

Galileo SEMI

Semi-automatic microtome



User Manual



CE IVD

DIAPATH



Manufacturer:

DIAPATH

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MANUAL INFORMATION

It is forbidden partly or in full to modify this manual in absence of any explicit authorization.

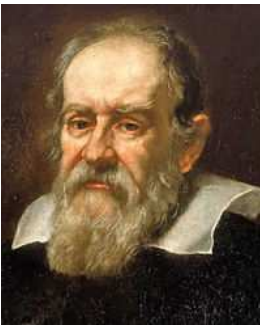
Information contained in this manual are subject to changes without prior notice.
Diapath S.p.A. has done as much as possible to assure the accuracy of this manual.
However, in case something seems to be wrong or not clear, please contact Diapath S.p.A or the distributor.

Diapath adopts continuously a development policy and reserves the right to make changes and improvements to any product described in this manual without prior notice. In no case Diapath S.p.A. will be considered responsible for possible losses of data or earnings or for any other datum.

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Inspired to:



Galileo Galilei (Pisa, 15th February 1564 – Arcetri, 8th January 1642) was an Italian physician, philosopher, astronomer and mathematician, considered the founder of modern science. His name is associated to important theories in dynamics and astronomy, such as telescope perfecting, which bring him to make important astronomic observations and to introduce the scientific method. Fundamental were his role in the astronomic revolution and his support to the heliocentric system and to the Copernican theory. His importance for the re-valuation of the science in general and of physics in particular is connected to discoveries that he made through several experiments such as relativity principle, the discover of Jupiter 4 moons, exactly called Galilean satellites, inertia principle and the discovery that speed fall is the same for all bodies independently from material or mass.



PREFACE

Destination of use

Galileo is a semi-automatic rotary microtome for creating thin sections of specimens embedded in paraffin.

The instrument may be operated by trained and qualified staff only.

It is possible to set up all process parameters, such as: sectioning and trimming thickness and the retraction value of the specimen holder before the stroke phase.

The reading of this manual and the maintenance are essential to use the equipment avoiding any situation of danger.

The operators shall be adequately trained in its use and must respect all safety rules and its use limits.

Instrument maintenance, due to trouble or malfunction, shall be performed by trained and authorized Diapath S.p.A. staff.

The instrument complies with CISPR 11 Class A rules: in case of domestic use, it may cause radio interferences. In this case, it is necessary a measurement and mitigation of such interference.

Before installing the instrument, perform an analysis of electromagnetic interferences.

Do not use the device near sources of strong electromagnetic radiations, such as radiofrequency waves generators. In this case the radiations may interfere with the instrument normal functioning.

Instrument has been projected according to the legislative decree 332/00 of 08th September 2000 "Accomplishment of 98/79/CE directive of 27th October 1998 concerning in vitro diagnostic medical devices" respecting electromagnetic compatibility rules:

- 2007/47/CEE Directive 93/42/EEC concerning the updating of Directives 98/79/EEC on medical devices and medical devices in vitro, which came into force on 21/03/2010 by Legislative Decree 25/2010.
- Legislative Decree 27th January 2010, n. 17 implementing Directive 2006/42/EC on machinery and amending Directive 95/16/EC relating to lifts.
- ISO9001(*): quality management system requirements.
- ISO13485(*): quality management system requirements for medical devices. Requirements for regulatory purposes and specific requirements of the application of ISO 9001(*)
- UNI CEI EN ISO 14971(*): application of risks management to medical devices.
- UNI EN 591(*): Instructions for use of in vitro diagnostic instruments for professional use.
- UNI CEI EN 980(*): Graphical symbols for use in the labeling of medical devices.
- EN 61326-1(*): Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements.
- EN 61326-2-6(*): Electrical equipment for measurement, control and laboratory use - EMC requirements. Part 2-6: Particular requirements - In vitro diagnostic medical devices (IVD).



- EN 61000-3-2(*): Electromagnetic compatibility (EMC) Part 3-2: Limits - Limits for harmonic current emissions. (equipment with input current $\leq 16A$ per phase).
- EN 61000-3-3(*)+ A1(*)+ A2(*): Electromagnetic compatibility (EMC) Part 3-3: Limits - Limitation of voltage fluctuations and of flicker in low voltage supply systems for equipment with rated current $\leq 16A$ and not subject to conditional connection.
- EN 61010-1(*): Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements.
- EN 61010-2-101(*): Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-101: Particular requirements for medical equipment for in-vitro diagnostics.
- The LED light according to standard EN62471 and classified in 1 Risk Group Category.

(* *In the applicable edition*)



QUALITY CONTROL

Diapath S.p.A. adopts quality management system ISO 9001(*) and ISO 13485(*) to project, make and improve the technical-scientific solution for the customer in medical and diagnostic in vitro systems, assuring high quality services with the help of an highly qualified and motivated staff to contribute to the improvement of Diapath S.p.A. products.

Diapath S.p.A. constantly looks for customer's satisfaction, tries to perceive their expectations and to treat the customer without any discrimination. Diapath S.p.A. assures the application of normative requirements.

Quality assurance of data furnished by Diapath S.p.A. is obtained through these activities:

- Use only reference material
- Execution of proofs of the whole production
- Correlation of different results

The internal quality control foresees to monitor the most difficult passages of an analytic process so as to verify their stability, to assure that quality parameters estimated during the validation or check of the method are valid also for real instruments and that they won't get worse in the course of the time.

Diapath S.p.A. tests its own products in accordance with some internal procedures, to reduce possibility of anomalies during the operation.

To identify and to find out its own instruments, Diapath S.p.A. uses some internal procedures in which we can find production recording, assembling recording, tests recording, serial number or batch code and configuration recording.

(*) *In the applicable edition*



SAFETY INFORMATION

Mentioned agreement and graphic symbols



Danger - The danger instructions signal situations that might cause death or serious lesions.



Caution - The caution instructions signal situations that might cause physical lesions to people or damages to things.



Biohazard - The biohazard instructions signal situations that might cause the contamination of people or parts involved in the process.



Cutting and shearing - The cutting and shearing instructions signal situations that might cause lesions to the operator.



Crush hazard - The crush hazard instructions signal situations where body parts might be crushed by moving parts.

Instructions of danger



Never disassemble, modify or repair the instrument or one of its parts without written authorization by Diapath S.p.A.



Do not use any kind of different power supply from the mentioned ones.



For use at voltages higher than 125V in the North American market must be used electricity supply cables with NEMA 6-15P plug, C13 plug connector and STJ cable with nominal capacity 13A 250V.



Instructions of caution



Do not place objects that are not involved in the use of the instrument.



The use of appropriated individual protection devices is recommended (For instance: gloves).

Instructions of biohazard



Keep attention to the possible biological hazard of the parts involved in the process.



Special individual safety measures shall be used by operators, in accordance with the standards for safety in the laboratories and product safety data sheets in relation to current rules.



Do not place objects that are not involved in the use of the instrument.

Safety training

All the operators must be trained to use the microtome safely.
After such training, the operators must have understood that:

- The microtome must be connected to a voltage source in accordance with electrical data label.
- The use of the microtome differently from Diapath instructions might compromise its functioning and the safety of the operator

Compliance with safety rules

All regulations related to safety, local codes and instructions that appear in the manual or on the equipment must be carefully observed to ensure personal safety and to prevent damage to the microtome. If the equipment is incorrectly used, the protection provided might be compromised.

DEFINITION OF ADOPTED SYMBOLS



In vitro diagnostic medical device



Electrical shocks risk



Manufacturer



Foot switch connection



Built in



Remote control



Danger



Conformity with
CAN/CSA-C22.2 No
61010-1 requirements,
2nd edition



Disposal



TUV certification



European Community approval
mark



See the user manual



RFID antenna



STORAGE AND HANDLING

For a correct conservation and functioning of the microtome, all the instructions provided in this manual concerning the maintenance and the installation shall be respected. Also the showed below environmental requirements shall be respected.

Storage and transportation temperature range:	da +5°C a +40°C
Storage humidity:	80%
Working temperature range:	Da +5°C a +40°C

The instrument can work with 80% relative humidity conditions for temperatures up to 31°C with a linear decrease up to 50% at the temperature of 40°C. Voltage variation can't exceed +/-10% the nominal value. The instrument is planned only for internal use and up to 2000 m o.s. altitude.



