User manual

LABPAD®
EVOLUTION

AVALUN®

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Connected Biology Everywhere

LABPAD®
EVOLUTION

Summary

⚠️ Caution

This user guide provides all required information to operate optimally the LabPad®Evolution.
Please read it carefully before using the reader for the first time.

1/ INTRODUCTION

1.1/ Intended use

LabPad® Evolution is a Point of Care (PoC) multi-measurements testing device, intended for healthcare professionals use only, in order to perform In Vitro Diagnostic (IVD) rapid tests from a small volume of biologic sample. This device must be operated only with a range of single use compatible tests called SmartChip. Each SmartChip in the panel allows for the test of one specific biologic measurement. Depending on the technology, there are two different formats of SmartChip respectively called Tsmart® and Ksmart® due to their geometrical shape.

LabPad® Evolution can be used either:

• As a standalone device allowing to store up to 1 000 results in its memory, which the user can select and display on the screen of the reader;
• As a connected device, via USB or Bluetooth, allowing its integration with information systems aimed at centralizing the processes of operators authorization/identification, patients identification, quality controls and results validation/management.

This user manual only provides instructions of use for the LabPad® Evolution. Therefore, before using this device, you must imperatively refer to the instructions of use of the compatible SmartChip tests in order to review their specifications, performances and conditions of use.

1.2/ Contents of the packaging

In the box you will find:
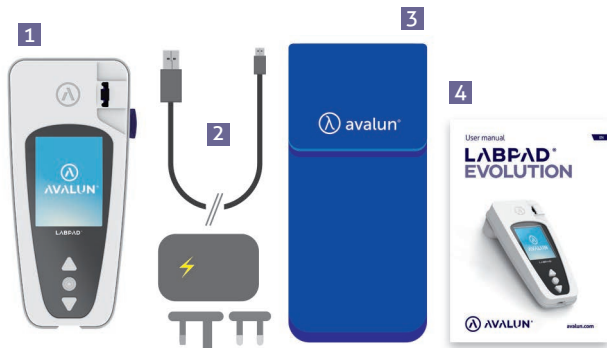
1 **The LabPad® Evolution reader**
2 **A Charger with a main unit and a micro USB-B cable**
3 **A Carrying case**
4 **The User manual**

Check that all these elements are included; if not, contact your reseller.

1.3/ Operating conditions and precautions of use

> ## ⚠ CAUTION
>
> **Operating conditions and precautions for safety use**
> To ensure the proper operation of the device as well as your own safety, please follow the below instructions:
> • Use your LabPad® Evolution in a location with sufficient lighting and with ambient temperature between 15 and 32°C (59° to 90°F);
> • To perform a test, place your device on a stable, flat, and vibration-free surface;
> • Do not insert any object other than a SmartChip in the insertion area, including during cleaning;
> • Use only the side black button to eject a SmartChip;
> • Do not drop the device; this may damage it and cause malfunction;
> • Carry your LabPad® Evolution in the carrying bag provided;
> • Use exclusively the battery charger provided. Do not use a damaged battery charger;
> • Follow storage and cleaning instruction.
>
> In case of improper use, the warranty provided by your reseller will not apply.

1.4/ Internal Quality Controls

LabPad® Evolution is a technologically advanced device performing automatically number of internal quality controls prior, during and after each measurement. If a problem subject to interfere with the measurement is detected, an error message such as "Error XX", where XX is the error number, is displayed on a red background on the screen of the reader *(See Section 9 « Error Messages»)*.

As example,
the following error screen
is displayed when inserting
an expired SmartChip:

The expiry date is one of
information encoded
in the Datamatrix of
the SmartShip.
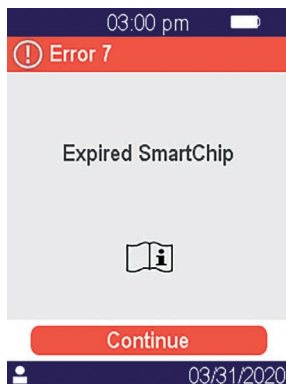
⚠ CAUTION

Appropriate control of the expiry date requires that the date and time of the reader are set properly beforehand *(See section 4 "Settings")*.

2/ OVERVIEW

2.1/ Reader

The LabPad® Evolution is an In Vitro Diagnostic (IVD) device allowing for the measurement of different biologic tests with the same reader. Its design allows for:

- Portability (270g weight)
- Autonomy (powered by chargeable batteries)
- Easy to use (3 buttons interface)
- Multi measurements
- Connectivity (Bluetooth Low Energy and USB)

2.2/ User interface

3 buttons allow to navigate the menus and make selections:

Use triangular buttons to navigate into the menus.

Use middle power button to select.

NOTE Pressing the middle power button for 2 seconds allows to switch on or off the device and to access to the settings menu (*See Section 3 «Starting Up»*).

2.3/ Color Screen

Status bar

Connection   **Time**   **Battery Charge**

Central part

Contextual information area

Display area

↓ Insert SmartChip

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Message area

Current date
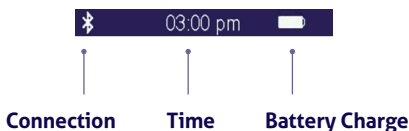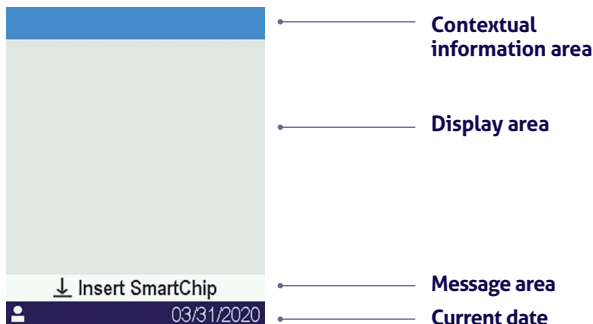
2.4/ Power Supply

The LabPad® Evolution is powered by a rechargeable battery and can be operated from an electrical power supply when charging. To charge the battery, connect the micro USB port located on the lower part of the device to the power adaptor using the provided USB cable, then the charger power adapter to a power supply.

The provided USB cable complies with CEI 61010 standard.
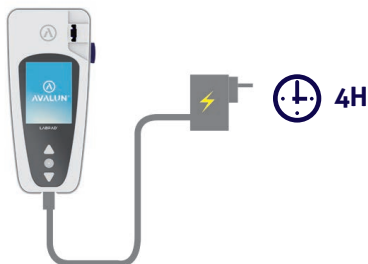
The socket outlet must be installed near the equipment and easily accessible.

