RESPINOR DXT®

Instructions for Use

V1.11 September 2025

Applicable to countries in the European Economic Area (EEA)

RESPINOR AS

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Organization no. 915417310

Product

Article nr.	Product name	Version
970-0003	DXT Control Unit	4.0

Parts

Article nr.	Product name	Version
830-0002	Power Supply	4.0
445-0004	Multiholder Clamp	4.0

Accessories

Article nr.	Product name	Version
820-0003	DXT Tape Kit	4.0
990-0002	DXT Sensor Kit	4.0

CE 0123

Table of Contents

Read all instructions before use.

RESPINOR only accepts responsibility for the device's safety, usability, and performance if:

- RESPINOR DXT® is used in accordance with its intended use.
- RESPINOR DXT® is used in accordance with product documentation.
- The user has completed self-guided training by reading the Instructions for Use (this document) and watching instructional videos prior to using RESPINOR DXT®.
- No modifications or repairs have been performed by the user on any parts of RESPINOR DXT®.

Abbreviations

Abbreviation	Definition
BMI	Body Mass Index
DE	Diaphragm Excursion
DXT	Diaphragm Excursion Technology
EMC	Electromagnetic Compatibility
ICU	Intensive Care Unit
IFU	Instructions For Use
ILD	Intermediate Level Disinfectant
LLD	Low Level Disinfectant
MV	Mechanical Ventilation
RF	Radio Frequency
RR	Respiratory Rate
SBT	Spontaneous Breathing Trial
WEEE	Waste from Electrical and Electronic Equipment
WLAN	Wireless Local Area Network

1. USE SPECIFICATION

1.1. INTENDED PURPOSE

RESPINOR DXT® provides real-time continuous monitoring of diaphragm movement.

1.2. CLINICAL BENEFITS

By identifying patients at increased risk of extubation failure during the weaning process from mechanical ventilation, RESPINOR DXT® has the potential to improve decision making and reduce the number of emergency re-intubations, and potential morbidity associated with mechanical ventilation, as well as ICU and hospital length of stay.

1.3. POSSIBLE SIDE EFFECTS

Some people may be sensitive to the adhesive medium in the DXT Tape Kit that fastens the DXT Sensor Kit to the skin. If you notice significant skin irritation around or under the Sensors, remove and stop using the Sensors.

1.4. INTENDED PATIENT POPULATION

RESPINOR DXT® is intended for use in adult patients ≥ 18 years of age.

1.5. INDICATIONS FOR USE

RESPINOR DXT® is intended to be used for monitoring diaphragm movement on adult patients in the ICU. RESPINOR DXT® can identify patients with low diaphragm excursions who are at increased risk of extubation failure during the weaning process from mechanical ventilation as an adjunctive measure to be used in addition to other criteria for evaluation of patients' suitability of extubation.

1.6. CONTRAINDICATIONS

Pregnancy, and body mass index (BMI) > 35 kg/m^2.

1.7. INTENDED USER PROFILE

RESPINOR DXT® will be used by healthcare professionals in the ICU.

1.8. INTENDED USE CONDITION

1.8.1 Cleaning and Disinfection Procedures

DXT Control Unit is designed to withstand standard cleaning and low to medium disinfectant solutions in the expected lifetime. DXT Sensor Kit can be used for a maximum of 15 times for use on the same patient. For specific details see section 4.10 of this document.

1.8.2 Duration and Frequency of Use

DXT Tape Kit	DXT Sensor Kit	DXT Control Unit
Single use only. Dispose after use. 	***Single patient, multiple use*** (max 15 times). Do not use on several patients. 	***Reusable.*** Expected lifetime of 4 years.

2. SAFETY INFORMATION

This chapter provides important safety information for using RESPINOR DXT® and includes a list and descriptions of warning and caution messages.

2.1. REPORTING OF SERIOUS EVENTS

In the event of a serious incident relating to RESPINOR DXT®, you are obliged to report back to the manufacturer and the competent authority of the Member State where you are established. See section 8 for contact information.

2.2. SAFETY CONVENTIONS

The IFU contains information about potential situations with undesirable outcomes, how to avoid these situations and the probable consequences if the provided instructions are ignored. This information is provided through two types of messages: warning and caution messages. The messages are written in such a manner that they first express what you *must do* or *must not do* to avoid the situation before a description of the undesirable outcome is presented. Lastly, the potential consequence of the outcome is stated, allowing you to evaluate the seriousness of the message.

Warnings are defined as:

WARNING!
Conditions, hazards, or unsafe practices that may result in:

- Human: serious, critical injury or death.
- Property: damage to surrounding equipment, or widespread damage or destruction
- Data: exposure of sensitive data

Cautions are defined as:

CAUTION!
Conditions, hazards, or unsafe practices that may result in:

- Human: negligible to minor injury
- Property: negligible to minor damage to surrounding equipment

2.3. RESPINOR DXT® SAFETY

WARNINGS!

- RESPINOR DXT® is intended for use by healthcare professionals in the ICU.
- Movement of the patient during examination may impact results. Users should exercise clinical judgement in the interpretation of results.
- Do not use RESPINOR DXT® until the materials present in this IFU have been reviewed and fully understood. Do not operate RESPINOR DXT® for purposes other than intended in this IFU.

2.4. BASIC SAFETY AND USAGE ENVIRONMENT

RESPINOR DXT® is intended to be operated individually as a stand-alone system.

See section 10 for operating and storage conditions.

RESPINOR DXT® is classified as ***MR unsafe*** and may pose unacceptable risks to the patient, medical staff, or other persons within the MR environment.

WARNING!

Projectile Hazard!

WARNINGS!

- Use only parts and accessories specified for use with RESPINOR DXT®, as listed on page 3. Substituting with non-approved parts and accessories may cause the system to perform improperly or may cause injury to the patient or operator.
- Do not connect RESPINOR DXT® to the hospital network because a cybersecurity breach can affect its function, delaying the weaning and resulting in patient injury due to reintubation.
- Use of any damaged equipment, parts, or accessories may cause the device to perform improperly and/or result in injury to the patient or operator. Refer servicing to qualified service personnel.
- No modification is allowed. Do not modify any equipment, parts, or accessories specified for use with RESPINOR DXT®, as listed on page 3. Modification may cause DXT to perform improperly or may cause injury to the patient or operator.

CAUTION!

- Ensure that DXT Control Unit is securely fastened with the multiholder clamp before operating. If it is not securely fastened, DXT Control Unit could fall and hit the patient or operator.

2.4.1 Classifications

Description	**Classification**
Protection against electric shock	Class II

Protection against harmful ingress of water or particulate matter	• DXT Control Unit: IP 20
	• DXT Sensor Kit:
	  ○ Sensor Assembly: IP 65
	  ○ Sensor connector: IP 50
	• Power supply: IP 4X

Applied parts	• DXT Sensor Kit: type BF • DXT Tape Kit: type BF
Mode of operation	Continuous
Method(s) of sterilization	None
Suitability for use in an oxygen rich environment	No

2.5. ELECTRICAL SAFETY

WARNINGS!

- Before use, carefully inspect the DXT Control Unit and DXT Sensor Kit. Always inspect them before and after cleaning, disinfecting, or using them. Check the cables, housings, and connectors for signs of damage, such as cracks or loose wires. To avoid the risk of electrical hazards, do not use the DXT Sensor Kit or DXT Control Unit if there is any sign of damage.
- Dropping the DXT Sensor Kit and/or DXT Control Unit may cause damage. Always inspect them before use. Check the cables, housings, and connectors for signs of damage, such as cracks or loose wires. To avoid the risk of electrical hazards, do not use DXT Sensor Kit or DXT Control Unit if there is any sign of damage.
- Use of accessories or parts other than those specified for use with RESPINOR DXT®, as listed on page 3, can result in increased electromagnetic emissions or decreased electromagnetic immunity of DXT. This can cause tissue heating or disturbance in other medical equipment and make calculated DE and RR values unreliable or display false respiratory cycles in graphs.
- Portable equipment, such as smart phones and PC's, with Bluetooth, or wireless local area network (WLAN), or other radio frequency (RF) communication, shall not be used closer than 30 cm (12 inches) to any part of DXT, including cables specified by RESPINOR.
- If one or both DXT sensors seem unusually hot, stop use immediately. Unplug the sensor(s) from DXT Control Unit. Submit a ticket for support to the manufacturer. The manufacturer's contact information is located in section 8.
- There are no user-serviceable parts. Do not open, remove covers, or attempt repair to avoid the risk of electrical shock.
- DXT Control Unit housing is designed to remain closed. Do not attempt to open it or tamper with the device's internals. Doing so may cause injury to the patient or operator.
- The DXT Sensors are designed to remain sealed. Do not attempt to open them or tamper with the device internals. Doing so may cause injury to the patient or operator.
- Spilling fluids into DXT Control Unit may damage it or present a fire shock hazard. Do not allow fluids to enter the device.
- Do not immerse DXT Sensor Kit beyond specified levels. Immersion beyond specified levels may result in electrical shock.
- Do not spray cleaning disinfectant solution on DXT Control Unit while it is turned on, and do not spray cleaning disinfectant solution directly into the openings at the back of the housing. This may cause damage to DXT Control Unit.
- Do not stack the DXT Control Unit with other electronic equipment. This may cause electromagnetic interference (EMI) that can result in loss or degradation of DXT's performance.

CAUTIONS!

- RESPINOR DXT® consists of sensitive electronic equipment and must be handled with care. Ensure you pull the plugs, not the cable, when disconnecting sensors or power supply from DXT Control Unit. This may cause damage to DXT Control Unit.
- When removing the DXT Sensor Kit from the patient's skin, be careful not to tug on the cables, as doing so can cause damage to either the cable or the Sensors.

2.5.1 Electromagnetic Compatibility (EMC)

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Loss or degradation of DXT's performance due to electromagnetic disturbances may cause:

1. Noise in the Live Feed diaphragm movement graph that may be attributed to actual breath cycles.
2. Measurements of diaphragm excursion per breath cycle and 1-minute median values can exceed 15% and 0.2 cm from the actual diaphragm excursion.
3. Calculations of respiratory rate per breath cycle and 1-minute median can exceed 2 breaths from the actual respiratory rate.

3. System Overview

RESPINOR DXT® (Diaphragm Excursion Technology: DXT) is a non-invasive ultrasound-based system that provides real-time, continuous information on diaphragm function.

The system is composed of the following (Figure 1):

- DXT Control Unit (A),
- DXT Sensor Kit:
  - Anterior Sensor (B), and
  - Posterior Sensor (C)
- DXT Tape Kit:
  - Anterior Tape (D), and
  - Posterior Tape (E),
- Multiholder Clamp (F) – hereafter referred to as Clamp,
- Power Supply (G).

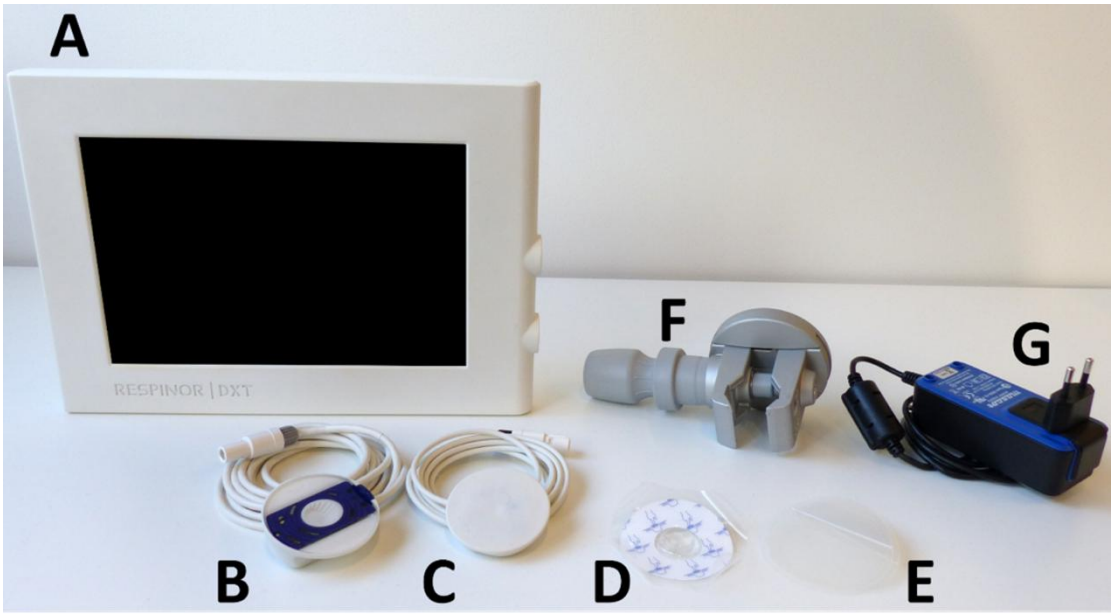


Figure 1. A: DXT Control Unit, B: DXT Anterior Sensor, C: DXT Posterior Sensor, D: DXT Anterior Tape, E: DXT Posterior Tape, F: Clamp, G: Power Supply.

