

REF

e34016 User Manual Egoo Health System Q200

IVD

CE

It is recommended to read and get an overview of this use manual first, before performing any analysis with the Egoo Health System.



egoo.health

INTENDED USE

The Egoo Health System is a transportable, automated in vitro diagnostic instrument, for qualitative determination of biological samples. The Egoo Health System is intended for use by healthcare professionals. It is intended for use in a laboratory environment.

The Egoo Health System includes Egoo instrument(s) connected to an Egoo Clinical Application installed on a laptop with Windows 10 or above. Up to five instruments may be connected to one Egoo Clinical Application.

The Egoo Health System uses Egoo Capsules specific for the biological parameter to be analysed.

SCOPE

This document provides instructions for correct and secure use of the Egoo Health System. Qlife does not accept warranty claims or product liability if the instructions are not followed by an operator of the system.

This document describes daily use and reference information and how to install and use the Egoo Health System.

Be aware that for each specific Egoo Health System biomarker you want to analyse, you should refer to the specific IFUs for instructions about sample preparation and capsule.

MATERIALS INCLUDED

- Egoo Instrument ^{REF}e78852
- Power cord adapted for the country of use
- User Manual Egoo Health System ^{REF}e34016 (present document)



MATERIALS REQUIRED BUT NOT INCLUDED

Be aware of special needs for the specific Egoo Health System biomarker you are analysing. See the specific 'Information for Use' for more information.

- PC/laptop with Windows 10 installed including the latest updates.
- Egoo Clinical application (software program used to perform analysis) installed on the PC/laptop.
- Barcode and QR-code reader. Recommendation: ZEBRA DS22088-HC.
- Personal protective equipment (gloves).
- As part of the Egoo Health System, there should also be an Egoo Capsule, that is used for qualitative or quantitative analysis of different biomarkers. See the specific Capsule IFU for this element and what is included in the specific package.

WARNING AND PRECAUTIONS

Symbols of danger provides instructions for use which needs to be complied to, to prevent risk of injury on person or instrument. There are two types of danger:

Type and danger	Symbol	Description
Warning		Death or personal injury
Precaution		Destruction of equipment

 **WARNING – Risk of electric shock**

Do not clean the instrument while connected to power supply.

 **WARNING – Risk of fire**

Do not clean the instrument while hot (above 30 degree Celsius).

 **WARNING – Risk of electric shock**

Place the instrument 1.5 meter from the patient bed.

 **WARNING – Risk of incorrect clinical decision making**

- A medical consultant must always interpret the result of a test within the clinically relevant context.

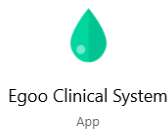
LIMITATIONS & RESPONSIBILITY



⚠ WARNING – Risk of infection

- The Ego Health System is to be used by healthcare professionals only and only healthcare professionals are to be handling patient samples.
- Use of the equipment by healthcare professionals does not require training.
- If distributing an Ego Instrument to a third party, this User Manual must be included.
- Discharge used equipment as electronic waste and all sample material, gloves, pipette tips and capsules as biohazard waste [1].
- All sample material should be considered potentially infectious and handled in accordance with good laboratory practice [3] and country, state, and local regulation.
- Incorrect handling of patient material may expose operator to potential infectious specimen. Gloves must be worn.

PROCEDURE



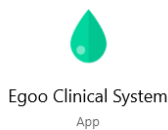
IT IS RECOMMENDED TO READ THIS INSTRUCTION BEFORE USE

- Put on gloves.
- Check that the PC/laptop has power and that all instruments are turned on (plugged in).
- Start the Ego Clinical Application on your PC/laptop. For download and installation issues, see below.
- Connect the barcode and QR-code reader to your PC/laptop.

NOTE: Before going forward with the Ego Clinical Application or getting the Ego Instrument ready for analysis, it is important that you prepare sample and capsule. Use the 'Instruction for Use' included in the specific Ego Health System biomarker e.g., Ego Capsule and Ego Lysis Buffer, that you need.

