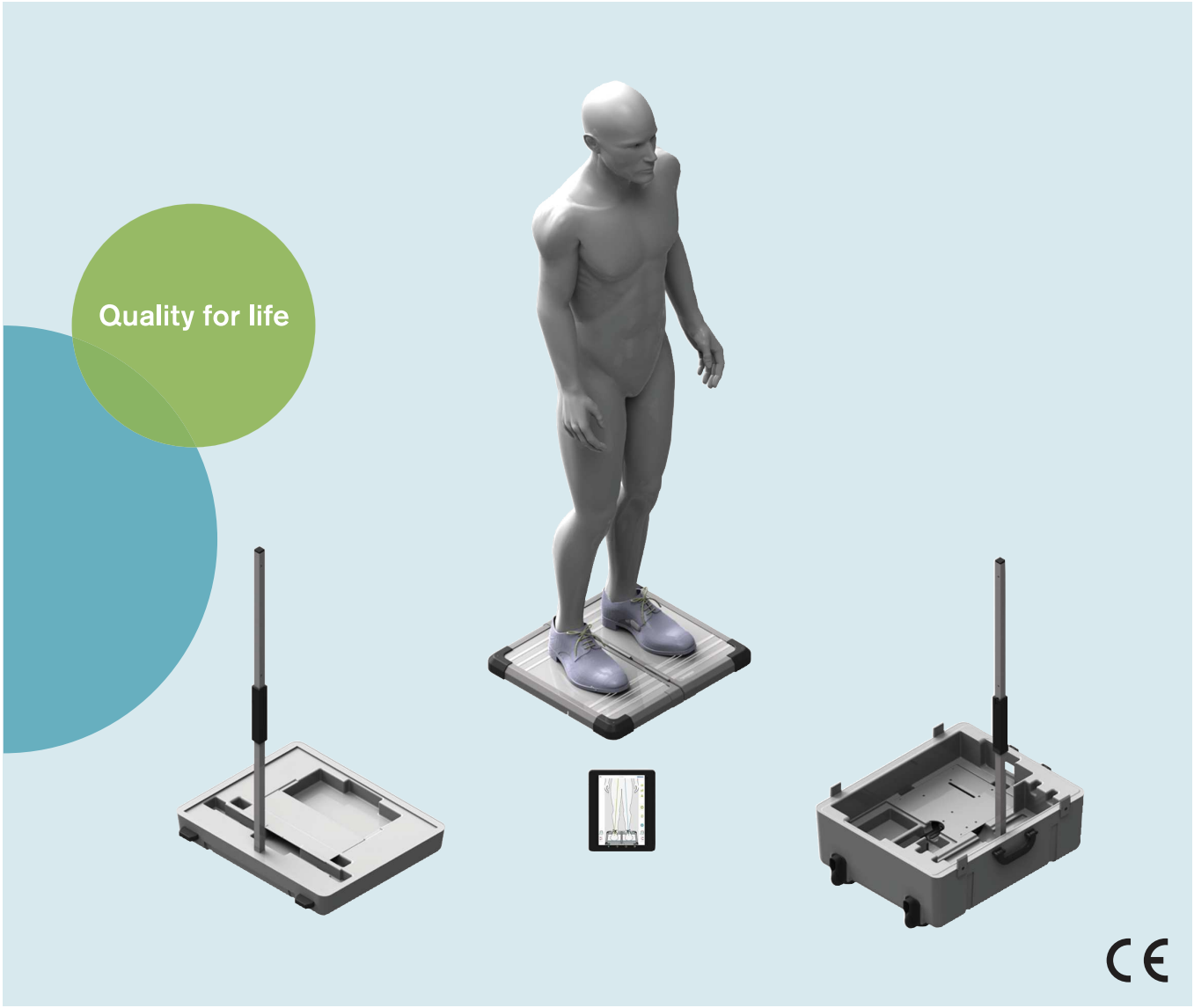
ottobock.



743L500 3D L.A.S.A.R. Posture

Table of contents

EN

1 Notes regarding the document

INFORMATION

Date of last update: 2022-08-24

- ► Please read this document carefully before using the product and observe the safety notices.
- ► Please contact the manufacturer if you have questions about the product or in case of problems.
- ► Report each serious incident related to the product to the manufacturer and to the relevant authority in your country. This is particularly important when there is a decline in the health state.
- ► Please keep this document for your records.

This document and the product are intended for orthopaedic technicians (technical knowledge: prosthetics and/or orthotics). Ottobock seminars, information materials and service are available for continuing education and questions (for contacts, see the manufacturer's address at the end of this document).

The illustrations show the user interface of the app in English. Next to the illustrations, the texts of the app user interface are reproduced in the language of the instructions for use.

Because of technical changes and updates, the illustrations may deviate from the product that is delivered.

Printed instructions for use are not included in the scope of delivery for the product. Printed instructions for use can be ordered free of charge by e-mail.

E-mail address: order-ifu@ottobock.com

Required information:

- Article number with version number for the desired language of the instructions for use
  - German: 647G1046-0=de_INT-13
  - English: 647G1046-0=en_INT-13
  - French: 647G1046-0=fr_INT-13
  - Italian: 647G1046-0=it_INT-13
  - Spanish: 647G1046-0=es_INT-13
  - Dutch: 647G1046-0=nl_INT-13
  - Hungarian: 647G1046-0=hu_INT-13
  - Czech: 647G1046-0=cs_INT-13
- Recipient’s complete address details

These instructions for use are available on the supplied tablet as single-language, colour PDF files. They can be displayed on the tablet or transferred from the tablet to a computer.

The use of the tablet is described in the user manual from the tablet manufacturer that is available on the tablet in all languages of the printed version of the product's instructions for use as single-language PDF files in colour. They can be displayed on the tablet or transferred from the tablet to a computer.

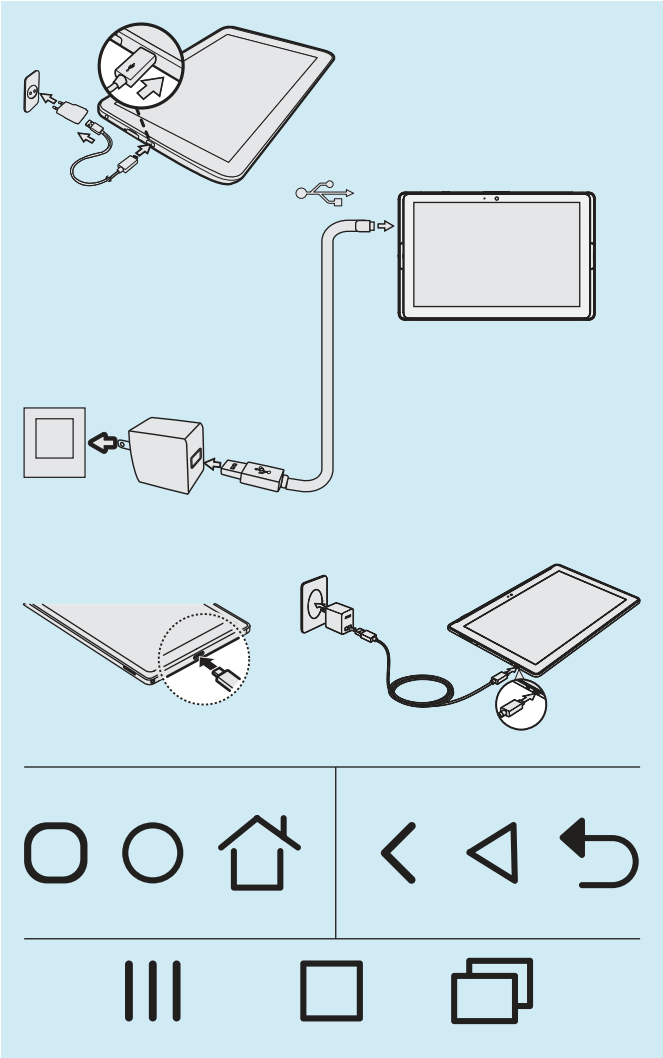
The current version of the user manual is available for download from the tablet manufacturer's website (see user manual).

Further information on the PDF files is found in the section "Reading the user manual for the tablet" (see page 16).

1.1 Meanings of pictograms in the illustration

❶	Numbering for a defined sequence	①	Numbering for the parts of an illustration
☺	Right	✕	Wrong

1.2 Illustration of the tablet and the user interface of the operating system



The illustrations used in this document show the tablet and the user interface of the operating system in simplified form.

Technical changes may result in deviations in the hardware (e.g. arrangement of the control buttons and connections) and the software (e.g. user interface of the operating system and apps).

The user manual for the tablet is available as a PDF file on the tablet and contains corresponding information from the tablet manufacturer regarding the hardware and the user interface of the operating system and the apps (section: “Reading the user manual for the tablet” – see page 16).

The adjacent illustration shows how different the hardware and user interface icons can be:

- Mains/charging plug connection on the tablet
- Control icons on the user interface (icons with same meaning)

Despite the differences between the tablets, their overall use is always very similar.

The “My files” app for viewing folders and files can have different names and looks.

The main file paths are the same for all tablets.

1.3 Explanation of warning symbols

⚠ CAUTION	Warning regarding possible risks of accident or injury.
NOTICE	Warning regarding possible technical damage.

1.4 General safety instructions

⚠ CAUTION

Damaged electronic components

Electric shock due to contact with live components

► Check the product for damage (e.g. cable, housing) prior to each use while in a de-energised state.

⚠ CAUTION

Non-observance of relevant documents when aligning prostheses and orthoses

Injuries and mal-positioning due to improper alignment

► Observe all documents relevant to the prosthetic and orthotic components (e.g. instructions for use, alignment recommendations, quick guides and technical information).

NOTICE

Contact with heat, embers or fire

Damage to the product due to high temperatures

► Keep the product away from open flames, embers and other sources of heat.

NOTICE

Operating the product outside of the permissible temperature range

Limited function due to product malfunction or damage

► Avoid operation in areas outside the permissible temperature range (section "Technical data" - see page 66).

NOTICE

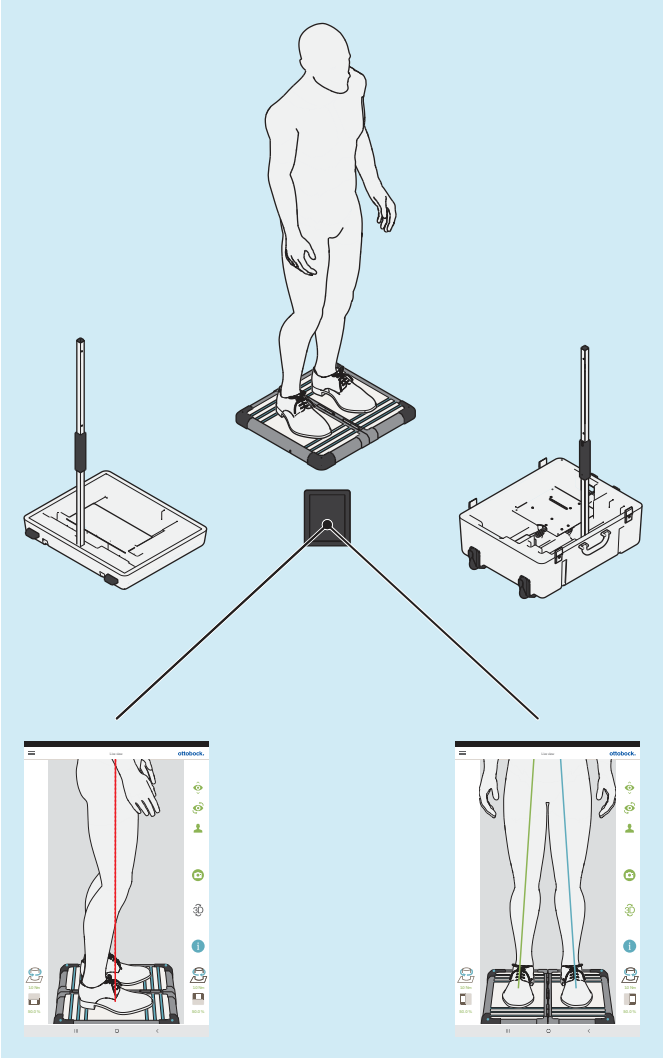
Improper use of the mini-computer and tablet

Product damage, loss of functionality, restriction of functionality and loss of data (for example, uninstalling the "3D L.A.S.A.R. Posture" app erases the database)

► Use the mini-computer and tablet exclusively according to the instructions for use, the user manual and the manufacturer's information materials.

► Only carry out the following activities if you are instructed to do so by Ottobock:
Connecting the mini-computer and tablet to a WiFi network and the Internet
Installing updates, installing and uninstalling apps, programmes and the operating systems

2 Product description



The 3D L.A.S.A.R. Posture is a measuring device intended for verifying and optimising the static alignment of prostheses and orthoses together with the patient.

The product's main components are a force measurement plate in two sections, two camera stands with two cameras each, a case, a mini-computer with power supply, a tablet with inserted micro-SD memory card and a battery charger with USB cable.

With the patient standing on the force measurement plate, the vertical and horizontal ground reaction forces as well as the torsion moments are measured. The mini-computer sends the data from the cameras and the force measurement plate to the tablet over the WiFi. On the tablet, the data are graphically overlaid onto the live camera shots in the form of load lines.

In 3D mode the blue and green load lines are based on the vertical and horizontal ground reaction forces.

When 3D mode is deactivated, the load lines are red and based only on the vertical ground reaction forces. As with the 743L100=* L.A.S.A.R. Posture, they constitute a vertical line above the resulting load transmission point. This mode is compatible with the 743L100=*. The static alignment of a prosthesis or orthosis can therefore be verified according to the alignment recommendations in the respective instructions for use.

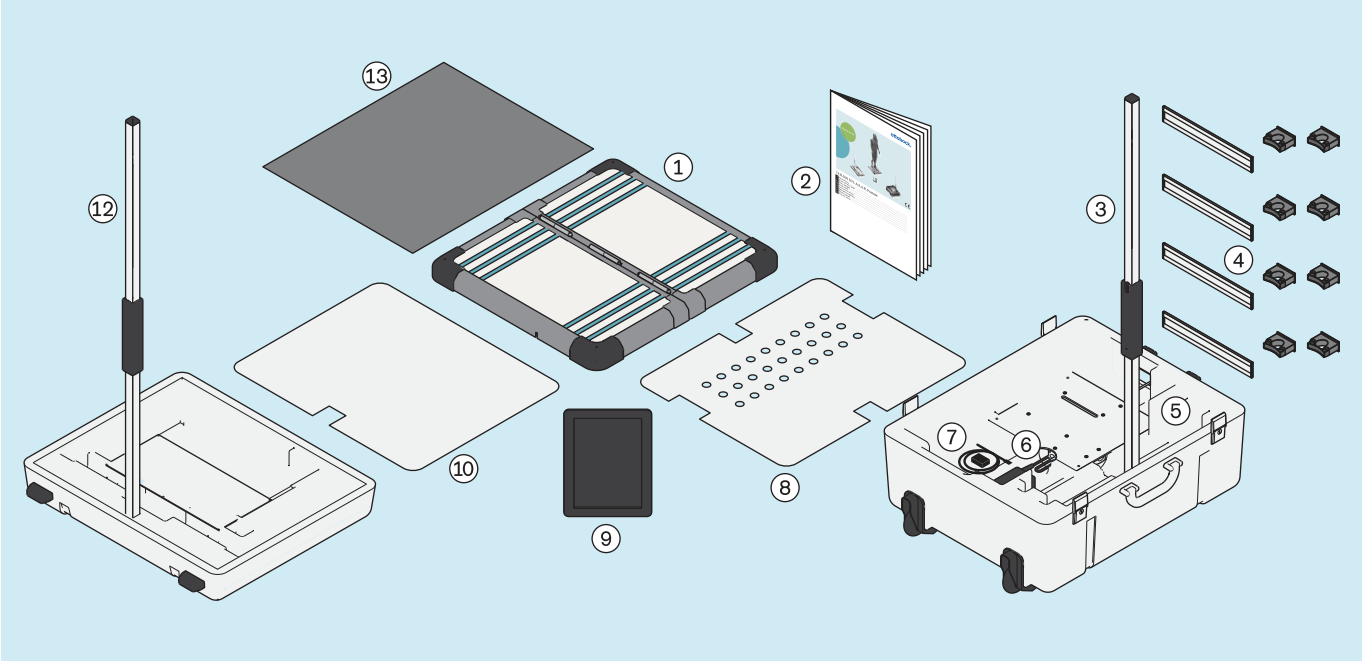
The app includes a patient database and is able to output patient data in the form of PDF or JPG files or in a special format for the Ottobock Data Station.

2.1 Lifetime

Expected lifetime: **5 years**

The design, manufacturing and requirements for the intended use of the product are based on the expected lifetime.

3 Scope of delivery



①: Force measurement plate in two sections

②: 647G1046=all_INT quick reference guide

③: Camera stand (with two cameras) for case, lower section

④: 743Y725 Wall holder for camera stand

⑤: Case, lower section

⑥: Mini-computer (with power supply unit)

⑦: Battery charger for tablet (with USB cable)

⑧: Cover plate for case, lower section

⑨: Tablet (with inserted micro-SD memory card)

⑩: Cover plate for case, upper section

⑪: Case, upper section

⑫: Camera stand (with two cameras) for case, upper section

⑬: Foam mat

Product components with reference numbers can be reordered separately.

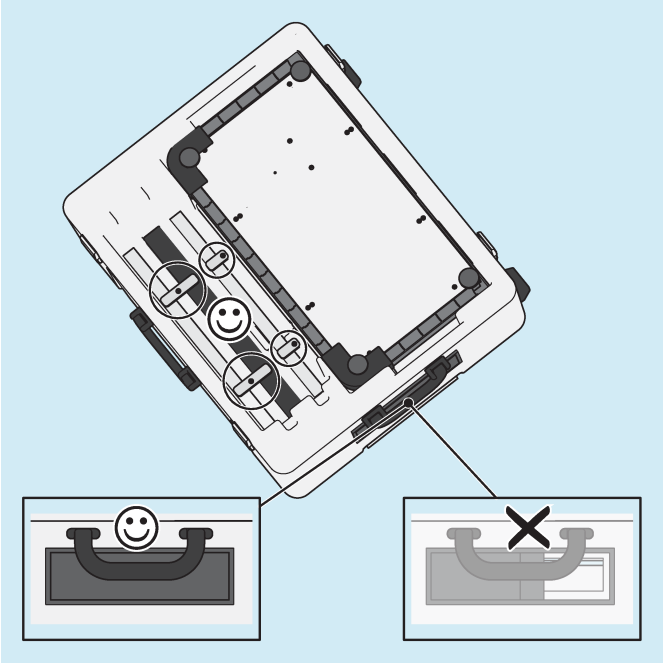
4 Preparing the product for use

INFORMATION

This document must be observed for installing the product and putting it into operation.

► **NOTICE! To avoid loss of functionality and damage to the product, only use components, spare parts and software approved by the manufacturer.**

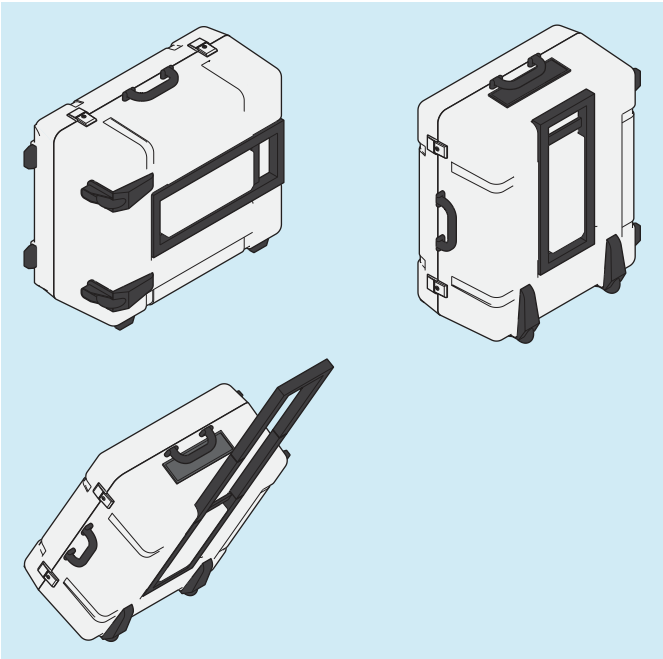
4.1 Transportation



► **NOTICE! To avoid damage during transportation, do not expose the product to severe vibrations, extreme temperatures and high relative humidity. Always keep the slider of the cable feedthrough closed during transportation to keep out foreign objects, dirt and humidity.**

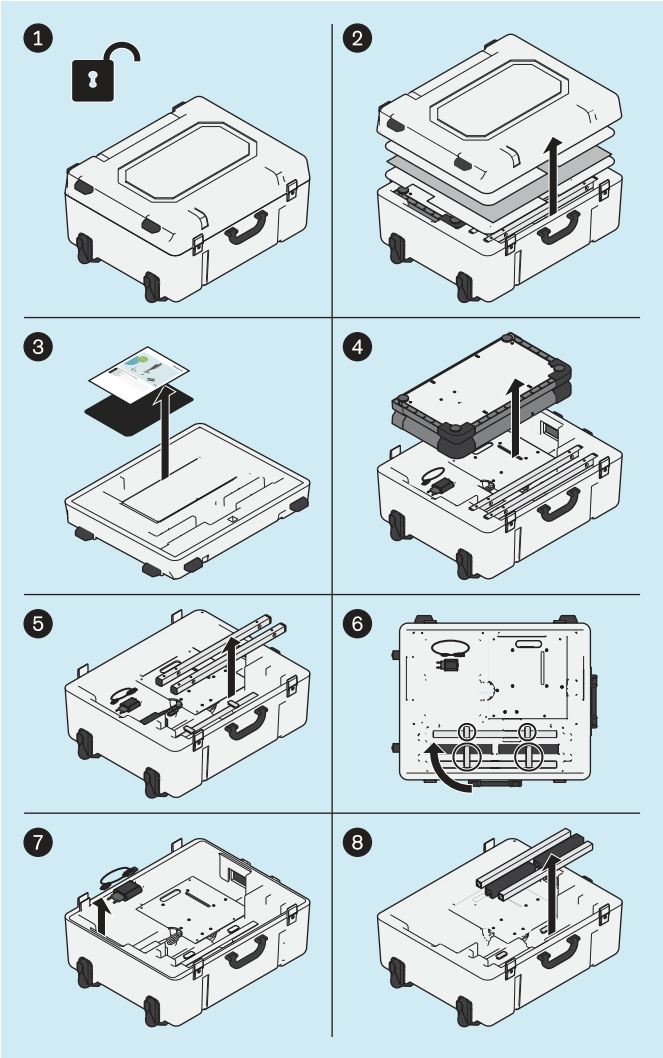
► Always use the product case for transportation.

