Measuring System for
Gait and Stance Analysis

FDM

Specifications
and
Operating Instructions

Table of contents

1 Introduction

Welcome to the User Manual for the zebris FDM measuring system.

This User Manual provides a basic understanding for operating the FDM measuring system. It provides essential information for the set up of the system and suggests basic principles for preparing the measuring procedure and data recording.

zebris Medical GmbH does not assume any liability for injury to personnel or patients, nor damage to the device caused by improper use of the FDM measuring system for gait and stance analysis.

All data about the measuring system FDM within this user manual has been collected, compiled and checked with the greatest possible care. Nevertheless a User Manual may remain subject to printing errors, faults and changes. Therefore we should like to point out that zebris Medical GmbH neither guarantees nor holds the legal responsibility or any liability whatsoever for consequences occurring due to incorrect data.

Should you become aware of any errors when using this User Manual, or should you find details that do not conform with your device, please kindly inform us. We shall then correct any possible errors as quickly as possible.

In the interests of continuous product development, the manufacturer reserves the right to carry out improvements to this User Manual and the product described therein at any time and without any further obligation.

Registered trade marks

Several brand names are referred within this User Manual. All these product names are used only for clarity's sake or for editorial reasons and are trademarks belonging to the respective companies. When using the brand names, the trade marks them and also the rights of the respective proprietors remain protected.

The name zebris is a registered trade mark and FDM identifies a product of the company, zebris Medical GmbH.

Copyright

1.1 Manufacturer and sales

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1.2 Conventions and symbols used

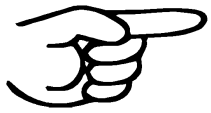
In this user manual the following conventions are used:

Warnings are marked as follows:

WARNING

"WARNING" symbols indicate a potential hazard to the health and safety of the users and/or patients. The warnings describe the risk involved and how it can be avoided.

Notes are shown in the following way:



NOTE

"NOTE" symbols indicate a potential danger that can cause damage to, or destroy the device. These NOTE symbols describe the danger involved and how this can be avoided.

This user manual is to be kept within easy reach so that the information it contains is available to the user at all times.

Notice on changes

In order to guarantee the quality of our products, we continually endeavor to improve our product line. It is possible that by the time this User Manual has been printed, the software and hardware configuration has undergone a further update. Therefore it is possible that some of the figures deviate from the product you have actually been supplied with.

1.4 Intended purpose of the FDM System

The FDM measuring system for stance and gait analysis is a PC-supported system for measuring force distribution. The regulations for using the system stipulate that it is only permitted to use the software applications supplied by the manufacturer. The pressure distribution measuring system FDM is classified as a non invasive, active diagnostic medical product of risk class I (with measurement function) which has been designed for temporary application.

Using the FDM system, gait and roll-off analyses can be carried out easily and quickly, with force distributions being recorded dynamically and evaluated. The data acquisition is carried out by means of 2-dimensional arranged capacitive sensors while the patient is standing or walking several steps on the measuring device. In this way information can be gained about the forces loaded on the lower extremities while standing or walking.

Using the measurement result, statements can be made regarding the forces loaded to the foot, and its shape during gait or stance. Parameters can be determined such as changes in the length and width of the foot, the condition of the longitudinal and transverse arches, the course of the center of gravity, the function of the toes and joints, as well as a large number of other parameters for the roll-off patterns.

The systems can be applied to patients of all ages provided that the patients do not bear any contraindications such as open injuries or skin infections which could cause a risk to other persons using the system later. The patient must be cognitively able to follow the operator’s instructions or otherwise has to be assisted by trained professionals.

The application and operation of the system may only be carried out by thoroughly trained qualified personnel such as clinical doctors, physiotherapists, orthopedics which posses the ability to evaluate the output data in medical aspects The manufacturer assumes no liability for any injury to persons, damage to property, or loss of data due to improper use of the software, the device or its components.

All functions of the system are accessed via the graphic user interface of the system software which is installed on commercially available PCs that is connected to the FDM system via a USB interface. The measuring data is processed under real time conditions and the results will be displayed on a color monitor. The captured data will be stored in a data base on the pc and can be evaluated either by replay with the viewer function or by means of an automatically generated report. Measurements and evaluations, including the preparatory work take a few minutes only and can be repeated at any time, as often as required without any hazard to the patient. The FDM system is specified to be set up and run under normal environmental conditions, inside dry, closed rooms such as laboratories, clinic, surgeries or orthopedic facilities.

If the FDM measuring system is used for diagnostic purposes, it is only permitted to implement it as an additional, diagnostic auxiliary. On no account may invasive surgery ever be carried out solely on the basis of the measuring results without further verification of the measuring data by additional methods.

Please thoroughly follow all instructions of this user manual in order to gain optimum use from the FDM system.

1.5 Personal safety, warnings and prohibitions

General safety instructions

- The operating instructions constitute an integral part of the FDM device and are to be kept readily available for all the users at all times, and/or in easy reach of the device.
- The exact observance of the operating instructions is a prerequisite for the intended use of the device.
- User safety and adherence to the given measuring accuracy are only guaranteed if the expendable items described in the operating instructions are used.
- The application and operation of the system and also the evaluation of the measuring data and their interpretation may only be carried out by trained qualified personnel. The manufacturer assumes no liability for any injury to persons, damage to property, or loss of data due to improper use of the software, the device or its components.
- The safety, reliability and function of the device can only be guaranteed if
  a) repairs are carried out by authorized zebris personnel
  b) the room for the installation conforms to the valid installation regulations
  c) the device is used in conformity with the operating instructions.
- Only operate the device using the stipulated mains voltage and the power supply unit delivered with the measuring system.
- Do set up the platform near a source of heating or in direct sunlight in front of a window as a rise in temperature can lead to inaccurate measuring results.
- If any fluids should penetrate the device, it is mandatory for the device to undergo a technical, safety test. Damaged plug connections and leads are to be replaced by an authorized service technician.
- Never insert any objects in the components of the measuring system.
- Should any malfunctions and/or defects be determined or suspected, it is mandatory for the device to be put out of operation immediately, marked as "Not working“ and prevented from being used by removing the mains cable.
- Be sure that all the mains and connection cables are laid safely and that they are protected against stepping on, so that nobody can trip over them. Check all the cables and the connection plug regularly for any damage.
- Should malfunctions and/or defects be determined or suspected, the device must be put out of operation immediately, marked as "Not working“ and prevented from being used by removing the mains cable.
- Should one of the situations in the following list occur, please do not fail to contact the manufacturer or the distributor authorized by zebris:
  a) The mains cable or mains plug has been damaged
  b) Fluid has been spilt over the main device or other system components
  c) The system fails to function perfectly, despite adherence to the operating instructions
  d) The housing or other system components has/have been damaged.
- Repairs, maintenance and new adjustments have to be done only by authorized and trained personnel. Storage and transport take place only in the original packaging.
- If the type plate or other important labels (warning notices) are damaged or obliterated they have to be replaced by the manufacturer for safety reasons.

- **Instructions concerning patients safety**

- The application and operation of the system and also the evaluation of the measuring data and their interpretation may only be carried out by trained qualified personnel. The manufacturer assumes no liability for any injury to persons, damage to property, or loss of data due to improper use of the software, the device or its component parts.
- The measuring system must be checked at regular intervals to make sure it is functioning properly. More details on this can be found in the section, "Maintenance of the Device" in this User Manual.
- The patients' data and measuring data may only be copied, moved, or deleted using the data-base function provided by the zebris application programs. In the case of data being changed intentionally without using the database functions, the user alone bears the full risks involved.
- The platform must be set up on a slip-proof underlay or installed in a catwalk, so as to exclude any danger to the test person caused by the platform sliding.
- Should any measures for treatment be taken on the basis of the measuring results, the measuring system may only be implemented as a supplementary means for evaluation by an expert. On no account can, or may invasive measures, or measures endangering the patient be carried out solely on the basis of the measuring results without further verification of the measuring data by additional methods.

Prohibited Use

- We warn explicitly against improper or prohibited use of the measuring system. This includes all the prohibitions included in the section on "Personal Safety, Warnings, and Prohibitions".
- The measuring system must not be put into operation by anyone who has not been familiarized in detail first by the trained personnel.
- Should malfunctions and/or defects be determined or suspected, the device must be put out of operation immediately, marked as "Not working“ and prevented from being used by removing the mains cable.
- Should there be any detectable damage to the device or component parts, they should be returned to the manufacturer for a safety check. It is not permissible to continue using the device or its component parts, as severe damage and serious injuries - even lethal injuries - may result. The manufacturer or authorized sales partner must always be contacted in all cases of fault or doubt.
- We also point out that if any changes are made to this certified device or its accessories without the prior written consent of zebris, your legal right to operate the device will be nullified.
- zebris measuring systems may not be operated in any other environmental conditions to those listed in the section, "Specifications", (e.g. in wet zones, moisture-prone areas, or in climatic, vacuum, hyperbaric or decompression chambers, etc.)

1.6 System components

In its basic configuration the FDM measuring system consists of the following components:

- FDM platform
- External power supply unit
- USB cable (Type A-A, 3.5 m length)
- zebris application software WinFDM
- IBM® compatible computer or notebook
- Cable guard with screws
- User Manual for platform and software

1.7 Computer requirements

As a rule, the measuring system FDM is supplied together with a computer. If the system is to be operated using other computers or components, the user must then inquire whether the intended coupling guarantees the necessary safety for the test person, the operator and the surroundings by consulting the manufacturer, the authorized zebris sales partner or by asking a specialist.