IT IS RECOMMENDED TO PREPARE SAMPLE AND CAPSULE BEFORE CONTINUING WITH THE STEPS BELOW.

STEP 1: CONNECT AND CHOOSE INSTRUMENT

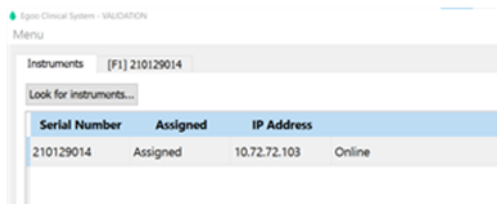


- Wait for the connection between the Ego Clinical Application and the Ego Instrument to be established. NOTE: *If this creates issues, try to close the application, and re-start the instrument. If there are still problems, contact support.*
- When connection is successful, the Ego Clinical Application shows Instrument serial number, assigned, IP code and online (figure 1). Verify the serial number on the instrument (found underneath).
- **Choose instrument** to use by selecting the tab of the instrument. NOTE: *Each instrument has a tab, and a F-key that can be used to access the instrument.*

NOTE: *If the instrument is not connected the sign * appears next to the serial number in the tab. Try to re-start the instrument. Do this by turning off the power, wait 5 seconds, and turn it on again.*

NOTE: *If the instrument disappears, try to re-start the application. If this is no success, try to re-start the instrument.*

Figure 1



STEP 2: START ANALYSIS – PRESS START

1. Start (Open drawer)
2. Scan sample id
3. Insert capsule in instrument
4. Scan Capsule QR Code
5. Close drawer
6. Wait for analysis...
7. Result
8. Send to Ego Calculation
9. Dispose capsule and close drawer

- **Choose 'Start'** or press ENTER to open the drawer. The drawer on the instrument opens automatically. When doing this, the instrument makes a some-what big noise. This is normal.
- When the drawer has opened, you are ready for the next step.
- **NOTE:** *If you are not ready with the capsule, you can close the drawer by carefully pushing on both sides of the drawer (step 7) and pressing the reset button on the screen. To open the drawer again, choose 'Start'.*

STEP 3: SAMPLE ID

1. Start (Open drawer)
2. Scan sample id pos 3
3. Insert capsule in instrument
4. Scan Capsule QR Code
5. Close drawer
6. Wait for analysis...
7. Result
8. Send to Ego Calculation
9. Dispose capsule and close drawer

- **Scan or enter sample ID** and press ENTER.
- **NOTE:** *This is not the QR-code, but your traceable ID. Make sure to have sample traceability. Write down numbers needed for later tracking.*
- **NOTE:** *Recommended barcode and QR-code reader can be found in chapter 1.9. See 'Instructions for Use' for how to prepare the sample. If labels with barcodes are used, scan the traceable ID barcode.*

STEP 4: PLACE THE EGEO CAPSULE

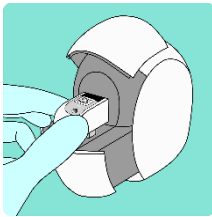
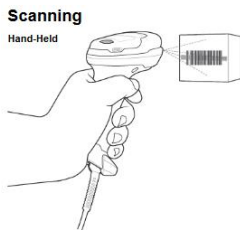


Figure 2



- **Place the Ego Capsule** in the instrument (figure 2).
- A slight click sound appears when the capsule is placed correctly.
- When the capsule is placed in the instrument you are ready for the next step.

STEP 5: SCAN QR-code



(New picture with QR-code needed)

- **Scan the QR-code.** When the QR-code is scanned you are ready for the next step.

