



Spindiag

Rhonda



Rhonda player

For all staff
SD000-01-I04-A01-EN

Instructions for Use

1 Information on this publication

Publication	Version	Changes
29 January 2021	SD000-01-I04-A01-EN	Initial publication in English.

1.1 Intended use

The Rhonda player is a component of an *in-vitro* diagnostic system. The Rhonda player is intended for use in combination with the various Rhonda disks (disposables).

Intended use

The Rhonda player is intended to be used in conjunction with Rhonda disks for *in-vitro* diagnostic purposes whereby the disposable Rhonda disk contains the sample and the application-specific biochemistry for analysis. One or two Rhonda disk(s) per analysis run can be processed. The Rhonda player provides suitable user interfaces to be operated by health care professionals and/or laboratory staff typically at the point-of-care in hospitals and/or in laboratories.


Embedded player software calculates results from the measured analysis data that are obtained during processing of the Rhonda disk(s). The calculated results of a measurement are provided via

suitable interfaces to external IT (e.g. HIS/LIS systems or mobile IT devices).

Based on the results, application-specific decisions can be drawn by responsible persons.

Additional information

The Ethernet port for transmitting the test results to a hospital and/or laboratory information system (HIS/LIS) is disabled by default.

Please contact the Spindiag customer service to discuss your individual requirements and your need for a connection to your hospital and/or laboratory information system (HIS/LIS) (see section [1.5 Manufacturer information](#)  5 in the *Instructions for Use*).

Please visit the Spindiag website to find out about existing connection options that have already been validated.

Spindiag website: www.spindiag.de

Indication

Indications for use of the Rhonda player are defined via the Rhonda disk-specific indication.

Contraindication

Contraindications for use of the Rhonda player are defined via the Rhonda disk-specific contraindications.

 *Instructions for Use of the respective Rhonda disk*

1.2 User information

Please read these Instructions for Use before working with the Rhonda player.

Keep the Instructions for Use in a safe, easily accessible place.

We would like our language to be as inclusive as possible. We have therefore used neutral formulations wherever possible.

The user information for the Rhonda player comprises:

- *Rhonda player - Instructions for Use*
- *Rhonda player - Network and Service Documentation*

The user information for the relevant Rhonda disk comprises:

- *Rhonda disk - Instructions for Use*
- *Rhonda disk - Analytical Principles*

1.3 Obtaining electronic copies

You can obtain electronic copies of all the Instructions for Use from the Spindiag website. All electronic Instructions for Use are available in a number of different languages.

Tablets, smartphones and the latest computers can display the electronic Instructions for Use directly in PDF format.

On older computers you will need a software program to display the PDF documents such as Adobe Acrobat Reader. You can obtain Adobe Acrobat Reader from the Adobe website.

 Spindiag website: ifu.spindiag.de
Adobe website: www.adobe.com

1.4 Reporting safety issues relating to the Spindiag system

If any difficulties occur whilst using the Rhonda player or the Rhonda disks, please report these by sending an e-mail to support@spindiag.de. If patients or users are harmed or their safety is affected you must comply with the statutory reporting obligations and deadlines. In such cases you can contact us by e-mail at support@spindiag.de or by telephoning +49 761 600 49 600.


1.5 Manufacturer information



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www.spindiag.de

If you need support on technical issues or training topics, please contact us by e-mail at support@spindiag.de or by telephoning +49 761 600 49 600.

For orders and other sales inquiries please contact us by e-mail at orders@spindiag.de or by telephoning +49 761 600 49 600.

- Please have the serial number of your Rhonda player to hand when contacting us. This is located on the nameplate (see [Abb. 3.2](#)  14).
- Do not attempt to repair the Rhonda player yourself.

1.6 Product names

These *Instructions for Use* refer to the following products.

Rhonda player

Processing device

Rhonda app

Optional app for tablets and the Rhonda player

Rhonda disk

Generic product name for all Rhonda disks

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2 Safety

Types of safety information

The colors below and the signal words *Warning*, *Caution* and *Notice* indicate the severity of a safety hazard or risk.



WARNING

SEVERE HAZARDS

- ▶ Failure to follow these warnings can lead to *severe personal injury*.



CAUTION

HAZARDS

- ▶ Failure to follow these warnings can lead to *mild or moderate personal injury*.

NOTICE

IMPORTANT INFORMATION

- ▶ Failure to follow these information can lead to *damage to property*.

Safety information of "Caution" type

Electric shock

The Rhonda player is still connected to power when the switch is in the OFF position (NO galvanic separation).

- ▶ To switch the Rhonda player OFF for maintenance, remove the power supply unit from the rear of the Rhonda player.
- ▶ Only use the Rhonda player with the power supply unit supplied and the power cable supplied.
- ▶ Do not operate the OFF switch or the power supply unit if your hands are wet.

Risk of injury from damage to the Rhonda player and risk of incorrect test results

Disks made by other manufacturers may generate incorrect test results and damage the Rhonda player.

- ▶ Use original Rhonda disks only.


Hazard due to high-frequency radiation or permanent magnets

Using the internal Bluetooth® module or the built-in permanent magnets may cause interference with pacemakers.

- ▶ If you have a pacemaker or other electrical medical device, consult your doctor before using the device.

