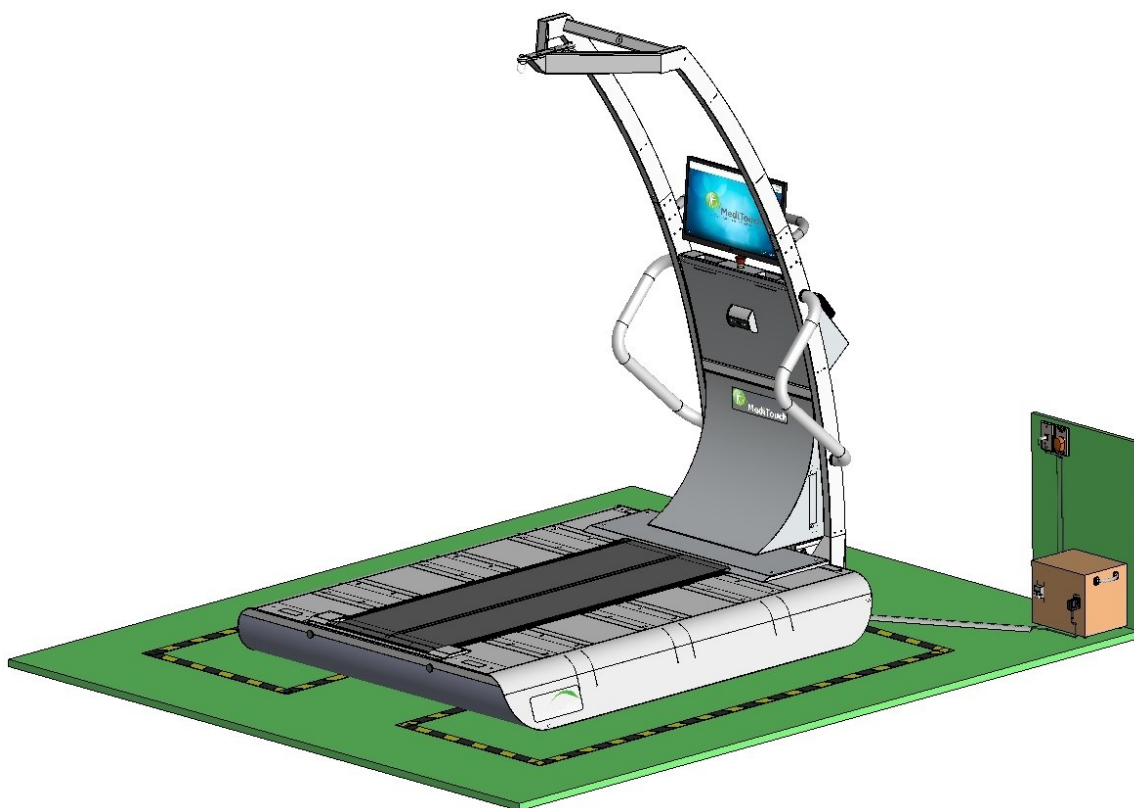


BalanceTutor™

Instruction For Use

August 2025



BalanceTutor a dynamic and static postural control trainer

This Instruction for Use (IFU) covers operation procedures for the following MediTouch product:

Product name: BalanceTutor
 Product model: HMBT100A
 UDI-DI: (01)07290019733829
 BASIC UDI-DI: 7290019733BT100U9

The BalanceTutor by MediTouch is a Perturbation Treadmill designed for postural control training has been tested to IEC medical standards for electrical safety. It is a Class I, Type BF device.

Type BF Medical Equipment



IEC 60601-1-1 compliant

IEC 60601-1-2 compliant

IPX-0

Date	Change description	Written by	Ver.
11 Feb 2016	Initial version	Ziv K.	160211
8 Nov 2017	Adding: Wearable sensor usability 9.2, 9.3, Update: Platform load bearing calculation	Ziv K.	171108
18 Jun 2018	Modification of (Special Care in Use)	Avraham C.	180618
03 Oct 2018	Modifications to comply with IEC60601-1 Ed 3.1	Ziv K.	181003
18 Feb 2020	Adding Gait Analysis evaluation	Ziv K.	200218
25 Feb 2020	Adding section: system security	Ziv K., Moshe D.	200225
22 Mar 2020	Evaluation reports parameters definitions	Avraham C.	200322
17 Jun 2020	Certificate update: ISO 9001:2015, ISO 13485:2016. Name plate EC rep details	Ziv K.	200617
24 Aug 2020	Adding postural analysis measures descriptions	Avraham C.	200824
20 Jul 2022	Changing company address, EC rep, name plate label	Ziv K.	220720
02 Feb 2023	Updating sections: Wireless devices, Harness. Updating: Images for newer software version, ISO certificates	Avraham C. Alan W.	230202
24 Jul 2023	Section Safety, Warnings, Precautions, Prohibitions: safety clarifications	Avraham C.	230724
10 Aug 2023	Adding product UDI-DI and Basic UDI-DI	Ziv K.	230810
23 Feb 2024	Update: Floor bearing capacity	Ziv K.	240223
27 Mar 2024	Update: Harness details	Ziv K.	240327
20 Aug 2024	Update: EC Rep, Images	Ziv K.	240820
24 Aug 2024	Update: Changes to implement MDD to IFU MDR requirements	Ziv K., Alan W.	240824
25 Aug 2025	Certificate update: ISO 9001:2015, ISO 13485:2016	Ziv K.	250825

E&EO



User Responsibility

When used, maintained, and serviced in line with the instructions contained in this manual and the information provided on accompanying labels or inserts, the device will function as intended. Regular inspection, as outlined in this document, is required to ensure safe and effective operation. The device must not be operated if it is defective. Components that are damaged, missing, excessively worn, deformed, or contaminated must be replaced without delay. If servicing or replacement is required, users should contact MediTouch for guidance, either in writing or by telephone. Repairs or maintenance may only be carried out according to MediTouch's official instructions and exclusively by personnel authorized or trained by MediTouch. Modification of the device is strictly prohibited unless prior written approval is obtained from MediTouch's Quality Assurance department.

The user assumes full responsibility for any failure, malfunction, or damage arising from improper use, inadequate maintenance, unauthorized repairs, or unapproved modifications. Any intervention not expressly permitted by MediTouch may invalidate the product warranty.

MediTouch Contact Information

MediTouch is available to address any inquiries or feedback regarding the BalanceTutor system. Users may contact trained staff including physiologists, physiotherapists, applications engineers, and customer support personnel for professional guidance and assistance with any questions or concerns.

MediTouch Headquarter

Address	1 Nirim Street, Tnuvot 4283000, Israel
Telephone	(972) 9 8637477
Fax	(972) 9 8652935
Website	www.meditouch.co.il

Service and Support

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Email	support@meditouch.co.il

Contents

User Responsibility.....	3
MediTouch Contact Information	3
Device Description	8
1 Safety Information, Warnings, Precautions and Restrictions	9
1.1 Safety Class	10
1.2 Patient and Therapist Security	10
1.3 Non-medical Electrical Devices Within The Surrounding	10
1.4 Environmental Requirements	11
1.5 Spare Parts	11
1.6 Labels, Locations, Interpretations	11
1.6.1 Name Plate	12
1.6.2 User Manual Labels	12
1.6.3 Warning Labels	12
1.6.4 Safety, Quality, and Conformity	13
1.6.5 Country-Specific Requirements and Use Environment	13
1.6.6 CE Marking	13
1.6.7 EMC Electromagnetic & Safety Compatibility	13
1.7 Indications	14
1.7.1 Perturbation Based Balance Training Indications	14
1.7.2 Special Care in Use	14
1.8 Contraindications	15
2 Installation & commissioning	16
2.1 Staff Members	16
2.2 Pre Installation Preparation	16
2.3 Unboxing	17
2.4 Assembly	17
2.5 Preparation for First Use	17
2.5.1 Electrical Connection	18

2.5.2 Network Setup	18
2.5.3 Initial Power-up & Remote Access:	18
2.5.4 Training	18
3 Instructions for Use	19
3.1 Illuminated System Status Indicators	19
3.2 Starting the BalanceTutor System	20
3.2.1 Installation, Overview, Checklist	20
3.2.2 Switching the Device ON	20
3.2.3 Start Working With Patients	21
3.3 Software Operation	22
3.3.1 Login	22
3.3.2 Homing Procedure	22
3.3.3 Patient List	23
3.3.4 Operational Modes	24
3.3.5 Trigger Treatment	25
3.3.6 Muscle Training	29
3.3.7 Evaluations	30
3.3.8 Signal Description	33
3.3.9 Reports	34
3.3.10 Session Log	42
3.3.11 COP	44
3.4 Patient Screen	47
3.4.1 Feedback	47
3.4.2 Perturbation Event Indicators	48
3.4.3 Visual Stimulation	49
3.4.4 Patient Instructions	51
3.4.5 System Indicators	51
3.5 System Security	52
3.5.1 Users	52
3.5.2 Anonymous Patient	53
3.5.3 System Hardening	54
3.5.4 Automatic System Log Off	55
3.6 Data Export	55
3.6.1 PDF	55

3.6.2 CSV	57
3.7 System messages	59
3.8 Handheld Operation	61
3.8.1 Setup Remote Control	61
3.8.2 Operation	61
3.9 End of Training Day Procedures	61
3.9.1 Switching Device OFF	61
3.10 Software Version Identifier	62
3.11 Device Cleaning	62
3.11.1 Touch and Patient Screens	62
3.11.2 Metal Structure	63
3.11.3 Harness	63
3.11.4 Running Belt	63
4 Safe and Effective Use	64
4.1 Suitable Clothing	64
4.2 Before Starting Training	64
4.3 Harness Use and Patient Safety	64
4.3.1 Putting On The Harness	65
4.3.2 Training Session Safety	66
4.4 Training Parameters	66
4.5 Troubleshooting and Emergency Procedures	66
4.5.1 Training Troubleshooting	66
4.5.2 Medical Emergency	66
5 Maintenance & Safety Inspections	67
5.1 Responsibilities	67
5.2 Daily Visual Inspection	67
5.3 Preventive Checks	67
5.4 Immediate Maintenance	68
5.5 Annual Inspection	68
6 When to Contact an Authorized Service Provider	69

7 Technical Specifications	69
8 Certificates	70
8.1 ISO 9001	70
8.2 ISO 13485	72
8.3 Certificate of compliance medical devices	73
Company details	73
EU Classification	73
EU Representative	73
FDA	73
Standards	73
9 End-of-Life Disposal	74



Device Description

The BalanceTutor by MediTouch is a Perturbation Treadmill that is an innovative device for postural control and balance training. The device consists of a treadmill mounted on a moving force plate platform. The platform moves in the medial/ lateral and forward/ backward plains to simulate a slip and a trip in both the standing and walking phase.

An innovative approach using wireless sensors and sensors integrated in the BalanceTutor allows for the provision of numerous kinds of controlled expected and unexpected perturbation. These kinds of perturbation can be generated in relation to the specific phase of gait namely in stance or swing phase in the gait cycle. In addition to controlled expected and unexpected perturbation in the standing and gait, the device also allows for Center of Pressure control practicing.



1 Safety Information, Warnings, Precautions and Restrictions

- ✓ Prior to operating the BalanceTutor system, the user must carefully review the entire IFU.
- ✓ Medical consultation is strongly recommended before beginning use.
- ✓ Only one individual may use the system at a time.
- ✓ Walking aids or support devices such as canes, walkers, or chairs must not be used with the BalanceTutor.
- ✓ No external equipment, including chairs, stools, or benches, may be placed on or attached to the system.
- ✓ Clinicians assisting a patient should recognize that treadmill movement may transmit mechanical forces to them and take appropriate precautions.
- ✓ Only suitable clothing and proper training shoes should be worn during operation.
- ✓ Improper, prohibited, or excessive use may result in serious injury or death.
- ✓ Training must be stopped immediately if the user experiences faintness, nausea, or dizziness, and medical advice should be sought.
- ✓ A complete warm up at walking speed is required before starting running or higher intensity activity.
- ✓ Operation of the BalanceTutor, including patient treatment, must be performed solely by therapists or doctors trained and certified by MediTouch.
- ✓ Use of the system is at the user's own risk; MediTouch assumes no responsibility for injury or damage caused by improper use.
- ✓ Individuals not participating in the session must maintain a minimum distance of two meters from the system.
- ✓ Only components, parts, or accessories installed, checked, and approved by MediTouch may be used.
- ✓ The system may only be used if the yearly maintenance check has been carried out and documented approved and certified by MediTouch or their authorized service representative.
- ✓ Training must not begin if abnormal operation is detected. If a malfunction occurs during a session, it must be stopped immediately using the emergency stop switch or the operator display software.
- ✓ Before any session, the safety harness must be properly fitted to the patient, and the patient confirmed to be secured and ready for training.



- ✓ The BalanceTutor is approved for patients weighing up to 135 kilograms. Patients exceeding this weight must not use the system.
- ✓ Before releasing or removing the safety harness, ensure the treadmill and perturbation functions are inactive and no automated program is running.
- ✓ If faults, abnormal conditions, or evidence of damage such as unusual sounds are observed, the session must be stopped immediately and a MediTouch authorized service representative notified.
- ✓ In the event of a power failure, the user must be lowered using the emergency release. Do not continue training until proper operation is guaranteed.
- ✓ All consulting, sales, installation, commissioning, instruction, inspection, maintenance, and repair activities must be carried out exclusively by personnel trained and certified by MediTouch.

1.1 Safety Class

The BalanceTutor is classified as a Class I medical electrical device.

1.2 Patient and Therapist Security

At your BalanceTutor medical product the user is protected / isolated from the mains in accordance with the safety standard referring to the requirements for leakage current values according to IEC60601-1-1. The connection of further mains-operated units to your BalanceTutor may cause that all the leakage currents add and the safety of the patient is reduced. Due to this the connection of further units may only be carried out on consultation with MediTouch.

The BalanceTutor system is designed to protect the user from mains electrical supply in compliance with the safety standards, including the limits for leakage current specified in IEC 60601-1. Connecting additional mains-powered devices to the BalanceTutor is forbidden and may result in cumulative leakage currents, potentially reducing patient safety.

1.3 Non-medical Electrical Devices Within The Surrounding

In case one or more of the BalanceTutor covers are removed, from any purpose such as maintenance or servicing the device, the user should comply the following to avoid any leakage current that might would flow from an electric device to the earth and subject.

- ! Disconnect the electrical plug of the BalanceTutor isolation transformer from the electrical socket.

- ! Disconnect any electrical equipment within 1.5m from the BalanceTutor.
- ! When servicing the BalanceTutor, the user must use proper safety equipment and protective clothing.

1.4 Environmental Requirements

MediTouch systems must not be operated in medical environments where there is a risk of explosion or in atmospheres that are easily flammable. The devices should not be installed in proximity to equipment such as X-ray machines, high-power motors, or transformers, as electromagnetic interference may distort measurements or render them invalid. High voltage power lines must be avoided in the vicinity of the system. MediTouch devices with mains connections are not to be used in wet or highly humid environments, such as swimming pools or saunas, nor inside environmental chambers.

Unless specified differently in the delivery documentation, MediTouch devices are intended for use under standard environmental conditions

- Temperature (usage): + 10° ... + 40° C
- Relative humidity: 30 ... 70 % (non-condensing)
- Air pressure: < 1.5 bar
- Temperature (storage): – 20° ... + 50° C.

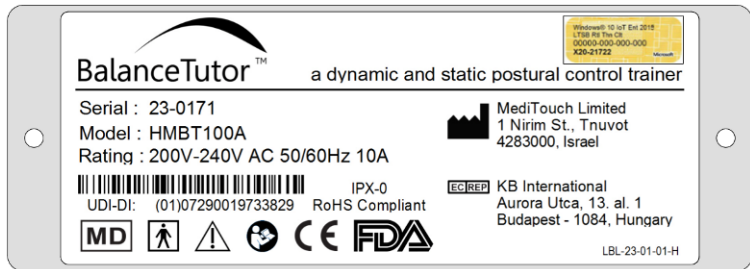
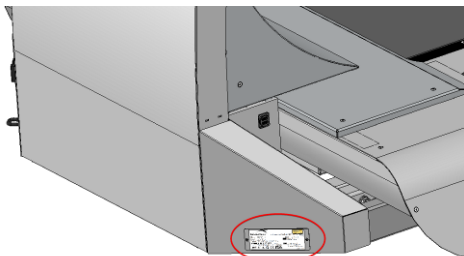
1.5 Spare Parts

Spare parts for the BalanceTutor system are expected to be available for 8 years. Users must obtain all replacement parts exclusively from MediTouch or its authorized representatives to ensure continued device safety, maintain warranty coverage, and preserve compliance for proper use.

1.6 Labels, Locations, Interpretations

Users must carefully read and understand all labels on the BalanceTutor system. These labels convey important safety information to ensure safe and effective use of the device. If any label becomes damaged or illegible, users should contact MediTouch immediately to obtain replacements.

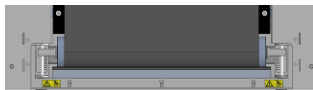
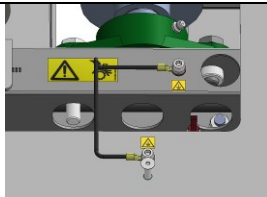
1.6.1 Name Plate

IMAGE	LOCATION
 BalanceTutor™ a dynamic and static postural control trainer Serial : 23-0171 Model : HMBT100A Rating : 200V-240V AC 50/60Hz 10A UDI-DI: (01)07290019733829 IPX-0 RoHS Compliant MD    KB International Aurora Utca, 13. al. 1 Budapest - 1084, Hungary LBL-23-01-01-H	

1.6.2 User Manual Labels

IMAGE	MESSAGE
	Refer to instruction manual / booklet
	Warning / Hazard /Safety precautions Pay attention to accompanying instructions
	Devices of the type BF
	Alternating current (AC)
	Bullet point
	Symbol for collection, treatment, recycling and disposal of waste electrical and electronic equipment (WEEE) as set out in Directive 2002/96/EC of 27 January 2003 of the European Parliament and of the Council on waste electrical and electronic equipment

1.6.3 Warning Labels

IMAGE	MESSAGE	DESCRIPTION	LOCATION
	Finger Trap Hazard	This label located on the back of the moving platform and indicates to technician about the pulley rotation and risk of finger trap.	
	Internal ground connection	This label located near any physical connection of ground wire to chases. Normally this label located within the device.	

1.6.4 Safety, Quality, and Conformity

The MediTouch system is designed and manufactured in accordance with the strict safety and quality requirements of the European Medical Device Regulation (EU) 2017/745. This device bears the CE marking, which signifies our declaration of its conformity with the applicable European Union legislation. The safety and quality of this product are ensured by our adherence to all relevant standards, including those referenced in our technical documentation. The product's design, construction, and performance meet the Essential Safety and Performance Requirements (ESPRs) of the MDR.

1.6.5 Country-Specific Requirements and Use Environment

This device is intended for professional use in medical facilities. The user is responsible for ensuring that the installation and operating environment comply with applicable local regulations and laws (e.g., electrical safety standards for medical facilities).

The device must only be operated in environments for which it is certified and approved as stated in the Technical Specifications section of this manual. Should you have any questions about local regulations or the appropriate use environment, please contact the manufacturer or your local distributor.

1.6.6 CE Marking

The CE marking on the device and its packaging confirms that the device is compliant with the European Medical Device Regulation (EU) 2017/745. By applying the CE marking, the manufacturer declares that the device meets all applicable General Safety and Performance Requirements (GSPRs) and is fit for its intended use.

A copy of the EU Declaration of Conformity, which lists the harmonized standards and common specifications applied, is available upon request.

1.6.7 EMC Electromagnetic & Safety Compatibility

The BalanceTutor system, intended for medical applications, has been designed in accordance with the European Union Council Directive 93/42/EEC. Applicable standards include electromagnetic compatibility (EMC) according to EN 60601-1-2 and safety requirements according to EN 60601-1, Edition 3.1. Certification and testing have been performed by ITL – Israel Testing Laboratories.

1.7 Indications

BalanceTutor is used to facilitate customized perturbation-based balance training.

1.7.1 Perturbation Based Balance Training Indications

- ✓ Stroke
- ✓ Head injury
- ✓ Spinal cord injury
- ✓ Multiple sclerosis
- ✓ Cerebral palsy
- ✓ Peripheral nerve injury
- ✓ Joint surgery / fracture
- ✓ New and seasoned amputees
- ✓ Muscle weakness
- ✓ Prosthetic
- ✓ Muscle / tendon strain
- ✓ Ligament strain
- ✓ Vestibular Rehabilitation; Dizziness, vertigo and equilibrium training
- ✓ Rehabilitation after sport injury
- ✓ Athletes training
- ✓ Fall prevention
- ✓ ADL activities improvement

1.7.2 Special Care in Use

In general, any kind of training by the device requires special attention to ability and medical condition of patient. However, the following list highlights particular training that requires specific care in use according to relevant therapy protocols and must be with the approval of a qualified physician/ doctor recommendation.

- ! Poor joint stability
- ! Soft tissue damage such as Muscle or ligaments tear
- ! Low Bone Density
- ! Post ACL/ PCL surgery
- ! Foot Drop

- ! Limb prosthesis
- ! Post orthopedic surgery including Hip, knee and Ankle surgery
- ! Epilepsy
- ! If an orthotic device like a splint is used or prescribed for the client then this should be used during BT sessions.
- ! When the patient uses walking aid devices like a stick or walker with the device.

1.8 Contraindications

Any medical condition, including cardiovascular, neurological, psychological, or physical impairments that limit safe use of the system, are contraindications for operating the device. The following contraindications must be considered prior to using the BalanceTutor system:

- ! Body weight exceeding 135 kg
- ! Severe fixed contractures
- ! Skeletal instability, including non-consolidated fractures, unstable spinal column, or severe osteoporosis
- ! Presence of open skin lesions
- ! Unstable circulatory conditions
- ! Cardiac-related contraindications

The above list of contraindications is not a complete list. The treating physician retains sole medical responsibility for determining patient suitability for BalanceTutor training.

2 Installation & commissioning

2.1 Staff Members

The following staff name members will need to be available during installation stages:

PROCESS	DURATION	HUMAN RESOURCE	LOCATION
Device installation	Approx. 5 hours	Authorized service representative and support worker	On site
Remote control	Approx. 1/2 hour	Institution system administrator	Remotely Pre-installation
Technical training	Minimum 1 hour	Distributor qualified technician Hospital clinical staff	On site
Clinical training	Minimum 2 hours	Distributor or MediTouch clinician Hospital clinical staff	Remotely, On site (optional)

2.2 Pre Installation Preparation

- ! Transport and installation of the BalanceTutor system must always be performed by the manufacturer, an authorized service team, or an authorized distributor to ensure proper setup and safety.
- ! A minimum safety area of 3 m x 3 m must be maintained around the BalanceTutor system, including the area in front of the treadmill, to provide sufficient free fall space.
- ! Use adjustable feet embedded in the device to correctly adjusted leveling and positioning. Improper leveling may result in noises such as knocking and mechanical noises.
- ! The ceiling height in the installation room must be at least 250 cm.
- ! The floor must have sufficient load-bearing capacity to support the full weight of the BalanceTutor system. This must be approved by the facility manager in the installation location. Floor bearing capacity calculation:

Ground frame unweighting system dimensions	L 189cm x W 101cm = 1.91m ²
The net weight of the BalanceTutor system is	375 kg
The maximum static allowed body weight of the subject is	135 kg
The dynamic weight of the subject is	135 x 3 = 405 kg
The overall weight loads of the system on the platform are	375 + 405 = 780 kg
<u>The bearing capacity of the platform is</u>	<u>780 kg = 408 kg/m²</u>

2.3 Unboxing

Unpacking the device must be done with care to prevent damage to the equipment or injury to personnel.

