FIOR & GENTZ

e-Cast Digital Casting Aid

EN

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1. Information

These instructions for use are addressed to qualified specialists in orthopaedic technology and do not contain any notes about dangers which are obvious to them. To achieve maximum safety, please instruct the patient and/or care team in the use and maintenance of the product.

2. Safety Instructions

2.1 Classification of the Safety Instructions

⚠ **DANGER**	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
⚠ **WARNING**	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
⚠ **CAUTION**	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
NOTICE	Important information about a possible situation which, if not avoided, leads to damage of the product.

2.2 All Instructions for a Safe Handling of the **e-Cast**

⚠ WARNING

Risk of Injury Due to Improper Handling of the Operator Device
Use the operator device as described in these instructions for use. The operator device is a sensitive electronic device with an integrated lithium-ion battery. Pay particular attention to:
- avoiding contact with strong heat or fire,
- not charging the operator device under direct sunlight, and
- not opening the operator device.

NOTICE

Failure of Function Due to Improper Handling
Do not expose the operator device to high humidity and do not immerse it in water.

NOTICE

Failure of Function Due to Improper Replacing of the Batteries
Replace the batteries of the sensors properly and as described in these instructions for use and use the battery type specified in these instructions for use.

NOTICE

Failure of Function Due to Missing O-Ring
Reinsert the O-ring before closing the sensor as described in these instructions for use, as otherwise water may enter the sensor.

NOTICE

Failure of Function Due to Improper Shock Loads
Handle the sensors with care and do not expose them to great shocks, e.g. by falling down or hammer blows.

NOTICE

Unsuitable Negative Cast Due to Improper Handling
The operator device must only be handled by qualified specialists in orthopaedic technology.

NOTICE

Unsuitable Negative Cast Due to Loosely Attached Sensors
Make sure that the sensors are attached firmly the whole time while making the negative cast.

NOTICE

Unsuitable Negative Cast Due to Continuing of the Measurement Without Sensors
Always start a new measurement once the sensors have been removed from the negative cast.

NOTICE

Unsuitable Negative Cast Due to Incorrect Calibration
Calibrate the sensors as described in these instructions for use and contact Technical Support if needed.
Note the following for the calibration:
- Calibrate the sensors once a year and after each battery replacement.
- Use a stable, plain surface (e.g. a suitable table) to calibrate the sensors.
- Remove casting residues and clean the sensors with a damp cloth to avoid uneven surfaces.
- Hold the sensor at its edges during calibration so that the sensor surface is not pushed in too much.

NOTICE

Damages to Operator Device, Sensors and Batteries Due to Improper Handling
Use the operator device and the sensors as described in these instructions for use. Pay particular attention to only expose them to:
- operating temperatures between +5 and +45°C and
- storage temperatures between -20 and +45°C.

3. Intended Use

The **e-Cast** is used for checking the joint angles. With an operator device you can control the leg position while making the negative cast, which makes it possible to cast professionally and correct the position easily with the patient lying or standing. The **e-Cast** must only be handled by a qualified specialist in orthopaedic technology.

4. Functioning of the e-Cast

The **e-Cast** was developed so that the joint angles can be checked and corrected while making the negative cast. The *e* stands for *electronic*. Depending on the orthosis type, you need two or three sensors for each measurement, which have to be attached to the patient's foot, lower leg and thigh. The **e-Cast** operator device saves the ideal position for the negative cast, thus helping to control the patient's leg position while making the cast.

5. Scope of Delivery WE3400

The **e-Cast** is delivered in a case. The case includes the following parts (fig. 1):

