RAPHAEL model and software information

Four models comprise the RAPHAEL ventilator family: the basic RAPHAEL, the RAPHAEL Silver, the RAPHAEL Color, and the RAPHAEL XTC[1]. In this manual the generic "RAPHAEL" refers to any device. The Silver symbol in the margin denotes features specific to the RAPHAEL Silver. The symbol in the margin denotes features specific to the RAPHAEL Color and RAPHAEL XTC.

Functionally, the RAPHAEL Silver, RAPHAEL Color, and RAPHAEL XTC are supersets of the basic RAPHAEL. In addition to the functions of the basic RAPHAEL, the RAPHAEL Silver, RAPHAEL Color, and RAPHAEL XTC also feature the ASV, DuoPAP, and APRV modes; tube resistance compensation (TRC); and enhanced monitoring in the form of dynamic loop and trend displays. The RAPHAEL Color has a 5.7-in. color screen, and the RAPHAEL XTC has a 10.4-in. color screen.

To determine the RAPHAEL model, look at the front of the device. The RAPHAEL XTC has an aluminum knob and "XTC" on its label. The RAPHAEL Color has a rainbow-colored circle on its knob and the word "Color" on its label. The RAPHAEL Silver has a silver circle on its knob, a silver label, and the word "Silver" on its label. The basic RAPHAEL has a plain, bluish-white knob and only the word "RAPHAEL" on its label. The model name is also visible during power-up in the System check screen.

The software version for the RAPHAEL is visible during power-up in the System check screen and in utilities window 2. This manual applies to the RAPHAEL ventilator with software version 3. If your RAPHAEL has a different software version, contact your HAMILTON MEDICAL representative or consult the product catalog on www.hamilton-medical.com for manual ordering information.

1. The basic RAPHAEL and the RAPHAEL Silver are not available in the USA

Definitions

WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTE:

Emphasizes information of particular importance.

This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.

Applies only to the RAPHAEL Color and RAPHAEL XTC

Applies only to the RAPHAEL Silver

General warnings, cautions, and notes

Intended use

The RAPHAEL ventilator is a continuous ventilator designed for ventilation of adult and pediatric patients weighing between 5 and 200 kg. The RAPHAEL ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The RAPHAEL ventilator is intended for use in a hospital or hospital-type facility, including use at a patient bedside or for intrafacility transport, provided compressed gas is supplied.

General operation notes

- The RAPHAEL ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician.
- Familiarize yourself with this operator's manual before using the ventilator on a patient.
- The displays shown in this manual may not exactly match what you see on your own ventilator.
- Not all ventilator models, accessories, and features in this manual are available in all markets.
- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Monitoring and alarms

- The RAPHAEL is not intended to be a comprehensive vital sign monitor for patients on life-support equipment. Patients on life-support equipment should be appropriately monitored by qualified medical personnel and suitable monitoring devices. The use of an alarm monitoring system does not give absolute assurance of warning for every form of malfunction that may occur with the ventilator.
- Do not silence the audible alarm when leaving the patient unattended.

- An alternative means of ventilation shall be available whenever the ventilator is in use. If a fault is detected in the ventilator and its life-support functions are in doubt, ventilation must be started without delay with such a device (for example, a resuscitation bag), using PEEP and/or increased oxygen concentration when appropriate. The ventilator must be removed from clinical use and serviced by qualified personnel.
- In case of malfunction of the ventilator's built-in monitoring and in order to maintain an adequate level of patient monitoring at all times, it is recommended that additional independent monitoring devices be used. The operator of the ventilator must still maintain full responsibility for proper ventilation and patient safety in all situations.

Fire and other hazards

- To reduce the risk of fire or explosion, do not place the RAPHAEL in a combustible or explosive environment. Do not use it with flammable anesthetic agents. Do not use it with any equipment contaminated with oil or grease.
- To reduce the risk of fire, do not use high-pressure gas hoses that are worn or contaminated with combustible materials like grease or oil.
- To reduce the risk of fire, use only breathing circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.
- In case of fire, immediately secure the patient's ventilatory needs, switch off the RAPHAEL, and disconnect it from its gas and electrical sources.

Service and testing

- To ensure proper servicing and to prevent possible physical injury, only qualified personnel should attempt to service the ventilator.
- To reduce the risk of electrical shock, do not open the ventilator housing. Refer the ventilator for servicing by qualified personnel.

- To reduce the risk of electrical shock, disconnect electrical power from the ventilator before servicing.
- Do not attempt service procedures other those specified in the service manual.
- Any attempt to modify the ventilator hardware or software without the express written approval of HAMILTON MEDICAL automatically voids all warranties and liabilities.
- If the device must be modified, relevant tests must be run to ensure the continuous safe use of the device.
- Use replacement parts supplied by HAMILTON MEDICAL only.
- The preventive maintenance program requires a general service every 5000 hours or yearly, whichever comes first.
- To ensure the ventilator's safe operation, always run the prescribed tests and calibrations before using the ventilator on a patient. If the ventilator fails any tests, remove it from service immediately. Do not use the ventilator until necessary repairs are completed and all tests passed.

Electromagnetic susceptibility

The RAPHAEL complies with the IEC 60601-1-2:2001 EMC (Electro Magnetic Compatibility) Collateral Standard. Certain transmitting devices (for example, cellular phones, walkie-talkies, cordless phones, paging transmitters), however, emit radio frequencies that could interrupt the RAPHAEL operation. Do not operate these transmitting devices within the vicinity of the RAPHAEL. Do not use the RAPHAEL in an environment with magnetic resonance imaging (MRI) equipment.

Section 6 lists the alarms that can possibly occur due to such disruption, along with the corresponding corrective actions. Consult your service representative in case of interrupted ventilator operation.

Electromagnetic emissions

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to both Part 15 of the FCC Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

User/owner responsibility

HAMILTON MEDICAL products are designed to function as described in the *Operator's Manual*. The user(s) of this equipment should not use parts that have failed, exhibit excessive wear, are contaminated, or are otherwise ineffective.

The products must not be modified in any manner.

The user/owner of these products shall have the sole responsibility and liability for any injury to persons or damage to property, including the product, resulting from:

- Operation not in accordance with the supplied and specified operator's manual
- Service and maintenance not in accordance with the authorized maintenance/operating instructions
- Service and maintenance conducted by an unauthorized service organization
- Modification of the equipment and any of its accessories
- Use of damaged, unauthorized, or unapproved components and accessories

Units of measure

Pressures are indicated on the RAPHAEL in cmH_2O or mbar. Hectopascals (hPa) are used by some institutions instead. Since 1 mbar equals 1 hPa, which equals 1.016 cmH_2O, the units may be used interchangeably.

Disposal

Dispose of all parts removed from the device according to your institution's protocol. Sterilize before nondestructive disposal. Follow applicable regulations regarding disposal or recycling.

Year of manufacture

The year of manufacture can be determined from the serial number label, which is on the RAPHAEL back panel. The first two digits of the part number are the last two digits of the year of manufacture.

Software version identification

The software version for the RAPHAEL is visible during power-up in the System check screen and in the utilities window 2. This manual applies to the RAPHAEL ventilator with software version 3.3 or greater.

Table of contents

Table of contents

Appendixes

List of figures

List of tables

1 General information

1.1 Introduction

The RAPHAEL intensive care ventilator provides ventilatory support to pediatric and adult patients between 5 and 200 kg.

Models. The RAPHAEL family includes the basic RAPHAEL, the RAPHAEL Silver, the RAPHAEL Color, and the RAPHAEL XTC. The RAPHAEL Silver, RAPHAEL Color, and RAPHAEL XTC are supersets of the basic RAPHAEL -- the RAPHAEL Silver, RAPHAEL Color, and RAPHAEL XTC include the additional modes DuoPAP, APRV, and ASV; tube resistance compensation (TRC); and enhanced monitoring in the form of dynamic loop and trend displays.

Ventilation. The RAPHAEL offers a full range of ventilation modes, ranging from adaptive volume-controlled, to pressure-controlled, to spontaneous, and to advanced modes.

Adaptive volume-controlled modes (S)CMV+ and SIMV+, pressure-controlled modes PCV+ and PSIMV+, and the spontaneous mode (SPONT) are available in the RAPHAEL. In the adaptive volume-controlled modes, the RAPHAEL's adaptive controller delivers the target volume with the lowest pressure possible, combining the benefits of pressure-controlled ventilation with a volume guarantee.

The noninvasive ventilation (NIV) mode, available in all models, permits the use of a mask or other noninvasive patient interface.

Advanced modes ASV® (adaptive support ventilation), DuoPAP", and APRV are offered in the RAPHAEL Silver, RAPHAEL Color, and RAPHAEL XTC only. ASV calculates an optimal breath pattern, based on minimal operator inputs and patient condition. It guarantees that the patient receives selected minute ventilation, at the lowest possible pressures. DuoPAP and APRV, two related modes, are forms of pressure ventilation. In these the operator sets two pressure levels, for inspiration (upper) and exhalation (lower), similar to having two levels of CPAP. Both modes provide a combination of control and spontaneous breaths and let the patient breathe freely throughout the entire breath cycle.

Patient-triggered breaths are flow-triggered. The RAPHAEL employs the biphasic ventilation concept, letting your patient breathe freely in all modes and phases. To reduce the patient's work of breathing while on the RAPHAEL, the device compensates automatically for the inspiratory and expiratory limb breathing circuit resistances. A pneumatic nebulizer connection is standard on the RAPHAEL. The Aerogen® Aeroneb® Pro ultrasonic nebulizer system is available as an option.

Monitoring. The RAPHAEL offers a variety of monitoring capabilities, including oxygen monitoring. It displays 19 monitored parameters as numbers. You can also see monitored data graphically, as a pressure, flow, or volume waveform (curve).

The RAPHAEL Silver, RAPHAEL Color, and RAPHAEL XTC offer several additional monitoring features. With these ventilators, you can choose to show data as a dynamic loop. The trending function lets you view up to 1, 12, or 24 hours of data, and you can use the cursor measurement function to determine a value at a selected point on the trend curve.

The RAPHAEL's monitored data is based on pressure and flow measurements collected by the HAMILTON MEDICAL proximal Flow Sensor, close to the patient between the Y-piece and the patient; or by the integral oxygen monitor.

Alarms. The RAPHAEL lets you set high pressure, high and low frequency, and low and high exhaled minute volume alarms. It offers an automatic alarm feature, which automatically adapts alarm settings based on the current patient status. An event log stores information about alarms that have occurred along with setting changes and other "events."

User interface. The ventilator's ergonomic design, which incorporates a press-and-turn knob and keys, let you easily access the ventilator settings and monitored parameters.

Configuration. The language, default monitoring display, and default control, alarm, and other settings can be preselected in the configuration mode.

Power. The RAPHAEL is normally powered from ac mains, covering ranges of 100 to 125 and 200 to 240 V ac, 50/60 Hz. In the event of an ac mains power failure, the internal backup batteries automatically switch on to provide power temporarily.

Mounting. An optional trolley and a bed mount are available for the RAPHAEL. The trolley can accommodate a VENTILAIR^{II} compressor plus two gas cylinders, when the optional gas cylinder holder is installed. Equipped with trolley and gas cylinder holder, the RAPHAEL can ventilate patients during intrafacility transport.

Options and upgrades. A communications interface option is available for the RAPHAEL. The interface lets you monitor the patient from a workstation, transmits alarms through a nurse call relay system, and transmits I:E timing signals.

1.2 Functional description

The following paragraphs describe the operation of the RAPHAEL ventilator from a hardware perspective.

1.2.1 System overview

The RAPHAEL is an electronically controlled pneumatic ventilation system. It is powered by ac with a battery backup to protect against power failure or unstable power and to facilitate intrahospital transport. The RAPHAEL's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.

The user provides inputs to the RAPHAEL microprocessor system through the keys and the press-and-turn knob. These inputs become instructions for the RAPHAEL's pneumatics to deliver a precisely controlled gas mixture to the patient. The RAPHAEL receives inputs from the Flow Sensor in the patient's airway and other sensors within the ventilator. Based on this monitored data, the RAPHAEL continually adjusts gas delivery to the patient. Monitored patient data is also displayed by the graphic user interface.

The RAPHAEL's microprocessor system controls gas delivery and monitors the patient. The gas delivery and monitoring functions are cross-checked by an alarm controller. This cross-checking helps prevent simultaneous failure of these two main functions and minimizes the possible hazards of software failure.

1.2.2 Gas supply and delivery

The RAPHAEL uses high-pressure oxygen and air from wall supplies, cylinders, or the VENTILAIR^{II} compressor (Figure 1-1). These gases enter through water traps with integrated high-efficiency particle filters.

Within the ventilator, the gas enters the RAPHAEL's pneumatic system. An electronic mixer combines oxygen and air according to the user-set concentration. This mixture fills a reservoir tank, which is maintained at a constant pressure. As the gas mixture is delivered to the patient, the pressure drops, and the reservoir is continually refilled. The high-pressure oxygen and air inputs are switched on and off as needed to maintain the pressure in the reservoir. The reservoir not only allows for high patient demand, but it also supplies the pneumatic nebulizer.

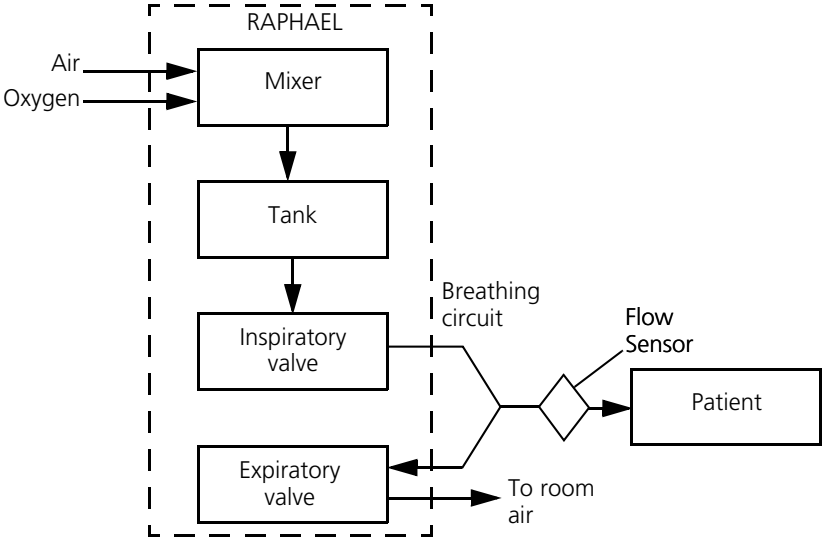


Figure 1-1. Gas delivery in the RAPHAEL

Gas in the tank supplies the inspiratory valve. The microprocessor controls the size of the inspiratory valve opening and the length of time it is open to meet the user settings. The opening of the valve is then adjusted based on feedback in the form of monitored data.

An oxygen cell (sensor) monitors the gas to be delivered to the patient. This galvanic cell generates a voltage proportional to the partial pressure of oxygen in the delivered gas. Neither the patient pressure nor the humidity of the inspired gas affects the oxygen measurement. The ventilator alarms if the monitored oxygen concentration is more than 5% above or below the oxygen setting, less than 18% or more than 104%.

The RAPHAEL delivers gas to the patient through the inspiratory limb breathing circuit parts, including the inspiratory filter, flex tubes, the humidification system, a water trap, the Y-piece, and the Flow Sensor.

Gas exhaled by the patient passes through the expiratory limb breathing circuit parts, including flex tubes, the Flow Sensor, the Y-piece, a water trap, and an expiratory valve cover and membrane. Gas is vented through the expiratory valve cover. Measurements taken at the Flow Sensor are used in the patient pressure, flow, and volume measurements. Exhaled gas from the patient never contacts internal components of the RAPHAEL.

The operations of the inspiratory and expiratory valves are coordinated to maintain system pressure levels.

1.2.3 Gas monitoring with the Flow Sensor

The RAPHAEL accurately measures flow, volume, and pressure in the patient's airway with the HAMILTON MEDICAL Flow Sensor. This proximal Flow Sensor lets the RAPHAEL recognize even the weakest of the patient's breathing efforts. Between its highly sensitive flow trigger and fast response time, the RAPHAEL helps minimize the patient's work of breathing.

Physically, the Flow Sensor is a thin membrane within a housing. The membrane allows bidirectional flow through its variable orifice (Figure 1-2).

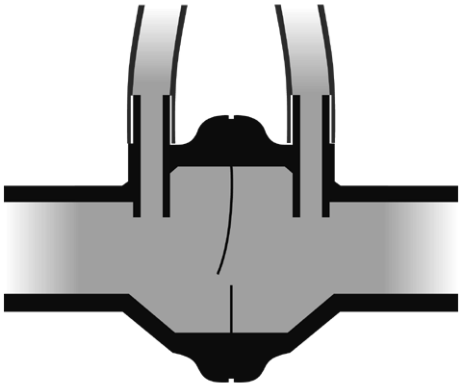


Figure 1-2. Flow Sensor variable orifice

The orifice changes its diameter depending on the flow rate. It opens progressively as the flow increases, creating a pressure drop across the orifice. The pressure difference is then measured by a high-precision differential pressure sensor inside the ventilator. The pressure difference varies linearly with flow over a range of 20 to 3000 ml/s. The patient's flow is determined from the pressure drop. The RAPHAEL calculates volume from the flow measurements.

The Flow Sensor is highly accurate even in the presence of secretions, moisture, and nebulized medications. The RAPHAEL continuously flushes the sensing tubes.

The RAPHAEL can work even without the Flow Sensor in a limited capacity.

An automatic Flow Sensor system check runs periodically.

1.3 Physical description

1.3.1 Breathing circuits and accessories

Figure 1-3 shows the RAPHAEL with its breathing circuit and accessories. See Appendix F for details on breathing circuits and accessories supplied by HAMILTON MEDICAL. See Table 1-1 for information on other compatible breathing circuits and accessories.

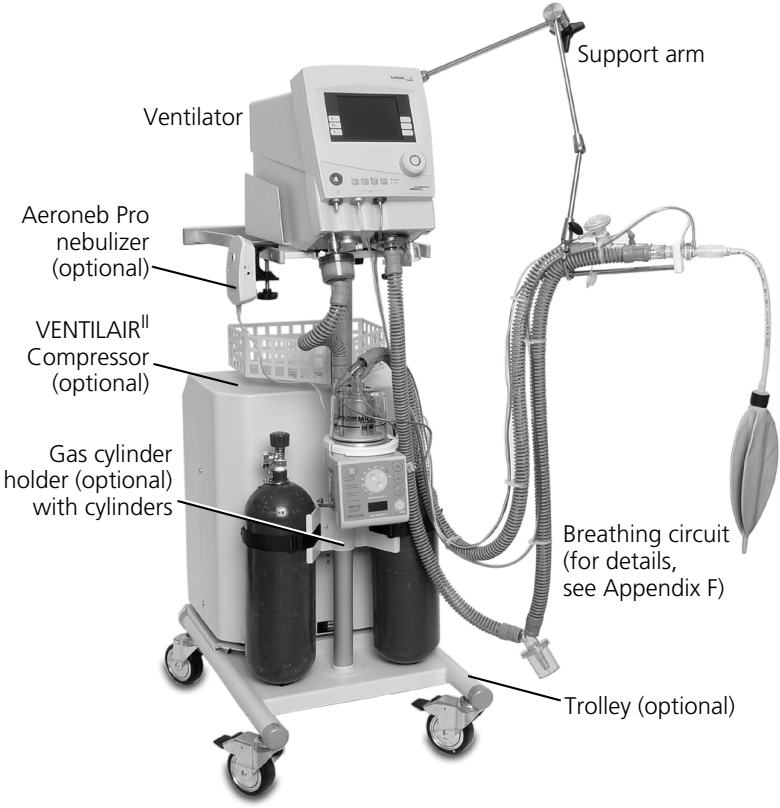


Figure 1-3. RAPHAEL with accessories

Table 1-1. Compatible parts and accessories

Part	Use...
Patient tubing circuit	• HAMILTON MEDICAL reusable patient tubing circuits • Other circuits that meet the specifications in Appendix A
Noninvasive patient interface	Face or nasal mask or mouthpiece
Inspiratory filter	• HAMILTON MEDICAL reusable inspiratory bacteria filter • Other filters that have a 22 mm female conical inlet connector, a 22 mm male outlet connector, and a pressure drop of < 2 cmH_2O at 60 l/min
Humidification device	• Any Fisher & Paykel humidifier. HAMILTON MEDICAL supplies the Fisher & Paykel MR850 humidifier. • Any active humidifier with a flow capability of up to 120 l/min • Heat and moisture exchanger
Flow Sensor	HAMILTON MEDICAL parts only (marked with the HAMILTON "H")
Expiratory valve membrane and housing	HAMILTON MEDICAL parts only
Compressor	HAMILTON MEDICAL VENTILAIR^{II} Compressor
Nebulizer	Pneumatic nebulizer jar specified for approximately 6 to 7 l/min, or Aerogen Aeroneb Professional Nebulizer System (Aeroneb Pro). A portable medical device for multiple patient use that is intended to aerosolize physician-prescribed medications for inhalation.

1.3.2 Ventilator unit

Figure 1-4 through Figure 1-8 show the controls, indicators, and other important parts of the RAPHAEL ventilator unit.

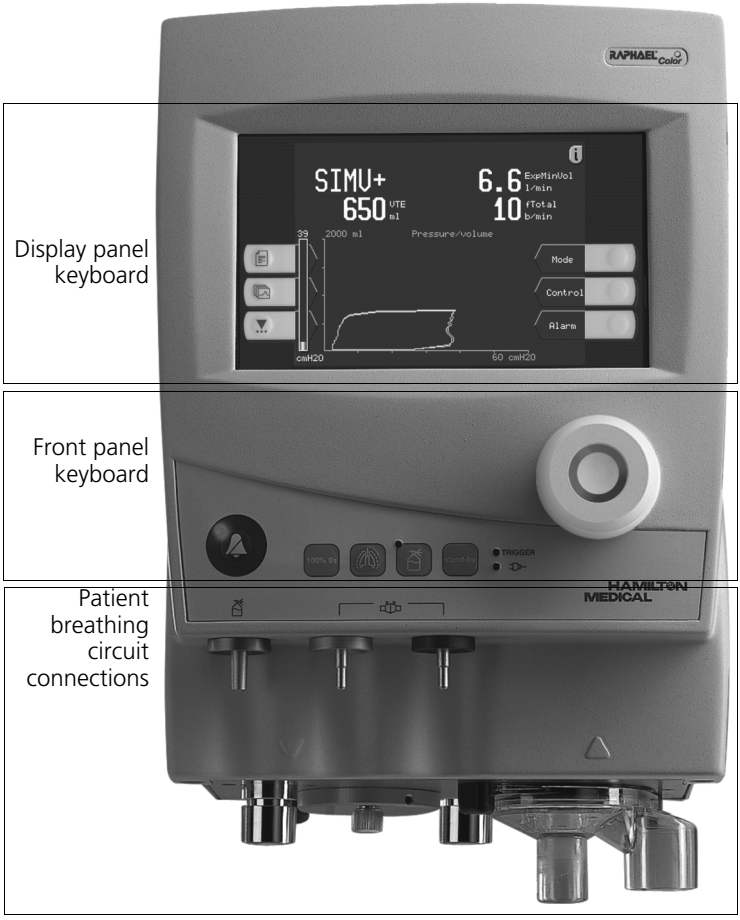


Figure 1-4. Front panel

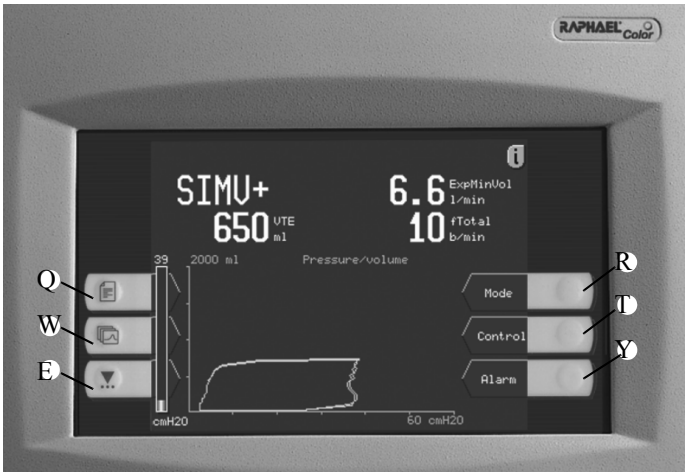


Figure 1-5. Display panel keyboard

Key	Description
Q	**Access key for numeric patient data window.** Accesses the numeric monitoring parameter windows.
W	**Access key for graphic selection window.** Opens the window to select a graphic for display. Choices include: • A pressure, volume, or flow waveform •A loop • A trend • The ASV target graphics screen
E	**Access key for utilities window.** Accesses the utilities windows. The first window allows the user to run the oxygen, Flow Sensor, and tightness tests and to adjust the audible alarm loudness. The second window contains ventilator-specific information, such as software and hardware revisions, options, operating hours, and battery status.
R **Mode**	**Access key for mode window.** Opens the mode setting window. This allows the user to select the ventilation mode, sigh, and apnea backup.

Key	Description
T **Control**	**Access key for control window.** Accesses the control setting windows. This allows the user to adjust control settings,  including those for tube resistance compensation.
Y **Alarm**	**Access key for alarm window.** Opens the alarm setting window. This allows the user to adjust alarm limits.

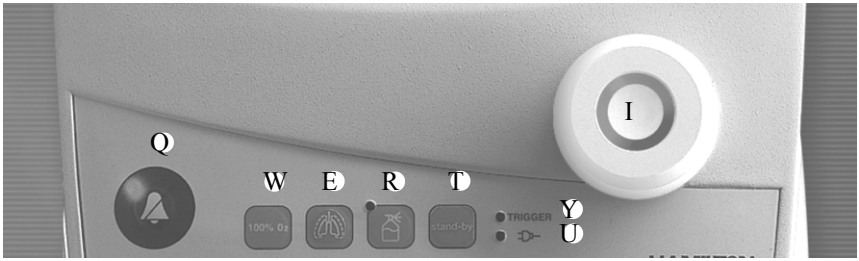


Figure 1-6. Front panel keyboard

Control/ indicator	Description
Q 	**Alarm silence key.** Silences the audible alarm for 2 min. The indicator is lit during alarm silence, and a symbol is displayed in the lower right-hand corner of the screen.
W 	**100% O_2 key.** Delivers 100% oxygen for 5 min. For details, see Section 7.1.
E 	**Inspiratory hold/manual breath/disconnection suppression key.** Triggers a mandatory breath when pressed and released during exhalation. Starts breath delivery during a disconnection. Triggers an inspiratory hold when held down during any breath phase. For details, see Section 7.2.
R 	**Nebulizer key.** Activates pneumatic nebulizer, during the inspiration phase. The indicator is lit whenever nebulization is active. Nebulization stops automatically after 30 min. You can switch it off earlier by pressing the key again. For details, see Section 7.3.
T 	**stand-by key.** Activates the stand-by (waiting) mode. When the mode is activated, the stand-by screen is displayed. For details, see Section 7.4.

Control/ indicator	Description
Y TRIGGER	**TRIGGER indicator.** Indicates the patient is triggering a breath.
U 	**ac power indicator.** Indicates the ventilator is connected to ac power. The battery is charging whenever this indicator is lit.
I	**Press-and-turn knob** for setting parameters

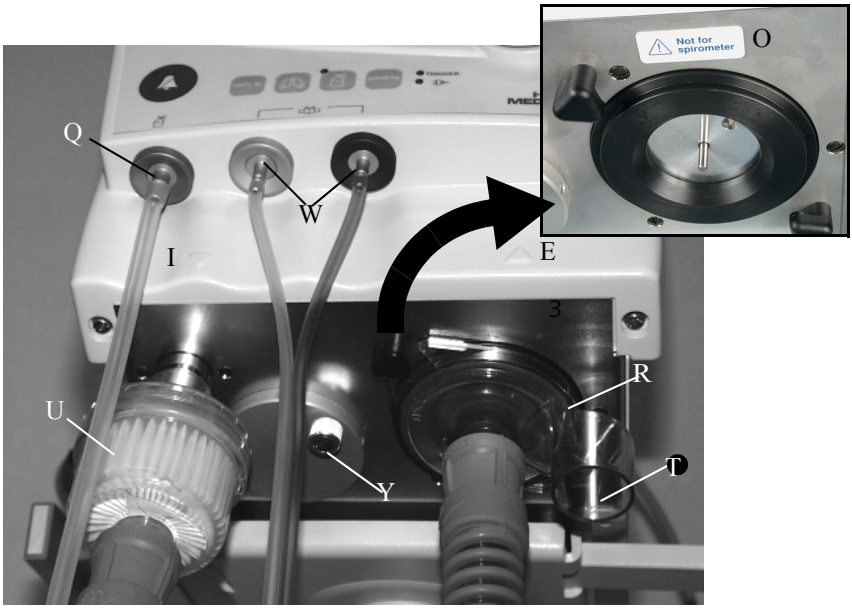


Figure 1-7. Patient breathing circuit connections

Item	Description
Q	**Pneumatic nebulizer output connector**
W	**Flow Sensor connection.** Always attach the blue tube to the blue connector and the clear tube to the silver connector. The blue tube should always be *toward the patient*.
E	**From patient port.** The expiratory limb of the patient breathing circuit and the expiratory valve are connected here.
R	**Expiratory valve cover and membrane**
T	**Exhaust port**. Expiratory valve cover opening to ambient air.
Y	**Oxygen cell carrier**

Item	Description
U	**Inspiratory filter**
I 	**To patient port.** The inspiratory filter and the inspiratory limb of the patient breathing circuit are connected here.
O **Not for spirometer**	**Not for spirometer label.** To prevent back pressure and possible patient injury, do not attach a spirometer, tube, or other device to the exhaust port of the expiratory valve housing.

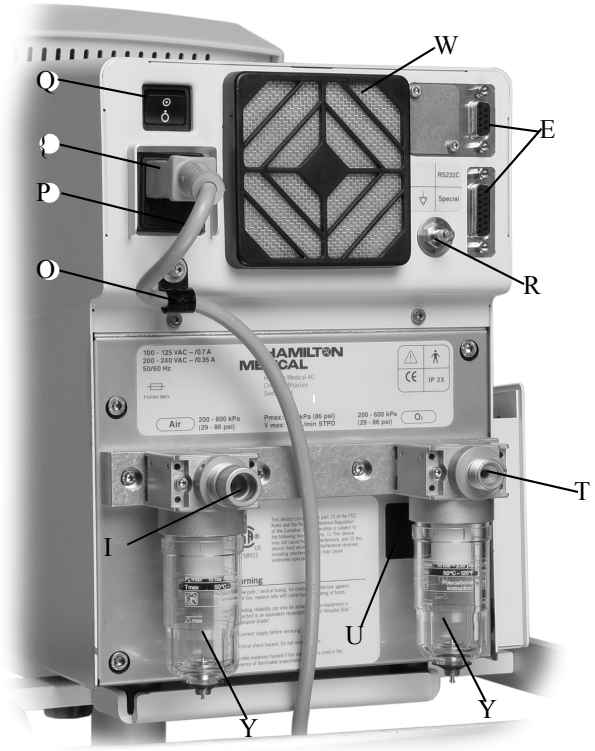


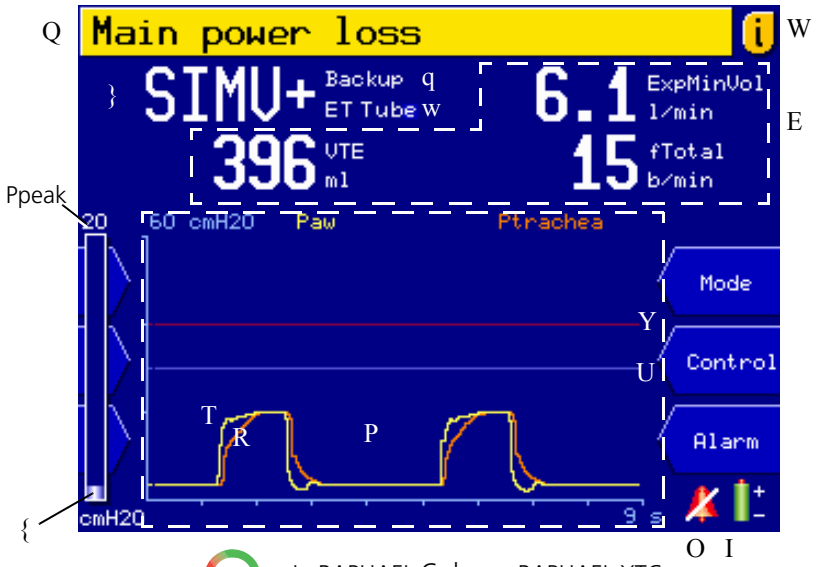
Figure 1-8. Rear view

Item	Description
Q ⊙ ○	**Power switch.** ⊙ represents the on position; ○ represents the off position for only a part of the equipment. In this position, power to the ventilator is turned off, but the batteries are charged if ac power is present.
W	**Fan filter**
E	**Communications interface connectors** (see Figure G-7 for details)
R	**Potential equalization (ground) point conductor terminal**

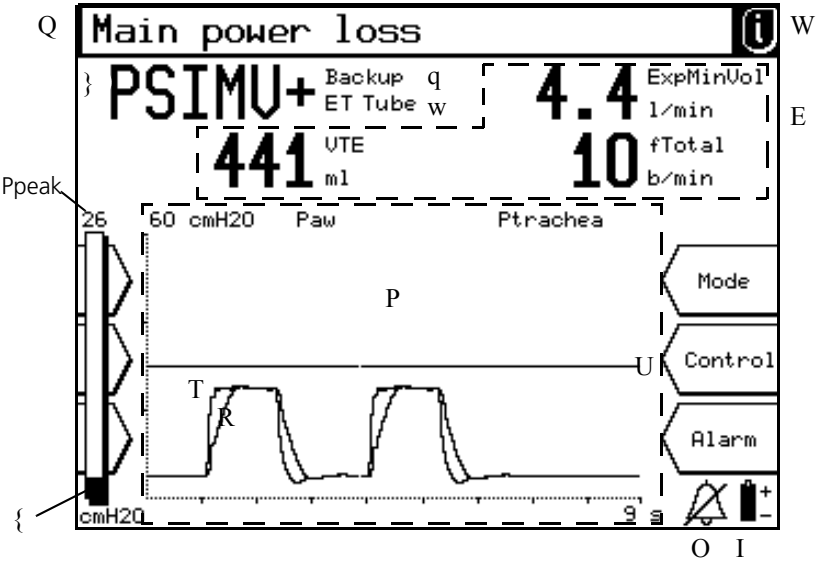
Item	Description
T	**High-pressure oxygen connector**
Y	**High-pressure gas water trap with filter**
U	**Serial number label.** Shows the ventilator's part number, serial number, and year of manufacture.
I	**High-pressure air connector**
O	**Power cord with clip**
P	**Fuse drawer.** This holds two 1.0 A, type T (slow-breaking), type H (high-current breaking), 250 V fuses.
{	**Power receptacle.** Make sure the power cord is secured with the power cord clip. When the ventilator is connected to ac power, the ac power indicator on the front panel is always lit. The batteries are always charging whenever the ventilator is connected to ac power, whether or not the power switch is on.

1.3.3 Screen

The screen provides information about the status of the patient and ventilator. The *basic screen* (Figure 1-9) is the default screen. You can directly access all the windows for mode, controls, alarms, monitoring, curve display, and utilities from the basic screen, even during normal ventilation.



a. In RAPHAEL Color or RAPHAEL XTC



b. In RAPHAEL Silver or basic RAPHAEL

Figure 1-9. The basic screen

Item	Description
Q	**Message line.** Displays alarm and other messages for user guidance and status report. See Section 6 for further information.
W 	**Event log indicator.** Indicates that events (alarms or ventilator setting changes) have occurred since the ventilator was powered on. The symbol guides the user to view the event log, which contains information on these events. View the event log contents by pressing the press-and-turn knob from the basic screen.
E	**Main monitoring parameters.** Three main monitoring parameters set by the user in the configuration mode
R 	**Ptrachea curve.** The tracheal pressure curve (orange in the RAPHAEL Color and RAPHAEL XTC, typically not as steep as Paw). Shown only if tube resistance compensation is active.
T	**Paw curve.** The airway pressure curve (yellow in the RAPHAEL Color and RAPHAEL XTC).
Y 	**Pmax.** A dark red line that Indicates the operator-set Pmax alarm limit when the pressure curve is shown.
U	**Pressure limitation.** Indicates Pmax - 10 cmH_2O when the pressure curve is shown. When the ventilator attempts to exceed this level, the ventilator invokes a **`Pressure limitation`** alarm.
I 	**Battery indicator.** Indicates that the RAPHAEL is running on its backup batteries. It also indicates the level of battery charge. If the symbol is gray, no information about the battery charge is available.
O 	**Alarm silence indicator.** Indicates that the audible alarm has been silenced. If the alarm condition is not resolved, the audible alarm resumes after 2 min.

Item	Description
P	**Graphic.** • Curve • Trend curve  • Loop • ASV target graphics screen
{	**Pressure gauge.** Indicates pressure in the patient's airway. Its synchronized fluctuation with chest movement also signifies normal ventilator operation. The number at the top of the gauge is the peak pressure (Ppeak) for the previous breath.
}	**Active mode**
q	**Apnea backup indicator.** Indicates apnea backup is enabled. When the ventilator is in apnea backup, the word **`Backup`** is highlighted.
w	 **TRC tube type indicator.** If tube resistance compensation is active, indicates the type of tube selected.

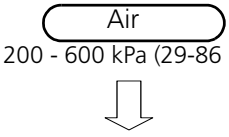
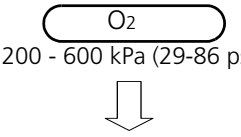
1.4 Back panel symbols

Table 1-2 describes the symbols used on the RAPHAEL back panel.

Table 1-2. Back panel symbols

	Fuse, 1.0 A, 250 V, type T (slow-breaking), type H (high-current breaking)
	Classification of Medical Electrical Equipment, type B, as specified by IEC 60601-1:1988

Table 1-2. Back panel symbols (continued)

	Refer to the operator's manual for complete information
	Potential equalization point (ground) conductor terminal, as specified by IEC 60601-1:1988
	CE Marking of Conformity.
IP 21	Indicates the degree of protection provided by enclosure (drip-proof), according to IEC 60601-1/ EN 60601-1
	Canadian Standards Association and National Recognized Test Laboratory approval
	Driving gas supply pressure for air
	Driving gas supply pressure for oxygen
	Emergency air intake and pressure release

2 Preparing for ventilation

2.1 Introduction

This section tells you how to set the ventilator up for operation, including connecting the electrical supply, connecting the air and oxygen supplies, connecting the ventilator breathing circuit and accessories, and startup.

WARNING

- **To permit the proper functioning of the RAPHAEL under emergency conditions, do not obstruct the emergency air intake and pressure release outlet located beneath the RAPHAEL.**
- **To prevent interrupted operation of the RAPHAEL or any accessories, use only accessories or cables that are expressly stated in this manual or that comply with IEC 60601-1-2. The use of accessories or cables other than those for which the RAPHAEL ventilator was designed can significantly degrade emission and immunity performance and is necessary to help ensure that the user will be able to operate the RAPHAEL ventilator as intended.**
- **To prevent interrupted operation of the RAPHAEL due to electromagnetic interference, avoid using it adjacent to or stacking other devices on it. If adjacent or stacked use is necessary, verify the RAPHAEL's normal operation in the configuration in which it will be used.**
- **To prevent back pressure and possible patient injury, do not attach a spirometer, tube, or other device to the exhaust port of the expiratory valve housing.**
- **To ensure uninterrupted patient ventilation, do not allow water traps to overflow. Check and empty water traps at appropriate intervals.**

CAUTION

- **To prevent oxygen accumulation and increased fire hazard, do not block the air exit holes.**
- **To prevent possible equipment damage, make sure the RAPHAEL is securely mounted to its trolley or shelf. It must be secured by its mounting screw (visible beneath the trolley or shelf).**
- **To prevent possible equipment damage, lock the trolley's wheels when parking the ventilator.**

NOTE:

Before using the ventilator for the first time, HAMILTON MEDICAL recommends that you clean its exterior and sterilize its components as described in Section 8.

2.2 Connecting to ac power

WARNING

To minimize the risk of electrical shock, plug the ventilator power cord into a grounded ac power receptacle. To ensure grounding reliability, use a special hospital-grade receptacle.

NOTE:

To prevent unintentional disconnection of the power cord, make sure the cord is secured with the power cord clip (Figure 2-1).

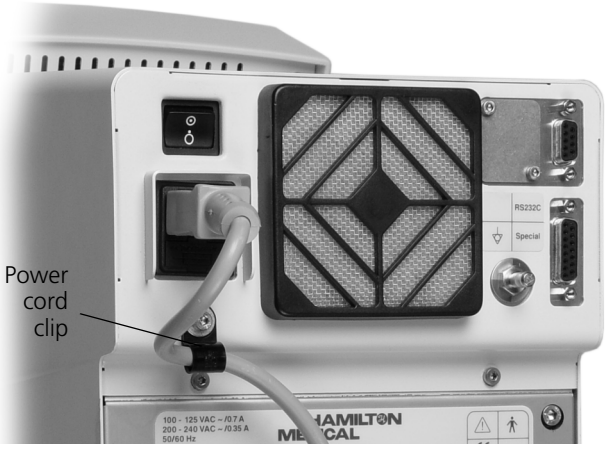


Figure 2-1. Power cord clip

Connect the RAPHAEL to a grounded ac outlet. When the ventilator is connected to ac power, the ac power indicator lights. Always check for the reliability of the ac outlet. If in doubt, connect the yellow-green marked potential equalization terminal to a ground marked hospital-grade.

2.3 Connecting the gas supplies

WARNING

- **Always check for the status of the oxygen cylinder before using the RAPHAEL during transport. The RAPHAEL ventilates the patient with 100% oxygen if it becomes disconnected from the compressed air supply.**
- **To minimize the risk of fire, do not use high-pressure gas hoses that are worn or contaminated with combustible materials like grease or oil.**

CAUTION

To prevent damage to the ventilator, connect only clean, dry medical-grade gases. Check for water and particle build-up in the gas supply water traps before each use.

NOTE:

- When using oxygen cylinders with the ventilator, it is recommended that you use pressure-reducing valves with fittings identical to that on the wall supply. This allows a seamless switchover if the cylinders become depleted.
- When in stand-by mode, the RAPHAEL consumes oxygen. Be aware of possible depletion of bottled oxygen.
- A self-emptying water trap kit is available for the RAPHAEL. See Table F-2 for ordering information.

The RAPHAEL uses compressed air and oxygen with pressures between 200 to 600 kPa (29 to 86 psi). It has DISS male gas fittings.

The compressed gases can come from central gas supplies, from gas cylinders, or from the VENTILAIR^{II} compressor. The RAPHAEL's trolley provides space for the compressor and two cylinders (if you have the optional cylinder mounting kit). If you are using gases from cylinders, fasten the cylinders to the trolley with the accompanying straps.

Connect the air and oxygen hoses to the RAPHAEL's inlet fittings, shown in Figure 2-2.

Figure 2-2. Connecting the air and oxygen supplies

2.4 Installing the humidifier

Install a humidifier to the RAPHAEL using the slide bracket on the trolley column (Figure 2-3). Prepare the humidifier as described in the manufacturer's operation manual.

Figure 2-3. Installing the humidifier

2.5 Installing the patient tubing support arm

Install the patient tubing support arm on either side of the trolley (Figure 2-4).

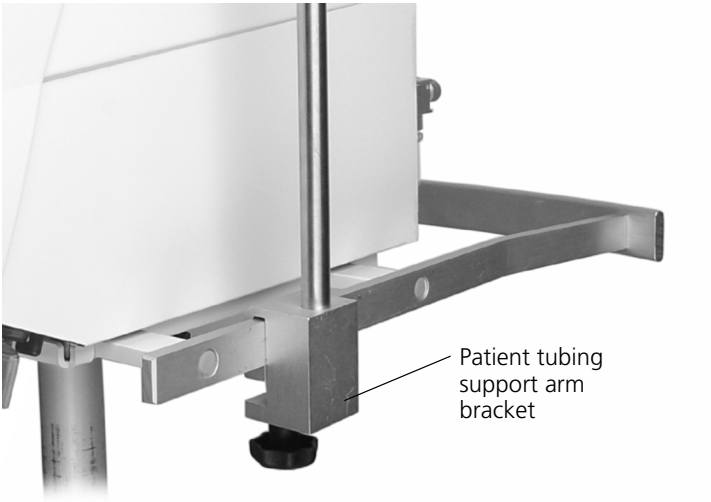


Figure 2-4. Installing the patient tubing support arm

2.6 Installing the patient breathing circuit

WARNING

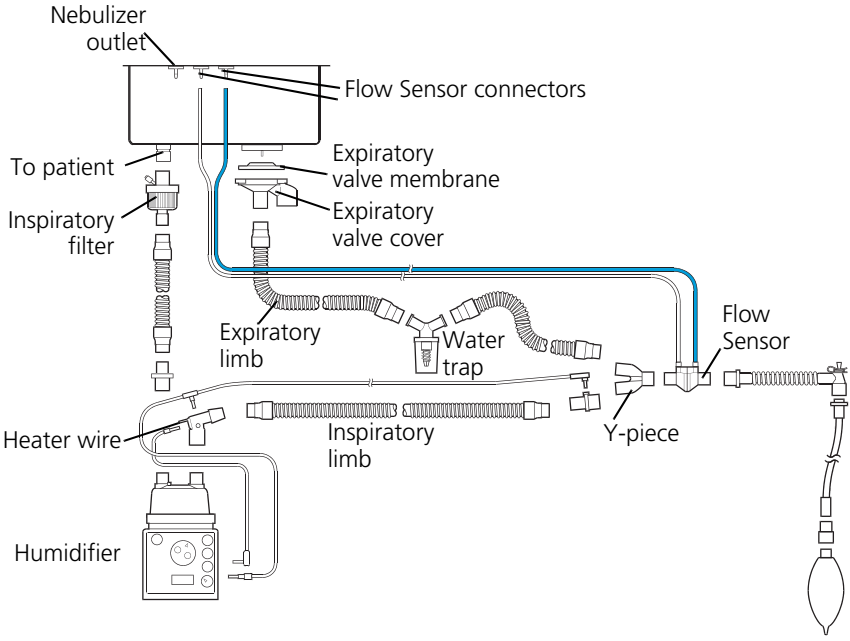
- **To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.**
- **To prevent patient or ventilator contamination, always use a bacteria filter between the ventilator and the inspiratory limb of the patient breathing circuit.**
- **To reduce the risk of fire, use only breathing circuits intended for use in oxygen-enriched environments. Do not use antistatic or electrically conductive tubing.**
- **To minimize the risk of occlusion, use breathing tubes manufactured in compliance with ISO 5367.**

NOTE:

- For optimal ventilator operation, use HAMILTON MEDICAL patient breathing circuits or other circuits that meet the specifications given in Section A.9.
- Any bacteria filter, HME, or additional accessories in the expiratory limb may substantially increase flow resistance and impair ventilation.
- To ensure that all breathing circuit connections are leak-tight, perform the tightness test every time you install a circuit or change a circuit part.
- Regularly check the water traps and the breathing circuit hoses for water accumulation. Empty as required.