3.1. DXT CONTROL UNIT

The DXT Control Unit processes the signal and displays the relevant information about the diaphragm function in real-time.

The Control Unit has three inputs for connecting the dedicated equipment and a switch for powering the device on and off (Figure 2):

- Power Supply (A),
- Power Switch (B),
- DXT Anterior Sensor (C1),
- DXT Posterior Sensor (C2).

Figure 2. DXT Control Unit. A: Power Supply connector, B: Power Switch, C1: DXT Anterior Sensor connector, C2: DXT Posterior Sensor connector.

3.2. DXT Sensor Kit

The DXT Sensor Kit consists of the DXT Anterior Sensor (A) and the DXT Posterior Sensor (B).

Figure 3. DXT Sensor Kit. A: Anterior Sensor, B: Posterior Sensor.

Figure 4. Front sides of DXT Sensors. A: DXT Anterior Sensor, B: DXT Posterior Sensor.

Both Sensors have a human body and vertical line engraved to assist in Sensor positioning.

- The **Anterior Sensor** has a transparent surface displaying the ultrasound transducer and a blue interior (Figure 4A).
- The **Posterior Sensor** is thinner than the Anterior Sensor and has a flat white surface (Figure 4B).

3.3. DXT Tape Kit

The DXT Tape Kit is specially designed to fasten the DXT Sensor Kit to the patient and consists of the DXT Anterior Tape (A) and the DXT Posterior Tape (B).

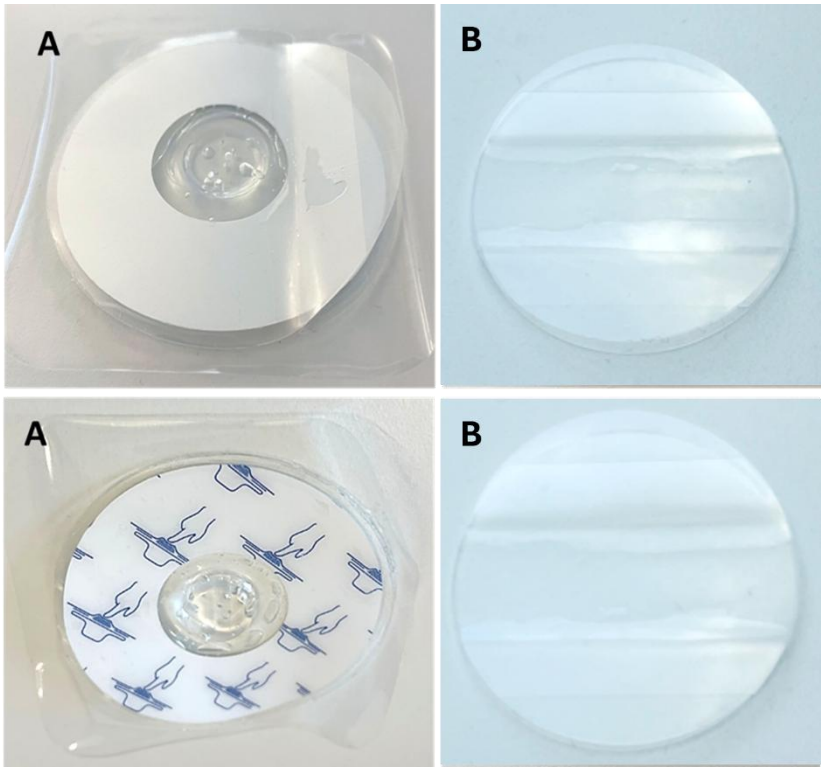


Figure 5. DXT Tape Kit. A: Anterior Tape, B: Posterior Tape.

The **Anterior Tape** is a double-sided tape that includes a pouch containing ultrasound gel.

- The Anterior Tape is white with blue print on one side.
- The Anterior Tape has a hole that acts as a window for the ultrasound transducer.

The **Posterior Tape** is a transparent double-sided tape.

- The Posterior Tape has double liners on both sides.

4. INSTALLATION AND USE

4.1. INSTALLING DXT BY THE PATIENT BED (INTRODUCTION VIDEO-1/8)

Unpack the DXT Control Unit, Clamp, and Power supply (Figure 6).

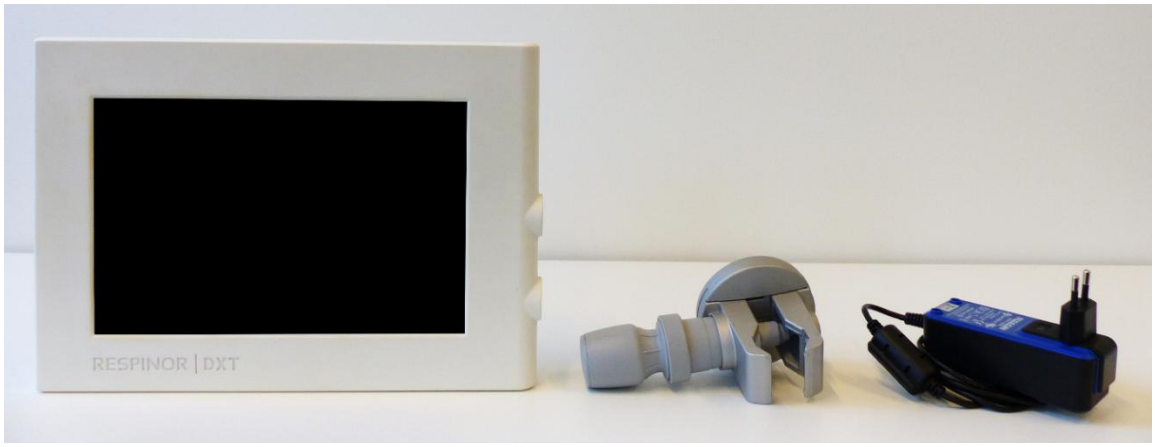
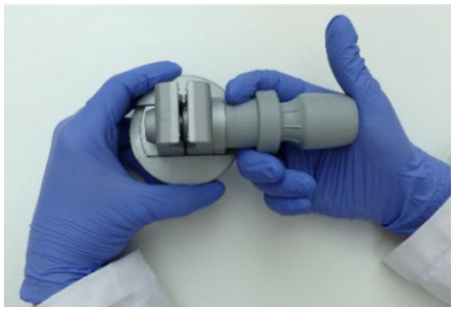
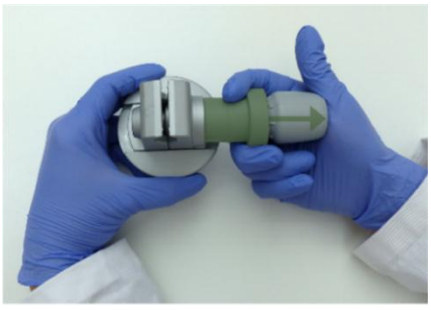


Figure 6. DXT Control Unit, Clamp and Power Supply.

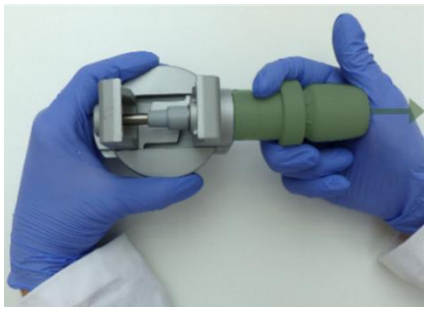
Fasten the Clamp to a pole near the patient's bed (e.g., a standard IV pole), as described below:



Step 1: Hold the plate and take the handle with the other hand and let two fingers grab the cylinder.



Step 2: Pull the two fingers toward the thumb to release the Clamp.



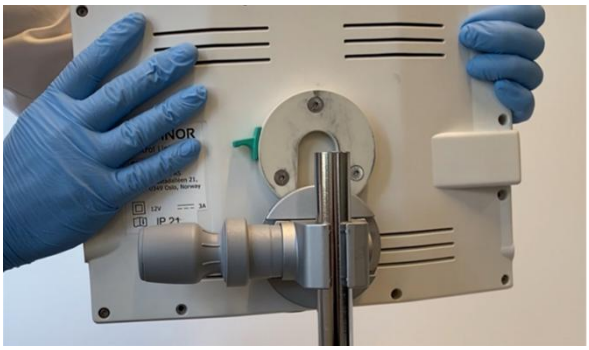
Step 3: Pull the hand holding the handle away from the Clamp to open the Clamp.

Step 4: Place the pole inside the opening of the Clamp and push your hand together to close the Clamp around the pole.

Step 5: Let go of the cylinder with your two fingers to lock the Clamp.

Step 6: Twist the handle to tighten the grip around the pole. Ensure the Clamp is securely fastened.

Fasten the Control Unit to the Clamp:



Step 1: Direct the bracket on the Control Unit towards the clamp from the top.

Step 2: Slide the Control Unit on the clamp until it clicks in place.

Connect the Power Supply and switch on the Control Unit:

Step 1: Connect the Power Supply on the left side of the Control Unit and connect the power plug to an electrical outlet.

Step 2: Power on the Control Unit by pressing the black power switch.

CAUTION!

- Ensure the Clamp is securely fastened to avoid the Control Unit becoming a fall hazard that can cause patient injury, such as bruises or cuts.
- Ensure the power cord is secured and do not cross highly trafficked areas to avoid creating a trip wire that can lead to a fall and cause injury, such as skin cuts, bruises, or sores.
- The DXT shall be installed in a manner where the mains power plug is easily accessible. It should be simple to disconnect when necessary.
- Carefully unpack the accessories from the secondary packaging to avoid paper cuts from the cardboard.

4.2. DXT Sensor Kit Preparation (Introduction VIDEO-2/8)

Prepare the DXT Sensor Kit with the DXT Tape Kit before positioning the Sensors on the patient.

- Start by unpacking a DXT Sensor Kit.

4.2.1 Attach DXT Anterior Tape to DXT Anterior Sensor

- First, verify that the Anterior Tape has not expired:

Verify that the Anterior Tape has not expired by checking the label on the back of the packaging.

The expiration date is marked with an hourglass and the number (17) as highlighted above.

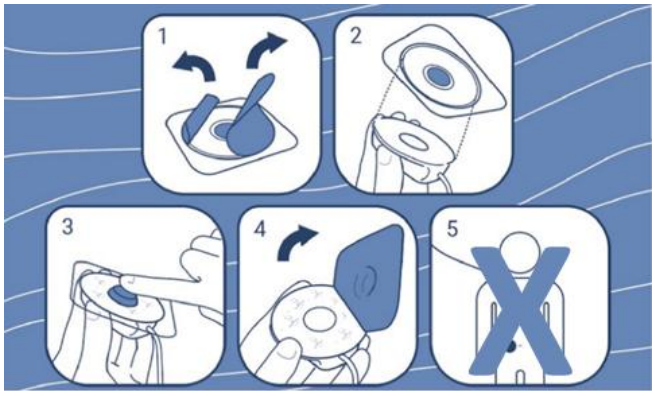
> WARNING!
>
> Never use DXT Anterior Tape after expiry date because the integrated ultrasound gel may dry out and can affect the measurements and lead to suboptimal time of weaning and patient injury due to reintubation.

- Unpack the Anterior Tape:

Step 1: Open the Anterior Tape packaging.

Step 2: Take out the Anterior Tape.

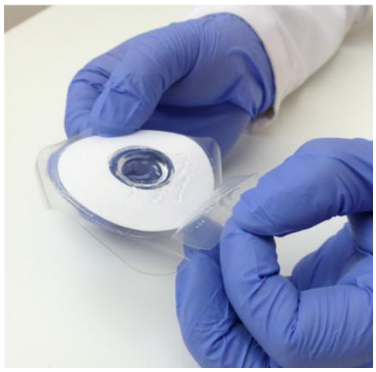
- Follow the steps on the Anterior Tape packaging from 1 to 4:



1. Remove the two liners on the white side of the Anterior Tape, the side *without* print:

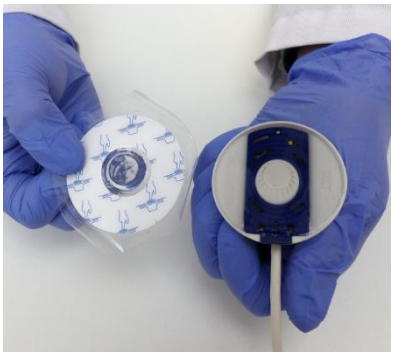
Step 1: Find the split and grab each liner.

Step 2: Pull off the largest liner.