1. Inspect the wooden crate for any signs of damage before unboxing. Report any damage to your distributor.
2. Use a standard pallet jack and 2-3 assistants to move the crated device to the designated staging area.
3. Carefully disassemble the crate and check all components against the provided packing list.
4. Remove all packing materials and safely transfer the components to the installation site. Note that the Bridge Base (90 kg), Frame Base (50 kg), and Frame Upper (80 kg) are heavy and require special handling.
5. After all components have been removed, dispose of the wooden crate in a designated recycling or waste area.

2.4 Assembly

WARNING: Only a qualified a MediTouch service authorized representative should perform the assembly of the BalanceTutor system. Unauthorized personnel and patients must be kept out of the assembly area.

1. Transport all components to the pre-designated installation area.
2. Follow the assembly steps as detailed in the separate Installation Guide supplied with the system.
3. As part of the assembly, define and set up a keep-out zone around the device to prevent any impact with moving parts.
4. Once the physical assembly is complete, a full Installation Report (Document No: DO-15-01-13) will be available from MediTouch signed both by the service representative and MediTouch. Following document template is hard copy printed and available in each shipped device.

2.5 Preparation for First Use

Before first use, ensure the following steps are completed.

2.5.1 Electrical Connection

Connect the device's power cord to the dedicated power line you prepared. Ensure the electrical source matches the specified requirements for your region (e.g., 230V AC or 208V AC).

2.5.2 Network Setup

A system administrator must connect the dedicated internet physical line to the device and confirm there are no port restrictions.

2.5.3 Initial Power-up & Remote Access:

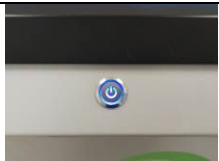
- ! The technician will power on the device and perform a system check.
- ! The system administrator will assist the technician in setting up remote access to the device for future software updates and maintenance.

2.5.4 Training

All staff who will operate the device must complete the required technical and clinical training sessions. The technical training covers system components and safety, while the clinical training covers operational procedures and patient safety.

3 Instructions for Use

3.1 Illuminated System Status Indicators

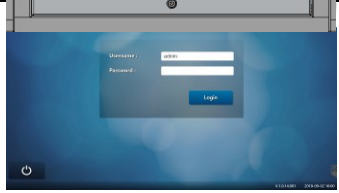
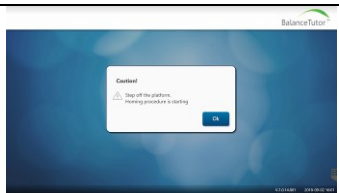
IMAGE	DESCRIPTION	LOCATION
	Emergency stop button pressed	Upper right to the touch screen
	PC ON/OFF momentary switch button	Below the touch screen
	Patient's screen	At the front of the patient
	Therapist's operation touch screen	Touch screen
	Isolation transformer power ON light	Frontal side of the isolation transformer

3.2 Starting the BalanceTutor System

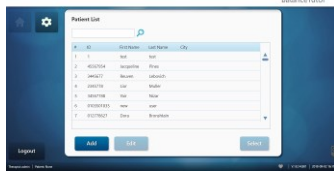
3.2.1 Installation, Overview, Checklist

As one time after the BalanceTutor installed, an authorized technician (distributor or service partner) has to check whether the installation of the device performed properly, before the customer is introduced into the operation of the BalanceTutor. A detailed information of the installation and check list of all the tests performed, need to be delivered to the customer. Ask from the installation manager a Summary Report (MediTouch reff. # DO-15-01-13).

3.2.2 Switching the Device ON

STEP	ILLUSTRATION	DESCRIPTION
1		Turn the isolation transformer dual switch to ON position and confirm the green light is illuminated.
2		Press one time on the  button to turn ON the computer of the BalanceTutor and let the operation system complete its loading.
3		Type Username: admin Password: admin
4		Perform perturbation platform calibration by pressing OK, so it will be located at the center of the device. Platform will move slowly to the end of its travel and turn the direction toward center.

3.2.3 Start Working With Patients

STEP	ILLUSTRATION	DESCRIPTION
1		Select patient from the list or add new and then press Select to start working with the device and the patient.
2		During the treatment, the patient can enjoy from instructions and guidance about the current state of the treatment presented at the patient's screen.

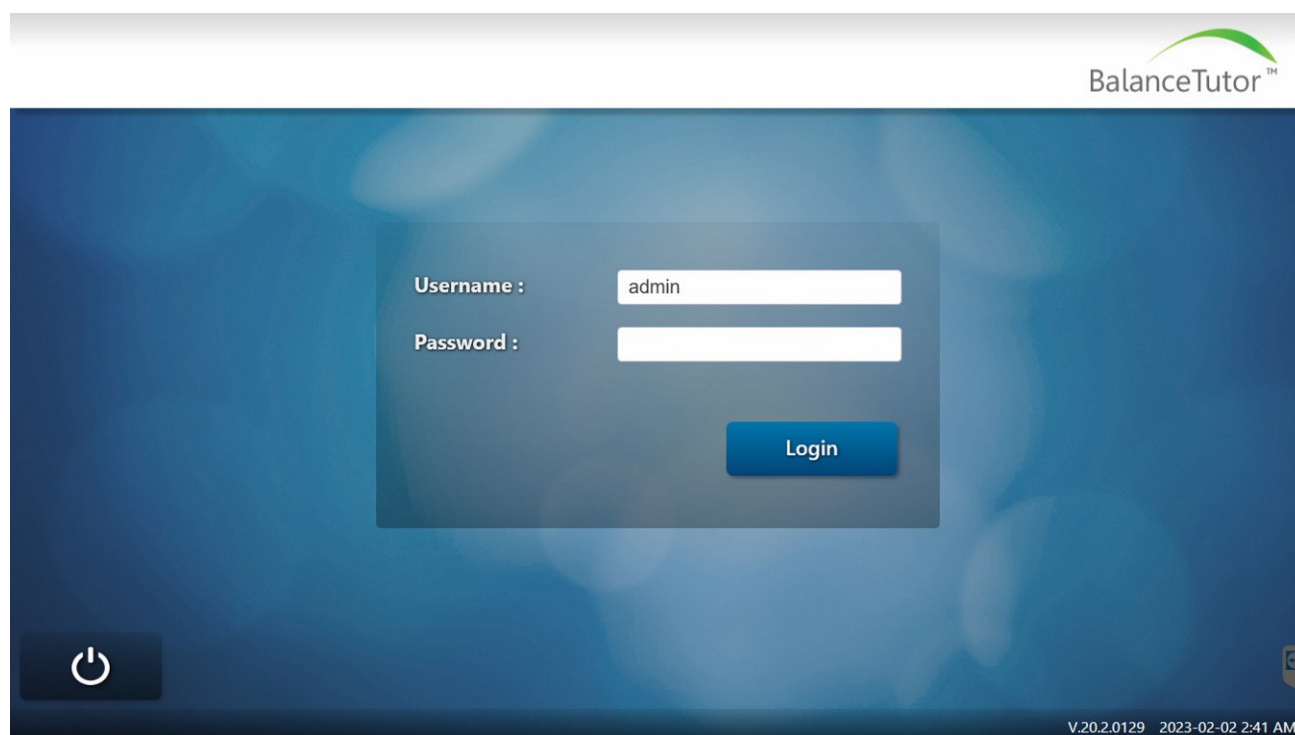
3.3 Software Operation

This section describes the operation of BalanceTutor software usage.

3.3.1 Login

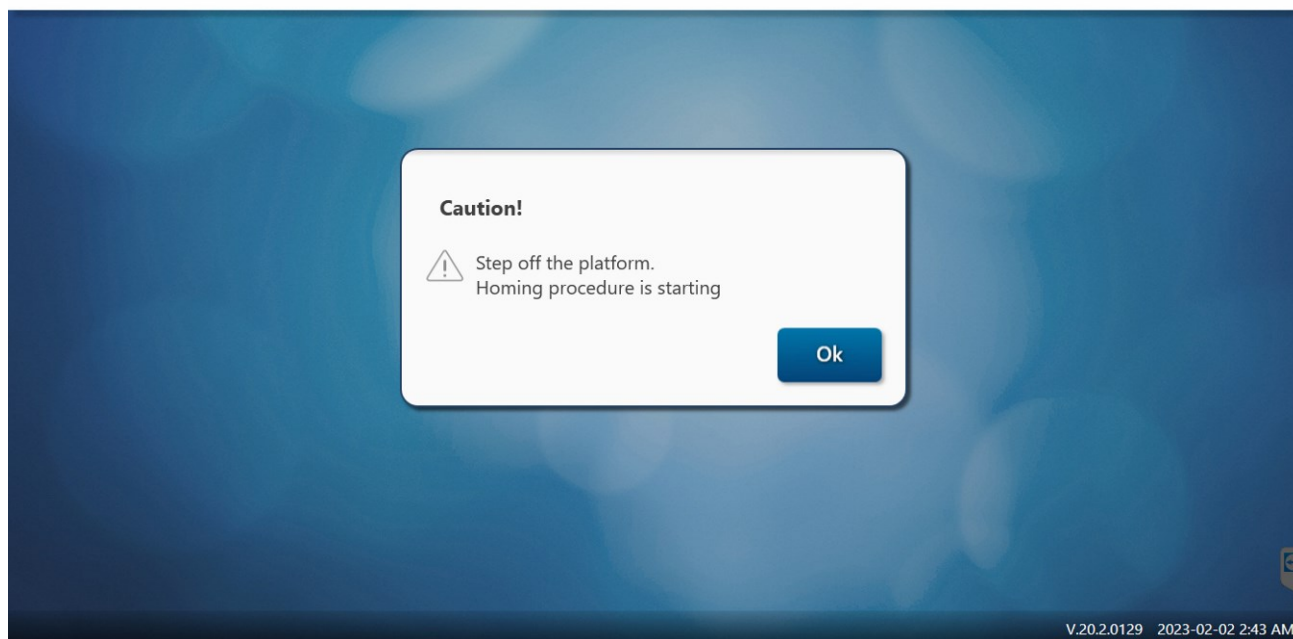
Type your username and password to login into the software.

Username: **admin** Password: **admin**



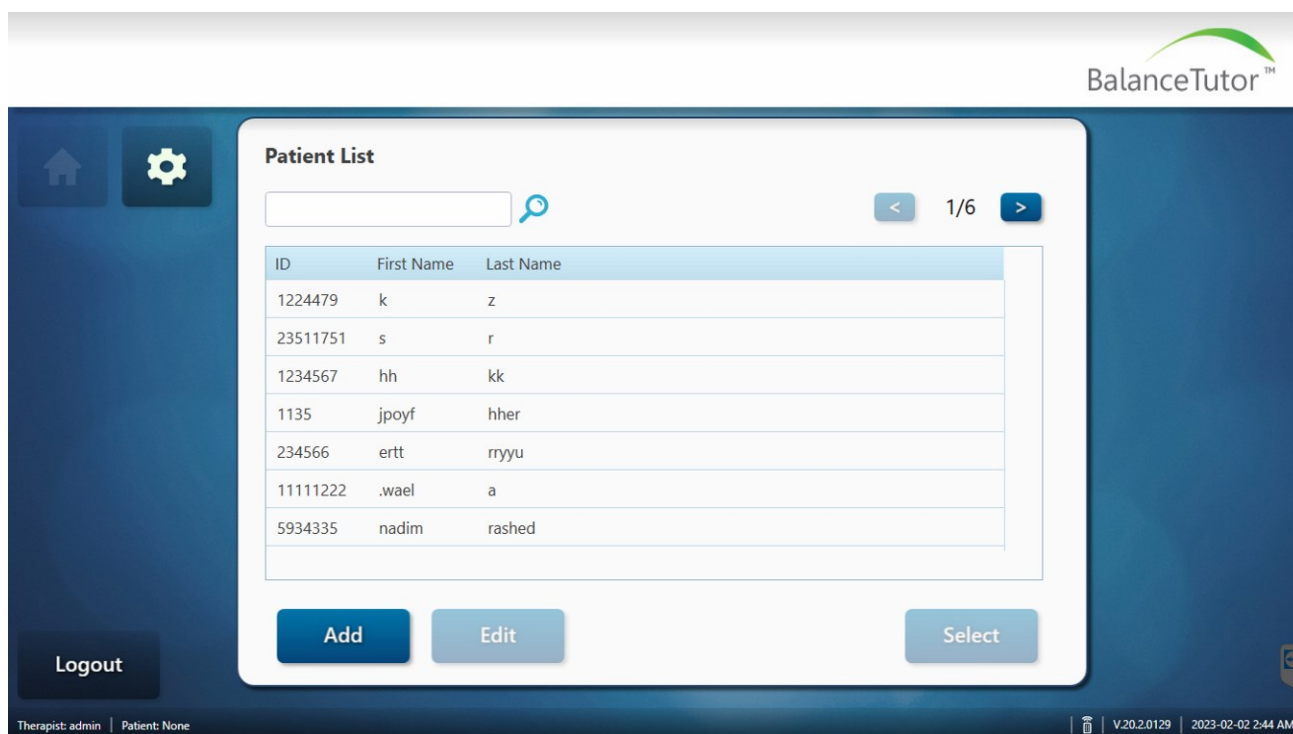
3.3.2 Homing Procedure

In order, the perturbation platform be located in the center of the device, a homing procedure required. By pressing OK, the platform will move one time to the right then return to the exact center of the device. This procedure done only one time each power up.



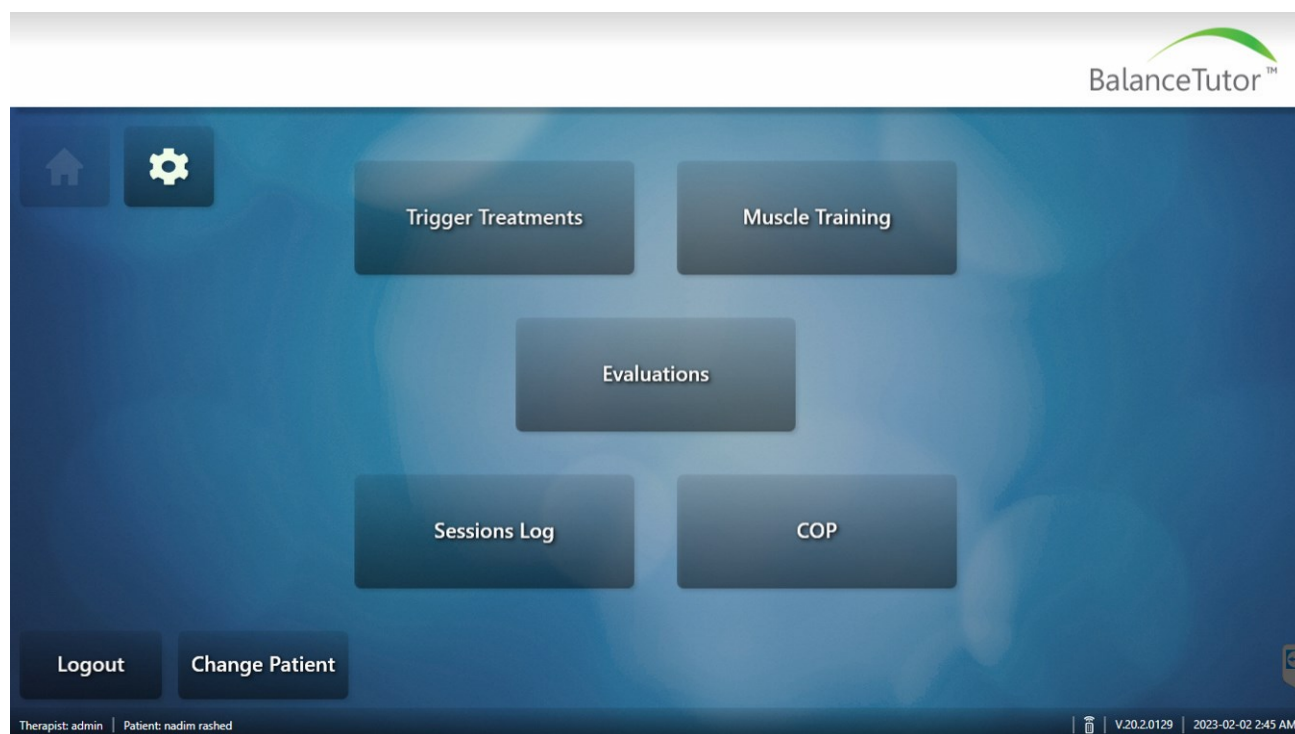
3.3.3 Patient List

In this stage you can create new patients, edit their profile and selecting a specific patient to start work with.



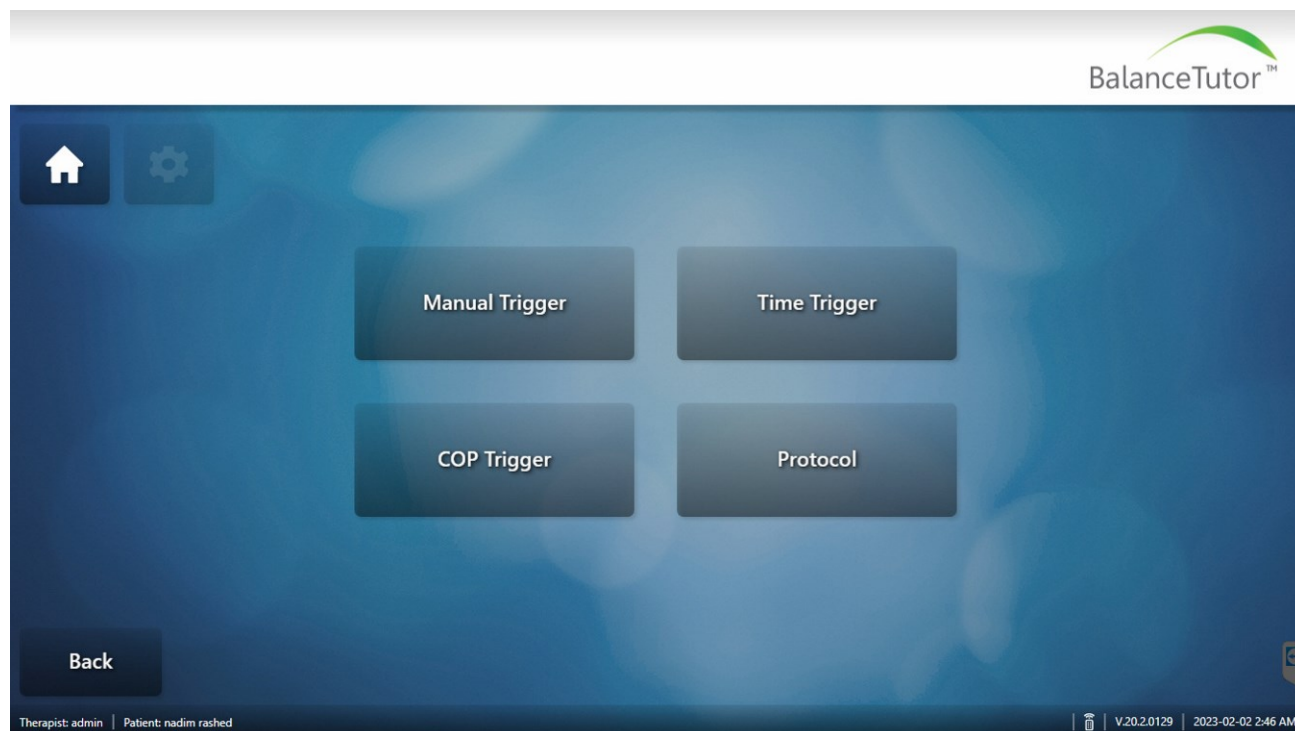
3.3.4 Operational Modes

BalanceTutor enables five main applications for postural control and balance therapy.



Trigger Treatment	A series of different approaches to trigger a perturbation
Muscle Training	A series of different perturbations related to different joints
Evaluations	A series of examinations to quantify postural control abilities
Session Log	Documentation and follow up of patient's progress
COP	A series of treatments based on patient's Center Of Pressure controlling

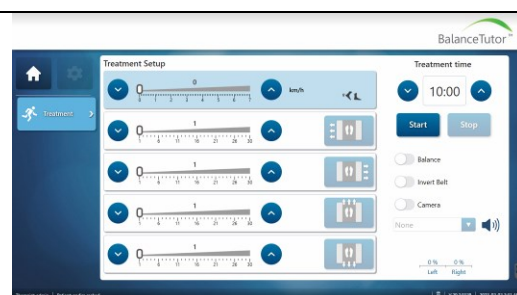
3.3.5 Trigger Treatment



Manual Trigger	Treatment is manually configured by the therapist during the session
COP Trigger	Perturbation is triggered according to specific phase of the gait
Time Trigger	Perturbation is triggered according to quantities of the perturbations
Protocol	A utility to customize a series of predefined perturbation types

3.3.5.1 Manual Trigger

The Manual Trigger mode is designed to allow the therapist full controlling of treatment parameters during the session such as walking speed, perturbation intensities and treatment time. The therapist can set the treatment manually according to the rehabilitation needs.



3.3.5.2 COP Trigger

The COP (Center of Pressure) trigger mode is designed to customize perturbation timing according to the specific phase of the gait such as Swing phase and Stance phase automatically.

This mode composed of 3 main stages (Baseline, Setup and Treatment) as described as follows:

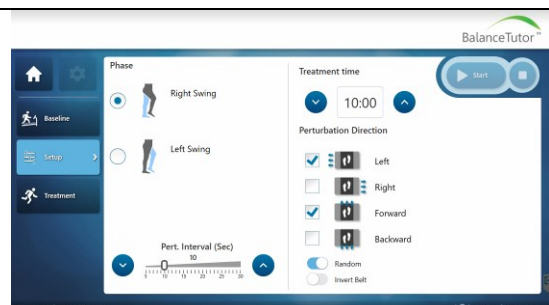
Baseline

The Baseline stage is designed to set the walking speed and Perturbation intensities in 4 directions according to patient abilities and rehabilitation needs.



Setup

The Setup stage is designed to define the manner of treatment such as phase of the gait, direction of the perturbation, Treatment time, perturbation time interval, perturbation sequence (random or block) and belt direction movement.



Treatment

The Treatment stage allows the therapist to follow the treatment process as well as to show or eliminate patient's feedbacks shown on his screen.



3.3.5.3 Time Trigger

The Time Trigger mode is designed to set the treatment according to the duration of the session (perturbation quantity) automatically.

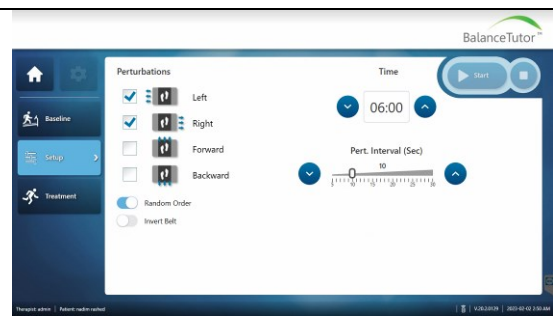
Baseline

The Baseline stage is designed to set the walking speed and Perturbation intensities in four directions according to patient's abilities and rehabilitation needs.



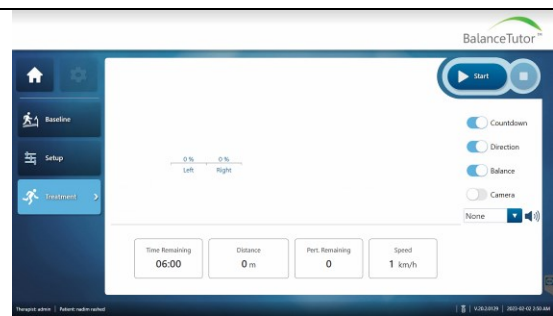
Setup

The Setup stage is designed to define the manner of treatment such as phase of the gait, direction of the perturbation, treatment time, perturbation time interval, perturbation sequence (Random or Block) and belt direction movement.



