RESMED

Elisée™ 350
Clinical Manual
English

Respiratory Care solutions
Making quality of care easy

Respiratory Care solutions

Making quality of care easy

Foreword

Definitions

This manual contains special terms and icons that appear in the margins. Their purpose is to draw your attention to specific or important information.

CAUTION
Explains special measures for the safe and effective use of the ventilator.

WARNING
Alerts you to possible injury.

Note: *Is an informative or helpful note.*

This Clinical Manual is for the Elisée™ 350 Li-Ion ventilator with software version 2.54 NIV+. It uses three different ISO-standard units for measuring pressure. These can easily be converted by the user: 1 mbar = 1 hPa = 1.016 cm H_2O.

Table of contents

1 Safety instructions

General advice

Other specific warnings and notes will be found throughout the text of the manual. This manual must be read and understood in full by the user before the ventilator is used on a patient.

This manual is intended for use by physicians, HME providers and nursing staff.

There is also a service manual for the ventilator, which is issued at ResMed training sessions. The Service Manual contains instructions for servicing the ventilator. It must be read and understood by the technicians responsible for servicing the ventilator.

- Use only the specific power cords supplied with the ventilator.
- Do not use the ventilator if it is damaged, if there are obvious external defects or unexplained changes in performance, or if one of its cords or accessories is damaged.
- The manufacturer accepts no liability for damage which may occur to the ventilator due to:
  - A configuration, maintenance or changes which do not comply with the instructions provided or do not have the manufacturer's prior approval
  - A configuration, maintenance or changes made by unauthorised persons.
- Monitoring the ventilator is of vital importance for ventilation-dependent patients.
- It is recommended that you have a backup means of ventilation available.
- Use the ventilator with CE-marked accessories only, and in compliance with the manufacturer's recommendations.

Using the Elisée 350

- During transport or in an emergency situation, do not leave a ventilated patient unsupervised, especially during volume-controlled ventilation.
- As the ventilator uses ambient air to function, it should not be used in a contaminated environment (in the presence of infectious agents, for example) or at the scene of a fire.
- The ventilator must not be turned on immediately after storage or transport in conditions different from the recommended operating conditions.
- The ventilator is splashproof (IPX4) if the following conditions are met:
  - It is used in its ergonomic transport bag
  - The mains supply pack is removed from the compartment under the ventilator
  - The ventilator is being operated on battery power.

  If the ventilator is operated outside of the above conditions, it is not protected against water penetration (IPX0).
- The Elisée 350 must not be covered or positioned in a way which could impede ventilation.
- Do not block the vents on the ventilator.
- Do not use the ventilator with antistatic or electrically conductive patient circuits.
- Do not use this device in the presence of flammable anaesthetics.
- If a technical alarm is triggered, switch off the ventilator and unplug the mains power and oxygen supplies.

Power supply

- Do not use the ventilator if either the power cord or the mains power pack is damaged.
- If there is interference on the electrical network, operate the ventilator on battery power.
- Use the specific power cord and the mains power pack supplied with the ventilator. The use of other mains power supplies may result in a risk to the patient.
- ResMed does not guarantee the operation of the ventilator when powered by a wheelchair battery.
- Do not plug the ventilator into a multi-socket plug board or an extension cord.
- When the ventilator has been disconnected from mains power and stored for an extended period of time, the backup battery will discharge. If the "ADJUST CLOCK" alarm is triggered when the ventilator is turned on, the battery must be recharged by connecting to mains power.

Oxygen

- We recommend that you disconnect the oxygen supply when the ventilator is in standby mode or turned off.
- Do not try to open or pierce the oxygen sensor.
- As the use of oxygen at high concentration may have physiological effects on the patient, it is imperative that you follow the instructions given by the attending physician.

Electromagnetic compatibility

- The user must ensure that the operation of the ventilator is not impaired by the concurrent use of devices such as defibrillators or diathermy, electrosurgical or radiology equipment or mobile phones.
- The ventilator may be affected by electromagnetic fields greater than 10 V/m.
- The use of accessories and power cords other than those specified may increase emissions from the ventilator or decrease its immunity.
- Precautions must be taken for the ventilator and its accessories with regard to Electromagnetic Compatibility (EMC); they must be installed and put into service in accordance with the information provided in this manual, in particular the information given in "Electromagnetic emissions and immunity" on page 98.

Technical specifications

- The pressure in the ventilator will not be lower than atmospheric pressure during the expiratory phase.
- The design of the ventilator and the properties of the motor ensure that the maximum pressure delivered by the ventilator cannot exceed 100 cm H_2O.
- The design of the ventilator ensures that, if the device were to stop, the patient would be able to breathe spontaneously and would not rebreathe exhaled air.
- In the event of turbine failure, the ventilator cannot be used even if a high-pressure oxygen supply is connected.
- In order to limit the rebreathing of exhaled air when the ventilator stops, the partial closure of the rotary slide valve ensures that the exhaled air passes through the expiratory valve of the expiratory limb rather than through the inspiratory limb.

Servicing and maintenance

- If anything unexpected occurs, contact your ResMed representative.
- To avoid the risk of electrocution/electrification, do not open the device casing. All procedures should be carried out by a technician trained in the maintenance of the ventilator.
- Before using the device for the first time, and also between patients, the accessories should be cleaned and disinfected.
- Faulty fuses in the power pack or on the printed circuit board must be replaced by a trained technician. The replacement fuses must have the same specifications and standards as the original fuses.
- Upon request, ResMed can provide information on the methods used during production and delivery to ensure the cleanliness of the components of the respiratory system.

Transport and storage

- When used during indoor transport, ensure that the Elisée 350 is securely attached to its support.
- The ventilator must not be exposed to direct sunlight, unless it is in its ergonomic transport bag.
- The ventilator must not be subjected to any violent impact when it is not in its ergonomic transport bag, nor allowed to fall.
- The ventilator must not be turned on immediately after storage or transport in conditions different from the recommended operating conditions.
- In the operating theatre, we recommend connecting the ventilator to mains power as soon as possible, so that the internal/external batteries can be recharged.

Recycling

- In accordance with Directive 2002/96/EC concerning waste electrical and electronic equipment, this device must be sorted and disposed of separately from other types of rubbish. It must not be disposed of with municipal waste. To dispose of this device, use the appropriate waste collection, reuse and recycling system available in your region.
- Whether new or worn out, the oxygen sensor contains toxic substances. It must be disposed of in accordance with the applicable waste processing regulations in your region and in accordance with local environmental legislation. Do not burn the sensor: there is a risk of toxic smoke.

2 Introduction

2.1 Field of application

This ventilator is intended for use exclusively by health care professionals.

The Elisée 350 is a dual-mode ventilator, capable of delivering pressure-based or volume-based, invasive or non-invasive ventilation to adult or paediatric patients (above 5 kg [11 lbs]).

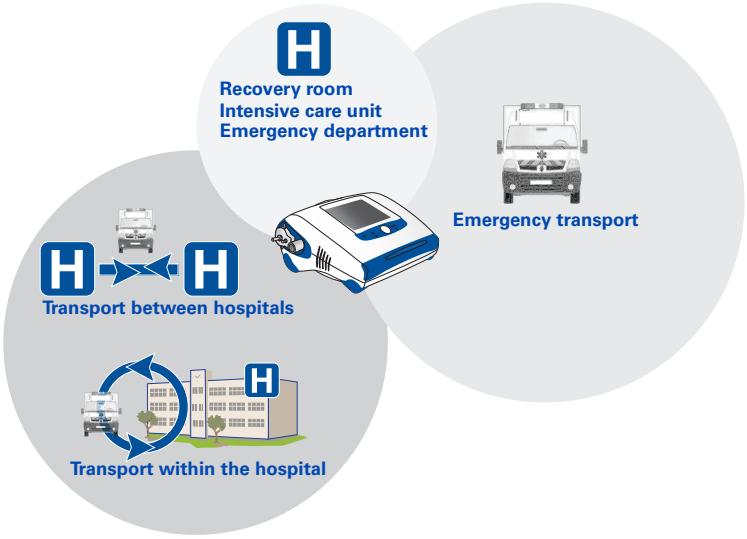
It is **not designed for neonatal ventilation**.

The ventilator's safety features and internal battery enable it to be used for continuous ventilation of ventilation-dependent patients.

The Elisée 350 is approved for use in intensive care and for continuous operation.

It is used:

- For transport (by road, sea or air)
  - For emergency ventilation: resuscitation, for instance at the scene of a traffic accident or a drowning
  - For transport within and outside the hospital: in an emergency situation, for planned transport over long distances, or for transferring patients on respiratory support.
- In the recovery room or intensive care unit.



2.2 Features at a glance

Features for emergency situations and in-hospital transport

The Elisée 350 comes with an ergonomic transport bag, which makes it possible to attach the ventilator securely to the vehicle.

The ventilator may be used at an altitude of up to 4000 metres (13,123 feet).

High-pressure and low-pressure oxygen supplies and FiO_2 measurement

The Elisée 350 enables the enrichment of insufflated gases with high-pressure oxygen (240 to 700 kPa maximum) up to an FiO_2 (inspired oxygen fraction) of 100%.

Through an internal oxygen sensor, the ventilator controls the FiO_2 automatically, based on the set value.

The accuracy of the FiO_2 measurements at a high altitude is guaranteed through an atmospheric pressure compensation device.

The Elisée 350 also enables enrichment with low-pressure oxygen, up to a pressure of 400 kPa.

Power supply options

The Elisée 350 can be operated from its internal battery, mains power, an external battery pack, or a vehicle power supply. These options, which can also be used simultaneously, provide considerable flexibility of use.

The Elisée 350 can switch between power supplies without having to stop ventilation (called a "hot swap").

Adjustable touch screen

The high-contrast LCD touch screen can be calibrated quickly and easily. In addition, the screen orientation can be inverted 180°.

Note: *The Elisée 350 has a full colour remote monitoring screen.*

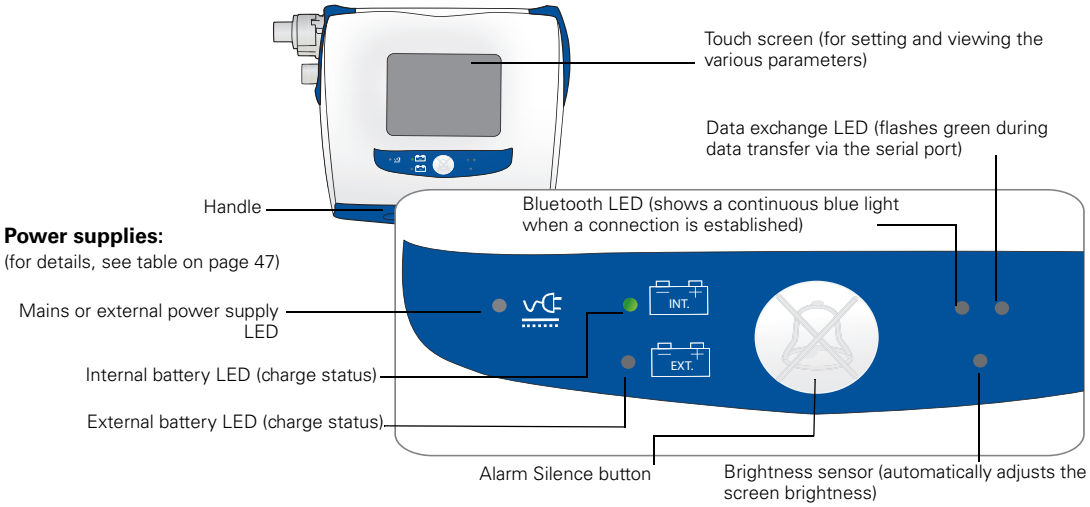
Ventilation modes

The Elisée 350 offers controlled, assisted and pressure-support ventilation modes, which can be used in a variety of combinations to ventilate a wide range of adult and paediatric patients:

- Assisted Controlled Ventilation:
  - (Assisted) Volume-Controlled Ventilation ((A)CV)
  - Assisted Pressure-Controlled Ventilation (PACV)
- Synchronised Intermittent Ventilation:
  - Synchronised Intermittent Mandatory Ventilation (SIMV)
  - Pressure-Synchronized Intermittent Mandatory Ventilation (PSIMV)
- Pressure Support (PS)
- Pressure Support with Minimum Tidal Volume ($PS.V_T$)
- Continuous Positive Airway Pressure (CPAP).

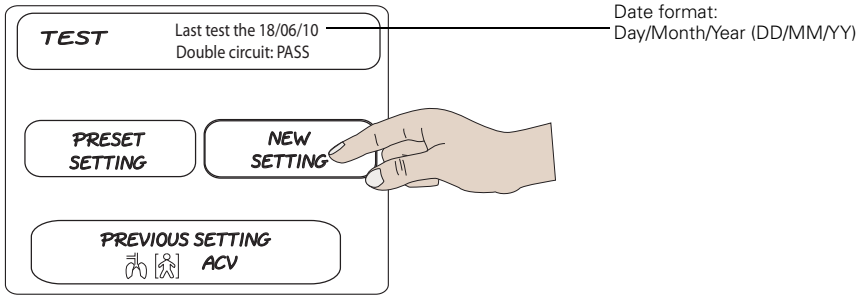
2.3 Overview

Top view

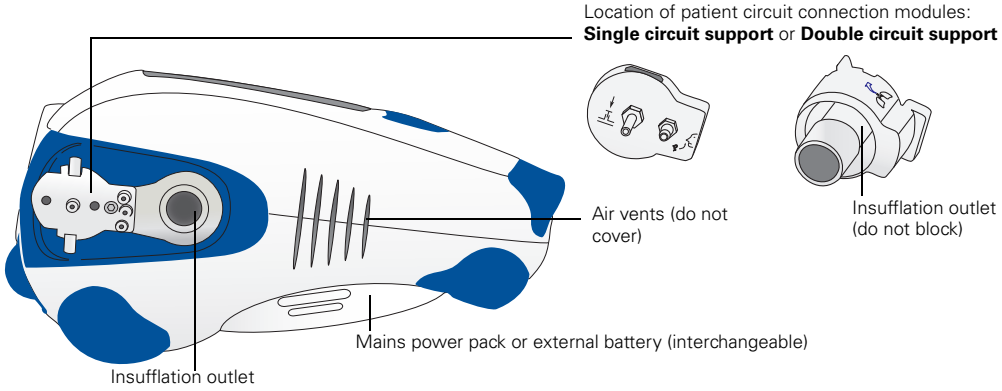


LCD touch screen

You can select screens and parameters by pressing the buttons on the touch screen. In some cases, for example when shutting down the ventilator, the button must be pressed for three seconds.



Left-hand side

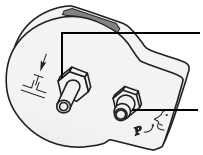


Patient circuit connection modules

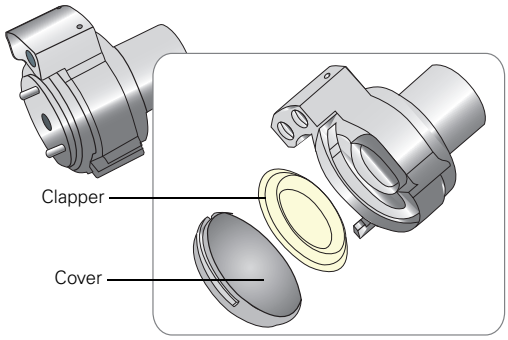
One of two modules can be connected to the left-hand side of the ventilator:

- The single circuit support, which has connectors for the expiratory valve control tube and the proximal pressure line
- The double circuit support, commonly known as the expiratory valve. This removable support has an external clapper where the expiratory limb of the circuit is connected.

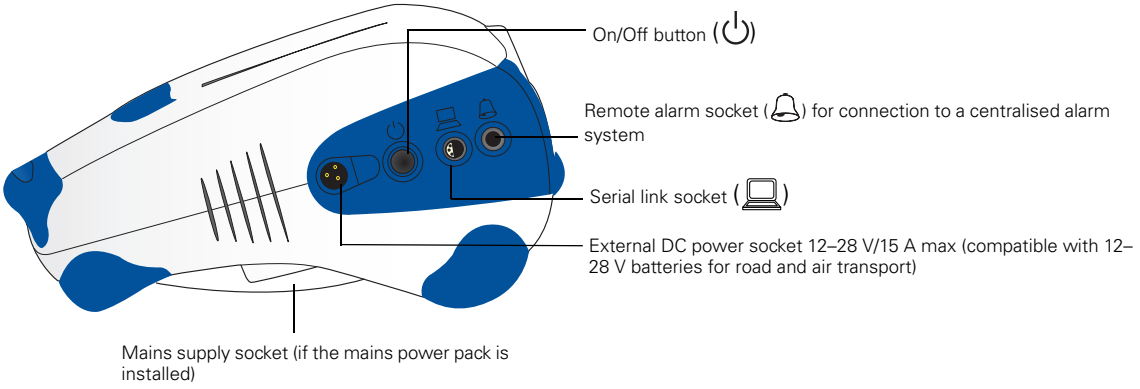
Single circuit support



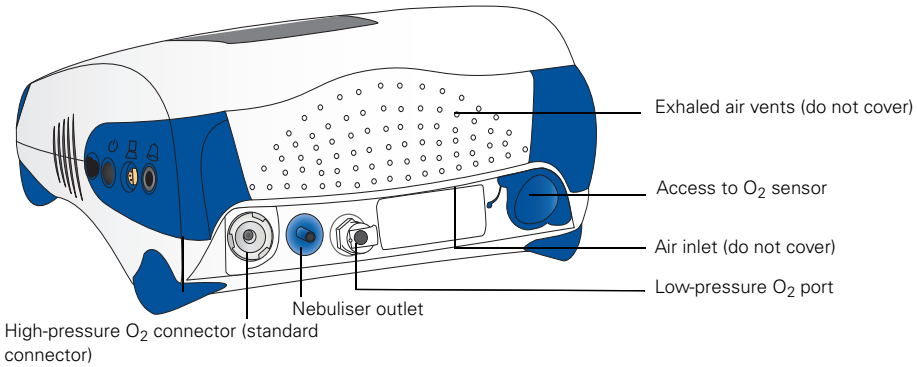
Expiratory valve



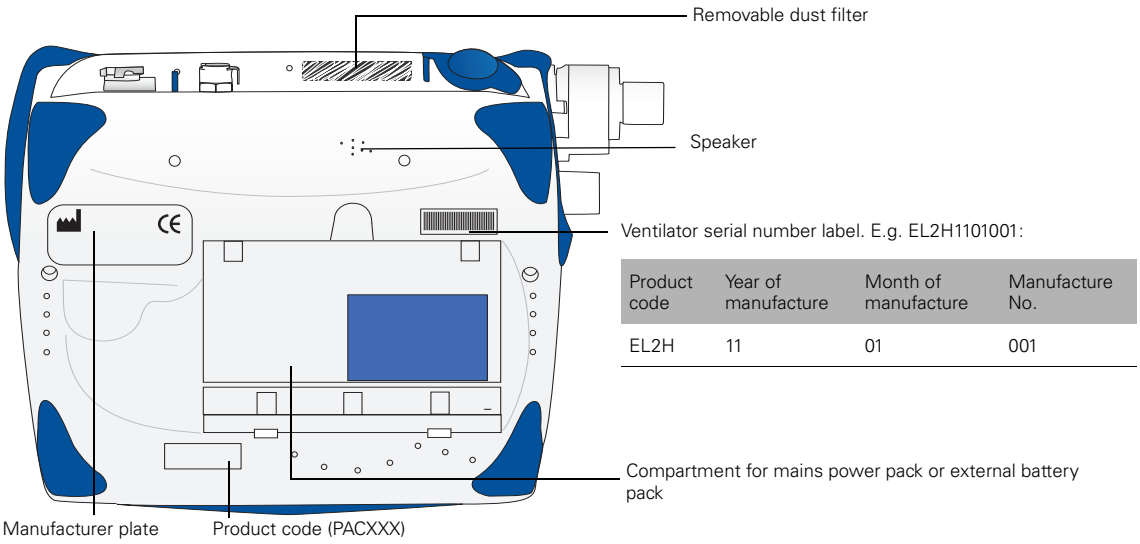
Right-hand side



Rear view



Underside view

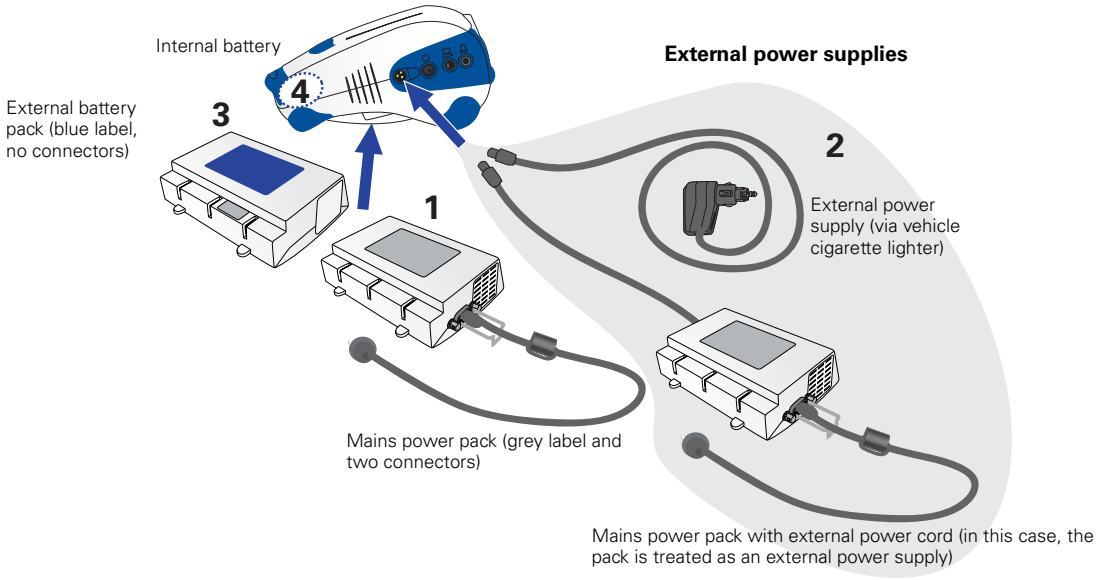


Product code	Year of manufacture	Month of manufacture	Manufacture No.
EL2H	11	01	001

2.4 Power supplies

The Elisée 350 can be used with several different power supplies. The device automatically selects the power supply to be used, according to the following hierarchy:

1. A mains power pack installed in the compartment under the device.
2. An external power supply connected to the Elisée external DC power socket, which could be:
   - A mains power pack located ouside the ventilator
   - An external power supply (12–28 V DC) via the cigarette lighter.
3. An external battery pack installed in the compartment under the device.
4. The internal battery.



CAUTION

Only power supplies or power cords designed and distributed by ResMed should be connected to the ventilator.

Note: *In the event of a loss of mains power, an audible and visual alarm is activated. It can be stopped by pressing the Alarm Silence button.*

1 Mains power pack

The pack is housed in the compartment located on the underside of the ventilator. It supplies the device with DC power, converted from mains power, and enables the internal battery to recharge.

Note: *If used outside of its compartment, the mains power pack is connected to the ventilator with an external power cord and is therefore treated as an external power supply (see next paragraph). Place the dummy pack in the compartment so that it is never left empty.*

CAUTION

The mains power pack is not splashproof (IPX0). Therefore, it should not be connected to the ventilator when there is a risk of water penetration.

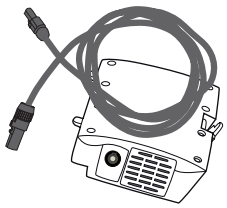
2 External DC power supply

An external DC power supply can be provided by:

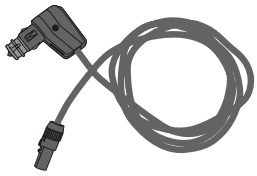
- The mains power pack, using the external power cord
- A DC power supply connected to the Elisée via the ResMed cigarette lighter connector.

CAUTION

Only power supplies able to deliver 12–28 V / 15 A can be connected through the DC power cord to power the ventilator.



External power supply cord (to connect the mains power pack to the Elisée)



DC power cord with ResMed cigarette lighter connector for power supply from vehicle

Note: *To switch the ventilator off, disconnect the external DC power supply.*

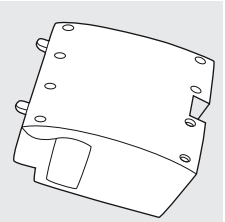
If the ventilator is turned off while connected to an external power supply, it automatically switches to standby mode to recharge the internal battery (and the external battery, if this is connected to the ventilator).

WARNING

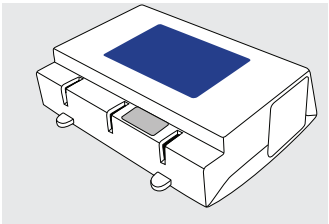
The external DC power supply should be capable of powering the device for at least one hour. If the external supply is less than 20 V during ventilation, the batteries will not be recharged.

3 External battery pack

Like the mains power pack, the external battery pack is housed in the compartment located on the underside of the ventilator. When available, this power supply is used in preference to the internal battery.



Top view



Underside view

During ventilation, the battery will be recharged if the voltage is higher than 20 V. However, when ventilation is not being delivered, the battery will be recharged whatever the voltage.

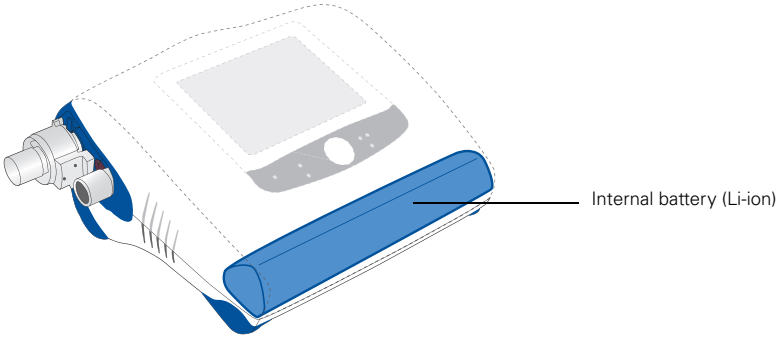
It is advisable to remove the external battery pack if the ventilator is stored for a prolonged period.

The external battery will be recharged when the ventilator is connected to:

- The mains power pack via the external power cord
- An external DC power supply.

When the charge of the external battery falls below 5%, the Elisée 350 switches to internal battery power.

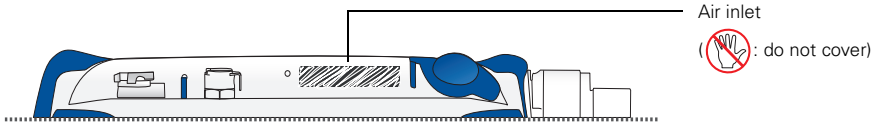
4 Internal battery



During ventilation, the internal battery will be recharged by an external power supply (external DC or mains) if the voltage is higher than 20 V. However, when ventilation is not being delivered, the battery will be recharged whatever the voltage.

2.5 Air inlet

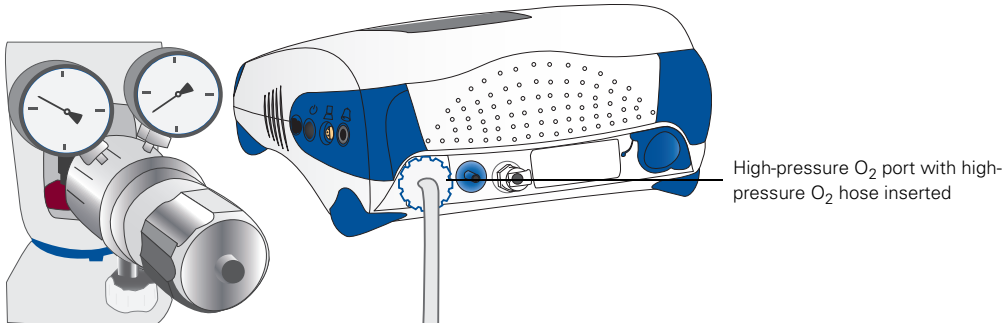
Ambient air passes through a removable dust filter before entering the air circuit.



