



COVBELD USER MANUAL

3 MINUTE REAL TIME DETECTION OF SARS COV-2

USR-02

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Intended Use

For use under the Emergency Use Authorization (EUA) only For in vitro diagnostic use

The CovBELD (CoronaVirus BELD) test is a cell-based assay that is used with the BELD instrument intended for the qualitative detection of the S1 spike protein antigen from SARS-CoV-2 in nasopharyngeal (NP) and nasal (NS) swab specimens after the swabs have been added to viral transport media from individuals who are suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 S1 spike protein antigen. Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Sample collection and handling

SAMPLE COLLECTION

Nasal Swab Sample

To collect a nasal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then remove it from the nostril.

Nasopharyngeal Swab Sample

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing

the swab into the posterior nasopharynx. Rotate the swab several times then remove it from the nasopharynx.

SAMPLE TRANSPORT AND STORAGE

Samples should be tested as soon as possible after collection. Based on data generated with influenza virus, nasal or nasopharyngeal swabs are stable for up to 24-hours at room temperature or 2° to 8°C.

If transport of samples with viral transport medium {VTM} is required, minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity. While holding the swab, the cap from the tube. Insert the swab into the tube and gently rotate the swab into the viral transport medium for 2-3 time and remove it. Based on data generated with influenza virus, nasal or nasopharyngeal swabs in VTM are stable for up to 72-hours at 2° to 8C.

Note: When using viral transport medium {VTM}, it is important to ensure that the VTM containing the sample is warmed to room temperature. Cold samples can lead to erroneous or invalid results. Several minutes will be required to bring a cold sample to room temperature.

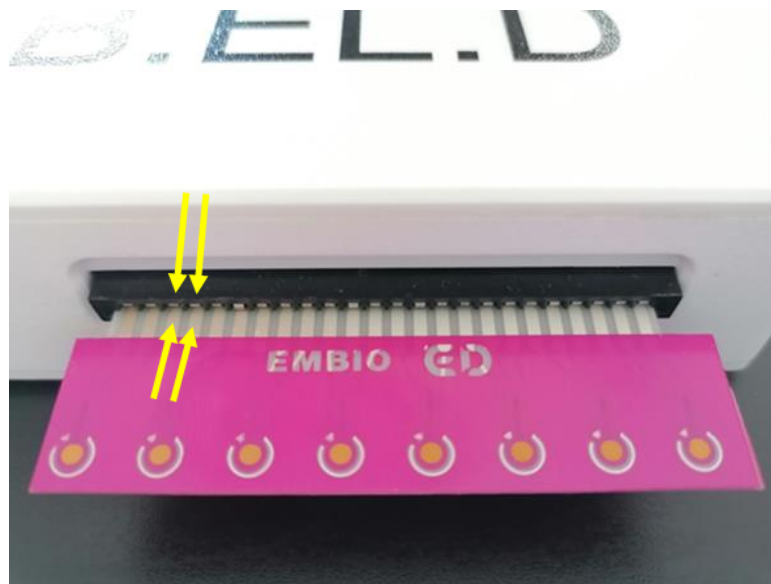
Test procedure

All clinical samples must be at room temperature before beginning the assay.

BIOSENSOR MEASUREMENT

- A. Connect the screen-printed electrode with the device and turn on the device. Be sure that the electrodes are aligned with the connectors.**