Treatment

The Treatment stage allows the therapist to follow the treatment process as well as to show or eliminate patient's feedbacks shown on his screen.



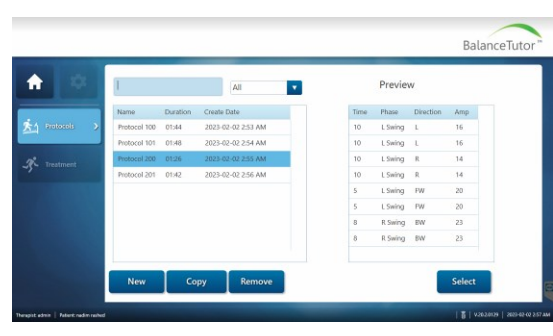
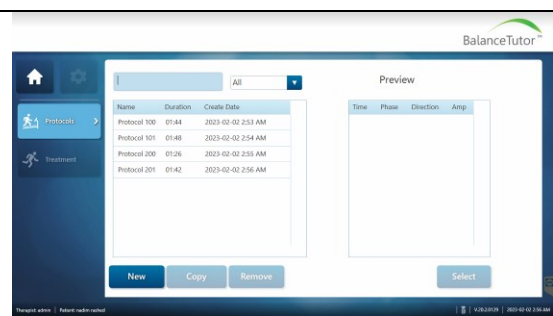
3.3.5.4 Protocol

The protocol mode is designed to build specific sessions that are composed of several kinds of perturbation types, such as both swing and stance phase during the gait or different perturbation interval, while such triggers detected using the COP technology. The therapist can choose a specific session from an existing protocol list or build a new protocol.

3.3.5.4.1 Choosing from existing protocol

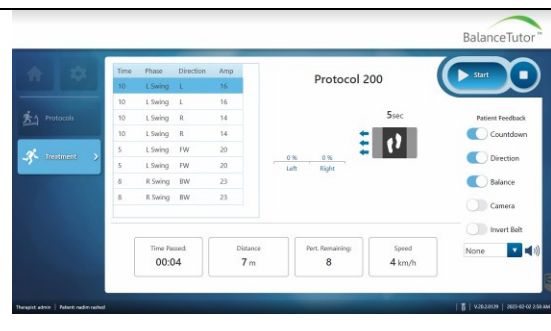
Protocols

The therapist chooses the specific protocol out of the protocol list and then presses the select button.



Treatment

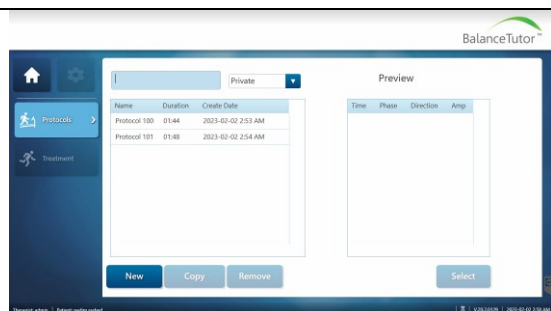
The Treatment stage allows the therapist to follow the treatment process as well as to show or eliminate patient's feedbacks shown on his screen. Changing the direction of the belt can be switched from here.



3.3.5.4.2 Creating new protocol

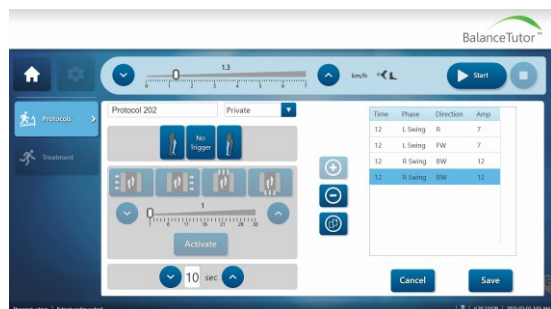
Protocol

Press on New button to create a new protocol.



The therapist can build a list of different perturbations events and defined them as a single protocol as follows:

1. Define protocol name
2. Define which trigger you intend to apply on specific task (Left Swing, Right Swing or No Tigger)
3. Define if the protocol Private or Public to all patients
4. Define perturbation direction
5. Define perturbation intensity. By pressing Activate you can check its actual intensity (active only in standing position).
6. Set time interval between two perturbations event
7. Press  to add a perturbation or  to remove or  to duplicate the selected perturbation event
8. After building of session as described above press Save to complete the protocol definishion



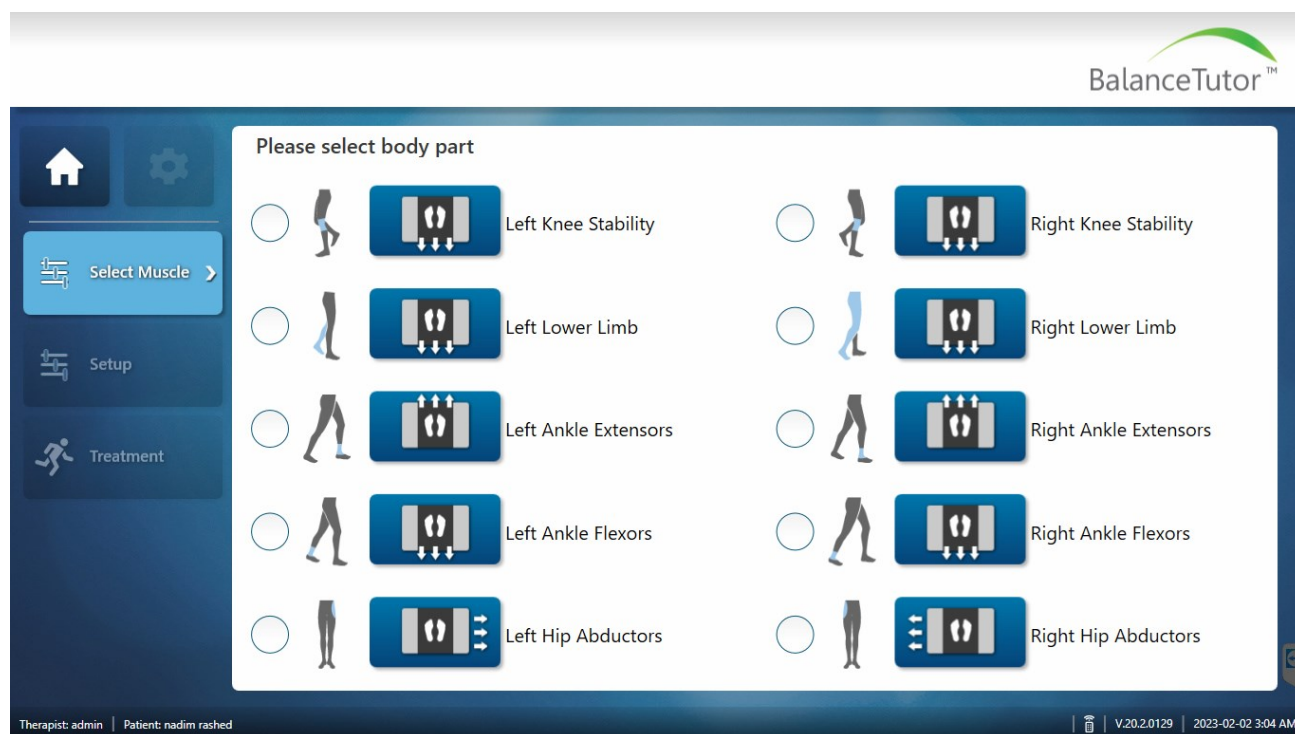
Treatment

The Treatment stage allows the therapist to follow the treatment process as well as to show or disappear the perturbation timing, direction and Balance (COP distribution) to the patient.



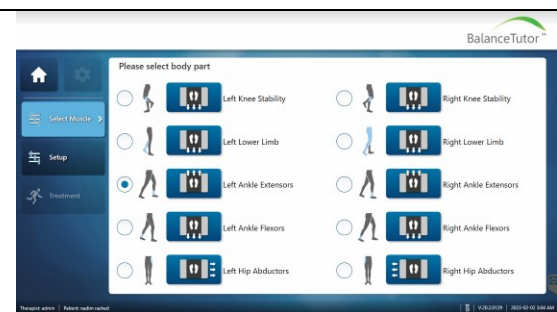
3.3.6 Muscle Training

The muscle-training mode is designed to set the kind of the perturbation according to the anatomy of the body.



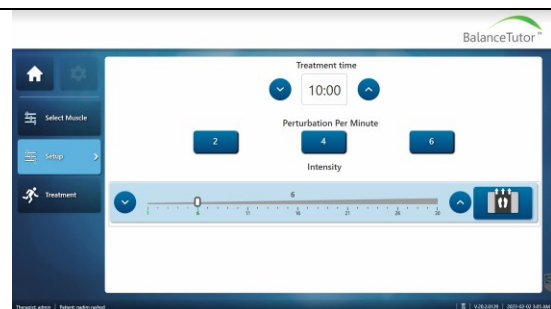
Select Muscle

Choose the area of the body as the aim of the rehabilitation.



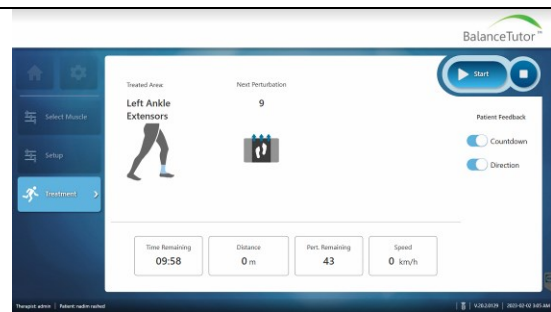
Setup

Choose the treatment time, the number of the perturbation per minute and the intensity of the perturbation. It should be noted, that the direction of the perturbation is automatically set.



Treatment

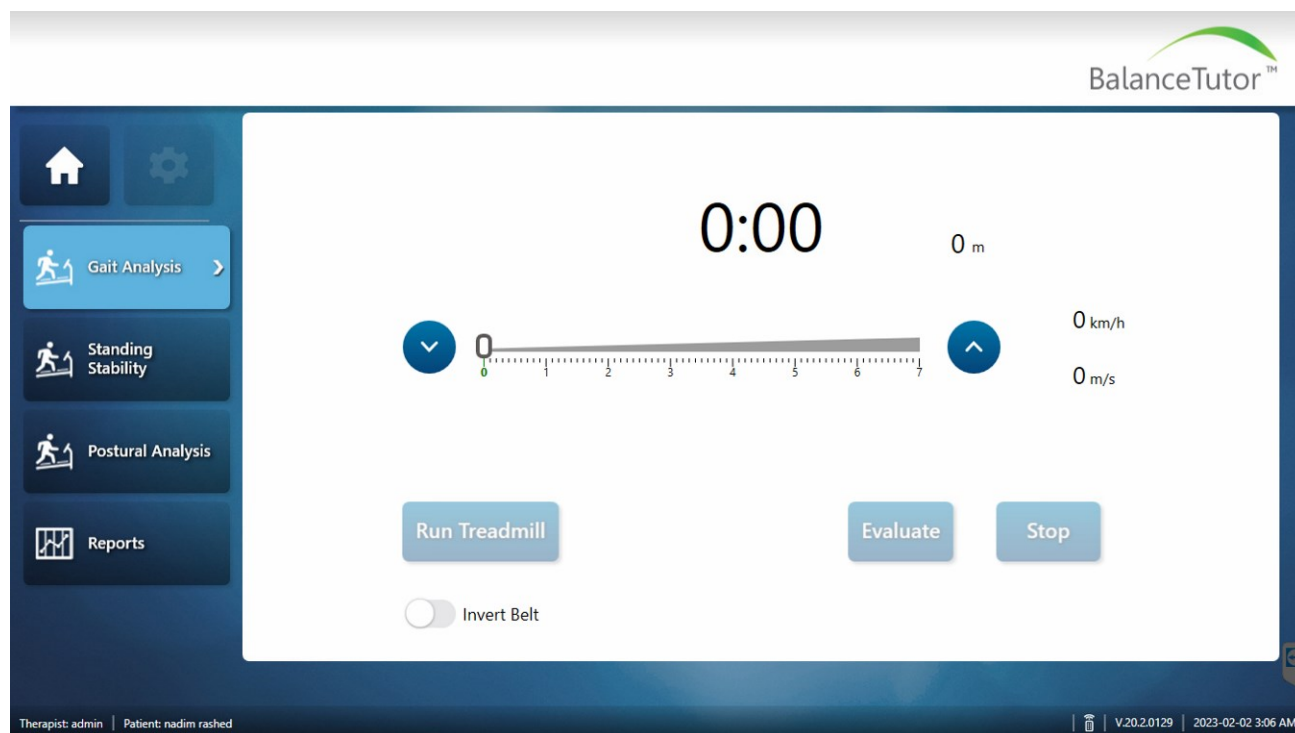
The Treatment stage allows the therapist to follow the treatment process as well as to show or eliminate patient's feedbacks shown on his screen.



3.3.7 Evaluations

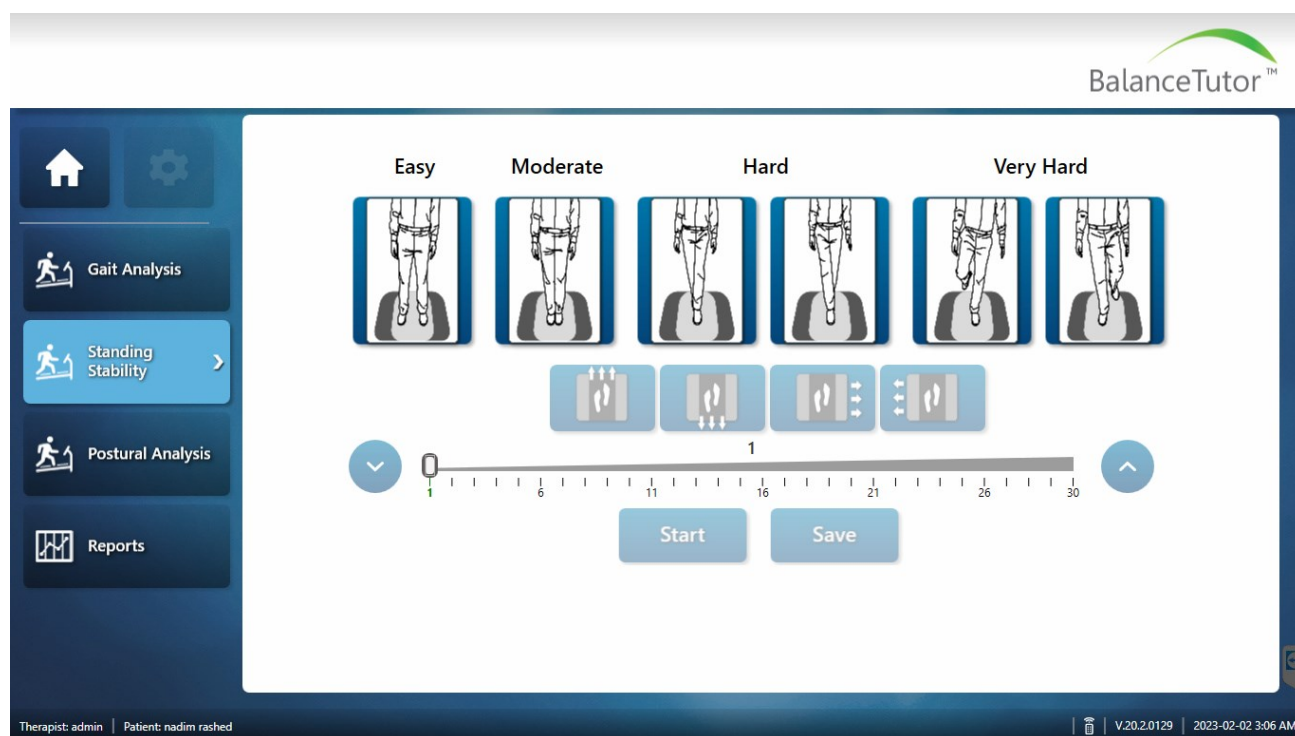
The evaluation mode is designed to evaluate Walking ability, Standing stability and Postural analysis.

3.3.7.1 Gait Analysis



• Evaluation purpose	To evaluate the patient's gait parameters such as Step Length, Step Width, Stride Length, Single and Double Support, Stance and Swing.
• Therapist instructions	Set the normal walking speed and record for 2min until evaluation finished.
• Comment	This evaluation is indicated for patient suffering form limited gait distance ability like less than 100 meters.
• License	This feature is license dependent and not supplied in the basic software package.

3.3.7.2 Standing Stability

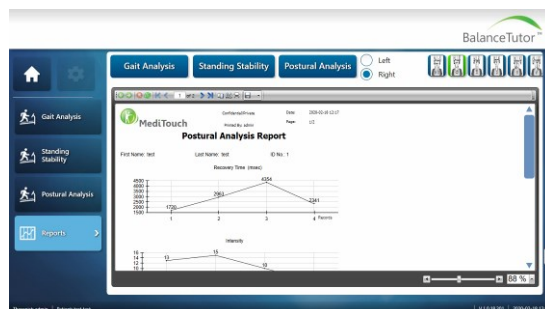
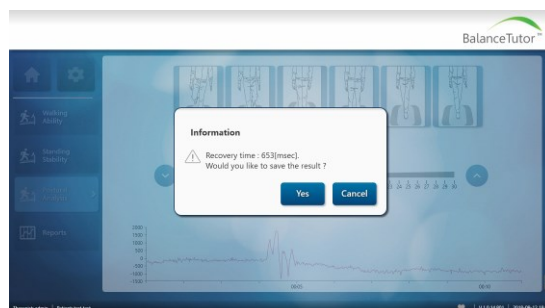
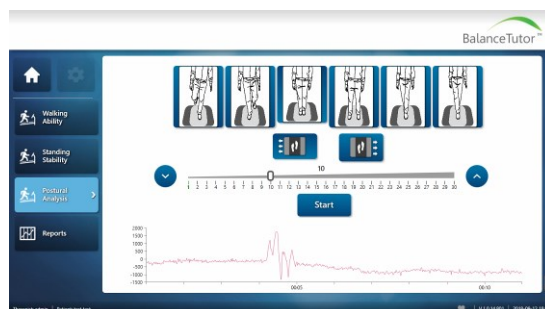
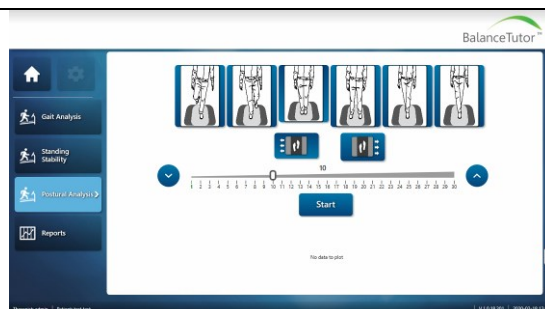
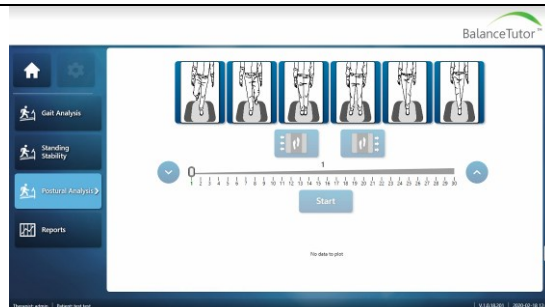


• Evaluation purpose	To evaluate the level of patients Compensatory Step Postural Response.
• Therapist instructions	Set the standing position, direction of the perturbation, level of the perturbation and start. Press save to document the evaluation.
• Comment	Choose the standing position according to patient ability.

3.3.7.3 Postural Analysis

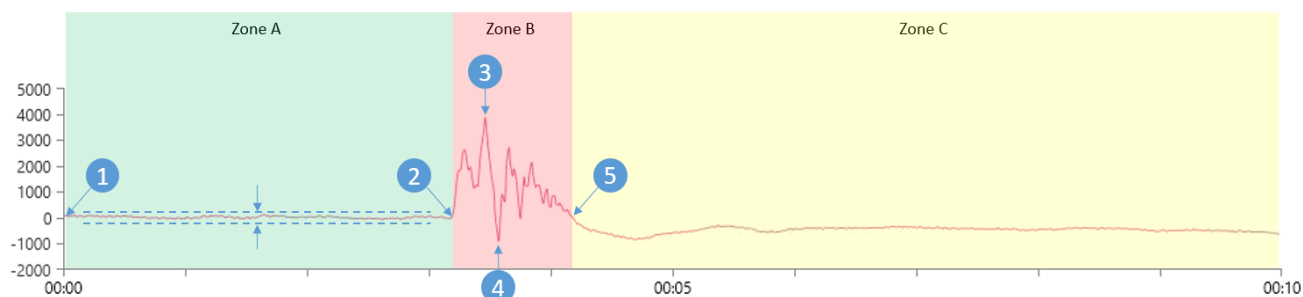
To evaluate the patient's reactive response ability in different stance positions when subjected to varying amplitudes of lateral and medial perturbations.

1. Therapist chooses the stance position
2. Therapist chooses either left or right perturbation
3. Therapist sets perturbation amplitude
4. Therapist instructs the patient to maintain the stance through the perturbation and not shift base of support whenever possible until advised
5. A reading will only be registered in the evaluation if the patient maintains the base of support
6. The therapist decides to save or discard the result of the eval
7. A report detailing stance position and direction and amplitude of perturbation together with the resulting reactive response is generated for the therapy records



3.3.8 Signal Description

The graph shows medial lateral movements of COP annotated by time points relating to the perturbation event and the body sway.



Zone A: Natural body sway behavior before perturbation

Zone B: Body reaction during the perturbation event

Zone C: Regaining of the natural body sway after perturbation

Time Point 1: Start of the recording

Time Point 2: Perturbation event

Time Point 3: First overshoot of the COP peak following perturbation event

Time Point 4: First undershoot of the COP peak following perturbation

Time Point 5: Return to resting sway

Recovery Time [msec]:	Time from perturbation event to regain resting sway following perturbation event
Reactive Response Time [msec]:	Time from perturbation event to first overshoot of COP peak
Peak [mm]:	Distance in mm from first overshoot to first undershoot
COP Travel [mm]:	Sum of the total length of COP excursions between perturbation event and return to resting sway

3.3.9 Reports

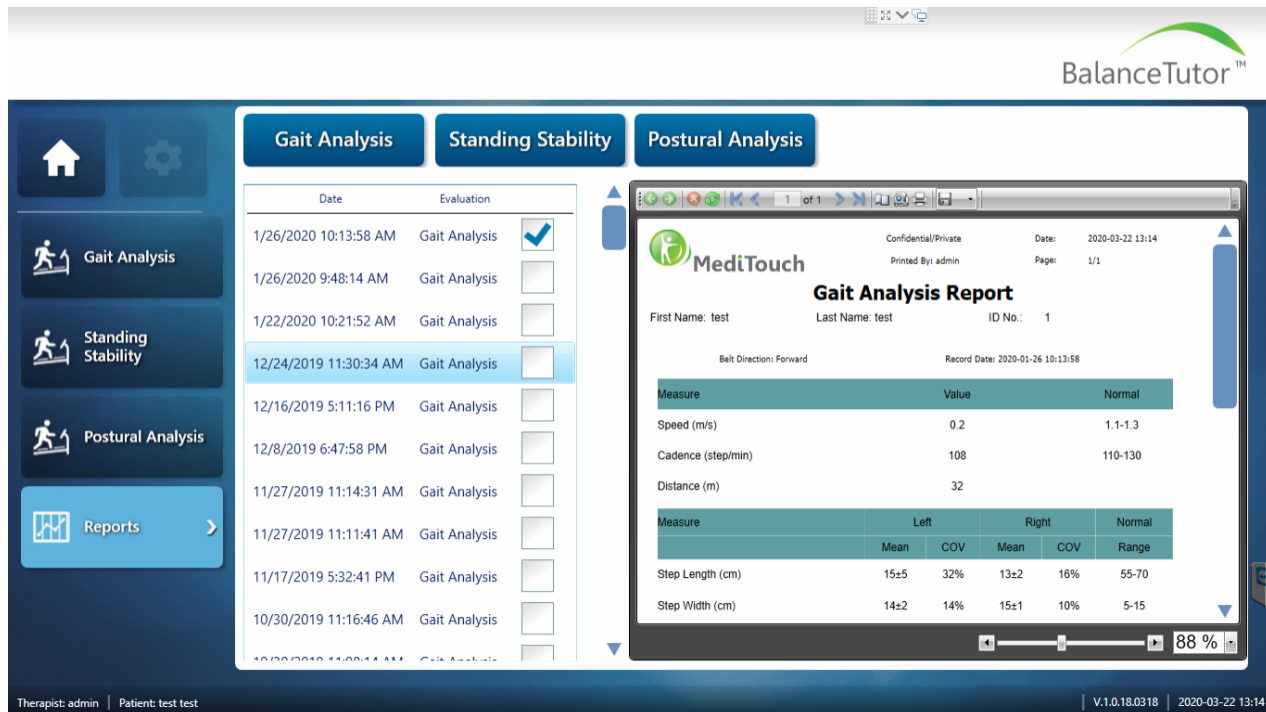
Reports of walking ability standing ability and postural analysis can be generated by clicking on the appropriate label in the top icons. These reports can be printed or saved as pdf files. A suite of validated functional balance evaluations and a gait assessment function has been incorporated into the BalanceTutor system. This functionality allows the therapist to generate and record validated measures to determine record and report on the client's reactive response ability, gait and walking standing and balance ability.

