

INSTRUCTIONS FOR USE (IFU)

LYSIS TIMER

SEMI-AUTOMATED SYSTEM FOR EUGLOBULIN LYSIS TIME
STUDY

REF: [LT-8V] / SN: [LT-V4-XXX]



Measuring instrument for professional use in a laboratory or similar environment

For research use only (RUO)

Not for use as part of in vitro diagnostic procedures

Exclusive distributor:  **[HYPHEN BioMed]**

Address: 155 rue d'Eragny, 95000 Neuville-sur-Oise, France

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Legal manufacturer



Address: 48 Square Eugène Herzog 54390 Frouard, FRANCE.

Instructions for use

These instructions explain the operation and handling of the [Lysis Timer] to ensure its safe and correct use with the dedicated consumables and accessories. Read these instructions carefully and make sure you understand all warnings and precautions before you start using [Lysis Timer].

Copyright

The copyright of this document is held the manufacturer of [Lysis Timer]: [SD Innovation]. Reproduction of part or all of its contents without the permission of the manufacturer or its local representative is a violation of intellectual property laws. However, it is permitted to make a backup copy for personal, non-commercial use. [HYPHEN BioMed] is a trademark of [Sysmex Corporation].

Non-assignment clause

Any transfer of [Lysis Timer] to a natural or legal person and under any condition whatsoever, entails the total exoneration of the manufacturer from its legal or conventional responsibilities for any damage or accident related to the use of [Lysis Timer].

Legend

Symbol	Meaning	Description
	Warning	A warning warns of a potentially dangerous situation for the operator or any other person in the operating environment. Failure to comply with this type of instruction may result in personal injury.
	Caution	A safety precaution warns of a potentially dangerous situation for the equipment. Failure to observe this type of instruction may result in damage to or failure of the equipment being used or other equipment in the operating environment. It also warns of a situation that could potentially cause discomfort to the operator.
	Information	Other important non-hazardous information to be considered.

1. Intended use

[Lysis Timer] is a semi-automated device for the study of euglobulin lysis time (or analysis of clot dissolution kinetics resulting from thrombin coagulation) in a sample of citrated human plasma in the presence of human tPA (recombinant) and silica (tPA-silica solution).

It is a measuring device for professional use in a laboratory or similar environment for research purposes only.



[Lysis Timer] is not to be used for in vitro diagnostic tests for medical purposes (i.e. to establish diagnostic results).

It measures the turbidity of the medium photometrically on each of its 8 measuring channels heated to 37°C.

This quantitative test aims to reproduce the manual method of Von Kaulla to obtain comparable results. It consists of introducing into a tube a micro-volume of citrated plasma incubated at 37°C into which a specific reagent is injected before starting the measurement. During the measurement, the sample is crossed by an infrared beam while being maintained at a temperature of 37°C and the instrument records the evolution of the clot from its formation to its destruction.

The dedicated software [LysisControl] installed on a PC and connected to the instrument, allows to control the 8 measurement channels, to record the sample and test data, to plot the measurement curves, to perform the calculations and to save the results.

2. Description of the equipment

2.1. Technical specifications

- Measuring channels: 8
- Temperature control: Measuring channels heated to $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$
- Duration of temperature rise and control: 20 minutes
- Protocol: Measurement of euglobulin lysis time / Analysis of clot dissolution kinetics
- Primary sample: human blood collected onto the trisodium citrate anticoagulant
- Sample volume (per test): 100 μL
- Reagents: CK093K "GFC-Test" HYPHEN BioMed:
 - R1: tPA with Silica
 - R2: Thrombin
- Test preparation:
 - introduce in a cuvette at 37°C :
 - 100 μL citrated plasma (Samples are tested undiluted)
 - 100 μL CK093K (R1 tPA with silica, homogenized before use)
 - Mix and incubate at 37°C , for about 1 minute then introduce:
 - 100 μL CK093K (R2 Thrombin)
 - Mix by vortexing.
- Measurement principle: Turbidity measurement
- Measuring method: Photometric method
- Dimensions: Height = 75mm; Width = 60mm; Depth = 175mm
- Weight: 1.1kg
- Electrical specifications instrument (input):
 - DC voltage: 12V
 - Rated current: 3.33A
 - Power rating (max.): 40W
- Electrical specifications AC power adapter:
 - Adapter with EU plug :
 - Input: 100-240VAC \pm 10%, 50/60Hz, 0.9-0.45A
 - Output: 12V (direct current) 3A, 36W MAX
 - *NOTE: This accessory is included with the purchase of the Lysis Timer*



Other types of compatible power adapters can be supplied. Contact your local representative for further information.

- Connections : USB port + Power adapter
- Communication cable: USB cable
- Temperature limits (operation / storage): [$19 - 30^{\circ}\text{C}$] / [$0 - 40^{\circ}\text{C}$]
- Humidity limits (operation / storage): [20% - 80%] RH non-condensing / [10% - 80%] RH
- Operating environment:
 - < 2000meter
 - pollution degree 2
- Computer requirements (minimum): Microsoft Windows 10 ®; Processor 1.5GHz; HDD 60GB; pdf reader
- Data processing functions: Controlling measurement channels, recording sample and test data, plotting measurement curves, performing calculations, and saving results
- Maintenance and cleaning: Cleaning with a non-corrosive disinfectant

2.2. Instrument and accessories



Figure 1: [Lysis Timer]; Power Adapter; USB Cable; Storage case (optional)



Other types of compatible power adapters can be supplied. Contact your local representative for further information.



[Lysis Timer] should only be used with the accessories provided.

2.3. Control and connections

[Lysis Timer] has the following controls and connections:



Figure 2: Controls and Connections

1. ON/OFF button
2. Power port
3. USB port
4. AC power adapter connector
5. USB communication cable connector

2.4. Consumables

For proper use of the [Lysis Timer], dedicated tubes are required:

- reference: [LT-CV]
- manufacturer: SD Innovation



These consumables are for single use only. Do not use other references, as they may

interfere with the measurement of the device.



