

INSTRUCTIONS FOR USE (USA) DeltaScan 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 ACUTE ENCEPHALOPATHY AND DELIRIUM	3
1.2 INDICATIONS FOR USE STATEMENT	4
1.3 INTENDED USE	4
1.4 INTENDED USER, USER PROFILE, AND USE ENVIRONMENT	5
1.5 INTENDED PATIENT	5
1.6 THE DELTASCAN MONITOR COMPONENTS	6
1.7 OPERATING PRINCIPLE, DELTASCAN OUTPUT	8
1.8 DELTASCAN OUTPUT EXPLAINED	9
1.9 SUGGESTED CLINICAL INTERPRETATION	11
1.10 SUMMARY OF CLINICAL PERFORMANCE TESTING (device validation)	11
2. HOW TO USE THESE INSTRUCTIONS FOR USE	15
2.1 GENERAL	15
2.2 MEANING OF THE SYMBOLS USED	15
3. TURNING ON AND OFF	16
4. PREPARATION FOR USE	17
5. USE	26
6. AFTER USE	31
7. CHARGING	32
8. MENU	34
8.1 VIEW LAST FIVE SCORES	34
8.2 SET LANGUAGE	34
8.3 START DEMO	34
8.4 EXIT MENU	34
9. MOUNTING TO A ROLLSTAND	35
10. CLEANING, STORAGE, AND MAINTENANCE	36
10.1 CLEANING	36
10.2 TRANSPORT AND STORAGE	36
10.3 MAINTENANCE	36
11. POSSIBLE PROBLEMS DURING USE	37
11.1 PROBLEMS, CAUSES, AND SOLUTIONS	37
11.2 ERRORS AND WARNINGS THAT CAN BE PRESENTED ON THE MONITOR SCREEN	39
11.3 ADVERSE EVENTS AND COMPLICATIONS	40
12. TECHNICAL AND REGULATORY INFORMATION	41
13. REFERENCES	45
14. ANNEX A: FULL LABELLING OF DELTASCAN PATCH PACKAGING	46

1. INTRODUCTION TO THE DELTASCAN MONITOR

1.1 ACUTE ENCEPHALOPATHY AND DELIRIUM

Acute encephalopathy and delirium are extremely common in hospitalized patients, for example, one third of general medical patients aged 70 years or older has delirium (Marcantonio *et al.*, 2017, NEJM). Acute encephalopathy and delirium are, by definition, the consequence of the same underlying medical condition (Slooter *et al.*, 2020, Intensive Care Med). Acute encephalopathy can present as subsyndromal delirium, or delirium. Acute encephalopathy can be assessed with EEG (Palanca *et al.*, 2017, BJA). Delirium is determined by clinical examination (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition). Acute encephalopathy and delirium occur in the same patient. Many patients with acute encephalopathy (*i.e.*, EEG alterations) develop delirium (*i.e.*, behavioral changes). Patients with acute encephalopathy and/or delirium should therefore also be seen as the same patient population. Clinically, there is a clear relation between the two, which is important to understand. The figure below presents the relationship between underlying conditions, acute encephalopathy, and delirium.

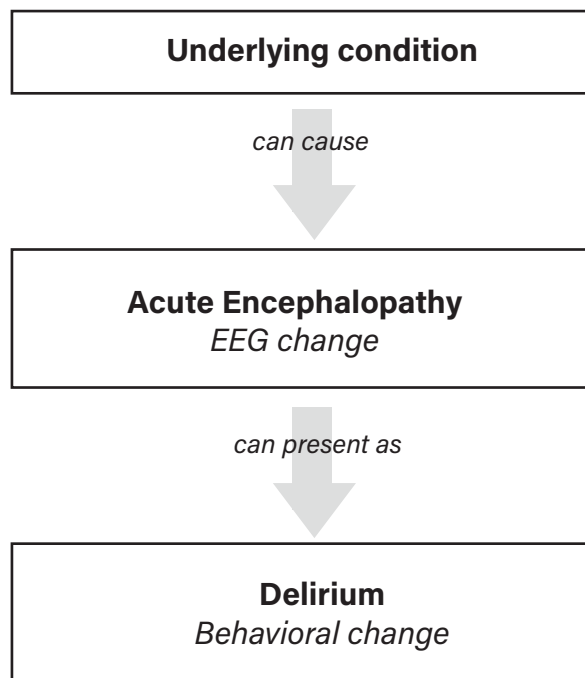


Figure 1: the relation between acute encephalopathy and delirium

USA

In everyday care, standard 21-lead EEG as well as delirium expert assessments are not routinely feasible. Therefore, checklists were developed for routine screening. The diagnostic performance in routine care settings, however, is found to be low as these tests have subjective elements. Patients can be best cared for when acute encephalopathy is assessed with an objective tool that helps to detect acute encephalopathy as early as possible, followed by further clinical assessment.

1.2 INDICATIONS FOR USE STATEMENT**1.2.1 Indications for Use Statement DeltaScan Monitor**

The DeltaScan Monitor provides the binary DeltaScan Output based on a technical index of polymorphic delta (PMD) waveshape detections made in the EEG from the bipolar Fp2 and Pz channel on adult patients (over 60 years of age) to aid in the diagnosis of acute encephalopathy.

DeltaScan should only be used by a healthcare provider as a component of a complete clinical evaluation or as support for the clinician's decision to pursue further testing. The device is NOT to be used as a stand-alone method in the evaluation or diagnosis of acute encephalopathy.

The intended patient is a hospitalized, awake adult (over 60 years of age), who is at risk of acute encephalopathy and delirium as decided by the responsible licensed healthcare physician or a medical professional working under the responsibility of a licensed healthcare physician.

The use environment is in hospitals:

- non-sterile environments;
- in departments like ICUs, wards, and other patient evaluation locations;

The DeltaScan Monitor is intended to be used in combination with the DeltaScan Patch through a proprietary connector design.

Please refer to the Instructions for Use below and the Instructions for Use on the Primary packaging of the DeltaScan Patch for more information.

1.2.2 Indications for Use Statement DeltaScan Patch

The DeltaScan Patch is an electrode that is applied directly to a patient's skin to record EEG signals. The DeltaScan Patch is intended to be used in combination with the DeltaScan Monitor through a proprietary connector design.

Please refer to the Instructions for Use on the Primary packaging of the DeltaScan Patch and the Instructions for Use below for more information.

1.3 INTENDED USE

The DeltaScan Monitor is a Neuropsychiatric Interpretive Electroencephalograph Assessment Aid (NIEAA). The Neuropsychiatric Interpretive Electroencephalograph Assessment Aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition.

Contraindications of the DeltaScan Monitor: none known.

Limitations for the DeltaScan Monitor: The DeltaScan Monitor cannot be used in an individual for whom an EEG recording is not valid, specifically a patient:

- on sedation (RASS -4 or -5);
 - persons under 60 years of age;
 - with a history of brain injury;
 - using Lithium/Clozapine;
 - with a metal or plastic implant in the upper hemisphere of the head;
 - with an active medical device in the head
-

The DeltaScan system cannot be used in subjects who are unable to follow three measurement instructions; the patient should (1) be awake, (2) be relaxed, and (3) keep the eyes closed.

The DeltaScan Patch is intended to be combined with the DeltaScan Monitor to enable the acquisition of electroencephalography (EEG) signals.

Contraindications of the DeltaScan Patch: none known.

Limitations for the DeltaScan Patch:

- Single use,
- Only to be used on intact skin at the sites of the electrodes of the Patch,
- Only to be used with the DeltaScan Monitor.

1.4 INTENDED USER, USER PROFILE, AND USE ENVIRONMENT

The DeltaScan Monitor should only be used by licensed healthcare physicians or medical professionals qualified to assess inpatient disorders and who are experienced in diagnosing acute encephalopathy and/ or delirium, or by other medical professionals working under the responsibility of a licensed healthcare physician.

See Section 1.2 for the intended use environment.

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

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

1.5 INTENDED PATIENT

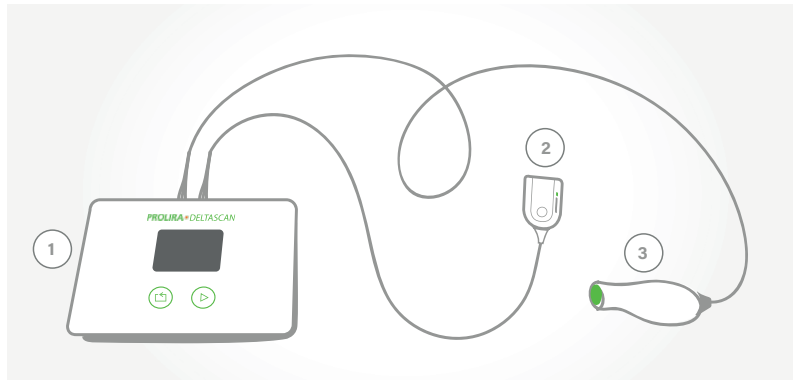
The intended patient is a hospitalized, awake adult (over 60 years of age), who is at risk of acute encephalopathy and/ or delirium as decided by the responsible licensed healthcare physician or a medical professional working under the responsibility of a licensed healthcare physician.

DeltaScan's algorithms are developed based on EEG data from patients who were calm, awake, and had their eyes closed. All clinical validation of DeltaScan is based on patients following these instructions. To obtain a meaningful DeltaScan Output, it is therefore important to instruct the patient according to these instructions and to release the Recording button every time the patient does not comply. See chapter 5 for a detailed explanation.

