setting Up the Ventilator for the Test

Before performing the test, do the following:

- Remove the three screws from the Filter Cover. Inspect the filter. Replace the filter if it is dirty. Reinstall the screws.
- Examine the 500 ml test lung and the patient circuit to ensure that there are no holes that will cause leaks.

- Verify that the AC power cord does not has frays or breaks.

➔ **To set up the ventilator for the test:**

1. Connect the detachable and Integral batteries.
2. Connect the AC power cord to an AC power source.
3. Connect a patient circuit with 500 ml test lung, to the FLIGHT 60 Ventilator.
4. Calibrate the exhalation valve See Section 5.4.5.
5. Press the On/Off button once. The ventilator performs a brief self-test and enters SETTINGS mode. During the self-test, verify that the ventilator purges, an audible alarm sounds and that all indicator LEDS illuminate.
6. Set the ventilator to the following Standard Test Settings *(STS)*:

Control	Setting
MODE	ACMV
Volume Control	500 ml
Ti	1.0 sec
f	15 b/min
Ptrig	-0.1 cmH2O/mbar
Low Pressure alarm limit	3 cmH2O/mbar
High Pressure alarm limit	99 cmH2O
Low MV alarm limit	0.0 L (minimum setting)
High MV alarm limit	50 L (maximum setting)
PEEP	0 cmH2O/mbar
PSV	0 cmH2O/mbar
Waveform	Square

7. Press the On/Off button to initiate ventilation.

9.2 Quick Check Procedure

9.2.1 Checking the Power Management

➔ **To check for power management:**

1. Disconnect the AC power cord. Verify that there is a Power Switchover caution message and intermittent audible caution.
2. Verify the EXT PWR indicator LED turns off, and the BAT indicator turns on to indicate that the ventilator is on battery power.

3. Verify that the arrows on the batteries icons facing down to indicate that the batteries are depleted.
4. Disconnect the detachable battery. Verify that there is a Low Battery caution message and intermittent audible caution.
5. Reconnect the detachable battery and the AC power.
6. Verify the EXT PWR indicator LED turns on, and the BAT indicator turns off.
7. Verify that the arrows on the batteries icons facing up to indicate that the batteries are charged.

9.2.2 Checking the Alarms

➔ **To check for High Presure alarm:**

1. Set the High P alarm limit to 10 cmH2O.
2. Verify that High Pressure alarm is activated (HIGH PRESSURE message display, visual and audible alarm and the indicator LED turns on).
3. Verify that inspiration ends when pressure reaches the high limit.
4. Set the High P alarm limit back to 99 cmH2O.
5. Verify that High Pressure alarm is deactivated
6. Press the Audio Paused button to clear the latched indicator LED.

➔ **To check for Low Presure alarm:**

1. Disconnect the test lung from the patient circuit.
2. Verify that Low Pressure alarm is activated within 3 breaths. (LOW PRESSURE message display, visual and audible alarm and the indicator LED turns on).
3. Reconnect the test lung to the patient circuit.
4. Verify that Low Pressure alarm is deactivated
5. Press the Audio Paused button to clear the latched indicator LED.

9.2.3 Checking the Monitored Parameters

➔ **To check for presure reading:**

1. Verify that both the Ppeak and the pressure gauge are within 10% or ±2 cmH2O of each other, whichever is greater.
2. Set the PEEP to 5 cmH2O.
3. Verify that both the Pbase and the pressure gauge are within ±2 cmH2O of each other. Reduce the PEEP to zero.

➔ **To check for volume reading:**

1. Verify that Vti and Vte are within 0.45 to 0.55 L.
2. Verify that MVi and MVe are within 6.5 to 8.5 L.

9.3 Check-Off Sheet

FLIGHT 60 Ventilator Quick Check

Pass/Fail Check-Off Sheet

Preparation for Use Tests	Indicate Result for each Test
Pretest Inspection Check	Pass _____ Fail _____
1. Power Management Check	Pass _____ Fail _____
Power Switchover Caution	Pass _____ Fail _____
Low Battery Caution	Pass _____ Fail _____
2. Alarms & Indicators Check	Pass _____ Fail _____
High Pressure Alarm	Pass _____ Fail _____
Low Pressure Alarm	Pass _____ Fail _____
3. Monitored Parameters Check	Pass _____ Fail _____
Peak Pressure	Pass _____ Fail _____
Base Pressure	Pass _____ Fail _____
Tidal Volume	Pass _____ Fail _____
Minute Volume	Pass _____ Fail _____

The ventilator is ready for operation when all tests have been completed successfully.