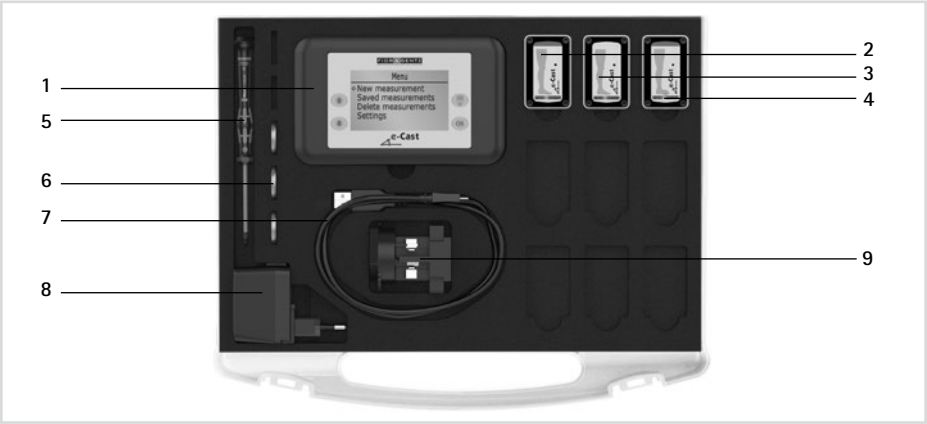

fig. 1

Item	Article number	Description
1	ET3400-T	operator device
2	ET3410-WE	sensor for the upper leg area
3	ET3420-WE	sensor for the lower leg area
4	ET3430-WE	sensor for the foot piece
5	WZ2067-T08	screwdriver, hexalobular socket, T8 x 60mm
6	ET0830-2450	3 x batteries for **e-Cast** sensors*
7	ET0710	charging cable
8-9	ET0780-01	power supply unit incl. primary adapters for Europa, USA/Japan, UK, Australia
w/o fig.	KL4200	glue dots for the fixation of the sensors, 48 pieces

Item	Article number	Description
w/o fig.	KL4601	washers for marking the mechanical pivot points, self-adhesive, 28 pieces

* When reordering the article, only one battery is delivered as a sales unit.

6. Putting the e-Cast Operator Device into Operation

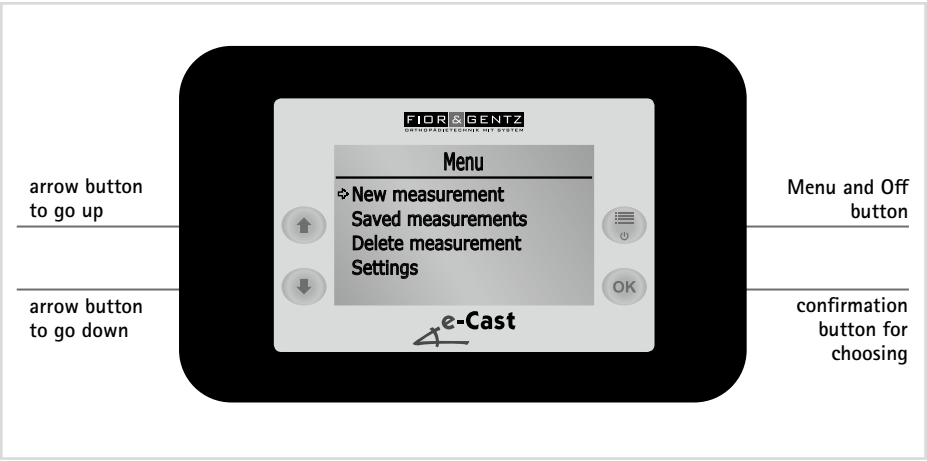

fig. 2

1 The operator device is delivered with a rechargeable battery. If the battery is low, first charge the operator device by using the delivered cable. Afterwards, it can immediately be put into operation.
2 Briefly press the Menu button to switch on the device. You can now see these four menu items on the display: **New measurement**, **Saved measurements**, **Delete measurements** and **Settings**.
3 If you do not use the operator device or the connected sensors for more than 20 minutes, the operator device switches off automatically. You can also switch off the device by pressing the Menu/Off button for two seconds.

7. e-Cast Sensors

7.1 Sensor Types

sensor for the upper leg area, red

sensor for the lower leg area, yellow

sensor for the foot area, green

fig. 3

A sensor set consists of three sensors which are marked with different colours (after the traffic light principle) and are attached to a certain spot on the leg. The red sensor has to be attached to the thigh, the yellow one to the lower leg and the green one to the foot (fig. 3).

7.2 Activating the Sensors

The sensors can be activated by slightly shaking them. You can see from the blinking that they are activated. If they are not connected to the switched on operator device, they switch off automatically within one minute. If they are connected to the switched on operator device, they stay activated as long as the operator device is switched on.

7.3 Storing Sensors During Transport

When transporting the sensors (e.g. in a car), it is possible that they get activated by the shocks. To save battery power, you should put the sensors in sleep mode during transport. There are two ways to put the sensors in sleep mode:

- Place the case in such a way that the sensors in it are upside down.
- Lay down the case in such a way that the sensors in it are face down, meaning the printed side is facing down.

You can also find information on storing sensors on the sticker in your **e-Cast** case.

