

INSTRUCTIONS FOR USE Monitor



Disclaimer

The DeltaScan Monitor is intended for use by healthcare professionals in a clinical setting, who are fully responsible to use the device in accordance with these Instructions for Use. The manufacturer Prolira BV can in no way be held liable if the DeltaScan Monitor is incorrectly used, is not maintained, is poorly maintained, is incorrectly set, or is used by unqualified persons.



These Instructions for Use may not be reproduced or used in any way without the prior written permission of Prolira BV. All rights reserved. Subject to alteration.

The compatible hardware and software versions for the DeltaScan Monitor that are subject of this Instructions for Use can be found in the compatibility Matrix on the Prolira website location <http://prolira.com/ifu-prolira-deltascan/>

TABLE OF CONTENTS

1.	INTRODUCTION TO THE DELTASCAN MONITOR	3
1.1	Intended Use	3
1.2	Intended User, User Profile, And Use Environment	3
1.3	Intended Patient	3
1.4	The DeltaScan Monitor Components	4
1.5	Operating Principle And Delirium Probability Score	6
2.	HOW TO USE THESE INSTRUCTIONS FOR USE	8
2.1	General	8
2.2	Meaning Of The Symbols Used	8
3.	TURNING ON AND OFF	9
4.	PREPARATION FOR USE	10
5.	USE	19
6.	AFTER USE	24
7.	CHARGING	25
8.	MENU	27
8.1	Last 5 Valid Results	27
8.2	Set Language	27
8.3	Start Demo	27
8.4	Exit Menu	27
9.	MOUNTING TO A ROLL STAND	26
10.	CLEANING, STORAGE, AND MAINTENANCE	27
10.1	Cleaning	27
10.2	Transport And Storage	27
10.3	Maintenance	27
11.	POSSIBLE PROBLEMS DURING USE	30
11.1	Problems, Causes And Solutions	30
11.2	Errors And Warnings That Can Be Presented On the Monitor Screen	32
12.	TECHNICAL AND REGULATORY INFORMATION	34
13.	REFERENCES	37
14.	ANNEX A: FULL LABELLING OF DELTASCAN PATCH AND BOX	38

1. INTRODUCTION TO THE DELTASCAN MONITOR

1.1 INTENDED USE

The DeltaScan Monitor is intended to support the clinical assessment of delirium by providing a Delirium Probability based on electroencephalography (EEG) signals.

The Delirium Probability or DeltaScan Score, which is the DeltaScan Monitor detection and monitoring parameter, may be used as an aid in the diagnosis of the state of a patient's delirium.

Contra indications and exclusions: children (under 18 years of age), patients under sedation, patients using Lithium, patients with a metal plate or a metal device in the head, patients with dementia or other conditions that affect slowing of EEG signals (such as brain injury), very agitated patients (not being able to follow measurement instructions, see section 1.3).

1.2 INTENDED USER, USER PROFILE, AND USE ENVIRONMENT

Intended user is a licensed healthcare physician or other medical professional working under the responsibility of a licensed healthcare physician.

Intended users can be colour-blind and still use the device safely.

Reading the Instructions for use is sufficient for safe and effective operation of the device.

The use environment is hospitals.

1.3 INTENDED PATIENT

The intended patient is a hospitalized, awake adult, who is at risk of delirium as decided by the responsible licensed healthcare physician or a medical professional working under the responsibility of a licensed healthcare physician. This implies that the patient is to be screened with the DeltaScan Monitor, meaning detection and monitoring for delirium is applied.

In order to take a measurement, the following instructions apply for the patient:

- be awake
- the patient should be relaxed, in sitting or lying position
- and keep the eyes closed

1.4 THE DELTASCAN MONITOR COMPONENTS

- 1) Monitor
- 2) Patch connector
- 3) Recording button

- 4) Charger for Monitor

- 5) The DeltaScan Monitor should exclusively be used with a DeltaScan Patch.

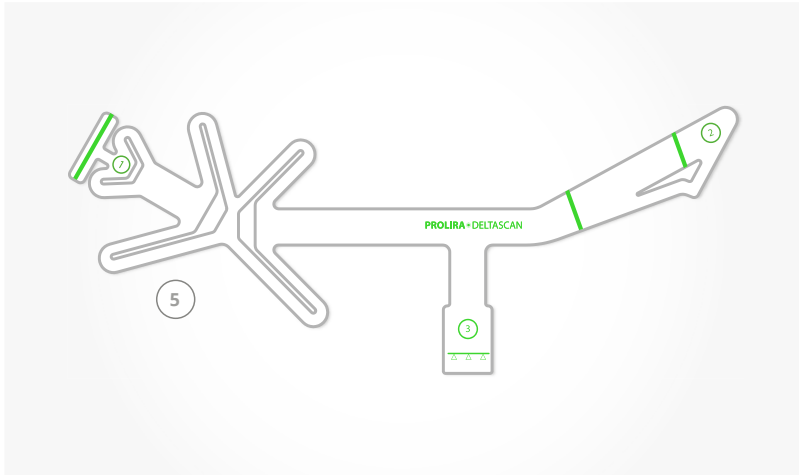
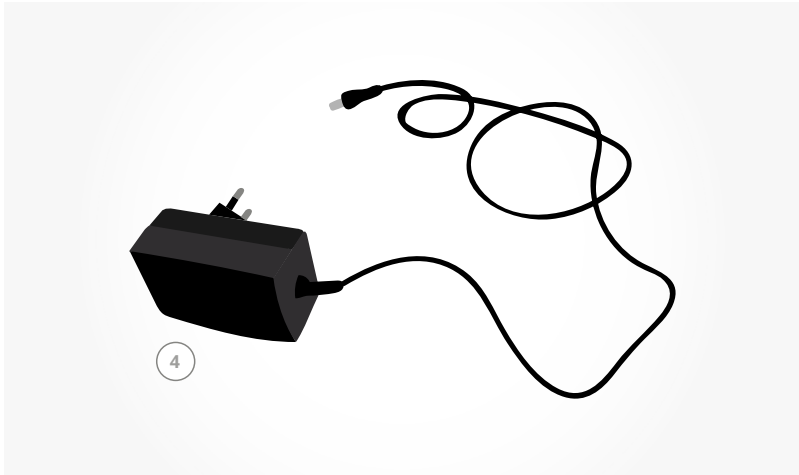
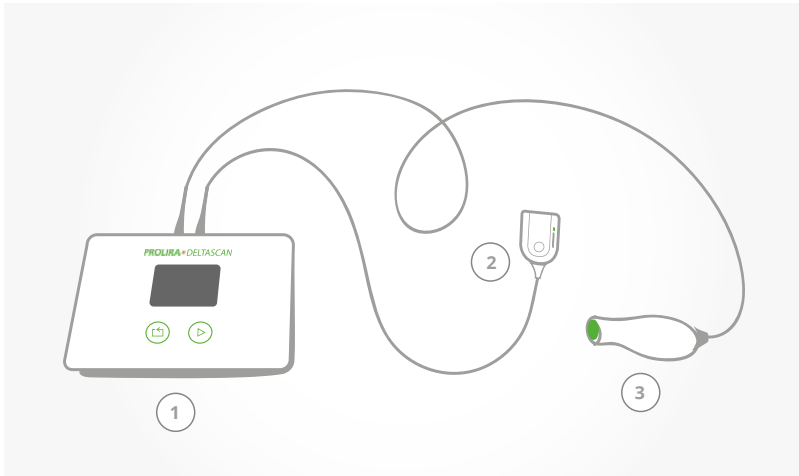


Figure 1: DeltaScan Monitor Components.

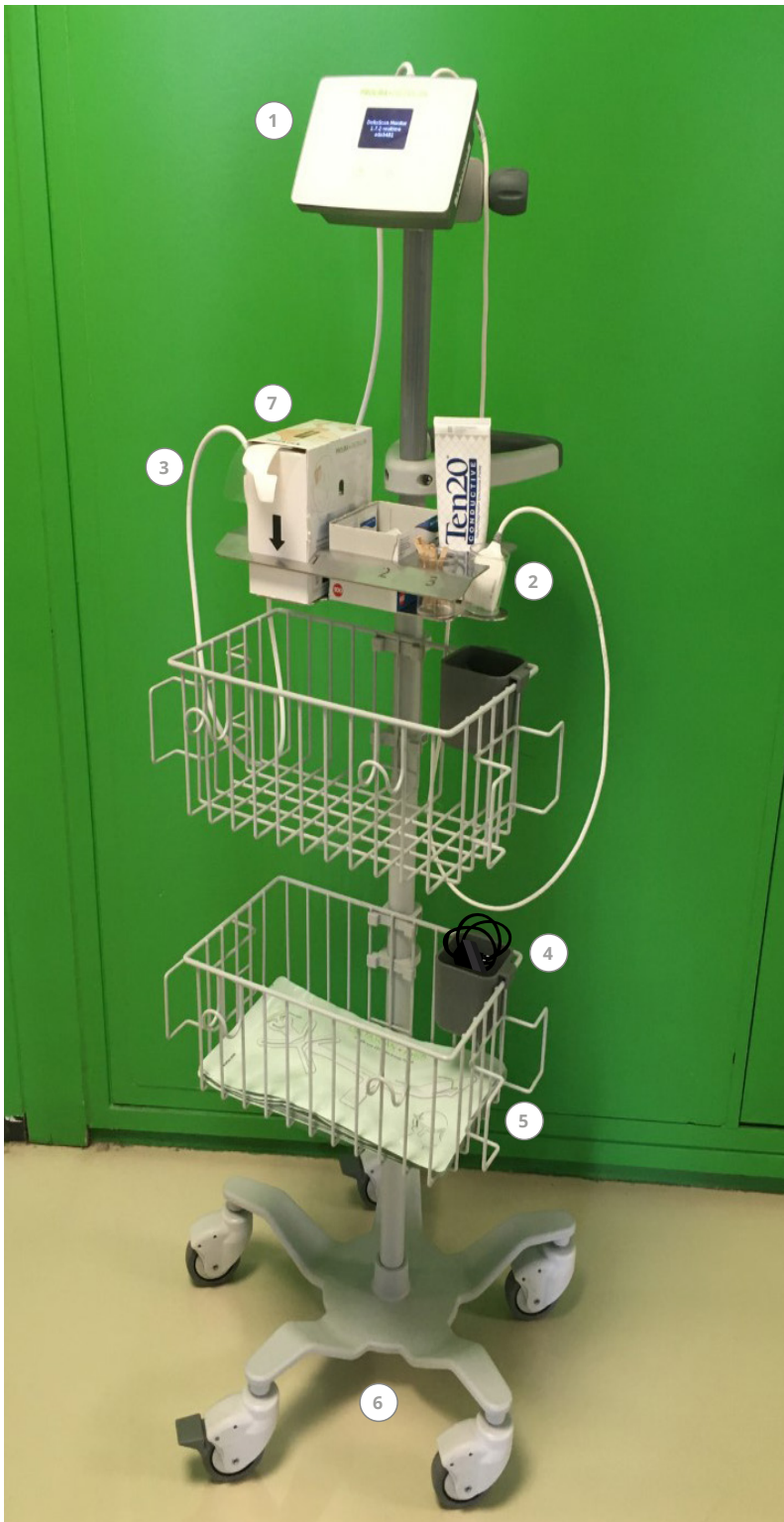


Figure 2: DeltaScan Monitor complete set-up.

