

DermaScan[®] C USB

Instruction Manual



CE

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1. Symbols



Attention, consult accompanying documents. Where applicable, this symbol can be found on the following pages.



Type B equipment acc. to EN 60601-1.



Class 2 equipment acc. to EN 60601-1.



Alternating current, single phase.



Waste Electrical and Electronic Equipment (WEEE).



2. Warnings

- Read this entire manual before using or showing to others how to use the DermaScan® C USB.
- Do not use the DermaScan® C USB if the device shows visible signs of damage or there is other reason to believe that the device is not functioning correctly.
- The performance of this product may be affected if it is stored or transported outside the range -10°C to 50°C (14°F to 122°F).
- The performance of this product may be affected if it is being used outside the range 10°C to 35°C (50°F to 95°F).
- The DermaScan® C USB is a fully self-contained device. However, if networked to other computer systems or exchanging data with other systems, the device may be subject to computer virus attacks potentially harmful to the software environment and recorded data. To reduce such risk, the installation of proper virus scanner software is recommended.
- Operation of the device requires administrator rights and, consequently, the operator may be able to change the settings of the operating system. Do not alter basic settings of the operating system (e.g. power options, user accounts). Changes to these settings cannot lead to risk of personal injury, but may lead to malfunction or lack of performance, which may or may not be recognized by the operator.
- The DermaScan® C USB as a system consists of a laptop PC, a scanning main unit, a handheld probe and a medical grade power supply to provide power to the PC as well as the main unit, and it is designed to meet international safety requirements. If external peripheral devices are connected to the PC it shall be observed, that such devices meet and are connected to mains in accordance with current legal safety requirements for the particular application of the device.

3. Intended use

DermaScan® C USB ultrasound units are intended to be used to visualize layers of the skin and subcutaneous tissues and to make approximate dimensional measurements. The use of these systems does not serve any diagnostic or therapeutic purpose.

4. System overview

The operation of the equipment is fully controlled by a laptop PC and it's the built-in pointing devices – usually a touch pad and two buttons. Optionally, other pointing devices may be connected – e.g. an external mouse or trackball.

Throughout this manual pressing the left button is referred to as “left click” and pressing the right button as “right click”, provided the device is set up for right hand operation.

DermaScan® C USB units are supplied with a medical grade power supply intended to be connected to a 100 – 240 VAC 50/60 Hz, ground protected mains supply. This power supply provides power to the DermaScan® C USB main unit, from where it is distributed to the laptop PC by means of the enclosed cable.



For safety reasons and to comply with international safety standards, do never use any other power supply for the laptop PC, when it is being used as part of the DermaScan® C USB equipment.

Only laptop PC's delivered by Cortex Technology shall be used with the system.

If an additional power supply for the laptop PC is supplied as part of the delivery, this power supply shall never be used for scanning purposes. It shall only be used, if the PC is disconnected from the DermaScan® unit.



Other peripheral devices (e.g. printers) are to comply with and to be individually connected to mains in acc. with current legal safety requirements for the specific application of the device.

In case of doubt, do not connect other mains connected peripheral devices to the laptop PC at the same time this is connected to the DermaScan® C USB main unit.

Do never connect multiple devices to mains using a power strip!



Fig. 1a. System components.

4.1. Assembly

All connectors are marked and/or coded eliminating the risk of incorrect connection of components.

- connect the power supply to the main unit rear connector.
- connect the USB cable to a USB port on the laptop PC then to the rear main unit USB connector.
- connect the main unit power output to the laptop PC power input.
- connect the 2D probe to the main unit front connector.
- connect the foot pedal. OBS: two types available – foot pedals equipped with a round metal connector are to be connected to the round connector on the main unit rear panel. Foot pedals with a USB connector are to be connected directly to a USB port on the laptop PC. The foot pedal is optional.
- If the main unit is mounted in the cradle place the probe holder on top of the cradle. OBS: the cradle is optional.
- connect the power supply to a ground protected mains outlet.

CRADLE ASSEMBLY

The optional cradle and the main unit can be assembled or disassembled by removing the securing bracket at the rear opening of the cradle, through which the main unit slides into the cradle. Then reposition the securing bracket. A Philips screwdriver is needed to perform this operation.



Fig. 1b. Cradle assembly.



Fig. 1c. Fully assembled system.

5. 2D scanning probe

This chapter applies to all 2D scanning ultrasound probes for the DermaScan® C USB irrespective of the probe model, scanning frequency and acoustical focusing.

5.1. General

The DermaScan C 2D-scanning heads or “B-probes” are scanning in a single plane, the so-called B-mode. The 2D scanning probes can be maneuvered manually for obtaining the needed scanning planes. Manual movement of the probe enables the user to search for areas of particular interest or other special tissue parameters, which can be detected by ultrasound.

All probes feature near real-time scanning at 6-8 frames per second and a closed water chamber. The 2D scanning head is connected to the DermaScan C main unit by an electric cable and connector. The instrument automatically detects the actual type of probe connected, i.e. no further adjustment is necessary, when switching probes.

5.2. Preparing the probe

Water has been selected as the ultrasound transmission medium to provide minimal attenuation of the acoustical signal. As a result, the scanning heads have an internal water-chamber (“water-path”), and for the operator’s convenience and the comfort of the patient/client all probes have an integrated disposable water barrier to prevent spillage. The barrier is made of a special plastic film-material, which allows high frequency ultrasound to pass with minimal attenuation and without compromising the image quality.

The water barrier is a film, intended to be disposed off between recordings to minimize the risk of cross-contamination.

The water chamber inside the scanning head is designed as an open chamber to reduce the risk of permanent contamination of the water. Also, an integrated pressure-relieving outlet prevents pressure build-up, which may lead to pulsation and movement of the scanned tissue.

The recommended water quality is demineralized water or distilled water. Plain tap water should be avoided due to the risk of mineral deposits on the front of the transducer. Such deposits will lead to poor image quality.

5.2.1. Mounting the Water barrier

Disassemble the front piece. Detach the protective paper on both sides of the frame mounted water barrier film and place it carefully on top of the transparent acrylic front piece, fig 2a.



Fig. 2a. Mounting the water barrier.

Then, firmly but carefully push the black oval ring onto the transparent acrylic nose.

Excessive film material and the paper frame is removed by a quick downward pull, which will make the film break over the edge of the transparent acrylic front piece, fig. 2b.



Fig. 2b. Mounting the water barrier.