7.4 Attaching the Sensors

Stick one of the delivered glue dots to each of the three sensors. Attach the sensors to the corresponding spot on the leg which is wrapped in compression film (fig. 4). Make sure that the sensors are attached firmly and that they are not upside down. If you have several sensor sets, pay attention to always use a red, a yellow and a green sensor for each measurement and not several with the same colour. If you want to produce an AFO, you only need the sensor for the lower leg (yellow) and the sensor for the foot (green). If you want to produce a KO, you only need the sensor for the thigh (red) and the sensor for the lower leg (yellow). For more information about the production technique for making a cast, refer to the online tutorials on the FIOR & GENTZ website.

fig. 4

7.5 Replacing the Batteries

1 You can replace the batteries of the sensors yourself when they are empty. To do so, first clean the sensor with a damp cloth or under running water. Dry it afterwards.
2 Unscrew the four countersunk flat head screws on the front of the sensor with the delivered T8 hexalobular screwdriver.
3 Open the sensor, e.g. by inserting a screwdriver into the gap under the sensor and levering the cover up.
4 Carefully take out the printed circuit board and turn it around. The battery is on the other side of the printed circuit board and can be pushed out gently with a narrow object.
5 Insert a new battery of the type **CR2450**.
6 Carefully remove the plaster which has accumulated between cover, housing and O-ring with a dry cloth.
7 When closing the sensor, make sure that the O-ring is properly placed before putting the cover back on and screwing it onto the sensor.

The battery replacement was successful if the sensor blinks after shaking it slightly.

8. Main Menu of the e-Cast Operator Device

In the main menu of the operator device you can start a new measurement, view a saved measurement, delete measurements or access the settings. To go to the main menu, press the Menu button.

You now see the following menu items on the display (fig. 5):

- New measurement
- Saved measurements
- Delete measurements
- Settings

To exit a menu item, press the Menu button. It then functions as Back button.

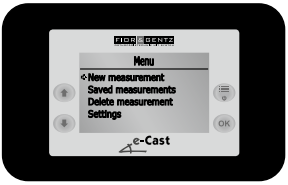

fig. 5

8.1 New measurement

Here, you can start a new measurement. To do so, you need the operator device and a sensor set. After having attached the sensors required for the orthosis type to the patient's leg (see paragraph 7.4), you can start with the measurement. Follow the steps listed below:

1 Select the menu item **New measurement**.

2 Now, you are in the area **Select patient data** (fig. 6) and have two options:

- Create new patient data: Select **<New>** and decide which orthosis type you would like to produce. You can choose between KAFO, AFO and KO as well as between the left and right leg. Then, enter the patient's initials (two letters) and confirm by pressing **Save**.
- Use previously created patient data: If you choose from previously created patient data, you can decide whether you would like to **Use connected sensors** or **Search for new sensors**. Then, enter the patient's initials (two letters) and confirm by pressing **Save**.

fig. 6

3 The operator device searches for the sensors. If you have several sensor sets, make sure that only one of the sensor sets is activated. Sensors which are not needed switch themselves off after one minute at the latest when they are not moved. The operator device then connects itself to the active sensors and you can start the measurement.

fig. 7

4 Bring the patient's leg in a horizontal position with the toes pointing upwards. The foot should be in the desired external rotation needed for the later orthosis (fig. 7). This position has to be kept for some seconds until you can see **Press OK** on the display. Press **OK**. If your patient has a tremor, the operator device is going to recognise it. It then calculates an average value and displays **Recognised tremor**. Confirm with **OK**.

5 Have the patient stand in their individual normal posture (fig. 8). Make sure that the position is the correct one because this is the one saved by the operator device and therefore it is decisive for the negative cast. The patient has to stay in this position for some seconds without moving until **Press OK** appears again. If there is a tremor, the operator device is going to recognise it here, too.

6 The position is now set. If you want to change this position, press **Back**. If you want to keep this position, press **Continue**. The patient can sit or lay down again. First, you will see the position of the ankle. With the arrows you can switch between the display of the ankle and the knee position (fig. 9–10). A dot on the bar indicates in which direction you have to move ankle or knee to reach the correct position. When the dot is in the middle, you have reached the correct position (fig. 10). For setting options for the display of the correct position also see paragraph 8.4.1 and 8.4.2.

fig. 8

fig. 9

This is how you proceed at every measurement. If you want to save several measurements at the same time in the operator device, you need a correspondent number of sensor sets.

8.2 Saved measurements

Once you have performed a measurement, the last measurement is shown when you switch on the operator device the next time. In the menu item **Saved measurements**, you can also see the last measurement or choose the desired one from various measurements, if existing (fig. 11). However, to continue a measurement, the sensors have to remain firmly attached and must not be removed in the meantime.

