MILESTONE
HELPING
PATIENTS

KOS

Rapid Microwave Labstation

Operator Manual

MM073-004 (June 2012)

Thank you for having selected our system and welcome to the ever growing world club of users for Milestone laboratory instrumentation.
We are sure that you will be completely satisfied with this new tool entering your laboratory.
We invite you to read carefully this operator manual and to keep it in reach for convenient and fast consulting.
For any possible clarification or any request for assistance please contact either our Representative in your country:

Or contact

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e-mail medical@milestonesrl.com

Please read the user manual before using the device!

SUMMARY

1. INTRODUCTION

1.1. Symbols used

An instruction accompanied by this symbol provides a cautionary statement: WARNING. Failure to follow the instruction may endanger the USER or cause damage to the instrument.

An instruction accompanied by this symbol provides a caution against electric shock. Be sure to follow the instruction to prevent accidents resulting from electric shock.

Biohazard.

Surface at danger temperature (more than 70°C, 158° F) do not touch.

Potentially flammable.

Laser source Class II.

Acid.

Aquatic pollution.

CE logo: this instrument complies with European community directives.

IVD medical device according to 98/79/EC directive.

Please read carefully this instruction.

Please read SERVICE Manual (operation for SERVICE only).

WEEE European directive symbol (2002/96/EC).
Electric/electronic device do not throw out in the environment.

1.2. Intended uses

The Milestone KOS and its accessories have been engineered for laboratory use and can therefore withstand the harshest laboratory conditions for continuous use in Histological sample preparation procedures.
The instrument is intended for laboratory use (indoor use) only.
The KOS Unit is specifically designed to semi automatically execute these processes for histopathological applications:

- Fixation, post-fixation
- Dehydration and clearing
- Paraffin WAX infiltration
- Antigen retrieval
- Special staining
- Decalcification

The Milestone KOS must be operated exclusively with the reagents listed in “Compatible reagents” chapter 1.7.

Any other use of the instrument is considered improper and may void the warranty provided by the manufacturer.

1.3. Technical specifications

Working Temperature: 15°C–30°C (59°F–86°F)
Humidity (relative): up to 80%
Maximum altitude: 2000m

This unit is developed to comply with the CAP-College of American Pathologists checklist for microwave instruments requirements.

1.3.1. Microwave unit

Microwave Power: Max 800 Watt.
Power Emission: The Power Emission (Pulse Width) is controlled by the KOS software. The microwave power output is regulated in 10 Watt increments. Control of microwave power is made by modification of the In and Out phase of the Magnetron.
Power supply: 230 V ~ 50 Hz, 8A (see table below)
230 V ~ 60 Hz, 8A (see table below)
115 V ~ 60 Hz , 15A (see table below)
For more detail refer to chapter 2.6.

VALID ONLY FOR KOS COMPLETE KIT (NOT FOR KOS BASIC):

SAFETY PACK	50-60Hz CAMERA PACK (according to voltage of the unit)
Reagents and Organic solvent detector sensor	Analogic camera 50Hz (PAL model) and 60Hz (NSTC model)
Humidity detection sensor	Front panel 5.6" color camera monitor
MW leakage sensor (included ALSO in KOS BASIC)	

1.3.2. Touch control terminal

It is possible to operate the unit by simply touching the icons on the screen.

Characteristics: TK-WIN10CEi-TFT-LCD color display
Resolution 800x600 pixels, 8''
Touch screen
Mass storage CF 256MB
RAM 256 MB
CPU 500MHz
Windows™ CE.NET 6.0

The manufacturer reserves the right change and/or improve specifications without notice and without incurring in obligation.

Programs: Multiple pre-stored programs, with customizable USER defined programs
I/O-Interface: 2x USB port 2.0, 1x LAN Ethernet 10/100 Mbps RJ-45

The two USB PORTS are located adjacent to the main power switch, on the back side of KOS unit.

1.3.3. GPR/K module

Characteristic: Maximum solution volume: 750 ml
Slide capacity: 40 slides max.
Over pressure safety valve: to release pressure at 2 bar (130-135ºC).
Maximum working Temperature: 120ºC

The manufacturer reserves the right change and/or improve specifications without notice and without incurring in obligation.

1.4. Transport and storage conditions

Temperature: -20℃ (-4℉) up to +60℃ (140℉)
Humidity: up to 50% (at 40℃ – 104℉) non–condensin g

Before turning the KOS on (when coming from a storage room) please let the unit reach working environmental conditions (at least half an hour).

1.5. Warning information

Should the equipment be used in different ways than those specified by the manufacturer, the warranty provided by the manufacturer may be void.

Main power plugs are considered disconnecting device. Disconnect all plugs from the socket outlet before assembling of the system, before connection of the accessories and before cleaning.

Equipment shall be connected to main a power socket outlet which is accessible and visible by the operator.

Equipment is provided with replaceable fuses, however their replacement is to be performed by properly authorized service personnel. If the system is still not properly working, please contact the local authorized and trained service representative of the manufacturer.

All parts of the equipment and all accessories shall be supplied only by the manufacturer.

DO NOT OPEN THE CHASSIS! Failure to follow the instruction in the documentation might lead to a reduction of device safety. If the equipment is not working properly, please contact your supplier or the manufacturer.

Do not remove the instrument, accessories, panels or cover. Only authorized and qualified SERVICE personnel may repair the instrument and access the instrument's internal components.

It is important that normal standards for safety and good laboratory practices are applied. Always use common sense and the best known practice when operating the instrument. Failure to follow the instructions in the documentation might lead to a reduction of device safety.
The Competent Authority owning the instrument has primary responsibility for accident-free operation together with designated personnel who operates SERVICE or repair it.

To avoid damage to the instrument, use only the reagents listed in section 1.7 Compatible Reagents. Failure to follow the instructions in the documentation might lead to a reduction of device safety.

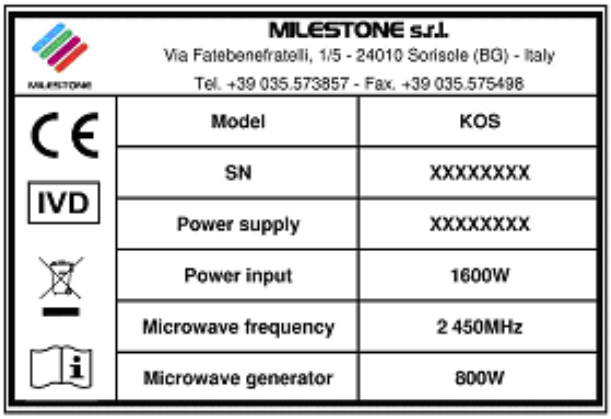
Use caution when handling hot, molten WAX.

METAL PARTS
Never introduce metal parts into the MAIN CAVITY.
High voltage discharges may cause uncontrolled increases of temperature, which could damage the unit and result in incorrect tissue processing also. Failure to follow the instructions in the documentation might lead to a reduction of device safety.

Be careful: exhaust reagents are toxic and carcinogenic.
Handle with care and follow the local standard regulations.

Caution – laser radiation. Class II: if opening, do not fix the beam. When opening the door, a laser beam appears to facilitate the correct positioning of the histomodule.

1.6. Instrument labeling explanation



Note only for Canada: this symbol indicates the compliance with the requirements of CAN/CSA-C22.2 No. 61010-1, 2nd edition, including Amendment 1.

1.7. Compatible reagents

Fixatives	Dehydration Clearing	Decalcification	Impregnation	Other
Milestone Finefix®	Milestone JFC solution	Ethylenediaminetetraacetic acid (EDTA) 20%	WAX, Histology grade	Saline solution
Formalin, buffered or unbuffered	Milestone Prowave® solution	Formic acid 12%		Histochemical stain for histology
Formalin saline	Ethanol	Hcl 10%		Sodium citrate 10 mM, pH 6.0
	Isopropanol			Tris/EDTA pH 9.0
	Methanol			
	Industrial Methylated Spirits			
				

Please refer to chapter 8.4 for purity grade of reagents.

DO NOT USE REAGENTS DIFFERENT FROM THOSE LISTED ABOVE.
In case of doubts please contact: application@milestonemedsrl.com.

Reagents other than those listed above may damage some components of the instrument.
Do not use acetone, benzene or trichlorethane in the instrument!
Fixatives containing mercuric salts, acetic or picric acid will corrode metallic components in the instrument and shorten instrument life.
If you choose to work with such fixatives, it is essential to perform a rack cleaning cycle with multiple water rinses each time after use, to minimize damage.

1.8. Waste disposal of the equipment

This instrument is an in-vitro medical device and it is usually installed in a laboratory where specimens and other biological tissues are present. For your safety, it is therefore required to clean and disinfect before entering in contact with it. You must also wear gloves when operating with the system.
It is required in case of return that the unit is cleaned and disinfected before sending it back to Milestone s.r.l. Non-disinfected devices will be no longer accepted and you will be contacted to get the relative disinfection cost.
International health rules require that shipments of biohazard materials are not done in standard packages (risk of sanctions).

Do not remove the side panels of the unit during the cleaning operations.

Before doing any operation disconnect the power supply.
Do not use direct or high-pressure water to clean the instrument.

For safety reason, any operation without the individual protective devices must be avoided.

It is recommended the use of enzymatic detergents and polyphenolic based disinfectants or chlorine substitutes to clean and disinfect the instrument. In alternative, to decontaminate the instrument, the use of a solution of 1:10 Bleach (recommended by the CDC for disinfecting) is also allowed.
For further information, please contact the manufacturer: **medical@milestonesrl.com.**

In addition, complying with directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE), the separate collection environmental managed of equipment is mandatory.
It is necessary to return the used equipment to the distributor or to inquire about the presence of a local empowered system for collection and disposal of WEEE.
The in-observance of Directive 2002/96/EC or of the local law which acknowledges it can have potential effects on the environment and human health.

This symbol indicates separate collection
for electrical and electronic equipment

If additional requirements on accident prevention and environmental protection exist in the country of operation, this instruction manual must be supplemented by appropriate instructions to ensure compliance to such requirements.

1.9. Waste disposal of reagents

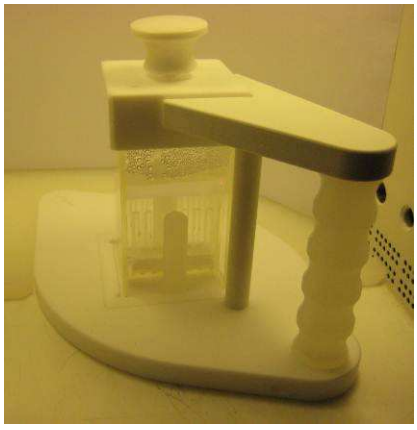
Handle with care and store in a cold dry space using a tightly closed container.
Vapors may collect in empty containers. Treat empty containers as hazardous.
Waste material should be disposed of in an approved incinerator or in a designated landfill site, in compliance with all federal, provincial and local government regulation.
Some reagents can have potential health effects and cause environmental pollution if not correctly disposed.

For further information please refer to the MSDS (Material Data Safety Sheet) provided by your supplier.

2. SETTING UP THE INSTRUMENT

2.1. Introduction to KOS

The KOS is a unit provided with state-of-art microwave Hardware/Software, that allows obtaining consistent and reproducible results in the histopathology laboratory, for high throughput tissue processing and other histological applications.
The system and its accessories have been engineered for laboratory use and can therefore withstand the harshest laboratory conditions for continuous use in Histological sample preparation procedures.
This manual refers to KOS, microwave Labstation and its application is suitable for NON vacuum processing of tissue specimens with a maximum thickness of up to 3 mm.

The KOS concept		
		
Microwave Tissue Processor	**Specially developed Histomodules**	**A set of prestored programs**

Milestone KOS is a precision instrument that requires the utmost care when it is unpacked and installed.

The weight of KOS is approximately 40kg (88lb) at least 2 people should remove the microwave unit from its box and locate it on the bench.

Provide a vibration free bench of at least 0.55m in width and 0.8m in depth, suitable for a weight of 50kg and place the KOS on it.

Make sure the unit is not placed against any side surface limiting the air cooling inlet/exhaust: let at least a distance of 10cm for each side.

Never install the KOS unit under a fume hood.
The presence of acids or caustic reagents may contaminate the air flow used for ventilating the electronic components, exposing them to possible corrosion or shorting of circuits.

CONNECTING CABLES	**Never** connect or remove cables when power to the unit is switched on, to avoid risk of damage.
METAL PARTS	**Never** introduce metal parts into the microwave chamber. High voltage discharges may cause uncontrolled increases in temperature, which could damage the unit.
CLEANING CAVITY AND DOOR	**Periodically inspect and clean cavity, door seals and hinges**. Do not use aggressive cleaning materials. If microwave exposed surfaces are not kept clean, local “hot Spots” are generated with possible corrosion of the metal surface.
FOOD	**Never** heat food in a microwave oven used for laboratory procedures.

2.2. Space requirements

Unit dimensions:

UNIT	Width: 340mm (14in)	Height: 550mm (22in)	Depth: 530mm (21in)
CAVITY	Width: 240mm (10in)	Height: 265mm (11in)	Depth: 290mm (11.7in)

Space dimensions required to locate the unit:

Width: 970mm (38in)	Height: 920mm (36in)	Depth: 1090mm (43in)

2.3. Unpacking and checking list

When unpacking, check that all parts correspond to the packing list included in the shipment. Utmost care must be made during unpacking of KOS, to avoid scratching or damage of the external coating. Check if your KOS (or KOS BASIC) part number corresponds to the voltage supply of the laboratory, please refer to chapter 1.3.1.

KOS is delivered in a **carton box** (weight 50kg-110lb) with these dimensions:

Width	600mm (23.6in)
Height	900mm (35.4in)
Depth	800mm (31.5in)

A separate carton box (W480mm/19in-H100mm/4in-D480mm/19in) is positioned over the main carton box: remove and keep it apart. This box contains accessories which will be used during the installation of the KOS.
Lift the main carton box up to facilitate KOS removal.
The KOS comes protected by a plastic bag to prevent problems of moisture infiltration during transportation.

Then open the box (or boxes) with accessories (optional).

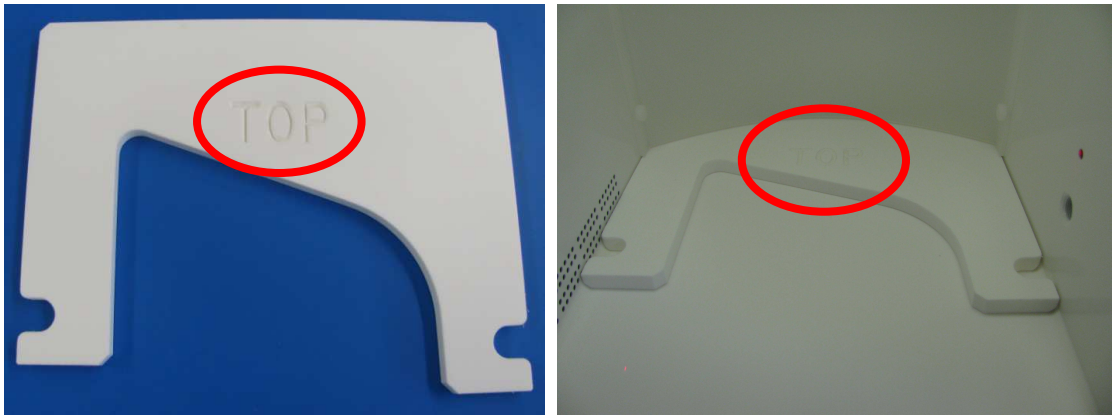
The KOS (or KOS BASIC) part number includes the following items:
1. Microwave unit complete with integrated Touch Control terminal
2. Power cord (x1)
3. Plastic hose + metal cable clamp
4. Operation Manual
5. USB Data Traveler
Accessories: Histomodules are supplied according to customer specific order (to be ordered apart).

POWER CORD	**Ref. P/N 67109** (115V ~ 60Hz) 	**Ref. P/N 70304** (230V ~ 50/60 Hz) 
PLASTIC HOSE and METAL CABLE CLAMP	**Ref. P/N 50332** 	**Ref. P/N 64757** 
OPERATION MANUAL and USB	**MM073** 	**Ref. P/N 62160** 

2.4. Final placement

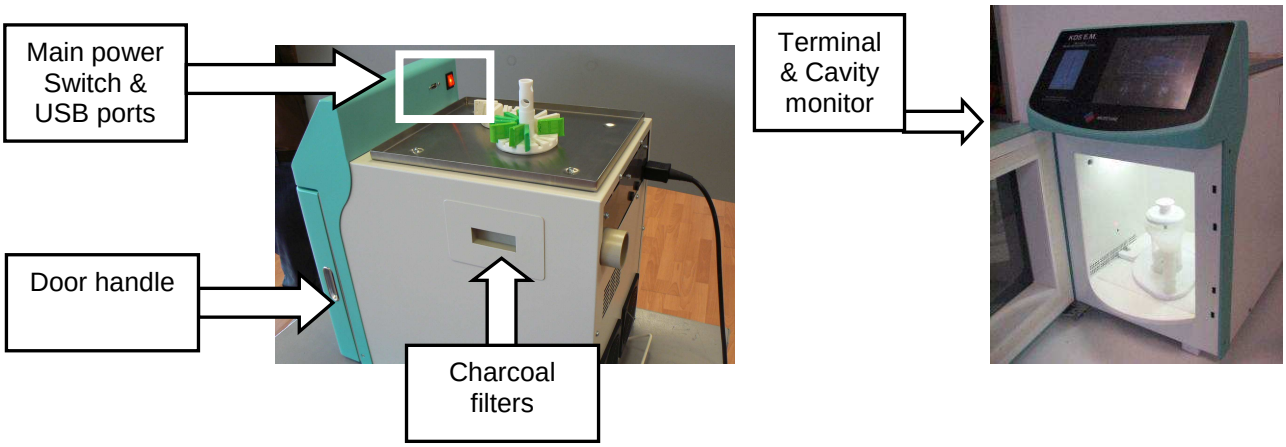
Now KOS unit can be positioned in its final place of use. When the instrument is positioned, it must be firmly placed. Make sure that the bench is level.
Insert the positioning plate in the KOS as shown below, with the mark TOP visible.

During the KOS SETUP the microwave unit should not be connected to the main power supply.



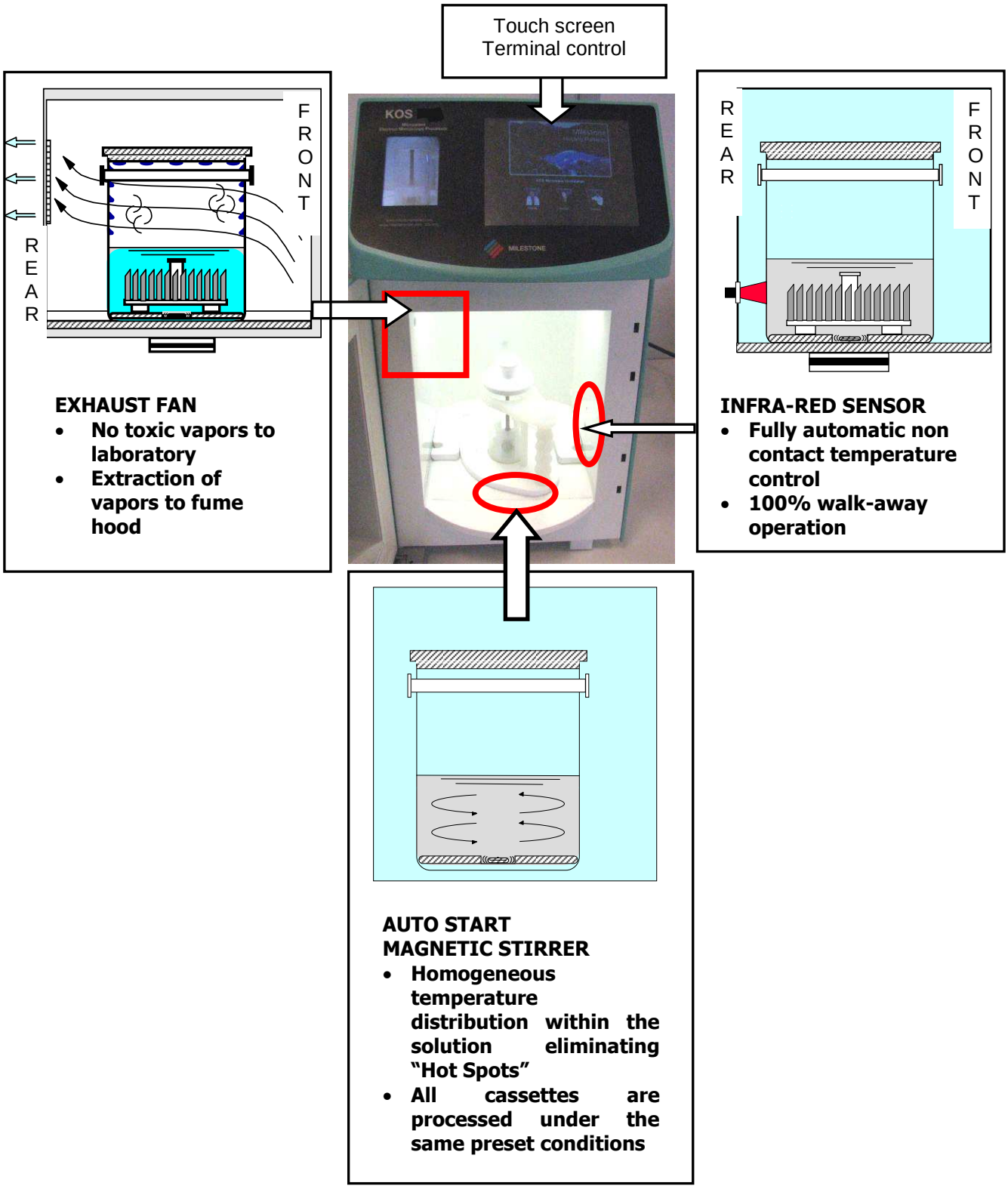
2.4.1. Product overview

The picture below shows the front view of the KOS system.
Pull the handle towards the operator to open the door. On door opening, microwave emission is turned off by 4 safety mechanical switches.



An overview of the back side of KOS is shown in the following picture.

The KOS has dedicated software, based on Windows CE (Microsoft Windows CE is a trademark of Microsoft Corporation). Use the touch screen pen to select the desired menu function.
The picture below shows the internal cavity of the KOS.
The KOS is neither a kitchen type nor a commercially modified kitchen type microwave unit. It is a rugged, heavy duty professional system, designed to guarantee many years of trouble free and safe operation.



2.5. Fume extraction system

The instrument is equipped with carbon filters (**Ref. P/N 67223**) to avoid the releasing of fumes into the laboratory environment. The carbon filter absorbs reagent fumes to prevent their diffusion into the laboratory atmosphere. To ensure the filters are effectively operating, they must be periodically replaced (see chapter 6.5 for details).

The KOS is vented, according to CAP requirements, through the external exhaust outlet positioned on the back of the instrument, with a hose dedicated to the external fume extraction system (if any).

Either the carbon filters or an external fume extraction system must be properly installed at all times, according to local regulations in force on laboratory safety.

In case of connection to an external fume extraction system, the customer is required to adapt the hose connector. The plastic hose supplied has these characteristics:

- Length: 2.5m(98in)
- External diameter: 55mm(2.15in)
- Internal diameter: 50mm(2in)

The external fume extraction system must permit an air flux of 36m^3/h (cube meter per hour), (21cfm).

Connect the black exhaust hose of 2.5m (Ref. P/N 50332) to the exhaust outlet located on the back panel of the unit.

Use the metal cable clamp (Ref. P/N 64757) to fix the hose to the exhaust outlet connection. Use a screw driver to tighten the metal cable clamp.

Now connect the other side of tube the fume extractor of the laboratory.

2.6. Power supply

Power supply line needs to have a ground connection (yellow/green, green or bare wire), do not use the white wire (neutral of power line). Power supply neutral has to be referred to ground.

Power line protection: 115V: Miniature circuit breaker curve C, 15A, interruption more than 6000A.
230V: Miniature circuit breaker curve C, 16A, interruption more than 6000A.
Residual current device: 30mA (Class I device).

Check if Voltage and Frequency on the back label of the KOS correspond to the power supply outlet in your laboratory.

POWER SUPPLY	KOS RED	KOS BLUE	KOS GREEN
	Ref. P/N	**Ref. P/N**	**Ref. P/N**
115 V ~ 60 Hz, 15A	67050/R	67050/B	67050/G
230 V ~ 50 Hz, 8A	67051/R	67051/B	67051/G
230 V ~ 60 Hz, 8A	67052/R	67052/B	67052/G

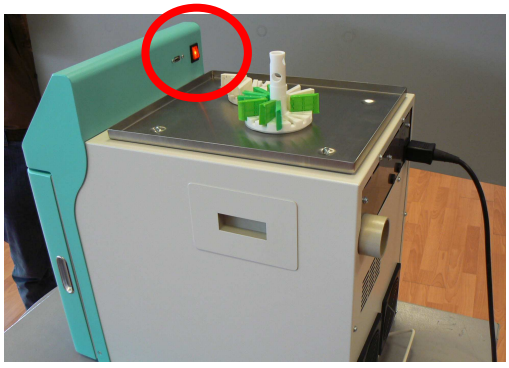
POWER SUPPLY	KOS BASIC RED	KOS BASIC BLUE	KOS BASIC GREEN
	Ref. P/N	**Ref. P/N**	**Ref. P/N**
115 V ~ 60 Hz, 15A	67000/R	67000/B	67000/G
230 V ~ 50 Hz, 8A	67001/R	67001/B	67001/G
230 V ~ 60 Hz, 8A	67002/R	67002/B	67002/G

Milestone microwave units must be connected to a grounded power supply to guarantee the optimal performance of all the high voltage components.
The unit chassis and the following components must be connected to the electrical ground to avoid any electromagnetic interference:

-High Voltage transformer
-Heating transformer
-Magnetron (microwaves generators)
-High Voltage diode and capacitors
-Microwaves diffuser

Milestone supplies the power cable, either for 115Vac or one for 230Vac, according to the correct voltage of your country.
Both versions are provided with ground connection.
During the installation, our distributor will check the compatibility of our cable plugs with the local electrical socket to guarantee the correct ground connection of the unit.

Now you can connect the power supply cable and switch the KOS ON, using the main power switch located on the back side panel of the microwave unit.



KOS is now ready for use.

2.7. Internet connection

It is necessary to connect KOS to Internet to get Remote Assistance SERVICE.

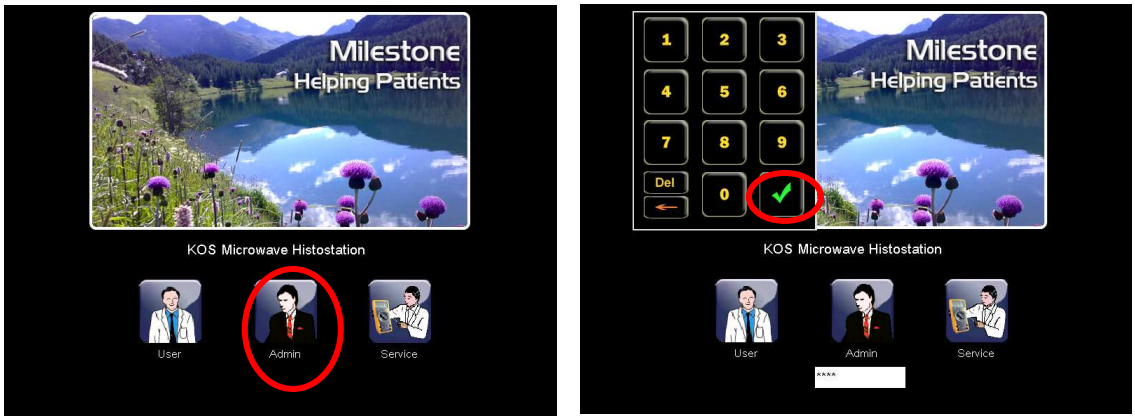
IT IS NOT ADMITTED TO RUN PROGRAMS WITH KOS WHILE USING REMOTE ASSISTANCE CONNECTION.
PROCESSES IN REMOTE ASSISTANCE ARE FOR TESTING USE ONLY, NEVER PLACE SPECIMEN INSIDE KOS.

In order to access the remote assistance (as described in the chapter 4.11.4), following data are needed from the Information Technology Department/Network ADMINISTRATOR of the laboratory:

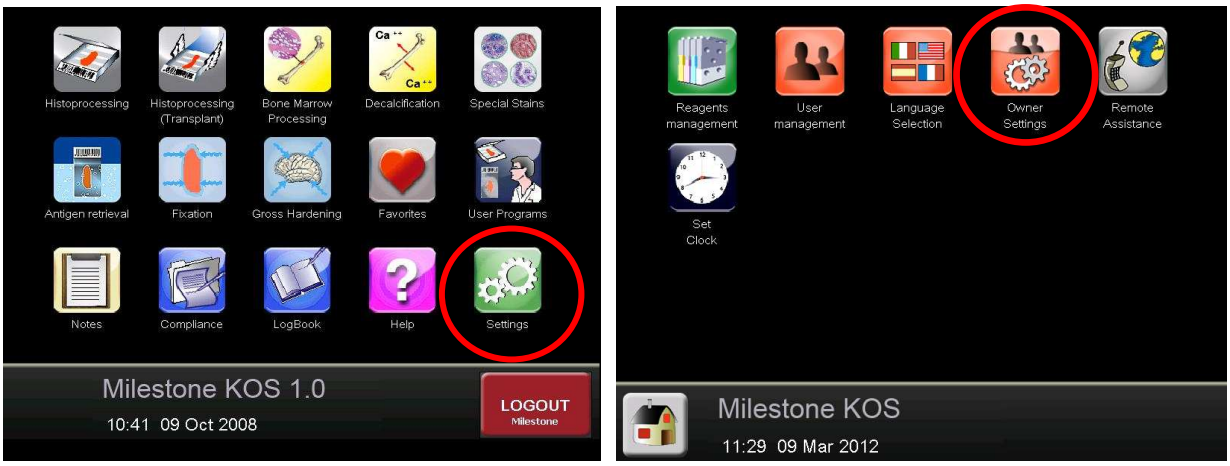
- LAN connection with standard RJ45 Ethernet cable and connector
- Dedicated IP address and Subnet Mask (strongly preferred to DHCP SERVICE); only port 80 has to be enabled without limitations
- LAN gateway and DNS server addresses
- At least 150kb/s real transfer rate (uploading and downloading).

When connecting KOS to remote assistance, it is necessary that Firewall, traffic data filters and all software are disabled. Milestone s.r.l. strongly suggests not to use the DHCP SERVICE, but fix the IP address in order to properly set up the LAN defenders.

From Log-in screen click on ADMINISTRATOR and insert the password (issued as a separate document inserted in the Operator Manual).

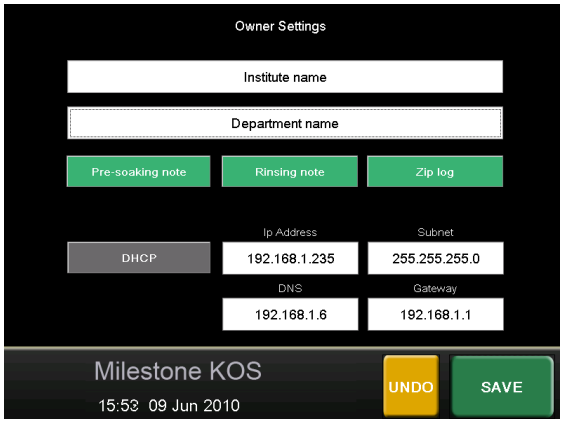


The Administrator HOME PAGE appears. Press SETTINGS to access the administrator screen and then press “OWNER SETTINGS”.

