RESPINOR DXT®

Technical Description

V1.7 November 2025

RESPINOR AS

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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
980-0002	DXT Tape Kit (10 pcs)	4.0
990-0003	DXT Sensor Kit (5 pcs)	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
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
ROHS	Restrictions of Hazardous Substances
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 sensor.

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 6 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 technical description 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 the IFU have been reviewed and fully understood. Do not operate RESPINOR DXT® for purposes other than intended in the IFU.

2.4. BASIC SAFETY AND USAGE ENVIRONMENT

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

Service, repairs and software updates shall only be performed by RESPINOR personnel.

See section 0 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

2.4.2 Approvals and Applied Test Levels

EMC Test	Test standard	Port	Test level (Compliance Professional healthcare)
Emissions			
Conducted emissions	CISPR11	AC Power port	Group 1, Class A
Radiated emissions	CISPR11	Enclosure	Group 1, Class A
Immunity			
Conducted RF Immunity	IEC 61000-4-6	AC Power Ports Patient Coupling Ports	3 Vrms (6 Vrms inside ISM)
Radiated RF Immunity	IEC 61000-4-3	Enclosure	80-2700 MHz: 80% AM 1 kHz 80% AM 2 Hz 3 V/m
ESD Immunity	IEC 61000-4-2	Enclosure	Contact: ± (8) kV Air: ± (2, 4, 8, 15) kV
RF wireless Proximity Test	IEC 61000-4-3	Enclosure	Acc 8.10
EFT Immunity	IEC 61000-4-4	AC Power Ports	± 2 kV (100 kHz)
Surge Immunity	IEC 61000-4-5	AC Power Ports (L-L)	± 0.5, ±1 kV
Magnetic Fields Immunity	IEC 61000-4-8	Enclosure	50 Hz or 60 Hz, 30A/m
Magnetic Proximity Test	IEC 61000-4-39	Enclosure	134.2 kHz, 65A/m 13.56 MHz, 7.5A/m
Supply Dips Immunity	IEC 61000-4-11	AC Power Ports	UT=0% for 0.5 cycle UT=0% for 1 cycle UT=70% for 25/30 cycles
Supply Interruptions Immunity	IEC 61000-4-11	AC Power Ports	UT=0% for 5 sec

2.5. ELECTRICAL SAFETY

WARNINGS!

- Before use, carefully inspect 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 DXT Sensor Kit or DXT Control Unit if there is any sign of damage.
- Dropping 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 sensor.

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.

Exposing DXT to electromagnetic disturbances beyond acceptable levels may lead to loss or degradation of DXT's performance. This 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/min 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).

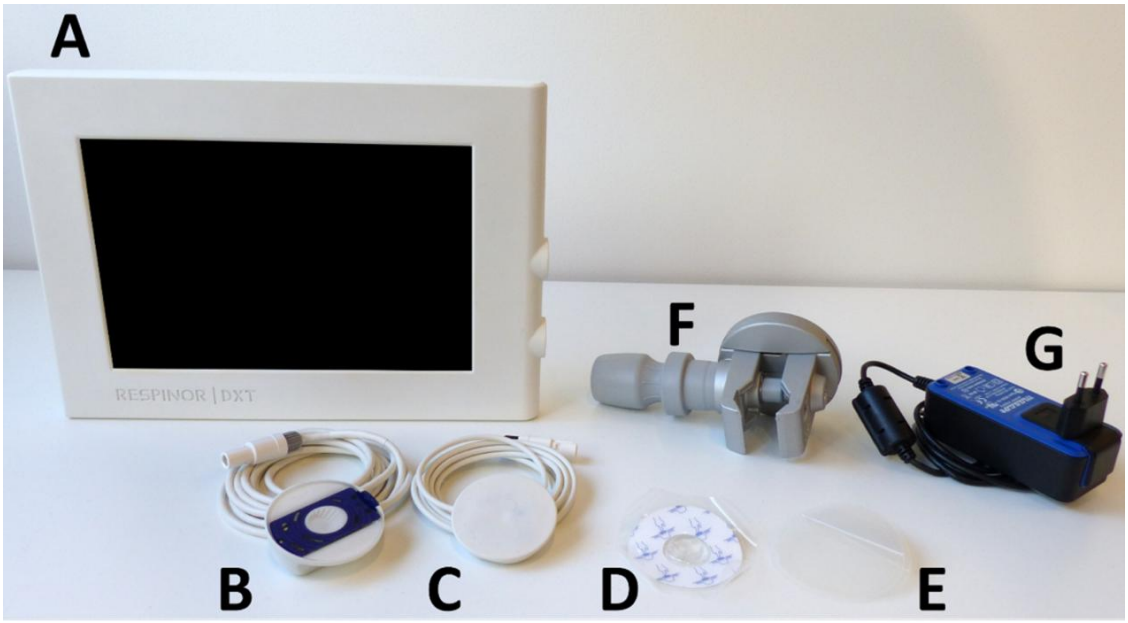


Figure 1. A: DXT Control Unit, B: DXT Anterior Sensor, C: DXT Posterior Sensor, D: DXT Anterior Tape, E: DXT Posterior Tape, F: Clamp, G: Power Supply.

3.1. Performance

The DXT provides detailed information on the diaphragm activity (specifically displacement range, frequency, and velocity), including registration of trends and progression to improve decision making and assess readiness for weaning from mechanical ventilation.

