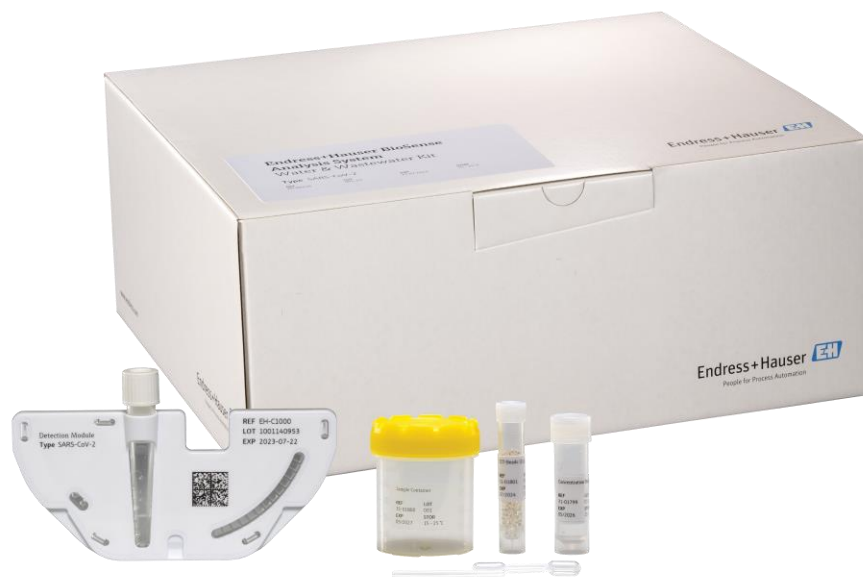


# Operating instructions

## Endress+Hauser BioSense

### Water & Wastewater Kit

### Type SARS-CoV-2



REF: BKB00-B01A1

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# 1 About this document



## 1.1 Document function

These operating instructions contains all information about the Endress+Hauser BioSense Water & Wastewater Kit, Type SARS-CoV-2, in the following operating instructions mainly referred to as “Kit”. 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 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  |
|--|--|
|  <b>CAUTION</b><br><b>Causes (/consequences)</b><br>▶ Corrective action | This symbol alerts to a dangerous situation. Failure to avoid this situation can result in minor or more serious injuries. |
|  <b>NOTICE</b><br><b>Cause/situation</b><br>▶ 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 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   |
| cp/ml      | Number of virus copies per milliliter of the sample                                  |
| Ct         | Cycle threshold for PCR amplification  |
| EXP        | Expiry date  |
| LOT        | Lot number   |
| PCR        | Polymerase chain reaction  |
| QuantCode  | Barcode for Endress+Hauser BioSense Analysis System sample quantification            |
| REF        | Reference number   |
| sampleID   | Barcode for sample labelling and assignment  |
| SARS-CoV-2 | Severe-acute-respiratory-syndrome Corona virus 2                                     |
| STOR       | Storage conditions   |
| TCT        | Target Concentration Technology  |
| userID     | Barcode for user login (see operating instruction of Endress+Hauser BioSense Device) |

*Table 2: All abbreviations and their description used in this document.*

## 1.4 Documentation

The following operating instructions complement these operating instructions and are available on demand (see chapter 8 *Support*):

- Operating instructions Endress+Hauser BioSense Device

## 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 instructions

### 2.1 Requirements for the personnel

- Read these Operating Instructions before use and take care that the document was understood.
- Keep the operating instructions in a safe but easily accessible place.

### 2.2 Intended use

- The Kit is intended for the use with wastewater samples only.
- Any use for other purposes is not permitted. Liability for improper use as well as resulting consequences is excluded.
- Do not use the Kit for anything other than its intended use.
- Use one Concentration Module and one Detection Module per wastewater sample.

### 2.3 Workplace and operational safety

- A visual inspection must always be carried out before use (see chapter 4.1 *Incoming acceptance*).
- Do not operate damaged reagents or products and protect them against unintentional operation.
- Label damaged products as defective. Defects must be reported to Endress+Hauser BioSense (see chapter 8 *Support*).
- Operation of the Kit is possible on any table or straight surface.

### 2.4 Product safety

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

#### NOTICE

#### Risk of personal injury

- Each component of the Concentration Module and the Detection Module is made for single use only!
- The Detection Module must not be exposed to direct sunlight in order not to influence the integrity of the measurement results.