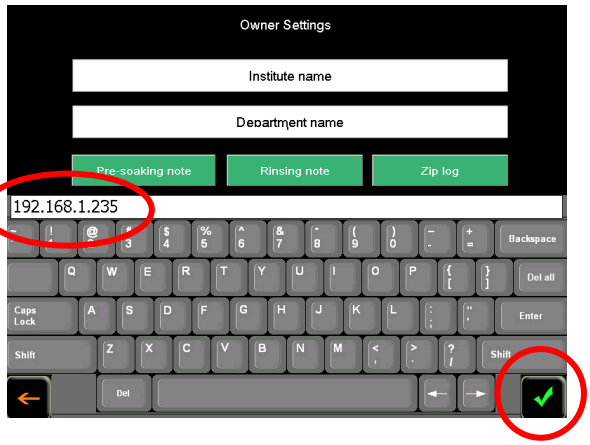


The following screen appears. Enter the data required supplied by the Network Administrator.
For example:

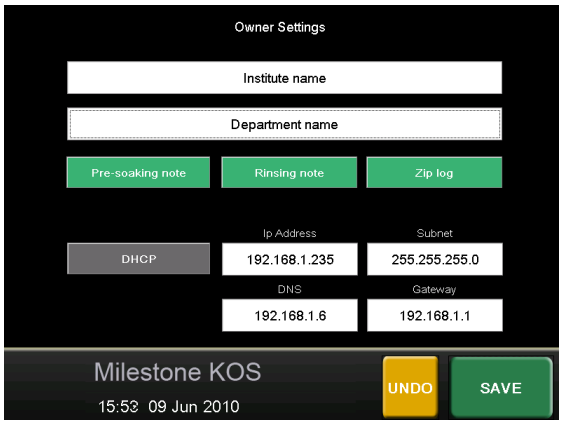
IP Address	192.168.1.200
Subnet Mask	255.255.255.0
DNS server address	192.168.1.6
Default Gateway add.	192.168.1.1

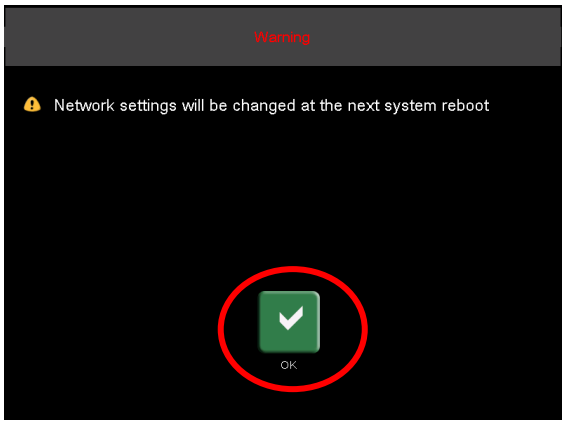


A keyboard appears when clicking on any white box; insert the number required and then press directly the green arrowed check box (in the figure below). Fill all white boxes with data network.



Press SAVE to store data, as shown below on the left and the message on the right appears.





Press Ok and restart the Unit, as indicated in the figure above.

2.7.1. How to start the Remote Assistance

In administrator screen, press “Settings” icon from the MAIN MENU, as indicated below.

The following screen appears and on selecting the REMOTE ASSISTANCE button, the icon turns in pink and is automatically activated. See below.

Once activated, do not press the REMOTE ASSISTANCE icon again (to avoid multiple activations) until you reboot the machine. Now remote service works with your instrument.

Do not disconnect nor restart the instrument during the remote connection.

ALWAYS COMMUNICATE THE SERIAL NUMBER (S.N.) OF THE UNIT.
MILESTONE CANNOT CONNECT TO UNIT WITHOUT THE S.N.
THAT IS AVAILABLE IN “HELP” ICON IN MAIN SCREEN.

2.8. Reagents

Complete the set up with reagents, by providing at least:

PROCESSING REAGENTS:

HISTOMODULE	4K	15K	30K	45K
REAGENTS' QUANTITY	200ml	900ml	1.4L	1.9L

- Formalin 10%, Finefix
- Absolute Ethanol
- Exhausted Ethanol for rinsing
- Absolute Isopropanol
- JFC-for processing of larger fatty tissues (3mm), use of Milestone JFC solution is recommended
- 0.7kg (1.54lb) for 45K-160g (0.35lb) for 4K WAX, Histology grade

DECALCIFICATION REAGENTS:

HISTOMODULE	4K	15K	30K	45K	60M	8SM
REAGENTS' QUANTITY	200ml	900ml	1.4L	1.9L	3L	2L

- EDTA 10% OR Formic acid 10% OR HCl 10%

ANTIGEN RETRIEVAL REAGENTS:

HISTOMODULE	16KS	20KS	40KS	80KS	GPR/K20S	GPR/K40S
REAGENTS' QUANTITY	100ml	1L	2L	3L	550ml	750ml

- Sodium citrate 10 mM, pH 6.0
- Tris/EDTA pH 9.0

SPECIAL STAINING REAGENTS:

- Histochemical stain for histology: 100ml

FIXATION REAGENT:

HISTOMODULE	4K	15K	30K	45K
REAGENTS' QUANTITY	200ml	900ml	1.4L	1.9L

- Formalin 10%, Finefix

GROSS HARDENING REAGENTS:

- Formalin 10%, Finefix, OR Saline solution: 3L

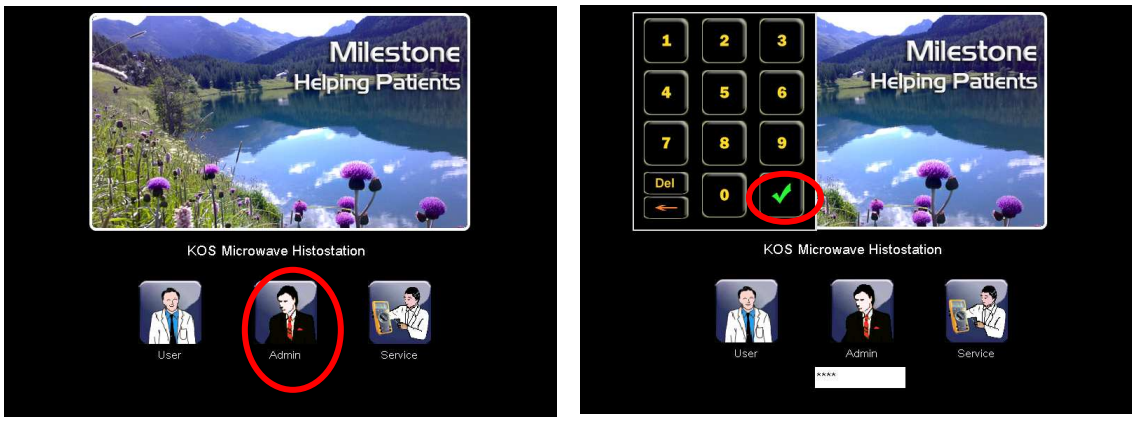
The above reagents must be onsite and available at time installation of unit.

The above reagents quantities are just a guideline, real quantities to be determined during process, according to number of cassettes placed in the rack, samples type/size used.

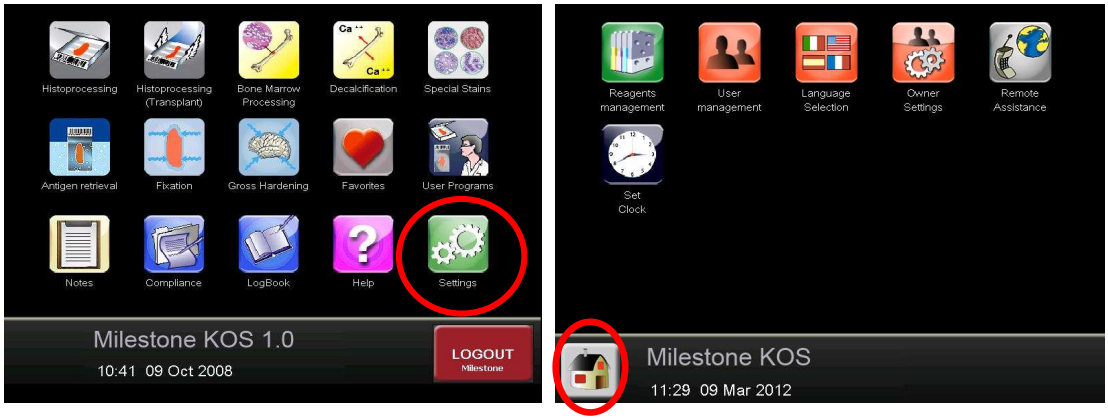
Refer to chapter 8.4 for purity grade of reagents.

2.9. Log IN and Log OUT

When the system is switched on, the LOG IN screen appears. Log in as Administrator is necessary to use the main functions. Therefore press “Administrator” button, insert the password (issued as a separate document inserted in the Operator Manual) and press the green arrowed check box (see below).

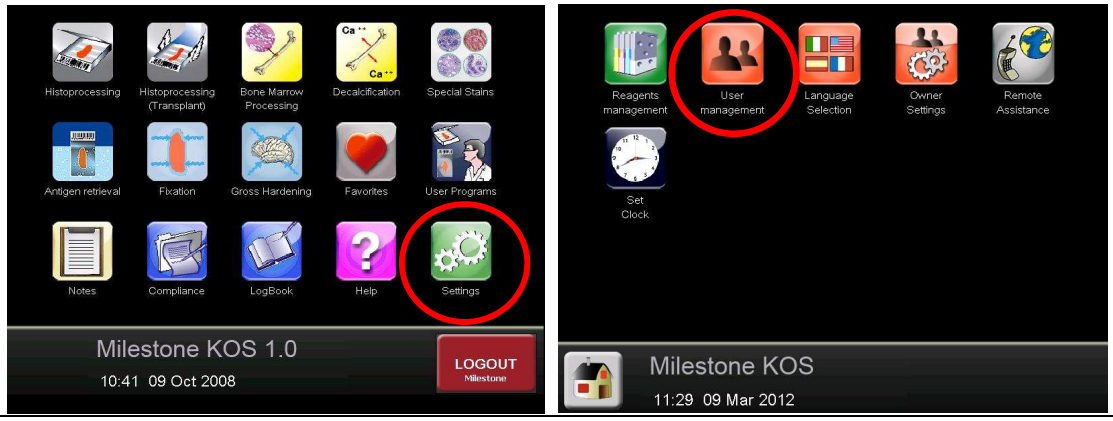


The Administrator HOME PAGE appears. As default, it shows the main programs.
From any screen, click on the Home icon circled in red (figure below) to go back to the home page.

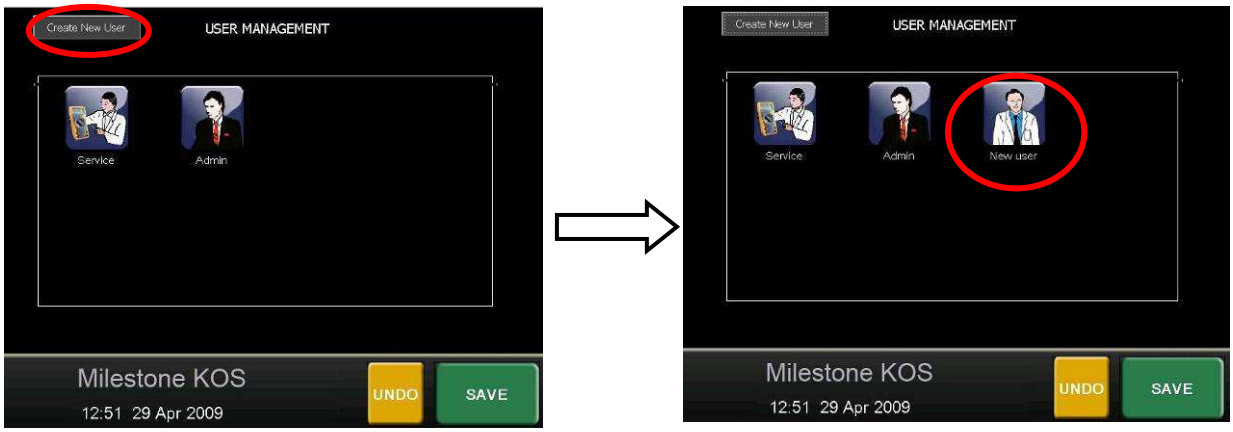


SERVICE Log-in is available for authorized personnel only (ADMINISTRATOR can access to a restricted SERVICE functions. SERVICE has complete access to the unit functionalities).

Administrator and Service can customize the HOME PAGE under the Users management, choosing between “Favorites” and “Main functions” (see below).
Go into the SETTINGS screen and select USER MANAGEMENT to create a new user.

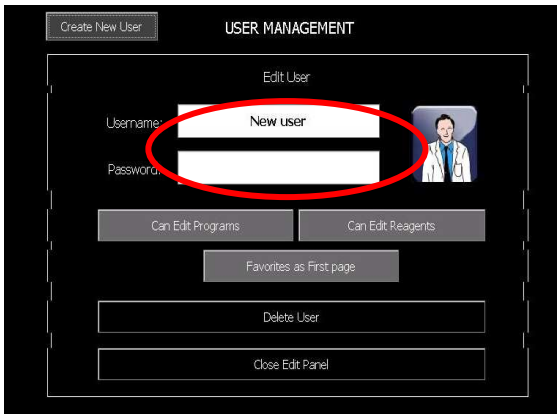


The User setting screen appears. Select CREATE A NEW USER; then press the NEW USER icon.

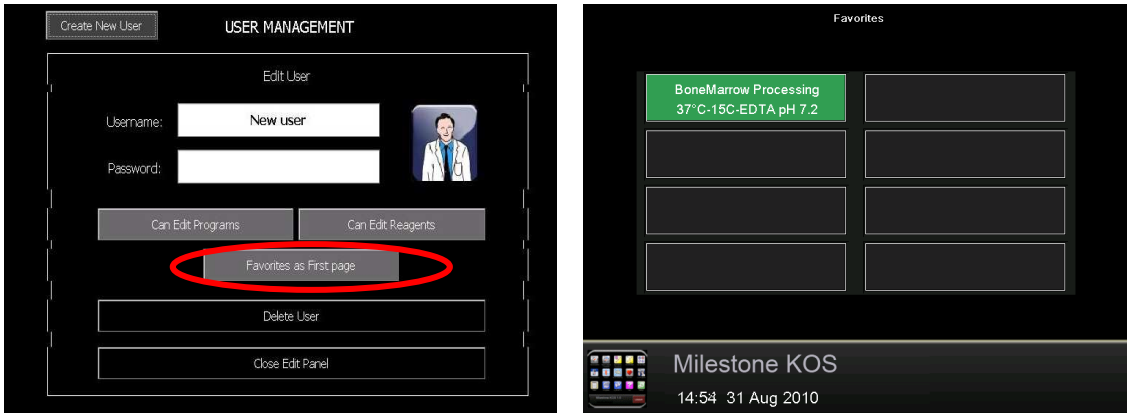


Enter the user name and password in the fields circled below (right).
In this page, select (all icons turn GREEN when activated):

Can edit programs	Enable user to create and modify programs
Can edit reagents	Enable user to create and modify reagents details (Ex: max number of processed cassettes)
Favorite as first page	Your home page shows the FAVORITES programs as default.

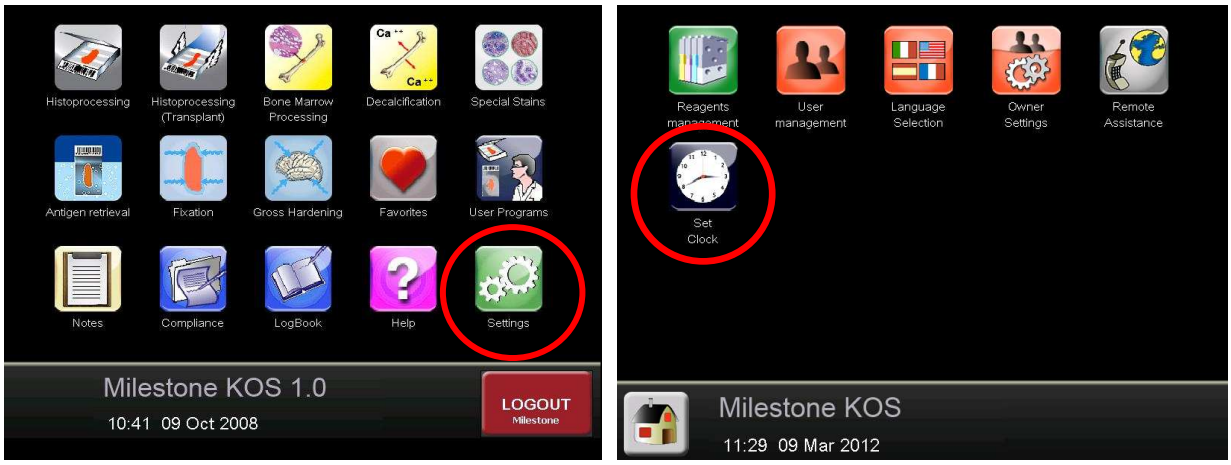


Click on the icon circled in red, as shown below to return to the Main Programs screen

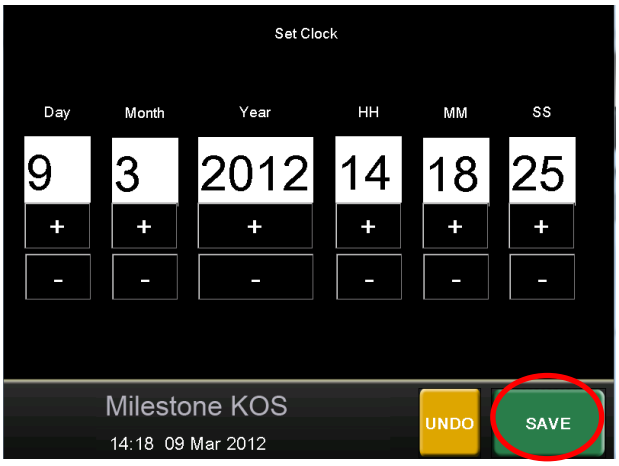


2.10. Set date and time

The SET CLOCK screen is accessed only by ADMINISTRATOR. Select SETTINGS icon from the MAIN MENU, then SET CLOCK button.

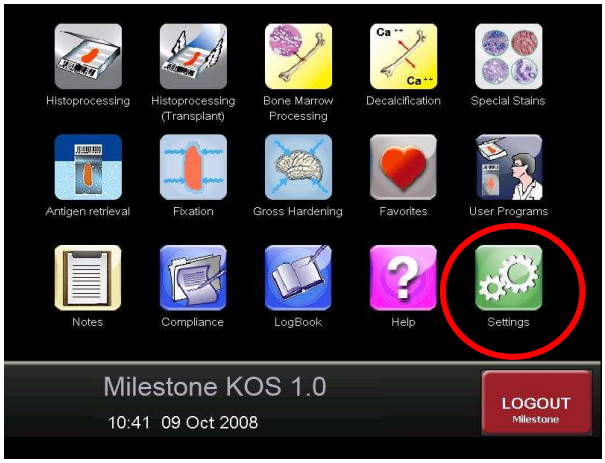


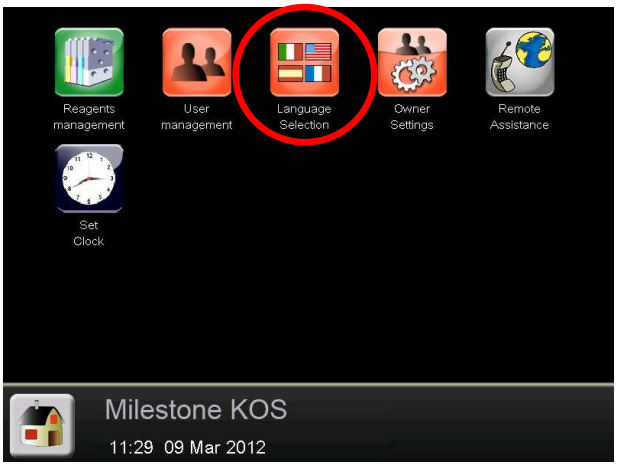
Use the +/- buttons to set the right date and clock, after selection of these parameters touch SAVE to make changes valid.



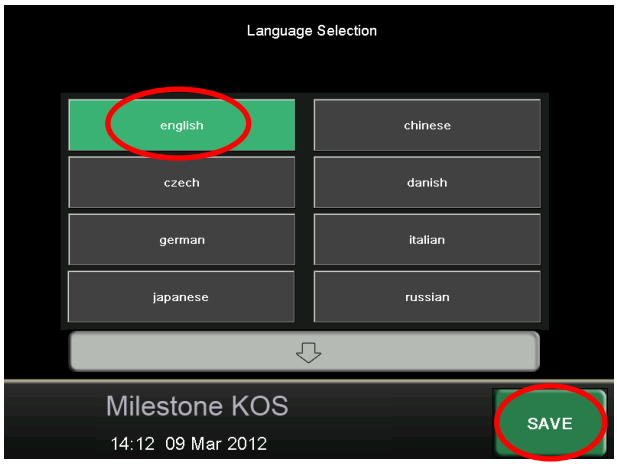
2.11. Set language

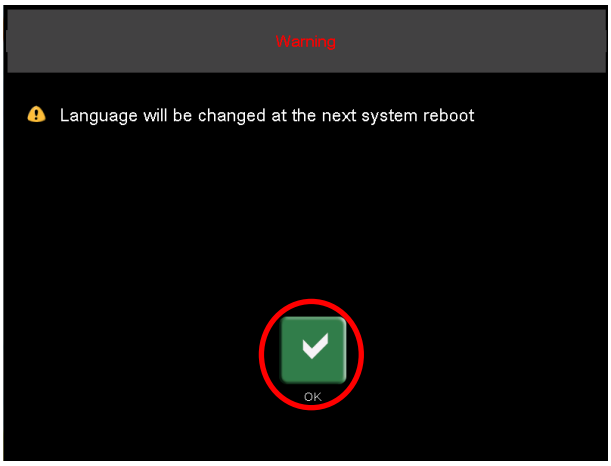
Select SETTINGS icon from the MAIN MENU, then LANGUAGE SELECTION as indicated below.





After selection of the language, touch SAVE to make changes valid. See below figure left.
A message appears advising that the language will be changed at the first system reboot, as shown below.
Press Ok and restart the Unit.





3. KOS HISTOMODULES AND ACCESSORIES

3.1. Histoprocessing (up to 3mm thickness)

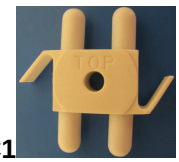
4 CASSETTES

4/K HISTOMODULES KIT for histoprocessing of up to 4 cassettes. Includes A-B-C			Ref. P/N 67390
Histomodule 4K for fixation, JFC, ethyl alcohol and isopropanol (qty. 3) includes **A1-A2-A3**  **A** Ref. P/N 67300	 **A1**	Glass container 250ml Ref. P/N 60578	
	 **A2**	Holder for histomodule 4K Ref. P/N 67306	
	 **A3**	Cover complete Ref. P/N 67311	
Histomodule 4K for WAX (qty. 1) includes **B1-B2-B3-B4**  **B** Ref. P/N 67360	 **B1**	Glass container 250ml Ref. P/N 67578	
	 **B2**	Heating disk diam. 125mm Ref. P/N 60575	
	 **B3**	Holder for histomodule 4K Ref. P/N 67306	
	 **B4**	Cover WAX complete Ref. P/N 67315	
Rack 4K complete (qty. 1)  **C** Ref. P/N 67301			

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

45 CASSETTES

45/K HISTOMODULES KIT for histoprocessing of up to 45 cassettes. Includes A-B-C		Ref. P/N 67391
Histomodule 45K for fixation, JFC, ethyl alcohol and isopropanol (qty. 1) includes **A1-A2-A3**  **A** Ref. P/N 67320	 **A1**	Glass container 135mm Ref. P/N 67336L
	 **A2**	Holder for histomodule 45K Ref. P/N 67326
	 **A3**	Cover complete Ref. P/N 67330
Histomodule 45K for WAX (qty. 1) includes **B1-B2-B3-B4**  **B** Ref. P/N 67370	 **B1**	Glass container Ref. P/N 67399
	 **B2**	Heating disk diam. 125mm Ref. P/N 67313
	 **B3**	Holder for histomodule 45K Ref. P/N 67326
	 **B4**	Cover WAX complete Ref. P/N 67332
Rack 45K complete (qty. 1) includes **C1**  **C** Ref. P/N 67325	 **C1**	Magnetic stirrer complete Ref. P/N 65594

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

3.2. Antigen retrieval

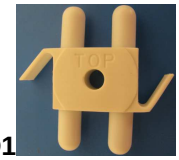
Antigen Retrieval procedures performed in a microwave oven are described in issued US patents. For this reason, Milestone microwave units sold in the US market with protocols for Antigen Retrieval are not available in the software.
Therefore the procedures, methods, accessories, software information regarding Antigen Retrieval included in this Operation Manual are NOT valid for the US market only.
Milestone s.r.l. provides microwave hardware suitable for carrying out a number of processes. Milestone does not provide any licenses or implied licenses to conduct any specific processes. It is responsibility of the user of the Microwave unit to ensure that a given process does not infringe any US patents.

16 SLIDES

<table>
<tr><th colspan="3">Histomodule 16KS for up to 16 slides complete.
Includes A-B-C</th><th>Ref. P/N
67350</th></tr>
<tr><td colspan="4">  </td></tr>
<tr><td colspan="2"> 
A</td><td colspan="2">TPX couplin jar
Ref. P/N 67337</td></tr>
<tr><td colspan="2"> 
B</td><td colspan="2">Cross magnetic stirrer
Ref. P/N 67344</td></tr>
<tr><td colspan="2" rowspan="3">Safety carrier complete
includes C1-C2-C3
 
C
Ref. P/N 67373</td><td> 
C1</td><td>Cover couplin jar
Ref. P/N 67404</td></tr>
<tr><td> 
C2</td><td>Safety carrier
Ref. P/N 67405</td></tr>
<tr><td> 
C3</td><td>Stirrer with base mounted
Ref. P/N 67402</td></tr>
</table>

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

40 SLIDES

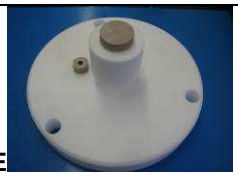
<table>
<tr><th colspan="2">Histomodule 40KS for up to 40 slides complete, with N 2 racks for 20 slides.
Includes A-B-C-D-E</th><th>Ref. P/N
67355</th></tr>
<tr><td rowspan="5">  </td><td> 
A</td><td>Glass container 3L
Ref. P/N 67336</td></tr>
<tr><td> 
B</td><td>Holder for histomodule 45K
Ref. P/N 67326</td></tr>
<tr><td> 
C</td><td>Cover complete
Ref. P/N 67330</td></tr>
<tr><td> 
D</td><td>Holder for rack for 20 slides complete
Ref. P/N 67371/A</td></tr>
<tr><td> 
E</td><td>Rack 20 slides
Ref. P/N 40156/2 (qty. 2).</td></tr>
<tr><td>Holder for rack for 20 slides complete includes D1
 
D
Ref. P/N 67371/A</td><td> 
D1</td><td>Magnetic stirrer complete
Ref. P/N 65594</td></tr>
</table>

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

It is possible to order the rack Ref. P/N 40156/2 in quantity 4 to run up to 80 slides.

20/40 SLIDES HIGH PRESSURE

Histomodule GPR/K for up to 40 slides complete, with N 2 racks for 20 slides. Includes A-B-C-D-E-F	Ref. P/N 67415
	
A 	Cooling tube Ref. P/N 60103
B 	Rack 20 slides Ref. P/N 40156/2 (qty. 2).
C 	Positioning plate GHM-KOS multifunctional Ref. P/N 67384
D 	Glass vessel Ref. P/N 67425
E 	Cover complete Ref. P/N 67422
F 	Stirring plate Ref. P/N 67429

To be used with positioning plate GHM-KOS multifunctional **Ref. P/N 67384** (supplied with the KIT GPR/K).

3.3. Decalcification and/or fixation

4 CASSETTES

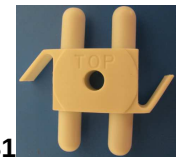
<table>
<tr><th colspan="3">Decalcification and fixation of up to 4 cassettes.
Includes A-B</th></tr>
<tr><td rowspan="3">Histomodule 4K for fixation and decalcification (qty. 1)
includes A1-A2-A3
 
A
Ref. P/N 67300</td><td> 
A1</td><td>Glass container 250ml
Ref. P/N 60578</td></tr>
<tr><td> 
A2</td><td>Holder for histomodule 4K
Ref. P/N 67306</td></tr>
<tr><td> 

A3</td><td>Cover complete
Ref. P/N 67311</td></tr>
<tr><td>Rack 4K complete (qty. 1)
 
B
Ref. P/N 67301</td><td colspan="2"></td></tr>
</table>

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

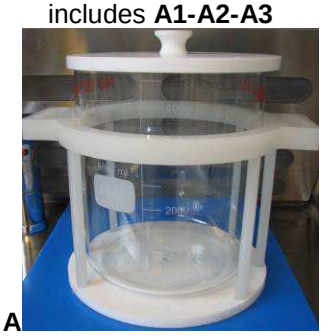
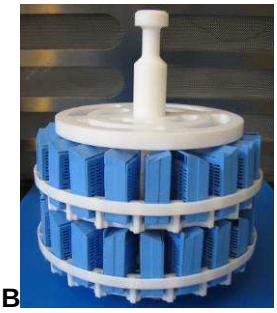
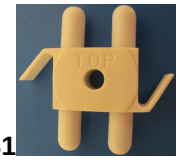
45 CASSETTES

<table>
<tr><th colspan="3">Decalcification and fixation of up to 45 cassettes.
Includes A-B</th></tr>
<tr><td rowspan="3">Histomodule 45K for fixation and decalcification (qty. 1)
includes A1-A2-A3
 
A
Ref. P/N 67320</td><td> 
A1</td><td>Glass container 135mm
Ref. P/N 67336L</td></tr>
<tr><td> 
A2</td><td>Holder for histomodule 45K
Ref. P/N 67326</td></tr>
<tr><td> 
A3</td><td>Cover complete
Ref. P/N 67330</td></tr>
<tr><td>Rack 45K complete (qty. 1)
includes B1
 
B
Ref. P/N 67325</td><td> 
B1</td><td>Magnetic stirrer complete
Ref. P/N 65594</td></tr>
</table>

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

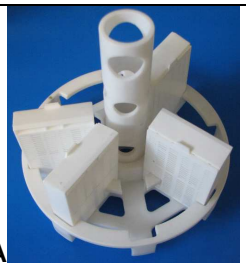
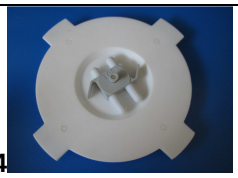
60 MEGA CASSETTES

<table>
<tr><th colspan="3">Starter Kit for mega cassettes for decalcification.
Includes A-B</th><th>Ref. P/N
67410</th></tr>
<tr><td rowspan="3">Histomodule 60 mega cassettes
includes A1-A2-A3
 
A
Ref. P/N 67409</td><td> 
A1</td><td colspan="2">Holder GHM-KOS
Ref. P/N 67385</td></tr>
<tr><td> 
A2</td><td colspan="2">Cover complete for GHM-KOS
Ref. P/N 67383</td></tr>
<tr><td> 
A3</td><td colspan="2">Glass container 5 litres
Ref. P/N 67388</td></tr>
<tr><td>Rack 60 mega cassettes
includes B1
 
B
Ref. P/N 60430</td><td> 
B1</td><td colspan="2">Magnetic stirrer complete
Ref. P/N 65594</td></tr>
</table>

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate GHM-KOS multifunctional **Ref. P/N 67384** (not included, to be ordered apart).