Due to size and weight (more than 30 Kg), the handling of the microtome must be performed by several people and with suitable lifting means.



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1

INSTRUMENT PLACEMENT AND INSTALLATION



Due to size and weight (more than 30 Kg), the handling of the microtome must be performed by several people and with suitable lifting means.

1.1 Unpacking

Unpack instrument parts taking care to not damage them. The instrument has been tested before the shipping.

Make sure about any serious damages to the packaging and to the instrument due to the transport. In case of damages, please contact Diapath or the local distributor.

1.2 Setting up before installation

Before the installation, please verify that electrical supply sources are set according to the data supplied by the manufacturer (see instrument specifics on Chapter 7).

Place the instrument on a plane surface, stable, vibration free and able to support at least the double weight of the product (see instrument specifics on Chapter 7).

Power cable should be easily accessible. Verify that the clearance between the instrument rear side and a possible wall is at least 20 cm.

The instrument must be installed with a side distance from possible walls of at least one meter.

1.3 Startup

ATTENTION

Instrument placement and installation must be performed by Diapath S.p.A. trained and authorized staff.

Perform the following installation steps:

- Place the instrument on a flat surface
- Assemble the activation handwheel
- Install, if required, all supplied accessories
- Connect the power cable of the instrument. Be sure to do this when the instrument is off



ATTENTION

Instrument must be connected to a grounded power socket!
DO NOT use extension cables

ATTENTION

The power cable plug disconnects the instrument from the electric system. Verify that the power cable plug is always easily accessible.



Connecting Remote Control - Symbol

The remote control connector is on the rear side of the instrument, identified by this symbol. Insert the connector and screw the threaded ring to lock off.

2

INSTRUMENT SETTING



2.1 Before the use

2.1.1 Controls before the use

It is a good practice to perform the following operations, before starting up the microtome:

- Verify that the power cable is in good conditions.
- Verify that the specimen holder can move freely up and down
- Verify that the knife and specimen holder are securely clamped to the instrument

2.1.2 License activation

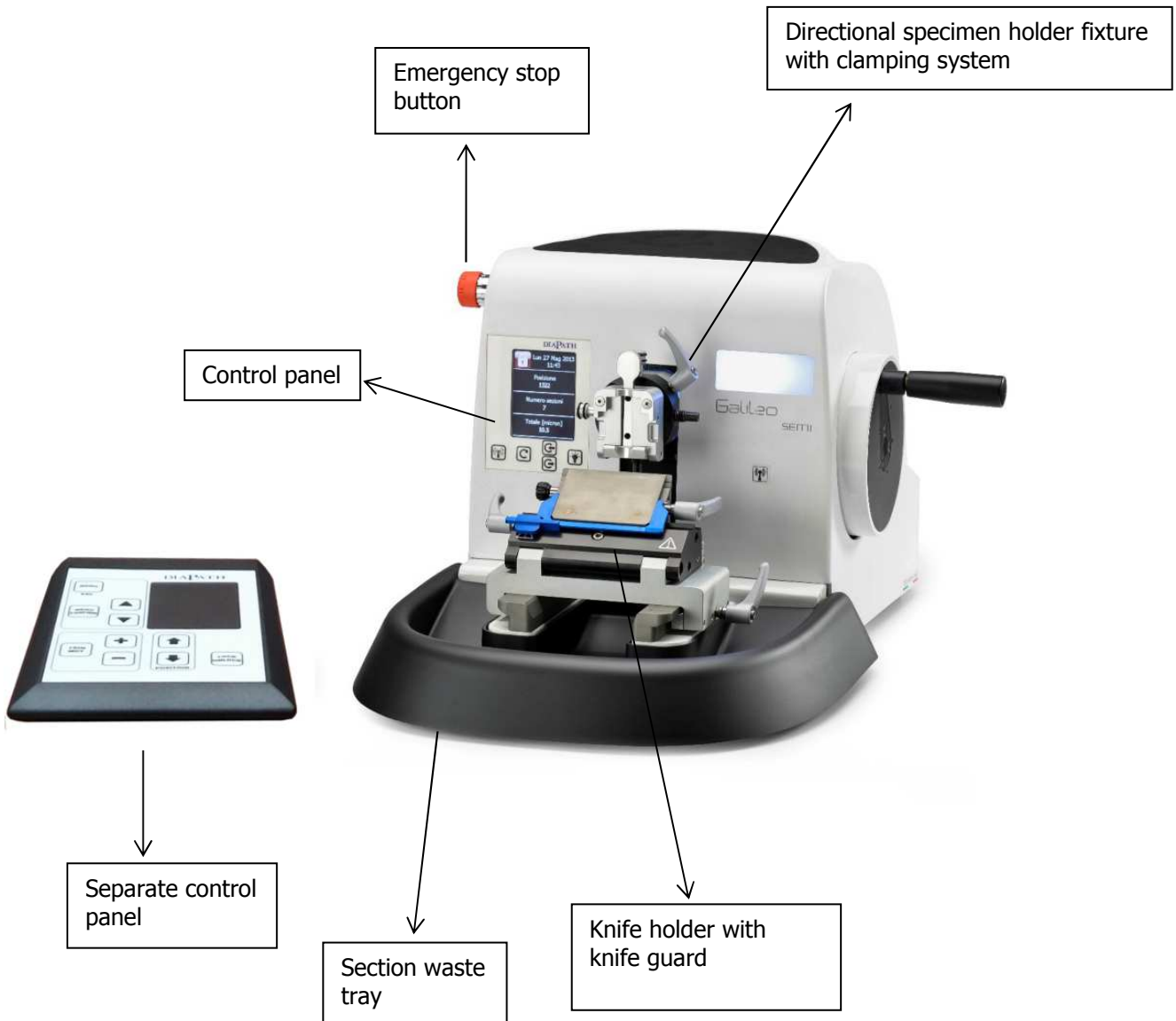
Before using Galileo microtome is necessary to activate the license, which can be:

- **Limited license:** the microtome is activated for a period of time, after which the coarse feed system is disabled. To reactivate the functioning, it is necessary to renew the license.
- **Unlimited license:** the microtome is activated unlimitedly, without an expiration date.

The license (and the following renewals in case of limited license) is activated by RFID system. To activate or renew the license, is necessary a valid RFID card and follow instructions described in section 4.2 and 4.3.