STEP 6: CLOSE THE DRAWER

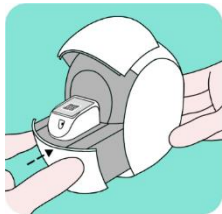
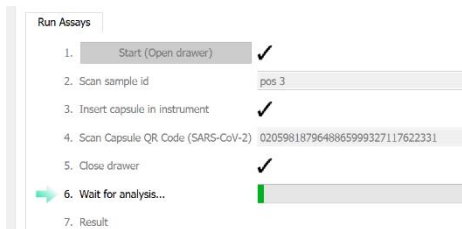
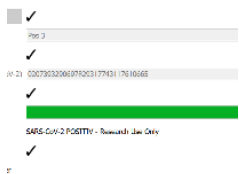


Figure 3

- **Close the drawer** (figure 3) on the instrument by carefully pushing on both sides of the drawer.
- **Wait** while the analysis takes place. Ego Clinical Application shows it is working. When the whole bar turns green, it is finished and the drawer will open.



<p>STEP 7: REMOVE THE CAPSULE</p>	<ul style="list-style-type: none"> Remove the capsule by supporting the Egoo Instrument with one hand and pulling the capsule out with the other. <p> WARNING – Risk of infection: Discard capsules as biohazard waste [1]. Follow good laboratory practice and country, state and local regulation.</p>
<p>STEP 8: NOTE RESULT</p>  <p style="text-align: center;">Figure 4</p>	<ul style="list-style-type: none"> Read and note the result of the analysis. NOTE: <i>The result is not saved in the application. It is HEAVILY RECOMMENDED, that the result is registered manually before more is done.</i> Make sure to have sample traceability. The result has two parts: What has the sample been analysed for – and what was found. <p>The result has two parts, in this case: SARS-CoV-2 and Positive (figure 4).</p>
<p>STEP 9: CLOSE THE DRAWER</p>	<ul style="list-style-type: none"> Close the drawer carefully. The instrument is now ready for the next analysis. Make sure that no capsule is left in the instrument. <p> WARNING – Risk of infection: Discard capsules as biohazard waste [1]. Follow good laboratory practice and country, state and local regulation.</p>

CLOSING THE EGGO HEALTH SYSTEM

- Make sure that all instruments have finalized analysis and no capsule is left in the instrument.
- Make sure that drawers are closed on all instruments.
- Turn off the power on all instruments.
- Shut down the Egoo Clinical Application on the computer.

TRANSPORT

Transport the Egoo Instrument and other parts of the Egoo Health System in the accompanying packaging.

STORAGE

Store the Egoo Instrument in a dry indoor environment at room temperature away from kids and pets.

CLEANING

- WARNING – Risk of infection**
Remember to use gloves.
 - WARNING – Risk of electric shock**
Do not clean the instrument while connected to power supply.
 - WARNING – Risk of fire**
Do not clean the instrument while hot (above 30 degree Celsius).
- Clean the equipment regularly if dust or liquid appears on the instrument. Comply with the following guidance for cleaning.

Cleaning of the outside and inside of the instrument

- WARNING – Risk of electric shock**
Do not clean the instrument while connected to power supply. Also make sure the instrument is below 30 degrees Celsius, before cleaning it. Wait two hours after the instrument has been in use to make sure the instrument is sufficiently cooled down. Disconnect the power supply before cleaning the instrument.
- PRECAUTION - Risk of ruining the instrument.**
Keep liquid out of contact with electrical parts of instrument.

NEEDED FOR CLEANING

- A cotton cloth
- Two cotton swabs
- One of the following reagents:
 - Ethanol

Do not use any other cleaning reagents, as they could potentially damage the electric circuit of the instrument.

PROCEDURE FOR CLEANING

Outside:

1. Before turning on the instruments, moisten a cotton cloth with ethanol and clean the instrument on the outside when there is visible dust/dirt.

Inside:

2. If visible dirt/dust is observed on the inside of the instrument around the capsule holder, take a dry cotton swab and cautiously wipe the area for cleaning.

FURTHER CLEANING

Follow local and national regulations for disinfection of instruments.

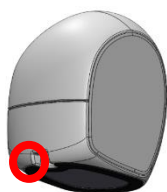
Further cleaning might be applied once a week for a period of two years.