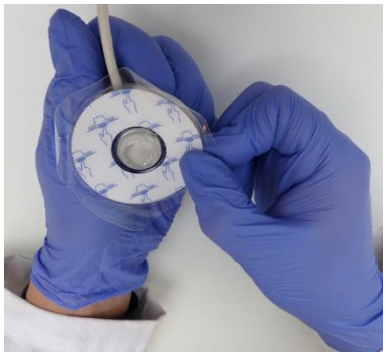


Step 3: Pull off the other liner.

2. Attach the Anterior Tape to the Anterior Sensor:



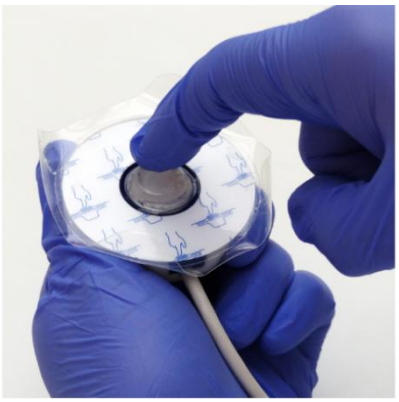
Step 1: Attach the Anterior Tape to the Anterior Sensor with the printed side up.



Step 2: Align the Anterior Tape and the Anterior Sensor. Ensure that the hole in the Anterior Tape is centered around the ultrasound transducer.

Step 3: Press the adhesive area **only**, not the pouch, to fasten the Anterior Tape to the Anterior Sensor.

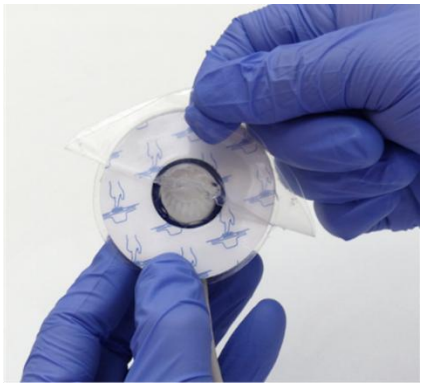
3. **Gently** tap the pouch with ultrasound gel:



Do not press too hard on the pouch. The gel only needs a gentle tap to make good contact with the Anterior Sensor.

4. Remove the tray from the Anterior Tape :

Step 1: Use one hand to remove the tray ***while holding the Anterior Tape*** with your thumb.



Step 2: Pull off the tray ***while holding the Anterior Tape in place*** on the Anterior Sensor.

Step 3: Pull the tray entirely off.

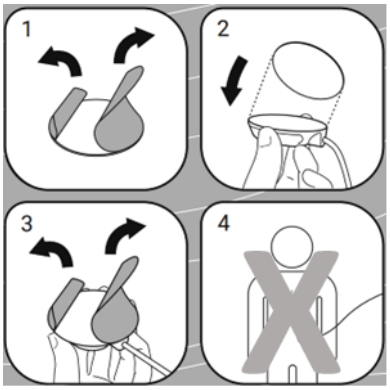
4.2.2 Attach DXT Posterior Tape to DXT Posterior Sensor

- Unpack the Posterior Tape:

Step 1: Open the packaging by tearing from one of the sides.

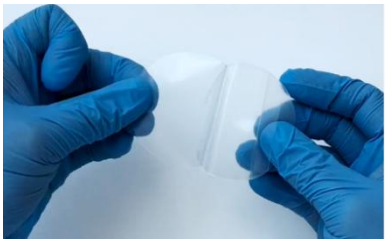
Step 2: Take out the Posterior Tape.

- Follow the steps on the Posterior Tape packaging from 1 to 3:

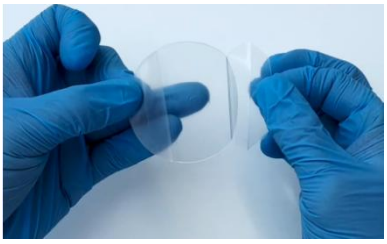


1. Remove the double tape liners on one side:

Step 1: Find the split and grab each liner.



Step 2: Pull off the largest liner.



Step 3: Pull off the other liner.

2. Attach the Posterior Tape to the Posterior Sensor:

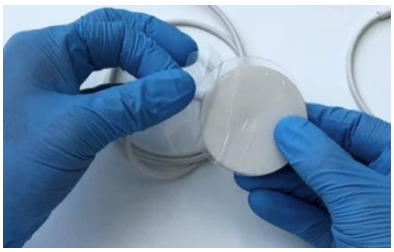
Step 1: Align the Posterior Tape and the Posterior Sensor.

Step 2: Attach the Posterior Tape to the Posterior Sensor.

3. Remove the double tape liners:

Step 1: Find the split and grab each liner.

Step 2: Pull off the largest liner.



Step 3: Pull off the other liner.

4.2.3 Start a New Examination on the Control Unit

- Push “New Examination” on the Control Unit:

Step 1: You are now ready to start a new examination.

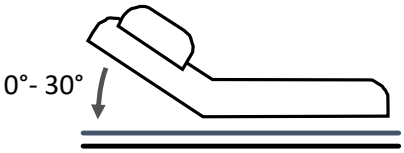
Step 2: Press the button “New Examination” on the screen.

- When pressing new examination, DXT will automatically generate a three-digit examination ID that can be entered in the patient’s journal.

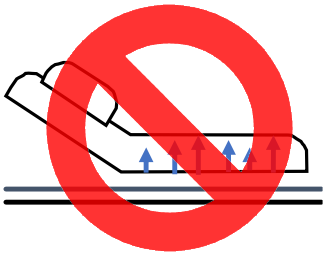
4.3. Position Anterior Sensor on Patient (Introduction VIDEO-3/8)

- Ensure the patient is lying on the back.
- Locate the area two fingers below the rib cage along the midclavicular line and wipe off excess sweat.
- Shave the area in case of significant amount of hair.

The patient must lie on the back in a near supine position.



The bed angle must be 30° or lower.



Pressure relief mattresses must be **turned off.**

> WARNING!
>
> Never use DXT with an active pressure relief mattress since the alternating surface can affect the measurements and lead to a suboptimal time of weaning and patient injury due to reintubation.

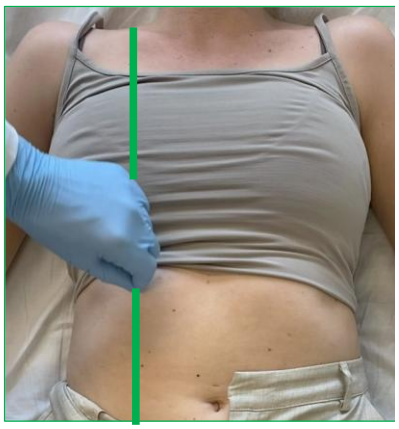
- Connect Anterior Sensor to Control Unit:

Step 1: Connect the Anterior Sensor to the upper connector on the right side of the Control Unit.

The message on the screen points towards the correct connector.

Step 2: Connect the GREY PLUG to the GREY CONNECTOR.

- **Position the Anterior Sensor:**
    - If the patient is underweighted or obese, see section 6.2.1.

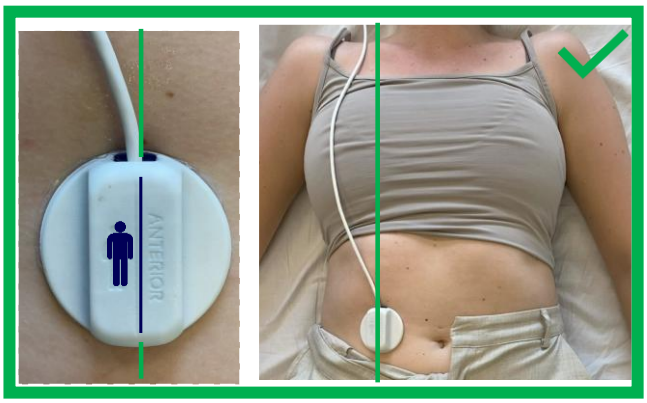


Step 1: Follow the right midclavicular line with your fingers.

Step 2: Position the Anterior Sensor 2 fingers below the rib cage.

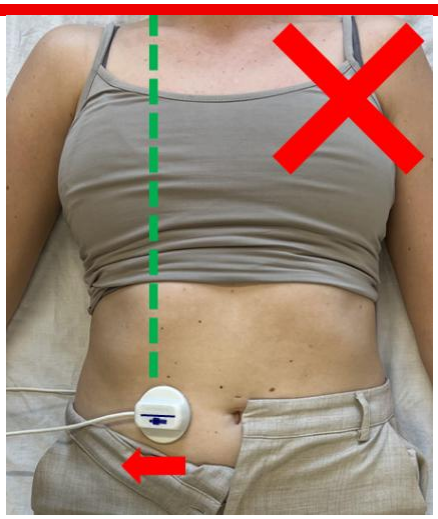
Step 3: Press the Anterior Sensor ***firmly*** against the skin.

- Verify correct Anterior Sensor orientation and position:

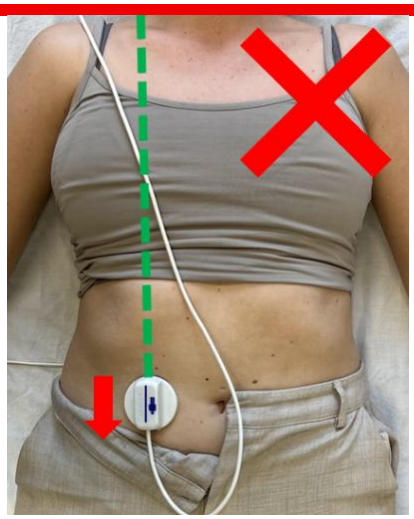


<u>Verify that</u>:

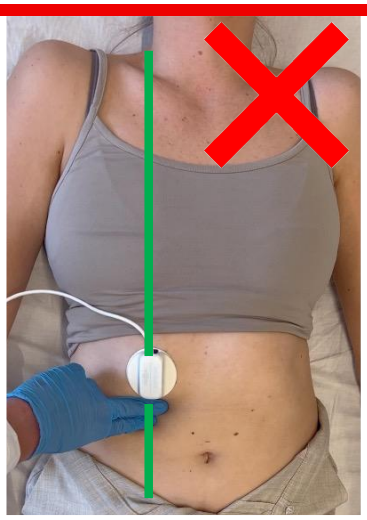
- The human body engraved on the Anterior Sensor matches the orientation of the patient.
- The indented line follows the midclavicular line.
- The cable is exiting towards the patient's head.



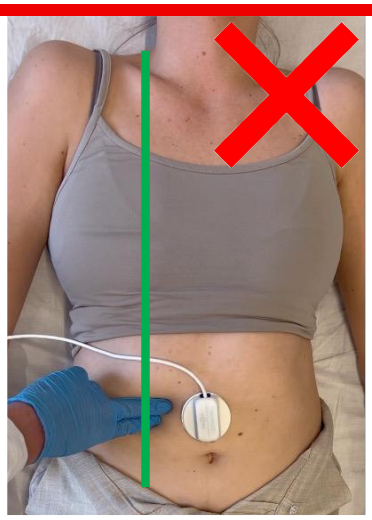
The engraved body does not match the patient and the indented line is not following the midclavicular line.



The engraved body does not match the patient's orientation (Anterior Sensor is upside down).



The Anterior Sensor is placed too high.



The Anterior Sensor is placed too far to the right.

WARNINGS!

- Only attach the DXT Anterior Sensor to intact skin to avoid patient exposure to biological contamination that can cause infection.
- Ensure DXT Anterior Sensor is properly placed and oriented because invalid placement can impact the measurements and affect time of weaning, resulting in patient injury from reintubation.

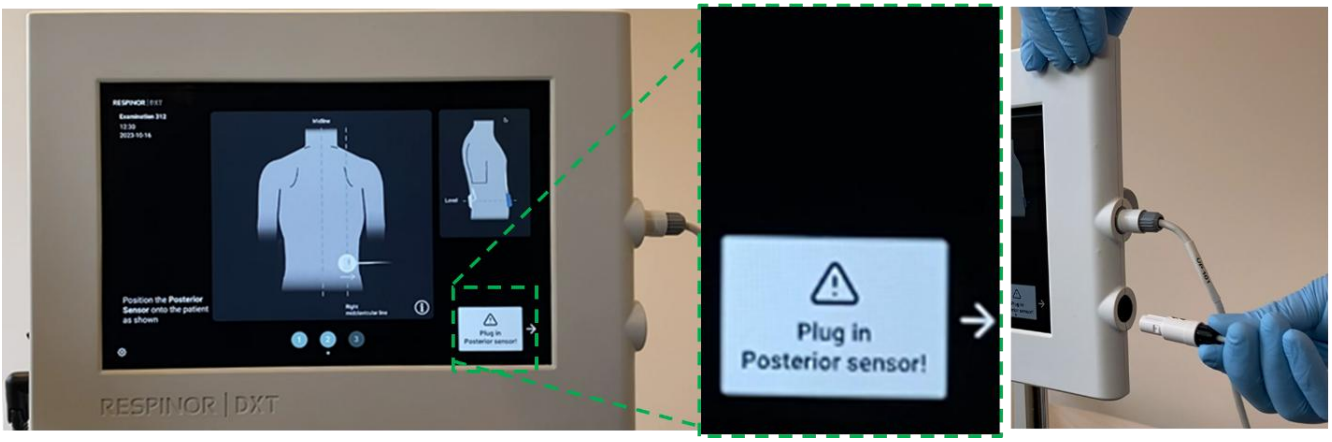
Press the “Continue” button:

Step 1: You are now ready to proceed to the next step.

