

BalanceTutor™

User Manual

Oct 2018



BalanceTutor a dynamic and static postural control trainer

This manual covers operation procedures for the following MediTouch product:

BalanceTutor BT100

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

E&EO



User Responsibility

This Product will perform as described in this User Manual and by accompanying labels and/or inserts, when it is assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically as described in this manual. A defective product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, it is recommended that a telephone or written request for service advice be made to MediTouch. This Product or any of its parts should not be repaired other than in accordance with instructions provided by MediTouch authorized representatives or by MediTouch Trained personnel. The Product must not be altered without the prior written approval of the MediTouch Quality Assurance Department.

The user of this Product shall bear the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than an MediTouch authorized representatives. Any unauthorized maintenance, repairs or equipment modification activities may void the MediTouch product warranty.

MediTouch Contact Information

MediTouch welcomes your inquiries and comments. Professional staff, including physiologists, physiotherapists, applications engineers, and customer support specialists are available to assist you with any questions you may have regarding your BalanceTutor system.

MediTouch Headquarter

Address 45 Hamelacha street, Netanya 42505, Israel
Telephone (972) 9 8637477
Fax (972) 9 8652935
Website www.meditouch.co.il

Service and Support

Address 45 Hamelacha street, Netanya 42505, Israel
Telephone (972) 9 8637475
Fax (972) 9 8652935
Email support@meditouch.co.il

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Device description

The BalanceTutor by MediTouch is a Perturbation Treadmill that is an innovative device for postural control and balance trainer. 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 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, Warnings, Precautions, Prohibitions

- ✓ Read the whole manual before use.
- ✓ Consult a doctor before using this device.
- ✓ Only one person at a time to use BalanceTutor.
- ✓ Do not use walk aid devices like stick or walker with the device.
- ✓ Use only with appropriate clothing and training shoes.
- ✓ Incorrect and/or forbidden use and/or overtraining can lead to serious injury or even death.
- ✓ If you feel close to fainting, the training has to be stopped immediately.
- ✓ If you feel sick or dizzy, stop training immediately and consult a doctor.
- ✓ Always warm up fully at walking speed before starting to run.
- ✓ Any kind of BalanceTutor operation including patient treatment must be carried out by only trained therapist/ doctor certified by MediTouch Company.
- ✓ Use at own risk - the manufacturer is not liable for damage.
- ✓ Anyone not involved in the training session must keep at least a safe distance of 2 meters away from any part of the system.
- ✓ Don't use any system/additional part/accessory which has not been installed or checked by MediTouch.
- ✓ BalanceTutor must only be used after equipment verification according to user manual.
- ✓ Do not start or carry out training if abnormal operation detected. If an abnormal operation occurs during a session stop the session immediately by the emergency stop switch or by the software in the operators display panel.
- ✓ Before start of any treatment on the BalanceTutor wear the safety harness on the patient and confirm patient is secured, safe and ready to start a treatment or a session.
- ✓ The BalanceTutor is approved for use with a maximum body weight of 135 kilograms. Heavier patients must not be trained with the BalanceTutor.
- ✓ Make sure, before releasing the user from the harness belt, the treadmill and the perturbation mode are not active and no automatic software program is in progress.
- ✓ If there are faults or abnormal or if there is evidence of damage (e.g. unusual sounds), the training session must be stopped immediately and a MediTouch authorized technician must be informed without delay.
- ✓ 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.

- ✓ The BalanceTutor system may only be used if maintenance has been carried out properly according to the instructions included in this user manual.
- ✓ Consulting, sales, installation, commissioning, instruction, inspections, maintenance and service repair works only through trained and by MediTouch certified personnel.

1.1 Electric safety / safety classes

The BalanceTutor is a class I ME equipment (Medical Electrical). Therefore,



To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Background:

In order to protect the user and the personnel, the association of German electro technicians Inc, (VDE) has published special directives for medical used rooms and electro-medical devices. Devices with a power supply therefore have to, in order to prevent the passing on of the mains voltage over to touchable metal pieces, be equipped with not only a reliable isolation of the parts being under voltage but also additional safety precautions.

The VDE-association divides it into so called safety classes. For electro-medical devices, licensed safety classes are mainly used the safety class I (i.e. safety precautions with protective wiring), and the safety class II, (i.e. safety measures without protective wiring but with double isolation): Devices of the safety class I are devices, where the metallic casing-parts are connected with the protective wire of the line net via the safety contact. In the case of an isolation error the inserted fuse element switches off.

1.2 Patient and Therapist security according to IEC 601-1

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 IEC 601-1. 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.

1.3 Connection of units installed outside medically utilized locations

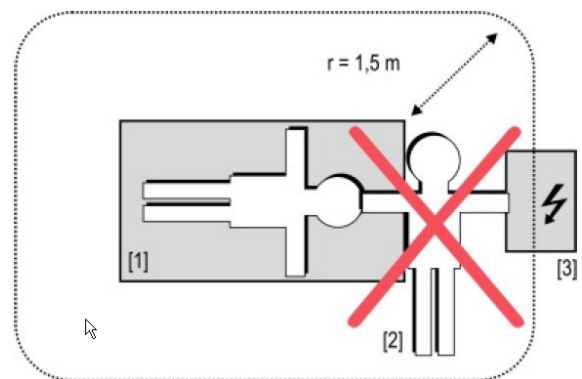
If units installed outside medically utilized locations (e.g. external printer, host computer etc.) are connected to a MediTouch unit installed in a medically utilized location the VDE 0750 regulations must be observed. Connection only via:

1. Optical fiber or optocoupler (4kV checked and approved) or ...
2. Protective isolation via insulation transformer according to IEC 601-1.

These units are to be connected to the equipotent conductor. Due to the increased safety requirements medical instruments may not be connected via extension leads or multi-way connectors.

1.4 Protection against the danger of electrical shocks

Casing and cover: Parts of non-medical electric devices within the surrounding of the subject, which, after having taken off the coverings etc. without the use of tools for a routine maintenance etc., are in touchable reach, have to operate with a voltage that does not exceed 25 volt alternate voltage and 60 volt direct voltage, which is produced by a separate source as described in IEC 601-1. According to this example the



leakage current would flow from the electric device to the earth end subject via the therapist/doctor.



Electrical equipment [3] and a subject [1] must never be touched by the doctor or trainer [2] at the same time.

1.5 Environmental requirements

MediTouch systems are not to be used in medically utilized rooms with a danger of explosions or in easily inflammable atmospheres. The devices must not be installed near to e.g. an x-ray device, motors or transformer with high connection power, as the electric and magnetic interference can falsify measurements or even make them impossible. High voltage lines must be avoided nearby the device. MediTouch electrical devices with mains connections must neither be used in wet and humid areas (e.g. swimming pool, sauna, etc.) nor in environmental chambers.

If not stated otherwise in the delivery information MediTouch devices are designed for operation in normal climatic surroundings (DIN IEC 601-1):

- Temperature: + 10° ... + 40° C
- Relative humidity: 30 ... 70 % (non-condensing!)
- Air pressure: < 1.5 bar (approx. 10,000 feet (3000m), without pressurization)

The system has to be protected from high humidity. Store the devices at a temperature of – 20° ... + 50° C.



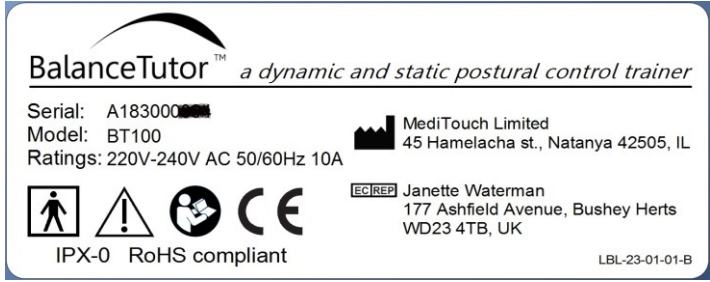
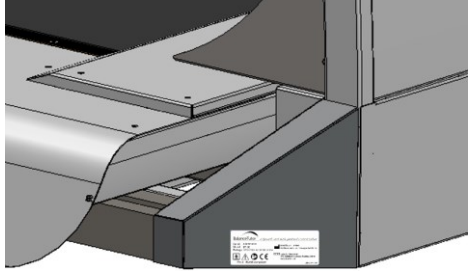
1.6 Economic life-time

The economic life time of the product is determined at common usage and application to 15 years, provided that after 10 years all electrical parts and component, as well as mechanical parts like for example deflection pulleys, are renewed (at damage or unusual heavy duty possibly earlier) and the recommended maintenance intervals are kept. Every maintenance and repair work needs to be carried out by authorized MediTouch technicians. For expendable parts a shorter life-time is due.







1.7 Labels, Locations, Interpretations

Read and understand the labels on the BalanceTutor. The labels provide safety information while using the device for safe and enjoyable exercise experience. Should any of the labels become damaged and unreadable, immediately contact MediTouch for replacements.


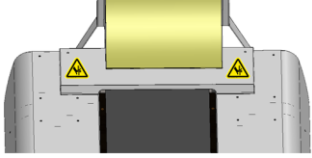




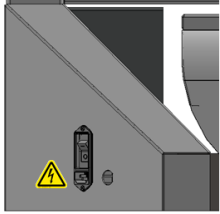
1.7.1 Name plate

IMAGE	LOCATION
	

1.7.2 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

1.7.3 Warning labels

IMAGE	MESSAGE	DESCRIPTION	LOCATION
	Hand Crush/Moving Parts	This label is located on areas where the moving platform slides below the stationary metal cover that present a pinch hazard. Hands or any other part of the body should not be placed in these areas during operation of the system.	
	Sitting Prohibited	This label located on the moving platform and indicates to any person not sit on the platform.	
	Protective Earth Ground	This label located near any physical connection of ground wire to chases. Normally this label located within the device.	Internal ground connection
	Electrical Shock/Electrocution	This label is located beside the electrical entrance of the device and indicates a high voltage is present in that location. If you see this label, do not get close to or disassemble any of the components to which it is attached. The high voltage can cause serious injury or death. Only a qualified MediTouch Service Technician should attempt any repairs in these areas.	

1.7.4 Safety standards, norms

All MediTouch systems are produced according to strict safety and quality controls. The product must not be used, if the certificates/permissions and the (according to the list of technical specifications) defined safety standards do not correspond with the local and country-specific requirements. The country-specific requirements must be compared before initial operation. Operate BalanceTutor system only, if the requirements correspond. Full list of applicable norms see also in the CE-certificate of compliance.

The standards with date in this manual with reference to design and construction characteristics refer to the up to date valid versions at the time of manufacture.

The standards with date in this manual applying to routine measurements and continual safety relevant measures (e.g. electrical measurements to determine leakage current, insulation resistances etc.) can and will change with time. Therefore the up to date valid versions of the respective standards at the time of measurement and their limit values, which can deviate then from the procedures and limit values in this manual, apply.

1.7.5 The CE mark

The **CE** mark on the nameplate of the device confirms the compliance to the council directive 89/336/EEC appendix I (EMC electromagnetic compatibility).

1.7.6 EMC Electromagnetic & Safety Compatibility

The BalanceTutor system for medical applications has been built corresponding to the European Union Council Directive 93/42/EEC Norms: EMC: EN60601-1-2, Safety: EN60601-1 Ed 3.1 Certification bodies: ITL – Israel Testing Laboratories.

1.8 Intended use – Indications

BalanceTutor can be used in Neuromuscular, Musculoskeletal rehabilitation, vestibular rehabilitation, sport training and fall prevention in geriatric field. There are varieties of medical indications that the system can be indicated as follows:



Consult a qualified doctor before using this device. The physician in charge is always responsible for indicating the training.

1.8.1 Neuromuscular Rehabilitation

- ✓ Stroke
- ✓ Head injury
- ✓ Spinal cord injury
- ✓ Multiple sclerosis
- ✓ Cerebral palsy
- ✓ Peripheral nerve injury

1.8.2 Musculoskeletal Rehabilitation

- ✓ Joint surgery / fracture
- ✓ Amputation
- ✓ Muscle weakness
- ✓ Prosthetic
- ✓ Muscle / tendon strain
- ✓ Ligament strain

1.8.3 Vestibular Rehabilitation

- ✓ Dizziness, vertigo and equilibrium therapy

1.8.4 Sport Training

- ✓ Rehabilitation after sport injury
- ✓ Athletes training

1.8.5 Aging

- ✓ Fall prevention
- ✓ ADL activities improvement

1.8.6 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 indications that require specific care in use according to relevant therapy protocols and must be with the approval of a qualified physician/ doctor recommendation.

- ! Joint instability following surgery or trauma.
- ! Soft tissue damage such as Muscle or ligaments tear.
- ! ACL/PCL restoration of Knee
- ! Droop foot
- ! Limb prosthesis
- ! Joint replacement like Hip, knee and Ankle.
- ! Epilepsy

1.9 Forbidden use – Contraindications

Any kind of medical problems including cardiovascular, mental or physical impairment leading to an inability to use the system are contraindicated for using of the device. The following contraindications must be taken into account before using of the BalanceTutor:

- Patients who are not able to stand or walk without walk aid devices or external assistance.
- Body weight greater than 135 kg
- Severely fixed contractures
- Bone instability (non-consolidated fractures, unstable spinal column, severe osteoporosis)
- Open skin lesions in the area of the lower limbs and torso
- Unstable circulation
- Cardiac (blood) contraindications
- Uncooperative or (self) aggressive behavior, such as transitory psychotic syndrome
- Severe cognitive deficits
- Patients with (long-term) infusions
- Mechanical ventilation
- Severe vascular disorders of the lower limbs
- In general, patients who have been ordered to remain in bed or immobile due to, for instance, osteomyelitis or other inflammatory/infectious disorders

The above list does not claim to be exhaustive. The decision as to whether a patient is suitable for treatment always comes under the remit of the physician in charge, who has sole medical responsibility for the treatment. As part of this, he must evaluate in particular, in each individual case, possible risks and side-effects of the treatment against the benefit gained from it. In addition, the patient's individual situation plays just as important a role as the basic risk assessment for specific patient groups.

Being a scientific discipline, medicine is subject to constant change in response to new knowledge and progress. It is therefore the task of the physician in charge to continually keep his knowledge up to date by reading the latest scientific literature and to acquire new knowledge during the course of treatment.

1.10 Clinical guidelines

When an unexpected perturbation is happening, Center of Mass (COM) is passively moving toward the perturbation direction. The body needs to react immediately (70-120 ms) to restrain this

unplanned COM passive movement. This reactive postural response is intended to stabilize the COM over the Base of Support by returning it back to initial position or to create new safe BOS for COM using a compensatory step. In these two cases the body tries to move actively to opposite direction of the applied perturbation.

There are several guidelines based the above concept how to formulate the appropriate perturbation according to rehabilitation aims as follows.

