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INSTRUCTIONS FOR USE

INTELLIGENT ESOPHAGEAL PRESSURE SYSTEM (IEPS)

Table of Content

ABBREVIATIONS

ARDS	Acute Respiratory Distress Syndrome
EtO	Ethylene Oxide
ICU	Intensive Care Unit
iEPC	intelligent Esophageal Pressure Catheter
iEPMS	intelligent Esophageal Pressure Measurement System
iEPS	intelligent Esophageal Pressure System
IFU	Instructions for Use
NEX^{+10}	Nose-Earlobe-Xyphoid distance + 10 cm
ΔP	Driving Pressure
P_{alv}	Alveolar Pressure
P_{aw}	Airway Pressure
Pes	Esophageal Pressure
PL	Transpulmonary Pressure
Ppl	Pleural Pressure
Pplat	Plateau Pressure
PEEP	Peak End-Expiratory Pressure
PIP	Peak Inspiratory Pressure

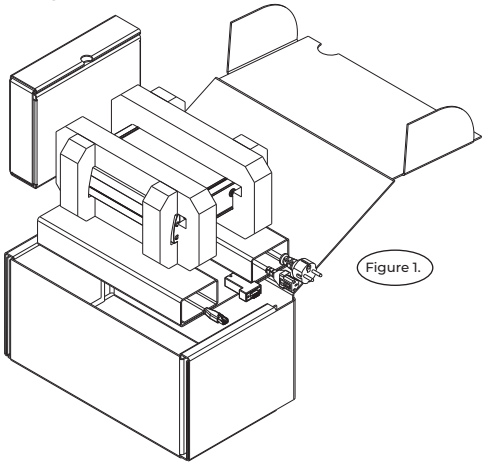
1. INTRODUCTION

This system pack IFU contains the information required to safely and effectively use the esophageal pressure system (IEPS) in combination with the Philips IntelliVue. This IFU should be used by caregivers of the Intensive Care Unit (ICU) who are familiar with nasogastric tube placement and the risks that are associated with these devices and their use.

2. PACKAGES CONTENT

The iEPS consists of the intelligent Esophageal Pressure Catheter (iEPC) and the intelligent Esophageal Pressure Measurement System (iEPMS). The interface cable is an accessory to the iEPMS. The iEPMS controls the iEPC and the interface cable. The content of the two packages is described below.

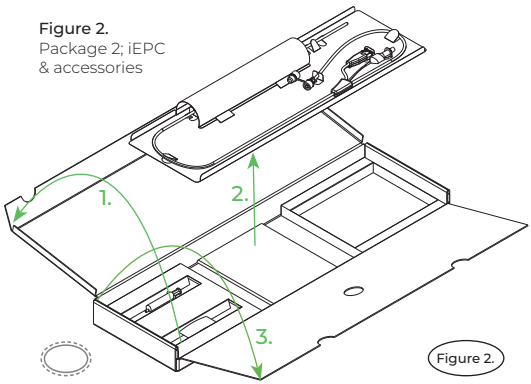
Figure 1.
Package 1; iEPMS



Package 1 contains an iEPMS, power supply cable, interface cable, IntelliBridge® EC5 module, connector cable and an IFU (Figure 1).

Package 2 (Figure 2) contains an iEPC, IFU, two lubricant sachets and a 5 mL syringe.

Figure 2.
Package 2; iEPC
& accessories



3. INTENDED USE

The iEPS is intended for use in ICU patients serving the following functions:

- Monitoring and measuring esophageal pressure, airway pressure and flow to monitor the respiratory physiology of the patient during mechanical ventilation;
- Administrating liquid nutritional media and medication.

The intelligent Esophageal Pressure System (iEPS) is intended for use in ventilated adult intensive care patients to measure esophageal pressure, airway pressure and flow to monitor the respiratory physiology of the patient (vital physiological parameters). The iEPS is NOT intended for continuous use beyond 5 days.

Additionally, the iEPS is intended for use in adult intensive care patients to provide enteral nutrition and medication through oral or nasal gastric placement. It is NOT intended for continuous use beyond 30 days.

4. INDICATIONS

The intelligent Esophageal Pressure System (iEPS) is inserted by nasal or oral intubation into the esophagus and is indicated for:

- Monitoring and measuring esophageal pressure, airway pressure and flow to monitor the respiratory physiology of the patient
- Administrating various types of liquid nutritional media and medication.

The intelligent Esophageal Pressure System (iEPS) is to be used in adult ICU patients receiving mechanical ventilation.

5. CONTRAINDICATIONS

The following contra-indications are applicable:

- The iEPC shall not be used in patients with head/neck trauma.
- The iEPC shall not be used in patients with anatomical abnormalities within the nasogastric route, such as but not limited to:
  - Esophageal varices;
  - Esophageal diverticulitis;
  - Tracheoesophageal fistula;
  - Esophageal stricture;
- The iEPC shall not be used in patients with craniofacial abnormalities.
- The iEPC shall not be used in patients with extremely disturbed coagulation.
- The iEPC shall not be used in patients with recent hemorrhage along the nasogastric route.
- The iEPC shall not be used in patients with recent surgical intervention within the nasogastric route.
- The iEPC shall not be used in patients with any obstruction along the nasogastric route.
- The iEPC shall not be used in patients within an MRI environment.

6. DEVICE DESCRIPTION

The iEPS consists of the iEPC (Figure 3), the interface cable (Figure 4), and the iEPMS (Figure 5).
The iEPC contains a triple lumen shaft: one lumen for the sensor, one lumen for administering enteral nutrition and medication, and one lumen for balloon inflation. The marking on the iEPC indicates the insertion depth from the tip of the iEPC. The sensor measures the pressure in the esophagus. A balloon placed above the sensor protects the sensor from esophageal wall interference. The tip of the iEPC contains three holes to administer enteral nutrition into the stomach. The proximal side of the iEPC houses a trifurcation with an RJ50 connector, an ISO 80369-3 certified purple enteral nutrition connector, a one-way valve to inflate the balloon, and a pilot balloon to verify inflation.

The interface cable connects the iEPC to the iEPMS. Raw values from the sensor in the iEPC are digitized and sent to the iEPMS, where it is analyzed and converted to clinically relevant signal tracings and parameters. The zero button on the interface cable hub is used to zero the sensor of the iEPC and sensors of the iEPMS. The color of the LED on the interface cable hub indicates if the zero procedure was successful (green), or unsuccessful / not yet performed (red). During the zero procedure, the color of the LED turns blue. The clip on the interface cable hub can be used to secure the interface cable to the patient's clothing. A flashing LED indicates that no connection can be made with the iEPC.

The iEPMS contains a socket for the power cable, a power button and a fuse drawer, a serial connector to the EC5 module, a socket for the interface cable, a LED providing the status of the iEPMS, and two pressure nipples for connection with a disposable differential flow sensor to acquire flow and airway pressure.

The iEPS should be used by caregivers of the ICU such as physicians, nurses, and trained medical staff with medical knowledge concerning nasogastric feeding tubes. The iEPC can be used in combination with a feeding pump and the Differential Pressure flow sensor adult (PN 007-00006). Note, a patient monitor is required to display the measurements of the iEPS. Currently, the iEPS is only compatible with the Philips IntelliVue® using the IntelliBridge® EC5 (Type #102) and EC10 modules, both with OpenInterface protocol.

Figure 3.

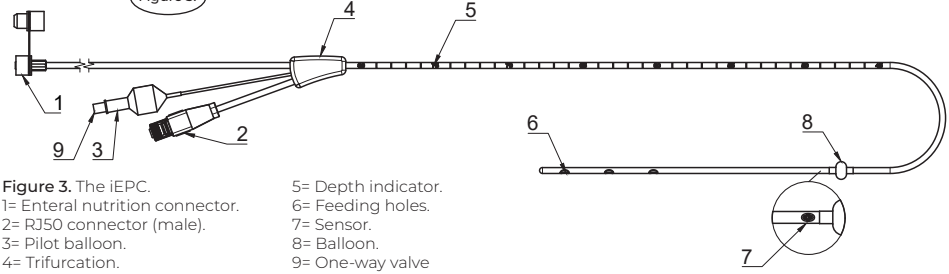


Figure 3. The iEPC.
1= Enteral nutrition connector.
2= RJ50 connector (male).
3= Pilot balloon.
4= Trifurcation.
5= Depth indicator.
6= Feeding holes.
7= Sensor.
8= Balloon.
9= One-way valve

Figure 4.

