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1 Introduction

1.1 The System

Otto Bock has further advanced the software for the fabrication of sockets for transtibial prostheses. With TT Design, prosthetists can make use of state-of-the-art application technology for individual socket fabrication, giving them an excellent alternative to conventional plaster techniques for individual, modern socket design.

The Otto Bock TT Design program offers prosthetists the possibility to create and process all data needed for a test- or interim socket at one go. Furthermore, they can use the software to select all prosthetic components needed for a transtibial prosthesis. After completion of prosthetic components selection, you just have to save the data and e-mail your order directly to the Otto Bock Service Fabrication. Based on your data we will fabricate your unique test socket out of ThermoLyn®. If ordered, the selected prosthetic components will be pre-assembled and sent to the prosthetist for trial fitting.

1.2 The TT Design Kit

The TT Design software is included in the TT Design kit that contains a range of clinical accessories designed to help you achieve consistent results. The accessories include:

1 743S20 Caliper Gauge to help mark critical features of the residual limb
2 743S30 Calibration Piece to calibrate the digital photographs
3 99B90=2 Residual Limb Socks (2 packs, 12 pieces) to give good contrast for the limb contours and to permit marking
4 743L234 Digital Camera
5 743S50 Black Photo Background
6 743S40 Alignment Device
7 623Z20 Velcro Fasteners for the calibration piece

1.3 The Basic Steps

Each design starts with an evaluation of the patient. A white sock is then put on the patient's residual limb and anatomical features are marked.

Digital photographs from the front and side are then taken to record the limb contours and the anatomical markings. A calibration piece is attached to the residual limb and appears in each digital photograph. This means that no manual measurements are required by the system. The entire evaluation and photography process takes place with the patient seated.

The TT Design software is able to rapidly produce a socket design from the digital photos. The software procedure involves:

- entering patient data and socket specification,
- reading and processing of the digital photos,
- assessment and, where needed, adjustment of the three dimensional socket model which the program calculates,
- selection of prosthetic components (optional), order quantity and accessories can be set,
- emailing of socket data to the Otto Bock Service Fabrication for production.

2 Installation

2.1 Computer Hardware – Recommended Specification

For 32-bit platforms:

- PC with a Pentium IV 650 / 3.4 GHz processor (x86) or faster
- 1 GB RAM

For 64-bit platforms:

- PC with an Intel Core2 (x64) or better
- 2 GB RAM

For 32-bit and 64-bit:

- At least 1 GB free hard drive space
- Graphics card with Open GL support
  - Minimum resolution 1024 x 764
  - 32 bit / 16.7 million colours
- CD-ROM drive or DVD-ROM drive
- Mouse and keyboard

2.2 Computer Hardware – Minimum Requirements

The minimum requirements for computer hardware for TT Design are as follows:

- PC with a Pentium III/ 1000 MHz processor (x86) or faster
- 512 MB RAM
- At least 1 GB free hard drive space
- Graphics card with Open GL support
  - Minimum resolution 1024 x 764
  - 32 bit / 16.7 million colours
- CD-ROM drive
- Mouse and keyboard

2.3 Software Specification

A Windows operating system is required for the application of TT Design.

The following 32-bit operating systems are supported:

- Microsoft Windows XP Professional SP2 or newer;
- Microsoft Windows XP Home Edition SP2 or newer;

- Microsoft Vista (all editions except Vista Starter);
- Microsoft Windows 7

The following 64-bit operating systems are supported:
- Microsoft Windows 7

Service pack 2 for Windows Vista or service pack 3 for Windows XP are strongly recommended.
In addition, a correctly configured e-mail program (e. g. Outlook, Outlook Express, Mozilla Thunderbird, etc.) and a web browser (Internet Explorer 8, Firefox 3.5) are required.
In the course of the installation process, the following components will be installed, unless they are already existing on the target system:
- Microsoft XML 6.1
- Microsoft.NET Framework 2.0
- Microsoft SQL Server 2005 Express SP3