USA

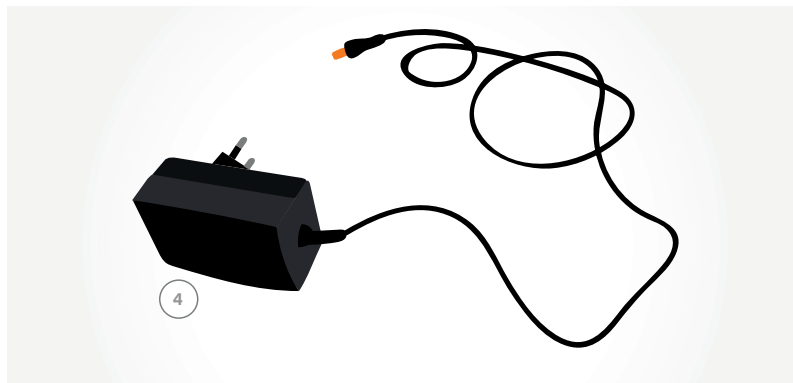


Warning! For patients on sedatives with a RASS -3, with dementia (MMSE \leq 24), and with (acute) brain injury, the DeltaScan Output can be higher than expected. For more severe and/or acute cases (i.e., of sedation, dementia and brain injury), it becomes less likely that a POSTIVE DeltaScan Output relates to an acute encephalopathic brain state. The meaning of NEGATIVE DeltaScan Output for these patients is most likely not altered. The DeltaScan Output for these patients should be interpreted accordingly.

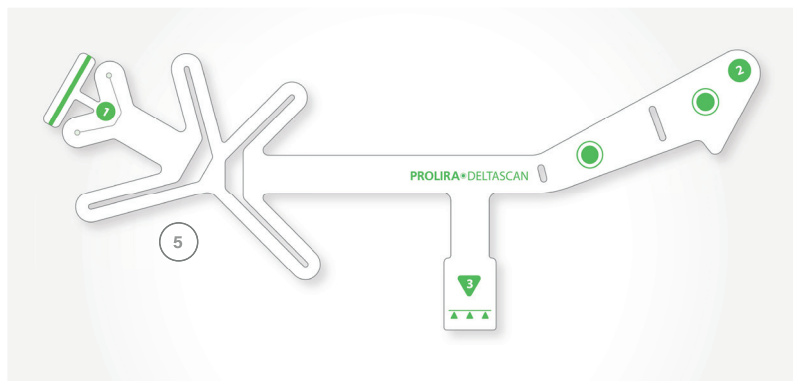


1.6 THE DELTASCAN MONITOR COMPONENTS

- 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 2: DeltaScan Monitor Components.



The DeltaScan Monitor (see Figure 3) consists of:

- 1) Monitor (1)
- 2) Patch connector (2) on cable
- 3) Recording button (3) on cable
- 4) Charger for Monitor with a strain relief cord (4)

The DeltaScan Monitor should only be used in combination with a DeltaScan Patch (See Figure 2: nr 5 and Figure 3: 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 3: nr 7).

The DeltaScan Monitor can be mounted to a GCX Rollstand (see Figure 3: nr 6), (see also section 9).

USA

Figure 3: DeltaScan Monitor complete set-up.

1.7 OPERATING PRINCIPLE, DELTASCAN OUTPUT

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

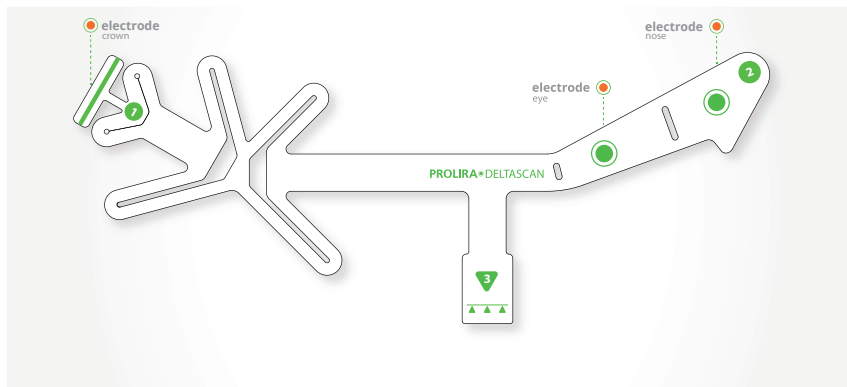
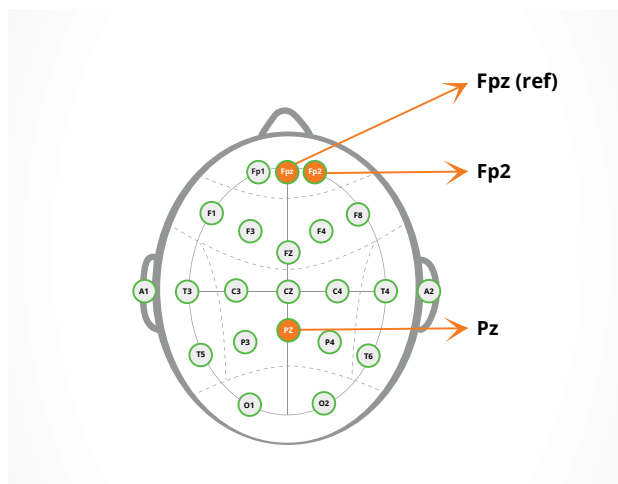


Figure 4: DeltaScan Patch includes 3 electrodes.



- The 1st electrode is placed 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 5).

Figure 5: DeltaScan Patch electrode locations.

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

Warning: DeltaScan is not to be used as a standalone diagnostic device. Do not rely on the DeltaScan Output alone for starting or adapting acute encephalopathy/delirium treatment (which may include administration of medication). Clinical assessment of the DeltaScan Output in conjunction with cognitive signs and/or other test results should be used for more comprehensive patient evaluation.

1.8 DELTASCAN OUTPUT EXPLAINED

Specific delta activity (PolyMorphic Delta activity; PMD) occurs in the EEG of patients with acute encephalopathy and delirium (*i.e.*, PMD waves are a known characteristic of acute encephalopathy and delirium). PMD is considered a sensitive and specific biomarker for acute encephalopathy and delirium in awake adults (over 60 years of age) without dementia, neurological trauma, or other causes of PMD in the awake state.

To understand Prolira's technology, first the basic concept of EEG power spectrum analysis in EEG is explained. Kooi *et al.* (2015, Chest) explain that a relative delta measure presents the relative amount of energy that is present in the EEG spectrum between 0.5Hz and 4Hz, divided by the energy in the whole spectrum of interest that lies between 0.5Hz and 30Hz. Kooi *et al.* used EEG segments that are handpicked by the researcher and that are relatively free of artefacts to perform their analysis. But, as with any automatically derived parameter, artefacts and poor signal quality may lead to inappropriate results. For example, eye movements are commonly present in a typical EEG segment (even in eyes closed EEG data). Furthermore, eye movements can present as waveshapes in the same frequency range as the waveshapes that are characteristic of acute encephalopathy and delirium (*i.e.*, energy in the delta frequency band). Therefore, a general relative delta measure will also count the energy of eye movements when automated algorithms provide the result in a clinical setting.

To deal with this situation, Prolira's technology specifically detects EEG waveshapes that are characteristic for acute encephalopathy and delirium, allowing to calculate a specific (rather than general) measure based on the amount of detected PMD waves in the EEG.

The detected and analyzed PMD waveshapes in the EEG are then translated into the 5-point DeltaScan Score, which is the DeltaScan's calibrated technical index.

The DeltaScan Output is NEGATIVE for acute encephalopathy for DeltaScan Score 1 or 2.

The DeltaScan Output is POSITIVE for acute encephalopathy for DeltaScan Score 3, 4 or 5.

See below in section 1.10 (Summary of clinical performance testing) for details on the clinical validation thereof.

Table 1 below indicates the clinical meaning of the DeltaScan Output and the technical meaning of the 5-point DeltaScan Score.



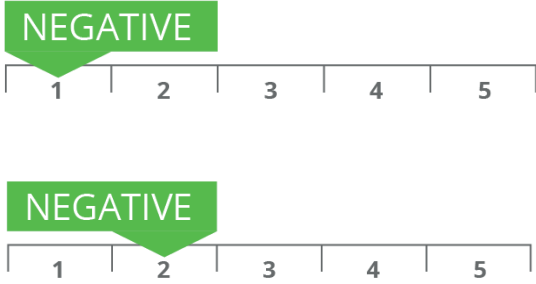
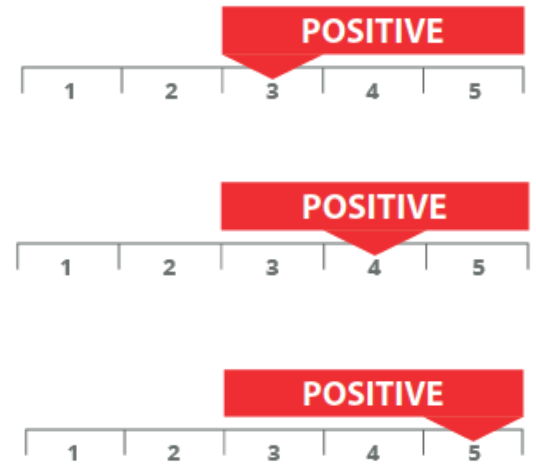
<i>DeltaScan result</i>	<i>Clinical meaning of DeltaScan Output</i>	<i>Technical meaning of DeltaScan Score</i>
 <p>The image shows two horizontal scales from 1 to 5. In the first scale, a green arrow points to '1' and a green box labeled 'NEGATIVE' is above it. In the second scale, a green arrow points to '2' and a green box labeled 'NEGATIVE' is above it.</p>	<p>NEGATIVE test for acute encephalopathy</p>	<p>For Score 1 and 2, PMD waveshapes are not or hardly detected in the EEG</p>
 <p>The image shows three horizontal scales from 1 to 5. In the first scale, a red arrow points to '3' and a red box labeled 'POSITIVE' is above it. In the second scale, a red arrow points to '4' and a red box labeled 'POSITIVE' is above it. In the third scale, a red arrow points to '5' and a red box labeled 'POSITIVE' is above it.</p>	<p>POSITIVE test for acute encephalopathy</p>	<p>For Score 3, 4 and 5, the amount of detected PMD waveshapes in the EEG increases</p>

Table 1: Technical and clinical meaning of a DeltaScan result.

