Tissue-Tek® Xpress® x120

SAKURA®

Rapid Tissue Processor

Operating Manual

Tissue-Tek® Xpress® x*120*

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Rapid Tissue Processor

Operating Manual

Manufactured for:
Sakura Finetek U.S.A., Inc.
Torrance, CA 90501 U.S.A.

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INTRODUCTION

Intended Use

The Tissue-Tek® Xpress® x120 is designed for the purpose of processing human and animal tissue specimens.

The instrument, as part of the histopathology process, is intended to facilitate the in vitro examination of human and animal tissue for morphology changes by a pathologist.

General Description

The Tissue-Tek® Xpress® x120 Continuous Rapid Tissue Processor is a self-contained tissue processor employing microwave and vacuum infiltration techniques. The instrument performs automatic rapid processing (fixation, dehydration, clearing, and paraffin impregnation) of tissue specimens in preparation for histological study and examination. The instrument incorporates individual processing stations, scheduling software, and an automated transfer system that provides for continuous processing of multiple sample baskets. Processing time for a single basket is approximately 65 minutes, with a maximum throughput (during continuous processing) of 120 specimens per hour.

NOTE: Maximum throughput is based on processing 40 cassettes per basket, where processing time for all processes is equal (15 minutes). Reduction in the number of cassettes processed per basket, or an increase in processing time will lower throughput.

In order to achieve continuous processing, the instrument utilizes a Transfer System that sequentially moves baskets containing tissue specimens from a Loading Station, through the four processing retorts to an Unloading Station for removal of the basket. The instrument employs scheduling software to efficiently process and transfer sample baskets.

The Tissue-Tek Xpress x120 instrument has the following features:

- Instrument can be configured for either Manual or Automatic start-up
- Compatible specimen types include Formalin fixed tissue, tissue fixed in Tissue-Tek Xpress Molecular Fixative
- Supports use of standard cassettes and Tissue-Tek® Paraform® cassettes (both microwavable); compatible cassettes include:

  Standard cassette (Tissue-Tek® Brand Uni-Cassette® Cassettes)

  Biopsy cassette (Tissue-Tek® Brand Uni-Cassette® Biopsy Cassettes)

  Tissue-Tek® Brand Paraform® Standard cassette

  Tissue-Tek® Brand Paraform® Biopsy cassette

  Tissue-Tek® Brand Paraform® Biopsy 13 x13 cassette

  Tissue-Tek® Brand Paraform® Biopsy Core cassette

  Tissue-Tek® Brand Paraform® Biopsy Shaved cassette

  Tissue-Tek® Brand Paraform® Orientation cassette
- Standard cylindrical basket with lid facilitates processing of up to 40 cassettes per basket; upper loading limit of basket is marked to aid in positioning cassettes
- Tissue-Tek® Paraform® magazines are compatible for use with the instrument (for use in conjunction with the Tissue-Tek® AutoTEC® Automated Embedding System). Each Tissue-Tek Paraform magazine holds up to 20 Paraform® cassettes. Two magazines linked by a handle can be placed in the Loading Station of the Tissue-Tek Xpress x120.
- Two user-selectable automated processing programs based on specimen thickness, Standard Program (15 minutes per retort) or Extended Program (30 minutes per retort).
- Maximum throughput of 120 cassettes per hour (under Standard Program, where each basket or pair of magazines processed contains 40 cassettes)
- Integral fume control system to prevent fumes from escaping the instrument

Safety Precautions

NOTES, CAUTIONS, WARNINGS, and other safety related labeling are provided throughout this manual to indicate levels of potential hazards as defined below:

NOTE Indicates a reminder or other helpful information.

CAUTION Indicates a potential hazard in which failure to follow instruction may result in damage to the Tissue-Tek® Xpress® x120 and/or other property, or may give poor processing results.

WARNING Identifies a potential hazard in which failure to follow instructions may result in serious injury to the operator and/or other personnel.

HOT SURFACE Indicates hot surfaces. Take precautions to prevent burns.

BIOHAZARD Possibility of infections depending on the type of specimens processed. Prevent infections by using Personal Protective Equipment (PPE) as required by OSHA and any applicable state or local regulations.

CAUTION: Do not use cassettes that contain metal or use metal lids. Do not place any metal items in Retorts #1 and #2.

CAUTION: When placing cassettes into the basket, do not allow cassettes to extend above the upper limit band.

CAUTION: The instrument uses flammable liquids. Do not use an open flame near the instrument.

CAUTION: When operating the instrument or when handling contaminated, bio-hazardous materials use Personal Protective Equipment (PPE) as required by OSHA and any applicable state or local regulations.

CAUTION: Operating the instrument for a use other than described in the operating manual could result in hazardous conditions.

CAUTION: Do not remove the Outer Panels on the instrument.

Cabinet Front (Figure 1-A)

Loading Station Access Door **1** — provides access to the Loading Station to allow loading of tissue specimens for processing. Access to the Loading Station is permitted/denied, under software control, depending on the current state of the instrument (see "*Loading Indicator*", below, for details). A switch associated with the access door serves as an interlock to immediately remove power from the Transfer System motors (see *"Transfer System (Figure 1-M)"* on page 1.11 for details) in the event the door is opened while a transfer is in process. An alarm sounds any time the Loading Station access door is open, even though the Loading Indicator is off. An alarm also sounds if the Loading Station access door is left open for 30 seconds or more while the Loading Indicator is illuminated.

Loading Indicator **2** — provides an indication of the status of the Loading Station access door:

Light Off – indicates "access denied" to the Loading Station access door; the door should not be opened. The Loading Indicator is "off" whenever there is a basket in the Loading Station or when the Transferring Arm is in motion.