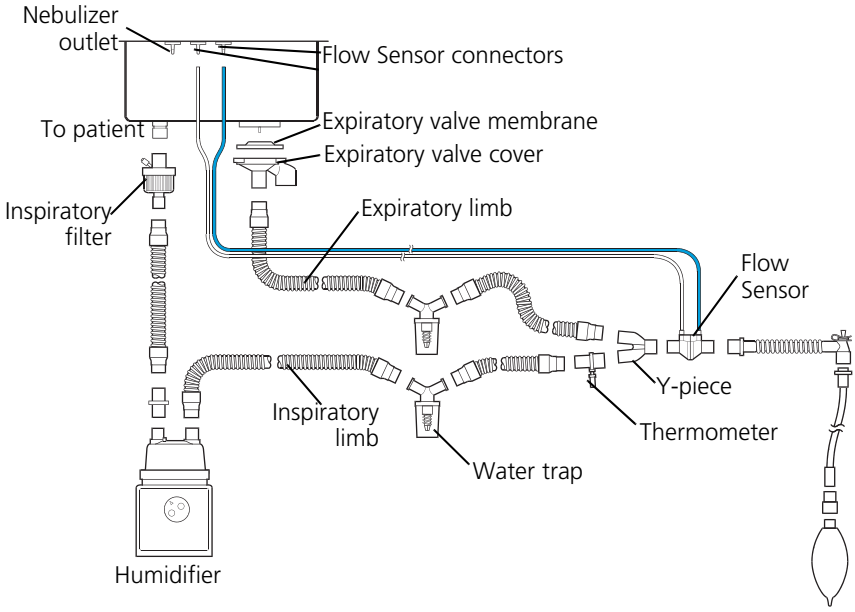
Install the patient breathing circuit as follows:

1. Select the appropriate breathing circuit for your patient:
   - 5 to 30 kg: 15 mm breathing circuit inner diameter
   - 30 to 200 kg: 22 mm breathing circuit inner diameter
2. Assemble the patient breathing circuit. Figure 2-5 through Figure 2-9 show typical circuit configurations; for ordering information, consult your HAMILTON MEDICAL representative. Follow the specific guidelines for the different parts.



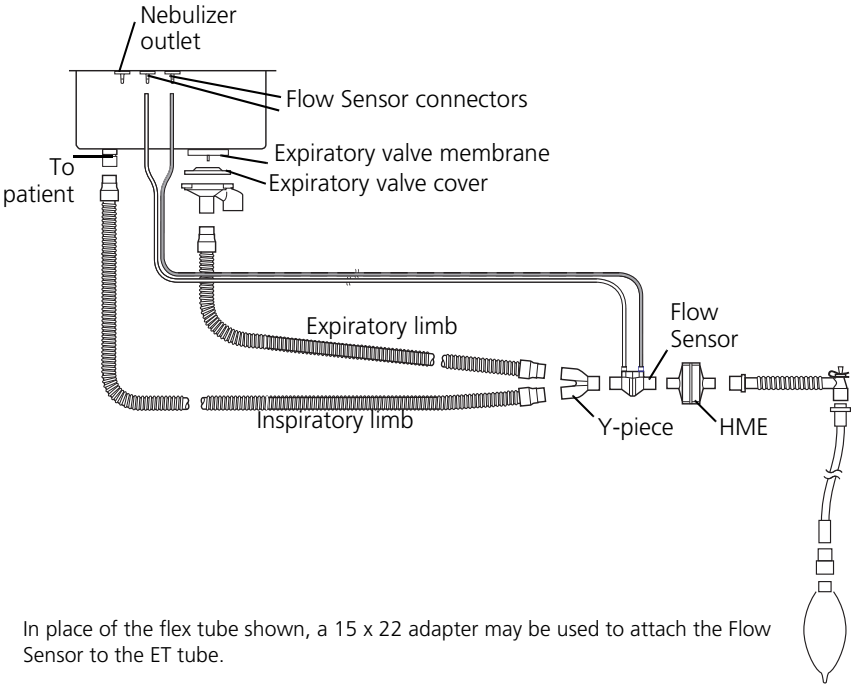
In place of the flex tube shown, a 15 x 22 adapter may be used to attach the Flow Sensor to the ET tube.

Figure 2-5. Patient breathing circuit for use with inspiratory heater wire



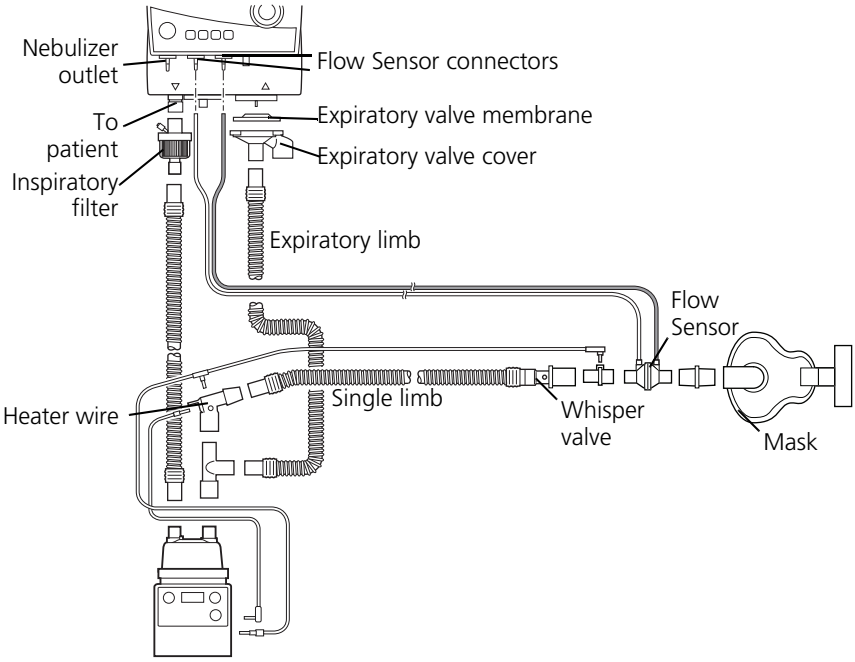
In place of the flex tube shown, a 15 x 22 adapter may be used to attach the Flow Sensor to the ET tube.

Figure 2-6. Patient breathing circuit for use without heater wires



In place of the flex tube shown, a 15 x 22 adapter may be used to attach the Flow Sensor to the ET tube.

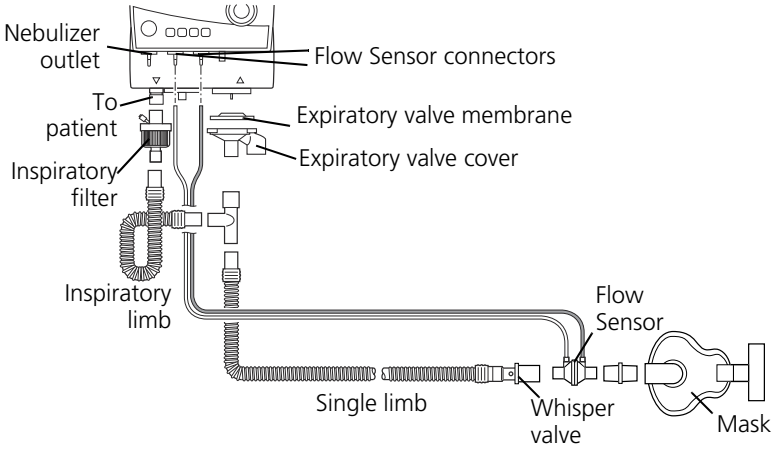
Figure 2-7. Patient breathing circuit for use with HME



The LiteCircuit may be used in conjunction with a central gas supply only. The VENTILAIR^{II} compressor cannot deliver sufficient flow for use with the LiteCircuit.

Figure 2-8. LiteCircuit 850 (single-limb) patient breathing circuit with humidifier (for use with NIV)[1]

1. Not available in the USA



The LiteCircuit may be used in conjunction with a central gas supply only. The VENTILAIR^{II} compressor cannot deliver sufficient flow for use with the LiteCircuit.

Figure 2-9. LiteCircuit Standard (single-limb) patient breathing circuit without humidifier (for use with NIV)

Expiratory valve membrane: Place the silicone membrane into the valve housing with the metal plate upwards (Figure 2-10). The side that is marked DOWN must be placed downwards.

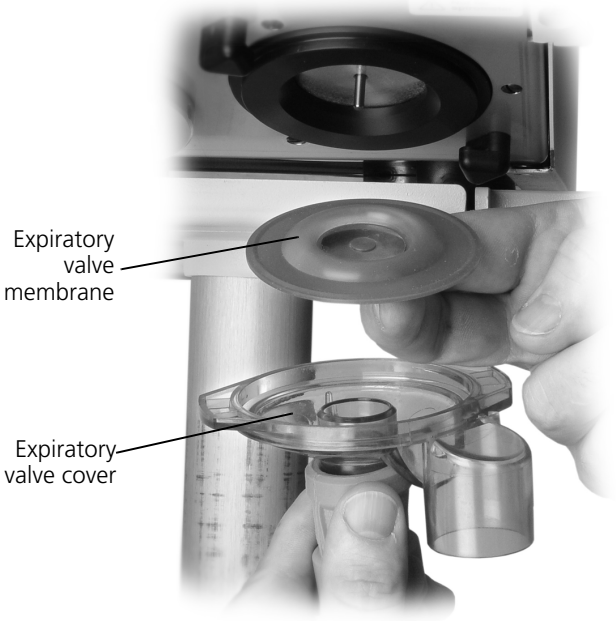
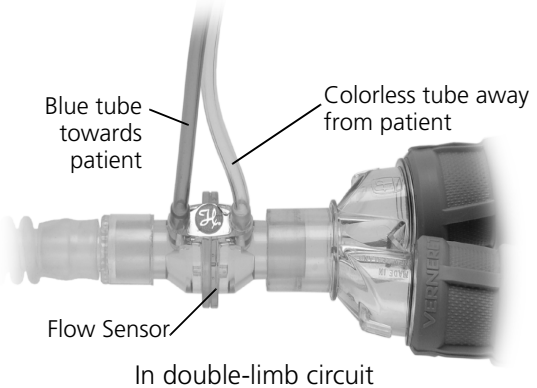
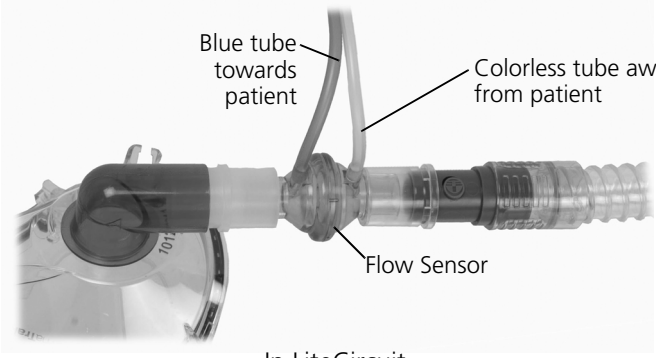


Figure 2-10. Installing the expiratory valve membrane and cover

Flow Sensor: Insert the Flow Sensor between the Y-piece or Whisper valve of the patient circuit and the patient connection (Figure 2-11). The blue tube is closest to the patient. Connect the blue and colorless tubes to the Flow Sensor connectors in the front panel. The blue tube goes to the blue connector. The colorless tube goes to the silver connector. Use a short section of flex tubing or a 15 x 22 adapter between the Flow Sensor and the actual patient connection. Position the Flow Sensor with the small tubings upright to prevent kinking and moisture buildup. Use the tubing clip to secure the Flow Sensor tubes to the patient circuit.



In double-limb circuit



In LiteCircuit

Figure 2-11. Installing the Flow Sensor

Properly position the breathing circuit after assembly. Make sure the hoses will not be pushed, pulled, or kinked during patient's movement, nebulization or other procedures.

2.7 Checking for the oxygen cell

The RAPHAEL uses an integrated oxygen cell to monitor the delivered oxygen concentration. A high-priority alarm sounds if the measured concentration is 5 percentage points above or below the set oxygen concentration.

Before operating the ventilator, make sure the cell is present, as follows (Figure 2-12):

1. Remove the thumbscrew that retains the oxygen cell carrier.
2. Pull out the oxygen cell carrier. Verify that the cell is present and connected. If the cell is not present, install a cell and reconnect the cell cable (see Section 8.3.3).
3. Replace the carrier and thumbscrew.
4. Perform an oxygen cell calibration (Section 3.2.3).

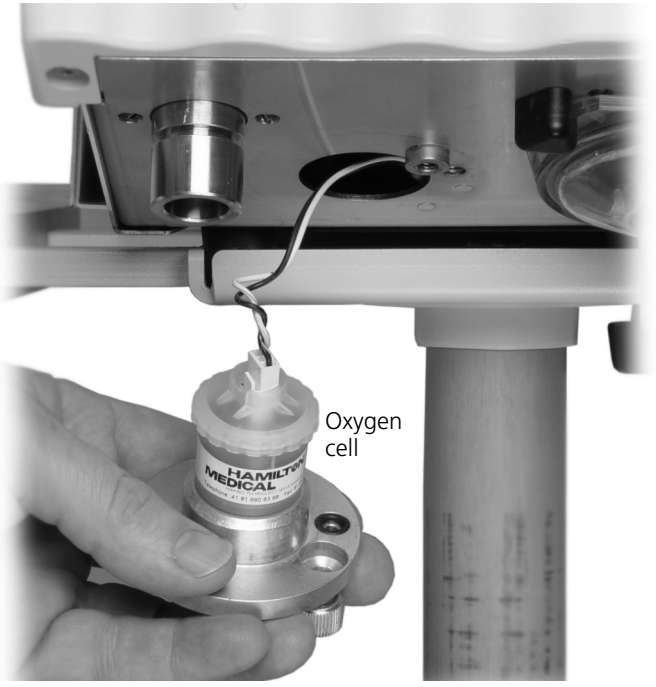


Figure 2-12. Checking for the oxygen cell

2.8 Installing a pneumatic nebulizer

WARNING

- **The use of an expiratory filter in conjunction with aerosol-generating nebulizer treatments may lead to a significant increase in expiratory circuit resistance. Excessive expiratory circuit resistance may compromise ventilation and result in an increased patient work of breathing and/or AutoPEEP.**
- **Connect the nebulizer in the inspiratory limb per your institution's policy and procedure. Connecting the nebulizer between the Flow Sensor and the endotracheal tube increases dead space ventilation.**

The RAPHAEL can power a pneumatic nebulizer connected to the nebulizer outlet. It provides 6 to 7 l/min flow. The nebulization function does not affect delivered oxygen concentration, patient triggering, or monitoring accuracy. The RAPHAEL compensates for the additional flow and keeps the delivered tidal volume constant. Be aware that the flow capability of your nebulizer jar affects the duration of medication delivery.

Connect the nebulizer and accessories as shown in Figure 2-13.

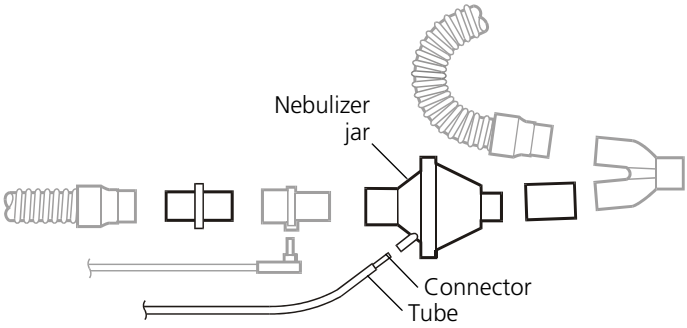


Figure 2-13. Connecting a pneumatic nebulizer

2.9 Installing the optional Aeroneb Pro ultrasonic nebulizer

The Aerogen Aeroneb Pro ultrasonic nebulizer system is available as an option for the RAPHAEL. Attach it to the mounting bracket (Figure 2-14). Consult the operating instructions supplied with the nebulizer for further installation and operating information.

Figure 2-14. Installing the Aeroneb Pro ultrasonic nebulizer

2.10 About the backup batteries

NOTE:

- The backup batteries are intended for short-term use only. They are not intended to be a primary power source.
- HAMILTON MEDICAL recommends that the ventilator's batteries be fully charged before you ventilate a patient. If the batteries are not fully charged and ac power fails, always pay close attention to the level of battery charge. There is no guarantee of a minimum ventilator operating time.

The RAPHAEL is backed up by batteries to protect it from low or power failure. When ac power fails to provide power during ventilation, the batteries automatically switch on with no interruption in ventilation. An alarm sounds to signal the switchover. A battery symbol appears at the bottom of the screen (Figure 2-15); it shows the level of battery charge. The batteries power the ventilator until ac power is again adequate or typically for 60 min (for new, fully charged batteries with default settings and a 2 l demonstration lung).

As further safeguards, the RAPHAEL provides a low-battery alarm. It also has a capacitor-driven backup buzzer that sounds for at least 2 min when battery power is completely lost.

The ventilator recharges the batteries whenever the ventilator is connected to ac power, with or without the power switch on.

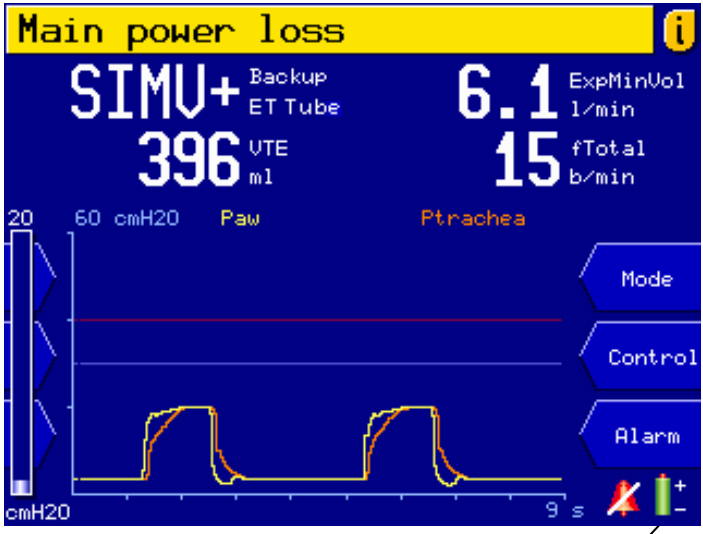


Figure 2-15. Battery symbol

Check the battery charge level before putting the ventilator on a patient and otherwise as required. (You can see the level of battery charge by opening utilities window 2 while the RAPHAEL is running on ac power or by observing the battery symbol. In the RAPHAEL Color and RAPHAEL XTC, a green symbol indicates charge level. If the symbol is dimmed or gray, no information about the battery charge is available.) If the batteries are not fully charged, recharge them by plugging in the ventilator for up to 6 hours, until the battery charge level is 80 to 100%. If the batteries are not fully charged at this time, have the ventilator serviced.

2.11 Starting up the ventilator

1. Switch on the ventilator power switch (Figure 2-16).

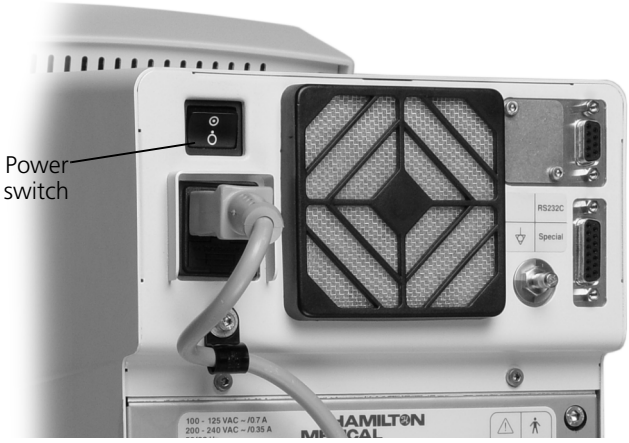


Figure 2-16. Power switch

2. You will see the System check screen (Figure 2-17). The screen shows the System check bar, the installed software versions, the installed options, and the ventilator's total operational hours. You will hear the speaker tone and the backup buzzer during the system check. The software version noted in the figure should match the version on the title page of this manual.

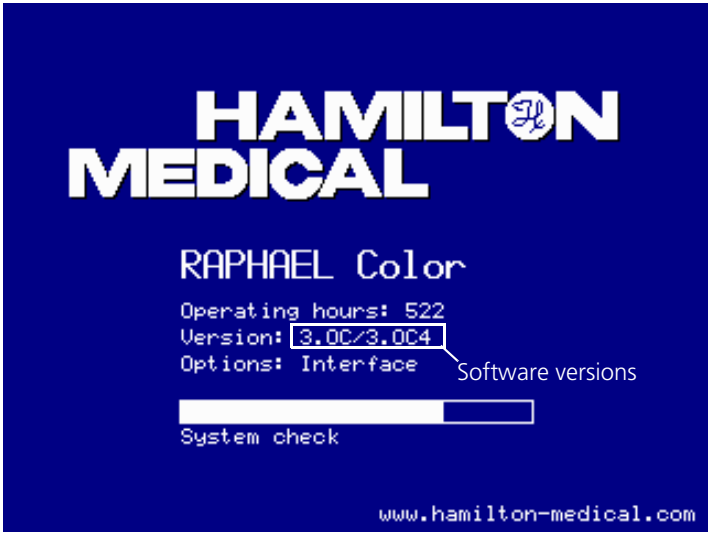


Figure 2-17. System check screen

WARNING

During the system check, make sure that both the buzzer and speaker sound (two beeps) and that front panel indicators light. If they do not, the alarm system may be malfunctioning. Remove the ventilator from use and contact service.

3. The bodyweight window opens (Figure 2-18). Press the utilities key (the bottom left-hand key) to open the utilities window. Run the required tests and calibrations (Table 3-1).

4. Start ventilation by doing one of the following:
   - **To resume ventilating with the last settings** in use before the RAPHAEL was switched off, select **`Last Setup`** and press the knob to confirm. The message bar displays **`Last setup activated`**. Select **`Start`**
   - **To change the ventilator settings,** press the knob to activate the **`Bodyweight`** value, then turn the knob to adjust the value. Press the knob again to confirm. The cursor automatically moves to **`Start`**. From here you can go to the mode and controls windows and make additional changes.
   - **To ventilate with default settings**, select **`Start`**.

NOTE:

If you select **`Last setup`** or default settings, it is recommended that you verify these settings, including the TRC settings, in the control window.

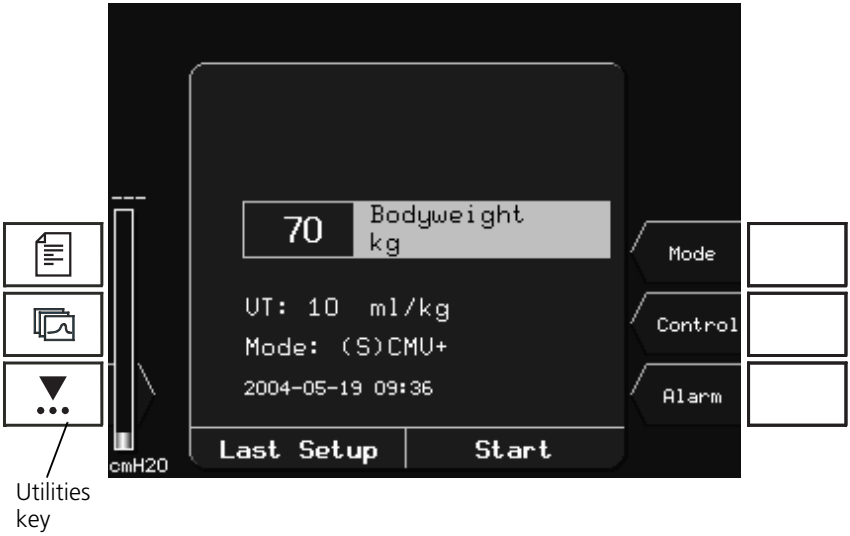


Figure 2-18. Bodyweight window

NOTE:

- If the RAPHAEL is new, be sure it has been properly configured for default language, main monitoring parameters, standard ventilation setup, curves display, time and date, and utilities (see Appendix D).
- If the date or time is incorrect, adjust as per Section E.7.
- To ensure the ventilator's safe operation, always run the prescribed tests and calibrations before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests passed.

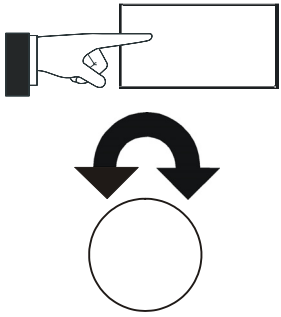
2.12 Shutting down the ventilator

Shut the RAPHAEL down by simply switching off the power switch.

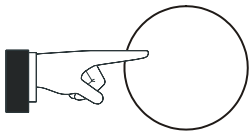
2.13 Guidelines for using the press-and-turn knob and the keys

The RAPHAEL's single knob, used in conjunction with the keys, lets you open and close windows, select and confirm parameters, and activate functions.

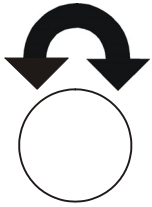
1. Open the window by pressing a key in the display panel keyboard.
2. Select a parameter by turning the knob.



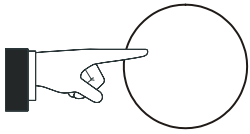
3. Activate the parameter by pressing the knob.



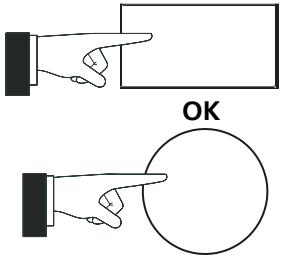
4. If applicable, select the desired value by turning the knob.



5. Press the knob again to confirm the selection. The window will close if the selected parameter is not confirmed after 30 s. The new selection will not be valid and the previous setting remains in effect.



6. Close the window by either pressing the corresponding key or by pressing the knob with the indicator in the "OK" position.



NOTE:

Windows automatically close after 30 s, except for the numeric patient data window and the apnea backup controls window, which stay open indefinitely.

3 Tests, calibrations, and utilities

3.1 Introduction

The tests and calibrations described in this section help verify the safety and reliability of the RAPHAEL. Perform the RAPHAEL's tests and calibrations as described in Table 3-1, in the order given. If a test fails, troubleshoot the ventilator as indicated or have the ventilator serviced. Make sure the tests pass before you return the ventilator to clinical use.

Table 3-1. When to perform tests and calibrations

Test or calibration	Perform in any of these cases
Tightness test (Section 3.2.1), Flow Sensor test (Section 3.2.2)	After installing a new breathing circuit or circuit component
Flow Sensor test (Section 3.2.2)	• After installing a new Flow Sensor • When a **`Volume measurement inaccurate`** alarm is annunciated • When there are unexplainable differences between monitored parameters and control settings
Oxygen cell calibration (Section 3.2.3)	After installing a new oxygen cell or when a related alarm occurs
Preoperational check (Section 3.3) **NOTE:** To ensure the ventilator's safe operation, always run the full preoperational check before using the ventilator on a patient. If the ventilator fails any tests, remove it from clinical use immediately. Do not use the ventilator until necessary repairs are completed and all tests passed.	Before placing a new patient on the ventilator (This is summarized on the *Preoperational check* card (PN 610696))
Alarm tests (Section 3.4)	As desired
Any applicable test	Whenever monitored data is questionable

3.2 Utilities

NOTE:

The utilities key is also active when the Bodyweight window is shown, giving you the chance to run tests and calibrations before ventilation starts.

The RAPHAEL has two utilities windows. Utilities window 1 lets you run the RAPHAEL's tests and calibrations (Section 3.2.1 through Section 3.2.3) and adjust the audible alarm loudness (Section 3.2.4). Utilities window 2 lets you determine information about your ventilator, including revision information, installed options, operating hours, hours since startup, and battery status.

Access the utilities windows by pressing the utilities key. Utilities window 1 opens (Figure 3-1). Select and open window 2 (Figure 3-2) by turning and pressing the knob or by pressing the key. To close these windows and return to the basic screen, select **OK**, then press the knob.

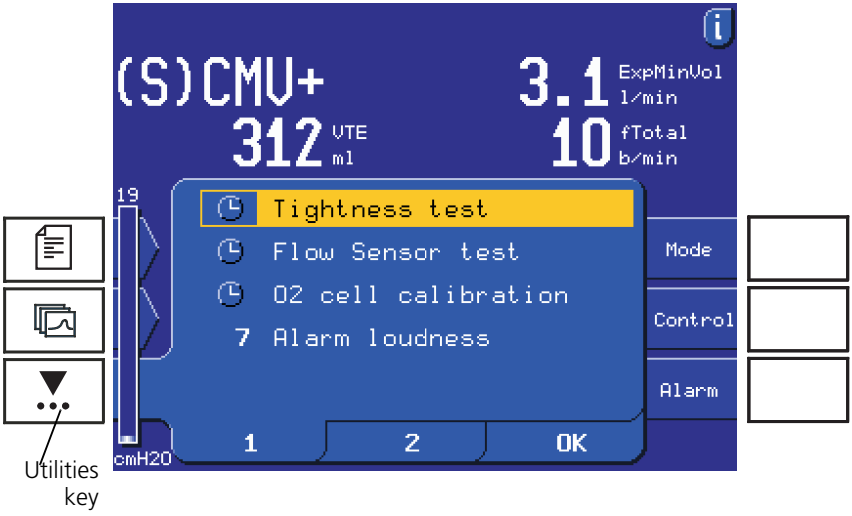


Figure 3-1. Utilities window 1

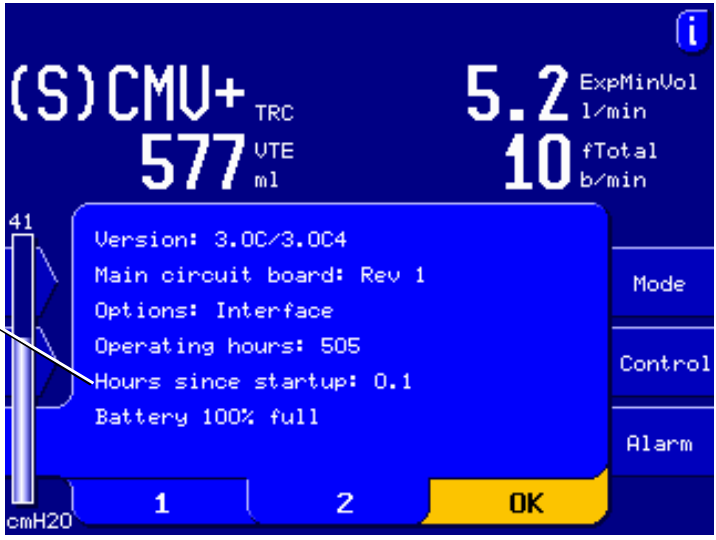


Figure 3-2. Utilities window 2

3.2.1 Tightness test

NOTE:

The patient must be disconnected from the ventilator during this test.

Principle of operation: This test checks for leakage in the patient breathing circuit. The ventilator is pressurized to 30 cmH_2O. The circuit is considered tight if this pressure can be maintained. If there is a leak, the pressure falls in proportion to the size of leak. The pressure gauge indicates the pressure level (Figure 3-3).

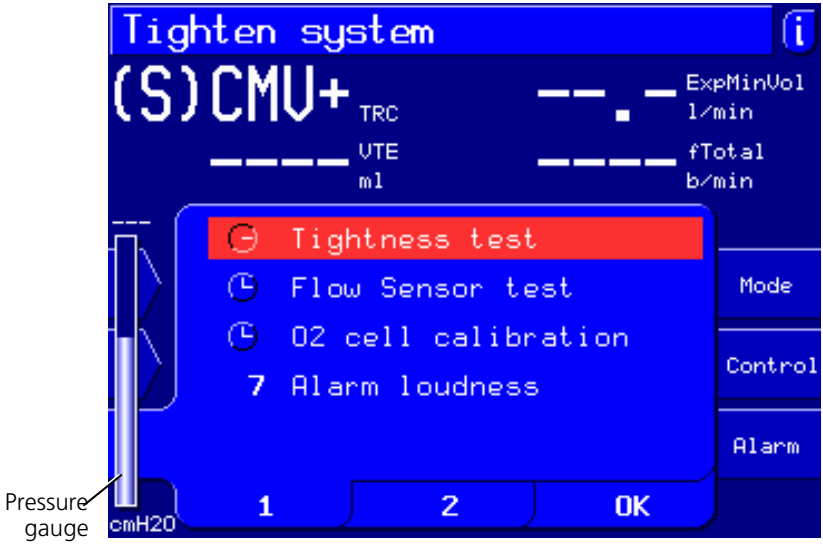


Figure 3-3. Pressure gauge during tightness test

Procedure for a double-limb circuit: Perform the tightness test as follows:

1. Set the ventilator up as for normal ventilation, complete with breathing circuit.
2. Activate **`Tightness test`** from utilities window 1.
3. If you have not already disconnected the patient, the message line displays **`Disconnect patient`**. Disconnect the patient now.
4. The message line displays **`Tighten system`**. Block the opening with a clean gauze-covered finger.
5. Wait and VERIFY that the message line displays **`Tightness test OK`**.

   If the message line displays **`Tightness test failed`**, check the circuit connections. Replace leaking parts and repeat the tightness test.
6. Reconnect the patient.

Procedure for a LiteCircuit (single-limb circuit): Perform the tightness test as follows:

1. Set the ventilator up as for normal ventilation, complete with the LiteCircuit.
2. Disconnect the Whisper valve together with Flow Sensor from the circuit.
3. Activate **`Tightness test`** from utilities window 1.
4. The message line displays **`Tighten system`**. Block the opening with a clean gauze-covered finger.
5. Wait and VERIFY that the message line displays **`Tightness test OK`**. If the message line displays **`Tightness test failed`**, check the circuit connections. Replace leaking parts and repeat the tightness test.
6. Reconnect the Whisper valve with Flow Sensor.
7. Repeat the **`Tightness test`** as described above (steps 3 to 5).
8. Wait and VERIFY that the message line displays **`Tightness test failed`**. If the message line displays **`Tightness test OK`**, check the Whisper valve, and repeat the tightness test.
9. Reconnect the patient.

3.2.2 Flow Sensor test

NOTE:

The patient must be disconnected from the ventilator during this test.

Principle of operation: This test checks the functioning of the Flow Sensor, including its measurement accuracy and triggering function.

Procedure: Perform the Flow Sensor test as follows:

1. Set the ventilator up as for normal ventilation, complete with breathing circuit and Flow Sensor.
2. Activate **`Flow Sensor test`** from utilities window 1.
3. If you have not already disconnected the patient, the message line displays **`Disconnect patient`**. Disconnect the patient now.
4. Follow the instructions displayed in the message line, turning the Flow Sensor as indicated.

NOTE:

If you are using a LiteCircuit, block the opening of the Whisper valve with a clean gauze-covered finger.

5. VERIFY that the message line displays **`Flow Sensor test OK`**.

   If the message line displays **`Flow Sensor failed`**, rerun the test. If the second attempt fails, install a new Flow Sensor.
6. Reconnect the patient, as indicated.

3.2.3 Oxygen cell calibration

WARNING

During the oxygen cell calibration, the ventilator delivers 100% oxygen, which may be harmful to the patient.

NOTE:

Calibrate the oxygen cell only after replacement or when a related alarm occurs. Excessive calibration can decrease the oxygen cell's life.

Principle of operation: During this 2-min calibration of the oxygen cell, the RAPHAEL delivers 100% oxygen.

Procedure: Perform this calibration as follows:

1. Activate **`O2 cell calibration`** from utilities window 1. The message line displays **`O2 calibration in progress`**.
2. After the test, VERIFY that **`O2 calibration OK`** is displayed.

   If **`O2 calibration failed`** is displayed, the cell may be depleted. Repeat the calibration. If the test still fails, replace the oxygen cell. If the cell is new, check the source and quality of the oxygen supply.

3.2.4 Alarm loudness adjustment

NOTE:

- If you decrease the alarm loudness during the night shift, do not forget to return it to its daytime setting!
- When the audible alarm first annunciates a high- or medium-priority alarm, it sounds at the operator-selected loudness level. After 40 s, each group of beeps becomes one level louder, up to level 10.

Adjust the loudness of the audible alarm as follows:

1. Activate **`Alarm loudness`** from utilities window 1 (Figure 3-4).
2. Turn the knob to adjust. The alarm will sound at the selected loudness level as you turn the knob. Press the knob to confirm the desired level.
3. Close the window.

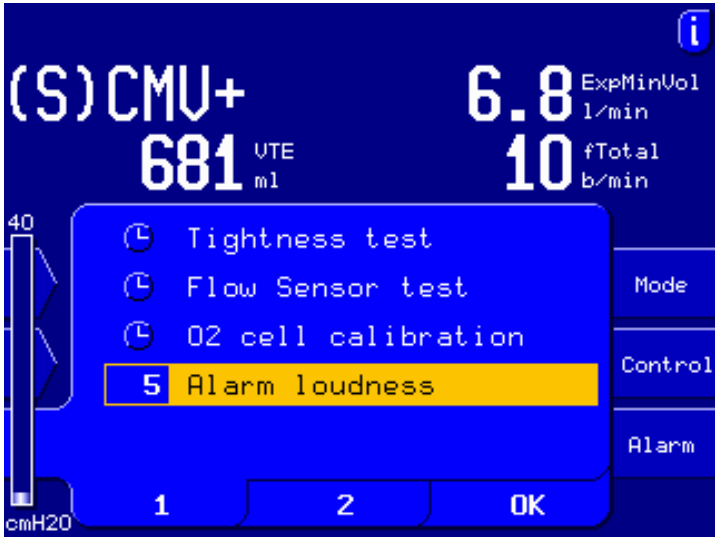


Figure 3-4. Adjusting alarm loudness

3.3 Preoperational check

WARNING

To prevent possible patient injury, disconnect the patient from the ventilator before running this test. Make sure another source of ventilatory support is available.

NOTE:

- Before performing this check, make sure that O_2 monitoring is configured on (when O_2 monitoring is configured off, the Oxygen measurement in the numeric patient data window displays **`Off`**).
- The preoperational check card attached to the ventilator provides an abbreviated version of this check.

Required materials: Use the setup below appropriate to your patient age group. To ensure that the ventilator also functions according to specifications on your patient, we recommend that your test circuit be equivalent to the circuit used for ventilation.

Adult patients, double-limb circuit	• Double-limb breathing circuit, 19 mm ID with 22 mm connectors • Flow Sensor, pediatric/adult • Demonstration lung, 2 l, with adult ET tube between Flow Sensor and lung (PN 151815 or equivalent)

Adult/ pediatric patients, LiteCircuit	• Single-limb breathing circuit, 19 mm ID with 22F connectors • Flow Sensor, pediatric/adult • Demonstration lung, 2 l, with adult ET tube between Flow Sensor and lung (PN 151815 or equivalent)
Pediatric patients, double-limb circuit	• Double-limb breathing circuit, 15 mm ID with 22 mm connectors • Flow Sensor, pediatric/adult • Demonstration lung, 0.5 l, with pediatric ET tube between Flow Sensor and lung (PN 151816 or equivalent)

Principle of operation: This test verifies the proper operation of important ventilation functions.

Procedure: Perform the preoperational check as follows:

1. Connect the ventilator to ac power and to compressed air and oxygen. Set the ventilator up as for normal ventilation, complete with appropriate breathing circuit, Flow Sensor, appropriate demonstration lung assembly (2 l for adult, 0.5 l for pediatric), and expiratory membrane and cover.
2. Start up the ventilator, and leave the **`Bodyweight`** window open.
3. VERIFY that the date and time shown are current.

   If the date and time are not current, adjust them (see Section E.7).

NOTE:

If your RAPHAEL does not show the date and time, it is an older version without a real-time clock, so this date and time check does not apply.

4. Open utilities window 1. Perform the **`Tightness test`** (Section 3.2.1). Perform the **`Flow Sensor test`** (Section 3.2.2).

5. Open utilities window 2. VERIFY that the battery charge level is between 80 and 100%.

   If the battery charge is not between 80 and 100%, charge the battery by plugging the RAPHAEL into ac power for up to 6 hours or until the battery is fully charged. If the battery cannot be fully charged within 6 hours, have the battery serviced.

6. Perform the function test by making the ventilator settings listed in Table 3-2 or Table 3-3. Open numeric patient data window 1, and after at least 2 min VERIFY that the monitored patient data is within the ranges listed.

7. Squeeze the demonstration lung several times, and VERIFY that the trigger indicator lights each time.

NOTE:

To achieve the correct test results, make sure that no autotriggering occurs during testing.

8. Switch on the pneumatic nebulizer, and VERIFY that there is flow during inspiration.

9. If the communications interface is installed and you intend to use its I:E outlet or remote alarm, VERIFY its correct functioning (Section G.3 or Section G.4).

Table 3-2. Adult function test settings and expected values

Control	Setting
Bodyweight	70 kg
Mode	(S)CMV+ or SIMV+
Rate	10 b/min
VT	350 ml
I:E or TI[1]	1:2 or 2.0 s
PEEP/CPAP	5 cmH_2O
Trigger	6 l/min
Oxygen	50%

Monitored parameter	Expected value
ExpMinVol	2.7 to 4.4 l/min
PEEP/CPAP	4 to 6 cmH_2O
VTE	300 to 400 ml
fTotal	9 to 11 b/min
TI	2.0 s
I:E	1:2
Oxygen	47 to 53%

1 Depends on mode

Table 3-3. Pediatric function test settings and expected values

Control	Setting
Bodyweight	15 kg
Mode	(S)CMV+ or SIMV+
Rate	20 b/min
VT	150 ml
I:E or TI[1]	1:2 or 1.0 s
PEEP/CPAP	5 cmH_2O
Trigger	6 l/min
Oxygen	50%

Monitored parameter	Expected value
ExpMinVol	2.28 to 3.78 l/min
PEEP/CPAP	4 to 6 cmH_2O
VTE	120 to 180 ml
fTotal	19 to 21 b/min
TI	1.0 s
I:E	1:2
Oxygen	47 to 53%

1 Depends on mode

3.4 Alarm tests

The RAPHAEL performs a self-check during start-up and continuously during operation. Alarm functionality is verified by this self-check. You may also want to run alarm tests, which demonstrate the alarms' operation.

Before performing the alarm tests, set the RAPHAEL up as for normal ventilation, complete with breathing circuit and 2 l demonstration lung assembly with ET tube.

3.4.1 High pressure

1. Make sure a 2 l demonstration lung assembly is connected to the RAPHAEL.
2. Put the RAPHAEL into the PCV+ mode.
3. Set the Pmax alarm to 15 cmH_2O above the measured Ppeak.
4. Squeeze the demonstration lung hard during inspiration.
5. VERIFY that the **`High pressure`** alarm is activated, inspiration ceases, and pressure falls to the PEEP/CPAP level.

3.4.2 Low minute volume

1. Let the ventilator deliver 10 breaths with no alarms.
2. Open the alarm window.
3. Adjust the low ExpMinVol limit so it is higher than the measured value.
4. VERIFY that the **`Low minute volume`** alarm is activated.

3.4.3 Oxygen supply and Low oxygen alarms

1. Set the Oxygen control to 50%.
2. Wait for 2 min.
3. Open the numeric patient data window.
4. Disconnect the oxygen supply.

5. VERIFY that the **Oxygen supply** alarm is activated and the displayed oxygen concentration decreases. VERIFY that the **Low oxygen** alarm activates.
6. Wait 30 s or until the oxygen concentration falls below 40%.
7. Reconnect the oxygen supply.
8. VERIFY that the **Oxygen supply** and the **Low oxygen** alarms reset. The **Low oxygen** alarm should reset when the measured oxygen exceeds 45%.

3.4.4 Disconnection

1. Disconnect the inspiratory limb or the demonstration lung.
2. VERIFY that the **Disconnection** alarm is activated.
3. Reconnect the inspiratory limb or the demonstration lung.
4. VERIFY that the alarm resets and that the RAPHAEL automatically resumes ventilation.

3.4.5 Main power loss

1. With the RAPHAEL connected to ac power, start it up.
2. Disconnect the power cord.
3. VERIFY that the **Main power loss** alarm is activated and that the battery symbol is displayed. It can take up to 90 s for the alarm to activate.
4. Reconnect the RAPHAEL to ac power.
5. VERIFY that the alarm resets and the battery symbol disappears. It can take up to 90 s for the alarm to reset.

3.4.6 Exhalation obstructed

1. Block the expiratory valve exhaust port.

NOTE:

If you are using a LiteCircuit, block the opening of the Whisper valve with a clean gauze-covered finger.

2. Observe the pressure rise.
3. VERIFY that the **`Exhalation obstructed`** alarm is activated following the **`High pressure`** alarm.

3.4.7 Apnea

1. Put the RAPHAEL into the SPONT mode.
2. Switch off apnea backup ventilation.
3. Squeeze the demonstration lung several times to trigger a breath. Wait for the set apnea time.
4. VERIFY that the **`Apnea`** alarm is activated.
5. Squeeze the demonstration lung again.
6. VERIFY that the TRIGGER indicator lights and the **`Apnea`** alarm resets.

4 Ventilator settings

4.1 Introduction

NOTE:

After you power on the ventilator, the settings you see are the default settings made at the time of configuration (see Appendix E) unless you chose the **`Last Setup`**.

This section tells you how to set up the RAPHAEL for ventilation on an individual patient. Prepare the ventilator as instructed in Section 2.

You must be familiar with selecting, activating, and confirming parameters. For details, see Section 2.13.

4.2 Entering the patient's ideal bodyweight

Enter the ideal bodyweight (IBW) for every new patient. The ideal bodyweight influences the default rate and tidal volume. This input helps the RAPHAEL to ventilate according to the patient's needs and capacity. The ideal bodyweight also influences the ExpMinVol alarm limit.

After the system check described in Section 2.11, you will see the bodyweight window (Figure 4-1). Refer to Table 4-1 or Table 4-2 to determine the relationship between a patient's height and ideal bodyweight.

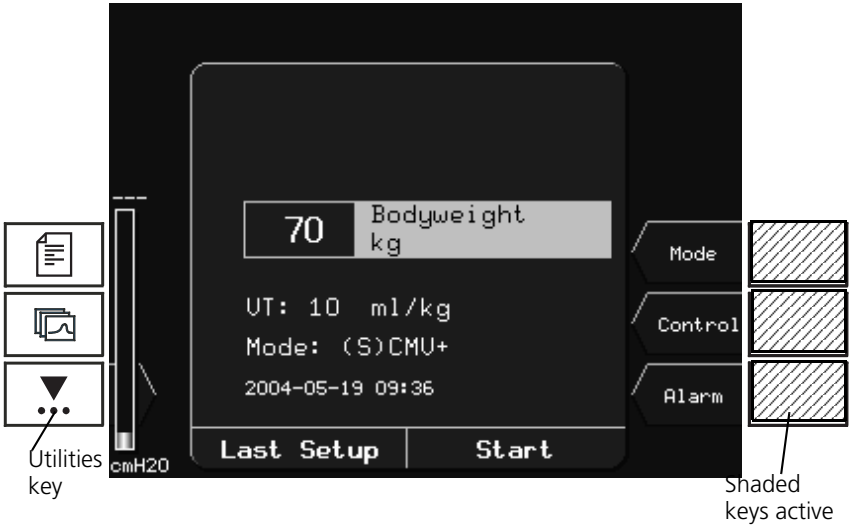


Figure 4-1. Bodyweight window

Do the following:

1. Activate **Bodyweight**.
2. Adjust the **Bodyweight** value. Activate by pressing the knob.
3. The cursor automatically moves to **Start**. Confirm. The RAPHAEL starts ventilation in the preset mode, which is shown on the screen.

