T&T medilogic

MEDIZINTECHNIK GmbH

Instructions for use
medilogic foot scanner

CE

2025-09

101.03.20_v04

Installation media inside

Content

1 Important information and hotline

We reserve the right to make changes and improvements to our products without being obliged to make these changes and improvements to previously delivered systems.
We accept no liability or consequential liability for loss of data or the consequences of loss or destruction of data in connection with the use of the system.
If you have any questions, you can reach us during normal *business hours Monday to Friday between 8.00 a.m. and 5.00 p.m. on the hotline telephone numbers +49 30-63306340 and +49 30-*63306341.

Manufacturer: T&T medilogic Medizintechnik GmbH
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www.medilogic.com
e-mail: medilogic@medilogic.com

Manufacturer registration: SRN: DE-MF-000011836

2 Introduction

Dear medilogic user!
After careful consideration, you have decided in favour of our *medilogic* system, for which we thank you.
We are convinced that the expectations you have associated with the purchase of this system will be fulfilled after a short familiarisation period. In order to keep this familiarisation period as short as possible, we have endeavoured to make the operating instructions as informative and easy to understand as possible without burdening you with unnecessary ballast.

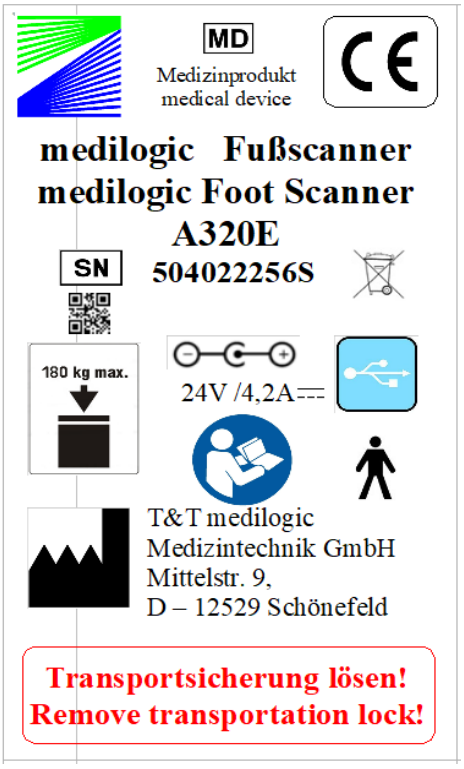
These instructions for use are addressed to you as a user of the medilogic system in order to provide you with all the necessary information and instructions. Instead of the term '*patient*', which is commonly used in the medical field, the term '*customer*' is used in these instructions for use and in the software. This takes account of the fact that in the practice of medical/orthopaedic care, the patient often takes on the role of a customer.

Every effort has been made to ensure that the information contained herein is complete and accurate. However, no guarantee can be given. If you notice anything in this respect, or if you believe that individual passages give rise to misunderstandings, please let us know so that the following edition of the instructions for use can be corrected accordingly.

2.1 Labelling

Important information and safety-related labelling can be found on the type plate on the housing parts of the medilogic foot scanner. All signs and symbols are explained in the following table.

UDI konfigurierbares Produkt configurable device (01)04260718630005 (11)241216 (21)00063	UDI-Label, QR code contains UDI-DI and UDI-PI: (01) UDI-DI [type of medilogic product] (11) Date of manufacture [yymmdd] (21) Serial number of the configurable product
MD	Medical device (labelling that it is a medical device)
CE	CE LABELLING
SN	SERIAL NUMBER Labelling of the device on the rating plate (y - individual number; YY = year of manufacture) SN: 5090JJyyyyy
	QR code contains serial number (SN)
	Safety sign: FOLLOW THE INSTRUCTIONS FOR USE!
	APPLICATION PART Type B according to EN 60601-1
	Do NOT dispose of in household waste, but to the collection point for electronic devices or to the manufacturer
	Manufacturer's details on the rating plate
	Device with USB cable removed
180 kg max.	MAXIMUM LOAD of the foot scanner with 180 kg body weight
	TRANSPORT SECURITY: Position secured Transport of the device is possible.
	TRANSPORT SECURING: Position unsecured No transport of the device!

<table>
<tr>
<td></td>
<td>Toggle switch on the device: 0 = Off, 1 = On</td>
</tr>
<tr>
<td>Type plate</td>
<td>
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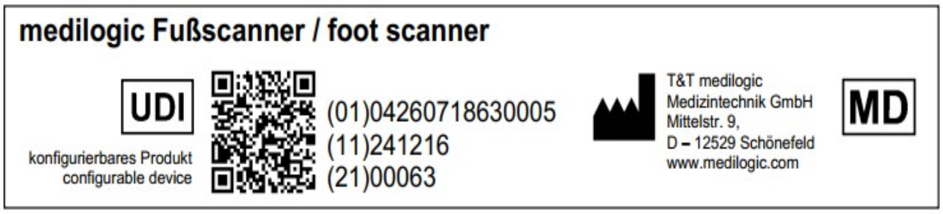
<td>
</td>
</tr>
</table>

3 medilogic foot scanner

3.1 Intended purpose

The medilogic foot scanner captures images of the sole of the foot for orthopaedic applications. A two-dimensional image is taken of the underside of the foot. This image supports the diagnosis and documentation of foot diseases and deformities. The visualised foot status supports, for example, the creation of medical-orthopaedic aids to correct foot deformities.

a) Benefit and indication (medical purpose)

The medilogic foot scanner is used as intended as a diagnostic aid in the field of orthopaedics and sports medicine to record basic data for the subsequent assessment of the status of the sole of the foot. The optical recording of the sole of the foot is an aid for obtaining the basic data for the manufacture, fitting and documentation of footwear and the documentation of foot status. The two-dimensional image of the foot supports the diagnosis and documentation of foot diseases and foot deformities. The visualised foot status supports, for example, the creation of medical-orthopaedic aids for the correction of foot deformities. In general, the medilogic foot scanner should be seen as a supplement in combination with a variety of other diagnostic and manual procedures, so that a comprehensive assessment of the individual condition cannot be made solely from the visualisation of the sole of the foot. It is the responsibility of the user (e.g. doctor or orthopaedic technician) to compare the conclusions from the measurement results with other examination methods, such as anamnesis, X-rays, etc. The medilogic foot scanner provides medical professionals in particular with a tool that enables even better diagnosis and internal documentation.

b) Contraindication / contraindication

The medilogic foot scanner may only be used in accordance with the application and safety instructions described in the chapter3.4 of the instructions for use. Use is NOT PERMITTED if the customers body weight is greater than 180kg or if the customer is unable to stand still and safely for the duration of the scanning process.

c) Intended use

The medilogic foot scanner is used as intended as a diagnostic aid in the field of orthopaedics and sports medicine to record basic data for the subsequent assessment of the status of the sole of the foot. The optical recording of the sole of the foot is an aid for obtaining the basic data for the manufacture, fitting and documentation of footwear and the documentation of the foot status. The two-dimensional image of the foot supports the diagnosis and documentation of foot diseases and foot deformities. The visualised foot status supports, for example, the creation of medical-orthopaedic aids for the correction of foot deformities. In general, the medilogic foot scanner should be seen as a supplement in combination with a variety of other diagnostic and manual procedures, so that a comprehensive assessment of the individual condition cannot be made from the visualisation of the sole of the foot alone. It is the responsibility of the user (e.g. doctor or orthopaedic technician) to compare the conclusions from the measurement results with other examination methods, such as anamnesis, x-rays, etc. The medilogic foot scanner provides medical professionals in particular with a tool that enables even better diagnosis and internal documentation.

d) Product description and mode of action

The medilogic foot scanner is an image capture of the sole of the foot for orthopaedic applications. An optical digital scan is used to capture a two-dimensional image in A3 format of the underside of the foot. The operator controls the system via the medilogic application software during the scanning process and subsequent evaluation. The customer stands with both feet, without socks, on the glass plate of the 2D scanner integrated in a sturdy housing. The pa-

tient remains still for the duration of the scanning process. There are two types of medilogic foot scanner:
- medilogic foot scanner A320: Standard, scanning time: 10 s
- medilogic foot scanner A360: high-speed, scanning time: 2 s

3.2 System description

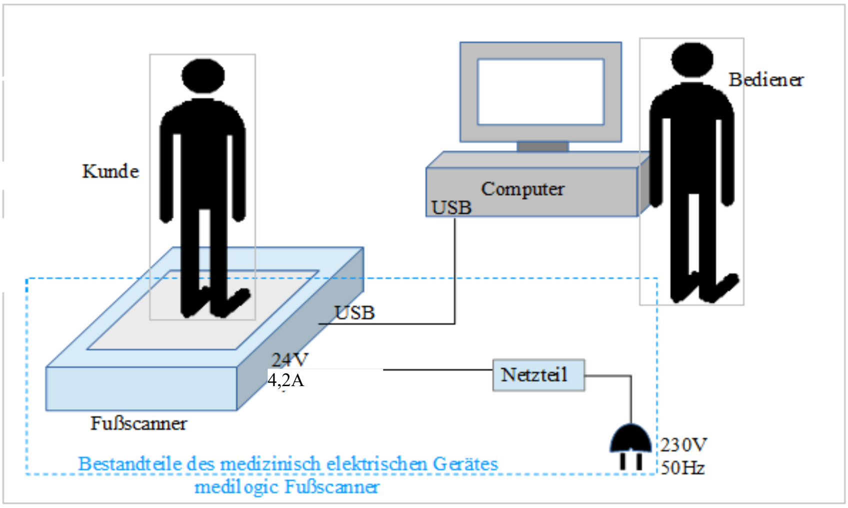
The *medilogic foot scanner* supplies its data via a USB interface. The foot status is visualised via a two-dimensional colour image.

The medilogic *software* running under WINDOWS® enables the results of the examination to be displayed on the computer monitor. Immediately after connecting the USB cable to the PC and the power supply unit to the mains connection, the device can be put into operation using the toggle switch.

The operation of the *medilogic software* is comparable to that of a playback device. The measurement (data recording) is started at the touch of a button (mouse click). Once the recording is complete, the scan can be viewed and supplemented with additional drawing elements, for example.
Scanned images can be printed out if required. It is possible to compare two examinations. To archive the data, each examination can be assigned to a customer and saved on the hard drive. The data can be analysed later at any time. A comprehensive data maintenance function allows the data to be saved, exported and re-imported as required.

In the following illustration, the system configuration of the medilogic foot scanner is explained in detail in the ***schematic diagram and scope of delivery.***

3.2.1 Schematic diagram medilogic foot scanner



The *medilogic foot scanner* ***is supplied with*** the following components:

System component	***Classification***
medilogic foot scanner type A320 or A360	Application part type B according to EN 60601-1
Power supply unit: Output: 24V 4.2 A ; Input: 230V 50Hz (Manufacturer: Mascot, Type: 2820)	Accessories
USB cable 1.5m	Accessories
Instructions for use	Accessories
medilogic software (USB stick)	Application software
Transport carton incl. moulded foam parts	Packaging

3.2.2 Combinability with accessories and other products

The medilogic foot scanner can only be used with the power supply unit supplied as an accessory, see chapter 3.2.1 or 7.1 . This power supply unit is therefore part of the medical electrical device (ME device) medilogic foot scanner'.
For the compatibility of the medilogic foot scanner with the computer system, please refer to the instructions in the chapter 4.2 must be observed. The minimum requirements for the computer system according to chapter 7.1 apply.
The software for the medilogic foot scanner includes an interface for easier data input
for the following Cherry card readers for the electronic health card (eGK):
- MTK+ Terminal ST-2052
- eHealth-BCS Keyboard G87-1504
- eHealth-BCS Terminal ST 1503

The medilogic foot scanner can NOT be combined with products from other suppliers.