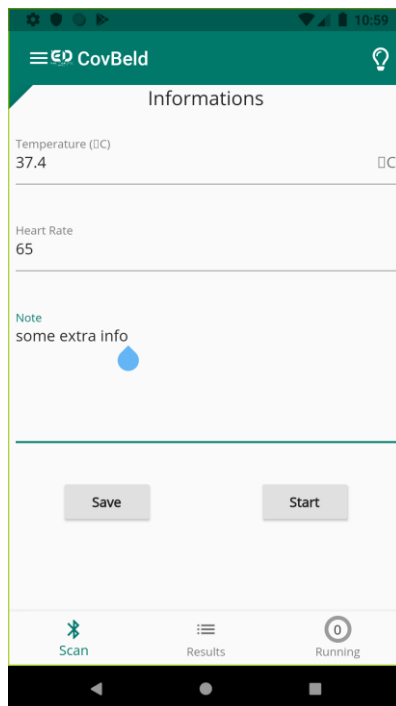




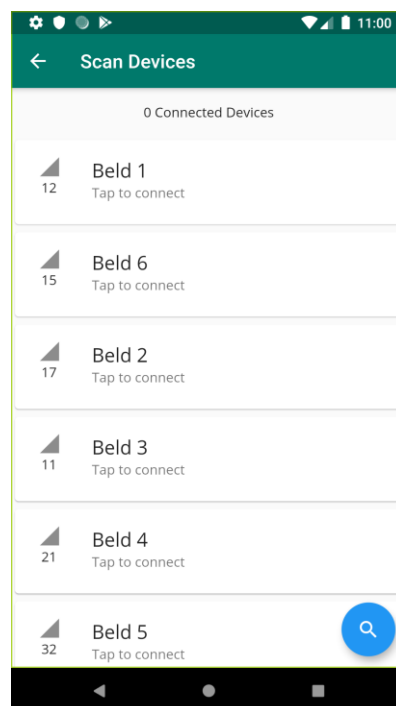
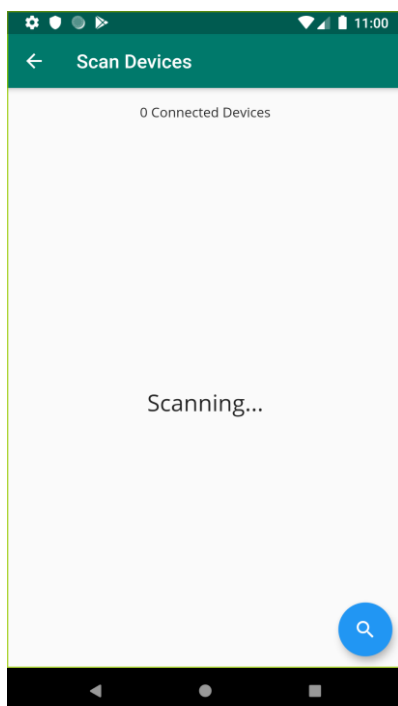
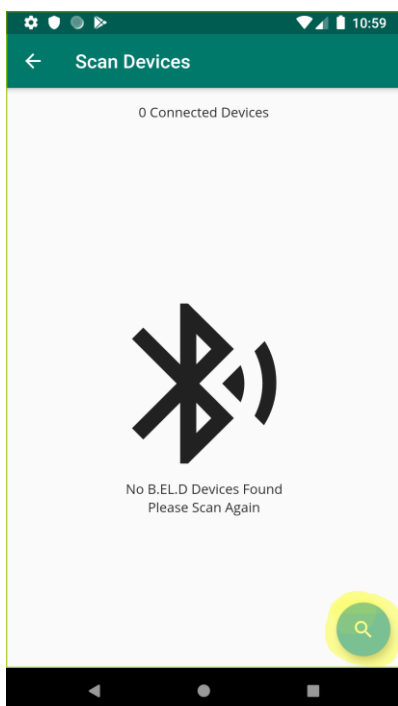
- B. Turn on the bluetooth functionality and location services on your mobile phone, open the application and login**



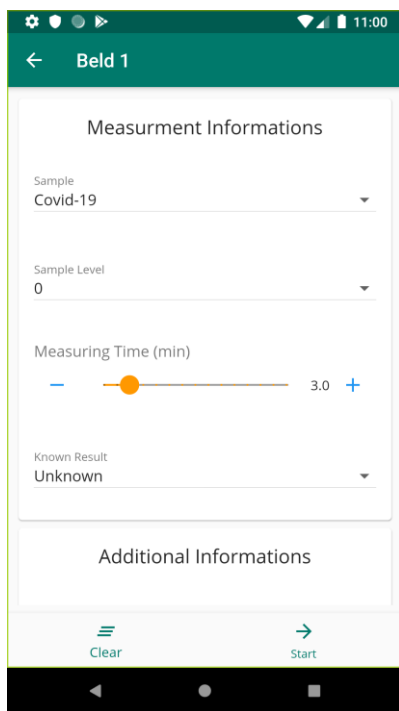
C. Complete the informations and press Start