Light On – indicates "access permitted" to the Loading Station access door; the door can be opened. The Loading Indicator is "on" when there is no basket in the Loading Station and the Transferring Arm is stationary.

The Loading Indicator is operational only when a user is logged onto the system.

Unloading Station Access Door **3** — provides access to the Unloading Station to allow unloading of processed tissue specimens. Access to the Unloading Station is permitted/denied, under software control, depending on the current state of the instrument (see "*Unloading Indicator*" on page 1.4 for details). A switch associated with the access door serves as an interlock to immediately remove power from the Transfer System motors (see Figure 1-M on page 1.11 for details) in the event the door is opened while a transfer is in process. An alarm sounds any time the Unloading Station access door is open, even though the Unloading Indicator is off. An alarm also sounds if the Unloading Station access door is left open for 30 seconds or more while the Unloading Indicator is illuminated.

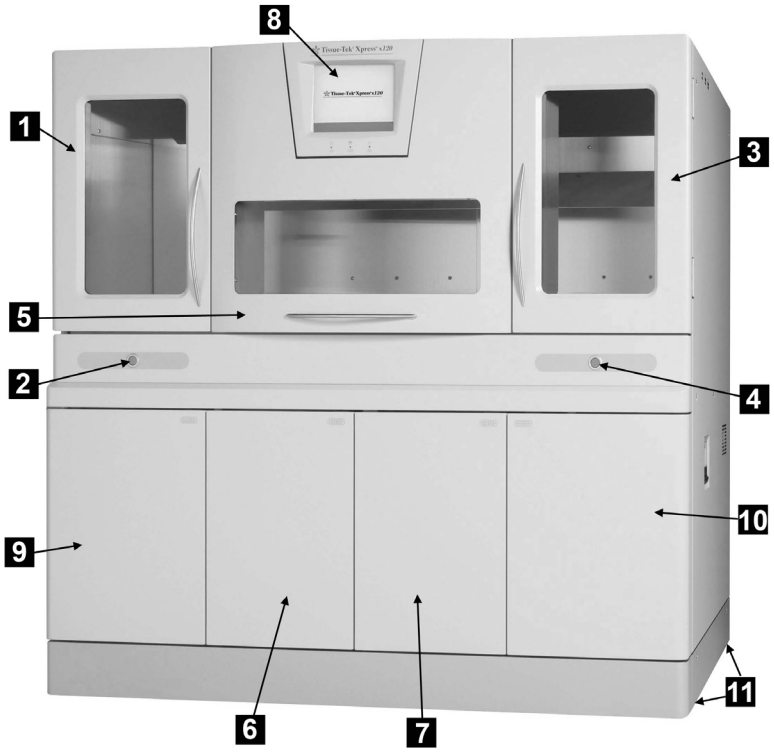


Figure 1-A

Unloading Indicator **4** — provides an indication of the status of the Unloading Station access door:

Light Off – indicates "access denied" to the Unloading Station access door; the door should not be opened. The Unloading Indicator is "off" whenever the Unloading Station is empty or when the Transferring Arm is in motion.

Light On – indicates "access permitted" to the Unloading Station access door; the door can be opened. The Unloading Indicator is "on" when there is a basket in the Unloading Station and the Transferring Arm is stationary.

Flashing – alerts the operator to remove the basket(s) from the unloading station or the access door is open and needs to be closed immediately.

Audible Alarm (not shown) – indicates the following:

- A tone sounds at the completion of a processing cycle (when a basket has arrived at the Unloading Station). Tone selection (from seven available tones), volume selection (high, middle, low), and pattern selection (continuous, intermittent, 30 seconds only) are user selectable (see "*Configuring System Settings*" on page 3.2 for details).
- A continuous tone sounds if an abnormal condition is detected during processing. The alarm condition must be acknowledged and/or cleared by the operator to cancel the alarm. Tone selection (from seven available tones) and volume selection (high, mid, low) are user selectable (see "*Configuring System Settings*" on page 3.2 for details).

Retort Access Door **5** — provides access to the Microwave and Vacuum Stations for purposes of cleaning and/or maintenance. Access to all four retorts is permitted/denied, under software control, when the instrument is processing specimens.

Retort #1 / #2 Reagent Cabinet Access Door **6** — provides access to retort #1 / #2 Reagent Cabinet for the purposes of replacing reagents.

Retort #3 / #4 Reagent Cabinet Access Door **7** — provides access to the paraffin oven for the purposes of replacing reagents.

Control Panel **8** — comprises the controls and indicators necessary to program and operate the instrument, and to monitor the instrument during processing (refer to *"Control Panel (Figure 1-O)"* on page 1.12 for details).

Fume Control System Access Door **9** — provides access to the fume control system for purposes of replacing the fume filter.

Overflow Bottle Access Door **10** — provides access to retorts #3 / #4 overflow bottles for purposes of cleaning and servicing.

Leveling Feet/Casters **11** — four casters are provided to allow for easy repositioning of the instrument. Adjustable leveling feet associated with each caster facilitate proper leveling of the instrument.

Cabinet Rear (Figure 1-B)

The power cord connector and external interface are located at the rear of the back cabinet.

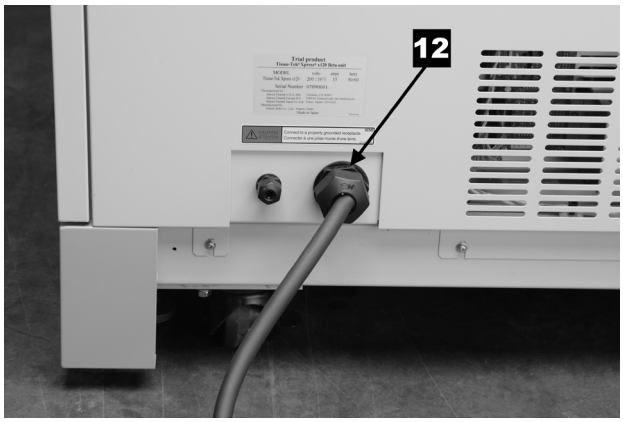


Figure 1-B

Power Cord Connector **12** — accepts the instrument end of the power cord; opposite end of the power cord may be connected to facility power.

