PLANTA PRESS

MANUAL

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Table of content

Table of content

1. The PlantaPress pressure measuring system

1.1 Intended use and intended users

The PlantaPress product is used as intended for the short-term recording of static and dynamic pressure distributions in the context of medical issues (e.g. in the field of orthopaedics, diabetology, decubitus prophylaxis, sports medicine, etc.). Anatomically adapted sensors enable the examination of different body regions (e.g. foot-shaped sensors or rectangular sensors for sitting and lying surfaces).

The pressure distributions obtained with PlantaPress are used as an aid for the production of customized support systems (e.g. orthopaedic shoe and foot supports, anatomically adapted seat cushions or reclining mats). PlantaPress can also be used to check the effectiveness of the manufactured support systems as part of quality control.

PlantaPress should always be seen as a supplement to other diagnostic and manual procedures. An assessment of the individual condition of the examined body region, the determination of pressure-relieving measures or the adaptation of patient positioning systems must not be based solely on the measurement results and visualizations obtained with PlantaPress!

It is the responsibility of the user (e.g. doctor or orthopaedic technician) to compare the conclusions drawn from the measurement results with other suitable examination methods. PlantaPress therefore only addresses medical professionals.

1.2 Target groups and medical conditions

1.2.1 Intended patient group

PlantaPress addresses patients with a need for individual positioning systems. This includes the following groups in particular:

- Patients with a need for individual insoles and custom-made shoes with a patient weight between 40kg and 120kg and a shoe size between 35 and 46. Custom-made shoes are possible for patients outside this specification.
- Patients with an increased risk of pressure sores with a body weight between 40 and 120 kg. This patient group includes, in particular, patients who regularly sit in a wheelchair or long-term bedridden patients who require pressure-relieving seat or reclining cushions. Custom-made products may be possible for patients outside this specification.

PlantaPress is a complementary tool for identifying and localizing pressure peaks and stress zones in the examined areas of the body that could potentially lead to pain or inflammation. In this context, PlantaPress can be used as an aid for the production of pressure-relieving support systems. PlantaPress cannot diagnose diseases.

1.2.2 Indications

PlantaPress is a supplementary aid for the following indications:

- diabetic or rheumatic feet,
- foot malpositions and deformities,
- orthopaedic problems of the foot,
- decubitus (category I).

1.2.3 Contraindications

The use of PlantaPress is not permitted if:

- the subject is unable to safely perform the activity required for the measurement procedure,
- the subject is unable to safely assume the posture required for the measurement procedure (e.g. standing/sitting)
- the subject has open wounds in the area of the body region to be examined.

1.3 System description

PlantaPress consists of pressure sensors that are geometrically adapted to the body region to be examined. Each pressure sensor contains up to 256 pressure-sensitive measuring points.
Sensors are available in sole and rectangular shapes.
Depending on the sensor type and the body region to be examined, the sensors are inserted into the patient's shoes or placed on sitting/lying surfaces. Each sensor is connected to a Wireless Module, which records the sensor data, stores it temporarily and transmits it wirelessly to a central Master Module.
The Master Module serves as a communication center and is connected to a free USB port on the PC. The Master Module can simultaneously record the sensor data from up to 4 Wireless Modules.

The "VisuPress" Windows software is used to operate and display measurement data. VisuPress has a modern user interface that optimally supports the performance of pressure measurements.

The following functions are included in VisuPress:

- Patient management
- Display of real-time measurement data
  - Pressure distribution
  - Center of gravity
- Recording function
- Playback function (real time and slow motion)
- Analysis functions
  - Hydrograph
  - Average values
  - Pressure maxima
  - Center of gravity curve
- PDF Report generation
- CSV data export

1.4 Scope of delivery

The PlantaPress pressure measurement system is housed in a compact transport case with integrated charging function.
The following system components are included in the standard scope of delivery:

Quantity	Component	Classification
2 pieces	Wireless Module with fastening strap	Application part according to DIN EN 60601-1
5 pair	Sensor soles double sizes 37/38 - 45/46	Application part according to DIN EN 60601-1
1 piece	USB Master Module	Accessory
1 piece	"VisuPress" software (on USB installation stick)	Accessory
1 piece	Transport case with integrated charging system	Accessory
1 piece	USB Cable	Accessory for transport case
1 piece	USB Power supply unit	Accessory for transport case

1.5 Technical data

System component / device	Technical data	
Transport case	Weight	approx. 6kg (with standard scope of delivery)
	Dimensions	460mm x 350mm x 240mm
	Power supply	max. 5V/2A via USB
	Charging system	2 x interface for wireless charging of the Wireless Modules (QI standard)
Wireless Module	Dimensions	85mm x 85mm x 30mm
	weight	90g
	Measuring channels	256
	Measuring frequency	max. 100Hz
	Power supply	LiPo battery
	Communication	Proprietary wireless connection to the Master Module
	Measuring range	approx. 15m indoors / approx. 100m outdoors
Master Module	Dimensions	55mm x 25mm x 17mm
	weight	20g
	Computer interface	USB
Sensor soles	Shoe size	Standard double sizes 35/36 - 45/46, customized sizes and shapes
	Thickness	approx. 2.5mm
	weight	approx. 175g (per pair / size 45/46)
	Sensor number	Standard sizes: 215 sensor cells, different number of sensors for customized designs
	Measuring range	1-60 N/cm
Operating conditions	Temperature	10°C – 30°C
	Humidity	Dry environment, air humidity < 70%

PC system requirements

Desktop PC or notebook with Windows 10 or 11 / 64 bit (with current version), at least Intel Core Processor i5 / i7 (4th gen) or AMD Ryzen 3 / 5 4xxx / 7 3xxx or newer, at least 8GB or more RAM, DirectX 11 graphics, screen with Full HD resolution (1920x1080)

1.6 Markings

Important details and safety-relevant information are shown on the type plates of the system components are represented by pictograms. The signs and symbols used are explained in the following table:

Sybol / Pictogram	Meaning
CE	CE marking
SN	Serial number in the format YYMMDDXXXX YY - Year of manufacture, two digits MM - month of manufacture DD - day of manufacture XXXX - consecutive number from the day of manufacture
UDI	Unique Device Identification (UDI)
MD	Indicates that the item in question is a medical device

Sybol / Pictogram	Meaning
	Follow the instructions for use!
	Application part type B according to DIN EN 60601-1
	Do not dispose of in household waste, but at a collection point for electronic devices or at the manufacturer!
	The name and address of the manufacturer can be found on the rating plate in the immediate vicinity of this symbol
	The name and address of the distributing company can be found on the rating plate in the immediate vicinity of this symbol
	Protect from moisture!

2. Notes on use and safety

Reporting of incidents:
Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the competent authority of the Member State in which the user and/or patient is established!

Data protection:
To protect against data misuse through access to stored personal data, the device running VisuPress (e.g. PC, laptop) must not be left unattended in an unlocked state during operation.

2.1 Application of PlantaPress

The use of PlantaPress is limited to the external surfaces of the human body.
PlantaPress is not intended for long-term examinations.
The duration of the examination should not exceed 15 minutes.

2.2 Transport case

The transport case is used to safely transport and load the Wireless Modules.
The transport case must be carried by the transport handle.
When placing the case on the floor or on tables, ensure that it stands securely.
There is an increased risk of pinching/crushing when closing the case lid.

2.3 Wireless Modules

Lithium polymer battery

The Wireless Modules have an integrated lithium-polymer battery. To avoid damaging the battery, the Wireless Modules must not be opened or exposed to increased humidity.
The lithium-polymer battery may only be replaced by the manufacturer of the PlantaPress system.

Charging the Wireless Modules

The Wireless Modules may only be charged by the integrated charging system of the transport case.
To ensure efficient charging of the Wireless Modules, they should be charged with the case lid open.
Charging with the case lid closed extends the charging time.

Heating of the Wireless Modules

The Wireless Modules heat up during the charging process. This can lead to unpleasant sensations for the patient.
Therefore, do not apply the Wireless Modules to the patient when they are warm!

2.4 Sensors

The sensor soles must not be damaged by sharp-edged or pointed objects.
The sensor surface and the connection cable must not be bent. The minimum permissible bending radius is 15 mm.
Tensile loads on the sensor cable must be avoided.

2.5 Attaching the sensor system to the customer

The sensor soles must be inserted into the shoe in such a way that the connecting cables on the outside of the legs are led out of the shoe. The Wireless Modules must be attached to the outside of the lower legs using the fastening straps supplied of the lower legs and connect them to the sensor soles.
Avoid creating loops with the sensor cable. If necessary, additional fixations should be made, to prevent the cables or Wireless Modules from getting caught. When using the device on patients with gait disorders the examiner is particularly required to monitor the patient during the measurement and prevent them from falling.

For hygienic reasons, PlantaPress must not be used barefoot.
Avoid direct skin contact by wearing socks.
The Wireless Module must also be placed over clothing (trousers / sock leg or similar).

A detailed description of “Attaching the Wireless Modules to the patient” is provided in 4.3.4 on page 25.
and the “Inserting the sensors into the shoes” is described in section 4.4.2 on page 27.

2.6 Moisture

PlantaPress may only be used in dry environments. Use in damp environments (e.g. outdoors in the rain) or handling liquids while using PlantaPress is therefore not permitted.

Contamination with wound fluids must be avoided!

2.7 Cleaning and disinfection

For reasons of hygiene and health protection, all reusable medical devices must be cleaned and disinfected after each use on the patient, must be cleaned and disinfected after each use on the patient. The hygiene regulations of the individual national and transnational legal provisions of medical practices, medical supply stores and clinics must be observed.
The following parameters for cleaning and disinfection must be observed, as these have been subjected to a validated procedure.
The cleanliness of the medical devices cannot be guaranteed if the reprocessing is carried out with deviating parameters.

⚠ **Contaminated or used medical devices must be separated from clean medical devices during use!**
Only use alcohol-free disinfectant wipes! Do not use liquid disinfectants!

Cleaning instructions

1. Wipe the Planta Press sensor base and Wireless Module with alcohol-free disinfectant wipes until they are completely wetted and allow to dry for the entire exposure time.
2. Visually check the cleanliness of the surface of the medical device.

⚠ **Repeat steps 1-2 if there is visible contamination.**

Then check the medical device for intactness.
The medical device must be free from other contamination, wear or damage.

2.8 Calibration

The calibration of the sensor soles must be checked at least once a year or every 5000 steps (whichever comes first) be checked by the manufacturer. The sensors must be sent to the manufacturer for this purpose.
The VisuPress software has a notification function for calibration.

2.9 Visual inspection

The following visual inspections must be carried out by the user at least once a month:

Visual inspection of the sensor soles

- Sensor surface clean?
- Sensor surface and cable free of kinks and superficial damage?
- Connector plug without damage?

