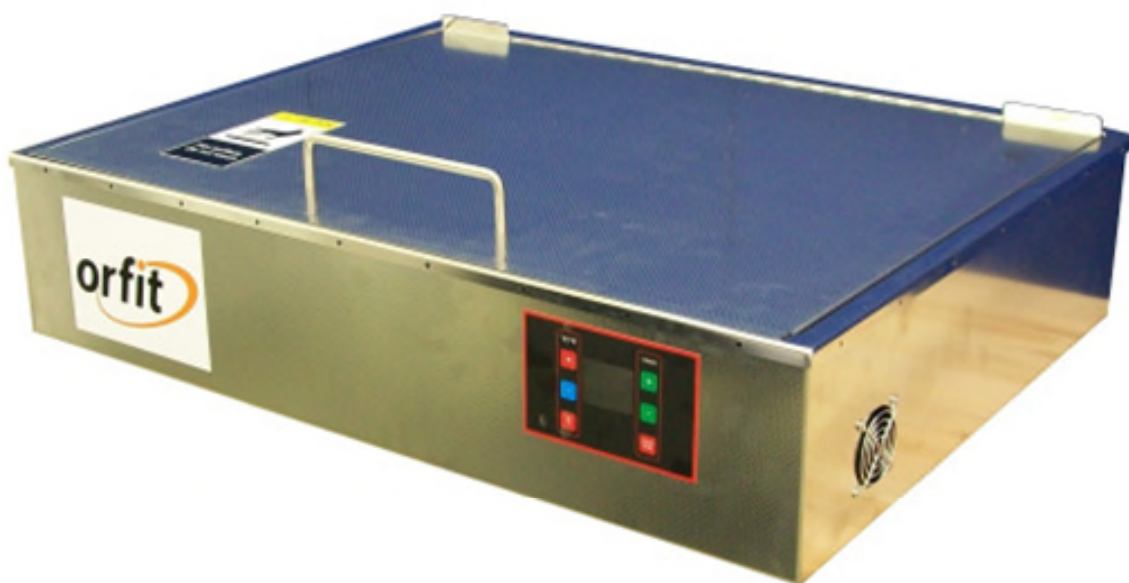


WATER BATH



Art. No. **35097/115/1400 (115V)**
35097/230/1400 (230V)

User information: Water bath Teflon mesh

Included in the 35097 water bath package is a Teflon mesh to be used when applying bolus material and other low temperature thermoplastic material products.

Place the Teflon mesh in between the material and the metal surfaces of the water bath grid to prevent both sticking to one another.

It is not recommended to use the Teflon mesh with radiotherapy masks.
The Teflon mesh floats and would thus prevent RT masks from submerging.
This in turn would prevent the thermoplastic material to heat up uniformly.

When activating Orfilight products, it is recommended to place both the thermoplastic material and the Teflon mesh underneath the metal grid to prevent floating and inhomogeneous activation of the thermoplastic sheet. Correct activation ensures that the RT mask or the thermoplastic material will become perfectly mouldable before applying it on the patient.

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1. Meaning of symbols



WARNING!

Here you will find important information and instructions which, if disregarded, create a risk of injury and accident.



ATTENTION!

Here you will find important information on inappropriate or unsafe handling of your appliance that could cause technical damage.



ADVICE

Here you will find practical advice and other useful information.

2. Operating instructions

2.1 Remarks to these operating instructions

- These operating instructions contain important information on the water baths art. Nos. 35097/115/1400 (115 V) and 35097/230/1400 (230 V) and should be kept near the appliance.
- The operating instructions help avoid dangers, as well as repair costs and down times, which, among other things, increases the reliability and life of the appliance in question.
- The water bath bears the CE mark in accordance with EC Council Directive 93/42/EEC concerning medical devices and satisfies the basic requirements of this Directive.
- Read the operating instructions carefully before first use of the water bath!
- This document, or extracts from it, may not be reproduced without the written consent of the manufacturer or his dealer.
- Errors and changes reserved.

3. Normal use

The water bath is only intended for the warming up of thermoplastic material for medical use.



- **This water bath is not suitable for direct heating without using water.**
- **The warming up of food and drinks, as well as other pharmaceutical and medical products, is not allowed and constitutes improper use.**
- **Direct application on the patient is not allowed.**

4. Description

- The water baths consist of tungsten steel with a contents capacity of ± 30 l.
- The water baths are available in 2 voltage versions:
Version 115 V/1400W – Art. No. 35097/115/1400
Version 230 V/1800W – Art. No. 35097/230/1400
- This water bath uses a splashproof plastic-coated keypad.

