INSTRUCTIONS FOR USE: PRESSURE SENSOR (Part No. 36.415.91)

9. MAINTENANCE

Product life: 5 years.

DISINFECTION

The foam padding (14) must be disinfected after each patient using a cloth soaked in disinfectant. Dry thoroughly. The rest of the device can be disinfected in the same manner as necessary.

⚠ Do not disinfect using flammable products.

REPLACING THE BATTERY:

To install or replace the battery (figure 8)

- Turn off the unit by pressing the black button (if it wasn't already turned off).
- Unscrew the 4 screws (15) of the battery housing using a Philips screwdriver.
- Remove the cover (7).
- Remove the existing battery from the battery holder (17) and disconnect it, taking care not to pull on the connector wires (16).
- Connect a new 9V alkaline battery type 6LF22 to connector (16).
- Insert the battery into the holder (17).
- Close the cover (7) and retighten the screws (15).

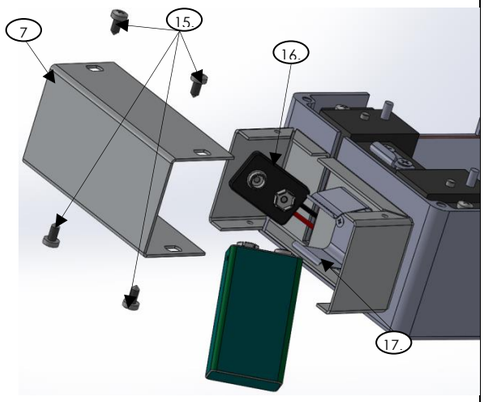

Figure8 : Chaping the battery

⚠
- Only the type of battery specified in this leaflet may be used.
- The device and batteries should be discarded in separate waste collection facilities and not together with household waste. Batteries should be discarded at the designated disposal facility, whereas the device must be sent to Francemed, which will handle its disposal in the appropriate manner.

Troubleshooting

- The device does not turn on
  If, after pressing the black button, nothing is displayed, check the battery connection and try again. If nothing happens, change the battery. If still nothing happens, remove the battery and send the device to Francemed in its box.
- The device does not turn off after pressing the black button
  Do not operate the device. Remove the battery and send the device to Francemed in its box.
- The device displays the same value and no longer reacts to pressure
  Do not operate the device. Remove the battery and send the device to Francemed in its box.
- For any other malfunction or in the event of maladjustment, severe shock or visible fault
  Do not operate the device. Remove the battery and send the device to Francemed in its box.

⚠
- Do not attempt to open the sensor case (except the battery housing to replace the battery).
- Do not modify the device. Our company shall not be responsible for any repairs of components performed by third parties.

CALIBRATION

- Once per year, before the date of next calibration indicated on the label, remove the battery and send the device to Francemed in its box.
- Do not use the device if the date of the next calibration has passed. Send the device to Francemed as soon as possible.

"In response to regulation requirements, *FRANCEMED* is financially supporting the Récylum Pro WEEE recycling process, which collects used electrical devices and equipment, such as lighting equipment, control and monitoring equipment and medical devices free of charge (find additional information on www.recylum.com)."

EXPLANATION OF SYMBOLS

Manufacturer	Please refer to the manual/instruction leaflet.	REF Product catalogue number
Manufacturing date	LOT Product lot number	MD Medical device

For additional information, please contact us or your dealer or consult the videos and documentation available at our website www.medicalex.info
Francemed can provide the instructions for use in paper form, at no additional cost, at the latest within 7 calendar days of receiving a request.

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INSTRUCTIONS FOR USE: PRESSURE SENSOR (Part No. 36.415.91)

Data concerning device safety are indicated by the following symbol ⚠

1. DESCRIPTION

The pressure sensor is CE1639 marked. It consists of two elements: the sensor case (Figure 1) and a compression plate (Figure 2). It is powered by a DC 9V battery (⎓), type 6LF22.