2.6 High-pressure oxygen port

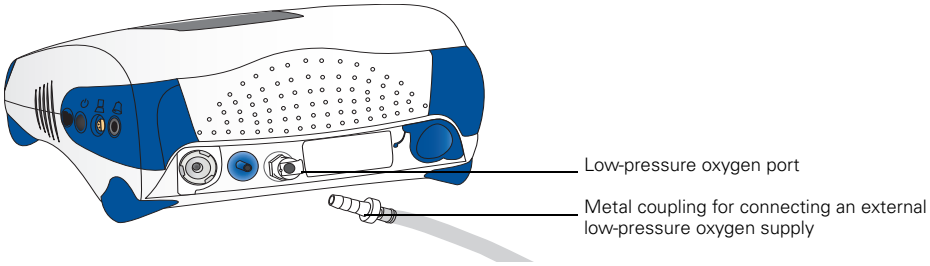
The high-pressure oxygen port accepts oxygen at a pressure of between 240 kPa and 700 kPa.

When high-pressure oxygen is in use, it replaces ambient air as the ventilator's air supply.



2.7 Low-pressure oxygen port

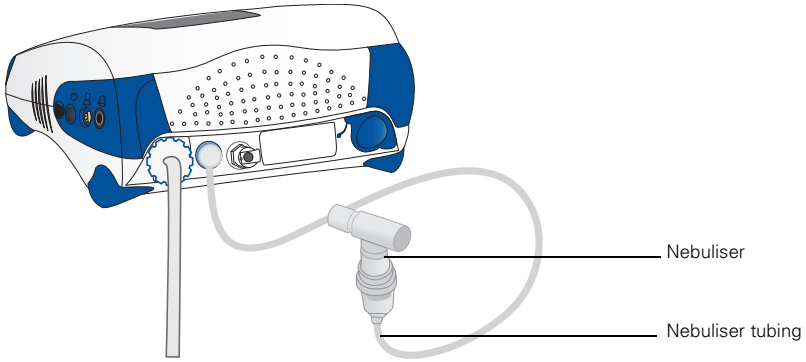
The low-pressure oxygen port can accept an oxygen supply at a pressure of up to 400 kPa.



2.8 Standard pneumatic nebuliser

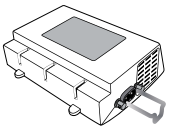
The nebulisation function is available only if the Elisée 350 is supplied with high-pressure oxygen.

The driving gas is pure oxygen with a maximum pressure of 200 kPa and a flow rate of 20 L/min.



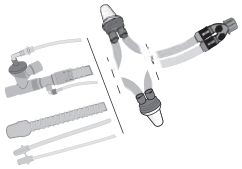
2.9 Accessories

Below is a non-exhaustive list of accessories available for use with the Elisée 350. Refer to the ResMed website (www.resmed.com) for more details (see "Technical specifications for accessories" on page 94 for the connection path).



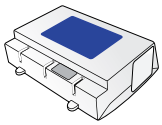
Mains power pack

Transport bag

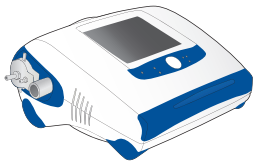


Patient circuit

Single circuit support



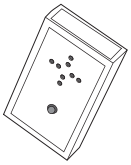
External battery pack



Clapper

Expiratory valve

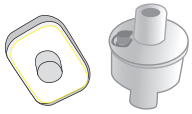
Transport trolley and support plate



Remote alarm

Mounting bracket

Transport bracket system



Antibacterial filter
HME filter

3 Ventilation

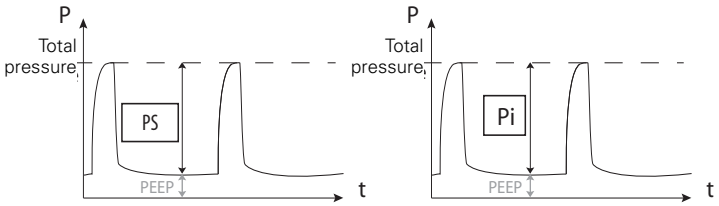
3.1 Ventilation parameters

Pressure Support and Inspiratory Pressure Pi (cm H_2O)

Pressure support is the pressure delivered by the ventilator in addition to the target PEEP during inspiratory phases in Pressure Support mode (PS on the graph below). In P(A)CV mode, the pressure added during the inspiratory phase is known as inspiratory pressure, or Pi.

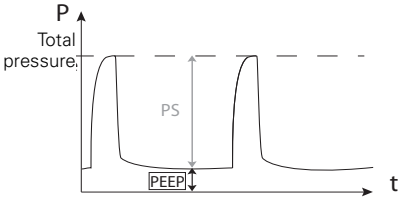
The total pressure corresponds:

- To the sum total of PS + PEEP in Pressure Support mode
- To the sum total of Pi + PEEP in the other pressure modes.



Positive End Expiratory Pressure PEEP (cm H_2O)

The pressure supplied by the ventilator and maintained during exhalation.



Continuous pressure (cm H_2O)

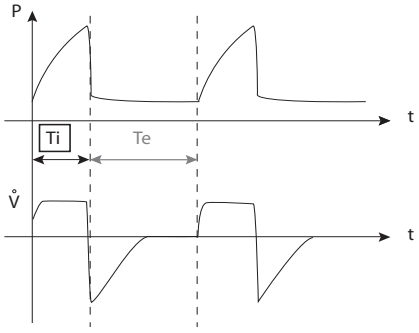
The pressure delivered to the patient (CPAP only).

Respiratory rate F (breaths per minute, bpm)

The number of breaths per minute, either delivered by the ventilator (controlled cycles) or initiated by the patient with the help of the triggers (assisted or assisted-controlled cycles).

Insufflation time Ti (s)

The time during which the ventilator is delivering insufflation to the patient.



Plateau time (s)

The period of time at the end of the inspiratory phase, during which there is no flow and the inspiratory and expiratory valves are closed.

Inspiratory time Tinsp (s)

The length of the inspiratory phase, corresponding to the total of the insufflation time plus the plateau time.

Maximum insufflation time Ti Max (s)

In the assisted modes, maximum time during which the machine delivers insufflation to the patient even if the set volume is not reached.

I:E ratio (inspiration to expiration ratio)

The ratio of inspiration time to expiration time (Te) for each breath.

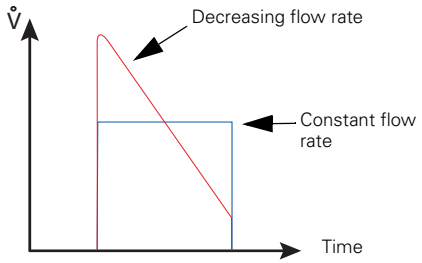
Example: If the respiratory rate is 20 bpm, each breath lasts for 3 seconds. If the I:E ratio is 1:2, Ti = 1 second and Te = 2 seconds.

Max. flow $\dot{V}$max (L/min) or inspiratory flow

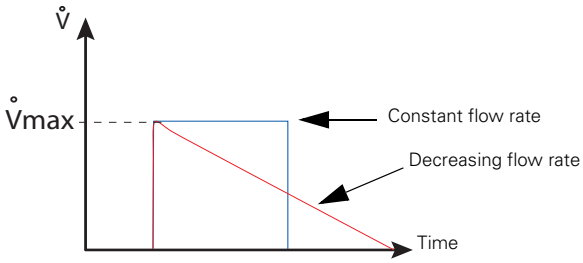
The maximum inspiratory flow delivered to the patient. Its setting in volume-controlled modes has a direct influence on the inspiratory time and the I:E ratio. It is fixed and known in volume-controlled modes, but variable and not controlled in pressure-controlled modes.

Flow shape

In volume-based modes, the flow rate delivered by the device may be constant or decreasing. The delivered tidal volume and the respiratory rate are maintained.



With I:E or Ti setting



With max. flow ($\dot{V}$max) setting

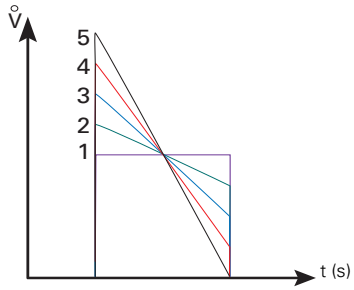
The flow level is set indirectly by the setting of the I:E ratio or the Ti, or directly by the setting of the Flow parameter:

- With a constant flow rate, the delivered flow is noticeably constant throughout the active inspiratory phase
- With a decreasing flow rate, the delivered flow decreases throughout the active inspiratory phase at the rate of one of four different gradients.

Note: *During ventilation, in ACV or SIMV mode, the duration of the insufflation time Ti is set directly on the Elisée 350 screen by pressing the Ti button, or indirectly through the setting of the $\dot{V}$ max or the I:E ratio.*

Influence of the choice of flow shape in ACV mode with the I:E ratio or the Ti set

In this case, the flow decreases at the rate of one of four downward gradients: 2, 3, 4 or 5.



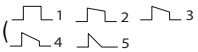
5: Max. flow = constant flow + 100%

4: Max. flow = constant flow + 75%

3: Max. flow = constant flow + 50%

2: Max. flow = constant flow + 25%

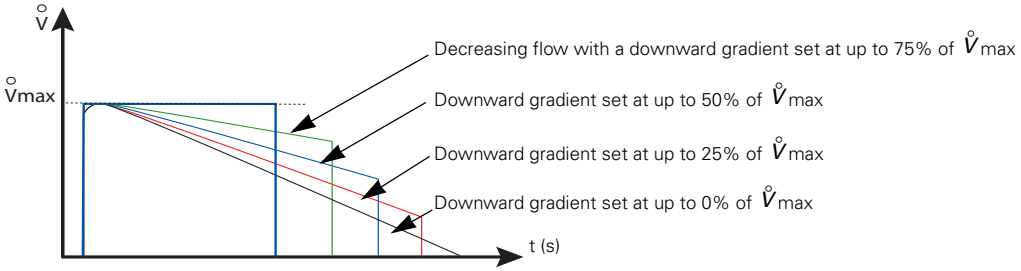
1: Constant flow

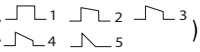
The Ti remains constant regardless of the flow shape selected (

). Only the $\dot{V}$max varies.

Influence of the choice of flow shape in ACV mode with the $\dot{V}$max set

The flow also decreases at the rate of one of four different gradients based on a percentage of the $\dot{V}$max:

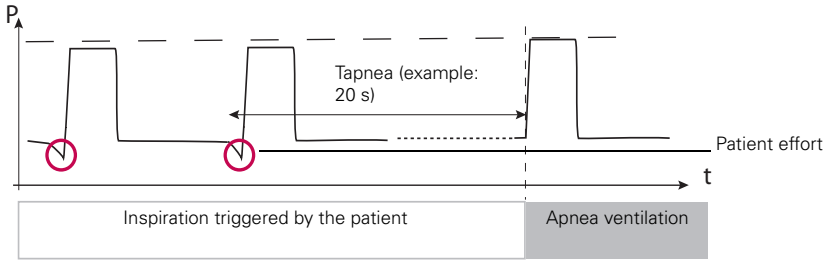


The $\dot{V}$max remains constant regardless of the flow shape selected (

). Only the Ti varies.

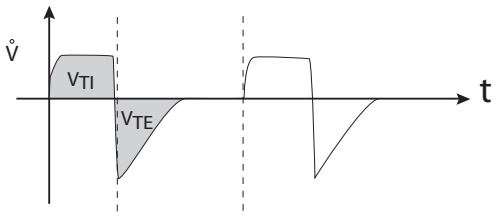
Apnea time Tapnea (s), specific to pressure support

Period of time after which, if inspiration is not initiated by the patient, the ventilator delivers an inspiratory cycle to the patient. The apnea time begins at the point when the last cycle was initiated by the patient. Example of apnea ventilation in PACV mode (Pi = 15 cm H_2O):



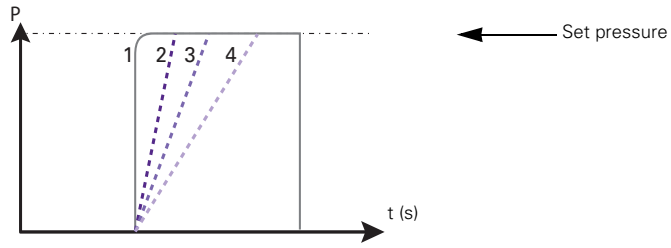
Tidal volume V_T (mL)

The volume of air insufflated to the patient by the ventilator (V_{TI}), and the volume of air exhaled by the patient (V_{TE}).



Rise time

The time it takes the ventilator to reach the set pressure. Four rise times are available, ranging from 1 (shortest rise time, 100 ms depending on ventilation) to 4 (longest rise time, up to 600 ms, depending on ventilation).



FiO_2 (%)

Inspired oxygen fraction in the gas mixture delivered to the patient.

Inspiratory trigger TgI

A value which allows an inspiratory phase to be triggered. Can be defined in terms of either flow or pressure:

- **Invasive inspiratory flow trigger TgI($\mathring{V}$)**

For use with a double circuit only. Recommended for ventilation requiring a very high level of trigger sensitivity.

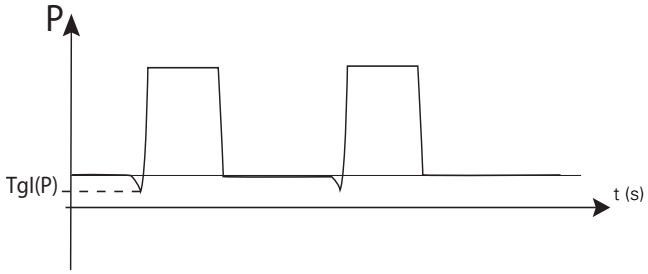
At the end of expiration, when the patient starts to inhale, the flow measured by the expiratory sensor becomes lower than the flow measured by inspiratory sensor. The ventilator triggers an inspiratory phase when this difference reaches the set value for the trigger (L/min).

The ventilator guarantees a constant minimum flow in the double circuit, called a *flow-by*, which makes it possible to detect the difference between the inspiratory and expiratory flow at the end of the patient's expiration.

- **Invasive inspiratory pressure trigger TgI(P)**

Operates with a single or double circuit.

A vacuum in the respiratory circuit during the expiratory phase triggers the inspiratory phase when the set trigger value is reached (measured in cm H_2O).

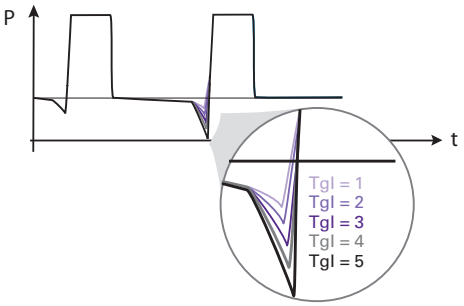


Non-invasive inspiratory trigger Tgl: Operates with a single or double circuit

It is activated according to the amplitude of the pressure variation when the patient makes an inspiratory effort. Activation of the trigger is based on several algorithms, making it possible to detect the patient's inspiratory effort, regardless of whether the patient's respiratory rate is rapid or slow. The trigger also takes into account the rate of unintended leaks in the circuit.

The values that may be chosen are:

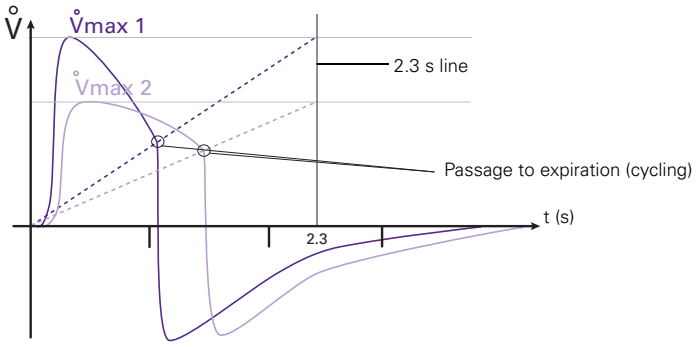
- From 1 to 5: 1 is the maximum sensitivity value (triggering of a cycle with minimal patient effort) and 5 is the minimum sensitivity value (the patient must make a greater effort to trigger a cycle)
- Auto: corresponds to a value between 2 and 3
- No (controlled ventilation).



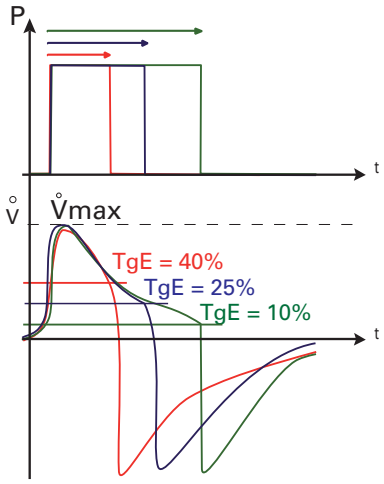
Expiratory trigger TgE

The value which defines the end of an inspiratory phase. It is configured as follows:

- **In automatic mode:** Adjusting the expiratory trigger in automatic mode allows the Ti to vary from one respiratory cycle to another, according to the effort characteristics of the patient. Thus, Ti varies according to the shape of the flow curve and the maximum flow value. An imaginary line (shown as a dotted line in the figure below) is drawn between the cycle start point and the point of the co-ordinates ($\dot{V}$max, 2.3 s line). Cycling occurs when the decelerating flow curve intersects with this imaginary line (which corresponds to cycling at approximately 30% of the peak flow).



- **In manual mode (%):** The expiratory trigger is expressed as a percentage of the maximum flow. The expiratory phase is triggered when the decreasing flow reaches the set flow percentage value.



3.2 Ventilation modes

The Elisée 350 offers seven ventilation modes:

- (Assisted) Volume-Controlled Ventilation ((A)CV)
- (Assisted) Pressure-Controlled Ventilation (P(A)CV)
- Synchronised Intermittent Mandatory Ventilation (SIMV)
- Pressure-Synchronized Intermittent Mandatory Ventilation (PSIMV)
- Pressure Support (PS)
- Pressure Support with Minimum Tidal Volume (PS.V_T)
- Continuous Positive Airway Pressure (CPAP).

(Assisted) Controlled Ventilation

In (Assisted) Controlled Ventilation, the device delivers cycles with a fixed inspiratory time and set volume ((A)CV mode) or set pressure (P(A)CV mode).

- In ACV and PACV modes, breaths can be triggered by the ventilator, by the patient (through the flow or pressure trigger) if the patient's respiratory rate is higher than the set respiratory rate, or by the user (by pressing the Manual breath button).
- If breaths are triggered by the ventilator alone, ventilation is no longer Assisted Controlled ventilation but **Controlled Ventilation (CV or PCV)**. On the screen, the "A" of ACV or PACV is greyed out.

In either of these modes, you can program recruitment cycles.

These cycles are always pressure-controlled, whether the device is in ACV or PACV mode. The ventilator triggers breaths for the patient. The adjustable parameters are:

- The recruitment period: the interval between two recruitment cycles, in minutes
- The recruitment size (s): the duration of insufflation during the recruitment cycle
- The recruitment pressure (cm H_2O): the pressure insufflated during the recruitment cycle.

When the device is in ACV mode, you can also set a plateau time using the End-inspiratory pause button.

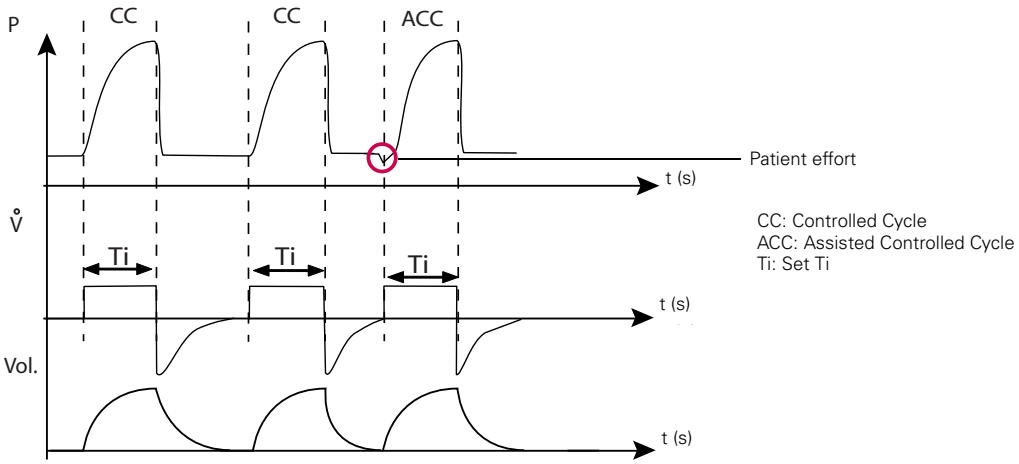
(Assisted) Volume-Controlled Ventilation ((A)CV)

In (A)CV mode, cycles are flow-controlled during a fixed inspiratory time to ensure the set volume is delivered. Controlled cycles are delivered according to the respiratory rate set by the clinician. In ACV mode, assisted controlled cycles can be triggered by the patient over and above the set respiratory rate.

Cycling occurs at the end of the inspiratory time (Ti) set by the user. For volume modes only, Ti is set either directly by means of the Ti setting, or indirectly by means of the I:E or $\dot{V}$ max settings, see "Selecting target parameters in ACV mode (during ventilation and while ventilation is stopped)" on page 63.

The adjustable parameters are as follows:

Adjustable parameters (CV/ACV modes)
V_T
F
Ti, max. flow ($\dot{V}$max) or I:E
Flow shape
Tplateau
PEEP
Inspiratory pressure and flow triggers (ACV only)
Recruitment parameters (period, size, pressure)
FiO_2



Note: *In (A)CV mode, the Elisée 350 delivers flow-controlled breaths. The airway pressure and the alveolar pressure depend on the resistance and compliance of the patient's respiratory system.*

WARNING

To avoid the risk of barotrauma, it is important to set the High Pressure alarm (Pmax) and to monitor the measured values, in particular the plateau pressure if a plateau time was set.

(Assisted) Pressure-Controlled Ventilation (P(A)CV)

In P(A)CV mode, cycles are pressure-controlled. The flow is adjusted so that the set pressure is maintained during a set inspiratory time.

The target Pi is added to the PEEP, so Total inspiratory pressure = Pi + PEEP. Controlled cycles are delivered according to the respiratory rate set by the user. In PACV mode, assisted controlled cycles can be triggered by the patient over and above the set respiratory rate.

The tidal volume and the minute volume are based on the resistance and compliance of the patient's respiratory system.

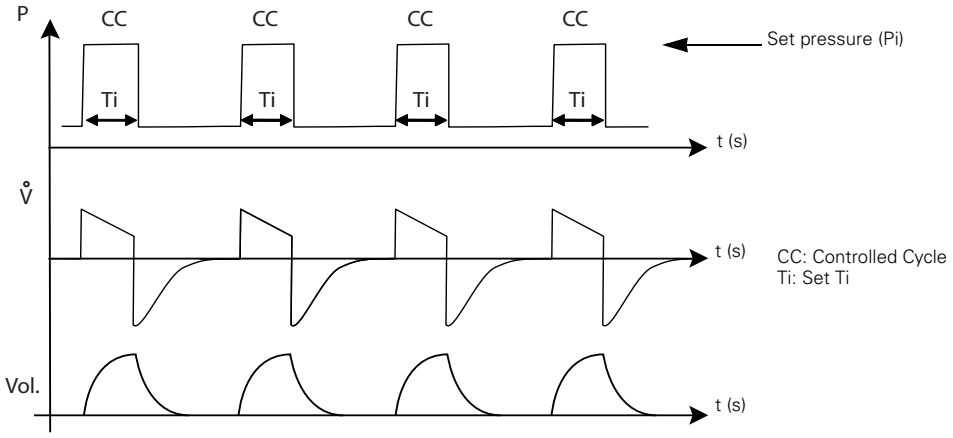
WARNING

In P(A)CV, the flow is adjusted so that a constant pressure is maintained. Consequently, the volume delivered may vary depending on compliance and resistance. It is therefore important to monitor the inspiratory and, in particular, the expiratory volumes through the min. and max. V_{TI} and V_{TE} alarms.

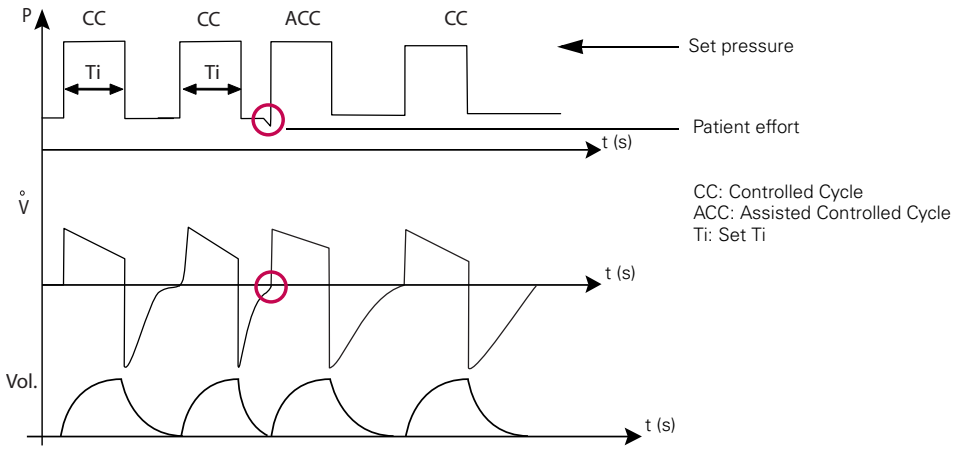
The adjustable parameters are as follows:

Adjustable parameters (PVC/PACV)
Pi
F
Ti
PEEP
Rise time
Inspiratory pressure and flow triggers (PACV only)
Recruitment parameters (period, size, pressure)
FiO_2

PCV mode:



PACV mode:



Synchronized Intermittent Mandatory Ventilation (SIMV and PSIMV)

These ventilation modes allow you to alternate between:

- Assisted ventilation cycles that are either flow-controlled (SIMV) or pressure-controlled (PSIMV)
- Cycles that allow the patient to produce spontaneous breaths with pressure support (PS).

They are generally used to wean patients off ventilation and help them regain respiratory independence.

Principle

A respiratory rate **F** is set on the device. This allows you to define a mechanical period, Tmech, in seconds, whereby:

$$Tmech = \frac{60}{F}$$

Tmech serves as a basis for triggering controlled cycles (CC). One minute of ventilation is segmented into set mechanical periods, and the respiratory rate remains unchanged.

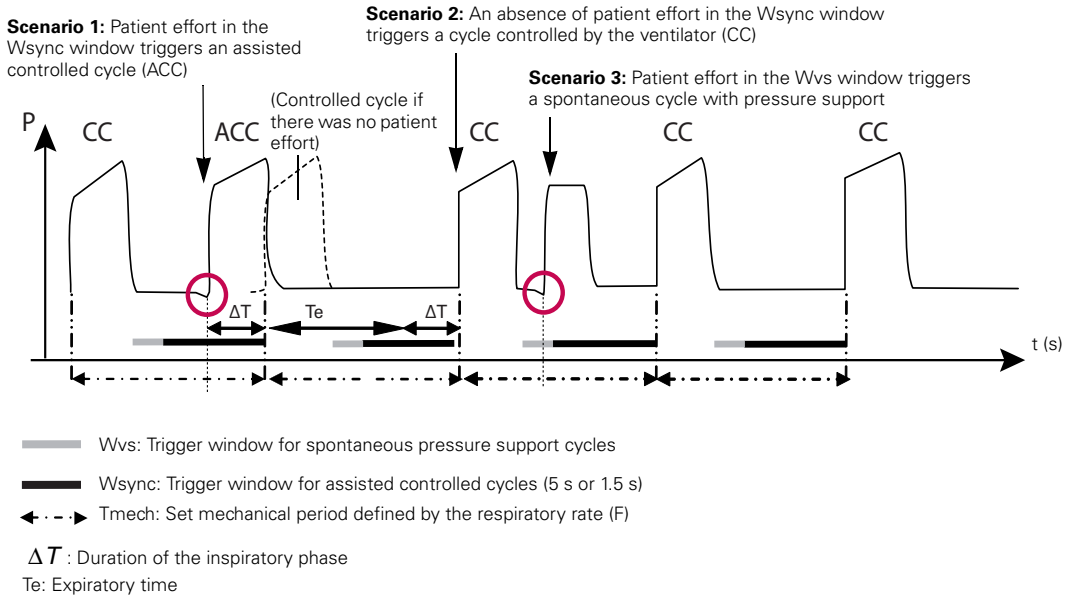
To synchronise the ventilator with the patient, a trigger window called **Wsync** (▬), for assisted controlled cycles (ACC), is defined before the start of a controlled ventilation cycle. This window is 5 s long for adults and 1.5 s long for paediatric patients.