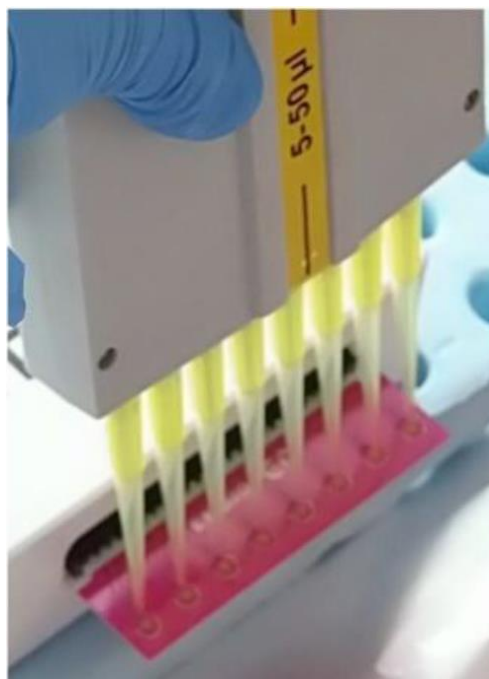
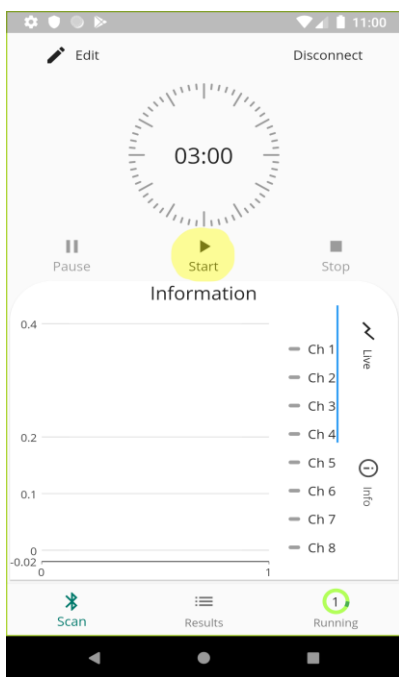
D. Press the search command and connect the application to the device



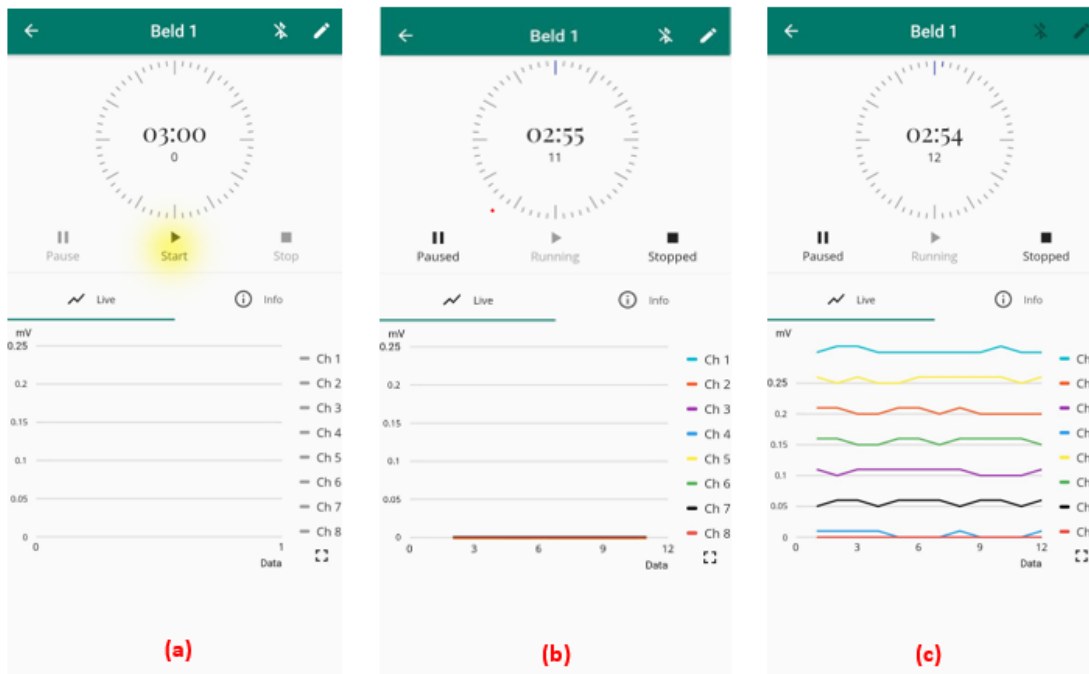
E. Fill the appropriate fields and press Start



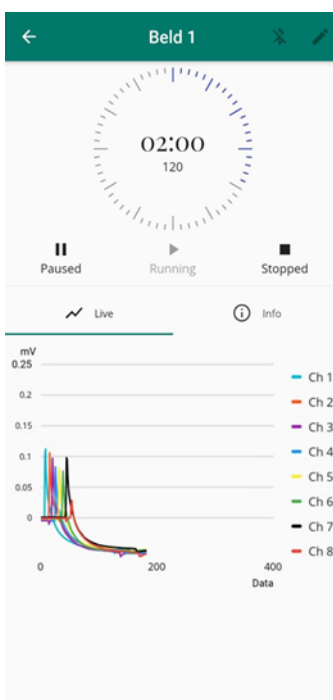
F. START the measurement and then add 20µl of the sample onto channels 1- 6 with a multichannel or single-channel automatic pipette



