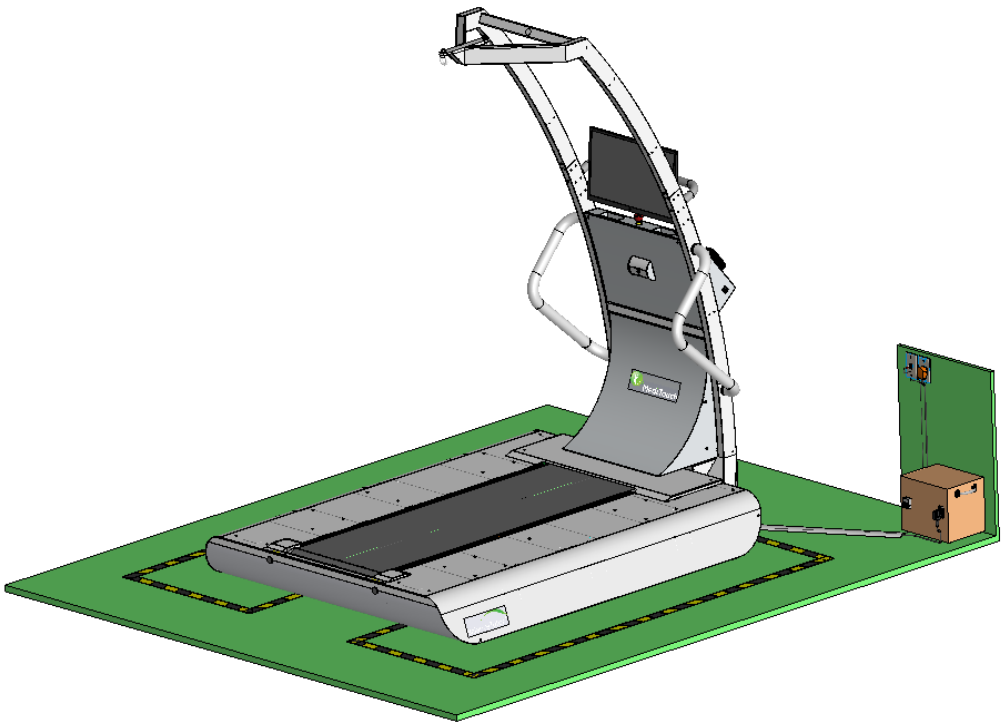
BalanceTutor™

Technical Specification

July 2025



BalanceTutor a dynamic and static postural control trainer

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This technical specification covers all critical components and physical elements for the following MediTouch product:

BalanceTutor BT100

The BalanceTutor dynamic and static postural control trainer 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

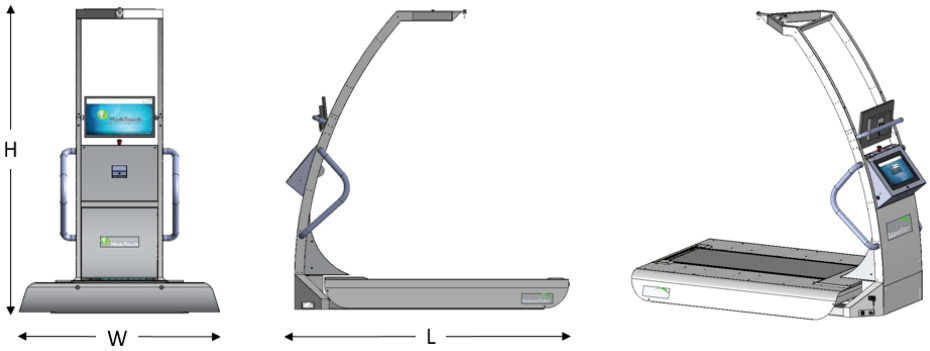
IEC 60601-1-2 compliant

IPX-0

Date	Change description	Written by	Ver.
01 Jan 2014	Initial version	Ziv K.	140101
13 Mar 2016	US ratings clarifications	Ziv K.	160313
23 Jun 2016	Voltage supply modification, OS change from Win7Pro to Win7Emb (WS7E), Transformer change from 2→2.3 kVA, Nameplate label, Lanyard addition, Wireless Interfaces, and other minor updates.	Ziv K.	160623
13 Sep 2016	Adding sensors sample rates, Change Bluetooth type from 2.0 to 4.0.	Ziv K.	160913
25 Oct 2016	Update Storage Temperature parameter, Adding SPL measure.	Ziv K.	161025
19 Jan 2017	Adding: Power consumption, warnings remarks	Ziv K.	170119
28 Jun 2017	Adding: Wireless sensors Service Time	Ziv K.	170628
06 Sep 2017	Updating product and shipping box weight	Ziv K.	170906
22 May 2018	Updating 3 Phase ratings	Ziv K.	180522
02 Oct 2018	Value conversion corrections (km/h to m/s), in treadmill perturbation parameter section. Update distance of Safety Stop Switch.	Ziv K.	181002
30 Dec 2018	Changes: Power Ratings, Computer OS, Product Label, Warnings modifications.	Ziv K.	181230
21 Jan 2020	Changes: effective running belt length from 140 to 156cm, images update, crate size.	Ziv K.	200121
03 Feb 2021	Adding: Camera, Remote control, Harnesses. Upgrading: BoxPC to ARK1551, Win10 IOT 2019, Changing: Patient screen and holder	Ziv K.	210203
21 Jun 2022	Adding: MD logo at 2nd page, updating name plate label, Changing company address	Ziv K.	220621
12 Oct 2023	Adding: S/N structure. Changes: Model Number from BT100 to HMBT100A, Name plate label	Ziv K.	231012
10 Nov 2024	Adding: Running belt area and Power consumption of Stand-by mode	Ziv K.	241110
21 July 2025	Changes: Name Plate Label. Adding: Software regulation	Alan W. Ziv K.	250721

E&EO

PARAMETER	DESCRIPTION
Product name	BalanceTutor
Product model	HMBT100A
Order P/N	HMBT100A
Applications	Balance and gait training. Instrumented biomechanical treadmill for research.
Overall dimensions	L: 233 cm (91.73“) W: 161 cm (63.38“) H: 245 cm (96.45“)

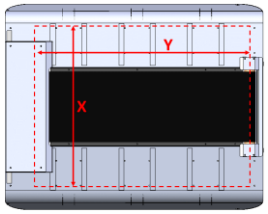


Effective running belt surface	▪ Length: 156 cm (61.5“) Width: 56 cm (22“) ▪ Shock load reduction for the joints ▪ Belt surface with anti-slip material ▪ Max. Permissible load: 150 kg (330 lbs.)
Device weight	485 kg (1070 lbs.) ±1%
Gross weight	665 kg (1466 lbs.) ±2%
Shipping box size	L: 2.11 m (6.9’) W: 1.66 m (5.4’) H: 1.07 m (3.5’) Volume: 3.74 m^3 (132’)
Treadmill Speed	0...±7.0 km/h (0... ±2 m/s)
Treadmill perturbation kinematics	Treadmill Speed: 3…194 cm/s Acceleration: 10…625 cm/s² Deceleration: 10…625 cm/s² Forward Distance: 3…87 cm Backward Distance: 1…146 cm
Lateral perturbation kinematics	Speed: 5…60 cm/s Acceleration: 25…200 cm/s² Deceleration: 25…200 cm/s² Distance: ±18 cm
Perturbation intensity	30 levels combining Acceleration, Deceleration, Distance, and target speed.
Running belt area	W: 55 cm (21.6”) L: 162 cm (63.8”)
Walking direction	▪ Forward and Backward ▪ In case of walking direction change, remove buckles from upper bridge hooks, place the person on the opposite side and fasten again the buckles to the same bridge hooks.
Power consumption	Min: 280W Max: 2300W
Stand-by mode	280W
Voltage supply	1 Phase 200V-240V AC L/N/PE 50/60Hz 16A circuit breaker, dedicated line. 3 Phase 200V-240V AC L1/L2/PE 50/60Hz 2x15A circuit breaker, dedicated line.
Electrical outlet	Worldwide According local standards USA 6-20R NEMA

Motor system	Treadmill:	Servo motor, 1.7kW, 3kRPM, 5.9Nm
	Perturbation:	Servo motor, 0.6kW, 3kRPM, 2.1Nm
Power transmission	Treadmill:	Gearbox ratio 5:1
	Perturbation:	Gearbox ratio 5:1
Motor drivers	Treadmill:	Servo digital drive, CPR 1610W, CC 6.5A, PC 13.0A
	Perturbation:	Servo digital drive, CPR 1140W, CC 4.0A, PC 8.0A

Electrical safety	External isolated transformer: Up to 230v/230v 50/60Hz 2.3kVA Under IEC-60601-1, B-3 UL Recognized, CE.
Leakage current	< 0.2mA
Safety power off switch	Emergency-off-switch (mains off), switch for immediate disconnection of motor and motor controllers power supply.
Safety stop switch	Stops lateral perturbation if ranges exceed from maximum of ±21.75 cm

Force sensors	Type:	Aluminum-Alloy IP65 single point load cell. X4 units
	Sensitivity:	2.0 ± 0.2 mV/V
	Force range:	0…250 kg
	Location range:	X: -65…+65 cm, Y: -80…+80 cm X: -25"…+25", Y: -31"…+31"



Motion feedback sensors	Device name	Model	Body part	Connection	Technology	Remark
	IMU	3DT100	Leg (R+L)	Bluetooth	6DOF (Acc & Gyro)	Optional add-on sensors

Sensors parameters		COP	IMU
	Baud Rate [Sample/Sec]	125	125
	Write to Log [Sample/Sec]	100	100
	Service Time [Hours]	N/A	4
	Charging current [mA]	N/A	< 500
	Operational Indications	Net & Total Load in [Kg]	Connection, Battery level

Interface

- System power On/Off switch via external isolation transformer with green indication LED
- PC power On/Off switch with blue indication LED
- Ethernet connection port: RJ45 10/100/1000
- Wireless connection: Bluetooth 4.0
- Wi-Fi connection
- Remote perturbation controller

Operator display	Type:	Touch screen Projected Capacity technology
	Characteristics:	Active matrix TFT LCD, 18.5", 16:9, 1366x768, 5ms, 1000:1
User display	24" 16x9 LED display, Stereo built-in speakers, Functional for visual output only.	
Internal computer	Type:	BoxPC
	Characteristics:	Fanless, Intel Core i5 8th Gen 1.6GHz, 2.5" 128GB SSD Drive, 4G DDR4-2400MHz, Gigabit Ethernet, Intel UHD Graphics 620, Win10 IoT Enterprise 2019 LTSC, DC 12V power input.