3

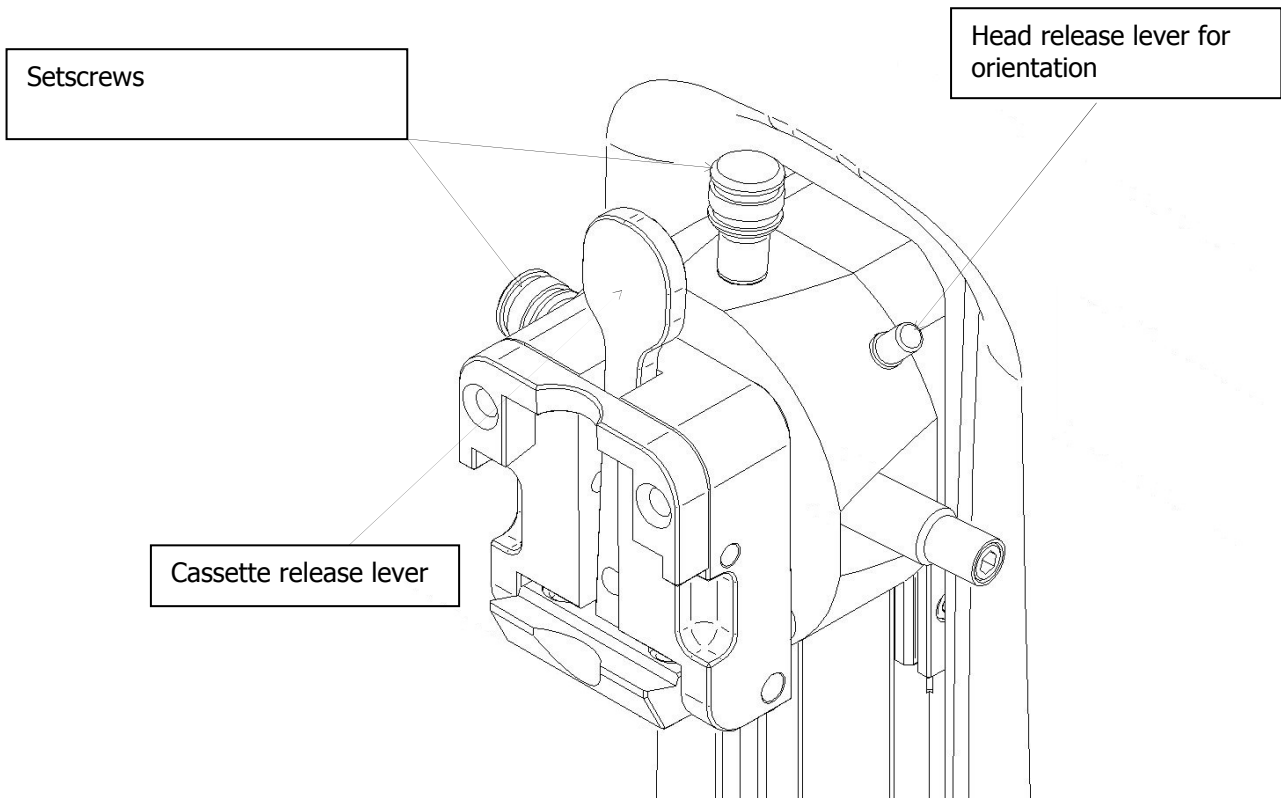
PARTS OF THE INSTRUMENT



Pic.1 - Parts of the microtome



3.1 Directional specimen holder with clamping system



Pic. 2 – Adjustable head

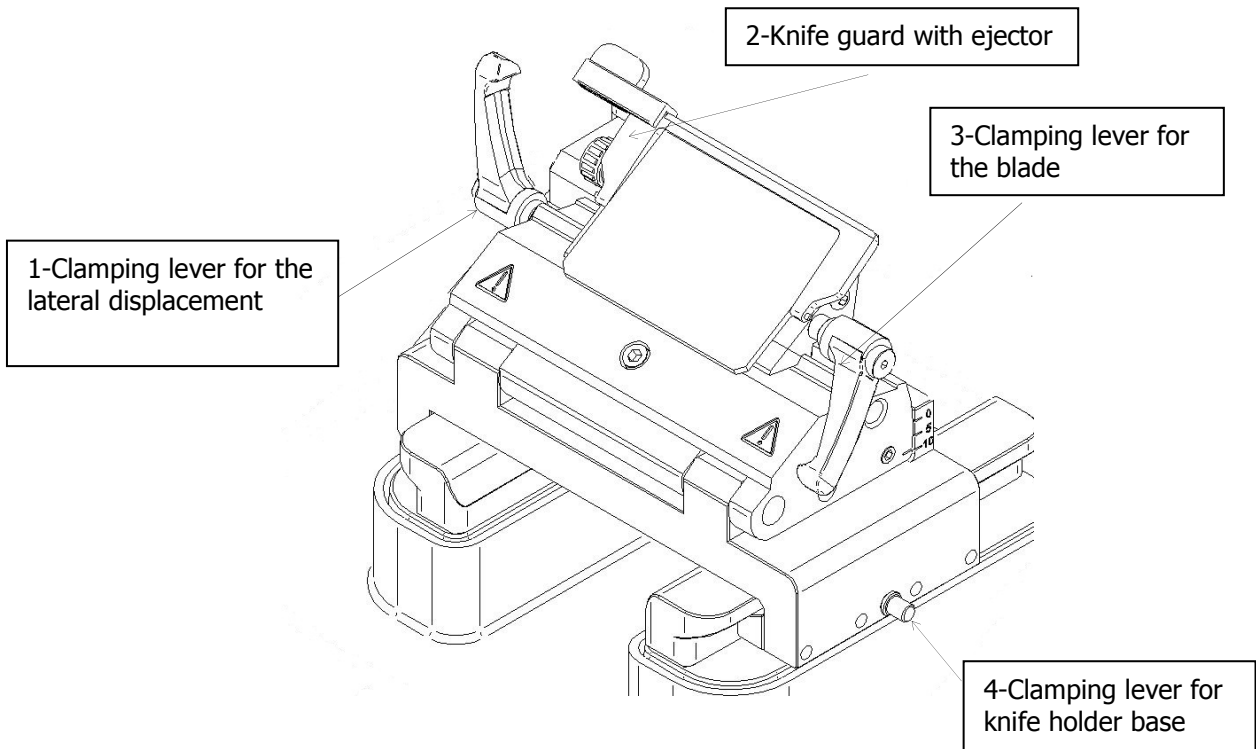
To perform the orientation of the specimen: unlock the cassette tension lever, use setscrews for an appropriate orientation of the specimen, lock the lever.

To mount the cassette in the clamp: push the lever and mount the specimen

ATTENTION

Specimen orientation must be performed only during the advancing phase. If performed during the retraction phase it may cause errors in the cutting thickness and damages to the specimen!

3.2 Knife holder



Pic. 3 - Knife holder

To move the knife holder toward the specimen, release lever 4, mount it and lock the lever 4.

To insert the blade, release the lever 3, push in the blade and lock lever 3. Cover always the cutting edge with the knife guard when the instrument isn't used. To remove the blade, use the ejector after releasing lever 3.

To move the blade right and left, release lever 1, mount the blade in the desired position and lock lever 1.

ATTENTION

Clamp always the specimen before clamping the blade.
Lock the handwheel and cover the knife-edge with the knife guard before performing any manipulation of the knife!

ATTENTION

Be careful especially with handling microtome blades: they are extremely sharp and can cause serious lesions!



3.3 Emergency stop switch

The emergency stop switch is on the left side of the microtome. The cutting motor stops immediately when the emergency stop switch is pressed. The specimen holder can be moved manually, allowing the user to operate for the safety.

To restore microtome functionality, switch off the emergency stop switch and wait that the specimen holder has completed the positioning at the beginning of the horizontal feed (position 0).

3.4 Optionals

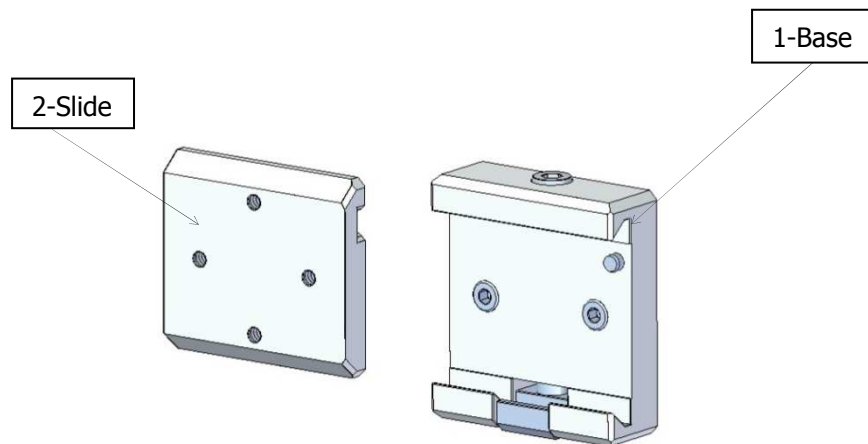
3.4.1 Clamp for mega cassettes

The clamp for mega cassettes allows to section mega cassettes with maximum length of 67mm.

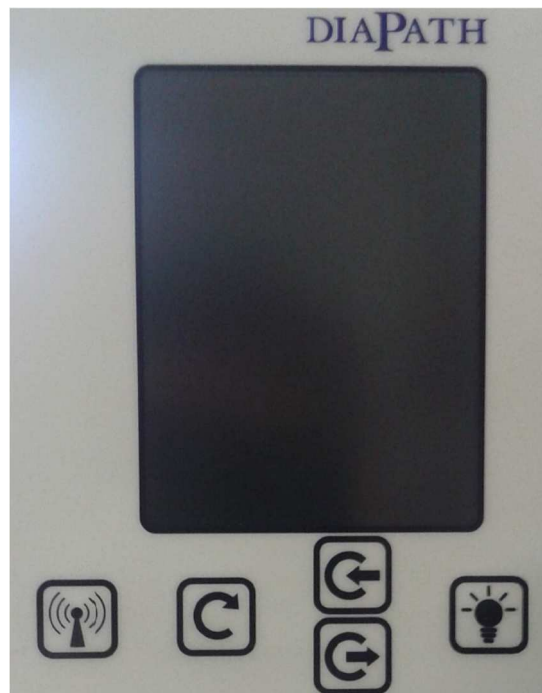
3.4.2 Rapid release kit

Rapid release kit, composed of a base (1) to be applied on the directional specimen holder, and a slide (2) to be applied to the clamps, allows to quickly replace clamps.

