iX5™ Ventilator

Operator's Manual

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The iX5 ventilator must be handled and operated only by qualified professionals.

Read this manual thoroughly before using the iX5 ventilator on patients.

After the initial reading, always keep this manual at an accessible location, for future consulting.

This equipment and its documents may be modified without any further notice to the user.

This Operator's manual refers to the iX5 ventilator, software version 6.nn.

Trade Name: iX5 Ventilator
Technical Name: Pressure and Volume Ventilator
ANVISA Registration no. 10243240052

Technician in Charge: Eng. Julio Cesar Zambon – CREA 0681886376

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Chapter 1   Intended Use

The iX5™ ventilator is intended to provide continuous respiratory support in an professional health care environment (e.g. hospitals). It may be used on neonatal through adult patients, invasively or noninvasively. It should only be operated by properly trained clinical personnel, under the direction of a physician.

The ventilator is suitable for use in institutional and intra-hospital transport settings. It is not intended for use as an emergency medical transport ventilator or homecare applications.

Standards

The **iX5** ventilator was developed, tested and certified in accordance with the following safety standards for electromedical equipment:

- **IEC 60601-1:2005 + Amendment 1:2012: Medical Electrical Equipment – Part 1**
  General Requirements for Basic Safety and Essential Performance

- **IEC 60601-1-2:2014: Medical Electrical Equipment – Part 1-2**
  General Requirements for Basic Safety and Essential Performance
  Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

- **IEC 60601-1-6:2010 + Amendment 1:2013: Medical Electrical Equipment – Part 1-6**
  General Requirements for Basic Safety and Essential Performance
  Collateral Standard: Usability

- **IEC 60601-1-8:2006 + Amendment 1:2012: Medical Electrical Equipment – Part 1-8**
  General Requirements for Basic Safety and Essential Performance
  Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems

- **ISO 80601-2-12:2011: Medical Electrical Equipment – Part 2-12**
  Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators

- **ISO 80601-2-55:2011: Medical Electrical Equipment – Part 2-55**
  Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors

Additionally, the design and manufacture of the iX5 ventilator complies with all the Brazilian and European legislation applicable to its product class.

Equipment Classification

This section features the classifications that can be applied to this product, in accordance with the safety standards listed on the previous item.

Each of these classifications is followed by a brief explanation about it. The exact definitions for each of the terms mentioned in this section can be found in *Section 12, Terminology, Symbols, and Definitions* of this manual.

Classification

Classification according to Directive 93/42/EEC, as amended by Directive 2007/47/EC

- **Class IIb**

Electrical Safety

Classification according to Standard IEC 60601-1:2005 + AMD1:2012

- **Class I Equipment**
  Equipment with electrically insulated metallic parts and a grounding terminal (plug with ground pin).

- **Internally energized equipment**
  Electric equipment capable of working by means of an internal battery.

- **Type B applied part**
  20 cm of the breathing circuit in contact with the patient providing protection against electric shock.

Protection against Liquid and Particle Ingress

Classification according to Standard IEC 60601-1:2005 + AMD1:2012

- IP21 equipment

Sterilization Methods

Classification according to Standard IEC 60601-1:2005 + AMD1:2012

- Autoclave

- Ethylene Oxide Sterilization

Safety

Classification according to Standard IEC 60601-1:2005 + AMD1:2012

- **Equipment not suitable for use in oxygen-rich environments**
  Equipment not suitable for use in environments featuring an oxygen concentration higher than 25%. In case of pressurized environments, the equipment is not suitable for use if, in such environment, the partial oxygen pressure is higher than 27.5kPa.

- **Equipment not suitable for use in the presence of an anesthetic mixture flammable with air, oxygen or nitrous oxide.**

Operation Mode

Classification according to Standard IEC 60601-1:2005 + AMD1:2012

- **Equipment for continuous operation**
  Equipment capable of operating for unlimited time without overheating.

Operating Principles

The iX5 ventilator features a modular design, focusing on safety and operational reliability, as well as easy maintenance. Additionally, it was designed to be an upgradable platform as new technologies become available.

The main modules are:

- Front Panel Module

- Electronic Actuation Module

- Electric Power Supply Module

- Pneumatic Control Module

- Rear Panel Module

Front Panel Module

The Front Panel Module is responsible for the user interface and the ventilator's main control. It consists of a liquid crystal display screen (LCD TFT), electronic boards, and control/quick access buttons.

The 12-inch colored liquid crystal display screen features high resolution (XGA 1024x768), high brightness and contrast, as well as anti-reflex and abrasion (scratches) resistant touch screen surface. The screen can be activated through finger touch, also working with gloves. Control actuation is done by touching the screen and/or using the main button for adjusting and confirming parameters. Some special functions also have quick access buttons.

The ventilator control is independent of the interface control; each of them is performed and supported by separate electronic boards and software. A monitoring routine independent from central processing supervises the entire system in order to prevent communication and/or control failures.

Electronics Module

The Electronics Module consists of electronic boards and transducers and it is responsible for actuating valves, monitoring of sensors, controlling the battery system, and activating alarms.

Electric Power Supply Module

The Electric Power Supply Module is responsible for powering the equipment and it consists of an AC stabilized power source and an internal rechargeable battery. An External Battery not recheargeable can be used optionaly. Both the internal and external batteries are sealed lead-acid.

Pneumatic Control Module

The Pneumatic Control Module is responsible for:

- Air and oxygen flow valves

- Exhalation valve

- Safety valve

- Nebulizer/Tracheal Gas Insufflation (TGI) actuation valve

- Paramagnetic oxygen sensor

- Pneumotachograph circuit

- Intake filters

The ventilator controls the air and oxygen flows by means of separate solenoid-actuated valves.

Each gas flow rate is measured by independent heated film sensors, calibrated for air and oxygen. Based on the measured flow rate values, the values continuously feed back in order to meet the set flow rate, volume and mixture composition (FiO2) parameters. The mixture resulting from the composition of air and oxygen flow rates is continuously measured by means of a paramagnetic oxygen sensor located inside the equipment, which data sample rate is 5 Hz.

During the installation, a Vyaire Authorized Technician must configure the equipment according to the altitude of the installation location, thus enabling the equipment, based on the barometric pressure, to properly compensate the controlled and monitored gas volume and oxygen concentration parameters.

The exhalation valve consists of a flexible diaphragm that actuates over a nozzle connected to the expiratory limb. The diaphragm actuation is done by means of a solenoid-actuated pilot valve. Based on the pressure values measured in the inspiratory and proximal route, the pilot

valve continuously feeds back, in order to keep the airway pressure at the desired value both on the inspiratory phase and on the expiratory phase.

The system also has two solenoid valves – one for compressed air and another for oxygen – their purpose is to keep constant the control pressure of the nebulization, TGI and safety valve valve systems. To control these systems, compressed air is preferably used; oxygen is only used in case of lack of compressed air or if the FiO2 used is too high.

When nebulization is used, the system enables the compensation of the tidal volume and of the oxygen concentration of the mixture supplied to the patient.

In specific cases, when it is impossible to keep the ventilation at safe levels, an safety valve is opened; this opens the ventilator circuit to enable the patient's spontaneous respiration.

To measure the flow rate and the volume on the external portion of the ventilator, flow sensors are used; they can be either proximal (mounted on the wye piece, close to the patient connection) or distal (mounted on the exhalation valve) type. An optical coupling located on the Pneumatic Control Module identifies the type of sensor in use.

The compressed air and oxygen pipelines are directly connected to the intake of the Pneumatic Control Module. In order to protect against the entry of water coming from the gas pipelines, trap filters are used and, in case of compressed air, two filters are used to provide additional safety.

Rear Panel Module

The Rear Panel Module is formed by electrical supply connections (AC/External Battery), the outlet of the fan from the supply source, and the communication ports, which, along the intake of the Pneumatic Control Module, constitutes the rear panel. In addition, the Rear Panel features an Equipotential Pin, according to the DIN 42801 standard. This Equipotential Pin is intended to the connection of a potential equalization conductor, which connects the equipment to the potential equalization conductor bus of the electrical installation (when available). The equipotential pin is provided along the iX5 ventilator in anticipation of potential applications comprising the use of other devices connected to one of the communication interfaces located on the Rear Panel.

Supply Sources

Power Supply

The iX5 ventilator is capable of working by means of three different types of power supply sources:

- AC Mains Power Supply
- Internal Battery
- External Battery

AC Mains Power Supply
Voltage: 100 – 240V (Full Range power supply – automatic switching)
Frequency: 50 / 60 Hz
Consumption: less than 130VA
Fuse: Time Lag T, L, 250VAC, 2.0A, IEC 60127-2/3

Internal Battery
PN: UP1290

Battery type: Valve Regulated Sealed Lead Acid Rechargeable Battery (leak proof)
Voltage: 12V
Charge capacity: 9.0 Ah
Autonomy: up to 3 hours (see Chapter 3, section Connection to Power Source)

External Battery

PN: UP12120 (or similar)

Battery Type: Valve Regulated Sealed Lead Acid Rechargeable Battery (leak proof)

Voltage: 12V

Charge Capacity: 12.0 Ah

Autonomy: Up to 5 hours
Fuse (PCB Mother-F3): Time Lag T, 125VAC/VDC, 4.0A, UL 248-14

Internal Fuses

Board	Fuse ID	Specification
Mother	F1	Time Lag T, 125VAC/VDC, 2.0A, UL 248-14
Mother	F2, F3, F4, F5	Time Lag T, 125VAC/VDC, 4.0A, UL 248-14
Transducer	F2	Time Lag T, 125VAC/VDC, 250mA, UL 248-14
Transducer	F3	Time Lag T, 125VAC/VDC, 375mA, UL 248-14

Pneumatic Supply

Intake gases: oxygen and compressed air (in accordance with ISO 7396-1)
Connection standard: NIST or DISS (gas input connector for Brazil is in accordance with NBR 12188 / NBR 11906)
Pressure range: 250 – 600 kPa (2.5 – 6.0 kg/cm^2)
Input flow(10s average) for each gas: 60 lpm at 280 kPa
Transient: less than 200 lpm for ≥ 3 (three) s

Intrinsic gas consumption: = 4 lpm (on standby mode)

NOTE
The volumes and flows of the intake gases are expressed at STPD (Standard Pressure Temperature Dry). The volume and flow supplied to the patient is corrected to compensate the fixed compliance of the respiratory circuit, the gas composition (FiO$_2$ and humidity), and the body temperature (BTPS).

Physical Features

Weight

Ventilator: 12 kg
Ventilator including Patient Circuit: 13 kg
Stand: 12 kg
Circuit Support Arm: 1 kg

Dimensions

Height: 300 mm
Width: 290 mm
Depth: 400 mm
Stand Height: 1110 mm

Stand

Finishing: Anti-corrosive epoxy paintwork
Casters: Four casters, four of them with locks
Weight: 12 kg
Height: 1110 mm

Chapter 2   Safety Warnings

Introduction

Please review the following safety information prior to operating the ventilator. Attempting to operate the ventilator without fully understanding its features and functions may result in unsafe operating conditions.

Be sure to read the Warning and Caution statements that appear throughout this document. These statements are defined in the following examples. In addition to the warnings and cautions, Note statements are provided where appropriate.

⚠️ *WARNING*

Warnings identify conditions or practices that could result in serious adverse reactions or potential safety hazards.

⚠️ *CAUTION*

Cautions identify conditions or practices that could result in damage to the ventilator or other equipment.

NOTE

Notes provide additional information to clarify an explanation or instruction.

Warnings

⚠️ *WARNING*

The following information indicates conditions that may result in safety risks to the patient and/or operator.

Operator's Responsibilities

- Before using the **iX5** ventilator with patients, it is essential to fully read and understand this manual. Using this equipment before fully understanding its features and functions may result in risk condition both for patient and operator, and for the equipment itself.

- After the initial reading, keep this manual in an accessible location for future consultation.

- The equipment should be used in accordance to this manual. For additional information, please contact Vyaire Customer Service.

- This equipment must be handled and operated only by qualified professionals.

- A qualified professional must be readily available whenever this equipment is being used in order to take the necessary actions should there be an alarm or any other event.

- Never operate this equipment before setting up its alarms. An alarm indicates the occurrence of a situation that requires the operator's attention and should never be ignored.

- Always keep an alternative means of ventilation (e.g. manual resuscitator) when this equipment is being used. In case of ventilator failure the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT death.

- Before using the equipment, always perform the IVT – Initial Verification Test, as described under *Section 10, Preventive Maintenance* of this manual.

- Never use this equipment in the presence of flammable anesthetic gases. This situation poses a risk of explosion.

- Do not use the ventilator in a hyperbaric chamber.

- Ensure the compatibility of the ventilator and all of the parts used to connect to the patient before use.

- The gas inlet of the ventilator must be used with Air and Oxygen only. Do not use xenon, helium, nitric oxide and anesthetic agents or other mixtures with the ventilator. Examples of anesthetic gases are: Nitrous oxide, Halothane, Enflurane, Isoflurane, Sevoflurane, and Desflurane nitric oxide.

- The ventilator accuracy can be affected by the gas added by use of a nebulizer.

- The patient's actual exhaled volume may differ from the exhaled volume reported by the ventilator when using non-invasive ventilation (NIV) due to leaks around the mask.

- Do not modify this ventilator without Vyaire's authorization. If this ventilator is modified, appropriate inspection and testing must be conducted to ensure its continued safe use.

- The assembly of the ventilator system and modifications during its service life require evaluation to ensure the requirements of IEC 60601-1:2005 + AMD1:2012 are met.

Maintenance

- This ventilator is life support equipment. Do not entrust its maintenance to unauthorized personnel. In case of problems or difficulties, please contact Vyaire or a Vyaire Authorized Technician.

- Do not use the equipment if it is not working within the specifications contained in this manual. In this case, interrupt its use and contact Vyaire or a Vyaire Authorized Technician.

- In order to ensure electrical protection and avoid the risk of fire, never replace the power cord or internal components (e.g. batteries or fuses) of this equipment. The improper replacement of the fuse voids the warranty and poses a risk to the operation of the equipment and to the safety of the operator and the patient.

- Lack of maintenance or maintenance performed by a non-accredited company will grant the product the status of tampered product, and this will subject those responsible to the sanctions provided by law. The change of basic equipment components will constitute the non-observance of the guidelines contained in this Operator's manual and it may affect the basic safety and essential performance of the equipment, including in relation to electromagnetic disturbances.

- The equipment shall not receive maintenance during operation. Performing maintenance during operation, including cleaning, may result in patient injury.

- Circuit diagrams, component part lists, descriptions and calibration instructions used to assist qualified personnel to repair the ventilator are in the iX5 Service Manual. Contact a Vyaire Authorized Technician for service assistance.

Accessories

- The complete list of parts, pieces and the recommended accessories are defined in chapter 11.

- Always use original Vyaire parts, pieces and the recommended accessories, in order to ensure the correct performance of this equipment and the validity of the warranty. In addition, this measure is also intended for the patient's and operator's safety.

- The use of non-original parts, pieces and the recommended accessories poses risk to the users, and does not meet the provisions of ANVISA and other local regulations, and the instructions contained in this Operator's manual. Incompatible parts, pieces and accessories can result in degraded performance.

- When using other equipment along this ventilator (e.g. heated humidifier), check the instructions provided with them.

- When accessories or other components are added to the breathing circuit, system inspiratory resistance and expiratory resistance will be increased. The operator must ensure that they do not exceed the following values (measurements performed at the patient connection during spontaneous respiration and normal equipment operation):

  Tidal Volume ≤ 50 ml (neonatal use)   6 cmH2O for 2,5 lpm

  50 ml ≤ Tidal Volume ≤ 300 ml (pediatric use)   6 cmH2O for 15 lpm

  Tidal Volume ≥ 300 ml (adult use)   6 cmH2O for 30 lpm

- All components of this ventilator and proprietary accessories are totally latex-free and comply with the biocompatibility standards, meeting the cytotoxicity, irritation and sensitivity requirements. The information of non proprietary accessories, are under responsibility of each corresponding manufacturer.

- Do not reuse single-use accessories. Reuse of single use accessories may cause inaccurate monitoring, alarms, and infection risk to the patient. Risks associated with reuse of single-patient use items include but are not limited to microbial cross-contamination, leaks, loss of part integrity, and increased pressure drop.

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

Cleaning, Disinfection and Sterilization

- Disinfection is a process capable of destroying pathogenic microorganisms, but it is not capable of destroying spores. Spores are only destroyed by means of the sterilization process.Before the first use, clean and sterilize the components of the breathing circuit, following the instructions shown under the *Section 9, Cleaning, Disinfection and Sterilization* of this manual. The frequency of exchange and sterilization of these circuits is defined by the protocols observed in each hospital.

- For sterile single use recommended accessories, verify the integrity of the package. In case of damage, follow the manufacturer's instructions for re-sterilization or discard.

- After sterilizing, rinse and dry properly the components of the breathing circuit in order to remove any chemical residue from them. Especially after the ethylene oxide sterilization, wait 24 to 48 hours before using the material again in order to ensure the aeration and the total removal of any residue this gas.

- Ensure the proper cleaning of the flow sensors, eliminating eventual solid residues deposited in its measurement ducts. The presence of such residues may affect the accuracy of such sensors.

- Do not reuse any component that is damaged or that is showing signs of wear.

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Pneumatic Supply

- Use only medical grade gases (dry and contaminant-free) in order to avoid internal damages to the equipment and risks to the patient.

- Intake gases – compressed air and oxygen – must be in accordance with the standards ISO 7396-1:2007.

- This ventilator is a high flow device and should only be connected to a pipeline installation that allows for the indicated flow at the terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimising the risk that the ventilator interferes with the operation of adjacent equipment

Batteries

- In case the **Low Internal Battery** alarm is activated, immediately connect the equipment to the power mains or to an external battery.

Discard

- All replaced parts and pieces must be discarded as set forth by the local legislation where the equipment is installed at the end of their expected service life.

- Discard all damaged parts removed from the ventilator during the maintenance procedures according to your institution's protocol.

- Sterilize contaminated parts before non-destructive disposal.

- Special attention should be given when discarding the internal lead-acid type battery, which must follow its manufacturer's instructions, described on the component's body.

- The same attention should be given when discarding the printed circuit boards and other electronic components, which must not be discarded as normal waste, since they can be hazardous to the environment.

Electric Safety

- To avoid the risk of electric shock, this equipment must only be connected to an AC Mains Power Supply with protective earth.

- In case of doubts about the mains grounding system integrity, run the equipment using its internal battery or an external battery.

- Never cut the ground pin in the equipment plug.

- Never use adaptors when connecting the equipment to the AC Mains Power Supply, always plug it directly into the mains outlet.

- Never use anti-static or electrically conductive hoses or tubes in the patient circuit.

- Never disassemble the ventilator cabinet. This situation poses a risk of electric shock.

- Never touch at same time the patient and either the rear panel (data communication ports and external battery connector) or non-medical electrical equipment and the patient. This may cause an unsafe electrical shock to the patient.

Electromagnetic Compatibility

- The use of this equipment requires special precautions regarding its electromagnetic compatibility.

- This equipment, when exposed to situations that are adverse to its specification, can generate or suffer electromagnetic interference.

- In the situation where essential performance is lost or degraded due to EM disturbances, the ventilator will activate the appropriate protection mechanisms (i.e. audible alarm, visual alarm, safety valve opening) going to a safe state and thus protecting the patient's integrity.

- In order to prevent harmful interferences, it is necessary:
  - To observe the distances between this equipment and other possible EMI (Electromagnetic Interference) emitters.
  - Only connect this equipment to a power outlet with protective grounding.
  - Never cut the grounding pin from the equipment's power cord plug.

- Use restrictions:
  - Radiofrequency equipment – mobile or portable – can interfere in the operation and performance of this ventilator.
  - Do not use this equipment in a magnetic resonance environment or close to high frequency surgical equipment or short wave therapy equipment.
  - The unauthorized modification of any element or component whose operation can be affected by electromagnetic fields voids the warranty of this product and may produce adverse results to its operation.
  - Use of other electrical equipment adjacent to or stacked with the ventilator may cause interference. If adjacent or stacked use is necessary, the ventilator should be observed to verify normal operation in the configuration in which it will be used.
  - The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). The ventilator is suitable for use in institutional and intra-hospital transport settings. It is not intended for use as an emergency medical transport ventilator or homecare applications.

Cautions

> ⚠ *CAUTION*
> The following information indicates conditions that may **affect** or **damage** the
> **equipment** and/or its **accessories**.

Installation

- The initial assembly of this equipment must be done only by Vyaire or by a Vyaire
  Authorized Technician. When in operation, never cover or position this equipment in such a
  way that its cooling air intake or outlet is blocked. This intake is located on the frontal lower
  portion of the equipment and remains unblocked when the equipment is properly mounted
  on its Stand. The outlet is located on the rear panel of the equipment, where there is a
  warning: 🚫 **– Do not obstruct.**

- Never operate this equipment when it is directly exposed to heat and sunlight.

- After positioning the equipment for operation, lock the Stand casters, in order to prevent it
  from moving inadvertently.

- The transportation of the ventilator can be done when it is mounted on the Stand.

Maintenance

- This equipment features safety seals on the closing bolts. If these seals are broken by
  unauthorized personnel, warranty will be voided.

- The use of non-original parts, pieces and recommended accessories poses a risk to the
  users, and does not meet the provisions of ANVISA and other local regulations and the
  instructions contained in this Operator's manual.

- In order to prevent premature wear of the equipment and to ensure the safe performance
  and within the required specifications, the following must be performed:

  IVT – Initial Verification Test

  This test checks the general condition of the equipment, as well as the aspects of
  cleanliness, assembly, and connections to the power and gas supply sources.

  It is recommended that it be performed daily or before each use, according to the
  instructions mentioned under *Section 10, Preventive Maintenance*.

  RI – Routine Inspection

  This inspection performs routine verification of the ventilation system during its use.

  It is recommended that it be performed several times a day or as required by your
  institution's policy, according to the instructions mentioned under Section 10, Preventive
  Mintenance.

  FVT – Functional Verification Test

  This test verifies the equipment's operation, including alarm and monitoring features. It is
  performed by simulating failure situations, using a lung simulator.

  It is recommended that it be performed before using the equipment with a patient or when
  there are doubts about the equipment's operation, according to the instructions mentioned
  under *Section 10, Preventive Maintenance*.

BPT – Battery Performance Test

It performs the verification of the status of the internal battery and the external battery (optional).

It is recommended that it be performed every 6 months to make sure batteries capacity is at least at the minimum level recommended, according to the instructions mentioned under Section 10, Preventive Mintenance.

APM – Annual Preventive Maintenance

It consists of the verification and eventual adjustment of the ventilator functions, as well as the replacement of parts that are worn or deteriorated due to their use, in order to extend the durability of the equipment and ensure its safe operation within the original specifications and the applicable normative requirements.

The yearly performance of APM is recommended, and it must be performed only by Vyaire or by a Vyaire Authorized Technician.

Cleaning, Disinfection and Sterilization

- Do not sterilize the equipment. Its internal components are not compatible with sterilization techniques.

- Do not submerge the equipment into liquid solution or allow liquids to enter into its internal part.

- Do not use abrasive materials on the ventilator's surface, especially on its screen. It is recommended to clean the screen with a 70% Isopropyl Alcohol-moist gauze.

- Do not use the following solutions for cleaning and/or disinfecting the components of the iX5 ventilator original breathing circuit; they can accelerate the degradation of the materials, causing the plastic components to crack or disintegrating the silicone tubes.

  - Phenol (> 5%)

  - Chlorinated Hydrocarbons

  - Ketones

  - Aromatic Hydrocarbons

  - Formaldehyde

  - Inorganic Acids

  - Hypochlorite

  - Quaternary Ammonium Compounds

- Components subjected to sterilization experience a natural degradation due to the characteristics of the processes employed. Vyaire define a maximum of 50 cleaning/sterilization cycles for the parts subjected to sterilization (see table 9-1).

- The accessory lifetime will depend on the care given while using and handling it.

Pneumatic Supply

- At each gas intake there is a coalescent filter capable of retaining solid particles up to 0.3 µm and liquid aerosols up to 0.75 µm that are suspended in the gaseous mixture. These filters must be periodically inspected. Whenever required, drain the water condensed in the collection cup in order to prevent it from entering into the equipment, compromising its operation. At the compressed air intake, apart the coalescent filter, there is a pre-filter, which can be seen on the ventilator's left-hand side. Should accumulated liquid be noticed

in the collection cup, perform the drainage by opening the pin located at the bottom of the cup.

- Pneumatic supply sources (oxygen and compressed air) must always be at a pressure between 250 and 600 kPa, and they must be capable of providing a flow of 60 lpm at 280 kPa. The transient will not exceed 200 lpm for ≥ 3 (three) s.

- Gas cross flow from one high pressure input port of one type of gas to another high pressure input port of a different gas will not exceed 100 mL/h under normal or single fault conditions.

Batteries

- Always use an External Battery in accordance with the specifications mentioned under *Section 1, General Specifications,* of this manual.

- For maximum battery autonomy, connect the equipment to the AC Mains Power Supply at least for 15 ininterrupted hours and up to 48 hours prior to use. After this period (48 hours), it is possible that a drop in the battery power level occurs depending on the battery's status of use.

- The battery service life depends on the ventilator's use conditions (frequency and duration of ventilator and/or internal battery use, environmental conditions of temperature and humidity, etc.); therefore its condition must be periodically checked.

- The storage the ventilator without recharging the battery for periods longer than two months may reduce the battery service life.

⚠ *CAUTION*

All parts and pieces replaced must be discarded as set forth by the local legislation where the equipment is installed.

Special attention must be given to the disposal of the internal lead-acid type battery, which must follow its manufacturer's guidelines, described on the component's body.

⚠ *CAUTION*

The iX5 ventilator does not charge its internal battery when connected to an External Battery.

For maximum battery autonomy, connect the equipment to the AC Mains Power Supply at least for 15 ininterrupted hours and up to 48 hours prior to use. After this period (48 hours), it is possible that a drop in the battery power level occurs depending on the battery's status of use.

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Chapter 3   Equipment Setup

The iX5 ventilator is a servo-controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for neonatal through adult patients. Its revolutionary user interface provides maximum flexibility with simple operator interaction. It has a flat panel color LCD with real-time graphic displays and digital monitoring capabilities, a touch screen for easy interaction, front panel buttons, and a dial for changing settings and operating parameters.

The iX5 ventilator is easy to clean and its design does not allow liquids to pool on the casing, reducing the likelihood of fluid leakage into the body of the ventilator.

Introduction

Setting Up the Rear of the Ventilator
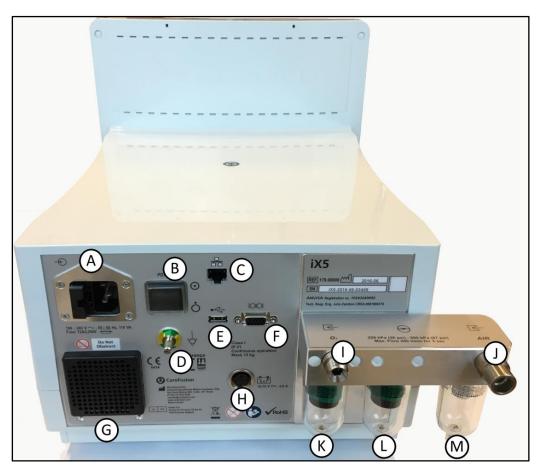
Figure 3-1. Rear Panel

A	AC Mains Power Supply connector		H	External Battery connector
B	Power ON/OFF switch		I	Oxygen hose connection
C	IT Network/Ethernet connector		J	Air hose connection
D	Equipotential pin		K	Oxygen primary intake filter
E	USB connector		L	Air primary intake filter
F	RS232 connector		M	Air secondary intake filter
G	Fan inlet			

> ⚠️ **WARNING**
> Do not connect any device different than those specified in the *Chapter 13 Data Communication Ports.*

Installation

The initial assembly of the equipment must be performed only by Vyaire or by Vyaire Authorized Technicians.

Positioning

Do not operate this equipment when it is directly exposed to heat and sunlight.

When in operation, do not cover or position this equipment in such a way that its cooling air intake or outlet is blocked. This intake is located on the frontal lower portion of the equipment and remains unblocked when the equipment is properly mounted on its Stand. The outlet is

located on the equipment's rear panel, where there is the warning: 🚫 – Do not obstruct.

Figure 3-2. Rear panel detail—Ventilation Output

To ensure proper operation, ensure that the power outlet used for the ventilator is easily accessible; disconnecting the power cord from the outlet is the only way to completely isolate the equipment from the supply mains. Do not position the ventilator in a way that makes it difficult to access the AC power cord.

After positioning the equipment for operation, lock the Stand casters, in order to prevent it from moving inadvertently.

To move the equipment make sure that it is in transport position: the circuit support arm is totally retracted and the Stand casters are unlocked.

> *NOTE*
> When using the circuit support arm make sure it only supports the pacient circuit. It shall not be used to support other accessories or devices.
>
> During transport never pull the ventilator by the circuit support arm.

> When using the pacient circuit with water traps, properly position it in the circuit support arm in order to have the water traps in the lowest level.
>
> Do not stretch the arm more than 80 cm from its assembling point.

> *NOTE*
> For optimal awareness of an alarm state, the ideal operator position is one meter in front of the iX5 screen at an angle subtended by 30 degrees from the screen midpoint horizontal and normal to the screen plane.

> *NOTE*
> When using the compressor, position the compressor so that none of the air vents are blocked. Good air ventilation prevents overheating.

Accessories

When using other equipment with this ventilator (e.g. heated humidifier and CO_2 monitoring equipment), ensure they comply with applicable standards and follow the instructions provided with them.

> *NOTE*
> All parts of the ventilator are suitable for use within the patient environment.

Environment Specifications

Room Temperature
Operation: +5 to +40°C
Transportation and Storage: -20 to +70°C

> ⚠ *CAUTION*
> The storage the ventilator without recharging the battery for periods longer than two months may reduce the battery service life.

Relative Humidity
Operation: 15 to 95% – without condensation
Transportation and Storage: 10 to 95% – without condensation

Atmospheric Pressure
Operation: 70 to 106 kPa (0.7 to 1.0 atm)
Transportation and Storage: 50 to 106 kPa (0.5 to 1.0 atm)

Connection to the Power Source

The iX5 ventilator is capable of working by means of three different types of power sources:

- AC Mains Power Supply
- Internal Battery
- External Battery

AC Mains Power Supply

Connect the equipment plug to a power mains outlet according to the specifications mentioned under *Section 1, General Specifications,* of this manual.

This equipment can be connected to AC Mains Power Supply ranging from 100V to 240V. The operator does not have to activate any voltage switching button.

> ⚠️ *WARNING*
>
> Always use AC Mains Power Supply with grounding pin connections. In case of doubts about the integrity of the power mains grounding system, run the equipment using its internal battery or an external battery.
>
> Never cut the grounding pin from the equipment plug, nor use adaptors when connecting the equipment to the AC Mains Power Supply. Always plug it directly into the power.

Internal Battery

The iX5 ventilator has an internal battery that enables its operation even when it is not connected to an external power source.

If the external power source (AC or External Battery) connected to the ventilator disconnects or fails, the ventilator will automatically switch to the internal battery, keeping all functionalities active.

The iX5 ventilator automatically charges its internal battery whenever it is connected to an AC Mains Power Supply.

External Battery

This alternative power supply is intended to provide an extended autonomy to the internal battery of the ventilator. It must be connected to a battery pack in accordance with the specified voltage and current.

In order to use the equipment connected to an external battery, use the battery and the optional power cord listed under *Section 11, Accessories, Parts, and Pieces*.

One end of this cord shall be connected to the equipment rear panel, on the input port with the

indication [EXT] , while the other end must be connected to the external battery according to the specifications mentioned under *Section 1, General Specifications,* of this manual.

When the AC Mains Power Supply fails, the ventilator will activate the visual and audible alarm "AC Line Fail" (Medium Priority) and the "Internal Battery" indicator lights up continuous yellow. To avoid undesirable noise, press twice the "Audio Pause / Alarm Reset" button and the alarm changes to visual and audible alarm "Battery in Use" (Low Priority).

An external battery can be connected to increase the operation autonomy up to 8 hours. If connected, the "Ext Batt" indicator light up continuous green.

The Ventilator will consume charge from the both batteries, internal and external (if connected),

The "Low Internal Battery" alarm (Medium Priority) will be activated when battery is near depletion, approximately 15 minutes of operation.

The Low Internal Battery alarm evolves to High Priority at least 5 min prior to the loss of all power.

Note: The Vent Inop alarm may be activated as the remaining power is not enough to sustain ventilation.

Once the AC Mains Power Supply is restored, the ventilator will recharge the internal battery. During the recharge time, the "Int Batt Level" indicator (LED) changes its color to inform the current battery level:

- Flashing Red: Charge below 30% of total capacity
- Continuous Orange: Charge between 80% and 30% of total capacity
- Continuous Green: Charge above 80% of total capacity

The recharge time is 15 hours to make sure the internal battery is fully charged.

When the internal battery is fully charged, the "Int Batt" visual indicator (LED) turns off.

The iX5 Ventilator does not recharge the external battery.

The Ventilator can operate on battery power:

Up to 3 hours when the internal battery is new and fully charged.

A minimum 90 minutes when the battery is maintained in accordance to the battery performance procedure. See "Testing Battery Performance".

Whether both batteries are present (Internal and External) the operating time is up to 8 hours when the batteries are new and fully charged.

Actual operating time on battery power depends on the ventilator settings, battery age, and level of battery charge. The battery capacity time is approximate. To maximize battery life, maintain a full charge and minimize the number of discharges. When the ventilator is on battery power, the battery icon appears at the top right of the screen.

> ⚠ *CAUTION*
>
> The iX5 ventilator does not charge its internal battery when connected to the External Battery.
>
> For maximum battery autonomy, connect the equipment to the AC Mains Power Supply at least for 15 ininterrupted hours and up to 48 hours prior to use. After this period (48 hours), it is possible that a drop in the battery power level occurs depending on the battery's status of use.

> ⚠ *WARNING*
>
> Do a battery test each 6 months to make sure battery capacity is at least 90 minutes. Replace the battery when necessary.

> ⚠ *WARNING*
>
> The iX5 ventilator does not charge the external battery. Always make sure to connect a fully charged external battery prior to use.
>
> As the batteries age with use, the time the ventilator will operate on battery power from a fully charged battery will decrease. Perform the battery test each 6 months according to Chapter 10 – "Battery Performance Test" section and provide the replacement if battery operation time is insufficient for your usage..

⚠️ *WARNING*

In case the Low Internal Battery alarm is activated, immediately connect the equipment to the AC Mains Power Supply or to an external battery. Otherwise, the ventilator will generate a Vent Inop alarm and will be led to an inoperative condition.

Check *Section 6, Alarms and Messages*, in this manual for more information about the internal battery charge status indications.

⚠️ *CAUTION*

The battery service life depends on the ventilator's use conditions (frequency and duration of ventilator and/or internal battery use, temperature and humidity room conditions, etc.).

The storage the ventilator without recharging the battery for periods longer than two months may reduce the battery service life.

Connection to the Gas Pipeline

Connect the compressed air and oxygen hoses supplied with the equipment to their corresponding inputs, located on the ventilator's rear panel. Connect the other end of each of these hoses to the corresponding gas source output.

Figure 3-3. Connection of the air and oxygen hoses

> ⚠ *WARNING*
> Use only medical grade gases (dry and contaminant-free) in order to avoid internal damages to the equipment and risks to the patient.

The equipment features internal regulating valves that ensure its operation under pressures ranging from 250 kPa (2.5 kg/cm^2) and 600 kPa (6.0 kg/cm^2). The optimum pressure range is between 300 kPa (3.0 kg/cm^2) and 500 kPa (5.0 kg/cm^2). Confirm if the gas sources are kept within this pressure range during the entire time the equipment is being used, and use external pressure regulating valves when required.

If necessary, it is possible to use the **iX5 ventilator** with only one supply gas. In this case, it will not be possible to adjust the oxygen concentration (FiO$_2$). If the equipment is connected solely to a compressed air source, the ventilation provided will only be 21% oxygen; if it is connected to an oxygen-only source, then the ventilation provided will be 100% oxygen.

> ⚠ *CAUTION*
> At each gas intake there is a coalescent filter capable of retaining solid particles up to 0.3 μm and liquid aerosols up to 0.75 μm that are suspended in the gaseous mixture. These filters must be periodically inspected. Whenever required, drain the water condensed in the collection cup in order to prevent it from entering into the equipment, compromising its operation. At the compressed air intake, apart from the coalescent filter, there is a pre-filter, which can be seen on the ventilator left-hand side. Should accumulated liquid be noticed in the collection cup, perform the drainage by opening the pin located on the bottom of the cup.
>
> Upon turning the equipment off, disconnect it from the oxygen source in order to reduce the risk of accumulating this gas inside it in case of eventual leaks.
>
> Pneumatic supply sources (oxygen and compressed air) shall be capable of supplying a flow up to 60 lpm at 280 kPa.

Figure 3-4. Gas intake filters

Breathing circuit assembly

Always use original parts, pieces and recommended accessories, in order to ensure the correct performance of this equipment and the validity of the warranty. In addition to that, this measure is also intended for the patient's and operator's safety.

All components of this ventilator and its original accessories are latex-free and comply with the biocompatibility standards, meeting the cytotoxicity, irritation and sensitivity requirements.

⚠️ *WARNING*

Before the first use, clean and sterilize the components of the breathing circuit, following the instructions shown in *Section 9, Cleaning, Disinfection, and Sterilization,* of this manual. The frequency of exchange and sterilization of these circuits is defined by the protocols observed in each hospital.