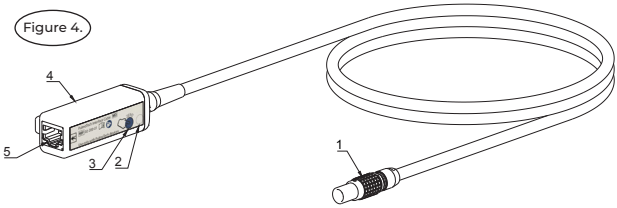


Figure 4. The Interface Cable.
1= LEMO connector (male).
2= LED light.
3= Zero button.
4= Interface cable hub.
5= RJ50 connector (female).

Figure 5.

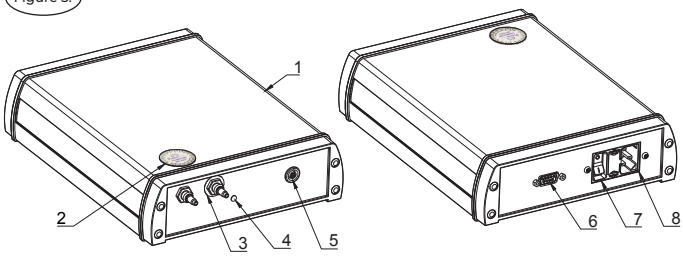


Figure 5. The iEPMS.
1= iEPMS.
2= Calibration sticker.
3= Pressure nipple flow label.
4= LED indication light.
5= Connector to interface cable.
6= Connector to EC5 module.
7= Power button.
8= Power supply connector.

7. WARNINGS & PRECAUTIONS

7.1. GENERAL SAFETY WARNINGS

- Neglecting the safety warnings can endanger the patient, caregivers, and the device. The following dangers may arise from improper device use:
  - Endangerment of the patient and medical staff due to electrical hazards.
  - Endangerment of the patient due to perforations of anatomical structures.
  - Failure of device functions.

NOTE: Failure to observe the safety warnings voids all damage claims and manufacturer liability.

- Only use the iEPS in accordance with this IFU. Not reading the IFU completely could endanger the patient, caregivers, and the device. Consult the IFUs of the devices connected to the iEPS.
- The iEPS is a Medical Device.
- Connection of the iEPS to the patient monitor (i.e. through the Philips® Modules) must be performed by trained professionals.
- Do NOT modify the iEPS without the authorization of PulmoTech B.V. Modification could cause damage to the device and its functioning.
- If the iEPS is modified with authorization of PulmoTech B.V., appropriate inspection and testing must be conducted following instructions provided by PulmoTech B.V. to ensure continued safe use of the iEPS.
- Only use original replacement parts and accessories authorized by PulmoTech B.V. to establish safety compliance. The use of any non-authorized parts voids the warranty and eliminates the manufacturer's liability.
- Do NOT use the device if damaged or defective.
  - Remove the iEPC when the sensor becomes unresponsive (to pressure).
- Qualification is needed prior to the use of iEPS. The user training and instructions provided by PulmoTech B.V. or certified representative must be followed. Unsuccessful or incomplete training prior to use could endanger the patient, caregivers, and the device, and voids the liability of the manufacturer.
- NEVER use a wet or damp device.
- Protect the device from condensation.
- Disconnect the iEPC from the interface cable prior to use of a defibrillator. Using a defibrillator with the iEPC still connected to the interface cable will result in degradation of performance.
- It is strongly recommended to replace the iEPC after a defibrillator is used with the iEPC in place. After using a defibrillator, the performance of the sensor cannot be guaranteed.

7.2. OPERATING CONDITIONS

- Do NOT use if the sterile packaging is damaged. Please contact PulmoTech B.V. immediately if the sterile packaging is damaged.
  - **CAUTION**: The device can lose its function due to external impact such as dropping the device.
  - **CAUTION**: The device can lose its function due to condensation.
  - **WARNING**: Do NOT use when sterile packaging is unintentionally opened before use.
  - **WARNING**: Do not to unintentionally open the sterile packaging before use, thereby exposing the iEPC to environmental conditions outside of those specified.
- Power supply
  - The iEPMS houses an EML15US05-S power supply (XP Power) which meets the IEC 60601-1 requirements.
  - Input: 85-264 VAC, 47-63 Hz.
  - **WARNING**: To avoid the risk of electric shock, the iEPS must only be connected to supply mains with protective earth.
- Cable and plug connections
  - **WARNING**: All cables should be placed safely to avoid tripping hazards.
  - **WARNING**: Any damaged cable must be replaced.
- Do NOT use in or in the proximity of an MRI scanner.
- Do NOT use the iEPS in an oxygen-enriched environment or in the vicinity of flammable (anesthetic) gasses.

7.3. ELECTROMAGNETIC INTERFERENCE

- This medical device manufactured by PulmoTech B.V. conforms to EN 60601-1-2:2015 standard for both immunity and emissions. It has been tested according to the requirements for Professional Healthcare Facility Environment.
- The iEPS is protected against electromagnetic interference and electrostatic discharges in the specialized environment, with an exception for near high-frequency surgical equipment and the radio frequency shielded room of a medical electrical system from magnetic resonance imaging (MRI), where the intensity of electromagnetic disturbances is high.
- The device is classified according to CISPR 11 as GROUP 1, CLASS A. The table of tests performed to meet the requirements of EN 60601-1-2:2015, clause 5.2.2, can be found in Appendix A. Further documentation in accordance with EN 60601-1-2:2015 is available at PulmoTech B.V. with contact details available in this IFU.
- Nevertheless, the following precautions need to be observed:
  - **WARNING**: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this and other equipment should be observed to verify normal operation.
  - **WARNING**: Use of accessories, transducers and cables other than those specified or provided by PulmoTech B.V. could result in increased electromagnetic emissions or decreased

electromagnetic immunity of this equipment and result in improper operation.
    - **WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the iEPS including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Malfunctioning of the device could be considered when one of the following occurs:
    - The device switches on or off by itself;
    - Abnormal pressures are shown in the data measured by the sensors.
- Electromagnetic interference could be resolved by:
    - Removing or switching off the source of interference when possible.
    - Turning the device off and on again.
- **NOTE**: Contact PulmoTech B.V. or its duly authorized representative immediately when interference continues.

7.4. MAINTENANCE, CARE AND DISPOSAL

- **WARNING**: Use before: see packaging and labeling. Do NOT use after the expiration date. Dispose of according to all applicable Federal, State and local Medical/Hazardous waste practices if expired.
- **WARNING**: Do NOT use the measurement function of the iEPC for longer than 5 days after insertion. Quality of measurements cannot be guaranteed after 5 days. The iEPC can still be used to administer enteral nutrition. Replace the iEPC when desired to continue the measurements.
- **WARNING**: Do NOT use the feeding function of the iEPC for longer than 30 days after insertion. Safety of the patient cannot be guaranteed after 30 days. Remove or replace the iEPC prior to exceeding 30 days of use.
- **WARNING**: Do NOT re-use the iEPC. The iEPC is single-use only and must not be cleaned or sterilized. Re-use could cause contamination and degradation of the sensor's performance. Dispose of after use according to all applicable Federal, State and local Medical/ Hazardous waste practices.
- **WARNING**: Do NOT rinse or immerse the iEPMS and interface cable in liquids or let liquids enter the devices and connectors. Cleaning and disinfectant solvents can negatively affect the connection and quality of the measurements.
- **CAUTION**: Device could be damaged by strong cleaning agents. Use recommended cleaning agents (see 7.4.1 'Cleaning and Disinfecting').

7.4.1. CLEANING AND DISINFECTION

- **WARNING**: ONLY use alcohol wipes for cleaning. Other cleaning and disinfecting agents could damage the device.
- **WARNING**: Clean the iEPMS, interface cable, EC5 module and connection cable thoroughly before and after each patient's use to prevent contamination.
- **WARNING**: Clean the iEPMS, interface cable, EC5 module and connection cable when an iEPC is replaced to prevent contamination.
- **WARNING**: Clean the iEPMS, interface cable, EC5 module and connection cable before storage.