The basis of the measurement principle is that the liver moves as a solid block of tissue with the same motion as the diaphragm just above. Hence, the DXT uses the liver motion as a proxy for the diaphragm motion. The transducer integrated into the Anterior Sensor emits short bursts of ultrasound each millisecond (pulse repetition frequency f_{PR} = 1 kHz). The phase shift between consecutive echoes returned by the liver allows to calculate the distance travelled by the tissue

between these two echoes. The instantaneous velocity and the total movement of the liver are then calculated.

Measurement principle: the Anterior Sensor is positioned so that the ultrasound beam is pointed in a direction that has a vector component that is parallel to the direction of motion, as shown in Figure 2. The Anterior Sensor is designed to emit a beam of ultrasound at an angle of 45° in a cranial direction (towards the head) with respect to the skin surface and into the liver tissue below.

To compensate for the outward/inward abdominal motion caused by respiration, affecting the Anterior Sensor position and the geometry of DXT measurements, a Posterior Sensor placed on the back of the patient is added to the DXT solution. The Posterior Sensor contains a magnetic distance measurement and accelerometers to quantify the abdominal motion and the angulation of the sensors (no acoustics).

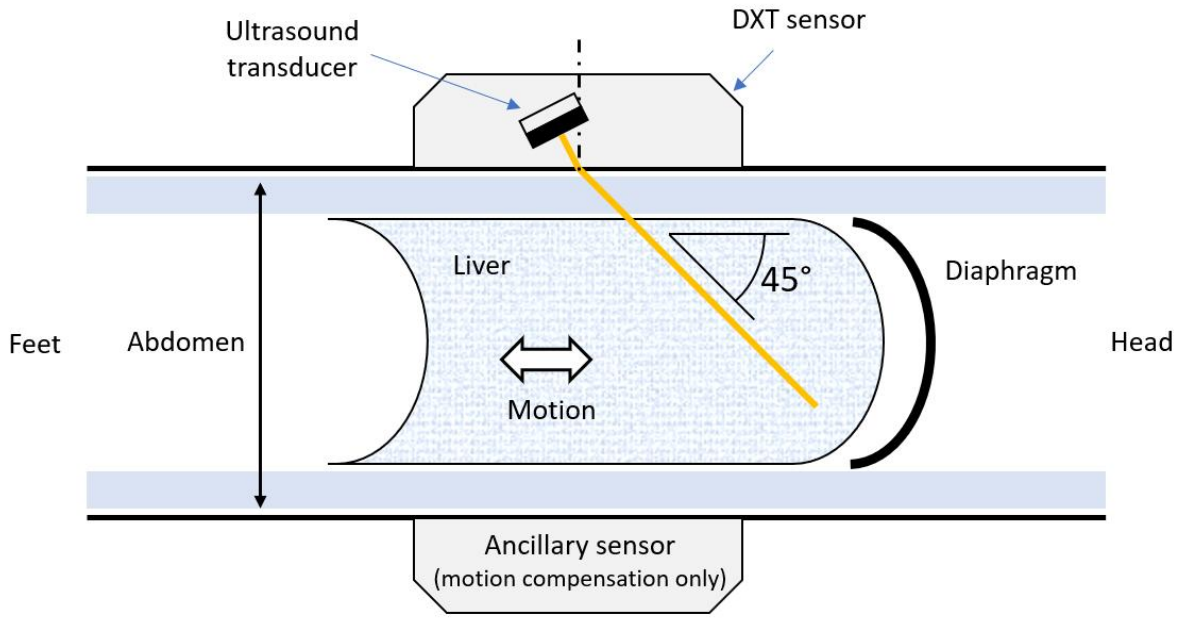


Figure 2. Measurement principle.

3.1.1 Essential Performance

The DXT measures and displays the diaphragm movement graphically in real time and accurately displays values for Diaphragm Excursion (DE) and Respiratory Rate (RR) per breath cycle, and the median values per minute. Additionally, the DXT accurately calculates the median DE for the 2nd minute of SBT where a value below 1.1 cm indicates an increased risk of reintubation.

3.2. 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. Additionally, a service port is secured and locked with a hard plastic cover and a security screw to restrict access (Figure 3):

- Power Supply (A),
- Power Switch (B),
- DXT Anterior Sensor (C1),
- DXT Posterior Sensor (C2),
- Service port protected by a hard plastic cover requiring tools to open (D).

Figure 3. DXT Control Unit. A: Power switch, B: Power supply connector, C1: DXT Anterior Sensor connector, C2: DXT Posterior Sensor connector, D: Service port.

3.2.1 Power Supply

The dedicated Power Supply contains means of protection for the patient and the user. The DXT shall therefore never be used with another power supply that is not listed in section 3 of this document.

3.2.2 Service Port

The service port shall be used only by RESPINOR personnel. The hard plastic cover shall never be removed and DXT Control Unit shall not be connected to hospital network or any other equipment than specified on page 3.

3.3. DXT Sensor Kit

The DXT Sensor Kit consists of the DXT Anterior Sensor (A) and the DXT Posterior Sensor (B) (Figure 4 and Figure 5).

Figure 4. DXT Sensor Kit. A: Anterior Sensor, B: Posterior Sensor.

Figure 5 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 5A).
- The **Posterior Sensor** is thinner than the Anterior Sensor and has a flat white surface (Figure 5B).

3.4. 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 6).