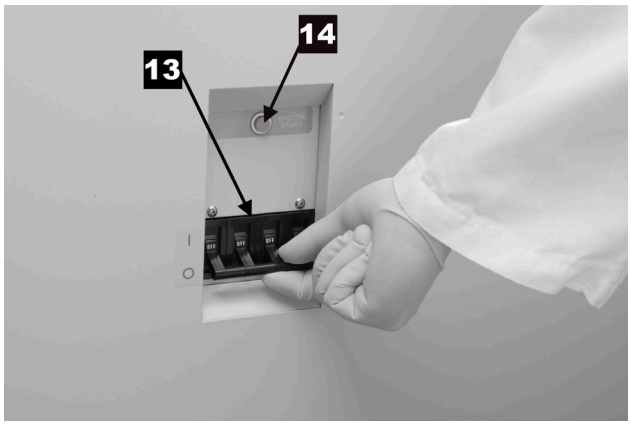


Figure 1-C

Power Switch 13 — Located on the right side panel of the cabinet (Figure 1-C), turns the power on and off.

System Start Button 14 —A button located on the right side panel above the power switch, (Figure 1-C) turns on the computer system.

Internal Light Button 15 — Turns the light inside the Tissue-Tek Xpress x120 on or off (Figure 1-D). The light must be manually turned off. Shutting down the instrument will not turn the light off.

USB Interface 16 — USB communication port for connection to a memory stick for transfer of data to an external PC (Figure 1-D).

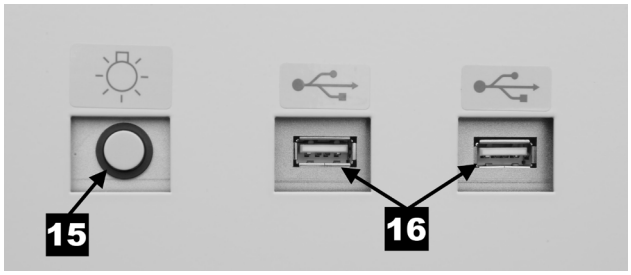


Figure 1-D

External Alarm Output Port — allows for connection of an external audible alarm to a switched no-voltage contact within the Tissue-Tek Xpress x120; contact is switched when an alarm condition occurs.

UPS Signal Input Port — provides for connection of the Tissue-Tek Xpress x120 to an external Uninterruptible Power Supply (UPS) or backup generator.

Location of Major Systems and Components

The Tissue-Tek Xpress x120 instrument is comprised of the following major systems and components (Figure 1-E):

- **Control Panel** 8
- **Loading Station** 17
- **Retort #1** 18
- **Retort #2** 19
- **Retort #3** 20
- **Retort #4** 21
- **Unloading Station** 22
- **Transfer System** 23
- **Fume Control System** 24
- **Reagent Cabinet** 25
- **Paraffin Oven** 26
- **Overflow Bottles** 27
- **Accessory Compartment** 28

Major systems and components of the Tissue-Tek Xpress x120 instrument are described in the following paragraphs.