1) Turn off iEPMS.
2) Remove power cable from wall socket.
3) Remove power cable from iEPMS by pressing the yellow lever on the power cable.
4) Disconnect the interface cable from the iEPMS.
5) Disconnect the EC5 module from iEPMS.
6) Clean the iEPMS, interface cable, EC5 module, power cable and connection cable with alcohol wipes. Make sure all connectors and cables are cleaned thoroughly, yet carefully.
- **WARNING**: Verify if the RJ50 socket on the interface cable is clean if exposed to an excessive amount of bodily fluids. If it is not possible to clean, replace the interface cable to prevent contamination and degradation of function.
- **CAUTION**: Clean thoroughly between all crevasses and underneath the attachment hook of the interface cable hub to prevent contamination. Twist the corner of the alcohol wipes for difficult-to-reach areas such as the inside of the eye on the clip.

7) Visually inspect if all connectors and surfaces are clean and remove any type of remaining contaminants when necessary.
8) Reconnect or store iEPMS, interface cable and the EC5 module with its connector cable.

7.4.2. STERILIZATION

- **CAUTION**: The iEPC is sterilized using ethylene oxide.
- **WARNING** : The interface cable and iEPMS are not sterilized. Sterilization can cause damage to these devices.

7.4.3. INSPECTION AND SERVICING

Inspection must be performed on a regular basis and follow medical device standards to establish the safety of the device.
    - Inspection of the EC5 module must be performed according to its manufacturer's specifications (Philips).
    - Inspection needs to be performed by qualified medical staff.

The internal pressure sensors of the iEPMS need to be recalibrated every two years. A calibration sticker on top of the iEPMS indicates the calibration due date.
Servicing of the iEPMS must be performed:
    - When malfunctioning is suspected.
    - During critical firmware releases, as communicated by PulmoTech B.V.

7.4.4. STORAGE

- Store the iEPMS, iEPC, EC5 module with its connector cable and interface cable in a dry, well-ventilated place away from sources of direct sunlight and heat to prevent damage. Use the original packaging for storage.
- Storage area must be clean and compliant with the conditions mentioned above.

7.4.5. DISPOSAL

- **WARNING**: The iEPC is SINGLE-USE ONLY and must be disposed of after use according to all applicable Federal, State and local Medical/Hazardous waste practices. Re-use could cause contamination and the performance of the sensor could not be guaranteed.
- **NOTE**: The iEPMS and the interface cable are multiple patient, multiple use and could be replaced by new original components manufactured or provided by PulmoTech B.V. After replacement, always follow the IFU.
  - Dispose of interface cable after 1 year of use according to all applicable Federal, State and local Medical/Hazardous waste practices.
  - Dispose of EC5 module and connector cable according to the specifications of the manufacturer (Philips).
  - Dispose of EC5 module, connector cable or interface cable according to all applicable Federal, State and local Medical/Hazardous waste practices if any malfunction is suspected or when damaged.

8. ANTICIPATED BENEFITS AND RISKS

8.1. INTENDED CLINICAL BENEFITS

The following intended clinical benefits are identified:

- Individual guidance based on esophageal pressure: relative pressures
  - Calculation of static and dynamic chest wall compliance, which can be utilized to calculate lung compliance when respiratory compliance is known[1].
    - An indication for the severity of respiratory distress (i.e. low compliant lungs with ARDS).
    - Determination of the dissipation of airway pressure into the chest wall.
  - Transpulmonary driving pressure (overview in [2])
    - Effective lung distending pressure to set the level of support.
  - Assessment of patient effort (dPes)
    - Optimizing ventilator settings for the trade-off between undersupport (desaturation) and oversupport (atrophy of the diaphragm)
    - The effort of respiratory muscles is integrated into the signal, and otherwise not assessed [3]
- Individual guidance based on esophageal pressure: absolute pressures
  - PEEP titration [4]
    - Indication for overdistention, based on end-expiratory transpulmonary pressure (PEEP may be lowered).
    - Indication for atelectasis (PEEP may be increased).
    - Reduced mortality and ventilator-free days with transpulmonary pressure guided PEEP strategy stratified to ARDS disease severity [5].

Please note that all the above-mentioned benefits, and their related clinical risks, are assessed in relation to other available bedside physiological parameters, such as (airway) plateau pressure (Pplat), driving pressure, Electrical Impedance Tomography (EIT), blood pressure and oxygenation.

[1] Talmor D, Sarge T, Malhotra A, O'Donnell CR, Ritz R, Lisbon A, Novack V, Loring SH. Mechanical ventilation guided by esophageal pressure in acute lung injury. N Engl J Med. 2008 Nov 13;359(20):2095-104. doi: 10.1056/NEJMoa0708638. Epub 2008 Nov 11. PMID: 19001507; PMCID: PMC3969885

[2] Pham T, Telias I, Beitler JR. Esophageal Manometry. Respir Care. 2020 Jun;65(6):772-792. doi: 10.4187/respcare.07425. PMID: 32457170; PMCID: PMC7362579

[3] Akoumianaki E, Maggiore SM, Valenza F, Bellani G, Jubran A, Loring SH, Pelosi P, Talmor D, Grasso S, Chiumello D, Guérin C, Patroniti N, Ranieri VM, Gattinoni L, Nava S, Terragni PP, Pesenti A, Tobin M, Mancebo J, Brochard L; PLUG Working Group (Acute Respiratory Failure Section of the European Society of Intensive Care Medicine). The application of esophageal pressure measurement in patients with respiratory failure. Am J Respir Crit Care Med. 2014 Mar 1;189(5):520-31. doi: 10.1164/rccm.201312-2193CI. PMID: 24467647

[4] Baedorf Kassis E, Schaefer MS, Maley JH, Hoenig B, Loo Y, Hayes MM, Moskowitz A, Talmor D. Transpulmonary pressure measurements and lung mechanics in patients with early ARDS and SARS-CoV-2. J Crit Care. 2021 Jun;63:106-112. doi: 10.1016/j.jcrc.2021.02.005. Epub 2021 Feb 25. PMID: 33676795; PMCID: PMC7906505

[5] Sarge T, Baedorf-Kassis E, Banner-Goodspeed V, Novack V, Loring SH, Gong MN, Cook D, Talmor D, Beitler JR; EPVent-2 Study Group. Effect of Esophageal Pressure-Guided Positive End-Expiratory Pressure on Survival from Acute Respiratory Distress Syndrome: A Risk-Based and Mechanistic Reanalysis of the EPVent-2 Trial. Am J Respir Crit Care Med. 2021 Aug 31. doi: 10.1164/rccm.202009-3539OC. Epub ahead of print. PMID: 34464237

8.2. RISK MINIMIZATION

The Risk Management Team of PulmoTech B.V. has performed a risk analysis. However, as a precondition the device must be serviced and inspected according to the manufacturer's specifications. Inspection and service must be performed by PulmoTech B.V. or a certified representative and in compliance with the safety instructions of this IFU.

8.3. POSSIBLE RISKS AND SIDE EFFECTS CONVEYED TO THE PATIENT

- Trauma to the nasopharynx.
- Pressure ulcers at facial skin.

9. INSTRUCTIONS FOR USE

9.1. WARNINGS

Do NOT use if the patient experiences esophageal pathology or conditions. Amongst others, but not limited to:

- Esophageal ulcerations;
- Tumors;
- Diverticulitis;
- Bleeding varices.

- Do NOT use if the patient experiences epistaxis (nose bleeding).
- Do NOT use after recent upper airway surgery.
- Do NOT use if the patient experiences any of the contraindications mentioned in chapter 5.

9.2. CONNECTION TO iEPMS

1) Carefully open package 2 containing the iEPMS, power cable, interface cable, and EC5 module with its connection cable.

- **WARNING**: Do NOT use when the content is damaged.

2) Position the iEPMS on the dry side of the patient's bed.
3) Connect the iEPMS with the power cable to a power source.

- **NOTE**: Do not force the plugs into the socket. Do not pull the cable when disconnecting plugs.

Figure 7.

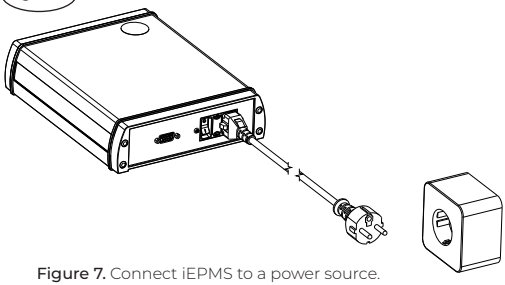


Figure 7. Connect iEPMS to a power source.

