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VERSION

200000-5

DATE

2020/12/28

INFORMATION

This device is subject to the EU Directive 2012/19/EU (WEEE). It is not registered for use in private households and may not be disposed of at municipal collection points for waste electrical and electronic equipment. ADAPTTECH LTD has authorized a firm to dispose of this device in the proper manner. For more detailed information, please contact ADAPTTECH LTD.

⚠ To properly use this medical device, read and comply with these instructions for use.

⚠ INSIGHT System is intended for use by qualified medical personnel only.

⚠ USA Federal Law restricts this device to sale by or on order of a physician.

WARRANTY

Adapttech warrants that the INSIGHT System is fit for the purposes and indications described in the labeling for a period of one (1) year from the date of purchase when used in accordance with the directions for use. Unless equipment is used in accordance with such instructions, this warranty is void and of no effect. No other express or implied warranty exists, including any warranty of merchantability or fitness for a particular purpose.

This warranty does not include the Sensors, Wearable, or any cables used with the INSIGHT System or Scanner. Adapttech's sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the INSIGHT System at Adapttech's discretion.

Adapttech shall not be liable for proximate, incidental, or consequential damages. Adapttech shall not be obligated under this warranty to repair or replace a damaged or malfunctioning INSIGHT System if such damage or malfunction is caused by the customer's use of patient sensors other than those manufactured by Adapttech.

This warranty is exclusive and is in lieu of all other warranties, expressed or implied, including Warranties of merchantability or fitness for any particular purpose.

Exemptions

Adapttech's obligation or liability under this warranty does not include any transportation or other charges or liability for direct,

indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Adapttech or repairs by people other than Adapttech or Cascade's authorized personnel.

This warranty shall not extend to:

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Warning

Adapttech can accept no liability for modifications and repairs to the devices made by the purchaser or unauthorised third parties without consulting the supplier.

We advise you to have any necessary repairs and regular servicing carried out by Adapttech or Cascade.

ABBREVIATIONS

LAN	Local Access Network
LED	Light Emitting Diode
IMU	Inertial Motion Unit
3D	Three Dimensional
RJ45	RJ45
RAW	Data not been subjected to processing
RH	Relative Humidity

INTRODUCTION

Adapttech INSIGHT is a medical device composed of 5 components to support prosthetists and physiotherapists to pinpoint the problematic issues causing discomfort, pain and tissue breakdown occurring in the residual limb-socket interface on lower limb amputees.

The system consists of:

INSIGHT Scanner

A laser scanner that scans the concave prosthesis inner surface, creates a 3D model of the socket in less than 90 seconds and automatically detects the position of the sensors.

INSIGHT Wearable

A wearable system that gathers biodata (both statically and dynamically), regardless of the patient's activities. This information helps identify the problematic points that affect the socket fitting.

INSIGHT App

Software that manages records, saves and tracks patients' history and follows their adaptation process throughout the entire rehabilitation phase. By merging the biodata collected by INSIGHT Wearable and mapping it over the 3D model created by INSIGHT Scanner, problematic issues occurring between the residual limb and the socket can be pinpointed.

INSIGHT Sensors

INSIGHT Sensors are a consumable part that connects to INSIGHT Wearable and are placed on the inside of the patient socket for pressure monitoring.

INSIGHT Wearable IMU

INSIGHT Wearable IMU is an INSIGHT Wearable accessory that gathers patient motion data and helps the system to identify patient gait phases.

Intended Use

INSIGHT™ (**IN**ner **S**ocket **I**nformation **G**at**H**ering **T**ool) is a tool intended to support healthcare professionals during prosthetic rectification and rehabilitation monitoring by merging biodata gathered through a wearable sensorized system with a 3D-model scan of the prosthetic socket's inner surface. Mapping the data over the model enables the system to pinpoint the problematic issues occurring in the residual limb-socket interface.

Product Codes

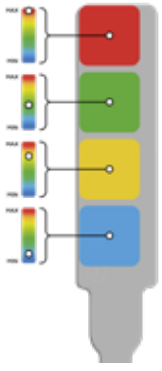
ATT0001 - INSIGHT Scanner
ATT0002 - INSIGHT Wearable (Small - 4 Strip Connectors)
ATT0003 - INSIGHT Wearable (Medium - 8 Strip Connectors)
ATT0004 - INSIGHT Wearable (Large - 12 Strip Connectors)
ATT0006 - INSIGHT Wearable IMU
ATT0007 - INSIGHT Sensors (Small - 4 sensors)
ATT0008 - INSIGHT Sensors (Medium - 6 sensors)
ATT0009 - INSIGHT Sensors (Large - 8 sensors)
ATT0010 - INSIGHT App
ATT0011 - iPad

INTERPRETING INSIGHT DATA

Basic principles of INSIGHT's Pressure Data

To extract the most clinical value out of insight's pressure acquisitions (static or dynamic), there are some basic principles to take into account:

- The measured pressure is relative (to all Sensors present in the socket), not absolute.
- Consequently, the color coding is not qualitative, but comparative. Red does not necessarily mean *"bad"*, but merely *"considerably more pressure than the lowest pressure being recorded"*.
- Pressure is being measured across the entire INSIGHT Sensor, not just on the coloured markers.



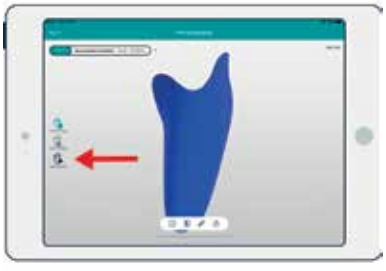
Understanding a static acquisition

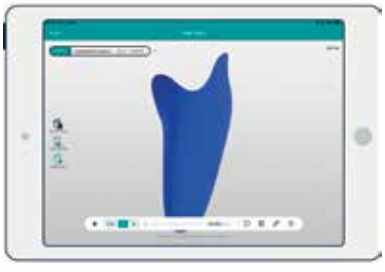
When reviewing a static acquisition, all the data interpretation principles from the "Basic Principles of INSIGHT's Pressure Data" apply.

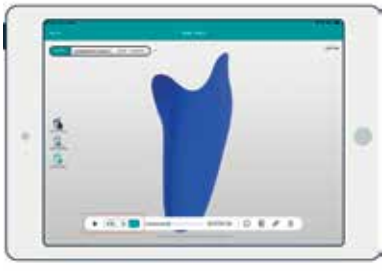
After selecting a static acquisition, on the lateral selector, choose the "Unprocessed" view.

In this view, the exact same data recorded during the acquisition can be played back, as if replaying a video. However, the view is fully interactive: the 3D model can be rotated or zoomed-in to analyse specific pressure spots or patterns.

This recording can be played back at slower/faster speeds.





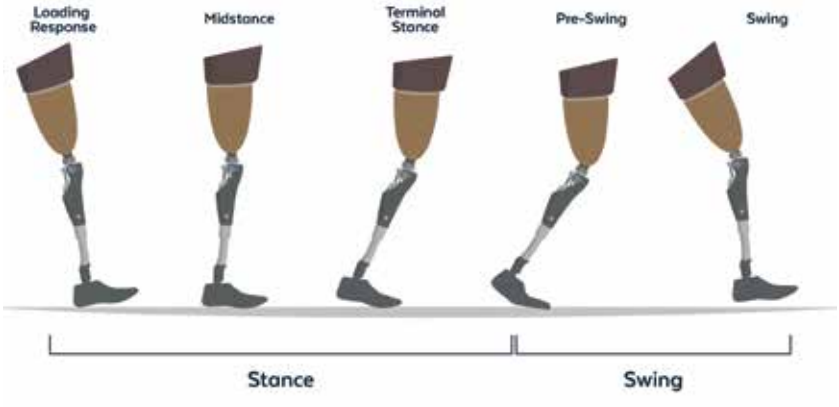


Understanding a dynamic acquisition

In a dynamic acquisition, additional data about the patient's gait is collected by the INSIGHT Wearable and the INSIGHT Wearable IMU. That data is used to generate new views over the collected pressure data.

The INSIGHT system automatically detects patient's strides and turns. Inside each stride, it detects 5 gait phases:

- **Loading Response:** the earliest stage of the stride, including ground contact at the heel.
- **Midstance:** body weight is fully over the amputated limb, with the foot in full ground contact.
- **Terminal Stance:** the body starts to be propelled forward as the heel leaves the ground.
- **Pre-Swing:** the latest stage of the stance, with the foot of the amputated limb barely touching the ground.
- **Swing:** the latest stage of the stride. The limb swings with no contact with the ground. Lasts until heel strike of the following stride.



The gait information is merged with the pressure data, yielding three views of the socket's pressure map designed to support all kinds of clinical analyses. In three different ways, they transform the measured data into clear visuals that will ultimately lead to actionable knowledge:

"Processed": In this view, the pressure in each gait stage of a stride is averaged, generating a pressure map for each phase. This map captures the overall trends of pressure distribution in each gait phase.

Processed

"Average Stride": In this view, data from all strides (excluding turns and stopping/starting strides) is averaged into one single virtual stride. Using the controls, a prosthetist can smoothly navigate through this stride and see how pressure distributes itself as the patient tackles the different challenges of gait. Additionally, the relative duration of each phase, often an indicator with clinical value, is shown.

Average stride

"Unprocessed": In this view, the entire dynamic acquisition can be reviewed. A small 3D human mimics the patient's actions (walking, stopping or turning), providing context to the pressure patterns being shown.

Unprocessed data

This recording can be played back at slower/faster speeds.

SYMBOLS

Warning/Caution

Flammable if damaged

Fragile

Manufacturer

Prescription Only

Magnetic Resonance Unsafe

Date of Manufacture

Warning: Laser beam

Batteries

Serial Number

Electrostatic sensitive devices

Direct Current

Catalogue Number

Classification Type BF Applied Part

The CE Mark means the device has met all essential requirements of European Medical Device Directive 93/42/EEC

Consult Instructions for Use

Fuse

AC Current Input

Separate Collection for Electric and Electronic Equipment

CONTENTS

INSIGHT Wearable

INSIGHT Sensors

INSIGHT App

First Use

FIRST USE

INSIGHT System's first-time use should always be accompanied by one of Adapttech or Cascade's qualified personnel. This is to help you understand the system, clear away any doubts and make sure there are no faults or warnings unattended.

The technician will help you create the respective Users, giving them their respective permissions and seamless integration of INSIGHT with your day-to-day workflow.

Before using INSIGHT for the first time, a list of all Clinics and Users (Prosthetists, Physiotherapists, etc.) should be created in order to correctly complete the Database and start using INSIGHT.

Inspect packaging before use and if damaged, please contact our technical department at support@adapttech.eu or via post at:

ADAPTTECH LTD.
Institute of Translational Medicine (ITM)
Heritage Building
Mindelsohn Way
B15 2TH Birmingham, UK.

If you have any questions regarding first-time use, please contact our technical department at support@adapttech.eu.

WARNINGS AND CAUTIONS

WARNING A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury

CAUTION A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or in damage to the equipment or other property

SAFETY CONSIDERATIONS

These Instructions for Use assume a working knowledge of monitoring equipment. To support proper, safe and accurate operation of equipment, read all operating instructions carefully before you use the INSIGHT System.

WARNING The wearable device and any other applied device parts should be removed before patient defibrillation.

WARNING To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use and on equipment labels.

WARNING The components will be serviced and maintained only by Adapttech or Cascade personnel.

WARNING No modification of the equipment is allowed. Modification of this equipment may cause interference with other devices, injury to patient and user including electric shock, burns or death.

COMMON USE

STEP 1

Select the number of INSIGHT Sensors to be used - between 4-12, depending on the socket size and the desired surface coverage.

STEP 2

Inspect strips for damage before use. Apply the strips vertically on the socket without overlapping strips or occluding markers. Leave the connectors hanging free to the outside of the socket.

STEP 3

Place the socket inside the INSIGHT Scanner, with the proximal part facing up.

STEP 4

Press and hold the "Close" button to close the socket holder. The system will stop automatically when in place. The loose connectors of the INSIGHT Sensors should stay clear of the socket holder.

STEP 5

Close the Scanner door. The system only operates when its door is closed, to every step of the process is safe.

STEP 6

Open Adapttech's App and follow the App's user guide.

STEP 7

Tap “Scan” to start acquiring the 3D model of the socket. While the scanning occurs, you can fill in the patient’s information in the tabs “Range of motion”, “Info” and “Photos”.

STEP 8

Once the scan is finished (as indicated by a message in the App), open the door and press and hold the “Open button” to release the socket.

STEP 9

Remove the socket and assemble it back on the prosthesis.

STEP 10

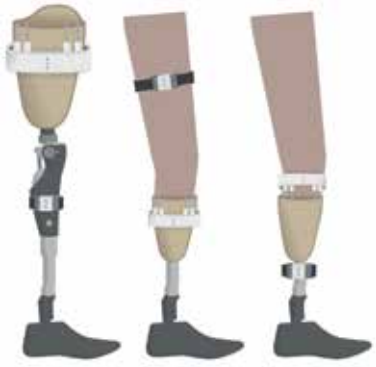
Place the INSIGHT Wearable around the socket. As suggested in the image, the logo should be placed laterally.

STEP 11

Connect the INSIGHT Sensors strips to the INSIGHT Wearable.

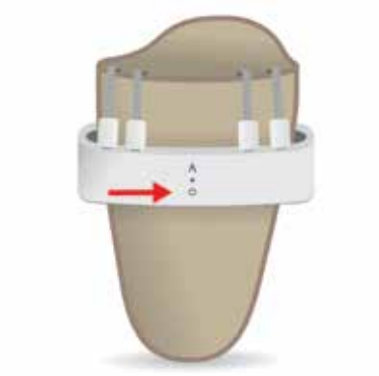
STEP 12

Patient can now wear the prosthesis.



STEP 13

In case of a dynamic analysis (with gait), a second INSIGHT Wearable device, IMU, should be added. The placement depends on the type of amputation, as suggested by the illustration above.



STEP 14

Turn the INSIGHT Wearable(s) device(s) on.

STEP 15

Connect the App with the selected device(s). Follow the App's user guide.

STEP 16

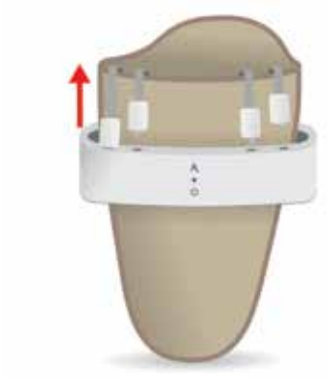
Start the tests. In the case of a static analysis, the patient stands upright and still. In a dynamic analysis, the patient is walking. Results are saved in the App.

STEP 17

After completing your analysis, tap "Save" and conclude the test.

STEP 18

Remove the prosthesis from the patient.



STEP 19

Turn off the device and disconnect the INSIGHT Sensors from the INSIGHT Wearable.

STEP 20

Carefully remove and store the INSIGHT Sensors (after cleaning them according to the instructions on page 88) and the INSIGHT Wearable.

STEP 21

Perform the necessary adjustments to the socket.

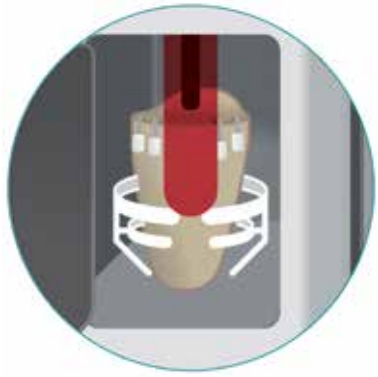
STEP 22

Repeat the process until satisfied with the results.

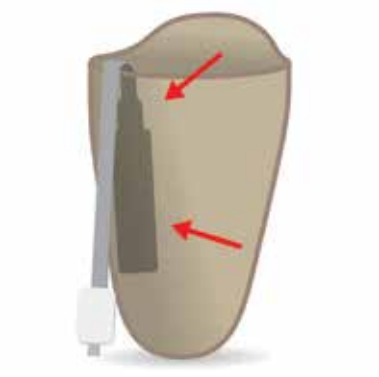
BEFORE USING

Check the socket to scan is within the size limitations of INSIGHT.
Max height: 250mm/9,84in
(for a socket 335mm/13,19in high)
Min height: 55mm/2,17in

Check there are no repeated INSIGHT Sensors

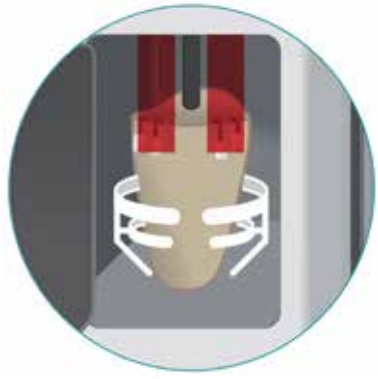


Ensure the optical element has a clear path to the socket's base, avoiding eventual concavities

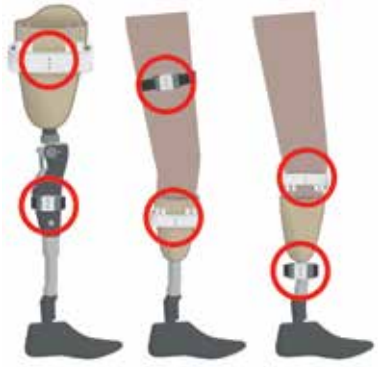


Properly adhere the INSIGHT Sensors (both the part inside and the part outside the socket).

Check INSIGHT Sensors are not overlapping each other



Ensure the socket is correctly positioned on the socket holder:
· Socket is upright and standing on its distal part
· Socket is as centered as possible



Make sure, if you are acquiring gait data, that the Wearables are correctly positioned and a static LED is on.

It's not recommended to scan transparent sockets without applying a scanning spray.

Sockets with low reflective inner surface use as much sensors as possible or add scanning spray to increase reflectivity for a better 3D Model.

INSIGHT Scanner

SAFETY INFORMATION

These Instructions for Use assume a working knowledge of monitoring equipment. To support proper, safe and accurate operation of equipment, read all operating instructions carefully before you use the INSIGHT Scanner device.

Catalogue Number


Warning/Caution

Alternating Current Input 110V-220V at 50 - 60 Hz


This side up


Fragile


Keep away from direct sunlight


Electrostatic sensitive devices

Prescription Only


Keep away from the rain


Separate Collection for Electric and Electronic Equipment


CE mark


Warning: Laser beam


Consult User Guide


Carry cart with wheels

Fuse

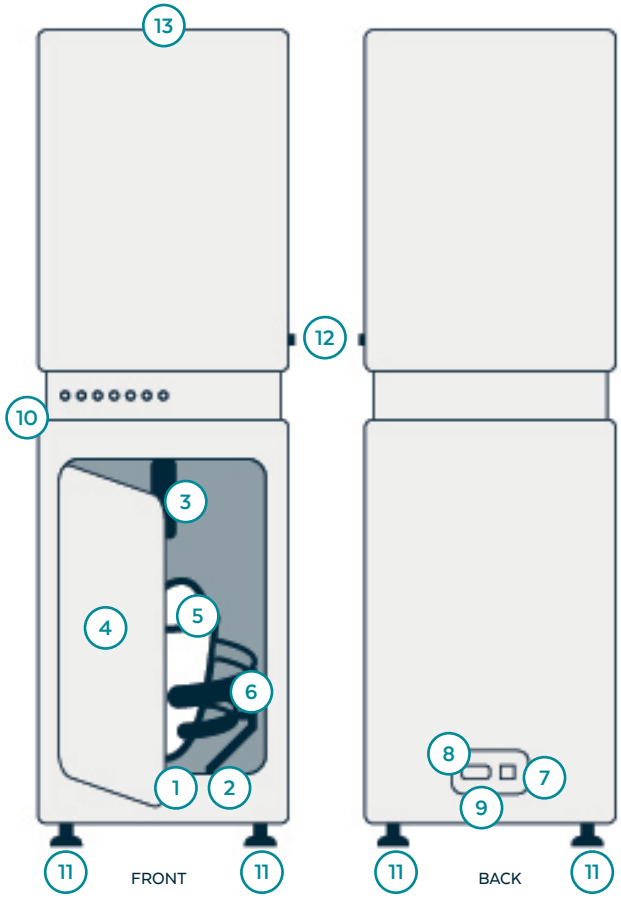

Recycling symbol

To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use and on equipment labels.

The components will be serviced and maintained only by Adapttech or Cascade personnel.

No modification of the equipment is allowed. Modification of this equipment may cause interference with other devices, injury to patient and user including electric shock, burns or death.

