System Manual
Dissolution Systems USP Method 4
Document version
Dissolution Systems USP Method 4

<table>
<thead>
<tr>
<th>Date</th>
<th>Document version*</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>02.10.2014</td>
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</tbody>
</table>

* When the document version X.Y was changed, X means a technical change and Y – a document change only.
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1 Introduction

Thank you for purchase of the ERWEKA USP 4 dissolution systems!

1.1 About this manual

This manual will help you during the work with a USP 4 dissolution system. It gives an overview of the different systems, with which the dissolution tests can be performed according to the USP Method 4. The systems consist of several components.

NOTE

This manual is valid only in connection with the manuals of the components of the used system!

You can see the information about instruction manuals you need additionally for the used system in section 3.2 “Overview of documents”.

NOTE

The manual is a part of the product. Read these manual completely and make sure that you understand the content. Keep this manual in a safe place so that it is available for any questions at a later date. This is important for warranty of permanent and accurate operation of the corresponding product.

The editorial team of ERWEKA appreciates your feedback regarding the present manual. Just send an e-mail to quality@erweka.com with your topic and “technical documentation” as a subject. Your reply contributes to our high quality level.

1.2 Service

Contact ERWEKA at service@erweka.com to receive the firmware updates, order the spare parts, in case of technical troubles or possible repairs. Please supply the following information:

- Type of the instrument (specified in the type label)
- Serial number of the instrument (specified in the type label)
- A short description of the fault
1.3 Safety instructions and symbols

**WARNING**
Warning indicates a possible hazardous situation which, if not avoided, could result in death or serious injury.

**CAUTION**
Caution indicates a possible hazardous situation which, if not avoided, could result in moderate or minor injury.

**Hazard due to electric shock!**

**NOTE**
Notice sign indicates a possible hazardous situation which, if not avoided, can lead to the equipment damage.

**This symbol provides you with additional useful information.**

**This symbol emphasizes the information to ensure smooth work process.**

1.4 Protection of the environment

Note that residues of the test products must be properly disposed of in accordance with the applicable environmental regulations.

According to the valid EC directives, all the electric parts should be disposed of appropriately.
2 Safety

2.1 Safety instructions

To guarantee the health and safety, read the following safety instructions.

WARNING
Wear the special protective clothing and glasses, if necessary!

CAUTION
Lay the cables so that not to stumble over them.

NOTE
ERWEKA instruments should be operated by qualified and trained personnel only! Knowledge of the dissolution tests and USP/EP methods is the main advantage for work with these instruments.

Pay attention to the on-site safety instructions for work in the laboratory and with the laboratory equipment!

2.2 Intended use

The ERWEKA USP 4 dissolution systems should be used exclusively for conducting the dissolution tests and connected with them testing and quality control of the tablets, dragee, oblongs and other formulations in the environment defined by ERWEKA.
3 Overview

3.1 USP 4 dissolution systems

Dissolution systems are used for tests of substance dissolution from solid dosage forms. At that the substance dissolution means the amount and speed with which the tested dosage form gives out the substance in the surrounding fluid medium.

Standardized range conditions of the dissolution tests are defined in the EU and US Pharmacopeia. The test with flow-through cell equipment is described for Apparatus 4 (EP, USP).

Dissolution of the low soluble substances under conditions of sinking can be observed and analyzed with the flow-through cell equipment. A change between different dissolution media is possible, e.g. the simulation of physiological conditions through pH-value changes during the dissolution. Due to the formulation, different flow-through cells are available.

The operation mode of the flow-through cell equipment is divided in open and closed.

Measurement and analysis of the test samples can be performed directly online through UV/Vis spectroscopy or after collecting the fractions with the help of HPLC.

ERWEKA USP 4 dissolution systems are USP 4 conform test systems.

All systems mentioned here are controlled via the Disso.NET 3.x software.
3.1.1 Basic Open System (manual)

This system contains the following main components to perform a dissolution test:

- Piston pump [2]
- Heater [3]
- DFZ instrument with flow-through cells [4+5]

The piston pump [2] transfers the medium [1] into the DFZ instrument [4] sustaining regular temperature by the heater [3]. The medium flows through the cells [5] with samples. After this the samples can be taken from the medium for the analytics [6].

**Open System** means that the permanently fresh dissolution medium flows through the cell, is collected and analytically measured.

Media with different pH-values can be used. The medium change is carried out with the help of a manual valve or an automatic valve station (e.g. VS 490).