Step 2: Press continue in the right bottom corner of the screen.

4.4. Position Posterior Sensor on Patient (Introduction VIDEO-4/8)

- Connect the Posterior Sensor to the Control Unit:



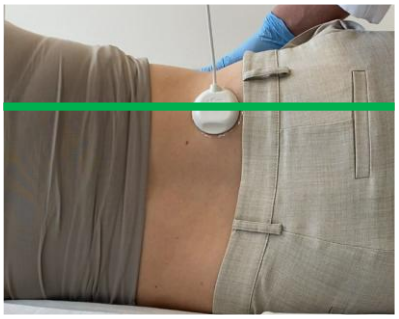
Step 1: Connect the Posterior Sensor to the lower connector on the right side of the Control Unit.

The message on the screen points to the correct connector.

Step 2: Connect the **BLACK PLUG** to the **BLACK CONNECTOR**.

- Position the Posterior Sensor on the patient's back:

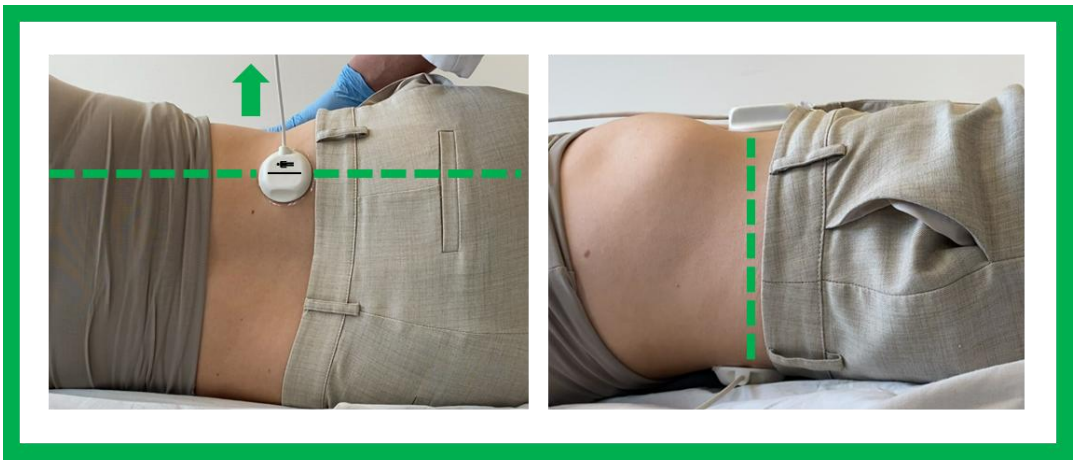
Step 1: Roll the patient over to the left side.



Step 2: Position the Posterior Sensor directly opposite of the Anterior Sensor, on the scapular line.

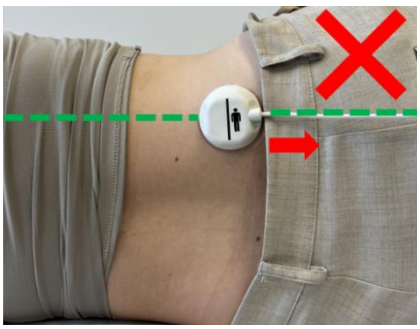
Step 3: Roll the patient on their back.

- Verify correct Posterior Sensor orientation and position:

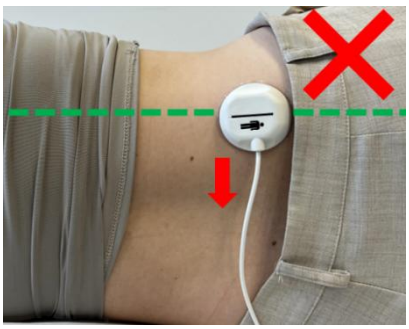


Verify that:

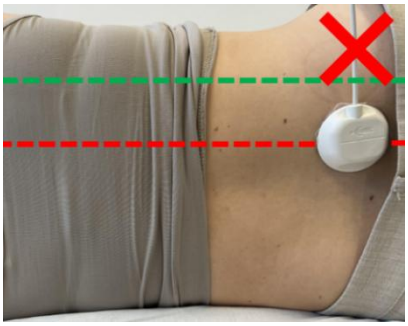
- The human body engraved on the Posterior Sensor matches the orientation of the patient.
- The indented line follows the scapular line.
- The cable is exiting on the patient's right-hand side.
- The Posterior Sensor is directly opposite to the Anterior Sensor.



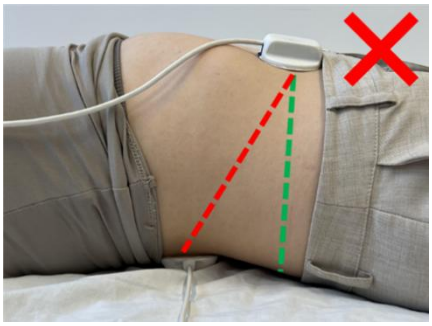
The engraved body does not match the patient's orientation, and the indented line is not following the scapular line.



The engraved body does not match the patient's orientation (Posterior Sensor is upside down).



The Posterior Sensor is positioned too close to the spine.



The Posterior Sensor is positioned too high on the torso.

WARNING!
Attach DXT Posterior Sensor to intact skin only to avoid patient exposure to biological contamination that can cause infection.

- Press the "Continue" button:

Step 1: You are now ready to proceed to the next step.

Step 2: Press continue in the right bottom corner of the screen.

4.5. CHECK SENSOR ORIENTATION AND DISTANCE (INTRODUCTION VIDEO-5/8)

The interactive Sensor Positioning screen displays the angles of the Anterior and Posterior Sensors and the distance between them, to assist in accurate sensor positioning (Figure 7).

- Correct sensor orientation and distance: **the axes are green,** and a symbol (✓) appears on the screen (Figure 7).

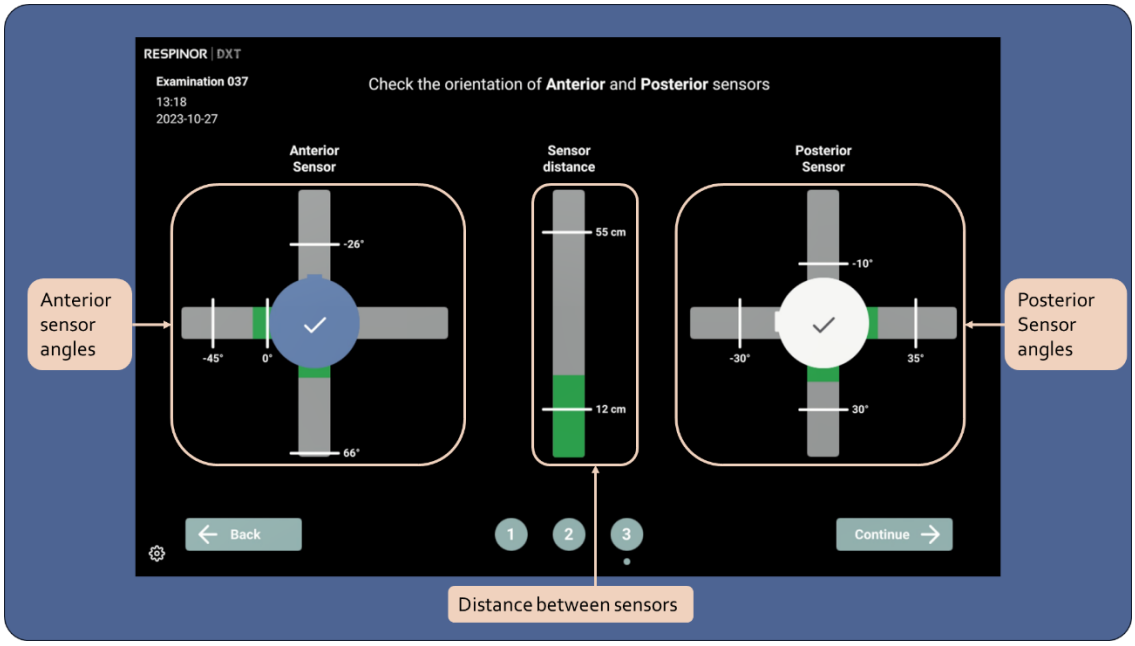


Figure 7. Example of correct orientation of Sensors and distance between Sensors.

- Incorrect sensor positioning: if the sensor orientation is outside of the acceptable range, **the associated axis turns red**, and a warning symbol (⚠) appears (Figure 8). You cannot continue until the issue has been successfully resolved.

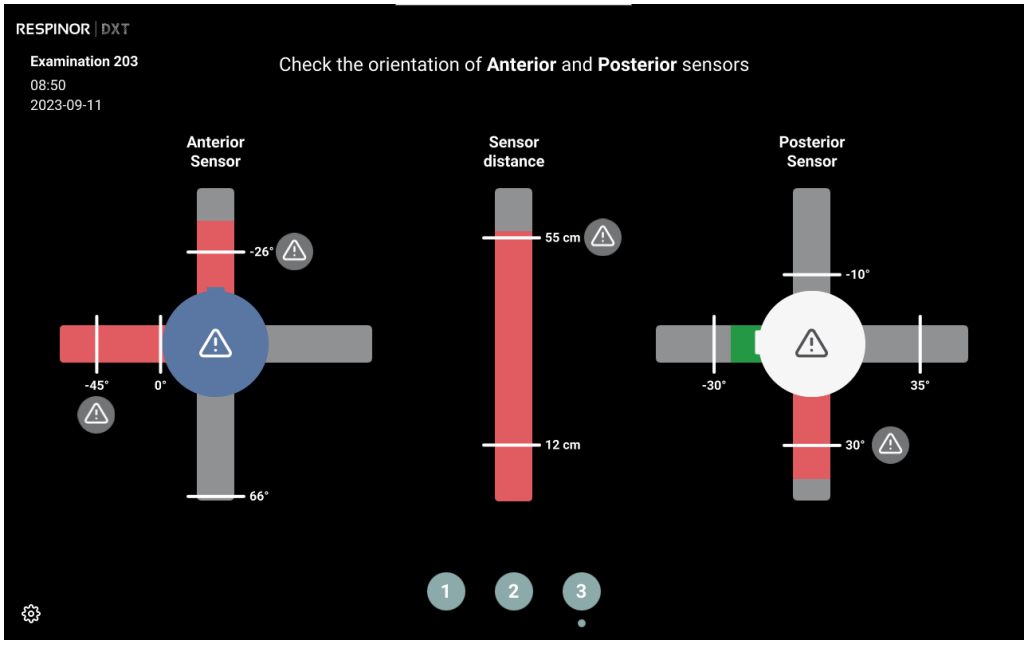


Figure 8. Example of incorrect Sensor orientation, and incorrect Sensor distance.

- **Example of incorrect sensor positioning in Figure 8:**
    - The Anterior Sensor orientation is incorrect in both axes, a warning symbol (⚠) and a red color appears.
    - The Posterior Sensor orientation is incorrect in only one axis, a warning symbol (⚠) and a red color appears.
    - The distance between the Anterior Sensor and the Posterior Sensor is too large, as indicated by the red bar in the middle.
    - The “Continue” button is removed, and the user shall correct the sensor positioning before continuing.

WARNING!

Always adhere to the instructions for connecting the DXT Sensors to the patient, as described in sections 4.3 and 4.4, to avoid erroneous measurements causing suboptimal time of weaning and patient injury due to reintubation.

4.6. START DXT EXAMINATION (INTRODUCTION VIDEO-6/8)

The DXT starts with an initialization process lasting 15-20 seconds.

If the patient is agitated or the signal quality is poor, see section 6.1 for troubleshooting.

4.6.1 Live Feed

After initialization of the DXT, the Live Feed is displayed:

- Figure 9 shows the Live Feed, highlighting the relevant features for an examination.
- For a more detailed overview of all the functions in the Live Feed, see section 5.