Now the black ring is supposed to contain the acrylic nose showing a smooth and slightly stretched film surface. The complete front piece is then gently pushed onto the oval metallic, lower part of the scanning head, fig. 2b.

The plastic film provides a plain, regular surface to function as water barrier and window for the ultrasound waves through the oval slit.

5.2.2. Water Injection

At the end of the probe there is an air-venting hole and a hole fitting a syringe for injecting water into the probe.

To inject water, fill approx. 50 ml water into the syringe, and inject the water gently through the hole (fig. 3) holding the probe upright. Keep injecting water until the water level reach the top of the open slit. In “Live” mode, the DermaScan C will now be displaying the water barrier film.

Please observe, that the air-breathing hole is never blocked or sealed. Water may intentionally come out of this hole if the maximum water content is exceeded.



Fig. 3. Injecting water.

5.2.3. Gel application

Prior to performing a recording, the ultrasound probe must be connected and prepared for scanning.

A small amount of gel should be applied into the open slit of the gel spacer, then use the little scraping tool to scrape off excess gel leaving an approx. 1 mm gel layer, see Fig. 4. Make sure no air bubbles are trapped in the gel.

Do not squeeze a thick layer onto the skin, as this will increase the skin-to-transducer distance and lead to unfocused images.

Clean off the plastic membrane using soft tissues immediately after scanning. Fresh gel shall not be reapplied until right before scanning.



Fig. 4. Applying gel.

5.3. Cleaning

After scanning, or at least after eight hours of operation, the water barrier film should be removed disposing the water and the film and allowing the transducer to dry out.

Arrange a container to collect the water coming from the scanning head. After removing the black oval ring from the scanning head, the film should be removed by gently pulling the acrylic nose out of the black oval ring. The front piece parts can be cleaned in solutions of mild detergents suitable for plastics (Scan-Diversey “DIVERSOL BX” or similar) or wiped off with alcohol for disinfection. Put the acrylic nose and the black oval ring back onto the scanning head without film for storage. The water chamber inside the scanning head can be cleaned by gently flushing with the same, mild solutions intended for use with rubber and plastics.

5.4. Probe maintenance

The daily maintenance of the 2D-scanning head is limited to the removal of water to reduce bacteria growth inside the water path and to allow the transducer to dry out. Always remove the plastic-film.

The occurrence of an oil-film inside the scanning head is normal and needs no attention on a daily basis. However, there may be a deposit of oil-film on the face of the transducer. This may cause a decreased image quality and should be removed by means of a soft cotton stick, fig. 5. Do not use solvents or hard objects to clean the transducer - just gently wipe off the deposits.



Fig. 5. Cleaning the transducer front.

6. Operation

6.1. Short form overview

6.1.1. Elements of the main screen

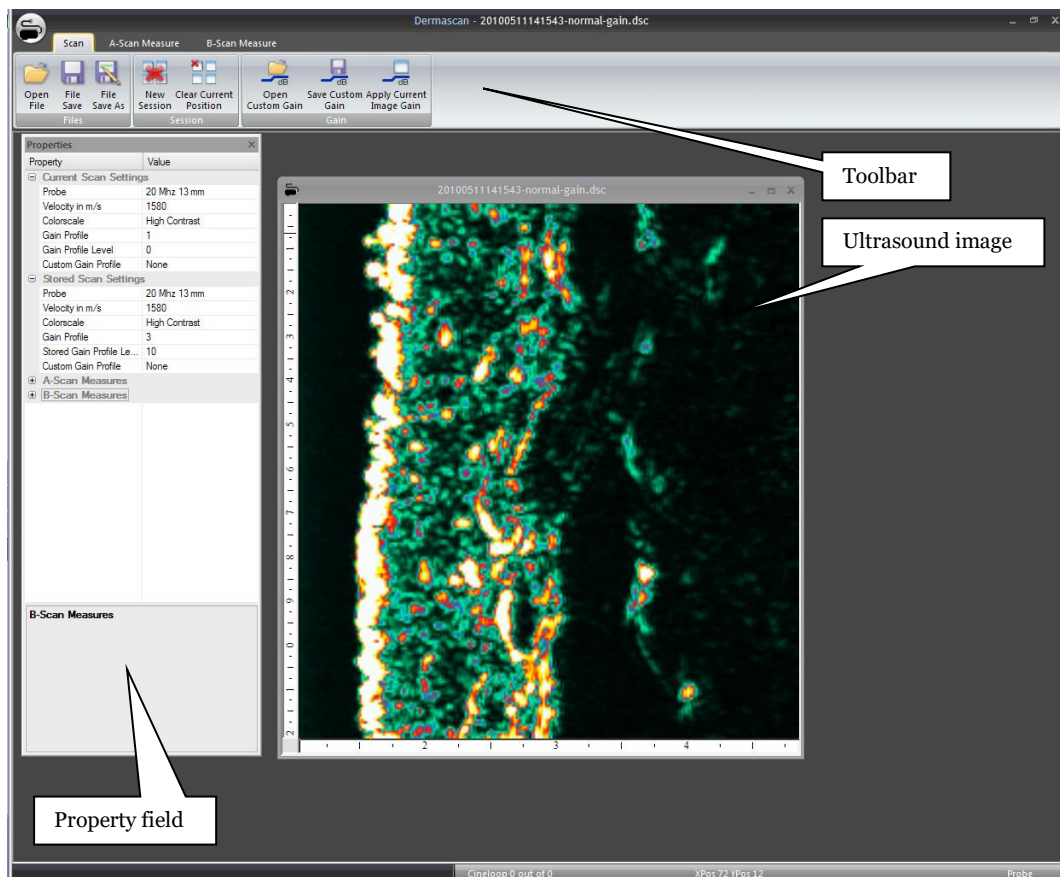


Fig. 6. Main screen.

Toolbar

The toolbar is divided in three sections for controlling the scanning, A-scan measurements and B-scan measurements respectively. Each set of controls is dealt with in depth in section 6.3 and 6.4.

Ultrasound image

The ultrasound image may be presented as either a full size image or minimized as a set of four split screen images, which can be directly compared. Click on the symbols in the upper right corner of the image to minimize, maximize or delete an image on the screen.

In split screen mode, the active image is selected by clicking inside the image. An active image can be identified by a highlighted outer frame.

Property field

The property field provides information about actual scan settings, settings for already recorded images as well as measured parameters. When making adjustments to settings or when performing measurements, the property field is automatically updated to reflect these actions.