KNOW YOUR DEVICE



INSIGHT Scanner

1 Lock Socket - Left Button

2 Release Socket - Right Button

3 Laser and Cameras (Scanner's head)

4 Door

5 Socket

6 Socket Holder

7 Ethernet Cable Socket

8 Power Cable Socket

9 Safety Fuse

10 LEDs

11 Adjustable Scanner Feet

12 Power Switch

13 Manual movement of scanner head knob

Package Contents

1 INSIGHT Scanner

User Guide

Power Cable

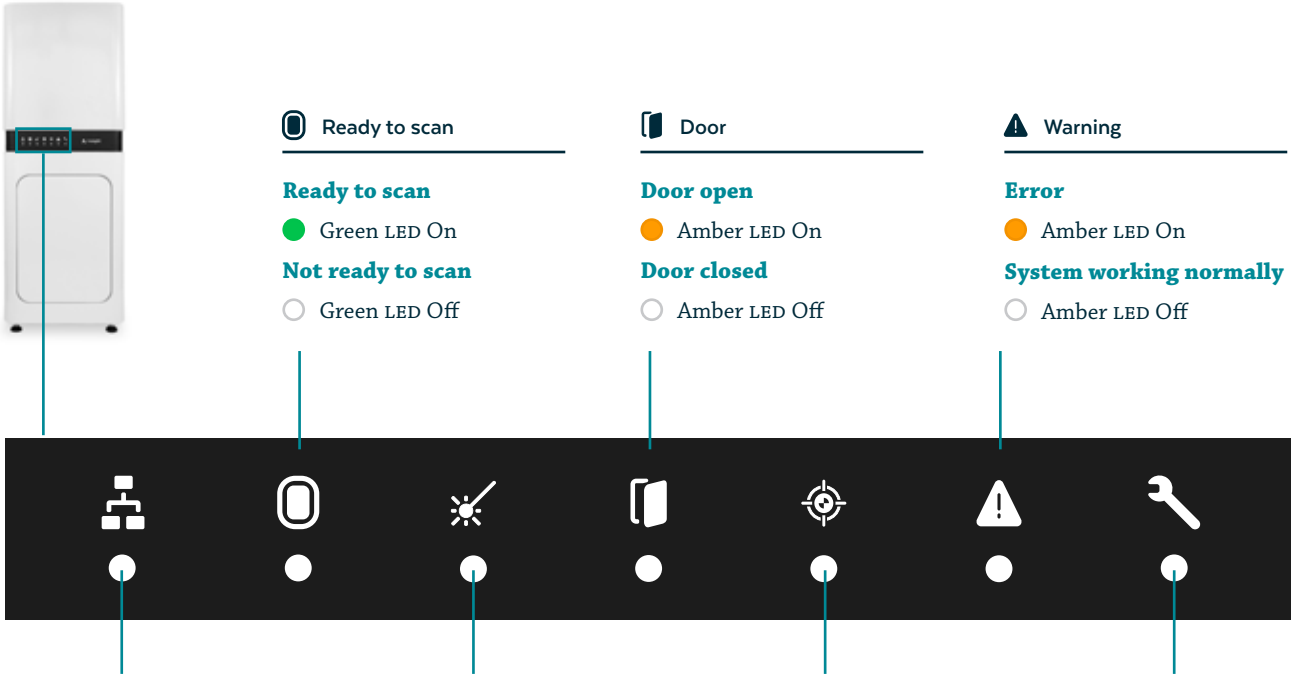
Ethernet Cable

Floor Fastening Kit

LED STATE

Symbols

Close Socket Holder	Ready to scan	Calibration
Open Socket Holder	Scan in progress	Maintenance
Network connection	Door	Warning



Ready to scan

Ready to scan
Green LED On
Not ready to scan
Green LED Off

Door

Door open
Amber LED On
Door closed
Amber LED Off

Warning

Error
Amber LED On
System working normally
Amber LED Off

Network connection

Booting
Blue LED Breathing
Connected
Blue LED On
Disconnected
Blue LED Off

Scan in progress

Scanning
White LED On
Not scanning
White LED Off

Calibration

Calibration Needed
Amber LED On
Scanner calibrated
Amber LED Off

Maintenance

Maintenance required
Red LED On

Contact Adapttech or Cascade to calibrate and service the scanner

FIRST USE

First use of the INSIGHT Scanner shall always be undertaken with support from Adapttech or Cascade. We will help to setup the scanner to ensure that the system is properly calibrated and running correctly.

Inspect packaging and Scanner for damage before use. Report any damage to Adapttech or Cascade before use.

SETUP

> ⚠ If the INSIGHT Scanner suffers any impact or vibration during setup contact Adapttech or Cascade before use.

HOW TO MOVE THE SCANNER

The INSIGHT Scanner should always be moved or adjusted by two or more people and always be placed directly on the ground. Hold by its corner and never on the recess on both sides should be used as a handle.

STEP 1

Look around the room where the INSIGHT Scanner will be placed, and search for the nearest power outlet and Ethernet port (RJ45 socket). The power and Ethernet cable are 2m/78in long.

STEP 2

Place INSIGHT Scanner close to a power outlet, with the door facing front. Please note that 20 cm/8 in of clearance on each side is required to open the Scanner's door

STEP 3

Adjust the height of the scanners feet to keep the weight distributed evenly. Do not over extend them, otherwise they will come loose. If so, thread them in again.

STEP 4

To adjust the height of each leg is important to identify the Safety Nut and the Foot Nut. The Safety Nut will lock and prevent height changes.
The Foot Nut will adjust the overall height of the foot.

STEP 5

Adjusting the INSIGHT Scanner foot the user must unscrew the safety nut with the spanner.

STEP 6

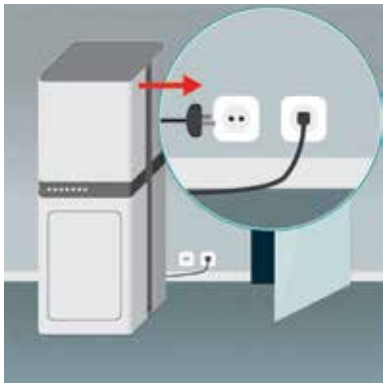
Then screw/unscrew the scanner foot to the desired height.

STEP 7

Adjust height.

STEP 8

Screw the safety nut with the spanner to lock the position.



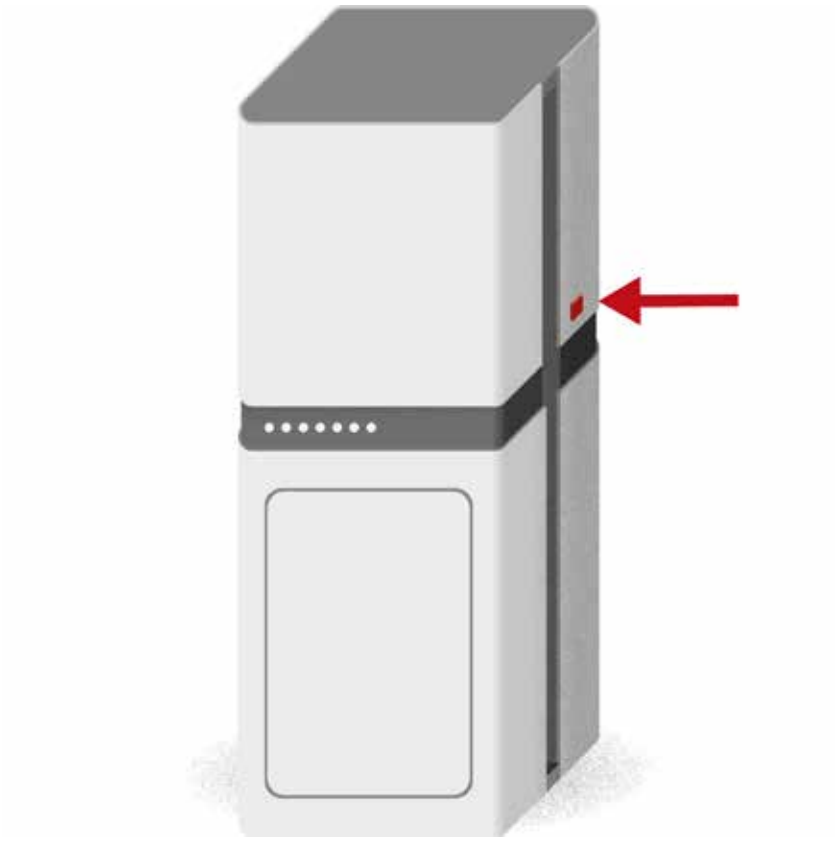
STEP 9

Connect the ethernet cable and power cable.

STEP 10

Press the power switch to turn on the INSIGHT Scanner and it will connect automatically to the network. The scanner is ready to be configured using the INSIGHT App.

POWER ON/OFF



To switch On or Off the scanner, press the red button on the right side of the device.
While the device is on, the power button will be light up.

CLOSE/OPEN SOCKET HOLDER

⚠ The socket holder will stop automatically even if you are pressing the “Open” or “Close” buttons if it finds significant resistance to movement.

⚠ The top of the socket must be above of the highest part of the socket holder.

STEP 1

Open INSIGHT Scanner door.

STEP 2

Press the “Close” button to close the socket holder.

STEP 3

Press the “Open” button to open the socket holder support.

PLACING THE SOCKET INTO THE SCANNER

> ⚠ INSIGHT Scanner contains a Class 2M Laser Product. Do not stare into the beam or view directly with optical instruments

STEP 1

Open INSIGHT Scanner door.

STEP 2

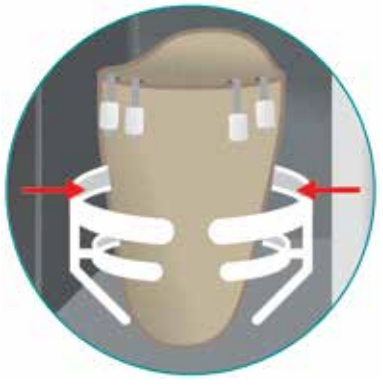
Press on the "Open" button, to open the socket support.

STEP 3

Adjust the gripper's height and place the socket into the scanner, between the supports.

STEP 4

Without letting go of the socket, press the "Close" button, to close the socket support.



STEP 5

Keep pressing until the movement stops and the socket is centered within the scanner shaft.

STEP 6

Close the door by pushing it, until the latch's magnet can hold the door shut.

CONNECTING THE APP TO AN INSIGHT SCANNER - START SCANNING

STEP 1

Select a Patient and tap on the "+" icon to add an new appointment.

STEP 2

Select the type of amputation and tap "Start"

STEP 3

On the 3D Model Screen, tap on the Scan Button.

STEP 4

Select the available scanner and tap "Connect".

STEP 5

The scanner is now scanning the patients socket.

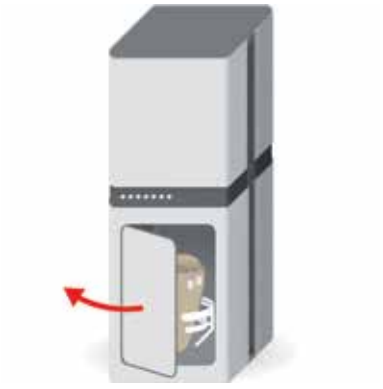
STEP 6

Wait until the 3D Model appears on screen.

REMOVING THE SOCKET

STEP 1

After the scan finishes, the App will show a message indicating that the scan is complete.



STEP 2

Open the INSIGHT Scanner door.

STEP 3

Hold the check socket and press the "Open" button to open the socket support.

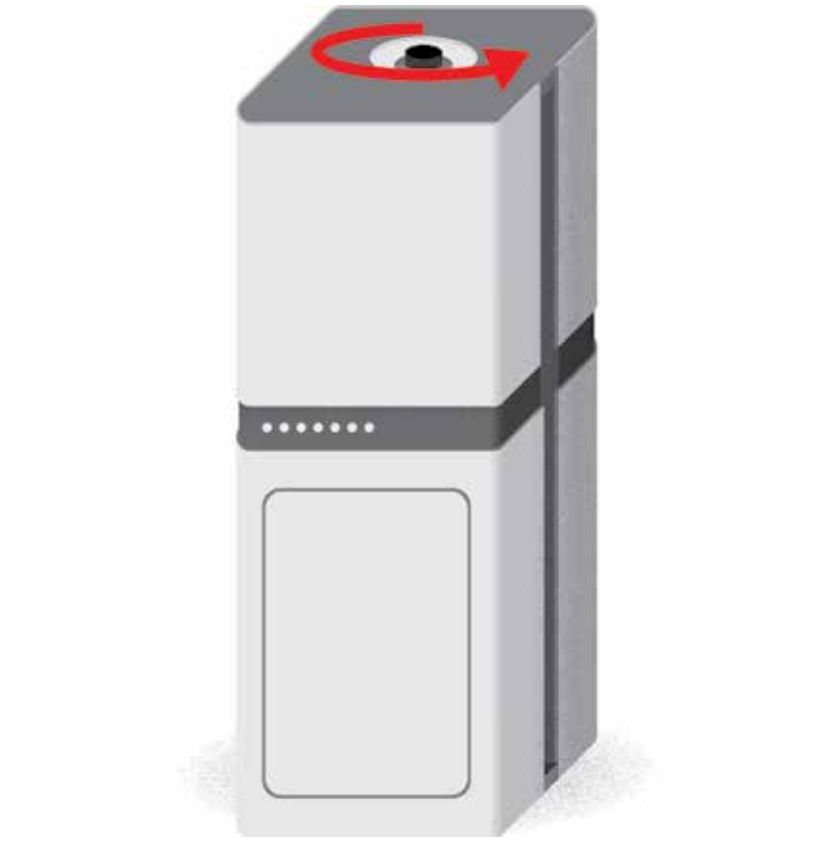
STEP 4

When the socket is loose, carefully remove it out of the Scanner.

STEP 5

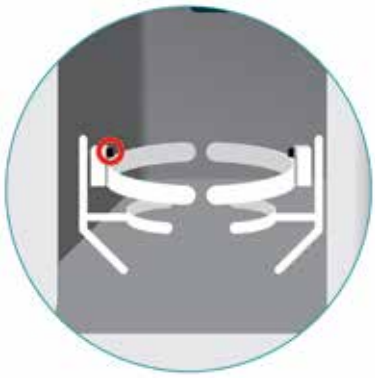
Close the Scanner door.

MANUAL MOVEMENT OF SCANNER HEAD



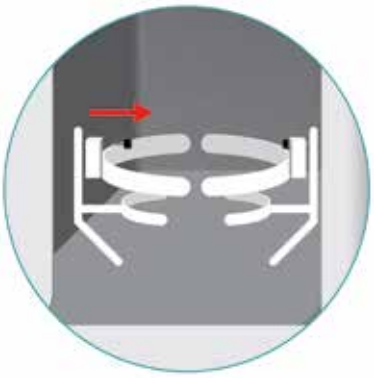
To move the Scanner head, take off the top enclosure by removing the 6 screws with an 2.5mm hex key, then turn the black knob to lift or lower. Turnning the knob clockwise it will raise the Scanner head. Only raise it high enough to safely remove the socket without damaging the Scanner cameras and laser assembly. Elevating it too much may damage the upper limit switch. The procedure will be necessary if there is an power outage, blown fuse, mechanical problem or software failure. If you find any abnormal resistance, please contact Adapttech or Cascade.

SOCKET GRIPPER HEIGHT ADJUSTMENT



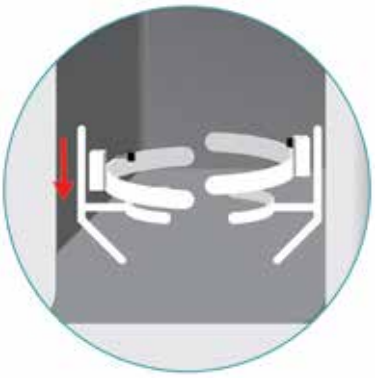
STEP 1

Pull the gripper pin to release the top tweezer.



STEP 2

Slide the tweezer down or up while pulling the pin.



STEP 3

When the tweezer is in place, release the knob. Try to move the knob up and down to make sure the pin is inserted in one of the locating holes.

MAINTENANCE

To clean the outside of INSIGHT Scanner, use a soft moist towel with water or alcohol. You can also clean the socket placement area (inside of the Scanner) the same way.

Do not apply any liquid or cleaning product to the INSIGHT Scanner's cameras and laser.

The INSIGHT Scanner should be cleaned in and out at least once a week.

Always leave INSIGHT Scanner's door closed when not in use.

Avoid dust accumulation inside the scanner.

Store the Scanner in a dry cool place at room temperature with relative humidity between 25-80% (non-condensing) and a temperature of 15-35 °C (59-95 °F).

If the sockets' 3D models are consistently distorted, please contact Adapttech or Cascade technical support.

The INSIGHT Scanner does not require any user maintenance, other than cleaning, and has no serviceable parts. No attempt should be made to open the Scanner with exception to to manually lower or raise the scanner head. In case of INSIGHT Scanner failure or damage contact Adapttech or Cascade.

TROUBLESHOOTING

The INSIGHT Scanner is not recognized by INSIGHT App.

Is the LAN cable connected to the scanner?
Is INSIGHT Scanner connected to the power outlet?
Is INSIGHT Scanner connected to the Internet?
Are both the INSIGHT Scanner and INSIGHT App on the same network?

The INSIGHT Scanner does not create a 3D model.

Is INSIGHT Scanner connected to the Internet?
Is the LAN cable plugged in?
Has your license expired?
Is the socket's inner surface reflective enough?

Sensors and 3D model do not match.

Have the INSIGHT Sensors been placed on top of each other?
Used two or more sensors with the same color markers?
Used more than maximum allowed strips (12)?

The Scanner's cameras are inside the socket so I cannot remove it.

On powering the Scanner the cameras will reset their position, allowing the socket to be removed. In case you do not have power to turn it on, the manual handle can be used to raise the cameras.

WARNING

- Do not attempt to open the scanner door when INSIGHT Scanner is in operation. This will automatically turn off the laser source and cancel the ongoing scan operation.
- Clean inside of scanner and socket support between patients to avoid risk of cross-contamination using a soft moist towel with water or alcohol.
- Do not place your hand or fingers on any moving part.
- Contains parts and assemblies susceptible to damage by electrostatic discharge (ESD).
- Scanner dropped/impact can cause a decalibration of scanner generating incorrect 3D models.
- Scanning operation will not start before closing the door.
- If the location of the sensors moves after the scan, you will need to scan again to update the location of the sensors.

TECHNICAL SPECIFICATIONS

Product Category

Electronic Laser Scanner

Product Description

INSIGHT Scanner is a laser scanner that scans the concave inner surface of a prostetic socket, creates a 3D model of it and automatically detects the position of the sensors.

MODEL

ATT0001

MEASUREMENT METHOD

Class 2M Laser - DIN EN 60825-1:2014

2 RGB Cameras

MEASUREMENT RANGE

54 to 655 mm (depth from standby position of the optical component)

ACCURACY

< 2 mm (at 200 mm)

SOCKET SIZE RESTRICTIONS

MINIMUM DIAMETER

55m

MAXIMUM DIAMETER

250mm

(for a socket of height 335mm)

CONNECTIVITY

Ethernet

PROTECTION AGAINST ELECTRIC SHOCK

Conductive parts are grounded and all conductors are surrounded by the enclosure

POWER

100-240 v AC 50/60Hz

CURRENT RATING

1.5A

FUSE RATING

2x Fuses 3A 250VAC (5x20 mm)

OPERATING CONDITIONS

HUMIDITY

25% to 80% RH (non condensing)

TEMPERATURE

15°C(59 °F) to 35°C (95° F)

TRANSPORTING/STORAGE CONDITIONS

The equipment should be stored out of direct sunlight and in a dry place

WEIGHT

100.4 kg / 221 pounds

ENCLOSURE MATERIAL

ABS Plastic

DIMENSIONS

WIDTH

637 mm / 25 in

HEIGHT

1710 mm / 67.3 in

DEPTH

550 mm / 21.6 in

SHELF LIFE

1 year

Notes

- These specifications are subject to change without notice.
- The device AC adapter is protected against solid foreign objects of 12 mm diameter and greater such as a finger.
- This device fulfils the provisions of Regulation (EU) 2017/745 by May 2020.
- This electronic laser scanner is designed according to the European Standard EN 60825 and the US Standard IEC 60825, and IEC 61010-1.
- This Adapttech product is produced under the strict quality system of ADAPTTECH LTD.

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Electromagnetic Emissions

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

Emissions	Compliance According to	Electromagnetic Environment
Radiofrequency (RF) emissions	Group 1	The Scanner only uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted RF emission, AC mains port + telecom lines **EN 61326-1** **EN 55011** **ANSI C63-4**	Class B	The Scanner is suitable for use in all establishments other than domestic and those directly connected to a public low voltage power supply network which supplies buildings used for domestic purposes.
Radiated RF emission **(EN55011:2009 + A1, CISPR11: 2009 + A1)**	Class A	
Harmonic Distortion **(EN61000-3-2 + A1+ A2, IEC61000-3-2 +A1 + A2)**	Class A	
Voltage Fluctuations and Flicker **(EN61000-3-3:2008, IEC61000-3-3:2008)**	Complies	

Electromagnetic Immunity

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

⚠ Adapttech's Scanner shall not be used close to RF communications equipment emitting at Very High Frequency Range (e.g. amateur radio, global position system, air traffic). Otherwise, it could result in degradation of the performance of this equipment could result.

Immunity Against	Compliance Level	Electromagnetic Environment
Electrostatic Discharge, ESD **(EN 61000-4-2:2009,** **IEC 61000-4-2:2008)**	Contact: 4kV Air: 8kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% so that electro-static charges are at suitable levels
Radiated RF EM fields **(EN61000-4-3:2006+A1+A2,** **IEC61000-4-3:2006+A1+A2)**	3V/m 80-1000MHz 3V/m 1400-2000MHz 1V/m 2000-2700 MHz 1kHz 80% AM	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrostatic Fast Transients/ Bursts **(EN61000-4-4:2004+A1,** **IEC61000-4-4:2004+A1)**	AC/DC Power Lines: ±1kV Signal: ±0.5kV	
Surges **(EN61000-4-5:2006,** **IEC61000-4-5:2005)**	AC Power lines ± 1 kV line to earth ± 0.5 kV line to line	
Conducted RF immunity **(EN61000-4-6:2009,** **IEC61000-4-6:2008)**	AC Power Lines 3Vrms 0.15-80 MHz 1kHz 80% AM Signal: ±0.5kV 3Vrms 0.15-80 MHz 1kHz 80% AM	
Voltage Dips and Interrupts **(EN61000-4-11:2004,** **IEC61000-4-11:2004)**	0 % residual for ±0,5 cycles 0 % residual for 1 cycles 70 % residual for 25 cycles 0 % residual for 250 cycles	

Guidance and manufacturer's declaration - electromagnetic immunity

The Adapttech's Scanner system is intended for use in the electromagnetic environment specified below. The customer or the user of the Adapttech's Scanner system should assure that it is used in such an environment.

Immunity Test	IEC 61326-1 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF **EN61000-4-6: 2009** **IEC 61000-4-6: 2008**	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Adapttech's INSIGHT Scanner system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF **EN61000-4-3: 2006 +A1+A2** **IEC 61000-4-3: 2006 +A1+A2**	3V/m 80-1000MHz 3V/m 1400-2000MHz 1V/m 2000-2700 MHz	3V/m 3V/m 1V/m	Recommended separation distance d=1.2√P 150 kHz to 80 MHz d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[1] should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. The ISM (industrial, scientific, and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Adapttech's INSIGHT Scanner system is used exceeds the applicable RF compliance level above, the Adapttech's INSIGHT Scanner system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Adapttech's INSIGHT Scanner system.

3. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. Radiated RF is expected to interfere with wearable system between 85 and 120 MHz

Recommended separation distances between portable and mobile RF communications equipment and Adapttech's Scanner.