If needed, you can use an online degasser device for medium preparation.
3.1.2 Open Offline System

This system consists of the Basic System with a fraction collector. Its components are following:

- Piston pump [2]
- Heater [3]
- DFZ instrument with flow-through cells [4+5]
- Fraction collector [6/7/8]

The piston pump [2] transfers the medium [1] into the DFZ instrument [4] with the regular temperature sustained by the heater [3]. The medium flows through the cells [5] with samples. After this they are directed to the fraction collector [6]. To obtain a representative sample, the fraction collector takes the parts of samples [7] from the flowing medium [6] via a 3-way valve in regular periods. The rest of medium is utilized through the output of fraction collector [9]. The collected representative samples can be analytically measured subsequently [8].

*Offline System* means that the samples are collected for the following measurement during the test.

Media with different pH-values can be used. The medium change is carried out with the help of a manual valve or an automatic valve station (e.g. VS 490).

If needed, you can use an online degasser device for medium preparation.
### 3.1.3 Closed Offline System

This system consists of the Automated Open Offline System with a medium reservoir and peristaltic pump. Its components are following:

- Medium reservoir LMT (that can be heated) [1/7]
- Piston pump [2]
- Heater [4]
- DFZ instrument with flow-through cells [3+5]
- Peristaltic pump [8]
- Fraction collector [9]
- Return of the fraction collector [10]


During the second cycle the medium for sampling is transferred from the medium reservoir [7] through the peristaltic pump [8] to the fraction collector [9]. Optionally the taken sample replaced by the corresponding volume of fresh medium is transferred to the medium reservoir [10].

**Closed System** means that the defined medium volume circulates in a cycle and in such a way flows through the cells repeatedly. More samples can be taken from the same medium.
3.1.4 Closed Online System

This system consists of the Basic Open System with a medium reservoir, peristaltic pump and spectrophotometer. Its components are following:

- Piston pump [2]
- Heater [4]
- DFZ instrument with flow-through cells [3+5]
- Medium reservoir LMT (that can be heated) [1/7/10]
- Peristaltic pump [8]
- Spectrophotometer [9]


During the second cycle [7] the peristaltic pump [8] transfers the medium to the spectrophotometer [9], where it is directly measured. From the spectrophotometer the medium is transferred into the medium reservoir again [10].

**Online System** means that during the test the direct measurements are carried out. The measurement results are displayed online.
3.1.5 Closed On-Offline System

This system represents a connection of Closed Online and Closed Offline System. Its components are following:

- Medium reservoir LMT (that can be heated) [1/7]
- Piston pump [2]
- DFZ instrument with flow-through cells [3+5]
- Heater [4]
- Peristaltic pump [8]
- Spectrophotometer [9]
- Fraction collector [10]
- Return of the fraction collector

The medium from the medium reservoir [1] is transferred through the piston pump [2] into the heated DFZ instrument [3, 4]. The medium flows through the cells with samples [5]. Afterwards it is transferred to the medium reservoir [6].

During the second cycle the medium is transferred from the medium reservoir [7] through the peristaltic pump [8] to the spectrophotometer [9] and is measured and/or filled afterwards into the fraction collector [10] as the sample.

Optionally the taken sample can be transferred to the medium reservoir replaced with the corresponding volume of the fresh medium [10].
3.2 Overview of documents

Due to the applied USP 4 dissolution system you need the following documentation:

<table>
<thead>
<tr>
<th>Systems</th>
<th>Components</th>
<th>Basic Open (manual)</th>
<th>Open Offline (automated)</th>
<th>Closed Offline</th>
<th>Closed Online</th>
<th>Closed On-Offline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online degasser</td>
<td>device (optional)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Software</td>
<td>Disso.NET 3.x</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>DFZ device</td>
<td>720 (R)</td>
<td>720 (R)</td>
<td>720 (R)</td>
<td>720 (R)</td>
<td>720 (R)</td>
<td></td>
</tr>
<tr>
<td>Flow-through cell</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Heater</td>
<td>DH 2000i</td>
<td>DH 2000i</td>
<td>DH 2000i</td>
<td>DH 2000i</td>
<td>DH 2000i</td>
<td></td>
</tr>
<tr>
<td>Piston pump</td>
<td>HKP 720</td>
<td>HKP 720</td>
<td>HKP 720</td>
<td>HKP 720</td>
<td>HKP 720</td>
<td></td>
</tr>
<tr>
<td>Fraction collector</td>
<td>—</td>
<td>FRL 724</td>
<td>FRL 724</td>
<td>—</td>
<td>FRL 724</td>
<td></td>
</tr>
<tr>
<td>Peristaltic pump</td>
<td>—</td>
<td>—</td>
<td>IPC 8</td>
<td>IPC 8</td>
<td>IPC 8</td>
<td></td>
</tr>
<tr>
<td>Spectrophotometer</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>optional: Agilent, Shimadzu,…</td>
<td>optional: Agilent, Shimadzu,…</td>
<td></td>
</tr>
<tr>
<td>Medium reservoir</td>
<td>—</td>
<td>—</td>
<td>LMT</td>
<td>LMT</td>
<td>LMT</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE**