Target: Weight bearing encouragement

Technique: Medial /Lateral Unexpected Perturbation

Clinical effect:

- ✓ Weight bearing through customized reactive response
- ✓ Proprioceptive and kinesthesia rehabilitation

Target: Ankle flexion rehabilitation

Technique: Forward to Backward unexpected Perturbation

Clinical effect:

- ✓ Fast and highly intensive activation of Gastrocnemius and Soleus muscles
- ✓ Unique technique for Forefoot weight bearing
- ✓ High level coordination of ankle agonist and antagonist muscle activation
- ✓ Unique facilitation of gait initiation

Target: Ankle extension rehabilitation

Technique: Backward to Forward Unexpected Perturbation

Clinical effect:

- ✓ Fast and highly intensive activation of ankle extensors muscles
- ✓ Unique technique for Rearfoot weight bearing
- ✓ High level coordination of ankle agonist and antagonist muscle activation

Target: Ankle instability rehabilitation

Technique: Multi-Direction Unexpected Perturbation

Clinical effect:

- ✓ High Level ankle neuromuscular coordination

- ✓ Static and Dynamic ankle joint stabilization
- ✓ High resolution of Proprioceptive and Kinesthesia activation

Target: ACL rehabilitation

Technique: Forward to Backward Unexpected Perturbation

Clinical effect:

- ✓ Fast and Highly Intensive activation of Knee muscles
- ✓ Use of ACL Proprioceptive and Kinesthesia abilities at maximum capacity
- ✓ Accurate and Fast Quadriceps and Hamstrings Coordination

Target: Neuromuscular coordination training

Technique: Kinetics and kinematics triggered perturbation

Clinical effect:

- ✓ Fast Co-contraction of Agonist and Antagonist muscles of the limb in stance phase
- ✓ Fast Co-ordination of Agonist and Antagonist muscles of the limb in swing phase
- ✓ Customized open- loop and closed-loop neuromuscular control

Target: Groin strain rehabilitation

Technique: Accelerated Perturbation while walking sideways

Clinical effect:

- ✓ Controlled contraction and stretching of the hip adductors

Target: Hip flexion rehabilitation

Technique: Forward to Backward Perturbation while standing and walking

Clinical effect:

- ✓ Unique technique for stretching of Iliopsoas in stance phase
- ✓ Fast contraction of Iliopsoas through automatic response at swing phase

Target: Hip extension rehabilitation

Technique: Backward to Forward Perturbation while standing and walking

Clinical effect:

- ✓ Fast contraction of Gluteus maximus through automatic response

Target: Hip abduction rehabilitation

Technique: Medial to Lateral Perturbation while standing and walking

Clinical effect:

- ✓ Fast contraction of Gluteus medius toward opposite direction of applied perturbation.

Target: Pure Reactive Response Training

Technique: Random Multi-Direction perturbation while running

Clinical effect:

- ✓ Improvement of Automatic Postural adjustment
- ✓ Faster compensatory step
- ✓ Improvement of Recovery time

Target: Multi task training

Technique: Multi-Direction perturbation

Clinical effect:

- ✓ Neuromuscular muscles coordination
- ✓ Fast Static and Dynamic multi-joints stabilization
- ✓ Optimal balance training

Target: Weight bearing

Technique: Shifting of Center of Pressure (COP)

Clinical effect:

- ✓ COP feedback training
- ✓ Challenging controlled proactive weight bearing



At the suspicion of unauthorized access or other reasons to lock the BalanceTutor device, the system has to be locked, signed as „blocked“ and secured against use (for example, unplug the power cord and to affix warning label).

2 Installation & commissioning

2.1 Staff members

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

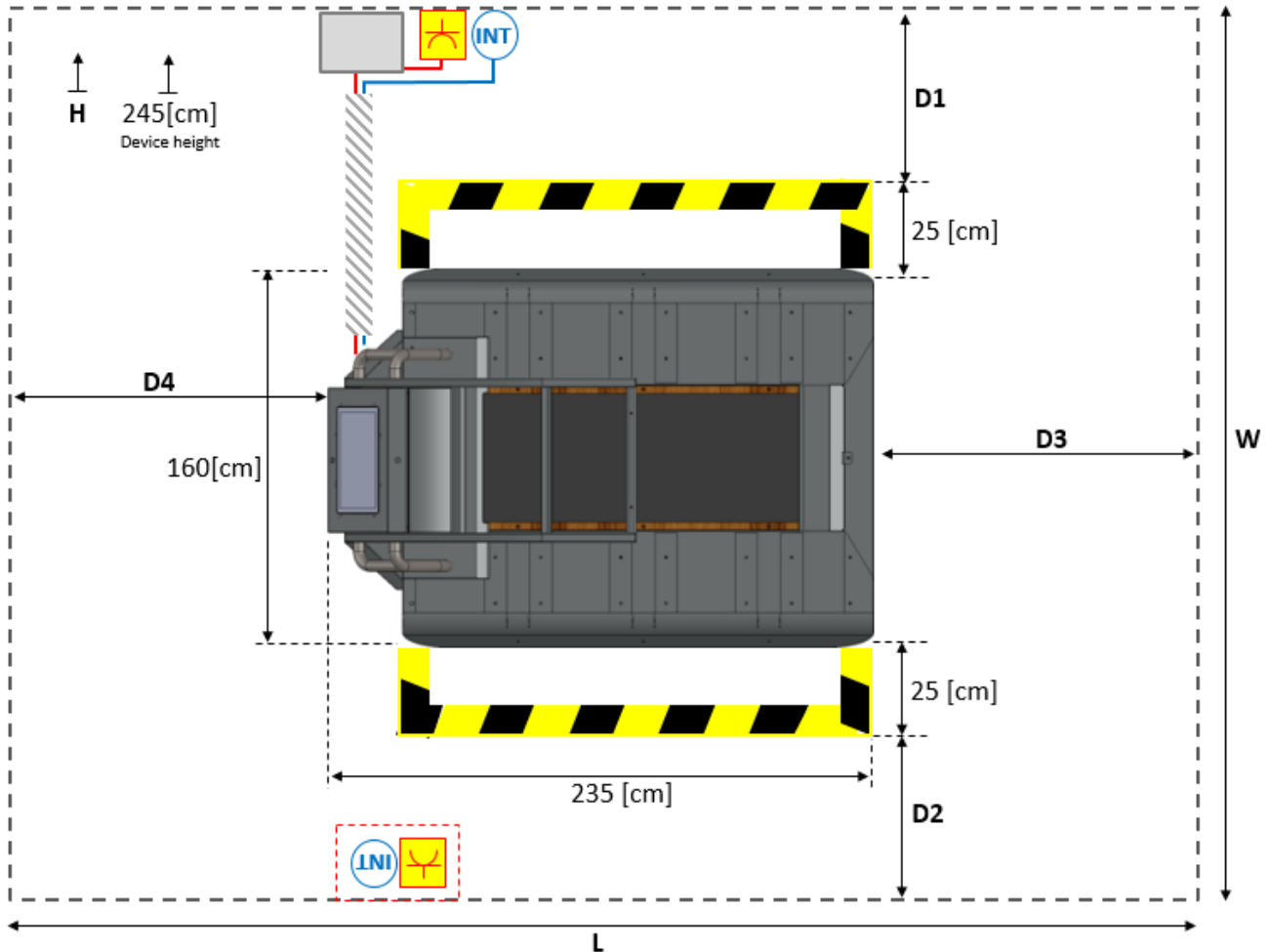
PROCESS	DURATION	HUMAN RESOURCE	LOCATION
Device installation	5 hour	Distributor qualified technician and assistant	On site
Remote control	1 hour	Institution system administrator	Remotely Pre-installation
Technical training	2 hour	Distributor qualified technician Hospital clinical staff	On site
Clinical training	1 day	Distributor or MediTouch clinician Hospital clinical staff	Remotely, On site (optional)









2.2 Staff members qualification

ROLL	MINIMAL QUALIFICATION SKILLS
Distributor technician	Mature technical skills. Solid understanding in mechanical assembly and maintenance and good understanding in electricity and electronics.
Therapist	Physical clinician, Physiotherapist, Occupational therapist or sport medicine trainer. Basic computer software orientation.

2.3 Device installation schematics

Guide lines detailing the correct installation area for the BalanceTutor.



ITEM	DESCRIPTION
	Power inlet (2 cases can be valid): 1 Phase: 230 Volt AC L/N/PE 50/60Hz 16A circuit breaker, dedicated line. 3 Phase: 190-230 Volt AC L1/L2/PE 50/60Hz 2x10A circuit breaker, dedicated line.
	Network RJ45 inlet (Optional)
	Optional location for Power and Network inlets
	Floor cable cover
	Internet line (Optional)
	Power line
	Isolation transformer (acts as a ON/OFF device power)
	KEEP OUT zone sticker (on floor)

2.4 Installation preparation form

Prior to installation the below table needs to be filled in:

PARAMETER	MIN.	COMMENTS	MEASURE
D1	40cm	Up to <u>10m cable</u> length from power and network inlets.	___ [cm]
D2			___ [cm]
D3		In case of camera capture system, consider appropriate distances.	___ [cm]
D4	60cm	Avoid impact with the entrance door	___ [cm]
W	300cm		___ [cm]
L	335cm		___ [cm]
H	250cm		___ [cm]
Circuit Breaker	1 Phase: 16A 2 Phase: 10A	Dedicated power line required	___ [A]
Power and Network inlets		Specify location on top of the schematics diagram	

DESCRIPTION	OPTION (mark your option)
Wall type	Stone / Sheetrock / Wood / Other _____
Floor type	Concrete / Parquet / Tile / PVC / Other _____
Ceiling type	Concrete / Aquatic / Sheetrock / Other _____

SITE DETAILS	
Organization name:	_____
Full address:	_____
Contact person:	_____
Tel:	_____
Mobile:	_____

Scan and email to: info@meditouch.co.il

Confirmed by:

Full Name

Signature



2.5 Installation procedure

In order to perform installation and to be familiar with the product's maintenance procedures, please refer to the following document:

File name: BalanceTutor Service Manual

File number: DO-15-01-12

3 Transport, Unpacking & Packaging

When receiving the machine in a crate or unpacked, make sure the machine, the accessories and/or the packaging is not damaged. If you discover any damage and/or missing parts make a note on the packing-list / delivery note of the carrier. Inform MediTouch and your dealer immediately in writing about any damages and/or missing parts.



The manufacturer does not undertake any liability for any damage, complaints and missing parts which is not reported immediately by delivery on the packing-list / delivery note.

Before you unpack the machine and accessories read instructions on the crate. Make sure that the machine, power connection cable or any optional equipment will not be damaged during unpacking. Pay special attention on small parts, so that you do not dispose them or any instructions with the packaging. Mostly all devices are delivered and assembled by MediTouch directly or by an authorized forwarder. If delivered by MediTouch the packaging may be taken back and recycled.

If the BalanceTutor system is being delivered by a carrier, you can recycle the packaging yourself or send it back to the manufacturer (transportation is to be paid by the customer). Often a recyclable transport tool or packaging or a transport-fuse (metal angle with screws) is included in the extent of delivery.

Ask your dealer and the carrier to take the packaging and the recyclable transport tool back to your dealer or to MediTouch at your own costs. In some cases, a credit note can be granted. Special packaging and/or carrier constructions must not be disposed unauthorized.

3.1 Transport to upper floors and through narrow doors

The BalanceTutor system is usually delivered on a MediTouch standard pallet (L 210cm x W 166cm x H 105cm) with a crate. The pallet can either be brought in fully loaded through doors with a minimum width of 135cm with the help of a forklift truck or a hand lift truck, or the single parts can be carried in by hand to the future location.



Some of the components weigh between 20 and 100 kg. Please notice that the installation must be done by MediTouch authorized technicians.



Transports of heavy devices must only be carried out by authorized staff in compliance with the safety standards. Otherwise there is serious danger for people and devices.

3.2 Mechanical installation

- In order to ensure proper installation and safety, the manufacturer, an authorized service crew or an authorized dealer must always perform transport and installation of the devices.
- For security reasons behind the BalanceTutor system is a safety area of at least 3m x 2m length and width or a minimum of the width of the equipment must be free for space to move. You must note that also the area in front of the treadmill is a safety area. So even in front of the treadmill, a safety area of at least 3m x 2m as a free fall space is required.
- The provided space for the BalanceTutor system must be even and horizontal.
- Models with leveling sockets (adjustable "feet") at the rear of the BalanceTutor system have to be adjusted so that they have a firm stand, otherwise it could lead to noises like knocking or rattling during the training. Check the level arrangement with a water-level at all axes on the frame.
- The bearing capacity of floor and ceiling in the building must be higher than the weight of the machine. It has to be approved for the MediTouch device by an authorized body of the operator. Example BalanceTutor in standard configuration, Dimensions ground frame unweighting system: L 232 cm x W 161 cm = 3.74 m² platform. Net weight of BalanceTutor system: 485 kg, static bodyweight of subject: 150 kg, dynamical weight of subject: 900 kg (up to 6 times the bodyweight), over all weight loads of system on platform: 1385 kg = bearing capacity of platform: 370 kg (~400 kg) / m².

3.3 Electrical installation



An overload or a voltage drop (even short-time) of more than 20 % of the mains voltage might cause malfunctions and/or defects and might totally switch-off the BalanceTutor system.

- Installation of any electrical device and MediTouch devices must only be carried out at a voltage power connection with ground wire including leakage-current protection-switch (interrupter) and according to VDE 0100 or/and the currently valid regulations and directives. Requirements for special locations, areas and establishments (e.g. medically used areas) must be strictly adhered. PE-connection (protection-earth contact) is stipulated at all running-machines. The voltage drop between the beginning of the consumer's installation and the wall socket must not be more than 4% (DIN VDE 0100-520). It is the consignee's and user's personal responsibility to check the correct functions of the mains connection

including the outlets and an authorized electrical engineer must check these points for perfect functions regularly (1 ... 4 years). Inspections of the electrical installations within the building are not incumbent on the supplier MediTouch.






- As standard, a dedicated power line of 230 Volt AC, 50/60 Hz is used with a 16A C type circuit breaker. In case of countries like USA where the voltage of a single phase is 120V, you need to use a the following wiring L1/L2/PE 50/60Hz 2x10A circuit breaker with a dedicated power line, In this case you will have 208V between L1 and L2.
- In case the BalanceTutor supplied with an external isolation transformer it required to be fixed to a wall and not be disconnected in any case.
- Before installing the BalanceTutor system please compare the specifications on the nameplate concerning the mains voltage and the mains frequency with your local characteristics. Connection only if identical.
- Check the main lead, the voltage power supply outlet and ground wire protection-contacts before plugging it in.
- Damaged leads and couplers and defective or dirty contacts have to be exchanged immediately. Rubber-leads can get porous and friable after some years.
- For further questions please ask your electrical engineer or MediTouch.



- **Plug the device directly into the wall socket with checked ground wire. Device has to be connected to a separate circuit. The use of an extension cables or a multiple plug sockets is not allowed.**
- **Electrical devices with mains connections must neither be used in wet and humid areas (e.g. swimming pool, sauna, etc.) nor in environmental chambers.**

4 Instructions For Use

4.1 Illuminated system status indicators




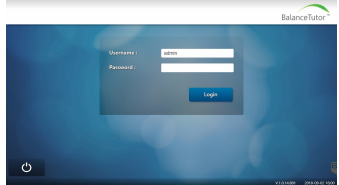
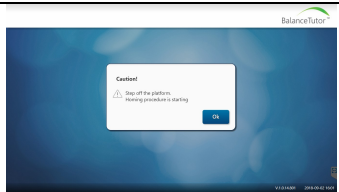
IMAGE	DESCRIPTION	LOCATION
	Emergency stop button pressed	Upper right to the touch screen
	PC ON/OFF momentary switch button	Below the touch screen
	Patient's screen	At the front of the patient
	Therapist's operation touch screen	Touch screen
	Isolation transformer power ON light	Frontal side of the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

4.2 Starting the BalanceTutor system

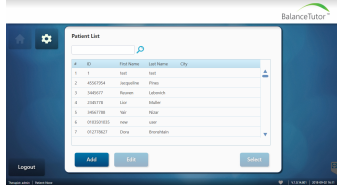
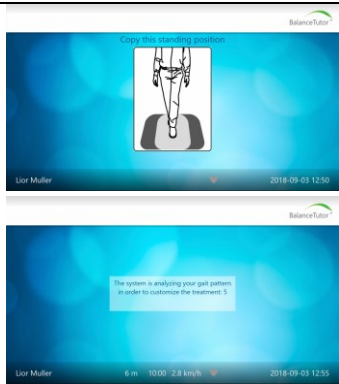
4.2.1 Installation, Overview, Checklist

As one time after the BalanceTutor has been installed, an authorized technician (distributor or service partner) has to check whether the installation of the device has been 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 encharged of the installation a Summery Report (MediTouch reff. # DO-15-01-13).