NOTE:

Before you start ventilation, the utilities, Mode, Control, and Alarm keys are active (see figure). This lets you perform tests/calibrations and change settings before ventilation.

Table 4-1. Determining adult IBW from height [1]

Height		IBW (kg)	
ft	m	Male	Female
5′0″	1.52	50	46
5′1″	1.55	52	48
5′2″	1.57	55	50
5′3″	1.60	57	52
5′4″	1.62	59	55
5′5″	1.65	62	57
5′6″	1.67	64	59
5′7″	1.70	66	62
5′8″	1.72	68	64
5′9″	1.75	71	66

Height		IBW (kg)	
ft	m	Male	Female
5′10″	1.77	73	69
5′11″	1.80	75	71
6′0″	1.82	78	73
6′1″	1.85	80	75
6′2″	1.88	82	78
6′3″	1.90	85	80
6′4″	1.93	87	82
6′5″	1.95	89	85
6′6″	1.98	91	87
6′7″	2.00	94	89

1. Source: Pennsylvania Medical Center. HAMILTON MEDICAL assumes no responsibility for the accuracy of this data. Use of this information is the responsibility of the clinician.

Table 4-2. Determining pediatric IBW from height[1]

Height		IBW (kg)
in.	cm	
19	50	6
21	55	6
23	60	7
25	65	8
27	70	8
29	75	9
31	80	10
33	85	11
35	90	12
37	95	14
39	100	15

Height		IBW (kg)
in.	cm	
41	105	17
43	110	19
45	115	20
47	120	23
49	125	25
51	130	28
53	135	31
55	140	34
57	145	37
59	150	41

1. Adopted from Traub SL; Johnson CE. Comparison of methods of estimating creatine clearance in children. Am J Hosp Pharm 1980;37:195-201. HAMILTON MEDICAL assumes no responsibility for the accuracy of this data. Use of this information is the responsibility of the clinician.

4.3 Changing the ventilation mode

The ventilation mode is displayed in the upper left-hand corner. To change the mode, do the following.

1. Open the mode window (Figure 4-2) by pressing the Mode key.
2. Select the mode (see Appendix B for details on all modes). Activate the selection.

   You may not see all the modes shown in the figure, because some modes may have been disabled during configuration.

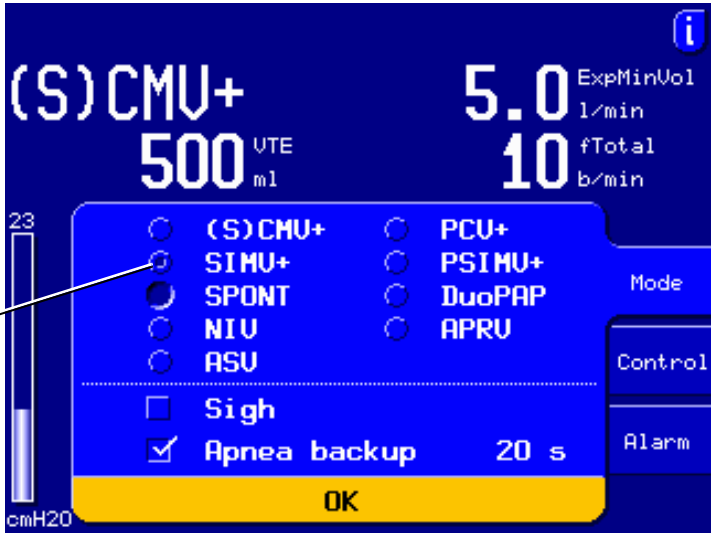


Figure 4-2. Mode window

3. The cursor automatically moves to **OK**. Confirm by pressing the knob or key. If you changed the mode, the control window opens so you can review the control settings (see Section 4.5.1).

4.4 Setting mode additions

You can enable the sigh and apnea backup function and adjust the apnea time from the mode window.

4.4.1 Enabling/disabling the sigh function

The sigh function delivers a sigh breath every 50 breaths. Sigh breaths are delivered at a pressure 10 cmH_2O higher than nonsigh breaths. The sigh function is not active in DuoPAP and APRV modes.

Enable or disable the sigh function as follows:

1. Open the mode window (Figure 4-2) by pressing the Mode key.
2. Select **Sigh**. Enable or disable it.
3. The cursor automatically moves to **OK**. Confirm by pressing the knob or key.

4.4.2 Enabling/disabling the apnea backup function and adjusting the apnea time

WARNING

HAMILTON MEDICAL recommends that apnea backup ventilation always be enabled.

4.4.2.1 About apnea backup ventilation

The RAPHAEL provides apnea backup ventilation, a mechanism that minimizes possible patient injury due to apnea or cessation of respiration. Apnea can occur in all modes except (S)CMV+, PCV+, and ASV. When the RAPHAEL is in such a mode and no inspiratory efforts are detected or control breaths are delivered during an operator-set interval, it declares apnea. If apnea backup ventilation is enabled, ventilation continues. The RAPHAEL's apnea backup is bidirectional, meaning that ventilation automatically resumes in the original support mode if the apnea episode ends.

When apnea backup ventilation is enabled, it provides ventilation after the adjustable apnea time passes with no breath attempts detected. When this occurs, the RAPHAEL automatically and immediately switches into apnea backup ventilation. It annunciates a low-priority alarm, displays **`Apnea backup activated`**, and provides ventilation at the settings shown in Table 4-3. You are asked to confirm the settings. If you do not confirm the settings, after 2 min the priority escalates to high.

If the patient triggers two consecutive breaths, the RAPHAEL reverts to ventilation at the original support mode and settings, and it displays **`Apnea ventilation ended`**.

Once apnea backup ventilation is enabled, it stays active in all applicable modes. Apnea backup ventilation requires no clinician intervention, although you can freely change the mode during apnea backup ventilation, either switching to a new mode or accepting the backup mode as the new mode.

When apnea backup ventilation is disabled, the high-priority alarm message **Apnea** is displayed when apnea occurs.

4.4.2.2 Procedure

Enable or disable the apnea backup function and adjust the apnea time as follows:

1. Open the mode window (Figure 4-2) by pressing the Mode key.
2. Select **Apnea backup**. Enable or disable it.
3. Select the apnea time (to the right of the words **Apnea backup**), activate it, and adjust the value. Press the knob to confirm.
4. Close the window by selecting **OK**.
5. When the RAPHAEL enters apnea backup ventilation, it displays the apnea backup controls window (Figure 4-3). Do one of the following:
   - Select **Reset** to resume ventilation in the mode and at the settings that were active before apnea backup began.
   - Check the control settings and change as desired. Select **OK** to continue ventilation in the backup (SIMV+ or PCV+) mode and at the displayed settings; these displayed settings are as described in Table 4-3.

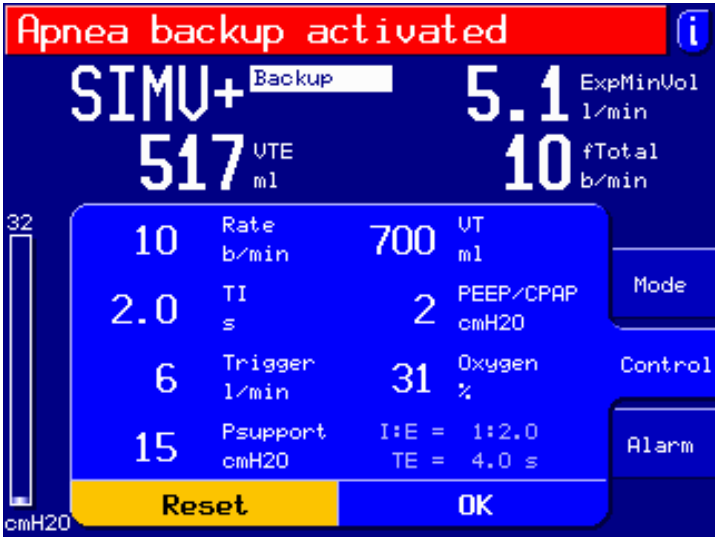


Figure 4-3. Apnea backup controls window

Table 4-3. Apnea backup ventilation control settings

Control	Setting
Mode	PCV+ (for NIV), SIMV+ (for all other modes)
Rate	Calculated from the patient's bodyweight
TI	Based on default I:E setting from the configuration mode.
VT	• Last active setting selected by the user for mandatory volume-controlled breaths, or • If the above value is missing, the RAPHAEL calculates it from the patient's bodyweight.
Others	Current settings or configuration values

4.5 Adjusting and confirming control settings

Table 4-4 describes the control settings and list their ranges. Some control settings, such as timing settings, are interdependent, so the actual range you see may be narrower than listed in the table.

NOTE:

Information may be displayed in the right-hand corner of control window 1, as follows:

- In all modes except ASV, SPONT, and NIV, timing parameters, determined from the timing settings, are displayed (see Figure 4-6). The definitions of I:E, Rate, TI, and T low parameters are identical to the settings described in Table 4-4. TE is the duration of the expiratory phase.

- In the ASV mode, **`Target MinVol = ...`** is displayed (Figure 4-4). This is the target minute volume to be delivered in ASV. Because this target minute volume depends on control settings, you will see this value change as you adjust the controls. See Appendix C for detailed information on ASV.

4.5.1 Adjusting and confirming control settings after mode change

After you select a different mode, the first of two control windows automatically opens (Figure 4-4). You must review and confirm these settings, or the mode change will not be recognized.

Figure 4-4. Control window 1 -- mode change to ASV

Review and confirm the control settings, as follows:

1. Carefully check the settings on window 1. If you want to change a setting, select the desired parameter. Activate it. Adjust the value, if needed. Repeat for any other desired parameters. Confirm the entire selection by selecting and activating **OK ...** The new mode now takes effect.
2. Control window 2 (Figure 4-5) automatically opens. The settings at the bottom of the window are tube resistance compensation settings (Section 4.6). Change any settings as described above.

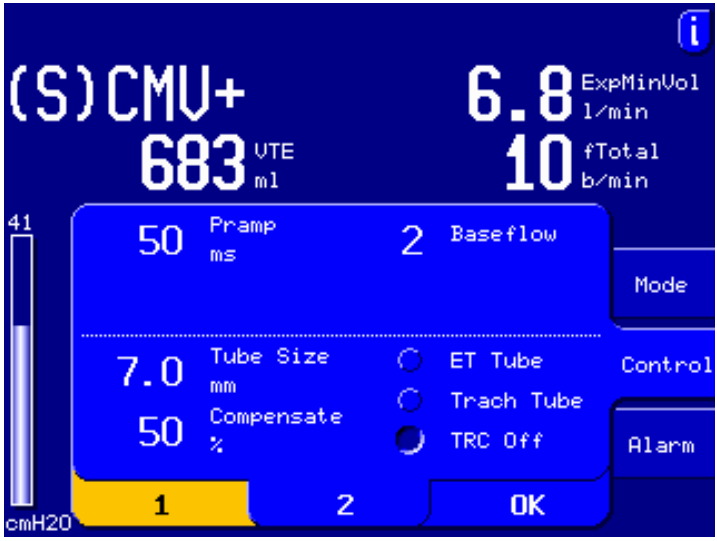


Figure 4-5. Control window 2

3. Close the window by selecting and activating **OK** or by pressing the Control key.

4.5.2 Adjusting control settings without mode change

Change the control settings at any time as follows:

1. Open control window 1 (Figure 4-6) by pressing the Control key.

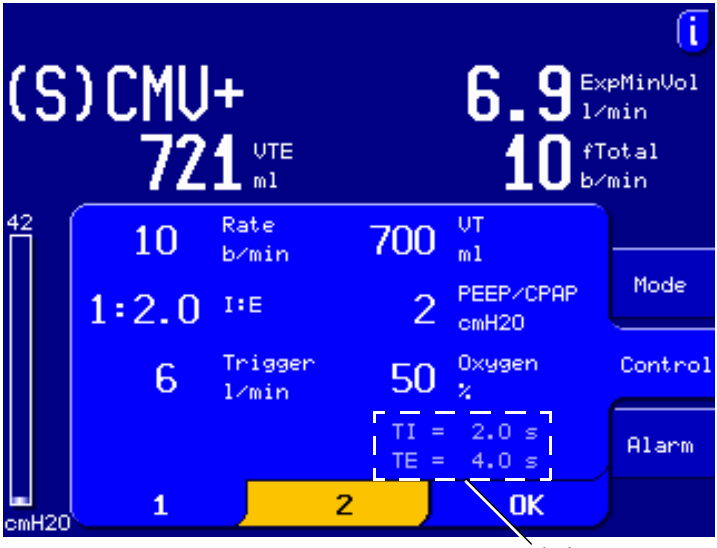


Figure 4-6. Control window 1 - no mode change

2. If you want to change a setting, select the desired parameter. Activate it. Adjust the value, if needed. Repeat for any other desired parameters.
3. Select **2** from the tabs at the bottom of the screen; activate it. Control window 2 (Figure 4-5) opens. The settings at the bottom of the window are tube resistance compensation settings (Section 4.6). Change any settings as described above.
4. Close the window by selecting and activating **OK** or by pressing the Control key.

NOTE:

Setting changes made through this window take effect immediately after you adjust the setting and press the knob. Selecting **OK** merely closes the window.

4.6 Setting tube resistance compensation (TRC)

WARNING

- **To prevent possible patient injury due to inappropriate compensation, make sure to set the tube type and size appropriately.**
- **TRC may induce autotriggering. If autotriggering occurs, lower or disable the TRC setting.**

NOTE:

- TRC is intended for use with spontaneously breathing patients. It is not recommended for use with passive patients.
- When TRC is enabled, the displayed Ppeak may be higher than expected (that is, the sum of the set PEEP/CPAP plus Pcontrol/Psupport). This is especially likely in passive patients with low airway resistance. Look closely at the calculated tracheal pressure.
- The tracheal pressure curve displayed is *calculated* from the proximal flow and pressure signals rather than *measured*.
- Setting **`Compensate`** to 0% displays a second pressure (tracheal) curve. This may prove useful for demonstration purposes, even when you don't want tube resistance compensation.

To reduce the patient's work of breathing while on the RAPHAEL, the ventilator's tube resistance compensation (TRC) feature offsets the flow resistance imposed by the endotracheal (ET) or tracheostomy tube. TRC may be active during both inspiration and exhalation in all modes except NIV.

Enable or disable TRC and adjust the settings as follows:

1. Open controls window **2** (Figure 4-7).

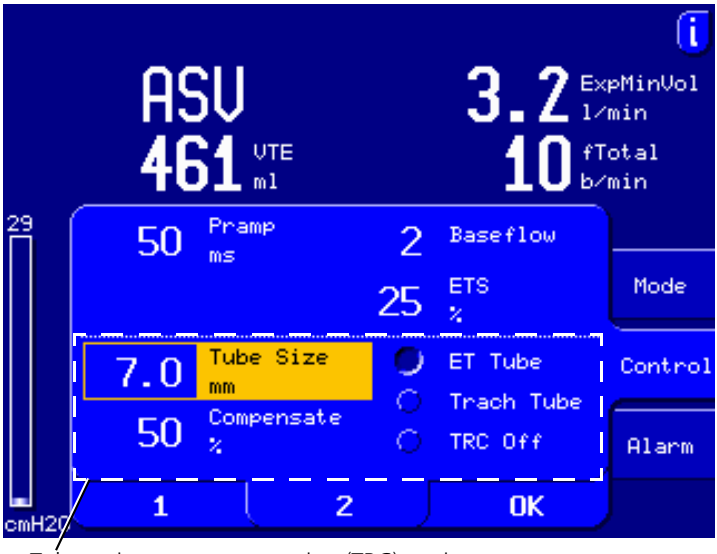


Figure 4-7. Setting TRC

2. Enable TRC as follows:
   a. Select the **Tube Size** (tube ID) setting. Adjust as required, then activate.
   b. Select the **Compensate** setting. Adjust as required, then activate. If the ET tube is shortened, lower the **Compensate** setting.
   c. Select and activate the **ET Tube** (endotracheal tube) or **Trach Tube** (tracheostomy tube) setting. The tracheal pressure curve will also be shown with the airway pressure curve, and the tube type will be shown at the top of the screen (Figure 4-8).

NOTE:

100% compensation means the maximum practicable compensation under the given conditions. It is not necessarily the theoretical full compensation of the tube resistance. Different tubes have different resistances, so you may have to adjust **Compensate** accordingly.

3. Disable TRC by selecting and activating **TRC Off**.
4. Close the window by selecting and activating **OK** or by pressing the Control key.

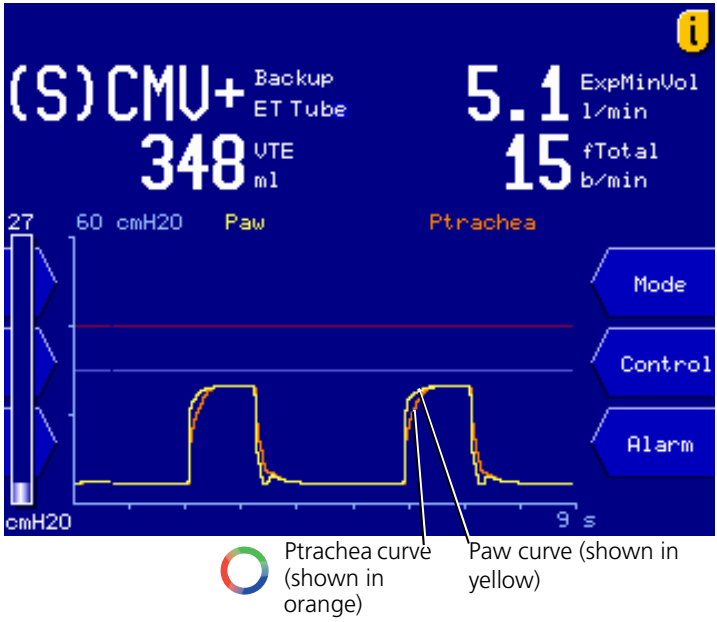


Figure 4-8. Ptrachea and Paw curves (with TRC active)

4.7 Control settings

Table 4-4. Control settings, mode additions, and ranges

Parameter	Definition	Range
%MinVol 	Percentage of minute volume to be delivered; regarded as the intended support level of ventilation. The RAPHAEL uses the %MinVol and the Bodyweight settings to calculate the target minute ventilation. When you adjust %MinVol, HAMILTON MEDICAL recommends you start with 100% and adjust it as necessary. Applies in ASV mode (see Appendix C).	25 to 350%
Apnea backup	A function that provides ventilation after the adjustable apnea time passes without breath attempts. Applies in SIMV+, PSIMV+, SPONT, DuoPAP, APRV, and NIV modes.	On or off
Apnea time	The maximum time allowed without a breath trigger, after which apnea is declared and the ventilator enters apnea backup, if enabled. Applies in SIMV+, PSIMV+, SPONT, DuoPAP, APRV, and NIV modes.	15 to 60 s

Table 4-4. Control settings, mode additions, and ranges (continued)

Parameter	Definition	Range
Baseflow	A continuous and constant gas flow from the inspiratory outlet to the expiratory outlet. It is essential for flow trigger. Increasing the Baseflow setting can reduce the ventilator's reaction time to the patient trigger, thus minimizing the work of breathing. This is especially useful in the NIV mode, where a higher Baseflow can serve to mitigate the effects of leakage. A setting of 2 provides a maximum baseflow of 4 l/min. Applies to all breaths in all modes. **NOTE:** • If you are using a LiteCircuit, set Baseflow to no greater than 2. With this type of circuit, the Baseflow setting does not have the same effect as with a double-limb circuit. • If you must use the ventilator for intrafacility transport, be aware of increased gas consumption possible at high Baseflow settings. • A high Baseflow setting may increase the noise level of the ventilator and may increase the possibility of a **Disconnection** alarm.	0 to 10 (when extended baseflow configured on) 0 to 2 (when extended baseflow configured off)
Bodyweight	Ideal bodyweight (see Table 4-1 and Table 4-2).	5 to 200 kg
ETS	Expiratory trigger sensitivity. The percent of peak inspiratory flow at which the ventilator cycles from inspiration to exhalation. Increasing the ETS setting results in a shorter inspiratory time, which may be beneficial in patients with obstructive lung disease. The ETS setting lets you match the inspiratory time of pressure-supported breaths to the patient's neural timing. Applies to spontaneous breaths.	5 to 70%

Table 4-4. Control settings, mode additions, and ranges (continued)

Parameter	Definition	Range
I:E	Ratio of inspiratory time to expiratory time. Based on the set rate and I:E, RAPHAEL calculates the inspiratory time. The inspiratory time is kept constant by the ventilator, but expiratory time can be shortened by the patient triggering. Applies to mandatory breaths in (S)CMV+ and PCV+ modes.	1:9.0 to 4.0:1
Mode	Ventilation mode.	(S)CMV+, PCV+, SIMV+, PSIMV+, SPONT, NIV  ASV, DuoPAP, APRV
Oxygen	Oxygen concentration to be delivered. Applies to all breaths in all modes.	21 to 100%
Pasvlimit 	Maximum pressure to be applied. For the ASV controller to function correctly, Pasvlimit must be at least 15 cmH_2O above PEEP/CPAP. Pmax is automatically adjusted so that it is 10 cmH_2O higher than Pasvlimit. Applies to all breaths in ASV.	7 to 70 cmH_2O
Pcontrol	Pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase. Applies to mandatory breaths in PCV+ and PSIMV+ modes.	5 to 50 cmH_2O above PEEP/CPAP

Table 4-4. Control settings, mode additions, and ranges (continued)

Parameter	Definition	Range
PEEP/CPAP	PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure), constant pressures applied to both inspiratory and expiratory phases. Applies to all breaths in all modes except APRV. **WARNING** **If you are using a LiteCircuit, a PEEP/CPAP below 4 cmH_2O may induce CO_2 rebreathing. (See Section B.6.3, Noninvasive ventilation (NIV).)**	0 to 35 cmH_2O
P high 	High airway pressure level. P high setting is *total* desired airway pressure, including PEEP/CPAP or P low. Applies to all breaths in DuoPAP and APRV modes.	0 to 75 cmH_2O
P low 	Low airway pressure level. Applies to all breaths in APRV mode.	0 to 35 cmH_2O

Table 4-4. Control settings, mode additions, and ranges (continued)

Parameter	Definition	Range
Pramp	Pressure ramp. Time required for inspiratory pressure to rise to the set (target) pressure. The Pramp setting lets you fine-tune the initial flow output during a pressure-controlled or pressure-supported breath to match the ventilator flow to the patient's demand. Short Pramp settings (50 ms) provide higher initial flow rates and result in faster attainment of the target pressure. This may benefit patients with elevated respiratory drive. Setting the Pramp too low, especially in combination with a small ET tube (high resistance), may result in a noticeable pressure overshoot during the early stage of inspiration and a **`Pressure limitation`** alarm. Setting the Pramp too high may prevent the ventilator from attaining the set inspiratory pressure. A square (rectangular) pressure profile is the goal. Lower Pramp values have been correlated with reduced work of breathing in certain patients. Applies to all breaths in all modes. **NOTE:** To prevent possible pressure overshoot in pediatric applications, it is recommended that Pramp be set to at least 75 ms.	50 to 200 ms
Psupport	Pressure (additional to PEEP/CPAP or P low) to be applied during the inspiratory phase. Pressure support helps the patient counteract the flow resistance of the breathing circuit and endotracheal tube. It compensates for the decreasing tidal volume and rising respiratory rate of a spontaneously breathing patient. Applies to spontaneous breaths in SIMV+, PSIMV+, SPONT, NIV, DuoPAP, and APRV modes.	0 to 50 cmH_2O above PEEP/ CPAP or P low

Table 4-4. Control settings, mode additions, and ranges (continued)

Parameter	Definition	Range
Rate	Respiratory frequency or number of breaths per minute. Applies to mandatory breaths in (S)CMV+, PCV+, SIMV+, PSIMV+, and DuoPAP modes.	8 to 80 b/min in (S)CMV+ 4 to 80 b/min in PCV+ 1 to 80 b/min in other modes
Sigh	Breaths delivered every 50 breaths to deliberately increase tidal volume by applying an additional 10 cmH_2O pressure. Applies in all modes except DuoPAP and APRV.	On or off
T high 	Duration of high airway pressure level. Applies to all breaths in DuoPAP and APRV modes.	0.1 to 30.0 s
TI	Inspiratory time or duration of inspiration phase. Applies to mandatory breaths in SIMV+ and PSIMV+ modes.	0.1 to 3.2 s
TI max	Maximum inspiratory time. Applies to spontaneous breaths in NIV mode.	1.0 to 3.0 s
T low 	Duration of low airway pressure level. Applies to all breaths in APRV mode.	0.2 to 30.0 s

Table 4-4. Control settings, mode additions, and ranges (continued)

Parameter	Definition	Range
TRC 	Tube resistance compensation. Reduces the patient's work of breathing by offsetting tube resistance.	
Tube type/ TRC disabled	Endotracheal (ET) tube, tracheostomy (Trach) tube, or TRC off.	ET tube, Trach Tube, TRC Off
Tube Size	Inner diameter (ID) of tube.	4.0 to 10.0 mm
Compensate	Percentage of compensation, where 100% is the maximum practicable compensation under given conditions.	0 to 100%
Trigger	The patient's inspiratory flow that triggers the ventilator to deliver a breath. **WARNING** **A sensitive Trigger setting may induce autotriggering**	OFF in (S)CMV+ and PCV+ modes only, 1 to 10 l/min in all modes
VT	Tidal volume delivered during inspiration. Applies to mandatory breaths in (S)CMV+ and SIMV+ modes.	50 to 2000 ml

4.8 Setting alarm limits

WARNING

To prevent possible patient injury, make sure the alarm limits are appropriately set before you place the patient on the ventilator.

You can set all alarms quickly using the Auto alarm function, but the settings may not be appropriate under all clinical conditions. HAMILTON MEDICAL recommends that you set the alarms manually when possible. When you do use the Auto alarm function, check the appropriateness of these settings at the earliest opportunity.

You can access the alarm window and change the settings for Pmax, low and high ExpMinVol, and low and high fTotal, at any time.

The RAPHAEL offers two alarm-setting options:

- You can individually set alarm limits. Table 4-5 lists the ranges for the alarm limits.
- Using the auto-alarm function, you can automatically set all alarm limits to values appropriate to the patient's bodyweight and to the monitored patient data. Table 4-6 lists the auto-alarm setting rules.

Review and adjust the alarm limits as follows:

1. Open the alarm window (Figure 4-9) by pressing the Alarm key.

NOTE:

- When one of these settable alarms is active, the alarm bar is red.
- The current measurement (airway pressure, expiratory minute volume, or breathing rate) is shown to the left of the alarm bar, and the current alarm limit is shown to the right. For the Pmax alarm, the Pressure limitation value is also shown.

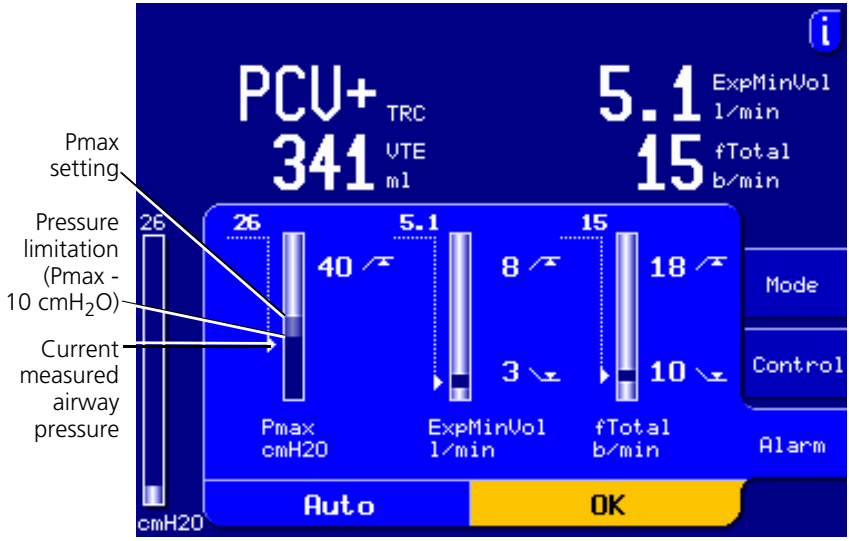


Figure 4-9. Alarm window

2. To select the auto-alarm function, do the following:
   a. Select **Auto**.
   b. Review the new alarm limits and verify that they are acceptable.

c. Close the window by selecting and activating **OK** or by pressing the Alarm key.

3. To set alarm limits, do the following:

   a. Select the desired parameter. Activate it. Adjust the value, if needed. Confirm. Repeat for any other desired parameters.

   b. Close the window by selecting and activating **OK** or by pressing the Alarm key

NOTE:

Setting changes made through this window take effect immediately after you adjust the setting and press the knob. Selecting **OK** merely closes the window.

Table 4-5. Alarm limit settings and ranges

Parameter	Definition	Range
ExpMinVol (low and high)	Low and high expiratory minute volume. A high-priority alarm is activated if the monitored expiratory minute volume is below or above the low or high alarm limits. **WARNING** **When ventilating pediatric patients with small diameter ET tubes and small set pressures, the Disconnection alarm may not be reliable. It is therefore very important to set and observe the low ExpMinVol alarm to ensure detection of disconnections.**	0.1 to 50 l/min

Table 4-5. Alarm limit settings and ranges (continued)

Parameter	Definition	Range
fTotal (low and high)	Minimum and maximum breathing rate. A medium-priority alarm is activated if the monitored breathing rate is below or above the low or high alarm limit.	0 to 99 b/min
Pmax	Maximum pressure. The highest pressure allowed in the patient breathing circuit. Once this pressure is reached, a high-priority alarm is activated and RAPHAEL relieves pressure until the pressure falls to the PEEP/CPAP level. During mandatory breaths, inspiratory pressure is limited to Pmax - 10 cmH_2O. A medium-priority **`Pressure limitation`** alarm is activated if the ventilator would need to exceed this pressure to deliver the required tidal volume.	PEEP + 15 to 80 cmH_2O

Table 4-6. Auto-alarm settings

Alarm limit	Setting (if measurements are available)	Setting (if measurements are not available)
ExpMinVol, low	Measured ExpMinVol x 0.6	(S)CMV+ rate x VT x 0.6
ExpMinVol, high	Measured ExpMinVol x 2.0	(S)CMV+ rate x VT x 2.0
fTotal, low	Measured fTotal x 0.6	(S)CMV+ rate x 0.6 (minimum as set in configuration mode)
fTotal, high	Measured fTotal x 1.4	(S)CMV+ rate x 1.4 (minimum as set in configuration mode)
Pmax	Measured Ppeak of last breath + 15 cmH_2O Minimum: 40 cmH_2O	40 cmH_2O or as set in configuration mode

5 Monitoring

WARNING

- **To prevent possible patient injury due to nonfunctional alarms and monitoring, HAMILTON MEDICAL recommends that flow sensing and oxygen monitoring always be enabled.**
- **In case of malfunction of the ventilator's built-in monitoring and in order to maintain an adequate level of patient monitoring at all times, it is recommended that additional independent monitoring devices be used. The operator of the ventilator must still maintain full responsibility for proper ventilation and patient safety in all situations.**

NOTE:

- To ensure that oxygen monitoring is always fully functional, replace an exhausted or missing oxygen cell as soon as possible or use an external monitor that complies with ISO 7767.
- Dashes displayed in place of monitored data indicate that valid values are not yet available; this is a transient state lasting for one breath.

5.1 Accessing patient data

During ventilation, you can view patient data on the RAPHAEL screen; Figure 5-1 shows an example of this basic screen. In addition, you can open the numeric patient data windows to view more data.

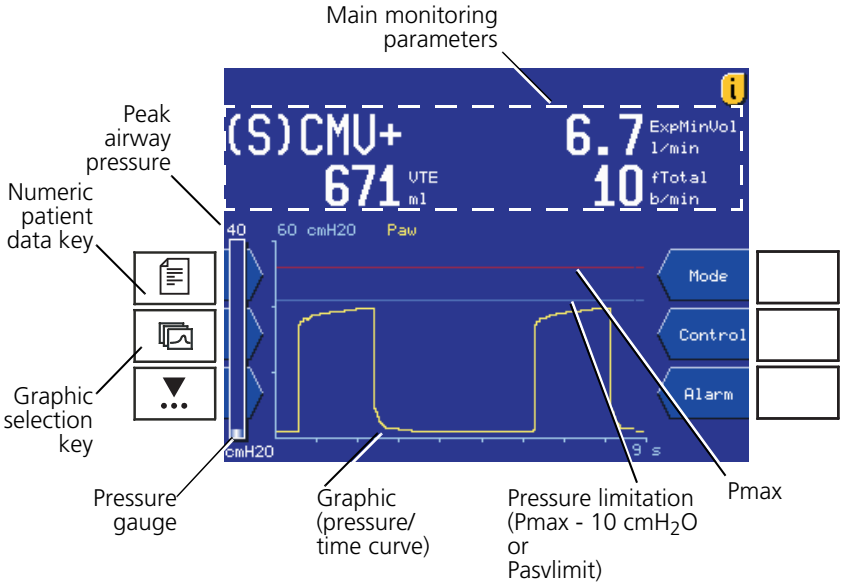


Figure 5-1. Basic screen showing curve

5.2 Basic screen

The basic screen (Figure 5-1) shows the patient's status, including:

- Active mode
- Three main (numeric) monitoring parameters. The choice of parameters is made by the user in the configuration mode.
- Graphic showing patient data. The graphic can be a curve, or, in the RAPHAEL XTC, RAPHAEL Color, or RAPHAEL Silver, a loop, trend, or ASV target graphics screen; the type of graphic is user-selected through the graphic selection key.

Silver

- Patient airway pressure, indicated by the pressure gauge with the peak pressure of the last breath displayed above the gauge.

The main monitoring parameters and the pressure gauge are always displayed on the RAPHAEL screen during ventilation. The two topmost left-hand keys are used to show more numeric monitored data and to select graphic.

5.3 Viewing more numeric patient data

Silver

You can view more numeric patient data in three windows, or, if ASV is active, in four windows. The ASV monitored parameter window provides numeric target and actual parameters for VT, fTotal, and ExpMinVol. You can open these windows anytime as long as a right-hand window is not open. Table 5-1 describes the monitored parameters.

To view the data, press the top, left-hand numeric patient data key. You will see the first window (Figure 5-2). Select and open window 2 (Figure 5-3), window 3 (Figure 5-4), or the ASV monitored parameter window (Figure C-5) by turning and pressing the knob or by pressing the key. To close these windows and return to the basic screen, select **OK**, then press the knob.

Figure 5-2. Numeric patient data window 1

Figure 5-3. Numeric patient data window 2

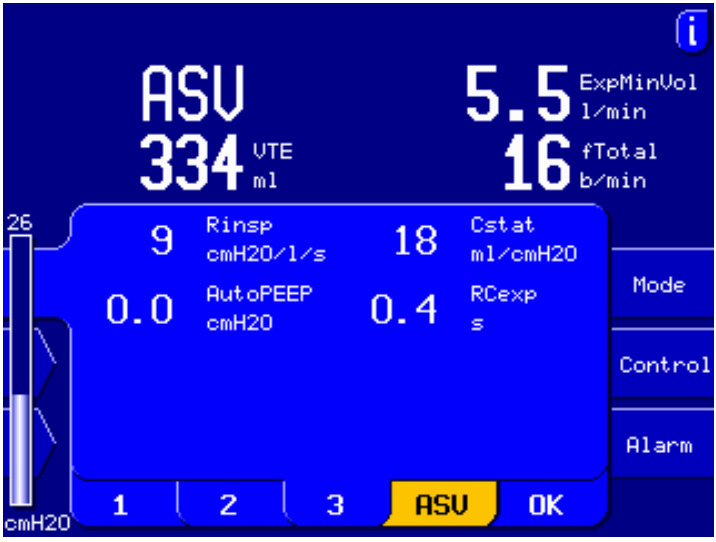


Figure 5-4. Numeric patient data window 3

5.4 Selecting type of graphic

Silver

The basic screen displays real-time patient data graphically. You can choose to display the data as a curve, or, in the RAPHAEL XTC, RAPHAEL Color, or RAPHAEL Silver, a dynamic loop, trend curve, or the ASV target graphics screen (if the RAPHAEL is in the ASV mode).

5.4.1 Selecting a curve

Select a curve for display as follows:

1. Press the graphic selection key to open the graphic selection window (Figure 5-5).
2. Select the Pressure/time, Flow/time, or Volume/time curve type, activate it, and confirm. Figure 5-1 is an example of a pressure/time curve.

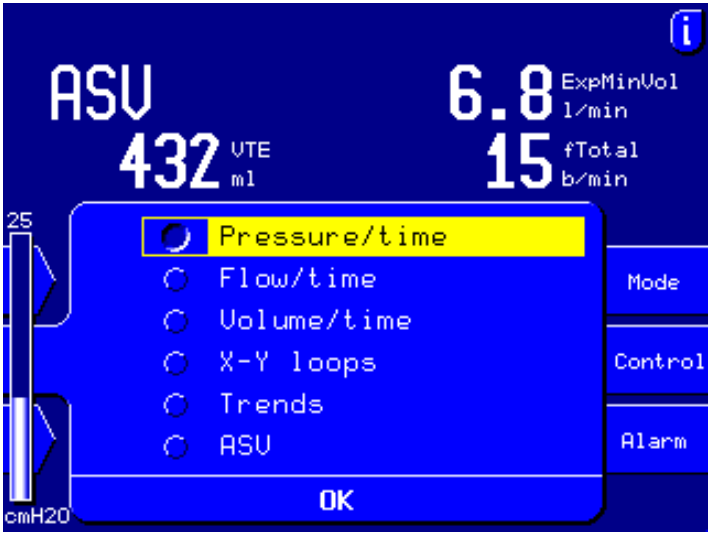


Figure 5-5. Graphic selection window

5.4.2 Selecting a loop

Silver

Select a real-time loop for display as follows:

1. Press the graphic selection key to open the graphic selection window (Figure 5-5).
2. Select **`X-Y loops`**, activate it, and confirm.
3. The loop selection window is displayed (Figure 5-6). Select and activate the desired X and Y axis parameters, then confirm. The loop is displayed (Figure 5-7).

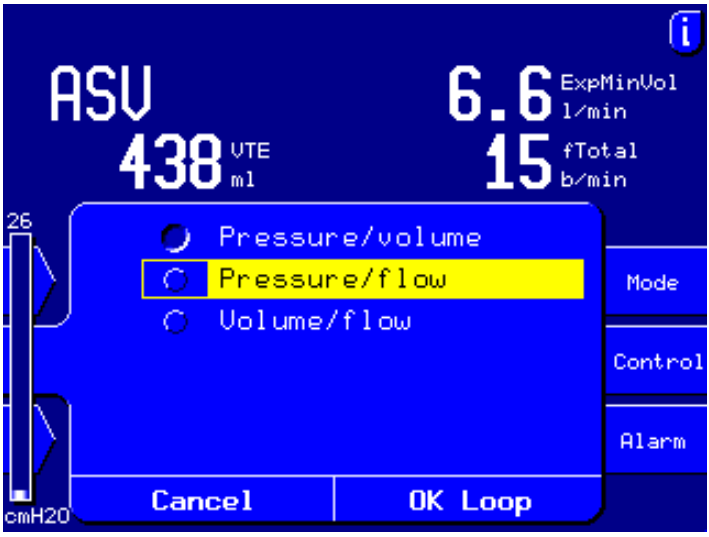


Figure 5-6. Loop selection window

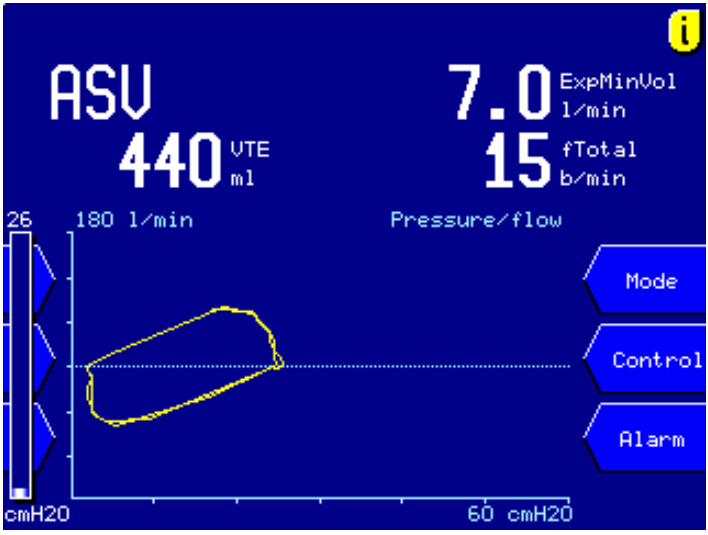


Figure 5-7. Loop screen

5.4.3 Trends

Silver

You can choose to show monitored parameters as a 1-, 12-, or 24-hour trend, and you can later examine the numeric values at points on the trend curve. From the time ventilation starts, the ventilator continually stores the monitored parameters *plus* the Pinsp and f Control parameters in memory, so any parameter (except fSpont) is available for trending. Pinsp is the target pressure (additional to PEEP/CPAP) applied during the inspiratory phase.

5.4.3.1 Selecting a trend

Select a parameter trend for display as follows:

1. Press the graphic selection key to open the graphic selection window (Figure 5-5).
2. Select **`Trends`**, activate it, and confirm.
3. The trend selection window is displayed (Figure 5-8). Select and activate the desired elapsed time, then confirm.

4. The trend parameter selection window is displayed (Figure 5-9). Select and activate the parameter to trend, then confirm.

NOTE:

In certain cases a pair of parameters is automatically trended together (ExpMinVol and MV Spont, fTotal and f Control, Ppeak and PEEP/CPAP).

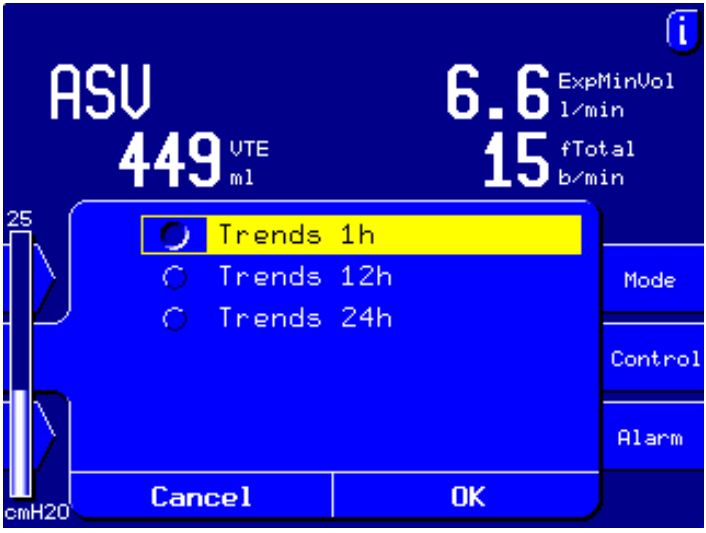


Figure 5-8. Trend selection window

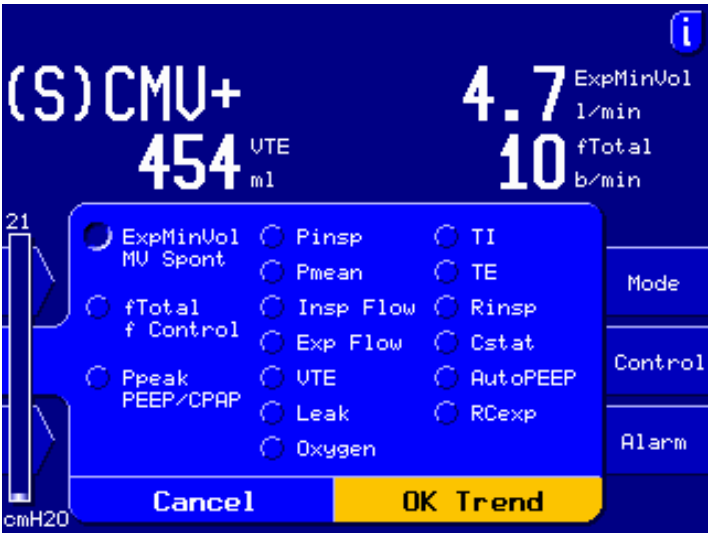


Figure 5-9. Trend parameter selection window

The parameter's history is displayed as a trend, starting from when ventilation last started or, if **`Last Setup`** was selected, for the time these settings have been used (Figure 5-10).

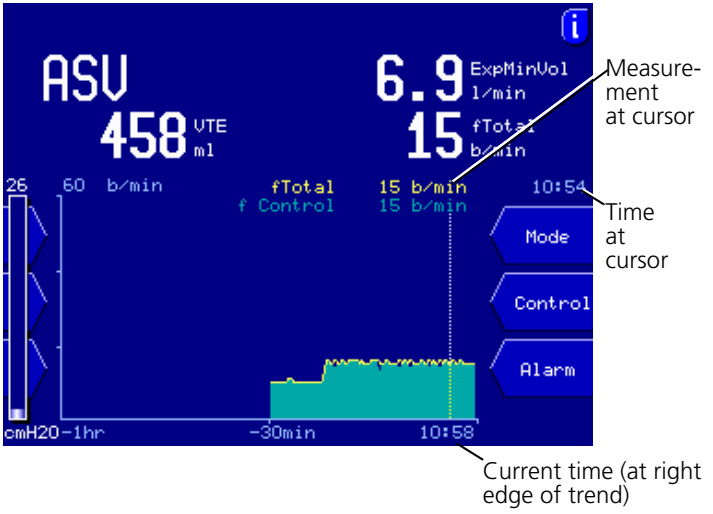


Figure 5-10. Trend screen

5.4.3.2 Viewing numeric values on a trend curve

To view the numeric value for a point on a trend curve, display the trend, then turn the knob until the dashed cursor line intersects the curve at the desired point. The value is shown on the trend screen (Figure 5-10), along with the actual time it was measured.

5.4.4 Selecting the ASV target graphics screen

The ASV target graphics screen (Figure C-10), which is accessible only in the ASV mode, shows how the adaptive lung controller moves toward its targets. It shows the target parameters for tidal volume, frequency, pressure, and minute ventilation.

Display the ASV target graphics screen as follows:

1. Press the graphic selection key to open the graphic selection window (Figure 5-5).
2. Select **ASV**, activate it, and confirm.

See Appendix C for detailed information on ASV, including how to interpret the data on the ASV screen.

5.5 Monitored parameters

NOTE:

The RAPHAEL measures inspiratory resistance (Rinsp), compliance (Cstat), and autoPEEP (AutoPEEP) continuously, during mandatory and spontaneous breaths in all modes, without interruption in ventilation. To obtain these measurements, the RAPHAEL uses a statistical technique called the least squares fitting (LSF) method[1].This method is applied on a breath-by-breath basis, without the need for special inspiratory flow patterns and occlusion maneuvers, provided that the patient is relaxed or nearly relaxed.

Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH_2O. After completion, return this control to its former setting.