SETTING UP THE EGGO SYSTEM



Opening the Ego Instrument Package

- Open the box by cutting the tape around the box, use a scissor or knife.
- Be careful when you use the cutting unit, so you do not ruin the product.
- Keep the box for eventual reuse if you need to transport the instrument and its parts.
- Open and remove the packaging.
- Check for content based on the list above.
- Check content for visual damage. If something is missing or defective, contact support.



Placement of the Ego Instrument



PRECAUTION – Risk of getting a wrong result

PRECAUTION – Risk of destruction of equipment

- Place the Ego Instrument on an even, horizontal, and stable surface e.g., a table, where there is also room for a PC or laptop.
- Make sure there is enough room around the Ego Instrument, so the drawer can open freely.
- Plug in the power cord to the socket.
- NOTE: *Only use the power cord that is delivered with the instrument.*

THE EGGO CLINICAL APPLICATION AND CONNECTING EGGO INSTRUMENT(S)



Ego Clinical System
App

Ego Clinical Application should be installed on a PC or laptop with Windows 10. It is recommended to run the latest Windows updates for security. The computer needs to be online and correctly configured regarding wi-fi, to be able to run the analysis of the samples. It is recommended that the set-up of computer and wi-fi is done by IT-department /It-support or with help from Qlife.

The Ego Clinical Application can be found here:

https://egoostorageprod.blob.core.windows.net/egoclinical/Qlife_Egoo_Clinical.zip

The first time you want to use the Ego Clinical Application, you need to log in. Use the Customer ID and Activation Key delivered from Qlife Aps. One Ego Clinical Application can connect to 5 Ego Instruments. First time you connect Ego Instruments to the Ego Clinical Application help from IT or Qlife support is needed. Also, with wi-fi issues or the need of changing wi-fi setting, please contact support.

PARAMETER DEFAULT SETTINGS RESULTS

Settings in the Ego Clinical Application:

Parameter	Unit	Number of decimals
DIAGNOSTIC ASSAY	Refer to specific Ego Capsule 'Instruction for Use'	None

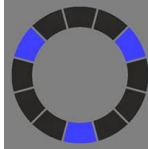

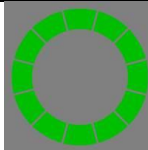
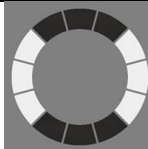
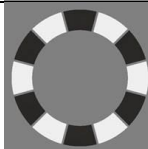
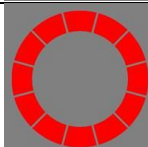
LANGUAGE

As a standard 'Windows standard language' is used in Ego Clinical Application. It is possible to change language. Danish and English is supported.

- Start the Ego Clinical Application
- Choose 'Menu' and 'Settings'. Then choose 'user interface language' and pick the language of your choice.

LIGHTS ON THE EGGO INSTRUMENT

On the top of the Ego Instrument is a small circle that lights up in different patterns and colours, depending on what the instrument is doing. When the drawer is open, it is not possible to see the lights.

Pattern	Description
	Searching for connection – this may take a while
	Connecting – this may take a while
	Ready for test
	Busy
	Running test
	Instrument error – please restart. If error persist, call support.

INSTRUMENT SERVICE

If the Ego Health System needs support or service, please contact your local Qlife representative. Please, have your customer ID and serial numbers ready. This information can be found on the labels of the instrument. Serial number is written: Hardware/SN (9 numbers).

