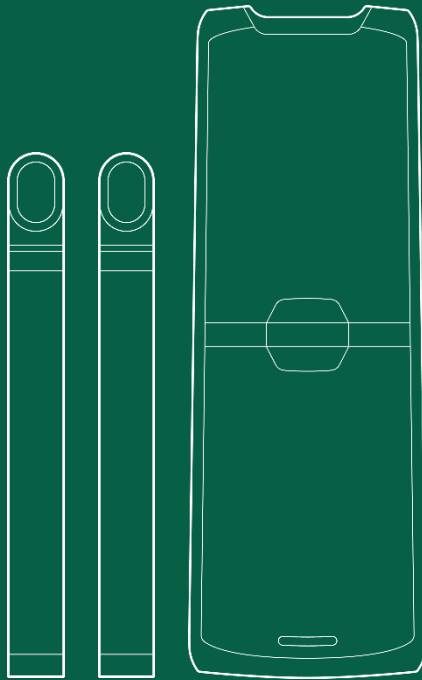


CytoQuant®

Instructions for use





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Thank you for selecting CytoQuant®

Your new CytoQuant® device uses a proprietary electrical detection technology to provide precise counts for intact bacteria and residues on production surfaces in just 30 seconds. We have designed CytoQuant® to be easy-to-use and to guide you through its operations. However, we still recommend reading through this manual before setting up and using the device. This way, you can ensure that CytoQuant® delivers accurate data and maximize its lifetime.

1. Copyright information

Copyright © 2021 Romer Labs Division Holding GmbH. All rights reserved. No part of this manual may be reproduced, stored in a retrieval system, or transmitted, by any means or in any form, without the prior permission of Romer Labs.

The information contained in this manual is subject to change without notice. Romer Labs assumes no responsibility for any errors that may appear in this or related documentation.

Document:	2021-CQ-MANUAL
Version:	4

All sales and technical enquiries should be addressed to:

Romer Labs Division Holding GmbH
Erber Campus 1
3131 Getzersdorf
Austria



2. Regulatory Limitations of Use

2.1 Declaration of Conformity

Romer Labs affirms that this product fulfills the essential requirements of the EMC directive 2014/30/EU when installed and operated in accordance with the instructions in this manual.

Safety and EMC standards



EN 61326-1

FCC part 15



EN 61000-3-2

EN 61000-3-3

2.2 WEEE and RoHS directive compliance

Based on the information provided by our supply lines, and our certain knowledge pertaining to our own processes, products supplied by Romer Labs are RoHS compliant according to RoHS 3 (Directive 2015/863).



Electrical and Electronical Equipment (EEE) should never be discarded as general waste. As part of our compliance with WEEE, we are able to receive and properly dispose of a CytoQuant[®] that you no longer use. Please contact your distributor or Romer Labs for further information.

3. Field of application

The CytoQuant® device is intended for use in cleaning validation within the food and feed industry. CytoQuant® detects and counts all bacteria in swab samples from surfaces in typical production environments.

Bacteria occur far more frequently than can typically be seen in traditional plate counts. Many bacteria cannot be cultured and are therefore unable to be measured with traditional methods. CytoQuant® is designed to detect all bacteria.

The device is not intended to be used regularly for samples that are known to contain excessive amounts of bacteria and particles.



Please read the following safety warnings before attempting to use CytoQuant®:

- CytoQuant® must not be operated in environments where flammable or explosive gases are present.
- If the device emits unexpected smoke or odors, turn it off immediately.
- Never use a damaged power supply.
- If larger amounts of liquid are spilled onto the device, turn it off. Carefully remove any sampling, cleaning, or storage vial that may be in the device as well as the CountCell™. Keep the device upright to allow liquid to drain from the bottom of the device. If in doubt, please contact your Romer Labs representative.