Documentation for a test system consists of the USP 4 system manual, guides (Disso.NET) and instruction manuals of the corresponding components. In this connection only it is complete and valid!
# 4 Technical Data

## 4.1 Volumes

<table>
<thead>
<tr>
<th>Identification / Item No.</th>
<th>Dimension [mm]</th>
<th>Dead volumes [ml]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System connection tubes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>482-051-0003</td>
<td>600</td>
<td>1.19</td>
</tr>
<tr>
<td>482-051-0008</td>
<td>1000</td>
<td>1.98</td>
</tr>
<tr>
<td>482-051-0004</td>
<td>1500</td>
<td>2.97</td>
</tr>
<tr>
<td><strong>Medium intake tube</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>000-463-00118</td>
<td>6 x 1 x 1500</td>
<td>18.9</td>
</tr>
<tr>
<td><strong>Piston pump HKP 720</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Input / 498-051-0001</td>
<td>850</td>
<td></td>
</tr>
<tr>
<td>Output / 000-463-00</td>
<td>850</td>
<td></td>
</tr>
<tr>
<td><strong>DFZ instrument DFZ 720 (R)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DFZ 720 internal / 482-051-0001</td>
<td>450</td>
<td>0.89</td>
</tr>
<tr>
<td>DFZ 720 R internal / 482-051-0002</td>
<td>800</td>
<td>1.58</td>
</tr>
<tr>
<td><strong>Heating spiral / 482-206-0001</strong></td>
<td>482-206-0001</td>
<td>4.8</td>
</tr>
<tr>
<td><strong>Fraction collector FRL 724</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sampling / 412-051-0003</td>
<td>1600</td>
<td>1.26</td>
</tr>
<tr>
<td>Return / 412-051-0003</td>
<td>1600</td>
<td>1.26</td>
</tr>
<tr>
<td>Valve tube / 412-051-0004</td>
<td>120</td>
<td>0.094</td>
</tr>
<tr>
<td>Needle / 412-105-0001</td>
<td>148</td>
<td>0.094</td>
</tr>
<tr>
<td><strong>Medium reservoir LMT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sampling tube / 450-105-0013</td>
<td></td>
<td>0.58 ml</td>
</tr>
<tr>
<td><strong>Peristaltic pump IPC 8</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>000-463-0057</td>
<td>2.79 x 4.56 x 400</td>
<td>2.45</td>
</tr>
<tr>
<td><strong>Spectrophotometer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agilent 8453/8454 Input / 000-463-00</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>Agilent 8453/8454 Output / 000-463-00</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>Shimadzu 1800 Input / 000-463-00</td>
<td>475</td>
<td></td>
</tr>
<tr>
<td>Shimadzu 1800 Output / 000-463-00</td>
<td>475</td>
<td></td>
</tr>
<tr>
<td>Perkin Elmer Lambda 25/35 Input / 000-463-00</td>
<td>850</td>
<td></td>
</tr>
</tbody>
</table>
### Flow-through cells

<table>
<thead>
<tr>
<th>Identification / Item No.</th>
<th>Dead volumes [ml]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>USP 22.6 tablet cell</strong></td>
<td></td>
</tr>
<tr>
<td>Tablet holder and 2 g glass beads (1 mm)</td>
<td>21.46</td>
</tr>
<tr>
<td>Tablet holder and 1 g glass beads (1 mm)</td>
<td>21.96</td>
</tr>
<tr>
<td>Tablet holder and a glass bead (5 mm)</td>
<td>22.46</td>
</tr>
<tr>
<td>Tablet inside and 2 g glass beads (1 mm)</td>
<td>21.46</td>
</tr>
<tr>
<td>Tablet on top of 1 g glass beads (1 mm)</td>
<td>21.96</td>
</tr>
<tr>
<td>Tablet on top of a glass bead (5 mm)</td>
<td>22.46</td>
</tr>
<tr>
<td><strong>USP 12.0 tablet cell</strong></td>
<td></td>
</tr>
<tr>
<td>Tablet holder</td>
<td>12.92</td>
</tr>
<tr>
<td><strong>USP implant cell</strong></td>
<td></td>
</tr>
<tr>
<td>Inside cell</td>
<td>2.11</td>
</tr>
<tr>
<td><strong>USP powder cell</strong></td>
<td></td>
</tr>
<tr>
<td>Powder in the middle</td>
<td>6.49</td>
</tr>
<tr>
<td><strong>USP stent cell</strong></td>
<td></td>
</tr>
<tr>
<td>Inside cell</td>
<td>1.39</td>
</tr>
<tr>
<td><strong>USP suppository cell</strong></td>
<td></td>
</tr>
<tr>
<td>Suppository in chamber A</td>
<td>17.27</td>
</tr>
</tbody>
</table>