Table 5-1 is an alphabetical list of the RAPHAEL's monitored parameters. All can be viewed in the numeric patient data windows (Figure 5-2 and Figure 5-3). The display of monitored parameters is updated every breath.

1. Giorgio A. Iotti, MD and Antonio Braschi, MD, *Measurements of Respiratory Mechanics during Mechanical Ventilation.* (Rhäzüns, Switzerland: HAMILTON MEDICAL Scientific Library,1999), PN 689122.

Table 5-1. Monitored parameters and ranges

Parameter	Definition	Range
AutoPEEP[1]	The difference between the measured and set PEEP. AutoPEEP is the abnormal pressure generated by air "trapped" in the alveoli due to inadequate lung emptying. Ideally, it should be zero. It is calculated using the LSF method applied to inspiration. When AutoPEEP is present, volutrauma or barotrauma might develop. In active patients, AutoPEEP may present an extra workload to the patient. AutoPEEP or air trapping results when the expiratory phase is too short. The expiratory phase might be too short under these conditions: • Delivered tidal volume too large • Expiratory time too short or respiratory rate too high • Circuit impedance too high • Expiratory airway obstruction	0 to 100 cmH_2O
Cstat[1]	Static compliance of the respiratory system, including lung and chest wall compliances. It is calculated using the LSF method. Cstat can help diagnose changes in elastic characteristics of the patient's lungs. **NOTE:** Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH_2O. After completion, return this control to its former setting.	0 to 999 ml/cmH_2O
Exp Flow	Peak expiratory flow.	0 to 180 l/min

Table 5-1. Monitored parameters and ranges (continued)

Parameter	Definition	Range
ExpMinVol[1]	Expiratory minute volume. The moving average of the monitored expiratory volume per minute, over the last 8 breaths, updated each breath. It is determined from the Flow Sensor measurement. When the patient triggers or the user initiates a breath in (S)CMV+ or PCV+ mode, the measured fTotal and ExpMinVol increase.	0 to 50 l/min
fSpont	Spontaneous breath frequency. The moving average of pressure-supported, flow-cycled spontaneous breaths per minute, over the last 8 breaths. An increased fSpont may indicate that the patient is compensating for a low compliance. This may indicate ventilatory fatigue due to imposed work of breathing.	0 to 99 b/min
fTotal	Total breathing frequency. The moving average of the patient's total breathing frequency over the past 8 breaths, including both mandatory and spontaneous breaths. It is updated every breath. When the patient triggers or the user initiates a breath in (S)CMV+ or PCV+ mode, fTotal is higher than the Rate setting.	0 to 99 b/min
I:E	Inspiratory:expiratory ratio. Ratio of the patient's inspiratory time to his expiratory time for every breath cycle. This includes both mandatory and spontaneous breaths. I:E may differ from the set I:E ratio if the patient breathes spontaneously. I:E is not displayed in DuoPAP and APRV modes.	9.9:1 to 1:9.9
Insp Flow[1]	Peak inspiratory flow, spontaneous or mandatory.	0 to 180 l/min

Table 5-1. Monitored parameters and ranges (continued)

Parameter	Definition	Range
Leak	Leakage percent. The percentage of the delivered inspiratory volume (VTI) that is not returned during exhalation. It is calculated from measurements at the Flow Sensor and averaged over the past 8 breaths. Leak can indicate leaks on the patient side of the Flow Sensor (endotracheal tube, chest tube). It does not include leakage between the ventilator and Flow Sensor.	0 to 100%
MV Spont[1]	Spontaneous expiratory minute volume. The moving average of the monitored expiratory volume per minute for spontaneous breaths, over the last 8 mandatory and spontaneous breaths.	0 to 50 l/min
Oxygen	Oxygen concentration of the delivered gas. It is measured by the oxygen cell in the inspiratory pneumatics. This parameter is not displayed if the oxygen cell is not installed or is defective.	18 to 105%
PEEP/CPAP	Monitored PEEP (positive end expiratory pressure)/CPAP (continuous positive airway pressure). The airway pressure at the end of exhalation. Measured PEEP/CPAP may differ slightly from set PEEP/CPAP, especially in actively breathing patients.	-10 to 100 cmH_2O
Pinsp	Inspiratory pressure, the target pressure (additional to PEEP/CPAP) applied during the inspiratory phase. Available in ASV and in trends.	0 to 75 cmH_2O

Table 5-1. Monitored parameters and ranges (continued)

Parameter	Definition	Range
Pmean	Mean airway pressure. The absolute pressure averaged over the breath cycle, or in the case of DuoPAP/APRV, over an entire cycle consisting of the high phase (T high) and low phase. Pmean is an important indicator of the possible impact of applied positive pressure on hemodynamics and surrounding organs.	-10 to 100 cmH_2O
Ppeak	Peak proximal airway pressure. The highest pressure during the previous respiratory cycle. It is influenced by airway resistance and compliance. It may be higher than expected due to the RAPHAEL's breathing circuit compensation. It may differ noticeably from alveolar pressure if airway flow is high. Ppeak is measured directly by the Flow Sensor.	-10 to 100 cmH_2O

Table 5-1. Monitored parameters and ranges (continued)

Parameter	Definition	Range
RCexp[1]	Expiratory time constant. The rate at which the lungs empty, as follows: **Actual TE** **% emptying** 1 x RCexp 63% 2 x RCexp 86.5% 3 x RCexp 95% 4 x RCexp 98% It is calculated from 75% VTE and the flow at 75% VTE. In adults, an RCexp value above 1.2 s indicates airway obstruction, and a value below 0.5 s indicates a severe restrictive disease. Use RCexp to set optimal TE (Goal: TE ≥ 3 x RCexp) • In passive patients: Adjust rate and I:E. • In active patients: Increase Psupport and/or ETS to achieve a longer TE. These actions may reduce the incidence of AutoPEEP.  The ASV controller uses RCexp to determine the optimal respiratory rate and the minimum expiratory time.	0 to 10 s

Table 5-1. Monitored parameters and ranges (continued)

Parameter	Definition	Range
Rinsp[1]	Resistance to inspiratory flow caused by the endotracheal tube and the patient's airways, during inspiration. It is calculated using the LSF method applied to the inspiratory phase. **NOTE:** Actively breathing patients can create artifact or noise, which can affect the accuracy of these measurements, however. To minimize patient participation during these measurements, you may want to increase Psupport by 10 cmH_2O. After completion, return this control to its former setting.	0 to 999 $cmH_2O/l/s$
TE	Expiratory time. In mandatory breaths, TE is measured from the start of exhalation until the set time has elapsed for the switchover to inspiration. In spontaneous breaths, TE is measured from the start of exhalation, as dictated by the ETS setting, until the patient triggers the next inspiration. TE may differ from the set expiratory time if the patient breathes spontaneously. TE is not displayed in the DuoPAP and APRV modes.	0 to 60 s

Table 5-1. Monitored parameters and ranges (continued)

Parameter	Definition	Range
TI	Inspiratory time. Patient's actual inspiratory time, updated for every breath, both mandatory and spontaneous. In mandatory breaths, TI is measured from the start of breath delivery until the set time has elapsed for the switchover to exhalation. In spontaneous breaths, TI is measured from the patient trigger until the flow falls to the ETS setting, which signifies the end of inspiration. TI may differ from the set inspiratory time if the patient breathes spontaneously. TI is not displayed in the DuoPAP and APRV modes.	0 to 30 s
VTE[1]	Expiratory tidal volume. The volume exhaled by the patient. It is determined from the Flow Sensor measurement. Because it is measured by the Flow Sensor, it does not show any volume lost due to compression or leaks in the breathing circuit. If there is a gas leak at patient side, the displayed VTE may be less than the tidal volume the patient actually receives.	-9000 to 9000 ml

1. Due to the changing and unpredictable leakage in NIV, this parameter cannot be used for reliable analysis of patient conditions. Close monitoring of clinical parameters and patient comfort is therefore critical.

6 Responding to alarms

6.1 Introduction

The RAPHAEL's visual and audible alarms notify the user of problems. These alarms can be categorized as high-, medium-, low-priority, and technical fault alarms. Each has corresponding visual and audible characteristics (see Table 6-1).

When an alarm condition is detected, an audible alarm sounds and the red indicator on top of the alarm silence key blinks. A message is displayed on the top (message) line of the screen or on the entire screen. If multiple messages are simultaneously active, only those messages with the highest priority are displayed, and if there are multiple messages of this same, highest priority, these messages alternate. (For example, if two high-priority messages are active, these alternate and any medium- or low-priority messages are not displayed.) Messages are stored in the event log for all alarms.

In addition, if the alarm is serious enough to possibly compromise safe ventilation, the RAPHAEL is placed into the ambient state. The ambient and expiratory valves are opened, letting the patient breathe room air unassisted.

You can adjust the loudness of the audible alarm; see Section 3.2.4.

6.2 How to respond to an alarm

Respond to an alarm as follows:

1. Check the patient.
2. Silence the alarm, if possible.
3. Correct the alarm condition by referring to Table 6-2. Open the event log to review reset alarms (Section 6.3). This information may help you troubleshoot alarms. Rerun any applicable tests, and verify that they pass.

NOTE:

If the condition that caused the alarms is corrected, the RAPHAEL automatically resets the alarm. You can see which alarms were reset in the event log.

Table 6-1. Alarm categories

Category	Visual alarm	Audible alarm	Action needed
High-priority	 White on red message Blinking message (other models)	A sequence of beeps (3 beeps, then 2 beeps) repeated until the alarm is reset. If the audible alarm is not silenced during the first minute, the backup buzzer also sounds.	The patient's safety is compromised. The problem needs immediate attention from the clinician.
Medium-priority	 Black on yellow message Nonblinking message (other models)	A sequence of 3 beeps repeated periodically. If the audible alarm is not silenced during the first minute, the continuous backup buzzer also sounds.	The problem needs prompt attention from the clinician.
Low-priority	 Black on yellow message Nonblinking message (other models)	Two sequences of beeps. This is not repeated.	Be aware that the patient's status may have changed.
User message	 White on blue message Nonblinking message (other models)	None	Follow instructions on screen.

Table 6-1. Alarm categories (continued)

Category	Visual alarm	Audible alarm	Action needed
Technical fault	Message on entire screen  White on red message	Continuous tone. This audible alarm cannot be silenced.	Secure alternative ventilation. Turn off the ventilator. Have the ventilator serviced.

WARNING

A technical fault places the ventilator into the ambient state. To prevent possible patient injury, immediately remove the patient from the ventilator and secure alternative ventilatory support. Contact service.

6.3 Event log

The event log contains data about ventilator alarms and setting changes (including date and time) that have occurred since the RAPHAEL was powered on or, if **`Last Setup`** was selected, for the time these settings have been used.

To open the log, first close any open windows. This highlights the event log symbol (Figure 6-1). Press the knob to open the event log. The most recent event is at the top. Select the up or down arrow by turning the knob. Press the knob repeatedly to scroll up or down as desired. Select and activate **`OK`** to close the event log.

NOTE:

In the configuration mode, you can view an extended version of the event log also containing events that occurred before the ventilator was powered on, up to a total of 1000 events (see Section E.8). This extended version does not contain more details about these events.

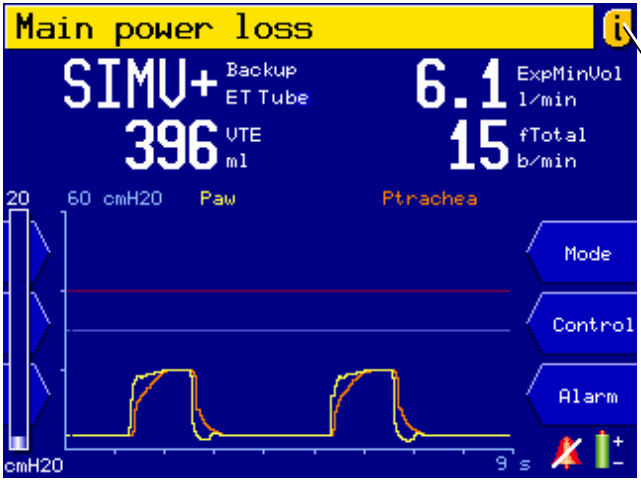
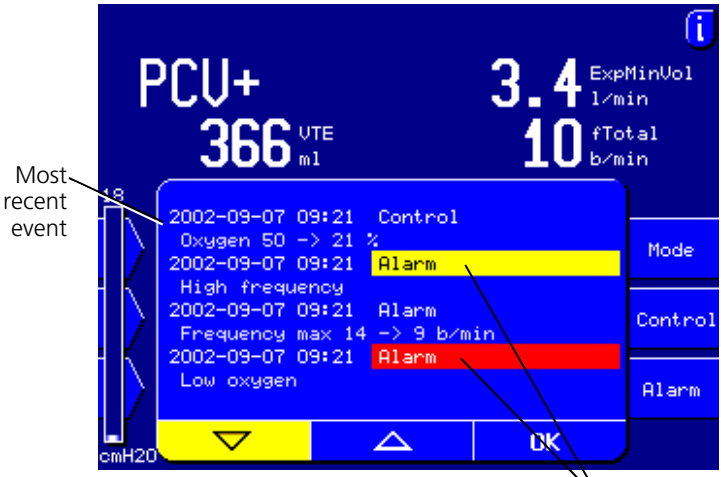
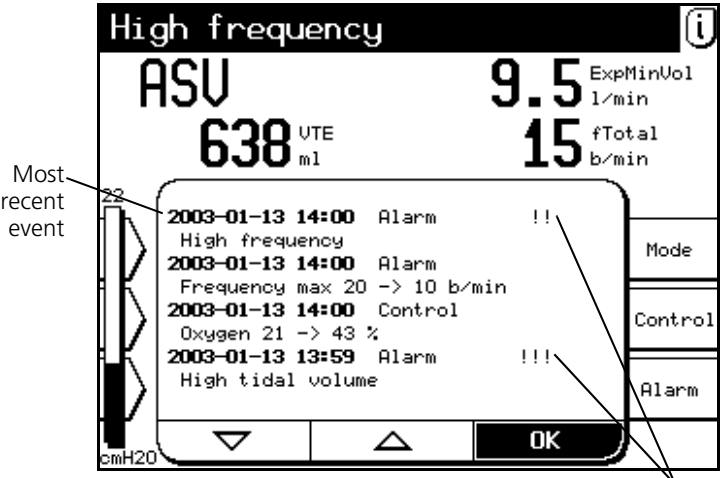


Figure 6-1. Event log symbol



Alarm priority (red = high priority, yellow = low or medium priority, white on blue = user message or others)

a. In RAPHAEL XTC or RAPHAEL Color



Alarm priority (3=high, 2=medium, 1=low)

b. In RAPHAEL Silver or basic RAPHAEL

Figure 6-2. Event log

6.4 Alarm and other messages

Table 6-2 lists the alarm and other messages displayed by the RAPHAEL.

Table 6-2. Alarm and other messages

Alarm	Definition	Action needed
100% O2 activated	*User message.* The 100% O_2 function was selected.	None.
Air supply	*High priority.* Input pressure of compressed air is < 200 kPa (29 psi), or air supply is not detected. The RAPHAEL will ventilate the patient with 100% oxygen. (Alarm is not activated when Oxygen setting is 100%.)	Check air supply. Increase air supply pressure.
Apnea	*High priority.* No breath delivered for the operator-set apnea time in SPONT, SIMV+, PSIMV+, DuoPAP, APRV, or NIV mode. Apnea backup is off.	Check the patient. Consider switching to a mandatory mode or increasing the mandatory rate, as applicable.
Apnea backup activated	*High priority.* Apnea backup has been on for 2 min, and the user has not confirmed the settings.	Adjust the control settings or press **Reset** to return to the former mode and settings.
	Low priority. No breath delivered for the set apnea time in SPONT, SIMV+, PSIMV+, DuoPAP, APRV, or NIV mode. Apnea backup is on.	Adjust the control settings or press **Reset** to return to the former mode and settings.
Apnea backup ended	*User message*. Backup mode was reset (by the operator or by the patient triggering two breaths), and the RAPHAEL is again ventilating in its original support (pre-apnea) mode.	No action required.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
ASV: Pressure limitation 	*Low priority.* The operator-set Pasvlimit is too low or %MinVol is too high, and the ventilator cannot deliver the calculated target tidal volume. For the ASV controller to function correctly, Pasvlimit must be at least 15 cmH_2O above PEEP/CPAP.	Check the patient. Consider suctioning or other therapy. Check the control settings. Consider increasing Pasvlimit to an appropriate level.
ASV:Unable to meet target 	*Low priority.* The operator-set %MinVol cannot be delivered, possibly because of setting conflicts.	Check the patient. Check the control settings. Consider decreasing the %MinVol setting or increasing Pmax to an appropriate level. Consider suctioning or other therapy.
	NOTE: Display the ASV target graphics screen to help troubleshoot this alarm.	
Battery power low	*High priority.* The backup batteries have a minimum of 10 min power left. This is displayed while the ventilator is running on its backup batteries.	Connect the RAPHAEL to ac power.
	Low priority. The backup batteries have a minimum of 10 min power left. This is displayed while the ventilator is running on ac.	For information only. The batteries are automatically recharged while the RAPHAEL is connected to ac power.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Check Flow Sensor	*High priority.* A Flow Sensor sensing line is disconnected or occluded. The RAPHAEL will switch over to PCV+ mode and continue ventilating the patient.	Check the Flow Sensor and the sensing lines. Confirm the PCV+ mode settings. The RAPHAEL automatically returns to its previous mode when the Flow Sensor check is successful.
Connect patient	*User message.* Instruction message during the Flow Sensor and tightness tests. It means the test is complete.	Reconnect the demonstration lung or patient.
Disconnect patient	*User message.* Instruction message at the start of the Flow Sensor and tightness tests.	Remove the patient from the circuit. Follow the instructions displayed.
Disconnection	*High priority.* The RAPHAEL sensed a disconnection of the breathing system; or, if flow sensing is disabled, it sensed that there was no pressure input to the ventilator through the blue Flow Sensor connector.	Check the patient. Check the breathing circuit. Check the gas supply. If flow sensing is disabled (Flow sensing deactivated alarm), make sure that there is a pressure sensing line connected between the Y-piece and the blue Flow Sensor connector.
Disconnection suppressed	*Low priority.* A **Disconnection** alarm was declared, but the user suppressed it for up to 2 min with the manual breath key. When a disconnection is suppressed, the ventilator can deliver breaths. Suppressing a disconnection is particularly useful when the user wants to start NIV, but has not yet successfully adjusted the patient's mask.	Check the patient for adequate ventilation. Check the breathing circuit for leaks. If ventilating in NIV mode, adjust the patient's mask, then press the manual breath key again to deactivate the suppression. If the **Disconnection** alarm persists, consider switching to an invasive mode.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Exhalation obstructed	*High priority.* The end expiratory pressure is ≥ (set PEEP + 5 cmH_2O).	Check the patient. Check for occlusion in the expiratory limb. Check the Flow Sensor tubes for occlusion. Contact service.
Fan failure	*High priority.* Malfunction of the fan at the rear of the RAPHAEL.	Disconnect the ventilator from the patient. Contact service.
	WARNING **A fan failure alarm could result in oxygen enrichment inside the ventilator and a subsequent fire hazard.**	

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Flow sensing deactivated	*Low priority.* Flow sensing (volume monitoring) is switched off. The RAPHAEL can only provide PCV+ ventilation, but without patient triggering, monitoring, or flow and volume alarms. If flow sensing is deactivated, make sure you provide a pressure input to the ventilator by connecting a pressure sensing line between the Y-piece and the blue Flow Sensor connector. If the ventilator does not sense this pressure input, it will activate a Disconnection alarm.	Reconfigure the ventilator for flow sensing, and connect the Flow Sensor with the blue tube toward the patient.
	WARNING **To prevent possible patient injury due to nonfunctional alarms and monitoring, make sure that flow sensing is enabled at all times. In order for RAPHAEL's monitoring and alarm functions to be fully operational, flow sensing and oxygen monitoring must be enabled when the ventilator is configured.**	
Flow Sensor missing	*High priority.* The RAPHAEL has detected that there is no Flow Sensor, but flow sensing is active. The RAPHAEL will switch over to PCV+ mode and continue ventilating the patient.	Make sure the Flow Sensor tubes are connected, with the blue tube toward the patient. Confirm the PCV+ mode settings. Install a Flow Sensor, if missing, and perform the Flow Sensor test.
Flow Sensor test failed	*User message.* The Flow Sensor test failed.	Rerun the test. If it fails again, install a new Flow Sensor.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Flow Sensor test in progress	*User message.* The test is in progress.	Wait.
Flow Sensor test OK	*User message.* The Flow Sensor test passed.	None.
High frequency	*Medium priority.* The measured fTotal is ≥ the set alarm limit.	Check the patient.
High minute volume	*High priority.* The measured minute volume is ≥ the set alarm limit.	Check the patient for hyperventilation.
High oxygen	*High priority.* The measured oxygen concentration is ≥ 5% above the set oxygen concentration. This alarm is disabled for 1 min after you adjust the oxygen control.	Check the patient. Check the air supply. Check the oxygen cell. Calibrate it.
High pressure	*High priority.* The measured inspiratory pressure is ≥ Pmax. The RAPHAEL relieves the pressure until it reaches the PEEP/CPAP level.	Check the patient. Check the breathing circuit and Flow Sensor tubes for kinks and occlusions.
High pressure during sigh	*Low priority.* The measured inspiratory pressure during sigh is ≥ Pmax. The sigh will only be partly delivered.	Check Pmax setting or disable sigh.
High tidal volume	*High priority.* The measured expiratory tidal volume is 1.5 x the set tidal volume (for (S)CMV+, SIMV+, and ASV).	Check the breathing circuit for leaks. This often occurs after the sudden removal of an occlusion (for example, a bronchoscopy).
IRV	*User message.* The set I:E ratio is above 1:1, leading to inverse ratio ventilation. Disabled in DuoPAP and APRV.	Check the I:E and Rate settings.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Last setup activated	*User message*. Ventilation will proceed with the last settings in use before the ventilator was switched off.	None.
Low Frequency	*Medium priority.* Measured fTotal ≤ the set limit.	Check the patient. Adjust the fTotal alarm limit. If the ventilator is in ASV, check the %MinVol and Body Wt settings. Consider suctioning, check for a kinked ET tube, or consider the possibility of acute asthma.
Low minute volume	*High priority.* The measured minute volume is equal to or below the set limit.	Check the patient for adequate ventilation. Increase the Rate, VT, or Psupport setting.
Low oxygen	*High priority.* The measured oxygen concentration is 5% below the set oxygen concentration. This alarm is disabled for 1 min after you adjust the oxygen control.	Check the patient. Check the oxygen supply. Check the oxygen cell. Calibrate it. Replace if it is exhausted. Provide alternative ventilation if necessary.
Main power loss	*High priority at first, then low priority after silenced.* The RAPHAEL is switching to battery power due to ac power loss. Typically, the battery backup lasts for 60 min.	Silence the alarm; in this case, the alarm silence key will silence this particular alarm indefinitely. This high-priority alarm will then become a low-priority alarm. Prepare for power loss. Obtain alternative ventilation. Check the ac power source.
No O2 cell in use	*Low priority.* There is no signal from the oxygen cell.	Install an oxygen cell or use an external monitor, according to ISO 7767.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
O2 calibration failed	*User message.* The oxygen cell was found to be exhausted during calibration.	Repeat the calibration. Replace the oxygen cell. If the cell is new, check the source and quality of the oxygen supply.
O2 calibration in progress	*User message.* Oxygen calibration in progress.	Wait.
O2 calibration OK	*User message.* The oxygen calibration was successful.	None.
O2 cell defective	*High priority.* One of these is true: Monitored Oxygen is between 3 and 18% or over 104%, and oxygen monitoring is enabled. The oxygen cell calibration failed and oxygen is available.	Recalibrate the oxygen cell. Install a new oxygen cell or remove the cell entirely. If you remove the cell, a low-priority **`No O2 cell in use`** alarm will be activated.
O2 monitoring deactivated	*Low priority.* Oxygen monitoring was disabled when the ventilator was configured.	Silence if desired to remove message

WARNING

- **To prevent possible patient injury due to nonfunctional alarms and monitoring, HAMILTON MEDICAL recommends that flow sensing and oxygen monitoring always be enabled.**
- **To ensure that oxygen monitoring is always fully functional, replace an exhausted or missing oxygen cell as soon as possible or use an external monitor that complies with ISO 7767.**

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Oxygen and air supply	*High priority.* Input pressures of compressed air and oxygen are below 200 kPa (29 psi), or supplies are not detected. The RAPHAEL lets the patient breathe room air via the ambient valve.	Provide alternative source of ventilation. Check air and oxygen supplies, or provide alternative compressed air and oxygen sources to the ventilator (VENTILAIR^{II} compressor and/or oxygen cylinder).
Oxygen supply	*High priority.* Input pressure of oxygen is below 200 kPa (29 psi), or the supply is not detected. The RAPHAEL will ventilate with 21% oxygen. (This alarm is deactivated if the RAPHAEL is set to ventilate with 21% oxygen.)	Check the patient. Check the oxygen supply. Provide an alternative source of oxygen or ventilation.
Power loss during ventilation	*High priority.* The ventilator was running on ac, ac power failed, the ventilator switched to battery, the ventilator ran until the battery was depleted, (technical failure), ac power again became available, so the ventilator restarted on ac. The bodyweight window is displayed and the ventilator waits for operator input before beginning ventilation. When the battery is depleted, a technical fault alarm is also activated. This technical fault alarm resets itself when ac power again becomes available.	Check the patient. Check the ventilator settings and restart ventilation.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Pressure limitation	*Medium priority before silencing; low priority after silencing.* Pinsp + PEEP/CPAP is 10 cmH_2O below Pmax. Volume delivery in (S)CMV+ and SIMV+ is limited. The set Pcontrol or Psupport cannot be reached.	Check the patient for adequate ventilation. Check ventilator setting and alarm limit.
Replace clock battery	*Medium priority.* The real-time clock battery is depleted, but the RAPHAEL can still be used.	Contact service.
Technical fault #x	*High priority.* A hardware malfunction was detected. The ventilator continue to ventilate the patient with the set parameters.	Contact service.
Technical fault #x	A hardware malfunction was detected. The ventilator is in the ambient state and the patient is breathing room air unassisted.	Contact service.
	WARNING **In some cases, you can turn power off and on to reset the ambient mode and continue ventilation. To prevent possible patient injury arising from an intermittent technical failure, HAMILTON MEDICAL recommends that you immediately remove any ventilator with a technical fault from use, record the number of the fault, and have the ventilator serviced.**	
Tighten system	*User message.* Instruction message during tightness test.	Block opening with clean gauze-covered finger.

Table 6-2. Alarm and other messages (continued)

Alarm	Definition	Action needed
Tightness test failed	*User message.* The RAPHAEL was unable to pressurize the breathing circuit to 25 cmH_2O during the tightness test.	Check the circuit connections. Replace leaking parts and repeat the tightness test.
Tightness test OK	*User message.* The tightness test passed.	None.
Time setting invalid	*Low priority.* Invalid time setting. Elapsed time is displayed for trending.	Set the correct time in the configuration mode.
Turn Flow Sensor	*High priority.* The Flow Sensor connections are reversed.	Rotate the Flow Sensor. The blue sensing line is proximal to the patient and must be attached to the blue connector. The clear sensing line is proximal to the ventilator and must be attached to the white connector.
	User message. Instruction message during Flow Sensor test.	Rotate the Flow Sensor.
Volume measurement inaccurate	*High priority.* VTE is much greater than the delivered volume.	Perform the Flow Sensor test. Contact service.

7 Special functions

7.1 100% O_2

The 100% O_2 function lets you deliver 100% oxygen for tracheal suctioning or for use during any short-term procedure.

1. Press the 100% O_2 key (Figure 7-1) for 1 s.

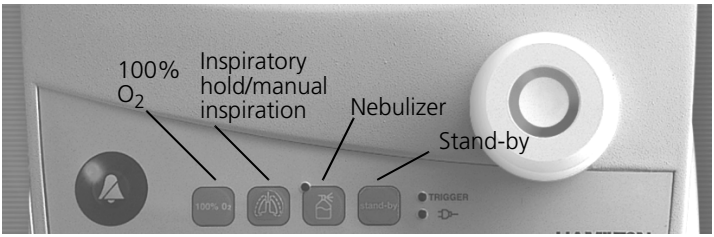


Figure 7-1. Special function keys

2. The RAPHAEL starts delivering 100% oxygen. After 20 to 30 s, oxygen concentration is stable at 100%. The RAPHAEL then delivers 100% oxygen for 4 min. Then it resets the concentration to the previous operator-set value. After 1 more min, oxygen concentration is stable at this setting.

   While this function is active, the message **`100% O2 activated`** is displayed.

NOTE:

To terminate delivery of 100% O_2 before it stops automatically, press the key again for 1 s. The RAPHAEL will resume ventilation at the set oxygen concentration.

7.2 Inspiratory hold/manual breath/disconnection suppression

This function (Figure 7-1) lets you perform an inspiratory hold maneuver, deliver a manual breath, or start breath delivery during a disconnection.

To deliver a manual breath only, press and release the inspiratory hold/manual breath key during exhalation. The RAPHAEL delivers a mandatory breath using the current active settings.

To perform an inspiratory hold, hold the key down during any breath phase. If the RAPHAEL is in exhalation, it delivers a mandatory breath, then performs a hold maneuver until the key is released, up to 15 s additional to the set inspiratory time. If the RAPHAEL is in inspiration, it performs a hold maneuver at the end of inspiration, lasting until the key is released, for up to 15 s additional.

To start breath delivery during a disconnection, press and release the inspiratory hold/manual breath key. This suppresses the disconnection condition for 3 min, until you press the key again to deactivate suppression, or for 1 min after a reconnection is detected. Suppressing a disconnection is particularly useful when you want to start NIV, but have not yet successfully adjusted the patient's mask. **`Disconnection suppressed`** is displayed during the suppression. Alarms that are suppressed during disconnection remain suppressed.

7.3 Nebulization

WARNING

The use of an expiratory filter in conjunction with aerosol-generating nebulizer treatments may lead to a significant increase in expiratory circuit resistance. Excessive expiratory circuit resistance may compromise ventilation and result in an increased patient work of breathing and/or AutoPEEP.

The nebulizer key (Figure 7-1) enables the RAPHAEL's pneumatic nebulization function for 30 min. While nebulization is active, the indicator on the key is lit. After 30 min, nebulization automatically stops. To terminate nebulization before 30 min elapse, press the key again.

The RAPHAEL's adaptive volume controller takes the added volume of the nebulized gas into account in determining tidal volume delivery. This additional volume of nebulized gas has no effect on oxygen concentration.

Use a nebulizer recommended by HAMILTON MEDICAL for effective nebulization.

7.4 Stand-by

WARNING

- **To prevent possible patient injury due to lack of ventilatory support, secure alternative ventilation for the patient before entering the stand-by mode. You must confirm that no patient is attached before entering the stand-by mode. Alarms are disabled during the stand-by mode.**
- **When in stand-by mode, the RAPHAEL consumes oxygen. Be aware of possible depletion of bottled oxygen.**

NOTE:

To keep the batteries fully charged, make sure the ventilator is connected to ac power while in stand-by mode.

The stand-by key puts the RAPHAEL into the stand-by mode. The stand-by mode is a waiting mode that lets you maintain ventilator settings while the RAPHAEL is not performing any ventilatory functions. This mode is useful when you want to prepare the ventilator and set the parameters before attaching it to a patient, or when you want to change the breathing circuit.

To start stand-by mode, first close the mode, control, or alarm window if open; disconnect the patient; then press the key for 2 s. Any other open windows automatically close, and you will see the stand-by screen (Figure 7-2). Upon activating the stand-by mode, if the RAPHAEL determines that the patient is not disconnected within 10 s, it restarts ventilation with the previous settings.

Figure 7-2. Stand-by mode window

During stand-by mode, you can access the right-hand windows by pressing the keys, and you can adjust the mode, control, and alarm settings. You can perform tests during stand-by by opening the utilities window.

To resume ventilation, press the key again or reconnect the patient. The basic screen appears. Ventilation restarts.

8 Maintenance

8.1 Introduction

Follow these maintenance procedures to ensure the safety and reliability of the RAPHAEL. All the procedures in this manual are intended to be performed by the operator. For further maintenance procedures, refer to the service manual.

8.2 Cleaning, disinfection, and sterilization

WARNING

- **To minimize the risk of bacterial contamination or physical damage, handle bacteria filters with care.**
- **To prevent patient exposure to sterilizing agents and to prevent premature deterioriation of parts, sterilize parts using the techniques recommended in this section only.**

CAUTION

- **Do not reuse single-patient use bacteria filters, Flow Sensors, and other accessories. They must be discarded after single use.**
- **Do not attempt to sterilize the interior of the ventilator. Do not attempt to sterilize the whole ventilator with ETO gas.**
- **Exposure to sterilizing agents may reduce the useful life of certain parts. Using more than one sterilization technique on a single part may damage a part.**

NOTE:

Because sanitation practices vary among institutions, HAMILTON MEDICAL cannot specify specific practices that will meet all needs or be responsible for the effectiveness of these practices. This manual only gives general guidelines for cleaning, disinfecting, and sterilizing. It is the user's responsibility to ensure the validity and effectiveness of the actual methods used.

The following subsections provide general guidelines for cleaning and decontaminating parts. Table 8-1 tells you the specific methods that are applicable to each RAPHAEL part. For parts not supplied by HAMILTON MEDICAL, refer to the manufacturer's guidelines. Do not attempt cleaning procedures unless specified by HAMILTON MEDICAL or the original manufacturer.

After cleaning and decontaminating parts, perform any required tests and calibrations described in Section 3.

Table 8-1. Decontamination methods for RAPHAEL parts

Part (material)	How to decontaminate	Remarks
Ventilator exterior, including housing, basket, gas supply hoses, and power cord	Wipe with an appropriate bactericidal agent after each patient use	Do not use alcohol as a disinfectant. It does not harm the ventilator but it has not been proven to be an effective bactericidal or bacteriostatic. Do not use acetone-based cleaning solutions or aromatic solvents. Do not clean the ventilator interior. This can damage internal parts.
Breathing tubes (silicone rubber)	Steam autoclave, pasteurize, chemically disinfect, or ETO sterilize	Roll tubes into large coils. Do not twist, kink, or cross tubes when sterilizing them. The tubing lumen should not have vapor or moisture before wrapping for autoclaving. Avoid exposing silicone rubber breathing tubes to grease, oil, silicone-based lubricants, organic solvents (benzene, ether, ketone, and chlorinated hydrocarbons), and acids and concentrated alkaline cleaning products, phenols, and derivatives.
Flow Sensor, single-patient use	Chemically disinfect (only if this single-patient use Sensor requires decontamination before use)	The Flow Sensor is designed for single use. It is delivered clean and ready for patient use. If the Sensor must be decontaminated, do not use hard brushes, pointed instruments, or rough materials. These can damage the Flow Sensor's membrane.

Table 8-1. Decontamination methods for RAPHAEL parts (continued)

Part (material)	How to decontaminate	Remarks
Flow Sensor, reusable (Mylar® membrane)	Pasteurize, chemically disinfect, ETO sterilize, or plasma sterilize	Do not use hard brushes, pointed instruments, or rough materials. These can damage the Flow Sensor's membrane. Do not apply temperatures greater than 62 °C (145 °F). Do not peroxide sterilize. The Flow Sensor is a limited-life device. The internal Mylar membrane fatigues with extended use. After cleaning, visually inspect the sensor body, tubings, and internal membrane. Discard sensor if there are signs of damage. Discard sensor if calibration fails two times.
Expiratory valve membrane (silicone rubber)	Steam autoclave, pasteurize, chemically disinfect, ETO sterilize, or peroxide sterilize	Inspect for damage; replace if necessary. Replace after 30 autoclave cycles.

Table 8-1. Decontamination methods for RAPHAEL parts (continued)

Part (material)	How to decontaminate	Remarks
Expiratory valve cover (polysulfone)	Steam autoclave, pasteurize, chemically disinfect, ETO sterilize, or peroxide sterilize	Solutions such as Medizyme, Pyroneg, Control 3, Solution 2, and Cidex have been tested according to the manufacturer's directions. Other brand names with similar active ingredients may also be suitable. Avoid these solutions; they may cause the cover to cloud or crack: ketones, hypochlorite, phenol (>5%), formaldehyde, inorganic acids, chlorinated hydrocarbons, and aromatic hydrocarbons. Do not autoclave if medications containing chlorinated or aromatic hydrocarbons are used.
Other accessories	Follow the manufacturers' guidelines	

8.2.1 General guidelines for cleaning

CAUTION

- **To prevent damage to breathing circuit parts, do not clean with hard brushes, pointed instruments, or rough materials.**
- **To prevent damage to breathing circuit parts, follow the soap manufacturer's instructions. Exposure to soap solution that is stronger than recommended can shorten the useful life of some products. Soap residue can cause blemishes or fine cracks, especially on parts exposed to elevated temperatures during sterilization.**

Cleaning is an integral part of the decontamination process, described in Section 8.2.2 through Section 8.2.4. Clean the RAPHAEL parts as follows:

1. Disassemble parts. Breathing circuits must be disassembled completely.
2. Wash parts in warm water and soap or mild detergent solution.
3. Rinse parts thoroughly with clean, warm water.
4. Air dry.
5. Inspect all parts, and replace if damaged.
6. If you will sterilize or disinfect the part, continue with the appropriate sterilization/disinfection/procedure (Section 8.2.2 through Section 8.2.4). Otherwise, reassemble and reinstall parts, and perform any required tests.

8.2.2 General guidelines for chemical disinfection

CAUTION

Table 8-1 lists materials of construction for the RAPHAEL parts. To prevent premature deterioration of parts, make sure the disinfecting chemical is compatible with the part material.

Disinfect the RAPHAEL parts as follows:

1. Clean (Section 8.2.1).
2. Disinfect with a mild bactericidal chemical solution. Acceptable chemicals include: Schülke & Mayr Lysetol® AF and Gigasept® FF, and Henkel-Ecolab Incidur® and Sekusept® PLUS. Solutions such as these have been tested according to the manufacturer's directions. Other brand names with similar active ingredients may also be suitable.
3. Reassemble and reinstall parts, and perform any required tests.

8.2.3 General guidelines for autoclave, ETO, or plasma sterilization

Autoclave, ETO, or plasma sterilize the RAPHAEL parts as follows:

1. Clean (Section 8.2.1).
2. Reassemble.
3. Autoclave or plasma sterilize.
4. Perform any required tests.

8.2.4 General guidelines for pasteurization or peroxide sterilization

Pasteurize the RAPHAEL parts as follows:

1. Clean (Section 8.2.1).
2. Disinfect.
3. Reassemble.
4. Perform any required tests.

8.3 Preventive maintenance

Perform preventive maintenance on your RAPHAEL according to the schedule in Table 8-2. You can view the hours of ventilator operation on the System check screen or in utilities window 2.

The following subsections provide details for some of these preventive maintenance procedures.

NOTE:

- HAMILTON MEDICAL requires that you document all maintenance procedures.
- Dispose of all parts removed from the device according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, oxygen cell, batteries).

Table 8-2. Preventive maintenance schedule

Interval	Part/accessory	Procedure
Between patients and according to your hospital's protocol	Breathing circuit (including mask, inspiratory filter, Flow Sensor, nebulizer jar, expiratory valve housing and membrane)	Replace with sterilized or new single-patient use parts. Run the tightness test and Flow Sensor test, as required (Section 3.2)
	Entire ventilator	Run the preoperational check (Section 3.3).
Every day or as required	Breathing circuit	Empty any water from hoses or water traps. Inspect parts for damage. Replace as necessary.
	Gas inlet water trap	Empty any water.
Every month (or more often, if required)	Fan filter (rear panel)	Check for dust and lint. If needed, clean or replace (Section 8.3.1).
	WARNING **To reduce the risk of patient cross-contamination through the fan filter, always perform maintenance at the prescribed interval.**	
Every 3 months (1250 hours)	Gas supply filter assemblies	Inspect filter. Replace if dirty or discolored. Clean filter housing if desired (Section 8.3.2).

Table 8-2. Preventive maintenance schedule (continued)

Interval	Part/accessory	Procedure
Yearly or every 5000 hours, whichever comes first, or as necessary	Oxygen cell	Replace if exhausted (Section 8.3.3).
	NOTE: Oxygen cell life specifications are approximate. The actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.	
	Ventilator	Perform preventive maintenance. Must be done by a qualified service technician according to instructions in the service manual.
Every 3 years or as necessary	Backup batteries	Replace. Must be done by a qualified service technician according to instructions in the service manual.
	NOTE: Battery life specifications are approximate. The actual battery life depends on ventilator settings, battery age, level of battery charge, and number of battery charge cycles. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.	
	Clock battery	Replace. Must be done by a qualified service technician according to instructions in the service manual.

8.3.1 Cleaning or replacing the fan filter

Remove the filter cover by pulling the frame (Figure 8-1). Either install a new filter; or wash the existing filter in a mild soap solution, rinse, and dry.

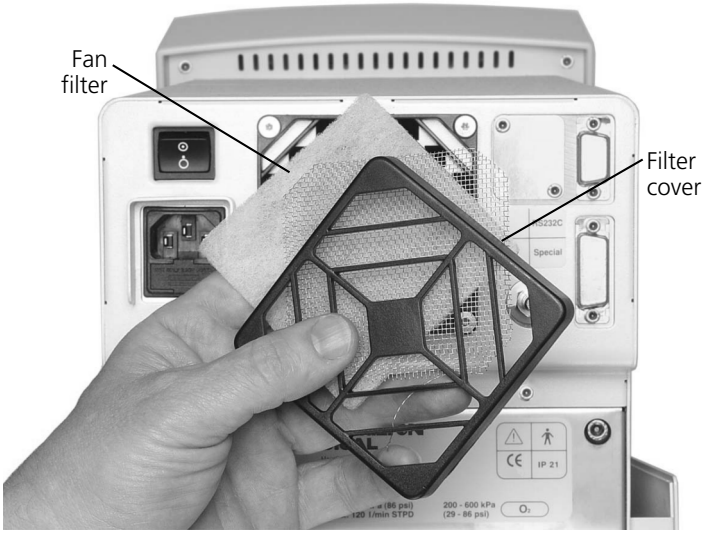


Figure 8-1. Removing the fan filter

8.3.2 Replacing gas supply filters

Disconnect the gas hoses. Unscrew the filter housing, then the filter (Figure 8-2). Install a new filter; never attempt to clean the filter. Clean the housing if desired (Section 8.2.1) and replace it.

NOTE:

A self-emptying water trap kit is available for the RAPHAEL. See Table F-2 for ordering information.

Figure 8-2. Replacing a gas supply filter

8.3.3 Replacing the oxygen cell

Unscrew the oxygen cell carrier, then disconnect the cell connector (Figure 8-3). Unscrew the cell from the carrier. Install the new cell, and reconnect the cell cable. Replace the cell carrier. Run the oxygen cell calibration.

WARNING

To reduce the risk of explosion, do not burn the oxygen cell or force the cell open.

NOTE:

Observe the orientation of the connector when installing the oxygen cell.

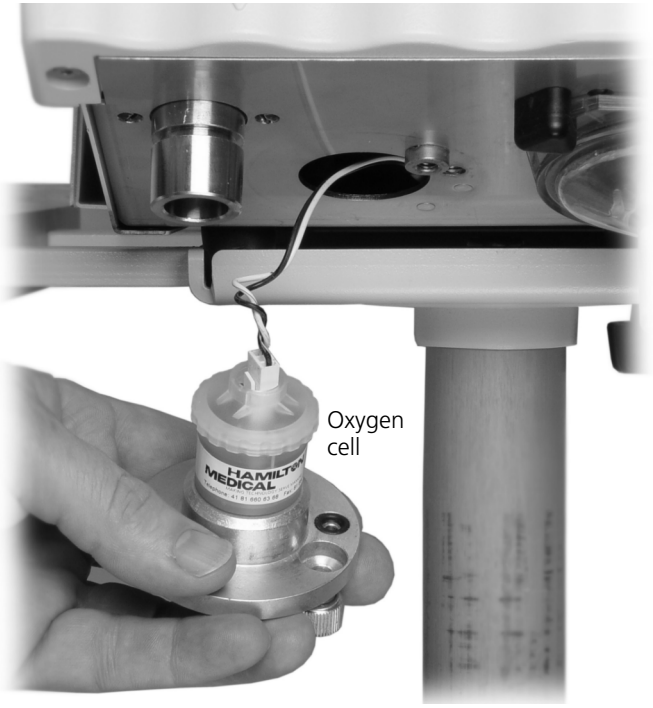


Figure 8-3. Replacing the oxygen cell

8.3.4 Replacing a fuse

WARNING

- **To reduce the risk of electrical shock, disconnect electrical power from the ventilator before removing a fuse.**
- **For continued protection against a fire hazard, replace fuses only with those of the same type and rating.**

Disconnect the power cord from the RAPHAEL. Remove the fuse holder by pressing down on the tab and pulling the holder out (Figure 8-4). Replace the fuse, and push the holder back in.

Figure 8-4. Replacing a fuse

8.4 Storage

To maintain the battery charge and to prolong the life of the batteries, keep the ventilator connected to ac power if possible. If this is not possible and you intend to store the ventilator for an indefinite period of time, disconnect the battery or recharge it every 3 to 6 months, depending on storage conditions (see specifications in Appendix A).

NOTE:

The batteries must be disconnected by a qualified service technician according to instructions in the service manual.

8.5 Repacking and shipping

If you must ship the ventilator, use the original packing materials. If these materials are not available, contact your HAMILTON MEDICAL representative for replacement materials.

APPENDIX

A Specifications

A.1 Physical characteristics

Table A-1. Physical characteristics

Weight	Ventilator only	RAPHAEL Color, RAPHAEL Silver, RAPHAEL	17 kg (37 lb)
		RAPHAEL XTC	18 kg (40 lb)
	Ventilator on trolley	RAPHAEL Color, RAPHAEL Silver, RAPHAEL	46 kg (101 lb)
		RAPHAEL XTC	47 kg (104 lb)
	Ventilator on trolley with VENTILAIR^{II}	RAPHAEL Color, RAPHAEL Silver, RAPHAEL	77 kg (170 lb)
		RAPHAEL XTC	78 kg (172 lb)
Dimensions (W x D x H)	Ventilator only	RAPHAEL Color, RAPHAEL Silver, RAPHAEL	23 x 53 x 35 cm (9.1 x 20.9 x 13.8 in.)
		RAPHAEL XTC	33 x 53 x 42 cm (13.0 x 20.9 x 16.5 in.)
	Ventilator on trolley with VENTILAIR^{II}	RAPHAEL Color, RAPHAEL Silver, RAPHAEL	46 x 66 x 140 cm (18.1 x 28.0 x 55.1 in.)
		RAPHAEL XTC	46 x 66 x 147 cm (18.1 x 28.0 x 57.9 in.)