#### NOTICE

#### Risk of false disposal

- Please comply to the federal, state, and local safety and environmental regulations. All waste should be considered as potentially infectious and must be handled and discarded according to the federal, state, and local safety regulations.

## 2.5 Important safeguards

#### NOTICE

#### Risk of personal injury and false results

- All due care and attention should be exercised in handling the materials and reagents contained in the Concentration Module and the Detection Module.
- Always wear gloves while operating with wastewater.

**⚠ CAUTION****Risk of personal injury**

- Never eat or drink any components of the Kit! Seek medical advice if swallowed.

## 3 Product description

### 3.1 Endress+Hauser BioSense Analysis System

The Endress+Hauser BioSense Analysis System consists of the Endress+Hauser BioSense Device and an application specific Endress+Hauser BioSense Kit. The following operating instructions describe the operation of the Endress+Hauser BioSense Water & Wastewater Kit, Type SARS-CoV-2. Information about the Endress+Hauser BioSense Device can be found in the separate operating instructions for the Device.

### 3.2 Endress+Hauser BioSense Kit, Type SARS-CoV-2

The Kit is designed for the detection of SARS-Cov-2 in the water & wastewater industry. The Kit is part of the BioSense Analysis System.

The Kit includes Concentration Modules and Detection Modules (see chapter 4.2 *Scope of delivery*).

The Concentration Module enables highly efficient and innovative concentration of wastewater with a concentration factor of 10 by following five simple handling steps. It contains all reagents and means for sample preparation.

The Detection Module enables automated nucleic acid extraction and real-time PCR based detection of SARS-CoV-2 virus particles by utilizing a microfluidic cartridge. The Detection Module serves as consumable and contains the sample-specific and the application-specific biochemistry for the analysis. All necessary reagents for processing are pre-stored on the Detection Module. Sophisticated microfluidic structures enable precise and repeatable automation of complex biochemical processes. The Detection Module is designed for use in the Endress+Hauser BioSense Device only. All main components of the Kit are displayed in *Figure 1*.



Figure 1: Picture of the main components of the Endress+Hauser BioSense Kit, Type SARS-CoV-2.

## 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 8 *Support*) of any damage to the packaging. Keep the damaged goods until the issue has been resolved.
2. Verify that the contents are undamaged. Notify the Endress+Hauser BioSense support (see chapter 8 *Support*) of any damage to the delivery contents. Keep the damaged goods until the issue has been resolved.
3. Do not operate damaged products and protect them against unintentional operation. Label damaged products as defective.
4. Check that the delivery is complete and nothing is missing. It is recommended to compare the shipping documents with the purchase order.

#### 4.1.1 Identifying the product

The order code and serial number of the product can be found in the following locations:

- On the Kit labels.
- In the delivery papers.

If there are any questions, please contact the Endress+Hauser BioSense support (see chapter 8 *Support*).

#### 4.1.2 Manufacturer address

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

### 4.2 Scope of delivery

Table 3 lists all the components included in the Kit and their reference numbers for ordering. Table 4 lists all the components of the Concentration Module.

| Part   | Quantity                   | REF         |
|--|----------------------------|-------------|
| Concentration Module, Type A1                | 10 x                       | BCB00-B00A1 |
| Detection Module, Type SARS-CoV-2            | 10 x                       | BDB00-B01A1 |
| Kit operating instructions (Type SARS-CoV-2) | 1 x                        | B-2001      |
| sampleID Labels                              | 30 x (3 x for each sample) | B-2002      |
| Certificate of analysis with QuantCode       | 1 x                        | B-2003      |

Table 3: List of all components included in the Endress+Hauser BioSense Water & Wastewater Kit, Type SARS-CoV-2 including the quantity and the reference number for orders.

| Concentration Module, Type A1                   | Quantity                      |
|---|-------------------------------|
| Sample container                                | 1 x                           |
| TCT Bead container including TCT Beads          | 1 x 2 g (pre-filled, sealed)  |
| Buffer container including Concentration Buffer | 1 x 3 ml (pre-filled, sealed) |
| Transfer pipette                                | 1 x                           |

Table 4: Quantity of components of the Concentration Module, Type A1.