### 4.2 Components

You will find the technical data of the components in the corresponding instruction manuals.
5 Installation

5.1 Unpacking and checking

Upon receiving the equipment, please, check that no physical damage has occurred to the packaging, material and instrument itself during the transportation.

If any damage is evident, notify ERWEKA immediately.

NOTE
Check all the fittings! They may have loosened during the transportation!

Once unpacked, position the instruments on a horizontal, plane surface, for example, a laboratory table.

5.2 Check of functioning

HAZARD DUE TO ELECTRIC SHOCK!
Electric instruments are to be plugged in to the safety sockets only!

The voltage of the existing current supply is to be compared to the indications on the type label!

Before opening electric instruments, disconnect them from the rear panel!

NOTE
ERWEKA accepts no liability in case of wrong connection!
Defective instruments should be opened by the authorized staff only!

You will find more information about operation and function of the definite components in the corresponding instruction manuals. See section 3.2 Overview of documents.
5.3 Installation of a test system

After all instruments have been unpacked and checked and their functioning has been identified, you can connect them in a system for USP 4 dissolution tests.

For setting of a USP 4 dissolution system use a flat surface of app. 200 cm length and 60 cm depth. The load-carrying capacity of this surface should constitute app. 100 kg. Instruments are aligned flatly with adjustment screws.

5.3.1 Tubing connections

All tubing connections are numbered.

**NOTICE**

**NOTE**
Too strong tightening of the connections can lead to the damages of the fittings. Pulling and turning the sampling system during the operation or cleaning should be avoided because this can lead to the damages too.

Make sure that the separate tubes are not damaged or pinched. Also the tubing system should be freely movable during operation!

Tighten the tube connector thoroughly with hand. The fittings should be screwed in the coupling pieces of the same length.

**NOTE**

Leakage or air in the system is caused mostly by damaged or false tubing.

5.3.2 Cable connections

All cable connections are numbered by the manufacturer. Each attaching plug has a label with port to which it should be connected.

**NOTICE**

**NOTE**
ERWEKA accepts no liability in case of wrong connection!
5.3.3 Connection plans

The following drawings depict how the instruments are connected in the different USP 4 test systems.

Basic Open System (manual)
Open Offline System (automated)
Open Offline System (including online degasser)
Closed Offline System
Closed Online System
Closed On-Offline System
6 Operation

6.1 Preparing for operation

**NOTE**
Before starting to work with the system ensure that all the containers through which the medium flows or which collect the medium (e.g. tubes, cells, tanks) are dry!

You will find detailed information about each system component (instrument) in the corresponding instruction manuals. Read about device configurations and settings via software in the Disso.NET 3.x manuals.

6.1.1 Preparing the media delivery

Depending on your system type, a different number of media with different pH values is provided.

Open systems are operated with 1 up to 4 different media. The media are supplied to either a manually switching valve (up to 2 media) or automatic valve station VS (up to 4 media).

An online degasser can be interposed to prepare the media with 4-7 pH values.

In closed systems the media are provided via a media reservoir (here LMT).

6.1.1.1 Valve station VS (optional)

The VS is used to automatically change up to 4 media (e.g. VS 490) during a test run. For this purpose the VS automatically fills the media tubes.

![Fig VS 490](image-url)
The VS is used in open systems. (See 5.3.3 Connection plans).

1. Connect the tubes between the device, the media and waste containers and eventually the degasser or the piston pump.

**NOTE**

Pay attention to tightness of the joints, free movement of the tubes and secure immersion of the tubes in the appropriate container.

Think carefully about the positioning of the media container. The media connections Inputs 1 - 4 are controlled in the test over Disso.NET.

### Diagram

![Diagram showing connecting points](image)

<table>
<thead>
<tr>
<th>E</th>
<th>Media container; providing the media to be used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 4</td>
<td>4 media inputs; up to four media used</td>
</tr>
<tr>
<td>A</td>
<td>Media output; the selected medium is further delivered from here</td>
</tr>
<tr>
<td>P</td>
<td>Filling and cleaning pump; control and adjustment over Disso.NET</td>
</tr>
<tr>
<td>W</td>
<td>Waste container</td>
</tr>
</tbody>
</table>

![Icon] Manual control of the VS -pump [P] can only happen with the appropriate access permissions on the Disso.NET device menu.
2. Connect the device (rear panel connector) with a safety socket. **Use the supplied AC adapter (24V)!**

Electric instruments are to be plugged in to the safety sockets only! Use the delivered mains cable only! The voltage of the existing current supply is to be compared to the indications on the type label!

**NOTE**
ERWEKA accepts no liability in case of wrong connection! Defective instruments should be opened by the authorized staff only!

3. Connect the network by using the supplied RS 232 cable (connection on the rear panel). If necessary, configure the RS 232 interface in the Disso.NET software.

4. Adjust the VS -pump in the **MS PumpCheck** menu of the Disso.NET.

![Fig. VS 490 media diagram](image)

Before the test, the tubes are automatically filled with the appropriate medium. The VS [P] pumps the medium into the waste container [W] until no more air is in the system. The media should be free of bubbles before getting into the valve [V].

**NOTE**
Adjust the VS -pump to ensure that the media tubes are filled with medium before the test until the valve location [V] of the VS and free of air inclusions! Air bubbles should not be in the system!

The automatic loading function runs in reverse order to the order of test runs! It is first filled with the medium, which is used in the last test run. Example: First run with water, second run with HCL. First HCL is filled, then water.
6.1.1.2 Online degasser device (optional)

The online degasser device is positioned between the valve station (VS) and piston pump (HKP 720) in the open system. (See section 5.3.3 Connection plans).

![Device connections](image)

**Device connections:**

1. Pump mode
2. Power LED
3. Pressure LED (green – ok)
4/5. Vacuum tubes
6. Fuse
7. Ground terminal
8. Power connection
9. Power switch

**Vacuum flow:**

1. Cut the long tube (delivery scope) into the length you need. The end face of the tube must be flat.
2. Insert the end of the tube into the one-touch joint coupler on the vacuum connection of the instrument. The adequate sealing property is achieved by pushing it firmly.
3. To disconnect the tube from the instrument, push off the release ring of the coupler and pull out the tube.

**Power connection:**

1. Plug in the mains cable of the online degasser device to a safety socket.

---

**NOTE**

ERWEKA accepts no liability in case of wrong connection! Defective instruments should be opened by the authorized staff only!
Flow path:

**NOTE**
Use only pH 4-7 media with the online degasser!

---

**Fig. Online degasser device**

1, 2 Vacuum circuit degasser connections. The vacuum pump [B] extracts the gas from the medium in the degasser [D].

3 Media tube connection from VS 490 [A] to the degasser [D].

4 Media tube connection from the degasser [D] to the distribution bar [C].

5 In the distribution bar [C] the incoming degassed medium is divided.

6 Individual small media tubes to the corresponding pump heads of the piston pump.

---

**NOTE**
Ensure that the outlet port of the online degasser device is connected to the suction side of the pump! Otherwise the pressure can damage the membrane in the instrument. The length of the medium tubes should be reduced to the minimum distance from the instrument to the pump. In case of too long tubes the air can be pressed backwards in the medium. The online degasser device is delivered in dry condition and must be filled with the medium that will be used later.
6.1.1.3 Preparing the medium reservoir (optional – e.g. LMT with heating)

1. Ensure that the medium reservoir is connected to the system. (See section 5.3.3 Connection plans.)

2. Fill the medium reservoir with demineralized water. Fix the medium containers with the clamping lever so that they do not leak or overturn in case of lifting.

3. Plug in the mains cable of the heater to a safety socket (optionally).

   Electric instruments are to be plugged in to the safety sockets only! Use the delivered mains cable only! The voltage of the existing current supply is to be compared to the indications on the type label!

4. Switch on the heater and set the required temperature on the regulator.

5. Wait until the temperature will be achieved.

6. Fill in the containers with the dissolution medium.

   The volume is predefined by the method.

7. Make sure that the tubes are exactly in their places in the medium containers and close the containers.

   NOTE
   ERWEKA accepts no liability in case of wrong connection!
   Defective instruments should be opened by the authorized staff only!

   NOTICE
   The voltage of the existing current supply is to be compared to the indications on the type label!
6.1.2 Preparing the piston pump (e.g. HKP 720)

1. Ensure that the piston pump is connected to the system. (See section 5.3.3 Connection plans.)
2. Plug in the mains cable of the piston pump to a safety socket.

4. Set the piston pump to the **PC mode** so that the pump could be controlled through the PC by doing the following actions:
   1. Press F3 on the foil keypad (setup menu will open).
   2. Select **PC Mode** with the arrow keys.
   3. Confirm with **Enter**.

6.1.3 Preparing the DFZ device

1. Fill the bath of the DFZ device with demineralized water to the marked filling level.
2. Position the bath cover with cells on the water bath and fix it with the screws.
3. Connect the tubing between the heater and water bath. (See the scope of DFZ instrument delivery for the tubing). Pay attention to the proper tubing connections.
4. Move the heater or fill the tubes with demineralized water before their connection to avoid the air in the system so much as possible.

**NOTE**

Do not bend the tubing!
To avoid the damage, make sure that the tubing is filled with water. The pump is not self-priming.
6.1.4 Preparing the heater (e.g. DH 2000i)

**NOTE**

**NOTE**

Before using the heater, the water bath should be filled with water to the marked level.

1. Ensure that the heater is connected to the system. (See section 5.3.3 Connection plans.)
2. Plug in the heater’s mains cable to a safety socket.

**WARNING**

Electric instruments are to be plugged in to the safety sockets only! Use the delivered mains cable only! The voltage of the existing current supply is to be compared to the indications on the type label!

**NOTE**

ERWEKA accepts no liability in case of wrong connection! Defective instruments should be opened by the authorized staff only!

3. Ensure that the round stopcock on the DFZ instrument is in closed position (-)!
4. Turn on the heater by using the mains switch on the back panel.

**INFO**

The integrated pump works when the heater is switched on so that the heated flow circulates in the DFZ instrument. The heating temperature is controlled from the PC and is set to 37°C by default.

**NOTE**

Choose a proper time point for switching the heater on because for the test start the foreseen temperature should be achieved.
6.1.5 Preparing the fraction collector (optional – e.g. FRL 724)

1. Ensure that the fraction collector is connected to the system. (See section 5.3.3 Connection plans.)
2. If needed, fill the substitute tank with the substitution medium. Filling height: almost under the outlet orifice.
3. If needed, make sure that the input end of the receiving tube of the pump for the substitution medium (substitution pump) is surely inserted in the container with sufficient amount of the substitution medium.
4. Ensure that the rack is located properly. (To view from the front, there are two round orifices from the right and two long orifices from the left in the lower corner joints.)

**NOTE**
False positioning of the rack leads to collision with damages!

5. Pay attention to appropriate selection and positioning of the glasses in rack.
6. Plug in the mains cable of the fraction collector to a safety socket.

**WARNING**
Electric instruments are to be plugged in to the safety sockets only! Use the delivered mains cable only! The voltage of the existing current supply is to be compared to the indications on the type label!

**NOTE**
ERWEKA accepts no liability in case of wrong connection! Defective instruments should be opened by the authorized staff only!
6.1.6 Preparing the peristaltic pump (optional – e.g. IPC 8)

1. Ensure that the peristaltic pump is connected to the system. (See section 5.3.3 Connection plans.)
2. Clutch the tubes and set the locking.

Note the position of the locking lever. In such a way it is guaranteed that in case of loosening the lever can be brought to the same position.

3. Plug in the mains cable of the peristaltic pump to a safety socket.

Electric instruments are to be plugged in to the safety sockets only! Use the delivered mains cable only! The voltage of the existing current supply is to be compared to the indications on the type label!

NOTE
ERWEKA accepts no liability in case of wrong connection!
Defective instruments should be opened by the authorized staff only!

4. Switch the peristaltic pump on.

5. Ensure that the percent is set (green LED Pump% shines).

6. In case this has not been done, set the percent in the following way:
   1. Switch off the pump.
   2. Switch it again and simultaneously press Settings for a moment.
   3. Select tubes with the arrow keys.
   4. Confirm with MaxCal (MaxCal = ok).
   5. Select ProC with the arrow keys.
   6. Confirm with MaxCal (MaxCal = ok).
   7. Switch off the pump.
   8. Switch it again and ensure that the green LED near Pump% shines.
6.1.7 Preparing the spectrophotometer (optional – e.g. Agilent)

1. Ensure that the spectrophotometer is connected to the system. (See section 5.3.3 Connection plans.)
2. Plug in the mains cable of the spectrophotometer to a safety socket.