► Lock the elements of the stand using the swivelling transport locking devices.



► Either lift the closed case by one of the two carrying handles or roll it, holding it by the extendable handle.

4.2 Unpacking



► Unpack the product components according to the illustration.

The following products are not included in the scope of delivery but needed for the specified field of application:

Wall mounting

743Y709 USB 3.0 with type A plug/socket (for larger distance between the PC and force measurement plate)

Use in GB

757L2 USB-Friwo power supply, medical (power supply/battery charger for tablet)

757S7=GB GB-adapter for USB-Friwo power supply

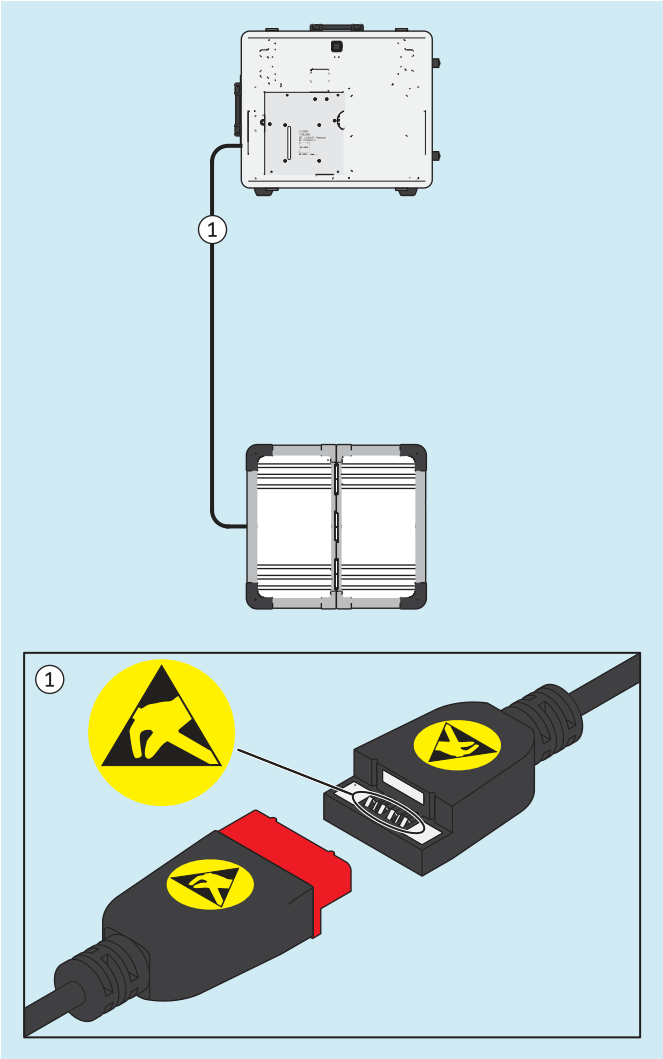
GB power cord for power supply of the mini-computer

Use in the USA

757L2 USB-Friwo power supply, medical (power supply/battery charger for tablet)

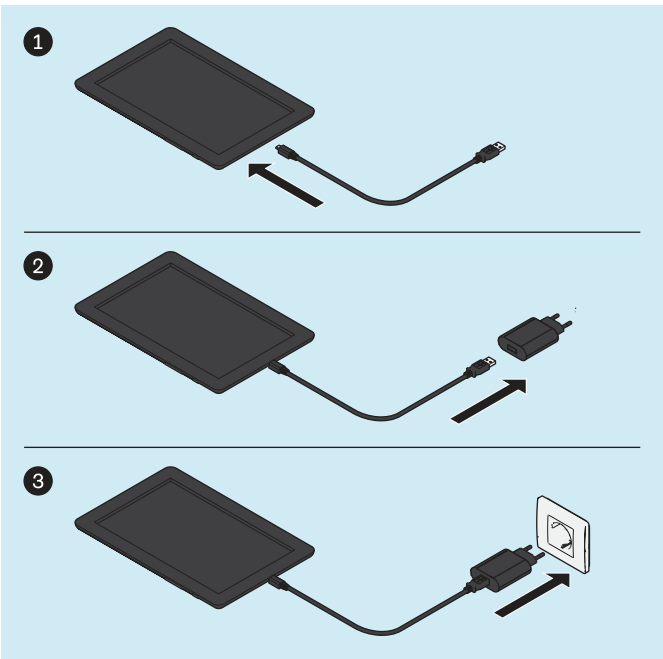
757S7=US US adapter for USB-Friwo power supply

The illustrations in this document only show the supplied standard cables.



► **NOTICE! To prevent electrostatic discharge, be sure to maintain a sufficiently safe distance between your fingers and the contacts of the magnetic USB coupling (> 10 mm).**

4.3 Charging the tablet

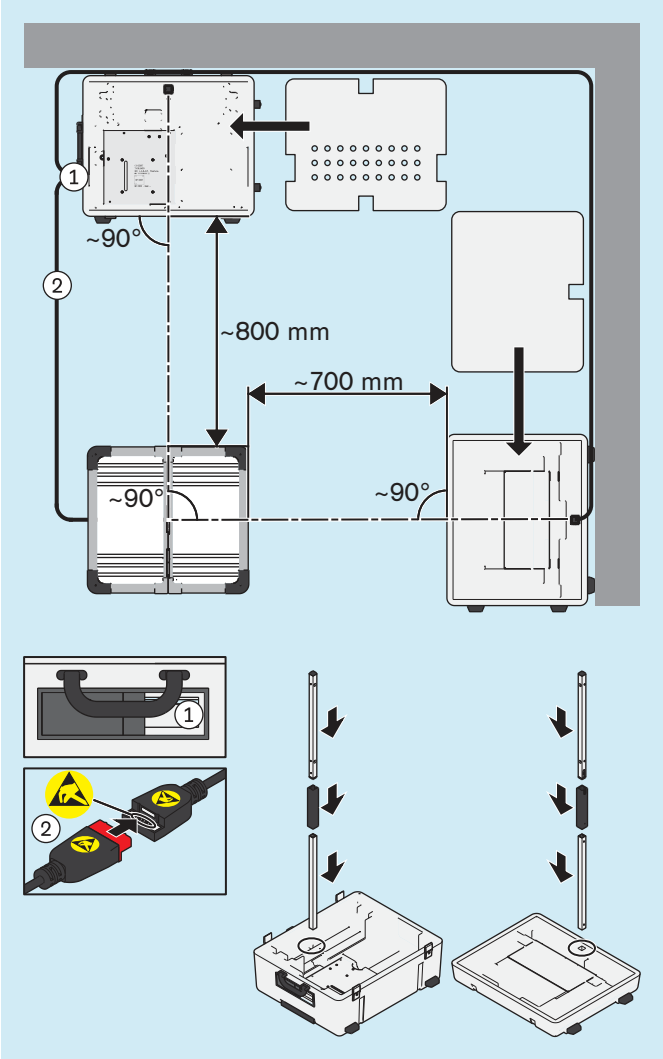


► **CAUTION! To protect against leakage currents, the patient is not permitted to come into contact with the tablet during charging, directly or indirectly (for instance through another person).**
Connect the product components in the illustrated sequence and fully charge the tablet.

4.4 Setup

INFORMATION

The distances between camera stands and the force measurement plate given in this document provide an approximate indication of space requirements and assist with setup. Subsequently the camera stands and force measurement plate are aligned with each other using crosshairs in the app (section "Alignment of the stands and force measurement plate" – see page 21). Deviations from the distance and angle values specified for the setup are possible.

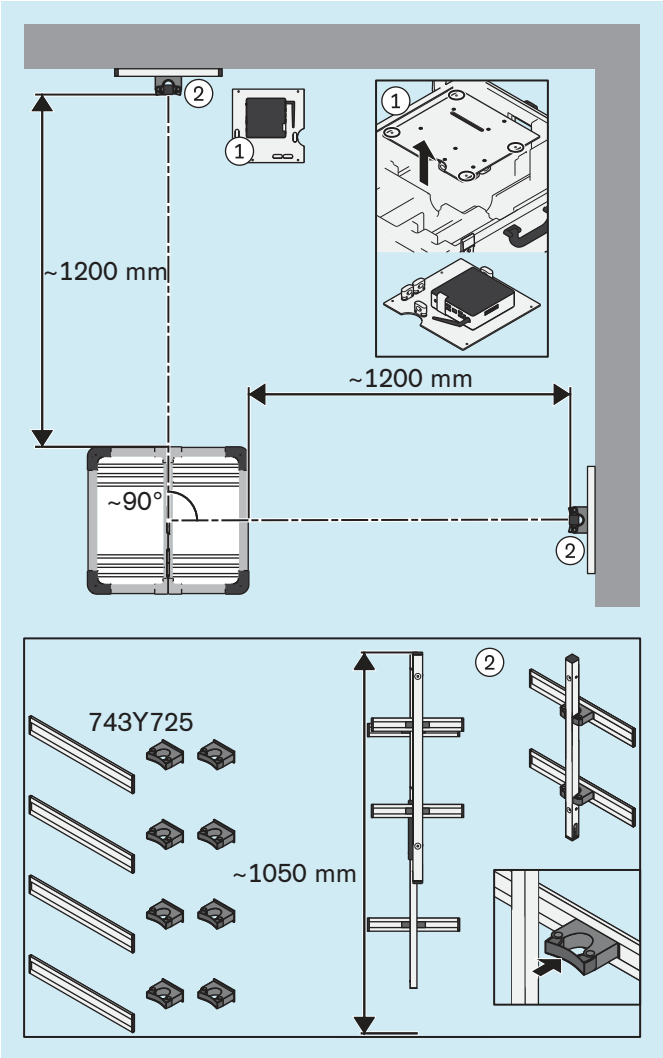


► Note the following points to select a suitable setup location:
  → Find a firm, level surface (such as laminate, concrete, PVC flooring, short pile carpet).
  → Position the stands as close to the walls as possible so the cable of the sagittal camera stand can be laid close to the wall, avoiding the risk of tripping.
  → Windows or light sources that are captured by the cameras must have a means of shading them (for instance roller shutters, curtains, switching off) if the shutter priority of the cameras is negatively influenced by backlighting.

► **CAUTION! Proceed carefully during setup to avoid injury and damage to the product components (such as cables).**
INFORMATION: The illustration shows the basic setup with the sagittal cameras aligned in the upper case section on the patient's right side. There are two possibilities to capture the patient's left sagittal side: 1. The patient turns by 180° to stand on the force measurement plate. 2. The force measurement plate is rotated 90° in place and then calibrated again. Alternatively the upper section of the case can be aligned with the patient's right side for the basic setup.
Set up the lower and upper sections of the case, the force measurement plate and the camera stands, and connect the cables.

► **INFORMATION: Ensure that the room is well illuminated at the installation location so that the patient and the measurement plate are well and evenly illuminated (without strong shadows).**

4.5 Optional: Using wall holders

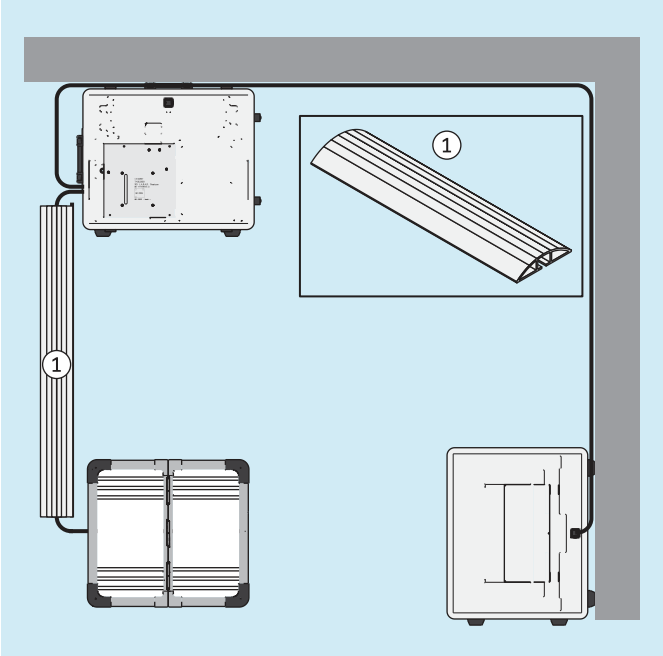


Instead of the standard setup for the camera stands in the holders of the upper and lower case sections, the upper sections of the camera stands may be installed in the 743Y725 wall holders.

The screws and dowels are not included in the scope of delivery since they have to be chosen according to the properties of the walls.

- ► Optionally the plate with the mini-computer can be removed from the lower section of the case and set up in a suitable location.
- ► **NOTICE! The wall holders have to be positioned on the walls so that the height of the camera stands can be adjusted and the wall holders do not interfere with the view angle of the cameras.**
  INFORMATION: For easier determination of the wall holder positions on the walls, initially using the setup with the upper and lower case sections is recommended in order to gain practical experience with the alignment of the camera stands relative to the force measurement plate. The holders can be moved in the rails so that subsequent alignment of the camera stands is possible (for example after rotating the force measurement plate).
  Install the wall holders on the walls according to the illustration.
- ► Push the camera stands into the wall holders.

4.6 Optional: Use of cable protectors

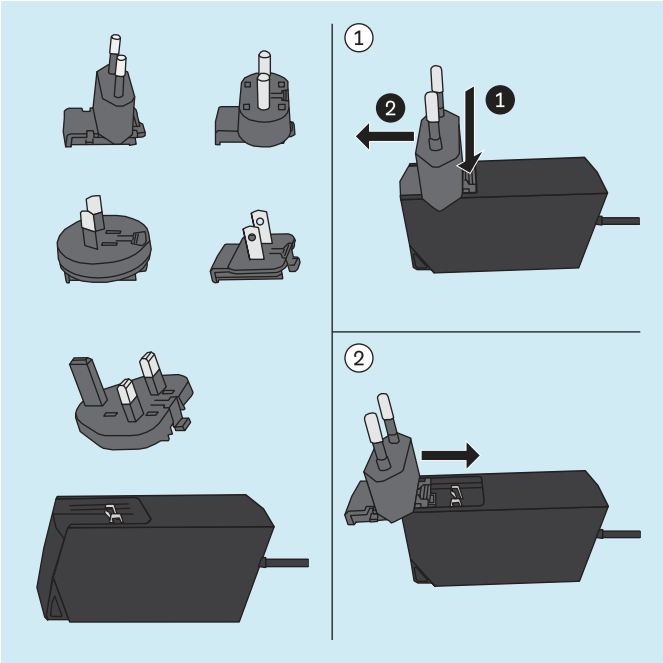


Optional cable protectors can be used to reduce the risk of tripping and damaging the cables.

The cable protectors are not included in the scope of delivery and can be obtained from specialist dealers.

- ► Position the cable protectors over the cables as shown.

4.7 Switching on

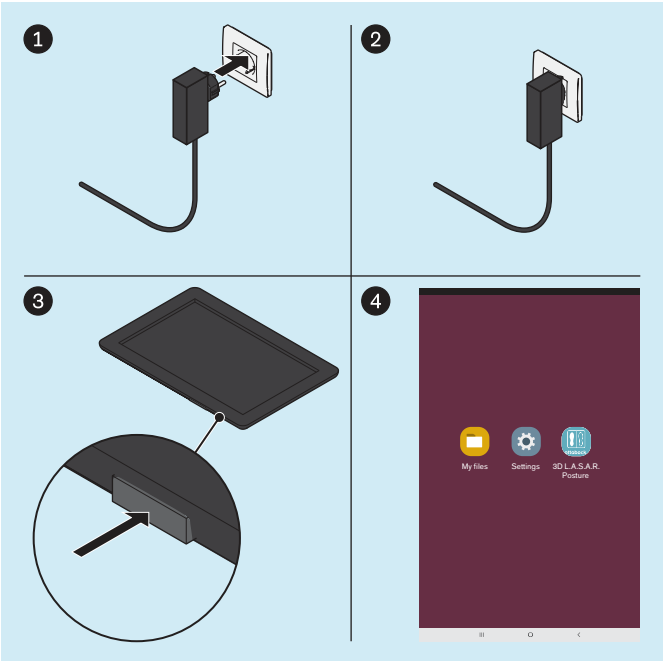


Power supply of the mini-computer

The power supply of the mini-computer includes various adapters with plugs for different countries.

- ► **CAUTION!** Always use only the adapter that fits the outlet.
- ► If none of the supplied adapters fits the outlet, obtain a suitable adapter as an intermediate piece between the power supply and outlet from an electronics retailer.

Using the example of the adapter for plug type C, the illustration to the left shows how the supplied adapter is disconnected from and connected to the power supply.



Mini computer

- ► Insert the plug of the mini computer's power supply into the outlet.
  → The operating system powers up.

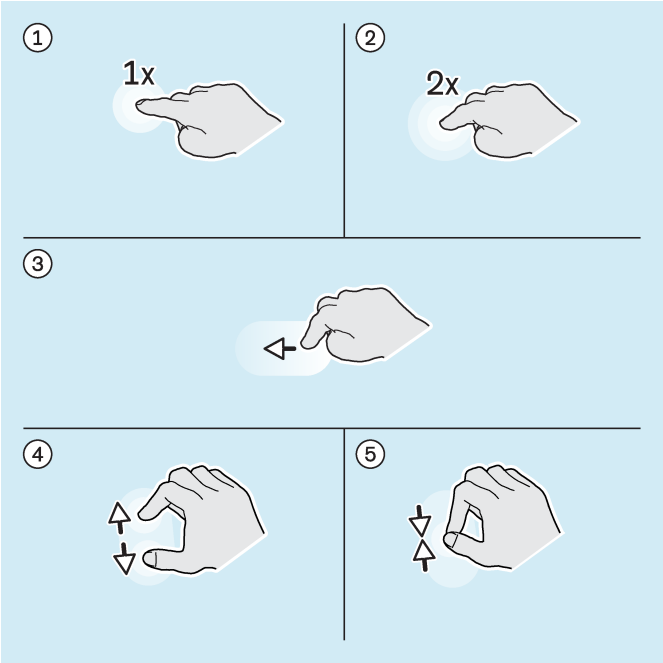
→ The mini computer is switched on.

Tablet

- ► Press the on/off button of the tablet for 2 seconds.
  → The operating system powers up.

→ The tablet is switched on and the start page is displayed (simplified in the illustration).

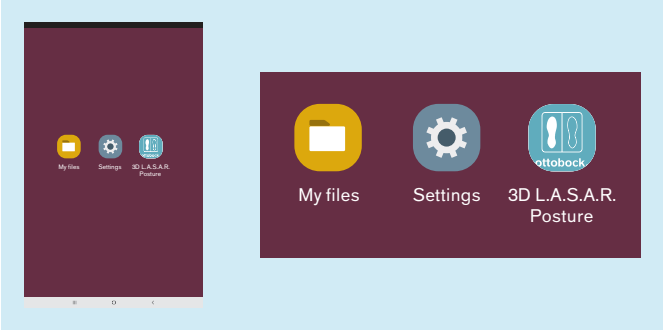
4.8 Reading the user manual for the tablet



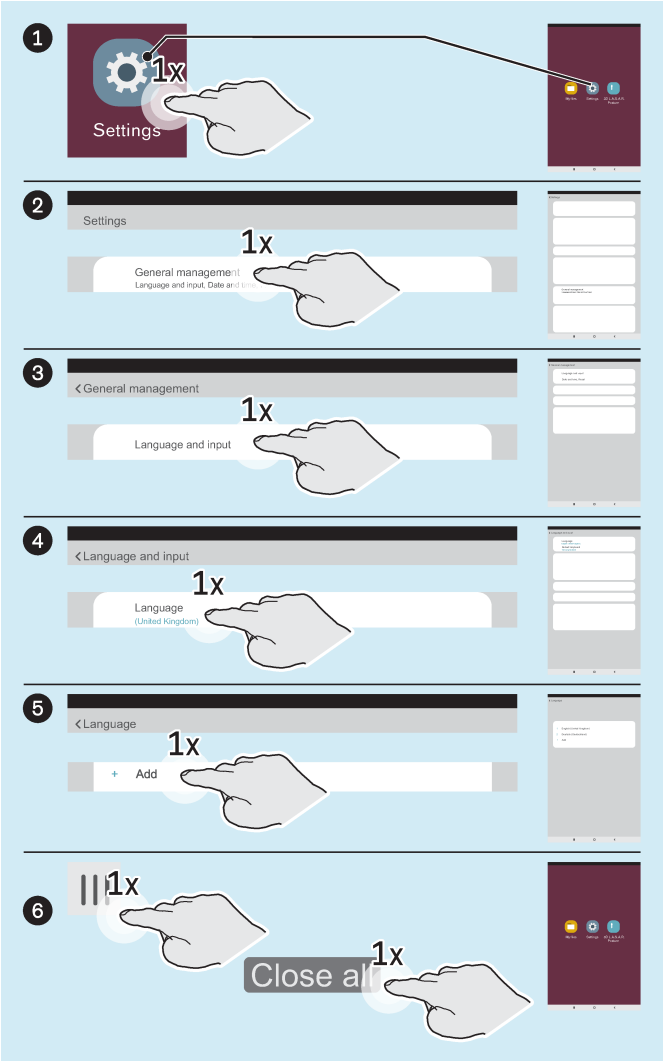
Important finger gestures for operating the "3D L.A.S.A.R Posture" app

①: 1x tapping
②: 2x tapping
③: Tapping and dragging
④: Zoom in
⑤: Zoom out

Unless otherwise described in this document, all app buttons in this document are operated by tapping them once.



The illustrations in this document highlight the most important icons on the user interface of the tablet by omitting the remaining icons. The positioning of the icons may deviate.



Optional: Changing the user interface language of the operating system

The default language of the "3D L.A.S.A.R. Posture" app is English. Only by changing the operating system language to one of the following does the app language change accordingly:

- German
- English
- French
- Spanish
- Italian
- Dutch
- Czech
- Chinese (simplified)

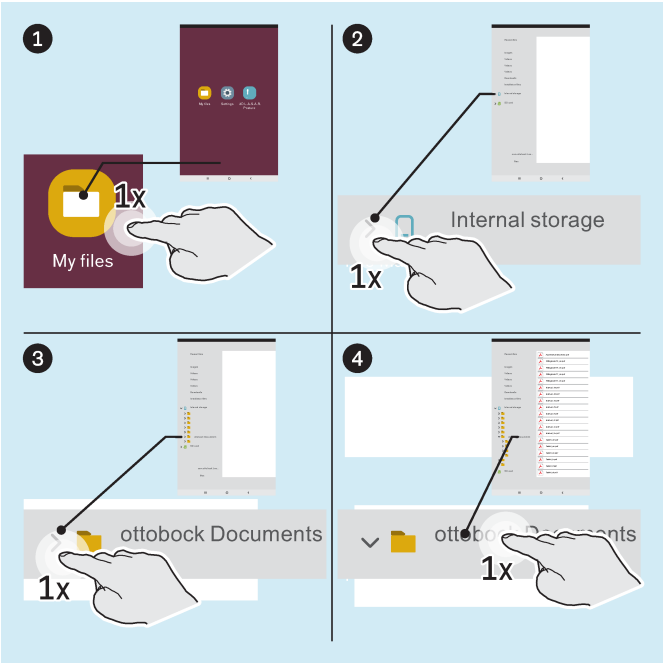
The default language of the user interface of the operating system is set to "English (United Kingdom)" and can be reset if needed as follows:

► Start the "Settings" app.