After each Wsync window (whether assisted or controlled), there is a **Wvs** window (▬) during which the patient can trigger a spontaneous breath with adjustable pressure support (see page 52 for instructions on setting the parameters). The patient is consequently relieved of part of the respiratory effort required to overcome the resistance of his/her respiratory system as well as the combined resistance of the ventilator, circuit, filter and water traps.

Note: *Make sure the respiratory rate is set below 10 bpm and an appropriate I:E ratio is set, so that the patient can make the most of this window for triggering a spontaneous breath with pressure support. For example:*

- *If F = 10 bpm, the respiratory cycle lasts 6 seconds (60/10). If Ti = 1.2 s, then Te = 4.8 s. Te < the 5 s minimum limit of the Wsync window. Therefore, Wsync extends throughout the entire expiratory phase and does not allow the patient to trigger any spontaneous breaths with pressure support between the controlled cycles.*
- *If F = 8 bpm, the cycle is 7.5 s. If Ti = 1.2 s, then Te = 6.3 s, which leaves 6.3–5, or 1.3 s for the Wvs window.*

How SIMV mode works:



Wvs: Trigger window for spontaneous pressure support cycles

Wsync: Trigger window for assisted controlled cycles (5 s or 1.5 s)

Tmech: Set mechanical period defined by the respiratory rate (F)

ΔT : Duration of the inspiratory phase

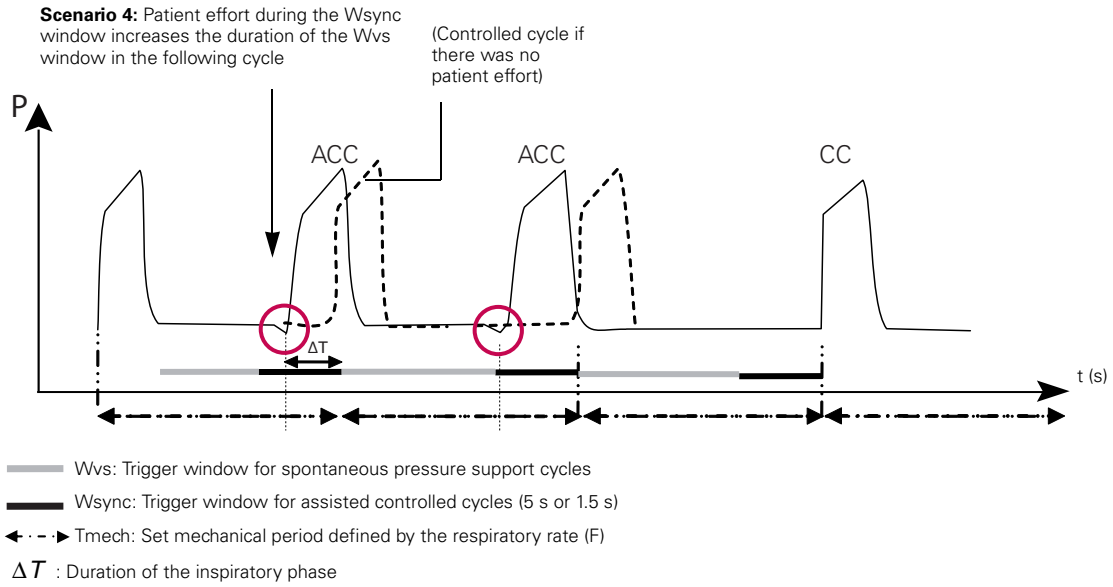
Te: Expiratory time

Triggering of (assisted) controlled cycles or spontaneous cycles with pressure support:

- If there is no patient effort (patient-initiated breath) during the Wsync window, at the end of the Wsync period the Elisée 350 delivers a controlled cycle (CC) based on the respiratory rate F set on the ventilator.
- If there is a patient-initiated breath during this window (see **Scenario 1** in the previous figure), the cycle will be assisted controlled (ACC), either pressure-controlled (in PSIMV mode) or volume-controlled (in SIMV mode).
- If there is no patient-initiated breath within the next Wsync window following an assisted controlled cycle (ACC) (**Scenario 2**), the Elisée 350 delivers a controlled cycle (CC). The expiratory time (Te) of the assisted controlled cycle is increased by the ΔT time (limited to 5 seconds for adults and 1.5 seconds for children), corresponding to the anticipated time for triggering the controlled cycle. The respiratory rate set on the ventilator therefore remains constant.
- If the patient initiates a breath during this window (**Scenario 3**), a spontaneous breath with pressure support is triggered.

Note: *If the patient initiates a breath during the Wsync window, the Wvs window is extended by* ΔT*, which corresponds to the time remaining before another controlled cycle is triggered (**Scenario 4**).*

How SIMV mode works – Scenario 4:



Note:

- *During SIMV, use the High Pressure alarm to monitor the level of pressure in the patient's airways and prevent barotrauma.*
- *In PSIMV mode, with both assisted controlled cycles and spontaneous cycles with pressure support, the tidal volume depends on the set pressure gradient and on the patient's respiratory mechanics. It is therefore important that you monitor the expiratory spirometry levels (expired tidal and minute volumes) to see the patient's role in pressure support.*

Adjustable parameters (SIMV)	Adjustable parameters (PSIMV)
F	F
Flow shape	Ti
V_T	Pi
Ti, max. flow or I:E	Ti, max. flow or I:E
PEEP	PEEP

Adjustable parameters (SIMV)	Adjustable parameters (PSIMV)
PS	PS
Ti Max	Ti Max
Rise time	Rise time
Inspiratory pressure and flow triggers	Inspiratory pressure and flow triggers
Expiratory trigger	Expiratory trigger
Tplateau	FiO_2
FiO_2	

Spontaneous ventilation

The Elisée 350 has two spontaneous ventilation modes:

- Standard pressure support (PS mode)
- Pressure support with minimum tidal volume (PS.V_T mode).

Both modes include apnea ventilation as backup ventilation for the patient, in the event that the patient stops triggering spontaneous breaths.

Pressure support (PS)

Pressure support is a targeted, pressure-controlled mode which supports the patient's spontaneous breathing. The beginning, end and duration of each cycle, as well as the respiratory rate, are determined by the patient. Cycles can be triggered either by the patient (through the flow or pressure trigger) or by the user (by pressing the Manual breath button).

Inspiratory phase

The start of each cycle is triggered by the patient. Once it has detected an inspiration, the Elisée 350 pressurises the inspiratory circuit to reach the set pressure. The time it takes to reach this pressure depends on the rise time setting. The peak flow delivered by the ventilator also depends on this setting.

During the pressure maintenance phase, the flow is delivered and adjusted according to the patient's needs and the resistance and compliance of the patient's respiratory system.

In Pressure Support mode, you can also set an **apnea time**, at the end of which the ventilator switches to apnea ventilation (backup ventilation) if the patient does not trigger a cycle. This apnea ventilation may be either barometric or volumetric, depending on the setting option selected.

Exiting apnea ventilation:

During apnea ventilation, the patient can trigger additional assisted controlled ventilation cycles. On the fourth consecutive patient-triggered cycle, the ventilator returns to pressure support mode.

The adjustable parameters are as follows:

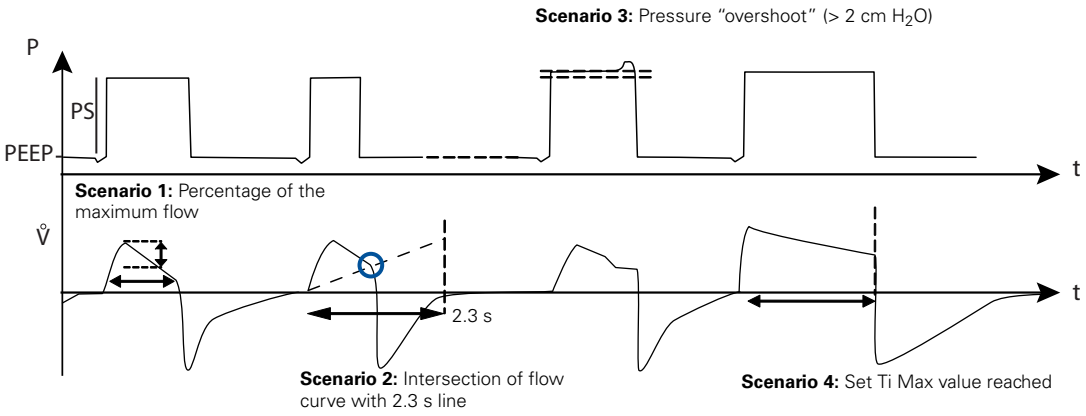
- In volume-controlled mode: the apnea time (Tapnea), the tidal volume (V_T), the respiratory rate (F), and the inspiratory time (Ti) (or $\dot{V}$max or I:E)
- In pressure-controlled mode: the apnea time (Tapnea), the inspiratory pressure (Pi), the respiratory rate (F), and the inspiratory time (Ti).

Note: *The trigger and PEEP settings for pressure support apply to apnea ventilation.*

Expiratory phase

The device cycles into the expiratory phase:

1. When the expiratory trigger setting is reached. The setting may be:
   - Based on the percentage of the maximum flow (**Scenario 1**, see figure)
   - Based on the intersection of the flow curve with the 2.3 s line (**Scenario 2**).
2. If the target pressure of 2 cm H_2O is exceeded during the decreasing flow stage. The excess pressure may be due to a patient-initiated active exhalation) (**Scenario 3**).
3. If, on reaching the maximum inspiratory time set by the user, none of the above conditions have been met (**Scenario 4**) (for example, if there is a leak in the circuit and the flow does not decrease fast enough in relation to the times set for the expiratory trigger).



Note: *The set PS level is added to the PEEP level.*

The adjustable parameters are as follows:

Adjustable parameters (PS)
PS
PEEP
Rise time
Inspiratory pressure and flow triggers
Expiratory trigger
Apnea parameters. Depending on the type of mode selected: • Volume-controlled mode: Tapnea, V_T, F and Ti (or $\dot{V}$ max or I:E) • Pressure-controlled mode: Tapnea, Pi, F and Ti.
Ti Max
Leak
FiO_2

WARNING

Unlike with the controlled cycles in CV and ACV modes, in Pressure Support mode, tidal volume is not fixed but depends on the patient's inspiratory effort and resistance and compliance characteristics. Tidal volume and minute volume must be monitored by setting volume alarms.

Pressure support with minimum tidal volume (PS.V_T)

This is a mixed mode which combines pressure support and volume-controlled ventilation to provide a high level of patient safety. In this mode, the ventilator delivers a minimum tidal volume in every cycle. This is necessary, for example, when the patient's inspiratory effort decreases, or the patient's compliance changes. PS.V_T mode is particularly appropriate for patients receiving invasive ventilation, or during weaning trials for patients treated for respiratory failure.

Inspiratory phase

The beginning of each cycle is triggered by the patient (through the flow or pressure trigger) or by the user (by pressing the Manual breath button).

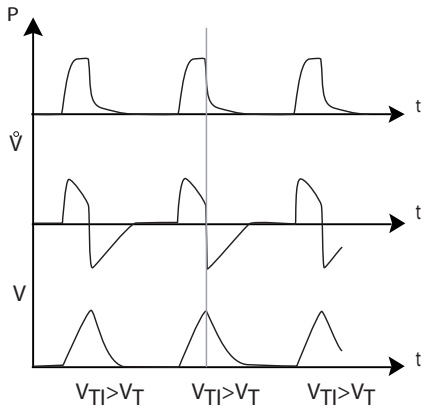
In PS.V_T mode, you can set an **apnea time**, at the end of which the ventilator switches to apnea ventilation if the patient does not trigger a cycle. This apnea ventilation may be either pressure-controlled or volume-controlled, depending on the setting option selected.

Exiting apnea ventilation:

During apnea ventilation, the patient can trigger additional assisted controlled ventilation cycles. On the fourth consecutive patient-triggered cycle, the ventilator returns to pressure support mode.

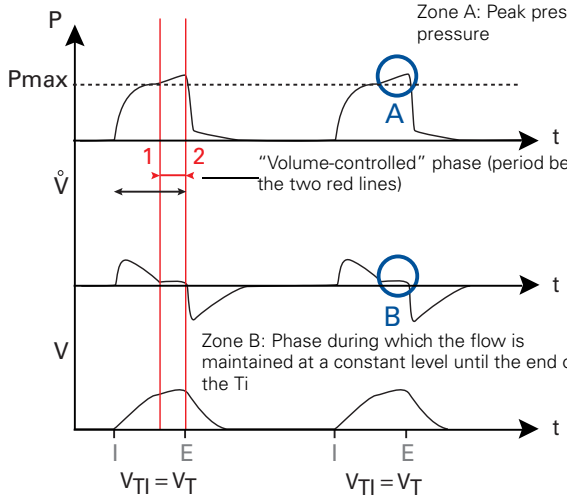
The delivered cycle begins with pressure support ventilation. The Elisée 350 constantly calculates, from the V_T already delivered and the inspiratory time remaining, whether the target minimum tidal volume (V_T) will be able to be delivered.

- If so, the Elisée 350 continues to deliver the cycle with pressure support.



The target minimum tidal volume is delivered through pressure support alone, without a switch to the volume-controlled part of PS.V_T mode. The inspiratory flow progressively reduces until the expiratory trigger threshold is reached.

- If not, the ventilator switches to volume-controlled mode, delivering the remaining portion of the tidal volume while maintaining an appropriate constant flow until the target minimum tidal volume is reached. Switching to volume-controlled mode means that the set pressure will be exceeded during that cycle in order for the minimum tidal volume to be delivered. The pressure cannot be exceeded by a value greater than the Pmax alarm setting.



Zone A: Peak pressure rising above the target pressure

Based on the pressure support and Ti Max settings, the ventilator detects, during the cycle, that the minimum tidal volume cannot be delivered. It therefore switches to volume-controlled mode and delivers a constant flow until the Ti Max is reached.

Note: *For optimum patient comfort, the minimum V_T should be set to a lower value than the V_{TE} recorded in Pressure Support mode. If it is set too close to the V_{TE} value, the volume-controlled part of PS.V_T will be triggered too frequently. However, you may disregard this rule if the benefit to the patient of a higher minimum V_T outweighs the importance of patient comfort.*

CAUTION

Under certain conditions, the minimum V_T cannot be delivered:

- When the delivered pressure reaches the Pmax value
- When certain parameter settings are reached (Low Ti, Low PS and High V_T).

Expiratory phase

When the cycle is entirely spontaneous (the device does not switch to volume-controlled mode), cycling to expiration occurs in the same way as in pressure support mode (see page 25).

When the ventilator switches to volume-controlled mode, delivering a constant flow in order to reach the minimum tidal volume within the time allowed (Ti Max), cycling occurs:

- When the inspired tidal volume (V_{TI}) reaches the set minimum tidal volume
- At the end of the maximum inspiratory time Ti Max
- If the pressure in the circuit reaches the Pmax safety threshold and the inspiratory flow is maintained at a constant level, causing a peak in pressure.

Adjustable parameters (PS.V_T)
V_T
Leak
Ti Max
PS
PEEP
Rise time
Inspiratory pressure and flow triggers
Expiratory trigger
Apnea parameters (Tapnea, F, Ti and V_T or Pi)
FiO_2

Continuous Positive Airway Pressure (CPAP)

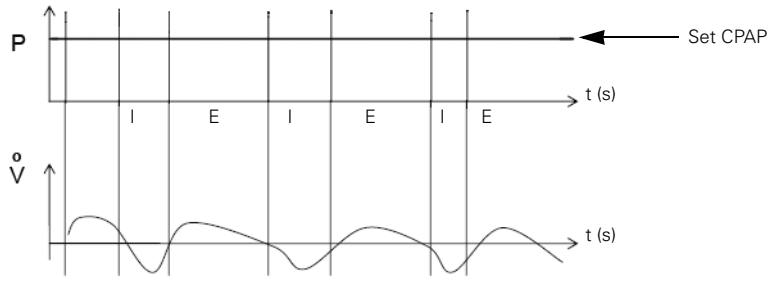
WARNING

CPAP mode is intended to be used when there is constant monitoring by health care personnel, in emergency situations, or during rehabilitation.
Do not use this mode without supervision for ventilation-dependent patients requiring continuous ventilation in an ICU, especially paediatric ICU patients.

This mode provides ventilation at one level only, with the inspiratory pressure within 1 cm H_2O of the expiratory pressure. On the Elisée 350 it is equivalent to a PS mode, but has only two adjustable parameters:

Adjustable parameters
Continuous pressure (CPAP)
FiO_2

The ventilator compensates for the drop in pressure caused by inspiration with an increase in flow. When the patient exhales, a counter-pressure is applied to the expiratory valve, making it possible to maintain the expiratory pressure at the CPAP level set by the user.



3.3 Ventilation settings and measurements

Ventilation parameters must be determined and set under the supervision of a physician or other competent and trained personnel.

Ventilation settings

Adult ventilation settings

		Ventilation type					
	Default value	**INVASIVE**		**NON-INVASIVE**		**Setting Increment***	**Precision of set values**
Parameter		Min.	Max.	Min.	Max.		
FiO_2 (%)	60	21	30	21	30	9	± 3
		30	100	30	100	5	
F (bpm)	15	2	50	2	50	1	± 1
Ti (s)**	1	0.3	3	0.3	3	0.1	± 0.1
I:E**	1:2.0	1:0.4	1:9.9	1:0.4	1:9.9	1:0.1	
Ti Max (s)	1.2	1	3	1	3	0.1	
Tapnea (s)	15	10	60	10	60	1	± 1
Pi (cm H_2O)	15	5	60	5	60	1	± 5%
PS (cm H_2O)	8	5	60	5	60	1	± 5%
PEEP (cm H_2O)	0	0	25	0	25	1	± 0.5 cm H_2O for values of 1–5 cm H_2O, 10% for higher values
CPAP (cm H_2O)	8	3	25	3	25	1	
V_T (ml)	500	300 1000	1000 2500	300 1000	1000 2500	10 100	± 10% or 10 ml
Max flow (L/min) $\dot{V}_{max}$**	60	10	120	10	120	1	
Rise time	1	1	4	1	4	1	
Tplateau (s)	0	0	2	0	2	0.1	± 0.1
Flow shape	1	1	5	1	5	1	
Recruitment period (min)	NO	1/NO	60	1/NO	60	1	
Recruitment size (s)	2	0.3 3	3 40	0.3 3	3 40	0.1 1	± 0.1

		Ventilation type					
	Default value	**INVASIVE**		**NON-INVASIVE**		**Setting Increment***	**Precision of set values**
Parameter		Min.	Max.	Min.	Max.		
Recruitment pressure (cm H_2O)	15	5	60	5	60	1	± 5%
Nebulisation duration (min)	15	1	30	1	30	1	Ti/60
Nebuliser flow (L/min)	7	5	20	5	20	1	

* The setting increment may vary depending on the parameter value. For example, for tidal volume (V_T), the values increase/decrease by 10 between 300 mL and 1000 mL and by 100 between 1000 mL and 2000 mL.
** The device will beep if the I:E ratio is inverted during adjustment of the parameters.

Paediatric ventilation settings

		Ventilation type					
	Default value	**INVASIVE**		**NON-INVASIVE**		**Setting Increment***	**Precision of set values**
Parameter		Min.	Max.	Min.	Max.		
FiO_2 (%)	60	21	30	21	30	9	± 3
		30	100	30	100	5	
F (bpm)	25	2	80	2	80	1	± 1
Ti (s)**	0.6	0.3	3	0.3	3	0.1	± 0.1
I:E**	1:3.0	1:0.4	1:9.9	1:0.4	1:9.9	1:0.1	
Ti Max (s)	0.8	0.5	2.5	0.5	2.5	0.1	
Tapnea (s)	10	5	20	5	20	1	± 1
Pi (cm H_2O)	12	3	60	3	40	1	± 5%
PS (cm H_2O)	6	3	60	3	40	1	± 5%
PEEP (cm H_2O)	0	0	20	0	20	1	± 0.5 cm H_2O for values of 1–5 cm H_2O, 10% for higher values
CPAP (cm H_2O)	6	3	20	3	20	1	
V_T (mL)	100	50	500	50	500	10 100	± 10% or 10 mL
Max flow (L/min) $\dot{V}_{max}$**	10	5	40	5	40	1	
Rise time	1	1	4	1	4	1	
Tplateau (s)	0	0	1.5	0	1.5	0.1	± 0.1
Flow shape	1	1	5	1	5	1	
Recruitment period (min)	NO	1/NO	60	1/NO	60	1	
Recruitment size	2	0.2 3	3 40	0.2 3	3 40	0.1 1	± 0.1
Recruitment pressure (cm H_2O)	15	5	60	5	60	1	± 5%
Nebulisation duration (min)	15	1	30	1	30	1	Ti/60
Nebuliser flow (L/min)	7	5	20	5	20	1	

Triggers used with a double circuit

: Non-invasive ventilation; : Invasive ventilation

		Default values		Minimum		Maximum		Increment
		Paediatric	Adult	Paediatric	Adult	Paediatric	Adult	
Inspiratory pressure trigger (cm H_2O)	ACV PACV	NO	NO	0.2	0.2	5.9/NO	5.9/NO	0.1
	PS PS.Vt SIMV PSIMV	NO	NO	0.2	0.2	6	6	0.1
Inspiratory flow trigger (L/min)	ACV PACV	1.5	3	0.2	0.2	9.9/NO	9.9/NO	0.1
	PS PS.Vt SIMV PSIMV	1.5	3	0.2	0.2	10.0	10.0	0.1
Non-invasive inspiratory trigger	ACV PACV	3	3	1	1	5/NO	5/NO	1
	PS PS.Vt SIMV PSIMV	3	3	1	1	5	5	1
Expiratory trigger	PS PS.Vt SIMV PSIMV	AUTO 25	AUTO 25	10	10	90/AUTO	90/AUTO	1

Note:

For the non-invasive inspiratory trigger:

- *Trigger = 1 is the maximum sensitivity value (triggering of a cycle with minimal patient effort) and Trigger = 5 is the minimum sensitivity value (the patient must make a greater effort to trigger a cycle).*
- *Trigger = Auto corresponds to a value of 3.*

For the expiratory trigger, the Auto value also corresponds to a value of 3.

Triggers used with a single circuit

: Non-invasive ventilation; : Invasive ventilation

		Default values		Minimum		Maximum		Increment
		Paediatric	Adult	Paediatric	Adult	Paediatric	Adult	
Inspiratory pressure trigger (cm H_2O)	ACV PACV	0.5	1.0	0.2	0.2	5.9/NO	5.9/NO	0.1
	PS PS.Vt SIMV PSIMV	0.5	1.0	0.2	0.2	6	6	0.1
Non-invasive inspiratory trigger	ACV PACV	3	3	1	1	5/NO	5/NO	1
	PS PS.Vt SIMV PSIMV	3	3	1	1	5	5	1
Expiratory trigger	PS PS.Vt SIMV PSIMV	AUTO 25	AUTO 25	10	10	90/AUTO	90/AUTO	1

Measurements

Measurements (unit)	Range	Actual measurement accuracy	Precision of displayed values
PEEP (cm H_2O)	0–100	± 5% or 0.5 cm H_2O	0.1
Pplat	0–100	± 5% or 0.5 cm H_2O	0.1
Pmean (cm H_2O)	0–100	± 5% or 0.5 cm H_2O	0.1
Ppeak (cm H_2O)	0–100	± 5% or 0.5 cm H_2O	0.1
FiO_2 (%)	0–100	± 10%	1
Ftot (bpm)**	1–99	± 1	1
Ti (s)	0.1–9.99 10.0–99.9	± 0.02% ± 0.02%	0.01 0.1
Te (s)	0.1–9.99	± 0.02%	0.01
I:E**	1:9.9–1:0.1 1:99–1:9.9	± 0.04% ± 0.04%	1:0.1 1:1
$\dot{V}e$ (L/min)	0.1–99.9	± 15%	0.1
$\dot{V}evs$ (L/min)	0.1–99.9	± 15%	0.1
V_{TI} or V_{TE} (mL)*	0–100 >100	± 10 mL ± 10%	1 1
Vte (mL) (double circuit only)	0–100 >100	± 10 mL ± 10%	1 1

* These measurements are given in ATPD (Ambient Temperature and Pressure, Dry) conditions except for the expiratory volume during patient ventilation. The latter is given in BTPS (Body Temperature, Ambient Pressure and Vapour Saturated) conditions, unless the BTPS option is disabled. The volume and flow measurements are corrected in order to take into account the oxygen content (the correction factor is calculated from the FiO_2 measurement).

** The F and I:E measurements are averaged over four cycles.

Oxygen consumption

In (A)CV mode, with V_T = 500 mL, PEEP = 7 cm H_2O, F = 15 bpm, and I:E = 1:2.0:

FiO_2 = 100%: O_2 consumption is 18 L/min ± 20%.

Interdependence of the parameters

Implicit (calculated) parameters

Some parameters are adjustable, others are calculated from the values set for the adjustable parameters: they are called implicit parameters. Te is an example of an implicit parameter, obtained from a calculation based on the values set for the adjustable parameters Ti and F (Te = 60/F – Ti).

These parameters are $\dot{V}$max, Ti, Te and I:E.

Note: *Ti, I:E and $\dot{V}$max can be either adjustable or implicit parameters depending on the original configuration selected for the ACV mode (parameter options). If the device beeps while the user is setting the parameters, it means the I:E ratio has been inverted because of an adjustment to one of the parameters.*

Implicit parameter limits

		Minimum value	Maximum value
Maximum flow ($\dot{V}$max)	Adult	10 L/min	120 L/min
	Paediatric	5 L/min	40 L/min
Ti		0.3 s	3.0 s
I:E		1:0.4	1:9.9
Te		0.45 s	

Limitation of the total inspiratory pressure

The upper limit of the total inspiratory pressure is: PS (or Pi) + PEEP = 60 cm H_2O or Precruit. = 60 cm H_2O.

Even if a value higher than 60 cm H_2O is displayed, this limit is always observed.

Interdependence of settings and measurements

The tables below display all of the measurements that vary if a setting is changed.

For ventilation in volume-based modes

	V_T	PEEP	F	Max flow ($\dot{V}$ max)	Flow shape	Tplateau	Tgl	I:E	Ti
Ti	✓		✓	✓	✓	✓		✓	
Te	✓		✓	✓	✓	✓	✓	✓	✓
I:E	✓		✓	✓	✓	✓	✓		✓
F							✓		
V_{TI}	✓								
V_{TE}	✓								
$\dot{V}_e$	✓		✓					✓	✓
$\dot{V}_{evs}$							✓		
PEEP									
Pplat	✓	✓		✓		✓			
Ppeak	✓	✓		✓		✓			
Pmean	✓	✓		✓	✓				
F/V_T	✓		✓				✓	✓	✓

For ventilation in pressure-based modes

	Pi/PS	PEEP	F	Ti	Inspiratory trigger	Expiratory trigger
Ti						✓
Te			✓	✓		✓
I:E			✓	✓		✓
F					✓	
V_{TI}	✓	✓				✓
V_{TE}	✓	✓				✓
$\dot{V}_e$	✓	✓	✓			✓
$\dot{V}_{evs}$					✓	
PEEP						
Ppeak	✓	✓				
Pplat	✓	✓				
Pmean	✓	✓				✓
F/V_T	✓	✓		✓	✓	

4 Setting up

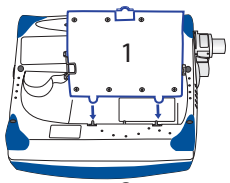
4.1 Power supplies

Mains power pack (housed in the compartment under the ventilator)

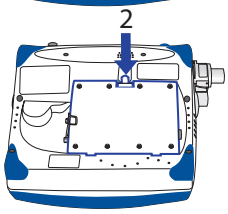
CAUTION

- Before installing the mains power pack, disconnect the power cord.
- Use only the power pack and the specific cord supplied with the ventilator.

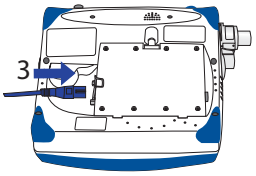
Connecting the device to mains power enables you to recharge the internal battery.



