



User Manual

For

BodiTrak LT

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1 INTRODUCTION

This manual applies to the model numbers BT1512 and BT1528.

The BodiTrak LT is an easy to use, stretchable, pressure and shear monitoring system that is applied on top of a seating surface. It assists in identifying and managing areas on a patient's skin where they may be experiencing high pressures and shear forces. It is a powerful tool to help prevent tissue trauma, increase patient comfort, monitor support surface performance and educate both clients and caregivers.

Using an attached Tablet, a person can easily access Risk and Gradient information. The software also includes a timer option with selectable time periods. The LT provides the patient or caregiver with essential information for improving patient care and reducing the expense of healing wounds.

2 COMPLIANCE

2.1 Canada

This Class A digital apparatus complies with the Canadian standard ICES-003. Cet appareil numérique de la classe A est conforme à la norme NMB-003 du Canada.

2.2 United States

The FCC has specified (in 47 CFR 15.105) that the following notice be brought to the attention of the users of this product:

“This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.”

The end user of this product should be aware that any changes or modifications made to this equipment without the approval of Vista Medical Ltd. could result in the product not meeting the Class A limits, in which case the FCC could void the user's authority to operate the equipment. Operation is subject to the following two conditions: (1) this



device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

2.3 Europe

The manufacturer of this product is in conformity with the European Medical Device Directive 93/42/EEC and complies with ISO 13485.

2.4 Product Testing

This product has been tested and found to comply with:

- CAN/CSA C22.2 No. 60601-1:2008
- ANSI/AAMI ES 60601-1:2005/A2:2010
- EN 60601-1:2006/A11:2011
- IEC 60601-1-2:2007 – edition 3

2.5 The following table shows classifications and environmental parameters for the BodiTrak pressure mat:

Medical Device Type	Class 1 with measurement function
Class for electromagnetic compatibility	Class A
Degree of protection against electric shock	Type B Applied Part
Degree of protection against ingress of water	IPX0
Mode of operation	Continuous
Environmental Operating Conditions	10 to 40°C 30 to 75% RH non-condensing 700-1060 hPa
Environment Storage Conditions	-40 to +70C 10 to 100% RH non-condensing 500 to 1060 hPa

3 WARNINGS

3.1 This equipment complies with IEC 60601-1, 3rd edition, which states the requirements for basic safety and essential performance. Using this equipment with accessories or cables other than those provided by Vista Medical may result in non-compliance with those requirements. No modification of this equipment is allowed.

3.2 This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as:

- Reorienting or relocating the affected receiving antenna
- Increasing the separation between the equipment and the receiver
- Connecting the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consulting the dealer or a qualified radio/TV technician for help

3.3 When external equipment such as a computer is connected to this equipment it should comply with EN 60950 for IT equipment, or the EN 60601-1-1 series for medical electrical equipment. Equipment not complying with EN 60601-1-1 shall be kept outside the patient environment, as defined in the standard, at least 1.5 m from the patient or the patient support.

3.4 Electrical interference, such as electrical transients or bursts, may cause the sensing mat to malfunction. Avoid using in close proximity to other equipment such as motors that have a high amount of electrical switching. If unavoidable, verify normal operation prior to use.



3.5 The USB connector with this warning symbol for electrostatic discharge (ESD) should not be touched directly, and connections should not be made, unless precautionary procedures are used. Users should be trained to recognize the symbol and to discharge themselves by touching grounded metal prior to handling the USB connector or plugging it in. If function stops due to ESD, unplug the mat, reboot the computer, and plug the mat back in.