3.3 Contraindications for the use of the medilogic pressure measurement system

The medilogic foot scanner may only be used in accordance with the application and safety instructions described in chapter 3.4.
Use is NOT PERMITTED if:
- the body weight of the customer is greater than 180kg or
- the customer is unable to stand still and securely for the duration of the scanning process

3.4 Special instructions for use

When using the *medilogic foot scanner* as a medical device, the following instructions must be observed to ensure proper and safe use.

In general, the system should only be handled by trained personnel who have been instructed in its operation. Particular care must be taken to ensure that the scanner glass pane is not damaged by sharp-edged or pointed objects. (see 7. of the hardware components

Warning! Modification of the ME device is not permitted!
Failure to comply with the warnings described in the operating instructions may result in damage to the system.
If cables are damaged or no longer functional, the manufacturer must be contacted.

The medilogic foot scanner can be combined as intended with the medilogic IBG system for recording the pressure distribution. Information and notes relating to the IBG system can be found in the corresponding medilogic IBG manual

Safety instructions
For the safety of the customer, the following precautions must be observed.
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.
The medilogic foot scanner is intended for temporary use for analysis purposes and therefore only for temporary use on patients. As the system is used barefoot, it is prohibited to use the system with open, weeping or bleeding skin areas for reasons of safety and hygiene.
In addition, the scanner interface can be used between switching from one patient to the next.
to prevent infections. The cleaning instructions described in the following section must be observed.
When using the medilogic system, the handling
with liquids is not permitted in order to avoid danger to the patient, user or system components.
The joint use of the medilogic system with a computer requires the proper functioning and electrical safety of the computer components. Therefore, only use a PC that conforms to IEC62386-1 or IEC 60601-1. Furthermore, the safety-relevant instructions in the section 4.2 for installing and checking the PC in operator responsibility must be observed.

The medilogic foot scanner is intended for use in an electromagnetic environment in which RF disturbances are controlled. The user should avoid electromagnetic interference by observing the ambient conditions specified in the guidelines in chapter 8.2 and by maintaining the recommended minimum distances from RF telecommunications equipment.

Warning! Do not use the medilogic foot scanner directly next to other devices outside of the guidelines in chapter 8.2 or in an unintended stacked form, as the unrestricted function of the devices can no longer be guaranteed. If use in the manner described above is nevertheless necessary, this device and the devices involved should be observed to ensure that they are working properly.

Cybersecurity

In addition to the general safety instructions, measures to secure the IT environment must also be observed. These serve to protect data, devices, and patient information from unauthorized access and manipulation. Therefore, please observe the following instructions:

The operator must ensure that the database server is operated in a protected network environment. To this end, separation into a separate network segment (e.g., VLAN) is recommended, whereby only authorized application servers are permitted to access the database service. Open connections to unsecure or external networks must be avoided.

The devices may only be operated with PCs that are intended for this purpose and configured accordingly. These must be secured with up-to-date security measures such as a firewall, anti-malware software, and regular security/operating system updates. In addition, access controls must be set up (e.g., the operating system's access control) to prevent use by unauthorized persons. It is recommended that regular backups of the data collected in medilogic be performed using a backup process.

The configuration of the devices is reserved exclusively for authorized specialist personnel. Access should be via individual login to prevent manipulation or uncontrolled changes.

Where possible, operation should be carried out in separate rooms that are isolated from other wireless networks. This makes it more difficult to interfere with the system unintentionally or gain unauthorized access.

Since, according to its intended purpose, the loss of function or data of the medilogic software does not pose a risk to patients or users, and a compromise of the IT environment is unlikely if the above measures are observed, the medilogic software does not include any access control measures or protective measures against cyber attacks.

The data connection to the hardware established by the medilogic system is a WPA2-encrypted direct connection as a WiFi network that is only active during operation of the medilogic software and is protected against attacks by encryption.

Cleaning and disinfection

The scanner surface and housing parts are cleaned with a soft, damp cloth without cleaning agents, taking great care to ensure that no moisture penetrates the housing parts. (no abrasive agents, no sharp objects)
To prevent the transmission of infection, the scanner surface must be disinfected before and/or after each customer.
To disinfect the scanner surface, wipe it with a disinfectant from the VAH list (Verbund für Angewandte Hygiene e.V.) in accordance with the criteria of the DGHM (German Society for Hygiene and Microbiology). The product description of the disinfectant must be observed. Wipes soaked with the disinfectant should be used; the disinfectant should not be applied as a liquid. *Bacillol® Tissues*, for example, are suitable for this purpose.

Furthermore, the user must ensure that there is no damage to the housing parts that could lead to injuries (e.g. sharp edges). Damaged components must be returned to the manufacturer for repair.
To ensure safety, please note that the system must never be used encapsulated or covered.

Parameters	How to comply?
Temperature	see 7.1 Ambient conditions
Humidity	No standing liquid (use soaked wipes - 3-4ml liquid per wipe)
Duration	until all areas have been safely reached (min. 30s)
Number of cycles	once after each use

Maintenance

The medilogic foot scanner is maintenance-free.

Warning! Any service or inspection should only be carried out when the ME device is not currently in use and, if possible, disconnected from the supply line.

- **Preventive inspection:**

In addition to the cleaning and disinfection of the device described in the section above, the operator to carry out the preventive inspection of the following components at least once a year:
- Glass surface clean, free of streaks or scratches that could interfere with image capture
- Scanner housing free from mechanical damage
- USB connection cable without damage, kink-free
- Electrical connection using the associated power supply unit without damage, kink-free, easy access to the plug for connection to the supply network

- **Replaceable parts / accessories**

Only the listed accessories are authorised for safe operation of the medilogic foot scanner. If a defective USB cable is detected, the manufacturer must always be contacted, as the USB cable provides essential protection for the user and operator.

Waste disposal

The components of the *medilogic foot scanner* contain electronic parts and must therefore be disposed of as electronic waste or returned to the manufacturer if defective. The components must not be disposed of with household waste

Storage and transport

To protect against dust, moisture and other contamination or damage, the system components must be stored in the system packaging or otherwise in a dust-free and safe place suitable for electronic measurement technology.
The medilogic foot scanner should always be stored lying flat. The system should always be transported in the packaging provided, consisting of a transport box including moulded foam parts. This will prevent damage to the system or accessories. Care must be taken to ensure that no loose parts are lying on the scanner glass pane, as otherwise the optical properties could be impaired.

Before each transport, the carriage of the foot scanner must be secured using the transport lock. To do this, set the slide switch on the underside of the device to the 'Secured'.

The transport carton used for delivery must be used for transport. The following note must be affixed to the outer packaging:

Do not drop, be careful, fragile!

Summary

Finally, a brief overview of the risks identified is provided in order to provide a clear, concise summary. This can be used for quick reference if required.

Category	Safety note
Preparation	➢ Checking the structure - safe and stable positioning of the device
	➢ Do not use the system with open skin areas!
	➢ Do not drop the system: Fragile!
Operation / Maintenance	➢ Monitoring of the examination by specialised personnel
	➢ System is for temporary use
	➢ Handling of liquids not permitted
	➢ given electrical safety of the associated PC system
	➢ Operating unit must not be operated encapsulated or covered
	➢ Operator protection measures against unauthorised access to computer systems and software through access control; against cyber attacks through anti-malware software and security patches; against data loss through backup process
Hygiene	➢ The surface must be disinfected after each measurement
	➢ Check for obvious contamination
	➢ Under no circumstances should the components be submerged in water during cleaning
Inspection	➢ Check for damage
	➢ Glass pane free from damage
	➢ USB cable and housing feed-through free from damage
Storage / Transport	➢ System components must be stored in the corresponding system pack-

	aging (or in a location suitable for electronic measurement techno-logy) ➢ System must be stored flat ➢ Transport lock on the underside for mechanical securing
	➢ The system must be transported in the packaging provided for this purpose
Waste disposal	➢ Proper disposal (electronic waste) or return to the manufacturer
Miscellaneous	➢ Device components must not be opened
	➢ Avoid electromagnetic influences (see guidelines in chapter 8.2)
	➢ No stacked use of devices (if it is nevertheless necessary, the devices must be constantly monitored)
	➢ If shipping is necessary, the system must be sent in the appropriate packaging to protect it from impact

Please note!

All serious incidents occurring in connection with the medilogic foot scanner that directly or indirectly lead to death, serious deterioration of health or where there is a possibility of death or serious deterioration of health must be reported to the manufacturer and the responsible local authority.

4 Installation and commissioning

4.1 Installing the hardware

4.1.1 Structure and preparation of the system

When the medilogic foot scanner is delivered, it is set up directly by the medical product consultant. The ready-to-use medilogic foot scanner basically consists of the 2D scanner in the correspondingly robust housing. Power is supplied via the supplied medical power supply unit and data is exchanged via the USB interface.
The intended operating location should not be illuminated by a direct light source. The suitability of the room lighting must always be checked beforehand by means of a regular test measurement. The following distances from light sources at the operating site must be observed to ensure optimum recording:

Light source position*	Minimum distance	optimal
Lateral (long housing edge)	100 cm	>120 cm
front / rear (short housing edge)	85 cm	>100 cm
*The distances apply to a room height of approx. 2.50 m and must be adjusted for deviating dimensions.		

The device should be set up straight and stable. Suitable surfaces are, for example, carpet or parquet flooring. The system is not screwed to the surface.

Taking into account the operating instructions for the assigned scanner, the hardware installation is completed by unlocking the scanner's transport lock and the system can be put into operation (see 4.1.2).
Before the actual commissioning, all points relating to the "preventive inspection" must be checked at . Special instructions for use

4.1.2 Establishing the USB connection and the operating status

To use the medilogic foot scanner, please install the corresponding device driver for the A320E or A360 Plus foot scanner from the supplied data carrier or by downloading it from our homepage: https://medilogic.com/de/faq/downloads/
Once the driver installation is complete, connect the scanner to the computer using the USB cable supplied and connect the scanner to the power supply using the power adapter also supplied.
power supply. *For safety reasons, make sure that the connecting cable to the power supply accessible in order to enable complete disconnection from the supply network immediately if necessary.*
To switch on, you will find the toggle switch on the front of the scanner:

The newly installed device is now recognised by the operating system.
During the first scanning process in the medilogic software, the scanning device (Plustek A320 or A360) is selected (once) by holding down the SHIFT key on your keyboard while pressing the scan button.

4.1.3 Installation of a chip card reader (eGK)

An optional chip card reader can be connected for quick entry of customer data when saving an examination at .
The medilogic software includes a interface to the following Cherry card readers for the *electronic health card (eGK)*:

- MTK+ Terminal ST-2052
- eHealth-BCS Keyboard G87-1504
- eHealth-BCS Terminal ST 1503

When installing a chip card reader**, the associated software** must **first be started** via the driver (located on the *medilogic* installation medium; can be installed via the installation selection: Additional hardware drivers) **before inserting the card reader**.
As each card reader has its own special driver, you should only use the card reader supplied by T&T medilogic GmbH with the device driver contained on the medilogic installation medium (alternatively via download: https://medilogic.com/de/faq/downloads/)

The card reader is then connected to your computer and can be activated in the medilogic programme under the menu item "Options" on the "Extra" tab using the " card reader" button.
Please note that the card reader should be plugged in before starting the medilogic programme, otherwise it will need to be reactivated in the programme.
You can then import the customer data when saving an enquiry or under 'Edit customer details' by pressing the *F12 key* on your computer keyboard.