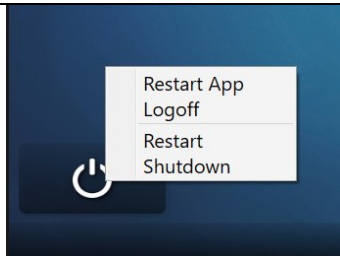

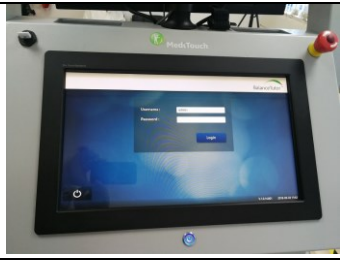


4.2.2 Switching the device ON

No.	Illustration	Description
[01]		Turn the isolation transformer dual switch to ON position and confirm the green light is illuminated.
[02]		Press one time on the  button to turn ON the computer of the BalanceTutor and let the operation system complete its loading.
[03]		Type Username: admin Password: admin
[04]		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.

4.2.3 Start working with patients

[01]		Select patient from the list or add new and then press Select to start working with the device and the patient.
[02]		During the treatment the patient can enjoy from instructions and guidance about the current state of the treatment presented at the patient's screen.

4.2.4 Switching the device OFF

[01]		Press on the  button on the touch screen then press Shutdown. The computer of the BalanceTutor will be shutdown.
[02]		Press one time on the  button to turn OFF the computer of the BalanceTutor.
[03]		Turn the isolation transformer dual switch to OFF position and confirm the green light is not illuminated.



- The intervals of switching off- and on must not be shorter than 1-2 minutes. Otherwise it could lead to interference.
- The system should be unplugged in case of longer breaks (for example overnight).

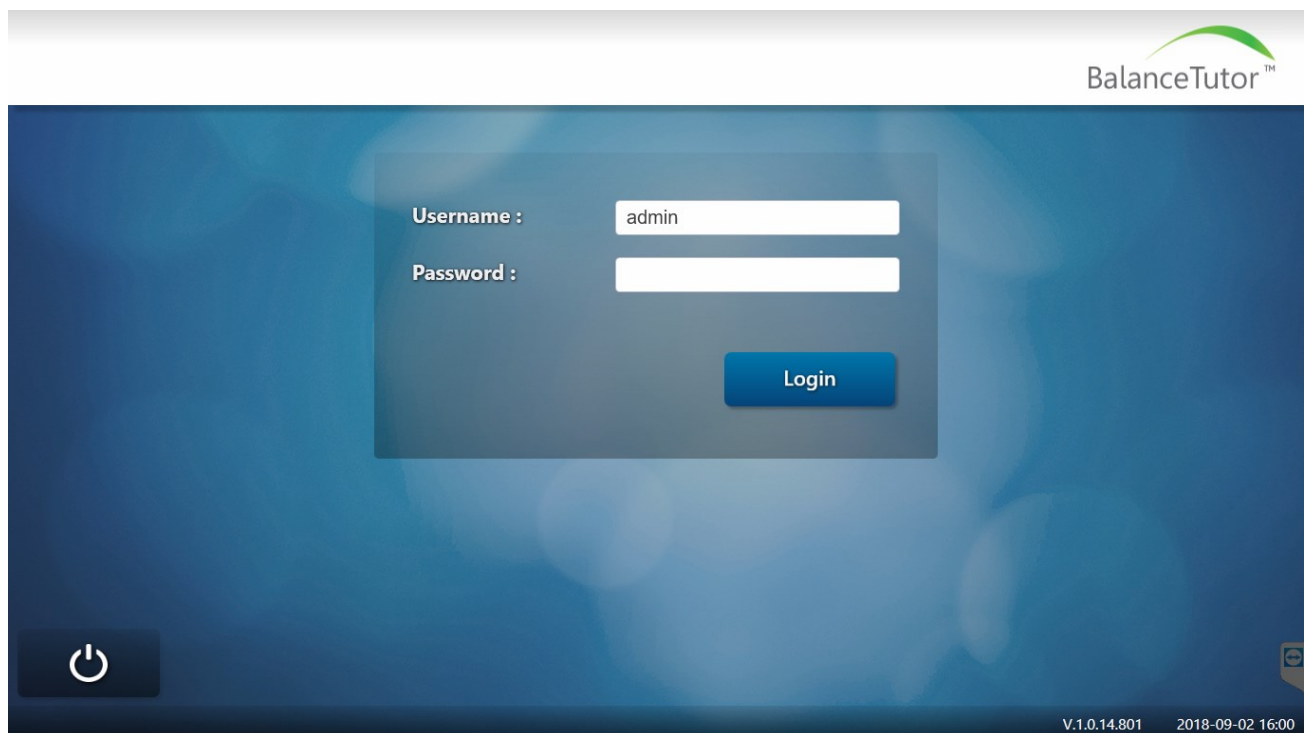
4.3 Software Operation

This section describes the operation of BalanceTutor software usage.

4.3.1 Login

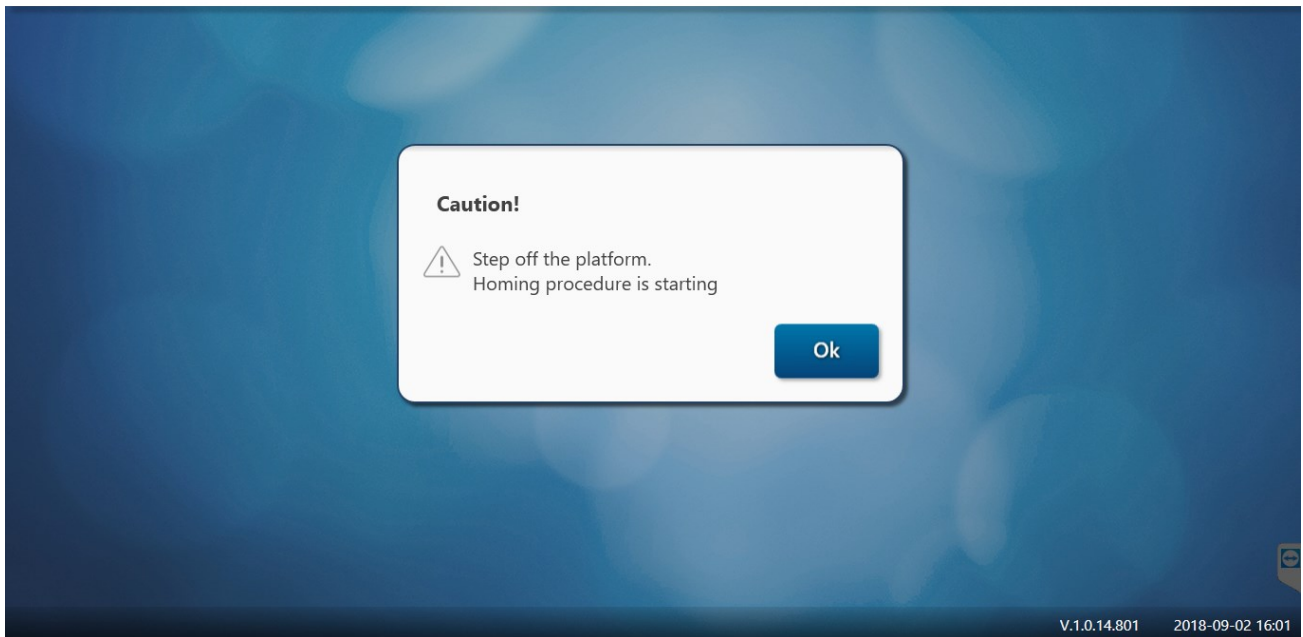
Type your username and password to login into the software.

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



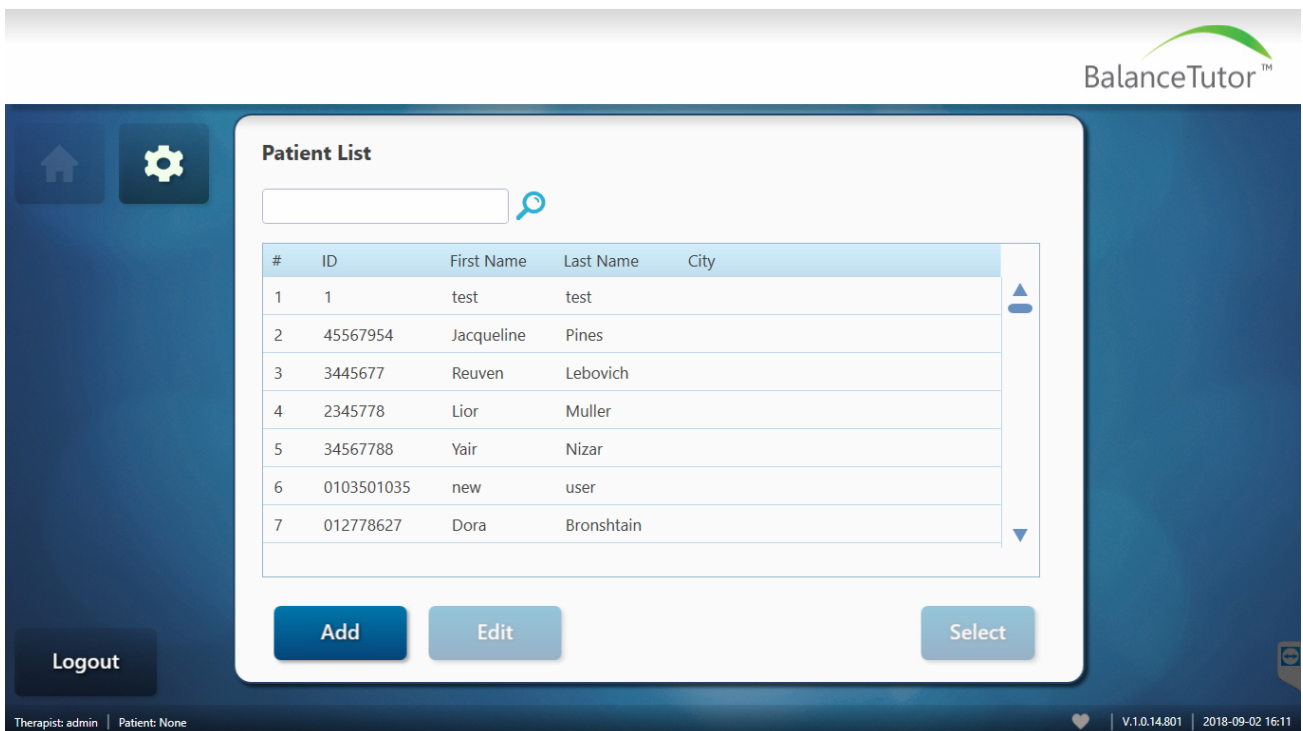
4.3.2 Homing stage

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.