10 Technical Specifications

10.1 Physical Specifications

Physical Characteristic	Specification
Ventilator Weight	6.3 kg
Ventilator Dimensions	11.641 in wide x 11.457 in deep x 9.803 in high 295 mm wide x 291 mm deep x 249 mm high
Reusable Single Patient Circuit	Reusable (single patient) 22 mm ID 180 cm. length adult/pediatric circuit with 2.75 mm ID proximal pressure sensing line, 2.75 mm ID exhalation valve control drive line, 2.75 mm I.D. flow sensing line, exhalation valve, flow sensing orifice and quick convector.
Single Use Patient Circuit	Single use 22 mm ID 180 cm. length adult/pediatric circuit with 2.75 mm ID proximal pressure sensing line, 2.75 mm ID exhalation valve control drive line, 2.75 mm I.D. flow sensing line, exhalation valve, flow sensing orifice and quick convector..
Connectors	Gas Outlet: ISO 22 mm OD conical Air/Oxygen Inlet: ISO 30 mm female fitting.

10.2 Pneumatic Specifications

Item	Specification
Over Pressure Relief Valve	Limits the maximum airway pressure to 110 ± 5 cmH2O.
Negative Pressure Relief Valve(Anti-Asphyxia)	Opening pressure is between -3 cmH2O to -6 cmH2O.
O2 sensor	MAX 16 by MAXTEC; range from 0 to 100% oxygen. Warm up time: less than 30 minutes after replacement.

10.3 Electrical Specifications

Voltage	Frequency	Current Consumption
100 – 240 VAC	50 – 60 Hz	1.25 Amp MAX
12 – 15 VDC	NA	4.8 Amp MAX

10.4 Internal Battery Specifications

Battery Characteristic	Specification
Detachable Battery	
Battery Type	Li-Ion
Nominal Voltage	14.8 VDC
Nominal Pack Capacity	5.2 AH
Charging Time	Three hours MAX
Integral Battery	
Battery Type	Li-Ion
Nominal Voltage	14.8 VDC
Nominal Pack Capacity	2.6 AH
Charging Time	Three hours MAX
Average operating time for both batteries working together: When new and fully charged, the batteries supply power for up to 12 hours of operation at these settings: ACMV mode, f=15, Volume Control=500 ml, Ti=1.0 sec, PEEP=0, Max. Airway pressure = 30 cmH2O/mbar, Power Save mode ON.	

10.5 Safety and Particular Standard Specifications

Standard	Specification
Safety	IEC60601-1 Medical electrical equipment general requirements for basic safety and essential performance.
	IEC60601-1-2 General requirements for basic safety and essential performance; Collateral standard: electromagnetic compatibility.
	IEC 60601-1-8 (2003) 1st edition Medical electrical equipment – Parts 1-8: general requirements for safety; Collateral standard: general requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems.
Particular	IEC60601-2-12:2001(E) Particular requirements for the safety of lung ventilators – Critical care ventilators (replace: ASTM-F 1100-90) (ISO 10651-1).
	ISO10651-3:1997 Lung ventilators for medical use – Part 3: Particular requirements for emergency and transport ventilators.
	ASTM F1246 -91:2005 Standard specifications for electrically powered home care ventilators – Part 1: positive-pressure ventilators and ventilator circuits.

10.6 Environmental Specifications

Condition	Range
Operating Temperature	-18 ^{O}C to 50 ^{O}C / -.4 ^{O}F to 122 ^{O}F
Storage Temperature	-20 ^{O}C to 60 ^{O}C / -5.8 ^{O}F to 160 ^{O}F
Operating Pressure (Altitude)	70 KpA to 110 KpA
Humidity	15% to 95% RH at 31 ^{O}C
Water Resistance	IP34 (splash proof) IEC 60529
Sinusoidal Vibrations	IEC 60068-2-6
Bump	IEC 68-2-29
Free Fall	IEC 60068-2-32
Random Vibrations Wide Band	IEC 60068-2-6

10.7 Air/Oxygen Entrainment Mixer Specifications

Item	Specification
Oxygen	35 psig to 90 psig (2.4 Bar to 6.2 Bar) full operating range
Air	Atmospheric pressure
FIO2 Control	Adjusted continuously from 21% to 100% accuracy ± 8%

10.8 Oxygen Blending Bag Kit Specifications

Item	Specification
Oxygen	0 to 10 L/min (calibrated)
Air	Atmospheric pressure
FIO2 Control	FIO2, indirectly adjusted from 21% up to 100% via oxygen flow (L/min)