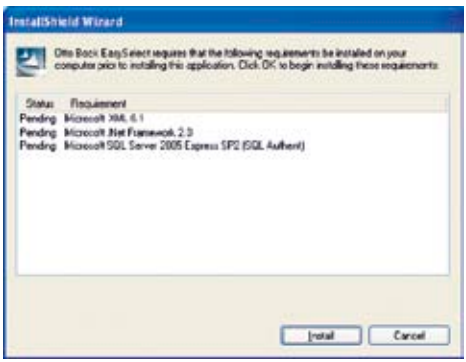
Before launching the installation, the installation program checks if you have sufficient free space on your hard drive and returns an error message if this is not the case. If this occurs, a corresponding amount of space must be freed up on the hard drive. All components required by the Otto Bock software will be automatically copied onto your hard drive by the installation program.

2.4 Installation

To run the installation program, start Windows and insert the Otto Bock TT Design CD into the CD-ROM drive. Installing the software requires administrative rights.
Installation by CD is normally launched automatically after the CD is inserted. If this is not the case, browse to the CD-ROM drive in Windows Explorer and start the program SETUP.EXE by double-clicking it.
After the installation program starts, the Setup Wizard presents a series of screens. Additional components are installed if required e.g. Microsoft.Net 2.0 Framework and Microsoft SQL Sever 2005 Express.

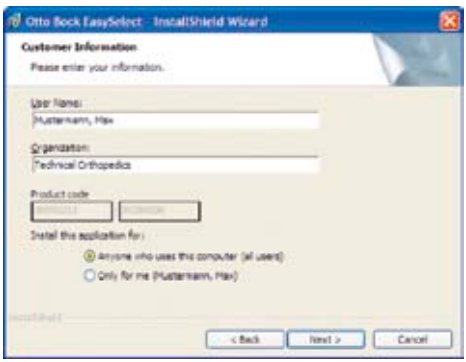
Notice:
For the function of the Otto Bock Data Station, Microsoft XML 6.1, Microsoft Net Framework 2.0 and Microsoft SQL Server 2005 SP3 Express are required in the so-called „Mixed Mode“.

- If Microsoft XML 6.1, Microsoft.Net Framework 2.0 and Microsoft SQL Server 2005 Express SP have not been installed yet, the following dialogue appears at the start of the installation process:



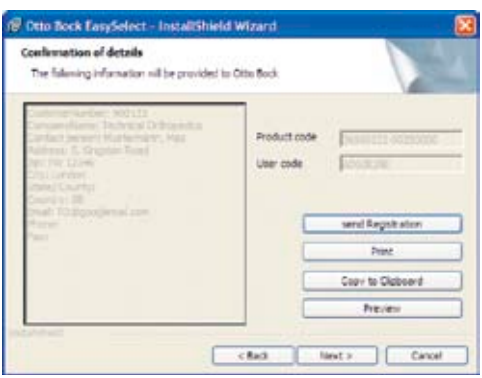
After clicking the “Install” button, follow the pre-defined installation process. This process can take some time.

- Read and agree to the license agreement
- Enter the name and company

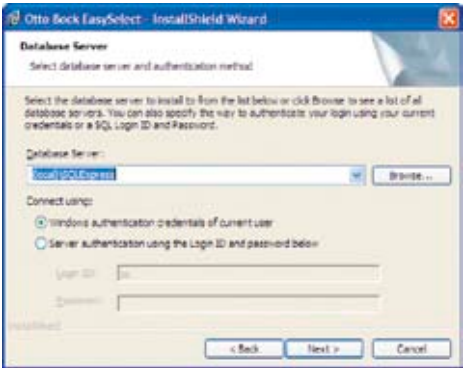


- Register the software with Otto Bock. You then receive product information from Otto Bock. However, it is possible to skip this step, although it is not recommended.