### 4.3 Transport and storage

The Kit is shipped at ambient temperatures. Store the Kit dry and at room temperature (15 °C to 25 °C). The Concentration Module and the Detection Module are stable until the expiration date printed on the label on the box or bag. Avoid storage in direct sunlight.

Before each use, ensure that all components included in the Kit are at room temperature.

## 4.4 Product use and warranty

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

The Kit is not designed for the usage of other starting materials or other amounts of starting materials/samples than those, referred to in these operating instructions (see chapter 2.2 *Intended use*).

The Detection Module is not functional, if any part of the Detection Module is loose.

If there are any questions, please contact the Endress+Hauser BioSense support (see chapter 8 *Support*).

## 5 Operation

### 5.1 Sample preparation and workflow

#### NOTICE

#### Risk of false results

- Read this chapter carefully before starting with the workflow. For information on the components see chapter 3 *Product description*.
- To avoid unintentional contamination, it is recommended to wear disposable gloves.

| Step  | Depiction |
|---|-----------|
| <p>1. Shake or stir the collected wastewater before use. The wastewater should be at temperatures between 5 °C and 25 °C. Open the sample container (1) and pour in 30 ml of the wastewater.</p> <p><b>NOTICE</b></p> <p><b>Risk of damaging the Detection Module</b></p> <ul style="list-style-type: none"> <li>The <b>sampleID</b> labels included in the Kit can be used for labelling the sample container or lid (1), and the Detection Module (2) (see "Label"). Do not cover the transparent areas on both sides and the QR-code on the white cover side. The Detection Module can be put into the stand (3) for the whole operation.</li> </ul> |           |
| <p>2. Add the TCT beads (4) to the sample and close the lid of the sample container (1). Immediately invert and shake the sample container.</p> <p><b>NOTICE</b></p> <p><b>Risk of losing the sample</b></p> <ul style="list-style-type: none"> <li>If the beads stick together or to the sample container, continue shaking.</li> </ul>  |           |
| <p>3. Let the sample container (1) sit for 30 minutes at room temperature to allow the TCT beads to concentrate the sample.</p>   |           |
| <p>4. After 30 minutes, open the lid of the sample container (1) and pour in the concentration buffer from the buffer container (5). Close the lid of the sample container tightly and shake the sample container for five seconds.</p> <p><b>NOTICE</b></p> <p><b>Risk of losing the sample</b></p> <ul style="list-style-type: none"> <li>Immediately start step 5.</li> </ul>  |           |

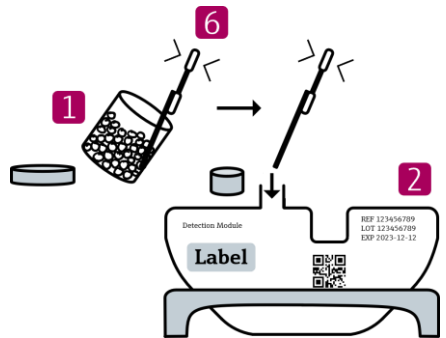
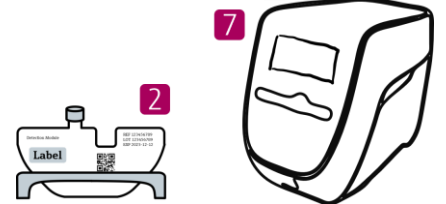
|   |  |
|---|--|
| <p>5. Open the lid of the Detection Module (2). Hold the sample container (1) at a slight angle and take out the concentrated sample with the provided pipette (6) by squeezing and releasing the upper bulb of the pipette. Make sure that the pipette is filled completely without air bubbles. Transfer the sample into the Detection Module by squeezing the upper bulb of the pipette. Close the Detection Module.</p> <p><b>NOTICE</b></p> <p><b>Risk of losing the sample</b></p> <ul style="list-style-type: none"> <li>▪ The pipette must be filled completely. This is visible by the lower bulb overflowing. There must be no air bubbles in the filled pipette (see chapter 6.1 <i>General troubleshooting</i>).</li> <li>▪ Do not turn the Detection Module upside down at any time after being filled with the sample.</li> </ul> |  |
| <p>6. For operation of the Endress+Hauser BioSense Device (7), please refer to the operating instructions of the Endress+Hauser BioSense Device.</p> <p>Proceed to the chapter “Operation” in the operating instructions of the Endress+Hauser BioSense Device to start the analysis of the Detection Module (2).</p>   |  |

Table 5: Description of the six sample preparation steps for an analysis.