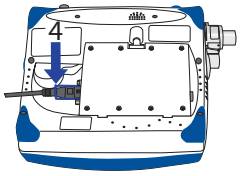
1. Insert the two nibs on the mains power pack into their slots.



2. Press firmly on the mains power pack until the clip locks into place.



3. Connect the mains power cord to the power port on the side of the pack.



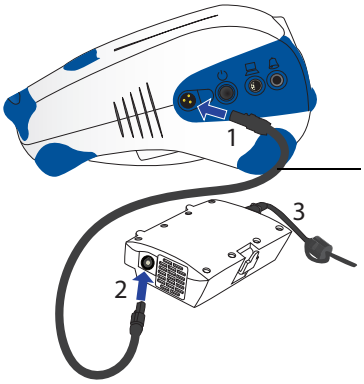
4. Fold the fastening clip into place to prevent the plug from accidentally coming out of its socket, then plug the cord into the wall socket and turn on the switch (if necessary).

External DC power supply

CAUTION

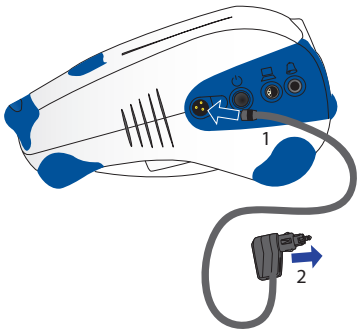
Never turn the ventilator on with the power pack compartment empty. Always use the dummy pack if no power pack is inserted.

Mains power pack located outside of the ventilator



1. Connect the external power cord to the socket on the ventilator.
2. Plug the other end into the connector on the mains power pack.
3. Plug the pack into a mains power outlet and switch on (if necessary).

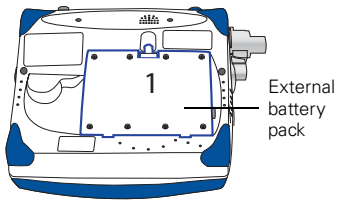
External power supply from a vehicle



1. Connect the 12–28 V DC power cord to the connector on the ventilator.
2. Plug the power cord with the ResMed cigarette lighter adapter attached into the cigarette lighter.

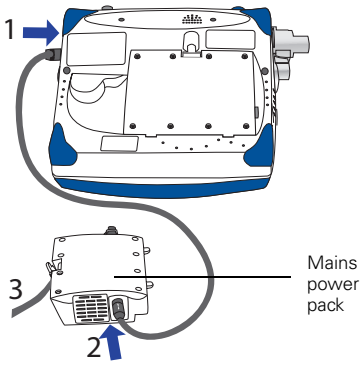
External battery pack

This is fitted and removed in the same way as the mains power pack. We recommend you remove the external battery pack when the ventilator is switched off.



1. Place the external battery pack (blue label) in the compartment. If it has a sufficient charge, the ventilator will start using it.

If the external battery needs charging, use the mains power pack and power cord:



1. Connect the power cord to the external DC power socket on the ventilator.
2. Connect the other end of the cord to the mains power pack.
3. Plug the pack into a mains power outlet and switch on (if necessary).

Note: *An external battery pack charger is available for Li-Ion type batteries.*

4.2 Patient circuits

The Elisée 350 can be operated with a single or double circuit, and has the option of an interchangeable expiratory valve system.

The Elisée 350 can be used with circuits of the following diameters:

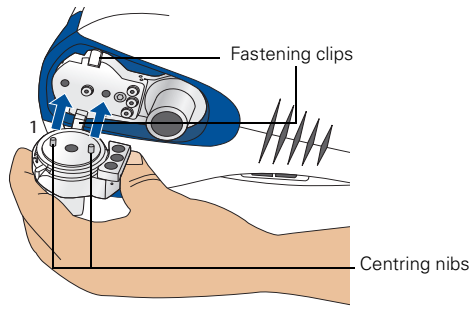
- 15 mm for ventilation with a tidal volume between 50 and 300 mL ("paediatric" circuits)
- 22 mm for ventilation with a tidal volume > 300 mL ("adult" circuits).

CAUTION

- **The ventilator automatically detects the patient circuit type and its characteristics during the manual test (see "3 Manual test" on page 48). This test must be performed each time the circuit is changed (type, brand, configuration, etc.) or an accessory is added/ removed.**
- **If you change any of the alarm settings, see Section 6.5 on page 74 for instructions on testing the alarms.**

Fitting the circuit support

To fit the double circuit support:



1. Position the centring nibs opposite their holes and press the expiratory valve onto the support until the fastening clips lock into place.

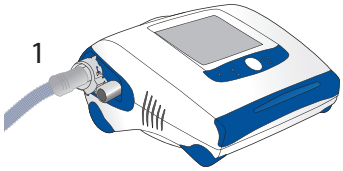
To remove the support, press the fastening clips in with one hand, and detach the support with your other hand.

Connecting the patient circuit (single or double)

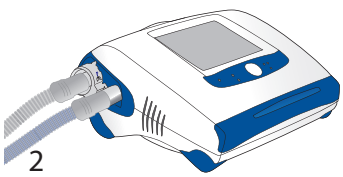
To obtain good performance, it is advisable to use the circuit supplied in the pack (single or double), or an equivalent circuit. See page 94.

Double circuit

Any circuit can be used with the Elisée 350, whether single or double, with or without water traps, reusable or single-use, as long as it has the same technical specifications as the recommended circuit (see "Technical specifications for accessories" on page 94).



1. Connect the expiratory limb to the exhaled air return port.



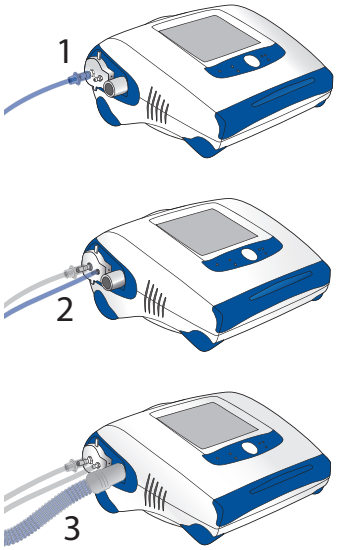
2. Then connect the inspiratory limb to the insufflation outlet.

Note: *Perform a manual test so that the Elisée 350 registers the new circuit configuration.*

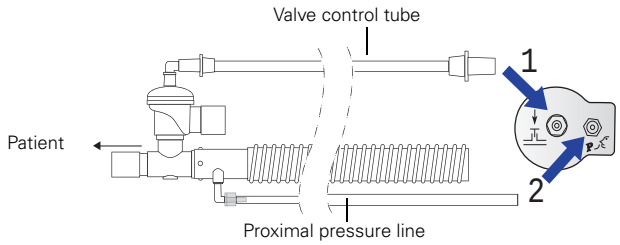
WARNING

Set a V_{TE} alarm threshold based on the measured expiratory volumes.

Single circuit



1. Connect the expiratory valve control tube.
2. Connect the proximal pressure line by pushing the tube onto the notched connector. Depending on the circuit used, it may be necessary to cut off the nozzle of the proximal pressure line.



3. Connect the inspiratory limb to the insufflation outlet.

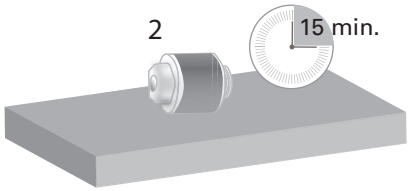
Note: *Perform a manual test so that the Elisée 350 registers the new circuit configuration.*

WARNING

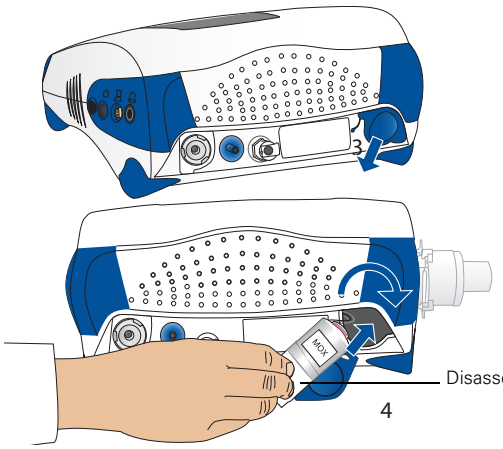
The end of the proximal pressure line must be placed as close to the patient as possible. Proximal pressure measurement is essential for insufflation pressure monitoring and pressure trigger sensitivity.

4.3 Oxygen

Installing the oxygen sensor

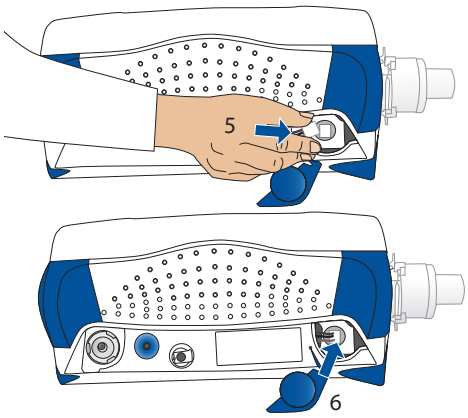


1. Switch off the ventilator.
2. Prepare the new oxygen sensor:
   - Check the expiry date (month and year) on the sensor packaging. It can be installed at any time before the date on the label.
   - Let the sensor sit in ambient air for 15 minutes.



3. On the Elisée 350, remove the protective cap from the sensor.

4. Using the disassembly tool supplied with the ventilator, place the sensor in its compartment and screw into place.



5. Plug the connector into the sensor.

6. Cover the sensor with the protective cap.
7. Switch the ventilator on, and perform a manual test to calibrate the sensor (see "3 Manual test" on page 48). If the message "REPLACE O_2 CELL" is not displayed on the screen, the sensor is operational.

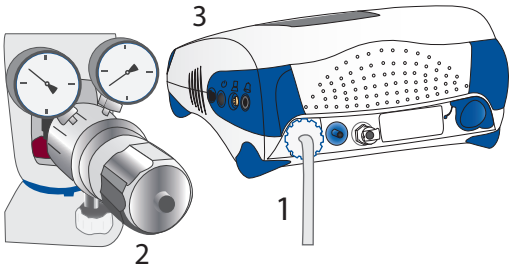
High-pressure oxygen

High-pressure oxygen can be sourced from:

- A wall supply
- An oxygen bottle fitted with a pressure regulator. We recommend that you set the regulator at 400 kPa ± 50 kPa.

WARNING
You must only use tubing that complies with the ISO 5359 standard.

With the ventilator in standby mode (the ventilator must not be in ventilation mode):



1. Connect the high-pressure oxygen supply to the O_2 port on the back of the ventilator.
2. If using an oxygen bottle, set the pressure regulator to 400 kPa ± 50 kPa, then open the bottle. If the bottle is opened before ventilation commences, the internal oxygen sensor will be calibrated to 100% FiO_2.
3. Set the FiO_2 value.
4. Begin ventilation. FiO_2 monitoring begins after 40 seconds.

Notes:

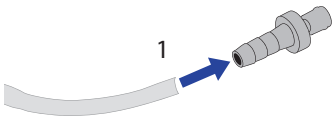
- *We recommend disconnecting all oxygen supplies when the device is on standby or switched off.*
- *The oxygen bottle can be replaced without stopping ventilation.*

Low-pressure oxygen

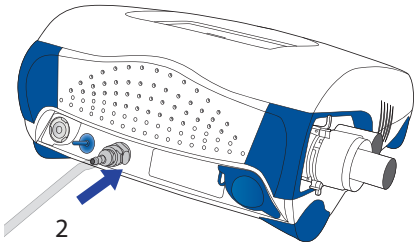
Low-pressure oxygen can be supplied by:

- An oxygen bottle fitted with a pressure regulator and a flow regulator
- An oxygen concentrator
- Wall-mounted O_2 fitted with a flow regulator.

CAUTION
Only connect oxygen once ventilation has commenced, and disconnect oxygen before stopping ventilation.



1. Insert the metal coupling.



2. Connect the oxygen tube to the ventilator.

4.4 Other accessories

In addition to the patient circuit, the user can use a humidification system, an antibacterial filter or a nebulisation system.

Any circuit can be used with the Elisée 350, whether single or double, with or without water traps, reusable or single-use, as long as it has the same technical specifications as the recommended circuit (see “Technical specifications for accessories” on page 94).

WARNING
A manual test must be performed every time the circuit configuration is modified.

Antibacterial filter and HME filter (heat and moisture exchange filter)

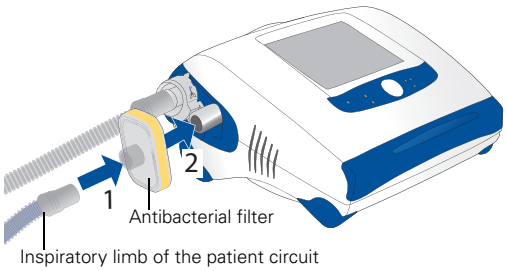
An antibacterial filter, a heat and moisture exchange filter (HME), or a combination HME/antibacterial filter, can all be used with the Elisée 350.

An antibacterial filter is commonly placed:

- At the point where the inspiratory limb connects to the ventilator, or
- Adjacent to the Y-connector, in a double circuit.

However, an HME filter or a combination HME/antibacterial filter can only be placed adjacent to the Y-connector.

Connecting an antibacterial filter:



1. Connect the filter to the inspiratory limb of the patient circuit, following the filter installation instructions.
2. Connect the filter to the insufflation outlet of the ventilator.

Note: *This filter also offers protection against dust and common allergens present in the air.*

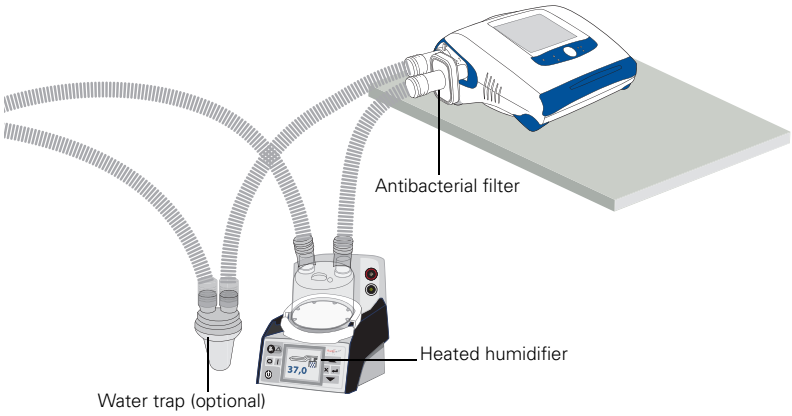
WARNING
The antibacterial filter must be installed in compliance with the manufacturer’s recommendations.

For further details, refer to the user guide for this accessory.

Active humidification system

A humidification system makes it possible to increase the amount of moisture in the air delivered to the patient. Set up the heater base and connect it to a power supply in accordance with the manufacturer's instructions.

Note: *If a heated circuit is being used with a humidification system, connect it to a power supply, then wait 15 minutes before performing a manual test so that the temperature and humidity can stabilise. This will ensure accurate measurement of the V_{TE} (when using a double circuit).*



WARNING

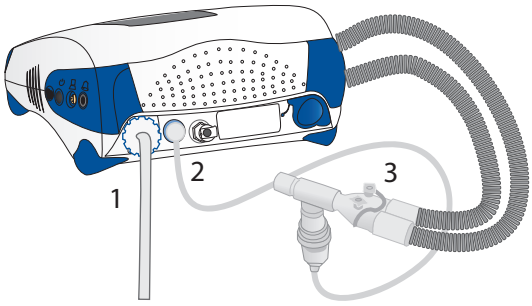
Set up the humidifier in accordance with the manufacturer's instructions. Always ensure that the ventilator and expiratory valve are placed above the humidifier and water traps.

Note: *The water traps must be emptied periodically.*

For further details, refer to the user guide for this accessory.

Standard pneumatic nebuliser

The driving gas is pure oxygen with a maximum pressure of 200 kPa and a flow rate of 20 L/min. Follow the manufacturer's instructions for assembling and connecting the nebuliser.



1. Connect the high-pressure oxygen hose.
2. Connect the nebuliser tubing.
3. Connect the nebuliser between the end of the patient circuit and the patient interface.

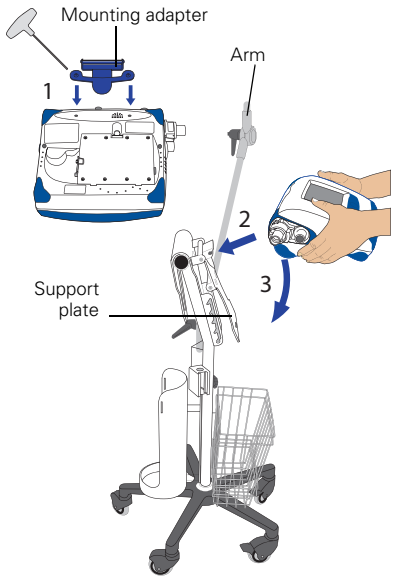
CAUTION

Do not insert a filter between the patient and the nebuliser.

Remote alarm

For further details, refer to the user guide for this accessory.

Trolley

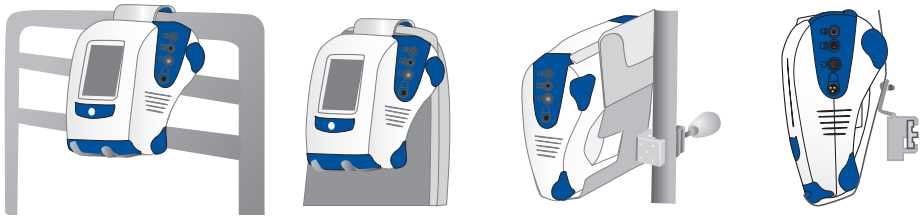


1. Use an Allen key to attach the mounting adapter to the Elisée 350.
2. Then connect the ventilator to the attachment groove on the trolley.
3. Swing the ventilator downwards so that it rests on the support plate.

Note: *An arm is attached to the trolley to hold the patient circuit.*

Mounting bracket

Use the mounting bracket to attach the ventilator to a bed frame, chair back or standard equipment support system.



For further details, refer to the user guide for this accessory.

Ergonomic transport bag

This bag is intended to carry and protect the ventilator during ventilation, both indoors and out of doors. It provides protection against moderate impacts and moderate rain exposure.

For further details, refer to the user guide for this accessory.

See also “Recommendations for use during transport” on page 50.

Transport bracket system

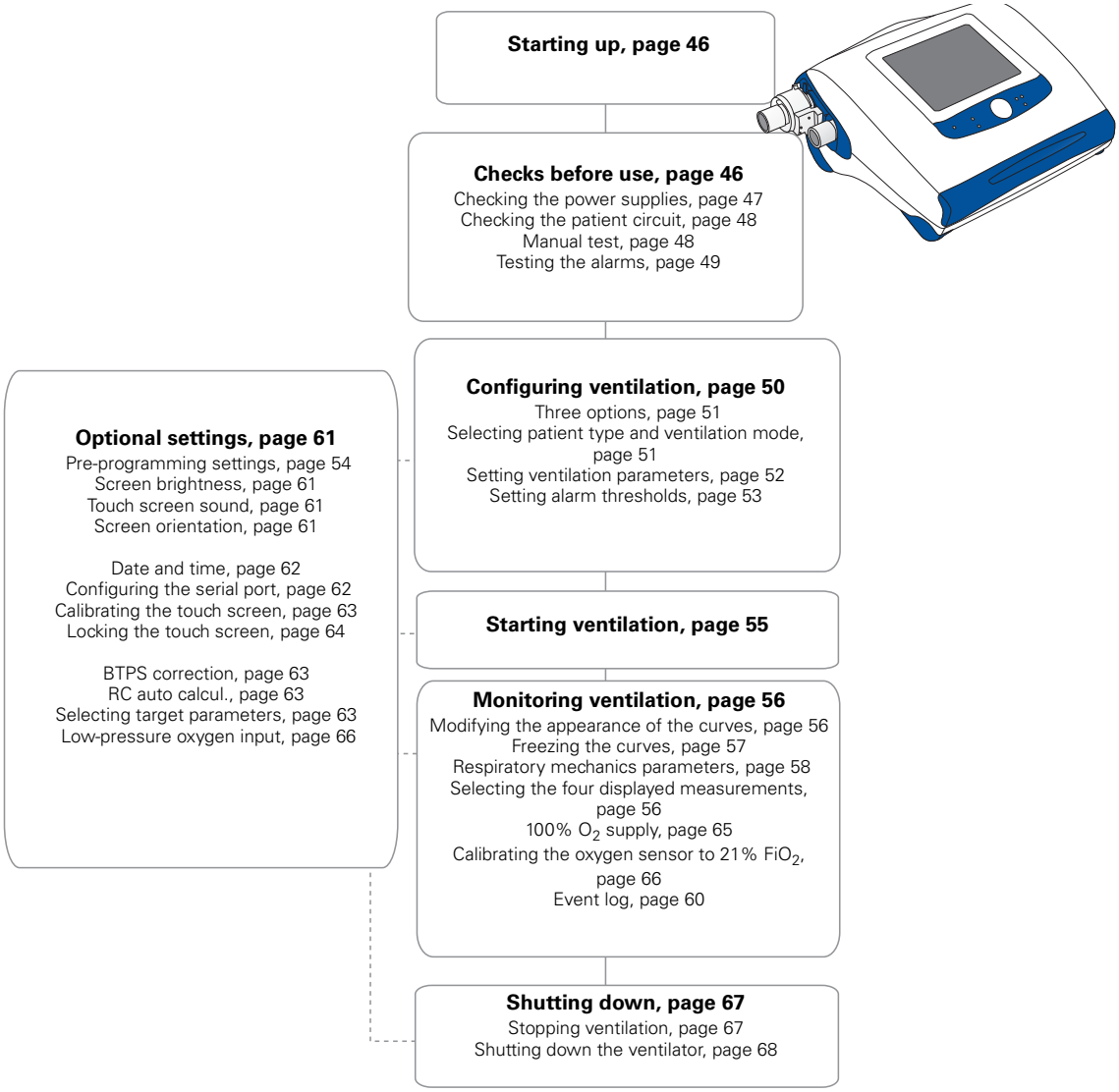
You can use this accessory to attach the ventilator, in its ergonomic transport bag, to a vertical pole in an emergency vehicle.

For further details, refer to the user guide for this accessory.

5 How to use Elisée 350

5.1 General outline of operations

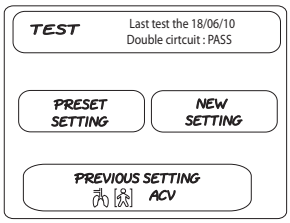
The outline below shows the four steps involved in checking the ventilator before use, and all of its functions.



5.2 Starting up

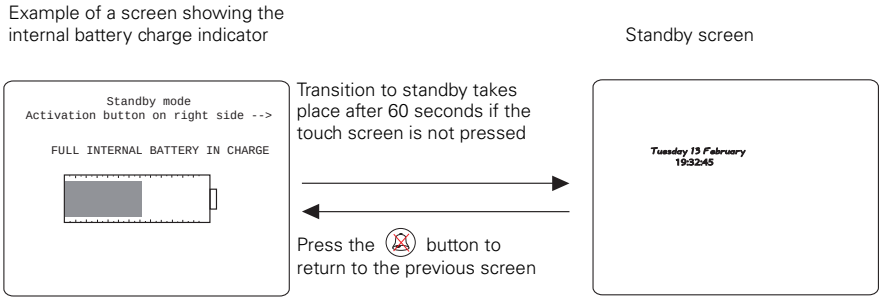
When the ventilator is running on battery power

1. Press the ⏻ button on the right-hand side of the device. The device performs its self-test, which includes:
   - Checking available power supplies
   - Setting the flow sensor offsets
   - Displaying the language of the software using the ISO 639-1 codes:
     (EN: English, DE: German, FR: French, IT: Italian, ES: Spanish, SV: Swedish, NO: Norwegian).
   - When the self-test is complete, the device displays the main screen:



When the ventilator is running on mains power

As soon as the device is connected to the mains supply, it conducts its self-test. You can then list the available power supplies, set the flow sensor offsets, and test the occlusion pressure calculation function (P0.1) (see "Respiratory mechanics parameters" on page 58). Next, the screen showing the internal and external battery charge indicator will be displayed.



1. Press the ⏻ button on the right-hand of the device. The main screen is displayed.

5.3 Checks before use

Before the ventilator is used for the first time, the user must:

1. Check the power supplies.
2. Check the patient circuit.
3. Perform a manual test.
4. Test the operation of the visual and audible alarms.

Each time the ventilator starts up and after every change in the circuit configuration, only the first three stages are necessary.

1 Checking the power supplies

Three LEDs on the front of the device indicate the charging status of the power supplies, whether the ventilator is on standby or delivering ventilation.

Power supply	Symbol and LED status	Meaning
Mains power pack or external power supplies	(green LED, not flashing)	Mains power pack or external DC supply present
	(LED off)	Neither mains power pack nor external DC supply present
Internal battery or external battery pack	(green LED, not flashing)	Battery charged
	(green LED flashing slowly)	Battery discharging
	(orange LED flashing slowly)	Battery discharging (battery low)
	(red LED flashing slowly)	Battery flat
	(orange LED flashing quickly)	Battery charging interrupted (battery temperature too high or too low)
	(green LED flashing quickly)	Battery charging

Notes:

- *When operating the device solely on battery power, ensure that the battery is sufficiently charged (green LED flashing slowly). If not, plug the ventilator into the mains power supply and switch on (if necessary).*
- *The battery charging status is displayed one minute after the ventilator is switched on. Each dash indicates a charge of around 25%.*
- *In the event of power failure, the event log and all of the settings will be saved, no matter how long it takes to restore power.*

Conditions for recharging the internal and external batteries

Note: *You should perform a complete charge/discharge cycle for internal and external batteries before use. Internal and external batteries reach optimal performance after three full charge/discharge cycles.*

If an external DC power supply (12–28 V DC / 15 A max) is in use, it must have enough charge to supply power for at least one hour.

Power supply status display

The following table lists the power supply symbols as well as the symbols that show whether the (internal/external) battery is charging or discharging.

Symbol	Meaning
	Internal battery present
	External battery present
EXT	External power supply present
	Mains supply present

2 Checking the patient circuit

Before connecting the patient to the ventilator, check the whole of the patient circuit to eliminate any risk of leaks or defective parts.

Check that:

- The expiratory circuit support matches the circuit type: single or double
- The patient circuit and accessories are properly connected to the expiratory circuit support.

Note: *Perform a manual test to ensure the ventilator has correctly identified the type of patient circuit installed.*

3 Manual test

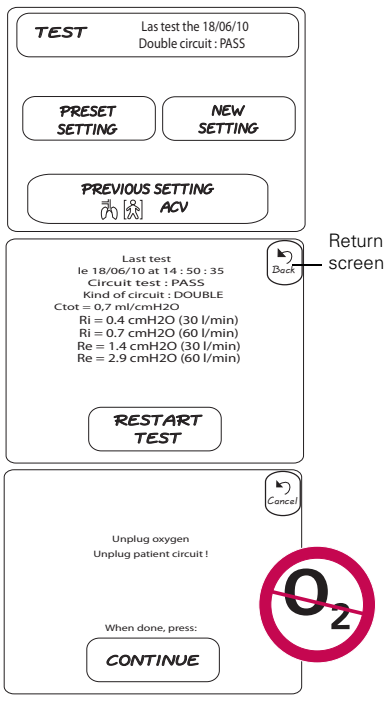
This test must always be performed before the ventilator is programmed for a new patient and whenever the circuit configuration is changed.

WARNINGS

- **The ventilator must not be connected either to a patient or to an oxygen supply during this test.**
- **If the test is unsuccessful, check the circuit configuration and repeat the test. Make sure you complete every step. If the test is again unsuccessful, stop using the ventilator and contact a technician.**
- **Make sure that when you perform this test, all the accessories that will be used during ventilation are connected. Repeat the test if an accessory is added or removed.**

This quick test (around 1 minute) consists of four stages:

- Measurement of the sensor offsets
- Checking for internal leaks in the ventilator
- Measurement of the inspiratory resistance of the circuit
- Measurement of the expiratory resistance and calibrating the expiratory flow (if a double circuit is connected), the circuit compliance and the O_2 sensor gain.

