Operating instructions **Device + Control Software**





REF: BAB00-A00A1+1



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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 <u>Table 3</u> all symbols on the device and their description are listed.

Symbol	Description and placement
CE	The CE Marking indicates conformity with health, safety, and environmental protection standards for products sold within the EEA. On the type plate.
K	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.
i	Please read operating instructions. On the type plate.
	Power consumption. On the type plate.
	On/off switch. On the back of the Device.
물물	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 (e.g. commercial laboratories). 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.

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.

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.

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.

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 <u>9.2 Maintenance tasks</u>.
- 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.

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	1, 2, X buttons
5	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 <u>Figure 2</u>Figure 2. These parts are named in <u>Table 5</u>. Corresponding symbols are displayed in <u>Table 3</u>.



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)

Number	Description
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.

ACAUTION

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

- Verify that the packaging is undamaged. Notify the Endress+Hauser BioSense support (see chapter <u>10.1 Contact</u> <u>information</u>) 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 <u>10.1 Contact</u> <u>information</u>) 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 <u>3.2.3 Type plate</u>).
- In the delivery papers.

If you have any questions, please contact Endress+Hauser BioSense support (see chapter <u>10.1 Contact information</u>).

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 <u>Table 7</u>.

Part	Quantity	Reference Number (REF)
Device + Control Software	1x	BAB00-A00A1+1
Control Software	1x	B-1008
Operating instructions device	1x	B-1003
Card with UserID and Connect Code	1x	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 <u>11 Technical data</u> to learn more about the operating conditions of the Device.

ACAUTION

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 <u>Table 7</u>).

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 <u>11 Technical data</u>.

A 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: <u>https://www.endress.com/endress-hauser-biosense-technology-portfolio</u>

- 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.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 <u>Figure 2</u>). The Device has a transport lock. The Device unlocks the transport lock when the ON/OFF switch (see <u>Figure 2</u>) 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 <u>5 Installation</u>.

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.

NOTICE

Risk of data loss

- During the measurement process avoid pushing the x-Button on the Device as it aborts the process and data will be lost.
- 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.

A 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 <u>3.2.4.1 Barcode scanner and</u> <u>barcodes</u>).	Endress+Hauser BioSense Device + Control Software UserID (1) Endress+Hauser
2	Select 1 at the Device to connect to the PC.	
3	Scan the Connect Barcode	Endress+Hauser BioSense Device + Control Software Connect Code(2)
4	When the device is ready to connect to the PC, the following display appears:	USB forwarding activated Data forwarding for utilities is active External interface forwards all data to internal interface

7.1.2 Run the Control Software

Step	Description	Depiction
1	Open the DeviceControlSoftware.exe file to run the Control Software.	
2	On the screen "HOME" you can either start a Measurement or open the Measurement Library (see <u>chapter</u> 7.2.2). To start a Measurement, click on MEASUREMENT. If PC and Device are not connected, you will be sent to the "CONNECT"-screen.	HOME CONNECTED CONNECTED
3	On the "CONNECT"-screen, first select your COM Port, then click "CONNECT". Active COM Port often is highest digit on list. After the connection with the PC has been established, the NEXT button turns active (color dark blue). Press NEXT to continue.	CONNECT DISCONNECTED
4	To add the first sample, click on ADD SAMPLE 1.	CONNECTED MEASUREMENT SETUP PROCESSING RESULT ADD SAMPLE 1 CANCEL NEXT

5	 Fill out SAMPLE NAME, Select the appropriate Method with which you want to analyze your sample The Lot number and the Expiration Date (which you can find on the Detection Module) 	ETUP PROCESSING SETUP PROCESSING SAMPLE NAME Sample NAME Select Method demo.mf Lot number Lot number Expiration Date (YYYY-MM-DD) YYYY-MM-DD CANCEL NEXT
6	To test a second sample, click on "Add Sample 2". If you only want to test one sample, directly click on NEXT.	ETUP PRCESSING SETUP PRCESSING SAMPLE NAME Beer tank 1 Select Method demo.mf 123456 Expiration Date (YYYY-MM-DD) 2024-05-01 CANCEL
7	Fill out the fields for Sample 2 according to step 5. The Method is already selected with the entry of Sample 1. To proceed click on NEXT.	ETUP PROCESSING SETUP PROCESSING SAMPLE NAME Beer tank 1 Select Method demo.mf 123456 Expiration Date (YYYY-MM-DD) 2024-05-01 CANCEL NEXT

8	The Detection Module slot opens.	MEASUREMENT CONNECTED strup PROCESSING RESULT
	The device is now waiting for the insertion of the Detection Module(s).	1 demo.mf ① 1 2 demo.mf ① 1 1 1 <
9	Insert the Detection Module(s) into the Detection Module slot. Wait until the Detection Module(s) is/are placed in the Device.	
10	After the Detection Module(s) is/are inserted and placed "Successfully inserted" is displayed. To proceed click on NEXT.	MEASUREMENT CONNECTED CONNECTED SETUP PROCESSING RESULT 1 demo.mf () 2 demo.mf () © Successfully inserted CANCEL NEXT