It is recommended to write the DeltaScan Output and Score in the (electronic) patient file.

1.9 SUGGESTED CLINICAL INTERPRETATION

The clinician will typically have a DeltaScan Output and their clinician's evaluation for clinical signs (behavioral changes) that could indicate delirium. Table 2 indicates how the additional information from the DeltaScan Monitor can be used with other existing clinical information.

Table 2 Suggested clinical interpretation for combined clinician's evaluation and DeltaScan Output

	DeltaScan Output NEGATIVE (green)	DeltaScan Output: POSITIVE (red)
Clinician positive for delirium signs	Negative result for acute encephalopathy, but <u>with</u> clinical signs of delirium <u>Further evaluate other causes of the observed clinical behavior to determine the correct diagnosis</u>	DeltaScan confirms clinician's evaluation
Clinician negative for delirium signs	DeltaScan confirms clinician's evaluation	Positive result for acute encephalopathy <u>without</u> clinical signs of delirium <u>Further evaluate causes for the presence of PMD in the EEG to determine the correct diagnosis</u>

Table 2 indicates that, especially when there is a difference in the clinician's evaluation and the DeltaScan Output, the combination aids the clinician in finding the correct diagnosis. Either by considering an alternative for the positive delirium signs (e.g., psychosis or hallucinations without delirium), or by providing evaluation that explains the presence of PMD waves in the EEG (e.g., a bladder infection, or acute kidney failure).

1.10 SUMMARY OF CLINICAL PERFORMANCE TESTING (device validation)

Diagnostic Performance testing of DeltaScan was done in the multi-center DeltaStudy, which ran between Q1-2018 and Q2-2021.

Clinical study design

The objective of the study presented here, called DeltaStudy, was to evaluate the diagnostic performance of the DeltaScan Monitor according to the Indications for Use and to evaluate repeatability.



The clinical investigation included the collection of EEGs with DeltaScan and clinical data on ICUs and wards. An EEG expert panel reviewed the DeltaScan EEGs and a clinical expert panel reviewed the clinical data to determine consensus diagnosis (majority vote) for acute encephalopathy and delirium, respectively.

For acute encephalopathy, the reference standard was defined by the assessment by 3 separate EEG experts of 4-minutes of EEG data recorded with DeltaScan. The EEG data was visually assessed by the EEG experts, for the presence of polymorphic delta activity to determine acute encephalopathy.

For delirium, the reference standard was defined by the assessment of clinical data by 3 clinical delirium experts separately. Clinical data included a researcher's interview based on DSM-5 criteria A-C through an extensive test battery, Electronic Health Record data, and description of the behavior of the patient. Clinical data were assessed on individual DSM-5 criteria, the presence of delirium, and the probability of delirium.

All EEG and clinical assessments were blinded to DeltaScan Output, prospectively planned, and performed as reviews of anonymized patient data. As the estimated diagnosis of acute encephalopathy and delirium we used the majority vote of 3 EEG experts, and 3 clinical delirium experts, respectively.

Subjects were adults on the ICU (avg. age 64 years; std = 13) and elderly on wards (avg. age 80 years; std = 7) in geographically distinct clinics (6 ICUs and 15 wards) in the Netherlands. It shall be noted that some Study Data in the ICU population does contain patients in the 18-60 range; however, the majority of the study population was 60, or above. In total, 606 patients were enrolled in the study of whom 434 patients (195 on ICUs and 239 on wards) fulfilled inclusion, but not exclusion, criteria. Due to COVID-19 restriction, the number of patients on ICUs is less than aimed for and that resulted in larger confidence bounds than anticipated.

A DeltaScan Output for each subject was determined from the DeltaScan EEG recording in the locked databases (ICUs and wards). To evaluate performance, the DeltaScan Outputs were compared with the estimated diagnosis of the two expert panels (references for acute encephalopathy and delirium).

Results: diagnostic performance of DeltaScan

The diagnosis of acute encephalopathy (EEG reference standard) was based upon the best estimate diagnosis results by consensus of the expert panels and was blinded to the DeltaScan Output. In 67% (291/434) of cases both reference standards agree. This result is in line with an earlier study (Hut *et al.*, 2021, *Psychiatry Clin Neurosci*; used same dataset as the calibration dataset for DeltaScan).

The results for the primary objective, diagnostic performance of DeltaScan for acute encephalopathy are provided in Table 3.

Table 3 Diagnostic performance results with 95% confidence intervals (95%CI) on acute encephalopathy for adults on the ICU and elderly patients on wards using the EEG reference. As the found prevalence was higher in the study as anticipated in the study design, the prevalence adjusted values for NPV, PPV, NPV+PPV and accuracy are also presented.

	ICU (n=195)	Ward (n=239)	Pooled ICU + ward (n=434)
NPV	0.854, CI = [0.77, 0.92]	0.830, CI = [0.76, 0.89]	0.840, CI = [0.79, 0.88]
Prevalence adjusted PPV	For 35% prevalence 0.894, CI = [0.85, 0.94]	For 25% prevalence 0.903, CI = [0.87, 0.93]	For 35% prevalence 0.871, CI = [0.84, 0.90]
PPV	0.761, CI = [0.66, 0.84]	0.825, CI = [0.72, 0.90]	0.791, CI = [0.72, 0.85]
Prevalence adjusted PPV	For 35% prevalence 0.689, CI = [0.61, 0.78]	For 25% prevalence 0.712, CI = [0.62, 0.82]	For 35% prevalence 0.745, CI = [0.69, 0.81]
NPV+PPV	1.615, CI = [1.50, 1.72]	1.655, CI = [1.55, 1.75]	1.630, CI = [1.56, 1.71]
Prevalence adjusted NPV+PPV	For 35% prevalence 1.585, CI = [1.47, 1.70]	For 25% prevalence 1.618, CI = [1.50, 1.74]	For 35% prevalence 1.618, CI = [1.53, 1.70]
Sensitivity	0.824, CI = [0.73, 0.90]	0.710, CI = [0.61, 0.80]	0.764, CI = [0.69, 0.82]
Specificity	0.800, CI = [0.71, 0.87]	0.904, CI = [0.84, 0.95]	0.859, CI = [0.81, 0.90]
AUROC	0.879, CI = [0.83, 0.93]	0.831, CI = [0.78, 0.88]	0.855, CI = [0.82, 0.89]
Accuracy	0.810, CI = [0.75, 0.86]	0.828, CI = [0.77, 0.87]	0.820, CI = [0.78, 0.86]
Prevalence adjusted accuracy	0.808, CI = [0.75, 0.87]	0.856, CI = [0.81, 0.90]	0.826, CI = [0.79, 0.86]

The overall performance of DeltaScan is strong (sensitivity, specificity, AUROC and accuracy). and almost meets the pre-specified criteria for NPV on the ICU (lower bound CI >0.80) and the ward (lower bound CI >0.85). The NPV end-points are missed due to a higher than anticipated prevalence (44% observed vs. 35% expected on the ICU and 39% observed vs 25% expected for the ward). Under the condition where the prevalence is adapted to the expected values, the pre specified criteria are met. The results for NPV+PPV for both the ICU and the ward exceed the pre specified criterium. In addition, the results are robust for some variation in study assumptions (sensitivity analysis).

Generalizability

The patients in this study are a good representation of the intended use population. From site to site, department to department, and between US and OUS, the prevalence of the condition can vary. Our sensitivity analysis on prevalence shows that performance remains strong regardless.



Repeatability of the DeltaScan results

The repeatability (test-retest reliability) of the DeltaScan Score was estimated from a set of DeltaScan EEG recordings in which each patient or volunteer was recorded 3 times within 30 minutes. There were 9 patients (same inclusion and exclusion criteria as the main DeltaStudy as presented above) and 30 volunteers included in this analysis. The intraclass correlation coefficient (ICC) of repeated DeltaScan Scores includes the 1-5 scale. The calculated ICC is 0.799 and $p = 0.0000$, which satisfies the pre-specified criteria of $ICC > 0.75$ and $p < 0.05$. The calculated ICC for the binary DeltaScan Output: ICC is 0.829, $p = 0.0000$.

Conclusion

These results present convincing evidence to justify the Indications for Use of the DeltaScan Monitor. The clinical data demonstrate that the DeltaScan Monitor performs as intended, is safe and effective for its intended use.

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 Output. 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
	Prescription use only		

Table 4: 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.

USA

3. TURNING ON AND OFF



Figure 6: 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 6).

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 7 minutes.

4. PREPARATION FOR USE

For a measurement, the following items are needed (also see Figure 2):

- a DeltaScan Patch (REF: 009.000.x).
- 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 or B) 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 7 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 laying on the right side cannot be measured.
- Patients sitting on a chair (or bed) are easiest to measure.



Figure 7.a: Recommended position for a DeltaScan measurement when the patient lies in bed.

Please note:

Use DeltaScan Monitor exclusively with DeltaScan Patch.

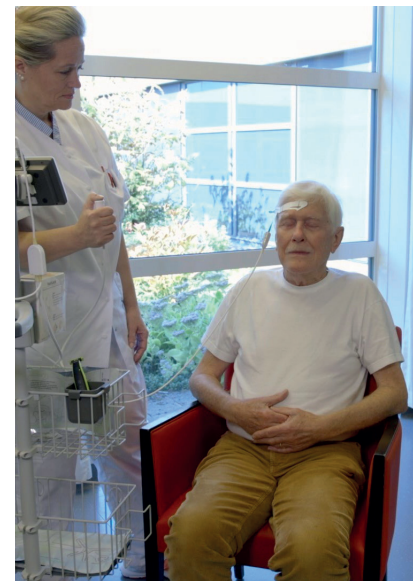


Figure 7.b: Patients may also lie on the left side, sit in bed or sit on a chair.

Please note:

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

USA

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 8.

