

LabPad[®] INR

User guide



English

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Thank you for choosing the LabPad® INR for your INR measurement. In order to use this device, you need to obtain the appropriate microcuvettes: single-use Tsmart® INR from the Avalun Company.

Caution

This user guide provides you with all the information you need to operate this device optimally. Before using the device for the first time, please read this guide thoroughly.

Healthcare professionals

Note for healthcare professionals: the information in yellow identified with this icon is exclusively and specifically for you. You are recommended to read it before any use of the device.

1 Introduction

1.1 Intended use

The LabPad® INR is a self-test In-Vitro Diagnostic (IVD) device designed to measure blood coagulation time and indicate INR value (International Normalized Ratio), Prothrombin Time (PT) and the Quick Time (QT).

Use of the LabPad® INR has been adapted for improved monitoring of your oral anticoagulant treatment through type vitamin K antagonists (VKA).

Before using this device, you must consult your physician in order to be sure there is no contraindications to its use. Your physician will provide a targeted therapeutic range with a low and a high value. This therapeutic range can be saved in the device ([see section 4.7 Therapeutic range for INR measurements](#)) to be recalled when displaying results ([see section 5.4 Performing a test and displaying result](#)). Your physician will also provide your INR test frequency as well as what you should do in case the test result deviates from the specified therapeutic range.

Use of an alternative method of measurement is recommended in the event of a transition period with a heparinized treatment.

You are advised at all times to follow your physician's prescriptions and advice. In case of doubt, consult your physician.

1.2 Measurement procedure

Operating principle



1 Insert the Tsmart® INR microcuvette into the LabPad® INR: the device switches on automatically.

2 When prompted, apply the blood drop onto the curved plate.

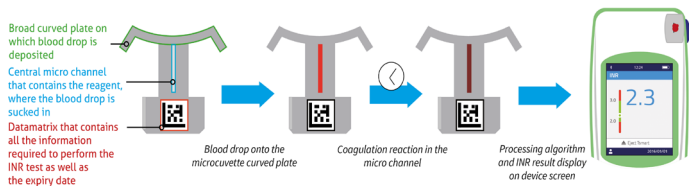
3 Consult your INR result displayed on the device screen.

4 Eject the Tsmart® microcuvette: the result can be transmitted via Bluetooth.

The single-use Tsmart® INR microcuvette contains a lyophilized reagent made of thromboplastin. When the blood sample is dropped on the microcuvette plate that has been previously inserted in the device (see section 5 Performing an INR test), it is sucked in by capillarity and gets mixed with the reagent. The coagulation reaction then begins.

The LabPad® INR initiates an optical analysis of the red cell movements that freeze when the clot is formed inside the microcuvette. The elapse time between blood drop and clot makes it possible to calculate the INR, PT, or QT, thanks to an algorithm.

Measuring principle

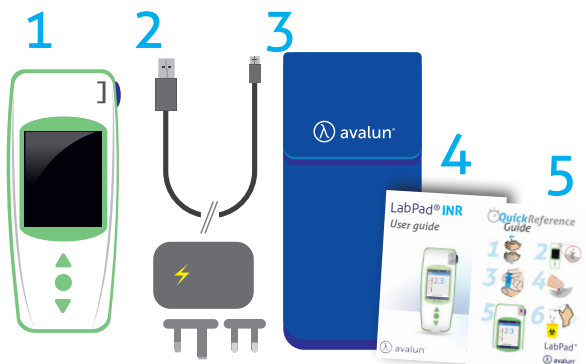


After the test is performed, the used microcuvette is discarded and the device is ready for a new test.

The test result is displayed on the device screen. The LabPad® INR can be configured so that this result is also shared via Bluetooth to a third-party application running on a smartphone for example (meaning an app download is required).

1.3 The LabPad® INR

In the box, you will find:



- 1) The LabPad® INR testing device
- 2) A battery charger including a power adapter and a micro USB-B cable
- 3) A carrying bag
- 4) A user guide
- 5) A quick reference guide

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

Operating conditions and precautions for safe use

To ensure the proper operation of the device as well as your own safety, please follow the instructions below.

- Use your LabPad® INR in a location with sufficient lighting and with ambient temperature between 15 and 32°C (59 to 90°F).
- Use your LabPad® INR only when the relative humidity level is under 85%.
- To perform a test, place your device on a stable, flat, and vibration-free surface.
- Do not insert any object other than a Tsmart® in the insertion area, including during cleaning.
- To eject the Tsmart® INR microcuvette use only the side blue button.
- Do not drop the device; this may damage it and cause malfunction.
- Carry your LabPad® INR in the carrying bag provided.
- Use exclusively the battery charger provided. Do not use a damaged battery charger.
- Follow the storage and cleaning instructions.
- Keep away from children.

If the device is used in a manner not specified by this user guide, the protection provided by the device may be impaired.



Healthcare professionals

See [section 5 Performing an INR test](#) for specific recommendations.

1.4 Quality Controls

The smart meter LabPad® INR is a technologically advanced device that runs several Quality Controls automatically before performing a test.

When a problem that could prevent the test from being performed occurs, an error message is displayed on the device screen. The standard error message is "Error XX", XX being the error reference number ([see section 8 Error messages](#)).

This message is associated with the icon .

Refer to [section 9](#) to solve the problem ([see section 9 Troubleshooting](#)).

The expiry date of the Tsmart® INR microcuvette is controlled with an autotest when inserted in the LabPad® INR. Its temperature is also regulated during measuring in order to ensure optimal conditions for biological reactions.