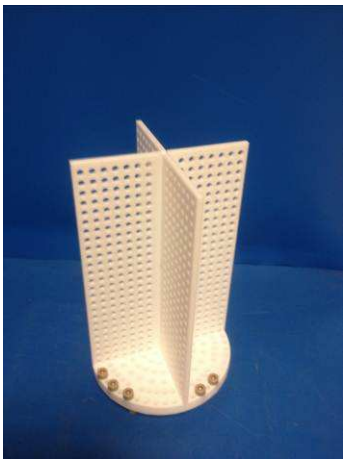
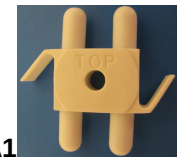
8 SUPER MEGA CASSETTES

<table>
<tr><th colspan="3">KIT 8 super mega cassettes for decalcification.
Includes A-B-C</th><th>Ref. P/N
67317</th></tr>
<tr><td colspan="4">  </td></tr>
<tr><td colspan="2"> 
A</td><td colspan="2">Rack 8 super mega cassettes for use with HISTOS unit
Ref. P/N 60301</td></tr>
<tr><td colspan="2"> 
B</td><td colspan="2">Positioning plate
Ref. P/N 67384</td></tr>
<tr><td rowspan="4">Histomodule for 8 super mega cassettes for KOS unit
includes C1-C2-C3-C4
 
C
Ref. P/N 67407</td><td> 
C1</td><td>Cover complete for GHM-KOS
Ref. P/N 67383</td></tr>
<tr><td> 
C2</td><td>Holder GHM-KOS
Ref. P/N 67385</td></tr>
<tr><td> 
C3</td><td>Glass container 5 litres
Ref. P/N 67388</td></tr>
<tr><td> 
C4</td><td>PTFE plate and new magnetic stirrer complete
Ref. P/N 60380</td></tr>
</table>

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate GHM-KOS multifunctional **Ref. P/N 67384** (supplied with the KIT).

INTERNAL DIVIDER

Internal divider suitable for histomodule Ref. P/N 67320 for decalcification of large specimens.		Ref. P/N 67443
Internal divider complete (qty. 1) includes **A1**  Ref. P/N 67443	**A1** 	Magnetic stirrer complete Ref. P/N 65594

When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

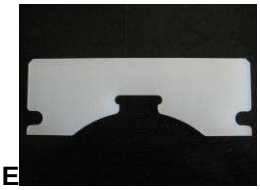
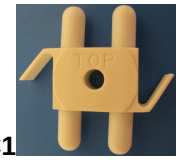
3.4. Special stains

16 SLIDES

<table>
<tr><th colspan="3">Histomodule 16KS for up to 16 slides complete.
Includes A-B-C</th><th>Ref. P/N
67350</th></tr>
<tr><td colspan="4">  </td></tr>
<tr><td colspan="2"> 
A</td><td colspan="2">TPX couplin jar
Ref. P/N 67337</td></tr>
<tr><td colspan="2"> 
B</td><td colspan="2">Cross magnetic stirrer
Ref. P/N 67344</td></tr>
<tr><td colspan="2" rowspan="3">Safety carrier complete
includes C1-C2-C3
 
C
Ref. P/N 67373</td><td> 
C1</td><td>Cover couplin jar
Ref. P/N 67404</td></tr>
<tr><td> 
C2</td><td>Safety carrier
Ref. P/N 67405</td></tr>
<tr><td> 
C3</td><td>Stirrer with base mounted
Ref. P/N 67402</td></tr>
</table>

To be used with positioning plate **Ref. P/N 67210** (supplied with unit).

3.5. GHM/K Gross hardening

<table>
<tr><th colspan="3">GHM/K histomodule for whole organs fixation complete.
Includes A-B-C-D-E</th><th>Ref. P/N
67394</th></tr>
<tr><td rowspan="5">  </td><td> 
A</td><td colspan="2">Holder GHM-KOS
Ref. P/N 67385</td></tr>
<tr><td> 
B</td><td colspan="2">Glass container 5 litres
Ref. P/N 67388</td></tr>
<tr><td> 
C</td><td colspan="2">Gross Hardening Module GHM-KOS
Ref. P/N 67375</td></tr>
<tr><td> 
D</td><td colspan="2">Cover complete for GHM-KOS
Ref. P/N 67383</td></tr>
<tr><td> 
E</td><td colspan="2">Positioning Plate GHM-KOS multifunctional
Ref. P/N 67384</td></tr>
<tr><td>Gross Hardening Module GHM-KOS complete includes C1
 
C
Ref. P/N 67375</td><td> 
C1</td><td colspan="2">Magnetic stirrer complete
Ref. P/N 65594</td></tr>
</table>

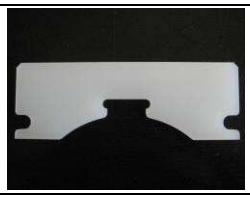
When required, remove the built-in stirrer by rotating the screw clockwise.

To be used with positioning plate GHM-KOS multifunctional Ref. P/N 67384 (supplied with unit).

3.6. Summary table

HISTOMODULE	Ref. P/N	APPLICATION
45K	67320	Tissue processing of up to 45 cassettes, for the fixation, JFC, ethyl alcohol and isopropanol steps, decalcification and high temperature procedures.
45K WAX	67370	Tissue processing of up to 45 cassettes, only for the WAX step.
4K	67300	Tissue processing of up to 4 cassettes, for the fixation, JFC, ethyl alcohol and isopropanol steps and decalcification.
4K WAX	67360	Tissue processing of up to 4 cassettes, only for the WAX step.
16KS	67350	Special stains (histochemical) and high temperature procedures for up to 16 slides.
40KS	67355	Antigen retrieval for up to 40 slides complete, with Nr. 2 racks for 20 slides each. N.B. Order Nr.4 racks for 20 slides each to run up to 80 slides.
GHM/K	67394	Gross hardening of organs for reliable uniform gross sectioning of whole organs.
GPR/K	67415	Antigen retrieval under pressure at high temperature for up to 40 slides complete, with Nr. 2 racks for 20 slides each.
8SM	67407	Histomodule 8 super mega cassettes for decalcification.
60M	67409	Histomodule 60 mega cassettes for decalcification.

RACK	Ref. P/N	APPLICATION
Rack for 45 cassettes	67325	Histoprocessing, Decalcification, Fixation.
Rack for 4 cassettes	67301	Histoprocessing, Decalcification, Fixation.
Rack for 20 slides	40156/2	High Temperature Procedures up to 120℃. Supplied in quantity 2. Order Nr.4 racks for 20 slides each, to run up to 80 slides.
Rack for 60 mega cassettes	60430	Decalcification.
Rack for 8 super mega cassettes	60301	Decalcification.
Internal divider	67443	Decalcification.

POSITIONING PLATE	Ref. P/N	APPLICATION	IMAGE
Standard	67210	Positioning plate specific for 45K, 4K, 16KS, 40KS cassettes modules.	
GHM-KOS multifunctional	67384	Positioning plate specific for GHM/K, GPR/K, 60 mega cassettes, 8 super mega cassettes modules.	

It's possible to run EM processing of samples by ordering the Starter Kit for EM processing and polymerization for KOS Unit (Operation manual MM078).
To operate your KOS for EM processing, ask for authorization to Milestone s.r.l, mail:
medical@milestonesrl.com
customersupport@milestonemedsrl.com

4. OPERATE WITH KOS

The KOS is controlled by an integrated touch control terminal, which is based on Windows CE operating system.

The system has numerous pre-stored programs for tissue processing, high temperature procedures, decalcification, fixation, gross hardening and special stains, with ability to store numerous customer defined programs.

Power output is automatically controlled by a PID (Proportional Integrative Derivative) algorithm, which allows the operator to set up the desired parameters (Time and Temperature) by simply drawing a curve. If a pre-stored program is used, it is only required to adjust the time of the procedure in relation to the specifications of the application.

The KOS allows the user to gain consistency and reproducibility of high quality results thanks to the working procedures based on the concept of TIME at TEMPERATURE. The unit will always reproduce the same conditions of temperature in the set times, by automatically adjusting the power level.

The KOS also allows the use of procedures based on the concept of TIME at POWER. The unit will always reproduce the same conditions of power in the set times, by automatically adjusting the temperature level.

The following sections will show how to run, modify and create a program with the Touch Control terminal.

If additional information is required on the operation of the software for each of the sections below, contact your local application support from your distributor.

4.1. Touch control

On switching the power to KOS, the unit will run through a system check and enter the main login screen user mode. The operator is required to log-in by touching the icon that relates to login (as an operator), either as a USER, ADMINISTRATOR or SERVICE, then entering the password using the numeric keyboard.

On accepting the numeric entry login code, the MAIN MENU will appear consisting of touch screen icons that are for specific applications, along with a number of ancillary functions.

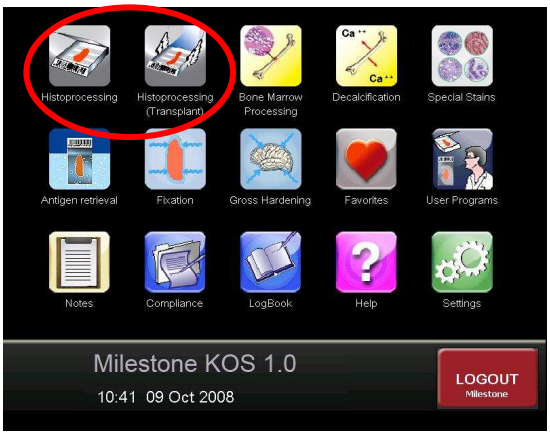
For added security, the system enables different authorized users to logon by having a LOGOUT function key at the bottom right of the screen and to prevent unauthorized use.

Milestone s.r.l recommends that these instructions are kept near the instrument to facilitate operations and better understanding of the software functions, especially when operating the unit for the first time.

4.2. Run programs

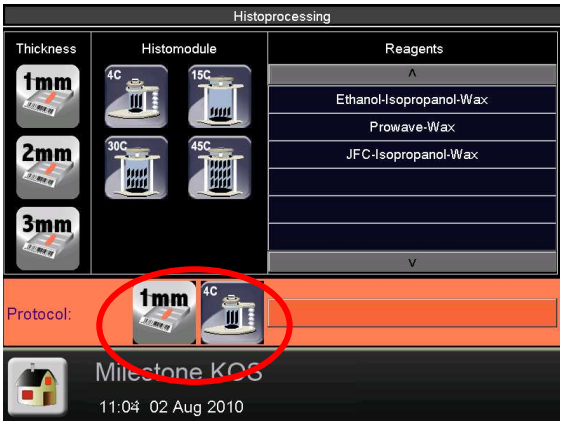
4.2.1. Histoprocessing

From the main menu screen, it is possible to select preset tissue processing. Select the HISTOPROCESSING icon for routine samples and the HISTOPROCESSING TRANSPLANT icon for transplant biopsies, as indicated below.
On selecting HISTOPROCESSING, the screen on the right appears. Using the touch screen, select the sample THICKNESS (1, 2 or 3 mm), the HISTOMODULE (4C, 15C, 30C or 45C) and the REAGENTS protocol to be used, see the example below:

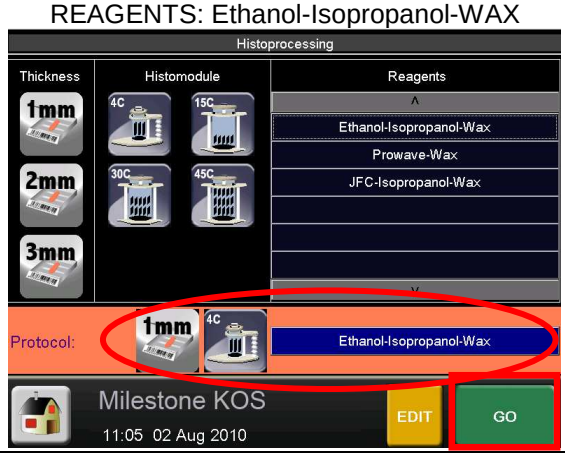


THICKNESS: 1mm

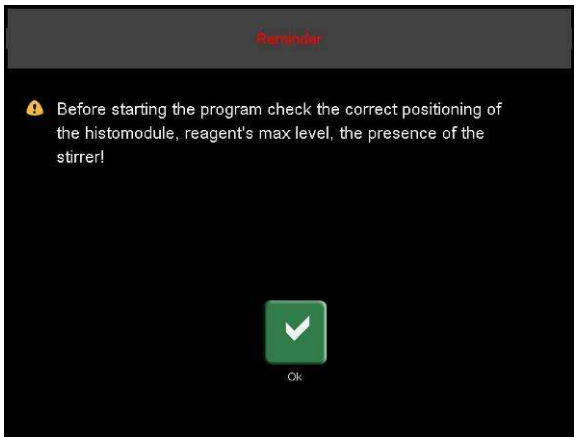
HISTOMODULE: 4C



REAGENTS: Ethanol-Isopropanol-WAX

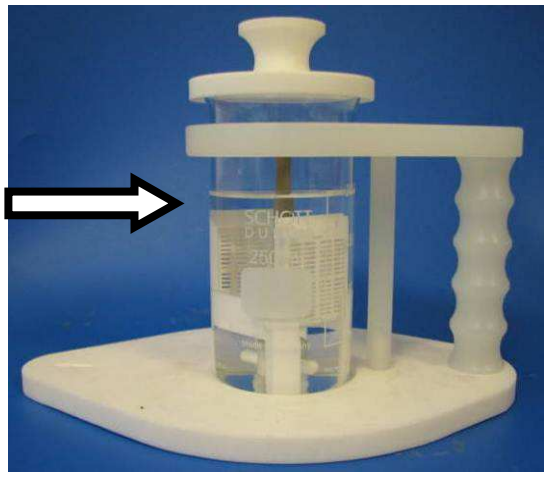


Now select the active green “GO” icon: a REMINDER screen appears (see the image below on the left).
The histomodule must match the positioning plate to be in proper position inside the cavity (left circle figure below). For further confirmation, check that the laser beam centers the rack (right circle).

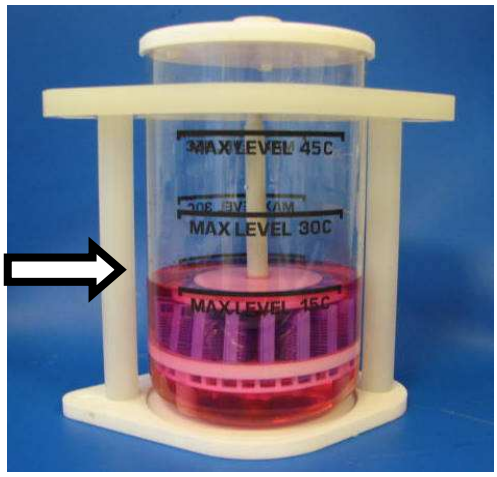


The correct level of reagents depends on the number of cassettes used:

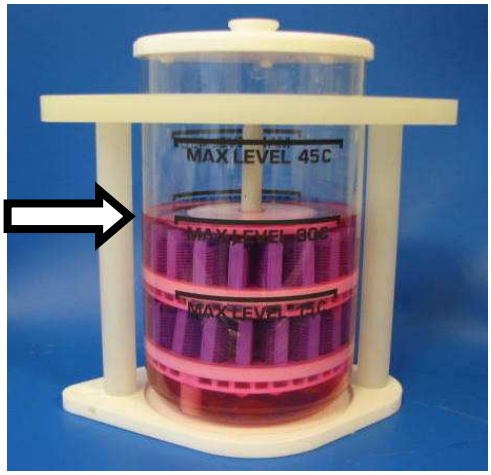
4C: the correct level is approximately 1cm (0.39 inch) above the cassettes (reagent about 200ml).



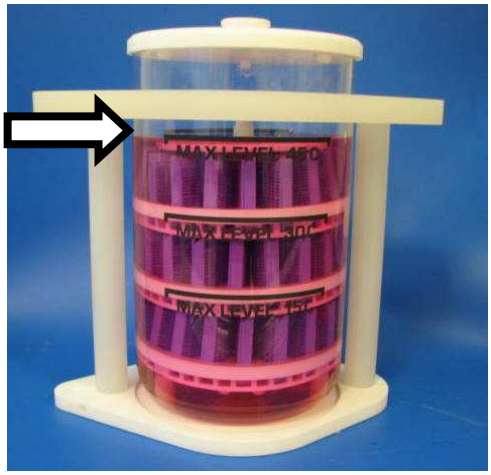
15C: the correct level is labeled on the Histomodule (reagent about: 900ml 1 cassette- 850ml 15 cassettes)



30C: the correct level is labeled on the Histomodule (reagent about: 1400ml 16 cassettes- 1350ml 30 cassettes)



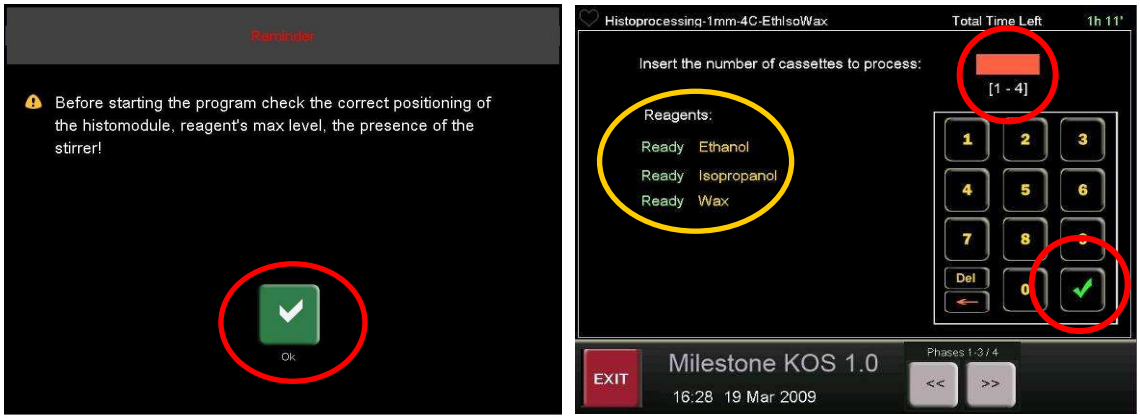
45C: the correct level is labeled on the Histomodule (reagent about: 1900ml 31 cassettes- 1850ml 45 cassettes)



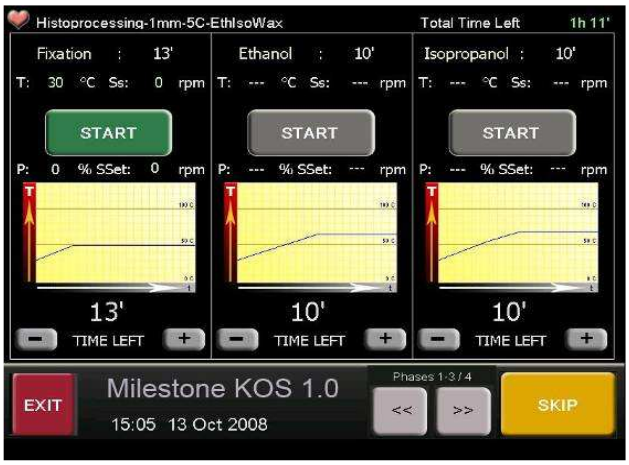
Load the RACK with cassettes and position the CASSETTE FIXING DISK on top. The fixing disk must always be used, in order to avoid possible spilling out of cassettes from the rack during the processing.

Position the module to fit with the positioning plate, when the module is correctly positioned, the reagent level is adequate and the magnetic stirrer is present, select OK in the REMINDER screen. See left figure next page.

The screen on the right (next page) appears displaying a keypad: ENTER the number of cassettes to process.
The Reagent Management System will be automatically updated and the number of cassettes selected will be added to the cassettes already processed, so that also the status of the different reagents is kept automatically updated up to their expiration time. For further information see also the chapter 4.11.1.
The yellow circle below displays the status of reagents. In this example, it is shown as READY, in other cases it can be NEAR LIMIT or EXPIRED.



After entering the number of cassettes to process, press the green arrowed check box. A display of the processing phases appears.



ICONS explanation:

START: highlighted in green will start the selected phase. When highlighted in gray color, it is not active.

SKIP: will advance the START icon to the next reagent phase: this allows manually start of a program at any phase required, if wishing to bypass a reagent phase. Note that the SKIP function will deactivate the previous phase by displaying COMPLETED, so do not use this function unless certain that this is what is required.

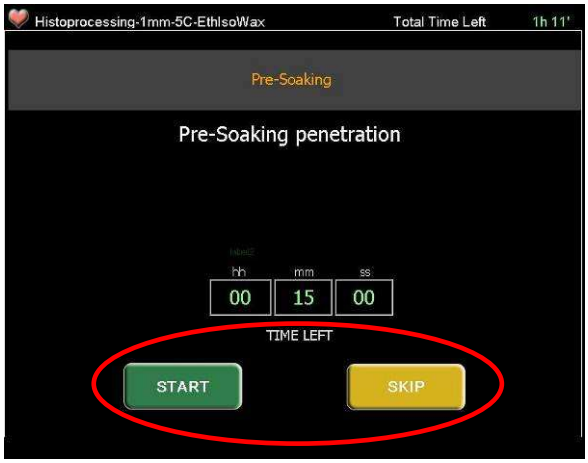
<< >>: to scroll the screen and see all reagent phases.

-/+: to SUBTRACT/ADD time to a selected phase, either running or to be run.

EXIT: to cancel and exit an application. A message appears requiring confirmation to abort the process or not. By choosing OK, user is required also to save any data up to the point of exiting.

FIXATION

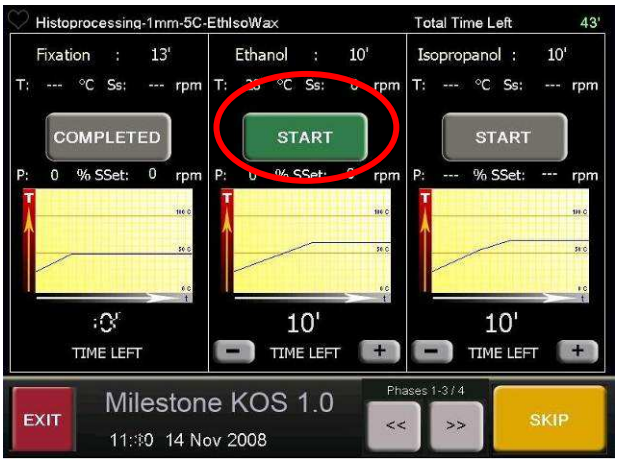
Start the tissue processing by first loading the cassettes into the rack and begin from FIXATION.
Fixation must be preceded by a Pre-soaking step at room temperature in formalin.



If the samples have been already fixed out of the KOS, bypass the pre-soaking step selecting the SKIP icon.
Otherwise, if samples have not been fixed yet, include the pre-soaking step pressing the START icon.
On completion of the Pre-soaking step, the Fixation phase will automatically start.
During the microwaving phase in formalin, a RED line, representing the real time temperature curve, will follow the BLUE preset temperature curve.
On completion of Fixation an audio alarm will sound (the operator can silence it on the screen).

ETHANOL

The screen now displays the GREEN START icon to the Ethanol phase. Transfer cassette rack to the ethanol module.
Select START for the Ethanol phase. The GREEN START icon will advance to a REMINDER screen, advising the operator to rinse the fixed samples in two changes of 100% ethanol, to remove formalin and water residue carryover.
On completion of the RINSING step, select DONE. See below right figure.

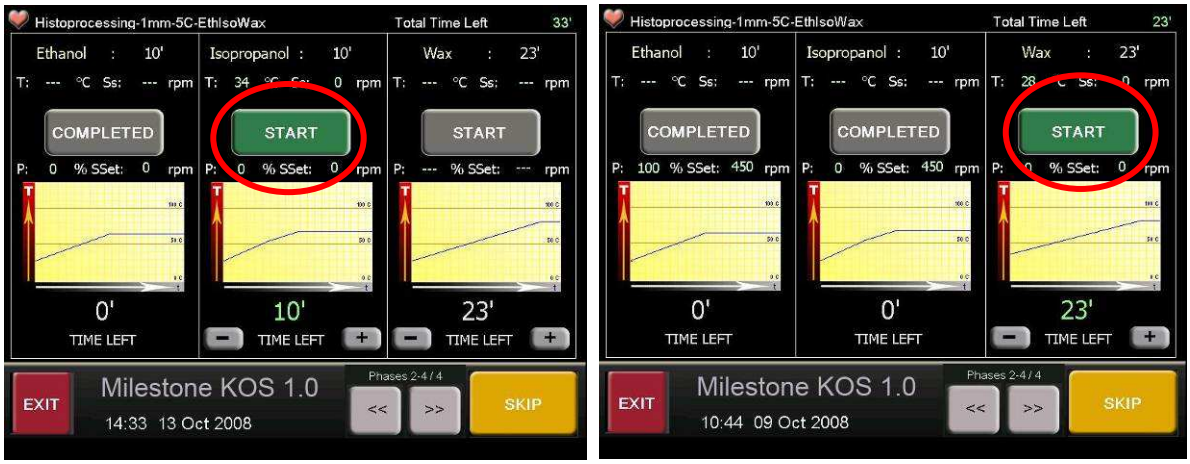


The screen will advance the GREEN START icon to the Ethanol Phase. On completion of DEHYDRATION and AUDIO ALARM sounds, cancel it.

ISOPROPANOL

The screen now advances the GREEN START icon to the Isopropanol phase. Transfer cassette rack to the Isopropanol module.

On completion of the Isopropanol phase an audio alarm sounds, cancel it. The GREEN START icon will advance to the WAX phase.



WAX Impregnation

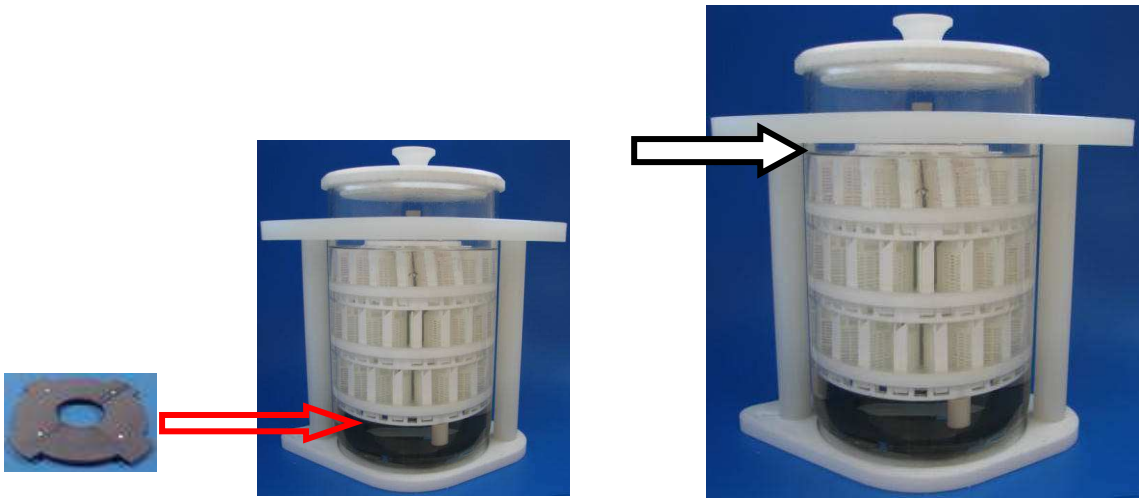
Now move the WAX module, currently sitting in your paraffin oven, to the KOS unit and transfer the cassette rack into the WAX module.

For WAX phase, remember to insert the HEATING DISK in the glass container before positioning the rack, as shown below, figure on the left. Failure to do this will damage the samples. For further information, see the chapter 3.

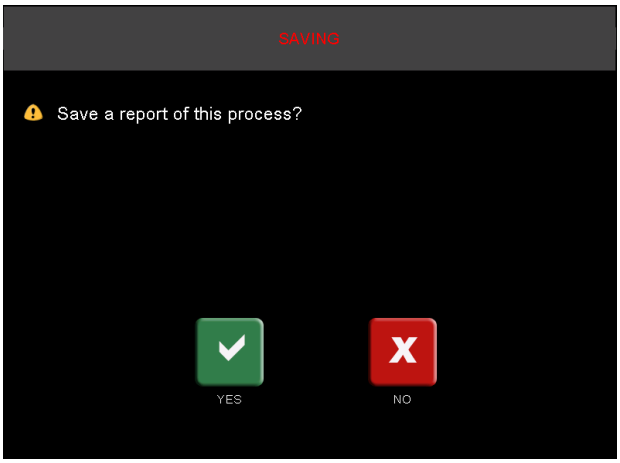
It is allowed to PUT ONLY MELTED WAX INSIDE the KOS.
Do NOT MELT WAX INSIDE KOS unit as this will damage the heating disk (warranty voided).
Melt wax only in an external oven.
When not in use, keep wax melted in an external oven so that it is ready for use.

When using rack 15K, 30K or 45K the paraffin level must be ready for use with up to 3 layers of cassettes (figure below on the right).
The level of WAX should reach the limit indicated on the glass (rack included, for any number of cassettes processed) but not exceed it.
Put approximately 0.7 kg of paraffin to reach the proper level of paraffin.

When using rack 4K, the correct level of paraffin is approximately 1cm (0.39 inch) above the cassettes.



Now START the WAX program: on completion of the WAX phase, an audio alarm sounds and this screen appears, asking to SAVE a report of the process. This report can be accessed later.

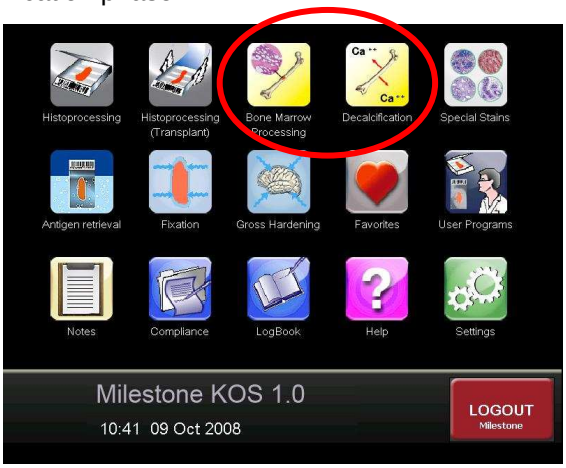


On completion of run and removal of rack, top up WAX level (the loss is due to tissue absorption and carry over from rack).
The WAX module is removed and taken to the embedding center where the cassettes are embedded.
The processing procedure is now complete and another processing run can be started.

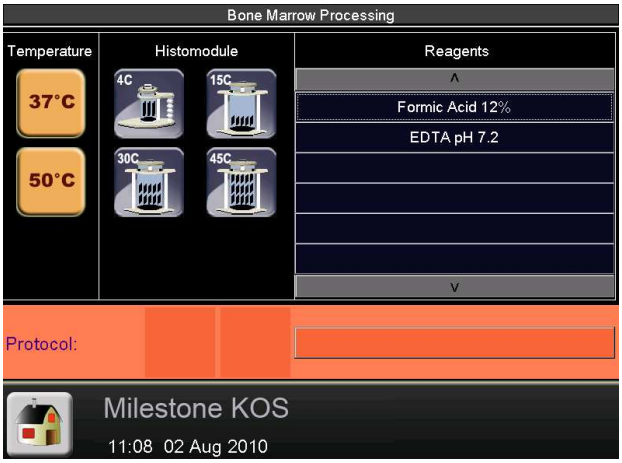
SCREENSAVER
Touch the graphical display of a running program to activate the SCREENSAVER, that displays the time remaining of the currently running phase. To exit screensaver and go back into the graphical display, touch the screen and the user name appears, enter the login PASSWORD in the white box by touching it.