- The on/off power switch is located on the rear of the unit.
- Microprocessor technology allows the target temperature to be set, displayed and stored via the graphic OLED display.
- The temperature regulator automatically adapts the heat supply to the requirements of the bath and keeps the temperature constant.
- The water bath complies with the relevant regulations of European directives for the product.
- The model is equipped with a side tap for emptying.

5. Delivery

- Prior to shipment, the water baths are subjected to a thorough safety-related and functional quality control and are carefully packed. Nevertheless it is advisable to check that all the contents are present immediately after taking delivery (see delivery note).
- Please check the packaging for transport damage after taking delivery. If necessary, document and report this immediately to your specialist dealer.
- Products may only be returned in undamaged cardboard packaging – primarily the original cardboard packaging.

6. Transport and storage

6.1 Ambient conditions:

Transport/storage: -10 ... +60 °C
 5 ... 80% humidity without condensation at an atmospheric pressure of
 860 ... 1060 hPa.

- Following transport at temperatures below freezing, the unit must be acclimatised and kept at room temperature for up to six hours prior to being used.



If the unit has not been acclimatised, components such as electronics may be affected.

- The unit may only be transported in a padded box that offers adequate protection.
- Permissible ambient conditions for transport, storage and operation can be found in the technical data.
- The maximum stacking height is 4 units on top of each other.
-

7. Safety instructions

Please read these instructions for use carefully before using the water baths.

- Avoid knocks to the housing, vibrations, damage to the control panel (keys, display) or abnormal levels of dirt.
- Make sure that the product is checked at regular intervals determined by operating conditions to make sure it is in good working order.
- The proper condition of the mandatory, warning, prohibitory and safety signs should be checked regularly, yet at least every 2 years.

- Make sure that the network has a low impedance, to avoid adversely affecting units operated on the same network.
- The unit has been designed for use in a controlled electromagnetic environment. This means transmitting devices such as mobile phones should not be used in the immediate vicinity of such environments.
- Other devices with components that are sensitive to magnetic fields, such as monitors, could be affected by magnetic radiation. We recommend observing a minimum distance of 1 m.
- Do not store in an aggressive atmosphere. Keep out of direct sunlight.

8. Responsibility of the operator

This product guarantees safe operation if installed, operated and maintained in accordance with general safety rules.

This section explains the potential dangers that can arise in connection with the operation of the water bath and lists the most important safety precautions to rule out such dangers wherever possible.

- The operator is responsible for the qualifications of the operating staff.
- Make sure that those who work with the water baths have been instructed in the relevant tasks.
- Operators are to receive regular instruction on the dangers inherent in their activities, as well as the measures to be taken to avert such dangers.
- Make sure that all those entrusted with operation, maintenance and installation have read and understood the safety information as well as the operating instructions.

9. Pictorial symbols on the name plate



Attention, read instructions for use

IP22

Degree of protection



Protection class I (protective conductor)



Identification in accordance with the Electrical and Electronic Equipment Act
(*Elektro- und Elektronikgerätegesetz – ElektroG*)
Old units must not be disposed of with household waste!



Year of manufacture



The CE mark indicates that this product satisfies the relevant requirements of EC directives

REF

Order number

10. Preparation

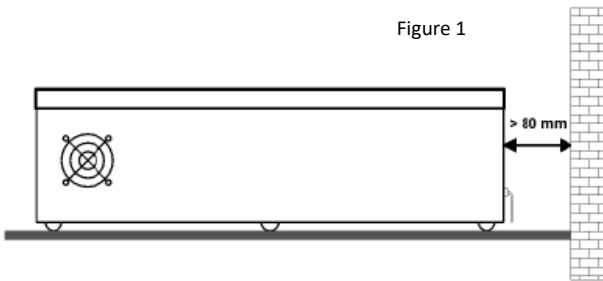
10.1 Positioning



CAUTION:

- The unit is not suitable for use in an explosive environment!

Figure 1



- Place the water bath on a level surface with sufficient load-bearing capacity.
- Maintain a distance of at least 40 mm between the back of the oven and the wall. Make sure the wall is not made of flammable material.
- Maintain a distance of at least 80mm between the ventilator at the side of the oven and the wall.
- Maintain a distance of at least 1,5m between the water bath and the patient.

10.2 Heating medium



Caution:

- Poor water quality can cause a risk of corrosion in the bath. The water quality (tap water) depends on local conditions.



We recommend using distilled water and de-ionised water rich in oxygen.

Corrosion is caused by rust in the water and the air. By using distilled water, corrosion will be minimized. Modern ion exchange systems should be used that do not use salt back-flushing to regenerate the ion exchange cartridges.

For the long-term reliability of water baths it is important that oxygen-enriched water is used.

Ions and minerals in the water can cause corrosion of stainless steel, since they attack the protective layer of chrome oxide. If this layer is damaged, the oxygen present in the water can regenerate the layer of oxide.