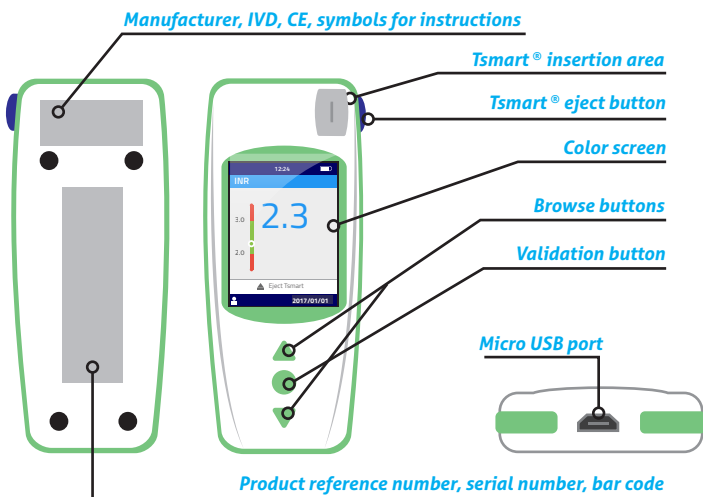
Caution

Control of the Tsmart® INR microcuvette's expiry date can be carried out properly only if the date & time have been configured beforehand ([see section 3 First use and general instructions for use](#)).

2 LabPad® INR overview

2.1 The device

The LabPad®



How the user interface works:



The green triangular buttons are for browsing the pages upwards or downwards.



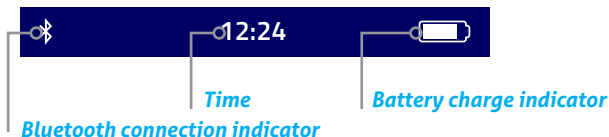
The center power button is for confirming the selection.

Note

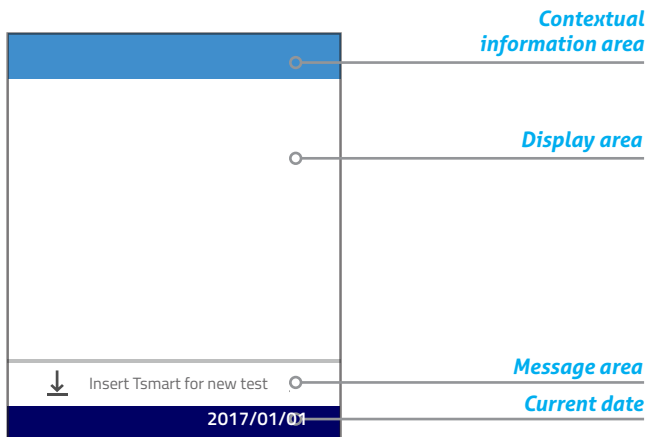
Pressing the center power button for more than 2 seconds is also used to switch the device on, switch it off and access the setting menu ([see section 3 First use and general instructions for use](#)).

2.2 Color screen

Status bar



Main display

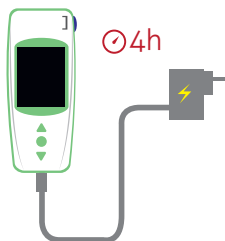


2.3 Power supply



The LabPad® INR can be operated on battery or from an electrical power supply. For the latter, connect the provided cable to the micro USB port located on the lower part of the device and the battery charger (power adapter) to a power supply. The provided cable complies with CEI 61010 standard.





To recharge the battery, connect the provided cable to the USB port located on the lower part of the device and the battery charger to a power supply.

The electrical socket must be installed close to the device and be easily accessible in order to be able to unplug quickly the battery charger in case of emergency.

The battery is fully charged when the indicator on the upper right part of the LabPad® INR screen is fully white. Device autonomy is between 40 and 70 tests, or 3 months without use.

To check the battery status during charging, press the center power button.

Battery indicator



100% 75% 50% 25%

According to the battery charge level, the indicator on the upper right part of the screen is fully white, 75%, half or 25% white.



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



The icon with the 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 in to 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](#)).

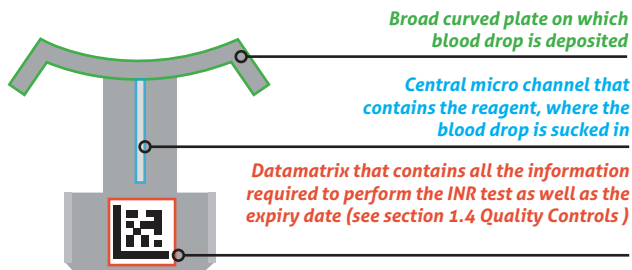


When a red battery is displayed full-screen, it means the battery charge is critical and the device will automatically switch off.

Quickly plug it in to a power supply.

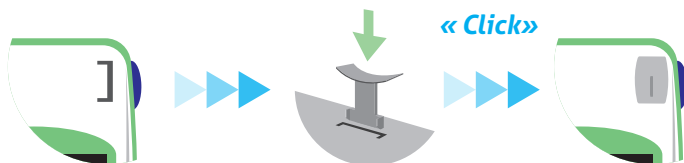
2.4 The Tsmart[®] INR microcuvette

The Tsmart[®]



Please refer to the microcuvette instructions for use that contain all information for an optimal use.

2.5 How to insert the microcuvette



! **Caution**

Do not use the side blue button to insert the microcuvette.

2.6 How to discard the microcuvette



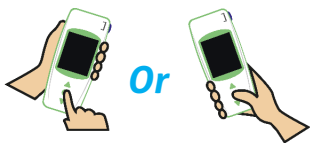
The side blue button releases the Tsmart® INR for discarding after use (see [section 5.5 Discarding the microcuvette](#)).

3 First use and general instructions for use

3.1 First use and initialization

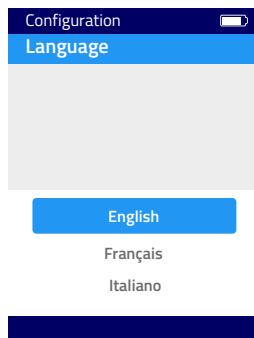
Caution

- When you use the LabPad® INR for the first time, plug it in power supply or charge the battery beforehand for at least one hour.
- Do not insert any Tsmart® INR before initialization is complete.