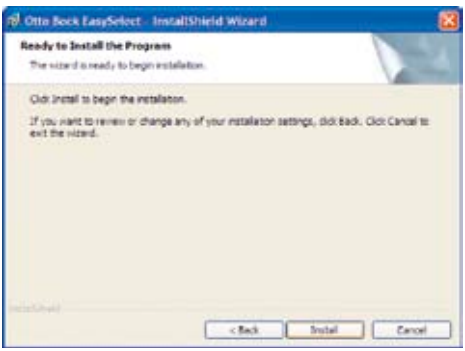
- A summary of the data that will be sent to Otto Bock when clicking the button “E-Mail Registration” will be shown. Another option is to click the “Print” button and fax your information to Otto Bock.



- After registration is complete or skipping the registration process this dialogue is shown. Select the “Next” button to continue.



The actual installation process is launched when the “Install” button is clicked.



At the end of the installation process, an icon for starting the Otto Bock software will be created on the Windows desktop.

Note:
The installation program creates an icon for the Otto Bock Data Station and not for TT Design! The Otto Bock Data Station is the platform for Otto Bock software.

2.5 Uninstalling

To uninstall the Otto Bock TT Design software, use the Windows uninstall function. Open the Control Panel on the start menu. Choose the "Software" function to display all installed software packages.
Select the entry "Otto Bock TT Design". Click the button "Add/Remove" to remove all components of TT Design from the hard drive. However, the patient data will not be deleted. This data is normally found under C:\Program Files\Microsoft SQL Server\MSSQL.1\MSSQL\Data\dmjobs.dat.mdf.

2.6 Starting the Program

The installation program adds an entry to the Windows start menu and the Windows desktop. The default location is "Start | Programs | Otto Bock | Otto Bock Data Station". Alternatively, you can double-click the Otto Bock Data Station icon on the desktop.
After launching the Otto Bock Data Station, please create a new patient, switch to the task type tab, and select the correct amputation height. You may also need to select the required options. For **TT Design**, you require the option **"Component Selection"**.
For more details, please see the online help file for the Otto Bock Data Station (also see section 3).

2.7 Closing the Program

You can close Otto Bock TT Design using one of four methods:

- "Exit" command on the "File" menu
- The "Close Window" button 
- Closing via the task bar
- Key combination Alt + F4.

3 Preparing the Patient

3.1 Preparing the Residual Limb

With the patient seated, assess the residual limb as normal by palpating the soft tissues and bony landmarks.

Next, pull the white sock over the residual limb and smooth out any wrinkles which tend to occur, especially at the distal end. The socks are suitable for all sizes of residual limb. With very small or conical residual limbs, small wrinkles often cannot be avoided. In such cases they can be retouched in the course of later photo processing. The 99B90=2 socks supplied in the TT Design kit have been found to give very consistent results and it is very important that only these socks are used.

Mark anatomical features on the sock using the red marker pen supplied in the TT Design kit. This pen has been found to be the most suitable for the TT Design system. It is very important that a red marker pen is used for marking the residual limb. These markings will later be used as a reference for areas which might need individual surface modification to prevent high pressures resulting in the socket. Of course, it is also possible to mark weight bearing surfaces. Marking of the peak and the border of the anatomical feature are most helpful.

Using the slot in the TT Design caliper (743S20), mark the mid of patellae ligamentum (MPL). For consistency, ensure that the rounded arm of the caliper is pressed firmly up against the distal edge of the patella. Check with the patient that the arm of the caliper is resting firmly in position before marking. Elongate the line laterally so that the position will also be visible on the lateral photo.

For the design of a supracondylar socket, the medial condylar level must be marked and the 'loaded' ML dimension above the femoral condyles must be measured. This is done by lowering the TT Design caliper (743S20) down on

to the femoral condyles whilst closing the arms of the the correct tissue compression is obtained. With the caliper in position, read the supracondylar ML measurement. Note this measurement directly on the patella, for example, to always have it available in the software. At the same time, the height of the ML measurement can be marked laterally on the residual limb through the slot in the caliper.

3.2 Attaching the Calibration Piece

Use the Velcro Fasteners to attach the 743S30 calibration piece to the anterior aspect of the tibia with the proximal 'foot' of the calibration piece lying over the tibial tubercle. The calibration piece should be attached to the front edge of the tibia and will therefore usually be slightly 'adducted'. For short residual limbs, the calibration piece may protrude beyond the distal end of the limb. The calibration piece is used to help you position the digital camera correctly when taking pictures.