4.2 Installation of the software

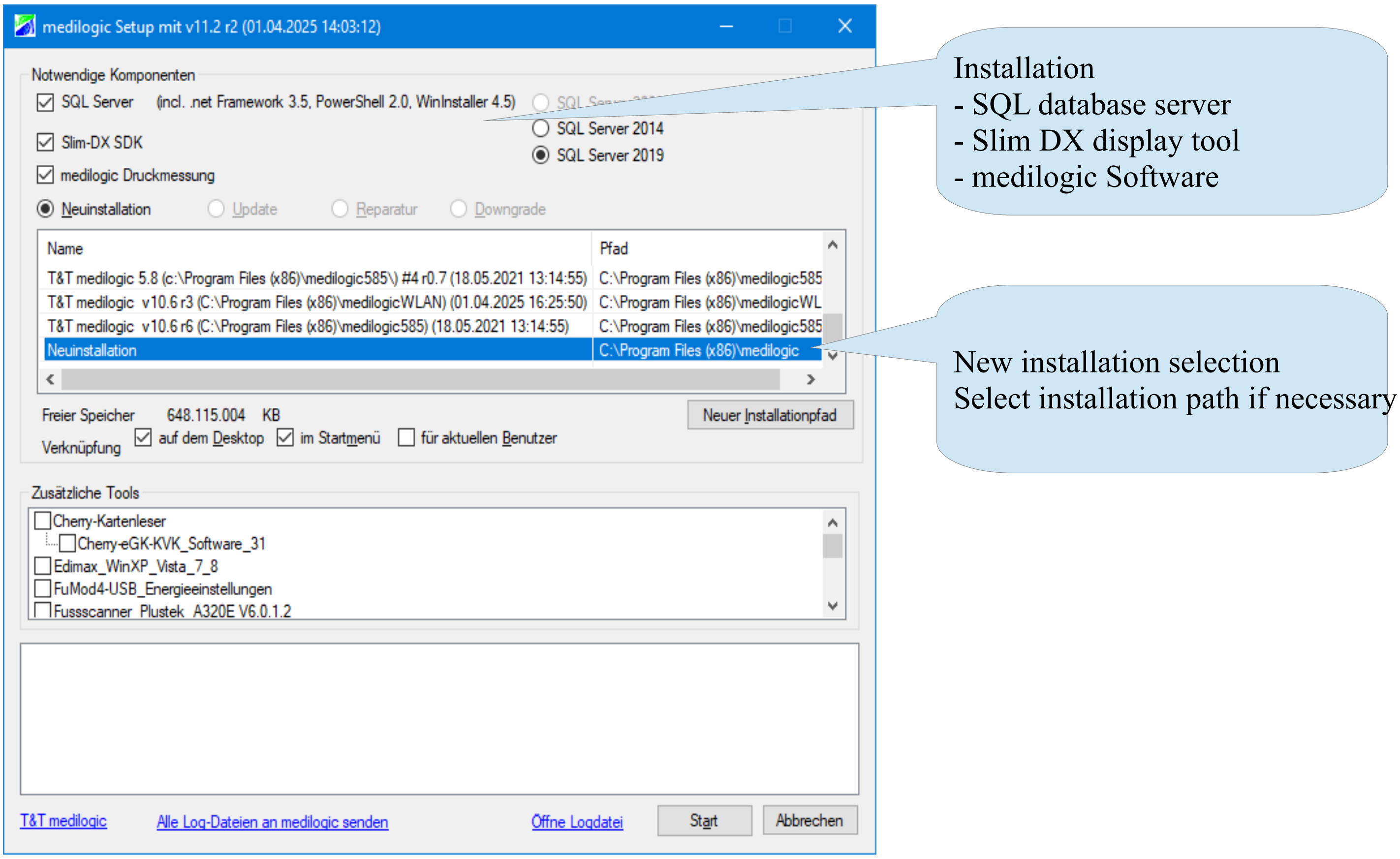
Before you can start working with the *medilogic* system, the software must be installed on your computer's hard drive. If you purchased the software and computer technology at the same time, the software has already been installed. Otherwise, the following points should be checked first:

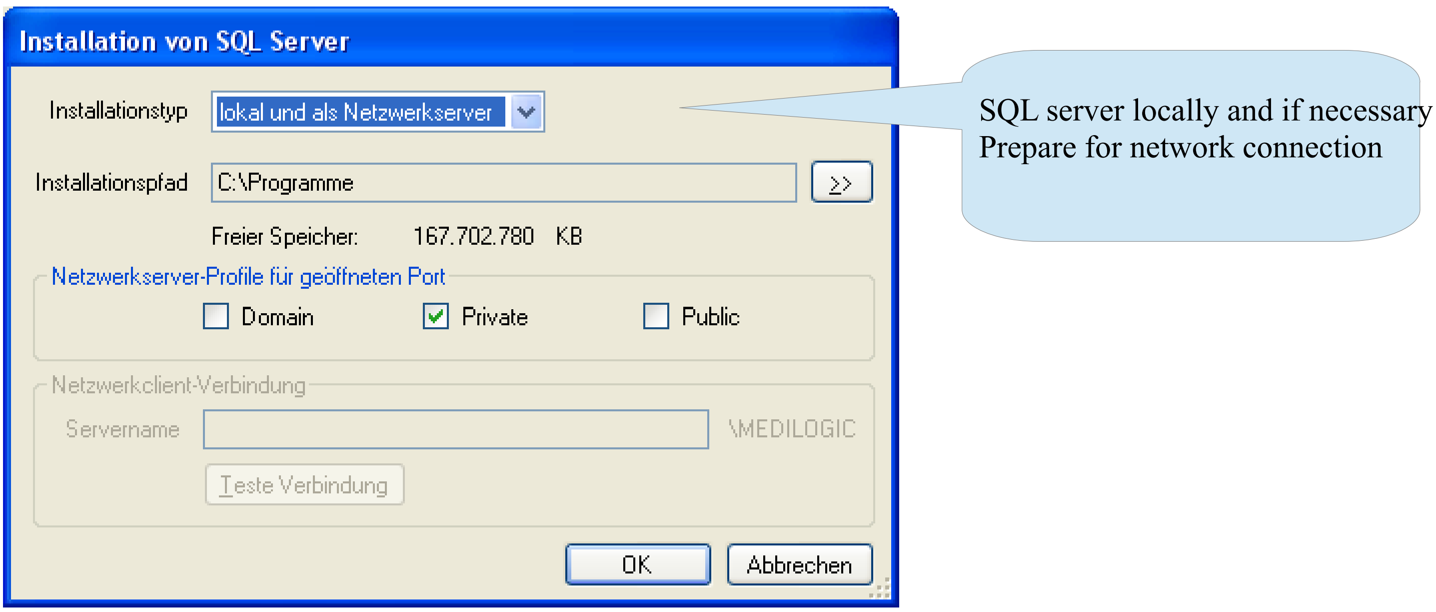
- The computer used is 100% IBM-compatible and fulfils the hardware requirements.
  See section 7.1
- The Windows operating system® 10 or 11 is already installed. If not, first install one of the operating systems according to the instructions.
- Required free capacity on the hard disc.
  The *medilogic foot scanner software* itself only requires around 200 MB of free hard disc space. At least 10 GB of free hard disc space is recommended for recordings and SQL server.
- *The computer system must be approved in accordance with IEC62386-1 or IEC 60601-1 and must be checked regularly in accordance with BGV A3 under the responsibility of the operator.*
- *Furthermore, DIN EN 60601-1 must be observed when operating the medical device (medilogic) and non-medical device (normal computer). This is also the responsibility of the operator.*
- In order to carry out the installation on your computer system, the appropriate authorisations are essential. Therefore, please log on to your system as a user with *full administration rights.*
- *Protection against unauthorised access* to your computer system and thus to the medilogic software and the data stored therein as well as *against cyber attacks on the computer system is the responsibility of the operator*. It is also the responsibility of the operator to secure the data collected by the medilogic system by means of a *suitable backup*. Backup functions are available in the medilogic software for this purpose.

To install the software in the graphical user interface WINDOWS® , it is only necessary to execute the medilogicSetup.exe file on the installation medium supplied.
For the initial installation, select the path in which the application is to be installed and start the process. For an update, the already installed medilogic versions are displayed in the table of the setup dialogue, please select the appropriate entry and start the process.

Installation selection of version 11.x

The use of medilogic version 11.x for the medilogic foot scanner requires the installation of an SQL server and the necessary auxiliary programmes. All necessary components are listed in the installation selection menu and must be installed as shown in the following illustration.





5 Carrying out an investigation

5.1 Quick start - preparation and procedure of a foot scan

If you already have experience of working with WINDOWS® , you will find it easy to get to grips with the programme. The easy-to-understand structure of the software and the deliberate limitation to what is necessary for practitioners means that there is no need for tedious familiarisation. This section provides an overview of the most important steps in the preparation and execution of an investigation. Details are explained in more detail in the respective chapters.

To use the medilogic foot scanner, please proceed as follows:

- ***Setup hardware*** See 4.1 Installing the hardware
- ***Installing the software*** See 4.2 Installation of the software

- ***Start medilogic foot scan***:
  Under WINDOWS® , double-click the *medilogic* symbol with the mouse. The *medilogic* programme will now start, make sure that the associated scanner is ready for operation. To do this, the power supply unit must be plugged in and the scanner switched on. Connect the scanner's USB cable to a free USB port on the PC.

- ***Preparation*** of the recording:
  Position the customer barefoot on the glass screen of the foot scanner. The placement should be as centred as possible with an even distance of approx. 1 cm between the feet and the edges of the scanning area. The feet must not be placed too close to each other to ensure clear foot recognition by the software. The customer should remain still during the scanning process without moving their feet. If necessary, suitable holding devices should be provided.
  Note: In order to minimise the impact on the image capture, it is advisable to tuck in the hem of long trousers. Coloured socks or bandages, excessively long trousers or large plasters may affect the image processing or the cropping of the feet.

- ***Starting*** an examination see 6.2 Software buttons
  You start recording data by pressing the scan button on the software. Only after the scanning process has been completed, when the scan carriage is back in its starting position, is the measurement finished and the customer can step off the sensor surface.

- ***Saving*** the recording under a customer data record see 6.3.1
  Enter first name, surname, date of birth and other personal data as required

- ***Evaluation*** of the recording see 6.2.8 ff.
  Evaluation of the foot status based on the plantar image; use of additional markings, length measurements, etc.; comparison of measurements

- ***Printing*** the recording see 6.4 Print
  Select the desired printout from the 'Print' menu

- ***End use*** by closing the software and switching off the toggle switch on the device.

Everything else should be easy to find out. Good luck !