To replace a clamp, release the upper screw, push the clamp toward left and insert a different clamp. Finally lock the upper screw previously released.



3.5 Control panel



Pic. 4 - Control panel

The control panel displays the current operating mode, possible alarms and information. It displays also information about current cutting session:

- Position of the specimen holder referring to horizontal feed;
- Number of completed sections
- **Cutting/Trimming** mode with its thickness in micron.

Control panel has 5 buttons:




Activation of RFID system and management of the license. In case of limited license, press this button to display remaining days to expiration; if pressed twice in 5 seconds, it enables the RFID system for license renewal or for log card writing (see section 4.3 and 4.4). In case of unlimited license, press this button to enable the RFID reader for log card writing (see section 4.4)




resetting of the set sections number counter



Management of positioning memory. Pressing the  button the present position is stored;

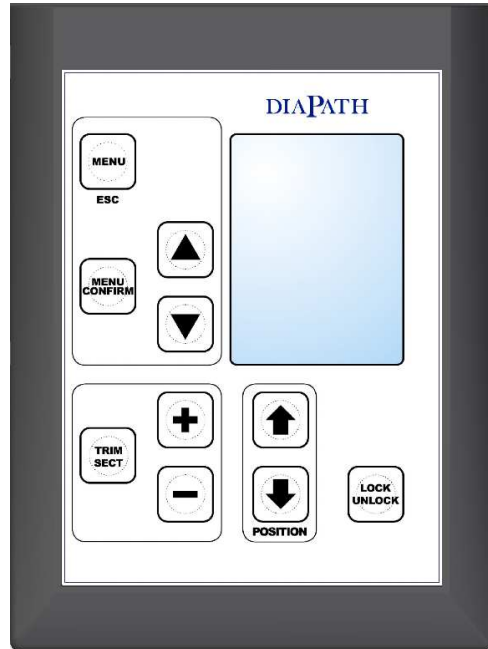


pressing the  button the specimen holder moves to the last stored position (see sect.4.5)



Switching on/off the light for slide visual inspection





3.6 Control interface



Pic. 5 - Control interface



The control interface allows to set up microtome operating parameters. During operating are displayed the thickness values in micron during the **Cutting/Trimming** mode.

Control interface has the following buttons:





-  LOCK/UNLOCK. When the microtome is in LOCKED  mode, the movement is automatically locked
-  POSITION: horizontal movement of the specimen holder. If pressed, they allow to position the specimen holder in the desired position.
-  TRIM/SECT: if pressed, it allows to select between:
 - **Cutting**
 - **Trimming**

NOTE: mode ON is displayed with white text, mode OFF with grey text.



-   If pressed, they allow to set up the section thickness. If the **Trimming** mode is ON is modified the **Trimming** thickness, otherwise the **Cutting** thickness.

- MENU: press it to gain access to microtome configuration menu (see sect.5.2).
Use the following buttons to surf the menu:

-  To choose the entry of the menu
- 
-  To confirm (and save) the selected entry of the menu
-  To exit from the current menu without saving

4




CONTROL PANEL FUNCTIONALITY

4.1 Main screen



Pic.6 - Main screen

After switching on the microtome using the power switch on the rear side, the control panel shows the main screen, similar to the one in the pic.5. The screen is divided in four sections:


- 1. Date, hour and system status:** system status is represented by the icon displayed on the upper left angle.
 -  **LOCKED:** system locked and safe
 -  **UNLOCKED:** the system can be moved manually by the handle. It is possible to section
- 2. Position:** it displays in which horizontal feed position the specimen holder is. When switching on the microtome, the specimen holder moves to the horizontal feed start position (Position 0). The horizontal feed has a maximum length of 30000, when reached an alarm message is displayed.
- 3. Section number:** it is the completed cuttings number counter. It can be cleared by pressing the  button.
- 4. Cutting/Trimming:** it displays the mode in operation and the section thickness in micron.

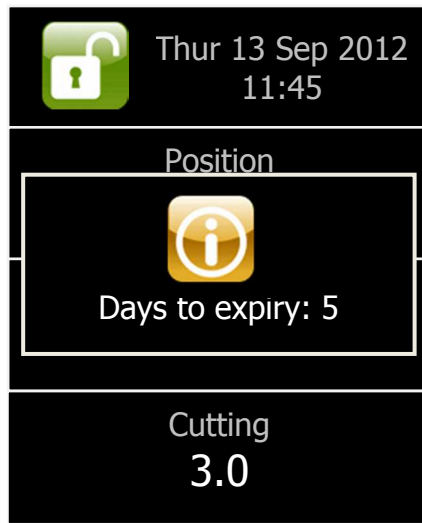
4.2 License activation

The activation is performed by RFID system: it is necessary to have the appropriated card.


There are two licenses:

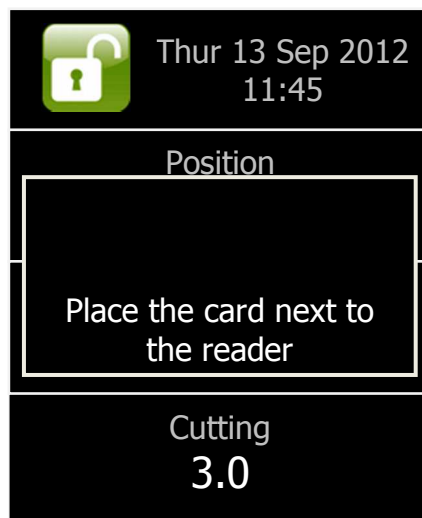
- **Limited license:** the microtome is activated for a period of time, after which the coarse feed system is disabled. To reactivate the functioning, it is necessary to renew the license.
- **Unlimited license:** the microtome is activated unlimitedly, without an expiration date.

To activate the license (limited or unlimited) press the  button. On display appears a pop up with the number of days remaining before expiration:



Pic. 7 - Expiry license pop-up

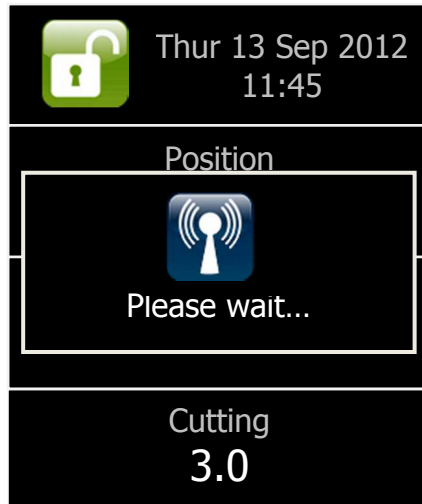
Pressing again the  button within 5 seconds the RFID system is activated. On the display appears the following message:



Pic. 8 - RFID card message screen

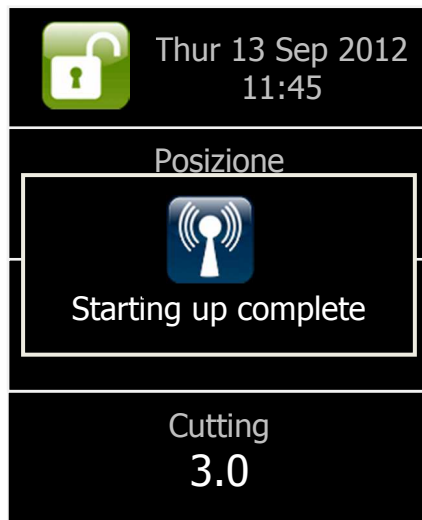


Bring the card close to the RFID reader, situated under the lit window. When the card reader tracks the card, appears the following message:



Pic. 9 - Tracking card screen

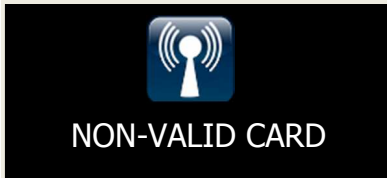
Keep the card close to the reader until appears the message confirming license activation:



Pic. 10 - Successful new license starting up screen

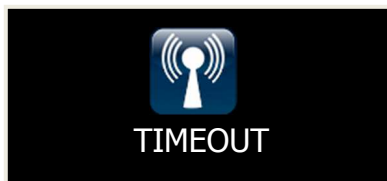


Possible error messages are:



NON-VALID CARD

The used card is not valid or already used. The license isn't activated and RFID system is deactivated



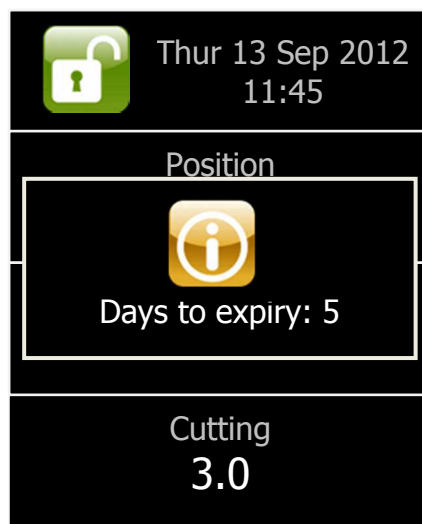
TIMEOUT

RFID reader didn't track any card within 5 seconds from the activation. The license isn't activated and RFID system is deactivated.