The DeltaScan Monitor (see Figure 2) consists of:

- 1) Monitor (1)
- 2) Patch connector (2) on cable
- 3) Recording button (3) on cable
- 4) Charger for Monitor (4)

The DeltaScan Monitor should only be used in combination with a DeltaScan Patch (See Figure 1: nr 5 and Figure 2: nr 5).

To improve fixation of the DeltaScan Patch electrode on the crown of the head (Pz location), it is advised to use a self-adhesive HairLock from the dispenser-box (see Figure 2: nr 7)

The DeltaScan Monitor can be mounted to a GCX Rollstand (see Figure 2: nr 6), (see also section 9).

1.5 OPERATING PRINCIPLE, AND DELIRIUM PROBABILITY SCORE

The dedicated, self-adhesive DeltaScan Patch includes 3 electrodes, to easily collect relevant EEG signals of the patient:

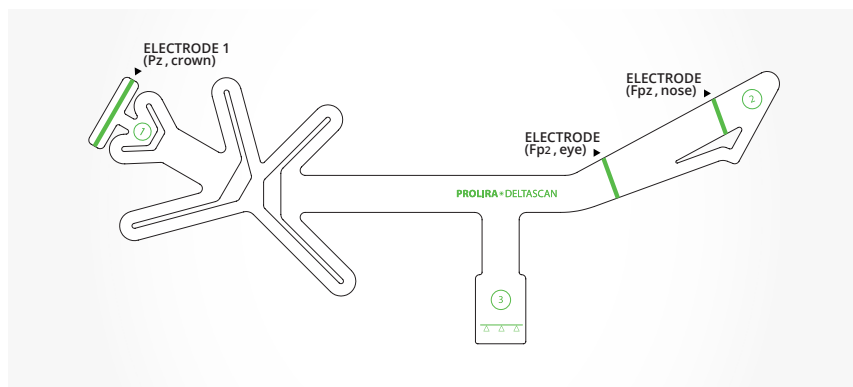
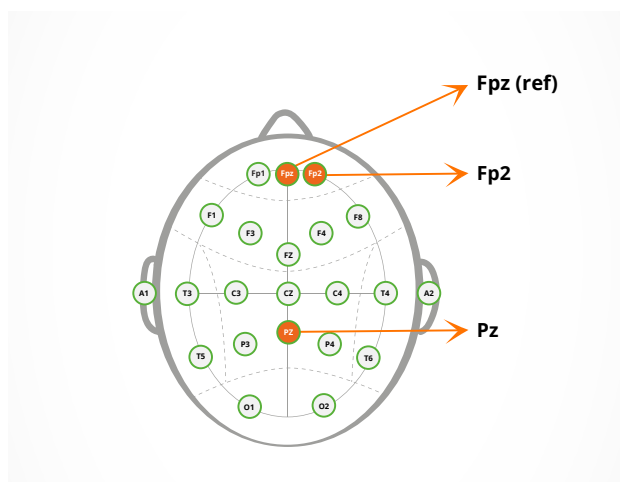


Figure 3: DeltaScan Patch includes 3 electrodes (3 green stripes).



- The 1st electrode on or close to Pz (on the crown of the head)
- a second electrode on or close to Fp2 (above the patient’s right eyebrow)
- a third (Reference) electrode on or close to Fpz (above the nose on the forehead)

Pz, Fp2 and Fpz refer to defined EEG electrode locations in the standard 10/20 EEG setup (see Figure 4).

Figure 4: DeltaScan Patch electrode locations.

The acquired EEG signals are amplified, digitized, and processed by the software algorithms of the DeltaScan Monitor, to present a Delirium Probability or DeltaScan Score to the user.

The DeltaScan Monitor provides signal analysis technology intended for use as an adjunct to clinical judgment. The DeltaScan Score should always be interpreted in conjunction with other available clinical signs for clinical judgment.

Do not rely solely on the DeltaScan Score alone for starting or adapting delirium treatment (which may include administration of medication). Clinical assessment should be leading in deciding on patient treatment.

The DeltaScan Monitor embeds state-of-the-art technologies for signal conditioning, signal quality judgement and artefact removal technologies, to minimize the disturbance of the EEG signals by artefacts. Artefacts appear in EEG signals, due to for example poor skin contact of electrodes, head and body motion of the patient, or eye movements.

To understand Prolira’s technology, the fundamentals of the proprietary waveshape analysis are explained. As published by Kooi et al. [1] and Numan et al [2], delirium leads to general slowing of EEG in the delta range (1 to 4 Hz).

The DeltaScan algorithm detects and quantifies those specific EEG waveshape patterns that are characteristic for delirium. These patterns differ from healthy EEG recordings.

The DeltaScan Monitor provides the user with the DeltaScan Score on a scale of 1 to 5.

Table1 explains the technical meaning and clinical interpretation of DeltaScan’s 5-point scale.






Score on DeltaScan Monitor	Technical meaning of each score	Clinical interpretation for each score – Delirium Probability
	The amount of characteristic waveshapes is very low, which corresponds with patients classified by delirium experts as NOT delirious. See [2,1] for the classification procedure.	Very unlikely
	The amount of characteristic waveshapes is low, which corresponds with patients classified by delirium experts as NOT delirious.	Unlikely
	The amount of characteristic waveshapes in the EEG corresponds ambiguously with patients classified by delirium experts.	Indecisive on whether the patient has delirium or not
	The amount of characteristic waveshapes is large, which corresponds with patients classified by delirium experts as delirious.	Likely
	The amount of characteristic waveshapes is very large, which corresponds with patients classified by delirium experts as delirious.	Very likely

Table 1: Delirium Probability – DeltaScan score.

It is recommended to write the Delirium probability (or DeltaScan score) in the patient file. Especially for scores 4 and 5 it is recommended to consult the patient’s healthcare physician without delay.

2. HOW TO USE THESE INSTRUCTIONS FOR USE

2.1 GENERAL

These Instructions for Use explain how the DeltaScan Monitor works and how to use it. Instructions can be identified by the word 'Step'. Follow the instructions carefully to obtain a reliable measurement and DeltaScan score. In the event of problems, please consult section 11 'Problems during use'.

Please note! Always keep a copy of the Instructions for Use near the DeltaScan Monitor (for example attached to the rollstand, in case the DeltaScan Monitor is mounted to a rollstand).

2.2 MEANING OF THE SYMBOLS USED



















	Manufacturer		Caution
	Serial number		Type BF applied part
	Catalogue number		Do not use if package is damaged
	Batch code		CE marking of conformity
	Temperature limit: 15 - 35 °C		Keep dry
	Humidity limitation: 10 - 95 RH		Separate Collection
	Refer to instruction manual/booklet		ESD Susceptibility Symbol
	Medical device symbol		Consult instructions for use
	Do not re-use		Use by date

Table 2: Symbols used.

Please note! If the label on the Monitor or Patch connector cable or Recording button cable is damaged or missing, please contact Prolira.

3. TURNING ON AND OFF

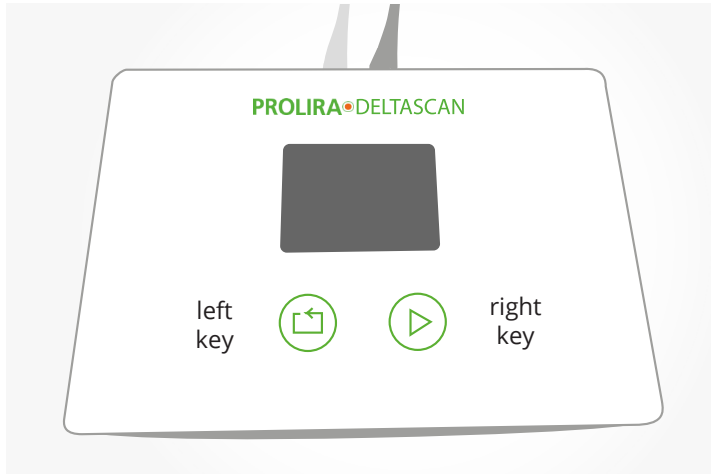


Figure 5: Location of the two keys on the Monitor.

The DeltaScan Monitor does not have an ON/OFF switch.

It turns ON by briefly pressing either one of the two keys on the Monitor (see Figure 5).

To turn it OFF, press either one of the two keys on the Monitor for 10 seconds.

The Monitor will switch OFF automatically if it is not used for 5 minutes.

4. PREPARATION FOR USE

For a measurement, the following items are needed (also see Figure 1):

- a DeltaScan Patch (REF: 001.000.A).
- if the patient has hair on the crown of the head at the position for electrode 1, it is advised to take measures for improved electrode contact: use a HairLock (REF: 003.000.A) to part the hair and keep surrounding hair gently out of the way.
- a DeltaScan Monitor (REF: 006.000.A) with Patch connector (REF: 006.901.A), and Recording button cable (REF: 006.902.A) plugged in.
- a Charger (REF: 006.004.A) for the DeltaScan Monitor, to be used in case the battery level is too low to take a measurement.

Figure 6 below indicates the location of the user, the patient, and the DeltaScan Monitor during a measurement on a patient in bed.

- Patients laying on their back are hardest to measure.
- Patients laying on their left side are generally easier to measure.
- Patients sitting on a chair (or bed) are easiest to measure.



Figure 6.a: Recommended position for a DeltaScan measurement when the patient lies in bed.

