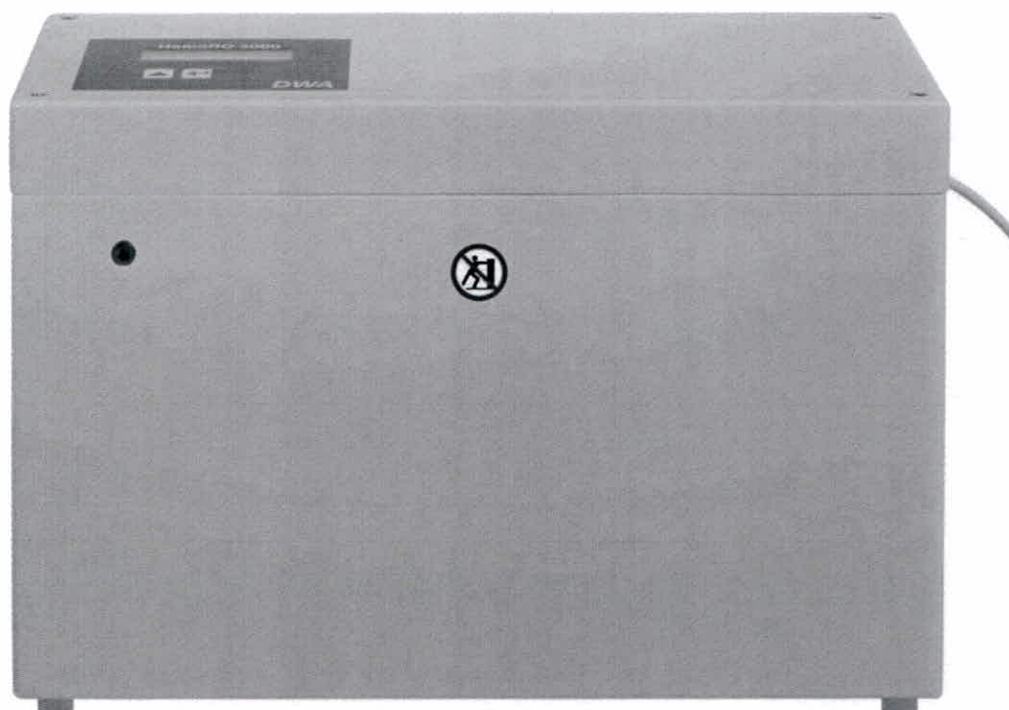


OPERATING INSTRUCTIONS

SINGLE-USER REVERSE OSMOSIS SYSTEM

HemoRO 3000

**DWA GmbH & Co. KG**

Großer Sand 8
76698 Ubstadt-Weiher
Germany

Tel.: +49 (0) 72 51 / 69 00-20
Fax: +49 (0) 72 51 / 69 00-115
E-mail: info@dwa-online.com
Internet: www.dwa-online.com



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.

Reprints, translations and reproductions in any form whatsoever, including in extracts, require the written approval of DWA GmbH & Co. KG.

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:

DWA GmbH & Co. KG
Großer Sand 8
76698 Ubstadt-Weiher
Germany

Tel.: +49 (0) 72 51 / 69 00-20
Fax: +49 (0) 72 51 / 69 00-115

This is a translation of the original operating instructions.

Content:

Explanation of the symbols used	5
1 Preliminary comment.....	5
2 General information	6
2.1 Applied directives and standards	6
2.2 Definitions of terms	6
2.3 Purpose	6
2.4 Intended use	7
2.5 Obligations of the operator.....	7
2.6 Qualification of the operating personnel	8
2.7 Packaging and transport	8
2.8 Scope of supply.....	9
2.9 Supplementary documentation	10
2.10 Spare parts.....	10
2.11 Disposal	10
2.12 Optional accessories.....	11
2.12.1 Water Guard.....	11
2.12.2 Optional pre-stage	11
2.12.3 Trolley	11
2.13 Consumables.....	11
3 Safety advice	12
3.1 Overall danger assessment	12
3.1.1 Dangers in home dialysis environments	12
3.2 General safety instructions	12
3.3 Danger due to electrical energy	13
3.4 Emissions.....	13
3.5 Electromagnetic compatibility	13
3.5.1 EMC sources in the environment of use.....	14
3.6 Safety features	15
4 Labelling.....	16
4.1 Type plate	16
4.2 Symbols of the type plate.....	17
4.3 Further markings	17
5 Specifications	18
5.1 Technical data.....	18
5.1.1 Variants	19
5.1.2 Possible combinations	19
5.1.3 Hard water operation	19
5.2 Quality and conductivity of the dialysis water	20
5.3 Microbiology	20
5.4 Flow chart.....	21
5.5 Functional description	22
5.6 Device views	23
5.6.1 Delivery condition: 02HRO3000, 02HRO3002	23
5.6.2 Operating mode: 02HRO3000, 02HRO3002	24
5.6.3 Delivery condition: 02HRO3110, 02HRO3111	25
5.6.4 Operational state: 02HRO3110, 02HRO3111	26
6 Installation	27
6.1 Requirements for the installation room	27
6.2 Installation conditions.....	28

7	Commissioning	29
7.1	Switching on.....	29
7.2	Switching the device off	29
8	Operation	29
8.1	Control panel	30
8.2	Display texts	31
8.2.1	Top line	31
8.2.2	Bottom line	32
8.2.3	Key functions.....	32
8.3	Switching operating modes	33
9	Operating modes	34
9.1	STANDBY	34
9.2	DIALYSIS	35
9.3	RINSING	36
9.3.1	Overview: Rinse cycles	37
9.4	DECALCIFICATION.....	38
9.4.1	Decalcification prompt.....	38
9.4.2	Conditions	39
9.4.3	Working steps	40
9.5	CHEMICAL DISINFECTION	41
9.5.1	Handling and safety instructions	41
9.5.2	Recommended disinfectants and composition	42
9.5.3	Amount of disinfectant	43
9.5.4	Conditions	44
9.5.5	Working steps	44
9.5.6	Releasing the dialysis operation again	45
9.6	FAULT	46
10	Information request.....	47
11	Maintenance and care.....	48
11.1	Inspection intervals	48
11.2	External cleaning.....	49
11.3	Sampling to determine the bacterial count.....	49
11.4	Replacing the pre-filter cartridge	50
12	Faults and messages	51
	Inventory.....	52

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".



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.



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**