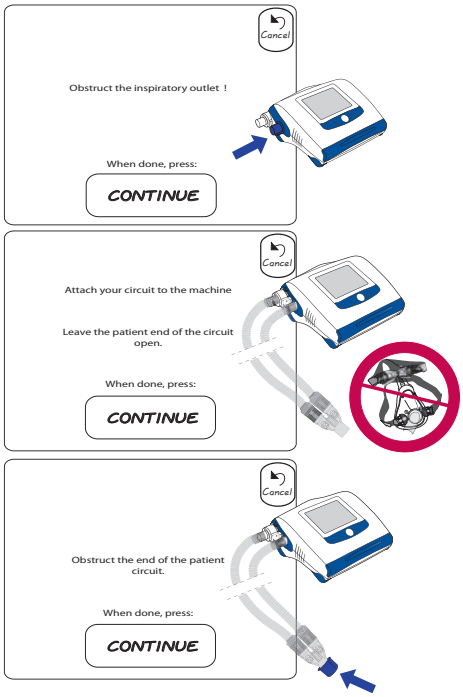


1. On the main screen, press the "Test" button.

The results of the last test are displayed.

2. Press the "Restart" button.

3. Follow the instructions displayed (disconnect the oxygen supply, the patient circuit and its accessories), then press "Continue". The ventilator measures the sensor offsets.



4. Cover the insufflation outlet on the ventilator, then press "Continue". The ventilator measures the rate of leak, if any.

5. Connect the patient circuit accessories, excluding the mask (the other end of the patient circuit should be left free), then press "Continue". The ventilator measures the inspiratory resistance at 30 L/min and 60 L/min.

6. Cover the free end of the patient circuit and press "Continue". The ventilator determines the type of patient circuit and its resistance and compliance, and calibrates the expiratory spirometry and the oxygen sensor.

The results of the test are displayed. They tell you:

- Whether the test failed or was successful
- What type of patient circuit is connected
- The resistance and compliance values of the patient circuit
- If the oxygen sensor is defective and must be replaced (if so, a flashing message appears on the screen). Replace the sensor and repeat the manual test.

7. If the test was successful, press Back to return to the main screen. If the test failed, press RESTART TEST to redo the test.

WARNINGS

- **If a double circuit is not connected properly while the device is performing the last step of the test (step 6), the device may incorrectly state that a single circuit is installed. If this happens, reconnect the circuit correctly, press Back, then redo the test.**
- **If the O_2 sensor is defective (the message "O2 sensor gain calculation: FAILURE" is displayed during the manual test or if the Replace O2 Cell alarm is triggered), do not use the device until the O_2 sensor has been replaced.**

4 Testing the alarms

The operation of all of the visual and audible alarms must be checked regularly, in particular prior to patient connection and during continuous ventilation.

See "Alarm testing procedures" on page 74.

5.4 Recommendations for use during transport

During transport, we recommend using the ventilator in its ergonomic transport bag, which must be firmly attached to the vehicle.

Before using the ventilator during transport, connect it to mains power for long enough to ensure that its internal and/or external batteries are charged.

In the hospital vehicle, before connecting the ventilator to a patient:

1. Check that the ventilator is in its transport bag, and that the bag is installed in the transport bracket system or any other secure attachment system according to the current legislation in your country.
2. Ensure that the device is powered (using one or more batteries, or an external power supply) in order to minimise temperature variations.
3. Perform a manual test.
4. Check that the compartment under the device is not empty; if necessary, insert the dummy pack.
5. Ensure that an additional O_2 bottle is available.

Note: *In accordance with the standard EN 794-3, it is recommended that the user has a means of backup ventilation available.*

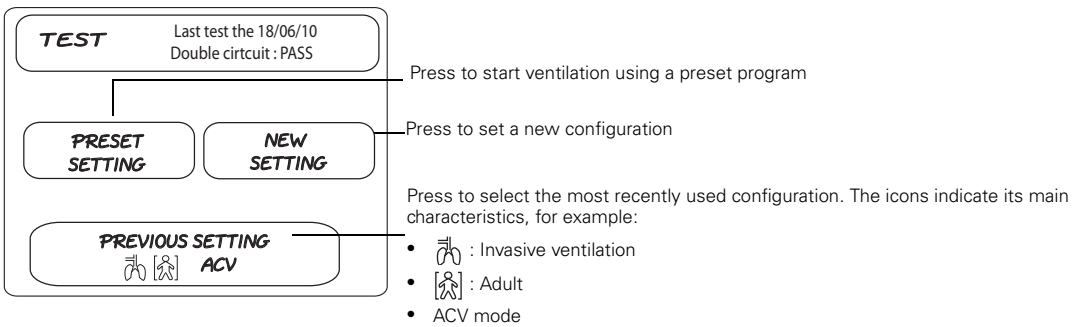
CAUTION

- **During transport, the mains power pack must not be in the compartment under the device, but may be connected to the ventilator through the external DC power socket.**
- **Do not use the ventilator in dangerous, explosive, or biologically contaminated situations.**

5.5 Configuring ventilation

The ventilator settings can be accessed from the main screen. There are three options:

- Setting a new configuration (all parameter settings are restored to their default values)
- Selecting the most recently used configuration
- Starting ventilation using one of five preset programs (see "Pre-programming settings" on page 54).



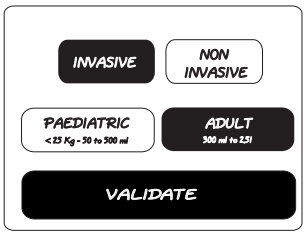
There are five steps involved in configuring the Elisée 350:

- Selecting the ventilation type (Invasive or Non-invasive)
- Selecting the patient type (Adult or Paediatric)
- Selecting the ventilation mode
- Setting the ventilation parameters
- Setting the ventilation alarm thresholds.

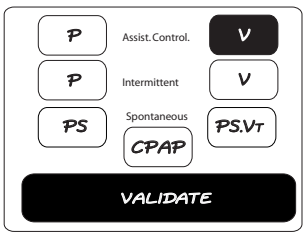
When all five steps are complete, patient ventilation can begin.

1 Selecting the ventilation type, patient type and ventilation mode

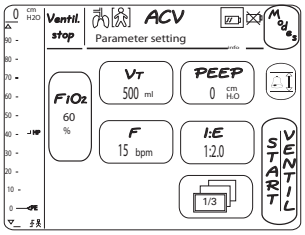
Turn on the ventilator. Once the main screen appears:



1. Press the appropriate buttons for the ventilation type and patient type, then press "Validate".



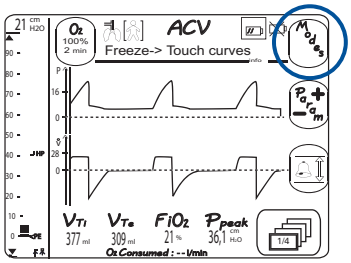
2. Next, press the button for the desired ventilation mode, then press "Validate".



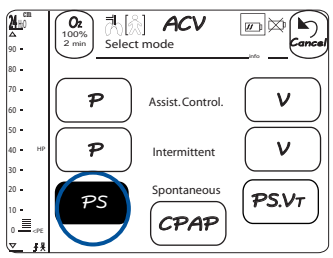
The parameters setting screen is displayed (see following paragraph "2 Setting ventilation parameters").

CAUTION

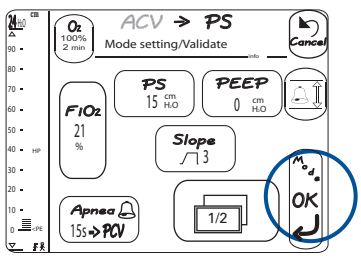
The ventilation mode can be changed during ventilation, but this should only be done by a doctor or a competent and qualified member of the health care staff. The following three screens (left to right) show the steps to follow:



1. Press the "Modes" button to access the mode change screen.



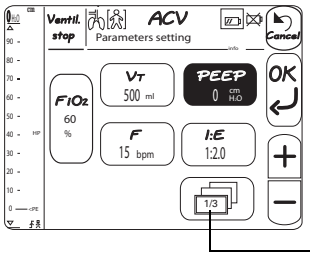
2. Select the new desired mode.



3. Press the 

button to confirm the mode and parameters.

2 Setting ventilation parameters

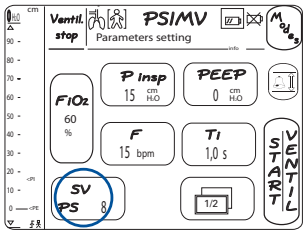


1. Press the button for the parameter you wish to change (here, PEEP).
2. Press + or − to set the value, then press OK to confirm.

Note: *It is possible to change several parameter values in succession and confirm them all at once.*

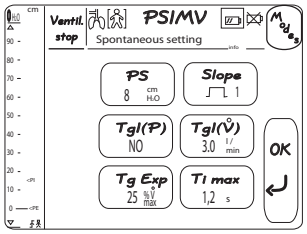
Press to navigate to the other parameter screens

Special case: Setting pressure support parameters for SIMV or PSIMV modes



1. On the parameters setting screen, press SV PS 8.

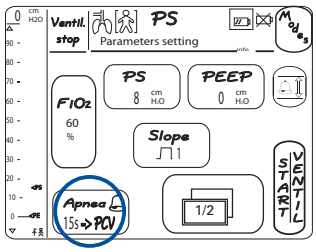
2. On the screen that is displayed, select the parameter you wish to change, use + or − to adjust the value, then press OK to confirm.

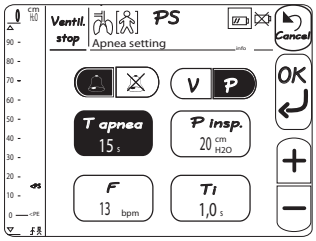


3. Press OK again to confirm all of the settings.

Note: *It is possible to change several parameter values in succession and confirm them all at once.*

Special case: Apnea ventilation parameters in PS (Pressure Support) mode





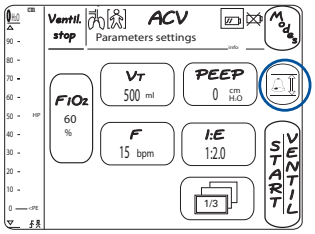
1. On the parameters setting screen, press Apnea 15s → PCV.

The specific screen for setting apnea ventilation parameters is displayed.

2. Deactivate the apnea alarm, or keep it activated.
3. Select the type of ventilation, either pressure-controlled ventilation P **(default value)** or volume-controlled V.
4. Select the parameters, adjust their values using + or −, then press OK to confirm or Cancel to cancel.

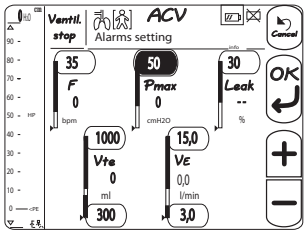
5. Press OK again to confirm all of the settings.

3 Setting alarm thresholds



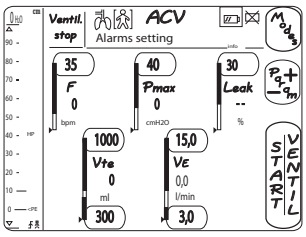
1. Press .

2. Press the value to be modified (here, Pmax = 50).



3. Press + or − to set the value (a flashing message appears at the top of the screen when the upper or lower limit is reached), then press OK to confirm.

Note: *It is possible to change several alarm thresholds in succession and confirm them all at once.*



Now you can:

- Set the ventilation mode again by pressing Modes
- Adjust the parameters again by pressing Param.

Setting the ΔPi alarm threshold – Special case

CAUTION

If you change any of the alarm settings, see Section 6.5 on page 74 for instructions on testing the alarms.

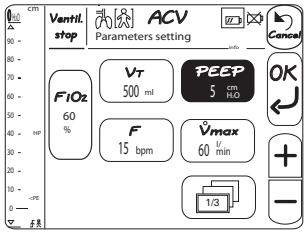
This setting is used:

- Usually for ventilation in volume-based modes
- With a single circuit. When using a single circuit, this is the only way of detecting when the patient circuit is disconnected.

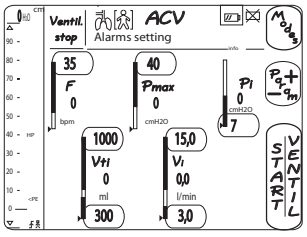
ΔPi represents the minimum pressure threshold to be maintained during inspiration. If the pressure falls below this threshold, the Low Pressure alarm is triggered.

Δ Pi = Pmax – PEEP, where Pmax is the maximum inspiratory pressure measurement.

Example of how to set the Δ Pi alarm threshold, with PEEP at 5 cm H_2O and the Δ Pi value at 7 cm H_2O:



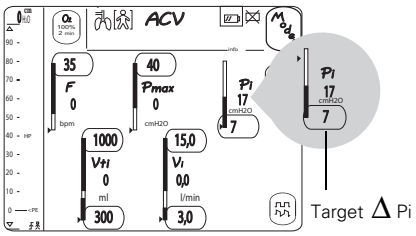
1. On the parameter settings screen, set the target PEEP to 5 cm H_2O.

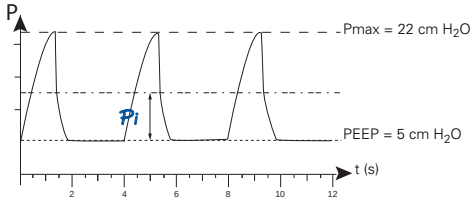


2. On the alarms screen, set Δ Pi to 7 cm H_2O. To avoid triggering the Low Pressure alarm, the pressure during inspiration must always exceed the threshold of 7 cm H_2O above PEEP.

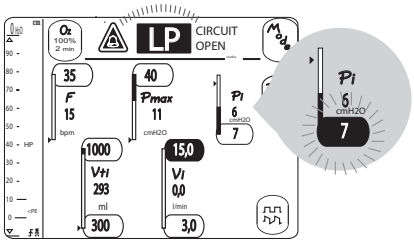
There are two possible scenarios:

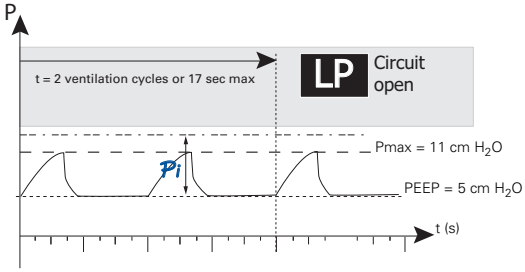
- The pressure during inspiration exceeds the threshold. In this case, the Elisée 350 considers the respiratory circuit to be closed (circuit not disconnected), and consequently the Low Pressure alarm is not triggered.





- The pressure during inspiration does not reach this threshold during a period of either two ventilation cycles or 17 seconds (maximum). In this case, the Elisée 350 considers the patient circuit to be open and the Low Pressure (Circuit Open) alarm is triggered.



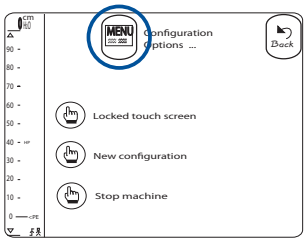


5.6 Pre-programming settings

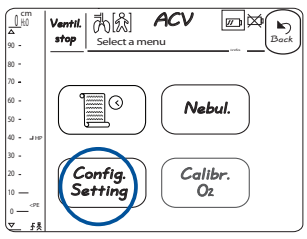
To pre-program settings:

- Create a new ventilation configuration or select the most recent configuration
- Save this configuration as one of the five preset programs, P1 to P5 (see the following figure).

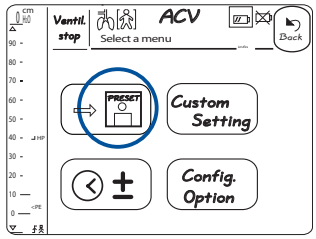
Creating a preset program



1. From the main screen, press the ⏻ button on the right-hand side of the device.
2. Press MENU.

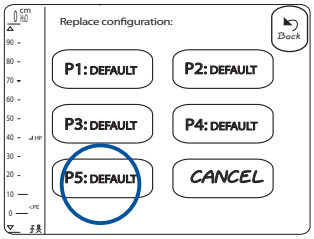


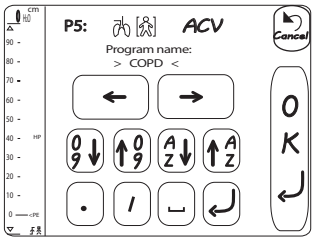
3. On the screen that is displayed, press Config. Setting.



4. Then press ⇨ PROG.

Select one of the five available programs.



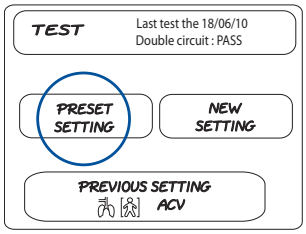


5. Use the alphanumeric buttons to change the program name (if necessary).

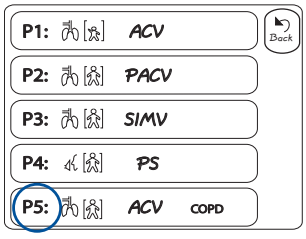
6. Use the left ← and right → arrow buttons to scroll through the characters in the name.

7. Press “OK” to save the program.

Using a preset program



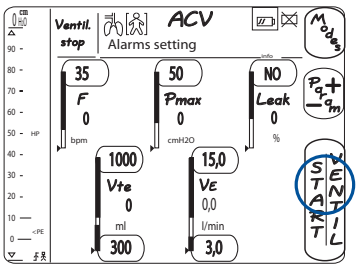
1. On the main screen, press PRESET SETTING.



2. Select the desired program. Patient ventilation will start immediately.

5.7 Starting ventilation

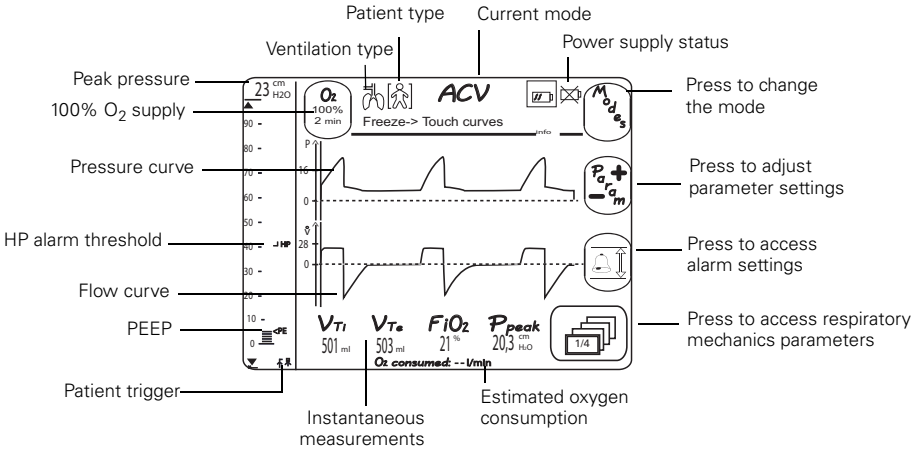
When all of the above configuration steps are complete, press “START VENTIL” to start ventilation.



5.8 The ventilator during ventilation

Monitoring ventilation

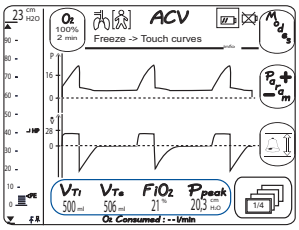
The curves screen appears as soon as ventilation is started:



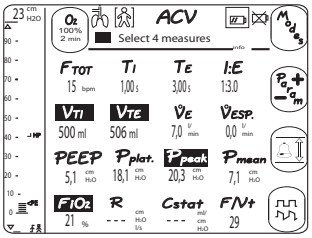
You can monitor ventilation continuously using the following tools on the curves screen:

- The bar graph
- The pressure and flow curves
- The instantaneous measurements for certain parameters
- The  symbol which appears below the bar graph to indicate a triggered cycle.

Selecting the four displayed measurements



1. Press one of the measurements displayed at the bottom of the screen.

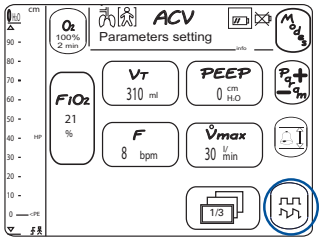


2. Select four measurements to be displayed.

3. Press  to return to the curves screen.

Modifying the appearance of the curves

You can change the appearance of the pressure and flow curves (filled or outline) as follows:

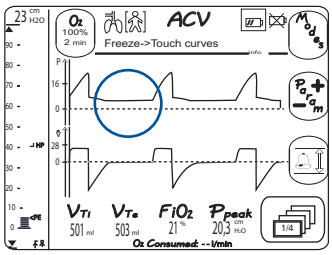


1. During ventilation, on the alarms or settings screen, press the  button for two seconds.

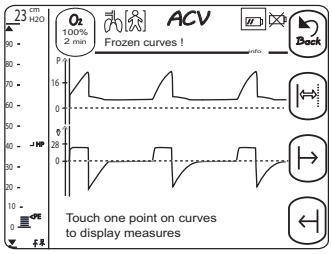
Outline curves change to filled curves, and vice-versa.

Freezing the curves

The Frozen Curves function allows you to view the instantaneous values of the flow, pressure and volume measurements at a given point on a curve.

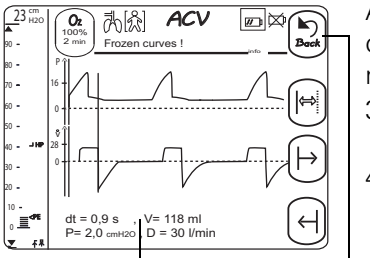


1. Press one of the curves.



The ventilator freezes the curves.

2. Touch any point on a curve to see the values at that point.



Instantaneous measurements

Press "Back" to unfreeze the curves

A vertical line appears, indicating the point selected on each curve, and the instantaneous flow, pressure and volume measurements at that point.

3. You can use the ⟵| and |⟶ buttons to move the line left or right.
4. To find the time (dt) between two values:
   - Position the vertical line on one of the values
   - Freeze this line by pressing the two-line button ⟷ (this line is then displayed as a dotted line)
   - A second vertical line will appear. Position it on the other value.

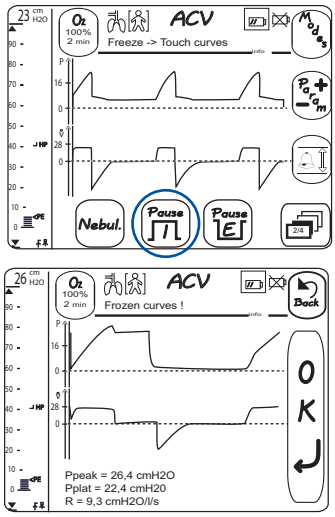
   The dt value is displayed at the bottom of the screen.

Respiratory mechanics parameters

On the curves screen, two screens display the ventilatory mechanics parameters, which can be accessed using the (screen 2/4) button and the (screen 3/4) button.

Plateau time

Pressing the End-inspiratory pause button inserts a plateau time at the end of the inspiratory cycle, once the minimum tidal volume has been reached. Hold your finger on the button for the desired length of the plateau time (max. 5 s). The ventilator will keep the inspiratory and expiratory valves closed, and no air flow will be delivered.



1. Press screen 2/4 .

2. Then press during the inspiratory phase to insert an end-inspiratory pause. The maximum pause time is **5 seconds**, after which expiration is automatically triggered.

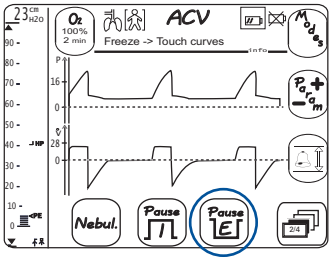
The screen displays the plateau pressure (Pplat), maximum pressure (Ppeak) and resistance (R) values.

3. Press "OK" to go to the frozen curves screen (see "Freezing the curves" on page 57) or to return to the curves screen.

Note: *Wait for the real-time curves to be displayed at the left-hand side of the screen before pressing the Pause button. Otherwise, the frozen curves will not display correctly.*

End-expiratory pause

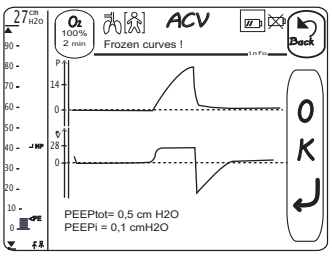
Pressing the End-expiratory pause button inserts a pause at the end of the expiratory cycle. During the pause, the ventilator keeps the inspiratory and expiratory valves closed.



1. Press screen 2/4 .

2. Then press during the expiratory phase to insert an end-expiratory pause. The maximum pause time is **12 seconds**, after which inspiration is automatically triggered.

The screen displays the total positive expiratory pressure (PEEPtot) and the intrinsic positive expiratory pressure (PEEPi).

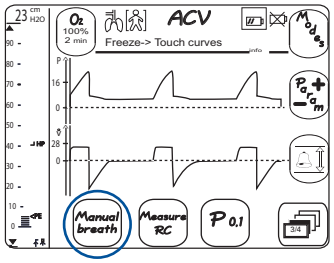


3. Press "OK" to go to the frozen curves screen (see "Freezing the curves" on page 57) or to return to the curves screen.

Note: *Wait for the real-time curves to be displayed at the left-hand side of the screen before pressing the Pause button. Otherwise, the frozen curves will not display correctly.*

Manual breath (not available in CPAP mode)

Pressing the Manual breath button immediately triggers an additional respiratory cycle.



1. Press screen 3/4  .
2. Press  to trigger an additional respiratory cycle.

Measure RC (Invasive ACV mode only)

WARNING

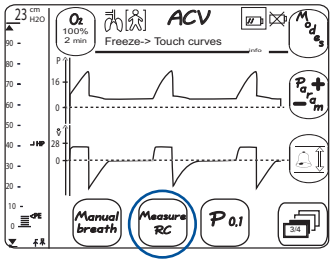
Pressing this button will alter the respiratory cycle while the measurements are being taken. Patient respiration may be impeded.

This function allows you to measure the patient's physiological respiratory characteristics: resistance, compliance, and intrinsic pressure.

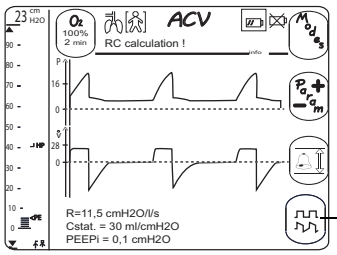
The ventilator delivers a square flow cycle with a 2.0 second end-inspiratory pause and a 0.5 second end-expiratory pause.

The formulae used to calculate the resistance and compliance are:

- R = (Pmax – Pplat) / $\dot{V}$max
- Cstat = V_{TI} / (Pplat – PEEPtot)
  where:
- PEEPtot = PEEPi + PEEP (before the end-expiratory pause).



1. Press screen 3/4  .
2. Press the  button.



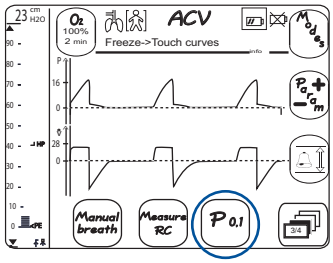
The ventilator performs the calculations and then displays the results at the bottom of the screen. The results are displayed for five minutes.

Press to return to the curves screen

P0.1 (invasive ventilation only)

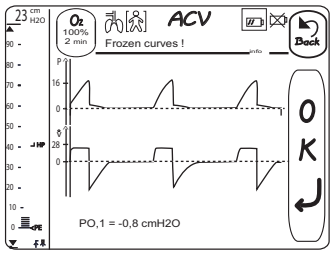
Press the P0.1 button to calculate the occlusion pressure.

The measurements are taken when the patient initiates a cycle. The negative pressure generated by the patient's inspiratory effort is measured 0.1 seconds after inspiration is triggered.



1. Press screen 3/4 .
2. Press the P0.1 button.

The ventilator performs the calculation and displays the P0.1 value.



3. Press "OK" to go to the frozen curves screen (see "Freezing the curves" on page 57) or Back to return to the curves screen.