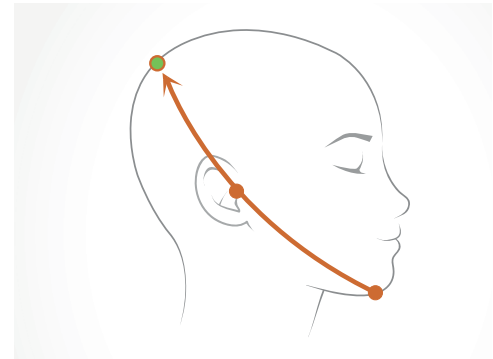


Figure 8: Crown of the head, correct position for DeltaScan Patch electrode 1 (and HairLock, in case HairLock is used).

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 9), and then apply part 2 (see Figure 10). 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 11.a.).

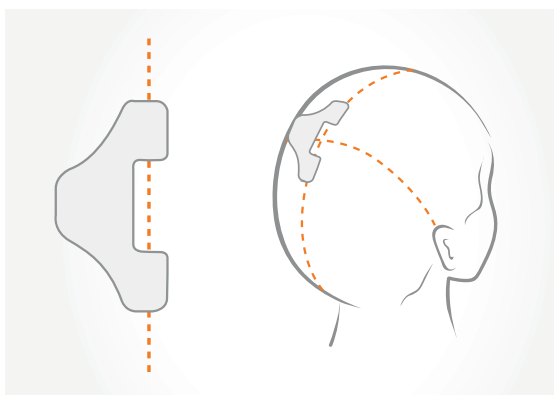
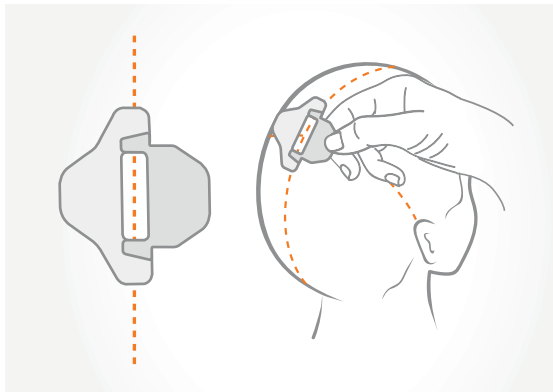


Figure 9: HairLock Part 1 correctly applied.

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.

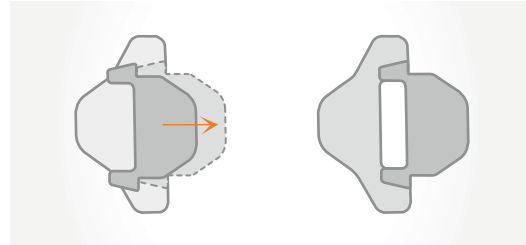


Figure 10: HairLock Part 1 and 2 correctly applied.

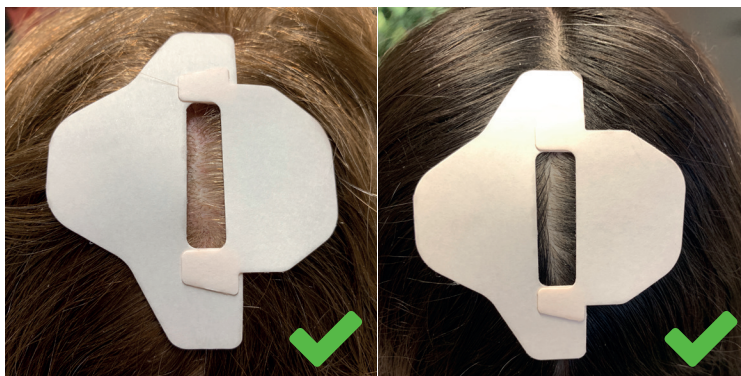


Figure 11.a: Parting in hair, with HairLock correctly applied: a strip of skin is exposed in the Hairlock slot.



Figure 11.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 12.a.). Use this Dynarex wipe, to scrub and wipe the skin in the HairLock slot and the skin on the patients forehead (see Figure 12.b).
- We further advise to apply a thin visible layer of Ten20 Conductive Neurodiagnostic electrode paste (Weaver and company, see Figure 13.a.) in the HairLock slot to improve adhesion of the electrode (see Figure 13.b).



Figure 12.a: Dynarex Electrode Skin Prep Pad.



Figure 13.a: Ten20 Conductive Neurodiagnostic Electrode Paste.



Figure 12.b: Scrub and wipe the skin in the HairLock slot and the skin on the patients forehead with Dynarex wipe.

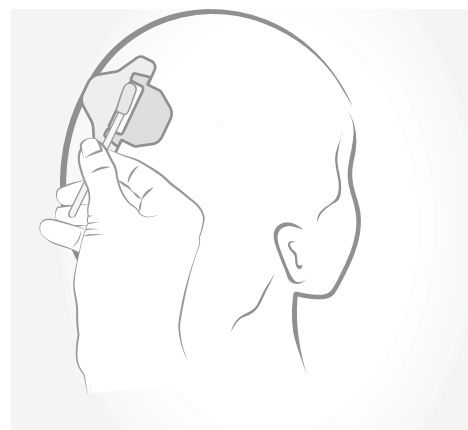


Figure 13.b: Ten20 applied in the HairLock slot.

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.

Please note: Keep DeltaScan Patch dry once removed from its packaging.

Please note: Use DeltaScan Patch on dry and intact 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.

- 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 14.
- 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 15.

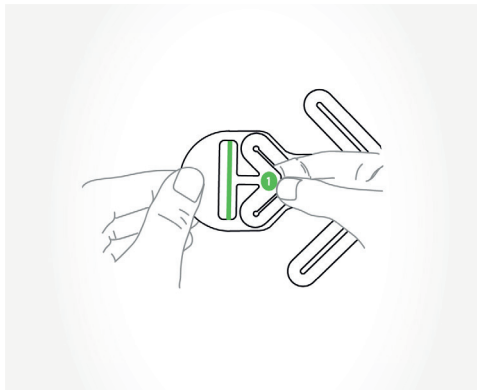


Figure 14: How to hold point 1 when 5 applying the DeltaScan Patch.

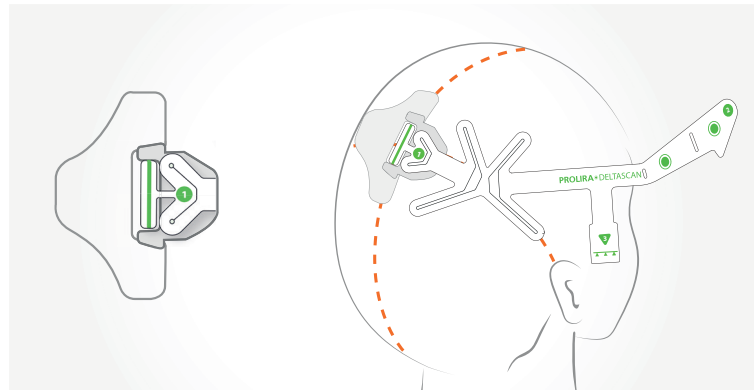


Figure 15: Position electrode 1 (the green stripe) of DeltaScan Patch on the crown of the head, in the HairLock slot, if a HairLock is used.

USA

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 16.
- Position the Nose electrode (the green dot 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 (nose indicator, under the green dot) points towards the nose. The other electrode (green dot) automatically is at the right position too, above the eyebrow. See Figure 17.

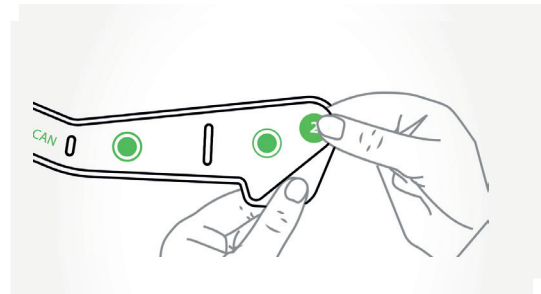


Figure 16: Remove the liner while holding point 2 of the DeltaScan Patch.

Step 6

- Press the Crown electrode (the green stripe at the crown) and the green logo at the temple firmly to the patient's skin.
- Firmly press the two front electrodes (the 2 green dots at the front) and do a 5 seconds countdown.

Please note: for the proper reception of EEG signals (brain activity is measured in microvolts, which are very small signals) 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).

Please note: If skin rash or other unusual symptoms develop, stop use and remove the Patch.

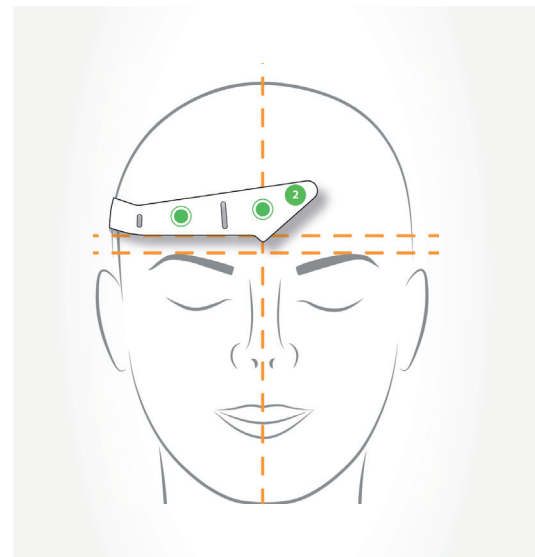


Figure 17: Position the electrodes above the nose and eyebrow.

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 18.

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 19.

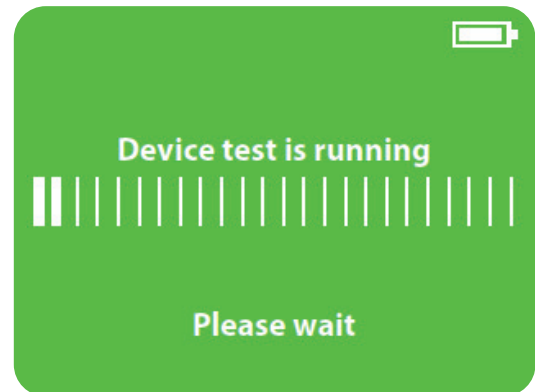


Figure 18: Monitor screen indicating that the 'device test' is running.