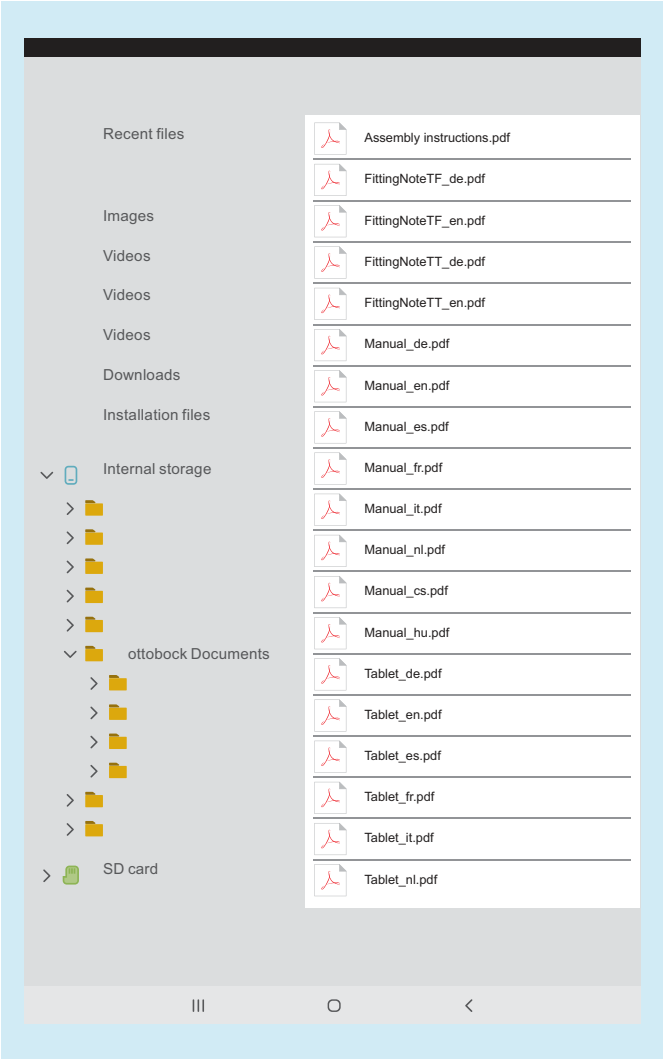
► Tap the other points as in the image until after tapping the language "English (United Kingdom)", the list of languages is displayed under "Language".

► Select the language.

► Now exit the "Settings" app as shown (6).



► Start the "My Files" app ("My files").



The following documents are available on the tablet as PDF files:

3D L.A.S.A.R. Posture quick reference guide

- Assembly instructions.pdf (several languages)

Assembly recommendations for TF modular lower limb prostheses

- FittingNoteTF_de.pdf (German)
- FittingNoteTF_en.pdf (English)

Assembly recommendations for TT modular lower limb prostheses

- FittingNoteTT_de.pdf (German)
- FittingNoteTT_en.pdf (English)

3D L.A.S.A.R. Posture – instructions for use

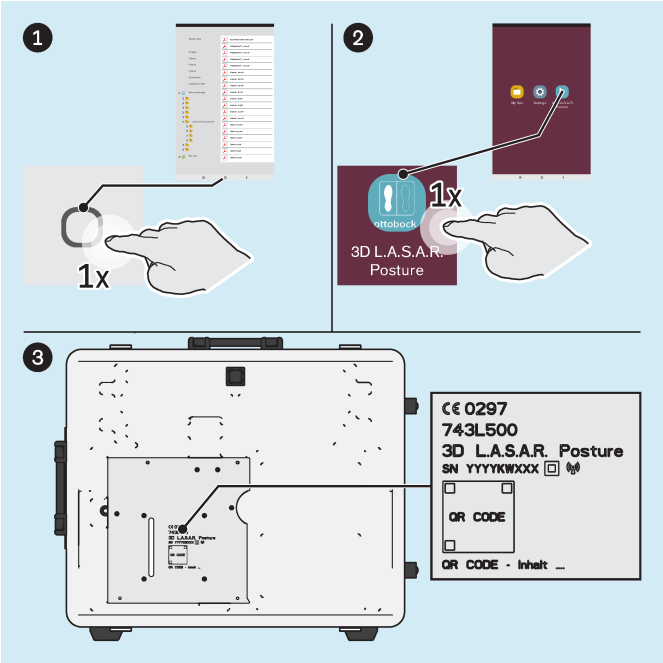
- Manual_de.pdf (German)
- Manual_en.pdf (English)
- Manual_fr.pdf (French)
- Manual_it.pdf (Italian)
- Manual_es.pdf (Spanish)
- Manual_nl.pdf (Dutch)
- Manual_cs.pdf (Czech)
- Manual_hu.pdf (Hungarian)

Tablet – user manual

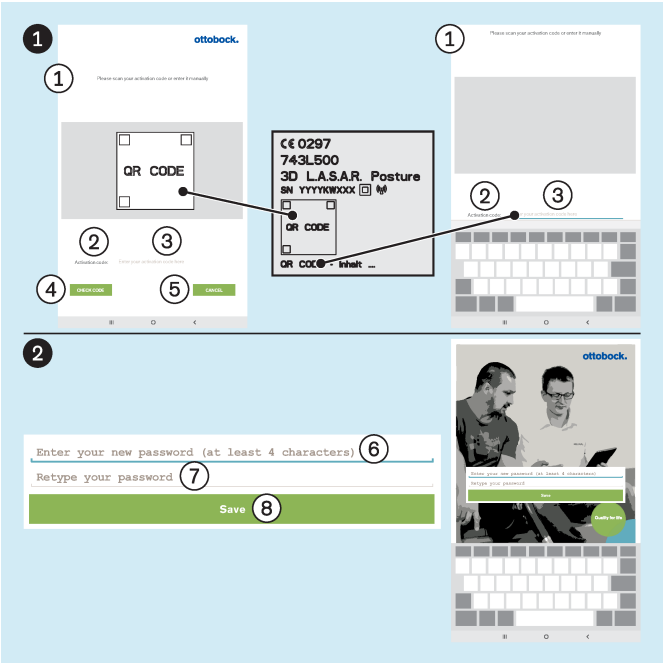
- Tablet_de.pdf (German)
- Tablet_en.pdf (English)
- Tablet_fr.pdf (French)
- Tablet_it.pdf (Italian)
- Tablet_es.pdf (Spanish)
- Tablet_nl.pdf (Dutch)
- Tablet_cs.pdf (Czech)
- Tablet_hu.pdf (Hungarian)

► Open the "Tablet_*.pdf" file in the desired language by tapping it once and read it entirely to learn how to use the tablet.

4.9 Starting the app for the first time



► Start the "3D L.A.S.A.R. Posture" app.
► Use the QR code lasered on the mounting plate of the mini-computer or the activation code below it the first time you start the app.



①: "Please scan your activation code or enter it manually"
②: "Activation code:"
③: "Enter your activation code here"
④: "**CHECK CODE**"
⑤: "**CANCEL**"
⑥: "Enter your new password (at least 4 characters)"
⑦: "Retype your password"
⑧: "**Save**"
► **NOTICE! Store the password securely to protect it against loss and third-party access.**

► Read and observe the adjacent and following text.

The app will only start if you tap ②: "**Accept**". Then a database is generated on the micro-SD memory card.

③: "**Reject**" – closes the app.

①: **General information**

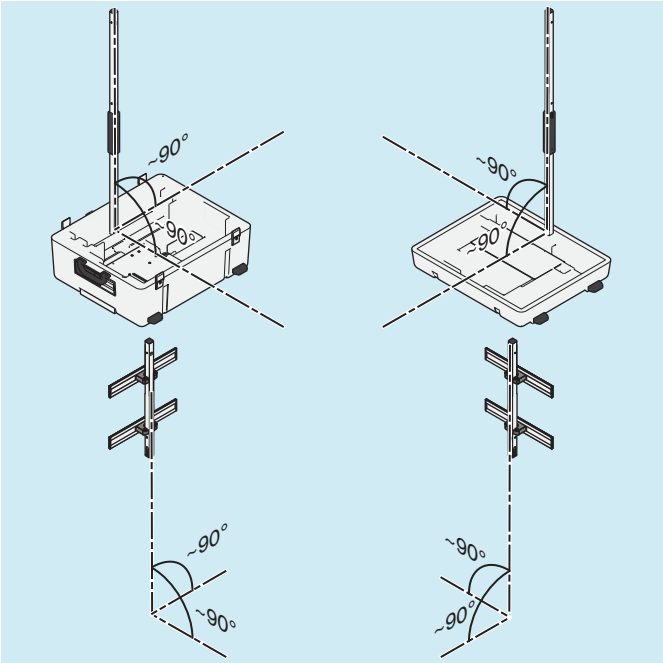
We have compiled all information presented in our app with due diligence. Nevertheless we do not guarantee the accuracy, integrity and timeliness of the information. By using this app, the user declares his/her consent to the following terms of use. This app is managed by Ottobock SE & Co. KGaA (hereinafter Ottobock). We reserve the right to modify the contents of our app at our discretion at any time and without prior notice in full or in part and/or to suspend the provision of such contents. All contents, information, documents, images and illustrations published in this app are the property of Ottobock. Please note that the texts and images used in our app are protected by the usage rights and copyrights of third parties. Furthermore, the products of Ottobock are subject to proprietary, trademark and patent rights as well as other protections under competition law. Even where Ottobock does not label them additionally using the ® symbol, it must be pointed out that our products are registered in the trademark register. The granting of access to this information does not create any rights thereto. The download of contents is permitted only if they are provided expressly for such purpose. Contents shall not be used commercially, modified, shared with a third party, duplicated, disseminated or published in any form without prior written consent. If you wish to use the contents, please contact our Customer Service. Please note that the shown forces and distances to anatomic landmarks are just general recommendations. When aligning the customised products, individual requirements of the patient must be taken into account. This device is for use by professionals/O&P professionals only (required expertise: lower limb prosthetics and orthotics). After adjusting the static alignment with this device, a check of the dynamic behaviour is required. Start any tests of alignment with the patient slowly and with a level that is suitable for the patient.

Disclaimer

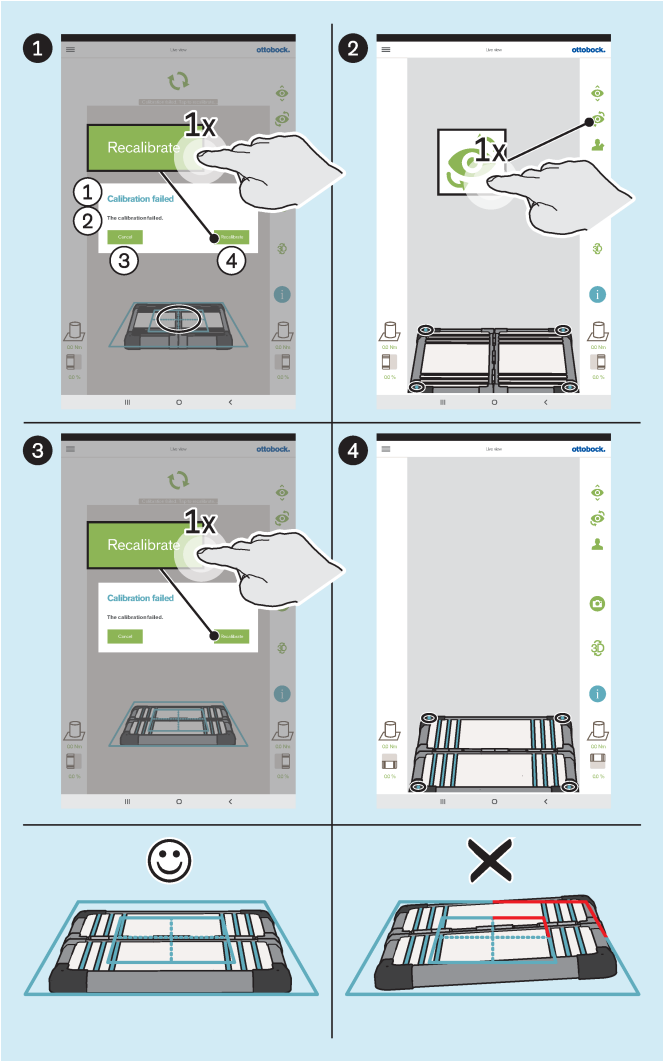
Ottobock rejects any liability for damage or injury suffered by the user or his/her patient. This limitation of liability excludes damage resulting from injury to life, limb or body if such damage results from a negligent breach of obligations on the part of Ottobock or from wilful or gross negligence on the part of its legal agents and vicarious agents. It also excludes any other damage caused by wilful or gross negligence or minor negligent breach of fundamental contractual obligations (= obligations whose fulfilment is necessary to achieve the objective of the agreement and on whose compliance the user may rely) on the part of Ottobock.

Protection of medical data
Where the app allows for the input of personal data (names, addresses, etc.), such data is entered voluntarily. The company Ottobock SE & Co. KGaA expressly states that such data shall not be shared with any third party and shall be used exclusively for the purposes of business relations. Furthermore, any storage of personal data may be subject to prior consent according to the respective local data protection law. Please notice that according to the respective local data protection law, an approval from your patient to use his/her data may be required before storing personal data or pictures of him/her and of his/her prosthetic or orthotic alignments. We strive to ensure that your data is not accessible to third parties by taking all reasonable technical and organisational precautions in storing them. However, we are unable to guarantee total data security for digital communications.

4.10 Alignment of the stands and force measurement plate



1) To avoid distortion of the camera image and possible error messages, set up the camera stands as close to vertical as possible (close to 90°).
2) Install the cables so that excessive tilting of the camera stands is avoided.



①: "Calibration failed"
②: "The calibration failed"
③: "**Cancel**"
④: "**Recalibrate**"

► Align the force measurement plate as follows:
  → The LEDs for positioning are within the outside blue frame.
  INFORMATION: LEDs that were not detected are indicated by a change of the frame colour to red in the affected corner area.
  → The crosshairs of the inner blue frame are centred over the middle of the force measurement plate.
  → The hinges of the force measurement plate are aligned with one of the two centre lines of the crosshairs.

► Perform the alignment with both the frontal and the sagittal camera views.

5 Use

INFORMATION

Other wireless communication equipment (e. g. wireless home network devices, mobile phones, cordless phones) in the vicinity of the product may cause interference. To correct this problem, increase the distance to the product or switch off the source of interference.

5.1 Protecting patient data

► **For the protection of patient data beyond the data protection laws of the user's country, note also the information in this section.**

The following files that contain patient data must be protected:

- **OB3DLasar.db**
  - This is the database file of the app that is created the first time the app is started. This file is encrypted with a password (PIN).
  - Storage path:
    External storage (SD card)/Android/data/com.ottobock.Lasar3DApp/files
- ***.pdf**
  - The user of the 3D L.A.S.A.R. app can create these files in the "Patient overview" area. These files are not encrypted.
  - Storage paths (this file format is stored in both paths simultaneously.):
    External storage (SD card)/Android/data/com.ottobock.Lasar3DApp/files/pdf
    Internal storage/ottobock Documents/pdf
- ***.jpg/*.zip**
  - The user of the 3D L.A.S.A.R. app can create these files in the "Patient overview" area. These files are not encrypted.
  - Storage paths (both file formats are stored in both paths simultaneously.):
    External storage (SD card)/Android/data/com.ottobock.Lasar3DApp/files/Images
    Internal storage/ottobock Documents/Images
- ***.lasar**
  - The user of the 3D L.A.S.A.R. app can create these files in the "Patient overview" area. These files are not encrypted. This special file format is intended for data exchange with the Ottobock Data Station.
  - Storage paths (both file formats are stored in both paths simultaneously.):
    External storage (SD card)/Android/data/com.ottobock.Lasar3DApp/files/Documents
    Internal storage/ottobock Documents/Documents

Protecting files from data loss

Any digital storage medium can lose files due to various influences. The following backup measures are therefore necessary:

► Back up files to another storage medium regularly (e.g. using a USB cable) – every day if possible.

► Check that the backed up files are readable with the appropriate program or app.

► Delete files only when they are no longer needed or have been backed up and checked to ensure they are readable.

Protecting files from unauthorised access

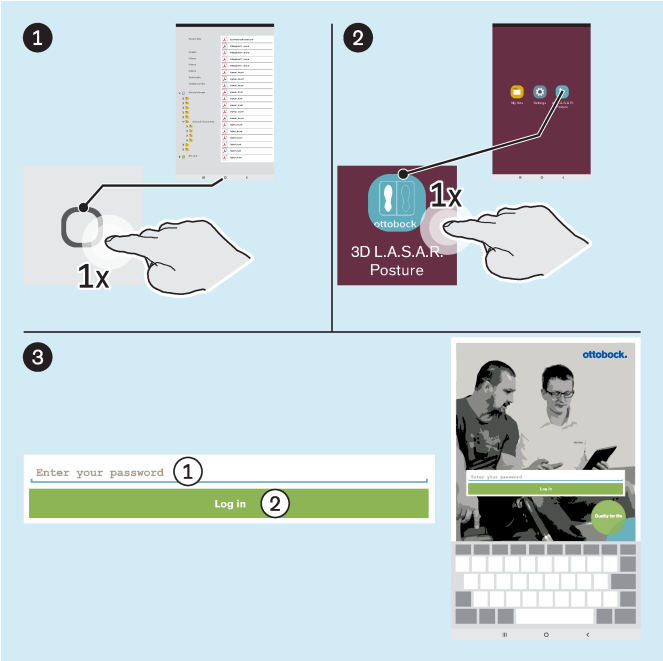
To protect the files from unauthorised access, the following measures are important:

► Keep the password (PIN) of the encrypted database file secret.

► Process the unencrypted files as quickly as possible, back them up and then delete them from the tablet.

► **Before sending to the manufacturer's service:**
Back up all files.
Delete files with patient data in the internal storage of the tablet.
Remove the SD card from the tablet and do not send it in with the tablet.

5.2 Starting the app

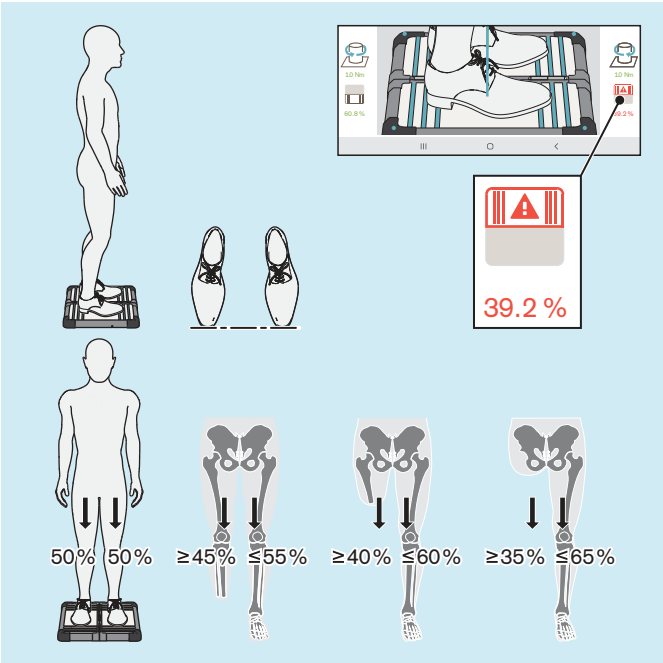


If the message window "**Allow 3D L.A.S.A.R. Posture to access the device location**" is displayed between ❷ and ❸, tap the "**Allow**" button in order for the app to work properly. If the "**Deny**" button is tapped inadvertently, follow the appropriate measures in the section "Connection failed" (see page 37).

①: "Enter your password"
②: "**Log in**"

5.3 Positioning the patient

► **INFORMATION: During positioning, ensure that the patient and the measurement plate are illuminated well and evenly (without strong shadows). Constant switching between camera playback and a black screen is a sign of insufficient illumination and requires that illumination be improved.**

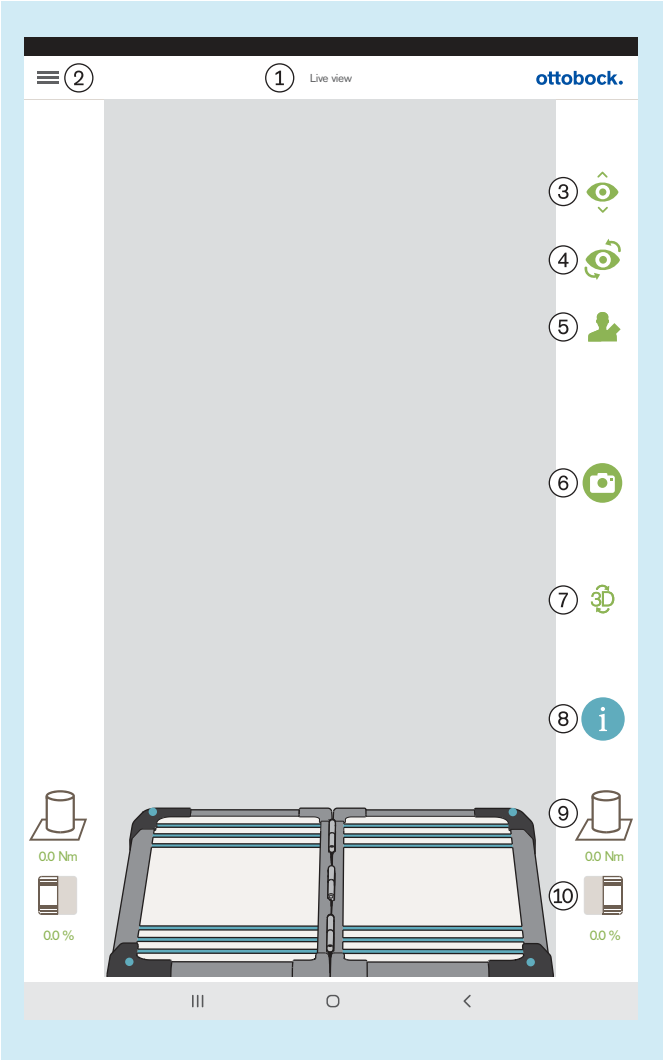


INFORMATION: The force measurement plate symbol and the corresponding numeric value are shown in red upon falling below 40%.