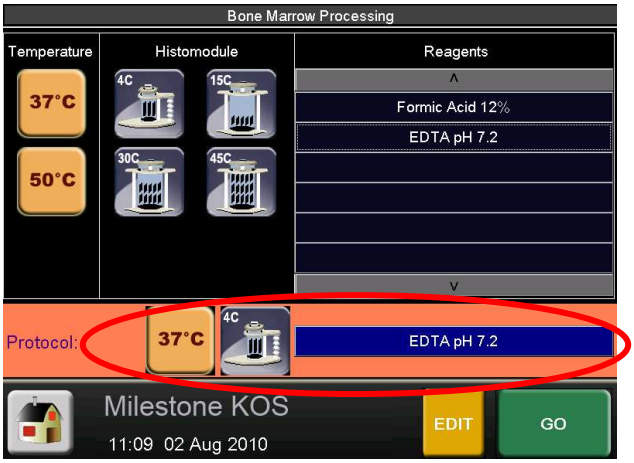
4.2.2. Decalcification

From the MAIN MENU screen select the DECALCIFICATION icon to be used. Note that BONE MARROW PROCESSING includes tissue processing after the decalcification, whereas DECALCIFICATION for larger bones will do ONLY the decalcification phase.

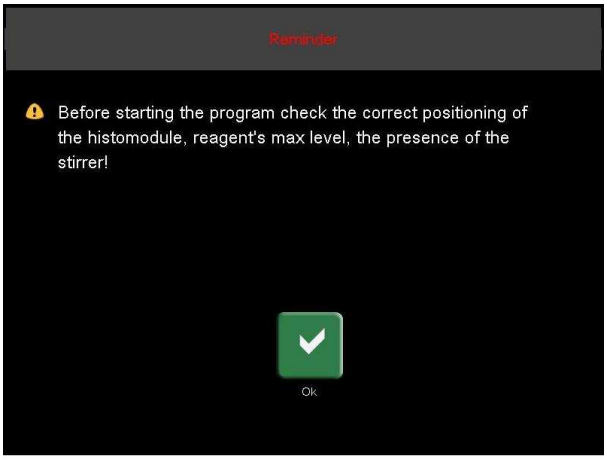


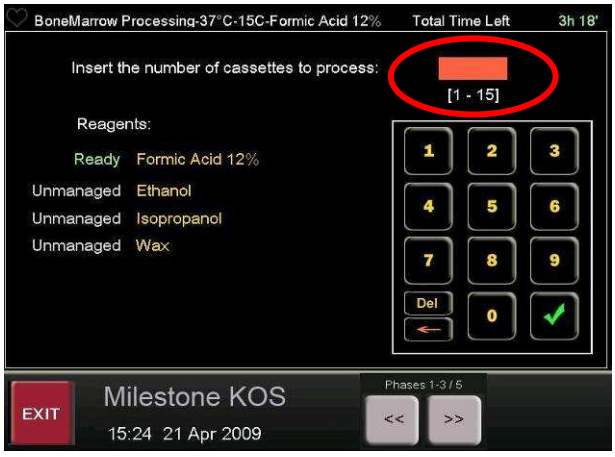
Select the BONE MARROW PROCESSING icon, the screen on the left appears.
The correct sequence is: first select the TEMPERATURE, second the HISTOMODULE, then the DECALCIFICATION REAGENT to use.



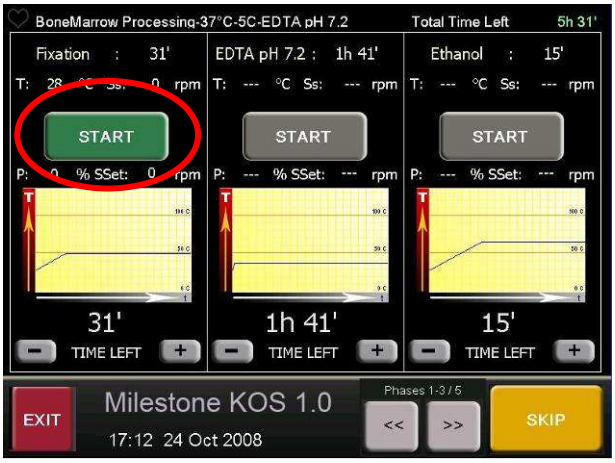


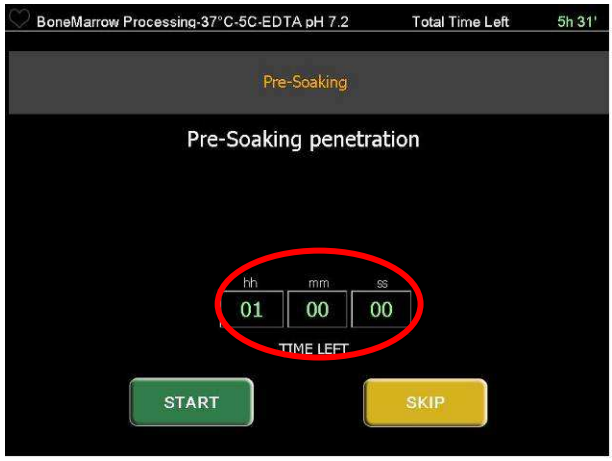
Press GO to reveal the program or select the EDIT icon, to copy and customize the parameters needed.
Press GO and the system will automatically show the entire sequence. Several screen prompts advise the action to take at each phase and step.
At the beginning this message appears (see below left figure). Check and confirm.
Then user is requested to enter the number of cassettes to be decalcified (right figure).



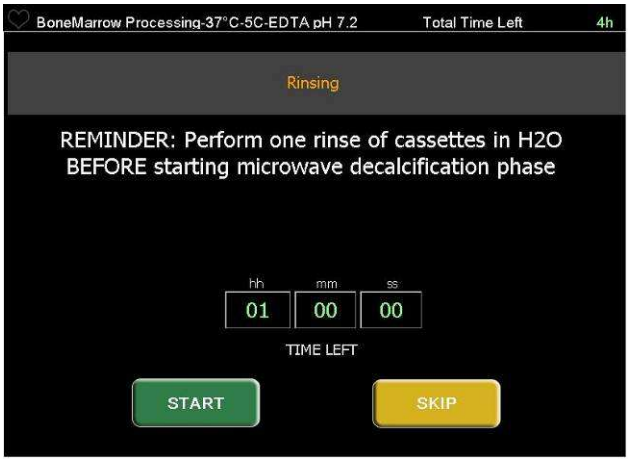


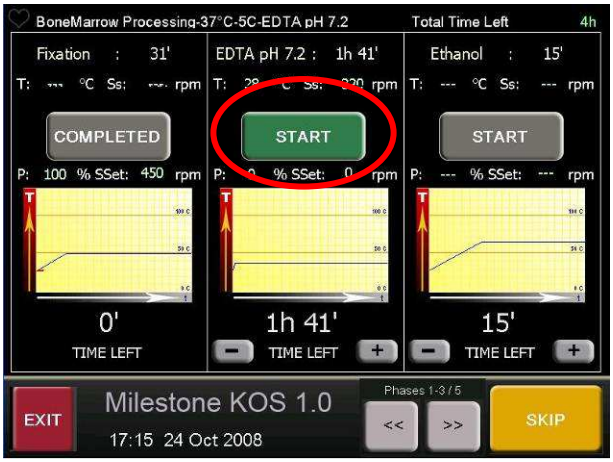
Now the FIXATION phase is displayed.
Press START and a screen appears, indicating the PRE-SOAKING PENETRATION time of tissues in fixative, before the microwave fixation phase.



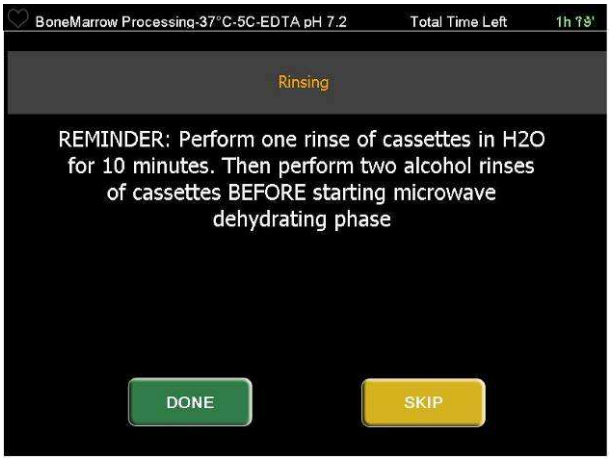


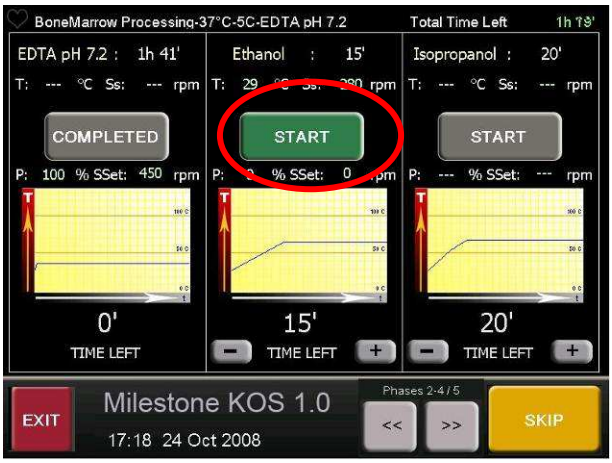
If tissues have been previously fixed, it is possible to SKIP the fixation phase and proceed to the DECALCIFICATION phase, by using the SKIP icon on the bottom of the screen.
Otherwise press the START icon to begin the fixation phase.
On completion of pre-soaking time in fixative, the system will AUTOMATICALLY START the microwave FIXATION phase.
On completion of FIXATION an AUDIO ALARM sounds, cancel the alarm. A screen appears reminding to perform a rinse in water before commencing the DECALCIFICATION phase (left figure below).
On completion of the rinsing time in water, an AUDIO ALARM sounds, cancel it. Now select the START icon for DECALCIFICATION (right figure below).



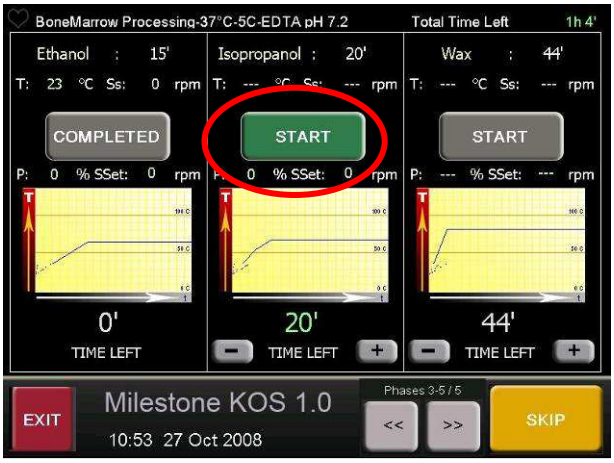


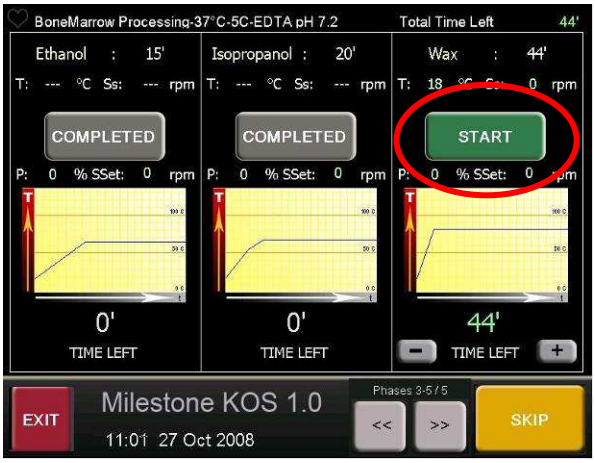
On completion of the DECALCIFICATION an AUDIO ALARM sounds, cancel it.
Now BEFORE starting the DEHYDRATION phase, a message advises to perform a rinse in water for 10 minutes followed by two quick rinses in ethanol (figure below left), press START to perform it.
Press SKIP icon to bypass this rinsing, if not required.
Start the DEHYDRATION phase by clicking on START icon (figure below right).





On completion of DEHYDRATION an AUDIO ALARM sounds, cancel it. Select the ISOPROPANOL clearing phase and press START (figure below left).
On completion of clearing in ISOPROPANOL an AUDIO ALARM sounds, cancel it.
Get the WAX module out from the paraffin oven. Please refer to the WAX phase described in the chapter 4.2.1 for proper use of WAX Histomodule. Then START the WAX phase (figure below right).



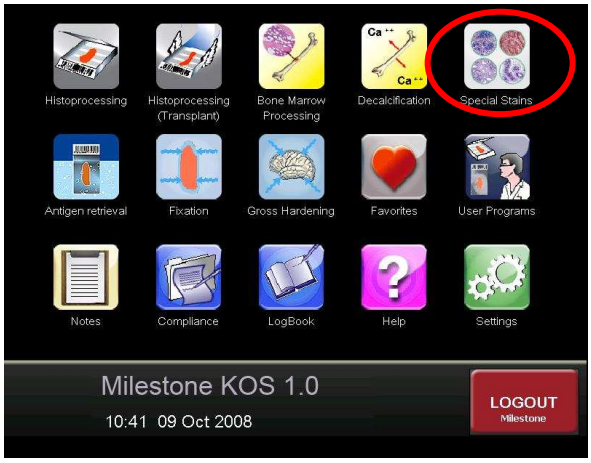


On completion of the last phase (WAX phase), the AUDIO ALARM sounds and a screen appears asking whether to SAVE a report for this process or not.

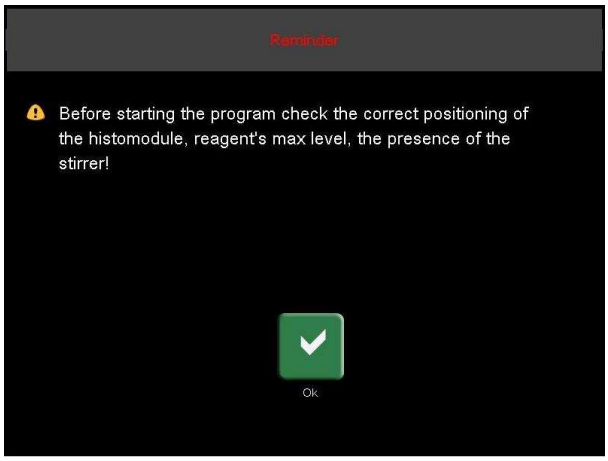
This report is essential for documenting the entire procedure just completed, which can be retrieved for review and printing at a later date.
Now transfer the cassettes to the embedding center and return the WAX module to the paraffin oven.
On completion of embedding, clean the cassette rack, so it is ready for the next run (see the Rack cleaning procedure chapter 6.2.1).

4.2.3. Special stains

From the MAIN MENU screen, select SPECIAL STAINS icon shown below.



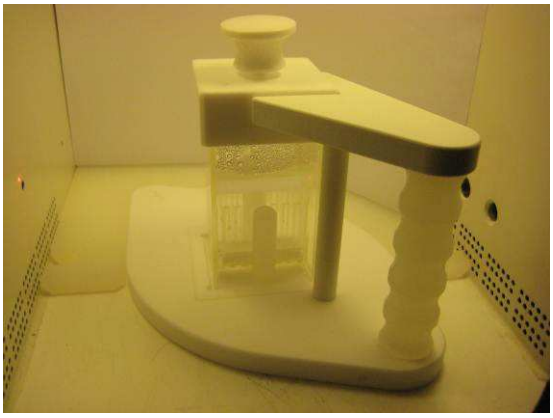
Select a stain, in the example below ELASTIC ORCEIN (figure left). A reminder screen appears (figure right).



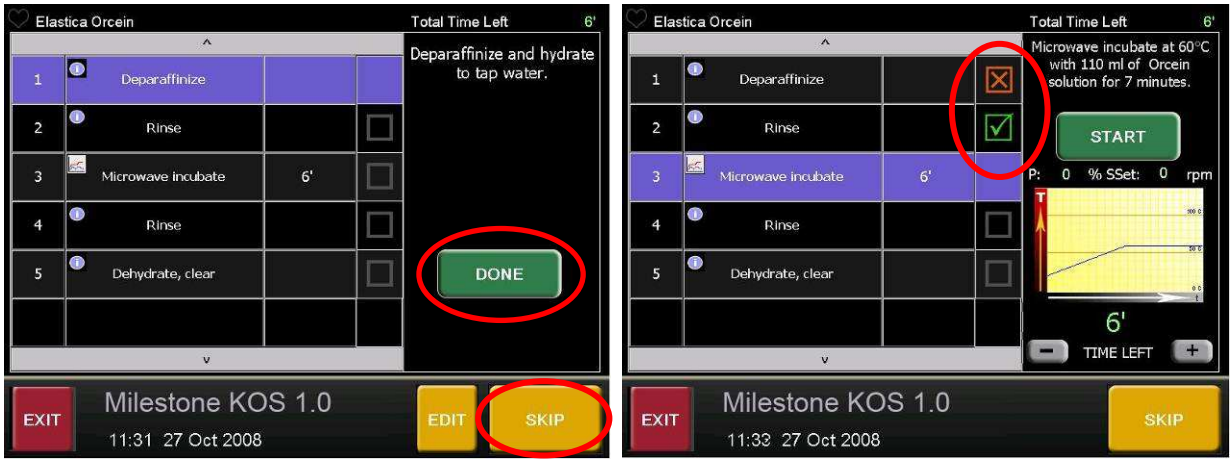
Select OK to go into the working program screen, showing the FULL STEP BY STEP PROCEDURE, from dewaxing to mounting of slides.

This detailed procedure is ideally suited for junior techs under training in the procedure.
For the experienced user the procedure can be customized to show only the MAIN steps.
For more details see the chapter 4.4.
Please remember that:

- **all non-microwave steps are performed outside the KOS unit**
- **all microwave steps are performed inside the KOS unit.**



In the screen below, move through each step by pressing DONE when completed, resulting in a green arrowed check box. By pressing the SKIP icon, the step is bypassed resulting in a red crossed check box.
In both cases, the program will advance to the next step.

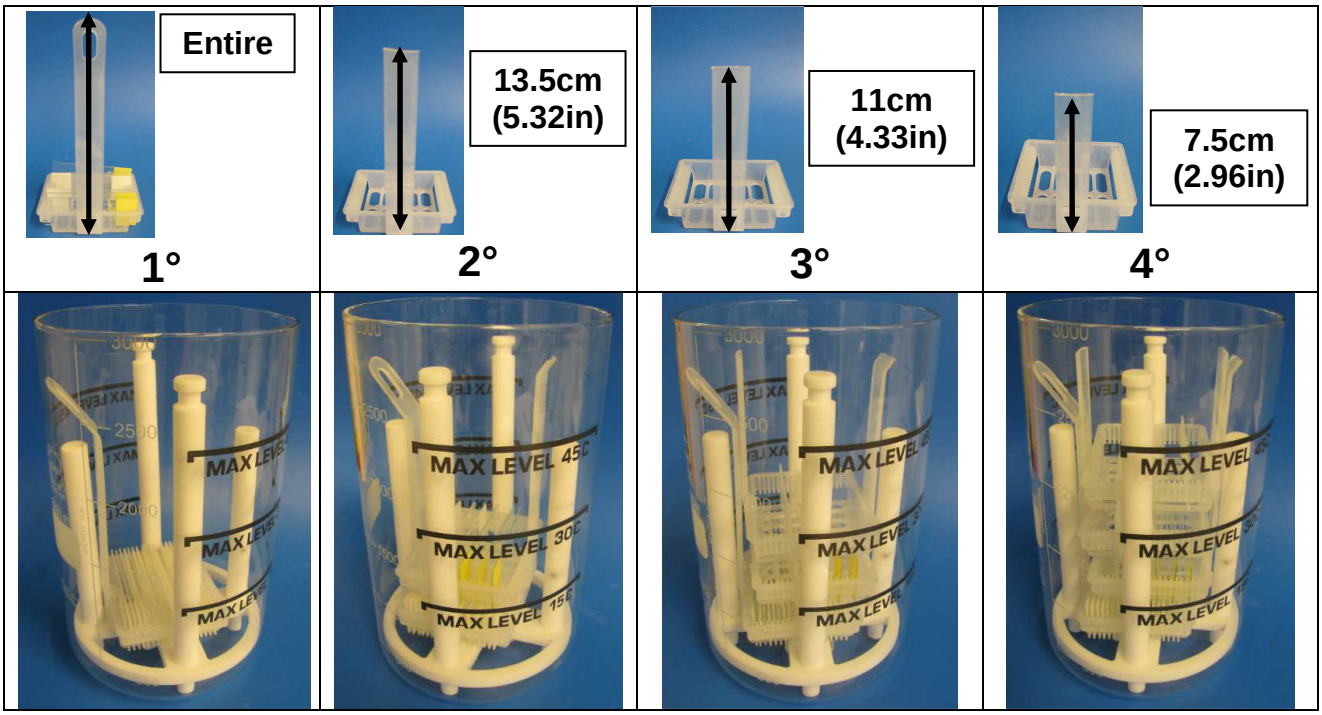


Go through all steps until the procedure is completed; a screen will appear asking to SAVE a report of this process, essential for documenting the entire staining procedure performed.

4.2.4. Antigen retrieval

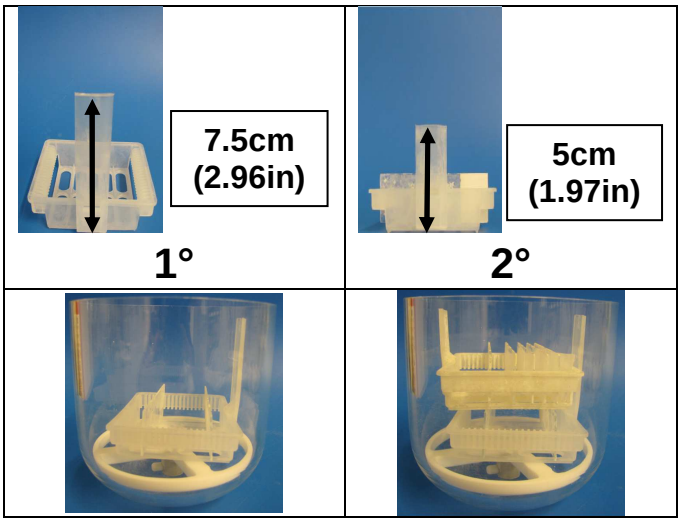
Use of rack for 20 slides inside histomodule 40KS or GPR/K requires a slight modification of the handle of these racks in order to have them perfectly fit inside the glass container.
These racks are supplied entire, with the long handle.
Pictures below indicate the height user had to cut the handle of the racks:

Histomodule 40KS



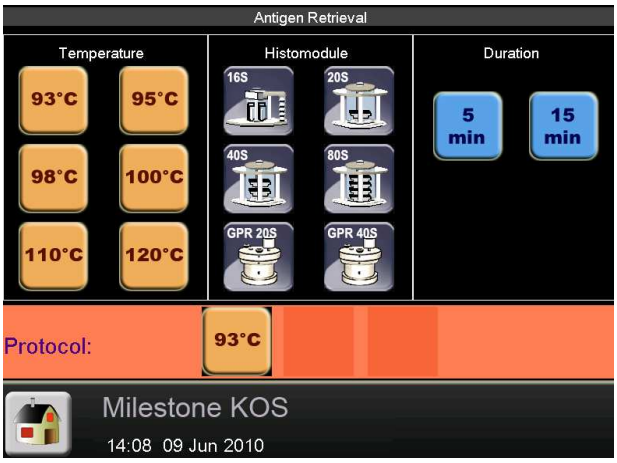
1. First rack is put on the bottom of the glass, no need of cutting the handle.
2. Second rack requires cutting at 13.5cm (5.32in) from the bottom.
3. Third rack requires cutting at 11cm (4.33in) from the bottom.
4. Fourth rack requires cutting at 7.5cm (2.96in) from the bottom.

Histomodule GPR/K



1. First rack requires cutting at 7.5cm (2.96in) from the bottom.
2. Second rack requires cutting must be cut at 5cm (1.97in) from the bottom.

From the MAIN MENU screen, select ANTIGEN RETRIEVAL, the screen on the right appears.



Using the touch screen function select:

- Temperature (93℃, 95℃, 98℃, 100℃, 110℃, 120℃),
- Histomodule (16S, 20S, 40S, 80S, GPR 20S or GPR 40S),
- Duration (5min or 15min).

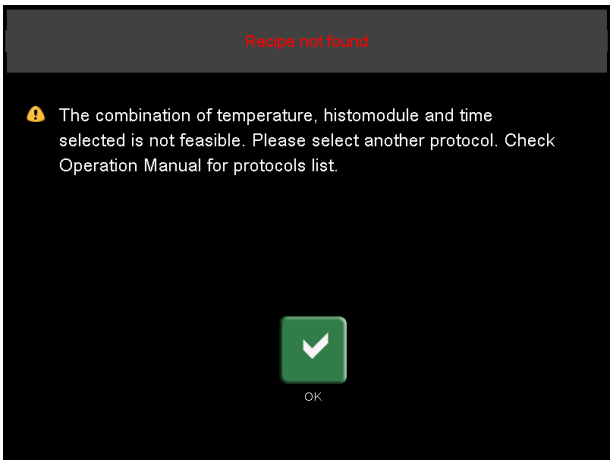
The duration (5min or 15min) refers to the Time at Temperature (93℃, 95℃, 98℃, 100℃, 110℃, 120℃).

When using more than 40 slides but less than 80 slides, select the program relating to the Histomodule 80S.

The default protocols for Antigen Retrieval are reported in the table below.

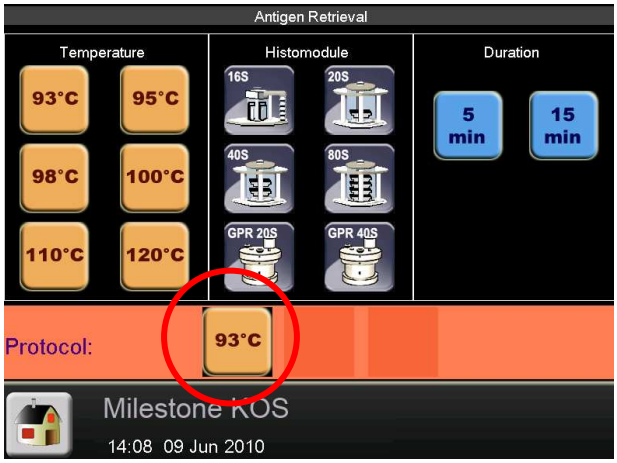
TEMPERATURE	HISTOMODULE	DURATION
93°C	16S	15MIN
95°C	20S-40S-80S	15MIN
98°C	20S-40S-80S	15MIN
100°C	GPR 20S-GPR 40S	5MIN
110°C	GPR 20S-GPR 40S	5MIN
120°C	GPR 20S-GPR 40S	5MIN

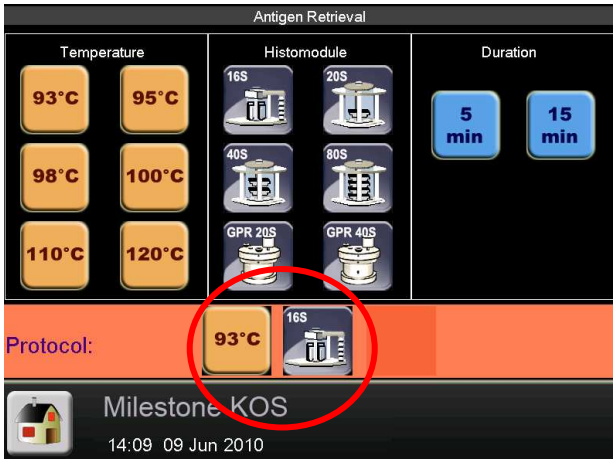
The following message appears when it is not selected a default program:

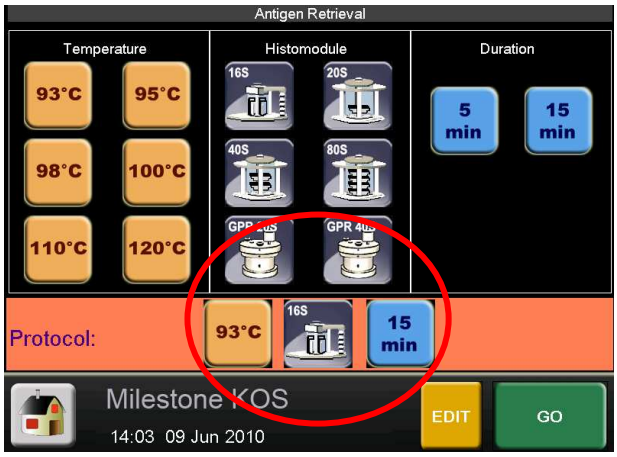


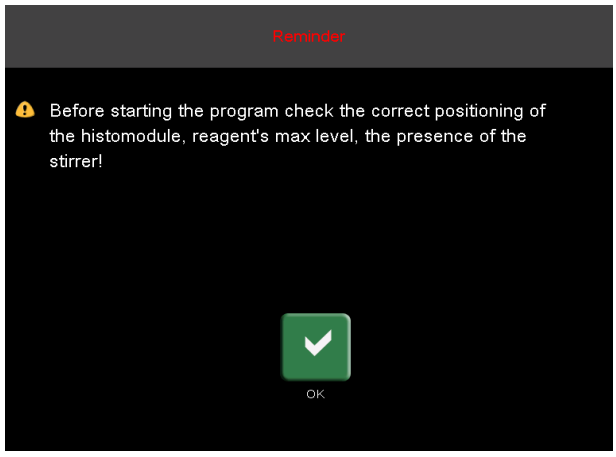
Click OK to go back to the home screen and choose a default protocol.

For example, select:
TEMPERATURE: 93℃
HISTOMODULE: 16S
DURATION: 15min

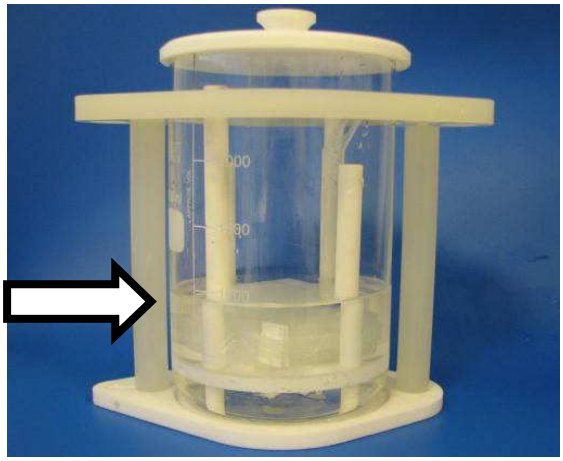








Press GO to reveal the program or select the EDIT icon, to copy and customize the parameters needed.
Press GO and the system will automatically show the confirmation screen (see above right figure).
On selecting OK on the REMINDER screen, the working program screen opens.
The correct level of reagents corresponds approximately to 1 cm (0.39 inch) above the slides.



GPR/K MODULE
Under Pressure High Temperature Antigen Retrieval up to 120℃.

DO NOT run programs with a maximum temperature set higher than 120℃.

Never open the locking nuts of the pressure reactor unless it has been cooled down: without proper cooling a sudden pressure release of hot vapors will occur.

DO NOT open the pressure release valve of the unit unless it has been cooled down: risk of hot vapors leakage that can affect operators safety.

DO NOT use glass reactor if cracked or damaged: replace it immediately.

DO NOT touch hot glass container before cooling, risk of burning.

When operating with the GPR/K, wear suitable laboratory grade coat, gloves, safety eye glasses.

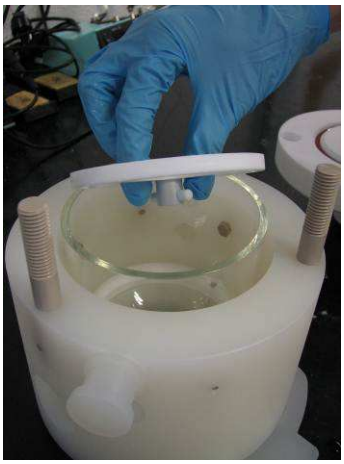
OPERATING PROCEDURE

Assemble GPR/K as follows:

1. Remove cover of GPR/K by first removing the pressure locking nuts by hand.

Proceed as follows: slightly unscrew ALL the nuts, make sure NOT to totally unscrew or remove any of them; when all nuts are partially unscrewed, proceed with taking them away one by one.