Visual inspection of the Wireless Modules and the Master Module

- Wireless Modules and Master Module clean and undamaged?
- Fastening straps incl. buckle undamaged?

Visual inspection of the transport case

- Transport case clean and undamaged?
- Electrical components checked by a qualified electrician (once a year)

If you notice any damage, please contact the manufacturer.

2.10 Storage and transport

To protect against dust, moisture and other contamination or damage, the system components must be stored and transported in the transport case. Please always ensure that the sensor soles are only stored in the compartments provided in the transport case.

Under no circumstances should the sensors be folded or crumpled.

2.11 Disposal

The medical device must be disposed of in accordance with the locally applicable regulations and environmental regulations. The degree of contamination of the medical device must be taken into account - decontamination prior to disposal may therefore be considered necessary.

The components of the medical device contain electronic parts and must therefore be disposed of as electronic waste in the event of a defect or returned to the manufacturer.

2.12 Modification / manipulation of system components

Any modification and manipulation of system components as well as improper use can lead to failure and void any warranty claims.

3. Quickstart

The following describes the most important steps you need to take to perform your first successful pressure measurement with the PlantaPress pressure measurement system:

1. When using PlantaPress for the first time, please install the VisuPress software from the supplied USB installation stick on your PC with Windows 10 or Windows 11 operating system.

2. Plug the USB Master Module into a free USB port on your PC. The USB Master Module will initially pulse yellow. If the PC is connected to the Internet, the required USB driver will be installed automatically, otherwise, please install the driver from the USB installation stick supplied.

3. Now switch on the Wireless Modules. After a few moments, both the Wireless Modules and the Master Module pulse green. The connection has been established.

4. Select the sensor size that matches your patient‘s shoe size.

5. Place the sensor soles in the shoes.

6. Attach the Wireless Modules to the patient‘s lower leg. Use the elastic straps supplied for this.

7. Now connect the insoles to the Wireless Modules. To do this, bring the sensor plug close to the sensor socket of the Wireless Module. Integrated magnets will help you to position it correctly. A light press on the sensor plug establishes the connection.

8. Now start the VisuPress software

9. Select an existing patient or create a new patient.

10. You can then connect to the measurement system:
- To do this, click on the “Connect” symbol.
- In the connection dialog, you will see an overview of the connected system components.
  If all components light up green, you can start the live view.

11. You can start your first recording by clicking the “Record” button at the top right of the screen.

12. Clicking the “Record” button again ends the recording.

13. The recording is downloaded from the Wireless Modules and automatically displayed in playback mode.

Detailed instructions on the functions and possibilities of the PlantaPress system and the associated VisuPress software can be found in the following chapters.

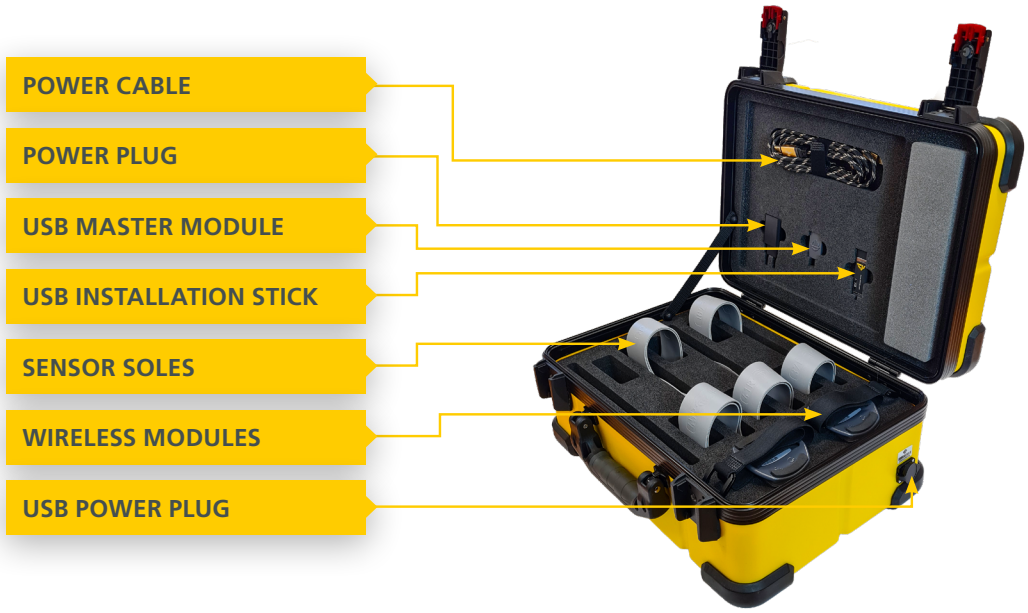
4. The PlantaPress Hardware

4.1 Transport case

4.1.1 Description

The transport case is used for safe transportation and storage of the system components. An integrated charging system allows the Wireless Modules to be conveniently charging of the Wireless Modules directly in the case.

The charging system is powered via a side-mounted USB port on the side. A cover cap protects the the USB port from dirt and moisture.



4.1.2 Charging the Wireless Modules

The Wireless Modules are charged directly in the case. To do this, carry out the following steps:

1. Remove the protective cover from the USB socket, located on the side of the case.
2. Connect the case to the mains using the USB cable + mains adapter supplied. (ATTENTION: Only use the the supplied cable + power supply unit)
3. If the Wireless Modules are not already in the case: Place the Wireless Modules in the recesses provided
4. The Wireless Modules signal the charging process by pulsing in color. The color indicates the current charging status of the Wireless Modules: The meaning of the color is explained in the following table explained in the following table:

LED Status	Meaning
one LED, red, flashing slowly	Battery <20%
one LED, yellow, flashing slowly	Battery ~50%
one LED, green, flashing slowly	Battery 100%

5. Once the Wireless Modules are fully charged, you can remove the USB cable and power supply unit and close the USB socket again.

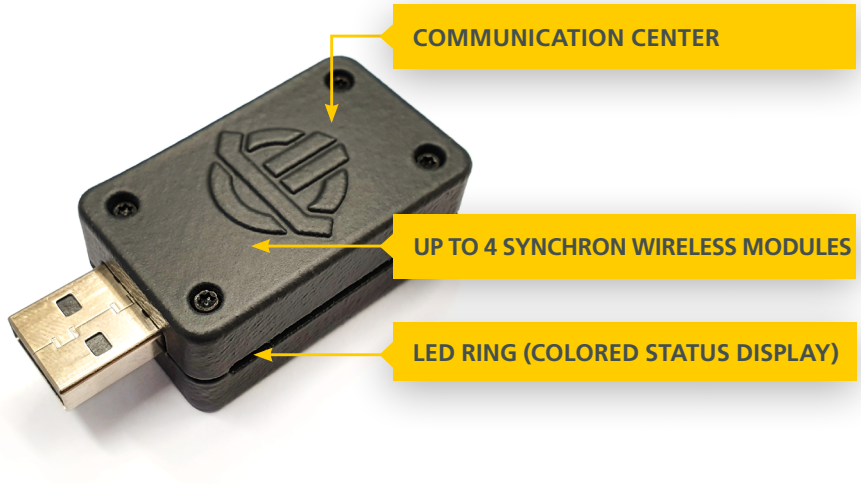
Caution: The Wireless Modules heat up during the charging process. To ensure efficient charging of the Wireless Modules, they should be charged with the case lid open. Charging with the case lid closed extends the charging time.

4.2 USB Master Module

4.2.1 Description

The Master Module is the communication center of PlantaPress. The Master Module is connected directly to the USB interface of a Windows PC. It can communicate simultaneously with up to 4 Wireless Modules, record their measurement data and forward it to the VisuPress software.

Like the Wireless Modules, it has an LED ring and indicates its system status using different colored light patterns. An overview of the possible LED ring light patterns can be found in the following table.



4.2.2 LED ring

Meaning of the light colors of the LED ring:

State	System status	LED mode
DISCONNECTED	No connection to a Wireless Module; communication inactive	double flashing; standard color green
CONNECTED	Connection to at least one Wireless Module; communication active	slow pulsing; standard color green
PAIRING	Master Module can connect to Wireless Module	fast pulsing; blue
OFF	Master Module is switched off	off

4.3 Wireless Modules

4.3.1 Description

The Wireless Modules are the central data acquisition units of PlantaPress. They are used to record the sensor data, stored and transmitted to the Master Module by radio. An integrated data memory guarantees that no data is lost even if the data is not lost even if the radio connection is interrupted. A circumferential LED ring provides information on the current system status by means of different colored light patterns. An overview of the light patterns can be found in section 4.3.3.

An integrated rechargeable battery enables up to 4 hours of uninterrupted use (depending on the required transmission power and ambient conditions). The battery can be charged directly in the transport case via a wireless interface (see section 4.1.2 on page 20). The operating elements of the Wireless Module are described in section 4.3.2. Instructions on how to correctly connect the Wireless Module can be found in section 4.3.4 on page 25.

4.3.2 Buttons

Button function:

Button	Function
Power Button	• Short press of the button: Switches the electronics on • Button pressed for longer than 2 sec.: Switches the electronics off • Display of the battery status with a short press of the button when switched on
Reset Button	• Short press of the button: Restarts the Wireless Module • Button pressed for longer than 5 sec.: Wireless Module is switched to the bootloader
Pairing Button	• Starts the pairing mode for the first pairing with the USB Master Module

4.3.3 LED Ring

Meaning of the light colors of the LED ring:

Context of use	System status	DTa	RCa	Signaling	
Normal operation	Switch on			LED ring lights up successively, starting with the power button, System is ready for operation when all LEDs light up; standard color: green	
	not connected		X	Complete LED ring: double flashing; standard color: green	Ring center flashes red
	connected			Complete LED ring: slow pulsing; standard color: green	
			X	Complete LED ring: slow pulsing; standard color: green	Ring center flashes red
		X		Complete LED ring: slow pulsing; standard color: green	
		X	X	Complete LED ring: slow pulsing; standard color: green	Ring center flashes red
	Switch off			LED ring lights up and goes out successively, starting with the power button Standard color: green	
Plugging in a sensor	Sensor detection			LED ring goes on and off successively on both sides, starting at the sensor connection; standard color: green	
Pairing button pressed	Pairing Mode active			Complete LED ring fast pulsing, color: blue	
Power button pressed	Battery status < 20%			all LEDs, red, fast flashing, 4x	
	Battery status ~50%			all LEDs, yellow, fast flashing, 4x	
	Battery status 100%			all LEDs, green, fast flashing, 4x	
in the case	Battery status < 20%			one LED, red, slow pulsating	
	Battery status ~50%			one LED, yellow, slow pulsating	
	Battery status 100%			one LED, green, slow pulsating	

DTa = Data Transmission active
RCa = Recording active

4.3.4 Attaching the Wireless Modules to the patient

The Wireless Modules are attached to the patient's lower leg using elastic straps. One elastic band is used for each Wireless Module. The elastic band is threaded through the side tabs of the Wireless Module so that it runs along the back.