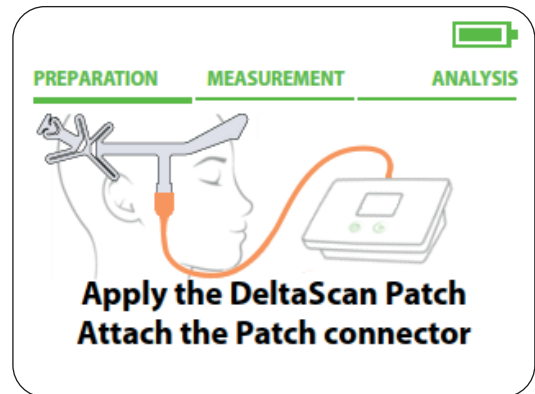


Figure 19: Monitor screen asks the user to apply and connect the DeltaScan Patch.

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 20.

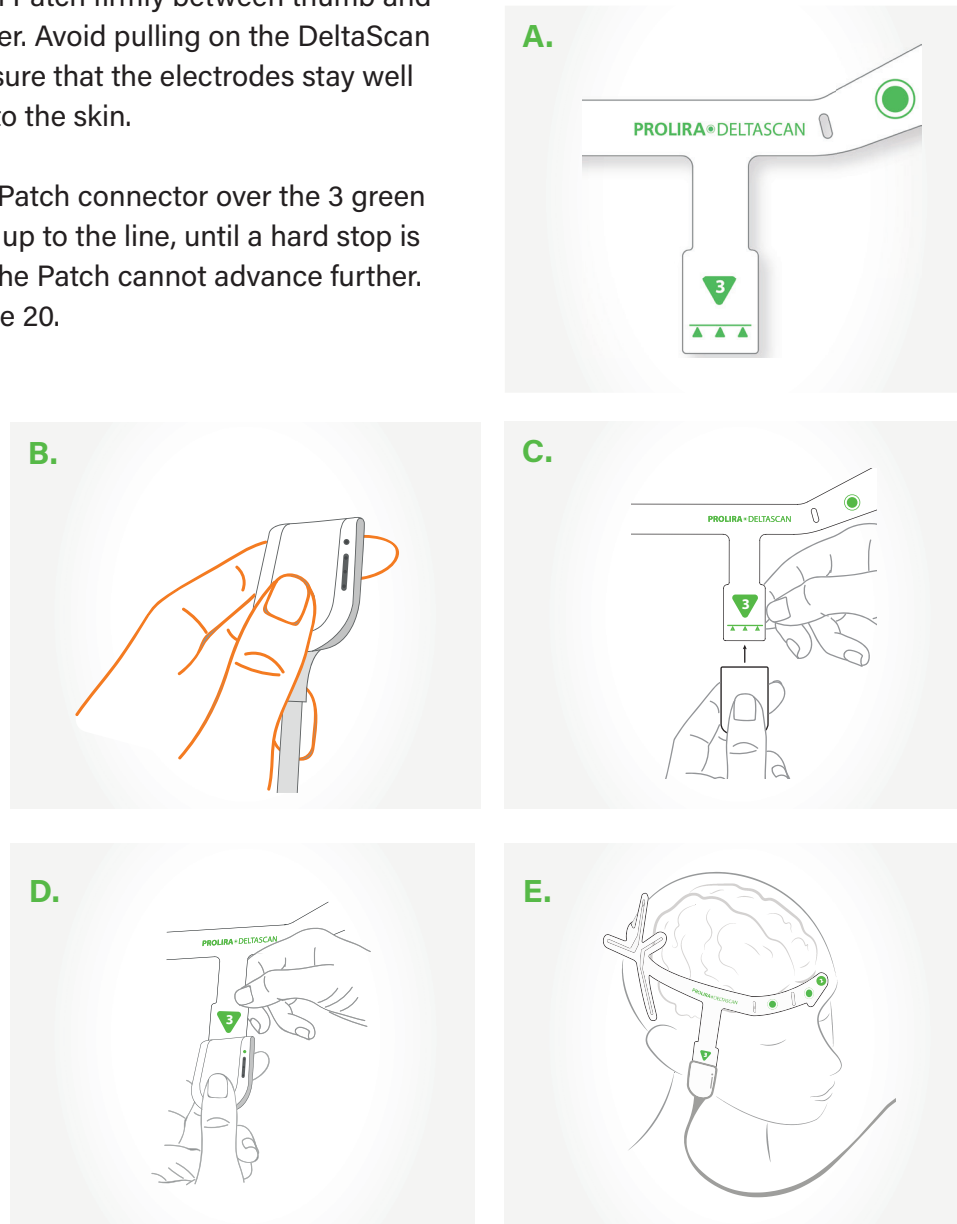


Figure 20:

- 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 20).

- Check if the Connection-LED (the top LED on the Patch connector) turns green, to indicate that the Patch is well connected (see Figure 21).
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 22.)

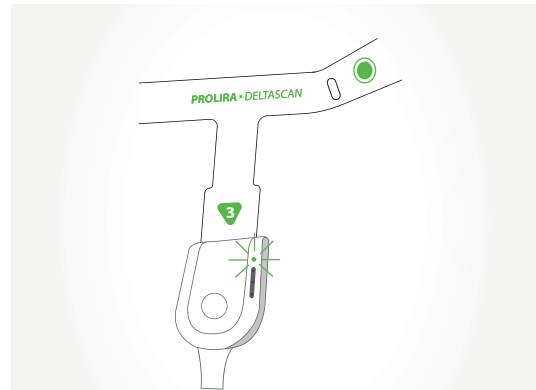


Figure 21: The Connection-LED is green if the DeltaScan Patch is well connected.

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 22: 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 23.

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 24 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 25.

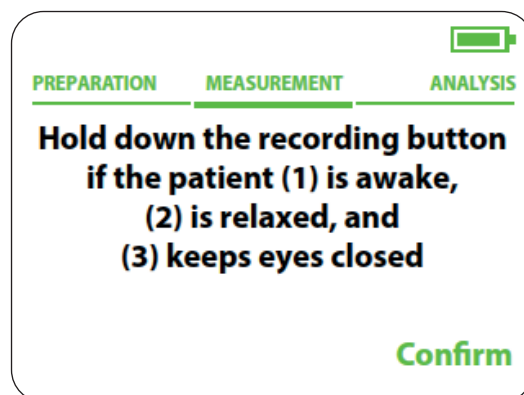


Figure 23: Monitor screen asking for confirmation of the instructions.

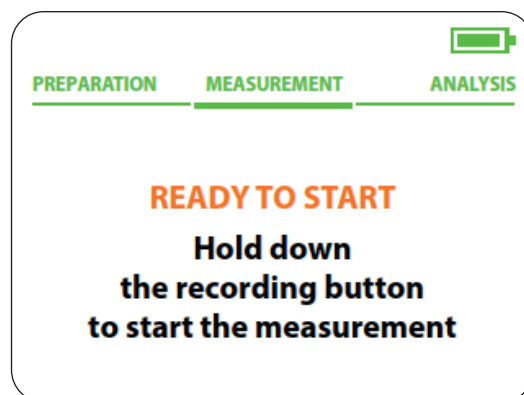


Figure 24: Monitor screen providing instructions to perform a measurement.

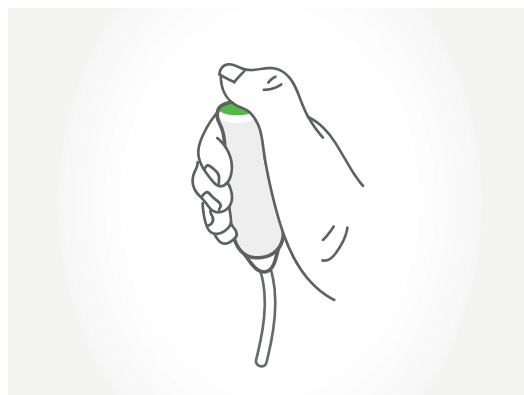


Figure 25: Recording button is pressed during measurement, as long as the patient complies to the 3 instructions.

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, for example, 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.

USA

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 26)
- The Monitor screen displays the PAUSED message (see Figure 27)

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 28 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.

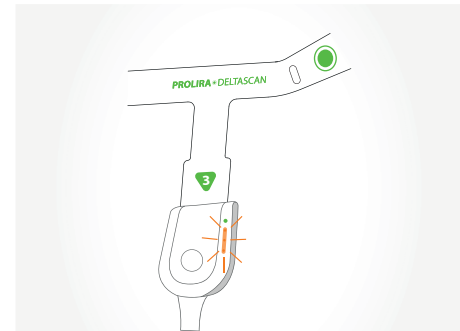


Figure 26: When the user releases the Recording button, the measurement is PAUSED. The strip of LEDs in the Patch connector blinks orange.

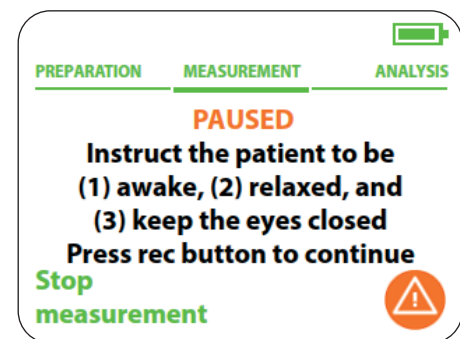


Figure 27: monitor screen indicating a measurement is paused.