If the water bath has not been used for a long time or the water has been boiled, we recommend replacing the water.

Clean the water bath weekly. This will prevent corrosion of the stainless steel. A suitable cleaning agent can be purchased from your Orfit Industries' distributor with the following article number: 35097/RE .



Do not use flammable heating mediums!



The manufacturer or his dealer will not accept any liability if an unsuitable heating medium is used!

11. Start-up

The unit must not be started if



- the cable or plug is damaged,
- the unit has fallen over,
- the unit displays obvious safety defects.
- Avoid the plug and switch unit getting wet.
- There is a serious threat of death if objects are inserted into the unit through openings in the casing, such as cooling slots, discharge openings and others.



- Make sure the correct voltage is being used as indicated on the name plate of the water bath. Always switch off the water bath first before plugging in !

Disconnect the unit from the mains:



- before cleaning and maintaining the unit,
- before emptying the tank,
- during a period of long absence.

11.1 Control panel - front

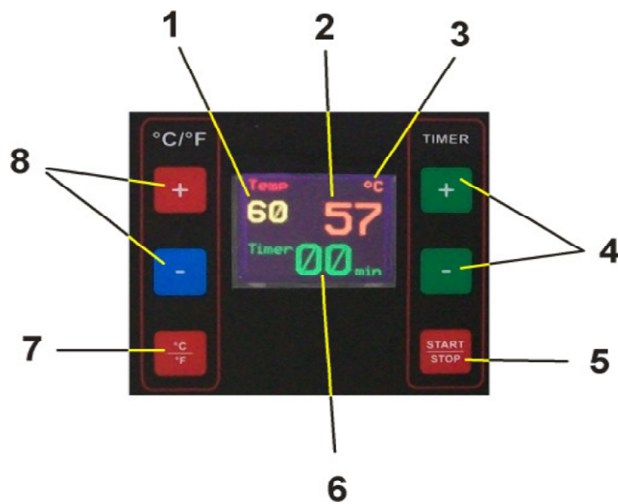


Figure 2

- 1 – TARGET temperature display
- 2 – ACTUAL temperature display
- 3 – Temperature display mode °C/°F
- 4 – Timer buttons
- 5 – Timer START/STOP button
- 6 – TIMER – time display
- 7 – Temperature mode switch
- 8 – Temperature adjustment
- 9 – Special indication “OK”
- 10 – Heating indication

The special indication “OK” is shown when the target temperature has been reached.



For daily use, take into account following preheating times under the conditions of lid closed, max. water level and 23°C water temperature.
 65°C = ± 70 min
 80°C = ± 100 min

11.2 Rear of unit

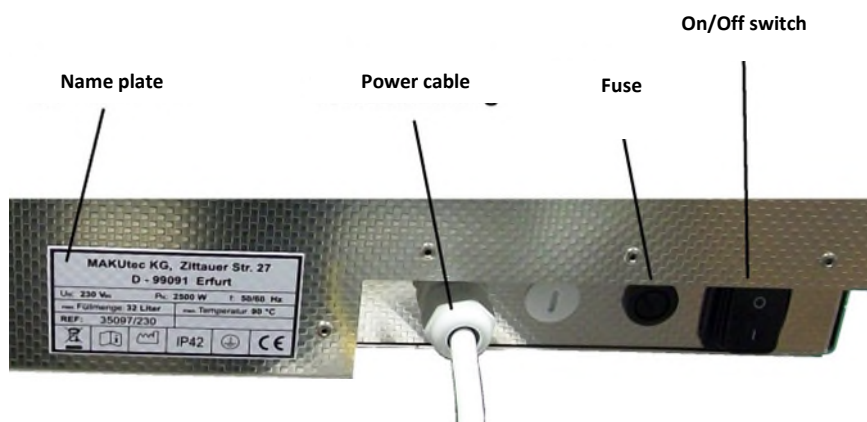


Figure 3

11.3 Sides of unit



Figure 4 – Fan outlet

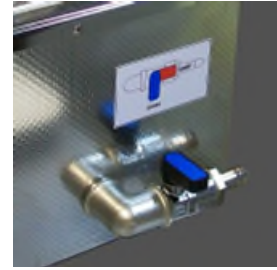


Figure 5 – Drain tap

11.4 Filling

The minimum and maximum filling heights are to be observed during filling, to avoid damaging of the bath.

There are corresponding marks on the inside of the water bath.



Figure 6

11.5 Emptying

- Switch off the water bath at on/off switch. Disconnect unit from mains.
- Connect a suitable hose to the nozzle of the drain tap and feed into a suitable container.
- Open the drain tap on the water bath.
- Once the bath is completely empty, close the tap.