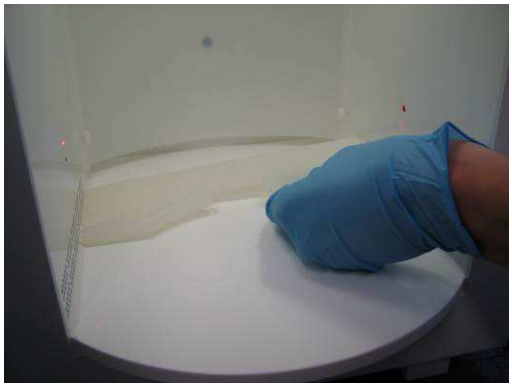
2. Insert the stirrer bar into the glass pressure vessel.



3. Insert slide rack with appropriately cut handle, add sufficient ER solution to cover the slides (approximately 550 ml for 20 slides and 750 ml for 40 slides).

4. Reposition the cover on the glass vessel and the pressure locking nuts into position and secure by hand. Proceed as follows: slightly screw ALL the nuts, make sure NOT to totally screw any of them; make sure that all nuts are totally screwed.

5. Insert positioning plate (Ref. P/N 67384) in the cavity. It should rest firmly against the back wall of the cavity.

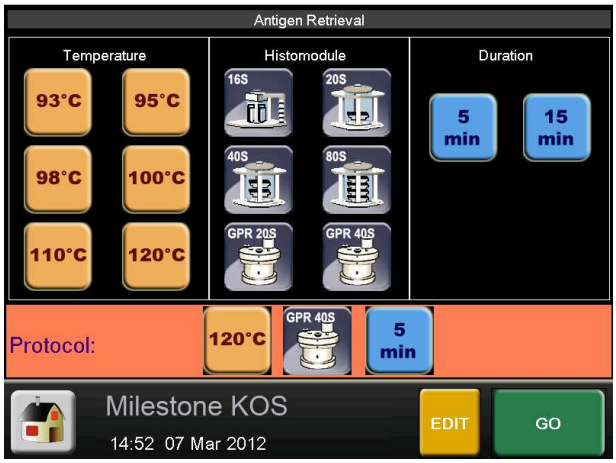


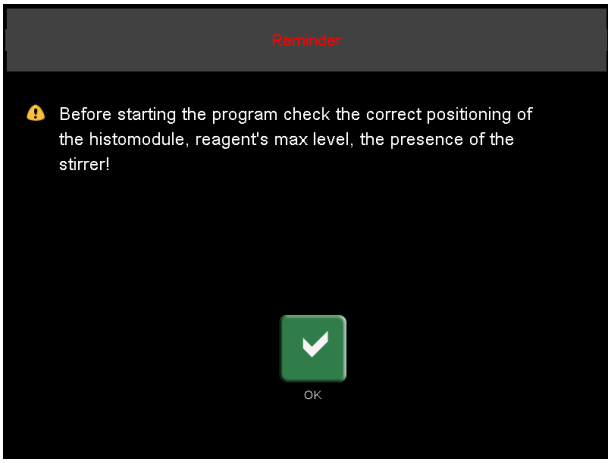
6. Lift the GPR/K using the safety handles and insert it into the cavity, firmly against the positioning plate to fit perfectly; the right position is shown in the picture below.

7. Choose the protocol:

TEMPERATURE	HISTOMODULE	DURATION
100°C	GPR20S-GPR40S	5MIN
110°C	GPR20S-GPR40S	5MIN
120°C	GPR20S-GPR40S	5MIN

For example:





Run the program by pressing the GO icon and the system automatically shows the confirmation screen (see above right figure).
Select OK to go to the working program screen.

On completion of Antigen program, the system warns the operator to SAVE a report of the Antigen program just completed.

8. Open the door, take the GPR/K out and slide in the cooling tube, turn on the water flow.

Take care of wearing gloves and safety eye glasses.

HIGH PRESSURE INSIDE.

Let it cool down for 5 minutes to get pressure back to normal.

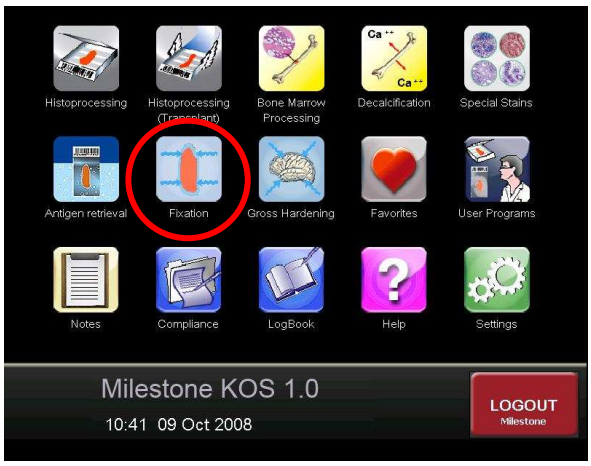
9. After cooling carefully lift the over pressure safety valve up. This assures the pressure is back to normal. Then it is possible to open the locking nuts.

10. Utmost attention must be paid when opening the GPR/K. If glass container does not separate from the cover (because of the vacuum generated during the cooling phase), do not force it but lift the over pressure safety valve up to let air in.

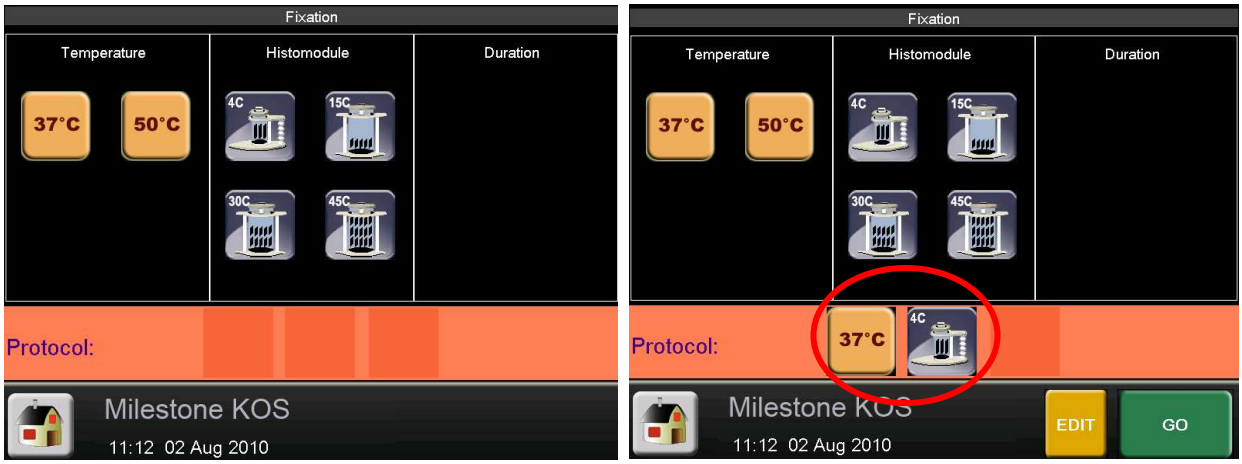
11. Take the slide racks out.

4.2.5. Fixation

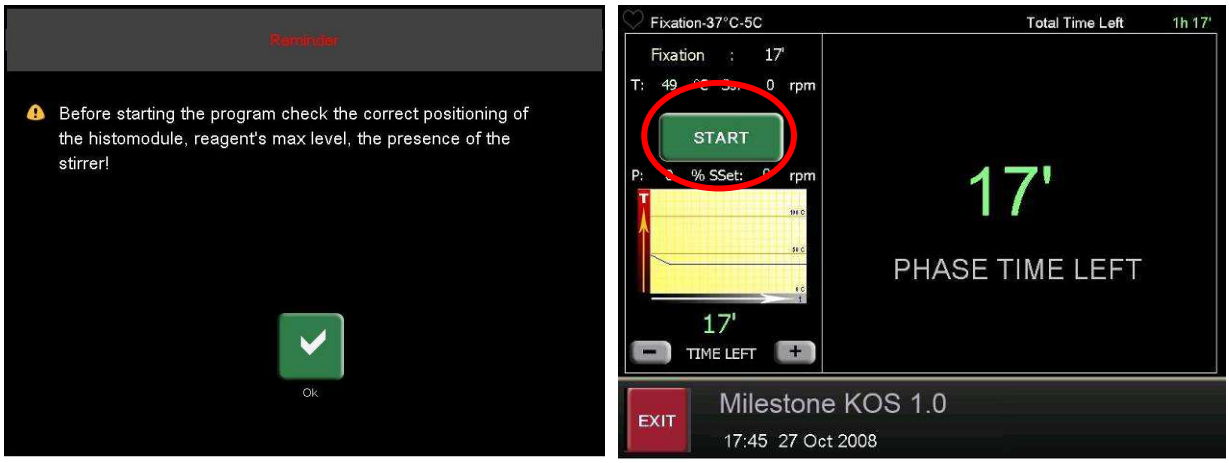
From the MAIN MENU screen, select FIXATION icon shown below.



The following screen appears: choose the fixation temperature and the histomodule to be used.



Press GO to reveal the program or select the EDIT icon to copy and customize the parameters needed.
On selecting GO the reminder screen appears (figure below left), press OK and the working program screen is displayed (figure below right).

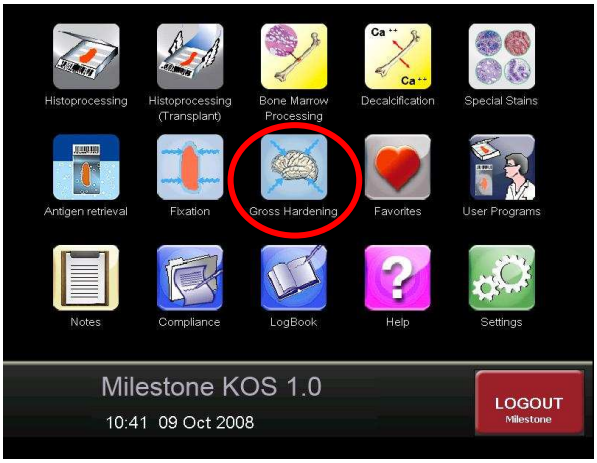


Pressing START, the system screen reminds a PRE-SOAKING penetration step, if required.
On completion of the pre-soaking time, the program will AUTOMATICALLY START the microwave fixation phase.

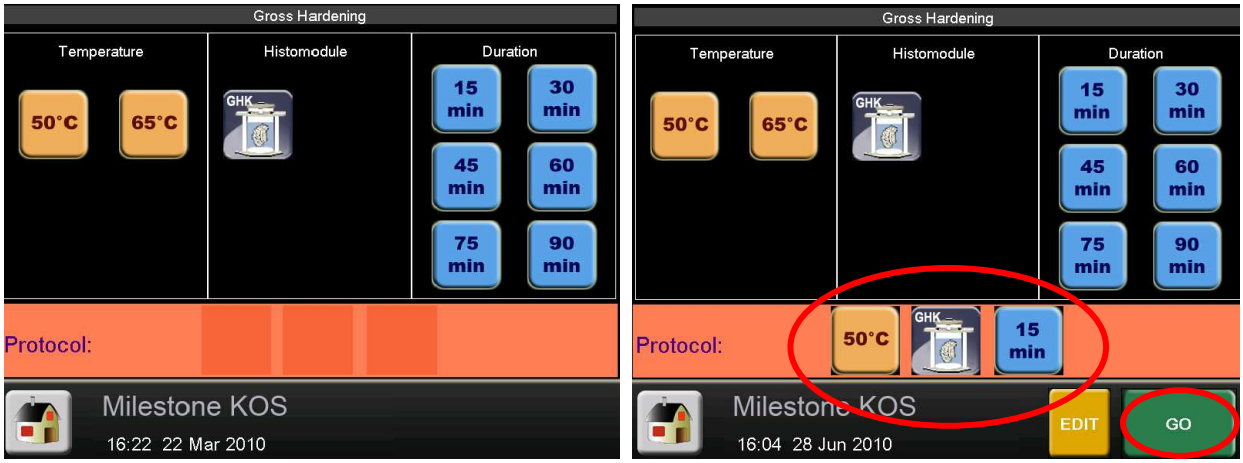
On completion of FIXATION, the system will display the screen requesting the operator to SAVE a report of the fixation program just completed.

4.2.6. Gross hardening

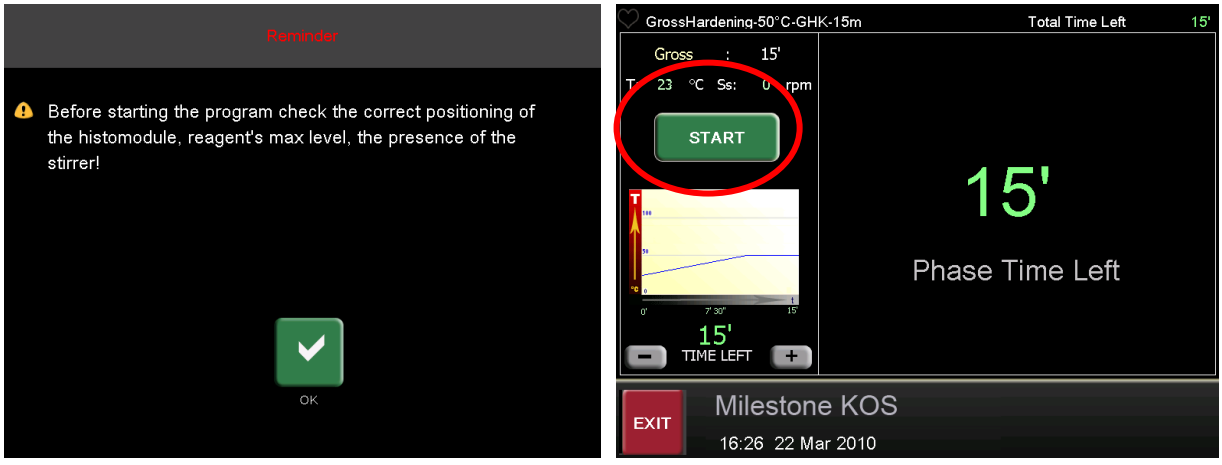
From the MAIN MENU screen, select GROSS HARDENING icon shown below.



The following screen appears: select the process temperature, the histomodule and the duration.



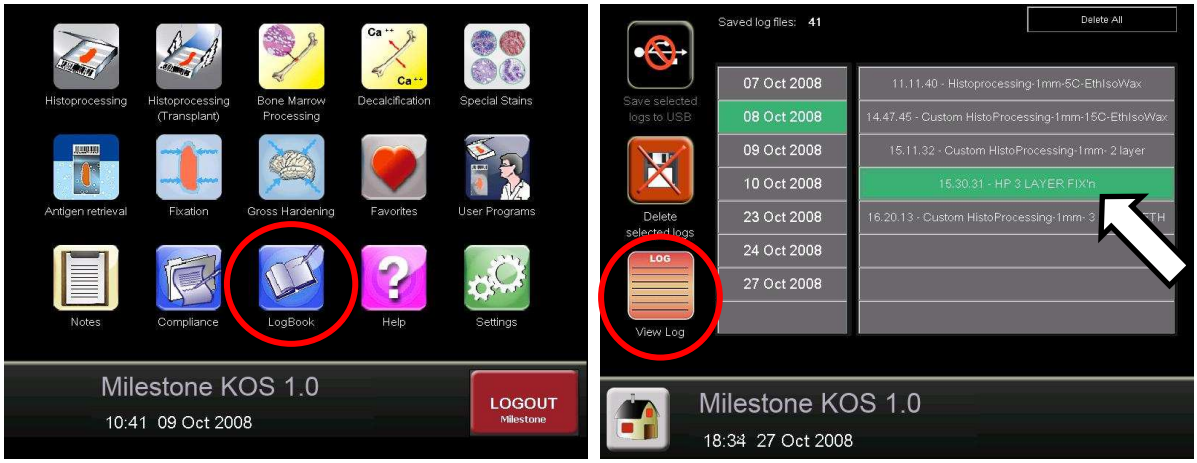
Press GO to reveal the program or select the EDIT icon to copy and customize the parameters needed.
On selecting GO the reminder screen appears (figure below left), press OK and the working program screen is displayed (figure below right).



On completion of GROSS HARDENING, the system will display a screen requesting the operator to SAVE a report of the program just completed.

4.3. Retrieving saved processing results

From the MAIN SCREEN, select LOG BOOK and the screen on the right appears: results, filed by DATE, and stored in the system are shown on the left.



Select a date and the relative list of results is displayed on the right. To view a specific file, select it and press View Log: the process executed is shown.

More detailed viewing information, as well as printing features, can be accessed using the Export function displayed below.
The exported files can then be viewed using our LOG VIEWER Software (supplied apart).
For further information see chapter 5.2.

At the end, exit using the HOME icon, as shown below.

4.3.1. How to delete a saved processing

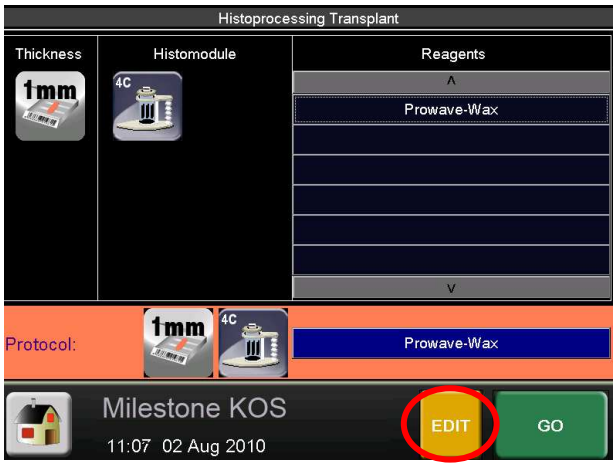
To DELETE a file or several files saved under a specific date, select and click on it/them, then press DELETE SELECTED LOGS icon.
"DELETE ALL" function: can be used to clear directly of all files that have been downloaded to a laptop via USB Key.
See the figure above, yellow rectangle.

4.4. How to modify a program

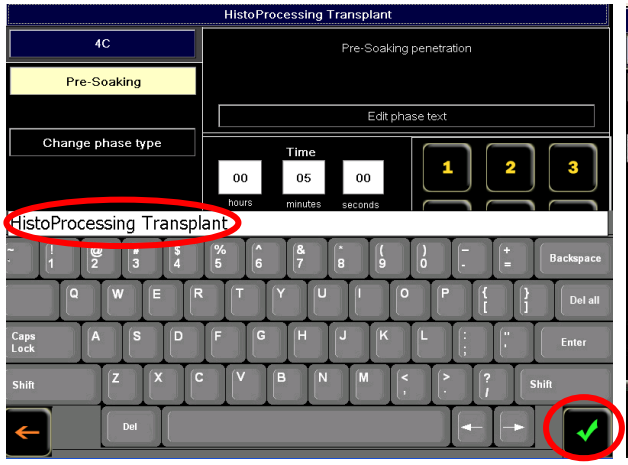
Before modifying any program, please remember to never change the ramping times, the heating rate (max power) and the default stirrer speed. Should any of these parameters be modified, contact your local application support from your supplier.

Modified applications are not listed under the corresponding icons of origin, but in a separate list under User Programs icon. For this reason it is severely recommended that any modified program is named appropriately.

To create a program irrespective of the application, select an existing program from the main menu below. On selecting the application, for example Histoprocessing Transplant, choose the processing protocol to be used as template. This procedure is similar to tissue processing procedure, but YELLOW “EDIT” icon must be selected instead of GREEN “GO” icon. See below.

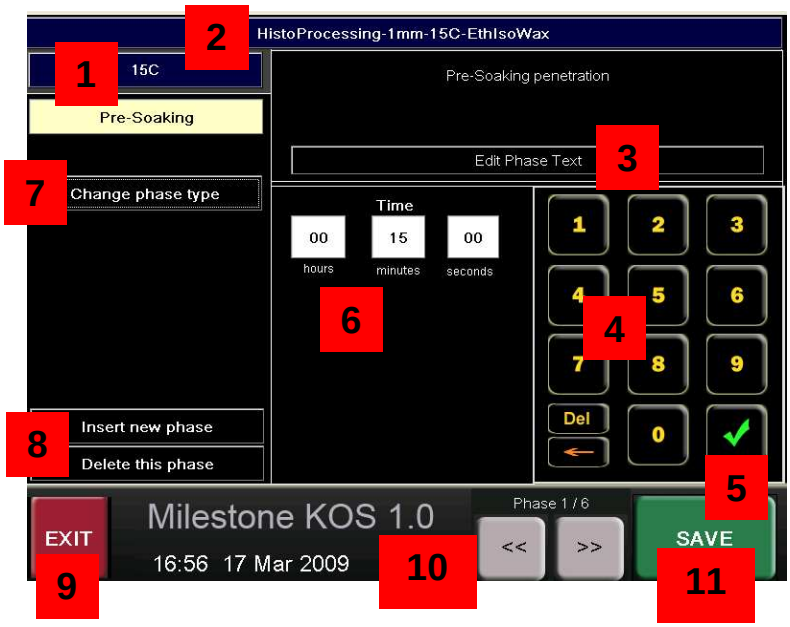


Click on EDIT icon, the following edit screen appears. To change the program name, enter the new one with the keyboard and press the green arrowed check box. Otherwise press directly the check box, if the name displayed is correct, as shown in the figure below.



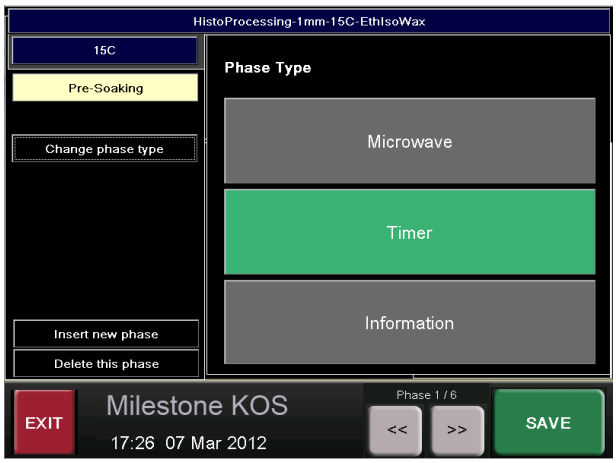
Do not use keyboard symbols to create a new program name (for example *, /, #). Use numbers, letters and only the symbol “-“.

Then the following edit screen appears. See the image below.



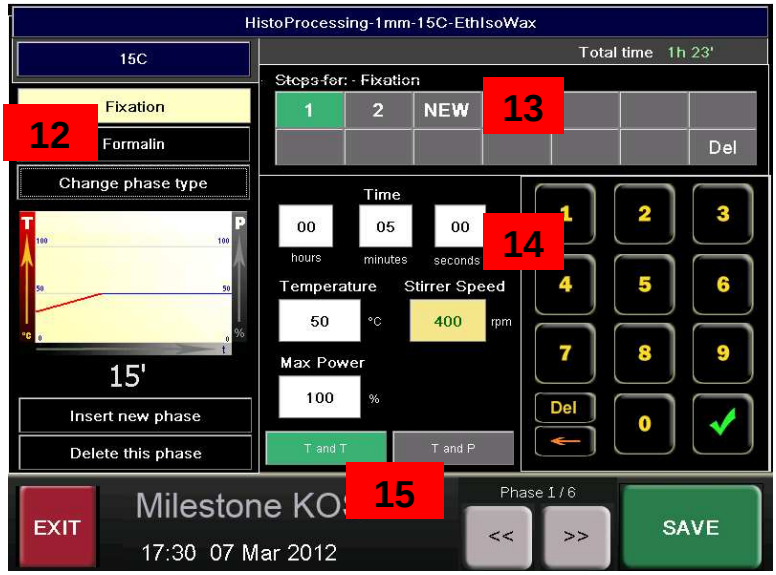
Edit Screen Function Areas

1. Histomodule in use (modification not allowed).
2. Current Name of Program in use: touch it to change the program name (a keyboard is displayed).
3. Phase function and edit box for text changes.
4. Numeric keypad for entering numerical values of point 6.
5. ENTER key for the numeric touch pad.
6. Entry boxes for phase time: they turn PINK on contact. Use the numeric keypad of point 4 to enter the values required.
7. Type of phase to be modified: click and select either Microwave, Timer or Information, as shown below.

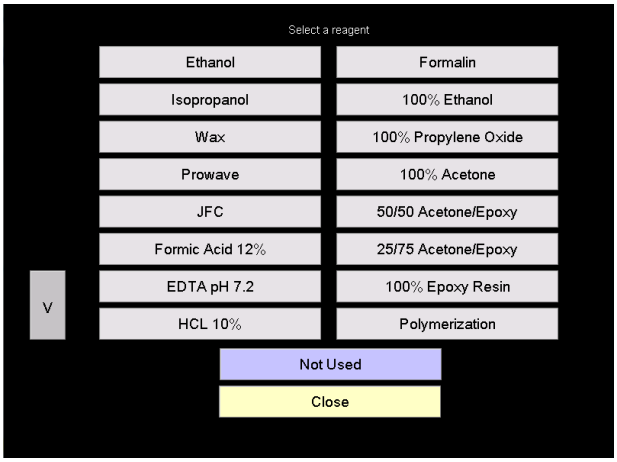


8. For changes that require the addition or deletion of phases of a program.
9. EXIT screen/program in use.
10. Scroll bar to move to phases that require changes.
11. SAVE icon to save final changes.

The following edit screen is visible when viewing phases with microwave steps.



12. Name of current reagent in use. Touch the icon to display a list of reagents and choose one, as shown in the figure below.



13. Setting the different steps of a phase.

14. It is possible, if required, to change time, temperature, etc parameters of all the steps of a phase by touching the corresponding numeric entry boxes (they turn pink) and inserting the desired values by keypad.

Before changing any program, please remember never to change the ramping times, the heating rate (max power) and the default stirrer speed.
Should any of these parameters be modified, contact your local application support from your supplier.

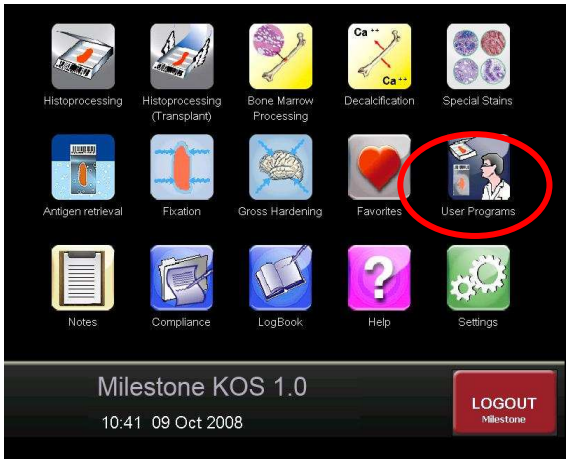
15. This icon allows setting up a TIME at POWER procedure. It is possible to set: Stirrer Speed, Fixed Power and Max Temperature, as shown in the figure above. Let default value set to 0℃, if control of Max Temperature parameter is not required. Entering of any value causes starting of an audio alarm if this value is exceeded during a test/run.

Leaving the Max Temperature parameter set to 0℃, i t is equivalent to letting the unit run at the default value of 120℃.

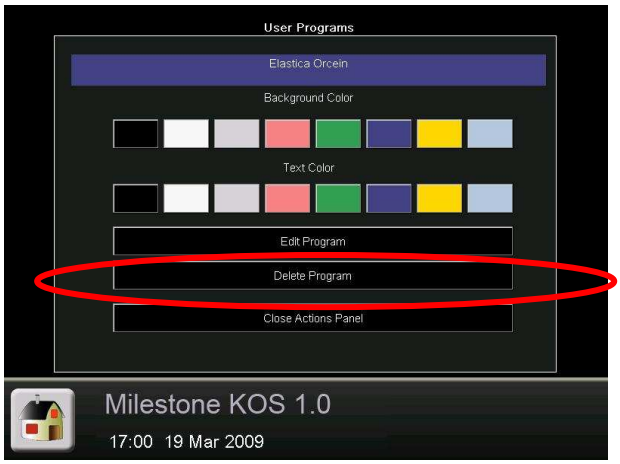
When all necessary changes have been completed, press SAVE.

4.5. Delete modified programs

Modified programs can be deleted as follows: from the main screen select the USER PROGRAMS icon, the list of user programs stored is displayed. See the image below.



Select the program to be deleted by touching and holding the touch until a new screen appears.



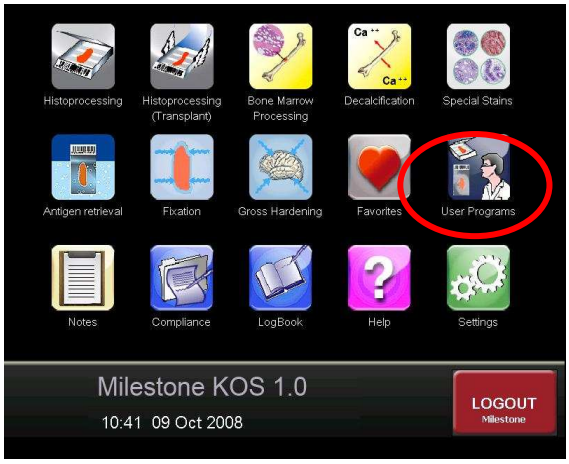
In this screen cancel a program by pressing “Delete Program”, resulting in removal of the stored user program.

In this screen it is also possible to edit programs that have been already modified or created. Any change made to an existing program will not be overwritten, but will create an additional program, as indicated in the next chapter.

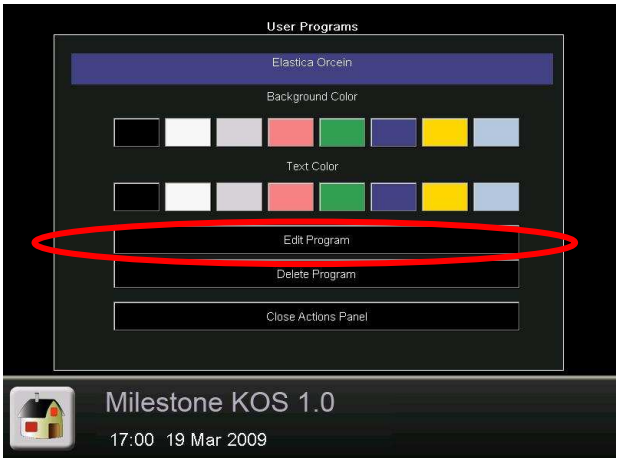
4.6. Edit modified programs

Before modifying any program, please remember to never change the ramping times, the heating rate (max power) and the default stirrer speed. Should any of these parameters be modified, contact your local application support from your supplier.

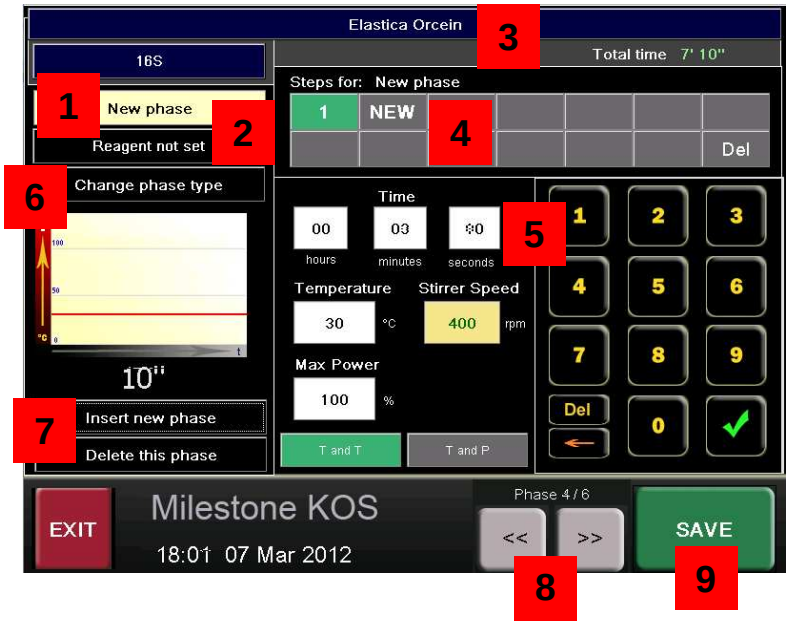
Here are the instructions how to MODIFY an existing application already customized and listed under the USER PROGRAMS icon.
First select the USER PROGRAMS icon. This will open the list of customized application programs.