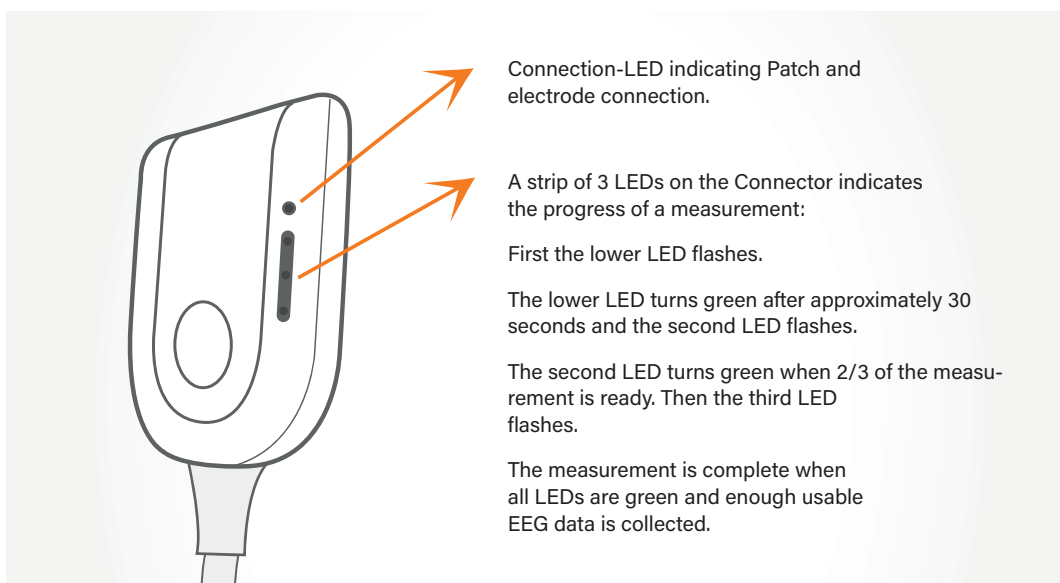


Figure 28: A strip of LEDs on the Patch connector indicates the measurement progress.

During a measurement, not only the Patch connector, but also the DeltaScan Monitor indicates the progress of the measurement (see Figure 29).

The measurement lasts a few minutes, until enough 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 Output (see Figure 30).

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.

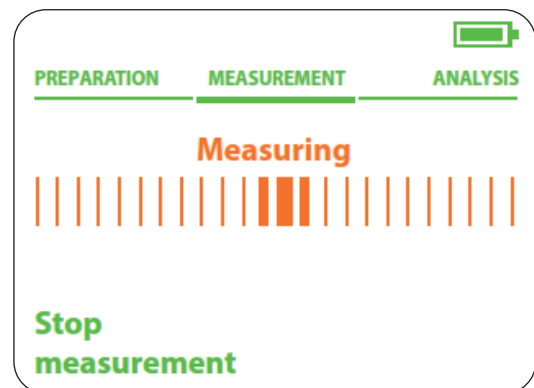


Figure 29: Monitor screen displays the measurement progress.

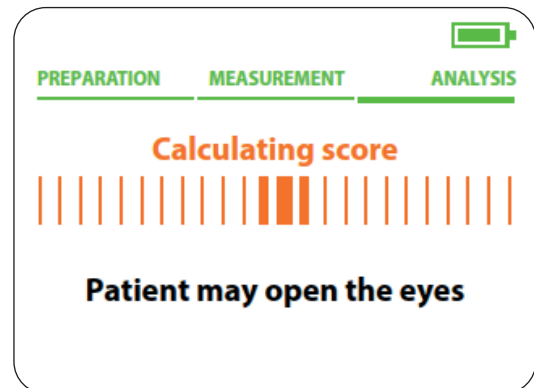


Figure 30: Monitor screen indicating the end of a measurement, calculating the DeltaScan Output.

If the Patch connector cable is disconnected during a measurement, the monitor shows screen of Figure 31. 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 Output, which is expressed as:

NEGATIVE: score 1 or 2

or

POSITIVE: score 3, 4 or 5

(See section 1.8 for an additional explanation).

See Figure 32 for an example of a result. It is strongly advised to write this down in the patient record.

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

In relation to defibrillation

Please note: Remove the DeltaScan Patch and the DeltaScan Monitor from the patient before applying defibrillation

Please note: Replace the DeltaScan Patch if it has been on the patient during defibrillation.



Figure 31: Patch connector got disconnected. Please start a new measurement.

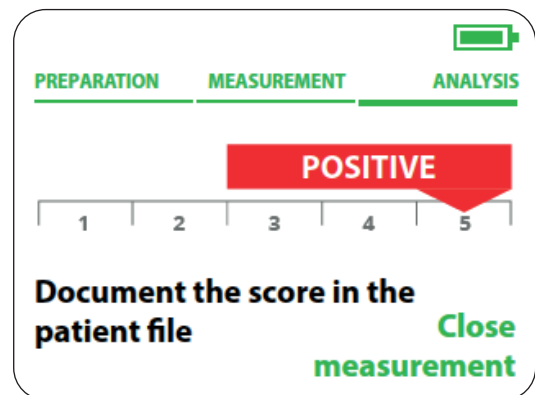


Figure 32: DeltaScan Monitor screen displaying the result of a measurement.

6. AFTER USE

Step 1

As soon as the measurement is finished and the DeltaScan Output is presented, 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.

Please note: Remove the DeltaScan Patch immediately from the patient's head, after measurement.

Please note: The DeltaScan Monitor switches OFF automatically if is it not used for 7 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.

USA

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.

It is suggested to use the strain relief cord provided with the charger and attach it to the rollstand pole.

To charge the DeltaScan Monitor, plug the charger in the power outlet at the back of the Monitor as indicated in Figure 33, and connect the power plug in the power socket.

Please note: 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 34.

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 35).

Remove the charger from the socket when taking the Monitor for use.

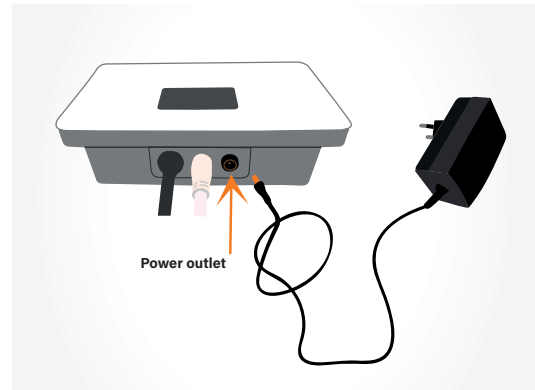


Figure 33: Power outlet of the DeltaScan Monitor.

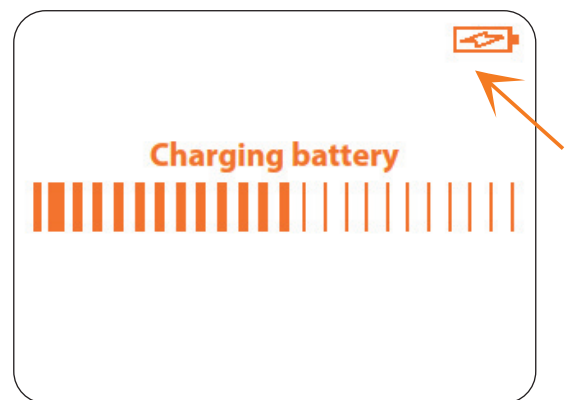


Figure 34: Monitor screen displaying that the device is charging.

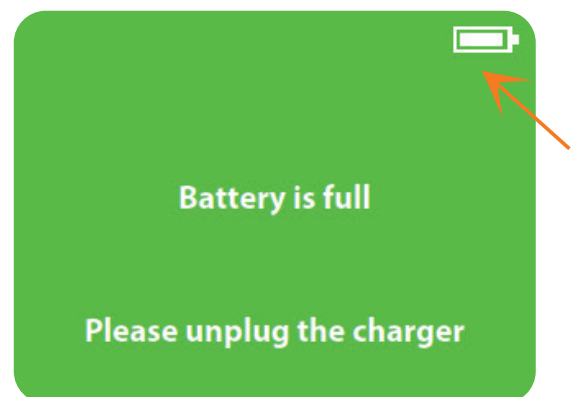


Figure 35: Monitor screen displaying that the battery is fully charged.

When the charger is unplugged, the device needs a restart. Instructions are displayed on the screen (see Figure 36).

If the battery is not full enough to take a measurement, the following screen is displayed (see Figure 37).



Figure 36: Monitor screen displaying that the device needs a restart after charging.

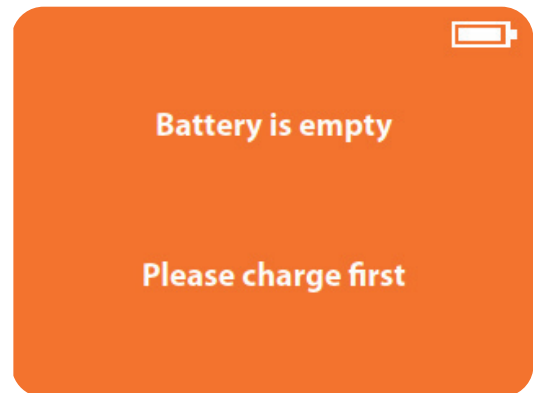


Figure 37: Monitor screen displaying that the device needs to be charged.

8. MENU

By simultaneously pressing both keys (left and right key together) on the Monitor for 3 seconds, a menu with following options appears (see Figure 38):

- 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.

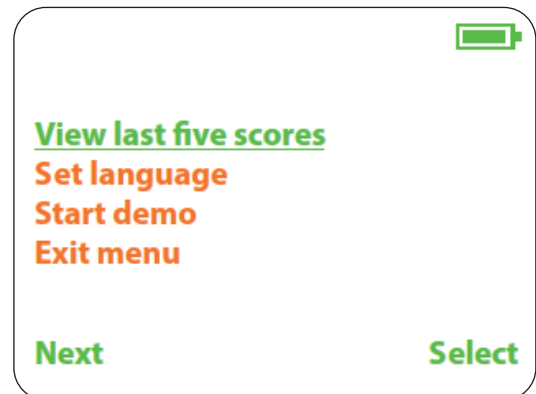


Figure 38: Monitor screen of device menu (available after simultaneously pressing both keys for 3 seconds).