► Carefully position the patient on the force measurement plate as shown in the illustration, observing the following points:
→ Standing relaxed
→ Looking forward
→ Standing centred on the force measurement plate
→ Hips parallel to the frontal plane
→ Feet hip-width apart (skeletal orientation) on the force measurement plate
→ Toes in one line
→ Even 50%:50% load distribution (deviating values apply for prosthesis wearers depending on the amputation level)
→ Arms hanging loose
→ Standing unsupported during measuring

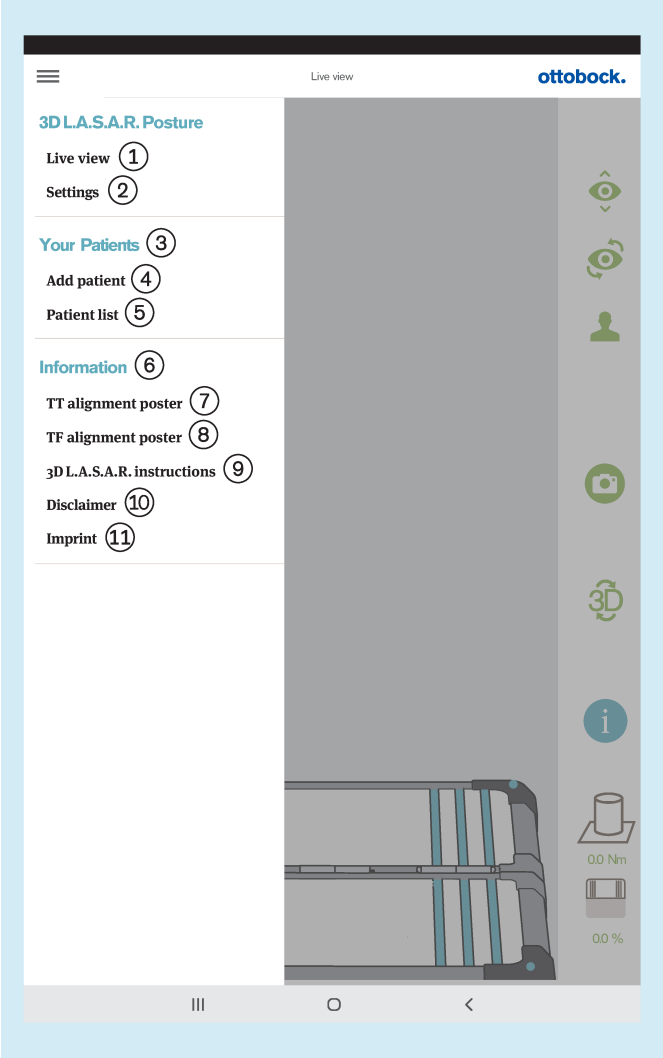
5.4 Using the app

5.4.1 Live view



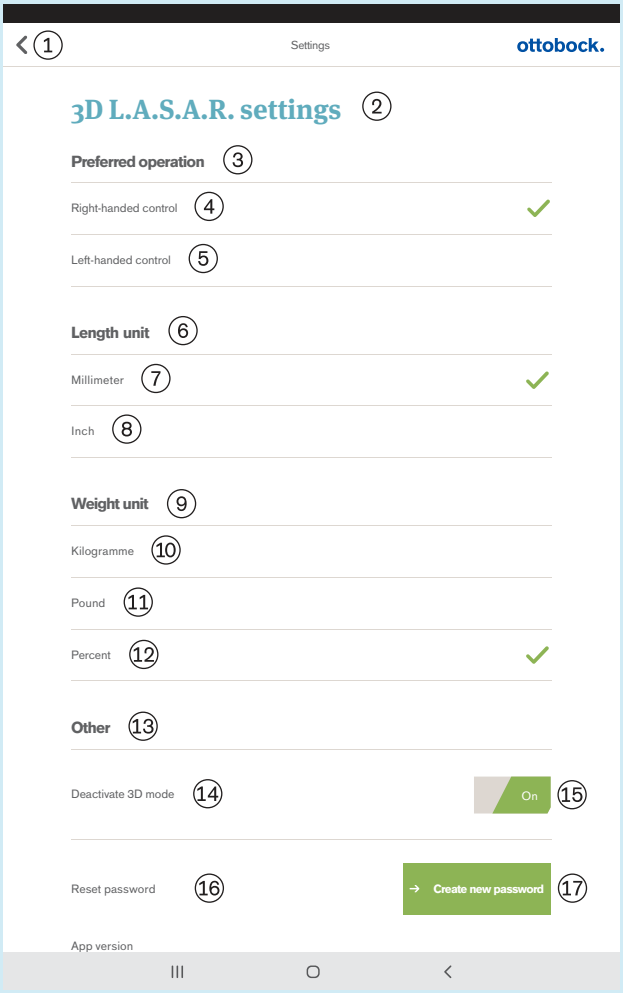
①: "Live view"
②: Show menu (section "Menu" – see page 26)
③: Switch between the two cameras on one stand
④: Switch between the two stands
⑤: Open the patient list (section "Patient list" – see page 31)
⑥: Record image (subsequently the image can be selected in the patient overview – section "Patient overview" – see page 32.)
⑦: Activate/deactivate 3D mode (green: 3D mode activated; dark grey: 3D mode deactivated)
⑧: Call up the tutorials (subsequently the image can be selected in the patient overview – section "Tutorial selection" – see page 30.)
⑨: Display for torsion moments
⑩: Display for patient weight (tap to switch between percent, kilograms and pounds)

5.4.2 Menu



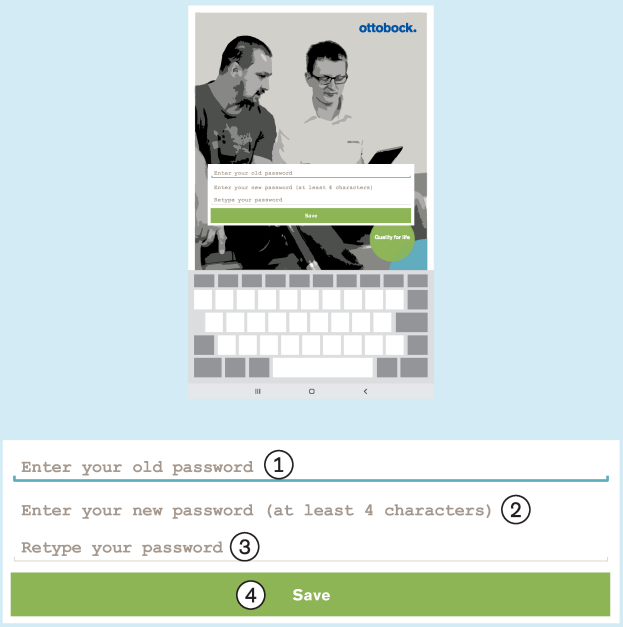
①: "**Live view**" (section "Live view" – see page 25)
②: "**Settings**" (section "Settings" – see page 27)
③: "Your Patients"
④: "**Add patient**" (section "Patient overview" – see page 32)
⑤: "**Patient list**" (section "Patient list" – see page 31)
⑥: "Information"
⑦: "**TT alignment poster**" (section "TT alignment poster" – see page 28)
⑧: "**TF alignment poster**" (section "TF alignment poster" – see page 28)
⑨: "**3D L.A.S.A.R. instructions**" (section "3D L.A.S.A.R. instructions" – see page 29)
⑩: "**Disclaimer**" (section "Disclaimer" – see page 29)
⑪: "**Imprint**" (section "Imprint" – see page 30)

5.4.2.1 Settings



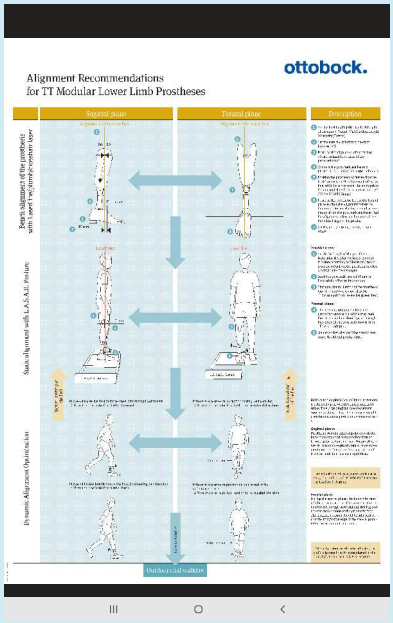
① Return to menu (section "Menu" – see page 26)
② "3D L.A.S.A.R. settings"
③ "Preferred operation"
④ "Right-handed control"
⑤ "Left-handed control"
⑥ "Length unit"
⑦ "Millimetre"
⑧ "Inch"
⑨ "Weight unit"
⑩ "Kilogramme"
⑪ "Pound"
⑫ "Percent"
⑬ "Other"
⑭ "Deactivate 3D mode"
⑮ "On"/"Off" (green: 3D mode activated; dark grey: 3D mode deactivated)
⑯ "Reset password"
⑰ "Create new password" (section "Create new password" – see page 27)

5.4.2.2 Create new password



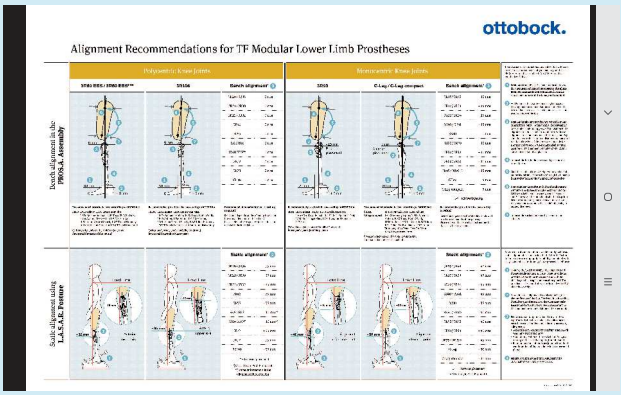
①: "Enter your old password"
②: "Enter your new password (at least 4 characters)"
③: "Retype your password"
④: "**Save**"

5.4.2.3 TT alignment poster



The PDF file is displayed in a different app. The "3D L.A.S.A.R. Posture" app can be called up again with the "Last Apps" button (section "Reading the user manual for the tablet" – see page 16).

5.4.2.4 TF alignment poster

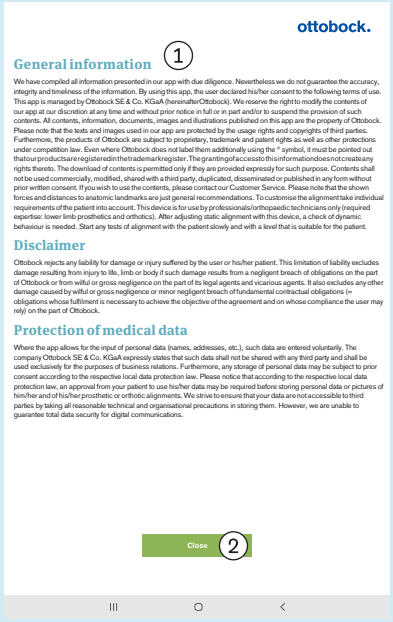


The PDF file is displayed in a different app. The "3D L.A.S.A.R. Posture" app can be called up again with the "Last Apps" button (section "Reading the user manual for the tablet" – see page 16).

5.4.2.5 3D L.A.S.A.R. instructions

The PDF file is displayed in a different app. The "3D L.A.S.A.R. Posture" app can be called up again with the "Last Apps" button (section "Reading the user manual for the tablet" – see page 16).

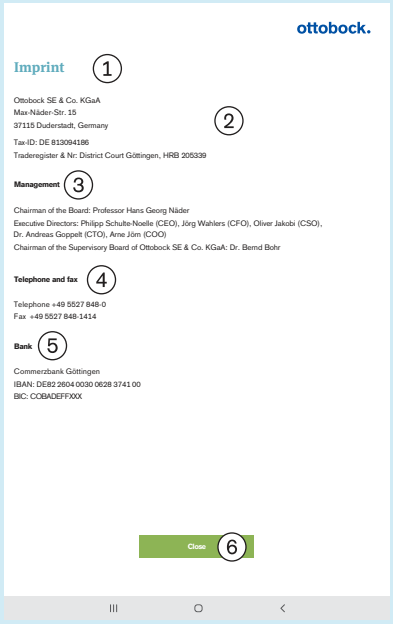
5.4.2.6 Disclaimer



① Text see section "Starting the app for the first time" (see page 19)

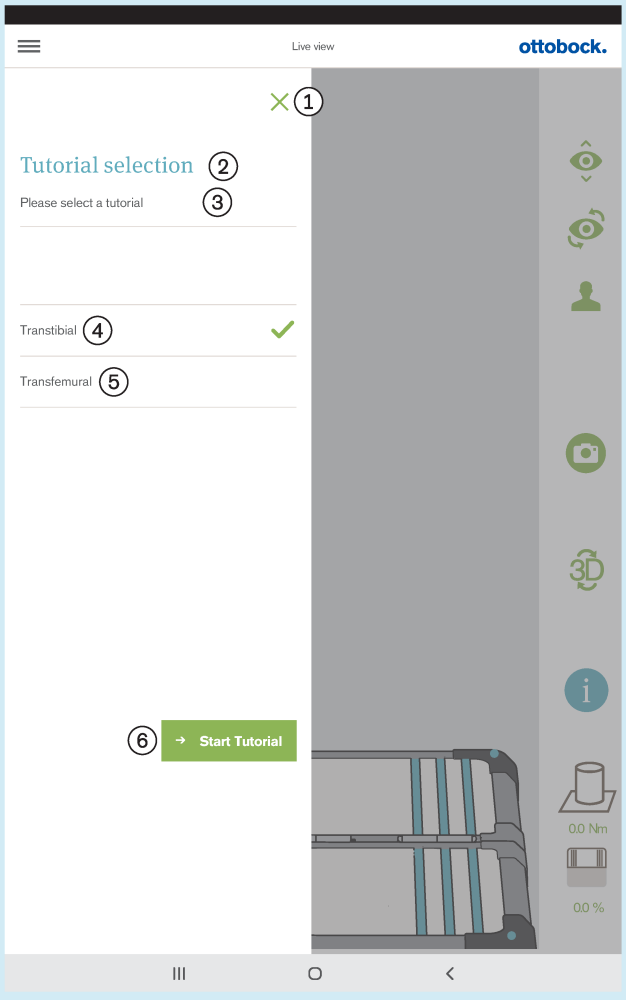
② "Close" – return to menu (section "Menu" – see page 26)

5.4.2.7 Imprint



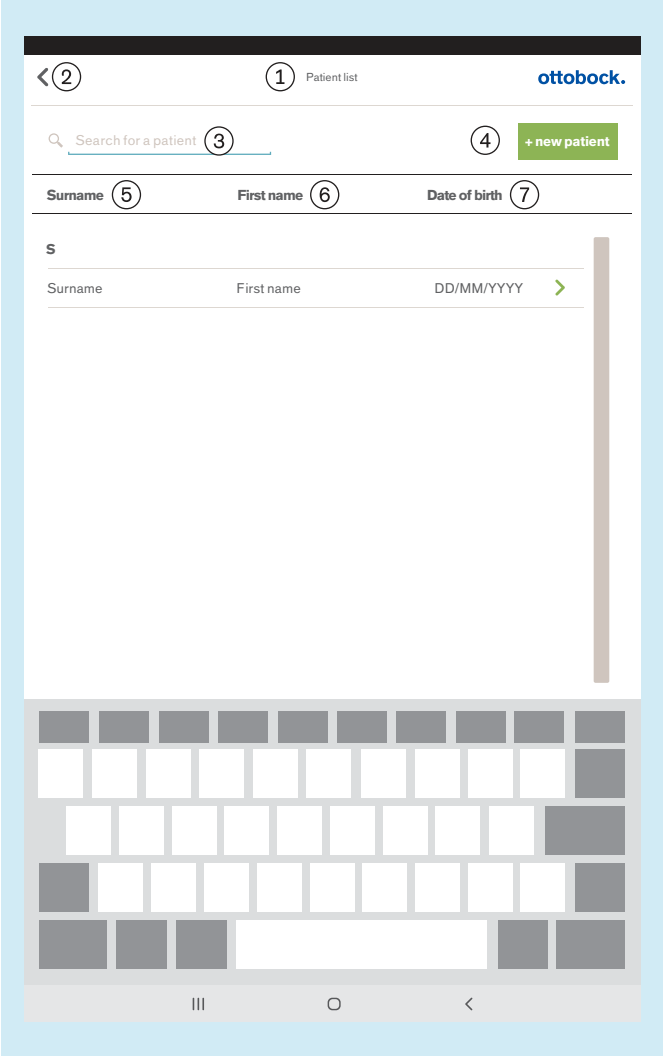
① “Imprint”
② Ottobock SE & Co. KGaA
Max-Näder-Str. 15
37115 Duderstadt, Germany
Tax-ID: DE 813094186 Registry court & no.: Göttingen District Court, HRB 205339
③ “Management”
Chairman of the Board: Professor Hans Georg Näder
Executive Directors: Philipp Schulte-Noelle (CEO), Jörg Wahlers (CFO), Oliver Jakobi (CSO), Dr Andreas Goppelt (CTO), Arne Jörn (COO)
Chair of the Supervisory Board of Ottobock SE & Co. KGaA: Dr Bernd Bohr
④ “Telephone and fax”
Telephone +49 5527 848-0
Fax +49 5527 848-1414
⑤ “Bank”
Commerzbank Göttingen
IBAN: DE82 2604 0030 0628 3741 00
BIC: COBADEFFXXX
⑥ “Close” – return to menu (“Menu” section – see page 26)

5.4.3 Tutorial selection



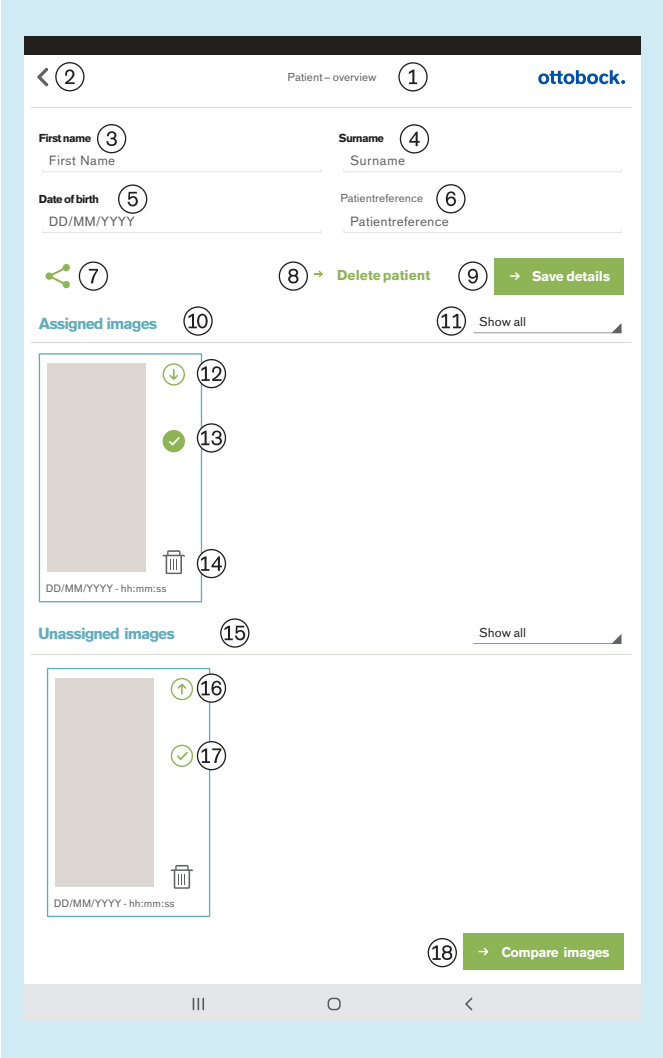
The tutorials show how the product can be used for prosthetic alignment. They do not take the place of reading and following the information in the instructions for use for the respective prosthetic components.
①: Close selection – return to live view (section "Live view" – see page 25)
②: "Tutorial selection"
③: "Please select a tutorial"
④: "**Transtibial**"
⑤: "**Transfemoral**"
⑥: "**Start Tutorial**"

5.4.4 Patient list



①: "Patient list"
②: Return to live view (section "Live view" – see page 25)
③: "Search for a patient"
④: "**+ new patient**" (section "Patient overview" – see page 32)
⑤: "Surname"
⑥: "First name"
⑦: "Date of birth"

5.4.5 Patient overview



①: Patient overview
②: Return to patient list (section "Patient list" – see page 31)
③: "First name"
④: "Surname"
⑤: "Date of birth"
⑥: "Patient reference" (a patient reference number or other short text can be entered here)
⑦: Create files with selected images (*.jpg/*.zip, *.pdf, *.lasar – section "Creating files" – see page 35)
⑧: Delete patient
⑨: "**Store details**" (patient data that have been entered are stored)
⑩: "Assigned images"
⑪: "Show all" (here the images can be filtered by creation date)
⑫: Move image from the assigned images to the unassigned images
⑬: Image selected
Images have to be selected for the comparison view, PDF generation and data exchange with the Ottobock Data Station.
Maximum selectable number: 6
⑭: Delete image
⑮: "Unassigned images"
⑯: Move image from the unassigned images to the assigned images
⑰: Image not selected
⑱: "**Compare images**" (section "Comparison view" – see page 34)

INFORMATION

The images recorded in the live view are stored in the app database on the micro-SD memory card. Recording additional images is no longer possible once the SD card is full. The database should be optimised and backed up regularly as follows:

Optimisation

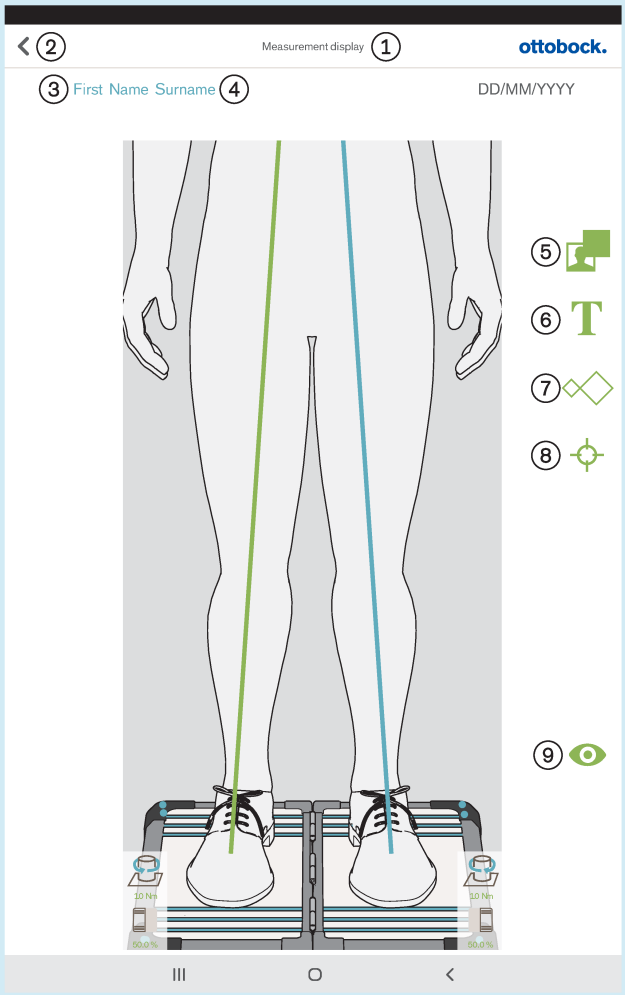
Unassigned images should be assigned to a patient as soon as possible, otherwise they cause major delays in loading the patient overview.