Now select and keep holding the touch on the program to be delete (in this example Elastica Orcein icon), until the EDIT screen appears.



If required, it is also possible to change the color of the TEXT and the BACKGROUND.
Now select the EDIT PROGRAM text box, as indicated above, to go into the EDIT SCREEN for changes to the application.
The edit window in the next page shows extensive editing capabilities.



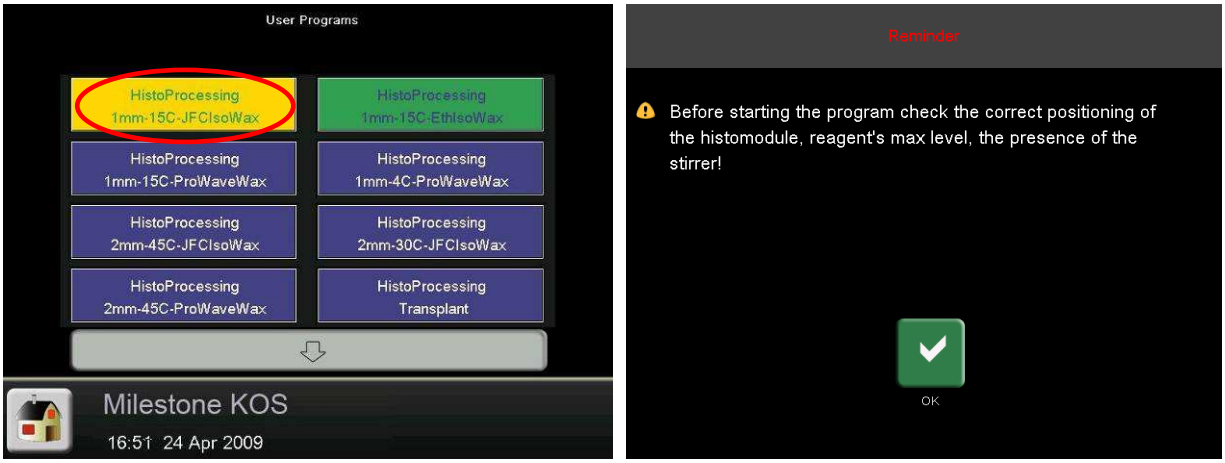
Edit Screen Function Areas:

1. Selected when it is required to add a new phase.
2. Name of current reagent in use. Touch the icon to display a list of reagents and choose one.
3. On selection allows operator to change the name of the application through a pop up keyboard display.
4. Setting the different steps of a phase.
5. It is possible to change time, temperature, etc parameters of all steps of a phase, by touching the corresponding numeric entry boxes: they turn pink, insert the desired values by keypad.
6. Type of the phase to be modified: click and select either Microwave, Timer or Information.
7. For DELETING or INSERTING a phase.
8. SCROLL arrows to select the desired phase.
9. SAVE changes made.

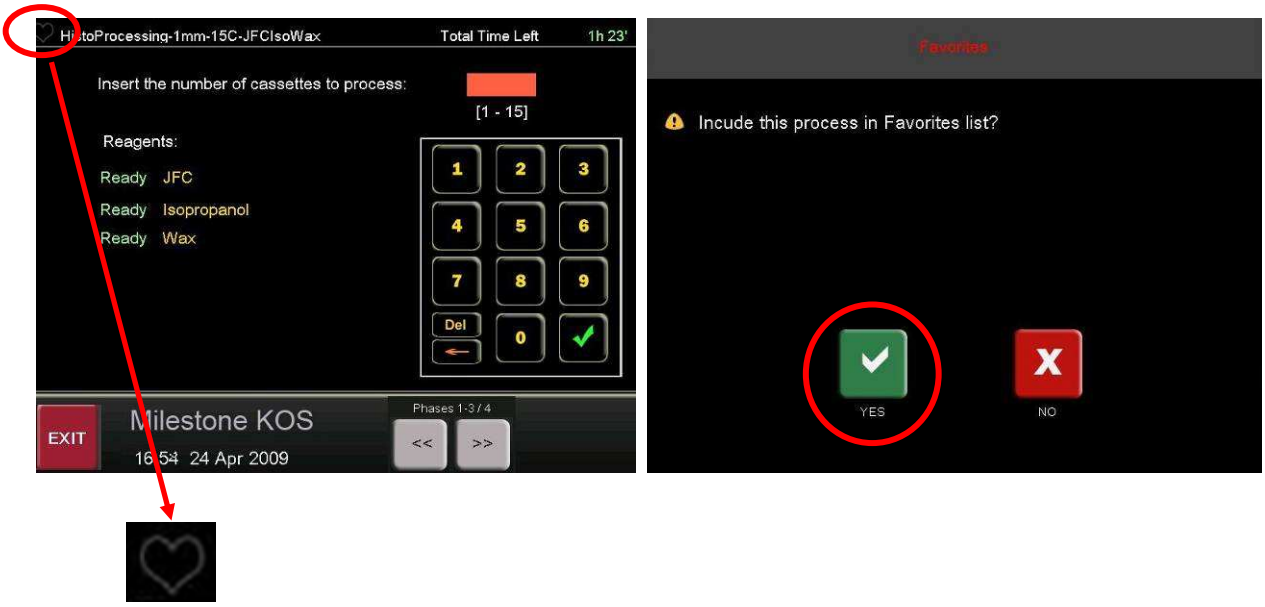
Milestone s.r.l recommends that these instructions are kept near the instrument to facilitate operations and better understanding of the software functions, especially when operating the unit for the first time.

4.7. Create and modify favorite display

To create a FAVORITE protocol, select the program of your interest (in this case, USER PROGRAM).
Now SELECT, for example, the first program (yellow icon) and a message requires to confirm that the positioning plate, the reagent and the stirrer are OK.



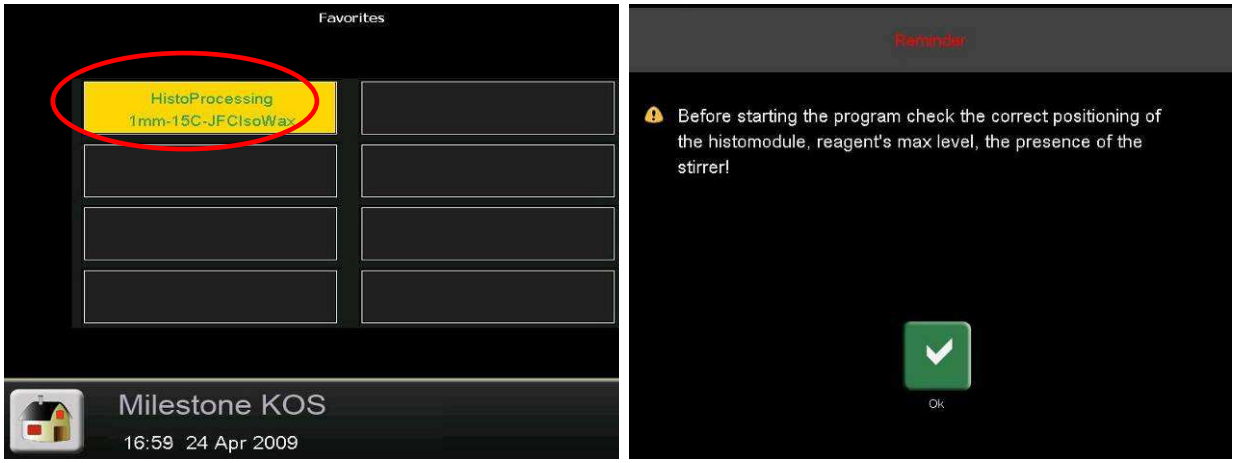
Select OK to go to the application startup, showing the keyboard to enter the number of cassettes to be processed.
Do NOT enter cassette numbers now, but select the HEART black icon positioned on the top left of the screen.
The following screen appears, asking for confirmation that the application has to be added to the FAVORITES. See below.



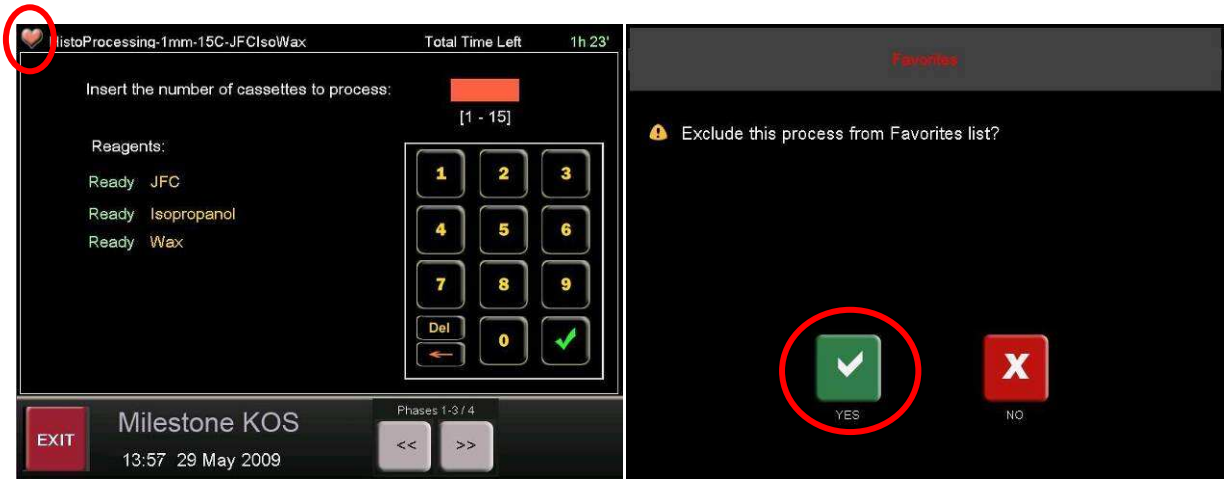
Selecting YES, the system goes back to the program ready to continue it, if required. If NOT, select the EXIT icon and go to the Favorites screen. That adds the selected USER PROGRAM to the FAVORITES list.

4.7.1. Delete from favorite list

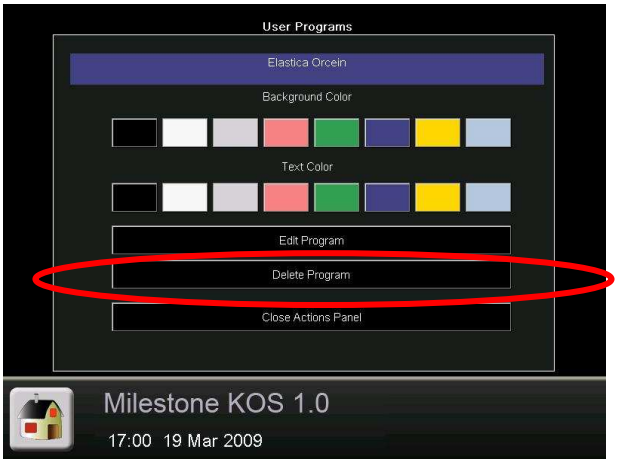
This procedure is similar to that to create a favorite program. Enter in favorites screen (see example below), and select the program icon to delete.
A message requires to confirm that the positioning plate, the reagent and the stirrer are OK, as indicated below.



Select OK to go to the application startup, showing the keyboard to enter the number of cassettes to be processed. Do NOT enter cassette numbers now, but select the HEART icon positioned on the top left of the screen.
The following screen appears, asking for confirmation that the application is to be deleted from the FAVORITES. See below.



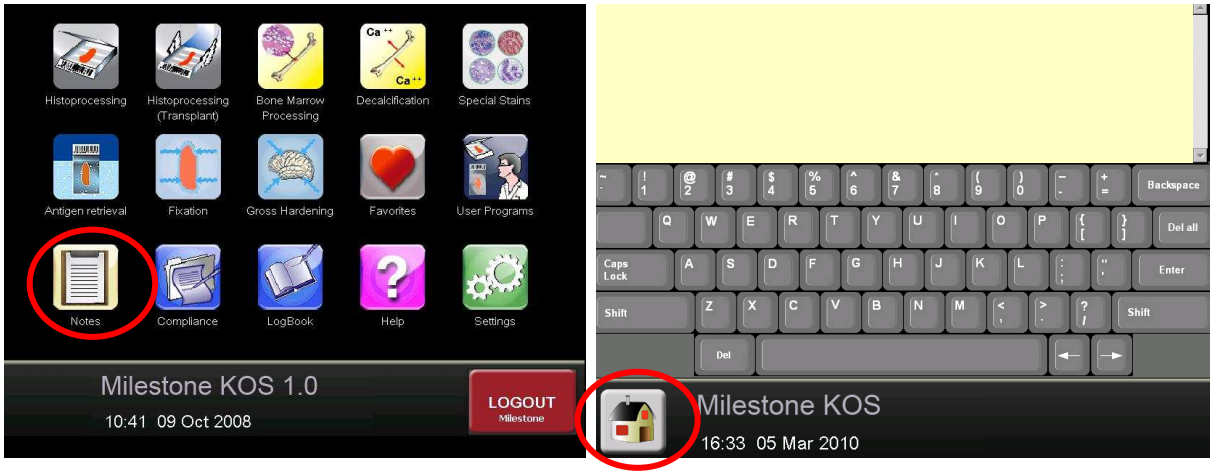
After deletion from the FAVORITES screen, the system goes back to the program ready to continue it, if required. If NOT, select the EXIT icon and go to the Favorites screen.
Another way to delete a program from the FAVORITES screen is to enter into USER PROGRAM and follow the instructions indicated in chapter 4.5 and delete as indicated.



If you DELETE any user PROGRAM as indicated above, this will delete that program from the FAVORITES.

4.8. Notes

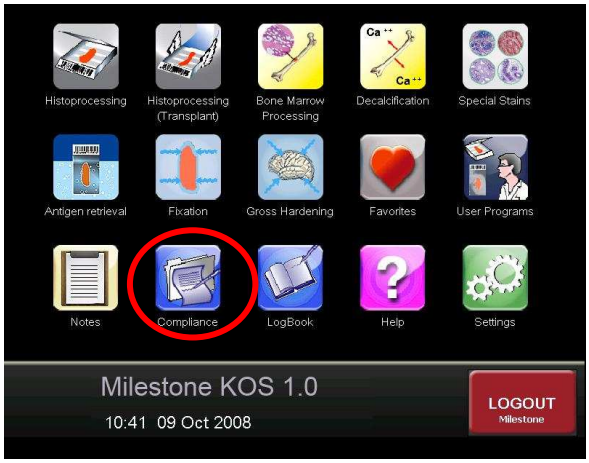
This screen allows writing any notes required.
From the main screen below select NOTES, as indicated below.
The screen on the right appears and notes can be entered by using the keyboard.



Click on Home icon to go back to MAIN SCREEN on completion of notes, as shown above.

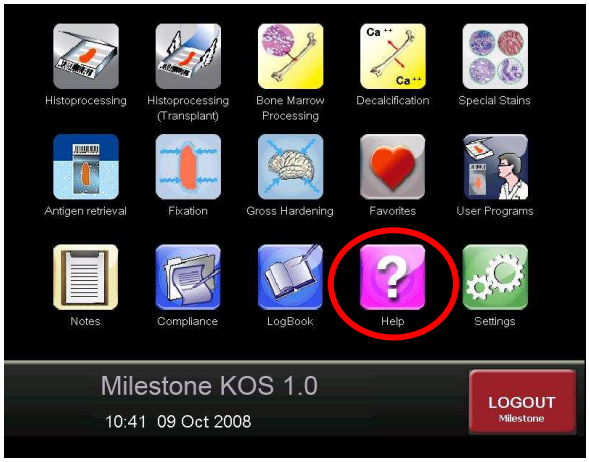
4.9. Compliance

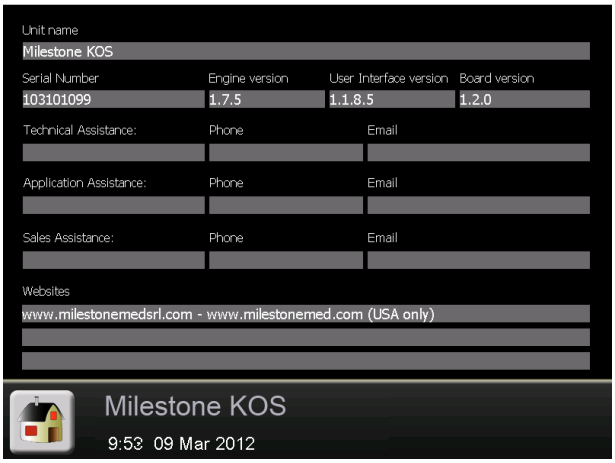
This function allows viewing that KOS complies with the CAP regulations.
From the main screen below select COMPLIANCE and the following messages appear.



4.10. Help

HELP function provides a series of useful information. From the main screen below select HELP.
The screen on the right appears showing:
Unit name, Serial Number, Software version (Engine, User Interface and Board) and other details (Technical, Application and Sales Assistance and website), where available.



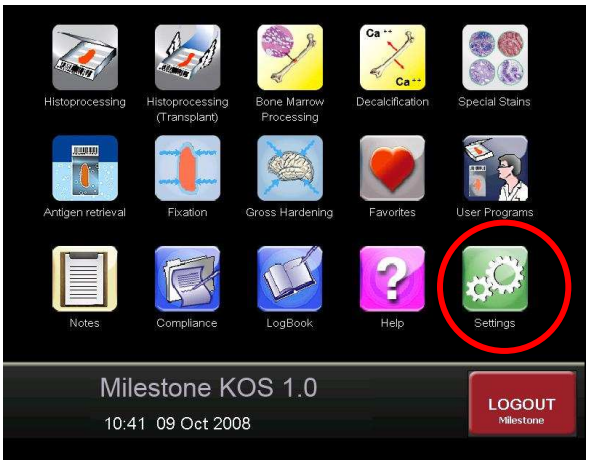


4.11. KOS system settings

Select the SETTINGS icon, as shown below and:

If ADMINISTRATOR is logged, the following screen appears.
The Administrator can access to:

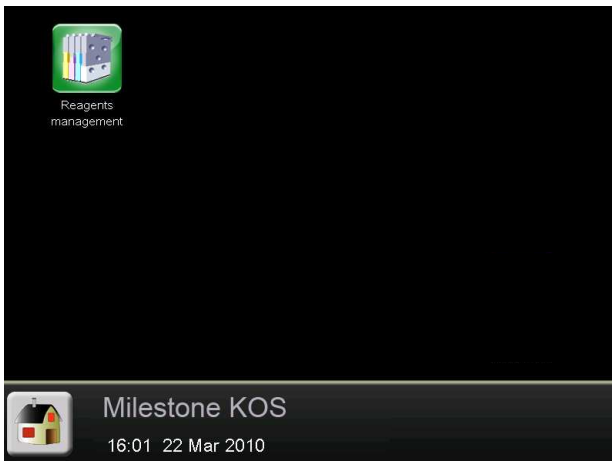
- Reagents management
- User management
- Language selection
- Owner settings
- Remote assistance
- Set Clock

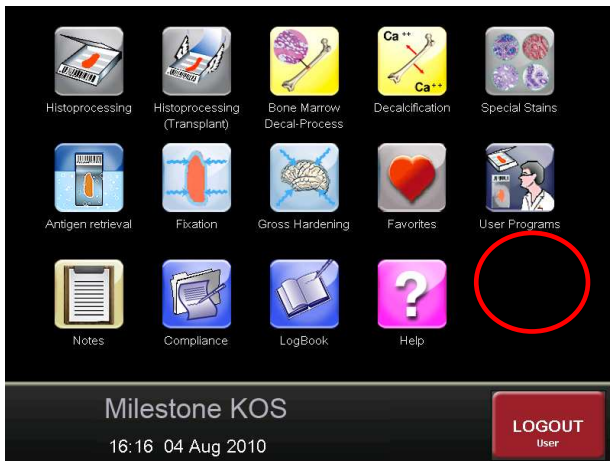


If a USER is logged and is enabled to manage reagents, the following screen appears.
A User is allowed to open only:

- Reagent management, if authorized (see left figure).

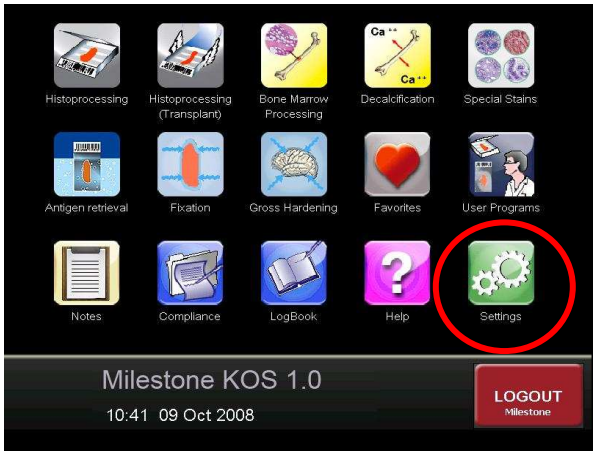
If a USER is logged but is not enabled to manage reagents, the SETTINGS icon disappears in Main screen, see right figure.

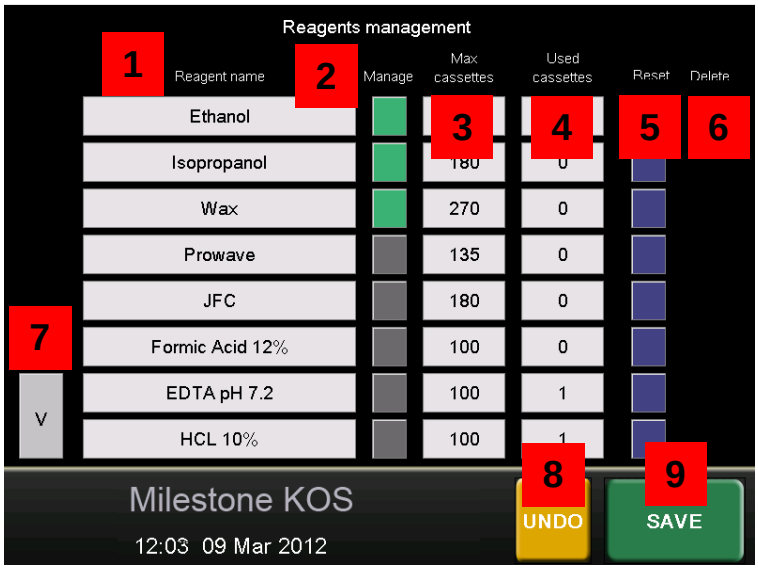




4.11.1. Reagents management

REAGENTS MANAGEMENT is accessible by the ADMINISTARTOR. Other users can access only if authorized by the administrator (set up in USER MANAGEMENT, as described in the chapter 4.11.2).
An authorized operator can select the SETTINGS icon indicated below figure left.
Select the REAGENTS MANAGEMENT, as indicated below figure right.

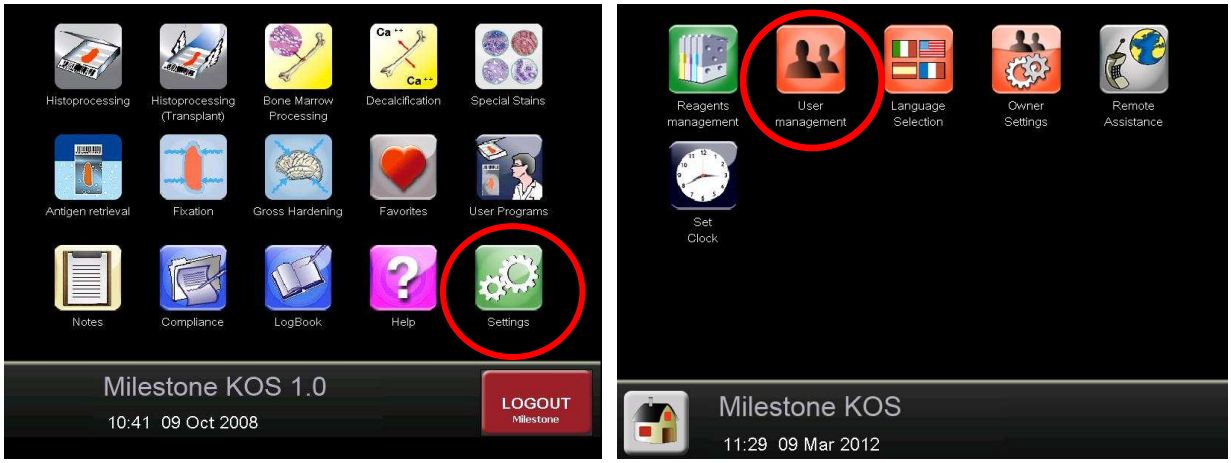




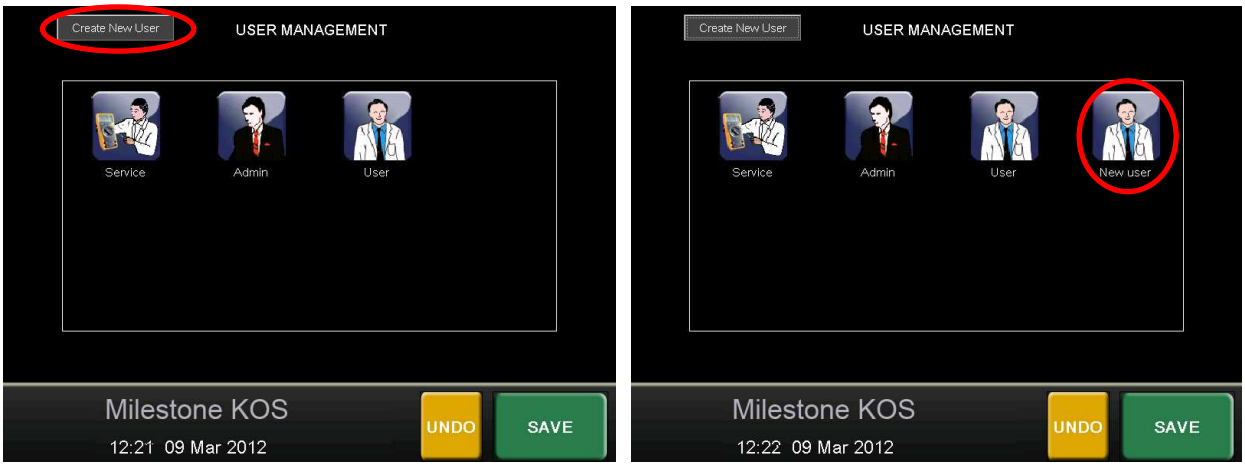
1. **Reagent**: list of reagents available, touch the reagent icon to change the text display, if required.
2. **Manage**: touch this square icon to activate the reagent management for that reagent (indicated by the color change to GREEN). Press this icon again to deactivate this management function (indicated by the color change to grey).
3. **Max Cassettes**: this feature is activated by touch and opens the numeric keypad to enter the max number of cassettes/slides to be processed.
4. **Used Cassettes**: when the number of cassettes/slides processed reaches the maximum value set, the system alerts you to change the reagent required.
5. **Reset**: to be carried out by the operator when the max number of cassettes/slides processed has been reached and the reagent has been changed. The operator is required to reset the value to zero using the numeric keypad.
6. **Delete**: it is displayed as active, as shown below, when NEW reagents are added to the listing of reagents. It is not active for preset reagents, as they are protected.
7. **V and Λ**: is the upward and downward scroll function of the reagent listing.
8. **UNDO**: to restore previous values in case a correction/editing is no more required.
9. **SAVE**: to save all changes made in the REAGENT MANAGEMENT screen.

4.11.2. User management

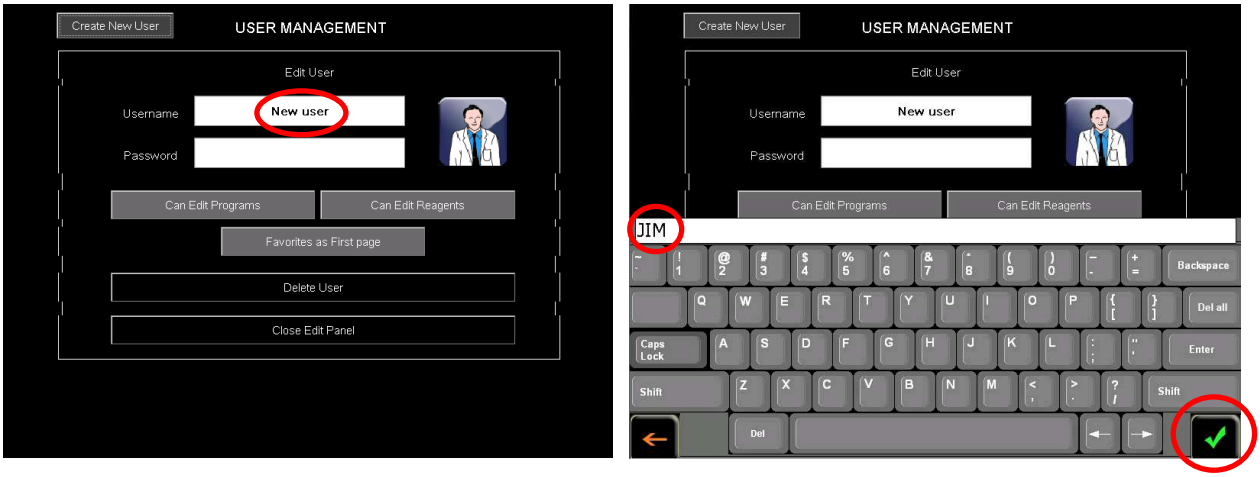
The USER MANAGEMENT screen can be accessed by the ADMINISTRATOR only in order to CREATE or MODIFY the list of AUTHORIZED USERS enabled, through a series of numeric password, to access to KOS functions.
In this section, Administrator can also modify existing password.
From the Main Menu select SETTINGS icon and enter in USER MANAGEMENT screen.



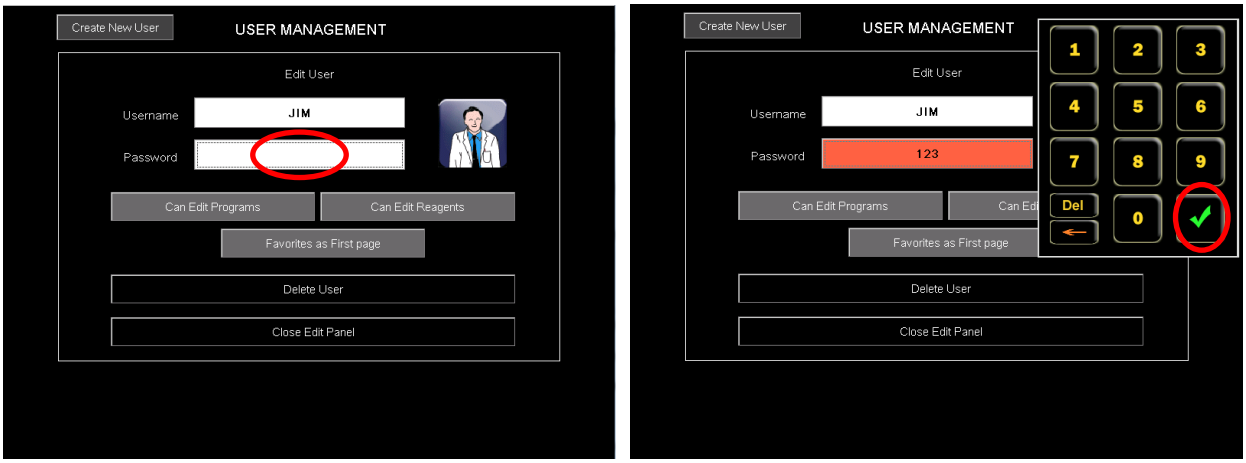
Select CREATE NEW USER icon: a New User is added to the User Management screen.
Select NEW USER icon: a keyboard is displayed on the screen.