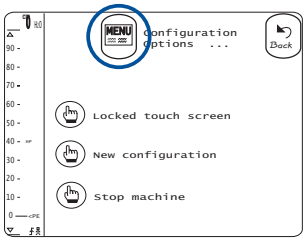
Note: *Wait for the real-time curves to be displayed at the left-hand side of the screen before pressing the P0.1 button. Otherwise, the frozen curves will not display correctly.*

Event log

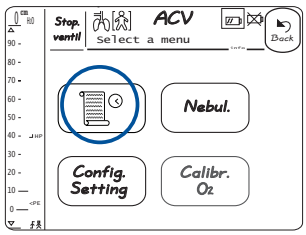
A black box records the 1170 most recent ventilator events that occur each day:

- Each time the ventilator was turned on or off
- Each time ventilation was started or stopped
- Triggered alarms
- Actions carried out on the ventilator (mode changes, parameter setting changes, etc.)
- The types of power supplies used and the charge status of the batteries
- The date and results of any manual tests performed.

To access the Event log:

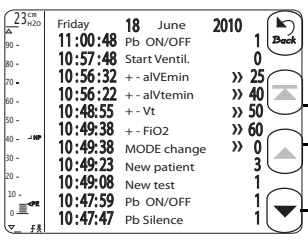


1. After selecting one of the configuration types (New, Most Recent or Preset) on the main screen, press the ⏻ button on the right-hand side of the device.
2. Press MENU.



The following screen is displayed.

3. Press .



Events are displayed in a chronological list.

Use the scroll buttons on the right-hand side of the screen to scroll through the list.

Press to access the screen showing the most recent events

Press to scroll up

Press to scroll down

Sample log entries:

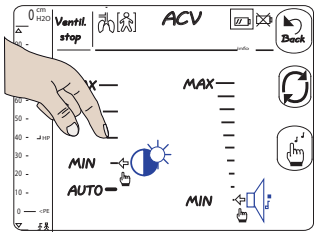
11:47:14 P MAXI	The Maximum Pressure alarm was triggered at 11:47:14.
11:55:12 Vt MINI	The Minimum Tidal Volume alarm was stopped at 11:55:12.
12:34:14 + - al HP » 60	The High Pressure alarm threshold was changed (new value: 60 cm H_2O).

5.9 Optional settings

Screen brightness (during ventilation or while ventilation is stopped)

WARNING

Check that the volume is appropriate for the level of background noise.

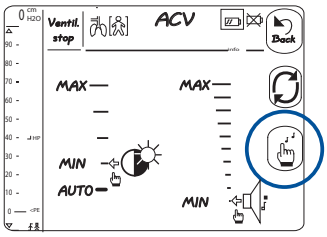


1. After configuring ventilation, press the button for 3 seconds until the screen shown on the left appears.
2. Press the brightness scale to change the setting. If set to "AUTO", the setting will self-adjust according to the ambient light and the screen lighting will turn off automatically after two minutes, provided that no alarm has been triggered and the button, button and the touch screen have not been pressed.

Note: *The screen brightness is reduced to its lowest level as soon as the Internal Battery Low alarm is triggered.*

Touch screen sound

On the brightness setting screen:

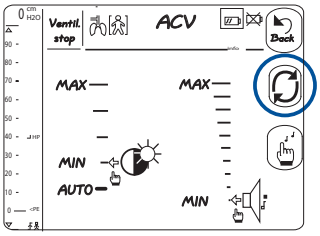


1. The picture on each button shows the action associated with it, but provides no information on current settings.

- Press the button to activate the beep sound.
- Press the button to deactivate the beep sound.

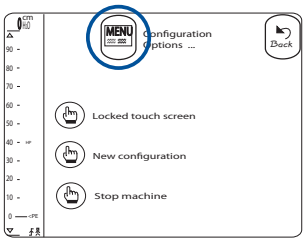
Screen orientation

The user can change the screen orientation based on where he/she is standing in relation to the ventilator.

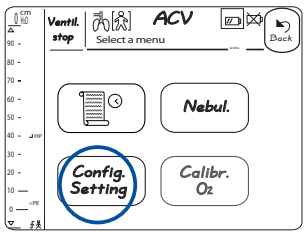


1. Press the button to invert the orientation of the screen.

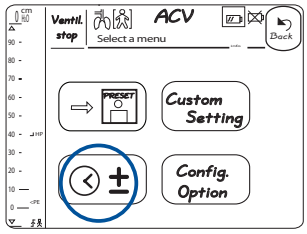
Date and time (during ventilation or while ventilation is stopped)



1. After selecting one of the configuration types (New, Most Recent or Preset) on the main screen, press the ⏻ button on the right-hand side of the device.
2. Press MENU.

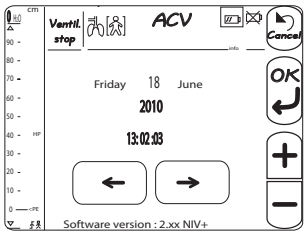


3. On the screen that is displayed, press Config. Setting.



The following screen is displayed.

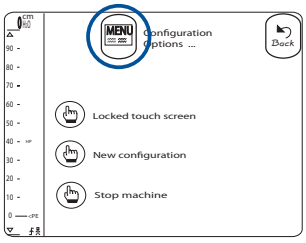
4. Press ⊙±.



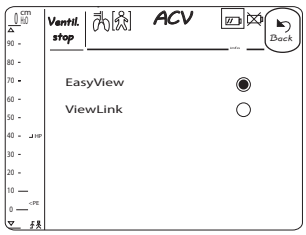
5. Press ← or → to move the cursor to the day-of-the-week field. It will start to flash.
6. Press + or − to obtain the desired value.
7. Repeat steps 5 and 6 to set the values for the day, month and year and for the hours, minutes and seconds.
8. Press "OK" to save these settings.

Configuring the serial port

The serial port is located on the right-hand side of the ventilator.



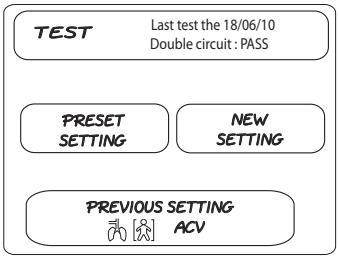
1. After selecting one of the configuration types (New, Most Recent or Preset) on the main screen, press the ⏻ button on the right-hand side of the device.
2. Press MENU.



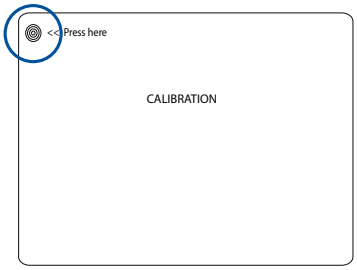
3. Press Config. Setting, then press Config. Option.
4. Select:
   - "EasyView" to exchange information via the ventilator's serial connection with computers or monitoring systems with ResMed's EasyView software installed
   - "ViewLink" to exchange information via the serial connection with monitoring systems compatible with Philips VueLink technology.

Calibrating the touch screen (while ventilation is stopped)

This operation allows the user to readjust the reactive areas of the touch screen.



1. On the main screen, press and hold ⏻ and 🔕 simultaneously until the calibration screen appears.



2. On the calibration screen, press the targets appearing in various places. Keep pressing until you hear a beep.

The touch screen is now calibrated and the main screen reappears.

BTPS correction

BTPS correction (body conditions: body temperature, ambient pressure and vapour saturated) is activated by default each time the ventilator is started.

It corrects the inspiratory and expiratory volumes on the double circuit. When the option is deactivated, the ventilator passes into ATPD mode (Ambient Temperature and Pressure, Dry), the mode used to calibrate the ventilator.

Note: *The BTPS correction varies depending on the atmospheric pressure, the temperature of the exhaled gases (estimated at 37°C), and the ambient temperature.*

RC auto calcul. (invasive ventilation and ACV mode only)

This option, always reset to NO each time the ventilator stops, automatically calculates the compliance and resistance of the patient's airways every 15 minutes.

The results are displayed on the measurements screen for 5 minutes.

Low-pressure oxygen input

This option activates the low-pressure or high-pressure oxygen supply.

- If "Low pressure oxygen input" is set to NO (when the ventilator starts up), the ventilator is programmed to use high-pressure oxygen.
- If "Low pressure oxygen input" is set to YES, the ventilator is programmed to use low-pressure oxygen.

Selecting target parameters in ACV mode (during ventilation and while ventilation is stopped)

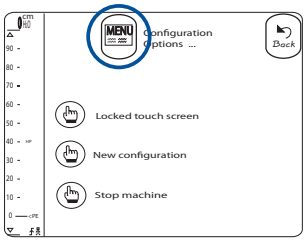
This parameter is saved in the memory when the ventilator is turned off.

The adjustable values during Assisted Volume-Controlled Ventilation (ACV) are:

- The inspiratory time (Ti)
- The max. flow ($\dot{V}$ max)
- The I:E ratio.

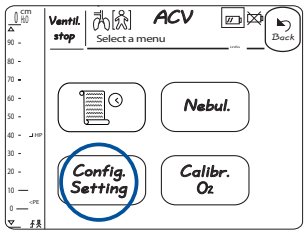
Note: *Modifying any one of these parameters can change the ventilation settings.*

To adjust the four aforementioned parameters (BTPS correction, RC auto calcul., Low pressure oxygen input and target parameter):

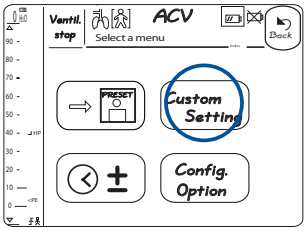


1. After selecting one of the configuration types (New, Most Recent or Preset) on the main screen, press the ⏻ button on the right-hand side of the device.
2. Press MENU.

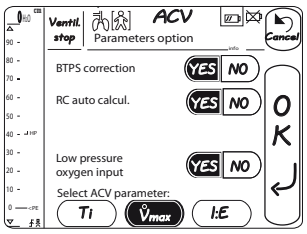
The following screen is displayed.



3. Press Config. Setting.



4. Press Custom Setting.



The parameter options screen displays the adjustable options:

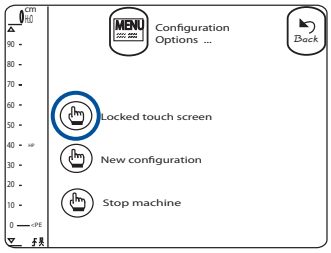
- BTPS correction
- RC auto calcul.
- Low pressure oxygen input
- Selection of target parameter (for ACV mode).

5. Press "YES" to activate or "NO" to deactivate one or more options, as desired.
6. Press "OK" to save the changes to the configuration. The previous screen is displayed again.

Locking the touch screen (during ventilation)

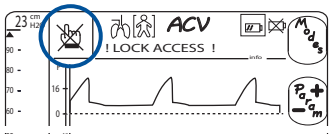
Locking the touch screen prevents accidental changes to settings.

The screen will unlock automatically when an alarm is triggered, and relock automatically two minutes after the alarm stops or after the last action performed on the ventilator.



1. Press the ⏻ button on the right-hand side of the device.
2. Press "Locked touch screen".

The locked screen icon is displayed on the main curves screen. The touch screen is now locked.



To unlock the touch screen, repeat the above steps, this time pressing "Unlocked touch screen".

5.10 Using oxygen

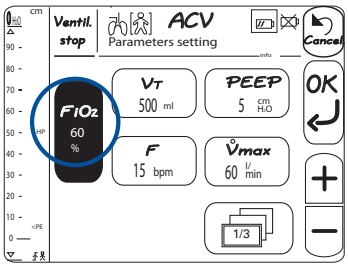
1 High-pressure oxygen

Before using high-pressure oxygen, check that:

- The oxygen sensor is installed in the ventilator (see "Installing the oxygen sensor" on page 38)
- The manual test was successful (which means that the oxygen sensor is working). See "3 Manual test" on page 48
- The high-pressure oxygen equipment is connected to the ventilator (see "High-pressure oxygen" on page 39)
- The "Low pressure oxygen input" parameter is set to NO (see "Low-pressure oxygen input" on page 63).

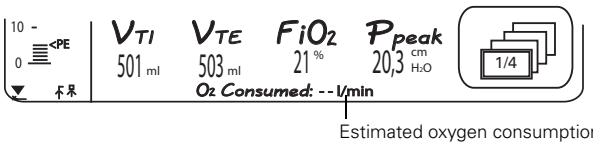
Setting the FiO_2

When you are configuring the device for ventilation, you can set the FiO_2 on the parameter settings screen:



Oxygen consumption display

During ventilation, the set value for FiO_2 is displayed, along with the estimated oxygen consumption.



Estimated oxygen consumption

Monitoring FiO_2 during ventilation

The FIO_2 MINI and FIO_2 MAXI alarms allow you to monitor the level of the FiO_2 measurement:

- FIO_2 MINI is triggered when the percentage of FiO_2 decreases by 10% for 30 seconds
- FIO_2 MAXI is triggered when the percentage increases by 10% for 30 seconds.

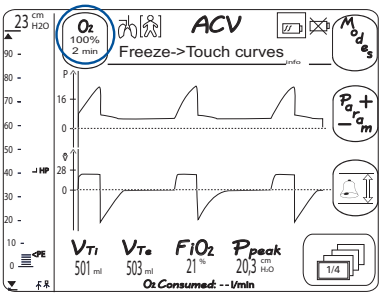
See the table under the heading "Type 1: Ventilation monitoring alarms" on page 70.

For the default values and the setting ranges for these alarms, see "Alarm settings" on page 73.

100% O_2 supply and calibrating the O_2 sensor

Pressing the button causes the ventilator to switch to delivering 100% oxygen. This button is also used to calibrate the O_2 sensor (it is not necessary to stop ventilation), if:

- You wish to pre-oxygenate the patient prior to disconnection, before suctioning for example
- The O_2 sensor has been replaced
- The FIO2 MINI or FIO2 MAXI alarm has been triggered
- The temperature changes during ventilation.



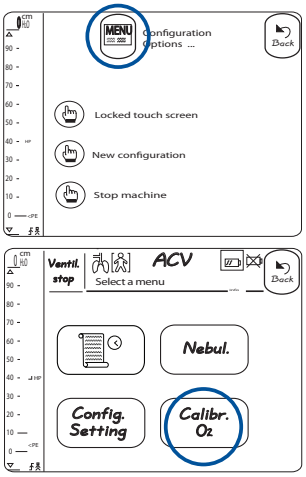
1. Press  to supply 100% FiO_2 for two minutes. The corresponding icon will flash.

2. Press  again to interrupt the supply before the end of the two minutes.

Note: *You cannot interrupt the oxygen supply during the first four ventilation cycles, because this is the time required to calibrate the sensor.*

Calibrating the oxygen sensor to 21% FiO_2

This function allows you to manually calibrate the oxygen sensor to 21% by passing ambient air through the sensor.



1. After selecting one of the configuration types (New, Most Recent or Preset) on the main screen, press the ⏻ button on the right-hand side of the device.
2. Press  .

The following screen is displayed.

3. Press "Calibr. O_2" to start the calibration.

2 Low-pressure oxygen

Before using low-pressure oxygen, check that:

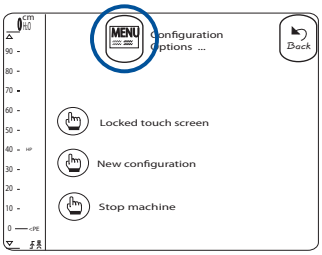
- The oxygen sensor is installed in the ventilator (see "Installing the oxygen sensor" on page 38)
- The manual test was successful (which means that the oxygen sensor is working). See "3 Manual test" on page 48
- The "Low pressure oxygen input" parameter is set to YES (see "Low-pressure oxygen input" on page 63).

5.11 Using the nebuliser

Before using the nebuliser, check that:

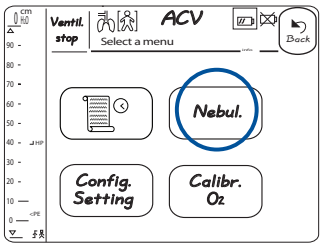
- The oxygen sensor is installed in the ventilator (see "Installing the oxygen sensor" on page 38)
- The manual test was successful (which means that the oxygen sensor is working). See "3 Manual test" on page 48
- The high-pressure oxygen equipment is connected to the ventilator (see "High-pressure oxygen" on page 39)
- The "Low pressure oxygen input" parameter is set to NO (see "Low-pressure oxygen input" on page 63).

Setting the parameters (during ventilation and while ventilation is stopped)

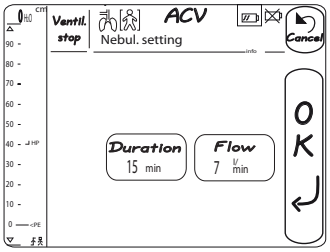


1. After selecting one of the configuration types (New, Most Recent or Preset) on the main screen, press the ⏻ button on the right-hand side of the device.
2. Press MENU.

The following screen is displayed.

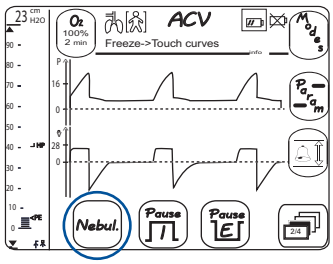


3. Press the "Nebul." button.



4. Set the nebulisation flow and duration parameters, then press "OK" to confirm.

Activating nebulisation (during ventilation)



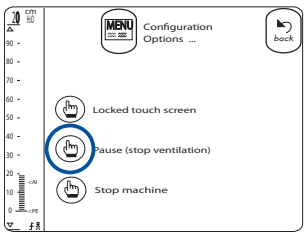
1. Press the "Nebul." button to activate nebulisation for a default duration of 15 minutes.

Note: *During nebulisation, the "Nebul. In use" icon replaces the O2 100% 2 min button. The use of nebulisation may affect the FiO_2 and delivered volumes.*

2. To stop a nebulisation cycle, press the "Nebul." button again.

5.12 Stopping ventilation/shutting down the ventilator

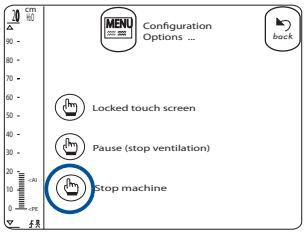
Stopping ventilation



1. Press the ⏻ button on the right-hand side of the ventilator.
2. Press ☝ "Pause (stop ventilation)" for three seconds.

Ventilation stops and the parameter settings screen is displayed.

Shutting down the ventilator



1. Press the ⏻ button on the right-hand side of the ventilator.
2. Press ☝ "Stop machine" for three seconds.

The message "STOP IN PROGRESS" flashes, then the device turns off.

3. When the audible alarm sounds, press the 🔕 button for at least one second.

Each time the ventilator is shut down, an audible signal is heard.

Forced ventilator shutdown

If there is a fault with the touch screen, a forced shutdown may be performed:

1. Disconnect the ventilator from the mains or external power supply.
2. Press ⏻ and 🔕 at the same time, and hold until the ventilator switches off (10 seconds).

6 Alarms and troubleshooting

WARNINGS

- You should check that the default thresholds set for activation of the alarms are appropriate before using the ventilator on a patient.
- If you set the alarm thresholds at extreme levels you risk making the alarms system ineffective.

There are three types of alarm:

- Ventilation monitoring alarms
- Technical alarms
- Servicing alarms.

Each alarm has a priority level that cannot be changed by the user:

- High priority
- Medium priority
- Low priority.

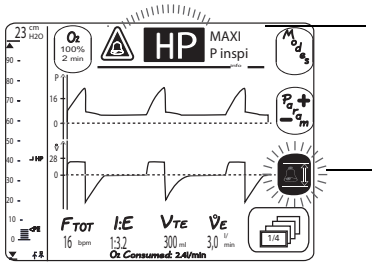
In addition, each alarm may be either:

- Permanently stopped (by pressing the button)
- Temporarily stopped (the audible signal is muted for two minutes, but the visual symbol remains displayed on the screen)
- Not stopped at all.

6.1 Alarm signal

When an alarm is triggered, this is indicated by:

- The audible signal sounding: this depends on the priority of the alarm. It is produced by two buzzers and a digital sound generator.
- Signals appearing on the screen (e.g. for the High Pressure alarm):



The alarm name flashes at the top of the touch screen

The alarms page access button flashes
On the alarms setting screen, the threshold that has been exceeded will also be flashing

- One of the LEDs on the LED panel flashing (red or orange, depending on the priority of the alarm).

Pressing the button mutes the audible signal but the symbol remains displayed on the screen.

Note: *It is possible to mute the audible signal of an alarm for two minutes simply by pressing the Alarm Silence button. The symbol will then start to flash. During this period, any alarm triggered will be indicated only by the flashing alarm name. Pressing again unmutes the alarm.*

6.2 Alarm types

Type 1: Ventilation monitoring alarms

If two alarms with different priority levels are triggered at the same time, the higher priority alarm takes precedence over the lower priority alarm. If two alarms with the same priority level are triggered at the same time, refer to the table under the heading "Relative alarm priorities" on page 73.

Note: *The 'Trigger threshold [can be stopped?]' column in the following table indicates for each alarm whether it can be stopped permanently (YES), stopped temporarily (2 min) or not stopped at all (NO).*

Symbol	Message	Alarm	Priority	Trigger threshold [can be stopped?]	Time to trigger
V	MINI Vt	Minimum Expired Tidal Volume **(double circuit)**	High	Alarm setting [2 min]	5 consecutive cycles above alarm threshold
V	MAXI Vt	Maximum Expired Tidal Volume **(double circuit)**	High	Alarm setting [2 min]	5 consecutive cycles above alarm threshold
V	MINI Vt	Minimum Inspired Tidal Volume **(single circuit)**	High	Alarm setting [2 min]	5 consecutive cycles above alarm threshold
V	MAXI Vt	Maximum Inspired Tidal Volume **(single circuit)**	High	Alarm setting [2 min]	5 consecutive cycles above alarm threshold
V	MINI V/min	Minimum Expired Minute Volume **(double circuit)**	High	Alarm setting [2 min]	Immediately
V	MAXI V/min	Maximum Expired Minute Volume **(double circuit)**	Low	Alarm setting [2 min]	Immediately
V	MINI V/min	Minimum Inspired Minute Volume **(single circuit)**	High	Alarm setting [2 min]	60 s
V	MAXI V/min	Maximum Inspired Minute Volume **(single circuit)**	Low	Alarm setting [2 min]	60 s
HP	MAXI P INSPI*	Maximum Inspiratory Pressure	High	Alarm setting [2 min]	3 consecutive cycles above alarm threshold
HP	MAXI P EXPI*	Maximum Expiratory Pressure	High	10 mbar + PEEP [2 min]	300 ms above alarm threshold
LP	LP – Low flow?	Minimum Pressure (volume-controlled modes) Double circuit	High	3 mbar + leak < 80% [2 min]	2 complete cycles below the threshold or maximum of 17 s
LP	CIRCUIT OPEN	Minimum Pressure (volume-controlled modes) Double circuit	High	3 mbar + leak ≥ 80% [2 min]	2 complete cycles below the threshold or maximum of 17 s
LP	CIRCUIT OPEN	Minimum Pressure (volume-controlled modes) Single circuit	High	Δ Pi alarm threshold [2 min]	2 complete cycles below the threshold or maximum of 17 s
LP	CIRCUIT OPEN	Minimum Pressure (pressure-controlled modes)	High	(Pi or PS) – 2 mbar at the end of inspiration [2 min]	2 complete cycles below the threshold or maximum of 17 s
LP	CIRCUIT OPEN	Minimum pressure (pressure-controlled modes, CPAP)	High	(CPAP+1)/3 during inspiration [2 min]	2 complete cycles below the threshold or maximum of 17 s
LP	LOW PEEP	Minimum Expiratory Pressure **(double circuit)**	Medium	Alarm setting [2 min]	30 cycles below alarm threshold
F	MAXI F	Maximum Respiratory Rate	Low	Alarm setting [2 min]	4 consecutive cycles above alarm threshold

Symbol	Message	Alarm	Priority	Trigger threshold [can be stopped?]	Time to trigger
O_2	MINI FIO_2	Minimum FiO_2	High	FiO_2 – 10% [NO]	Maximum of 20 consecutive cycles below alarm threshold
O_2	MAXI FIO_2	Maximum FiO_2	High	FiO_2 + 10% [NO]	Maximum of 20 consecutive cycles above alarm threshold
O_2	O_2 FAULT	HP O_2 missing	High	$FiO_2 \neq 21\%$ or button pressed and HP $O_2 \geq 0.5$ bar [2 min]	Immediately
	WRONG CIRCUIT	Device configured for single circuit (manual test), but a double circuit is connected	High	$V_{TE} > 10\%$ of V_{TI} [2 min]	6 cycles
	MAXI LEAKS	High Leak	High	Alarm setting [2 min]	6 consecutive cycles above alarm threshold
	PATIENT APNEA	Apnea	Medium	Tapnea [2 min]	Immediately
	INT BATT EMPTY	Internal Battery Flat	High	Charge < 5% [NO]	Immediately
	INT BATT LOW	Internal Battery Low	Medium	Charge < 15% [2 min]	Immediately
	EXT BATT EMPTY	External Battery Flat	Medium	Charge < 5% [2 min]	Immediately
	EXT BATT LOW	External Battery Low	Low	Charge < 15% [2 min]	Immediately
	EXT BATT MISSING	No External Battery	Low	- [YES]	Immediately
	EXT MISSING	External Power Supply Disconnection	Low	- [YES]	1 s
	MAINS MISSING	Mains Disconnection	Low	- [YES]	1 s
	TEST FAILED	Manual Test Interrupted	High	If one of the four test steps fails [2 min]	-

* In pressure-controlled modes, the Pmax alarm threshold cannot be set to a value lower than the delivered Pi + PEEP (or the delivered pressure support). If the user sets an alarm threshold lower than this pressure value, the alarm threshold setting will be ignored. In this situation, the delivered Pi + PEEP (or PS + PEEP) becomes the Pmax alarm threshold.

Note: *The Battery Flat and Battery Low alarms are deactivated as soon as the Elisée 350 is connected to the mains or to an external DC power supply. Press* *to remove the alarm message from the screen.*

Type 2: Technical alarms

CAUTION

If a technical alarm (TECH[n]) is triggered, stop ventilation and contact your technical department.

Symbol	Message	Alarm	Priority	Solution
	TECH [n]	Numbered technical alarm [n]	Varies according to the alarm number [n]	Refer to the Service Manual for detailed information on these alarms
	ADJUST CLOCK	Time lost	Low	Set the time (see page 62). If the problem persists, refer to the Service Manual
	INSPI RESIST	High Inspiratory Resistance	Low	See "Troubleshooting" on page 78
	EXPI RESIST	High Expiratory Resistance	Low	See "Troubleshooting" on page 78
	VENTIL STOP	Unintended Ventilation interruption	Low	Restart ventilation. If the problem persists, refer to the Service Manual
	NiMH BATTERY	Wrong Battery Type (NiMH instead of Li-Ion)	Low	See "Troubleshooting" on page 78
	FIO_2 21	21% FiO_2	High	Replace the O_2 sensor. If the problem persists, contact your technical department

Type 3: Servicing alarms

Symbol	Message	Alarm	Priority	Solution
	REPLACE O_2 CELL	Faulty O_2 sensor	Low	Replace the O_2 sensor, then recalibrate, either by performing a manual test (see page 48) or by pressing the O2 100% 2 min button (see page 65)
	REPLACE BLOWER	Turbine Service	Low	Contact your technical department

6.3 Alarm priorities

Each alarm has a priority level that cannot be changed by the user:

- High priority
- Medium priority
- Low priority.

If two alarms with different priority levels are triggered at the same time, the higher priority alarm takes precedence over the lower priority alarm.

Category	Definition	Visual signal	Audible signal
High-priority alarms	Emergency signal. The operator must respond immediately	Red LED flashing quickly 	10 beeps every 10 s: a digital sound alternating with buzzers
Medium-priority alarms	The operator should respond as soon as possible	Orange LED flashing slowly 	3 beeps every 25 s: a digital sound alternating with buzzers
Low-priority alarms	Alarm signal. The operator must check the alarm	Orange LED lit, not flashing 	2 beeps every 30 s: a digital sound alternating with buzzers

Relative alarm priorities

	High-priority alarms	Medium-priority alarms	Low-priority alarms
Highest priority	LP – Low Flow?	EXT BATT EMPTY	NiMH battery
	LP – CIRCUIT OPEN	INT BATT LOW	EXT BATT MISSING
	MAXI P inspi	LOW PEEP	EXT BATT LOW
	O_2 FAULT	PATIENT APNEA	EXT MISSING
	MAXI LEAKS		MAINS MISSING
	MAXI P expi		EXPI resist
	WRONG CIRCUIT		INSPI resist
	MINI V/MIN		MAXI V/MIN
	MINI Vt		MAXI F
	MAXI Vt		ADJUST CLOCK
	FIO_2 21		VENTIL STOPPED
	MAXI FIO_2		REPLACE BLOWER
	MINI FIO_2		REPLACE O_2 CELL
Lowest priority	PRESENCE O_2 HP		
	INT BATT EMPTY		
	TEST FAILED		

6.4 Alarm settings

CAUTION

If you change any of the alarm settings, see Section 6.5 on page 74 for instructions on testing the alarms.