A.2 Environmental requirements

Table A-2. Environmental requirements

Temperature	Operating: 10 to 40 °C, 5 to 85% relative humidity, noncondensing, out of direct sunlight Storage: Down to -20 °C for < 48 hours, up to 60 °C for < 168 hours, 5 to 85% relative humidity, non-condensing
Atmospheric pressure	600 to 1100 hPa

A.3 Pneumatic specifications

Table A-3. Pneumatic specifications

Oxygen and air inlet supplies	Pressure: 200 to 600 kPa (29 to 86 psi) Flow: Maximum of 120 l/min STPD
Oxygen cell life	1 year or 5000 hours nominal. Actual cell life depends on operating environment. Operation at higher temperatures or higher oxygen concentrations shortens cell life.
Gas mixing system	Delivered flow: 120 l/min typical, 180 l/min maximum, 30 l/min continuous Operating pressure range: 200 to 600 kPa (29 to 86 psi)
Connectors	Inspiratory limb connector: ISO 22 mm male/15 mm female conical Expiratory limb connector (on expiratory valve): ISO 22 mm male/15 mm female conical Air and oxygen inlets: DISS male/optional NIST

A.4 Electrical specifications

Table A-4. Electrical specifications

Input power	100 to 125 V ac, 50/60 Hz, 0.7 A 200 to 240 V ac, 50/60 Hz, 0.35 A Power consumption: 40 VA typical
Mains fuses (2)	250 V, 1.0 A, type T (slow-breaking), type H (high-current breaking)
Leakage current	Earth leakage current: 100 µA maximum Enclosure/patient leakage current: 100 µA maximum
Batteries	12 V dc x 2, 2.2 Ah Type: Lead-acid Operating time (for new, fully charged batteries): 1 hour typical, 30 min minimum, 2 hours maximum. Actual operating time depends on ventilator settings, battery age, and level of battery charge. Recharge time: 6 hours maximum while ventilator is connected to ac power Storage: Charge batteries once every 6 months if ambient temperature ≤ 25 °C (77 °F). Reduce charging interval to half for every 10 °C (18 °F) increase in ambient temperature. **NOTE:** Battery life specifications are approximate. The actual battery life depends on ventilator settings, battery age, level of battery charge, and number of battery charge cycles. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.
Alarm	Volume: 50 to 85 dB(A) at 1 m Silence duration: 2 min

A.5 Control settings and mode additions

Table A-5 lists the RAPHAEL's control settings and mode additions, their ranges, default settings, and accuracies. Table A-6 lists the control settings that apply to the various ventilation modes. Table A-7 lists the factory settings for these same controls; these settings apply if the ventilator is not configured (see Appendix E).

Table A-5. Control setting and mode addition ranges, accuracies, and resolutions

Setting	Range	Default setting	Accuracy	Resolution
%MinVol	25 to 350%	100%	Not applicable	5
Alarm loudness	1 to 10	7	Not applicable	1
Apnea backup	Off or on	Set during configuration	Not applicable	Not applicable
Apnea time	15 to 60 s	Set during configuration	±1	5
Baseflow	0 to 10 (when extended baseflow configured on) 0 to 2 (when extended baseflow configured off) (The applied baseflow depends on patient tubing system. A setting of 2 provides a maximum baseflow of 4 l/min.)	2	Not applicable	1
Bodyweight	5 to 200 kg	Set during configuration	Not applicable	1

Table A-5. Control setting and mode addition ranges, accuracies, and resolutions (continued)

Setting	Range	Default setting	Accuracy	Resolution
ETS (expiratory trigger sensitivity)	5 to 70% (of inspiratory peak flow)	25%	Based on monitored flow specifications (see Section A.7)	5
I:E	1:9.0 to 4.0:1 (inspiratory time 0.1 to 12 s)	Set during configuration	TI of ±0.1 s	0.1 (< 1:4) 1 (≥ 1:4)
Modes	(S)CMV+, PCV+, SIMV+, PSIMV+, SPONT, NIV (all models)	Set during configuration	Not applicable	Not applicable
	 ASV, DuoPAP, APRV			
Oxygen	21 to 100%	Set during configuration	±3% of full scale	1
Pasvlimit	5 to 70 cmH_2O	30 cmH_2O	±1.5	1
Pcontrol (pressure control)	5 to 50 cmH_2O above PEEP/CPAP	Set during configuration	±1.5	1
PEEP/CPAP	0 to 35 cmH_2O	Set during configuration	±1	1
P high (high airway pressure level)	0 to 75 cmH_2O	Set during configuration (PEEP/CPAP + Pcontrol)	±1.5	1
P low (low airway pressure level)	0 to 35 cmH_2O	PEEP/CPAP configuration setting	±1	1
Pramp	50 to 200 ms	50 ms	±10	25

Table A-5. Control setting and mode addition ranges, accuracies, and resolutions (continued)

Setting	Range	Default setting	Accuracy	Resolution
Psupport (pressure support)	0 to 50 cmH_2O above PEEP/CPAP or P low	Pcontrol configuration setting	±1.5	1
Rate	8 to 80 b/min ((S)CMV+) 4 to 80 b/min (PCV+) 1 to 80 b/min (all other modes)	5 kg: 35 b/min 6 to 8 kg: 25 b/min 9 to 20 kg: 20 b/min 21 to 29 kg: 15 b/min 30 to 39 kg: 14 b/min 40 to 59 kg: 12 b/min 60 to 200 kg: 10 b/min	±1	1
Sigh	Off or on	Set during configuration	Not applicable	Not applicable
T high (duration of high airway pressure level)	0.1 to 30.0 s	Determined from configuration setting of I:E and calculated Rate	±0.1	0.1 (≤ 5.0) 1 (> 5.0)
TI (inspiratory time)	0.1 to 9.0 s	Determined from configuration setting of I:E. If the calculated Rate < 15 b/min, the default TI is based on a Rate of 15 b/min.	±0.1	0.1
TI max	1.0 to 3.0 s	1.5 s	±0.1	0.1
T low (duration of low airway pressure level)	0.2 to 30.0 s	Determined from configuration setting of I:E and calculated Rate	±0.1	0.1 (≤ 5.0) 1 (> 5.0)
Trigger	Off ((S)CMV+ and PCV+ modes only) 1 to 10 l/min (other modes)	Set during configuration	Not applicable ±1	Not applicable 1

Table A-5. Control setting and mode addition ranges, accuracies, and resolutions (continued)

Setting	Range	Default setting	Accuracy	Resolution
Tube resistance compensation (TRC)	ET tube, Trach tube, or TRC off Tube size: 4.0 to 10.0 mm Compensate: 0 to 100%	TRC off Tube size: 7.0 mm Compensate: 50%	Not applicable Not applicable Not applicable	Not applicable 0.5 10
VT (tidal volume)	50 to 2000 ml	Set during configuration	±10% or 10 ml, whichever is greater	10 (≤ 1000) 50 (> 1000)

Table A-6. Controls active in RAPHAEL ventilation modes

<table>
<tr><th></th><th colspan="2">Mandatory modes</th><th colspan="2">SIMV modes</th><th colspan="2">DuoPAP/APRV</th><th colspan="2">Pressure support</th><th>Special</th></tr>
<tr><td>Mode</td><td>(S)CMV+</td><td>PCV+</td><td>SIMV+</td><td>PSIMV+</td><td>DuoPAP</td><td>APRV</td><td>SPONT</td><td>NIV</td><td>ASV</td></tr>
<tr><td rowspan="2">Timing</td><td colspan="6">Rate</td><td>T low</td><td colspan="2" rowspan="2">--</td></tr>
<tr><td colspan="2">I:E</td><td colspan="2">TI</td><td colspan="2">T high</td></tr>
<tr><td>Mandatory breath control</td><td>VT</td><td>Pcontrol</td><td>VT</td><td>Pcontrol</td><td colspan="3">P high</td><td colspan="2">--</td></tr>
<tr><td rowspan="3">Sponta-neous breaths</td><td colspan="2" rowspan="3">--</td><td colspan="6">Psupport</td><td>--</td></tr>
<tr><td colspan="7">ETS</td></tr>
<tr><td colspan="5">--</td><td>TI max</td><td>--</td></tr>
<tr><td>Baseline pressure</td><td colspan="6">PEEP/CPAP</td><td>P low</td><td colspan="2">PEEP/CPAP</td></tr>
<tr><td rowspan="6">General</td><td colspan="9">Bodyweight</td></tr>
<tr><td colspan="9">Trigger</td></tr>
<tr><td colspan="9">Pramp</td></tr>
<tr><td colspan="9">Baseflow</td></tr>
<tr><td colspan="9">Oxygen</td></tr>
<tr><td colspan="7">TRC</td><td>--</td><td>TRC</td></tr>
<tr><td>ASV-specific</td><td colspan="8" rowspan="2">--</td><td>%MinVol</td></tr>
<tr><td>Pasvlimit</td></tr>
</table>

A.6 Factory settings

At the factory the RAPHAEL is configured to the settings in Table A-7. You can reset the RAPHAEL to these settings in the configuration mode (see Appendix E).

Table A-7. Factory settings

Parameter	Default setting
%MinVol	100%
Alarm loudness	7
Altitude	700 m (2297 ft)
Apnea backup	On
Apnea time	20 s
Baseflow	2
Bodyweight	70 kg
ETS	25%
ExpMinVol alarm	Low: 4 l/min High: 14 l/min
Extended Baseflow Range	Disabled
fTotal alarm	Low: 6 b/min High: 14 b/min
Flow sensing	On
Graphic	Pressure/time curve
I:E	1:2.0

Table A-7. Factory settings (continued)

Parameter	Default setting
Language	English **NOTE:** The language is not reset when you configure the ventilator to Factory settings.
Main monitoring parameters and their positions	Ventilation mode: Top left of screen VTE: Bottom left of screen ExpMinVol: Top right of screen fTotal: Bottom right of screen
Mode	(S)CMV+
O_2 monitoring	On
Oxygen	50%
Pasvlimit	30 cmH_2O
Pcontrol (pressure control)	15 cmH_2O (above PEEP/CPAP)
PEEP/CPAP	2 cmH_2O
P high	17 cmH_2O
P low	2 cmH_2O
Pmax alarm	40 cmH_2O
Pramp	50 ms
Psupport (pressure support)	15 cmH_2O (above PEEP/CPAP)
Rate	5 kg: 35 b/min 6 to 8 kg: 25 b/min 9 to 20 kg: 20 b/min 21 to 29 kg: 15 b/min 30 to 39 kg: 14 b/min 40 to 59 kg: 12 b/min 60 to 200 kg: 10 b/min
Sigh	Off

Table A-7. Factory settings (continued)

Parameter	Default setting
T high	2.0 s
TI (inspiratory time)	2.0 s
TI max	1.5 s
T low	4.0 s
Trigger	6 l/min
Tube resistance compensation	Tube size: 7.0 mm Compensate: 50% TRC off
VT (tidal volume)/kg	10 ml/kg

A.7 Monitored parameters

Table A-8 lists monitored parameters and their ranges and resolutions. Pressure, flow, and volume measurements are based on readings from the Flow Sensor. Directly measured (non-calculated) parameters have the following accuracies, provided the Flow Sensor and oxygen cell are calibrated:

- Flow-related parameters: ± 25 ml/s or 10%, whichever is greater
- Volume-related parameters (expressed under ATPD (ambient temperature, pressure, dry) conditions but measured close to the patient's airway so reflecting close-to-BTPS conditions): ±20% or 20 ml (single use Flow Sensor), ±15% or 15 ml (reusable Flow Sensor), whichever is greater
- Pressure-related parameters: ±5% or 1 cmH_2O, whichever is greater
- Oxygen: ±3%, independent of patient pressure

Table A-8. Monitored parameter ranges and resolutions

Parameter	Range	Resolution
AutoPEEP (unintended positive end-expiratory pressure)	0 to 100 cmH_2O	0.5
Cstat (static compliance)	0 to 999 ml/cmH_2O	1
Exp Flow (peak expiratory flow)	0 to 180 l/min	0.1
ExpMinVol (expiratory minute volume)	0 to 50 l/min	0.1
fSpont (spontaneous breath frequency)	0 to 99 b/min	1
fTotal (total respiratory rate)	0 to 99 b/min	1
I:E (inspiratory:expiratory ratio)	1:99 to 9.9:1	1 (1:10 to 1:99) 0.1 (9.9:1 to 1:9.9)
Insp Flow (peak inspiratory flow)	0 to 180 l/min	0.1
Leak	0 to 100%	1
MV Spont (spontaneous expiratory minute volume)	0 to 50 l/min	0.1
Oxygen	18 to 105%	1
PEEP/CPAP	-10 to 100 cmH_2O	1
Pinsp (inspiratory pressure)	-10 to 100 cmH_2O	0.1
Pmean (mean airway pressure)	-10 to 100 cmH_2O	0.1
Ppeak (peak pressure)	-10 to 100 cmH_2O	1
RCexp (expiratory time constant)	0 to 10 s	0.1
Rinsp (inspiratory flow resistance)	0 to 999 cmH_2O/l/s	1
TE (expiratory time)	0 to 60 s	0.1
TI (inspiratory time)	0 to 30 s	0.1
VTE (expiratory tidal volume)	-9000 to 9000 ml	1

A.8 Alarms

Table A-9 lists the ventilator alarm settings, their ranges and resolutions, plus the automatic and standard alarm settings. Table A-10 lists the ventilator's nonadjustable alarms and their triggering conditions.

Table A-9. Adjustable alarm setting ranges

Alarm	Range	Automatic setting	Default setting	Resolution
Apnea[1]	15 to 60 s	Not applicable	Set during configuration	1
ExpMinVol, low	0.1 to 50 l/min	Measured ExpMinVol x 0.6 if measurement available; otherwise, (S)CMV+ rate x VT x 0.6	Based on Rate and VT	0.1
ExpMinVol, high	0.1 to 50 l/min	Measured ExpMinVol x 2.0 if measurement available; otherwise, (S)CMV+ rate x VT x 2.0	Based on Rate and VT	0.1
Pmax	15 to 80 cmH_2O	Measured Pmax of last breath + 15 cmH_2O, minimum of 40 cmH_2O if measurement available; otherwise, 40 cmH_2O or as set in configuration mode	Set during configuration	1
fTotal, low	0 to 99 b/min	Measured fTotal x 0.6 if measurement available; otherwise, (S)CMV+ Rate x 0.6 (minimum as set in configuration mode)	Set during configuration	1
fTotal, high	0 to 99 b/min	Measured fTotal x 1.4 if measurement available; otherwise, (S)CMV+ Rate x 1.4 (minimum as set in configuration mode)	Set during configuration	1

1. Located in the mode window

Table A-10. Nonadjustable alarm triggering conditions

Alarm	Triggering conditions
Air/oxygen supply	Input pressure of either air or oxygen < 200 kPa (29 psi)
Apnea backup	Ventilator in apnea backup due to no breath trigger for the set apnea time (in SPONT, SIMV+, PSIMV+, DuoPAP, APRV, and NIV modes)
Battery low	Minimum of 10 min power remaining
Disconnection	For two consecutive breaths, any of these is true: • VTexp < 1/8 delivered volume for VT setting > 50 ml (all modes except NIV) • Pmax < (PEEP + Pcontrol) - 5 cmH_2O • Pmax < (PEEP + Psupport) - 5 cmH_2O • Ptank < 250 cmH_2O for more than 2.5 s (all modes except NIV) The alarm is reset when both of these are true for two consecutive breaths: • Airway pressure ≥ 3 cmH_2O or expiratory flow ≥ 45 ml/s • Ptank ≥ 250 cmH_2O for at least 500 ms
Exhalation obstructed	Monitored PEEP/CPAP > (set PEEP/CPAP + 5 cmH_2O) for 2 consecutive breaths
Check Flow Sensor	Sensing lines disconnected or occluded
High oxygen	Monitored oxygen ≥ (Oxygen setting + 5% of setting)
High tidal volume	Delivered inspiratory tidal volume =1.5 x set VT
Inverse ratio	Monitored or set I:E ≥ 1:1
Low oxygen	Monitored oxygen ≤ (Oxygen setting - 5% of setting), minimum 18%
Oxygen cell defective	Monitored oxygen ≤ 18%

Table A-10. Nonadjustable alarm triggering conditions (continued)

Alarm	Triggering conditions
Oxygen and air supplies	Input pressures of both supplies < 200 kPa (29 psi)
Pressure limitation	Pinsp + PEEP/CPAP ≥ (Pmax - 10 cmH_2O)
Volume measurement inaccurate	VTE > 2 x delivered volume (for delivered volumes > 20 ml) or (VTE - delivered volume) > 20 ml (for delivered volumes ≤ 20 ml)
Others	ASV:Pressure limitation, ASV: Unable to meet Target, Fan failure, Flow Sensor missing, main power loss (switching to battery), oxygen cell missing, Replace clock battery

A.9 Breathing circuit specifications

Table A-11 lists specifications for HAMILTON MEDICAL breathing circuits.

NOTE:

When altering the HAMILTON MEDICAL breathing circuit specifications given (for example, when adding accessories or components), make sure not to exceed these inspiratory and expiratory resistance values of the ventilator breathing system, as required by ISO 10651-1: adult, 6 cmH_2O at 60 l/min or pediatric, 6 cmH_2O at 30 l/min.

Table A-11. Breathing circuit specifications

Parameter	Specification
Resistance[1]	Adult circuit (19 mm ID with 22F connectors, flow of 60 l/min): Inspiratory limb: < 5.8 cmH_2O/l/s Expiratory limb: < 5.8 cmH_2O/l/s Pediatric circuit (15 mm ID with 22F connectors, flow of 30 l/min): Inspiratory limb: < 2.7 cmH_2O/l/s Expiratory limb: < 5.5 cmH_2O/l/s
Compliance[1]	Adult circuit (19 mm ID with 22F connectors): 2 ml/cmH_2O Pediatric circuit (15 mm ID with 22F connectors): 1.9 ml/cmH_2O
Volume[1]	Adult circuit (19 mm ID with 22F connectors): 2.4 l Pediatric circuit (15 mm ID with 22F connectors): 1.8 l Flow Sensor: 9 ml (single-patient use) or 11 ml (reusable)
Bacteria filter	Particle size: Captures particles of 0.3 µm (micron) with > 99.99% efficiency Resistance: < 2 cmH_2O at 60 l/min

1. Based on the patient circuit configuration shown in Figure 2-5, including one water trap but without a humidifier. Additional accessories will increase these values and may result in decreased patient comfort.

A.10 Other technical data

Table A-12 lists other ventilator technical data.

Table A-12. Other technical data

Setting	Value
Expiratory trigger sensitivity	ETS setting
Flow pattern	Decelerating
Maximum inspiratory time (SPONT breaths)	3.2 s (modes other than NIV) 1.0 to 3.0 s (NIV mode)
Expiratory/P low time	Minimum of 0.2 s (DuoPAP/APRV mode), maximum of 60/Rate - 0.1 s (DuoPAP mode) or 30s (APRV mode) 20% of cycle time, minimum of 200 ms, maximum of 800 ms (except in DuoPAP/APRV)
Tests and special functions	Tightness test, oxygen cell calibration, Flow Sensor test, 100% oxygen flush, manual breath/inspiratory hold maneuver, nebulization, stand-by
Limited pressure	0 to 100 cmH_2O, ensured by overpressure and ambient valves
Minimum working pressure	Depends on PEEP/CPAP. Ensured by Disconnection alarm.
Maximum working pressure	75 cmH_2O, ensured by high pressure limit (Pmax)
Trigger	1 to 10 l/min, measured at Flow Sensor

Table A-12. Other technical data (continued)

Setting	Value
Measuring and display devices	Pressure and volume measurements: Type: Differential pressure transducer, variable orifice Sensing position: Patient Y-piece Measurements: See Table A-8
	Oxygen measurement: Type: Galvanic cell Sensing position: Inspiratory pneumatics Measurement: Delivered oxygen concentration, range: 18 to 105% Response time: 20 s, as per ISO 7767
	Display of settings, alarms, and monitored data: Type: LCD (liquid crystal display) Size (RAPHAEL Color, RAPHAEL Silver, and RAPHAEL): 320 x 240 pixel / 120 x 89 mm / 4.7 x 3.5 in. (W x H) 144 mm / 5.7 in. (diagonal) Size (RAPHAEL XTC): 640 x 480 pixel / 211 x 158 mm / 8.3 x 6.2 in. (W x H) 264 mm / 10.4 in. (diagonal) Other displays: Type: LED (4) Functions: Alarm silence, nebulizer, trigger, ac power
Minute volume capability	Up to 30 l/min

A.11 Standards and approvals

The RAPHAEL ventilator was developed in accordance with pertinent FDA guidances and North American and international standards. It has been certified to applicable CSA standards and bears the CSA mark.

The ventilator is manufactured within an EN ISO 9001/ EN 46001/ certified quality assurance system.

The ventilator's IEC 60601-1/EN 60601-1 classification is protection class I, type B, pollution degree 2, installation category II, internally powered, drip-proof equipment, continuous operation.

A.12 EMC declarations (IEC/EN 60601-1-2)

The RAPHAEL ventilator is intended for use in the electromagnetic environment specified in Table A-13, Table A-14, and Table A-15. The customer or the user of the RAPHAEL ventilator should ensure that it is used in such an environment.

The RAPHAEL is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RAPHAEL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RAPHAEL as recommended in Table A-15, according to the maximum output power of the communications equipment.

Table A-13. Guidance and manufacturer's declaration – electromagnetic emissions

Emissions test	Compli-ance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The RAPHAEL ventilator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RAPHAEL ventilator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table A-14. Guidance and manufacturer's declaration – electromagnetic immunity[1]

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-1-1	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. Due to its internal battery the RAPHAEL ventilator is immune against mains power interruptions up to 30 min.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table A-14. Guidance and manufacturer's declaration – electromagnetic immunity[1] (continued)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the RAPHAEL ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61 000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[2] 10 Vrms 150 kHz to 80 MHz in ISM bands[4]	10 Vrms 10 Vrms	$d = 0.35\sqrt{P}$ $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[3]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[4], should be less than the compliance level in each frequency range[5]. Interference may occur in the vicinity of equipment marked with the symbol 

1. U_T is the ac mains voltage prior to application of the test level.

2. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
3. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.3 GHz are intended to decrease the likelihood that mobile/ portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
4. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RAPHAEL ventilator is used exceeds the applicable RF compliance level above, the RAPHAEL ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RAPHAEL ventilator.
5. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table A-15. Recommended separation distances between portable and mobile RF communications equipment and the RAPHAEL ventilator[1]

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)[2,3,4,5]			
	150 kHz to 80 MHz outside ISM bands $d = 0.35\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

1. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
2. For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
3. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
4. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
5. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

A.13 Warranty

LIMITED WARRANTY

THE WARRANTY DESCRIBED IN THIS AGREEMENT IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. HOWEVER, IMPLIED WARRANTIES ARE NOT DISCLAIMED DURING THE PERIOD OF THIS LIMITED WARRANTY.

Whereas HAMILTON MEDICAL guarantees its products to be shipped free from defects in material and workmanship.

Whereas the warranty doesn't include disposable items. Disposable items and consumable products are considered to be of single use or of limited use only and must be replaced regularly as required for proper operation of the product following the operator's manual.

Whereas HAMILTON MEDICAL shall have no obligations nor liabilities in connection with the product other than what is specified herein, including without limitation, obligations and/or liabilities for alleged negligence, or for strict liability. In no event shall the company be liable for incidental or consequential damages, either direct or contingent.

This Limited Warranty shall be void and not apply to:

A. If the product has not been installed and connected by an authorized local representative of HAMILTON MEDICAL in accordance with the instructions furnished by HAMILTON MEDICAL;

B. If no evidence is present that the occurrence of damage/repair happened within the certified warranty period;

C. If the serial number has been altered, effaced or removed and there is no bill of sale or evidence to verify the product's purchase date;

D. If the defects arise from misuse, negligence, or accidents or from repair, adjustment, modification or replacement made outside HAMILTON MEDICAL's factories or other than an

authorized service center or authorized service representative;

E. If the product has been mechanically or electronically altered without specific written authorization from HAMILTON MEDICAL.

Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty, but carry only the unexpired portion of the original Limited Warranty.

To obtain service under this Limited Warranty, claimant must promptly notify the country's sales partner of HAMILTON MEDICAL regarding the nature of the problem, serial number and the date of purchase of the Product.

Except as stated above, HAMILTON MEDICAL shall not be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages.

B Modes of ventilation

B.1 Introduction

This section discusses the principles of operation for the RAPHAEL's ventilation modes. It lays the groundwork by describing the biphasic concept, which is at the heart of the device's pneumatic design and which is vital to understanding how the RAPHAEL ventilates in all modes.

The RAPHAEL offers the following ventilation modes:

- Mandatory modes
  - (S)CMV+ (synchronized continuous mandatory ventilation)
  - PCV+ (pressure-controlled ventilation)
- Synchronized intermittent mandatory ventilation (SIMV) modes
  - SIMV+
  - PSIMV+ (pressure-controlled SIMV)
- SPONT (spontaneous) mode
- Advanced modes
  - ASV (adaptive support ventilation)
  - DuoPAP (duo positive airway pressure)
  - APRV (airway pressure release ventilation)
  - NIV (noninvasive ventilation)

Volume-controlled modes in the RAPHAEL are delivered by an adaptive volume controller. Combining the advantages of pressure-controlled ventilation with volume-targeted ventilation, the adaptive volume controller ensures that the target tidal volume is delivered but without undue application of pressure, even when lung characteristics change. The operation of the adaptive volume controller is described as part of the (S)CMV+ mode description, Section B.3.1.

In the RAPHAEL, all mandatory breaths have a decelerating flow waveform. There are no negative pressures generated during exhalation.

B.2 The biphasic concept

It is widely accepted that early spontaneous breathing is beneficial for many ventilated patients, provided the device lets the patient inspire and exhale whenever the respiratory muscles contract and relax. In other words, the ventilator needs to be in synchrony with the patient's muscle contractions, regardless of how the ventilator's controls are set.

Accordingly, the RAPHAEL's pneumatics were designed to permit the patient's free spontaneous breathing. The ventilator never forces the patient into a preset breathing pattern but always yields to spontaneous breathing. This is achieved through a special valve control system independent of any trigger mechanism. This concept is called "biphasic," because gas can flow into and out of the patient at any time. The biphasic concept applies in all RAPHAEL ventilation modes.

Implementation of the biphasic concept improves patient breathing comfort[1], as spontaneous breathing is encouraged[2], less sedation is required even with prolonged inspiratory phases[3], and there is a free delivery of flow to the patient at any time. The decelerating inspiratory waveform improves gas distribution, oxygenation, and lowers peak pressures[2,3,4,5,6].

1. Cinnella G, Conti G, Lofaso F, Lorino H, Harf A, Lemaire F, Brochard L, Effects of assisted ventilation on the work of breathing: volume-controlled versus pressure-controlled ventilation. *Am J Respir Care Med* 1996 Mar;153(3):1025-33
2. Kuhlen R, Putensen C, Editorial: Maintaining spontaneous breathing efforts during mechanical ventilatory support, *Int Care Med* 1999;25:1203-5
3. Sydow M, Burchardi H, Ephraim E, Zielmann S, Crozier TA, Long-term effects of two different ventilatory modes on oxygenation in acute lung injury. Comparison of airway pressure release ventilation and volume-controlled inverse ratio ventilation. *Am J Respir Crit Care Med* 1994 Jun;149(6):1550-6
4. Al-Saady N, Bennett ED, Decelerating inspiratory flow waveform improves lung mechanics and gas exchange in patients on intermittent positive pressure ventilation. *Int Care Med* 1985;11(2):68-75
5. Tharatt R St, Allen RP, Albertson TE, Pressure controlled inverse ratio ventilation in severe adult respiratory failure, *Chest* 1988 Oct;94(4):755-62
6. Davis K Jr, Branson RD, Campbell RS, Porembka DT, Comparison of volume and pressure control ventilation: is flow waveform the difference? J *Trauma* 1996 Nov;41(5):808-14

Figure B-1 through Figure B-3 illustrate this concept. Figure B-1 shows a passive patient ventilated by pressure-controlled ventilation. Gas flows into the patient when pressure rises and gas flows out of the patient when inspiratory pressure falls.

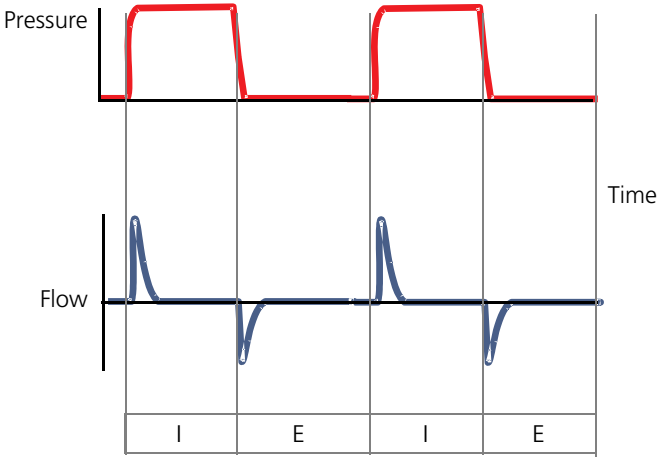


Figure B-1. Conventional pressure-controlled ventilation in a passive patient. Flow to patient during inspiration (I); flow from patient during exhalation (E) only.

Figure B-2 shows a partially active patient during conventional pressure-controlled ventilation when the trigger is disabled. If respiratory activity is present during the machine-determined inspiratory phase, gas flows only into the patient. Gas flow out of the patient is impossible due to the closed expiratory valve (see Flow curve).

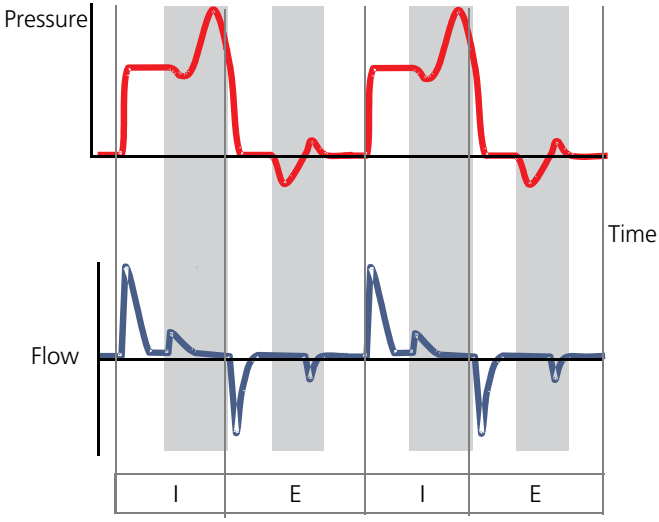


Figure B-2. Conventional pressure-controlled ventilation in an active patient when the trigger is off. Pressure increases when the patient tries to exhale (E) and pressure decreases when the patient tries to inspire (I), as valves are closed.

During the machine-determined expiratory phase, gas flows only out of the patient. Gas flow to the patient is impossible due to the closed inspiratory valve (see Flow curve).

Figure B-3 shows a partially active patient in the RAPHAEL's biphasic PCV+ mode. Note that inspiration and exhalation are possible at any time, thereby offering the best synchronization possible between patient and machine. PCV+ acts like an artificial atmosphere to the patient: the machine varies the airway pressure to guarantee a minimal ventilation and the patient contributes whatever they can.

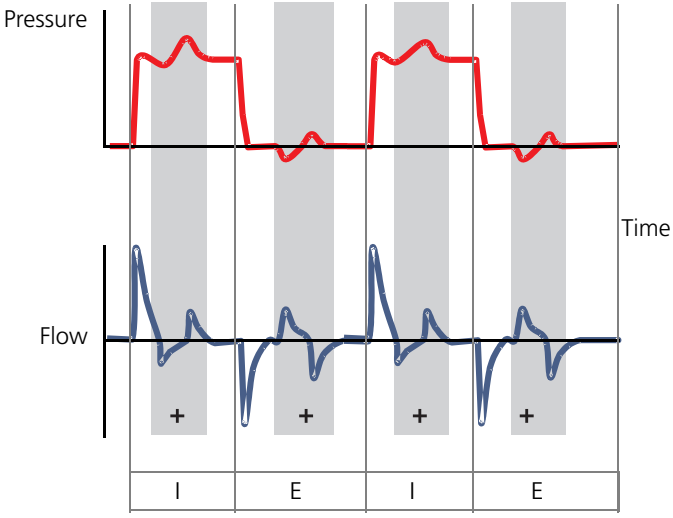


Figure B-3. Biphasic PCV+ in an active patient when trigger is off. The patient can freely inspire and exhale during any phase of ventilation (+).

B.3 Mandatory modes

The mandatory modes of ventilation ((S)CMV+ and PCV+) deliver time-cycled mandatory breaths, either volume-controlled or pressure-controlled, respectively.

When the patient triggers or the user initiates a breath, the respiratory rate increases, while both the inspiratory time and the tidal volume (for (S)CMV+) or the inspiratory pressure (PCV+) remain constant. The minute volume increases as a result.

The RAPHAEL's mandatory modes allow free breathing capability. At any time of the cycle, the RAPHAEL allows patients to freely breathe in and out whenever they feel comfortable doing so.

B.3.1 Synchronized controlled mandatory ventilation ((S)CMV+)

The (S)CMV+ mode provides volume-controlled mandatory breaths only. The control settings active in the (S)CMV+ mode are shown in Figure B-4. The tidal volume (VT) setting defines the delivered volume. The Rate and I:E control settings determine the breath timing. Breaths can be triggered by the ventilator, patient, or user.

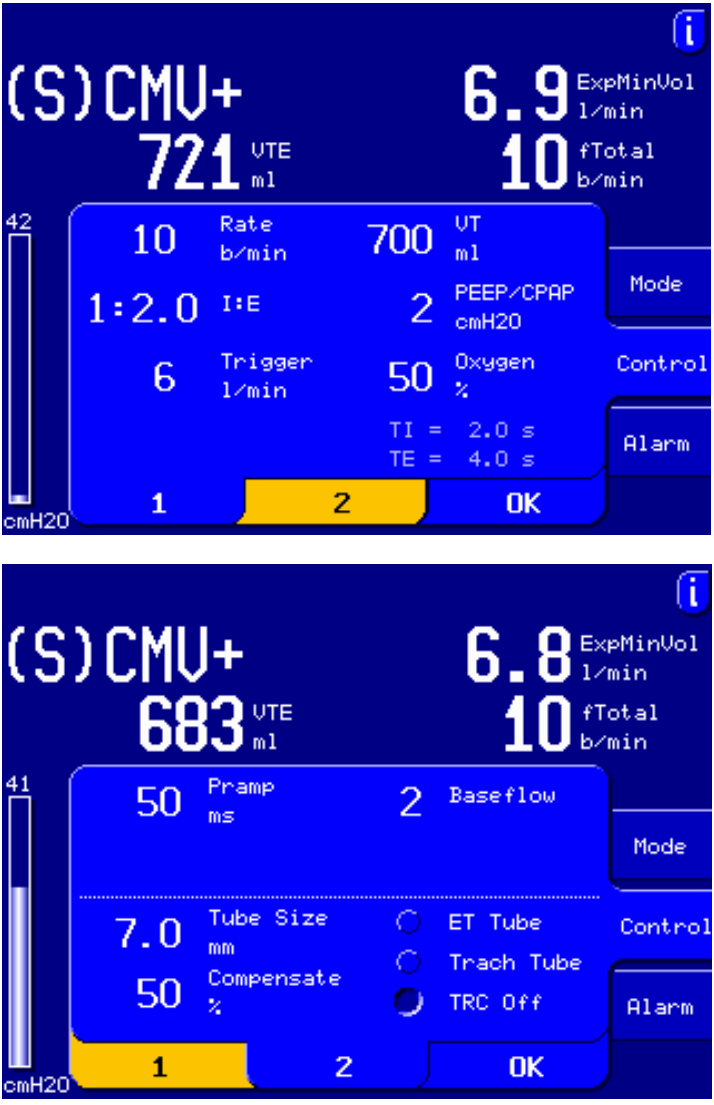


Figure B-4. (S)CMV+ control windows

B.3.1.1 Principle of operation

The (S)CMV+ mode achieves control of tidal volume according to a new concept, the adaptive volume controller. The adaptive controller combines the advantages of pressure control ventilation with those of volume ventilation. For each breath, the adaptive controller compares the user-set tidal volume with the average of delivered and exhaled tidal volumes. The adaptive controller in turn adjusts the inspiratory pressure that will be applied during the next breath, in order to obtain the target volume. The inspiratory pressure is adjusted in steps, to a maximum of 2 cmH_2O per breath. The adaptive controller adjusts the inspiratory pressure so it is between (PEEP + 5 cmH_2O) and (Pmax - 10 cmH_2O), to a maximum of 50 cmH_2O above PEEP (Figure B-5).

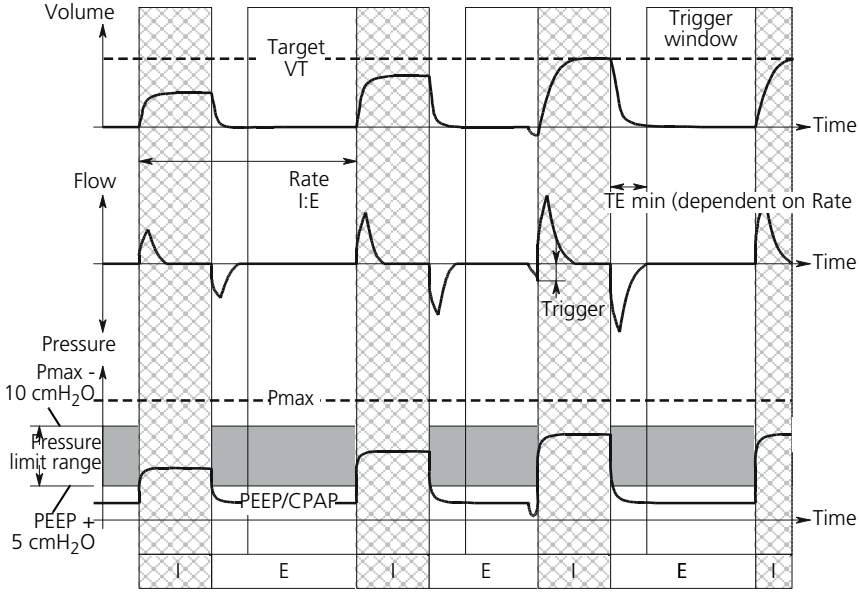


Figure B-5. Breath delivery by the RAPHAEL (S)CMV+ adaptive controller

B.3.1.2 Benefits of (S)CMV+

While the (S)CMV+ mode performs volume control of ventilation, the patient can trigger mandatory breaths, as well as freely inspire and exhale. By means of the adaptive controller, the patient is assured of the required tidal volume despite changes in respiratory system compliance, airway resistance, intrinsic PEEP, or the patient's respiratory activity. The user-set tidal volume is always achieved, but with all these advantages of pressure control ventilation:

- For passive patients, a decelerating flow pattern
- For actively breathing patients, substantial inspiratory pressure and high flow capability from the start of inspiration
- For actively breathing patients, the freedom to influence the instantaneous flow

Because of the special characteristics of the (S)CMV+ mode, its application is wider than that of conventional CMV. The (S)CMV+ mode, however, may be contraindicated if there is a large leak from the tracheal tube.

B.3.2 Pressure-controlled ventilation (PCV+)

The PCV+ mode provides pressure-controlled mandatory breaths only. The control settings active in the PCV+ mode are shown in Figure B-6. The pressure control (Pcontrol) setting defines the applied pressure. The Rate and I:E control settings determine the breath timing. Breaths can be triggered by the ventilator, patient, or user.

In PCV+ breaths, substantial pressure is applied as soon as inspiration starts. In passive patients, this results in a decelerating flow pattern, particularly favorable for flow distribution. In actively breathing patients, this results in a high flow capability at the beginning of inspiration, a phase in which the patient's flow demand is typically high. Moreover, pressure control lets actively breathing patients influence the instantaneous flow at any time.

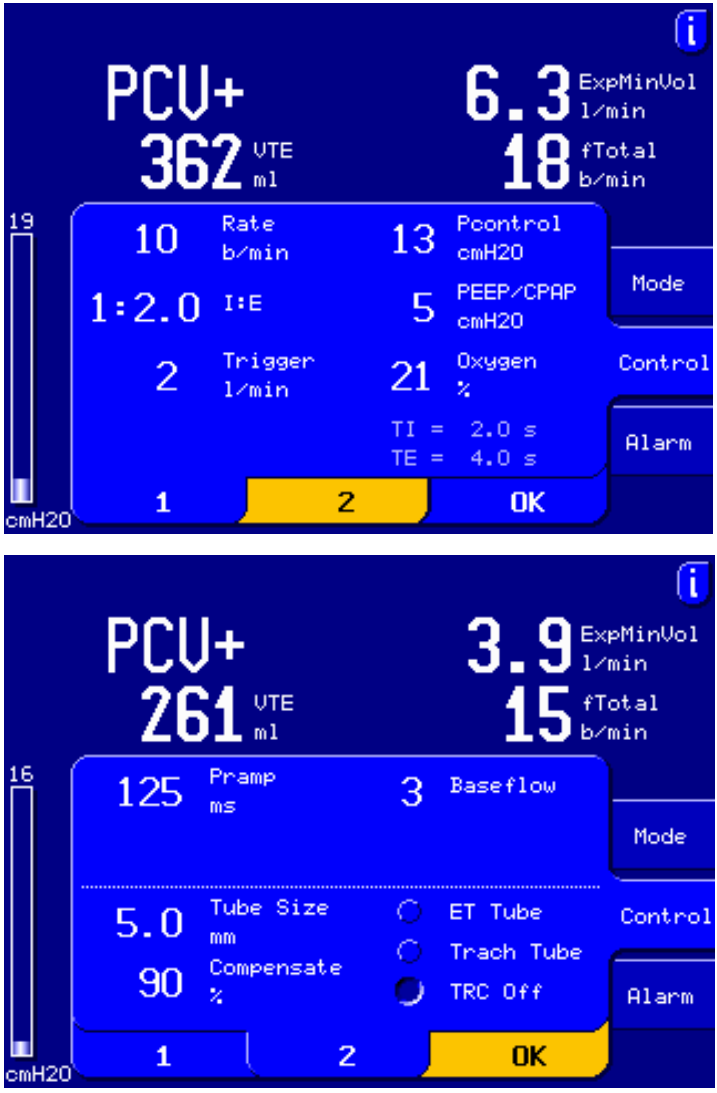


Figure B-6. PCV+ control windows

The PCV+ mode, while delivering a preset pressure, does not guarantee delivery of a fixed tidal volume, especially during changes in respiratory system compliance, airway resistance, auto-PEEP, or patient's respiratory activity.

To help you monitor the patient's status during the PCV+ mode, the RAPHAEL's basic screen displays exhaled minute volume, total respiratory rate, and real-time curves for flow, pressure, or volume versus time. The RAPHAEL's alarm system constantly checks the patient's minimum and maximum expiratory minute volume. A high-priority alarm is activated if minute volume is low or high.

B.4 SIMV (synchronized intermittent mandatory ventilation) modes

The RAPHAEL's SIMV modes (SIMV+ and PSIMV+) guarantee that one or more breaths will be delivered within an interval determined by the user-set Rate. A combination of mandatory and spontaneous breaths may be delivered.

Each SIMV breath interval includes Tmand and Tspont portions (Figure B-7). During Tmand, the ventilator waits for the patient to trigger a breath. If the patient does trigger a breath, the ventilator immediately delivers a mandatory breath. If the patient does not trigger a breath, then the ventilator automatically delivers a mandatory breath at the end of Tmand. After the mandatory breath is delivered, the patient is free to take any number of spontaneous breaths for the remainder of Tmand and Tspont.

Apnea backup ventilation can be activated in the SIMV modes.

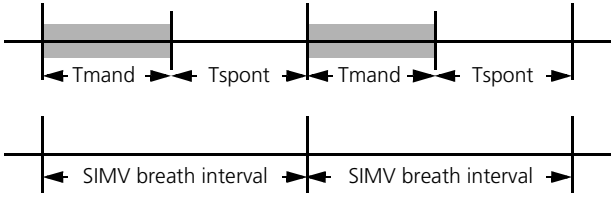


Figure B-7. Breath delivery in SIMV modes

B.4.1 SIMV+ mode

In the SIMV+ mode, the mandatory breaths are (S)CMV+ breaths. These can be alternated with SPONT breaths. The control settings active in the SIMV+ mode are shown in Figure B-8.

The SIMV+ mode guarantees volume delivery. Minute volume, a function of tidal volume and breath frequency, is taken care of by the mandatory breaths. At the same time, this mode helps the patient gain full control of his breathing pattern by allowing spontaneous breaths and synchronizing those with the mandatory breaths.

Because of these characteristics of the SIMV+ mode, it is chosen both as a ventilatory support and a weaning modality.

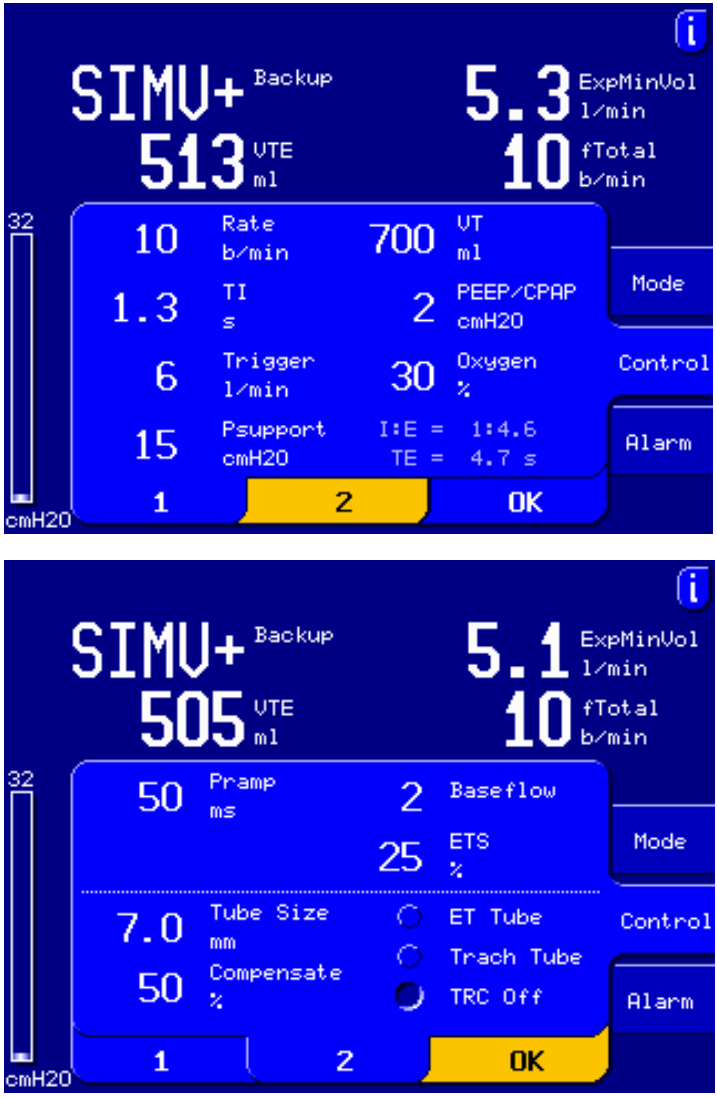


Figure B-8. SIMV+ control windows

B.4.2 PSIMV+ mode

In the PSIMV+ mode, the mandatory breaths are PCV+ breaths. These can be alternated with SPONT breaths. The control settings active in the PSIMV+ mode are shown in Figure B-9.

