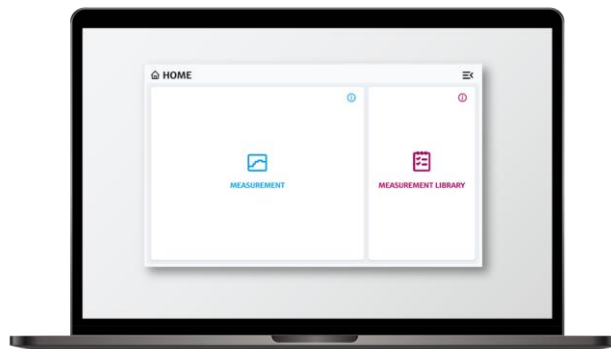


Operating instructions

Device + Control Software



REF: BAB00-A00A1+PA

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1 About this document

1.1 Document function

These operating instructions contain all information about the Device with accompanying Control Software in the following mainly referred to as “Device” and “Control Software”. Great care has been taken to ensure that all information contained in the operating instructions is correct and complete at the time of publication.

This document describes the state at the time of publishing. It needs not necessarily to agree with future versions. These operating instructions as well as the Endress+Hauser Analysis System is subject to change without notice.

1.2 Warnings

The structure of the information and their meaning are shown in [Table 1](#).

Structure of Information	Meaning
⚠ WARNING Causes (/consequences) ▶ Corrective action	This symbol alerts you to a dangerous situation. Failure to avoid the dangerous situation can result in a fatal or serious injury.
⚠ CAUTION Causes (/consequences) ▶ Corrective action	This symbol alerts you to a dangerous situation. Failure to avoid this situation can result in minor or more serious injuries.
NOTICE Cause/situation ▶ Action/note	This symbol alerts to situations which may result in loss of function or damage to property.

Table 1: The structure of information symbols and warnings and their meaning.

1.3 List of abbreviations

In [Table 2](#) all abbreviations and their description used in this document are listed in alphabetical order.

Term	Description
°C	Degree Celsius
AC	Alternating Current
CE	European Conformity (from French « Conformité Européenne »)
DC	Direct Current
EEA	European Economic Area
I/O	Input/Output
IVD	In vitro diagnostics
m / cm / mm	Meter / centimeter / millimeter
PCR	Polymerase chain reaction
UserID	Barcode for user login in the Device
Connect Code	Barcode for connecting to the Control Software
V	Volt
W	Watt
WEEE	Waste Electrical and Electronic Equipment

Table 2: Abbreviations and their description used in this document.

1.4 Symbols on the device

In [Table 3](#) all symbols on the device and their description are listed.





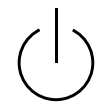


Symbol	Description and placement
	The CE Marking indicates conformity with health, safety, and environmental protection standards for products sold within the EEA. On the type plate.
	The WEEE symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. On the type plate.
	Please read operating instructions. On the type plate.
	Power consumption. On the type plate.
	On/off switch. On the back of the Device.
	Ethernet interface. On the back of the Device.
	USB interface. On the back of the Device.

Table 3: Symbols used.

1.5 Registered trademarks

Registered names, trademarks, etc. mentioned in this document should not be assumed to be unprotected by law, even if they are not explicitly marked as registered names or trademarks.

2 Basic safety instruction

2.1 Requirements for the personnel

- Installation, commissioning, and maintenance of the measuring system may be carried out only by specially trained technical personnel.
- The operating personnel must have read and understood these operating instructions and must follow the instructions contained therein.
- Keep the operating instructions in a safe but easily accessible place.

2.2 Intended use

The Device is a Detection Module-based integrated analysis system. It is intended to be used for the targeted analysis of nucleic acids in non-IVD liquid samples. The Device is primarily installed in laboratories, company laboratories, hygiene laboratories, laboratory-type rooms, non-laboratory-type enclosed rooms directly at the end customer (e.g. sewage treatment plants, plants, industrial associations, cruise ships, hotels) or at central facilities. The Device can be operated by personnel with minimum training.

Any use for other purposes is not permitted. Liability for improper use as well as resulting consequences is excluded.

2.3 Electrical safety

The user is responsible for complying with the following safety conditions:

- Installation guidelines.
- Local standards and regulations electromagnetic compatibility.

The product has been tested for electromagnetic compatibility in accordance with the applicable international standards for industrial applications. The electromagnetic compatibility indicated applies only to a product that has been properly connected.

2.4 Operational safety

Before commissioning:

- Verify that all connections are correct.
- Ensure that electrical cables are undamaged.
- Do not operate damaged products and protect them against unintentional operation.
- Label damaged products as defective.

During operation:

- If faults cannot be rectified: products must be taken out of service and protected against unintentional operation.

CAUTION

External influences; risk of malfunction, damage to the Device or personal injury.

- The Device must not be exposed to direct sunlight in order not to influence the integrity of the measurement results.
- Avoid operating the Device in rooms with high humidity and direct contact with liquids.
- Avoid the penetration of liquids into the Device.
- Do not expose the Device to strong heat sources.
- Always lift the Device upright.
- Avoid vibrations.

2.5 Product safety

The product is designed to meet state-of-the-art safety requirements. The Device complies with relevant product safety regulations and meets international safety standards.

CAUTION

Electric shock

- Despite the OFF switch position, the Device is still connected to the mains (not galvanically isolated).
- To switch the Device OFF for maintenance, unplug the power supply unit from the back of the Device.
- Only use the Device with the supplied power supply unit and power cable.
- Do not operate the OFF switch or the power supply unit with wet hands.

WARNING

Danger from permanent magnets

- The built-in permanent magnets can cause interference to people and sensitive devices in the vicinity of the Device.
- If you wear a pacemaker or other electromedical device, consult your doctor before using the Device.
- Operate devices that are sensitive to magnetic fields at a sufficient distance from the Device.
- Handle cards with magnetic strips at a sufficient distance from the Device.

⚠ CAUTION**Hazards due to moving parts and improper use**

The use of moving parts involves the risk of shearing or cutting injuries if a person reaches into the unit. Failure to follow the instructions for use or improper use may result in defects, property damage, personal injury, hazardous situations or incorrect test results.

- Do not reach into the Detection Module slot.
- Only use original Detection Modules. Only load the Detection Modules with the sample materials intended for this purpose (for detailed instructions please refer to the operating instructions of the Kit).
- Measurements may only be carried out by trained and instructed personnel. Maintenance work may only be carried out by qualified and instructed personnel.
- Only clean the Device with the cleaning agents as defined in chapter [9.2 Maintenance tasks](#).
- Use the latest version of the operating instructions. You can obtain digital versions of the latest operation instructions from Endress+Hauser BioSense GmbH on request.

2.6 Important safeguards

- Do not use the Device for anything other than its intended use.
- Do not drape the power cord over counters or on hot surfaces.
- Do not open the enclosure of the Device.

⚠ CAUTION**Risk of injury due to damage to the Device and risk of incorrect test results**

- Detection Modules from other manufacturers can give incorrect results and damage the Device. Only use original Detection Modules.

⚠ WARNING**Risk of personal injury and property damage when lifting the Device**

- The Device is a heavy piece of equipment. Keep this in mind when lifting the Device to avoid personal injury or property damage.
- Use appropriate lifting techniques, hold the Device by the bottom with both hands, and make sure the Device stands securely when setting it down.
- To avoid personal injury, make sure the Device is disconnected from all wired connections before lifting.

3 Product description

3.1 Endress+Hauser BioSense Analysis System

The Endress+Hauser BioSense Analysis System consists of the Device with accompanying Control Software and an application specific Kit. The following operating instructions describe the operation of the Device. Information about the Kit can be found in the separate operating instructions for the Kit.

3.2 Device

The Device includes all the hardware required for controlled Detection Module handling as well as PCR cycling and sensitive fluorescence readout. The accompanying Control Software controls the Device and analyses the data – no manual data interpretation is necessary.

3.2.1 Front panel

Front view of the device with all main parts highlighted in [Figure 1](#). These parts are named in [Table 4](#).