In order to check the battery indicator when charging, press the middle power button.

Battery indicator

| 100% | 75% | 50% | 25% |

According to the battery level, the indicator on the upper right of the screen is fully white when the battery is full, and respectively, 75%, half or 25% white.

The indicator is red when the reader does not have enough battery power to perform a test. Quickly plug it in power supply.

The icon with lightening symbol means the battery is charging.

> **NOTE** Whatever the battery charge, it is always possible to perform an INR test by plugging the device into a power supply.

> **NOTE** It is advised not to store the device when the battery is low. When the battery is totally empty, saved data are not lost but the device must be configured again *(see Section 3.1 First use and initialization).*

2.5/ Compatible SmartChip Tsmart® et Ksmart®

The LabPad® Evolution operates with a range of compatible single-use disposable SmartChip tests. Each SmartChip allows for the performance of a specific biology test.

Depending on the technology used, there are two SmartChip compatible tests: Tsmart® and Ksmart®.

Tsmart® format, is used for INR testing, consisting of a microfluidic microcuvette embedding a dried or freeze-dried reagent (dry chemistry):
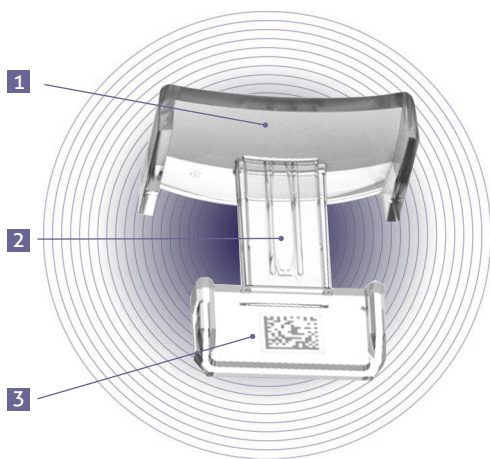
1 Broad curved plate on which blood drop is deposited

2 Central micro channel that contains the reagent, where the blood drop is sucked in

3 Datamatrix identifying the test and containing its batch number, expiry date and all information required for testing.

K SMART ®

Ksmart® format, used for lateral flow testing:
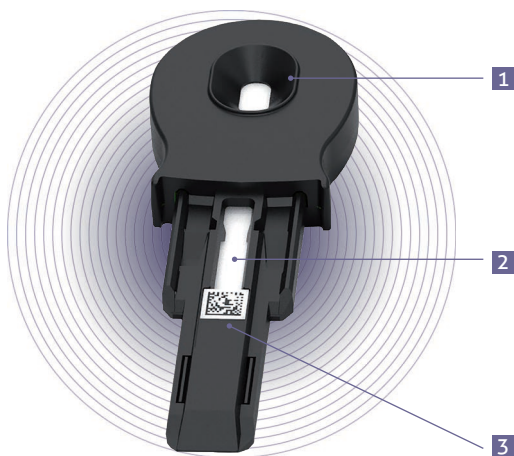
1   **Sample drop zone**

2   **Testing zone embedding the reagents**

3   **Datamatrix identifying the test and containing its batch number, expiry date and all information required for testing.**

Before using a SmartChip, refer to its user instructions for specifications, performances and conditions of use.

NOTE

The panel of SmartChip tests for LabPad® Evolution expands regularly. When a new SmartChip is made available, the software of the reader needs to be updated, this can be done remotely *(Cf. Chapitre 11 «Software updates and online support»).*

2.6/ SmartChip Insertion
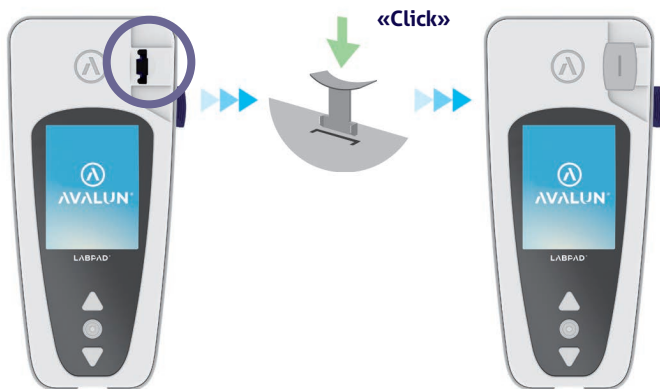
2.7/ Contact-free SmartChip ejection

To discard the SmartChip pick up your LabPad®, turn it down face towards the floor above a biological waste bin or any other appropriate recipient for biological sample, and press the side black button:

To minimize the risk of contamination, this unique ejection system was designed such as user never gets in contact with a used SmartChip.

> ### ⚠ CAUTION
> Do not manually remove a used SmartChip from the insertion slot of the readers, it may damage its internal mechanics.

3/ STARTING UP

3.1/ First use and initialization

> ### ⚠ CAUTION
> When using the LabPad® Evolution for the first time, plug it in power supply or charge the battery beforehand for at least one hour. Do not insert any SmartChip before initialization described below is complete.

Press the middle power button to switch on. When LabPad® Evolution is started for the first time, initialization process begins right after displaying the splash screen.

This initialization process consists in 4 steps:

1. Language preference
2. Display and acknowledgement of advises concerning the use of the product
3. Date and time format preferences
4. Date and time setup

At each step, use the triangular buttons to browse up or down to select the appropriate option and the middle power button to validate and move to the next step.

Once the initialization steps are complete, the following home screen is displayed:
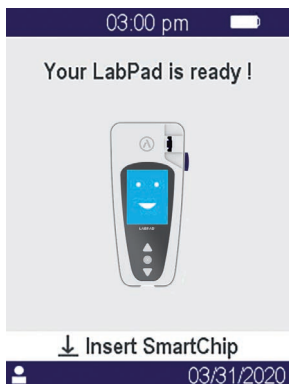
Your LabPad® Evolution is ready to use.

> ⚠️ **CAUTION**
>
> Make sure that date and time displayed on the screen are corrects.
> Go to «Settings» menu to proceed to appropriate adjustments
> otherwise (*Cf. Section 4 «Settings»*).

3.2/ Switching on

Once the initialization process is complete, the reader starts up.