WARNING

If the computer is not supplied with the measuring system, the manufacturer shall not be held liable for any damage or malfunctions arising from a faulty coupling. Should additional hardware be built into the computer or software installed, the manufacturer shall not be liable for any malfunctions or damage occurring.

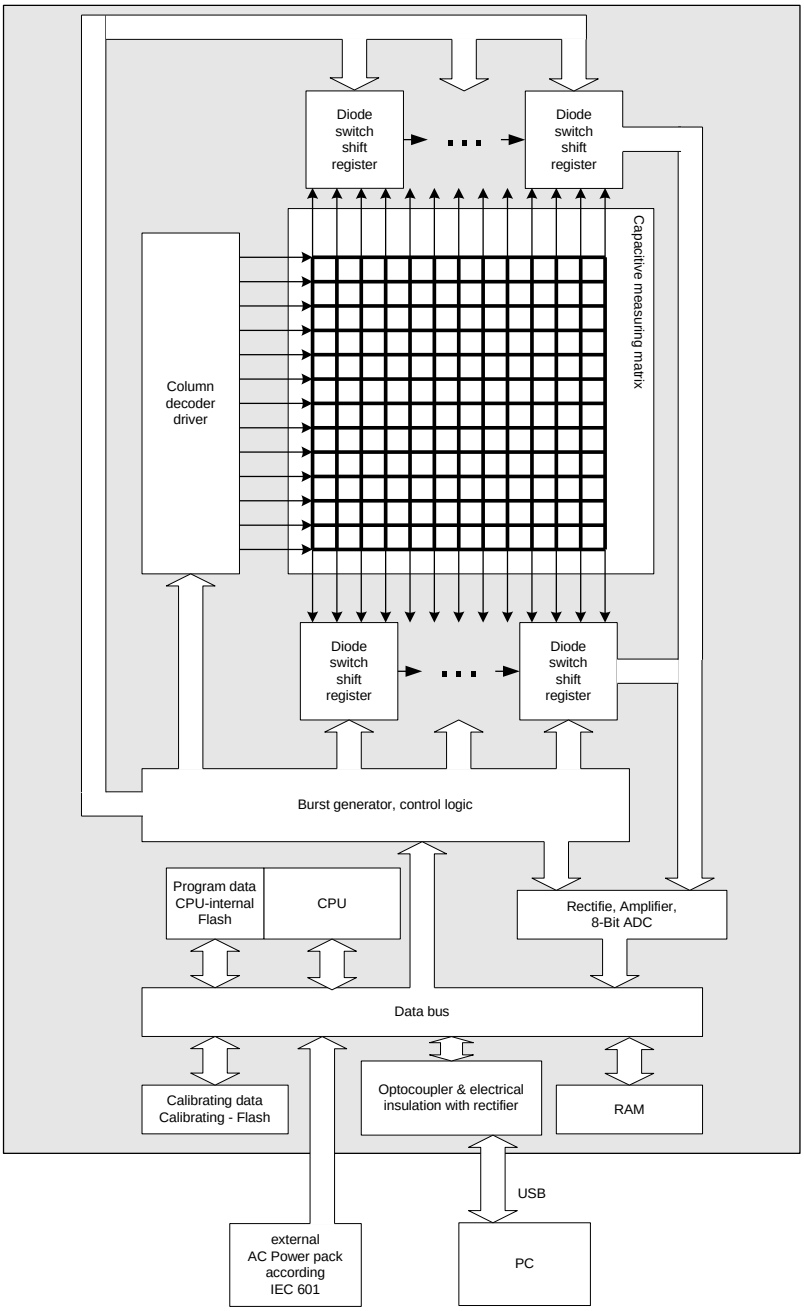
Computers suitable for operation with the FDM measuring system must meet the following minimum requirements:

- IBM® AT or 100% compatible computer with Pentium IV processor
- 1024 MB RAM
- VGA graphics card with a 1024 x 768 resolution and a color depth of 24 bit true color
- Color monitor with the corresponding resolution
- Windows XP/Vista
- Mouse
- Keyboard
- USB interface

1.8 Measuring principle

The system contains a measuring matrix consisting of capacitive pressure sensors that are arranged in columns and lines running closely next to each other. For determining the force distribution over the measuring matrix the capacity proportional to the force exerted is determined for each individual sensor. To do this, the drive logic generates a number of sinus burst signals equivalent to the number of columns via the column decoder, and transmits them to the respective measuring column. The analog signal coupled into the shift register over the lines is proportional to the pressure-dependent capacity and is passed on for further processing to the control and signal-processing electronics and transmitted to the PC from there and shown on the display.

Schematic circuit diagram of the measuring system



2 Technical data

2.1 General specification for the FDM-Sensor

The sensors of the different FDM system only vary in size of the measuring area, the number of single sensors included in the sensor module and the supported sampling frequency. All other technical data is identical.

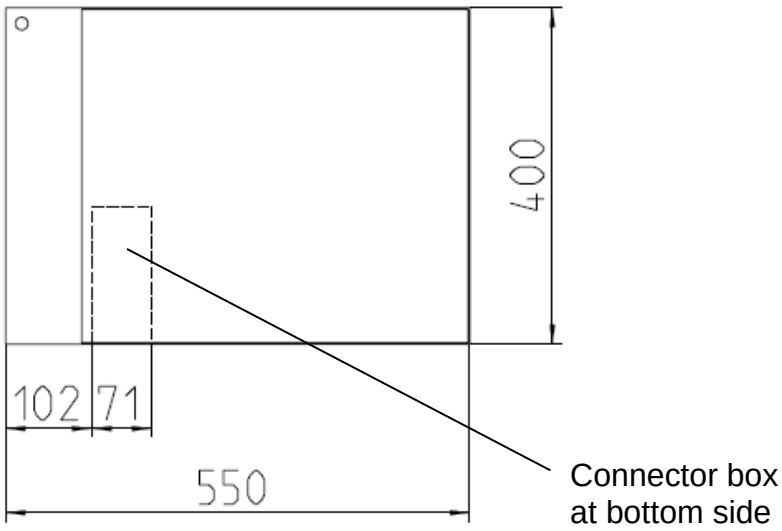
Interfaces	USB Synchronization input/output Video synchronization Infrared synchronization
Connection	Interface box on the bottom of housing frame
Measuring principle	capacitive force measurement
Operating voltage	16-18V DC
Power consumption	max. 40W
Power supply via external power supply unit	100 - 240V AC / 50 - 60 Hz
Operating temperature range	15 to 40°C
Storage temperature	-10 to +60°C
Permissible max. relative humidity	80%
Measuring Range	1 – 120 N/cm^2
Accuracy of the calibrated measuring range	(1 – 80 N/cm^2) ±5% (FS)
Hysteresis	< 3 % (FS)
Physical resolution	1.4 sensors /cm^2

2.2 Technical data of FDM multi function force plates

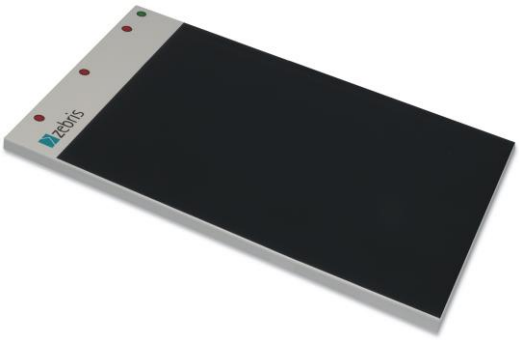
Platform Type FDM-SX

Item number	124.3010
Dimensions (L x W x H)	55 x 40 x 2.1 cm (L x W x H)
Weight	4.8 kg
Sampling frequency	120 Hz
Number of sensor	1920
Sensor surface	94.8 x 40.6 cm (L x W)

Dimensions for integration into walking range

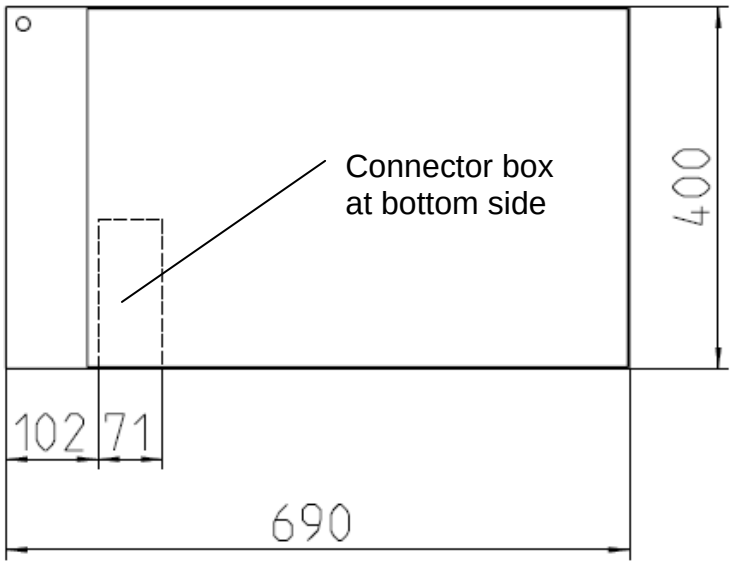


Platform Type FDM-S



Item number	124.3005
Dimensions (L x W x H)	69 x 40 x 2.1 cm (L x W x H)
Weight	6.5 kg
Sampling frequency	120 Hz optional 240 Hz
Number of sensor	2560
Sensor surface	54.2 x 33.9 cm (L x W)