4 INSTALLATION

4.1 System Requirements

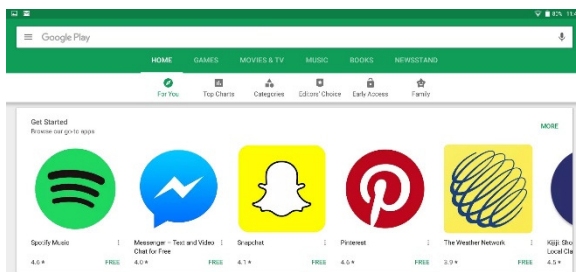
- | |
|--|
| i. Tablet with Android 6.0 (OS) or greater |
|--|

4.2 System Components Included

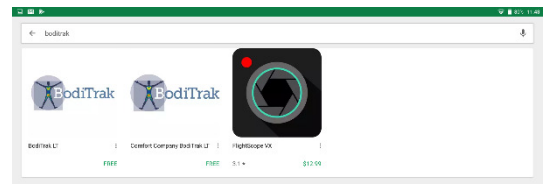
- | | |
|---|--|
| i. Sensor mat with USB cable and built-in Wi-Fi or
ii. Optional DataPort wireless module | iii. Quick Set Up Guide in PDF
iv. User Manual in PDF |
|---|--|

4.3 Software Installation Instructions

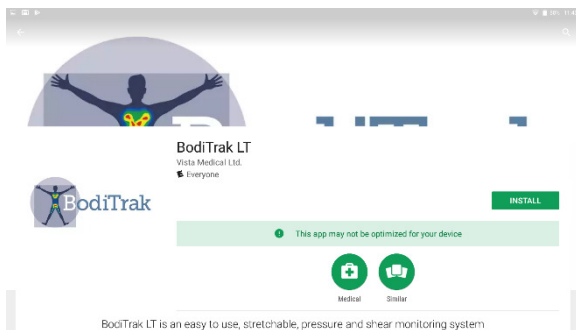
- Using the tablet go to Google Play Store
- In the search box type: BodiTrak



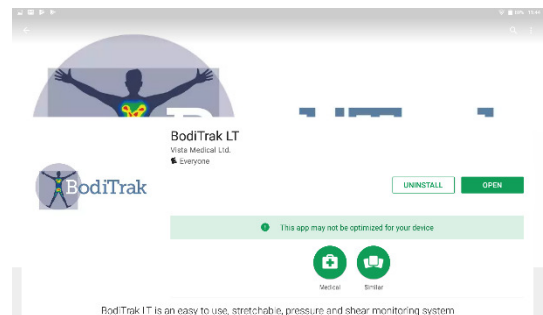
- Choose BodiTrak LT



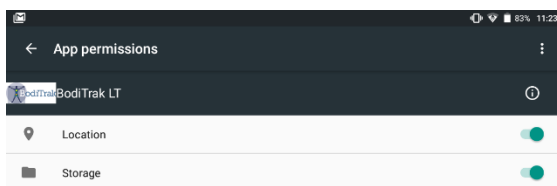
- Tap Install button



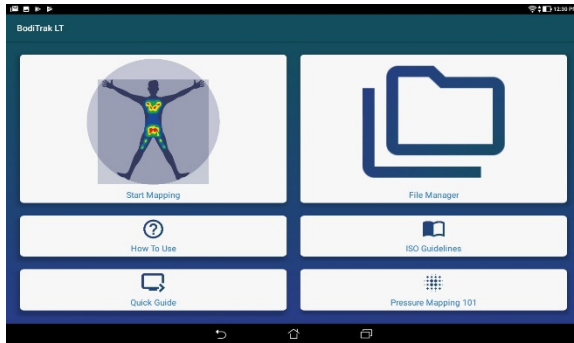
- Tap Open button



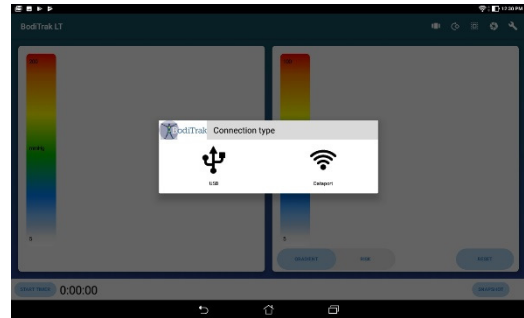
- If prompted for permissions, enable location and storage



7. Tap 'Start Mapping'



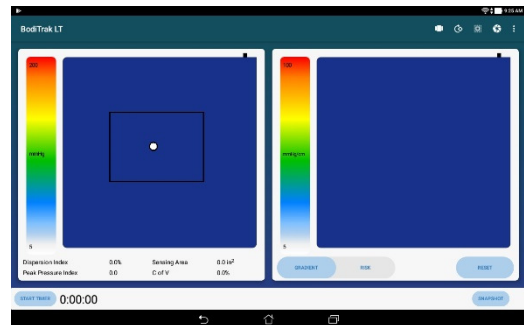
8. Choose the connection type from the message box.



9. If you choose USB, then plug the Micro USB cable from the pressure mat into the tablet's Micro USB port and select OK to allow access.

10. If you choose DataPort, then go to your device's Wi-Fi settings, select the BodiTrak's 2 or the Data Port's SSID you wish to connect to and input the provided password. BodiTrak's 2 SSID and password can be found on the tag attached to the USB cable. Data Port's SSID and password is shown on a tag attached to your module.

11. If the blue mats appear on the User Interface the connection was successful.



12. If you are experiencing difficulties with the software or physical set up, contact technical support at [800-847-3157](tel:800-847-3157)

5 USING THE BODITRAK LT SYSTEM

5.1 From the tablet Home screen tap the BodiTrak LT shortcut, or go to Apps Drawer and select the icon for BodiTrak LT.

5.2 Select “Start Mapping”.

5.3 If the blue mats appear on the User Interface the connection was successful.

5.4 Key Item: The system has 2 modes: On-the-Go scanning and Multiple Comparison. You can switch back and forth by tapping the “square in a square” icon.

5.5.1 On-the-Go Scanning Mode

This mode is intended to provide a quick and easy way to assess a person’s situation on a surface over time. The scanning starts as soon as you plug in the sensing mat and select ‘start mapping’.

The display is divided to show two seat images as shown here in Figure 1. The image on the left displays normal force pressures. The image on the right is for gradient and risk considerations.

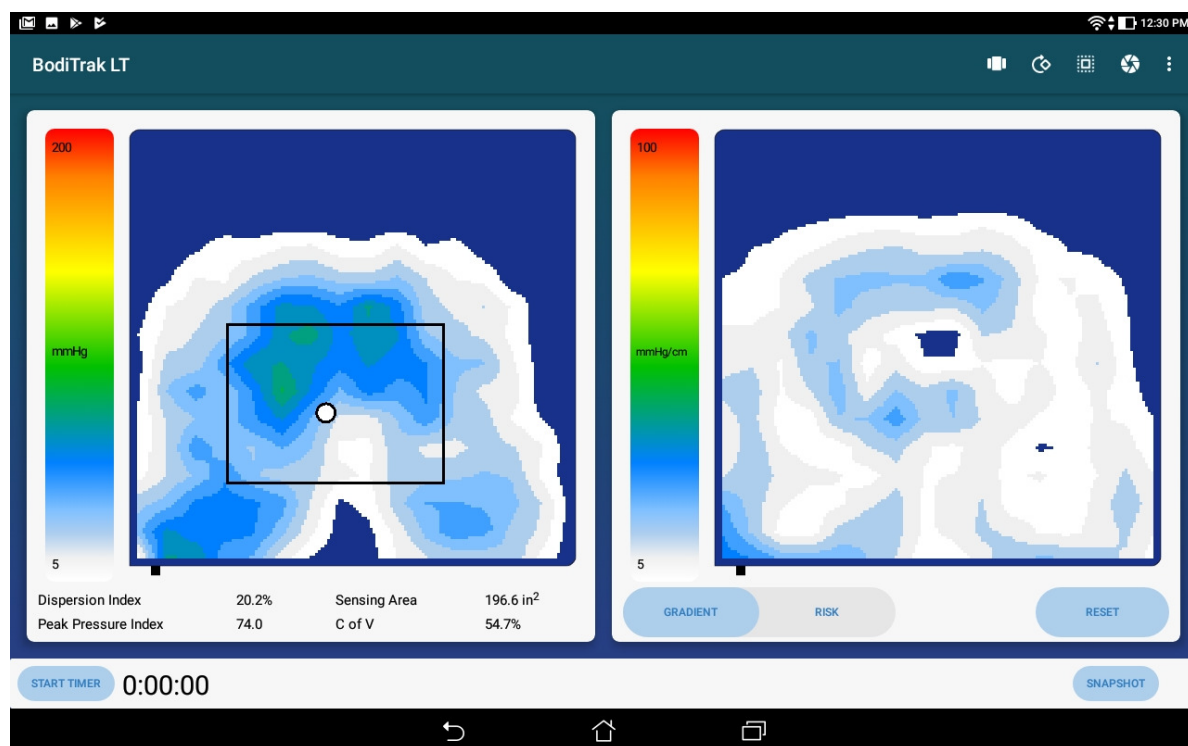


Figure 1 – User Interface

On the left hand side of the display you will observe:

- a color bar indicating the level of pressure from 5-200 mmHg, or a chosen pressure range
- the center of pressure on the mat, represented by a white dot
- the Dispersion Index box: a rectangle defined as 8 sensors across and 6 sensors down which you can drag to a desired location (for example the ischial-sacrum area) to calculate the Dispersion Index
- statistics which are useful for considering solutions and are explained as follows:

Dispersion Index (%) – The sum of pressure distributed over a region (for example the ischial tuberosity (IT) and the sacral-coccygeal region) divided by the sum of pressure readings over the entire sensor mat, expressed as a percentage. A value of 50% or more is indicative of a potential risk of skin trauma.

Peak Pressure Index – The average of the highest recorded pressure values within a 9 to 10 cm² area (the contact area of an IT). PPI is a better comparative bench mark than average seat pressures.

Sensing Area (in²) – The area of the mat the client is resting on which is displaying above the minimum setting, e.g. 5 mmHg. Generally you want a larger sensing or contact area as this means the area of support has increased.

C of V (%) – The coefficient of variation shows how evenly the pressure is distributed across a support surface. It is expressed as a percentage, and is normally the inverse of the sensing area. It is better to have a lower CoV value, but be careful to compare to the pressure map; you may have a low CoV but still have a high localized force somewhere in the seat surface.

On the right side of the display you will observe:

- Gradient and Risk display choices, as shown here in Figure 2

GRADIENT (spatial pressure)



RISK (pressure vs. time)

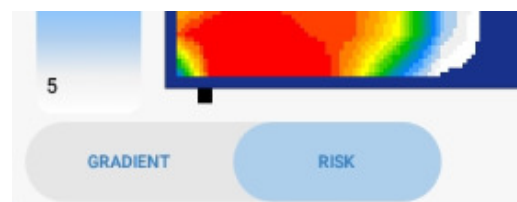


Figure 2 – Risk and Gradient

RISK TAB – The Risk tab will be highlighted when chosen. The pressure map indicates tissue loading over time and is expressed in mmHg/hour. It helps the client or caregiver to understand where the skin may be most at risk of tissue trauma and repositioning may be required. (The software is based on Reswick-Rogers pressure/time curve.)

GRADIENT TAB – The Gradient tab will be highlighted when chosen. The pressure map identifies areas of the skin that may be affected by shear forces and is expressed as mmHg/cm. Areas of fastest change in pressure over the surface of the seat are displayed as hotter colors. It is believed that where pressures change quickly from one location to another there is a risk of shear occurring to tissue.