These powerful assessments allow the therapist to establish a baseline showing the patient's functional ability at a given time during Physical therapy. This baseline measurement will allow the therapist to gain an objective insight into an individual's balance and gait deficits and a better understanding of the importance of these deficits to functional ability and the performance of activities of daily living.

In addition, the evaluations provide functional measures that are helpful in predicting the benefit that patients may expect to receive from therapeutic intervention with reactive response training. Furthermore, by comparing evaluations during follow up treatments sessions the therapist can demonstrate and report on improvements in the patient's balance and gait ability. Therefore, these objective measures allow the therapist to better customize reactive response training, improve balance, and gait ability.

3.3.9.1 Gait Analysis

Single report:



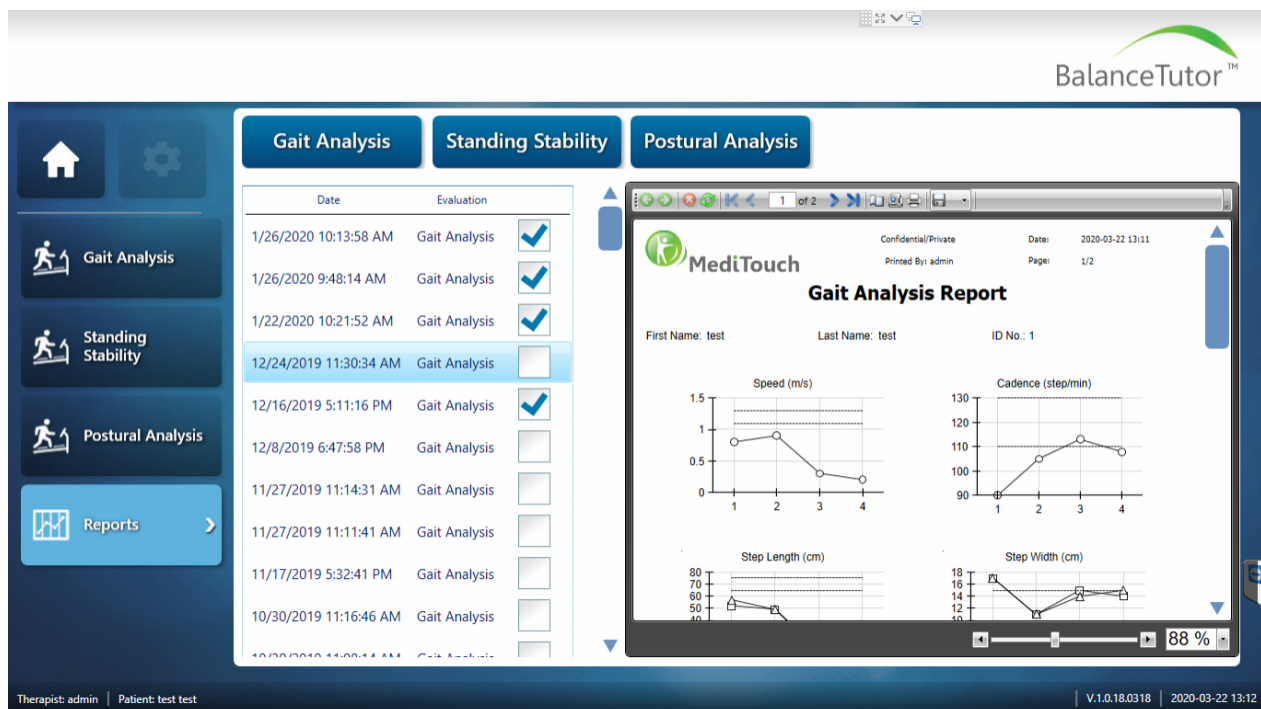
The screenshot displays the BalanceTutor software interface. On the left is a navigation menu with icons for Gait Analysis, Standing Stability, Postural Analysis, and Reports. The main area has three tabs: Gait Analysis, Standing Stability, and Postural Analysis. The Gait Analysis tab is active, showing a list of evaluations with columns for Date, Evaluation, and a checkbox. The selected report is for 12/24/2019 at 11:30:34 AM. On the right, a preview of the 'Gait Analysis Report' is shown. The report includes patient information (First Name: test, Last Name: test, ID No.: 1), belt direction (Forward), and record date (2020-01-26 10:13:58). It contains two tables of gait parameters.

Measure	Value	Normal
Speed (m/s)	0.2	1.1-1.3
Cadence (step/min)	108	110-130
Distance (m)	32	

Measure	Left		Right		Normal Range
	Mean	COV	Mean	COV	
Step Length (cm)	15±5	32%	13±2	16%	55-70
Step Width (cm)	14±2	14%	15±1	10%	5-15

The bottom status bar shows 'Therapist: admin | Patient: test test' and 'V.1.0.18.0318 | 2020-03-22 13:14'.

Accumulated data report:



The screenshot displays the BalanceTutor software interface with the accumulated data report. The Gait Analysis tab is active, and the selected report is for 12/24/2019 at 11:30:34 AM. The preview on the right shows the 'Gait Analysis Report' with four line graphs representing Speed (m/s), Cadence (step/min), Step Length (cm), and Step Width (cm) over four steps. The graphs show fluctuations in the data points.

The bottom status bar shows 'Therapist: admin | Patient: test test' and 'V.1.0.18.0318 | 2020-03-22 13:12'.

Documentation for single record:



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Date: 2020-03-22 13:21
Page: 1/1

Gait Analysis Report

First Name: test Last Name: test ID No.: 1

Belt Direction: Forward Record Date: 2020-01-26 10:13:58

Measure	Value	Normal
Speed (m/s)	0.2	1.1-1.3
Cadence (step/min)	108	110-130
Distance (m)	32	

Measure	Left		Right		Normal Range
	Mean	COV	Mean	COV	
Step Length (cm)	15±5	32%	13±2	16%	55-70
Step Width (cm)	14±2	14%	15±1	10%	5-15
Stride Length (cm)	27±5	18%	27±4	16%	140-160
Single Support (% of gait cycle)	33±6	17%	41±9	21%	37-45
Double Support (% of gait cycle)	14±7	51%	13±8	63%	10-25
Stance (% of gait cycle)	59±8	13%	67±5	7%	55-65
Swing (% of gait cycle)	41±8	19%	33±5	15%	35-45

Comments:

Full Name: _____ Signature: _____

Report Guidelines:
 This report shows the spatial-temporal parameters of the gait cycle and allows both a comparison between the right and left side and normal values of these parameters at the normal average walking speed during 2min.
 COV = Coefficient of Variation.

Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd... Data is only valid if signed by authorized therapist

Hamelacha 45, Poleg Industrial zone,
Netanya, Israel.

Tel: (972)-9-8637477
Fax: (972)-9-8852935

www.meditouch.co.il
info@meditouch.co.il

Speed (m/s)	The speed at which the subject is walking.
Cadence (step/min)	The rate at which a person walk, expressed in steps per minute
Distance (m)	A numerical measurement of how far the subject walks during a given time.
Step Length (cm)	The distance between the point of initial contact of one foot and the point of initial contact of the opposite foot.
Step Width (cm)	The distance between the outer most borders of two consecutive footprints.
Stride Length (cm)	The distance between successive points of initial contact of the same foot.
Single Support (% of gait cycle)	A stage in stance phase, at which only one foot is in contact with the ground.
Double Support (% of gait cycle)	A stage that both feet are simultaneously in the stance phase

Stance (% of gait cycle)	The entire time that a foot is on the ground.
Swing (% of gait cycle)	The entire time that the foot is in the air.
Mean	An average of a certain parameter.
COV	Coefficient of Variation (COV) is the ratio between the standard deviation and the mean of certain parameter.
Normal Range	An average of normal gait spatio-temporal parameters of adults. Bogdan Pietraszewski et al, 2012 http://www.actabio.pwr.wroc.pl/Vol14No3/2.pdf

Documentation for accumulated records:

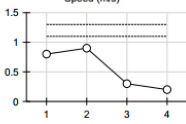


Confidential/Private Date: 2020-03-22 13:23
Printed By: admin Page: 1/3

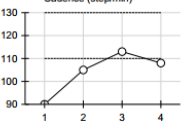
Gait Analysis Report

First Name: test Last Name: test ID No.: 1

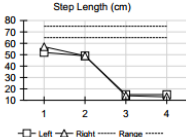
Speed (m/s)



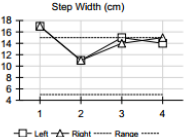
Cadence (step/min)



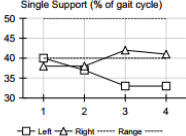
Step Length (cm)



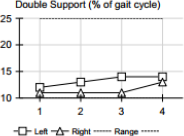
Step Width (cm)



Single Support (% of gait cycle)



Double Support (% of gait cycle)

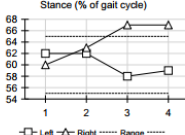


Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd.. Data is only valid if signed by authorized therapist
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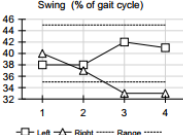


Confidential/Private Date: 2020-03-22 13:23
Printed By: admin Page: 2/3

Stance (% of gait cycle)



Swing (% of gait cycle)



Stride Length (cm)



Comments:

Full Name: _____ Signature: _____

Report Guidelines:
This report shows the spatial-temporal parameters of the gait cycle and allows both a comparison between the right and left side and normal values of these parameters at the normal average walking speed during 2min.

Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd.. Data is only valid if signed by authorized therapist
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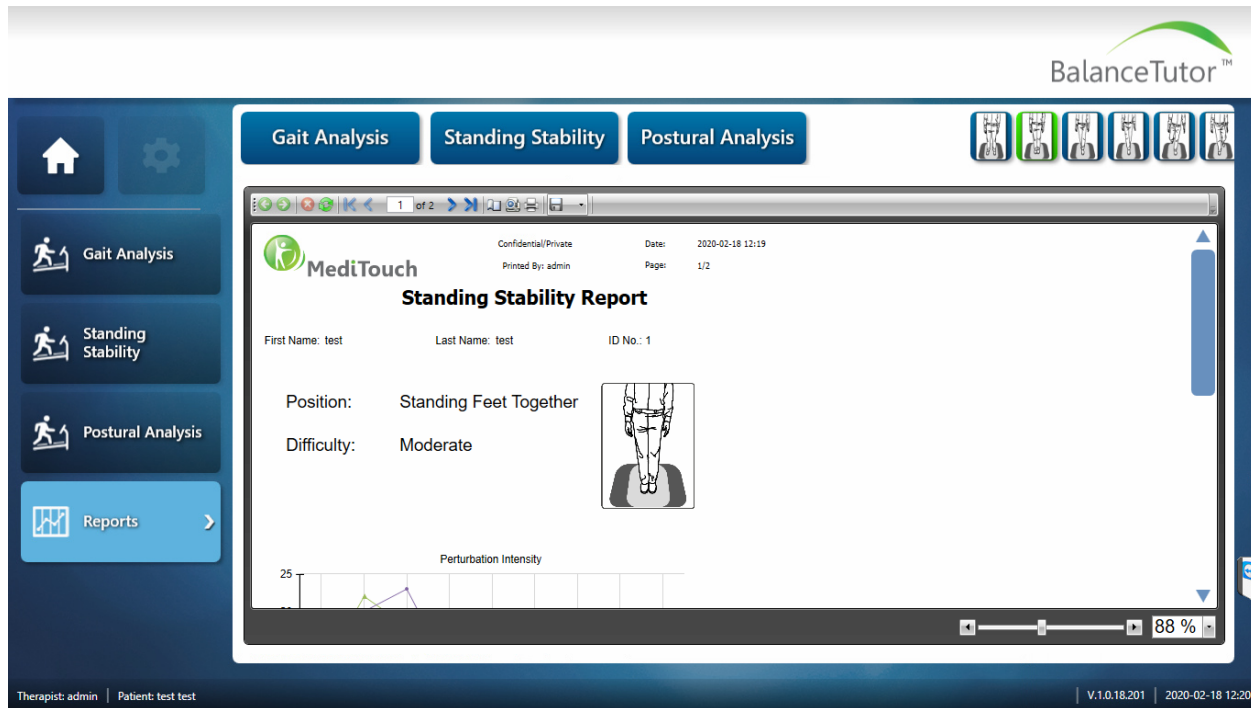


Confidential/Private Date: 2020-03-22 13:23
Printed By: admin Page: 3/3

Record #	Date [yyyy-MM-dd mm:ss]	Speed [km/h]	Speed [m/s]	Cadence [step/min]	Duration [mm:ss]	Distance [m]	Belt Direction
1	2019-12-16 17:11:16	3	0.83	90	02:00	109	Forward
2	2020-01-22 10:21:52	3.2	0.89	105	02:00	148	Forward
3	2020-01-26 09:48:14	1	0.28	113	02:00	50	Forward
4	2020-01-26 10:13:58	0.9	0.25	108	02:00	32	Forward

Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd.. Data is only valid if signed by authorized therapist
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3.3.9.2 Standing Stability

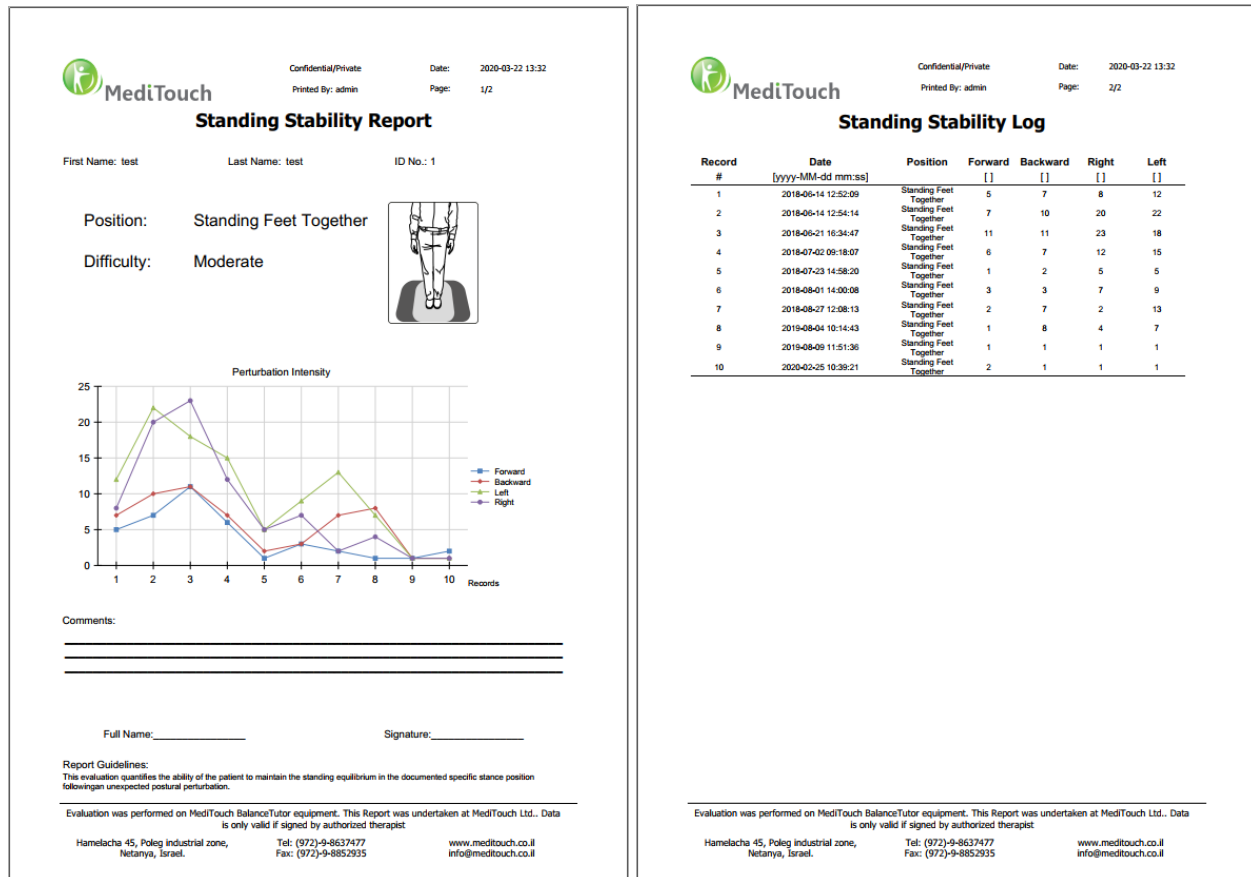


The screenshot shows the MediTouch BalanceTutor software interface. The top navigation bar includes 'Gait Analysis', 'Standing Stability' (selected), and 'Postural Analysis'. The left sidebar has icons for 'Gait Analysis', 'Standing Stability', 'Postural Analysis', and 'Reports'. The main window displays the 'Standing Stability Report' for a patient named 'test' (ID No.: 1). The report includes the following information:

- Position:** Standing Feet Together
- Difficulty:** Moderate
- Diagram:** A diagram of a person standing with feet together.
- Graph:** A line graph titled 'Perturbation Intensity' showing intensity over 10 records. The y-axis ranges from 0 to 25. The graph shows four data series: Forward (blue), Backward (red), Left (green), and Right (purple).

At the bottom of the interface, it shows 'Therapist: admin' and 'Patient: test test'. The version is V.1.0.18.201 and the date is 2020-02-18 12:20.

Documentation for accumulated records:

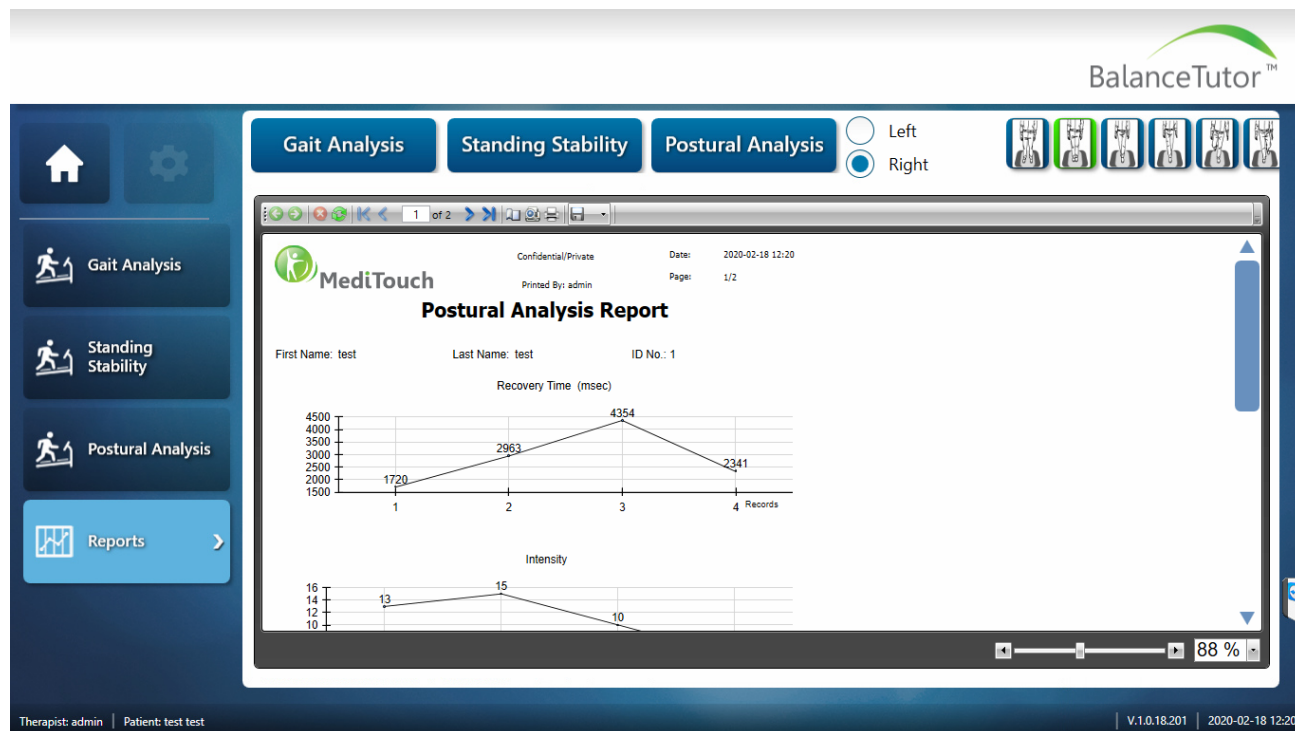


The image shows two printed reports from MediTouch. The left report is a 'Standing Stability Report' for a patient named 'test' (ID No.: 1). It includes the same information as the screenshot: Position (Standing Feet Together), Difficulty (Moderate), a diagram of a person standing with feet together, and a line graph titled 'Perturbation Intensity' showing intensity over 10 records. The graph shows four data series: Forward (blue), Backward (red), Left (green), and Right (purple). The right report is a 'Standing Stability Log' showing a table of accumulated records. The table has columns for Record #, Date, Position, Forward, Backward, Right, and Left. The data is as follows:

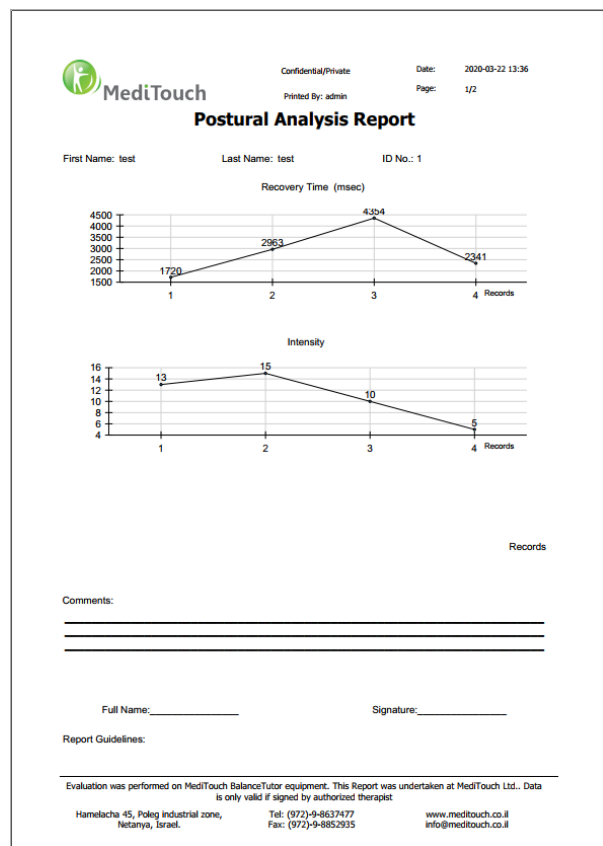
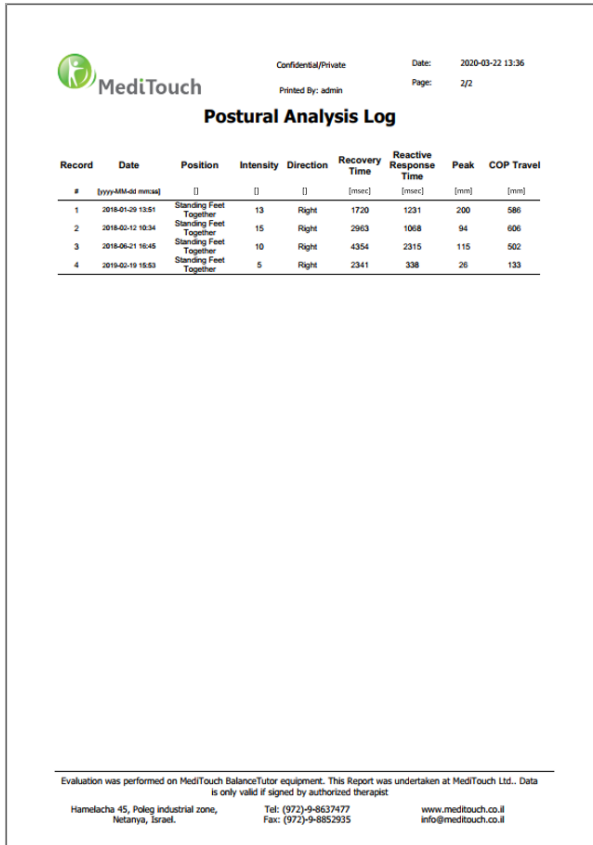
Record #	Date [yyyy-MM-dd mm:ss]	Position	Forward	Backward	Right	Left
1	2018-06-14 12:52:09	Standing Feet Together	5	7	8	12
2	2018-06-14 12:54:14	Standing Feet Together	7	10	20	22
3	2018-06-21 16:34:47	Standing Feet Together	11	11	23	18
4	2018-07-02 09:18:07	Standing Feet Together	6	7	12	15
5	2018-07-23 14:58:20	Standing Feet Together	1	2	5	5
6	2018-08-01 14:00:08	Standing Feet Together	3	3	7	9
7	2018-08-27 12:08:13	Standing Feet Together	2	7	2	13
8	2019-08-04 10:14:43	Standing Feet Together	1	8	4	7
9	2019-08-09 11:51:36	Standing Feet Together	1	1	1	1
10	2020-02-25 10:39:21	Standing Feet Together	2	1	1	1

Both reports include contact information for MediTouch: Hamelacha 45, Poleg Industrial zone, Netanya, Israel. Tel: (972)-9-8637477, Fax: (972)-9-8852935, www.meditouch.co.il, info@meditouch.co.il.