Dimensions for integration into walking range

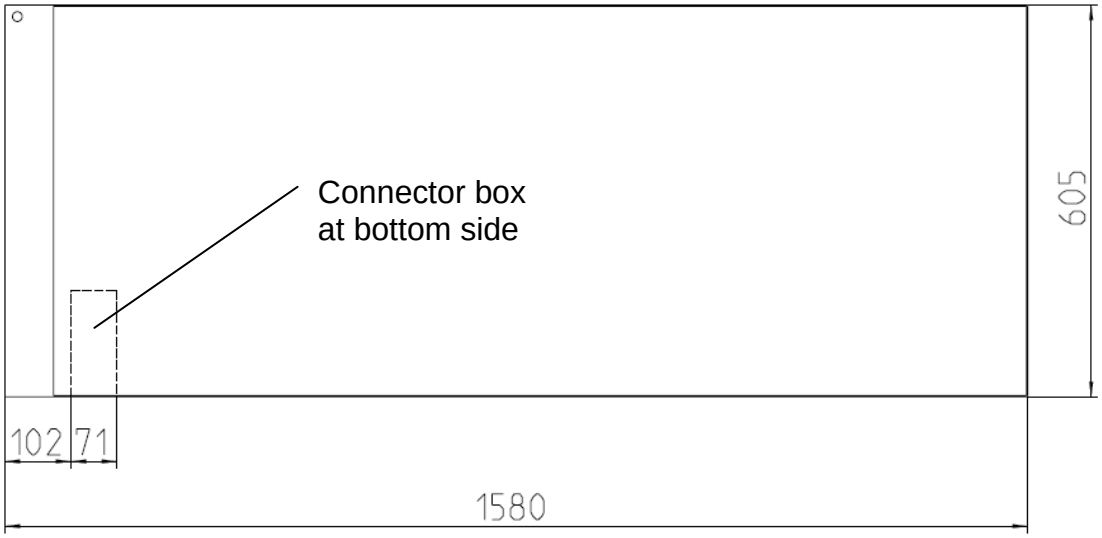


2.3 Technical data of FDM system for stance and gait analysis

Platform Type FDM 1.5

Item number	124.3015
Dimensions (L x W x H)	158 x 60.5 x 2.1 cm (L x W x H)
Weight	approx. 16.5 kg
Sampling frequency	100 Hz optional 200 / 300 Hz
Number of sensor	11264
Sensor surface	149 x 54.2 cm (L x W)

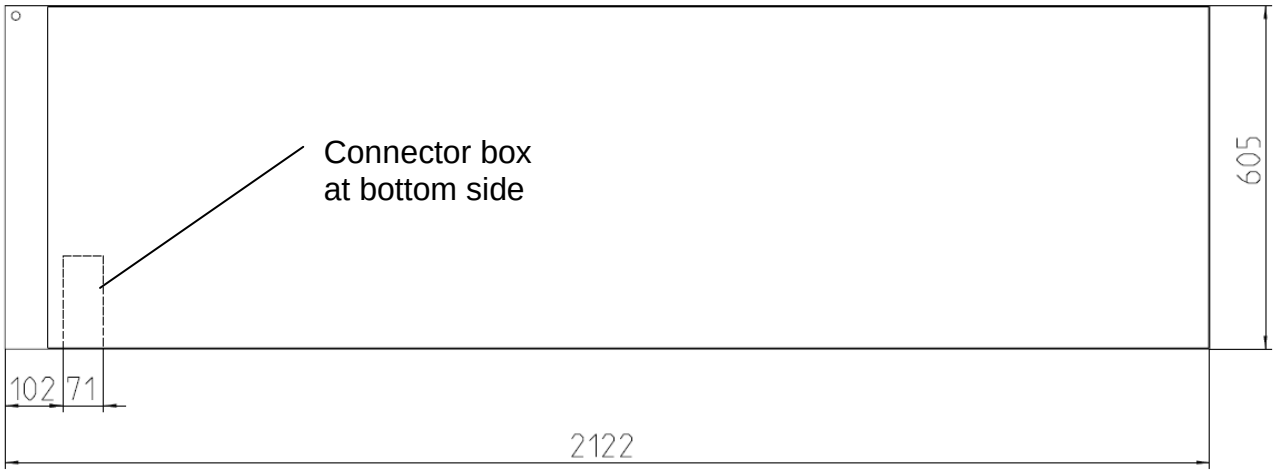
Dimensions for integration into walking range



Platform Type FDM 2

Item number	124.3020
Dimensions (L x W x H)	212 x 60.5 x 2.1 cm (L x W x H)
Weight	approx. 25 kg
Sampling frequency	100 Hz optional 200 Hz
Number of sensor	15360
Sensor surface	203.2 x 54.2 cm (L x W)

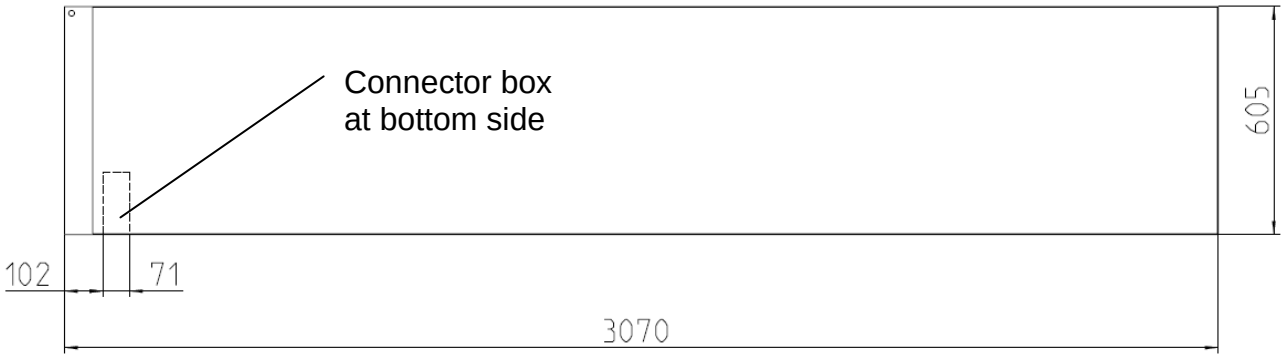
Dimensions for integration into walking range



Platform Type FDM 3

Item number	124.3030
Dimensions (L x W x H)	307 x 60.5 x 2.1 cm (L x W x H)
Weight	approx. 35 kg
Sampling frequency	100 Hz
Number of sensor	22528
Sensor surface	298.1 x 54.2 cm (L x W)

Dimensions for integration into walking range



2.4 Specifications for the external power supply unit

All zebris FDM system can be operated by the same type of external power supply.

Input	**Output**
100 - 240 V AC	16V DC
50 - 60 Hz	60 W

Cable Length

AC-Cable	1.7 m
DC-Cable	5 m

Pin arrangement / polarity

NOTE	It is absolutely necessary to connect the external power supply unit to a power outlet that contains a ground contact in order to secure fault free and save operation of your FDM-T system. In case it is necessary to use a mains adapter make absolutely sure that it has ground contacts as well.

NOTE	Be sure to position the measuring system in a way that allows easy access to the power outlet at any time in case it is necessary to disconnect the system from mains supply.

3 Setup and operation of the FDM System

3.1 General information

The floor where the device is set up must be absolutely even and horizontal. For further details on setting up the measuring platform please see the section "Recommendations for Recording Data".

3.2 Status indicator LED

green flashing The power supply unit is connected to mains and a correct supply voltage is provided. A USB connection is not established yet or recognized. The platform is not ready for initialization or measurement.

green permanent The power supply unit is connected to mains and a correct supply voltage is provided. A USB connection is established and recognized. The platform is ready for initialization or measurement.

orange flashing A measurement is in process.

orange permanent A measurement is in process and infrared synchronization signals (from other zebris devices) are received. The orange flashing signalizes that valid synchronization signals are received.

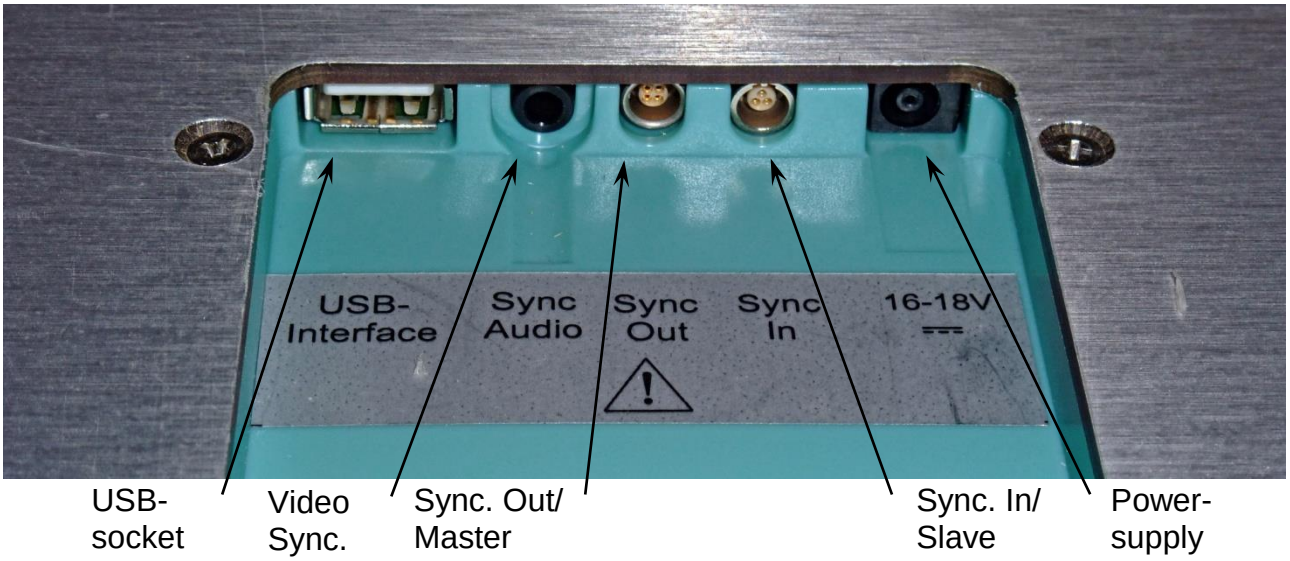
3.3 How to switch the platform On/Off

The platform is switched on and off by software control as soon as the WinFDM software on the PC is started. If the device has been connected correctly, the green LED operating indicator illuminates on the housing of the platform.