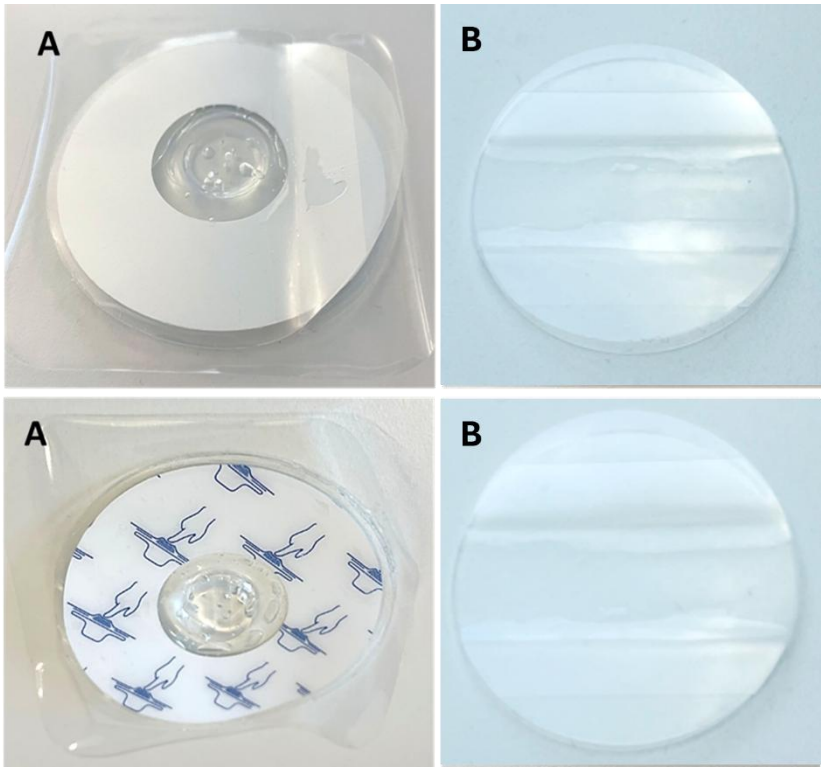


Figure 6. DXT Tape Kit. A: DXT Anterior Tape, B: Posterior Tape.

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

- The Anterior Tape is white with a 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 DXT Control Unit, Clamp and Power Supply (Figure 7).

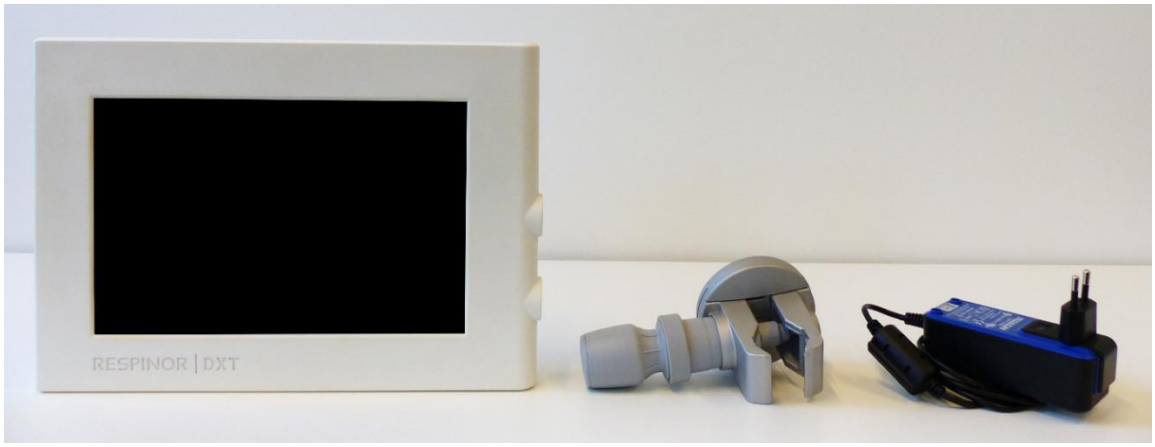
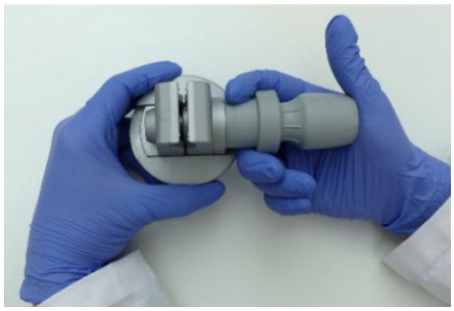
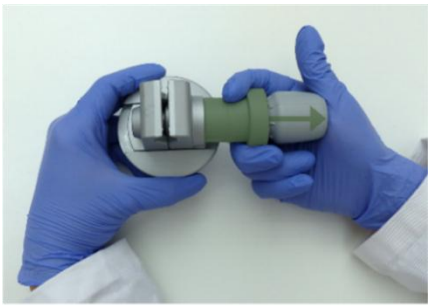


Figure 7. DXT Control Unit, Clamp and Power Supply.

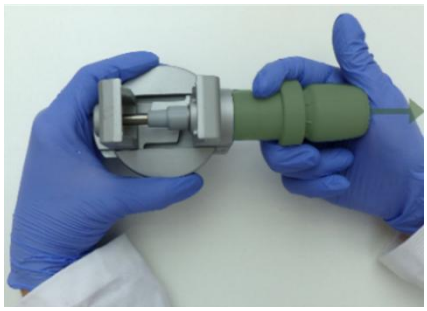
Fasten the Clamp to a pole near the patient's bed (e.g., a standard IV pole), as described below:



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.