Delete unassigned images that are no longer needed.

Backup

Close the app and copy the contents of the micro-SD card to another storage medium (connection: tablet --> USB cable --> computer).

5.4.5.1 Measurement display



The "Tapping and dragging" gesture is used for positioning on the image. The gesture "2x tapping" is used to select. Selected objects can be changed or deleted.

①: "Measurement display"

②: Save and return to the patient overview (section "Patient overview" – see page 32)

③: The patient's first name is shown here.

④: The patient's surname is shown here.

⑤: Drag black frame onto the image

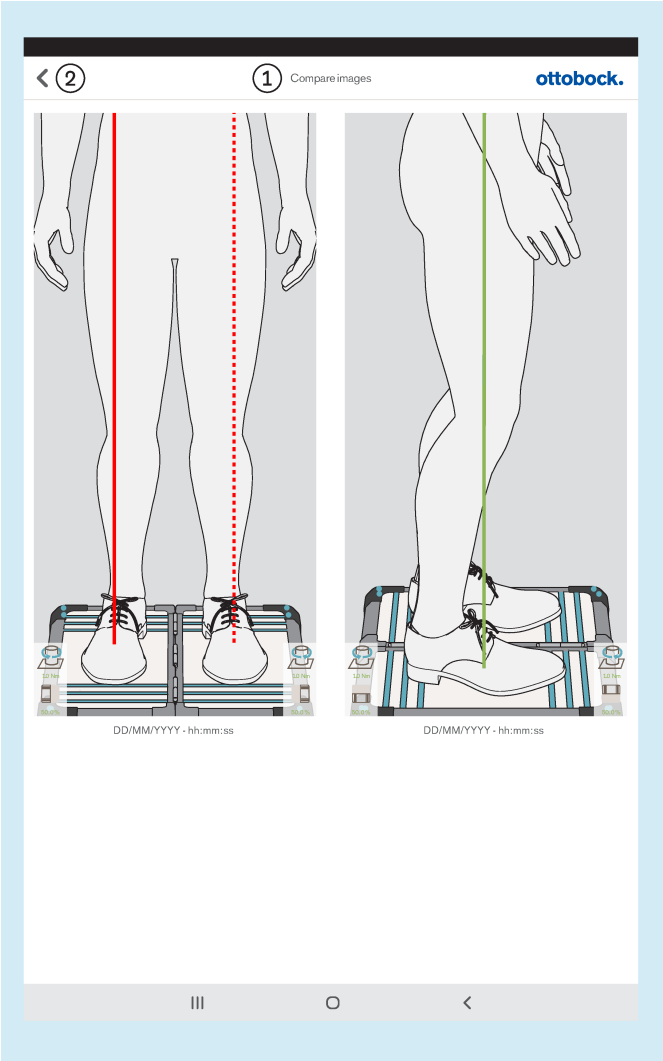
⑥: Drag text field onto the image

⑦: Drag one or more gauges onto the load lines (sagittal view: only dragging onto the load lines of the lateral side is possible)

⑧: Drag one or more reference points onto the load lines (sagittal view: only dragging onto the load lines of the lateral side is possible)

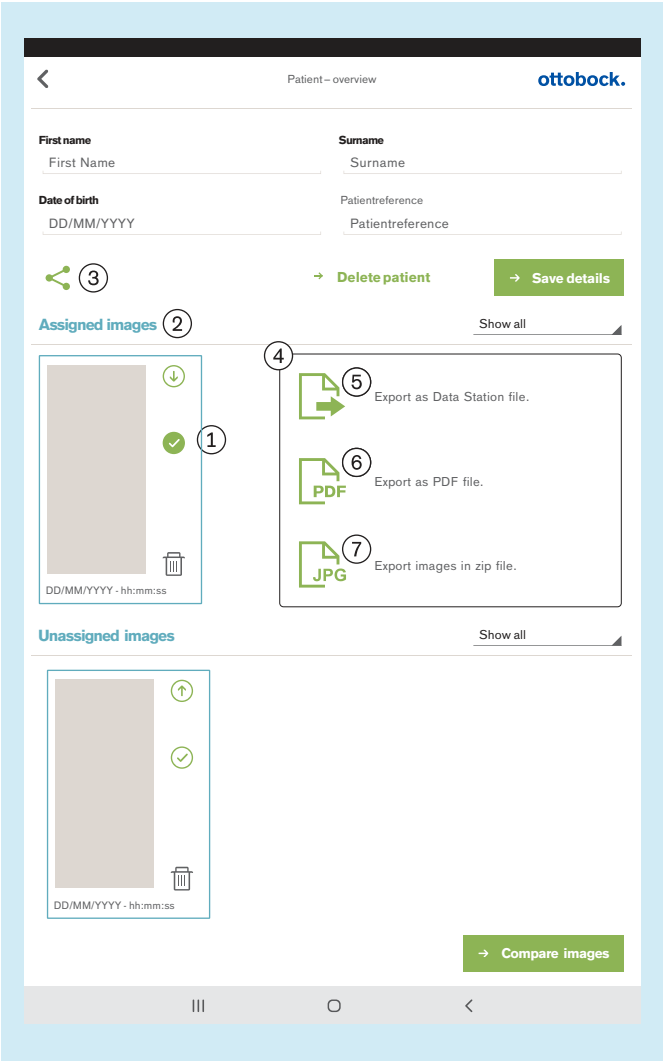
⑨: Save and return to live view (section "Live view" – see page 25)

5.4.5.2 Comparison view



①: "Compare images"
②: Return to patient overview
2x tapping an image opens the measurement display (section "Measurement display" – see page 33).

5.4.5.3 Creating files



If one or more images ① are selected under "Assigned images" ②, they can be exported using the ③ icon.

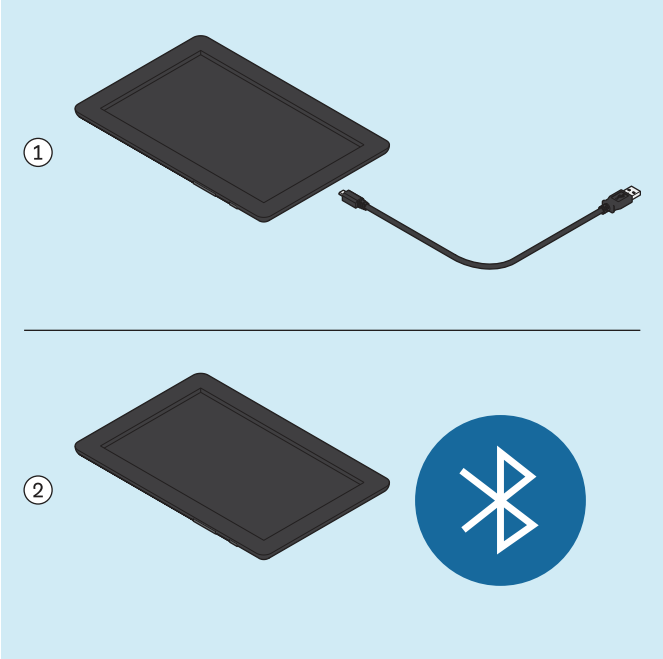
The small ④ window opens, which has the following options for export:

⑤: "Export as Data Station file." (section "LASAR files" – see page 35)

⑥: "Export as PDF file." (section "PDF files" – see page 36)

⑦: "Export images in zip file." (section "JPG and zip files" – see page 36)

5.4.5.3.1 LASAR files



The special file for data exchange with the Ottobock Data Station has the file extension "*.lasar".

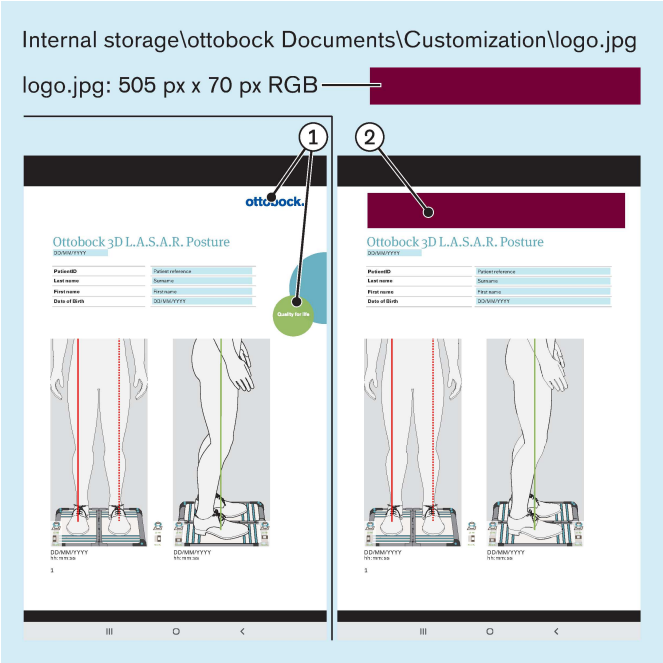
- Storage paths (lasar files are stored in both paths simultaneously.):
  External storage (SD card)/Android/data/com.ottobock.Lasar3DApp/files/Documents
  Internal storage/ottobock Documents/Documents

The file can be transferred to another computer using the USB cable ① or Bluetooth ② (see user manual for the tablet - other than transfer with the USB cable, this is the only supported transmission method).

5.4.5.3.2 PDF files

①: "PatientID" (patient reference)
②: "Surname"
③: "First name"
④: "Date of Birth"
The PDF file is displayed in a different app. The "3D L.A.S.A.R. Posture" app can be called up again with the "Last Apps" button (section "Reading the user manual for the tablet" – see page 16).
The file can be transferred to another computer using the USB cable or Bluetooth (see user manual for the tablet).

- Storage paths (PDF files are stored in both paths simultaneously.):
  External storage (SD card)/Android/data/com.ottobock.Lasar3DApp/files/pdf
  Internal storage/ottobock Documents/pdf



Instead of the Ottobock logo ①, a custom logo ② can also be used for generating the PDF file.
The logo must be stored as a jpg file with the following properties:

- Colour space: RGB
- Dimensions: 505 pixels (width) x 70 pixels (height)

The logo must be stored in the following path in the tablet's internal storage:

- Internal storage\ottobock Documents\Customization\logo.jpg

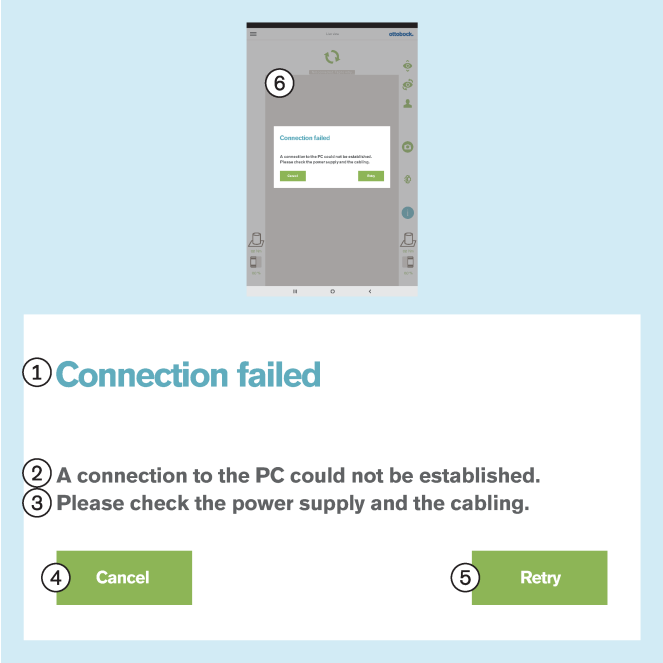
5.4.5.3.3 JPG and zip files

When using "Export images in zip file.", the images are always stored as JPG and zip files.

- Storage paths (the files are stored in both paths simultaneously.):
  External storage (SD card)/Android/data/com.ottobock.Lasar3DApp/files/Images
  Internal storage/ottobock Documents/Images

5.5 Troubleshooting error messages

5.5.1 Connection failed



Error message text:

①: "Connection failed"

②: "A connection to the PC could not be established."

③: "Please check the power supply and cabling."

④: "**Cancel**"

⑤: "**Retry**"

⑥: "Not connected. Tap to retry ..."

Possible causes:

- No power to the mini-computer
- Mini-computer still booting up (operating system/software)
- Mini-computer crashed
- The QR code scanned or activation code entered does not match the product
- "**Deny**" was tapped in the message window "**Allow 3D L.A.S.A.R. Posture to access the device location**" when starting the app (see the section "**Starting the app**" - see page 24).

Measures:

► Carry out the appropriate measures depending on the cause (for example connect the power; wait for boot-up to finish; restart the mini-computer; check and reenter the code).

► Tap once on "**Retry**".

► To revoke the denial of access to the location information, tap "**Apps**" under "**Settings**" on the tablet. In the app list, tap "**3D L.A.S.A.R. Posture**". In the app settings, tap "**Rights**", find the "**Location**" setting that is set to off and turn it on.

5.5.2 Platform not connected

Error message text:

①: "Platform not connected" (force measurement plate)

②: "Please remove any loads from the platform and then connect the cable between the PC and the platform."

③: "**OK**"

Possible causes:

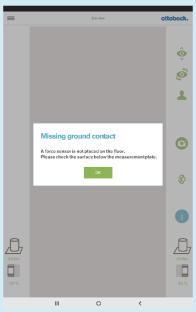
- Magnetic USB plug has been disconnected
- USB plug not connected to mini-computer
- Mini-computer software has crashed
- Defective cable
- Defective force measurement plate
- Electromagnetic interference

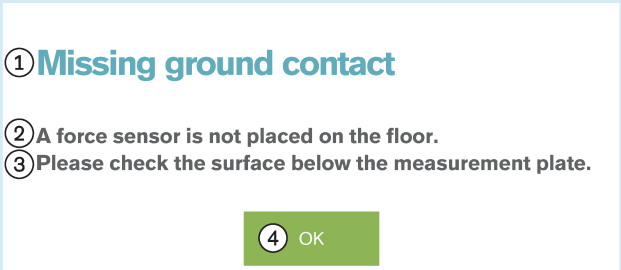
Measures:

► Carry out the appropriate measures depending on the cause (for example connect USB plug; wait for booting to finish; restart the mini-computer; have defective components repaired by Ottobock Service).

- In case of electromagnetic interference, disconnect the USB plug connection for 15 seconds and then connect it again. Restart the mini-computer if necessary (disconnect the mains plug, wait 3 minutes and connect it again).
- Tap on "**OK**" x 1.

5.5.3 Missing ground contact





Error message text:

①: "Missing ground contact"

②: "A force sensor is not placed on the floor."

③: "Please check the surface below the measurement plate." – Apply the load to the force measurement plate as evenly and consistently as possible. Avoid a point load near the edge of the plate since this can also cause this error message.

④: "**OK**"

Possible causes:

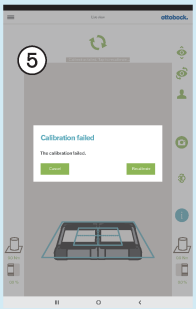
- Uneven floor
- Defective sensor in the force measurement plate
- Defective circuit board in the force measurement plate

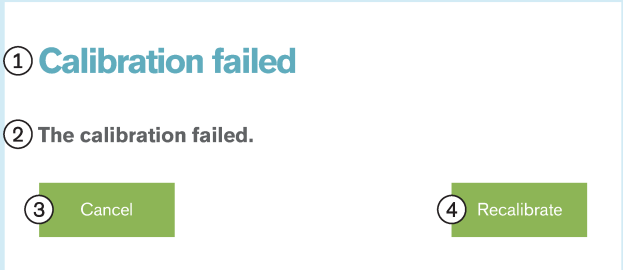
Measures:

► Carry out the appropriate measures depending on the cause (for example level the force measurement plate on an even floor; have defective components repaired by Ottobock Service).

► 1x tap on "**OK**".

5.5.4 Calibration failed





Calibration in this section deals with the cameras' ability to detect the position of the force measurement plate.

Error message text:

①: "Calibration failed"

②: "The calibration failed"

③: "**Cancel**"

④: "**Recalibrate**"

Possible causes:

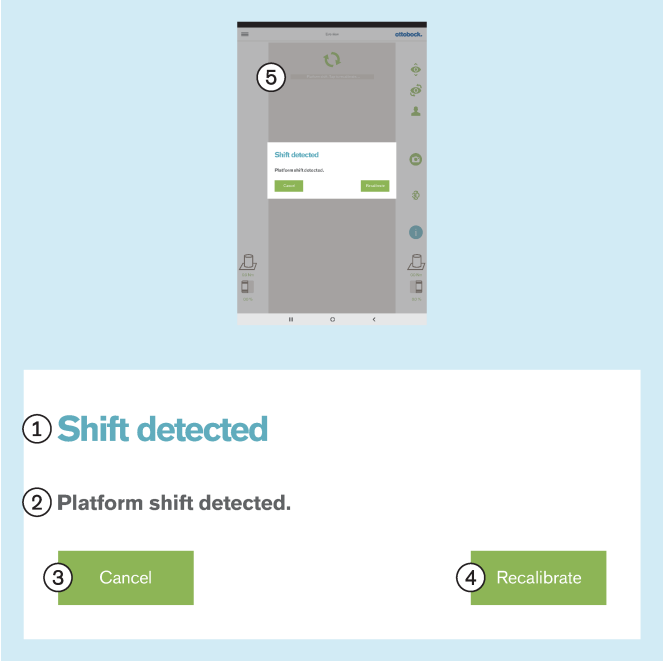
- One or more LEDs are not recognised, are covered or are outside the outer blue frame
- The camera stand or force measurement plate was moved during the calibration
- Overexposed image (white)
- Underexposed image (black)
- Backlighting

Measures:

► Carry out the appropriate measures depending on the cause (for example align the force measurement plate and camera stands so that all LEDs are recognised within the outer blue frame; restart the mini-computer in case of incorrect exposure).
Take corresponding steps to prevent backlighting

► 1x tap on "**Recalibrate**".

5.5.5 Shift detected



Error message text:

①: "Shift detected"

②: "Platform shift detected"

③: "**Cancel**"

④: "**Recalibrate**"

Possible causes:

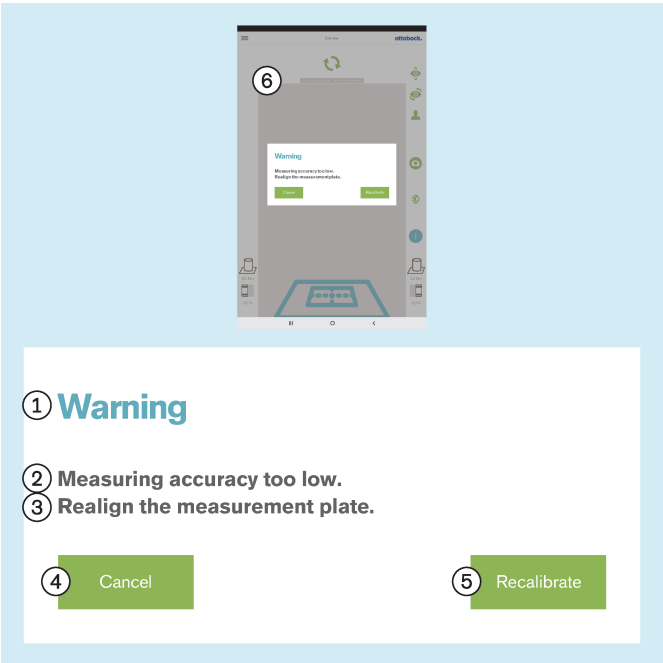
- The camera stand or force measurement plate was moved
- All LEDs were pushed out of position
- Underexposed image (black)

Measures:

► Carry out the appropriate measures depending on the cause (for example align the force measurement plate and camera stands so that all LEDs are recognised within the outer blue frame; restart the mini-computer in case of incorrect exposure).

► 1x tap on "**Recalibrate**".

5.5.6 Warning



Error message text:

①: "Warning"

②: "Measuring accuracy too low."

③: "Realign the measurement plate." – Position the force measurement plate closer to the camera stand to use the full camera resolution.

④: "**Cancel**"

⑤: "**Recalibrate**"

Possible causes:

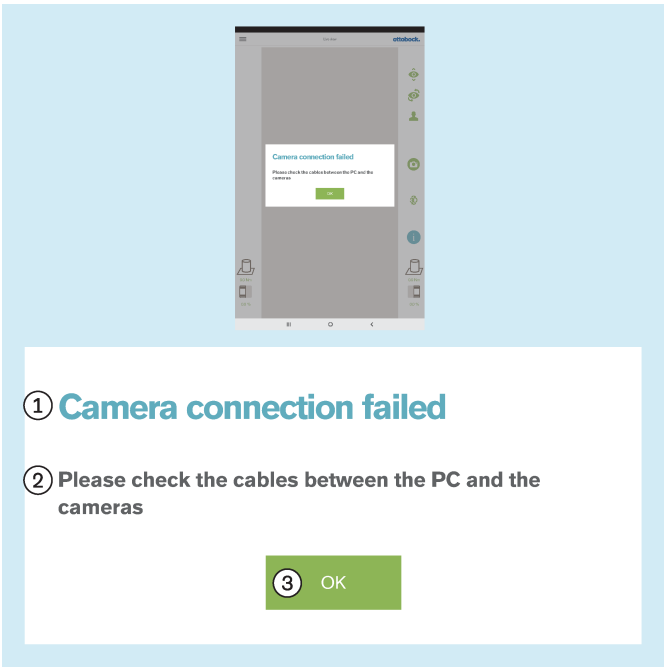
- Force measurement plate rotated too much relative to the camera
- Camera stand tilted away from the force measurement plate too much
- Camera too far away from the force measurement plate

Measures:

► Carry out the appropriate measures depending on the cause (for example align the force measurement plate and camera stands so that all LEDs are recognised within the outer blue frame, that the crosshairs of the inner blue frame are centred over the middle of the force measurement plate, and that the hinges on the force measurement plate are aligned with one of the two centre lines of the crosshairs; align the camera at a 90° angle; reduce the distance between the camera and force measurement plate).

► 1x tap on "**Recalibrate**".

