



SURFACE TVC USER MANUAL

USR -06

Issue 1

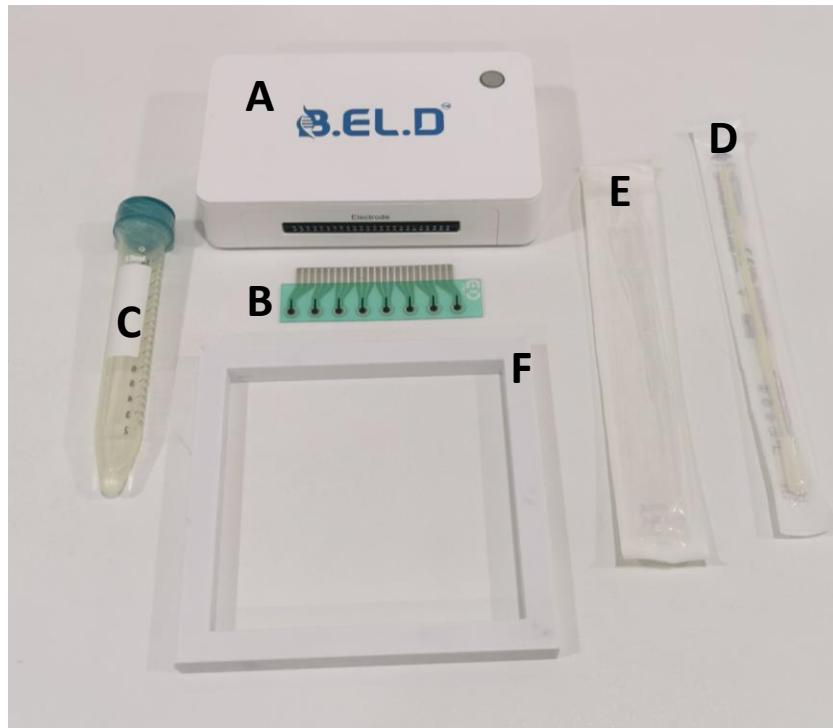
01/02/2023

Pages: 11

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B.EL.D Kit Components



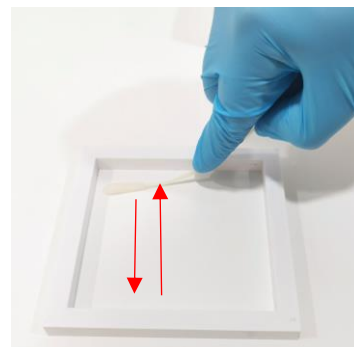
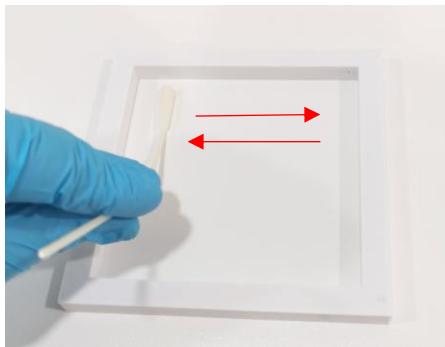
- A. B.EL.D Device
- B. Electrode
- C. Sample container: 15ml disposable plastic test tube with 2ml of buffer solution
- D. Swab
- E. Disposable plastic pipette
- F. Template 10x10cm

Sample preparation and handling

- A. Put on a new pair of gloves and clean the surface to be sampled. Dip the head of a new swab in the buffer solution and flick off any excess wetting agent. Do not dip a used swab in the buffer solution.