When accessories or other components are added to the breathing circuit, system inspiratory resistance and expiratory resistance will be increased. The operator must ensure that they do not exceed the following values (measurements performed at the patient connection during spontaneous respiration and normal operation of the equipment):

Tidal Volume ≤ 50 ml	6 cmH$_2$O for 2.5 lpm
50 ml ≤ Tidal Volume ≤ 300 ml	6 cmH$_2$O for 15 lpm
Tidal Volume ≥ 300 ml	6 cmH$_2$O for 30 lpm

⚠️ *WARNING*

All parts of the breathing circuit assembly are subjected to the patient's gas. Therefore, those parts shall be properly discarded, if single-use, or sterilized, according to *Chapter 9, Cleaning, Disinfection and Sterilization* or instructions for use of third-party recommended accessories.

To avoid contamination of the ventilator's manifold with body fluids or expired gases, always use an Inspiratory filter connected to the Gas Output port. In case of contamination, internal components shall be replaced.

Selection of the Patient Breathing Circuit and Flow Sensor

Select the breathing circuit and the flow sensor based on the patient's weight.

Ideal Body Weight (IBW)	Patient Category	Breathing Circuit	Flow Sensor
From 300 g to 3000 g	Neonatal	Neonatal/Pediatric	Neonatal Proximal
From 3.1 kg to 30 kg	Pediatric	Neonatal/Pediatric	Pediatric Proximal
More than 30 kg	Adult	Pediatric/Adult	Expiratory

⚠ *CAUTION*
In the case where humidification filter is used, it should be assembled between the proximal flow sensor and the patient connection in order to protect the sensor against exhalation-generated condensation.

NOTE
To avoid the risk of inacurate measures, always use the neonatal proximal flow sensor for intended volumes equal or below 50 ml.

NOTE
If a flow sensor is not compatible with the selected patient weight (IBW), a medium priority alarm (Wrong Flow Sensor) will be activated. In this case, the operator must initially check whether the weight selected on the IBW control is correct; if it is, the sensor must be replaced.

NOTE
Make sure that the flow sensors are properly cleaned; eliminate residues deposited in the measurement ducts. The presence of residue may affect the accuracy of these sensors.

NOTE
Upon acknowledging the flow sensor and periodically (every 5 minutes), the iX5 ventilator performs a flow sensor Autozero process. This process is meant to both eliminate the condensation found on the two ways of the sensor measurement pipe and reset the flow zero point, in order to ensure the monitoring accuracy.

NOTE
The volume and flow supplied to the patient is corrected to compensate the compliance of the respiratory circuit (as calculated during accessory self-check function), the gas composition (FiO_2 and humidity), and the body temperature (BTPS). All other gas volumes and flows measurements are expressed at STPD (Standard Pressure Temperature Dry).

Exhalation Valve Connection

In order to ensure that the diaphragm and exhalation valve have been assembled correctly, proceed according to the orientation label attached on the equipment's side panel.

- Turn the ventilator off or press the **Standby Mode** button.

- Carefully position the diaphragm on the exhalation port, located on the equipment's side panel. Check to ensure that the embossed part of the diaphragm is facing outwards.

- Insert the exhalation valve perpendicularly, following the fitting position. Turn it slightly to the right, until locking it.

- To disassemble the exhalation valve, press the button with the instruction *Push to Unlock* and turn the valve body to the left.
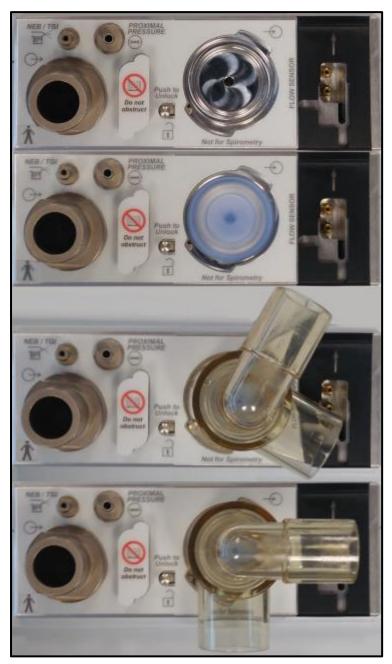
Figure 3-5. Exhalation valve assembling sequence.

⚠ *WARNING*
Handle the diaphragms carefully. Before assembling them, check whether they are intact, without any tears or punctures.

⚠️ *WARNING*

Do not use the exhalation valve exhaust port for spirometry or to gauge the equipment. Due to the bias flow of the ventilator, the gas exhaust volume is greater than the actual tidal volume exhaled by the patient.

Patient Circuit Assembly

Assemble the selected patient breathing circuit and connectors according to the instructions provided with them. Then connect each part to the ventilator.

Connect the Inspiratory filter to the Gas Output port, then connect the inspiratory limb of the breathing circuit to the Inspiratory filter output.

Connect the expiratory limb of the breathing circuit to the exalation valve connector.

Connect the proximal pressure line of the breathing circuit to the Proximal Pressure port at the ventilator.
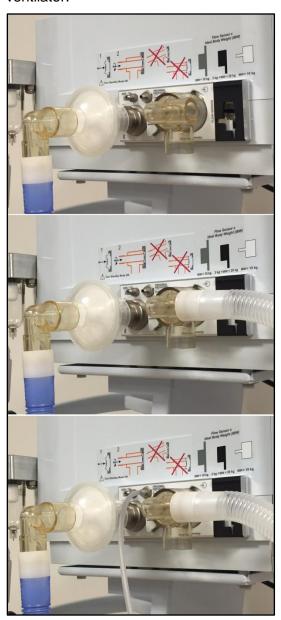
Figure 3-6. Side panel connections: inspiratory limb, expiratory limb and proximal pressure line

Connecting the Humidifier

The ventilator is designed to work with active humidification (refer to the humidifier instructions for detailed information on humidifier connections and use).

Fit the humidifier heater on the front rail of the ventilator's stand.

Connect the provided elbow to the Inspiratory filter attached to the Gas Output port.

Connect a tube between the elbow and the chamber's input.

Connect the Inspiratory limb of the breathing circuit to the chamber's output.

> ⚠️ *WARNING*
> To avoid contamination of the ventilator's manifold with body fluids or expired gases, always use an Inspiratory filter connected to the Gas Output port. In case of contamination, internal components shall be replaced.

> ⚠️ *WARNING*
> Do not use anti-static or electrically conductive tubes along the pacient circuit of this ventilator.

> ⚠️ *WARNING*
> When assembling the proximal pressure line, make sure that there is no type of resistance or obstruction along its length.

> ⚠️ *WARNING*
> When assembling the circuit on the ventilator, make sure that there is no obstruction on the opening of the side panel with the indication Warning: 🚫 - Do not obstruct. This is the safety valve intake, which opens when the equipment is not operating (Vent Inop alarm), allowing the patient to breath spontaneously.
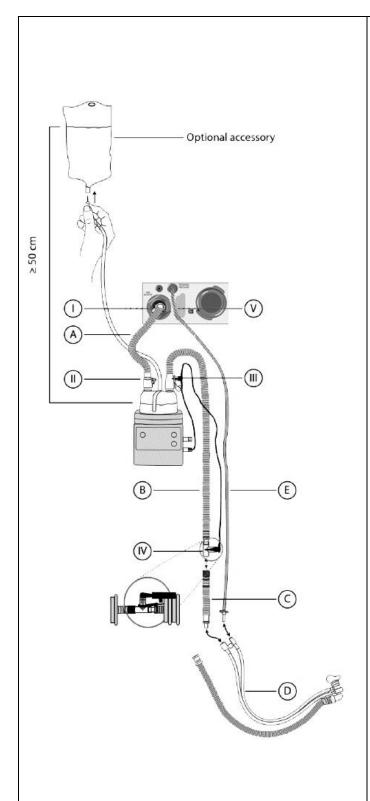
Figure 3-7. Side panel detail – safety valve intake.

IF LP Generator Assembly

For assembling the IF LP generator breathing system, follow the steps below:

Optional accessory

≥ 50 cm

1. Gather the nCPAP supplies:
• Single-limb, heated breathing circuit
• IF LP Generator kit
• Fixation device
• Humidifier and chamber
• Sterile water supply (optional)
NOTE: Discard the extra bag of adapters found in the circuit package.

2. Attach the water chamber to the humidifier, and connect it to the water feed system (if being used). Follow the manufacturer instructions for the proper set-up.

3. Connect the gas delivery tubing (A) to the gas output port on the ventilator (I) and the humidifier chamber port (II).

4. Connect the elbow connector on the heated breathing circuit (B) to the humidifier chamber. Insert the heater wire plug into the wire socket. Securely insert the temperature probe into the port on the circuit elbow (III). Insert the second temperature probe (IV) into the airway port at the distal end of the breathing circuit.

5. Connect the non-heated section (C) to the drive line of the generator assembly (D).
NOTE: When an isolette warmer is being used, an extension tube may be used to extend the generator assembly (D). Connect the Infant Flow extension tube to the end of the Infant Flow generator exhaust tube.

6. Connect the proximal pressure line (E) to the proximal pressure port on the ventilator (V) and the pressure line on the generator.
NOTE: The recommended temperature for inspired gases is between 96.8ºF (36ºC) and 98.6ºF (37ºC), but never higher than 98.6ºF (37ºC).

Flow Sensor Connection

Proximal Flow Sensors

Assemble the flow sensor body on the wye piece, taking care so that the pressure intakes are always facing upward.

Connect the other end of the sensor to the equipment's side panel, observing the assembly sequence shown below:

Figure 3-8. Proximal flow sensors assembly

⚠ *WARNING*

When connecting the flow sensor, carefully observe the two pressure intake limbes. Make sure that the limb identified by a colored line along the duct is facing the wye piece. The other limb, with no identification along the duct, must be facing the patient connection.

⚠ *CAUTION*

In the case where a humidification filter is used, it shall be assembled between the proximal flow sensor and the patient connection in order to protect the sensor against exhalation-generated humidity.

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Expiratory Flow Sensor

Assemble the Expiratory Flow sensor on the exhalation valve.

Connect the other sensor end to the equipment side panel, as shown.
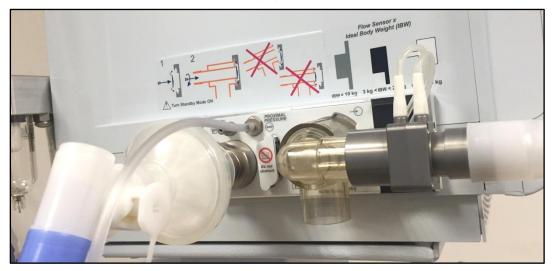
Figure 3-9. Expiratory flow sensor assembly

HME, Nebulization and TGI Connection

HME

When using an expiratory flow sensor, install an HME filter between the wye piece and the endotracheal tube.

When using a proximal flow sensor, install an HME filter between the flow sensor and the endotracheal tube.

Nebulization

Install a standard nebulizer on the inspiratory limb of the patient breathing circuit, connecting its end to the auxiliary output identified as **Nebulizer/TGI**, located on the equipment's side panel.

TGI

Assemble the NIV/TGI connector between the wye piece and the patient connection. Insert a catheter through the orifice of the connector plug into the ET tube. Place the catheter close to the carina, following the protocols recommended by the hospital.

Connect the other end of this catheter to the auxiliary output identified as **Nebulizer/TGI,** located on the equipment's side panel.

⚠️ *WARNING*

Do not use heated humidifier nor a nebulizer with HME. The combined use of one of these items can increase the resistance of HME.

Always monitor the filters for increased resistance or blockage.

> ⚠️ *WARNING*
> The use of expiratory filters may cause monitored tidal fluctuations. The volume and pressure alarms should be set at appropriate levels for the patient.
>
> Always monitor the filters for increased resistance or blockage.

> ⚠️ *CAUTION*
> When the NIV/TGI connector is being used to connect the breathing circuit to a non-invasive interface (mask), make sure to use the blind plug in order to prevent leaks.

Connecting the Patient to the Ventilator

Ensure that the breathing circuit and the additional items (e.g. HME, flow sensor, humidifier, etc.) are properly assembled. Using humidifier, check the water level.

Turn the equipment On according to the instructions in Chapter 4 Operation.

Verify the breathing circuit trhough the Accessory Self-Check function according to the instructions in Chapter 4 Operation.

Set the ventilation parameters and alarms according to the instructions in Chapter 4 Operation.

Connect the breathing circuit to the patient's airway interface.

Start ventilation.

Chapter 4   Operation

Turning the equipment On

Make sure all the gas connections, power cord and breathing circuit are properly assembled as indicated in the Chapter 3 Equipment Setup, also make sure that there is no patient connected to the ventilator.

Turn the On/Off switch located on the equipment's rear panel.

Autotest Routine

An autotest routine will be automatically initiated and if a failure is detected, the equipment will not start operating. When a failure that prevents the equipment from operating safely is detected, it will be indicated on the front panel, and the equipment will not start operating until the failure is resolved.
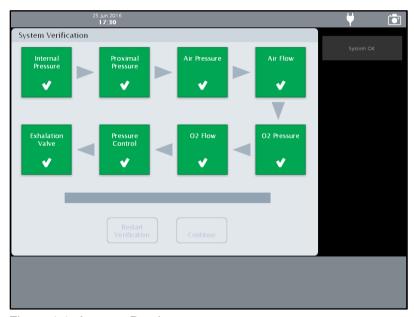
Figure 4-1. Autotest Routine

> **NOTE**
> When only one of the gas sources is being used, the autotest routine will indicate a failure to the inactive gas source, but it will not prevent the operation from starting. The operator will evaluate whether the situation represents a safe operational condition.

Patient Category Selection

After the autotest routine, the ventilator will automatically switch to the patient selection screen.

Since the **iX5 ventilator** is capable of storing all set parameters into memory even when it is turned off, it is possible to make the ventilator recover the last configuration by pressing the **Return to Last Patient** button.In the case of a new patient, it is possible to choose between **Neonatal, Pediatric,** and **Adult**.
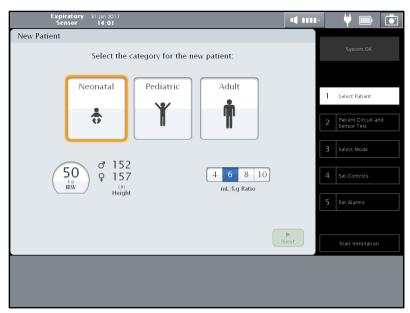
Figure 4-2. Patient Selection: Current or New

Scales	Neonatal patient	300 g ≤ **IBW** ≤ 3000 g
	Pediatric patient	3.1 kg ≤ **IBW** ≤ 30 kg
	Adult patient	**IBW** > 30 kg

The patient category is used by the ventilator to automatically adjust the control scale limits. When a ventilation mode change occurs, the ventilator will automatically assume safe values for critical parameters, based on the type of patient, waiting for readjustments and/or confirmation by the operator.

When the parameters are set above the limits typically used (Safe Limits), the ventilator will show an alert warning. However, if the operator so desires, they can accept the value outside the recommended range.

Accessory self-check function

The accessory self-check function measures the patient circuit's compliance and resistance, in order to provide optimized conditions to the patient's ventilation.

The user should start a "Patient Circuit and Flow Sensor Test" every time a New Patient is selected or if the patient circuit is changed.

⚠ *CAUTION*
Make sure the breathing circuit and the additional items (e.g. HME, flow sensor, humidifier, etc.) are properly assembled, as recommended in Chapter 3. Using humidifier, check the water level.

⚠ *WARNING*
Before proceeding, make sure that NO PATIENT is connected to the ventilator.

When choosing the "Start Test Now" button, the equipment will start the Patient Circuit and Flow Sensor Test function.
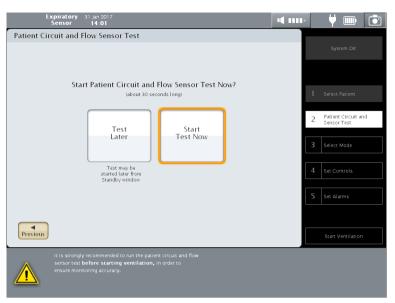
Figure 4-3. Start Test Now

Select the type of humidifying system that will be used for the patient circuit configuration.
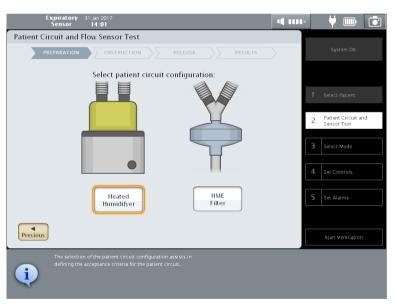
Figure 4-4. Type of Humidifying System Selection

Obstruct the circuit wye piece and press the Next button. Make sure there are no leaks through the patient breathing circuit.

Figure 4-5. Circuit Wye Piece Obstruction

Open circuit after the wye piece and press the *Next* button.
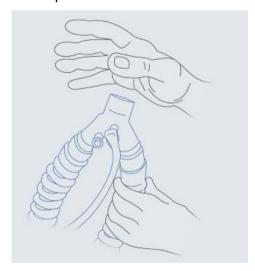
Figure 4-6. Open Circuit

Before running the test, the ventilator will show a message to indicate if the patient circuit and the flow sensor are ready for use.

If it is ready, select the *Proceed* button.

If the ventilator shows a message indicating that the patient circuit and/or the flow sensor are inappropriate for use or that the patient circuit can be usable with caution, the user can select the *Repeat Test* button in order to start the verification all over again.

Every time these messages come to the user, the *Help* button can be selected in order to provide additional information about **Possible Cause** and **Solution**.

⚠️ *WARNING*

When the Accessory Self Check function shows the messages "inappropriate for use" or "usable with caution", the user must know that if the *Proceed anyway* button is selected, patient ventilation may present inaccuracies.

NOTE
If the flow sensor test does not successfully passed or not executed, the VG mode will not be enabled.

Table 4-1. Ventilation System / Breathing Circuit Parameters

Parameter		Value
Inspiratory and Expiratory Resistance	Adult	0 to 6 cmH$_2$O @ 30 lpm
	Pediatric	0 to 6 cmH$_2$O @ 15lpm
	Neonatal	0 to 6 cmH$_2$O @ 2.5lpm
Circuit Compliance	Adult	0.5 to 7 mL/cmH$_2$O
	Pediatric	0.1 to 4 mL/cmH$_2$O
	Neonatal	0.1 to 4 mL/cmH$_2$O

Table 4-2. Dead Space of the Flow Sensors

Flow Sensor	Value	Tolerance
Neonatal Proximal	0.8 mL	5%
Pediatric Proximal	0.8 mL	5%
Expiratory	17.5 mL	5%

⚠ *WARNING*
Always disconnect the patient from the ventilator prior to running the function.

When changing any accessories in the patient circuit, run the function to ensure the circuit compliance and the resistance values are adequate.

A proper patient circuit is necessary to maintain the accuracy described in this manual.

Ventilation Mode Selection

After selecting the patient category, the ventilator switches to the ventilation mode selection screen. Select the intended ventilation mode for the patient, see section *Ventilation Modes*.

Controls Selection

After selecting the ventilation mode, the ventilator automatically switches to the ventilation controls selection screen. Set the intended vantilation parameters. See section *Ventilation Modes* in this chapter and *Basic Controls and Advanced Settings Characteristics and Ranges* in *Chapter 5*.

Alarm Selection

After selecting the control parameters, the ventilator automatically switches to the alarm limit selection screen. Set the alarms according to the intended patient ventilation. See *Adjustable Alarms* in *Chapter 6*.

Making changes

If changes are needed during ventilation follow the steps below:

Ventilation mode – press the Ventilation Summary Button.

Controls – use either the Ventilation Summary Button or Quick Access buttons (may vary according to the selected mode).

Alarms – press the Alarm button.

NOTE
To confirm the changes press Apply button. You can discard the changes by pressing the Cancel button.

⚠️ *WARNING*
Hospital institution is responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use.

Always use original Vyaire parts, pieces and recommended accessories, in order to ensure the correct performance of this equipment and the validity of the warranty. In addition, this measure is also intended for the patient's and operator's safety.

The use of non-original parts, pieces and recommended accessories poses risk to the users. Incompatible parts can result in degraded performance.

The accessories are defined in chapter 11.

Turning the equipment Off

Make sure that the patient is not connected to the ventilator. Otherwise, select Standby Mode and disconnect the patient from the breathing circuit.

Turn the On/Off switch located on the equipment's rear panel. After the shutdown, the ventilator will generate a continuous auditory signal to indicate that the ventilator is turned off. Press the Audio Pause/Alarm Reset button to finish the procedure.

Ventilation Modes

Introduction

The ventilation modes are organized into four groups: **Assisted/Controlled, SIMV, Spontaneous** and **Non-Invasive Modes**.

The **iX5 ventilator** offers the following ventilation modes:

Assisted-Controlled	VC – Volume Control	Adult / Pediatric
	PC – Pressure Control	Adult / Pediatric / Neonatal
	TCPL – Time Cycled Pressure Limited	Pediatric / Neonatal
	PRVC – Pressure Regulated Volume Control	Adult / Pediatric
	VG – Volume Guarantee	Neonatal
SIMV+PS	VC – Volume Control	Adult / Pediatric
	PC – Pressure Control	Adult / Pediatric / Neonatal
	TCPL – Time Cycled Pressure Limited	Pediatric / Neonatal
	PRVC – Pressure Regulated Volume Control	Adult / Pediatric
	VG – Volume Guarantee	Neonatal
Spontaneous	PS – Pressure Support + Backup	Adult / Pediatric / Neonatal
	APRV/BiPhasic – Airway Pressure Release Ventilation	Adult / Pediatric / Neonatal
NIV (non-invasive)	Bilevel PC – Bi-level Positive Airway Pressure	Adult / Pediatric
	nTCPL – Non Invasive Time Cycled Pressure Limited	Neonatal
	CPAP – CPAP + Backup	Adult / Pediatric / Neonatal
	nCPAP – Nasal CPAP + Backup	Neonatal
	Biphasic LP – Biphasic for use with LP Generators	Neonatal
	nCPAP LP – Nasal CPAP for use with LP Generators	Neonatal

Assist Control Ventilation (A/C)

In Assist Control ventilation mode, all breaths initiated and delivered are mandatory breaths. The initiation of a breath is triggered by one of the following:

- Patient effort activates the inspiratory trigger mechanism,

- The breath interval, as set by the RATE control, times out,

- The operator presses the **MANUAL BREATH** button.

Initiation of a breath by any means resets the breath interval timing mechanism. It is possible for the patient to initiate every breath if he/she is breathing faster than the preset breath rate. If the patient is not actively breathing, the ventilator automatically delivers breaths at the preset interval (set breath rate), initiating the inspiratory phase.

The end of the inspiratory phase is determined by a time cycle or a flow cycle. .
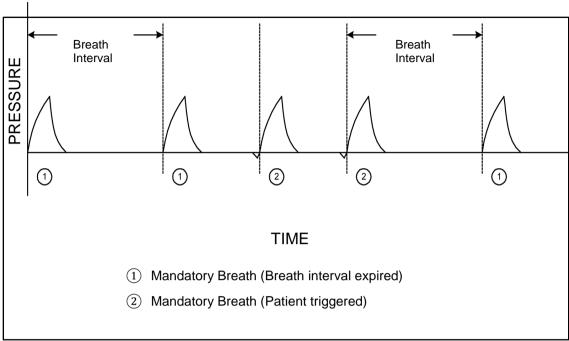
Figure 4-7, Assist Control Ventilation Waveform

Synchronized Intermittent Mandatory Ventilation (SIMV)

In **SIMV** mode, the ventilator can deliver both mandatory and demand breath types. Mandatory breaths are delivered when the SIMV "time window" is open and one of the following occurs:

- A patient effort is detected;

- The breath interval has elapsed with no patient effort detected;

- The **MANUAL BREATH** button has been pressed.

For mandatory demand breaths, the end of the inspiratory phase is determined by a time cycle or a flow cycle. For demand breaths, delivery and terminating of the inspiratory phase are determined by the settings for Pressure Support (PS), PEEP, rise time %, and PS cycle value.

Pressure Support (PS) is active for demand breaths in **SIMV** mode.
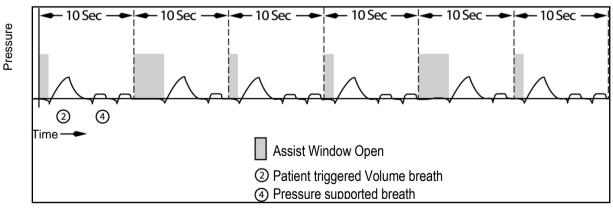
Figure 4-8. SIMV Waveform

The breath interval is established by the preset breath rate. It resets as soon as the interval time determined by the set breath rate has elapsed, or when the **MANUAL BREATH** button is pressed.

Spontaneous Ventilation
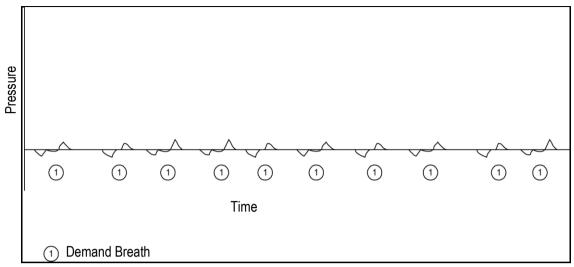
Figure 4-9. CPAP Waveform

In this mode, all breaths are patient-initiated demand breaths unless the **MANUAL BREATH** button is pressed or apnea backup ventilation is activated. When the **MANUAL BREATH** button is pressed, a single breath is delivered at the currently selected apnea backup control settings.

The delivery and terminating of the inspiratory phase are determined by the settings for Pressure Support (PS), PEEP, rise time %, and PS cycle value.

Pressure Support (PS) is active in this mode.

NOTE
If PS level is insufficient to meet patient demand, premature termination of the breath may occur with auto-triggering.

In these cases the PS level should be increased slightly.
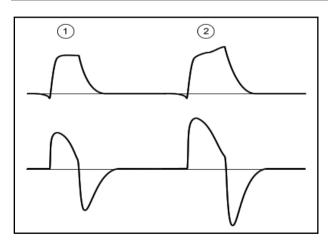
Figure 4-10. PS Waveform

In Figure 4-10, breath number 1 represents the pressure and flow tracing which occurs when the PS level is adequate to meet the patient demand. Breath number 2 shows what happens when the PS level is insufficient.

Non-Invasive Ventilation:

> ⚠️ *WARNING*
> Exhaled volume of the PATIENT can differ from the measured exhaled volume due to leaks around the mask.

The iX5 ventilator performs non-invasive ventilation with a standard dual limb circuit. For pediatric/adult non-invasive modes (Bilevel PC and CPAP), it is required a mask with no bleed holes. For neonatal non-invasive modes (nCPAP, nTCPL), it is required a nasal prong.

The initiation of a breath is triggered by one of the following, depending on the chosen mode:

- Patient effort activates the inspiratory trigger mechanism,

- The breath interval, as set by the RATE control, times out,

- The operator presses the MANUAL BREATH button.

For Bilevel PC and nTCPL the initiation of the inspiratory phase can be delivered by both mandatory and demand breath types and cycled by time or flow.

For CPAP and nCPAP the initiation of the inspiratory phase is delivered by demand breaths and cycled by flow, terminating the inspiratory phase.

> *NOTE*
> Excessive leaks around the mask or prong may result in false triggering of the ventilator or assertion of disconnect alarms.

Leak Compensation

The ventilator incorporates a leak compensation system. This system compensates for baseline leaks at the patient interface or around the patient's endotracheal tube. It only provides baseline leak compensation and is not active during breath delivery.

For non-invasive modes (Bilevel PC, CPAP, nCPAP and nTCPL), the maximum leak compensation is 120 lpm for adults, 80 lpm for pediatrics and 30 lpm for neonatal patients.

For all the other modes, the maximum leak compensation is 60 lpm for adults, 40 lpm for pediatrics and 20 lpm for neonatal patients.

Backup Ventilation

When an event of Anea occurs, the ventilator sends a mandatory cycle of backup ventilation, started from the Apnea alarm independently of the ventilation mode selected (controlled, assisted or spontaneous), according with the sction 6 Alarms. Especially in PS, CPAP, nCPAP and APRV modes, there are extra controls available for backup ventilation. When any of those modes is selected, you MUST:

- Set the primary and advanced settings for the selected mode.

- Set the primary controls appearing at the top-right of the touch screen, for the apnea breath type.

For each selected mode, the respective Backup Ventilation is as follows:

Selected Mode	Apnea Backup Mode	Backup Parameters
PS	PC	Backup Rate, Insp Time, Insp Pres
CPAP	Bilevel PC	Backup Rate, Insp Time, IPAP
nCPAP	nTCPL	Backup Rate, Insp Time, Pres Limit
APRV	PC	Backup Rate, Insp Time, Insp Pres

Apnea Backup ventilation is initiated when the patient's spontaneous monitored rate is lower than the adjusted backup rate.

Apnea Backup ventilation will terminate when one of the following criteria are met:

- The patient initiates a spontaneous breath

- A manual breath is delivered

Neonatal Ventilation

The ventilator provides 4 different Neonatal nasal non-invasive modes: nCPAP, nTCPL, nCPAP LP and Biphasic LP.

The nCPAP LP and Biphasic LP modes are dedicated for use only with LP generators and interfaces.

For use with other interfaces, you shall use the nCPAP or nTCPL modes.

For non-invasive ventilation, select the non-invasive option after selecting the neonatal patient category.
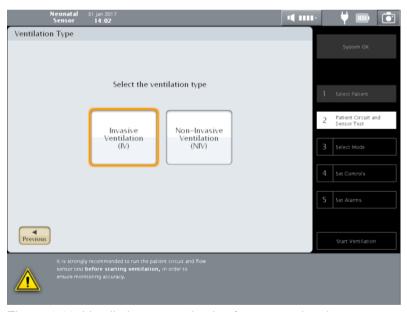
Figure 4-11. Ventilation type selection for neonatal patient

Select the appropriate interface by pressing Nasal Prong or LP Generator button. After selected the interface, only the respective modes will be available
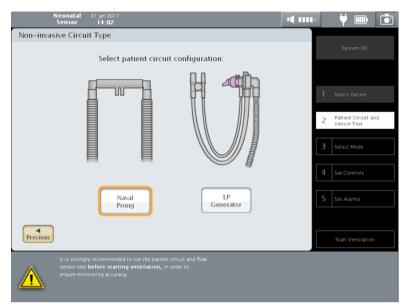
Figure 4-12. Neonatal interfaces choice

Breath Types

This section contains a brief description of the breath types and ventilation mode combinations available for adult, pediatric and neonatal patients.

There are two basic breath types:

- Mandatory breaths (delivered according to set ventilator parameters), and

- Demand breaths (triggered by the patient)

All breaths are defined by four variables:

- Trigger (initiates the breath),

- Control (controls the delivery),

- Cycle (primary breath termination), and

- Limit (secondary breath termination).

VC – Volume Control

Description

In this mode, the ventilator provides inspiratory flow set on control **Insp Flow** until the tidal volume set on the control **Tidal Vol** is reached, cycling to volume.

The inspiratory pressure will depend on the set parameters (**Insp Flow, Tidal Vol** and **PEEP**) and on the patient's respiratory mechanics.

The **iX5 ventilator** provides three waveforms (**Waveform**) of the inspiratory flow controlled on the **VC** mode*:*

- Constant Flow (⎍)

- Decreasing Flow (◣)

- Sinusoidal Flow (∩)

NOTE

In the case of decreasing flow, the value set on **Insp Flow** will be the mean inspiratory flow of each cycle. The initial flow (peak) will be 50% greater than the set value, and the end flow, 50% lower. Therefore, an inspiratory time and an I:E ratio equivalent to a constant flow cycle will be maintained.

In case of sinusoidal flow, the value set on **Insp Flow** will be the mean inspiratory flow of each cycle. The initial flow (peak) will be 56% greater than the set value. Therefore, an inspiratory time and an I:E ratio equivalent to a constant flow cycle will be maintained.

NOTE

The VC mode is not enabled for neonatal patients.

The Intra-Breath Demand System in Volume Ventilation

The iX5 ventilator features an intra-breath demand system in Volume Controlled ventilation, designed to provide additional flow to the patient during periods of demand.

It continuously measures the Peak Inspiratory Pressure (**Ppeak**) throughout the breath cycle and compares the Ppeak measurement to its previous value. Should the Ppeak decrease by the 2 cmH$_2$O, the ventilator will recognize the patient demand and automatically allows flow to exceed the set Peak Flow, thereby meeting the patient's demand.

The maximum demand flow is 180 lpm for adult patients and 100 lpm for pediatric patients.

Settings

Basic Settings	
%O$_2$	% Oxygen
Volume	Tidal Volume
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
Flow Trig	Flow Trigger
Insp Flow	Inspiratory Flow
Insp Pause	Inspiratory Pause
Advanced Settings / Maneuvers	
Waveform	Flow Pattern (Decelerating/Square/Sinusoidal)
Pres Trig	Pressure Trigger
Sigh	Sigh
Neb	Nebulization
TGI	Tracheal Gas Insufflation
Slow Flow	Slow Flow Maneuver

Circuit Compliance Compensation

The volume of gas delivered during a VC mode is increased to include the set volume, plus the volume lost due to the compliance effect of the circuit.

Preset Values:

Adult patients (IBW setting higher than 30 kg): 1.96 mL/cmH$_2$O

Pediatric patients (IBW equal or lower than 30 kg): 1.08 mL/cmH$_2$O

> *NOTE*
> As iX5 ventilator uses preset values for compliance compensation, it is important to use breathing circuits with compatible values of compliance. Therefore Vyaire recommends using Vyaire approved circuits.

VC + PS – Volume Controlled Ventilation + Pressure Support

Description

In **VC+PS** mode, spontaneous cycles are interspersed with mandatory cycles, which can be assisted by pressure support (**PS**). Upon detecting the patient's effort, the ventilator helps the respiration of the patient, increasing the airway pressure until the set pressure support (**PS**) level is reached. The resulting flow is decreasing and its amplitude depends on the patient's respiratory mechanics or the patient's effort. Cycles are terminated when the inspiratory flow falls to the set PS Cycle value. On spontaneous cycles with pressure support, the volume delivered to the patient depends on the level of the pressure support, on the PS cycle, and on the patient's effort and respiratory mechanics.

Settings

Basic Settings	
%O$_2$	% Oxygen
Volume	Tidal Volume
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
PS	Pressure Support
Flow Trig	Flow Trigger
Insp Flow	Inspiratory Flow
Insp Pause	Inspiratory Pause
Advanced Settings / Maneuvers	
Waveform	Flow Pattern (Decelerating/Square/Sinusoidal)
Pres Trig	Pressure Trigger
Rise	Pressure Rise
PS Cycle	Flow Cycle % for spontaneous breaths
AAC	Artificial Airway Compensation
Sigh	Sigh
Neb	Nebulization
TGI	Tracheal Air Insufflation
Slow Flow	Slow Flow Maneuver

PC – Pressure Controlled

Description

In this mode, the ventilator continuously controls the inspiratory flow in order to reach and maintain the pressure on the patient's airway on the value set by the operator on the **Insp Pres** control. The time during which such pressure will be maintained is set by the operator on the **Insp Time** control.

Settings

Basic Settings	
%O$_2$	% Oxygen
Insp Pres	Inspiratory Pressure
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
Flow Trig	Flow Trigger
Insp Time	Inspiratory Time
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Rise	Pressure Rise
PC Cycle	Flow Cycle % for mandatory breaths
AAC	Artificial Airway Compensation
Sigh	Sigh
Neb	Nebulization
TGI	Tracheal Gas Insufflation

PC + PS – Pressure Controlled Ventilation + Pressure Support

Description

In the **PC+PS** mode, spontaneous cycles are interspersed with mandatory cycles, which can be assisted by pressure support (**PS**). Upon detecting the patient's effort, the ventilator helps the respiration of the patient, increasing the airway pressure until the set pressure support (**PS**) level. The resulting flow is decreasing and its amplitude depends on the patient's respiratory mechanics or the patient's effort. Cycles are terminated, when the inspiratory flow falls to the set PS Cycle value. On spontaneous cycles with pressure support, the volume delivered to the patient depends on the level of the pressure support, on the PS cycle, and on the patient's effort and respiratory mechanics.

Settings

Basic Settings	
%O₂	% Oxygen
Insp Pres	Inspiratory Pressure
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
Flow Trig	Flow Trigger
Insp Time	Inspiratory Time
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Rise	Pressure Rise
PC Cycle	Flow Cycle % for mandatory breaths
PS Cycle	Flow Cycle % for spontaneous breaths
AAC	Artificial Airway Compensation
Sigh	Sigh
Neb	Nebulization
TGI	Tracheal Gas Insufflation

TCPL – Time Cycled Pressure Limited

Description

This mode is indicated for the ventilation of neonatal and pediatric patients only.

In this mode, during the mandatory cycles, the ventilator maintains a constant flow in the airway, and the exhalation valve controls the expiratory pressure (**PEEP**) and the inspiratory pressure limit **Pres Limit**.

In this mode, during the mandatory cycles, the pressure in the airway is simply limited, and not controlled. Depending on the values set to continuous flow (**Cont Flow)** and inspiratory time **Insp Time**, and the patient's respiratory mechanics, it is possible that the pressure in the airway will not reach the intended inspiratory pressure value. The set flow **Cont Flow** must be enough to meet the patient's demand.