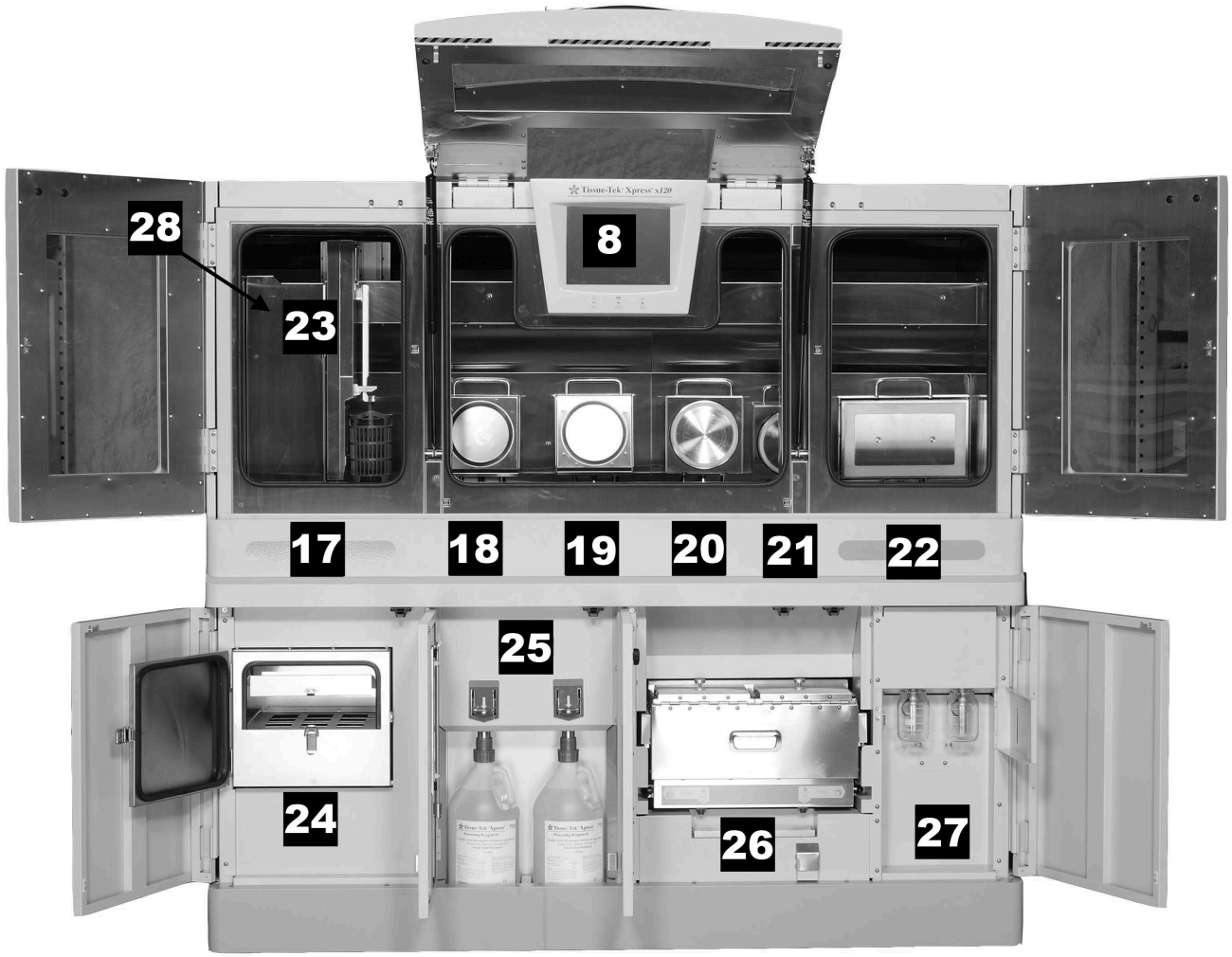


Figure 1-E

Loading Station (Figure 1-F)

Figure 1-F

The Loading Station (Figure 1-F) is an unheated, reagent-filled, removable stainless steel container **17** that facilitates the loading of a single basket or two Paraform® magazines, containing a maximum of 40 tissue cassettes, into the Tissue-Tek Xpress x120. The Loading Station retort holds a maximum of approximately 1.8 liters of reagent (Preprocessing Solution, product code 7115).

Access to the Loading Station is facilitated by an access door in the Cabinet Front (see *"Cabinet Front (Figure 1-A)"* on page 1.3 for details).

A removable lid protects the retort contents (reagent) when the instrument is not in operation.

Microwave Stations (Retorts #1 and #2)

NOTE: Retort #1 and Retort #2 are identical.

At these Mircrowave Stations (Retorts #1 and #2) (**18**, **19**, Figure 1-G) dehydration and clearing processes are performed. The reagent in the Microwave Station retorts is heated by radiating microwaves. Each Microwave Station is comprised essentially of a microwave retort and associated microwave unit (microwave applicator and power supply), preheating chamber, reagent container, and reagent cabinet.

Microwave Retorts (Figure 1-G)

Figure 1-G

Each microwave retort supports the processing of a single basket or two Paraform magazines containing a maximum of 40 cassettes. Each microwave retort has a designated reagent supply level of approximately 1.44 liters, with a maximum capacity of approximately 1.74 liters. Filing and draining of the retorts is accomplished by a reagent flow circuit operating under software control. The flow control circuit incorporates an interlock that prevents reagent from draining out of the retort if a reagent container is not in place in the reagent cabinet.

A two-level reagent level detector is provided. The lower level is used to stop supplying reagent when replenishing; the upper level is used to prevent reagent overflow. When the upper level sensor is actuated, an audible alarm sounds, and the line pump is stopped.

A software controlled temperature regulation unit allows control of reagent temperature at 51°C. The set temperature for the microwave retorts is established during installation, according to elevation of the installation site. A bubbling pump is employed to supply volatilized reagent to the microwave retort to aid in equalizing the temperature of the reagent within the retort.

A hinged lid protects the retort contents during processing. The lid is opened automatically during transfer operations, and may be opened manually when no power is applied to the motor to allow for cleaning and maintenance of the retort. Each retort lid has a sensor that prevents the associated microwave unit from being energized in the event the lid is not fully closed, and immediately turn off the magnetron in the event the lid is opened during processing.

Preheating Chambers

Preheating chambers are used to temporarily store reagent when draining Retorts #1 and #2 prior to transferring a basket or magazines. The Preheating Chambers are located between the retorts and the reagent containers, and keep the reagents warm during basket/magazine transfers. No user access is required except when cleaning the Preheating Chamber sight tubes (see "*Preheating Chamber Sight Tube*" on page 7.11). Each preheating chamber has a maximum capacity of approximately 2.4 liters.

A three-sensor level detection circuit is provided for reagent level detection.

- The lower-level detector is used to stop supplying reagent (after supplying approximately 0.6 to 0.8 liter) when replenishing reagent in Retorts #1 and #2. The sensor is also used to detect low reagent volume level for reagent replenishing.
- The mid-level sensor is used to prevent overflow from the preheating chamber during reagent transfer from the retort to the preheating chamber. When the mid-level sensor is actuated, reagent is drained from the retort to the reagent container rather than being transferred to the preheating chamber.
- The upper sensor is used to prevent reagent overflow. The sensor is actuated at approximately 2.5 liters. When the upper sensor is actuated, an audible alarm sounds, and the line pump is stopped.

A software-controlled temperature regulation unit maintains temperature in the preheating chamber.

