



# Seramun *SpotSight*<sup>®</sup> plate mono

Device for software controlled image capture of *SeraSpot*<sup>®</sup> tests  
in 96-well microtitration plates

 SP-PLATE-D  *In-vitro*-diagnostic device 



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## Used symbols:



Manufacturer



Date of manufacture



Device for *In-vitro*-Diagnostics



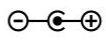
Electrical equipment to be disposed according to the directive 2002/96/EC.  
Electrical and electronic waste.



Supply voltage



USB connection



Connecting DC



Information



Note on malfunctions or damage to the equipment if the instructions are not followed.

## Used abbreviations:

A	Ampere
AC	Alternating current
°C	Degree Celsius
CMOS	Complementary metal-oxide-semiconductor
CE	CE marking, EU directive compliance
cm	Centimeters
DC	Direct current
EN	European standard
Hz	Hertz
kg	Kilograms
LED	Light-emitting diode (LED)
min	Minutes
OD	Optical density
PC	Personal computer
REF	Reference number
s	Seconds
SN	Serial number
USB	Universal Serial Bus
(v/v)	percentage volume per volume

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## NOTE



This manual is part of the components of delivery. Always keep the manual at hand. It is important that this manual is read completely and carefully before operating the scanner Seramun *SpotSight*<sup>®</sup> plate mono.

## 1 Introduction

### 1.1 Method SeraSpot<sup>®</sup> tests

*SeraSpot*<sup>®</sup> tests are immunoassays in an array format in wells of 96-well microtitration plates manufactured by Seramun Diagnostica GmbH (spot Immunoassay, SIA). The assays allow the simultaneous detection of several different analytes in fluids (e.g. in serum or plasma). The analytes can include antigens or antibodies. These are bound by specific capture molecules printed at nanoliter scale on the bottom of the wells of 96-well microtitration plates geometrically arranged as dots (spots) forming a parameter field (array). The bound analytes are detected by detection molecules. The arrangement of single spots within the array is carried out according to a predetermined layout, which allows the exact assignment of the parameters.

In case of immunochemical detection, bound analytes of sample are detected by enzyme labeled detector molecules, usually antibody or antigen conjugates of Horseradish Peroxidase (HRP). The detection comprises a HRP-specific substrate reaction with hydrogen peroxide and a colorless solution of 3,3',5,5'-Tetramethylbenzidine (TMB). This results in formation of colored reaction products in form of pale blue to dark blue spots within the parameter field (array). The color intensity of spots is correlated to the analyte concentration. Colored spots are visible by eye.

Following removal of the excess of liquid substrate, the arrays (spot pattern) can be digitized as images by the scanner Seramun *SpotSight*<sup>®</sup> plate mono and evaluated on the basis of the given array layouts. Alternatively, a visual evaluation of the analysis / of images is possible using a predetermined template, which reflects the arrangement of parameters within the used array.

### 1.2 Intended use



Seramun *SpotSight*<sup>®</sup> plate is a device for software controlled image capture of *SeraSpot*<sup>®</sup> tests in 96-well microtitration plates manufactured by Seramun Diagnostica GmbH. Operation of the device requires a separate PC with installed software Seramun *SpotSight*<sup>®</sup> scan for device control and result analysis (not included in delivery).

The analysis of the captured images is performed using the software Seramun *SpotSight*<sup>®</sup> scan.



The device is intended for use by trained personnel. Clinical diagnostics is just approved only with *in-vitro*-diagnostics made by Seramun Diagnostica GmbH. The instructions of use must be strictly adhered.

### 1.3 Functional principle of Seramun *SpotSight*<sup>®</sup> plate mono

The device contains a XY displacement unit having a plate holder for receiving a 96-well microtitration plate. In idle mode, the plate holder is positioned within the device. Performing a measurement starts by moving the plate holder out of the scanner with simultaneous opening the front lid. Afterwards the plate holder of the scanner can be loaded with a microtitration plate.

The scanner cannot be used without a connected PC and associated software Seramun *SpotSight*<sup>®</sup> scan for scanner control and data processing.