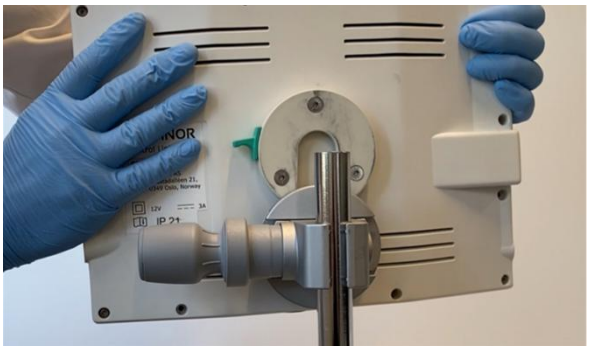
Step 3: Pull the hand holding the handle away from the Clamp to open the Clamp.

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. 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 8) 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 8. Lift the green handle to release DXT from the Clamp.

5. Functions

5.1. New Examination

After powering on the DXT, the user can start a new examination.

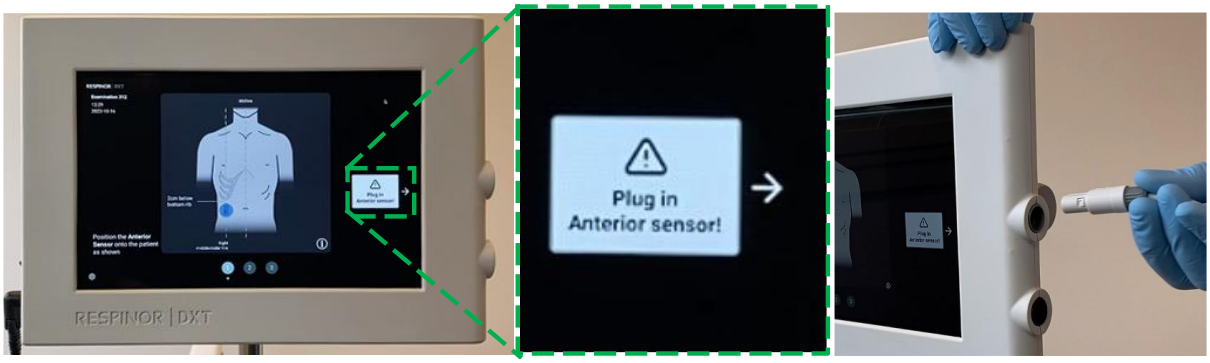
Step 1: You are now ready to start a new examination.

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

5.2. Positioning Wizard

The Positioning Wizard initializes when the button “New Examination” is pressed. The Positioning Wizard guides the user through the necessary steps to setup the system and position the DXT Sensor Kit correctly on the patient.

The first step in the Positioning Wizard shows how to position the Anterior Sensor:

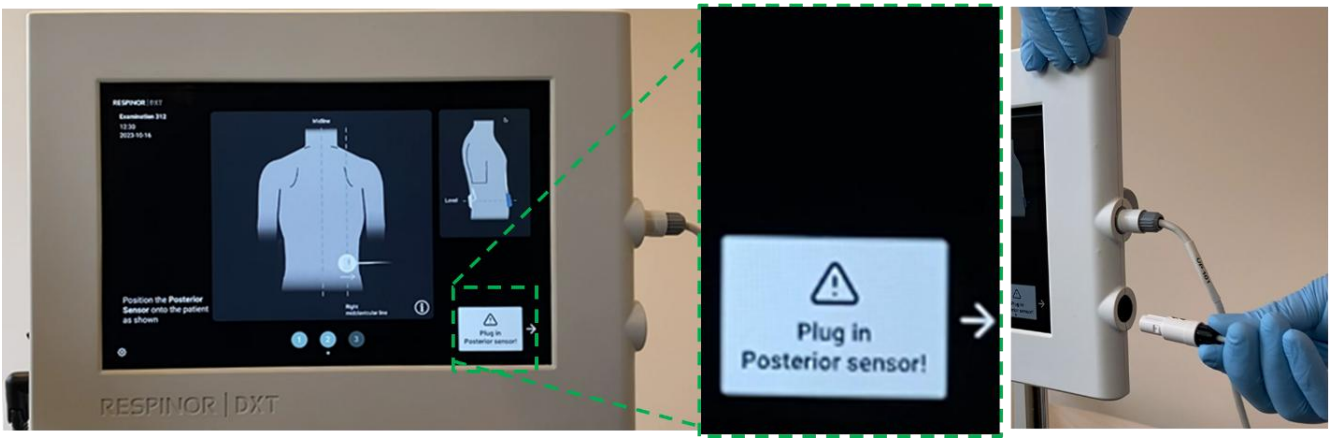


Step 1: Connect the Anterior Sensor to the upper connector on the right side of the Control Unit.

The message on the screen points towards the correct connector.

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

The second step in the Positioning Wizard shows how to position the Posterior Sensor:



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**.

The last step in the Positioning Wizard is to check the orientation of the Anterior Sensor and Posterior Sensor and the distance between them (Figure 9). Both sensors have an integrated Inertial Measurement Unit (IMU) to measure angles and an electromagnet to measure the Magnetic Distance Measurement (MDM) used to calculate the distance between the sensors. The IMU and MDM signals are used in the DXT signal processing algorithms to compensate for the abdominal movements and calculate the compensated diaphragm displacement.