Contact your local representative for further information.

2.5. Reagents required

[Lysis Timer] should only be used with the following reagents:

- R1 tPA with Silica / R2 Thrombin (ref CK093K – HYPHEN BioMed)



Follow the instructions for use provided by the reagent manufacturer.



Likely quantities of reagent that may be released from [Lysis Timer]: each tube may contain 200 μ L of reagents. [Lysis Timer] can therefore release a total of 1600 μ L of reagent.



Contact your local representative for further information.

2.6. Other materials required



Refer to the list of laboratory equipment required in the reagent instructions for use.

3. Compliance and safety

3.1. Compliance

[Lysis Timer] complies with the European EMC Directive 2014/30/EU and the European Low Voltage Directive 2014/35/EU.

3.2. Warnings and residual risks

3.2.1. Electromagnetic risk

- ▲ Do not use [Lysis Timer] in the immediate vicinity of sources of high electromagnetic radiation such as intentionally unprotected radio frequency sources, as these may interfere with the proper functioning of the device.
- ▲ It is recommended that an electromagnetic environment assessment be performed before the [Lysis Timer] is put into operation.
- ▲ [Lysis Timer] has been tested according to EN/IEC 61326-1 (2020) and EN/IEC 61326-2-6 (2020). Classification: Class B, Group 1 (Residential Environment) according to EN 55011/CISPR11.

3.2.2. Electrical risk

- ▲ Connect the [Lysis Timer] power adapter to an earthed mains socket suitable for the electrical specifications (frequency and voltage) of the adapter.
- ▲ Position [Lysis Timer] so that it is easy to access the power plug to disconnect it from the mains in case of danger.
- ▲ Handle [Lysis Timer] cables carefully when disconnecting and reconnecting to the instrument or to the power supply.
- ▲ Stop using [Lysis Timer] if any of its cables are damaged. Contact your local representative if necessary.
- ▲ Do not replace the AC adapter of [Lysis Timer] with another adapter. The adapter may have inappropriate electrical characteristics and/or may not comply with applicable standards. In this case, the manufacturer is no longer able to guarantee electrical safety. Contact your local representative if necessary.
Do not handle the AC adapter with wet hands, especially when connecting/disconnecting the plug to the mains.
- ▲ Do not wet or immerse [Lysis Timer], the AC adapter or their connectors.
- ▲ Do not insert any object into the measuring channels of [Lysis Timer] other than specified accessories.
- ▲ Do not insert any objects into the connectors of [Lysis Timer], USB cable or AC adapter cable.
- ▲ The protection level of [Lysis Timer] and its accessories may be impaired if they are not used according to the manufacturer's recommendations.

3.2.3. Risk of infection and chemical risk


















- ▲ Wear a laboratory coat, gloves, and goggles when handling blood samples.
- ▲ Wear protective gloves during maintenance and servicing.
- ▲ Clean and disinfect the [Lysis Timer] before any maintenance and before reprocessing at the end of the unit's life.
- ▲ During and after use, consumables (glass tubes) may present infectious and microbial risks, so they must be handled with care and disposed of in accordance with the local regulations in force concerning infectious waste.

- ▲ Reagents to be used with [Lysis Timer] may present infectious or microbial risk (because may contain materials of human and animal origin) or may be toxic. Respect the warnings and precautions in the instructions for use provided with the reagents by the manufacturer.

3.2.4. Risk of fire or explosion

- ▲ Do not use [Lysis Timer] near flammable substances, or in places with high oxygen concentration to avoid the risk of fire or explosion.
- ▲ Do not spray flammable substances on [Lysis Timer].

3.3. Symbols

	See warnings in the operating instructions
	Biohazard - potentially infectious
	Direct current
	Catalogue number
	Serial number
	Distributor
	Manufacturer
	Manufacturing date
	Storage temperature limits
	Equipment subject to selective collection for European Union countries
	Indoor use only
	See precautions for use in the instructions for use
	Complies with applicable European Directives
	USB cable connector
	ON position
	OFF position
	Power adapter connector

3.4. Precaution for use

3.4.1. General use

- [Lysis Timer], its accessories and consumables should be used only by qualified laboratory technicians and in accordance with good laboratory practice.
- To guarantee the safety and performance of the [Lysis Timer], any intervention, repair or modification of the device by personnel not authorised by the manufacturer is prohibited and will void the warranty.

3.4.2. Commissioning and installation

- During installation, check the integrity of [Lysis Timer] and accessories.
Position the [Lysis Timer] in such a way that it is easy to handle and to avoid pulling on the cables during use.
- Carefully remove the 2 protective rods positioned in channel n°1 and n°8 of the [Lysis Timer] by rotating them upwards. Keep them with the packaging for reuse in case of transport.
- Leave enough space (e.g., 10cm) around the [Lysis Timer] for air circulation.
- To ensure the temperature of the [Lysis Timer] remains consistent, do not use the unit under air conditioning or any other source that may affect this setting.
- Place the [Lysis Timer] on a clean, flat surface away from moisture, splashing water and sources of heat energy.
- Updates to the [LysisControl] software should be carried out under the supervision of your local representative.
- When updating the operating system of the control PC, the minimum configuration specifications must be observed to ensure compatibility with the [LysisControl] software.
- The use of [Lysis Timer] does not require an internet connection, however, it is strongly recommended to install and keep up to date an anti-virus software suitable for the control PC environment.
- The manufacturer declines any responsibility in case of malfunction of [Lysis Timer] or the [LysisControl] software caused by a virus or hacking.
- The manufacturer accepts no liability for data protection violations caused by viruses or hacking.