Reagent Cabinet (Figure 1-H)

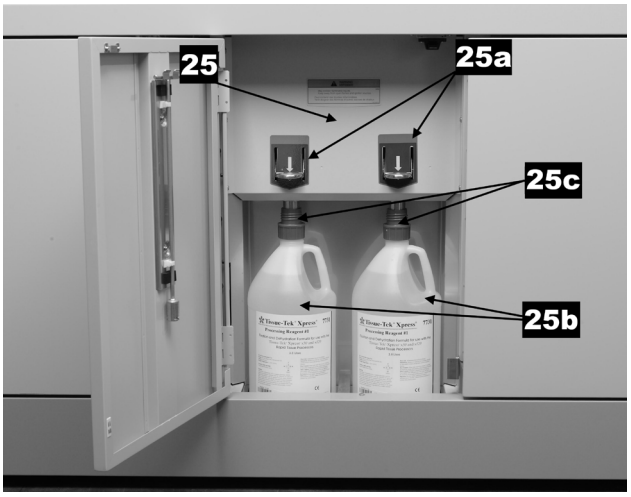


Figure 1-H

The reagent cabinet **25** is accessed through a door in the cabinet front (see *"Cabinet Front (Figure 1-A)"* on page 1.3 for details). The reagent cabinet provides storage space for the reagent containers used by Retorts #1 and #2. A two-position locking lever **25a** associated with each Retort couples the associated reagent container with the reagent flow circuit, and secures the container in place in the cabinet. The reagent cabinet also interfaces with the Tissue-Tek Xpress x120 fume control system (see "*Fume Control System*" on page 1.11 for details).

The reagent containers **25b** are disposable containers that hold the processing reagents for Retorts #1 and #2. Each reagent container is equipped with a two-piece cap/connector **25c**. The upper cap is used during shipment and storage of the container. The lower cap facilitates connection of the container to the Tissue-Tek Xpress x120 system. The same reagent is used in Retorts #1 and #2. The caps and labels are color-coded blue so that the containers cannot be mistaken for other reagents.

Vacuum Stations (Retorts #3 and #4)

NOTE: Retort #3 and Retort #4 are identical.

These Vacuum Stations (Retorts #3 and #4) (**20**, **21**, Figure 1-I) are where the paraffin impregnation processes are performed. The vacuum in the vacuum retort increases removal of the Microwave Station reagents from the tissue specimens, and improves paraffin impregnation of the specimens. Each Vacuum Station is comprised essentially of a vacuum retort with integral retort heater, vacuum pump, paraffin oven, and overflow bottles.

Vacuum Retorts (Figure 1-I)

Figure 1-I

Each vacuum retort supports the processing of a single basket or two Paraform magazines containing a maximum of 40 cassettes. Each vacuum retort has a maximum reagent capacity of approximately 2.0 liters. Filling of the retorts is accomplished by a vacuum pump and reagent flow circuit operating under software control. An ultrasonic sensor is provided for reagent level detection. The sensor is used to stop supplying reagent (at approximately 1.7 liters), when replenishing. The retorts utilize gravity to drain reagent to the paraffin oven.

A software-controlled temperature regulation allows control of reagent temperature at 65°C. An over temperature control (thermal fuse) prevents overheating of the reagent.

A hinged lid protects the retort contents during processing. The lid is opened automatically during transfer operations, and may be opened manually when no power is applied to the motor to allow for cleaning and maintenance of the retort.

Vacuum pumps are used to pump reagent (melted paraffin) into the Vacuum Station retorts. The vacuum pump for Vacuum Retorts applies vacuum for 80 seconds, and then is off for 10 seconds (no vacuum applied). This cycle is repeated continuously.

Reagent is drained from the Vacuum Station retorts to the paraffin oven by gravity. Drain time is approximately five minutes.

Paraffin Oven (Figure 1-J)

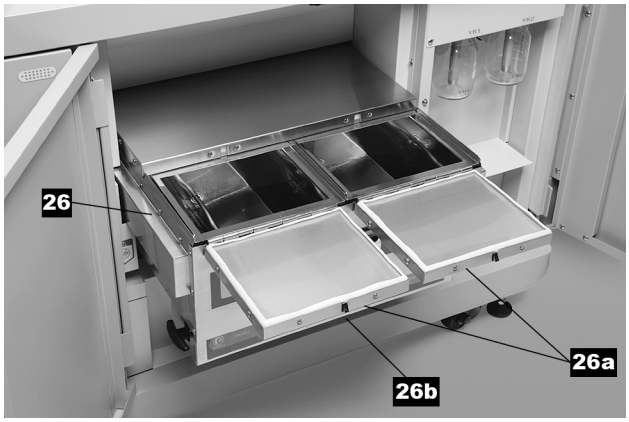


Figure 1-J

The paraffin oven **26** is accessed through a door in the cabinet front (see *"Cabinet Front (Figure 1-A)"* on page 1.3 for details). The paraffin oven is a two-compartment, drawer-mounted container that provides for the storage and heating (melting) of the Vacuum Station reagents. The oven has the capability to melt paraffin at a rate of 2.4 kg (3.0 liters) within 4 hours. Temperature of the paraffin oven is controlled at the set temperature of Vacuum Stations Retorts #3 and #4 by a software-controlled temperature regulation unit. An over temperature control (thermal fuse) prevents overheating of the reagent.

The oven incorporates separate compartments for Vacuum Station Retort #3 and Vacuum Station Retort #4 reagents. Each compartment has a capacity of approximately 3.0 liters of paraffin chips. A reagent level mark in each compartment indicates the proper reagent level inside the compartment (approximately 3.0 liters).