4) Connect the LEMO connector (male side) on the interface cable to the iEPMS (female side).

Figure 8.

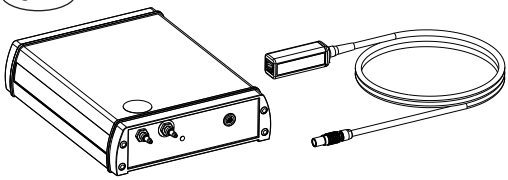


Figure 8. Connect the interface cable to the iEPMS

5) Connect the iEPMS through the IntelliBridge® EC5 and EC10 modules to the Philips IntelliVue® system.

- **NOTE**: IntelliBridge® EC10 module is not provided by PulmoTech B.V. Consult the appropriate documentation when installing the Philips IntelliVue® and IntelliBridge® EC10 module.

Figure 9.

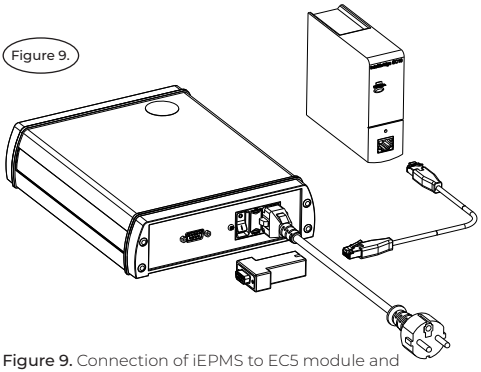


Figure 9. Connection of iEPMS to EC5 module and connector cable

6) Turn the iEPMS on by turning the power switch from 'O' (off) to 'I' (on).
7) Turn on the Philips IntelliVue® (not provided by PulmoTech B.V.).
- **NOTE**: Make sure the power cable is connected to the socket.
8) Carefully open package 1 containing the iEPC, IFU, lubricant and syringe.
- **WARNING**: Do NOT use when the sterile packaging is damaged.
- **WARNING**: Do NOT use when sterile packaging is unintentionally opened before use.
9) Carefully open the sterile packaging of the iEPC.
10) Gently release the RJ50 connector from the pouch card.
11) Connect the interface cable (RJ50 socket) to the iEPC (male side of the RJ50 connector).

Figure 10.

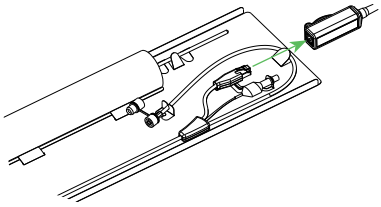


Figure 10. Release RJ50 connector from pouch card and connect to interface cable.

- **NOTE**: The iEPMS will initialize automatically once the iEPC is connected, as indicated by a blinking LED light on the interface cable hub. A pressure waveform will be visible on the patient monitor. This output does NOT have a function yet and is only an indication that the iEPC has been connected properly.
- **NOTE**: If the LED keeps blinking, try to reconnect the iEPC until a connection has been established.
- **NOTE**: After the zero procedure (section 9.3), the signal of esophageal pressure must be 0 cmH2O.

9.3. ZERO PROCEDURE

12) Carefully release the inflation tail and feeding tail from the pouch card.
13) Open the pouch card dome by gently pressing the two clips down and lifting the dome with your other hand.

Figure 11.

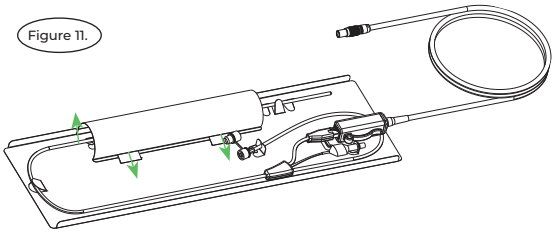


Figure 11. Open the pouch card dome and release the inflation tail and feeding tail from the pouch card.

14) Rotate the iEPC such that the sensor is facing upwards in the pouch card.

Figure 12.

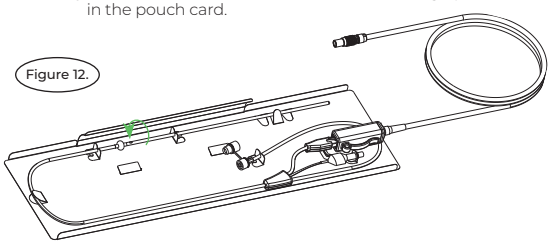


Figure 12. Rotate the iEPC such that the sensor is facing upwards.

15) Source readily available sterile gauze pads from the inventory.
- **WARNING**: Use approximately two layers or a double folded sterile gauze pad to perform the zero procedure.

16) Wet the sterile gauze pad with sterile water.
- **WARNING**: The sensor of the iEPC must be in a humid environment when zeroed, do NOT submerge in a solution. An improperly performed zeroing procedure could result in inaccurate absolute esophageal pressure measurements.

17) Gently place a wet gauze pad on the sensor increase the humidity in proximity to the sensor. Wait for a minumum of **two minutes** with a wet guage pad on the sensor.
- **WARNING**: A waiting period of less than two minutes can result in inaccurate absolute esophageal pressure measurements.
- **NOTE**: Do not use force, or press down on the wet gauze pad. Excessive weight can offset the pressure measurements and result in inaccurate absolute esophageal pressure measurements.

Figure 13.

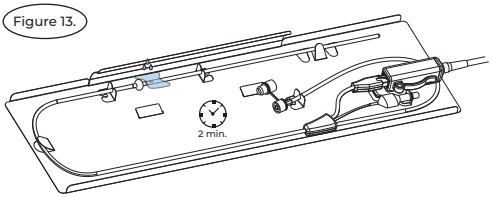


Figure 13. Wetting the sensor prior to pressing the zero button.

18) Zero the sensor by pressing the zero button on the interface cable hub for **at least 2 seconds**. Make sure that the wet gauze pad is still on the sensor. The LED light will turn blue during the zero procedure and green when the zero procedure was successfully performed. Verify that the patient monitor displays Pes = 0 cmH2O, which verifies a performed zero procedure. If not, repeat the procedure from step 15 and onwards.
- **NOTE**: The LED light is red when the iEPC has not yet been zeroed. The LED light remains red when the zero procedure was not successful. Repeat from step 15 on if the LED remains red.
- **WARNING**: Flow sensor must NOT be connected to the ventilator tubing during the zero procedure. The zero procedure will not be effective for the flow and airway pressure signal when the flow sensor is connected to the ventilator tubing.

19) Dispose of the sterile gauze pads according to all applicable Federal, State and local Medical/Hazardous waste practices.
- **NOTE**: As soon as the sterile gauze pads are removed from the sensor the pressure signal on the patient monitor will drift. This is normal behavior as the relative humidity close to the sensor changes.

Figure 14.

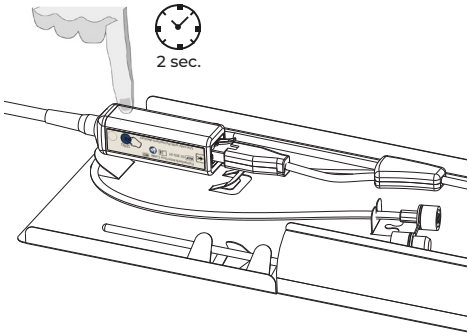


Figure 14. Press the zero button for 2 seconds

9.4. PREPARATION

20) Connect BOTH tubes of the flow sensor to the nipples on the iEPMS.
Connect the blue tube that originates from the patient side of the flow sensor to the **blue**-labeled nipple.
Connect the white tube that originates from the ventilator side to the other nipple.
Verify the correct connection of tubing to the iEPMS.

- **WARNING**: BOTH nipples must be connected before the flow sensor is connected to the ventilator system. The sensor in the iEPMS might be damaged when only one nipple is connected.
- **WARNING**: The flow sensor must NOT be connected to the ventilator tubing during the zero procedure. The zero procedure for flow and airway pressure will not be effective when the flow sensor is connected to the ventilator tubing.
- **WARNING**: If another flow sensor is placed in the system (e.g. as input for a ventilator) assess the impact on the measurements, as flow sensors placed in series are prone to decreased accuracy of measurements.
- **WARNING**: Only use the Differential Pressure flow sensor adult (PN 007-00006), provided by PulmoTech BV, factory calibration is solely applicable for this specific flow sensor.
- **WARNING**: The differential flow sensor is primarily intended to acquire airway pressure. The accuracy of flow-derived parameters is limited and should be treated with caution.