Spread out the 743S50 black background cloth underneath the residual limb removing any wrinkles. The purpose of the black background is to get a good contrast between the residual limb and background in the digital pictures.

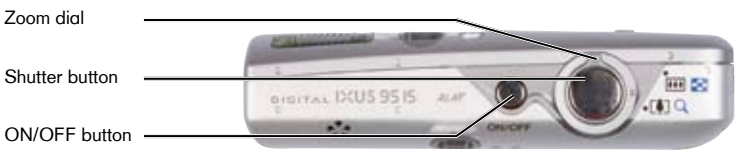
Make sure that the residual limb is not positioned into the background cloth, since this would change the contour.

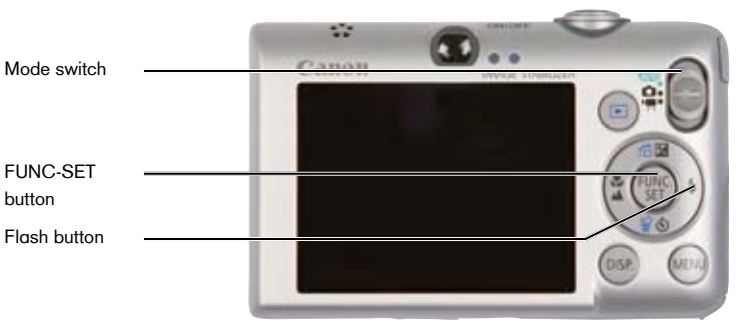
Set the patient's knee flexion angle to 15° with the aid of the 743S40 alignment device. Check that the patient is sitting with thighs parallel so the femur and tibia are in one line when viewed from the front. There is often a tendency for an amputee to sit with thighs slightly apart and with a rotated hip joint giving an externally rotated residual limb. The patient should remain in this correct position while both digital pictures are taken.

4 Using the Digital Camera

4.1 Basic Functions

Please read the camera manual and take some test photos before using the camera with a TT Design patient.





Note the following points when working with the digital camera:

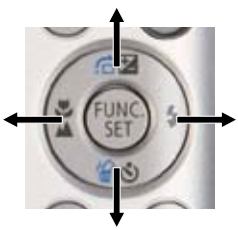
Before taking a photo:

- Before using the camera, ensure that the memory card has been inserted.
- Switch on the camera by pressing the ON/OFF button and make sure that the mode switch is set to shooting mode.

- The camera should be in the *Manual*-Mode:
- To verify this, press the FUNC-SET button once and use the arrow keys to set Manual. Press the FUNC-SET button once again to exit the menu. Make sure that the red eye reduction is turned off (**no** eye symbol in the top right-hand corner of the display), and that the flash is activated (flash symbol in the top right-hand corner of the display); if this is not the case, turn on the flash by pressing the button with the flash symbol. Furthermore, no macro or wide angle setting should be activated. If activated, turn it off by pressing the macro switch (flower symbol).
- Set to maximum optic zoom using the zoom dial.

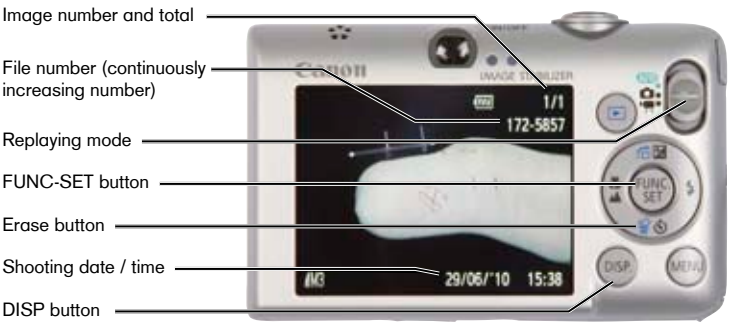
Taking photos

- Push the *Shutter* button down halfway. Position the camera so that the crosshair inside the viewfinder (auto focus field) points to the patient's residual limb.
- When the upper indicator light turns orange, the auto focusing process is finished (two beeps sound).
- If the lower indicator light blinks yellow, the camera is too close to the subject to focus. Note that the camera should be around 1 metre from the patient's limb.
- Press the *Shutter* button fully. You will hear the shutter sound when the shot is complete. Do not move the camera until you hear this sound. The upper indicator blinks green while the image is written onto the memory card. Every photo must be taken with the flash activated.



