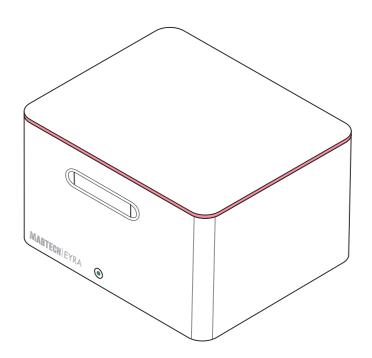
Operating Instructions





Mabtech EYRA™

Multiplex instrument

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Introduction

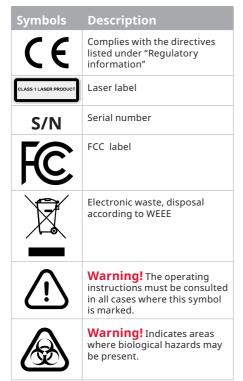
Intended use

Mabtech EYRA $^{\text{m}}$: Measurement of signals generated in an *in vitro* bead-based assay for the detection of analytes in solution.

For research use only.

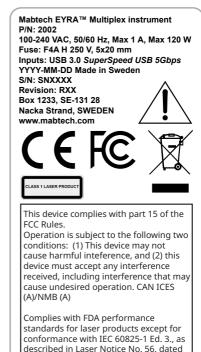
Symbols

These symbols are shown on the instrument:



Labels

Instrument label:



Contact information

Mabtech AB Augustendalstorget 9 SE-131 52 Nacka Strand Sweden

May 8, 2019.

Customer service: Phone: +46 8 716 27 00

E-mail: mabtech@mabtech.com

Regulatory information

The Mabtech EYRA™ Multiplex instrument complies with the following directives:

| Directive | Applied standards |
|--|---|
| CE mark for the European Economic Area (I | EEA) |
| 2014/30/EU – Electromagnetic Compatibility Directive (EMC) | EN IEC 61326-1, edition 4:2021-06-04; edition 3:2013-01-11 EN 55011 (Class B)*, edition 5:2016-04-01 +A1:2017-04-21 +A11:2020-03-06 +A2:2021-04-09 EN IEC 61000-3-2 (Class A), edition 5:2019-03-01 +A1:2021-04-09 edition 4:2014-08-22 EN 61000-3-3, edition 3:2013-08-23 +A1:2019-08-02 +A2:2021-11-05 +A2/AC:2022-01-28 |
| 2014/35/EU – Low Voltage Directive (LVD) | EN 61010-1, edition 3:2010-10-15 +A1:2019-02-22 +A1:2019/AC:2019-04-26 EN 60825-1, edition 5:2014-08-08 +A11:2021-02-19 EN IEC 61010-2-081, edition 3:2020-05-22 |
| 2011/65/EU – Restriction of Hazardous Substances Directive (RoHS) | • CENELEC EN IEC 63000, edition 1:2018-12-07 |
| North America | |
| CFR Title 21Food and Drug Parts 1040 | § 1040.10: 2023-04-01§ 1040.11: 2023-04-01 |
| CFR Title 47 FCC Part 2 | • § 2.906 SDoC:2022-10-01 |
| CFR Title 47 FCC Part 15 (Class B)* | § 15.107:2022-10-01§ 15.109:2022-10-01 |
| ICES-Gen | • Issue 2: 2024-02-23 |
| ICES-003 | • Issue 7:2020-10-15 |
| CAN ICES(A) / NMB(A)* | |
| REDR C1370 | • 2022-09-27 |
| International Standards | |
| EMC | IEC 61326-1, edition 3:2020-10-26; edition 2:2012-07-10 CISPR 11*, edition 6:2015-06-09 +A1:2016-06-23 +A2:2019-01-18 IEC 61000-3-2, edition 5:2018-01-26 +A1:2021-07-14; edition 4:2014-05-26 IEC 61000-3-3, edition 3:2013-05-14 |

+A1:2017-05-18 +A2:2021-03-25

| Directive | Applied standards |
|-----------|--|
| Safety | • IEC 61010-1, edition 3:2010-06-10 +A1:2016-12-16 +A1 C1:2019-03-21 |
| | • IEC 60825-1, edition 3:2014-05-05 |
| | • IEC 61010-2-81, edition 3: 2019-02-12 |

^{*} Class A for Conducted Emission on the AC port but Class B for Radiated Emission.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Quality Management System (QMS)

| Standard | Description |
|--|---|
| EN ISO 13485:2016, edition 4:2016-03-02 +A11:2021-09-08 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| EN ISO 9001:2015, edition 4:2015-09-15 | Quality management systems – Requirements |

Safety

Before you install or operate the system, you must read the safety information. There is a risk of user injury or damage to the system if the instructions in this manual are not followed.