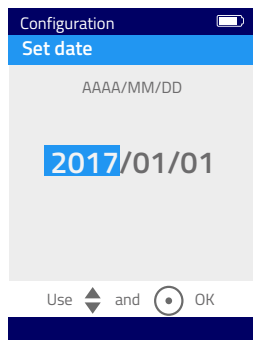


When using for the first time, press the center power button. The LabPad® INR starts with “welcome” and begin the initialization process. You will be able to change the language just after this.

Continue the initialization process using the triangular buttons to browse up or down and the center power button to validate and go to the next step.

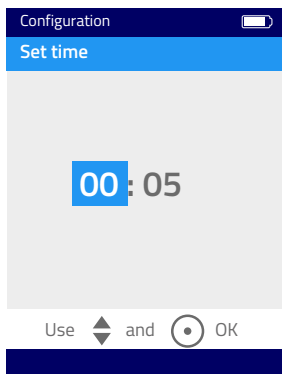
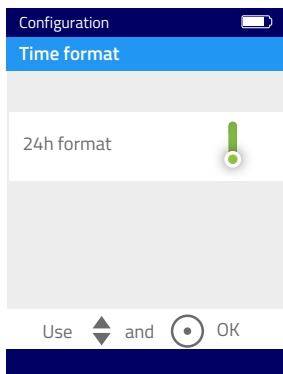


- 1) The LabPad® INR starts
- 2) Select the desired operating language
- 3) Once the operating language is set, that will make the device start again in case of change, read carefully the instructions of use displayed successively on the screen. Press "Continue" to go to the next steps.

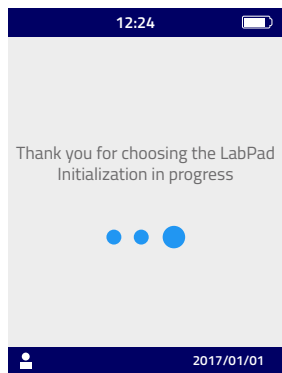


- 4) Set date & time. Format is AAAA/MM/DD for year, month and day.

If you set the wrong date, you can correct it through the "Settings" menu ([see section 4 Settings](#)).



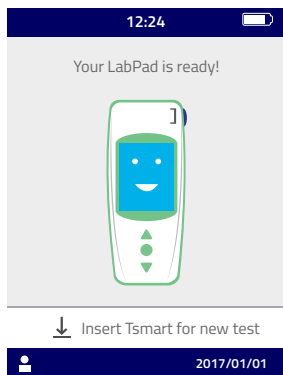
Once completed, the start screen is displayed and the device configures itself.



! **Caution**

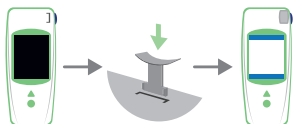
Verify that the date & time are correct. If incorrect, you will have to adjust them from the "Settings" menu (see [section 4 Settings](#)).

5) When you get this screen, the device is ready to be used.



3.2 Operating

Once configured, the device switches on:



- Automatically when you insert a Tsmart®



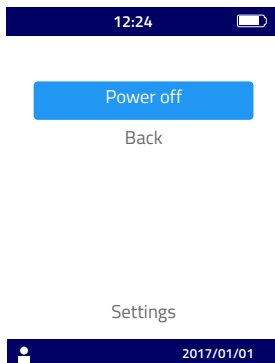
- When you press the center power button for 2 seconds

- When you connect the device with the USB cable provided

3.3 Power off

The device switches off automatically after 2 minutes without use; to change this duration, follow the instructions in [section 4.5 Power off](#).


It also switches off when you press the center power button for 2 seconds and you select "Power off".



3.4 Full reset

Caution

A full reset means a definitive loss of all results saved in the memory as well as a cancellation of personal settings (the factory settings will be restored).

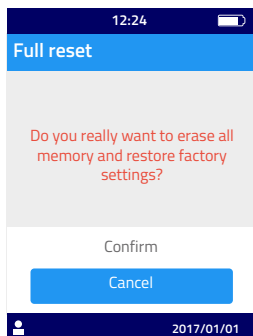
Before resetting the device, the battery charge must be checked. If the indicator is red  , plug it in to a power supply.



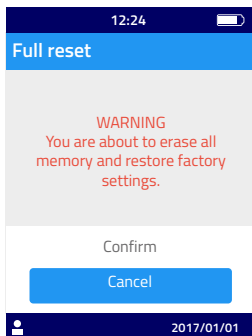
5S

You can reset the device by pressing both browse buttons during at least 5 seconds.

A first confirmation screen is displayed.



Once confirmed, a second confirmations screen is displayed.



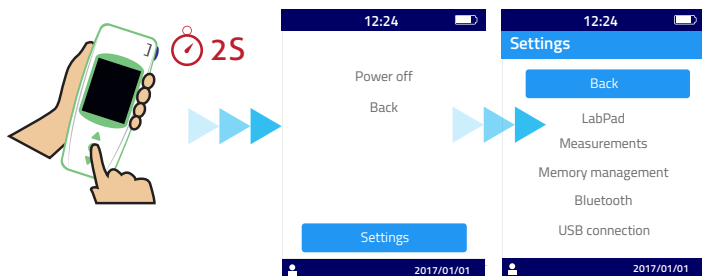
Once confirmed with the center power button, the device starts again and steps are identical to the first use and configuration ([see section 3.1 First use and initialization](#)).

4 Settings

You can set these parameters on the LabPad®:

- Language of the user interface
- Date & time format
- Date & time
- Screen brightness
- Power off
- Measurement unit
- INR therapeutic range
- Memory management
- Bluetooth connection

You can access “Settings” by pressing the center power button for 2 seconds and selecting “Settings”.