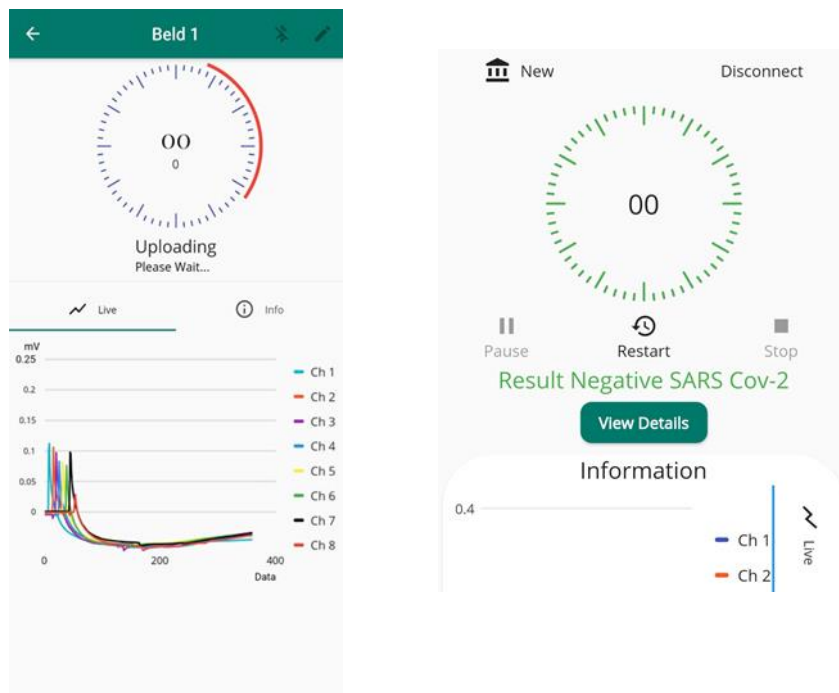
ATTENTION, if the lines on the chart do not appear after pressing the start button do not add the sample. Stop the measurement and start it again (a). Ensure that the lines are visible in the chart and they all start at 0 mV before adding the sample (b). In case lines do not start at 0 mV (c) stop the measurement and start it again.



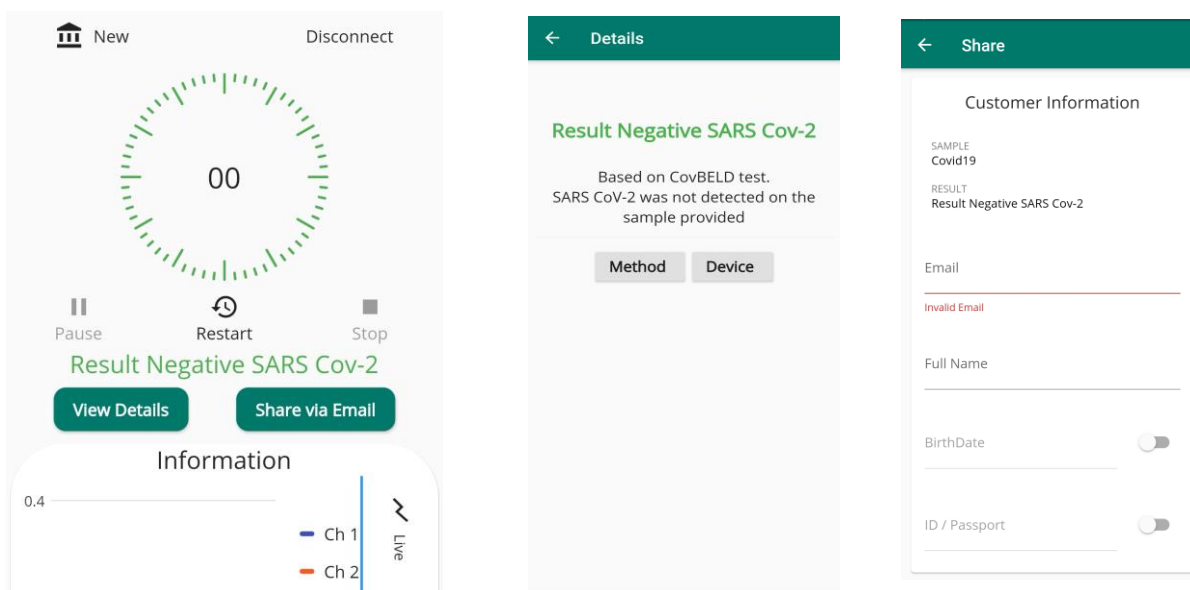
G. Once the first minute has passed, immediately start adding 20 μ L of the biosensors onto the same channels as above hence the final volume in each channel will be 40 μ L.