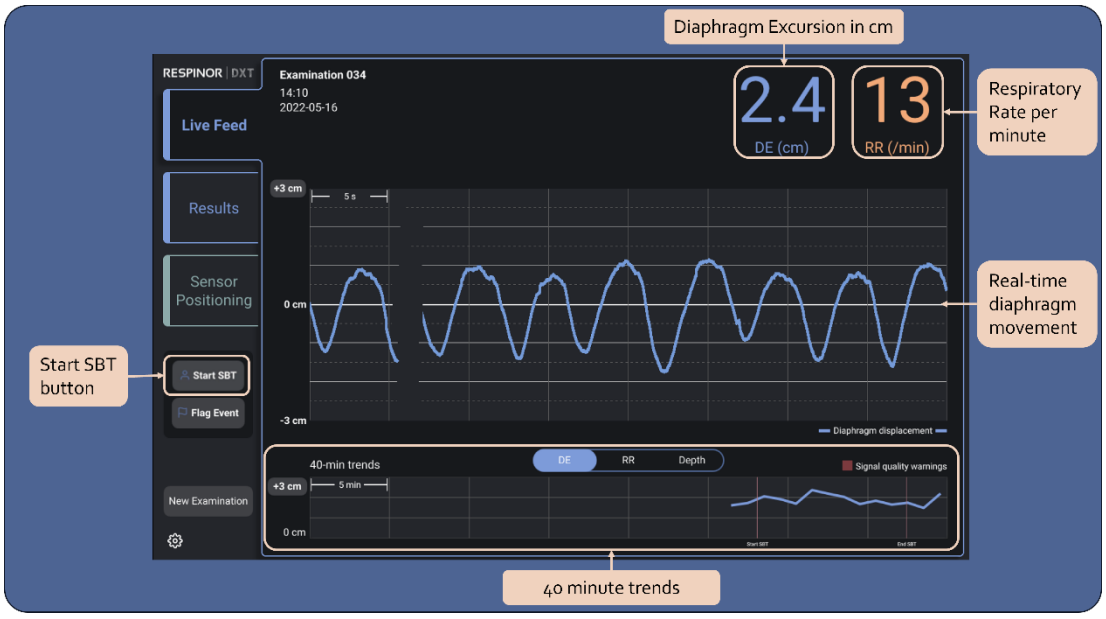


Figure 9. Overview of the Live Feed.

The Live Feed provides vital information about the patient's diaphragm function at three levels:

1. **Real-time diaphragm movement (Figure 10):**
   - The graph shows the real-time diaphragm movement as a blue line.
     - The downward movement in the graph represents inspiration.
     - The upward movement in the graph represents expiration.
     - The movement is centered around 0 cm, where zero is the average of the movement over time.
   - The graph shows diaphragm movement during the last 40 seconds.
     - The vertical axis represents diaphragm movement in centimeters.
     - The user can adjust the graph size by pressing the maximum value on the upper left side (of the graph).

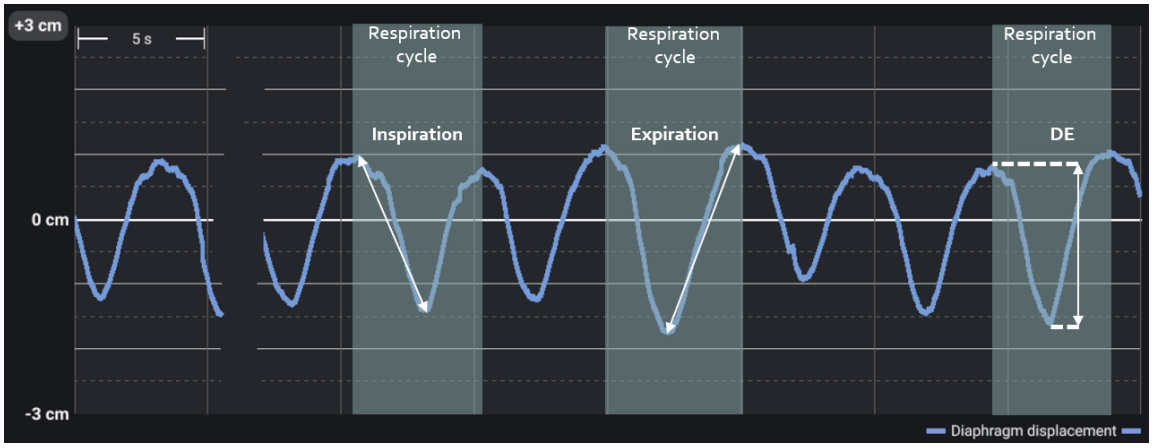


Figure 10. Real-time graph of diaphragm movement. The inspiration phase, expiration phase, and visualization of how DE is calculated are highlighted.

2. **DE and RR values (top right corner):**
   - The values are calculated as highlighted in Figure 9 and updated for each breath cycle.
   - The values represent the previous breath cycle.

Diaphragm Excursion (DE) is the movement of the diaphragm during inspiration.
DE measures the contraction of the diaphragm. The DXT reports DE in centimeters (cm).

3. **40-minute trends and Depth:**
   - The graph at the bottom of the screen shows minute by minute the median DE or RR over the last 40 minutes of the examination. The user can switch between DE and RR by pressing the buttons above the graph. The scale of the DE and RR trends can be adjusted by pressing the button “+3 cm” or “40 /min” respectively.
   - The Depth is a graphical view of the measurement depth automatically selected by DXT. This view is for signal evaluation and troubleshooting for more advanced users and is explained more in detail in section 5.1.3.

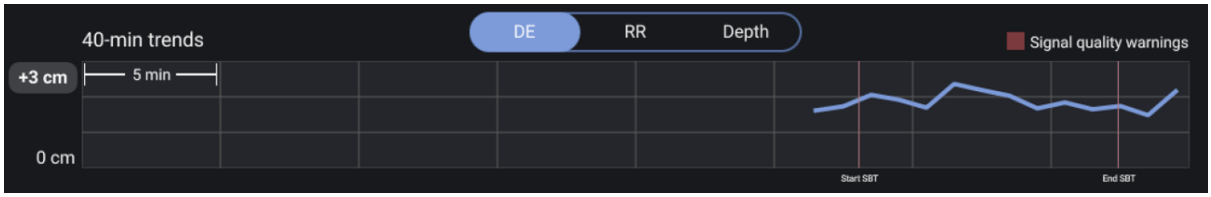


Figure 11. Graphical view of 40-minute trends.

WARNING!
A Respiratory Rate (RR) outside the range of 7-40 cycles/minute (see section 9) can affect the measurements and lead to suboptimal time of weaning and patient injury due to reintubation.

4.6.2 Start SBT

30 seconds after the initialization has been completed, the DXT is ready to start SBT. This is indicated by:

- The information message “DXT ready for SBT” appearing on the top of the screen (Figure 12 – 1A), and
- The button “Start SBT” blinking (Figure 12 – 1B).

Once you start the SBT on the patient, press the “Start SBT” button on the DXT.

- A window appears, asking you to confirm that the SBT is starting.
- The time of start is indicated in the Live Feed plot (Figure 12 – 2).

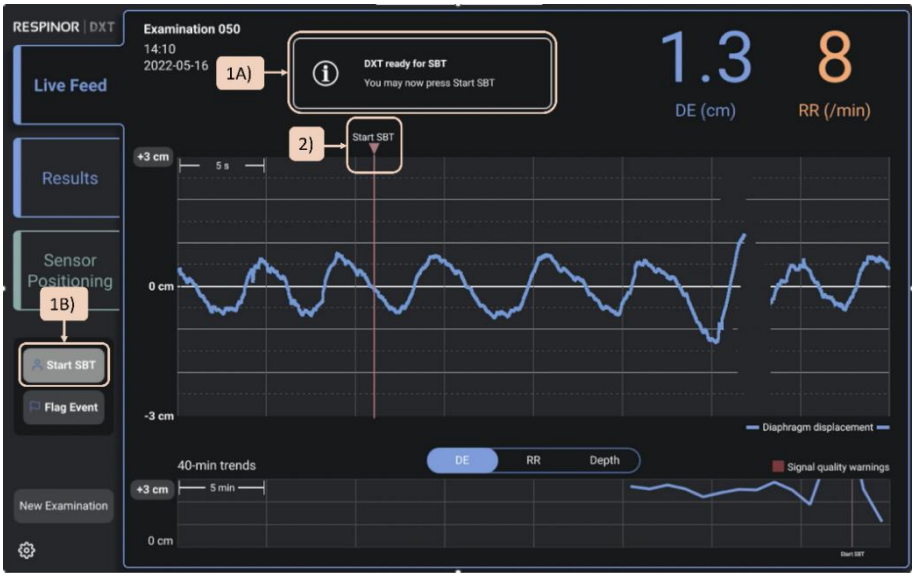


Figure 12. DXT Control Unit ready for SBT start.

4.7. EVALUATE DXT RESULTS (INTRODUCTION VIDEO-7/8)

The DXT results will be ready 2 minutes after the start of SBT. This is indicated by the information message “SBT result is ready” appearing on the top of the screen (Figure 13-1).

To see the results, press the “Results” tab on the left side of the screen (Figure 13-2).

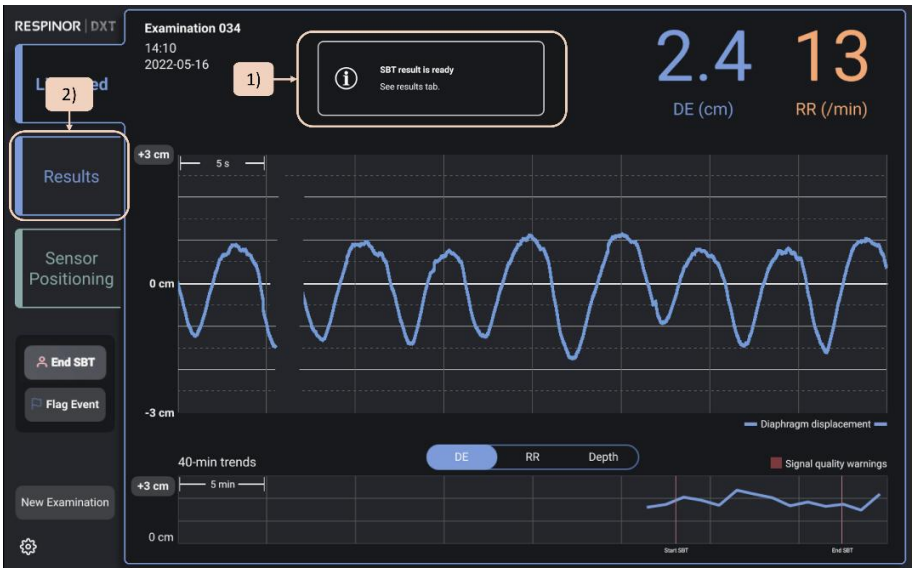


Figure 13. SBT result is ready.

You are then directed to the Table view of the results (Figure 14). The SBT result is displayed to the left of the table. You shall use this value when evaluating the DXT results:

A median DE value below 1.1 cm during the 2nd minute of SBT indicates an increased risk of reintubation.

In the example shown in Figure 14, the SBT result is 3.0 cm. This DE is above 1.1 cm, indicating that this patient does not have an increased risk of reintubation due to diaphragm dysfunction. See APPENDIX A – Medical for further information.

Figure 14. Example of SBT result.

The Table view displays median DE and RR for each minute of the examination (Figure 15).

Figure 15. Results table.

WARNING!

- Always use the DXT as an ***adjunct to other clinical data*** to avoid making the wrong decision, leading to patient injury from reintubation.
- RESPINOR DXT® shall not be used to assess the risk of extubation failure in patients with central or spinal neurological injury involving central ventilatory control, or with the presence of a neuromuscular disease involving respiratory muscles.

4.8. End the Examination (Introduction VIDEO-8/8)

- Press the button “End SBT” when the SBT has been completed.
- Power off the DXT Control Unit to end the DXT examination. The maximum examination length is 2.5 hours (after 2.5 hours, the DXT Control Unit will automatically return to the main screen shown in section 4.2.3).
    - Press the power switch on the left side of DXT Control Unit.
- Gently remove the Anterior Sensor and Posterior Sensor from the patient.
    - Wipe off the remaining ultrasound gel from the abdomen.
    - Ensure that no tape leftovers are stuck on the patient.
- Remove the Anterior Tape and Posterior Tape from the Anterior Sensor and Posterior Sensor respectively, and dispose them according to section 4.11.
- Clean or recycle the Anterior Sensor and Posterior Sensor according to use:
    - If the Anterior Sensor and Posterior Sensor will be used several times on the same patient, follow the cleaning and disinfection procedure described in section 4.10.
    - If no more examinations are required for this patient: dispose of the Anterior Sensor and Posterior Sensor according to section 4.11.
- Clean the DXT Control unit according to section 4.10.

CAUTION!

Remove the DXT Sensor Kit after the examination to avoid the patient laying on the DXT Posterior Sensor for too long, which can cause tissue damage.

4.9. Disassemble DXT and Clamp

The DXT Control Unit can be detached from the Clamp by lifting the green handle on the backside of the Control Unit (Figure 16) and simultaneously lifting the Control Unit upwards.