First, the XY displacement unit moves the 96-well plate to the image module station. Subsequently, the microtitration plate is gradually moved from well to well through the image module. The image module comprises a light box (below the microtitration plate) and a CMOS camera (above the microtitration plate). During crossing of the station the image capture of the wells is performed. The obtained images are transferred to the scanner-connected PC and processed, stored and analyzed using the software Seramun *SpotSight*<sup>®</sup> scan. The image acquisition of a complete 96-well microtitration plate takes about 7 min. A calibration of the image module is not required.

After completion of the imaging process, the plate holder moves back to the position of the slot occupancy. The imaged plate can be removed.

### 1.4 Limitations in the application

The device has to be used in a dust free environment.

The settling of dust or lint on the light panel located below the microtitration plate can affect the image capture.

Furthermore, the operation of the device in the vicinity of vapors from solvents and acidic vapors should be avoided. These can cause damage to the image module and thus the image capture might be impaired.

Exposition to direct sunlight, for example by placing the product adjacent to a window is to be avoided in order not to affect the image acquisition by acting of scattered light from the outside.

The use of vibrating devices in proximity to the scanner affects the precision of the movement of the XY displacement unit with microtitration plate holder.

The scanner Seramun *SpotSight*<sup>®</sup> plate mono has to be connected directly to the PC via the supplied USB cables.

If external USB hubs are inserted within the USB cable connections between the scanner and the operating PC, or if the USB compounds are extended by additional USB cables, an error-free functioning of the equipment is not given.

The operation of the scanner has to be done only with the supplied external power supply.



## 1.5 Safety instructions



The use of the scanner Seramun *SpotSight*<sup>®</sup> plate mono presupposes the existence of basic safety precautions in clinical chemistry laboratories, which are designed to minimize injury, fire, or electric shock hazards.

If hazardous materials have been spilled on or into the unit, ensure proper decontamination of the device. During the decontamination powder-free disposable gloves, protective goggles and protective clothing must be worn. Requisite laboratory disinfection reagents have to be applied if the device has been come in contact with human samples. Alternatively, a solution of 70% (v / v) isopropanol or ethanol can be used. Before starting decontamination, the 24 V power cord and the USB cables have to be drawn from the bushes.

The operator has to ensure that the moving equipment components cannot come into contact, e.g. with clothing or hair.

The device may only be opened by authorized personnel.

Any kind of changes to the unit will void the warranty and the CE conformity.

All serious incidents occurring in relation with Seramun *SpotSight*<sup>®</sup> plate mono must be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient are located.

## 2 Description of Seramun *SpotSight*<sup>®</sup> plate mono scanner

### 2.1 Transport packing and unpacking of Seramun *Spot Sight*<sup>®</sup> plate mono scanner

The scanner Seramun *SpotSight*<sup>®</sup> plate mono is supplied in a transport box. Upon receipt of the delivery, the box for shipping must be examined for damages. Any damage should be reported immediately to the manufacturer. The transport of the device within the transport box has to be upright in accordance with the markings attached on the box.

Opening the transport box is made by cutting the adhesive tape. Cutting of the tapes should not be done with a long cutting instrument. The unit and all other under 2.2. listed components are packed in foam elements that prevent slipping of the box contents.

First, the upper foam elements and the laterally-placed accessories are to be removed. Thereafter, the device can be removed from the outer package. It has to be placed on a clean, stable and level work surface.

Finally, the completeness of the delivery against the listed components of the delivery note has to be checked including the serial number of the device (rear of device) with the serial number stated on the delivery note.

The transport box and the foam elements have to be kept for future transport.



## 2.5 Function elements of the Seramun *SpotSight*<sup>®</sup> plate mono scanner

See Figures 3 and 4

**Figure 3:** Loading with 96-well plate

- (3a) closed device
- (3b) opened device with released slot (7) for one 96-well microtitration plate
- (3c) view of the open device with released plate holder (7) for one 96-well microtitration plate. The plate holder contains a built-in grayscale filter (8).
- (3d) View of the open device with released plate holder (7), loaded with one 96-well microtitration plate (9). The 96-well microtitration plate has to set with A1 at the upper left position of the plate holder (fig. 3d, 9).