Best Practice:

- Only pull the elastic band as tight as is comfortable for the patient. comfortable for the patient.
- Do not apply the Wireless Modules and elastic bands to bare skin.

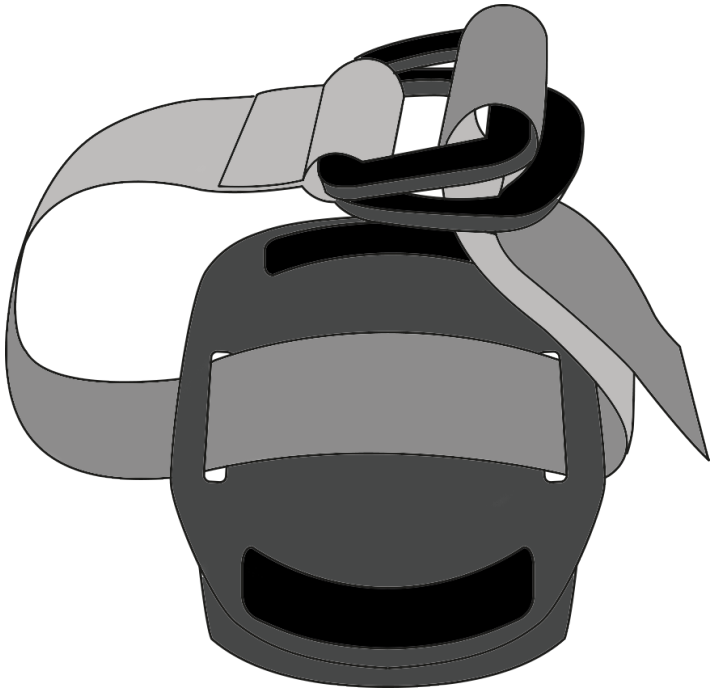
1.

2.

3.

4.

Closure scheme:

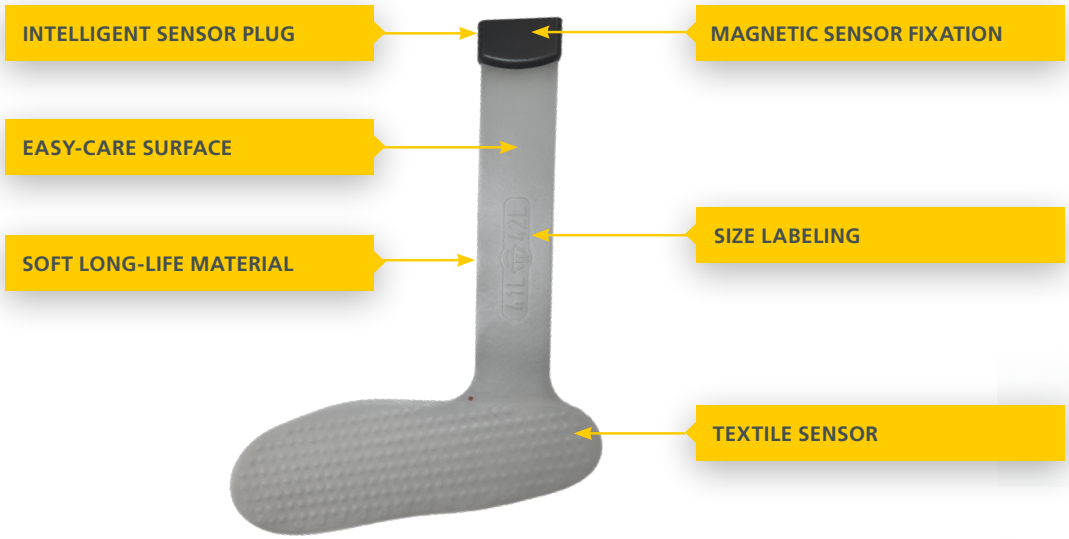


4.4 Sensors

4.4.1 Description

The sensors form the heart of PlantaPress. Depending on the shape, size and application, each sensor contains up to 256 pressure-sensitive measuring points. Sensors in sole and rectangular shapes are available as standard. Customized production for special measuring tasks is possible. The sensors have a completely textile structure and are therefore particularly soft and supple. The textile structure is protected by a robust protected by a robust artificial leather cover.

The connection between the sensor and the Wireless Module is established via an intelligent connector.
This ensures that all information about the sensor is automatically transmitted to the Wireless Module when the sensor is plugged in, so that the user does not have to for the user.
Magnets integrated into the sensor plug make it easier to correct positioning of the sensor plug when plugging the sensor the Wireless Module (Magnetic Positioning System).



PLANTA PRESS

4.4.2 Inserting the sensors into the shoes

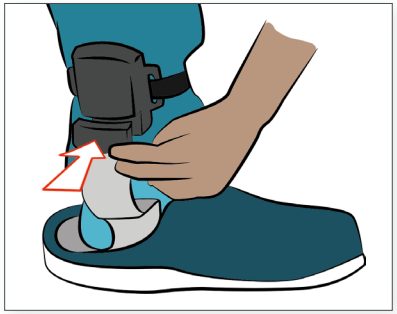
The sensor soles must be inserted into the shoe in such a way that the connecting cables are led out of the shoe on the outside of the legs. are led out of the shoe. The sensor surface and the connection cable must not be kinked or damaged by sharp-edged objects. The minimum permissible bending radius of the sensor soles and the connection cable is 15 mm. Tensile loads on the sensor cable must be avoided.

Best Practice:

- Grasp the outer sides of the sensor sole with one hand. Apply light pressure to the outside of the sole so that it curves lengthways.
- Now insert the sole into the shoe. Due to the curvature of the sole, the sole retains its shape and can be pushed forward to the tip of the shoe.
- Now release the sole and correct the position if necessary.
- Make sure that the sole lies crease-free in the shoe and that the connection cable is led out smoothly on the outside of the shoe.

4.4.3 Connecting the sensors to the Wireless Modules

To connect the sensors to the Wireless Modules, bring the sensor plug close to the sensor socket of the Wireless Module.
Integrated magnets help you to position it correctly.
A light press on the sensor plug establishes the connection.
To attach the Wireless Modules to the patient, see 4.3.4 on page 25.



5. The VisuPress software

The VisuPress software is supplied on a USB Stick together with the product case.
It is only suitable for computers with the Microsoft Windows 10 or 11 operating system.

5.1 Installation

Connect this USB stick to your computer and start the setup contained on it.
The VisuPress setup may start automatically after connecting the USB stick.

Follow the instructions of the installation wizard.

Once the installation has been successfully completed, you will find a shortcut for the VisuPress software on your desktop.
Another shortcut has been created in the Windows Start menu.

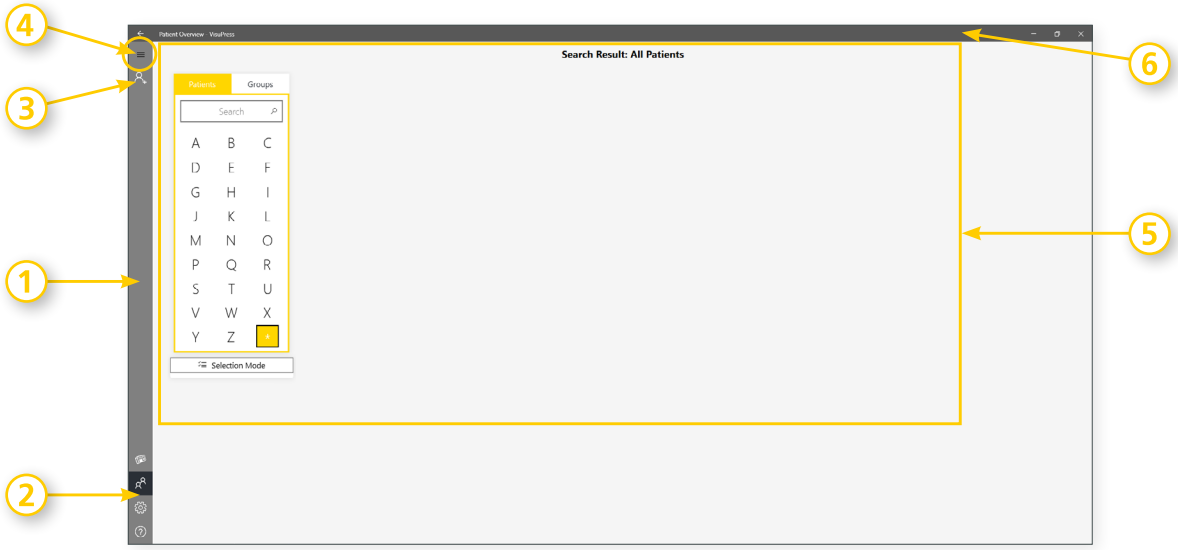
5.2 Structure of the User Interface

The VisuPress user interface is divided into several areas. On the left-hand side of the screen there is an always accessible navigation bar (1). The navigation bar contains static menu items (2). Dynamic, context-related menu items are displayed in the upper area (3).

To see a textual description of the menu items in addition to the icons, the navigation bar can be folded out using a toggle switch at the top (4).

If you have called up one of the menu items in the navigation bar, the “Back button” appears at the top of the bar, which you can use to return to the previously opened view in the navigation process. The behavior is similar to the back button of a web browser.

To the right of the navigation bar is an area in which the contents of the respective program functions are displayed (5). The title bar (6) always indicates which view (menu item) is currently open.



Structure of the APP

Tip: Tooltips with additional explanations will be shown if you position the mouse pointer on items or buttons for a short time.

5.3 Patient management

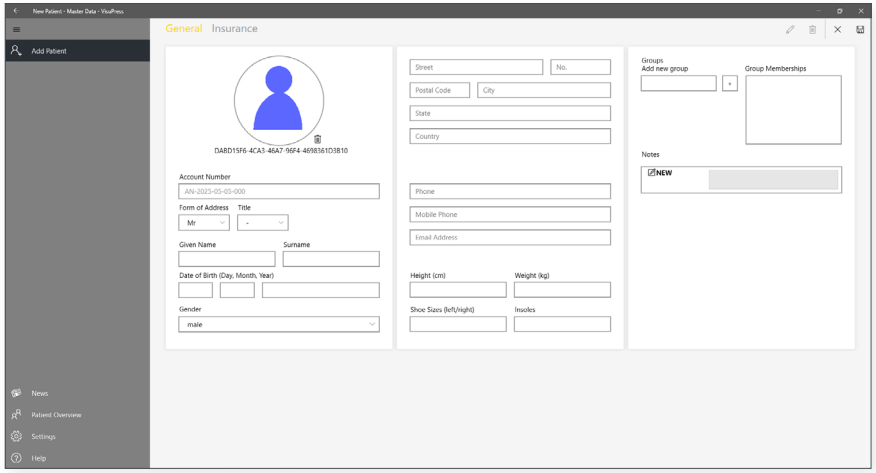
Patient management is the central entry point in VisuPress. New patients can be created here and existing patients can be managed. Patient management also offers convenient functions for searching for and grouping patients.