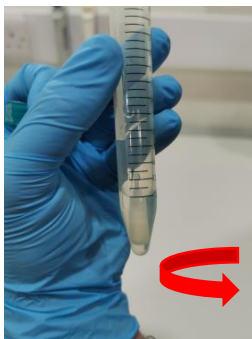
- B. Place the plastic template on the surface to be sampled. Press the swab head against the sampling surface with moderate pressure, so that the whole face of the head contacts the surface. Move the swab back and forth over the entire surface area inside the template following a horizontal direction i.e., left to right. Turn the swab head over and repeat the strokes using a vertical direction i.e., top to bottom as shown in the pictures below.**



- C. Place the swab head into the vial and clip the head off at the notch marks on the edge of the swab. Cap vial securely.**

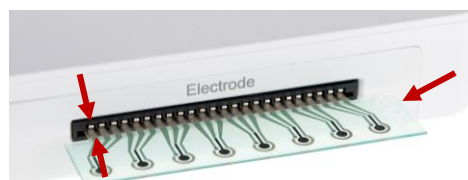


D. Shake well for 10 seconds. Sample is ready for analysis.



Test procedure

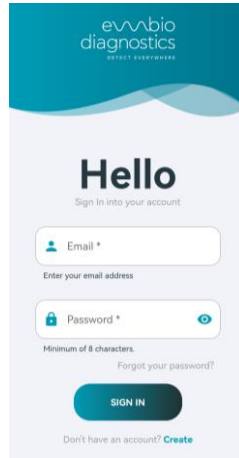
A. Remove the plastic cover of the electrode and connect the screen-printed electrode with the device. Be sure that the electrode is aligned with the pins of the connector. The logo on the electrode must be always on your right.



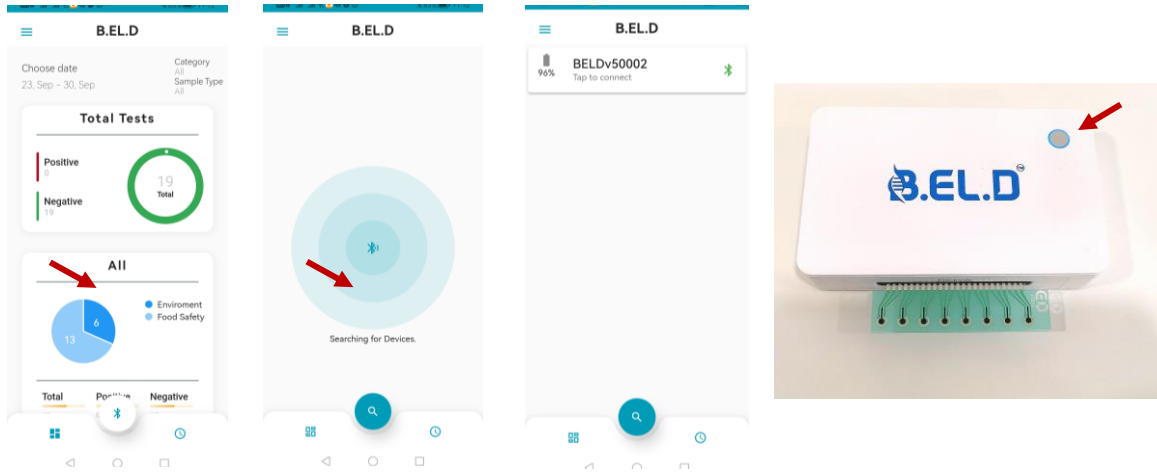
B. Press the multi-functional button of the device for approximate 8 seconds, until the led indicator becomes white. The device now is discoverable, you can connect to the B.E.L.D device using our mobile application.