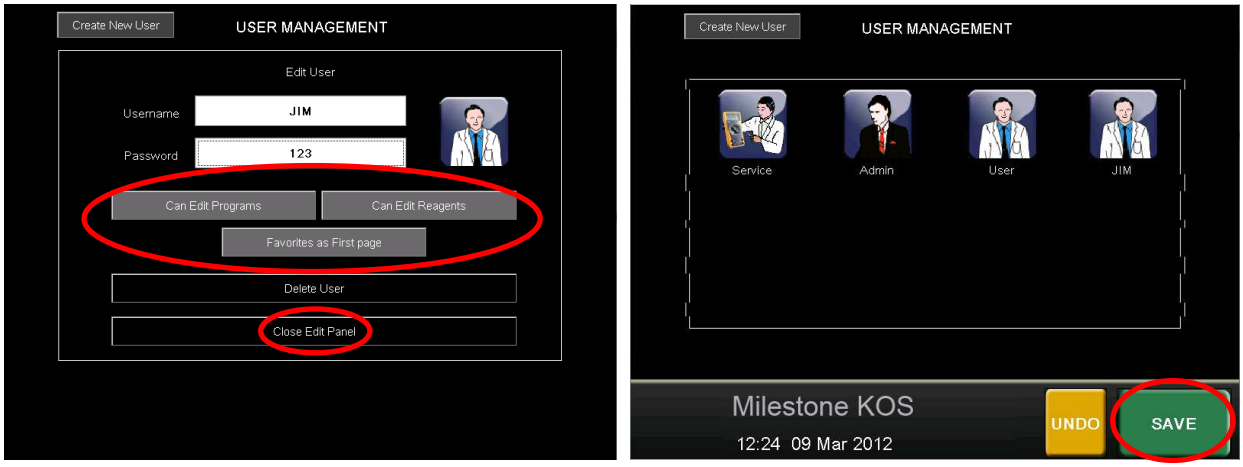
Administrator has to enter NAME and PASSWORD for the New User (see JIM user in the example below).
Selecting the USERNAME box, enter the New User NAME, for example “JIM” using the numeric keyboard and press the green arrowed check box to confirm.



Selecting the PASSWORD box, enter the ACCESS CODE value, for example “123” using the numeric keypad and press the green arrowed check box to confirm.

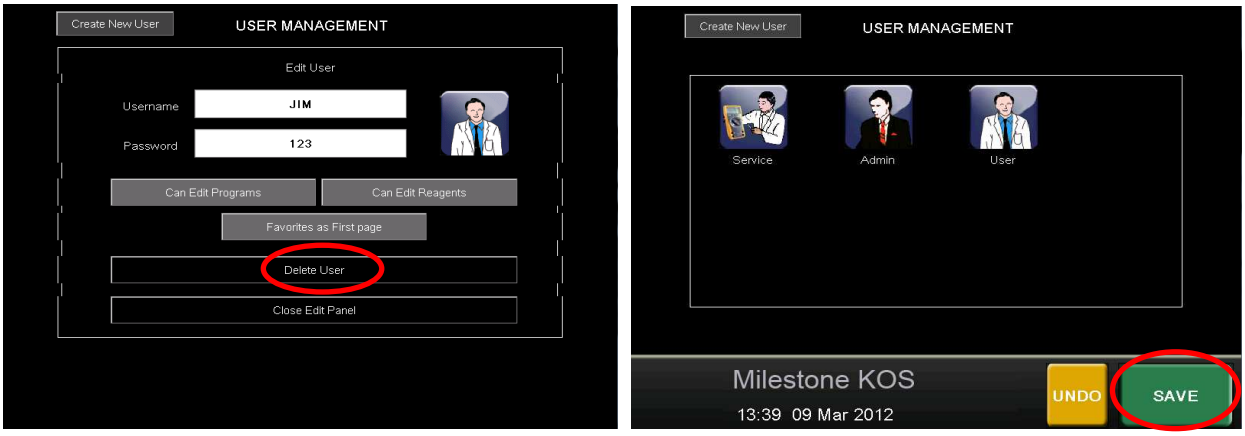


By selecting the three grey icons in the figure below, the ADMINISTRATOR can also give the user the access to reagents management, to programs management and to set the user’s Favorites page as First Page (icons turn GREEN when activated).



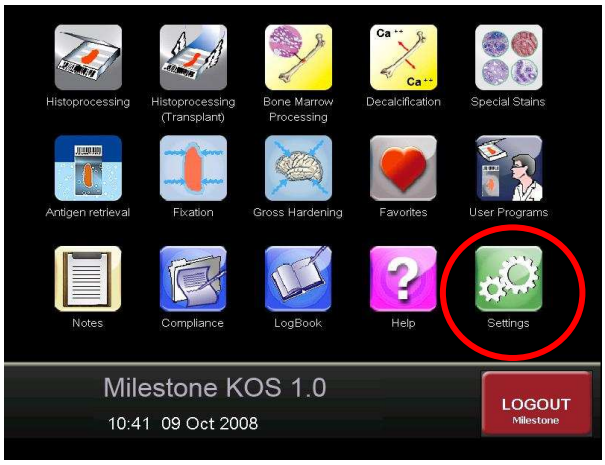
Select CLOSE EDIT PANEL in the figure above to exit the USER MANAGEMENT screen. In the following screen select SAVE to make all the changes active.
On selecting SAVE the system will exit to the SETTINGS screen. This completes the process of creating a users list.

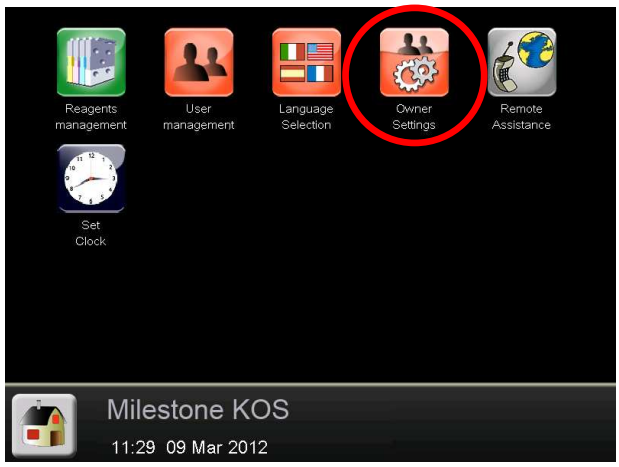
Administrator is authorized to delete an existing user: go to USER MANAGEMENT screen, select the USER icon to cancel and touch on DELETE USER icon, as indicated in the next figures.
On completion the system goes to USER MANAGEMENT screen. Select SAVE , as shown below.

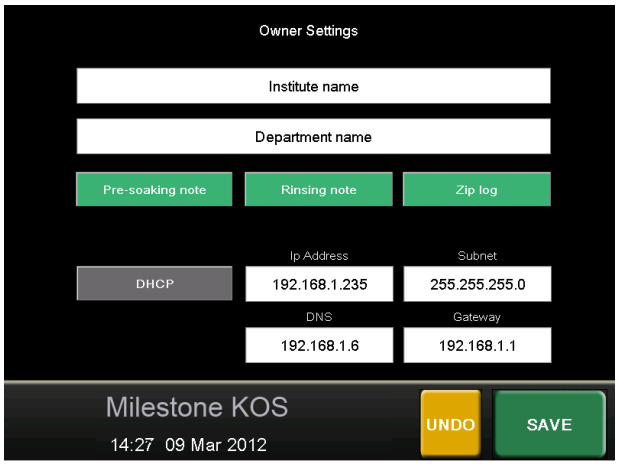


4.11.3. Owner Settings

From the main screen below select SETTINGS, then OWNER SETTINGS.







In this page it is possible to set:

1. Institute name: that owns the unit.
2. Department name: that owns the unit.

Touching any of the two dialogue boxes, a keyboard emulator appears, enter the text required.

3. Pre-soaking note: when activated (GREEN color), a reminder screen appears before any fixation phase, reminding to perform pre-soaking in fixative (for example, see the chapter 3.1).

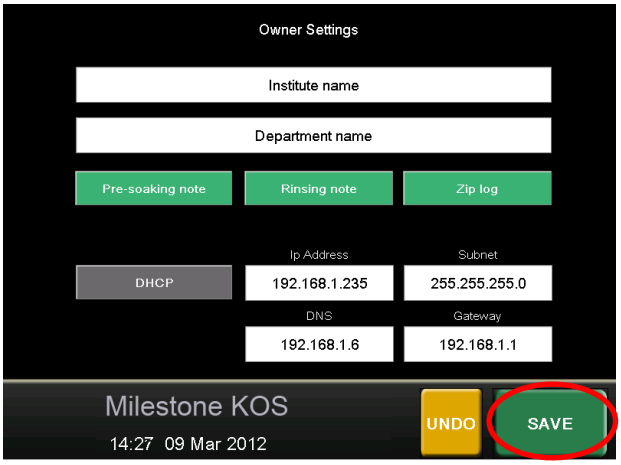
Touch this button to inactivate it (GRAY color); in this case the pre-soaking reminder screen will never appear.

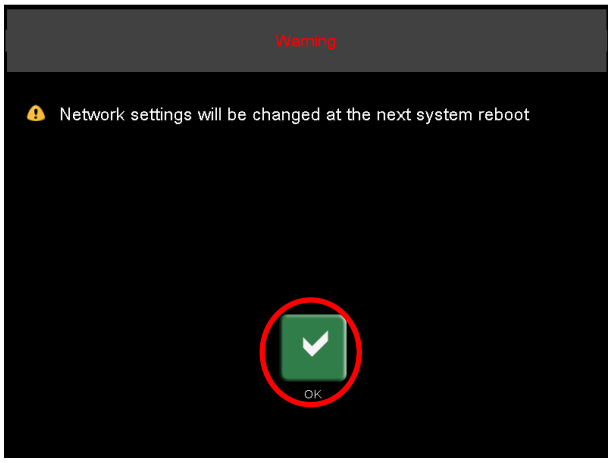
4. Rinsing Note: when activated (GREEN color), a reminder screen appears before any ethanol and decalcification phase, reminding to perform a rinse (for example, see the chapter 4.2.2).
Touch this button to inactivate it (GRAY color); in this case the rinsing reminder screen will never appear.

5. Zip logs: when activated (GREEN color), all programs are stored in zip format. Touch the button to inactivate it (GRAY color). In this case all programs are stored in xml format.
See the chapter 5.1 Export processing from the terminal to the USB.

6. For how to set the Network settings see the chapter 2.7.

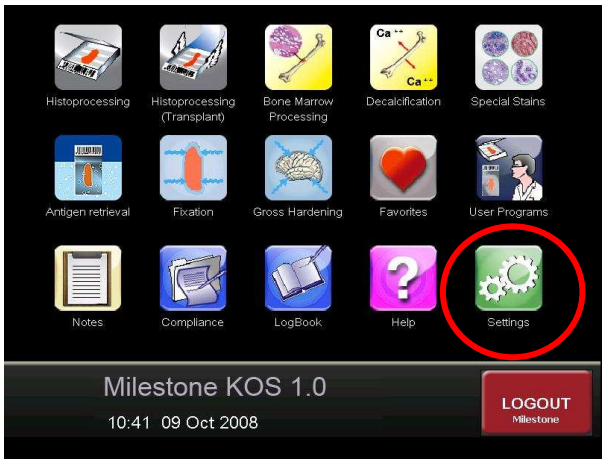
When you make changes, the SAVE icon must be pressed before exiting the OWNER SETTINGS screen.
A message appears, press Ok and restart the Unit, as indicated in the figure below.

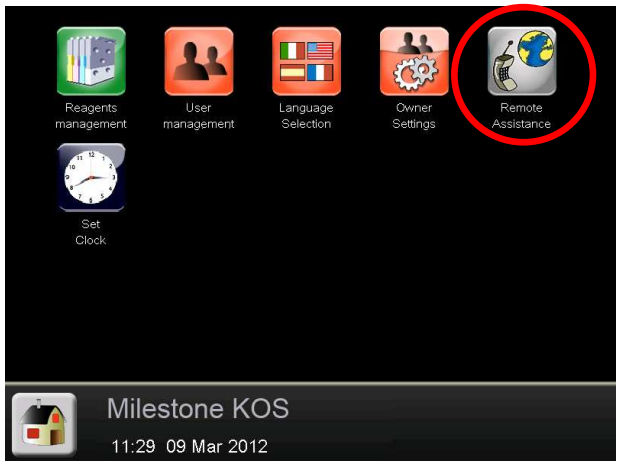




4.11.4. Remote Assistance

The REMOTE ASSISTANCE screen is accessed only by ADMINISTRATOR. Select SETTINGS icon from the MAIN MENU, then REMOTE ASSISTANCE button (refer to chapter 2.7.1).





Once activated it is not possible to press the REMOTE ASSISTANCE icon again (to avoid multiple activations) until you reboot the machine.
At this point remote service works with your instrument.
Do not disconnect nor restart the instrument during the remote connection.

ALWAYS COMMUNICATE THE SERIAL NUMBER (S.N.) OF THE UNIT.
MILESTONE CANNOT CONNECT TO UNIT WITHOUT THE S.N.
THAT IS AVAILABLE IN "HELP" ICON IN MAIN SCREEN.

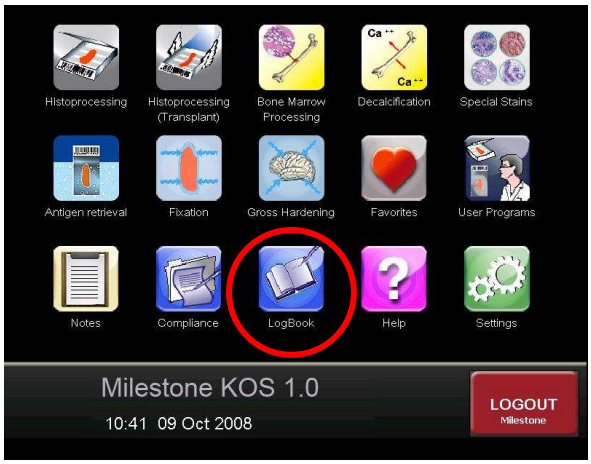
5. REPORTING

KOS provides the documentation necessary for the report activity of the Laboratory. In fact it is possible to export a document including all necessary information like the real time and temperature performed by the unit.

5.1. Export processing from the terminal to the USB

Insert the USB memory stick in its slot (back side of the Unit). It is supplied by Milestone with the unit, as it allows the downloading of stored data, as well as containing the viewing Software for opening the Stored graphics data from the processing runs. Allow around 30 seconds for the USB to be recognized. If using a USB Key other than that supplied by Milestone, ensure it has a capacity less than 1 Gbyte with ample memory space.

From the MAIN SCREEN select LOG BOOK, selecting LOG BOOK the screen on the right appears.



This allows to export all the saved processed graphics: select the logs of interest and press the “Export Saved processing” button.

Alternatively choose Delete selected or Delete ALL if you want to definitely eliminate one file only or every file saved, respectively.

5.2. Install the LogViewer

5.2.1. Open process

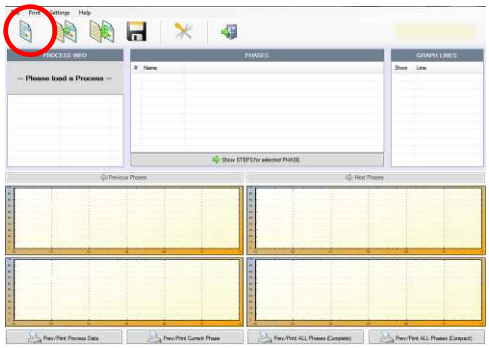
- On your laptop or desktop computer open the LogViewer folder and double click on the “Setup.exe” icon to install the program. Then, double click on the “ReportViewerSP1Eng.exe” icon in the LogViewer folder to install the printing data program on your desktop. The LogViewer software is now ready to work.

If you have Microsoft Windows Vista or better installed on your PC, the ReportViewer software is not needed.

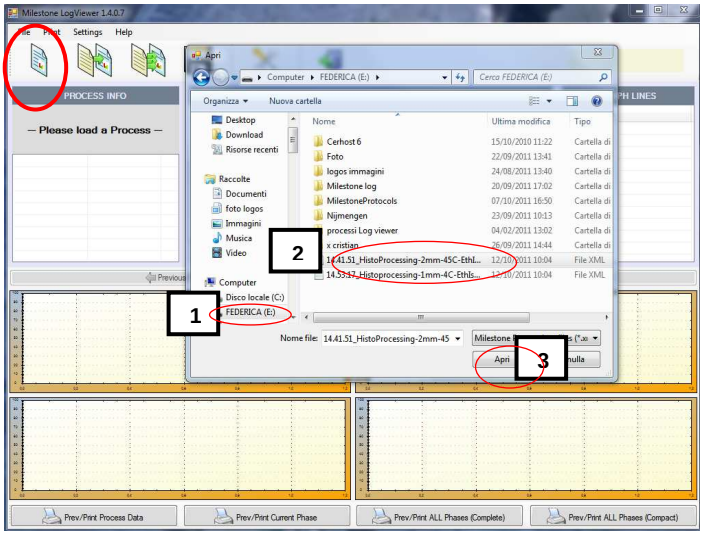
- Plug the USB memory stick where the processes are stored and copy them on the key.
- Open the LogViewer software (going to “Start Menu\All programs\Milestone srl\Milestone LogViewer” or clicking on the “LogViewer” icon created on your desktop).

HELP FILE: select “Help” and “How to” from the menu to view detailed instructions about the software.

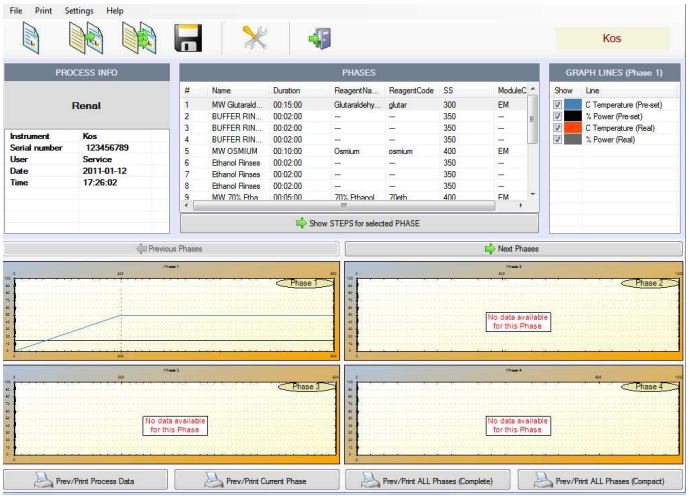
- Plug the USB key in your PC and select ”Open” icon to import a single process.



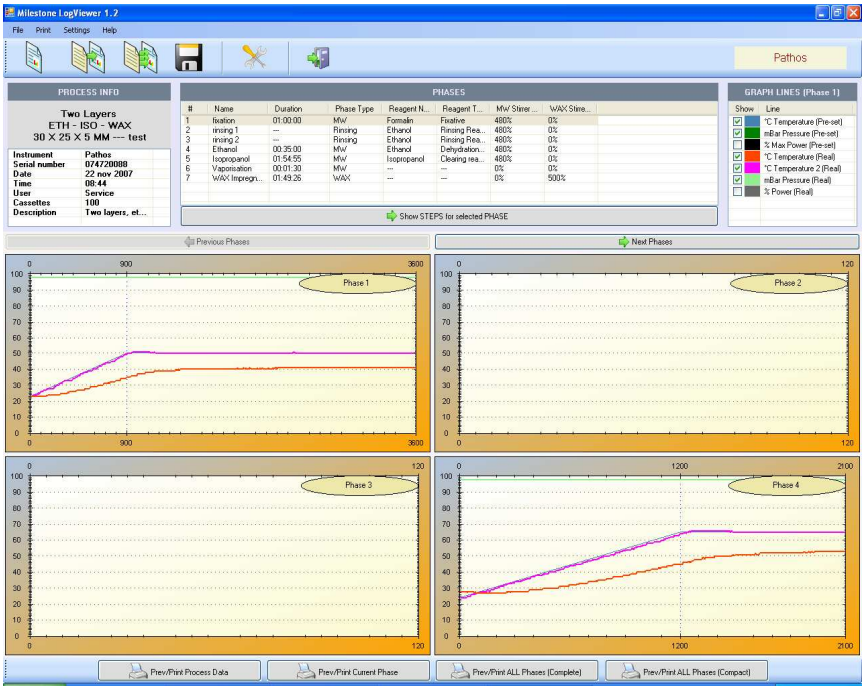
- Selecting ”Open” icon appears the following screen. Select the USB key with the process stored **1**, select the single process **2**, then press “Open” **3**.



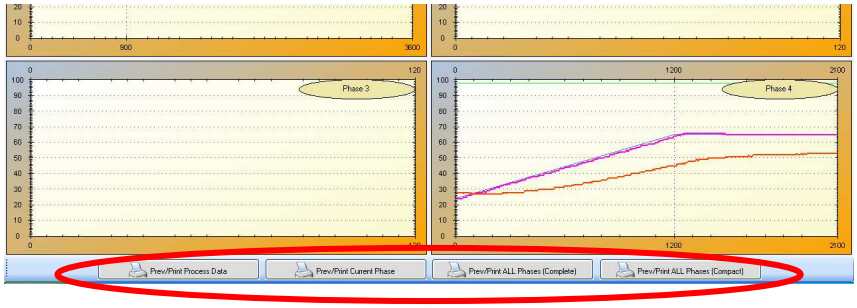
- The processing curves done will be shown as in the picture below.



- The fields describe the data of interest such as: phases done, starting time, reagent used and number of cassettes. Click directly on one curve to enlarge it, or on the arrows to view next phases.



- Once the file has been opened, preview/printing of the curves is possible by selecting the appropriate buttons as below:



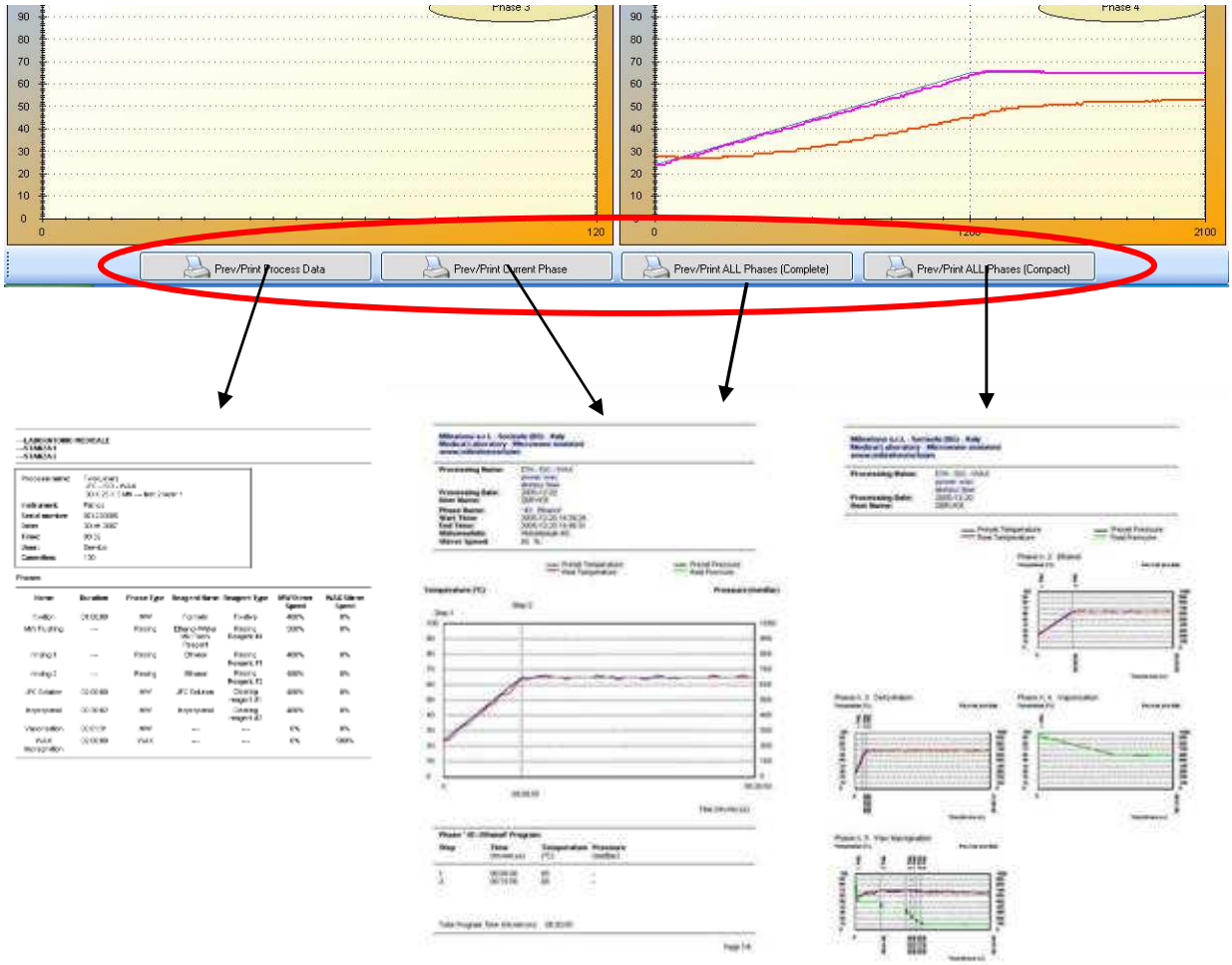
Printing of Process Data, Current Phase, All Phases in full or compact view is possible by pressing the respective button.

5.2.2. Print process

- Before printing, choose “Printing options” under “Settings” menu and customize the settings, if necessary.

- Modification of the heading of the pages, edit of the label is also possible under “Printing options” menu.

- Select one run and press “Print process data” or “Print current phase” to print out the curve (red Circle). Press “Print ALL phase “ icon, choose the “complete” (one phase – one page) or the “compact” (one page) format to print out the whole processing.



6. MAINTENANCE

6.1. Introduction

Maintenance of KOS is carried out at two levels:
The FIRST is at laboratory level: a simple routine maintenance can prevent the likelihood of more serious problems. Minimal routine maintenance is required by laboratory personnel that use KOS. The following procedure is recommended to ensure optimal performance of KOS.
The SECOND level of maintenance is technically more detailed and is beyond the scope of normal laboratory personnel. The unit requires once a year a technical preventive maintenance to maintain the high performance and prevent any malfunction.

Contact annually your local distributor or Milestone offices directly: customersupport@milestonemedsrl.com for how to perform Preventive Maintenance and regular inspections in order to maintain your KOS within safe operative standards.

6.2. After each run

1. Ensure that KOS is generally kept clean after each use. Do not use abrasives or sharp instruments that may damage surfaces.
2. Clean as soon as possible the rack (from WAX) after every processing cycle to remove completely the WAX.
3. Ensure that the WAX level reaches the MAX level.

The paraffin level volume must be ready for use with up to 3 layers of cassettes.
The level of wax should reach the limit indicated on the glass (rack included, for any number of cassettes processed) and it must not exceed that level. To achieve the proper level of paraffin, you must enter approximately 0.7kg (1.54lb) of paraffin.
If you use the rack 4K, the correct level of paraffin is approximately 1cm (0.39 inch) above the cassettes.
On completion of run and removal of rack, top up wax level due to tissue absorption and carry over loss from rack.

4. Check the reagent quality and change them when expired or dirty.

6.2.1. Rack cleaning procedure

This procedure takes only few minutes and allows an optimal removal of WAX traces away from KOS RACK after processing. There are two different operating ways:

FIRST WAY (room temperature)

1. Just after the end of WAX phase, when the rack is still warm, remove cassettes and place the rack into a glass container of about 2 liters.

Fill it up with approx. 2 liters of cleaning solution (ex. Iso-Paraffin such as Regenx®, or MicroClean® in Europe or Clear Rite3® in USA or xylene or equivalent WAX cleaning as a sort of aromatic alternative) enough to cover all the three layers.

2. Now agitate the rack by moving it up and down until it is completely clean.
3. Take the rack out from the container and dry it using normal laboratory wipes.
4. Alternatively, let the solution evaporate from the rack placing it under the fume hood.
5. Check that the rack is clean and, if required, repeat the sequence as described above.
6. Afterwards rinse the rack into alcoholic solution.

SECOND WAY: HistosMATE

It is possible to clean the rack inside the HistosMATE instrument (Milestone s.r.l.).

XYLENE to clean the rack is NOT allowed when using the HistosMATE.

Milestone has developed an AUTOMATIC rack cleaner: the HistosMATE.
For further info open our website page www.milestonemedsrl.com or contact our representative in your country.

6.3. Weekly

Check that the infra-red temperature sensor surface is not dirty.
Wipe out the inner surface of the Microwave unit with Isopropanol to remove any residues of dirt.

6.4. Monthly

Replace wax if severely contaminated by reagent or physically dirty

6.5. Every six month

KOS is equipped with two charcoal filters (Ref. P/N 67223) for your safety and for good laboratory environment.

In case your KOS is connected to an external fume extractor or to a fume hood, these two filters should be changed EVERY YEAR.
Otherwise, if there is no external fumes extractor, we recommend to change them EVERY 6 MONTHS.

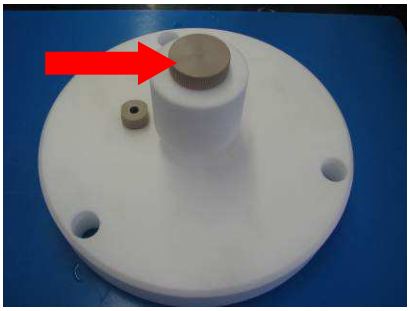
How to proceed:

- The charcoal filters are positioned on the lateral side of KOS (see the figure below).
- Remove the panel by hand and then the two filters.

6.6. Yearly

Call your SERVICE support for preventive maintenance contract.

ONLY FOR GPR/K MODULE:
Unscrew the top brown plastic cover, slide out the transparent silicon tube and replace it (Ref. P/N 60109), if damaged.



Replace (yearly or whenever the ring shows signs of damage) the red sealing ring (Ref. P/N 67424) of the GPR/K cover.


7. TECHNICAL TROUBLESHOOTING

The following table provides the KOS operator and service technician with possible causes in the event a problem develops with the unit.

PROBLEM	DIAGNOSIS
Difficulties in switching on the Touch Control: display dark or fully lightened or crossed by vertical and horizontal lines.	-Repeat switching Off/On the MAIN Kos SWITCH on the unit.
The unit does not switch on.	-2 Fuses 8AT-250V power mains grid or 2 Fuses 15AT-125V (6.3 x 32mm). -Check if you power to the unit from the power line. Main Switch broken. (Service technician).
There is no microwave emission.	-The door of the unit is not well closed. -Heating transformer. (Service technician). -Door-handle switches. (Service technician). -The magnetron or its fan is malfunctioning which causes magnetron overheating and activation of the temperature sensor located on it. (Service technician).
After 5 seconds magnetron heating time the program does not start and the display shows “DOOR NOT CLOSED”.	-The door is not perfectly closed. -Door-handle switches. (Service technician).
Temperature Alarm Display.	-Check the correct positioning of Histomodule. -Check the presence of the stirrer. -Check the correct reagent volume level in use.
Humidity Vapor Alarm Display.	-Check the presence of the histomodule lid and that is in correct position. -Check the presence of the stirrer.
Solvent Vapor Alarm Display.	-Check the presence of the histomodule lid and that is in correct position. -Check the presence of the stirrer.