Figure 15.

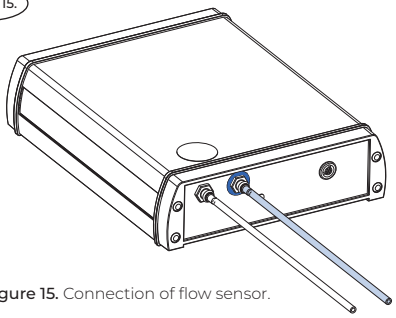


Figure 15. Connection of flow sensor.

21) Place the patient (when possible) in a semi-recumbent position (45 degrees) or supine position, with the head in a neutral position or slightly flexed forward.
22) Determine the nostril with the best airflow to insert the iEPC.
23) Gently release the iEPC from the pouch card.

- **CAUTION**: Hold the iEPC close to the pouch card it is secured in and gently pull the iEPC loose from the clips. Pulling from the tip of the iEPC or too far from the pouch card could cause damage to the iEPC.

Figure 16.

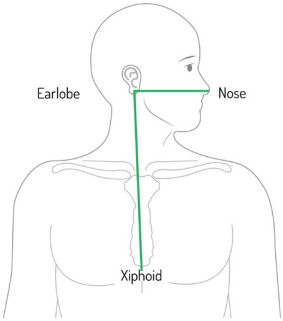


Figure 16. Determination of insertion depth using the NEX+10 method.

24) Determine and note the insertion depth by measuring the distance from the Nose to the Earlobe to the Xyphoid and add 10 cm, also known as the NEX+10.

- NOTE: Insertion depth from the tip of the iEPC can be read from the centimeter demarcation printed on the iEPC.
- WARNING: If the patient is diagnosed with sinusitis, do NOT use the nasogastric but the orogastric route.

25) Deflate the balloon with the syringe on the one-way valve of the iEPC.

- **NOTE**: The pilot balloon will deflate as well.

Figure 17.

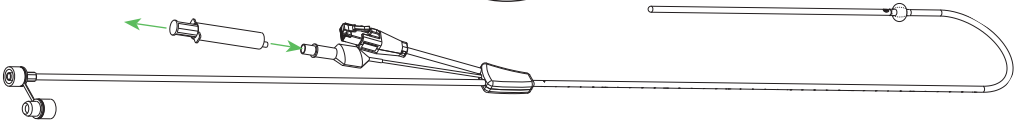


Figure 17 . Deflation of the balloon

9.5. INSERTION OF iEPC

26) Apply lubricant on the distal tip of the iEPC.

- **WARNING**: Make sure the lubricant is not in contact with the sensor. Sensor contact could result in deviating pressure measurements.
- **WARNING**: Make sure the lubricant does not occlude the feeding holes. Occlusion could result in obstruction of the feeding lumen.

Figure 18.

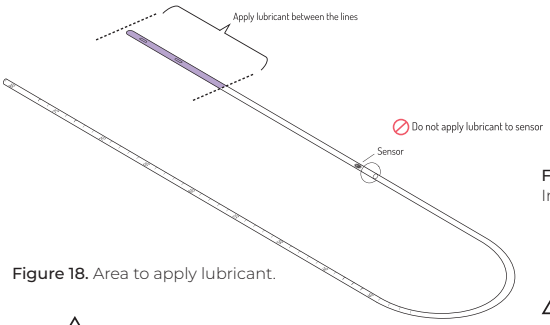


Figure 18. Area to apply lubricant.

27) Insert the iEPC slowly and with gentle advancing motion straight into the nasal cavity and via the esophagus into the stomach according to the predetermined insertion depth (step 24).

- **WARNING**: Do NOT force the iEPC. If obstruction occurs, slightly withdraw, twist the iEPC and try again. Forced insertion of the iEPC could lead to patient injury.
- **WARNING**: Avoid tracheal placement. This can be identified by, but not limited to; airway obstruction, coughing, high pH gastric aspirate and an X-ray.

Figure 19.

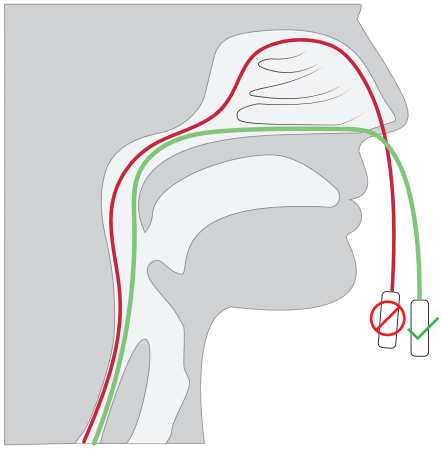


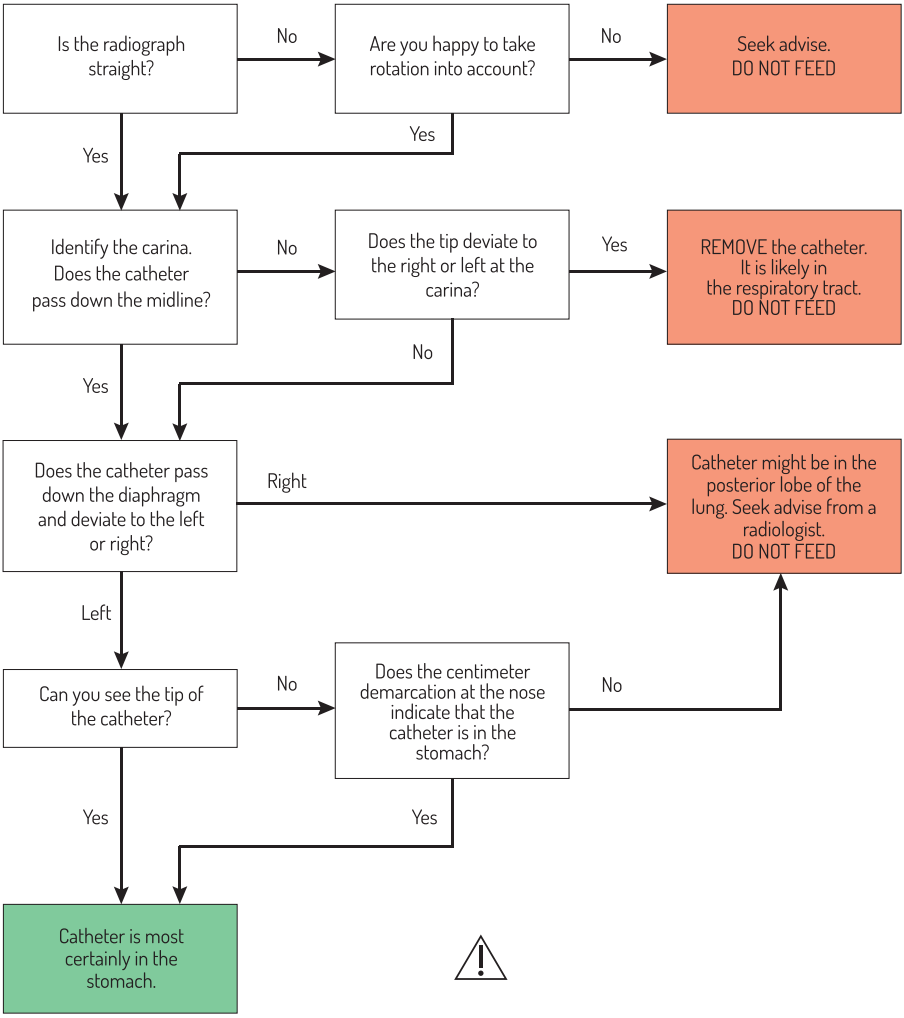
Figure 19. Intersection of the nasal cavity. Insert straight into the nasal cavity.

