Preliminary instructions for use microfluidics device

Cover page

In the future, the cover page should show the name and a picture of our device. In addition, the CE certification and the place of manufacture should be indicated.

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Introduction

Our Microfluidic device enables the fast, efficient and standardized production of liposomes for the encapsulation of siRNA molecules for fast in vitro testing as well as carriers for therapeutics. The operation of the device is completely automatic. That ensures easy usage and no need for special qualifications for the operation. The device includes a microfluidics chip for one-time use but can also be replaced by a custom made chip for your own purposes. Also included are liquid containers for the two solutions required to get started with microfluidics-based synthesis as well as for the collection of the prepared liposomes, compatible syringe pumps are required.

The resulting particles are biocompatible and biodegradable and can be further modified to target specific tissues and/or receptors. Liposomes encapsulating siRNA particles synthesized with the device can be used for biomedical research applications such as gene delivery.

Safety Notes

The microfluidic device as well as the microfluidic chip are not suitable for usage in diagnostic procedures.



| <u>[</u>] | Before using the microfluidic device, make sure that you are informed about the safety notes and procedures related to used equipment and reagents. |
|------------|--|
| | During the usage of the device, always wear gloves, safety glasses and a lab coat. |
| | For all experiments, perform a biosafety risk assessment, mitigation, decontamination, and waste disposal procedures in accordance with established national and institutional guidelines. |

| Make sure that there are no flammable or explosive sources in the surrounding area during usage. | |
|--|--|
| To avoid potential shock hazard, do not touch the cables or power plugs with wet hands and always unse the correct plug configuration. Make sure that the connection between the cable and the system is secure. Only use power cables supplied with the microfluidics device, other cables may damage the system. | |

The device should only be used for the applications specified in the Introduction and only with equipment mentioned in the materials section. We also recommend cleaning the microfluidic chip with our offered washing solution only. We accept no liability for improper use or for the use of MF chips which do not originate from our production.

Materials

The following materials are required for a functional microfluidic device:

| Materials | supplied | Quantity |
|--|----------|----------|
| microfluidic device | yes | 1 |
| microfluidic chip | yes | 1 |
| bottle with rinsing liquid | yes | 2 |
| replaceable liquid containers for the device | yes | 4 |
| Syringe pumps | no | 2 |
| Syringes compatible with syringe pumps | no | 2 |

The table is not complete and is primarily intended to illustrate how this section will be structured in terms of content in the future.

Components

In the future, this section should show a picture of our microfluidics device and our chip as well as a description of the single components to make the reader familiar with the structure of our device and our chip.

Unpacking and Repacking

The device as well as the chip were checked for integrity and functionality before being packed. Nevertheless, we ask you to check the supplied components immediately after unpacking. If you find any defects, please return the products to us in their original packaging. On the enclosed supplementary sheet, please indicate the identified defect.

Transportation and storage

This point should give information about the transportation and storage of the device.

Installation and Setup

The first part of this section will describe the setup of our device with the help of illustrations. At the same time, the reader's attention will be drawn to possible dangers during the individual steps.

The second section contains information on installing the software on a computer, which enables the user to record and evaluate the measured values of the device. It contains requirements to the PC and instructions on how to install the software as well as a detailed description of the individual functions of the software.

Procedure Step 1: Prepare solutions

This section describes the preparation of the lipid solution in ethanol as well as the siRNA solution in PBS. Both solutions can then be used to produce siRNA loaded liposomes with our microfluidic chip. We also point out that the customer can also produce other nanoparticles, using his own chip. Unfortunately, we cannot provide a protocol for the production of these solutions.

Step 2: Operate the microfluidic system

This part describes step by step how to synthesize drug-encapsulated liposomes with the device and how to acquire data using the software. Here illustrations are intended to provide a better understanding too. Possible hazards are highlighted after the corresponding steps.

Step 3: Maintenance and cleaning

This chapter deals with the maintenance and cleaning process of the device. This section is significant because our device is classified under Class Is of the MDR and therefore must be maintained in a sterile condition. At the same time, proper and regular maintenance of the device can extend its lifetime, saving costs and resources.

Troubleshooting

The section "troubleshooting" enumerates possible error reports, warning signals of the device and problems that may occur during the operation of the device and provides the reader with possible actions on how to fix the problem. Below are some useful examples that we plan to include in our manual in the future.

- 1. System does not power on
- 2. Software Issues
- 3. Nanoparticles are not in the desired size range
- 4. Polydisperse nanoparticles
- 5. Uneven flow
- 6. Leak in system
- 7. Blockage of micromixing microfluidics chip

Disposal



This marking on the product, accessories or literature indicates that the product and its equipment are classified as Electrical or Electronic Equipment and should not be disposed of with other household waste at the end of their working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and

recycle them responsibly to promote the sustainable reuse of material resources. You can contact your local government office for details of where and how you can take these items for environmentally safe recycling or send it back to the manufacturer for recycling. This product and its electronic accessories should not be mixed with other commercial wastes for disposal.

Image sources

- Figure Warning-Sign: https://freesvg.org/triangular-warning-sign-with-an-exclamation-mark-vector-graphics
- Figure user manual: https://freesvg.org/joede-read-manual
- Figure safety glasses.https://freesvg.org/protective-eye-wear
- Figure Gloves: https://freesvg.org/yves-guillou-protections-6
- Figure Lab coat: https://freesvg.org/lab-coat-1573205990
- Figure Biohazard: https://freesvg.org/biohazard-warning-vector-sign
- Figure Fire Hazard: https://freesvg.org/fire-hazard-warning-sign-vector-image
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- Figure Disposal-Sign: https://freesvg.org/disposal-symbol