4. Technical parameters

CytoQuant®	Version 1.0
Dimensions	230x80x95 mm/ 9.0x3.1x3.7 inch
Net weight	742 g/26 oz
Input voltage (power supply unit)	100-240V~/50-60Hz
Input voltage (CytoQuant®)	12V/2000 mA
Operating temperatures	+5° C to +30° C/ +41° F to +86° F

5. Measurement specifications

Parameter	
Measurement time	30 seconds
Measurement range	< 15,000 – 10,000,000 intact cells/ml < 50,000 – 10,000,000 particles/ml
Carry-over between samples	Approx. 1-2%
Sample temperature	+5 to +30 °C/ +41° F to +86° F
Total no. of measurements	800 measurements per CountCell™

6. Contents of package

Please make sure that your CytoQuant® box contains the following items:

Item	Quantity
CytoQuant®	1
Power supply	1
Adapters for EU, AU, UK, and USA/JP	4
USB-A Male/USB-Micro-B Male 1 m	1
Manual	1

The supplied items are designed only for this device and may not be compatible with other devices.

Only use accessories or consumables approved by Romer Labs for CytoQuant®.

Using unapproved accessories or consumables may cause performance issues, malfunctions, or permanent damage to the device.



7. Correct handling of the device

Please read the following guidelines for correct handling before you use the device:

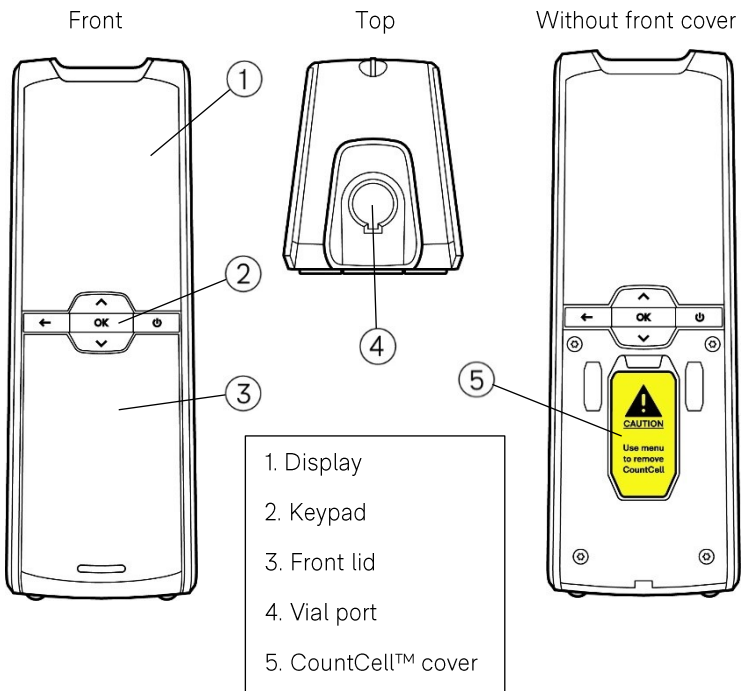
- Never swab surfaces that are visibly dirty.
- Please handle with care. Improper handling, such as dropping the device, can damage the hardware.
- Only the front cover is designed to be removed by the user. Do not otherwise open the case of the device. Opening the case can cause permanent hardware damage and void the warranty.
- Do not use alternative cleaning agents in the device. Use only the supplied cleaning and storage vials. Other cleaners and detergents may permanently damage the device.
- The device must be in an upright position when measuring a sample. Do not turn the device upside down or sideways when measuring a sample.
- Do not remove the CountCell™ when there is a vial in the device – this will cause fluid to leak from the vial into the device. If this happens, immediately wipe off all visible liquid and allow the device to dry for 48 hours.
- Do not insert a vial when there is no CountCell™ inserted - this will cause fluid to leak from the vial into the device. If this happens, immediately wipe off all visible liquid and allow the device to dry for 48 hours.
- Do not remove or replace the CountCell™ before activating the removal process via the menu.
- Always follow the on-screen instructions.