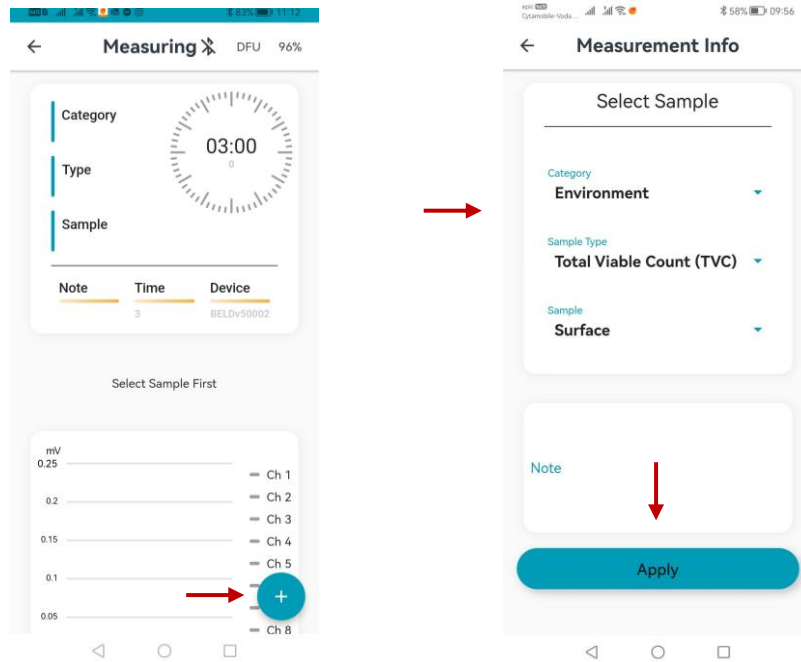
- C. Turn on the Bluetooth functionality and location services on your mobile phone, open the application and login.



- D. Press the Bluetooth button and then the search command and connect the application to the device. Once the device is connected to the application, the indicator becomes blue.



- E. Tap the “+” button and fill the measurements info in the appropriate fields (select your Category, Sample Type and Sample). Press Apply.

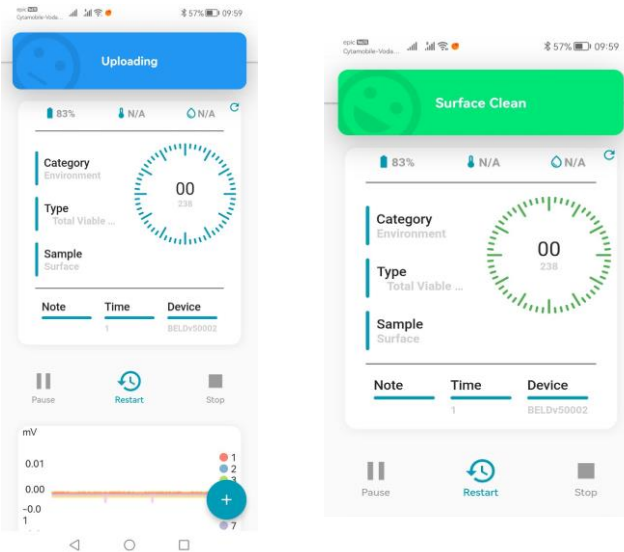


- F. START the measurement and then add two drops of the sample onto each channel 1- 8 with disposable plastic pipette.



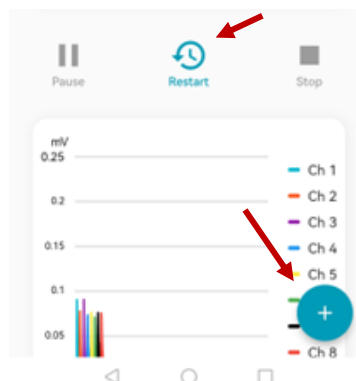
ATTENTION, if the lines on the chart do not appear after pressing the start button do not add the sample. Stop the measurement and start it again. Ensure that the lines are visible in the chart and they all start at 0 mV before adding the sample. In case lines do not start at 0 mV stop the measurement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

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



Product	Result	
	Surface clean	Surface dirty
TVC for Surfaces	The surface is considered as clean. The agent used for cleaning was efficient.	The surface is considered dirty. The agent used for cleaning was not efficient. Proceed with further cleaning.

- H. For each new measurement press Restart and then press “+” to add new information for the next sample. You will now be ready to start the next measurement.



Warnings and precautions









- 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.
- 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.

Symbols glossary

	Temperature limitation
	Manufacturer
	Catalogue Number
	Contains sufficient for 12 or 24 or 48 Tests
	Refer to instructions for use
	Lot Number
	Use-by Date – indicates the date after which the unopened IVD/Quality Control Material cannot be used
	Do not re-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:

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