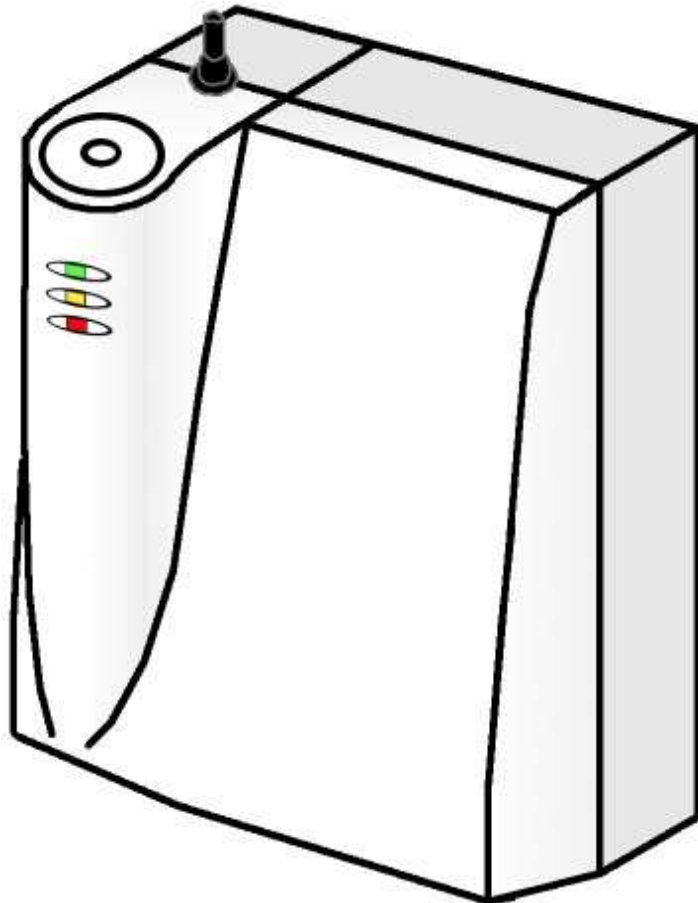


SwayStar™

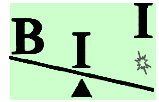


v3.00 **CE** 0438

User Manual English
valid for version 3.00

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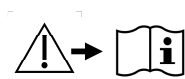
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2 Introduction

2.1 General

You have purchased a **SwayStar™** System (Measuring Device and Software) from **BESTec-etp** in cooperation with **BII** to measure balance and perform movement analyses. We thank you for your trust in our product. **SwayStar™** has been developed and manufactured according to the specifications and regulations of the current available technology. The **SwayStar™** Measuring Device fulfils the requirements for functionality and safety and has the CE-mark according to the Medical Device Directives 93/42/EEC and 2007/47/EEC for medical products.

As part of our legal responsibilities to the user, apart from wishing to facilitate the use of the system, we created this manual....	...which describes the technique and use of the system
	...which provides you with advice for storage and care of the system
	...and helps you with troubleshooting.



Every person, who uses this product, should have read the paragraphs of this manual, which are marked with this symbol. Please retain this manual. It should be available for all employees at all times. This will avoid handling errors and insures undisturbed operating of the system.

The texts and pictures in this manual do not necessarily correspond to the shipment received, and the symbols are not mapped to scale.

2.2 Technical safety



Before using the device for the first time, check it for any transportation damage. Before connecting and starting up the **SwayStar™** it is imperative to read the manual in order to avoid faulty installation. Please carry out the instructions carefully to be able to use **SwayStar™** without any problems. If the instructions are not understood please contact your local distributor or the manufacturer.

Please notice, that the device has an active power source (lithium-ion-battery). To recharge the battery, use the cables provided with the device.

Do not open the device or one of its components!

If you have a problem with the device or one of its components, please contact your supplier or technical contact person or BII directly via the Webpage (www.b2i.info – Technical support - Incident Reporting).

As a power source, in Europe, respectively USA/Canada, for charging the internal batteries only, you should use a properly installed power socket (220 / 230 Volt, 50 Hz; 110 Volt, 60 Hz). The power cord is only to be removed from the power socket by grasping and pulling out the plug. Do not touch the plug with wet hands. Do not loop or bend the power cord or connecting cable around sharp edges. In general; protect the connecting cable and power cord against any mechanical damage. Lay the cables from the device avoiding the risk of compressing the cables and do not place anything on the power cord.



Following DIN EN 60601-1-2 you should notice that for the **SwayStar™** device special precautions should be taken concerning electromagnetic (EM) exposure. The device was tested according to EM-guidelines and is safe for use under normal circumstances. Portable and mobile HF-equipment can not influence the function of the device.