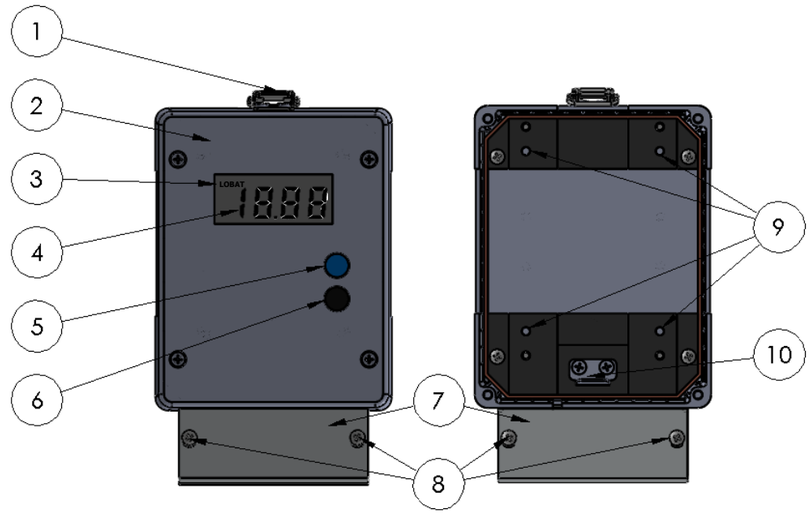

Figure 1: Main components of the sensor unit

Figure 2: Main components of the compression plate

No.	Description
1.	Lever clasp
2.	Sensor case
3.	"LOBAT" - Low battery indicator
4.	Measured pressure display (1)
5.	Blue button (mean pressure calculation)
6.	Black button (ON/OFF)
7.	Battery housing
8.	Battery housing screw
9.	Pressure needles: elements that transmit the force of the compression plate to the sensors.
10.	Compression plate retaining clip
11.	Compression plate hook
12.	Pressure needle guide holes
13.	Insertion tab
14.	Foam plate

⚠ The foam plate (14) is the part of the device that is applied to the patient. This is a B-type surface (represented by the symbol 🚹). The sensor case (2) and the battery housing (7) are also surfaces that may be involuntarily applied to the patient's body. They are also type B surfaces.

⚠ (1) The sensor indicates the pressure in PSI. It can measure pressure values between 0 and 10 PSI. This is not a high-precision device and the measurement error of approximately 15%. To facilitate the interpretation of measurement results, Francemed decided to use PSI units, which are used in international publications on thoracic compression systems for the treatment of pectus carinatum. The conversion base is 1 PSI ≈ 6.9 kPa.

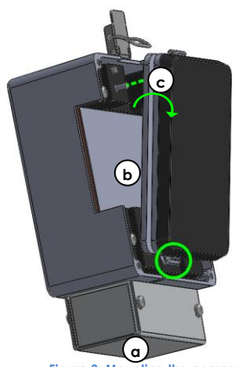

Figure 3: Mounting the compression plate on the sensor case

2. ASSEMBLY

The compression plate is attached to the sensor case (Figure 3):
(a) by placing the insertion tab (13) into the retaining clip (10),
(b) then correctly inserting the pressure needles (9) into the guide holes (12).
(c) Finally, the plate is maintained in place by locking the lever clasp (1) into the hook of the compression plate (11).
The thoracic compression brace includes a compression plate that is similar to the plate supplied with the pressure sensor. The installation of the sensor case on the brace is thus performed in a similar manner.

⚠ Do not assemble components from different sources. Use only parts supplied by our company. Otherwise, we shall assume no responsibility.

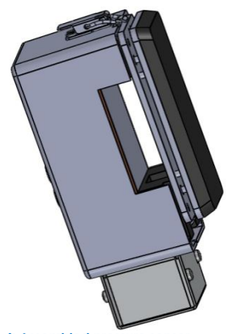

Figure 4: Assembled pressure sensor

INSTRUCTIONS FOR USE: PRESSURE SENSOR (Part No. 36.415.91)

3. MAIN INDICATIONS

The pressure sensor is designed for exclusive use within the Dynamic Compression System.
This product is exclusively intended for performing the pressure measurements described in the "General instructions for use" section of this leaflet.

4. CONTRAINDICATIONS

Do not use the device for patients with a significant skin lesion at the thoracic wall deformity.

5. ADVERSE EFFECTS AND POSSIBLE COMPLICATIONS

While measuring the pressure for initial correction PIC, patient may have a vasovagal episode. Practitioner should be prepared to intervene in case it happens.
Any possible side effects and complications related to this product are the consequences of inaccurate measurements taken with the device. Erroneous measurements may cause producing a poorly-fitting custom-made dynamic compression brace and application of inappropriate pressure on the patient. This can result in:

- Discomfort
- Redness
- Skin discoloration
- Irritations
- Respiratory discomfort
- Back and chest pain
- Wrong deformity correction
- Delay in the treatment
- Termination of treatment

6. GENERAL INSTRUCTIONS FOR USE

The required measurements are the Pressure for Initial Correction (PIC) and the Pressure of Treatment (POT). These measurements must be taken with the pressure sensor provided by our company.
The Pressure for Initial Correction is the pressure to be applied on the deformity so that the thoracic wall takes a normal shape.
The correction pressure is the pressure exerted by the brace on the thoracic wall.

Figure 5: Measuring the PIC

Measuring the Pressure for Initial Correction (PIC)

The Pressure for Initial Correction is measured at the first visit.