3.4.3. Operation


- It is strongly recommended to have [Lysis Timer] checked during annual preventive maintenance. For information, contact your local representative.
- Each laboratory must establish appropriate quality control under its exact working conditions.
- Use [Lysis Timer] only with the specified consumables (glass tubes) and reagents.
- Before each use, check that there is no debris in the measuring channels of [Lysis Timer].
- If the [Lysis Timer] or any of its accessories are dropped, knocked or if you are unsure of their integrity, stop use and contact your local representative.
- If any liquid or other substance enters the [Lysis Timer], which may damage or interfere with its operation, discontinue use, and contact your local representative.
- Do not use [Lysis Timer] in the vicinity of other vibrating equipment (e.g., centrifuge).
- It is the user's responsibility to ensure the security, integrity and backup of personal data entered the [LysisControl] software. To protect the system against illegitimate access, unwanted modification or deletion of data, it is strongly recommended to:
 - Activate and assign access rights (ACL) to each user via the operating system settings of the control PC and those of the [LysisControl] software

- Enable automatic screen saving so that the PC screen is switched off after a period of inactivity and the user of the current session must log in when the screen is switched on again. NOTE: Do not enable the computer's auto-sleep feature to avoid interrupting a test in progress due to a power failure during the sleep mode.

3.4.4. Storage and transport

- If the environment in which the device is located is particularly hot and humid (e.g., non-air-conditioned laboratory in a tropical environment), protect [Lysis Timer] and its accessories outside working hours to prevent moisture from entering the device.
- To prevent dust and the like from entering the measurement channels when [Lysis Timer] is not used for a long period of time, it is recommended that a clean, empty glass tube be placed in each of the 8 channels or that it be stored in its original packaging.
- Before transporting [Lysis Timer], insert the 2 protection rods into channels n°1 and n°8 of the device by turning them downwards, then place it back in its original packaging with all the necessary protections. If necessary, ask your local representative for further instructions beforehand.

3.4.5. End of life and waste of disposal

- [Lysis Timer] and its accessories contain components that may cause environmental hazards if the regulations applicable to the disposal of waste electrical and electronic equipment are not followed.
- According to the European Directive 2012/19/EU, the pictogram  means that [Lysis Timer] and its accessories are subject to separate collection in the territories of the European Union. The equipment at the end of its life must therefore be handed over to an appropriate collection point for treatment.
- In other countries, the end-of-life equipment must be treated in accordance with local regulations.
- After use, the consumables (glass tubes) may present infectious and microbial risks and must therefore be disposed of in accordance with the local regulations in force concerning hazardous waste.

4. Installation, commissioning, and configurations

4.1. Installation

4.1.1. Software installation

- Download the installation folder by clicking on the link: <https://www.sd-innovation.fr/pub/app/lysis timer>
- Right click on the folder to extract the file
- Double-click on the unzipped folder
- Double-click on the "lysisControl.exe" folder
- Authorise the installation, if necessary
- NOTE: It is advisable to create a shortcut to "lysiscontrol.exe" (on the PC desktop for example) to be able to access the software more quickly.

4.1.2. Removing protective rods



Figure 3: Protection rods

- Remove the 2 protective rods positioned in channel n°1 and n°8 of the device by rotating them upwards.

4.1.3. Connections



Figure 4: Connections

- Connect the power adapter to the [Lysis Timer] port (1)
- Connect the power adapter plug to the power supply
- Connect the USB cable to the [Lysis Timer] port (2)
- Connect the USB cable to the PC port
- The installation is finished

4.2. Switching and connecting

- Press the ON/OFF button of [Lysis Timer]:
 - The device is switched on when the button is pressed and the green light is on
 - The device is switched off when the button isn't pressed and the green light is off

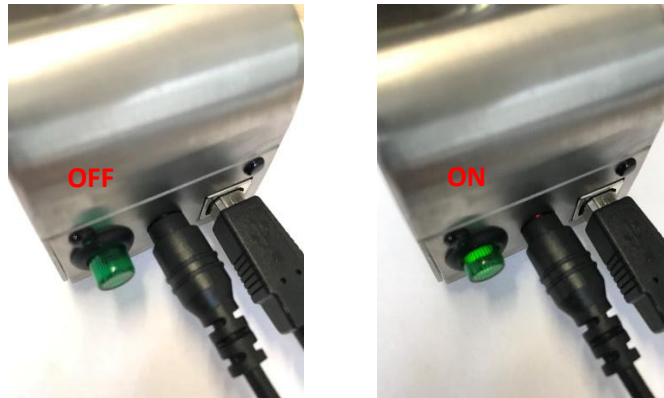



Figure 5: ON / OFF status

- All 8 channels are flashing to indicate that the unit is waiting to be connected to the control PC



Figure 6: Channels waiting for connection

- Double click on the software icon "LysisControl.exe" to start the application
- If the status bar indicates that the device is not connected "Disconnect device":
 - Go to the "Device Manager" of the PC operating system
 - Check the tab dedicated to communication ports (usually named "Com Ports") to find the number of the communication port concerned "COMX" (e.g., COM3)
 - Go back to "LysisControl" and click on 
 - Fill in the port number (e.g., COM3); click on "OK"

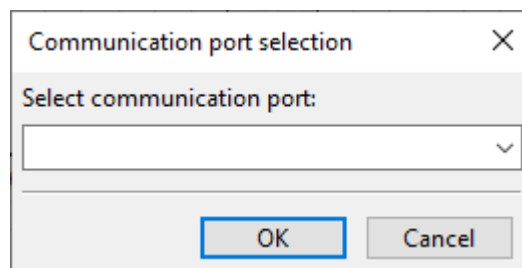



Figure 7: Communication Port Selection Window

- The icon  changes colour to indicate that the device is connected
- The temperature of the device measured in real time appears in the status bar to indicate that the channel heating system is active
- The device is ready for use