2.3 Instructions for use

General instruction: Handle your device with care! Always store the device properly in the suitcase and hold it safely in your hands when manipulating it. This will prevent the device from being dropped and therefore damage to the device. **Always check the attachment of the device to the belt, to prevent unintended detachment or dropping of the device from the belt.**



Only use the accessories (Bluetooth[®] Adaptor, power supply, power cord etc.) that were provided to you with the **SwayStar™** device. You cannot perform a measurement while the device is connected with the power cord. The device recognizes connection to the power cord and will only allow measurements when the battery has been charged (notice chapter 8 „Charging the battery“!). You can check the power-status by looking at the control-LED (see chapter 9 „Lower LED (control-LED)“).



The device should be shut down after use, by switching it off at the main switch (see left), because the device remains active when turned on until the battery is empty. Please check the control-LED (see chapter 9) and the position of the switch, so that you do not have to recharge the battery between measurements; this will save you time.



The device should not be exposed to temperatures under +20°C and over +40°C during measurements but also when the device is stored. In lower or higher temperatures, safe use of the device is not possible; moreover it can influence the measurement results.



The **SwayStar™** device is not protected against water sprays. To guarantee that it functions safely, it should not be used in bath or simming rooms, nor should it be exposed to high humidity. Optimal use is warranted in dry rooms. If the device is used outside it should be kept far from water sources, e.g. basins or buckets of water.



The use of the device with patients is only allowed by specialized medical staff. SwayStar should not be used on patients for whom wearing a tight fitting belt is contrary to or detrimental to their medical condition. During measurements, an assistant should be present to help the patients with the tasks and prevent falling in case of loss of balance. This warrants a safe use of **SwayStar™**.



The **SwayStar™** system (device and accessories) should only be transported and stored in the suitcase that is delivered with the device. The suitcase has been specially developed, so that the system and its accessories can be stored in a safe manner.

2.4 System requirements

Hardware minimal requirements PC:

Pentium III / 850 MHz

128 MB memory (Network-PC: 256 MB)

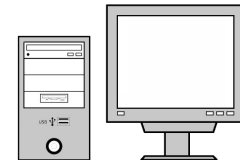
8-fold CD-ROM or DVD-ROM drive

Graphic-card with 16 MB memory
(Laptops with „Shared Video Memory“ are not recommended)

USB-port

30 MB free hard-disc memory for the installation

500 MB free hard-disc memory, (for Network-PC: 1GB) for saving the data



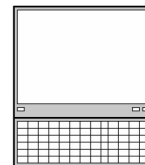
Software minimal requirements PC:

Windows NT, 2000 or XP (Home and Professional)

Internet-Explorer (Version 4.0 and higher)

Adobe Reader

Administrator rights to install the driver and software
(contact your system administrator)



If you would like to print the measurements and analyses, you will need an additional printer (not provided in shipment).

2.5 Durability

The expected durability of **SwayStar™** is dependent on the quality of the handling, cleaning, as well as transport and storage. With appropriate use and cleaning, a life-span of 10 years is presumed. Exceptions are the plugs and lithium-ion-batteries, and other non-durable components.

3 Delivery - Hardware

Please check that the product was delivered to you with all its components.

Nr.	Description	Product number
01	SwayStar™ device V3.00 (product number with all hardware and software items listed here is with /T added, that is 109996/T)	109996
02	SwayStar™ USB Adapter (Bluetooth™ Dongle)	109984
03	Power supply unit FRIWO MPP15 with power cord (2 m)	109978
04	Power adapter EURO	109787
05	Power adapter UK	109788
06	Power adapter USA	109789
07	Power adapter Australien	109790
08	Software Key (USB Stick)	155065
09	SwayStar™ Belt size M	109993
10	SwayStar™ Belt size XXL	109992
11	Locking bars 2 off plus 1 spare	151577
12	Targus™ Multimedia remote presentation controller	155068
13	SwayStar™ Hardware Manual	110210
14	SwayStar™ Suitcase	109991

Note:

The above components can be ordered separately using the respective article number.

3.1 Delivery Software

Nr.	Description	Product number
15	Operator software SwayStar™ (accompanying CD-ROM)	155066
16	Software manual SwayStar™ (accompanying CD-ROM)	155067
	Standard Windows-PC or Laptop with USB-port	Not included in delivery

4 Description of SwayStar™

4.1 The System

SwayStar™ is an easy to use and precise measuring system of body movements during standing and gait, or during other movements. It is designed for use with patients that have balance or orthopaedic problems, which could be caused especially by ageing, neurological deficits, whiplash injuries or hip joint problems.

SwayStar™ consists of a measuring device, which is held in place on the lower part of the patient's back with the help of a belt. Its very sensitive sensors measure angle and angular velocity of the trunk. The connection to the PC, in which the movements of the patients are recorded, is established using a wireless radio communication (Bluetooth®). By means of a proprietary **SwayStar™** software program, the different variables are processed, recorded and calculated. The level of accuracy is extremely high (<0,01 °/s).