After taking a photo

- The digital photos can be checked on the LCD display on the back of the camera by setting the mode switch to *Replaying* Mode.
- The display indicates a file number (a continuously increasing number), date and time the picture was taken, and image number together with total number of pictures on the memory card. If this is not the case, you can activate the display by pressing the DISP button.



- Photos that are not needed can be deleted using the erase button either immediately or later, once the photos have been transmitted to the computer.

Transmitting the photos from the camera to the computer

There are two ways:

A) Removal of the memory card

B) With the USB interface cable

A) Press the memory card to release the locking mechanism; now you can remove the memory card from the camera. Insert the SD memory card into the corresponding memory card reader on your computer. You can now use Windows Explorer to transmit and save the photos in a file folder.

B) Plug the USB interface cable to your camera and connect it with your computer. The camera is recognized as a file storage device. If not, then please install the supplied camera software on your computer. You can now use Windows Explorer to save the photos in a file folder so they are available in the program for socket design.

4.2 Taking Photos of the Residual Limb

Essential camera adjustments:

- Resolution: 1600×1200 (M2)
- Red eye reduction: *off*
- Flash: *on*
- Macro or wide angle: *off*
- Manual mode

If necessary, the resolution M2 (1600 x 1200 pixels) must be set in the function menu. Use the cursor keys for the following settings: flash *on*, red eye reduction *off*, wide angle or *Macro off* (see section: Before taking a photo, page 32).

Taking photos

For best accuracy, it is important that the digital camera is at least 1 metre away from the residual limb when photos are taken. With the camera at the maximum zoom setting, an average residual limb should fill the viewfinder with a camera distance of 1 to 1.5 metres. It is essential that the entire residual limb is visible, up to around 10 centimetres proximal of the patella, as well as the entire calibration piece. The black background cloth 743S50 must be in position behind the limb. It is very important that the recommended residual limb flexion of 15° is maintained for both, the anterior and the lateral photo.
The red and yellow 'fins' on the calibration piece are used to ensure correct camera position. By simply positioning the camera so **neither the red nor the yellow** sides of the 'fins' are seen will ensure that the camera position is correct.
This gives a direction of view from the camera at right angles to the calibration piece.

Tip!
Focus on the calibration piece with your eye and hold your head so that you can see none of the 'fins' color; than simply put the camera's viewfinder in front of your eye and take the photo. This is quicker and more precise than orienting the camera using the display.

Using the guidelines above, take one anterior and one lateral photo of the residual limb, ensuring correct camera orientation and 15° residual limb flexion. It is very important that the calibration piece is not moved in between taking photos. It is also very important that the sock remains in the same position used when making the pen markings. You may also take several photos and then chose the two best digital photos.

Position the mode switch of the camera at *Replaying* Mode and check the photos. If necessary, take further photos.

Attention: It is very important that the calibration piece is not moved in between taking photos. If the calibration piece has been moved, both photos must be taken once again.

Wrong – too low, neon yellow surface visible

Wrong – too high, neon red surface visible

Correct – only white anterior ede visible

5 Online Help and Program Version

5.1. Advice for Using Online Help

After launching the Otto Bock Data Station, the integrated help file supports you during your tasks. You will find it in the menu "Help | Otto Bock Data Station Help F1". It also contains the online help for TT Design.

5.2 Determining the Program Version

You can determine the program version using the menu "Help | About… "This opens a window that contains information regarding the version of the Otto Bock Data Station and TT Design you have installed.
You should have this information available whenever you contact one of our support representatives.