Settings

Basic Settings	
%O$_2$	% Oxygen
Pres Limit	Pressure Limit
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
Flow Trig	Flow Trigger
Cont Flow	Continuous Flow
Insp Time	Inspiratory Time
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Neb	Nebulization
TGI	Tracheal Gas Insufflation

TCPL+PS – Time Cycled and Pressure Limited + Pressure Support

Description

When **TCPL+PS** mode is used, the spontaneous cycles can be assisted by the pressure support **PS**. During the spontaneous cycles, the ventilator can increase the inspiratory flow beyond the set **Insp Flow**, in order to maintain the pressure support and meet the patient's demand.

Settings

Basic Settings	
%O$_2$	% Oxygen
Pres Limit	Pressure Limit
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
PS	Pressure Support
Flow Trig	Flow Trigger
Cont Flow	Continuous Flow
Insp Time	Inspiratory Time
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Rise	Pressure Rise
PS Cycle	Flow Cycle % for spontaneous breaths
AAC	Artificial Airway Compensation
Neb	Nebulization
TGI	Tracheal Gas Insufflation

PRVC – Pressure Regulated Volume Controlled

Pressure Regulated Volume Control (PRVC) breaths are pressure breaths where the pressure level is modulated by the ventilator to achieve a preset volume. PRVC breaths are:

- Controlled by pressure (inspiratory + PEEP) and volume

- Limited by pressure (inspiratory + PEEP + margin)

- Cycled by time or flow

- PRVC breath operation is as follows:

  - When PRVC is selected, a volume controlled test breath is delivered to the patient. This test breath consists of a volume controlled cycle with the equal Vol Target set, with inspiratory flow rate calculated using Vol Target and the adjusted inspiratory time (T Insp). The test cycle always includes an inspiratory pause of 200 ms.

  - The measured plateau pressure in this cycle is used as the initial control pressure for the subsequent cycle.

  - The next breath and all subsequent breaths are delivered as pressure control breaths.

  - Inspiratory pressure is modulated by the ventilator to maintain the target volume. The maximum step change between two consecutive breaths is 2 cmH$_2$O.

The test breath sequence is initiated when any of the following occur:

- Entering the Mode (PRVC)

- Exiting Standby

- Changing the Target Volume

- Disconnecting and reconnecting (replacing) the flow sensor

- Deactivating any of the following alarms:

  - Circuit Disconnection

  - Circuit Occlusion

  - Vent Inop

  - High Ppeak

> **NOTE**
> Demand Flow is active for all mandatory breaths. The maximum peak inspiratory pressure achievable by the ventilator is limited by the high peak pressure alarm setting.

> ⚠️ **WARNING**
> In PRVC breaths, the pressure may be regulated between the PEEP and High Ppeak alarm – 5 cmH2O in order to achieve the Vol Target setting. The PEEP and High Ppeak alarm settings should be set at appropriate levels for the patient to avoid over or under delivery of pressure.

Settings

PRVC (A/C) Mode

Basic Settings	
%O$_2$	% Oxygen
Vol Target	Volume Target
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
Flow Trig	Flow Trigger
T Insp	Inspiratory Time
Advanced Settings / Maneuvers	
Pres Trigger	Pressure Trigger
Rise	Pressure Rise
PC Cycle	Flow Cycle % for mandatory breaths

PRVC + PS – Pressure Regulated Volume Controlled + Pressure Support

Description

When the **PRVC+PS** mode is used, the spontaneous cycles can be assisted by the pressure support (**PS**).

Settings

PRVC+PS (SIMV) Mode

Basic Settings	
%O$_2$	% Oxygen
Vol Target	Volume Target
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
PS	Pressure Support
Flow Trig	Flow Trigger
T Insp	Inspiratory Time
Advanced Settings / Maneuvers	
Pres Trigger	Pressure Trigger
Rise	Pressure Rise
PC Cycle	Flow Cycle % for mandatory breaths
PS Cycle	Flow Cycle % for spontaneous breaths
AAC	Artificial Airway Compensation

VG – Volume Guarantee

Description

Volume Guarantee breaths are pressure control breaths where the pressure level is modulated by the ventilator to achieve a preset tidal volume (Vol Target).

VG breath operation is as follows:

- When VG is selected, pressure controlled test breath, to the set P Backup, is delivered to the patient. Default is 15 cmH$_2$O (P Backup).

- The next breath will deliver an inspiratory pressure based on the dynamic compliance of the previous breath and the set tidal volume (Vol Target).

- Inspiratory pressure is modulated by the ventilator to maintain Vol Target. The maximum step change between two consecutive breaths is 2 cmH$_2$O. The maximum tidal volume delivered in a single breath is determined by Vol Limit.

> **NOTE**
> Breath to breath variation of delivered pressure will not be more than 4 cmH$_2$O between successive breaths of the same trigger type (time vs. patient triggered).

> **NOTE**
> Volume Guarantee is only available in the neonatal patient size and requires the use of a proximal flow sensor.

> ⚠ **WARNING**
> In VG breaths, the pressure may be modulated between Pres Min and Pres Max in order to achieve the Vol Target setting. The Pres Min and Pres Max settings should be set at appropriate levels for the patient to avoid over or under delivery of pressure.

Settings

Basic Settings	
%O$_2$	% Oxygen
Vol Target	Volume Target
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
Flow Trig	Flow Trigger
P Backup	Backup Pressure
Insp Time	Inspiratory Pause
Cont Flow	Continuous Flow
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Breath Av	Breath Average
Pres Min	Pressure Minimum
Pres Max	Pressure Maximum
Vol Limit	Volume Limit
Rise	Pressure Rise

P Backup
Backup Pressure (cmH$_2$O)

In VG, P Backup is used for test breaths and acts as a backup pressure setting during certain alarm conditions.

Range: 5–40 cmH$_2$O

Default: 15 cmH$_2$O.

> **NOTE**
> The **P Backup** value is the absolute pressure value for the breath. Example: if the **Pres Limit** is set to 15 cmH$_2$O and **PEEP** is set to 5 cmH$_2$O, the pressure will be limited to 15 cmH$_2$O.

> ⚠️ *WARNING*
> Disconnecting the proximal flow sensor or removing it from the circuit while VG Mode is active will cause the ventilator to deliver pressure ventilation at the set P Backup.

> ⚠️ *WARNING*
> The P Backup setting should be set at an appropriate level for the patient to avoid under or over delivery of tidal volume during test breaths or flow sensor disconnect.

Maximum and Minimum Pressure (Pres Max and Pres Min)

Pres Max and Pres Min settings determine the range wherein the ventilator will modulate the inspiratory pressure during VG mode.

Breath Av
Breath Average (b/min)

The **Breath Av** setting in **VG** allows the clinician to set the number of breaths for which the ventilator uses to calculate the average volume delivered. Using **Breath Av** can help with irregular breathing patterns and help to provide a basis for a more consistent regulated pressure delivery.

> *NOTE*
> When in **SIMV** mode, **Breath Av** does not take into consideration the spontaneous triggered breaths. **Breath Av** will take the average of the previous mandatory breaths for the target volume.

Mode	Patient	Minimum	Maximum	Default
VG VG + PS	Neonatal	1	60	1

Vol Limit

This is the maximum tidal volume delivered to the patient during the maneuver. This setting has no effect on the settings during normal ventilation and can be set to any tidal volume desired independent of the current mode of ventilation.

Range: 10 to 120 mL
Default: 2 x **IBW** x **mL/kg**

VG + PS – Volume Guarantee + Pressure Support

Description

When the **VG+PS** mode is used, the spontaneous cycles can be assisted by the pressure support (**PS**).

Settings

Basic Settings	
%O$_2$	% Oxygen
Vol Target	Volume Target
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
PS	Pressure Support
Flow Trig	Flow Trigger
P Backup	Backup Pressure
Insp Time	Inspiratory Pause
Cont Flow	Continuous Flow
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Breath Av	Breath Average
Pres Min	Pressure Minimum
Pres Max	Pressure Maximum
Vol Limit	Volume Limit
Rise	Pressure Rise
PS Cycle	Flow Cycle % for spontaneous breaths

PS + Backup

Description

The minimum pressure support level is PEEP + 5 cmH_2O in adult and pediatric applications, independent of the set PS pressure level. In neonatal applications the minimum pressure support level is zero.

PS breaths are:

- Controlled by pressure (PS level + PEEP)
- Limited by pressure (PS level + PEEP)
- Cycled by flow (PS Cycle)

Settings

Basic Settings	
%O$_2$	% Oxygen
PEEP	Positive End Expiratory Pressure
PS	Pressure Support
Flow Trig	Flow Trigger
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Rise	Pressure Rise
PS Cycle	Flow Cycle % for spontaneous breaths
Neb	Nebulization
Backup Settings	
Backup	Backup Rate
Insp Pres	Inspiratory Pressure
Insp Time	Inspiratory Time

CPAP + Backup

Description

In this mode, the ventilator only maintains the continuous expiratory pressure and, if necessary, guarantees backup cycles.

Settings

Basic Settings	
%O$_2$	% Oxygen
CPAP	Positive End Expiratory Pressure
Flow Trig	Flow Trigger
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Neb	Nebulization
Backup Settings	
Backup	Backup Rate
IPAP	Inspiratory Positive Airway Pressure
Insp Time	Inspiratory Time

nCPAP

Description

This is a spontaneous, non-invasive mode, specific for neonates ventilated with nasal prongs. In this mode, the ventilator maintains the continuous expiratory pressure and continuous flow (**Cont Flow**).

Settings

Basic Settings	
%O$_2$	% Oxygen
PEEP	Positive End Expiratory Pressure
Cont Flow	Continuous Flow
Pres Trig	Pressure Trigger
Backup Settings	
Backup	Backup Rate
Pres Limit	Pressure Limit
Insp Time	Inspiratory Time

NOTE
The Insp Hold and Exp Hold buttons are not active in nCPAP mode.

NOTE
Volume monitoring is not available in this mode. It is recommended to remove flow sensor from the breathing circuit.

nTCPL

Description

This is a controlled, non-invasive mode, specific for neonates ventilated with nasal prongs.

In this mode, during the mandatory cycles, the ventilator maintains a constant flow in the airway, and the exhalation valve controls the expiratory pressure (**PEEP**) and the inspiratory pressure limit **Pres Limit**.

In this mode, during the mandatory cycles, the pressure in the airway is limited, and not controlled. Depending on the values set to continuous flow (**Cont Flow**) and inspiratory time (**Insp Time**), and the patient's respiratory mechanics, it is possible that the pressure in the airway does not reach the intended inspiratory pressure value. The set flow **Cont Flow** must be enough to meet the patient's demand.

Settings

Basic Settings	
%O$_2$	% Oxygen
Pres Limit	Pressure Limit
Insp Time	Inspiratory TIme
Rate	Respiratory Rate
PEEP	Positive End Expiratory Pressure
Pres Trig	Pressure Trigger
Cont Flow	Continuous Flow

NOTE
The Insp Hold and Exp Hold buttons are not active in nTCPL mode.

NOTE
Volume monitoring is not available in this mode. It is recommended to remove the flow sensor from the breathing circuit.
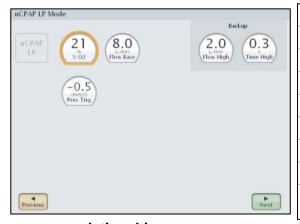
nCPAP LP

Description

This is a spontaneous, non-invasive mode, specific for neonates ventilated with LP generators and interfaces. In this mode, the ventilator maintains a continuous flow (**Base Flow**) to reach the continuous CPAP pressure.

Settings
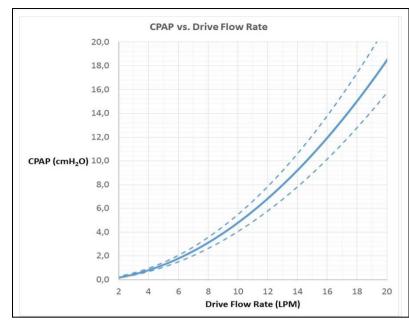
Basic Settings		**Flow /**
%O$_2$	% Oxygen	
Base Flow	Baseline Continuous Flow	
Pres Trig	Pressure Trigger	
Backup Settings		
Flow High	Flow High	
Time High	Time with Flow High	

pressure relationship

The Infant Flow LP driver is subject to a direct relationship between the controlled enriched gas flow and airway pressure. A nomogram illustrating the relationship between constant airway pressure and flow settings is shown in Figure 4-13. For example, 8 lpm gas flow provides approximately 5 cmH2O.

Flow Pressure Nomogram (for reference only) is showing typical flow pressure relationships. This is not meant to establish actual product performance.

Figure 4-13. Flow pressure nomogram

NOTE
Individual devices have a tolerance of up to ±15 percent from that illustrated in the nomogram, and in particular, at pressures below 2cmH2O.

NOTE
The Insp Hold and Exp Hold buttons are not active in nCPAP LP mode.

NOTE
Manual Insp function will use Flow High and Time High settings to generate a manual inspiration.

NOTE
Volume monitoring is not available in this mode. Flow sensor should be removed from the breathing circuit.

NOTE
To deliver manual breaths, the Pressure High flow meter must indicate a flow that is above zero.

⚠ **CAUTION**
• The nCPAP LP mode has been designed and tested using only Vyaire accessories. Only accessories approved for use by Vyaire should be used. If in doubt, please contact your local sales representative.

• If the patient pressure is inconsistent with set flow, be aware of possible leaks, connection faults or occlusion

• Monitor the breathing circuit for excessive condensation and drain and replace circuit as necessary.

> ### ⚠ WARNING
>
> • Do not use the IF LP generators with dry unheated gas.
>
> • Under certain conditions (minimum supply pressure and maximum gas demand, including auxiliary output) output flow rates and therefore pressure delivered to the generator may be reduced.
>
> • Nasal CPAP therapy in general can cause nasal irritation, septal distortion, skin irritation and pressure necrosis. Adherence to the recommended usage instructions for the IF LP system may reduce the incidence of these complications.

Biphasic LP

Description

This is a bi-phasic, non-invasive mode, specific for neonates ventilated with LP generators and interfaces. In this mode, the ventilator switches between two levels of pressure, achieved by adjusting the Base Flow and High Flow. The Rate button defines how many times per minute the ventilator switches between the Base Flow and the High Flow

Settings
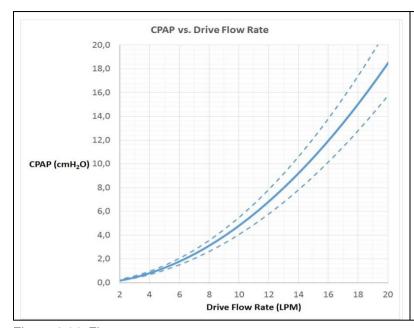
Basic Settings	
%O$_2$	% Oxygen
Base Flow	Baseline Flow
Flow High	High Flow
Time High	Time in High Flow
Rate	Respiratory Rate
Pres Trig	Pressure Trigger

Flow / pressure relationship

The Infant Flow LP driver is subject to a direct relationship between the controlled enriched gas flow and airway pressure. A nomogram illustrating the relationship between constant airway pressure and flow settings is shown in Figure 4-13. For example, 8 lpm gas flow provides approximately 5 cmH2O.

Flow Pressure Nomogram (for reference only) is showing typical flow pressure relationships. This is not meant to establish actual product performance.

Figure 4-14. Flow pressure nomogram

NOTE
Individual devices have a tolerance of up to ±15 percent from that illustrated in the nomogram, and in particular, at pressures below 2cmH2O.

NOTE
The Insp Hold and Exp Hold buttons are not active in Biphasic LP mode.

NOTE
Volume monitoring is not available in this mode. It is recommended to remove flow sensor from the breathing circuit.

NOTE
To deliver manual breaths, the Pressure High flow meter must indicate a flow that is above zero.

⚠ *CAUTION*
• The Biphasic LP mode has been designed and tested using only Vyaire accessories. Only accessories approved for use by Vyaire should be used. If in doubt, please contact your local sales representative.

• If the patient pressure is inconsistent with set flow, be aware of possible leaks, connection faults or occlusion

• Monitor the breathing circuit for excessive condensation and drain and replace circuit as necessary.

⚠ *WARNING*
• Do not use the IF LP generators with dry unheated gas.

> • Under certain conditions (minimum supply pressure and maximum gas demand, including auxiliary output) output flow rates and therefore pressure delivered to the generator may be reduced.
>
> • The Pres High flow meter may be adjusted to zero when the BiPhasic mode is not required for the patient.
>
> • Nasal CPAP therapy in general can cause nasal irritation, septal distortion, skin irritation and pressure necrosis. Adherence to the recommended usage instructions for the IF LP system may reduce the incidence of these complications.

Airway Pressure Release Ventilation (APRV/Biphasic)

Description

APRV/BiPhasic is a time-cycled pressure mode, where the ventilator cycles between two different baseline pressures based on time; this can be synchronized with patient effort. Controlled ventilation can be maintained by time cycling the transitions between baseline pressures. Additionally, pressure support can be added to improve comfort for the spontaneous breathing patient.

In this mode, the patient is allowed to breathe spontaneously at two preset pressure levels. These are set using the **Pres High** and **Pres Low** controls. The maximum duration at each pressure during timed cycling is set with the **Time High** and **Time Low** controls.

The ventilator synchronizes the change from Pressure Low to Pressure High with the detection of inspiratory flow or the first inspiratory effort detected within the T Delay window. Transition from Pressure High to Pressure Low occurs with the first end of inspiration detected after the T Delay window

Settings

Basic Settings	
%O$_2$	% Oxygen
Pres High	Pressure High
Time High	Time High
Pres Low	Pressure Low
Time Low	Time Low
Flow Trig	Flow Trigger
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
T Delay	Time Delay
PS High	Pressure Support High
PS Low	Pressure Support Low
Rise	Pressure Rise
PS Cycle	Flow Cycle % for spontaneous breaths
AAC	Artificial Airway Compensation
Neb	Nebulization
Backup Settings	
Backup	Backup Rate
Insp Pres	Inspiratory Pressure
Insp Time	Inspiratory Time

⚠️ *WARNING*

The PS High setting is measured above the P High setting. The PS High setting should be set at an appropriate level for the patient to avoid over delivery of pressure in support breaths during Pressure High. Also, High Ppeak alarm should be set above Pres High + PS High in order to avoid improper alarm activation.

NOTE

Time High and Time Low are maximum time settings for a time-cycled transition. Actual times may vary depending on the patient's spontaneous breathing pattern and the T Delay setting. Setting the T Delay as zero cycles the transition between pressure levels on time only and will not provide synchronization with patient efforts.

NOTE

The Manual Breath, Insp Hold and Exp Hold buttons are not active in APRV / BiPhasic.

① = Demand Breath
② = Spontaneous Breath triggers change to Pressure High
③ = Spontaneous Breath triggers change to Pressure Low
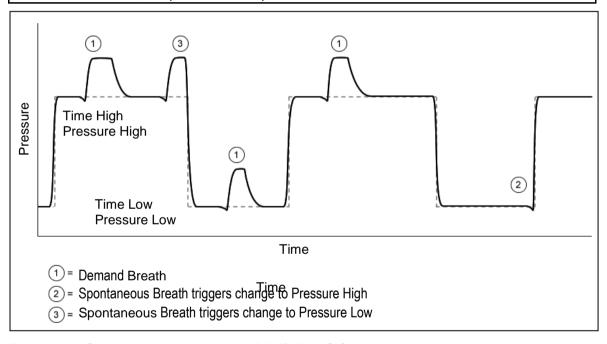
Figure 4-15. Spontaneous breathing on APRV/BIPHASIC Mode

① = Backup Cycles above Pressure Low
② = Backup Cycles above Pressure High
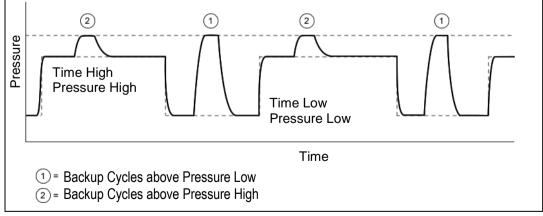
Figura 4-16. Backup ventilation on APRV/BIPHASIC mode

Bilevel / PC

Description

This is a controlled non-invasive mode, specific for pediatric and adult patients, ventilated with masks.

The joint and simultaneous operation of the flow and exhalation valve allows the patient to exhale during the inspiratory phase of the controlled pressure cycles. That means, in each phase, if the patient exerts an inspiratory effort, the ventilator will increase the airway flow to meet the inspiratory demand; if the patient exerts an expiratory effort, the ventilator will relief the airway pressure, keeping it in its set level (**PEEP** or **IPAP**).

Settings

Basic Settings	
%O$_2$	% Oxygen
IPAP	Inspiratory Positive Airway Pressure
Insp Time	Inspiratory Time
Rate	Respiratory Rate
EPAP	Expiratory Positive Airway Pressure
Flow Trig	Flow Trigger
Advanced Settings / Maneuvers	
Pres Trig	Pressure Trigger
Rise	Pressure Rise
PC Cycle	Flow Cycle % for mandatory breaths
PS Cycle	Flow Cycle % for spontaneous breaths
Neb	Nebulization

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Chapter 5   Ventilation Features

Buttons and LEDs

Figure 5-1. User interface, showing buttons and LEDs

Button Letter	Function
A	Standby
B	100% O_2
C	Manual Insp
D	Exp Hold
E	Insp Hold
F	Setup
G	Panel Lock
H	Audio Pause / Alarm Reset
I	Main Knob
J	Power
K	AC Line
L	Ext Batt
M	Int Batt
N	Int Batt Level
O	Master Alarm

Front Panel Buttons and LEDs

Standby Mode (Standby)

This button is located on the front panel and puts the ventilator on standby mode.

- The ventilator suspends operation, interrupting the ventilation functions, monitoring, and alarms, with the exception of the trend curves.

- The operator can proceed to adjust all control and alarm parameters.

- The operator can access all information stored in the ventilator's memory (trend curves).

- The operator can change any parts of the circuit assembly while in Standby Mode.

⚠️ *WARNING*

Ensure that the breathing circuit and the additional items (e.g. HME, flow sensor, humidifier, etc.) are properly assembled. Using humidifier, check the water level.

Verify the breathing circuit through the Accessory Self-Check function according to the instructions in Chapter 4 Operation.

- To start the programmed ventilation, the operator must press the **Standby Mode** button again, or the **Start Ventilation** button on the screen.

   When the **Standby Mode** button is pressed after an oxygenation period, activated by the **100% O$_2$** button, a suction sequence starts. This sequence is described under **100% O$_2$** control.

   The activation of this function is indicated by the corresponding LED signal.

NOTE

During **Standby Mode**, iX5 sends a constant flow of 4 lpm to avoid gas overheating in the patient circuit when using a heated humidifier.

100% O$_2$ – Oxygenation/Suction Maneuver

Pressing the 100% O2 button starts the oxygenation process, adjusting the oxygen concentration to 100% for 3 minutes. If the button is pressed again within 1 minute, the maneuver will be interrupted, immediately returning to the previously set oxygen concentration value.

For opens suction and closed suction instructions, see *Chapter 5 – Advanced Features - Suction*

Manual Insp – Manual Cycle

This button (located on the front panel) starts a controlled cycle on the selected mode. The ventilator ignores this command, if the button is pressed during the inspiratory phase or during the initial period of 300ms of the expiratory phase.

Exp Hold – Manual Expiratory Pause

This button (located on the front panel) enables a pause at the end of the expiratory phase of the respiratory cycle. The button can be activated at any time, and will activate at the end of the next exhalation.

In order to make the detection of the pause easier, the indicating LED remains flashing from the time the button is depressed until the start of the pause, remaining lit during the entire time of the pause.

The pause can be activated either by c:

- *One Touch*: an automatic pause will be activated at the end of the next exhalation, with a fixed duration of 2 seconds.

- *Press and Hold:* while the operator keeps the button pressed, the pause will be maintained for a maximum time of 15s.

> *NOTE*
>
> The expiratory pause measures the ***Auto PEEP*** or the **Occlusion Pressure *P0.1*** (measured 100ms after the pause start).
>
> For further information about these parameters, see *Section 7, Monitoring Features,* of this Manual.

Insp Hold – Manual Inspiratory Pause

This button (located on the front panel) initiates a pause at the end of the inspiratory phase of the respiratory cycle. The button can be activated at any time, and the pause will only be activated at the end of the next inspiration.

In order to make the detection of the pause easier, the LED indicator remains flashing from the moment the button is pressed until the pause starts, remaining lit during the entire pause time.

The pause can be activated either by One Touch or by Press and Hold:

- *One Touch*: an automatic pause will be activated at the end of the next inhalation, with a fixed duration of 2 seconds.

- *Press and Hold:* while the operator keeps the button pressed, the pause will be maintained for a maximum time of 15s.

> *NOTE*
>
> During the inspiratory pause, in the absence of flow, the equalization between the alveolar pressure and the airway pressure occurs, monitored on the manometer. Therefore, it is possible, during the inspiratory pause, to directly check on the ventilator manometer, or on the graphic or digital display, the ***Plateau Pressure*** value (**alveolar pressure at the end of inhalation**, **lung elastic pressure**, **plateau pressure**).
>
> For more information about the monitoring of ***Plateau Pressure***, check *Section 7, Monitoring Features,* in this Manual.

Setup

This menu, accessed through the **Setup** button located on the front panel, grants access to the system information and general configurations.

Screen Setup

The **screen brightness** control enables the adjustment of display's luminosity, providing more comfort to the operator/patient in rooms with less light.

The **sleep mode** option enables a secondary luminosity adjustment, always inferior to the main adjustment, which becomes effective 20 seconds after the last action of the operator on the equipment screen. The ventilator automatically assumes the brightest level, when any alarm occurs or when the operator touches any control.

Sound Setup

The loudspeaker volume control makes the configuration of the volume level of the sound alarm possible. This control does not allow the muting of the alarms.

> **NOTE**
> The tidal volume supplied on pressure-based ventilation modes depends both on the applied inspiratory pressure and on the lung mechanics.

Insp Pres
Inspiratory Pressure (cmH₂O)

This control enables the adjustment of the Inspiratory Pressure value over PEEP, applied to the mandatory cycles in the **PC** modes.

For example: for a **Insp Pres** set to 20 cmH_2O with a **PEEP** of 5 cmH_2O, the final inspiratory pressure value in the airway will be 25 cmH_2O.

The Inspiratory Pressure is actively maintained by the simultaneous control of the flow valves and the exhalation valve during the entire respiratory cycle. The flow is automatically set to meet the patient's demand and/or compensate leakages while the pressure is relieved whenever the patient makes an expiratory effort.

The pressure's rise time, from **PEEP** to (**PEEP + Insp Pres)** will depend on the **Rise** adjustment.

Scale	All Patients	5 to 80 cmH_2O
	Default Value	15 cmH_2O

> **NOTE**
> On the **PC** mode, the controlled pressure value **Insp Pres** is above to the **PEEP** value.

Insp Flow
Inspiratory Flow (lpm)

This control enables the adjustment of the inspiratory flow in **VC** mode.

Besides amplitude, the **VC** mode enables the selection of three different waveforms:

- Constant flow (⊓)

  The value of the set flow is kept constant throughout the entire inspiratory time.

- Decreasing flow (◣)

  The initial flow (***Insp Peak Flow***) will be 50% greater than the set value, while the end of cycle flow will be 50% lower than the value set on **Insp Flow**. Therefore, the inspiratory time and the I:E ratio will be maintained equivalent to those of a constant flow cycle at a lower airway pressure.

- Sinusoidal flow (◠)

  The initial flow (***Insp Peak Flow***) will be 56% greater than the set value, in order to maintain the inspiratory time and the I:E ratio equivalent to those of a constant flow cycle.

Scales	Pediatric Patient	2 to 50 lpm
	Default Value	20 lpm
	Adult patient	2 to 120 lpm
	Default Value	30 lpm

Insp Time
Inspiratory Time (s)

This control enables the adjustment of the inspiratory time on **PC, TCPL , PRVC, VG, Bilevel PC,** and **nTCPL** modes.

Scales	Neonatal Patient	0.10 to 15.0 s 0.10 to 5.0 s on nTCPL and nCPAP modes
	Default Value	0.50 s 0.30 s on VG, nTCPL and nCPAP modes
	Pediatric Patient	0.10 to 15.0 s 0.50 to 5.0 s on CPAP and Bilevel PC modes
	Default Value	0.75 s 0.50 s on PRVC mode
	Adult Patient	0.10 to 15.0 s 0.50 to 15.0 s on PRVC modes 0.50 to 5.0 s on CPAP and Bilevel PC modes
	Default Value	1.00 s

Time High
Time with high pressure or flow (s)

This control enables the adjustment of the time wherein the flow remains in the upper level adjusted on **nCPAP LP and Biphasic LP** modes. For the **APRV** mode, this control enables the adjustment of the time while the pressure remains in the upper level adjusted.

Scales	Neonatal Patient	0.10 to 5.0 s on nCPAP LP and Biphasic LP modes
	Default Value	0.30 s on nCPAP LP and Biphasic LP modes
	Pediatric / Adult Patient	0.2 to 30.0 s on APRV mode
	Default Value	4.0 s on APRV mode

Time Low
Time with low pressure (s)

This control enables the adjustment of the time wherein the pressure remains in the lower level adjusted on **APRV** mode.

Scales	Pediatric / Adult Patient	0.2 to 30.0 s on APRV mode
	Default Value	0.5 s on APRV mode

Rate
Respiratory Controlled Rate (/min)

This control enables adjustment of rate of the controlled cycles supplied by the ventilator.

Scales	Neonatal Patient	1 to 180 bpm 1 to 120 bpm on VG mode 1 to 60 bpm on nTCPL and Biphasic LP modes
	Default Value	30 bpm 20 bpm on nTCPL and Biphasic LP modes
	Pediatric Patient	1 to 180 bpm 1 to 60 on PRVC mode 1 to 40 on Bilevel PC mode
	Default Value	20 bpm
	Adult Patient	1 to 180 bpm 1 to 40 bpm on PRVC and Bilevel PC modes
	Default Value	12 bpm

PEEP
Positive End-Expiratory Pressure (cmH$_2$O)

> ⚠ *WARNING*
> If High Ppeak alarm is set too close to PEEP setting, Circuit Occlusion alarm may be triggered.

This control enables the adjustment of the expiratory pressure level on all modes.

The **PEEP** expiratory pressure is actively maintained by simultaneously controlling the flow valves and the exhalation valve. The flow is automatically set to meet the patient's demand and/or compensate leakages, maintaining the functional residual capacity while the pressure is relieved whenever the patient makes an expiratory effort.

Scales	Neonatal Patient	0 to 50 cmH$_2$O 0 to 25 cmH2O on VG mode 0 to 15 cmH$_2$O on nCpap and nTCPL modes
	Pediatric and Adult Patients	0 to 50 cmH$_2$O
	Default Value	5 cmH$_2$O

> *NOTE*
> On the **PC** mode, the controlled pressure value **Insp Pres** is above to the **PEEP** value.

> *NOTE*
> When changing the **PEEP**, check the set value on the **High Ppeak** alarm. If the **PEEP** is set close to or above the set alarm value, there may be some limitation of ventilation, since detection of the **High Ppeak** alarm causes the ventilator to cycle to exhalation.

Pres Limit
Pressure Limit (cmH$_2$O)

This control enables the adjustment of the Pressure Limit value, where the **Pres Limit** value is an absolute pressure value, applied to the mandatory cycles on the **VG, TCPL, nTCPL and nCPAP** modes.

For example: for a **Pres Limit** value set to 20 cmH$_2$O with a **PEEP** of 5 cmH$_2$O, the final inspiratory pressure value in the airway will be 20 cmH$_2$O.

Mode	Patient	Minimum	Maximum	Default
TCPL TCPL + PS	Neonatal Pediatric	5	80	20
PC PC + PS PS + Backup	All	NA	NA	OFF (120)
Bilevel PC	Pediatric Adult	NA	NA	OFF (40)
nTCPL nCPAP + Backup	Neonatal	5	30	10

NOTE
The minimum possible **Pres Limit** adjustment will be within 5 cmH$_2$O above the set expiratory pressure **(PEEP) for TCPL** mode, and 2 cmH$_2$O above the set **PEEP** level for **nCPAP** and **nTCPL** modes.

NOTE
The **Pres Limit** value is the absolute pressure value for the breath. Example: if the **Pres Limit** is set to 15 cmH$_2$O and **PEEP** is set to 5 cmH$_2$O, the pressure will be limited to 15 cmH$_2$O.

Cont Flow
Continuous Base Flow (lpm)

The **Cont Flow** control sets the continuous flow used in the breath delivery for **VG, TCPL, nTCPL** and **nCPAP** modes.

Scales	Neonatal Patient	2 to 30 lpm 2 to 20 lpm on nTCPL and nCPAP modes
	Default	6 lpm 8 lpm on nTCPL and nCPAP modes
	Pediatric Patient	2 to 50 lpm
	Default	20 lpm

Flow Base
Continuous Base Flow (lpm)

The **Flow Base** control sets the continuous flow used in the breath delivery for **nCPAP LP** and **Biphasic LP** modes.

Scales	Neonatal Patient	2 to 15 lpm
	Default	8 lpm

Flow High
High Flow to increase baseline CPAP (lpm)

The **Flow High** control sets the flow used in the breath delivery for **Biphasic LP** mode and in backup breaths in **nCPAP LP** mode. **Flow High** is delivered above the **Flow Base** setting.

NOTE
The resulting flow in breath delivery in **Biphasic LP** and **nCPAP LP** modes is the sum of **Base Flow** and **Flow High**. Example: if the **Flow Base** is set to 8 lpm and **Flow High** is set to 4 lpm, the resulting flow used in breath delivery will be 12 lpm. The resulting flow is limited to 20 lpm.

Scales	Neonatal Patient	0 to 10 lpm
	Default	2 lpm

Vol Target
Volume Target (ml)

The **Vol Target** control is active in **VG** and **PRVC**. The tidal volume target is based on the previous exhaled measured tidal volume. **Vol Target** is based on previous mandatory breaths, spontaneous breaths are excluded from the calculation.

NOTE
When **Breath Av** is active, the target volume will be based on the previous breath average cycles. Example, if **Breath Av** is set to 1, then the volume target will be based on the previous exhaled volume. If the **Breath Av** is set to 3, then the volume target will be based on the average of the last 3 mandatory breaths.

Mode	Patient	Minimum	Maximum	Default
PRVC PRVC + PS	Pediatric	20	500	**IBW x mL/kg**
	Adult	100	2000	**IBW x mL/kg**
VG VG + PS	Neonatal	2	100	**IBW x mL/kg**

NOTE
Excessive leaks may reduce the ability to achieve the desired Volume Target.

NOTE
Delivered volume may be reduced if inspiratory time and/or flow are inadequate to achieve the Volume Target. Volume guarantee will attempt to compensate by increasing delivered pressure up to 4 cmH2O below the pressure limit. The Low Volume alarm will be activated if the expiratory volume falls below the alarm threshold.

Back Up
Back Up Rate (b/min)

The **Back Up** control sets a Backup breath rate in **PS, CPAP, nCPAP** and **APRV** modes.

Mode	Patient	Minimum	Maximum	Default
PS + Backup	Neonatal	OFF, 1	60	OFF
	Pediatric	OFF, 1	40	
	Adult	OFF, 1	40	
nCPAP	Neonatal	OFF, 1	40	
CPAP	Pediatric	OFF, 1	40	
	Adult	OFF, 1	40	
APRV	Pediatric	OFF, 1	40	
	Adult	OFF, 1	40	

CPAP
Continuous Positive Airway Pressure (cmH$_2$O)

This control enables the adjustment of the expiratory pressure level in CPAP modes.

Mode	Patient	Minimum	Maximum	Default
CPAP + Backup	Pediatric Adult	0	20	5

PS
Pressure support (cmH$_2$O)

This control enables the adjustment of the pressure support to above the **PEEP**, on the spontaneous cycles in the **SIMV/CPAP** mode.

When the patient's effort is detected, the ventilator increases the inspiratory flow and pressure in the airway, up to the resulting inspiratory pressure value (**PEEP + PS**).

For example: for a pressure support set to 20 cmH$_2$O with a **PEEP** of 5 cmH$_2$O, the final inspiratory pressure value in the airway will be 25 cmH$_2$O.

The ventilator will finish the cycle, when the inspiratory flow reaches the cycling flow value set on the **PS** cycle control.

The pressure rise time, from **PEEP** to (**PEEP + PS)** will depend on the **Rise** adjustment.

Scales	Neonatal Patient	Off, 5 to 80 cmH$_2$O
		Off, 2 to 30 cmH$_2$O on VG mode
	Pediatric and Adult Patients	Off, 5 to 80 cmH$_2$O
	Default Value	15 cmH$_2$O
		5 cmH$_2$O on VG mode

NOTE
On spontaneous cycles with pressure support, the **PS** value is added to the **PEEP** value.

NOTE
During the respiratory cycles on **PCV**, **NIV,** and other modes using the programmed **PS**, the ventilator supplies a demand flow (free flow) of up to 180 lpm for adult, 100 lpm for pediatric, and 30 lpm for neonatal patients.

IPAP
Inspiratory Positive Airway Pressure (cmH$_2$O)

This control enables the adjustment of the Inspiratory Pressure Limit in non-invasive **Bilevel PC** mode. The **IPAP** value is an absolute pressure value, for example: when **IPAP** is set to 20 cmH$_2$O with **EPAP is set to** 5 cmH$_2$O, the final inspiratory pressure value in the airway will be 20 cmH$_2$O.

The Inspiratory pressure rise time from EPAP to IPAP is controlled via the Rise control in advanced settings.