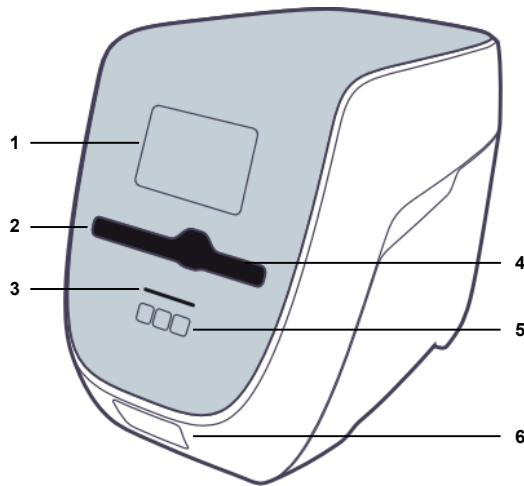


Figure 1: Front view of the Device.

Number	Description
1	Display
2	Detection Module slot
3	Status indicator
4	Internal barcode scanner
5	1, 2, X buttons
6	External barcode scanner

Table 4: Description of the front panel components.

3.2.2 Back panel

Back view of the device with all main parts highlighted in [Figure 2](#)Figure 2. These parts are named in [Table 5](#). Corresponding symbols are displayed in [Table 3](#).

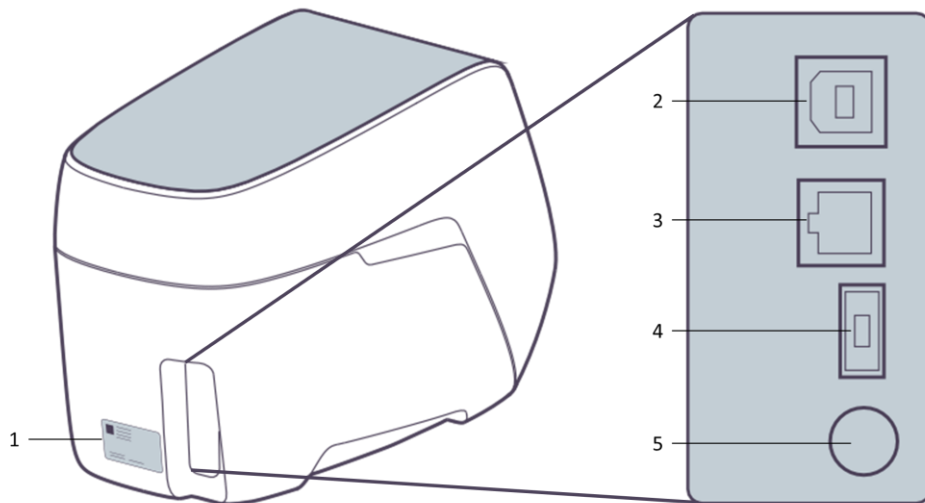


Figure 2: Back view of the Device (left). Zoomed view of the input panel (right).

Number	Description
1	Type Plate
2	USB Port (to connect the device to the Windows PC running the Control Software)
3	Ethernet Port (for service purposes only)
4	Power input
5	ON/OFF switch

Table 5: Description of the back panel components.

3.2.3 Type plate

The type plate is depicted in [Figure 3](#). All parts are described in [Table 6](#).

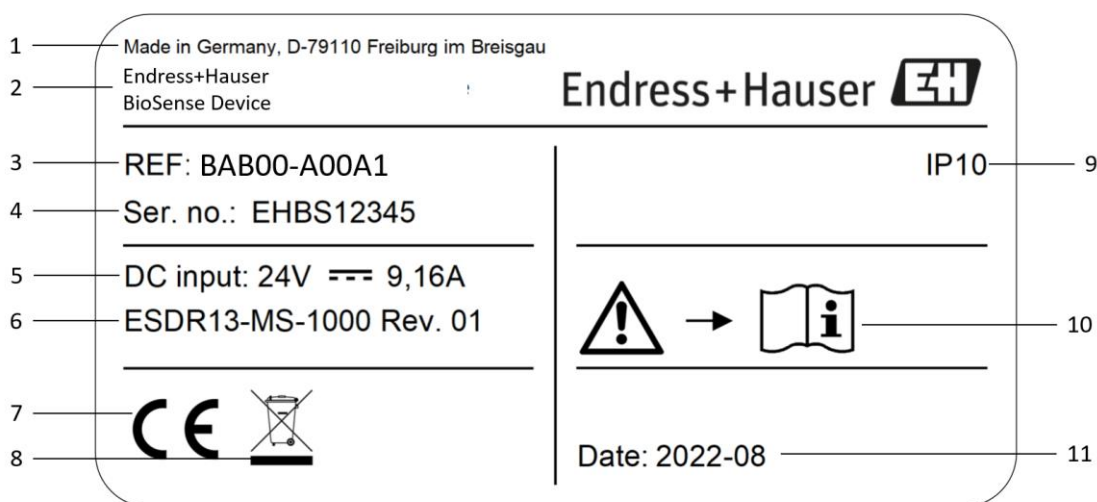


Figure 3: Type plate of the Device.

Number	Description
1	Address of the legal manufacturer
2	Product name
3	Reference number
4	Serial number
5	DC input rating
6	Type plate version
7	CE marking
8	WEEE symbol
9	IP rating
10	Reference to operating instructions
11	Manufacturing date

Table 6: Information on the type plate.

3.2.4 Operator control

3.2.4.1 Barcode scanner and barcodes

The Device's barcode scanner is intended to scan the **UserID** and **Connect Code**.

- **UserID**: The user must log in to operate the Device. For this purpose, a **UserID** card is enclosed with the Device. Start any operation (e.g. start analysis, cancel analysis, display results) by scanning the QR Code on the **UserID** card with the barcode scanner of the Device. This means you are logged in for the duration of the subsequent action. There is no need to log out of the Device or save anything. The user will be logged out automatically after a period without interaction. Keep the **UserID** card safe and protected from unauthorized access by third parties.
- **Connect Code**: Barcode for connecting to the Control Software on the Windows PC.

3.2.4.2 1 and 2-Button

The 1 and 2-Button is intended to select options as displayed on the screen.

3.2.4.3 x-Button

The x-Button is intended to cancel a process by pressing the button for more than 3 seconds or go back to the previous step by pressing the button for less than 3 seconds.

3.2.4.4 Energy saving mode

The Device automatically enters a power-saving mode to save energy. The energy-saving mode is recognizable by a white pulsing of the status indicator and touch buttons and a standby symbol on the device screen. To wake the Device from energy-saving mode at any time, select 1, 2 or x or scan **UserID**.

3.2.5 Status indicator

The status indicator (see [Figure 1](#)) has two colors with the following indications:

- White: Ready (pulsating = energy-saving mode).
- Red: An error occurred.

3.3 Detection Module stand

A Detection Module stand is included in the accessories of the Device. It allows the storage of Detection Modules during preparation.

CAUTION

Risk of contamination

- Make sure to place the Detection Modules with the inlets facing upward in the Detection Module stand to prevent the sample to be spilled on the workplace.

4 Incoming product acceptance and product identification

4.1 Incoming acceptance

1. Verify that the packaging is undamaged. Notify the Endress+Hauser BioSense support (see chapter [10.1 Contact information](#)) of any damage to the packaging. Keep the damaged packaging and goods until the issue has been resolved.
2. Verify that the contents are undamaged. Notify the Endress+Hauser BioSense support (see chapter [10.1 Contact information](#)) of any damage to the delivery contents. Keep the damaged goods until the issue has been resolved.
3. Check that the scope of delivery is complete and nothing is missing. It is recommended to compare the shipping documents with your order.
4. Do not operate damaged products and protect them against unintentional operation. Label damaged products as defective.

4.1.1 Identifying the product

The REF Number and LOT number of the product can be found in the following locations:

- On the type plate (see chapter [3.2.3 Type plate](#)).
- In the delivery papers.

If you have any questions, please contact Endress+Hauser BioSense support (see chapter [10.1 Contact information](#)).

4.1.2 Manufacturer address

Endress+Hauser BioSense GmbH, Georges-Köhler-Allee 302, 79110 Freiburg, Germany

4.2 Scope of delivery

All delivery contents and reference numbers are listed in [Table 7](#).

Part	Quantity	Reference Number (REF)
Device + Control Software	1x	BAB00-A00A1+PA
Control Software	1x	B-1008
Operating instructions device	1x	B-1003
Card with UserID and Connect Code	2x	B-1006
Detection Module stand	1x	B-1001
Power supply unit	1x	SD000-01-S02-A01
Mains cable	1x	SD000-01-S03-A01
USB cable	1x	B-1007
Optional: Laptop with pre-installed Control Software	1x	B-1009

Table 7: List of delivery contents in the Device.

4.3 Product use and warranty

The Device is to be used exactly as described in these operating instructions. It is forbidden to carry out any modifications to the Device. Endress+Hauser BioSense GmbH does not give any warranty for the functionality or reliability of the Device if any modifications are performed to the Device or the Device is not used according to the operating instructions. Endress+Hauser BioSense GmbH is not liable for damages caused by improper use of the Device.

5 Installation

5.1 Site requirements

Select a location for the Device that meets the following requirements:

- Make sure that the area is protected from excessive humidity and dust, direct sunlight, strong temperature fluctuations, heat sources and vibrations.
- Set up a safety area of around 10 cm around the Device where there are no other objects.
- The Device must not be set up or operated in the immediate vicinity of sources with strong electromagnetic radiation (e.g. unshielded RF sources), as these may interfere with the proper operation of the Device.
- The Device requires unobstructed access to the Detection Module slot, the back of the Device, the ON/OFF switch, the barcode scanner, the screen and the touch buttons.
- Position the Device so that the power supply is freely accessible, and the Device can be disconnected from the power supply at any time.

- Before installing and using the Device, read chapter [11 Technical data](#) to learn more about the operating conditions of the Device.

⚠ CAUTION**Risk of injury during operation if installation site is unsuitable**

- Do not place any other equipment or store any hazardous substances in this safety area.
- Do not lean onto the Device.
- Do not cover the ventilation slots and openings of the Device.

5.2 Putting the Device into operation

Lift the Device out of the packaging and place it on a flat and stable surface. Please hold the Device at the bottom. Remove all accessories and check if the package content is complete (see [Table 7](#)).

5.2.1 Initial hardware setup

To operate the Device please connect the following parts:

1. The mains cable to the power supply.
2. The power supply unit to port 4 of the device (see [Figure 2](#)).
3. The mains cable to a wall socket. Do not use a multiple socket.
4. Connect the device to the PC on which the Control Software is installed using the supplied USB cable. The recommended minimum hardware requirements can be found in chapter [11 Technical data](#).

⚠ CAUTION**Risk of coming into contact with dangerous electrical voltage**

- Do not use damaged or incorrect power supply units.

5.2.2 Initial software setup

The software can be requested via contact form: <https://www.endress.com/endress-hauser-biosense-technology-portfolio>

1. Request the software via contact form. You will receive an email containing a download link.
2. After clicking the link, the default browser opens a window, and the download starts automatically.
3. Wait until the download has finished successfully. Now you can close the window.
4. Execute the DeviceControlSoftware-*X.X.X*-win64.exe file in your default download folder.
5. The installer guides you through the installation process.

NOTICE**Use of the Device Control Software by several users on one PC**

- It is possible to use the Device Control software from different user accounts on one PC.
- Each user account that installs the software automatically receives an entry in the start menu and a desktop icon. If other users wish to use the software, they must also carry out the installation.
- All user accounts access one central storage location on the PC for the analyses they have performed.
- If a user uninstalls the software, it is removed for all user accounts and desktop icons no longer work. The data from the analyses performed is retained in the central storage location.

6 Commissioning

6.1 Starting the device for the first time

The ON/OFF switch is located on the back of the Device (see [Figure 2](#)). The Device has a transport lock. The Device unlocks the transport lock when the ON/OFF switch (see [Figure 2](#)) is switched to ON and locks it when it is switched OFF in a controlled manner. While the Device is processing or ejecting Detection Modules or while there are still Detection Modules in the Detection Module slot of the Device, switching OFF is not possible and will result in an error message. In cases of error messages, switching OFF is aborted. Do not disconnect the power cable from the power socket until the Device is completely switched off.

6.2 Changing the installation location of the Device

For changing the installation location of the Device perform the following steps:

- Take the Device out of operation (see chapter [7.3 Putting Device out of operation](#)).
- Move the Device to a new location. Always transport the Device upright. If necessary, use aids such as a trolley for transport. Use both hands to transport the Device. Avoid vibrations.
- Set up the Device at the new location as described in chapter [5 Installation](#).

7 Operation

7.1 Starting an analysis

NOTICE

Risk of data loss

- Make sure that the power saving mode and sleep mode are deactivated on the PC where you are using the control software. Also do not turn off the monitor of the PC, as this can lead to a deactivation of the USB ports.
- During the measurement process do not sign out or switch the windows user as it aborts the process and data will be lost.

NOTICE

Combination of different Detection Modules

- Only Detection Modules of the same type can be analysed in the same run.



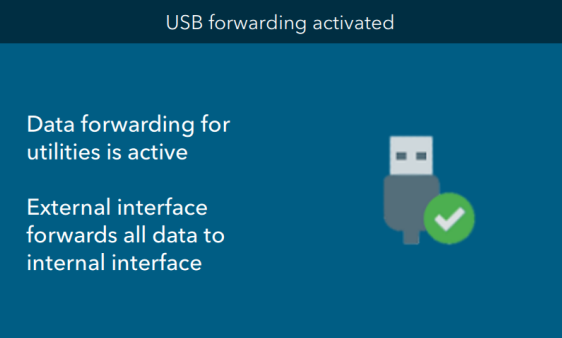
⚠ CAUTION

Risk of injury

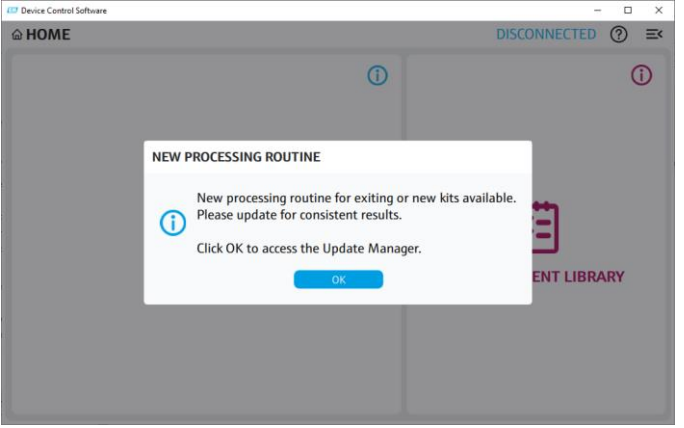
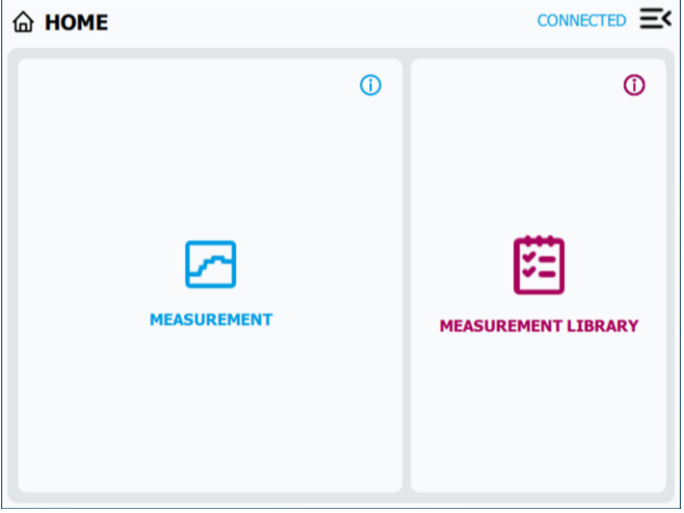
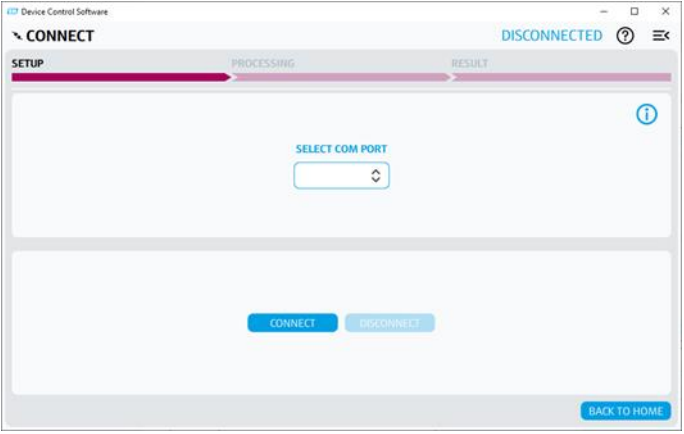
- Do not insert your hand or fingers into the Detection Module slot.
- Do not insert any objects other than Detection Modules into the slot.