![Electric instruments are to be plugged in to the safety sockets only! Use the delivered mains cable only! The voltage of the existing current supply is to be compared to the indications on the type label!]

![NOTE]

**NOTE**
ERWEKA accepts no liability in case of wrong connection! Defective instruments should be opened by the authorized staff only!

3. Switch on the spectrophotometer.
4. Install the cuvettes with the corresponding slot thickness.

6.1.8 Preparing the flow-through cells

1. Equip the flow-through cell properly.

![More about this in the flow-through cell manual.]

2. Ensure that the round stopcock on the DFZ instrument is in closed position (-).
3. Install the equipped flow-through cells on the DFZ instrument.
### 6.1.9 Checklist of the preparations for the USP 4 Test

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>done</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System</strong></td>
<td>Clean and dry</td>
<td></td>
</tr>
<tr>
<td><strong>Water bath is filled.</strong></td>
<td>DFZ instrument</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium reservoir (optional)</td>
<td></td>
</tr>
<tr>
<td><strong>Tubing</strong></td>
<td>complete, proper, tight, free movable, unbroken</td>
<td></td>
</tr>
<tr>
<td><strong>Tube ends</strong></td>
<td>firmly positioned in corresponding containers</td>
<td></td>
</tr>
<tr>
<td><strong>Control connections</strong></td>
<td>complete, proper</td>
<td></td>
</tr>
<tr>
<td><strong>Cable connections</strong></td>
<td>heater</td>
<td></td>
</tr>
<tr>
<td></td>
<td>piston pump</td>
<td></td>
</tr>
<tr>
<td></td>
<td>fraction collector (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>heater in medium reservoir (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>peristaltic pump (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>spectrophotometer (optional)</td>
<td></td>
</tr>
<tr>
<td>Mains switch on</td>
<td>heater</td>
<td></td>
</tr>
<tr>
<td></td>
<td>piston pump</td>
<td></td>
</tr>
<tr>
<td></td>
<td>fraction collector (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>heater/stirrer in medium reservoir (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>peristaltic pump (optional)</td>
<td></td>
</tr>
<tr>
<td>PC mode on</td>
<td>piston pump</td>
<td></td>
</tr>
<tr>
<td>Set the display in percent</td>
<td>peristaltic pump (IPC 8)</td>
<td></td>
</tr>
<tr>
<td>Insert the PT 100</td>
<td>DFZ instrument (optional)</td>
<td></td>
</tr>
<tr>
<td>Operation temperature in water bath</td>
<td>DFZ instrument with PT 100 (optional)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>medium reservoir (optional)</td>
<td></td>
</tr>
</tbody>
</table>
6.2 Start of the USP 4 Test

It is important to switch all the instruments on before starting the software.

Make sure that the preparations were done successfully according to section 6.1.9 Checklist of the preparations for the USP 4 Test.

You will find the information about switching the instruments on/off in the corresponding instruction manuals. Pay attention to the safety information mentioned in them!

1. Ensure that the tubing is connected properly and, if necessary, the output and input ends of the corresponding tubes are fixed in the containers.

2. The flow-through cells are to be filled with the samples and installed on the DFZ instrument.

3. The circulation is to be switched on and the temperature of the heated water should achieve the value necessary for the test. To sustain the temperature in the flow-through cells, set the round stopcock of the DFZ instrument in open position (I). The appropriate cylinders of the cell stations are filled with the heated water.

In test systems controlled through Disso.NET 3.x software:

The actual temperatures are displayed.

The corresponding data for the test should be entered on the PC.

The test will begin by clicking **Start**.

For operation with Disso.NET 3.x read the information about the test start in the Disso.NET 3.x User’s Guide.
6.3 During the operation

During the test procedure pay attention to the following:

Temperature offsets (DFZ instrument / medium reservoir)

**NOTE**

The temperature in the water bath should be 37°C for the test start and do not exceed 50 °C.

Filling with heated water

Output volume of the medium

You will find the information about filling and volume in the instruction manuals of the components and your test specification!
6.4 Switching off

6.4.1 Ending the test

In test systems controlled through Disso.NET 3.x software:

The corresponding message about the test end appears on the monitor. The test can be finished by clicking **End**, but the actual test run will be completed. The test can be stopped by clicking **Abort**.

![Info](image1)

For operation with Disso.NET 3.x read the information about the test end in the Disso.NET 3.x User’s Guide.