5.5.7 Camera connection failed



Error message text:

①: "Camera connection failed"

②: "Please check the cables between the PC and the cameras"

③: "**OK**"

Possible causes:

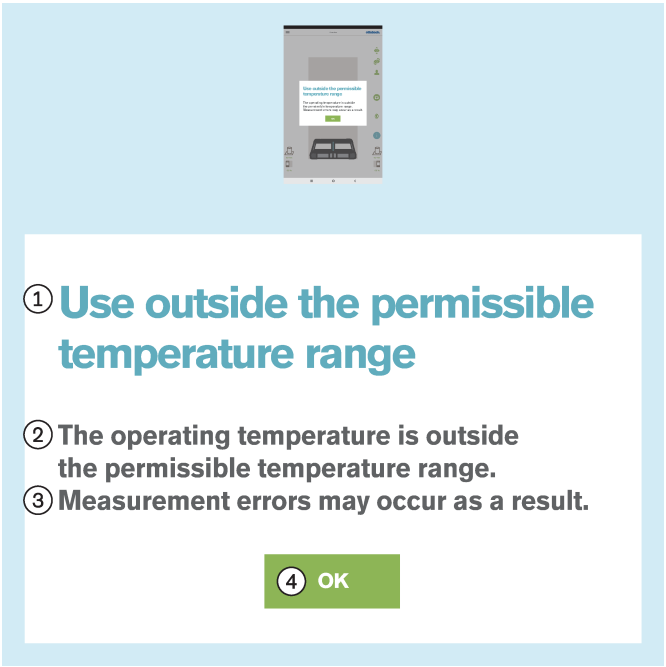
- USB plug not connected to mini-computer
- Mini-computer software has crashed
- Defective cable
- Defective camera

Measures:

► Carry out the appropriate measures depending on the cause (for example connect USB plug; restart the mini-computer; have defective components repaired by Ottobock Service).

► 1x tap on "**OK**".

5.5.8 Use outside of the permissible temperature range



Error message text:

①: "Use outside of the permissible temperature range"

②: "The operating temperature is outside the permissible temperature range."

③: "Measurement errors may occur."

④: "**OK**"

Possible causes:

- The ambient temperature is **< +15 °C**.
- The ambient temperature is **> +30 °C**.

Measures:

► Use the product exclusively within the permissible temperature range (**+15 °C – +30 °C**).

► Tap on "**OK**" once.

5.5.9 Use outside the allowable weight range

Error message text:

①: “Use outside the allowable weight range”

②: “The weight exceeds the allowable weight. Measurement errors and product damage may occur.”

③: “**OK**”

Cause:

- The patient’s weight exceeds the allowable weight for the product **(150 kg)**.

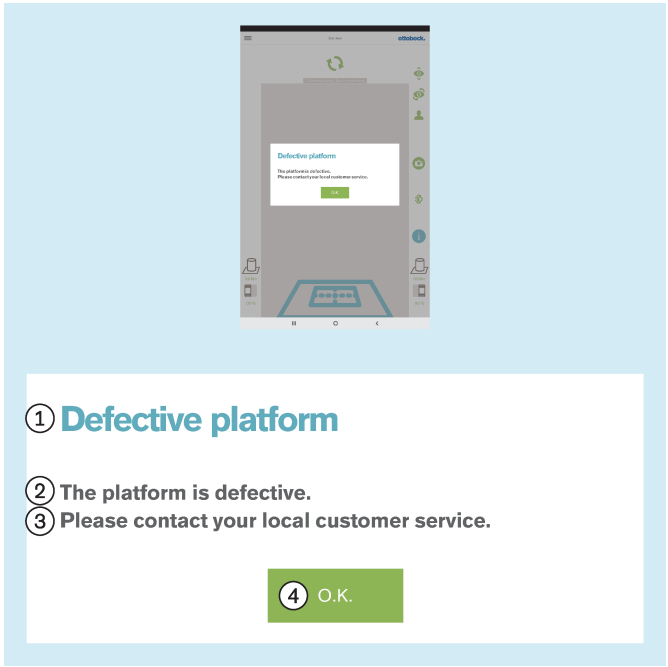
Actions:

► Have the patient get off the measurement plate immediately.

► Tap “**OK**” once.

► Inspect the measurement plate for damage and have it repaired if necessary.

5.5.10 Defective platform



Error message text:

①: "Defective platform"

②: "The platform is defective."

③: "Please contact your local customer service."

④: "**OK**"

Possible causes:

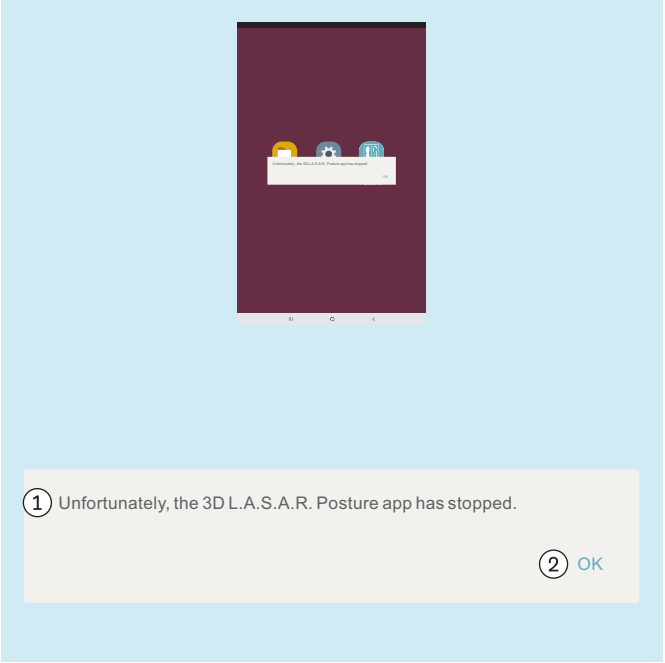
- Broken cable
- Torn cable
- Defective circuit board

Measures:

► Have the defective force measurement plate repaired by Ottobock Service.

► 1x tap on "**OK**".

5.5.11 Unfortunately, the 3D L.A.S.A.R. Posture app has stopped.



Error message text:

①: "Unfortunately, the 3D L.A.S.A.R. Posture app has stopped."

②: "**OK**"

Possible causes:

- Unexpected app error

Measures:

► 1x tap on "**OK**" and restart the app.

► Contact Ottobock Service if this problem recurs often.

5.6 Frequently asked questions (FAQ)

Live view

- **What should I do if the camera image only appears in the live view with a major delay?**

Delays are caused by WiFi problems. In case of a long delay (> 5 seconds), try the following steps to solve the problem:

1. Check if anything in the vicinity (such as metallic objects, WiFi router) is interfering with the WiFi signal. For example, do not place the mini-computer in a metal cabinet or shelf.
2. Switch from the live view to the patient overview. This resets the WiFi connection.
3. Restart the product (switch off according to the section "Switching off" - see page 56, wait 30 seconds, switch on according to the section "Switching on" - see page 15).

Internet

- **Is Internet access required to use the product?**

Internet access is not required to use the product. A connection to the Internet is prohibited for security reasons.

Hardware

- **Can different hardware be used?**

Using hardware that has not been approved for the purpose by Ottobock is prohibited.

- **Can I verify that the device is still measuring correctly?**

Press on the plate with a gymnastics rod. The 3D vector has to run directly on the rod from the tip to the load transmission point (section "Checking the calibration" – see page 56)

- **Can the force measurement plate be wet cleaned?**

Wet cleaning is possible as described in the section "Cleaning" (see page 59).

- **Can additional markings be applied to the force measurement plate?**

The force measurement plate is marked with orientation lines for patient alignment. Colour markings and stickers may be applied to the plastic edge, provided they are not highly reflective and do not cover the LEDs.

- **What is the maximum permissible patient weight?**

150 kg

Mini-computer

- **What does the beep mean after turning on the mini-computer?**

The beep tells you that the mini-computer has been turned on and the operating system is booting up.

- **How can I tell that the mini-computer has booted up?**

Some time after the mini-computer is turned on (about one minute), all four LEDs on the force measurement plate flash at the same time at least twice. A WiFi network with "3DLASAR" in the SSID (name) is visible to WiFi-capable devices (such as telephones, laptops, tablets).

Tablet

- **Can a different tablet be used?**

In order to ensure the reliability of the product as a measuring device, only the supplied tablet may be used.

- **Can the tablet be used without the micro-SD card?**

No, because the patient database is stored on the micro-SD card.

- **Can the tablet be used for e-mail?**

This is not possible because the tablet may not be connected to the Internet. Only Bluetooth or the USB cable may be used for transferring data.

- **Can the images be sent and printed from the tablet?**

The images cannot be exported directly. However, two formats are provided for the export of images and patient data:
1. PDF files
2. Data Station files
Bluetooth or the USB cable is used for transfer to a computer. The data can be printed using a PDF viewer program or the Ottobock Data Station.

Software

- **Are software updates provided? How do you find out about them?**

Ottobock informs you of software updates and provides detailed installation instructions.
The information is sent by e-mail.

- **Is installing a new operating system for the tablet permitted?**

Installing a new operating system may lead to problems with the app. Therefore, an operating system update may be installed only when Ottobock instructs you to do so. Otherwise, update reminders and installation messages on the tablet may **not** be confirmed and carried out.

- **What happens if the "3D L.A.S.A.R. Posture" app is deleted?**

"3D L.A.S.A.R. Posture" app

NOTICE! Deleting the app erases the database on the micro-SD card.

You **must back up the databasebefore** the app is uninstalled on the instructions of the Ottobock service.

- **Is the app available in my national language?**

The app is available in the following languages: German, English, French, Spanish, Italian, Dutch, Czech and Chinese. Ottobock informs customers when additional languages become available.

- **What are the QR code and activation code needed for?**

The codes are needed to connect the mini-computer to the tablet during setup. Without this connection the "3D L.A.S.A.R. Posture" app is not functional.

- **Where are the QR code and activation code located?**

The codes are lasered onto the bottom section of the case on the mounting plate of the mini-computer (section "Starting the app for the first time" – see page 19).

- **Can different passwords be used for different users?**

Yes, by assigning a different micro-SD card to each user. Then the app creates a separate database with a password on each micro-SD card.

- **Is it possible to display the total patient weight?**

No, the app only displays the values separately for the two sides of the force measurement plate. The total value can be calculated by adding the individual values. These weights are only approximate since the scale function of the 3D L.A.S.A.R. Posture is not calibrated.

- **What happens if you forget the password?**

The password cannot be reset or restored. Ottobock is also not able to open the database. Therefore, be sure to store the password safely in order to avoid data loss.

- **Where is the password noted?**

The password is selected once during setup. Subsequently, it can be changed but not read.

- **Can I change my password?**

The password can be changed in the settings (section "Settings" – see page 27).

- **Are personal data safe against unauthorised access?**

The data are stored in an encrypted database on the micro-SD card. Encryption is via the login to the app. PDF files and Data Station files generated with the app are not encrypted. Therefore, they need to be protected against unauthorised access and securely erased if necessary.

- **How can the app database be backed up?**

By copying the contents of the micro-SD card to another storage medium.

- **Is it possible to save the data if the tablet is defective?**

The data are stored on the micro-SD card. It can be removed and subsequently used in a replacement tablet, provided it was not damaged. Taking backup copies of the SD card contents at regular intervals is therefore recommended so the data can be restored if necessary.

- **What can be done if the tablet cannot be turned on?**

Check whether the charge level of the tablet is sufficient and connect it to the battery charger if necessary. Hold the On button long enough to turn on the device.

- **Can the tablet be used while it is charging?**

CAUTION! To protect against leakage currents, the patient is not permitted to come into contact with the tablet during charging, either directly or indirectly (for instance through another person).

Setup

- **Can the device also be used outdoors?**

Only if the ambient conditions permit this (dry, constant lighting and solid/even surface) and safe use is assured.

- **Does the force measurement plate have to be centred in front of the case?**

Yes, to achieve the best possible accuracy.

- **What is the best way to lay the cables from the case?**

The camera cables should be kept out of the working area for the O&P professional as far as possible to avoid tripping (section "Setup" – see page 13). The cable between the case and force measurement plate should be laid as straight as possible and has a detachable magnetic connection.

Using the product

- **Can the alignment guidelines be used in 3D mode?**

The stored alignment guidelines only apply when 3D mode is deactivated.

- **Can the device be used for bench alignment without the L.A.S.A.R. Assembly?**

No, since the weight of the prosthesis alone would be too low to work with sufficient accuracy.

Error messages

- **What can be done if the error message "Connection failed" is displayed repeatedly even though the mini-computer has booted up?**

Check the WiFi settings on the tablet to verify that WiFi is active and connected to the network named "3D_L.A.S.A.R._20XXXXXXX". If necessary, disconnect the power plug from the mini-computer and connect it to the outlet again to perform a restart.

- **How is the error message "Missing ground contact" corrected?**

Operate the force measurement plate on a firm, even surface. Distribute the load evenly or apply it to the centre of the plate.

- **How can the error messages "Calibration failed", "Shift detected" and "Warning" be avoided?**

Good lighting in the room, no backlighting for the cameras and a floor that is not too dark are important factors to obtain a good image quality. The alignment of the camera stands and force measurement plate has to be carried out according to the section "Alignment of the stands and force measurement plate" (see page 21).

- **What can be done if the device calibrates frequently?**

Make sure that none of the four LEDs on the force measurement plate are concealed from the perspective of the cameras. Remove reflective objects from the vicinity of the force measurement plate. Ensure constant, even lighting. Make sure that the camera and the force measurement plate are not exposed to direct sunlight (for instance light coming through a window).

- **What can I do if the force measurement plate is connected but not found?**

With the help of the live view on the tablet, position the force measurement plate so that it is as close as possible to the lower edge of the image but the four LEDs are still visible. In the live view, the force measurement plate must be visible at the bottom edge of the image, as close as possible to parallel and centred. Remove all reflective objects from the vicinity of the force measurement plate. Ensure constant ambient lighting (consistent brightness). Make sure the camera is not backlit (for instance by light coming in through a window). Check the connection of the USB magnetic plug. Disconnect and reconnect the connection if necessary.

Service

- **What defective product components can be sent to Ottobock Service individually by the customer, and for which ones do all system components have to be sent?**

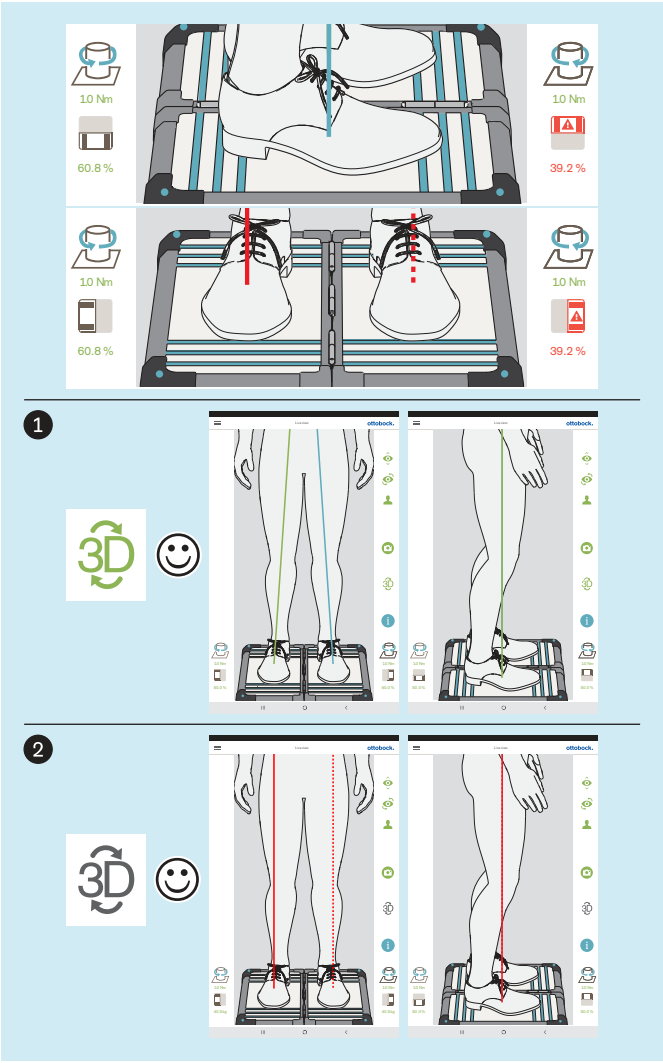
Sent individually: force measurement plate, micro-SD card, tablet
Sent with all system components: cameras, mini-computer, case

5.7 Optimising the alignment of prostheses and orthoses

INFORMATION

The information in this document provides a brief overview of the possibilities offered by the 3D L.A.S.A.R. Posture for optimising the static alignment of prostheses and orthoses. Ottobock training for the 3D L.A.S.A.R. Posture imparts theoretical and practical knowledge for using it successfully.

Optimum static alignment makes it possible for the patient to stand in a relaxed posture and establishes the basis for optimisation during the dynamic trial fitting.



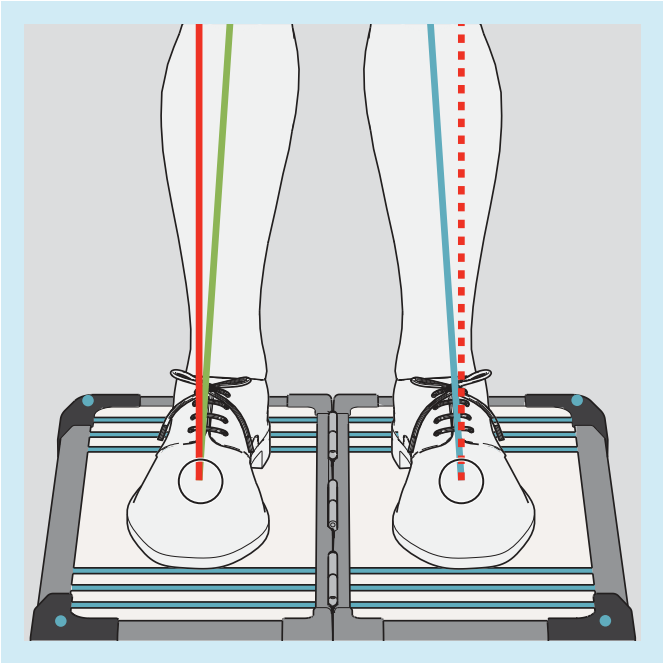
Optimising the alignment of prostheses and orthoses is performed in the following sequence:

1. Optimisation with 3D mode activated (see page 49) – 3D symbol: green
2. Optimisation with 3D mode deactivated (see page 52) – 3D symbol: dark grey

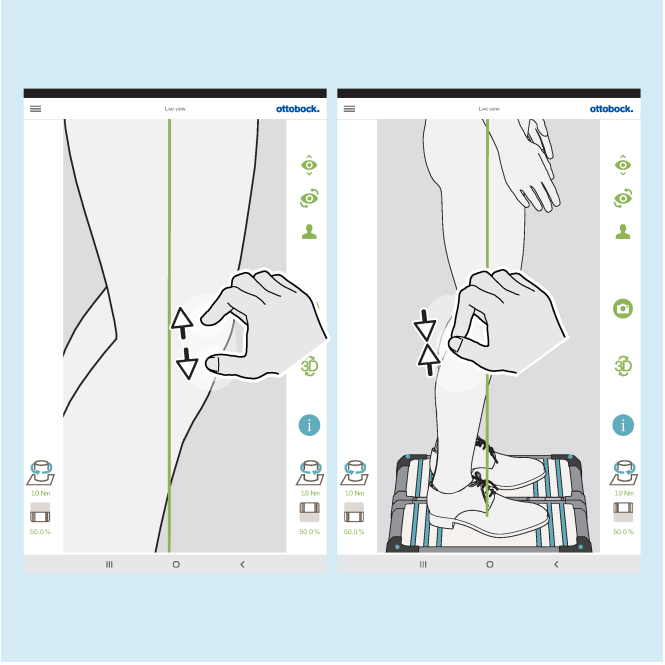
It is important that the patient stands on the force measurement plate with a relaxed body posture as far as possible (section "Positioning the patient" - see page 24). If this is the case, it can be assumed that deviations from the characteristics for optimum, relaxed standing are caused by sub-optimal static alignment and can be changed through corresponding corrections.

The following characteristics indicate optimum, relaxed standing:

- **Sagittal load line**
  3D mode activated and deactivated: parallel to each other, overlapping, bottom end of the load line (load transmission point or force transmission point) in the centre of the foot
- **Frontal load lines**
  3D mode activated: runs through knee centre
  3D mode deactivated: runs along the lateral patella edge
- **Load ratio between the plates**
  ~ 50:50 (load ratio for prosthetics: section "Positioning the patient" - see page 24
  The symbol and value are shown in red if the value is less than 40%.



The force transmission points (bottom ends of the load lines) are in the same place whether 3D mode is activated or deactivated (see markings in the illustration). Simultaneous display is not possible in the app.



The image in the live view can be zoomed in and out for better control.

5.7.1 Optimisation with 3D mode activated

INFORMATION

The illustrations that follow show load lines with 3D mode activated, with an incorrect course since it does not correspond to the optimum course described in the previous section. Possible causes are listed, identifying what may be wrong and therefore how the static alignment has to be optimised. The course of the load lines with 3D mode deactivated is shown in addition.

Due to their fundamental importance for the illustrations in this section, the possible causes and solutions listed below are identified according to their numbers.