4.2 Applications

The device and its software can be used for the following purposes:

■	Clinical examinations of balance and other motor functions
■	Checking the progress of a treatment or post-operative status of a surgical operation
■	Scientific studies on standing and walking capacities in humans

Other applications are not permitted. For questions about this, contact BESTec-etp or BII.

4.3 Procedures

The patient makes various movements, while walking and standing, spontaneously or on instruction. Inside the **SwayStar™** device are high-precision sensors that recognize and record minute and large changes in the movement and orientation of the patient. The device measures exactly movements of the patient because it is directly attached to the patient and does not significantly interfere with or hinder the patient's movements. In this way, all the body movements of the patient; for instance, bending sideways or making backwards and forwards movements, can be recorded precisely by the **SwayStar™**.

4.4 Special advantages

Its small size and light weight make **SwayStar™** (figure 1) easy to operate and comfortable for the patient while in use. The assembly and use of the **SwayStar™** system is fast and uncomplicated, because the system consists of few elements. The patient can move freely, as the connection from the **SwayStar™** device to the PC is established through a wireless Bluetooth® connection. **SwayStar™** can be used inside and outside a building, which makes it possible to examine individual patients with different clinical signs as well as normal subjects.

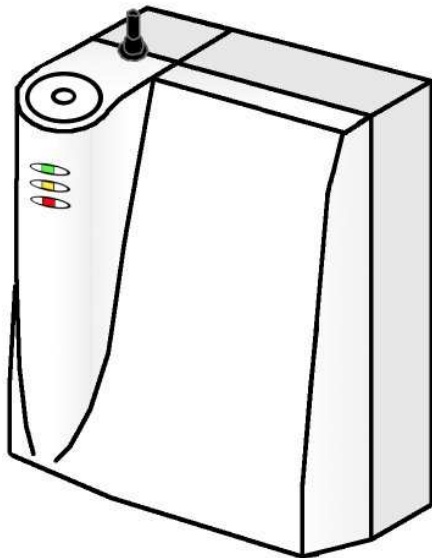


Figure 1

5 Special Features



The wireless transmission of measurement data using Bluetooth® permits mobility of the patient during tests. The wireless range is maximum 100m (Bluetooth® Class 1, outside). The data is received through the USB-Bluetooth® Dongle (Bluetooth® Class 1), which are provided with the device.

The power supply of the **SwayStar™** device is provided with integrated lithium-ion-batteries. Charging occurs through the external charger appropriate for the battery type. The power supply occurs using a multi-pin slide-on connector of the power cord to the power supply unit.

The capacity of the (fully charged) battery guarantees a measurement duration (continuous operation; middle LED is green) of maximum 40 minutes. Afterwards, the system electronics can operate, but the sensors cannot be activated before the battery is charged again.



It is not possible to charge the battery and perform measurements with the device at the same time. Please note the instructions for use!

6 Installation of recommended software and driver

6.1 Installation of the software

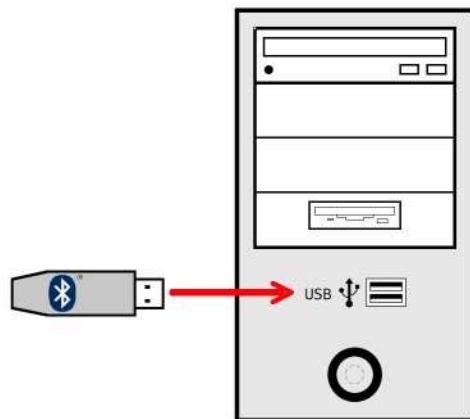


Before the **SwayStar™** system can be used with Bluetooth®, it is mandatory to install its software and driver on the PC. The software is provided to you on the accessory CD. Please, put the CD in the CD-drive. The CD will start automatically, when „Auto start“ is not deactivated. In this case, start Windows-Explorer and click on the CD-drive. Please follow the instructions on the screen.

6.1.1 Installation of the Bluetooth® driver for the Dongle

First install the driver for the Bluetooth® Dongle. Afterwards, plug the dongle in a free USB-port.

To start the installation of the Bluetooth® driver for the dongle, click on the designated link in the main menu of the CD. Follow the instructions. Afterwards, read the following:



After installing the driver successfully, the dongle can be plugged in a free USB-port (see figure 2). The USB-port can be located at the front or the back of your PC, or at the side of your laptop.

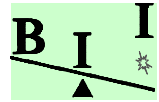
Do not plug the Bluetooth-dongle in an external USB-adaptor or similar device, to guarantee a trouble-free use.