6.4.2 Removing the cells

![Notice](image2)

**NOTE**

Before opening the cell station ensure that:

- The round stopcock is in closed position (–).
- There is no heated water in the cylinder.
- The pump or corresponding medium delivery unit is switched off.

![Info](image3)

You will find the information about the removal and disassembly of flow-through cells in the flow-through cell and DFZ instruction manuals. Pay attention to the safety information mentioned in them!
7 Maintenance

7.1 Cleaning

Hazard of electric shock when cleaning the electric instruments!
Disconnect the power supply!
Switch off and unplug the instrument for cleaning!

7.1.1 General cleaning

NOTE
Always clean the whole system at the end of each test run!

NOTE
Do not use an excessively damped cloth to wipe the instrument! This may cause the damage!
Use clear lukewarm water!
Apply only light pressure when cleaning!

If the surface is exceptionally dirty or gritty, "rinse" it first by lightly swabbing a saturated cloth over it and allowing surfactants to drain away.
Dry by blotting gently with a clean, dry cloth.

Wash and replace the cleaning cloth often, otherwise the dirt or dust will rub into the surface!
If necessary and instructions are not against, a mild, not rubbing cleansing agent can be used.

### 7.1.2 Cleaning controlled by software

In test systems controlled through Disso.NET 3.x software:

The cleaning procedure is defined as a routine.
The precise hints for cleaning are given in the corresponding software menu.

You will find the information about cleaning of the system in the Disso.NET 3.x User’s Guide.

### 7.1.3 Cleaning of the components

**NOTE**

You will find the information about cleaning of the components in the corresponding instruction manuals of the used components. Pay attention to the safety instructions mentioned there!
7.2 Inspection and maintenance

Make sure that the system components (instruments and tubing connections) are regularly inspected and always clean.

Read about this in the instruction manuals of the used components.

To ensure a long lifetime of your units and systems we recommend regular maintenance performed by our specialized staff.

**NOTE**

Spilt medium should be removed immediately! The corresponding place on the instrument should be cleaned!

Check regularly:

- Quality of demineralized water in the bath
  
In case of low quality the demineralized water should be replaced with the fresh demineralized water!

- Tightness and durability of the tubes

The tubes are inserted manually and it is enough to obtain the tight connection.

**NOTE**

Do not seal with the sealing material or PTFE band!
In systems with spectrophotometer

Check regularly:
- Is a baseline correction needed?
- Must the lamp be replaced?

Find out more information in the instruction manual of the used instrument.

<table>
<thead>
<tr>
<th>If using Shimadzu spectrophotometer:</th>
<th></th>
</tr>
</thead>
</table>
| Base Line Correction | monthly | 1. Switch the instrument on and enter the main menu.  
2. Select F3 Maintenance.  
3. Select 2."Instrument Base Line Correction".  
4. Select 2."Correction Instrument".  
5. Answer Yes.  
6. Confirm with Enter. |
| Lamp Replacement | after 2000 h | 1. Switch the instrument on and enter the main menu.  
2. Select F3 Maintenance.  
3. Select 3."Reset Lamp Usage Time".  
4. You will see the operation hours till lamp replacement. |

Pay attention to the instructions of Shimadzu!

For longer standstills:

NOTE
If the instruments are not used for the long time, they should be emptied and cleaned!
### 8 Troubleshooting

<table>
<thead>
<tr>
<th>Description of failure</th>
<th>Possible reasons</th>
<th>Fixing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of the circulating medium volume</td>
<td>Leakage in the system</td>
<td>Check the system, renew the untight connections and replace the defective gaskets / tubing / containers.</td>
</tr>
<tr>
<td></td>
<td>The filter is blocked</td>
<td>Clean or replace the filter.</td>
</tr>
<tr>
<td>The circulating water is contaminated</td>
<td>The filters are blocked.</td>
<td>Clean or replace the filters.</td>
</tr>
<tr>
<td>Temperature is not achieved</td>
<td>Heater is defective.</td>
<td>See the instruction manual of the heater.</td>
</tr>
<tr>
<td>Software does not display the components</td>
<td>Control connection does not function.</td>
<td>Check and, if necessary, replace the cable.</td>
</tr>
<tr>
<td></td>
<td>PC mode is not set where it is necessary.</td>
<td>Check and, if necessary, change the menu settings of the corresponding components.</td>
</tr>
<tr>
<td></td>
<td>The instrument was switched off for the time point of the software start.</td>
<td>Switch on the instrument and restart the software.</td>
</tr>
</tbody>
</table>

Read about the troubleshooting also in the corresponding chapters of the components’ instruction manuals. For more information contact the ERWEKA service department.