28) Verify correct placement of the sensor in the esophagus by performing an end-expiratory occlusion (Baydur maneuver or positive occlusion test).
In spontaneously breathing patients, the occluded breathing effort will generate the change in airway pressure and esophageal pressure.
In passive patients, apply an external compression to the rib cage on both sides of the chest during the end-expiratory occlusion(s).
Transpulmonary pressure should not change, i.e. the magnitude in change of airway pressure and esophageal pressure should be the same. The ratio should be between 0.8 and 1.2. A freeze screen can be used to acquire values (see section 9.6.2)

- **NOTE**: Reposition the iEPC if the ratio between Pes and Paw is not between 0.8 and 1.2.
- **WARNING**: Initiating measurements with values outside the 0.8 and 1.2 range could be indicative of incorrect placement and can result in deviating pressure measurements.

29) For correct gastric placement it is highly recommended to take an X-Ray. An pH aspirate can be performed if gastric acid inhibitors are not applied. Reposition the iEPC if placement is incorrect.

- **NOTE**: Please consult the applicable national guidelines for the pH cut-off value. If not available, a cut-off value with a pH lower than 5.5 is recommended.
- **NOTE**: The flowchart below provides a guideline to read the X-ray correctly.



30) Deflate the pilot balloon to make sure no air is inside the balloon system. Inflate the balloon with 3.0 mL using the syringe on the one-way valve.

- **NOTE**: Make sure the balloon is deflated prior to 3.0 mL inflation.
- **CAUTION**: Do NOT use more than 3mL as over-inflation could result in a leaking balloon system and therefor decreased quality of esophageal pressure measurements.
- **CAUTION**: Verify if the pilot balloon remains inflated after insertion. A deflated pilot balloon indicates deflated balloon (e.g. < 3.0 mL) which could result in decreased quality of esophageal pressure measurements.

Figure 20.

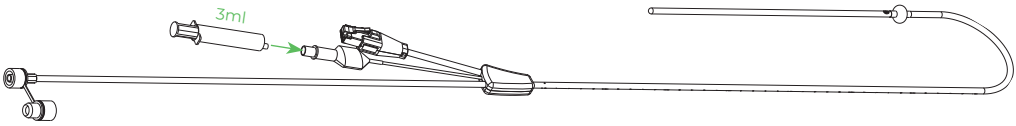


Figure 20. Inflation of the balloon .

31) Secure the iEPC with medical tape on the patient's nose and secure the interface cable hub with a safety pin or with the clip to the patient's clothes.

Figure 21.

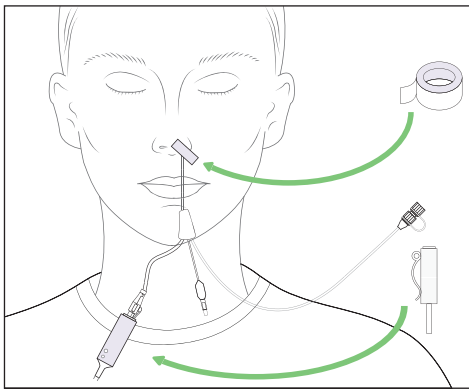


Figure 21.
Secure the iEPC and the interface cable.

32) Connect the enteral nutrition connector of the iEPC to the available enteral nutrition feeding device and start feeding according to the manufacturer's instructions.

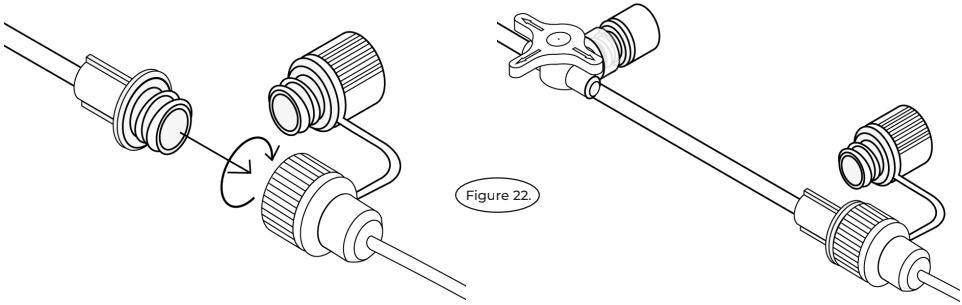


Figure 22.

Figure 22. Connection of the enteral nutrition connector to tubing of feeding device.

9.6. DATA ACQUISITION

Data output is available for a maximum of 2 waveforms and 6 parameters (value captured every 6 seconds, median over 120 seconds)

Waveforms:

- Esophageal pressure (Pes)
- Transpulmonary pressure (PL)
- Airway Pressure (AWP)
- Flow (AWF)

- **NOTE**: The pressure measurements are expressed in cmH2O.

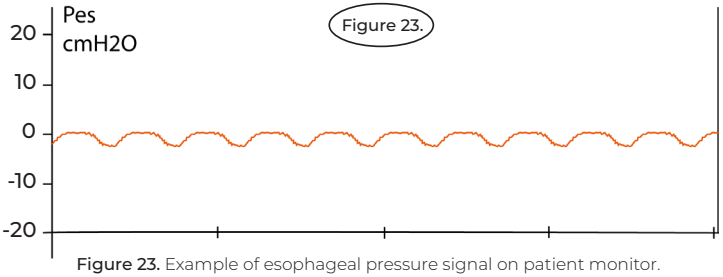


Figure 23. Example of esophageal pressure signal on patient monitor.

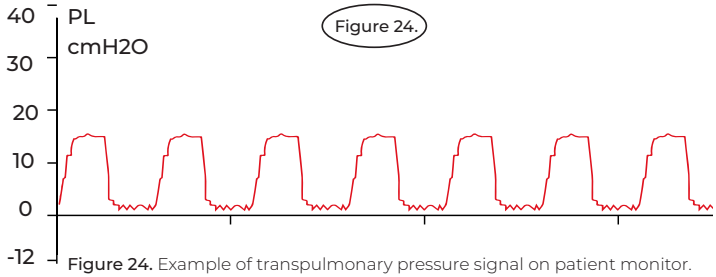


Figure 24. Example of transpulmonary pressure signal on patient monitor.

Parameter	Description	Parameter	Description
PawMax	Maximum airway pressure	PesMax	Maximum esophageal pressure
PawMin	Minimum airway pressure	PesMin	Minimum esophageal pressure
dPaw	Delta airway pressure	dPes	Delta esophageal pressure
PLMax	Maximum transpulmonary pressure	dPL	Delta transpulmonary pressure
PLMin	Minimum transpulmonary pressure		

- **WARNING:** Be aware of cardiac oscillations during measurements (see Figure 25 for an example). Cardiac oscillations can negatively impact both absolute esophageal pressure and esophageal pressure swings (relative esophageal pressure) and their related parameters. The following measures are recommended if cardiac oscillations are negatively impacting the measurements:
  - Twist and move the iEPC up and down and/or deflate and inflate the balloon in order to position the sensor away from the esophageal wall.
  - If measuring in the supine position, slightly tilt the patient to the right side (e.g. using a wedge pillow), allowing the relief of the weight mediastinal structures on the esophagus.

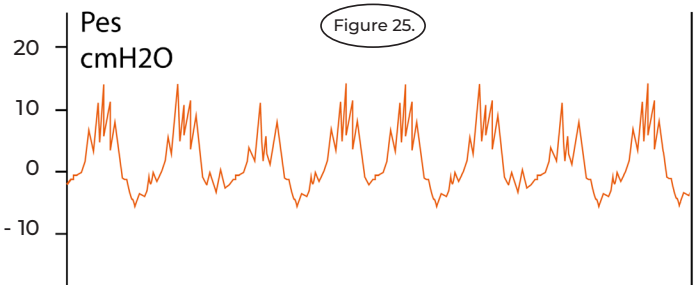


Figure 25.

Figure 25. Example of cardiac oscillations within the esophageal pressure signal.

9.6.1 SELECTION OF WAVEFORMS AND PARAMETERS ON THE PATIENT MONITOR

33) Press on one of the graphs on the IntelliVue display (touch screen). A grey pop-up window is displayed.
34) Press 'Auxiliary Device'. A grey pop-up window is displayed.
35) Press 'Device Driver'. A grey pop-up window is displayed.
36) Press either 'Setup Waves' to select waveforms or 'Setup Numerics' to select a parameter. Another grey pop-up screen is displayed. This shows which waveforms or parameters are represented on the patient monitor.
37) Select the applicable waveform or parameter you want to delete from the patient monitor.
38) Press 'Delete' on the left bottom of the screen.
39) Press 'Add' and select the applicable waveform or parameter.
40) Press the 'X' on the upper right of the grey pop-up window to close the pop-up window.