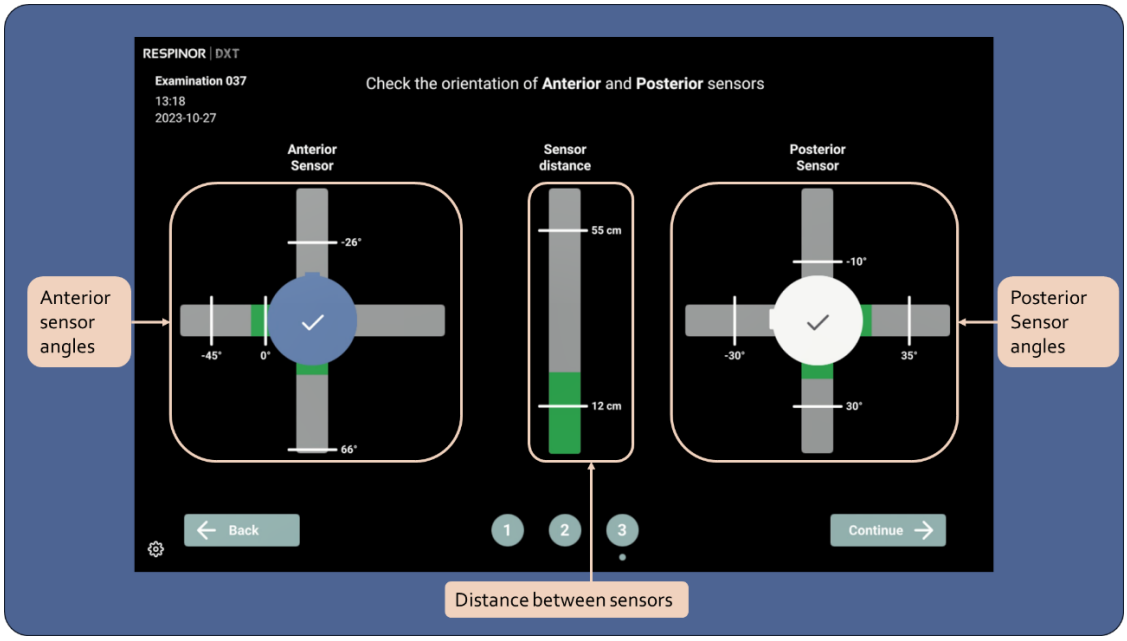


Figure 9. Sensor orientation and distance between sensors.

Please see the Instructions for Use and Introduction videos 3, 4, and 5 for a more detailed description of the Positioning Wizard.

5.3. Examination Views

A tab panel on the left side of the screen allows the user to navigate through three different views (Figure 10):

- Live Feed,
- Results,
- Sensor Positioning.

Three buttons on the left side of the screen allow the user to: 1) start/end an SBT; 2) flag an event (such as a patient coughing); and 3) start a new examination. At the bottom left of the screen, a cogwheel allows the user to access the DXT settings (see section 5.4).

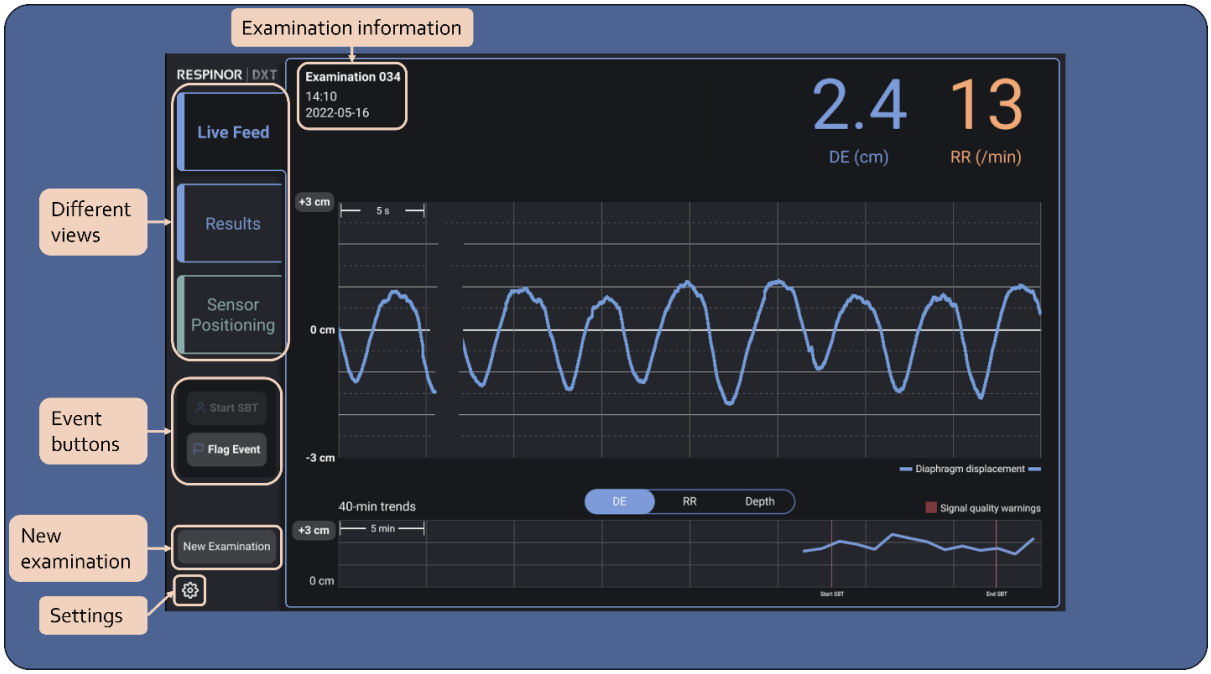


Figure 10. Tab panel for different views and buttons.

5.3.1 Live Feed View

The DXT starts an initialization process lasting 15-20 seconds to scan through the patient's body and locate the optimal depth. If the patient is agitated or the signal quality is poor, this process may take longer.