Note: Pressure measurements and recordings are always assigned to a specific patient. It is therefore necessary to first select or create a new patient in order to be able to carry out a pressure measurement.

5.3.1 Creating and editing patient profiles

VisuPress always starts with the patient overview. When you start the program for the first time, this view is empty. To create a new patient profile, select the menu item “Add patient” in the navigation bar at the top of the patient overview.

At the top of the input screen there is a navigation bar that can be used to switch between the “General” and “Insurance” tabs. There are also controls for editing and deleting patient data, as well as for discarding and saving changed data.



The input screen allows you to enter a wide range of information and comments about the patient. However, not all fields have to be filled in, only an “Account number” is mandatory. However, it is recommended to fill in at least the name fields so that the patient profile can be found quickly later.

Account number

The account number enables a unique identification of the patient. When a new patient profile is created, VisuPress automatically generates an account number which is made up of “year-month-day + a consecutive number”. However, you can also assign your own account number (e.g. the customer number of an existing administration system or similar).

Grouping

Under “Add new group” you can assign the patient profile to a group. To do this, enter the title of the desired group in the corresponding input window. Existing groups that match your entry will be displayed. Use the “+” button to link the patient profile to the group. A patient profile can be assigned to several groups at the same time.

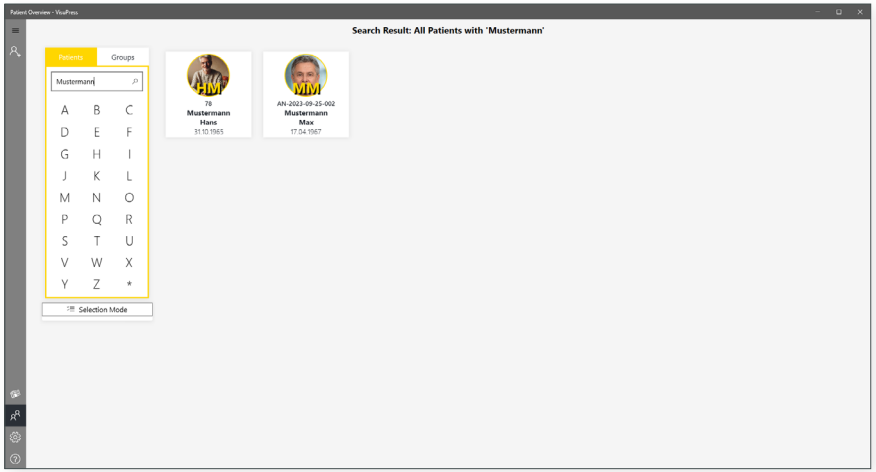
Notes

On the “General” page, you can also make free notes about the person. The notes are listed in chronological order. The most recent note is always at the top of the list, the oldest at the bottom. Notes can also be edited at a later date.

For each note, the time of creation and the time of the last time of the last change are also saved and displayed.
If you select an entry in the notes list, it is enlarged to improve readability and text entry. In addition, a small menu bar with possible actions is displayed at the top right of the note.

5.3.2 Search and filter patient profiles

The search and selection dialog is located on the left-hand side of the patient overview. The search results that correspond to the current search filter are displayed on the right-hand side.



The listed results of a search are represented by square list elements on which a photo (if a photo has been assigned), the surname and given name as well as the date of birth are displayed for patients. To make the search even easier, the patient's initials are also displayed.

The "Patient" and "Group" tabs at the top of the search dialog can be used to switch between the patient and group view. The star filter * lists all patient profiles.

The following search and filter functions are also available:

Letter filter

The letter filter filters according to the initial letters of the surnames of the patients or group names.

Free text search

With the free text search, you can search for given names, surnames, dates of birth or account numbers. It is sufficient to enter parts of the search terms. The search can be started with the Enter key or by clicking on the magnifying glass symbol. As you enter the search term, possible search hits are automatically suggested as a list below the input field and can be selected at any time.

Group search

By selecting a patient group, only patients within this group are displayed. The search and filter functions last used are retained and are also preset after the program is restarted.

5.3.3 Exporting, deleting or grouping patient profiles

The “Selection mode” button is located below the search dialog in the patient overview.
In selection mode, several patients or groups can be selected from the current patient overview according to the current search mode and edited together.

The following options are available for editing:

Export patient data
The patient data of all selected patient profiles is exported. If a group has been selected, the patient data of all group members is exported.

Deleting patient data
The patient data of all selected patient profiles are deleted.

Attention! If a group has been selected, only the group will be deleted. The patient profiles it contains are retained. If you want to delete all members of a group, first filter the members of the group and then delete them separately.

Assigning a group
All selected patient profiles are assigned to this group. If patient groups have already been selected, all patients profiles contained in these groups are also assigned to this additional group.

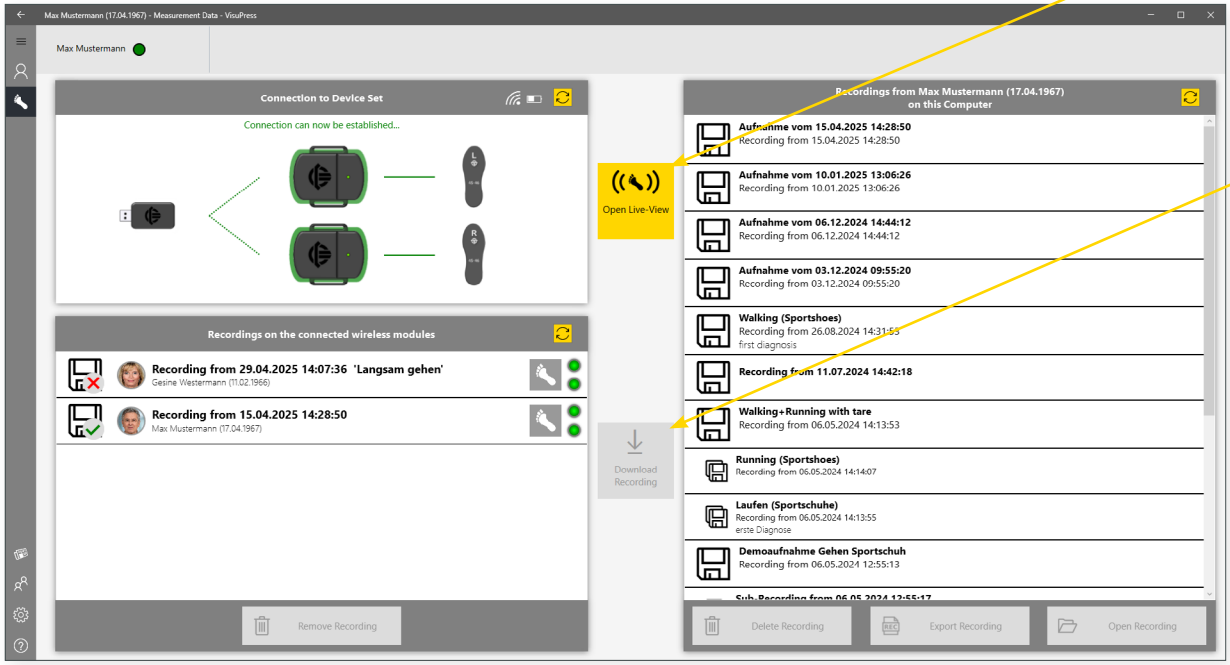
5.4 Measurement data acquisition

To record measurement data, first connect to the measurement system. Pressure measurements and recordings with PlantaPress are assigned to a specific patient, so you must select or create a patient before proceeding. Once a patient is selected, the measurement data view can be accessed via the left-hand navigation bar.

When you open the measurement data view, the measurement data start screen is displayed first. It is divided into a left-hand “Online” area with the connection display and the recording list of the connected wireless modules and the right-hand “Offline” area with the recording list of the recordings saved locally on the computer.

The following measurement data views are available:

- Foot pressure measurement (foot symbol)
- Seated pressure measurement (symbol with seated person)[1]



In the middle is the “Open live view” button, which becomes active as soon as the connection to the measuring system is established.

Below this is the “Download recording” button, which can be used to transfer previously selected recordings saved on the wireless modules to the computer.

Like the navigation bar, the menu bar can be extended using the “More” button (far right) to also display the labeling of the buttons.

[1] optionally available

5.4.1 Recording measurement data

5.4.1.1 Establishing a connection with PlantaPress

As soon as the measurement data start screen is opened, an attempt is automatically made to establish a connection to the components of the measurement system.

The connection view supports you in establishing the connection and provides the following information about the measuring system:

- Overview of the system components (USB Master Module, Wireless Modules, sensors)
- Connection status of the system components
- Charge status and radio signal strength of the Wireless Modules
- Type and size of the connected sensors

Follow the instructions in the connection view to establish a connection with PlantaPress. The connection is established according to the following diagram:

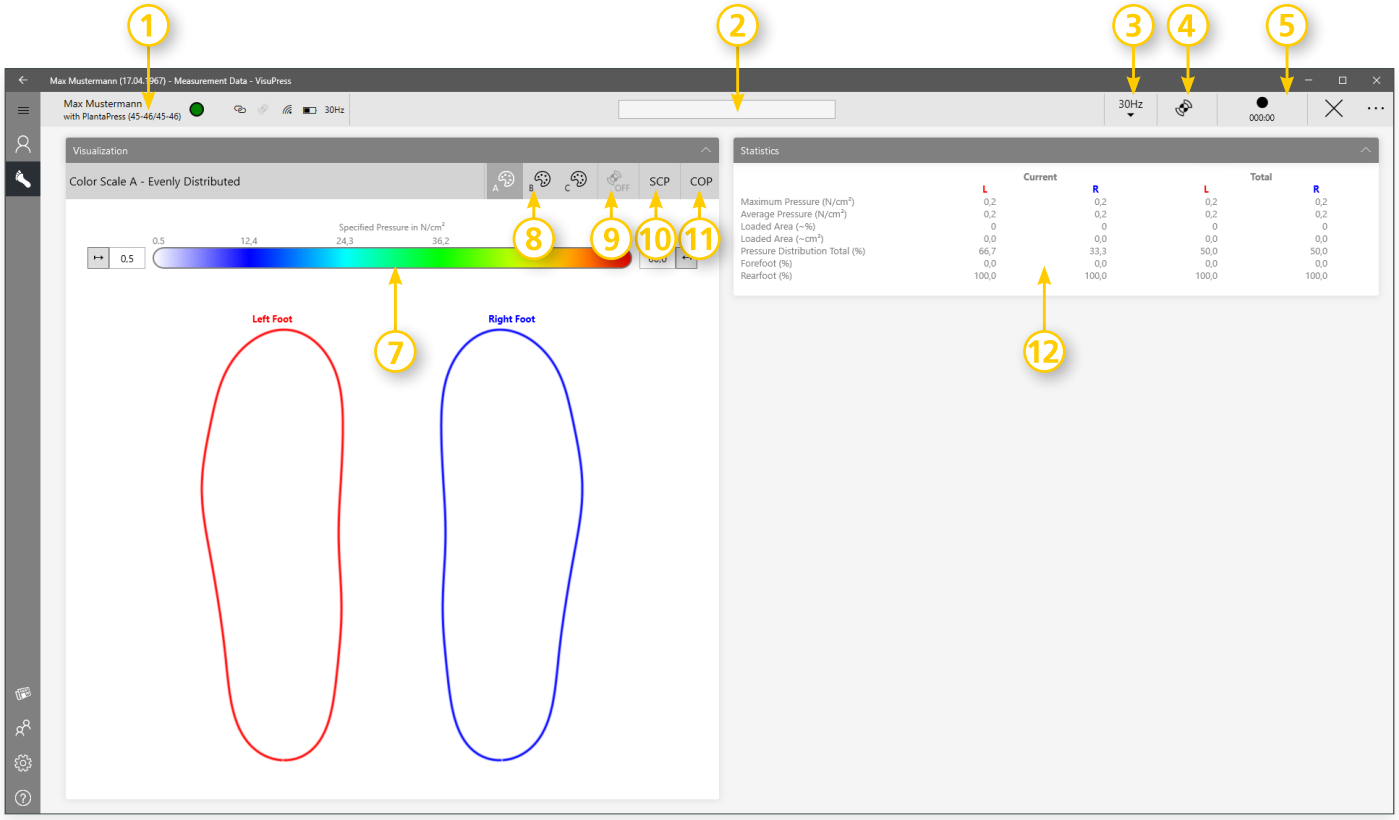
1. Find the USB Master Module on the PC.
   The USB Master Module symbol initially appears gray.
   As soon as the USB Master Module connected to the PC has been detected, the symbol appears in color and pulsates in the color of the USB Master Module.
2. Switch on the Wireless Modules.
   The Wireless Module icons initially appear gray. As soon as the Wireless Modules have been detected, the symbols appear in color and pulsate in the color of the Wireless Modules.
   In addition, the connecting lines between the Master Module and the Wireless Modules are colored green. As soon as the wireless modules are connected, the list of recordings on the wireless modules is updated and it is possible to select recordings and transfer them to the computer.

Note: **In order to established a connection between the Wireless Modules and the USB Master Module, they have to be paired with each other. The components are usually already paired when delivered and only need to be paired again after resetting to factory settings („5.5.4 Device Management“ on page 52).**

3. Connecting sensors
   The sensor icons initially appear gray. As soon as the sensors connected to the Wireless Modules have been detected, the symbols appear in color. In addition, the type and size of the sensors are displayed and the connection lines between the Wireless Modules and the sensors are colored green.
   Once all system components have been connected, the live view can be started.

5.4.1.2 Displaying live measurement data

Once a connection to the measurement system has been established, the Live View can be opened. The current pressure distribution and selected statistical values are displayed here in real time. In addition, various display options can be selected, taring can be carried out and recordings can be started. The function of the individual operating elements is described on the following page.



1 Patient data

2 Measurement designation

3 Measuring frequency

4 Tara function

5 Recording function

6 Pressure distribution

7 Color scale

8 Color palette

9 Toggle Tara

10 Toggle SCP

11 Toggle COP

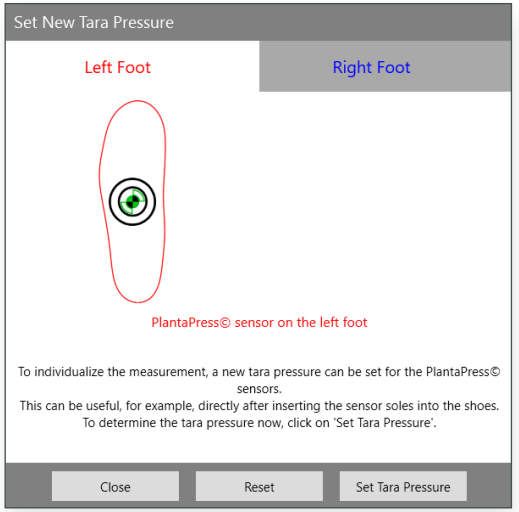
12 Statistics display

1. **Display for patient data**
   Name, date of birth and currently used sensors
2. **Name of the measurement (optional)**
   The name entered here is used as the title for the recording.
   If no name is entered, recordings are marked with
   the recording date instead.
3. **Measurement frequency (which the measurement data is recorded)**
   The measurement frequency entered here only refers to the
   recordings. Live data is displayed at a maximum of 30 Hz.
4. **Tara function**
   This button can be used to activate the tare function
   function can be activated - see section “5.4.1.4” on page 39.
5. **Button for the recording function**
   The button can be used to start recordings
   and time-controlled or manually stopped.
6. **Display of the pressure distribution**
   Display of the pressure distribution of the sensors in real time.
   If the mouse pointer is positioned over the sensor visualization
   the mouse pointer turns into a target cross and the pressure
   value measured at this point is displayed with pinpoint accuracy.
7. **Color scale with minimum and maximum values**
   The color scale is used to assign print values to colors.
   The minimum and maximum of the color scale can be set using
   the input fields to the left and right of the color scale.
   The buttons for automatically setting the minimum and maxi-
   mum values of the color scale are also located here.
8. **Color palette**
   These buttons can be used to switch between different color
   palettes for the color scale. The available color palettes have
   different color distributions, which allows different areas of the
   pressure distribution can be highlighted.
9. **Toggle Tara**
   This button is used to specify whether the tare values
   of the sensor are used for the measurement data display.
10. **Display the Center of Pressure within a single sensor (SCP)**
    This button can be used to display the center of pressure of the pres-
    sure distribution within a sensor in real time and in analysis images.
11. **Display of Center of Pressure between both sensors (COP)**
    When using two sensors, this button can be used to display
    the **Center of Pressure** between the sensors (COP) in real time
    and in analysis images..
12. **Statistics display**
    The statistics display shows the current instantaneous value
    for each sensor and the value over time as well as the entire
    recording for the following parameters:

    - Maximum Pressure (N/cm^2)
    - Average Pressure (N/cm^2)
    - Loaded Area (%)
    - Loaded Area (cm^2)
    - Total Pressure Distribution (%)
    - Pressure Distribution forefoot (%)
    - Pressure Distribution rearfoot (%)

5.4.1.3 Tare Sensors

If required, the tare dialog can be started via the tare button on the live measurement data display. The tare function for the PlantaPress sensors is comparable to the tare function of a kitchen scale and allows you to set the currently measured pressure distribution to zero. Taring can be undone at any time using the “Reset” button in the tare dialog.



5.4.1.4 Recording measurement data

In the Live View, you have the option of recording the measurement data of the PlantaPress sensors. To do this, click on the “Record” button in the menu bar. If you want to record measurement data over a defined period of time, you can also set a recording duration here. The recording is stopping automatically after the specified time has elapsed[2].

A measurement frequency between 1Hz and 100Hz can be selected for the recording. The default setting is 30Hz. As soon as a recording is in progress, the “Record” button flashes.

The measurement data is recorded on the Wireless Modules at the selected measurement frequency. Once recording has been started, no active radio connection is required between the Wireless Modules and the USB Master Module. As long as there is a wireless connection, the current measurement data is displayed in the Live View of VisuPress.

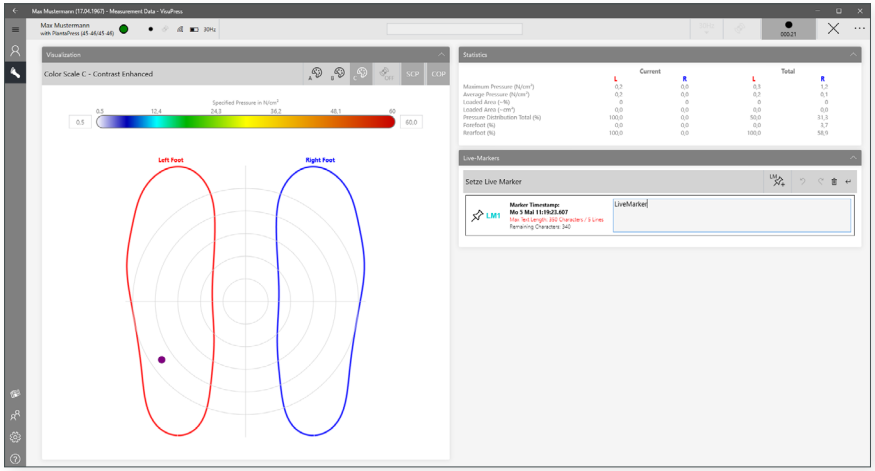
To end the recording manually, press the Record button again. If there is no connection between the Master Module and the Wireless Modules, you must first establish a connection to stop the recording.

[2] optionally available

5.4.1.5 Live Markers

Live Markers with comments can be set during a recording. The Live Markers can be used to mark special points in time within a recording.

The Live Markers are saved together with the recording and can be used as reference points within a recording. The maximum text length for a Live Marker are 350 Characters or 5 Lines



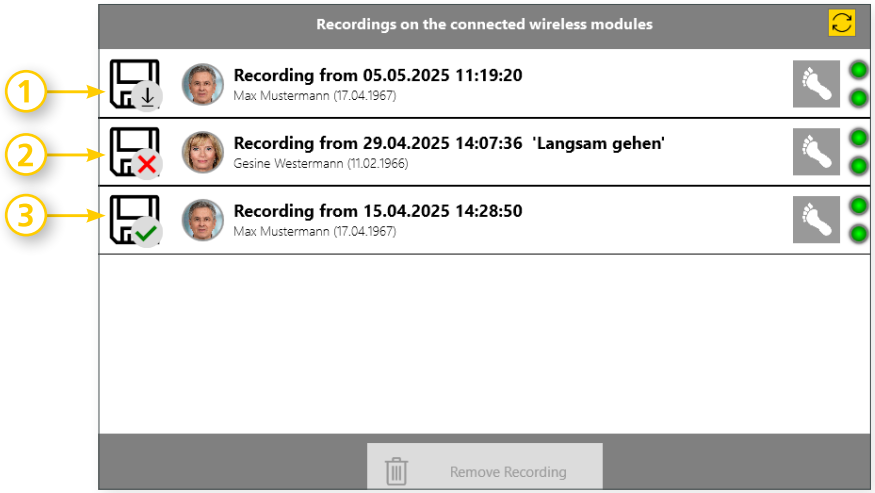
5.4.2 Saving measurement data

During a recording, the measurement data is temporarily stored on the Wireless Modules. This means that no active wireless connection between the Wireless Modules and the USB Master Module is required during a recording. After the recording is stopped, the data must first be saved by the Wireless Modules in VisuPress.