## 5.2 Re-analyze a concentrated sample

For later analysis, the remaining concentrated liquid in the sample container can be stored in the empty buffer container at +4 °C for up to 24 hours.

To repeat an analysis, see chapter 5.1 *Sample preparation and workflow* step 5 and step 6.

## 5.3 Disposal of the used Modules

After completion of the sample preparation, all components of the concentration module must be disposed of in a waste container. The concentrated liquid must be disposed of in a waste container together with the storage container after 24 hours.

The Detection Module must be disposed of immediately after ejection from the Endress+Hauser BioSense Device. Regardless of a successful or failed analysis of the Detection Module in the Device, the Detection Module must be disposed of immediately in a waste container.

### ⚠ CAUTION

- The Detection Module must be considered potentially contaminated with SARS-CoV-2 nucleic acids.

## 5.4 Results

### 5.4.1 Display results

Immediately after the ejection of the Detection Modules, the Endress+Hauser BioSense Device displays the test results directly (see chapter *Figure 2*).

Table 6 describes all possibly displayed information on the result screen and gives an explanation.

### ⚠ CAUTION

#### Disclaimer: Incorrect quantification results

- The results are only applicable to samples analyzed exactly according to the operating instructions. Changes in the procedure may lead to altered or even false results.



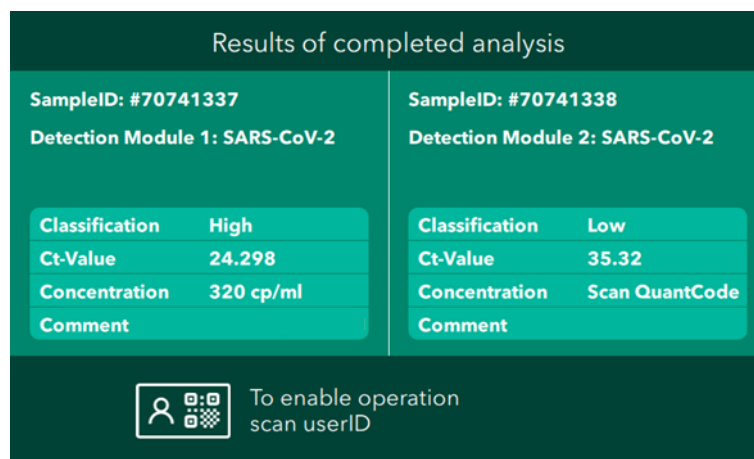


Figure 2: Example of a result screen shown on the Endress+Hauser BioSense Device after a completed analysis.

| Display               | Explanation   |
|-----------------------|---|
| #sampleID             | QR code information used for sample assignment.   |
| SARS-CoV-2            | Specification type of the Detection Module.   |
| Classification        | <i>High, medium, low, positive, or negative</i> result, or <i>invalid</i> analysis (see below). |
| High                  | Positive result with a high viral load.   |
| Medium                | Positive result with a medium viral load.   |
| Low                   | Positive result with a low viral load.  |
| Positive              | Positive result with an unquantifiable viral load.  |
| Negative              | Negative result with no measurable viral load.  |
| Invalid               | No analysis possible.   |
| Ct-Value              | Ct-values give an indication of the viral load.   |
| Concentration         | The viral load in the sample is expressed as virus copies per milliliter (cp/ml).               |
| Scan QuantCode        | Appears if the QuantCode was not scanned yet to quantify a sample.                              |
| Comment               | Additional information, e.g. potentially inhibited, no quant possible                           |
| Potentially inhibited | Results are not reliable and can therefore not be quantified.                                   |
| No quant possible     | Quantification of the viral load is not possible.   |
| Microfluidic Fail     | An error occurred during processing of the Detection Module. No analysis possible.              |

Table 6: List of all possible information displayed on the result screen and their explanation.

### 5.4.2 Recall results

Test results from completed analyses can be retrieved on the Endress+Hauser BioSense Device screen at any time. Although another analysis is currently running, the results of an earlier analysis can still be viewed. The Device can store up to 1000 runs. These readings can be recalled by performing the following steps:

- For operation of the Endress+Hauser BioSense Device, please refer to the operating instructions of the Endress+Hauser BioSense Device.
- Scan the relevant sampleID (see chapter 4.2 *Scope of delivery*).
- The Endress+Hauser BioSense Device displays the corresponding results (see *Figure 3*).