To change language, date & time format, date, time, brightness and power off, select “LabPad”.

To choose a memory management for test results, select “Memory management”.

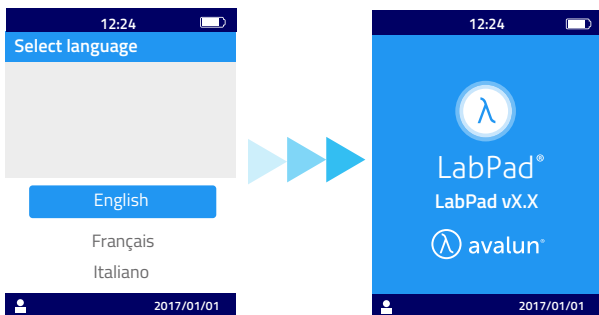
To set an INR range and a measurement unit, select “Measurements”. When the automatic memory management mode is not selected, you can manually erase results from “Measurements” ([see section 4.8 Memory management](#)).

- ▲ Use the browse buttons to select the parameter to change
- and the center power button to validate and go to the next
- ▼ step.

4.1 Language

! **Caution**

Changing the user interface language will make the device start again.



Once the new language is validated, wait for one of these two screens.



4.2 Date & Time format

1) Date format

12:24

Set date format

Date:

MM/JJ/AAAA

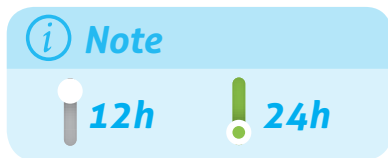
JJ/MM/AAAA

AAAA/MM/JJ

2017/01/01

2) Time format

24hr or 12hr (am/pm)



4.3 Date & Time

Set Date and then Time.

If you make a mistake, validate and then start again to set Date & Time from the beginning.

12:24

Set date

AAAA/MM/JJ

2017/01/01

Use and OK

2017/01/01

12:24

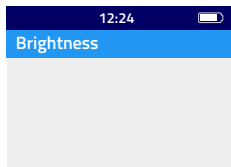
Set time

00:05

Use and OK

2017/01/01

4.4 Brightness



Minimum

Medium

Maximum

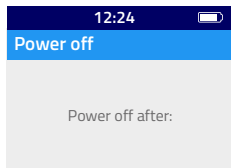


Brightness is set by default at the maximum level.

You can choose to decrease it to reduce battery consumption.

4.5 Power off

Choose the period of time before the device automatically powers off.



2 min

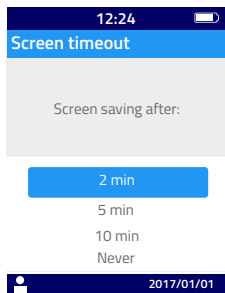
5 min

30 min

1 h



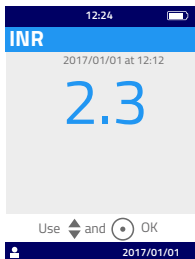
If you choose a period of time over 30 min., you will also have to choose a screensaver time.



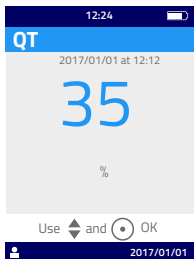
4.6 Measurement unit

The default setting first displays an INR measurement with the INR value, but it is possible to visualize the same result in seconds (PT Prothrombin Time) or percentage (QT Quick Time %) by pressing the center power button then the browse buttons ([see section 6.2 Reviewing results](#)).

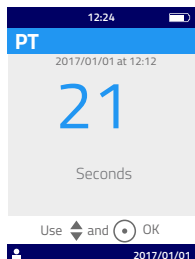
To display results in another unit first, select “Measurements” then “Measurement unit”. Select “Prothrombin Time” (PT) or “Quick Time” (QT); this choice will be applied to all future measurements. You can modify this setting as many times as you wish by just repeating the steps.



INR test result



QT test result



PT test result

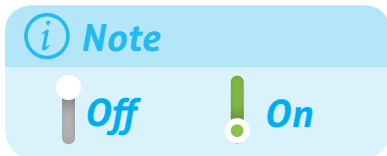
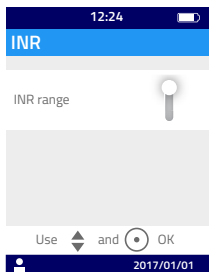
If the test result is outside the measuring range of the device (see [section 13 Technical specifications](#)), an error message is displayed (see [section 8 Error messages](#)).

4.7 Therapeutic range for INR measurements

You must consult your physician before setting the therapeutic range (see [section 1.1 Intended use](#)).

To set a therapeutic range, select "Measurements", "Measurement unit", then "INR".

1) Enable "INR range"



2) Enter the minimum value then the maximum value with the browse buttons.

The default setting is 2.0 to 2.5. You can adjust the minimum value up to 3.5 and the maximum value up to 4.5. When you increase the minimum value, the maximum value increases simultaneously to maintain a gap of at least 0.5.

Once set, the range is applied to all future measurements. It can be modified as many times as necessary by repeating the steps from 1).

To disable the "INR range" function, select "Off" at step 1).



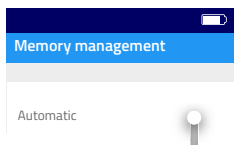
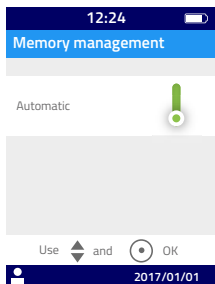
Healthcare professionals

Do not set a therapeutic range when the LabPad® INR is used to follow several patients.