4.3. Home page

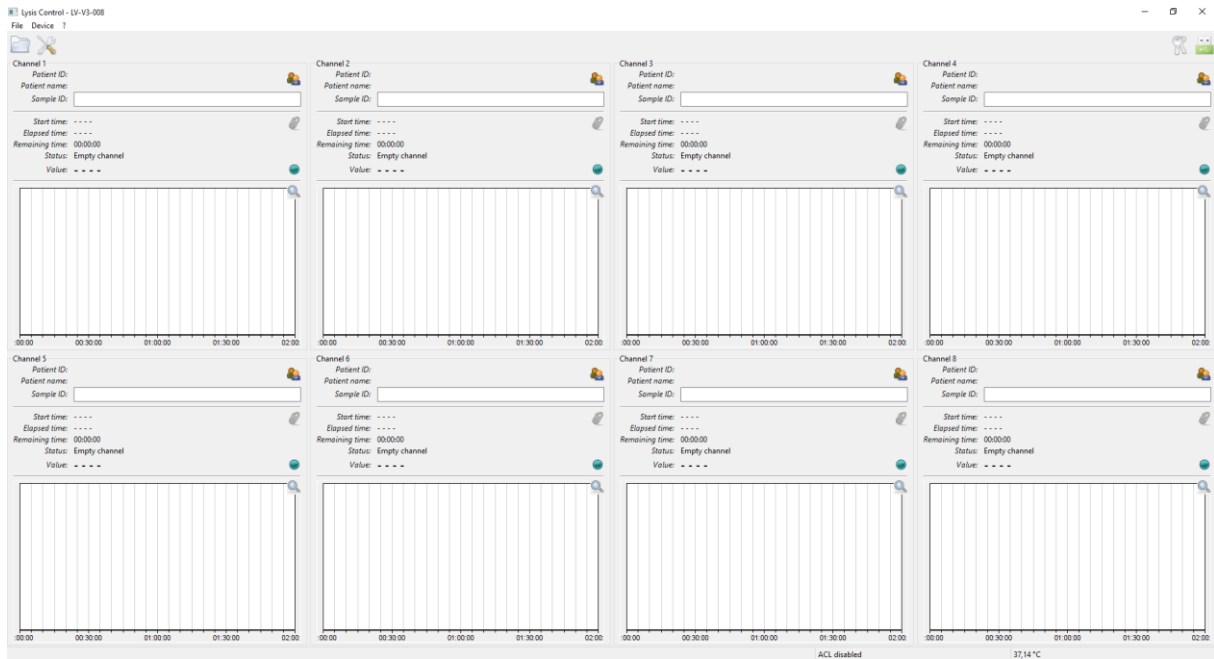










Figure 8: Home page of the [LysisControl] software

- [File]
 - Load analysis...
 - Settings...
 - User logout...
 - Change password...
 - Quit
- [Device]
 - Device information...
 - Device connect / unconnect
- [?]
- About...
- 
 - Quick access to patient list and test files
- 
 - Quick access to settings options
-  / 
 - Quick access to select a communication port to connect a device
- 
 - Quick access to the user logout / login window (login / password) when access rights are enabled
- 
 - Quick access to the measurement details

- 
 - Click to start a measurement
- 
 - Quick access to "Change measurement duration..."; "Export..."; "Save as PDF..." and "Reset channel acquisition..."

4.4. Settings

To access the settings menu, click on "File / Settings..."

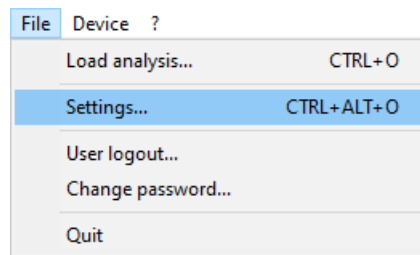


Figure 9: Access to Settings

4.4.1. General settings

This menu allows the following configurations:

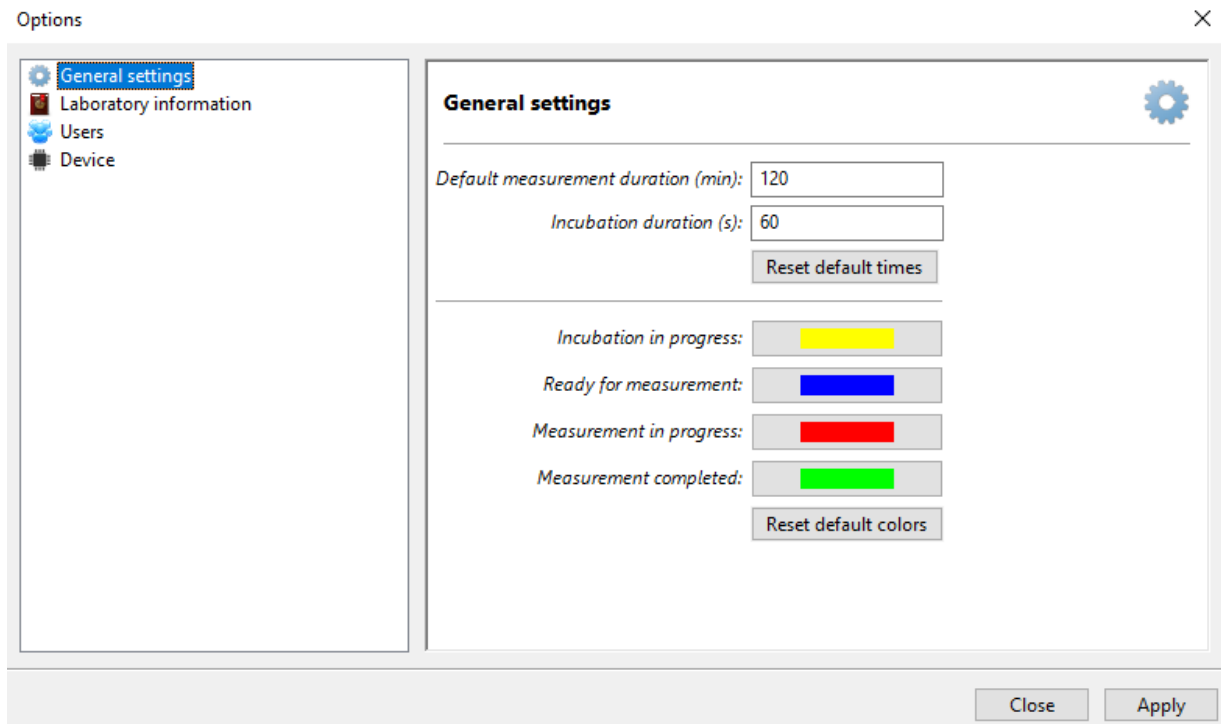


Figure 10: Settings window

- Default measurement time in minutes:
 - 120min (factory setting)
 - If necessary, change the default time and click on "Apply"

- If you need to return to the factory default time (120min), click on "Default time" and then "Apply"



Caution: If this parameter is changed, make sure that the measurement time is not too short.