4.3 Limited license renewal

At license expiration, the coarse feed system is deactivated. To reactivate it, provide a card for license renewal and proceed as follows.

1. Pressing the  button: on display appears a pop up with days remaining before expiry:




Pic. 11 – Pop-up of remaining days to license expiration

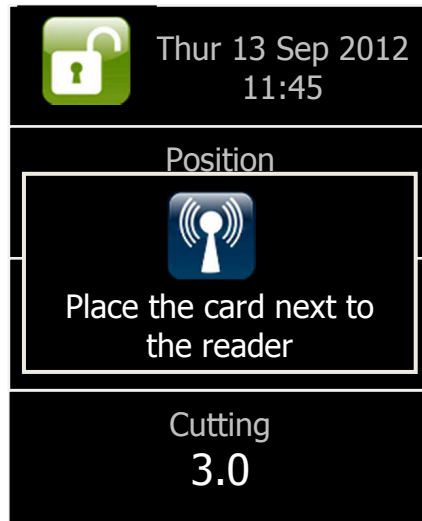
ATTENTION

If number of remaining days is less than 45, the pop up appears, as note, each time the microtome is switched on.

If the number of remaining days is less than 30 the pop up alarm is accompanied by an acoustic alarm.

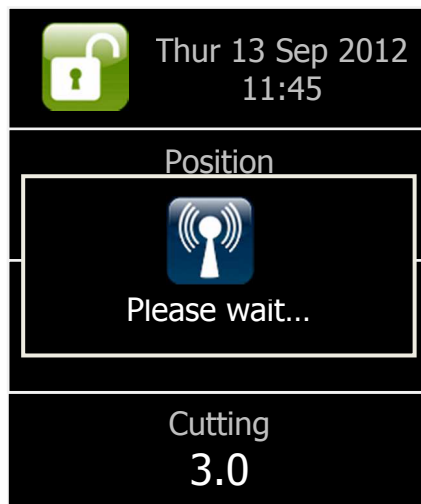


- Pressing again the  button within 5 seconds the RFID system is activated. On display appears the following message:



Pic. 12 - RFID card message screen

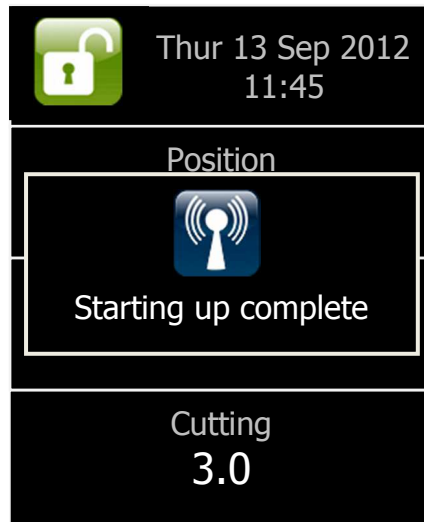
- Bring the card close to the RFID reader, placed under the back lit panel. When the card reader tracks the card, appears the following message:



Pic.13 - Card tracking message screen

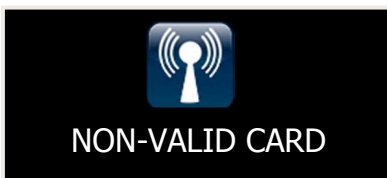


4. Keep the card close to the reader until appears the message confirming successful procedure:



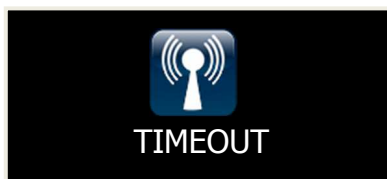
Pic. 14 - Successful new license starting up screen

Possible error messages are:



NON-VALID CARD

The used card is not valid or already used. The license isn't renewed and RFID system is deactivated




TIMEOUT

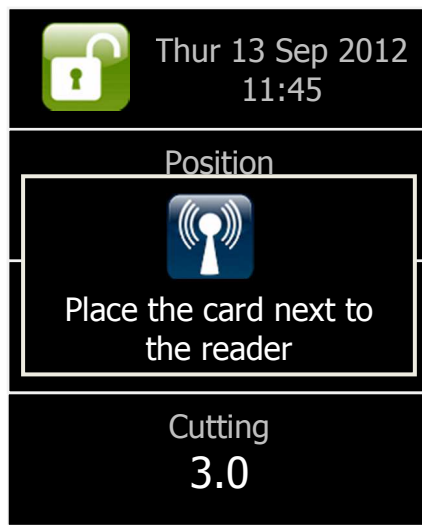
RFID reader didn't track any card within 5 seconds from the activation. The license isn't renewed and RFID system is deactivated.

4.4 Log card creation

The Galileo microtome RFID system allows to create a card containing the log of the operations carried out by the RFID system itself.

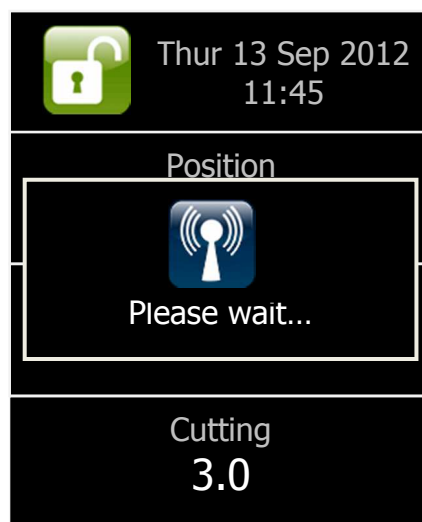
Provide oneself with the appropriated card and proceed as follows:

1. Press the  button (once if unlimited, twice if limited license) until appears the pop up with the following message:



Pic. 15 - RFID card message screen

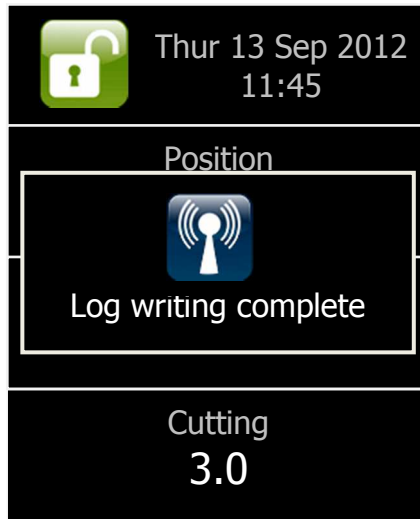
2. Bring the card close to the RFID reader, placed under the back lit panel. When the card reader tracks the card, appears the following message:



Pic. 16 - Tracking card message screen



3. Keep the card close to the reader until appears the message confirming log creation:



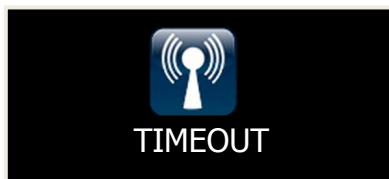
Pic. 17 - Complete log codification screen

Possible error messages are:



NON-VALID CARD

The used card is not valid or already used. The log hasn't been created and RFID system is deactivated.