You can switch on the reader by:

• pressing the middle button for 2 seconds

• connecting the reader with the supplied USB cable
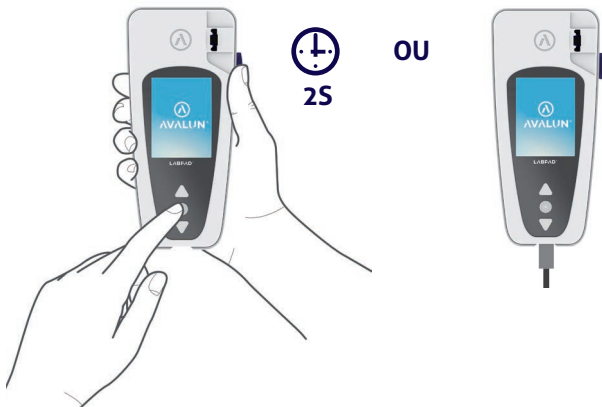
3.3/ Switching off

To switch off the reader press the central button for 2 seconds and then select «Power off».

NOTE By default, the reader switches off automatically after 10 minutes without use; you may change this duration according to your needs (*Cf. Section 4 «Settings»*).
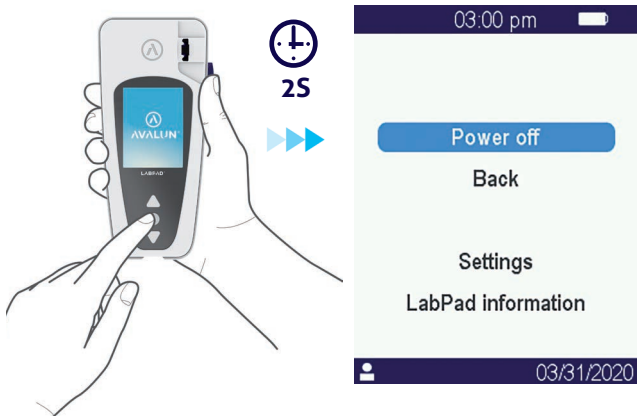
3.4/ Reinitialization

The reinitialization process allows to restore LabPad® Evolution status as obtained following its first use and initialization.

> ### ⚠ CAUTION
> Reinitialize the LabPad® Evolution means that all results stored in the memory will be definitively erased and that default settings will be restored.

Before starting the reinitialization process, the charge level in the battery must be checked: in case the indicator is red ▭ , reader must be plugged into an appropriate mains supply using the provided charger.

To start the reinitialization process, press simultaneously both triangular buttons for at least 5 seconds.

A first confirmation screen appears.
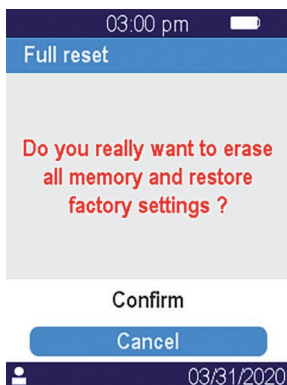
After validation, a second confirmation screen appears.
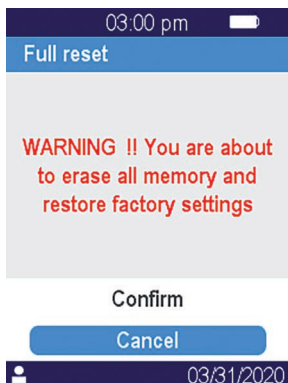
Once started, reinitialization steps are identical to first use and initialization ones *(See Section 3.1 «First use and initialization»).*

4/ SETTINGS

4.1/ Settings menu

Press the validation button for 2 seconds to access settings menu:
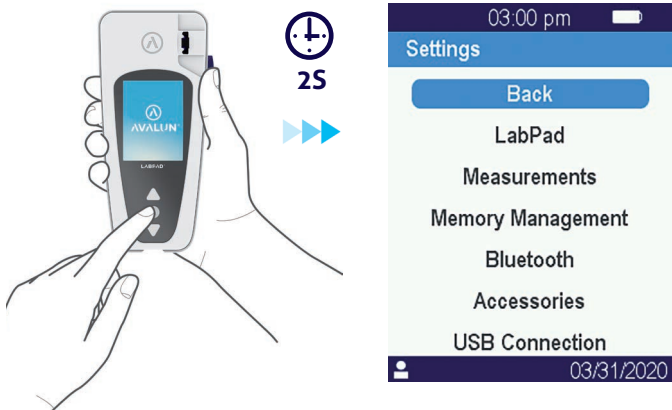
Then use triangular navigation buttons to select option required.

4.2/ Adjustable parameters and functionalities of the settings menu

Adjustable parameters and functionalities of the settings menu are made available through submenus as follows:

LabPad :

. Language of the user interface

. Date & time format

. Current date & time

. Screen brightness

. Auto Power-Off period

Measurements

. Performance of an auto-tests sequence to ensure that the electronic and the optical system are intact and suitable for operation.

. Performance of Liquid Quality Controls

(See Section 8 « Quality control»)

. Configurations specific to SmartChip tests

Memory Management: Management of stored results

Bluetooth : Worflow integration through Bluetooth
(See Section 5 «Workflow integration»)

Accessories: Direct connection setup to a Bluetooth bar code reader or printer

USB Connection: this status allows for online support when connected to a PC using the provided USB cable
(See Section 11 «Software updates and online support»)

4.3/ Configuration of compatible SmartChip

When selecting the submenu «Measurements» from «Settings», the list of compatible SmartChip tests get displayed on the screen.
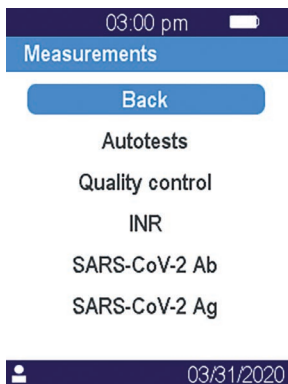
> **NOTE** In case of a compatible SmartChip is not appearing in the list, it means that a software update is required (*See Section 11 «Software update and online support»*)

Select required SmartChip for configuration.

The configuration of a SmartChip test may include in particular the selection of the measurement unit or procedure as respectively shown for INR and du SARS-CoV-2 Ag in examples below:

4.4/ Addition regarding memory management

Default setting for memory management is «Automatic», meaning that when memory is full the oldest result will be automatically erased to store a new one.