PRODUCT SPECIFICATIONS

Specification	Description
Dimensions (with x dept x high)	55 x 100 x 110 mm
Weight	0.750 kg
Start-up time	Less than 5 minutes
Analysis-time per sample	Assay dependent
Size of test	Assay dependent
Number of analysis pr hour	Assay dependent
Data storage capacity	Up to 1 analysis per instrument. Data from the instrument is passed on and stored pseudonymously on a remote server.
Operations temperature	15 to 30 °C
Maximal sound level	54 dBA



ENVIRONMENTAL SPECIFICATIONS

Specification	Value
Location	For indoor use only
Operations temperature	15 to 30°C
Operations relative humidity	20-80%
Operations pressure	738 to 1013 hPa, from sea-level to 2,591 m above sea-level
Storage temperature in transport	-20°C to 60°C
Air humidity in transport	<95%
Air pressure in transport	600 – 1060 hPa
Power supply	Related voltage: 100-240 VAC± 10%; 50/60 Hz Maximal voltage fluctuation: ±10% Class 1 power supply
Power use	Average power supply:< 10 W Maximal power supply: 22W
Pollution	2 (occasional conductivity caused by condensation)
Heat-spread	< 60 W
EMC- emission and immunity	The instrument complies with emission and immunity requirements regulated by EN/IEC 61326-2-6. The instrument is designed and tested in relation to EN 55011/CISPR 11, Group 2, Class B. Do not use the instrument close to any strong electromagnetic radiation (e.g., a shielded intentional RF source, as these may affect the functioning of the instrument)
Spatial demands	Ensure sufficient space around the instrument to avoid overheating. Do not place the instrument so that it is stuffy. Ensure easy access to the circuit breaker.

POWER SUPPLY

Wires, sockets, and connections etc. shall comply with national regulations. If this is not met, the Ego Health System will be ruined.

Land	Specifications for power supply
Europa (265 VAC)	100-240V~50/60Hz 0.3A

PATENTS & TRADEMARKS

Qlife products are covered within one or several patents or patent applications.

System Performance

Procedures described in this manual must be adhered to ensure system performance and prevent risks. Qlife cannot ensure the nature of system functionality if the system is not installed, used, and maintained in accordance with Qlife procedures or if accessories that do not meet Qlife’s specifications are used.

Qlife guarantees that the data media on which the system software is arranged are free of material and artisanal defects when use for three months after delivery, cf. billing date.

Third-party software and trademarks

Use of Qlife's product is subject to terms and conditions included in the Microsoft Azure user base®.

Warranties and Disclaimer

Qlife only guarantees what is explicitly stated. Warranties explicitly stated in this document assume that the system is installed, used, and maintained in accordance with Qlife’s procedures and that only accessories complying with Qlife specifications are used.

Qlife disclaims any responsibility for system functionality if the system is not installed, used, and maintained in accordance with Qlife procedures or if accessories are used that do not meet Qlife’s specifications.

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Changes

The contents of this document are subject to change without notice. While attempting to ensure correct information in this document, which changes from time to time, Qlife disclaims any liability for errors or omissions.

REFERENCES

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2. Zhe Xu*, Lei Shi*, Yijin Wang et al. Pathological findings of COVID-19 associated with acute respiratory distress syndrome. *Lancet Respir Med* 2020; 8: 420–22
3. Hoser MJ, Mansukoski HK, Morrical SW, Eboigbodin KE. Strand Invasion Based Amplification (SIBA®): A novel isothermal DNA amplification technology demonstrating high specificity and sensitivity for a single molecule of target analyte. *PLoS One*. 2014;9(11):1–20.
4. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline – Fourth Edition. CLSI document M29-A4E. 2014.

SYMBOLS

Symbol	Explanation	Symbol	Explanation
	Warning – Death or personal injury		Precaution – Destruction of equipment
	Consult instruction for use		Expiration date
	Batch number		Do not reuse
	Manufacturer		Catalogue number
	Temperature limitations		Do not use if the packaging is broken
	Number		In vitro diagnostic equipment
	European conformity		Serial number
	<p>To be discharged as electronic waste (WEEE).</p> <p>The symbol indicates that Qlife has taken necessary steps to comply with the 2012/19/EC for electronic waste (WEEE).</p> <p>When reaching expiry date, the instrument must be collected and reused according to national requirements. Contact Qlife or a Qlife distributor for advice. WEEE includes material potentially hazardous for the environment and human health.</p>		