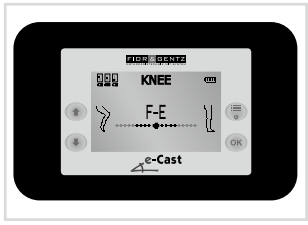

fig. 10

8.3 Delete measurements

With this menu item, you have the possibility to delete old measurements (fig. 12). To do so, select the measurement you want to delete and confirm by pressing **Yes**.

fig. 11

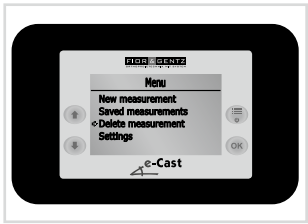

fig. 12

8.4 Settings

8.4.1 Display options

When displaying the correct position, you can always see the dorsiflexion and plantar flexion of the ankle and the flexion and extension of the knee. In the menu item **Display options** (fig. 13), you can choose whether you would also like to see the pronation-supination of the ankle and the genu varum/genu valgum of the knee. To do so, place or remove the ticks according to your preference and press **Save**.

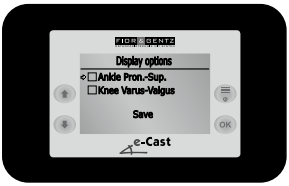

fig. 13

At delivery status, the display options **Ankle Pron.–Sup.** and **Knee Varus–Valgus** are deactivated to facilitate the initial handling. Decisive for the later functionality of the orthosis are the dorsiflexion and plantar flexion of the ankle and the extension and flexion of the knee.

8.4.2 Sound options

In this menu item, you can select whether there should be a beep when the dot on the bar gets closer to the saved position. If the actual position differs too much from the saved one, no beep is emitted. If the dot is in the middle right from the beginning, meaning you have found the correct position right away, there is also no beep. You have four possibilities for the sound setting:

- A beep is always emitted when you get closer to the correct position.
- A beep is only emitted when you get closer to the correct flexion-extension and dorsiflexion-plantar flexion.
- A beep is only emitted when you get closer to the correct pronation-supination and genu varum-genu valgum.
- There is never any beep emitted.

To do so, place or remove the ticks according to your preference and press **Save** (fig. 14).

fig. 14

8.4.3 Display brightness

You can set the display brightness by choosing between values from 0 to 5 with the Arrow buttons (fig. 15). At 0, the display light is switched off, whereas 5 is the maximum brightness level. Press **OK** to save. The lower you set the display brightness, the longer is the rechargeable battery's life.

fig. 15

8.4.4 Language

You can set the language of the operator device in the menu item **Language** (fig. 16). You can select between German and English. At delivery, the German language is preset. Choose the desired language with the arrow and confirm by pressing **OK**.

fig. 16

8.4.5 Device info

Here, you can see the device version of the operator device in order to check if your operator device is up to date. To do so, go to "Software Updates" (see QR code, fig. 24) in the download section on the FIOR & GENTZ website and compare your device version with the latest one.

The versions of the last three sensors that were connected to the operator device are also shown in this menu item (fig. 17).

fig. 17

8.4.6 Update sensors

When updating the operator device (see paragraph 11), the sensor update is downloaded simultaneously, if there is an update. In the menu item **Update sensors**, you can then see if there is an update. Here, you can update each active sensor separately. If you have activated several sensors, the operator device can show up to eight sensors. If there is an update available, you can select an item, e.g. **Update yellow sensor**. If there is no update, this menu item cannot be selected (fig. 18). Always update all three sensors of a sensor set if there is an update available.

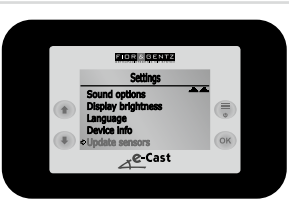

fig. 18

8.4.7 Calibrate sensors

In order to ensure that your measurements with the **e-Cast** are as exact as possible and to minimise any deviations of these measurements, you should calibrate all sensors once a year and after each battery replacement. To do so, choose **Settings** in the menu of the operator device and subsequently the menu item **Calibrate sensors** (fig. 19). Here, you can calibrate each active sensor separately. If you have activated several sensors, the operator device can show up to eight sensors.

Additionally, the display shows when the active sensors were last calibrated (e.g. **3 month(s) ago**) or if a sensor's calibration is recommended (fig. 20). The display also shows a message if the sensor needs to be updated first before it can be calibrated.