: Non-invasive ventilation; : Invasive ventilation

	Default value		Settings range				
Value:			**Minimum**		**Maximum**		**Increment**
Patient type:	**Child**	**Adult**	**Child**	**Adult**	**Child**	**Adult**	
Max. resp. rate (bpm)	35		15	10	99		1
Max. pressure (cm H_2O)	30	40	5		99		1
Maxi $\dot{V}e$ (L/min)	5	15	3.5		19.5 / NO	39.5 / NO	0.5
Mini $\dot{V}e$ (L/min)	1.0	3	0.2		10.0	20.0	0.2
Maxi $\dot{V}i$ (L/min)	5.0	15	3.5		19.5 / NO	39.5 / NO	0.5
Mini $\dot{V}i$ (L/min)	1.0	3	0.2		10.0	20.0	0.2
Maxi Vte (mL)	750	1000	50		200		10
			200	600	750 / NO	1000	50
	550			1000		2400 / NO	100

	Default value		Settings range				
Value:			**Minimum**		**Maximum**		**Increment**
Patient type:	**Child**	**Adult**	**Child**	**Adult**	**Child**	**Adult**	
Mini Vte (mL)	10	300	10 / NO	NO / 10	500	1000	10
				1000		2300	100
Maxi Vti (mL) (Pressure-controlled modes)	750	1000	50		200		10
			200	500	750 / NO	1000	50
	550			1000		2400 / NO	100
Maxi Vti (mL) (Volume-controlled modes)	750	1000	50	50	200		10
			200	200	750 / NO	1000	50
	550			1000		2400 / NO	100
Mini Vti (mL)	10	300	10 / NO	10 / NO	500	1000	10
				1000		2300	100
Δ Pi (cm H_2O)	3		1		20		1
High Leak (%)	NO		20		80 / NO		1

6.5 Alarm testing procedures

CAUTION

The visual and audible signals of all alarms must be tested regularly to ensure they are working properly, particularly:

- Prior to connection to a patient, before continuous ventilation
- After any configuration or alarm setting change.

Note: *Some alarms may have a reaction time of several seconds before they are activated or deactivated.*

Testing the power supply alarms

1. Connect a patient circuit (double or single) fitted with a Maquet test lung to the ventilator and perform the manual test.
2. Set the mode to ACV, Adult.
3. Mute any alarms which may be triggered (by pressing the Alarm Silence button twice).
4. Perform the following test for each power supply type (mains, external DC and external battery):

Action	Visual alert	Audible signal
Connect the power supply	Off	Off
Disconnect the power supply	Flashing	Sounding
Reconnect the power supply	Steady	Off
Press the Alarm Silence button	Off	Off

Tests which apply to both single and double circuit alarms

1. Connect a patient circuit (single or double) fitted with a Maquet test lung to the ventilator and perform the manual test.
2. Set the mode to ACV, Adult.
3. Set the ventilation parameters as follows:

V_T = 450 mL	$\dot{V}$ max = 28 L/min
PEEP = 0 cm H_2O	Trigger = NO
F = 15 bpm	FiO_2 = 21%

4. Start ventilation and perform the following actions:

Alarm	Action	Visual alert	Audible signal	Time the alarm takes to trigger
CIRCUIT OPEN	Disconnect the patient circuit expiratory limb	Flashing	Sounding	2 cycles
	Reconnect the patient circuit expiratory limb	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MAXI F	Adjust the upper alarm threshold to F = 10 bpm	Flashing	Sounding	4 cycles
	Adjust the upper alarm threshold to F = 35 bpm	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MAXI P INSPI	Adjust the upper alarm threshold to Pmax = 10 cm H_2O	Flashing	Sounding	3 cycles
	Adjust the upper alarm threshold to Pmax = 60 cm H_2O	Steady	Off	
	Press the Alarm Silence button	Off	Off	

5. Connect a high-pressure oxygen supply and a 2 litre test lung to the ventilator, then set the following values:

V_T = 2000 mL	$\dot{V}$ max = 53 L/min
PEEP = 5 cm H_2O	Trigger = 2
F = 10 bpm	FiO_2 = 21%

6. Set the V_{TE}, Ve, and Pmax alarm thresholds to their respective minimum and maximum values.
7. Start ventilation and perform the following actions:

Alarm	Action	Visual alert	Audible signal	Time the alarm takes to trigger
MINI FIO_2	Set FiO_2 to 100%	Flashing	Sounding	2 minutes
	Set FiO_2 to 21%	Steady	Off	
	Press the Alarm Silence button	Off	Off	

8. Disconnect the oxygen and change the ventilation mode to PS.
9. Set the ventilation parameters as follows:

PS = 15 cm H_2O	PEEP = 5 cm H_2O	Ti = 1.2 s
Tapnea = 15 s	F = 15 bpm	
Pi = 15 cm H_2O	Trigger = 3	FiO_2 = 21%

10. Start ventilation and perform the following actions:

Alarm	Action	Visual alert	Audible signal	Time the alarm takes to trigger
PATIENT APNEA	Trigger 4 inspiratory cycles	Steady	Off	Tapnea
	Wait without triggering further inspiratory phases	Flashing	Sounding	
	Press the Alarm Silence button	Off	Off	
O_2 FAULT	Set the FiO_2 to 90%	Flashing	Sounding	2 minutes
	Set the FiO_2 to 21%	Steady	Off	
	Press the Alarm Silence button	Off	Off	

Tests for double circuit-only alarms

1. Connect a double patient circuit fitted with a Maquet test lung to the ventilator and perform the manual test.
2. Set the mode to ACV, Adult.
3. Set the ventilation parameters as follows:

V_T = 500 mL	$\dot{V}$max = 28 L/min
PEEP = 0 cm H_2O	Trigger = NO
F = 15 bpm	FiO_2 = 21%

4. Start ventilation and perform the following actions:

Alarm	Action	Visual alert	Audible signal	Time the alarm takes to trigger
MINI Vt	Adjust the upper alarm threshold to V_{TE} = 2000 mL and the lower alarm threshold to V_{TE} = 800 mL	Flashing	Sounding	5 cycles
	Adjust the lower alarm threshold to V_{TE} = 150 mL	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MAXI Vt	Adjust the upper alarm threshold to V_{TE} = 250 mL	Flashing	Sounding	5 cycles
	Adjust the upper alarm threshold to V_{TE} = 2000 mL	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MAXI V/min	Adjust the lower alarm threshold to $\dot{V}$e = 0.2 L/min and the upper threshold to $\dot{V}$e = 6.5 L/min	Flashing	Sounding	Immediately
	Adjust the upper alarm threshold to $\dot{V}$e = 30.0 L/min	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MINI V/min	Adjust the lower alarm threshold to $\dot{V}$e = 11.0 L/min	Steady	Off	Immediately
	Adjust the lower alarm threshold to $\dot{V}$e = 0.2 L/min	Off	Off	
	Press the Alarm Silence button	Off	Off	

5. Set the mode to PACV, Adult and perform the following actions:

Alarm	Action	Visual alert	Audible signal	Time the alarm takes to trigger
MAXI LEAKS	Adjust the upper alarm threshold to Leak = 20% then create a slight leak in the circuit (e.g. by slightly loosening the expiratory limb of the circuit)	Flashing	Sounding	6 cycles
	Adjust the upper alarm threshold to Leak = 80% and stop the leak	Steady	Off	
	Press the Alarm Silence button	Off	Off	

Tests for single circuit-only alarms

1. Connect a single patient circuit fitted with a Maquet test lung to the ventilator and perform the manual test.
2. Configure the device for ACV mode, adult ventilation, then set the ventilation parameters as follows:

V_T = 500 mL	I:E = 1:2.0
PEEP = 0 cm H_2O	Trigger = 3
F = 15 bpm	FiO_2 = 21%

3. Set the mini Vti, maxi Vti, min $\dot{V}$i and max $\dot{V}$i alarm thresholds to their respective minimum and maximum values.
4. Start ventilation and perform the following actions:

Alarm	Action	Visual alert	Audible signal	Time the alarm takes to trigger
MAXI P EXPI	Block the single circuit valve outlet	Flashing	Sounding	1 cycle
	Unblock the single circuit valve outlet	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MINI Vt	Adjust the upper alarm threshold to V_{TE} = 2000 mL and the lower alarm threshold to V_{TE} = 600 mL	Flashing	Sounding	5 cycles
	Adjust the lower alarm threshold to V_{TE} = 150 mL	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MAXI Vt	Adjust the upper alarm threshold to V_{TE} = 250 mL	Flashing	Sounding	5 cycles
	Adjust the upper alarm threshold to V_{TE} = 2000 mL	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MAXI V/min	Adjust the upper alarm threshold to $\dot{V}$i = 4.5 L/min	Flashing	Sounding	Immediately
	Adjust the upper alarm threshold to $\dot{V}$i = 20.0 L/min	Steady	Off	
	Press the Alarm Silence button	Off	Off	
MINI V/min	Adjust the upper alarm threshold to $\dot{V}$i = 25.0 L/min and the lower alarm threshold to $\dot{V}$i = 12.0 L/min	Flashing	Sounding	Immediately
	Adjust the lower alarm threshold to $\dot{V}$i = 0.2 L/min	Steady	Off	
	Press the Alarm Silence button	Off	Off	

6.6 Troubleshooting

WARNING
If, after trying these solutions, the activated alarm persists, turn the device off and contact your technician.

Alarms that cannot be stopped

Symbol	Message	Priority	Cause	Solution
INT.	INT BATT EMPTY	High	Internal battery charge less than 5%	Change the power supply
O_2	MINI FIO_2	High	Supplied FiO_2 too low	Check that an oxygen supply is connected and press the O_2 100% 2 min button (see page 65)
O_2	MAXI FIO_2	High	Supplied FiO_2 too high	Check that an oxygen supply is connected and press the O_2 100% 2 min button (see page 65)
	NiMH BATTERY	Low	An unknown external battery pack has been connected	Connect a compatible external battery pack (Li-Ion type)

Alarms that can be stopped temporarily (muted for 120 seconds)

Symbol	Message	Priority	Cause	Solution
O_2	O_2 FAULT	High	HP O_2 supply missing	Connect the high-pressure O_2 tube
	PATIENT APNEA	Medium	No spontaneous cycles were inititated during Tapnea starting from the end of the previous expiratory phase	Check for leaks from the mask or tubing. If necessary, adjust the apnea time. For the double circuit only, adjust the trigger value
EXT.	EXT BATT EMPTY	Medium	External battery charge less than 5%	Connect the device to mains supply or change the external battery pack
EXT.	EXT BATT LOW	Low	External battery charge less than 15%	Connect the device to mains supply or change the external battery pack
INT.	INT BATT LOW	Medium	Internal battery charge less than 15%	Change the power supply
LP	CIRCUIT OPEN	High	Patient circuit is poorly connected	Reconnect the patient circuit
			Patient circuit is faulty	Change the patient circuit
	TEST FAILED	High	Manual test failed	Repeat the manual test
F	MAXI F	Low	Respiratory rates exceed the upper threshold of the Respiratory Rate alarm	Check that Respiratory Rate alarm and inspiratory trigger settings are correct
	MAXI LEAKS	High	Leaks exceed the upper threshold of the High Leak alarm	Check that the High Leak alarm threshold setting is correct and check the integrity of the patient circuit
	WRONG CIRCUIT	High	Type of patient circuit used is different from the one determined by the test	Check the circuit and repeat the test
LP	LOW PEEP	Medium	The PEEP delivered to patient is lower than the target PEEP	Check the integrity of the patient circuit
HP	MAXI P EXPI	High	The expiratory pressure is too high compared with the target PEEP	Check the expiratory valve control and check the patient circuit is not blocked

Symbol	Message	Priority	Cause	Solution
HP	MAXI P INSPI	High	The pressure in the circuit is higher than the High Pressure alarm threshold	Check the alarm threshold is correctly set and the patient's airway is clear, and check the integrity of the patient circuit
V	MAXI V/min	Low	The patient's minute volume is higher than the Maximum Minute Volume alarm threshold.	Check the alarm threshold is correctly set and check the integrity of the patient circuit and the expiratory valve function
V	MINI V/min	High	The patient's minute volume is lower than the Minimum Minute Volume alarm threshold	Check the alarm threshold is correctly set and check the integrity of the patient circuit and the expiratory valve function
V	MAXI Vt	High	The tidal volume is higher than the upper threshold for the Tidal Volume alarm	Check the alarm threshold is correctly set and check the integrity of the patient circuit and the expiratory valve function
V	MINI Vt	High	The tidal volume is below the lower threshold for the Tidal Volume alarm	Check the alarm threshold is correctly set and check the integrity of the patient circuit and the expiratory valve function

Alarms that can be stopped permanently

Symbol	Message	Priority	Cause	Solution
EXT	EXT BATT MISSING	Low	The external battery pack is disconnected	Reinstall the external battery pack or confirm the disconnection by pressing the Alarm Silence button
	EXT MISSING*	Low	Loss of external DC power supply	Check the external DC supply connection or confirm disconnection by pressing the Alarm Silence button
	EXPI RESIST	Low	Abnormal expiratory resistance in the patient circuit	Change the patient circuit and perform the manual test
	INSPI RESIST	Low	Abnormal inspiratory resistance in the patient circuit	Change the patient circuit and perform the manual test
	MAINS MISSING	Low	No mains power pack in the compartment under the device or at the external power socket	Check the connection between the mains power socket and mains power pack, or if the mains power pack is connected to the external power socket, check this connection or confirm the disconnection of mains power by pressing the Alarm Silence button

* If a mains power pack located outside of the power pack compartment (treated as an external power supply) is disconnected, this will trigger the external power supply alarm, not the mains power alarm.

WARNING

In the event of a complete loss of power, or if the ventilator is shut down intentionally, alarms will automatically stop after 120 seconds. You should check that this occurs by performing the Power Supply alarm test (see page 74).

7 Maintenance and disinfection

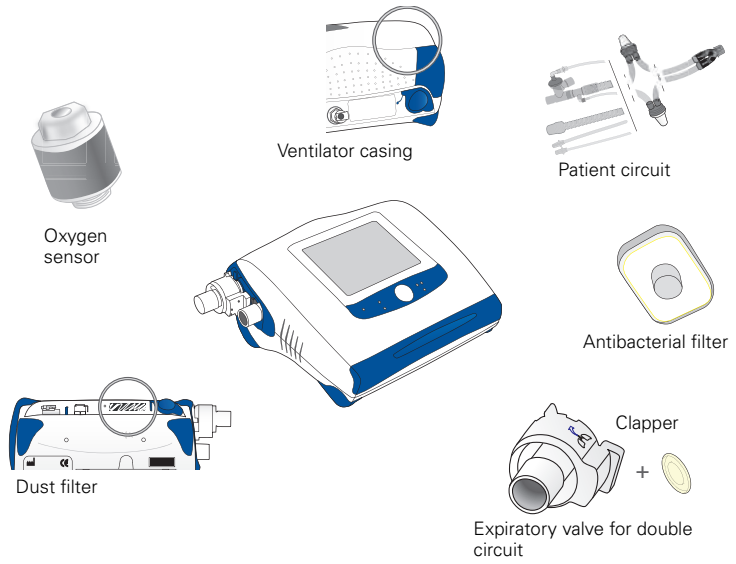
WARNING

The device should be cleaned and disinfected before it is used for the first time, and also between patients.

The disinfection of the ventilator must be carried out as stated in the manufacturer's instructions and in accordance with the current protocol of the health care institution.

Service personnel must be familiar with cleaning and disinfection protocols as well as the precautions required for certain materials.

The following figure shows the components which need to be cleaned and/or replaced:



7.1 Maintenance schedule

Any recommendations concerning cleaning frequency and the replacement of disposable components are provided by the manufacturers of those components. As an indication, this table provides information on the components that must be cleaned before reuse.

	Maintenance frequency	
	For the same patient	**Between patients**
Patient circuit	Hospital protocol or manufacturer	Yes
Antibacterial filter	If used for antiviral and antibacterial protection, refer to the manufacturer's instructions	Yes
Expiratory valve for double circuit	Hospital protocol or one week	• With antibacterial filter: hospital protocol or one week • Without filter: clean between patients
Dust filter	Every 6 months at least	
Nebuliser	Hospital protocol or manufacturer	Yes
Oxygen sensor	Refer to ventilator alarm if necessary	
Device casing	Hospital protocol or one week	Yes

7.2 List of cleaning/replacement tasks

WARNING
After cleaning or replacing any accessory in the patient circuit, always perform a manual test.

Patient circuit

Follow the hospital protocol and the recommendations of the manufacturer:

- For the disinfection and cleaning of reusable circuits
- For the replacement of disposable circuits.

The patient circuit must be replaced for each new patient.

Antibacterial filter

Follow the hospital protocol and the manufacturer's recommendations.

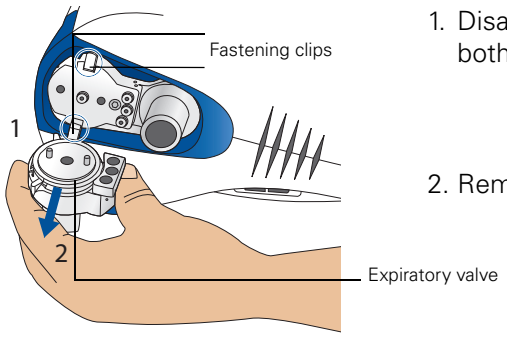
If the antibacterial filter is used to protect against bacteria and viruses, it should be inserted in the inspiratory limb of the patient circuit. It should be changed as directed by the manufacturer.

Note: *ResMed recommends the use of a proximal antibacterial filter in accordance with the practices in effect in the hospital.*

The antibacterial filter must be changed for each new patient.

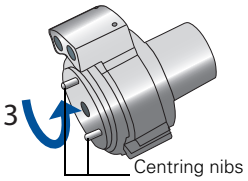
Expiratory valve for double circuit

1 Disassembly

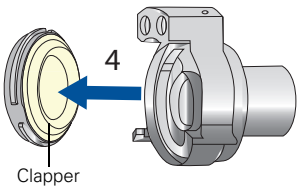


1. Disassemble the valve by pressing simultaneously on both fastening clips.

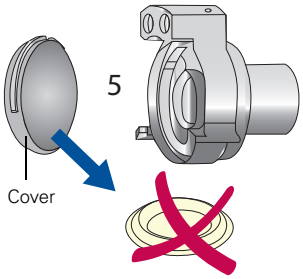
2. Remove the valve from the ventilator.



3. Hold the support in one hand. Place the index finger and thumb of your other hand on the two centring nibs.



4. Press down on the centring nibs and pull out the clapper holder by twisting in an anti-clockwise direction.



5. Remove the clapper and discard it.

Note: *The clapper on the expiratory valve is always discarded prior to autoclaving or disinfection, and replaced with a new one.*

2 Maintenance operations

WARNING

It is contra-indicated to clean the double circuit expiratory valve in an automatic washing machine due to the risk of damaging its integrated flow measurement system.

Technique	Permitted (Yes/No)	Method/Recommendation
Autoclaving	**Yes**	134°C for 18 minutes
Automatic washing machine	**No**	-
Cold disinfection	**Yes**	See the following paragraph

Cold disinfection protocol

ResMed recommends the disinfection of the double circuit expiratory valve according to the following protocol. This protocol allows cleaning, pre-disinfection, and complete cold disinfection through two cycles. Proceed as follows:

1. Disassemble the expiratory valve and throw away the valve clapper.
2. Disinfection Cycle A (using a pre-disinfecting cleaning solution: HEXANIOS G+R or Salvanios pH 7):
   - Immerse all parts (except the clapper) for 15 minutes in the pre-disinfecting detergent, i.e. HEXANIOS G+R diluted to 0.5%, or Salvanios pH 7 diluted to 0.5%.
   - During immersion, gently remove any visible dirt with a soft brush.
   - Rinse under running water.
   - Dry on a paper towel.
3. Disinfection Cycle B (using ANIOXYDE 1000, a high-performance disinfecting solution):
   - Immerse fully for 30 minutes in the activated, high-performance disinfecting solution ANIOXYDE 1000.
   - Rinse under running water.
   - Dry on a paper towel.
4. Reassemble the expiratory valve using a new valve clapper.

Note: *After the twentieth cycle, fine whitish lines may appear on the valve. These will not affect its performance in any way.*

CAUTION

Do not use a high-pressure air generator to dry the valve more rapidly as this would damage its honeycomb structure.

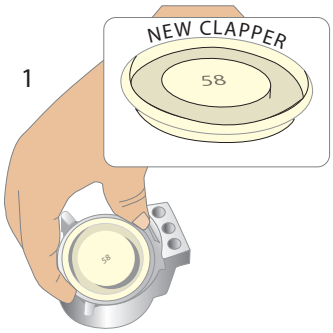
Autoclaving

If required by your hospital protocol, the expiratory valve can be sterilised by autoclave. Prior to autoclaving, the valve must be dismantled and cleaned in a detergent bath. Proceed as follows:

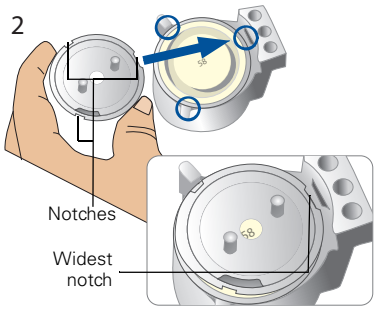
1. Disassemble the expiratory valve and throw away the valve clapper.
2. To clean:
   - Immerse all parts (except the clapper) for 15 minutes in the pre-disinfecting detergent, i.e. HEXANIOS G+R diluted to 0.5%, or Salvanios pH 7 diluted to 0.5%.
   - During immersion, gently remove any visible dirt with a soft brush.
   - Rinse under running water.
   - Dry on a paper towel.
3. To autoclave:
   - Put the disassembled parts of the expiratory valve in an autoclave at a temperature of 134°C (273°F) for 18 minutes.
4. Reassemble the expiratory valve using a new valve clapper.

Note: *After the twentieth cycle, fine whitish lines may appear on the valve. These will not affect its performance in any way.*

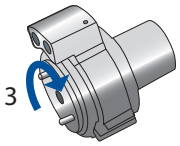
3 Reassembly



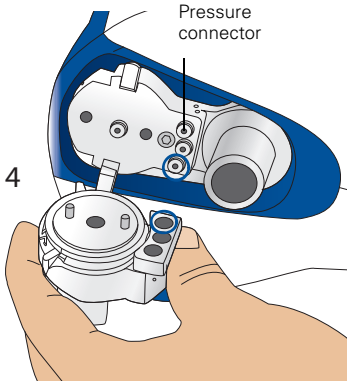
1. After autoclaving or disinfecting the expiratory valve, place a clapper in the holder so that the side with a number on it is visible, as in the figure opposite.



2. Line up the three notches with the locking nibs and push firmly.

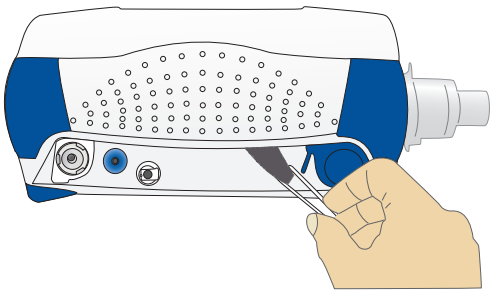


3. Lock the support together by turning the clapper holder clockwise as far as you can.



4. Replace the expiratory valve by matching up all three pressure connectors with the corresponding holes on the valve.

Replacing the dust filter

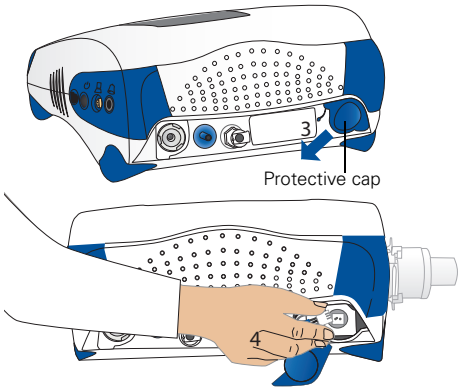


1. Use tweezers to pull the filter out of its compartment.
2. Insert the new filter into the compartment and push it in until flush with the casing.

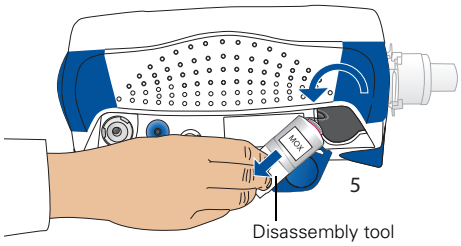
Replacing the oxygen sensor

Note: *The replacement frequency for the oxygen sensor varies from 6 to 12 months. This frequency is given as an indication only and varies depending on the duration of ventilation, the oxygen concentration used and the ambient temperature. When the sensor expires, the ventilator will tell you that it is time to replace it (see "3 Manual test" on page 48).*

Disassembly

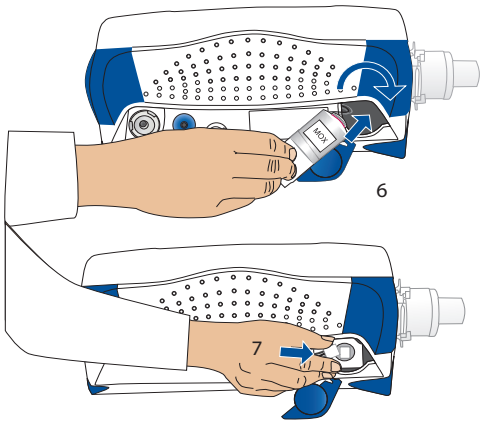


1. Switch off the ventilator.
2. Prepare the new oxygen sensor:
   - Check the expiry date (month and year) on the sensor packaging; it can be installed at any time before the date on the label.
   - Let the sensor sit in ambient air for 15 minutes.
3. On the Elisée 350, remove the protective cap from the sensor.
4. Disconnect the sensor connector.

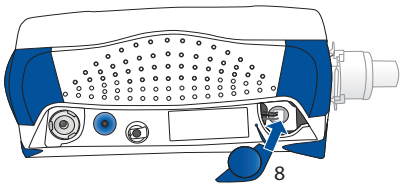


5. Unscrew the sensor using the disassembly tool supplied with the ventilator and remove the sensor from its housing.

Reassembly



6. Position the new sensor and use the disassembly tool to screw it into place.
7. Remove the disassembly tool from the sensor and plug the connector back in.



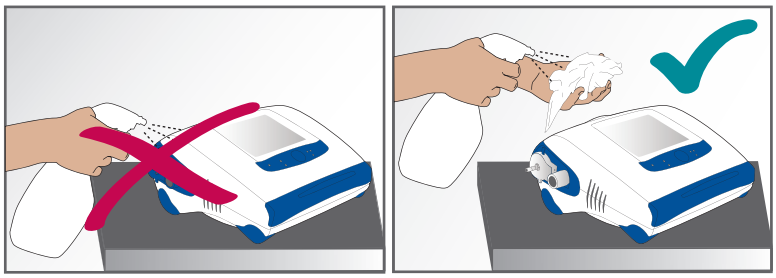
8. Replace the protective cap.
9. Switch the ventilator on and perform a manual test. If the message “REPLACE O2 CELL” is not displayed on the screen, the sensor is operational.

Ventilator casing

Clean the outside of the device with a dry cloth or, if necessary, with a damp sponge.

WARNING

- The ventilator may be disinfected using current procedures approved by your service centre. However, users are strongly advised not to use abrasive powders or solvents.
- If other products are used, they must comply with the conditions set by the pharmacopoeia of your country, must be known not to leave any residue and must not affect the operation of the ventilator.
- Never spray any liquid directly onto the ventilator casing.