6 Description of the *medilogic*

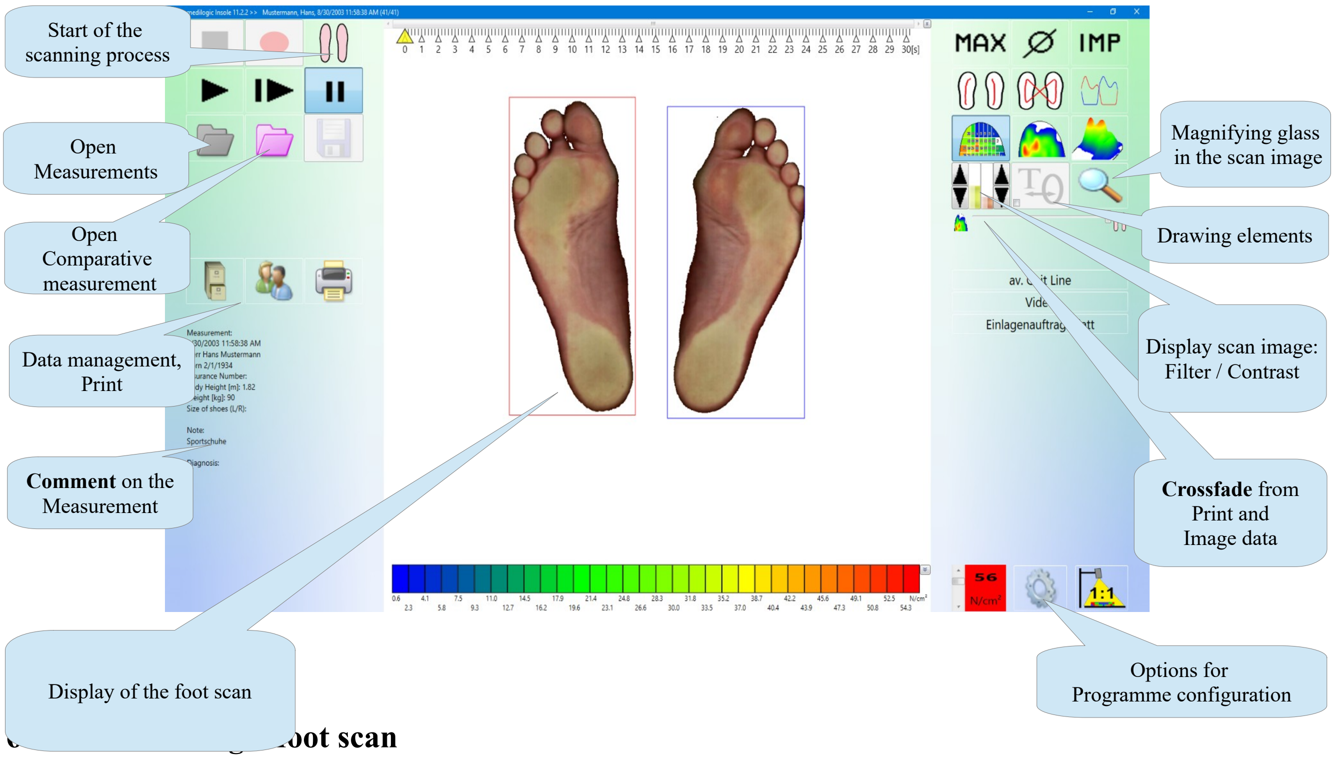
6.1 *medilogic systems* - General overview

The description of the programme is divided into the following main sections:

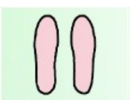
- Firstly, the function of the *buttons* displayed on the user interface is described. These buttons are used to control all important functions for recording and analysing measurements *see 6.2Software interface buttons (basic programme display)*
- This is followed by a detailed description of all menu items of the programmes. *see from 6.3 Data*

6.2 Software interface buttons (basic programme display)

The software from version 10.x for the medilogic systems offers the option of switching to the new basic programme display in the Options menu. Here, all programme functions are accessed via easily accessible buttons (icons) on the restructured interface.
However, the important operating functions have been retained with the previous symbols, so that the changeover will be very easy for the user.
Some additional information is stored in the title bar of *medilogic*. The name of the customer currently being processed and the date and time of the measurement can be read there. This information is also displayed on the left-hand side of the screen as information on the measurement; comment; diagnosis.
Below you will find an overview of the new basic programme display with labelling of the operating elements, in particular the functions for operating the foot scan. The button functions explained in the following chapter apply to both the classic and the new basic programme display; where applicable, the icons from both programmes are listed:



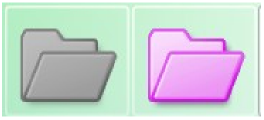
oot scan



The button with the two feet is the button for starting the foot scan. The recording of a measurement can be started by pressing the button. The measurement (not the

comparison measurement) is always recorded.
While the scan carriage is scanning the feet from front to back, they must not be moved. If you hold down the Shift key at the same time while you are on the record button with the mouse, the desired scanner can be selected if you have several Twain-compatible scanners.
devices installed in your system.
When positioning the feet, ensure that there is a distance to the edge of the scanning area of approx. 1 cm is maintained and a gap remains between the two feet.

6.2.2 Measurement / comparative measurement loading



Use the grey folder button to open the current measurement from the database and the magenta folder to call up a comparative measurement for comparison. The corresponding chapter6.3.2 orFehler: Verweis nicht gefunden of these instructions for use contains detailed explanations of the functionality.

6.2.3 Comparison of two visualisations

➢ The following buttons only appear if a comparison measurement has been loaded in the *medilogic pressure measurement* programme. Here you can set what you want to analyse and which of the two loaded measurements are displayed. The following evaluation modes are possible:

- Current measurement (is also always used for recording)

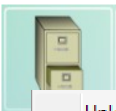
-Comparison measurement (additionally loaded measurement)

- Comparison of the left feet of both measurements

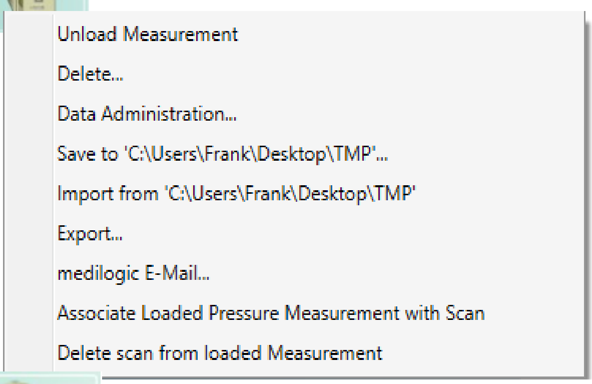
- Comparison of the right feet of both measurements

If you are in the comparison display of the left or right feet of both analyses, the corresponding information of the respective analysis is currently displayed in the header and in the comments window when the mouse arrow is positioned over one of the two soles or plate halves.
see 6.3.3Load comparative measurement

6.2.4 Data management

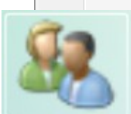


This button is only available in the new basic programme display and is used to access the data management functions and the various measurement data export interfaces.



In the classic basic programme display, these functions can be found in the 'Data' menu.
Detailed explanations of the functionality can be found in the corresponding chapter 6.3 of these instructions for use.

6.2.5 Customer details



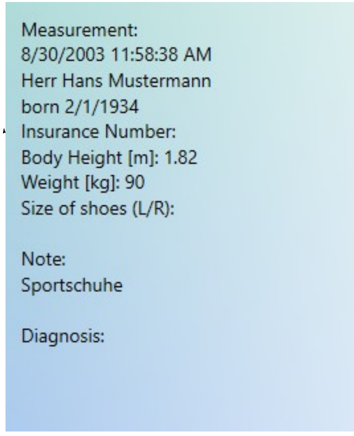
This button gives you access to editing customer details (e.g. names, addresses) and the option to create new customers before a measurement.

In the classic basic programme display, these functions can be found in the 'Data / Edit customer details' menu. Detailed explanations of the functionality can be found in the corresponding chapter6.3.5 of these instructions for use.

6.2.6 Print

The printer symbol opens the list of available printouts.
Detailed explanations of the functionality can be found in the corresponding chapter 6.4 of these instructions for use.

6.2.7 Display Comments

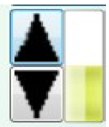


An optional comment is displayed for each measurement in the comments window, which is entered when the measurement is saved at . To display or switch off the comment, select "Display comments" in the Options menu. *(ee 6.5.1Options "Display / General ")* The size and position of the comments window can be changed as required by moving it on the programme interface with the left mouse button.
You can change an existing comment for a loaded measurement or write a new comment by <u>double-clicking with the left mouse button in the comments window or on the display area of the main window.</u> You are now in the input mode of the comments window (the cursor flashes) and can write the text. Right-click in the comments window to open the context menu with the following additional functions:

- *Undo* all entries/changes since the start of input mode
- *Select all* to delete the entire text, etc.
- Selection of existing text modules to be able to enter recurring text lines more quickly
- *Add a new text module* to supplement the existing text modules
- *Delete entry* to customise the list of text modules.

Once you have entered or changed the comment, click anywhere on the programme interface or close the comment input window. The entries are then saved for measurement.

6.2.8 Determine foot area / adjust filter value

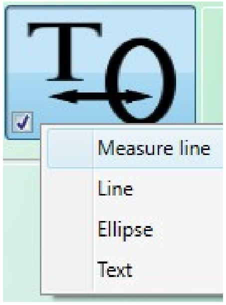


After the scanning process, the software automatically determines the image area in which the left and right foot are located. The prerequisite for this process is sufficient brightness contrast between the foot and the image background. The left foot is marked by a red frame and the right foot by a blue frame.
By touching the frame with the left mouse pointer, it can be moved in the image or adjusted in size at the corners. This makes it possible to exclude distracting areas of the image, such as a trouser hem resting on the scanner.
If required, the filter threshold for fading out the image background can be adjusted manually using the Up/Down arrow button.

6.2.9 Adjust contrast value

The contrast setting of the displayed scan can be adjusted manually using this slider. This is particularly useful depending on the screen settings and the print quality. The value set for a workstation is saved and restored when the software is restarted.

6.2.10 Drawing

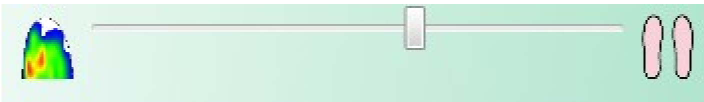


By ticking this button, you can show the drawing elements in the scan image, making them visible in the printout. At the same time, the button becomes active and you can open the drawing tools.
Clicking on this button makes the drawing elements displayed in the context menu available. Select an entry with the left mouse button and then place it in the image area with a mouse click.
The drawing element can now be aligned in the image using the red position markers that appear, grabbed and moved in the centre using the mouse pointer and deleted by clicking the right mouse button.
The text field is edited after double-clicking on the element: a green input field appears. Once you have entered the text, press the ENTER key to accept it.

6.2.11 Magnifying glass

The magnifying glass is used to view a section of the scan image enlarged in an additional display window. The displayed area is indicated by a red dashed square in the scan and can be moved and resized by touching it with the left mouse button. Changing the size of the zoom area thus influences the magnification factor. When the magnifying glass is activated, the footer areas cannot be changed

6.2.12 Overlay of scan and print image



This slider is only visible if a pressure measurement has been linked to the foot scan and is used to set the degree of blending of the scan and pressure measurement.
This can be changed continuously and by clicking on the scan or print image, you can switch to the non-overlaid display.
To combine pressure measurement and scan, please read section 6.3.10

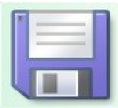
6.2.13 Options

This button gives you access to the programme options.
In the classic basic programme display, these functions can be found in the 'Options' menu. Detailed explanations of the functionality can be found in the corresponding section6.5 of these instructions for use.