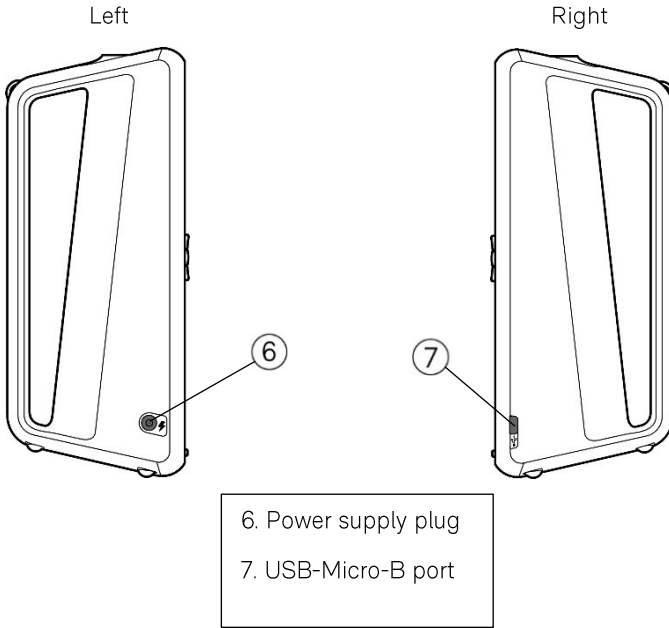
Deviating from the above guidelines can be cause for loss of warranty.

8. Device overview

8.1 Component overview and functions

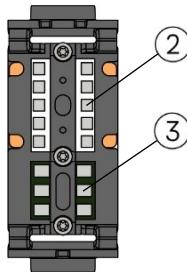
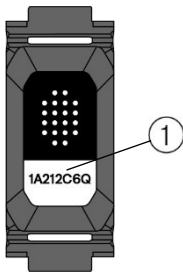
This section provides an overview of the device components and basic functions.





CountCell™ top

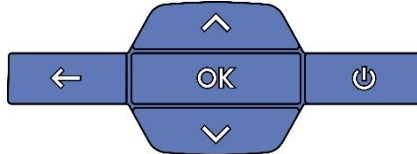
CountCell™ inverse








1. CountCell™ ID
2. CountCell™
3. Calibration chip

8.2 Keypad overview

This section provides an overview of the buttons on the device and their basic functions:



Button	Designation	Function
	ON/OFF button	<ul style="list-style-type: none"> • Turns the device on and off
	OK button	<ul style="list-style-type: none"> • Selects the highlighted item on the display
	RETURN button	<ul style="list-style-type: none"> • Returns to menu • Returns to previous page • Stops an ongoing measurement
	UP button	<ul style="list-style-type: none"> • Navigates up in the menu
	DOWN button	<ul style="list-style-type: none"> • Navigates down in the menu



9. Consumables

This section describes consumables that are used in CytoQuant®.

Swab kit

The swab kit is used for swabbing surfaces and collecting samples to be measured with CytoQuant®. The vials are sterile.

Cleaning vial

The cleaning vial removes larger pieces of debris, foodstuffs, and other particles that may be introduced into the flow system.

Storage vial




The storage vial keeps the device entirely free from bacterial growth when the device is not in use. A storage vial must be inserted into the device every time the device is turned off.

CountCell™

The CountCell™ is used to measure the impedance of the electrical signal, thus providing precise counts of intact bacteria and particles. One CountCell™ can be used for 800 measurements.

10. Initial setup






Perform the following steps when using the device for the first time:









1. Charge the device.
2. Turn on the device by pressing .
3. If your CytoQuant device comes without a CountCell™ inserted, see section 10.1 “Set time, date and time zone”.
4. If your CytoQuant® device comes with a CountCell™ already inserted, the device will prompt you to perform a 2-step cleaning procedure* before using it for the first time:
 - a. Insert a cleaning vial and press  to begin the cleaning step. Discard the cleaning vial when program has finished.
 - b. Insert an unused swab vial, press  to flush the flow system. Discard the swab vial when program has finished.

* Read more about this in section 11.6 “Dry-out effect”.



10.1 Set time, date, and time zone

To set the time, date, and time zone, enter the menu via the  button. Use to the   buttons to navigate to “Settings” and press . Navigate to “Time and date” and press .

- a) Set time and date: Use   to adjust the time or date. Press  to submit and  when finished.
- b) Set time zone: Use   to select the country and city. Press  to submit and  when finished.

