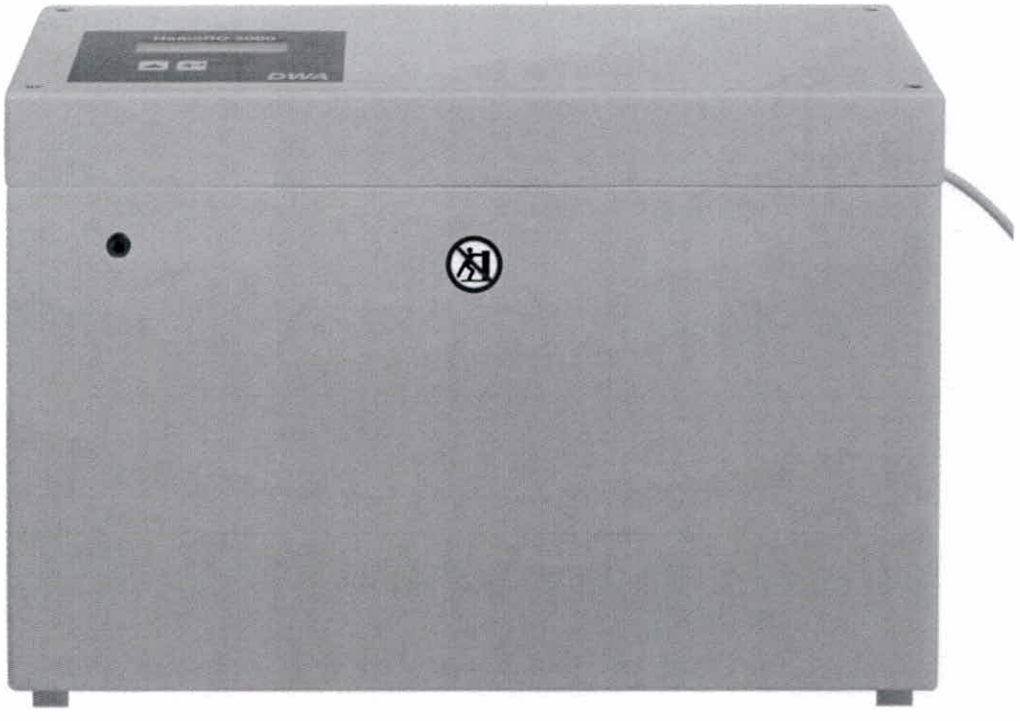
00073039

DWA

OPERATING INSTRUCTIONS

SINGLE-USER REVERSE OSMOSIS SYSTEM

HemoRO 3000



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CE 0044

Conformity with the Council Directive 93/42/EEC concerning medical devices is declared for the device described here.

These operating instructions apply to devices of the product series:

HemoRO 3000

from software version **L20**

Serial number: SN _____

These operating instructions are part of the scope of supply. They must be kept ready close at hand and also remain with the device in the event of resale.

We reserve the right to make changes in relation to the data and figures published in these operating instructions, due to further technical development.

These operating instructions are not subject to an alteration service.

Status of the operating instructions: **2016-06**, you can find out the current status at:

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This is a translation of the original operating instructions.

Content:

Explanation of the symbols used

Refers to **useful information** and **important advice** in the respective factual connection.

Refers to a **possibly dangerous situation**.
If you do not act carefully, **property damage** could result.

Refers to a **dangerous situation**. If you do not avoid these, **personal damage**, including **very severe injuries**, may be the result!

Denotes a minimum and maximum **temperature limit**.

Symbol for **separate collection of electrical and electronic devices** and **bringing into circulation after 13th August 2005**.

Symbol for "reference/item number".

Warning of dangerous electrical voltage!

Observe the **expiry date**!

1 Preliminary comment

These operating instructions are intended to serve all users as a basis for action for the safe and danger-free use of the device. The operating instructions contain important information for the operation and care of the device and concerning how to proceed in the event of malfunctions.

Read the operating instructions, follow the stated instructions and always keep the operating instructions close to hand.

Read the operating instructions before you carry out activities on the device!