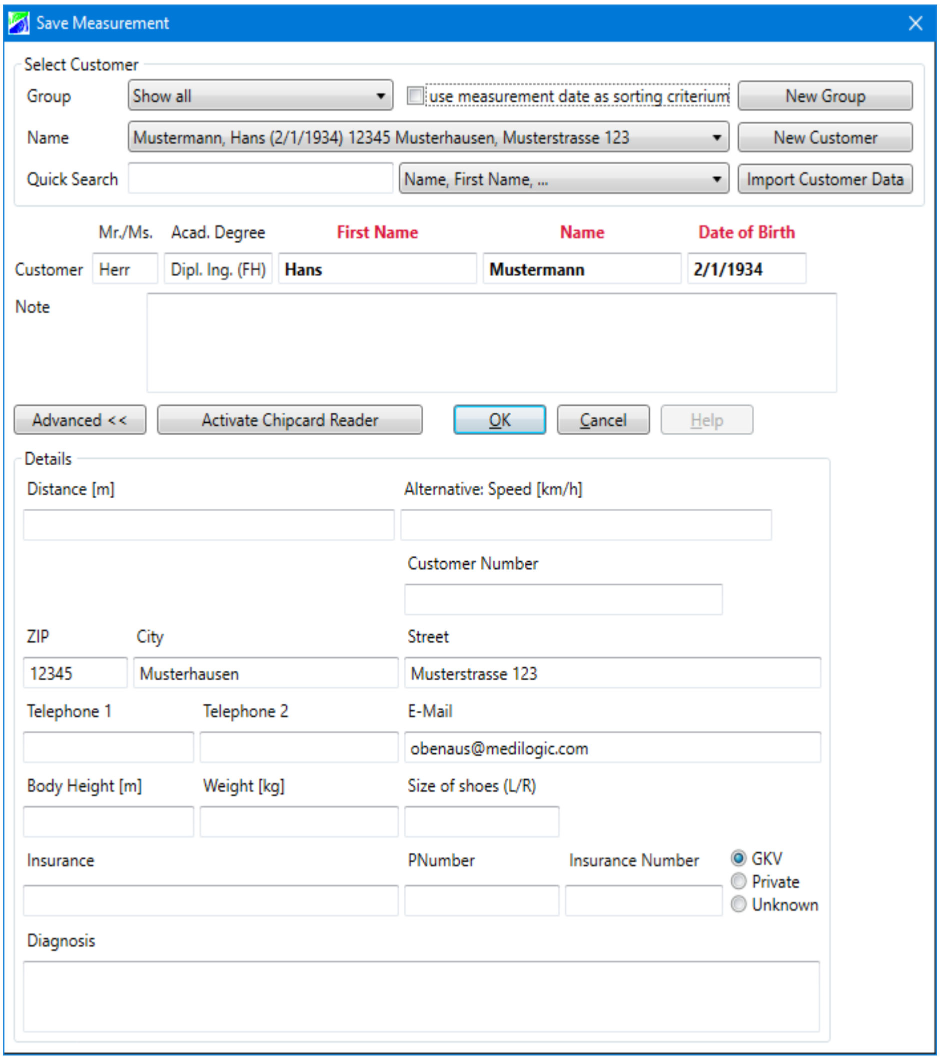
6.3 Data

The data of a measurement can be saved and reloaded for later viewing or evaluation. By default, the data is saved in the "\DATA" subdirectory on the medium (hard drive, network drive, etc.) on which the *medilogic* programme is located.
The surname and first name (date of birth if applicable) of the person measured, as well as the date and time of the measurement, are used to identify a measurement. In addition, the measurements can be described in more detail by entering a comment for each measurement.

6.3.1 Save data



Once a measurement has been completed, the measured data can be saved.
The dialogue window for saving is opened via the menu Data / Save. To simplify the process, the Save dialogue box can be opened automatically immediately after the end of the scanning process. This can be set via Options / Comfort settings : "Display measurement Save after recording".



To save a measurement at , the "Customer" is identified in the centre of the window. *The surname, first name and date of birth of the person being measured must be entered*. The date and time of the measurement are automatically determined and saved at the end of the measurement.
It is not mandatory to enter a comment, but it is also saved for the respective measurement. To make it easier to enter comments and diagnostics, existing text modules can be inserted using the context menu with the right mouse button. *see 6.2.7 Display Comments*

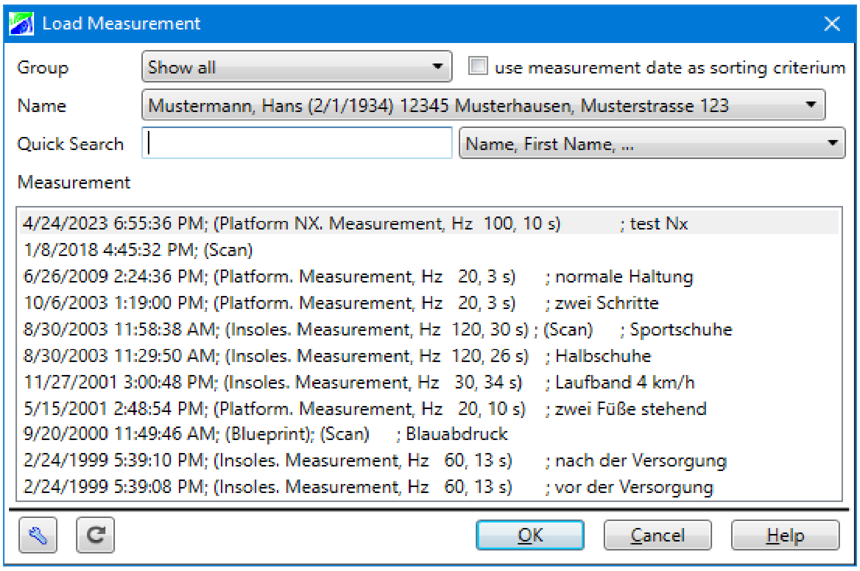
If you use a chip card reader to enter customer data and this has been installed in your operating system, you can switch on access to the device by pressing the 'Activate card reader' button. Activation is retained until you have started the software once without the card reader being plugged in.
By pressing the "Advanced" button, additional customer-specific information (address etc.) can be entered, which can then be used as required via the Data / Edit customer details menu. Pressing "Advanced" again hides the additional information again. *see 6.3.5 Edit customer*

In the upper window area "Select customer", you have the option of selecting a previously saved customer to assign the current measurement to. The selection is made according to the desired customer group. (If no grouping is required, the "Show all" group is used).
All customers in the selected group are then listed in the "Name" selection box. The customer names are sorted alphabetically by default and can be sorted by the date of the last measurement if desired by ticking the box. The list of names sorted by measurement date makes it easier to find the last persons measured.
You can search for a name by entering it in the "Search for" field, whereby the relevant customer is displayed in the "Name" field after entering the initial letter. The associated information for this customer is now automatically transferred to the centre section of the window and can be added as required (in particular comments on the current measurement).
In the same way, you can also search for the customer's insurance number, customer number or date of birth if this is set as a search criterion in the drop-down box next to the "Search for" field.
If the customer is not yet in the list, an entry can be added using the "New customer" button (all fields are deleted). If a new customer group is to be created, please press the "New group" button, otherwise select a group to which the customer is to be assigned.
When saving further measurements at , the last person is preset in each case. If this setting is correct (if several measurements are taken with one person), you only need to confirm with the "OK" dialogue button. Otherwise, press "New customer" and enter the new data in the corresponding fields.
To switch between the fields, press the TAB key or click with the left mouse button in the corresponding field.

<u>Note:</u> For quick input, you are immediately in the First name field after calling up the save dialogue, press the RETURN button to switch to the "Name" field and then press RETURN to switch to "Date of birth". With the next RETURN, press the "OK" button and the measurement is saved immediately.
The menu item Data / Save remains locked until the end of a new measurement. This prevents a measurement from being saved twice.
If the database module was configured to use external customer databases when the *medilogic* system was set up, it is possible to access existing customer management programmes or the data of a health insurance card reader and thus facilitate input. If you enter the customer data using a chip card reader, all the customer information available on the card will be inserted in the corresponding fields as soon as the card is inserted. If the card reader was not inserted when the programme was started, it can be reactivated later by pressing the 'Activate card reader' button. *see 6.5.2*"

6.3.2 Load data

Saved data can be reloaded. This means that this data is available again for viewing or analysing. To do this, select the menu item Data / Load.



To load the data at , select the relevant customer group (otherwise select "Show all") and select the person you are looking for by selecting the customer name. The customer names are sorted alphabetically by default and can be sorted by the date of the last measurement if desired by ticking the box. The list of names sorted by measurement date makes it easier to find the last person measured.
The corresponding measurement can then be clicked on in the list below. The entries in the list contain the date and time of the measurement and, if applicable, the comment text entered. After selecting a measurement, the loading of the data is triggered by pressing the "OK" dialogue button.
Similar to the "Save measurement" dialogue window, you can also search for a specific name or health insurance number when loading by entering it in the "Search text" field.
You can recognise the type of measurement (e.g. scan, IBG measurement, sole measurement, plate measurement) by the name of the individual measurements (after the measurement date in brackets). If you select a measurement from a different programme mode, *medilogic* automatically switches to the relevant mode.

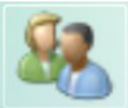
6.3.3 Load comparative measurement

In the *medilogic programme*, it *can* often be helpful to enable the comparison of a second data set by loading a comparison measurement.
To do this, select the menu item Data / Load comparative measurement. The dialogue window corresponds to Loading the current measurement. (*see 6.3.2 Load data)*
After loading the comparative measurement, another button field becomes visible. The black foot symbols stand for the first loaded measurement, the purple foot symbols stand for the comparison measurement. *6.2.3*
For the comparative measurement, all analyses can be carried out as usual. The comparison of the current measurement and comparative measurement is carried out for one foot at a time. The selection is made using the corresponding buttons.

6.3.4 Deleting measurements / persons / groups

Via the menu item Data / Delete... it is possible to delete measurements, customers and customer groups from the computer that are no longer required.
The object to be deleted is selected in the same way as the function *at 6.3.2Load data* . By pressing the "Delete group", "Delete customer" or "Delete measurement(s)" buttons, the objects displayed in the selection are irrevocably deleted from the hard drive. *For this reason, please check whether the selected objects are really to be deleted before confirming the security question.*

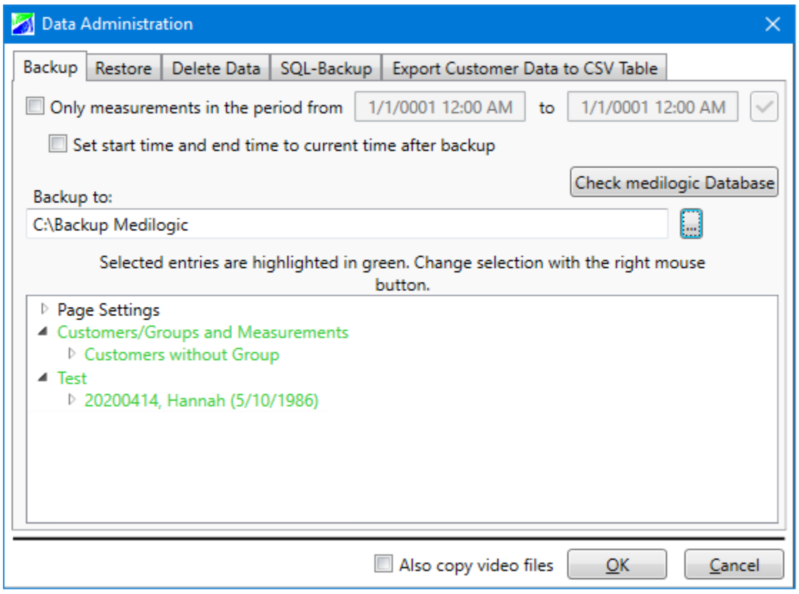
6.3.5 Edit customer data



The Data / Edit customer details menu is used to edit the information on the customers stored in the database (name, address, etc.). In addition, the "New group" or "New customer" buttons can be used to add new database entries before saving a measurement . The procedure here corresponds to the description in *6.3.1Save data* . The entry can also be made via external databases or the chip card reader. *see 6.5.2"* The "New group assignment" function can be used to assign the selected customer and all their measurements to a different group.
When the dialogue is opened, the last customer processed is always displayed. However, any customer can be accessed via the selection functions.
As soon as a customer's entries are edited, the change to another customer is blocked; the change must first be confirmed by clicking "Apply".
Note: The " Remarks on measurement" field is disabled in this dialogue, as these remarks are always assigned to a specific measurement. The entry is made as described in *6.2.7Display Comments* .