TIMEOUT

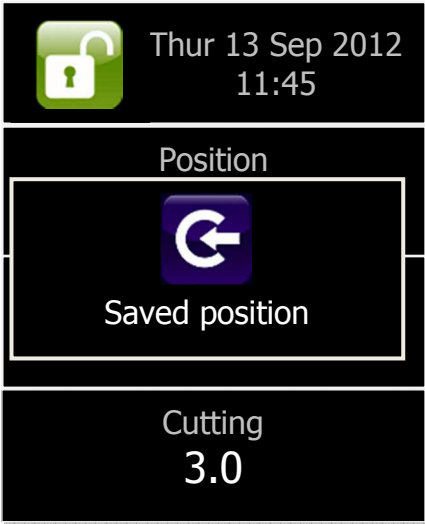
RFID reader didn't track any card within 5 seconds from the activation. The log has not been created and the RFID system is deactivated.



4.5 Positioning memory

The  and  buttons allow to manage positioning memory in order to have the possibility to bring the specimen holder to the stored position, to easily return to first cuttings position.

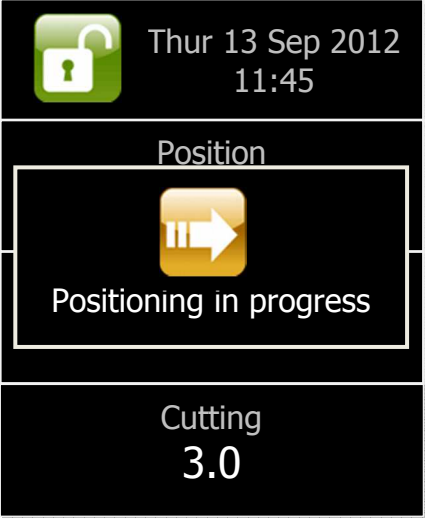
Pressing the  button the present position, on which the operator wants to return, is stored. A popup signals the successful position memorization:



Pic. 18 - Memorization of specimen holder position screen

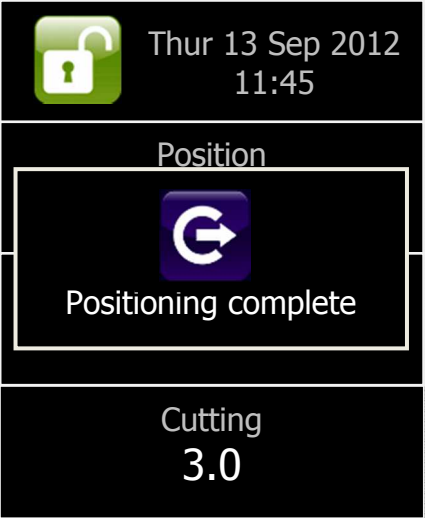


To return to the stored position, press the  button



Pic. 19 - Specimen holder under positioning screen

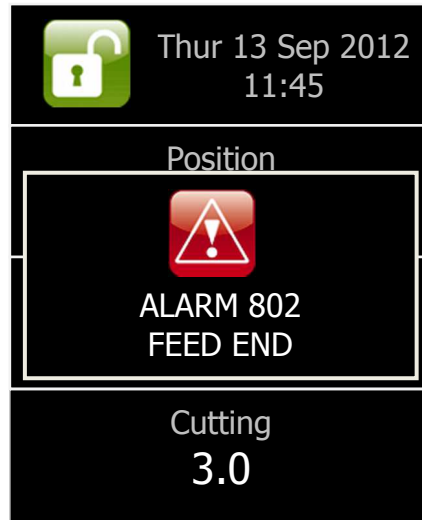
When the specimen holder reaches the stored position, a confirmation message appears:



Pic. 20 - Specimen holder stored position screen

4.6 Alarm messages



If a functioning anomaly occurs, an alarm message appears in the pop-up:

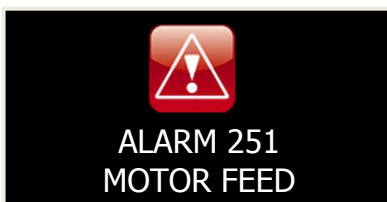


Pic. 21 - End running alarm screen

Alarm messages are the following (identification of each alarm by a 3 numbers code):



ALARM 802 FEED END: The horizontal feed end has been reached (Position = 30000): the specimen holder can't move anymore. The alarm message disappears if the holder returns (pressing the  on the control interface or  button on the control panel to return to stored position).



ALARM 251 MOTOR FEED: Bad functioning of automatic feed system occurs.



ALARM 150 REMOTE CONTROL: A problem with connection to control interface occurs.



**ALARM 151
CONNECTION**

ALARM 151 CONNECTION: a problem on communication protocol between electronic boards occurs.



**ALARM 801
IN EMERGENCY**

ALARM 801 IN EMERGENCY: this message appears when emergency button is pressed. Unlocking it the message disappears.



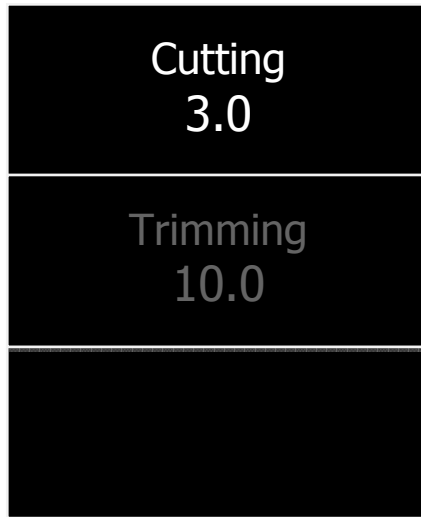
**ALARM 750
EXPIRED LICENSE**

ALARM 750 EXPIRED LICENSE: the license of the microtome is expired and feed system is deactivated. To reactivate instrument functioning, provide yourself a RFID activation card and proceed as in sect. 4.3.

5

CONTROL INTERFACE FUNCTIONALITY

5.1 Main screen

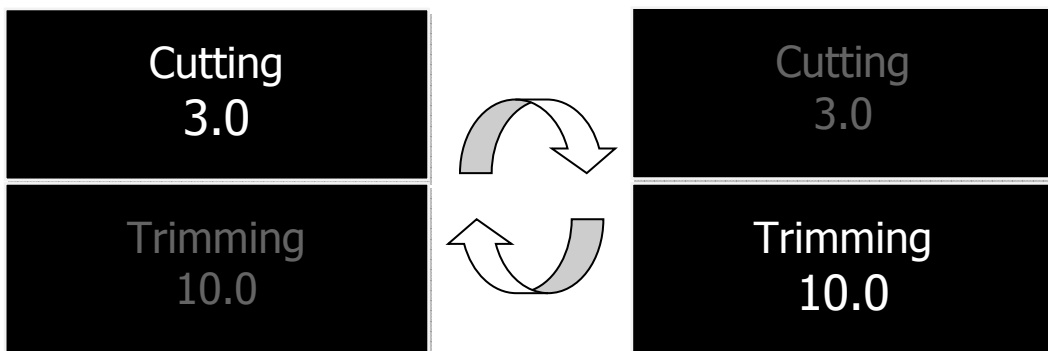


Pic. 22 - Main screen

After switching the on microtome, using the rear power switch, the control interface displays the main screen, similar to the one in the picture above.

The main screen displays the thickness of the section in micron during **Cutting** and **Trimming** mode. The

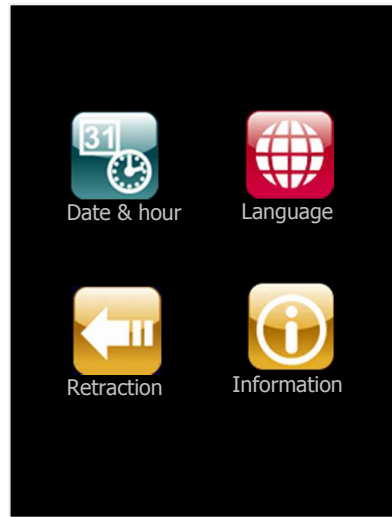
mode ON is displayed in white color, the mode OFF in grey color. To switch between modes press the button.




Press the buttons to modify the value of the thickness for the mode ON.




5.2 Configuration menu







Pic. 23 - Configuration menu screen

Press the  button to enter configuration menu (see Pic. 23).