The Adapttech's Scanner is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Adapttech's Scanner can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Adapttech's Scanner as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 khz to 80 mhz d=1.2√p	80 mhz to 800 mhz d=1.2√p	800 mhz to 2,5 ghz d=2.3√p
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2 The ism (industrial, scientific, and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.** **NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			

LASER SPECIFICATIONS

The laser is located at the bottom end of the shaft inside the Scanner.

The laser is not intended to be controlled in any way by the user. This is automatically controlled whenever the Scanner is operating. The only access point to the laser is by opening the door of the Scanner. However, whenever this happens the laser is automatically turned off.

LASER CLASS

Class 2M under DIN EN 60825-1

WAVELENGTH

520 nm

MAXIMUM POWER OUTPUT

3 mW

PATTERN

Solid Line Circle (45°)

PULSE PATTERN

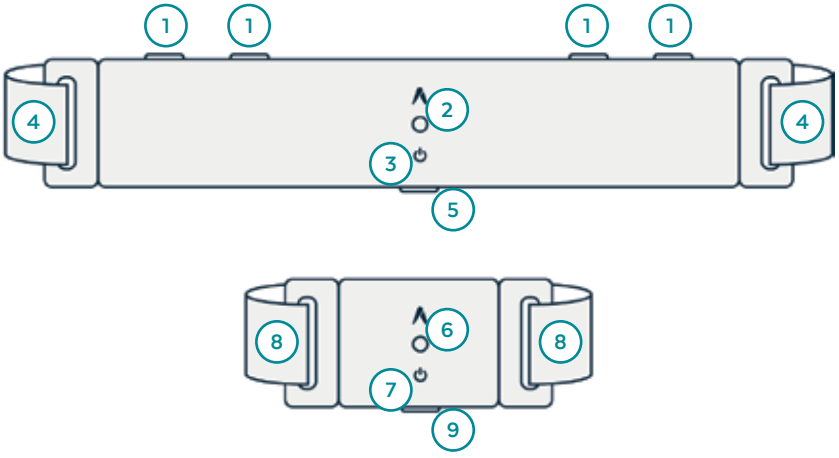
Continuous

LASER RADIATION

Do not stare into the beam or view directly with optical instruments

INSIGHT Wearable

KNOW YOUR DEVICE



INSIGHT Wearable

1 Sensor Strip Connector
2 Status/ID LED
3 Power Button
4 Elastic Band
5 Charger Connector

INSIGHT Wearable IMU

6 LED
7 Power Button
8 Elastic Band
9 Charger Connector

Package Contents

1 INSIGHT Wearable
1 INSIGHT Wearable IMU
User Guide
INSIGHT Wearable Power Supply
Micro-USB Cable

INSIGHT Wearable and INSIGHT Wearable IMU LED'S Meaning

LED Next to Power Button

Searching for Connection

Blinking Blue

Connected to INSIGHT App

Fixed Color

LED Next to Micro-USB

While Charging

Fixed Amber

Charged

No Light

SAFETY INFORMATION

These Instructions for Use assume a working knowledge of monitoring equipment. To support proper, safe and accurate operation of equipment, read all operating instructions carefully before you use the INSIGHT Wearable device.

Catalogue Number

Warning/Caution

Direct Current 3.7V - 5V

Bluetooth® Low Energy

Fragile

Classification Type BF Applied Part

Magnetic Resonance Unsafe

Prescription Only

Batteries

Separate Collection for Electric and Electronic Equipment

CE mark

Flammable if damaged

Consult User Guide

> The wearable device and any other applied device parts should be removed before patient defibrillation.

> To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use and on equipment labels.

> The components will be serviced and maintained only by Adapttech or Cascade personnel.

> No modification of the equipment is allowed. Modification of this equipment may cause interference with other devices, injury to patient and user including electric shock, burns or death.

> Only connect to the devices USB ports the provided cables and sensors.

FIRST USE

INSIGHT System's first-time use should always be done accompanied by one of Adapttech or Cascade qualified personnel. We will help you to setup the device to ensure that every system is properly calibrated and running correctly.

SETUP

STEP 1

Remove all components from the box: the Wearable, Wearable IMU the Micro-USB cable and the power adapter for charging.

STEP 2

Use the Micro-USB cable included and connect the wall plug to charge the device. This action will charge the device.

STEP 3

After the device has been charged, disconnect the Micro-USB cable from the INSIGHT Wearable and Wearable IMU and turn the devices on by pressing its button for 1 second.

STEP 4

A white blinking LED means that the device is ready to pair with the INSIGHT App.

STEP 5

After using it, turn off the device by pressing the power button again.

CHANGING DEVICES COLOR ID

STEP 1

On the Home Screen, tap on the Settings button.

STEP 2

Select Color Update option, and select the desired wearable.

STEP 3

Select the color and press Change Color.

STEP 4

The wearable device has been assigned with the new Color ID.

CHARGING

The INSIGHT Wearable must be fully charged before first use. It will take approximately 2h15 for the Wearable and 2h for the IMU, to fully charge the battery using the Micro-USB cable and wall plug provided.

To charge the battery of INSIGHT Wearable, disconnect any INSIGHT Sensor, connect the Micro-USB Cable into the correct port at the bottom of the device. When the amber LED lights up, it has started charging. Once it is fully charged, the LED will switch off.

With a full charge the device can run up to 8-18 hours continuously.

When the INSIGHT Wearable charger is connected to power, its green LED lights up.

⚠ Do not use INSIGHT Wearable or INSIGHT Wearable IMU while charging.

PLACING INSIGHT WEARABLE ONTO THE PATIENT

STEP 1

Choose an INSIGHT Wearable device with a size adequate to the socket in analysis.

STEP 2

Press on the plastic lock button to open the elastic band.

STEP 3

Place the device on the side or in front of the socket of the patient.

STEP 4

Close the plastic lock and adjust the elastic to tighten the grip.

STEP 5

Place the IMU Case (below or above the knee) on the same leg that the device is attached and tighten the elastic for grip.

STEP 6

Place the socket onto the patient.

STARTING ACQUISITION

STEP 1

Place INSIGHT Wearable onto the patient.

STEP 2

Connect INSIGHT Sensors to INSIGHT Wearable.

STEP 3

Turn on the device by clicking on the button. A color LED will start blinking.

STEP 4

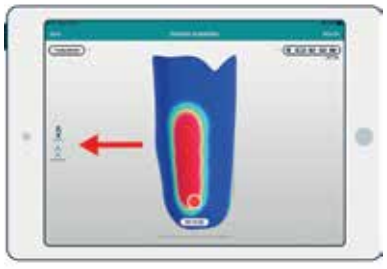
On the INSIGHT App, after scanning the socket, tap on “Gather Data”.

STEP 5

Select the desired INSIGHT Wearable from the list (the ID and color on the device’s label matches the ID and color on the list).

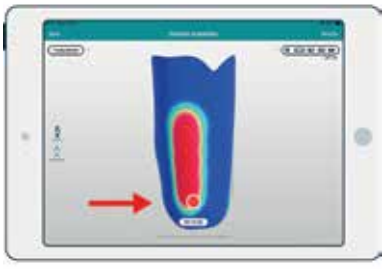
STEP 6

If you wish to make a dynamic acquisition, two Wearables are required. Tap “Connect”on the ones you wish to use for the acquisition.



STEP 7

On the Acquisition screen, select the type of test: either Static or Dynamic (see page 132).

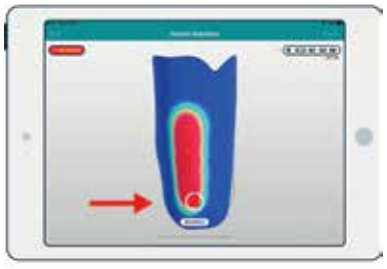


STEP 8

Tap Record (Red Button).

STEP 9

Recording started. Live pressure distributions over the socket are being provided.



STEP 10

When enough data has been gathered (30 seconds for a static test, 1 minute / 30 strides for a dynamic one), stop recording.

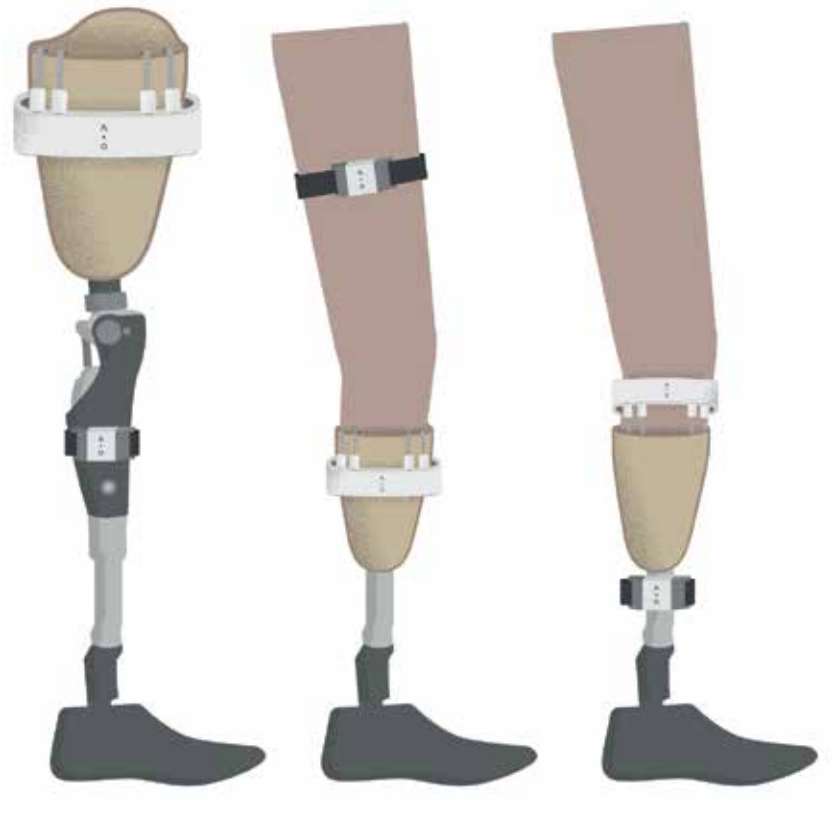
STEP 11

Give the recording a recognizable name.

STEP 12

Tap “Save”.

PLACING INSIGHT WEARABLE IMU



The placement of the INSIGHT Wearable IMU changes with the type of amputation of the patient. If the amputation is above the knee, the IMU is placed below the knee (in the pylon). If the amputation is below the knee, the IMU is placed above the knee. In both cases, the logo should be orientated laterally.

CONNECTING THE WEARABLE TO THE APP

STEP 1

On the INSIGHT App, after scanning the socket, tap on “Gather Data”.

STEP 2

Turn on the INSIGHT Wearable devices and look for their Color ID

STEP 3

Select the desired devices from the list (the Color ID on the device matches the Color ID on the list).

STEP 4

If you wish to make a dynamic acquisition, two Wearables are required. Tap “Connect”on the ones you wish to use for the acquisition.

STEP 4

The devices, when connected, will switch to the same color.

CONNECTING SENSORS

STEP 1

After the sensors are placed in the socket, place INSIGHT Wearable on the check socket.

STEP 2

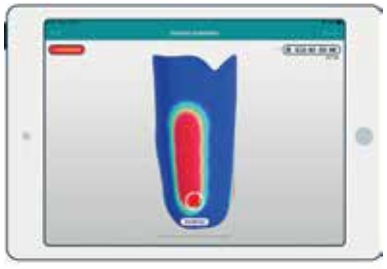
Connect the INSIGHT Sensors to the top side of the INSIGHT Wearable. There is no fixed order or required orientation in the connections. The Sensors will briefly flash amber when successfully connected.

STEP 3

After all sensors are connected to the device, start gathering data.

DISCONNECTING SENSORS

> ⚠ If and INSIGHT Sensor is disconnected during the acquisition, the value for the pressure will be 0.



STEP 1

Finish the Recording.

STEP 2

Turn off INSIGHT Wearable.

STEP 3

Disconnect the INSIGHT Sensors from the INSIGHT Wearable, as suggested in the image.

STEP 4

Remove the INSIGHT Wearable and, if needed, clean it.

MAINTENANCE

Clean the INSIGHT Wearable and Wearable IMU with a soft moist towel with water or alcohol.

INSIGHT Wearable and Wearable IMU should be cleaned after every patient.

Avoid any hard impact on the equipment.

Store the device in a dry cool place at room temperature.
Do not store INSIGHT Wearable and Wearable IMU with a completely drained battery.

INSIGHT Wearable should be stored on a flat surface, at room temperature and humidity. It should be protected from dust or accidental drops or falls.

INSIGHT Wearable and Wearable IMU does not require any user maintenance, other than cleaning, and has no serviceable parts. No attempt should be made to open the Wearable or the Wearable IMU.

TROUBLESHOOTING

INSIGHT Wearable or INSIGHT Wearable IMU is not recognized by INSIGHT App?

Is INSIGHT Wearable switched on?

Is INSIGHT Wearable's battery charged?

Is the INSIGHT Wearable within range of the INSIGHT App (10m)?

INSIGHT Wearable or INSIGHT Wearable IMU doesn't switch on?

Does INSIGHT Wearable or INSIGHT Wearable IMU have the battery charged?

Have you tried to connect to the power charger?

WARNING

- Wearable and Wearable IMU devices drop can damage the electronic circuitry making the wearable device malfunction.
- Wearable and Wearable IMU devices not attached correctly can cause wrong data.
- A Wearable and Wearable IMU devices not fully charged may fail due to low battery earlier than expected causing unreliable/missing data.
- Placing a very tight Wearable device and Wearable IMU to the patient can cause a pressure injury onto the patient.
- Wearable and Wearable IMU devices not being cleaned and dried as specified may cause transfer of infection between patients.
- Wearable and Wearable IMU devices being immersed in a liquid will damage the devices

TECHNICAL SPECIFICATIONS

Product Category

Wearable Pressure Measurement Unit

Product Description

INSIGHT Wearable is a wearable sensorized system that dynamically gathers biodata, regardless of the patient's activities, which helps identify the problematic points that affect the socket fitting. This wearable system is composed of INSIGHT Sensors, INSIGHT wearable main unit and INSIGHT Wearable IMU. INSIGHT Sensors will connect to INSIGHT wearable main unit which collects the data acquired by the pressure sensors on the INSIGHT sensor strips.

MODEL

ATT0002; ATT0003; ATT0004; ATT0006

MEASUREMENT METHOD

2x IMU and Pressure Sensors

CONNECTIVITY

Micro-USB

RATING

5V DC

POWER SUPPLY

5VDC AC adapter w/ current output up to 1500 mA

POWER SOURCE

1 Li-Poly battery @ 4.2V

WEARABLE

650 mAh

IMU

500 mAh

BATTERY LIFE CYCLE

approx. 500 cycles

BATTERY LIFE

WEARABLE

8h to 18h

IMU

~21h

CHARGING TIME

WEARABLE

2h15

IMU

2h

OPERATING CONDITIONS

CHARGING

+10°C (50°F) to +35°C (95°F)

OPERATION

-10°C (14°F) to +35°C (95°F)

ATMOSPHERIC PRESSURE RANGE

70,0 kPa to 106,0 kPa

HUMIDITY

45% to 85% RH

TRANSPORTING/STORAGE CONDITIONS

Battery > 70% charged

WEARABLE WEIGHT

256 g (small)

320 g (medium)

384 g (large)

EXTERIOR MATERIAL

ABS Plastic

Fabric (99%PES 1%EA)

ENCLOSURE MATERIAL

Medical Grade Silicone

DIMENSIONS (SMALL)

WIDTH

155 mm / 6.1 in

HEIGHT

50 mm/ 1.97 in

DEPTH

27 mm / 1 in

DIMENSIONS (MEDIUM)

WIDTH

290 mm / 11.4 in

HEIGHT

50 mm/ 1.97 in

DEPTH

27 mm / 1 in

DIMENSIONS (LARGE)

WIDTH

395 mm / 15.5 in

HEIGHT

50 mm/ 1.97 in

DEPTH

27 mm / 1 in

SHELF LIFE

1 YEAR

@ -20°C (-4°F) to 30°C (86°F) with battery >70% charged

3 MONTHS

@ -20°C (-4°F) to 45°C (113°F) with battery > 70% charged

1 MONTH

@ -20°C (-4°F) to 60°C (140°F) with battery > 70% charged

Notes

- These specifications are subject to change without notice.
- The device AC adapter is protected against solid foreign objects of 12 mm diameter and greater such as a finger.
- This device fulfils the provisions of Regulation (EU) 2017/745 by May 2020
- This device is designed according to the US Standard es 60601-1.
- This Adapttech product is produced under the strict quality system of ADAPTTECH LTD.

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Electromagnetic Emissions

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

Emissions	Compliance According to	Electromagnetic Environment
Radiofrequency (RF) emissions **CISPR 11**	Group 1	The wearable system only uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted rf emission **(EN55011:2009 + A1)** **CISPR 11** **in charging mode**	Class B	The wearable system is suitable for use in all establishments including those directly connected to a public low voltage power supply network.
Radiated RF emission **(EN55011:2009 + A1)** in battery and charging mode	Class B	
Harmonic Distortion **(EN61000-3-2 + A1+ A2)** in charging mode	Class A	
Voltage Fluctuations and Flicker **(EN61000-3-3:2013)** in charging mode	Complies	

Electromagnetic Immunity

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

> ⚠ Adapttech's wearable system (INSIGHT Wearable, Wearable IMU and Sensor) shall not be used close to RF communications equipment emitting at Very High Frequency Range (e.g. amateur radio, global position system, air traffic). Otherwise, degradation of the performance of this equipment could result.

Immunity Against	Compliance Level	Electromagnetic Environment
Electrostatic Discharge, ESD **(EN 61000-4-2:2009)** in battery and charging mode	Contact: ± 8kV Air: ± 15kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% so that electro-static charges are at suitable levels
Radiated RF EM fields **EN61000-4-3:2006 + A1 + IS1 + A2** in battery and charging mode	3V/m 80-1000MHz 1000-6000MHz 1kHz 80% AM	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment **EN61000-4-3:2006 + A1 + IS1 + A2** in battery and charging mode	As detailed in section 8.10 of standard. Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrostatic Fast Transients/ Bursts **(EN61000-4-4:2012)** In charging mode Surges **(EN61000-4-5:2012)** In charging mode Conducted RF immunity **(EN61000-4-6:2014)** In charging mode	AC and DC Power Lines: ± 2kV Signal: ± 1kV 100 kHz repetition frequency ± 1 kV line to line 3Vrms (6Vrms in ISM bands) 0.15-80 MHz 1kHz 80% AM	
Voltage Dips and Interrupts **(EN61000-4-11:2004)** In charging mode	0 % UT ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT ; 1 cycle and 70 % UT ; 25/30 cycles Single phase: at 0° 0 % UT ; 250/300 cycle	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity

The Adapttech's wearable system is intended for use in the electromagnetic environment specified below. The customer or the user of the Adapttech's wearable system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF **IEC 61000-4-6**	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands[1]	3V 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the Adapttech's wearable system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance d=1.2√P 150 kHz to 80 MHz d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[2] should be less than the compliance level in each frequency range. [3] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. The ISM (industrial, scientific, and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.
2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Adapttech's wearable system is used exceeds the applicable RF compliance level above, the Adapttech's wearable system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Adapttech's wearable system.
3. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. Radiated RF is expected to interfere with wearable system between 85 and 120 MHz.

Recommended separation distances between portable and mobile RF communications equipment and Adapttech's wearable system (INSIGHT Wearable, Wearable IMU and Sensors).

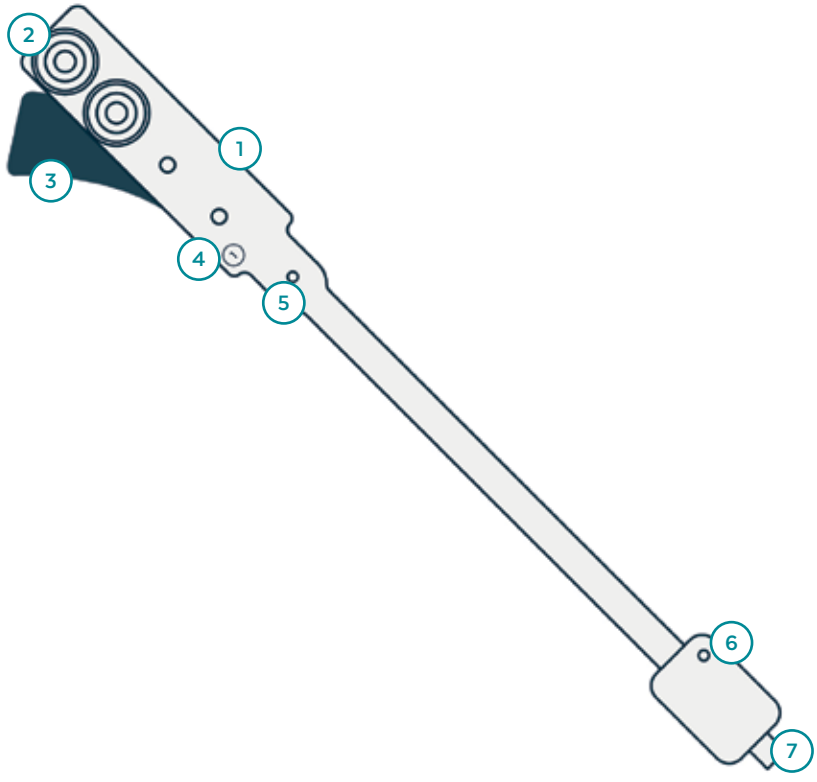
The Adapttech's wearable system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Adapttech's wearable system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Adapttech's wearable system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 hz to 80 mhz	80 mhz to 800 mhz	800 mhz to 2,5 ghz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2 The ism (industrial, scientific, and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.** **NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			

INSIGHT Sensors

KNOW YOUR DEVICE

⚠ INSIGHT Sensors can only be used in 8 separate data acquisition sessions.



INSIGHT Sensor

1 Sensor Strip
2 Marker
3 Re-usable Adhesive
4 Sensor ID
5 Vent
6 Enclosure
7 Connector

Package Contents

16 Sensors
User Guide

LED'S Meaning (Sensor enclosure)

Discard Sensor Strip

Continously blinking

Connected to INSIGHT Wearable

1 Second Amber

SAFETY INFORMATION

INSIGHT Sensors may come into physical contact with the patient's residual limb in order to gather pressure data and are therefore considered Type BF applied parts.

