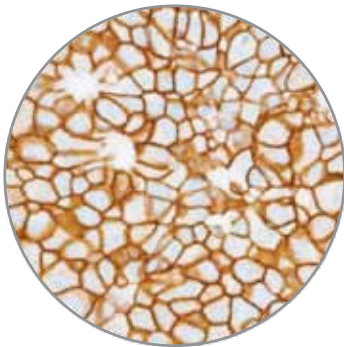
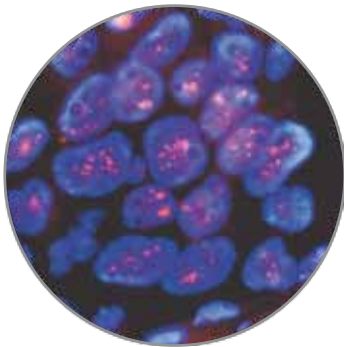




MILESTONE
H E L P I N G
P A T I E N T S

**Full compliance to ASCO/CAP*
recommendations
for HER2, ER testing**



FixMATE

Automatic Tissue Fixation System

Standardization and documentation of the preanalytical step

FixMATE Automatic Tissue Fixation System

The Problem. Control of fixation

Accurate control of all steps of the preanalytical process is a prerequisite for precise, reliable and consistent diagnostic assays. Recent publications* have evidenced that standardization and documentation of the **all important fixation step** will lead to improved I.H.C. assays.

Manual fixation

Leaving the specimens in a container with formalin overnight or longer does not fulfill the requirements for controlled fixation.

- How many hours/minutes is overnight?
- What was the temperature of the fixative?
- Was stirring available for temperature homogeneity?
- After how many cassettes was formalin substituted?
- Was the pH constant?
- What kind of documentation is available?

Automatic fixation

Until now, documented fixation protocols could only be obtained by placing specimens in an automatic tissue processor.

This means holding a high performance instrument almost idle for hours/days waiting for the fixation process to be completed and documented.

The Solution. FixMATE Automatic Tissue Fixation System

A new productivity and quality control tool to run user-defined fixation protocols.

Fully automatic, the FixMATE allows complete control of the fixation parameters:

- Temperature. From room temperature to 60°C
- Time. Up to 95 hours 52 minutes
- Stirring of solution
- Automatic rinsing with ethanol
- Automatic holding of fixation step with saline/PBS solution
- Constant pH of solution during process (closed system)
- Automatic reagent management



*Consensus Recommendations on Estrogen Receptor Testing in Breast Cancer By Immunohistochemistry.
Hadi Yazji, MD et al.
Appl immunohistochem Mol Morphol - volume 16, Number 6, December 2008

ASCO/CAP Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer
A. C. Wolff et al. Arch Pathol Lab Med - Vol. 131, January 2007

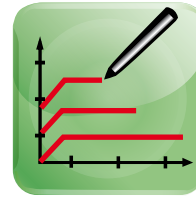
1) Select the fixation protocol to fit your workflow



Single run



Single run + holding



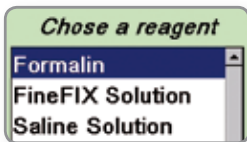
Multiple run

2) Enter fixation data

1 - Enter run I. D. through virtual keyboard



2 - Select fixative



Run I.D.: test breast tissue **1**

Chose a reagent

Formalin **2**

Time: 8 hr 30 min **3** Temp.: 37°C **4** Nr. of cassettes: 20 **5**

Run I.D.: test breast tissue
 Nr. of cassettes: 20
 Reagent: Formalin
 Temperature: 37°C
 Run time: 8hr30min
 Run will end on: Wed, 10-Mar-2010, at 22:57

Start Save

3 - Set fixation time in hours /minutes.
Up to 95 hours 59 minutes.

4 - Enter temperature of fixation from room to 60°C.

The built-in sensors, the P.I.D. (*Proportional, Integral Digital*) control of the resistance heated cavity plus the powerful stirring assure precise control and homogeneity of temperature for all specimens.

5 - Enter number of cassettes of actual run through virtual keyboard.

After reaching a preset number (e.g. 500/1000) the user will be advised to renew the formalin solution. The ratio: volume of specimen/formalin is 1:20, as suggested by literature.