Figure 2

Notes:

The benefit of plugging the dongle in the same socket every time is that Windows will not have wait for hardware recognition every time you want to use the dongle. When the hardware recognition has been completed the first time, you should restart the system, even when you are not asked to do this. In Windows XP SP2 the Bluetooth driver of Windows will bed itself into the system software. After restarting the computer, this will be exchanged with the Bluesoleil software.

When the version of the Bluesoleil software is lower than 2.3, you should actualise it, by using the update that you can find here: <http://www.bluesoleil.com/download/index.asp>
Choose the standard (evaluation) version.



6.2 SwayStar™ Software Update

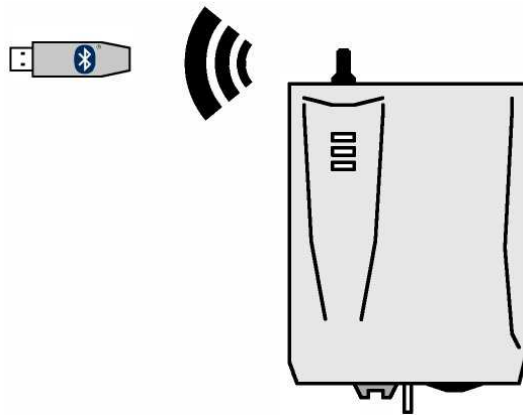
When the software is successfully installed, an internet update can be performed after starting the **SwayStar™** programme: click on the internet update in the menu 'Help'.

It is also possible to perform the update directly through the internet. You can download the update here: <http://www.b2i.info> (click on „SwayStar Installation“ on the left in the menu and then click on „Download Area“. Then you can select the designated update-link in the main screen).

7 Getting started / Assembly

The batteries are not charged when delivered. After installing the software and driver, as well as connecting all elements, you should charge the battery completely before a measurement is started. See chapter 8 „Charging the battery”!

7.1 Step 1: Connecting the SwayStar™ device



The **SwayStar™** hardware for connecting to the PC, is made up of the device itself and the Bluetooth® dongle (Figure 3). The data transfer occurs wireless.

Figure 3

Be sure that the device is switched off and the battery is charged.

The PC must be switched on and the driver for the Bluetooth® dongle must be installed (Chapter 6.1.1 „Installation of the Bluetooth® driver for the dongle”).

Plug the Bluetooth® Dongle in the same USB-port as during the installation (Figure 2). Wait until the system recognises the dongle (Bluetooth® symbol appears on the Windows-Taskbar and changes in colour from red to white).

Note: The Bluetooth® standard contains several communication- and authorisation procedures, which can take up to 10 seconds. When your PC does not respond immediately, please wait!

7.1.1 Checking the Bluetooth® connection

This is only obligatory for the first installation, after you can proceed to 7.3.



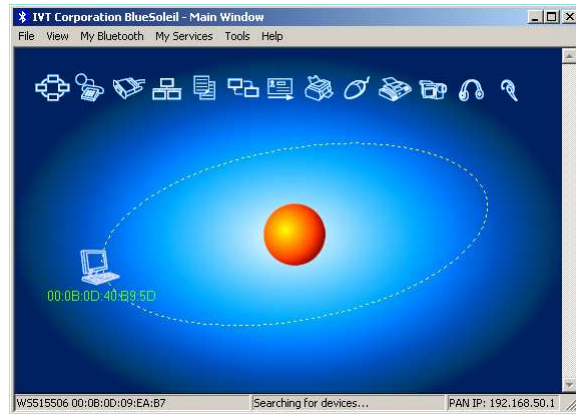
The description given here is only one example; it can differ from the recommended installation routine of the dongle manufacturer. Please read the manual of the Bluetooth® Dongle that was delivered with the device.

Double-click the Bluetooth® symbol in the task list or click the Bluetooth-icon on the desktop, when available. Turn the device on and make sure the power supply cable is disconnected. The upper and middle LED will be orange for one second. Afterwards, the upper LED should be green (Status: OK). Choose “Classic View” in Bluetooth Window to get the window displayed below.

Please wait 3 seconds, before proceeding.

Click the ‘sun’ or press F5 („Bluetooth® Search Devices“). The software will search for available devices in the area. Please wait 3 seconds before proceeding.

When the **SwayStar™** device is found, each Bluetooth® device has its own identification name.



The identification name of the device is „SwayStar-Box“ with the corresponding Serial number, e. g. „SN1224“ Double-click on the device to see the available services (yellow symbols).

The **SwayStar™** device makes one service available. Double-click on this service; the Bluetooth® will try to make a connection.



When a connection could be made with the device, a yellow authorization balloon tip will open which points at the Bluetooth® symbol in the task list. Do not close this balloon tip, but click in the middle of it. An authorization dialog opens and demands a PIN (Personal Identification Number). The PIN is the serial number of the device, e.g. „SwayStar-Box SN1224“ has a PIN that is: „1224“.