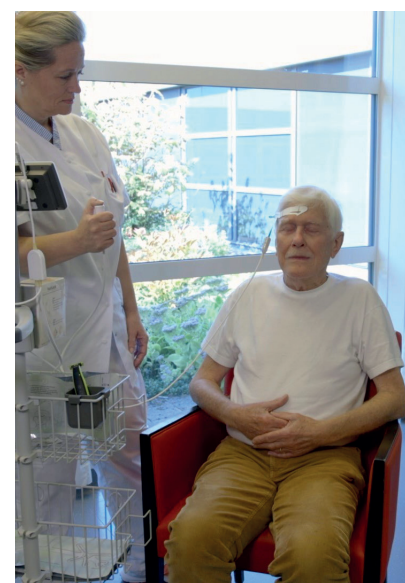


Figure 6.b: Patients may also lie on the left side, sit in bed or sit on a chair.



Warning!

Use DeltaScan Monitor exclusively with DeltaScan Patch.



Warning!

Do not use the device when damage is visible on the device or its cables.

For a correct measurement with DeltaScan, carry out the following preparation steps, to apply a single use DeltaScan electrode Patch correctly to the patient's head.

Please note! The labelling of the DeltaScan Patch is included in full in Annex A.

Step 1: Determine the crown on the head

- The crown of the head is the correct position for electrode 1 of the DeltaScan Patch. This position can be determined according to Figure 7.

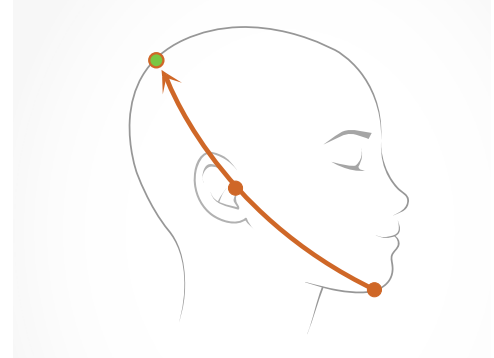


Figure 7: Crown of the head, correct position for DeltaScan Patch electrode 1 (and HairLock, in case HairLock is used).

Step 2: Prepare the crown, such that a hair free strip of skin is exposed

- If the patient has hair on the crown of the head, to improve electrode contact with the skin, it is advised to prepare the crown.
 - Make a vertical parting line in the hair and apply the self-adhesive HairLock, as it helps to gently keep surrounding hair out of the way. First apply Hairlock part 1 (see Figure 8), and then apply part 2 (see Figure 9). If HairLock part 1 and 2 are correctly applied on the head, a strip of skin is exposed in the slot between HairLock part 1 and 2 (see Figure 10.a.).

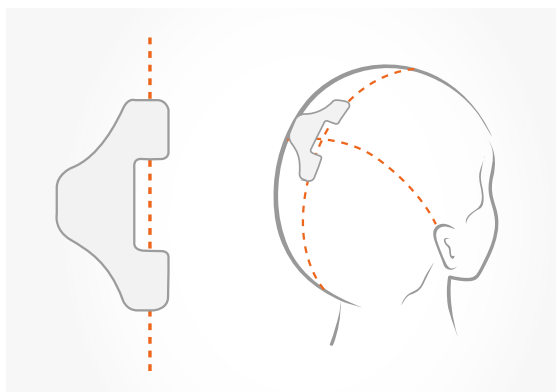
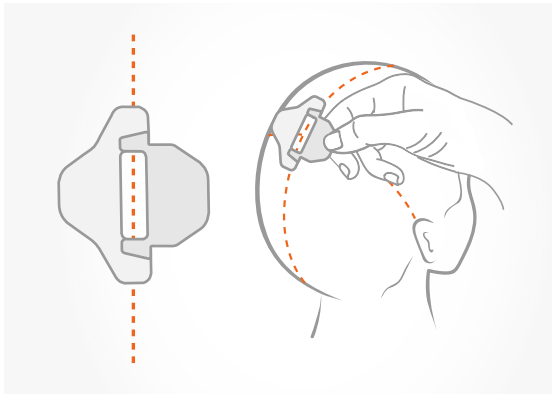


Figure 8: HairLock Part 1 correctly applied.

HairLock part 1

- Position Hairlock part 1 just left of the crown on the middle of the head.



HairLock part 2

- Slide Hairlock part 2 over part 1 align and press for fixation.

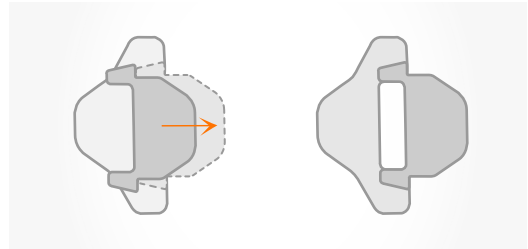


Figure 9: HairLock Part 1 and 2 correctly applied.

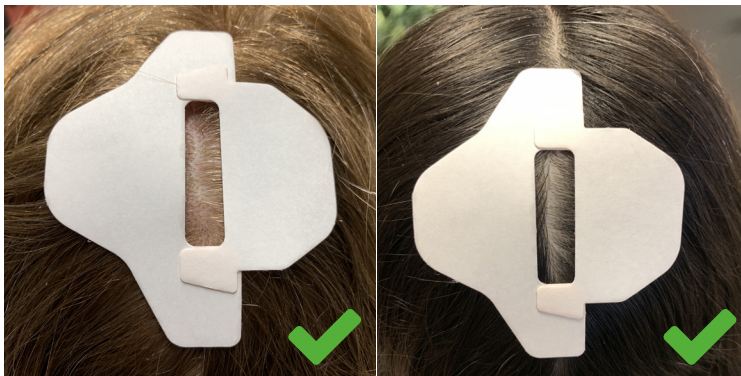


Figure 10.a: Parting in hair, with HairLock correctly applied: a strip of skin is exposed in the Hairlock slot.



Figure 10.b: HairLock not correctly applied, there is no parting in the hair, and there is no skin exposed. Furthermore, HairLock part 2 is not correctly aligned.

Step 3: Prepare the skin of the patient for a good EEG

- To ensure a good EEG with DeltaScan, it is important to ensure good electrode contact with (good adhesion on) the skin.
Prolira advises the use of a Dynarex Electrode Skin Prep Pad (see Figure 11.a.). Use this Dynarex wipe, to scrub and wipe the skin in the HairLock slot and the skin on the patients forehead.
- We further advise to apply a thin visible layer of Ten20 Conductive Neurodiagnostic electrode paste (Weaver and company, see Figure 11.b.) in the HairLock slot to improve adhesion of the electrode (see Figure 12).



Figure 11.a: Dynarex Electrode Skin Prep Pad.



Figure 11.b: Ten20 Conductive Neurodiagnostic Electrode Paste.





Figure 12: Ten20 applied in the HairLock slot.

Step 4

Take a packaged DeltaScan Patch, and tear the packaging open.
Remove the DeltaScan Patch from its packaging and keep the Patch dry.

Please note! Only use if the packaging of the DeltaScan Patch is intact, dry, and if the date of use is not past the expiry date.

 **Warning!** Keep DeltaScan Patch dry once removed from its packaging.

 **Warning!** Use DeltaScan Patch on dry skin only.

Please note! In case of wet skin, for example caused by sweating, please dry the patient's skin first, before applying the Patch.

Please note! The DeltaScan Patch must not yet be connected to the DeltaScan Patch connector.

- Hold point 1 of the DeltaScan Patch between thumb and index finger. Remove the liner from the back of point 1, as indicated in Figure 13.
- Position the electrode (indicated by a green stripe) on the crown of the patient's head (in the HairLock slot if a HairLock is used), as indicated in Figure 14.

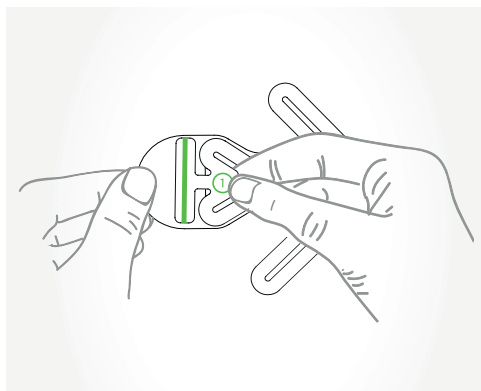


Figure 13: How to hold point 1 when applying the DeltaScan Patch.

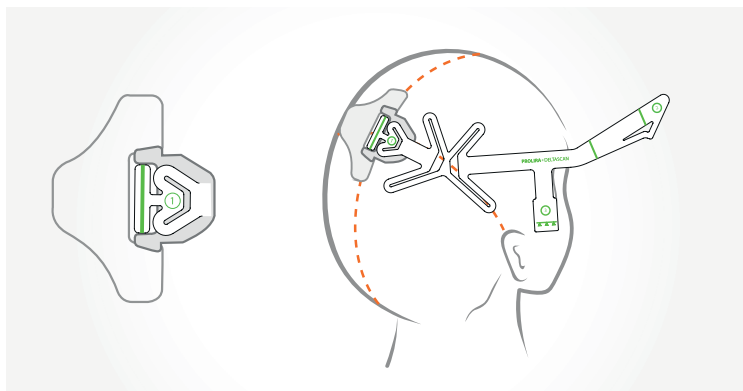


Figure 14: Position electrode 1 (the green stripe) of DeltaScan Patch on the crown of the head, in the HairLock slot, if a HairLock is used.

Step 5

- Face the patient. Hold point 2 of the DeltaScan Patch between thumb and index finger, and remove the liner, as indicated in Figure 15.
- Position the Reference electrode (the vertical green stripe next to nr 2) at the center of the forehead above the nose, and one finger above the eyebrow. The triangle shape of the DeltaScan Patch (under the green stripe) points towards the nose. The other electrode (green stripe) automatically is at the right position too, above the eyebrow. See Figure 16.

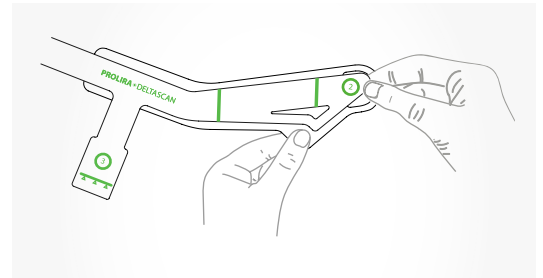


Figure 15: Remove the liner while holding point 2 of the DeltaScan Patch.