After the END of the measurement, the result will appear on your mobile screen and the data will be uploaded automatically.



H. By pressing the “View Details” command a new slide will open with the details of the result. By pressing the “Share via Email” command a new slide will open where you can fill in your details and send the test result as a report via email. For a new measurement press NEW and then EDIT to the enter the new information for the next sample in order to be ready for a new measurement.



Warnings and precautions

- For in vitro diagnostic use.
- Do not use the biosensors beyond the expiration date.
- Use appropriate precautions in the collection, handling, storage, and disposal of samples.
- Use of Nitrile, Latex (or equivalent) gloves is recommended when handling samples.
- Test electrodes are for one use only.
- The user should not open the tube containing the biosensors exposing it to the ambient environment until is ready for immediate use.
- If the biosensor solution contacts the skin or eye, flush with copious amounts of water.
- To obtain accurate results, the Package Insert instructions must be followed.
- Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
- Sample collection and handling procedures require specific training and guidance.
- Use the appropriate Fixed Volume Pipette in accordance with test procedures.
- To obtain accurate results, the test should not be used inside a laminar flow hood or in a heavily ventilated area.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.

Troubleshooting










Faults	Actions
User enters false Credentials	Error message appears. User must enter the right credentials.
User forgot his password	Can press “Forgot Password?” button to restore the password.
User (email) already exists	Error message appears. Must use a different password.
Wrong password. a) Password does not meet the requirements (e.g. short length) b) Confirm password does not match.	Error message appears. Must enter Password that meets the requirements.

Wrong information accidentally entered	Completed measurements can be found in the results tab. Edit is available.
Bluetooth is off	Turn on Bluetooth
Location Permission disabled	User must navigate to app permissions and enable Location.
No results found	Check if there are active BELD devices nearby. Beld device must not be connected to another mobile app.
Cannot connect to BELD device	a) BELD Must not run on low battery b) BELD device must be in close proximity (<2m) to the mobile phone and no obstacles located between them c) If a and b does not fix the problem then restart both the BELD and mobile app.
Accidentally wrong parameters	a) Sample code and Sample Level can be edited after the measurement has finished. b) If the sample is incorrect, the measurement must run again (each sample corresponds to a different algorithm) c) Measurement time must be >3 minutes.
The chart remains empty after the start button is pressed	a) Stop measurement and check if BELD is still connected. If it is connected press start again. If it is disconnected or pressing start does not fix the problem then start again with a new measurement.
Result is stuck in "Uploading"	a) Check your internet connection b) If no result appears in 2 minutes, the measurement must be taken from the beginning.
User enters wrong email data	If "share via email screen" is still open a new email can be sent, otherwise the measurement must be taken from the beginning.
User enters wrong phone number	If "share via email screen" is still open a new sms can be sent, otherwise the measurement must be taken from the beginning.
Email or SMS has not arrived	Email and phone must be in the correct form.
Possibility of accessing the user's data	Only non-sensitive data is stored and encrypted in the database. Communication via the application is also encrypted via SSL.

Kit storage and stability

Store the kit at 4°C temperature. On the day of the test let the biosensors and samples warm up to room temperature. Cold samples can lead to erroneous or invalid results.

Symbols glossary

	Temperature limitation
	Manufacturer
	Catalogue Number
	Contains sufficient for 12 or 24 or 48 Tests
	“CE Mark “. This product fulfils the requirements of the European Directive 98/79/EC on in vitro diagnostic medical devices.
	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Do not re-use
	Refer to instructions for use

EMBIO Diagnostics Ltd customer services:

For product enquiries please contact **EMBIO Diagnostics Ltd** Customer Services at info@embiodiagnostics.eu or for further contact details please visit embiodiagnostics.eu. Any adverse results experienced with the use of this product and/or quality problems should also be reported to **EMBIO Diagnostics Ltd** Customer Services by email: k.loizou@embiodiagnostics.eu.

Return policy:

Please contact **EMBIO Diagnostics Ltd** Customer Services for terms and conditions.

Limited warranty:

Please contact **EMBIO Diagnostics Ltd** Customer Services for terms and conditions.

Manufacturer Information:

EMBIO Diagnostics Ltd, Athalassas Avenue 8B, Nicosia, Cyprus.



“CE Mark” applies to **EMBIO Diagnostics Ltd BELD device**, Disposable electrodes and Biosensor