Please insert the PIN code and click [OK].


The Bluetooth® connection has now been established; this is confirmed by the symbol that is now green.



7.2 Step 2: Setup of the SwayStar™ software

Start the **SwayStar™** programme. You can now press F5 or select "Record" in the menu, and select "Discover port".

The **SwayStar™** programme looks in the Bluetooth®-area for the device. When this is found, it is shown in a small dialog. Make sure the device is selected and click [OK].

After the connection is successfully made, and the availability of the system is checked, the record symbols  are unlocked.



Option – especially when the record symbols were not unlocked – you can do the following:

Select „Settings“ in the menu list „Options“ and open the section „Sensors“. Select „Model 2“. Now, click on the animated picture. The procedure mentioned above, is started and the availability of the device is tested. After the device was successfully recognised and the functionality was successfully tested, please leave the dialog „Settings“ by clicking [OK]. The system has now been configured for Bluetooth® and the record symbols are unlocked. Now you can start with the measurements.

When problems occur, check whether the device is switched on, the power supply cable is **not** connected and the Bluetooth® dongle is successfully installed. Repeat the procedure mentioned above when necessary. When the problem still occurs, please contact your distributor.

When the authorisation-balloon appears again after switching the device on, you can close the balloon tip without any further action.

7.3 Step 3: attach the SwayStar™ to the patient

7.3.1 Placement of the belt



The **SwayStar™** device locks onto a belt, which is stretched around the waist of the patient (see figure 4). Four pins on the sensor box assure it's correct location on the belt and Velcro adhesion holds the box on the belt. Two locking plates, one on either side of the sensor box (see below) ensure a snug fit to the belt.



The belt is held at kidney height (L3-5) and then the flexible flap, is stretched over the stomach and closed so that the belt is tight around the body. (For heavy-built individuals, the second belt (extra large size (XXL) can be used.) For stabilising the device, the two bands on the outside of the belt are stretched and closed. The plate on the belt for attaching the **SwayStar™** device should be located at the back of the patient.

Figure 4



The device has to be attached, pressed onto the belt, and locked in place. If it cannot be locked, then the belt is not correctly mounted with respect to the sensor box. The attachment needs to be checked before putting the belt around the patient. When the device is not firmly attached to the belt, it should be pressed on the belt harder and moved around on it to improve the Velcro adhesion. When the adhesion is insufficient, the device can fall off without the locking plates in place! The belt should not be worn directly on the skin. Take care that the patient wears a T-Shirt or something similar. Put the belt around the patient, with the device already attached to it.

The belt can be adjusted to body circumferences. The belt must sit firmly in place so that precise measurements can be achieved. It should not, however, restrict the patient's movements. Two belts, in size M and XXL, are delivered to you with the system to meet all possible waist requirements for patients.

On the topside of the **SwayStar™** device, is an integrated water level. With this, the **SwayStar™** device, now attached to the patient, can be aligned exactly in the vertical position so that the sensors can detect all fluctuations accurately. A slightly off-vertical angle will not significantly affect the measurements. Larger deviations, recognisable by an offset of the water level, should be corrected with help of belt adjustments or altering the placement of the device on the belt. You should make sure the device is attached to the body as is shown in figure 4.

To start a recording select a recording protocol as described in the software manual. After every set of measurements the elements of the **SwayStar™** system should be put in the suitcase, to avoid damage to the system.

8 Charging the batteries



The device recognises the power connection automatically and will stop sensor use for measurements. During the whole charging procedure, measurements are not possible for safety reasons. Charging the battery of the device, while it is attached to the belt on the patient is not permitted, because the patient could for example stumble over the cord.

To charge the battery the country-specific adapter (figure 5) should be plugged on the power supply unit. We recommend to switch off the device during this procedure. To start the charging, you plug the power cord in the multi-pin socket on the **SwayStar™** device. Connecting the power supply unit to the power wall socket completes the procedure to start charging the battery. The battery will be charged automatically through a charging current-controller.