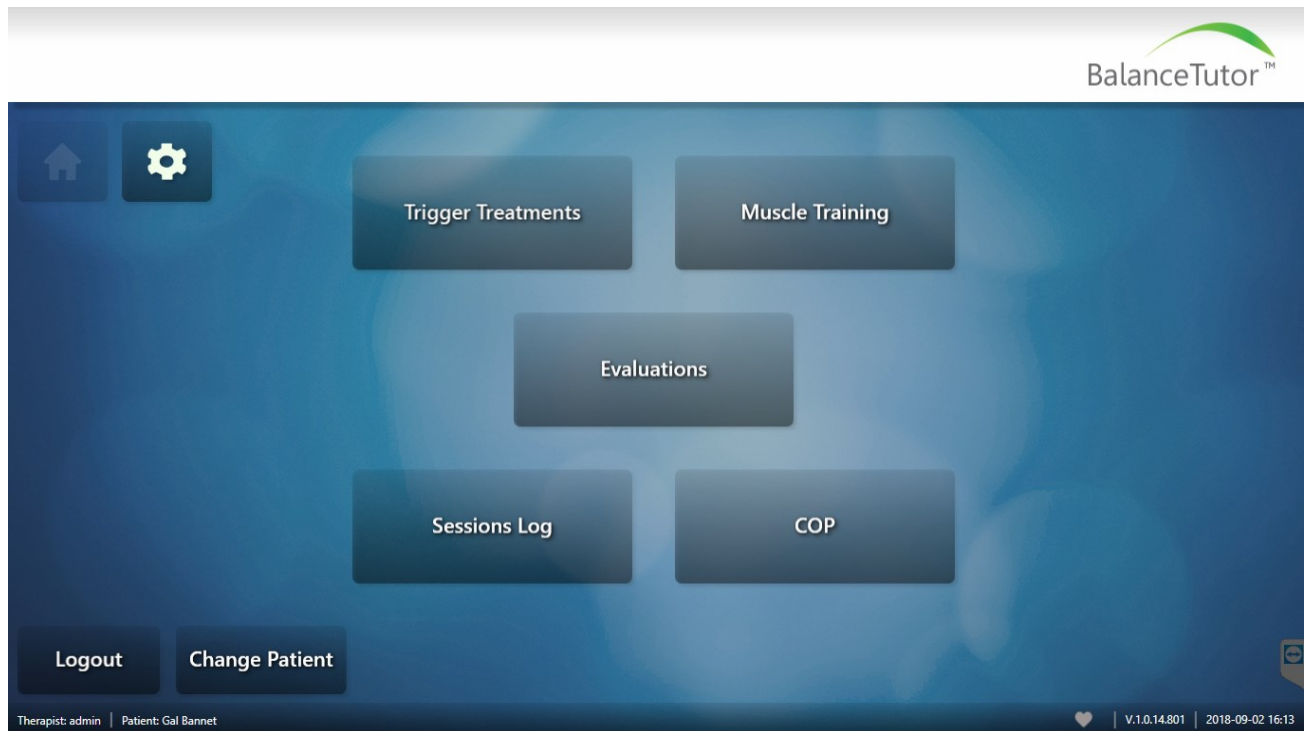
4.3.3 Patient List

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



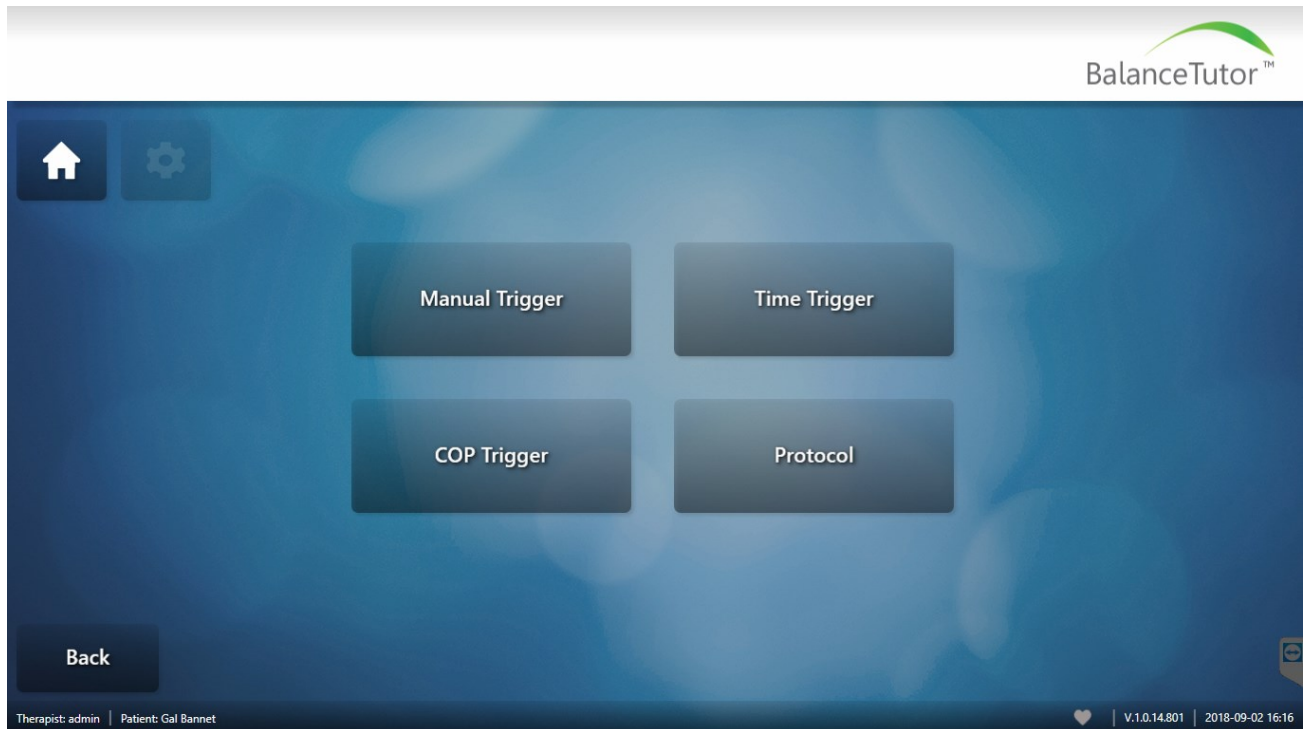
4.3.4 Operational Modes

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

4.3.5 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

4.3.5.1 Manual Trigger


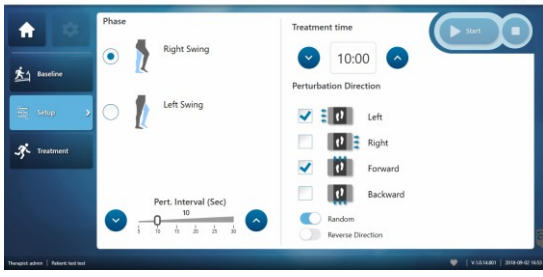
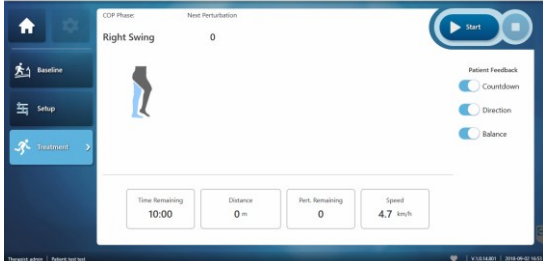
The Manual Trigger mode is designed to allow the therapist full controlling of treatment parameters during the session such as walking speed, perturbation intensities and treatment time. The therapist can set the treatment manually according to the rehabilitation needs.



4.3.5.2 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:

<p>Baseline</p> <p>The Baseline stage is designed to set the walking speed and Perturbation intensities in 4 directions according to patient abilities and rehabilitation needs.</p>	
<p>Setup</p> <p>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.</p>	
<p>Treatment</p> <p>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.</p>	

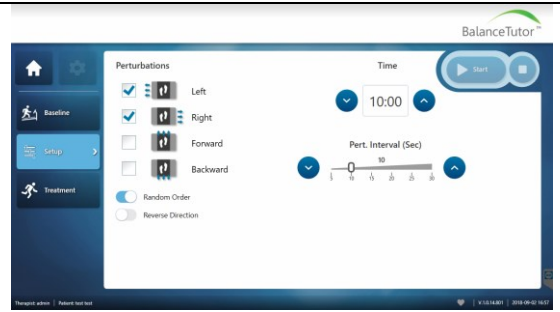
4.3.5.3 Time Trigger

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

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

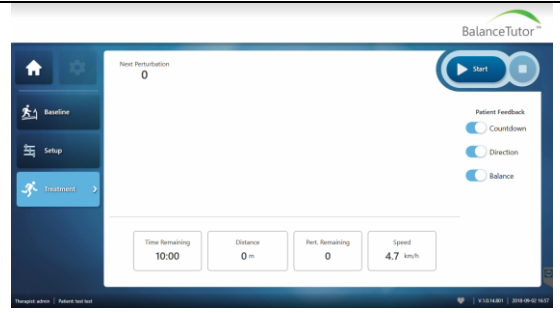
Setup

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.



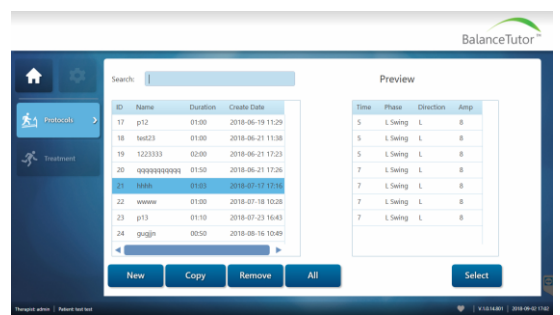
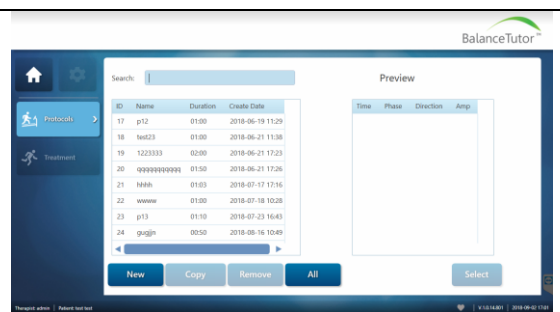
4.3.5.4 Protocol

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.

4.3.5.4.1 Choosing from existing protocol

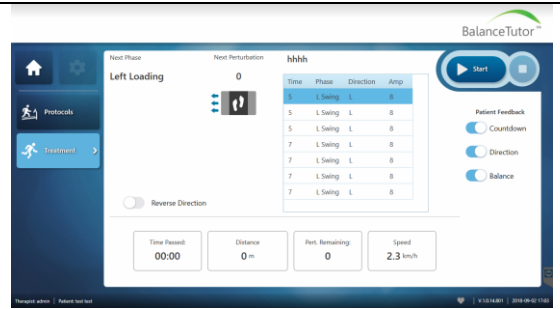
Protocols

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



Treatment

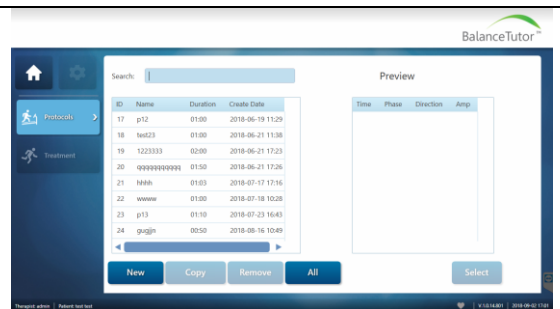
The Treatment stage allows the therapist to follow the treatment process as well as to show or eliminate patient's feedbacks shown on his screen. Changing the direction of the belt can be switched from here.






4.3.5.4.2 Creating new protocol

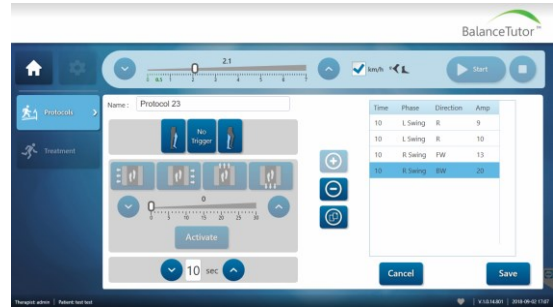
Protocol

Press on New button to create a new protocol.



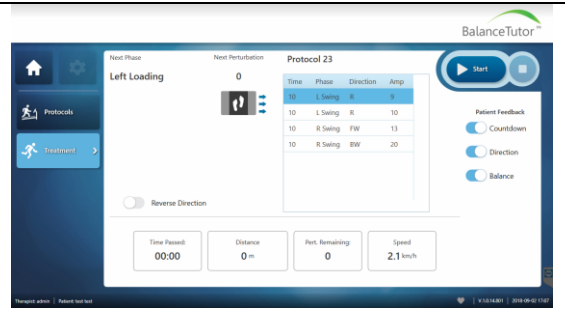
The therapist can build a list of different perturbations events and defined them as a single protocol as follows:

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



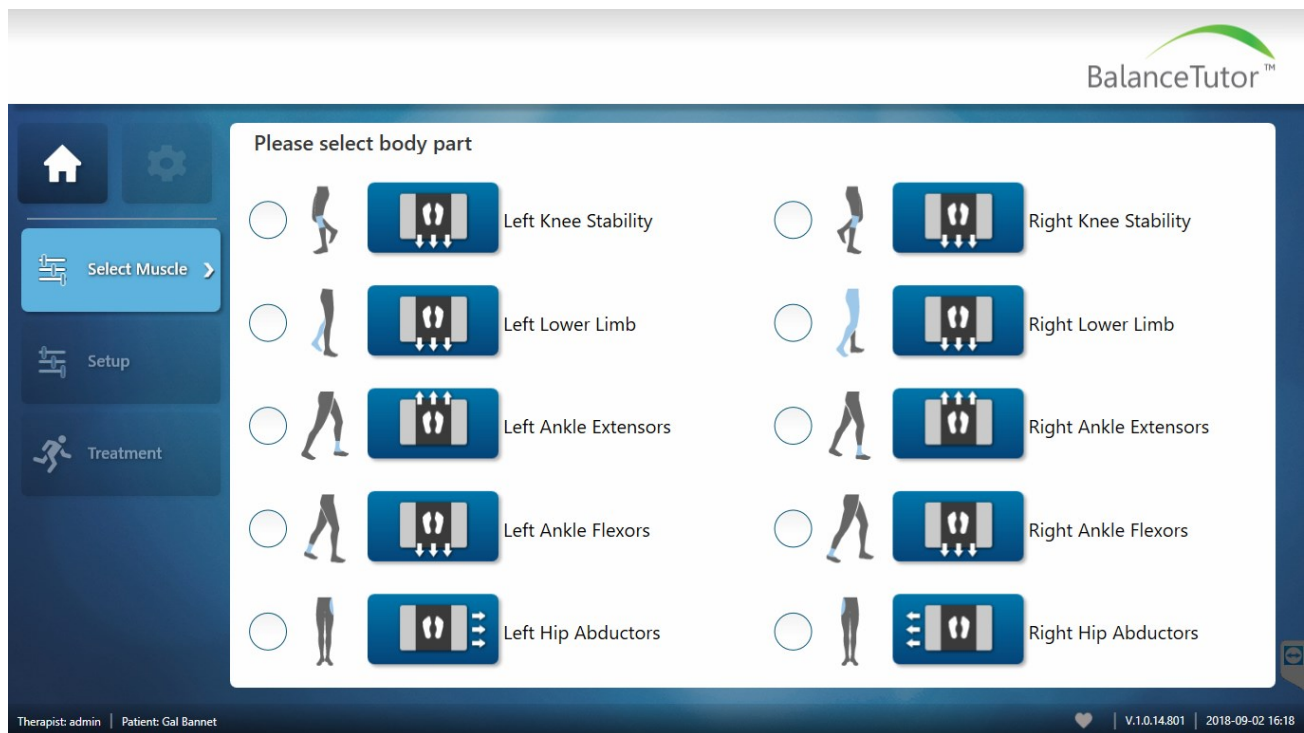
Treatment

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.



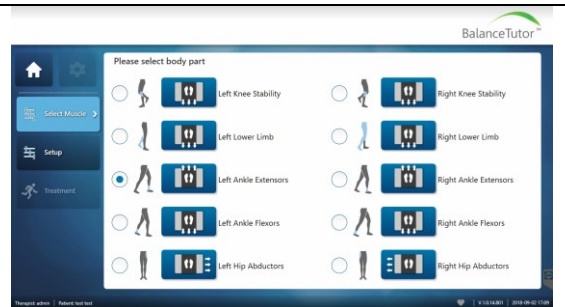
4.3.6 Muscle Training

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



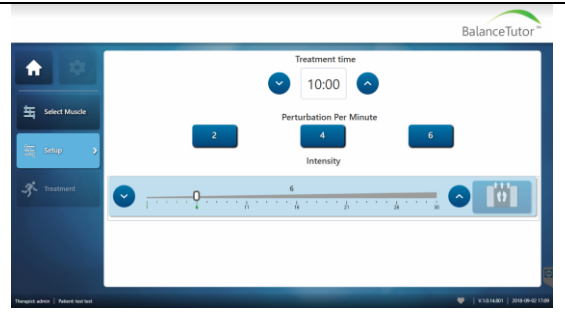
Select Muscle

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



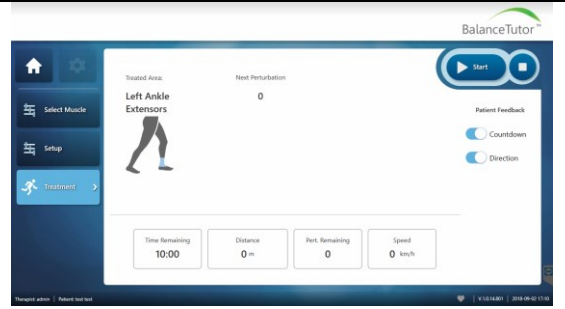
Setup

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

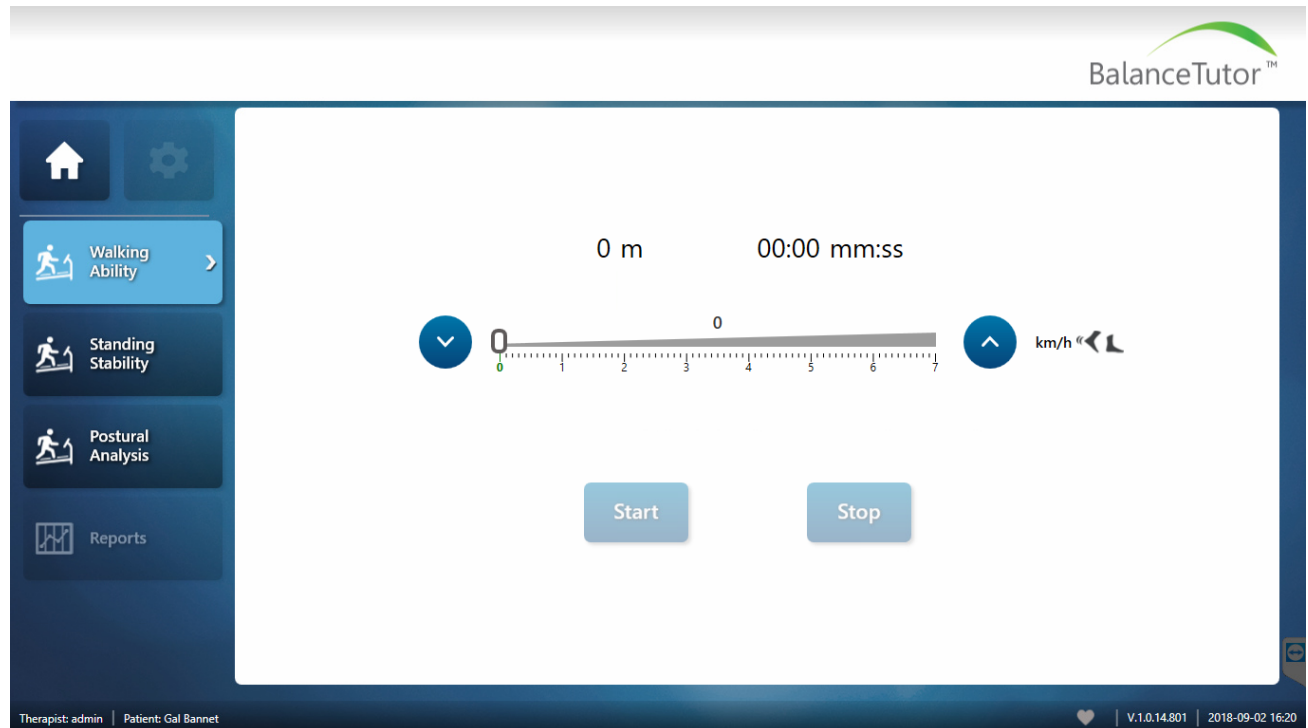
The Treatment stage allows the therapist to follow the treatment process as well as to show or eliminate patient's feedbacks shown on his screen.