ATTENTION

It is possible to enter configuration menu only if system is in LOCKED  mode

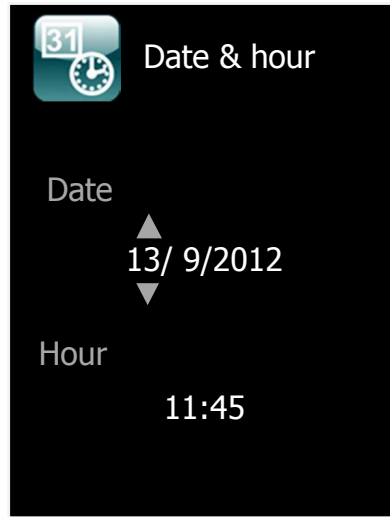
Use the following buttons to surf the menu:

- 
-  To scroll the menu
-  To confirm the choice
-  To go back to the previous screen. This button is the "ESCAPE" function: if pressed, in any configuration menu, it allows to go back to the previous screen without saving changed settings



5.2.1 Setting date and hour

Select the **Date & hour** entry in the configuration menu to enter the related menu:



Pic. 24 - Date & hour menu screen

The two triangular symbols show which field between data or hour can be changed.



Press the buttons to set up the value in the activated field.



Press the button to move to the following field.

The fields are activated in the following sequence:

DAY -> MONTH -> YEAR -> HOUR -> MINUTES

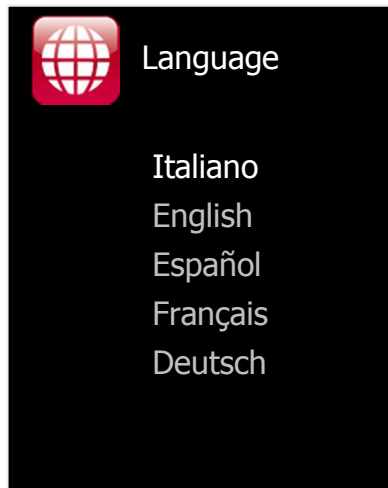


Press the button to go back to previous menu without changes.






5.2.2 Configuring language

Select the **Language** entry in the configuration menu to enter the related menu:



Pic. 25 - Language setting screen

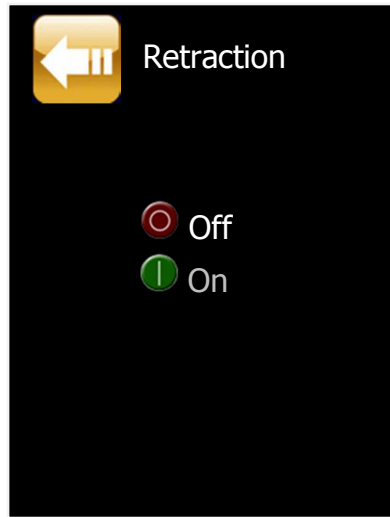


Press the   buttons to choose the language and press the  button to confirm.





5.2.3 Configuring retraction

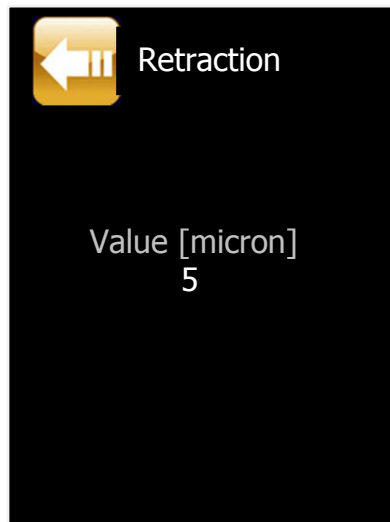
Select the **Retraction** entry in the configuration menu to enter the related menu:



Pic. 26 - Configuration retraction screen




Selecting the entry  **Off**, the specimen holder **don't** retract before vertical stroke.

Select the entry  **On** to enter the screen in which to set up the retraction value in micron.



Pic. 27 - Retraction value setting screen

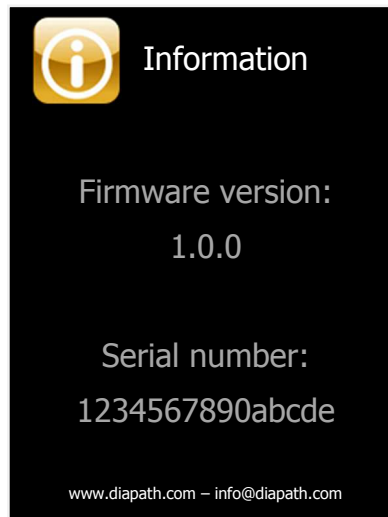


Press the   buttons to set up the desired value and then confirm with the  button.



5.2.4 Displaying information screen

Select **Information** entry in the configuration menu to enter the screen with microtome serial number (16 digits) and firmware version of each electronic sheet (**C**= control board, **L**= local board, **R**= remote board).



Pic. 28 - Information display screen

6

PERFORMANCES AND LIMITATIONS



Galileo is a rotary microtome projected to create histological sections of specimens embedded in paraffin.

Users might use the equipment according to the limits described in this manual and following moral and good-sense procedures.

The warranty is valid only if all performances and use limitations described in this manual are respected.

Diapath S.p.A. refuses any contractual and non-contractual responsibility for damages caused by any mistakes done working in the non-compliance of instructions given by the manufacturer.

Diapath S.p.A. refuses any responsibility if the microtome is not connected to electrical systems according to the local regulations.

Any other use not indicated in this manual is to consider as inappropriate and dangerous. We suggest to protect the microtome from an improper use that could be dangerous.

Environmental electromagnetic conditions should be evaluated before instrument use.

Do not use the instrument near high electromagnetic radiations sources: they could interfere with instrument working.

It is operator's responsibility ensure to keep an environment electromagnetically compatible with instrument features.

7

SPECIFICS AND INSTALLATION



Semi-automatic microtome Galileo SEMI	
Technical features	
Dimensions (WxDxH)	400x675x350 mm
Weight	40 Kg
Electrical features	
Supply voltage	115-230 V~ ±10%
Frequency	50-60Hz
Maximum power consumption	200VA
Power cable	type F(Schuko) – type B - type I
Fuses	F3.15 AL 250V
Overvoltage category	2
Altitude	Up to 2000 m
Environmental features	
Relative humidity	80%
Operative temperature range	From 5°C to 40°C
	Horizontal and plane surface able to support the double of the product weight. Keep away from any direct heating sources or humidity. Place the instrument in a way that the main power supply plug can be easily removed. The instrument isn't suitable for external use
Pollution degree	2
General features	
Noise level	Max 60 dBA
Certifications	CE - IVD - cTUVus



Technical features	
Cutting thickness setting range	0.5 - 100 micron
	0.5 - 5 micron in 0.5 micron increments 5 - 20 micron in 1 micron increments 20 - 30 micron in 2 micron increments 30 - 60 micron in 5 micron increments 60 - 100 micron in 10 micron increments
Trimming section thickness setting range	1 - 600 micron
	5 - 30 micron in 5 micron increments 30 - 100 micron in 10 micron increments 100 - 200 micron in 20 micron increments 200 - 600 micron in 50 micron increments
Object feed	30 mm +- 1 mm, feed motion via step motor
Vertical stroke	70 mm
Maximum specimen size	55 x 50 mm (68 x 50 with clamp for mega-cassettes)
Horizontal specimen orientation	8°
Vertical specimen orientation	8°
Specimen rotation	360°
Specimen retraction	5 - 100 micron in 5 micron increments, can be turned off

8

CLEANING AND MAINTENANCE

ATTENTION

Before each action indicated below, switch the instrument off.

ATTENTION

We suggest using suitable individual protection media (gloves, masks, etc. according to the situations) to perform the cleaning safely.

8.1 LCD display cleaning

To clean the display, use a screen detergent (in accordance with the instructions defined by the detergent manufacturer).

8.2 External surfaces

If necessary, clean the surfaces with a cloth dampened with water or water and soap, then wipe with a dry cloth.

ATTENTION

Do NOT use any solvents to clean the exterior painted parts.

8.3 Instrument cleaning frequency

We recommend you to perform the complete cleaning of the instrument at the end of each working day.

9

SCHEDULED MAINTENANCE

This chapter describes cleaning and inspections to be performed on the entire system. Maintenance plans need daily, monthly and six-month checks.

Clean each part of the instrument at least once a week for a correct and lasting instrument use.

ATTENTION

Before cleaning, perform decontamination as specimens could be potentially infectious. Follow all laboratory regulation, disinfect section waste tray and the parts in contact with the operator: handle; remote control. We suggest using suitable individual protection media (gloves, masks, etc. according to the situations) to perform in safety these cleaning.