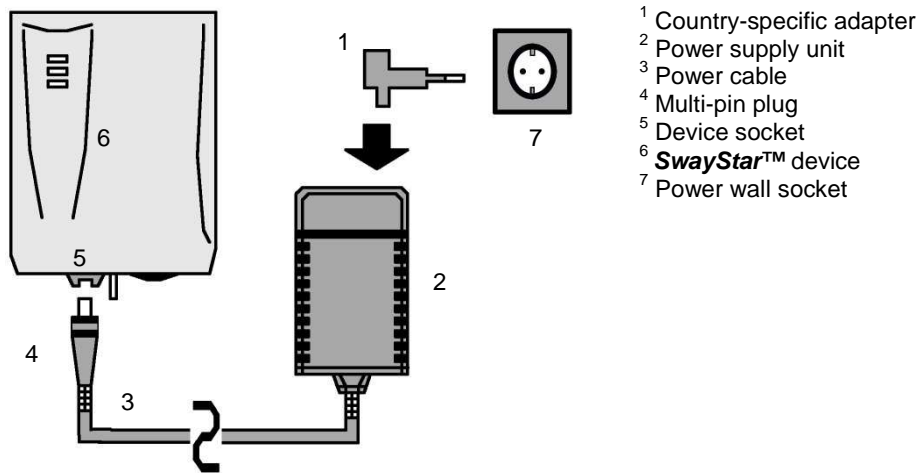





Figure 5

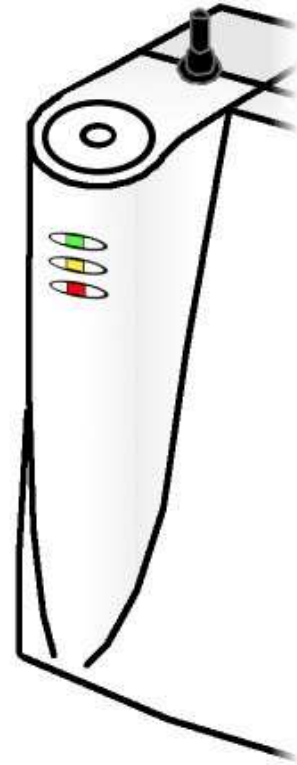
The charging procedure will be stopped automatically, when the battery is fully charged. This takes about 4,5 hours. When you turn on the device, you can check whether the battery is fully charged by looking at the indicator lights (chapter 9: Indicator lights). When this is the case you can proceed with measuring.

9 Indicator lights



On the front side of the **SwayStar™** device there are three indicator lights (LEDs).

9.1 Upper LED (Power status)



Off	The device is switched off.
Green 	The device is switched on. Power supply is okay (battery fully charged) and the device is ready for measurements.
Orange 	The device is switched on. The power supply is critical. Please end the measurement and recharge the battery (chapter 8).
Red 	The device is switched on, but a measurement is not possible, because insufficient power is available. Current measurements will be aborted and the sensors will be switched off and cannot be switched on again. Please turn the device off, using the main switch and recharge the battery (chapter 8).



9.2 Middle LED (Sensor status)

Off	The sensors are off. A measurement has not yet been started.
Green 	The function test was performed successfully. The sensors are on. A measurement has not yet been started.
Orange 	The sensors are on and a measurement has been started.

9.3 Lower LED (Charging status)

Off	The charging-controller is off and the battery is not being charged.
Red 	The battery is being charged (the power cord has been connected, see chapter 8)
Flashing red 	Internal charging error. Please turn the device off and contact your distributor for technical support.

10 Cleaning / Care / Maintenance

10.1 Cleaning and care

Before cleaning the device, insure that the power cable has been removed from the wall socket.

Contact surfaces of plugs and sockets should not be exposed to humidity. No liquid should infiltrate the measuring device.

To clean and disinfect the device and the connecting cables, use a moist cloth and standard disinfectants.

The belts are made out of a very sturdy material and can be cleaned easily with commonly available disinfectants.



Do not use aggressive substances (e.g. sand), which can scratch the surface. Do not use acidly or corrosive agents (e.g. hydrochloric acid). Do not use agents that alter the structure of the lacquered surface of the device (e.g. agents with high acetone levels).

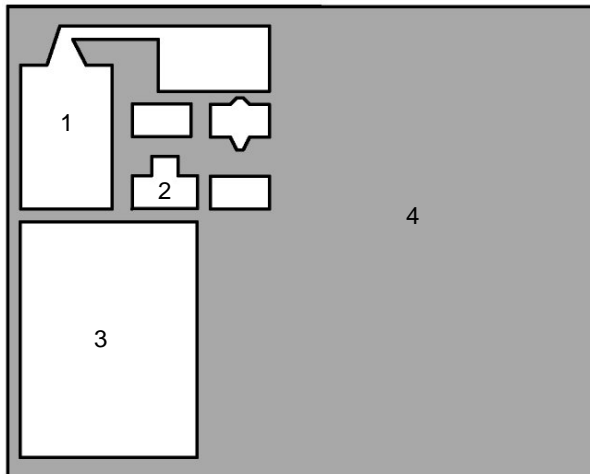
10.2 Maintenance

Regular maintenance of the **SwayStar™** is not required.