The Clamp is released from the pole by pulling the inner cylinder away from the clamp and pulling the handle in the same direction to increase the grip size.

Figure 16. Lift the green handle to release DXT from the Clamp.

4.10. Cleaning and Disinfection

The DXT Control Unit shall be cleaned according to standard practices.

- Clean the DXT Control Unit with wipes. The approved solutions are listed in Table 1 according to the instructions of the cleaning solution.

The DXT Sensor Kit shall be cleaned if several examinations are required for one patient according to standard practices:

- Clean the surface of the Sensors and cables with wipes with any of the approved solutions listed in Table 1 according to the instructions of the cleaning solution.
- Be careful not to spill any fluid into the electrical plugs.
- After cleaning, rinse Sensors and cables thoroughly for at least one minute with clean (drinking water quality) room temperature water to remove all traces of cleaning solution.
- Pat dry with a clean, soft, lint free cloth. Allow to fully air dry before storing or re-using on the same patient.

WARNINGS!

- DXT Control Unit must be cleaned after each use due to the risk of biological contamination that can infect the patient.
- Do not use DXT Sensor Kit on several patients. The Sensor Kit is for single patient multiple use only. This reduces the risk of biological contamination that can cause infection to the patient.

4.10.1 Appropriate Cleaning and Disinfectant Solutions

Table 1 lists appropriate solutions for cleaning and disinfecting the equipment. The list is not all-inclusive, so please contact RESPINOR for assistance if a solution is not included and its suitability is uncertain.

Table 1. List of acceptable cleaning and disinfectant solutions for DXT Control Unit and DXT Sensor Kit.

Solution/system	Qualified Use	Active Ingredient	Disinfectant Type
Oxivir Excel Wipe	Wipe	Hydrogen Peroxide	LLD, ILD

CAUTIONS!

- Only use low- to intermediate-level solutions for cleaning and disinfection since high-level disinfectant solutions can chemically deteriorate the equipment.
- Exposing the patient to stronger chemicals may cause allergic skin reactions.

4.11. Safe Disposal

After use, DXT Tape Kit shall be disposed of in accordance with the hospitals and local authorities' established methods for similar accessories, or potentially biohazardous parts if there is any suspicion of such.

The DXT Control Unit and Sensor Kit are electric and electronic equipment that shall be disposed of using separate collection, treatment, recovery/recycling, and environmentally sound disposal methods and should never be discarded with municipal waste. This also concerns any potentially biohazardous accessories and parts. Please contact your local authorities to determine the appropriate method.

Components of the device may contain lead or mercury and is then accompanied with the symbols in the column to the right. Such devices must be recycled or disposed of in accordance with local, state, or federal laws.	(Pb) or (Hg)

5. ADDITIONAL FEATURES

Section 4 of this instruction manual describes all necessary features of DXT to perform a successful examination. This section describes additional features of DXT that you should familiarize yourself with.

5.1. LIVE FEED

Live feed is the default view after initialization of DXT. In addition to the features described in section 4, the following features and views can be accessed from the live view (Figure 17):

- Examination information is available in the top left corner of the screen.
- Event buttons are available for:
  - Marking the start and end of SBT *(explained in section 4),*
  - Flagging other patient related events.
- Assess signal quality with the Depth graph
- You can navigate between 3 different views:
  - Live Feed,
  - Results,
  - Sensor Positioning.
- You can start a new examination.
- You can access the settings.

The different features and views are described in the following sections.

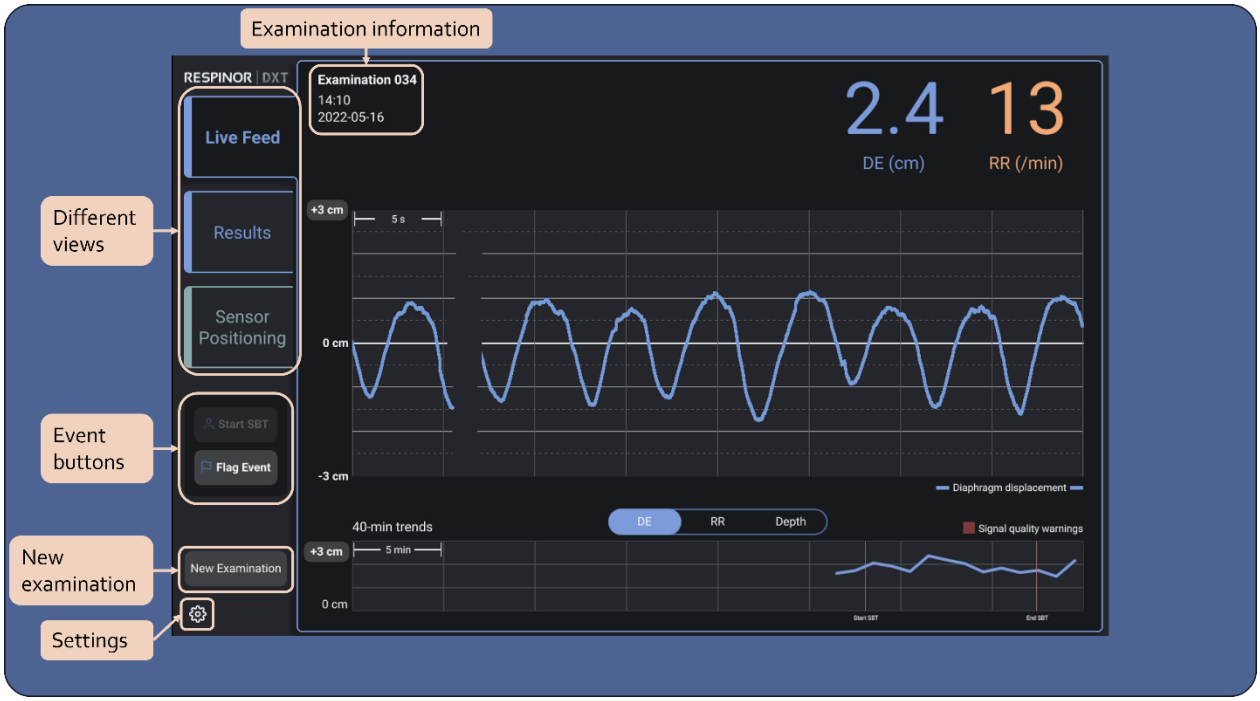
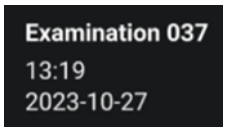


Figure 17. Complete overview of Live Feed.

5.1.1 Examination Information

In the top left corner of the Live Feed, the following information is displayed:



- Examination ID,
- Time and date.

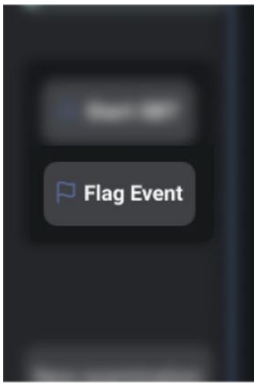
The examination ID is automatically generated by the system. The ID consists of the word "Examination" and a three-digit number increasing by 1 for each examination.

The time is in "hh:mm" format and the date are in "YYYY-MM-DD" format.

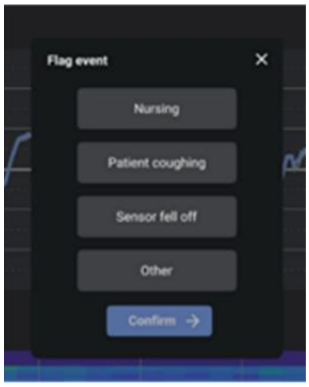
5.1.2 Flagging Events

The "Flag Event" button located on the left side of the Live Feed allows the user to mark events that may be of relevance (e.g., if nursing took place during the examination).

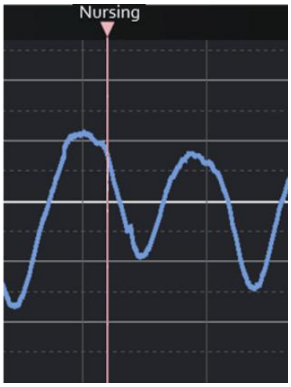
- To flag an event, press the "Flag event" button and specify the event.
- A menu of predefined events will appear (see figure below).
    - If no predefined events are appropriate, you can specify the event by pressing "Other."
- When an event is registered, the event will appear in Live feed and the table in Result view.



Step 1: Press the 'Flag event' button.



Step 2: Select the appropriate event.



Step 3: The event will appear in Live feed.

Step 4: The event also appears in Results table.

5.1.3 Depth Graph

Pressing the "Depth" tab above the trend graph on the Live Feed enables the user to assess the signal quality.

- The depth graph shows the magnitude of the DE at different depths.
- Yellow means higher excursion, and blue means lower.
- The raw ultrasound signal appears as a white line behind the blue line in the Live Feed graph.
- The depth automatically selected by DXT is shown as a red line across the graph.
- The color scale is automatically adjusted every 5 seconds.

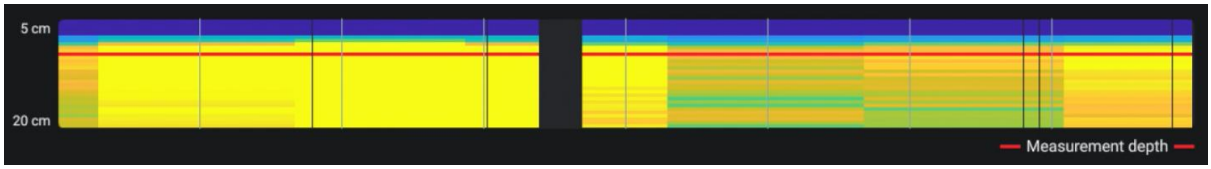


Figure 18. Depth graph.

5.1.4 Graphical View of the Results

In addition to the table (described in Section 4), the results can be displayed graphically to facilitate monitoring of trends over time.

- In the Results view, you can access the graphical display of the results by pressing the button at the top of the screen (Figure 19).
- The Graph view shows the median DE (as a blue line) and RR (as an orange line) minute by minute.

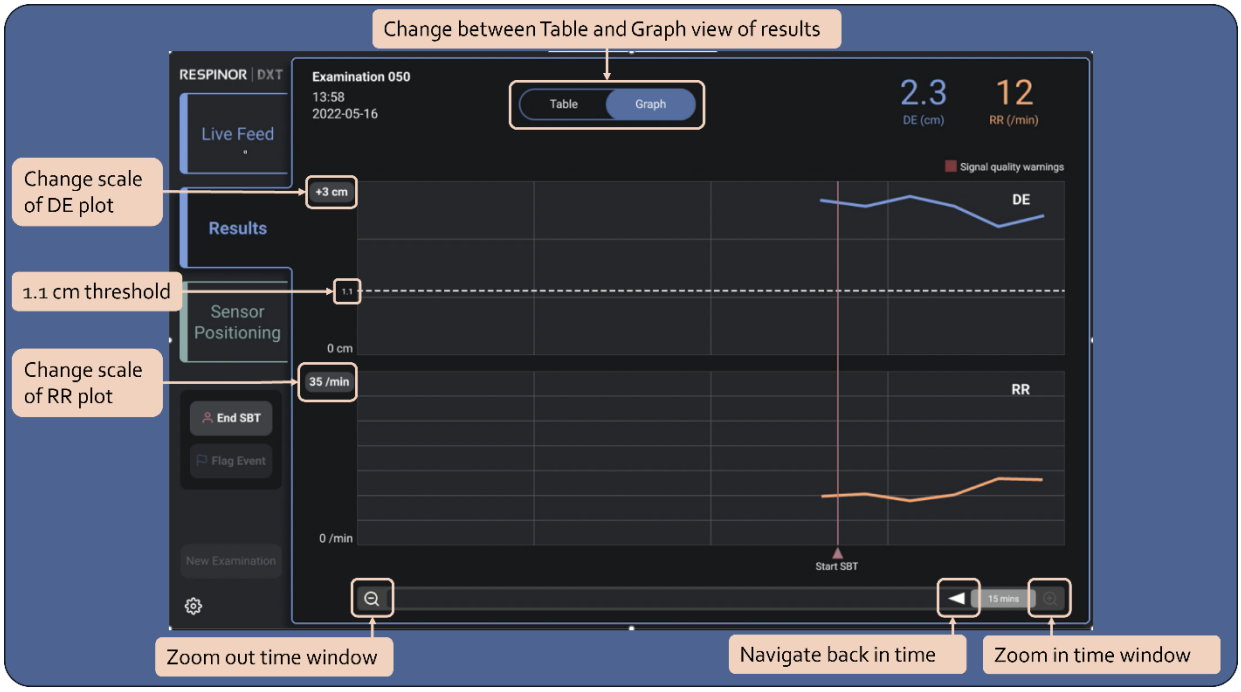


Figure 19. Results view Graph format.

