Instruction for Use
Phoenix Move

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Written by: Nipro Pure Water GmbH

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CE

For the Phoenix Dialysis Media Supply Systems type Phoenix Move, conformity is declared in accordance with EC directives Medical Device Regulation 2017/745.

Preface

In this instruction for use you will find all the information required for the installation and operation of the Phoenix Dialysis Media Supply Systems.
Please keep the instruction for use close at hand near the system.

This instruction for use applies to the system with the **UDI** number:

Please write the UDI number in the box. The UDI number is on the device label.

Nipro Pure Water GmbH
Werner-von-Siemens-Str.2-6
76646 Bruchsal – Germany

Tel.: 0049 7251-32 19 7810
Fax: 0049 7251-61 89 943

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1. General

1.1. Scope of delivery

The scope of delivery includes the following parts, depending on the variant:

- Phoenix Move

1.2. Device combination

The Phoenix Move device can be combined with the following devices:

- Multiloop
- Dialysis machines with 220/230V
- Commercially available electrical appliances with 220 / 230V

1.3. Accessories and consumables

There are no consumables for Phoenix Move. Headphones or internet cable socket as accessories.

1.4. Notes for the operator

The operator is responsible for:

- The professional and intended use
- Compliance with occupational safety and accident prevention regulations
- The technical instruction of the operating personnel
- Informing the local technician about any malfunction of the system

1.5. Laws and norms

The following standards and laws were applied:

- Medical Device Regulation 2017/745
- Medical Product Law Implementation Act (MPDG)
- ISO 13485:2016
- EN ISO 14971:2019
- EN IEC 60309-1
- EN IEC 60309-2
- EN 15233-1
- DIN VDE 0753-4

1.6. Symbols used in this manual

Stands for a dangerous situation. Failure to observe can result personal injury or property damage.

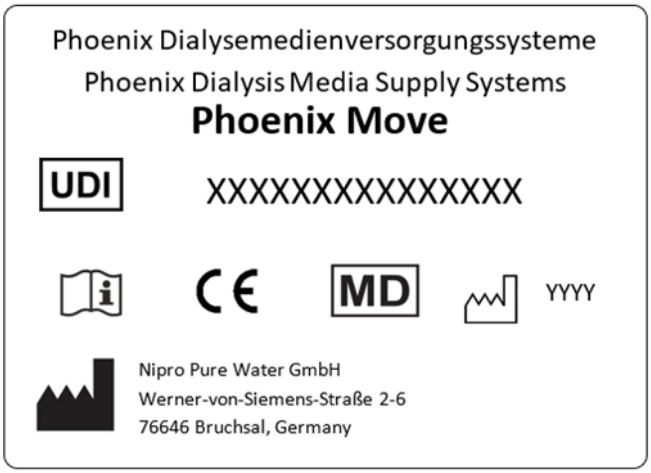
Stands for important information and valuable tips.

1.7. Transport and Storage

Protect the system from frost and moisture.

Protect from strong vibrations and impacts.

1.8. Product label



CE-Mark

Year of manufacture

Manufacturer

Medical Device

Consult instructions for use

Unique Device Identifier

1.9. Warning notices for the device

It is forbidden to enter the area or to step on the device.

1.10. Decommissioning

Protect the system from frost and moisture

Protect from strong vibrations and impacts.

1.11. Disposal

During the implementation of the WEEE directive of the European Community, the disposal of old electrical devices as well as electronic and electrical subassemblies in the household waste is no longer permitted.
These parts must be disposed of in an environmentally friendly manner in accordance with the locally applicable laws such as: WEEE.

1.12. Lifetime

The product is designed for a service life of 10 years from the date of production.

2. Intended purpose

The Phoenix Dialysis Media Supply Systems are not active devices used for enhancing the access of electrical current to dialysis machines, parking lot for the pure water (Permeate) and concentrates hoses that comes from Permeate and Concentrate Distribution Systems (PDS and CDS). A connection to the central drain system is also integrated.

The device has no medical intended purpose itself.

The supplied pure water and concentrates are used to form dialysate for use in hemodialysis therapies.

The duration of use corresponds to the duration of dialysis and is therefore usually short-term.

The device may only be operated by trained clinical staff

The device should be checked for dirt and damage before use and must not be operated in the event of damage

The movable arm must not be loaded with additional weight

No extension cables or multiple sockets may be connected to the electrical connections

The device should not be touched while hot cleaning is being carried out

2.1. Contraindications

The device has no contraindications.

3. Safety

3.1. Risk assessment

If the instructions for use are observed, the device does not pose any sever risk.

4. Technical Data

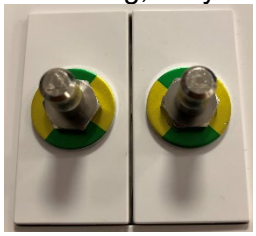
Phoenix Move:

- Arm length 700mm
- Up to 6. Electrical sockets 220/230V
- Grounding socket
- CEE Connection for dialysis machine
- Up to 3 parking lots for the concentrate hoses
- One parking lot for the permeate hose
- One parking lot for the drain hose

5. Description of the system

5.1. Assemblies

Grounding, dialysis machine connection and electrical sockets for the French version:



6. Installation

The installation instruction for Phoenix Move should be considered for the installation. The document contains further details on the installation. The document is supplied with each device with the instruction for use separately.

The installation must be carried out by the manufacturer or personnel trained and authorized by the manufacturer.

6.1. Environment conditions

- Relative humidity <90% at 20 ° C
- Room temperature between + 10 ° C and + 35 ° C
- No storage of easily inflammable materials in the vicinity of the device
- No storage of chemicals in the vicinity of the device

6.2. Electrical installation

All electrical connections must be made by a qualified electrician. All electrical concerns must be checked by a qualified electrician.

6.3. Initial start-up

When using the device for the first time, it must be cleaned of dirt and dust. All parking spaces and couplings must also be disinfected before being used for the first time.

7. Maintenance and cleaning

7.1. External cleaning

Stains and dust can be removed with a cloth and a commercially available cleaner. It is also possible to use disinfectants to clean the surfaces. Please also observe the internal cleaning and disinfection regulations.

7.2. Maintenance intervals

Measure	Time interval	Comment	Implementation through
Disinfection of the couplings and parking lots	Every time you connect and disconnect the hoses.	NA	User
Safety checks	Yearly	NA	Manufacturer or persons authorized by the manufacturer

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