Use the cursor to deselect «Automatic» for manual memory management:
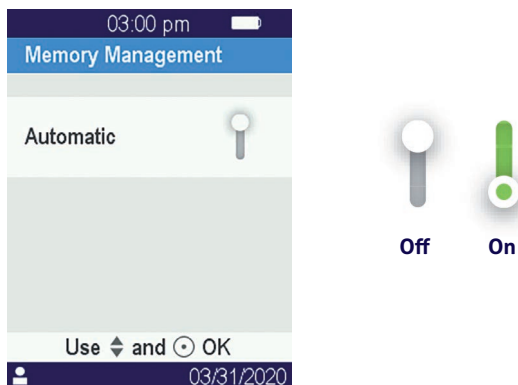
When automatic memory management is deselected, a new option called «Results deletion» is made available as part of submenu «Measurements». This option allows to delete older results starting from the oldest one by using the navigation buttons.

⚠ CAUTION

Results deletion is final.

NOTE When automatic memory management is deselected and memory is full, performing a new test will not be allowed *(See Section 9 "Error messages")*.

4.5/ Accessories

Two optional Bluetooth accessories may be paired to LabPad® Evolution for adaptation to specific practices:
• A **bar code reader** for patient identification
• A **thermal printer** for results printing

03:00 pm

Accessories

Back

Printer

Scanner

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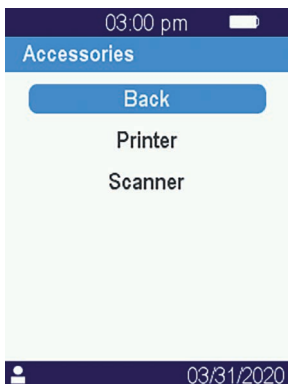
Select the accessory to be paired with the reader and follow its instruction manual for pairing.

5/ WORKFLOW INTEGRATION

5.1/ Workflow integration

LabPad® Evolutions is designed to integrate with information systems whose functions are to centralize and manage processes for operators certification/identification, patients identification, quality control and results validation/notification.

Such integration can be achieved via USB or Bluetooth.

Upon first connection to an information system, LabPad® Evolution inherits automatically the configuration of this information system. When switching on the reader afterwards, this configuration inheritance may be noticeable through the display of the mention "Operated by" followed by a specific logo which was downloaded from the information system.

Example of a LabPad® Evolution configured by an imaginary laboratory called "Buenavista Lab":

Beyond the display of a specific logo when switching on, parameters that may be configured by the information system are as follows:

• Possibility to perform a test without identifying beforehand the patient;

• Recording with the result of all patient information received or of the patient identifier only (in that last case, patient information such as name, first name, date of birth and sex will be displayed only once when performing the test for identity monitoring);

• Recording with the result of all operator name received or of its identifier only (in that last case, operator name will be displayed only once when performing the test);

• Limited use for a certain duration or a certain number of test performances until next quality control;

• Locking of the meter for missing or expired quality control.

⚠ CAUTION

Configuration inherited when connecting to an information system is not reversible, unless proceeding to a reinitialization
(See Section 3.4 «Reinitialization»).

5.2/ USB connection

USB connection is mostly used to connect to a service running on a PC in the background. Check with the administrator of your information system that such service is correctly installed and properly launched before connecting using the USB cable.

The connection to the service running in the background is automatic. Once connected and configured with parameters inherited from the information system, the USB connection indicator is displayed on the left side of the status bar of the LabPad® Evolution:

5.3/ Bluetooth connection

Bluetooth connection is mostly used to connect to a service running on smartphone or a tablet in the background. Check beforehand with the administrator of your information system that such service is correctly installed and properly launched on the targeted device.

Then proceed as follows to connect your reader via Bluetooth:

1. Select «Bluetooth» from the settings menu
(See Section 4 «Settings»).

The activated or deactivated Bluetooth status remains unchanged when switching off and on the reader.

2. Activate Bluetooth using
the cursor.

03:00 pm	
Bluetooth	

Connect to:

New device

Known device

Cancel

03/31/2020
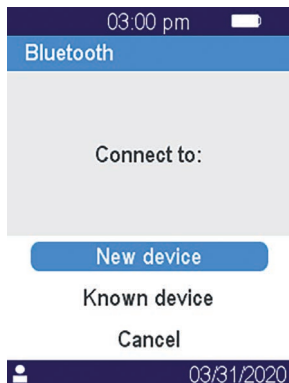
3. Select «New device»
When connecting a new device,
a 6 digits PIN code preceded by the
mention «waiting for connection»
is displayed on the screen.
For example:

03:00 pm	
Bluetooth	

LabPadBlue
Waiting for connection
Code: 000666

Back

03/31/2020
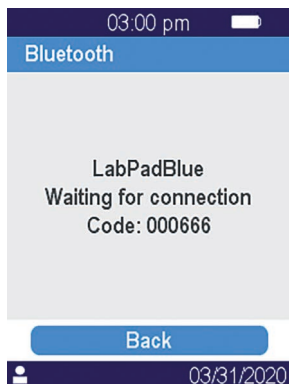
This means that the LabPad® Evolution is ready to be paired from the
Bluetooth device.

4. Refer to the user manual of the Bluetooth device or of the service to connect in order to select the LabPad® Evolution to be paired and enter the 6 digits PIN code when prompted.

Once paired and configured with parameters inherited from the information system, the Bluetooth connection indicator is displayed on the left side of the status bar of the LabPad® Evolution:
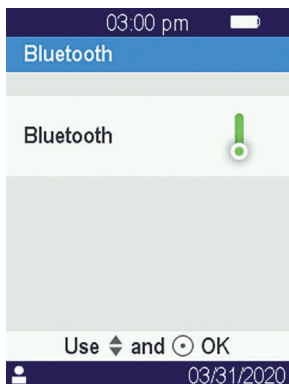

NOTE

Once paired, the Bluetooth device and the LabPad® Evolution are supposed to automatically reconnect whenever they are in their Bluetooth range.

6/ SMARTCHIP RAPID TEST PERFORMANCE

6.1/ Getting ready

To perform a SmartChip test, place the LabPad® Evolution on a stable even surface that is not exposed to vibrations, and have all the material you need for measuring ready:

• A SmartChip rapid test in its protective pouch (use only a LabPad® Evolution compatible rapid test within its expiry date);

• Sampling tools as specified by the instructions for use of the SmartChip;

• In case of capillary blood collection, make sure to use approved professional disposable lancets (it is usually recommended to use 21 gauge lancets). Also bring a gauze or paper tissue and a bandage.

• Single-use gloves and other recommended personal protective equipment.