10.2 Insert CountCell™

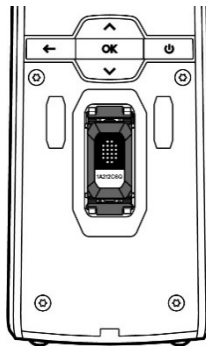
If you have received your device without a CountCell™ already inserted, follow these steps to insert the CountCell™:

- a. Remove the front cover and the protective cover to access the CountCell™ holder†.
- b. Insert the CountCell™ as shown in the diagram below. Click it firmly into place.


(a)



(b)





- c. After the CountCell™ has been inserted correctly, the device will prompt you to perform a 2-step cleaning procedure as described in Section 10.
- d. Return to the Home screen by pressing .
The device is now ready for use.


† Whenever you remove or replace a CountCell™, you must use the menu to change the CountCell™. Otherwise, you can damage the device.

11. Basic operation

This section describes the basics of using CytoQuant®. Before continuing, perform the initial setup as described in section 10.

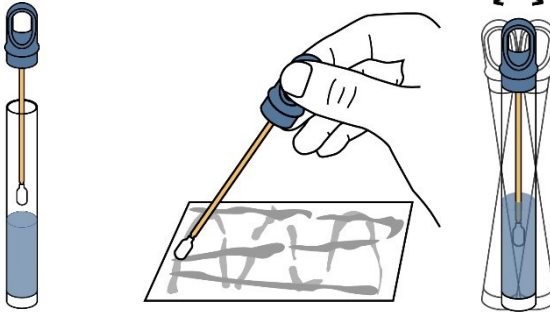
11.1 Start-up

Prior to using the device to measure samples, perform the start-up procedure as follows:

1. Turn on the device by pressing .
2. DO NOT REMOVE the storage vial during start-up as the device will automatically empty the storage liquid into the system.
3. The device will display that it is ready after the start-up process has completed.

11.2 Measuring samples

Follow this procedure to prepare samples:



1. Open swab kit
2. Swab area of interest
3. Insert into vial and shake

1. Open swab kit by unscrewing the swab and removing it from the vial. Be careful not to touch the swab or swab shaft.
2. Swab sampling area. Use the swab to collect your sample from a surface area or crevice(s) appropriate to your production environment.
3. Re-insert the swab into the vial and screw it closed.
4. Shake the vial for 5 seconds to distribute the bacteria evenly.
5. Insert the swab vial into the vial port and press "Measure."

11.3 Using the cleaning vial

The cleaning procedure should always be performed:


- when the device prompts you to do so, for example, after an error message.
- after a day of measurements and before powering the device down.
- if you are not planning to use the device for 30 minutes or longer.
- after every 20th measurement.

Follow these steps to clean the internal flow system of CytoQuant®:

1. Insert a cleaning vial into the vial port.
2. Select “Clean” from the menu and press the OK button. CytoQuant® will now flush the system with the cleaning solution.
3. The cleaning procedure is complete after around 20 seconds. CytoQuant® is now ready for use.

11.4 Shutting down

Follow this procedure to ensure that the device is shut down correctly:

1. Press  to display the power-off menu.
2. Follow the steps indicated on the display.
3. Leave the storage vial in the device during storage.




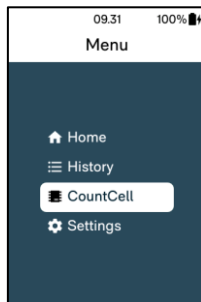
4. Charge the device if needed.

11.5 Exchanging or removing the CountCell™

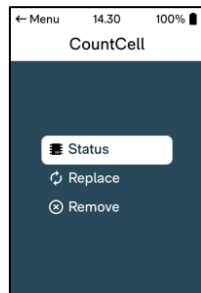


You must follow the steps in the menu to replace or remove the CountCell™. Failing to do so can lead to a loss of warranty.

Access the menu to replace or remove the CountCell™ by pressing . Select the “CountCell™” menu item.



Select replace or remove and follow the on-screen guide.



11.6 “Dry-out effect”

A 2-step cleaning procedure is necessary to avoid the “dry-out effect”. The “dry-out effect” happens when the system has been disinfected and the CountCell™ and/or a vial is removed. An open system allows the disinfection liquid to evaporate, leaving residues in the system that will interfere with the first measurement if not flushed out.

You can see the 2-step cleaning procedure upon receipt of the device or if you have removed the CountCell™ and/or a vial. Read section 16 for correct storage of the device.