4.3.7 Evaluations

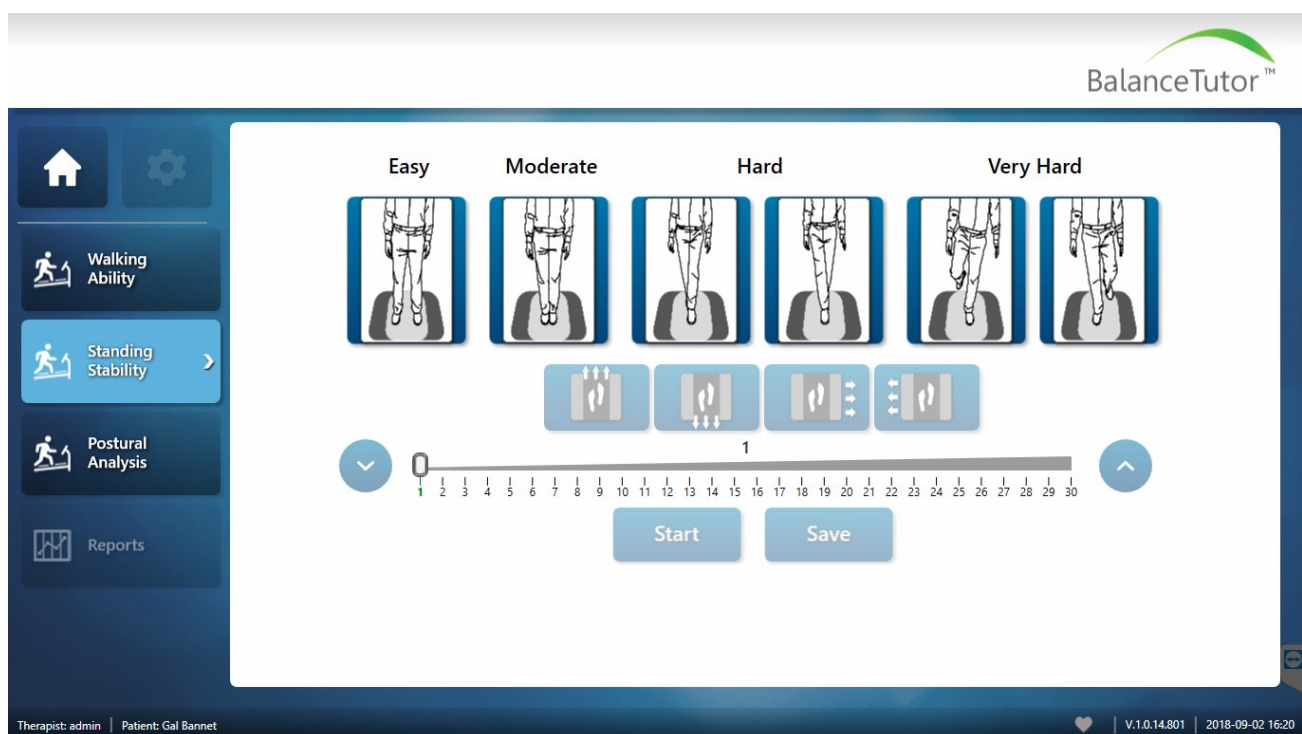
The evaluation mode is designed to evaluate Walking ability, Standing stability and Postural analysis.

4.3.7.1 Walking Ability



<ul style="list-style-type: none"> • Evaluation purpose 	To evaluate the patient's ability in regards to walking speed and distance.
<ul style="list-style-type: none"> • Therapist instructions 	Set the walking speed for the gait evaluation and stop the the gait according to patient's ability.
<ul style="list-style-type: none"> • Comment 	This evaluation is indicated for patient suffering form limited gait distance ability like less than 100 meters.

4.3.7.2 Standing Stability

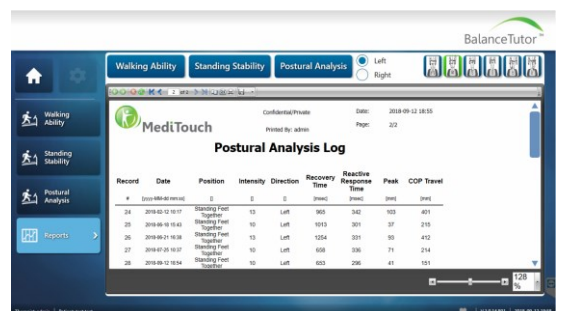
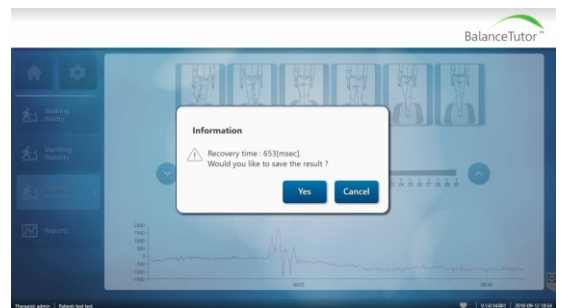
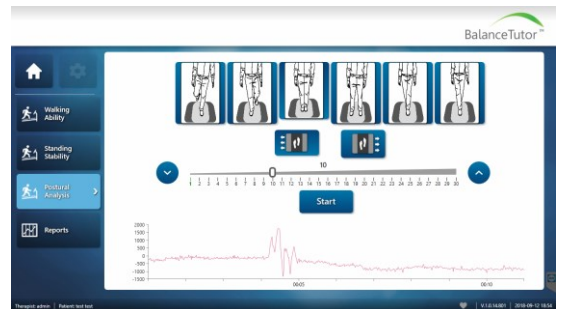
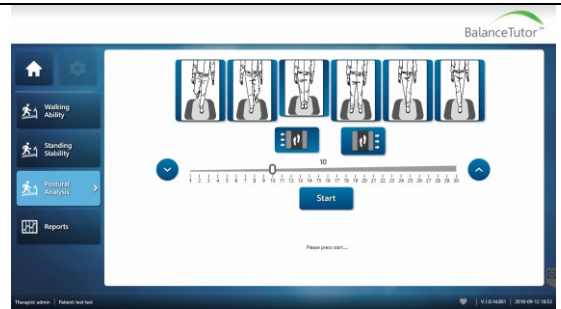
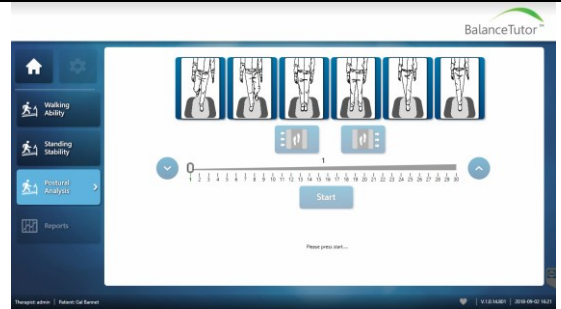


<ul style="list-style-type: none"> • Evaluation purpose 	To evaluate the level of patients Compensatory Step Postural Response.
<ul style="list-style-type: none"> • Therapist instructions 	Set the standing position, direction of the perturbation, level of the perturbation and start. Press save to document the evaluation.
<ul style="list-style-type: none"> • Comment 	Choose the standing position according to patient ability.

4.3.7.3 Postural Analysis

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

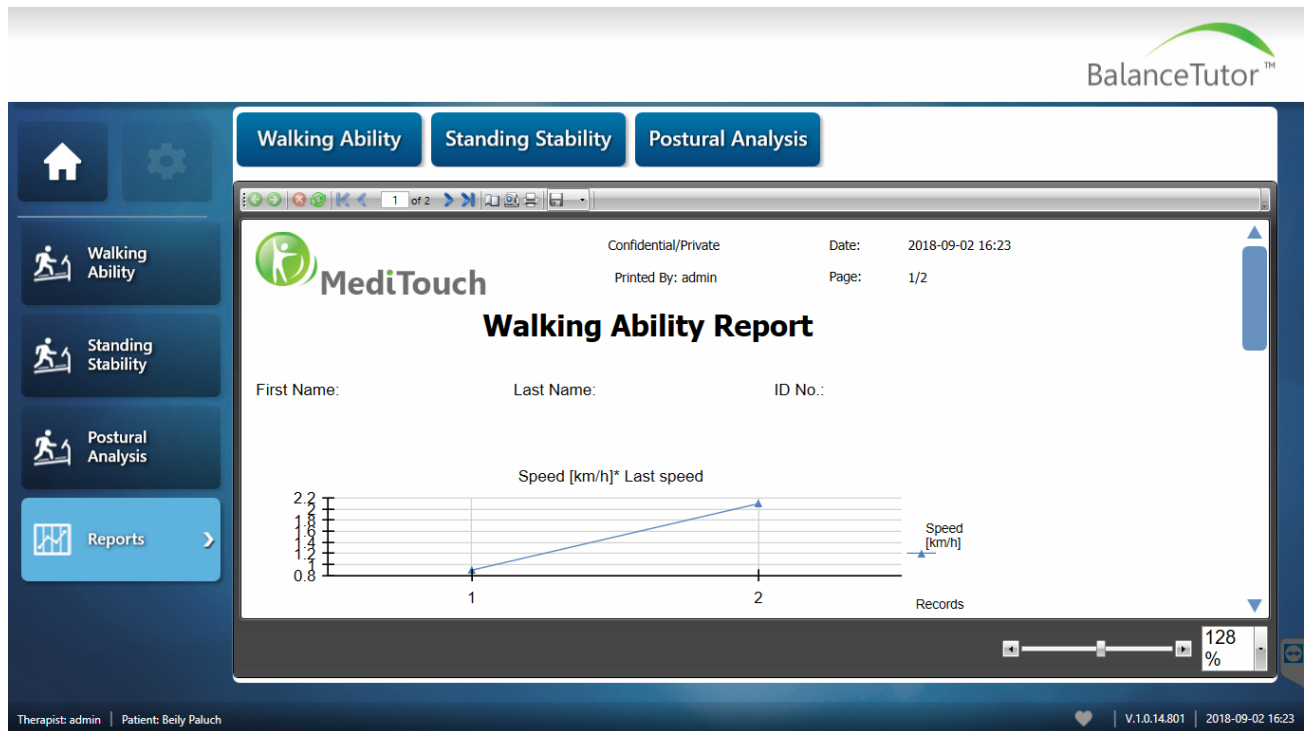
1. Therapist chooses the stance position
2. Therapist chooses either left or right perturbation
3. Therapist sets perturbation amplitude
4. Therapist instructs the patient to maintain the stance through the perturbation and not shift base of support whenever possible until advised
5. A reading will only 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



4.3.8 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.

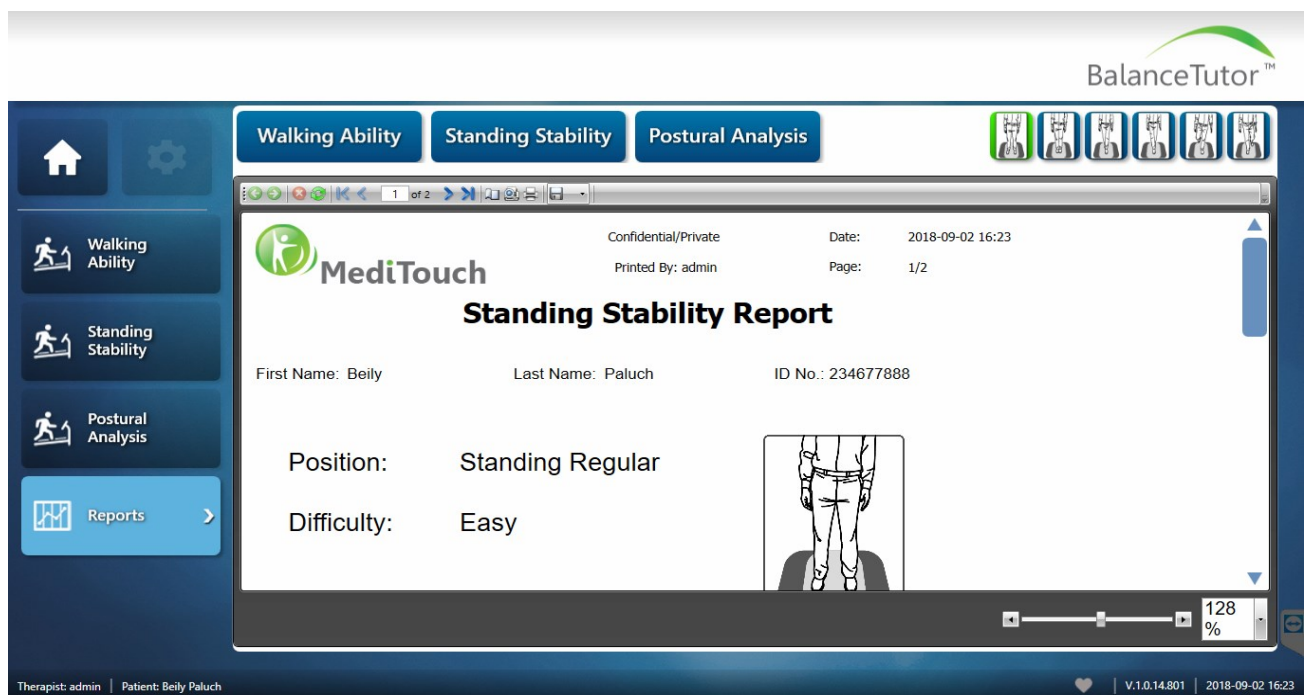
4.3.8.1 Walking Ability



The screenshot shows the 'Walking Ability Report' interface. At the top right is the 'BalanceTutor™' logo. Below it are three tabs: 'Walking Ability', 'Standing Stability', and 'Postural Analysis'. The 'Walking Ability' tab is selected. On the left is a navigation sidebar with icons for 'Walking Ability', 'Standing Stability', 'Postural Analysis', and 'Reports'. The main content area displays the report details:

- MediTouch logo and 'Confidential/Private' status.
- Date: 2018-09-02 16:23, Printed By: admin, Page: 1/2.
- Walking Ability Report**
- Fields for First Name, Last Name, and ID No. (all empty).
- Graph titled 'Speed [km/h]* Last speed' showing a line graph with two data points at x=1 and x=2. The y-axis ranges from 0.8 to 2.2.
- Bottom right corner shows a zoom slider and '128%'.
- Footer: Therapist: admin | Patient: Beily Paluch | V.1.0.14.801 | 2018-09-02 16:23