These Instructions for Use assume a working knowledge of monitoring equipment. To support proper, safe and accurate operation of equipment, read all operating instructions carefully before you use the INSIGHT Sensors.

REF
Catalogue Number

Warning/Caution

Fragile

Classification Type BF Applied Part

MR
Magnetic Resonance Unsafe

Rx only
Prescription Only

CE
ce mark

Separate Collection for Electric and Electronic Equipment

Consult User Guide

IF DAMAGED
Flammable if damaged

⚠ The wearable device and any other applied device parts should be removed before patient defibrillation.

⚠ To maintain patient safety, adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use and on equipment labels.

⚠ The components will be serviced and maintained only by Adapttech or Cascade personnel.

⚠ No modification of the equipment is allowed. Modification of this equipment may cause interference with other devices, injury to patient and user including electric shock, burns or death.

FIRST USE

The INSIGHT Sensors do not require any first use support procedures from Adapttech or Cascade.

⚠ Do not use the sensors on damaged skin or open wounds.

SETUP

Before use, check that INSIGHT Sensor is not creased or fully/partially torn and has no stains or marks over the region of colored markers which may compromise their visibility

STEP 1

Remove the INSIGHT Sensors from the packaging.

STEP 2

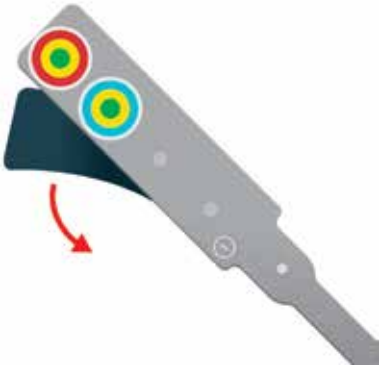
Use alcohol with cotton or a disposable towel to disinfect the sensors. They are now ready to use.

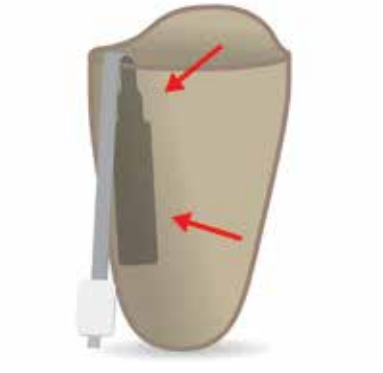
PLACING INSIGHT SENSORS IN THE SOCKET

⚠ Do not use the sensors on damaged skin or open wounds

⚠ Do not place Sensors over socket valves or threaded holes.

⚠ Do not overlap Sensors and do not strain the strip's connection to the connector.





STEP 1

Use alcohol with cotton or a disposable towel to disinfect the sensors.

STEP 2

Remove protective plastic that protects the adhesive.

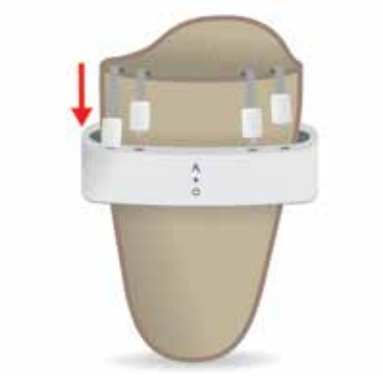
STEP 3

Press from the bottom to the top of Strip to ensure better adhesion. Ensure the colored patterns are not placed over socket concavities. Leave the vent out of the socket.

CONNECTING SENSORS

STEP 1

After the Sensors are placed in the socket, place the INSIGHT Wearable around the outside of it.



STEP 2

Connect the INSIGHT Sensors to the top side of the INSIGHT Wearable. There is no fixed order or required orientation in the connections. A successfully connected Sensor will briefly flash amber upon connection

STEP 3

After all Sensors are connected to the device, start gathering data.

REMOVING INSIGHT SENSORS FROM THE SOCKET

INSIGHT Sensors should be disposed as clinical waste when they are used over 8 times.

STEP 1

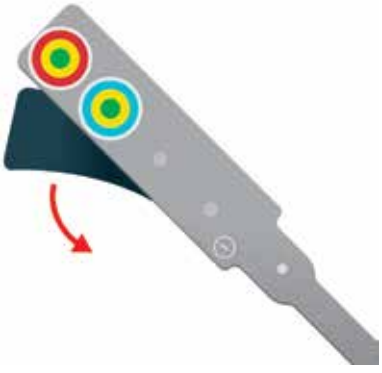
After disconnecting them from the INSIGHT Wearable, carefully peel away the Sensors from the socket's inner surface.

STEP 2

Apply alcohol to cotton cloth or a disposable towel.

STEP 3

Wipe both sides of the INSIGHT Sensor (cleaning will not take away its adhesive properties).



STEP 4

Place the original protective plastic over the adhesive side of the Sensors.

STEP 5

Store the Sensors on a flat surface.

CLEANING SENSORS

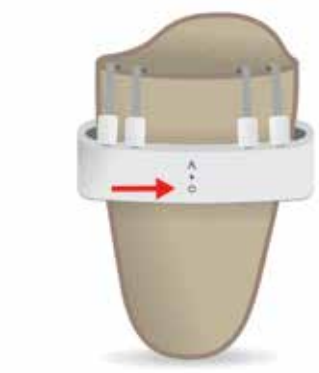
STEP 1

Apply alcohol to cotton cloth or a disposable towel.

STEP 2

Wipe both sides of the INSIGHT Sensor (cleaning will not take away its adhesive properties).

DISCONNECTING SENSORS



STEP 1

Turn off INSIGHT Wearable.

STEP 2

Disconnect the INSIGHT Sensors from the INSIGHT Wearable. Pull from the sensor encolsure

MAINTENANCE

INSIGHT Sensors must be cleaned before and after every usage. This won't damage the materials, which have been tested to withstand this cleaning method.

Avoid cutting or excessively bending the Sensors which could cause fatal damage to the sensors.

Store the sensors flat in a dry cool place at room temperature.

INSIGHT Sensors should be stored with the protective plastic cover over the adhesive, and be placed on a flat surface, at room temperature and humidity. Sensors should be protected from dust and accidental drops or falls.

INSIGHT Sensors do not require any user maintenance, other than cleaning, and has no serviceable parts. No attempt should be made to open INSIGHT Sensors.

WARNING

- Do not place sensors over damaged skin or open wounds
- Electromagnetic interference – Do not use the INSIGHT system near strong electromagnetic fields as they could interfere with the proper operation of the system.
- If sensors are dropped inspect strips and connectors for damage. Damage to sensors can cause incorrect output.
- Sensors placed incorrectly can overlap provoking a mismatch between 3D model and pressure sensors.
- Overlapping the sensors in the socket will provoke a mismatch between 3D model and pressure sensors.
- Ensure sensors are correctly attached to the wearable device. If not correctly plugged in, the sensors will not be recognized by the INSIGHT App.

TROUBLESHOOTING

The INSIGHT Sensors are not recognized by INSIGHT App?

Are INSIGHT Sensors correctly plugged into INSIGHT Wearable?

Have the INSIGHT Sensors exceeded 8 usages - do they flash when connected?

Is there any visible physical damage to the sensors?

The INSIGHT Sensors are not working properly?

Do the INSIGHT Sensors have a fixed amber LED on?

Are the INSIGHT Sensors properly connected to the INSIGHT Wearable?

TECHNICAL SPECIFICATIONS

Product Category

Pressure Measurement Strip

Product Description

INSIGHT Sensors are a consumable part that connects to INSIGHT Wearable and are placed on the inside of the patient socket for pressure monitoring.

MODEL

ATT0007; ATT0008; ATT0009

MEASUREMENT METHOD

Force sensing resistance

MEASUREMENT RANGE

20 mbar to 7 bar

ACCURACY

+/-20%

DURABLE PERIOD

8 Acquisitions

CONNECTIVITY

USB - Note: Plug into INSIGHT Wearable Processing Unit only.

POWER SOURCE

This device is powered by INSIGHT Wearable Processing Unit

SHELF LIFE

2 years

OPERATING CONDITIONS

TEMPERATURE

-20°C (-4°F) to 35°C (95°F)

HUMIDITY

<= 95% RH

ATMOSPHERIC PRESSURE

70,0 kPa to 106,0 kPa

TRANSPORTING/STORAGE CONDITIONS

TEMPERATURE

-40°C(-40°F) to 85°C (185°F)

HUMIDITY

<= 95% RH

WEIGHT

9.88 g

EXTERIOR MATERIAL

Polyurethane Film Coated

ENCLOSURE MATERIAL

Biocompatible Material

Re-usable adhesive

DIMENSIONS (SMALL)

WIDTH

306 mm / 12 in

height

29 mm / 1.14 in

DEPTH

0.3 mm / 0.12 in

DIMENSIONS (MEDIUM)

WIDTH

399 mm / 15.7 in

HEIGHT

29 mm / 1.14 in

DEPTH

0.3 mm / 0.12 in

DIMENSIONS (LARGE)

WIDTH

506 mm / 20 in

HEIGHT

29 mm / 1.14 in

DEPTH

0.3 mm / 0.12 in

Notes

- These specifications are subject to change without notice.
- This device fulfils the provisions of the Medical Device Directive - 93/42/EEC.
- This device is designed according to the Standard IEC 60601-1.
- This Adapttech product is produced under the strict quality system of ADAPTTECH LTD.

adapttech

CE

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

Emissions	Compliance According to	Electromagnetic Environment
Radiofrequency (RF) emissions **CISPR 11**	Group 1	The sensors system only uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted RF emission **(EN55011:2009 + A1)** **CISPR 11** in charging mode	Class B	The wearable system is suitable for use in all establishments including those directly connected to a public low voltage power supply network.
Radiated RF emission **(EN55011:2009 + A1)** in battery and charging mode	Class B	
Harmonic Distortion **(EN61000-3-2 + A1+ A2)** in charging mode	Class A	
Voltage Fluctuations and Flicker **(EN61000-3-3:2013)** in charging mode	Complies	

Electromagnetic Immunity

This equipment is intended for use in the electromagnetic environment specified below. The user of this equipment should assure that it is used in such an environment.

> ⚠ Adapttech's wearable system (INSIGHT Wearable, Wearable IMU and Sensor) shall not be used close to RF communications equipment emitting at Very High Frequency Range (e.g. amateur radio, global position system, air traffic). Otherwise, degradation of the performance of this equipment could result.

Immunity Against	Compliance Level	Electromagnetic Environment
Electrostatic Discharge, ESD **(EN 61000-4-2:2009)** in battery and charging mode	Contact: ± 8kV Air: ± 15kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% so that electro-static charges are at suitable levels
Radiated RF EM fields **EN61000-4-3:2006 + A1 + IS1 + A2** in battery and charging mode	3V/m 80-1000MHz 1000-6000MHz 1kHz 80% AM	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment **EN61000-4-3:2006 + A1 + IS1 + A2** in battery and charging mode	As detailed in section 8.10 of standard. Complies	
Electrostatic Fast Transients/ Bursts **(EN61000-4-4:2012)** In charging mode Surges **(EN61000-4-5:2012)** In charging mode Conducted RF immunity **(EN61000-4-6:2014)** In charging mode	AC and DC Power Lines: ± 2kV Signal: ± 1kV 100 kHz repetition frequency ± 1 kV line to line 3Vrms (6Vrms in ISM bands) 0.15-80 MHz 1kHz 80% AM	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips and Interrupts **(EN61000-4-11:2004)** In charging mode	0 % UT ; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT ; 1 cycle and 70 % UT ; 25/30 cycles Single phase: at 0° 0 % UT ; 250/300 cycle	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity

The Adapttech's wearable system is intended for use in the electromagnetic environment specified below. The customer or the user of the Adapttech's wearable system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF **IEC 61000-4-6**	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands[1]	3V 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the Adapttech's wearable system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance d=1.2√P 150 kHz to 80 MHz d=1.2√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[2] should be less than the compliance level in each frequency range. [3] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

1. The ISM (industrial, scientific, and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.

2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Adapttech's wearable system is used exceeds the applicable RF compliance level above, the Adapttech's wearable system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Adapttech's wearable system.

3. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. Radiated RF is expected to interfere with wearable system between 85 and 120 MHz.

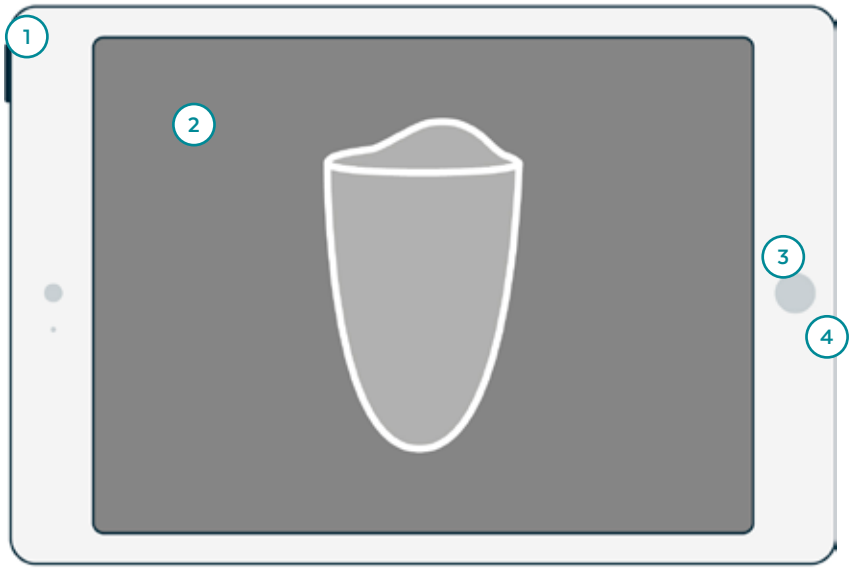
Recommended separation distances between portable and mobile RF communications equipment and Adapttech's wearable system (INSIGHT Wearable, Wearable IMU and Sensors).

The Adapttech's wearable system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Adapttech's wearable system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Adapttech's wearable system as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter		
	150 hz to 80 mhz	80 mhz to 800 mhz	800 mhz to 2,5 ghz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **NOTE 2 The ism (industrial, scientific, and medical) bands between 0.15MHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957MHz to 27.283MHz; and 40.66MHz to 40.70MHz.** **NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			

INSIGHT App

KNOW YOUR DEVICE



INSIGHT App

1 Power Button
2 Touch Screen
3 Home Button
4 Power Connector

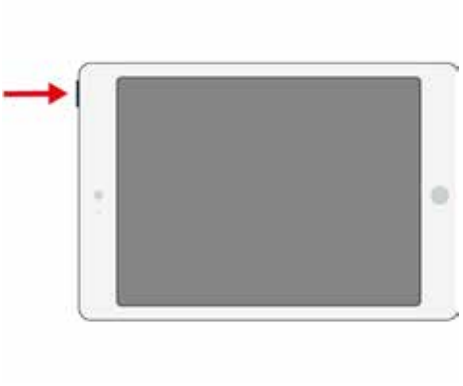
Package Contents

iPad
iPad User Guide
iPad Charger
Pre-installed INSIGHT App

FIRST USE

First time use of the INSIGHT App shall always be undertaken with support from Adapttech or Cascade. We will help to setup the device to ensure that the system is properly calibrated and running correctly.

SETUP



STEP 1

Turn on the iPad.

STEP 2

Connect iPad to the clinic's wireless network.

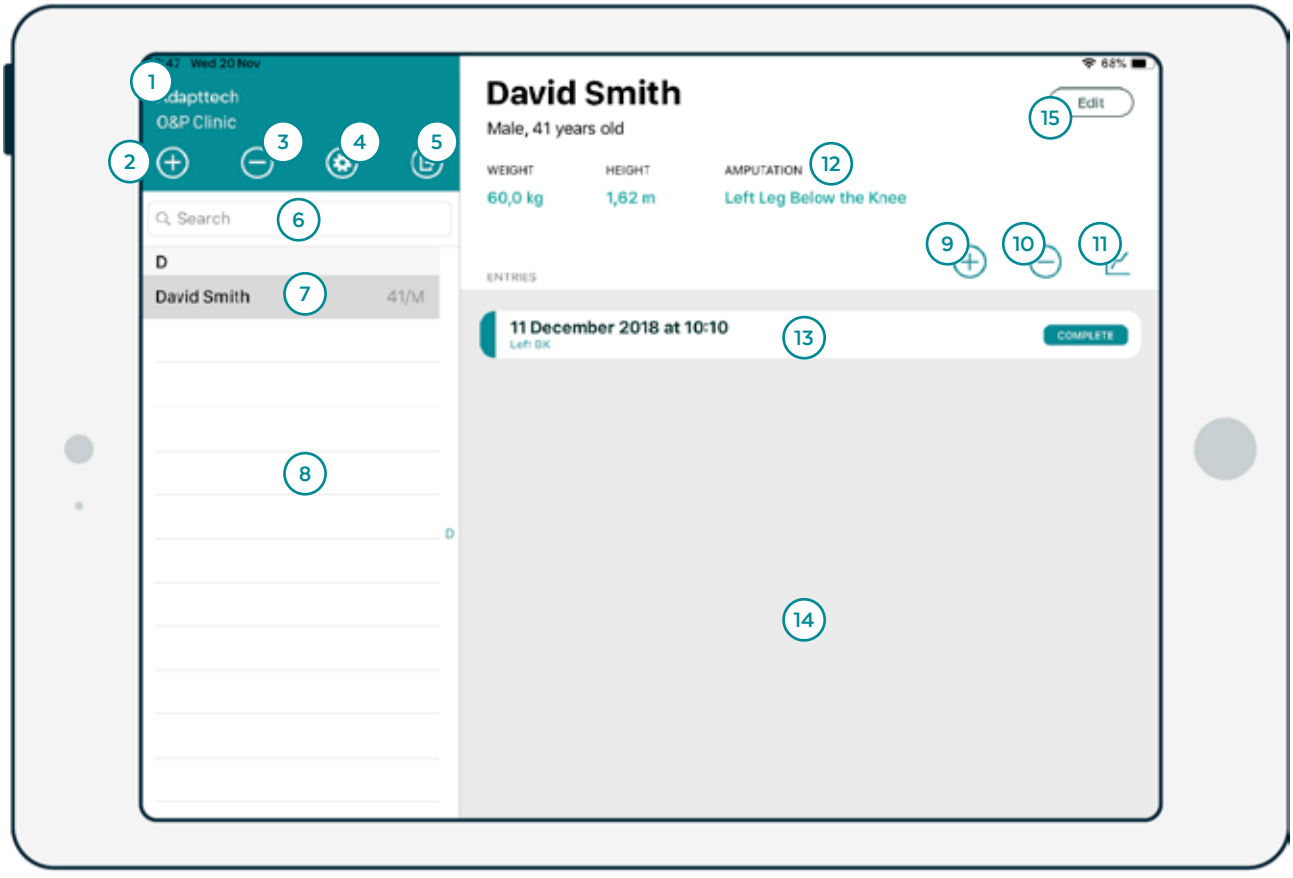
STEP 3

Open INSIGHT App.

STEP 4

Log In with provided user account from Adapttech.

HOME SCREEN



1 **User Name** Displays username

2 **Add New Patient** Add New Patient to the clinic

3 **Delete Patient** Removes patient from list

4 **Settings** Open Settings

5 **Log Out** End open session

6 **Search** Search Patient in the list

7 **Selected Patient** Patient Name/Age/Gender

8 **Patient List** Clinic Patient list displayed

9 **New Entry** Add new entry for selected patient

10 **Delete Entry** Removes entry from list

11 **History** Displays patient history

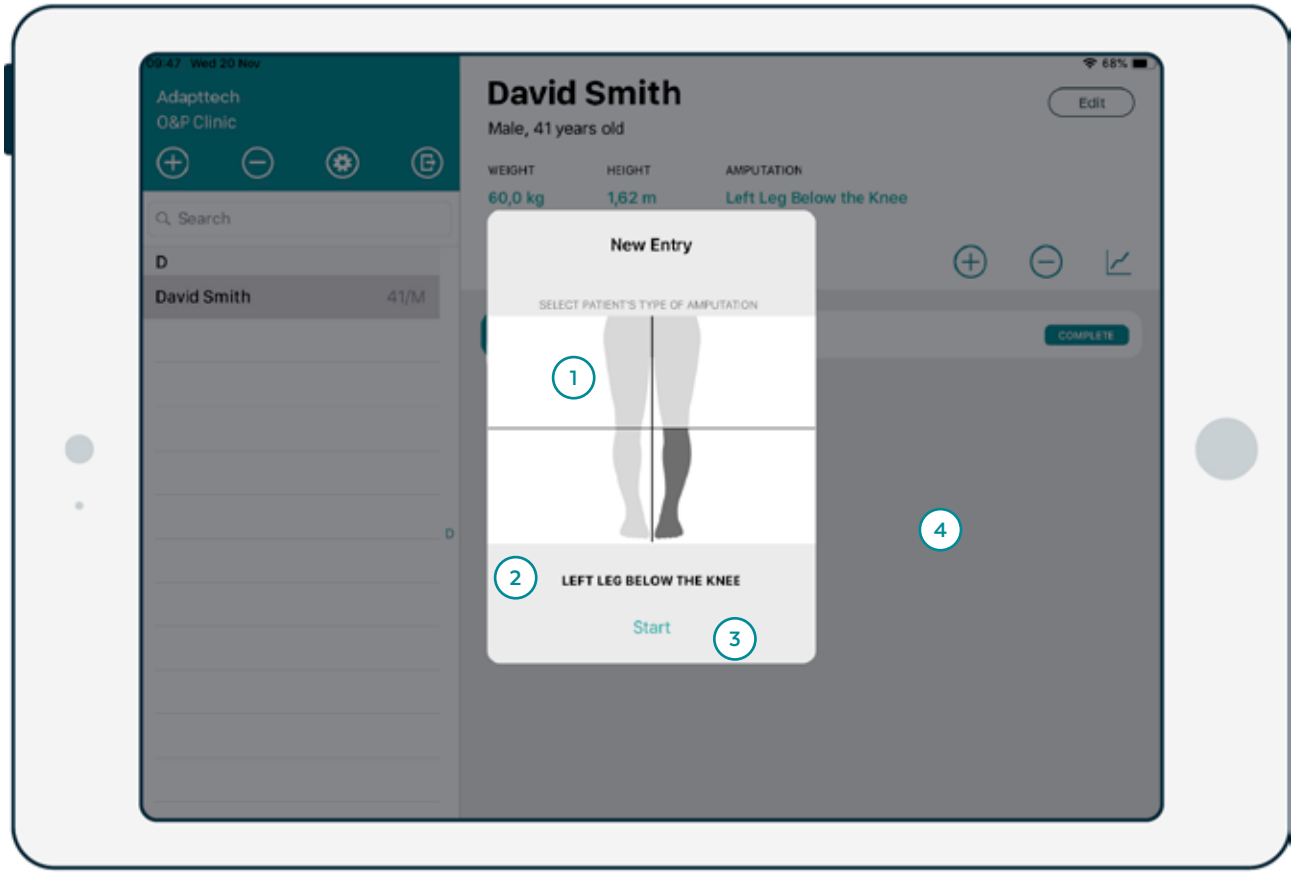
12 **Patient Information** Displays selected patient information

13 **Patient Entry** Available entry for selected patient

14 **Entry List** Selected patient entry list

15 **Edit Patient** Edit patient information

NEW ENTRY SCREEN



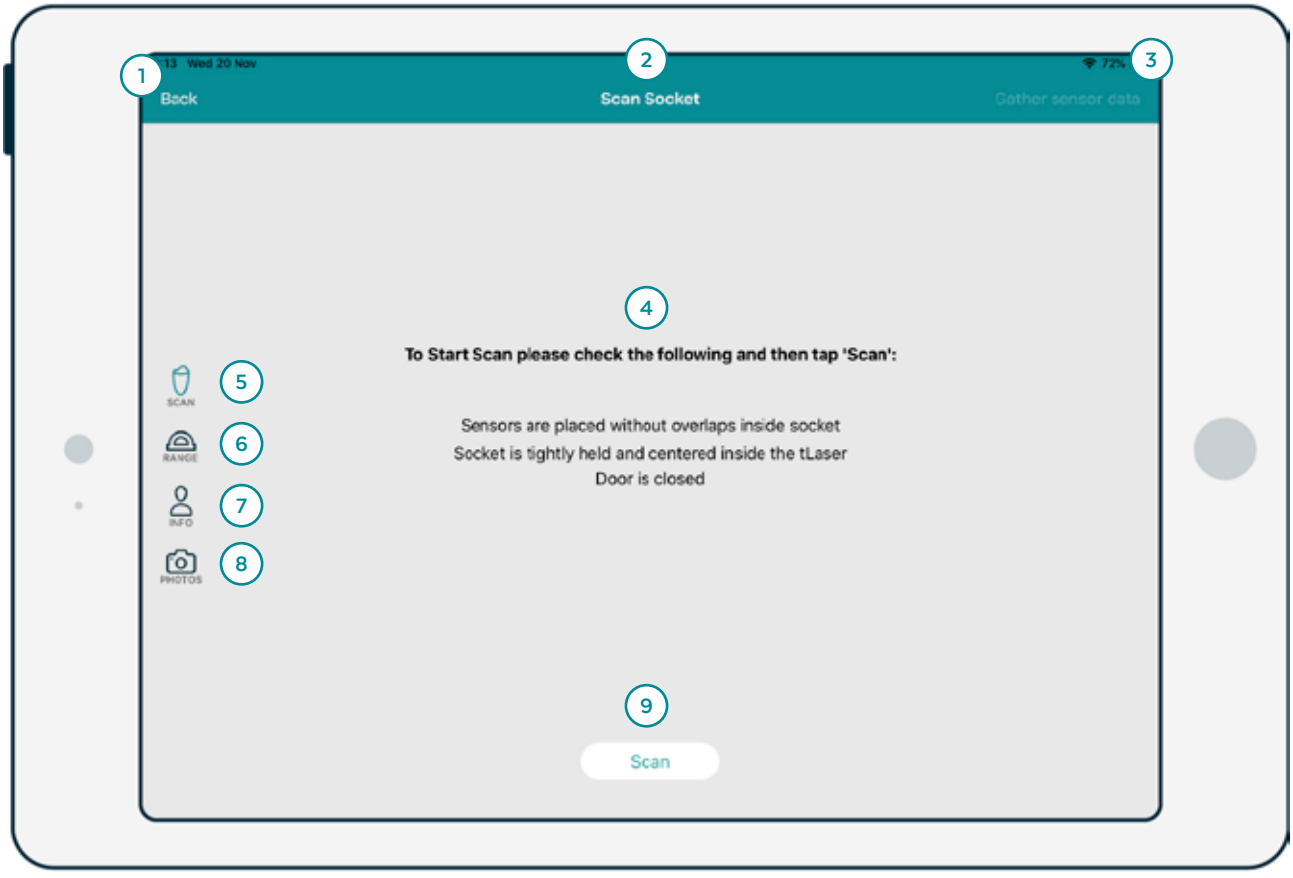
1 **Type of amputation** Selects the type of amputation

2 **Type of amputation indicator** Indicates the type of amputation

3 **Start Button** Start appointment

4 **Back** Cancel the appointment

START SCAN SCREEN



1 **Back** Returns to Home screen

2 **Screen Title** Indicates the current screen

3 **Gather Sensor Data** Goes to Gather Data Screen

4 **Check list/3D Model** Checklist to comply before scanning. After scanning displays the 3D Model

5 **3D Model Page** Manage 3D Model and control Scanner

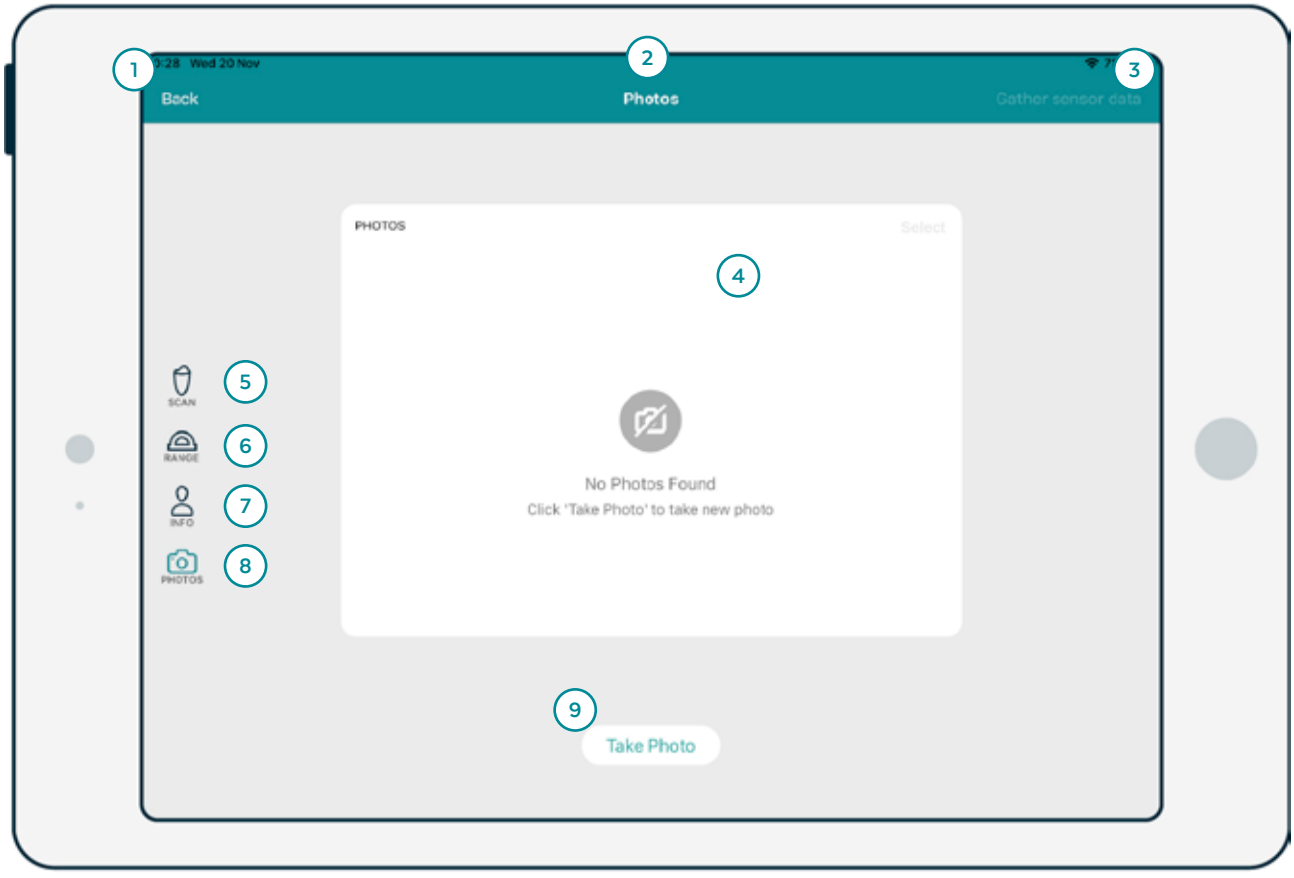
6 **Range of Motion** Goes to Range of Motion screen

7 **Patient Information** Goes to Patient Information screen

8 **Photo** Goes to Photo Screen

9 **Scan** Start scanning socket

PHOTO SCREEN



1 **Back** Returns to Home screen

2 **Screen Title** Indicates the current screen

3 **Gather Sensor Data** Goes to Gather Data Screen (only available after scanning)

4 **Photos** Displays the photos taken

5 **3D Model Page** Manage 3D Model and control Scanner

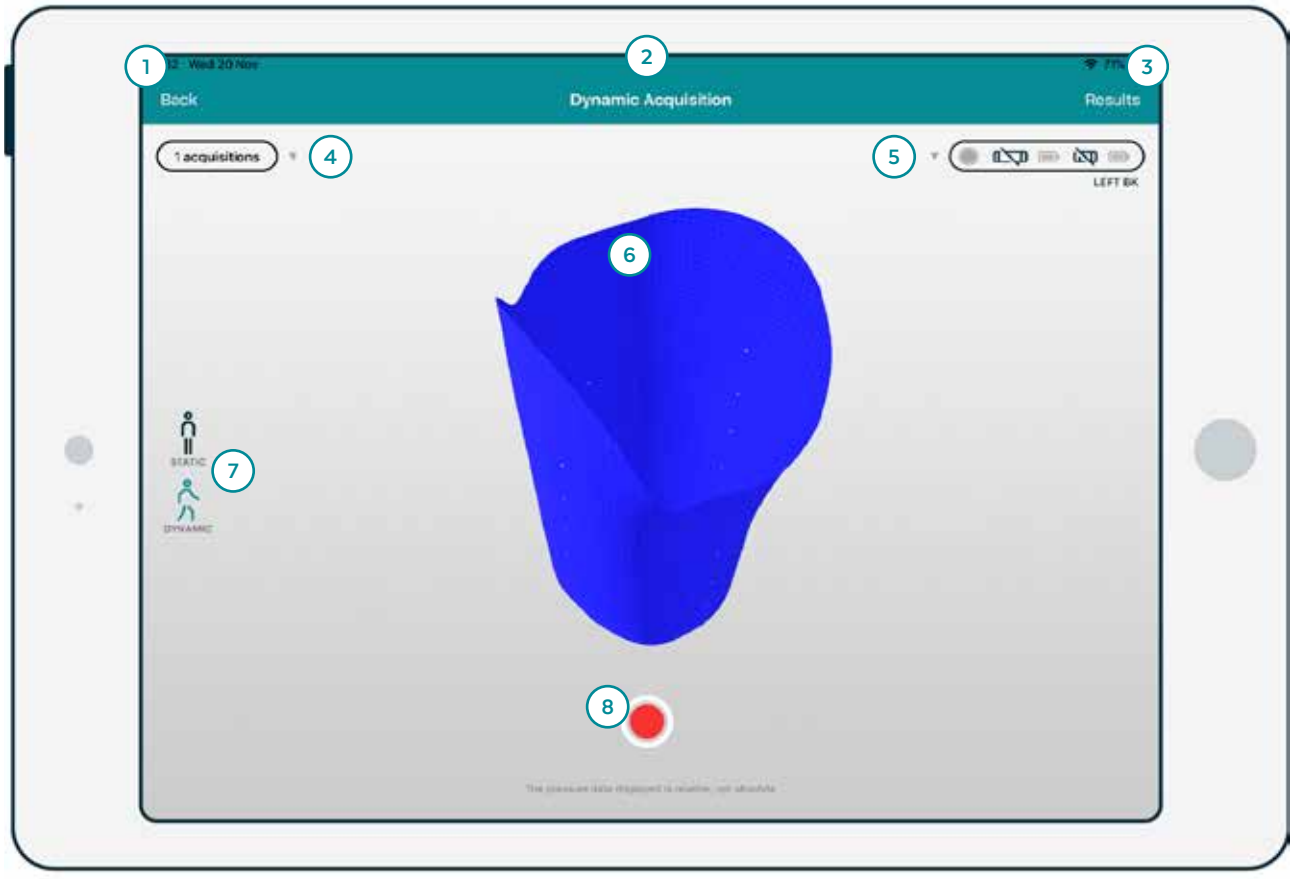
6 **Range of Motion** Goes to Range of Motion screen

7 **Patient Information** Goes to Patient Information screen

8 **Photo** Goes to Photo Screen

9 **Photo** Takes photos

GATHER DATA SCREEN



1 **Back** Returns to New Entry screen

2 **Screen Title** Indicates the current screen

3 **Results** Goes to Review Data Screen

4 **List of Recordings** Stores and Manage the recording made

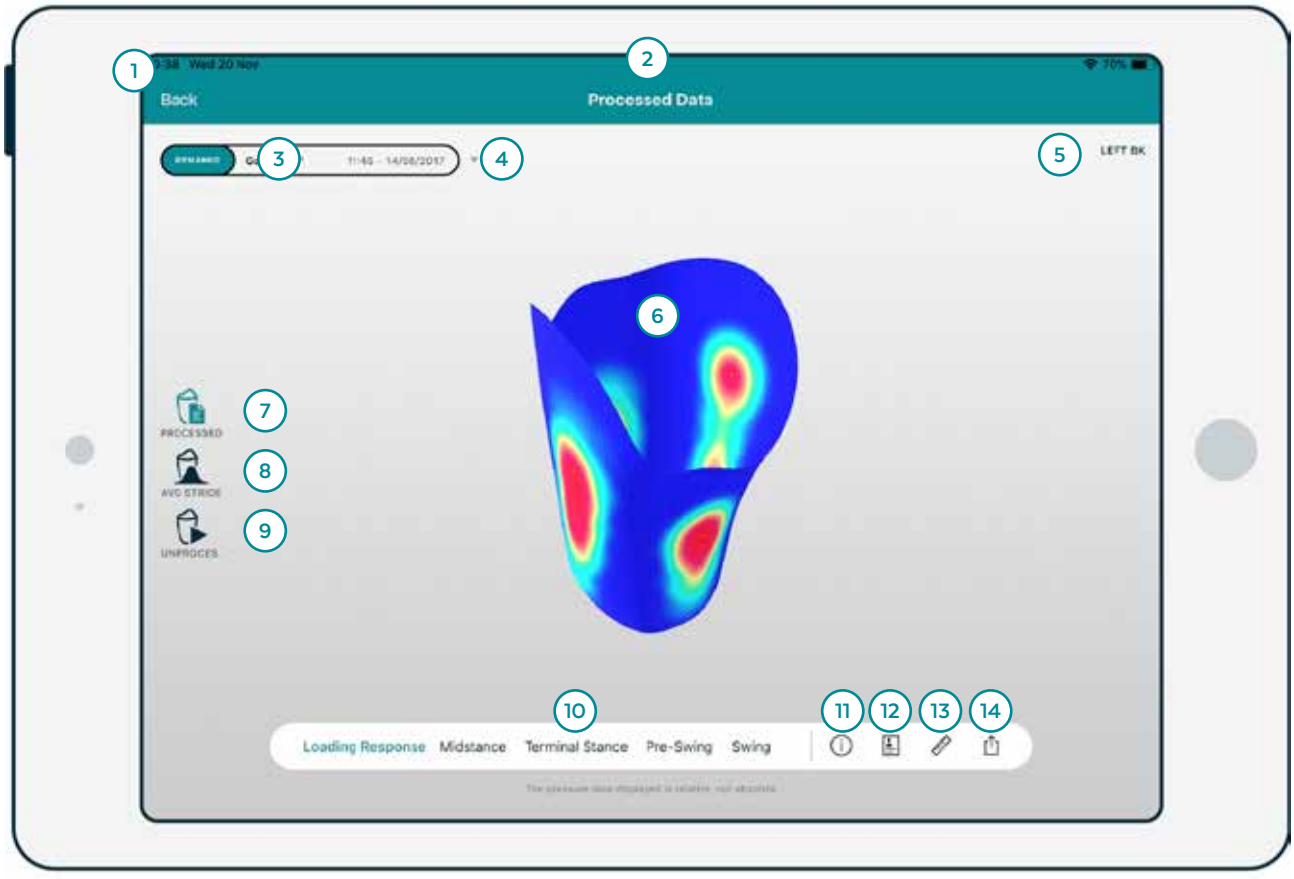
5 **Type of Amputation/Device Connected** Displays type of amputation and manages the connected devices to the App (connection state and battery)

6 **3D Model** 3D Model

7 **Type of Test** Type of test selector

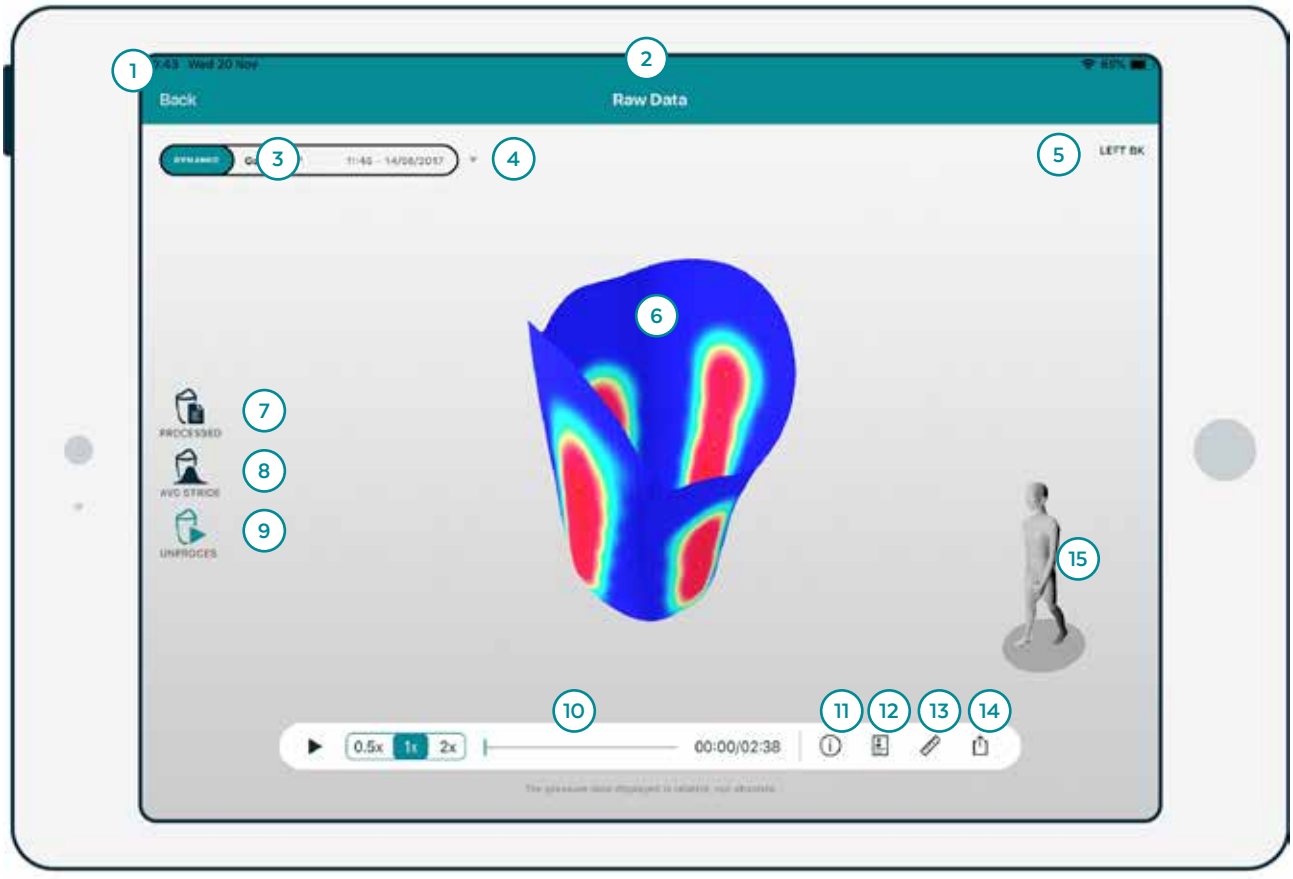
8 **Record Button** Start recording gait and pressure data

REVIEW ENTRY (GAIT) SCREEN



1 **Back** Returns to Gather Data screen
2 **Screen Title** Indicates the current screen
3 **Active Recording** Selected recording
4 **List of Recordings** Displays recordings made
5 **Type of Amputation** Displays type of amputation
6 **3D Model** 3D Model with pressure data
7 **Processed Data** Displays processsed data
8 **Average Stride** Displays the average stride
9 **Unprocessed Data** Displays unprocessed data
10 **Gait Phases** Gait Phase Selector
11 **Patient Information** Displays patient information
12 **Report** Creates a patient report
13 **Measurement Tool** Open Measurement Tool
14 **Export** Export Snapshot or 3D Model

REVIEW ENTRY (REAL TIME) SCREEN



1 **Back** Returns to Gather Data screen

2 **Screen Title** Indicates the current screen

3 **Active Recording** Selected recording

4 **List of Recordings** Displays recordings made

5 **Type of Amputation** Displays type of amputation

6 **3D Model** 3D Model with pressure data

7 **Processed Data** Displays processsed data

8 **Average Stride** Displays the average stride

9 **Unprocessed Data** Displays unprocessed data

10 **Unprocessed Data Controls** Play, Playack speed and timeline

11 **Patient Information** Displays patient information

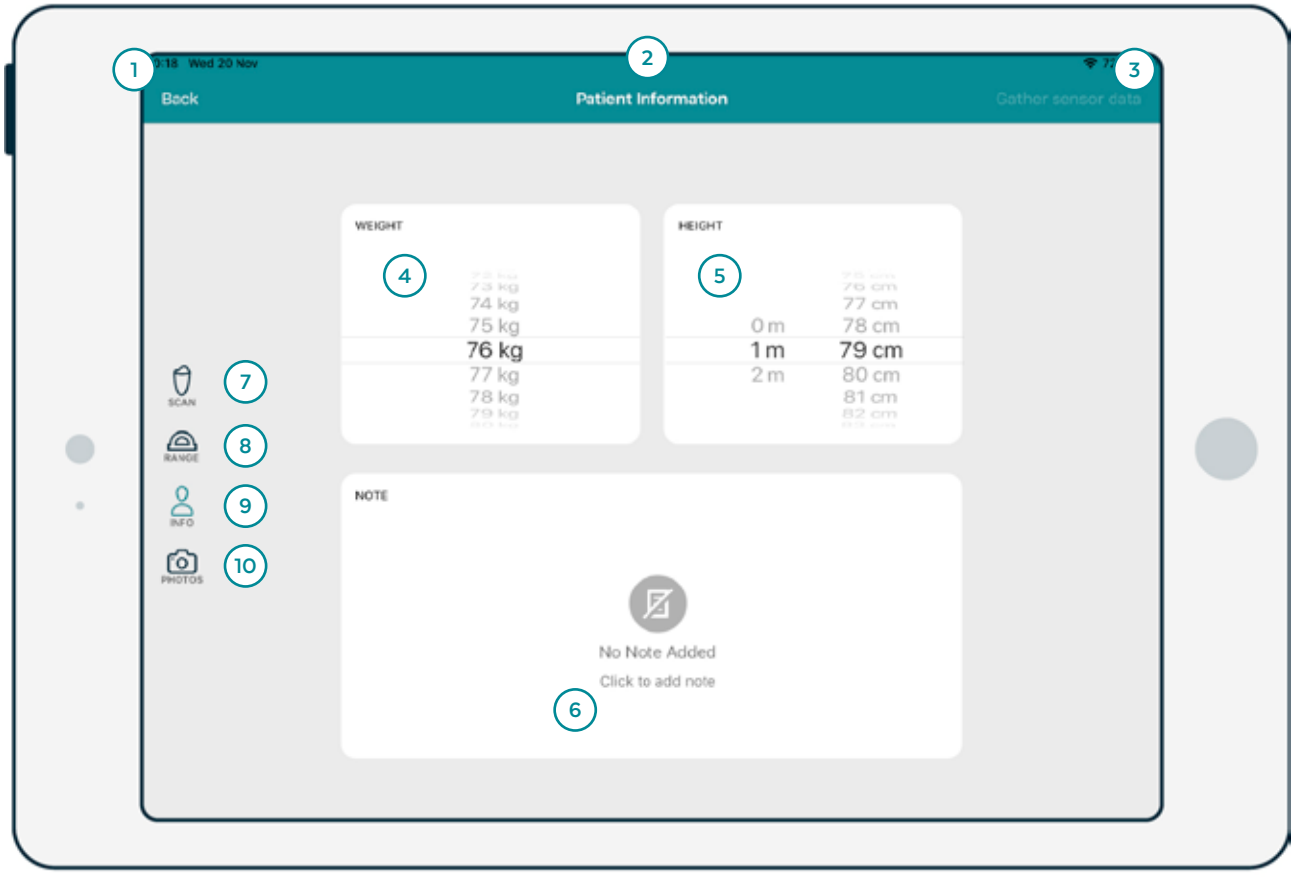
12 **Report** Creates a patient report

13 **Measurement Tool** Open Measurement Tool

14 **Export** Export Snapshot or 3D Model

15 **Gait Phase** 3D Model that indicates gait phases

PATIENT INFORMATION SCREEN



1 **Back** Returns to Home screen

2 **Screen Title** Indicates the current screen

3 **Gather Sensor Data** Goes to Gather Data Screen

4 **Weight** Select patient weight

5 **Height** Select patient height

6 **Note** Add/Read notes

7 **3D Model** Page Manage 3D Model and control Scanner

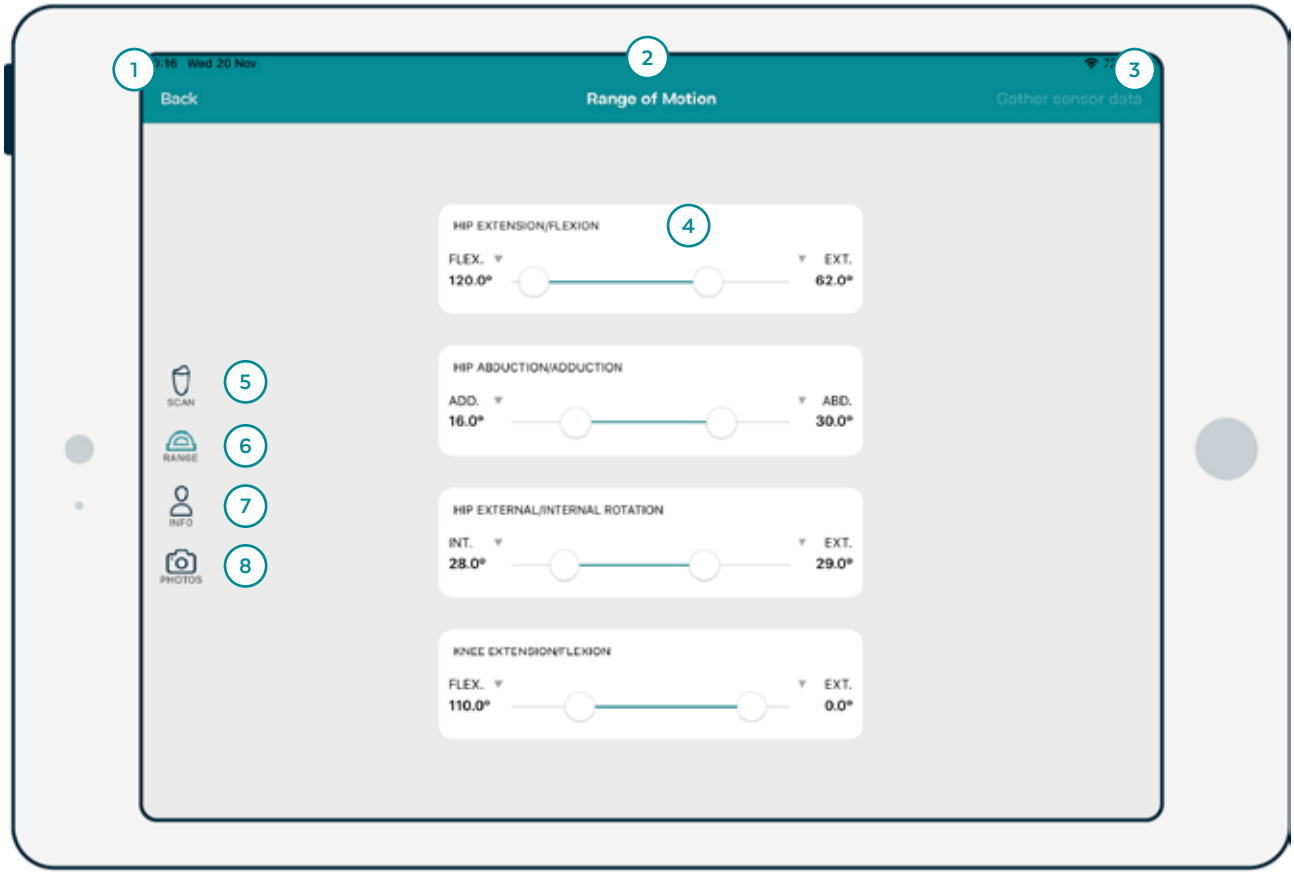
8 **Range of Motion** Goes to Range of Motion screen

9 **Patient Information** Goes to Patient Information screen

10 **Photo** Goes to Photo Screen

RANGE OF MOTION SCREEN

> ⚠ The range of motion feature must be selceted on the settings.



1 **Back** Returns to Home screen

2 **Screen Title** Indicates the current screen

3 **Gather Sensor Data** Goes to Gather Data Screen

4 **Range Of Motion** Input patient range of motion

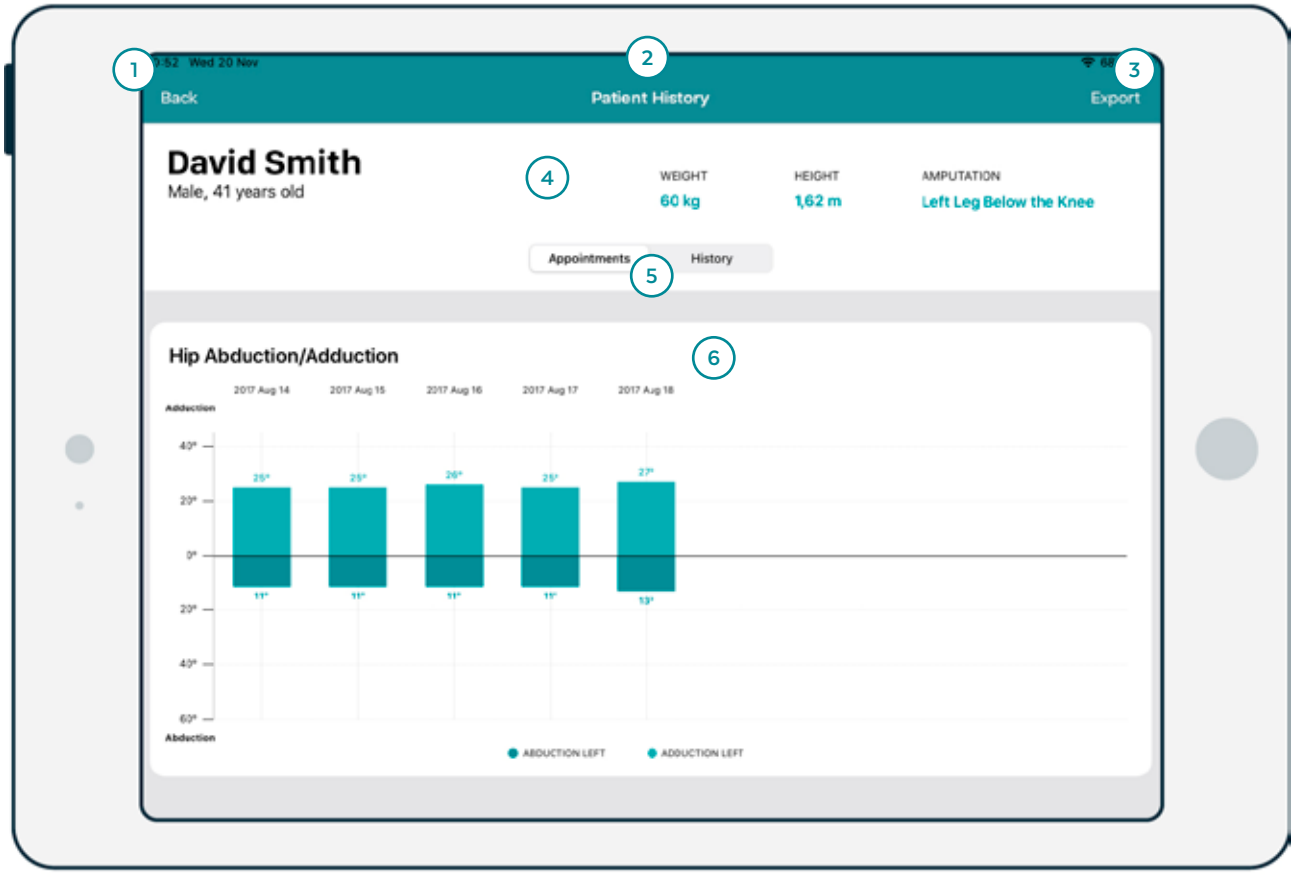
5 **3D Model Page** Manage 3D Model and control Scanner

6 **Range of Motion** Goes to Range of Motion screen

7 **Patient Information** Goes to Patient Information screen

8 **Photo** Goes to Photo Screen

HISTORY SCREEN



1 **Back** Returns to previous screen

2 **Screen Title** Indicates the current screen

3 **Export** Export report to PDF

4 **Patient Information** Displays patient information

5 **Data Filter** Switch the data visualization between Appointment or History

6 **History** Patient history translated in graphs

REPORT SCREEN

1 **Cancel** Returns to previous screen

2 **Patient** Patient Name/Entry data

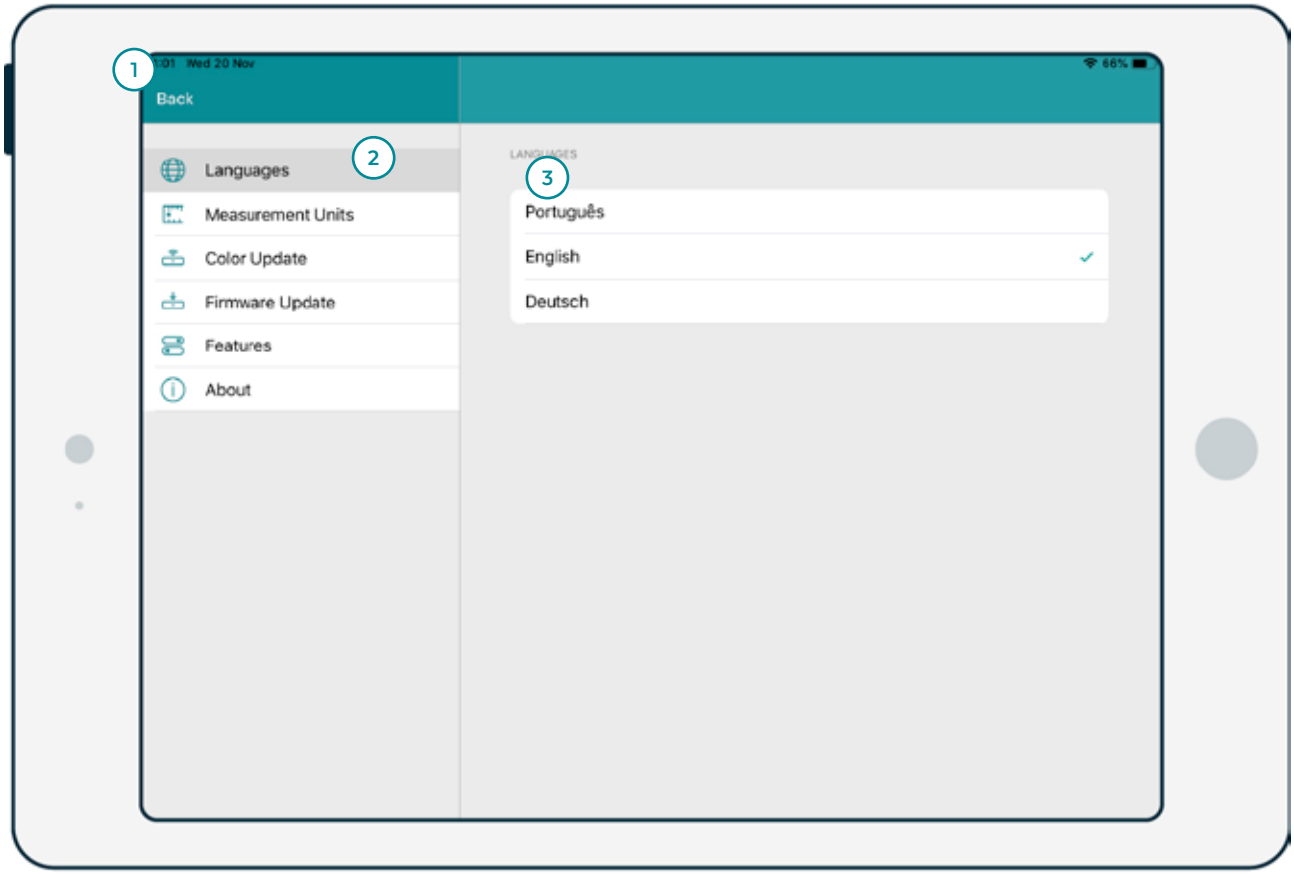
3 **Export** Export report to PDF

4 **Patient Information** Displays patient information

5 **Range of Motion** Displays patient Range of Motion

6 **3D Model** Displays Socket Pressure Profile in different angles/points of view

SETTING SCREEN



1 **Back** Returns to Home screen

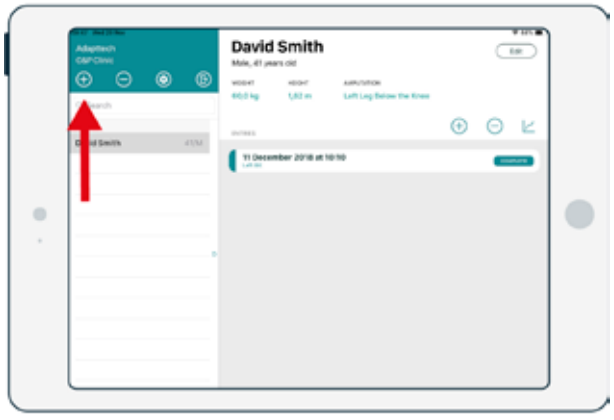
2 **Options** Available settings

3 **Option Selected** Option for the selected setting

MANAGING CLINICS

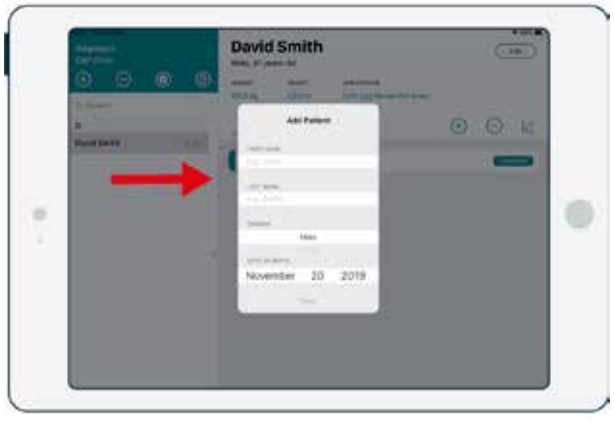
When the customer enrolls with the INSIGHT system, Adapttech or Cascade will create the existing clinics where the system will be used. If there are changes to the customer clinics, the manager will be able to edit and configure the settings in the software's back office.

ADDING PATIENTS



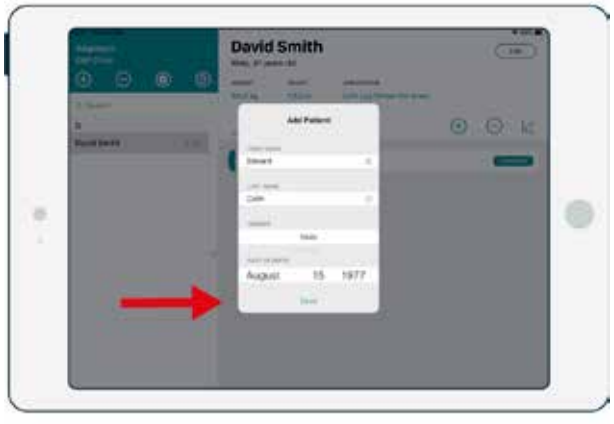
STEP 1

On the Home Screen, tap on the “+” icon.



STEP 2

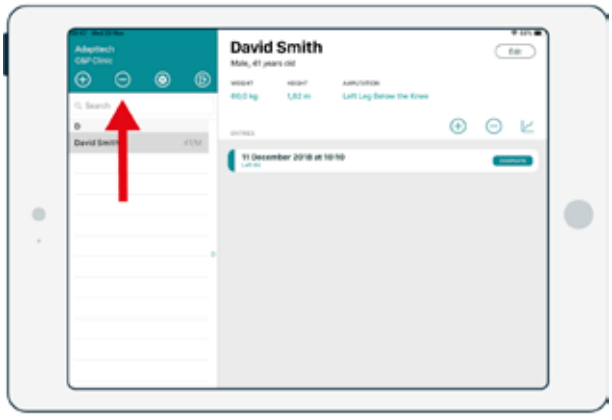
Fill Patient information on the correspondent text fields.



STEP 3

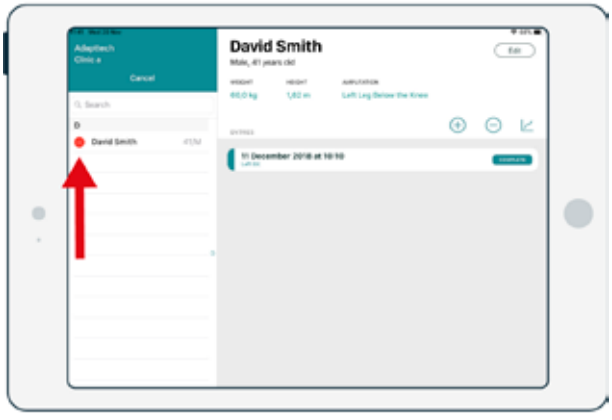
Tap “Save”.

REMOVING PATIENTS



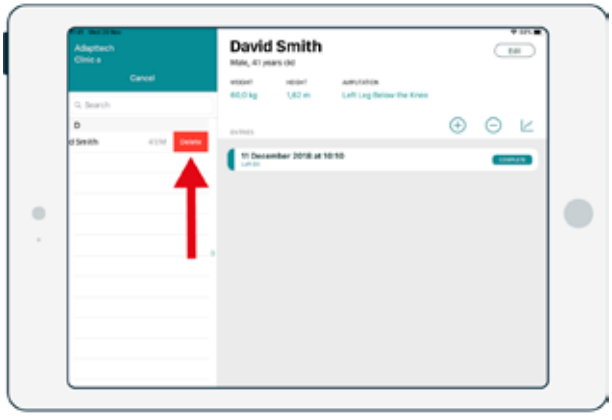
STEP 1

On the Home screen, tap on the “-” button.



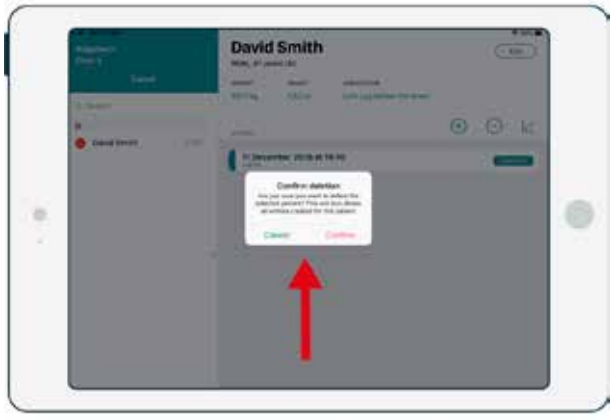
STEP 2

Select the patient to delete by tapping on the red icon in front of the name.



STEP 3

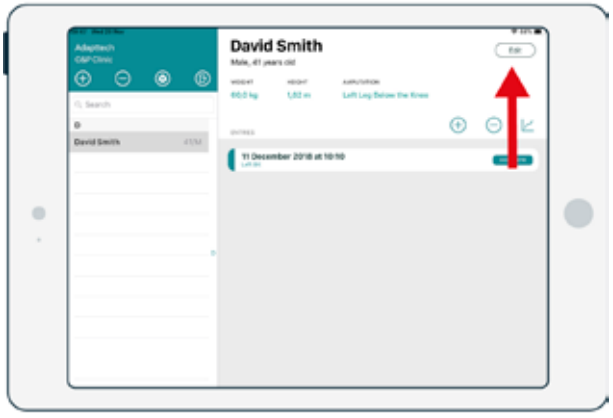
Tap on “Delete”.



STEP 4

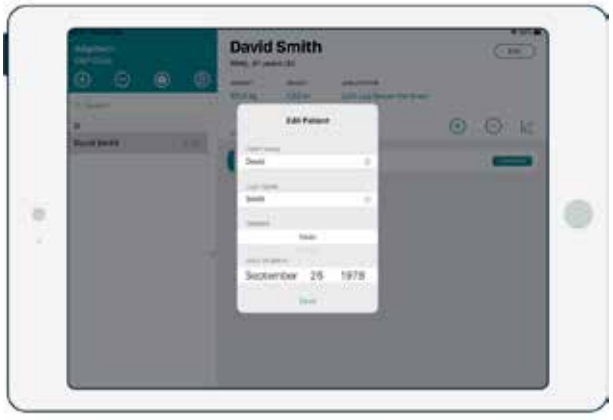
Tap on “Confirm”.

EDITING PATIENT INFORMATION



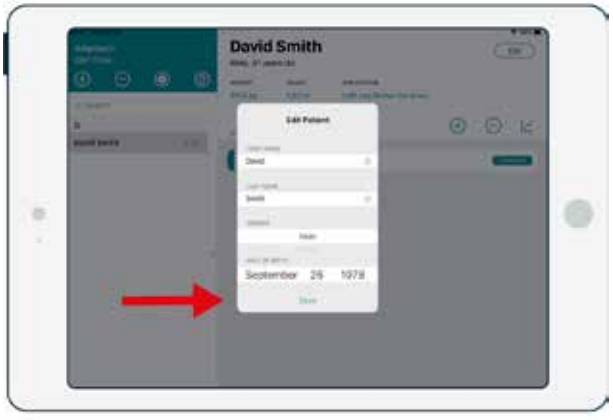
STEP 1

Tap on the “Edit” button



STEP 2

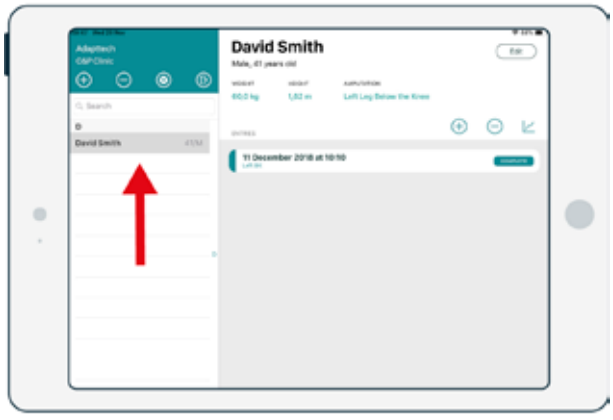
Make the desired changes.



STEP 3

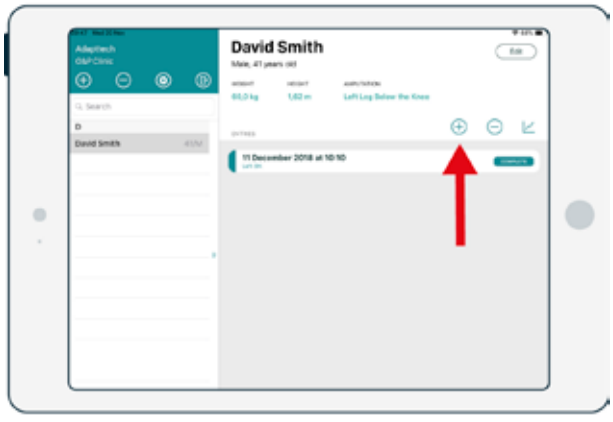
Tap “Save”.

STARTING NEW ENTRY



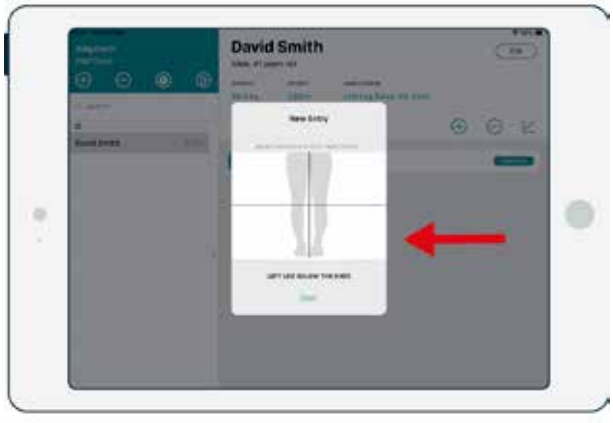
STEP 1

Select the Patient.



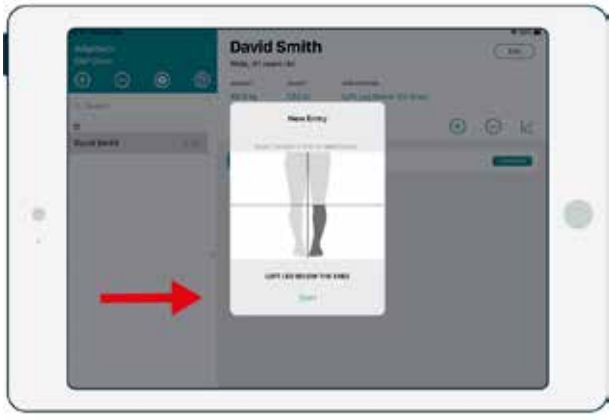
STEP 2

Tap on “New Entry”.



STEP 3

Select the type of amputation by tapping over the amputated limb segment.



STEP 4

Tap “Start”.

SELECT INSIGHT SCANNER

STEP 1

In an Entry, go to the 3D Model screen and tap on the “Scan” button.

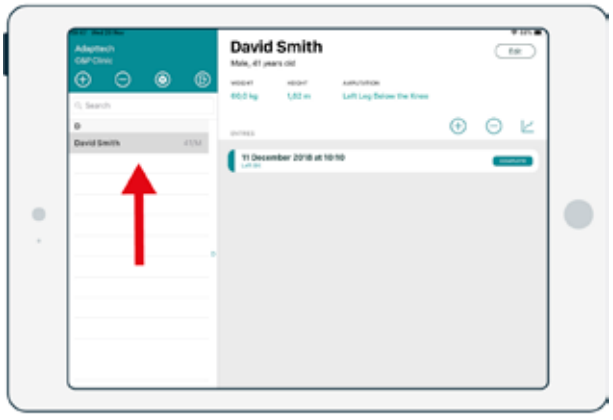
STEP 2

Select the desired INSIGHT Scanner (powered on Scanners connected to the current clinic).

STEP 3

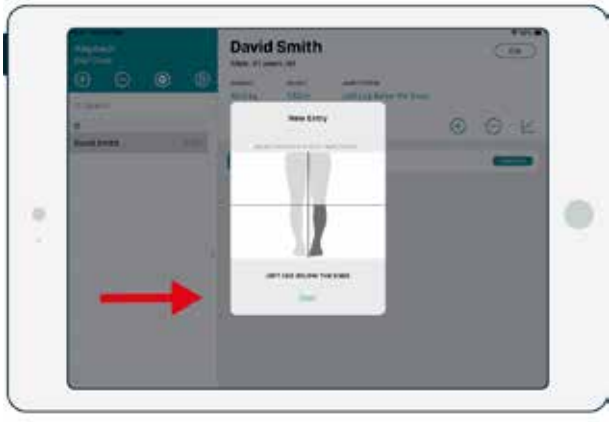
Tap “Connect”.

START SCANNING



STEP 1

Select a Patient.



STEP 2

Add new Entry.

STEP 3

Tap “Scan”.

STEP 4

Select the desired INSIGHT Scanner (powered on Scanners will appear automatically on screen).

STEP 5

Wait until the 3D Model is displayed on the screen.

STEP 6

Scan complete.

ADDING PATIENT INFO TO ENTRY

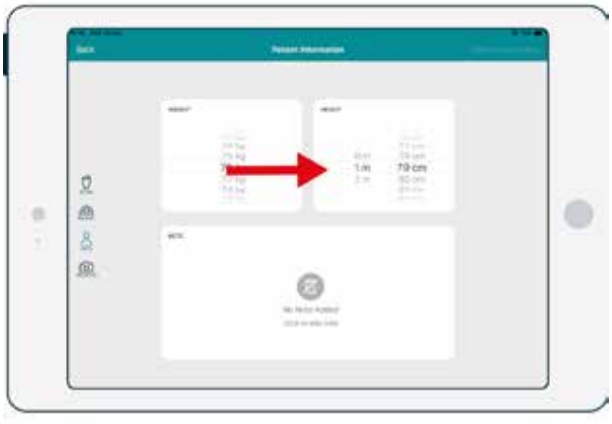
⚠ Information is automatically saved

STEP 1

On the 3D Model window, tap on the "Patient Information" icon.

STEP 2

Select the patient's Weight.



STEP 3

Select the patient's Height.

STEP 4

If needed, write any notes about the patients.

RE-SCANNING THE SOCKET

STEP 1

After the scan has finished, tap the “Scan Again” icon.

STEP 2

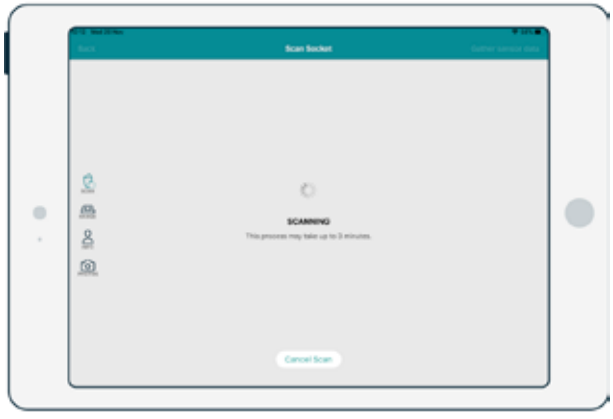
Tap “Confirm” to overwrite the existing scan.

STEP 3

Tap the “Scan” Button.

STEP 4

Select the desired INSIGHT Scanner.



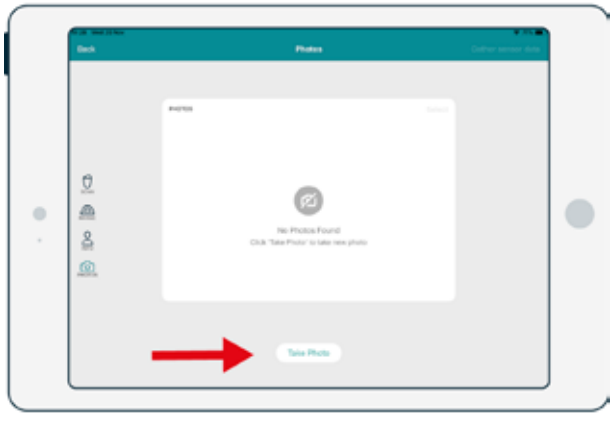
STEP 5

Wait until the scan finishes and the 3D model is displayed on the screen.

PHOTO TOOL

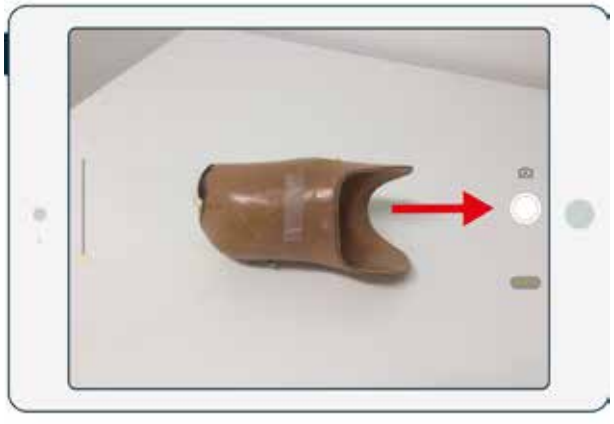
STEP 1

On the 3D Model window, tap on the “Camera” icon.



STEP 2

Tap “Take Photo” Button.

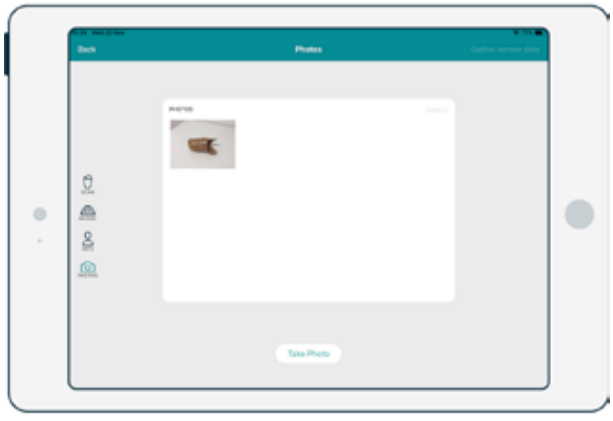


STEP 3

Capture the desired picture.

STEP 4

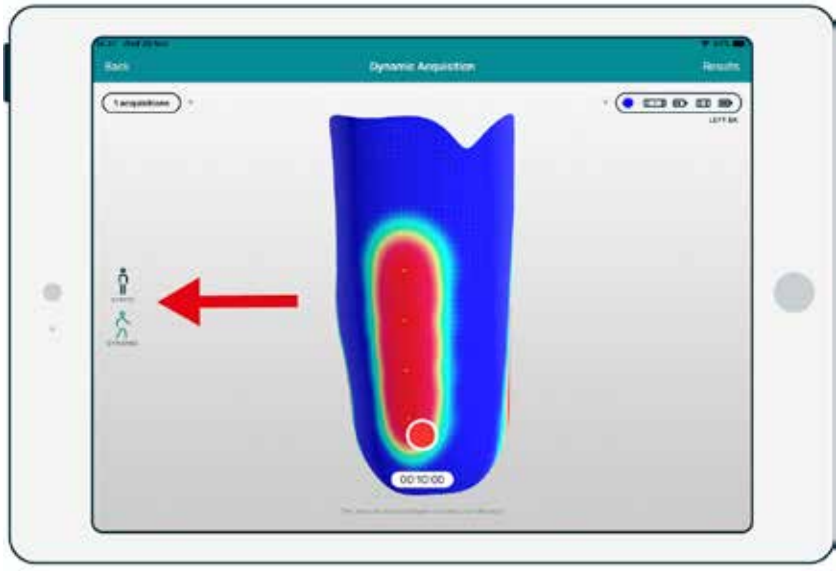
Tap “Use Photo”. The photo is then saved.



STEP 5

To see any previously saved image, just tap on it.

STATIC AND DYNAMIC TESTS



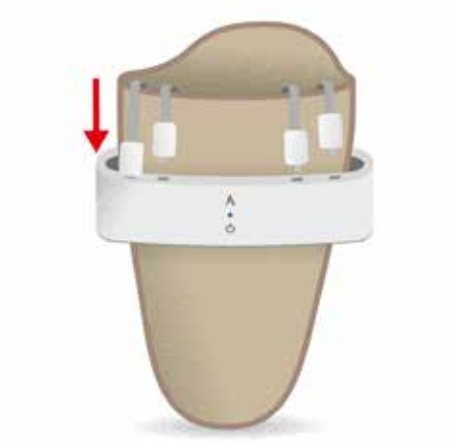
When recording a patient's pressure data, two types of tests can be chosen:

A **Static** test, where the patient stands upright for stands upright for at least 30 seconds.
A **Dynamic** test, where the patient walks for for at least 60 seconds.
Choosing the appropriate recording type is very important, as it helps INSIGHT understand the test being done and automatically labels it.

STARTING ACQUISITION

STEP 1

Place INSIGHT Wearable onto the patient.



STEP 2

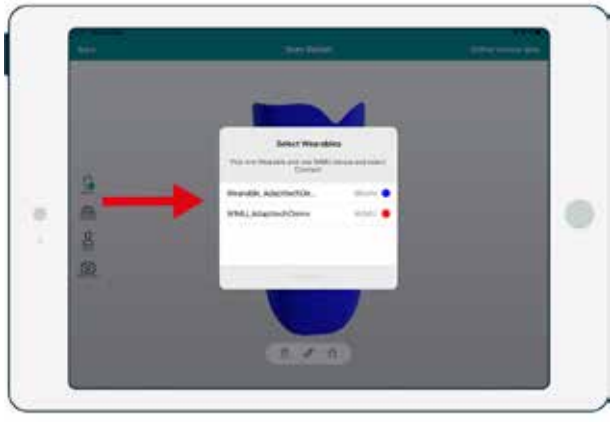
Connect INSIGHT Sensors to INSIGHT Wearable.

STEP 3

Turn on the device by clicking on the button. The respective Color ID of the device will start blinking.

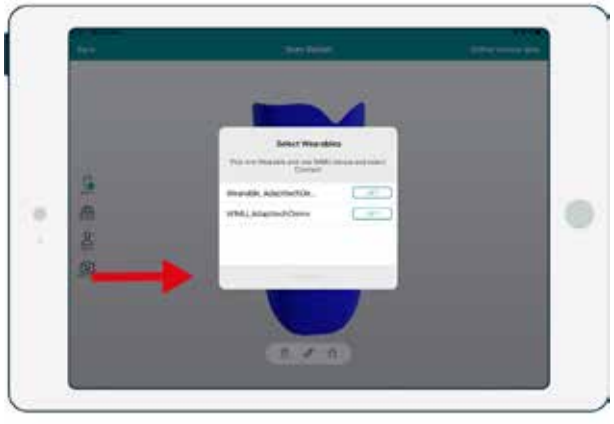
STEP 4

On the INSIGHT App, after scanning the socket, tap on “Gather Data”.



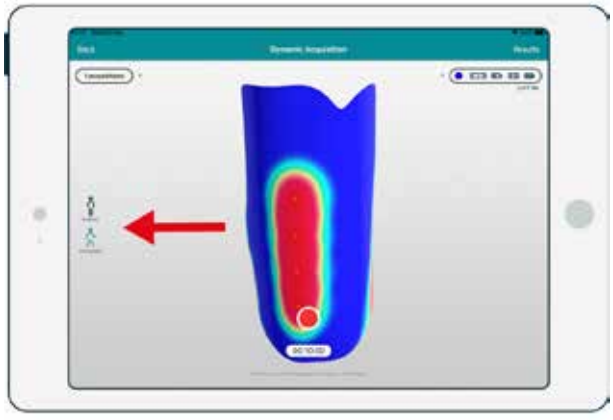
STEP 5

Select the desired INSIGHT Wearable from the list (the ID on the device’s label matches the ID on the list).



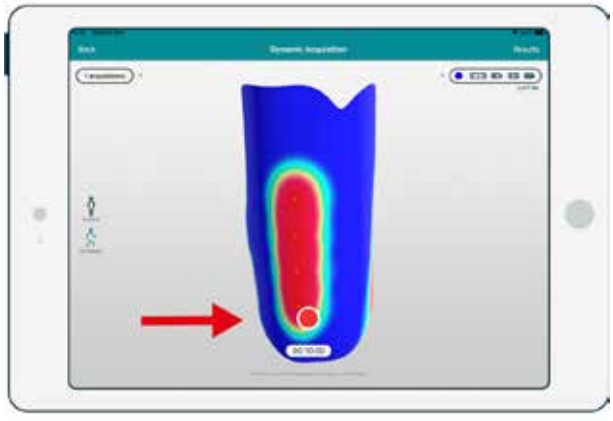
STEP 6

If you wish to make a dynamic acquisition, two Wearables are required. Select one Wearable and one WIMU and then tap “Connect” on the ones you wish to use for the acquisition.



STEP 7

On the Acquisition screen, select the type of test: either Static or Dynamic (see page 132).

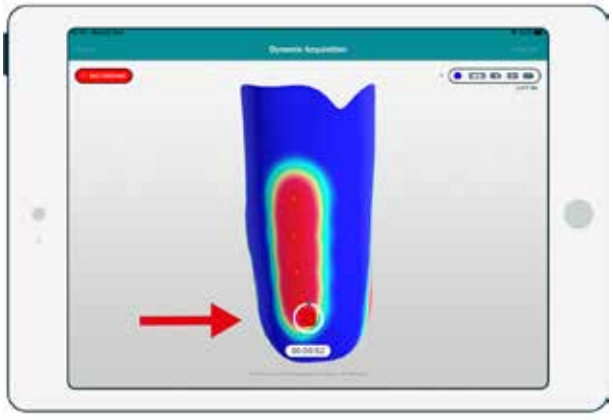


STEP 8

Tap Record (Red Button).

STEP 9

Recording started. Live pressure distributions over the socket are being provided.