Mode	Patient	Minimum	Maximum	Default
Bilevel PC CPAP + Backup	Pediatric Adult	5	40	15

EPAP
Expiratory Positive Airway Pressure (cmH$_2$O)

This control adjusts the expiratory pressure level in **Bilevel PC** mode.

Mode	Patient	Minimum	Maximum	Default
Bilevel PC	Pediatric Adult	0	20	5

Pres Trig
Pressure Trigger (cmH$_2$O)

Sets the level below PEEP at which the inspiratory trigger mechanism is activated. When the pressure in the patient circuit falls below the set PEEP by the set pressure trigger level, the ventilator will cycle to inspiration.

Mode	Patient	Minimum	Maximum	Default
VC VC + PS PC	Neonatal	-10	-0.3	OFF
PC + PS PS + Backup TCPL TCPL + PS PRVC PRVC + PS VG VG + PS APRV Bilevel PC CPAP + Backup	Pediatric Adult	-10	-0.5	OFF
nTCPL nCPAP Biphasic LP nCPAP LP	Neonatal	-10	-0.1	OFF

Flow Trig
Flow Trigger (lpm)

The inspiratory flow trigger mechanism is activated when the Net Flow becomes greater than the Flow Trig setting. Net Flow is defined as [Delivered Flow − Exhaled Flow] (or proximal inspiratory flow when using a proximal flow sensor).

Scales	Neonatal Patient 0.2 to 2 lpm; OFF
	Default Value 0.5 lpm
	Pediatric Patient 0.5 to 5 lpm; OFF
	Default Value 1.0 lpm
	Adult Patient 2 to 15 lpm; OFF
	Default Value 2.0 lpm

NOTE
During expiratory phase, iX5 ventilator provides a preset Bias Flow of 4 lpm.

NOTE
Whenever the patient's effort reaches the set sensitivity level, the *Patient Effort* indicator will be displayed on the ventilator screen.

> **NOTE**
> The improper pressure sensitivity (**Pres Trig**) or flow sensitivity (**Flow Trig**) adjustment may result in the autocycling of the equipment due to the occurrence of false-positive alarms or due to not detecting the patient's real efforts.

> **NOTE**
> The **iX5 ventilator** does not allow the simultaneous adjustment of the **Pres Trig** or **Flow Trig**. The adjustment of a value in any of the trigger sensitivities (**Flow Trig** or **Pres Trig**) will automatically turn the other off.

Insp Pause
Inspiratory Pause (s)

This control enables the activation of an inspiratory pause in the controlled and assisted cycles on the **VC** mode, according to the set pause time (**Insp Pause**).

Scale	Pediatric and adult patients 0.0 to 2.0 s
	Default Value 0.0 s

> **NOTE**
> During the inspiratory pause, in the absence of flow, the equalization between the alveolar pressure and the airway pressure occurs, monitored on the manometer. Therefore, it is possible, during the inspiratory pause, to directly check on the ventilator manometer, or on the graphic or digital display, the *Plateau Pressure* value (**alveolar pressure at the end of inhalation**, **elastic pressure of the lung**, **plateau pressure**).

Advanced Settings Characteristics and Ranges

Waveform Tab

This control enables the adjustment of the inspiratory flow in **VC** mode.

Besides amplitude, the **VC** mode enables the selection of three different waveforms:

- Decreasing flow ( )

  The initial flow (*Insp Peak Flow*) will be 50% greater than the set value, while the end of cycle flow will be 50% lower than the value set on **Insp Flow**. Therefore, the inspiratory time and the I:E ratio will be maintained equivalent to those of a constant flow cycle at a lower airway pressure.

- Sinusoidal flow ( )

  The initial flow (*Insp Peak Flow*) will be 56% greater than the set value, in order to maintain the inspiratory time and the I:E ratio equivalent to those of a constant flow cycle.

- Constant flow ( )

  The value of the set flow is kept constant throughout the entire inspiratory time.

Scales	Pediatric Patient	2 to 50 lpm
	Default Value	20 lpm
	Adult patient	2 to 120 lpm
	Default Value	30 lpm

Rise
Inspiratory Rise Slope (%)

The Inspiratory Rise setting controls the slope of the pressure rise during a mandatory breath, whether it is in **Insp Pres, P Backup, PS** or **IPAP**. This control affects the inspiratory flow and with a higher Rise% to pressure, there will be a higher flow required.

The Inspiratory Rise control is not active for TCPL breaths.

Scales	All Patients	25% (slow) to 100% (fast)
	Default Value	50%

NOTE
All patient range 25-100%

A Rise % higher means a faster rise or pressure slope = 100%, conversely a slower Rise % percentage equates to a slower rise or pressure slope = 25%.

PC Cycle
Pressure Control Flow Cycle for Mandatory Breaths in PC and PRVC

This control sets the ability to turn flow cycle on or off for mandatory pressure breaths in PC, PRVC and Bilevel PC modes. When **PC Cycle** is active, the control sets the percentage of peak inspiratory flow at which the inspiratory phase of a pressure breath is terminated..

Scales	All Patients	10 to 75%
	Default Value	OFF

NOTE
When PC Cycle is active, the mandatory pressure breaths will be terminated based on either flow cycle or time cycle, whichever comes first.

A lower percentage of flow cycle such as 10% can mean a longer breath cycle, while a higher flow cycle percentage such as 75% may mean a shorter breath cycle.

PS Cycle
Pressure Support Flow Cycle %

The **PS Cycle** control sets the percentage of peak inspiratory flow at which the inspiratory phase of a pressure breath is terminated.

Scales	All Patients	10 to 75%
	Default Value	25%
	Neonatal Patients	10%

NOTE
A lower percentage value of flow cycle such as 10% can mean a longer breath cycle, where a higher flow cycle percentage such as 75% may mean a shorter breath cycle.

Sigh Tab

Sigh
Sigh Breath On/Off

This control determines whether a sigh breath will be active in either **VC** or **PC** breath types. The control is can be set either on or off. The ventilator will deliver a sigh breath when this setting is ON. The sigh breath configuration, duration and frequency delivered is determine by the **Sigh %,** Sigh **Breaths** and Sigh **Interval** control settings.

Range: On/Off

Default: Off

Sigh%
Sigh%

The Sigh% sets the configuration of the Sigh Breath by percentage. For example, if the ventilator is in **VC** and the **Sigh %** is set to 50%, the Sigh breath will deliver a volume breath 1.5 times or 50% greater than the set Volume control. In **PC**, if the Sigh % is set to 25%, the delivered Sigh breath will be 1.25 time higher or 25% greater than the set **Insp Pres** control. Sigh breaths are active in both **VC** and **PC**.

Mode	Patient	Minimum	Maximum	Default
VC VC + PS PC PC + PS	Pediatric Adult	25	50	25

Cycle Breath
Cycle Breath

This control sets the number of sigh breaths that can occur in one sequence.

Mode	Patient	Minimum	Maximum	Default
VC VC + PS PC PC + PS	Pediatric Adult	1	3	1

Cycle Interval
Cycle Interval

This control sets the interval for when the Sigh breaths will occur. Example, if the Sigh Interval is set to 20, the ventilator will deliver a number of Sigh Breaths based on the **Sigh Cycle** setting, at the **Sigh%** size every 20 breaths as set by the **Sigh interval.**

Mode	Patient	Minimum	Maximum	Default
VC VC + PS PC PC + PS	Pediatric Adult	20	100	20

Nebulizer Tab

Nebulizer On/Off
Nebulizer (lpm)

This feature enables the auxiliary flow for nebulization. The user should activate nebulization after a standard nebulizer is connected and positioned on the inspiratory limb of the breathing circuit. The nebulization flow is compensated in order to maintain the previously set oxygen concentration in all breath types and volume compensates in **VC** only.

Scales	Nebulization Flow	
	Neonatal patient	3 lpm
	Pediatric patient	6 lpm
	Adult patient	6 lpm

Mode

Sync: Nebulization is synchronized with the patient's inspiratory flow only

Cont: Nebulization is delivered continuously throughout the breath cycle, both on inspiration and expiration.

Neb time
Nebulization time (mins)

The user is able to select the nebulization time, when the time is reached the nebulization flow is automatically terminated.
Range: 5–30 min.
Default: 15 min.

> ⚠️ *WARNING*
> The ventilator accuracy can be affected by the gas added by use of a external nebulizer.

TGI Tab:

TGI on/off

This control enables the Tracheal Gas Insufflation maneuver.
Range: On/Off

TGI
Tracheal Gas Insufflation (lpm)

This feature promotes the "flushing" of CO_2 retained in the airways during exhalation. Flow is synchronized with the expiratory phase of the breath cycle.

A non-proprietary catheter designed for this maneuver is positioned at the patient's carina.

> *NOTE*
> The delay in the activation of the TGI flow (**TGI Delay**) is intended to be in synchrony with the patients exhaled gas, increasing the flushing efficiency and minimizing the risk of auto-**PEEP** occurring.

Scale	TGI Flow	
	Neonatal Patient	3 lpm
	Pediatric Patient	6 lpm
	Adult Patient	6 lpm

AAC Tab

AAC On/Off
Artificial Airway Compensation On/Off

This control switch enables **AAC** in **PC** and **PS** breath types.

AAC%
Artificial Airway Compensation %

The **AAC%** control sets the percentage of resistance that is being applied to endotracheal tube (ETT) for compensation. For example, a setting of 75% results in a 75% resistance compensation of the ETT.

NOTE
AAC is available only in Pediatric and Adult patient sizes.

Range: 10-75%

Default: 10%

ETT Size
Endotracheal Tube Size (mm)

This ETT Size setting is where the user identifies the size of the ETT being used. From this setting the resistance of the tube is calculated and is used for resistance compensation set in **AAC%**.

Range: 2.0–12.0 mm

Default: 8.0 mm

Advanced Setting Tab

APRV:
T Delay
Time Delay (secs)

Setting a time delay in APRV helps synchronize the transition from both Pressure High and Pressure Low with the end of the patients expiratory cycle.

NOTE
In very high respiratory rates, if the T Delay is active, it may not allow the transition from both Pressure High and Pressure Low.

Mode	Patient	Minimum	Maximum	Default
APRV	Pediatric Adult	OFF; 0,2	1.0	OFF
	Infant	N/A	N/A	N/A

PS High
Pressure Support High (cmH2O)

This control allows the user to set Pressure Support during **Time High** in **APRV / BiPhasic**. If **PS High** is activated, during **Time High**, the ventilator will deliver the set pressure support for spontaneous triggered breaths.

⚠️ *WARNING*
The PS High setting is measured above the P High setting. The PS High setting should be set at an appropriate level for the patient to avoid over delivery of pressure in support breaths during Pressure High.

NOTE
High Ppeak alarm should be set above Pres High + PS High in order to avoid improper alarm activation.

Mode	Patient	Minimum	Maximum	Default
APRV	Pediatric Adult	OFF; 5	80	OFF
	Infant	N/A	N/A	N/A

PS Low
Pressure Support Low (cmH2O)

This control allows the user to set Pressure Support during **Time Low** in **APRV / BiPhasic**. If **PS Low** is activated, during **Time Low**, the ventilator will deliver the set pressure support for spontaneous triggered breaths.

Mode	Patient	Minimum	Maximum	Default
APRV	Pediatric Adult	OFF; 5	40	OFF
	Infant	N/A	N/A	N/A

VG:
Breath Av
Breath Average (Breath)

The **Breath Av** setting in **VG** allows the clinician to set the number of breaths for which the ventilator uses to calculate the average volume delivered. Using **Breath Av** can help with irregular breathing patterns and help to provide a basis for a more consistent regulated pressure delivery.

> *NOTE*
> When in **SIMV** mode, **Breath Av** does not take into consideration the spontaneous triggered breaths. **Breath Av** will take the average of the previous mandatory breaths for the target volume.

Mode	Patient	Minimum	Maximum	Default
VG VG + PS	Neonatal	1	60	1

Vol Limit
Volume Limit

The **Vol Limit** setting sets the volume limit for a Volume Guarantee breath. When the volume delivered to the patient meets or exceeds the preset **Vol Limit**, the inspiratory phase of the breath is terminated.

Mode	Patient	Minimum	Maximum	Default
VG VG + PS	Neonatal	10	120	2 x **IBW** x **mL/kg**

Pres Min
Pressure Minimum (cmH$_2$O)

The **Pres Min** control works as a pressure minimum band and also as the inspiratory pressure used for the test breath sequence in **VG**. The default for the test breath is 10cmH20 unless otherwise changed by the user. The pressure minimum is displayed on the monitoring screen with a colored line displaying where the **Pres Min** is set. When the **Pres Min** limit is reached an alarm notification will be exerted.

> *NOTE*
> In VG breaths, the pressure may be modulated between Pres Min and Pres Max in order to achieve the Vol Target setting. The Pres Min setting should be set at an appropriate level for the patient to avoid under delivery of pressure.

Mode	Patient	Minimum	Maximum	Default
VG VG + PS	Neonatal	5	30	10

Pres Max
Pressure Maximum (cmH$_2$O)

The **Pres Max** control works as a pressure maximum band in **VG**. The pressure maximum is displayed on the monitoring screen with a colored line displaying where the **Pres Max** is set. When the Pressure Maximum limit is reached the breath will cycle to exhalation.

> *NOTE*
> In VG breaths the pressure may be modulated between Pres Min and Pres Max in order to achieve the Vol Target setting. The Pres Max setting should be set at an appropriate level for the patient to avoid over delivery of pressure.

Mode	Patient	Minimum	Maximum	Default
VG VG + PS	Neonatal	10	70	20

P Backup
Backup Pressure (cmH$_2$O)

In **VG**, **P Backup** is used for test breaths and acts as a backup pressure setting during certain alarm conditions.

> ⚠️ *CAUTION*
> If a proximal flow sensor is used it must be attached at both the patient wye and at the ventilator connection to ensure proper function of the iX5 ventilator.

> *NOTE*
> Excessive inspiratory flow rates or highly compliant ventilator circuits may allow delivery of a tidal volume that exceeds the volume limit setting. This is due to the ventilator circuit recoiling and providing additional tidal volume to the patient. Delivered tidal volumes should be closely monitored to ensure Volume Limit accuracy.

Slow Flow Maneuver

The Slow Flow maneuver allows the clinician to determine opening pressures of the lung during a slow flow volume controlled breath. Because this maneuver is performed at a slow inspiratory flow rate the effects of respiratory system resistance are minimized.

> *NOTE*
> Performance of the Slow Flow maneuver requires a passive patient. In the event that a patient effort is detected the ventilator will abort the maneuver and returns to normal ventilation at the current settings.

The Slow Flow maneuver screen allows the operator to set:

Vol Max – This is the maximum tidal volume delivered to the patient during the maneuver. This setting has no effect on the settings during normal ventilation and can be set to any tidal volume desired independent of the current mode of ventilation.

Range: 300 to 2000 mL

Default: 500 mL

P Max – This is the maximum inspiratory pressure during the maneuver.

Range: 10 to 80 cmH$_2$O

Default: 30 cmH$_2$O

T Max – This is the maximum duration of the maneuver.

Range: 5 to 40s

Default: 20 s **Flow – This is the inspiratory flow used to deliver the maneuver tidal volume.**

Range: 4 to 20 lpm

Default: 6 lpm

Mode
I (Inspiratory)
I+E (Inspiratory and Expiratory)

It defines whether the maneuver will perform during the inspiratory phase of the breath, or during both inspiratory and expiratory phases. Default: I+E
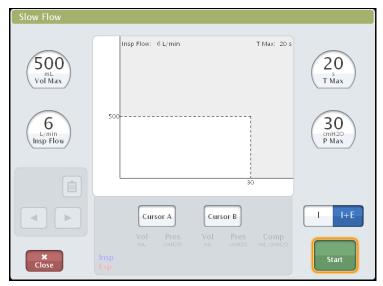
Figure 5-2. Slow Flow Maneuver Screen

During this maneuver, only the P x V loop graph will be visible on the corresponding area of the screen. After the maneuver is completed, the **Freeze** function will be automatically activated, enabling the use of the cursor to determine the inflection point of the P x V loop.

NOTE
All maneuver control settings are independent of control settings in normal ventilation.

⚠️ *WARNING*
Normal ventilation is suspended for the duration of the maneuver. The patient should be evaluated for contraindications prior to executing the maneuver. The patient should be directly monitored by trained medical personnel during the maneuver.

Suction

There are two ways to do the suction procedure:

Open

Pressing the 100% O2 button starts the oxygenation process, adjusting the oxygen concentration to 100% for 3 minutes. If the button is pressed again within 1 minute, the maneuver will be interrupted, immediately returning to the previously set oxygen concentration value.

> **Phase I –** Pre-Oxygenation – 100% O_2 (LEDs: **100% O_2** lit, **Standby Mode** off):

- Pressing the **100% O_2** button starts the oxygenation process, adjusting the oxygen concentration to 100% for 3 minutes. If the button is pressed again within 1 minute, the maneuver will be interrupted, immediately returning to the previously set oxygen concentration value.

- After 3 minutes, if the **Standby Mode** button is not pressed, then Phase IV is started with the oxygen concentration returning to the previously set value at a rate of 20% per minute.

> **Phase II –** Suction – Standby Mode (LEDs: **100% O_2** lit, **Standby Mode** lit):

- After pressing the **Standby Mode** button during Phase I sequence, the operator can disconnect the patient from the ventilator and start the suction procedure, while the ventilator is in Standby Mode for up to 1 minute without alarms.

- The operator can reconnect the patient and resume ventilation at any time, by pressing the **Standby Mode** button or the **Start Ventilation** button again. In case the **Standby Mode** button or the **Start Ventilation** button has not been pressed after 1 minute, a continous visual signal is activated followed by an audible alarm every 15 seconds, warning the operator to reconnect the patient to the ventilator and resume ventilation.

> **Phase III –** Post-Oxygenation – 100% O_2 (LEDs: **100% O_2** lit, **Standby Mode** off):

- After reconnecting the patient and pressing the **Standby Mode** button or the **Start Ventilation** button, the ventilator will maintain the oxygen concentration at 100% for 3 more minutes, or until the **100% O_2** button is pressed again, returning to the previously set oxygen concentration value at the rate of 20% per minute (Phase IV).

> **Phase IV –** Weaning (LEDs: **100% O_2** flashing, **Standby Mode** off)

- The return from the 100% oxygen condition to the previously set concentration is performed gradually, at a rate of approximately 20% of O_2 per minute.

Closed

Closed-suction procedure

The following pressure ventilation modes may be used with a closed suction catheter:
- PC
- PC + PS
- PS
- APRV/BiPhasic

Use the proper patient settings and follow the hospital institution protocols for the closed-suction procedure.

Alarms, such as, patient disconnected, low Vte, apnea, and other may occur during use of a closed suction catheter. To perform suctioning without nuisance alarms, set alarms at minimum sensitivity or perform an open suction procedure.

6-1

Chapter 6   Alarms and Messages

Alarms

Introduction

The **iX5 ventilator** features **low**, **medium,** and **high priority** visual and audible alarms, classified according to the urgency required for the action to be taken by the operator.

Low Priority Alarm

It requires a **brief** response from the operator. Its visual indication is in a **continuous blue** color and it has an associated audible indication of a single pulse every 60 seconds..

Medium priority alarm

It requires a **fast** response from the operator. Its visual indication is in a **flashing yellow** color, associated with an audible indication of 3 pulse every 25 seconds.

High priority alarm

It requires an **immediate** response from the operator. Its visual indication is in a **flashing red** color, associated with an audible indication of 10 pulses (5 + 5) every 10 seconds.

Priority	High	Medium	Low
Situation	Warning	Caution	Advisory
Visual Indication	Red	Yellow	Blue
Audible Indication	Every 10s	Every 25s	Every 60s

Alarm status

An alarm is considered **active** when the condition that has generated it remains present in the system. This alarm is indicated by an audible and visual signal (Master Alarm and flashing message on the upper area of the screen). When the condition that has originated an alarm ceases to exist, it goes to the **persistent** status, characterized by a visual sign only (non-flashing message on the upper area of the screen).

> *NOTE*
> The messages with higher priority are displayed in an alternating way, according to the following list:
>
> - High priority active alarms
>
> - Medium priority active alarms
>
> - Low priority active alarms
>
> - High priority persistent alarms
>
> - Medium priority persistent alarms
>
> - Low priority persistent alarms
>
> - When there are no items from a higher order, the next order items will be alternated until there are no messages.

> *NOTE*
> A numerical indicator displaying the total number of existing alarms is shown on the right-hand side of the message area whenever there is more than one simultaneous occurrence. Upon touching the screen on the visible alarm message or on the message counter, a list of active and persistent alarms will be displayed, which will be automatically closed after 5 seconds or with a new touch on the list.

> *NOTE*
> For optimal awareness of an alarm state, the ideal operator position is one meter in front of the iX5 screen at an angle subtended by 30 degrees from the screen midpoint horizontal and normal to the screen plane.

> *NOTE*
> To ensure that the device is accurately calibrated, perform the Functional Verification Test (FVT) outlined in Chapter 10. The FVT procedure must be performed prior to connecting the patient to the device.

Audio Paused / Alarm Reset
(Alarm silenced and clearing of inactive alarms)

This button, located on the front panel, silences the active alarm for **120 seconds**; it can be reactivated, if the button is pressed again within this period. The lighting of the yellow-colored LED indicates that the audio is temporarily silenced.

The alarm reset button clears visual indicators for alarms that are no longer active.

> *NOTE*
> The Audio Paused / Alarm Reset button does not prevent alarm activation when a new alarm generating condition occurs.

Ventilation Alarms

> *NOTE*
> The adjustment ranges for each of the ventilator alarms may vary, depending on the type of patient selected (neonatal, pediatric or adult) and the ventilation mode applied (invasive or non-invasive ventilation).

> *NOTE*
> Unless it is specifically stated, the alarm signal generation delay is of one breath cycle.

> *NOTE*
> Do not adjust any of the Alarm Limit settings to an extreme value. Selecting an extreme value can make the alarm system inadequate for the patient.

Autoset

This feature suggests values for the alarm limits to make the adjustment easier.

The limits suggested by the ventilator depend on the type of patient selected, as well as on the monitoring and control setting conditions during ventilation.

To adjust the alarms using this feature, the operator shall Press the **Autoset** button, check the values suggested for each alarm and confirm them by pressing the "Apply" button. The alarm limits are indicated by operator action when needed.

Note: This feature is not available on the initial setting. It is enabled only after ventilation has already started.

Alarm and Event Log Screen

The **iX5 ventilator** stores the log of all alarms and events occurred during the last **72 hours** or the last **10.000 records**, whichever happens first (older records are discarded after that limit is reached). Each record contains its date, time, type and identification indication.

When **iX5 ventilator** experiences a total loss of power (mains and internal battery depleted), the log is maintained by the system.

The list of events can be filtered to display alarms only, events only or both types of occurrences.

Adjustable Alarms

Low Peak Pressure
Parameter: Low Ppeak (cmH$_2$O)
High Priority

This alarm defines the minimum airway pressure limit that must be reached during the inspiratory phase of the controlled and/or assisted and spontaneous cycles with pressure support greater than 5 cmH$_2$O.

Mode	IBW	Min	Max	Default	Auto Set
VC PC TCPL PS+Backup	All	3	70	To a maximum of 25 cmH2O	Ppeak – 5
VG	Neo	3	70	PEEP + Pres Min – 5	PEEP + Pres Min – 5
PRVC	Ped Adult	3	70	PEEP + 5	PPeak – 5
APRV	Ped Adult	3	70	Pres Low + PS Low – 5	Pres Low + PS Low – 5
nTCPL nCPAP+Backup	Neo	2	30	7	Ppeak – 5
Biphasic LP nCPAP LP	Neo	2	15	5	Ppeak – 5
Bilevel PC CPAP+Backup	Ped Adult	3	60	To a maximum of 25 cmH$_2$O	Ppeak – 5

High Peak Pressure
Parameter: High Ppeak (cmH$_2$O)
High Priority

> ⚠️ **WARNING**
> If High Ppeak alarm is set too close to PEEP setting, Circuit Occlusion alarm may be triggered.

This alarm defines the maximum airway pressure limit during the inspiratory phase of controlled, assisted and spontaneous cycles.

If, during the inspiratory phase, the pressure limit established by the alarm is reached, the ventilator will immediately interrupt the cycle and return to the set expiratory pressure (**PEEP**) value.

Mode	IBW	Min	Max	Default	Auto Set
VC PC TCPL PS+Backup	All	10	120	30	Ppeak + 5
VG PRVC	VG – Neo PRVC – Ped/Adult	10	120	PEEP + Pres Max + 10	PEEP + Pres Max + 10
APRV	Ped Adult	10	120	Pres High + PS High + 10	Pres High + PS High + 10
nTCPL nCPAP+Backup	Neo	5	40	20	Ppeak + 5
Biphasic LP nCPAP LP	Neo	5	20	15	Ppeak + 5
Bilevel PC CPAP+Backup	Ped Adult	5	40	30	Ppeak + 5

Low Minute Volume
Parameter: Low Min Vol (L)
Medium Priority

This alarm defines the minimum **exhaled minute volume** limit, considering mandatory and spontaneous cycles.

Mode	IBW	Min	Max	Default	Auto Set
VC	Ped	OFF; 0.10	20.0	(Volume x Rate) – 40%	Min Vol – 40%
	Adult	OFF; 1.0	40.0		
PC TCPL	Neo	OFF; 0.01	2.0	(IBW x mL/kg x Rate) – 40%	Min Vol – 40%
	Ped	OFF; 0.10	20.0		
PS+Backup	Adult	OFF; 1.0	40.0	OFF	OFF
VG	Neo	OFF; 0.01	2.0	(Vol Target x Rate) – 40%	Min Vol – 40%
PRVC	Ped	OFF; 0.10	20.0	(Vol Target x Rate) – 40%	Min Vol – 40%
	Adu	OFF; 1.0	40.0		
APRV	Ped	OFF; 0.10	30.0	OFF	OFF
	Adult	OFF; 1.0	40.0		
nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF
Bilevel PC CPAP+Backup	Ped	OFF; 0.10	20.0	OFF	OFF
	Adu	OFF; 1.0	40.0		

High Minute Volume
Parameter: High Min Vol (L)
Medium Priority

This alarm defines the maximum **exhaled minute volume** limit, considering mandatory and spontaneous cycles.

Mode	IBW	Min	Max	Default	Auto Set
VC	Ped	0.10	30.0; OFF	(Volume x Rate) + 40%	Min Vol + 40%
	Adult	1.0	60.0; OFF		
PC TCPL	Neo	0.01	3.0; OFF	(IBW x mL/kg x Rate) + 40%	Min Vol + 40%
	Ped	0.10	30.0; OFF		
PS+Backup	Adult	1.0	60.0; OFF	OFF	OFF
VG	Neo	0.01	3.0; OFF	(Vol Target x Rate) + 40%	Min Vol + 40%
PRVC	Ped	0.10	30.0; OFF	(Vol Target x Rate) + 40%	Min Vol + 40%
	Adult	1.0	60.0; OFF		
APRV	Ped	0.10	30.0; OFF	OFF	OFF
Bilevel PC CPAP+Backup	Adult	1.0	60.0; OFF	OFF	OFF
	Ped	0.10	30.0; OFF		
nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF

Low Volume
(Low Exhaled Tidal Volume)
Parameter: Low Vol (mL)
Medium Priority

This alarm defines the minimum **exhaled tidal volume** limit on mandatory cycles. It is activated after **three consecutive mandatory cycles** whose monitored **exhaled tidal volume** is smaller than the limit set on the alarm.

Mode	IBW	Min	Max	Default	Auto Set
VC	Ped	OFF; 10	500	Volume – 50%	Volume – 50%
	Adult	OFF; 100	2,000		
PC TCPL APRV PS+Backup	Neo	OFF; 1	50	(IBW x mL/kg) – 50%	Vte – 50%
	Ped	OFF; 10	500		
	Adult	OFF; 100	2,000		
VG	Neo	OFF; 1	50	Vol Target – 50%	Vol Target – 50%
PRVC	Ped	OFF; 10	500	Vol Target – 50%	Vol Target – 50%
	Adult	OFF; 100	2,000	Vol Target – 50%	Vol Target – 50%
nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF
Bilevel PC CPAP+Backup	Ped	OFF; 10	500	(IBW x mL/kg) – 50%	Vte – 50%
	Adult	OFF; 100	2,000		

High Volume
(High Exhaled Tidal Volume)
Parameter: High Vol (mL)
Medium Priority

This alarm defines the maximum **exhaled tidal volume** limit on mandatory and spontaneous cycles.

Mode	IBW	Min	Max	Default	Auto Set
VC	Ped	10	500; OFF	Volume + 50%	Volume + 50%
	Adult	100	2,000; OFF		
PC TCPL APRV PS+Backup	Neo	1	50; OFF	(IBW x mL/kg) + 50%	Vte + 50%
	Ped	10	500; OFF		
	Adult	100	2,000; OFF		
VG	Neo	1	50; OFF	Vol Max + 5	Vol Max + 5
PRVC	Ped	10	500; OFF	Vol Target + 50%	Vol Target + 50%
	Adult	100	2,000; OFF	Vol Target + 50%	Vol Target + 50%
nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF
Bilevel PC CPAP+Backup	Ped	10	500; OFF	(IBW x mL/kg) + 50%	Vte + 50%
	Adult	100	2,000; OFF		

Apnea
Parameter: Apnea (s)
Medium / High Priority

This alarm is active on all ventilation modes and defines the **maximum apnea limit** (period without patient's inspiratory effort). In the event of apnea, the ventilator delivers a **backup cycle** according to the parameters set by the user for mandatory cycles.

This alarm starts with Medium Priority and evolves to High Priority in the event of three consecutive apnea periods.

Mode	IBW	Min	Max	Default	Auto Set
VC PC TCPL VG PRVC	All	3	60; OFF	(60/Rate) + 5	Te + 5
APRV	All	3	60; OFF	OFF	OFF
PS+Backup	Neo	3	60; OFF	5	OFF
	Ped	3	60; OFF	10	
	Adult	3	60; OFF	15	
nTCPL nCPAP+Backup	Neo	3	60; OFF	OFF	OFF
Biphasic LP nCPAP LP	Neo	3	60; OFF	OFF	OFF
Bilevel PC CPAP+Backup	Ped	3	60; OFF	10	Te + 5
	Adult	3	60; OFF	15	Te + 5

Low Respiratory Rate
Parameter: Low Rate (/min)
Medium Priority

This alarm defines the minimum **respiratory rate** limit, considering mandatory and spontaneous respiratory cycles.

Mode	IBW	Min	Max	Default	Auto Set
VC PC TCPL VG PRVC APRV PS+Backup Bilevel PC CPAP+Backup	Neo	OFF; 4	120	25	Rate – 30%
	Ped	OFF; 4	120	15	
	Adult	OFF; 4	120	5	
nTCPL nCPAP+Backup	Neo	OFF; 4	60	20	Rate – 30%
Biphasic LP nCPAP LP	Neo	OFF; 4	60	10 on Biphasic LP OFF on nCPAP LP	Rate – 30%

High Respiratory Rate
Parameter: High Rate (/min)
Medium Priority

This alarm defines the maximum **respiratory rate** limit, considering mandatory and spontaneous respiratory cycles.

Mode	IBW	Min	Max	Default	Auto Set
VC PC TCPL VG PRVC APRV PS+Backup Bilevel PC CPAP+Backup	Neo	4	180; OFF	50	Rate + 30%
	Ped	4	180; OFF	30	
	Adult	4	180; OFF	20	
nTCPL nCPAP+Backup	Neo	4	80; OFF	40	Rate + 30%
Biphasic LP nCPAP LP	Neo	4	80; OFF	40 on Biphasic LP OFF on nCPAP LP	Rate + 30%

Low FiO2
Parameter: Low FiO2 (%)
Medium Priority / High Priority

This alarm defines the minimum oxygen concentration (FiO_2) limit measured in the gas mixture supplied to the patient. It is activated whenever the measured concentration (FiO_2) is below the alarm set value.

Mode	IBW	Min	Max	Default	Auto Set
All	All	OFF; 19	100	$\%O_2$ – 5	FiO2 – 5

> ***NOTE***
> The FiO2 Low alarm evolves to High Priority when the measured concentration value is lower than or equal to 18%.

High FiO2
Parameter: High FiO2 (%)
Medium Priority

This alarm defines the maximum oxygen concentration (FiO_2) limit measured in the air/oxygen mixture supplied to the patient. It is activated whenever the measured concentration (FiO_2) is above the alarm set value.

Mode	IBW	Min	Max	Default	Auto Set
All	All	19	100; OFF	$\%O_2 + 5$	$FiO_2 + 5$

Low PEEP
Parameter: Low PEEP (cmH$_2$O)
Medium Priority

This alarm defines the minimum **expiratory pressure (PEEP)** limit measured in the airways. It is activated when the difference between the airway pressure value during the expiratory phase and the **PEEP** value set is higher than the set value, observing the following conditions:

- For expiratory times shorter than 15 seconds and after 3 consecutive cycles.

- For expiratory times greater than 15 seconds, the alarm will activate immediately.

This alarm is defined 3 cmH$_2$O below the set **PEEP**, with the exception for nTCPL, nCPAP+Backup, Biphasic LP and nCPAP LP modes:

Mode	IBW	Min	Max	Default	Auto Set
nTCPL nCPAP+Backup	Neo	0	15	PEEP – 2	PEEP – 2
Biphasic LP nCPAP LP	Neo	0	15	2	PEEP – 2

High PEEP
Parameter: High PEEP (cmH$_2$O)
Medium Priority

This alarm defines the maximum expiratory pressure (**PEEP**) limit measured in the airways. It is based on the PEEP setting and is activated whenever the pressure in the airway during the expiratory phase is above the **PEEP** value on the current cycle, on the following conditions:

- For expiratory times shorter than 15 seconds and after 3 consecutive cycles.

- For expiratory times greater than 15 seconds, the alarm will activate immediately.

This alarm is defined 5 cmH2O above the set **PEEP**, with the exception for nTCPL, nCPAP+Backup, Biphasic LP and nCPAP LP modes:

Mode	IBW	Min	Max	Default	Auto Set
nTCPL nCPAP+Backup	Neo	3	20	PEEP+2	PEEP + 2
Biphasic LP nCPAPLP	Neo	3	20	7	PEEP + 2

Non-adjustable Alarms

Auto PEEP
Low Priority

The **Auto PEEP** alarm is activated if the Expiratory Flow does not reach a minimum value at the end of exhalation on three consecutive cycles. This minimum value is defined from the **Expiratory Peak Flow** value**.**

Non-adjustable value	All patients	50% of the Expiratory Peak Flow value

Auto Trigger
High Priority

The **Auto trigger** alarm is activated if, during three consecutive cycles, the start of an assisted or spontaneous cycle with **Expiratory Time** smaller than half of the **Inspiratory Time** (equivalent to a I:E ratio = 2:1) is detected.

Technical Alarms (non-adjustable)

Low O2 Pres
Low Oxygen Intake Pressure (kPa)
High Priority

The **Low O2 Pressure** alarm is activated if the oxygen intake pressure is lower than **250 kPa** (2.5 kg/cm^2) and oxygen concentration (**% O$_2$**) set on the ventilator is higher than **21%**. If the oxygen flow is insufficient to meet the programmed demand, the ventilator will automatically compensate the flow with compressed air, eventually leading to the activation of the **Low FiO2** alarm. If the oxygen intake pressure reaches levels below **120 kPa** (1.2 kg/cm^2), the ventilator switches to air intake and continues operating on the **Low O2 Pressure** alarm condition.

> *NOTE*
> On the **Low O2 Pressure** condition, the ventilator checks the air pressure level, also activating the **Low Air Pressure** alarm, in case it also features a value lower than **250kPa (**2.5 kg/cm^2).

Low Air Pres
Low Air Intake Pressure (kPa)
High Priority

The **Low Air Pressure** alarm is activated if the compressed air intake pressure is lower than **250kPa** (2.5 kg/cm^2) and if the oxygen concentration **(% O2)** set on the ventilator is lower than **100%**. If the air flow is insufficient to meet the programmed demand, the ventilator will automatically compensate the flow with oxygen, eventually activating the **High FiO2** alarm. If the oxygen intake pressure reaches levels below **120 kPa** (1.2 kg/cm^2), the ventilator switches to the oxygen intake and continues operation on the **Low Air Pressure** alarm condition.

> *NOTE*
> In the **Low Air Pressure** condition, the ventilator checks the oxygen pressure level, activating the **Low O2 Pressure** alarm, in case it also features a value lower than **250 kPa** (2.5 kg/cm^2).

> ⚠ *WARNING*
> In the event that the ventilator cannot meet the required inlet pressure, the Gas Fail alarm will be triggered and the ventilator will go into an inoperative state and activate the Vent Inop alarm. Remove the patient from the device and provide an alternate source of ventilation.

High O2 Pres
High Oxygen Intake Pressure (kPa)
High Priority: Pressure > 600 kPa

The **High O2 Pressure** alarm is activated if the oxygen intake pressure exceeds **600 kPa** (6.0 kg/cm^2). In this situation, the operator must reduce the intake pressure, using, for example, pressure reducing valves.

As a safety feature, the ventilator also integrates an intake pressure relief valve mechanism for each gas, set to **650 kPa** (6.5 kg/cm^2). If the pressure exceeds this value, the valves will open to the atmosphere, limiting the ventilator supply pressure.

Ext High O2 Pres
Oxygen Intake Overpressure (kPa)
High Priority: Pressure > 660 kPa

In extreme situations, when the intake pressure exceeds the **660 kPa** limit, the alarm displays **O2 Overpressure**, with **High Priority**, enters a Vent Inop condition, and generates a Vent Inop alarm.

High Air Pres
High Air Intake Pressure (kPa)
High Priority: Pressure > 600 kPa

The **High Air Pressure** alarm is activated if the compressed air intake pressure exceeds **600 kPa** (6.0 kg/cm^2). In this situation, the operator must reduce the intake pressure, using, for example, pressure reducing valves.

As a safety feature, the ventilator also integrates intake pressure relief valve mechanisms for each gas, set to **650 kPa** (6.5 kg/cm^2). If the pressure exceeds this value, the valves will open to the atmosphere, limiting the ventilator supply pressure.

Ext High Air Pres
Air Intake Overpressure (kPa)
High Priority: Pressure > 660 kPa

On extreme situations, when the intake pressure exceeds the **660 kPa** limit, the alarm also starts displaying **Air Overpressure**, with **High Priority**, besides entering the inoperative condition, also generating the **Vent Inop** alarm.

⚠️ *WARNING*
Whenever the **O2 Overpressure** or the **Air Overpressure** condition occurs, the ventilator enters an inoperative condition, generating the **Vent Inop** alarm.

Internal Fail
High Priority

This alarm is activated for internal device failures requiring the user to discontinue use and find alternate methods of ventilation as soon as possible. Depending on the severity of the failure detected by the safety circuits, the ventilator can go to the inoperative condition, generating the **Vent Inop** alarm. In this situation, when both **Vent Inop** and **Internal Fail** alarms occur simultaneously, immediately stop using the equipment.

NOTE
In the occurrence of the **Internal Fail** alarm, contact Vyaire or a Vyaire Authorized Technician.

Vent Inop
High Priority

The **Vent Inop** alarm indicates that the ventilator is not operating and the electronic and pneumatic controls are inactive.

The inoperative condition can be generated by a power or intake gas supply failure, when the following alarms are also generated:

- Power Fail

- Gas Fail

- O2 Overpressure

- Air Overpressure

NOTE
The return to adequate power and gas supply conditions eliminates the **Vent Inop** condition.

The **Vent Inop** condition can also be generated by a technical failure, when the alarms associated with the failures indicated below are generated:

- Internal Fail

- Gas Administration Fail

- Regulator Pressure Fail

- Exhalation Valve Fail

- Low Internal Battery

NOTE
In the event of a **Vent Inop** alarm associated with a technical failure, immediately stop using the ventilator and contact Vyaire or a Vyaire Authorized Technician.

NOTE
The **Vent Inop** alarm is associated to a full-screen indication, highlighting the presence of this alarm condition.

The full-screen can be minimized by touching any point of the highlighted region. In case the alarm condition is not eliminated, the full-screen indication returns after 30 seconds.

Gas Fail (kPa)
High Priority

The **Gas Fail** alarm is activated when the ventilator cannot meet the minimum required demand, even after switching to the remaining gas. This condition occurs when both the air and the oxygen intake pressure is lower than **120 kPa** (1.2 kg/cm^2).

⚠️ *WARNING*
Whenever the Gas Fail condition occurs, the ventilator enters an inoperative condition, generating the Vent Inop alarm.

Power Fail
High Priority

The **Power Fail** alarm is activated when a failure in any internal voltage in the ventilator occurs.

⚠️ *WARNING*
Whenever a Power Fail condition occurs, the ventilator enters an inoperative condition, generating the Vent Inop alarm.

Patient disconnected
High Priority

The **Patient disconnected** alarm is activated when a patient disconnection is detected, when the difference between the volume supplied and the exhaled one is **equal to or greater than 95%.**

> *NOTE*
> The **Patient disconnected** alarm is associated to a full-screen indication, highlighting the presence of this alarm condition.
>
> The full-screen can be minimized by touching any point of the highlighted region. In case the alarm condition is not eliminated, the full-screen indication returns after 30 seconds.

Circuit Occlusion
High Priority

> ⚠ *WARNING*
> Circuit Occlusion alarm may be triggered if High Ppeak alarm is set too close to PEEP setting.

During ventilation, iX5 continuously monitors the difference between the pressure measured at the wye piece and the internal pressure of the manifold, measured at the gas output port. This difference takes into consideration the pressure drop generated by the flow in the inspiratory limb. The maximum acceptable value is:

Category	Formula
Adult	13.0 cmH2O + (0.0038 * measured Flow^2 - 0.0088 * measured Flow) cmH2O
Pediatric and Neonatal	13.0 cmH2O + (0.01 * measured Flow^2 - 0.0482 * measured Flow) cmH2O

If the maximum acceptable value is exceeded for more than 30 ms during inspiratory phase, or 60 ms during expiratory phase, then Circuit Occlusion alarm is activated.

Also, during exhalation phase, the pressure is verified against the maximum acceptable values of:

Category	Formula
Adult and Pediatric	PEEP + MAXIMUM(0.15 * PEEP; 10) cmH2O
Neonatal	PEEP + MAXIMUM(0.15 * PEEP; 10) cmH2O

If the maximum acceptable value is exceeded for more than 150 ms for neonatal category, 250 ms for pediatric category, or 400 ms for adult category, then Circuit Occlusion alarm is activated. Also, if the airway pressure reaches the High Ppeak alarm before the the persistence time is reached, then Circuit Occlusion alarm is activated.

After patient circuit is obstructed and the above conditions are met, the Circuit Occlusion alarm is generated in no longer than two breath cycles or 5 s, whichever is greater.

When the Circuit Occlusion alarm is activated, the ventilator immediately opens the safety valves for a 5 seconds period. After this period, the safety valve is closed and the ventilator attempts to control a PEEP of 5 cmH2O during 3 seconds. If it succedes, the ventilator understands that the cause of obstruction was cleared, therefore the alarm is changed from active to the persistent status and normal operation of ventilation is resumed. If the ventilator doesn't succeed to control a PEEP of 5 cmH2O during 3 seconds, the ventilator understands that the cause of obstruction remains. Therefore it is started a new cycle of opening the safety

valve for 5 seconds, closing the safety valve and attempt to control a PEEP of 5 cmH2O during 3 seconds.

Patient Circuit Leak
Low Priority

The **Patient Circuit Leak** alarm is activated if a leak in the breathing circuit is detected, when the difference between the supplied volume and the exhaled one is **equal to or greater than 50%** and **lower than 95%**.

This alarm is not activated in the **TCPL, nTCPL and nCPAP_Backup** modes.

Wrong Flow Sensor
Medium Priority

This alarm is activated if the type of the flow sensor connected to the ventilator differs from the patient category, as defined by the **IBW**. The sensor is identified by its connector through an optical sensor.

Flow Sensor Disconnect
Low Priority

This alarm is activated if the presence of a Proximal Flow Sensor or an Expiratory Flow Sensor is not detected. The flow sensors are identified by the connector through an optical sensor.

Gas Supply Fail
High Priority

This alarm is activated if the controlled flow differs from the supplied flow, measured by the internal flow sensor. Depending on the severity of the failure detected by the safety circuits, the ventilator can go to the inoperative condition, generating the **Vent Inop** alarm.

Standby Time Elapsed
High Priority

This alarm is activated if, after the maximum suction period (60 seconds), during the **100% O2** maneuver, ventilation has not been resumed through the activation of the **Standby Mode** button.

Low Internal Battery
Medium / High Priority

The Low Internal Battery alarm is activated when battery is near depletion, approximately 15 minutes of operation. The Low Internal Battery alarm evolves to High Priority at least 5 min prior to the loss of all power.

Note: The Vent Inop alarm may be activated as the remaining power is not enough to sustain ventilation.

NOTE
The estimated operating time after activating the Low Internal Battery alarm may vary according to the battery service life and the ventilator use mode.

⚠️ *WARNING*
When the **Low Internal Battery** alarm is activated, immediately connect the equipment to the power mains or to an external battery.

If the ventilator is not connected to a power source, the ventilator will go into an inoperative condition, generating the Vent Inop Alarm.

Internal Battery Fail
High Priority

The **Internal Battery Fail** alarm is activated when a failure on the internal battery or in the charging circuit is detected.

AC Line Fail
Medium Priority

The **AC Line Fail** alarm is activated with **Medium Priority** when the ventilator is powered by its internal battery, due to an AC Mains Power Supply failure.

After this alarm has been muted by the operator, by pushing the **Audio Paused/Alarm Reset** button, it will be replaced by the **Low Priority Battery in Use** alarm (see below).

High External Battery Voltage

High Priority

The High External Battery Voltage alarm is activated when the external battery voltage connected to Ext Batt port is above 14.5 V dc.

Internal Battery in Use
Low Priority

The Internal Battery in Use alarm is activated with **Low Priority** when the ventilator is powered by its internal battery, always after the **AC Line Fail** alarm has been muted (see above).

This alarm is also indicated by the **Internal Battery** LED on the ventilator's front panel.

Low Setup Battery
Low Priority

The **Low Setup Battery** alarm is activated if a failure is detected on the PCI Control RAM battery, which ensures that the last setup set into the machine is kept in the memory when the equipment is turned off. This alarm is only activated when the ventilator is turned on or as soon as the failure is detected, being cancelled after the **Audio Paused/Alarm Reset** button has been pressed. In this case, contact Vyaire or a Vyaire Authorized Technician, and arrange for the battery to be replaced as soon as possible because the ventilator data storage feature will be lost.

Fan Fail
Medium Priority

The **Fan Fail** alarm is activated when a failure on the internal cooling system of the ventilator is detected. In this case, stop using the equipment as soon as possible, and contact Vyaire or Vyaire Authorized Technician.

Exhalation Valve Fail
High Priority

The **Exhalation Valve Fail** alarm is activated when a failure on the exhalation valve control is detected. Depending on the severity of the failure, the ventilator can go into an **Internal Fail** or **Vent Inop** condition. In this case, stop using the equipment as soon as possible, and contact Vyaire or Vyaire Authorized Technician

Autozero Error
Medium Priority

The **Autozero Error** alarm is activated when a failure during the autozero routine of the transducer responsible for the measurement of the external flow (Proximal Flow Sensor or Expiratory Flow Sensor) is detected. In this case, stop using the equipment as soon as possible, and contact Vyaire or Vyaire Authorized Technician

Regulator Pressure Fail
High Priority

The **Pressure Regulator Fail** alarm is activated when a failure on the Pressure Regulator control is detected, which is responsible for the actuation of several ventilator systems.

This failure can be caused by lack of intake gas supply, when the **Gas Fail** alarm is also activated. In this situation, restoring the intake gases will eliminate the failure condition.

The **Pressure Regulator Fail** can also be caused by a technical problem, where the **Vent Inop** alarm will also be activated. In this case, stop using the ventilator immediately, and contact Vyaire or Vyaire Authorized Technician

Keyboard Fail
Medium Priority

The **Keyboard Fail** alarm is activated when a failure in the communication between the quick access buttons and the ventilator control circuits is detected. In this case, stop using the ventilator as soon as possible, and contact Vyaire or Vyaire Authorized Technician

Motherboard Fail
High Priority

The **Motherboard Fail** alarm is activated when a failure in the communication between the motherboard and the ventilator control circuits is detected. Stop using the ventilator as soon as possible, and contact Vyaire or Vyaire Authorized Technician

Ventilator Off
Audible Beep

When the device is turned off with the **On/Off** switch, the ventilator generates a sound until the operator presses the **Audio Paused/Alarm Reset** button.

Table 6-1. High Priority Alarms

Alarm	Possible Causes	Recommended Actions
Apnea[1]	Inspiratory sensitivity is too high.	Check whether the inspiratory sensitivity is properly set.
	Apnea Alarm is incorrectly set.	Check whether the ventilator alarm is correctly set.
Auto Trigger	Detection of start of an assisted or spontaneous cycle with expiratory time shorter than half of the Inspiratory Time (equivalent to an I:E ratio = 2:1), during three consecutive cycles.	Check whether the pressure and flow sensitivity values set on the equipment are not too low. Check whether there is any leakage in the breathing circuit.
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Low Internal Battery [3]	Battery near depletion (at least 5 min since the High Priority alarm is activated).	Urgently charge the internal battery by connecting to AC Mains Power Supply.
Patient Disconnected	The breathing circuit is disconnected from the patient.	Connect the patient back to the ventilator.
	Breathing circuit leak	Check for the presence of holes or tears on the breathing circuit, or whether the parts are properly assembled.
	Defective flow sensor.	Replace the flow sensor.
Internal Battery Fail	Failure on the internal battery or on the battery charging circuit.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician

Table 6-1. High Priority Alarms

Alarm	Possible Causes	Recommended Actions
Motherboard Fail	Failure in the communication between the motherboard and the ventilator control circuits or failure on the equipment internal power sources.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Power Fail	Failure on one or more ventilator internal power sources.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Gas Fail	Cannot meet the intake gas demand, even after switching to alternate gas.	Ensure the air or oxygen intake pressure above 250 kPa (2.5 kg/cm^2) at least.
Gas Supply Fail	Controlled flow differing from the supplied flow, as measured by the internal flow sensor.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Internal Fail	Internal technical failures detected by the ventilator safety circuits.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Pressure Regulator Fail	Failure in the Regulator Pressure control, which is responsible for the actuation of several ventilator systems.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
	Compressed air and/or oxygen intake pressure below the specified limit.	Feed the compressed air and/or oxygen intake with a pressure greater than the lower specified limit of 250 kPa (2.5 kg/cm^2).
Exhalation Valve Fail	Punctured or misplaced diaphragm.	Check the diaphragm's conditions and whether it has been properly mounted. If necessary, replace the diaphragm.
	Damaged or misplaced exhalation valve.	Check the exhalation valve conditions and whether it has been properly mounted. If necessary, replace the exhalation valve.
	Exhalation valve control failure.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Low FiO2$_2$	Low oxygen intake pressure.	Check whether the oxygen intake pressure is within the specified range from 250 kPa (2.5 kg/cm^2) to 600 kPa (6.0 kg/cm^2).
	Value regarding the compensation for local altitude not properly set during the installation of the equipment.	Contact Vyaire or Vyaire Authorized Technician
	Uncalibrated oxygen sensor.	Contact Vyaire or Vyaire Authorized Technician
Circuit Occlusion	High resistance due to saturated filter.	Replace Filters.
	High resistance between the inspiratory and expiratory limbs, resulting in the increase of the pressure difference above the acceptable limit.	Check for the presence of foreign bodies or occlusion on the breathing circuit.
	Obstruction of the expiratory limb.	Check for the presence of foreign bodies or occlusion on the expiratory limb.
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
High Air Pres	Compressed air intake pressure above the specified limit.	Feed the compressed air intake with a pressure lower than the specified upper limit of 600 kPa (6.0 kg/cm^2).
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician

Table 6-1. High Priority Alarms

Alarm	Possible Causes	Recommended Actions
Low Air Pres	Compressed air intake pressure below the specified limit.	Feed the compressed air intake with a pressure higher than the specified lower limit of 250 kPa (2.5 kg/cm^2).
	Clogged coalescent filter.	Replace the coalescent filter.
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
High O$_2$ Pres	Oxygen intake pressure above the specified limit.	Feed the oxygen intake with a pressure lower than the specified upper limit of 600 kPa (6.0 kg/cm^2).
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Low O$_2$ Pres	Oxygen intake pressure below the specified limit.	Feed the oxygen intake with a pressure higher than the specified lower limit of 250 kPa (2.5 kg/cm^2).
	Clogged coalescent filter.	Replace the coalescent filter.
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
High Ppeak	The upper respiratory airway pressure alarm limit was exceeded. The patient is fighting the ventilator, or coughing.	Check patient's condition, the ventilation waveforms, and the alarm limits..
	Blocked ETT	Check the breathing circuit and ETT.
	Secretion build-up in the breathing circuit.	Unobstruct/suction the airway and/or ETT.
	Water build-up in the water trap or the circuit, if they are not correctly positioned.	Drain the water traps and check whether there is water accumulated in the circuit.
	Alarm improperly set.	Check whether the alarm set on the ventilator is correct.
	Change to the patient's respiratory mechanics (increased resistance or reduced compliance)	Reassess ventilation parameters (volume, inspiratory pressure, PEEP, etc.)
	PEEP set above the alarm settings.	Check whether the PEEP and alarm settings are appropriate.
Low Ppeak	Leakage or disconnection	Check whether the exhalation valve is properly connected. Check for leakage in the breathing circuit.
	Leaking cuff.	Insufflate the cuff, checking whether the system is properly sealed.
	Punctured or misplaced diaphragm.	Check the diaphragms condition and if it was correctly positioned. If necessary, replace the diaphragm.
	Alarm improperly set.	Check whether the alarm is correctly set.
	Change to the patient's respiratory mechanics (reduced resistance or increased compliance)	Reassess the ventilation parameters (volume, inspiratory pressure, PEEP, etc.)
	On the volume controlled or time-cycled modes, the Inspiratory Flow set is insufficient to meet the patient's inspiratory effort.	Increase the Inspiratory Flow.
	Exhalation valve control system failure.	Contact Vyaire or Vyaire Authorized Technician

Table 6-1. High Priority Alarms

Alarm	Possible Causes	Recommended Actions
Ext High Air Pres	Compressed air intake pressure well above the specified limit with risk of compromising the patient safety and damaging the equipment internal components.	Feed the compressed air intake with a pressure lower than the upper specified limit of 600 kPa (6.0 kg/cm^2).
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Ext High O$_2$ Pres	Oxygen intake pressure well above the specified limit with risk of compromising the patient safety and damaging the equipment's internal components.	Feed the oxygen intake with a pressure lower than the upper specified limit of 600 kPa (6.0 kg/cm^2).
	Equipment malfunction.	Stop using the equipment and contact Vyaire or Vyaire Authorized Technician
Standby Time Elapsed	Not resuming the ventilation after the maximum period intended for suction (60 seconds), during the 100% O$_2$ maneuver.	During the 100% O$_2$ maneuver, make certain that the **Standby Mode** button is pressed within the maximum 60-seconds period intended for suction.
Vent Inop	Detection of major failures that may compromise the patient safety and/or the operation of equipment's internal components.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
	Lack of minimum gas source requirements to initiate ventilation.	Supply at least one of the gas sources with a minimum pressure of 250 kPa (2.5 kg/cm^2) to establish the ventilation.

1. This alarm starts with medium priority, evolving to high priority after 3 consecutive apnea periods.
2. This alarm will assume the high priority condition if the concentration is lower than or equal to 18%. In other cases, the alarm will be a medium priority one.
3. This alarm starts with medium priority, evolving to high priority at least 5 min prior to battery depletion.

Table 6-2. Medium Priority Alarms

Alarm	Possible Causes	Recommended Actions
Apnea[1]	The trigger sensitivity is too high.	Check whether the trigger sensitivity is properly set.
	Apnea Alarm is improperly set.	Check whether the ventilator alarm is correctly set.
Autozero Error	Failure during the autozero routine of the transducer responsible for the measurement of the external flow (Proximal Flow Sensor or Expiratory Flow Sensor)	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Keyboard Fail	Failure in the communication between the keyboard and the ventilator control circuits or detection of any button pressed for more than one minute.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Low Internal Battery[3]	Battery near depletion (approximately 15 min since the Medium Priority alarm is activated).	Urgently charge the internal battery by connecting to AC Mains Power Supply.
Fan Fail	Internal ventilator cooling system failure.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
AC Line Fail	Lack of AC Mains Power Supply.	Connect the equipment to AC Mains Power Supply as soon as possible in order to prevent the internal battery from being fully discharged.
	The power cord is not properly connected.	Remove the power cord's fixation support, check whether the cable is properly connected and fix the power cord's support again.
	The power cord is damaged.	Replace the power cord.
	The power outlet to which the power cord is connected does not have power.	Use a different power outlet.
	Blown power source fuse.	Contact Vyaire or Vyaire Authorized Technician to provide the replacement of the fuses.
High FiO$_2$	Low air intake pressure.	Check whether the air intake pressure is within the specified range from 250 kPa (2.5 kg/cm^2) to 600 kPa (6.0 kg/cm^2).
	Value regarding the compensation for local altitude not properly set during the installation of the equipment.	Contact Vyaire or Vyaire Authorized Technician
	Uncalibrated oxygen sensor.	Contact Vyaire or Vyaire Authorized Technician
Low FiO2$_2$	Low oxygen intake pressure.	Check whether the oxygen intake pressure is within the specified range from 250 kPa (2.5 kg/cm^2) to 600 kPa (6.0 kg/cm^2).
	Value regarding the compensation for local altitude not properly set during the installation of the equipment.	Contact Vyaire or Vyaire Authorized Technician
	Uncalibrated oxygen sensor.	Contact Vyaire or Vyaire Authorized Technician
	Improper pneumatic supply source with low O$_2$ concentration.	Provide a suitable pneumatic supply source.

Table 6-2. Medium Priority Alarms

Alarm	Possible Causes	Recommended Actions
High Rate	Respiratory rate greater than the set value.	Ensure that the ventilator configurations are properly defined for the patient's condition and that the alarm set value is correct.
	Occurrence of respiratory autocycles depending on the ventilator sensitivity adjustment.	Check whether the sensitivity value set in the equipment is not too low.
Low Rate	Respiratory rate lower than the set value.	Ensure that the ventilator configurations are properly defined for the patient's condition and that the alarm set value is correct.
	Ventilator does not detect the patient's effort.	Check whether the sensitivity value set in the equipment is too high.
High PEEP	Expiration valve locked.	Check the breathing circuit pipe system and the exhalation valve.
	Increased expiratory resistance.	Check whether there is any obstruction in the expiratory limb.
	Water build-up in the water trap or circuit, in case they are not correctly positioned.	Drain the water traps and check whether there is no water accumulated on the circuit.
	High respiratory rate	Check on the graph whether the expiratory time is shorter than the required for exhalation.
	Defective equipment.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Low PEEP	Leakage or disconnection	Check whether the exhalation valve is properly connected. Check leakage in the breathing circuit.
	Leaking cuff.	Insufflate the cuff, checking whether the system is properly sealed.
	Punctured or misplaced exhalation diaphragm.	Check the exhalation diaphragm's condition and whether it was correctly positioned. If necessary, replace the diaphragm.
WrongFlow Sensor	The flow sensor connected to the ventilator does not match the **IBW** range set in the equipment.	Check whether the type of sensor connected matches the **IBW** range set in the ventilator, according to the table under *Sections 3 and 6, Equipment Set-up or Alarms and Messages,* of this manual.
	Defective optical sensor of the flow sensor detection board.	Contact Vyaire or Vyaire Authorized Technician
High Volume	The expiratory tidal volume alarm limit has been exceeded on 3 respiratory cycles.	Check the patient's condition, ventilator waveforms and alarm limits..
Low Volume	The inspiratory tidal volume alarm limit has not been reached.	Check the patient's condition, ventilator waveforms and alarm limits.
	Leakage or disconnection.	Check whether the exhalation valve is properly connected. Check for leaks in the patient airway or circuit.

Table 6-2. Medium Priority Alarms

Alarm	Possible Causes	Recommended Actions
	Leaking cuff.	Insufflate the cuff, checking whether the system is properly sealed.
	Punctured or misplaced diaphragm.	Check the exhalation diaphragm's condition and whether it was correctly positioned. If necessary, replace the diaphragm.
	Improperly set alarm.	Check whether the ventilator's alarm is correct.
High Min Vol	The upper minute volume alarm limit has been exceeded.	Check the patient's condition, ventilator waveforms, and alarm limits.
	Defective flow sensor.	Replace the defective flow sensor.
	Water in the flow sensor.	Drain the humidity condensate. Dry the flow sensor.
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician
Low Min Vol	The lower minute volume alarm limit has not been reached.	Check the patient's condition, ventilator waveforms, and alarm limits.
	Leakage in respiratory system.	Establish a respiratory system without leakages.
	Defective flow sensor.	Replace the defective flow sensor.
	Equipment malfunction.	Stop using the ventilator and contact Vyaire or Vyaire Authorized Technician

1. This alarm starts with **medium priority** then evolving to **high priority** after three consecutive periods of apnea.
2. This alarm will assume the **high priority** condition if the concentration is lower than or equal to 18%. In other cases, the alarm will be a **medium priority** one.
3. This alarm starts with medium priority, evolving to high priority at least 5 min prior to battery depletion.

Table 6-3. Low Priority Alarms

Alarm	Possible Causes	Recommended Actions
Auto PEEP	Expiratory Flow is above the minimum flow at the end of exhalation on three consecutive cycles.	Properly adjust the respiratory rate.
	Occurrence of respiratory autocycles due to the ventilator sensitivity adjustment.	Check whether the sensitivity value set in the equipment is not too low.
Battery in Use	Lack of AC Mains Power Supply.	Connect the equipment to AC Mains Power Supply as soon as possible in order to prevent the internal battery from being fully discharged.
	The power cord is not properly connected.	Remove the power cord's fixation support, check whether the cable is properly connected and fix the power cord's support again.
	The power cord is damaged.	Replace the power cord.
	The power outlet to which the power cord is connected does not have power.	Use a different power outlet.
	Blown power source fuse.	Contact Vyaire or Vyaire Authorized Technician to provide the replacement of the fuses.
Low Setup Battery	Failure in the battery of the PCI Control RAM, which ensures that the last machine setup remains in the memory.	Contact Vyaire or Vyaire Authorized Technician
Flow Sensor Disconnected	The flow sensor is not connected to the ventilator.	Connect the flow sensor to the ventilator.
	Defective flow sensor connector.	Replace the flow sensor.
	Defective optical sensor of the flow sensor detection board.	Contact Vyaire or Vyaire Authorized Technician
Patient Circuit Leak	Low exhaled tidal volume.	Check for leaks in the breathing circuit.
	Clogged flow sensor (with water).	Check the presence of impurities in the sensor or water build-up.
	Defective flow sensor.	Replace the flow sensor.

Visual Indicators

Power
Continuous Green color

The **Power On** visual indicator (LED) is activated whenever the equipment is turned on by the **On/Off** switch located on the rear panel.

AC Line
Continuous Green

The **AC Line** visual indicator (LED) is activated whenever the equipment is connected to AC Mains Power Supply. This indication remains active even when the equipment is turned off.

Ext Batt
Continuous Green

The **Ext Batt** visual indicator (LED) is activated whenever the equipment is connected to an External Battery by means of the existing external connection located on the rear panel. This indication remains active even when the equipment is turned off.

Int Batt
Off / Continuous Yellow / Flashing Green

The **Internal Battery** visual indicator (LED) remains off when the battery is charged and the equipment is connected to AC Mains Power Supply. In the absence of an AC Mains Power Supply, the **Internal Battery** visual indicator (LED) changes to the continuous yellow state, indicating that the internal battery is in use. When the AC Mains Power Supply is connected again, the **Internal Battery** visual indicator (LED) starts flashing in green color to indicate that the battery is being recharged, regardless if the equipment is turned on by the **On/Off** switch or not.

- Off: Charged Internal Battery

- Continuous Yellow: Internal Battery in Use

- Flashing Green: Internal Battery being Recharged

Int Batt Level
Continuous Green / Continuous Orange / Flashing Red

The **Battery Level** visual indicator (LED) allows the identification the autonomy of the internal battery through its different colors:

- Continuous Green: Charge above 80% of total capacity

- Continuous Orange: Charge between 80 and 30% of total capacity

- Flashing Red: Charge below 30% of total capacity

NOTE
The Battery Level visual indicator is activated whenever the equipment is turned on by the On/Off switch or, when turned off, if it is connected to AC Mains Power Supply.

⚠ *WARNING*
When the battery charge reaches levels below 5% of the total capacity, the ventilator will be led to an inoperative condition, generating the Vent Inop alarm.

Messages

Table 6-4. Alarm Messages

Alarms	Type	Window Message
All	Warning	Warning! Values below [set alarm] may hide an unsafe physiologic condition.
		Warning! Values above [set alarm] may hide an unsafe physiologic condition.
AutoSet	Warning	Warning! Please check all suggested values before applying these changes.
FiO_2	Note	Note! High FiO2 cannot be set lower than Low FiO_2.
		Note! Low FiO2 cannot be set higher than High FiO_2.
Min Vol	Note	Note! High Min Vol cannot be set lower than Low Min Vol.
		Note! Low Min Vol cannot be set higher High Min Vol.
PEEP	Note	Note! High PEEP cannot be set lower than Low PEEP.
		Note! Low PEEP cannot be set higher than High PEEP.
Ppeak	Note	Note! High Ppeak cannot be set lower than Low Ppeak.
		Note! Low Ppeak cannot be set higher than High Ppeak.
Rate	Note	Note! High Rate cannot be set lower than Low Rate.
		Note! Low Rate cannot be set higher than High Rate.
Volume	Note	Note! High Volume cannot be set lower than Low Volume.
		Note! Low Volume cannot be set higher than High Volume.

Table 6-5. Control Messages

Controls	Type	Window Message
All	Warning	Warning! Values below [set value] may be unsafe for the patient.
		Warning! Values above [set value] may be unsafe for the patient.
Volume	Note	Note! Values above [set value] cannot be reached. Check Flow and Rate settings.
Flow	Note	Note! Values below [set value] cannot be reached. Check the Volume and Rate settings.
Rate	Note	Note! Values above [set value] cannot be reached. Check the Volume and Flow settings.

Table 6-5. Control Messages

Controls	Type	Window Message
		Note! Values above [set value] cannot be reached. Check Insp Time setting.
Insp Time	Note	Note! Values above [set value] cannot be reached. Check the Rate setting.
Insp Pause	Note	Note! Values above [set value] cannot be reached. Check Volume, Insp Flow and Rate settings.
Insp Pres	Note	Note! Pressures cannot be set higher than 120 cmH$_2$O. Also check PEEP setting.
Insp Pres	Note	Note! Pressures cannot be set higher than P Limit. Also check PEEP setting.
PEEP	Note	Note! Pressures cannot be set higher than 120 cmH$_2$O. Also check Insp Pres setting.
PEEP	Note	Note! Pressures cannot be set higher than P Limit. Also check Insp Pres setting.
P Supp	Note	Note! Pressures cannot be adjusted above 120 cmH$_2$O. Also check the PEEP adjustment.
	Note	Note! Pressures cannot be adjusted above 40 cmH$_2$O. Also check the PEEP adjustment.
	Note	Note! Pressures cannot be adjusted above P Limit. Also check the PEEP adjustment.
P Insp	Note	Note! Pressures cannot be adjusted above 40 cmH$_2$O.
PEEP	Note	Note! PEEP must be at least 5 cmH$_2$O lower than Insp Pres.
	Note	Note! PEEP must be at least 5 cmH$_2$O lower than P Limit.
	Note	Note! Pressures cannot be adjusted above P Limit. Also check the P Supp adjustment.
	Warning	Warning! Prior to increasing PEEP, check whether the High Pressure alarm will not limit or prevent ventilation.
P Limit	Note	Note! P Limit must be adjusted to at least 5 cmH$_2$O above the PEEP adjustment.
High Pressure	Note	Note! The High Pressure alarm cannot be adjusted below the Low Pressure alarm.
Low Pressure	Note	Note! The Low Pressure alarm cannot be adjusted above the High Pressure alarm.
High Vol Min	Note	Note! The High Vol Min alarm cannot be adjusted below the Low Minute Vol alarm.
Low Minute Vol	Note	Note! The Low Minute Vol alarm cannot be adjusted above the High Vol Min alarm.

Table 6-5. Control Messages

Controls	Type	Window Message
High Tidal Vol	Note	Note! The High Tidal Vol alarm cannot be adjusted below the Low Tidal Vol alarm.
Low Tidal Vol	Note	Note! The Low Tidal Vol alarm cannot be adjusted above the High Tidal Vol alarm.
High Rate	Note	Note! The High Rate alarm cannot be adjusted below the Low Rate alarm.
Low Rate	Note	Note! The Low Rate alarm cannot be adjusted above the High Rate alarm.
Autoset	Caution	Attention! Please check all the suggested values before applying the changes.

NOTE

Notes: They restrict the value adjustment, but they indicate the cause to make it easier to understand and/or overcome the limitation.

Warnings: They do not restrict the value adjustment, but notify a condition of risk to the patient.

Actions: They only require attention to related events.

Chapter 7   Monitoring Features

Introduction

The monitoring of patient ventilation occurs in real time, on a continuous basis, and based on flow, pressure, time, and oxygen concentration signals.

Pressure monitoring is performed close to the patient (mouth pressure or proximal pressure), through a proximal pressure line on the wye piece of the circuit.

On the iX5 ventilator, the flow monitoring can be performed both on the wye pieceof the circuit (proximal position), through the Neonatal or Pediatric Proximal Flow Sensors, as well as on the exhalation valve (distal position), through the Expiratory Flow Sensor.

The distal monitoring is performed when the Expiratory flow sensor is connected to the exhalation valve. In this case, the ventilator monitors the Inspiratory Flow by means of the internal flow sensors, and the exhaled flow by means of the flow sensor on the exhalation valve.

The proximal monitoring is performed when Proximal Flow Sensors, suitable for each type of patient (Pediatric or Neonatal), are used. In this case, both inhaled and exhaled flows are monitored at the same point, close to the patient. This configuration is particularly suitable for monitoring neonatal and pediatric patients.

The flow sensor selection must follow the type of patient, identified in the ventilator through the IBW.

NOTE
To avoid the risk of inacurate measures, always use the neonatal proximal flow sensor for intended volumes equal or below 50 ml.

IBW	Patient Category	Breathing Circuit	Flow Sensor
From 300 g to 3000 g	Neonatal	Neonatal/Pediatric	Neonatal Proximal
From 3.1 kg to 30 kg	Pediatric	Neonatal/Pediatric	Pediatric Proximal
More than 30 kg	Adult	Pediatric/Adult	Expiratory

NOTE
If a flow sensor is not compatible with the selected patient weight (IBW), a medium priority alarm (Wrong Flow Sensor) will be activated. In this case, the operator must initially check whether the weight selected on the IBW control is correct; if it is, the sensor must be replaced.

NOTE
Make certain that the flow sensors are properly cleaned; eliminate residues deposited in the measurement ducts. The presence of residue may affect the accuracy of these sensors.

NOTE
When using a humidification filter, to protect the sensor from the humidity generated through the patient's exhalation, the filter should be assembled between the proximal flow sensor and the patient connection.

> **NOTE**
> Upon acknowledging the flow sensor periodically (every 5 minutes), the iX5 ventilator performs a flow sensor Autozero process. This process is meant to both eliminate the condensation found on the two ways of the sensor measurement pipe and reset the flow zero point, in order to ensure the monitoring accuracy.

> **NOTE**
> The volume and flow supplied to the patient is corrected to compensate the fixed compliance of the respiratory circuit, the gas composition (FiO_2 and humidity), and the body temperature (BTPS). All other gas volumes and flows measurements are expressed at STPD (Standard Pressure Temperature Dry).

Numerical Monitoring

Ppeak
Peak Pressure (cmH$_2$O)

It indicates the pressure at the end of the inspiratory cycle.

Pplat
Plateau Pressure (cmH$_2$O)

When an Inspiratory Pause (**Insp Pause** or **Insp Hold**) is programmed, it indicates the inspiratory pressure at the end of the respiratory cycle (when the flow is zero). When there is no Inspiratory Pause, it indicates the pressure during the transition from the inspiratory to the expiratory phase, at the moment, when the flow is zero.

Pmean
Mean Airway Pressure (cmH$_2$O)

It indicates the mean airway pressure of the last **40 seconds**, being updated at every **10 seconds**.

PEEP
Positive End Expiratory Pressure (cmH$_2$O)

It indicates the expiratory pressure at the end of exhalation. During Bilevel PC mode, this parameter is identified as EPAP. During CPAP+Backup and nCPAP LP modes, it is identified as CPAP.

AutoPEEP
Auto PEEP Pressure

It indicates the **Auto PEEP** pressure, which is measured **200 ms** before the start of a controlled cycle. The measurement is done by momentarily pressing the **Exp Hold** button preceding a controlled cycle (without patient's effort). The **Auto PEEP** indication is shown on the same field where **PEEP** is displayed, with the corresponding modified title and value; remaining active on the screen for **1 minute** – after this time, the field shows the **PEEP** value again.

PEEPpause
PEEP Pause Pressure

It indicates the **PEEP** pressure, which is measured during an expiratory hold maneuver. The measurement is done by continuously pressing the **Exp Hold** button and waiting until the next cycle is hold.

P 100
Occlusion Pressure at 100 ms

It indicates the **P 0.1** value, occlusion pressure measured **100 ms** after the start of an inspiratory effort (assisted or spontaneous cycles). The measurement is done by momentarily pressing the

Exp Hold button preceding a patient's effort. The **P 0.1** indication is shown on the same field where **PEEP** is displayed, with the corresponding modified title and value; the screen remains active for **1 minute** – after this time, the field shows the **PEEP** value again.

Vte
Exhaled Tidal Volume (L)

It indicates the exhaled tidal volume (controlled, assisted and spontaneous) at each cycle.

Vti
Inspired Tidal Volume (L)

It indicates the inspired tidal volume (controlled, assisted and spontaneous) at each cycle.

Vte/kg
Volume / Weight Ratio (mL/kg)

It indicates the exhaled tidal volume adjusted for patient ratio. IBW should be properly set in order to avoid incorrect monitoring of Vte/kg.

Min Vol
Total Exhaled Minute Volume (L)

It indicates the minute volume, including controlled, assisted and spontaneous cycles.

Leak
Circuit Leakage (%)

It indicates the difference between the inspired and exhaled tidal volumes in terms of % difference.