Step 6

Press the 3 electrodes (the 3 green stripes) and the green logo firmly to the patient's skin for five seconds.

Please note! for the proper reception of EEG signals (which are microvolts of brain activity) it is very important that the electrodes have good contact with the skin. Therefore, the electrodes must be pressed and well attached to the skin, before the start of a measurement. During a measurement the electrodes may not be touched (not even a pillow or headrest may push against or touch the electrodes).

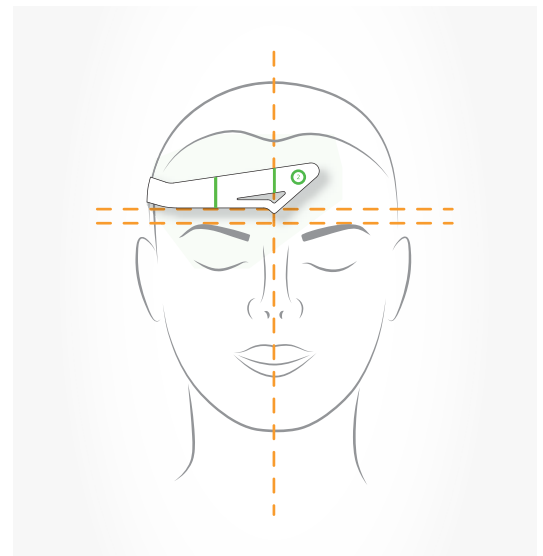


Figure 16: Position the electrodes above the nose and eyebrow.

Step 7

Turn the DeltaScan Monitor ON. Wait until the 'device test' is completely run. While running the 'device test', the Monitor displays the screen of Figure 17.

Step 8

When the device test was successful, the Monitor screen will automatically ask the user to apply and connect the DeltaScan Patch, as is displayed in Figure 18.

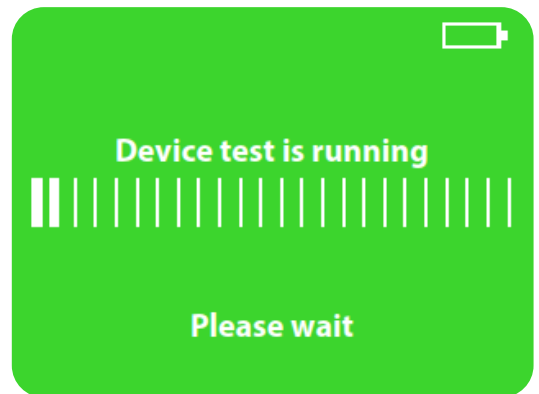


Figure 17: Monitor screen indicating that the 'device test' is running.

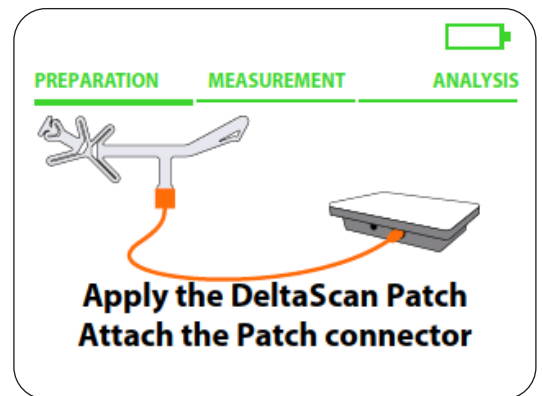


Figure 18: Monitor screen asks the user to apply and connect the DeltaScan Patch.

Step 9

- Connect the Patch connector to the DeltaScan Patch that is already applied to the patient's head. Hold point 3 of the DeltaScan Patch firmly between thumb and index finger. Avoid pulling on the DeltaScan Patch, ensure that the electrodes stay well attached to the skin.
- Slide the Patch connector over the 3 green triangles, up to the line, until a hard stop is felt, and the Patch cannot advance further. See Figure 19.

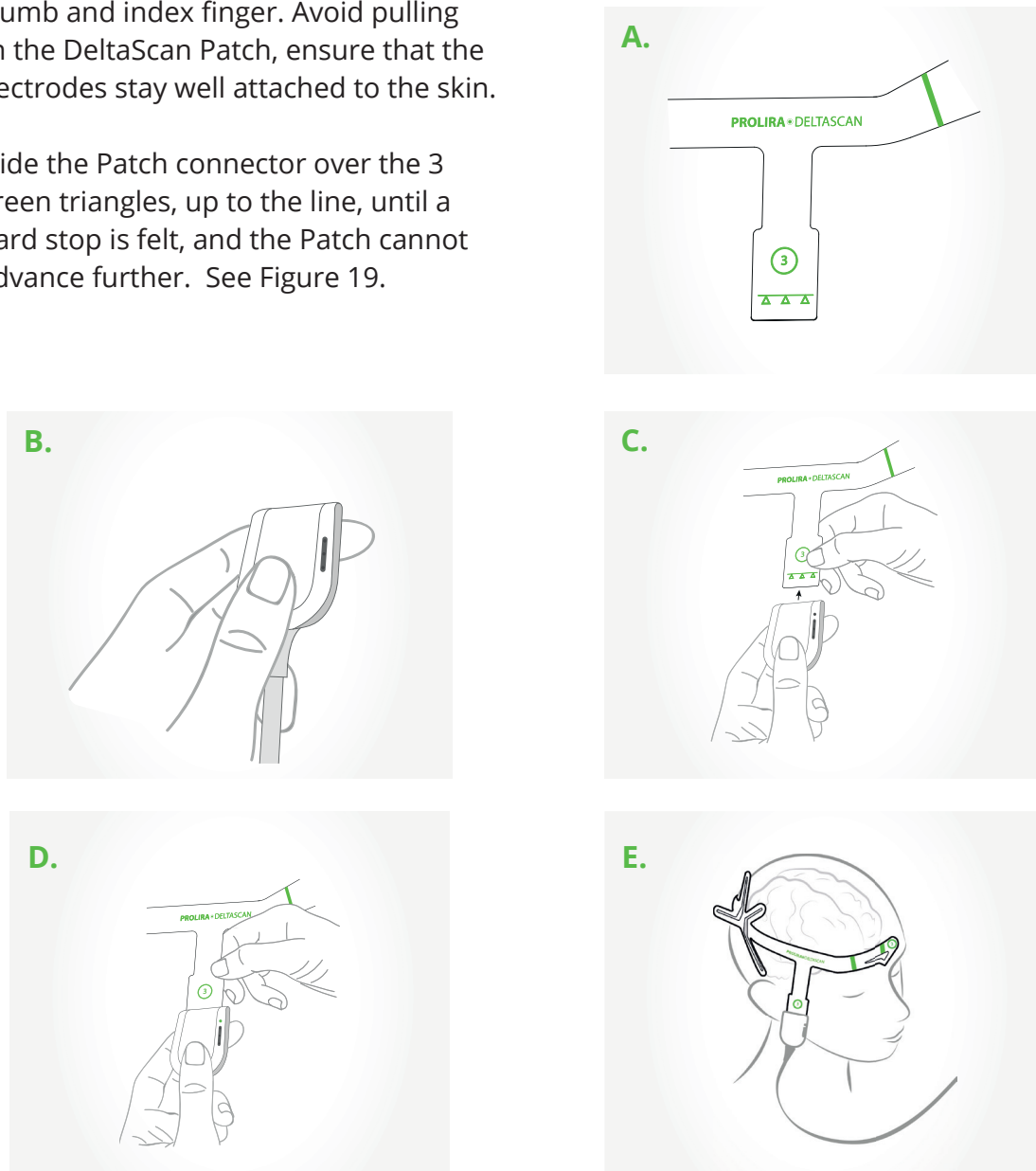


Figure 19:

- A) Point 3 on the DeltaScan Patch (positioned on the right cheek of the patient) with indication for inserting the Patch into the Patch connector.
- B) Hold the Patch connector between thumb and index finger.
- C) Slide the Patch connector over the 3 triangles on the DeltaScan Patch.
- D) Slide the Patch connector up to the line, until a hard stop is felt.
- E) The Patch is now well connected. The Connection-LED should now be green (see Figure 18).

- Check if the Connection-LED (the top LED on the Patch connector) turns green, to indicate that the Patch is well connected (see Figure 20).
If the Patch connector is not correctly attached to the Patch or if the electrodes do not make proper contact to the patient's skin, the Connection-LED will blink orange. In that case, check the Patch connector and/or press electrodes firmly to the patient's skin for contact. Repeat until the Connection-LED turns green.
Also, the monitor indicates if the Patch connector is well attached (see Figure 21.)

Please note! In case of repeated mal connection, remove the DeltaScan Patch from the patient's head.

Then start again at step 3: re-prepare the skin and apply a new Patch to the patient. Then reattach the Patch connector, until the Connection-LED turns green.

Please note! It may require a little force to insert the DeltaScan Patch into the Patch connector.

Please note! Ensure the Patch connector cable is free and not entangled with the Recording button cable or anything else.

The preparation is now completed, and a measurement can be taken.

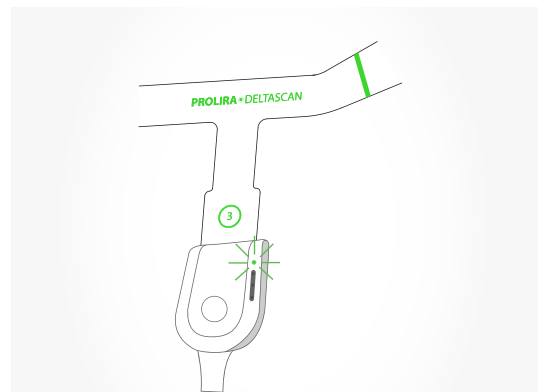


Figure 20: The Connection-LED is green if the DeltaScan Patch is well connected.

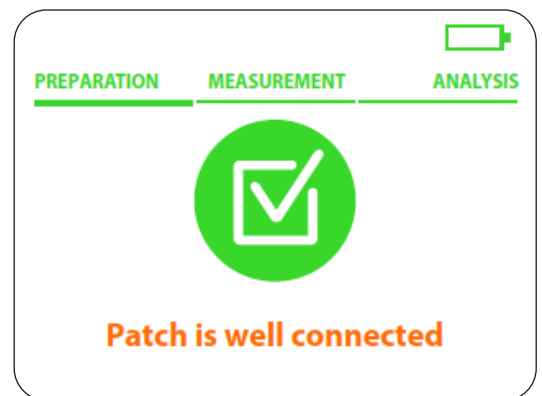


Figure 21: Monitor screen when Patch and electrodes are well connected.