Possible causes

1a) Improper bench alignment

2a) Static alignment with shoes not optimised

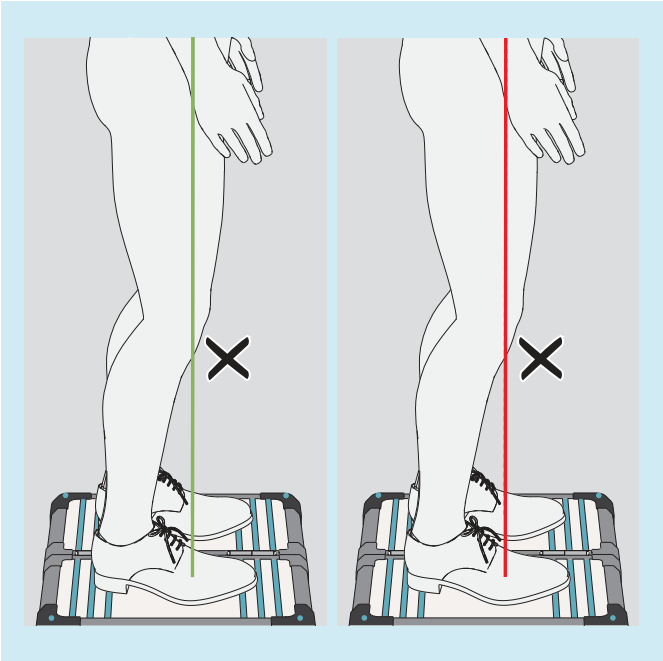
3a) No adjustment for different heel heights of different shoes

Possible solutions

1b) Ensure proper bench alignment

2b) Optimise static alignment with shoes (prosthetics: adjust plantar flexion)

3b) Adjust different heel heights of different shoes to one heel height using insoles (also take the contralateral side into account)



Deviations in the course of the load lines in 3D mode

- Force transmission point not in foot centre but in forefoot area

Possible causes

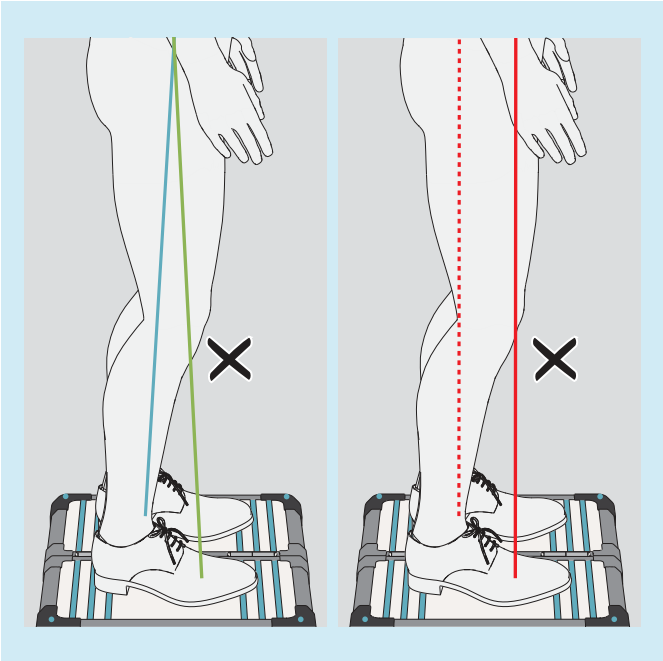
- 1a), 2a)
- Patient balancing on the balls of both feet

  Possible solutions

  – 1b), 2b)

  – Ask the patient to stand upright

  – By reducing plantar flexion, shift the force vector in the posterior direction so the patient stands upright naturally



Deviations in the course of the load lines in 3D mode

- Force transmission points far away from each other
- Significantly tilted towards each other at the top

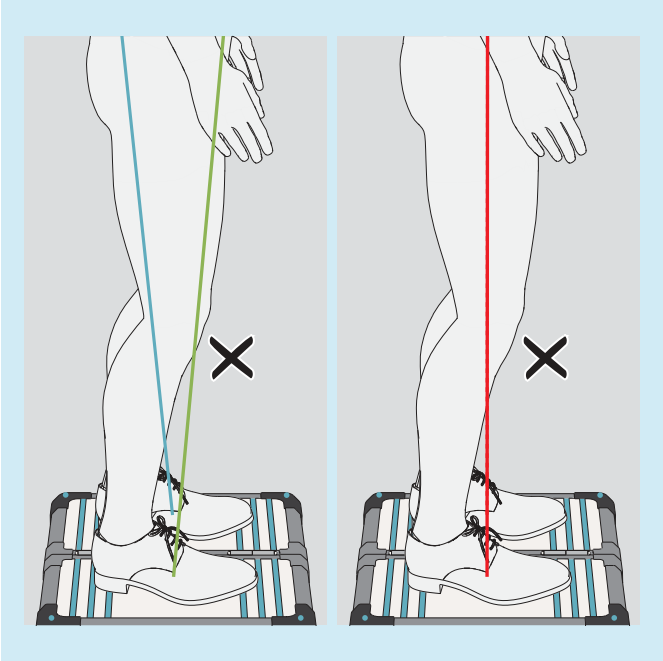
Possible causes

- 1a), 2a), 3a)
- TF prostheses: pes equinus position for knee stabilisation
- Orthosis: spasm

  Possible solutions

  – 1b), 2b), 3b)

  – Orthosis: use suitable means to establish ground contact of the elevated heel to make force transmission more balanced



Deviations in the course of the load lines in 3D mode

- Force transmission points close together
- Significantly tilted away from each other at the top

Possible causes

- Hips not parallel to frontal plane
- 1a), 2a)
- Subjective instability of the prosthetic knee joint
- Unfavourable component selection
- Changes on the contralateral side
- Excessive compensation for a hip flexion contracture
- Unfavourable load application to the prosthetic socket

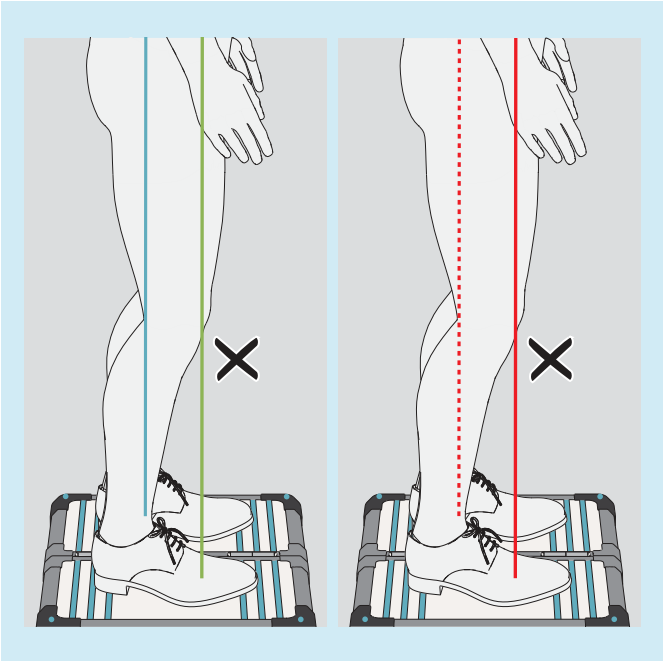
  Possible solutions

  – 1b), 2b)

  – Use a prosthetic knee joint with stance phase support

  – Take hip flexion contracture into account for optimisation during the dynamic trial fitting

  – Evenly distribute load application to the prosthetic socket



Deviations in the course of the load lines in 3D mode

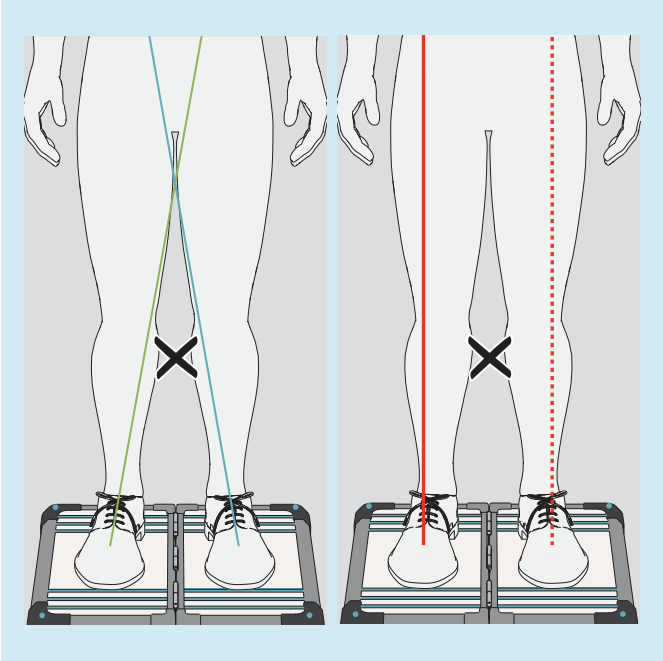
- Force transmission points far away from each other
- Parallel to each other

Possible causes

- 1a), 2a), 3a)
- Unfavourable component selection
- Socket problems
- Changes on the contralateral side

  Possible solutions

  – 1b), 2b), 3b)



Deviations in the course of the load lines in 3D mode

- Not through knee centre
- Significantly tilted towards each other at the top

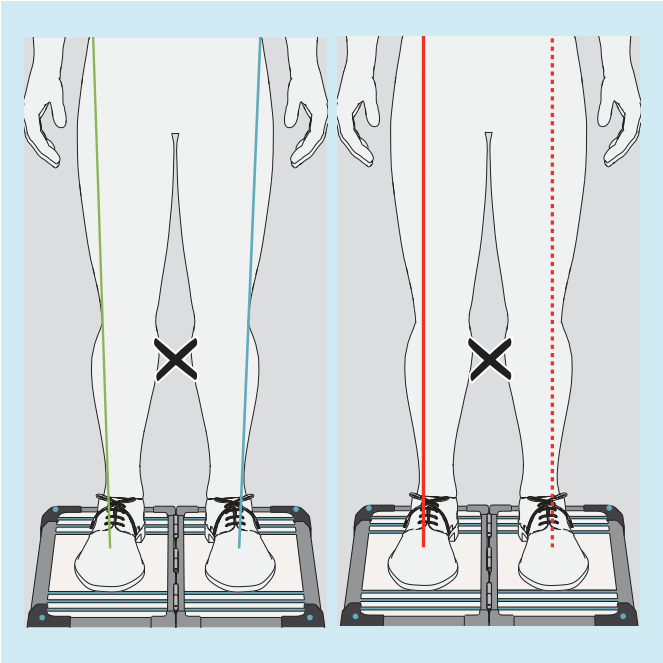
Possible causes

- 1a), 2a)
- Abduction moment of the hip
- Load of the prosthetic socket on the medial socket brim (TF prosthesis)

  Possible solutions

  – 1b), 2b)

  – Reduce pressure on the medial socket brim



Deviations in the course of the load lines in 3D mode

- Not through knee centre
- Significantly tilted away from each other at the top

Possible causes

- 1a), 2a)
- Adduction moment in the hip

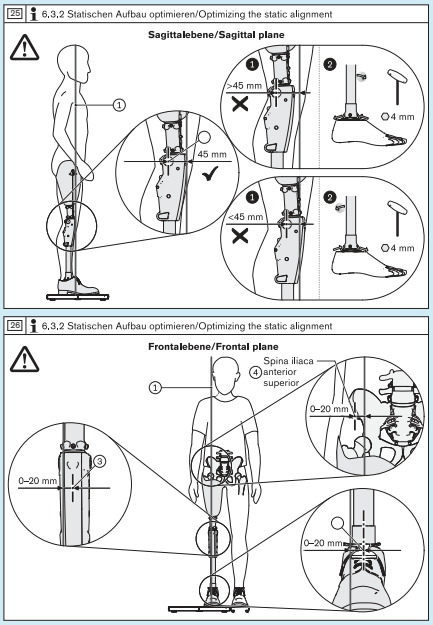
  Possible solutions

  – 1b), 2b)

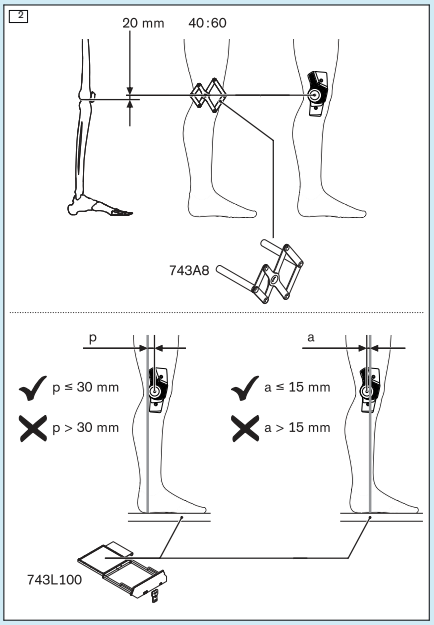
5.7.2 Optimisation with 3D mode deactivated

5.7.2.1 Alignment recommendation examples

1



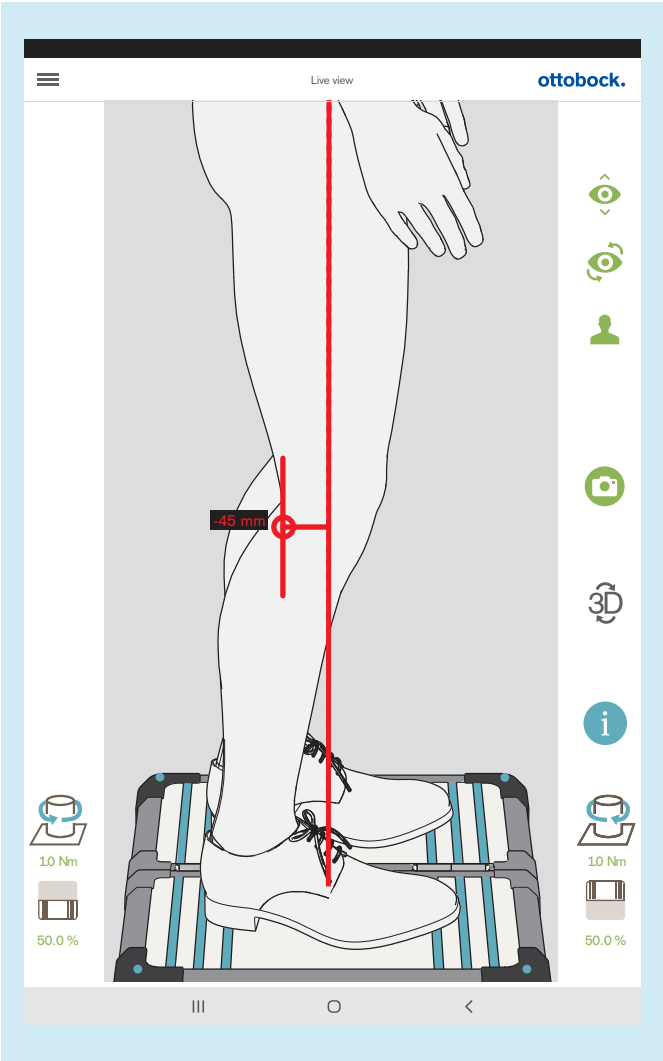
2



5.7.2.2 Using auxiliary lines

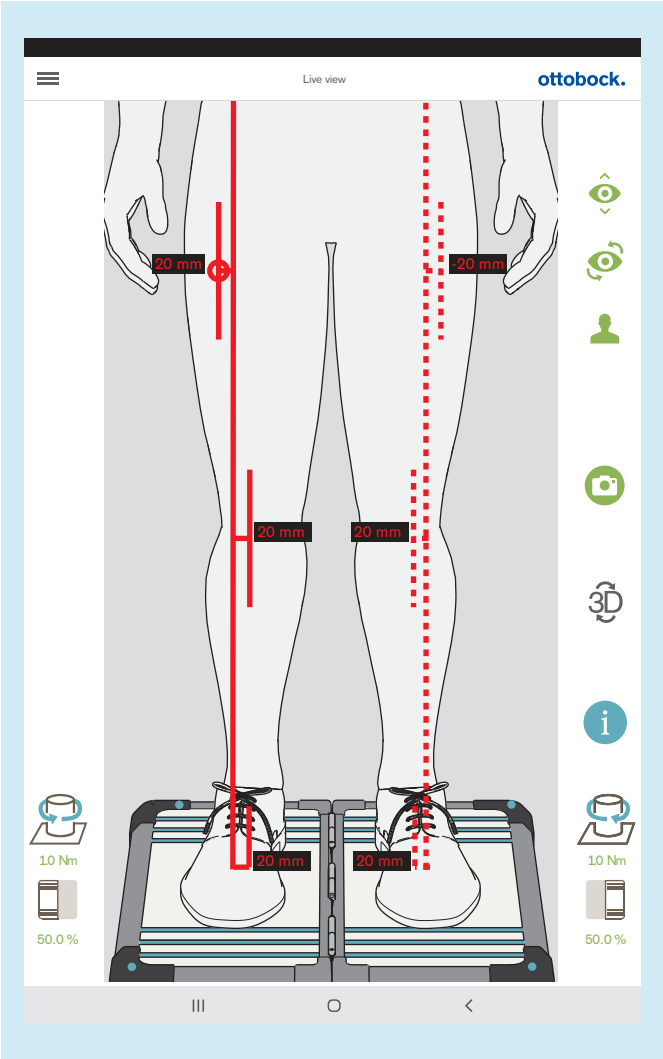
① Example of an alignment recommendation for static alignment from sample instructions for use for a prosthetic knee joint

② Example of an alignment recommendation for static alignment from sample instructions for use for an orthotic knee joint

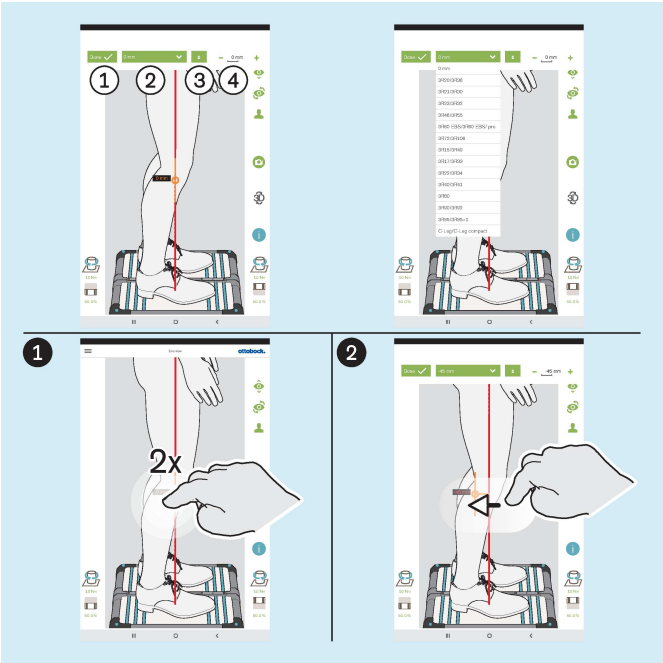


The illustration shows how the alignment recommendation for the sagittal view from the sample instructions for use for the prosthetic knee joint can be readjusted and checked with an auxiliary line in the live view.

Drawing auxiliary lines is described in the following.



The illustration shows how the alignment recommendation for the frontal view from the sample instructions for use for the prosthetic knee joint can be readjusted and checked with several auxiliary lines in the live view.



①: "Done" – 1x tapping closes the pop-up for the auxiliary line

②: "0 mm" – The list with the reference numbers of prosthetic knee joints for which the value for the alignment reference point in the sagittal view is stored is available here.

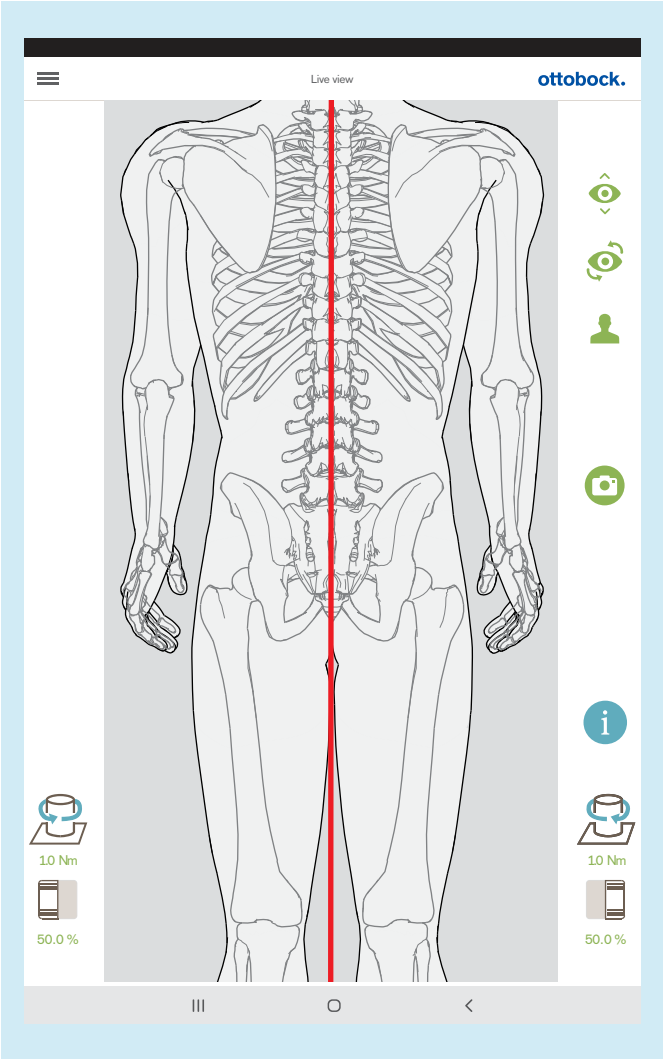
③: "±" – 1x tapping positions the auxiliary line on the opposite side of the load line – this function is important when the list with reference numbers of prosthetic knee joints is used, since the alignment in the live view is opposite depending on the amputation side, and has to be checked and corrected as needed

④: "- 0 mm +" – Change the value by 1x tapping of + and - or by entering the value

Drawing auxiliary lines

❶ 2x tapping on the load line opens the popup for the auxiliary line – a maximum of three auxiliary lines can be positioned on the load line. In the sagittal view, this is only possible on the load line facing the camera.

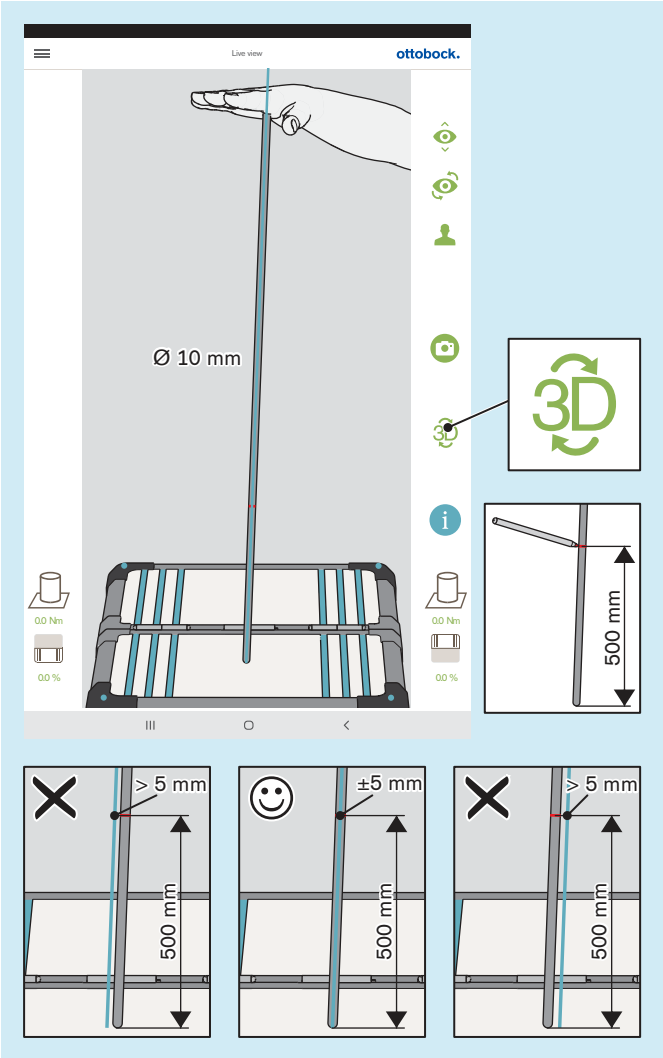
❷ Tapping and dragging can be used to position the auxiliary line.