3.3.9.3 Postural Analysis



Documentation for accumulated records:

MediTouch

Confidential/Private Date: 2020-03-22 13:36
Printed By: admin Page: 2/2

Postural Analysis Log

Record	Date	Position	Intensity	Direction	Recovery Time [msec]	Reactive Response Time [msec]	Peak [mm]	COP Travel [mm]
1	2018-01-09 13:51	Standing Feet Together	13	Right	1720	1231	200	586
2	2018-02-12 10:34	Standing Feet Together	15	Right	2963	1068	94	606
3	2018-06-21 16:45	Standing Feet Together	10	Right	4354	2315	115	502
4	2019-02-19 15:53	Standing Feet Together	5	Right	2341	338	26	133

Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd., Data is only valid if signed by authorized therapist

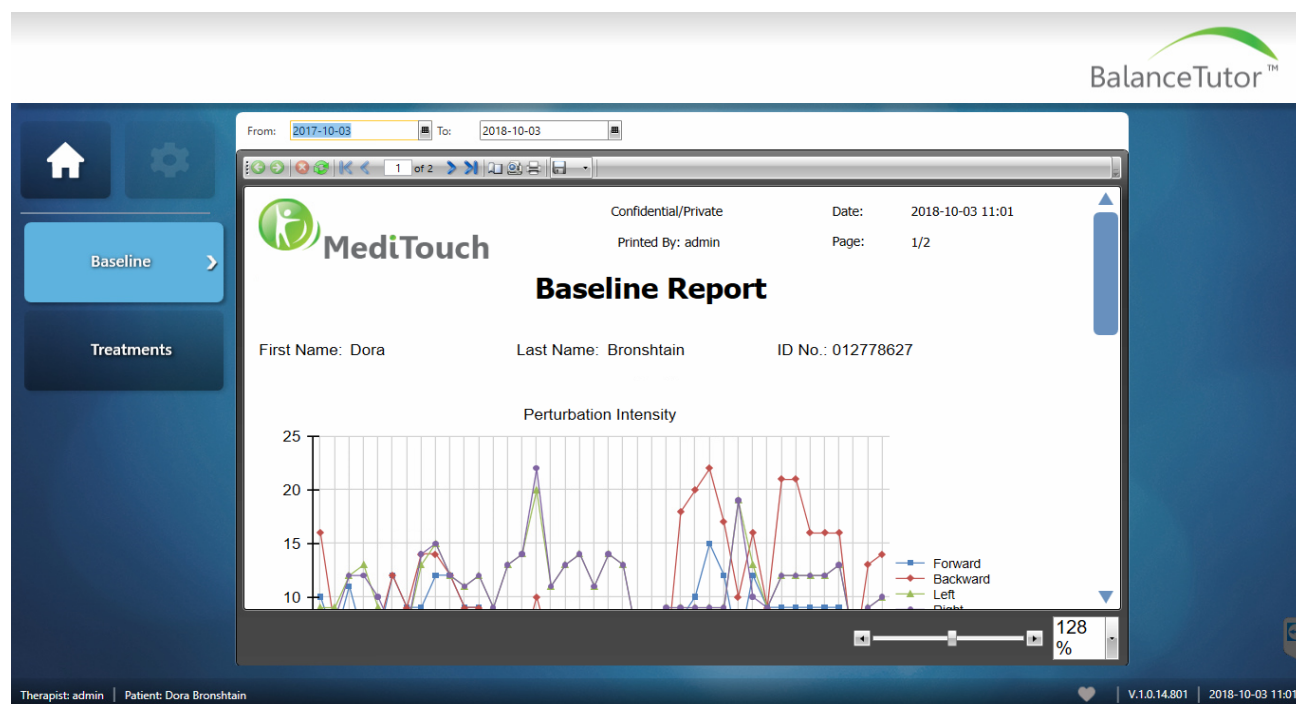
Hamelacha 45, Poleg Industrial zone, Netanya, Israel. Tel: (972)-9-8637477 Fax: (972)-9-8852935 www.meditouch.co.il info@meditouch.co.il

Record	The chosen records of the evaluation that the user wishes to appear on the report.
Date	The date that the report is initiated.
Position	A particular way in which the subject is placed on the system
Intensity	The magnitude of the postural unexpected perturbation. It refers to how far the platform is moving during the fixed time of 300 ms. It is scaled from 1 to 30. For instance intensity 10 means that the platform is moving 10 cm for 300 ms.
Direction	The direction that the platform is moving toward
Recovery Time	The period of time that the body recovers from an unexpected perturbation.
Reaction Response Time	The period of time that the body needs to react (detecting time) to the unexpected perturbation.
Peak	Peak-to-peak amplitude is the change between peak (highest and lowest amplitude value).
COP Travel	The total distance that the cop is moving. (COP excursion)

3.3.10 Session Log

A session Log is an inquiry of Baseline changes and all Treatment conducted in patient's activity history.

3.3.10.1 Baseline



Baseline report can be generated by clicking on the appropriate label in the top icons.

These report can be printed or saved as pdf files.



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Date: 2018-09-02 17:18
Page: 1/2

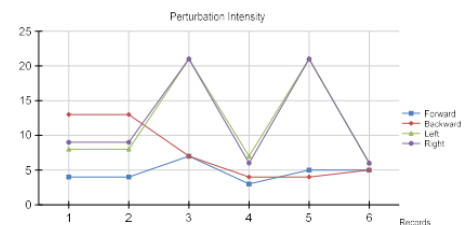
Date: 2018-09-02 17:18
Page: 2/2

Baseline Report

First Name: Svika Last Name: Catz ID No.: 3131885

Baseline Record Log

Record #	Date [yyyy-MM-dd mm ss]	Walking Speed [km/h]	Forward []	Backward []	Left []	Right []
1	2018-08-20 12:43	3	4	13	8	9
2	2018-08-27 14:32	2.5	4	13	8	9
3	2018-08-29 13:14	0	7	7	21	21
4	2018-08-29 13:26	0	3	4	7	6
5	2018-08-29 13:43	0	5	4	21	21
6	2018-08-29 13:49	0	5	5	6	6




Comments:

Full Name _____ Signature _____

Report Guidelines:
A threshold value set by a therapist indicates balance ability prior to reaction response. A baseline which not followed by a treatment is erased. Perturbation intensity mode that includes acceleration, target speed, distance and duration changes according to the selected walking speed.

Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd., Data is only valid if signed by authorized therapist

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Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd., Data is only valid if signed by authorized therapist

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3.3.10.2 Treatments



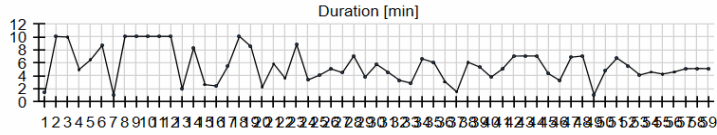
Confidential/Private
Printed By: admin

Date: 2018-10-03 11:01
Page: 1/2

Date: 2018-10-03 11:01
Page: 1/2

General Treatment Report

First Name: Dora Last Name: Bronshtain ID No.: 012778627



Distance [m]

1000 T

128 %

Therapist: admin Patient: Dora Bronshtain

V.1.0.14.801 2018-10-03 11:01

Treatments report can be generated by clicking on the appropriate label in the top icons.

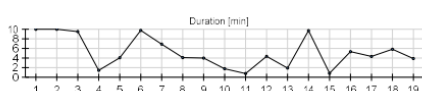
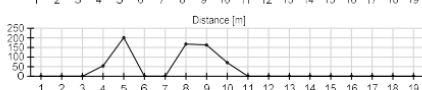
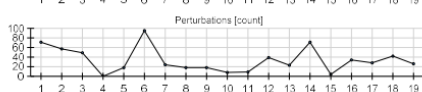
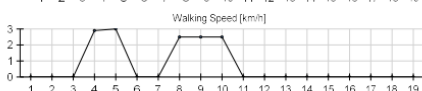
These report can be printed or saved as pdf files.



Confidential/Private Date: 2018-09-02 17:22
Printed By: admin Page: 1/2

General Treatment Report

First Name: Svika Last Name: Catz ID No.: 3131885

Comments:

Full Name: _____ Signature: _____

Report Guidelines:
An overview summarizing treatment's duration, distance, amount of perturbations and walking speed of each treatment. Each graph includes a record number that represents the specific time and occurrence of the treatment.

Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd., Data is only valid if signed by authorized therapist.

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Confidential/Private Date: 2018-09-02 17:22
Printed By: admin Page: 2/2

Treatments Record Log

Record #	Date [yyy-MM-dd mm:ss]	Duration [min:sec]	Distance [m]	Speed [km/h]	Perturbations [count]	Treatment [type]
1	2018-08-20 12:10	10:00	0	0	71	Manual Trigger
2	2018-08-20 12:20	10:00	0	0	57	Manual Trigger
3	2018-08-20 12:31	09:31	0	0	49	Manual Trigger
4	2018-08-20 12:40	01:27	54	2.9	0	Manual Trigger
5	2018-08-20 12:43	04:04	201	3	18	Time Trigger
6	2018-08-27 14:13	09:46	0	0	95	Manual Trigger
7	2018-08-27 14:23	06:54	0	0	24	Manual Trigger
8	2018-08-27 14:32	04:06	168	2.5	18	Time Trigger
9	2018-08-27 14:39	04:00	163	2.5	18	Time Trigger
10	2018-08-27 14:44	01:47	71	2.5	8	Time Trigger
11	2018-08-27 14:50	00:47	0	0	9	Manual Trigger
12	2018-08-27 14:51	04:22	0	0	39	Manual Trigger
13	2018-08-27 14:57	01:55	0	0	23	Manual Trigger
14	2018-08-29 13:14	09:43	0	0	71	Time Trigger
15	2018-08-29 13:26	00:50	0	0	4	Time Trigger
16	2018-08-29 13:27	05:20	0	0	34	Time Trigger
17	2018-08-29 13:33	04:20	0	0	28	Time Trigger
18	2018-08-29 13:43	05:50	0	0	42	Time Trigger
19	2018-08-29 13:50	03:54	0	0	26	Time Trigger

Total Records: 19
Total Days: 3
Total Treatment Duration: 01:38:36 HH:MM:SS
Total Walking Distance: 657 m
Minimum Walking Speed: 0 km/h
Maximal Walking Speed: 3 km/h
Total Perturbations: 634
Total Treatment Types: 2

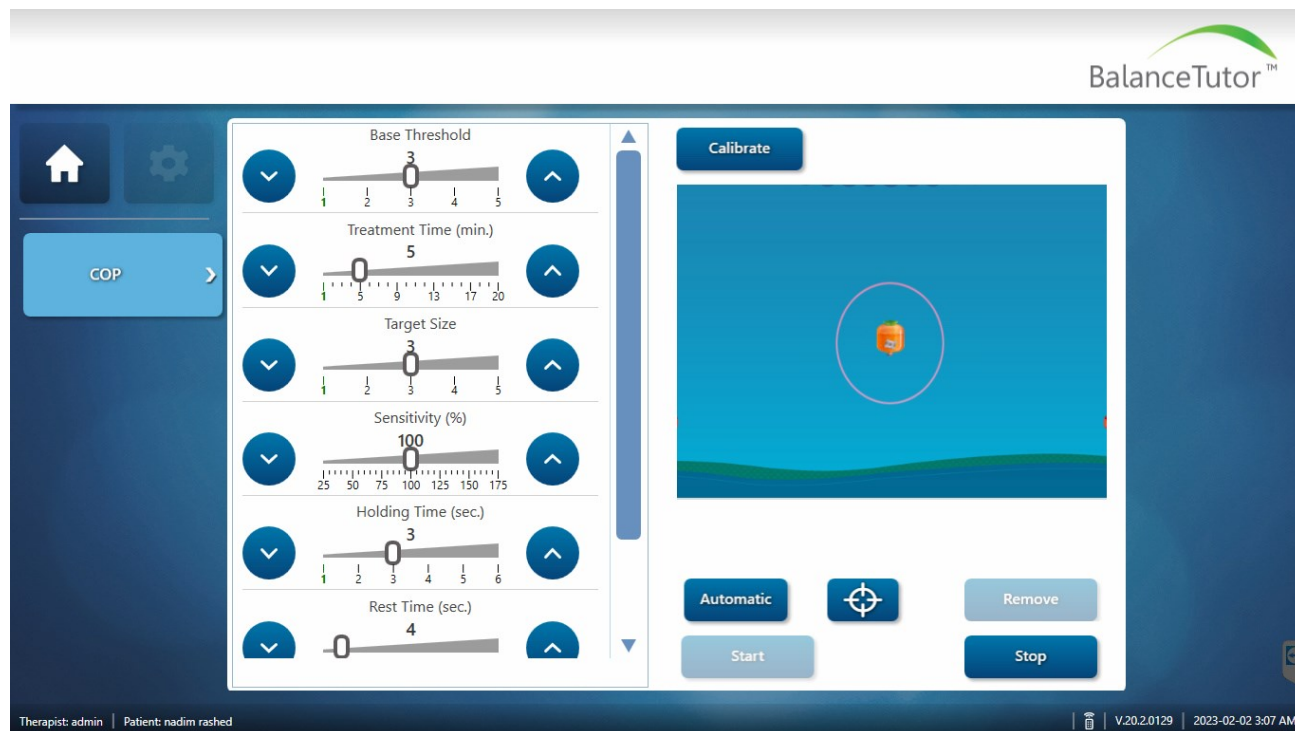
Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd., Data is only valid if signed by authorized therapist.

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Netanya, Israel. Tel: (972)-9-8637477 www.meditouch.co.il
Fax: (972)-9-8852935 info@meditouch.co.il

3.3.11 COP

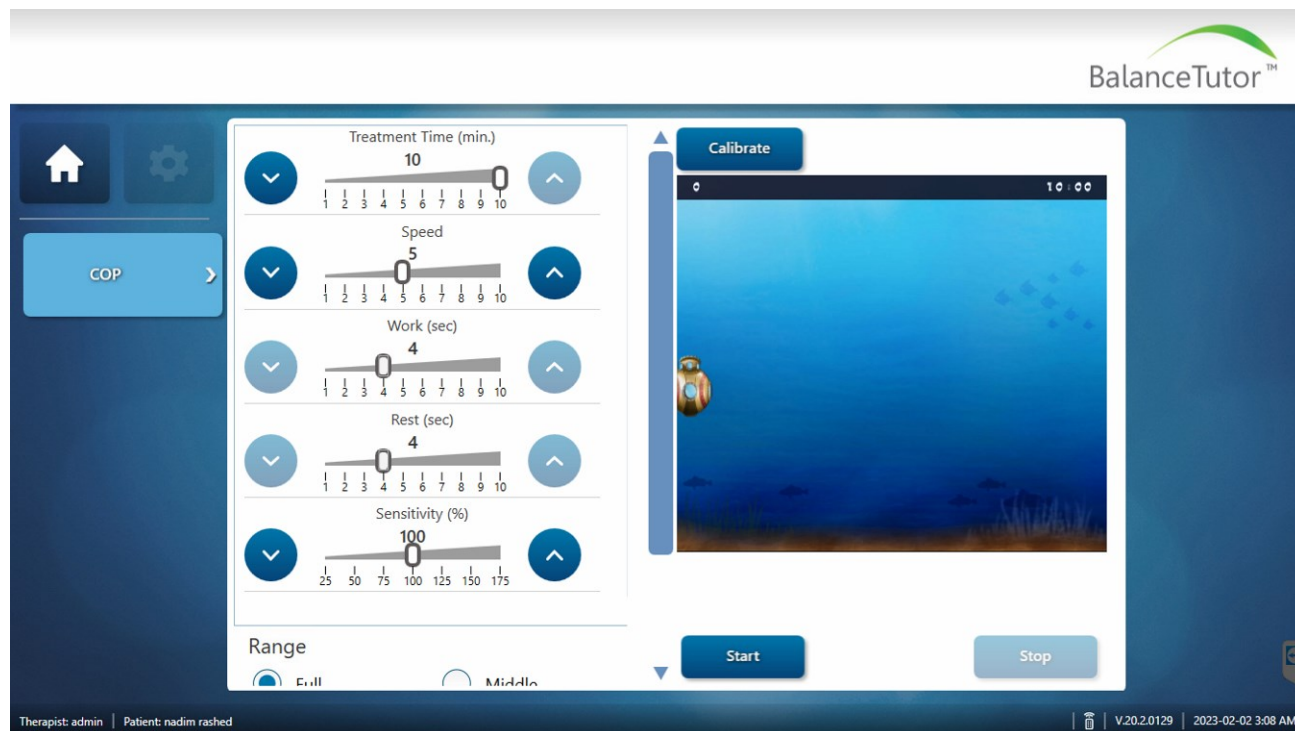
The COP task have been designed to facilitate repetitions of isolated weight shifting practice in any stance position. The practice can be customized according to the patient's weight shifting movement ability and the therapists objective for practice.

3.3.11.1 Fruit Shop



• Treatment purpose	To facilitate anterior/ posterior and medial lateral weight shifting practice in any stance position/
• Therapist instructions	➤ Choose stance position ➤ Calibrate the fruit jug to this start position ➤ Instruct patient to do anterior/ posterior medial lateral body shifts ➤ Press target icon button to set a target for each weight shift from the calibrated start position. Or press automatic to generate targets ➤ Press start to commence the
• Comment	No force can be applied to force plate apart from patient

3.3.11.2 Submarine



• Treatment purpose	To facilitate anterior/ posterior and medial lateral weight shifting practice in any stance position/
• Therapist instructions	➤ Choose stance position ➤ Choose medial/ lateral of anterior posterior task ➤ Direct patient to do appropriate weight shift exercise and press calibrate ➤ Check Range icon on left ➤ Set treatment parameters according to patient's ability ➤ Press start
• Comment	No force can be applied to force plate apart from patient

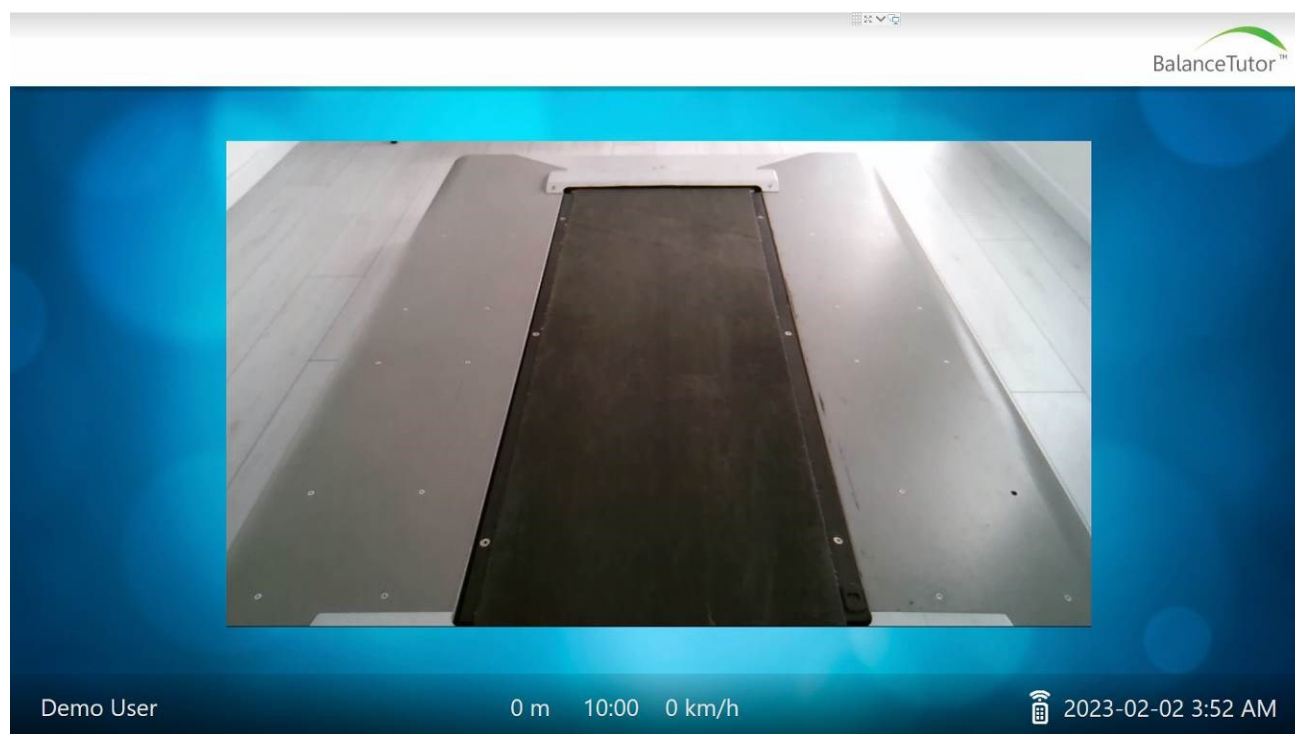
3.4 Patient Screen

The patient screen displays different combinations including Feedback (Live Camera and Balance symmetry), Perturbation Event Indications (Time Indicator and Direction Indicator), Visual Stimulation (Optic flow, optokinetic and VOR), Patient Instructions and System Indicators (Patient name, Distance completed, Treatment Time, Walking speed, Remote control, Date and Time and Heart Rate Monitor).