- Incubation time in seconds:
 - 60s by default (factory setting)
 - If necessary, change the time then click on "Apply"
 - If you need to go back to the factory default time (60s), click on "Default time" then on "Apply"



Caution: If this parameter is changed, make sure that the incubation time is not too short.

- Channel colours:
 - The colours are defined by default (factory configuration)
 - To define new colours:
- Click on the colour to be modified
- Select the desired colour then click on "OK" then on "Apply"
 - If you need to return to the factory default colours, click on "Default colours" and then on "Apply"



Caution: Make sure that the 4 defined colours are always different from each other.

4.4.2.Laboratory information

This menu allows you to define the information to be included in the results reports:

Figure 11: Laboratory information window

- Enter the necessary information
- Click on "Apply"

4.4.3.Users

To protect the data processed by the software, in particular the personal data of patients and users, it is advisable to activate the software access rights (ACL).

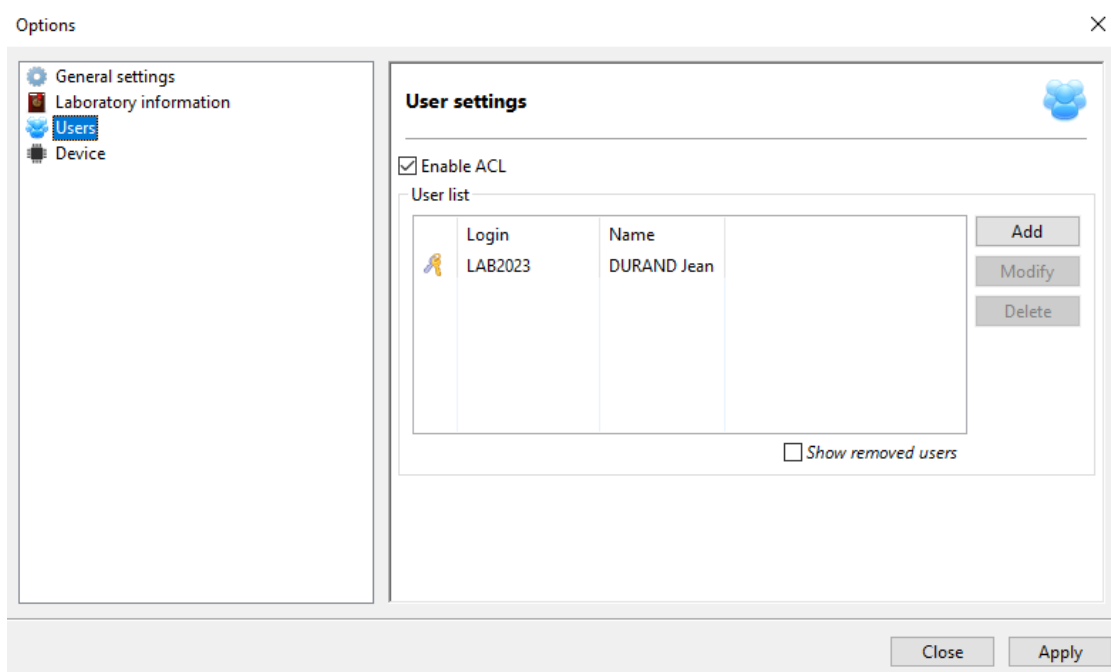


Figure 12: User settings window

To do that:

- Click on "Enable ACLs".
- Click on "Add"

Is admin

Is active

Figure 13: New User window

- Create a new user profile for the administrator:
 - Enter the data
 - Click on "Administrator" and "Active" then "OK"
 - Only administrators have the following rights:
 - Create, modify, and delete user accounts

- Create and modify administrator accounts
 - Modify device settings (access to the "Settings" window)
- Create profiles for other users (non-administrators):
 - Enter data
 - Click on "Active" while keeping "Administrator" unchecked and then on "OK"
- When all users have been created, click on "Apply".

4.4.4. Device settings

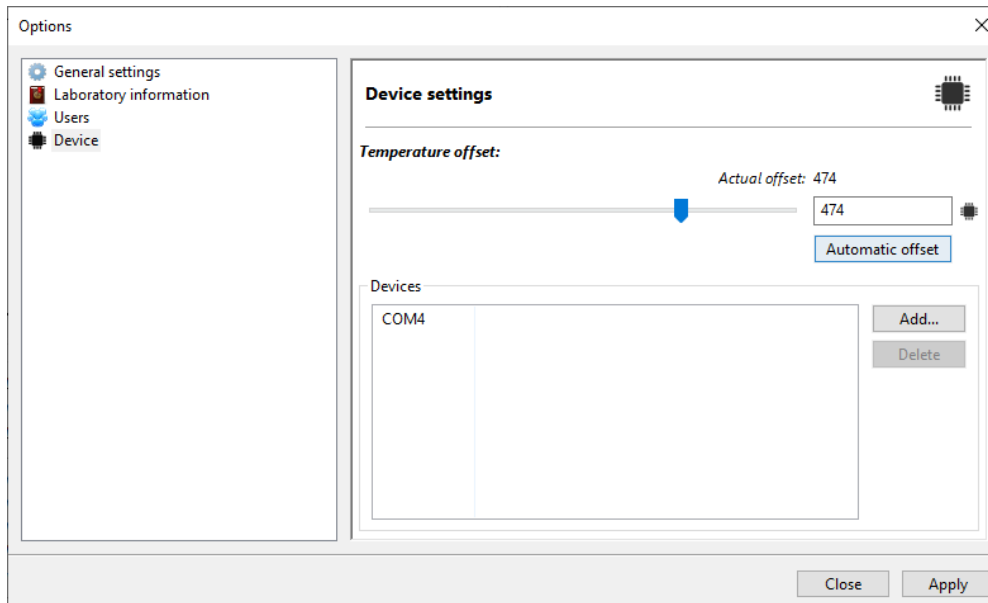


Figure 14: Device Settings Window

Temperature offset:

The device temperature is set at the factory according to measurements taken with a calibrated external thermometer. This setting can be viewed in "Peripherals/Device information.../Offset".