6.3.6 Data administration (data backup / restore / delete data /SQL-Backup / export customer data)

When using the medilogic system, it is often useful to save the measurement results to an external storage medium from time to time or to transfer the data to another computer. The menu item Data / Data maintenance is used for this purpose.



Function " Backup"
The existing data can be saved to a destination selected by the user via Data backup. The customer information, the associated measurements and the customised print page settings are saved in a *.tar file. If the "Copy video files too" checkbox is ticked, please check whether the backup medium has sufficient storage space available.
Before starting a data backup, it is advisable to use 'Test the medilogic database' to check whether all file assignments etc. are correct in order to create an error-free backup.
Note: Please always back up or transfer your measurement data using this procedure, as manually copying individual measurement files will result in the loss of customer data.

Function "Restore"
Data restoration works in the opposite way to data backup, in which the data is restored from an existing backup medium to the *medilogic* software. The *.tar file created during the backup must be accessed.

Function „Delete data"
To clean up your database, you have the option of deleting measurements from a specific period or customer entries without measurements. Please note that this deletion cannot be undone and should therefore be handled with care.

Function "SQL-Backup"
The data backup (backup of the SQL database) is carried out automatically in defined cycles. A distinction is made here between the global SQL database with customer data and measurements and the local SQL database, which saves the individual program settings of the medilogic system for each Windows user.
The backup process is carried out automatically at the first program start of each day.
Note: If you use the SQL database in a network with several client computers, the SQL backup is only necessary from one client.

Function " Export customer data to CSV table"
This function converts the customer-specific information stored in the database into a csv file that can be read by Office programmes. This allows you to the make customer data stored in accessible for other applications, such as mail merge. A complete export or a selection of individual customers is possible. see *6.3.5Edit customer*

6.3.7 Save to... ; Import from...

To transfer individual measurement files, you can use the menu item Data / Save to... menu item allows you to save the current measurement to a disc or any storage medium (e.g. USB stick, network drive). The prerequisite for this is that the target directory specified under 'Options / Extra' is not write-protected and has sufficient free storage space. *see 6.5.2"*
The measurement file(s) saved on the storage medium can then be read in on another *medilogic* system via the menu item 'Import from...'.
If set in the options, the information on the storage medium is deleted after the import and the measurement is displayed immediately if necessary.

6.3.8 E- Mail - the electronic mail


This menu item allows you to send the data of the current measurement via e-mail or to receive the data of a measurement and integrate it into your own system so that it can be analysed in your own system.

How does E- Mail work? - short introduction
The prerequisite for use is that you have an e- mail account with some provider, i.e. your own e-mail address . We also assume that this account is only used for this specific task, the transfer of medilogic

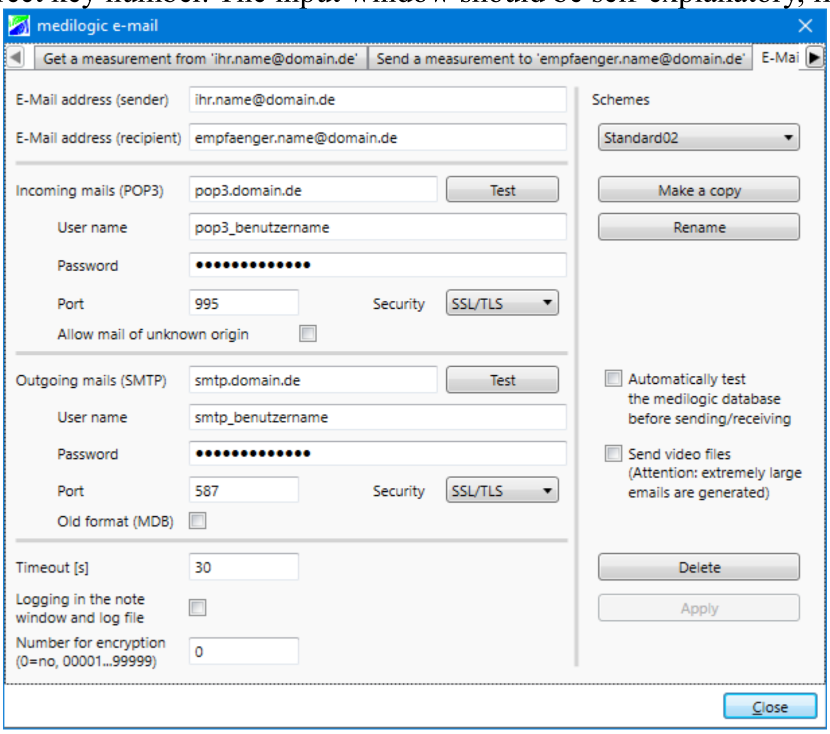
data. As there are a number of providers of free E- mail accounts, this is not a particular restriction, but simplifies handling.

Let's assume that Andreas would like to send an e-mail to Beate. The following steps must then be taken:

1. Andreas presses the "Send" button when the E- mail is ready to be sent. The software then establishes a connection between Andreas' computer and his E- mail provider. A specific protocol is used between these two computers, the "SMTP" (Simple Message Transfer Protocol). This is a simple protocol without authentication. To avoid problems such as spam mails, many providers want to know who sent the E- mail. There are various methods for this. One possibility is the "POP before SMTP" method, in which Andreas first receives e- mails before sending them and authenticates himself with his user name and password. "SMTP_Auth" is an extension of the simple "SMTP", which allows authentication of the sender. This method, which is currently the most common, is preset in medilogic.
2. After Andreas has successfully authenticated himself with his provider, the e-mail is transferred there.
3. Andreas' provider sends this E- mail to the POP server of Beate's provider, which then holds the E- mail ready for Beate.
4. Beate presses the "Fetch" button so that her computer establishes a connection to her provider's computer (POP server). Beate's user name and password are transmitted to the POP server and the mail is then transferred.

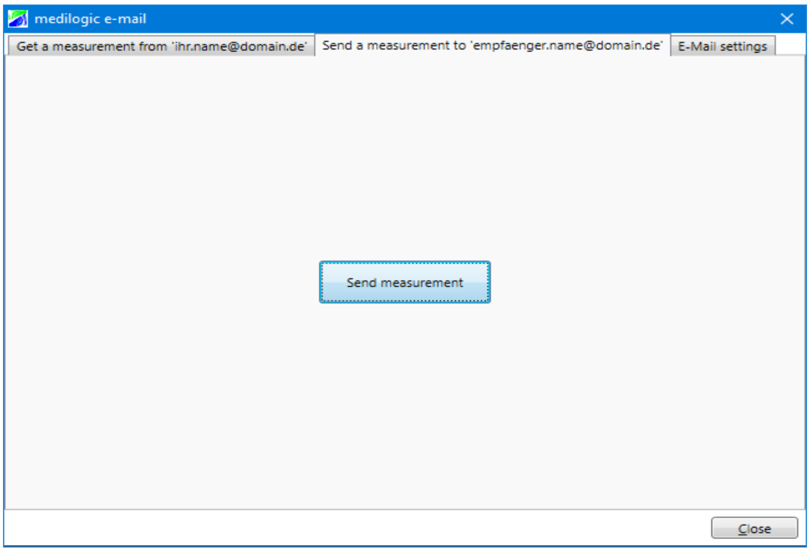
E- Mail settings

As you can see from the last section, a number of settings are required for E- Mail communication. These settings are entered in the medilogic software in the menu item "Data/ E- Mail/ E- Mail settings".
If you do not know any of this data, please contact your e-mail provider.
For data protection reasons, it is recommended to use encryption. A 5-digit key number is used for this purpose. In this case, the recipient can only read in the customer data and measurements with the correct key number. The input window should be self-explanatory, if not please contact the hotline.



Get measurement from ihr.name@domain.de
After you have made the POP3 settings in the E- mail settings, first check whether there are any e-mails for you. If this is the case, the two buttons "Retrieve measurement" and "Delete E- mail" will also be active.
When retrieving mails, you can tick the box at the bottom to select whether the data should also be deleted from the server immediately (or not) and whether the measurement should be displayed in the medilogic system immediately after retrieval.
To optimise the processing time for a large number of E- mails, you can reduce the number of E- mails to be listed.

Send measurement to receiver. name@domain.de



After you have entered the SMTP settings as well as the recipient and sender in the E- mail settings, you can send the current measurement via E- mail by clicking on "Send measurement".

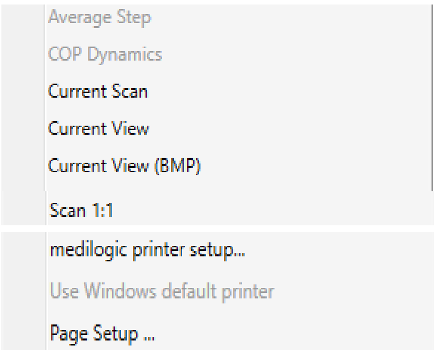
6.3.9 Data export to third-party programmes

With this menu item, it is possible to write the data of the current measurement to a file that can be read by third-party programmes. In this way, the measurement data is written to a csv table that can be read by spreadsheet programmes such as MS Excel for statistical evaluations. The foot scans can also be transferred to the computerised insole milling machine of the ID:CAM, pedcad, IETEC, ComfortSpline or Ortho-Fit systems, among others.

6.3.10 Associate scan with pressure measurement

When using the foot pressure measurement and the foot scan together, it is possible to link both measurement processes. This fixed assignment of the foot scan to a pressure measurement is possible as soon as you have loaded a pressure measurement into the display.
After selecting the "Associate scan with loaded pressure measurement" menu item, you can permanently assign any foot scan to the active pressure measurement. This means that when you load this linked process, the pressure measurement and foot scan will be displayed together in future. The positioning of the foot scan is also restored.
You can undo the link using the "Delete scan from loaded measurement" menu item.
The optional combination of the foot scan with the IBG module enables simultaneous recording of the plantar foot image and the plantar pressure distribution.

6.4 Printout



In principle, all images visible on the monitor can also be printed out. Important information about the person being measured is also printed out.
There are several ways to output the information displayed on the screen to a printer installed under WINDOWS®
Note: As with all menus, the items that cannot currently be executed are greyed out and cannot be operated.

The printer is selected via Print / Set up printer. The following is an overview of the different variants of a printout.

6.4.1 Printout - Current Scan

This function prints the currently visible image and additional personal information such as surname, first name and the comments entered. This means that the printout can later be assigned to the person being measured. If the measurement data has not yet been saved, the printout is made without any personal details. It is therefore advisable to save the customer's measurement before printing . The company logo is also printed.
If the activation tick has been set in the button for the drawing elements, these elements also appear in the printout.