8.1 VIEW LAST FIVE SCORES

Users can look back at the last 5 valid DeltaScan results.

Each result 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 39). By pressing the right key, the user can go to the next demo screen.

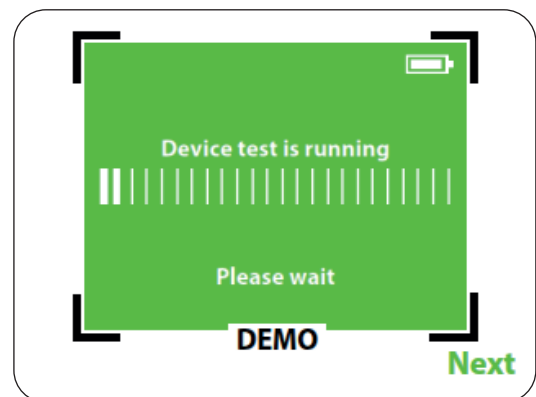


Figure 39: Example of a demo screen.

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).

9. MOUNTING TO A ROLLSTAND

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 40), that fit into the 2 screw holes in the back of the DeltaScan Monitor.

Please note: 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.

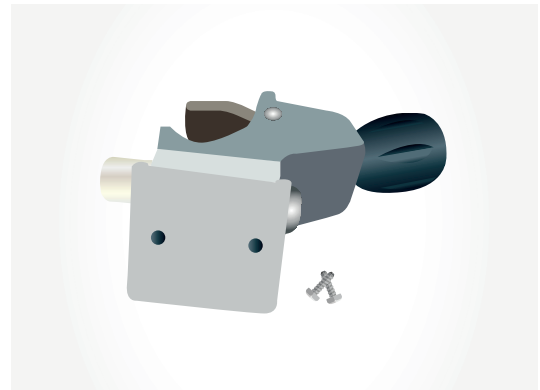


Figure 40: GCX pole-clamp and two bolts to attach the DeltaScan Monitor. The pole-clamp can be clamped to a GCX light weight rollstand.

10. CLEANING, STORAGE, AND MAINTENANCE

10.1 CLEANING

The DeltaScan Monitor including the Patch connector, recording button, and cables can be cleaned with

- Ethanol ($\leq 70\%$)
- H_2O_2 ($\leq 3\%$)(e.g., Oxiwipe (1.5% H_2O_2), and also Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipe (1.4% H_2O_2), and Diversey™ Oxivir TB Disinfectant Wipes (0.5% H_2O_2)
- Bacillol® 30 Tissues and Bacillol® 30 Sensitive Tissues
- PDI Sani-Cloth® Bleach Germicidal Disposable Wipe – Orange Cap"

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:

- 32 to 113°F/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

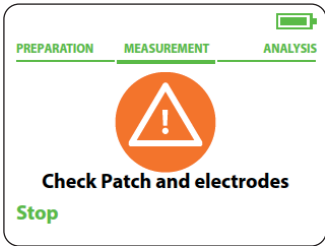

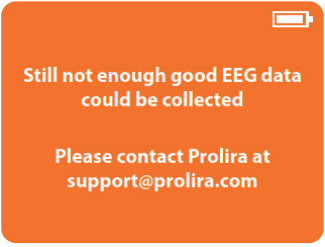

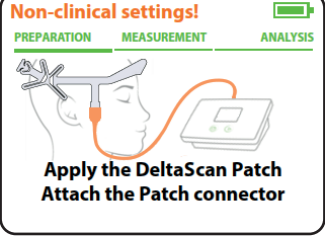
11.1 PROBLEMS, CAUSES, AND SOLUTIONS

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.


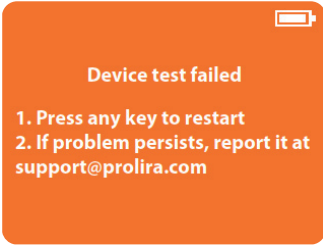


USA

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 their 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 or grinding the teeth	Ask the patient to relax the jaw muscles. Try another measurement.
		(Excessive) sweating of patient	Remove the DeltaScan Patch, dry the skin, use a Dynarex wipe again and apply a new DeltaScan Patch.
		If this message occurs repeatedly, it is possible that something unexpectedly disturbs 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. 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		In case the device shows "Non-clinical settings!" at the top of the screen, the user must have the device checked by a technician from Prolira.

USA

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. 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. Please contact Prolira to share your experience and the Device Error number (99 in this example) that occurred. Prolira can learn from it, and improve the device.</p> <p>This message can also be present on the start up screen.</p>

11.3 ADVERSE EVENTS AND COMPLICATIONS

There are no known adverse events or complications.

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: 009.000.x)

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, Mean Well, GEM30I12-P1J (REF: 006.004.B)

Monitor

Dimensions 111 x 156 x 51,5 mm (length x width x height)

Weight ~ 720 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)

Please note: 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, or performed on instruction of Prolira.

Patch connector cable

Dimensions ~1500 mm (length)

Weight ~50 g (included in the weight of the Monitor)

Recording button cable

Dimensions ~1500 mm (length)

Weight ~150 g (included in the weight of the Monitor)

USA

Charger: AC/DC Medical Adapter (Type: Mean Well, GEM30I12-P1J)

Dimensions	75 x 39 x 56 mm (length x width x height)
Weight	192 g
Input	115VAC/1A/60Hz; 230VAC/0.35A/50Hz
Output	12V DC; 2.5A, 30W 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 (<100µA), 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, which is providing no incorrect DeltaScan Score. The DeltaScan Score value should not change during EMC disturbances. When the DeltaScan Monitor does not provide a DeltaScan Score at all this will not lead to an unacceptable risk and is therefore allowed. Testing confirmed that under influence of EMC disturbance, DeltaScan will not provide an incorrect result. It might present no result at all.

The DeltaScan Monitor is considered ME EQUIPMENT or ME SYSTEM that is suitable for use in hospital environment.

The DeltaScan is classified as CISPR11 ME equipment and ME system.

The DeltaScan Monitor is compliant with EN 60601-1-2:2015 for immunity in professional healthcare facility and residential environments, the applied IMMUNITY Test Levels are shown in the Electromagnetic immunity tables below.

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 (EMISSION Classification CISPR 11 class B).


Electromagnetic emissions		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions (CISPR 11)	Group 1, Class B	The DeltaScan Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. Class B equipment is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
RF Emissions (CISPR 11)	Group 1, Class B	Class B equipment is equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic Emissions (IEC61000-3-2)	N/A	The rated power of the DeltaScan Monitor is 50W or less.
Voltage fluctuations / flicker emissions (IEC61000-3-3)	N/A	The DeltaScan Monitor is unlikely to produce significant voltage fluctuations or flicker.


Electromagnetic immunity		
Immunity test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) (IEC 61000-4-2)	±2kV, ±4kV, ±6kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2kV, ±4kV, ±6kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
	Electromagnetic Environment - Guidance Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	
Radiated RF Electromagnetic Field (IEC 61000-4-3)	10 V/m and 3V/m 80 MHz to 2.7GHz	10 V/m and 3V/m 80 MHz to 2.7GHz
Proximity fields from RF wireless communication systems (IEC 61000-4-3)	Refer to Electromagnetic immunity table below	Refer to Electromagnetic immunity table below
Electrical fast transient/burst (IEC 61000-4-4)	Input/output lines + 1,0 kV AC/DC Power supply 2,0 kV	AC Power supply 2,0 kV
Surge (IEC 61000-4-5)	±0.5 kV, ±1 kV AC/DC Power supply line(s) to line(s) ±0,5kV, ±1,0kV, ±2,0kV AC/DC Power supply line to earth ±0,5kV, ±1,0kV, ±2,0kV Input/output lines line to earth	±0.5 kV, ±1 kV AC Power supply line(s) to line(s) ±0,5kV, ±1,0kV, ±2,0kV AC Power supply line to earth
RF Common mode/Conducted susceptibility (IEC 61000-4-6)	3 Vrms, 6V in ISM and amateur radio bands. 150 kHz to 80 MHz	3 Vrms, 6V in ISM and amateur radio bands. 150 kHz to 80 MHz
Power frequency (50-60 Hz) magnetic field (IEC 61000-4-8)	30A/m	N/A, the DeltaScan Monitor doesn't contain components which are sensitive to magnetic fields (i.e. Hall sensors).
Voltage dips (IEC 61000-4-11) Voltage interruptions (IEC 61000-4-11)	0%Ut for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%Ut for 1 cycle At 0° 70%Ut for 25/30 cycles (50/60 Hz) At 0° 0%Ut for 250/300 cycles (50/60 Hz)	0%Ut for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%Ut for 1 cycle At 0° 70%Ut for 25/30 cycles (50/60 Hz) At 0° 0%Ut for 250/300 cycles (50/60 Hz)
NOTE: U_T is the a.c. mains voltage prior to application of the test level.		

Electromagnetic immunity						
Test frequency (MHz)	Band (MHz)	Antenna polarization	Modulation	maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	Horizontal	Pulse modulation 18 Hz, 50%	1.8	0.3	27
		Vertical				
450	430-470	Horizontal	Pulse modulation 18 Hz, 50%	2	0.3	28
		Vertical				
710 745 780	704-787	Horizontal	Pulse modulation 217 Hz, 50%	0.2	0.3	9
		Vertical				
810 870 930	800-960	Horizontal	Pulse modulation 18 Hz, 50%	2	0.3	28
		Vertical				
1720 1845 1970	700-1900	Horizontal	Pulse modulation 217 Hz, 50%	2	0.3	28
		Vertical				
2450	2400-2570	Horizontal	Pulse modulation 217 Hz, 50%	2	0.3	28
		Vertical				
5240 5500 5785	5100-5800	Horizontal	Pulse modulation 217 Hz, 50%	0.2	0.3	9
		Vertical				



 **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

Please note: Dispose of this device as electronic waste according to local regulations.

Please note: The DeltaScan Patch is considered household waste.