This setting may only be changed by an authorized service technician (manufacturer or its authorized representative). Any other modification to the offset may interfere with the correct device operation.

Devices:

- Click on "Add..."
- Enter the serial port number corresponding to the device connection: "COMX" (e.g., "COM2")

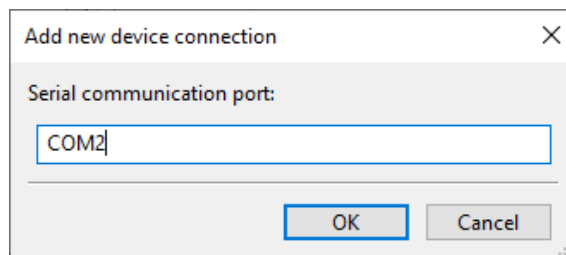



Figure 15: Add New Connection window

- Click on "OK" and then on "Apply"

- To delete communication ports, select the port number to be deleted and click on "Delete"
- NOTE: The ports entered in the list will then be accessible by clicking on the icon 

5. Test preparation and identification

5.1. Sample collection and reagent preparation

The sample to be studied is human plasma previously collected on citrated anticoagulant.



Follow the instructions for use provided by the reagent manufacturer, including warnings and precautions for use.


The reagents to be used are as follows:

- R1 tPA with Silica / R2 Thrombin (ref CK093K – HYPHEN BioMed)



Follow the instructions for use provided by the reagent manufacturer, including warnings and precautions.

5.2. Test identification

- Click on  in the measurement channel to be used

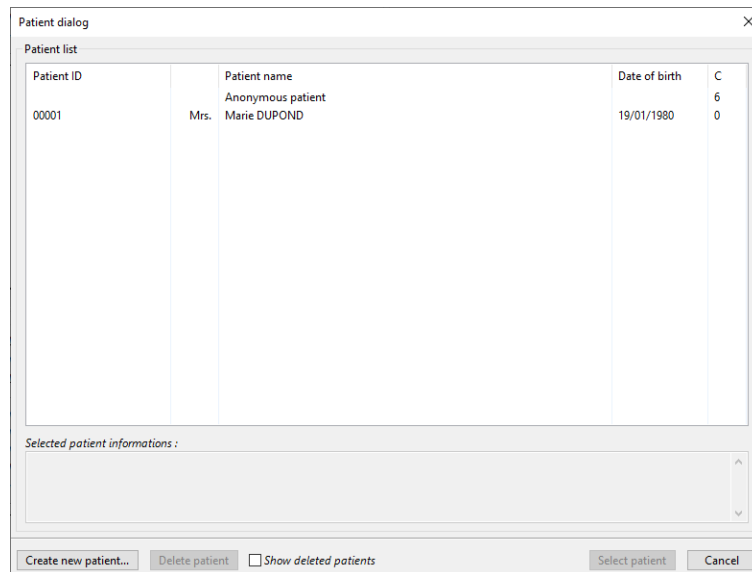


Figure 16: Patient list window

- Then click on "Create new patient... »

Figure 17: New Patient Window

- Enter the necessary information
- Click on "OK"
- For a patient that has already been created, click on the patient's name in the patient list and then click on "Select Patient".
- NOTE: In the patient list, the "C" column indicates the number of tests performed with the patient
- In the "Pathway" window corresponding to the patient "Sample ID", enter the sample identification number.

Figure 18: Sample ID



After selecting the patient, the patient's first and last name may appear on the main interface. To protect personal data from unauthorised access, it is advisable to activate the access rights and the screen saver via the "Settings" of the PC and, in addition, to activate the "ACL" access rights via the "Settings" of the software [LysisControl].

5.3. Solution preparation and tube placement



Always use tubes dedicated to [Lysis Timer]. Use of other tube references may affect measurement performance.

- Take a new, clean glass tube
- Inject:
 - 100 μ L of citrated plasma
 - then 100 μ L of reagent R1 tPA with Silica (ref CK093K HYPHEN BioMed)

- Insert the tube containing the preparation into the chosen measuring channel:



Figure 19: Tube insertion and incubation

- Immediately after insertion, the measurement channel used lights up in a certain colour to indicate that the incubation period is in progress (default duration: 60 seconds) for the purpose of heating the sample to 37°C.

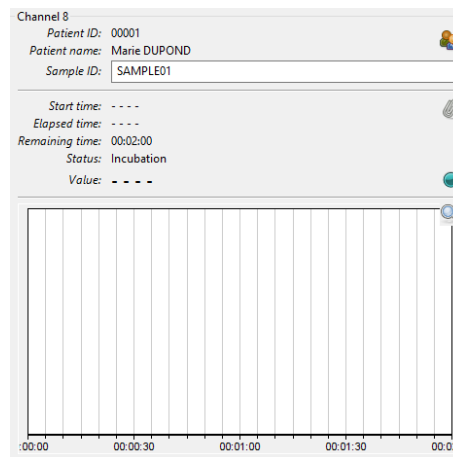


Figure 20: Channel interface– Incubation status

- At the end of the incubation period, the channel changes colour to indicate that the instrument is ready to measure.