6.2/ Patient identification

If LabPad® Evolution is paired with a bar code reader accessory *(See section 4.5 «Accessories»)* or integrated in a workflow *(See Section 5 «workflow integration»)* patient identification is required prior to performing a test.

The following error message will be displayed upon SmartChip insertion otherwise:
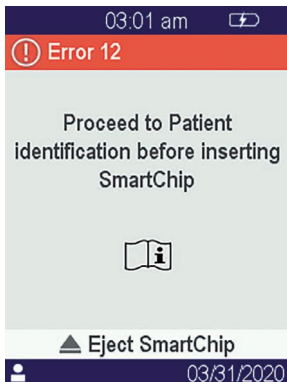
Before processing to patient identification:

• Make sure that the LabPad® Evolution is switched on and displays the welcome screen;

• Depending of the connection type, check that the corresponding indicator is displayed on the left of the upper bar:

Bar code reader
Bluetooth accessory

Bluetooth device

USB device

Using the bar code reader Bluetooth accessory for patient identification:

• After reading the bar code, a screen prompting for SmartChip insertion is displayed:
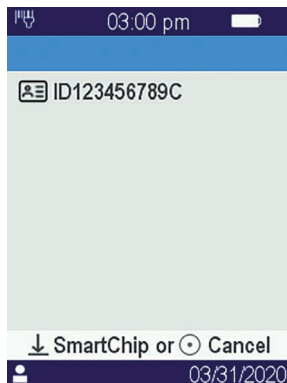
• Make sure that the patient Id is shown at the top of the display
• The LabPad® Evolution is ready for SmartChip insertion.

Identifying the patient from a device connected with Bluetooth or USB:

• Refer to the documentation provided by the administrator of your information system to proceed to patient identification from the connected device (data entry from, bar code or QR code reading, choosing from a list, etc.) and to precise the nature of biologic test to perform.

Once completed, a screen prompting for designated SmartChip insertion is displayed. Examples:
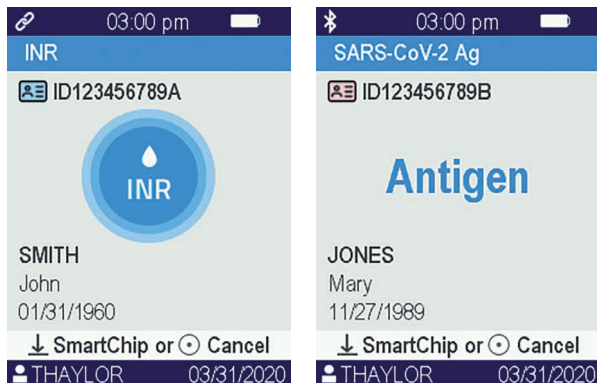
• Make sure that all information shown on the screen are correct:
    . Nature of the biologic test to perform
    . Patient information (ID and, as it may be, name, first name, date of bith and sex)
    . Operator name on the left side of the info bar at the bottom of the screen

• The LabPad® Evolution is ready for the insertion of the designated SmartChip

Performing a test without the prior identification of a patient:

In order to allow for usage of the reader in any circumstances, especially in case of emergency, the reader may be configured to enable performing a test without identifying patient. In this case the option "New test" is made available when pressing for at least 2 seconds the middle button:
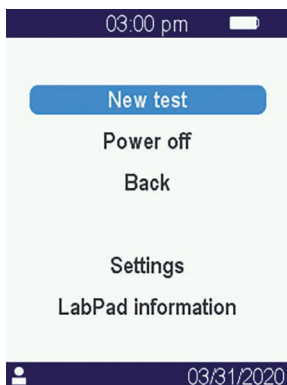
> ⚠️ **CAUTION**
>
> Performing a test without identifying patient in not always permitted. This option may have been disabled by the connected information system *(See Section 5 «Workflow integration»)*.
> If there is any doubt contact your administrator.
> Note that retrospectively reconciliate the result of the test with patient information will not be possible.

6.3/ Tsmart® test sampling and reading

Open the pouch to take out the Tsmart® and insert it into the insertion slot of the LabPad® Evolution.
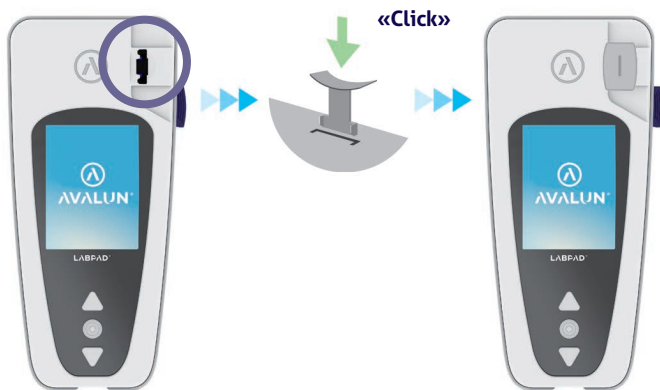
Following Tsmart® insertion, the reader performs required internal quality controls and prepares to perform the test, which may include preheating for instance. Quality control of the Tsmart® is automatically performed. In case an error occurs during this initialization phase, the corresponding error message is displayed on the screen and the Tsmart® must be ejected *(See Section 9 «Error messages»)* : you will have to repeat the process, using another Tsmart® when required.

When the reader gets ready to perform the test, you have 2 minutes to proceed to capillary blood collection and drop the blood on the curved plate of the Tsmart®.
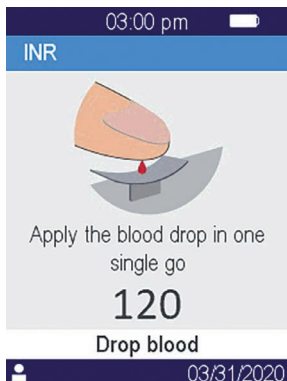
Prick the side of a fingertip of the patient. A minimum volume of 3µL of blood is required to fill the central micro channel. Do not squeeze the finger, as this may lead to incorrect results.
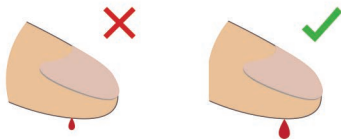
The central micro channel of the Tsmart® is designed to suck the blood in as soon as the drop touches the center of the plate. Approach the finger gently and carefully towards the plate to apply the blood drop onto it.

For proper filling, it is important not to press the finger on the plate.