 **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.

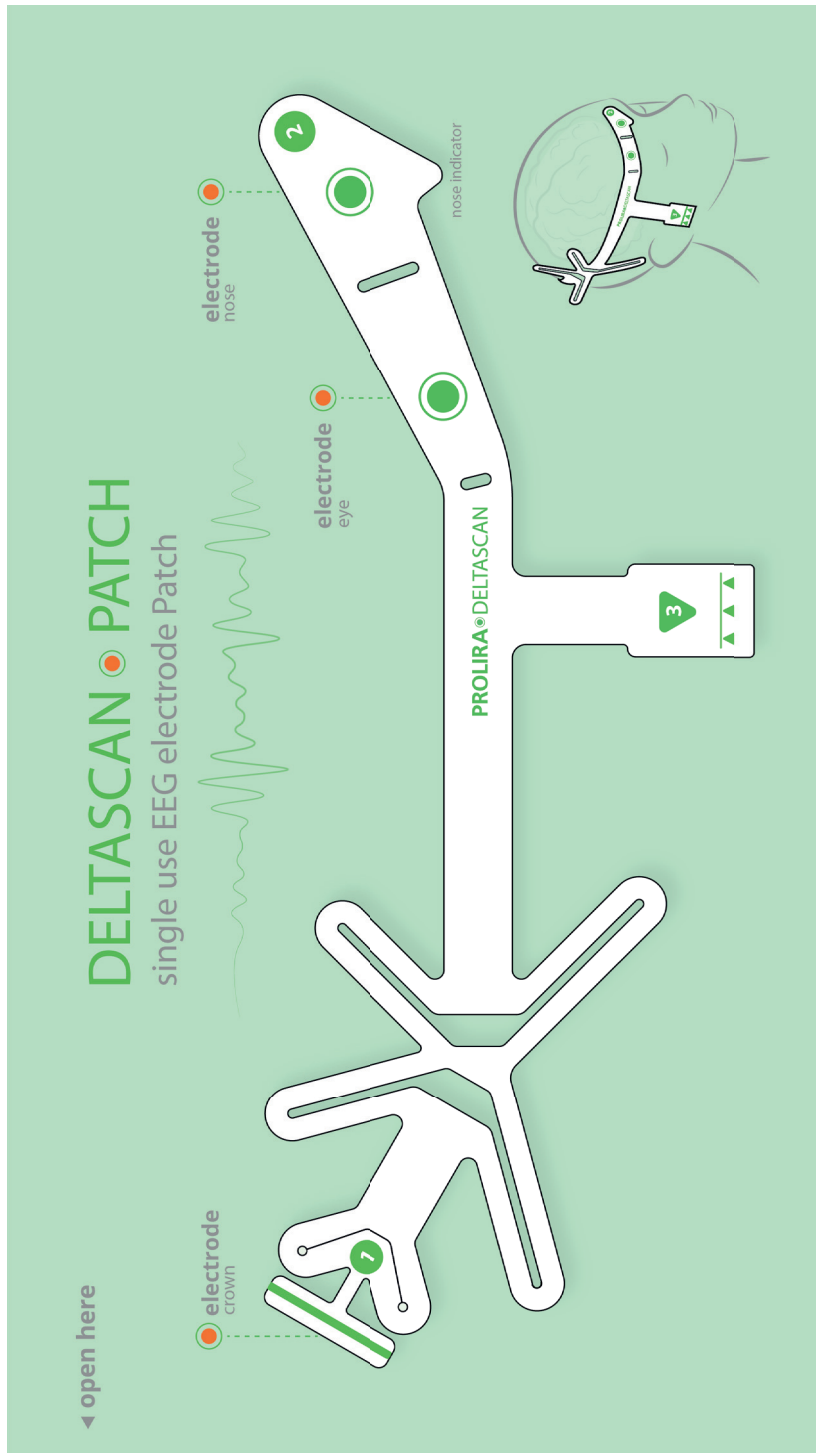
Regulatory notices

Please note: Any serious incident that has occurred in relation to the device should be reported to Prolira.

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).
- [3] S. Hut *et al.*, "EEG and clinical assessment in delirium and acute encephalopathy," *Psychiatry and Clinical Neurosciences*, 2021.
- [4] E. R. Marcantonio, "Delirium in Hospitalized Older Adults," *N. Engl. J. Med.*, vol. 377, no. 15, pp. 1456-1466, Oct. 2017.
- [5] A. J. C. Slooter *et al.*, "Nomenclature of Delirium, Acute Encephalopathy and Related Terms: Quantification of Selective Citations and Position Statement," *Intensive Care Med*, 2020.
- [6] B. J. A. Palanca, T. S. Wildes, Y. S. Ju, S. Ching, and M. S. Avidan, "Electroencephalography and delirium in the postoperative period," *Br. J. Anaesth.*, vol. 119, no. 2, pp. 294-307, 2017.
- [7] *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.*

14. ANNEX A: FULL LABELLING OF DELTASCAN PATCH PACKAGING



1) Front label of DeltaScan Patch packaging

2) Back label of DeltaScan Patch

STEP 1

- Hold point 1 between thumb and index finger.
- Remove liner from the back of point 1.
- Position the electrode (stripe) on the crown of the head (in the HairLock slot, in case a HairLock is used).

STEP 2

- Hold point 2 between thumb and index finger. Remove liner.
- Position the nose indicator at the center of the forehead above the nose and one finger above the eyebrow.

STEP 3

- Hold point 3 and insert the Patch into the Patch connector up to the mark.

STEP 4

- Press the nose and eye electrode (dots) firmly for 5 seconds.
- Press the **PROLIRA® DELTASCAN** logo.

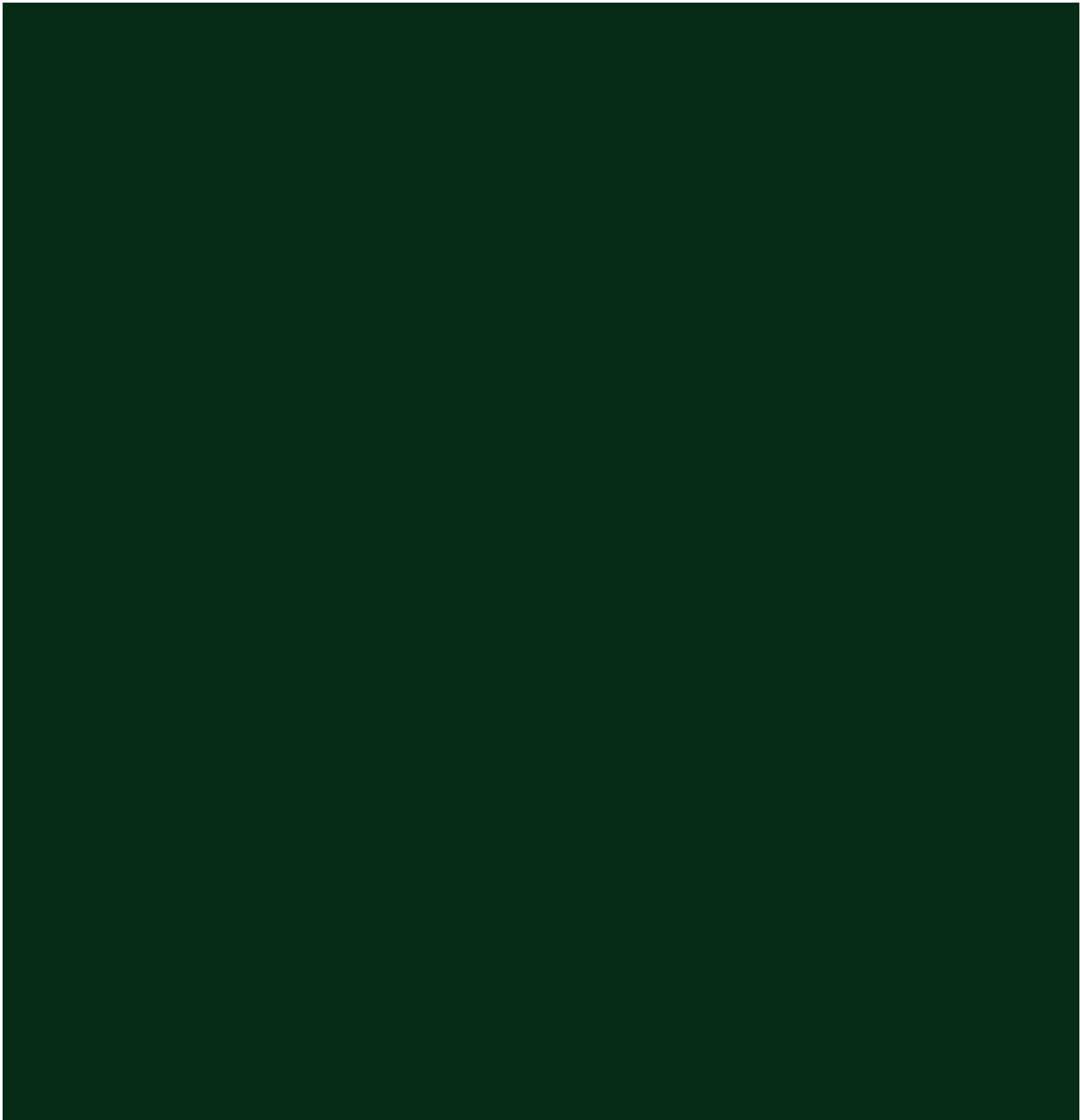
Prolira BV
 Prudalan 8
 3584 CH Utrecht
 The Netherlands
 www.prolira.com
 support@prolira.com
 Label V28

Use exclusively with
 DeltaScan Monitor
 Keep dry once removed
 from its packaging
 Use on dry and intact
 skin only
 Remove immediately
 after the measurement

REF 009.000.B
 MD REF Only
 15°C - 35°C
 100%
 CE

LOT

USA



Prolira BV
Padualaan 8, 3584 CH, Utrecht, The Netherlands
support@prolira.com
www.prolira.com

Copyright: Prolira BV