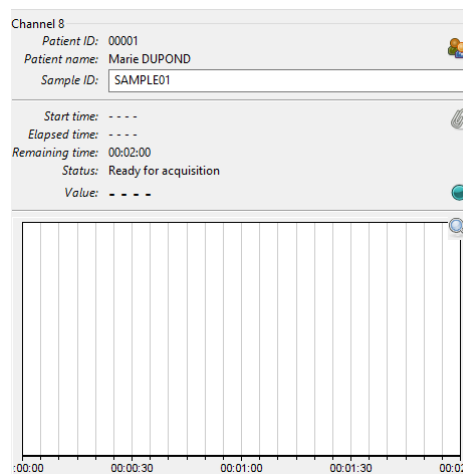


Figure 21: Channel interface – Ready for Acquisition Status


6. Measurement and analysis results

6.1. Measurements starting and monitoring

- Introduce into the tube containing the mixture to be analysed (plasma + R1 tPA with Silica)
 - 100 µL of R2 Thrombin (ref CK093K HYPHEN BioMed)



Follow the instructions for use provided by the reagent manufacturer, including warnings and precautions.

- Immediately afterwards, mix carefully by vortexing the tube, and click  to start the measurement.
- The measurement channel changes colour to indicate that the measurement has started.

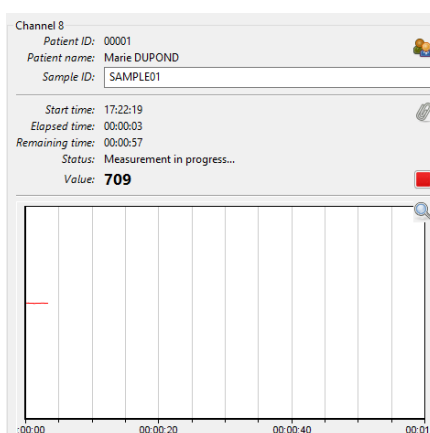



Figure 22: Channel interface – Measurement in progress status

- The lysis time is measured and the graph showing the evolution of the measurement curve is displayed in real time.
- Click on  to zoom on the graph.

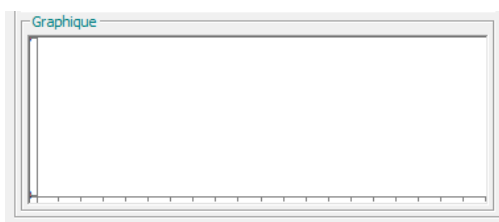



Figure 23: Real time measurement zoom

- NOTE: It is possible to interrupt the measurement by clicking on .

6.2. Analysis and export results

End of measurements:

- At the end of the measurements, the channel changes colour on the device.

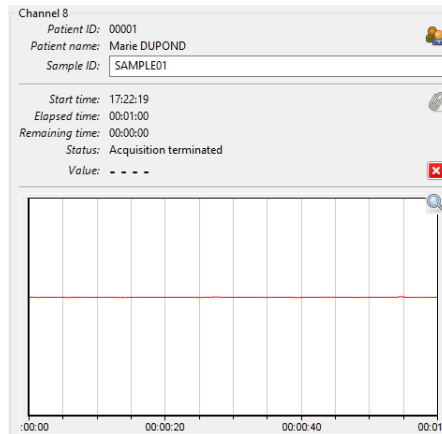


Figure 24: Channel Interface - Acquisition terminated status

- Carefully remove the tube from the channel.



To facilitate removal, twist the tube while pulling it upwards.


- Dispose of the contents of the tube and then the tube according to good laboratory practice.




The tubes are for single use only, do not reuse.

- NOTE: It is possible to start a new measurement on the channel by clicking on. Previous measurements will not be deleted as they have already been saved in the system.

Results analysis:

- Click on  in the measurement channel to open the analysis file for the relevant patient.

Or:

- Click on  to access the patient list
- Click on the line corresponding to the patient's name
- Click on the line corresponding to the test file to be analysed
- Click on "Open"

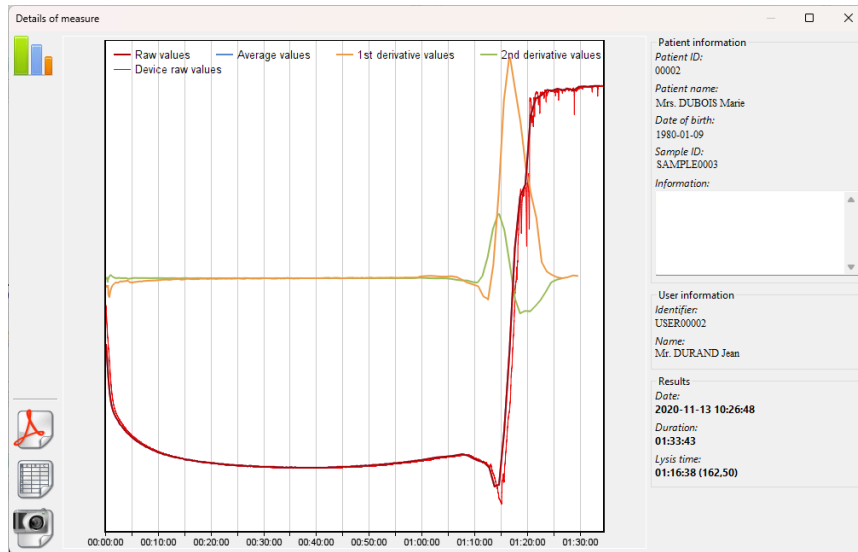



Figure 25: Measurement Details window

- The following data and results are presented:
 - Test start date and time: YYYY-MM-DD h:min:s
 - Duration / Measurement time: h:min:s
 - Lysis time: h:min:s (Maximum slope of the curve: XX,XX)
 - Lysis time measurement curves:
 - Raw values
 - Average values
 - Derivative values
 - Second derivative values
 - Raw device values

- NOTE: The "raw instrument values" are the values as directly measured by the instrument, while the "raw values" have been resampled.

- These curves can be displayed according to the selected averaging mode:
 - None
 - 3-point smoothing
 - 5-point smoothing
 - 7-point smoothing
 - Double smoothing on 7 points
 - Triple smoothing on 7 points

- It is possible to select the curve(s) to be displayed and the averaging mode by clicking on .