3.4 Setup of the FDM platform

In order to set FDM platform into operation, the power supply unit, the USB-cable of type A-A as well as the installations CD with the WinFDM application software will be required. All components are included within the shipment of the FDM system.

All cable connections between platform and PC will be established by the connector box located at the bottom of the platform



USB-socket | Video Sync. | Sync. Out/ Master | Sync. In/ Slave | Power-supply

In case the measuring system has been shipped without PC, please install the WinFDM software to your PC first. For assistance and details on the installation procedure please refer to the user manual of the WinFDM software.

NOTE

Please make absolutely sure that you have <u>installed the zebris software</u> <u>before connecting</u> the FDM platform to the computer using the USB cable.

When this step is skipped it may result in severe problems with the driver installation! The Windows operating system registers the location of the driver on the hard disk when the FDM platform and the PC are connected for the first time.
If at this time there is no compatible zebris software installed on the PC, the driver will subsequently not be able to be allocated.

NOTE

How to solve problems with the hardware driver
Should problems with the hardware driver of the FDM platform occur then disconnect the platform from the PC and restart it. Now proceed with installing the WinFDM software another time and reconnect the platform when the installation procedure has been finalized.

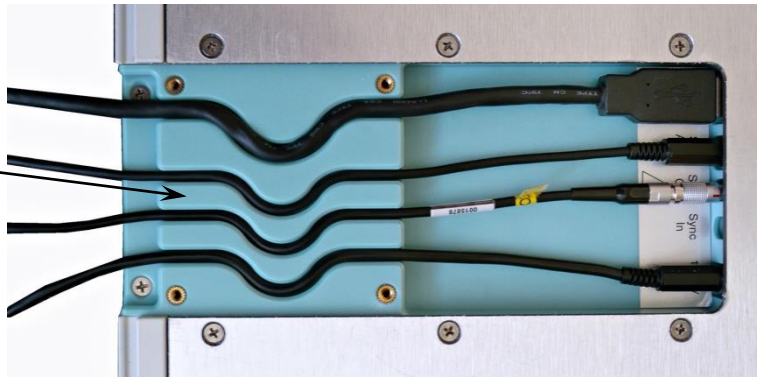
If the WinFDM software is installed correctly then attach the power supply unit to a mains outlet and the power socket of the interface box. In case it is necessary to use a mains adapter make absolutely sure that it has ground contacts. This is necessary for your measuring system to operate safely.

Finally connect the USB-socket by means of the USB-cable to the PC.

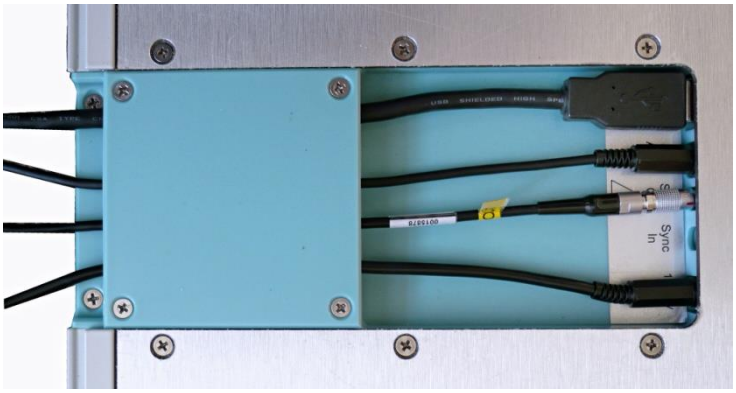
WARNUNG

Never use a USB-Hub or similar device to connect the platform to the PC. Only by plugging the platform directly to a USB port of the PC the functionality of the platform can be guaranteed. zebris does not take any liability for any injury to persons, damage to property, or loss of data due to improper connection of the platform.

safety lock



If the power supply unit and the USB cable are connected to the sockets of the platform, please close the lid of the safety lock and fasten it to the housing by means of the four screws supplied with the platform.



WARNING

Set all connection cables in a way that prevents patients, or persons taking part in the measuring procedure from trip over them. (If necessary anchor the cables with adhesive tape to the floor.)

3.5 Setting the system out of operation

In order to set the system out of operation please close the WinFDM software first, then exit the Windows operating system and shut down the PC. In the next step disconnect the power supply unit of the FDM sensor and the treadmill from mains supply.

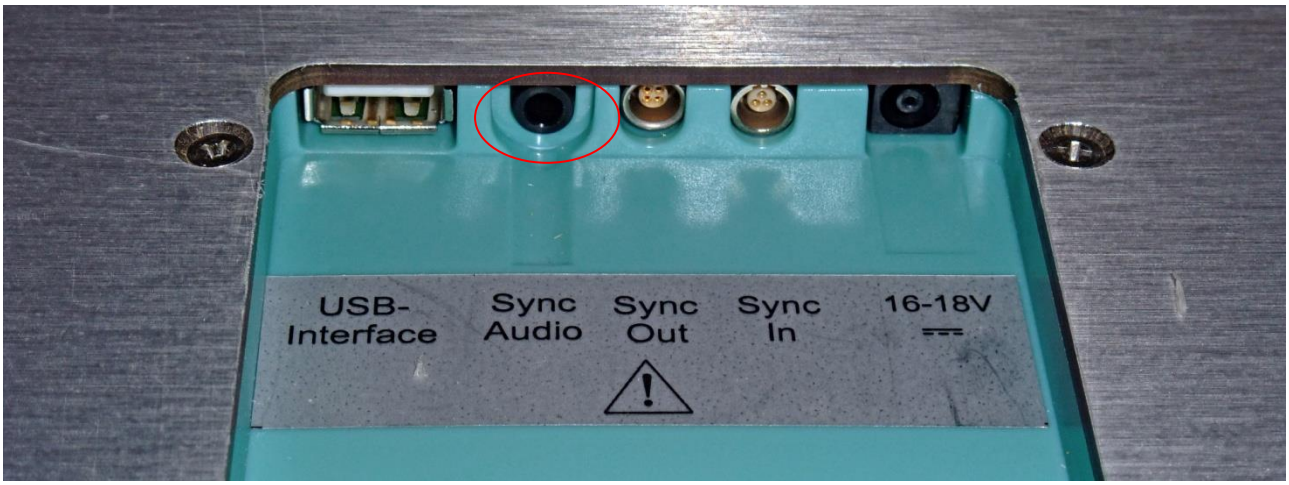
4 Synchronization of the FDM platform

The FDM platform offers several options for recording the platform measuring data synchronously with such of other measuring devices.

In order accomplish synchronized recording of motion data, digital video or EMG the platform provides synchronization inputs and outputs with galvanic separation.

4.1 Synchronizing the FDM Platform with video data (Sync Audio)

The Sync-Audio socket serves for synchronizing the platform measurement and recordings of commercially available video cameras utilizing the external microphone input of the camera.



The synchronization is effected by imprinting a tact signal on the soundtrack of the video recording. This data is evaluated automatically by the application software WinFDM for synchronizing the platform data and the video signal.

For the connection to the video camera the following synchronization cable is required:

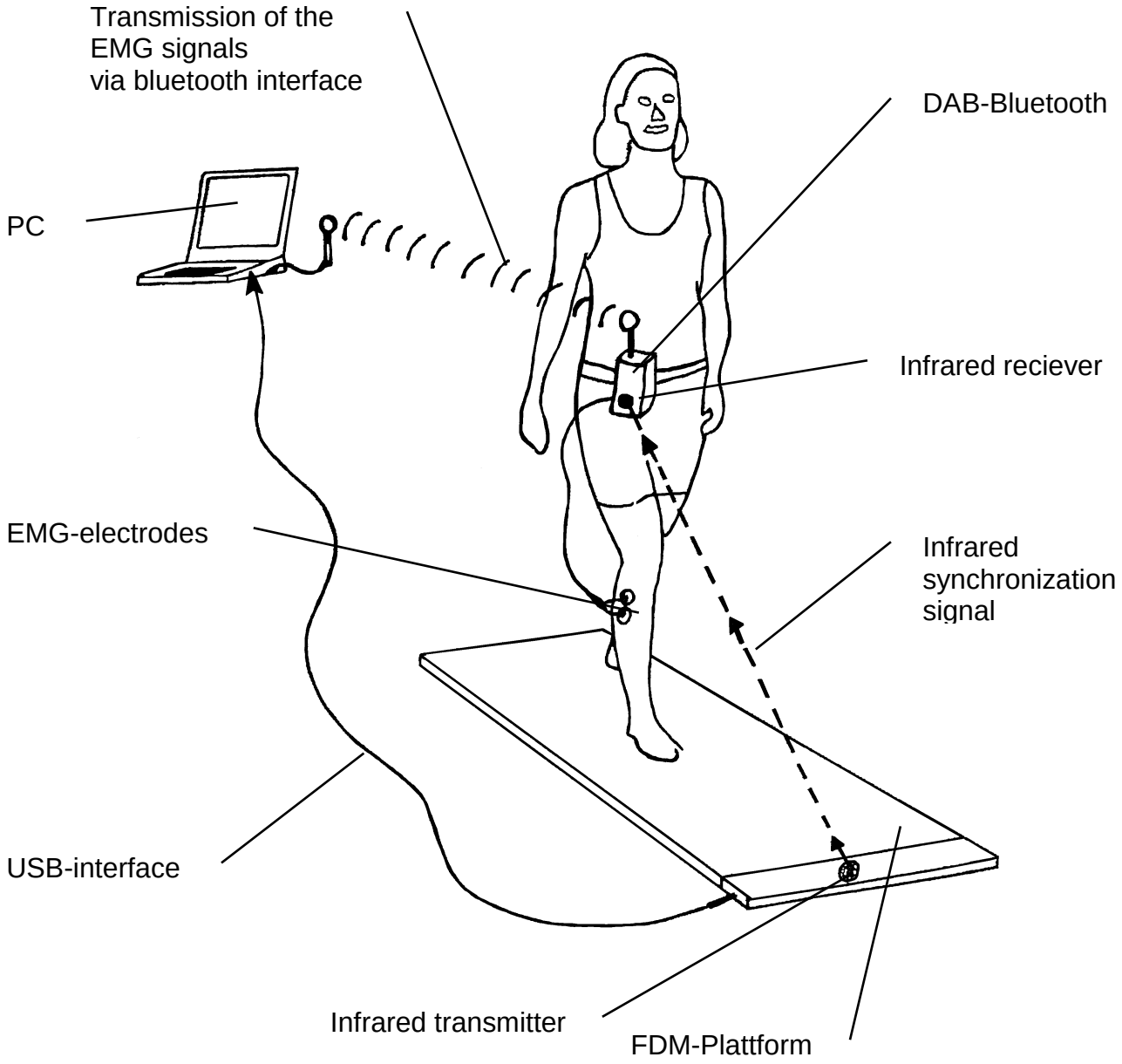
Item No. 1830016/Video Sync-Control cable,
cable length 7m with amplifier and control LED.

4.2 Infrared synchronization with zebris DAB-Bluetooth (EMG)

For synchronizing the FDM system with the zebris DAB-Bluetooth the optionally available IR interface which will be integrated within the platform housing is required.

FDM platform and DAB-Bluetooth are synchronized automatically as soon as both devices have been switched on and a measurement is started.

The following schematic diagram shows the interconnection of the FDM-platform and the zebris DAB-Bluetooth.

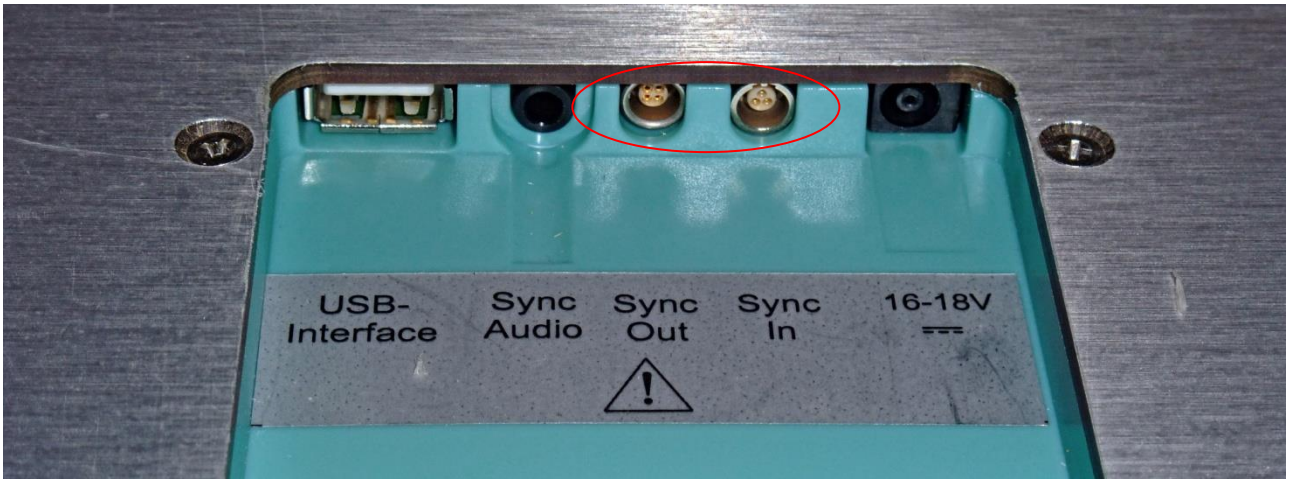


4.3 Combine two FDM platforms of the same type

Two FDM platforms of the same type can be combined (Master – Slave) in order to double usable walking range. To accomplish this task a synchronization cable is required.

Item No. 1830019/SC-PP Sync. Cable, length 10m

Both platforms have to be connected to separate USB ports of the same PC. By means of the synchronization cable the „Sync Out“ socket of the master platform has to be connected to the „Sync In“ socket of the slave platform. The WinFDM software then will recognize the platform combination automatically and show the corresponding sized measuring area.

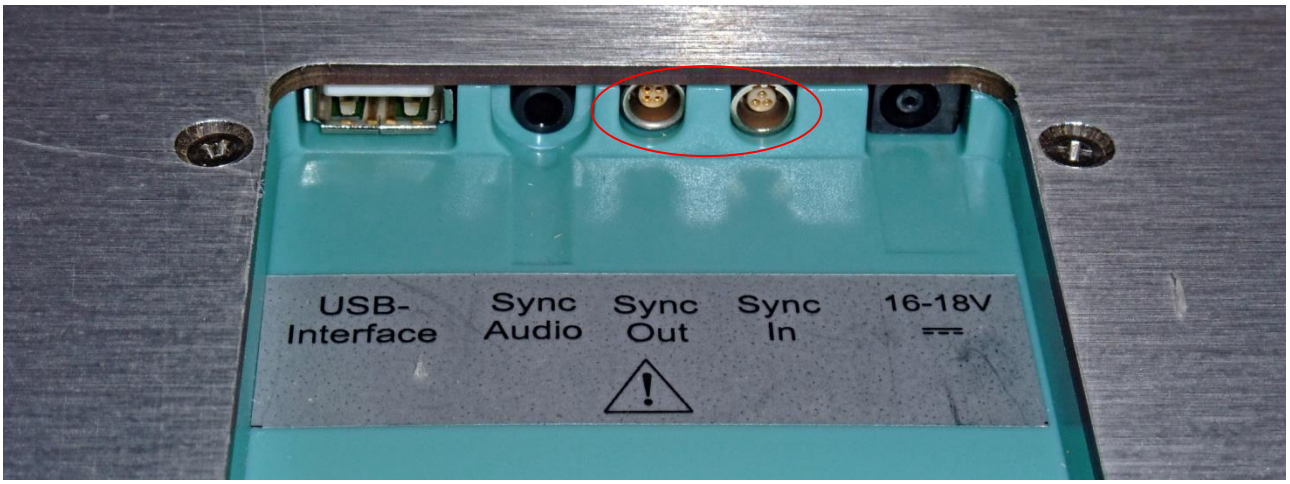


NOTE

Be sure to position both platforms as shown below when connecting them for doubling the walking range.

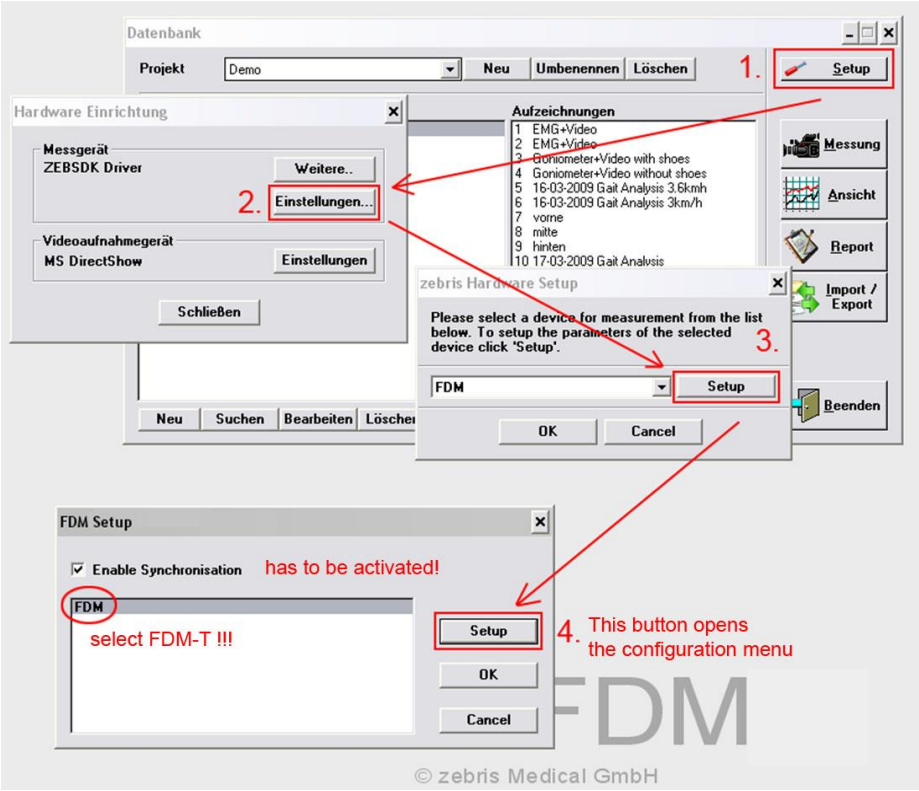
4.4 Synchronization of third party devices with the FDM system

The **SYNC-IN** and **SYNC-OUT** sockets provide inputs and outputs for support of „frame by frame“ In- and Out synchronization. Both sockets are galvanic protected from the platform.