**Figure 4:** Display mode (2) of front panel during operation

- (2a) the on-off symbol is lit after turning on the device with the power switch (1)
- (2b) the spot symbol is lit after turning on the scan process in software Seramun *SpotSight*<sup>®</sup> scan

## 2.6 Placement of device and installation

### **Placement of device**



The device has to be placed on a clean, horizontal, plane work station without exposition to direct sunlight and sources of particles or dust. The proximity of vibrating equipment or the impact of vibration on the device has to be avoided.

Environmental conditions: Working temperature 15°C...30°C / relative humidity 20% ... 90%, no condensation. The device is not designated for use in cold labs.

### **Removing the transportation lock of the transport carriage**



The transport carriage is fixed with a transportation lock. The scanner may not be connected to the AC adapter nor to the computer before the transportation lock is released.

The transportation lock must be removed using the delivered L-shaped Allen key (fig. 1, D) before starting up the unit, otherwise the scanner may be irreversibly damaged.

The release of the transportation lock must be performed according to the manual "Removal and installation of the transportation lock of the transport carriage" enclosed with the delivery.

### **Connection of device**



For power connection a main electricity of 230V (AC) is needed.

The scanner Seramun *SpotSight*<sup>®</sup> plate mono is connected to the separately supplied PC with installed software Seramun *SpotSight*<sup>®</sup> scan using the two provided USB cables (fig. 1, C). The USB sockets are located on the rear panel of the device (fig. 2, 6.1 and 6.2).

The USB cables must not be replaced by other suppliers. They must be connected directly to the external PC. An error-free functioning of the equipment cannot be guaranteed when using an interposed USB hub.





The supplied 24V power supply (fig. 1, B) has to be used exclusively. It has to be connected to the 24V connection of the device (fig. 2, 6.3)..



## 2.7 Function test

To activate the device use the power button (fig. 2, 1 or fig. 4, 1). The power state will be shown by the power indicator (fig. 4, 2a).

After switching on, the initialization starts. The initialization starts with a signal sound followed by movement of the XY displacement unit. During initialization, the 2 symbols of the front panel are lighted up. After finishing the initialization, the on-off symbol is lighted up only. The scanner is now ready for measurement.

The device is not ready when no sound is audible and the movements will not happen. In this case repeat the start procedure. If the device will not run through the initiation sequence, contact the supplier.

## 2.8 Device application

Switching on the unit should be done only when the connected computer was started.



The scanner Seramun *SpotSight*<sup>®</sup> plate mono is switched on by pressing the power button (fig. 2, fig. 1 and 4, 1). The device status is indicated by lighting the corresponding indicator of the front panel (fig. 4, 2a).

After switching on, the initialization starts. The initialization starts with a signal sound followed by movement of the XY displacement unit. During initialization, the 2 symbols of the front panel are lighted up. After finishing the initialization, the on-off symbol is lighted up only. The scanner is now ready for measurement.

Subsequently, the software Seramun *SpotSight*<sup>®</sup> scan installed at the connected PC has to be started. The several steps of using the software Seramun *SpotSight*<sup>®</sup> scan are described in the instructions for use for the software Seramun *SpotSight*<sup>®</sup> scan. Before starting the application insert the 96-well microtitration plate into the plate holder.

Based on the version of Seramun *SpotSight*<sup>®</sup> scan software the software generates and exports reports, application data and single images.

### Note:

The 96-well microtitration plate has to set with A1 at the upper left position of the plate holder (fig. 3d, 9). The plate holder offers a pressure element for a stable plate insertion.



## 2.9 Turning the device off

The software Seramun *SpotSight*<sup>®</sup> scan should be discontinued before the device is switched off by pressing the power button (Figure 2, Figure 1 and 4, 1). After pressing the power button, the lights of the corresponding functional element of the front panel (Figure 4, 2a) disappears.

The device has no stand-by-mode.

## 2.10 Setting the device out of operation



After switching off the device (see 2.9.) the USB cable and the 24V connection cable can be pulled out of the sockets. The transportation lock should be installed according to the manual “Removal and installation of the transportation lock of the transport carriage” enclosed with the delivery by using the L-shaped Allen key (fig. 1, D).