6.4.2 Printout - Scan 1:1

The image currently displayed on the screen is printed in its original size. For printing in original size, the paper format previously set on the printer is analysed by the *medilogic program.* The 1:1 printout is then adapted to the paper format found. This means that the 1:1 printout of the measurement results on A4 paper format is often printed on two sheets.

6.4.3 Printout to BMP file

The currently displayed print image can also be saved as an image in a *.bmp file instead of being printed on paper, which can then be used in other applications. After calling up the menu item "Current view (BMP)" in the Print menu, a subdirectory "pictures" is created in the programme directory (by default: C:\programme (x86)\medilogic). The bmp file is then located there, the file name of which is composed as follows Name_First_Name_Date_of_Birth_ffd. no.
It is also possible to save in BMP format at any time by holding down the SHIFT key when selecting the print scheme.
The path setting for the BMP export can be configured in Options/Extra: Change picture path (see section 6.5.2 Options "Extra")

6.4.4 Printer setup

In the Print / medilogic printer setup menu, the dialogue window known from WINDOWS® is called up to select and set up the printer. The WINDOWS® standard printer is used by default.
The paper format (portrait format must be selected) and the print quality can be set in this dialogue window. The latter is also responsible for the print speed and colour consumption.
The parameters that can be set in the setup are printer-specific. If in doubt, refer to your printer manual or ask your printer dealer.

When printing to a black and white printer, the software automatically switches briefly from the colour table to the grey scale table in order to display the print differences in a meaningful way.
To simplify daily work, the "Do not display printer dialogue before printing" function can be selected under Options / Comfort settings after the printer has been set up. The printout is then activated immediately after selecting the print scheme in the Print / Print menu.

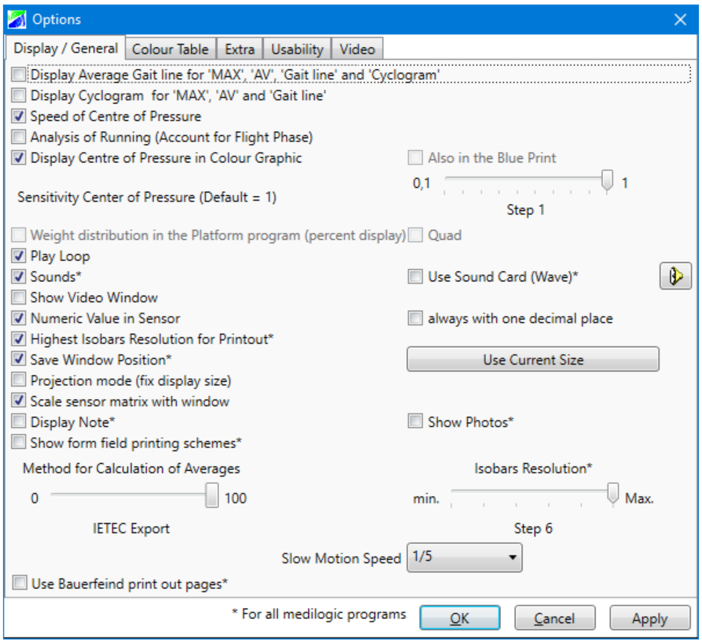
6.4.5 Integration of a company logo

When printing from the medilogic programme, your company logo can be integrated. It is displayed in the top right-hand corner. The company logo should be available as a Windows bitmap and have the name LOGO.BMP. It must then be copied to the path C:\PROGRAMME\MEDILOGIC on the computer on which the programme is installed. The existing LOGO.BMP file will be replaced.

6.5 Options

Various settings can be made in *the medilogic* software under the menu item "Options..." in order to adapt the programme to specific requirements.
The activated status of an option is indicated by a tick on the menu item. Selecting this menu item again switches this status off again. The settings are saved and are therefore also effective when *medilogic* is restarted. Settings that are valid for all programmes are marked with an * and therefore only need to be adjusted in one of the programmes.
A number of functions from the options menu are only relevant for pressure measurement. Only the options relevant to the foot scan are described below.

6.5.1 Options "Display / General "



Function: "Remember window position"
When the program is restarted, the program window and all dialogue windows appear exactly where they were previously closed on the desktop. This allows you to determine in which area the windows should always open. After the first installation, this function is initially deactivated and should therefore be activated when the programme is started for the first time.

Function: "Scan window scaling for projection"
With this option, the window size for the original display using medilogic projection is saved by the programme so that the correct size is displayed each time the programme is restarted.

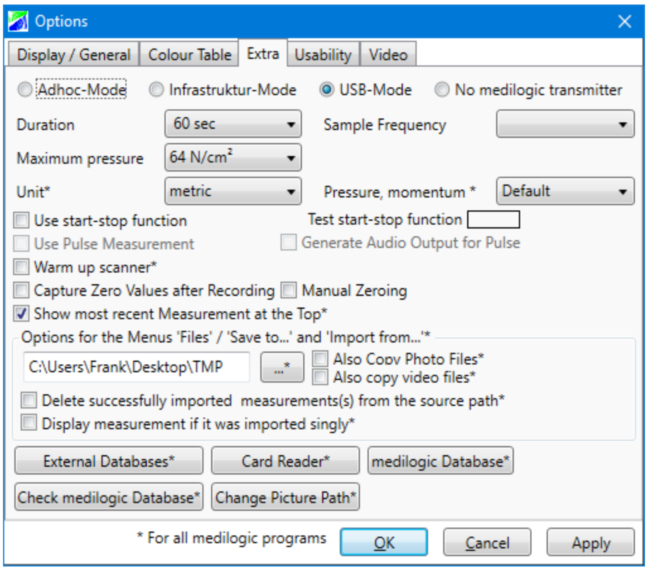
Function: "Scale sensor matrix with window"
With this option, the sensor matrix is displayed depending on the size and format of your programme window. Especially with 16:9 screen resolutions, this scaling should NOT be used in order to obtain an undistorted display of the soles/plates.

Function: " Show comments "
You can use this option to decide whether the corresponding comment is displayed permanently or not. If this option is selected, the comment is displayed in an extra window. When loading and saving measurements, the associated remarks are always displayed in the respective selection lists of the measurements.
See6.3.1Save data *See6.2.7Display Comments*

Function: "Show photos"
This function allows you to assign up to 9 digital images to each saved measurement. For documentation purposes, the images or photos can be still images from a digital video camera or, when using the video window, individual images from the saved video sequence. The photos are permanently assigned to the corresponding measurement and displayed again in the photo window when the measurement is loaded later . A special print scheme enables an overview printout of the photos.

6.5.2 Options "Extra"

The software is usually set up by a technician from the manufacturer, who will make the necessary adjustments to the programme on your computer. We would therefore like to take this opportunity to remind you that if you are unsure about the settings, you should first contact the manufacturer via the hotline.



Function: "Show most recent measurement at the top"

In the dialogues Data and Comparison measurement - Load, this setting causes the last recorded measurement to be displayed at the top of the list and all others to follow according to their measurement date.

Function: "Options for Files Save to... / Import from..."
Fast data exchange via a mobile storage medium can be conveniently carried out in the Data menu using ' Save to...' or 'Import from...'. The options are used to configure which drive is used, whether photos/ videos are also transferred and whether the data should be deleted from the source data carrier and displayed immediately.

Function: "medilogic database"
This menu item can be used to specify the SQL server where the database with the customer measurements is located. The setting of the location where the database of customer measurements is located refers to applications within a network. With this setting, different computers on which the *medilogic* software has been installed can access one and the same database and therefore one and the same data without the need for time-consuming synchronisation of the data records.
This makes it possible, for example, to record measurements at one measuring station and *simultaneously* analyse measurements on other computers.

Function: "Check medilogic database"

To check for inconsistencies within the medilogic database, this function is used to check the correct connection between persons, measurement files and database entries. This test should be carried out at regular intervals, especially before a complete backup.

Function: " External databases"

In this menu item, you can make settings for external databases/sources. The main purpose of integrating these external data sources is to simplify the entry of customer data when saving measurements. So if you are already a user of a customer database, you can also use this data for the *medilogic* system so that multiple entries can be avoided.

In the " *database name*" line, you can select the database you are using from the list of databases, provided the database manufacturer supports this. To do this, the corresponding name must be selected and a tick activated next to the word "used". This gives you the option of using several data sources at the same time.

The default path of the corresponding database is specified in the next line " *database path*". If you have installed the database by default, you do not need to change this setting. In other cases, you can specify the corresponding path under " Database search". The "Window visible" item can be activated or deactivated with a mouse click. This is always possible and useful if the data can be read in automatically in the "Save data..." menu item.

The currently supported customer databases - can be found in the " *database name*" section described above. If the database you are using is not listed, please contact the manufacturer of the medilogic system.

see 6.3.1 Save data

Function: " Card reader"

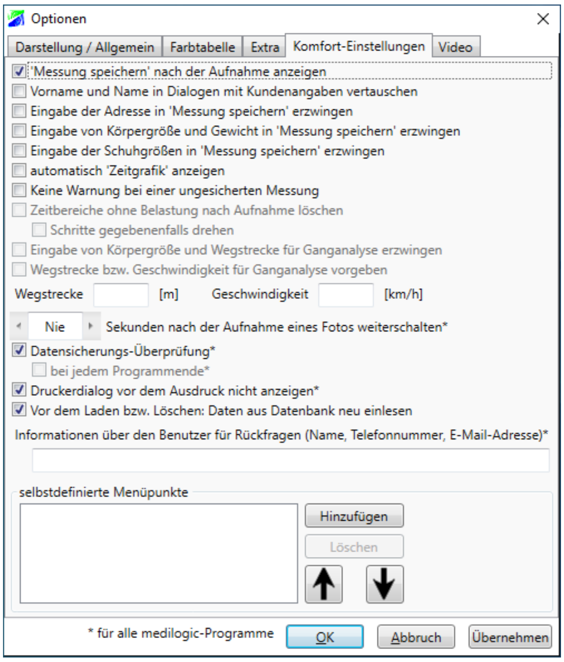
This function enables the configuration of a chip card reader to read the customer data from the health insurance card or the new electronic health card. For this purpose, an external card reader (depending on the setting, the 'Chip-Drive SCR335' from SCM Microsystems GmbH or the 'Cherry-eGK-KVK' is addressed by the *medilogic* programme when saving a measurement and the manual entry of the customer data is no longer necessary. The matching card reader is offered by the manufacturer as an optional accessory for the *medilogic system*.

Function: "Change picture path"

Here you can specify whether the image files created with the 'Current view (BMP)' print scheme should be saved in a directory other than the default directory: 'Pictures' in the medilogic programme directory.

6.5.3 Options "Usability settings"

This group of options offers you special programme settings to simplify your daily work with the *medilogic* system. Depending on the current measurement procedures and habits, you can specify certain "reactions" of the programme.



Function: "Show 'Save Dialogue' after recording"

The Save dialogue opens automatically after pressing the Stop button or after the maximum measurement time has expired at the end of a measurement. If saving is not desired in individual cases (e.g. if the measurement is terminated prematurely), you can switch back to online display mode by clicking "Cancel" in the Save dialogue.

Function: "Swap first name and man in dialogs with customer information"

Depending on your data entry habits, the order of the input fields First name and Last name can be swapped. This prevents accidental entry in the wrong field.

Function: "Make entering size of shoes mandatory"

If you want to save your customer's shoe size for each measurement, activating this option prevents the entry from being forgotten. The input field is highlighted in colour in the 'Save measurement' dialogue.
The same will be active when selecting address or body heith and weight mandatory.