Warning! Risk of personal injury if instructions are not followed.



Warning! Indicates areas where biological hazards may be present.



Caution! Risk of material damage if instructions are not followed.



Note: General information or advice on optimal use of the system.



Warning! The Mabtech EYRA™ Multiplex instrument must only be used by trained persons.



Warning! Do not remove the instrument cover, as this may expose you to hazardous laser radiation that can harm skin and eyes. All internal service and maintenance must be performed by an authorized technician. Contact Mabtech for more information.



Warning! Do not keep or use flammable liquids near the system. Risk of fire.



Warning! Use caution when you eject the plate holder. The plate holder protrudes 12 cm from the instrument when fully ejected. Risk of physical injury.



Warning! Do not look inside the instrument during reading. Risk of injury to skin and eyes from laser radiation.



Warning! Follow the instructions in this manual when you lift or move the instrument. Risk of injury to the persons or damage to the system.



Warning! Do not use the instrument near sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the operation of the instrument.



Warning! Do not connect faulty equipment to the system. Risk of electrical shock and damage to the system.



Warning! Connect all cables correctly when you install the system. Risk of electrical shock.



Warning! To disconnect power, unplug either end of the power cable. Place the instrument so that the plug can be easily separated from the wall socket.



Warning! It is not recommended to use biohazardous substances with EYRA™. However, in cases when biohazardous substances have been used, follow appropriate biosafety procedures, use personal protective equipment, and adhere to appropriate local biosafety and biohazard guidelines or regulations.



Caution! Only use the microtiter plate types specified under "Technical specifications." Other plates can cause malfunction and electrical failure.



Caution! Use caution when placing the microtiter plate into the plate holder, as the edges are sharp and may cause injury.



Caution! Use caution when placing the microtiter plate into the plate holder to avoid spilling liquid.



Caution! Use caution when inserting the microtiter plate into the instrument using the software to avoid pinching your fingers.

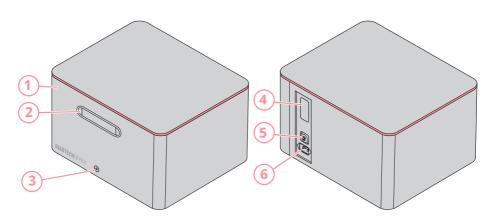


Caution! Do not place objects near or on the instrument. Vibrations from the instrument can make objects fall.



Caution! This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Product description



Overview

| Number | Description | Number | Description |
|--------|----------------------|--------|----------------------------|
| 1 | Cover | 4 | Label |
| 2 | Door to plate loader | 5 | USB port |
| 3 | Power button | 6 | IEC inlet with fuse holder |

In this package

The following parts are included in the package:

- Mabtech EYRA™ Multiplex instrument
- USB cable
- Power cable
- Spare fuse
- Operating Instructions (this manual)

Cleaning/Decontamination

Clean the outside of the Mabtech EYRA $^{\text{TM}}$ Multiplex instrument with a damp cloth when needed.

Before you send the system to any third party, fill out a certificate of decontamination to ensure that the instrument does not contain any potential contaminants.



Warning! Wear appropriate personal protective equipment when handling parts that come into contact with potentially biohazardous samples.

Please note that Mabtech cannot accept any instrument or parts that may be contaminated with biohazardous substances such as viable biological agents, harmful quantities of chemicals, or radioactive materials.



Note: Users of the Mabtech EYRA™ Multiplex instrument need to provide Mabtech with a certificate of decontamination before scheduled service visits. Microbial agents that pose risk or threats to health of service technicians must be declared. Mabtech will not perform service on instruments or parts that may be contaminated.

Disposal



By the end of the instrument life, recycle at a designated local reception point for Waste Electrical and Electronic Equipment (WEEE). You must not discard the instrument as household waste.