1. Fasten the compression plate supplied with the pressure sensor to the back of the sensor case (see para. 2 - Assembly).
2. Have the patient stand with the back against a wall, facing the practitioner (Figure 5).
3. Hold the sensor case in a completely upright position, do not touch the compression plate and turn on the device by pressing the black button (6) (Figure 6). The device is calculating the reset pressure and displays the value “0.00” (the pressure measured at this stage becomes zero on the measuring scale.) If the value displayed is not 0.00, turn off the device by pressing the black button and restart the process (step 3).
4. Apply the compression plate to the patient's chest, at the place of the deformity. Gradually exert pressure on the deformity until the thoracic wall takes a normal shape, namely until the deformity has been completely absorbed (see Figure 5). The increasing pressure can be observed on the device display. While maintaining this pressure, press the blue button (5) and wait for 5 seconds (as long as the 3 bars are visible and a value is displayed). The PIC value is the value that is displayed on the device in blinking mode. This value is the mean value of the pressure exerted over these 5 seconds. Release the pressure and record the value and press the black button to turn off the device.

Important! Make sure that the patient remains motionless during the entire measurement.

5. Take this measurement three times (resuming from step 3), then calculate the average of the obtained PIC values.
6. If the PIC value is lower than 5 PSI (≈ 34.5 kPa), you can expect good results in a short time. For PIC values between 5 and 7.5 PSI the treatment will be longer. If the PIC value is higher than 7.5 PSI (≈ 52 kPa), a positive outcome of the treatment using the Dynamic Compression System is not guaranteed for this patient. It is the surgeon's decision, in consultation with the patient, whether to carry out the treatment anyway or not.
7. Record the PIC value in the prescription.
8. Take the measurements of the thoracic wall using the thorax ruler (see the Instructions for Use of the thorax ruler) and record the values in the prescription.

Figure 6: How to hold the device to turn it on and while it resets itself

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Measuring the Pressure of Treatment (POT)

The pressure of treatment is measured at the initial placement of the brace, and subsequently at each monthly checkup.

1. After assembling the brace, adjusting the straps and fitting the compression plate at the proper height, unfasten the brace hinge.
2. Install the pressure sensor case on the compression plate attached to the brace (see para. 2 - Assembly).
3. Hold the front plate of the brace with one hand making sure that the compression plate does not touch the patient's chest, while maintaining the unit in an upright position. Do not touch the compression plate while the device turns on and resets itself. Turn the device on by pressing the black button. The device resets itself.
4. Close the brace by clasping the hinge.
5. Ask the patient to breathe normally. Press the blue button. The device will display 3 bars for 5 seconds and then a value in blinking mode (see Figure 7). The pressure of treatment is this value. It is the mean value of the pressure exerted by the brace on the chest over these 5 seconds.
6. To avoid discomfort and/or skin lesions, the POT value must be less than or equal to 2.5 PSI (≈ 17.3 kPa). To change the POT, adjust the brace settings (refer to the Instructions for Use of the brace).
7. Before carrying out a new POT measurement, turn off the sensor by pressing the black button, then follow the instructions in step 2. It is critical to power on the device only when the sensor has been fastened to the brace, but before the compression plate has been placed on the patient. This ensures that the reset is properly performed.

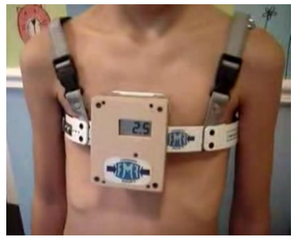

Figure 7: Measuring the POT

It is imperative to turn on the device only when the sensor is attached to the sling but the compression plate is not exerting pressure on the patient to ensure that the tare is done in the right conditions.

- Do not take any measurements when the LOBAT indicator (3) is displayed. In such a case, change the battery (refer to para. 9 - Maintenance).
- The values obtained with the pressure sensor should always be critically examined to detect a possible maladjustment of the device. The practitioner should always make sure that the patient feels comfortable wearing the brace.
- Watch out for any sign of patient discomfort while using the device.
- The interpretation of measurements taken with the pressure sensor must be carried out only under the supervision of a physician.
- Remove the battery if the device will remain unused for an extended period of time.

7. PRECAUTIONS AND WARNINGS

- Make sure that the product conforms to the indications on the packaging.
- Proceed to a visual inspection of the device to detect possible damage that could compromise its normal operation.
- Do not let the device come into contact with surfaces or substances that could damage its surface.
- In case of serious damage or visible defect, do not use the device.
- The device may generate electromagnetic or other interference. In such a case, the user may have to take appropriate steps.
- To disconnect the device from any source of energy, disconnect the battery.
- Do not immerse the device in any fluids.

8. UTILISATION AND STORAGE CONDITIONS

Handle with care.
Store the device in its packaging, namely in its box.
The device should be stored at a temperature between 0 and 40°C, a relative humidity between 10 and 90% and atmospheric pressure between 50 and 106kPa.
The device should be operated at a temperature between 10 and 25°C, a relative humidity between 30 and 60% and atmospheric pressure between 70 and 106kPa.