5. USE

Step 1

Once all preparation steps have been carried out properly, the Monitor displays the screen of Figure 22.

The user is asked to read the instructions "Hold down the recording button


- if the patient is (1) awake,
- (2) is relaxed and
- (3) keeps eyes closed"

The user must Confirm this step by pressing the right key on the Monitor (close to the word "confirm" on the screen).

Step 2

Figure 23 displays the screen that provides the instructions for the start of the measurement.

The user must hold down the Recording button to start the measurement, see Figure 24.

 **Warning!** Make sure that the patient is (1) awake, (2) relaxed and (3) keeps the eyes closed while taking a measurement.

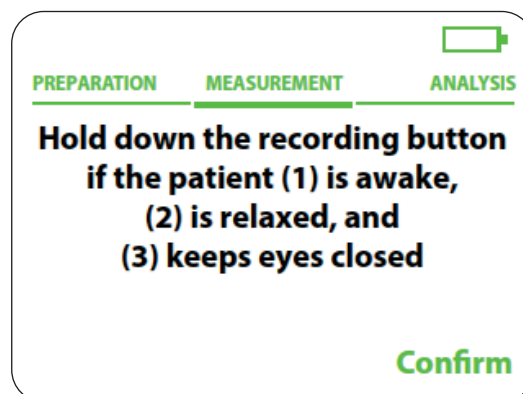


Figure 22: Monitor screen asking for confirmation of the instructions.

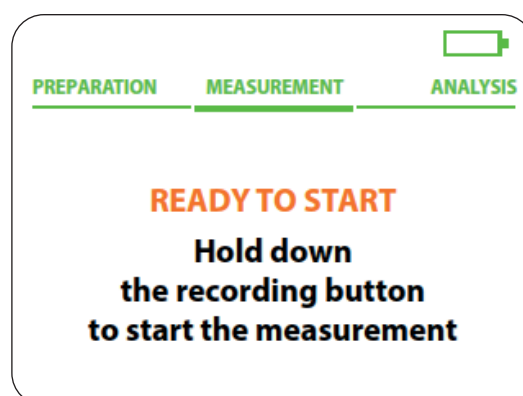


Figure 23: Monitor screen providing instructions to perform a measurement.



Figure 24: Recording button is pressed during measurement, as long as the patient complies to the 3 instructions.

Step 3

IMPORTANT: measure only if the patient complies to the instructions!

A successful DeltaScan measurement takes about 2 minutes, but sometimes a measurement may take longer.

It is very important that the patient follows the instructions during the entire measurement. Following the instructions means that the patient:

- (1) is awake,
- (2) is relaxed (sits or lies calm and keeps the muscles in the face relaxed, e.g. does not clench the jaws, does not talk or frown)
- (3) keeps the eyes closed.

The user keeps pressing the recording button, as long as the patient complies to the instructions. During the EEG measurement, the user must stay focused on the face of the patient and check continuously whether the patient still complies to the three instructions.

It is the user's responsibility to release the Recording button immediately, if the patient does not comply to the instructions. Releasing the Recording button means that the EEG measurement is interrupted (paused).

Reasons for releasing the recording button (and pausing the EEG measurement) are:

A. Patient falls asleep.

The user releases the recording button immediately.

The user wakes the patient up and reinstructs the patient.

As soon as the patient complies, the user can press the Recording button again and the measurement continues.

B. Patient is not relaxed.

Patient is e.g. clenching the jaw, grinding the teeth or talking. The user releases the recording button immediately. The user instructs the patient to relax and sit or lie still. As soon as the patient complies, the user can press the Recording button again and the measurement continues.

C. Patient opens the eyes.

The user releases the recording button immediately.

The user instructs the patient to close the eyes again.

As soon as the patient complies, the user can press the recording button again and the measurement continues.

When the user releases the recording button, the measurement is PAUSED.

This is made clear by:

- The strip of LEDs in the Patch connector, that blinks orange (see Figure 25.a)
- The Monitor screen displays the PAUSED message (see Figure 25.b)

The Patch connector that is positioned on the right cheek of the patient, contains 1 Connection-LED and a strip with 3 Progress-LEDs. The LED strip provides feedback about the measurement progress, while the user can continue to focus on the patient.

Figure 26 below explains strip of Progress-LEDs.

The user can resume the measurement, without losing the EEG data that was already collected successfully, by pressing the Recording button again.

Suggestion! The user may be able to support the patient to comply; it might help to talk to the patient, to provide comfort and encouragement, but remember that the patient is not allowed to talk.

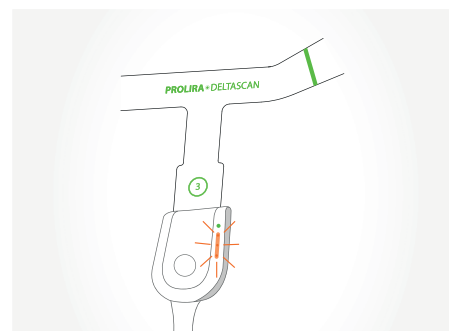


Figure 25.a: When the user releases the Recording button, the measurement is PAUSED. The strip of LEDs in the Patch connector blinks orange.

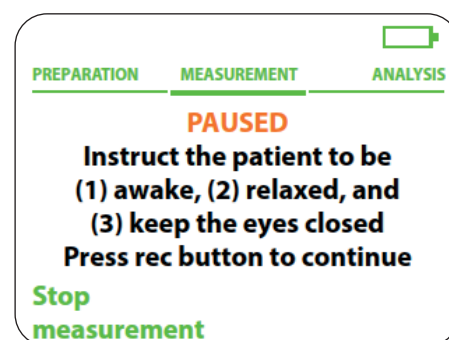
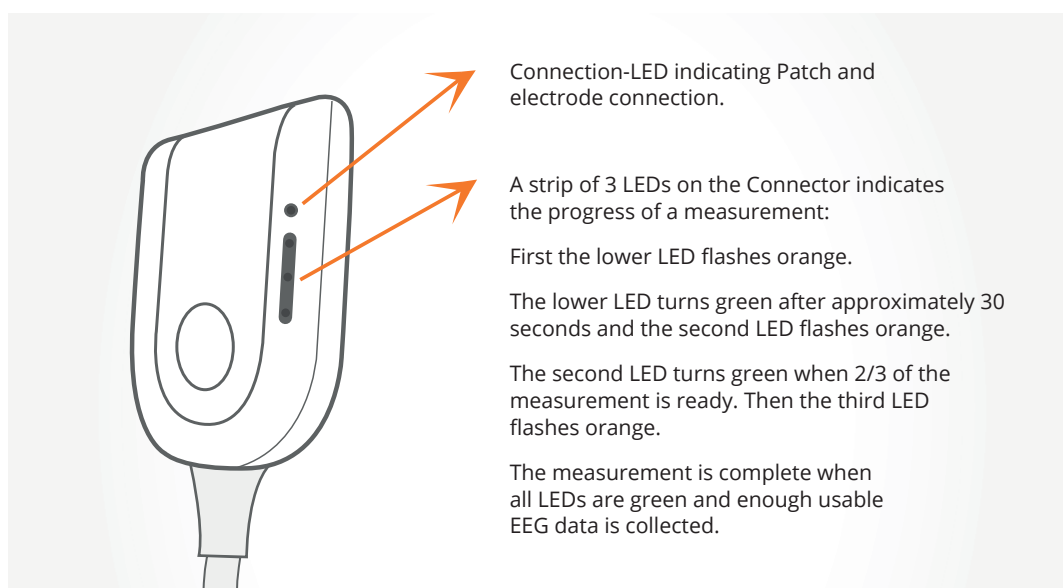


Figure 25.b: monitor screen indicating a measurement is paused.



Connection-LED indicating Patch and electrode connection.

A strip of 3 LEDs on the Connector indicates the progress of a measurement:

First the lower LED flashes orange.

The lower LED turns green after approximately 30 seconds and the second LED flashes orange.

The second LED turns green when 2/3 of the measurement is ready. Then the third LED flashes orange.

The measurement is complete when all LEDs are green and enough usable EEG data is collected.

Figure 26: A strip of LEDs on the Patch connector indicates the measurement progress.

During a measurement, not only the Patch connector, but also the DeltaScan Monitor indicates the progress of the measurement (see Figure 27).

The measurement lasts until 120 seconds of useable EEG data is collected. During the measurement, the DeltaScan Monitor will continuously and automatically judge all acquired EEG data for its usefulness.

The better the electrodes are applied and the better the patient complies to the instructions, the higher the quality of the EEG data, and the faster the measurement will be finished.

Step 4

After a successful measurement, the Monitor automatically switches to the analysis phase, calculating the DeltaScan score (see Figure 28).

Please note! The device checks every minute whether there is enough progress in gathering good data. If at one of these moments (max. 4 minutes), it was not possible to acquire enough useable EEG data from the patient, the measurement will stop. The user can immediately start a new measurement on the patient, but it is advised to assess the position and condition of the patient first, to redo the skin preparation, and to apply a new Patch. It might be practical to find a more relaxed position for the patient such that compliance to the three instructions is easier for the patient.

Please note! The user can stop a measurement anytime during a recording, by pressing the left key on the DeltaScan Monitor. In this case, it is not possible to continue the measurement.

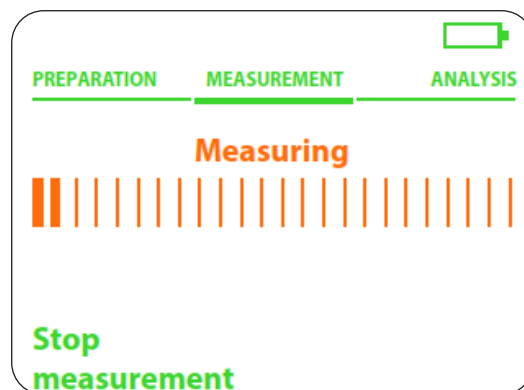


Figure 27: Monitor screen displays the measurement progress.