The device, the USB cable and the power adapter with 24V connection cable can be stored in the transport box between the foam elements. The scanner has to be stored at a temperature of 15°C ... 30°C and a relative humidity of 20% ... 90%. The unit must not be exposed to condensation.

## 3 Care of the device



The case of Seramun *SpotSight*<sup>®</sup> plate mono can be cleaned using wet tissues impregnated with water or 70% (v/v) isopropanol. During cleaning, powder-free disposable gloves must be worn.

If the device has been in contact with human samples, requisite laboratory disinfection reagents have to be applied. Alternatively, a solution of 70% (v/v) isopropanol or ethanol can be used. During the decontamination powder-free disposable gloves, protective goggles and protective clothing must be worn.

## 4 Maintenance



It is recommended to perform an annual preventive maintenance of the scanner Seramun *SpotSight*<sup>®</sup> plate mono by the supplier or by the supplier authorized service.

Preventive maintenance to be performed by the user is not required. It is also not necessary to replace consumables or replace spare parts.

The scanner should be included into the annual retest of portable electrical equipment (i.e., DIN VDE 0701-0702 (Protection Class III)).

## 5 Transportation and shipping the device

Before removing the device from the laboratory or before servicing work, the unit must be cleaned as described in "3. Care of the device". The device must be shipped using the original packaging.



The transportation lock should be installed according to the manual “Removal and installation of the transportation lock of the transport carriage” enclosed with the delivery.

The device must be shipped using the original packaging.

## 6 Disposal

### 6.1 Disposal of the device

The device must not be disposed as unsorted municipal waste. It must be treated as electrical and electronic waste. The directive 2002/96/EC on waste electrical and electronic equipment has to be complied.

### 6.2 Disposal of packing materials

If the package is not to be used for future storage devices, it can be returned to the supplier of the device.

## 7 Troubleshooting

The scanner Seramun *SpotSight*<sup>®</sup> plate mono has no error indication. Possible errors can be:

- (a) Power does not turn on.
  - a. Solution: Check connection of the power supply. Inspection of the 230V outlet where the power cord connects the power supply.
- (b) Initialization sequence does not start after switching.
  - a. Solution: Repeat power-up.
- (c) No images are transferred to the connected PC
  - a. Solution: Check USB cable connection.
  - b. Solution: Restart of the software Seramun *SpotSight*<sup>®</sup> scan at the connected PC. Repeat initialization sequence of the device.
- (d) Unevenly illuminated images
  - a. Solution: Operate the scanner not in direct sunlight.
- (e) Images out of focus
  - a. Solution: Restart the software Seramun *SpotSight*<sup>®</sup> scan on the connected computer. Repeat initialization of the device. Repeat scan.
- (f) 96-well microtitration plate inserted obliquely into the XY displacement unit, XY displacement unit clamps
  - a. Solution: Turn the device off. Pull 24V connection cable from socket. Open the front lid gently forward manually. Move the plate holder of the XY displacement unit carefully until the microtitration plate can take out. Attention: Once the device is turned on never move the plate holder of the XY displacement unit manually.



If malfunctions of the device cannot be solved, the supplier should be contacted. In addition, the supplier should be contacted if other not described errors occur.

## 8 Specifications

Image capture	measuring principle: resolution: light source: diffuse, image recording: measuring time per 96-well plate: power supply:	CMOS camera, color 5 megapixel controllable LED backlight, white sequentially approx. 7 min 24V DC vs. XY-controller
Dimensions	380 x 400 x 180 mm (15.0 x 15.8 x 7.1 in)	
Weight	9.9 kg (21.1 lb)	
External power supply	Input AC 100-240V 50-60Hz / Output DC +24V 2.7A	
Interfaces	2x USB 2.0	
Working temperature	15°C ... 30°C	
Relative humidity	20% ... 90%, no condensation	