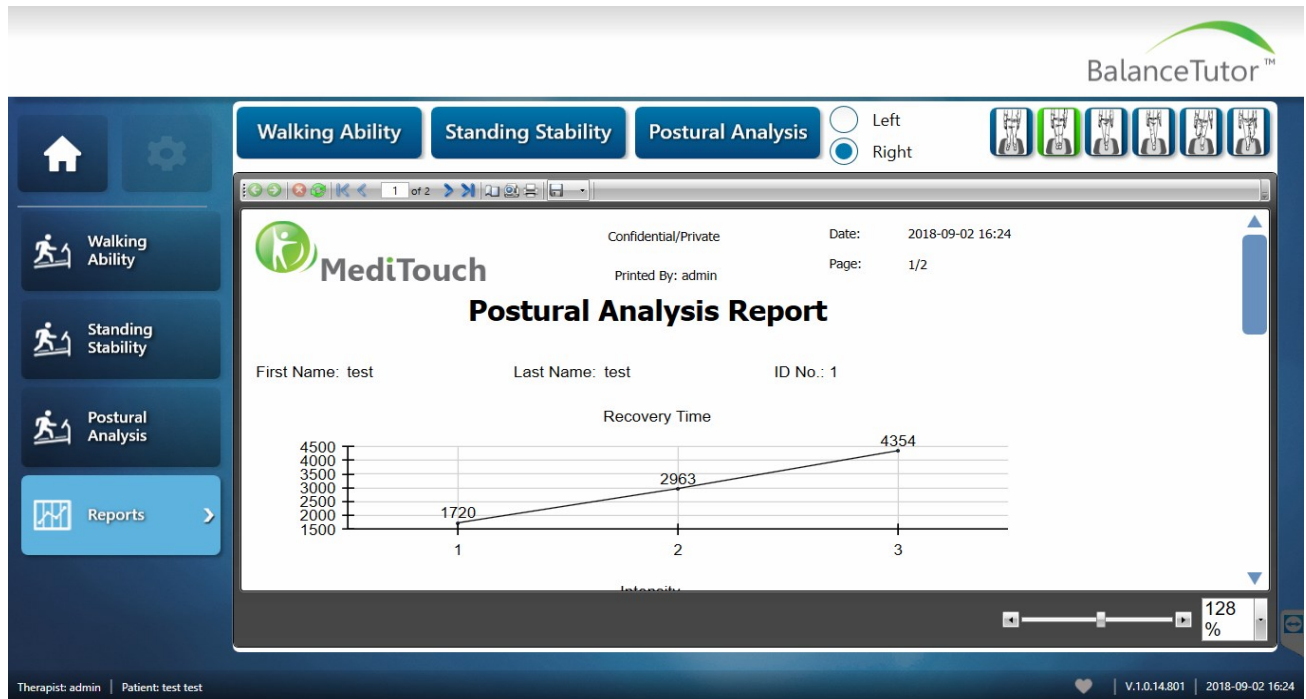
4.3.8.2 Standing Stability



The screenshot shows the 'Standing Stability Report' interface. At the top right is the 'BalanceTutor™' logo. Below it are three tabs: 'Walking Ability', 'Standing Stability', and 'Postural Analysis'. The 'Standing Stability' tab is selected. On the left is a navigation sidebar with icons for 'Walking Ability', 'Standing Stability', 'Postural Analysis', and 'Reports'. The main content area displays the report details:

- MediTouch logo and 'Confidential/Private' status.
- Date: 2018-09-02 16:23, Printed By: admin, Page: 1/2.
- Standing Stability Report**
- Fields for First Name: Beily, Last Name: Paluch, ID No.: 234677888.
- Position: Standing Regular
- Difficulty: Easy
- Diagram of a person standing.
- Bottom right corner shows a zoom slider and '128%'.
- Footer: Therapist: admin | Patient: Beily Paluch | V.1.0.14.801 | 2018-09-02 16:23

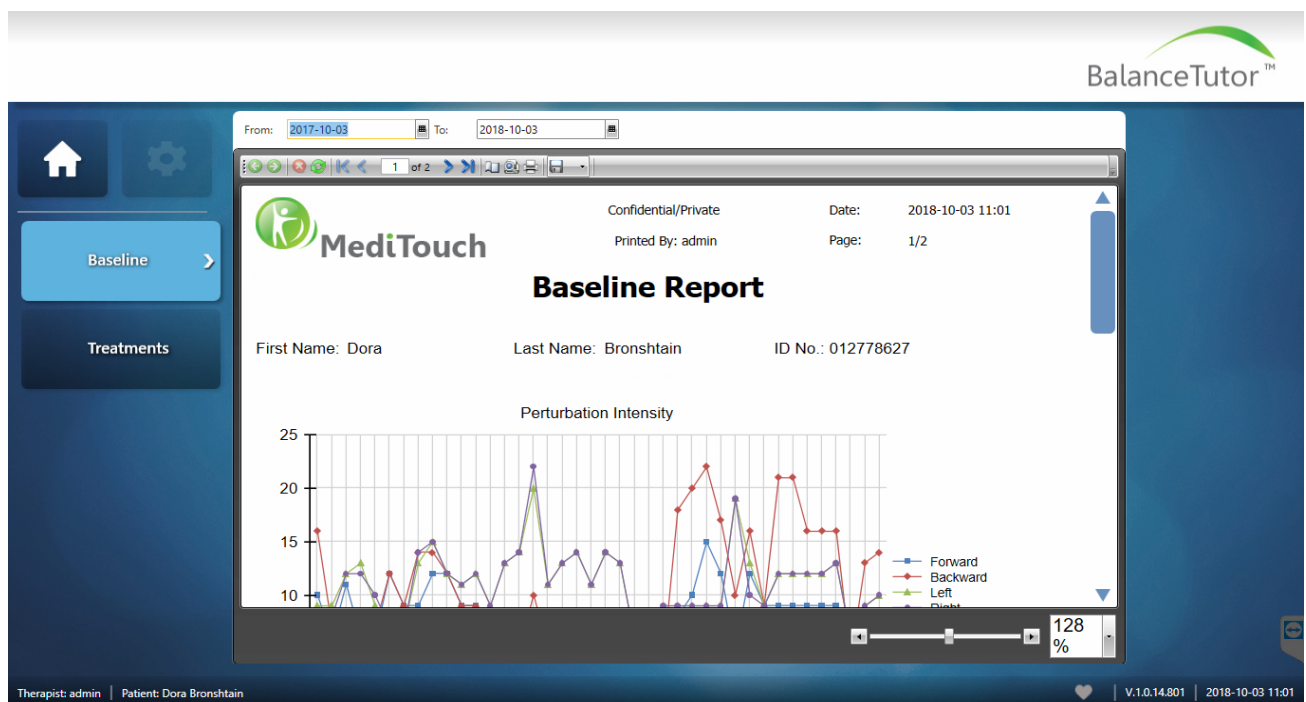
4.3.8.3 Postural Analysis




4.3.9 Session Log

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

4.3.9.1 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.



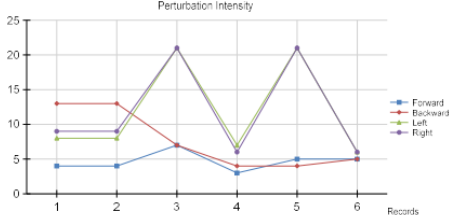
Confidential/Private
Printed By: admin
Pages: 1/2

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


Baseline Report

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

Perturbation Intensity



Walking Speed (km/h)



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.

Hamelacha 45, Poleg industrial zone,
 Netanya, Israel.

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

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



Confidential/Private
Printed By: admin
Pages: 2/2

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

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

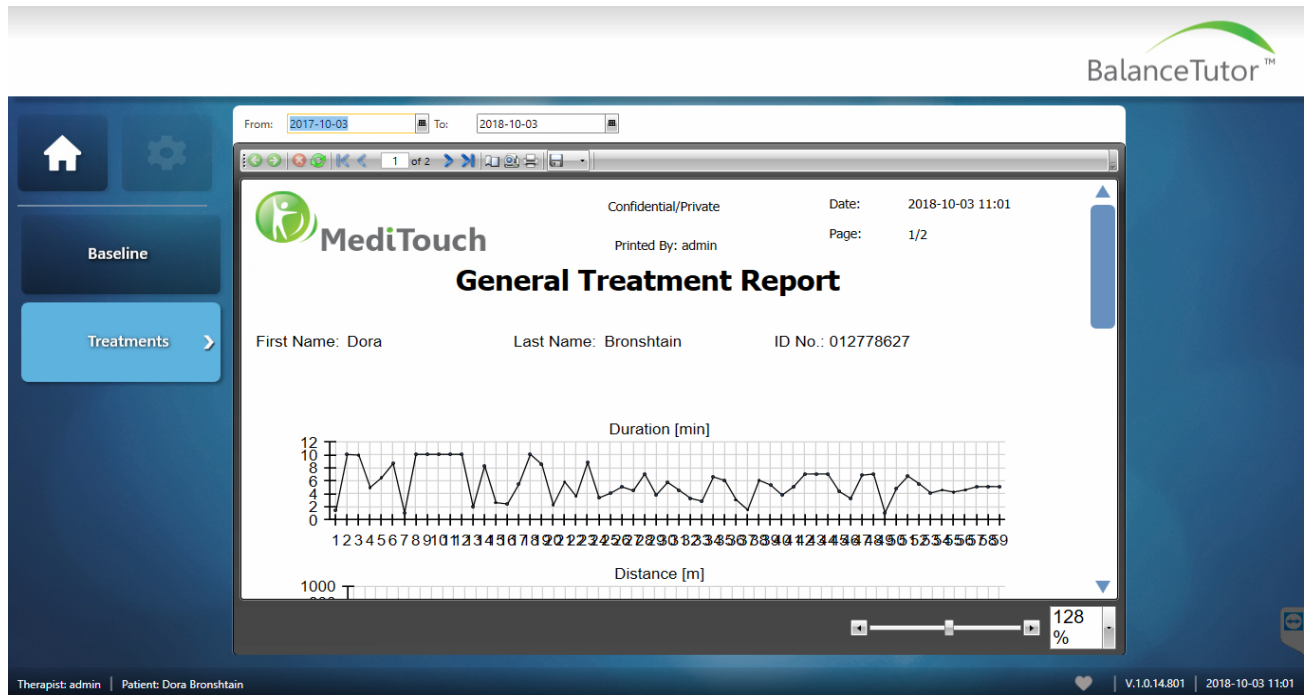
Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd., Data is only valid if signed by authorized therapist.

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www.meditouch.co.il
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4.3.9.2 Treatments



BalanceTutor™

From: 2017-10-03 To: 2018-10-03

Confidential/Private Date: 2018-10-03 11:01
Printed By: admin Page: 1/2

General Treatment Report

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

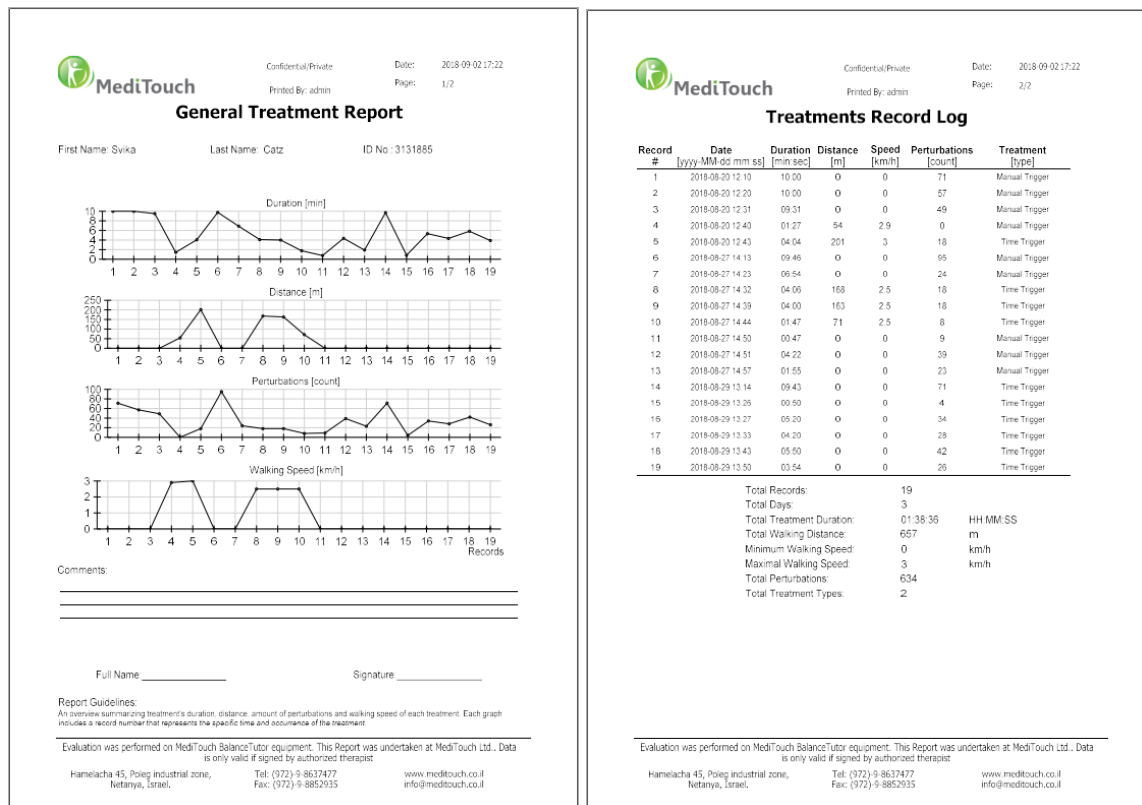
Duration [min]

Distance [m]

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.



MediTouch 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

Duration [min]

Distance [m]

Perturbations [count]

Walking Speed [km/h]

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

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

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

Treatments Record Log

Record #	Date [yyyy-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 13:28	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	05:00	0	0	42	Time Trigger
19	2018-08-29 13:50	03:64	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

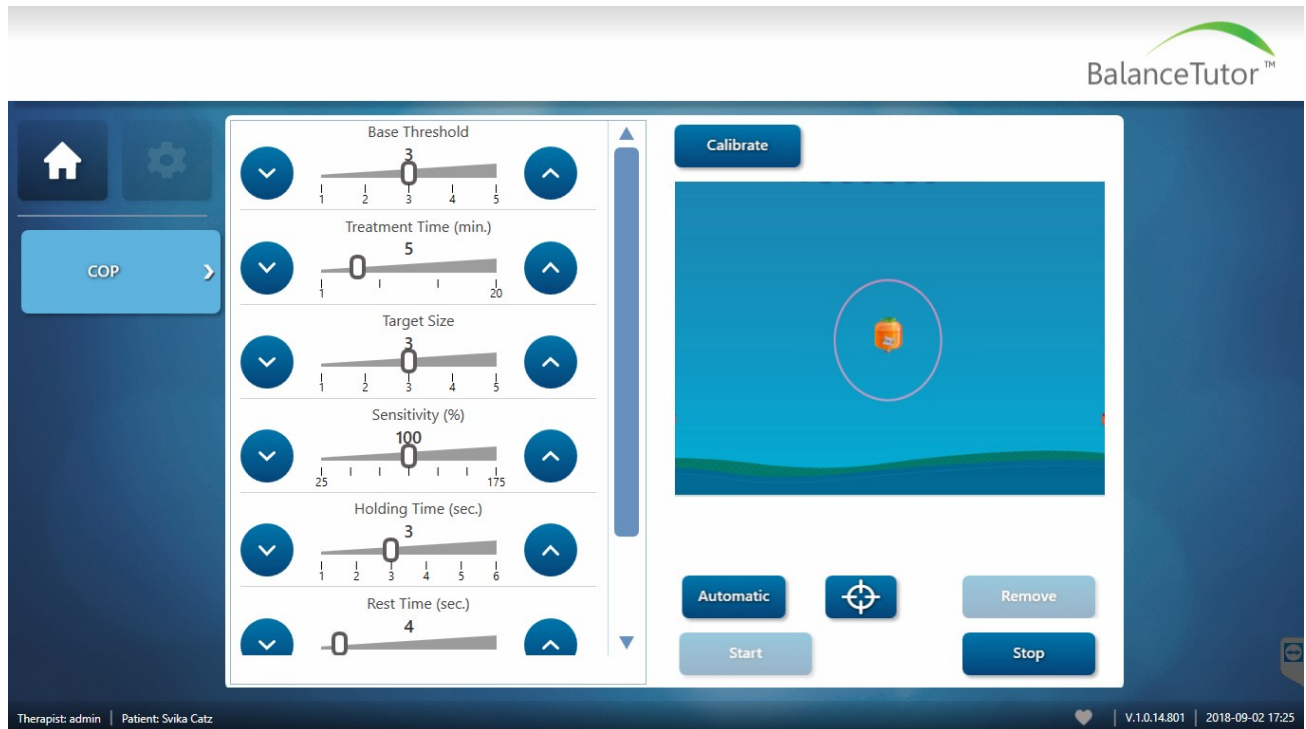
Evaluation was performed on MediTouch BalanceTutor equipment. This Report was undertaken at MediTouch Ltd., Data is only valid if signed by authorized therapist