Function: "Do not display printer dialogue before printing"

After selecting a specific print scheme in the Print / Print menu, the printout is immediately sent to the printer. The printer driver dialogue is omitted. This option is useful if all printer configurations have been made and printing is always done on the same printer.

Function: "User defined menu items"

For quick access to frequently used submenu items, such as special print schemes, we offer you the option of selecting individual menu items from the list of available menu items and placing them on the right-hand side of the main window a self-defined name. This makes routine work with the medilogic system even easier and allows you to carry out a well-founded analysis in just a few simple steps.

7 Description of the hardware components

The medilogic foot scanner is designed as a flatbed scanner for installation in a base plate.
designed. The two types of foot scanner A320 and A360 are externally identical and differ only in the different scanning speed. For each type, the appropriate hardware
hardware driver must be installed on the computer for each type.
It is an optical scanning of the foot surface from below, which rests on the glass pane.
The person being examined can be standing or sitting. For optimum optical detection, it is necessary that no extraneous light falls directly into the scanner. For this purpose, a darkened measuring booth or similar devices should be used to shield the scanner from direct light.
Interfering light influences are shown in the image by 'background effects' outside the foot, which can reach right up to the edge of the foot under certain circumstances. Please also refer to the setup instructions in the section 4.1.1 Structure and preparation of the system
The foot scanner is a maintenance-free device that is supplied with power via the power supply unit provided and is connected to the computer via a USB port.
Please observe the safety instructions described in the section 3.4 regarding the installation and operation of the foot scanner operation of the foot scanner.

7.1 Technical data of the medilogic foot scanner

Flatbed scanner:
LxWxH: 63.5cm x 43cm x 11cm
Scanning area: 43cm x 30 cm
Weight approx. 15 kg
Max. permissible load with a body weight of 180 kg

Connections:
USB connection to the computer
230V mains voltage, 50Hz
Operation only with the original power supply unit supplied: 24V 4.2A (manufacturer: Mascot, type: 2820)
Disconnection from the mains supply by pulling out the mains plug

Ambient conditions:
Storage/transport: Do not drop, caution fragile!
-20 to +40°C; 20-80% rel. humidity, non-condensing; 700-1060hPa atm. pressure
Operation: +5 to +30°C; 20-80% rel. humidity, non-condensing, 700-1060hPa atm. pressure

Test certificates:
EMC test report no. according to DIN EN 60601-1-2
Electrical safety test report no. G0M-1504-4662-SCMED31-001N-V02
Registration of the State Health Office Reg. no. DE/CA 76/H 00103466

Computer system (recommended minimum equipment):
- 16 GB RAM
- x86 compatible processor
- 1 free USB interface type A for 2D foot scanner
- Additionally 1 free USB- interface if chip- card reader is connected
- Operating system: Windows® 10 or 11
- IEC 62386-1/ IEC 60601-1 - compliant computer system

8 Appendix:

8.1 Possible system messages and their meaning[1]

The *medilogic* programme automatically intercepts any errors that occur and displays them on the screen. The most important of these and the necessary reaction to them are briefly explained here.

8.1.1 Note: "The scan device is not connected"

The scanning process cannot be started because the medilogic software cannot address the scanner. Please check whether the cable connections (USB port and power supply unit) are established and whether the scanner is switched on using the toggle switch.
the scanner is switched on using the toggle switch.
If the scanner driver has set the device to energy-saving mode, you can reactivate the scanner by switching it off and on again using the toggle switch.
If you are using a scanner other than the one mentioned in the information text, please hold down the Shift key while clicking on the scan button in the software. Then the
the selection window for all the scanner drivers installed on your computer will appear.

8.1.2 Note: "Scan-Ident faulty. Your scanner may not have warmed up yet"

This message appears after the scanning process and indicates unsuccessful optical recognition of the Scan-Ident label. This is usually due to insufficient warm-up of the scanner light. The warm-up can be improved accordingly by scanning again; if necessary, additional preheating of the scanner can be activated in Options/Extra.
In unfavourable lighting conditions, e.g. direct sunlight on the scanner glass, recognition may also be disturbed.
recognition may also be impaired. Please use suitable positioning of the scanner
or darkening agents to avoid direct sunlight or spotlights in the examination room.

8.1.3 Note: "The feet could not be recognised in the scan image"

This message appears if the feet have not been clearly detected by the programme. This can be caused by an unfavourable positioning of the feet on the sensor surface. The feet should be centred at least 1 cm away from all side edges. Furthermore, the feet should not be too close together.
Another reason for a failed foot detection is the existing lighting situation. In this case, please check the specifications described in chapter 4.1.1 .
In most cases, the measurement can still be used, but manual adjustments are necessary. In the scan view (the slider for the overlay must be moved all the way to the right), the red frame for the left foot and the blue frame for the right foot are then manually aligned over the images. Use the "Increase filter value" slider to remove the feet.

1 For messages specific to pressure measurement, please refer to the corresponding instructions for use

8.2 Interference radiation and safety distances - Manufacturer's declaration on EMC

The following tables must be observed with regard to EMC (electromagnetic compatibility) for safety reasons. They are part of the certification in accordance with standard EN 60601-1-2 and are taken from this standard accordingly.
Portable and mobile RF communications equipment (radios) should be used no closer to any part of the medilogic system, including connecting cables, than the recommended separation distance given in the tables below.
In the following tables, the term *ME device* is used for 'medical electrical device' and specifically describes the *medilogic foot scanner type A320 or A360* described in these instructions for use.

8.2.1 Cable lengths of accessories for all medilogic products

Connection cable	***Cable length***
USB connection to the computer system	150 cm
DC voltage connection to the power supply unit (24V)	75 cm
Connection of net part to mains voltage (230V)	175 cm

8.2.2 Electromagnetic emissions: Manufacturer's declaration and guidelines (Table 1 according to EN60601-1-2)

<table>
<tr><th colspan="3">Guidelines and manufacturer's declaration - Electromagnetic emissions</th></tr>
<tr><td colspan="3">The ME device is intended for use in the electromagnetic environment specified below. The user of the ME device should ensure that it is operated in such an environment.</td></tr>
<tr><td>Interference emission measurements</td><td>Agreement</td><td>Electromagnetic environment - Guidelines</td></tr>
<tr><td>HF emissions to CISPR 11</td><td>Group 1</td><td>The ME device uses RF energy exclusively for its internal function. Therefore, its RF emissions are very low and it is unlikely that neighbouring electronic devices will be disturbed.</td></tr>
<tr><td>HF emissions to CISPR 11</td><td>Class 1A</td><td rowspan="3">The ME device is suitable for use in establishments other than domestic and those directly connected to the public low-voltage power supply network that also supplies buildings used for domestic purposes</td></tr>
<tr><td>Emission of harmonics according to IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Emission of voltage fluctuations/ flicker according to IEC 61000-3-2</td><td>Not applicable</td></tr>
</table>

8.2.3 Electromagnetic immunity: Manufacturer's declaration and guidelines (Table 2 according to EN 60601-1-2)

Guidelines and manufacturer's declaration - Electromagnetic immunity			
The ME device is intended for use in the electromagnetic environment specified below. The user of the ME device should ensure that it is operated in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Match level**	**Electromagnetic environment - Guidelines**
Discharge of static electricity (ESD) according to IEC 6100-4-2	± 6 kV Contact discharge ± 8 kV Air discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%
Fast transient electrical disturbances / bursts according to IEC 61000-4-4	± 2 kV for mains cables ± 1 kV for mains cables	± 2 kV for mains cables ± 1 kV for mains cables	No special requirements for the operating environment. Supply lines should correspond to the typical values found in business and hospital environments
Surges according to IEC 6100-4-5	± 1 kV Voltage outer conductor outer conductor ± 1 kV Voltage outer conductor-earth earth	± 1 kV Voltage outer conductor outer conductor ± 1 kV Voltage outer conductor-earth earth	No special requirements for the operating environment. Supply lines should correspond to the typical values found in business and hospital environments
Voltage dips, short-term interruptions and fluctuations in the supply voltage in accordance with IEC 61004-11	< 5% UT (> 95% collapse of the UT) for 1/ 2 period 40% UT (60% dip in UT) for 5 periods 70% UT (30% dip in UT) for 25 periods < 5% UT (>95% dip in the UT) for 5s	< 5% UT (> 95% collapse of the UT) for 1/ 2 period 40% UT (60% dip in UT) for 5 periods 70% UT (30% dip in UT) for 25 periods < 5% UT (>95% dip in the UT) for 5s	No special requirements for the operating environment. Supply lines should correspond to the typical values found in business and hospital environments
Magnetic field at the supply frequency (50/60Hz) according to IEC 601114-8	3 A/m3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to the typical value found in business and hospital environments.
Note: U_T is the AC mains voltage before application of the test levels			

8.2.4 Electromagnetic immunity: manufacturer's declaration and guidelines for ME devices that are not life-sustaining

Guidelines and manufacturer's declaration - Electromagnetic immunity

The ME device is intended for use in the electromagnetic environment specified below. The user of the ME device should ensure that it is operated in such an environment.

Interference immunity tests	**IEC 60601 test level**	**Match level**	**Electromagnetic environment - Guidelines**
Conducted RF disturbance variables according to IEC 61000-4-6 Radiated RF disturbances according to IEC 61000-4-3	$3V_{\text{effective value}}$ 150kHz to 80MHz 3V/m 80MHz to 2.7GHz	3V 3V/m	Portable and mobile radio equipment should be used at no closer to the ME equipment, including cables, than the recommended safety distance calculated from the equation applicable to the transmitting frequency. **Recommended safety distance in metres:** $d=(3{,}5/3)*\sqrt{P}$ $d=(3{,}5/10)*\sqrt{P}$ for 80MHz to 800MHz $d=(7/10)*\sqrt{P}$ for 800MHz to 2.7GHz with P as the nominal power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d as the recommended safety distance in metres (m). The field strength of stationary radio transmitters should be lower than the compliance level[b] at all frequencies according to an on-site investigation[a]. Interference may occur in the vicinity of devices bearing the following symbol. 

Note 1: The higher frequency range applies for 80 Mhz and 800MHz.

Note 2: These guidelines may not apply in all cases. The propagation of electromagnetic quantities is influenced by absorption and reflection from buildings, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ME device is used exceeds the applicable RF compliance level above, the ME device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ME device.

[b] Over the frequency range from 150kHz to 80MHz, the field strength should be less than 3V/m.

8.2.5 Recommended safety distances between portable and mobile HF telecommunication devices and the ME device

Recommended safety distances between portable and mobile HF telecommunication devices and the ME device			
The ME device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ME device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the ME device as recommended below, according to the output power of the communications equipment.			
Rated power P of the transmitter W	**Protective distance, depending on the transmission frequency** m		
	150kHz to 80MHz $d=(3{,}5/3)*\sqrt{P}$	**80 Mhz to 800MHz** $d=(3{,}5/10)*\sqrt{P}$	**800MHz to 2.7GHz** $d=(7/10)*\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33
For transmitters whose maximum rated power is not specified in the table above, the recommended safety distance d in metres (m) can be determined using the equation associated with the relevant column, where P is the maximum rated power of the transmitter in watts (W) as specified by the transmitter manufacturer. Note 1: The higher frequency range applies for 80 Mhz and 800MHz. Note 2: These guidelines may not apply in all cases. The propagation of electromagnetic quantities is influenced by absorption and reflection from buildings, objects and people.			