- a start timer and time indicator that can sound an alarm at a chosen time to remind a client to shift their weight
- a Reset Risk button used to reset the risk display



On the top of the display you will observe:

- A three dots icon which gives you a drop-down showing two options, Data Port Connection and Settings. If you tap on Settings you will see the following options:

USER SETTINGS	
Maintain Weight	On or off. Useful for normalizing pressure readings over extended periods of time. User's weight must be input.
User Weight	Insertion of user's weight
Timer Duration	Set time duration before alarm sounds
Connect via DataPort	On or off

PRESSURE MAT SETTINGS	
PSI Units	On or off
mmHg Pressure Max	Can set maximum displayed values
PSI Pressure Max	Can set maximum displayed values
Sensor Rotation	On or off
RISK VIEW SETTINGS	
Risk Threshold	Can set the level of mmHg/hr at which risk data is displayed. Normally set to 20.
Risk Multiplier	Demo feature (usually set at 1 for use in monitoring or 20 to artificially accelerate time for demo mode). Set higher to display quicker.
CENTER OF PRESSURE	
Center of Pressure	On or off. Shows center of pressure on mat
Center of Pressure Tail Length	Can set from zero to several seconds
OTHER SETTINGS	
Sensing Area Metric Units	On or off
Orientation Portrait	On or Off
APPLICATION INFORMATION	
Version	Displays Current Version

- A Snapshot icon (Figure 3) which allows you to take a screenshot. This will allow you to take a picture of the current screen at any time during the On-the-Go scanning. When the snapshot button is tapped you will be asked to enter User Information (Figure 4) and when you select OK the image will be saved.

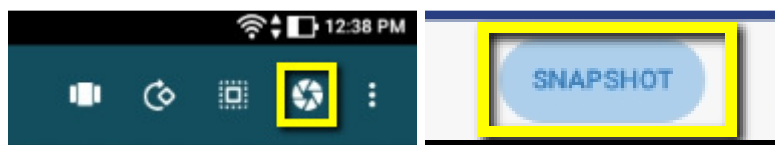


Figure 3 – selecting the snapshot icon

The image can be located by going to the BodiTrak LT home page and selecting the File Manager icon. You can delete or export snapshots by selecting an image and tapping either button. Exporting the image sends it to the tablet's document folder.

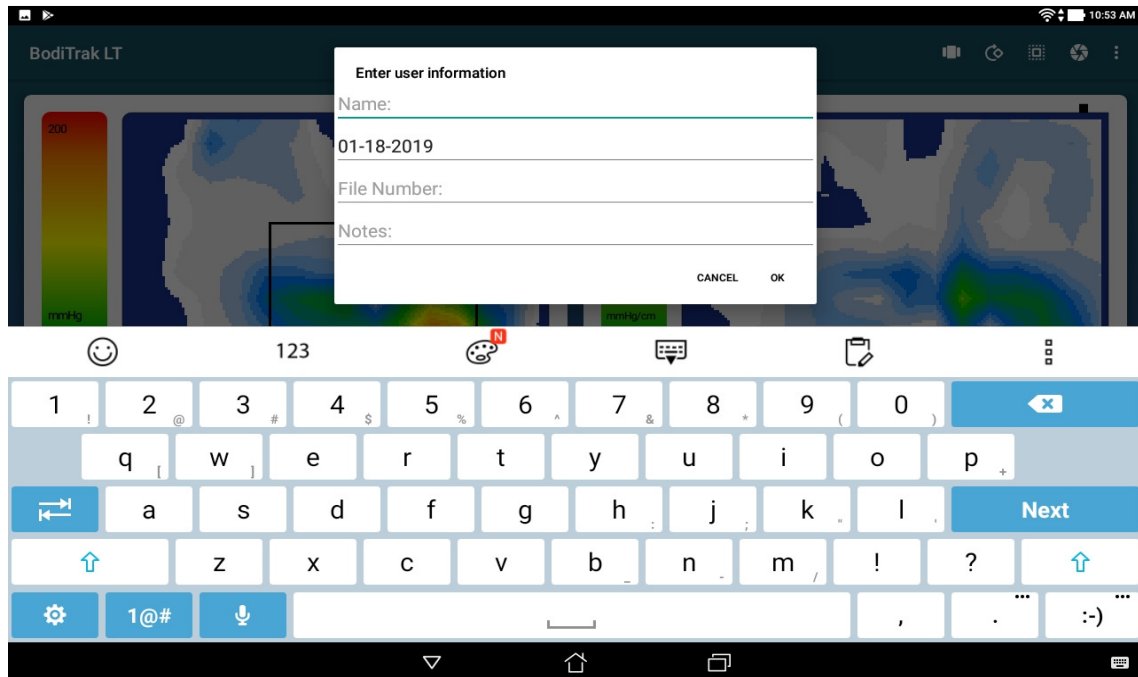


Figure 4 – entering user information

- A circular arrow icon which will rotate the view of the mat 180 degrees.



5.5.2 Multiple Comparison Mode

The Multiple Comparison is a comparison tool for considering solutions to seating issues. A series of up to four images are taken in sequence to allow for side by side comparison.

To begin the comparison wizard click the “square in a square” icon as shown in Figure 5.



Figure 5 – Square in a square icon

A 'Start Comparison' button will appear on the bottom right of the screen as shown in Figure 6.



Figure 6 – Multiple Comparison user interface

When the Start Comparison button is touched an information dialogue box will appear as shown in Figure 7. This will allow the user to input relevant data to identify the images later.

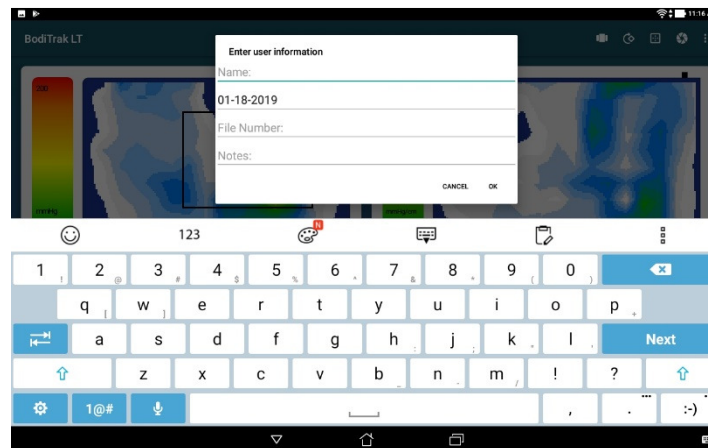


Figure 7 – User information dialogue box

When the user information is entered and OK is selected, the scan page returns, as shown in Figure 8.

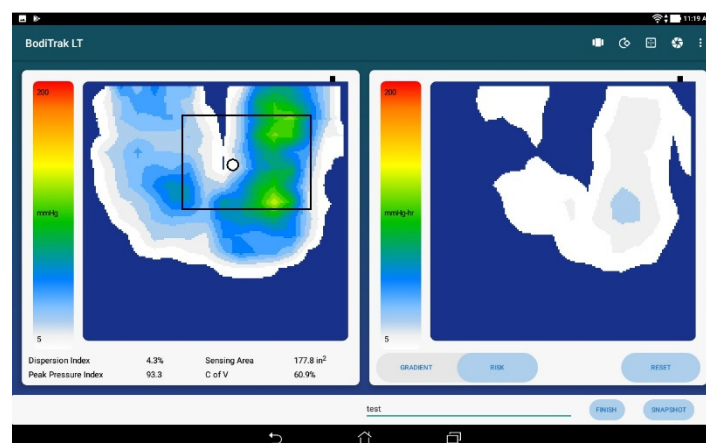


Figure 8 – Multiple Comparison page

Enter a name for the image in the 'comments' field to the right of the finish button (Figure 8) and then touch the Snapshot button. A screenshot will be saved. You can repeat this step up to three more times. If you wish to stop before all four screenshots are taken simply tap the Finish button.

After you have taken the snapshots a screen will appear showing all of the images together (Figure 9). You can select any one of the images to see an enlarged view.

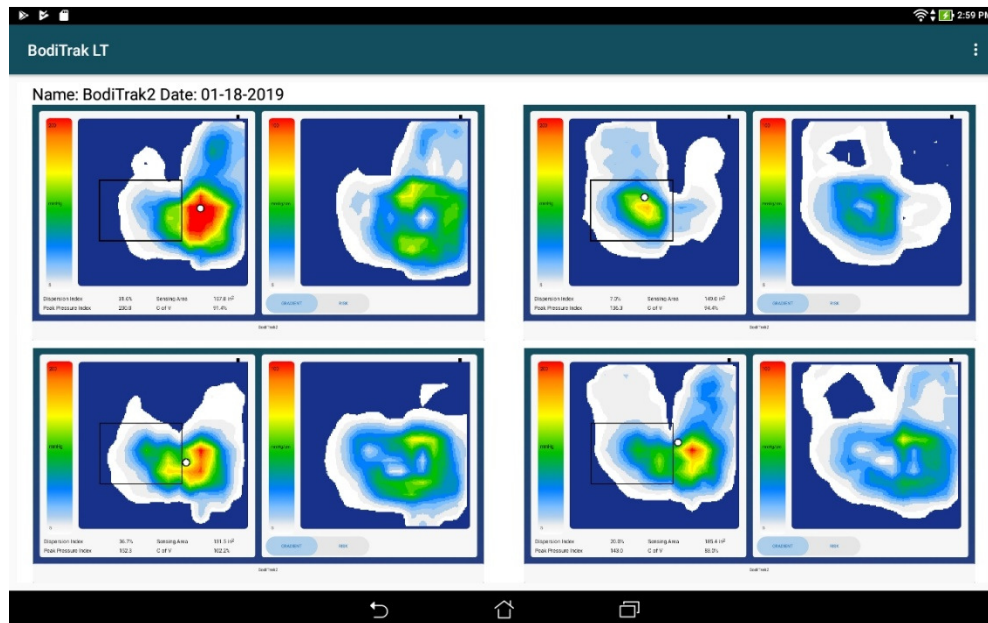


Figure 9 – Multiple Comparison Report display

A pdf file is automatically generated. The image can be located by going to the BodiTrak LT home page and selecting the File Manager icon.

6 CARE OF THE BODITRAK MAT

- Do not pull on or carry the mat by the USB cable.
- Place the mat gently on surfaces by using the corners.
- Do not pivot on the mat.
- Do not pull on the edges of the mat while it is under a client.
- The covering on the pressure sensing mat should not be in direct contact with broken skin.
- Do not pinch the mat between moving components of a support surface.
- Do not fold the mat
- Store the mat flat or in the original packaging by rolling the mat around the foam tube and storing in the shipping cylinder.
- If your mat has a ferrite installed on the USB cable do not remove it.
- It is the operator's responsibility to ensure all cables are in good condition; inspect all cables for nicks or abrasions prior to each use.

7 CLEANING THE BODITRAK MAT

BodiTrak pressure sensing mats are typically covered in polyurethane coated nylon/Lycra stretch fabric.

- Unplug the mat before cleaning.
- For daily cleaning, we recommend wiping down with a damp, not wet cloth using a mild soap and water solution.
- Mild alcohol based cleaners and cleaners containing no more than 10% bleach in non-wetting amounts may also be used.
- Other cleaners / disinfectants sold under the following names may also be used: Viraguard, Cavicide, Vitre Tb, and SeptFx.
- Undiluted bleach and Hydrogen Peroxide are not recommended.
- Cleaning products or disinfectants must be thoroughly wiped off after using them.
- Allow the mat to dry thoroughly before use or storage.