Filling must be completed in one go.
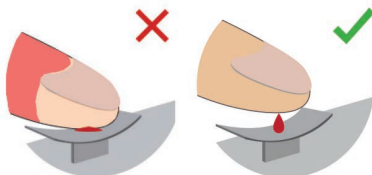
> **⚠ CAUTION**
> Do not squeeze the finger.
> Apply the blood drop in one go.
> Squeezing the finger or dropping the blood in more than one go may lead to incorrect results.
> Usage of micropipettes is recommended in order to decouple blood collection and blood dropping.

Keep your finger slightly above the plate until the screen changes and you hear a «beep». The screen then indicates that the measurement is in progress.

Wipe the blood in excess and apply the bandage.

6.4/ Ksmart® test sampling and reading

6.4.1/ Principle

Ksmart® tests principle is based on the migration of a biologic sample within a cellulose strip which is functionalized to capture the target (protein, enzyme, virus, …). Sample must be dropped into the drop zone of the Ksmart® prior to Ksmart® insertion.

Taking and depositing the sample:

1. Open the pouch to take out the Ksmart® and lay it flat on a table;

2. Refer to Ksmart® instructions to collect the sample to be tested.

NOTE
Each Ksmart is designed for a specific type of biologic sample (capillary blood, nasopharyngeal,...) that must be collected using supplied materials only;

3. Once collected and associated with the diluent when required, the biologic sample must be dropped into the drop zone of the Ksmart® prior to Ksmart® insertion.
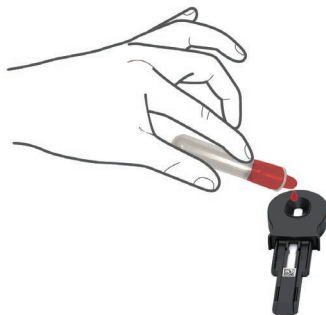
6.4.2/ Reading

Depending on Ksmart® test configuration made in the settings *(See Section 4.3 «Configuration of compatible SmartChip»)*, the Ksmart® must respectively be inserted either whiting 2 minutes following sample dropping ("Standard" reading by default), or after a specific delay ranged from 10 to 30 minutes depending of elected test, which

corresponds to the length of time required to read the test once completed ("Endpoint" reading):

• When reading is performed in «Standard» mode, the reader is automatically managing the duration of the test performance.

• When reading is performed in « Endpoint » mode, it is the responsibility of the operator to insert the Ksmart® in the reader within the specified time range following dropping the sample. As a matter of fact, a premature or late insertion may lead to incorrect results.

6.5/ Result display and SmartChip ejection

Once a biologic test performance is complete, the LabPad® Evolution displays the result in full screen and beeps until the SmartChip is ejected by the oprerator. After SmartChip ejection, the reader stops beeping and display returns to the reverse chronological list of stored results, such as last obtained result is located at the top of the list *(See Section 7.1 «Browsing the list of results»)*.

NOTE

If an error occurs during the test, a red bar with an error number is displayed. You must eject the SmartChip and refer to *section 9 «Error Messages»* for likely causes and possible solutions.

7/ RETRIEVING SAVED RESULTS

Results are automatically stored in the memory of the reader. Up to 1000 results can be stored in reader's memory.

7.1/ Browsing the list of results

Use the triangular navigation buttons to scroll through the results list.
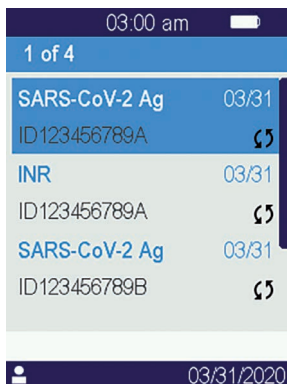
Hold down navigation buttons to scroll at a faster pace until you find the desired positioning in the list.

Scrolling indicator
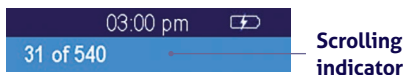
7.2/ Selecting one result for display

Press the middle button to display all available information related to selected result.

If at least one of the name, first name, date of birth or sex information is known for the patient, those are displayed in a first screen.

Press again the middle button to display the result which, depending on the test, may be displayed in several screens. When several units are available, use triangular navigation buttons to select the desired one.

Examples:
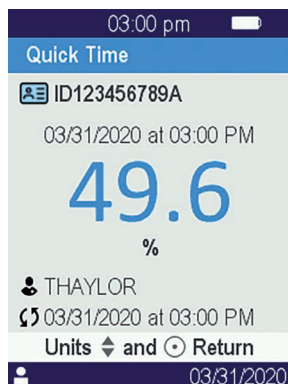
8/ QUALITY CONTROL

8.1/ Usage of a Liquid Quality Control (LQC)

To ensure that the unit is functioning properly, the LabPad® Evolution allows to perform a quality control test using Liquid Quality Controls (LQC). Each LQC is specific to one SmartChip and cannot be used with another one (refer to instructions for use of the LQC).

8.2/ How to start a quality control test

Select «Settings», then «Measurements», then «Quality control» then «Continue». Once the LabPad® Evolution is ready to start a quality control,the following screen is displayed:
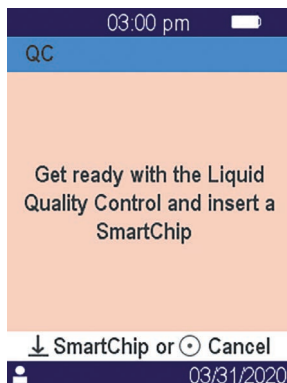
Refer to the instructions for use of the LQC to prepare the sample before inserting the SmartChip corresponding to the quality control to be performed. When the sample is ready, proceed in the same was as if it was to perform a routine test.

NOTE Since the process of performing a quality control is identical as performing a routine test, the screens background of the graphical user interface remain in pink color for the duration of quality control performance in order to differentiate.