Hazards due to improper use

Failure to follow the Instructions for Use or improper use of the Rhonda player may cause defects, personal injury or damage to property, hazardous situations or incorrect test results.

- ▶ Use original Rhonda disks only.
- ▶ Only load the Rhonda disks with the designated sample materials.
- ▶ Measurements must only be performed by training and instructed users.
- ▶ Maintenance works must only be performed by qualified and instructed personnel.
- ▶ Only clean the Rhonda player with the designated cleaning agents (see [7.1 Cleaning](#)  34).
- ▶ Keep these Instructions for Use in a safe place.
- ▶ Use the correct, updated version of the Instructions for Use. Go to www.spindiag.de to check for the latest version.

Environmental influences

Risk of malfunction, damage to Rhonda player or personal injury.


- ▶ The Rhonda player must not be exposed to direct sunlight, to avoid compromising the integrity of the measurement results.
- ▶ Do not operate the Rhonda player in areas with high levels of atmospheric humidity and avoid direct contact with liquids.
- ▶ Do not allow liquids to penetrate into the Rhonda player.

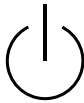
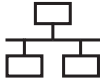







Heat hazards

Risk of malfunction, damage to Rhonda player or personal injury.

- ▶ Do not expose the Rhonda player to severe heat sources.

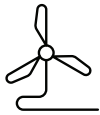
List of symbols of the Rhonda player

	CE mark in accordance with Directive 98/79/EC
	Read the Instructions for Use
	Manufacturer Located on the nameplate on the back of the Rhonda player
	Date of manufacture Located on the nameplate on the back of the Rhonda player
	Catalog number Located on the nameplate on the back of the Rhonda player
	Serial number of the Rhonda player Located on the nameplate on the back of the Rhonda player
	Power consumption Located on the nameplate and the Rhonda player both on the back of the Rhonda player
	Note on disposal of electrical equipment in accordance with WEEE Directive Located on the nameplate on the back of the Rhonda player

	On/off switch Located on the back of the Rhonda player
	Ethernet port Located on the back of the Rhonda player
	USB port Located on the back of the Rhonda player
	<i>In-vitro</i> diagnostic medical device Located on the nameplate on the back of the Rhonda player
	Global Trade Item Number Located on the nameplate on the back of the Rhonda player
	Do not use if package is damaged On transport packaging
	This way up On transport packaging
	Keep away from rain On transport packaging
	Fragile; handle with care On transport packaging



Temperature limit
On transport packaging



Indicates that the Rhonda player is in
power saving mode



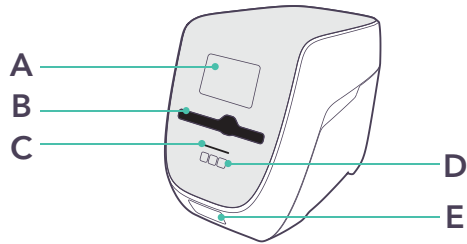
Bluetooth®-compatible
The Bluetooth Special Interest Group
(SIG) is the owner of the Bluetooth®
word mark and figure marks (logos)
(the Bluetooth trademarks). They are
used by Spindiag GmbH under
license.



3 Overview

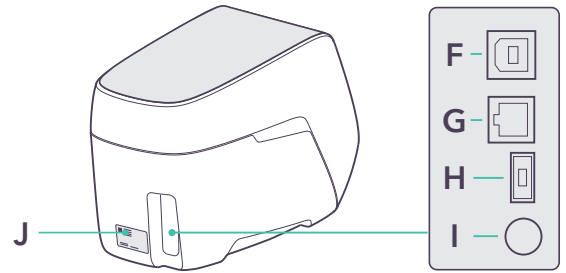
3.1 Components of the Rhonda player

The Rhonda player and the various Rhonda disks form a system for rapid detection of infectious pathogens. They can analyze one sample in one Rhonda disk or two samples in two Rhonda disks simultaneously per analysis run.



- A Display
- B Disk slot for inserting/removing Rhonda disks
- C Status indicator
- D Touch buttons 1, 2 and X
- E Barcode scanner

Abb. 3.1 Front view of Rhonda player



- F USB port
- G Ethernet port
- H Power connection
- I On/off switch
- J Nameplate with serial number

Abb. 3.2 Rear view of Rhonda player

A range of different test-specific Rhonda disks are available.

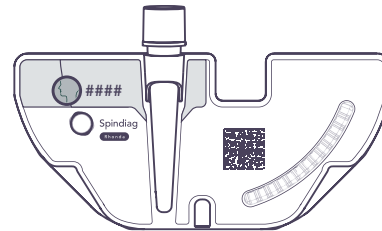


Abb. 3.3 Example of a Rhonda disk

The procedure required for taking samples from patients will depend on the precise Rhonda disk used.

I For suitable sample material, see *Instructions for Use* for the specific Rhonda disk

3.2 Operating principles

The operation of the Rhonda player is based on a consistent set of principles. So you'll quickly and intuitively learn how to use it.

Barcode scanner and user barcode cards


Every user must log on to operate the Rhonda player. Logon is by personal, non-transferable user barcode cards which are enclosed with the Rhonda player and distributed under internal guidelines of your facility (see [4.2 Changing settings](#)  22).





Abb. 3.4 User barcode card



You can scan your personal user barcode card and patient barcode using the barcode scanner on the Rhonda player.

You must scan your user barcode card with the barcode scanner on the Rhonda player every time you want to start operating the device (e.g. initiating an analysis, canceling an analysis, displaying results). You are then logged on until the action is complete.


You do not have to log off from the Rhonda player or save anything on the player. You are automatically logged off after a predefined time.

functionality

You can process 1 or 2 Rhonda disk(s) at the same time. Select  or  on the Rhonda player before the test. Once you have entered the selected number of Rhonda disks the analysis starts automatically.

You can change the number of Rhonda disks by simply selecting  or  at any time until the analysis starts. Once the analysis has begun, however, you cannot add any more Rhonda disks. Wait until the analysis is complete before processing more Rhonda disks.

functionality

If there is an emergency and you need to cancel an analysis while it is running, hold down the  button for **more than 3 seconds**. You cannot re-insert Rhonda disks that have been used in a canceled analysis in the Rhonda player for another analysis; they must be disposed of.




CAUTION

RISK OF INFECTION, RISK OF INCORRECT TEST RESULTS




Removing the swab from a prepared Rhonda disk after an analysis causes uncontrolled carry-over of sample material and reagents.

- ▶ Do NOT open a Rhonda disk if it contains a swab.
- ▶ Do NOT remove a swab after it has been inserted into the Rhonda disk.
- ▶ Dispose of processed or invalid Rhonda disks unopened.

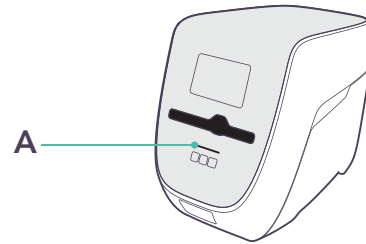
Pressing the  button **for less than 3 seconds** returns you to the previous step. You can also do this at the last step to log off from the Rhonda player manually. You will only need to log off manually on rare occasions, for example if another user wants to log on.

Power saving mode

The Rhonda player is designed for continuous operation and should be kept permanently switched on to prevent testing delays. The Rhonda player automatically switches to power saving mode to protect the components and the environment. The status indicator and the touch buttons flash white when the player is in power saving mode.

You can wake the Rhonda player from power saving mode at any time by selecting ,  or , scanning your personal user barcode card or removing a processed Rhonda disk if one is present in the disk slot. The Rhonda player will be ready to operate immediately.

Status elements

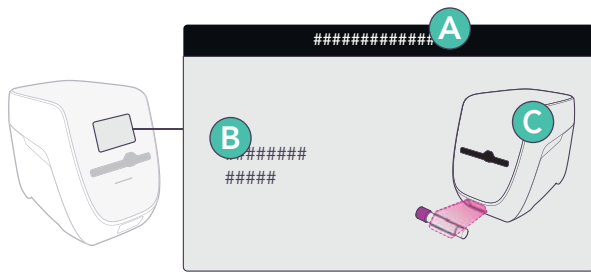


A Status indicator

Abb. 3.5 Front view of Rhonda player

The status indicator has four colors which it uses to display as follows:

- White: ready
(flashing = power saving mode)
- Blue: Analysis running
- Turquoise: Analysis completed successfully
- Pink: A problem has occurred



- A** Status
- B** Instruction for action required
- C** Illustration of action required

Abb. 3.6 Elements on display

Status **A** corresponds to the color shown on the status indicator. **B** describes the action to be carried out and **C** illustrates it.

Data security

The Rhonda player processes the user data and patient information that the user records on the barcode scanner, and assigns them to the test results. You should only record numerical, pseudonymized identifiers on the scanner, with no unencrypted names or dates of birth.

The operator is responsible for complying with data protection law.

You should only use the Rhonda player in a protected area that is secured against unauthorized access.

If you return the product to the Spindiag customer service, make sure there is no personal data on the Rhonda player.

3.3 Analysis principle

The Rhonda disks allow for fully automated *in-vitro* diagnostic testing. The analysis principle using the Rhonda disks is based on real-time polymerase chain reaction (PCR). The Rhonda disks contain all the reagents required to test the sample once it is inserted. The Rhonda player heats and spins the Rhonda disks for the analysis in a predefined sequence. You may occasionally hear a noise while the disk is being analyzed. This is normal. During the analysis the Rhonda disks generate a fluorescence signal which the Rhonda player measures and assess at the end of a run.

 For details of the analysis principle and data analysis, see *Analytical Principles for the specific Rhonda disk*

4 Installation

4.1 Setting up the Rhonda player

You need to set up a new Rhonda player before testing samples. Any user can set up the Rhonda player with no restrictions. Hospital technicians and IT employees can commission the Rhonda player completely and connect it with a POCT middleware or hospital/laboratory information system (HIS/LIS).





WARNING

RISK OF PERSONAL INJURY AND DAMAGE TO PROPERTY

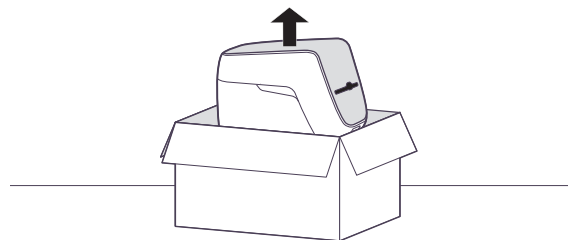
The Rhonda is a heavy piece of equipment. You should take this into account when lifting the Rhonda player to avoid personal injury or damage to property.

- ▶ Use suitable lifting techniques, hold the bottom of the Rhonda player tight with both hands and ensure the Rhonda player is securely positioned when it is lowered into place.
- ▶ Always lift the Rhonda player in an upright position. Do not jolt the player.

1. **CAUTION!** Damage impairs the safety and functioning of the Rhonda player. Damaged Rhonda players must not be commissioned. Check the Rhonda player packaging for damage.

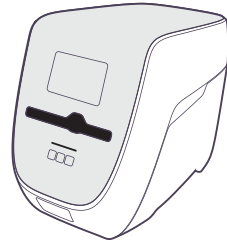
- ① If there is any, please contact the Spindiaag customer service.
[1.5 Manufacturer information](#)  5
- ① The weight and dimensions of the Rhonda player are provided in chapter [8.4 Technical data](#)  38.

2. Lift the Rhonda player out of the packaging and place it on a stable base.

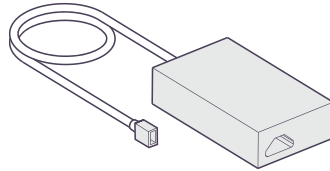


3. Check that all the components have been delivered:

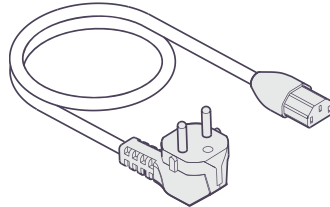
Rhonda player
ESDR11-MB-1000



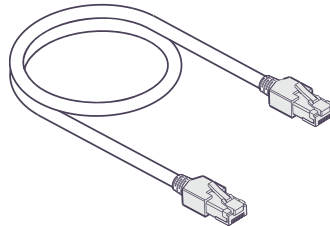
Power supply unit
(PSU)
SD000-01-S02-A01



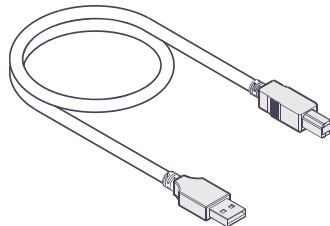
Power cable
SD000-01-S03-A01



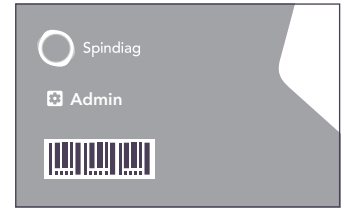
Ethernet cable
(optional)
SD000-01-S01-A01



USB cable
(optional)
SD000-01-S04-A01



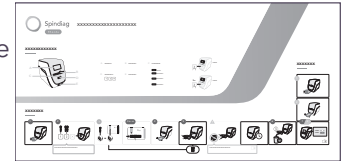
Administrator
barcode card
SD000-01-S05-A01



User barcode cards
(10 pcs)
SD000-01-S06-A01



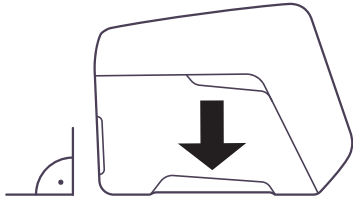
Rhonda player -
Quick Reference Guide
SD000-01-I06-A01-EN



Rhonda player -
Instructions for Use
SD000-01-I04-A01-EN


4. **CAUTION!** Risk of injury during operation if installed at an unsuitable site

Select an installation site for the Rhonda player that meets the following specifications:

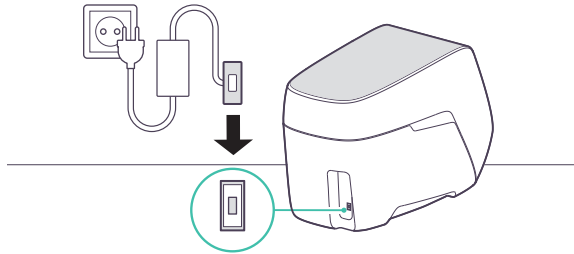


- Select a stable, level, dry and clean work surface.
 - Ensure that the area is protected against excessive atmospheric humidity and exposure to dust, direct sunlight, severe fluctuations in temperature, heat sources and vibrations.
 - **Caution!** Always keep the Rhonda player a safe distance (approximately 10 cm) away from other objects.
 - **Caution!** Do not install ANY other equipment within this safety radius and do not store ANY hazardous materials there.
 - **Caution!** Do not spend any more time within the safety radius than absolutely necessary to operate the equipment.
 - **Caution!** Do not lean on the Rhonda player.
- Do NOT block the airflow to the sides of the Rhonda player. Do not cover any slots or openings used to ventilate the Rhonda player.
 - The Rhonda player must NOT be installed or operated in the immediate vicinity of sources of electromagnetic radiation such as unshielded HF sources since these can prevent the Rhonda player from working properly.
 - The Rhonda player needs unhindered access to the disk slot for the Rhonda disks, the back of the Rhonda player, the on/off switch, the barcode scanner, the display and the touch buttons.
 - When installing the Rhonda player, ensure that the power supply unit is not hidden and the Rhonda player can be disconnected from the electricity supply at any time.

5. Place the Rhonda player on the work surface.

- ① Before installing and using the Rhonda player, read the chapter [8.4 Technical data](#)  38 to familiarize yourself with the operating conditions (temperature and humidity) of the Rhonda player.

6. **CAUTION!** You are at risk of coming into contact with hazardous electric current if you use a damaged or unauthorized power supply unit. Connect the following components:



- a. The power cable to the power supply unit
 - b. The power supply unit to the Rhonda player
 - c. The power cable to a wall socket
- i Do NOT use power strips.
 - The Rhonda player switches on automatically and the status indicated is *Ready*.
 - i You can now use the Rhonda player in standalone mode without connecting it to any IT system.
 - i Before the Rhonda player can be connected to your hospital/laboratory information system (HIS/LIS), your in-house IT employee must complete commissioning.
 - i Alternatively you can connect the Rhonda player to the Rhonda app for tablets.

7. Keep a record to show that the Rhonda player is properly installed.

 [Rhonda player - Network and Service Documentation](#)

4.3 Optional: connecting Rhonda app  23

4.2 Changing settings

Persons responsible for the equipment who have an administrator barcode card can configure the Rhonda player. See below for how to use the predefined barcodes to configure the device.


Are the required materials available?

- Administrator barcode card

Preconditions met?

- The Rhonda player status shows *Ready*.

You can only log in as Administrator when the status shows *Ready*.

1. Log in with your administrator barcode card.
 - The Rhonda player displays the main menu for persons responsible for the equipment.
2. Follow the instructions on the display.
3. Use the barcodes shown in chapter [8.5 Barcodes for configuration](#)  40, for example to change the language.

4.3 Optional: connecting Rhonda app

The Rhonda app is an added option for connecting the Rhonda player. You can also use the Rhonda app to configure the Rhonda player.

Are the required materials available?



- ❑ Prepared tablet

The tablet is available from Spindiag as an option.

- ❑ Administrator barcode card

1. Scan the administrator barcode card.
 - ☑ The Rhonda player displays the main menu for persons responsible for the equipment.
2. Open the Rhonda app on the tablet.
3. Switch the Rhonda player to Bluetooth® pairing mode by following the instructions in the Rhonda app and on the Rhonda player.

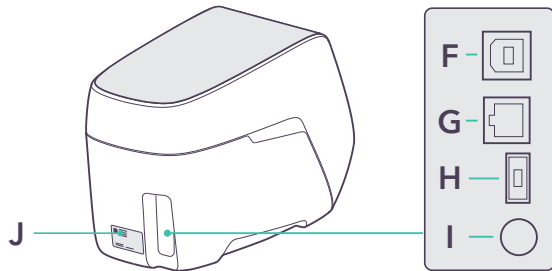
4.4 Changing Rhonda player installation site

1. Shut down the Rhonda player.
[8.2 Shutting down the Rhonda player](#)  37
2. **NOTICE** Always transport the Rhonda player in an upright position.
Transport the Rhonda player to the new installation site. You may need to use an aid such as a trolley to move the player. Use both hands when transporting the player. Do not jolt the player.
3. Position the Rhonda player at the new installation site in accordance with [4.1 Setting up the Rhonda player](#)  19.

5 Operation

5.1 Switching Rhonda player on and off

The on/off switch is located on the back of the Rhonda player.



- | | |
|---------------------------|---------------------------------------|
| F USB port | I On/off switch |
| G Ethernet port | J Nameplate with serial number |
| H Power connection | |

Abb. 5.1 Rear of Rhonda player

The Rhonda player has a transport lock. The transport lock *unlocks* the Rhonda player when it is *switched on* and *locks* it when it is *switched off* under controlled conditions. Before the Rhonda player switches off it sends all remaining test results to a POCT middleware or hospital/laboratory information system (HIS/LIS) as applicable. If sending is not possible the Rhonda player displays an error message.

While the Rhonda player is processing or ejecting Rhonda disks, or there are still Rhonda disks in the Rhonda player disk slot, the off switch cannot be operated and generates an error message.

The switching off procedure is canceled if an error message appears. Do NOT remove the power cord from the Rhonda player.

[4.1 Setting up the Rhonda player](#) [19](#)
[User information Rhonda player - Network and Service Documentation](#)

5.2 Analyzing samples

You can analyze 1 or 2 samples at the same time. They may be 2 samples from different patients or 2 samples from the same patient.

Are the required materials available?

- Original Rhonda disks

You CANNOT use all Rhonda disks in combination to test 2 samples at the same time. If you are testing 2 samples at the same time, check the permitted combinations for the different Rhonda disks: See [Instructions for Use](#) for the specific Rhonda disk

- Your personal user barcode card

Preconditions met?