11.7 Downloading data from CytoQuant®

You can download measurements from CytoQuant® by connecting it to your computer with the supplied USB cable. CytoQuant® will appear as a USB-drive when the device is turned on and connected to your computer.

CytoQuant® will generate a .csv file upon connecting to the computer. The .csv file has twelve columns with the following information: program, start time, measurement ID, device ID, software version, CountCell™ ID, intact cells/ml, total particles/ml, (total particles – intact cells)/ml, LF SNR, HF SNR, and errors.

As you sample, be sure to record both the measurement ID displayed by CytoQuant® and the location from which the sample was taken.

11.8 Battery and charging



When the battery is fully charged, it has a lifespan of approximately 2 hours of heavy use.

We recommend disconnecting the device from the charger during use.



The device will display a low-battery warning at 20% and 10% of battery capacity.






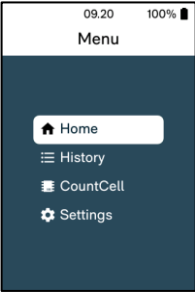



When the battery is completely discharged, the device will automatically turn off. Connect the charger to the device to charge the battery.

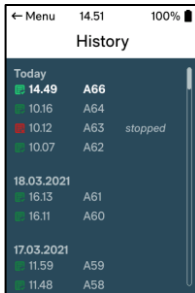


The device may become warm if used while the charger is connected. While this will not influence measurements, it is still not recommended.

12. Overview of display and menu items

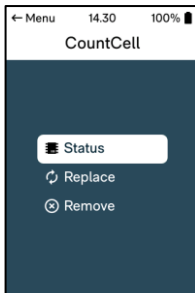
This section provides an overview of the display and menu items in CytoQuant®.

Display	Description
	<p>Home/Ready:</p> <ul style="list-style-type: none"> Shows time and battery status. Use  to access the menu. Press  to continue.
	<p>Menu:</p> <ul style="list-style-type: none"> Use   to navigate. Press  to select an option Home: returns to the home screen. History: shows a list of previous measurements. CountCell™: shows number of measurements that can still be performed on the CountCell™. Settings: see section “Settings” below.



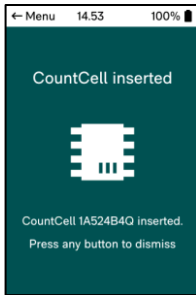
Menu → History

- Shows results from the last 100 measurements.
- Press to display a measurement saved on the device.
- **Note** that all measurements are saved in a .csv file as explained in section 11.6 “Downloading data from CytoQuant®”.



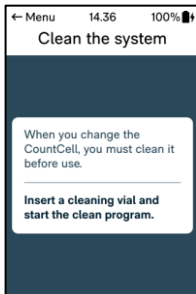
Menu → CountCell™

- **Status:** Shows how many measurements can still be performed using the current CountCell™. E.g., 595/800 means that there are 595 measurements remaining of a total of 800.
- **Replace/Remove:** Lets you replace or remove the CountCell™. Follow the instructions on the screen to replace or remove CountCell™.



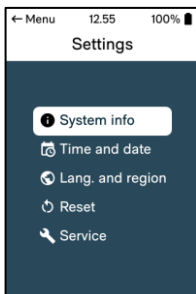
Menu → CountCell™ → Replace

- This screen guides you through the replacement process of CountCell™.
- The screen shows the CountCell™ ID.
- Press any button to dismiss.



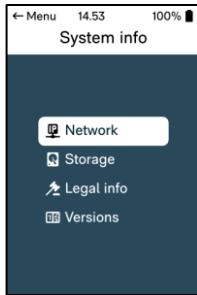
Menu → CountCell™ → Replace → Clean

- After inserting a new CountCell™, you must perform a cleaning step. This ensures a clean CountCell™.
- Insert a cleaning vial and start the cleaning program.