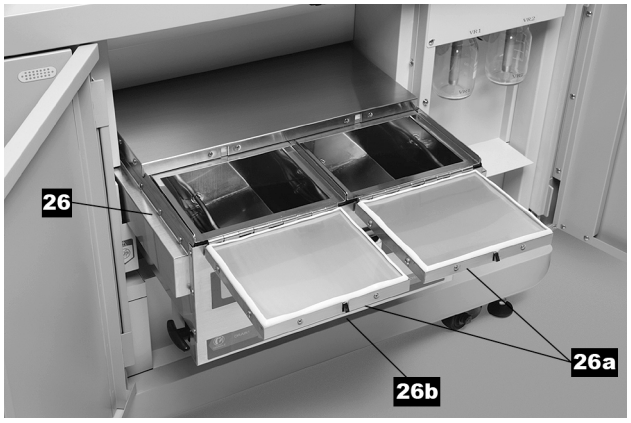


Figure 1-J

The oven compartments are not removable, but slide in and out of the Tissue-Tek Xpress x120 cabinet for purposes of filling, draining, and maintenance. A spigot facilitates the draining of the reagents (see *"Retort #3 and #4 Paraffin Replacement"* on page 7.5). Each compartment is covered by a protective hinged lid **26a**. A drip pan **26b** is provided at the front of the paraffin oven to prevent drips of melted paraffin from falling to the floor around the unit that may occur during the filling or maintenance of the oven.

Overflow Bottles (Figure 1-K)

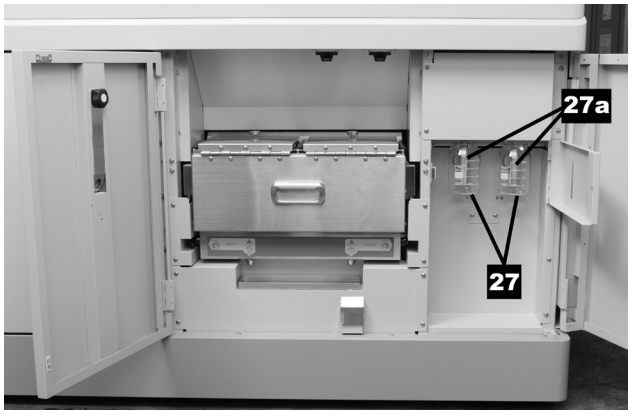


Figure 1-K

An overflow bottle **27** associated with each Vacuum Retort serves as an overflow receptacle in the event excess reagent (paraffin) is pumped into the associated retort. Each bottle has a capacity of 250 milliliters. A proximity sensor **27a** (located behind each overflow bottle) is provided for reagent level detection. The overflow bottles are accessed through a door in the cabinet front (see *"Cabinet Front (Figure 1-A)"* on page 1.3 for details).

Unloading Station (Figure 1-L)

The Unloading Station provides for storage of baskets or magazine sets after completing tissue processing. Access to the Unloading Station is facilitated by an access door in the Cabinet Front (see *"Cabinet Front (Figure 1-A)"* on page 1.3 for details). The Unloading Station is comprised essentially of a dual-retort, heater, and transport tray.

Figure 1-L

The dual-retort **22** allows for temporary storage of two processed baskets or four Paraform magazines containing a maximum of 80 tissue cassettes. The retort is removable for ease in cleaning. A software-controlled temperature regulation unit maintains the paraffin in the processed specimens in a molten state prior to transport and paraffin imbedding.

The heater allows control of retort temperature at 65°C. An over temperature control prevents overheating.

A hinged lid protects the contents of the retorts during storage. The lid is opened automatically during transfer operations, and may be opened manually when no power is applied to the motor to allow for cleaning and maintenance of the retort.

A transport tray is provided to prevent paraffin dripping when removing and manually transporting baskets from the Tissue-Tek Xpress x120 to a paraffin embedding center. The transport tray facilitates transport of two baskets or four Paraform magazines simultaneously.

Transfer System (Figure 1-M)

The Transfer System performs the automated process of transferring baskets from the Loading Station to the Microwave and Vacuum Stations, and ultimately to the Unloading Station. The Transfer System is comprised of a motor-driven transfer arm **23** that provides for movement in the X (horizontal) and Z (vertical) axes.

Figure 1-M

When the instrument is not processing specimens, the transfer arm can be moved manually.

A drip pan **23a** associated with the transfer arm prevents reagent from dripping onto the top panel in the instrument when a basket is transferred between stations. A disposal tray liner **23b** receives reagent drips. A rotational drive associated with the drip pan automatically retracts the drip pan to allow the transfer arm to raise or lower a basket. The drip pan is returned to its location beneath the basket while traveling horizontally between stations.

Fume Control System (Figure 1-N)

Figure 1-N

The Fume Control System **24** is comprised essentially of a hood, activated carbon absorption filter, and exhaust fan. The Fume Control System is accessed through a door in the cabinet front (see *"Cabinet Front (Figure 1-A)"* on page 1.3 for details).

The Fume Control System hood serves to prevent hazardous fumes from leaking to the outside of the instrument. The system collects reagent fumes from inside the instrument and passes them through an activated carbon absorption filter to reduce fume emissions to acceptable levels. The filtered air is then discharged to the atmosphere. The fume control exhaust fan is active whenever power is applied to the instrument. In the event the fume control exhaust fan fails while the instrument is in operation (processing is being performed), an audible alarm sounds.

Additionally, a duct is provided on the instrument rear panel to facilitate connection of the Fume Control System to a facility exhaust system.

Control Panel (Figure 1-O)

The Control Panel **8** provides the operating controls and indicators necessary to operate the instrument, monitor system operation, configure system settings, and view status and historical reports.

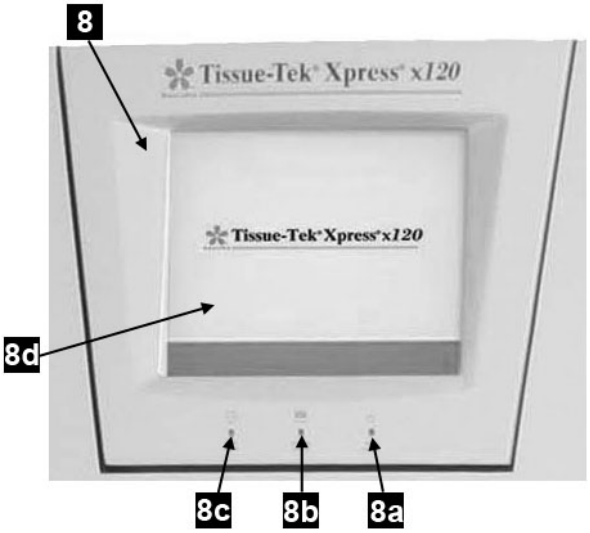


Figure 1-O

Main Power Indicator **8a** — lights when main power is applied to the instrument.

System Status Indicator **8b** — provides an indication of the current status of the system. Flashes when the WARMING UP SYSTEM mode is in process. Lights steady on when the system is ready for processing.

Auto Start / Shutdown Indicator **8c** — indicates the Auto Start/Shutdown function is activated (see *"Section 3, Setting Ready/Shutdown Times"* on page 3.7).

LCD Display **8d** — 800 X 600 pixel touch screen LCD display. The instrument sounds a tone whenever a key, button or text field is actuated (with the exception of the 10-key keypad and alpha keyboard). When in processing mode, provides the data entry and display screens to login to the system, prepare a basket for processing, and monitor processing status (see "*Section 4, Operating Instructions*" for details). When in utility mode, provides the data entry and display screens to manage instrument users, configure system settings, and view statistical data (see "*Section 3, Customization of Settings*" and "*Section 4, Operating Instructions*" for details).

Specifications

Models Covered By This Manual:

Product Code	Name/Description
7720	Tissue-Tek® Xpress® x120 Continuous Rapid Tissue Processor (200 VAC) (USA)
7721	Tissue-Tek® Xpress® x120 Continuous Rapid Tissue Processor (200 VAC) (Asia)
7722	Tissue-Tek® Xpress® x120 Continuous Rapid Tissue Processor (230 VAC) (Europe)

Power Requirements:

Model 7720 – 200VAC ±10%, 50/60Hz, single-phase, 20 amps

Model 7721 – 200VAC ±10%, 50/60Hz, single-phase, 20 amps

Model 7722 – 230VAC ±10%, 50/60Hz, single-phase, 20 amps

Power Ratings:

Model 7720 – 200VAC, 50/60Hz, single-phase, 15 amps

Model 7721 – 200VAC, 50/60Hz, single-phase, 15 amps

Model 7722 – 230VAC, 50/60Hz, single-phase, 13 amps

Noise Level: Less than 65 db

Hazardous Fume Control

Complies with the following requirements for acetone as fume emissions in laboratories:

1,000 ppm, Occupational Safety and Health Administration (USA); 750 ppm, Industrial Safety and Health Law (Japan); 500 ppm, Maximale Arbeitsplatz-Konzentration (Europe)

Environmental Requirements:

Operating:

Temperature Range: +15°C to +35°C

Relative Humidity: 30% to 85%, non-condensing

Relative Atmospheric Pressure: 70 to 106 kPa (525 to 795 mm Hg)

Pollution Degree: 2

Storage:

Temperature Range:-10°C to +65°C

Relative Humidity: 30% to 95%, non-condensing

Relative Atmospheric Pressure: 70 to 106 kPa (525 to 795 mmHg)

Dimensions:

Height:	162 cm (63.8 in.)
Width:	170 cm (66.9 in.)
Depth:	70 cm (27.6 in.)
Weight:	465 kg (1023 lbs)

Instrument Life Expectancy: 7 years (with instrument powered on 24 hours a day, every day)

Safety Standards

Electrical Safety:

For Model 7720 –

cETL Certification

Complies with:

UL 61010-1: 2nd Ed.: 2004,

CAN/CSA-C22.2 No. 61010-1: 2nd Ed.: 2004,

CAN/CSA-C22.2 No. 61010-2-010:04, IEC61010-2-010: 2003

CAN/CSA-C22.2 No. 61010-2-081:04, IEC61010-2-081: 2001

CAN/CSA-C22.2 No. 61010-2-101: 04, IEC61010-2-101: 2002

FDA Registration (Regulation No. 864.3875)

For Model 7721 –

Japanese Pharmaceutical Law

Complies with:

Quality Management System- ISO 13485: 2003

Electrical Safety

JIS C 1010-1:	2005
IEC61010:	2001 (ed2)
IEC61010-2: 010:	2003
IEC61010-2-081:	2001
IEC61010-2-101:	2002

EMC- JIS C1806-1: 2001

Risk Management- JIS T 14971: 2003

For Model 7722 –

Complies with:

LVD, IVD

EN61010-1:	2001 (ed2)
EN61010-2-010:	2003 (ed2)
EN61010-2-081:	2001
EN61010-2-101:	2002

EMC

CISPR11:	1999 Group 1 Class A (EN55011)
EN50082-1:	1997
EN61000-3-3:	1994 Amendment 1&2 (2001)
EN61000-4-2:	1995 Amendment 1&2 (2001)
EN61000-4-3:	2002
EN61000-4-4:	2004
EN61000-4-5:	1995 Amendment 1
EN61000-4-6:	1996 Amendement1&2&3&correction1
EN61000-4-11:	2004

Regulatory Information:

FDA Certified with ETL evaluation (USA); complies with requirements of The Pharmaceutical Affaires Law (Japan); CE Certified in compliance with the requirements of EMC Directive, LV Directive in Europe (Europe)

INSTALLATION

Turning Instrument Power On or Off

The main power to the entire instrument is turned on and off by the power switch **1** (Figure 2-A), located on the right side panel. In the up position the switch turns the power on and in the down position the switch turns the power off.