6.1.2. Zoom and scroll

In scanning mode as well as when scanning is stopped, the +/- keys will perform a horizontal zoom function and the arrow right/left will make the image scroll.

6.2. The good image

6.2.1. What is a good image

A good image delivers as much possible information in the best possible quality to the viewer in a given situation. In other words, what is being seen on the image should be a result of tissue properties, not a result of artifacts and improper settings of the device.

The properties and composition of the human skin and subcutaneous tissues vary throughout the body and between individuals as a result of many factors (e.g. genetic, age, sex, disease), and the system needs to adapt accordingly.

In the following examples will be shown to establish a common understanding of what to expect as well as commonly seen artifacts and how to avoid them.

6.2.2. Understanding the ultrasound image

As the focused ultrasound beam propagates through the tissue, it travels through medias with different compositions in density. Such change in density will cause part of the ultrasound beam to be reflected, thus generating signals to be received by the device, and part of the ultrasound beam to be transmitted further into the tissue.

Tissue, which is homogeneous in structure provides no or little density change and, accordingly, it will generate no or few and weak reflections – it appears black. As an example blood, fat and muscle generates only few and weak reflections. The same is true for tumor mass in general, whereas normal skin contains a

variety of structures with different densities - it appears as a visible area with varying intensities. In fig. 7 the individual structures of a normal forearm image are identified.

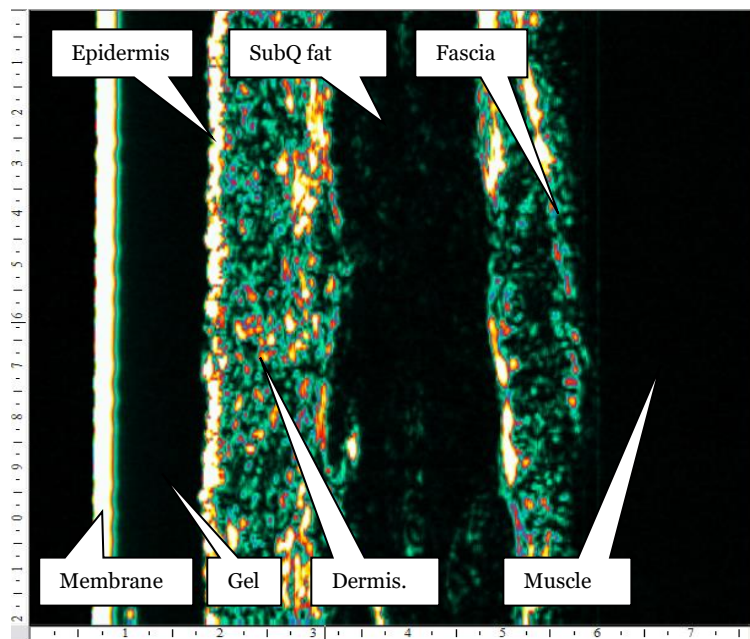


Fig. 7. Normal skin image.

Fig. 8 and 9 shows examples of less reflective material.

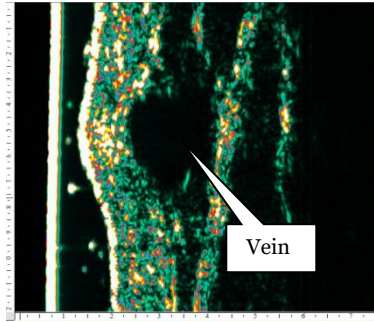


Fig. 8. Normal skin over vein.

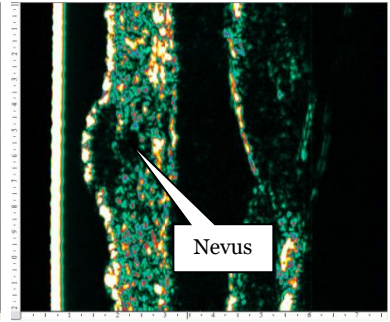


Fig. 9. Intradermal nevus.

6.2.3. How to make a good image

Gain setting.

Most importantly, the amplification of the signal should be set correctly. As the focused sound beam travels through the tissue it gets attenuated. Since attenuation increases with the frequency, high frequency ultrasound is subject to a high degree of attenuation, which limits the penetration drastically.

Within certain limits, such attenuation can be compensated for by increasing the amplification as a function of the depth. In the DermaScan® C USB this feature is referred to as *swept gain* control. This feature allows for individual setting of both the gain level and the gain profile and, practically, the device offers both preset profiles as well as full operator control (see sect. 6.3.5: Gain).

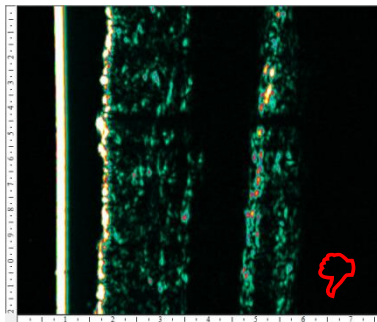


Fig. 10. Low gain image. Press “arrow up” to increase intensity.

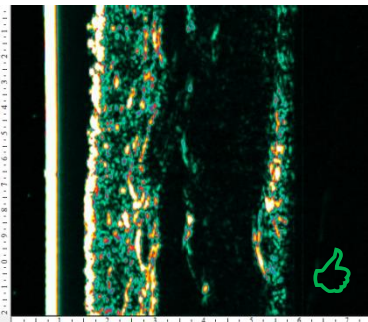


Fig. 11. Normal gain image. Good intensity level and distribution, no adjustment needed.

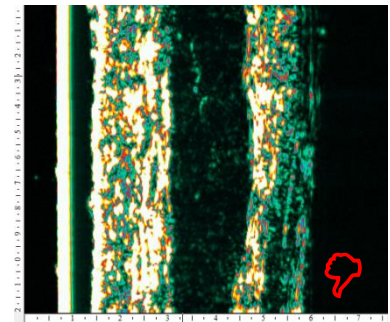


Fig. 12. High gain image. Press “arrow down” to lower intensity level.