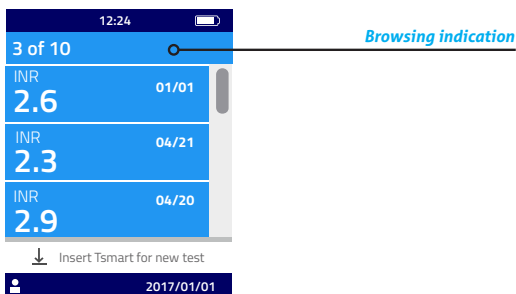
4.8 Memory management

Select "Memory Management" in the settings. The default memory management is automatic, which means that, when memory is full, the oldest result is automatically erased to allow the new test result to be saved.

To manage the memory manually, disable "Automatic", and confirm with the center power button.



When automatic management is off, a new option from the "Measurements" menu allows you to select a range of results to erase, starting from the oldest one. From "Measurements", select "Results deletion"; the screen below is then displayed.



Use the browse buttons to select the range of results to erase.

One confirmation screen will be displayed; you will have to validate using the center power button before deletion is effective.

Caution

All deletion of results is definitive.

Note

When automatic memory management is off and memory is full, the device will not allow any new measurement ([see section 8 Error messages](#)).

5 Performing an INR test

5.1 Prior recommendation

You must configure the device before performing a first measurement ([see section 3 First use and general instructions for use](#)).

5.2 Getting ready

Place your LabPad® INR on a stable, flat, and vibration-free surface. Prepare everything you will need for the test:

- a Tsmart® INR in its protective pouch; check that you exclusively use a microcuvette whose expiration date is not passed. Date format is YYYY-MM-DD for Year, Month, and Day.
- a single-use lancet or a lancing device with a new needle. Check that they are adapted to the INR measurement; a 21G lancet is recommended. Please refer to the manufacturer's instructions for use or seek the advice of a healthcare professional.
- dressing gauze or a paper tissue.
- a bandage.



Healthcare professionals

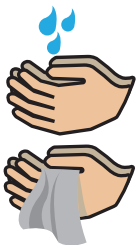
Additionally, use single-use gloves. Make sure lancets or lancing devices are adequate for healthcare professionals use.

5.3 Applying the blood drop onto the microcuvette



Healthcare professionals

Make sure the patient's hand is warm and relaxed. Blood sampling should be done preferably on the ring or middle finger. Disinfect the finger and leave it to dry completely or dry it with a soft rag or lint-free cloth.



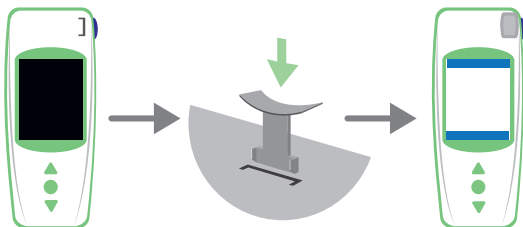
Wash your hands with warm soapy water and dry them thoroughly with a soft rag or lint-free cloth.




Caution

Residual water or disinfectant on the skin can dilute the blood drop and may lead to incorrect results.

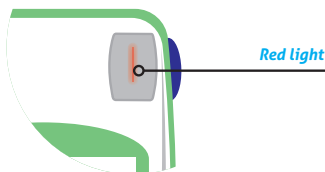
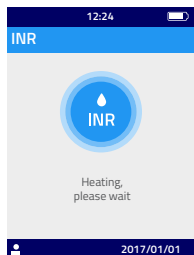
1) Open the pouch to take out the microcuvette, and insert it in the insertion area of the LabPad® (see section 2.5 How to insert the microcuvette).

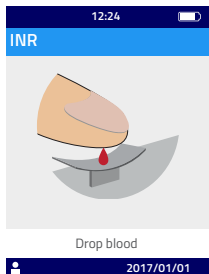


Quality control of the microcuvette is automatic. If the expiry date has passed, error code 7 is displayed together with the icon  (see section 8 Error Messages). In this event, you must change the microcuvette (see section 5.5 Discarding the microcuvette) and start again.

Heating process is in progress.

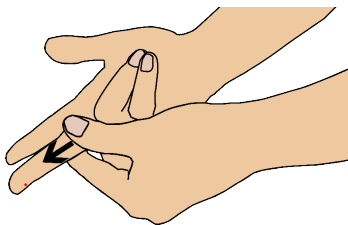
You may notice a red light in the device, in the middle of the microcuvette. This is part of normal processing.



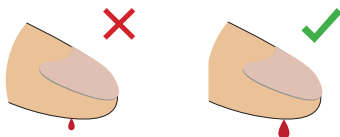


2) When the “drop blood” icon is displayed, you have 2 minutes to prick your finger and drop the blood on the microcuvette curved plate.

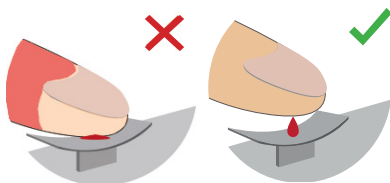
Check that your hand is warm. If necessary, gently massage your finger, preferably the ring or middle finger. Massage it towards the fingertip to facilitate the blood drop.



Prick the side of a fingertip of your dominant hand: your right hand if you are right-handed or left if you are left-handed. Use the lancet or the lancing device with your opposite hand to obtain a blood drop. A minimum volume of $3\mu\text{L}$ of blood is required to fill the central micro channel. Do not squeeze your finger, as this may lead to incorrect results.



The central micro channel is designed to suck the blood in as soon as the drop touches the center of the plate. Approach your finger gently and carefully towards the plate to apply your blood drop onto it. For proper filling it is important not to press your finger on the plate. Filling must be completed in one go.