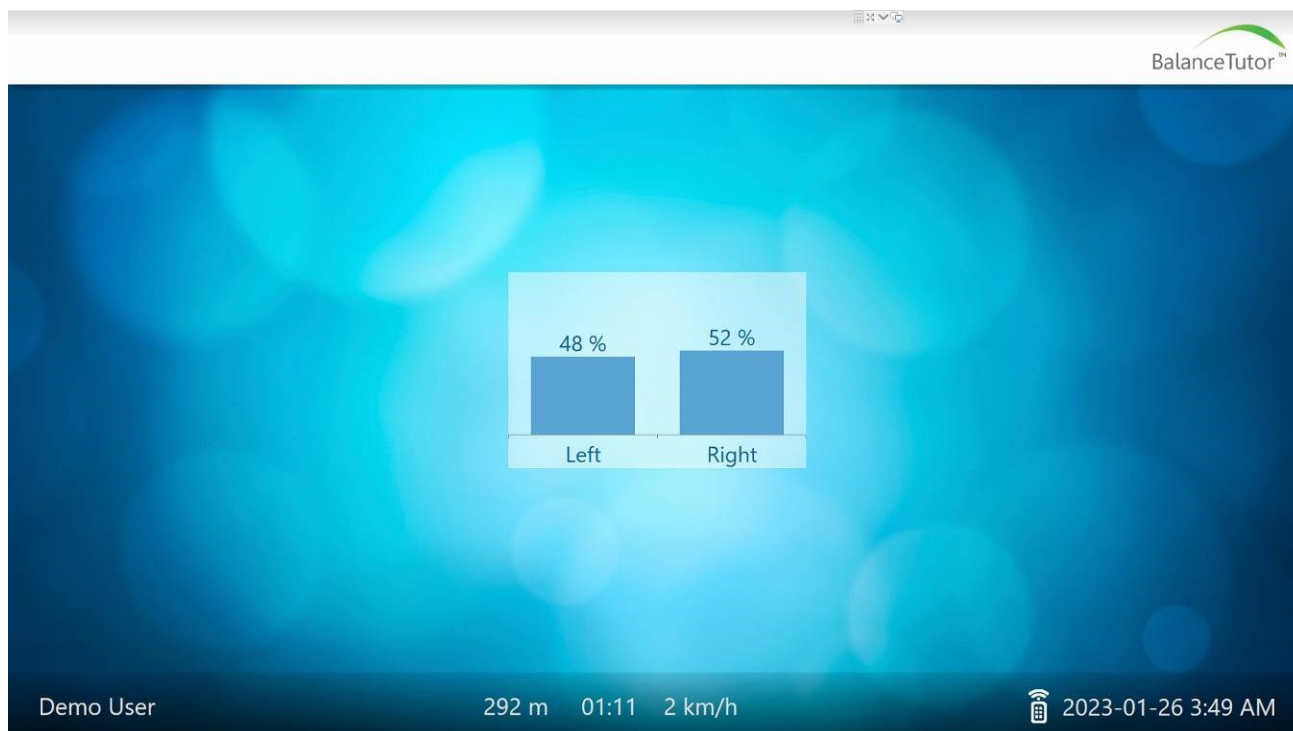
3.4.1 Feedback

The system provides two kinds of feedback including:

- Visual feedback: Posture and gait using an adjustable forward facing camera,

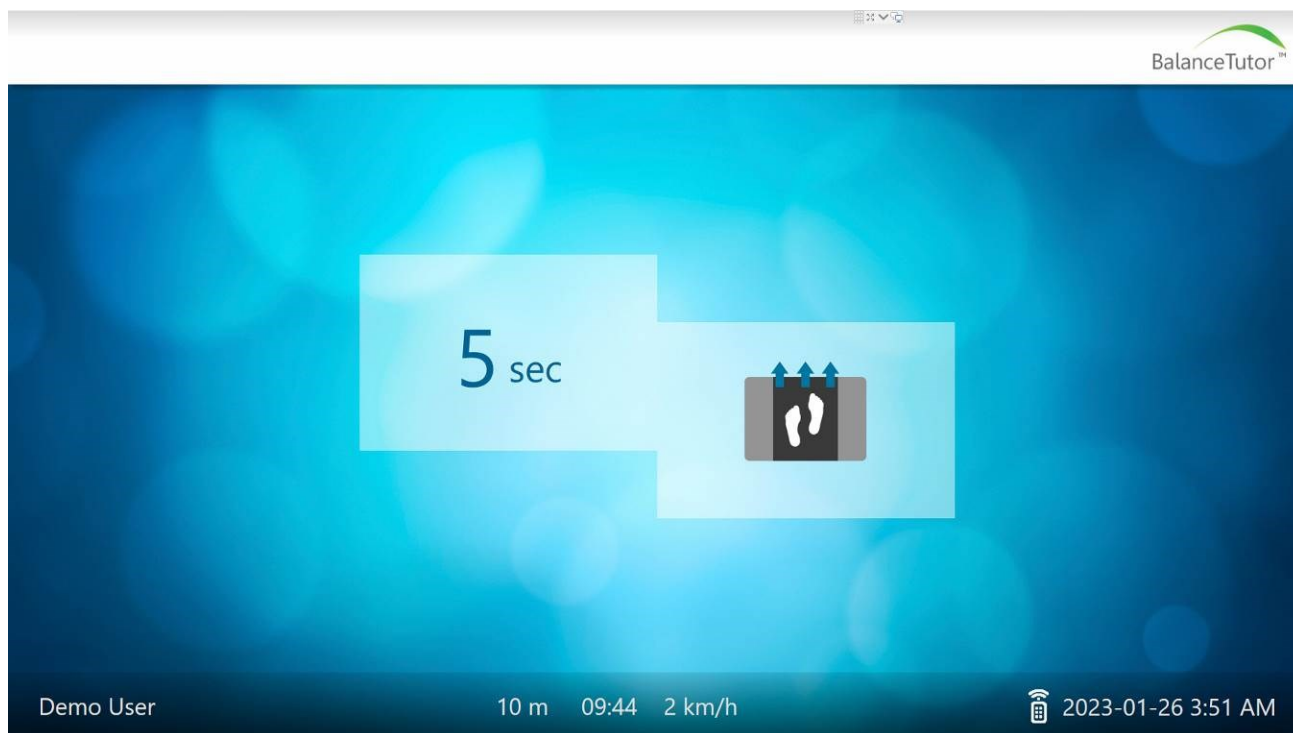


➤ Balance Symmetry: Distribution of right and left sided weight bearing during gait



3.4.2 Perturbation Event Indicators

A description of the time to and direction of the next perturbation event.

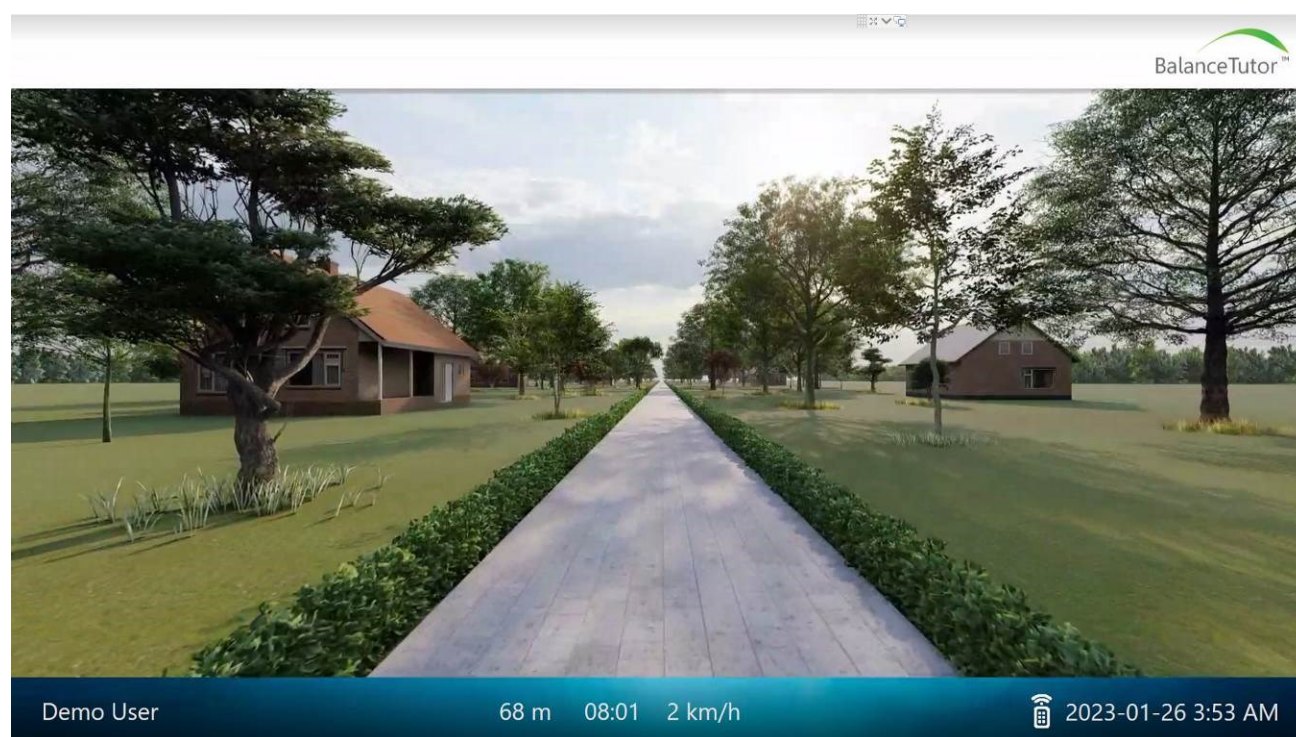


3.4.3 Visual Stimulation

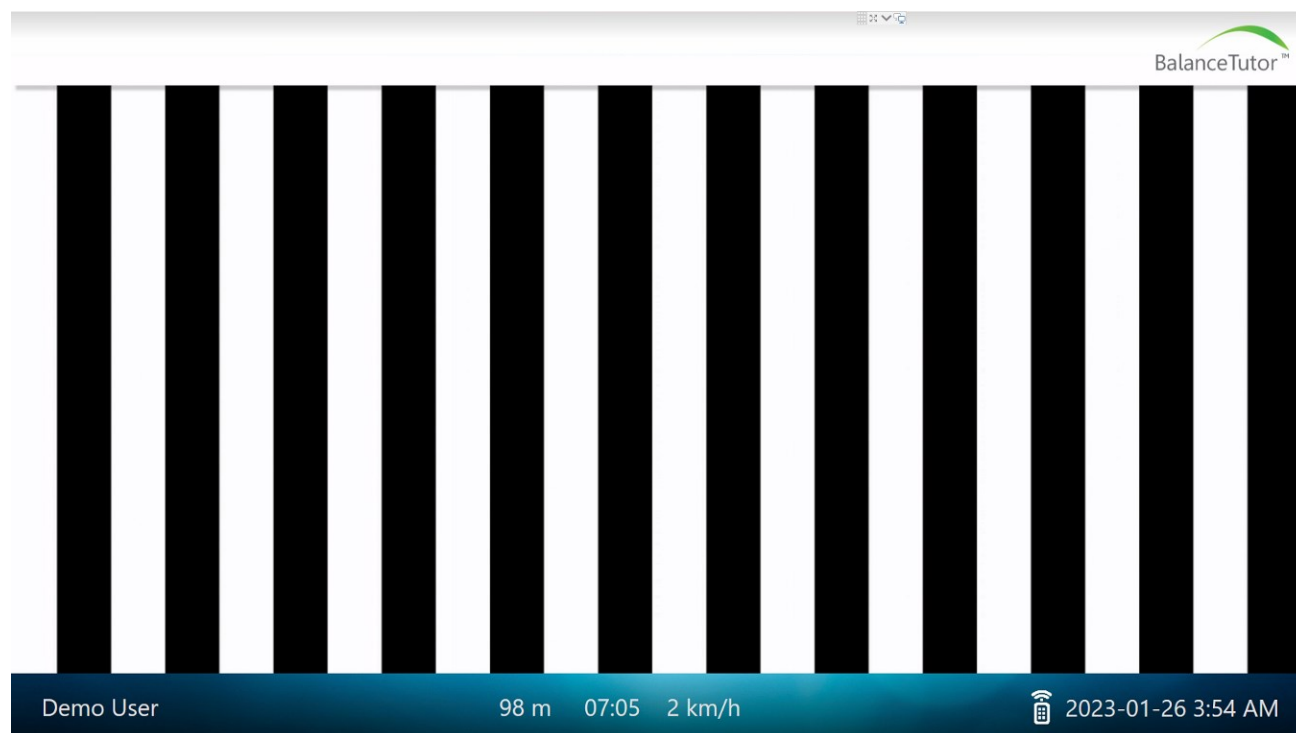
Virtual Environment (VEs) and Semi-Immersive Virtual Reality can be displayed to the patient. This allows the therapist to manipulate practice conditions to engage motivation, motor control, cognitive processes, and sensory integration ability. Visual stimulation enables goal-oriented and repetitive practice to enhance rehabilitation outcomes.

Virtual environments consist of diverse everyday life scenarios including outdoor environments such as forests and the street, Indoors environments such as supermarkets and malls.

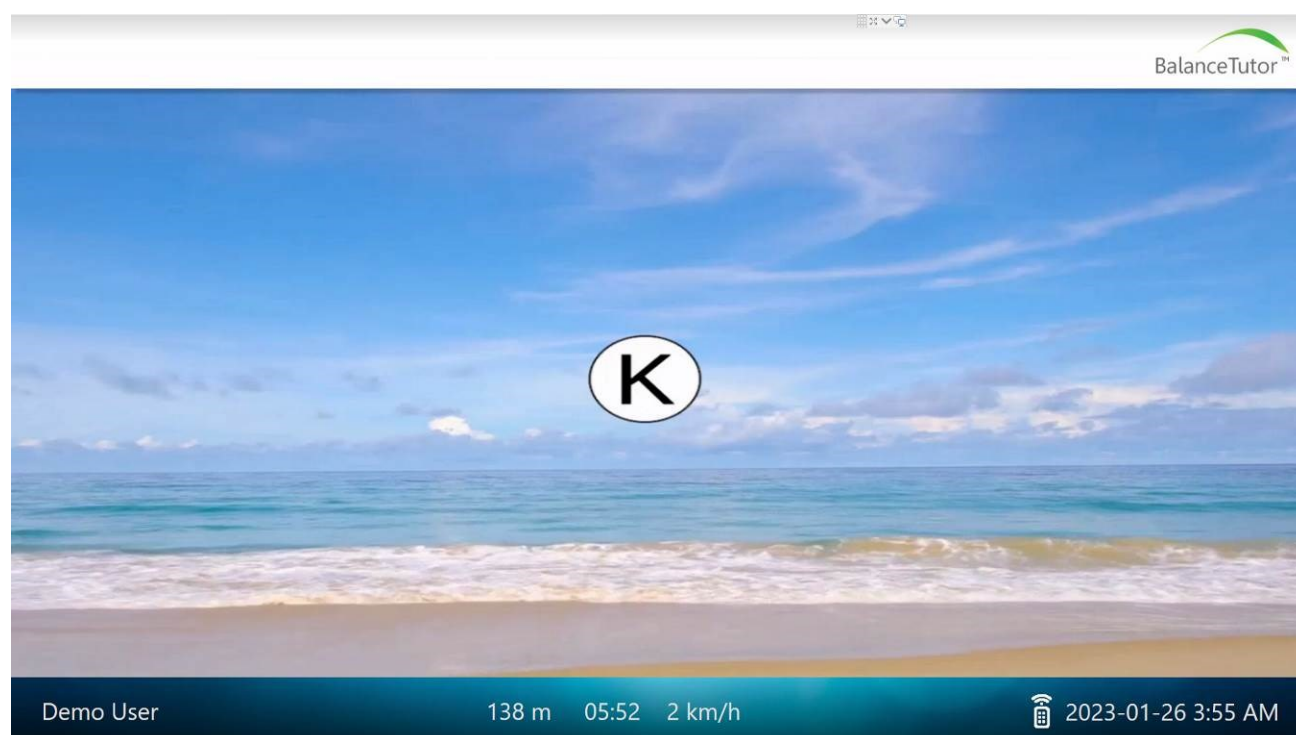
3.4.3.1 Optic flow



3.4.3.2 Optokinetic

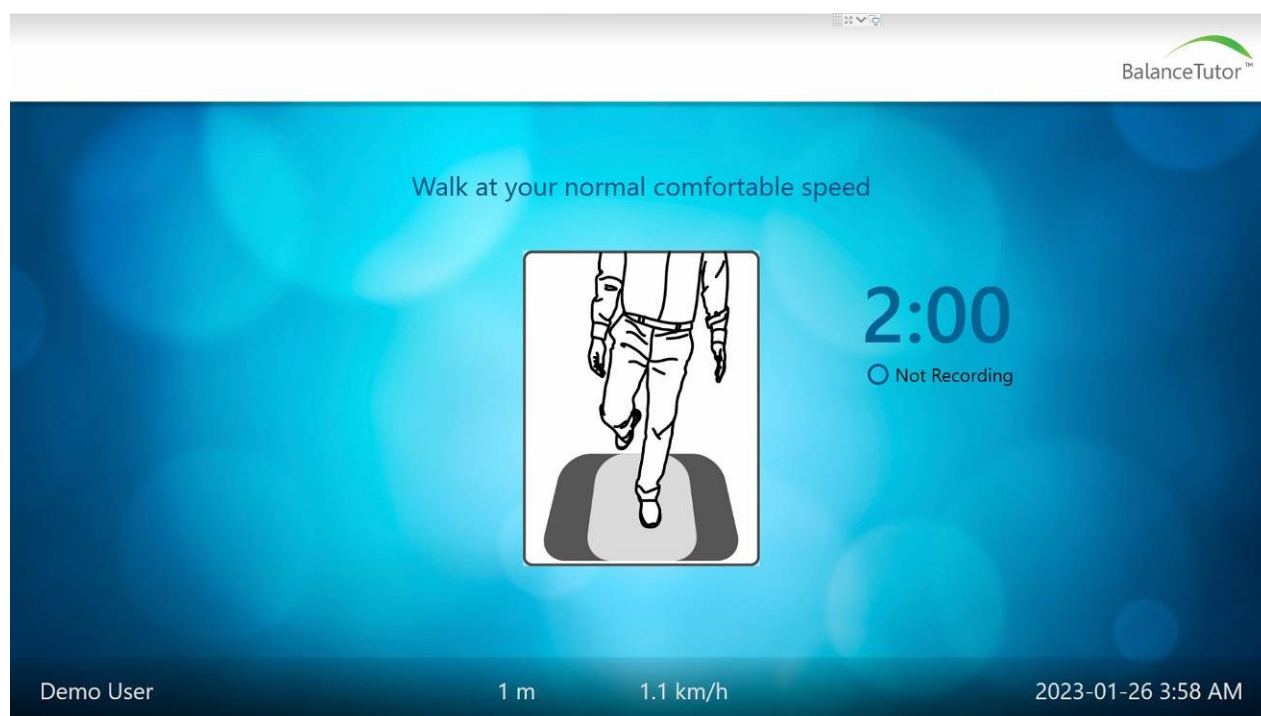


3.4.3.3 VOR



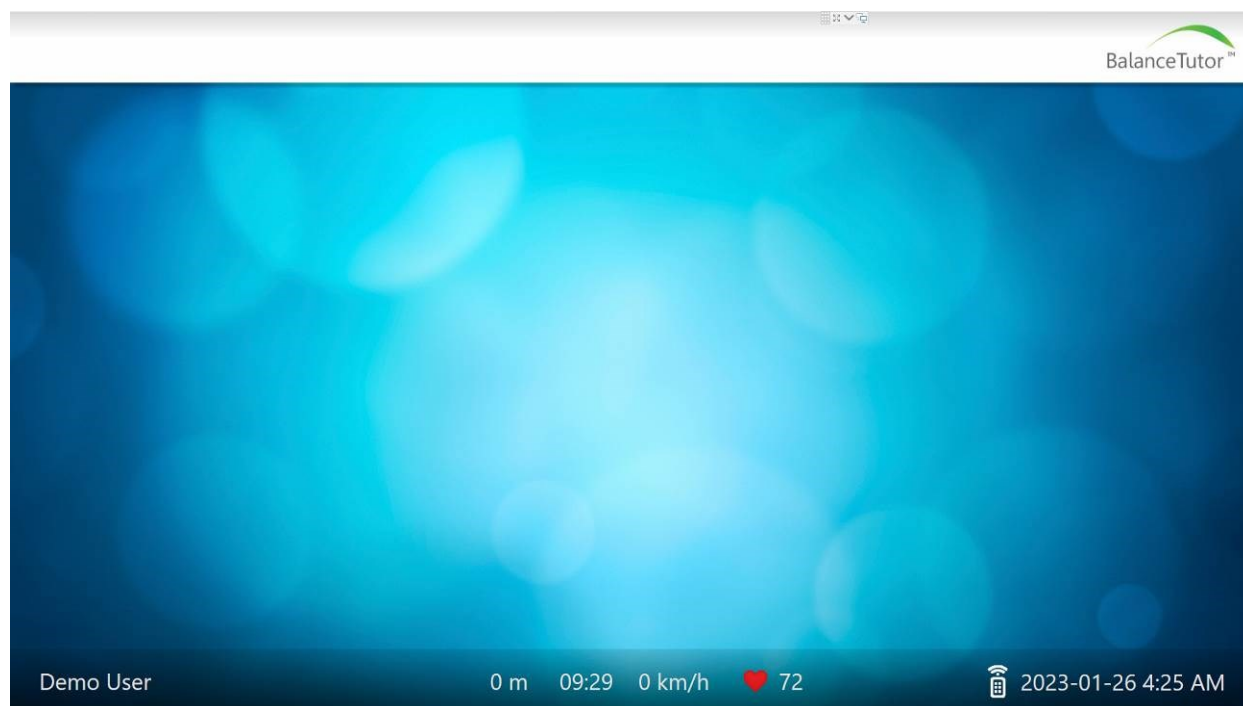
3.4.4 Patient Instructions

Patient instructions pertaining to compliance with evaluation conditions are displayed to the patient.



3.4.5 System Indicators

The therapist Screen displays several indicators presented on a line at the bottom of the patient screen. The indicators includes Patient Name, Distance Completed, Treadmill Speed, Remote Control, Date and Time and Heart Rate Monitor.



3.5 System Security

The BalanceTutor software is a standalone system that requires no resources nor authentications from outside the system to function. The embedded computer within the BalanceTutor cannot be added to an organizations' domain. Therefore, the built in users within the BalanceTutor software cannot be added to Active Directory or organizations' Group Policy. However, internal users can be created, managed and supervised within the application.