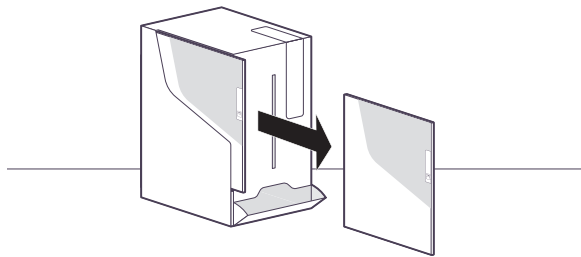
- ❑ You are wearing gloves and further personal protective equipment such as gowns, face shields, masks, and eye protection in accordance with regional and lab-specific policies.
- ❑ You have taken patient samples.

Suitable sampling kit and sample material:
See [Instructions for Use](#) for the specific Rhonda disk


- ❑ The sample is marked with a patient barcode.

▶ Preparing the sample

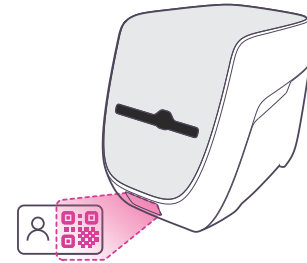
1. To prepare the sample, see [Instructions for Use](#) and [Quick Guide](#) for the specific Rhonda disk.



▶ Preparing the Rhonda player


1. Remove any old Rhonda disks from the disk slot and dispose of them.
 - ❶ See [Instructions for Use](#) for the specific Rhonda disk.
 - ❶ See [5.4 Removing Rhonda disks](#)  29

2. Scan your personal user barcode card.





3. **CAUTION!** Canceling a test delays test results and may mean a new sample has to be taken from the patient. Only cancel the analysis if absolutely necessary.

If an analysis is currently running, you can either:


- a. come back later.
- b. Or, to stop an analysis while it is running, hold down the  button **for more than 3 seconds.**

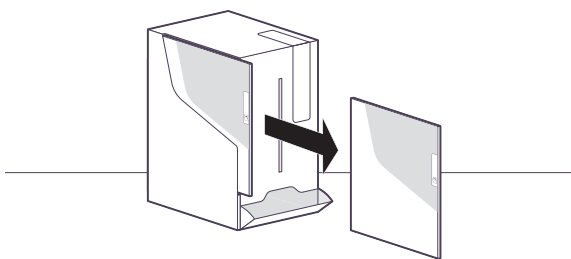
- ❶ You CANNOT reuse the Rhonda disks after the analysis is canceled. See [Instructions for Use](#) for the specific Rhonda disk.

4. You can analyze 1 or 2 samples at the same time:

- a. For 1 sample, select .
- b. For 2 samples, select .

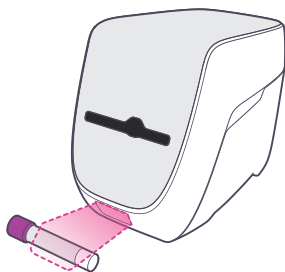
▶ Preparing the Rhonda disk

1. **CAUTION!** sample mix-ups where 2 samples are inserted: Prepare the Rhonda disk using sample 1 first and insert the Rhonda disk with sample 1 first (see ▶ [Starting the test](#)  27) before starting on sample 2.
To prepare the Rhonda disk, see [Instructions for Use](#) and [Quick Guide](#) for the specific Rhonda disk.



▶ Starting the test

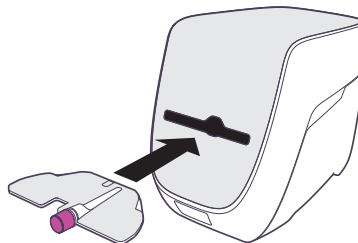
1. Scan the patient barcode for sample 1.




2. **CAUTION!** When inserting/removing the Rhonda disk, make sure your hand or fingers do not enter the disk slot. Do not insert any items other than Rhonda disks into the disk slot.

Insert the Rhonda disk with sample 1 into the disk slot,

- a. holding the Rhonda disk by the sample cap. The Rhonda player automatically scans and detects the specific Rhonda disk.
- b. Ensure that the patient data on the sample match the patient data on the display:
Sample mix-up ruled out?
Rhonda disk matches required test?



- ✓ If you selected 1 sample earlier the analysis starts after 10 seconds.
- ⓘ At this point, you can still increase the number of samples to be processed by selecting .

- i The Rhonda player will not accept any Rhonda disks that have passed their expiration date, Rhonda disks that have been used previously or Rhonda disks that are not installed on the Rhonda player. In these cases an error message is displayed and the Rhonda disk is rejected. If this is the case, the Rhonda disk must be disposed of.
 - i No excessive force is required when inserting the Rhonda disk into the Rhonda player. If you have inserted the Rhonda disk correctly into the disk slot, the Rhonda player automatically retracts the Rhonda disk.
- 3.** If you selected 2 samples earlier, repeat all steps starting with ▶ [Preparing the Rhonda disk](#) 📖 27 with sample 2.
- The test will start after the Rhonda disk with sample 2 is inserted.
 - i At this point, you can still reduce the number of samples to be processed by selecting 1.
 - i The testing time for 2 samples is the same as the testing time for 1 sample.

5.3 Implementing quality controls

Spindiag explicitly recommends conducting regular measurements with external quality controls. The procedures to be followed for routine testing of patient samples and for quality controls are identical. It is only the sample material that is different.