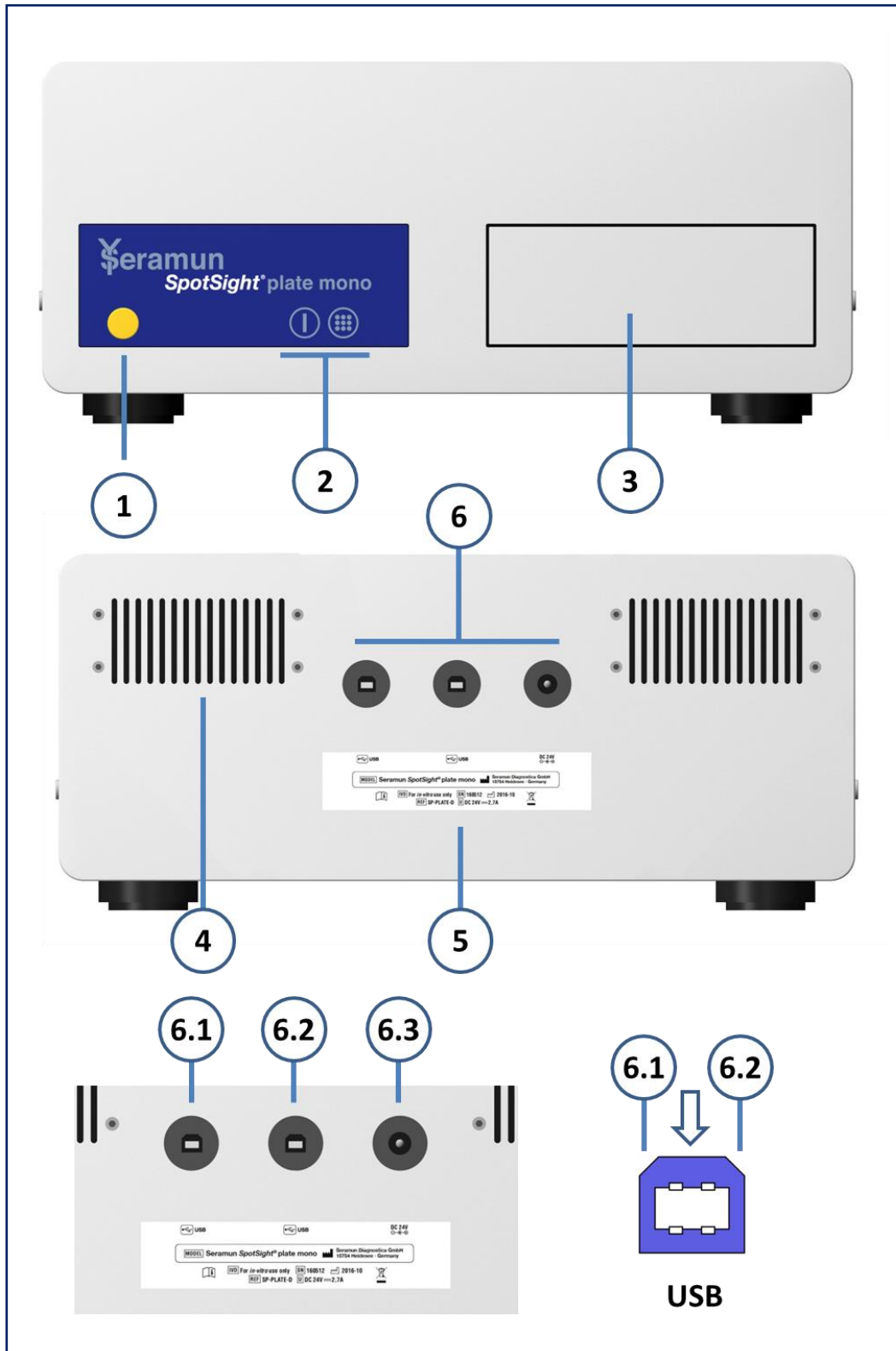
The unit conforms to EN 61326-2-6: 2006-10 (electromagnetic compatibility), EN 61010-1: 2010 and 3 Edition and EN 61010-2-101: 2002 (Safety requirements for electrical equipment for application, control, and laboratory use, special requirements for *in-vitro*-diagnostic use).