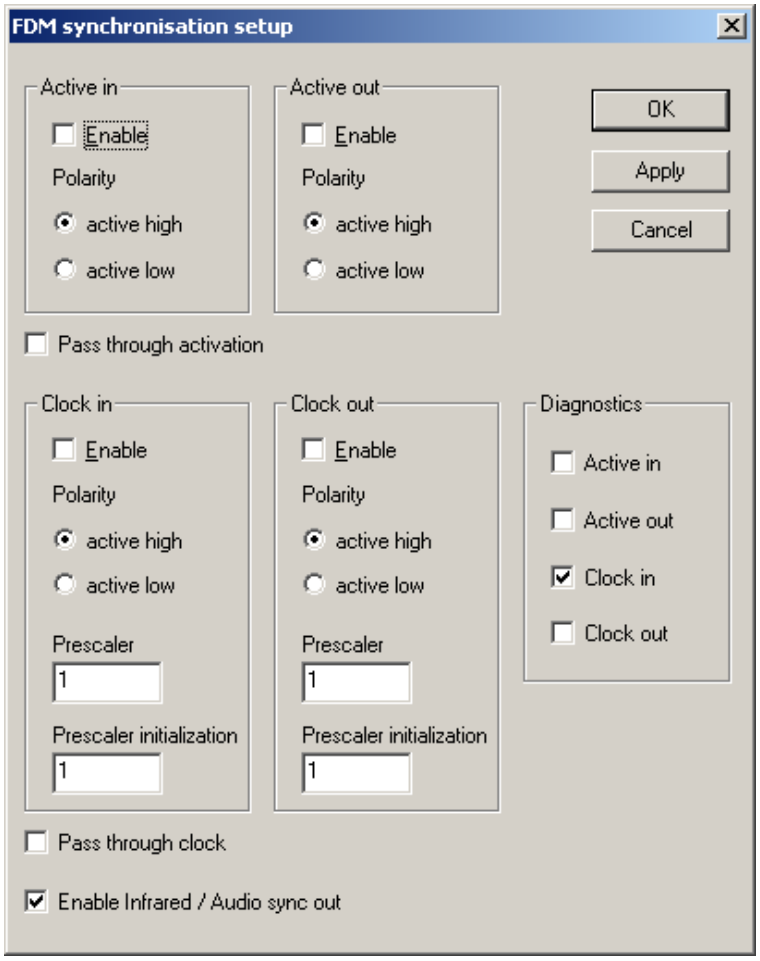


NOTE	Patient’s safety is guaranteed by means of galvanic separation acc. to to the provisions of IEC 601-1 when a third party device is synchronized with the FDM system. This allows non medical equipment to be synchronized with the FDM system as long as such devices are out of patients reach. Nevertheless the user is completely responsible for the safety of all third party devices used in combination with the FDM system.

The WinFDM software provides a configuration window which allows adapting the synchronization exactly to the parameters of interfaces from third party devices.



Configuration window of the FDM synchronization



OK stores the settings in the device configuration and closes the dialog.

Apply sets the configuration shown in the dialog to the attached device – without storing it to the device configuration!

Cancel closes the dialog without storing anything.

Each signal (**Active in/out, Clock in/out**) can be enabled, and the polarity can be inverted.

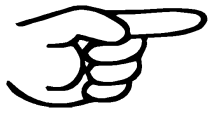
By **Pass through activation** each Signal can be forwarded from the input to the output. If a signal is passed through, the corresponding output configuration has no effect; the output level will be always the same as the input level.

If the input signal polarity is set to "**Active Low**", the output will be the inverted input signal.

Forwarding is done by hardware and thus works without any significant latency.

Clock in/out can be also divided by a **Prescaler**. If the prescaler is set to 1, then the system will start a measurement on each synchronization impulse. Higher prescaler values work as divider. In case the prescaler is set to 2 then a measurement will be started on every second impulse only. Set the **Prescaler initialization** value to the count of clock events you want to be "ignored" before the first clock event passes the prescaler.

By **Enable Infrared / Audio sync** infrared- and video synchronization can be enabled/disabled simultaneously. It is not possible to access them individually.



NOTE

Active in/out, Clock in/out are active during recording only, in preview mode of the data acquisition application they are disabled automatically, even if you enable them in setup.

The **Diagnostics** box allows testing of the **Active in/out, Clock in/out** signals. The "Active in" and "Clock in" checkboxes show the corresponding input levels; By checking or unchecking the active out and clock out checkboxes you can set the level of the corresponding output pins at the SYNC-IN and SYNC-OUT sockets. Note that the polarity of the diagnostic checkboxes is affected by the corresponding "**Polarity**" radio buttons (**active high/low**) of each signal.

Example configurations for the synchronization of third party devices

zebris system is providing the sync-signal

Synchronize external 3rd party device by start/stop signal

Enable **"Active out"**. Connect the ***"Active Out" pin of the SYNC-OUT socket*** to start/stop input pin of the other device. The active out is set when the measurement is started and removed when the measurement stops. If the external device needs its start pin to be pulled low, set active out polarity to active low.
Note: Output pins may toggle during device initialization.

Synchronize external 3rd party device sample-by-sample via clock signal generated by the zebris system

Enable **"Clock out"**. Connect the ***"Clock Out" Pin of the SYNC-OUT socket*** to the trigger input of the other device. The device will generate a trigger pulse each time a single measurement is recorded.

Third party device is providing the sync-signal

Synchronize the zebris device by start/stop from an external 3rd party device

Enable **"Active in"**. Connect the activation signal from the other device to the ***„Active In" Pin from the SYNC-IN socket*** of the zebris device.
If the external device sets its output to low level during measurement, set the active in polarity to "active low".

Synchronize the zebris device sample-by-sample by a clock generated by an external 3rd party device

Enable **"Clock in"**. Connect the clock signal from the external device to the ***„Clock In" Pin from the SYNC-IN socket*** of the zebris device.
If the zebris device should trigger its measurement at the falling edge of the clock signal, set the clock in polarity to "active low". Otherwise, the raising edge will trigger the measurement.

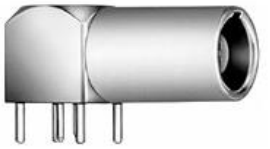
Combinations

All signals can be used simultaneously as well. If both active In and clock In are enabled, the clock signal will trigger measurements only while the active In signal is present. Trigger pulses from the clock In signal which occur while there is no active In signal will be ignored.

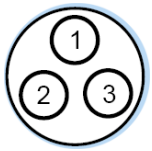
Synchronization input (SYNC-IN)

If a third party device is connected to the synchronization input SYNC-IN then depending on the setting of the configuration window from the application software the measurement will start/stop or “frame by frame” synchronized by a signal from the third party device. Input is protected against faulty polarisation and pin 1 is set to +5V ("1") by an internal pull-up- resistor 2.7 kΩ. If this input is set to 0 V ("0") i.e. by a switch or break contact than the SYNC-IN is triggered.

Built-in LEMO – Jack at Front of ZEBRIS Gauge
Series „00“, 3-pin, fitting Nut 30°
LEMO- Part. No. EPA.00.303.NLN

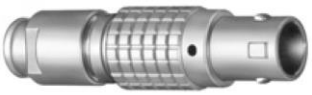


View
Front side



Fitting Nut: 30°

Respective Plug:
Type of plug for SYNC-IN: LEMO- Part No. FGA.00 303.CLADxxxx



View
Solder side

Fitting Nut: 30°

Pin assignment:

Pin 1	Clk_In
Pin 2	Active_In
Pin 3	GND

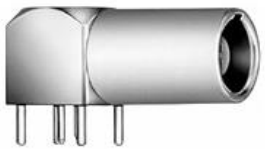
Electrical specifications:

Input resistance (pull-up 5 V)	2.7 kΩ
VIH (High-Level Input Voltage)	>= 2.0 V
VIL (Low-Level Input Voltage)	<= 0.8 V
Required min. pulse time for triggering	1 ms

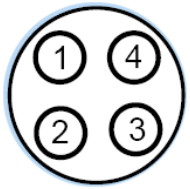
Synchronization output (SYNC-OUT)

If a third party device is connected to the synchronization output SYNC-OUT then depending on the setting of the configuration window from the application software will trigger a synchronized measurement of the third party device either via start/stop or “frame by frame” mode.

Built-in LEMO – Jack at Front of ZEBRIS Gauge
Series „00“, 4-pin , fitting Nut 0°
LEMO- Part. No. EPG.00.304.NLN



View
Front side



Fitting Nut: 0°

Respective Plug:
Type of plug for SYNC-IN: LEMO- Part. No. FGG.00 304.CLADxxxx

View
Solder side

Fitting Nut: 0°

Pin assignment:

Pin 1 +5 V
Pin 2 GND
Pin 3 Active_Out
Pin 4 Clk_Out

Electrical specifications:

Type of plug for SYNC-OUT	LEMO- Part No. FGG.00 304.CLADxxxx
Output resistance	100 Ω
High-Level	>= 2.0 V
Low-Level	<= 0.8 V

5 Recommendations for recording data

To receive significant data from FDM systems some principle guidelines should be followed. This chapter describes the ideal conditions for recording measurement data.