The precise quality controls to be conducted depend on the specific Rhonda disk used and are described in the application-specific [Instructions for Use](#) for the Rhonda disk.

Depending on how regional and laboratory-specific policies are applied, the Rhonda player will indicate when quality control is required. Depending on what mode is configured, this may mean that no further testing can be performed until quality control measurements have been successfully conducted. For more details, see regional and laboratory-specific policies.

📖 5.2 Analyzing samples 📖 25

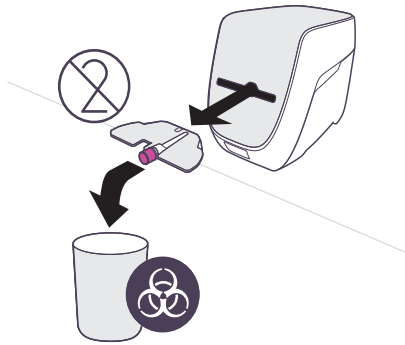
For information on quality controls, see [Instructions for Use for the specific Rhonda disk](#)

5.4 Removing Rhonda disks

When an analysis is complete the Rhonda player automatically ejects the Rhonda disk(s).

1. **CAUTION!** If the analysis shows an error, refer to chapter 6 [Troubleshooting](#)  31.

Remove the Rhonda disk from the Rhonda player and dispose of the Rhonda disk.



 For information on disposing of Rhonda disks, see *Instructions for Use* for the specific Rhonda disk.

5.5 Displaying results

You can display test results for completed tests on the Rhonda player display at any time.

The Rhonda player displays the test results immediately after the test.

Dispose of ejected Rhonda disks properly.

[5.4 Removing Rhonda disks](#)  29

▶ Displaying results - at a later point in time

1. Scan your personal user barcode card.
 - ① If another test is running you can still display the results of an earlier test.
2. Scan the relevant patient barcode.
 - ☑ The Rhonda player displays the results associated with the barcode.

Possible test results

The Rhonda player displays a qualitative result *positive* or *negative* for all the different Rhonda disks:

- *Positive* means that the analyte(s) targeted by the Rhonda disk is/were *detected*.
- *Negative* means that the analyte(s) targeted by the Rhonda disk was/were *not detected*.

See also [1.1 Intended use](#)  2.

A test may also show the result *Invalid*, *Locked* or *Analyzing*:

- *Invalid* means that the Rhonda disk is part of a lot that has generated an invalid result in in-house quality control tests. A test may also be invalid if the controls integrated in the Rhonda disk do not match expected values and it is therefore impossible to verify that no errors occurred during the test.

If applicable, contact your Quality Officer.

You may be able to prepare a substitute sample to conduct a second test.

See [Instructions for Use](#) for the specific Rhonda disk.

- *Locked* means that the sample was analyzed with a Rhonda disk that is part of a lot that has not yet been tested in in-house quality control tests. You should ensure that the latest quality

control test is conducted quickly to unlock the result.


- *Analyzing* means that the sample is still currently being tested. Come back later.

 For more details on results, see [Analytical Principles](#) for the specific Rhonda disk



6 Troubleshooting

If an error occurs, an error message will usually appear on the Rhonda player display. These are errors that you can fix yourself and then carry on or start the task you originally planned. Simply follow the instructions on the display.

If a message appears on the display referring you to the person responsible for the equipment, or the Spindiag customer service, please contact the person responsible for the equipment so they can fix the error or ask the Spindiag customer service to do so (see chapter [1.5 Manufacturer information](#)  5). Wherever possible, make a note of the error code on the display to quote to the person responsible for the equipment or the Spindiag customer service.

In this section we look at how to fix errors that cannot be fully explained on the Rhonda player display.

Scanned user ID not valid

Description of error: Either the barcode scanned does not belong to a user barcode card or the user barcode card scanned belongs to a blocked or expired username.

How to fix the error: Ensure that you scan a user barcode card when prompted. If the error persists, ask the person responsible for the equipment to activate your user barcode card. This may require training (or re-training).

No connection to local network

Description of error: The Rhonda player is configured for a connection to a server software program but there is no network cable connected.

How to fix the error: Follow the instructions on the display to make a connection. Alternatively, if this status is indicated, the person responsible for the equipment can log in with an administrator barcode card and disable the connection to the server software.



7 Maintenance

7.1 Cleaning

You can only clean the surfaces of the Rhonda player; this may be done on a routine basis or as required.

Are the required materials available?

- ❑ Cleaning cloth
- ❑ Suitable cleaning solution:
70% ethanol or
10% bleach
- ❑ Water
- ❑ Paper towels

Preconditions met?

- ❑ You are wearing gloves and further personal protective equipment such as gowns, face shields, masks, and eye protection in accordance with regional and lab-specific policies.
- ❑ The Rhonda player is NOT currently processing any Rhonda disks.

NO cleaning is required following a sample analysis. This is because it is only the Rhonda disks that come into contact with the sample during analysis, not the surfaces of the Rhonda player.