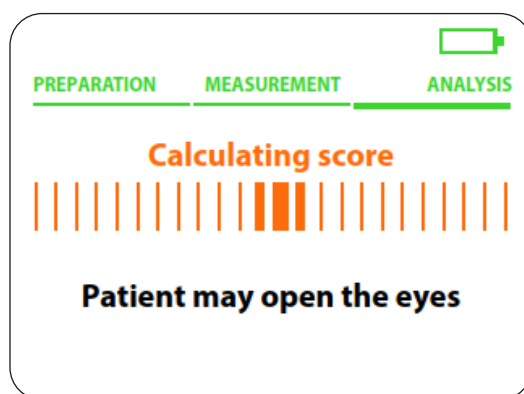


Figure 28: Monitor screen indicating the end of a measurement, calculating the DeltaScan Score.

If the Patch connector cable is disconnected during a measurement, the monitor shows screen of Figure 29 . A new measurement can be started after reconnecting the Patch connector to the Patch and after pressing the right key on the monitor (close to the words “New measurement”).

Only in case of pausing a measurement, by releasing the Recording button, it is possible to resume the measurement. Then, the EEG data that is already collected before pausing, is saved.

Step 5

The DeltaScan Monitor will automatically calculate and present the DeltaScan Score, which is expressed as:

1, 2, 3, 4 or 5.

(See section 1.5 for an explanation of the scores).


See Figure 30 for an example of a score.


It is strongly advised to write the score down in the patient record.

Do not rely solely on the DeltaScan Score alone for starting or adapting delirium treatment (which may include administration of medication). Clinical assessment should be leading in deciding on patient treatment.

Please note! When the device memory is full, the oldest files are deleted first when starting a new measurement.

In relation to defibrillation

 **Warning!** Remove the DeltaScan Patch and the DeltaScan Monitor from the patient before applying defibrillation

 **Warning!** Replace the DeltaScan Patch if it has been on the patient during defibrillation.

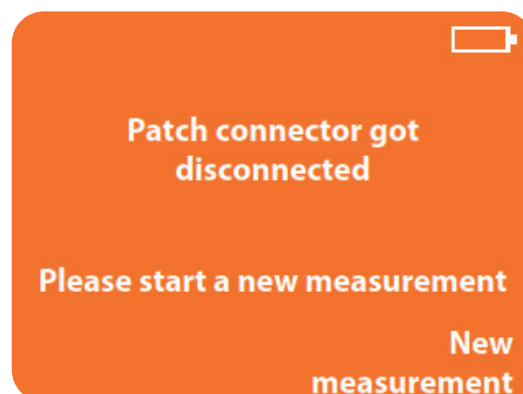


Figure 29: Patch connector got disconnected Please start a new measurement.

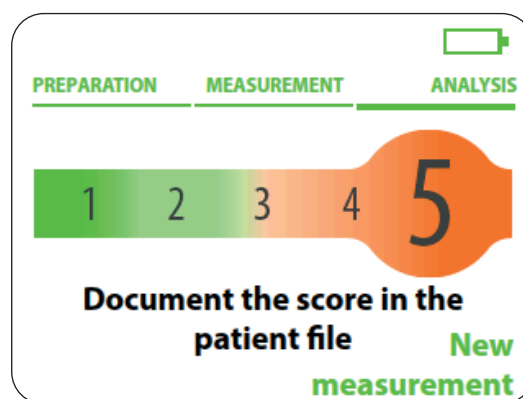


Figure 30: DeltaScan Monitor screen displaying the result of a measurement.

6. AFTER USE

Step 1

As soon as the measurement is finished and the Delirium Probability is calculated, disconnect the Patch connector from the DeltaScan Patch and remove the DeltaScan Patch (and HairLock too, in case a HairLock is used) from the patient's head.

Remove residue of the Ten20 paste from the patient's head with warm water or a Dynarex wipe.



Warning! Remove the DeltaScan Patch immediately from the patient's head, after measurement.

Please note! The DeltaScan Monitor switches OFF automatically if it is not used for 5 minutes.

Step 2

Store the DeltaScan Monitor on a convenient location.

If necessary, plug the charger in the DeltaScan Monitor to charge the battery.

Please note! Only charge the battery when the DeltaScan Monitor is not connected to a patient.

Please note! Make sure the Patch connector cable and recording button cable are stored in such a way that they do not damage.

7. CHARGING

The DeltaScan Monitor is designed such that it can operate for 48 hours without charging under normal clinical conditions (i.e. about 60 measurements can be taken). It is, however, advised to charge the battery daily, to make sure that the device is always ready for use.

To charge the DeltaScan Monitor, plug the charger in the power outlet at the back of the Monitor as indicated in Figure 31, and connect the power plug in the power socket.

Warning! Use the DeltaScan Monitor only in combination with the supplied charger (see section 12).

During charging the Monitor screen displays a progress bar as indicated in Figure 32.

Please note! The device can also be charged when it is OFF. In that case it does not show a progress bar.

When the battery is full, the Monitor screen displays it accordingly (see Figure 33).

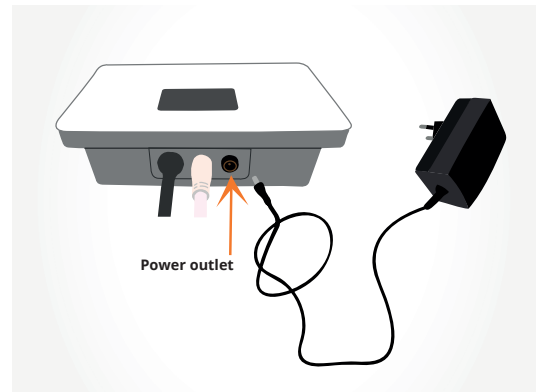


Figure 31: Power outlet of the DeltaScan Monitor.

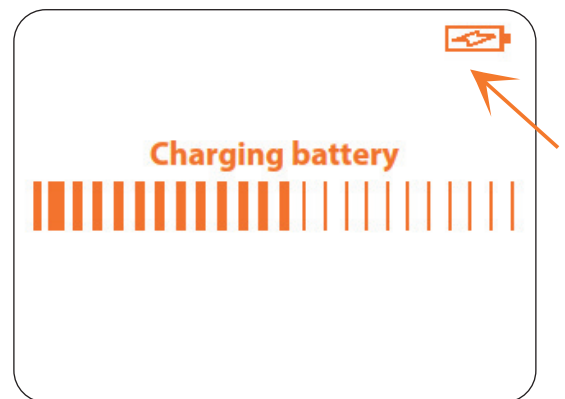


Figure 32: Monitor screen displaying that the device is charging.

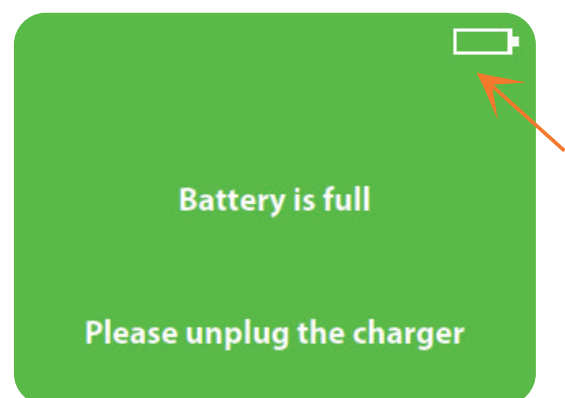


Figure 33: Monitor screen displaying that the battery is fully charged.

When the charger is unplugged, the device needs a restart. Instructions are displayed on the screen (see Figure 34).

If the battery is not full enough to take a measurement, the following screen is displayed (see Figure 35).

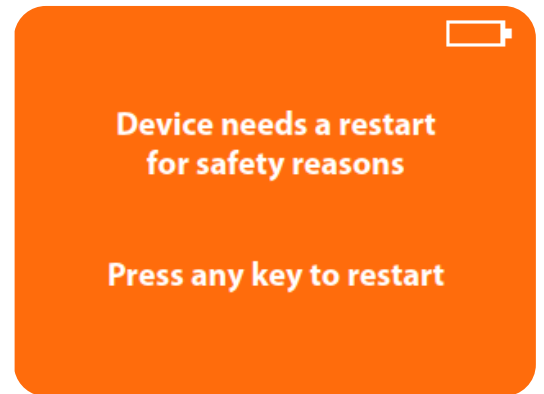


Figure 34: Monitor screen displaying that the device needs a restart after charging.

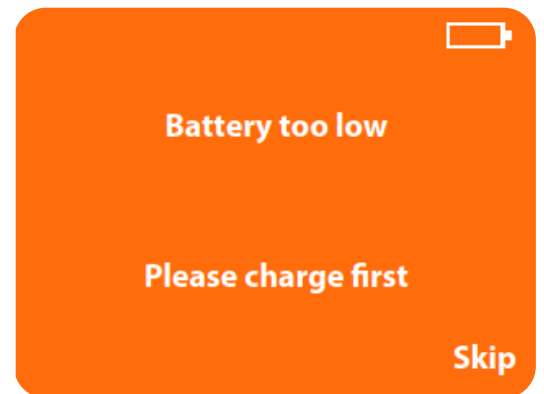


Figure 35: Monitor screen displaying that the device needs to be charged.

8. MENU

By simultaneously pressing both keys (so both the left and the right key) on the Monitor for 3 seconds, a menu with following options appears (see Figure 36):

- View last five scores
- Set language
- Start demo
- Exit menu

The user can navigate through the menu with the left (Next) and right (Select) key on the Monitor.

The active option of the menu is always green and underlined, inactive options are orange.

8.1 VIEW LAST FIVE SCORES

Users can look back at the last 5 measurements results

(the last 5 Delirium Probability scores).

Each score is presented in a different screen.

Pressing 'Next' (the left key on the screen) will show the next result. If less than 5 valid results are stored in the DeltaScan Monitor, only the available results are presented.

8.2 SET LANGUAGE

The DeltaScan Monitor can be set to three different languages: English, German, and Dutch.

8.3 START DEMO

"Start demo" allows the user to go through all the screens (steps) of a measurement procedure, bypassing the need to connect to a patient. The demo looks like a slide show, and the screens in the demo mode always have 4 black corners as well as the word DEMO centrally at the bottom of the screen (see Figure 37). By pressing the right key, the user can go to the next demo screen.

8.4 EXIT MENU

When the option "Exit menu" is activated by the user, the DeltaScan Monitor will return to Step 7 (Preparations for use, device test when starting the device up).