Warning:



- There are thermal hazards when opening the lid of the bath: burning, scalding, superheated steam, hot touchable parts and surfaces.
- Do not empty the heating medium while hot!
- Check the temperature of the bath medium prior to emptying, e.g. briefly switch the unit off and read the temperature.

11.6 Setting of parameters

- After the unit is switched on, the current parameters and temperature of the water bath appear in the display. The temperature is shown in either °C or °F. This can be edited by using **button 7** on the control panel (figure 2).
- **Button 8** sets the target temperature. If both buttons are pushed for more than 3 seconds, the set value is saved. This saving process is acknowledged by a signal.
- The timer time is set using **buttons 4**. The time can be corrected even if the timer has already started. Starting the timer (**button 5**) enters the current time value in the memory, making this available for a new start once the time has elapsed.

11.7 Open-circuit protection

- Appropriate overtemperature protection is incorporated in case the water bath is accidentally switched on without any heating medium.



CAUTION!

- If the bath is used without a heating medium, temperatures in excess of 130 °C can occur inside the bath.
- Unplug the unit immediately and open the lid to allow it to cool.

!! RISK OF BURNING !!

- Increased temperatures on the base plate can cause permanent mechanical deformation and permanent discolouring of the base plate.
- The underlying functionality of the bath is maintained despite these changes. The bath is again ready for use once it has cooled to room temperature.

12. Technical data

Water bath	Unit	Value
Operating temperature range	°C °F	20 °C ... 90 °C 68 °F ... 194 °F
Temperature stability	°C	± 5 °C
Temperature adjustment		digital
Cancellation	°C	1 °C ± 1 digit
Heating capacity (230 V)	W	1800 ± 10 %
Heating capacity (115 V)	W	1400 ± 10 %
Bath opening	cm	54.5 x 74
Bath depth	cm	9.5
Max. usable contact surface	cm	51 x 69
Max. filling height	cm	8
Filling capacity	litre	26
External dimensions (WxDxH)	cm	78 x 58 x 17
External dimensions (WxDxH) (with drain tap and lid handle)	cm	82 x 58 x 22
Weight (230V)	kg	23.5
Weight (115V)	kg	25
Ambient temperature	°C	5 ... 40
Power supply art. No. 35097/230 (230 V)	Vac	230 ± 10 %
Net frequency	Hz	50...60
Power consumption at 230 V	A	6.5 ± 10 %
Power supply art. No. 35097/115 (115 V)	Vac	115 ± 10 %
Net frequency	Hz	50...60
Power consumption at 115 V	A	13 ± 10 %
1x Fuse for 115V / 1400W and 230V / 1800W 6,3mm x 32mm (¼" x 1 ¼")	A	16 slow blow

Safety precautions to IEC 61010-2-010:

Safety temperature / run-dry protection permanently set 105 °C.

Classification to DIN 12876-1 Class I.

Ambient conditions to IEC 61 010-1:

For indoor use only.

Up to 2000 m in height – sea level.

Ambient temperature: +5 ... +40 °C.

Humidity:

Maximum relative humidity 80% for temperatures up to 31 °C, decreasing linearly to 50% rel. humidity at a temperature of 40 °C.

Voltage fluctuations of $\pm 10\%$ are permissible.

Protection type to EN 60 529:	IP 22
Unit corresponds to protection class	I
Overvoltage category	II
Degree of contamination	2

EMC requirements to EN61326-1:

The unit is a group 1 ISM device (uses HF for internal purposes) and has been assigned to class A (industrial and commercial area).

European medical legislation

The unit meets the requirements of the European medical legislation for electrical medical devices EN 60601-1-2 and EN 55011 – class B.

13. EC conformity

The products described in the operating instructions comply with the requirements of the following European directives:

Low Voltage Directive

On the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.

EMC Directive

On the harmonization of the laws of Member States relating to electromagnetic compatibility.

MDR Regulation

In accordance with EC Council Regulation 2017/745 concerning medical devices.

14. Warranty

- The warranty for the water bath is 2 years. It is neither extended nor renewed by any guarantee work being carried out.
- In the event of a complaint, the guarantee is limited to improvement, free repair or new delivery, at our discretion.
- Faulty parts are repaired or replaced free of charge, provided there is evidence of material or manufacturing faults in the event of a problem or defect.
- Additional claims excluded!
- All damage claims lapse if:
 - the unit is opened by unauthorised persons, repairs are carried out by unauthorised persons or the unit is not used in accordance with the guidelines,
 - the product in question is used or operated contrary to the instructions for use and the intended purpose,
 - no original accessories or replacement parts are used,
 - the usage tips in these operating instructions are ignored.

15. Manufacturer

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Note:

It is prohibited to make alterations to this text without prior approval from Orfit Industries.



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Ref. No. 50008

VERSION 14

LAST UPDATE: 17/07/2023

REVISION DATE: 17/07/2025