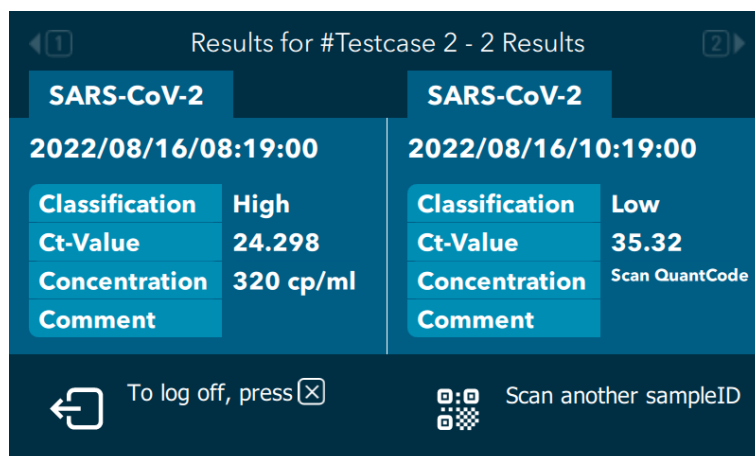


Figure 3: Example of a result screen shown on the Endress+Hauser BioSense Device if results are recalled from the Device storage.

## NOTICE

### Risk of data loss

- Make sure to note down the results regularly.
- Only up to 1000 runs can be stored on the Device. If more than 1000 runs are performed, old data will be overwritten.

## 6 Diagnostics and troubleshooting

In case of questions or errors, please contact Endress+Hauser BioSense support (see chapter 8 Support).

### 6.1 General troubleshooting

In some error cases it is possible to fix errors by following the actions in Table 7. In all other cases, please contact Endress+Hauser BioSense support (see chapter 8 Support).

| Error description   | Action   |
|---|--|
| 5.1 Sample preparation and workflow step 3:<br>Residual liquid in the sample container is above the 10 ml marker after the incubation time of 30 minutes at room temperature.               | Let the sample sit at room temperature until the residual liquid level is below the 10 ml marker.  |
| 5.1 Sample preparation and workflow step 5:<br>The pipette cannot be filled completely due to air bubbles in the pipette, or there is no visible overflow in the lower bulb of the pipette. | Before following step 5, tap the bottom of the sample container on a table or wait for 10 seconds to allow the liquid to flow to the bottom of the sample container. Now follow the operation in step 5. If there is no overflow in the adjoining chamber but the pipette seems full and without air bubbles, keep following the operation.  |
| 5.4 Results:<br>The result shows an invalid run or a potentially inhibited sample.  | If a repeated analysis of this sample is desired, perform the operation as described in 5.1 Sample preparation and workflow from step 1 to step 4. Before continuing with step 5, transfer the liquid from the sample container into the empty concentration buffer container by performing the transfer procedure described in step 5 at least twice. Wait five minutes to let the wastewater particles in the liquid settle to the bottom of the concentration buffer container. Carefully remove the liquid on top of the concentration buffer container as described in step 5 and continue the operation. |

Table 7: Troubleshooting of diverse cases. The action can be carried out in specific cases of errors.

## 7 Maintenance

### 7.1 Control samples

Endress+Hauser BioSense recommends carrying out regular measurements with external control samples. These controls are shipped together with the first order of the Endress+Hauser BioSense Analysis System and should be ordered and tested every time after (re-) installation and movement of the Endress+Hauser BioSense Device.

The quality controls for the Endress+Hauser BioSense Water & Wastewater Kit, Type SARS-CoV-2 contain a positive control with a specific concentration of SARS-CoV-2 and a negative control without SARS-CoV-2. The controls are already labelled with their sampleID and should be handled like a concentrated sample including concentration buffer. Follow steps 5 and 6 of the operation described in chapter 5.1 *Sample preparation and workflow*. The results should display a positive result for the positive control and a negative result for the negative control without the indication for potential inhibition (see chapter 5.4 *Results*). If this is not the case, contact the Endress+Hauser BioSense support immediately (see chapter 8 *Support*).

## 8 Support

### 8.1 Contact information

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

[ehbs.endress.com](http://ehbs.endress.com)

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