3) New protocol is set

Run I.D.: test breast tissue
 Nr. of cassettes: 20
 Reagent: Formalin
 Temperature: 37°C
 Run time: 8hr30min
 Run will end on: Wed, 10-Mar-2010, at 22:57

Start Save

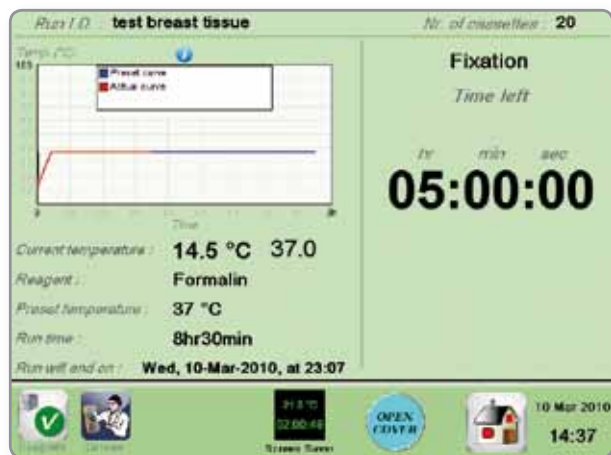


The variable volume cavity accepts racks from any conventional tissue processor.



As well as all Milestone racks for the Histos and Pathos families.

4) Press **START**. Process will run automatically



The microprocessor controlled system will accurately reproduce the set temperature curve for the time specified. Cassettes will be processed by a continuous flow of formalin through powerful magnetic stirring. FixMATE is a closed system with built-in exhaust connection to eliminate fumes. At the end of the fixation cycle, formalin is automatically drained to the original bottle. One or more rinsing cycles with ethanol follow. The user will be alerted 2 minutes before the end of the cycle, by an audible alarm. The specimens are fixed, rinsed and ready for the dehydration/clearing steps, in a tissue processor.

Flexibility in fixation protocols



Single run

Automatic single step fixation plus rinsing

This protocol covers fixation at a preset temperature and time. At the end of the cycle, formalin is drained and one or more rinsing steps with ethanol (e.g. 75%) are automatically carried out at standardized cycles (2-3 minutes). User is alerted that cycle is completed by audible alarm.

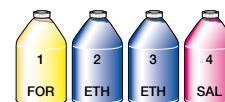


Single run + holding

Fixation plus holding step. Weekend/holidays

A very useful feature when fixation time is over during weekend or at unsuitable times for the lab workflow. When fixation time is elapsed, formalin is automatically drained. After a first rinse, a saline, PBS or other holding solution is pumped in, to stop the fixation process.

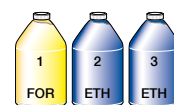
Specimens are held at room temperature until user manually intervenes for starting draining and rinsing steps. **Typical case: breast specimens arriving in the lab on a Friday afternoon and fixation time is set at 8 hours.**



Multiple run

Simultaneous run of different time protocols

Whenever fixation protocols are set for longer periods (24-48-72 hours). This program will allow setting 3 simultaneous different fixation protocols, with loading at different times. The temperature must be the same for each protocol. Rinsing steps are to be carried out externally, to avoid interference with the protocols still running.



Full documentation

With the FixMATE, documentation of every factor influencing the fixation process is stored in a log book for easy retrieval.