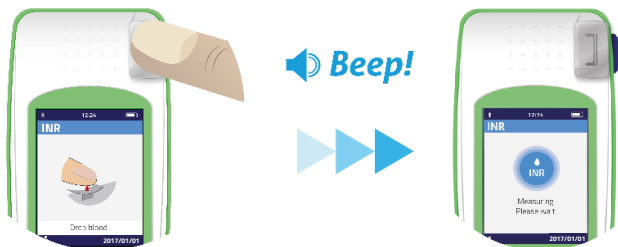
Caution

Do not squeeze your finger.
Apply the drop of blood in one single action.
Squeezing your finger or drop your blood in more than one single action may lead to incorrect results.

Healthcare professionals

Apply light pressure to the finger and massage it towards the fingertip to facilitate the blood drop. Prick the side of the fingertip with a lancet or a lancing device.
Approach the finger gently and carefully towards the plate, and keep it slightly above the plate. Do not squeeze the finger on the microcuvette.

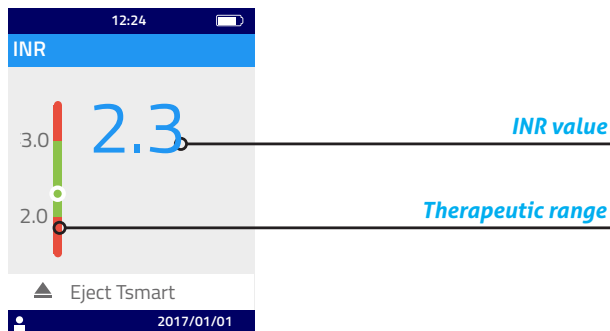
Keep your finger slightly above the plate until the screen changes and you hear the “beep”. The screen shows the measurement is in progress.



If necessary, wipe the excess blood and apply the bandage.

5.4 Performing a test and displaying result

The measurement is performed automatically within 2 minutes, and the result is displayed with the measurement unit set using the “Settings” (see section 4.6 Measurement unit).



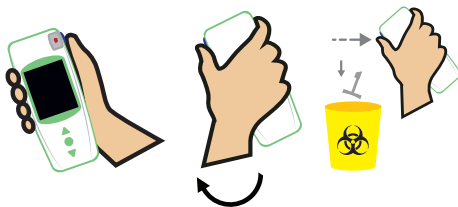
When the test result is in the therapeutic range, the round indicator is in the green zone (●); on the contrary, if it is out of the range, the indicator is in the red zone (●).

In this last case, make sure you follow the procedure determined with your physician or contact a healthcare professional. In case of doubt, consult your physician.

During measurement, if this icon (⚠) is displayed next to a number, there has been an error and the test cannot be performed. Refer to [section 8 Error messages](#) which lists suspected causes and solutions.

5.5 Discarding the microcuvette

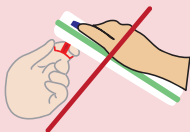
To discard the microcuvette, pick up your LabPad®, turn it down face towards the floor above a bin or any other appropriate recipient, and press the side blue button.



The microcuvette is released and drops by itself. Use a bin dedicated to biological waste if possible.

If the microcuvette resists and does not drop by itself, repeat this step, pressing the side blue button and keeping it pressed a little longer than the first time.

! **Caution**



Do not try to pull the Tsmart® INR, as you may damage the microcuvette and leave part of it inside the device.

Once the Tsmart® INR is discarded, the screen displays the list of results with the newest result at the top.

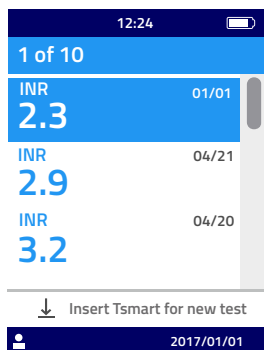


To transfer a result, refer to [section 7 Sharing results via Bluetooth](#).

6 Retrieving saved results

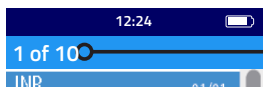
All results are automatically saved in the device memory, which can save up to 1,000 measurements.

6.1 Browsing the list of results



To find a result, use the triangular buttons to browse the list of results.

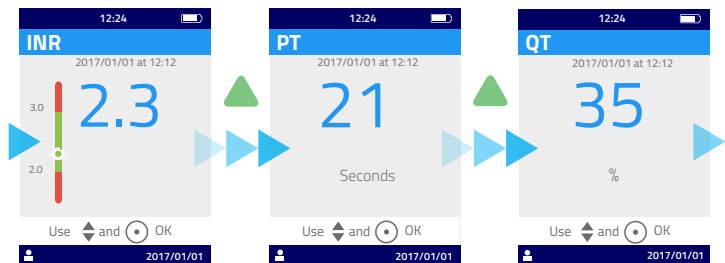
To browse quickly in the list of results, use one of the two triangular buttons, holding it until you get the result you wish.



Browsing indication

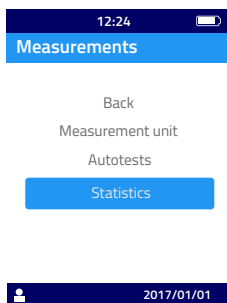
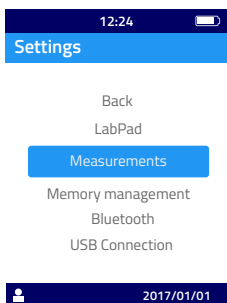
6.2 Reviewing results

Press the center power button to display all details related to a particular result (date and time of test, transmission status and conversion in other units).



6.3 Trend statistics of the INR range

When at least two INR results with a set therapeutic range have been saved in the memory within the last 60 days ([see section 6 Retrieving saved results](#)), it is possible to display trend statistics. In the “Settings” menu, select “Measurements”, then “Statistics”.



Note

Statistics include only the results corresponding to the tests performed with the last therapeutic range setting.

These statistics are displayed in the format of colored pie charts showing percentages of results respectively inferior to, superior to, and within the therapeutic range. Use the browse buttons if necessary to reset the period to examine.

To go back to the “Settings” menu, press again the center power button.

