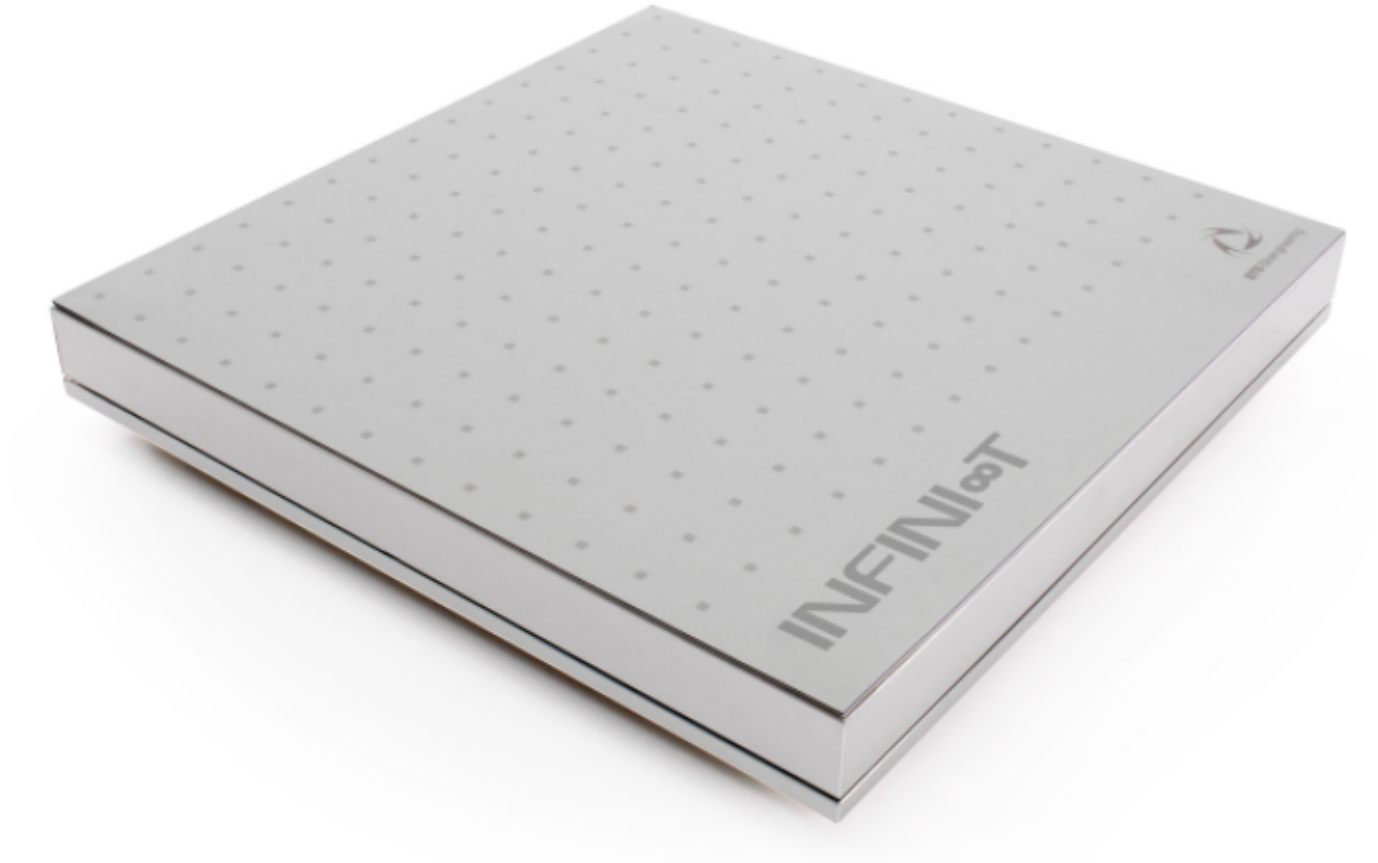

user manual

english

version 2.1.4

BTS Bioengineering

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Contents

Icons, symbols and acronyms

Symbol in the instructions for use. The icon represents the information which requires special attention.

Symbol on the equipment.
Symbol for “Manufacturer”. This symbol shall be adjacent to the name and address of the manufacturer.

Symbol on the equipment. Caution, consult the accompanying documents.

Symbol on the equipment and in the users’ instructions.
Symbol for the separate disposal of electrical and electronic equipment, in accordance with Directive 2002/96/CE (WEEE).
The equipment belongs to Group 8 (medical equipment). In force in the nations of the European Union, Norway and Switzerland.

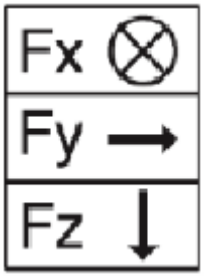
Symbol on the equipment:
Type B applied part. Although the device never comes in contact with the patent (therefore it doesn’t have a proper “applied part”), the insulation class of the device (according to IEC 60601-1) is “Class I”.

Symbol on the equipment.
Symbol located next to the model number (ref. to catalogue).

Symbol on the equipment.
Symbol located next to the serial number on the equipment.

Symbol on the equipment.
The CE mark indicates that the device satisfies the essential requirements of the Medical Devices Directive 93/42/EC.

Symbol for prescription only. U.S. Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.



Symbol on the equipment.
Symbol for the System of reference of the forces measured.

No. 5019 (IEC 60417) Protective earth (ground): To identify any terminal which is intended for connection to an external conductor for protection against electrical shock in case of a fault, or the terminal of a protective earth (ground) electrode.

Read operating instructions

Symbol for Voltage: 48 Vdc nominal supply voltage
37,0 Vdc – 57,0 Vdc – range

Disposal (WEEE)

In disposing of the equipment observe the legal prescriptions.
In accordance with Directive 2002/96/CE (WEEE) all equipment supplied after 13/08/2005 may not be disposed of in general domestic waste. This equipment belongs to Category 8 (medical equipment) and it is classified in the Business-to-Business sector.

The symbol of the crossed out rubbish bin indicates that the equipment must not be disposed of in normal domestic waste.

For further information about proper disposal and recycling, please contact your local reseller or BTS S.p.A. directly.

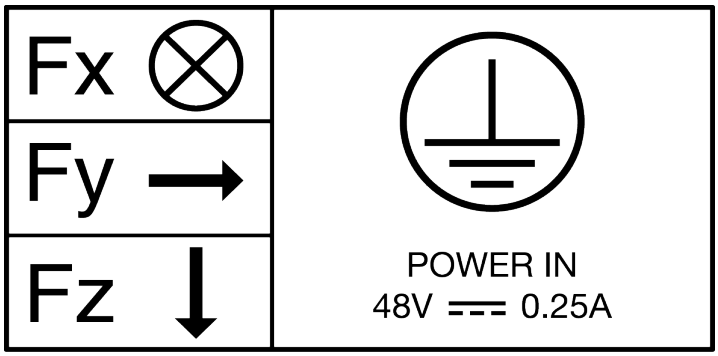
Intended use

Is a force platform, which measures ground reaction forces throughout its surface, allowing a deep analysis of a subject's static postural condition and dynamic postural condition.

Regulatory Label

The regulatory label on the force plate is:

BTS SpA
Via Risorgimento, 9
Noventa Padovana (PD)
I-35027 Italy
btsbioengineering.com



The following label is added only for shipments to Brazil, both on the device and on the package:

Warning

We recommend to carry out any kind of operation keeping strictly to the security regulations contained in this manual.
The safety of the system cannot be guaranteed if these conditions are not respected.

P-6000 is a Medical Device according to the European Directive 93/42/ EC and further amendments, included Directive 2007/47/EC which use must always be under the supervision of qualified and certified personnel, according to the local regulations. Federal (USA) laws restrict this device to sale by or on the order of a physician or a properly licensed practitioner.

This device is intended to be used by healthcare professionals. This device may cause radio interferences or may disrupt the operation of nearby equipment. It may be necessary to make mitigation measures, such as re-orienting or re-locating the device or shielding the location.
To install the device, refer exclusively to BTS S.p.A. authorized technicians.

To avoid risk of electric shock, this equipment must be connected to external protective earthing system.

The results of the acquisitions must be assessed by people legally authorized by national laws, who possess the suitable necessary knowledge of anatomy and muscular function.

Do not stand on the platform for a time exceeding 10 minutes, the platform (without mat) could reach a temperature between 41-43°C.

The device must be used in the intended environment (see Appendix B).

The use of the device for other purposes and with methodologies different from those indicated in this manual are not to be considered congruent with the precise use of the device.

Do not wet or dip in water the device or its parts.

Use only the power supply unit provided by BTS S.p.A. If a different power supply unit is used, the compliance to IEC 60601-1 is not
ensured.

Only BTS S.p.A. authorized technicians may maintain and operate servicing to the system. BTS S.p.A. cannot be held responsible for system safety should the instrument be opened, repairs carried out, third parties software be installed, or system components be replaced by persons other than those authorized by BTS S.p.A.

In case of accidental fall of the device, or other accident, refer to the authorized technical support.

The use of other cables and accessories, than the ones provided by BTS S.p.A., may negatively affect EMC performance

The use of other accessories, than the ones provided by BTS S.p.A., results in non-compliance

Only original components must be used, otherwise BTS S.p.A. cannot assure the safety of the instrument. If components other than the original ones are used the BTS S.p.A. Warranty is invalidated. Should it be necessary to replace any part of the system, only original BTS S.p.A. parts may be used.

Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously, through a medical power supply. Medical power supply unit is intended for disconnection from the mains and shall be easily reachable to the user.

Means for isolation external: Medical Power Supply.

External power supply is not part of the investigation.

Warning: No modification of this equipment is allowed.

Connecting the device to a non-conforming electrical system, could damage the device, the operator and the patent.
BTS S.p.A. cannot be held responsible for damages due to the connection of the device to a non-conforming electrical system. The connection to an electrical system not provided with a cabin distribution medium/law voltage (i.e. home electrical system) may cause difficulties to the electromagnetic compatibility in other environment due to conducted and radiated disturbances.

Information contained in this manual are subject to change without notice and does not constitute product specifications or any obligations on the part of BTS S.p.A.

copyright

This equipment is an instrument for the movement analysis, classified as medical equipment in accordance with European Directive 93/42/EEC and further amendments.

General description

Is a modular sensory floor which measures ground reaction forces throughout its surface, allowing a deep analysis of a subject's static postural condition and dynamic postural condition.

The subject can move freely and any contact to floor is used for the dynamic analysis of movement. This feature makes it an essential, one of a kind tool for the diagnosis and comprehension of complex conditions suffered by patients with severe neuro-motor dysfunctions. It can also be used for the performance of biofeedback training for posture and for maximizing sports professionals' athletic performance.

Is a high performance force platform, it's fully digital and equipped with twelve sensors (transducers) for each platform which break force into its different components and perform an accurate, high-frequency analysis.

By adding optional video cameras (up to four) it's possible to watch and record the subject from different angles, give a superimposed representation (augmented reality) of direction and intensity of force vectors: knowledge about the direction of reactive force in relation to the joints allows the evaluation of functional overload, injury prevention, the detection of possible load asymmetries, and the adoption of the most successful rehabilitation therapy.

Applications

Is highly recommended in order to:

- Analyse load symmetry and plan medication or surgery treatments in orthopaedics;
- Perform postural evaluations and/or neurological investigations (stabilometric);
- Consider postural re-education therapy;
- Prevent injuries and enhance sports' performance.

Components

The standard configuration includes:

- 1,2,4,8 or 16 BTS (depending on the configuration) • 1 PoE HUB each 4 force platforms
- Connection cables.

The following optional components are available:

- Analog interface (optional configuration of BTS) • Squared model (optional dimensions 40 x 40 cm) • Modular walkway
- BTS VIXTA video system (up to 4 video-cameras)
- BTS Digivec Software

Recommended environment

Is developed for IN-DOOR applications, with a humidity range of 50-80% (see Appendix B – environmental specifications).

The appropriate surface to positon the force platform must have a solid foundation (concrete, cement or linoleum), with the following main characteristics:

- Clean and non-slip to ensure a firm positioning of the force platform;
- Level at 2 mm;
- Minimal vibration transmitting ability. Also little vibration could disturb the measure;
- The environment of use mustn't have a humidity degree out of the range specified in Appendix B, or be subject to water infiltration near the location of the device.

For the protection against bust and water infiltration, refer to the definitions of IP codes (Ingress Protection rating) specified in CEI EN 60529/1997 (ex CEI 70-1) which specifies the environmental protection provided by the enclosure of electrical equipment.

The IP code assigned is IP42.

The installing operations must be performed exclusively by BTS S.p.A. authorized technicians.

Connecting the device

Before switching on, follow the instructions below:

1. Connect each module to the PoE HUB through one of the provided LAN cables; 2. Connect the PoE HUB to the PC, through another LAN cable;
3. Finally connect the power supply cable of the PoE HUB to the mains supply.

Now the BTS is ready to be used.

Each HUB PoE could be connected to a maximum of 4 force platforms. If more platforms should be connected, be aware to use more of the provided HUB PoE and to use the provided switch to connect the HUBs each other.

Application software

BTS could be provided with the following BTS software:

- BTS Digivec (see next Chapter) and VIXTA video cameras;

BTS has been developed to be integrated to all BTS systems for motion analysis, so it could be acquired by all application software of
the BTS SMART-Suite and by the analysis software:

- BTS SMART-Analyzer
- BTS SMART-Clinic
- BTS SMART-Performance

To acquire the previously listed software, refer to their specific user manuals.

System maintenance

The replacement or update of the hardware configuration will be performed exclusively by BTS S.p.A. authorized technicians.

Should be protected by dust, humidity and water. Be careful to avoid shocks which could due to malfunctioning of the system.

For the protection against bust and water infiltration, refer to the definitions of IP codes (Ingress Protection rating) specified in CEI EN 60529/1997 (ex CEI 70-1) which specifies the environmental protection provided by the enclosure of electrical equipment.

For updates and maintenance please refer exclusively to BTS S.p.A. support (helpdesk@btsbioengineering.com).

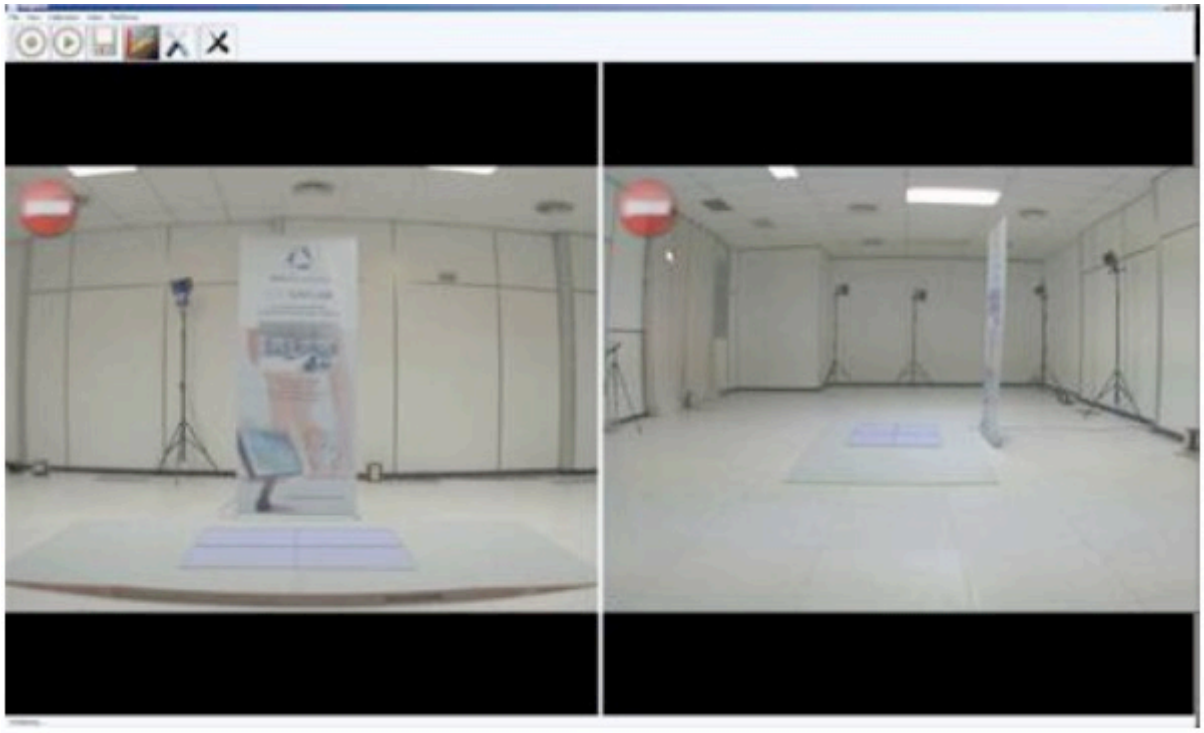
Keep the original packaging to benefit the warranty conditions. BTS S.p.A. cannot be held responsible for unauthorized or autonomous maintenance operations.

BTS Digivec software

Could be acquired using BTS Digivec software and VIXTA video cameras, through a few simple steps.

Connect VIXTA video cameras to the switch for LAN cables connected to the PC.
Run the Digivec program clicking the file “3Digivec.vsb”, or selecting the shortcut on your desktop.

Once run the program, the following window will be displayed, showing the images of the cameras watching installed in the laboratory:

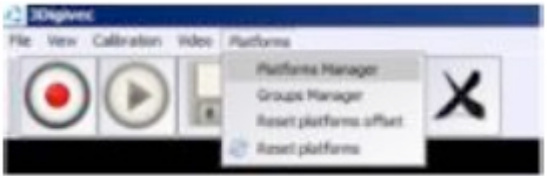


The prohibition symbol indicates that it is not possible to acquire data in the present configuration.

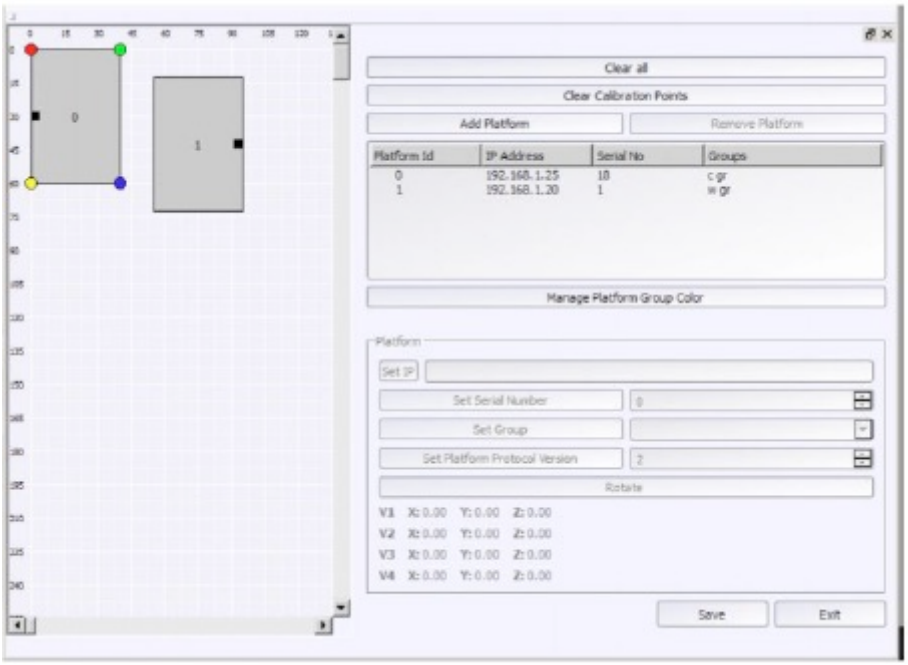
To allow performing the acquisition is required to set the configuration and the calibration of the force platforms in the laboratory, to align the images acquired by the cameras to the forces acquired in the laboratory.

Platforms configuration

Select in the tool bar the item “Platforms Manager” and then the item “Platforms” in the drop-down menu:



Now the window “Platform Configuration” will be displayed. This window allows setting the spatial configuration of the platforms in the laboratory:



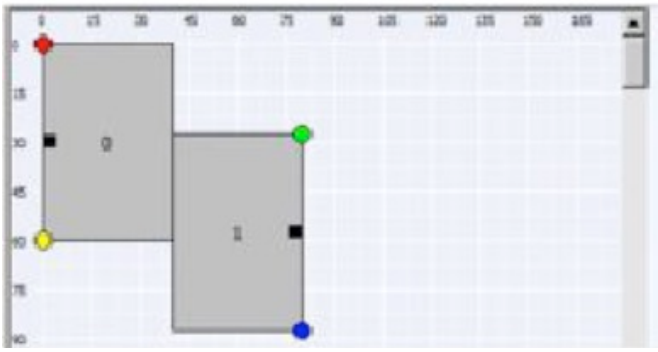
This window allows also to set the number of platforms to use and the configuration data for each of them:

- IP Address;
- Serial Number;
- Group (see paragraph “Groups”);
- Firmware version (default value =2);

Once set all mandatory data, go on with the calibration of the configuration set.

First of all, positon the configuration of the platforms according to their real positioning in the laboratory, shifting the rectangles in the correspondent positon.

The platform marked with “0” is the platform of reference for the configuration system (one of the corner represents the origin).
Once defined the position of the platforms, positon the 4 calibration balls (red, green, blue, yellow) displayed in the configuration window, putting them on the ends of the platforms (it is advisable to cover the maximum volume, putting the balls on the extreme corners of the external platforms) as shown below:



Push “Save” to save the set configuration and return to the main menu.

If data inserted are correct the prohibition symbol will disappear.

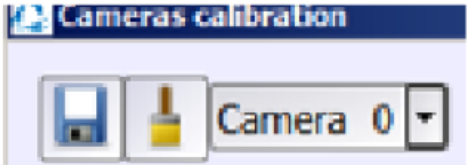
Platforms calibration

Select from the tool bar the icon “New Calibration”:

Position the calibration balls on the 3D image as just done on the configuration window. Be careful to maintain the correspondence of the colors used in the configuration window.

The magenta ball should be positioned vertically aligned on the red ball, at a distance of 60 cm. To allow an easier positioning of the magenta ball, use the calibration kit with one harm long 60 cm, provided by BTS S.p.A. (the tern should be positioned on the first corner of the platform of reference).

This will allow the real time update of the correspondence between the virtual platforms (in blue) and the real platforms in the video image.
The calibration should be repeated for each camera, selectable in the drop-down menu of the calibration window:

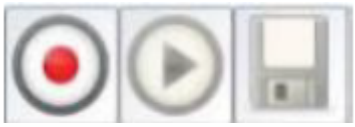


If the balls are not visible, their positon could be reset, using the icon “Reset Calibration” () in the calibration window.

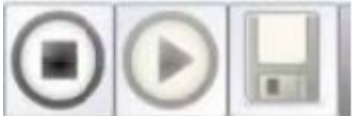
Once completed the calibration for all cameras, push the icon “Save” ().

Data Acquisition

The data acquisition is now allowed.
Push “REC” to start acquiring the video and TDF data of the measured forces;



Push “Stop” to end the acquisition;



Push “Save” to save the acquisition.

The “Play” button allows displaying the video with the forces applied.

For each acquired camera there's a video and TDF. File containing the data related to the acquired forces.

For further information, refer to BTS Digivec software User Manual.

Groups

Through the configuration window it's allowed to assign each platform to pre-set groups, platforms could be assigned to the same group allowing to display the total group acquisition, selecting the option "Show Group" in the visualization menu "View" in the toolbar.

To select the group, select the option "Manage Platform Group Color" in "Platform Configuration":

The window "Groups Manager" allows adding, removing or modify pre-set groups. Default groups couldn't be deleted, but it is possible to set their color.

Default's groups are:

- l gr: left foot's group;
- r gr: right foot's group;
- No Group: no group is assigned.

If platform are assigned to the same group, it is allowed to display data and forces for the same anatomical part and to analyse its functionality and performance (i.e.: the left or right leg, for forces measured by two platform a single force vector will be displayed, representing the result of the two forces).

The assignation to groups is allowed through the "Platform Configuration" windows and while viewing acquired data.

Data view

From the drop-down menu "View" in the toolbar, it is possible to set all data view option:

- 3D Scheme (default option): displays the 3D acquisition environment;
- Plate visible: to display also the virtual platforms (blue color);
- Reference system visible: to display the system of reference;
- Show resultant: to display the resultant of applied forces;
- Show group: to display each group;

- Show force vectors: to display force's vectors;
- Walkway: to display only the upper surface of the platforms, useful when there's a walkway.

Forces should be superior to the minimum detection threshold of 30 N (3 kg). Lower forces are not measured.

Configurations

Is a modular sensory floor, which could be composed by multiple units, placed in an ad hoc walkway to provide the user a complete sensorized floor, configurable for different acquisition requirements.
is the squared model which differs only for dimensions which are 40 x 40 cm instead of 60 x 40 cm.

Appendix A

Technical features

Interface	LAN (10/100 Ethernet)
Signal Output	Digital
Power Supply	PoE with proprietary switch
Single Module* Weight and dimensions	28kg, sensitive area 60 x 40 cm, minimum height 5 cm
Capacity (X and Y) for each sensor	Up to +- 8000N
Capacity (Z) for each sensor	Up to 8000 N
Sensitivity / Resolution	16 bit on the selected range
Sensitivity deviation over plate surface	<1.0% Full Scale Output
Hysteresis	<0.2% Full Scale Output
Linearity	<0.2% Full Scale Output
Sensing elements	Patented strain gage architecture
Amplifier	Built-in
Mounting Hardware	Not required
Protection degree	IP42
Compliance to Standards	Safety: EN 60601-1
	EMC: 60601-1-2

*equivalent to 1 traditional platform

Appendix B

Environmental Specifications

	Min	**Max**	**Notes**
Temperature of use	10° C	40°C	
Humidity of use	50%	80%	Relative, in absence of condenses
Atmospheric Pressure	70	106	kPa

Appendix C

Electromagnetic compatibility

Complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2007) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in an electromagnetic environment.

Needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section.

Portable and mobile RF communications equipment can affect medical electrical equipment.

EMC (IEC 60601-1-2: 2007)

Guidance and manufacturer's declaration – electromagnetic emissions		
Is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The P-6000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The P-6000 is suitable for use in industrial environments or in laboratories and is not intended for use in domestic areas.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The P-6000 is intended for use in the electromagnetic environment specified below. The customer or the user of the P-6000 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±2kV, ±4kV, ±6kV contact ±2kV, ±4kV, ±8kV air	±2kV, ±4kV, ±6kV contact ±2kV, ±4kV, ±8kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	
Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<0% UT (>100% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 0% UT (> 100% dip in UT) for 5 sec	Not Applicable	
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
Is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms (V1=3)	Portable and mobile RF communications equipment should be used no closer to any part, including cables, than the recommended separation distance calculated
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E1=3)	

			from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2 √ P 150 kHz to 80 MHz d=1.2 √ P 80 MHz to 800 MHz d=2.3 √ P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which is used exceeds the applicable RF compliance level above, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment
is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference

by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz d=1.2 √ P	**80 MHz to 800 MHz d=1.2 √ P**	**800 MHz to 2.5 GHz d=2.3 √ P**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D

Technical Support

Preserve the original package, which should be used in case of sending in place for repair. Failure to retain the original packaging, will invalidate the warranty.

For problems or suggestions, please contact the technical support of BTS S.p.A.:

Email helpdesk@btsbioengineering.com
Tel. +39 02 366 490 00
Fax +39 02 366 490 24

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helpdesk: +1 (929) 255 9134