The Live Feed is the default view after the initialization of the DXT (Figure 11). The Live Feed view shows:

- The Diaphragm Excursion (DE) and Respiratory Rate (RR) calculated for each breath cycle at the top right corner of the screen,
- The real-time movement of the diaphragm as a blue line in the graph in the middle of the screen. This is the movement compensated for the abdominal movements by the IMU and the MDM measurements. The scale can be adjusted by pressing the value at the upper left of the graph.
- The 1-minute median DE or RR over the last 40 minutes of the examination in the graph at the bottom of the screen. The user can switch between DE and RR by pressing the buttons above the graph. The Depth option is also available to display a graphical view of the measurement depth automatically selected by the DXT.

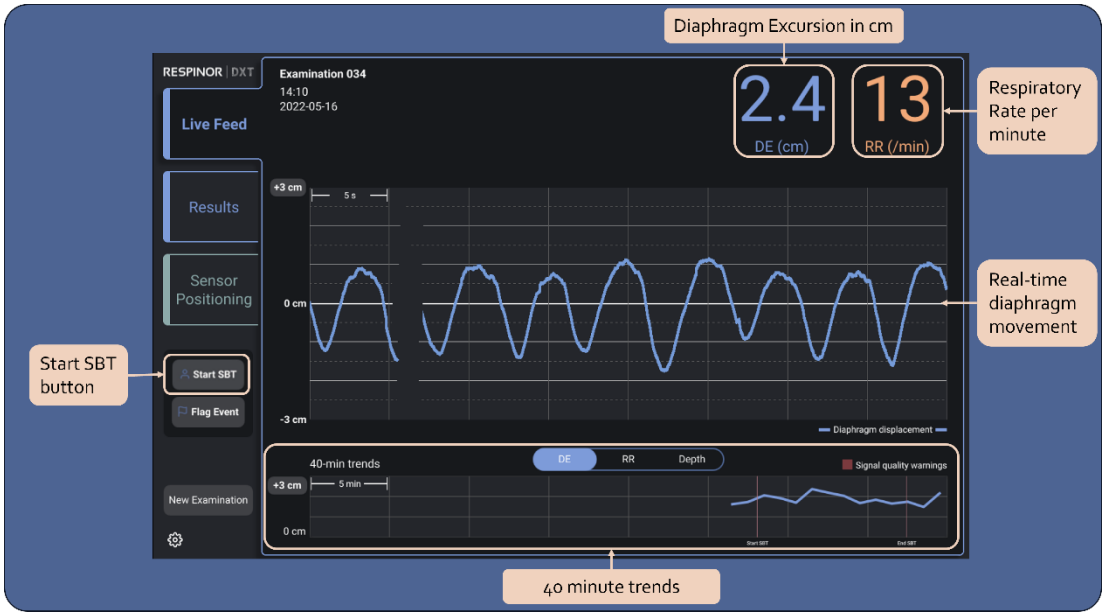


Figure 11. Live Feed view.

5.3.2 Results View

The Results view contains 1-minute median values for DE and RR, presented in a table format (Figure 12) and graphically. Additionally, the SBT result (i.e. the 2nd minute median DE) is calculated and displayed 2 minutes after the button "Start SBT" has been pressed. If the button "Start SBT" is not pressed, the SBT result displays "-.-". If the value of the 2nd minute median DE has been compromised due to a warning, the SBT result turns red and a warning symbol (⚠) is shown next to "-.-" (Figure 13).

Figure 12. Results view.

Figure 13. SBT result compromised by a warning.

5.3.3 Sensor Positioning View

The Sensor Positioning view provides the same view as the orientation screen in the Positioning Wizard.

5.4. SETTINGS

The Settings view contain the Examination Database, Setup, and Information tabs.

5.4.1 Examination Database Tab

The data from the Results view is stored in the Examination Database after the examination is completed (Figure 14). The Examination Database stores 10 examinations before the first examination is overwritten. The examinations are anonymized, and it is necessary to know the examination ID, or time and date of examination, to go back and review the data.

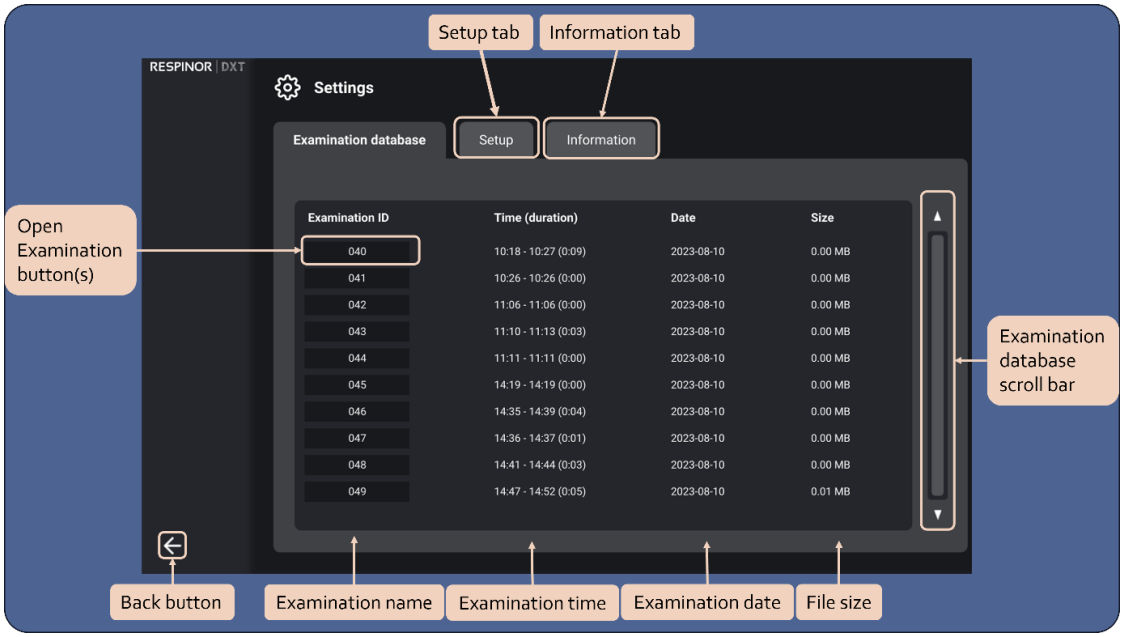


Figure 14. Examination Database.