- **NOTE**: Consult the Philips IntelliVue IFU for more information.

9.6.2 FREEZE SCREEN

41) On the Philips Intellivue Monitor, press the waveform and select 'Freeze Wave' to screen-freeze it.

- **NOTE**: Interpret the esophageal and transpulmonary pressure measurements according to local protocol.

9.7 MAINTENANCE

- **WARNING**: Do NOT use the feeding function the iEPC for longer than 30 days. The safety of the patient cannot be guaranteed after 30 days.
- **WARNING**: Do NOT use the measurement function of the iEPC for longer than 5 days. Quality of measurements cannot be guaranteed after 5 days.
- **WARNING**: Prior to performing measurements check the correct placement of the iEPC (step 28 and 29).
- **WARNING**: Flush the feeding lumen of the iEPC at least every 4 hours, and before and after administering medication to prevent clogging and obstruction.
- **WARNING**: If possible, dissolve medication in water before administering through the iEPC to prevent clogging and obstruction.
- **WARNING**: Ensure medication is adequately crushed, without remaining large chunks.
- **WARNING**: When the feeding lumen of the iEPC is clogged (as indicated by a fault message on the feeding pump), flush with at least 30 mL lukewarm water. Replace the iEPC if resolving the clog is not possible. Repeat steps 8 to 32 of this IFU for successful preparation and insertion of the iEPC.

42) Stop the feeding pump.
43) Turn the 3-way stopcock such that the feeding tube is blocked in the direction of the feeding pump.
44) Flush with at least 30 mL lukewarm water using a syringe on the 3-way stopcock.
45) Remove the syringe.
46) Turn the 3-way stopcock back to its original position.
47) Start the feeding pump.

Figure 26.

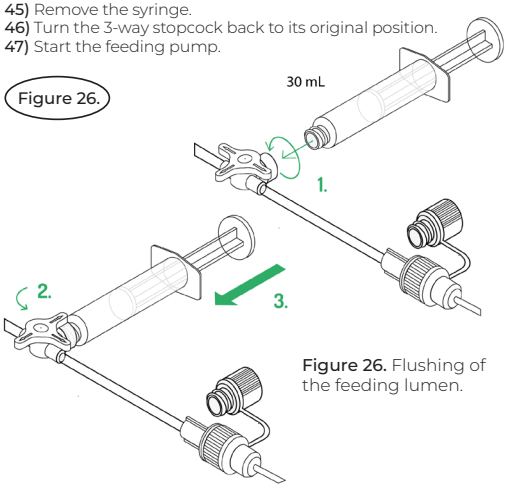


Figure 26. Flushing of the feeding lumen.

9.8 DISPOSAL OF iEPC

48) Stop the feeding pump.
- NOTE: Consult the operating instructions in the IFU of the applicable enteral nutrition pump.
- CAUTION: Make sure the feeding pump is turned off before disconnecting the enteral nutrition connector.

49) Disconnect the iEPC from the feeding pump tubing by turning the enteral nutrition connector in a counterclockwise direction (Figure 27).

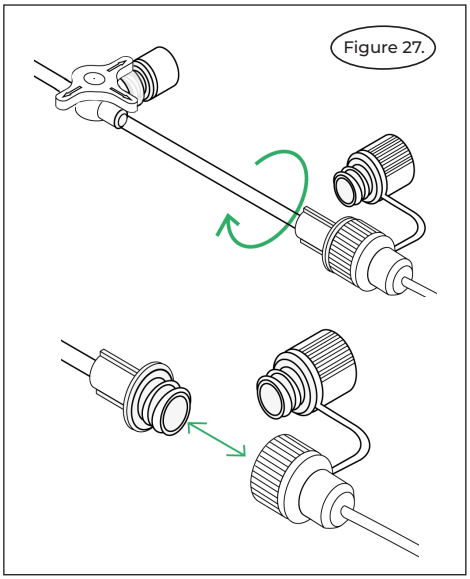


Figure 27. Disconnect iEPC from feeding pump.

50) Disconnect the iEPC from the interface cable by pressing the clip on the RJ50 connector (Figure 28).

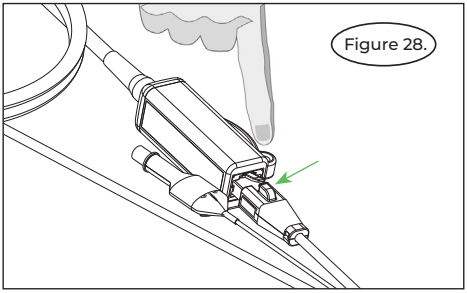


Figure 28. Disconnect iEPC from interface cable.

51) Remove the fixation tape located on the patient's face.
52) Deflate the balloon with the syringe.

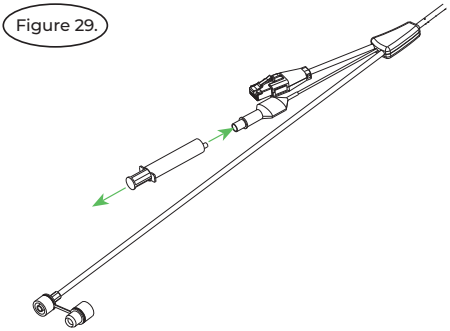


Figure 29. Deflation of the balloon.

53) Gently withdraw the iEPC from the patient.

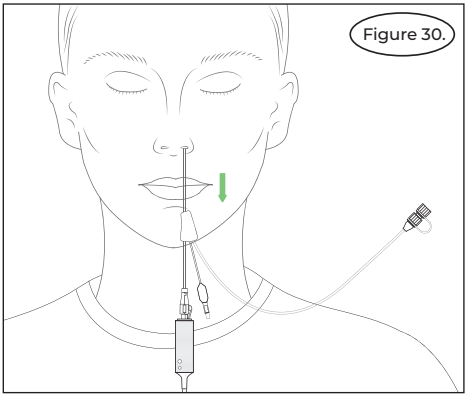


Figure 30. Withdraw iEPC from patient.

54) Dispose of the iEPC according to all applicable Federal, State and local Medical/Hazardous waste practices.

55) Clean the iEPMS, interface cable, EC5 module, connector cable and power cable according to regional cleaning protocol.

- NOTE: see 7.4.1 'Cleaning and Disinfecting'.

10. SPECIFICATIONS

Properties iEPS	Design
General Medical Electrical Specifications - Classification - Applied part type	Class I Type BF
Properties iEPC	**Design**
iEPC material	Polyurethane
Packaging dimensions (W x D x H)	594 mm x 184 mm x 46 mm
Weight	412 g
Outer diameter	12 Fr (4 mm)
Sensor material - Body - Surface - Bond pads - Protective layer	Silicon Polyimide Aluminum Epoxy
Sensor pressure range	-300 to 1000 mmHg = -408 to 1360 cmH_2O
Sensor operating temperature	0 ˚C to 60 ˚C
Sensor humidity	Within accuracy specifications at >90% RH
Sensor accuracy	+- 3.5 cmH_2O up to 5 days
Sensor frequency response	>100Hz (limited by sample rate)
Sample rate	100Hz
Number of sensors	1
IP Rating	No IP rating claimed
Usage time - Feeding - Pes measurements	 30 days 5 days
Shelf life	1 year
Sterilization method	1 full cycle of Ethylene Oxide (EtO) Sterilization
Sterility Assurance Level (SAL)	10-6
Transport conditions - Ambient temperature and Relative Humidity	-29 ˚C to 60 ˚C 15 to 85%
Operating conditions - Operating temperature - Pressure range	10 ˚C to 40 ˚C -300 mmHg to 1.000 mmHg = -408 to 1360 cmH_2O
Storage conditions - Ambient temperature - Relative Humidity - Store in a dry well ventilated place	 15 ˚C to 25 ˚C 15 to 85%