It is avalilable only for non-invaisive modes in pediatric and adult patients (CPAP+Backup and Bilevel PC modes) and for neonatal patients in invasive modes (TCPL, PC, VG, PS+Backup)

Rate
Total Respiratory Rate (/min)

It indicates the total respiratory rate, including controlled, assisted and spontaneous cycles.

Spon Rate
Spontaneous Respiratory Rate (/min)

It indicates the respiratory rate on spontaneous cycles only.

I:E
I:E Ratio

It shows the digital indication of the ratio between the inspiratory time and the expiratory time values for each of the respiratory cycles.

FiO$_2$
Fraction of Inspired Oxygen (%)

It indicates the oxygen concentration of the mixture inspired by the patient. The monitoring of the oxygen concentration is performed on the inspiratory limb, inside the ventilator.

NOTE
Oxygen monitor time duration from start-up to providing accurate measurements in the Gas Output Port is less than 20s.

The Oxygen monitor Response Time in the gas output port is less than 20s. To know the delay between the gas output port and the patient's wye piece, see the *%O$_2$ Delay on Chapter 13*.

The oxygen sensor has indirect contact with the patient via gas passing at Gas Output Port.

> FiO2 measures are automatically corrected based on barometric pressure defined during installation procedure.

PIFR
Peak Inspiratory Flow Rate

It indicates the maximum Inspiratory Flow of the respiratory cycle.

PEFR
Peak Expiratory Flow Rate

It indicates the maximum Expiratory Flow of the respiratory cycle.

Te
Expiratory Time (s)

It indicates the Expiratory Time of the respiratory cycle.

Ti
Inspiratory Time (s)

It indicates the Inspiratory Time of the respiratory cycle.

Rinsp
Airway Inspiratory Resistance (cmH$_2$O/L/s)

It indicates the airway resistance, measured at the start of the inspiratory phase. It is calculated from the airway pressure, PEEP, and the Inspiratory Flow.

- *$Rinsp = (Paw^* - PEEP) / Flow^*$*

Where *Flow** and *Paw** are the Inspiratory Flow and the airway pressure values measured **100ms** after the start of the respiratory cycle, respectively.

Rexp
Airway Expiratory Resistance (cmH$_2$O/L/s)

It indicates the airway resistance measured during the expiratory phase. It is calculated from the Plateau Pressure, PEEP, and the Expiratory Peak Flow.

- *$Rexp = (Pplat - PEEP) / PEFR$*

Cstat
Respiratory System Static Compliance (mL/cmH$_2$O)

It indicates the respiratory system static compliance. It is calculated from the Plateau Pressure, the pressure at the end of the exhalation and the exhaled tidal volume.

- *$Cstat = Vte / (Pplat - PEEP)$*

Cdyn
Respiratory System Dynamic Compliance (mL/cmH$_2$O)

It indicates the respiratory system dynamic compliance. It is calculated from the peak pressure, the pressure at the end of exhalation, and the exhaled tidal volume.

- *$Cdyn = Vte / (Ppeak - PEEP)$*

RC exp
Expiratory Time Constant (s)

It indicates the respiratory system time constant value during the expiratory phase. It is calculated from the Expiratory Resistance and the Static Compliance.

- *$RC\ exp = Rexp \times Cstat$*

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WOBv
Ventilator Respiratory Work (J/L)

It indicates the respiratory work performed by the ventilator for overcoming the elastic and resistive forces on the respiratory system and the patient circuit. It is calculated from the airway pressure and the inhaled volume.

- *WOBv = ∫P dV*

RSBI
Rapid Shallow Breathing Index

It indicates the ratio between spontaneous respiratory rate and the exhaled tidal volume at the same moment.

- *RSBI = Spon Rate / Vte*

> *NOTE*
>
> RSBI is a weaning measurement that is used to evaluate the patient's readiness to be weaned from the ventilator.

Graphic Monitoring

Graphic Screen

> *NOTE*
> The iX5 ventilator allows the operator to configure the screen and is capable of displaying up to 5 curves simultaneously, in real time.

▮▮ – Freeze

This button allows momentarily freezing (stopping) graph plotting. While the function is active, a cursor will be visible, and it can be moved by rotating the **Main Button**, showing instantaneous values of graphic readings. Plotting will remain frozen until the button is pressed again or if there is no activity with the cursor for **60 seconds**.

Patient Effort
Patient's Inspiratory Effort Indicator

It indicates the occurrence of a patient's inspiratory effort, enough to reach the sensitivity level set by the **Trigger** control.

The indication can be directly observed on the **Pressure** graphic or on the **Flow** graphic, depending on the type of set sensitivity.

Bar Graph
Airway Pressure (cmH$_2$O)

The airway pressure measurement, taken at the wye piece of the patient, is shown on a linear display with a vertical bar whose height corresponds to the pressure measured at every moment.

On this bar, the **Peak Pressure**, **Mean Pressure**, and **PEEP** values are indicated for each cycle.

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Curves and Loops

The **iX5 ventilator** allows the visualization of the following ventilation curves:

- Pressure x Time

- Flow x Time

- Volume x Time

- Pressure x Volume

- Volume x Flow
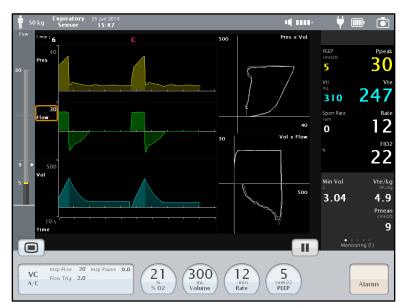
Figure 7-1. Curves and Loops

For the three first curves, there is a difference in curve colors in the inspiratory and expiratory phases of the respiratory cycles.

It is possible to adjust the scale for each of the parameters, just touching on the corresponding axis of the graphic.

The scales applied to each of the parameters of the loops (Pressure, Flow, and Volume) are the ones chosen for the ventilation curves.

iX5 ClearView™ Screen

This screen displays the main ventilation parameters in a clean and visually clear fashion.

The **iX5 ventilator ClearView Screen** is an important surveillance feature, because it allows the operator to immediately identify the patient's conditions, even at distance.
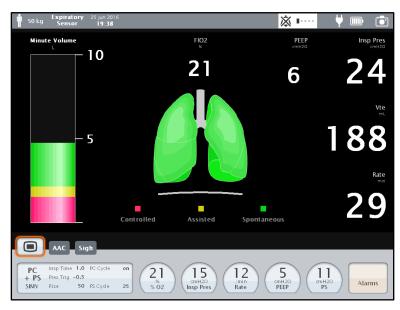
Figure 7-2. iX5 ClearView Screen

Lung Icon

A color-coded, lung-shaped icon is shown at the center of the screen, and it moves with the respiratory cycle **Rate** in a synchronized way. The color of the lung denotes the trigger mechanism for each breath.

- Red – Mandatory
- Yellow – Triggered
- Green – Spontaneous
- Orange – Apnea.

In addition to that, the amplitude of the icon's movement is directly related to the **Volume** of each respiratory cycle.

Numerical Parameters

The following parameters are shown on this screen:

- **Volume**: Exhaled Tidal Volume
- **Rate:** Total Respiratory Rate
- **Ppeak**: Peak Pressure (Positive Inspiratory Pressure)
- **PEEP**: Positive End Expiratory Pressure
- **FiO2:** Measure Oxygen Concentration

Minute Volume Bargraph

The **Minute Volume** is shown on a linear display with a vertical bar whose colors identify the portion of the minute volume coming from **Controlled**, **Assisted** and **Spontaneous** cycles. These portions of the Minute Volume Bargraph are also color coded Red, Yellow and Green, similar to the Lung Icon.

Trend Screen

The **iX5 ventilator** stores a series of ventilation parameters and displays them as trends.

The trend graphics store up to **72 hours** of data, and they can be visualized on 15-minute, 1-, 2-, 4-, 8-, and 12-hour scales.

- **PEEP**: Positive End Expiratory Pressure

- **Ppeak**: Peak Pressure (Positive Inspiratory Pressure)

- **Rate**: Total Respiratory Rate

- **FiO₂**: Oxygen Concentration

- **Volume**: Exhaled Tidal Volume

- **Min Vol**: Minute Volume

- **mL/kg**: Volume / Weight Ratio

- **Rinsp**: Airway Inspiratory Resistance

- **Cstat**: Respiratory System Static Compliance
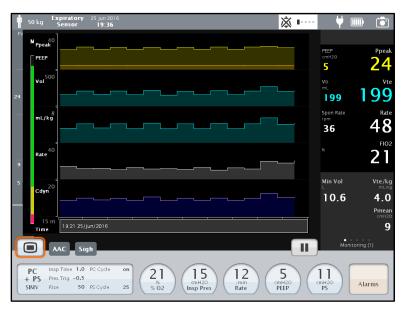
Figure 7-3. Trends

Alarm and Event Log

The **iX5 ventilator** stores the log of all alarms and events occurred during the last **72 hours** or the last **10.000 records**, whichever happens first (older records are discarded after that limit is reached). Each record contains its date, time, type and identification indication.

When **iX5 ventilator** experiences a total loss of power (mains and internal battery depleted), the log is maintained by the system.

The list of events can be filtered to display alarms only, events only, or both types of occurrences.

Figure 7-4. Alarm and Event Log

Chapter 8   Troubleshooting

Table 8-1. Troubleshooting Symptoms, Problems, and Solutions

Symptom	Problem	Solution
The Power On light indication is off and the equipment is operating.	LED is out.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	Failure in the communication with the side LED board.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
The AC Line light indicator is off.	The power cord is not properly connected.	Remove the power cord's fixation support, check whether the cable is properly connected and fix the power cord fixation support again.
	The power cord is damaged.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	The power outlet to which the power cord is connected does not have power.	Use a different power outlet.
	Blown power source fuse.	Contact Vyaire or Vyaire Authorized Technician to provide the replacement of the fuses.
	LED is out.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	Failure in the communication with the side LED board.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
The Ext Batt light indicator is off.	The power cord is not properly connected.	Check whether the cable is properly connected.
	The power cord is damaged.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	The External Battery is defective.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	LED is out.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	Failure in the communication with the side LED board.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.

Table 8-1. Troubleshooting Symptoms, Problems, and Solutions

Symptom	Problem	Solution
The Internal Battery light indicator does not light up when the ventilator is disconnected from an AC Mains Power Supply.	LED is out.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	Battery charging system failure.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	Failure in the communication with the side LED board.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
The Battery Level light indicator is off when the equipment is operating.	LED is out.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	Failure in the communication with the side LED board.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
The button light indicator and the Master Alarm light indicator (in alarm condition) are off.	LED is out.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
	Failure in the communication with the button board and with the Master Alarm LED board.	Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
During ventilator start-up, autotest routine shows failure.	Both air and O2 inlet gases are not connected.	Failure during initialization of ventilator internal sensors or actuators.
	Exhalation valve and diaphragm are not properly assembled.	Check if diaphragm and exhalation valve are properly assembled, as indicated in chapter 3, Exhalation Valve Connection.
	Failure during initialization of ventilator internal sensors or actuators.	Press the button to restart verification. If the problem persists, contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.
Ventilator is auto triggering.	Leakage in the breathing circuit is causing the ventilator to auto cycle.	Check leakages in the respiratory circuit. Reduce the flow-triggered sensitivity or change from flow- to pressure-triggered sensitivity. Make certain the IBW has been properly configured.
Patient cannot trigger assisted/spontaneous cycles.	Improperly adjusted sensitivity.	Adjust the sensitivity to detect the patient's efforts.
Parameter and pressure graphic monitoring loss (*Ppeak*, *Pplat*, *PEEP*, *Pmean*).	Proximal pressure reading loss.	Check whether the proximal line is in perfect condition and whether it is properly connected to the equipment.
The Plateau Pressure features the "---" indication.	When configured without **Insp Pause** or in the absence of the **Insp Hold** command, the ventilator voids the *Pplat* field.	Configure an **Insp Pause** or activate the **Insp Hold** command to obtain an accurate *Pplat* value.

Table 8-1. Troubleshooting Symptoms, Problems, and Solutions

Symptom	Problem	Solution
There is no ventilation and the **High Pressure** alarm is active.	**PEEP** adjustment is above the **High Press** alarm adjustment.	Properly adjust the **PEEP** and **High Press** parameters.
The **Insp Hold** function is not activated.	The **Insp Hold** function is only enabled in the presence of assisted and/or controlled cycles.	Check whether there is a programmed respiratory rate.
The ventilator does not supply the set volume (**Vte** and **Vti** are smaller than the set value).	The **High Press** alarm prevents the volume from being supplied on the inspiratory period.	Check whether the alarm is correctly set. Aspirate the patient. Check whether the hygroscopic filter is saturated.
	Defective proximal flow sensor.	Provide the replacement of the proximal flow sensor.
	Leaking breathing circuit.	Check the integrity and the assembly of the breathing circuit and its parts.
The **High External Battery Voltage** alarm is active.	Incorrect battery connected to Ext Batt port.	Replace the external battery by one indicated in Chapter 1, section Supply Sources. Perform the Functional Verification Test to check that the equipment is not damaged. If the equipment was damaged, contact Vyaire or a Vyaire authorized Technician.
The ventilator does not supply the set volume (**Vte** and **Vti** are greater than the set value).	The **Sigh** parameter is active.	Disable this parameter.
Exhaled tidal volume (**Vte**) is smaller than the set one or it is instable.	Defective Expiratory Flow Sensor.	Replace the Expiratory Flow sensor.
With a Flow Sensor properly connected, there is a message in the diplay "No sensor" and/or an alarm "Flow sensor desconected" is activated.	Defective Flow Sensor.	Replace the Flow Sensor.
	Proximal Adult Flow Sensor attached.	Replace by the Expiratory Flow Sensor. The Adult Proximal Flow Sensor is not compatible with this version.
	Defective optical sensor of the Flow Sensor detection board.	Contact Vyaire or Vyaire Authorized Technician
Minute volume (**Min Vol**) shows a different value from the expected one.	This parameter is a direct consequence of the total respiratory rate (**Rate**) and the exhaled tidal volume (**Vte**).	Check whether the total respiratory rate (**Rate**) and the exhaled tidal volume (**Vte**) values are within expectations.
Oxygen concentration (**FiO2**) different from the set one.	Low oxygen and/or compressed air intake pressure.	Adjust both intake pressures within the specified range from 250 kPa to 600 kPa (2.5 kg/cm^2 to 6.0 kg/cm^2).
	Uncalibrated oxygen sensor.	Contact Vyaire or a Vyaire Authorized Technician.
	Unsuitable pneumatic supply source with low O_2 concentration.	Provide a suitable pneumatic supply source.

Table 8-1. Troubleshooting Symptoms, Problems, and Solutions

Symptom	Problem	Solution
Oxygen concentration (*FiO₂*) shows indication "---".	Failure in oxygen sensor.	Contact Vyaire or a Vyaire authorized Technician.
I:E ratio with a different value from the one expected.	The Inspiratory Pause (Insp Pause) parameter is active.	Disable the **Inspiratory Pause** (**Insp Pause**) or consider it when checking the calculation shown on the screen.
	The ratio depends on flow and respiratory rate parameters.	Check whether the flow and respiratory rate parameters are within expectations.
	The **I:E** ratio has reached the limit 3:1 (on volume-cycled modes) or 4:1 (on time-cycled modes).	On time-cycled modes, reduce the inspiratory time. On volume-cycled modes, increase the flow and/or reduce the volume.
Expiratory Peak Flow (***PEFR***) with different value from the expected one.	Obstruction in the breathing circuit.	Check the condition of the filters coupled to the breathing circuit, if applicable. Check the water or impurity build-up in the flow sensor. Check whether the breathing circuit tubes are not folded, interrupting the free flow passage.
Inspiratory (***Rinsp***) and expiratory (***Rexp***) resistance with values different from the expected ones.	Obstruction in the breathing circuit.	Check the condition of the filters coupled to the breathing circuit, if applicable. Check the water or impurity build-up in the flow sensor. Check whether the breathing circuit tubes are not folded, interrupting the free flow passage.
	Loss of proximal pressure reading.	Check whether the proximal line is in perfect condition and properly connected to the equipment.
	The inspiratory resistance (***Rinsp***) depends on ***Ppeak***, ***PEEP*** and ***Flow*** parameters. The expiratory resistance (***Rexp***) depends on ***Pplat***, ***PEEP*** and ***Flow*** parameters. The variation can be related to any parameter composing the calculated value.	Check whether the indicated parameters are within expectations. In case of ***Rexp***, configure an **Insp Pause** or Pres **Insp Hold** to obtain a valid ***Pplat*** value and, consequently, a ***Rexp*** value.
Expiratory Resistance features the "---" indication.	When configured without **Insp Pause** or in the absence of the **Insp Hold** command, the ventilator voids the ***Rexp*** field.	Configure an **Insp Pause** or activate the **Insp Hold** command to obtain an accurate ***Rexp*** value.
Static compliance (***Cstat***) with a different value from the expected one.	Leaking breathing circuit.	Check the integrity and assembly of the breathing circuit and its parts.
	Loss of proximal pressure reading.	Check whether the proximal line is in perfect condition and properly connected to the equipment.

Table 8-1. Troubleshooting Symptoms, Problems, and Solutions

Symptom	Problem	Solution
	The static compliance depends on *Volume*, *Pplat* and *PEEP* parameters. The variation can be related to one of the parameters composing the calculated value.	Check whether the indicated parameters are within expectations. Configure an **Insp Pause** or Pres **Insp Hold** to obtain a valid *Pplat* value and, consequently, a *Cstat* value.
Cstat features the "---" indication.	When configured without **Insp Pause** or in the absence of the **Insp Hold** command, the ventilator voids the *Cstat* field.	Configure an **Insp Pause** or activate **Insp Hold** command to obtain an accurate and valid *Cstat* value.
Dynamic compliance (*Cdyn*) with a different value from the expected one.	Leaking breathing circuit.	Check the integrity and assembly of the breathing circuit and its parts.
	Loss of proximal pressure reading.	Check whether the proximal line is in perfect condition and properly connected to the equipment.
	Dynamic compliance depends on *Volume*, *Peak* pressure and *PEEP* parameters. The variation can be related to any of the parameters composing the calculated value.	Check whether the indicated parameters are within expectation.
Upper controlled volume (**Volume**) adjustment limitation – dependant message.	Violation of the 3/4 rule (**I:E** ratio must be smaller than 3:1 on volume-cycled modes).	To enable adjustments above the rule-limited value, increase the Inspiratory Flow (**Flow**), reduce the respiratory rate (**Rate**) or reduce the automatic Inspiratory Pause (**Insp Pause**).
Lower controlled volume (**Volume**) adjustment limitation – dependant message.	Values lower than the limited value result in Inspiratory Time (*Insp Time*) < 100 ms.	To enable adjustments below the rule-limited value, reduce the Inspiratory Flow (**Flow**).
Upper Inspiratory Flow (**Flow**) adjustment limitation – dependant message.	Violation of the 3/4 rule (**I:E** ratio must be smaller than 3:1 on volume-cycled modes).	To enable adjustments above the rule-limited value, reduce the controlled volume (**Volume**), reduce the controlled rate (**Rate**) or reduce the automatic Inspiratory Pause (**Insp Pause**).
Lower Inspiratory Flow (**Flow**) adjustment limitation – dependant message.	Values lower than the limited value result in Inspiratory Time (*Insp Time*) < 100 ms.	To enable adjustments below the rule-limited value, increase the controlled volume (**Volume**).
Upper controlled rate (**Rate**) adjustment limitation – dependant message.	Violation of the 3/4 or 4/5 rule (**I:E** ratio must be smaller than 3:1 on pressure-cycled modes, or 4:1 on time-cycled modes).	To enable adjustments above the rule-limited value, reduce the controlled volume (**Volume**), increase the Inspiratory Flow (**Flow**) or reduce the automatic Inspiratory Pause time (**Insp Pause**) on volume-cycled modes, or reduce the Inspiratory Time (**Insp Time**) on time-cycled modes.
Upper Inspiratory Time (**Insp Time**) adjustment limitation – dependant message.	Violation of the 4/5 rule (**I:E** ratio must be smaller than 4:1 on time-cycled modes).	To enable adjustments above the rule-limited value, reduce the controlled rate (**Rate**).

Table 8-1. Troubleshooting Symptoms, Problems, and Solutions

Symptom	Problem	Solution
Upper automatic Inspiratory Pause (**Insp Pause**) time adjustment limitation – dependant message.	Violation of the 3/4 rule (**I:E** ratio must be smaller than 3:1 on volume-cycled modes).	To enable automatic Inspiratory Pause (**Insp Pause**) time adjustments above the rule-limited value, reduce the controlled volume (**Volume**), reduce the controlled rate (**Rate**) or increase the Inspiratory Flow (**Flow**).
Inspiratory Pause Time (**Insp Pause**) is automatically reset.	Ventilation mode modification.	Adjust a new Inspiratory Pause time (**Insp Pause**) every time the ventilation mode is changed, if required.
Ventilator cannot be turned off by the On/Off switch.	Ventilator permanently connected to the AC Mains Power Supply, external battery or internal battery.	Keep the **Audio Pause/Alarm Reset** button pressed for 10 seconds.
		Contact Vyaire or Vyaire Authorized Technician to arrange for the repair of the ventilator.

⚠ *NOTE*

In case of a failure not foreseen in this manual, stop using the equipment and immediately contact Vyaire or a Vyaire Authorized Technician.

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Chapter 9   Cleaning, Disinfection, and Sterilization

ISO 17664 Compliance

According to ISO 17664, "It remains the responsibility of the processor to ensure that the reprocessing as actually performed using equipment, materials, and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process.":

Autoclave and Ethylene Oxide Sterilization have been validated, and the instructions for these methods have been written to be in compliance with ISO 17664:2004

Indicated Processes

> **NOTE**
> The components in the gas pathways that can become contaminated with body fluids or expired gases during both normal and single fault conditions are: Inspiratory filter and any other filters used in the patient circuit, Exhalation Valve, Exhalation Diaphragm, Flow Sensors, Proximal Line, Nebulizer, Nebulizers Tees, Humidification Chamber, Suction Systems and Patient Interfaces.

Ventilator Body

The cleaning of the exterior of the **iX5 ventilator**—except the main display—can be done using a common germicide or antibacterial agent.

It is recommended to clean the main display with gauze moistened with **70% Isopropyl Alcohol**.

> **NOTE**
> Do not sterilize the equipment. Its internal components are not compatible with sterilization techniques.
>
> Do not submerge the equipment into a liquid solution or allow liquids to enter into the internal parts of the ventilator.
>
> Do not use abrasive materials on the ventilator's surface, especially on its screen.
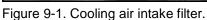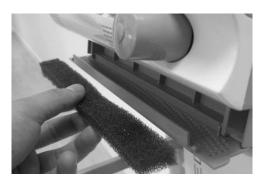
Cooling Air Intake Filter

The cleanliness of the **Cooling Air Filter** must be periodically checked, according to the *Section 10, Preventive Maintenance*, of this manual.

If necessary, this filter must be carefully washed with **warm water and neutral detergent**. After washing, it must be thoroughly rinsed and completely dried.

Figure 9-1. Cooling air intake filter.

Expiratory Flow Sensor

> ⚠ *CAUTION*
>
> During or after cleaning / sterilizing:
>
> Do not direct high pressure air / water streams to the internal part
>
> Do not put any type of object in the internal part
>
> Such actions can damage the metallic film inside the sensor, compromising the reading of equipment flow.

Breathing Circuit and all parts declared in Table 9-1

> ⚠ *WARNING*
>
> Before the first use, clean and sterilize the components of the breathing circuit, following the instructions contained in this section. The frequency of exchange and sterilization of these circuits is defined by the protocols observed in each hospital institution.

> ⚠ *WARNING*
>
> After the sterilization, properly rinse and dry the components of the breathing circuit in order to remove any chemical residues from them. Especially after the ethylene oxide sterilization process, wait from 24 to 48 hours before using the material again in order to ensure the aeration and the complete elimination of any gas residues.
>
> Do not reuse any component that is damaged or shows signs of wear.

> ⚠ *CAUTION*
>
> Never let oils, grease and petroleum jellies touch the silicone components since these products can chemically attack them, affecting their physical properties.
>
> Components subjected to sterilization experience a natural degradation due to the characteristics of the processes employed. Vyaire define a maximum of 50 cleaning/sterilization cycles for the supplied parts, even if they are performed in accordance with the conditions explicitly mentioned in this manual (see table 9-1). For the third parties accessories, see the recommendation of each manufacturer.
>
> Do not use the following solutions for cleaning and/or disinfecting the components of the breathing circuit because they can accelerate the degradation of the materials, causing cracks on the plastic components or disintegration of the silicone tubes.
>
> - Phenol (> 5%)
> - Chlorinated Hydrocarbons
> - Ketones
> - Aromatic Hydrocarbons
> - Formaldehyde
> - Inorganic Acids
> - Hypochlorite
> - Quaternary Ammonium Compounds

Description of the Indicated Processes

Table 9-1. Indicated Process Table

Part	Part Number	Indicated processes
Elbow 90° Adaptor	100.00116	L + ETO L + AC
Exhalation Valve	177.00437	L + ETO L + AC
Exhalation Diaphragm	132.01362A	L + ETO L + AC
TGI/NIV Connector	100.00202	L + ETO L + AC
Expiratory Flow Sensor	179.00734	L + ETO L + AC
Pediatric Proximal Flow Sensor	136.00311	L + ETO L + AC
Neonatal Proximal Flow Sensor	136.00347	L + ETO L + AC

Caption

L: Washing

ETO: Ethylene Oxide Sterilization

AC: Autoclave

Washing (L)

Prior to any sterilization process, the components must be properly washed.

This process consists of immersion in a neutral solution with enzymatic detergent, at a temperature between 35 and 65°C, for approximately 10 minutes.

Rinse thoroughly with distilled or filtered water and let it dry on a clean environment before proceeding with the sterilization.

Ethylene Oxide (ETO)

The ethylene oxide (C_2H_4O) gas sterilization process must comply with standard ISO 11135-1 – Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

The following procedure indicates the ETO sterilization process.

1. Manually clean the parts

2. Wrap the parts in a sterilization wrap.

3. Place the wraps into the machine's chamber.

4. Preconditioning

   - Temperature: 50°C – 55°C

   - Relative humidity: 35% – 85%

   - Time: 60 minutes

5. Follow the machine's instructions for use to program it with the following settings:

- Temperature: 50 – 55 °C
- Sterilization phase (Time): 4 hours
- Forced aeration: 9 pulses
- Relative humidity: 35 – 85 %
- ETO concentration: around 600 mg/L

6. After the finishing of the sterilization cycle, unload the parts.

7. Wait from 24 to 48 hours before using the material again in order to ensure the aeration and the complete elimination of any gas residues.

8. Store the parts in the sterilization wrap until they are ready to use.

9. Prior to use, check the parts for deterioration and discard if damaged.

10. Install the component in the ventilator according to the instructions on *Chapter 3*.

11. Proceed with the Accesory Self-Check Function according to the instructions on *Chapter 4.*

Autoclave (AC)

The sterilization and autoclave process must comply with the standard ISO 17665-1 – Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization.

The following procedure indicates the autoclave sterilization process.

12. Manually clean the parts

13. Wrap the parts in a sterilization wrap.

14. Place the wraps into the autoclave machine.

15. Follow the autoclave machine's instructions for use to program it with the following settings:
- Pressure of the chamber: 2,0 – 2,5 kgf/cm2
- Sterilization cycle at 134° C for 4 minutes.
- 20-minute drying cycle.

16. After the finishing of the sterilization cycle, unload the parts.

17. Allow the parts to cool in room air inside the sterilization wrap.

18. Store the parts in the sterilization wrap until they are ready to use.

19. Prior to use, check the parts for deterioration and discard if damaged.

20. Install the component in the ventilator according to the instructions on *Chapter 3*.

21. Proceed with the Accesory Self-Check Function according to the instructions on *Chapter 4.*

Chapter 10   Preventive Maintenance

Introduction

To prevent the premature equipment wear and achieve a safe performance within the required specifications, Vyaire recommends that the following procedures be performed:

Procedure	Frequency
IVT – Initial Verification Test	Daily or before each use
RI – Routine Inspection	Several times a day or as required by institution's policy
FVT – Functional Verification Test	Before each use or when there are doubts about the operation of the equipment
BPT - Battery Performance Test	Each six months
APM – Annual Preventive Maintenance	Yearly

⚠ **WARNING**

This ventilator is life-support equipment. Do not entrust its maintenance to unauthorized personnel. In case of problems or difficulties, contact Vyaire.

Do not disassemble the ventilator cabinet. This situation poses a risk of electric shock.

To ensure the electrical protection and avoid risk of fire, never replace the equipment fuse. The improper fuse replacement voids warranty and poses a risk to the equipment operation and to the operator's and patient's safety.

Lack of maintenance or maintenance performed by a non-accredited company will grant the product the status of tampered product, and this will subject those responsible to the sanctions provided by law. The change of basic equipment components will constitute the non-observance of the guidelines contained in this Operator's manual and it may affect the basic safety and essential performance of the equipment, including in relation to electromagnetic disturbances.

The procedures indicated above shall be performed only by trained personnel in the operation of the equipment (for IVT, RI and FVT) or in the maintenance of the equipment (for FVT and BPT). APM shall be perfomed only by Vyaire technician or technician authorized by Vyaire.

The equipment shall not receive maintenance during operation. Performing maintenance during operation, including cleaning, may result in patient injury.

IVT – Initial Verification Test

This test performs the verification of the equipment general state, as well as cleanliness, assembly, and connections to the power and gas supply sources aspects.

It is recommended that it be performed daily, or before each use, according to the instructions:

General State

- Check the general state of the equipment in order to ensure that it has not been dropped or damaged in such a way that its safe operation can be compromised.

- Check the status of the cooling air intake filter and, if required, wash it according to the instructions contained under *Section 9, Cleaning, Disinfection, and Sterilization,* of this manual. This filter is located on the lower portion of the equipment's front panel.

Power Source Connection

- If the equipment is connected to an AC Mains Power Supply, check the general state of its power cord and plug. Make certain that it is directly connected to a grounded power mains outlet.

- If the equipment is connected to an external battery, check whether it has the features contained under *Section 1, General Specifications,* of this manual.

- Check the internal battery charge level. For maximum battery autonomy, connect the equipment to the AC Mains Power Supply at least for 15 ininterrupted hours and up to 48 hours prior to use. After this period (48 hours), it is possible that a drop in the battery power level occurs depending on the battery's status of use.

Gas Pipeline Connection

- Check the integrity of the air and oxygen supply hoses. Confirm that they do not have cracks and/or leaks.

- Only use medical grade (dry and contaminant-free) gases, in order to avoid internal damages to the equipment and risks to the patient.

- Check the air and oxygen intake filters. If necessary, drain the condensed water from their collection cups.

Automatic Self-Test

- The system runs an automatic self-test every time it is powered on. This process checks flow and pressure functions and identifies if gases sources and internal valves are intact and ready for use. In case of failure, the system will require a new cycle of verification. If the failure persists, user must contact **Vyaire** or **Vyaire-Authorized Technician**.

Cleaning

- Check the general cleanliness of the equipment.

- Check the cleanliness of the breathing circuit. If necessary, assemble a sterilized circuit.

- Ensure the proper cleaning of the flow sensors, eliminating eventual solid residues deposited on their measurement ducts. The presence of such residues may affect the accuracy of these sensors.

- Check the state of the Cooling Air Intake filter. If necessary, wash it carefully with warm water and neutral detergent. After washing, rinse it and dry it thoroughly.

Assembling

- Check the operation of the support arm from the breathing circuit and the Stand caster locks.

- Check the conservation status of the components of the breathing circuit. Do not reuse any part that is damaged or worn.

RI – Routine Inspection

This inspection performs routine verification of the ventilation system during its use. The operator needs to perform the inspection as indicated by the table below:

Parts	Inspection
Patient circuit	Check for water build-up in the circuit and in the water traps and empty as needed. Check for secretion build-up in the circuit and replace as needed.
Humidifier Chambers	Check the water level.
Bacteria filters	Check resistance across patient circuit filters. Perform the Accessory Self-Check function as needed.
Air and Oxygen intake filters	Check for water build-up and empty as needed.

It is recommended that it be performed several times a day or as required by your institution's policy.

FVT – Functional Verification Test

This test performs the functional verification of the equipment, as well as the operation of the alarm and monitoring features by simulating failure situations, using a lung simulator.

Vyaire recommends performing the FVT – Functional Verification Test before each use, or when there are doubts about the operation of the equipment, in order to check whether the ventilator and its accessories are working according to their specifications.

Preferably, it is recommended to perform the **FVT,** setting the ventilator with the parameters that will be applied to the patient. Using a calibrated lung simulator, simulate failure situations to check the operation of alarm and monitoring features, according to the specifications contained in this manual.

Below, there are some parameters that can be used as reference for performing the FVT on adult, pediatric and neonatal patients.

⚠ *NOTE*
Do not use the equipment if it is not working within the specifications contained in this manual. In this case, interrupt its use and immediately contact Vyaire or Vyaire-Authorized Technician.

NOTE
For the performance of the FVT – Functional Verification Test Vyaire recommends a LS2000 Lung Simulator or equivalent, duly calibrated.

Adult Standard

- Assemble the pediatric/adult breathing circuit and the expiratory flow sensor, according to *Section 3, Equipment Setup,* of this manual.

- Connect the lung simulator into the circuit (after the flow sensor).

- Adjust the simulator according to the following parameters:

    - **Resistance:** 20 cmH$_2$O/L/s

    - **Compliance:** 50 mL/cmH$_2$O

- Set the ventilator to the following parameters:

Mode	VC – A/C	
IBW	40	kg
% O2	21	%
Volume	500	mL
Insp Flow	30	lpm
Waveform	Square	
Rate	15	/min
PEEP	5	cmH$_2$O
Flow Trig	off	
Pres Trig	off	
Insp Pause	0.5	s

- Check, on the equipment's display to ensure the following monitored parameters match the values shown below:*

Ppeak	25 ± 5	cmH$_2$O
PEEP	5 ± 1	cmH$_2$O
Pplat	15 ± 5	cmH$_2$O
Pmean	11 ± 2	cmH$_2$O
Vte	500 ± 50	mL
Min Vol	7.50 ± 0.75	L
Rate	15 ± 1	/min
FiO$_2$	21 ± 1	%

The highlighted fields are directly influenced by the accuracy of the lung simulator used. The values shown on the table are intended for reference purposes only and have been based on a simulator with the above-described features.

- Set **% O$_2$** to 100%. Wait for some breath cycles and check to ensure the equipment's display is monitoring this parameter and following any changes.

- Check and ensure that the **pressure, flow,** and **volume** curves are compatible with the ventilation parameters and the ventilation mode in use.

- Set the alarm limits to values compatible with the parameters in use. Change the set parameters in the ventilator to generate alarm conditions, checking their performance on the monitor.

> *NOTE*
> FiO$_2$ monitor is not calibrated by the operator before or during use. If it is detected error related to FiO$_2$ monitoring value, contact Vyaire or Vyaire Authorized Technician.

Pediatric Standard

- Assemble the neonatal/pediatric breathing circuit and the pediatric proximal flow sensor, according to *Section 3, Equipment Setup,* of this manual.

- Connect the lung simulator into the circuit (after the flow sensor).

- Adjust the simulator according to the following parameters:
  - Resistance: 50 cmH$_2$O/L/s
  - Compliance: 20 mL/cmH$_2$O

- Set the ventilator to the following parameters :

Mode	TCPL – A/C	
IBW	20	kg
% O2	21	%
Cont Flow	15	lpm
Insp Time	1.00	s
Rate	20	/min
PEEP	5	cmH$_2$O
Pres Limit	70	cmH$_2$O
Flow Trig	off	
Pres Trig	off	

- Check on the equipment's display to ensure the following monitored parameters match the values shown below:*

Ppeak	30 ± 5	cmH_2O
PEEP	5 ± 1	cmH_2O
Pmean	11 ± 2	cmH_2O
Vte	250 ± 25	mL
Min Vol	5.00 ± 0.5	L
Rate	20 ± 1	/min
FiO_2	21 ± 1	%

The highlighted fields are directly influenced by the accuracy of the lung simulator used. The values shown on the table are intended for reference purposes only and have been based on a simulator with the above-described features.

Set **% O₂** to 100%. Wait for some breath cycles and check to ensure the equipment's display is monitoring this parameter and following any changes.

- Check and ensure that the **pressure, flow,** and **volume** curves are compatible with the ventilation parameters and the ventilation mode in use.

- Set the alarm limits to values compatible with the parameters in use. Change the set parameters in the ventilator to generate alarm conditions, checking their performance on the monitor.

> *NOTE*
> FiO_2 monitor is not calibrated by the operator before or during use. If it is detected error related to FiO_2 monitoring value, contact Vyaire or Vyaire Authorized Technician.

Neonatal Standard

- Assemble the neonatal/pediatric breathing circuit and the neonatal proximal flow sensor, according to *Section 3, Equipment Setup,* of this manual.

- Connect the lung simulator into the circuit (after the flow sensor).