When the top camera is used, 3D mode is automatically deactivated.

This view can be used to adjust the leg length. When the load on the legs is approximately equal and the knees are extended, the spinous processes of the vertebral bodies have to be above each other as parallels to the vertical reference line shown in red. The tutorials for TT prostheses and TF prostheses illustrate the use of this function (section "Tutorial selection" – see page 30).

5.8 Checking the calibration



Calibration in this section serves to check the measuring accuracy of the product against specified tolerances.

> **Test interval:** 1x per year

> **Test equipment:** gymnastics rod with rounded ends (Ø 10 mm)

> **Mode:** 3D mode activated (green)

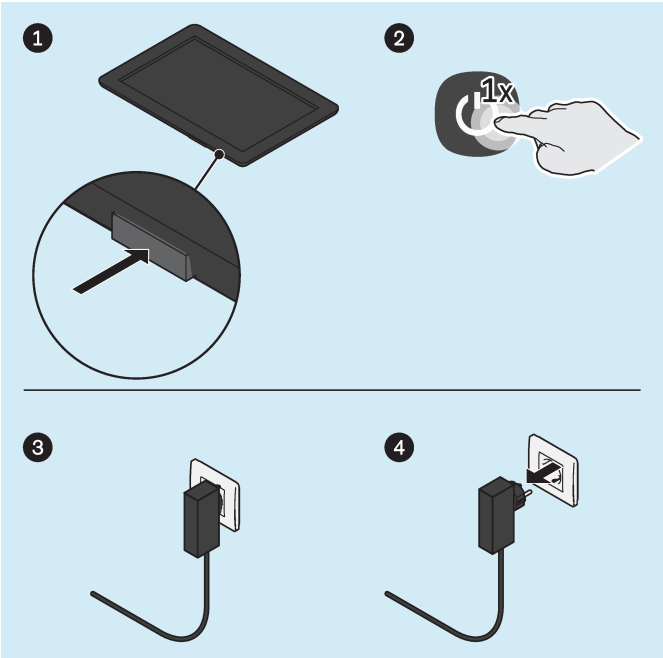
► With your hand flat, move the gymnastics rod to different positions.
Pause at each position without sliding the gymnastics rod on the force measurement plate, thereby generating additional moments.
Check the load line on the gymnastics rod while pausing.

→ The load line has to follow the longitudinal axis of the gymnastics rod and may not deviate more than ±5 mm from the marked height of 500 mm, which corresponds to the edge of the gymnastics rod.

→ If the deviation is > 5 mm, the force measurement plate has to be sent to the manufacturer for service.

► **NOTICE! Send the 3D L.A.S.A.R. Posture to the manufacturer every two years to have the calibration checked.**

5.9 Switching off



Tablet

► Press the on/off button of the tablet for 2 seconds.

► Confirm the shutdown message.

→ The tablet is turned off.

Mini computer

► Pull the plug of the mini computer's power supply out of the outlet.

→ The mini computer is switched off.

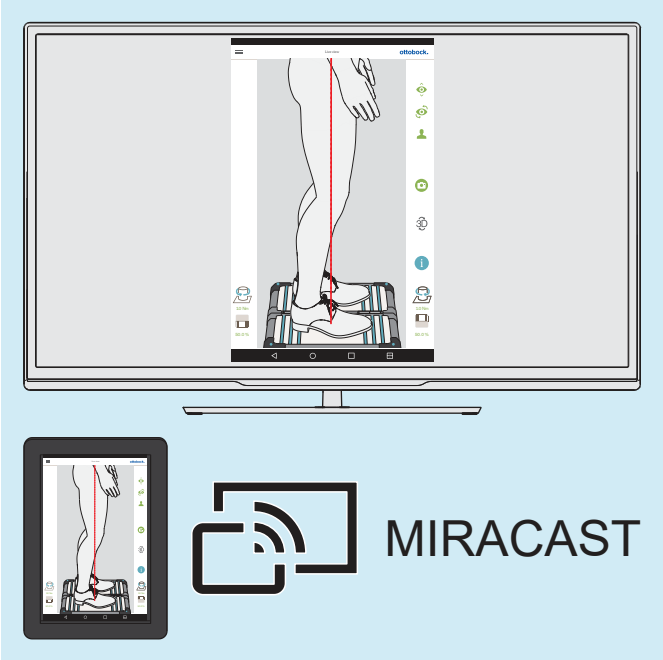
5.10 Display of the tablet screen on another screen

The tablet supplied enables the wireless display of the screen on another device (e.g. television, laptop) via a direct WiFi connection. To do this, a direct WiFi connection between the tablet and the WLAN device is used.

There is no guarantee that the tablet screen can be displayed on another screen because this depends on the compatibility of the devices used. Problems can often be solved by trying out different settings and searching the Internet.

Depending on the tablet supplied, the tablet screen may be transferred to another screen in different ways.

Tablets with transfer via Miracast (LG V700, Asus ZenPad 10, Acer Iconia One 10)

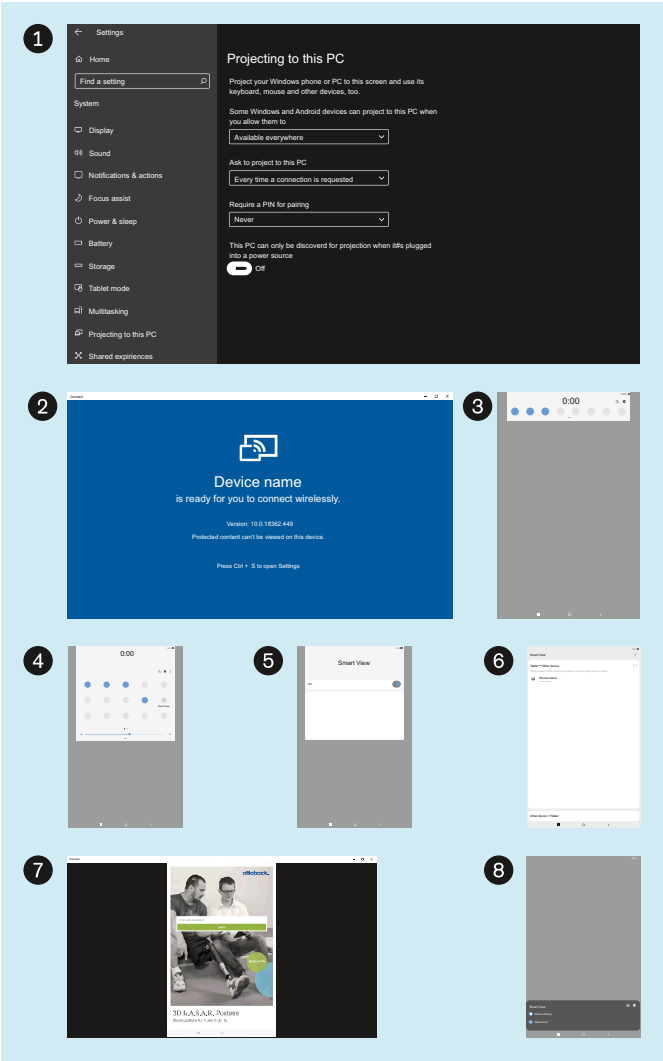


The tablet screen can be transferred to and displayed on another device over a wireless connection using Miracast, a peer-to-peer radio screencast standard (for example a television screen or monitor with Miracast HDMI dongle or a computer with Miracast adapter).

Further information about Miracast is available on the Internet or from an electronics retailer.

► For display on another device, observe the instructions for the tablet or device and the Miracast dongle or adapter.

Tablets with transfer via Smart View (SAMSUNG SM-T510, SM-X200)



The image shows how the tablet screen can be transferred to a Windows 10 PC.

No VPN connection may be activated on the computer.

Information on transferring to other computers and televisions is available on the Internet.

- ► ❶: Via "Settings" – "System" – "Projecting to this PC", select the settings "Available everywhere", "Every time a connection is requested", "Never" and "Off".
- ► ❷: Start the Windows app "Connect".
- ► ❸: Open the settings screen on the tablet by swiping down from the upper edge.
- ► ❹: Expand the settings screen and tap on "Smart View".
- ► ❺: Switch on "Smart View".
- ► ❻: Select the device (Windows PC) for transfer.
- ► ❼: The tablet screen is transferred.
- ► ❽: To end transfer, select "Disconnect" on the tablet or close the "Connect" app.

6 Cleaning

⚠ CAUTION

Improper cleaning

Skin irritation, formation of eczema or infections due to contamination with germs

► Clean the product regularly.

Cleaning the camera lens

> Use an optical brush in case of dust.
> In case of light soiling, use a dry, soft cleaning cloth for lenses or glasses.
> In case of heavier soiling, use a moist cleaning cloth for lenses or glasses.

► Clean the camera lens.

Cleaning the tablet

► Follow the instructions in the tablet user manual for cleaning the tablet.

Cleaning light soiling

1) Clean the product with a damp, soft cloth.
2) Dry the product with a soft cloth.
3) Allow to air dry in order to remove residual moisture.

Cleaning heavier soiling

> **Required materials:** colourless, alcohol-free disinfectant (verify material compatibility!), soft cloth

1) Disinfect the product with the disinfectant.
2) Dry the product with a cloth.
3) Allow to air dry in order to remove residual moisture.

7 Maintenance and repair

7.1 Retrieving important system information for service department

INFORMATION

Important system information from the product is required when contacting the manufacturer's service department. As shown in this section, this can be retrieved and then forwarded via the app.

- ▶ ❶: Tap the menu icon to display the menu.
- ▶ ❷: In the menu, tap "Settings" ("Settings").
- ▶ ❸: Swipe to scroll to the very bottom.
- ▶ ❹: Tap the "Display additional system information" ("Display additional system information") button.
- ▶ ❺: Swipe to scroll to the very bottom until all system information is displayed.
- ▶ ❻: Take a photo of the system information or take a screenshot to send it to the service department.

7.2 Checking the calibration

INFORMATION

To ensure the required measuring accuracy and maintain the status as a medical device, timely calibration checks need to be carried out both by the customer and the manufacturer's service department according to this section.

Check by the customer

- **Test interval:** Annually

► Perform the check according to the section "Checking the calibration" (see page 56).

Check by the manufacturer's service department

- **Test interval:** Every two years

INFORMATION

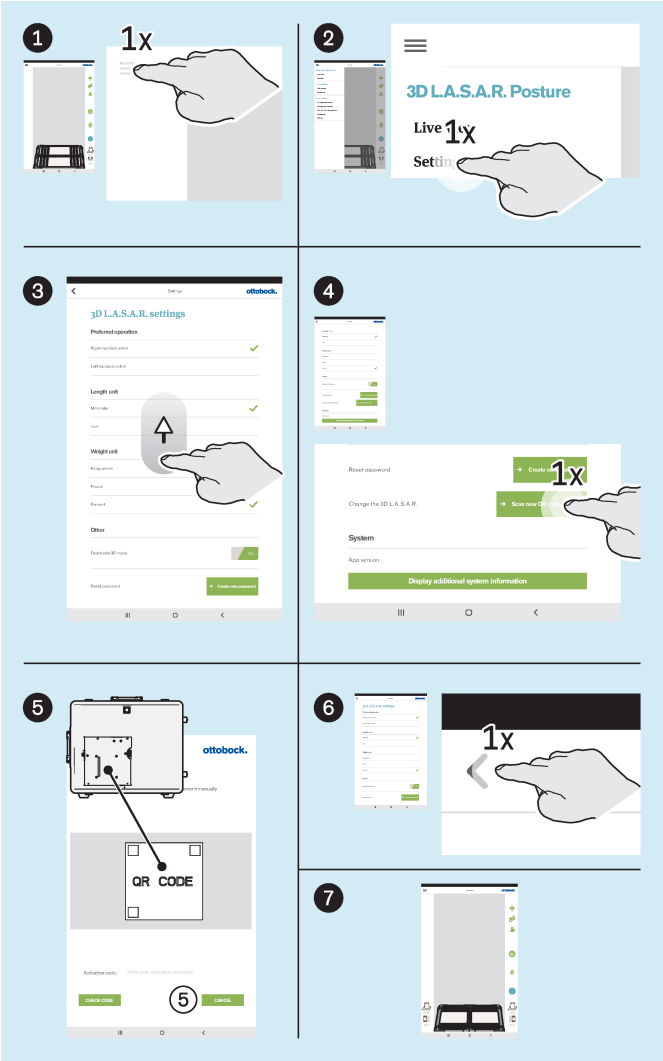
As a precaution, the manufacturer's service department checks the calibration by replacing components that are critical to measuring and performing a detailed check of the calibration.

► Back up all files.
► Delete files with patient data in the internal storage of the tablet.
► Remove the SD card from the tablet once it has been switched off and do not send it in with the tablet.
► Send the 3D L.A.S.A.R. Posture with its case to the manufacturer's service department.

7.3 Using the database in another 3D L.A.S.A.R. Posture

INFORMATION

The instructions in this section must be followed to use the database with patient data on another 3D L.A.S.A.R. Posture. If the “Change the 3D L.A.S.A.R.“ function is not available in the app user interface, the software must be updated by the manufacturer’s service department.



- Insert the SD card into the tablet while it is switched off.
- Switch on the tablet and start the app.
- ❶: Tap the menu icon to display the menu.
- ❷: In the menu, tap “Settings” (“Settings”).
- ❸: Swipe to scroll to the very bottom.
- ❹: Under “Change the 3D L.A.S.A.R.“ (“Change the 3D L.A.S.A.R.”), tap the “Scan new QR code“ (“Scan new QR code”) button.
- ❺: Scan the QR code lasered on the mounting plate of the mini-computer.
- ❻: Tap the “<” icon to switch to the live view.
- ❼: Wait until the connection between the product components has been established.

Afterwards, normal use is possible again.

8 Disposal

In some jurisdictions it is not permissible to dispose of the product with unsorted household waste. Improper disposal can be harmful to health and the environment. Observe the information provided by the responsible authorities in your country regarding return, collection and disposal procedures.

9 Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly.

9.1 Liability

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorised modification of the product.

9.2 CE conformity

The product meets the requirements of Regulation (EU) 2017/745 on medical devices. The CE declaration of conformity can be downloaded from the manufacturer's website.

The product meets the requirements of the RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic devices.

This device meets the requirements of the European Directive 2014/30/EU. The declaration of conformity was created by the manufacturer according to Annex II of the Directive.

This product meets the requirements of the European Directive 1999/5/EC for radio equipment and telecommunications terminal equipment. The conformity assessment was carried out by the manufacturer of the tablet and the manufacturer of the mini-PC.

9.3 Trademarks

All product names mentioned in this document are subject without restriction to the respective applicable trademark laws and are the property of the respective owners.

All brands, trade names or company names may be registered trademarks and are the property of the respective owners.

Should trademarks used in this document fail to be explicitly identified as such, this does not justify the conclusion that the denotation in question is free of third-party rights.

9.4 Local Legal Information

Legal information that applies **exclusively** to specific countries is written in the official language of the respective country of use in this chapter.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) This device may not cause harmful interference, and

2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/ TV technician for help.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Caution: Exposure to Radio Frequency Radiation.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada’s licence-exempt RSS(s)..

Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

(1) L'appareil ne doit pas produire de brouillage;

(2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Caution: Exposure to Radio Frequency Radiation.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population.

Caution: Federal law (USA) restricts this device to sale by or on the order of a practitioner licensed by law of the State in which he/she practices to use or order the use of the device.

10 Symbols Used

CE	Declaration of conformity according to the applicable European directives
SN YYYY WW NNN	Serial number of the device
	Legal manufacturer
	In some jurisdictions it is not permissible to dispose of these products with unsorted household waste. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the instructions of your national authority pertaining to return and collection.
	Please note the instructions for use
	Type B applied part
	Component at risk of electrostatic discharge
	Non-ionising radiation
MD	Medical device

11 Technical data

Supply voltage (mini PC)	110–240 V AC/50–60 Hz
Supply voltage (tablet battery charger)	110–240 V AC/50–60 Hz
Weight (3D L.A.S.A.R. Posture, complete in case)	20 kg
Case dimensions	280 x 630 x 520 mm
Operating temperature	15°–30° C
Dust and water resistance (applies only to the force measurement plate)	IP21 (protection against penetration of solid foreign objects with a diameter > 12.5 mm, protection against vertically dripping water)
Max. body weight	150 kg

Measuring tolerances	
Centre of pressure (COP) at the bottom end of the load line	The following tolerances refer to the camera view shown on the tablet. ± 1,5 mm (left-right alignment) ± 6 mm (depth alignment)
Relative body weight	± 3% of the measured value

Directives and manufacturer's declaration – electromagnetic interference		
The 743L500 3D L.A.S.A.R. Posture is designed for operation in an electromagnetic environment as specified below. The customer or user of the 743L500 3D L.A.S.A.R. Posture must ensure that the device is operated in such an environment.		
Interference measurements	**Compliance**	**Electromagnetic environment - directives**
HF emissions according to CIS-PR11	Group 1	The 743L500 3D L.A.S.A.R. Posture uses HF energy exclusively for its internal FUNCTIONING. Therefore its HF emissions are very low and interference with neighbouring electronic devices is unlikely.
HF emissions according to CIS-PR11	Class B	The 743L500 3D L.A.S.A.R. Posture is intended for use in all facilities including residential, and those connected directly to the PUBLIC SUPPLY NETWORK which also supplies buildings used as residences.
Emission of harmonics according to IEC 61000-3-2	Class D	
Emission of voltage fluctuations/flicker according to IEC 61000-3-3	Complies	

Directives and manufacturer's declaration – electromagnetic interference immunity			
The 743L500 3D L.A.S.A.R. Posture is intended for operation in the electromagnetic environment specified below. The customer or user of the 743L500 3D L.A.S.A.R. Posture must ensure that the device is operated in such an environment.			
INTERFERENCE IMMUNITY TESTS	**IEC 60601 test level**	**Compliance level**	**ELECTROMAGNETIC ENVIRONMENT – Directives**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±4 kV contact discharge ±4 kV air discharge A higher compliance level is not technically possible because of the components for patient safety available on the market.	Floors should be wood, concrete or ceramic tile. The relative humidity must be at least 30 %.
Electrical fast transient/bursts according to IEC 61000-4-4	± 2 kV for power lines ±1 kV for input and output lines	± 2 kV for power lines ±1 kV for input and output lines	The quality of the supply voltage should be equivalent to a typical commercial or hospital supply. The error message from the section "Platform not connected" may occur (see page 37). If this happens, complete the steps described in that section.
Surges according to IEC 61000-4-5	±1 kV voltage (line-to-line voltage) ±2 kV voltage (line-to-earth voltage)	±1 kV voltage (line-to-line voltage) ±2 kV voltage (line-to-earth voltage)	The quality of the supply voltage should be equivalent to a typical commercial or hospital supply.
Voltage drops, short interruptions and fluctuations of the supply voltage according to IEC 61000-4-11	< 5 % U_T (> 95 % drop of U_T) for ½ period 40 % U_T (60 % drop of U_T) for 5 periods 70 % U_T (30 % drop of U_T) for 25 periods < 5 % U_T (> 95 % drop of U_T) for 5 s	< 5 % U_T (> 95 % drop of U_T) for ½ period 40 % U_T (60 % drop of U_T) for 5 periods 70 % U_T (30 % drop of U_T) for 25 periods < 5 % U_T (> 95 % drop of U_T) for 5 s	The quality of the supply voltage should be equivalent to a typical commercial or hospital supply.
Magnetic field with supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at the mains frequency should be equivalent to the typical levels for commercial or hospital environments.
NOTE: U_T is the mains voltage before applying the test levels.			

Directives and manufacturer's declaration – electromagnetic interference immunity

The 743L500 3D L.A.S.A.R. Posture is intended for operation in the electromagnetic environment specified below. The customer or user of the 743L500 3D L.A.S.A.R. Posture must ensure that the device is operated in such an environment.

INTERFERENCE IMMUNITY TESTS	**IEC 60601 test level**	**Compliance level**	**ELECTROMAGNETIC ENVIRONMENT – Directives**
Conducted HF interference according to IEC 61000-4-6 Radiated HF interference according to IEC 61000-4-3	3 V_{eff} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile wireless equipment should not be used at a lesser distance from the 743L500 3D L.A.S.A.R. Posture, including the lines, than the recommended safety distance calculated using the equation applicable for the transmission frequency. **Recommended safety distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.4\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the nominal output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). The field strength of stationary radio transmitters at all frequencies according to an on-site investigation[a] should be less than the compliance level.[b] Interference is possible in the vicinity of devices that bear the following symbol. 

NOTE 1: The higher value applies at 80 MHz and 800 MHz.

NOTE 2: These directives may not be applicable in all cases. The propagation of electromagnetic factors is influenced by absorption and reflection by buildings, objects and people.

[a] The field strength of stationary transmitters such as base stations of radio telephones and mobile land radio equipment, amateur radio stations, AM and FM radio and television stations cannot be precisely determined theoretically in advance. To determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the 743L500 3D L.A.S.A.R. Posture is used exceeds the above compliance level, the 743L500 3D L.A.S.A.R. Posture should be monitored to confirm it is functioning as intended. If unusual performance characteristics are observed, additional measures may be required such as repositioning the 743L500 3D L.A.S.A.R. Posture or moving it to a different location.

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

Recommended safety distances between portable and mobile HF telecommunication equipment and the 743L500 3D L.A.S.A.R. Posture

The 743L500 3D L.A.S.A.R. Posture is designed for operation in an electromagnetic environment where HF interference is controlled. The customer or user of the 743L500 3D L.A.S.A.R. Posture can help prevent electromagnetic interference by maintaining the minimum distance – which depends on the output of the telecommunication device as specified below – between portable and mobile HF telecommunication equipment (transmitters) and the 743L500 3D L.A.S.A.R. Posture.

Nominal output of transmitter M	**Safety distance depending on the transmission frequency** M		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.4\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.76
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with no maximum nominal output specified in the table above, the recommended safety distance d in metres (m) can be determined using the equation in the respective column, where P stands for the maximum nominal output of the transmitter in watts (W) according to the transmitter manufacturer's information.

NOTE 1: The higher frequency range applies at 80 MHz and 800 MHz.

NOTE 2: These directives may not be applicable in all cases. The propagation of electromagnetic factors is influenced by absorption and reflection by buildings, objects and people.

Ottobock SE & Co. KGaA
Max-Näder-Straße 15 · 37115 Duderstadt · Germany
T +49 5527 848-0 · F +49 5527 848-3360
healthcare@ottobock.de · www.ottobock.com