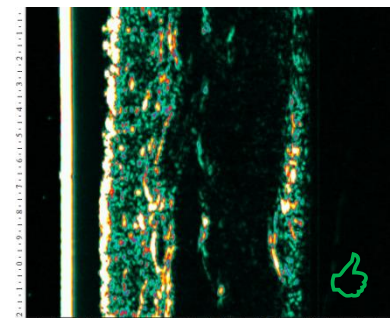
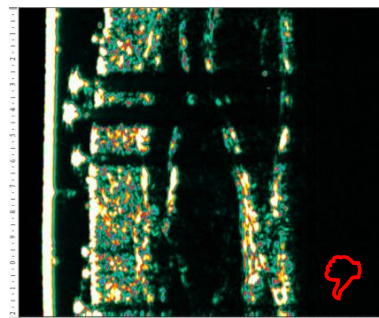
Artifacts.

A correct gain setting cannot correct for artifacts. These shall to the highest possible extent be eliminated – examples below:

Fig. 13. Hair and air bubbles.

Hairs and tiny air bubbles will block the signal and cause horizontal shadows throughout the image (left image).

Cure: Using a soft paper towel or similar, clean off all gel



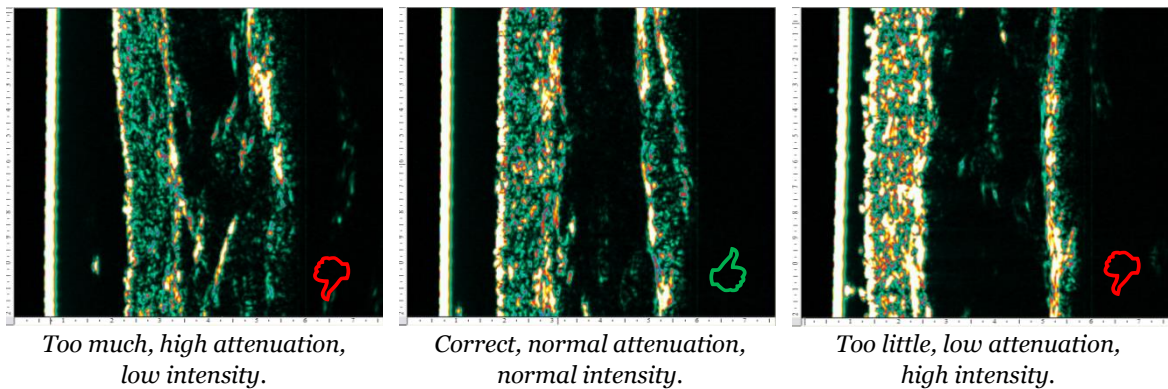
from the probe front and the skin surface. Re-apply fresh gel and move the probe to a less hairy scanning area. If necessary, hairs may be shaved off the surface (right image).

Fig. 14. Gel layer thickness.

The thickness of the gel layer serves the purpose of establishing acoustical contact and to maintain a correct and reproducible distance from the transducer front and the skin surface.

Too much gel (left image) will increase the distance (= increase attenuation), and the target may move out of the focal zone (= poor image definition).

Too little gel (right image) will shorten the distance (= decrease attenuation), and the target will move out of the focal zone (= poor image definition).



Cure: The middle image shows the correct amount of gel after scraping excess gel off the transducer front (see sect. 5.2.3.). A layer of approx. 1 mm is provided by the opening in the black, oval front piece mounted on the probe. The thickness can be observed as the distance from the plastic film to the skin surface as measured on the bottom ruler.

Fig. 15. Holding the probe.

At any time during the scanning process, the probe should be held perpendicular to the skin surface in both directions. Otherwise, the image may be distorted leading to inaccurate measurement of distance and also intensity levels - a result of varying distance to the skin surface along the scanning line (see image top vs. bottom).

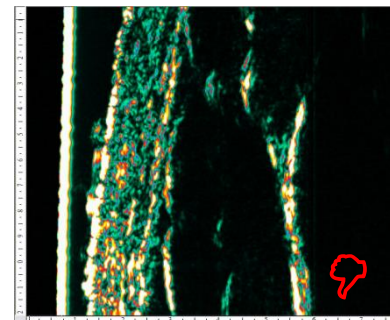


Fig. 16. Lack of gel.

At any time during the scanning process, the opening in the black, oval front piece of the probe should be filled up with gel. Failing to do so will lead to major black areas within the image – bottom part of image.

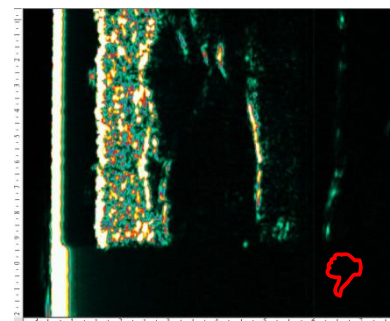
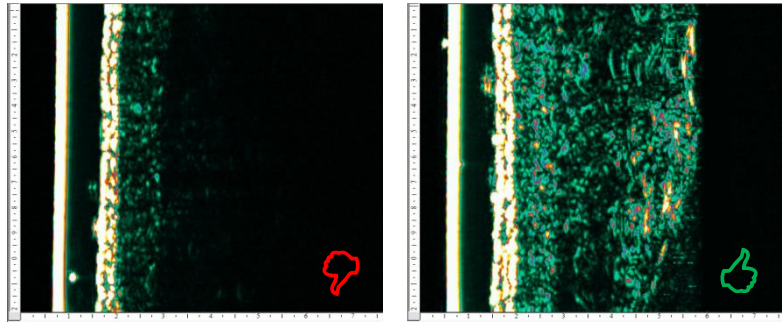


Fig. 17. High attenuation.

The properties of the skin varies all over the body and between individuals. In particular areas like the palm, the underside of the fingers and sole develop very thick and highly attenuating skin. Such areas may prove difficult to penetrate, and gain compensation is often necessary.



The left image shows the underside of a finger recorded with gain setting 1 (linear, horizontal). The right image shows the same finger recorded with sloped gain setting 3 and further stepped up using the ↑ key.

6.2.4. Considerations

Before recording an image, the purpose of the recording should be considered.

Is the purpose just a one-time visualization of the tissue – i.e. the image will not be compared to a previous or later recording – focus can be on producing the best visual image. Accordingly, the gain setting can be freely manipulated to get the best looking result.

However, if the recording needs to be compared to a previous or later recording, attention to the gain setting is advised. To obtain images, which can be cross-compared both visually and when performing measurements, it is necessary to standardize the recording procedure. To do this, make sure to use the same gain setting for all recordings (see sect 6.3.5: Gain).

Also, keep control over the amount of gel used (see sect. 5.2.3.). Too much or too little gel will change the distance to the target object and, consequently, change the position of the target object within the focal zone of the transducer. Incorrect distance may lead to unfocused images and incorrect intensity levels in the images.

By scraping off excess gel, the correct amount of gel will be left on the probe to ensure an appropriate distance to the target for the probe being used.

In particular, when performing intensity analysis, the gain setting should remain the same for all images being part of the analysis. As there may be a great deal of inter-individual and day to day variation, this may result in some images not being visually optimal.

6.3. Scanning

6.3.1. Preparation

Prior to performing a recording, the ultrasound probe must be connected and prepared for scanning. A detailed description on how to mount the plastic membrane, inject water into the probe and to apply gel can be found in section 5.

Further, it may facilitate the scanning procedure to apply a drop of gel to the skin area to be scanned. Gently distribute the gel in a thin layer – just enough to make the skin wet. This will facilitate sliding the scanning probe over the skin.

A good coupling gel of medium viscosity is recommended. If the gel is too hard it is more likely to collect air bubbles, which will effectively block the ultrasound signal. If it is too liquid, it will easily run off the skin.

It is of utmost importance to keep a fixed and well-defined thickness of the gel layer between the skin surface and the plastic membrane of the probe. Accordingly, the procedure for applying the gel (section 5.2.3) should be followed closely.

6.3.2. Start/stop scanning

By pressing the “S” key on the keyboard the device will alternate between starting and stopping the scanning probe. As an alternative, an optional foot pedal is available.

Then place the probe on the skin and move it gently until excess gel has been squeezed out. The thickness can be monitored on the bottom ruler of the image.

6.3.3. Moving the probe

When moving the probe across the skin in search of the right scanning area, the gel layer between the probe and skin should be observed. Lifting the probe off the skin to move it to another area will leave an amount of gel on the skin surface. Consequently, there will be a lack of gel on the probe when repositioning it on the skin, unless the gel layer is topped up and scraped off again.

Also, moving the probe on and off the skin will accumulate tiny air bubbles in the gel, which will block the ultrasound signal.

Therefore, if possible slide the probe across the skin instead of lifting it off and putting it back on. Sliding the probe will lead to a minimal loss of gel and less signal blocking air bubbles in the gel.

6.3.4. Cineloop

The DermaScan® C produces images in real-time at a rate of approx. 7 images per second. The built-in CINELOOP- feature is a function, which automatically captures up to 100 images in real-time. Once the maximum of 100 images is reached, the system will start replacing the oldest images and keep the latest 100 images (a time sequence of approx. 15 seconds) in a temporary memory. Upon stopping the scanning probe, the last cross-sectional image in this loop will be displayed, however, any image kept in the loop may be accessed (by pushing the arrow up/down keys on the keyboard), analyzed and stored.

It is also possible to store the complete loop by choosing the *.dcl format in the “save” menu. An image counter at the bottom of the screen indicates the image number currently being captures/visualized.

6.3.5. The SCAN toolbar

FILES

Open File: click to identify and open previously saved images. The image will be opened in the active split screen image position.

File Save: click to save the active image. If the active image has been previously saved, the saved image will be overwritten. If the active image represents a new and unsaved recording, a “save” menu will appear.

The default format for saving is *.dsc. This is a special format only compatible with the DermaScan® C software. Other formats may be selected in the “save” menu.

File Save As: click to save the active image. A “save” menu will always appear whether the image has been previously saved or not.

The default format for saving is *.dsc. This is a special format only compatible with the DermaScan® C software. Additional formats may be selected at the bottom of the screen. Tick-off to save in *.jpeg and *.tiff formats as appropriate in addition to *.dsc format.



Fig. 18. Files.

SESSION

New Session: click to clear all image positions simultaneously. Unsaved images will be permanently erased.

Clear Current Position: click to clear the currently active image position. An unsaved image will be permanently erased.



Fig. 19. Session.

GAIN

At any time during live scanning, the amplification of the ultrasound signal (i.e. the intensity of the image) may be adjusted. Simply press the number keys 1-4 to obtain one of the four preset gain profiles. The selected profile is simultaneously illustrated in the Property field (*to be added*).

Fig. 20 illustrates the impact of the gain setting:

- the upper image is recorded with a linear and horizontal gain setting (gain key 1). Dermis is well visualized, however, there is a lack of information from the subcutaneous space due to attenuation of the signal.
- the lower image is identical to the upper image, but recorded with a sloped gain setting (gain key 3). A sloped gain compensates for attenuation by automatically increasing the amplification as a function of penetration. Please note the clear improvement of the image quality in depth, where connective tissue in the fat and muscle fascia is now clearly visible.

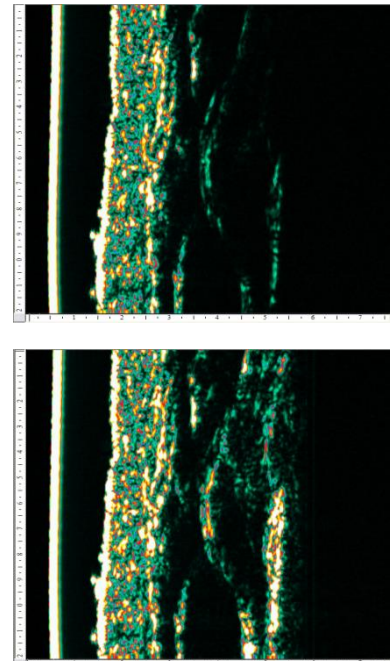


Fig. 20. Impact of gain setting.

If further adjustment is needed, the gain level may be modified up or down by the arrow up/down keys on the keyboard. See how to obtain the good image in sect. 6.2.

After modifying a preset gain setting, this setting may be saved for later use as a customized gain setting. There is no limitation to the number of saved, customized gain settings.

The Property field will automatically update to reflect the currently selected gain setting.

Save Custom Gain: click to save a customized gain setting. A menu will open, and after entering a name and selecting a location for the file, it will be saved with the *.gai extension, which identifies it as a DermaScan® C USB gain profile.

Open Custom Gain: click to open a customized gain setting. Once opened, the number key 5 will automatically become a shortcut to this gain setting.



Fig. 21. Gain.

In addition to saving specific gain settings for later use, any saved image will automatically contain information about the gain setting used for this particular image.

This feature facilitates reusing gain settings from previously recorded images in order to objectively compare new and old recordings.

Apply Current Image Gain: Any image may contain different gain settings. Simply click this button to make the gain setting for the currently selected active image become the gain setting for the next recording. The Property field will update accordingly.

6.4. Image analysis

6.4.1. A-scans.

An ultrasound image is composed by a number of so-called A-scan lines to form a cross-sectional image – the B-scan image.

It is beyond the scope of this manual to provide a detailed explanation of the terms A-scan and B-scan, but the reader is encouraged to seek additional literature, which deals with these terms in depth.

Here it shall only be noted, that A-scan measurements provide one-dimensional information originating from a line entering the skin in a specific point on the surface and going into the tissue to a maximum penetration depth determined by the attenuation factors in the tissue and/or technical factors in the system.

Ref. fig. 22 A-scans are presented on the screen as curves with peaks representing the reflection strength originating from changes in the density of the tissue – i.e. no density changes = homogeneous tissue.

A total of 224 (0 – 223) can be individually assessed within each B-scan image. On the A-scan curve, markers can be accurately positioned to performed distance measurements between peaks hereby measuring the distance between and thickness of structures. A-scans measurements are always performed as peak-to-peak measurements.

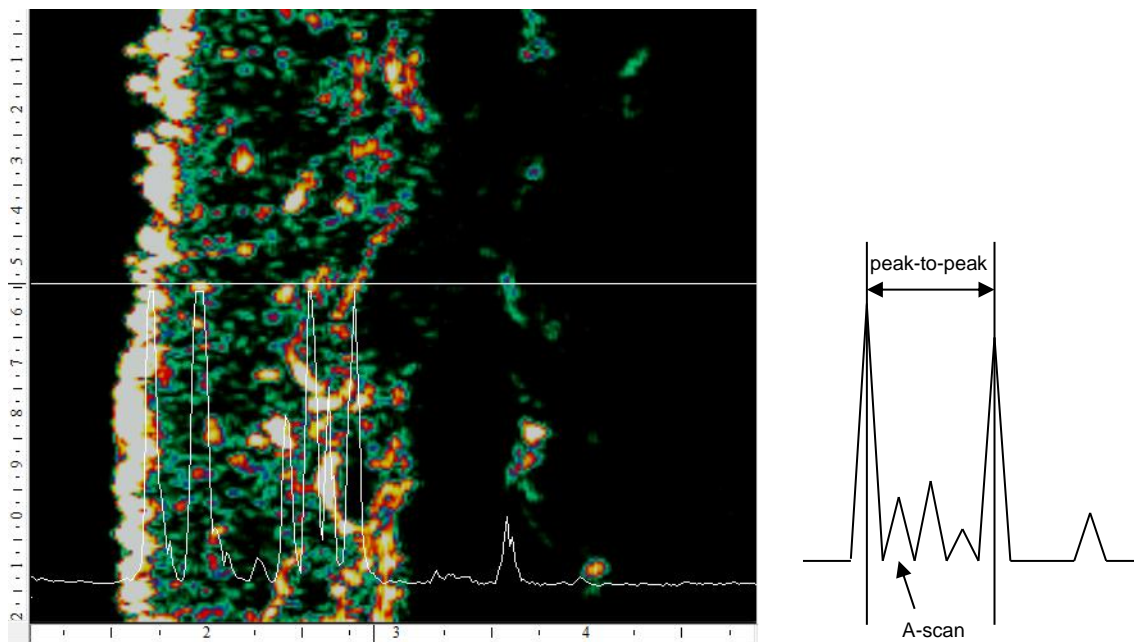


Fig. 22. A-scan.

6.4.1.1. A-scan measurement toolbar.

Click A-Scan Measure to view the toolbar. Once entering the A-scan measurement mode, the cross-sectional image will be maximized and slightly dimmed to make the curves and markers more visible.

By moving the cursor over the image, curves and markers will become visible.

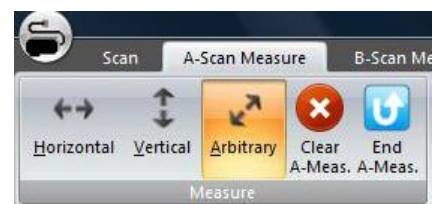


Fig. 23. Measure.

HORIZONTAL

Click to perform horizontal (in-depth) measurements. Move the cursor over the image, and a horizontal straight line will indicate the actual position within the cross-sectional from which the A-scan curve originates. The A-scan line number (0 – 223) is indicated at the bottom of the screen. Click once to position the first marker, then move the cursor and click again to position the second marker. The distance between the markers is continuously updated in the Property field. Clicking a third time will make it possible to move to another A-scan line to perform additional measurements. By doing so, it is possible to manually calculate an average distance between the markers. The Property field keeps updating as new measurements are added.

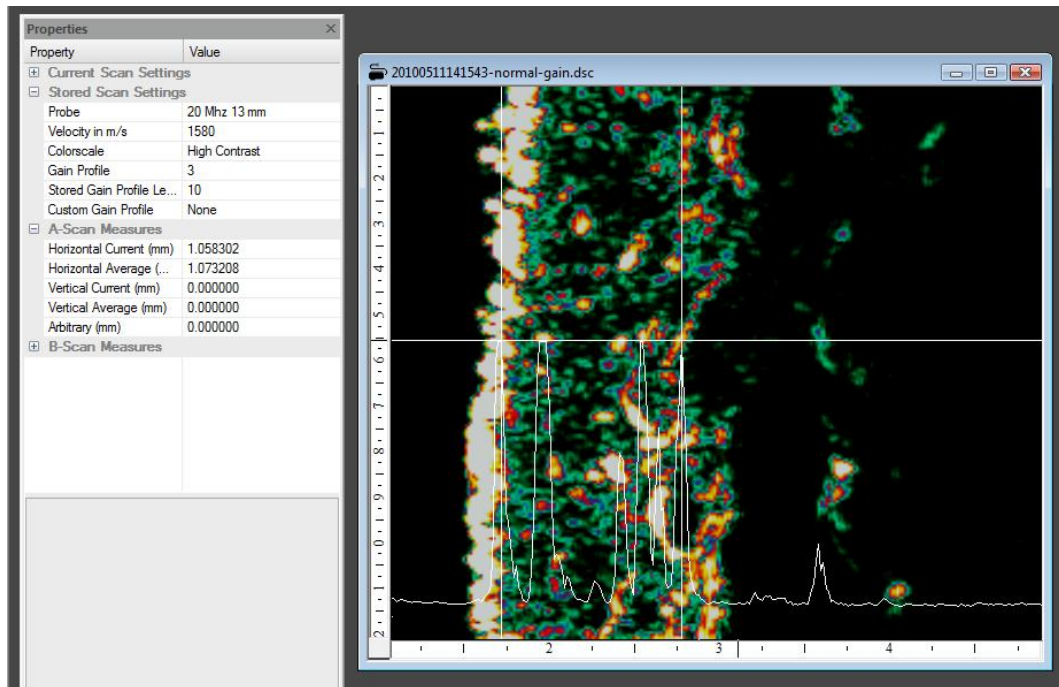


Fig. 24. A-scan horizontal measurements (skin thickness measurement shown).

VERTICAL

Similar to horizontal measurements except the movement direction is turned ninety degrees.

ARBITRARY

Click to obtain a cursor, which can be freely positioned within the image. Once positioned, click and drag a line to the measurement end-point. The Property field will update automatically and show the line length between the start- and end-point.

CLEAR A-MEAS.

Click to erase A-scan measurements.

END A-MEAS.

Click to leave the A-scan measurement mode. Measurements will not be lost. A right-click on the touch pad or mouse provides a shortcut to this function.

6.4.1.2. B-scan measurement toolbar.

Click B-Scan Measure to view the toolbar. The toolbar will change according to the *Type* selection on the left hand side (*Edge Detection* or *ROI*).

EDGE DETECTION

Edge detection is used to calculate the distance between two automatically detected lines – e.g. when measuring the average skin thickness over the full scan length.

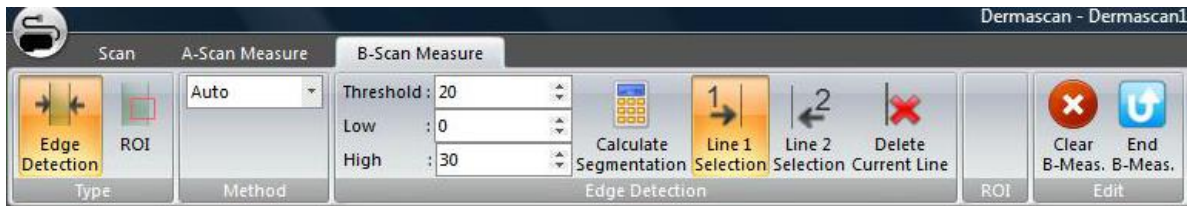


Fig. 25. Edge detection toolbar.

Edge detection is associated with a setting of the detection sensitivity relative to the captured A-scans – here referred to as the Threshold setting. To detect the edge accurately the threshold should be set as high as possible, however, due to the imperfect nature of ultrasound images a setting between 20 and 50 would normally prove practical (default is 30). Very clear borderline structures with high intensity allows for a higher setting, whereas irregular borderlines may require a lower setting.

When two edges are defined on the same A-scan, the distance between them is calculated. This is repeated for all included A-scans within the cross-sectional B-scan, and the average as well as max. and min. distance is calculated.

Compared to peak-to-peak measurement as in A-scan measurement mode, edge detection leads to a systematic and reproducible overestimation of distance depending on the threshold setting, see fig. 26.

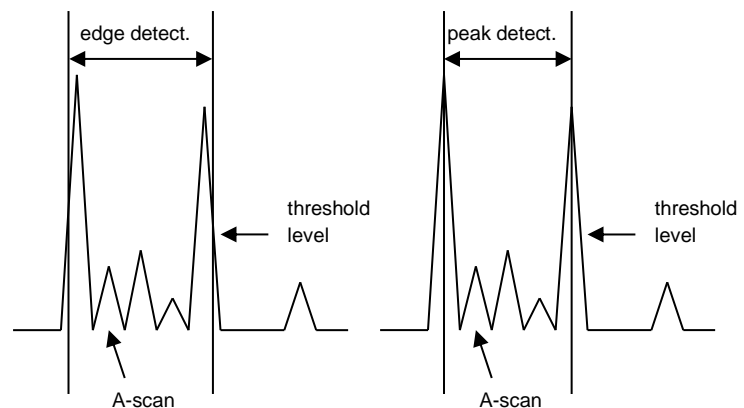


Fig. 26. Edge vs. peak detection.

In the following we will use *line 1* to detect the skin surface and *line 2* to detect the underside of the dermis:

- Select border line number 1 and *automatic* in the toolbar and move the pointer to the image. The pointer will change to a right/left arrow. If a left edge on the image is to be detected, the starting point (the center of the pointer) should be positioned to the left of the edge.
- Set the starting point with a “left click”, and move the pointer to the end point of the edge to be defined. The pointer will be connected to the previous point (in this case the starting point) by a line and the pointer will change to a single arrow indicating the search direction relative to the starting point.
- With the pointer indicating a search direction towards the edge to be detected, the edge detection is completed by a double click.
- Repeat the same procedure for borderline 2. After both lines are detected, the Property field will update to show the average, max. and min. distance (skin thickness). Max. and min. distance between *line 1* and *2* will be shown as a yellow and blue horizontal line in the image, see fig. 27.

To facilitate edge detection of the full vertical length the pointer will snap to the bottom/top edge of the image, however, the edge detection may be started from any vertical position of the pointer.

