User manual

L[‡]\BP\D

Professional use only



This instruction for use (IFU) **must be read** carefully prior to use LabPad+ and must be carefully followed.



7 Parvis Louis Néel 38000 Grenoble - France **T :** +33 (0)4 58 00 37 46 welcome@avalun.com





Connected Biology Everywhere

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Summary

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1/ Description

Intended to be used by healthcare professionals, LabPad+ is a smartphone/tablet application that connects via Bluetooth to AVALUN's LabPad® devices. Once connected, LabPad+ allows to perform a biological test by associating to the result all the useful traceability information concerning the test performed, the operator, the patient and any contextual comments.

2/ Equipment required

- A Smartphone or a tablet (Android or iOS) with a Bluetooth connection.
- A LabPad® INR or a LabPad® Evolution device.

3/ Equipment required

• Make sure the smartphone/tablet is connected to Internet.

• Follow the smartphone/tablet instructions to connect to the relevant store (Google Play or Appel Store) in order to download and install LabPad+.

4/ Creation of a user account

A user account with a valid email address is required to use LabPad+.

In order to create a user account, launch LabPad+, select "*Create an Account*" and enter your email address and desired password (password must have 6 characters minimum with at least 1 digit). An email from contact@avalun.com will be sent to the given email address for verification. Follow the link "*Verify email address*" in the body of the mail in order to confirm the address and be allowed to access the application.

Then:

• Enter your first and last names. Please note that when the application is configured for the operator's name to be associated with the test result, it is this last name that will be recorded.

• If you are using LabPad+ in a laboratory network and have been assigned a specific operator identifier by your network administrator, uncheck "*Generate automatically my identifier* "¹ to enter it. Leave the checkbox validated otherwise.

- Read and accept the Terms and conditions of use.
- Allow or not the storage of patients and results information in the memory of the used smartphone/tablet².

¹ "My identifier" is an internal unique identifier for the operator to be linked to all results started from the account. By default this identifier is automatically generated by LabPad+ when creating the account. However, in case results will ultimately be sent to an information system such as a LIS (Laboratory Information System) or EMR (Electronic Medical Record), where an operator identifier has already be assigned to identify the owner of the account, "Generate automatically my identifier" must be DE-selected to allow this already assigned identifier to be manually entered (refer to your network administrator for more information).

² "The storage of patients and results information in the memory of the smartphone/tablet is on the sole and complete responsibility of the user. In particular, before accepting that these data are stored on his smartphone, it is up to the user of the LabPad+ application to verify that this storage is in accordance with applicable laws and regulations.

5/ First LabPad Connection

5.1/ Make sure your LabPad® in pairing mode

Go to the setup menu and select the Bluetooth option to activate the Bluetooth and enter the pairing mode:



5.2/ Connect your LabPad® with LabPad+

Once launched for the first time, LabPad+ displays an empty list of results and the bottom banner indicates that no LabPad is selected:

E Resul	ts Unidentified	Quality Control
	None	
No LabPad selects	rd	+ Select LabPad

Press the "Select LabPad" button to view available LabPads within range, select the LabPad to connect and enter the code displayed on the LabPad screen when prompted:



6/ Main menu

The main menu allows for LabPad Selection, Synchronization, Settings, Account management, Version information and logout. To access the main menu select the " (=) " button shown on the left of the upper banner.



Note that user's information are displayed at the top of the main menu.

6.1/ LabPad Selection

Once a LabPad has been connected (*see section 5*), this LabPad becomes the default LabPad associated with the user's account and will automatically be reconnected as soon as it is in range. The "LabPad Selection" option allows you to choose another LabPad to be associated by default with the user's account. Once selected, the list of available LabPads in range is displayed on the screen:

	Available LabPads	
*	LabPad910000013	>
*	LabPad086000193	>
*	LabPad733000130	>
		0

If you do not find the desired LabPad in the list, make sure it is in range and in pairing mode *(see section 5-1)* and retry. Select the desired LabPad and enter the code if prompted.

6.2/ Synchronization

If LabPad+ was configured at installation to allow the storage of patients and results information in the memory of the smartphone/tablet (*see section 4*), this option allows to download new results from the connected LabPad. NOTE

By default, a synchronization is automatically performed at the end of each test to download the result, which means that this option is mainly useful when Bluetooth connection has been lost during the performance of a test, or if automatic synchronization has been deselected in the settings (see section 6-3-b below).

6.3/ Settings



a) Confidentiality

By default, operator name and all available patient information (lastname, firstname, birthdate, gender) are associated to the results exactly as they were sent by LabPad+. However, for confidentiality reasons and/ or to comply with local regulations (such as the European RGPD for instance), it might be necessary to only store patient and operator IDs.

Do determine what information will be stored with the results in the memory of the LabPad, simply select appropriate options.

b) Synchronization

If LabPad+ was configured at installation to allow the storage of patients and results information in the smartphone/tablet memory (*see section 4*), a synchronization is automatically performed at the end of each test started with LabPad+ to download the result.

If you do not want such a synchronization to be performed at the end of each test, simply deselect the option. If you deselect it, new results will have to be downloaded by manual synchronization *(see section 6-2 above)*.



Regardless of the configuration choice made for this parameter, tests or QCs not initiated from the application will require synchronization from the main menu to be downloaded.

6.4/ Account Management

Select this option to modify first and last names associated to the user account or to modify the password.

7/ Starting a test with LabPad+

Before starting a test, you must have read the LabPad user manual as well as the manual for the test you wish to perform.

7.1/ Prepare for the test

Make sure that your LabPad[®] is ready to accept a Bluetooth command, which means that the Bluetooth icon is displayed on the left side of the top banner of the screen and that the central part of the screen displays the list of stored results (which may be empty if the memory has been erased or if the LabPad has just been put into service):



Figure 1 First use of the LabPad (left), LabPad already with several result stored on it(right).