8.3/ Performing a quality control test: example of the INR

After inserting a Tsmart® INR, the heating screen is displayed on a pink background, while the mention "QC" (for "Quality Control") is displayed directly next to the name of the measurement in the title bar:
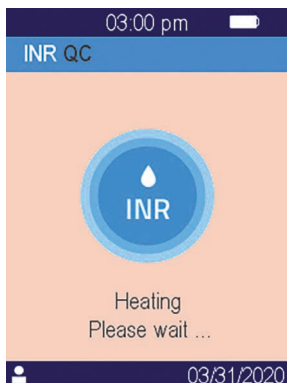
After heating, operator is prompted to drop a couple of drops of LQC on the curved plate of the Tsmart® to perform the quality control test:
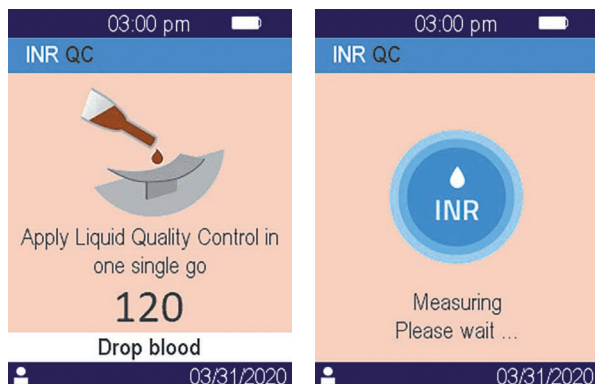
Once coagulation occurs, result is displayed in full screen and reader beeps until the Tsmart® is ejected.
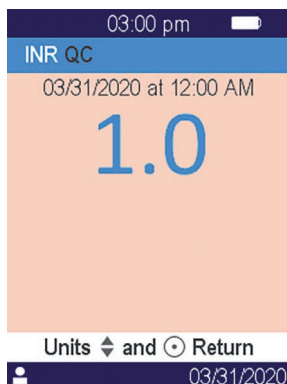
8.4/ Storage of quality control results

Quality control results are stored by LabPad® Evolution in the same way as routine results. Hence, only the "QC" mention is displayed directly next to the measurement descriptions allows to differentiate a quality control from a routine test when browsing the list of results:

9/ ERROR MESSAGES

If an error occurs, an error message such as "Error XX",
where XX is the error number, is displayed on a red background
on the screen of the reader.
Refer to the below table for likely causes
and possible solutions.

Messages during the test preparation

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION	ADDITIONAL INFORMATION
01	Low battery	The battery charge is not sufficient to perform a test.	Eject the SmartChip and immediately plug the power adapter to a power supply.	The same SmartChip can be inserted again within 1 min. Beyond this delay, using another SmartChip is recommended.
02	Memory full	There is not enough space in the memory to save an additional result.	Eject the SmartChip. Erase at least one result from the memory or set memory management to "automatic" *(see section 4.4 Memory management)*.	The same SmartChip can be inserted again within 1 min. Beyond this delay, using another SmartChip is recommended.
03 et 04	Inadequate ambient temperature	The ambient temperature is either too high, (above 32°C/90°F), or too low (below 15°C/59°F), for performing the test.	Eject the SmartChip and place the device for at least 30 minutes in a place where the ambient temperature complies with the operating conditions *(see section 14 Technical specifications)*.	Repeat the test with another SmartChip.
05	Insufficient ambient brightness	There is not enough light to perform the test.	Eject the SmartChip. Make sure your location gets sufficient light to perform the test.	The same Tsmart® can be inserted again within 1 min. Beyond this delay, using another Tsmart® is recommended.
06	Data reading error	The SmartChip is not inserted properly or the Datamatrix is damaged / absent.	Eject the SmartChip and insert it again as far as it will go. If an error occurs again, use another SmartChip.	

Messages during the test preparation

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION	ADDITIONAL INFORMATION
07	Expired SmartChip	The SmartChip has expired.	Eject the SmartChip. Make sure that the date of the reader is set to the current date and to use an unexpired SmartChip.	The same SmartChip can be inserted again within 1 min. Beyond this delay, using another SmartChip is recommended.
08	Defective SmartChip	The SmartChip has stayed too long outside its pouch or has already been used.	Eject the SmartChip and repeat the test with another SmartChip.	
09	SmartChip not inserted properly	The SmartChip is not inserted properly.	Eject the SmartChip and insert it again as far as it will go. If an error occurs again, use another SmartChip.	The same SmartChip can be inserted again within 1 min. Beyond this delay, using another SmartChip is recommended.
10	Error during autotests	An error has occurred during autotests.	Eject the SmartChip, restart the device *(See Section 3.3 Power off)*, and try again.	Il the problem persists, contact your local support.
11	SmarChip insertion not allowed	A SmartChip was inserted while the reader was in a status where a new test cannot be performed.	Eject the SmartChip and follow instructions to start a test performance before inserting it again.	The same SmartChip can be inserted again within 1 min. Beyond this delay, using another SmartChip is recommended.

Messages during the test preparation

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION	ADDITIONAL INFORMATION
12	Proceed to Patient identification before inserting SmartChip	A SmartChip was inserted prior to patient identification.	Eject the SmartChip and proceed to patient identification before inserting it again.	The same SmartChip can be inserted again within 1 min. Beyond this delay, using another SmartChip is recommended.

Messages during the test

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION	ADDITIONAL INFORMATION
100	Blood drop timeout	You have dropped your blood beyond the 2 min. allotted time.	If the blood drop has not reached the micro-cuvette plate, the same microcuvette can be immediately inserted to try again.	Do not repeat the test more than twice with the same microcuvette.
101	Error during the test	An error occurred during the test.	Eject the SmartChip and repeat the test with another SmartChip.	If the error occurs again, contact your reseller.
102	Incorrect filling	The micro-cuvette has not been filled properly.	Eject the microcuvette and repeat the test with another Tsmart®, making sure you strictly follow the instructions for applying blood.	
103	Inadequate coagulation		Eject the microcuvette and repeat the test with another Tsmart® INR, making sure you strictly follow the instructions for applying blood.	

Messages during the test

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION	ADDITIONAL INFORMATION
104	SmartChip released or ejected	The SmartChip was not inserted properly, it moved or was ejected.	If the SmartChip is still in the slot, make sure to discard it completely, then press the validation button. Repeat the test with another SmartChip making sure that you insert it as far as it goes and that the reader is placed on a flat and vibration-free surface.	
105	Inadequate coagulation ⚠ **CAUTION** abnormal high coagulation time possible		Eject the microcuvette and repeat the test with another Tsmart® INR, making sure you strictly follow the instructions for applying blood.	
106	Endpoint Reading: control line not found	Blank Ksmart or inappropriate sampling or premature insertion of the Ksmart or defective Ksmart	Eject Ksmart and repeat the test with another Ksmart	Make sure to strictly follow instructions found on the notice of the Ksmart for sampling and endpoint reading
107	Soiled Ksmart	Inappropriate sampling or defective Ksmart	Eject Ksmart and repeat the test with another Ksmart	

Messages during the test

N°	ERROR MESSAGE	LIKELY CAUSE	POSSIBLE SOLUTION	ADDITIONAL INFORMATION
108	Unreadable Ksmart	Defective Ksmart	Eject Ksmart and repeat the test with another Ksmart	
109	Standard reading: control line not developing	Blank Ksmart or inappropriate sample or defective Ksmart	Eject Ksmart and repeat the test with another Ksmart	Make sure to strictly follow instructions found on the notice of the Ksmart for sampling
200	Inappropriate SmartChip	An inappropriate SmartChip is inserted.	Eject the SmartChip and use a compatible SmartChip to perform the test.	
210 and after	LabPad internal error	An error occurred during the test.	Eject the SmartChip, restart the device *(See Section 3.3 Power off)*, and try again.	If the error occurs again, contact your reseller.