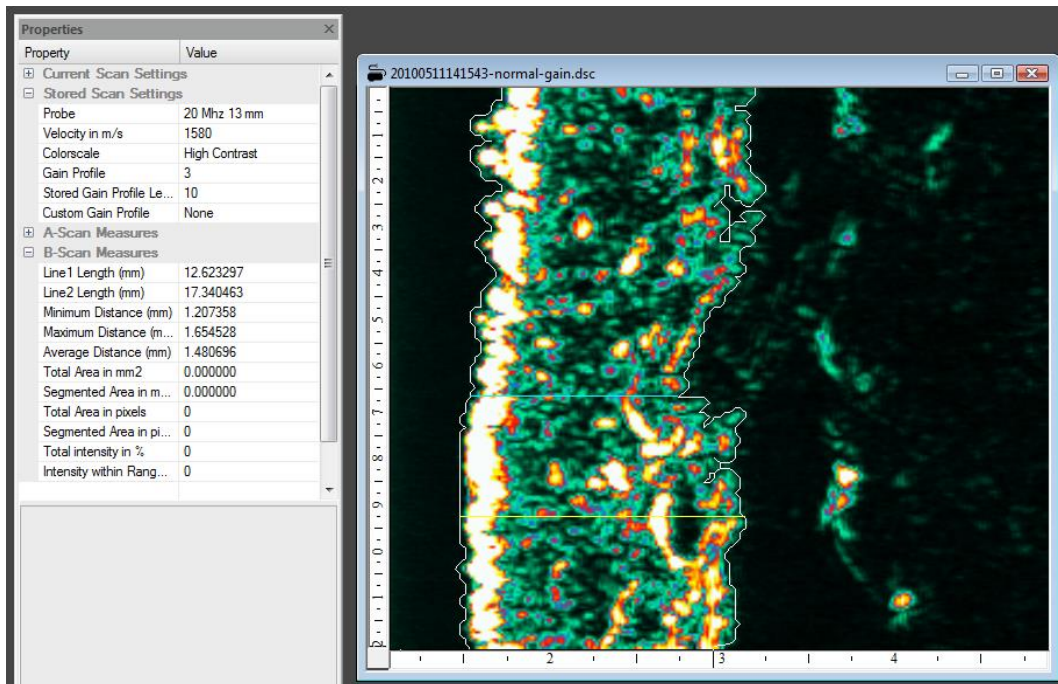


Fig. 27. Edge detection.

Manual assistance/correction in the edge detection process is provided by selecting *freehand* instead of *automatic* in the toolbar.

As an example, artifacts in the image in terms of shadows from hair may cause the automatic edge detection algorithm to follow the contour of the shadow. To avoid this, the automatically detected borderline may be erased with the *delete key* on the keyboard back to a point before the artifact. Now move the pointer to the toolbar and select *freehand* (or use the shortcuts “F” or “A” to toggle between *automatic* and *freehand* mode), draw the contour by hand as needed (left click while drawing), then re-select *automatic* in the toolbar (or press “F” or “A” again) and return to the image to finish the edge detection process.

A line may be completely erased using the *Delete Current Line* symbol in the toolbar.

INTENSITY SEGMENTATION

Intensity segmentation is the calculation of the size of an image area, which falls within a specific intensity interval as set by the low/high intensity level settings in the toolbar (fig. 25). Low/high refers to the lower/higher level setting of the intensity interval.

Initially, two borderlines must be defined using the edge detection as described above. Then click *Calculate Segmentation* in the toolbar.

The Property field will update to reflect this calculation: *Line length* is the full length of the detected edges, *minimum/maximum/average distance* is the horizontal distance between the detected edges respectively, *total* and *segmented* area is calculated in sqmm and as a pixel count, *total intensity* refers to the mean intensity within the border lines and *intensity within range* refers to the mean intensity of the segmented area (scale 0 – 100%).

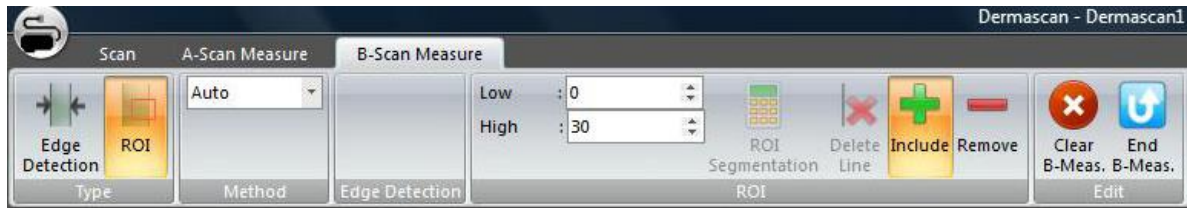


Fig. 28. ROI toolbar.

REGION OF INTEREST (ROI)

Instead of performing a full segmentation within pre-defined borderlines as above, it is possible to select individual areas, so-called regions of interest (ROI), for which the size and mean intensity is calculated.

Select *ROI* in the type-field of the toolbar (fig. 28.). Place the pointer inside the *ROI* on the image and left click. The *ROI* turns red in color and the measurements in the Property field are updated. More *ROI*'s may be added to the calculation by repeating the procedure. Similarly, an *ROI* may be removed from the calculation. Adding or subtracting *ROI*'s is controlled by the +/- buttons in the toolbar (fig. 28.).

Finally, *ROI*'s may be manually restricted by selecting *Method: Freehand* (or shortcut "F") in the toolbar, then draw the *ROI* and click the *ROI Segmentation* button in the toolbar (fig. 28.) to calculate the size of the segmented area inside the *ROI*.

CLEAR B-MEAS.

Click to erase B-scan measurements.

END A-MEAS.

Click to leave the A-scan measurement mode. Measurements will not be lost. A right-click on the touch pad or mouse provides a shortcut to this function.

7. Maintenance

No preventive maintenance is needed. The main unit contains no user serviceable parts inside and shall not be opened by unauthorized personnel.

8. Trouble shooting

Error	Possible cause	Solution
No external power on laptop PC and/or main unit.	Missing mains cable to external power supply. Laptop PC not connected to main unit power output.	Check cables and connections to external power supply, main unit and laptop PC.
Error message when starting up DermaScan® USB application on Laptop PC: "Please connect your DermaScan USB to your computer".	Main unit is disconnected. No power to main unit.	Connect main unit to Laptop PC USB port. Connect main unit to external power
Probe is scanning, but no image on screen.	Gain setting is too low. Probe lacks water.	Adjust gain. Check membrane for holes and replace if necessary. Refill probe.
Horizontal black lines across the image.	Shadows from hair. Shadows from air bubbles in the gel.	Remove hair. Wipe gel off the probe and skin. Apply fresh gel and repeat scanning.
Probe does not respond when pressing "S".	Probe is disconnected from the main unit. Probe is not recognized by the system. Defective probe or system.	Connect probe. Check connection to main unit. Contact local dealer or manufacturer for service.

9. Declaration of Conformity

EC – DECLARATION OF CONFORMITY

We hereby declare that the products listed below conform to the requirements of “DIRECTIVE 2004/108/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC” and “DIRECTIVE 2006/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits”:

DermaScan® C USB

Manufacturers name and address:

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Implemented standards:

DS/EN 61000-6-1

DS/EN 61000-6-3

DS/EN 61010-1

DS/EN 61187

DS/EN 50419

Place and date: Hadsund 2016/08/26

Sign.:


Christian S. Thomsen, CTO