## 9 Figures

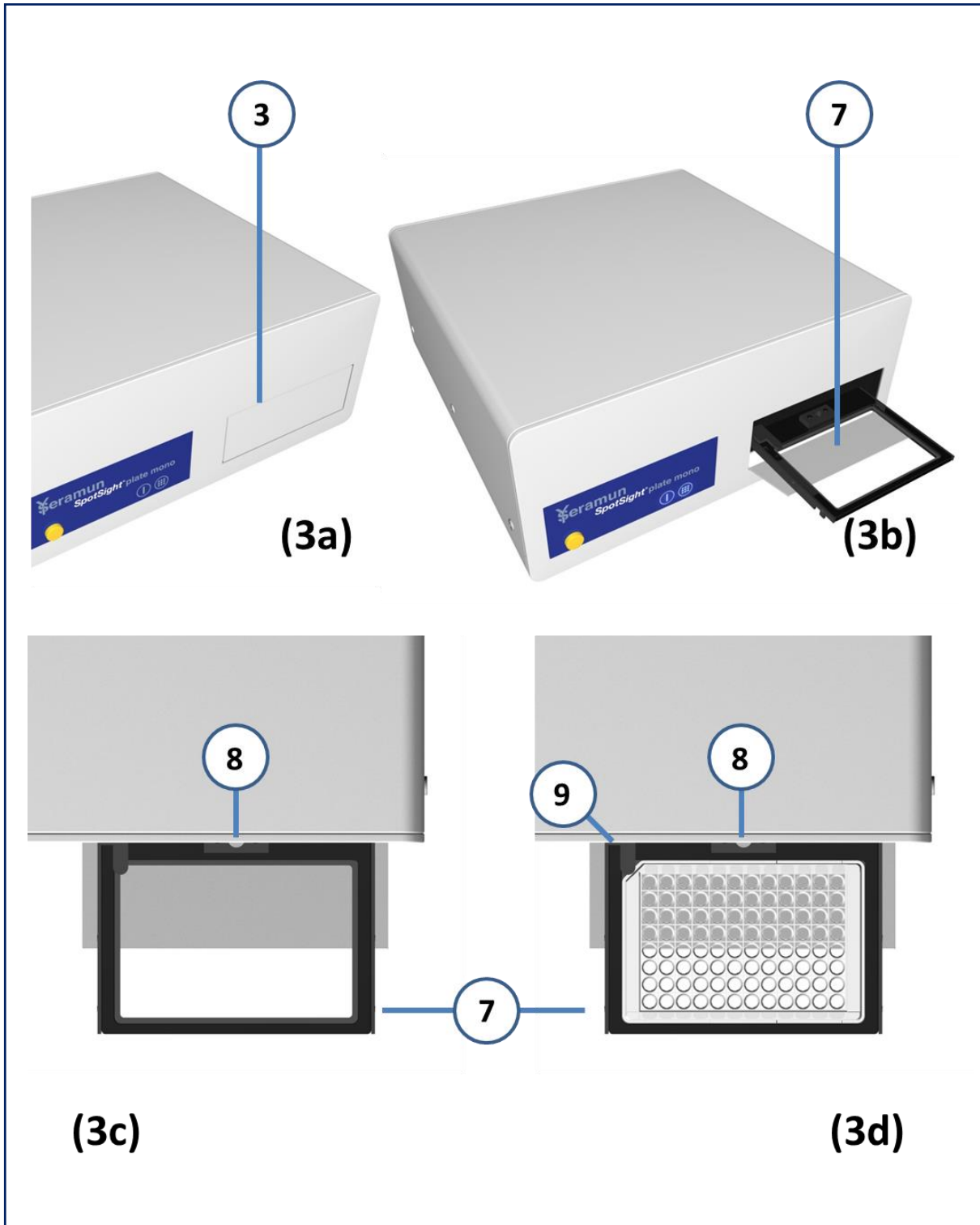
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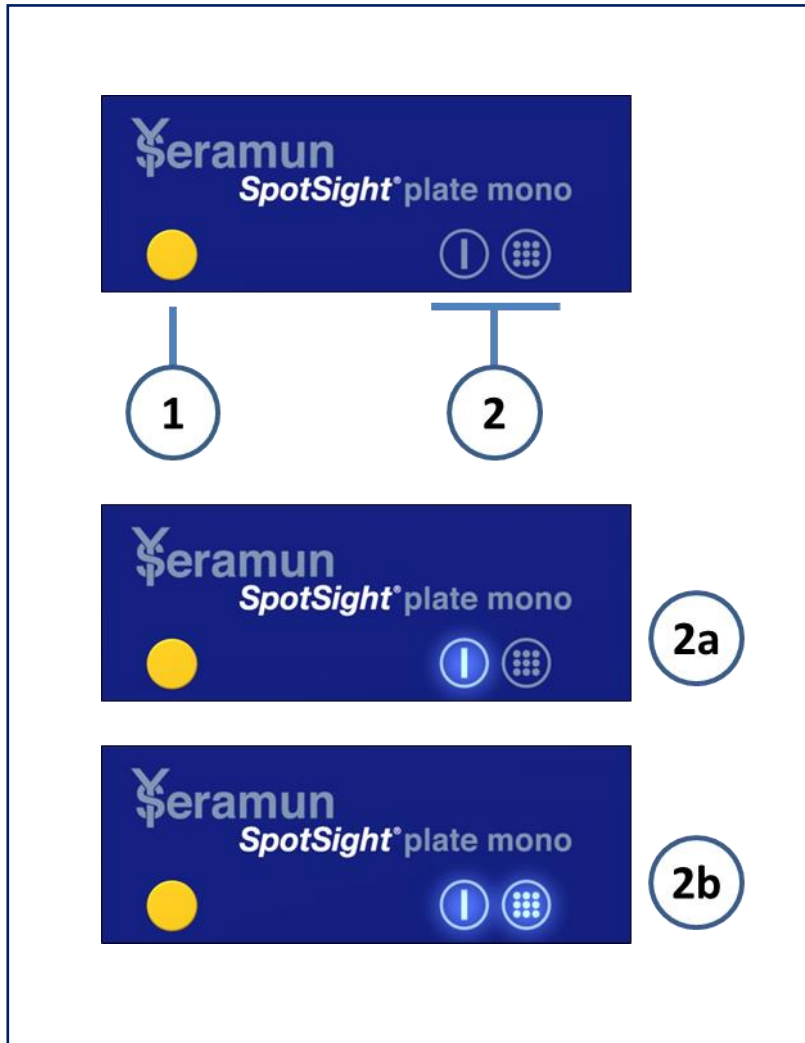
**Figure 1:** Scanner Seramun *SpotSight*® plate mono, scope of delivery



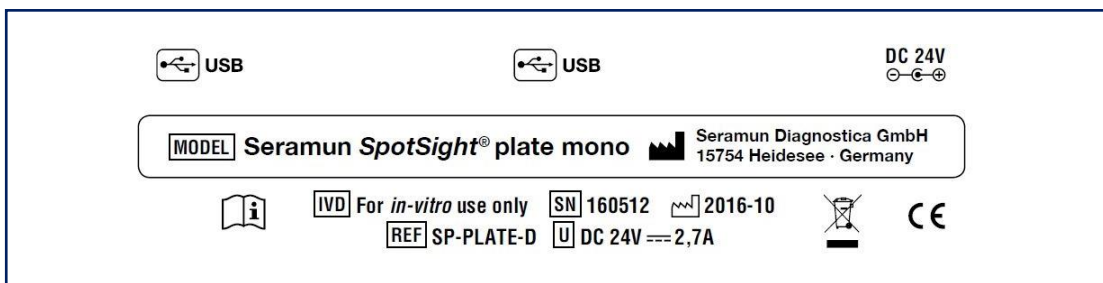
**Figure 2:** Scanner Seramun SpotSight® plate mono, components, front and rear view



**Figure 3:** Scanner Seramun SpotSight® plate mono, functional elements, loading with 96-well plate



**Figure 4:** Scanner Seramun *SpotSight*® plate mono, view of the front panel, function indicators



**Figure 5:** Scanner Seramun *SpotSight*® plate mono, type label



## 10 Revision History

<b>Section</b>	<b>Modifications</b>
4	note to include in annual test similar to DIN VDE 0701-0702
10	added Revision History

**Notes**

**Notes**

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