Warranty

Refer to the Mabtech General Terms & Conditions of Sale found on http://www.mabtech.com/terms-and-conditions or the contractual agreement between the seller and the buyer.



Caution! Failure to obey the instructions in this manual will void the warranty.



Caution! The safety of any system or equipment that incorporates the Mabtech EYRA™ Multiplex instrument is the responsibility of the person connecting the instrument to that system or equipment.

Technical specifications

Power supply

| AC input voltage | 100 to 240 VAC |
|-------------------|---|
| AC input current | Max 3 A @100-240 VAC |
| AC frequency | 50/60 Hz |
| DC input voltage | 5 VDC, 1 A max |
| Power consumption | 120 W max |
| Fuses | Quick-Acting F4A H, 250 VAC (H = High Breaking Capacity (Ceramic tube)) |

Operation and Maintenance

| Interfaces | 1 USB 3.0 port |
|--|---|
| Dimensions (H × W × D) | 375 mm x 602 mm x 516 mm |
| Weight | 36.4 kg |
| Environmental specifications | For indoor use only, +5°C to +40°C (+41°F to +104°F) Altitude up to 2000 m Relative humidity range: 5–95% Pollution Degree 2 |
| Mains supply tolerance (%) or absolute mains supply values (voltage fluctuations of the nominal voltage) | +/-10% |
| Transient overvoltages | Overvoltage Category II Surge Level 3 (CM 12 ohm) & 4 (DM 2 ohm): 2 kV- 1.2/50 µs |
| IP class | IP20 |

Key features

| Read/calculation speed | 25 minutes |
|------------------------|--|
| Resolution (H × W) | 2048 × 2048 pixels |
| Approved plate types | Greiner (96-well, PS, F-BOTTOM (CHIMNEY WELL)) |

The Mabtech $EYRA^{TM}$ Multiplex instrument must be connected to a computer equipped with the Mabtech EYRA Opal -software.

Setup and installation



Warning! Follow the instructions in this manual when you lift or move the instrument. Risk of injury to person or damage to the system.



Warning! Do not use or keep flammable liquids near the system. Risk of fire.



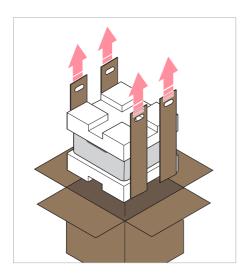
Caution! The instrument is heavy. Place it on a solid table. Use two people to lift or move the instrument.

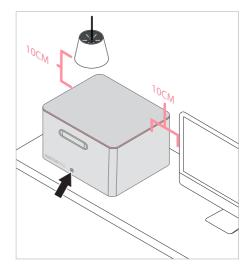


Caution! Keep other equipment more than 10 cm away from the instrument. Risk of malfunction caused by overheating.



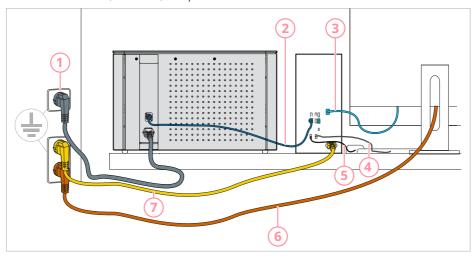
Note: Keep the packaging in case the system needs to be sent back to Mabtech for service.





 Lift the Mabtech EYRATM Multiplex instrument out of the box using the handles. Due to its weight, ensure two people are lifting it. Place the Mabtech EYRA™ Multiplex instrument upright on a solid table. Remove the inner packaging. Make sure that you have received all components specified in the section "In this package" on page 8.

3. Connect the USB, Ethernet, and power cables



| Number | Description | Number | Description |
|--------|-------------------------------|--------|---------------------|
| 1 | Power cord EYRA | 5 | Mouse cord |
| 2 | USB cord | 6 | Power cord monitor |
| 3 | Display port cable (marked D) | 7 | Power cord computer |
| 4 | Keyboard cord | | |



Warning! Do not connect faulty equipment to the system. Risk of electrical shock and damage to the system.