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4.3.10 COP

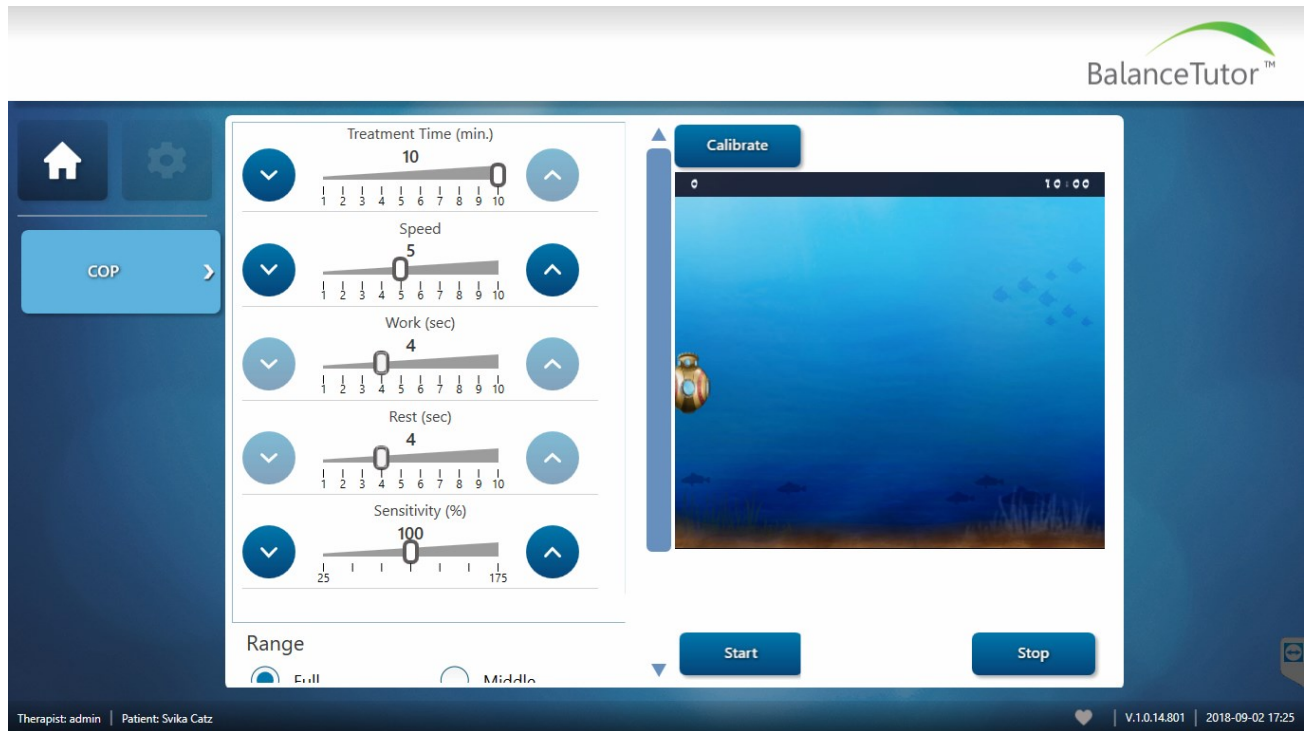
The COP task have been designed to facilitate repetitions of isolated weight shifting practice in any stance position. The practice cabn be customized according to the patient’s weight shifting movement ability and the therapists objective for practice.

4.3.10.1 Fruit Shop



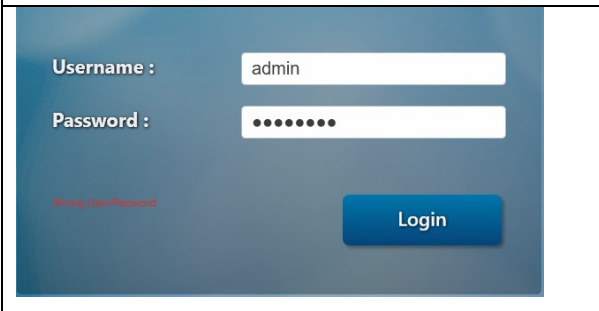
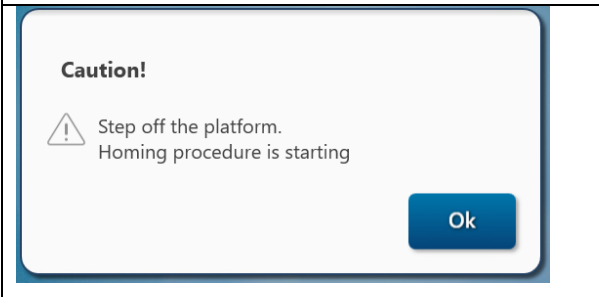

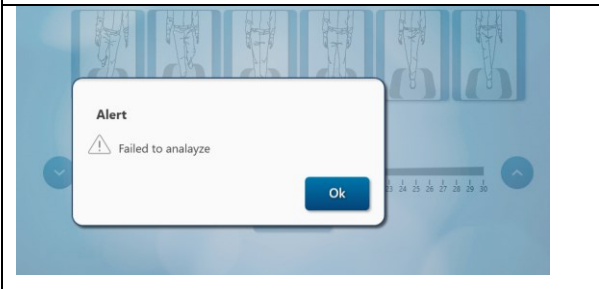
<ul style="list-style-type: none"> • Treatment purpose 	<p>To facilitate anterior/ posterior and medial lateral weight shifting practice in any stance position/</p>
<ul style="list-style-type: none"> • Therapist instructions 	<ul style="list-style-type: none"> ➤ Choose stance position ➤ Calibrate the 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
<ul style="list-style-type: none"> • Comment 	<p>No force can be applied to force plate apart from patient</p>


4.3.10.2 Submarine



<ul style="list-style-type: none"> • Treatment purpose 	<p>To facilitate anterior/ posterior and medial lateral weight shifting practice in any stance position/</p>
<ul style="list-style-type: none"> • Therapist instructions 	<ul style="list-style-type: none"> ➤ 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
<ul style="list-style-type: none"> • Comment 	<p>No force can be applied to force plate apart from patient</p>

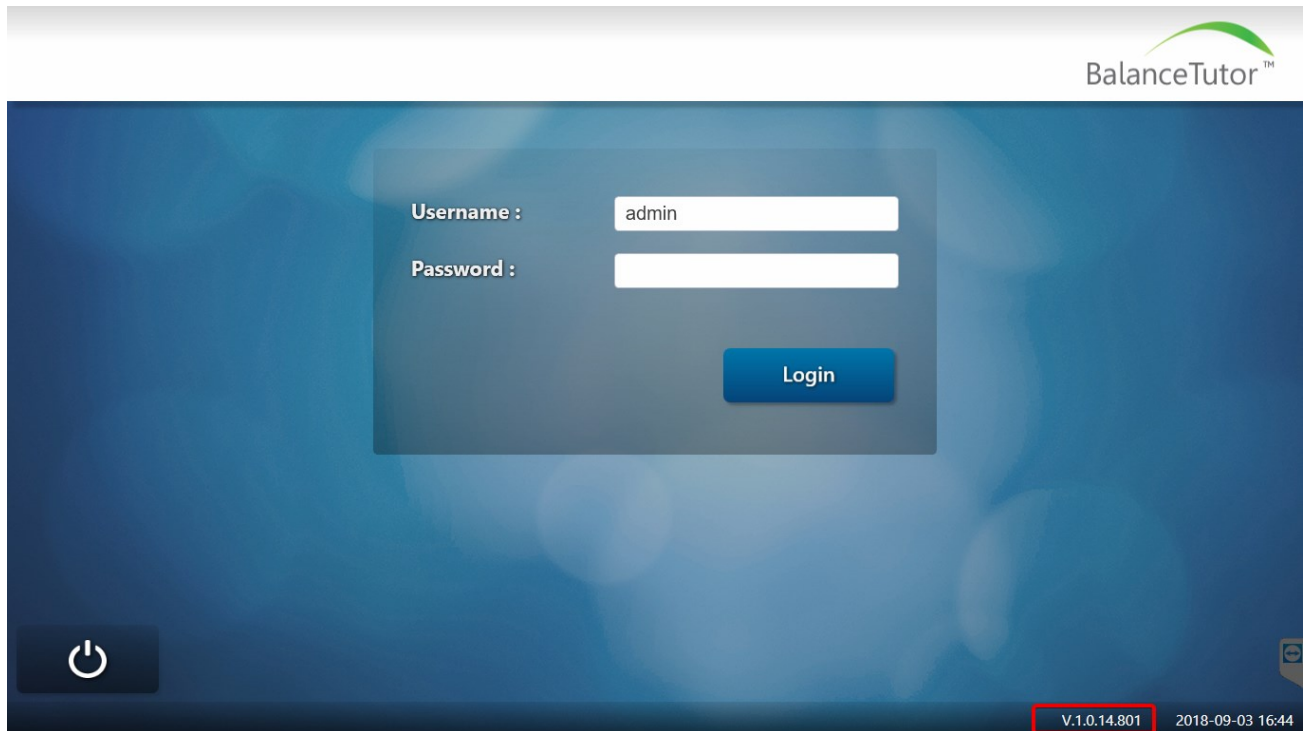
4.4 System messages

IMAGE	DESCRIPTION	SEVIRITY
	Wrong User/Password at login	Error
	The perturbation platform start with homing procedure.	Message
	An attempt of the system to start homming procedure but one of the following preventing it: <ol style="list-style-type: none"> Emergency stop button pressed 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

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

4.5 Version identifier

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



5 Training

5.1 General notes

5.1.1 Suitable clothing

Wearing appropriate clothing can reduce the patient's risk of skin irritation and lesions. We suggest patients wear tight-fitting pants made of soft cotton. Clothes made of thick, rough, fabrics with thick seams or very loose pants are unsuitable. Synthetic materials can cause mild burns on the skin due to friction. Patients should wear flat, closed shoes on the treadmill. Suitable shoes must be worn to ensure a regular gait pattern.



If users have long hair, there is a danger of their hair getting caught in the treadmill during treatment. For this reason, we recommend that long hair is kept tied up at all times using a hairnet or other means.

5.1.2 Before starting training

You must explain in detail to patients about what the BalanceTutor does before their first training session. Make patients aware of the benefits and risks of training as well as the concept of perturbation.

5.2 Safety harness

The BalanceTutor comes with single UNI size safety harness

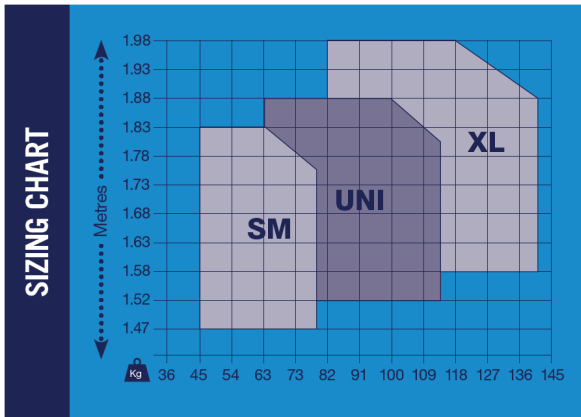
5.2.1 Putting on the harness

Note:

Before putting the safety harness on, make sure the patient is wearing appropriate clothing. Loose fitting and slick clothing will tend to allow vest to ride up.

When putting on the safety harness, remember that a tight fit provides greater support and feels more comfortable when unweighted. Avoid pressure around the chest and around the legs. The vest must support the person from the legs, not from the chest, arms, ribs or hips. Always fasten the straps in the order given in these instructions.

5.2.2 Sizes



Description

MediTouch P/N

Fall Protection Harness S	DS-06-01-02-A
Fall Protection Harness UNI	DS-06-01-01-A
Fall Protection Harness XL	DS-06-01-03-A

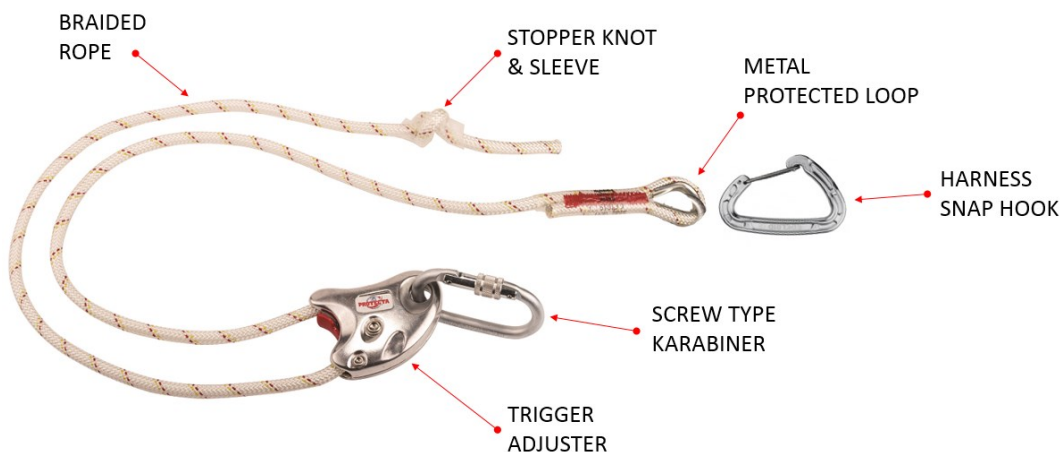
Standards:

CE EN361, CE EN358, CE EN1497

5.2.3 Harness features



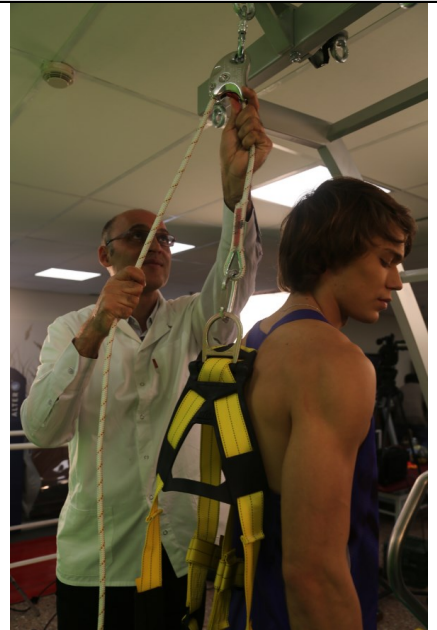
5.2.4 Trigger positioning lanyar



5.2.5 Harness setup

STAGE 1 – Harness level adjustment

Adjust harness level to patient's height using the red trigger adjuster.



STAGE 2 – Wearing the harness

Wear the harness and confirm its height according to the image.



STAGE 3 – Buckle leg straps

Buckle leg straps and adjust their length if required.



STAGE 4 – Buckle chest straps

Buckle chest straps



STAGE 5 – Tension adjustment

Adjust rope tension using the red trigger adjuster to allow;

- A. Secured height in case of a fall.
- B. Comfortable movement tolerance.



5.3 General advice for training

The user should find these instructions helpful when providing treadmill therapy manually. Apart from drawing on the literature published on this subject, these instructions are also mainly based on the experiences of physiotherapists. This series of instructions is obviously not exhaustive.

When receiving manual treadmill/perturbation therapy, patients should carry out as many activities on their own as is medically sensible, making the best possible use of their remaining functions. The following principle should be applied in order to ensure this happens: depending on the user's training status, provide him with as little assistance and only support as much weight as is medically indicated. The purpose of the treatment is to achieve regular, symmetrical movement in both legs.