CAUTION

RISK OF INFECTION, RISK OF INCORRECT TEST RESULTS AND RISK OF PERSONAL INJURY AND DAMAGE TO PROPERTY

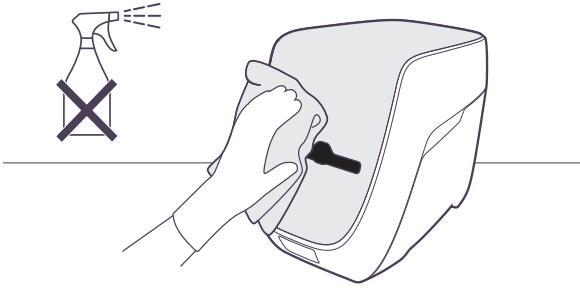
- ▶ DO NOT use aggressive cleaning agents such as acetone.
- ▶ DO NOT spray cleaning agents on the Rhonda player.
- ▶ If there is reason to suspect that the interior of the player is contaminated, please contact the Spindiag customer service.

NOTICE

RISK OF DAMAGE TO THE RHONDA PLAYER

- Damage caused by spilt liquid invalidates the warranty.
- ▶ Ensure that no chemicals or other liquids penetrate the Rhonda player or leak out of it.

1. Soak the cleaning cloth in the cleaning solution.
2. Clean all accessible surfaces on the Rhonda player.



3. Wet a paper towel with water and remove any residual cleaning agent by wiping down the surface of the Rhonda player. Repeat this procedure twice.
4. Dry the surface of the Rhonda player with a clean paper towel.

8 Technical information

8.1 Obtaining Rhonda disks





You can obtain Rhonda disks directly from Spindiag or from authorized dealers. The Spindiag website contains ordering options and a list of authorized dealers.

 [Spindiag website: www.spindiag.de](http://www.spindiag.de)

8.2 Shutting down the Rhonda player

1. Remove all old Rhonda disks from the Rhonda player.
2. Switch the Rhonda player OFF. If prompted on the display remove the plug from the socket and then disconnect the power cable from the Rhonda player.
3. If the Rhonda player is connected via an Ethernet and/or USB cable, disconnect these too.
4. Store the Rhonda player in a place that is protected against dust and humidity until its next use.

8.3 Disposing of the Rhonda player

1. Shut down the Rhonda player as described in [8.2 Shutting down the Rhonda player](#)  37.
2. Return the Rhonda player for disposal to Spindiag.
 - ① Ensure that you return the Rhonda player in the original packaging used for the faulty or replacement Rhonda player. If the original packaging is not available, please contact the Spindiag customer service (see [1.5 Manufacturer information](#)  5). Ensure that the Rhonda player is properly prepared (see [8.2 Shutting down the Rhonda player](#)  37) before placing it in the packaging.
 - ① Ensure that it does not present a biological or chemical hazard. You must submit a written declaration of clearance to Spindiag. If there is, or you suspect there may be a biological or chemical hazard, please contact the Spindiag customer service (see [1.5 Manufacturer information](#)  5)

8.4 Technical data

Environmental conditions during operation

Mains supply requirements	External power supply: AC input: 100 - 240 V, 3 A, 50 - 60 Hz; DC output: 24 V, 9.16 A Power supply for Rhonda player: DC input 24 V DC +/- 2%: 9.16 A. Operate the Rhonda player with the PSU supplied only.
Fuse	1 × 10 A, fast switching (cannot be replaced by user)
Overvoltage category	II
Pollution degree	Pollution degree 2 in accordance with DIN EN 61010-1
Temperature	15°C - 35°C
Atmospheric humidity	20% - 80% rel. atmospheric humidity, non-condensing
Operating altitude ("standard elevation zero")	0 to 3000 m



Transport conditions

Temperature	+5°C - +40°C
Humidity	5% - 85% rel. atmospheric humidity, non-condensing

Storage conditions

Temperature	+5°C - +40°C
Humidity	5% - 85% rel. atmospheric humidity, non-condensing

Mechanical data and features

Dimensions	Width: 233 mm Height: 296 mm Depth: 414 mm
Weight	12 kg
Type of test	Determined by specific Rhonda disk
Number of tests	1 Rhonda disk per test or 2 Rhonda disks per test simultaneously
User inputs	3 touch buttons on the front: 
Barcode scanner	External scanner supports: Data matrix (2D), EAN-13 (1D); code 128 (1D) Internal scanner scans barcodes on Rhonda disk when inserted. If the barcode formats you use are unsupported contact Spindiag customer service (1.5 Manufacturer information  5).
Noise	< 75 dB
Ethernet port	Rear of Rhonda player: 1 × 10/100 Base-T-Ethernet for connecting to hospital/laboratory information system (HIS/LIS) or via POCT middleware Input/output voltage 3.3 V

USB ports	Rear of Rhonda player: 1 × USB 2.0 Type B for connecting authorized accessories Input/output voltage 4.75 V - 5.35 V
Wireless interface	Bluetooth® Low Energy (LE)
Storage capacity	Up to 1000 test results
Display	800 × 480 pixels RGB, 4.3" IPS TFT, brightness up to 800 cd/m ²

8.5 Barcodes for configuration

Persons responsible for the equipment who have an administrator barcode card can use the following barcodes to configure the Rhonda player

4.2 Changing settings  22

Change language

German



Change time zone

Europe/Berlin





carbon neutral
natureOffice.com | DE-616-JRYLGT7
print production