5.4.2 Setup Tab

The Setup tab indicates the displayed language in the GUI, corresponding to the official language of the country where the DXT is provided. For countries with multiple official languages, the user can change the language by clicking on the button.

It is also possible to set the DXT time and date (Figure 15):

- To set the date, press on the numbers in boxes in the “Set date” section, and set the number up or down to match a reference calendar. The format used by the DXT is “YYYY/MM/DD” (the number on the left is the year, the number in the middle is the month, and the number on the right is the day).
- To set the time, press on the numbers in the boxes in “Set time” section, and set the number up or down to match a reference clock. The format used by the DXT is “HH:MM” (the number on the left is hours, and the number on the right is minutes).

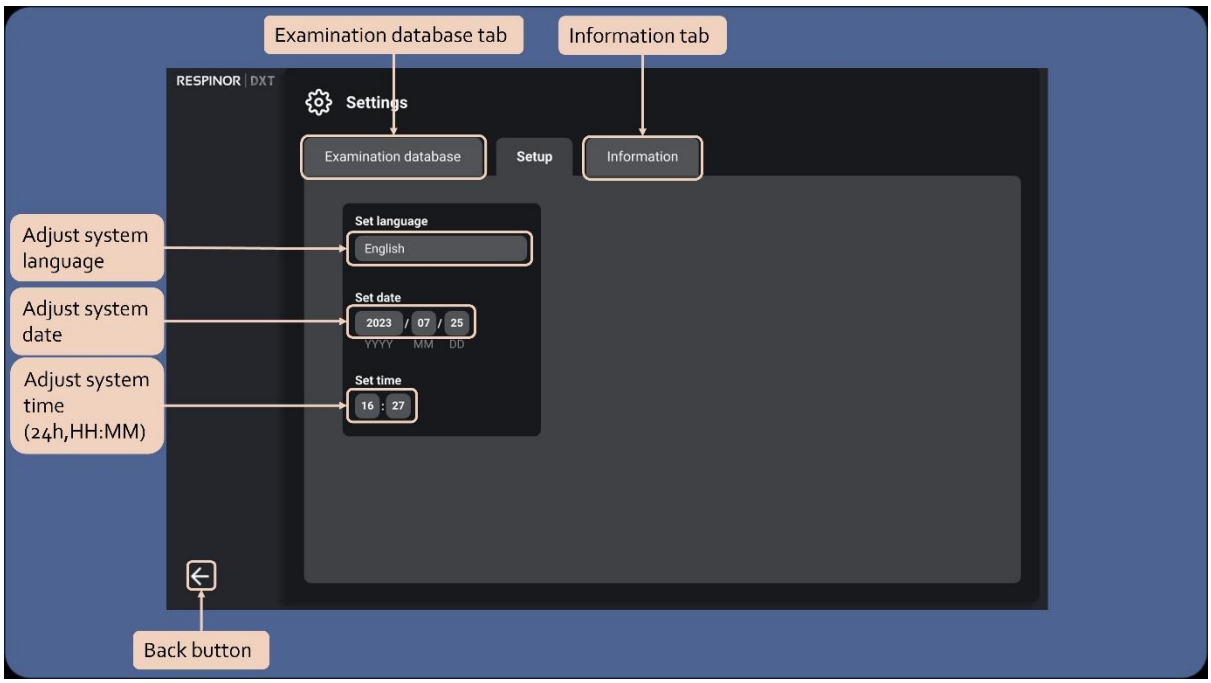


Figure 15. Setup tab.

5.4.3 Information Tab

The Information tab contains information about the DXT system (Figure 16), such as:

- The IP address of the device,
- The free storage space in the device,
- The DXT software versions,
- The serial numbers of the connected Anterior Sensor and Posterior Sensor.