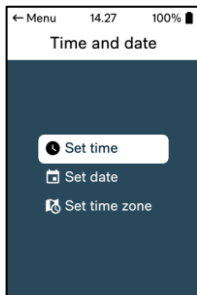
Menu → Settings:

- **System info:** Shows device information
- **Time and date:** Change time and date settings
- **Lang. and region:** Change language and region settings
- **Reset:** Reset device settings and data
- **Service:** Run device diagnostics



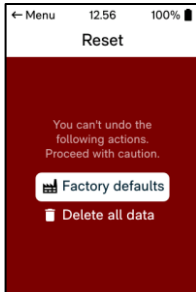
Menu → Settings → System info:

- **Network:** Shows device hostname and the local IP address if connected to the internet.
- **Storage:** Displays the current data storage capacity.
- **Legal Info:** Shows software licenses relating to CytoQuant®.
- **Versions:** Shows versions of device hardware, firmware, and software.



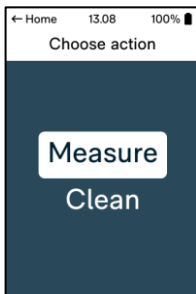
Menu → Settings → Time and date:

- **Set time/Set date:** Use to adjust the time or date. Press to submit and when finished.
- **Set time zone:** Use to select the country and city. Press to submit and when finished.



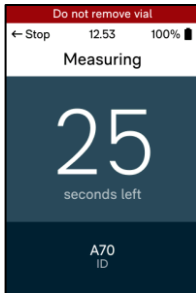
Menu → Settings → Reset

- Allows you to reset the device to factory defaults or to delete all data stored on the device.
- You cannot undo these actions.
- You must restart the device after resetting.



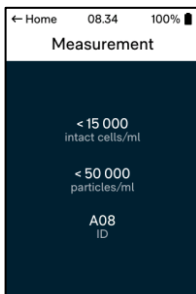
Menu → Home → Choose action:

- Can only be entered when a vial or swab is inserted in the device.
- Use to select an action and press to initiate the action.
- **Measure:** Starts a measurement.
- **Clean:** Cleans the flow system.



Choose action → Measuring:

- Shows the time remaining in the current measurement.
- Shows the measurement ID as well as a combination of letters and numbers.
- **Be aware of the warning at the top of the display: do NOT remove the vial while measuring as it may severely damage the device!**
- After a measurement has finished, the device automatically empties the flow system.



Result screen:

- Shows the result (intact cells/ml and particles/ml) and measurement ID.
- Record the measurement ID and location at which the sample was taken as the result disappears from the display as soon as the next action is started.
- You can always access the results of the measurement via the history screen.



13. Simple troubleshooting

If your CytoQuant™ is unresponsive or slow, some simple troubleshooting may resolve any issues. If the problem persists, please contact your Romer Labs® sales representative.

Your device does not turn on.

The battery may be empty. Charge the device for at least 30 minutes and try turning it on again.

The device responds slowly or freezes.

If your device is sluggish or unresponsive, you may need to restart it. In this case, force a hard power-off by holding the off button for about 10 seconds until the device shuts down.

I continue to get measurement errors.

See section 14 “Advanced troubleshooting.” If the steps listed there do not help, contact your sales representative.

14. Advanced troubleshooting

If an error code appears, always follow the on-screen instructions first. If these do not resolve the issue, consult the error code list below and attempt the corresponding solution.



CytoQuant™ displays error codes at the top of the screen.

Refer to this error code for the advanced troubleshooting in this section.

The system will interrupt an ongoing measurement and empty the flow system if an error message appears before the measurement is completed. However, some error messages cannot appear until after the measurement is completed.

The most common errors are listed in the table below. If these troubleshooting steps fail to resolve the problem or if other errors occur, contact your sales representative.

Error code	1000 – Measurement error
Technical explanation	There is no current between the measuring electrodes in the CountCell™.
Possible cause	The most likely cause is a poor or wet connection between the CountCell™ and the device.
Troubleshooting	<p>Solution 1: Clean the flow system using a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.</p> <p>Solution 2: Use the menu to exchange the CountCell™ - see 11.5 Exchanging or removing the CountCell™. Remove the CountCell™ and reinsert it while following the on-screen guide. Clean the flow system using a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.</p>

Error code	1001 – Measurement error
Technical explanation	There is an imbalance between the measuring electrodes in the CountCell™.
Possible cause	This error triggers when something adheres to electrodes in the CountCell™, thus changing the current. This could be particles that are

charged or have a high affinity to metal.