- Adjust the simulator according to the following parameters:
  - Resistance: 50 cmH₂O/L/s
  - Compliance: 30 mL/cmH₂O

- Set the ventilator to the following parameters:

Mode	TCPL – A/C	
IBW	2	kg
% O2	21	%
Cont Flow	5	lpm
Insp Time	1.00	s
Rate	30	/min
PEEP	5	cmH_2O
Pres Limit	70	cmH_2O
Flow Trig	off	
Pres Trig	off	

- Check on the equipment's display to ensure the following monitored parameters match the values shown below:*

Ppeak	15 ± 2	cmH$_2$O
PEEP	5 ± 1	cmH$_2$O
Pmean	10 ± 2	cmH$_2$O
Vte	100 ± 10	mL
Min Vol	3.00 ± 0.3	L
Rate	30 ± 1	/min
FiO$_2$	21 ± 1	%

* The highlighted fields are directly influenced by the accuracy of the lung simulator used. The values shown on the table are intended for reference purposes only and have been based on a simulator with the above-described features.

Set **% O$_2$** to 100%. Wait for some breath cycles and check to ensure the equipment's display is monitoring this parameter and following any changes.

- Check and ensure that the **pressure, flow,** and **volume** curves are compatible with the ventilation parameters and the ventilation mode in use.

- Set the alarm limits to values compatible with the parameters in use. Change the set parameters in the ventilator in order to generate alarm conditions, checking their performance on the display.

> **NOTE**
> FiO$_2$ monitor is not calibrated by the operator before or during use. If it is detected error related to FiO$_2$ monitoring value, contact Vyaire or Vyaire Authorized Technician.

Alarm Testing

Once the ventilator is set according to the chosen patient, follow the procedures below in order to check the alarm system. If the alarm does not activate as expected, verify the ventilator settings and repeat the tests. If the failure persists, interrupt its use and contact Vyaire authorized service assistance.

Adjustable Alarms

After 1 minute of ventilation, press button "Alarms" then press "Autoset". The ventilator should set the best limits according to the chosen patient.

Change the set parameters in the ventilator in order to generate alarm conditions for each of the parameters below, checking their activation both visual and audible. Once the activation is confirmed, return the parameter to the previous value.

- Low Ppeak
- High Ppeak
- Low Min Vol
- High Min Vol
- Low Vol
- High Vol
- Low Rate
- High Rate
- Apnea
- Low FiO2
- High FiO2

Non-Adjustable and Technical Alarms

After the test above, return to the original alarm conditions by pressing the "Autoset" button and follow the procedures below in order to check the remaining alarms.

Patient Disconnected

During ventilation, disconnect the inspiratory limb at the wye piece and verify if the alarm is activated in no more than 3 breaths.

Reconnect the inspiratory limb. The alarm must be de-activated.

Circuit Occlusion

During ventilation, make a total occlusion of one of the limbs, inspiratory or expiratory. Verify if the alarm is activated and the pressure in the circuit is reliefed. Release the patient circuit from the occlusion and verify that the ventilation is resume in less than 15 s.

Gas fail

Make sure both gas supply (Air and O_2) are properly connected to the pipeline and ventilator.

During ventilation, set FiO_2 to 100%, wait 3 breaths and disconnect the O_2 hose from the pipeline. The ventilator will switch to the Air supply and the ventilation must remain. The Low O_2 Press alarm is activated. Note that the FiO_2 monitor will drop until 21%.

Reconnect the O_2 hose. The alarm must be de-activated.

During ventilation, set FiO_2 to 21%, wait 3 breaths and disconnect the Air hose from the pipeline. The ventilator will switch to the O_2 supply and the ventilation must remain. The Low Air Press alarm is activated. Note that the FiO_2 monitor will increase until 100%.

Reconnect the Air hose. The alarm must be de-activated.

During ventilation, disconnect both (Air and O_2 hoses) from the pipeline. Verify that Vent Inop alarm is activated.

Reconnect the hoses. The alarm must be de-activated.

AC Line fail

During ventilation, disconnect the power cord from the power mains. Verify that the alarm is activated. The ventilator will switch to the internal battery and the ventilation must remain.

Reconnect the power cord. The alarm must be de-activated.

> ⚠ *CAUTION*
> The alarm volume shall be set in a reasonable value according with the environment noise level. Otherwise, alarm conditions may not be recognized.

BPT – Battery Performance Test

It performs the verification of the status of the internal battery and the external battery (optional).

Testing Internal Battery Performance

Performance testing is recommended every 6 months to make sure battery capacity is at least 90 minutes.

Only use batteries recommended by Vyaire. See section "APM – Annual Preventive Maintenace". If the batteries need to be replaced, contact an authorized service to install them.

- Connect the ventilator to the AC Mains Power Supply for 15 hours to make sure the internal battery is fully charged. When the AC external source is connect the "Internal Battery" visual indicator (LED) starts flashing in green color to indicate that the battery is recharging. When the internal battery is fully charged the visual indicator (LED) stops flashing and turns off.

- Set the following parameters:

Parameters	Adjustment
IBW	15 kg
Patient	Pediatric
Resistance	50cmH2O/L/s
Compliance	5 ml/ cmH2O
Circuit Patient	Infant
Flow Sensor	Pediatric Proximal
Mode	PCV / SIMV
Rate	20/min
Insp. Pressure	15 cmH2O
PEEP	5 cmH2O
Insp. Time	0,75s
Flow Trigger	1.0 lpm
FiO$_2$	21%
Pressure suporte	15 cmH2O
Rise	50%
PS Cycle	25%
PC Cycle	Off
Alarms	Auto set
Sound Setup	60%
Screen brightness Setup	80%; Sleep Mode 20%

- Start Ventilation

- Disconnect power cord from de mains power source.

  o If the internal battery remains the ventilation for 90 minutes or longer, the battery has the sufficient charge.

  o If the internal battery do not remains the ventilation for 90 minutes, contact an authorized technician to replace the battery.

NOTE
After this test is completed, connect the ventilator to the main power source for 15 hours to make sure the internal battery is fully charged before it is used.

Testing External Battery Performance

Performance testing is recommended every 6 months to make sure battery capacity is at least 7 hours.

Only use batteries recommended by Vyaire. See section "APM – Annual Preventive Maintenace". If the batteries need to be replaced, contact an authorized service to install them.

To test an external battery follow the steps below.

- Make sure the external battery is fully charged.

- Make sure the "Internal Battery Performance Test" above was succesfuly performed.

- If the internal battery is not fully charged, connect the ventilator to the AC Mains Power Supply for 15 hours to make sure the internal battery is fully charged. When the AC external source is connect the "Internal Battery" visual indicator (LED) starts flashing in green color to indicate that the battery is recharging. When the internal battery is fully charged the visual indicator (LED) stops flashing and turns off.

- Set the following parameters:

Parameters	Adjustment
IBW	15 kg
Patient	Pediatric
Resistance	50cmH2O/L/s
Compliance	5 ml/ cmH2O
Circuit Patient	Infant
Flow Sensor	Pediatric Proximal
Mode	PCV / SIMV
Rate	20/min
Insp. Pressure	15 cmH2O
PEEP	5 cmH2O
Insp. Time	0,75s
Flow Trigger	1.0 lpm

FiO$_2$	21%
Pressure suporte	15 cmH2O
Rise	50%
PS Cycle	25%
PC Cycle	Off
Alarms	Auto set
Sound Setup	60%
Screen brightness Setup	80%; Sleep Mode 20%

- Start Ventilation

- Disconnect power cord from de mains power source.

- The "AC Line" visual indicator turns off and "Internal Battery" lights up continuous yellow.

- Connect an external battery (See external battery specifications).

- The "Ext Batt" visual indicator (LED) lights up continuous green.

  o If the ventilator remains operative for 8 hours or longer, the external battery is appropriate for use.

  o If the ventilator does not remain operative for at least 7 hours, contact an authorized technician to replace the battery.

- Reconnect power cord to AC Mains Power Supply, the "AC Line" visual indicator lights up and "Ext Batt" and "Internal Battery" visual indicators turns off.

NOTE
After this test is completed, provide the recharge of the external battery and make sure it is ready for use.

APM – Annual Preventive Maintenance

The iX5 ventilator is composed of complex electronic, mechanical, and pneumatic components. Because the iX5 ventilator is respiratory life-support equipment and its electronic components and some of its pneumatic components, are, in their own nature, subject to deviations in their settings from time to time, we suggest that an Annual Preventive Maintenance (APM) be conducted, to check each function of the ventilator and return it to optimal performance and safety conditions, whenever a deviation is detected.

The APM is a service requested by the customer and solely provided by a Vyaire technician or a technician authorized by Vyaire. The replacement of parts subject to normal usage wear and tear is also part of the APM service. The process to check and adjust the equipment is conducted in accordance to the requirements of a certified Quality Management System, using calibrated measuring equipment that are traceable to primary standards.

APM has the following characteristics:

- APM is a service to be requested by the customer every **12 months**.

- Only a Vyaire technician or a **Technician Authorized** by Vyaire can conduct interventions in Vyaire products preserving the conditions of the original equipment.

- **APM** is limited to equipment, and does not include the accessories.

The table below shows recommended parts to be replaced in the APM:

Acessories Part #	Description	Interval
130.01362A	Exhalation diaphragm	12 months
150.00562	Air inlet filter	12 months
179.A0740	Battery set	12 months
401.00028	Coalescent filter, green (X2)	12 months
401.00030	Sintered filter, white	12 months
136.00311	Pediatric Proximal Flow Sensor	As needed*
136.00347	Neonatal Proximal Flow Sensor	As needed*
179.00734	Expiratory Flow Sensor	As needed*
177.00437	Exhalation Valve Body	As needed*
100.00116	Elbow 90º Adaptor	As needed*
100.00202	TGI/NIV Connector	As needed*

* Inspect and look for cracks or deterioration to determine if replacement is needed.

⚠ *NOTE*
This equipment features safety seals on the closing screws. If these seals are broken by unauthorized personnel, warranty will be voided.

⚠ *CAUTION*
The battery service life depends on the ventilator's use conditions (ventilator and/or internal battery use frequency and time, environmental conditions of temperature and humidity, etc.). The storage the ventilator without recharging the battery for periods longer than two months may reduce the battery service life.

⚠ *CAUTION*

Vyaire recommends the use of original parts, pieces and recommended accessories. The use of different parts other than those mentioned on the list of accessories is the operator's sole responsibility.

All parts and pieces that need to be repaired or replaced during the maintenance process must be replaced by original components. The use of non-original components may compromise the equipment safety, implying in product tampering and thus voiding the warranty.

All parts and pieces replaced during the maintenance processes must be discarded in compliance with the local legislation where the equipment is installed.

Special attention must be given to the internal lead-acid type battery, which must follow its manufacturer's guidelines, described on the side of the component.

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Chapter 11   Accessories, Parts, and Pieces

Introduction

This Chapter indicates parts and accessories that are validated for use with iX5.

Warnings and Cautions

> ⚠ *CAUTION*
>
> Please contact Vyaire for the latest accessory, parts and piece lists for the iX5 ventilator. Always use original parts, pieces, and recommended accessories, in order to ensure the correct performance of this equipment and the validity of the warranty. In addition, this measure is also intended for the patient's and operator's safety.
>
> Never use anti-static or electrically conductive hoses or tubes in the patient circuit.
>
> All of the components of iX5 ventilator circuits (silicone tubes, plastic connections, and plastic flow sensors) meet the cytotoxicity, irritation and sensitivity requirements.
>
> The iX5 ventilator recommended circuits provides protection against electric shock considering 20 cm of the breathing circuit in contact with the patient (TYPE B applied part).
>
> It is not expected that the applied part reach temperatures over 43 °C in worst case conditions and using the recommended accessories. Always use recommended humidifiers/heaters in order to prevent temperatures that may harm the patient.

> ⚠ *CAUTION*
>
> Components subjected to sterilization experience a natural degradation due to the characteristics of the processes employed. Vyaire define a maximum of 50 cleaning/sterilization cycles for the parts of the original breathing circuit (see table 9-1).

> ⚠ *WARNING*
>
> Use of accessories, transducers and cables other than those specified or provided by Vyaire could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Always use original Vyaire parts, pieces and the recommended accessories, in order to ensure the correct performance of this equipment and the validity of the warranty. In addition, this measure is also intended for the patient's and operator's safety.

- The use of non-original parts, pieces and the recommended accessories poses risk to the users, and does not meet the provisions of ANVISA and other local regulations, and the instructions contained in this Operator's manual. Incompatible parts, pieces and accessories can result in degraded performance.

Parts and Accessories

Part #	Description
Intermed Equipamento Médico Hospitalar Ltda accessories with CE certification/ certified with iX5 Ventilator	
136.00311	Pediatric Proximal Flow Sensor
136.00347	Neonatal Proximal Flow Sensor
179.00734	Expiratory Flow Sensor
177.00437	Exhalation Valve Body
130.01362A	Exhalation Diaphragm
179.01200	iX5 ventilator Stand
177.01000	iX5 ventilator Circuit Support Arm
100.00202	TGI / NIV Connector
031.00643	External Battery Power Cord
100.00116	Elbow 90º adapter
Intermed Equipamento Médico Hospitalar Ltda accessories without CE certification	
100.19000	Neonatal/Pediatric Breathing Circuit with water trap **
100.21000	Pediatric/Adult Breathing Circuit with water trap **
100.20000	Neonatal/Pediatric Breathing Circuit **
100.22000	Pediatric/Adult Breathing Circuit **
408.00002	O2 Hose DISSF X DISSF 3m, Green **
408.00003	Air Hose DISSF X DISSF 3m, Yellow **
141.00000	LS2000 Lung Simulator **
158.00001	LS1000 Test Lung Neonatal **
159.00001	LS1500 Test Lung Pediatric / Adult **
014.11201B	External Battery UNIPOWER UP12120 *
* Similar battery may be used provided that the specification of Chapter 1 (section Supply Sources) is followed.	
** Not for sale in countries that requires CE certification	
Vyaire Corporation accessories with their own CE certification	
306.00126	26404-001 Infant Flow LP generator kit without nasal prongs, with Fisher & Paykel RT132 neonatal single-limb, heated circuit. Single Patient Use. Box of 10
306.00127	26405-001 Infant Flow LP generator kit without nasal prongs, with Fisher & Paykel RT132 neonatal single-limb, heated circuit. Single Patient Use. Box of 20
306.00128	7772000LP Infant Flow LP generator kit without nasal prongs. Included: Dual-jet, variable flow generator and sizing guide. Single patient use, box of 10

Part #	Description
306.00129	7772020LP Infant Flow LP generator kit with nasal prongs Included: Dual-jet, variable flow generator, sizing guide and small, medium and large nasal prongs Single patient use, box of 10
306.00130	7772010 Infant Flow LP starter kit. Included: 5 Infant Flow LP generator kits with S, M, L prongs; 2 XS, S, SM, M, L and XL headgear sizes; 2 XS, S, SM, M, L and XL nasal masks sizes; 2 XL nasal prongs; and 2 XS nasal prongs Single patient use
306.00131	7772011 Infant Flow LP generator kit/Fisher & Paykel MR730 or MR850 breathing circuit Included: Infant Flow LP generator kit with prongs and neonatal, single-limb, heated breathing circuit Single patient use, box of 10
306.00132	7772021 Infant Flow LP generator kit/Fisher & Paykel MR730 or MR850 breathing circuit Included: Infant Flow LP generator kit with nasal prongs and neonatal, single-limb, heated breathing circuit Single patient use, box of 20
Nasal Masks	For use with the Infant Flow LP generator Single patient use, pack of 10
306.00133	777002XS Green - Extra small
306.00134	777002S Pink – Small
306.00135	777002M Blue – Medium
306.00136	777002L Purple – Large
306.00137	777002XL Clear - Extra large
Nasal Prongs	For use with the Infant Flow LP generator Single patient use, pack of 10
306.00138	777000XS Green - Extra small
306.00139	777000S Pink – Small
306.00140	777000M Blue – Medium
306.00141	777000L Purple – Large
306.00142	777000XL Clear - Extra large
Headgear	For use with the Infant Flow LP generator assembly Single patient use, box of 10
306.00143	777040XS Extra small - 17–21 cm
306.00144	777040S Small - 21–26 cm
306.00145	777040SM Small-medium - 24–28 cm
306.00146	777040M Medium - 26–32 cm
306.00147	777040L Large - 32–37 cm
306.00148	777040XL Extra large - 37–42 cm
Bonnets	For use with the Infant Flow LP generator assembly Single patient use, pack of 10
306.00149	777010 Size 000 – White - 18–20 cm
306.00150	777012 Size 00 – Gray - 20–22 cm
306.00151	777014 Size 0 - Pink - 22–24 cm
306.00152	777016 Size 1 - Lt. brown - 24–26 cm
306.00153	777018 Size 2 - Yellow - 26–28 cm
306.00154	777020 Size 3 - Lt. blue - 28–30 cm
306.00155	777022 Size 4 - Gold - 30–32 cm
306.00156	777024 Size 5 – Green - 32–34 cm
306.00157	777026 Size 6 - Lt. burgundy - 34–36 cm
306.00158	777028 Size 7 – Orange - 36–38 cm

Accessories supplied by third parties with their own CE certification	
305.00005	DHR280 Compressor for iX5 Ventilator
305.00006	DHR280 Stand
305.00009	DHR280 Water Trap Filter
408.00202	25534-001 O2 Hose NISTF X NISTF 3m, W, BayCorp
408.00203	25544-001 Air Hose NISTF X NISTF 3m, B/W, BayCorp
408.00204	25538-001 O2 Hose NISTF X AFNORF 3m, W, BayCorp
408.00205	25548-001 Air Hose NISTF X AFNORF 3m, B/W, BayCorp
408.00206	25539-001 O2 Hose NISTF X BSF 3m, W, BayCorp
408.00207	25549-001 Air Hose NISTF X BSF 3m, B/W, BayCorp
408.00208	25536-001 O2 Hose NISTF X DINF 3m, W, BayCorp
408.00209	25546-001 Air Hose NISTF X DINF 3m, B/W, BayCorp
408.00210	25532-001 O2 Hose DISSF X DISSF 3m, W, BayCorp
408.00211	25542-001 Air Hose DISSF X DISSF 3m, B/W, BayCorp
408.00212	25531-001 O2 Hose DISSF X DISSF 3m, G, BayCorp
408.00213	25541-001 Air Hose DISSF X DISSF 3m, Y, BayCorp
408.00214	25537-001 O2 Hose NISTF X UNIFORF 3m, W, BayCorp
408.00215	25547-001 Air Hose NISTF X UNIFORF 3m, B/W, BayCorp
100.15016	Humidification Chamber MR340S Fisher&Paykel – reusable
100.15017	Humidification Chamber MR370 Fisher&Paykel – reusable
Accessories supplied by third parties without CE certification	
830.00043	Heated Humidifier GlobalTec GT2000 – 110V **
830.00046	Heated Humidifier GlobalTec GT2000 – 220V **
830.00066	Heated Humidifier GlobalTec GT5000 Plus – 110/220V **
830.00071	Temperature Sensor EQA200 for GT5000 Plus - GlobalTec **
830.00044	Humidification Chamber GT-250 **
138.01900	Pressure Regulating Valve Air, Moriya (P/N 100.149) **
138.02900	Pressure Regulating Valve O2, Moriya (P/N 100.147) **
** Not for sale in countries that requires CE certification	

Table 11-1. Recommended Accessories with their own CE certification

Part #	Description
RT206	Breathing Circuit, Adult, Disposable, w/ Expiratory Water-trap, Pressure Line and MR290V autofeed humidification chamber, Fisher&Paykel (10)
RT106	Breathing Circuit, Adult, Disposable, w/ Expiratory Water-trap and Pressure Line and w/o humidification chamber, Fisher&Paykel (10)
RT225	Breathing Circuit, Infant (flow > 4 lpm), Disposable, w/ Expiratory Water-trap, Pressure Line and MR290V autofeed humidification chamber, Fisher&Paykel (10)
RT125	Breathing Circuit, Infant (flow > 4 lpm), Disposable, w/ Expiratory Water-trap and Pressure Line and w/o MR290V autofeed humidification chamber, Fisher&Paykel (10)
RT019	Inspiratory/Expiratory Breathing Circuit Filter, Fisher&Paykel
RT020	Expiratory Breathing Circuit Filter, Fisher&Paykel (20)
HEPA (001852)	HEPA Filter, AirLife

Table 11-1. Recommended Accessories with their own CE certification

Part #	Description
28HEPA (70538)	HEPA Filter, Hsiner
28FHMET (70531-FB)	HME Filter, Hsiner
Bacterial/Viral (001851)	Bacterial/Viral Filter, AirLife
04FBVG	Bacterial/Viral Filter, Vital Signs
002438	Nebulizer, w/ Baffled Tee Adapter, Mouthpiece, 7" tubing and 6' flexitube, Air Life, Misty Max 10
MR850	Heated Humidifier, w/ Heater Wire (900MR805), Temperature Probe (900MR869), Fisher&Paykel
MR810	Heated Humidifier, w/ Evatherm (900MR810), Fisher&Paykel
MR290VX	Auto-Fill Humidification Chamber, Disposable, Fisher&Paykel (10)
80MDI06	Closed Suction 72-hour System, w/MDI port, 6 Fr, Pacific Hospital Supply (Free Trachea, Newmed)
80MDI08	Closed Suction 72-hour System, w/MDI port, 8 Fr, Pacific Hospital Supply (Free Trachea, Newmed)
80MDI10	Closed Suction 72-hour System, w/MDI port, 10 Fr, Pacific Hospital Supply (Free Trachea, Newmed)
80MDI12	Closed Suction 72-hour System, w/MDI port, 12 Fr, Pacific Hospital Supply (Free Trachea, Newmed)
80MDI14	Closed Suction 72-hour System, w/MDI port, 14 Fr, Pacific Hospital Supply (Free Trachea, Newmed)
80MDI16	Closed Suction 72-hour System, w/MDI port, 16 Fr, Pacific Hospital Supply (Free Trachea, Newmed)
RT041S	Full Face Mask, Non-vented, Small size, Single Use, Fisher&Paykel
RT041M	Full Face Mask, Non-vented, Medium size, Single Use, Fisher&Paykel
RT041L	Full Face Mask, Non-vented, Large size, Single Use, Fisher&Paykel
04MAPF	Clear, Flexible Dome, Air-Filled Cushion Face Mask w/ no Top Valve, Disposable, Size #0, Vital Signs
04MANF	Clear, Flexible Dome, Air-Filled Cushion Face Mask w/ no Top Valve, Disposable, Size #1, Vital Signs
04MAIF	Clear, Flexible Dome, Air-Filled Cushion Face Mask w/ no Top Valve, Disposable, Size #2, Vital Signs
04MATF	Clear, Flexible Dome, Air-Filled Cushion Face Mask w/ no Top Valve, Disposable, Size #3, Vital Signs
04MACAPF	Clear, Flexible Dome, Air-Filled Cushion Face Mask w/ no Top Valve, Disposable, Size #4, Vital Signs
04MAAF	Clear, Flexible Dome, Air-Filled Cushion Face Mask w/ no Top Valve, Disposable, Size #5, Vital Signs
04MAAG	Clear, Flexible Dome, Air-Filled Cushion Face Mask w/ no Top Valve, Disposable, Size #6, Vital Signs
20160	Air Cushion Mask With Valve, Size #0, Extra Large Adult, Hsiner (30)
20161	Air Cushion Mask With Valve, Size #1, Extra Large Adult, Hsiner (30)
20162	Air Cushion Mask With Valve, Size #2, Extra Large Adult, Hsiner (30)
20163	Air Cushion Mask With Valve, Size #3, Extra Large Adult, Hsiner (30)
20164	Air Cushion Mask With Valve, Size #4, Extra Large Adult, Hsiner (30)

Table 11-1. Recommended Accessories with their own CE certification

Part #	Description
20165	Air Cushion Mask With Valve, Size #5, Extra Large Adult, Hsiner (30)
20166	Air Cushion Mask With Valve, Size #6, Extra Large Adult, Hsiner (30)
10110	Silicone Mask, One Shape Design, Transparent, Autoclavable, Size #0, Small Infant, Hsiner
10111	Silicon Mask, One Shape Design, Transparent, Autoclavable, Size #1, Large Infant, Hsiner
10112	Silicone Mask, One Shape Design, Transparent, Autoclavable, Size #2, Small Child, Hsiner
10113	Silicone Mask, One Shape Design, Transparent, Autoclavable, Size #3, Child, Hsiner
10114	Silicone Mask, One Shape Design, Transparent, Autoclavable, Size #4, Small Adult, Hsiner
10115	Silicone Mask, One Shape Design, Transparent, Autoclavable, Size #5, Large Adult, Hsiner

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Chapter 12   Terminology, Symbols, and Definitions

Terminology

The main terms used in this manual, defined by standard IEC 60601-1:2005 + AMD1:2012, are presented hereinafter:

1 – ACCOMPANYING DOCUMENTS

Documents supplied along the equipment or accessory, containing all relevant information for the equipment's user, operator, and installer or assembler, especially regarding safety.

2 – CLASS I EQUIPMENT

Equipment in which the electric shock protection is not only based on the basic insulation, but it has one additional safety precaution. This additional safety consists of a feature connecting the equipment to the protective grounding conductor integrated to the facility fixed wiring in order to prevent accessible metallic parts from being energized in case the basic insulation fails.

3 –TYPE B APPLIED PART

Part applied in compliance with the prescriptions specified in standard IEC 60601-1:2005 +AMD1:2012 for providing protection against electric shock.

4 – PROTECTIVE GROUNDING TERMINAL

Terminal connected to the conductive parts of a class I equipment for safety purposes, and foreseen to be connected to an external protective grounding system by means of a protective grounding conductor.

Symbology

The symbols used in this document and defined in the following table are intended to draw attention to important information and special content. Pay particular attention to the content identified with these symbols.

Table 12-1. The meaning of the symbols used in this document is presented in this table.	
⚠	General warning ISO 7010-W001
⚠	Caution ISO 7000-0434A
🏭	Manufacturer Indicates the medical device manufacturer
EC | REP	Authorized representative in the European Community Indicates the authorized representative in the European Community

Table 12-2. The meaning of the standardized symbols printed on the equipment is presented in this table.

Symbol	Reference	Description
∿	IEC 60417-5032	Alternating current
⎓	IEC 60417-5031	Direct current
▭	IEC 60417-5016	Fuse
⏚	IEC 60417-5019	Protective grounding terminal
IP21	IEC 60529	Equipment is protected against vertically dripping water and against the penetration of solid particles with diameters greater than or equal to 12.5mm
⚠	ISO 7000-0434A	Caution! Check ACCOMPANYING DOCUMENTS
◯	IEC 60417-5265	Off, for only a part of the equipment
⊙	IEC 60417-5264	On, for only a part of the equipment
⊖→	IEC 60417-5034	Input
→⊕	IEC 60417-5035	Output
🧍	IEC 60417-5333	Equipment with Type B applied part
⚡	IEC 60417-5036	Dangerous electric voltage
⊕	Variant of ISO7000(2621)	Pressure
⊕	ISO 7000-0233	Pressure measurement
⧖	Vyaire symbol	Nebulizer
✓RoHS	N/A	RoHS Compliant
|◯|◯|	IEC 60417-5850	Serial interface
•⤙	usb.org	USB port
⧉	IEC 60417-5988	Computer network
EXT	Variation of ISO7000(0247)	External Battery

	EN 50419	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)
REF	ISO 7000-2493	Catalogue number
SN	ISO 7000-2498	Serial number
	IEC 60417-5021 IEC 60878-01-24	Equipotential Pin
	IEC 60417-5570	Unlocking
	ISO 7010-M002	Mandatory to follow instructions for use
	ISO 7010-P023	Do not obstruct
	ISO 7010-P017	Do Not Push (Do not push on the iX5 ventilator while it is mounted on the cart.)
	Vyaire variant of ISO7010(P001)	Not User Serviceable
	IEC 60417-1:5307	Alarm Indication
	EN 980-5.12	Manufacturer Indicates the medical device manufacturer
EC REP	EN 980-5.13	Authorized representative in the European Community Indicates the authorized representative in the European Community

Table 12-2. The meaning of the standardized symbols printed on the equipment is presented in this table.

Table 12-3. The meaning of the standardized symbols printed on the equipment packaging is presented hereinafter:

Symbol	Standard	Description
	ISO 780:1997(E) Symbol No. 1	FRAGILE: The content of the packaging is fragile; therefore, it shall be handled with care.
	ISO 780:1997(E) Symbol No. 3	THIS SIDE UP: It indicates the position of the top of the packaging.
	ISO 780:1997(E) Symbol No. 4	PROTECT AGAINST SUNLIGHT: The packaging must be sheltered from sunlight.
	ISO 780:1997(E) Symbol No. 6	PROTECT AGAINST RAIN: The packaging must be sheltered from rain.
	ISO 780:1997(E) Symbol No. 14	MAXIMUM STACKING: It indicates the maximum number of identical packages that can be stacked.
	ISO 780:1997(E) Symbol No. 17	TEMPERATURE LIMIT: It indicates the limit temperature for storing and handling the packaging as cargo being transported.
	ISO 7000:2004 (E/F) Symbol No. 2620	Humidity limitation
	ISO 7000:2004 (E/F) Symbol No. 2621	Atmospheric pressure limitation
✓RoHS	N/A	RoHS Compliant
LOT	ISO 7000-2492	Batch code
QTY	Vyaire symbol	Quantity of items inside the box
REF	ISO 7000-2493	Catalogue number
SN	ISO 7000-2498	Serial number
EC REP	EN 980-5.13	Authorized representative in the European Community. Indicates the authorized representative in the European Community
	ISO 7000-1135	General symbol for recovery/recyclable

Table 12-3. The meaning of the standardized symbols printed on the equipment packaging is presented hereinafter:

	EN 980-5.6	MANUFACTURING DATE: It indicates the manufacturing date of the equipment.
	EN 980-5.12	MANUFACTURER: It indicates the equipment's manufacturer
CE XXXX	CE COMPLIANCE MARK	CE COMPLIANCE: It indicates that the System complies with the European Council Directive 93/42/EEC, as amended by Directive 2007/47/EC. The "xxxx" stands for the certification number issued by the Certifying Entity used by the manufacturer's Quality System.

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Chapter 13   Technical Specifications

Controls and Monitors Accuracy

The accuracy of controls and monitors described in this chapter is maintained under de following conditions:

- Using the ventilator according to the Intended Use described in Chapter 1.
- Assemblying the ventilation system according to the Equipment Setup described in Chapter 3.
- Performing the Autotest Routine when the ventilator is turned on (automatically performed as described in Chapter 4) and after a 30 minute warm-up period.
- Using patient circuit only with the recommended configurations and recommended accessories according to the Chapter 3 and Chapter 11.
- Performing the Accessory Self-Check Function described in Chapter 4.
- Performing ventilator maintenance as described in Chapter 10.

Table 13-1. Delivery Accuracy

Inspiratory Pressure	± (2.5 cmH2O + 5% of the set pressure)
PEEP	± (2.0 cmH2O + 5% of the set PEEP)
Tidal Volume	± (5 ml + 10% of the set volume)
Delivered O2 concentration*	For intended volumes above 50 ml: ± 3 % v/v For intended volumes equal or below 50 ml: ± (Volume fraction of 2,5 % + 2,5 % of the set %O2)

Table 13-2. Monitors Accuracy

Monitors based on pressure measurement: Ppeak PEEP / CPAP Pmean Pplat Paw	± (2.0 cmH2O + 5% of the actual value)
Monitors based on volume measurement: Vte Vti Vte/kg Vol FRC Min vol	± (4.0 ml + 15% of the actual value)
Monitors based on time measurement: Rate Spon Rate	± (1.0 bpm + 10% of the actual value)
FiO2*	± (Volume fraction of 2.5 % + 2.5 % of the gas level)
Note: Oxygen monitor time duration from start-up to providing accurate measurements in the Gas Output Port is less than 20s. Drift: less than 0.4% over 24 h. *Ventilating a patient with cyclical pressure of up to 100 cmH2O may add tolerance errors up to 2% (V/V).*	

Measurement Uncertainty

Accuracy of iX5 is verified against a test system which has the uncertainties indicated in the table below:

Table 13-3. Measurement Uncertainty

Measured Parameter	Uncertainty
Volume	± 2.3 %
Inspiratory Pressure	± 2.7 %
PEEP / CPAP	± 5.4 %
FiO2	± 0.5 %
Time	± 5.0 %

Controls

Table 13-4. Adjustable Parameters

Control Parameters	Mode	IBW	Lower Limit Min	Lower Limit Safe	Upper Limit Safe	Upper Limit Max	Resolution	Default
% O$_2$ (%)	All	All	21	—	—	100	1	21
Backup Backup Rate (/min)	PS+Backup CPAP +Backup	Neo	OFF; 1	10	—	60	1	OFF
		Ped	OFF; 1	10	—	40	1	OFF
		Adu	OFF; 1	6	—	40	1	OFF
	nCPAP+Backup	Neo	OFF; 1	10	—	40	1	OFF
Breath Av Breath Average (cycles)	VG	Neo	1	—	—	60	1	1
Cont Flow Continuous Flow (lpm)	TCPL	Neo	2	4	15	30	1	6
		Ped	2	10	30	50	1	20
	VG	Neo	2	4	15	30	1	6
	nTCPL nCPAP	Neo	2	4	15	20	1	8
CPAP Countinuous Positive Airway Pressure (cmH$_2$O)	CPAP + Backup	Ped	0	5	15	20	1	5
		Adu	0	5	15	20	1	5
EPAP Expiratory Pressure (cmH$_2$O)	Bilevel PC	Ped	0	5	15	20	1	5
		Adu	0	5	15	20	1	5
PC Cycle	PC, PC+PS,	Neo	OFF; 10	—	—	75	5	OFF

Table 13-4. Adjustable Parameters

Control Parameters	Mode	IBW	Lower Limit		Upper Limit		Resolution	Default
			Min	Safe	Safe	Max		
Expiratory Trigger for mandatory breaths (%)	PRVC, PRVC+PS Bilevel PC	Ped	OFF; 10	—	—	75	5	OFF
		Adult	OFF; 10	—	—	75	5	OFF
PS Cycle Expiratory Trigger for spontaneous breaths (%)	VC+PS, PC+PS, PRVC+PS, TCPL+PS, APRV, PS+Backup, CPAP+Backup	Neo	10	—	—	75	5	10
		Ped	10	—	—	75	5	25
		Adult	10	—	—	75	5	25
Flow Trig Flow Inspiratory Trigger (lpm)	VC, PC, TCPL, PRVC, VG, APRV, Bilevel PC, PS+Backup, CPAP+Backup	Neo	0.2	—	—	2.0; OFF	0.1	0.5
		Ped	0.5	—	3.0	5.0; OFF	0.5 – 1.0: 0.1 1.0 – 5.0: 0.5	1.0
		Adu	2.0	—	10.0	15.0; OFF	2.0 – 5.0: 0.5 5.0 – 15.0: 1.0	2.0
Flow Base	Biphasic LP nCPAP LP	Neo	2	—	—	15	1	8
Flow High	Biphasic LP nCPAP LP	Neo	0	—	—	10	1	2
IBW Ideal Body Weight (kg)	All	Neo	0.3	—	—	3	0.3 – 1: 0.01 1 – 3: 0.05	2
		Ped	3.1	—	—	30	3.1 – 10: 0.1 11 – 30: 1	15
		Adu	31	—	—	110	1	50
Insp Flow Inspiratory Flow (lpm)	VC	Ped	2	10	30	50	1	20
		Adu	2	30	80	120	1	30
Insp Pause Inspiratory Pause (s)	VC	Ped	0.0	—	—	2.0	0.1	0.0
		Adu	0.0	—	—	2.0	0.1	0.0
Insp Pres Controlled Pressure (cmH$_2$O)	PC	All	5	10	35-PEEP, min 30	80	1	15
Insp Time Inspiratory Time (s)	PC, TCPL, PS+Backup	Neo	0.10	0.25	1.00	15.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 0.5 10.0 – 15.0: 1.0	0.50

Table 13-4. Adjustable Parameters

Control Parameters	Mode	IBW	Lower Limit		Upper Limit		Resolution	Default
			Min	Safe	Safe	Max		
		Ped	0.10	0.50	2.00	15.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 0.5 10.0 – 15.0: 1.0	0.75
		Adu	0.10	0.75	3.00	15.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 0.5 10.0 – 15.0: 1.0	1.00
	PRVC	Ped	0.10	0.50	2.00	15.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 0.5 10.0 – 15.0: 1.0	0.5
		Adu	0.50	0.75	3.00	15.0	0.5 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 0.5 10.0 – 15.0: 1.0	1.00
	VG	Neo	0.10	0.25	1.00	15.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 0.5 10.0 – 15.0: 1.0	0.30
	Bilevel PC, CPAP + Backup	Ped	0.50	—	2.00	5.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 5.0	0.75
		Adu	0.50	0.75	3.00	5.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 5.0	1.00
	nTCPL nCPAP	Neo	0.10	—	2.00	5.0	0.1 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 10.0: 5	0.30
IPAP Inspiratory Pressure (cmH$_2$O)	Bilevel PC and CPAP+Backup	Ped	5	10	35	40	1	15
		Adu	5	10	35	40	1	15
P Backup Backup Pressure (cmH$_2$O)	VG	Neo	5	–	–	40	1	15
PEEP Positive End Expiratory Pressure (cmH$_2$O)	VC, PC, TCPL, PRVC, PS+Backup	All	0	5	15	50	1	5
	VG	Neo	0	5	15	25	1	5
	nTCPL, nCPAP+ Backup	Neo	0	5	10	15	1	5