Software

- Touch user interface oriented
- Perturbation triggered treatments
- Perturbation intensity scale 1-30
- Treatment protocol builder
- COP (Center of Pressure) treatments
- Treatment row data record and export (to csv format)
- Patient/Therapist feedback and status data: Treatment parameters, heartrate, gait phase, Load

- Self-projection feedback via real time camera
- Gait Analysis module (add-on feature)

Safety harness belt

- 2 supplied sizes: S/M, L/XL
- Fall protection support lanyard with height adjustment

Sound Pressure Level (SPL)

78dB Test condition: A maximum measured value sampled at 1m Euclidian distance around the device.

Ambient condition

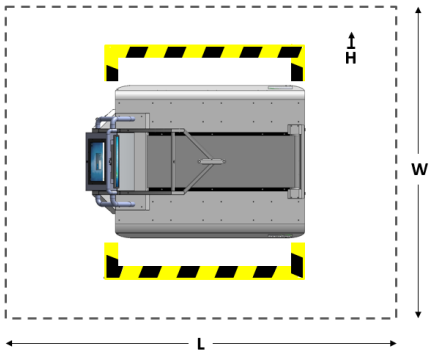
Usage temperature:	+10...+40°C
Storage temperature:	-20…+50°C
Relative humidity:	30...70 % (non-condensing!)
Atmospheric pressure:	700...1060 hPa

User dimensions

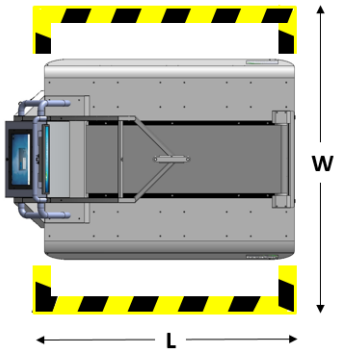
Maximal weight:	135kg (297 lbs.)
Height range:	120cm (47") … 190cm (75")

Facilitation

Minimal room dimensions
L: 335cm (132") W: 300cm (120") H: 250cm (99")
Device centered at middle of the room.



Keep out zone
L: 235cm (93") W: 210cm (83")
To avoid collision at perturbation mode.

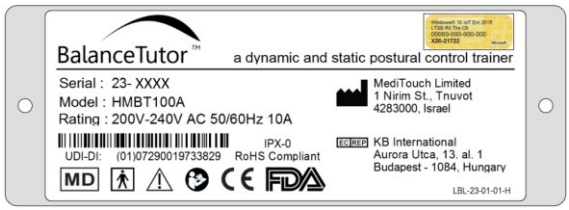


Floor
Any floor type, avoid carpet.

Warnings

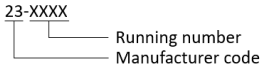
- No children under the age of six allowed to operate the device or treated without certified personnel.
- It is mandatory to fasten the user with harness to prevent injury cause by a fall.
- The exercise, constantly be supervised by a physiotherapist or a medical doctor in the field of orthopedics and/or neurology.
- Patient not allowed to use the BalanceTutor with an open shoes such as sandals. We strongly recommend running shoes.
- Cables and cuffs not allowed for the patients' hands.
- Disregard of warnings and/or the use of the BalanceTutor without a fall protection system is strictly. Prohibited and may lead to accidents and injuries with fatal consequences.

Product Label



Product Tracking

Each BalanceTutor device has a manufacturer serial number. Each serial number relates to its production batch.



Safety & EMC

Directive 93/42/EEC; EN 60601-1; EN 60601-1-1; EN 60601-1-2 (EMC approved); ISO 9001; EN ISO 13485; Emergency-off-switch (mains off), transformer for potential-isolation from the mains under IEC-601-60601-1, B-3 UL Recognized.
GMDN® Code 33015

Device Classification Rationale

The device is classified as Class I under MDR 2017/745, Annex VIII Chapter 6.

A. It has been assessed that Rule 9 is not applicable as perturbation intensities are not hazardous.
B. It has been assessed that Rule 11 does not apply because:
- The software does not provide information used for diagnostic or therapeutic decisions.
- The software does not monitor physiological processes.
- The software is intended solely to provide movement ability feedback without clinical interpretation, with all movement ability reference points derived from research data.

Conclusion: Under Rule 11 and 13, the BalanceTutor qualifies as a Class I medical device.

Safety class / category	Class I Medical device	
Classification	MDR 2017/745 Annex VIII	
Manufacturer	Name:	MediTouch Ltd.
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