ATTENTION

Dispose contaminated material according to the laboratory regulations, handling waste as potentially contaminated waste.

9.1 Checking the directional specimen holder

Once a month check that the directional specimen holder isn't obstructed, otherwise clean it and lubricate orientation hemispheres.

9.2 Cleaning the knife holder

We recommend you to perform the cleaning of the knife holder at the end of each working day. Be careful to remove all paraffin and section residues.

ATTENTION

Before cleaning, be sure that microtome is switched off and blade/knife is removed.

9.3 Cleaning the clamp

We recommend to perform the cleaning of the clamp after each use. Be careful to remove all paraffin residues.

9.4 Cleaning the section waste tray

We recommend to perform the complete cleaning of the section waste tray at the end of each working day. Be careful to remove all residues.



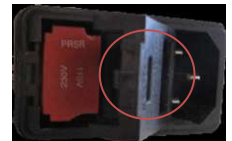
9.5 Replace fuses

To replace fuses:

- Switch the unit off and unplug it (Pic. 29)
- Open fuse housing with light pressure on point shown in Pic.30
- Remove fuses (see Pic. Pic. 31) and check that the filament is not interrupted; in that case replace the fuse with one with the same rating, positioning it in place (For ratings see section 11.0)
- Connect the power cable and switch the unit on



Pic. 29



Pic. 30



Pic. 31

See section "Troubleshooting" in case of functioning problems.

If problem persists, contact Diapath or the local distributor.

ATTENTION

We suggest a preventive maintenance operation at least once in a year.

10

TROUBLESHOOTING



The instrument does not turning on	
Possible cause	Corrective action
The power cable is disconnected	Check the connect of the power cable
Electrical system protections are intervened	Set again the protection
Microtome protections are intervened	Check and if necessary replace power fuses
No voltage	Contact the engineering service or qualified staff for the verification of electric systems
Power key has not been pressed	Press the key on the control panel
The specimen holder does not move	
Possible cause	Corrective action
The end of the residual path has been reached	Move the specimen holder to position 0
Stepper motor is locked	Contact Diapath or the local distributor
Cutting too thin/thick sections	
Possible cause	Corrective action
Blade, knife holder or specimen holder not clamped properly	Check clamping system of each mechanism
The specimen is not clamped properly	Check that the cassette is securely blocked in the cassette clamp
The blade is dull	Laterally displace the knife holder; insert a new blade
Clearance angle of the blade too small	Change using clearance angle settings
Cutting deformation	
Possible cause	Corrective action
The blade is exhausted	Use a new blade
The specimen is too warm	Cool the specimen before cutting
Noises during cutting	
Possible cause	Corrective action
The clearance angle is too wide	Change clearance angle until you have found the optimum angle
Insufficient clamping of specimen clamp or knife holder	Check all screw and clamp connections on the specimen holder system and the knife holder
High blade consumption	
Possible cause	Corrective action
Too great of a cutting force was applied	Adjust the cutting speed and/or section thickness

If problems persist or are not described in the previous chart, contact Diapath S.p.A. or the local distributor.



SPARE PARTS LIST

Description	Article code
COMPLETE BODY GALILEO SEMI	SDSMA9008
KNIFE HOLDER GALILEO MICROTOME	SDSPL9001N
SECTIONS HOLDER CLAMP	SDSMA9015
SECTION WASTE TRAY GALILEO	SDSMS0096
WIRED REMOTE CONTROL L GALILEO SEMI	SDSMS9033
COMPLETE ELECTRONIC SHEET GALILEO UL	SDSMA9059
COMPLETE ELECTRONIC SHEET GALILEO	SDSMA9006N
MOTOR ROTATION ASSEMBLY	SDSMA9012

11

WEEE DIRECTIVE

11.1 WEEE directives

Before uninstalling the instrument, perform its decontamination, according to current laboratory standards. Before transporting the instrument, insert it into a suitable packaging to minimize the risk of contact with the parts of the instrument.

In compliance with EU Directive 2002/96/EC or waste electrical and electronic equipment (RAEE), this electrical product must not be disposed of as unsorted municipal waste. Please dispose of this product by returning it to the point of sale or to your local collection or recycling point.

The directive gives measures to prevent production of electronic and electrical equipment waste and their re-employment, recycling and other way of collection to reduce disposal waste volume.

The Directive RAEE/WEEE (electronic and electrical equipment waste) assists the different collecting of technological waste coming from the disuse of electric equipment malfunctioned, broken or not repairable.

This directive RAEE (electronic and electrical equipment waste) introduces the concept of "empty to return" for the electronic and electrical waste, or rather the old equipment withdrawal when you buy a new one.

Diapath S.p.A. is an ecor'it member, global system of WEEE management (electronic and electrical equipment waste) home and professional in the Italian territory.

To guarantee an efficient and effective system of separated collection of WEEE for the Italian territory, in accordance with the law device, ecor'it uses suppliers that are the better of existent reality concerning disposable technique, withdrawal and recycle.

In the European territory the RAEE responsible (electronic and electrical equipment waste) is the manufacturer.

The European directive 2002/96/CE of European Parliament and council of 27th January 2003 on "electrical and electronic equipment waste WEEE" defines manufacturer who:

- i. Produce or sell electronic and electrical equipment under its brand;
- ii. Sell under its brand equipment produced by other suppliers. The reseller is not considered as "the manufacturer" if the equipment has manufacturer's trademark according to the point I;
- iii. Imports or exports electronic or electrical equipment to a member state concerning a professional activity.

11.2 Warranty certificate

DIAPATH

**CERTIFICATO DI GARANZIA
GUARANTEE CERTIFICATE**

Prodotto: Microtomo semi automatico
Product: Semi-automatic rotary microtome

Modello: Galileo
Model: Galileo

Serial number: vedi targhetta matricolare posta sullo strumento
Serial number: see nameplate on the instrument

**Fabbricante
Manufacturer**
Diapath S.p.A.
Via Savoldini, n.71
24057 Martinengo (BG)
Italia

**Mandatario marcatura CE
Authorized Representative**
Diapath S.p.A.
Via Savoldini, n.71
24057 Martinengo (BG)
Italia

Diapath S.p.A. nella persona del Presidente Sig. Vladimiro Bergamini, dichiara sotto la propria responsabilità che il prodotto Microtomo semi automatico Galileo è stato progettato e costruito secondo le direttive dei dispositivi diagnostici in vitro.
Diapath S.p.A. in the person of Mr. Vladimiro Bergamini, declares under its sole responsibility that the product, Galileo semi-automatic rotary microtome, has been designed and built according to in vitro diagnostic medical devices instruction.

Questo prodotto dovrà essere installato, mantenuto ed usato come descritto nel manuale fornito insieme al prodotto.
This product shall be installed, maintained and used as indicated in the Operating Manual supplied with the product.

Diapath S.p.A. garantisce che il presente prodotto al momento della consegna all'acquirente è conforme agli standard di qualità ed esente da difetti apparenti.
Diapath S.p.A. guarantees that its product, when delivered to the buyer, suits quality standards and exempts from any obvious defects.

La garanzia riguarda i difetti del materiale e/o di costruzione e decorre dalla data di spedizione o collaudo positivo e copre per 12 mesi (o come da condizioni contrattuali accettate) tutte le parti che compongono lo strumento. Non sono coperte da garanzia le parti danneggiate per cattiva o errata manutenzione, insufficienze o malfunzionamento degli impianti elettrici, per trascuratezza o incapacità d'uso e per tutte le cause di ogni genere non dipendenti da Diapath S.p.A.
Guarantee concerns defects of the material, or/and construction. It elapses from the date of the invoice. It covers 12 months (or as stated in any particular other agreements) all components of the device. The damaged parts are not covered by guarantee due to bad or incorrect maintenance, electrical systems malfunctioning or lacks, negligence or improper use and due to all causes not depending by Diapath S.p.A.

Luogo e data / *Place and date:* Martinengo (BG), 13/03/2015

Firma / *Signature* Diapath S.p.A.
Il Presidente/ The President
Bergamini Vladimiro



Il presente documento è valido per gli usi consentiti dalla legge/ *The present document is valid for uses permitted by law*

MCQ181-1 Certificato di Garanzia_IT_EN_Galileo_SEMI_130315

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USER MANUAL Galileo SEMI EN



C#4MKT1020