5.1 Walking range

The best conditions for measurements with platforms of the FDM-S type will be reached by integration of the system in a walking range. The complete walking range must be plane with the surrounding floor. This way the test person won't know the position of the platform and gives a workaround to the tendency that test persons try to walk exactly on the sensor area. The width of the stage should be about 1,20m. We recommend a distance of about 4m from start to FDM-S platform and no less than 3m behind. With such a walking stage it is easier to measure normal walking without acceleration or deceleration.

Of course the same set up can be used to measure with the method of first step. The first step method is described as follow: The patient stands on one side of the platform in a distance to reach the platform by the first step. For measurement the patient hits the sensor area by the first step and moves on. This kind of measurement guaranties reproducible steps and results. Notice: These results differ more or less from these by normal walking.

5.2 Data recording

Please observe the exercise of the patient strictly. Only steps where the complete ground contact of the foot is located on the sensor area may be used for evaluation. If not the complete foot area was measured by the system (foot did partially not hit the sensor area) the step can not be evaluated.

5.3 Gait velocity

For the measurement a normal (individual) and constant walking velocity is necessary. Ideally an additionally measurement, e.g. by photo sensors, can proof the velocity for notice. Naturally the patients adapt to the measurement situation within a few minutes. After a few trials, walking seems normal. A change in velocity of about 5 % is non-effective.

5.4 Posture

A visual control of the behaviour pattern of normal gait is recommended. Trials with atypical behaviour pattern should be deleted from interpretation. The patient has to look straight ahead and must not be disturbed by paying attention to the platform or monitor. Marks on the wall in front of the patient can provide orientation to hit the platform.

5.5 Acrosclerosis

Different measurements (e.g. P.R. Cavanagh, *The Foot* (1994) **4**, 123-135) show an increase of plantar pressure peaks of about 30 % by acrosclerosis (e.g. weals). The interpretation of measurement data has to include the existence of plantar acrosclerosis.

6 Maintenance

6.1 General maintenance information

The correct maintenance and care helps to prevent damage and guarantees the safety of the device.

Prior to switching on the measuring system, check whether the mains cable, mains plug, mains socket and mains input on the device are in proper condition.

Immediate maintenance measures are to be carried out if:

- fluid enters the device
- cable or cable connections have been damaged
- covers have been damaged
- a malfunction or a fault is suspected or has been detected

The maintenance of the device or individual parts of thereof must only be carried out by zebris Medical GmbH or a person who has been explicitly authorized by zebris to do this.

WARNING

Should any malfunctions and/or defects be determined or suspected, the device must be put out of operation immediately, marked as "Not working" and prevented from being used by removing the mains cable. In such case be sure to contact the manufacturer or an authorized sales partner.

For the user's safety, we recommend checking all the connection cables at regular intervals to make sure that they are not damaged. If the mains cable is damaged it should on no account be used any longer. In this case please contact the manufacturer.

NOTE

The correct measuring function of the measuring system should be checked at regular intervals (please also observe the instructions in chapter 1.2 of this operating manual).

6.2 Checking the FDM Sensor

Control measures

NOTE

The measuring system must be checked at regular intervals to ensure that the measuring system is functioning properly.

Should any damage to the measuring surface become evident (e.g. something fell hard on the black measuring surface), no further measurements must be taken. If visible damages are detected not further measurements are permitted.

After carrying out a baseline measurement, no measuring values may be shown for a condition without any load. In addition, the force distribution images are to be checked regularly for untypical measuring patterns. These include above all, line or column-shaped measuring patterns deviating from the surrounding values.

Whenever faults occur or in case of doubt, the manufacturer or sales partner authorized by zebris must always be contacted.

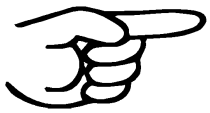
Calibration measures

The measuring accuracy of the sensors for the force distribution measurement is to be checked from time to time using a defined application of force.

To do this, the user, knowing the body weight, can stand on the platform on one foot. The platform must show the approximate body weight, taking the force of gravity, the sensors at the edges that may not be subject to the full pressure, and the measuring tolerance into consideration.

In case of deviations larger than > ±5% of max range a recalibration at manufacturers side is required.

Should the display be incorrect, a recalibration by the manufacturer is required.



NOTE

As a general rule, it is highly recommended checking the measuring platform every two years and having it recalibrated in order to permanently ensure the given measuring accuracy.

6.3 Cleaning and disinfection

Cleaning

The platform and accessories are cleaned with a moist cloth while the device is switched off and the mains plug taken out.

NOTE

Do not use any aggressive agents to clean the measuring system.

WARNING

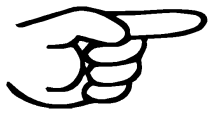
Please be absolutely sure to switch off the device and pull the mains plug out of the socket before you commence disinfecting and cleaning.

Disinfection

The platform can be disinfected by wiping over with suitable agents. To clean, wipe the platform with a cloth soaked in disinfection liquid.

Recommended disinfection agent:

Composition approx. 25% ethanol, 35% Propanol
E.g. Mikrozid Liquid / Schülke & Mayr or similar agents



NOTE

If you apply disinfection agent be sure to follow the recommendations given by the manufacturer of the disinfection agent strictly. Especially consider the rules concerning the commended application time of the agent.

WARNING

On no account directly pour disinfection fluids or other liquids over the FDM platform.
Should any liquid enter the platform it is likely to be damaged.

WARNING

The fluids required for disinfecting and cleaning must be stored, prepared and kept ready for use exclusively in the containers provided, in order to avoid them being mistaken for other fluids.

7 Storage, transport and disposal

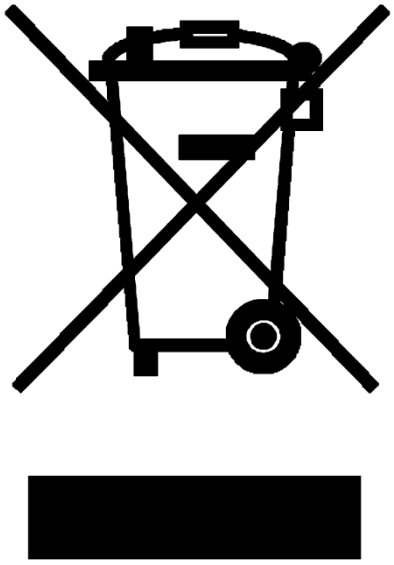
7.1 Storage and transport

The transport and storage of the system or its parts should take place only within the original packaging.

Storage Temperature: -10 to +60°C

7.2 Disposal

This symbol states that according to the directive on waste electrical and electronic equipment (2012/19/EEC) the product must not be disposed by means of the domestic waste system. Within Europe this device must be forwarded to a specific waste disposal system.



Therefore regular disposal is carried out by the manufacturer. For this purpose the system should be shipped to the manufacturer and will be forwarded to regular disposal by zebris.

The improper interaction with electronic waste could lead to negative effects for the environment and the public health because of potential hazardous materials which are frequently contained within electric and electronic devices. Additionally with the proper disposal of this product you will contribute to the effective use of natural resources.

8 Safety standards and system classification

8.1 Classification acc. to Annex IX of Directive 93/42/EEC

Class I with measurement function

8.2 Safety of medical electrical devices

The system meets the requirements of the standards DIN EN 60601-1

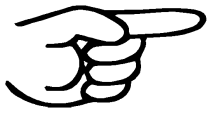
Electrical Safety Standard **BF** 

Safety class II

Steady state conditions

8.3 Connecting the FDM-System to other electrical devices

Important notes on medical electronically systems



NOTE

You are allowed to combine the system only with additional tools that fulfill the regulations EN 60950 / EN 60601 part 1.
The electrical combination of the complete system is to be done according to EN 60601-1-1.

WARNING

The computer and other non-medical tools have to be located beyond the reach of the patients (1.5 m).

8.4 Electromagnetic compatibility Guideline & Manufacturer Declaration

The FDM-system meets all requirement of international standard EN 60601-1-2.
(Medical electrical equipment - Part 1-2: General requirements for safety -Collateral standard:electromagnetic compatibility requirements and tests)

Test Center:

SCHWILLE - ELEKTRONIK
Produktions- und Vertriebs GmbH
Benzstrasse 1A
85551 Kirchheim

Test Report 2575

More detailed information concerning the EMC-data of the FDM-system and manufacturer instruction is provided within the tables of this chapter.

 WARNING	Electrical equipment in the medical field is subject to particular precautionary measures as regards the EMC (Electromagnetic Compatibility) and must be installed and put into operation in accordance with the instructions given below.

 WARNING	Even though the motion analysis system FDM fully complies with the requirements of the standard EN 60601-1-2 it cannot be completely exempted that portable and mobile RF communications equipment may affect the system. If ever possible such devices should not be operated within close proximity of the system environment during measurements.

 WARNING	The use of accessories, particularly cables for connecting to the PC, which are not supplied by zebris for the FDM force-distribution measuring system, or explicitly recommended for use with the device, can lead to a reduced resistance to interference of the FDM force-distribution measuring system.

 WARNING	The FDM force-distribution measuring system may on no account be used in the direct proximity of, or stacked with other equipment. Should it be unavoidable to have the operation set up in the direct proximity of, or stacked with other devices, it is mandatory to monitor the device and check that the operation for this arrangement conforms to the regulations.