11 Storage and transport

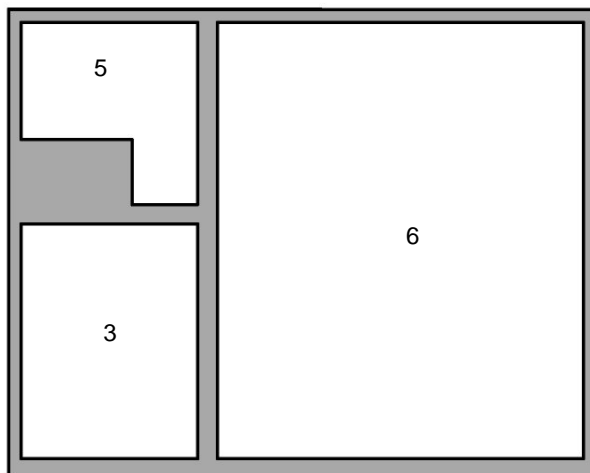
The suitcase, delivered with the system, should be used for the storage and transport of the device and accessories, so that the **SwayStar™** system, as well as its module and the accessories will not be damaged. Without the protection against dust and light, the durability of your **SwayStar™** can be reduced. The suitcase consists of 3 layers; one is in the cover, two on top of each other in the suitcase itself.

When you open the suitcase, you will see the following arrangement of the elements:



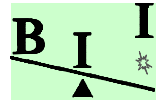
- ¹ Power supply unit and power cord
- ² Adapter plug for all EU-countries and the USA
- ³ **SwayStar™** device
- ⁴ Printed manual

Directly underneath this layer is another layer with the following elements:



- ³ **SwayStar™** device
- ⁵ CD-ROMs, Bluetooth-Dongle
- ⁶ Space for Notebook (not delivered)

In the cover, after you have opened the Velcro® fastener, you will find the belts for attaching the **SwayStar™** device to patients.



12 Troubleshooting

When the upper and middle LED on the front side of the **SwayStar™** device are light green and the lower LED is off, the system is ready for use. The middle LED will light orange, when the software is started and there is a connection between the **SwayStar™** device and the PC.

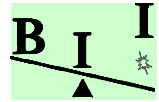
12.1 One or more LEDs are not light

Error	Troubleshooting
Upper LED is not lit	Check the position of the on-off switch on the underside of the housing. The switch must be on "ON".
Middle LED is not green before measuring	The sensor inside the SwayStar™ could be damaged. In this case, contact your technical support or distributor.
Middle LED is not orange after starting a measurement	Check that all the elements of SwayStar™ are properly connected to each other and the device is switched on. Check the connection tot the PC or laptop. Is the Bluetooth-Dongle installed correctly? Is the right COM-port selected? (see chapter 7) If the LED still does not light up, it could be that the SwayStar™ is faulty. In this case, contact your technical support or distributor.

12.2 No connection to the **SwayStar™** device (through Bluetooth®)

First read chapter 6 and 7 and the manual that was delivered with the Bluetooth® dongle. Buildings, (high)-voltage lines, wireless networks, computer monitors, or other electromagnetic interfering fields, can disturb the communication between **SwayStar™** and your PC. Take care that, when possible, all devices in the recording area are switched off that are not necessary.

When you are not able to solve your problem, please contact your distributor or technical support. They are competent to help you.



13 Warranty

The **SwayStar™** device is constructed of high-quality materials with the most modern technology and is inspected under high-standard quality control.

Your device is warranted against manufacturing defects, defective components and below-specified performance characteristics. If any of these occur, you are entitled to a repair without cost or a partial or complete replacement.

The warranty is valid for 24 months and commences on the date of delivery to the user (delivery receipt) plus 10 working days.

The warranty is valid if the equipment does not show evidence of impact, liquid damage, operation contrary to operating instructions, incorrect storage or transportation, or otherwise handled improperly. The warranty is also invalid, when another, than provided, power supply unit or power cord was being used.

The warranty is automatically terminated if any unauthorized tampering with the **SwayStar™** device occurs or if any other manipulation of the device or accessories occurred.

14 Declaration of conformity

BESTec-etp Freiburg
BREISGAU ELECTRONIC SERVICE TECHNOLOGIE - GmbH

EC Declaration of Conformity
for
SwayStar™
(Balance Analysis System)
complying with the Council Directive 93/42 EEC

We declare in the responsibility of

BESTec-etp Freiburg GmbH
Breisgau Electronic Service Technologie
Riegeler Straße 4a
79111 Freiburg, Germany

that the medical device **SwayStar™** (including all components according the attached part list) complies with the relevant regulations of the Council Directive 93/42 EEC of 14 June 1993 concerning medical devices (Amended by Directive 2007/47/EC of the European Parliament and of the council of 5 September 2007) on the basis of its concepts, design and issued realization.

In particular we declare that the product complies with the „Essential Requirements“ according Annex I of the Council Directive 93/42 EEC.