The PSIMV+ mode does not guarantee the delivery of an adequate tidal volume at all times. When using this mode, carefully monitor changes in the patient's status.

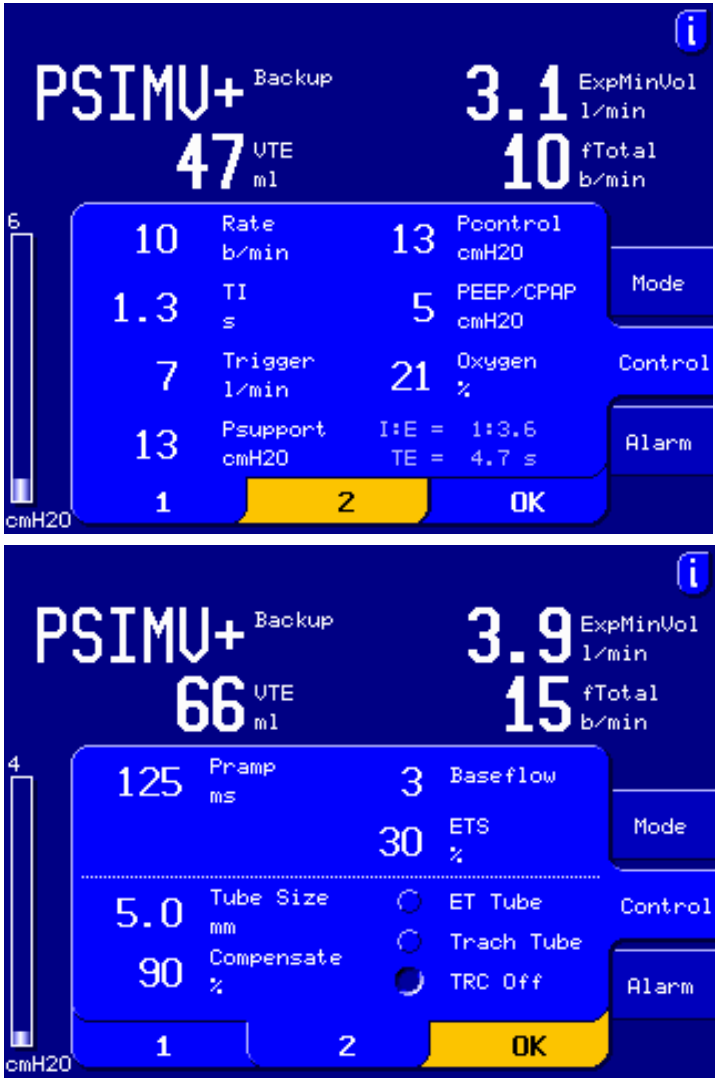


Figure B-9. PSIMV+ control windows

B.5 Spontaneous mode (SPONT)

In the spontaneous (SPONT) mode, spontaneous breaths and user-initiated manual (mandatory) breaths are delivered. In this mode, the RAPHAEL functions as a demand flow system. The patient's spontaneous breathing efforts can also be supported with the set pressure support. When pressure support is set to zero, the RAPHAEL in the SPONT mode functions like a conventional CPAP system. Apnea backup ventilation may be enabled in the SPONT mode. The control settings active in the SPONT mode are shown in Figure B-10.

The pressure support (Psupport) setting defines the applied pressure. The patient determines the breath timing. Breaths can be triggered by the patient or user.

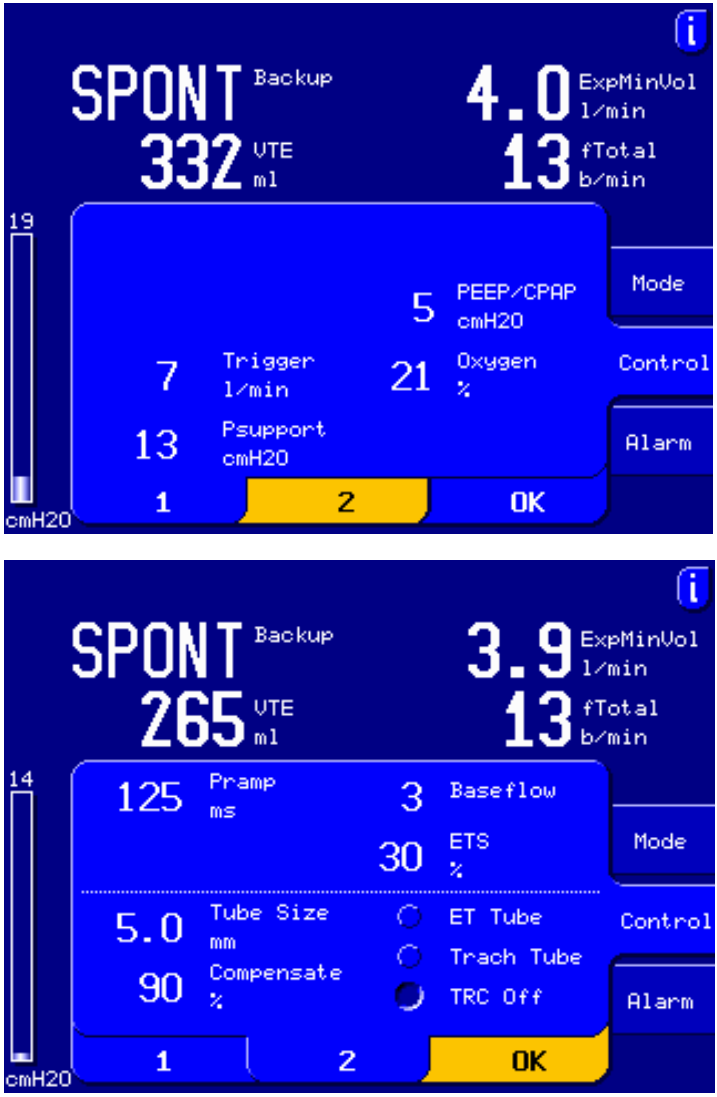


Figure B-10. SPONT control windows

B.6 Advanced ventilation modes

B.6.1 Adaptive support ventilation (ASV)

Silver

See Appendix C for detailed information on this mode.

B.6.2 DuoPAP (duo positive airway pressure) and APRV (airway pressure release ventilation)

Silver

B.6.2.1 Introduction

DuoPAP and APRV are two related forms of pressure ventilation designed to support spontaneous breathing on two alternating levels of CPAP. In these modes, the ventilator switches automatically and regularly between two operator-selected levels of positive airway pressure or CPAP (P high and PEEP/CPAP or P low). Both modes permit a combination of mandatory and spontaneous breaths. The patient may breathe freely at either level; pressure support can be added to these spontaneous breaths. Cycling between the levels is triggered by DuoPAP/APRV timing settings or by patient effort. Pressure/time curves for these modes are shown in Figure B-13 and Figure B-14.

The control settings active in the DuoPAP mode are shown in Figure B-11. The control settings active in the APRV mode are shown in Figure B-12.

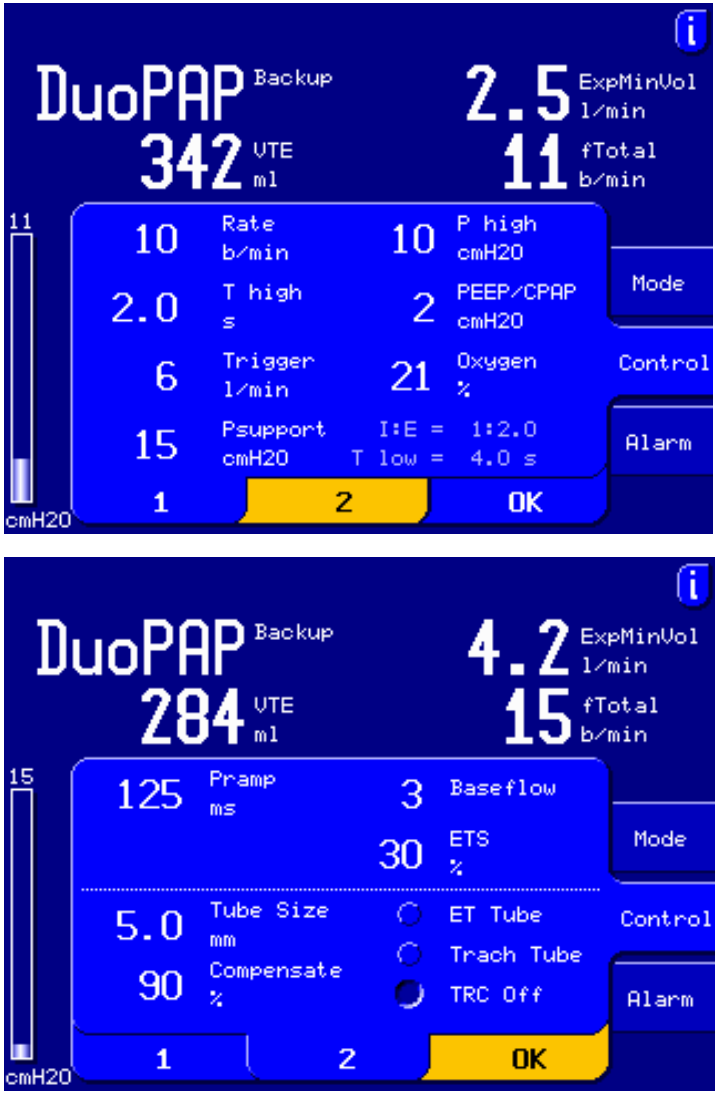


Figure B-11. DuoPAP control windows

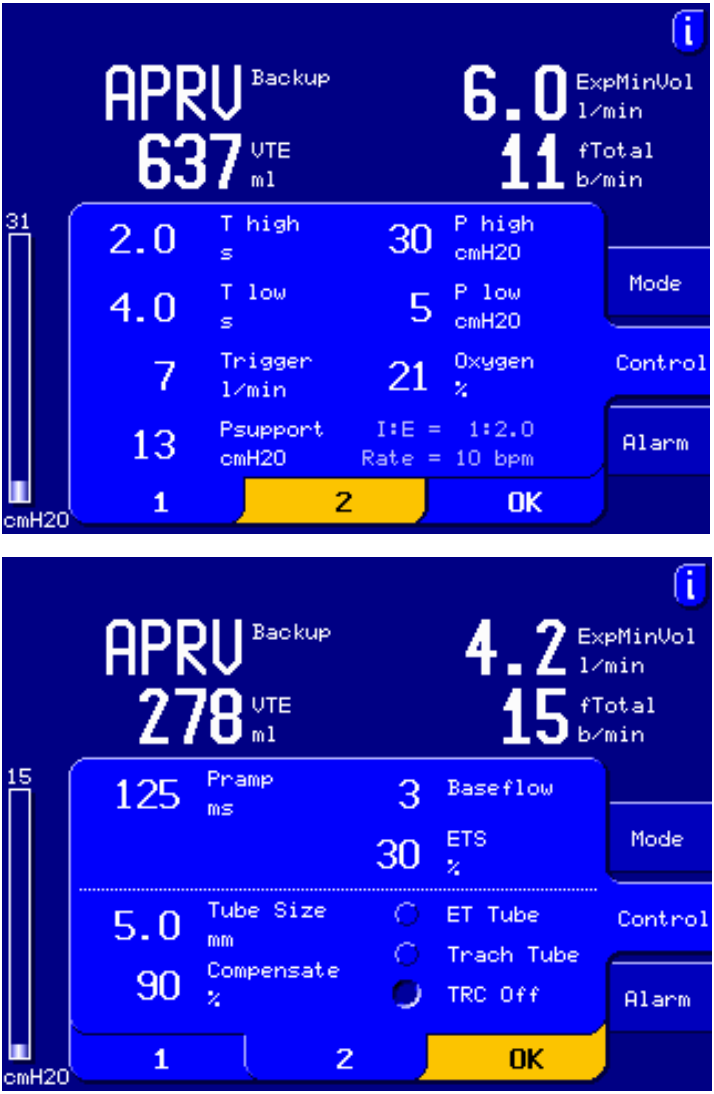


Figure B-12. APRV control windows

In DuoPAP (Figure B-13), the switchover between the two levels is defined by pressure settings P high and PEEP/CPAP and time settings T high and Rate. Like PEEP/CPAP, P high is relative to *atmospheric pressure*. In APRV (Figure B-14), the switchover is defined by pressure settings P high and P low and time settings T high and T low. In DuoPAP, PEEP/CPAP is the baseline for Psupport, while in APRV, P low is the baseline for Psupport -- Psupport is relative to *PEEP/CPAP* or *P low*.

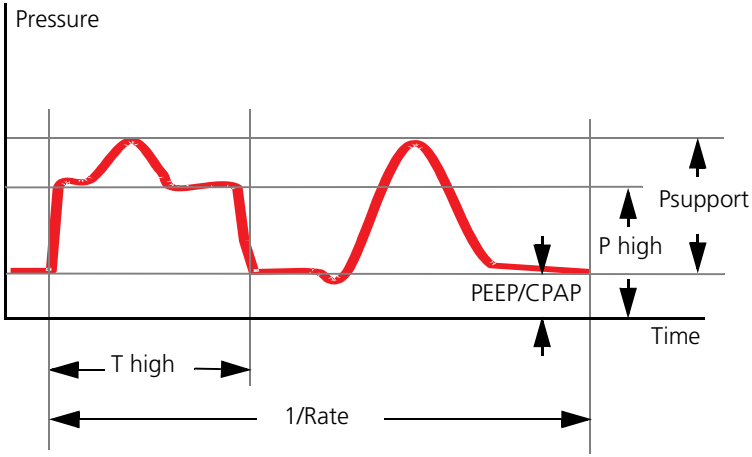


Figure B-13. DuoPAP pressure curve

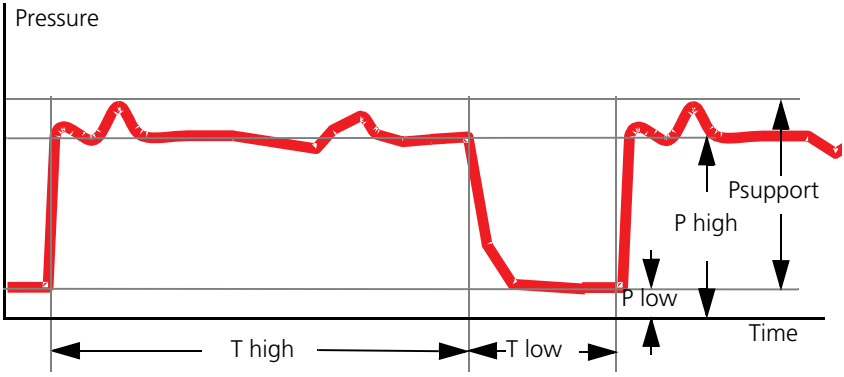


Figure B-14. APRV pressure curve

B.6.2.2 Differences between DuoPAP and APRV

As the figures show, the two modes differ in the operator settings required to determine the breath pattern. In DuoPAP, you set Rate and T high to establish the breath timing. In APRV, you set T high and T low to establish the time at each level. T low in APRV, however, remains constant independent of synchronization. In other words, if the patient triggers a breath before T high ends, T high becomes shorter than the operator-set value, but the T low phase always lasts for the operator-set time. In DuoPAP you set P high and PEEP/CPAP to establish the two pressure levels, while in APRV you set P high and P low.

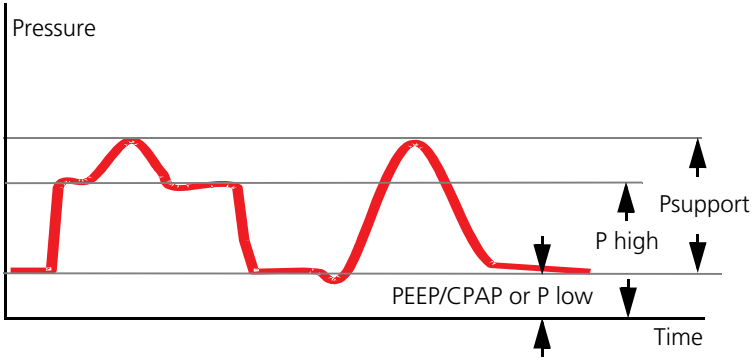
In clinical use, these two ventilation modes typically differ in the time allowed at the lower pressure level. When using DuoPAP, operators tend to prefer relatively long times at both the high and low pressure levels to allow spontaneous breathing at both. When using APRV, operators tend to prefer relatively long T high and shorter T low settings, so that the spontaneous breathing is mostly done at the upper pressure level. The pressure is then "released" to the lower pressure level just long enough for the lung volume to decrease, then is immediately returned to the upper pressure level.

B.6.2.3 The many faces of DuoPAP and APRV

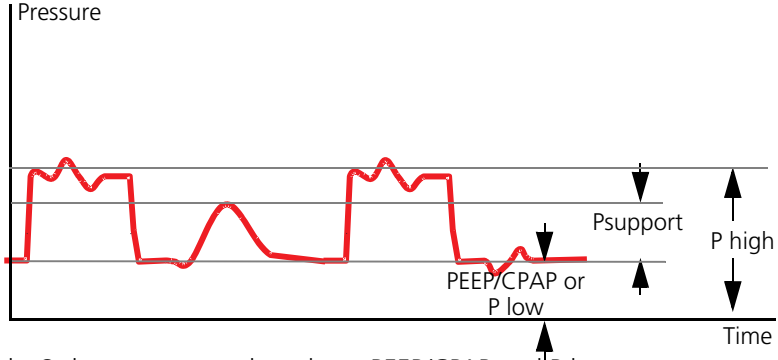
With different patients and with different combinations of control settings, DuoPAP and APRV can be made to resemble a variety of conventional ventilation modes. At conventional settings and in the absence of spontaneous breathing, DuoPAP and APRV resemble PCV+. As you decrease the rate, keeping T high short relative to the time at the lower pressure level, the modes look more like PSIMV+, with spontaneous breaths following mandatory breaths. If you set the breath cycle time to a total of 7.5 to 15 s with just enough time at the low level to allow full or near-full exhalation, these modes look like classical APRV. By setting PEEP/CPAP / P low and P high equal to one another and adjusting other parameters, the modes can be made to resemble SPONT.

B.6.2.4 Pressure support in DuoPAP/APRV breaths

Pressure support can be set to assist spontaneous breaths in DuoPAP/APRV, whether they occur at the PEEP/CPAP / P low or P high level. Psupport is set relative to PEEP/CPAP / P low -- the target pressure becomes PEEP/CPAP / P low + Psupport. *That means that spontaneous breaths at the P high level are supported only when this target pressure is greater than P high.* Figure B-15 (a) shows the situation where breaths at both the low and high levels are pressure-supported. Figure B-15 (b) shows the situation where only breaths at the low level are pressure-supported.



a. All spontaneous breaths pressure-supported



b. Only spontaneous breaths at PEEP/CPAP and P low pressure-supported

Figure B-15. Pressure support in DuoPAP/APRV

B.6.2.5 Synchronization

To adapt easily to the patient's spontaneous breathing pattern the change-overs from low to high pressure level and vice versa are synchronized with the patient's spontaneous breathing.

The frequency of the change-over is kept constant, even with patient synchronization, by defining a trigger time window.

B.6.2.6 References

- **Rasanen J et al.** Airway pressure release ventilation during acute lung injury: a prospective multicenter trial. Crit Care Med 1991 Oct;19(10):1234-41.
- **Stock MC, Downs JB et al.** Airway pressure release ventilation. Crit Care Med 1987 May;15(5):462-6.
- **Antonsen K et al.** Invasive ventilation. Classification, technique and clinical experiences with BIPAP/APRV (Biphasic Positive Airway Pressure/Airway Pressure Release Ventilation. Ugeskr Laeger 1996 Jan 22;158(4):413-9.
- **Rathgeber J.** Ventilation modes and strategies in intensive care medicine. Anaesthesiol Reanim 1997;22(1):4-14.
- **De Carvalho WB et al.** Airway Pressure release in postoperative cardiac surgery in paediatric patients. Rev Assoc Med Bras 2000 Apr-Jun;46(2):166-73.

B.6.3 Noninvasive ventilation (NIV)

B.6.3.1 Introduction

NOTE:

- Noninvasive ventilation (NIV) in critically ill patients should only be used by properly trained and experienced personnel.
- As a precaution, you must be prepared to intubate the patient and start invasive ventilation at any time while NIV is in use.
- The use of a mask may increase dead space. Always heed the mask manufacturer's instructions when using NIV.
- When using a standalone compressor -- rather than a central gas supply -- pay special attention to the following:
  - Make sure the Baseflow setting is appropriate and that the extended baseflow range is configured off (see Section E.7)
  - Make sure the mask fits well
  - Monitor the compressor periodically to ensure a sufficient air supply

  This is particularly important for NIV, because the compressor, in conjunction with a leaky patient interface, may not provide sufficient air supply. In severe cases, this can cause a **`Disconnection`** alarm on the RAPHAEL and water accumulation in the RAPHAEL water trap.

The noninvasive ventilation (NIV) mode is the RAPHAEL's implementation of noninvasive positive pressure ventilation (NPPV). NIV may use as its patient interface a mask, mouthpiece, or helmet-type interface, rather than an invasive conduit such as an endotracheal tube.

Used for years in home care and subacute care settings, NPPV can also benefit intensive care ventilation patients by decreasing the need for intubation and promoting early extubation. Benefits such as

reduced mortality (COPD patients), reduced ventilation time (COPD and ARF patients), and reduced complication rates (of ventilator-associated pneumonias) have been clearly demonstrated[1,2].

Intended for actively breathing patients, NIV is an adaptation of the RAPHAEL's SPONT mode. In NIV, pressure support ventilation (PSV) is provided through a non-vented or non-ported mask interface. Because this open breathing circuit permits air to leak around the mask or through the mouth, the ventilator achieves and maintains the prescribed PSV pressure by adjusting the inspiratory flow. If the leak is large, the ventilator's inspiratory flow can be large -- up to 180 l/min -- thus compensating at least in part for most leaks. The NIV mode was designed to minimize nuisance leak-related alarms.

The control settings active in the NIV mode are shown in Figure B-16.

B.6.3.2 Benefits of NIV

NIV offers these short-term benefits:[1,2]

- Relieves respiratory symptoms
- Optimizes patient comfort
- Reduces work of breathing
- Improves or stabilizes gas exchange
- Improves patient-ventilator synchrony
- Minimizes risks associated with aspiration, intubation, injury to the mucus membranes and teeth, and circulatory reactions

NIV offers these long-term benefits:

- Improves sleep duration and quality
- Maximizes quality of life
- Enhances functional status
- Prolongs survival

1. Mehta S et al**.** Noninvasive ventilation. Am J Respir Crit Care Med 2001 Feb;163(2):540-77.
2. Hess DR. The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. Respiratory Care 2004 Jul;49(7):810-25.

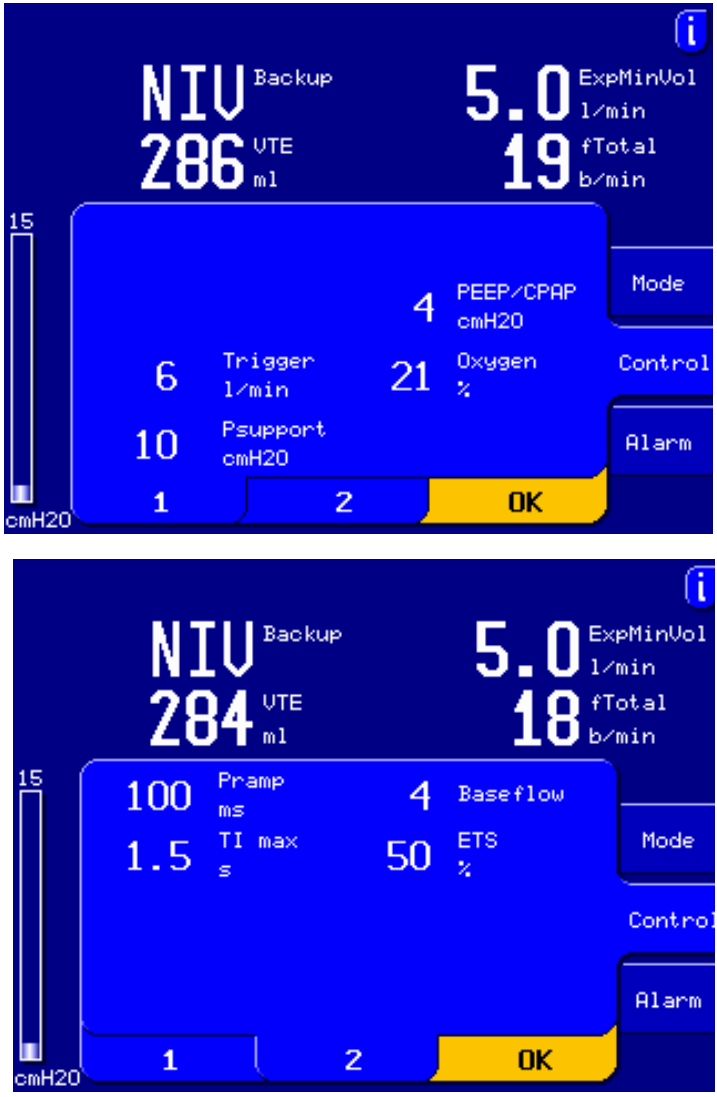


Figure B-16. NIV control windows

B.6.3.3 Required conditions for use

WARNING

- **To prevent possible patient injury, do not use NIV on patients with no or irregular spontaneous breaths. NIV was intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.**
- **To prevent possible patient injury, do not attempt to use NIV on intubated patients.**

Be sure that the following requirements are met when using NIV:

- The patient must not be intubated.
- The patient must be able to trigger the ventilator and must have regular spontaneous breaths.
- The patient must be awake.
- The patient must be able to maintain an adequate airway.
- The clinician's instructions must be strictly followed.
- The patient must be monitored by external monitors.
- Intubation must be possible at any time.
- The mask should fit face structures well.
- The patient must meet at least one of the of the following criteria:
  - They demonstrate respiratory distress, displaying moderate to severe dyspnea, increased over usual, and respiratory rate > 24 with accessory muscle use and paradoxical breathing
  - They demonstrate one of the following gas exchange abnormalities: $PaCO_2$ > 45 mmHg and pH < 7.35 *or* PaO_2/FiO_2 < 200

B.6.3.4 Contraindications

- Intolerance of interface
- Inability to trigger breath
- Facial or brain injury
- Recent upper airway or esophageal surgery
- Hemodynamic instability
- Gastric distension
- Inability to protect airway
- Acute sinusitis or inflammation of middle ear
- Life-threatening nosebleed that could cause inhalation of blood
- Low blood pressure

B.6.3.5 Adverse reactions

- Skin breakdown from interface (pressure sores)
- Aspiration
- Conjunctivitis
- Gastric insufflation
- Claustrophobic reaction
- Potential hemodynamic instability

B.6.3.6 Selecting a patient interface

The quality and performance of the patient interface largely determine the effectiveness of NIV. A face (oronasal) mask that covers the mouth and nose or a nasal mask that covers the nose only, a mouthpiece, or a helmet-type interface may be used with NIV. In general, a face mask is more efficient than a nasal mask, but a nasal mask is better tolerated. Consider the following additional advantages and disadvantages when selecting a patient interface:

Type	Advantage	Disadvantage
Face mask	• Little patient cooperation required • Little leakage • Ability to sleep	• Verbal communication not possible • Gastric distension • Greater dead space
Nasal mask	• Comfort • Verbal communication possible • Little dead space	• Patient cooperation required • Oral leakage
Mouthpiece	• Simple to use • Inexpensive	• Nasal air leakage • Greater dead space

In general a mask used with the NIV mode should meet these requirements:

- It must be of the non-vented/non-ported design.
- It should fit face structures well.
- Gas leakage should be controllable at low mask application pressures
- The material in contact with the face should be soft, biocompatible, and nonallergenic
- It should be easy to install and remove
- It should remain properly positioned when the patient moves their head

If you try using a nasal mask, but there is significant gas leakage through the open mouth, switch to a face mask.

B.6.3.7 Managing patient anxiety

- Explain the goal of noninvasive ventilation
- Prearrange how the patient will communicate his needs
- Use disconnection suppression when starting ventilation
- Let the patient grow accustomed to the mask by starting with low pressure settings and by holding the mask to the patient's face before tightening the strap. Let the patient remove the mask for a short time to speak or drink.

B.6.3.8 Control settings

WARNING

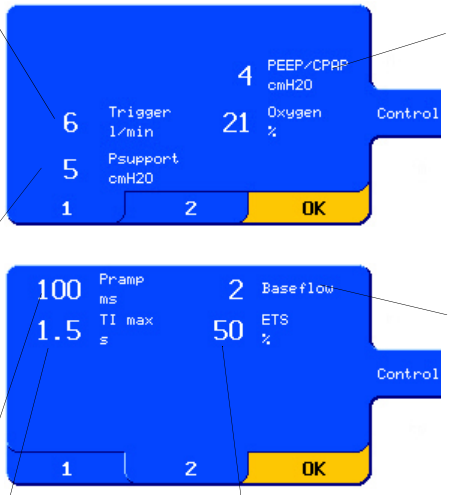
Peak pressures exceeding 33 cmH_2O may increase the risk of aspiration due to gastric insufflation[1]. When ventilating with such pressures, consider using an invasive mode.

How to set controls in NIV. When ventilating a patient in the NIV mode, start with the initial settings shown in Figure B-17. PEEP/CPAP adjusts the expiratory airway pressure (EPAP) and Psupport adjusts the inspiratory airway pressure (IPAP).

Adjust the settings as needed to optimize synchronization, to optimize breath volume and/or PCO_2, to minimize fatigue of accessory muscles, to relieve dyspnea, and to reduce respiratory rate. Frequency should be ≤ 25 b/min.

Titrate ventilation and oxygenation. Adjust settings as the patient's condition and leak change. Adjust the alarms appropriately.

1. Bach JR, Alba AS, Saporito LR. Intermittent positive pressure ventilation via the mouth as an alternative to tracheostomy for 257 ventilator users. Chest 1993;103:174-182.



4 – 8 l/min
Decrease to aid triggering. Increase in case of autotriggering or leak.

5 – 10 cmH$_2$O[1]
Adjust to obtain appropriate tidal volumes (6 to 8 ml/kg).

Minimum setting[1]**, or 4 cmH$_2$O for single-limb circuit**[2]
Adjust further, considering oxygenation and AutoPEEP (< 10)[1].

≥ 2
Increase to reduce work of breathing.

100 ms
Reduce if patient is air-hungry.

0.25 to 0.5 s longer than actual spontaneous inspiration time
Set it long enough so that ETS has a chance to cycle ventilator.

50%
Increase for larger leaks. Find the optimal ETS that lets the ventilator cycle into exhalation with a Ti of 1.0 to 1.2 s.

1. American Respiratory Care Foundation. Consensus Conference: noninvasive positive pressure ventilation. Respir Care 1997;42:364-9.
2. Respironics, Inc. BiPAP Vision Ventilator Support System Clinical Manual. Murrysville, Pennsylvania USA: Respironics, Inc.; 2000; 9-4.

Figure B-17. Making initial control settings in NIV

About ETS and TI max. In case of a significant leak, the inspiratory flow may never fall below ETS, thus not allowing the ventilator to cycle into exhalation and resulting in endless inspiration. For this reason, the TI max setting was added, providing an alternative way to cycle into exhalation. When inspiration lasts longer than TI max, the RAPHAEL cycles into exhalation.

It is the most comfortable for the patient when the ventilator cycles based on the ETS setting rather than TI max, however. Make sure the TI max setting is sufficiently long to give ETS the chance to cycle the ventilator. Adjusting the TI max setting increases or decreases the allowable inspiratory time. Increasing ETS above the default 25% allows the ventilator to terminate inspiration at a higher flow, in order to accommodate larger leaks.

Figure B-18 and Figure B-19 show the effect of leakage on cycling into exhalation. Figure B-18 shows the case with no leakage; here the default ETS setting of 25% is appropriate. Figure B-19 shows the case with leakage on the patient side.

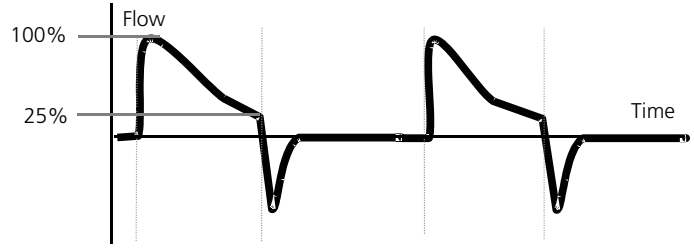


Figure B-18. Cycling into exhalation, no leakage

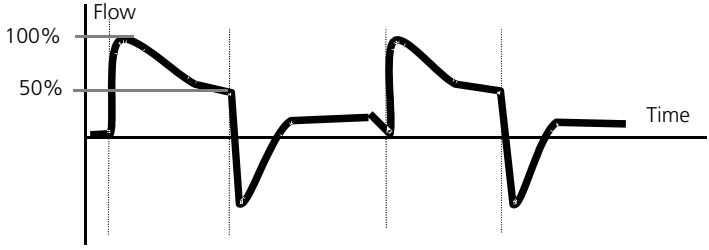


Figure B-19. Cycling into exhalation, leakage on patient side

B.6.3.9 Alarms

Volume alarms are less meaningful in NIV than in other modes, because of the unpredictable gas leakage in this mode. These alarms are based on the returned expiratory gas volume measured at the Flow Sensor; this value may be significantly lower than the delivered minute volume, because the delivered volume is the sum of the displayed ExpMinVol and the leakage volume. To avoid nuisance volume alarms, set the low ExpMinVol alarm to a low level.

Because NIV is a pressure mode, however, do pay attention to the pressure-related alarms. If the defined PEEP and inspiratory pressure can be maintained, the device is compensating the gas leak sufficiently.

NOTE:

When the RAPHAEL declares a **`Disconnection`** alarm, the pneumatic system stops breath delivery and applies a flow of approximately 20 l/min. When airway pressure rises to 3 cmH_2O or exhaled tidal volume exceeds 50 ml, the RAPHAEL again starts ventilating. Alternatively, you can override the alarm and manually start ventilation by pressing the manual breath key. Disconnection will be suppressed for up to 3 min, permitting the ventilator to deliver breaths until you press the key again to deactivate suppression, or for 1 min after a reconnection is detected.

B.6.3.10 Monitored parameters

NOTE:

Due to the changing and unpredictable amount of leakage, these numeric monitoring parameters cannot be used for reliable analysis of patient conditions: ExpMinVol, RCexp, Rinsp, Insp Flow, MV Spont, AutoPEEP, and Cstat. Close monitoring of the clinical parameters and patient comfort is therefore of critical importance.

Due to the leakage at the patient interface, displayed exhaled volumes in NIV may be substantially smaller than the delivered volumes. The Flow Sensor, a bidirectional device proximal to the patient, measures both the delivered volume and the exhaled tidal volume, then displays the difference as Leak (leakage percent). Use Leak to assess the fit of the mask or other noninvasive patient interface.

While a leak at the patient interface influences the tidal volume measurement, leaks in the breathing circuit itself do not influence the tidal volume measurement.

Besides all the other clinical parameters, TI, Ppeak, PEEP/CPAP, I:E, fTotal, Pmean, and fSpont can be used to assess the patient's ventilatory status.

B.6.3.11 Additional notes about using NIV

Due to some unique characteristics of NIV, consider the following points when using it. As with any mode of ventilatory support, monitor the patient closely to evaluate the adequacy of the prescribed therapy.

Starting ventilation in NIV. When you start NIV but before the patient interface is successfully adjusted, the RAPHAEL may declare a **`Disconnection`** alarm. You can override the alarm and manually start ventilation under this circumstance by pressing the manual breath key. Disconnection will be suppressed for up to 3 min, permitting the ventilator to deliver breaths until you press the key again to deactivate suppression, or for 1 min after a reconnection is detected.

Maintaining PEEP and preventing autotriggering. Significant leakage may be present in NIV, which may serve to reduce the actual applied PEEP/CPAP and give rise to autotriggering. Adjust the Trigger control as needed to maintain PEEP and to prevent autotriggering in the presence of leakage in NIV. If the monitored PEEP/CPAP is too low, increase the Trigger setting. If you cannot achieve the set PEEP, check the mask fit. If the mask fit cannot be improved, select an alternative treatment method.

Checking mask fit and position. For NIV to function as intended, the mask must fit well and remain in place. It is desirable to maintain a good seal and minimize leakage.

Check the mask position regularly and adjust as necessary. If the mask slides away from the mouth and nose (patient disconnection), reinstall and secure it. React promptly and appropriately to any alarms.

The ventilator's Leak parameter provides one indicator of mask fit. NIV becomes ineffective with a Leak greater than 50%. You can also check the proper fit of the mask by verifying that the patient can trigger and flow-cycle inspiration and by verifying that Ppeak is:

(Psupport + PEEP/CPAP) ±3 cmH_2O

CO_2 rebreathing in NIV (double-limb breathing circuits). CO_2 rebreathing per breath may increase in NIV. This may occur, because there is not the usual dead space reduction from an endotracheal tube or tracheostomy, and because the mask or other noninvasive interface creates additional dead space. Consider this additional dead space when prescribing a specific type of noninvasive patient interface. Despite the use of a noninvasive interface, the dead space ventilation per minute may decrease if the therapy results in an increase in tidal volume and decrease in respiratory rate.

CO_2 rebreathing in NIV (LiteCircuit). In general the risk of CO_2 rebreathing increases with decreasing pressure. Because with low pressure there is just a small flow through the expiratory port (Whisper valve), insufficient CO_2 is removed to prevent rebreathing. This effect is more pronounced with PEEP/CPAP settings under 4 cmH_2O.

The possibility of rebreathing also increases with longer inspiration times. A longer inspiration time decreases the exhalation time, so that less CO_2 can be removed from the tube before the next inspiration begins. This effect is more pronounced when the I:E ratio approaches 1:1.

B.6.3.12 References

- **Hess DR.** The evidence for noninvasive positive-pressure ventilation in the care of patients in acute respiratory failure: a systematic review of the literature. Respir Care 2004 Jul;49(7):810-25.
- **Mehta S et al.** Noninvasive ventilation. Am J Respir Crit Care Med 2001 Feb;163(2):540-77.
- **Arroliga AC.** Noninvasive positive pressure ventilation in acute respiratory failure: does it improve outcome? Cleveland Clin J Med. 2001 Aug;68(8):677-80.
- **Hill NS.** Noninvasive ventilation in chronic obstructive pulmonary disease. Clin Chest Med. 2000 Dec;21(4):783-97.
- **AARC.** Consensus statement: Noninvasive positive pressure ventilation. Respir Care 1997;42(4):365-9.
- **Evans TW et al.** Noninvasive positive pressure ventilation in acute respiratory failure: Report of an international consensus conference in intensive care medicine, Paris, France, 13 - 14 April 2000. Reanimation 2001;10:112-25.

B.7 IntelliTrig (intelligent trigger) function

With HAMILTON MEDICAL's IntelliTrig function, the RAPHAEL can automatically adapt to changing breath patterns and system leaks to achieve optimum synchronization between patient and device.

To achieve this synchronization, IntelliTrig compensates any leaks and resistances between the RAPHAEL and the patient, and with each breath it measures the leakage at the patient interface (mask). With this information IntelliTrig adapts the trigger mechanism so that leakage and the changing breath pattern do not influence the operator-set trigger sensitivity (flow trigger).

APPENDIX C ASV (adaptive support ventilation)

C.1 Introduction

In 1977, Hewlett et al. introduced mandatory minute volume (MMV). "The basic concept is that the system is supplied with a metered, preselected minute volume of fresh gas, from which the patient breathes as much as he is able, the remainder being delivered to him via a ventilator. Thus the patient is obliged to breathe, one way or the other, a Mandatory Minute Volume MMV" (Hewlett 1977).

Since then, many ventilators have included versions of MMV under different names. However, all commercially available MMV algorithms have clear limitations, which lead to certain risks for the patient (Quan 1990). These include rapid shallow breathing, inadvertent PEEP creation, excessive dead space ventilation, and inadvertent wrong user settings due to very complicated use.

Adaptive Support Ventilation (ASV) was designed to minimize those risks and limitations. ASV maintains an operator-preset, minimum minute ventilation independent of the patient's activity. The target breathing pattern (tidal volume and rate) is calculated using Otis' equation, based on the assumption that if the optimal breath pattern results in the least work of breathing, it also results in the least amount of ventilator-applied inspiratory pressure when the patient is passive. Inspiratory pressure and machine rate are then adjusted to meet the targets. A lung protection strategy ensures ASV's safety. In contrast to MMV, ASV attempts to guide the patient using a favorable breathing pattern and avoids potentially detrimental patterns like rapid shallow breathing, excessive dead space ventilation, breath stacking (inadvertent PEEP), and excessively large breaths.

Contrary to what may be believed, ASV does not eliminate the need for a physician or clinician. However, ASV alleviates the need for tedious tasks and laborious readjustments of the ventilator; thus, it is a modern tool for the clinician. As such, ASV does not make clinical decisions. ASV executes a general command from the clinician and the clinician can modify it. This command can be summarized as follows, where the modifiable parts are in bold:

Maintain a **preset minimum minute ventilation**,

take spontaneous breathing into account,

prevent tachypnea,

prevent autoPEEP,

prevent excessive dead space ventilation,

fully ventilate in apnea or low respiratory drive,

give control to the patient if breathing activity is okay,

and do all this without exceeding an applied pressure of Pasvlimit**.**

This appendix explains in practical terms how to use ASV at the patient's bedside and provides a detailed functional description. Since Otis' equation (Otis 1950) is the cornerstone of the optimal-breath pattern calculation, this equation is included and described. A table of detailed technical specifications and pertinent references is also given.

WARNING

This appendix describes ASV as it is implemented in the HAMILTON MEDICAL RAPHAEL ventilator (software version 3). It does not replace the clinical judgment of a physician and should not be used for clinical decision making.

C.2 ASV use in clinical practice

ASV does not require a special sequence of actions. It is used in much the same way as are conventional modes of ventilation. Figure C-1 summarizes how to use ASV, while the subsequent subsections explain it in detail. Figure C-2 shows the control settings active in the ASV mode.

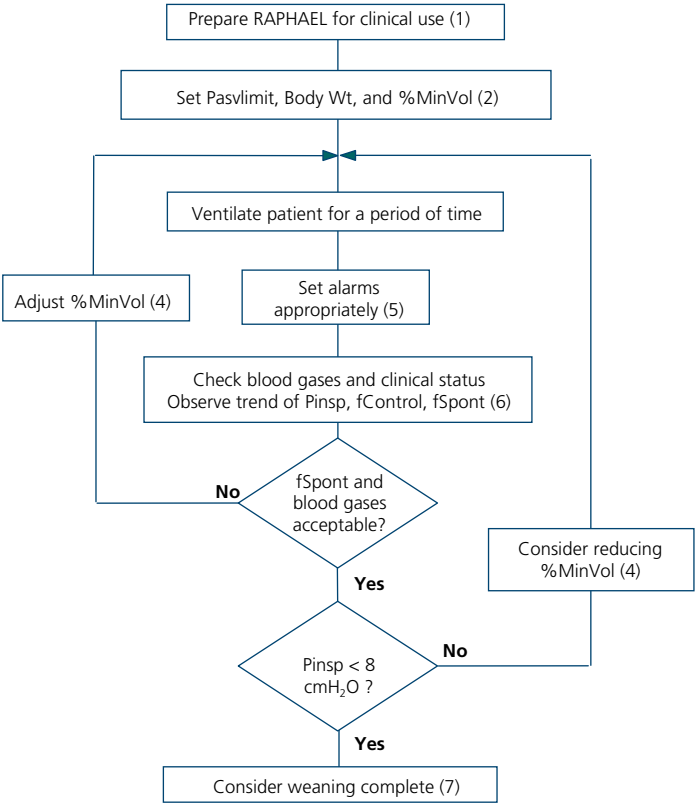


Figure C-1. Clinical use of ASV. The numbers in parentheses are step numbers, which are explained in the next subsections.

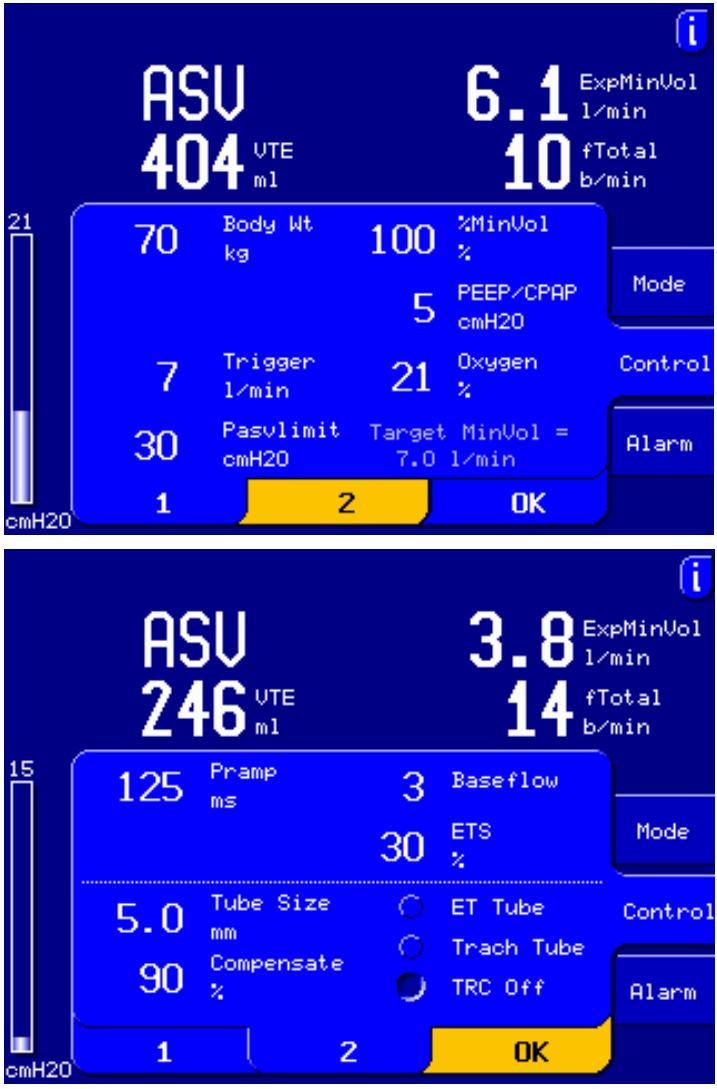


Figure C-2. ASV control windows

Step 1: Preoperational procedures

It is important to prepare the RAPHAEL for clinical use according to Section 2. This includes, but is not limited to, performing the preoperational procedures and testing indicated.

Step 2: Preparing the RAPHAEL before connecting a patient

ASV requires that you set the following three basic parameters:

Pasvlimit	Maximum pressure to be applied, in cmH_2O
Body Wt	Patient's ideal body weight, in kg (see Table 4-1 or Table 4-2)
%MinVol	Desired minute ventilation, in % of normal values

It is suggested you do the following before connecting the patient to the ventilator:

1. Remove the demonstration lung, when a demonstration lung is used, and silence the alarm.
2. Set PEEP/CPAP and Oxygen values according to clinical requirements.
3. Activate ASV in the mode window and then close the window. The control window automatically opens and permits access to the Body Wt, %MinVol, and Pasvlimit controls.
4. Enter the appropriate ideal body weight for the patient as Body Wt. If in doubt, consult Table 4-1 or Table 4-2.
5. Enter the appropriate %MinVol. A safe starting value is 100%. If appropriate, add 10% per °C (5% per °F) above normal body temperature and 5% per 500 m (1500 ft) above sea level.
6. Enter the maximum pressure to be applied as Pasvlimit. For the ASV controller to function correctly, Pasvlimit must be at least 15 cmH_2O greater than PEEP/CPAP.