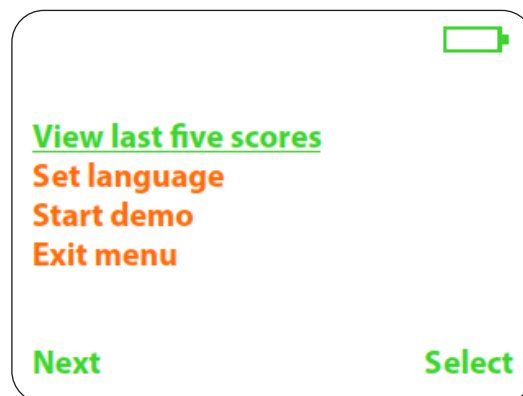


Figure 36: Monitor screen of device menu (available after simultaneously pressing both keys for 3 seconds).

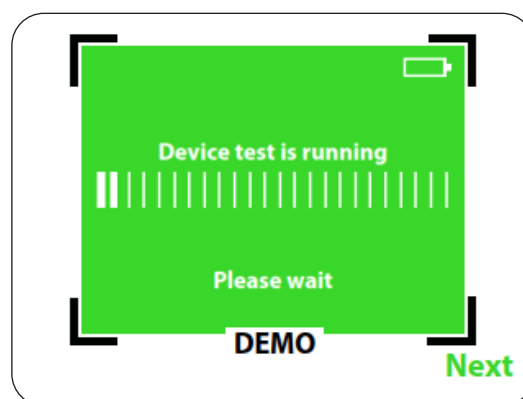



Figure 37: Example of a demo screen.

9. MOUNTING TO A ROLL STAND

It is advised to mount the DeltaScan Monitor to a rollstand. The proper way of doing this is to use a GCX pole-clamp type PH 0062 82B and two DIN 912 M4x8 bolts (see Figure 38), that fit into the 2 screw holes in the back of the DeltaScan Monitor.

 **Warning!** Only attach the Monitor to the pole-clamp with the right bolt size (DIN 912 M4x8 bolts) and only use the screw holes that are already present in the DeltaScan Monitor.

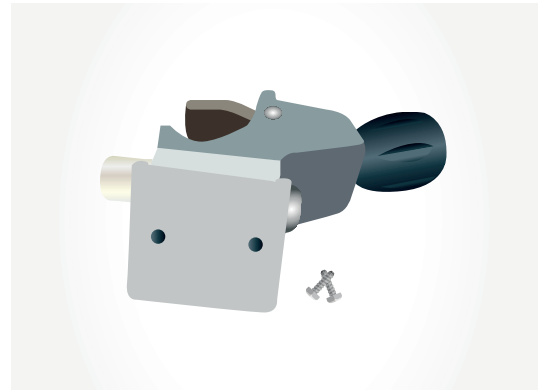


Figure 38: GCX pole-clamp and two bolts to attach the DeltaScan Monitor. The pole-clamp can be clamped to a GCX light weight rollstand.

10. CLEANING, STORAGE, AND MAINTENANCE

10.1 CLEANING

The DeltaScan Monitor including the Patch connector, recording button, and cables can be cleaned with ethanol ($\leq 70\%$).

10.2 TRANSPORT AND STORAGE

Store the DeltaScan Monitor in a dry room. For practical reasons, it is advised to mount the DeltaScan Monitor on a roll stand.

The recommended GCX lightweight roll stand with 2 baskets can not only accommodate the DeltaScan Monitor on the pole clamp, but also the DeltaScan Patches, the Charger and accessories like HairLocks. This ensures that all possible items will be present for use

Permissible environmental conditions for transport and storage are:

- 0 to 45 °C
- 10 to 95 RH

Please note! These conditions differ from the operating conditions (see section 2).

10.3 MAINTENANCE

The DeltaScan Monitor requires no periodic maintenance.

Each time the device is switched ON, it automatically performs a device test.

If this test passes, the device is fit for use.

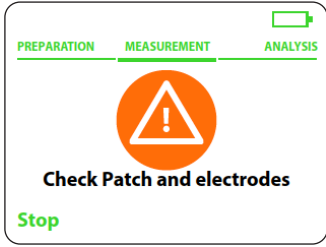
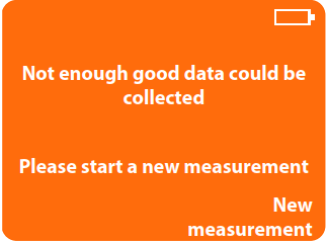


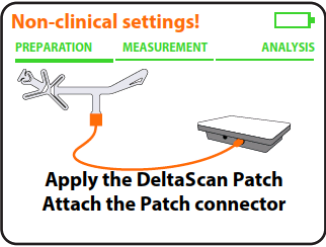
11. POSSIBLE PROBLEMS DURING USE


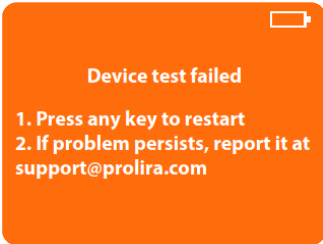


11.1 PROBLEMS, CAUSES, AND SOLUTIONS

Nr.	Problem	Possible cause(s)	Solution(s)
1a	The DeltaScan Patch detaches from the patient's skin (the Connection-LED on the Patch connector is blinking orange)	Excessive sweating of patient	Remove the DeltaScan Patch, dry the skin, use a Dynarex wipe again and apply a new DeltaScan Patch.
		The use date of the DeltaScan Patch is passed the expiry date	Apply a new DeltaScan Patch with a valid expiry date.
		The DeltaScan Patch is used for more than 15 minutes	Apply a new DeltaScan Patch.
1b	The DeltaScan Patch detaches, specifically the electrode on the crown of the head (the Connection-LED on the Patch connector, is blinking orange)	Hair is present under electrode 1	Remove the DeltaScan Patch, make a good parting in the hair and use HairLock part 1 and 2 correctly, wipe the skin with Dynarex, apply Ten20 in the HairLock slot, and apply a new DeltaScan Patch.
		Electrode 1 is stretched / elongated and pulled off the scalp on the crown	Remove the DeltaScan Patch, use a HairLock to improve fixation of the electrode and apply a new Patch.
		Electrode detaches at one side	Remove the DeltaScan Patch, try to find a flatter spot on the patient's scalp, wipe the skin with Dynarex and apply a new DeltaScan Patch.
2	The screen 'electrodes well connected' does not appear on the monitor, while the electrodes are attached well to the skin.	Dirt and dust is present in the Patch connector preventing good contact.	The Patch connector is equipped with a small hole on the side. Blow strongly through the hole to remove any dirt and dust from the Patch connector. Connect again.
3	The DeltaScan Patch is damaged	Miscellaneous	Replace the DeltaScan Patch.

Nr.	Problem	Cause(s)	Solution(s)
4	The DeltaScan Monitor is not being charged	The charger is not plugged in in the DeltaScan Monitor and/or wall power socket	Check charging procedure in chapter 7 'Charging'.
		The charger is defective	Use another DeltaScan charger, or contact Prolira.
		The charger cable is defective	Use another DeltaScan charger, or contact Prolira.
5	The DeltaScan Monitor could not get enough useable EEG data in 4 minutes	Patient is not relaxed, but restless	Make sure the patient is calm and in a comfortable position. Try another measurement.
		Patient tenses muscles, for example neck muscles to hold his/her head up or has many eye movements	Make sure the patient is calm and in a comfortable position. Try another measurement.
		Patient is clenching the jaw of grinding the teeth	Ask the patient to relax the jaw muscles. Try another measurement.
		Something unexpected is disturbing the measurement	Please take pictures of the situation, and contact Prolira.
6	Any other unexpected event of the DeltaScan Monitor	Miscellaneous	Please take pictures of the situation, and contact Prolira.

11.2 ERRORS AND WARNINGS THAT CAN BE PRESENTED ON THE MONITOR SCREEN

Related to problem No	Monitor screen	Explanation
1a and 1b		The electrode contact is insufficient. See the table in section 11.1 for possible causes and resolutions.
5		The device was not able to acquire enough useable EEG data in 4 minutes of measuring. See the table in section 11.1 for possible causes and resolutions.
5		If after three attempts, the device was still not able to acquire enough useable EEG data in 4 minutes of measuring. Please contact Prolira to share your experience. Prolira can learn from it, and improve the device.
N/A		Possible hardware failure. Please contact Prolira to share your experience. Prolira can learn from it, and improve the device.
N/A		When the device shows this non-clinical setting, this text appears in the top of the screen. The user must have the device checked by a technician from Prolira.

Related to problem No	Monitor screen	Explanation
N/A		<p>This screen is presented when the DeltaScan Monitor is switched ON when the Patch connector cable is not well connected to the DeltaScan Monitor.</p> <p>In that case please contact support@prolira.com</p>
N/A		<p>When the DeltaScan Monitor is turned ON, it automatically runs a device test.</p> <p>A failing device test may have several causes.</p> <p>First, try pressing any button to reboot the monitor.</p> <p>When the problem remains, please contact Prolira to share your experience. Prolira can learn from it, and improve the device.</p>
N/A		<p>Reconnect the Patch connector to the Patch on the patient's head and press the right key on the Monitor to start a new measurement.</p>
N/A		<p>An unexpected error occurred.</p> <p>Please contact Prolira to share your experience and the Device Error number (6 in this case) that occurred.</p> <p>Prolira can learn from it, and improve the device.</p>

12. TECHNICAL AND REGULATORY INFORMATION

Product name	DeltaScan Monitor
Model/Type	Release 2 (R2)
Components	Monitor (REF: 006.000.A) Patch connector cable (REF: 006.901.A) Recording button cable (REF: 006.902.A) Use only with DeltaScan Patch (REF: 001.000.A)

The compatible hardware and software versions for the DeltaScan Monitor that are subject of this Instructions for Use can be found in the compatibility Matrix on the Prolira website location <http://prolira.com/ifu-prolira-deltascan/>

Charger AC/DC Medical Adapter	Type: Mean Well, GSM25E12-P1J (REF: 006.004.A)
-------------------------------	---

Monitor

Dimensions	111 x 156 x 51,5 mm (length x width x height)
Weight	721 g
Protection against Electrical shock	Internally powered ME equipment Type BF applied part
IP-classification	IP22
Mode of operation	Continuous operation (no minimum deactivation or OFF time required)



Warning! The battery should only be replaced by an engineer of Prolira.