Guidelines and Manufacturer's Statement - Electromagnetic Emission		
The FDM force-distribution measuring system is intended for use in the electromagnetic environment described below. The customer or user of the FDM force-distribution measuring system should ensure that it is operated in such an environment.		
Emitted interference measurements	**Compliance**	**Electromagnetic environment guidelines**
RF emissions acc. to CISPR 11	Group 1	The FDM force-distribution measuring system uses RF energy exclusively for its internal functions. Therefore its RF emission is very low and it is unlikely that electronic equipment in close proximity will experience interference.
RF emissions acc. to CISPR 11	class B	The FDM force-distribution measuring system is intended for use in all facilities including those in residential areas and those directly connected to a public utility network also supplying buildings used for residential purposes.
Emission of harmonic oscillations acc. to IEC 61000-3-2	class B	
Emission of voltage fluctuations / flickers acc. to IEC61000-3-3	in compliance	

Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity			
The FDM force-distribution measuring system is intended for use in the electromagnetic environment described below. The customer or user of the FDM force-distribution measuring system should ensure that it is operated in such an environment.			
Interference immunity tests	**IEC 60601 test levels**	**Compliance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV atmospheric discharge	± 6 kV contact discharge ± 8 kV atmospheric discharge	Flooring should be of wood or concrete or laid with ceramic tiles. If the flooring is made of synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interferences/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment.
Blackouts, brownouts and fluctuations of the power supply acc. to IEC 61000-4-11	< 5% U_T (> 95% crash of the U_T) for ½ period 40% U_T (60% crash of the U_T) for 5 periods 70% U_T (30% crash of the U_T) for 25 periods < 5% U_T (> 95% crash of the U_T) for 5 s	< 5% U_T (> 95% crash of the U_T) for ½ period 40% U_T (60% crash of the U_T) for 5 periods 70% U_T (30% crash of the U_T) for 25 periods < 5% U_T (> 95% crash of the U_T) for 5 s	The quality of the supply voltage should be the same as the voltage of a typical business or hospital environment. If the user of the FDM force-distribution measuring system requires the continuation of functionality also after power interruptions/disruptions, it is recommended to provide the FDM force-distribution measuring system with power from an uninterruptible power supply.
Magnetic field with supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of the mains power frequency should comply with the typical values of a business and hospital environment.
NOTE A U_T is the a.c. main voltage prior to applying the test levels.			

Guidelines and Manufacturer's Statement - Electromagnetic Interference Immunity

The FDM force-distribution measuring system is intended for use in the electromagnetic environment described below. The customer or user of the FDM force-distribution measuring system should ensure that it is operated in such an environment.

Interference immunity tests	**IEC 60601 test levels**	**Compliance level**	**Electromagnetic environment guidelines**
			Portable and mobile wireless sets should not be used in closer proximity to the FDM force-distribution measuring system, including the cables, than the recommended safety distance, that is calculated on the basis of the formula suitable for the transmitting frequency. **Recommended safety distance:**
Conducted RF interference quantities acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1{,}2\sqrt{P}$
Radiated RF interference quantities acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2.5 GHz
			With *P* as the rated output of the transmitter in watts (W) according to the information provided by the manufacturer of the transmitter und *d* as the recommended safety distance in meters (m). The field strength from fixed RF transmitters as determined by an electromagnetic site survey [a] is less than the compliance level [b] in all the frequencies. Interference is possible in the proximity of devices featuring the following pictograph 

NOTE 1 The higher value applies in the case of 80 MHz and 800 MHz

NOTE 2 These guidelines may not be applicable in all situations. The spread of electromagnetic waves is influenced by absorption and the reflections of buildings, objects, and people

a The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile services, ham radio stations, AM and FM radio and TV broadcasters is theoretically not 100% predictable. A site study is recommended to determine the electromagnetic environment as a result of stationary RF transmitters. If the measured field strength at the site of the FDM force distribution measuring system exceeds the compliance levels listed above, the FDM force distribution measuring system must be monitored to document its proper functionality at every place of application. Additional measures might become necessary, e.g. modifying the orientation or moving the location of the FDM force-distribution measuring system, if unusual performance characteristics are observed.

b The field strength is less than 3 V/m for the frequency range of 150 kHz to 80 MHz

Recommended Safety Distances between Portable and Mobile RF Telecommunications Devices and the FDM/FDM force-distribution measuring system

The FDM force-distribution measuring system is intended for use in an electromagnetic environment where RF interference quantities are controlled. The customer or user of the FDM force-distribution measuring system can contribute towards preventing electromagnetic emissions by complying with the minimum distance between portable and mobile RF telecommunications devices (transmitters) and the FDM force-distribution measuring system, as recommended below in accordance with the maximum output power of the communication device.

Rated output of the transmitter (W)	**Safety distance based on the transmitting frequency (m)**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2{,}3\sqrt{P}$
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

The safety distance for transmitters with a rated output not listed in the table above, can be calculated by applying the formula corresponding to the respective column, whereby P is the rated output of the transmitter in watts (W) as specified by the transmitter manufacturer.

NOTE 1 between 80 MHz and 800 MHz the higher value is valid.

NOTE 2 These guidelines may not be applicable in all situations. The spread of electromagnetic waves is influenced by absorption and the reflections of buildings, objects, and people.

8.5 Declaration of conformity medical platforms

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

zebris Medical GmbH

Hersteller / manufacturer	**zebris Medical GmbH** Max-Eyth Weg 43 88316 Isny Deutschland / Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

das Medizinprodukt / the medical device	**Kraftverteilungsmesssystem FDM** **Force Distribution Measurement System FDM**
Modell/Typ / Model/Type	**FDM-SX, FDM-S** **FDM-1.5, FDM-2, FDM-3**
UMDNS Nummer / UMDNS Code	**17-242**
Klassifizierung / classification	**Im**
nach Regel / according to rule	**12**

den Anforderungen der unten genannten Richtlinien / Normen soweit anwendbar entspricht.
meets all requirements of the directives and standards listed below which apply to it.

Konformitätsbewertungsverfahren nach / conformity assessment procedure acc. to	**Richtlinie 93/42/EWG Anhang V** geändert durch Richtlinie 2007/47/EWG **Directive 93/42/EEC Annex V** amended by Directive 2007/47/EEC
Angewandte harmonisierte Normen / Applied harmonized standards	**DIN EN 1041** **DIN EN 10993-1** **DIN EN 13485** **DIN EN 14971** **DIN EN 15223-1** **DIN EN 60601-1** **DIN EN 60601-1-2** **DIN EN 62304** **DIN EN 62366**

Diese Konformitätserklärung gilt für alle oben gelisteten Medizinprodukte welche am oder nach dem Ausgabedatum von zebris hergestellt worden sind. Die Gültigkeit dieser Konformitätserklärung endet mit der Veröffentlichung einer Konformitätserklärung neueren Datums, falls dies durch technische Änderungen am Produkt oder durch Änderungen von Richtlinien oder Normen erfolgen muss, spätestens jedoch mit Ablauf des CE-Zertifikats nach Richtlinie 93/42/EWG mit Nr. CE 573437.

This declaration of conformity is valid for all medical devices listed above which have been manufactured by zebris at or after the date of issue. The validity of this declaration expires with the release of a new declaration due to technical or legal amendments – however latest at the expiry date of the CE-certificate according to directive 93/42/EEC with certificate number CE 573437.

D-88316 Isny, 21. Juni 2013

Wolfgang Brunner
Geschäftsführer / Managing Director
zebris Medical GmbH

Benannte Stelle / Notified Body
BSI Group Deutschland GmbH
D-60314 Frankfurt am Main

CE 0535

8.6 Declaration of conformity non medical platforms

EG - KONFORMITÄTSERKLÄRUNG
EC - DECLARATION OF CONFORMITY

zebris Medical GmbH

Hersteller / manufacturer	**zebris Medical GmbH** Max-Eyth-Weg 43 88316 Isny Deutschland / Germany

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that

Produktname / Product name	**Kraftverteilungsmesssystem FDM** **Force Distribution Measurement System FDM**
Modell/Typ / Model/Type	**FDM-G, FDM-GP, FDM-J** **FDM-RW1.7, FDM-RW2.4**

den Anforderungen der unten genannten Richtlinien / Normen soweit anwendbar entspricht.
meets all requirements of the directives and standards listed below which apply to it.

Konformitätsbewertungsverfahren nach / conformity assessment procedure acc.	**Richtlinie 2004/108/EG und Richtlinie 2006/95/EG** **Directive 2004/108/EEC and Directive 2006/95/EEC**
Angewandte Normen / Applied Standards:	**DIN EN 9001** **DIN EN 50081-1** **DIN EN 55022** **DIN EN 50081-2** **DIN EN 55024** **DIN EN 60950-1**

Das Qualitätsmanagementsystem der zebris Medical GmbH erfüllt alle Anforderungen von DIN EN ISO 9001, ist zertifiziert und jährlich überwacht durch BSI Group Deutschland GmbH, Frankfurt.

Diese Konformitätserklärung gilt für alle oben gelisteten Produkte welche am oder nach dem Ausgabedatum von zebris hergestellt worden sind. Die Gültigkeit dieser Konformitätserklärung endet mit der Veröffentlichung einer Konformitätserklärung neueren Datums, falls dies durch technische Änderungen am Produkt oder durch Änderungen von Richtlinien oder Normen erfolgen muss.

The quality management system of zebris Medical GmbH fulfills all requirements of DIN EN ISO 9001 and is certified and annually monitored by BSI Group Deutschland GmbH, Frankfurt.

This declaration of conformity is valid for all products listed above which have been manufactured by zebris at or after the date of issue. The validity of this declaration expires with the release of a new declaration due to technical or legal amendments.

D-88316 Isny, 28. Juni 2013

Wolfgang Brunner
Geschäftsführer / Managing Director
zebris Medical GmbH

CE

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