NOTE:

Pmax is automatically adjusted so that it is 10 cmH_2O higher than Pasvlimit This prevents nuisance alarms when the ASV controller delivers a sigh breath, for example.

7. Enter the desired trigger sensitivity.

   You can leave the ETS setting at its standard value unless clinical judgment calls for adjustments.

8. Close the control window.

9. Connect the patient to the ventilator. This will initiate three test breaths.

Alternative Step 2: Setting up the RAPHAEL while the patient is ventilated in another mode

ASV requires that you set the following three basic parameters:

Pasvlimit	Maximum pressure to be applied, in cmH_2O
Body Wt	Patient's ideal body weight, in kg (see Table 4-1 or Table 4-2)
%MinVol	Desired minute ventilation, in % of normal values

It is suggested you do the following when switching from another mode to ASV:

1. Activate ASV in the mode window and then close the window. The control window automatically opens and permits access to the Body Wt, %MinVol, and Pasvlimit controls.

2. Enter the appropriate ideal body weight for the patient as Body Wt. If in doubt, consult Table 4-1 or Table 4-2.

3. Enter the appropriate %MinVol. A logical starting point is a %MinVol setting that will result in the same minute volume as the previous mode. The resulting target minute volume is displayed at the bottom of the control window and on the

ASV target graphics screen. A safe start is 100%. If appropriate, add 10% per °C (5% per °F) above normal body temperature and 5% per 500 m above sea level.

4. Enter the maximum pressure to be applied as Pasvlimit. For the ASV controller to function correctly, Pasvlimit must be at least 15 cmH_2O above PEEP/CPAP.

NOTE:

Pmax is automatically adjusted so that it is 10 cmH_2O higher than Pasvlimit This prevents nuisance alarms when the ASV controller delivers a sigh breath, for example.

5. You can leave the previous patient trigger sensitivity and ETS unchanged unless clinical judgment calls for adjustments.
6. Close the **Control** window. This will initiate three test breaths.

Step 3: Compensation for changes in apparatus dead space

The RAPHAEL calculates the (anatomical or "series") dead space based on the ideal body weight entered and calculated as 2.2 ml per kg (1 ml per lb). This dead space is a nominal value that is valid, on average, for intubated patients whose endotracheal tube is connected to the Y-piece of the ventilator by means of a standard catheter mount. If this dead space is altered by an artificial airway configuration such as a the use of a heat and moisture exchange filter (HME) or nonstandard tubing, modify the Body Wt setting accordingly to take into account the added or removed dead space.

It is suggested that you consider the following points:

- A shorter than standard endotracheal or tracheostomy tube has a minor effect and probably does not require compensation.
- The use of different sizes of endotracheal tube has a minor effect, and probably does not require compensation.

- A much longer-than-normal catheter mount may be important, and may require compensation.
- A bacterial filter or an HME may have an important effect. The volume of these devices, for an adult, is on average 50 to 60 ml, but may be as high as 95 ml (Mallinckrodt Hygroster). A simple rule of thumb is to add 10% Body Wt if using an HME.

NOTE:

Changes in alveolar dead space due to ventilation/ perfusion mismatch must be compensated via the %MinVol control.

Step 4: Adjusting ventilation: maintaining adequate ventilation

Once ASV is started, the RAPHAEL calculates an optimal breath pattern and associated target values for tidal volume and rate according to the rules in Section C.4. ASV then adjusts the inspiratory pressure (Pinsp) and machine rate (fControl) to achieve the targets.

Once the set targets are reached, the result of the ventilation needs to be assessed. All RAPHAEL monitored parameters can be used for this purpose. However, to assess respiratory acid-base status, it is recommended that arterial blood gases be measured and minute ventilation be adjusted accordingly. Table C-1 provides examples of how to adjust the %MinVol setting.

WARNING

It is inappropriate to use the Body Wt control to adjust minute volume. Always use the %MinVol control to adjust ventilation.

Table C-1. Blood gas results and other conditions with possible ASV adjustments

Condition	%MinVol change	Remarks
Normal arterial blood gases	None	--
High $PaCO_2$	Increase %MinVol	Pay attention to inspiratory pressures
Low $PaCO_2$	Decrease %MinVol	Pay attention to mean pressures and oxygenation status
High respiratory drive	Consider increase in %MinVol	Consider sedation, analgesia, or other treatments
Low O_2 saturation	None	Consider increase in PEEP/CPAP and/ or Oxygen

Step 5: Alarm settings review and special ASV alarms

To monitor the breathing pattern, you must review the alarm settings periodically and set them according to clinically acceptable values. As described below, ASV changes the breathing pattern according to the respiratory system mechanics and within the boundaries resulting from the operator's settings for ASV. However, you can closely monitor ASV's actions through the alarm system, since the alarm settings work totally independently of ASV.

It is possible to select a %MinVol that is incompatible with the lung-protective rules that govern ASV (for a detailed description, see Section C.3.3). For example, the operator might want a high ventilation for a COPD patient in spite of severe pulmonary obstruction. In such a case, ASV tries to achieve the maximum possible ventilation and alarms that **`ASV: Unable to meet target`**. Such a case is shown in

Figure C-3, where a high ventilation (300% at 70 kg) was set by the operator for a patient with severely obstructed lungs (Raw (total airway resistance) = 40 $cmH_2O/l/s$). The high ventilation moves the minimum minute volume curve to the right while the obstructive disease causes the safety limit of rate to shift to the left. These two effects cause the minute volume curve to lie outside the safety limits as determined by the lung-protective rules strategy (see functional description below). ASV thus chooses the safest point closest to the user-set minute volume.

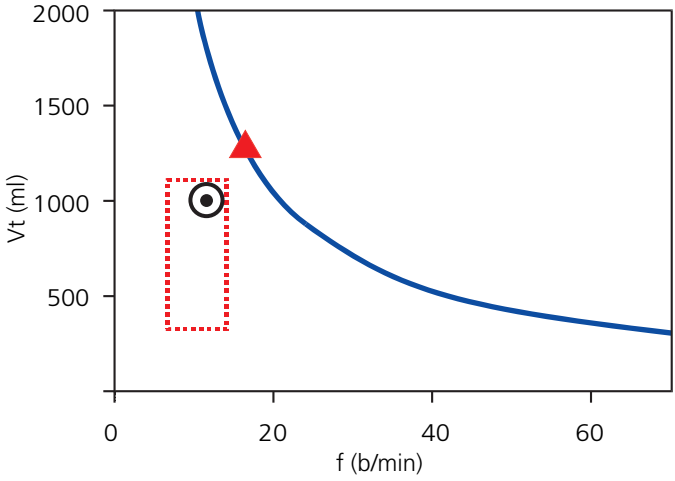
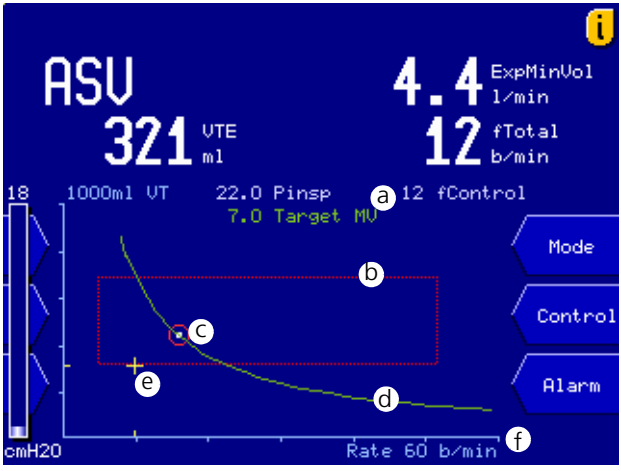


Figure C-3. Hypothetical example of high %MinVol setting incompatible with the lung-protective rules strategy. The open circle denotes the actual target, the closed triangle (never shown on the ventilator) denotes the (energetically) optimal target according to Otis' equation. The RAPHAEL will alarm and inform the user that the ASV target cannot be achieved.

Step 6: Monitoring ASV

ASV interacts with the patient continuously. Whenever the patient's respiratory mechanics change, ASV adapts to this change. Whenever the patient's breathing activity changes, ASV adapts. To let you view the current status, the RAPHAEL provides the ASV target graphics screen (Figure C-4) and the ASV monitored data window (Figure C-5).

To monitor progress over time, it is recommended that the trends for Pinsp, fTotal, and fSpont be plotted. These trends, together with the %MinVol setting, must be interpreted. Table C-2 through Table C-4 give an overview of typical ventilatory patterns and their possible interpretation from a technical point of view.



a. Pinsp = inspiratory pressure set by ventilator, in cmH_2O, Target MV = target minute volume to be delivered, in l/min, fControl = machine rate, in b/min.

b. Safety frame in which target point may move.

c. Target point, formed by intersection of target tidal volume and target rate (fTotal).

d. Minute volume curve.

e. Actual measured point, formed by intersection of measured tidal volume and rate.

f. Horizontal axis for rate (f). Vertical axis for tidal volume (VT).

Figure C-4. ASV target graphics screen

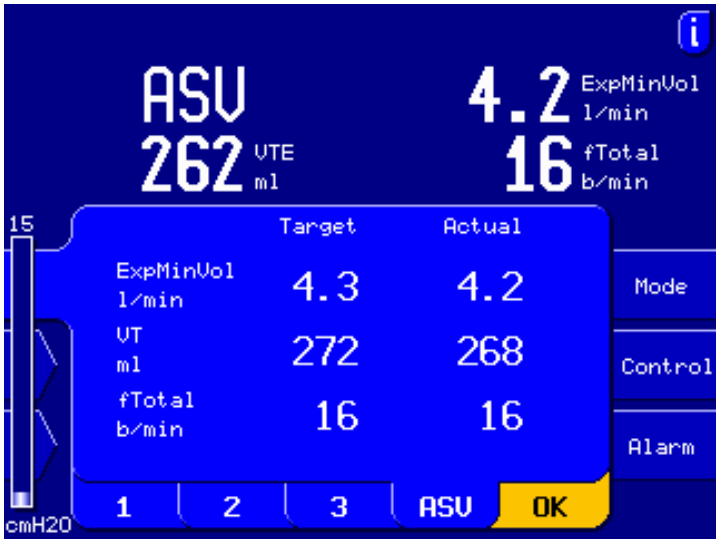


Figure C-5. ASV monitored parameter window

Table C-2. Interpretation of breathing pattern at 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
> 10	> 10	0	Fully controlled, mechanical ventilation. To start weaning, consider reducing %MinVol.
> 10	0	Accept-able	Supported spontaneous breathing. Consider reducing %MinVol.
< 8	0	Accept-able	**Unsupported breathing**. Consider extubation.
> 10	0	High	Dyspnea. Consider increasing %MinVol and other clinical treatments. Check for autotriggering.

Table C-3. Interpretation of breathing pattern at much higher than 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
> 10	> 10	0	Fully controlled mechanical ventilation. Check arterial blood gases. To start weaning, consider reducing %MinVol.
> 10	0	Acceptable	Supported spontaneous breathing. Check reason for increased ventilation requirement. Consider reducing %MinVol.
< 8	0	Acceptable	**Unsupported breathing.** Check reason for increased ventilation requirement. Consider reducing %MinVol and extubation.
> 10	0	High	Dyspnea. Check reason for increased ventilation requirement. Consider other mode of ventilation and clinical treatment. Check for autotriggering.

Table C-4. Interpretation of breathing pattern at much lower than 100% MinVol setting

Pinsp	fControl	fSpont	Interpretation
>10	> 10	0	Danger of hypoventilation. Check arterial blood gases and consider increasing %MinVol.
>10	0	Acceptable	Enforced weaning pattern. Monitor arterial blood gases and patient respiratory effort. Consider decreasing or increasing %MinVol accordingly.
<8	0	Acceptable	**Unsupported breathing**. Consider extubation.
>10	0	High	Dyspnea. Consider increasing %MinVol and other clinical treatments. Check for autotriggering.

Step 7: Weaning

Weaning patients from the ventilator is a clinical task that requires tremendous experience and involves more than just ventilation issues. This appendix does not intend to provide clinical information other than that needed to operate the ventilator with ASV.

ASV always allows patients to take spontaneous breaths. Episodes of spontaneous breathing can occur and are supported by ASV even within a period of fully controlled ventilation. In other words, weaning can start with ASV so early that it may go unrecognized clinically. It is therefore important to monitor the spontaneous efforts of the patient over time.

The weaning progress can be monitored in the trends display when inspiratory pressure (Pinsp), total rate (fTotal), and spontaneous rate (fSpont) are plotted. If the patient tolerates minimum respiratory support after a period of time with

Pinsp < 8 cmH_2O

fControl = 0

weaning can be considered achieved, if minimum

fSpont is acceptable

ExpMinVol is acceptable

What is "acceptable" must be defined by the clinician.

It may be necessary to reduce the %MinVol setting to 70% or even lower to "motivate" the patient to resume spontaneous breathing. If a patient can sustain minutes or even hours with a low %MinVol setting, it does not mean that weaning is complete. In fact, the %MinVol setting must always be interpreted in conjunction with the level of Pinsp needed to achieve the set minute ventilation. Only if Pinsp and fControl are at their minimal values can weaning be assumed to be complete

C.3 Detailed functional description of ASV

C.3.1 Definition of normal minute ventilation

ASV defines normal minute ventilation according to the graph in Figure C-6.

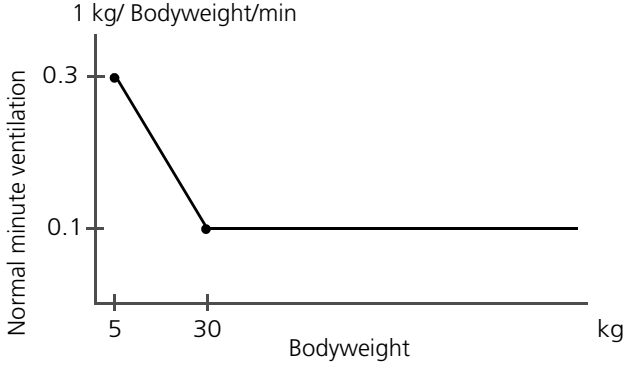


Figure C-6. Normal minute ventilation as a function of bodyweight

For example, for a Body Wt setting of 70 kg, normal minute ventilation corresponds to 7 l/min.

C.3.2 Targeted minute ventilation

When selecting ASV, it is necessary to select an appropriate minute ventilation for the patient. Minute ventilation is set with the %MinVol control, which, together with the Body Wt control, determines the total minute ventilation in liters per minute.

A %MinVol setting of 100% corresponds to a normal minute ventilation, as defined above. A setting less than 100% or higher than 100% corresponds to a minute ventilation lower or higher than normal.

From the %MinVol, the target minute ventilation (in l/min) is calculated as:

Bodyweight (in kg) x NormMinVent (in l/kg/min) x (%MinVol/100)

where NormMinVent is the normal minute ventilation from Figure C-6.

For example, with a %MinVol = 100 and a Body Wt = 70 kg, a target MinVol of 7 l/min is calculated. This target can be achieved with a number of combinations of tidal volume (VT) and respiratory rate (f). This is shown in Figure C-7, where all possible combinations of VT and f lie on the bold line, the target minute volume curve.

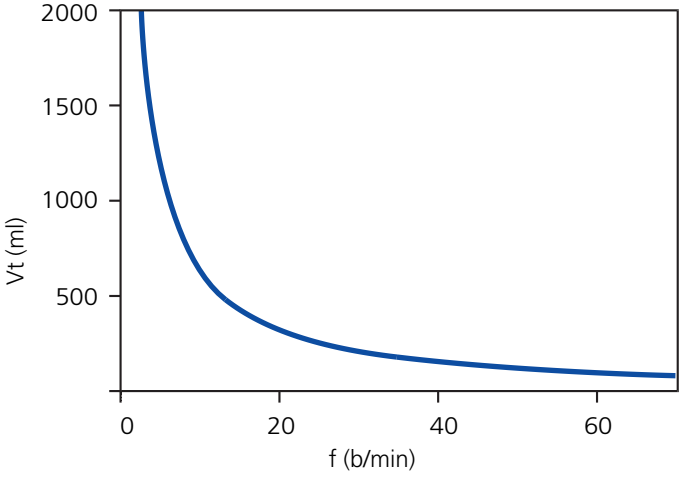


Figure C-7. MinVol = 7 l/min. All possible combinations of VT and f which result in a minute ventilation of 7 l/min lie on the bold line.

C.3.3 Lung-protective rules strategy

Not all combinations of VT and f shown in Figure C-7 are safe for the patient. The high tidal volumes would overdistend the lungs and the small tidal volumes may not produce alveolar ventilation at all. Another risk lies in inadequate respiratory rates. High rates could lead to dynamic hyperinflation or breath stacking and thus inadvertent PEEP. Low rates may lead to hypoventilation and apnea. It is therefore necessary to limit the number of possible combinations of VT and f.

In limiting the possible combinations of VT and f, ASV uses a double strategy:

- The operator input for ASV determines the absolute boundaries.
- Internal calculations based on patient measurements further narrow the limits to counteract possible operator errors and to follow changes of respiratory system mechanics.

The effect of the strategy is shown in Figure C-8 and explained in the subsequent subsections.

A: High tidal volume limit

The tidal volume applied by ASV is limited (see A in Figure C-8) by two operator settings: Pasvlimit and Body Wt.

The operator is required to set the Pasvlimit before connecting a patient to the RAPHAEL. It was recommended by a group of physicians (Slutsky 1994) that the plateau pressure not exceed 35 cmH_2O.

For example, a normal 70 kg normal (post-operative) patient would have a compliance of about 50 ml/cmH_2O. With a PEEP level of 5 cmH_2O and a Pasvlimit of 35 cmH_2O, the effective pressure swing would be 30 cmH_2O. This in turn would lead to an effective VT of equal to or less than 1500 ml. If the patient's lungs stiffen, say to a compliance of 30 ml/cmH_2O, the maximum tidal volume becomes 900 ml.

If the operator sets the Pasvlimit to a very high pressure, say 50 cmH_2O, the target volume is limited by the second criterion: 22 x Body Wt. For the 70 kg sample patient, a maximum target volume of 1540 ml results.

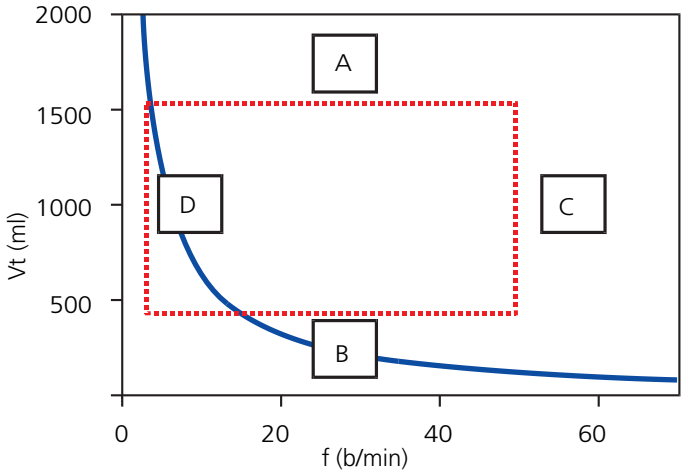


Figure C-8. Lung-protective rules strategy to avoid high tidal volumes and pressures (A), low alveolar ventilation (B), dynamic hyperinflation or breath stacking (C), and apnea (D)

B: Low tidal volume limit

The minimum target VT in ASV (see B in Figure C-8) is determined by the Body Wt setting and corresponds to 4.4 ml/kg. Thus, in a 70 kg patient, the minimum target VT is 308 ml.

The danger with low tidal volumes is insufficient alveolar ventilation. The determining parameter for alveolar ventilation is dead space (Vd). Tidal volume must always be larger than Vd. It is widely accepted that a first approximation of dead space can be obtained by the following simple equation (Radford 1954):

$$Vd = 2.2 \times \text{Body Wt} \quad (1)$$

The lower limit for tidal volume is based on this equation and calculated to be at least twice the dead space. In other words, the minimum VT is 4.4 x Body Wt.

C: High rate limit

The maximum rate (see C in Figure C-8) is derived from the operator settings, %MinVol and Body Wt. The equation used to calculate the maximum rate is as follows:

fmax = target MinVol / minimum VT (2)

For example, the 70 kg patient described above would have a maximum rate of 22 b/min, when %MinVol is set to 100%.

However, if the operator chooses an excessively high %MinVol of, say, 350%, the maximum rate becomes 77 b/min. To protect the patient against such high rates, ASV employs a further safety mechanism, which takes into account the patient's ability to exhale.

A measure of the ability to exhale is the expiratory time constant (RCexp) (Marini 1989, Brunner 1995). In order to achieve a nearly complete exhalation to the equilibrium point of the respiratory system (90% of the maximum potential volume change), an expiratory time of at least 2 x RCexp is theoretically required. For this reason, ASV calculates the maximum rate based on the principle of giving a minimum inspiratory time equal to 1 x RCexp and a minimum expiratory time equal to 2 x RCexp, which results in the following equations:

fmax = 60 / (3 x RCexp) =20 / RCexp
fmax ≤ 60 b/min (3)

For example, the 70 kg patient with a respiratory system compliance of 50 ml/cmH_2O (equal to 0.05 l/cmH_2O), an airway resistance including endotracheal tube of 5 cmH_2O/l/s, and a resistance of the expiratory hose and valve of another 5 cmH_2O/l/s, would have an RCexp of

0.05 l/cmH_2O x (5+5) cmH_2O/l/s = 0.5 s

and thus a maximum rate of 40 b/min. Since this value is higher than the one calculated above, the lower of the two values is in effect, i.e., 22 b/min.

D. Low rate limit

The lowest target rate (see D in Figure C-8) is fixed at 5 b/min. This low rate in turn limits the maximum tidal volume to 1400 ml in the example of the 70 kg patient above, when %MinVol is set to 100%.

C.3.4 Optimal breath pattern

Although the lung-protective rules strategy limits possible combinations of VT and f, ASV prescribes an explicit target combination. In fact, Figure C-8 shows considerable room for selection within the dotted rectangle. The selection process is an exclusive feature of ASV. The basic assumption is that the optimal breath pattern is identical to the one a totally unsupported patient would choose naturally, provided that patient is capable of maintaining the pattern.

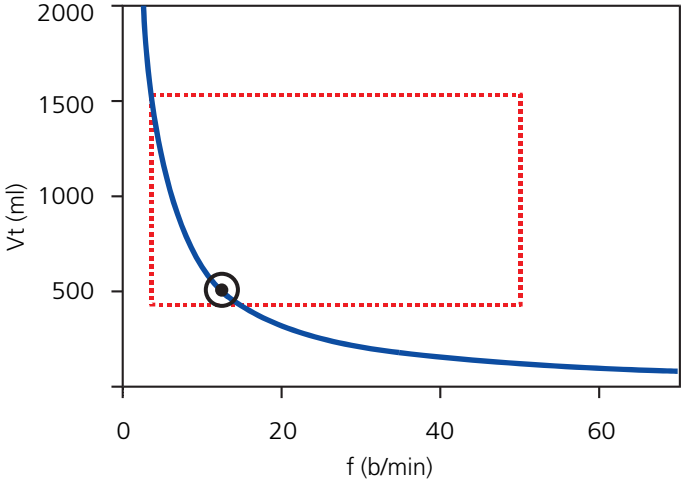


Figure C-9. ASV target screen. The rectangle shows the safety limits; the circle shows the target breath pattern.

According to textbooks of physiology, the choice of breathing pattern is governed by either work of breathing or the force needed to maintain a pattern. ASV uses the original equation by Otis (Otis 1950) and calculates the optimal rate based on operator entries of %MinVol and Body Wt as well as on the measurement of RCexp (see Section C.4).

For example, with the 70 kg patient, a setting of 100 %MinVol, and a measured RCexp of 0.5 s, the optimal rate is 15 b/min according to Otis' equation.

Once the optimal rate is determined, the target VT is calculated as:

VT = target MinVol / optimal rate (4)

In the example of the 70 kg patient, the target VT becomes 467 ml (see Section C.4 for details).

Figure C-10 summarizes the calculations done in the previous subsections and shows the position of the target breathing pattern as well as the safety limits imposed by the lung-protective rules strategy.

C.3.4.1 Initial breaths: How ASV starts

The question is, how to achieve the target values in a given patient if it is not known whether or not the patient can breathe spontaneously. For this purpose, ASV employs a synchronized intermittent mandatory pressure ventilation mode.

Every breath triggered by the patient is pressure-supported and flow-cycled, i.e., the transition to exhalation is made based on flow. In contrast, if the patient does not trigger the breath, the delivery of the breath is pressure-preset and time-cycled.

The following controls can be set by the operator:

- PEEP/CPAP
- Oxygen
- Trigger type and sensitivity

The following controls are adjusted automatically by ASV and thus cannot be adjusted by the operator:

- SIMV rate: to change total respiratory rate
- Inspiratory pressure level: to change inspiratory volume
- Inspiratory time: to allow gas flow into the lungs
- Startup breath pattern

To safely start ASV, the operator inputs initial parameters through the Body Wt control, according to Table C-6.

Three initial test breaths are delivered. The resulting rate and tidal volume are measured and compared with the target values. ASV then responds according to the differences between the actual and target VT as well as the actual and target rates.

C.3.4.2 Approaching the target

Figure C-10 shows a possible scenario after the three initial test breaths. The actual breath pattern, which is plotted as a cross, shows clear deviation from the target. The task of ASV is now to move the cross as close to the circle as possible.

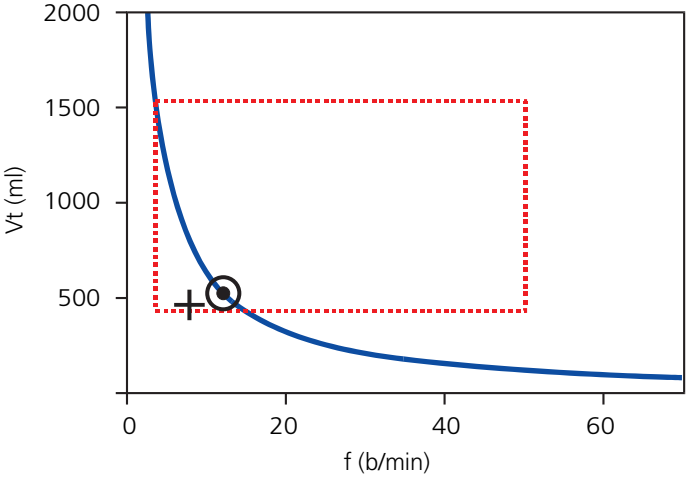


Figure C-10. Example of a situation after the three initial breaths. The cross marks the actual measured values for VT and rate.

To achieve the target, the following strategy is used:

- If actual VT < target VT, the inspiratory pressure is increased.
- If actual VT > target VT, the inspiratory pressure is decreased.
- If actual VT = target VT, the inspiratory pressure is left unchanged.
- If actual rate < target rate, the SIMV rate is increased.
- If actual rate > target rate, the SIMV rate is decreased.
- If actual rate = target rate, the SIMV rate is left unchanged.

As a result, the cross in Figure C-10 moves toward the circle. The actual VT is calculated as the average of inspiratory and expiratory volumes of the last 8 breaths. This definition compensates in parts for leaks in the breathing circuit, including the endotracheal tube.

C.3.5 Dynamic adjustment of lung protection

The operator preset values are not changed by ASV, and the corresponding safety limits remain as defined above. However, if the respiratory system mechanics change, the safety limits change accordingly and as defined in Section C.3.3. The safety limits are updated on a breath-by-breath basis.

For example, if the lungs stiffen, the high VT limit is lowered proportionally, and the high fTotal limit is increased according to Otis' equation (see Section C.4).

This dynamic adjustment ensures that ASV applies a safe breathing pattern at all times. In graphical terms, the dotted rectangle changes as shown in Figure C-11.

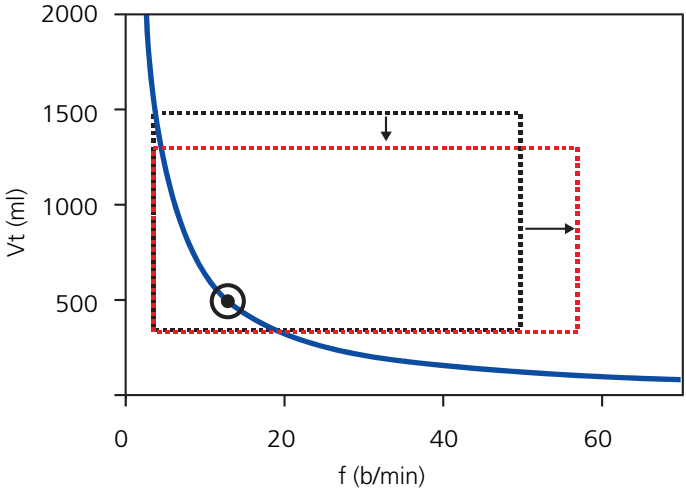


Figure C-11. Lung-protective limits are changed dynamically and according to the respiratory system mechanics. However, the limits derived from the operator input are never violated.

C.3.6 Dynamic adjustment of optimal breath pattern

Once calculated, the optimal breath pattern is revised with each breath according to the measurements of RCexp and dynamic compliance. Otis' equation is applied and a new target breathing pattern is calculated. Under steady-state conditions, the targets do not change. However, if the patient's respiratory system mechanics change, the target values also change.

For example, if the bronchi of our normal 70 kg patient (being ventilated at 15 b/min and with a VT of 467 ml) constrict due to asthma, the expiratory resistance increases to values higher than 5 $cmH_2O/l/s$. For this reason, more time is needed during exhalation for the lungs to reach the end-expiratory equilibrium position. Technically speaking, RCexp has increased and this increase requires a longer expiratory time. For a given minute ventilation, this calls for an increase in VT and a decrease in rate (longer expiratory time). Otis' equation yields the following new targets: f = 11 b/min and VT = 636 ml. Figure C-12 shows the change. Note also that the increase in resistance results in a decrease in the volume/pressure ratio (V/P). The changes in RCexp and dynamic compliance affect the safety limits accordingly and with each breath (see previous subsection).

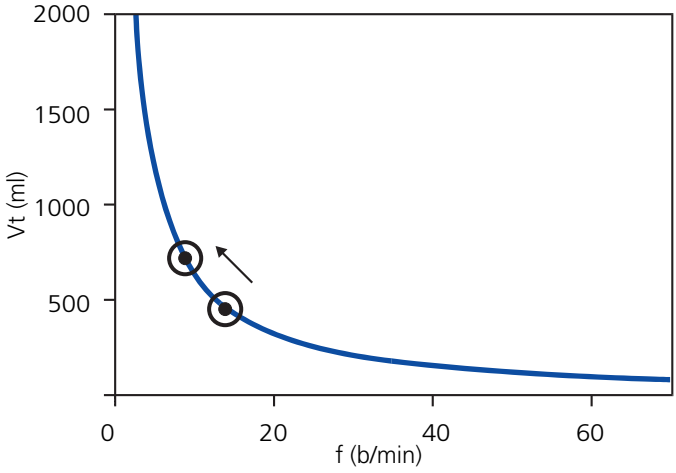


Figure C-12. Changes of target values in broncho-constriction. For clarity, the safety limits are omitted. For clinical examples, see Belliato 2000.

C.4 Minimum work of breathing (Otis' equation)

Otis' basic question was: how do mammals choose their breathing pattern and on what parameters does it depend (Otis 1950)? The same question was investigated years before by Rohrer and a very similar result was obtained (Rohrer 1925). The hypothesis was that the breath pattern with the least work of breathing (WOB) is chosen by mammals. Figure C-13 below shows the relationship between rate and WOB graphically, for resistive load, elastic load, and total load to breathing.

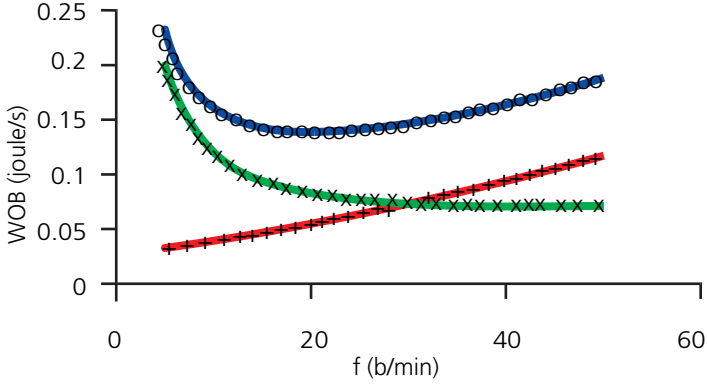


Figure C-13. Three different relationships between rate and WOB are plotted for a hypothetical lung: (+) purely resistive load causes WOB to rise with rate, (x) purely elastic load creates highest load at low rates, (o) the total lung shows a clear minimum which can be calculated according to the equation below.

The following equation was found to represent the rate where WOB is minimum:

$$f = \frac{\sqrt{1 + 2a \times RCexp \times (MinVol - f \times Vd)/Vd} - 1}{a \times RCexp}$$

where *a* is a factor that depends on the flow waveform. For sinusoidal flows, *a* is $2\pi^2/60$.

The corresponding tidal volume is calculated as:

VT = MinVol/f

Example: A 70 kg male patient with normal lungs (Rtotal = 5 $cmH_2O/l/s$, expiratory resistance hose and valve = 5 $cmH_2O/l/s$, Crs = 50ml/cmH_2O) may have a measured RCexp of 0.5 s, an estimated Vd of 154 ml, and an operator-set %MinVol of 100%. With these values, the target MinVol becomes

MinVol = 100% x 70 kg x 0.1 l/min/kg = 7 l/min

Next, Otis' equation is applied with the following parameters:

MinVol = 7 l/min

Vd = 154 ml

RCexp = 0.5s

$a = 2\pi^2/60$

f = 10 b/min (determined using Table C-6)

The result is a new rate f(1)

f(1) = 15 b/min

This rate is again inserted into Otis' equation, the calculation is performed again, and the next estimate for rate f(2) is obtained. This procedure is repeated until the difference between subsequent results for rate (f) becomes lower than 0.5 b/min. In the present example, one iteration step is sufficient, i.e.,

ftarget = 15 b/min

Finally, the target tidal volume is obtained by dividing MinVol by f:

VTarget = 7000 ml/min / 15 b/min = 467 ml

C.5 ASV technical data

Table C-5 lists technical data related to ASV. Underlined parameters are operator-set in the ASV mode.

Table C-5. ASV technical data

ASV-related operator settings	
%MinVol	25 to 350%
Body Wt (ideal body weight, IBW)	5 to 200 kg
Internal calculations	
MinVol (target)	In l/min, target minute volume is calculated as: Body Wt (in kg) x NormMinVent (in l/kg/min) x %MinVol/100 where NormMinVent is the normal minute ventilation from Figure C-6.
fTotal	In b/min, calculated on the basis of Otis' equation
Vd	2.2 ml/kg Body Wt
VT (target)	MinVol/ f(target)
ASV monitor	
Target values (numerical)	MinVol, VT, fTotal
Actual achieved values (numerical)	MinVol, VT, fTotal
Status of patient (numerical)	fSpont, fControl, Pinsp
Graphics display (curve)	f versus VT, target value, actual value, safety boundaries
Alarms	
All RAPHAEL alarms are functional except apnea alarms	See Section 6
Special	**ASV: Pressure limitation**, **ASV: Unable to meet target**

Table C-5. ASV technical data (continued)

Performance specifications	
Response time (90% of steady state)	< 1 min (typical)
Overshoot/undershoot	< 20%
Maximum pressure change per breath	2 cmH_2O
Lung-protective rules	
Maximum VT	Depends on Pasvlimit setting and volume/pressure ratio (V/P) However, normally MinVol/5, but always < 22 ml/kg x Body Wt
Minimum VT	4.4 ml/kg x Body Wt
Maximum machine rate	Depends on RCexp
Minimum target rate	5 b/min
Maximum Pinsp	Pasvlimit
Minimum Pinsp	5 cmH_2O above PEEP/CPAP
Minimum inspiratory time (Ti)	RCexp or 0.5 s, whichever is longer
Maximum inspiratory time (Ti)	2 s
Minimum expiratory time (Te)	2 x RCexp or 0.5 s, whichever is longer
Maximum expiratory time (Te)	12 s
I:E range	1:4 to 1:1

C.6 Initialization of ventilation

When ASV is started, the RAPHAEL delivers three test breaths in the synchronized intermittent mandatory pressure ventilation mode. the RAPHAEL automatically selects the values for SIMV rate, inspiratory time (Ti), and inspiratory pressure (Pinsp) based on the operator-selected Body Wt setting, and according to Table C-6.

Table C-6. Initial breath pattern

Body Wt (kg)	Pinsp (cmH_2O)	Ti (s)	SIMV rate (b/min)
5	15	0.6	35
6 to 8	15	0.6	25
9 to 11	15	0.6	20
12 to 20	15	1	20
22 to 29	15	1	15
30 to 39	15	1	14
40 to 59	15	1	12
60 to 89	15	1	10
90 to 100	18	1.5	10
> 100	20	1.5	10

C.7 References

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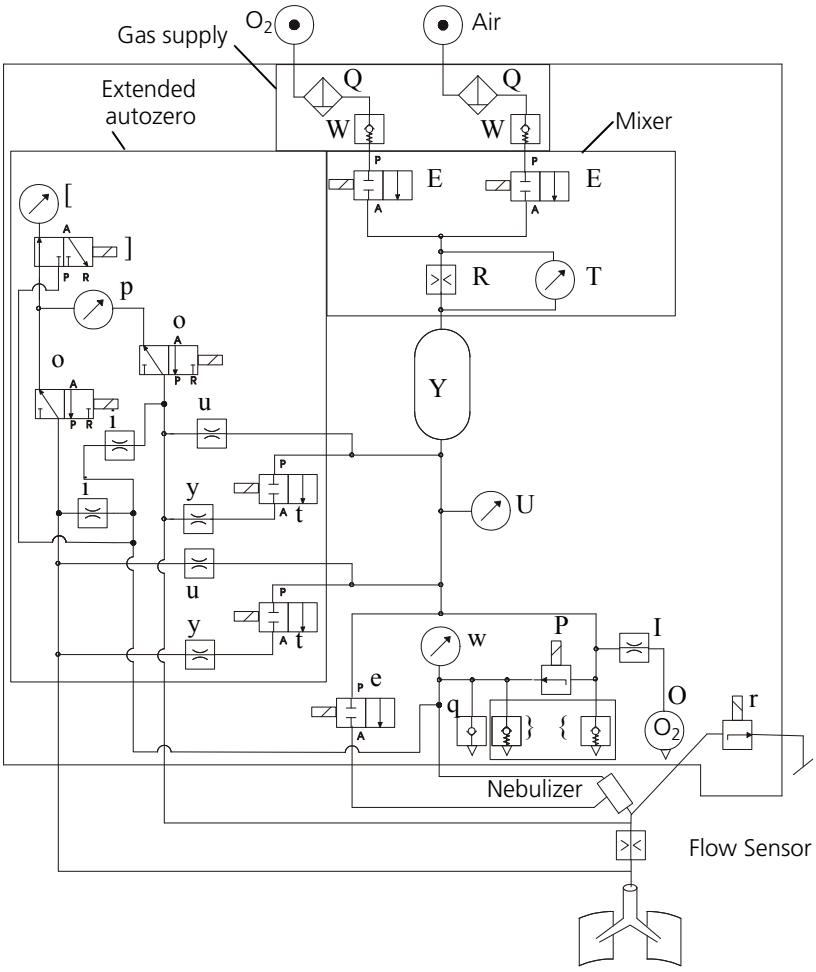
- **.....more** and updated references on www.hamilton-medical.com

APPENDIX

D Pneumatic system



Legend

Q Microfilter with condensate drain

W Check valve

E Mixer valve

R Orifice

T Pressure sensor (dP_{mixer})

Y Tank, 2 liter

U Pressure sensor (P_{tank})

I Flow restrictor, oxygen measurement

O Oxygen cell

P Inspiratory valve

{ Overpressure valve, tank

} Overpressure valve, patient

q Ambient valve

w Pressure sensor (P_{vent})

e Nebulizer valve

r Expiratory valve

t Sensor testing valve

y Flow restrictor, increased rinse flow

u Flow restrictor, base rinse flow

i Flow restrictor, overpressure protection dP_{ptm}

o Autozero valve

p Pressure sensor (dP_{ptm})

[Pressure sensor (P_{prox})

] Valve ($P_{vent\ zero}$)

APPENDIX

E Configuration

E.1 Introduction

The configuration mode lets you set default values for ventilator parameters according to your institution's protocols. It also lets you enable and disable the oxygen monitoring and flow sensing capabilities, and view up to 1000 events stored in the event log. You typically configure the ventilator when you first acquire it, before you put it on a patient.

If you decide not to change the configuration, the ventilator will default to the factory settings (Table A-7).

E.2 Accessing the configuration mode

To access the configuration mode, power on the ventilator, then immediately press the knob. Do not release the knob until the system check is finished. You will see the **Configuration** mode screen (Figure E-1).

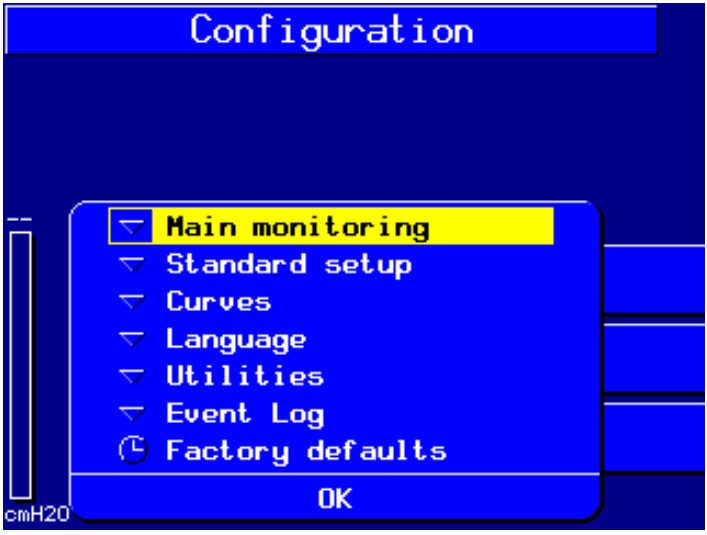


Figure E-1. Configuration mode screen

E.3 Language: Selecting the default language

The RAPHAEL offers different languages to choose from. Select the language, as follows:

1. From the configuration mode screen, select **`Language`**. You will see the language window.
2. Select the desired language, activate, and confirm. You will return to the **`Configuration`** mode screen.

E.4 Main monitoring: Selecting the default patient data display

This function lets you select the main monitoring parameters to be displayed on the basic screen. Select the main monitoring parameters, as follows:

1. Select **`Main monitoring`**. You will see the main monitoring parameter window (Figure E-2).
2. A parameter position will be enclosed by a yellow box. Turn the knob to select the parameter you want displayed in this position. Press the knob to activate.

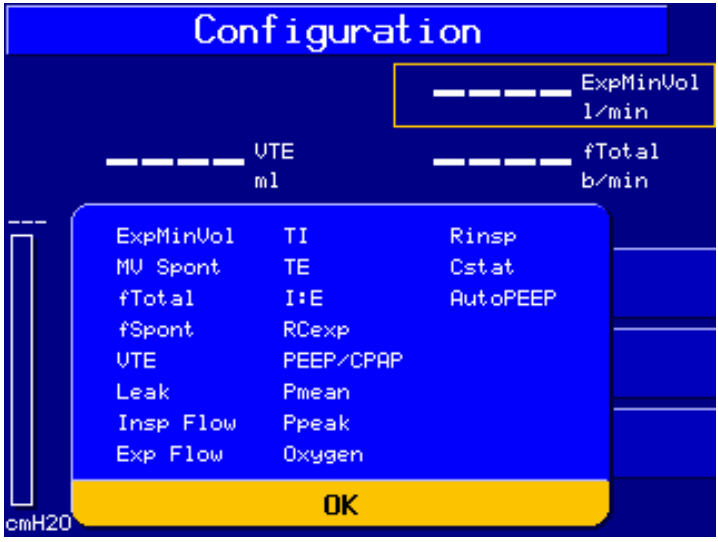


Figure E-2. Main monitoring parameter window, configuration mode

3. Repeat for the other two parameter positions.
4. Confirm all selections. You will return to the **`Configuration`** mode screen.

E.5 Standard setup: Selecting the default control settings

This function lets you define default values for ventilation. This includes the ideal bodyweight input, standard mode of ventilation, control parameters, and the alarm limits for Pmax and fTotal. Select the default values from the ranges shown in Table E-1, as follows:

1. Select **`Standard setup`**. You will see the **`Bodyweight`** window (Figure E-3).

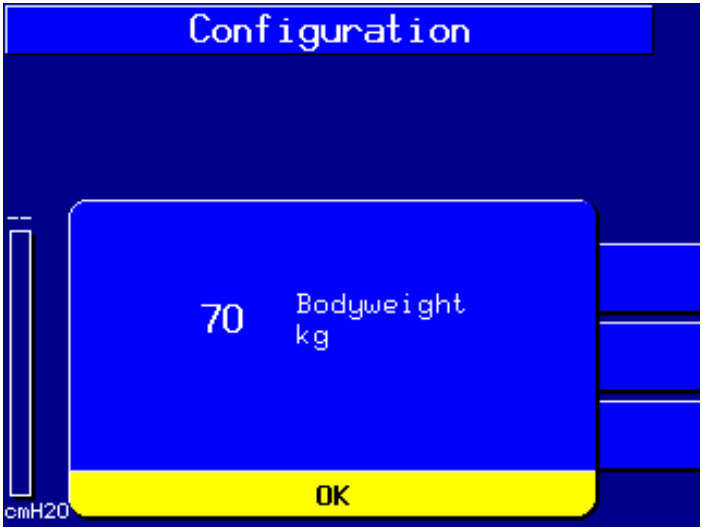


Figure E-3. Bodyweight window, configuration mode

2. Select **`Bodyweight`** and activate. Adjust the patient's bodyweight and activate. Confirm.

3. You will see the available modes window (Figure E-4). Select a mode. Enable or disable to display or suppress the mode; suppressed modes will not be shown in the mode window during ventilation. Continue with remaining modes. Confirm.

NOTE:

PCV+ and SIMV+ are always enabled. PCV+ is used in case of Flow Sensor problems. SIMV+ is used as an apnea backup mode.