Here is a list of errors that may appear during KOS processing. You will be asked to ignore any warning that appears or not, to decide whether to continue or stop the phase of the process.

ERRORS	DESCRIPTION
COM error	Shut down and restart the machine. If the problem persists, contact your Service support.
Communication error, please reboot	Shut down and restart the machine. If the problem persists, contact your Service support.
Communication error, the application is running without the Engine component. If this is not intended for administration purposes, please restart.	Shut down and restart the machine. If the problem persists, contact your Service support.
Delta T Limit Reached	The difference between the preset temperature and the real temperature exceeds 10°C.
Temperature exceeds tolerance limits	The temperature measured during a process exceeds the tolerance limit of 130°C.
Door open, close and click Ok to continue	The door of KOS is open and it is necessary to close it to continue the process.
Humidity Sensor Alarm	The humidity measured during a process exceeds the setting limit.
MW Leakage Sensor Alarm	The MW leakage measured during a process exceeds the setting limit.
Organic Solvent Sensor Alarm	The organic solvent concentration measured during a process exceeds the setting limit.
The exhaust fan speed is too low	Shut down and restart the machine. If the problem persists, contact your Service support.

8. GOOD PROCESSING PRACTICE

8.1. Specimens

Size

1. Processing times are a direct function of specimens size.
   Milestone factory stored protocols are based on following standardized sizes (for standard cassette of internal dimensions: 30 x 25 x 5 mm, external dimensions: 40 x 28 x 6 mm):
   - Transplant (Small biopsy cylinders of about 0.5mm diameter)
   - 1mm (Small biopsy cylinders of about 1mm diameter)
   - 2mm (Biopsy 10 x 5 x 2mm)
   - 3mm (Biopsy 15 x 10 x 3mm)

2. As a general rule, user must take in consideration that each additional 1mm thickness will require about 1 hour processing (for example: 1mm takes 1 hour; 2mm takes 2 hours, 3mm takes 3 hours).
   Universal biopsy cassette can accommodate up to 5mm thick samples. Make sure that the thickness is the one specified for the processing protocol selected.
   Milestone has developed the CheckLITE, a user-friendly, non-contact device that automatically signals with a green light when the specimen is cut at the desired thickness. For further information on CheckLite, contact Milestone s.r.l. at **medical@milestonesrl.com** or your local distributor.

Protocol and Type of specimen

Select the appropriate protocol in relation to the size of specimens to be processed.

1. With Milestone technology, different types of specimens can be simultaneously processed (kidney, heart, colon, liver) in the same run. The time at temperature pre-stored protocols are suited for the **most sensitive tissue.**

2. Specimens with different thickness but all up to 3mm can be simultaneously run. While the temperature is set for the most sensitive tissue, the processing time is set for the thickest specimen. This means that, if 1, 2, 3mm thick specimens are to be processed together, the 3mm protocol must be selected.

3. Biopsies of ≤ 1mm thickness (like renal or gastric biopsies) require separate processing, because of their small size, for that purpose we have developed the Transplant programs.

Fatty tissues

Fatty tissues are some of the most difficult tissues to process. Milestone s.r.l. has patented a very effective reagent, the JFC solution (Ethanol, Isopropanol and long chain Hydrocarbon) which, in combination with microwaves technology, assures best results. For further information on JFC Solution, contact Milestone s.r.l. at **medical@milestonesrl.com** or your local distributor.

8.2. Fixation

Fixation is the all important first step of tissue processing. Tissues that have not been optimally fixed can give bad morphology and processing artifacts.

Before starting the dehydration/clearing steps, tissue must be properly fixed.
Fixation can be carried out either using formalin or Milestone s.r.l. formalin-free FineFIX solution.
For further information on FineFix, contact Milestone s.r.l. at **medical@milestonesrl.com** or your local distributor.

Tissue can be fixed overnight at room temperature.
For faster fixation result, Milestone s.r.l. microwave units have a preset protocol.
The Microwave time required for each mm of thickness is of about 10 minutes at 50℃.

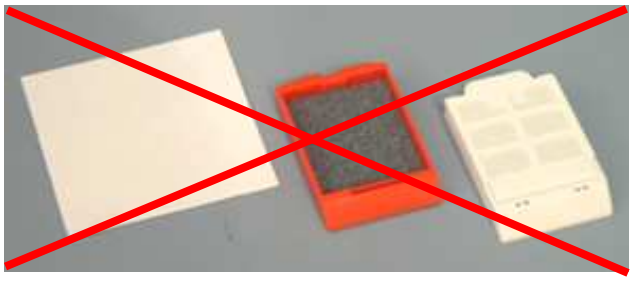
8.3. Beware

The use of inserts like **sponges** or **thick paper** or the use of **small mesh cassette** negatively influences the correct flow of the reagent through the cassette. Use only insert of lens paper or cassette with large mesh to allow proper unobstructed flow of reagent.

In the case sponges are used, increasing of the Ethanol, JFC Isopropanol and WAX processing time by half of the preset time is recommended.

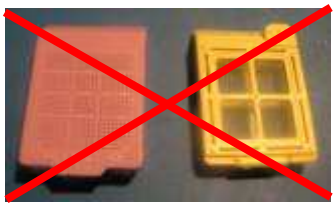
Lens paper – Biopsy large mesh cassette

YES



Thick paper – Sponges – small mesh cassette

NO



The use of **Nylon made** cassettes (like Mesh Cassettes shown in the picture below) in our microwave units must be avoided.

NO

If you are already using particular kind of cassettes, please contact either our application support: application@milestonemedsrl.com with details of the type of cassettes utilized, so that we can check whether they are suitable to be used in our microwave units.

8.4. Reagents

Reagents loaded must be 99% reagent grade.

Make sure to follow the software reagents' reuse settings (please refer to chapter 4.11.1). Check them daily to minimize inconsistent results.

Purity of **reagents**:

1. When the water concentration in the reagents is more than 3% volume, a progressive loss of dehydrating effect takes place. This problem can be caused by an overshooting limit of "maximum number of cassette to process" or "Max number of processing cycle to use" for the respective reagents.

2. Insufficient cleaning of the rack after processing can contaminate reagents with traces of WAX.

WAX:

1. Can be reused several times because is left uncontaminated after every protocol.
Make sure to follow the software WAX' reuse settings.

Milestone s.r.l. has collected some cause/effect scenarios that affect tissue quality. For further information see MW tissue processing troubleshooting guide and MW decalcification troubleshooting guide pag. 93 and 100.

8.5. Tissue processing selection guidelines

Ethanol-Isopropanol-WAX

1. Ethanol-Isopropanol recommended as the standard routine method for small to medium-large size biopsies.
2. Fat content of the tissue is kept to a minimum (< 2mm thickness).
3. Very Cost effective for general tissue-processing.
4. Strongly recommended for processing of Renal/Gastric, breast core biopsies and equivalent tissue size.

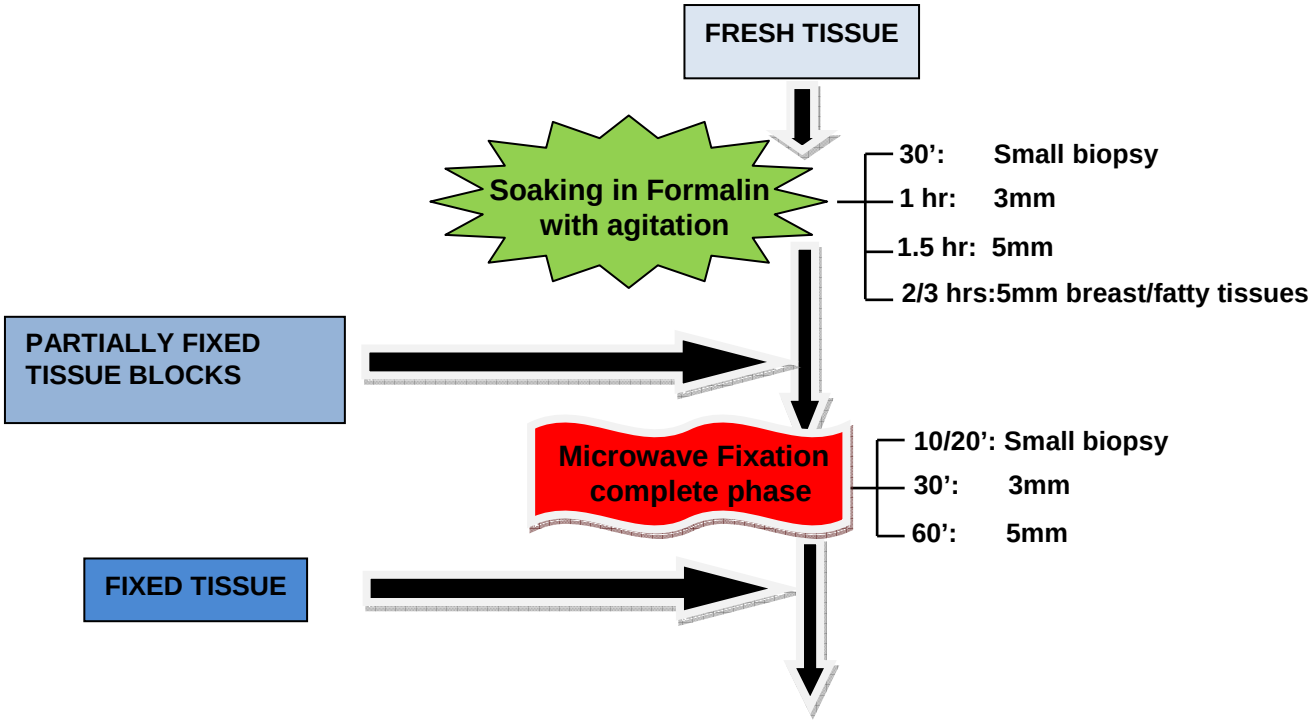
JFC-Isopropanol-WAX

1. JFC-ISO sequence is strongly recommended for high fat content such as Breast / Lipoma up to full size cassette in less than 4 hours.

PROWAVE-WAX

1. PROWAVE is a "one step" solution that can be used for tissues where overnight fixation time is uncertain, since PROWAVE can also act as a secondary fixative.
2. Ideally suited for non-fatty tissues (up to 5mm thick) or moderate lipid content tissues (up to 3mm thick).

TISSUE PROCESSING SELECTION GUIDELINES



FRESH RENAL BIOPSIES

Soaking in Formalin up to 30 min.

↓

Microwaving in Formalin
5 min. ramping time to 50℃
10 min. holding at 50℃

↓ Washing in Ethanol 1 min

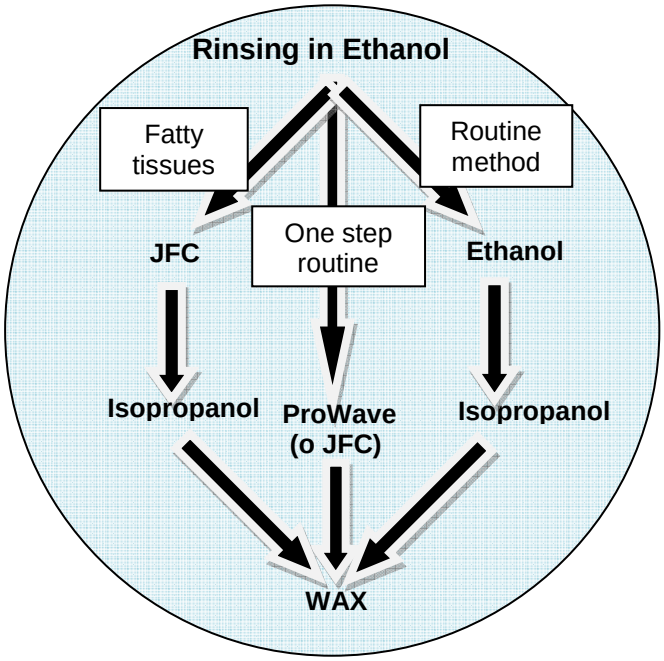
Ethanol 100% - 10 min total time.

↓

Isopropanol 100% - 10 min total time.

↓

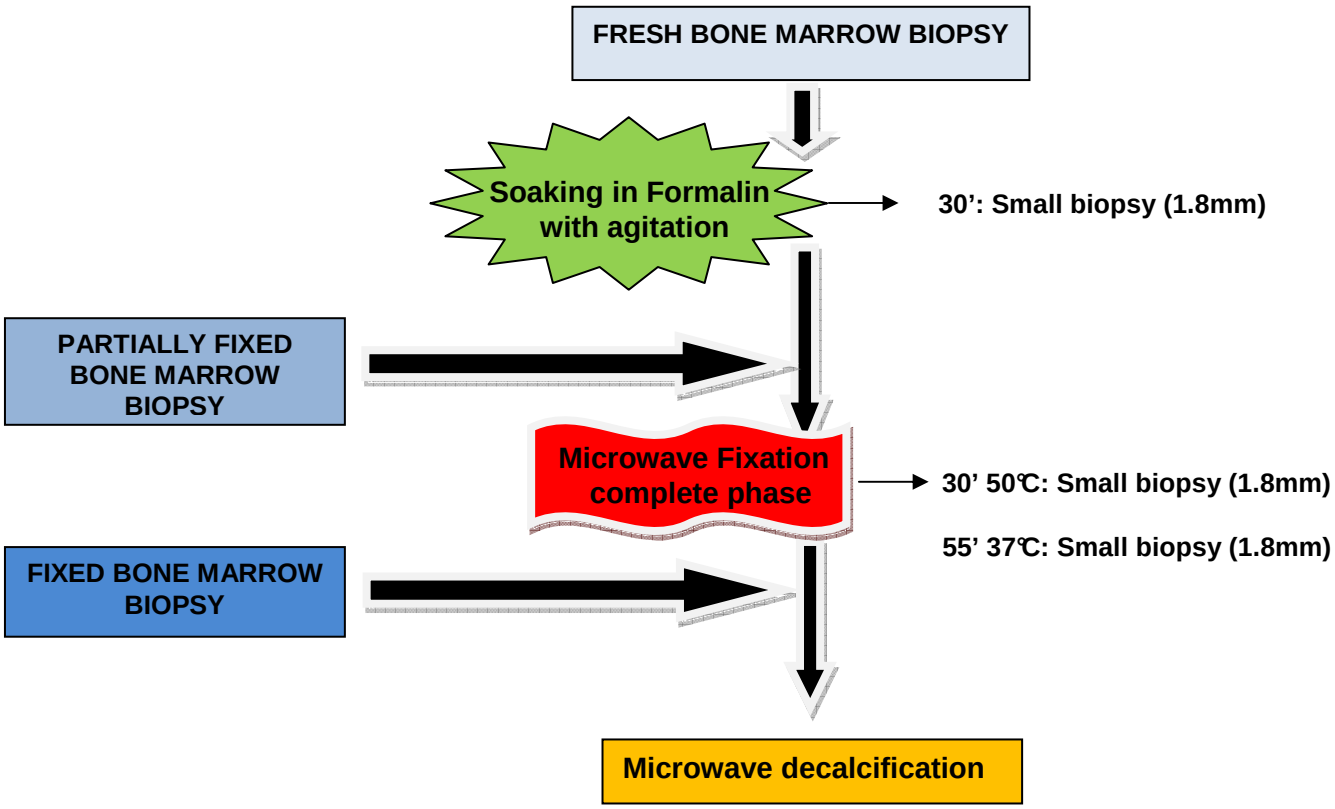
WAX 15-20 min.



8.6. Bone decalcification guidelines

MILESTONE
HELPING PATIENTS

DECALCIFICATION GUIDELINES



EDTA 10%(pH 7.2-7.4) 37℃	EDTA10% (pH7.27.4) 50℃	FORMIC 10% 37℃	FORMIC 10% 50℃
18 hours	3.5 hours	1.5 hours	1 hour

All above are indicative time-range for generic small biopsies of 1.8mm.
Milestone anyway recommends that checking of the bone samples during a decalcification program is done at least at half of the above time. So that user can better define optimum protocols for its samples.

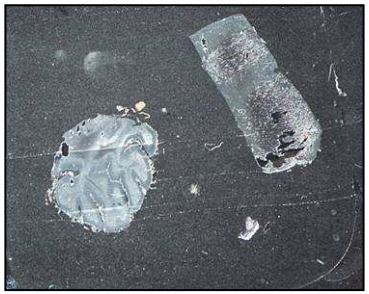
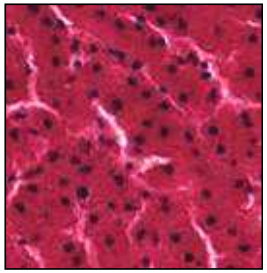
EDTA 10% (pH 7.2-7.4): recommended solution for optimal morphology, IHC and molecular biology.

Microwave decalcification with both EDTA and Formic acid leads to satisfactory morphology, IHC and molecular biology but it's of paramount importance not to over-decal tissue, hence check of the bones' status must be consistently performed.

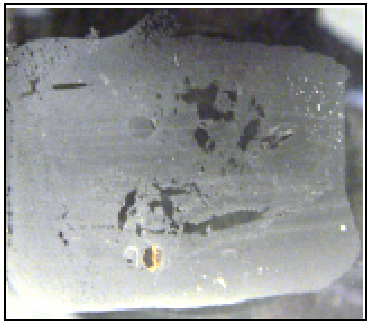
When the users decide to make their own protocols, temperature above 50℃ should be avoided.

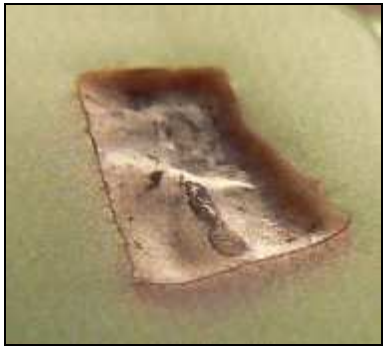
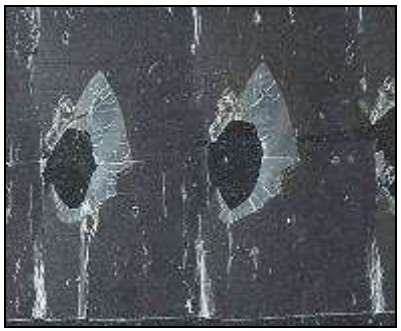
A. APPENDIX

A.1. MW tissue processing troubleshooting guide

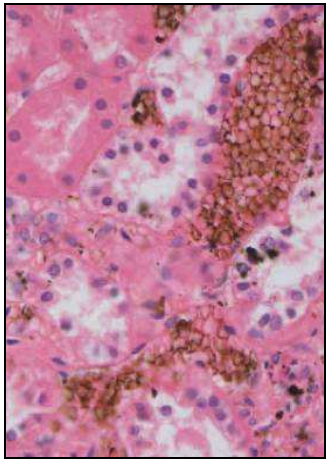
PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
Pyknotic nuclei and severe cytoplasmic distortion of the tissue section. **Poor dehydration.** Tissue sections have the microscopic appearance of pyknotic nuclei and severe cytoplasmic distortion (overheated appearance). Opaque white surface appearance and softness of some areas of the block after the trimming.	  	**1.** Tissue has been poorly fixed and processed exclusively with JFC solution (JFC is NOT a fixative). **2.** Water contamination of microwave ethanol step due to carry over of water from rinsing alcohols or the quality of ethanol in use with microwave is less than 100% (poor dehydration). **3.** Water carry over is increased in rinsing alcohols by the use of sponge biopsy pads (poor dehydration). **4.** For small biopsy samples: inadequate dehydration due to use of paper wraps that restricts the flow of reagents. For larger biopsies: processing time selected is inadequate for dehydration. **5.** Additives used in some commercial formalin fixative preparations interfere with JFC, even though tissues are well fixed in formalin (rare occurrence).	**1.** Tissues to be fixed overnight in formalin, if using JFC exclusively. Introduce an ethanol microwave step to post fix tissues with ethanol, prior to using JFC. **OR** Use Ethanol-Isopropanol processing. **2.** Replace used microwave ethanol with fresh 100% ethanol (pure or reagent grade). **AND** Implement regular checks of ethanol with a Hydrometer, to ensure that microwave ethanol is 100% quality (water free). **3.** Introduce an extra (third) ethanol rinse to ensure sponge pads are well cleansed. **4.** For small biopsies with biopsy wraps: do not use the small biopsy run but instead increase the processing time in the ethanol and Isopropanol to compensate for the wraps restricting reagent flow. **AND** For larger samples sizes: increase the processing time. **5.** Introduce an ethanol microwave step to wash out the contaminants from the tissues, prior to using JFC.

PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
Specimens partially or completely detached from surrounding WAX. Tissue block surface appears to collapse “Dry back” and samples appear partially or completely detached from surrounding WAX when the tissue is observed the next day. Tissue block very difficult to section.	 	**1.** Processing time is inadequate for the tissue size selected, resulting in incomplete dehydration/clearing and WAX impregnation. Tissues that retain any of the solvent will escape by next day, producing this effect, varying according to the size.	**1.** Select the correct processing time, or select longer processing time for the sample size.

PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
Inadequate Clearing of fat. The block face has a “greasy” feeling. Tissue block difficult to section. When section placed on water bath the section breaks up. Softness of some areas of the block after the trimming.	  	**1.** Processing time for tissue is inadequate for the size selected, resulting in incomplete removal of fats, especially from fatty specimen blocks, such as breast. This can be seen when processing the larger blocks, where processing times become more critical to accommodate the larger sizes. **2.** Use of isopropanol as clearing agent for fatty tissues is inefficient for the removal of fats, especially the larger blocks of breast. **3.** Reuse life of dehydration or clearing reagent has been exceeded.	**1.** Select the correct processing time, or select longer processing time for the sample size. **AND** Reduce tissue thickness when preparing wet tissue blocks, if reducing processing times is not desired. **2.** Use JFC as the alternative clearing agent. **AND** Significantly reduce tissue block thickness (50%) as well as increase WAX impregnation time (compromise method, not recommended as it may be impractical to implement routinely). **3.** Replace the dehydration/clearing reagent or reduce the number of times the solution is reused.

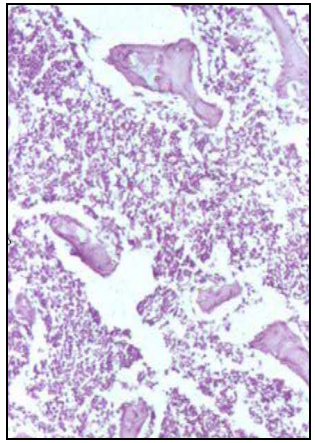
PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
Collapse of block upper face after sectioning. Tissue block surface appears to collapse “Dry back” when the tissue is observed the next day. This occurs even though you have easily cut a section of the block from the previous day. Tissue block not difficult to section the same day.	  	**1.** Tissue has been sufficiently dehydrated and cleared (dry tissue) allowing sections to be cut, however WAX impregnation is not entirely complete with residual amounts of the previous solution remaining. Indicated by continued bubbling originating from the tissue blocks in the final stage (near the end) of the WAX program. Does not occur in smaller blocks, but may appear as tissues increase in size. The result is that tissues that retain any of the solvent will escape by next day, producing this effect, varying according to the size.	**1.** Retrospectively increase WAX impregnation time by melting the block down and placing it into molten WAX in a WAX oven for convenience. At least an hour. **AND** Prospectively increase standard WAX impregnation times. Approx. 30 minutes for the longest processing program. For the shorter processing programs approximately 15 minutes increase in WAX time.

PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
White appearance of block face. Tissue block surface looks unprocessed after trimming the block (opaque white surface). Section can be easily cut and when placed on water bath it does not explode. “DRY” feel of block face in unprocessed areas, usually in the centre of the larger blocks.	  	**1.** Tissue has been sufficiently dehydrated and cleared (dry tissue), however WAX impregnation is not complete. Indicated by continued bubbling originating from the tissue blocks in the final step of the WAX program. Can be seen when processing larger blocks, where times become more critical to accommodate the larger sizes.	**1.** Retrospectively increase WAX impregnation time by melting the block down and placing it into molten WAX in a WAX oven for convenience. **AND** Increase standard WAX impregnation times for future processing runs.

PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
Pigment deposits in microscopic section. Microscopic picture shows pigment deposits (black/brown) at sites of hemorrhagic deposits (Blood vessels, Spleen and products of conception).		**1.** Hemorrhagic tissue that has not been adequately fixed (stabilized) will display deposits of formalin pigment at sites where there are abundant red blood cells. Present in tissues with hemorrhagic sites such as major blood vessels, where there are abundant red blood cells and related breakdown deposits, this especially includes the Spleen.	**1.** Confirm that the pigment is actually formalin pigment and not hemosiderin (Iron break down products of red blood). **AND** To remove pigment retrospectively, if it interferes with diagnosis, then use the standard formalin pigment removal treatment method that uses Picric Acid. **AND** Prospectively, to avoid this from occurring is to ensure that hemorrhagic tissue is well fixed before by microwave fixation or conventional fixation, before microwave processing.

PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
Fatty tissue collapses in block and microscopic section. **Macro**: fatty tissue block structure size looks much smaller than the original piece placed in the cassette (appears collapsed). **Micro**: the fatty section does not that honeycomb appearance of fatty cells and instead the fat cells are collapsed into themselves (squashed together).	BEFORE  AFTER 	**1.** Tissue size is too large for adequate fixation to occur and stabilize the tissue to withstand subsequent exposure to reagents, such as JFC. **2.** Present in larger fatty tissue blocks where there is an absence of connective tissue parenchyma to hold fat cells in place: connective tissue provides a framework to support fatty cells in place. More likely to be seen in larger fatty tissue blocks and not in smaller fatty biopsies such as breast core biopsies.	**1.** Ensure that tissue fixation for the larger tissue blocks has been performed conventionally for at least overnight, or with microwave fixation prior to microwave processing: don't assume tissue is well fixed when dealing with larger size samples. **AND** If using JFC as the only processing agent, then change to a program that utilizes JFC followed by Isopropanol, where Isopropanol helps stabilize fatty cell structure. **2.** Use of Isopropanol as the last reagent step before WAX infiltration will reduce the risk of fatty cell collapse, so a preset protocol for fatty tissue should employ Isopropanol or ProWave as the last reagent step prior to WAX infiltration

A.2. MW decalcification troubleshooting guide

PROBLEM	BLOCK/SLIDE	POSSIBLE CAUSES	RIMEDIAL ACTION
Inadequate decalcification: Areas of the tissue section containing unremoved calcium. Appearance of dark blue areas in the trabeculae.		**1.** Section was not placed in decalcifying solution before processing. **2.** Section was left in decalcifying solution for too little time.	**1.** Ensure that tissues containing calcium are placed in decalcifying solution. **2.** Surface decalcification by carefully facing the block and then treating the exposed face with the decalcifying solution. The block after must be rinsed well and the first ribbon taken. **AND** Check the end point of decalcification carefully, use radiography if necessary to determine completeness of decalcification. A manual instrument can be a needle. **AND** Increase standard DECALCIFICATION times for future decalcifications.
Excessive Decalcification: Loss of nuclear detail and nuclear staining. Decrease in basophilic staining properties.		**1.** Section left in decalcifying solution for too long time. **2.** Section not well fixed before placing in decalcifying solution.	**1.** Rigorously monitor the end point of decalcification using radiography if necessary or a manual needle. **2.** Ensure good fixation before placing sections in decalcifying solution.

A.3. Summary

Problem	Cause	Remedy
Pyknotic nuclei and severe cytoplasmic distorsion	Poorly fixed.	→Extend fixation time.
	Poor fixation/JFC reaction.	→Use JFC/Isopropanol program.
Poor Dehydration	Alcohol contamination (water).	→Replace alcohol.
	Use of sponge Pads/ inefficient biopsy Pads.	→Extend processing time. →Use sponge alternatives.
	Processing cycle too short.	→Use appropriate size processing cycle.
Specimens detached from surrounding WAX	Processing cycle too short.	→Use appropriate size processing cycle. →Reduce tissue block thickness.
Incomplete Clearing of fat	Processing cycle too short.	→Use appropriate size processing cycle. →Reduce tissue block thickness.
	Isopropanol inefficient for fat clearing.	→Use JFC as alternate clearing agent. →Reduce tissue block thickness.
	Dehydration/Clearing agent reuse life exceeded.	→Replace Dehydration or Clearing reagent.
Collapse of block face after sectioning	WAX infiltration not entirely complete.	→Increase WAX infiltration time.
White appearance of block face	WAX infiltration not entirely complete.	→Increase WAX infiltration time.
Pigment deposit in sections	Incomplete fixation of blood.	→Perform pigment test to exclude whether formalin pigment or hemosiderin deposits. →Include MW fixation or extend conventional fixation time.
Fatty tissue collapse in blocks & microsections	Inadequate fixation of tissue, reacting with JFC.	→Fix tissue conventionally overnight or include MW fixation. →Use JFC followed by Isopropanol protocol for processing.
	Absence of connective tissue parenchyma to support delicate fatty network structure.	→Use JFC followed by Isopropanol protocol for processing.
Inadequate decalcification	Not decalcified before processing.	→Use decalcifying solution for bones
	Decalcification time too short.	→Surface decalcification of blocks. →Check the end point of decalcification. →Extend decalcification time.
Excessive Decalcification	Decalcification time too short	→Check the end point of decalcification.
	Poorly fixed.	→Extend fixation time.

B. APPENDIX

B.1. How to manage samples while an alarm is occurring during histoprocessing

1. Never leave samples in open air or under fume hood, to avoid drying.
2. Put samples as quickly as possible into an external container with one of the following reagent in a quantity sufficient to cover all samples:

   Either ETHANOL (90-100%) or ISOPROPANOL

3. Check the wetness level of at least 10% of samples (in different parts of the rack). If wetness level appears:

GOOD WETNESS WITH NO DOUBTS

A. Let samples in reagent.

B. Check the step when the emergency situation occurred.

C. Check if the unit can be used for a new cycle (*).

D. Restart with the same program skipping the phases already performed and restart from the correct step.

Select the correct step to start from in the following table:

NOT GOOD WETNESS

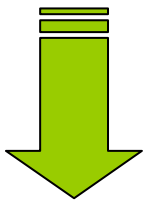
A. Follow the recovery laboratory internal protocols for air dried samples.

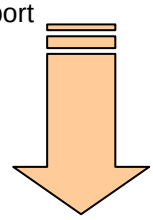
If not available, follow Milestone suggested recovery protocol.

B. Check if the unit can be used for a new cycle (*).

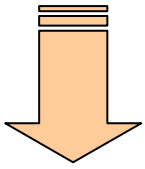
C. Restart the processing cycle.

(*) If necessary, contact your local customer support





ALARM OCCURRED DURING THE FOLLOWING PROCESSING STEP	RESTART FROM:
• FIXATION	Fixation step (fixation uncertain)
• ETHANOL	Ethanol step
• ISOPROPANOL	Isopropanol step
• WAX IMPREGNATION	WAX impregnation step



MILESTONE SUGGESTED RECOVERY PROTOCOL FOR AIR DRIED SAMPLES

1. Absolute alcohol 2 changes, 1 hour each.
2. 95% alcohol 2 changes, 1 hour each.
3. Running tap water for 30 minutes.
4. Place in formol-glycerol solution (*) until tissues become soft and pliable with gentle pressure. Tissues may remain in formol-glycerol for up to 8 hours without adverse results.
5. Reprocess on tissue processor in usual manner.

If samples have been put in WAX, it is necessary to start with the dewaxing step: Xylene, 3 changes, 1 hour each

Formol-Glycerol Working Solution:

Formalin- Sodium Acetate, (Stock)	*90ml*
Glycerin (Glycerol)	*10ml*

Formal-Sodium Acetate (Stock):

Formaldehyde, 38-40%	*10ml*
Sodium Acetate	*2.0 gm*
Tap Water	*90ml*

(*) Should Formol-Glycerol not be available, use tap water, even if the quality of the recovery is lower.

CE IVD

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