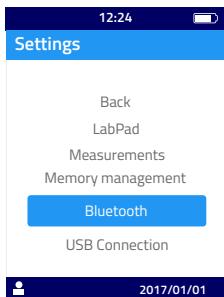
7 Sharing results via Bluetooth

You can share test results via Bluetooth with tablets or smartphones that comply with the CEI 60950 standard. To make your tablet or smartphone communicate via Bluetooth with your LabPad® INR, you must install a compatible application beforehand.

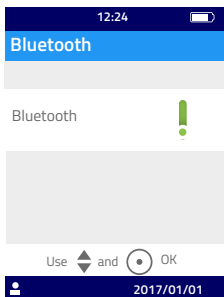
7.1 Bluetooth configuration

1) On the device you wish to connect with your LabPad® INR, check that Bluetooth is activated.

2) Select “Bluetooth” from the “Settings” menu (see [section 4 Settings](#)).



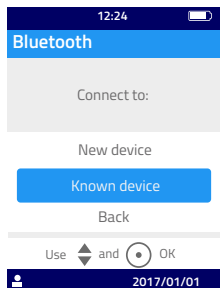
3) Enable Bluetooth, and confirm with the center power button.



Note

Switching the LabPad® INR on or off does not affect the last Bluetooth setting, regardless of the Bluetooth activation status.

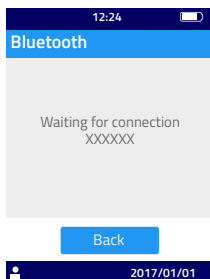
4) The following screen offers the possibility to connect a new device or get back to the “Settings” menu. Select the desired option with the center power button.



The connected Bluetooth icon consequently appears on the upper left part of the LabPad® INR screen.



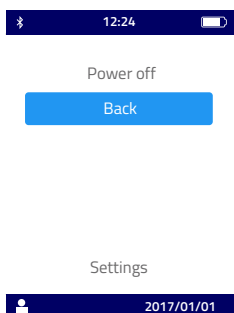
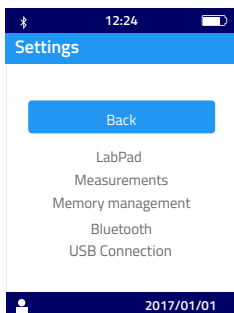
5) When the connection option for a new device is selected, a 6-digit PIN code is displayed with the message “Waiting for connection”. You must enter this PIN code on the new device to initiate a connection (see the user guide of the device and follow the steps).



When the connection is active, a confirmation message is displayed and the connected Bluetooth icon appears on the upper left part of the screen.



Select "Back" twice to exit the "Settings" menu, and to be able to perform a test.



7.2 Operating with Bluetooth

When a device that has been connected to your LabPad® INR beforehand is close by, the Bluetooth connection is activated automatically and the Bluetooth icon appears on the upper-left part of the screen. In this event, any results awaiting transmission are immediately transferred by the LabPad® INR to the other device.

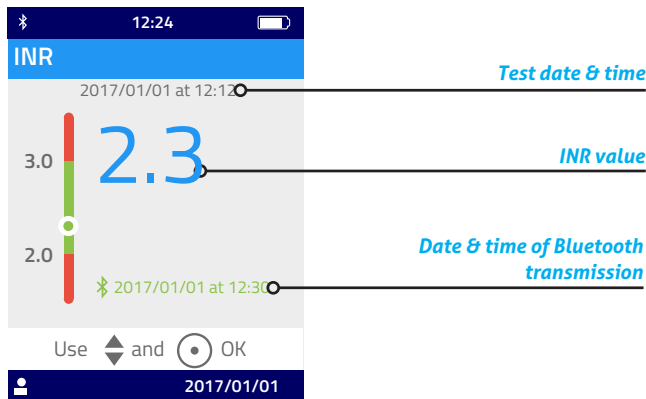
7.3 Result display with Bluetooth

Once the Tsmart® INR is discarded (see [section 5.5 Discarding the microcuvette](#)), the list of results appears with the indication of transmission:



12:24	
1 of 10	
INR	01/01
2.3	
INR	04/21
2.9	
INR	04/20
3.2	
↓ Insert Tsmart for new test	
2017/01/01	

To check transmission date & time, select a result. The screen then displays the following:



8 Error messages

When an error occurs, this icon  appears followed by "Error XX".

Refer to the tables below to identify the error.

Messages during the test preparation

N°	Error message	Suspected cause	Possible solution	Additional information
1	Low battery	The battery charge is not sufficient to perform a test.	Eject the microcuvette and immediately plug the battery charger into a power source.	The same Tsmart® INR can be inserted again within 5 min. Beyond these 5 min., you are recommended to use another Tsmart® INR microcuvette.
2	Memory full	There is not enough space in the memory to save the result.	Eject the microcuvette. Erase at least one result from the memory or select "automatic" in the memory settings (see section 4.8 Memory management).	The same Tsmart® INR can be inserted again within 5 min. Beyond these 5 min., you are recommended to use another Tsmart® INR microcuvette.
3 and 4	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 microcuvette and place the device at least 30 min. in a place where the ambient temperature complies with the operating conditions (see section 13 Technical specifications)	Repeat the test with another Tsmart® INR.

Messages during the test preparation

N°	Error message	Suspected cause	Possible solution	Additional information
5	Insufficient ambient brightness	There is not enough light to perform the test.	Eject the microcuvette. Make sure your location gets sufficient light to perform the test.	The same Tsmart® INR can be inserted again within 5 min. Beyond these 5 min., you are recommended to use another Tsmart® INR microcuvette.
6	Data reading error	The microcuvette is not inserted properly or the Datamatrix is damaged / absent.	Eject the microcuvette and insert it again as far as it will go. If an error occurs again, use another Tsmart® INR microcuvette.	
7	Expired Tsmart	The microcuvette has expired.	Eject the microcuvette and check the date displayed on the LabPad® INR. If this date is not correct, set the current date and insert the microcuvette again. If the date is correct, use another Tsmart® INR whose expiry date is valid.	The same Tsmart® INR can be inserted again within 5 min. Beyond these 5 min., you are recommended to use another Tsmart® INR microcuvette.