Table 13-4. Adjustable Parameters

Control Parameters	Mode	IBW	Lower Limit		Upper Limit		Resolution	Default
			Min	Safe	Safe	Max		
Pres High Pressure High (cmH$_2$O)	APRV	Ped	5	10	35-PLow, Min 30	80	1	15
		Adu	5	10	35-PLow, Min 30	80	1	15
Pres Limit Pressure Limit (cmH$_2$O)	VG	Neo	5	—	—	—	1	15
	TCPL	Neo	5	10	35	80	1	20
		Ped	5	10	35	80	1	20
	nCPAP, nTCPL	Neo	5	10	20	30	1	10
Pres Low Pressure Low (cmH$_2$O)	APRV	Ped	0	—	15	45	1	5
		Adu	0	—	15	45	1	5
Pres Max Pressure Maximum (cmH$_2$O)	VG	Neo	10	—	—	70	1	20
Pres Min Pressure Minimum (cmH$_2$O)	VG	Neo	5	—	—	30	1	10
Pres Trig Pressure Inspiratory Trigger (cmH$_2$O)	VC, PC, TCPL, PRVC, VG, APRV, Bilevel PC, PS+Backup, CPAP+Backup	Neo	OFF; -10.0	-5.0	—	-0.3	-10.0 – -1.0:0.5 -1.0 – -0.3:0.1	OFF
		Ped Adu	OFF; -10.0	-5.0	—	-0.5	-10.0 – -1.0:0.5 -1.0 – -0.5:0.1	OFF
	nTCPL, nCPAP, Biphasic LP, nCPAP LP	Neo	OFF; -10.0	-5.0	—	-0.1	-10.0 – -1.0:0.5 -1.0 – -0.1:0.1	0.5
PS Pressure Support (cmH$_2$O)	VC+PS, PC+PS, PS+Backup	All	OFF; 5	10	35-PEEP, (if PEEP<5)	80	1	15
	TCPL +PS	Neo	OFF; 5	10	35-PEEP, (if PEEP<5)	80	1	15
		Ped	OFF; 5	10	35-PEEP, (if PEEP<5)	80	1	15
	PRVC +PS	Ped	OFF; 5	10	35-PEEP, (if PEEP<5)	80	1	15
		Adu	OFF; 5	10	35-PEEP, (if PEEP<5)	80	1	15
	VG +PS	Neo	OFF; 2	5	15-PEEP,(if PEEP<5)	30	1	5

Table 13-4. Adjustable Parameters

Control Parameters	Mode	IBW	Lower Limit Min	Lower Limit Safe	Upper Limit Safe	Upper Limit Max	Resolution	Default
PS High Pressure Support during Pres High (cmH$_2$O)	APRV	Ped Adu	OFF; 5	10	25,(if P High>5) 30-P High,(if P High<5)	80	1	OFF
PS Low Pressure Support during Pres Low (cmH$_2$O)	APRV	Ped Adu	OFF; 5	10	25 (if Pres Low>5) 30-Pres Low (if Pres Low<5)	40	1	OFF
Rate Respiratory Rate (/min)	VC, PV, TCPL	Neo	1	20	60	180	1	30
		Ped	1	10	40	180	1	20
		Adu	1	6	30	180	1	12
	PRVC	Ped	1	10	40	60	1	20
		Adu	1	6	30	40	1	12
	VG	Neo	1	10	40	120	1	30
	Bilevel PC	Ped	1	10	—	40	1	20
		Adu	1	6	30	40	1	12
	nTCPL	Neo	1	20	40	60	1	20
	Biphasic LP	Neo	1	—	—	60	1	20
Rise Pressure Rise Slope (%)	PC, PRVC, VG, APRV, Bilevel PC, PS+Backup, CPAP+Backup	All	25	—	—	100	5	50
T Delay Time Delay (s)	APRV	Ped Adu	OFF; 0.2	—	—	1.0	0.1	OFF
Time High Time High (s)	APRV	Ped Adu	0.2	—	—	30	0.2 – 1.00: 0.1 1.0 – 5.0: 0.2 5.0 – 10.0: 0.5 10.0 – 30.0: 1.0	4.0
	Biphasic LP, nCPAP LP	Neo	0.10	—	—	5.0	0.10 – 1.00: 0.05 1.0 – 3.0: 0.1 3.0 – 5.0: 0.5	0.30
Time Low Time Low (s)	APRV	Ped Adu	0.2	—	—	30	0.2 – 1.00: 0.1 1.0 – 5.0: 0.2 5.0 – 10.0: 0.5 10.0 – 30.0: 1.0	0.5
Vol Limit Volume Limit (mL)	VG	Neo	10	20	75	120	10 – 20: 1 20 – 120: 5	2 x IBW x mL/kg

Table 13-4. Adjustable Parameters

Control Parameters	Mode	IBW	Lower Limit		Upper Limit		Resolution	Default
			Min	Safe	Safe	Max		
Vol Target Volume Target (mL)	PRVC	Ped	20	100	300	500	10	IBW x mL/kg
		Adu	100	200	700	2000	100 – 1000: 10 1000 – 2000: 50	IBW x mL/kg
	VG	Neo	2	10	50	100	2 – 20: 1 20 – 100: 5	IBW x mL/kg
Volume Controlled Volume (mL)	VC	Ped	10	50	350	500	10	IBW x mL/kg
		Adu	100	250	750	2000	10 – 1000: 10 1000 – 2000: 50	IBW x mL/kg
Volume / Weight Ratio (mL/kg)	All	All	—	—	—	—	4, 6, 8, 10	6
Waveform Flow Pattern	VC	Ped	—	—	—	—	Square Decelerating Sine	Square
		Adu	—	—	—	—	Square Declining Sine	Square

Table 13-5. Maneuvers Settings

Control Parameters	Mode	IBW	Lower Limit		Upper Limit		Resolution	Default
			Min	Safe	Safe	Max		
Neb Time Nebulization Time (min)	VC, PC, TCPL, APRV, Bilevel PC, PS+Backup, CPAP+Backup	All	5	—	—	30	1	15
Neb Flow Nebulization Flow (lpm)	VC, PC, TCPL, APRV, Bilevel PC, PS+Backup, CPAP+Backup	Neo	—	—	—	—	—	3
		Ped	—	—	—	—	—	6
		Adu	—	—	—	—	—	6
Neb Mode Nebulization Mode	VC, PC, APRV, Bilevel PC, PS+Backup, CPAP+Backup	All	—	—	—	—	Continuous / Syncronized	Syncronized

Table 13-5. Maneuvers Settings

Control Parameters	Mode	IBW	Lower Limit		Upper Limit		Resolution	Default
			Min	Safe	Safe	Max		
	TCPL	Ped Neo	—	—	—	—	Continuous / Syncronized	Continuous
TGI Delay TGI Delay (ms)	VC, PC, TCPL	All	0	—	—	500	100	300
TGI Flow TGI Flow (lpm)	VC, PC, TCPL	Neo	—	—	—	—	—	3
		Ped	—	—	—	—	—	6
		Adu	—	—	—	—	—	6
% Sigh Sigh SIze (%)	VC, PC	Ped Adu	25	—	—	50	5	25
Cycle Breath Cycles with sigh (cycles)	VC, PC	Ped Adu	1	—	—	3	1	1
Cycle Interval Cycles without sigh (cycles)	VC, PC	Ped Adu	20	—	—	100	1	20
AAC Automatic Airway Compensarion (%)	PC TCPL APRV, PS+Backup	Ped Adu	10	—	—	75	5	10
ET Size Endotracheal Tube Diameter (mm)	PC TCPL APRV, PS+Backup	Ped Adu	2.0	—	—	12.0	0.5	8.0
Slow Flow Maneuver	VC, PC	Adu	—	—	—	—	I I+E	I+E
Slow Flow Vol Max (mL)	VC, PC	Adu	300	—	750	2,000	300 – 1,000: 50 1,000 – 2,000: 100	500
Slow Flow P Max (cmH$_2$O)	VC, PC	Adu	10	—	35	80	1	30
Slow Flow T Max (s)	VC, PC	Adu	5	—	—	40	1	20
Slow Flow Insp Flow (lpm)	VC, PC	Adu	4	—	—	20	1	6

NOTE
The controlled flow and volume values are expressed in BTPS (Body Temperature and Pressure, Saturated).

Pressure Limits

Maximum Limited Pressure: 120 cmH$_2$O ±5%. It is ensured by the safety valve.

Maximum Working Pressure: It is ensured by the High Peak Pressure alarm. See range of High Peak Pressure alarm in Chapter 6, Alarms and Messages. If, during the inspiratory phase, the pressure limit established by the alarm is reached, the ventilator will immediately interrupt the cycle and return to the set expiratory pressure (PEEP) value. If the pressure remains high at the expiratory phase, the ventilator will open the safety valve and activate the obstruction alarm.

> *NOTE*
> The ventilator does not generate subatmospheric airway pressures during exhalation.

Flow Limits

Maximum Inspiratory Flow (Demand): 180 lpm

%O$_2$ Delay

The length of time required to achieve intended oxygen concentration in the patient connection depends on the ventilation settings and the patient circuit. This time delay may be up to the values described in the table below, considering worst case configuration.

Delivered volumes	Time duration from 21% to 90% at patient connection port
500 ml	Less than 76 s
150 ml	Less than 188 s
30 ml	Less than 208 s

Ventilation Alarms

Table 13-6. Adjustable Physiological Alarms

Alarms	Priority	Mode	IBW	Min	Max	Default	Auto Set
Low Ppeak Low Inspiratory Pressure (cmH$_2$O)	High	VC PC TCPL PS+Backup	All	3	70	PEEP+10 (if PEEP<10) 25 (if PEEP>10)	Ppeak – 5
		PRVC	Ped Adu	3	70	PEEP + 5	Ppeak – 5
		VG	Neo	3	70	PEEP + Pres Min – 5	PEEP + Pres Min – 5
		APRV	Ped Adu	3	70	Pres Low + PS Low – 5	Pres Low + PS Low – 5
		Bilevel PC CPAP+Backup	Ped Adu	3	40	PEEP+10 (if PEEP<10) 25 (if PEEP>10)	Ppeak – 5
		nTCPL nCPAP+Backup	Neo	2	30	7	Ppeak – 5
		Biphasic LP nCPAP LP	Neo	2	15	5	Ppeak – 5
High Ppeak High Inspiratory Pressure (cmH$_2$O)	High	VC PC TCPL PS+Backup	All	10	120	30	Ppeak + 5
		PRVC	Ped Adu	10	120	PEEP + 30	Ppeak + 10
		VG	Neo	10	120	PEEP + Pres Max + 10	PEEP + Pres Max + 10
		APRV	Ped Adu	10	120	Pres High + PS High + 10	Pres High + PS High + 10
		Bilevel PC CPAP+Backup	Ped Adu	5	60	30	Ppeak + 5
		nTCPL nCPAP+Backup	Neo	5	40	20	Ppeak + 5
		Biphasic LP nCPAP LP	Neo	5	20	15	Ppeak + 5
Low Min Vol Low Minute Volume (L)	Medium	VC	Ped	OFF; 0.10	20.0	(Volume x Rate) – 40%	Min Vol – 40%
			Adult	OFF; 1.0	40.0		
		PC TCPL PS+Backup	Neo	OFF; 0.01	2.0	(IBW x mL/kg x Rate) – 40%	Min Vol – 40%
			Ped	OFF; 0.10	20.0		
			Adult	OFF; 1.0	40.0		
		PRVC	Ped	OFF; 0.10	20.0	(Vol Target x Rate) – 40%	Min Vol – 40%
			Adu	OFF; 1.0	40.0		
		VG	Neo	OFF; 0.01	2.0	(Vol Target x Rate) – 40%	Min Vol – 40%
		APRV	Ped	OFF; 0.10	20.0	(IBW x mL/kg x Rate) – 40%	Min Vol – 40%
			Adult	OFF; 1.0	40.0		
		Bilevel PC CPAP+Backup	Ped	OFF; 0.10	20.0	OFF	OFF
			Adu	OFF; 1.0	40.0		

Table 13-6. Adjustable Physiological Alarms

Alarms	Priority	Mode	IBW	Min	Max	Default	Auto Set
		nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF
High Min Vol High Minute Volume (L)	Medium	VC	Ped	0.10	30.0; OFF	(Volume x Rate) + 40%	Min Vol + 40%
		VC	Adult	1.0	60.0; OFF		
		PC TCPL	Neo	0.01	3.0; OFF	(IBW x mL/kg x Rate) + 40%	Min Vol + 40%
		PC TCPL	Ped	0.10	30.0; OFF		
		PC TCPL	Adult	1.0	60.0; OFF		
		PS+Backup	Neo	0.01	3.0; OFF	OFF	OFF
		PS+Backup	Ped	0.10	30.0; OFF	OFF	OFF
		PS+Backup	Adult	1.0	60.0; OFF	OFF	OFF
		PRVC	Ped	0.10	30.0; OFF	(Vol Target x Rate) + 40%	Min Vol + 40%
		PRVC	Adu	1.0	60.0; OFF		
		VG	Neo	0.01	3.0; OFF	(Vol Target x Rate) + 40%	Min Vol + 40%
		APRV	Ped	0.10	30.0; OFF	OFF	OFF
		APRV	Adult	1.0	60.0; OFF		
		Bilevel PC CPAP+Backup	Ped	0.10	30.0; OFF	OFF	OFF
		Bilevel PC CPAP+Backup	Adu	1.0	60.0; OFF		
		nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF
Low Vol Low Tidal Volume (L)	Medium	VC	Ped	OFF; 10	500	Volume – 50%	Volume – 50%
		VC	Adult	OFF; 100	2,000		
		PC TCPL APRV PS+Backup	Neo	OFF; 1	50	(IBW x mL/kg) – 50%	Vte – 50%
		PC TCPL APRV PS+Backup	Ped	OFF; 10	500		
		PC TCPL APRV PS+Backup	Adult	OFF; 100	2,000		
		PRVC	Ped	OFF; 10	500	Vol Target – 50%	Vol Target – 50%
		PRVC	Adult	OFF; 100	2,000	Vol Target – 50%	Vol Target – 50%
		VG	Neo	OFF; 1	50	Vol Target – 50%	Vol Target – 50%
		Bilevel PC CPAP+Backup	Ped	OFF; 10	500	(IBW x mL/kg) – 50%	Vte – 50%
		Bilevel PC CPAP+Backup	Adult	OFF; 100	2,000		

Table 13-6. Adjustable Physiological Alarms

Alarms	Priority	Mode	IBW	Min	Max	Default	Auto Set
		nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF
High Vol High Tidal Volume (L)	Medium	VC	Ped	10	500; OFF	Volume + 50%	Volume + 50%
			Adult	100	2,000; OFF		
		PC TCPL APRV PS+Backup	Neo	1	50; OFF	(IBW x mL/kg) + 50%	Vte + 50%
			Ped	10	500; OFF		
			Adult	100	2,000; OFF		
		PRVC	Ped	10	500; OFF	Vol Target + 50%	Vol Target + 50%
			Adult	100	2,000; OFF	Vol Target + 50%	Vol Target + 50%
		VG	Neo	1	50; OFF	Vol Max + 5	Vol Max + 5
		Bilevel PC CPAP+Backup	Ped	10	500; OFF	(IBW x mL/kg) + 50%	Vte + 50%
			Adult	100	2,000; OFF		
		nTCPL nCPAP+Backup	Neo	–	–	OFF	OFF
Apnea Apnea Time (s)	Medium / High	VC PC TCPL PRVC VG	All	3	60; OFF	(60/Rate) + 5	Te + 5
		APRV	All	3	60; OFF	OFF	OFF
		PS+Backup	Neo	3	60; OFF	5	OFF
			Ped	3	60; OFF	10	OFF
			Adult	3	60; OFF	15	OFF
		Bilevel PC CPAP+Backup	Ped	3	60; OFF	10	Te + 5
			Adult	3	60; OFF	15	Te + 5
		nTCPL nCPAP+Backup	Neo	3	60; OFF	5	Te + 5
		Biphasic LP nCPAP LP	Neo	3	60; OFF	OFF	OFF

Table 13-6. Adjustable Physiological Alarms

Alarms	Priority	Mode	IBW	Min	Max	Default	Auto Set
Low Rate (1/min)	Medium	VC PC TCPL PRVC VG APRV PS+Backup Bilevel PC CPAP+Backup	Neo	OFF; 4	120	25	Rate – 30%
			Ped	OFF; 4	120	15	
			Adu	OFF; 4	120	5	
		nTCPL nCPAP+Backup	Neo	OFF; 4	60	20	Rate – 30%
		Biphasic LP	Neo	OFF; 4	60	10	Rate – 30%
		nCPAP LP	Neo	OFF; 4	60	OFF	Rate – 30%
High Rate (1/min)	Medium	VC PC TCPL PRVC VG APRV PS+Backup Bilevel PC CPAP+Backup	Neo	4	180; OFF	50	Rate + 30%
			Ped	4	180; OFF	30	
			Adu	4	180; OFF	20	
		nTCPL nCPAP+Backup	Neo	4	80; OFF	40	Rate + 30%
		Biphasic LP	Neo	4	80; OFF	40	Rate + 30%
		nCPAP LP	Neo	4	80; OFF	OFF	Rate + 30%
Low FiO_2 (%)	Medium	All	All	OFF; 19	100	$\%O_2 - 5$	$FiO_2 - 5$
High FiO_2 (%)	Medium	All	All	19	100; OFF	$\%O_2 + 5$	$FiO_2 + 5$
Low PEEP (cmH_2O)	Medium	nTCPL nCPAP+Backup	Neo	0	15	PEEP – 2	PEEP – 2
		Biphasic LP	Neo	0	15	2	PEEP – 2
Low CPAP (cmH_2O)	Medium	nCPAP LP	Neo	0	15	2	CPAP – 2
High PEEP (cmH_2O)	Medium	nTCPL nCPAP+Backup	Neo	3	20	PEEP + 2	PEEP + 2
		Biphasic LP	Neo	3	20	7	PEEP + 2
High CPAP (cmH_2O)	Medium	nCPAP LP	Neo	3	20	7	CPAP + 2

Table 13-7. Non-adjustable Physiological Alarms

Alarms	Prior.	Mode	IBW	Auto Set
Low FiO$_2$ (%)	High	All	All	≤ 18%
Low PEEP (cmH$_2$O)	Medium	VC PC TCPL PRVC VG APRV Bilevel PC PS+Backup CPAP+Backup	All	3
High PEEP (cmH$_2$O)	Medium	VC PC TCPL PRVC VG APRV Bilevel PC PS+Backup CPAP+Backup	All	5
Auto PEEP (cmH$_2$O)	Low	All	All	End expiratory flow > 50% of Exp Peak Flow
Auto Cycle	High	All	All	3 consecutive assisted/spontaneous cycles with I:E > 2:1

Table 13-8. Technical Alarms

Alarms	Prior.	Mode	IBW	Limits
Patient Disconnected	High	All	All	NA
Patient Circuit Leak	Low	Except nTCPL and nCPAP	All	NA
Circuit Occlusion	High	All	All	See Circuit Occlusion alarm at Chapter 6
Wrong Flow Sensor	Medium	All	All	Sensor type incompatible with patient category
Flow Sensor Disconnected Disconnection of Flow Sensor	Low	All	All	Absence of flow signal
Standby Time Elapsed	High	All	All	> 60 seconds
Low Air Pres Low Air Intake Pressure (kPa)	High	All	All	< 250
High Air Pres High Air Intake Pressure (kPa)	High	All	All	> 600

Table 13-8. Technical Alarms

Alarms	Prior.	Mode	IBW	Limits
Ext High Air Pres Extremely High Intake Pressure (kPa)	High	All	All	> 660
Low O_2 Pres Low Oxygen Intake Pressure (kPa)	High	All	All	> 250
High O_2 Pres High Oxygen Intake Pressure (kPa)	High	All	All	> 600
Ext High O_2 Pres Extremely High Oxygen Intake Pressure (kPa)	High	All	All	> 660
Gas Fail (kPa)	High	All	All	< 120 (for both intakes)
Gas Administration Fail	High	All	All	NA
Power Fail	High	All	All	NA
AC Line Fail AC Mains Power Supply Failure and Battery Input	Medium	All	All	NA
Internal Battery in Use	Low	All	All	NA
High External Battery Voltage	High	All	All	> 14.5 Vdc
Low Internal Battery	Medium / High	All	All	Battery near depletion: - Approximately 15 min (Medium Priority) - At least 5 min (High Priority)
Internal Battery Fail	High	All	All	NA
Low Setup Battery	Low	All	All	NA
Autozero Error	Medium	All	All	NA
Fan Fail	Medium	All	All	NA
Exhalation Valve Fail Exhalation Valve Control Failure/PIP-PEEP	High	All	All	NA
Pressure Regulator Fail Pressure Regulator Control Failure	High	All	All	NA
Keyboard Fail	Medium	All	All	NA
Motherboard Fail	High	All	All	NA
Internal Fail	High	All	All	NA
Vent Inop Ventilator Inoperative	High	All	All	NA
Ventilator Off	–	All	All	NA

Sound Pressure

Alarm volume: 72.5 ± 22.5 dBA @ 1 meter.

Ventilator without compressor: 52 dBA when measured in accordance with ISO 3744.

Ventilator with compressor: 57 dBA when measured in accordance with ISO 3744.

Sound Power

Ventilator without compressor: 63 dBA when calculated in accordance with ISO 3744.

Ventilator with compressor: 68 dBA when calculated in accordance with ISO 3744.

Monitors

Table 13-9. Measured Parameters

Parameter	Range	Resolution
Ppeak Inspiratory Pressure (cmH_2O)	0 – 120	0 – 120: 1
PEEP / CPAP Positive End Expiratory Pressure (cmH_2O)	0 – 120	0 – 120: 1
Pmean Mean Airway Pressure (cmH_2O)	0 – 120	0 – 120: 1
Pplat Plateau Pressure (cmH_2O)	0 – 120	0 – 120: 1
Vte Expiratory Tidal Volume (L)	0.000 – 3.00	0.000 – 0.999: 0.001 1.00 – 3.00: 0.01
Vti Inspiratory Tidal Volume (L)	0.000 – 3.00	0.000 – 0.999: 0.001 1.00 – 3.00: 0.01
Vte/kg Volume / Weight Ratio (mL/kg)	0.000 – 3.00	0.000 – 0.999: 0.001 1.00 – 3.00: 0.01
Vol FRC (in APRV only) Functional Residual Capacity (mL)	0.000 – 3.00	0.000 – 0.999: 0.001 1.00 – 3.00: 0.01
Leak (only in adult and pediatric NIV modes and neonatal IV modes) Circuit Leakage (%)	0 – 100	1
Min Vol Minute Volume (L)	0.00 – 99.9	0.00 – 9.99: 0.01 10.0 – 99.9: 0.1
Rate Total Respiratory Rate (/min)	0 – 180	0 – 180: 1
Spon Rate Spontaneous Respiratory Rate (/min)	0 – 180	0 – 180: 1
I:E I:E Ratio	1:99 – 9.9:1	1:99 – 9.9:1: 1
PIFR Peak Inspiratory Flow Rate (lpm)	0 – 180	1
PEFR Peak Expiratory Flow Rate (lpm)	0 – 180	1
Paw Airway Pressure (Manometer) (cmH_2O)	-10 – 120	-10 – 120: 1

Table 13-9. Measured Parameters

Parameter	Range	Resolution
FiO₂ Inhaled Oxygen Fraction (%)	0 – 100	0 – 100: 1

Filtering and Smoothing Techniques

The measured and calculated values displayed or used to control suffer from noise removal processes in order to deliver a more significant result. This is performed by the inclusion of signal filters. These filters are part of the accuracy described in the technical description and are defined by:

- Pressure and flow readings: Low Pass Filter (median type) with time constant of 40 ms.

- FiO₂ reading: Nonlinear Filtering (fashion type) with a maximum time of 2 s update.

Filter Specifications

Table 13-10. Filter Specifications

Part #	Manufacturer	Technical Specification
RT019	Fisher&Paykel	Compliance 0.13mL/cmH₂O Deadspace: 38 ml Flow resistance: 1.08 ± 0.18 cmH2O @ 45 lpm Viral efficiency: > 99.99 % Organism: ΨX174 Bacteriophage Bacterial efficiency: > 99.9997 % Organism: Bacillus subtillis Mean particle size: 3μm
RT020	Fisher&Paykel	Bacterial efficiency: > 99.9997 % Viral efficiency: > 99.99 % Flow resistance: 1.018 ± 0.18 cmH2O @ 45 lpm Deadspace: 38 ml
Bacterial/Viral (001851)	AirLife	Bacterial filtration efficiency (BFE): 99.9% Viral filtration efficiency (VFE): 99.7% Flow resistance: 0.90 cmH2O at 1.0 l/s (after 48 h) Deadspace: 43mL
HEPA (001852)	AirLife	Bacterial filtration efficiency (BFE): > 99.9999 % Viral filtration efficiency (VFE): > 99.9999 % Flow resistance: 1.7 cmH2O @ 1.0 l/s (after 48 h) Deadspace: 84 ml
28HEPA (70538)	Hsiner	Bacterial filtration efficiency: 99.999 % (3.2 μ) Viral filtration efficiency: 99.99 % (3.2 μ) Flow resistance: 58.8 Pa @ 30 lpm Deadspace: 135 ml
28FHMET (70531-FB)	Hsiner	Bacterial filtration efficiency: 99.999 % (3.2 μ) Viral filtration efficiency: 99.99 % (3.2 μ) Flow resistance: 2.02 cmH2O @ 30 lpm Deadspace: 38 ml
04FBVG	Vital Signs	Bacterial filtration efficiency: 99.997 % Viral filtration efficiency: 99.94 % Flow resistance: 1.8 cmH2O @ 60 lpm Deadspace: 27 ml

Table 13-11. Calculated Parameters

Parameter	Calculation / Description
Rinsp Airway Inspiratory Resistance (cmH_2O/L/s)	Rinsp = (Paw* – **PEEP**) / Flow* Where **Flow*** and **Paw*** are respectively the inspiratory flow and airway pressure values measured 100ms after the start of the respiratory cycle.
Rexp Airway Expiratory Resistance (cmH_2O/L/s)	Rexp = (Pplat – **PEEP**) / PEFR
Cstat Static Compliance (mL/cmH_2O)	Cstat = Vte / (Pplat – **PEEP**)
Cdyn Dynamic Compliance (mL/cmH_2O)	Cdyn = *Vte* / (*Ppeak* – **PEEP**)
RC exp Expiratory Time Constant (s)	RC exp = Rexp x Cstat
Te Expiratory Time (s)	It indicates the expiratory time of the respiratory cycle.
Ti Inspiratory Time (s)	It indicates the inspiratory time of the respiratory cycle.
WOBv Ventilator Respiratory Work (J/L)	**WOBv** = $\int$P dV
RSBI Rapid Shallow Breathing Index	RSBI = Spont Rate / Vte
P 100 Occlusion Pressure at 100 ms (cmH_2O)	It indicates the **P 0.1** value – pressure measured 100 ms after the start of the inspiratory effort (assisted or spontaneous cycles).
PEEPpause PEEP during Exp Hold	It indicates the **PEEP** value – pressure measured during an Expiratory Hold maneuver.
AutoPEEP Auto PEEP (cmH_2O)	It indicates the **Auto PEEP** value – pressure measured 200 ms before the start of a controlled cycle.

Ventilation System

Essential Performance

The Essential Performance of the system consists of delivery of ventilation at the patient-connection port within the alarm limits adjusted by the operator or the generation of an alarm, as required by **ISO 80601-2-12:2011: Medical Electrical Equipment – Part 2-12** Particular Requirements for Basic Safety and Essential Performance of Critical Care Ventilators.

The verification of the Essential Performance will be conducted by Functional Verification Test-FVT, as described in Chapter 10.

> ⚠️ *WARNING*
> In the situation where essential performance is lost or degraded due to EM disturbances, the ventilator will activate the appropriate protection mechanisms (i.e. audible alarm, visual alarm, safety valve opening) going to a safe state and thus protecting the patient's integrity.

Data Communication Ports

> ⚠️ *WARNING*
> Connection of the ventilator to other equipment may result in previously unidentified risks to patients, operators, or third parties. The institution should identify, analyze, evaluate, and control these risks. Subsequent changes to data communication ports may introduce new risks and require additional analysis.
>
> Do not touch the patient and either data communication ports or non-medical electrical equipment and the patient at the same time. This may cause an unsafe electrical shock to the patient.

USB

Used for screen captures. External USB memory storage device ("flash drive") is required to extract the stored images.

> ⚠️ *CAUTION*
> Do not turn on the equipment with the external USB memory storage device connected. Performing this operation will unable the equipment to start. If that happens, remove the external USB memory storage device, turn off the equipment and turn it on again.

RS 232

The RS 232 port is intended only for maintenance and shall be accessed only by trained people authorized by Vyaire.

⚠ *CAUTION*
Do not connect any equipment in the RS 232 port during normal operation. The presence of any voltage or current from other electrical equipment may result in previously unidentified risks to patients, operators, or third parties.

IT Network/Ethernet

The IT Network port on the rear panel may be used to output data to other equipment. The ventilator share information from measured data, including waveforms and alarms. The ventilator doesn't allow change of ventilation mode settings, start of maneuvers or change of alarm settings through IT network port. The connection to other equipment, e.g. an IT network server, is performed by Dynamic Host Configuration Protocol (DHCP). As this connection is stablished and the ventilator receives an Internet Protocol (IP) address from the receiving system, the ventilator may send data through the use of iX5 IT Network Protocol. The receiving system must use the iX5 IT Network Protocol in order to request and receive data from the ventilator. Information on iX5 IT Network Protocol is available by contacting Technical Support.

⚠ *CAUTION*
Failure to implement iX5 Network Protocol will result in failure in sending data by the ventilator to the receiving system.

iX5 shall be only connected to IT system compliant with IEEE 802.3u.

Use a cable category CAT 5E or better to connect to the ventilator IT network port.

Note: Category CAT 5E is defined by standard ANSI/TIA/EIA-568 .

Connection of the ventilator to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. The facility should identify, analyze, evaluate and control these risks.

Note: IEC 80001-1:2010 provides guidance for the facility to address these risks. IEC 80001 1:2010 refers to "Application of risk management for IT-networks incorporating medical devices Part 1: Roles, responsibilities and activities".

⚠ *CAUTION*
Subsequent changes to the IT network could introduce new risks and require additional analysis. Changes to the IT network include:

• Changes in the IT network configuration.

• Connection of additional items to the IT network.

• Disconnecting items from the IT network.

• Update of equipment connected to the IT network

• Upgrade of equipment connected to the IT network.

The delay time from detection of an alarm condition to the signal leaving the ventilator IT network port is up to two seconds. The facility is responsible for any additional delays introduced by the equipment connected to the ventilator IT network port.

> ⚠️ *WARNING*
> Only the ventilator should be relied upon for alarm signal generation and information. Do not rely on the IT network connection for distribution and receipt of alarm signals. Therefore, a DISTRIBUTED ALARM SYSTEM should not be used as the only mean to recognize alarm signal generation.

Eletromagnetic Compatibility

Table 13-12. Electromagnetic Emission Tests

Emission Test	Standard	Specifications
Radiated Emission	CISPR 11 Ed. 5.0 (2009) + A1 (2010)	Group 1 / Class A
Conducted Emission	CISPR 11 Ed. 5.0 (2009) + A1 (2010)	Group 1 / Class A
Harmonic Distortion	IEC 61000-3-2 Ed. 3.0 (2005) + A1 (2008) + A2 (2009)	Class A
Voltage Fluctuations and Flicker	IEC 61000-3-3 Ed. 3.0 (2013)	-

Table 13-13. Electromagnetic Immunity Tests

Immunity Test	Standard	Test Levels

Electrostatic Discharge (ESD)	IEC 61000-4-2 Ed. 2.0 (2008)	± 8 kV - contact
		± 2, 4, 8, 15 kV - air
Radiated RF electromagnetic fields	IEC 61000-4-3 Ed. 3.0 (2006) + A1 (2007) + A2 (2010)	3V/m, 80% AM at 1 KHz 80 MHz – 2700 MHz
Proximity fields from RF wireless	IEC 61000-4-3 Ed. 3.0 (2006) + A1 (2007) + A2 (2010)	27 V/m, 380 MHz – 390 MHz 28 V/m, 430 MHz – 470 MHz 9 V/m, 704 MHz – 787 MHz 28 V/m, 800 MHz – 960 MHz 28 V/m, 1700 MHz – 1990 MHz 28 V/m, 2400 MHz – 2570 MHz 9 V/m, 5100 MHz – 5800 MHz
Electrical fast transient and burst (EFT&B)	IEC 61000-4-4 Ed. 3.0 (2012)	± 2 kV, 100 KHz – AC Mains
		± 1 kV, 100 KHz – I/O ports
Surges	IEC 61000-4-5 Ed. 2.0 (2005)	± 0,5, 1, 2 kV - AC Mains (Line to Ground)
		± 0,5, 1 kV - AC Mains (Line to Line)
		± 2 kV – I/O (Line to Ground)
Conducted disturbances induced by RF fields	IEC 61000-4-6 4.0 (2013)	3V with 6V ISM, 80% AM at 1 KHz 150 KHz – 80 MHz
Voltage dips/ interruptions on power supply input lines	IEC 61000-4-11 Ed. 2.0 (2004)	100% drop, 0,5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% drop, 1 period 30% drop, 25/30 periods
Power frequency magnetic field	IEC 61000-4-8 Ed. 2.0 (2009)	30 A/m, 50 or 60 Hz

Table 13-14. Test specification for Enclosure Port Immunity to RF wireless communications equipment

The iX5 ventilator is intended for use on an electromagnetic environment where the RF perturbations are controlled. The user can help preventing electromagnetic interference keeping a minimum distance between mobile and portable RF communication equipment (transmitters) and the ventilator (as recommended below), according to the maximum communication equipment output power.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 KHz desviation 1 KHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18Hz	2	0,3	28
870						
930						
1720	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400 - 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	2	0,3	9
5500						
5785						

NOTE: If necessary to achieve the Immunity Test Level, the distance between the transmiting antenna and the ME Equiment or ME System may be reduced to 1m. The 1m tet distance is permitted by IEC 61000-4-3.
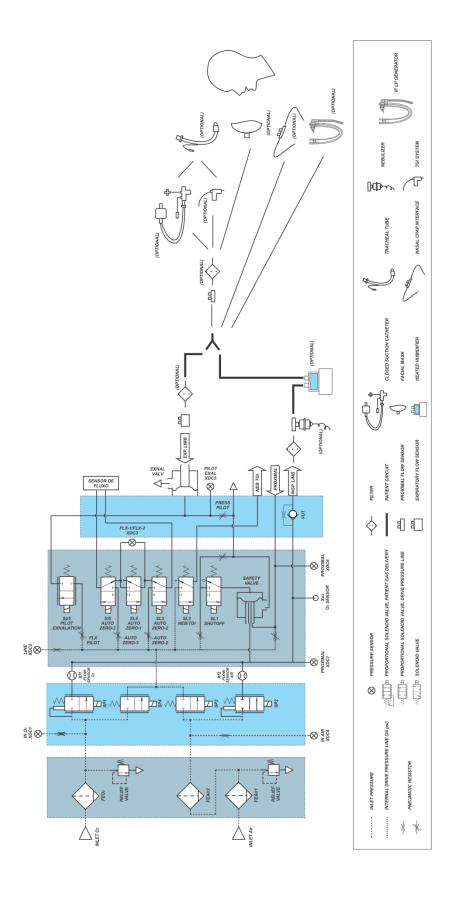
a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an Alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Pneumatic Diagram

See Chapter 3 for correct assembly of the breathing circuit assembly

Appendix A   ***Warranty Term***

The iX5 ventilator is warranted to be free from defects in material and workmanship and to meet the published specifications for 24 (twenty four) months.

The liability of Vyaire (referred to as the Company) under this warranty is limited to replacing, repairing or issuing credit, at the discretion of the Company, for parts that become defective or fail to meet published specifications during the warranty period; the Company will not be liable under this warranty unless (A) the Company is promptly notified in writing by Buyer upon discovery of defects or failure to meet published specifications; (B) the defective unit or part is returned to the Company, transportation charges prepaid by Buyer; (C) the defective unit or part is received by the Company for adjustment no later than four weeks following the last day of the warranty period; and (D) the Company's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Any authorization of the Company for repair or alteration by the Buyer must be in writing to prevent voiding the warranty. The equipment features safety seals on the closing bolts. If these seals are broken by unauthorized personnel, equipment warranty is voided.

In no event shall the Company be liable to the Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder.

The Company warranties as herein and above set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by the Company or its agents in connection with the Buyer's order of the products furnished hereunder.

Limitation of Liabilities

This warranty does not cover normal maintenance such as cleaning, adjustment or lubrication and updating of equipment parts. This warranty shall be void and shall not apply if the equipment is used with accessories or parts not manufactured by the Company or authorized for use in writing by the Company or if the equipment is not maintained in accordance with the prescribed schedule of maintenance.

The warranty stated above shall extend for a period of 24 (twenty four) months, with the following exceptions:

1. Elastomeric components and other parts or components subject to deterioration, over which the Company has no control, are warranted for 60 (sixty) days from date of receipt.

2. Internal batteries are warranted for 90 (ninety) days from the date of receipt.

The foregoing is in lieu of any warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of the Company.

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Appendix B　　**Contact and Ordering Information**

How to Call for Service with Vyaire Authorized Technicians

To get help on performing installation, any of the preventive maintenance routines or to request service on your ventilator, to schedule training (for operation or maintenance) or to obtain iX5 ventilator parts, pieces, and accessories contact Vyaire at:

Hours: 7:30 AM to 4:30 PM (BRT) Monday through Friday
Phone: 55 (11) 4615-9380
e-mail: GMB-BRA10-Support-BR@Vyaire.com

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