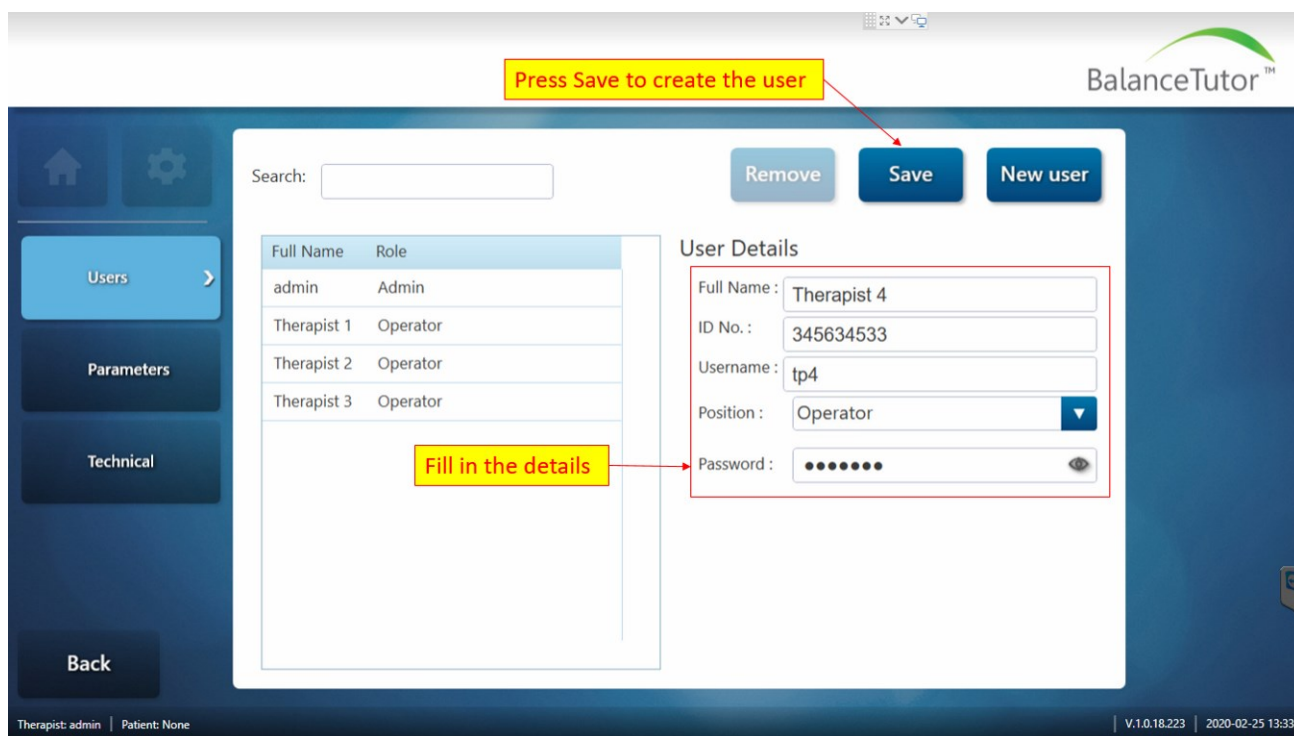
3.5.1 Users

There are two types of internal users in the system, Admin and Operator. Both users enable complete use of the system with all its modules and abilities. Only the Admin user has the option to configure the software system. The default Administrator user login details are:

Username: **admin** Password: **admin**

To create an operator user, do the following:

1. Access the application as Administrator
2. Press the Setting button
3. Fill in the details of the new user and select Position as Operator
4. Press Save
5. A new user will be added to the left users list



BalanceTutor™

Press Save to create the user

Search:

Remove Save New user

Full Name	Role
admin	Admin
Therapist 1	Operator
Therapist 2	Operator
Therapist 3	Operator

Fill in the details

User Details

Full Name :

ID No. :

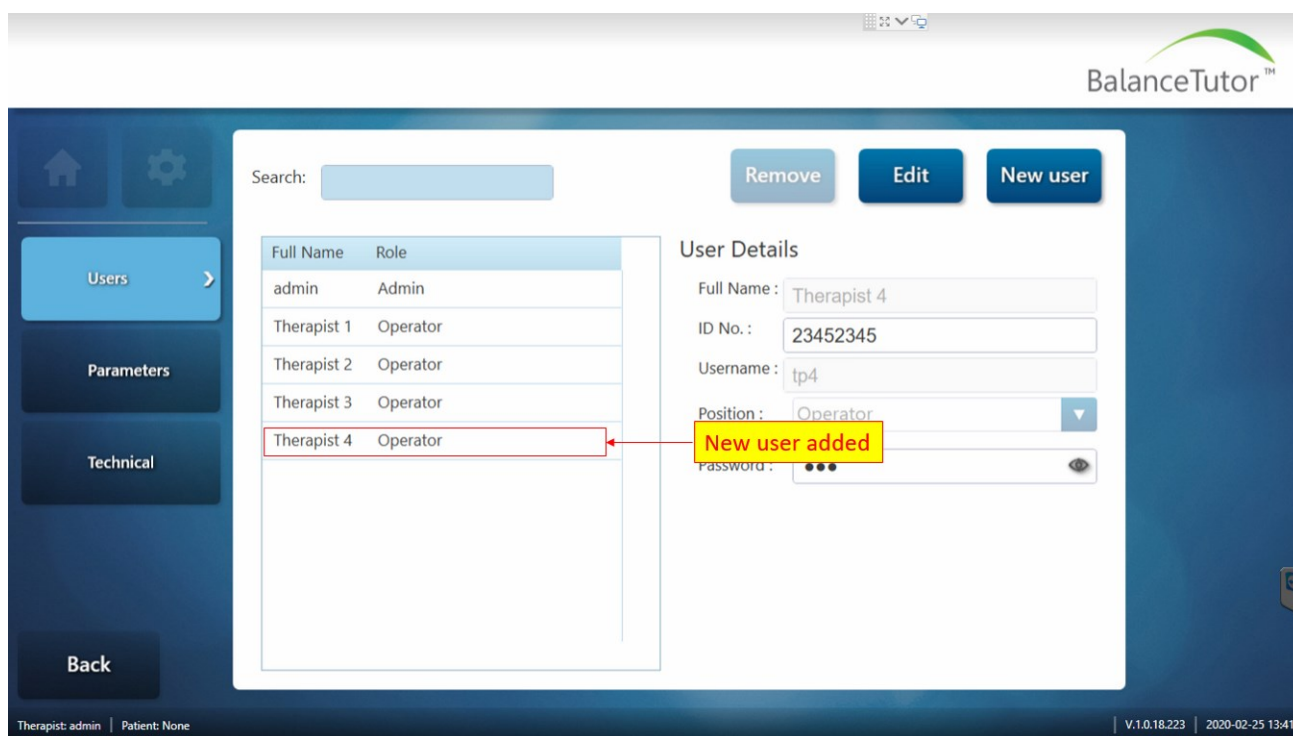
Username :

Position :

Password :

Therapist: admin | Patient: None

V.1.0.18.223 | 2020-02-25 13:33



3.5.2 Anonymous Patient

In some organization there is a request to keep patients identity anonymous.

The system provides this option using the following steps:

1. Access the application as Administrator
2. Press the Setting button
3. Press Parameters
4. Press Edit
5. Check the Anonymous Patient box
6. Press Save

Following this process patient will be added with initials only and a four-digit identifier number created by the user as demonstrated in the following example.



Therapist: admin | Patient: None

V.1.0.18.223 | 2020-02-25 14:22



ID	First Name	Last Name
1276	D	L
4563	Y	R
4443	U	R
5541	O	R
3322	P	L
6671	E	M
1230	F	Y

Logout

Therapist: admin | Patient: None

V.1.0.18.223 | 2020-02-25 14:24

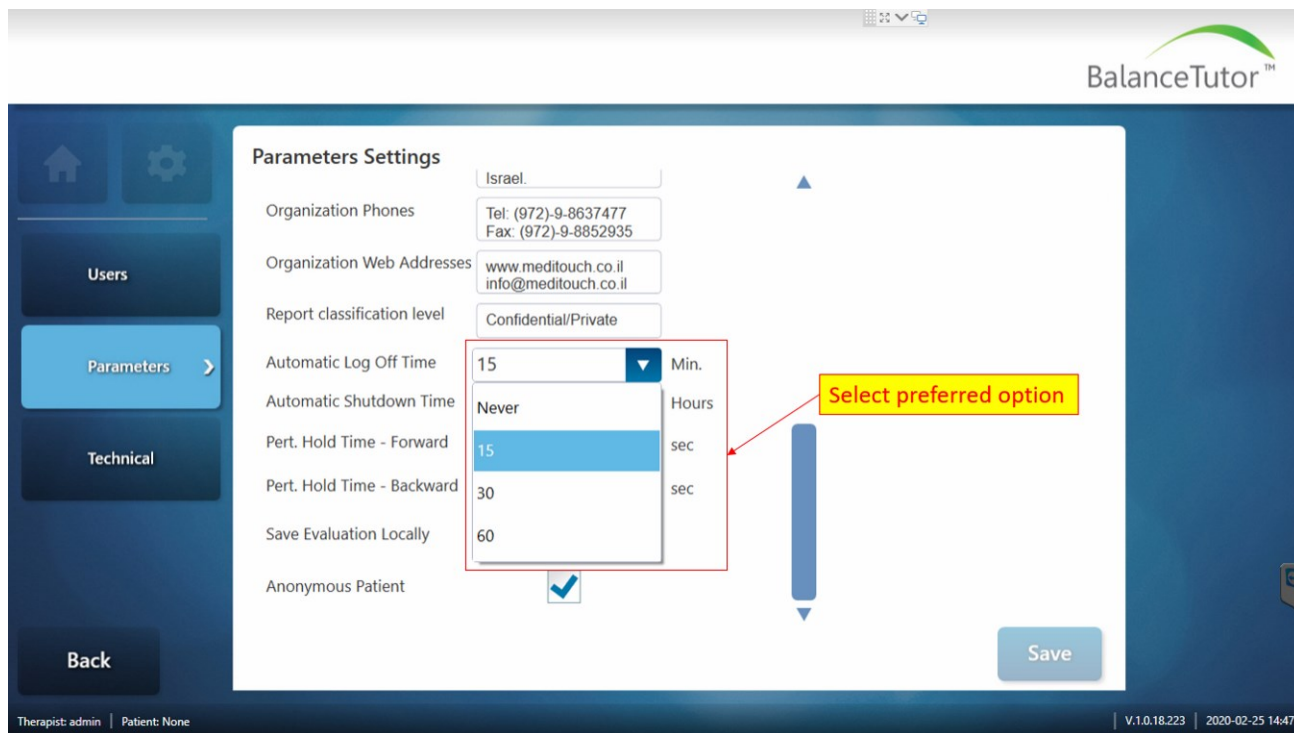
3.5.3 System Hardening

The SSD (Solid State Drive) within the embedded computer of the BalanceTutor my can configured to be solidified. There is an option supplied by MediTouch IT team to disable the ability of deleting or inserting files to the file system in order to protect the integrity of the operation system the

BalanceTutor use. Such specific customer requirements can lead to additional annual service charges.

3.5.4 Automatic System Log Off

The system provides an additional security option to automatically log off the last user following inactivity.



BalanceTutor™

Parameters Settings

Organization Phones: Israel. Tel: (972)-9-8637477 Fax: (972)-9-8852935

Organization Web Addresses: www.meditouch.co.il info@meditouch.co.il

Report classification level: Confidential/Private

Automatic Log Off Time: 15 Min. (dropdown menu highlighted with a red box and a yellow callout box saying 'Select preferred option')

Automatic Shutdown Time: Never Hours

Pert. Hold Time - Forward: 15 sec

Pert. Hold Time - Backward: 30 sec

Save Evaluation Locally: 60

Anonymous Patient: ☒

Save

Therapist: admin | Patient: None | V.1.0.18.223 | 2020-02-25 14:47

3.6 Data Export

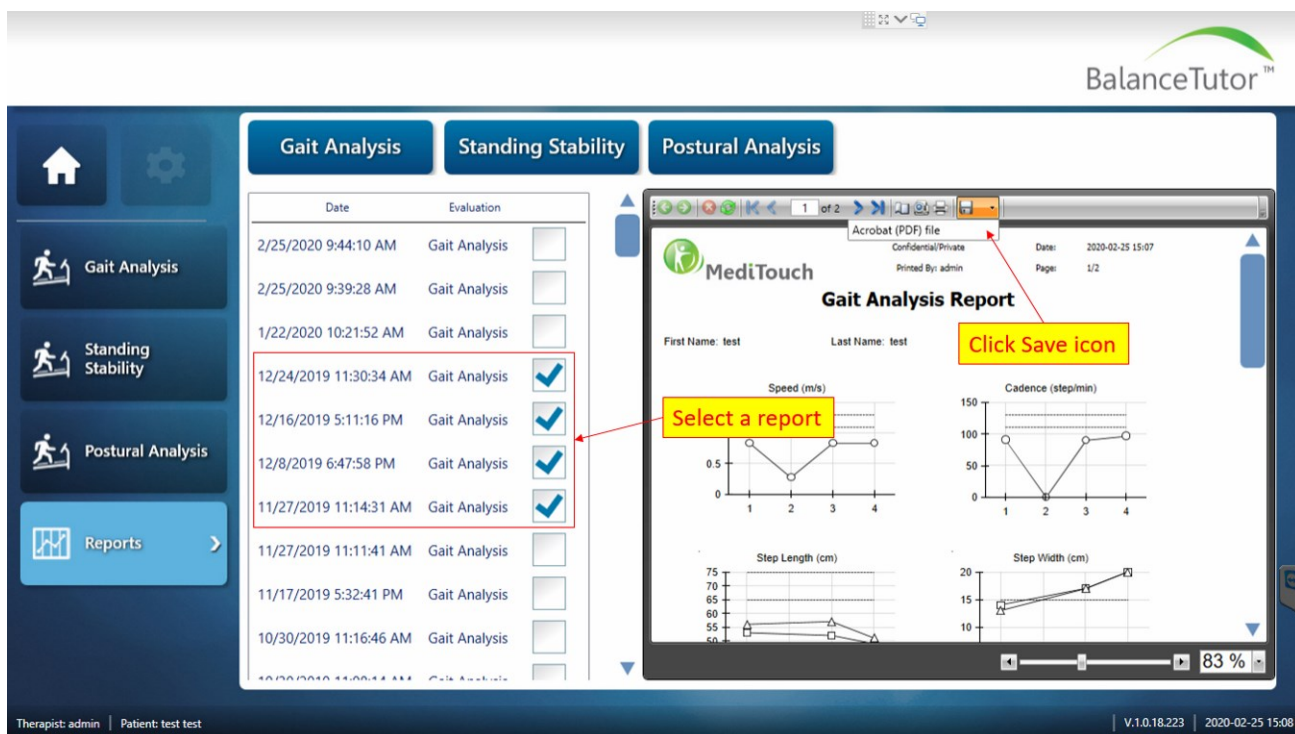
The BalanceTutor software generates two kind of files, PDF and CSV.

3.6.1 PDF

A PDF file is generated from the report module of the software. These reports may include evaluation results or clinical measures performed by the therapist or researcher.

In order to export a report, use the following steps:

1. Select a patient
2. Go Evaluation or Sessions Log
3. Choose a Report
4. Click the Save icon
5. Save file in computers' directory



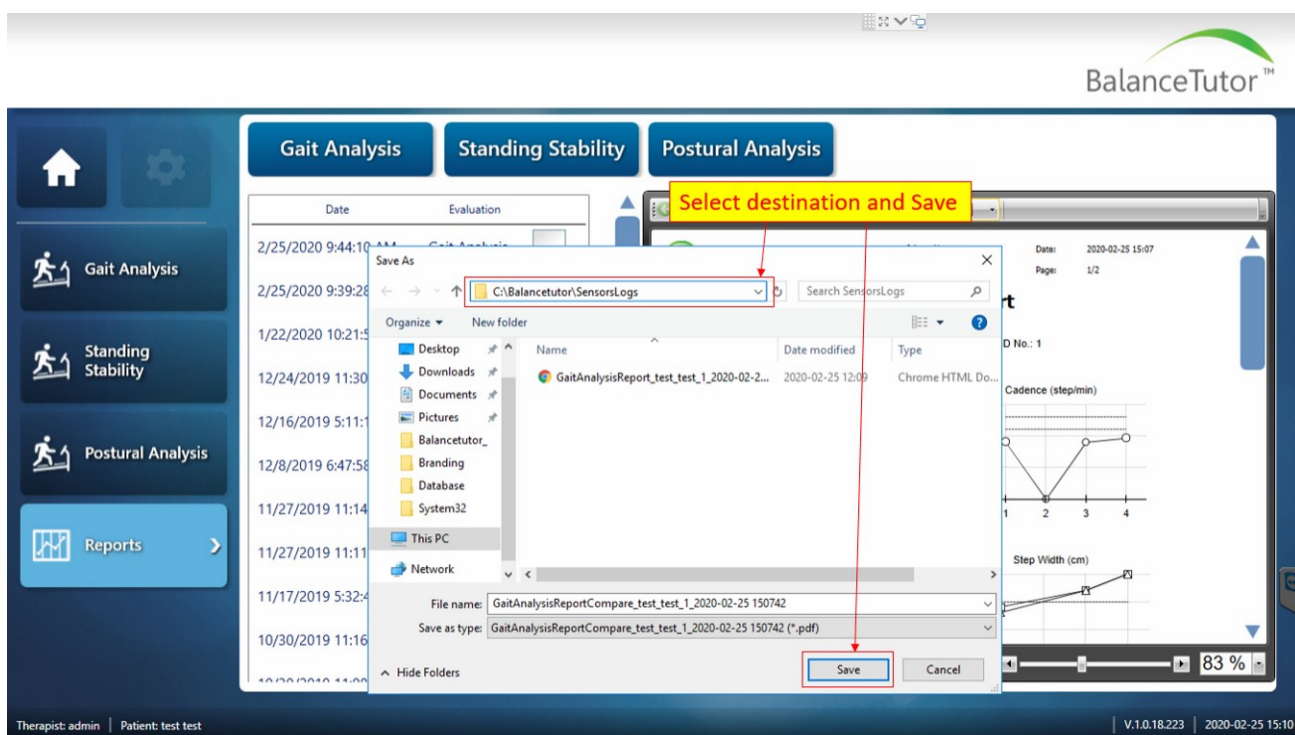
BalanceTutor™

Gait Analysis Standing Stability Postural Analysis

Date	Evaluation	
2/25/2020 9:44:10 AM	Gait Analysis	☐
2/25/2020 9:39:28 AM	Gait Analysis	☐
1/22/2020 10:21:52 AM	Gait Analysis	☐
12/24/2019 11:30:34 AM	Gait Analysis	☒
12/16/2019 5:11:16 PM	Gait Analysis	☒
12/8/2019 6:47:58 PM	Gait Analysis	☒
11/27/2019 11:14:31 AM	Gait Analysis	☒
11/27/2019 11:11:41 AM	Gait Analysis	☐
11/17/2019 5:32:41 PM	Gait Analysis	☐
10/30/2019 11:16:46 AM	Gait Analysis	☐

Therapist: admin | Patient: test test

V.1.0.18.223 | 2020-02-25 15:08



BalanceTutor™

Gait Analysis Standing Stability Postural Analysis

Select destination and Save

Save As

File name: GaitAnalysisReportCompare_test_test_1_2020-02-25 150742

Save as type: GaitAnalysisReportCompare_test_test_1_2020-02-25 150742 (*.pdf)

Save Cancel

Therapist: admin | Patient: test test

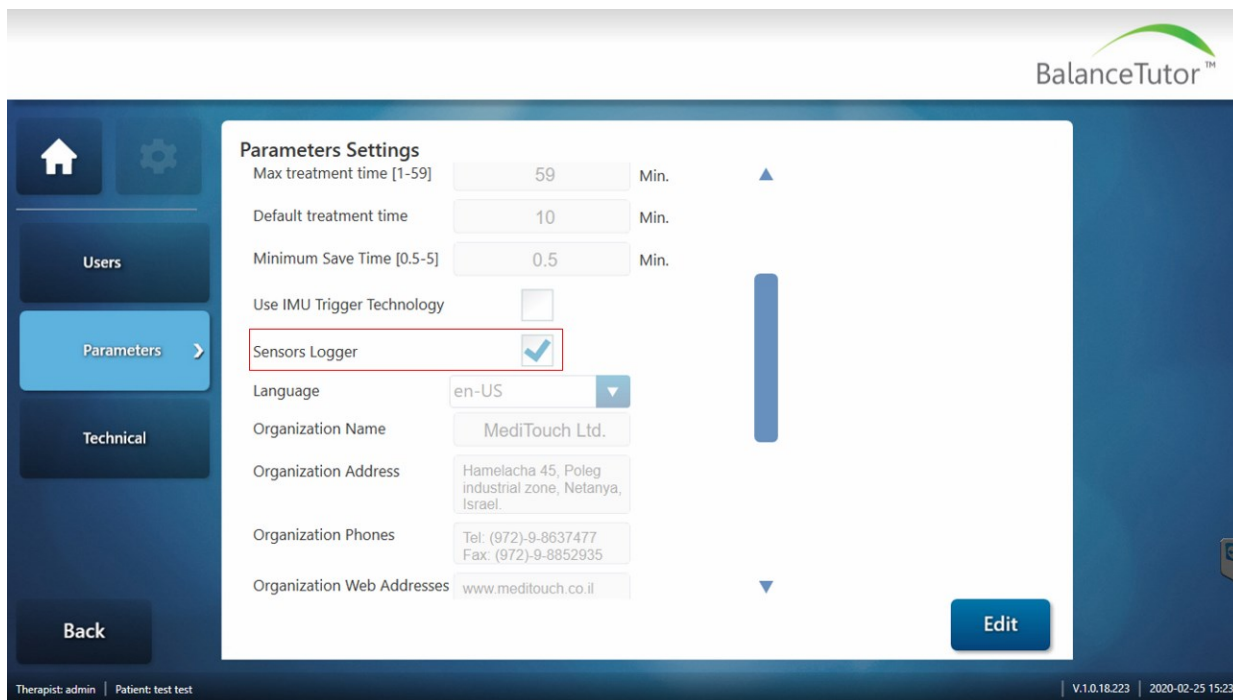
V.1.0.18.223 | 2020-02-25 15:10

3.6.2 CSV

CSV files are generated automatically (saved automatically in c:\balancetutor\sensorlogs\) after each treatment or an evaluation. The content is raw data of Sampled Time, COP Sensors, IMU's (an option) and Perturbation states. Sample rate is 65-70 samples/second.

In order to enable CSV file to be saved automatically, follow the next steps:

1. Access the application as Administrator
2. Press the Setting button → Press Parameters
3. Press Edit and Check the Sensors Logger box
 - * Evaluations may also be saved by checking the Save Evaluation Locally box as well
4. Press Save



BalanceTutor™

Parameters Settings

Max treatment time [1-59] 59 Min. ▲

Default treatment time 10 Min.

Minimum Save Time [0.5-5] 0.5 Min.

Use IMU Trigger Technology ☐

Sensors Logger ☒

Language en-US ▼

Organization Name MediTouch Ltd.