Messages during the test preparation

N°	Error message	Suspected cause	Possible solution	Additional information
8	Defective Tsmart	The microcuvette has stayed too long outside its pouch or it has already been used.	Eject the microcuvette and repeat the test with another Tsmart® INR.	
9	Tsmart not inserted properly	The microcuvette is not inserted properly.	Eject the microcuvette and insert it again as far as it will go. If an error occurs again, use another Tsmart® INR microcuvette.	The same Tsmart® INR can be inserted again within 5 min. Beyond these 5 min., you are recommended to use another Tsmart® INR microcuvette.
10	LabPad failure during autotests	An error occurred during autotests.	Eject the microcuvette, restart the device (see section 3.3 Power off), and try again.	If the error occurs again, contact your reseller.

Messages during the test

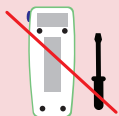
N°	Error message	Suspected cause	Possible solution	Additional information
100	Blood drop timeout	You have dropped your blood beyond the 2 min. allotted time.	If the blood drop has not reached the microcuvette plate, the same microcuvette can be immediately inserted to try again.	Do not repeat the test more than twice with the same microcuvette.
101	Error during the test	An error occurred during the test.	Eject the microcuvette and repeat the test with another Tsmart® INR.	If the error occurs again, contact your reseller.
102	Incorrect filling	The microcuvette has not been filled properly.	Eject the microcuvette and repeat the test with another Tsmart® INR, making sure you strictly follow the instructions for applying blood (see section 5.3 Applying the blood drop onto the microcuvette).	
103	Inadequate coagulation		Eject the microcuvette and repeat the test with another Tsmart® INR, making sure you strictly follow the instructions for applying blood (see section 5.3 Applying the blood drop onto the microcuvette).	

Messages during the test

N°	Error message	Suspected cause	Possible solution	Additional information
104	Tsmart released or ejected	The microcuvette was not inserted properly, it moved or was ejected.	If the microcuvette is still in the device, make sure to discard it completely, then press the validation button. Repeat the test with another Tsmart® INR making sure that you insert it as far as it goes and that the LabPad® 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 (see section 5.3 Applying the blood drop onto the microcuvette).	
200	Inappropriate Tsmart	An inappropriate microcuvette is inserted.	Eject the microcuvette and use a proper Tsmart® INR to perform the test.	
210 and over	LabPad internal error	An error occurred during the test.	Eject the microcuvette, restart the device (see section 3.3 Power off), and try again.	If the error occurs again, contact your reseller.

9 Troubleshooting

Caution



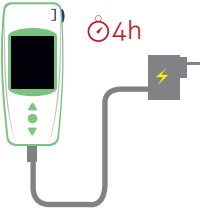
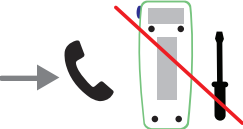


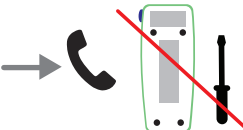
Never attempt to open the device. In case of doubt, contact your reseller.

Caution



If you notice a damage to your device (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 8 Error messages](#).

Problem found	Possible solution	
The device 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.	
Battery cannot be charged	Contact your reseller. Do not open the device; there are no small batteries inside.	
The device is working but there are numbers and meaningless letters on the screen.	Hold down the center power button for more than 20 seconds.	
The device is frozen on a display	Hold down the center power button for more than 20 seconds.	
The Tsmart® INR is broken inside the device	Do not open the device. Contact your reseller.	

10 Storage and transportation

Store the LabPad® INR in a dry place; refer to [section 13 Technical specifications](#) for further details on temperatures acceptable for the device.

Make sure no liquid is projected on the device, in order to ensure that proper functioning is maintained.

If you need to carry your LabPad® INR, use the carrying bag provided in the box and make sure the device is firmly inserted in order to avoid shocks. Before unpacking your device, check there has been no damage during transportation, otherwise contact your reseller.

11 Cleaning

! Caution



The LabPad® INR 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.



Make sure not to drop any liquid in the Tsmart® 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.

12 Warranty

The LabPad® INR is under warranty by your reseller. In the event of defect (see [section 9 Troubleshooting](#)) during the warranty period, the device can be repaired or exchanged. Please contact your reseller.

13 Technical specifications

Range	INR 0.8-8 PT 7.2-72 seconds QT 10-110%
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 Memory capacity is not affected by whether or not the battery charger is plugged in.
Bluetooth	Low Energy
Interface	Micro USB B port

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 $\pm 10\%$ of the nominal voltage. Can withstand temporary overvoltage occurring on the main supply and transient voltages up to the levels of overvoltage category II. Altitude up to 2,000 m. Environment: maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C. Applicable pollution degree of the intended environment: 2
Beep	Factory setting for beep frequency is 4,000Hz.
Dimensions	L 17.25cm W 7.21cm H 3.18 to 2.26cm
Weight	230g net

14 List of icons



You can apply your blood drop



Heating or measuring is in progress



An error occurred



Battery fully charged



Battery $\frac{3}{4}$ full



Battery half-full



Battery $\frac{1}{4}$ full



Battery empty



Battery is charging



The device is connected to another device via Bluetooth

15 List of symbols



CE marked product



Manufacturer



In-Vitro Diagnostics device (IVD)



Read the user guide



Discard in a bin dedicated to electronic waste



Serial number



Global Trade Item Number



Product reference



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



AVALUN SAS
7, Parvis Louis Néel
38000 Grenoble, France
LabPad INR_IFU EN V6_1117