Follow the steps of the operator device to calibrate a sensor.

After you have finished calibration, you can repeat it with the other sensors by activating (shaking) and choosing the required sensor in the menu item **Calibrate sensors.**

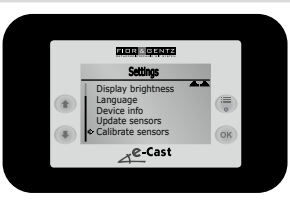

fig. 19

fig. 20

9. Indication of Rechargeable Battery's/Battery's State of Charge

9.1 Rechargeable Battery's State of Charge of the Operator Device

At the operator device you can see the rechargeable battery's state of charge at the top right when displaying the correct ankle and knee position (fig. 21). It indicates the state of the rechargeable battery of the operator device. The rechargeable battery lasts about 15 hours at maximum display brightness. To extend the rechargeable battery's life, you can lower the display brightness.

fig. 21

9.2 Battery's State of Charge of the Sensors

At the operator device you can see the battery's state of charge at the top left when displaying the correct ankle and knee position. It indicates the state of the batteries of the three connected sensors (fig. 22). You can only see the battery's state of charge when the sensors are connected and activated. If the sensors are not connected or not activated, there are three crosses displayed (fig. 23). If the batteries are almost empty, they blink on the display. The lifespan of the batteries is about 150 hours.

fig. 22

To prevent the sensors from activating during transport, you can put them in sleep mode. To do so, store the sensors in the case in such a way that they are either upside down or face down (see also paragraph 7.3).

fig. 23

10. Charging the e-Cast Operator Device

The operator device has a rechargeable battery. To charge the operator device, connect it to the delivered cable and adapter.

11. Updating the e-Cast Operator Device

When a new update is available, the operator device can be updated with the delivered cable via "Software Updates" (see QR code, fig. 24) in the download section on the FIOR & GENTZ website (for the sensors update see paragraph 8.4.6). We recommend to check if your operator device is still up to date at regular intervals and to update it if necessary. In the menu item **Device info**, you can see which version is on your operator device. To update the operator device, proceed as follows:

fig. 24

1 Download the update and open the file.
2 Connect the operator device to your computer using the cable.
3 You must neither turn off the device nor remove the cable during the updating process.
4 Turn on the operator device.
5 If an update is available, you can see the message "Currently connected to ET3400-T version XXX. Device can be updated to version XXX.". If your device is up to date, it says "Currently connected to ET3400-T version XXX. Device is up to date.".

12. Dirt Removal from the e-Cast Operator Device

To clean the operator device, use a damp cloth. Do not hold the device under running water. We recommend wrapping the operator device in cling film while making the cast to keep it dry and clean.

13. Dirt Removal from the e-Cast Sensors

The sensors can be cleaned with a damp cloth or under running water. However, do not immerse them in a water bath. It is also possible to disinfect the sensors.

14. Advice on Production Techniques

For information on how to proceed when using the **e-Cast** also see the fold-out poster (see QR code, fig. 25) included in the **e-Cast** case.

You will find information on the general production technique for making a negative cast (see QR code, fig. 26) on the FIOR & GENTZ website in the section "Online Tutorials".

fig. 25

fig. 26

15. Short Guide for a New Measurement

1 Go to the menu item **New measurement** and choose between new or previously created patient data. In the first case, decide which orthosis type (KAFO, AFO or KO) you would like to produce for which leg (left or right). In the latter case, decide if you want to **Use connected sensors** or **Search for new sensors**.
2 Save the patient's initials and wait until the operator device is connected with the sensors.
3 Bring the patient's leg in a horizontal position with the toes pointing upwards and the foot being in the desired external rotation. Press **OK**.
4 Have the patient stand in their individual normal posture and press **OK**.
5 Confirm again by pressing **Continue** to start with the casting. You will then see the position of the ankle and the knee. With the Arrow buttons you can switch between the ankle and the knee display. When the dot is in the middle, you have reached the correct position.

16. Signs and Symbols

Do not dispose of electronic devices with household waste. Dispose of the device and accessories at official delivery points for electronic devices.

temperature limit values for storage/for transportation

17. Disposal

The product must not be disposed of with the residual waste (fig. 27). Dispose of the device and accessories at official delivery points for electronic devices.

fig. 27

18. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply.

Since we are not able to check the compliance of handling and dealing with batteries, we cannot assume any liability for any damages or costs caused by batteries.

The information in these instructions for use is valid at the date of printing. The contained product information serves as guidelines. Subject to technical modifications.

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