- The horizontal axis shows the trends over the last 15 minutes as default.
  - Use the scroll bar at the bottom of the screen to navigate through the whole examination.
  - Zoom out by pressing the magnifying glass with a minus sign on the lower left side of the graph. The maximum time window is 2.5 hours.
  - Zoom in by pressing the magnifying glass with a plus sign on the lower right side of the graph. The maximum zoom is 15 minutes.
- The vertical axis represents the DE in cm and RR in breaths/min.
  - The range of each axis can be adjusted independently by pressing the upper limit values on the left side of the graph.
- Flagged events, such as patient coughing and nursing, and the start/end time of SBT, are shown in the graph.

- Events are marked as thin vertical red lines crossing both diagrams and are labelled below the diagram at the bottom.

5.1.5 Sensor Positioning View

- Shows the Sensor orientation overview (Figure 7).
- It can be used if you want to check Sensor positioning, e.g., if the patient is agitated.
- By pressing the “Positioning illustrations” tab, you can see the same illustrations of the Sensor positions as shown in the positioning guide.

5.1.6 New Examination Button

- Press the button “New Examination” to start a new patient examination.
  - This will stop any ongoing examination and create a new unique examination ID.
- You will be directly brought back to the Anterior Sensor positioning view (Section 4.3)

5.1.7 Settings Button

The cogwheel located on the bottom left of the Live feed will direct you to the DXT settings. The settings consist of three tabs:

- Examination Database,
- Setup,
- Information.

5.1.7.1 Examination Database

The Examination Database contains the information found in the “Results” view (see section 5.1.4) of the last 10 examinations identified by the examination ID (Figure 20).

- If the examination ID is not entered in the patient’s journal, the user can identify the patient based on the time and date of the examination.
- After pressing the desired examination ID, a window containing the graph and table from the Results view (Figure 19 and Figure 14) will appear on the screen.

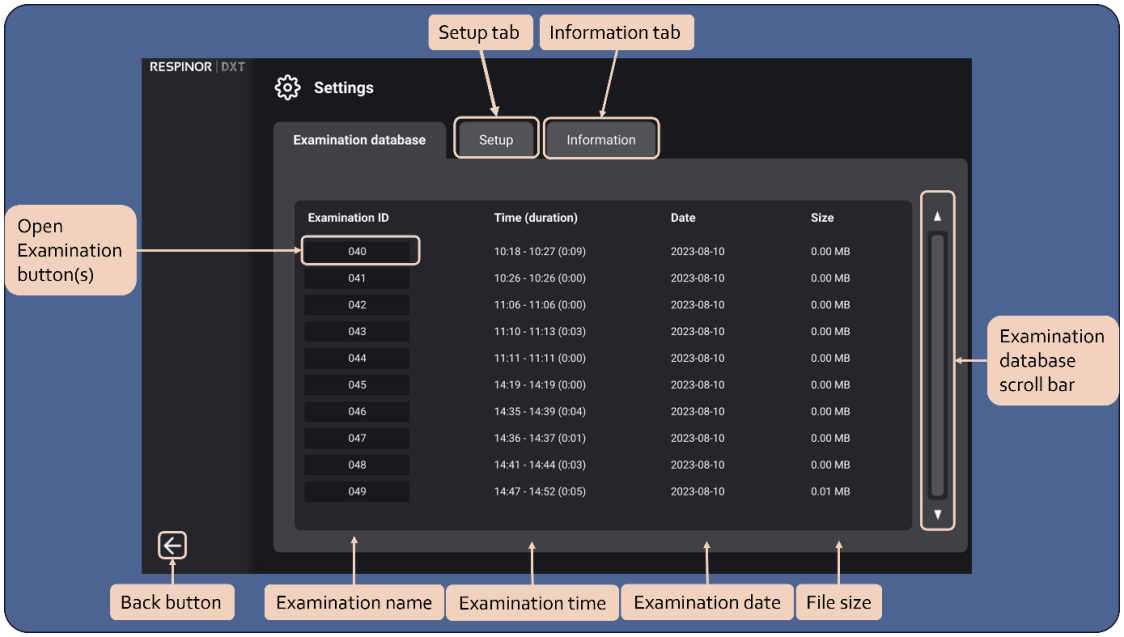


Figure 20. Examination Database tab.

5.1.7.2 Setup Tab

In the Setup tab, you can view the language and adjust the time and date. This is important to get the correct time associated with the stored examinations. Please refer to the technical description of RESPINOR DXT® for more information.

5.1.7.3 Information Tab

The Information tab contains system information. This information is only applicable if you need to consult RESPINOR AS for assistance. Please refer to the technical description of RESPINOR DXT® for more information.

6. TROUBLESHOOTING

6.1. WARNING MESSAGES

DXT has automatic quality control of the measurements. There are four different warning messages that will inform you about situations that can affect the quality of the DXT measurements, the action to correct the error, and if the results have been significantly impacted because of this.

Warning messages in **Live Feed** will inform you in real time about situations that may have caused noise in the measurements, in order for you to identify and correct the cause.

The warning messages will appear at the top of the screen as shown in Figure 21, and are displayed as long as they are active. The warning messages will automatically disappear if the cause is corrected.

The specific warning messages are outlined in the sections below. You can also press directly on the warning message on the screen to get more information.

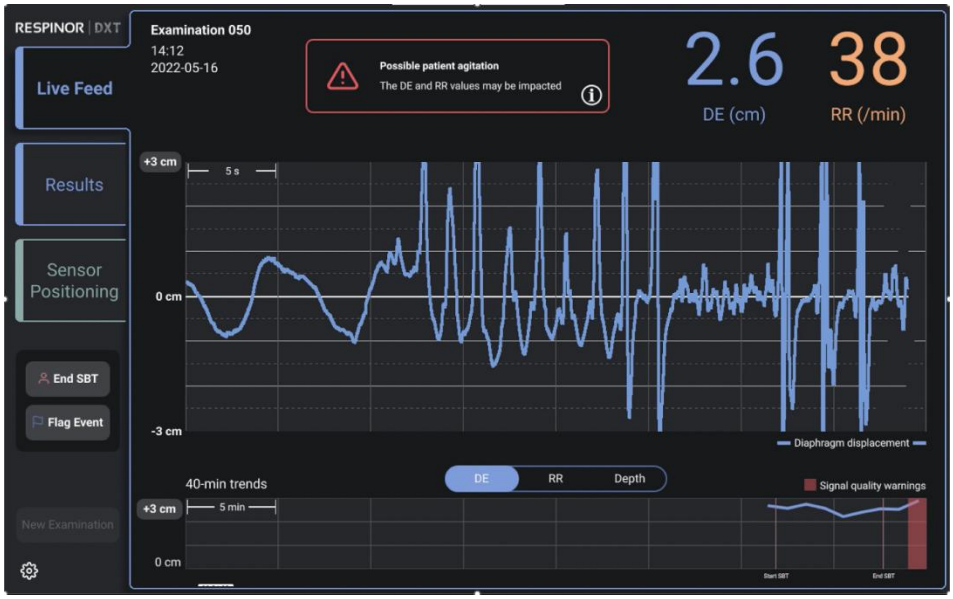


Figure 21. Warning message in Live Feed.

6.1.1 Possible Patient Agitation (Troubleshooting VIDEO-1/4)

The "Possible patient agitation" warning (Figure 22) will appear if the patient is moving significantly during an examination. Excessive movement of the patient can impact the measurements and the calculation of the DE and RR values. If the patient agitation is prolonged and affects the calculation of the results, the DXT will automatically detect this and indicate it in the results tab as described in section 6.1.5.

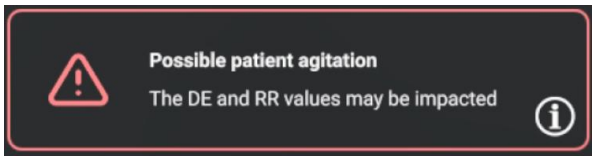


Figure 22. Possible patient agitation.

Agitation is normal for mechanically ventilated patients during the weaning process. No action is required to correct the warning message. However, **users are advised to ignore the DE and RR values that are marked as affected in the Results tab due to patient agitation.**

6.1.2 Poor Acoustic Coupling Detected (Troubleshooting VIDEO-2/4)

The "Poor acoustic coupling" warning (Figure 23) will appear if the connection between DXT Anterior Sensor and the patient is unsatisfactory. The most likely cause for this warning message is insufficient ultrasound gel between the Anterior Sensor and patient's skin.

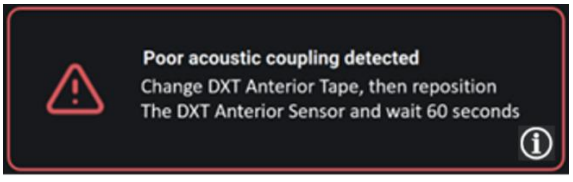


Figure 23. Poor acoustic coupling.

How to solve:
Option 1: Remove possible air between the Anterior Sensor and patient.

- Press the Anterior Sensor firmly against the abdomen.

Option 2: Change the Anterior Tape and reposition the Anterior Sensor.

- Remove the Anterior Sensor and wipe off remaining gel from the Anterior Sensor and patient.
- Use a new Anterior Tape and check that there is sufficient ultrasound gel in the tape hole.
  - NB! Do not press the pouch containing ultrasound gel too hard.
- Reposition the Anterior Sensor according to section 4.3.
- **Wait up to 60 seconds for the warning message to disappear.**

6.1.3 *Poor Signal Quality* (Troubleshooting VIDEO-3/4)

The "Poor signal quality" warning (Figure 24) informs that the DXT has detected noise in the measurements, and it is therefore difficult to calculate valid DE and RR values. The most likely cause for this warning message is wrong positioning of the Anterior Sensor.

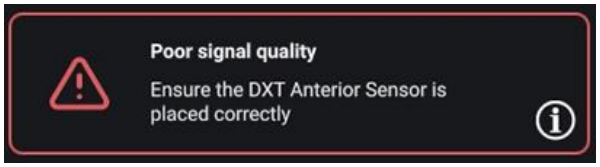


Figure 24. Poor signal quality.

How to solve:
Reposition the Anterior Sensor:

- Remove the Anterior Sensor and wipe off remaining gel from the Anterior Sensor and patient.
- Use a new Anterior Tape and check that there is sufficient ultrasound gel in the tape hole.
- Reposition the Anterior Sensor and ensure to align it with the midclavicular line.
  - NB! Removing the Anterior Sensor may cause the poor acoustic coupling warning to appear. This is expected.
- **Wait up to 60 seconds for the poor acoustic coupling warning to disappear.**

6.1.4 Please Restart the DXT (Troubleshooting VIDEO-4/4)

The "Please restart the DXT" warning (Figure 25) is related to system errors that can impact the calculation of the DE and the RR. If such an uncommon event should occur, please restart the DXT Control Unit. You do not have to remove the Sensor Kit when restarting DXT.

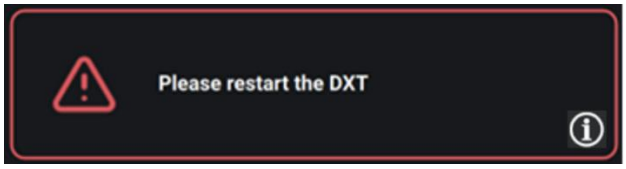


Figure 25. Please restart the DXT.

6.1.5 Warning Messages in Results

The DXT will automatically detect if the results have been significantly impacted by poor measurements. This will be displayed both in the Graph view and Table view of the results. **Users are advised to ignore the DE and RR values that are marked as affected in the Results** and not use these numbers for any clinical decision making.

6.1.5.1 *Warning Message for the SBT Result*

- If the value for the second minute of the SBT has been affected by noise, the enlarged value on the left of the table will not be displayed and highlighted as follows:
  - The value is replaced by "-.-" accompanied by a warning symbol.
  - The box around the number will change from blue to red.
- By clicking the warning symbol, a popup window displays the warning messages that have affected the specific minutes of the examination.

Figure 26. Difference between a good (left) and noisy (right) result of the second minute of SBT.

6.1.5.2 *Warning Messages in Table View*

- The 1-minute median values displayed in the Results table can be affected by noise in the measurements and may become unreliable.
- This is indicated by a warning symbol (⚠) on the left side of the table, as indicated by the red arrows in Figure 27.

Figure 27. Warning messages in table view of results.

- By clicking the warning symbol, a popup window displays the warning messages that have affected the specific minutes of the examination.

WARNING!
If warning messages are displayed, do not rely on the measurements, and consult section 6.1 for troubleshooting. Wrong decision-making can result in suboptimal weaning time and patient injury due to reintubation.

6.1.5.3 Warning Messages in Graph View

- In the Graph view of the results, the median DE and RR values affected by noise in the measurements are indicated by a warning symbol (⚠) in a red field that outlines the data in the affected minute (Figure 28).