11	Confirm the start of the measurement process by clicking on START PROCESSING. The Device now starts to run the automated process consisting of lysis and real-time PCR and automated data analysis.	I demo.mf I demo.mf START PROCESSING Serted I demo.mf I demo.mf I demo.mf I demo.mf Start PROCESSING Serted Data confirmation has the responsibility of processing the measurement. Once completed, the screen will display the findings. Serted BACK START PROCESSING Serted
12	During processing, the status and remaining time are displayed. If you want to cancel the processing, press cancel. This results in abortion of the processing and ejection of the Detection Modules. NOTICE Risk of data loss • During the measurement process avoid pushing the x-Button on the Device as it aborts the process and data will be lost.	Image: Measurement Connected Image: measurement RESULT Image: measurement RESULT <t< td=""></t<>
13	When the measurement has finished the status bar shows 100% and the status "FINISHED". To continue click on NEXT.	CONNECTED CONNEC

14	All Detection Modules will be ejected from the Device. Dispose closed Detection Module with sample according to operating instructions of the Kit.	MEASUREMENT STUP PROCESSING Reader Tank 1 Beer Tank 1 PROCESS PROCESS PROCESS PROCESS PROCESS PROCESS PROCESS PROCESS PROCESS PROCESS P
15	After disposal of all modules click on CONTINUE.	I Beer Tank 1 Genooff PROCESS FINISHED CONTINUE CONTINUE

7.2 Results

7.2.1 View results

Step	Description	Depiction
1	After the analysis the results of the analysis are displayed.	MEASUREMENT CONNECTED
	You can sort them either by the QUALITY PARAMETER or by the RESULT.	1 Beer Tank 1 dema.mf (i) 1 Beer Tank 1 dema.mf (i)
		QUALITY PARAMETER RESULT ↓ QUALITY PARAMETER RESULT ↓
		L. brevis DETECTED L. brevis DETECTED
	NOTICE	horAgene DETECTED horAgene DETECTED
	Risk of data loss	horCgene DETECTED horCgene DETECTED
	 Do not close the software before the Detection Modules are ejected 	BACK TO HOME

7.2.2 Recall results

Step	Description	Depiction		
1	1 To recall results, start the Control Software Click on MEASUREMENT	ப் номе		
	LIBRARY.		٥	O
			MEASUREMENT	MEASUREMENT LIBRARY

2	2 Choose the result, you would like to check in detail. For sorting the result, use the search and the sort function.		MENT LIBRARY		CONNECTED
		ТҮРЕ	NAME	DATE 👃	RESULTS
		demo-neg	Biertank 1	2024/04/19/13:47:17	DETECTED NOT DETECTED
		demo-neg	Biertank 2	2024/04/19/13:47:17	DETECTED NOT DETECTED
		SpoilageIdent4	Biertank 1	2024/04/19/13:42:28	DETECTED NOT DETECTED
		SpoilageIdent4	Biertank 2	2024/04/19/13:42:28	OETECTED NOT DETECTED
		demo	Demo 1 demo	2024/04/17/17:47:54	2 NOT DETECTED
		demo	Demo 2 demo-neg	2024/04/17/17:47:54	OETECTED NOT DETECTED
		demo	Demo	2024/04/17/17:38:41	2 NOT DETECTED
		demo-inv	Demo-Inv	2024/04/17/17:35:04	DETECTED NOT DETECTED
		demo-invdisk	Demo-InvDisk	2024/04/17/17:31:13	OETECTED
		demo-pos	Demo-Pos	2024/04/17/17:27:30	DETECTED NOT DETECTED
3	You can sort the selected result by Quality parameter (alphabetically).	MEASUREM	AENT LIBRARY	/04/19/13:47:17	
		de Quality Para	amatar 🕈	RESULT	ED
		L. brevis		NOT DETECTED	ED IN
		sp horA gene		NOT DETECTED	TED
		de horC gene		NOT DETECTED	ED
		de de de de			ED ED ED ED ED ED ED ED ED ED ED ED ED E

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 <u>11 Technical data</u>).

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 <u>10.1 Contact information</u>). 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 <u>Table 8</u>.

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
After starting the measurement, an error is detected during the initial pressure build-up	MEASUREMENT CONNECTED PROCESSING REMAX I Beer Tank 1 Beer Tank 1 ERROR Beer Tank 1 Error during initial pressure build-up. Please check the operating instructions or contact the support. OK CANCEL	Briefly disconnect the device from the mains and reconnect it. The DMs will be ejected. Check the DM for possible contamination. If you do not find any contamination or defects, start a new measurement. If the error occurs again, please contact support.
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 after swithing 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 does not require any subsequent cleaning. This is because only the Detection Modules and not the surfaces of the Device come into contact with the sample material during the sample analysis.

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.

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 <u>10.1 Contact information</u>).

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 (<u>support.ehbs@endress.com</u>) concerning all support tasks.

10.2 Return

Decommission the Device as described in chapter <u>7.3 Putting Device out of operation</u>, 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 <u>9.2</u> <u>Maintenance tasks</u>).

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 <u>Table 9</u> to <u>Table 13</u>.

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 ± 2 %: 9.16 A.
Fuse	1 x 10 A fast switching (not user replaceable)
Overvoltage category	Ш
Pollution degree	Pollution degree 2 according to DIN EN 61010-1

Temperature	15 ℃ to 35 ℃		
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 conditions.		
Parameter	Value		
Temperature	+5 °C to +40°C		
Humidity	5 % to 85 % relative humidity, non-condensing		
	Table 11: 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 1	2: Mechanical data and equipment features.		

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

Table 13: Recommended minimum hardware requirements for Control Software

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