10/ TROUBLESHOUTING

⚠ CAUTION

Do not open the LabPad® Evolution. In case of doubt, contact your reseller.

⚠ CAUTION

If you notice a damage to your LabPad® Evolution (cracked screen glass, side button broken...etc.), contact your reseller.

When this message is displayed: (!) "Error XX", XX being the error reference number, *see section 9 Error messages*.

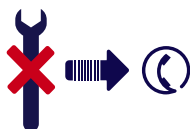| PROBLEM FOUND	POSSIBLE SOLUTION	
The LabPad® Evolution is not working	Plug the battery charger in and check the battery icon: if it is red, leave it to charge for at least 4 hours.	4H

| PROBLEM FOUND	POSSIBLE SOLUTION	
Battery cannot be charged	Contact your reseller. Do not open the device; there are no small batteries inside.	
The LabPad® Evolution is working but there are numbers and meaningless letters on the screen.	Hold down the middle power button for more than 20 seconds.	
The LabPad® Evolution is frozen on a display	Hold down the middle power button for more than 20 seconds.	
The Tsmart® INR is broken inside the device	Do not open the device. Contact your reseller.	
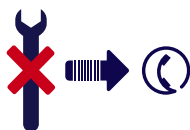
11/ SOFTWARE UPDATES AND ONLINE SUPPORT

LabPad® Evolution software updates are regularly provided, especially when launching new biologic tests. Such updates as well as certain support services might be performed remotely by connecting via Internet to specific web services made available by Avalun.

Whenever a software update or support service is required, your reseller will provide the link to the appropriate web service.

Then proceed as follows:

1. Have a Microsoft Windows or MacOS PC connected to Internet ready

2. Follow the link provided by your reseller. In case the Internet navigator is not launched automatically, copy the provided link into its address bar

3. When the service gets started, a window is displayed with instructions to be followed in order to connect to LabPad® Evolution, that is:

a. Connect the LabPad® Evolution to the PC using the provided USB cable

b. On the LabPad® Evolution select «Synchronization » from the «Settings» menu *(See Section 4.1 « Settings menu »)*

4. When the connection between the reader and the remote service has been established, follow instructions prompted by the navigation screen
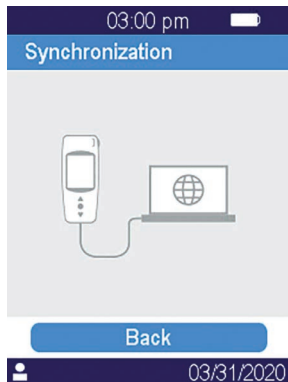
12/ CLEANING

⚠ **CAUTION**

The LabPad® Evolution can be cleaned with soapy water or alcohol (ethanol) with a lint-free cloth. Do not apply any liquid directly on the device or use any spray. The use of or any other abrasive liquid is not recommended.

⚠ **CAUTION**

Make sure not to drop any liquid in the SmartChip insertion area; if this occurs, do not use the device and immediately contact your reseller. Be especially careful not to use any liquid in spray.

13/ WARRANTY

The LabPad® Evolution is under warranty by your reseller.
In the event of defect *(See Section 10 Troubleshooting)*
during the warranty period, the device can be repaired or exchanged.
Please contact your reseller for more information.

14/ TECHNICAL SPECIFICATIONS

Operating conditions	Place the device on a stable,
	flat and vibration-free surface.
	Ambient temperature 15-32°C/ 59-90°F
	Relative humidity level <85%
	Use the device indoor only.

Storage conditions	Temperature -20 to +70°C / -4 to 158°F
Transport conditions	Temperature -20 to +70°C / -4 to 158°F
Memory	1,000 measurements

Bluetooth	Low Energy 2.4 Ghz 0db
Interface	Port micro USB B
Battery	Lithium-ion Polymer 3.7V 2100mAh
	Complies with IEC 62133 standard

Battery charger	100-240V, 50-60Hz, input 0.2A output
	1.0A, 5Vdc
	When charging, the range of temperature
	accepted is 5 to 40°C / 41 to 104°F.
	Can withstand main supply voltage fluctuations
	up to ±10% of the nominal voltage.

Beep   Factory setting for beep frequency is 4,000Hz

Dimensions   L 17.2cm W 7.4 cm H from 2.0 to 4.6 cm

Weight   270g net

15/ LIST OF ICONES USED

	Navigation buttons
	Validation button
	attery is fully charged
	Battery is ¾ full
	Battery is half-full
	Battery is ¼ full
	Battery needs charging
	Battery is charging
	Bluetooth connection indicator
	USB connection indicator
	Barcode reader connection indicator
	Printer connection indicator
	Measurement setting in progress
	Reader is ready for SmartChip insertion

 Apply a blood on Tsmart® curved plate

 Apply a couple of droops of QLC on the Tsmart® curved plate

 INR test in progress

 An error occurred

Patient information:

 Pink background: female

 Blue background: male

 Operator

 Date of first transmission

 Never transmitted result

 Current logged user

16/ LIST OF SYMBOLS USED

$C\,\epsilon$	CE marked product
▲▲	Manufacturer's name and address
IVD	In Vitro Diagnostic Device (IVD)
〔i〕	Read the user guide
⊠	Discard in a bin dedicated to electronic waste
SN	Serial number
REF	Product reference
GTIN	Global Trade Item Number
∫	Temperature limits between which the device can be safely exposed
⚠	Refer to the documents inserted in the box

Symbols of the battery charger:

DC voltage

AC voltage

The protection of the battery charger is ensured by
means of double insulation.

Symbol of the laser inside the device:

Class I laser device

C E

AVALUN SAS
7, Parvis Louis Néel
38000 Grenoble – France

avalun.com