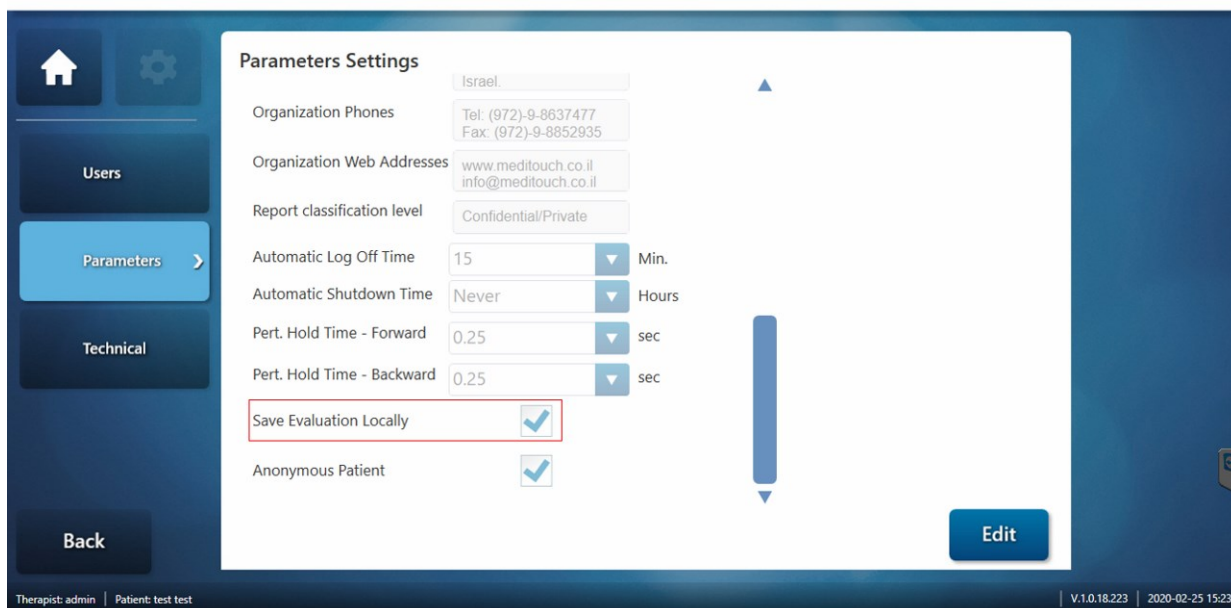
Organization Address Hamelacha 45, Poleg industrial zone, Netanya, Israel.

Organization Phones Tel: (972)-9-8637477 Fax: (972)-9-8852935

Organization Web Addresses www.meditouch.co.il ▼

Edit

Therapist: admin | Patient: test test | V.1.0.18.223 | 2020-02-25 15:23



Parameters Settings

Organization: Israel

Organization Phones: Tel: (972)-9-8637477, Fax: (972)-9-8852935

Organization Web Addresses: www.meditouch.co.il, info@meditouch.co.il

Report classification level: Confidential/Private

Automatic Log Off Time: 15 Min.

Automatic Shutdown Time: Never Hours

Pert. Hold Time - Forward: 0.25 sec

Pert. Hold Time - Backward: 0.25 sec

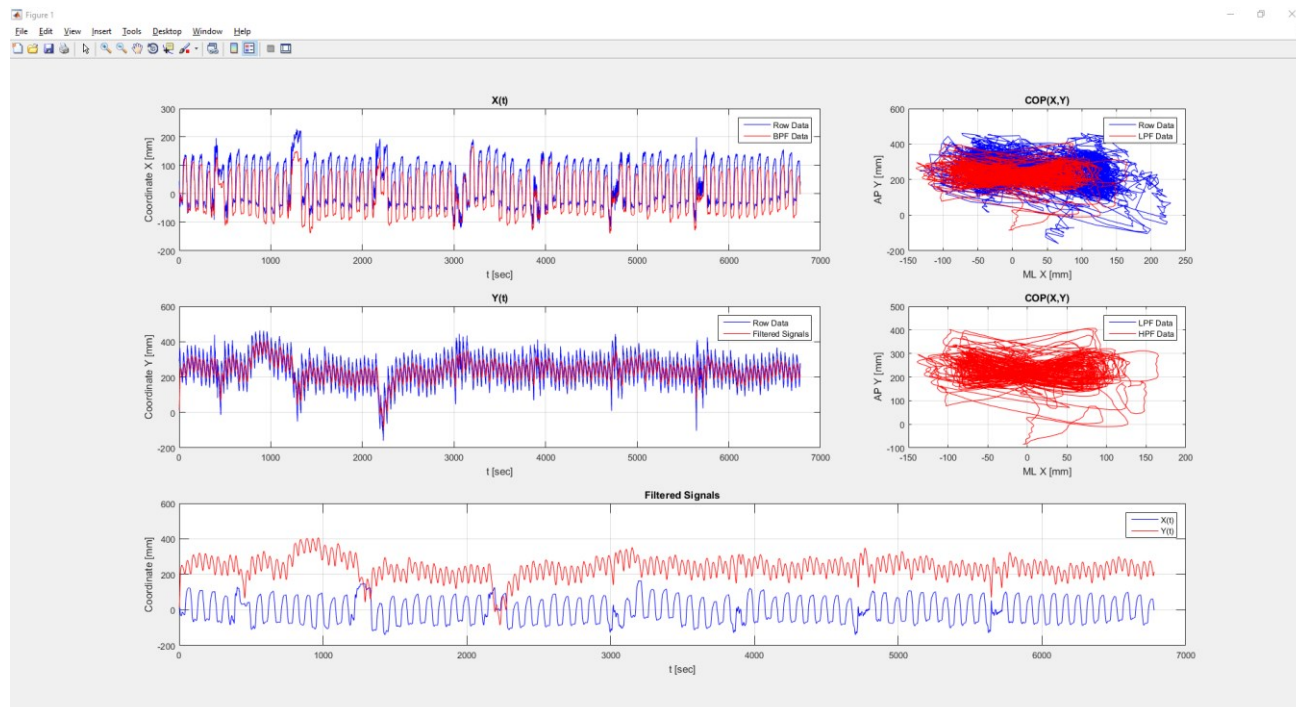
Save Evaluation Locally: ☒

Anonymous Patient: ☒

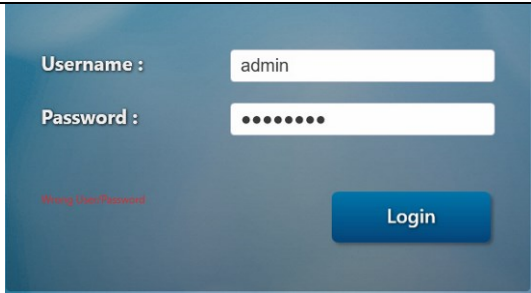
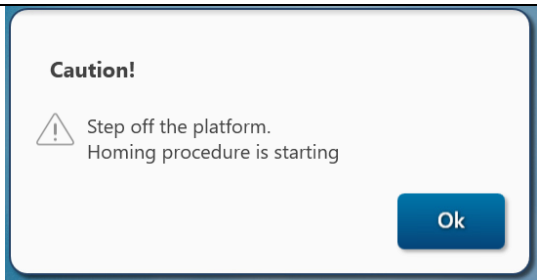
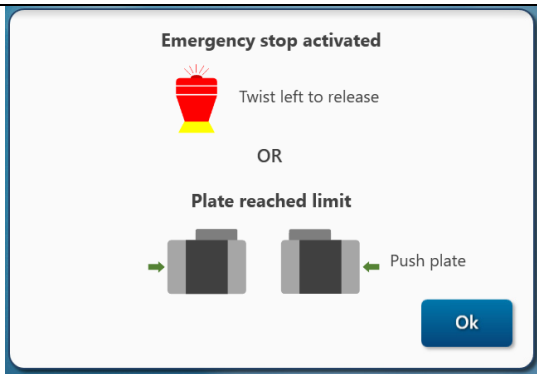
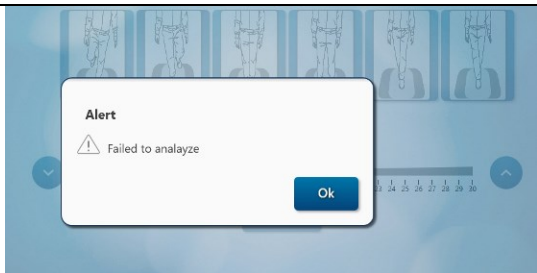
Edit

Therapist: admin | Patient: test test | V.1.0.18.223 | 2020-02-25 15:23

All CSV files can be extracted to a comfortable visual view using Matlab *.m file procedure. Please see the following an example describing COP behavior during perturbations.



3.7 System messages

IMAGE	DESCRIPTION	SEVIRITY
	Wrong User/Password at login	Error
	The perturbation platform start with homing procedure.	Message
	An attempt of the system to start homing procedure but one of the following preventing it: 1. Emergency stop button pressed 2. Perturbation plate located maximally to the right or to the left	Fault
	Failed to analyze recorded data from the COP sensory system. It caused because no one is standing on the platform.	Fault

Evaluation Summary: Perturbation Intensities: Forward: 3 Backward: 6 Right: 4 Left: 1 Would you like to save the result ? No Yes	Different Evaluations will present similar messages that summarizes patient performances.	Message
Treatment Summary Distance: 94 m Speed: 4.7 km/h Duration: 01:15 Min. Ok	Different Treatments will present similar messages that summarizes device parameters that applied to the patient.	Message
Warning Baseline has been changed would you like to save it ? Yes Cancel	Change in Baseline will lead a warning message for a new set of perturbation intensities will be next on in treatments.	Warning

3.8 Handheld Operation



3.8.1 Setup Remote Control

To activate the remote control, wait for the software to fully load. Then, press any button on the remote one time. A green indicator light will confirm that the remote control is communicating with the system.

Step	Description	Indication
1.	Turn on the system and enter the application	
2.	Press on any button of the remote control	
3.	Icon of the remote control will turn from white to green. The location of the icon at lower right side of the application.	
4.	Communication of the remote control turn off after 30min of no press	

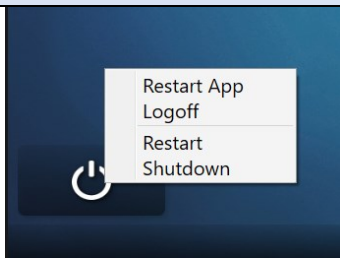
3.8.2 Operation

The remote control operates in specific scenarios for clinician use:

1. Emergency Button operates always on any state of the software.
2. Perturbations can be triggered and treadmill speed adjusted in Manual Trigger.

3.9 End of Training Day Procedures

3.9.1 Switching Device OFF

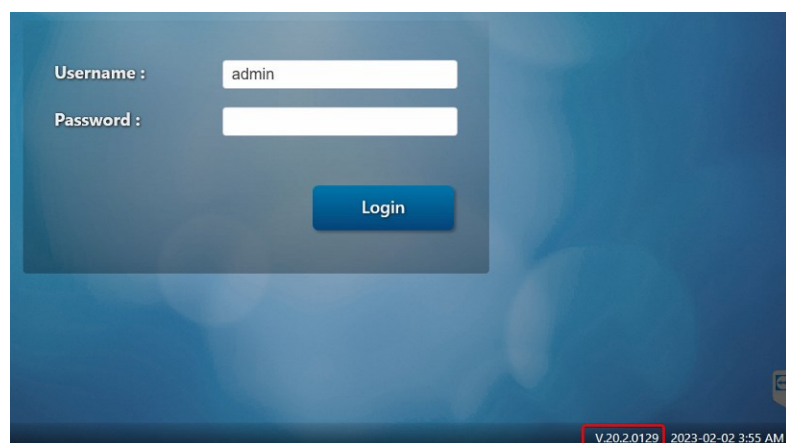
STEP	ILLUSTRATION	DESCRIPTION
1		Press on the  button on the touch screen then press Shutdown. The computer of the BalanceTutor will be shutdown.

2		Press one time on the  button to turn OFF the computer of the BalanceTutor.
3		Turn the isolation transformer dual switch to OFF position and confirm the green light is not illuminated.

Note: If any concerns on software and/or mechanical performances are noted, please report your organization responsible for the equipment or the authorized MediTouch representative.

3.10 Software Version Identifier

Each version of the BalanceTutor software has a unique version number that could be detected from the bottom right screen.



3.11 Device Cleaning

Following manufacturer recommended cleaning procedure of the various components of the BalanceTutor device:

3.11.1 Touch and Patient Screens

Duration	Daily
Material	Use a standard Screen Cleaner with a microfiber cloth.
Procedure	Turn OFF the device and pull the electrical plug from the wall socket. Clean touch screen at the beginning of each working day or when there are many fingerprint on the screen. Regarding the patient screen, cleaning is on demand.

Prohibition	Do not use any materials/ liquids beside the definition above. Any other material may harm and damage the screen surface. Confirm the liquid Alcohol-free, Ammonia-free and Phosphate-free.
-------------	--

3.11.2 Metal Structure

Duration	Weekly
Material	Normally use a light moistened cloth to clean metal surfaces of the device. For disinfection, MediTouch recommends the Bacillol® tissues (popular in Europe) or Oxivir® 1 (popular in USA) wipes, which is an Alcohol-based rapid disinfectant for disinfecting alcohol resistant surfaces.
Procedure	Turn OFF the device and pull the electrical plug from the wall socket, clean all parts of the device excluding the screens.

3.11.3 Harness

Duration	Daily
Material	Use Bacillol® tissues (popular in Europe) or Oxivir® 1 (popular in USA) wipes, which is an Alcohol-based rapid disinfectant for disinfecting alcohol resistant surfaces.
Procedure	Clean all webbing surfaces and pads used that composed the harness.

3.11.4 Running Belt

Duration	Monthly
Material	Use a light wet (water) cloth to clean the black running belt of the device. No special need for disinfection process.
Procedure	Turn OFF the device and pull the electrical plug from the wall socket, clean all running belt surface by sliding the running belt.

4 Safe and Effective Use

4.1 Suitable Clothing

To minimize the likelihood of skin irritation or the development of lesions, patients are advised to select clothing that is soft and closely fitting. Garments constructed from coarse or heavy fabrics, those with pronounced seams, or overly loose clothing are considered inappropriate. Use of synthetic materials may lead to mild friction-related burns. Footwear should consist of flat, fully enclosed shoes when using the treadmill, as proper shoes are essential to maintain a consistent and safe gait pattern.

4.2 Before Starting Training

Before a patient's first training session, you must take the time to explain the process in detail. Make them aware of the following:

- ! The device's purpose - Explain what the BalanceTutor does and how it will be used to help them.
- ! Benefits and Risks - Clearly communicate the potential benefits of the training, as well as any associated risks.
- ! The concept of perturbation - Explain that the device will generate small, unexpected movements (perturbations) to challenge their balance. This is crucial for patient safety to ensure they are not startled by the movements.

4.3 Harness Use and Patient Safety

The BalanceTutor comes with compatible set of harnesses to allow correct fit to patients' size and a trigger positioning lanyard to attach the harness to the frame-anchoring ring.

#	P/N	DESCRIPTION	IMAGE	PACKING LIST?
1	DS-06-02-12-A	Support Lanyard		Included

2	DS-06-01-41-A	Fall Protection Harness S-M	 <u>Front</u> <u>Rear</u>	Included
3	DS-06-01-40-A	Fall Protection Harness L-XXL		Included
4	DS-06-01-30-A	Fall Protection Harness XS		Not Included*

* Size that fits for children. Item is not included in the basic pack and can be ordered separately.

4.3.1 Putting On The Harness

Before fitting the safety harness, ensure the patient is wearing appropriate clothing. Loose-fitting or slick clothing may cause the vest to ride up and compromise its effectiveness.

1. Choose the correct harness size.
2. Place the harness on the patient and connect it to the BalanceTutor's rope.
3. Tighten all buckles, including those for the trunk and legs. Ensure there is no excess slack.
4. A tight fit provides optimal support and feels more comfortable. Avoid pressure around the patient's chest and legs.



4.3.2 Training Session Safety

During all training sessions, the patient's safety is paramount.

1. Continuous Monitoring - Ask the patient how they are feeling at regular intervals. Stop the training session immediately if the patient feels unwell.
2. Strap Check - Periodically check to see if any straps or buckles have become loose or twisted. Stop the session to retighten any loose straps.
3. Buckle Integrity - If any buckle opens, stop the training session immediately. Check the buckle for damage. If it is intact, you may continue the session. If it is defective, the session must be ended.

4.4 Training Parameters

1. Duration and Frequency - Training duration and frequency should be determined by the patient's physical ability.
2. Speed and Perturbation Intensity and directions - Should be adapted to the patient's abilities and clinician's objectives.

4.5 Troubleshooting and Emergency Procedures

4.5.1 Training Troubleshooting

If you encounter any of the following issues, take immediate action:

1. Danger Zone Alert - If a person or object is inside the danger zone, stop the training session immediately. Do not restart the session until the area is clear.
2. Unusual Mechanical Sounds or any mechanical abnormal behavior - If the treadmill makes unusual sounds or exhibits abnormal mechanical behavior, stop the training session immediately and report to the person in your organization responsible for the equipment or the authorized MediTouch representative.

4.5.2 Medical Emergency

In the event a patient becomes unconscious, immediately call for emergency medical assistance.



5 Maintenance & Safety Inspections

A training system is only safe if it is maintained regularly and according to specified instructions. Preventive maintenance can prevent future problems and is essential for the device's long-term safety.

WARNING: Disregarding warnings, improper use, or lack of maintenance can lead to injury, death, or device damage and will result in a loss of liability and warranty.

5.1 Responsibilities

Maintenance must be performed by MediTouch or a MediTouch authorized service representative. We recommend a yearly preventive maintenance contract. For assistance, contact your authorized service provider.

Note: In case of a detected malfunction, a defect, or an unreadable safety label, the device must be taken out of operation. You need to contact the person responsible for the system at your organization. The supplier and authorized service personnel must be informed in writing.

5.2 Daily Visual Inspection

Perform the following visual checks before each use:

1. General Check - Inspect the device for any visible damage. If any damage is suspected, do not use the BalanceTutor.
2. Cleanliness - Clean any debris from the floor before turning on the device. Clean the therapist touch screen and check the harnesses, straps, and padding for dirt.
3. Harness Integrity - Check the stitching and buckles on the harnesses and leg straps. Defective components must be replaced.

5.3 Preventive Checks

The following checks are to be performed by qualified personnel to ensure the device remains safe.

1. Power Entry - Before each use, check the circuit cable, plug, and outlet socket for any damage.
2. Treadmill Belt - Confirm the treadmill belt is at the correct tension. If it is too loose, use the two hexagonal screws on the back pulley to tighten it.

3. Perturbation Plate - After switching on the device, confirm the perturbation platform is centered. If not, alert for maintenance.

5.4 Immediate Maintenance

Immediate maintenance by an authorized service engineer is necessary if any of the following occur:

1. Discontinue use if the electrical cables or connectors are damaged.
2. Stop using the device if the lateral moving platform is stuck or does not return to its center position.
3. If any fluid gets into the device, take it out of operation immediately.
4. Discontinue use if any coverings or safety warning labels have fallen off.
5. Check the harness and lanyard for any signs of wear; replace them if needed.
6. If you detect or suspect any defect or malfunction, stop using the device and contact an authorized service representative.
7. Stop use and alert service personnel if the BalanceTutor software crashes or restarts unexpectedly.
8. Discontinue use if you hear strange, periodic mechanical noises from the motor systems.

5.5 Annual Inspection

These inspections and tests must be performed annually by an authorized service representative to ensure the continued safety and performance of the device.

1. Structural Integrity – The service engineer will check the device's metal construction for any visual damage, rust, or deformation.
2. Software - The engineer will confirm that the BalanceTutor software is running the latest version. This ensures you have all of the most recent safety and performance updates.
3. Mechanical Systems - The inspection will include checking the running belt tension and confirming that there is no backlash in the lateral transmission system, Mechanical noises, correct lubrication level in all moving parts.
4. Electrical Safety - The service engineer will perform a series of electrical safety tests, including checking the protective earth resistance, isolation resistance, and leakage current. This confirms that the device remains electrically safe for all users.
5. Full Report - For a complete list of all inspection items, refer to the MediTouch Annual Service Report (Document No: DO-15-01-18).



6 When to Contact an Authorized Service Provider

For all problems that cannot be solved by your local clinic technical support or are not listed in this IFU, you must immediately contact a MediTouch authorized service representative. Never attempt to perform maintenance or repairs on the device yourself.

7 Technical Specifications

Product technical specification file could be found under the following MediTouch document part number: DO-15-01-01

8 Certificates

8.1 ISO 9001

Certificate of the SII (The Standards Institution of Israel) and the IQNET (The International Certification Network) according to ISO 9001-2015:





Building
trust
together.

CERTIFICATE

THE STANDARDS INSTITUTION OF ISRAEL
has issued an IQNET recognized certificate that the organization:

MEDITOUCH LTD.

1, Nirim St., Tnuvot 4283000, Israel

Has implemented and maintains a Quality Management System

For the following scope:

Planning, development, manufacturing, marketing and service for medical rehabilitation devices.

which fulfills the requirement of the following standard:

ISO 9001:2015

Issued on:	23/08/2025
First issued on:	23/08/2010
Expires on:	23/08/2028

Registration Number: IL - 82474




Alex Stoichitulu
President of IQNET


Avital Weinberg
VP Quality & Certification Division



This attestation is directly linked to the IQNET Members original certificate and shall not be used as a stand-alone document

IQNET Members*: AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISO Italy CQC China CGM China CQS Czech Republic Cre Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia ICS Bosnia and Herzegovina INTECO Costa Rica IRAM Argentina JQA Japan KFAQ Korea LSQA Uruguay MIRTEC Greece MSZT Hungary Nemko AS Norway NSAIreland NYCE-SIGE Mexico PCBC Poland Quality Austria Austria SII Israel SIQ Slovenia SIRIM QAS International Malaysia SGS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.sii.org.il

8.2 ISO 13485

Certificate of the SII (The Standards Institution of Israel) and the IQNET (The International Certification Network) according to ISO 13485-2016:

 THE STANDARDS INSTITUTION OF ISRAEL	CERTIFICATE This is to certify that the Quality Management System of MEDITOUCH LTD. 1, Nirim St., Tnuvot 4283000, Israel Has been assessed and reviewed by SII - QCD and complies with the requirements of: ISO 13485:2016 This Certificate is Applicable to Planning, development, manufacturing, marketing and service for medical rehabilitation devices.		
	Initial Approval: 23/08/2010 Valid From: 23/08/2025 Valid Until: 23/08/2028	Certificate No.: 103769	
SII-QCD assumes no liability to any party other than the client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with SII-QCD requirements for system certification. The continued validity may be verified via scanning the code with a smartphone, or via website www.sii.org.il. This certificate remains the property of SII-QCD.			
 The standards Institution of Israel 42 Chaim Levanon St. Tel-Aviv 6997701	 Dr. Gilad Golub CEO	 R.N 513601898	 Avital Weinberg VP Quality & Certification Division
Page 1 of 1		The Standards Institution of Israel - Your Preferred Choice	

8.3 Certificate of compliance medical devices

Company details

Name: MediTouch Ltd (SRN: IL-MF-000025321)

Address: 1 Nirim St., Tnuvot, 4283000 Israel

EU Classification

Applicable EU regulation and Annex: Complying with European Medical Device Regulation ,Class 1, (EU) MDR 2017/745 VIII requirements, including declaration of conformity (according to Annex IV) including all general safety and performance requirements

EU Representative

Name: KB International (SRN: HU-AR-000034102)

Address: Blokland 52 2 th 2620, Albertslund, Denmark

FDA

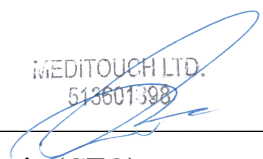
FDA certified

Standards

The following listed and fulfilled norms are elements of our production:

- EN 60601-1
- EN 60601-2
- EN ISO 9001:2015
- EN ISO 13485:2016
- IEC-601-60601-1, B3

1 Nirim, Tnuvot, Israel. August 25, 2025



MEDITOUCH LTD.
513601398

Ziv Kuniz (CTO)

9 End-of-Life Disposal

At the end of its service life, the BalanceTutor system must not be disposed of with general municipal waste. The device contains electrical and electronic components that must be handled in accordance with local environmental regulations, as required by the EU Medical Device Regulation (MDR) 2017/745.

To ensure proper disposal, follow these instructions:

1. Do not dispose of the device in a landfill or with household trash.
2. Contact your local MediTouch representative or an authorized recycling facility for guidance on proper disposal.
3. Dispose of the device in accordance with the WEEE (Waste Electrical and Electronic Equipment) directive or other applicable national and local regulations for electronic waste.