Physical connections iEPC	· RJ50 connection plug · One-way valve · ENFit nutrition connector
Properties iEPMS	**Design**
Dimensions (W x D x H) · iEPMS packaging · Interface cable packaging	 · 414mm x 254mm 210mm · 242 mm x 201mm x 59 mm
Sensor operating pressure range · 5” · 40”	 · 0 - 5 “H_2O = 0 - 12.7 cmH_2O · 0 - 40 “H_2O = 0 - 101.6 cmH_2O
Sensor accuracy · 5” · 40”	 · ± 0.2 cmH_2O or ±3.0% (whichever is greater) within -4.0 to +4.0 cmH_2O (differential pressure) · ± 0.2 cmH_2O or ±3.0% (whichever is greater) within -100 to +100 cmH_2O
Sensor frequency response	200Hz (limited by sample rate)
Sample rate	200Hz
Sensor operating temperature	-25˚C to 85 ˚C
Sensor humidity	Within accuracy specifications at <95% RH
Sensor drift	<1.0 cmH2O within 1 hour
Interface cable material	Polyurethane
Number of sensors	2
Recalibration period	2 years
Transport conditions - Ambient temperature - Relative Humidity	 -25˚C to 60˚C 15 to 85%
Operating conditions - Operating temperature - Humidity	 10˚C to 40˚C 0 to 95% (non-condensing)
Storage conditions - Ambient temperature - Relative Humidity - Store in a dry well ventilated place	 2˚C to 40˚C 15 to 85%
Interface cable Length / Diameter	2 m / 6,3 mm
Power supply - Input - Power cable length	 100-240 VAC; 0.4-0.2 A; 50-60 Hz; 170 cm ± 10 cm
Connector cable between EC5 and EC10 modules	Supplied cable with 2 RJ45 connectors, max. 2.5 m. CAT5 or better, straight wired
Physical connections	· Pressure port (Paw) · Fuse drawer · Pressure port (Flow) · DSUB (EC5) · LEMO (interface cable) · Power (mains)
Fuses (located in fuse drawer)	T 800 mA H 250V (5 x 20 mm)
Performance tests	· Communication with sensors and zero procedure · Flow and Paw related output · Pes and PL-related output · 24h duration test Please refer to Annex A for IEC 60601-1-2 related tests and Appendix B for IEC 60601-1 related tests.

11. EXPLANATION OF SYMBOLS

Symbol	Description	Symbol	Description
	Medical device manufacturer		Keep dry
	Date of manufacture		Temperature limitation
	Use-by date (yyyy-mm(-dd))		Humidity limitation
	Manufacturer's batch code		Do not re-use
	Reference number		Consult instructions for use
	Sterilized using ethylene oxide		Warning/ caution
	Do not use if packaging is damaged		CE Mark + notified body number DEKRA
	Fragile handle with care		Cleaning symbol
	Type BF applied part		Keep away from sunlight
	Medical Device		Unique Device Identifier
	Serial number		Single sterile barrier with protective packaging outside
	Single sterile barrier		Mandatory action: read instructions for use

APPENDIX A: EN 60601-1-2 TABLE

The following tests are performed to meet all the requirements of EN 60601-1-2:2015, clause 5.2.2.

EMISSION tests and compliance criteria		
1	Mains terminal disturbance voltage (Conducted EMISSIONS) According to CISPR 11:2009 - Input power: < 20 kVA	Power supply (XP Power) has been evaluated to EN55022, class B for conducted and radiated emissions.
2	Electromagnetic radiation disturbances (Radiated EMISSIONS) According to CISPR 11:2009 - Input power: < 20 kVA	30 – 230 MHz; 40* / 50* dB (µV/m)** 230 -1000 MHz; 47* / 57* dB (µV/m)** * Quasi-peak ** 10 m / 3 m measuring distance
3	Harmonic current emissions IEC 61000-3-2:2018	Not Applicable
4	Voltage changes, voltage fluctuations and flicker emission IEC 61000-3-3:2013	Not Applicable
IMMUNITY tests and test levels		
5	Electrostatic discharge immunity According to IEC 61000-4-2 - Enclosure port - Patient coupling port - SIP / SOP port	±8 kV contact; ±2 kV, ±4 kV, ±8 kV, ±15 kV air
6	Radiated RF electromagnetic fields immunity According to IEC 61000-4-3 - Enclosure port	3 V/m, 80 MHz to 2.7 GHz 80 % AM at 1 kHz
7	Proximity fields from RF wireless communications equipment immunity According to IEC 61000-4-3 - Enclosure port	Max. power 2 W Distance: 0.3 m Max. test level: 28 V/m See table 9 of IEC 60601-1-2: 2014
8	Electrical fast transient/burst immunity According to IEC 61000-4-4 - AC power port only - SIP /SOP Ports	- AC port tested as part of the power supply evaluation EN61000-4-4, level 2, performance criteria A - SIP /SOP – Not Applicable (Cable length < 3 m)
9	Surge immunity According to IEC 6100-4-5 - AC power port only - SIP / SOP ports	- AC port tested as part of the power supply evaluation EN61000-4-5, installation class 3, performance criteria A - Not Applicable for SIP /SOP ports. No ground connection

IMMUNITY tests and test levels		
10	Conducted disturbances induced by RF fields immunity According to IEC 61000-4-6 - AC power port - SIP /SOP ports - Patient coupling port	3 V, 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz, 80 % AM at 1 kHz - AC port tested as part of the power supply evaluation EN 61000-4-5, 3 V, performance criteria A - Not applicable for SIP/SOP ports as cable length < 3m
11	Rated power frequency magnetic fields According to IEC 61000-4-8 - Enclosure port	Not Applicable
12	Voltage dips and variations immunity According to IEC 61000-4-11 - AC power port	AC port tested as part of the power supply Evaluation EN 61000-4-11, 30 % 10 ms, 60 % 100 ms, 100 % 5000 ms, performance criteria A, B, B
13	Voltage interruptions immunity According to IEC 61000-4-11 - AC power port	AC port tested as part of the power supply evaluation EN 61000-4-11, 30 % 10 ms, 60 % 100 ms, 100 % 5000 ms, performance criteria A, B, B

APPENDIX B: EN 60601-1 TABLE

Clause of EN-IEC 60601-1	Test/measurement	Applicability
4.11 / 7.2.7	Input power measurement	Yes
8.4.3	Residual voltage measurement	Yes
8.6.4	Ground bonding test	Yes
Clearance: 8.9.1.10 Creepage: 8.9.1.4	Clearance and creepage distances	Yes
8.8.2	Distance through insulation	No, no thin film material used
7.3.3 / 15.4.3.4	Lithium reverse current test	No lithium battery present
8.7.3	Earth leakage, touch current and patient leakage current	Yes
4 / 8 / 9 / 11 / 13 / 15 / 16 and Annex A / G / I / K	Abnormal operation and fault conditions	Yes
8.8.3	Electric strength test	Yes

Clause of EN-IEC 60601-1	Test/measurement	Applicability
5.7 / (8.9.3)	Humidity test	No, the power supply is certified. No hazardous voltages or hygroscopic materials are present within the EUT.
8.5.5	Defibrillation-proof applied part tests	No, no defibrillation-proof applied part present.
Thermal measurements		
11.1	Thermal behaviour	Yes
Mechanical tests		
5.9.2 / 9.4.4 / 15.3.x	Mechanical strength test	Yes
9.4	Mechanical stability test	Yes
Miscellaneous tests		
5.3	Durability and legibility of labelling	Yes

APPENDIX C: CMH_2O TO PASCAL CONVERSION TABLE

The following conversion can be applied for the conversion from cmH_2O to Pascal.

Application	cmH_2O	Pascal
iEPC pressure accuracy range	3.5	343.2
iEPC sensor pressure range (lower boundary)	-408	-40,011
iEPC sensor pressure range (upper boundary)	1,360	133,370
iEPMS sensor pressure range (lower boundary)	0	0
iEPMS sensor pressure range (upper boundary)	101.6	9963.6

PulmoTech B.V.
Kamerlingh-Onnesstraat 5, 9351 VD
The Netherlands, Leek, Groningen

www.pulmo-tech.com

KvK: 71364897
RSIN: 858687409
BTW: NL858687409B01

Report PulmoTech B.V. and the competent authority of the Member State in which the user and/or patient is established if any serious incident has occurred in relation to the iEPS.

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PulmoTech B.V.
Kamerlingh Onnesstraat 5
9351 VD Leek
The Netherlands

Stevinstraat 8
9351 VK Leek
The Netherlands

info@pulmo-tech.com

www.pulmo-tech.com