2 General information

2.1 Applied directives and standards

- **Council Directive 93/42/EEC of 14 June 1993 concerning medical devices**
- **IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**
- **IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - requirements and tests**

2.2 Definitions of terms

Permeate	Water with a reduced proportion of contents, which is obtained by pre-treatment and reverse osmosis.
Dialysis water	Treated water that meets the requirements of ISO 13959 and is suitable for applications in haemodialysis and related therapies (Source: ISO 23500).
Concentrate	Water with an increased proportion of ingredients that is held back by the membrane in the reverse osmosis process.
RO	means "reverse osmosis system".

i In this application, permeate is used as dialysis water. In the document, the term "permeate" relates mainly to technical aspects of the process, "dialysis water" generally denotes the end-product for the treatment.

2.3 Purpose

The single-user reverse osmosis system ***HemoRO 3000*** produces dialysis water and supplies it to a connected dialysis machine through a hose line that fulfils the function of a dialysis water main.

i Dialysis water is obtained through the membrane separation process "reverse osmosis".

2.4 Intended use

The single-user reverse osmosis system ***HemoRO 3000*** may exclusively be used to produce and distribute dialysis water. Other applications, in particular the use of media other than those specified in the technical data may lead to hazardous situations and must absolutely be refrained from!

Any deviating use shall be considered to be contrary to intended use. Operating the device in the event of defective safety features and the incorrect installation, commissioning, operation and repair of the device shall also be considered to be contrary to intended use. *DWA* GmbH & Co. KG shall not be liable for any resulting damage.

Changes in performance of the device and the use of non-original spare parts shall require the review and approval of *DWA*.

The compliance with the prescribed operating and maintenance instructions shall also be part of the intended use.

2.5 Obligations of the operator

The operator is in general responsible for

- the selection of the components of the water preparation system and water distribution system,
- the compatibility of the individual components with each other,
- adherence to the safety regulations and the taking of precautions for work safety and accident prevention,
- the intended use of the device by instructed operating personnel,
- the instructing of operating personnel,
- the managing of an inventory,
- the carrying out of the technical inspections, in adherence to deadlines, by trained skilled personnel (called *maintenance personnel* in the following) and
- the carrying out of appropriate tests to ensure compliance with the requirements, as soon as changes were made to the system.

2.6 Qualification of the operating personnel

Operating personnel must receive instruction in the operation of the device and the special features of operation. Only instructed persons of legal age may use the device!

Instruction by the manufacturer or *maintenance personnel* takes place during commissioning and when required. Further training is not necessary for the operation of the device.

Maintenance personnel is exclusively trained by *DWA* and receives, after successful completion of training, a certificate valid for two years which authorises its bearer to carry out the commissioning, maintenance, repair and inspection of the electrical safety of the device.

2.7 Packaging and transport

Follow the accident prevention regulations and handling instructions on the packaging!

Attention:

Do not throw; do not put weight on!

- Packing size: 800 mm x 520 mm x 460 mm (W x H x D)
- Weight of the packaged device: max. 35 kg

Protect from frost and heat!

Storage and transport from +1 °C to +45 °C

Attention:

If condensation occurs during transport between two places with different temperatures and high humidity, the device must be dry before it can be turned on!

The drying time must be at least 36 hours at 25 °C.

2.8 Scope of supply

The scope of supply includes a complete ***HemoRO 3000*** device as ordered, incl. operating instructions and the following parts:

Item	Quantity	Unit	Item no.	Name
1	1	Pack	20KSET110	Sampling set
2	1	Pack	SO8B08490	Decalcification set
3	1	Pack	SO8B09816	Castor set
4	1	Piece	SO8B27003	Feed water connection 3/4" IT
5	1	Piece	SO8B70013	Dialysis water hose line
6	1	Piece	SO8D08443	Pipe bracket for concentrate discard
7	3	Metre	ZG05SI021	Silicone hose 14x3 white (DN8)
8	2	Metre	ZG05SI016	Silicone hose 14x3 black (DN6)
9	6	Piece	ZG05V9416	Ear clamp 16.5
10 *)	1	Pack	CDPR00605	Filter cartridge F20 25 µm
11 *)	1	Piece	SO8B08452A	Pre-filter unit F20
12 *)	1	Piece	YY0000003	Spanner for filter housing F20

**) applies only to REF 02HRO3000 and REF 02HRO3002*