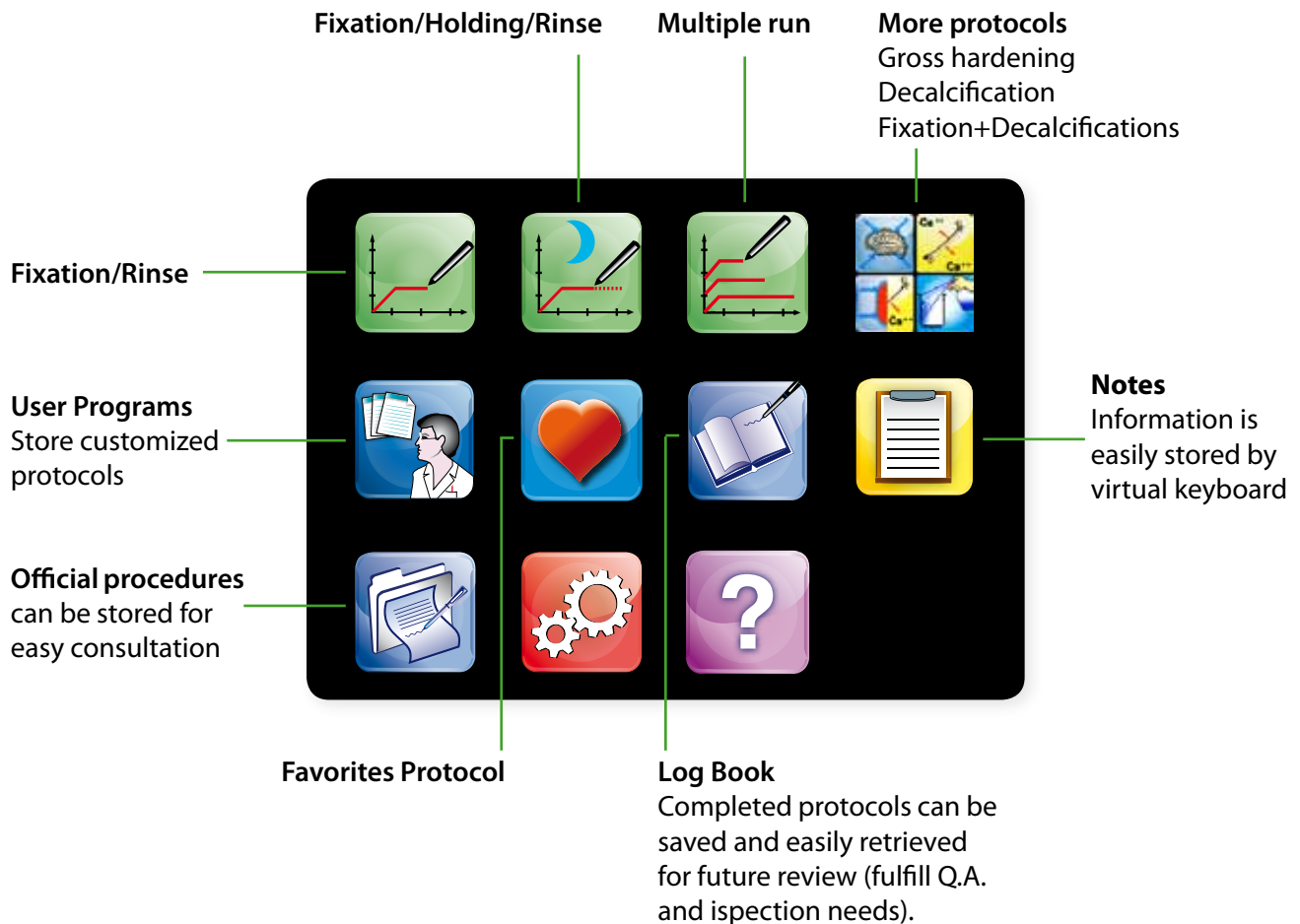
Fixation protocols can be transferred to a USB stick and then printed through USB port for Quality Assurance and Compliance regulations.

Full compliance to ASCO/CAP* recommendations for HER2, ER testing.



- Type of fixative
- Start and finish time/date of fixation
- Temperature solution
- Specimens ID
- Operator ID

Simplicity at best. Icon-driven software



The advantages of FixMATE

An innovative, task-specific “tool” for standardized and documented performance-based protocols. Full compliance to ASCO/CAP* recommendations for HER2, ER testing. Suitable for racks from any conventional tissue processor as well as all Milstone racks .

Complete control of fixation parameters.

- Temperature
- Time
- Stirring
- Rinsing
- Specimen/fixative volume ratio
- Holding step

Packed with the latest sensor technology



- Dual push/pull exhaust system
- No formalin fumes to the lab
- 2 USB ports
- Drawer for up to 4 bottles (1 US gallon or 5 litres volumes)
- Simple, effective snap-on connectors
- No transfer of reagents

MILESTONE



HELPING PATIENTS

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