After stopping a recording, the user can decide whether he wants to transfer it directly from the wireless modules to the computer and then open it, or whether he wants to remain in live mode to start another recording if necessary.

5.4.2.1 Recordings on the Wireless Modules

Only recordings from the currently selected patient can be transferred. If recordings from other patients are to be transferred, the respective patient must first be selected in the patient database.



1 Recordings that have not been transferred are marked with a download symbol.

2 Recordings that have already been transferred are marked with a green tick.

3 Recordings that cannot be transferred because they belong to an other patient are marked with a red X.

Multiple recordings can be transferred at the same time by making multiple selections. It is also possible to delete recordings.

Note: **Recordings remain on the Wireless Modules even after they have been transferred to VisuPress. It is therefore recommended to delete existing recordings from the Wireless Modules at regular intervals in order to keep sufficient storage space for new recordings.**

5.4.3 Displaying saved measurement data

5.4.3.1 Displaying recordings

Saved recordings are always linked to the corresponding patient.
To load a recording, the corresponding patient have to be selected.
Use the search function in the patient administration to find the desired patient, select it and switch to the Measurement Data View.
If recordings have already been saved for the selected patient, these are displayed on the right-hand side of the measurement data start view in the list of locally saved recordings.

In this list of recordings on this computer, the name, the date and time of creation and the start of the most recent Notes are displayed for each element to simplify assignment.

After opening, the recording is first analyzed by VisuPress and then displayed in the Playback View. The Playback View is similar to the structure of the live measurement data view (see section “5.4.1.3 Displaying Live Measurement Data“ on page 36), but there are additional control elements for Notes and analyses as well as the playback control.

Functional description of the additional operating elements:
(legend on the following page)

1. **Creation of a PDF Report**
   Creation of a PDF Report with selected measured values and analysis images. (see section “5.4.3.4“ on page 46).
2. **Exporting the recording in .csv format**
   Export the measurement data in .csv format. (“5.4.3.5“ on page 47).
3. **Export the recording in VisuPress format**
   Exports the recording including the associated patient data in VisuPress format. Enables the direct import of the recording to other computers with VisuPress software.
4. **Delete Recording**
   Deletes the current loaded recording.
5. **Comment area**
   In this area, notes can be stored for the recording. In addition to notes, Live Markers created during the recording and Analysis Markers are also stored here. For detailed information, see section “5.4.3.3“ on page 45.
6. **Analysis Area**
   The Analysis Area offers trimming and analysis functions. The window also contains the Playback Control and allows you to play back the recording. For detailed information, see section “5.4.3.2“ on page 44.

1 Export CAM

2 PDF Report

3 Export CSV

4 Export recording

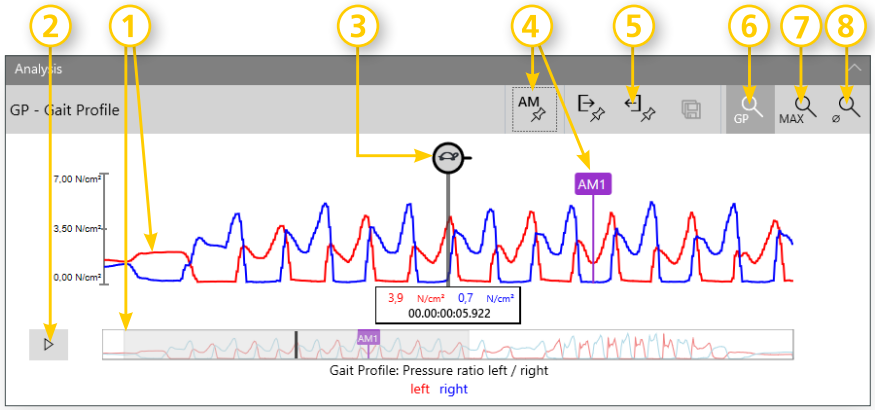
5 Delete recording

6 Comment Area

7 Analysis Area

5.4.3.2 Analysis Functions

The analysis window contains various control elements for playing, trimming, commenting and analyzing a recording.
The available functions are explained in detail below:



1. **Gait Profile**

   In the center of the analysis window, the Gait Profile is displayed over the entire recording (bottom) and over a short time period of approx. 10 seconds (middle). The Gait Profile represents the average pressure over time for each sensor. The red curve represents the left sensor and the blue curve the right sensor.

2. **Play Recording**

   The recording can be played back using the “Play” button.
   The corresponding pressure distribution of the sensors is displayed in the playback window at every point in time within the Gait Profile.

3. **Position Indicator**

   The position over time is indicated by the Position Indicator (3).
   By clicking on any point within the Gait Profile, the Position Indicator can be moved directly to this point. The Position Indicator can also be moved slowly in a desired direction by holding down the left mouse button, allowing the recording to be played back at a variable speed and in any direction.
   By clicking several times on the symbol at the top of the Position Indicator, the playback speed can be varied.
   The pressure values and the time at the respective position are displayed at the lower end of the Position Indicator. By clicking on the displayed time, you can switch between absolute and relative time.

4. **Analysis Markers**

   With the help of Analysis Markers, selected points within the Gait Profile can be done with comments.

5. **Cut Function**

   The Cut function can be used to extract relevant sections from the Gait Profile. To do this the start and end point of the relevant area are selected with the Cut Markers. The selected area can then be saved in a Sub Recording. The Sub Recording is hierarchically subordinated to the original recording, while the original recording is retained.

6. Standard display of the Gait Profile

This is the standard display of the Gait Profile. The recording can be played back in this view, positions within the recording can be jumped to directly and Analysis Markers can be placed.

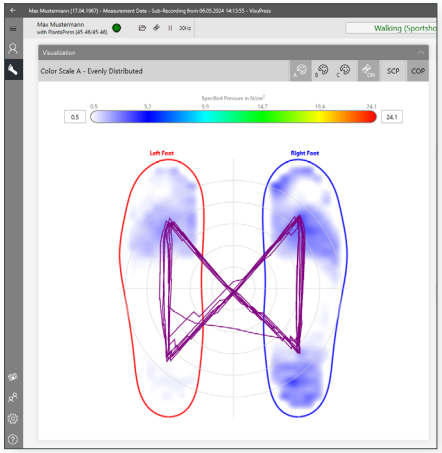
7. Maximum Pressure Image

The sensor visualization shows a Maximum Pressure Image.
The maximum pressure values measured at each sensor position over the entire recording time are combined into one image.
In this image, the absolute maximum pressure is marked for each sensor. In addition, the time at which the absolute maximum pressure occurred is marked for each sensor in the Gait Profile Overview.

8. Average Pressure Image

The sensor visualization shows an average pressure Image.
The average pressure is calculated for each sensor position over the entire recording time and combined into one image

Note: The COP and SCP buttons can be used to display the center of the pressure curves for the entire recording above the maximum and average graph.



5.4.3.3 Comment functions

VisuPress offers various comment functions that can be used to document the recording. Comments are sorted according to when they were created and stored in the “Diagnosis and comments” area. The most recent comment is at the top of the list.
The following comment types are available:

Live Markers

Live Markers[1] are comments that are created while the measurement data is being recorded (see section “5.4.1.6“ on page 39“).
Live Markers consist of an annotation and a marker within the Gait Profile. They are therefore assigned to a specific position within the Gait Profile. They can be used to mark events or trigger points during recording.

Tip: Click on the annotation to jump directly to the corresponding marker in the Gait Profile.

Analysis Marker (1)

Analysis Markers[1] can be created during data analysis.
Analysis Markers consist of an annotation and a marker within the Gait Profile. They are thus assigned to a position within the Gait Profile. They can be used during data evaluation to special measured values or anomalies in the recording.

Tip: Click on the note to jump directly to the corresponding marker in the Gait Profile is jumped to directly.
Note: For Live Marker and Analysis Marker, explicit measurement data pages can be created in the PDF Report

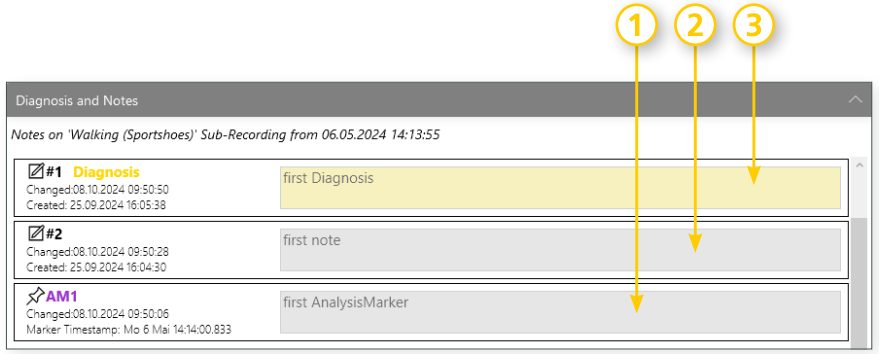
Notes (2)

Simple annotations can be used to store general information about the recording, without reference to a specific point in time within the recording.

Diagnosis (3)

Notes can also be marked as a diagnosis. The relevant notes are thereby highlighted and are an explicit part of the PDF Report.

Note: VisuPress does not make diagnoses itself. The diagnosis anntations are merely a tool to store diagnoses made by medically qualified persons in VisuPress and to mark them separately!



[1] The maximum text length for this marker is 350 characters or 5 lines.

5.4.3.4 Generate PDF Report

A report in .pdf format can be created for each recording. To do this, load the corresponding recording and start the .pdf export via the "Create PDF Report" button in the menu bar of the playback view. You can then select which views and data you would like to export.