Please note! Servicing of the DeltaScan Monitor should only be performed by an engineer of Prolira using the most recent version of the Servicing Manual.

Patch connector cable

Dimensions	~1500 mm (length)
Weight	circa 50 g (included in the weight of the Monitor)

Recording button cable

Dimensions	~1500 mm (length)
Weight	circa 150 g (included in the weight of the Monitor)

Charger: AC/DC Medical Adapter

Dimensions 790 x 54 x 33 mm (length x width x height)

Weight 230 g

Input 100-240VAC; 50/60 Hz; 0.7-0.35A

Output 12V DC; 2.08A, 25W max

Electrical isolation Technical information of the medical adapter (SUPPLY MEANS) state:
“The circuitry design meets the international medical standard (2x MOPP), having an ultralow leakage current (<50µA), fitting the medical devices in direct electrical contact with the patients.”
In addition, the design of the DeltaScan Monitor electronics prevent operation of the device when the charger is connected.


EMC compliance


The DeltaScan Monitor has an essential performance according to EN 60601-1-2:2015. Under influence of EMC disturbance, DeltaScan will not provide a wrong result. It might present no result at all.


The DeltaScan Monitor is compliant with EN 60601-1-2:2015 for immunity in professional healthcare facility and residential environments.

The DeltaScan Monitor is compliant with EN 60601-1-2:2015 for emission Class B according to CISPR 11.

Please note! The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas, hospitals and residential environments (CISPR 11 class B).



 **Warning!** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally

 **Warning!** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 **Warning!** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the DeltaScan Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Other technical warnings

 **Warning!** Dispose of this device as electronic waste according to local regulations.

  **Warning!** Only trained technical or research personnel may open up the device and/or get a USB connection to the device.

 **Warning!** No modification of this equipment is allowed.

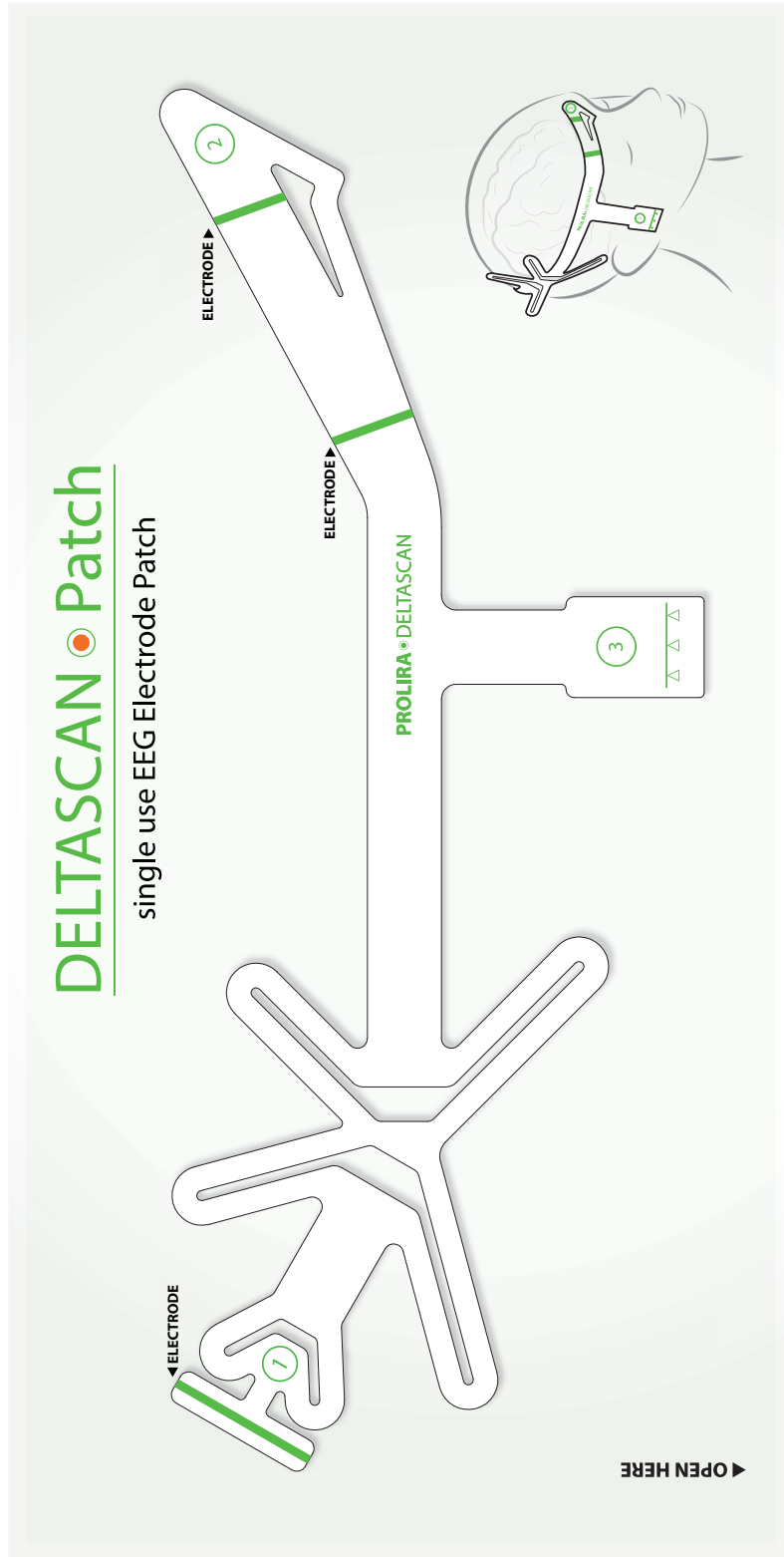
Regulatory notices

Please note! Any serious incident that has occurred in relation to the device should be reported to Prolira and the competent authority of the Member State in which the user and/or patient is established

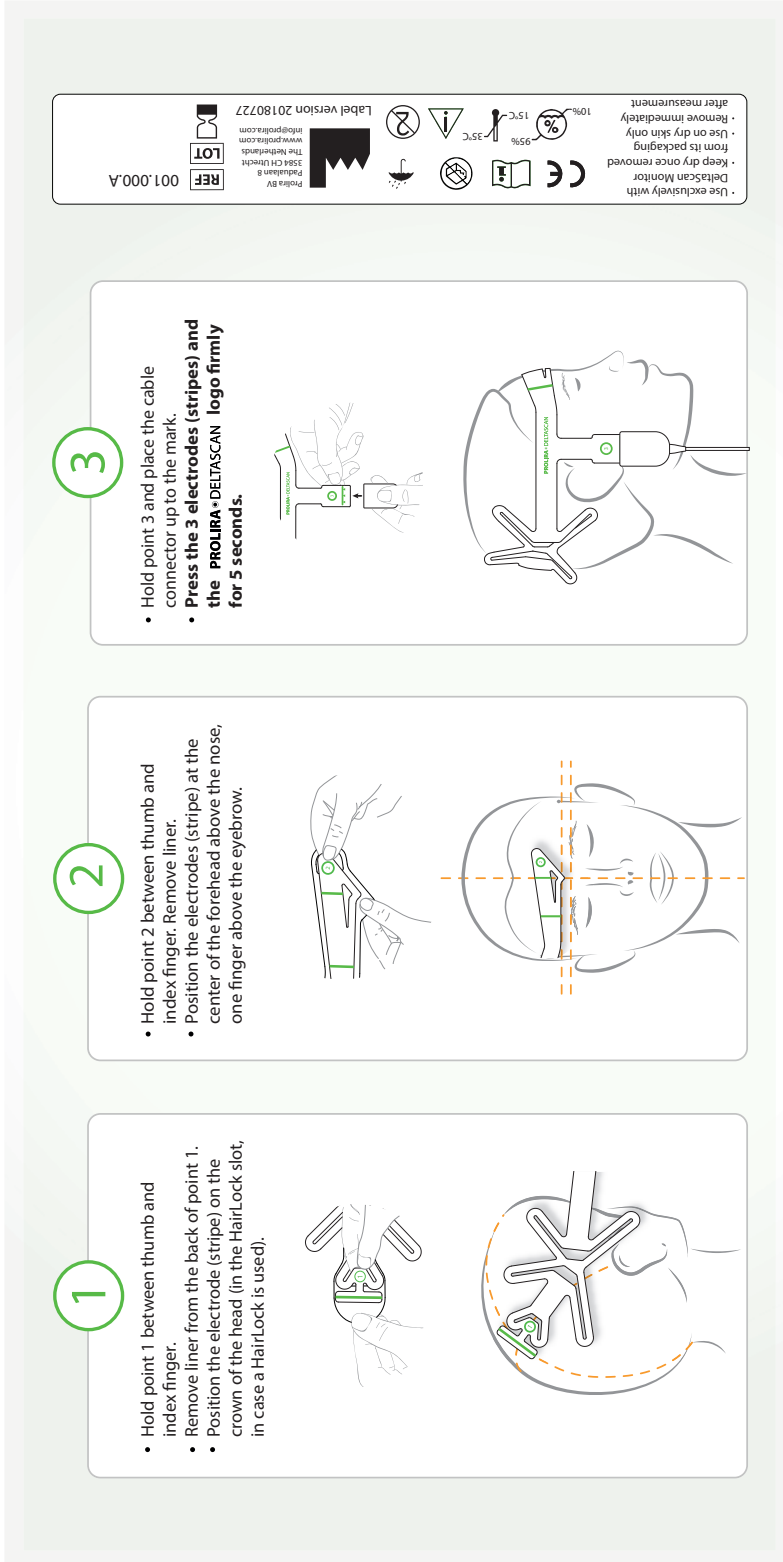
13. REFERENCES

- [1] A. W. Van Der Kooi et al., "Delirium detection using EEG: What and how to measure," Chest, vol. 147, no. 1, pp. 94-101, 2015.
- [2] T. Numan et al., "Delirium detection using relative delta power based on 1 minute single-channel EEG: a Multicenter Study", British Journal of Anaesthesia, vol. 122 nr 1, pp 60-68 (2019).

14. ANNEX A: FULL LABELLING OF DELTASCAN PATCH AND BOX



1) Front label of DeltaScan Patch



2) Back label of DeltaScan Patch