From the "identified" list of results, select the "+" button located at the bottom right of the screen.



7.2/ Enter patient information and chose the test to be performed

Select " IIIII " if you have a barcode or QR code containing patient information (this step is optional):



Navigate through the input form to enter or modify the desired fields. Entering at least the patient ID is mandatory to perform a test.

Patient		
ID1234567898		
First Name Mary		
Last Name JONES		
Date of birth		
Female		
Test INS		
Cancel		Dw
1987	September	25
1988	October	26
1989	November	27
1990	December	28
		29

Select the test to be performed.

← New test	
Patient	10
Identifier ID1234567898	
First Name Mary	
Last Name	
Date of bith 27/11/1989	
Gender Female	
Test	
O INR	
SARS-CoV-2 Ag	
	Stud

7.3/ Start the test

After verifying that the patient information entered and the test selected are correct, press the start button located at the bottom right of the screen. All the information needed to perform the test is transmitted to the LabPad, which then waits for the relevant SmartChip to be inserted:



Refer to the Instruction For Use of the SmartChip to proceed to the test performance with the LabPad. Unless the automatic synchronization at the end of the test to download the result was deselected in the settings *(see section 6-2 above)*, LabPad+ remains in standby for the receipt of the result for the duration of the test.

When the test is finished, LabPad+ displays again the list of «Identified» results and, unless LabPad+ was not configured at installation to allow the storage of patients and results information in the memory of the smartphone/tablet, the new record corresponding to the test result appears at the top of the list:



8/ Downloading and viewing results on the smartphone/tablet

If LabPad+ was configured at installation to allow the storage of patient and results information in the smartphone/tablet memory *(see section 4)*, all test results will be available for download at any time by selecting the synchronization option from the main menu. Otherwise, only the quality control results can be downloaded.

Depending on the configuration choice made for the synchronization parameter in the setup menu, a download of the result can also be performed automatically at the end of each test (setting by default), except for tests that were not started from LabPad+ but directly from the LabPad device (*see section 6-3 b*).

Once downloaded, results will be presented in 3 separate lists:

- List of "Identified" results, which includes all the results to which a patient identifier is associated (i.e. the results of the tests that were initiated from LabPad+);
- List of "Unidentified" results, which includes all the results to which there was no patient identifier associated (i.e. the results of the tests that were initiated directly from the LabPad device);
- List of "Quality Controls", which includes all quality control results.

Each of these lists presents the results in reverse chronological order of download (i.e. the last downloaded result appears at the top of the list):.

-	i Result	8		
	Identified	Unidentified	Quality Control	
E	SARS-C ID123456	oV-2 Ag (7898	31/03	>
6	SARS-C ID123450	oV-2 Ag (789A	31/03	>
E	INR ID123456	789A	31/03	>
E	BARS-C	oV-2 Ag (7898	31/03	>
E	ID123456	i789C	31/03	>
				Ð
	Lei	Pad910000013	is ready	

Figure 2 Identified result (left), unidentified result (middle), Quality Control (right)

To access all available information about a particular result, browse the list to select it:





If you want to delete the result displayed on the screen, select the trash can icon located on the right of the top banner

Once a result is selected, it is possible to add one or more contextual comments:



9/ Logout

To ensure limited access to the information stored in the smartphone/tablet memory, it is strongly recommended to end the user session at the end of each use by selecting the logout option from the main menu:





Closing LabPad+ application also ends the user session.

10/ Error messages

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION
-4	LabPad software obsolete. Please, upgrade your LabPad with the latest software	The LabPad software version is not compatible with LabPad+.	Contact your reseller to obtain the online software update procedure for your LabPad.
-2	This LabPad cannot be selected because it already belongs to another network	This LabPad cannot be connected to the LabPad+ network because it is currently assigned to another fleet due to its connection to another professional medical network, e.g. a Laboratory Information System (LIS).	You will only be able to connect this LabPad if you perform its full reset by pressing both browse buttons for 5 seconds. Caution: a full reset means a definitive loss of all results saved in the memory as well as of personal settings (the factory settings will be restored). Consult your LabPad User Manual for more information.
-1	Bluetooth communication lost with LabPadxxxxxxx	LabPadxxxxxxx is no longer within Bluetooth range of the smartphone/tablet. Bluetooth has been turned off on the smartphone/tablet and/or LabPadxxxxxxxx.	Make sure Bluetooth is enabled on both devices and that they are within Bluetooth range, then select retry.
143	LabPadxxxxxxx is unable to perform the test because its quality control status is currently invalid	The last quality control performed on LabPadxxxxxxx was a failure or LabPadxxxxxxxx received a blocking command when connecting to a third party network	Repeat the quality control procedure. In case of further failure, contact your reseller.

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION
136	Test order was rejected by LabPadxxxxxxx because it is cur- rently running a task or displaying a menu which is not compatible with running a new test.	The LabPad is currently running a task or displaying a menu which is not compa- tible with running a new test.	Refer to section 7-1 of this LabPad+ user manual.
-2	Communication error occurred. If this problem persists, please contact support.	The LabPad is no longer within Bluetooth range of the smartphone/tablet.	Make sure the LabPad is within the Bluetooth range of the smartphone/tablet and retry. If the problem persists contact your local support.



In case an error message appears on the LabPad, refer to the «Error Messages» chapter of the LabPad user manual for likely causes and possible solutions.



AVALUN SAS 7, Parvis Louis Néel 38000 Grenoble – France

Graphic design : Patrick Delgado / Inooui Design welcome@inooui.design



avalun.com

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