- **Ask patient how he is feeling in regular intervals. Stop training session if the patient does not feel well.**
- **Have the straps on the harness belt become loose? Stop the training session and retighten any loose straps on the harness belt. Check to see whether the straps and buckles are twisted.**
- **If the harness belts' buckles opened? Stop the training session and close the open buckles. Check that the buckles are still intact. If you do not detect any defects you can continue training. The training session must be ended if any buckles are defective.**

5.4 Training duration and frequency


Training duration and distance are determined by the user's physical ability. We recommend short training sessions of 10-15 minutes to begin with, which can be adapted to the progress the patient is making during the course of treatment. Current scientific knowledge about training stipulates as a requirement for maximum motor learning success that the organism has recovered as fully as possible (90-95% recovery) (Schnabel et al. 1997). This is equivalent, for instance, to a rest period of 18 hours between two training sessions, which basically allows a training session every day using the BalanceTutor. However, the decision about whether training can be carried out every day must always be made by the user, based on the requirements and abilities of the individual user.

5.5 Selecting training parameters


The decision as to which speed, acceleration and perturbation parameters should be used during the training session depends on the user's abilities. In general, the increase in the speed of movements should be adapted individually to the progress the user is making during treatment. Selecting

treadmill and perturbation speeds and accelerations that are deliberately slow may be beneficial to patients when they are learning or relearning to walk and/or training their reaction times in case of a fall, especially at the start of treatment. In particular, being able to achieve a more effective and also more deliberate control of their movement can have a positive impact.

5.6 Training troubleshooting

	<ul style="list-style-type: none"> ▪ Is there a person or object inside the danger zone? <p>Stop the training session immediately and make sure that there is no other person or object inside the danger zone before restarting.</p> <ul style="list-style-type: none"> ▪ Do you notice the treadmill making jerky movements or unusual sounds? <p>Stop the training session and carry out a functional check without a patient. Contact the treadmill producer.</p> <ul style="list-style-type: none"> ▪ The patient cannot be lowered for technical reasons (winch and emergency release are no longer working)? <p>Do not attempt to remove the user from the device on your own. Ask for assistance from one or more people you have called upon, and they can lift the user while you then undo the buckles on the harness belt.</p>
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5.7 Patient becomes unconscious

	<p>A user may have difficulties with circulation control when standing up from a seated position due to reduced muscle activity and paralysis of the vegetative nervous system. If the user suddenly becomes unconscious the emergency physician must be informed and the user lay down immediately or tilted backwards if sitting in a wheelchair.</p>
---	--

5.8 After training

- Stop the treadmill and perturbations or any running sessions.
- Loosen the belt straps and remove the harness belt from the user.

5.9 At the end of a training day

- Switch OFF the BalanceTutor according to the manufacturers' orders.
- Pull the plug out of the socket, to separate the BalanceTutor from the current.

6 Clinical Guidelines

Sufficient postural control ability is essential element for active daily living activities and falls prevention. Balance will be lost because of an insufficient proactive response or following an unexpected perturbation like a slip or a trip.

Postural control and Balance is obtained by Proper function of several body systems such as Vestibular, Visual, Somatosensory system in addition to proper physical and cognitive abilities.

These important systems and abilities can be impaired following various Neuromuscular and/or Musculoskeletal injuries or disease leading to imbalance because of impaired proactive and Reactive response ability.

Specific proactive and Reactive training is needed to improve and retain postural control and Balance ability in Standing and walking situation.

6.1 Clinical Applications

BalanceTutor enables Perturbation based-Balance Training and Center of Pressure (COP) practicing to improve and retain postural control and balance ability by following methods.

6.1.1 Weight-Bearing Encouragement

Weight-bearing encouragement practice can be achieved by BalanceTutor in different positions and difficulty levels.

A Perturbation based Balance training and/or Center of Pressure (COP) feedback practicing can be used for Weight-bearing practicing according to patient abilities and rehabilitation needs.

6.1.2 Compensatory Step Respond

BalanceTutor enables to generate several kinds of compensatory step response during the gait. There are two main compensatory responses namely crossing or side stepping which can be achieved by providing specific perturbation during swing phase of right or left leg.

6.1.3 Vestibular Rehabilitation

BalanceTutor enables unique vestibular rehabilitation to improve vestibular function. Vestibular function practices such as gaze stabilization or head moving in standing or walking while the surface of support can be moved to different directions like medial/ lateral side enables special practice to vestibular system.

6.1.4 Muscle Activation

BalanceTutor facilitates activation of specific muscle according to rehabilitation needs. For instance, forward/ backward perturbation in standing position can facilitate activation of ankle Extensors /Flexors following.

6.1.5 Somatosensory System Training

Balance therapy program based internal feedback using BalanceTutor system enables professional training of somatosensory system likes proprioception or kinesthesia sensation. A series of block and random expected and unexpected perturbation in addition to customized Center of Pressure (COP) feedback integrated in to the system, allow for customized training of somatosensory system and deep sensation improvement.

6.1.6 Multi-Task

Functional walking is a multi-task needing proper physical and cognitive ability. This task requires coordination of automatic body movement during the gait together with cognitive process like reading or thinking.

BalanceTutor allows for training of Perturbation based- Balance Training together with cognitive practice in standing and walking situation.

6.1.7 Standing Stability

BalanceTutor system allows for standing stability improvement using customized Perturbation based- Balance Training as well as Center of Pressure (COP) practicing.

The customized Perturbation based- Balance Training can include controlled expected and/ or unexpected perturbation in standing position for proactive and reactive response ability improvement. Center of Pressure (COP) practicing can be also used for postural adjustment response improvement.

The difficulty level of the training can be set according to different kind base of support while standing and/or different level of the perturbation.

6.1.8 Walking Stability

BalanceTutor system allows for providing customized Perturbation Based- Balance Training to improve Proactive and Reactive responses also in walking in addition to standing position.



Walking stability training using BalanceTutor can be achieved by practicing of computerized perturbation according to specific Gait phase such as Stance, Swing or Double Support phase during the walking.


7 Maintenance & Safety Inspections

The MediTouch authorized service engineers are happy to help you in the case of occurring problems.

A preventive maintenance can avoid problems in the future and is indispensable for the safety of such technical devices. Therefore, ask for an annual preventive maintenance contract, which is highly recommended by the manufacturer, from our service department. Some basic regular maintenance and regular safety checks are obligatory!

A therapy system can only be safe if it is maintained on a regular basis and according to specified instructions.

Maintenance must usually be carried out by MediTouch or by MediTouch authorized persons every 12 months. Some preventive checks must also be carried out at shorter intervals.

	<ul style="list-style-type: none">▪ In case of any detected and/or assumed malfunctions and/or defects and/or unreadable safety warning labels the device has to be taken out of operation, the device has to be marked and secured against operation and the supplier and authorized service personnel has to be informed in writing.▪ Disregard of warnings, disregard of intended and forbidden use, safety precautions and also unauthorized or lack of maintenance and/or regular safety checks may lead to injuries or death and/or can damage the device and will result in loss of any liability and warranty.▪ Before intervening in the device for safety reasons switch the BalanceTutor system OFF and pull the mains plug out.▪ During all maintenance works and safety tests make sure that no third parties are directly or indirectly in contact with the device under test and/or the technician performing the test. Keep a safety area of 2 m radius clear.
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7.1 Preventive maintenance

7.1.1 Power entry to the device

Before switching the device ON always check the circuit cable, plug, outlet socket and circuit entry of the device.

7.1.2 Treadmill belt set to the correct tension

Before initiating the system check if the belt is in the correct tension. If it is too loose, perform tightening using the two hexagonal screws that are adjusting the back pulley.

7.1.3 Perturbation plate centering

After switching the device ON confirm the perturbation platform is centered to the stationary part of the device. If not, alert for maintainancy.

7.2 Immediate maintenance

Immediate maintenance is necessary if:

- The device has been under high mechanical stress (push, power supply cable and/or interface cable defect through driving over it or pulling it)
- Lateral moving platform is stuck (from some obstacle or from any non-visible cause)
- Fluid has got into the device
- Cable and/or connector plug have been damaged
- Coverings and/or safety warnings have fallen Off
- The rope or the deflection pulleys show sign of wear
- A defect or malfunction of the device has been detected or is suspected
- The BalanceTutor software crashes and/or restarting
- Strange periodical mechanical noises come from motor systems

Only a properly and regularly serviced device is safe. The maintenance of the devices has to be performed by the service engineers authorized by MediTouch, preferably within the scope of a maintenance contract.

7.3 Regular inspections/examinations

Following list will containe which elements to be examined or inspected every year by MediTouch or any any technical personel authorized by MediTouch:

- Check metal construction for: Visual damage, rust, paint scraped, metal deformation.
- Confirm the BalanceTutor software running with the latest version.
- Running belt tension adjusted to the correct tension
- No backlash on lateral transmission system
- Electrical safety test; Protective Earth Resistance, Isolation Resistance and Leakage current.

- For full fulfillment of the inspection report see MediTouch Annual Service Report with document number: DO-15-01-18


7.4 Visual inspection dirt / damage – daily before training

- Carry out a general visual inspection to check for any damage to the device and support system. If any damage is suspected the BalanceTutor must not be used.
- Clean any remains on the floor before turning ON the device.
- Clean the therapist touch screen.
- Check that no one is standing within the keep out zone indicated with the yellow-black lines surrounding the device or the barriers defined in the installation stage.
- Carry out a check for dirt, especially on the harnesses, leg straps, padding and Velcro fasteners and treadmill ramp (slipping hazard!). Dirty orthopedic components should be washed.
- Check the stitching and catches on the harnesses and leg straps. Defective orthopedic components must be replaced.


8 Wearable sensors

Wearable MediTouch motion feedback devices can be worn during static and dynamic balance training in order to provide feedback on the user's body part positions and instructions on the correct positioning and movement of body parts. The feedback also provides additional motivation to take part and complete the exercise task.

8.1 Setup IMU sensors

Step	Description	Indication
1.	Turn IMU sensor ON	
2.	Confirm IMU sensors connected to the software	
3.	Assemble IMU to strap	
4.	Wear strap to right and left leg exterior side	
5.	Go to COP trigger treatment and confirm gait detection	Ding Dong sounds during walking

8.2 Setup Heart Rate monitor

Step	Description	Indication
1.	Turn the heart rate monitor ON by pressing 3sec on top switch	
2.	Wear the heart rate monitor on your wrist and wait until sensor connects to the software	

9 Troubleshooting



In case of any detected and/or assumed malfunctions and/or defects or unreadable safety warning labels the device has to be taken out of operation, the device has to be marked and secured against operation and the supplier and authorized service personnel has to be informed in writing.

9.1 Touch screen is not responding

In a case that there is no communication with the PC, and the treadmill motors continuing there action/program. You need to press immediately the emergency button to stop the motors activity and then pressing the blue light button to reset the operation system of the PC.

9.2 Interference factor

9.2.1 Mechanical

Mechanical obstacles could bring the perturbation platform to a failure state. Pay attention to the following obstacles; Wall, some obstacle between floor and bottom of the platform, human leg, etc.

9.2.2 Electrostatic Discharge

If the user moves around the devices they can be electro statically charged with up to several thousand volts. If then the user touches a metal piece, keys or display, it can lead to an electrostatic discharge between the user and the device. Electrostatic discharges can in certain cases result in interference of the device. Generally those electrostatic discharges are without harm for the user as well as for the device, but can be quite unpleasant. The main causes for electrostatic discharges are the choice of clothes, the sole of a shoe and the movement. Very dry air and many light fittings can also lead to the same results.

Solution: Try different clothes or shoes, humidify the air in the room, and switch part of the light fittings off. Please inform the manufacturer if you detect such interference.

9.2.3 Source of Interference

The devices should not be installed near to e.g. an x-ray device, motors or transformer with high connection power, as the electric and magnetic interference can falsify measurements. Very strong sources of interference (e.g. above the limit according to EMT) can influence the functions of the device.



High-tension power lines nearby and electrical devices without **CE** - sign and without a certificate of compliance for electro-magnetic-tolerance should be avoided as well.

10 Technical specifications

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

11 Certificates

11.1 ISO 9001-2008

Certificate of the SII (The Standards Institution of Israel) and the IQNET (The International Certification Network) according to ISO 9001-20:



THE STANDARDS INSTITUTION OF ISRAEL



INTERNATIONAL CERTIFICATION NETWORK



MGMT. SYS.
RvA C 096



INTERNATIONAL
ACCREDITATION FORUM



The Standards Institution of Israel

CERTIFICATE

This is to certify that the Quality Management System of

MEDITOUCH LTD.

45 Hamelacha st., Poleg Industrial Zone, Netanya, Israel 42505

Has been audited and registered by SII-QCD as conforming to the requirements of

ISO 9001:2015

This Certificate is Applicable to

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

Certificate No.: 82474	Certificate Issue Date: 08/09/2016
Initial Certification Date: 23/08/2010	Certification Expiry Date: 07/09/2019

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.



Dani Etzioni
Deputy Director General





Eli Cohen-Kagan
Director, Quality & Certification Division

Page 1 of 1

Our Vision: To Enhance Both Global Competitiveness of our Services, with our Uncompromised Quality and Integrity

11.2 ISO 13485-2003

Certificate of the SII (The Standards Institution of Israel) and the IQNET (The International Certification Network) according to ISO 13485-2003:



11.3 Certificate of compliance medical devices



Certificate of Compliance for devices for medical and rehabilitation purposes

- **Manufacturer**
 - Name: MediTouch Ltd.
 - Tel: +972 9 8637477
 - Fax: +972 9 8852935
 - Address: 45 Hamelacha, Poleg industrial zone, Netanya 42505, Israel.
- **Product**
 - Classification according to 93/42 EEC:
 - Classification according to DIN EN 957-1:2005-1:
- **Model:** BT100

We herewith declare that the above mentioned type meets following standards:

European Council Directive 93/42 EEC (MDD medical device directive), the appendix I+II of the directive 93/42 EEC are being applicable.

The CE – mark gets affixed to the product.

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

EN 60601-1

EN 60601-2

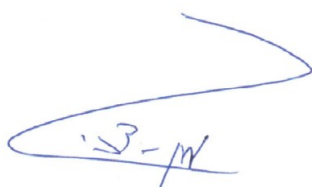
EN ISO 9001:2015

EN ISO 13485:2003

IEC-601-60601-1, B3

This certificate of compliance covers the BalanceTutor which is produced by MediTouch. The validity of this certificate of compliance expires on the release date of a certificate of compliance with a later issue date, which may be necessary due to technical modifications or due to changes of standards, guidelines and directives.

45 Hamelacha, Netanya, Israel. October 15, 2018



Giora Ein-Zvi
CEO



Ziv Kuniz
CTO

12 Disposal

By request and at the expense of the client MediTouch might take over the disposal of old devices and devices no longer functioning. Please contact info@meditouch.co.il for a detailed offer. Note the information for possible disposal of the BalanceTutor system parts or components through the client or a subcontractor.

The MediTouch devices are marked with following sign / symbol on the name plate:
Symbol for collection, treatment, recycling and disposal of waste electrical and electronic equipment (WEEE) as set out in Directive 2002/96/EC of January 27, 2003 of the European Parliament and of the Council on waste electrical and electronic equipment are necessary to reduce the waste management problems linked to the heavy metals concerned and the flame retardants concerned.



12.1 Disassemble and cut up

Use personal protective equipment, when cutting up material of any kind with the appropriate tools (eye-protection, dust mask, etc.). Contact info@meditouch.co.il to receive the safety-data-sheet according to European Commission Directive 91/155/EEC for a material.

13 Appendix

13.1 Instruction & Commissioning

Once the installation of the BalanceTutor system has been completed and a final installation summary delivered to the customer, MediTouch employee or its partner starts with the instruction and commissioning of the device. See for reference MediTouch doc number DO-15-01-12 section 4 (installation procedure)

It is important to include all people in the instruction and commissioning, who are going to work with the BalanceTutor system. After the instruction is completed the instruction protocol is to be signed by the MediTouch technician and all trained persons and sent back, together with the signed delivery note and the registration form, to MediTouch. See for reference MediTouch doc number DO-15-01-13 section 7 (Training)