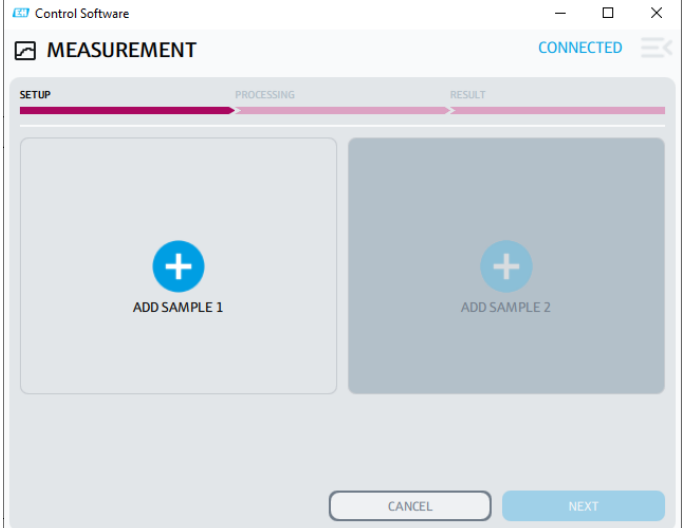
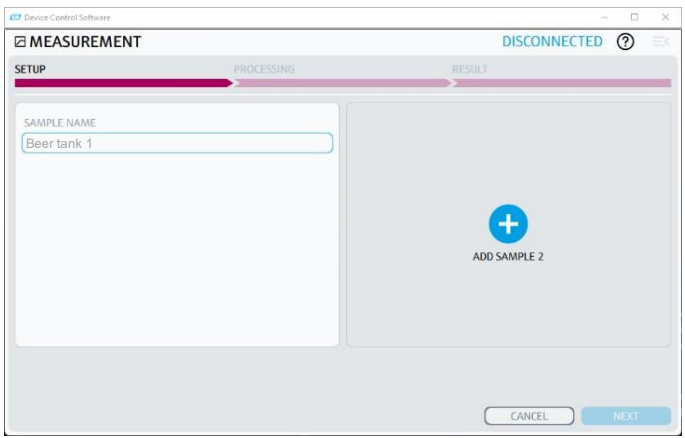
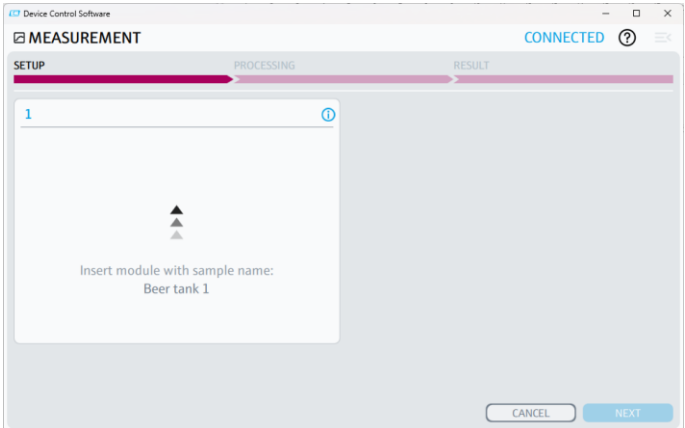

7.1.1 Connect the Device with the PC

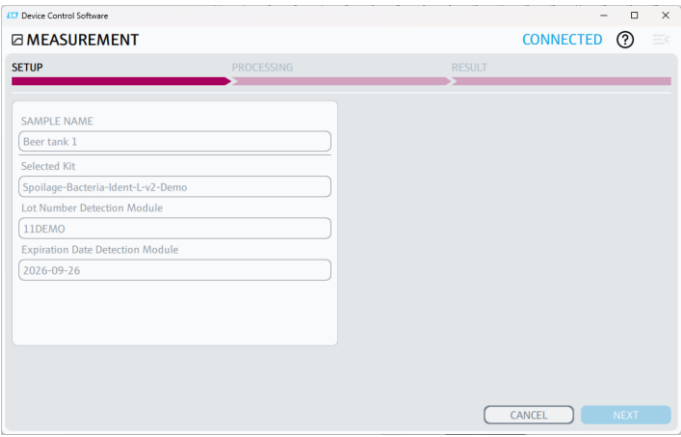
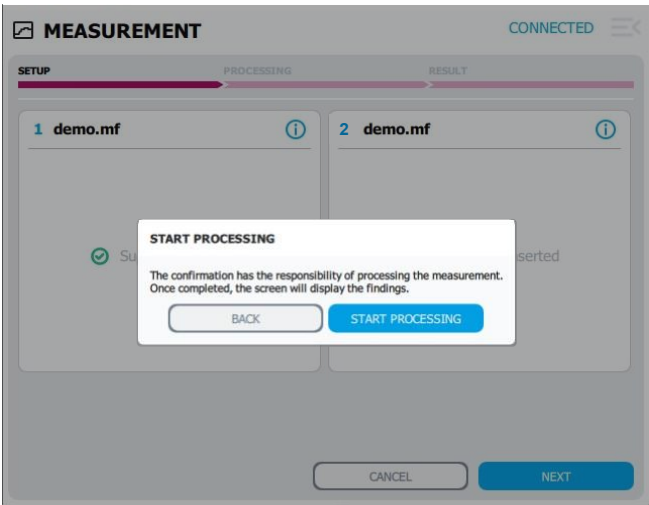
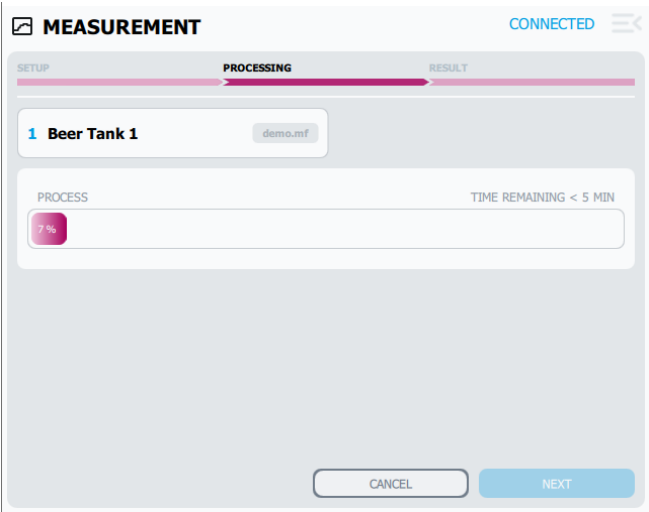
Prepare the sample and Detection Modules as described in the operating instructions of the Kit and place them on the Detection Module stand. Note: Do not place the Detection Module stand on top of the Device.

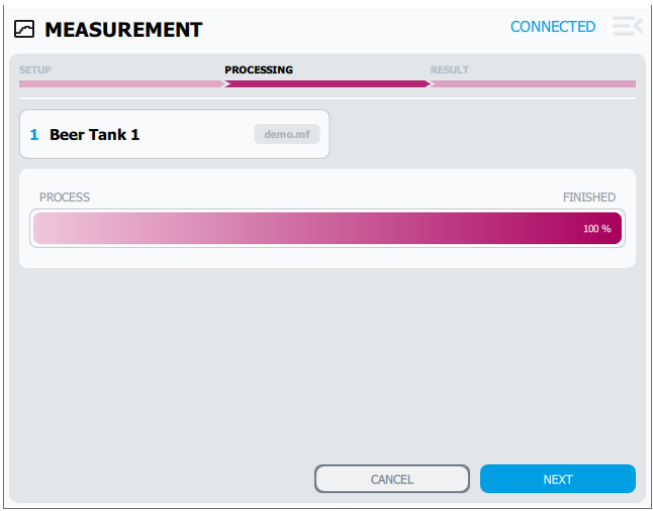
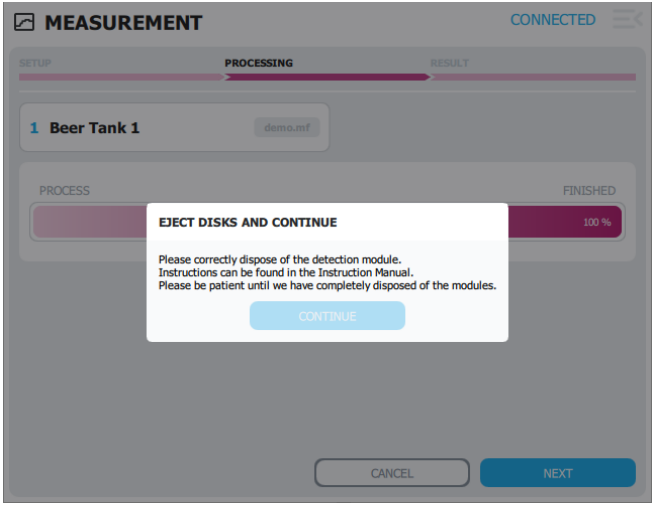
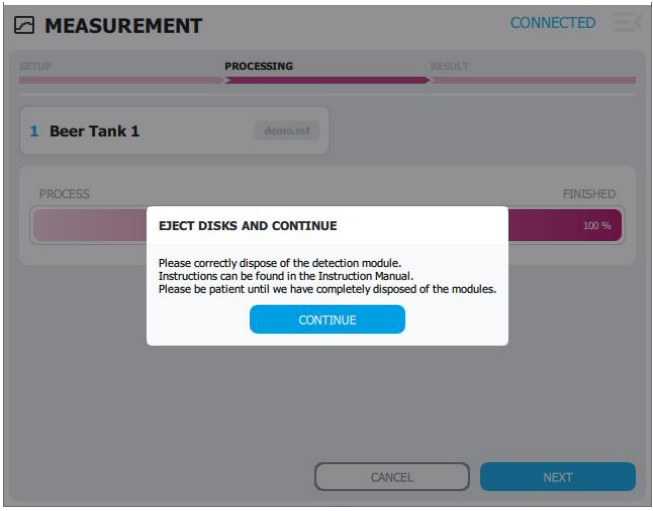
Step	Description	Depiction
1	Scan the UserID with the barcode reader (see chapter 3.2.4.1 Barcode scanner and barcodes).	
2	Select 1 at the Device to connect to the PC.	
3	Scan the Connect Barcode	
4	When the device is ready to connect to the PC, the following display appears:	

7.1.2 Run the Control Software and start an analysis

Step	Description	Depiction
1	<p>Open the DeviceControlSoftware-X.X.X-win64.exe file to run the Control Software.</p> <p>NOTICE</p> <p>Each time the software is restarted, a check for updates to the processing routines is carried. If updates are available a message appears after a restart (see 7.2.3 Updating the processing routines).</p>	
2	<p>On the screen “HOME” you can either start a Measurement or open the Measurement Library (see chapter 7.2.2).</p> <p>To start a Measurement, click on MEASUREMENT.</p> <p>If PC and Device are not connected, you will be sent to the “CONNECT”-screen.</p>	
3	<p>On the “CONNECT”-screen, first select your COM Port, then click “CONNECT”.</p> <p>Active COM Port often is highest digit on list.</p> <p>After the connection with the PC has been established, the NEXT button turns active (color dark blue). Press NEXT to continue.</p>	

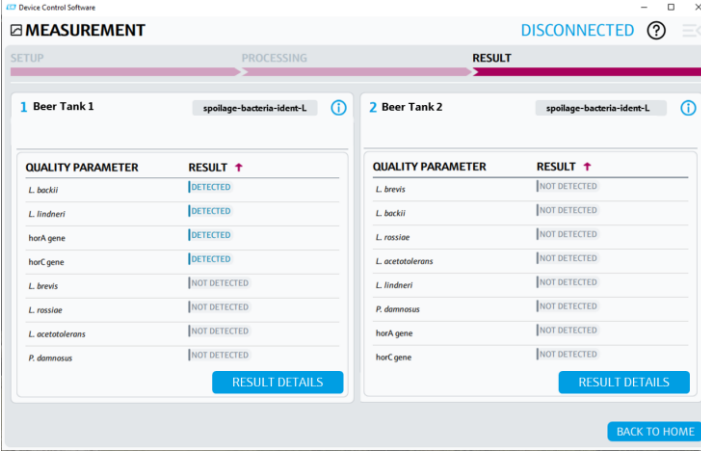
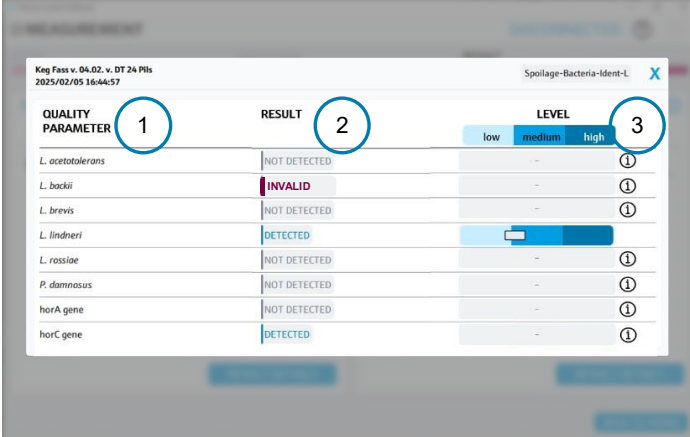
<p>4</p>	<p>To add the first sample, click on ADD SAMPLE 1.</p>	 <p>The screenshot shows the 'MEASUREMENT' window in 'CONNECTED' status. A progress bar at the top indicates the 'SETUP' phase is active. Two large buttons are visible: 'ADD SAMPLE 1' on the left and 'ADD SAMPLE 2' on the right, both featuring a blue plus sign icon. At the bottom, there are 'CANCEL' and 'NEXT' buttons.</p>
<p>5</p>	<p>Enter a name for your sample in the SAMPLE NAME field. You can choose any name you like.</p> <p>To test a second sample, click on “Add Sample 2”. If you only want to test one sample, directly click on NEXT.</p> <p>NOTICE</p> <p>If you have selected “ADD SAMPLE 2” but only want to test one sample, you can undo this step by clicking on the blue “X” on the right.</p>	 <p>The screenshot shows the 'MEASUREMENT' window in 'DISCONNECTED' status. The 'SAMPLE NAME' field is now populated with 'Beer tank 1'. The 'ADD SAMPLE 2' button remains visible. The 'NEXT' button is highlighted in blue, indicating it is the next step.</p>
<p>6</p>	<p>The slot for the detection module is opened.</p> <p>The device is now waiting for the detection module(s) to be inserted.</p>	 <p>The screenshot shows the 'MEASUREMENT' window in 'CONNECTED' status. A dialog box is displayed with the text 'Insert module with sample name: Beer tank 1'. Above the text are three upward-pointing triangles. The 'NEXT' button is highlighted in blue.</p>
<p>7</p>	<p>Insert the Detection Module(s) into the Detection Module slot.</p> <p>Wait until the Detection Module(s) is/are placed in the Device.</p>	 <p>A line drawing of the BioSense device. A hand is shown inserting a detection module into a slot on the front of the device. A power cord is also visible on the left side.</p>

<p>8</p>	<p>The Kit, LOT number, and expiration date are automatically read inside the device via the internal barcode reader.</p> <p>To test a second sample, click on “Add Sample 2”. If you only want to test one sample, directly click on NEXT.</p>	
<p>9</p>	<p>Confirm the start of the measurement process by clicking on START PROCESSING.</p> <p>The Device now starts to run the automated process consisting of lysis and real-time PCR and automated data analysis.</p>	
<p>10</p>	<p>During processing, the status and remaining time are displayed.</p> <p>If you want to cancel the processing, press cancel. This results in abortion of the processing and ejection of the Detection Modules.</p>	

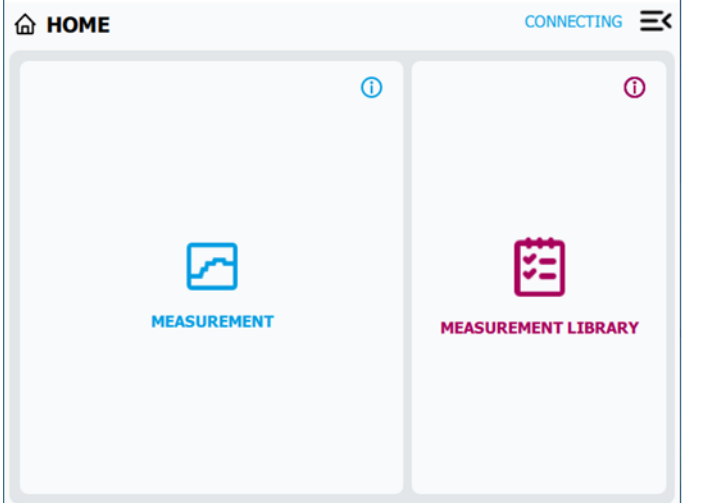
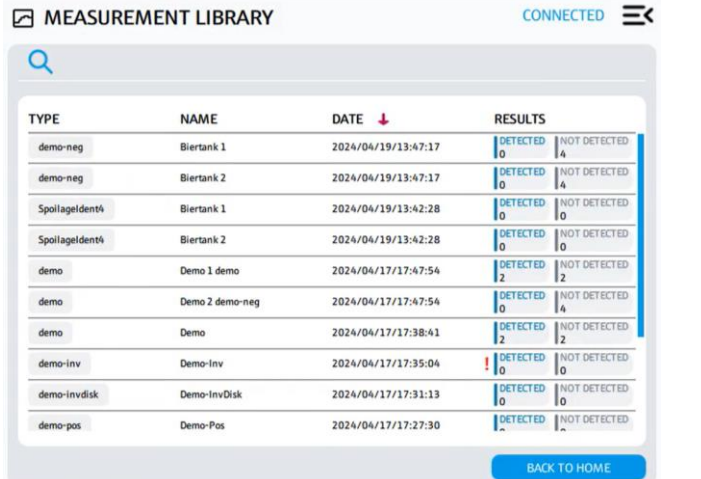
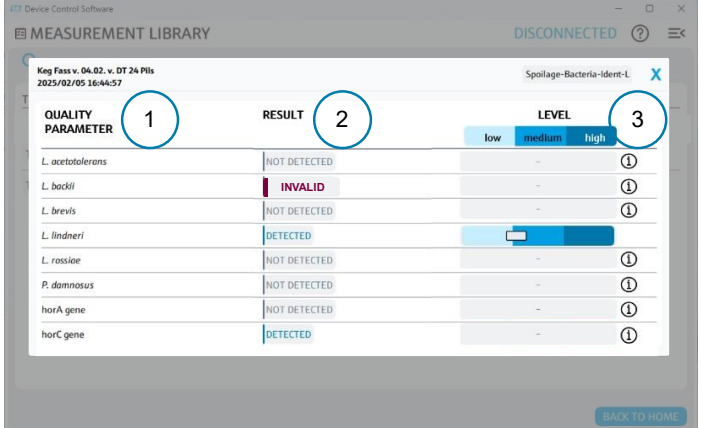
<p>11</p>	<p>When the measurement has finished the status bar shows 100% and the status "FINISHED".</p> <p>To continue click on NEXT.</p>	 <p>The screenshot shows the 'MEASUREMENT' screen with a progress bar at 100% and the status 'FINISHED'. The screen includes a 'BEER TANK 1' section with a 'demo.mf' file, a 'PROCESS' bar, and 'CANCEL' and 'NEXT' buttons at the bottom.</p>
<p>12</p>	<p>All Detection Modules will be ejected from the Device.</p> <p>Dispose closed Detection Module with sample according to operating instructions of the Kit.</p>	 <p>The screenshot shows the 'MEASUREMENT' screen with a dialog box titled 'EJECT DISKS AND CONTINUE'. The dialog box contains the text: 'Please correctly dispose of the detection module. Instructions can be found in the Instruction Manual. Please be patient until we have completely disposed of the modules.' and a 'CONTINUE' button.</p>
<p>13</p>	<p>After disposal of all modules click on CONTINUE.</p>	 <p>This screenshot is identical to the previous one, showing the 'EJECT DISKS AND CONTINUE' dialog box on the 'MEASUREMENT' screen.</p>

7.2 Results

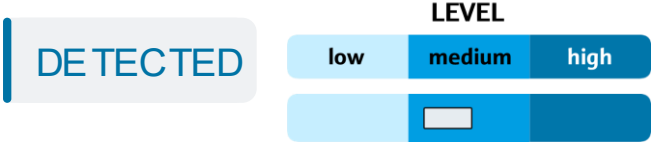




7.2.1 View results

Step	Description	Depiction
1	<p>After the analysis the results of the analysis are displayed.</p> <p>You can sort them either by the QUALITY PARAMETER or by the RESULT.</p> <p>NOTICE</p> <p>Risk of data loss</p> <ul style="list-style-type: none"> Do not close the software before the Detection Modules are ejected 	
2	<p>The screen is divided into the following sections:</p> <ol style="list-style-type: none"> 1. QUALITY PARAMETER 2. RESULTS (see 7.2.3 Description of the results display) 3. LEVEL: The view of the RESULT DETAILS shows a classification of the level for the detected QUALITY PARAMETERS, starting with “low” (low level), via ‘medium’ to “high” (high level). 	

7.2.2 Recall results

Step	Description	Depiction																																																							
1	To recall results, start the Control Software. Click on MEASUREMENT LIBRARY.	 <p>The screenshot shows the 'HOME' screen of the control software. At the top, it says 'CONNECTING'. Below this, there are two large buttons: 'MEASUREMENT' on the left and 'MEASUREMENT LIBRARY' on the right. Each button has an information icon in the top right corner.</p>																																																							
2	Choose the result, you would like to check in detail. For sorting the result, use the search and the sort function.	 <p>The screenshot shows the 'MEASUREMENT LIBRARY' screen, which is 'CONNECTED'. It features a search bar at the top and a table of measurement results. The table has columns for TYPE, NAME, DATE, and RESULTS. The RESULTS column is further divided into 'DETECTED' and 'NOT DETECTED' counts.</p> <table border="1" data-bbox="826 981 1465 1317"> <thead> <tr> <th>TYPE</th> <th>NAME</th> <th>DATE</th> <th>DETECTED</th> <th>NOT DETECTED</th> </tr> </thead> <tbody> <tr> <td>demo-neg</td> <td>Biertank 1</td> <td>2024/04/19/13:47:17</td> <td>0</td> <td>4</td> </tr> <tr> <td>demo-neg</td> <td>Biertank 2</td> <td>2024/04/19/13:47:17</td> <td>0</td> <td>4</td> </tr> <tr> <td>Spollagidentá</td> <td>Biertank 1</td> <td>2024/04/19/13:42:28</td> <td>0</td> <td>0</td> </tr> <tr> <td>Spollagidentá</td> <td>Biertank 2</td> <td>2024/04/19/13:42:28</td> <td>0</td> <td>0</td> </tr> <tr> <td>demo</td> <td>Demo 1 demo</td> <td>2024/04/17/17:47:54</td> <td>2</td> <td>2</td> </tr> <tr> <td>demo</td> <td>Demo 2 demo-neg</td> <td>2024/04/17/17:47:54</td> <td>0</td> <td>4</td> </tr> <tr> <td>demo</td> <td>Demo</td> <td>2024/04/17/17:38:41</td> <td>2</td> <td>2</td> </tr> <tr> <td>demo-inv</td> <td>Demo-Inv</td> <td>2024/04/17/17:35:04</td> <td>0</td> <td>0</td> </tr> <tr> <td>demo-invdisk</td> <td>Demo-InvDisk</td> <td>2024/04/17/17:31:13</td> <td>0</td> <td>0</td> </tr> <tr> <td>demo-pos</td> <td>Demo-Pos</td> <td>2024/04/17/17:27:30</td> <td>0</td> <td>0</td> </tr> </tbody> </table>	TYPE	NAME	DATE	DETECTED	NOT DETECTED	demo-neg	Biertank 1	2024/04/19/13:47:17	0	4	demo-neg	Biertank 2	2024/04/19/13:47:17	0	4	Spollagidentá	Biertank 1	2024/04/19/13:42:28	0	0	Spollagidentá	Biertank 2	2024/04/19/13:42:28	0	0	demo	Demo 1 demo	2024/04/17/17:47:54	2	2	demo	Demo 2 demo-neg	2024/04/17/17:47:54	0	4	demo	Demo	2024/04/17/17:38:41	2	2	demo-inv	Demo-Inv	2024/04/17/17:35:04	0	0	demo-invdisk	Demo-InvDisk	2024/04/17/17:31:13	0	0	demo-pos	Demo-Pos	2024/04/17/17:27:30	0	0
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3	<p>You can sort the selected result by Quality parameter (alphabetically).</p> <p>The screen is divided into the following sections:</p> <ol style="list-style-type: none"> 1. QUALITY PARAMETER 2. RESULTS (see 7.2.3 Description of the results display) 3. LEVEL: The view of the RESULT DETAILS shows a classification of the level for the detected QUALITY PARAMETERS, starting with “low” (low level), via ‘medium’ to “high” (high level). 	 <p>The screenshot shows a detailed view of a result from the 'MEASUREMENT LIBRARY'. The screen is divided into three sections: 'QUALITY PARAMETER' (1), 'RESULT' (2), and 'LEVEL' (3). The 'LEVEL' section shows a classification of the level for the detected quality parameters, starting with 'low' (low level), via 'medium' to 'high' (high level).</p> <table border="1" data-bbox="826 1496 1497 1765"> <thead> <tr> <th>QUALITY PARAMETER</th> <th>RESULT</th> <th>LEVEL</th> </tr> </thead> <tbody> <tr> <td>L. acetotolerans</td> <td>NOT DETECTED</td> <td>-</td> </tr> <tr> <td>L. backii</td> <td>INVALID</td> <td>-</td> </tr> <tr> <td>L. brevis</td> <td>NOT DETECTED</td> <td>-</td> </tr> <tr> <td>L. lindneri</td> <td>DETECTED</td> <td>low</td> </tr> <tr> <td>L. rossiae</td> <td>NOT DETECTED</td> <td>-</td> </tr> <tr> <td>P. dammosus</td> <td>NOT DETECTED</td> <td>-</td> </tr> <tr> <td>horA gene</td> <td>NOT DETECTED</td> <td>-</td> </tr> <tr> <td>horC gene</td> <td>DETECTED</td> <td>-</td> </tr> </tbody> </table>	QUALITY PARAMETER	RESULT	LEVEL	L. acetotolerans	NOT DETECTED	-	L. backii	INVALID	-	L. brevis	NOT DETECTED	-	L. lindneri	DETECTED	low	L. rossiae	NOT DETECTED	-	P. dammosus	NOT DETECTED	-	horA gene	NOT DETECTED	-	horC gene	DETECTED	-																												
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7.2.3 Description of the results

Depiction	Description
<p>The measurement was successful. The quality parameter was detected.</p> <p>The software indicates levels ranging from low to high.</p>	 <p>The image shows a grey rounded rectangle with the word "DETECTED" in blue. To its right is a "LEVEL" indicator consisting of three colored segments: "low" (light blue), "medium" (medium blue), and "high" (dark blue). A white bar is positioned within the "medium" segment, indicating the detected level.</p>
<p>The measurement was successful. The quality parameter was detected.</p> <p>Explanation:</p> <ul style="list-style-type: none"> ▪ If inhibitory substances, such as cleaning products, are present in the sample, the PCR reactions may be impaired. Such inhibition can affect both the internal control and the quality parameter. ▪ Although possible inhibition can be detected via internal control, it is not possible to quantify the extent to which the quality parameter is affected. ▪ In such cases, the quality parameter can still be detected, but a reliable assessment of its level is not possible as the original reaction conditions have been changed. 	 <p>The image shows a grey rounded rectangle with the word "DETECTED" in blue.</p>
<p>The measurement was successful. The quality parameter was not detected.</p>	 <p>The image shows a grey rounded rectangle with the words "NOT DETECTED" in grey.</p>
<p>The result of the measurement was deemed invalid by the Control Software. One reason for this may be, for example, the testing of an unsuitable sample. One reason for this may be, for example, that an unsuitable sample was tested.</p> <p>For further details, we can evaluate your analyses in an individual data analysis.</p>	 <p>The image shows a grey rounded rectangle with the word "INVALID" in red.</p>
<p>An error occurred during the analysis.</p> <p>In some cases, an error cause (e.g. "USB connection lost"), an error code and a request for action are also displayed.</p>	 <p>The image shows a red circle with a white 'X' inside, followed by the text "Measurement failed." in grey.</p>

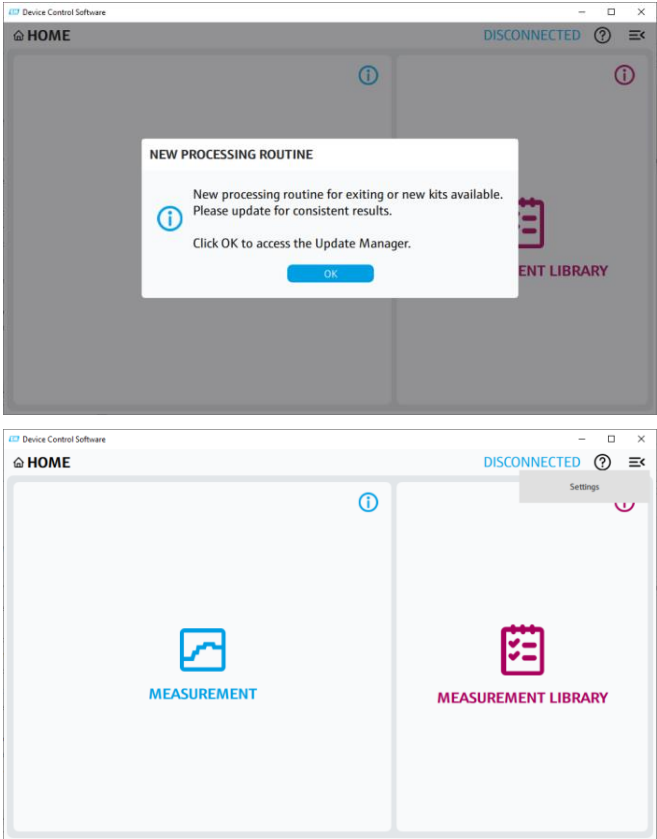
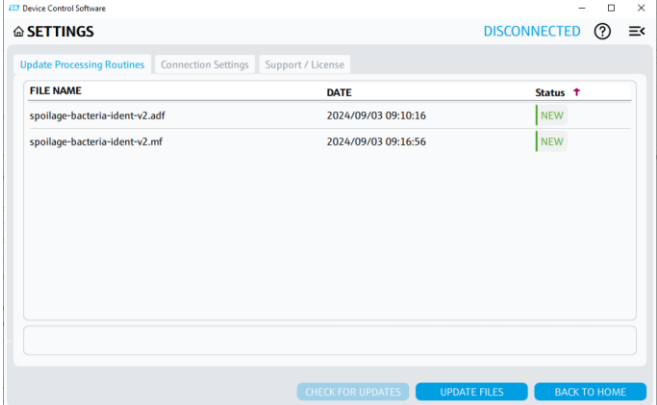
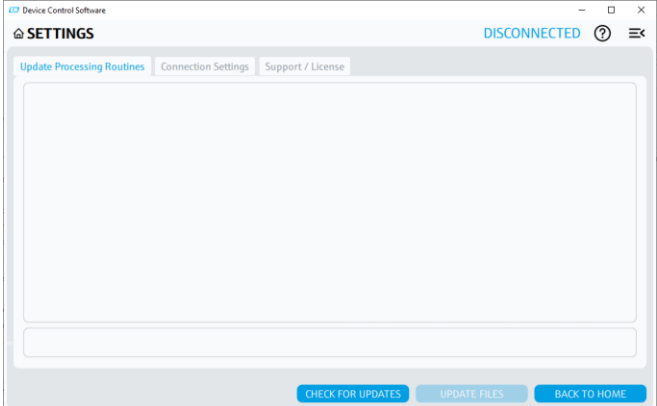
Different results can occur within one analysis. An invalid result has no influence on the validity of the other results.

7.2.4 Updating the process routines

The Control Software offers you the function of updating the processing routines. This is useful when updating products or after the release of new products in order to keep the routines up to date. A check is carried out each time the software is restarted. A check for updates can also be started manually.

NOTICE

To enable the Control Software to check whether you are using the latest processing routines, use the software at regular intervals while your PC is connected to the Internet.

Step	Description	Depiction									
1	<p>Start the control software. If new or changed processing routines are available, a message appears. Confirm this by clicking “OK” to access the update manager.</p> <p>You can also open the Update Manager by clicking on the menu icon in the top right-hand corner, then selecting “Settings”.</p>										
2	<p>New processing routines are displayed in the Update Manager. Click on “UPDATE FILES” to download them. The process usually only takes a few seconds.</p> <p>The routines are then available for future measurements (see 7.1.2 Run the Control Software and start of an analysis).</p>	 <table border="1" data-bbox="826 1227 1453 1464"> <thead> <tr> <th>FILE NAME</th> <th>DATE</th> <th>Status</th> </tr> </thead> <tbody> <tr> <td>spoilage-bacteria-ident-v2.adf</td> <td>2024/09/03 09:10:16</td> <td>NEW</td> </tr> <tr> <td>spoilage-bacteria-ident-v2.mf</td> <td>2024/09/03 09:16:56</td> <td>NEW</td> </tr> </tbody> </table>	FILE NAME	DATE	Status	spoilage-bacteria-ident-v2.adf	2024/09/03 09:10:16	NEW	spoilage-bacteria-ident-v2.mf	2024/09/03 09:16:56	NEW
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3	<p>If no updates are displayed, you can click “CHECK FOR UPDATES” and receive feedback on whether there are any pending updates.</p> <p>The PC must be connected to the Internet during the check and update process.</p>										

7.3 Putting Device out of operation

To take the Device out of operation perform the following steps:

- Remove all Detection Modules from the Device.
- Switch the Device OFF.
- When the screen prompts you to do so, unplug the power supply from the wall socket and then disconnect the power supply from the Device.
- Disconnect the USB cable.
- Store the Device in a dust- and moisture-proof location until the next time it is used (for more information please refer to chapter [11 Technical data](#)).

8 Diagnostics and troubleshooting

8.1 General troubleshooting

In most cases of error, the operating software will guide you directly on how to correct the error. If the screen refers to the support, please contact Endress+Hauser BioSense GmbH support (see chapter [10.1 Contact information](#)). If possible, make a note of the displayed error code and device Number for the person responsible for the device or for support in order to rectify the error. All errors whose correction cannot be fully explained on the operating software are explained in [Table 8](#).

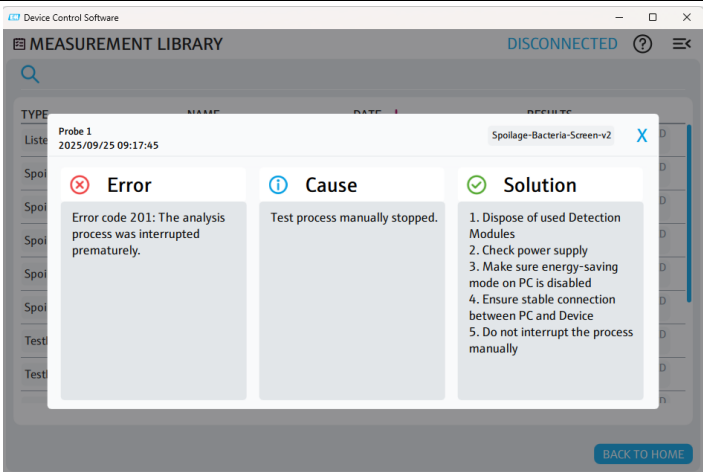
Error	Error description	Troubleshooting
Scanned UserID or Connect Code Invalid	A barcode was scanned that is not a UserID nor a Connect Code	Make sure that you scan a UserID or a Connect Code when prompted. If the error persists, please contact Endress+Hauser BioSense support.
The Device does not shut down as intended or does not respond to user inputs	Shutdown sequence or running process was interrupted	Disconnect the mains cable, wait for 10 seconds, reconnect the mains cable and re-start the device by pressing the ON/OFF switch
An error message appears during use. The error is explained in three columns: Error (error description), Cause (description of the cause of the error), and Solution (procedure for troubleshooting).		Follow the troubleshooting steps (under Solution). If the error persists or you are prompted to do so, contact support at support.ehbs@endress.com .
Self-check after switching on the Device	After a certain number of operating hours, the Device requires a so-called self-check. It starts automatically after switching on the Device.	Wait until the process of self-check has been completed.

Table 8: Error description and troubleshooting.

9 Maintenance

9.1 Control samples

Endress+Hauser BioSense recommends carrying out regular measurements with external control samples. These are available from Endress+Hauser BioSense Support (see chapter [10.1 Contact information](#)).

9.2 Maintenance tasks

Clean the surfaces of the Device as needed or routinely. Other parts cannot be cleaned. A sample analysis requires no subsequent cleaning as only the Detection Modules, not the Device surfaces, contact the sample material.

For cleaning of the surfaces please use the following protocol:

- Prepare the cleaning solution. 70 % Ethanol can be used.
- Soak the cleaning cloth in the cleaning solution. It should be damp but not dripping wet.
- Clean all accessible surfaces of the Device.
- Dampen a paper towel with water and wipe the surface of the Device to remove any residual cleaning solution.
- Repeat this process twice.
- Dry the surface of the Device with a fresh paper towel.

NOTICE

Risk of getting in contact with cleaning solution

- During cleaning, wear gloves and, in accordance with regional specific regulations, personal protective equipment.

CAUTION

Danger of infection, danger of false test results and danger of personal injury and property damage

- Do not use aggressive cleaning agents, such as acetone.
- Do not spray cleaning agents directly onto the Device or inside the Detection Module slot.
- If you have reason to believe that the interior is dirty and contaminated, contact Endress+Hauser BioSense support (see chapter [10.1 Contact information](#)).

NOTICE

Risk of damage to the Device

- Damage caused by liquid spillage will invalidate the warranty.
- Make sure that no chemicals or other liquids enter the Device.

10 Support

10.1 Contact information

Please contact Endress+Hauser BioSense support (support.ehbs@endress.com) concerning all support tasks.

10.2 Return

Decommission the Device as described in chapter [7.3 Putting Device out of operation](#), then return the Device to Endress+Hauser for disposal. When repacking the Device for shipment, the original packaging materials of the defective or replacement Device must be used. If the original packaging materials are not available, contact Endress+Hauser BioSense support before packing and ensure that the Device is properly prepared (see chapter [9.2 Maintenance tasks](#)).

Ensure that the Device does not present a biological or chemical hazard. You must declare the harmlessness in

writing to Endress+Hauser (a Declaration of decontamination can be obtained by the Endress+Hauser BioSense support). If a biological or chemical hazard is present or suspected, contact Endress+Hauser BioSense support.

11 Technical data

The ambient conditions during operation, transport conditions, storage conditions, mechanical data and equipment features are listed below in [Table 9](#) to [Table 12](#).

Parameter	Value
Mains power requirements	External power supply: AC input: 100 to 240 V, 3 A, 50 to 60 Hz DC output: 24 V, 9.16 A Power supply of the Device: DC input 24 V DC \pm 2 %: 9.16 A.
Fuse	1 x 10 A fast switching (not user replaceable)
Overvoltage category	II
Pollution degree	Pollution degree 2 according to DIN EN 61010-1
Temperature	15 °C to 35 °C
Humidity	20 to 80 % relative humidity, non-condensing
Altitude above normal zero	0 to 3000 m

Table 9: Ambient conditions during operation.

Parameter	Value
Temperature	+5 °C to +40 °C
Humidity	5 % to 85 % relative humidity, non-condensing

Table 10: Transport and storage conditions.

Parameter	Value
Dimensions	Width: 233 mm Height: 296 mm Depth: 414 mm
Weight	12 kg
Analysis	Determined by the specific Kit
Number of tests	1 Detection Module per analysis or 2 Detection Modules at the same time per analysis
User input elements	Three touch buttons on front: 1, 2, X
Barcode scanner	External scanner supported: Data Matrix (2D), EAN-13 (1D); Code 128 (1D) Internal scanner scans barcodes on input Detection Modules
Noise level	< 75 dB
Ethernet interface	1 x 10 / 100 Base-T Ethernet (for service purposes only)

USB ports	1 x USB 2.0 Type B
Memory capacity	Up to 1000 runs
Display	800 x 480 pixel RGB, 4.3" IPS TFT, up to 800 cd/m ² brightness

Table 111: Mechanical data and equipment features.

Parameter	Value
Processor	Quad-core
Memory	8GB RAM
Storage	250GB
Operating System	Windows 10 or higher

Table 122: Recommended minimum hardware requirements for Control Software

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