Troubleshooting

Solution 1: Clean the flow system using a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.

Solution 2: Use the menu to exchange the CountCell™ - see 11.5 Exchanging or removing the CountCell™. Remove the CountCell™ and insert the same CountCell™ back in while following the on-screen guide. Perform a cleaning step with a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.

Error code	1100-1141 – Measurement error
Technical explanation	The electrical signal contains too much electrical noise.
Possible cause	A very high number of very small particles or bacteria can be misinterpreted as signal noise. Other causes include outside interference on the electronics or damage to the device.
Troubleshooting	Make sure the electrodes in the CountCell™ are free of deposits that can cause electrical noise. If the electrodes are unimpeded, then your sample may be outside conductivity



specification. Contact your sales representative if in doubt.

Solution 1: Clean the device using a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.

Solution 2: Use the menu for exchanging the CountCell™ - 11.5. Exchanging or removing the CountCell™. Remove the CountCell™ and insert the same CountCell™ back in while following the on-screen guide. Perform a cleaning step with a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.

Error code	2000 – Device is severely clogged
Technical explanation	The average velocity of the particles and bacteria that pass through the CountCell™ is much lower than expected.
Possible cause	The error is most likely caused by a large particle clogging the filter in the CytoQuant® Swab Kit, the inlet of the CountCell™, or some other part of the flow system.

Troubleshooting Clean the device using a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.

Error code **2010, 2020 – CountCell™ is clogged**

Technical explanation The CountCell™ has two measuring channels that should always measure the same concentration. Errors 2010 and 2020 are triggered when different concentrations are measured in the two measuring channels in the CountCell™. The difference is too large to be explained by statistical deviation and therefore must be caused by a clogging of one of the measuring channels.

Possible cause The most likely cause of either one of these errors is that something has lodged itself into one of the measuring channels. This could happen if a sample with a very high concentration of bacteria or particles was run through with the system.

Troubleshooting Clean the device using a cleaning vial. Verify the solution by measuring an unused CytoQuant® Swab Kit.


Error code	2030, 2040 – CountCell™ is severely clogged
Technical explanation	This error is very similar in nature to errors 2010 and 2020. However, CytoQuant® can detect artifacts in the sample, indicating that the clogging is more severe than in errors 2010 and 2020.
Possible cause	The most likely cause of either one of these errors is that a large object has lodged itself into one of the measuring channels.
Troubleshooting	Clean the flow system using a cleaning vial. Repeat this with a different cleaning vial. Confirm that the cleaning solved the problem by measuring an unused CytoQuant® Swab Kit.

15. Shipping CytoQuant®

You may at some point need to ship your device. If this is the case, please adhere to the following shipping procedure:

- Insert a cleaning vial
Go to Menu → Settings → Service → Prepare to ship

The device will automatically clean the system with the storage liquid.

- Remove the cleaning vial and press  to shut down.
- Ship CytoQuant® with the CountCell™ inserted in the device.

Please note that some devices may contain software that can guide you through the “Prepare to ship” program.



Always follow the shutdown procedure stated in section 11.4 Shutting down. You may only deviate from this procedure when shipping the device.



16. Storage and maintenance

Maintain your device by carefully following these guidelines.

- If the device is in use, store the device with a storage vial inserted as described in section 11.4 “Shutting down”.
- The device must be stored in a dry place within a temperature range of +5°C to +35°C (41°F to 95°F).
- Do not store or use the device or power supply in a location with high levels of steam, humidity, dust, or vibration.
- Do not allow your device to be exposed to direct sunlight for extended periods of time.
- Clean the surface of the device with a clean, soft cloth moistened with a solution of 70 % alcohol.
- If the device is exposed to other liquids, such as oil, wipe it with a damp, soft cloth and then dry it thoroughly.
- The CountCell™ is rated to perform 800 measurements. If the CountCell™ needs to be changed, follow the instruction as described in section 11.5 “Exchanging or removing the CountCell™”.
- Sampling, cleaning, and storage vials must be stored within a temperature range of +5°C to +25°C (41°F to 77°F) and away from direct sunlight.

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