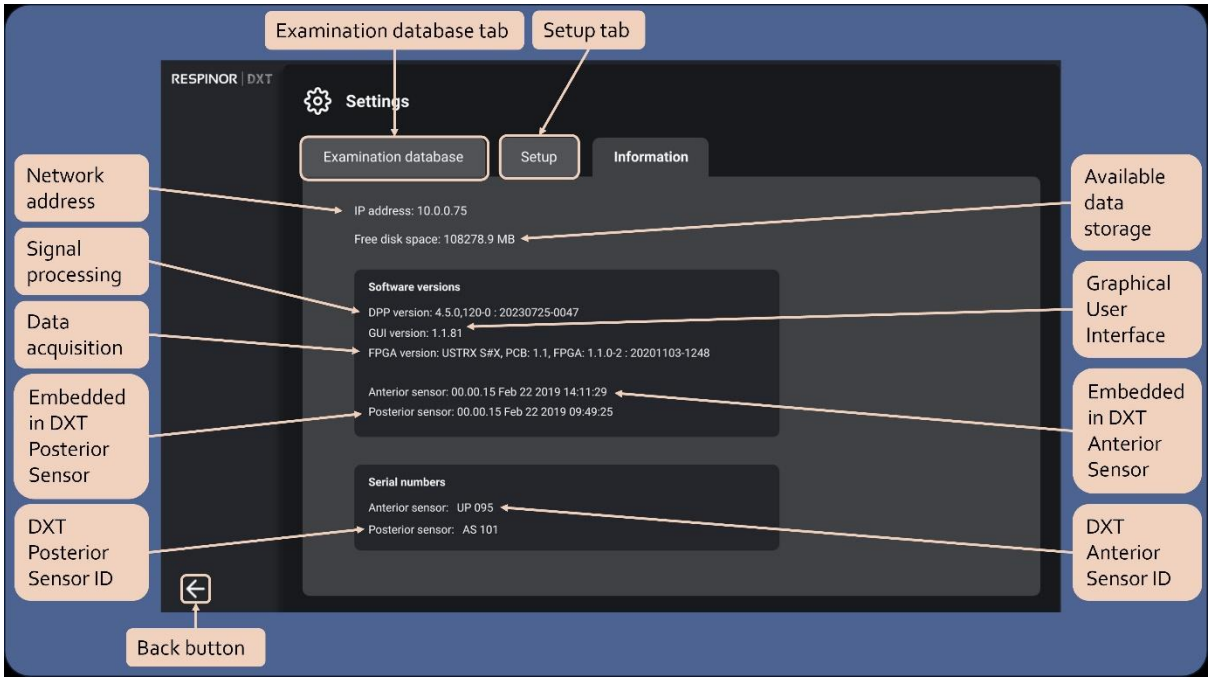


Figure 16. Information tab.

6. 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!

- The DXT Control Unit shall be cleaned after each use due to the risk of biological contamination that can infect the patient.
- Do not use the 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.

Table 1 lists the appropriate solutions for cleaning and disinfecting the equipment. The list is not exhaustive, 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.

6.1. Safe Disposal

After use, the 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 DXT 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

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 5.4.2 for instructions.

7.3. Service and Calibration

Service shall only be performed by RESPINOR personnel. Therefore, circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist servicing will only be made available for 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.

7.3.3 Replacement of Parts

There are no repairable parts, and the only replaceable parts are the Power Supply and Clamp. New Power Supply and Clamp can be ordered from RESPINOR according to the parts list located on page 2 of this document.

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.
Quality assurance of DXT Sensor Kits in production.	- Median value of the DE calculation over one minute within ±5% compared to reference measurement for ultrasound echoes at 1 cm DE. - Median value of the DE calculation over one minute within ±5% compared to reference measurement for magnetic distance measurement at 1 cm DE.

10. System Specifications

10.1. Operating Conditions

The DXT shall only be used in the ICU, and shall be used 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

The DXT Control Unit has a lifetime of 4 years, and the 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.

The 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

The DXT Control Unit and the 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.

The 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

Amount of ultrasound elements	Single element	
Magnetic flux density	< 27 µT	
Ultrasound frequency	2 MHz	
Audible acoustic energy	Max 25.5 dB-A	
Scan depth	3-15 cm	
Display mode	Live view, median DE/RR trend view in plots and table format	
Touch screen Update frequency	25 Hz	
Local data storage capacity	128 GB	
Power consumption	Typical: 10.8 W	Maximum: 14.4 W
Input power supply, voltage	Typical: 110 – 240 VAC	Maximum: 250 VAC
Input power supply, frequency	50-60 Hz	
Output power supply, voltage	12 VDC	
Dimensions (mm)	DXT Control Unit: 306.94 x 214.98 x 44.4 DXT Anterior Sensor: Ø56.98 x 18.37 DXT Posterior Sensor: Ø55.00 x 13.95 DXT Anterior Tape: Ø61.00 DXT Posterior Tape: Ø59.00 Power supply: 101 x 48.5 x 37 Clamp: Ø20 x 150	
Weight (g)	DXT Control Unit: 1561 DXT Anterior Sensor: 84 DXT Posterior Sensor: 64 DXT Anterior Tape: 3 DXT Posterior Tape: < 1 Power supply: 212 Braun Clamp: 500	

10.5. Regulatory Compliance

RESPINOR DXT® is compliant with the regulations and standards listed in the following sections.

10.5.1 MDR

RESPINOR DXT® is compliant with the Medical Device Regulation (MDR) 2017/745/EU.

10.5.2 IEC

RESPINOR DXT® is compliant with:

- IEC 60601-1:2005 + A1:2012 + A2:2020 (ed 3.2),
- IEC60601-1-2:2014 + A1:2020 (ed 4.1),
- IEC 60601-1-6:2010 + A1:2013 + A1:2020 (ed. 3.2),
- IEC 60601-2-37:2007 + A1:2015 (ed 2.1),
- IEC 62304:2006 + A1:2015 (ed 1.1),
- IEC 62359:2010/ AMD1:2017,
- IEC 62366-1:2015 + A1:2020 (ed 1.1).

10.5.3 ISO

RESPINOR DXT® is compliant with:

- EN ISO 10993-1:2020,
- EN ISO 10993-10:2021,
- EN ISO 10993-18:2020,
- EN ISO 13485:2016 + A11:2021,
- EN ISO 14155:2020,
- ISO 14971:2019 (ed 3.0),
- ISO 15223-1:2021,
- EN ISO 20417:2021.

10.5.4 Environmental Regulation

RESPINOR DXT® is compliant with 2011/65/EU (ROHS), EC/2006/1907 (REACH), EU/2012/19 (WEEE), and EC/2006/66.

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

CE 0123