STEP 10

When enough data has been gathered (30 seconds for a static test, 1 minute / 30 strides for a dynamic one), you can stop recording.

STEP 11

Give the recording a recognizable name.

STEP 12

Tap “Save”.

SELECTING INSIGHT WEARABLE

STEP 1

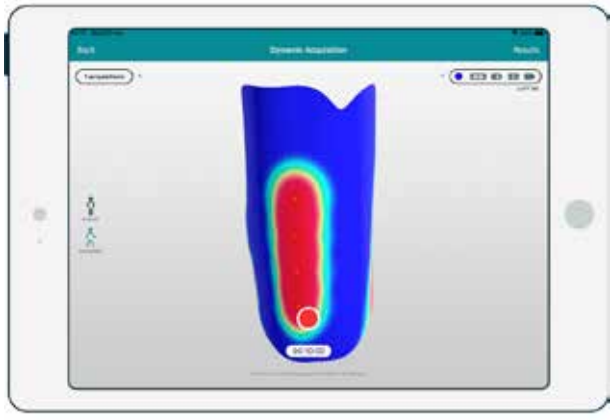
On the INSIGHT App, after scanning the socket, tap “Gather Data”.

STEP 2

Select the desired INSIGHT Wearable from the list (the color ID on the device’s label matches the color ID on the list).

STEP 3

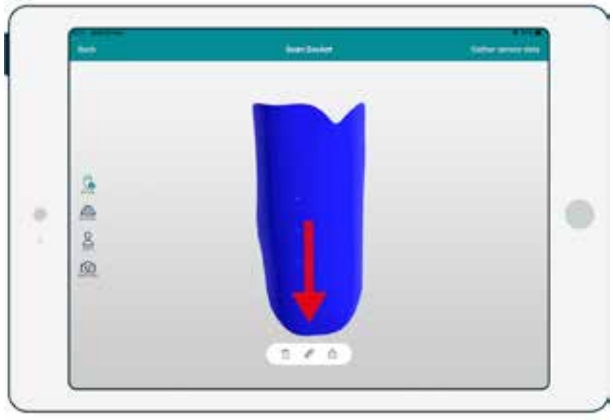
Tap “Connect”.



STEP 4

Start recording.

MEASUREMENT TOOL

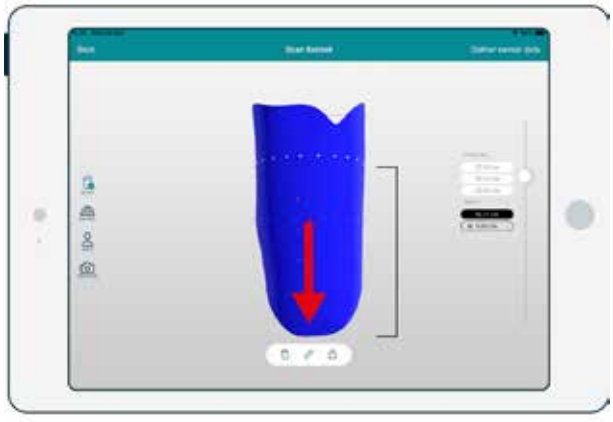


STEP 1

On the 3D Model or Gather Data windows, tap on on the “Ruler” icon.

STEP 2

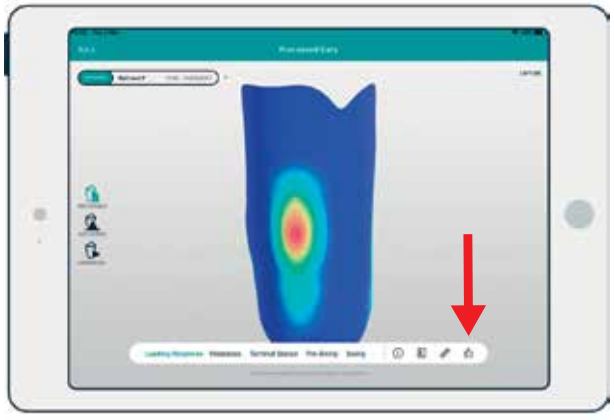
Move the slider to get the socket’s perimeters at the desired location.



STEP 3

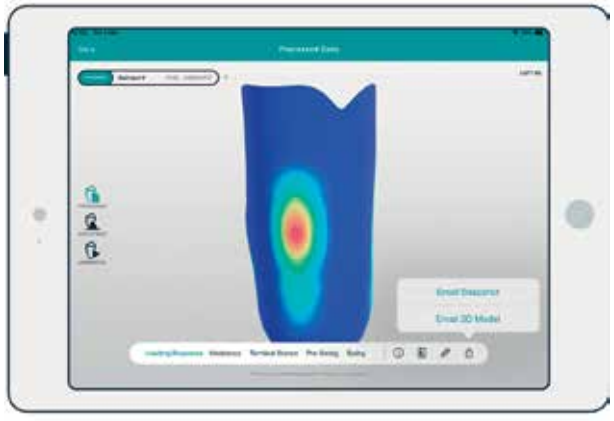
Tap again on the “Ruler” icon to close the tool.

EXPORT 3D MODEL IN STL FORMAT



STEP 1

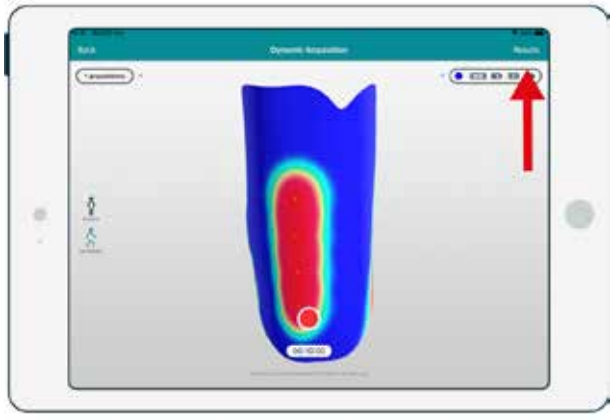
For sharing, further editing in a 3D CAD/CAM software or 3D printing, a socket's digital model can be exported and emailed in the STL format, tap on the "Export" icon.



STEP 2

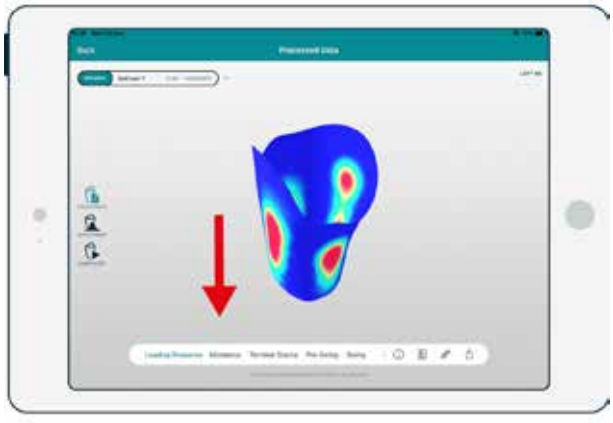
Then, tap "Email 3D model" and the file will be sent to the clinician's e-mail.

REVIEW RECORDING (PROCESSED GAIT ACQUISITION)



STEP 1

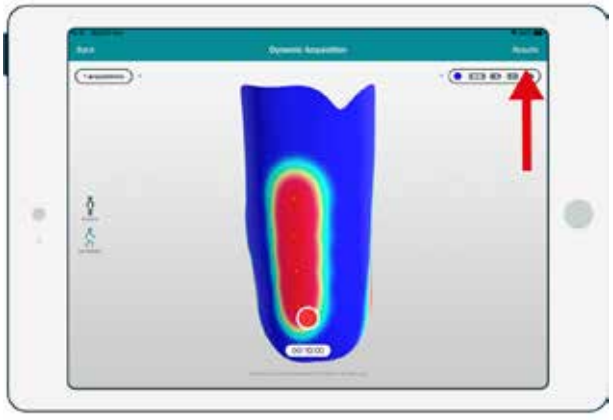
On the INSIGHT App, after you have finished dynamic data, tap on “Results”.



STEP 2

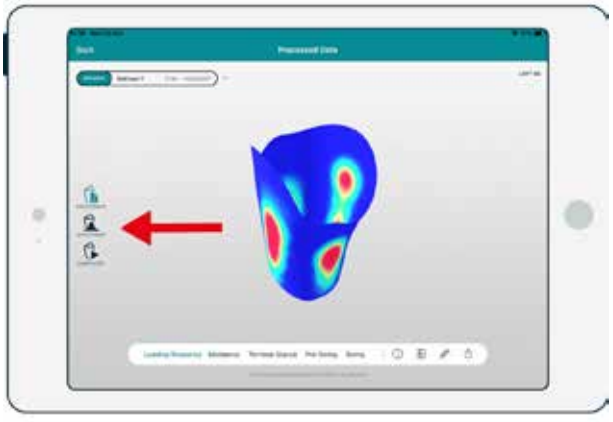
On the bottom of the screen switch between the gait phases to view the pressure distribution in the 3D Model.

REVIEW RECORDING (AVERAGE STRIDE)



STEP 1

On the INSIGHT App, after finish recording data, tap on "Results".



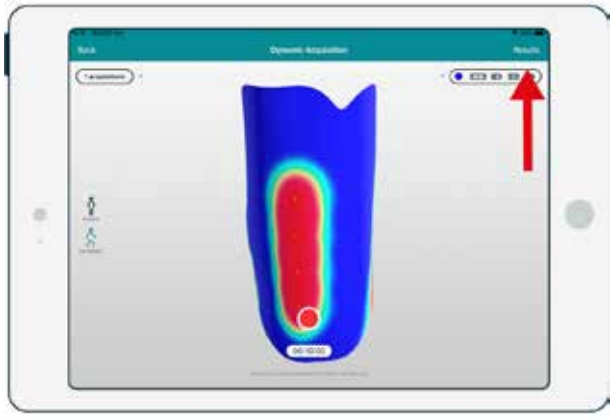
STEP 2

On the Review data screen, tap on the "Average Stride" button.

STEP 3

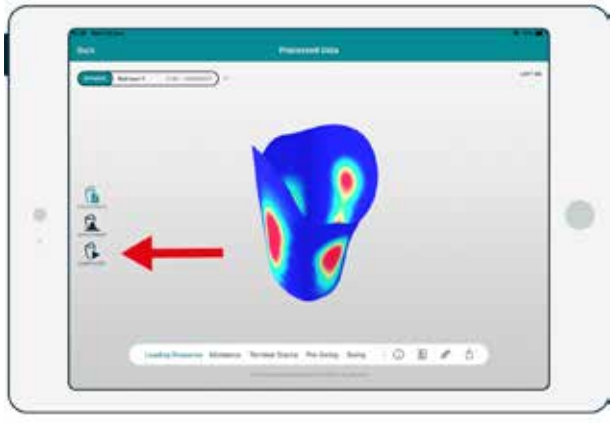
On the bottom of the screen press play, or use the slider to see animated in the 3D Model the pressure distribution in relation to the gait phase, indicated by the human 3D model in the bottom right corner.

REVIEW RECORDING (REAL TIME DATA)



STEP 1

On the INSIGHT App, after finish recording data, tap on "Results".



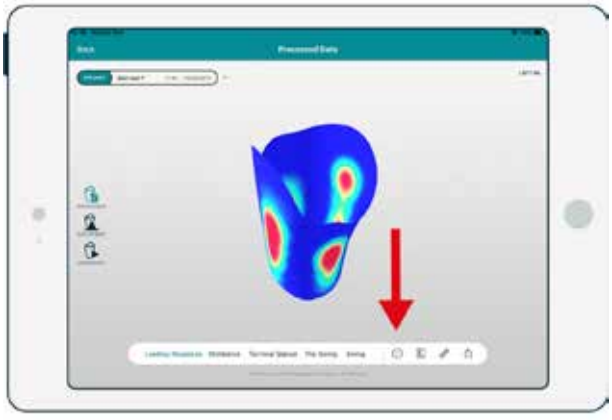
STEP 2

On the Review data screen, tap on the "Real Time Results" button.

STEP 3

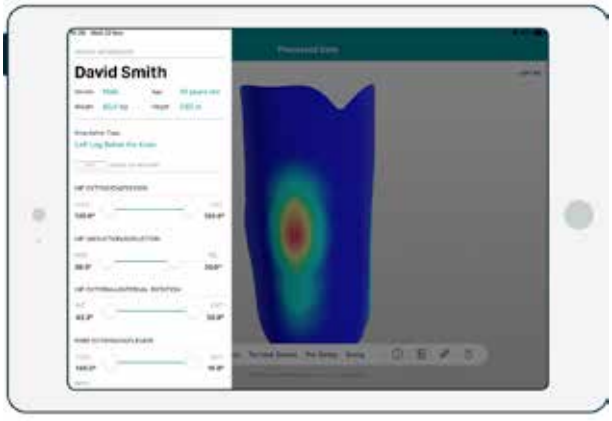
On the bottom of the screen press play, or use the slider to see the animated 3D model the pressure distribution in relation to the gait phase, indicated by the human 3D model in the bottom right corner.

VIEWING A PATIENT'S REPORT (RESULTS SCREEN)



STEP 1

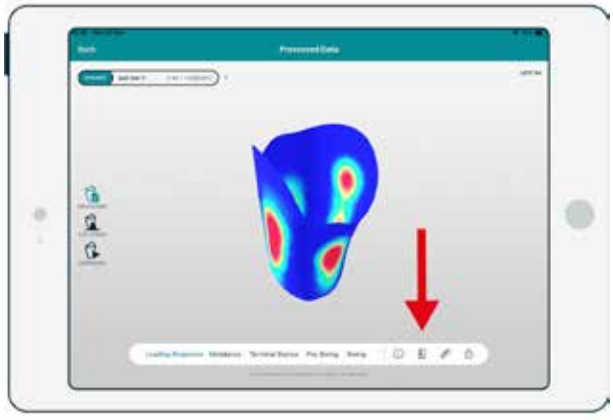
Tap on the "Patient Information" icon.



STEP 2

View Report, tap on cancel to return to previous screen or export to get the report in PDF format.

PATIENT REPORT (RESULT SCREEN)



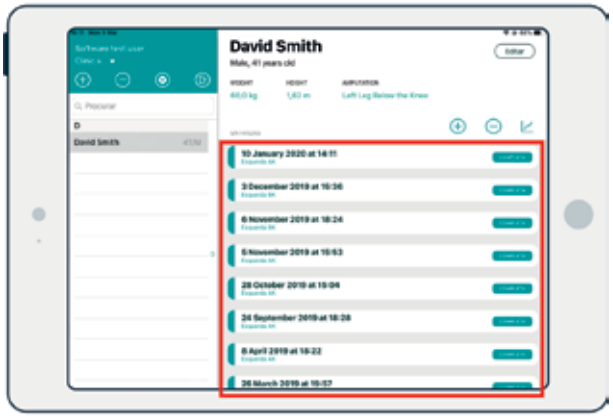
STEP 1

On the result Screen, tap on the “Patient Report” Icon.

STEP 2

View Report, tap on cancel to return to previous screen or export to get the report in PDF format.

SWITCHING BETWEEN RECORDINGS



Accessing previous acquisitions

A patient's previous data recordings, either static or dynamic, can be reviewed at anytime through INSIGHT App.

From the main page, select a specific appointment of a patient.

The appointment page will appear. The selector on the top left allows choosing between different recordings acquired in that appointment. Recordings will be identified by their type (static/dynamic) and the name chosen when saving them.

SYSTEM ERRORS MESSAGES

"Unable to navigate to next page"

Software couldn't process data to move to next step. Check if any task is still in process (Scanning, processing data) and try again.

"Unable to get data/patient/appointment"

Software couldn't retrieve required data/patient/appointment. Check if iPad is connected to the correct network and try again.

"Unable to save data/patient/appointment"

Software couldn't save data/patient/appointment. Check if any task is still in process (Scanning, processing data) and try again. Check if iPad is connected to the correct network and try again.

"Unable to update data/patient/appointment"

Software couldn't update data/patient/appointment. Check if iPad is connected to the correct network and try again.

"Unable to delete data/patient/appointment"

Software couldn't delete data/patient/appointment. Check if iPad is connected to the correct network and try again.

"Invalid First Name"

Couldn't save information, insert a valid first name without any punctuation or numbers.

"Invalid Last Name"

Couldn't save information, insert a valid last name without any punctuation or numbers.

“Please fill out first name field”

Can’t add or edit patient without first name. Add patient first name.

“Date of birth cannot be after current date”

Can’t add a date of birth that is ahead of the current date, insert a valid date.

“Unable to authenticate user”

Software couldn’t validate user, select the option “Forgot Password?”. You will receive an e-mail to proceed with the password change. After following the steps on the email, try to log in again with the new password.

“The URL you have entered is invalid”

Please check if the URL is typed correctly and try again. If the problem persists, contact Adapttech for a URL check.

“Unable to load patient history”

Software couldn’t retrieve patient history. Check if the iPad is connected to the correct network and try again.

“Unable to send report”

Software couldn’t send report. Check if the iPad is connected to the correct network and try again.

“Unable to send recovery email”

Check if the iPad is connected to the correct network and try again.

“Unable to complete scan”

Couldn’t complete scan. Check if any warning is active on the scanner. Check if scanner and iPad are connected to the correct network.

“Entries without scan cannot be saved”

Couldn’t save entry. To save entry, make a scan of the patient socket.

“It’s not possible to gather pressure data for scans without sensor information”

To gather pressure data, use the INSIGHT Wearable and INSIGHT Sensors. Place INSIGHT Sensors into the socket before scanning.

“Error while sending mesh stl file to user email”

Software couldn’t send 3D file through email. Check if the iPad is connected to the correct network and try again.

“Error while sending snapshot to user email”

Software couldn’t send snapshot through email. Check if the iPad is connected to the correct network and try again.

“Bluetooth® Service is not available”

Check if iPad Bluetooth® is active in settings. Check if the INSIGHT Wearable and IMU are switched on.

“An error occurred while connecting to device”

Software couldn’t connect to the device, try again. Check if the INSIGHT Wearable and IMU are within range of iPad. If the problem still occurs, pair the devices to the iPad.

"Connection to Wearable was lost"

Check if the INSIGHT Wearable and IMU are within range of iPad. Connect to the Wearable again. If the problem still occurs, pair the devices to the iPad.

"Error occurred while changing device color"

Check if the INSIGHT Wearable and IMU are within range of iPad. Reconnect to the device and change the device color. If the problem still occurs, pair the devices to the iPad.

"Recording time limit has been reached, tap 'ok' to Save"

Recorded time has exceeded, tap "ok" to save recording and start a new recording.

"Acquisition will be dismissed, since capture time is insufficient"

The acquisition is too short to process information, record more time to gather enough data to process.

"Application can not be used if permission is not granted for access to the device's camera"

Grant permission for the INSIGHT App to access the iPad camera on the iPad settings.

"iPad lost wi-fi connection"

Try to reconnect to the wi-fi network from iPad settings menu, and/or verify if iPad is within the wi-fi network reach.

MAINTENANCE

Follow Apple's maintenance recommendations for cleaning the iPad.

Avoid dust accumulation on the iPad ports as this may cause bad electrical contact when charging.

Store the iPad in a dry cool place at room temperature, as described by the Apple's usage recommendations.

Regularly charge the iPad battery.

TROUBLESHOOTING

I cannot login into the INSIGHT App:

Are your username and password correct?

Does the iPad have internet connection?

If none of the above, please contact Adapttech or Cascade support

I cannot see all of my clinics on Onboard/Settings:

Do you have internet connection?

If the internet connection is ok, please contact Adapttech or Cascade support

I cannot see my patients:

Do you have internet connection?

Are you accessing the correct clinic?

If none of the above, please contact Adapttech or Cascade support

I cannot see my patient entries:

Does the iPad have internet connection?

If the internet connection is ok, please contact Adapttech or Cascade support

The INSIGHT Scanner in my clinic does not appear in the selection list:

Does the iPad have internet connection?

Is the Scanner in your clinic powered on?

Is the scanner in your clinic is connected to the right network?

If none of the above, please contact Adapttech or Cascade support

The scan result is malformed or distorted:

Please contact Adapttech or Cascade support

The photo gallery is not storing pictures/is not showing previous pictures data I enter is not being saved:

Does the iPad have internet connection?

If the internet connection is ok, please contact Adapttech or Cascade support

The report I created was not delivered to my email:

The email can take up to 30 minutes to arrive at the inbox.

Are you checking the same email you logged in with?

If your email is correct, please contact Adapttech or Cascade support

The INSIGHT Wearable does not appear in the selection box:

Is the INSIGHT Wearable turned on?

Are you within range of the device (10m)?

Is Bluetooth® enabled on your iPad?

Does the App have permission to use the iPad Bluetooth?

If none of the above, please contact Adapttech or Cascade support

Results are not appearing in the selection box:

Does the iPad have internet connection?

If none of the above, please contact Adapttech or Cascade support

Static results are not showing correctly:

Was the result collected following the User Guide best practices?

Does the iPad have internet connection?

If none of the above, please contact Adapttech or Cascade support

Dynamic results are not showing correctly:

Was the result collected following the User Guide best practices?

Does the iPad have internet connection?

If none of the above, please contact Adapttech or Cascade support

Real Time results are not showing correctly:

Was the result collected following the User Guide best practices?

Does the iPad have internet connection?

If none of the above, please contact Adapttech or Cascade support

TECHNICAL SPECIFICATIONS

Product Category

Software Application

Product Description

INSIGHT App is a software that manages, records, saves and tracks the patient's history and follows their adaptation process throughout the entire rehabilitation phase.

MODEL

ATT0010

CONNECTIVITY

Bluetooth® & Wi-Fi

OPERATING SYSTEM

iOS

Notes

- These specifications are subject to change without notice.
- The device AC adapter is protected against solid foreign objects of 12 mm diameter and greater such as a finger. The optional AC adapter is protected against vertically falling water drops which may cause issues during a normal operation.
- This device fulfils the Medical Devices Directive - 93/42/EEC.
- This Adapttech product is produced under the strict quality system of ADAPTTECH LTD.

adapttech

CE

TECHNICAL ASSISTANCE

If you have any technical issues, please contact our support department at support@adapttech.eu or via post at:

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B15 2TH Birmingham, UK

Contact your Cascade sales representative.

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