7.3 Preventative maintenance

Every 12 months, the ventilator must be serviced by a qualified technician. This service must include a check of all the functions, calibration of the pressure and volume measurement devices and a safety check incorporating testing of the alarms.

Preventative maintenance schedule

Servicing	Frequency	People qualified to perform service
Oxygen sensor	Six months (this period will vary depending on the oxygen concentration used and the ambient temperature)	Trained technicians
Preventative maintenance	Yearly	Trained technicians
Preventative maintenance	10,000 hours	Trained technicians

For details of the servicing tasks, refer to the Service Manual.

8 Technical specifications

8.1 Technical description and operation

CAUTION
This section is intended for qualified technicians trained by ResMed.

Technical description

The Elisée 350 is a volumetric and barometric ventilator. The air flow is generated by a turbine from ambient air flowing through the air inlet. The Elisée 350 can therefore operate without a pressurised air supply. Closed-loop control between the turbine and a valve allows the pressure and the volume of air delivered to the patient to be monitored accurately.

An oxygen port enables the enrichment of the insufflated air up to an FiO_2 of 100%.

The ventilator body consists of a printed circuit board and a pressurised air assembly connected to a turbine.

Printed circuit board

Controls the operation of the ventilator through the main microcontroller. The main microcontroller controls:

- Power supply switching
- Ventilation measurements and controls
- Temperature measurements of the ambient air, insufflated air and internal battery
- The alarms
- The user interfaces.

A second microcontroller monitors the activity of the main microcontroller.

Pressurised air assembly

The pressurised air assembly consists of:

- A main turbine for ventilation
- A PEEP microturbine to maintain positive end expiratory pressure
- A rotary slide valve providing closed-loop control of flow rates and pressures
- An I/E solenoid valve which controls the inspiratory and expiratory phases
- A spontaneous inspiration valve
- An electromagnet dedicated to the P0.1 function
- Solenoid valves dedicated to cleaning the double circuit support
- A regulator monitored by a proportional solenoid valve which controls the high-pressure oxygen flow.

The pressurised air assembly also contains integrated sensors to monitor ventilation:

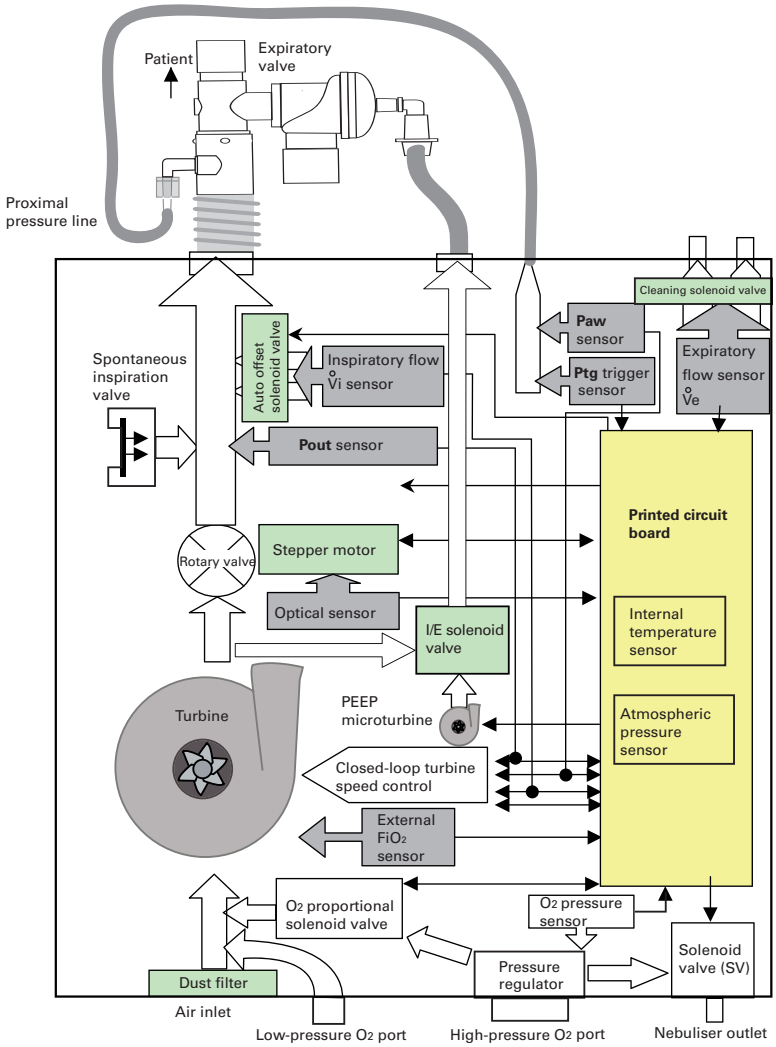
Sensors	Measurement range
Proximal pressure sensor (**Paw**)	0–100 cm H_2O
Proximal pressure sensor for pressure triggering (**Ptg**). This sensor is more precise than the Paw sensor. It measures negative pressure values and patient effort	-10 cm H_2O – +40 cm H_2O
Expiratory flow sensor (for monitoring exhaled air in double circuits), $\dot{V}e$	0–180 L/min
Inspiratory flow sensor for monitoring inhaled air, $\dot{V}i$	0–180 L/min
Safety turbine outlet pressure sensor (**Pout**)	0–100 cm H_2O
Chemical sensor measuring external FiO_2	0–100%
Oxygen pressure sensor for the pressure regulator outlet, PO_2	0–700 kPa
Safety chemical sensor for measuring O_2 concentration, O_2S (leak)	0–100%
Atmospheric pressure sensor, Patm	15–115 kPa
Temperature sensor	-15°C – +90°C
Hall-effect turbine speed sensor	0–65,000 rpm

How the ventilator works

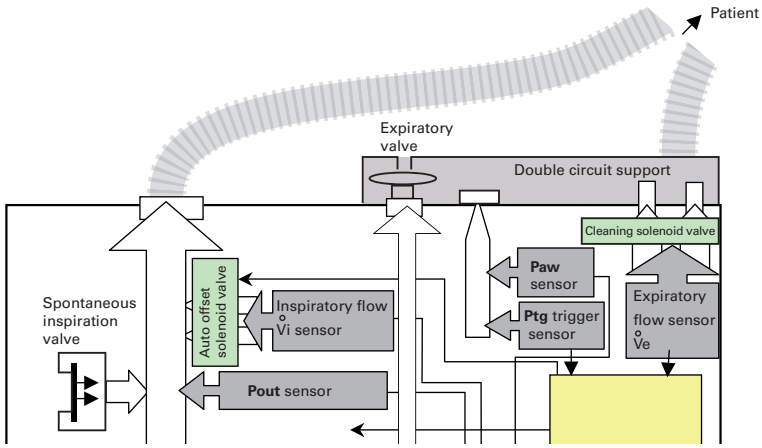
- Outside air is sucked in through a dust filter.
- It may be enriched with oxygen using the low-pressure oxygen port (400 kPa max., 15 L/min max.) or the high-pressure oxygen port (240–700 kPa max.). The FiO_2 is monitored using a dedicated chemical sensor. At first, the high-pressure oxygen is released at 190 kPa maximum: a pressure sensor measures the presence and pressure of oxygen. Then a proportional solenoid valve regulates the flow of oxygen injected into the turbine. This oxygen pressure can also be used, via a solenoid valve, to control a nebuliser.
- The turbine then compresses the oxygen/air mixture. The turbine enables closed-loop control of the required pressures and flow rates. The turbine speed is regulated by the microprocessor on the basis of the set parameters. It is controlled either by the inspiratory flow sensor in volume-based modes, or by the proximal pressure sensor in pressure-based modes.
- At the turbine outlet, a rotary valve controlled by a stepper motor controls the level and shape of air pressure and flow with precision.
- An I/E solenoid valve controls the expiratory valve, which in turn controls the inspiratory and expiratory times.
- There is also a microturbine which can generate a counter-pressure during the expiratory phase to maintain the level of PEEP.
- A sensor dedicated to triggering complements the proximal pressure sensor in detecting patient effort.
- For safety reasons, an inspiratory valve allows the patient to breathe spontaneously regardless of the status of the ventilator.
- The solenoid valves dedicated to cleaning remove humidity from the double circuit support to improve expiratory spirometry.
- The P0.1 electromagnet creates a total obstruction of the circuit so that the patient effort can be measured.
- An atmospheric pressure sensor corrects the measurements recorded by the other sensors.
- A temperature sensor monitors increases in internal temperature, and controls the cooling fans.
- Two solenoid valves (auto offset) enable automatic recalibration of the inspiratory flow sensor offset.

Note: *Only the high-pressure oxygen port provides control of the oxygen concentration.*

Block diagram of Elisée 350 with single circuit



Block diagram of Elisée 350 with double circuit



8.2 Elisée 350 technical specifications

Dimensions and weight

- Dimensions: 290 x 250 x 130 mm (11" x 10" x 5")
- Weight of the ventilator: 4.15 kg (9.1 lbs)
- Weight of the mains power pack: 0.45 kg (1 lb)
- Weight of the external battery pack: 0.75 kg (1.7 lbs)
- Weight of the ventilator:
  - with the mains power pack: 4.55 kg (10.0 lbs)
  - with the external battery pack: 4.95 kg (10.9 lbs).

Electrical specifications

- Class of the device: Class II, type BF
- Mains supply: 110–240 V AC; 50/60 Hz; 0.67–1.33 A
- External DC power supply: 12–28 V DC; max 15 A
- Internal battery: Li-Ion; 14.4 V DC; 6.3 AH
- External battery: Li-Ion, 14.4 V DC; 6.3 AH
- Power consumption: Max. 75 VA.

Battery life and recharging

In the following conditions:

Adult, Invasive, PCV mode, Pi = 20 cm H_2O, PEEP = 0 cm H_2O, F = 15 bpm, Ti = 1.2 s, Invasive pressure trigger = NO, Invasive flow trigger = NO, Rise time = 3, Maquet 190 test lung, Patient circuit CIR009727, $V_{TE} \approx 425$ mL, BTPS = NO, screen brightness: minimum, altitude: 100 m, temperature = 20°C:

- The internal battery will last for a minimum of 3 hours
- With an internal battery and an external battery pack, the ventilator can be operated for a minimum of 6 hours
- Recharging: The battery charge time is nearly 6 hours per battery, with the device connected to the mains supply (with an external power supply < 20 volts, the batteries will not be recharged during ventilation).

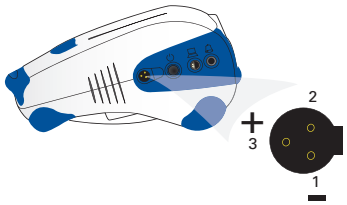
The useful life of an internal battery is two years (500 charge/discharge cycles). To ensure optimum performance over this time period, it must be completely discharged and recharged once every six months.

When the charge of the internal battery falls below a certain level, the Low Battery alarm will be triggered, followed by the Empty Battery alarm, which indicates that ventilation will stop.
The time that elapses from when the Low Battery alarm sounds to when ventilation stops is 5 minutes minimum in the following conditions: PCV mode, Pi = 20 cm H_2O, PEEP = 0 cm H_2O, F = 15 bpm, Ti = 1.2 s, Invasive pressure trigger = NO, Invasive flow trigger = NO, Rise time = 3, Patient circuit CIR009727, Maquet 190 test lung, V_{TE} = 425 mL, Screen brightness: Minimum, Altitude: 100 metres, Temperature: 20°C. This time may vary according to the configuration used and the ventilation conditions (major leaks, etc.).

In the interval between the end of ventilation and total ventilator shutdown, it is possible to restart ventilation immediately by connecting the ventilator to a power supply (external or mains supply).

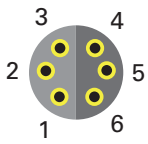
External power supply ( )

- Female power socket FRB DB315
- 12 to 28 V DC / 15 A max.



RS232 serial link socket ( )

ResMed-specific equipment.



1: TXD
2: RXD
3: GND
4: +5V
5: Digital input/output (0/5 V)
6: NC

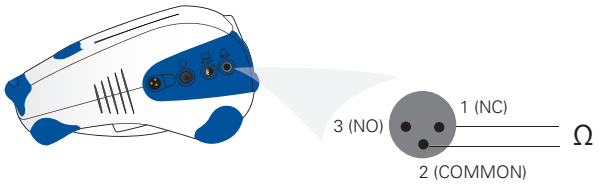
Note: *The manufacturer accepts no liability for damage to the device caused by the use of a cord which does not comply with the recommendations.*

Remote alarm ( )

WARNING
The manufacturer accepts no liability for damage to the device caused by connection to a remote alarm which does not comply with the specifications provided.

Electrical connection with remote alarm box via specific cord.

Binder 3-pin female Series 712 connector



Remote alarm relay:
Max. intensity: 0.25 A
Max. Voltage: 100 V DC connected to ground or 0 V connected to the device

Note: *The ventilator casing is not electrically polarised. It has its own power supply.*

Volume level

Volume level: < 40 dBA @ 1 m

When the device is operating on mains power and both buzzers are activated, the volume level is:

- 86 dBA at a distance of 1 m
- 78 dBA at a distance of 3 m.

Pressurised air specifications

High-pressure oxygen port: 240–700 kPa, 150 L/min maximum

Low-pressure oxygen port: 400 kPa, 15 L/min maximum

Pressurised air interface:

- High-pressure oxygen:
  Female connector (built-in)
  Male connector (cord)
- Low-pressure oxygen:
  Female connector (built-in): 1.8 NPT thread with clapper. CPC product code: MCD10-02.
  Male connector (cord): CPC product code: MC22-03.

Performance data

Mechanic and pneumatic performance: 0–100 cm H_2O at a flow rate of 0–180 L/min.

Air pressure supply (minute volume) adjustment range:

- Adult: 0.6–72.5 L/min
- Paediatric: 0.1–25 L/min.

Monitoring device: black box (events data storage), EasyView 370 monitoring screen.

Trends cannot be recorded.

Filtering and smoothing method: an average of 5 measurements taken at intervals of 2 ms.

Pressure

Maximum pressure: 99 cm H_2O in volume-controlled mode, 60 cm H_2O in pressure-controlled modes.

To obtain these maximum pressures:

- For ventilation in pressure modes:
  Set up PACV with Pi = 50 cm H_2O and PEEP = 10 cm H_2O, and connect a double circuit fitted with a Maquet test lung to the ventilator. Start ventilation.
- For ventilation in volume modes:
  Set up Adult, Non-invasive ACV and set the V_T to 0.65 L and the Pmax alarm to 99 cm H_2O. Connect a double circuit and block the other end. Start ventilation and check that the HP alarm is triggered.

Maximum pressure in single-fault conditions: 100 cm H_2O.

Negative pressure during expiration: None.

Note: *The High Pressure alarm is triggered when the inspiratory proximal pressure is higher than the High Pressure alarm threshold for three cycles, separated by no more than two cycles during which the alarm setting is not exceeded.*

As a safety feature, if the turbine output pressure is higher than 100 cm H_2O, the 30 V power supply to the turbine is cut off. This is achieved by means of an electronic pressure switch which is independent of both the microprocessor and the proximal pressure sensor.

Resistances

Ventilator with double circuit (Ø 22 mm), product code CIR009727

- Inspiratory resistance @ 60 L/min: 0.7 cm H_2O
- Expiratory resistance @ 60 L/min: 1.7 cm H_2O
- Inspiratory resistance @ 30 L/min: 0.4 cm H_2O
- Expiratory resistance @ 30 L/min: 1.0 cm H_2O.

Note: *Adding accessories to the patient circuit may increase resistance in the system.*

Ventilator with double circuit (Ø 22 mm), product code CIR009727 & accessories (filter, humidifier, etc.)

- Device volume: 1700 mL
- Device compliance: 1.7 mL/cm H_2O
- Inspiratory resistance @ 60 L/min: 4.3 cm H_2O
- Expiratory resistance @ 60 L/min: 3.0 cm H_2O.

High-pressure oxygen

- High-pressure oxygen port: 240–700 kPa, 150 L/min maximum
- In (A)CV mode, with V_T = 500 mL, PEEP = 7 cm H_2O, F = 15 bpm, I:E = 1:2.0 and FiO_2 = 100%: O_2 consumption = 18 L/min ± 20%.

Operating, storage and transport

Normal operating conditions

- Ambient temperature when the device is running on battery power: -10°C to +40°C (14 to 104°F)
- Ambient temperature required for recharging the batteries during operation: +5°C to +40°C (41 to 104°F)
- Ambient relative humidity: 10% – 95%
- Atmospheric pressure: 600 to 1100 hPa.

CAUTION
The performance of the device is not guaranteed in operating conditions other than those described above.

Storage conditions

- Storage temperature: -10°C to +50°C (14 to 122°F)
- Ambient relative humidity: 10–90%
- Atmospheric pressure: 500 to 1100 hPa
- The device is fragile. Keep dry and store in its operating position or in its bag.

CAUTION
We recommend that you store the device in its packaging or in its bag. If the device is stored outside of its packaging, it must be placed flat on its base.

Conditions for transport when not delivering ventilation

When returning to the service centre, the ventilator and its accessories must be transported inside the ResMed packaging. They must be transported in the following conditions:

- Storage temperature: -10°C to +50°C (14 to 122°F)
- Relative humidity: 10–90%
- Atmospheric pressure: 500 to 1100 hPa.

CAUTION
The device is fragile.

Conditions for transport during ventilation

- The Elisée 350 may be used during transport up to an altitude of 4000 metres (13,123 feet).
- If the ventilator is to be used during transport, it should remain inside its ResMed bag.
- For indoor transport on a gurney or for attachment to a bed rail, the mounting bracket can be used.
- The position of the ventilator during ventilation has no influence on its operation.
- When using the device in an ambulance or patient transfer vehicle, the ventilator can be secured by means of the straps on the bag or placed in the Elisée transport bracket system.
- Normal operating conditions apply.

Fire prevention

- In single-fault conditions, the flammable materials have an ignition temperature higher than the minimum required by the relevant standards.

8.3 Technical specifications for accessories

The ventilator must be used with CE-marked accessories and in compliance with the manufacturer's recommendations. The electrical accessories must be in compliance with the electrical safety and electromagnetic compatibility standards (IEC60601-1, IEC60601-1-2). The list of accessories is available at www.resmed.com; click on "Clinicians", then go to the "Products" page, then "Ventilation Devices", then "Ventilation Accessories".

CAUTION
The user must ensure that the total resistance of the patient circuit and ventilation accessories does not exceed 6 cm H_2O for a flow rate of 60 L/min (in adult ventilation), or 6 cm H_2O for a flow rate of 30 L/min (in paediatric ventilation).

Patient circuit with water traps

- Circuit product code: CIR009727
- Diameter of the connector: 22 mm
- Maximum internal volume of circuit: 1000 mL
- Compliance = 1.0 mL/cm H_2O.

Oxygen sensor

Electrochemical sensor (MediceL MOX-20 or equivalent):

- Pressure scale: 0.5–2.0 bar
- Output voltage: 0.8 V – 1.25 V @ 1013 hPa, air @ 50% humidity and 20°C (68°F)
- Response time: 750 ms
- Linearity: linear from 0 to 100% oxygen
- Range of measurement: 0–100%
- Long-term sensor drift: < 10% over a period of one year at ambient temperature
- Useful life: from 6 months to one year after the date indicated on the sensor (duration depends on the oxygen level and the duration of use)
- Accuracy: ± 1%.

CAUTION
The sensor must be installed before the expiry date indicated.

Antibacterial filter

Type of filter: Intersurgical Filta-Guard or equivalent:

- Filter: anti-bacterial / antiviral
- Connector: 22 female and 22 male / 15 female
- Bacterial and viral retention: > 99.999%
- Resistance @ 30 L/min: 1.1 cm H_2O
- Resistance @ 60 L/min: 2.2 cm H_2O
- Compliance: 0.2 mL/cm H_2O
- Compressible volume: 66 mL
- Internal volume: 200 mL
- Duration of use: 24 hours.

Humidifier

The humidifier used must meet the following requirements:

- Maximum operating pressure: > 80 cm H_2O
- Max. flow rate: 180 L/min
- Pressure drop at 180 L/min: < 3 cm H_2O
- With spontaneous breathing: < 3 cm H_2O
- Air loss at maximum pressure: < 20 mL/min
- Average compliance: 0.3 to 0.5 mL/cm H_2O
- Liquid flow rate: 10 to 25 mg/L.

Nebuliser

Type: Intersurgical Cirrus or equivalent.

Maximum A-weighted sound pressure level: 48.1 dBA

Any brand of nebuliser may be used, provided it is able to function at a maximum pressure of 200 kPa and a maximum flow rate of 20 L/min.

Dust filter

ResMed-specific equipment.

Note: *The manufacturer accepts no liability for damage to the device caused by the use of a filter which does not comply with the recommendations.*

8.4 Operating symbols and abbreviations

Symbols displayed on the screen

Power supply symbols

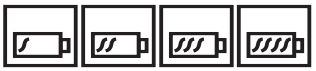
Mains power

External DC power supply

Internal battery

None Flat

Approx. internal battery charge



25% 50% 75% Battery full

External battery

None

Approx. external battery charge

25% 50% 75% Battery full

Ventilation symbols

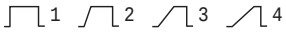
Ventilation type

Invasive Non-invasiv

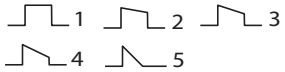
Patient type

Adult Paediatric

Rise time level



Flow shape



Patient effort indicator (trigger)

Abbreviations

Abbreviation	Definition	Abbreviation	Definition
PS	Pressure Support	Ppeak	Peak pressure
$PS.V_T$	Pressure Support with Minimum Tidal Volume	Pplat	Plateau pressure
Cancel.	Cancellation	Recruit	Recruitment
auto	Automatic	R	Static resistance
LP	Low pressure	T	Time
CPAP	Continuous Positive Airway Pressure	Te	Expiratory time
Cstat	Static compliance	TgE	Expiratory trigger
F	Respiratory rate	TgI(P)	Inspiratory pressure trigger
FiO_2	Inspired oxygen fraction	$TgI(\dot{V})$	Inspiratory flow trigger
Ftot	Total respiratory rate	Ti Max	Maximum inspiratory time
HP	High pressure	ACV	Assisted Volume-Controlled Ventilation
I:E	Ratio of inspiratory time to expiratory time	SIMV	Synchronised Intermittent Mandatory Ventilation
insp.	Inspiratory	$\dot{V}e$	Expired minute volume
max.	Maximum	Ventil.	Ventilation
min.	Minimum	$\dot{V}evs$	Expired minute volume (during spontaneous cycles)

Abbreviation	Definition	Abbreviation	Definition
Nebul.	Nebulisation	$\dot{V}_{max}$	Maximum flow
Custom. Setting	Customised Setting	PACV	Pressure Assisted Volume-Controlled Ventilation
P	Pressure	PSIMV	Pressure-Synchronised Intermittent Mandatory Ventilation
P1 to P5	Ventilation programs P1 to P5	V	Volume
Param	Parameter	SV	Spontaneous ventilation
PEEP	Positive End Expiratory Pressure	V_T	Tidal volume
Pi	Inspiratory pressure	V_{TE}	Expired tidal volume
Pmean	Mean pressure	V_{TI}	Inspired tidal volume

Symbols on the LED panel

Mains power LED

Internal battery LED

External battery LED

8.5 Symbols on the device casing

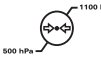
Warning and information symbols

 Class II electrical equipment;  BF-type electrical device;  Follow instructions for use;  Keep dry; Direct current; Alternating current;  Take precautions against electrostatic discharge;  Do not block; CE0123 CE-marked device (notified body TÜV Süd, CE0123);  Device subject to separate collection;  Manufacturer;  Serial number;  On/Off;  Alarm Silence.

Sockets and connections

 Exhaled air return port;  Air insufflation towards the patient;  Proximal pressure line;  Oxygen port;  Nebuliser outlet;  Expiratory valve control;  Serial link socket;  Remote alarm.

Transport and storage

 Store this way up;  Fragile;  Keep dry;  Relative humidity for transport and storage;  Temperature limits;  Atmospheric pressure limits.

8.6 Applicable standards

This ventilator complies with the following standards:

- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance: Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance: Collateral standard: Usability
- IEC 60601-1-8: Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance: Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-12 (ISO 10651-1): Medical electrical equipment – Part 2-12: Particular requirements for the safety of lung ventilators: Critical care ventilators
- EN 794-1: Lung ventilators – Part 1: Particular requirements for critical care ventilators
- EN 794-3: Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators
- EN 1789: Medical vehicles and their equipment – Road ambulances
- ISO 21647: Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 5356-1: Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets
- ISO 14971: Medical devices – Application of risk management to medical devices.

CE-marked device in accordance with Directive 93/42/EEC (Notified body: TÜV Süd – CE0123).

8.7 Electromagnetic emissions and immunity

Guidance and manufacturer's declaration – electromagnetic emissions

The Elisée 350 is intended for use in the electromagnetic environment specified below. The client or user of the Elisée 350 should ensure that it is used only in such an environment.

Emissions tests	Compliance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	The Elisée 350 uses RF energy only for its internal functions. Consequently, 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 Elisée 350 is suitable for use in all establishments other than domestic and can be used in domestic establishments and those directly connected to the public low voltage power supply network which supplies buildings used for domestic purposes, provided that the following warning is heeded: **⚠ WARNING** This device/system is intended to be used only by health care professionals. This device/system may cause RF interference or it may interfere with the operation of a nearby device. It may be necessary to take the appropriate measures to attenuate this interference, such as re-orienting or relocating the Elisée 350 or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Protection of the general electric network – Voltage fluctuations/ flicker emissions	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The Elisée 350 is intended for use in the electromagnetic environment specified below. The client or user of the Elisée 350 should ensure that it is used only in such an environment.

Immunity test	IEC 60601-1-2 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 materials, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for electric power lines ± 1 kV for inlet/outlet lines	± 2 kV for electric power lines ± 1 kV for inlet/outlet lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV between phases ± 2 kV from phase to earth	± 1 kV between phases ± 2 kV from phase to earth	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (95% dip in U_T) for 0.5 cycles <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 sec	<5% U_T (95% dip in U_T) for 0.5 cycles <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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Elisée 350 requires continuous operation during mains power interruptions, it is recommended that the Elisée 350 be powered from an emergency power supply
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	
			Portable and mobile RF communications equipment should be used no closer to any part of the Elisée 350, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter **Recommended separation distance:**
Conducted RF disturbances IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside the ISM band[a]	3 Vrms	$d=1.17\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz inside the ISM band[a]	10 Vrms	$d=1.20\sqrt{P}$
Radiated RF disturbances IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d=1.20\sqrt{P}$ 80 MHz to 800 MHz $d=2.30\sqrt{P}$ 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)[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: U_T is the voltage of the AC network, prior to application of the test level, included between 100 and 240 VAC.
Note 2: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 3: It is possible that these guidelines do not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
a 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.
b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are intended to reduce the probability of interference that the portable and mobile communications equipment may produce if it is introduced inadvertently into patient environment. For this reason, an additional factor of 10/3 was introduced into the formulae used to calculate the recommended separation distance for these transmitters in these frequency ranges.
c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and 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 Elisée 350 is used exceeds the applicable RF compliance level above, the Elisée 350 should be observed in this environment to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Elisée 350.
d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

WARNING

The Elisée 350 must not be used in the vicinity of other equipment or placed on or beneath other equipment (see the following table). If this is the case, ensure that it works correctly when placed in the location where it will be used.

Recommended separation distances between portable and mobile RF communications equipment and the Elisée 350

The Elisée 350 is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Elisée 350 can help prevent electromagnetic interference by maintaining the minimum separation distances between portable and mobile RF communications equipment (transmitters) and the Elisée 350 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz outside of ISM band $d=1.1\sqrt{P}$	150 kHz to 80 MHz inside the ISM band $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.2	1.2	2.3
10	3.7	3.80	3.80	7.27
100	11.7	12	12	23

For transmitters rated at a maximum output power not listed in the table above, the recommended separation distance d in meters (m) can be estimated 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.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 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.
Note 3: An additional factor of 10/3 was introduced into the formulae used to calculate the recommended separation distance for the transmitters in the ISM frequency bands, between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz; it is intended to reduce the probability of interference that the portable and mobile communications equipment may produce if it is introduced inadvertently into patient areas.
Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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