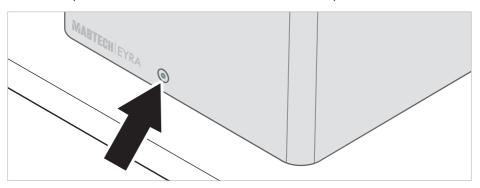


Caution! Connect the Mabtech EYRA™ Multiplex instrument to a grounded outlet. The input voltage must be between 100-240 VAC, 50-60 Hz.



Note: In the event of power failure, the instrument might have to be restarted.

4. Push the power button to turn on the Mabtech EYRA™ Multiplex instrument.



How to use the Mabtech EYRA™ Multiplex instrument

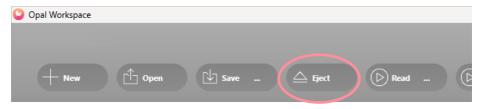


Warning! Wear appropriate personal protective equipment when handling parts that come into contact with potentially biohazardous samples.

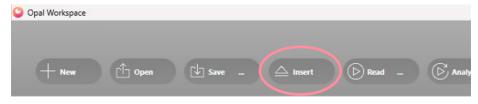
1. Start the computer and click on the program symbol.



2. Click **Eject**. The instrument ejects the plate loader.



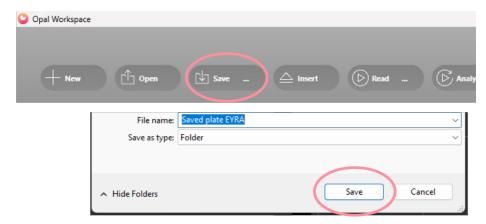
- 3. Put the microtiter plate in the plate loader.
- 4. Click **Insert**. The instrument retracts the plate loader.



Click Read. The instrument reads and analyzes the plate.



6. Click **Save** and select a folder. Click **Save**.



Service, maintenance, and transport



Warning! Do not remove the cover of the instrument. Injury to eyes from UV light can occur. All internal service and maintenance work must be done by a technician approved by Mabtech. Contact Mabtech for more information.



Caution! Only use shielded signal cables that are shorter than 3 m to comply with applicable EMC requirements. If the USB cable is longer than 2 m, the connection between the instrument and the computer can stop working.



Caution! Use only the parts specified below. Using other parts will void the warranty.

Return the equipment in the same box that it arrived in for repair/service/transport. Environmental conditions for transport and storage should be according to IEC 60068-2 and IEC 60721-3:

- Public transportation: -40 to +70°C
- Storage locations: -25 to +55°C

Only the following parts can be replaced by the user:

| Part | Description |
|-------------|--|
| Power cable | 240 V/10 A (international) or 100 V/15 A (North America)IEC 60320-1 C13 connector |
| USB cable | Shielded USB cable Type A 3.0 male - type B 3.0 male ≤ 2m |
| Fuses x 2 | Cartridge fuses SP 5×20 250V 4A IEC 60127-2 Quick-Acting F, H (H = High Breaking Capacity (Ceramic Tube)) |

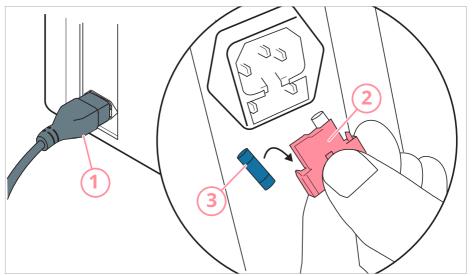


Note: All components in Mabtech EYRA™ are compliant with RoHS(Restriction of Hazardous Substances Directive, 2011/65/EU).

To replace the fuses



Warning! Disconnect the power before replacing the fuses. Risk of electrical shock.



- 1. Pull out the power cable from the IEC inlet.
- 2. Remove the fuse holder from the IEC inlet with a flat screwdriver or similar tool.
- 3. Replace the fuses.
- 4. Plug the fuse holder and the power cable back in.



Developed and manufactured by MABTECH AB, Sweden, whose quality management system complies with the standards ISO 9001:2015 & ISO 13485:2016.





The products are for research use only.

MABTECH shall not be liable for the use or handling of the product or for consequential, special, indirect or incidental damages there from.

Mabtech AB (Head Office) Sweden Tel: +46 8 716 27 00 mabtech@mabtech.com Mabtech, Inc. USA Tel: +1 513 871-4500 mabtech.usa@mabtech.com

www.mabtech.com