The compliance of the manufacturing steps in conjunction with the conformity of the product with the measuring requirements has been verified with an audit, performed by

mdc medical device certification GmbH
(Notified Body Number 0483)
Kriegerstraße 6
70191 Stuttgart, Germany

Based on this Audit, evidence has been provided that the Quality Management System meets the requirements according Annex V – chapter 3 of the Council Directive 93/42 EEC.


The product has been classified as Class I with measuring function according to the Intended Use and the relevant Implementation Rules.

The validity period of this Declaration of Conformity ends with the validity period of the certificate of the Notified Body - mdc medical device certification GmbH - on 28.06.2017.

This Declaration of Conformity is no longer valid in case of modifications of the products which are not permitted by BESTec-etp Freiburg GmbH.

BESTec-etp Freiburg GmbH
Breisgau Electronic Service Technologie
Riegeler Straße 4a
D-79111 Freiburg
www.BESTec-GmbH.de

10.10.11
Freiburg,


Detlef Burger
CEO, Marketing & Sales
BESTec-etp Freiburg GmbH

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15 Technical data

Equipment type	Active medical product
Classification according to IEC EN 60601-1	Equipment of protection class II
Classification according to MDD 93/42 Appendix IX	Medical product of class I with measurement function.
Ingress Protection according to IEC 60529	IP 51

15.1 SwayStar™ device

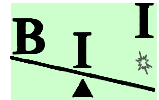
Dimensions	15cm x 11cm x 9cm
Weight	ca. 750g
Temperature range (Operating and Storage)	+20°C to + 40°C (Storage until +10°C)
Sensors (2x) Drift und Random Walk	<6 degs/hour, <0.6 degs/rt-hr
Operating voltage (Max, Min)	12 to 5.8 V DC (d.c. voltage)
Input current when charging	1,25A
EMV Examination	According to EN 60601

15.2 Bluetooth® Module

Transmitting power	Class 1 (max. 20dBm)
Range	Max. 100m
Transmission frequency	2400MHz - 2483.5MHz (USA, Europe)
Conform	Bluetooth® Specification v1.1

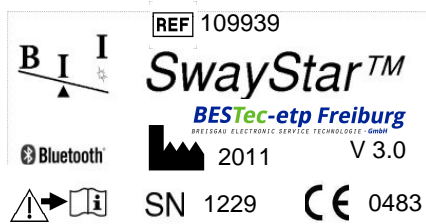
15.3 Power supply

Battery	
Battery type	2x lithium ion battery
Voltage	2x 3,7V
Capacity	930mAh
Charging time	Max. 4,5 hours (when fully discharged)
Period of operation	Max. 40 Minutes (when used continuously)

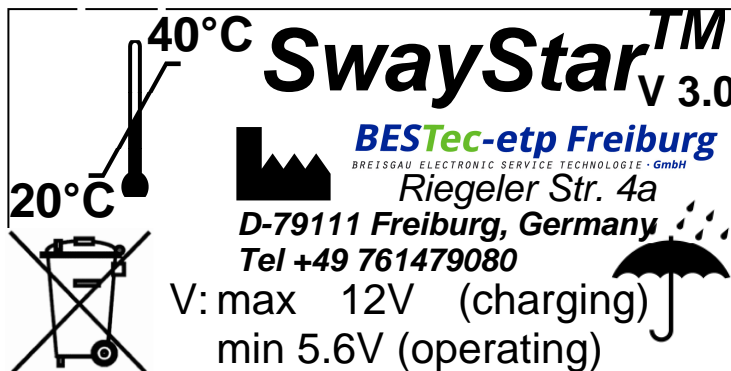


Power supply unit	
Input voltage	100 - 240V AC (alternating voltage) / 50 – 60 Hz
Input current	0,4A
Output voltage	12V DC (d.c. voltage)
Output current	1,25A
Frequency	47 - 63Hz
Power output	15 Watt

15.4 Labelling



The labels consist of all necessary details about the device and details necessary for following the instructions in the manual. The manufacturer, the manufacture labelling, the serial number, as well as the CE-symbol are clearly visible.

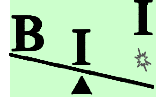


15.5 Disposal



All elements of the system must be disposed as electronic waste and not as normal waste. The different materials (plastic, battery, electronically elements) should be separated and disposed according to regulations or recycled.





16 Manufacturer

SwayStar™ Hardware Measuring Device

Address	BESTec-etp Freiburg GmbH (Breisgau Electronic Service Technologie) Riegeler Strasse 4a D-79111 Freiburg
Telephone	+49-761-47908-0
Tele fax	+49-761-47908-181
Email	info@BESTec-GmbH.de
Internet	http://www.BESTec-GmbH.de

Cooperationspartner for SwayStar™ Software and Development

Address	Balance International Innovations GmbH Postfach 11 CH-3807 Iseltwald
Telephone	+41-79-637-8284
Telefax	
Email	info@bi2.info
Internet	http://www.b2i.info