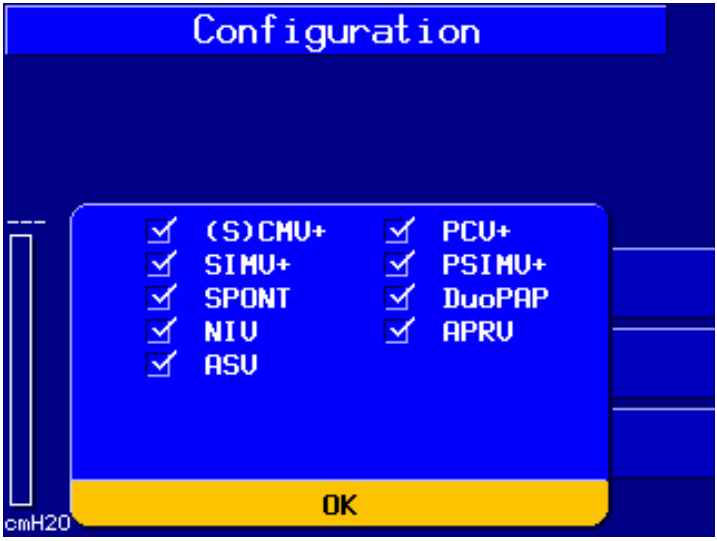


Figure E-4. Available modes window

4. You will see the mode window (Figure E-5). Choose the desired default mode; this is the mode in which the ventilator will automatically start up. Enable or disable sigh and apnea backup as desired. Adjust the default apnea time. Confirm.

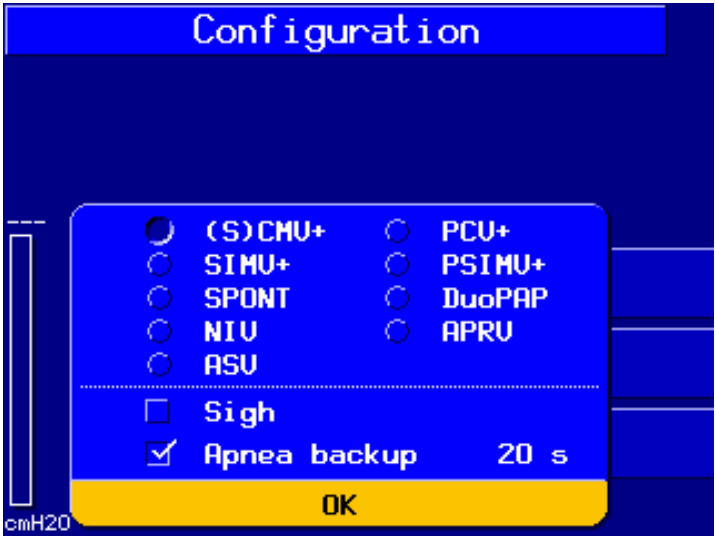


Figure E-5. Mode window, configuration mode

5. You will see control window 1 (Figure E-6). Set the default values for the first control parameter and activate (for control parameter ranges, see Table E-1). Adjust and activate. Repeat for the other control parameters. Open control window 2 (Figure E-7) and repeat. Confirm.

NOTE:

- The Pcontrol configuration setting is also the default setting for Psupport.
- The VT/kg configuration setting is used to calculate the default Rate.
- In the SIMV modes, the I:E configuration setting determines TI. If the calculated Rate < 15 b/min, the default TI is based on a Rate of 15 b/min.
- In DuoPAP and APRV, timing settings are determined from the calculated Rate and I:E. The PEEP/CPAP configuration setting is the default P low setting in the APRV mode. The sum of the PEEP/CPAP and Pcontrol configuration settings is used as the P high setting.

Figure E-6. Control window 1, configuration mode

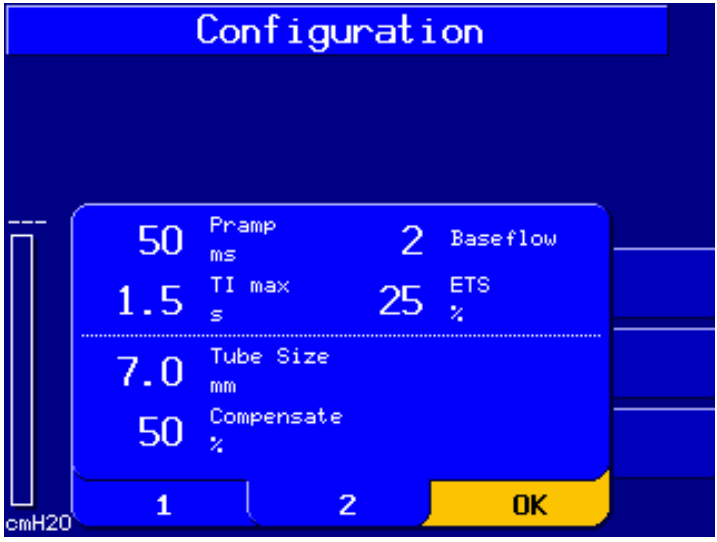


Figure E-7. Control window 2, configuration mode

6. You will now see the alarm window (Figure E-8).

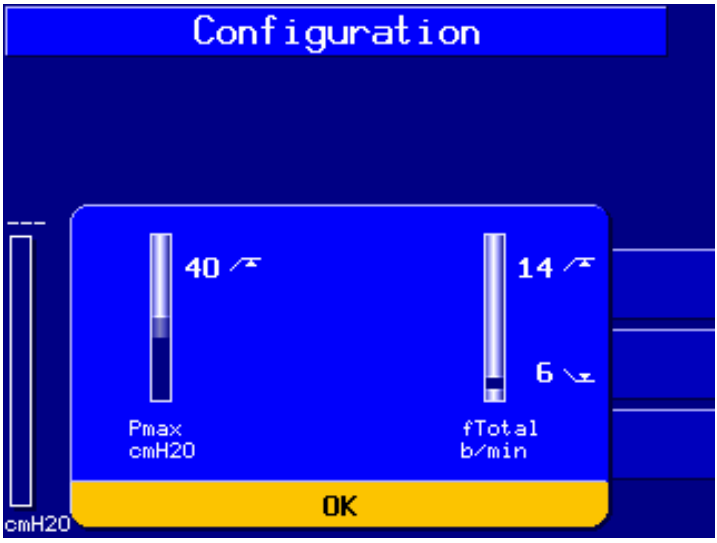


Figure E-8. Alarm window, configuration mode

7. Adjust the values for Pmax and fTotal. Confirm. You will return to the **`Configuration`** mode screen.

NOTE:

The alarm limits for ExpMinVol are automatically set based on the Rate and VT, which are in turn based on the bodyweight (see Table 4-6).

E.6 Curves: Selecting the default curve parameters

This function lets you set the default curve to be displayed on the basic screen.

1. Select **Curves**. You will see the curve selection window (Figure E-9).

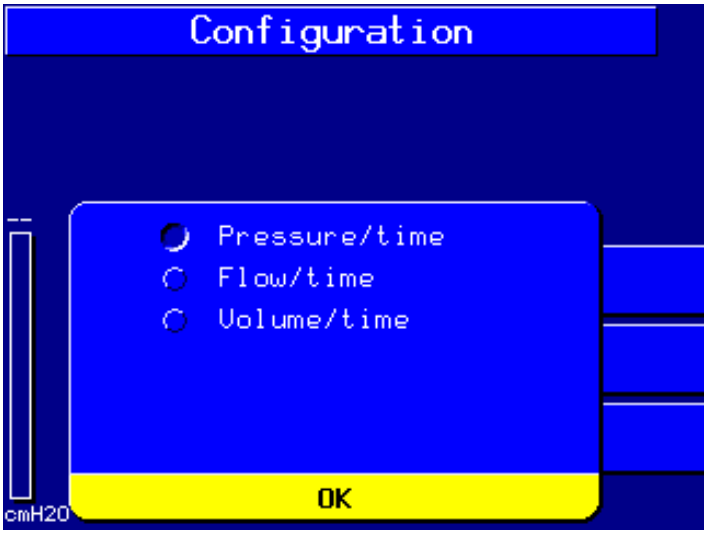


Figure E-9. Curves selection window, configuration mode

2. Select the desired curve and activate. Confirm. You will return to the **Configuration** mode screen.

E.7 Utilities

This function lets you enable and disable flow sensing and oxygen monitoring, enable an extended baseflow range, set the default alarm loudness, set the altitude, and set the date and time. When the extended baseflow range is enabled, the Baseflow control may be adjusted over its full range of 0 through 10; this range can be selected if the ventilator is connected to a central air supply. Otherwise, the Baseflow control may be adjusted over the range 0 through 2. (See Table 4-4 for information about setting the Baseflow.) The altitude setting is used to compensate flow and volume measurements.

WARNING

HAMILTON MEDICAL recommends that flow sensing always be enabled to facilitate monitoring and to safeguard the patient. If you choose to disable flow sensing, you must still provide the RAPHAEL with a patient pressure input by connecting a sensing line between the Y-piece and the blue Flow Sensor connector. The RAPHAEL will not ventilate unless it senses this pressure input; it will activate a `Disconnection` alarm.

NOTE:

When oxygen monitoring is disabled, the RAPHAEL activates a low-priority alarm and displays the message **`O2 monitoring deactivated`**.

When flow sensing is disabled, the following are true:

- Only the PCV+ mode is active.
- A low-priority **`Flow sensing deactivated`** alarm is activated.
- Patient triggering is disabled.
- Flow and volume monitoring and related alarms are disabled.

1. Select the utilities function. You will see utilities window 1 (Figure E-10).

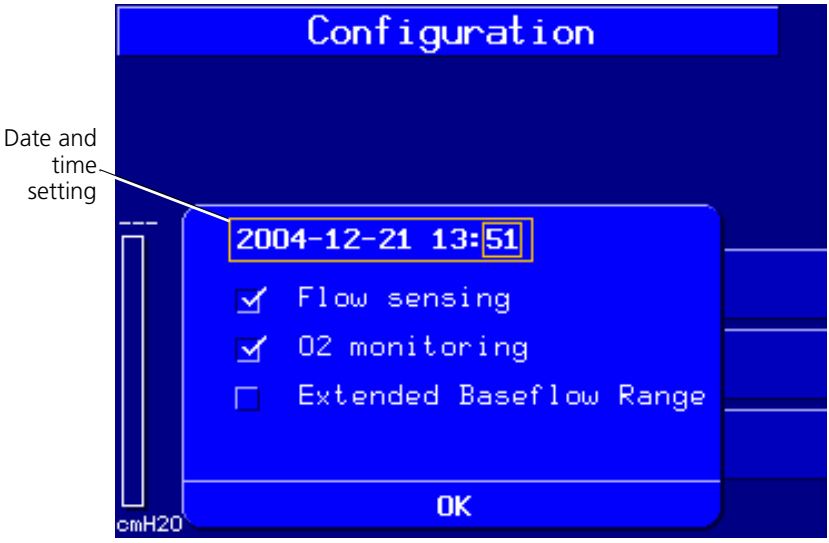


Figure E-10. Utilities window 1, configuration mode

2. Select the function you wish to change.

   For date and time setting, turn the knob to scroll to the desired element, then press the knob to activate. Adjust and activate. Repeat with rest of date and time.

   For flow sensing, oxygen monitoring, or extended baseflow range, press the knob to enable or disable it.

3. Continue with the other functions. Confirm.

4. You will see utilities window 2 (Figure E-11).

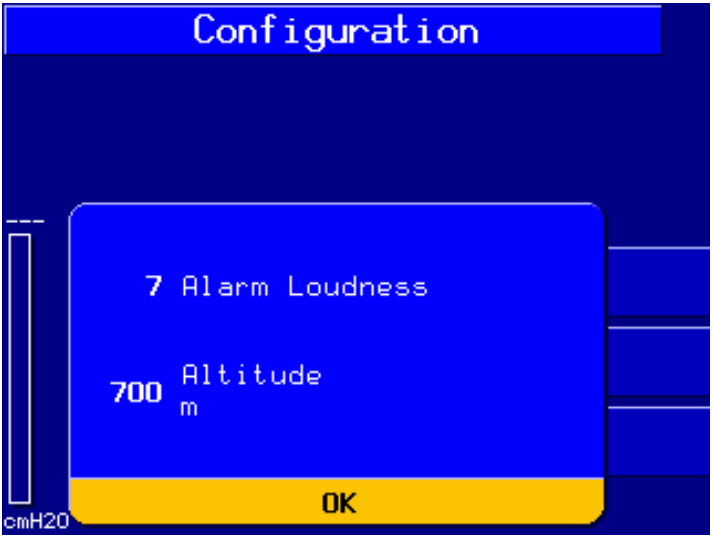


Figure E-11. Utilities window 2, configuration mode

5. Select the function you wish to change.

   For alarm loudness or altitude, press the knob then turn to activate the function, then turn the knob to adjust. For alarm loudness, the alarm will sound at the selected loudness level as you turn the knob. Press the knob to confirm the desired level.

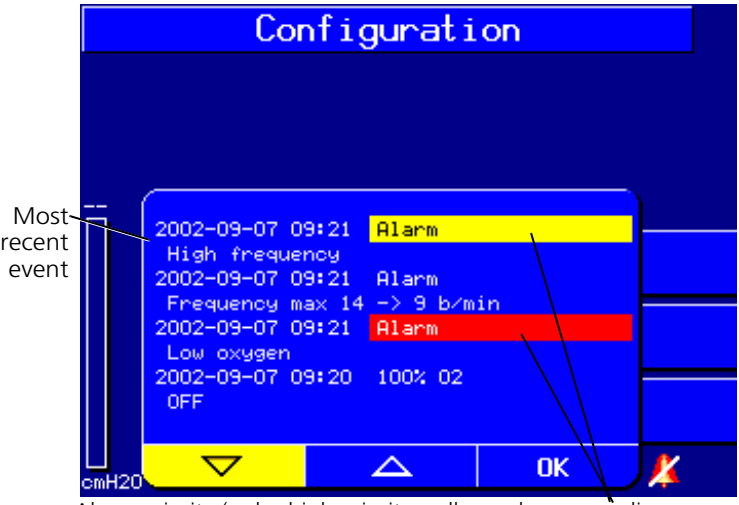
6. Confirm. You will return to the configuration mode screen.

E.8 Event log

The event log (Figure E-12) contains data about the last 1000 alarms and setting changes, including the date and time they occurred. This is an extended version of the event log you can view during ventilation. It contains not only the events that occurred since power-on, but also those that occurred beforehand. The extended version does not contain more details about these events.

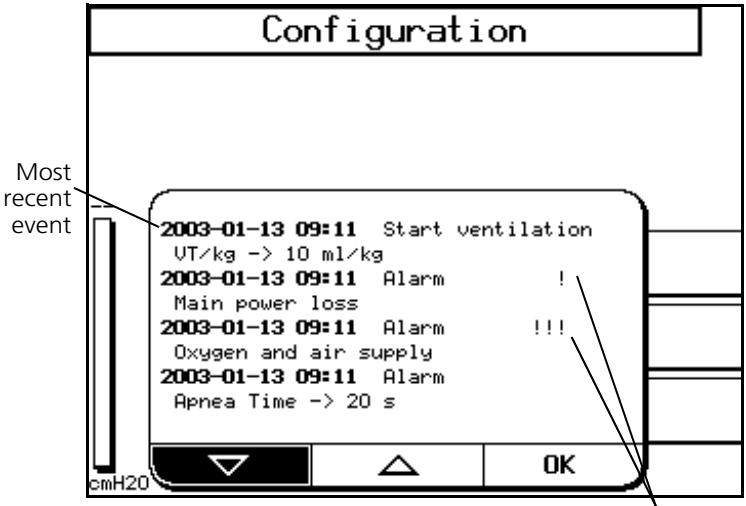
Examine the event log as follows:

1. Select **Event Log**. The event log will open with the most recent event at the top.
2. Select the up or down arrow by turning the knob. Press the knob repeatedly to scroll up or down as desired.
3. Select **OK** to close the event log and return to the **Configuration** mode screen.



Alarm priority (red = high priority, yellow = low or medium priority, white on blue = user message or others)

a. In RAPHAEL XTC or RAPHAEL Color



Alarm priority (3 = high, 2 = medium, 1 = low)

b. In RAPHAEL Silver or basic RAPHAEL

Figure E-12. Event log, configuration mode

E.9 Factory defaults

This function returns all values (except language) to the factory defaults (see Table A-7). The previous user settings are lost.

E.10 Configuration parameter ranges

Table E-1 shows the setting ranges for configuration parameters.

Table E-1. Configuration parameter ranges

Parameter	Range
Controls	
Apnea backup	On or off
Apnea time	15 to 60 s
Baseflow	0 to 2
Bodyweight	5 to 200 kg
ETS	10 to 50%
Flow sensing	On or off
I:E[1]	1:3.0 to 1:1 **NOTE:** In SIMV+ and PSIMV+ modes, TI is calculated from the I:E ratio, based on a rate of 15 b/min.
Modes	• Any number of modes from this list may be enabled (visible in modes window): (S)CMV+, SIMV+, SPONT, NIV, ASV, PCV+, PSIMV+, DuoPAP, APRV • One mode from list may be configured as the default mode

Table E-1. Configuration parameter ranges (continued)

Parameter	Range
O_2 monitoring	On or off
Oxygen	40 to 100%
Pcontrol[1]	10 to 25 cmH_2O
PEEP/CPAP[1]	0 to 5 cmH_2O
Pramp	50 to 200 cmH_2O
Sigh	On or off
TI max	1.0 to 3.0 s
Trigger	1 to 10 l/min
Tube resistance compensation Tube size Compensate	 5.0 to 10.0 mm 10 to 100%
VT/kg[1]	6 to 12 ml/kg **NOTE:** The ratio between bodyweight and the delivered tidal volume is set here in ml/kg bodyweight. Based on this and the initial patient bodyweight input, the RAPHAEL calculates the target tidal volume. This allows the user to implement the institution's philosophy of hyper- or hypoventilating patients.

Table E-1. Configuration parameter ranges (continued)

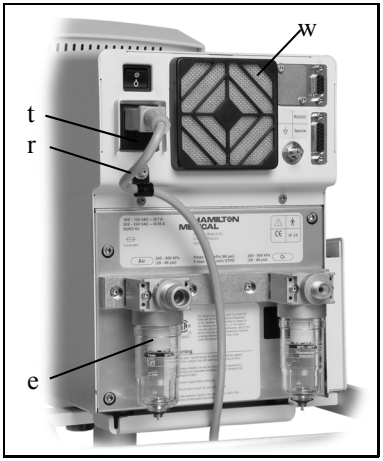
Parameter	Range
Alarms	
fTotal alarm, low and high	0 to 99 b/min
Pmax alarm	Minimum: Whichever is greater: • PEEP/CPAP setting + Pcontrol + 10 cmH_2O, or • 25 cmH_2O Maximum: 45 cmH_2O
Monitoring	
Patient data display	Three parameters can be selected for display from entire range of monitored parameters (Table 5-1)
Type of graphic	Pressure/time, flow/time, volume/time
Language	English, Chinese, Czech, Dutch, French, German, Hungarian, Italian, Japanese, Norwegian, Polish, Portuguese, Russian, Spanish
Utilities	
Flow sensing	Enabled or disabled
O_2 monitoring	Enabled or disabled
Extended Baseflow Range	Enabled or disabled
Alarm loudness	7 to 10
Altitude	0 to 4000 m (0 to 13,123 ft)

1. See p. E-8 for further details.

APPENDIX

F Parts and accessories

Table F-1, Table F-2, and Figure F-1 show the operator-replaceable RAPHAEL parts. For additional parts and accessories, contact your HAMILTON MEDICAL representative.



Rear view

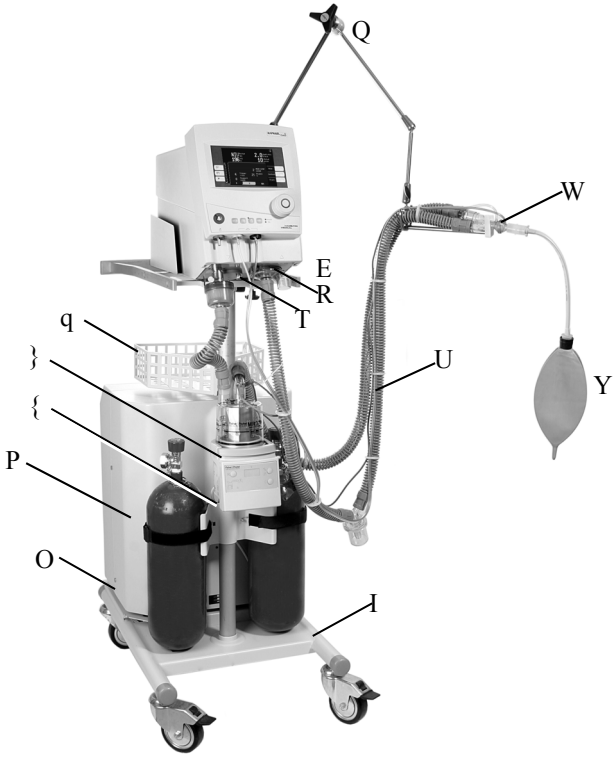


Figure F-1. Ventilator parts and accessories

Table F-1. Ventilator parts and accessories (non-US)

Item no. (Figure F-1)	Description	Part no.
Q	Support arm, quick-positioning, with attaching clamp	281533
W	Flow Sensor, pediatric/adult, single-use (package of 10)	279331
	Flow Sensor, pediatric/adult, reusable (package of 10)	155362
E	Membrane, expiratory valve (package of 5)	151233
R	Cover, expiratory valve	151228
T	Oxygen cell, Catalyst	396008
Y	Demonstration lung with ET tube, 2 l, with 22M/15F connector (adult)	151815
	Demonstration lung with ET tube, 0.5 l, with 22M/15F connector (pediatric)[1]	151816
U	Patient breathing set (See your HAMILTON MEDICAL representative for ordering information)	--
I	Trolley	157240
O	Adapter, VENTILAIR^{II} to RAPHAEL trolley	157243
P	VENTILAIR^{II} medical air compressor, 220 to 240 V ±10%, 50 Hz/230 V ±10%, 60 Hz	155600
	VENTILAIR^{II} medical air compressor, 100 to 115 V ±10%, 50/60 Hz	155601
{	Cylinder mounting kit, for trolley	157241
}	Humidifier (See your HAMILTON MEDICAL representative for ordering information)	--
q	Basket, for trolley	157242
w	Filter, fan	281264

Table F-1. Ventilator parts and accessories (non-US) (continued)

Item no. (Figure F-1)	Description	Part no.
e	Microfilter, gas inlet, 5 µm (microns)	279676
r	Power cord (See your HAMILTON MEDICAL representative for ordering information)	--
t	Fuse, T 1.0 A H 250 V (2 required)	363077
y	Nebulizer set, pneumatic, reusable[1]	151983
u	Operator's manual, RAPHAEL, software version 3, English[1]	610994
	Operator's manual, RAPHAEL, software version 3, French[1]	610995
	Operator's manual, RAPHAEL, software version 3, German[1]	610996
	Operator's manual, RAPHAEL, software version 3, Italian[1]	610997
	Operator's manual, RAPHAEL, software version 3, Spanish[1]	610998
i	Card, preoperational check, English[1]	610696
	Card, preoperational check, French[1]	610697
	Card, preoperational check, German[1]	610698
	Card, preoperational check, Italian[1]	610699
	Card, preoperational check, Spanish[1]	610700
o	Card, ASV, English[1]	610877
	Card, ASV, French[1]	610878
	Card, ASV, German[1]	610879
	Card, ASV, Italian[1]	610880
	Card, ASV, Spanish[1]	610881

Table F-1. Ventilator parts and accessories (non-US) (continued)

Item no. (Figure F-1)	Description	Part no.
p	Bed mount[1]	157314
[	Water bottle holder[1]	281575
]	Water trap kit, self-emptying[1]	157359
A	Cable, ventilator serial connector to computer, 2.5 m (8.2 ft). Shielded on male (ventilator) side only.[1]	157354

1. Not shown

Table F-2. Ventilator parts and accessories (US)

Item no. (Figure F-1)	Description	Part no.
Q	Support arm, quick-positioning, with attaching clamp	281533
W	Flow Sensor, pediatric/adult, single-use (package of 10)	279331
	Flow Sensor, pediatric/adult, reusable (package of 10)	155362
	Flow Sensor, pediatric/adult, reusable (package of 50)	53120
E	Membrane, expiratory valve (package of 5)	151233
R	Cover, expiratory valve	151228
	Cover, expiratory valve (package of 5)	51228
T	Oxygen cell	51254

Table F-2. Ventilator parts and accessories (US) (continued)

Item no. (Figure F-1)	Description	Part no.
Y	Demonstration lung with ET tube, 2 l, with 22M/15F connector (adult)	151815
	Demonstration lung with ET tube, 0.5 l, with 22M/15F connector (pediatric)[1]	151816
U	Patient breathing set (See your HAMILTON MEDICAL representative for ordering information)	--
I	Trolley	157240
O	Adapter, VENTILAIR^{II} to RAPHAEL trolley	157243
P	VENTILAIR^{II} medical air compressor, 100 to 115 V ±10%, 50/60 Hz	155601
{	Cylinder mounting kit, for trolley	157241
}	Humidifier (See your HAMILTON MEDICAL representative for ordering information)	--
q	Basket, for trolley	157242
w	Filter, fan	281264
e	Microfilter, gas inlet, 5 µm (microns)	279676
r	Power cord with US plug, hospital-grade, 2.5 m (8.2 ft)	355139
t	Fuse, T 1.0 A H 250 V (2 required)	363077
y	Operator's manual, RAPHAEL, software version 3, English[1]	610994
u	Card, preoperational check, English[1]	610696
i	Card, ASV, English[1]	610877
o	Bed mount[1]	157314
p	Water trap kit, self-emptying[1]	157359

Table F-2. Ventilator parts and accessories (US) (continued)

Item no. (Figure F-1)	Description	Part no.
[	Oxygen supply hose, 3 m (10 ft)[1]	52010
]	Air supply hose with inline filter, 3 m (10 ft)[1]	52025
	Air supply hose, 3 m (10 ft)[1,3]	52020
A	Cable, ventilator serial connector to computer, 2.5 m (8.2 ft). Shielded on male (ventilator) side only.[1]	57232

1. Not shown

APPENDIX G Communications interface option

G.1 Introduction

The communications interface option offers these capabilities:

- The **RS-232 interface** outputs monitored data, ventilator settings, and alarms to a patient monitor or computer.
- **The I:E timing outlet** outputs signals for time of insufflation and exhalation. These are used for special applications, such as an external nebulizer.
- The **remote alarm outlet** outputs alarm signals to a nurse's call device.

A ventilator with this option has two connectors at the back (Figure G-7). The patient monitor or computer connects to the RS232C connector. The nurse's call or other device connects to the Special connector.

WARNING

To reduce the risk of excessive leakage current due to ground loops and to prevent electromagnetic interference, make sure the connecting cable has a high-quality shield and is grounded properly *on one side only*, either at the ventilator or receiving device.

NOTE:

All devices connected to the RAPHAEL must be for medical use and meet the requirements of IEC 60601-1.

G.2 RS-232 interface

The RS-232 interface lets the RAPHAEL send monitored data, waveforms, modes, control settings, and alarms to a patient monitor or computer through the RS232C connector. Table G-2 lists the pin assignments for this connector.

G.2.1 Patient monitor

WARNING

To prevent possible patient injury when using a patient monitor, check the patient and the ventilator whenever the monitor reports a ventilator alarm. Not all monitors provide detailed alarm message information.

NOTE:

- Your monitor may not recognize and report all modes and parameters (for example, ASV mode, peak pressure monitoring parameter). It also may not recognize some specific alarms, but report them as general alarms. In such cases, HAMILTON MEDICAL recommends that you read the data directly from the RAPHAEL screen.
- Silencing the RAPHAEL's audible alarm does not automatically silence the audible alarm of the remote patient monitor.
- To connect your RAPHAEL to a monitor other than those described below, contact your HAMILTON MEDICAL representative.

With the RS-232 interface, the RAPHAEL ventilator can send data to a Spacelabs, GE Marquette, Schiller, Dräger, Datex-Ohmeda, or Nihon Kohden patient monitor.

Using the RAPHAEL with a patient monitor requires the hardware shown in Figure G-1. Interfacing hardware specific to the manufacturers' monitors is listed in Table G-1. Order this interfacing hardware directly from the monitor manufacturer.

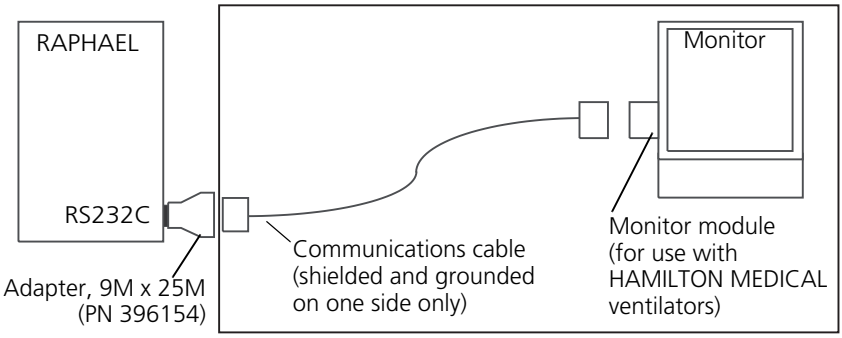


Figure G-1. RAPHAEL connected to a patient monitor

Table G-1. Interfacing hardware for patient monitors

Manufacturer	Interfacing hardware required	Notes
Spacelabs Medical (GE Medical Systems)	Flexport and cable for HAMILTON MEDICAL ventilators	
GE Marquette Medical Systems	Octanet and cable for HAMILTON MEDICAL ventilators	Tram-net is not compatible
Schiller	Cable for HAMILTON MEDICAL ventilators	
Dräger Medical	MIB II Protocol Converter or MIB II Duo Protocol Converter and -GALILEO MIB interface cable	For use with Infinity Modular Monitors (formerly Siemens Medical)
Datex-Ohmeda PDMS (patient data management system)	deioEthernetbox and cables	deioClinisoft system (known earlier as Datex-Ohmeda S/5 CCIMS)
Nihon Kohden BSM-4100/5100 series bedside monitor	QI-407P interface	

G.2.2 Computer

WARNING

The computer connected to the RAPHAEL should be for medical use and meet the requirements of IEC 60601-1. Alternatively, a battery-powered laptop computer may be used. Do not connect other types of personal computer, because such computers do not fulfill the requirements of the standard. Consult a technical specialist or safety inspector in your hospital for more information.

With the RS-232 interface, the RAPHAEL can transmit data from the ventilator to your computer. Data from the ventilator can ultimately be manipulated using software such as Microsoft Excel. This is a useful tool for data management and clinical studies.

This application requires the hardware shown in Figure G-2. It also requires the Data Logger software and manual; contact your HAMILTON MEDICAL representative.

For more information about the communications protocol, contact HAMILTON MEDICAL.

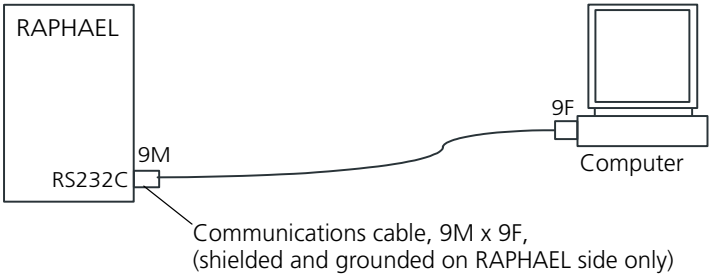


Figure G-2. RAPHAEL connected to a computer

G.3 Inspiratory:expiratory (I:E) timing outlet

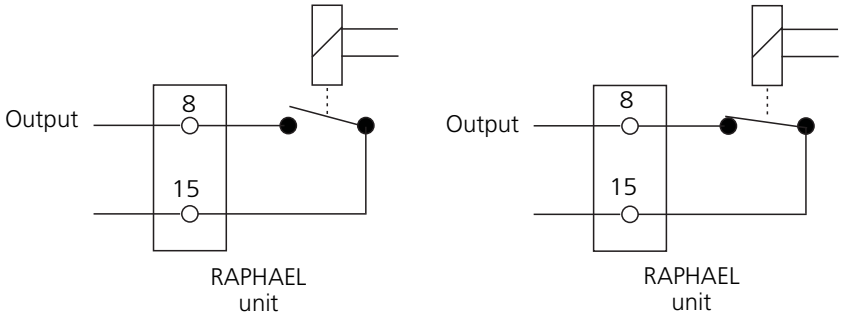
NOTE:

Before using the I:E timing outlet, make sure that the outlet is operational. To do so, connect the RAPHAEL to the external device and verify the correct functioning of the device.

The I:E timing outlet lets your RAPHAEL send I:E timing signals through the 15-pin (Special) connector. This is useful when administering nitric oxide (NO) or using an external nebulizer.

This application requires the hardware shown in Figure G-3. Table G-2 lists the pin assignments for this connector. The I:E timing capability is based on a relay inside the ventilator; the relay positions are shown in Figure G-4.

Figure G-3. RAPHAEL connected to an external device through the Special connector



Relay position during exhalation **Relay position during insufflation**

Figure G-4. I:E timing outlet relay positions

G.4 Remote alarm outlet

WARNING

If the remote alarm function is used in an isolation ward, regularly check that the remote alarm function is operational.

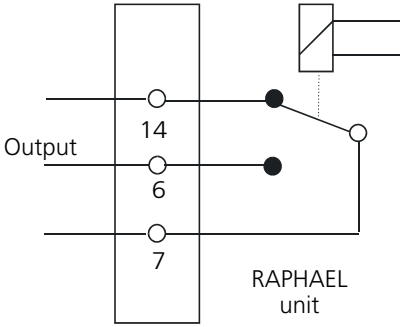
NOTE:

Before operating the remote alarm function, make sure that the remote alarm function is operational. To do so, connect the RAPHAEL to the nurse's call device. Create an alarm on the RAPHAEL, and verify that the nurse's call is activated. Now silence the alarm on the RAPHAEL, and verify that the nurse's call is deactivated.

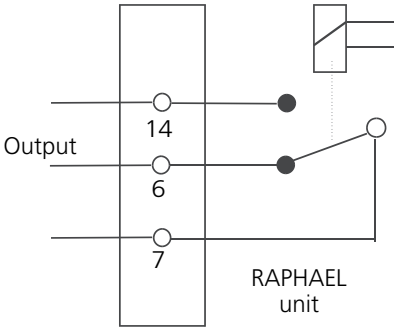
The remote alarm (nurse's call) capability allows alarm conditions to be annunciated at locations away from the ventilator (for example, when the ventilator is in an isolation room). The RAPHAEL sends alarm signals to a nurse's call device through the 15-pin (Special) connector. Table G-2 lists the pin assignments for this connector.

The RAPHAEL alarm silence key silences the audible portions of the alarms at both the ventilator and the remote alarm device.

The remote alarm capability is based on a relay inside the ventilator. Figure G-5 shows the alarm and non-alarm positions for the relay for newer ventilators; it applies if your ventilator has an interface board of revision 01, which was produced beginning in March 2004. Figure G-6 shows the positions for the relay for older ventilators; it applies if your ventilator has an interface board of revision 00. You can use either pins 7 and 14 or pins 7 and 6, depending on the logic of your nurse's call system (normally open or normally closed).

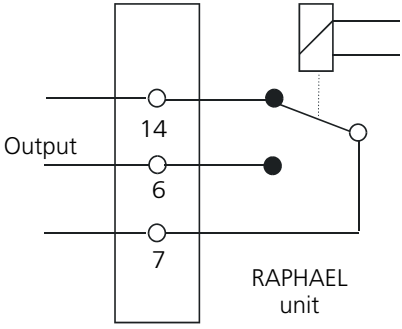


Relay position in nonalarm condition or alarm silenced

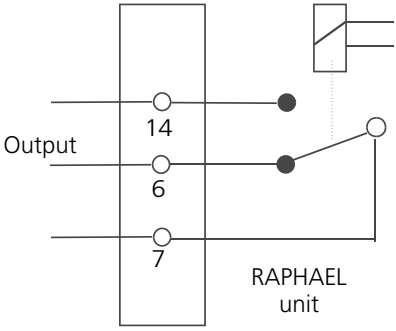


Relay position in alarm condition (not silenced) or ventilator unpowered

Figure G-5. Remote alarm relay positions (newer units)



Relay position in alarm condition (not silenced)



Relay position in nonalarm condition, alarm silenced, or ventilator unpowered

Figure G-6. Remote alarm relay positions (older units)

G.5 Connector pin assignments

Figure G-7 shows the locations of the interface connectors and pins. Table G-2 lists the pin assignments for these connectors.

The maximum allowable voltage and current between the relay contacts are 48 V, 0.2 A (I:E timing outlet) and 48 V, 0.5 A (remote alarm outlet).

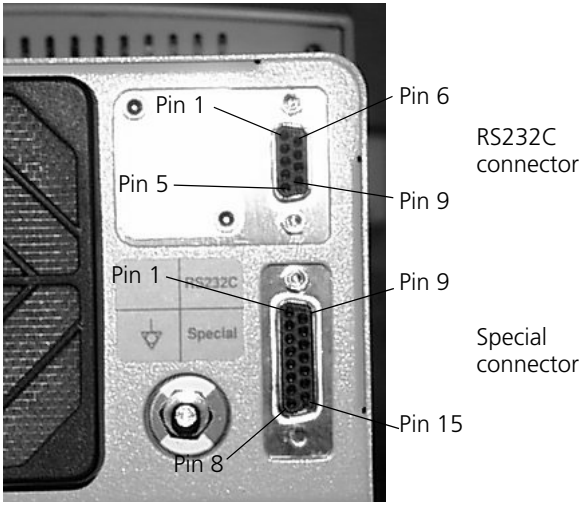


Figure G-7. Interface connectors

Table G-2. Interface connector pin assignments

RS232C connector	
Pin	**Signal**
1	--
2	RXD
3	TXD
4	DTR
5	GND (signal ground)
6	DSR
7	RTS
8	CTS
9	--
Shield	Chassis ground

Special connector	
Pin	**Signal**
1	--
2	--
3	--
4	--
5	--
6	Remote alarm return (see Figure G-5 or Figure G-6)
7	Remote alarm
8	I:E relay
9	--
10	--
11	--
12	--
13	--
14	Remote alarm return (see Figure G-5 or Figure G-6)
15	I:E relay return
Shield	Chassis ground

G.6 Communications protocol

Contact your HAMILTON MEDICAL representative for protocol details. This will aid you in developing software to interface a device to the RAPHAEL.

Glossary

%MinVol	Percentage of minute ventilation, a control setting.
A	Ampere, a unit of current.
ac	Alternating current.
adaptive volume controller	Delivers volume-controlled breaths in the RAPHAEL. Ensures that the target tidal volume is delivered but without undue application of pressure, even when lung characteristics change.
alarm silence key	Silences alarm sound for 2 min.
ambient state	An emergency state, in which the ventilator opens the ambient and expiratory valves and closes the inspiratory valve. This lets the patient breathe room air unassisted by the ventilator. The ventilator enters the ambient state when it detects a technical fault.
apnea	Cessation of breathing.
apnea time	The maximum time allowed without a breath trigger, an alarm setting made in the mode window.
APRV	Airway pressure release ventilation mode.
ASV	Adaptive support ventilation, a positive pressure ventilation mode intended to adapt with the patient as they progress from full mechanical ventilation to spontaneous breathing.
ATPD	Ambient temperature, pressure, dry.
AutoPEEP	Unintended positive end-expiratory pressure, a monitored parameter.
Baseflow	A continuous and constant gas flow from the inspiratory outlet to the expiratory outlet, a control setting. It is essential for flow trigger.
b/min	Breaths per minute.

Body Wt	A setting that specifies the patient's bodyweight assuming normal fat and fluid levels. RAPHAEL uses this setting to determine tidal volume, breath rate, and preset alarm limits. Also called Bodyweight.
Bodyweight	A setting that specifies the patient's bodyweight assuming normal fat and fluid levels. RAPHAEL uses this setting to determine tidal volume, breath rate, and preset alarm limits. Also called Body Wt.
BTPS	Body temperature, barometric pressure at sea level, saturated with water vapor.
breathing circuit	Includes the inspiratory-expiratory tubing, humidifier, filters, and water traps.
CE	A certification mark.
cm	Centimeter, a unit of length.
cmH_2O	Centimeters of water, a unit of pressure. 1 cmH_2O is approximately equal to 1 mbar, which equals 1 hPa.
CMV	Controlled mandatory ventilation.
COPD	Chronic obstructive pulmonary disease.
CPAP	Continuous positive airway pressure.
CSA	Canadian Standards Association.
Cstat	Static compliance, a monitored parameter.
DIN	Deutsche Institut für Normung (German institute for standardization).
DISS	Diameter index safety standard, a standard for high-pressure gas inlet fittings.
DuoPAP	Duo positive airway pressure ventilation mode.
EN	European Norm, a European standard.
ET	Endotracheal.
ETO	Ethylene oxide.

ETS	Expiratory trigger sensitivity, a control setting. The percent of peak inspiratory flow at which the ventilator cycles from inspiration to exhalation.
Exp Flow	Peak expiratory flow, a monitored parameter.
ExpMinVol	Expiratory minute volume, a monitored parameter and alarm setting.
fControl	Mandatory breathing frequency, a monitored parameter in ASV mode.
FRC	Functional residual capacity, the volume in the lungs at the end-expiratory position.
fSpont	Spontaneous respiratory rate, a monitored parameter.
fTotal	Total breathing frequency, a monitored parameter and alarm setting. The moving average of the patient's total breathing frequency over the past 8 breaths.
ft	Foot, a unit of length.
HME	Heat and moisture exchanger (artificial nose)
hPa	Hectopascal, a unit of pressure. 1 hPa is equal to 1 mbar, which is approximately equal to 1 cmH_2O.
Hz	Hertz, or cycles per second, a unit of frequency.
IBW	Ideal bodyweight.
ICU	Intensive care unit.
IEC	International Electrotechnical Commission.
I:E	Inspiratory:expiratory ratio. Ratio of inspiratory time to expiratory time. On the RAPHAEL, I:E is a setting and a monitored parameter.
IMV	Intermittent mandatory ventilation.
in.	Inch, a unit of length.
Insp Flow	Peak inspiratory flow, a monitored parameter.

inspiratory hold	A respiratory maneuver in which gas is retained in the patient's airways, often for X-raying purposes. You initiate an inspiratory hold through the inspiratory hold/manual breath key.
IntelliTrig	Intelligent trigger, a feature that ensures that the set trigger sensitivity can trigger a breath independent from leakage and breath pattern.
ISO	International Standards Organization, a worldwide federation of national standards bodies.
kg	Kilogram, a unit of mass.
kPa	Kilopascal, a unit of pressure.
l	Liter, a unit of volume.
l/min	Liters per minute, a unit of flow.
Last Setup	A setting in the **Bodyweight** window that lets you resume ventilating with the last settings in use before the RAPHAEL was switched off.
lb	Pound, a unit of weight.
Leak	Leakage percent, a monitored parameter. The difference between the delivered and exhaled tidal volumes measured at the Flow Sensor, as a percentage of delivered volume. It does not include the leakage between the ventilator and Flow Sensor.
leak compensation	A function that provides baseline pressure stability so that ventilator trigger sensitivity can be set to achieve optimal patient triggering synchrony.
LiteCircuit	A single-limb breathing circuit for use in NIV. Its has an exhaust port for venting CO_2.
m	Meter, a unit of length.
manual breath	A user-triggered mandatory breath started by pressing the inspiratory hold/manual breath key. RAPHAEL delivers the manual breath using the current active settings.
mbar	Millibar, a unit of pressure. 1 mbar equals 1 hPa, which is approximately equal to 1 cmH_2O.

ml	Milliliter, a unit of volume.
ms	Millisecond, a unit of time.
MV Spont	Spontaneous expiratory minute volume, a monitored parameter.
NIST	Noninterchangeable screw thread, a standard for high-pressure gas inlet fittings.
NIV	Noninvasive ventilation mode.
NPPV	Noninvasive positive pressure ventilation
O_2	Oxygen.
Oxygen	Oxygen concentration of the delivered gas, a setting and monitored parameter.
Pasvlimit	Maximum pressure to be applied during ASV, a control setting.
Paw	Airway pressure.
Pcontrol	Pressure control, as set in PCV+ and PSIMV+ modes. Pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase.
PCV+	Pressure-controlled ventilation mode.
peak flow	Maximum flow during the breath cycle.
PEEP	Positive end-expiratory pressure.
PEEP/CPAP	PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure), constant pressures applied to both inspiratory and expiratory phases. On the RAPHAEL, PEEP/CPAP is a setting and a monitored parameter.
P high	High airway pressure level, a control setting.
Pinsp	Inspiratory pressure, the target pressure (additional to PEEP/CPAP) applied during the inspiratory phase.
P low	Low airway pressure level, a control setting.
Pmax	Maximum pressure allowed in the patient breathing circuit, an alarm setting.

Pmean	Mean airway pressure, a monitored parameter.
Ppeak	Peak airway pressure, a monitored parameter.
Pramp	Pressure ramp, a control setting. The time required for the inspiratory pressure to rise to the set (target) pressure.
psi	Pounds per square inch, a unit of pressure.
PSIMV+	Pressure-controlled synchronized intermittent mandatory ventilation mode.
Pramp	Pressure ramp, a control setting.
Psupport	Inspiratory pressure support, a setting valid during SPONT breaths. Psupport is pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase.
Ptank	Reservoir tank pressure.
Ptrachea	Tracheal pressure.
Rate	Breath frequency, or number of breaths per minute, a setting.
RCexp	Expiratory time constant, a monitored parameter.
Rinsp	Inspiratory flow resistance, a monitored parameter.
s	Second, a unit of time.
(S)CMV+	Synchronized controlled mandatory ventilation mode.
sigh	Breaths delivered to deliberately increase tidal volume at a regular interval. If enabled, a sigh breath delivered every 50 breaths with an additional 10 cmH_2O.
SIMV+	Synchronized intermittent mandatory ventilation mode.
SPONT	Spontaneous mode of ventilation.
stand-by	The ventilator is in a waiting state, during which time there is no breath delivery.
STPD	Standard temperature and pressure, dry. Defined as gas gas at 0 °C (273 °K), barometric pressure at sea level, and dry.

TE	Expiratory time, a monitored parameter. TE is the time interval from the start of expiratory flow to the start of inspiratory flow.
technical fault	A type of alarm, resulting because RAPHAEL's ability to ventilate safely is questionable. RAPHAEL enters the ambient state when a technical fault is declared.
T high	Duration of high airway pressure level, a control setting.
TI	Inspiratory time, a setting and a monitored parameter. TI is the time interval from the start of inspiratory flow to the start of expiratory flow.
TI max	Maximum inspiratory time, a control setting.
T low	Duration of low airway pressure level, a control setting.
Tmand	Time period for the mandatory breaths in the SIMV+/ PSIMV+ breath interval.
TRC	Tube resistance compensation.
Trigger	The patient's inspiratory flow that causes the ventilator to deliver a breath, a setting.
Tspont	Time period for spontaneous breaths in the SIMV+/ PSIMV+ breath interval.
Tube resistance compensation (TRC)	A feature that reduces the patient's work of breathing by offsetting the flow resistance imposed by the ET or tracheostomy tube.
V	Volt, a unit of electric potential.
VA	Volt-ampere, a unit of electric power.
VT	Tidal volume, a setting.
VTE	Expiratory tidal volume, a monitored parameter. It is the integral of all negative flow measurements during exhalation.

Index

B

C

D

E

F

G

H

I

K

L

M

N

O

P

R

S

T

U

V

W