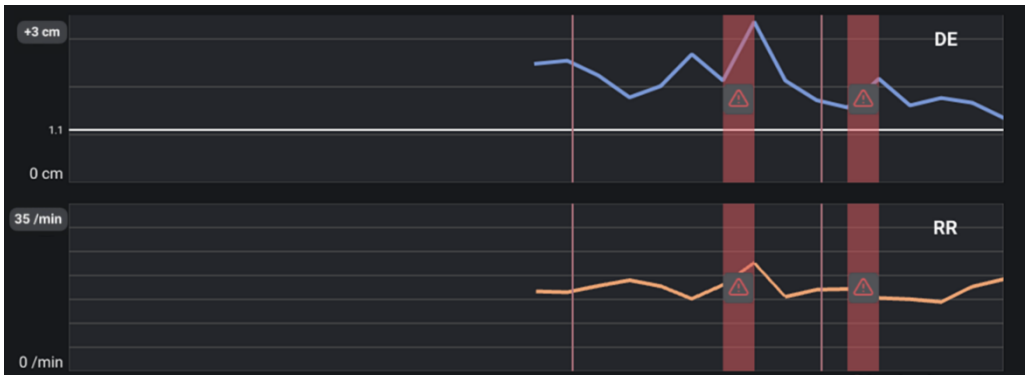


Figure 28. Warning messages in the Graph view of the results.

6.2. SENSOR POSITIONING

6.2.1 Adjusting the Positioning of the Sensors due to Patient Anatomy

The patient's abdominal anatomy can affect the optimal position of DXT Anterior Sensor and require the user to reposition the Anterior Sensor. The optimal position might be **superior** along the midclavicular line for a lean person, while the optimal position might be **inferior** on an obese patient. This is illustrated in Figure 29.

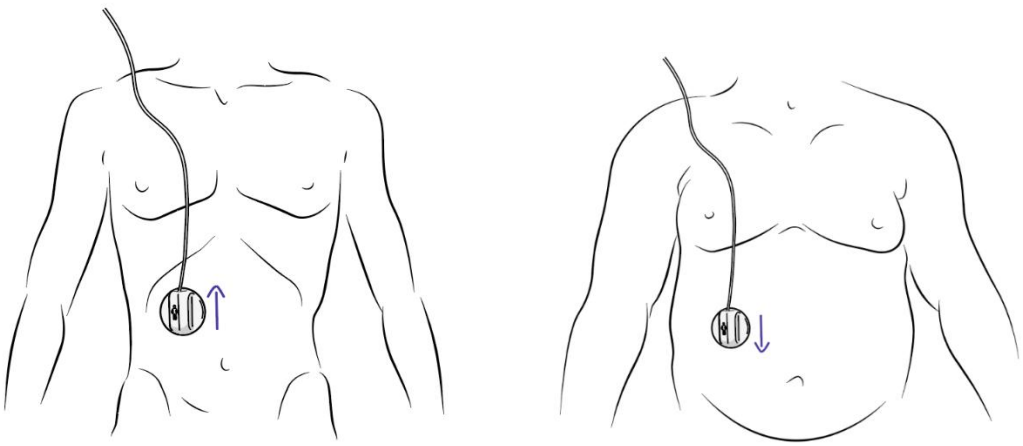


Figure 29. The optimal position of DXT Anterior Sensor shifts superiorly if the patient is lean and inferiorly if the patient is obese.

6.3. Wrong Time and Date

Please check that the system clock is correct in the setup tab in the Settings view and adjust it if it deviates from the correct time. Consult RESPINOR if new examinations still have the wrong associated time.

6.4. DXT is Not Powering On

If the device does not start when the power is connected and the power is switched on, please ensure that the power supply is connected to the Control Unit and the electrical outlet. The Power Supply has a blue light that should be lit. If the DXT Control Unit still does not start, consult RESPINOR.

7. MAINTENANCE

7.1. BEFORE AND AFTER USE

Follow the safety information in section 2.

7.2. TIME AND DATE

DXT is a standalone system and cannot synchronize the clock automatically. Therefore, the clock must be verified against the local time each month and adjusted accordingly. See section 5.1.7.2 for instructions.

7.3. SERVICE AND CALIBRATION

Service shall only be performed by RESPINOR personnel.

7.3.1 Software Updates

Software updates are handled by RESPINOR and shall only be performed by approved personnel by RESPINOR. RESPINOR will contact and organize with the customer when a software update is required.

7.3.2 Calibration

RESPINOR DXT® does not require any calibration prior to use.

8. CONTACT INFORMATION

RESPINOR AS

Address: Gaustadalléen 21, 0349 Oslo, Norway
Phone: +47 24 02 25 54
Mail: mail@respinor.com
www.respinor.com

9. PERFORMANCE CHARACTERISTICS

Characteristic	**Value(s)**
Radiation (for medical purpose)	Ultrasound, non-ionizing
Ultrasound characteristics	- Single element - Unfocused - 2 MHz center frequency
Scan depth	3-15 cm
Ultrasound intensity	- Mechanical Index (MI): Below 1. - Thermal Indices (TI): Below 1.
Correlation vs. conventional B-mode ultrasound	0.88
Audible acoustic noise	Max 25.5 dB-A
Resolution of DE	0.1 cm
DE range	[0-10] cm
DE accuracy	4.8%
RR detection Range	[7-40] breaths per minute
RR accuracy	3.6%
Responsiveness of real-time display of DE and RR	Updates within 2 breath cycles.

10. System Specifications

10.1. Operating Conditions

DXT must only be used in the ICU, and must be within the following conditions:

- Temperature: +10°C to +30°C,
- Humidity: 30% to 80% (non-condensing),
- Atmospheric pressure: 80 kPa to 106 kPa.

10.2. Storage Conditions and Shelf Life

DXT Control Unit has a lifetime of 4 years, and DXT Sensor Kit has a shelf life of 3 years when stored in the original packaging and away from sunlight and within the following conditions:

- Temperature: -10°C to +30°C,
- Humidity: 10% to 85% (non-condensing),
- Atmospheric pressure: 80 kPa to 110 kPa.

DXT Tape Kit has a shelf life of 2 years when stored in the original packaging and away from sunlight and within the following conditions:

- Temperature: 15°C to 30°C,
- Humidity: 10% to 85% (non-condensing),
- Atmospheric pressure: 80 kPa to 110 kPa.

10.3. Transportation Conditions

DXT Control Unit and DXT Sensor Kit can be transported within the following conditions:

- Temperature: -18°C to +38°C,
- Humidity: 10% to 85% (non-condensing),
- Atmospheric pressure: 75 kPa to 110 kPa.

DXT Tape Kit can be transported within the following conditions:

- Temperature: +15°C to +38°C,
- Humidity: 10% to 85% (non-condensing),
- Atmospheric pressure: 75 kPa to 110 kPa.

10.4. Technical Specifications

For specifications other than EMC, please refer to the technical description of RESPINOR DXT®.

Symbols

Symbol	Symbol Title	Standard Reference	Standard Title	Description
Rx only	Prescription only	21 CFR 801.15(c)(1)(i)F 21 CFR 801.109	Labeling-Medical devices; prominence of required label statements Labeling-Prescription devices	Requires prescription in the United States
	TYPE BF APPLIED PART	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment	Identifies a type of BF applied part complying with IEC 60601-1
	General warning sign	ISO 7010-W001	Graphical symbols — Safety colors and safety signs — Registered safety signs Graphical symbols — Safety colors and safety signs — Registered safety signs	Signifies a general warning
	Caution	ISO 7000- 0434B	Graphical symbols for use on equipment — Registered symbols Graphical symbols for use on equipment — Registered symbols	Signifies that caution is necessary when operating the device or control close to where the symbol is placed
	MR Unsafe	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Signifies that the device is MR Unsafe
	CE marking with notified body identification number	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II)	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable	Signifies European technical conformity of medical devices approved by notified body TUV SUD

		RED 2014/53/EU (Articles 19, 20, Annex II)	European Union Acts	
CE	CE marking	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II) RED 2014/53/EU (Articles 19, 20, Annex II)	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts	Signifies European technical conformity of self-certified medical devices
IP 65	Ingress protection rating, IP 65	IEC 60601-1, Table D.3, Symbol 2	Medical electrical equipment	Indicates the electronics are protected inside a dust-tight closure and against water jets. This rating applies to DXT Anterior Sensor and DXT Posterior Sensor
IP 20	Ingress protection rating, IP 20	IEC 60601-1, Table D.3, Symbol 2	Medical electrical equipment	Indicates the electronics are protected against solid objects over 12 mm but has no protection against water intrusion. This rating applies to DXT Control Unit
	Waste Electrical and Electronic Equipment	EN 50419-6414	Marking of electrical and electronic equipment (EEE) in respect to separate collection of waste EEE (WEEE)	Indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic
	General symbol for recovery/ recyclable	ISO 7000-1135	Graphical symbols for use on equipment — Registered symbols	Indicates that the marked item or its material is part of a recovery or recycling process
UDI	Unique device identifier	ISO 15223-1 Clause 5.7.10	Medical Devices — Symbols to be used with medical device labels, labelling and	Indicates a carrier that contains Unique Device Identifier information

			information to be supplied	
	Manufacturer	ISO 7000-3082	Graphical symbols for use on equipment	Identifies the legal manufacturer
	Date of manufacture	ISO 7000-2497	Symbols for use in the labelling of medical devices	Identifies the date of manufacture
	This way up	ISO 7000-0623	Graphical symbols for use on equipment	Indicates correct upright position of the transport package
	Keep dry	ISO 7000-0626	Graphical symbols for use on equipment	Indicates a medical device that needs to be protected from moisture
	Fragile, handle with care	ISO 7000-0621	Graphical symbols for use on equipment	Indicates that the contents of the transport package are fragile, and the package shall be handled with care
	Do not use if package is damaged and consult instructions for use	ISO 7000-2606	Graphical symbols for use on equipment	Indicates that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices
	Keep away from sunlight	ISO 7000-0624	Graphical symbols for use on equipment	Indicates that transport package shall not be exposed to sunlight
	Temperature limit	ISO 7000-0632	Graphical symbols for use on equipment	Indicates the temperature limits to which the medical device can be safely exposed
	Humidity limitation	ISO 7000-2620	Graphical symbols for use on equipment	Indicates the range of humidity to which the medical device can be safely exposed

	Atmospheric pressure limitation	ISO 7000-2621	Graphical symbols for use on equipment	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	Catalogue number	ISO 7000-2493	Graphical symbols for use on equipment	Identifies the manufacturer's catalogue number, for example on a medical device or the corresponding packaging
	Batch code	ISO 7000-2492	Graphical symbols for use on equipment	Identifies the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging
	Serial number	ISO 7000-2498	Graphical symbols for use on equipment	Identifies the manufacturer's serial number, for example on a medical device or its packaging
	Use-by date	ISO 7000-2607	Graphical symbols for use on equipment	Indicates the date after which the medical device is not to be used
	Single patient multiple use	ISO 7000-3706	Graphical symbols for use on equipment	Indicates single patient multiple use
	Do not re-use	ISO 7000-1051	Graphical symbols for use on equipment	Indicates that the item is for single use only and must not be used more than once, for example on packages of medical disposables
	Medical device	EN ISO 15223-1 Clause 5.7.7	Medical Devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the item is a medical device

	Refer to instruction manual/booklet	ISO 7010- M002	Graphical symbols — Safety colors and safety signs — Registered safety signs	Signifies that the instruction manual/booklet must be read
	Direct current	IEC 60417-5031	Graphical Symbols for Use on Equipment	Indicates that the equipment is suitable for direct current only
	Class II equipment	IEC 60417-5172	Graphical Symbols for Use on Equipment	Indicates that the equipment meets the safety requirements specified for Class II equipment according to IEC 61140

APPENDIX A – MEDICAL DEFINITIONS

MEDICAL TERMS

Diaphragm Excursion (DE) is the movement of the thoracic diaphragm during breathing. DE measures the contraction of the diaphragm.

- Ventilator Induced Diaphragm Dysfunction (VIDD) is defined as rapid deterioration of diaphragm muscle endurance and strength.
- Diaphragm dysfunction can be defined as an excursion < 1.1 cm.

Respiratory Rate (RR) is the number of breaths a person takes per minute.

Spontaneous Breathing Trial (SBT) assesses the patient's ability to breathe while receiving minimal or no ventilator support. SBTs are used to identify patients who are likely to fail extubation from mechanical ventilation.

BACKGROUND FOR USING DE DURING WEANING FROM MV

It is known that diaphragm dysfunction plays a major role in ventilator dependency and significantly increases the risk of worsened outcomes. In mechanically ventilated (MV) patients, diaphragm dysfunction is associated with a higher risk of extubation failure.

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