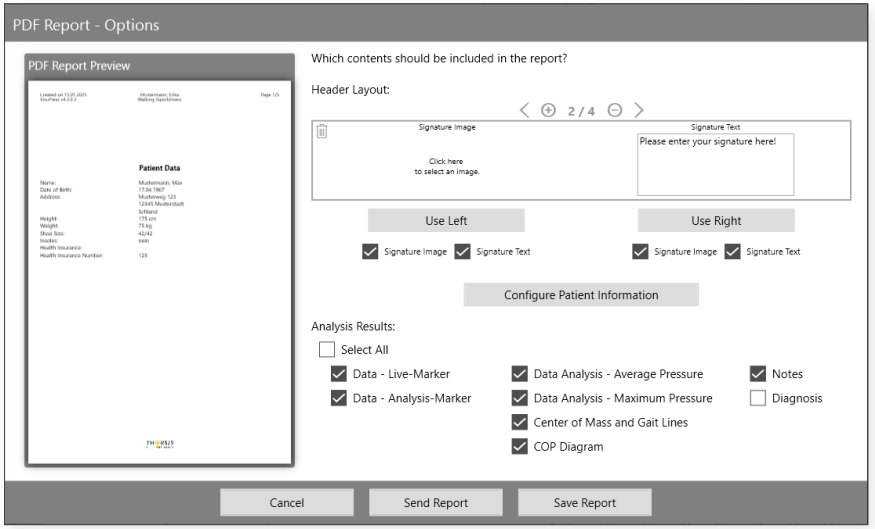
The following options are available:

- Graphical elements for the header of the PDF Report
  Two different graphics can be used for the header of the report with the logo or address of the creator of the report can be created and selected. The created Header Elements are saved and can be reused for further reports.

- Configuration of Patient Information
  The patient master data can be defined for transfer to the PDF Report.

- Results of the analysis, notes and diagnostic texts
  Various analysis images are available, which can be included in the PDF Report.

- Live and analysis marker measurement data pages
  A separate page is generated for each marker in the PDF Report which contains the comment text, the pressure data table and an image at the time of the marker.



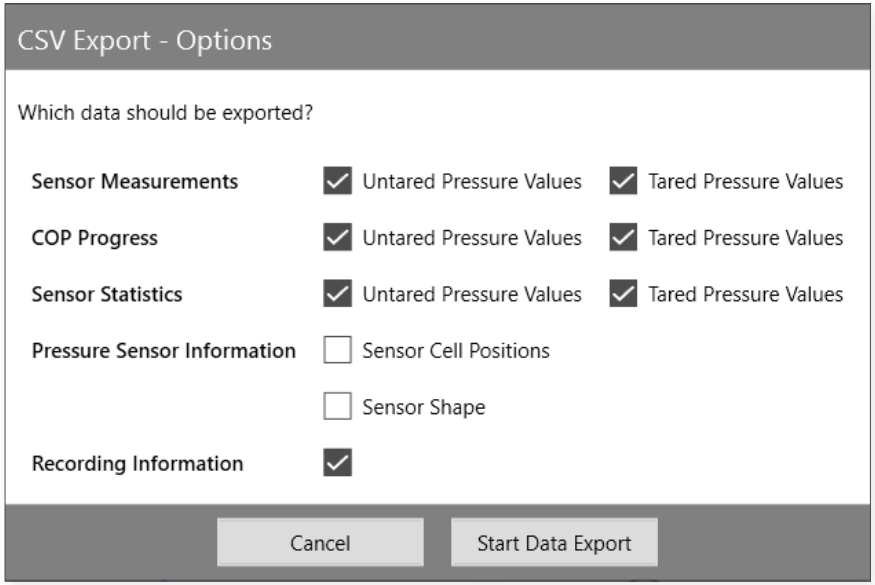
A preview of the first page of the report with Header Elements and the patient data is displayed.
After selecting the data and presentations, the PDF Report can either be saved on the PC or sent using the standard e-mail program.
With the latter option a .pdf file is first generated and then automatically attached to a newly created e-mail. Once a recipient has been specified, the report can be sent immediately.

Note: **A standard e-mail program that supports the MAPI32 interface must be configured in the operating system for the "Send Report" option to work as described.**

5.4.3.5 Generate CSV Export

Recordings can be exported in .csv format for further analysis.
To do this, load the corresponding recording and start the .csv export via the „CSV export“ button in the menu bar of the playback view.
You can then select which data you would like to export.
The following options are available:

- Measured Values of the Sensors
- COP history
- Statistics of the Sensors
- Sensor information
  (sensor contour + position of the sensor cells) as graphics
- Recording Information



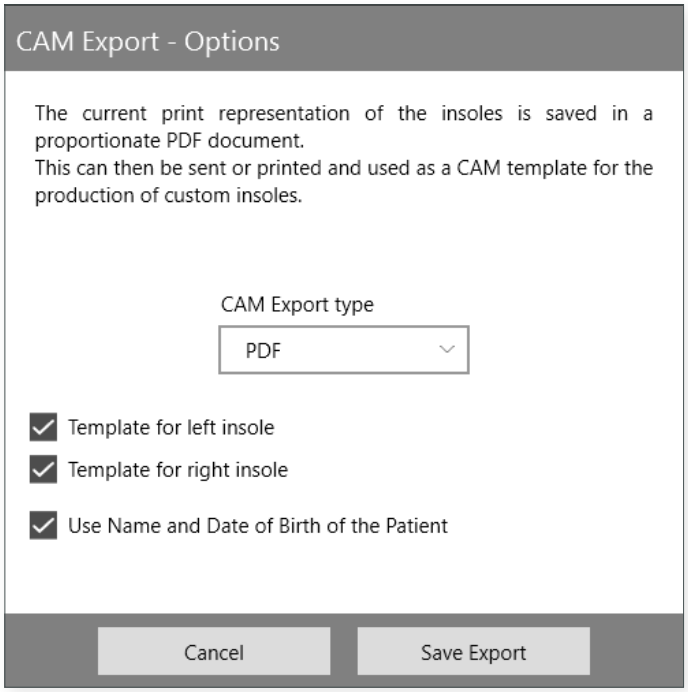
By default, the generated CSV files contain the synchronized start time of the recording as a UTC timestamp in the file name, accurate to the millisecond.

The .csv files are structured as follows:

- The first line contains the separator character definition.
  (default is semicolon “;”)
- The second line contains the headings for the following columns with the measurement data, separated by the separator character.
- The list of measurement data begins on the third line, with each line representing a “frame”, i.e. a data package.
  The columns are also separated by the separator character.
  - A “frame” or data packet always consists of a consecutive time stamp in milliseconds as an integer (first column) and the pressure values of the sensor cells as a decimal number of data type ‘float’ (following columns).
  - The decimal separator depends on the regional and language settings .Windows system regional & language settings. For example, in a German Windows the comma “,” is used, while in an English Windows the point “.” is used.

5.4.3.6 Generate CAM export

The currently displayed pressure distribution or any analysis view can be output as a CAM export.
This can then be used as a true-to-scale template for manual or computer-aided production, for example when milling an insole.
The production template is saved as a PDF document.



The following information can be found in the header of the document:

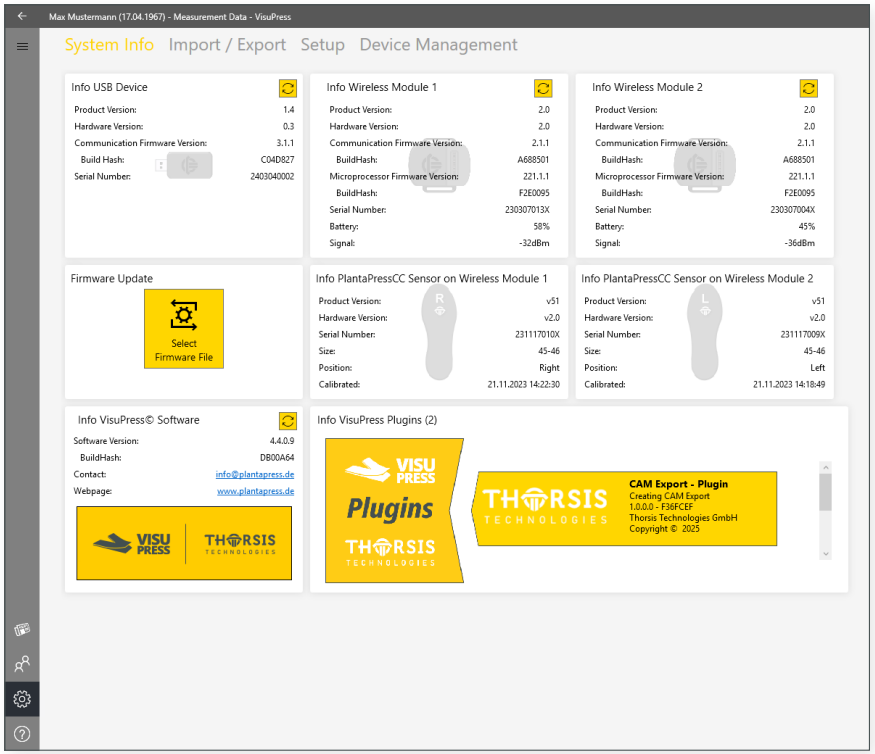
- AccountID
- Recording date
- Exact time of measurement (if no analysis view)
- Type of measurement data display Image:
  - Current time in recording
  - Maximum pressure
  - Average pressure
- Type of sensor / shoe size / left / right / dimensions
- Software version
- Page number and total number of pages
- Name and date of birth of the patient (optional)

5.5 Settings

The „Settings“ menu item is located at the bottom of the navigation bar on the left-hand side of the main window.
The settings are grouped thematically in different tabs.

5.5.1 System Info and Firmware Update

The „System Info“ tab displays version information on the VisuPress software and the individual components of the measuring system.
The USB Master Module must be connected to the Computer in order for the information from the measuring system to be displayed.
The Wireless Modules must also be switched on and paired with the USB Master Module.
To obtain additional information on the sensors, these must be connected to the Wireless Modules. Click on the synchronization buttons to call up the device information.

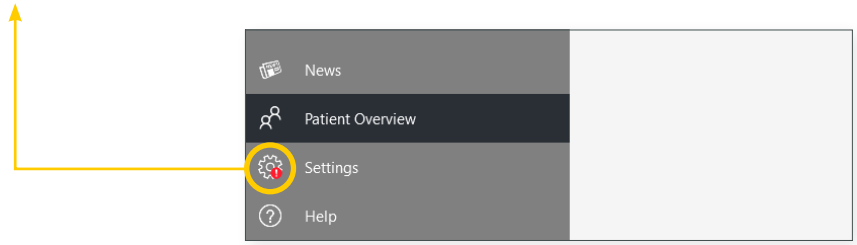


The tab also contains the button for installing new firmware for the devices of the PlantaPress measuring system. The update wizard guides you fully automatically through the update process.

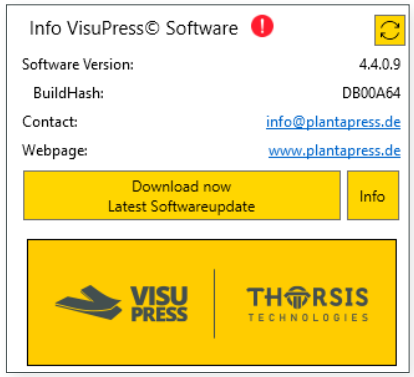
Requirements for Firmware Update:

- USB Master Module is connected to the Computer
- Wireless Modules are switched on, sufficiently charged and paired with the USB Master Module

If a new software version of the VisuPress software is available, a corresponding notification is displayed by means of a red icon on the menu icon of the settings page.