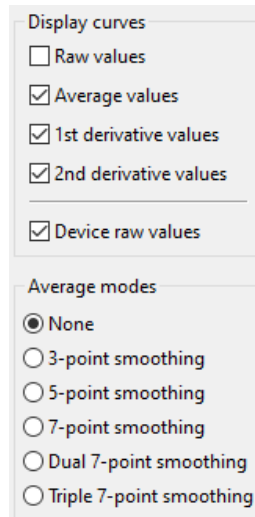





Figure 26: Curve display option

Results exportation:

NOTE: It is advisable to save all analyses in a single folder to be able to manage all personal patient data as a backup. This makes it possible, for example, to delete the data before sending the device for maintenance to prevent third parties from accessing the data.

It is possible to export data in different formats:

- Report form in .pdf format:
 - Click on  then save on the PC in the desired folder
- Raw measurement data files:
 - Click on  and save on the PC in the desired folder
 - This file can be opened in .txt or spreadsheet format for analysis.
 - NOTE: The time of the raw data file is UTC and will be offset from the actual time of the test depending on the time zone the device is in at the time of the test.
- Image of the measurement graph:
 - Click on  then save on the PC in the desired folder
 - NOTE: It is possible to define the size of the image (width x height) before exporting it in order to obtain a better rendering.

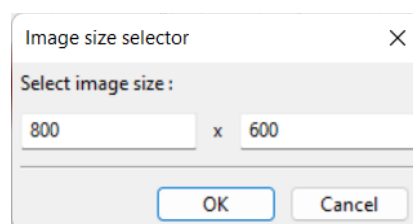


Figure 27: Image size selection window

Results interpretation:



Lysis Timer] instrument is for research purposes only. Refer to the operating instructions provided by the reagent manufacturer for further information on interpreting results.

7. Maintenance

7.1. Cleaning and disinfection



Turn off [Lysis Timer] and unplug the AC adapter and USB cables before each cleaning - disinfection.



Wear a pair of protective gloves during cleaning and disinfection to avoid the risk of infection.



It is essential to prevent dust, liquid or any other element from entering the [Lysis Timer] channels in order to guarantee correct and safe operation of the device. If this happens (e.g. liquid spillage, device not properly protected during storage, etc.), only the manufacturer will be able to clean and disinfect the measurement channels during factory maintenance. In case of doubt about the cleanliness of the measurement channels (possible presence of liquid or dust), contact your local representative.

The surface cleaning - disinfection of the [Lysis Timer] must be carried out after each day of use.

To do this, use a clean cloth slightly soaked in a non-corrosive cleaning and disinfecting product compatible with plastics and stainless steel (e.g., product dedicated to the cleaning - disinfection of medical devices) in order to remove blood sample residues and avoid any risk of contamination.

7.2. Metrological control, maintenance, and updates



To guarantee the safety and performance of [Lysis Timer], any opening, intervention, repair or modification of the device by unauthorised personnel is prohibited and, failing this, will void the manufacturer's warranty.



Turn off [Lysis Timer] and unplug the AC adapter and USB cables before performing any maintenance (except for operations requiring the activation of the device's features).



Wear a pair of protective gloves during maintenance to avoid the risk of infection.

Metrological control, preventive maintenance, and corrective maintenance of the [Lysis Timer] should be carried out in accordance with the manufacturer's specifications.

It is recommended that metrological control and preventive maintenance be performed at least once a year to ensure traceability, reliability, and accuracy of measurements.

Corrective maintenance must be carried out as soon as a malfunction or degradation of the device is possible, about a change in its appearance, likely to have an impact on its performance. In this case, stop using [Lysis Timer] and contact your local representative.

Updates to the [LysisControl] software should be performed with the assistance of your local representative.

8 After sales service

8.1 Warranty

[Lysis Timer] is warranted by the manufacturer to operate under normal use in accordance with the labelling and documentation provided with [Lysis Timer], its accessories and consumables. For details of the warranty conditions, please refer to the general terms and conditions of sale.

To ensure the performance and integrity of [Lysis Timer], it is recommended that annual preventive maintenance is carried out.

In normal use, the life of [Lysis Timer] is estimated at 5 years after its commissioning. After this period, factory maintenance is required to ensure a complete check of the device.

8.2 Troubleshooting

Malfunction	Common cause	Correction
[Lysis Timer] does not turn on	Power switch is not in the ON position. AC adapter is not connected	Press the ON button on the unit or plug in the adapter
[Lysis Timer] does not connect to [LysisControl]	The communication port set in the interface is not correct	Check the communication port in the PC menu and change the port in the interface if necessary
PC operating system malfunctions when connecting [Lysis Timer]	Bug in the connection process	Turn the PC off and on again and resume the connection process
[Lysis Timer] or [LysisControl] does not detect the insertion of the tube	The tube is not inserted far enough into the measurement channel	Remove the tube and insert it into the device again with a little more force
[Lysis Timer] temperature is not at 37° C on the [LysisControl] status bar before starting the incubation period	It is necessary to wait for a certain period for the heating temperature to reach 37°	Wait at least 20 minutes after switching on the device to bring it up to temperature before starting the incubation period
The real-time measurement curve remains flat after starting the measurements	No tube has been inserted in the channel, or an empty tube or no reaction occurs in the mixture	Check that the pre-analytical process has been performed correctly. If not, repeat the test.
The measurement curve shows an abnormal pattern	Error in the pre-analytical process or faulty measuring system	Check that the pre-analytical process has been carried out correctly.

8.3 Support

- Download link for the [Lysis Control] software installation folder:
<https://www.sd-innovation.fr/pub/app/lysisimer/>
- Exclusive distributor:



Address: 155 rue d'Eragny, 95000 Neuville-sur-Oise, France

- Local representative:

For assistance, contact your local representative:

Company:

Contact:

Address:

Phone:

Email:

Internet: