Seramun SpotSight® well

Device for image acquisition of SeraSpot® tests in wells of a 96-well microtiter plate

REF SP-WELL-A

IVD In-vitro diagnostic medical device

CE

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UDI	Unique device identifier	IVD	In-vitro diagnostic medical device		Manufacturer
	Date of manufacture		USB port	SN	Serial number
	Electrical device, to be disposed of in accordance with national or international guidelines		Caution	REF	Article number
	Consult instructions for use				

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Abbreviations used:

CMOS	Complementary metal-oxide-semiconductor
EN	European Standards
LED	Light-emitting diode
PC	Personal computer (desktop PC, laptop or tablet)
USB	Universal serial bus

NOTE

These instructions for use form part of the scope of delivery of the Seramun SpotSight® well device and must always be kept at hand.

The instructions for use should be read in full before using the device.

1 Intended use

The product Seramun SpotSight® well is an IVD device for image acquisition of arrays by a laboratory professional user in a laboratory environment. The product is used in combination with the Seramun SpotSight® scan software for image evaluation and the kits of the SeraSpot® product line.

The product must not be used with tests other than the SeraSpot® spot immunoassays, in the near patient setting and by lay persons.

2 Mode of operation

Seramun SpotSight® well contains an image capture module (Figure 1) consisting of a CMOS camera with lens and a light panel.

The device may only be used when connected to a PC (desktop PC, laptop or tablet) with a Windows operating system and with the Seramun SpotSight® scan software installed. The device is supplied with the necessary operating voltage via the USB port of the connected PC. The device is ready for operation as soon as the Seramun SpotSight® scan software installed on the connected PC is started. The images captured by the device are transferred to the connected PC and indexed, saved and evaluated by the Seramun SpotSight® scan software.

The well holder supplied with the device is required for the image capture process. The well holder contains 8 openings for holding up to 8 wells of a 96-well microtiter plate (MTP). For the purposes of image capture, the loaded well holder is moved manually from well to well through the device. The well holder latches at the respective position of the well before the image is captured. The sequence of movement of the well holder is displayed and checked by the Seramun SpotSight® scan software.

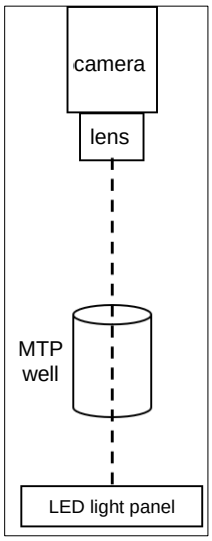

Figure 1: Schematic diagram of the image capture module consisting of CMOS camera with lens and LED light panel.

3 Operation of Seramun SpotSight® well

3.1 Safety instructions

The following instructions must be noted before unpacking and setting up the device:

The installation location must be clean, dry and dust-free.

The device must be protected from the ingress of liquids.

The device must be used in a solvent-free and acid-free environment.

Do not expose the device to direct sunlight.

The device must not be exposed to vibrations.

The device is not suitable for operation in cold rooms.

The device may only be opened by qualified personnel authorised by the manufacturer. Unauthorised opening of the device will invalidate any manufacturer's warranty.

All serious incidents related to Seramun SpotSight® well must be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is domiciled.

3.2 Scope of delivery

The Seramun SpotSight® well is delivered in an outer box, which if necessary is in turn packed in a shipping box with filling material.

The completeness of the delivery must be checked against the components listed in the certificate of analysis or delivery note. The serial number of the device (bottom of the device, Figure 3) must be compared with the serial number stated in the certificate of analysis or delivery note.

The outer box, shipping box and filling material must be kept for possible later return.

Figure 2: Device and its components.
(A) Seramun SpotSight® well device
(B) USB cable (A/Micro-B)
(C) Well holder

Not shown, but part of the scope of delivery: Instructions for use of the device and the Seramun SpotSight® scan software, transport packaging.

Figure 3: Example of nameplate on Seramun SpotSight® well.

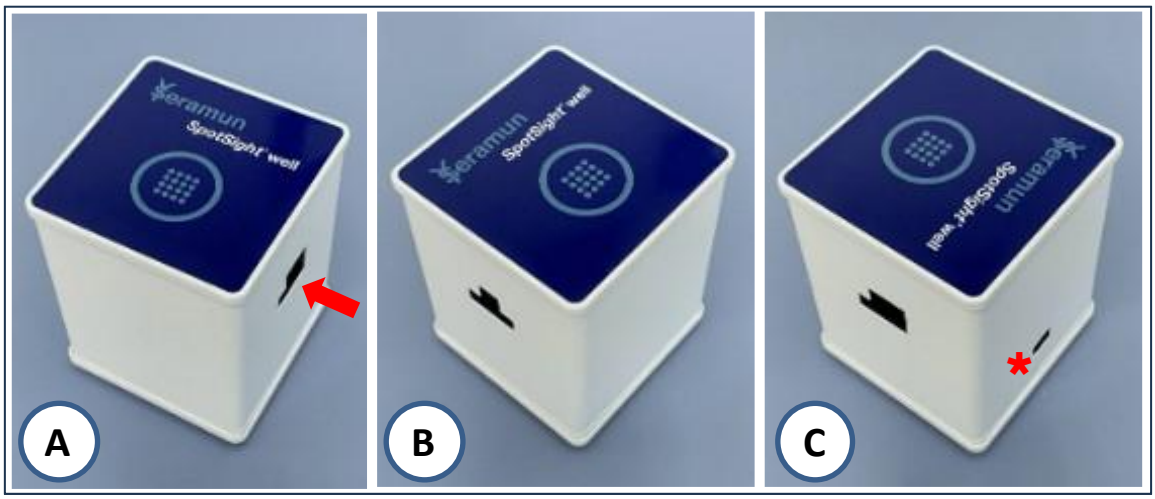

Figure 4: Views of device.
(A) Infeed side for the well holder (arrow)
(B) Outfeed side for the well holder
(C) USB Micro-B connection (asterisk)

3.3 Device connection and function test

After connecting Seramun SpotSight® well via the supplied USB cable (Figure 2 (B), Figure 4(C)) to a suitable PC, a new drive with the name SPOTSIGHTW will appear on the PC screen.

The USB cable must be connected directly to the PC. Error-free device function cannot be guaranteed if intermediate USB hubs are used.

The original USB cable must not be substituted by cables from other suppliers.

On the SPOTSIGHTW drive (MicroSD card inserted in the device), there is an installation file for the Seramun SpotSight® scan software. The setup must be carried out in accordance with the instructions issued during the installation process.

Do not delete or rename the MicroSD card inserted in the device or any files on the former.

After successful setup, start up the installed software (see the instructions for use for the Seramun SpotSight® scan software). After logging in, the software connects to the device.

For details, see the instructions for use for the Seramun SpotSight® scan software.

If the Seramun SpotSight® scan software does not return any error messages when the device is connected to the PC, the serial number of the device will appear in the top panel of the software screen. The device is ready for operation.

3.4 Device use

To import processed SeraSpot® tests with the device, the developed wells to be captured must be summarised as sample requests in a work list in the Seramun SpotSight® scan software. The well holder must be loaded with the corresponding wells according to the order of the sample requirements. The recesses in the well holder are marked A...H. Loading always starts with position A. Figure 5 (C, D) shows examples of how the well holder is loaded.

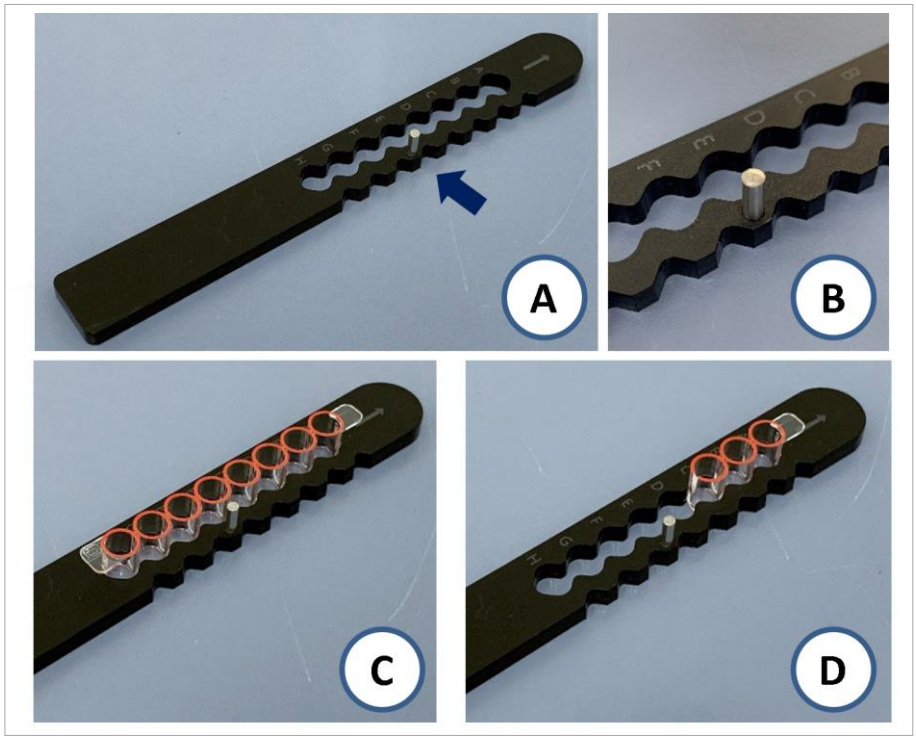

Figure 5: Well holder

(A) Well holder with positioning pin (arrow)
(B) Positioning pin
(C) Well holder, loaded with an 8-well strip
(D) Well holder, loaded with a 3-well fragment of an 8-well strip

Prior to image capture, the Seramun SpotSight® scan software prompts the user to insert the well holder loaded with wells into the device from the infeed side in the first position specified by the software. The device housing (Figure 4) and the positioning pin of the shaft holder (Figure 5 (A, B)) are designed to prevent the well holder being introduced incorrectly. Due to the shape of the well holder, it latches at the positions of the wells and is pushed through the device from one well position to the next (Figure 6).

Figure 6: Use of well holder
(A) Before insertion of well holder
(B) Device with inserted well holder

Depending on the version of Seramun SpotSight® scan software installed on the computer, the software creates and exports results in the form of reports, data and individual images.

For details, see the instructions for use for the Seramun SpotSight® scan software.

After image capture is completed, remove the well holder from the device. The captured wells can be removed so that the well holder can be used for the next image capture run.

3.5 Switching off the device

If the device is no longer being used, the Seramun SpotSight® scan software must be closed. The USB cable of the device must then be disconnected from the PC.

If the device is not to be used for a longer period of time, it should preferably be stored in the outer box at room temperature in a dry place and protected from dust.

4 Cleaning

Clean the housing of the Seramun SpotSight® well device using damp cloths.

If the device has come into contact with human samples, the disinfectant reagents prescribed by the laboratory must be used.

Do not allow any liquids to get inside the device!

5 Maintenance

Regular maintenance is not necessary.

6 Spare parts

Designation	Item number	Quantity
Seramun SpotSight® well holder	SP-WELL-A-HOLDER	x1
USB connection cable (A/Micro-B)	SP-WELL-A-USB	x1

7 Transport or shipping of the device

Before removing the device from the laboratory or returning it, the device must be cleaned as described in section 4.

The device must be shipped in the original packaging. The accessories of the device (USB cable and well holder) must be returned with the device.

8 Waste disposal

8.1 Disposal of the device

The WEEE Directive stipulates that customers and end users in EU countries must not dispose of electronic and electrical equipment or electronic and electrical accessories with regular household waste. The manufacturer must therefore be contacted before disposal of the device.

Customers outside the EU should also contact the manufacturer before disposal of the device.

8.2 Disposal of the packaging

Packaging must be disposed of in accordance with national and local legal regulations.

9 Troubleshooting

Seramun SpotSight® well does not have an error display. Possible errors that may occur are:

Observed error	Possible cause	Troubleshooting measures
SPOTSIGHTW drive not visible/not accessible on PC screen	USB cable connection not plugged in correctly	Check USB cable connection and reconnect cable
	USB cable defective	Request a replacement cable from the manufacturer
	Internal MicroSD card renamed	Rename MicroSD card to SPOTSIGHTW
	Internal MicroSD card defective	Contact manufacturer
	Files on internal MicroSD card deleted or damaged	Contact manufacturer
Software installation does not start	Internal MicroSD card defective	Contact manufacturer
	Files on internal MicroSD card deleted or damaged	Contact manufacturer
Error message when software connects to device / serial number of device is not displayed in software	USB cable connection not plugged in correctly or USB connection unstable	Check USB cable connection and reconnect cable
		Restart the Seramun SpotSight® scan software, repeat initialisation cycle, repeat scan process
Error message when software connects to device / serial number of device is not displayed in software	Files on internal MicroSD card damaged	Reinstall Seramun SpotSight® scan software with setup[1]
Images are not transferred to the connected PC	USB cable connection not plugged in correctly or USB connection unstable	Check USB cable connection
		Restart the Seramun SpotSight® scan software, repeat initialisation cycle, repeat scan process
		Reinstall Seramun SpotSight® scan software with setup[1]
	Well holder has no positioning pin	Order spare part from the manufacturer
Uneven image illumination	Direct proximity of the device to a window	Do not expose the device to direct sunlight

Observed error	Possible cause	Troubleshooting measures
Images blurred	Wells not inserted correctly in the well holder	Insert wells correctly in the well holder

⚠ [1] Note: If the software is reinstalled to rectify the error, the archive of the existing software installation is lost. A backup copy of the archive must be created before a new installation.

If the described faults cannot be rectified, contact the manufacturer. The manufacturer must also be contacted if other faults not described here occur.

10 Technical data

Image capture	Camera type: Resolution: Light source:	CMOS camera, colour 5 megapixels LED light panel, diffuse, white
Dimensions	85 x 85 x 107 mm	
Weight	1.24 kg	
Interface	USB 2.0 (A/Micro-B)	
Power supply	by connected PC via USB (DC, 5V, 1.5A (max.))	

The device complies with the European standards EN 61326-2-6:2006, EN 61326-1:2013, EN 55032:2012, EN 55035:2017, EN 61010-1:2010, EN 61010-2-101:2017.

11 Change history

Version	Section	Changes
2024-01	Entire document	New document