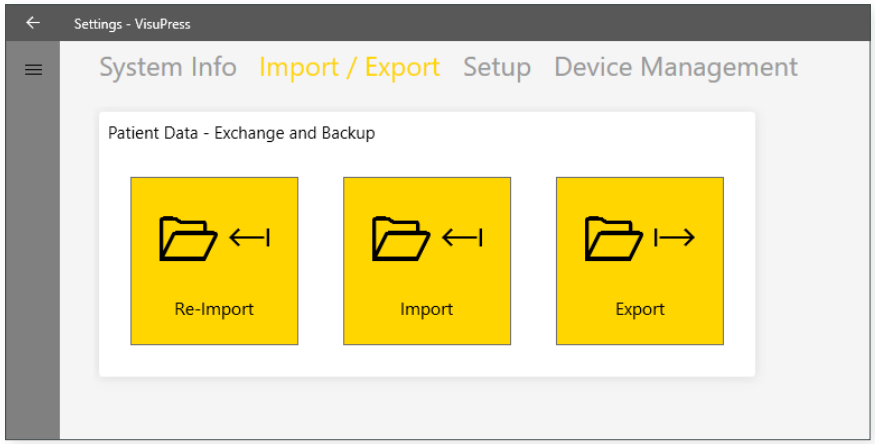


If an update notification is displayed, the new software version can be downloaded directly from the settings page.



5.5.2 Import / Export

In the „Import/Export“ tab, you have the option of exporting or importing the existing patient data (master data + admissions). This makes it possible to create backup copies or to migrate the complete patient data to another computer.



When importing, existing patient data is combined with the imported patient data to form a common database. Existing master data and identically dated recordings of identical patients are overwritten during the import!

The „Re-import“ option is only available for previously used VisuPress version 3.x.x and migrates their patient data into the current format of the VisuPress installation with database (v4.x.x).

5.5.3 Setup

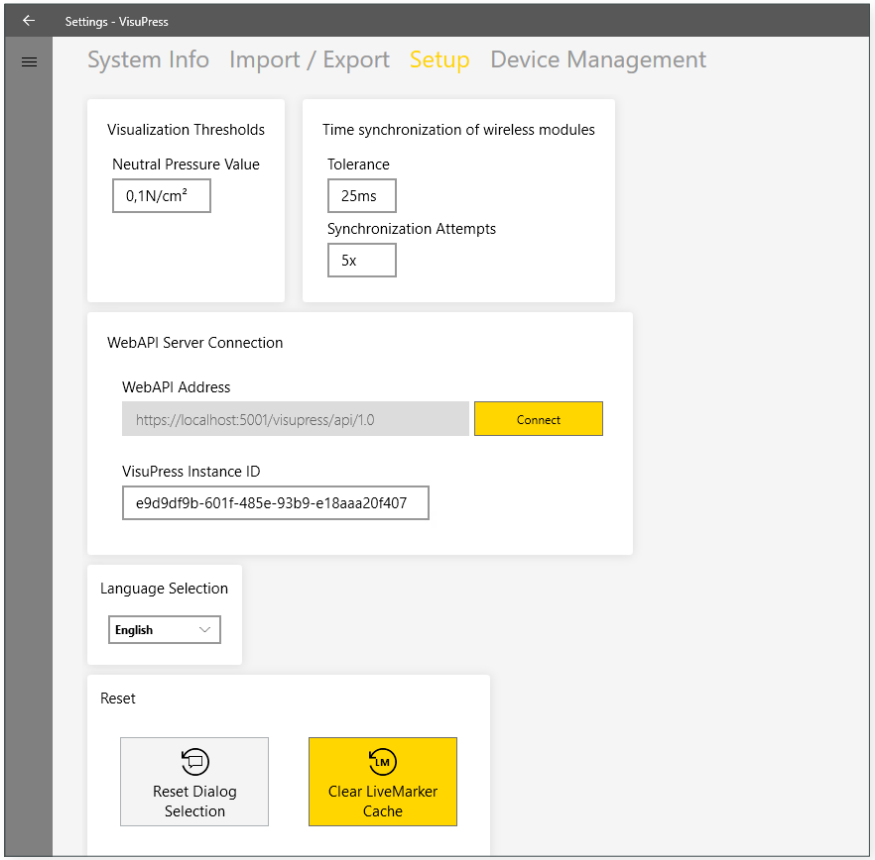
The „Setup“ tab contains the following setting options:

- Setting the Neutral Pressure
  Values below this threshold are ignored for the display and evaluation.

- Tolerance values for the time synchronization of the Wireless Modules
  Definition of the maximum permissible time deviation between several Wireless Modules and the number of synchronization attempts. The default value is a tolerance of 25ms for 5 synchronization attempts. These values should only be changed after consultation with the manufacturer!

- Address of the VisuPress database server

- Language Selection
  You can select the language for the user interface of VisuPress application.



Note: Resetting the Live Marker cache removes set Live Markers from all recordings not yet saved on the computer permanently.

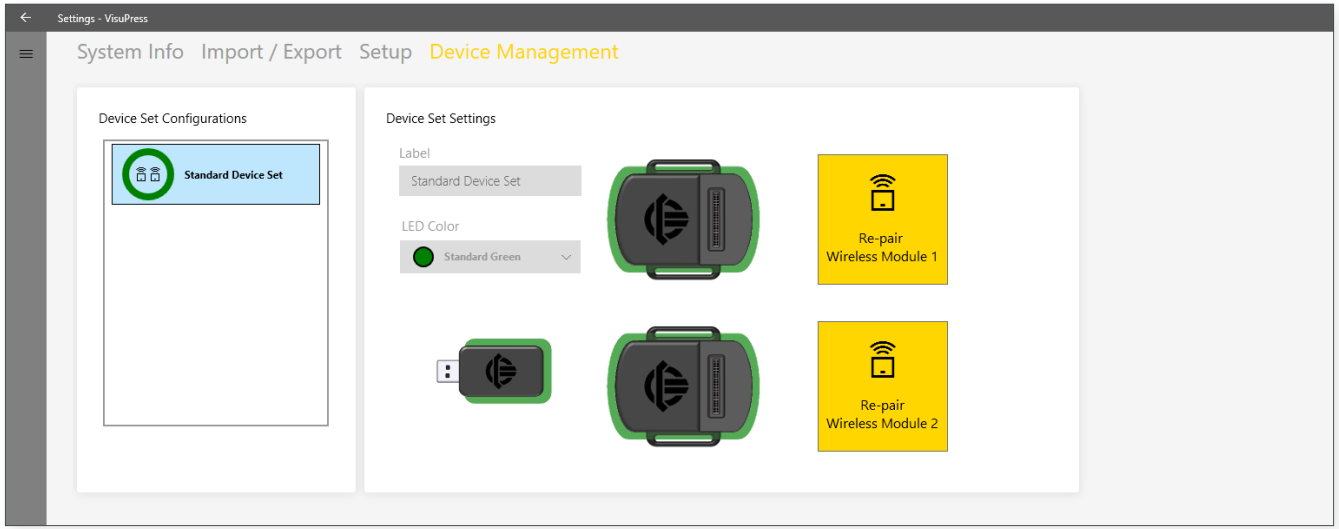
5.5.4 Device Management

In order for a connection to be established between the Wireless Modules and the USB Master Module, they have to be paired with each other.
The coupling of the components of the standard device set is usually already present in the delivery state and only needs to be renewed after resetting to factory settings.

To set up the standard device set, i.e. to establish the coupling between the Master Module, please open the “Settings” menu item in the lower area of the navigation bar and switch to the “Device management” tab.

Follow the instructions below to pair the device set consisting of the USB master and the Wireless Modules:

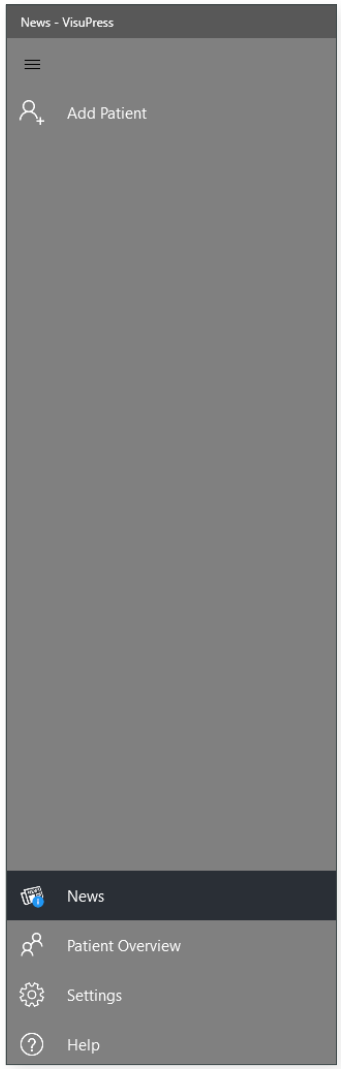
1. Connect the USB Master Module to a USB port on the computer. The USB master symbol initially appears gray. As soon as the USB Master Module has been detected, the symbol appears in color and pulses in the LED color of the device set.
2. Switch on the Wireless Module.
3. Click on the pairing button next to the Wireless Module symbol. The USB Master Module, the USB Master Module symbol and the corresponding Wireless Module symbol now flash blue.
4. Press the pairing button on the Wireless Module. The Wireless Module now also flashes blue.



After successful pairing, the Master Module pulses, the Wireless Module and the associated symbols in the connection dialog in the LED color of the device set. Carry out the steps again to pair the other Wireless Module with the USB Master Module.

5.6 News

At the bottom of the navigation bar you will find the menu item “News” in the first position.
In the “News” display area, interesting information about Thorsis Technologies medical products, product promotions, relevant news on the subject of orthopaedic and diabetic foot bedding as well as orthopaedic insole care or biomechanical foot analysis.



6. Manual update

Version	Date	Description
1.0	Mar. 2020	Initial version
2.0	Jun. 2022	Update version
2.1	Dec. 2022	Update version valid from the following component versions: Wireless Module V1.3.1; USB Master Module V0.3; Sensors; PlantaPressCC V1.0; PlantaPress V3.0; Case V1.0; VisuPress V4.1.8
2.2	Feb. 2024	Update version valid from the following component versions: Wireless Module V2.0; USB Master Module V1.0; Sensors; PlantaPressCC V2.0; PlantaPress V3.0; Case V1.0; VisuPress V4.3.0
3.0	June. 2024	Change to charging system (all component versions of version 2.2 remain unaffected in their validity)
3.1	Oct. 2024	Content Update
3.2	Jan. 2025	Content Update
3.3	May 2025	VisuPress Functional-Update

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