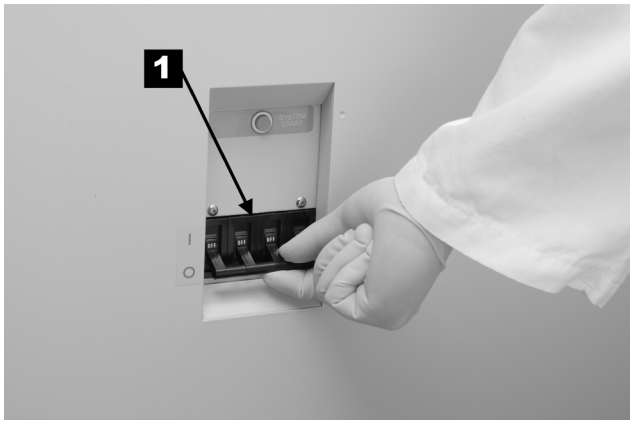


Figure 2-A

Turning the Power Off (for extended nonuse)

The Tissue-Tek® Xpress® x120 instrument has been designed to run continuously. However, if it ever becomes necessary to turn the unit off for extended periods (weeks or months), it is recommended that all reagents be drained from the instrument and the instrument processing chamber be thoroughly cleaned and disinfected. The loading station, unloading station, and retort access doors should then be left open until the interior of the instrument is completely dry. Once dry, close the access doors to keep the interior free of dust and debris.

General Information

This section provides information on determining a location for, and installing, the Tissue-Tek® Xpress® x120 instrument. Installation should be performed by a qualified instrument service technician *only*. The Tissue-Tek Xpress x120 instrument must be installed correctly to ensure proper operation and service.

Read this operating manual carefully before attempting to operate the Tissue-Tek Xpress x120 instrument. Follow all instructions carefully.

CAUTION: The Tissue-Tek Xpress x120 is a precision instrument and must be handled accordingly. Rough handling or dropping will disturb or damage internal components. Always handle the instrument with care.

Environmental Factors

As with all sensitive electronic equipment, avoid prolonged exposure to excessive temperature and humidity. Temperature and humidity should be held relatively constant to obtain the highest degree of operating stability. The ambient operating temperature range of the instrument is 15° to 35°C (59° to 95°F). The ambient operating humidity range is 30% to 85% relative humidity, noncondensing.

Locate the instrument in a **well-ventilated** area, avoiding exposure to corrosive vapors, direct air currents, or temperature extremes. Avoid proximity to direct sunlight, open windows, sinks, ovens, open flames, hot plates, radiators, and dry ice baths. Locate the instrument away from any equipment that consumes a high voltage or large current, including large refrigerators and ovens. Since the instrument is very heavy, the floor must be solid and level.

Be sure the instrument is located near a power source that meets the electrical requirements (voltage and amperage) specified on the rating label located on the rear of the instrument. The power receptacle must be grounded and should be a clean, noise-free, dedicated line.

Ensure that the selected installation site provides sufficient clearance to allow for proper operation if the instrument, and to provide adequate ventilation for the condenser, vacuum pump, microwave units, fans, and pumps.

Set Reagent Bottle

1. Place the new reagent container in the reagent cabinet in the appropriate position.
2. Press down on the reagent container locking lever until it engages the "LOCKED" position, coupling the reagent container with the reagent supply system (Figure 2-B).

Figure 2-B

Pre-Start Checks

Prior to the first processing run each day, perform the following pre-start checks and services:

- Verify a new drip tray liner has been placed on the Transfer Arm drip pan.

NOTE: If necessary, replace the drip tray liner on the Transfer Arm drip pan (see "*Drip Tray Liner* Replacement" on page 7.7 for details).

- Verify that the Loading Station container is filled with Pre-Processing Solution (product code 7115).
- Verify the handle of the loading station container is resting on the rim of the container.
- Verify the Transfer Arm is not holding a basket or magazine set, and that there are no or magazines baskets in the Loading Station, Unloading Station, or in any retort.
- Verify that all retort lids are closed. If any lids are open, close them manually.
- Verify both reagent containers are full. Ensure both reagent containers are in their proper positions in the cabinet, and that locking levers for both containers are in the locked position.

NOTE: If the reagent containers are not full, replace the reagents prior to starting the system (see "*Reagent Replacement*" on page 7.4 for details).

- Verify both paraffin ovens contain sufficient amounts of paraffin.

If necessary, verify the Unloading Station retort contains a sufficient amount of paraffin.

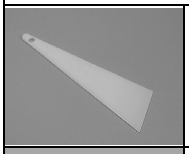
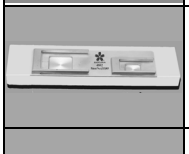
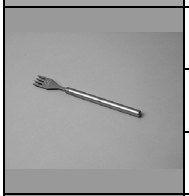
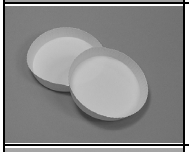
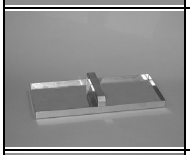
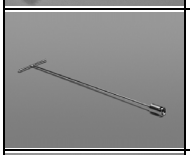
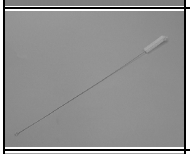
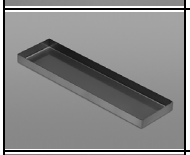
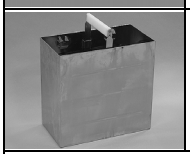
NOTE: If sufficient paraffin is not available in either paraffin oven, replace the paraffin prior to starting the system (see *"Retort #3 and #4 Paraffin Replacement"* on page 7.5 and *"Unloading Station Paraffin Replacement"* on page 7.7 for details).

NOTE: It is recommended to ensure proper processing of tissue specimens, reagent sets MUST be changed at the same time.

Unpacking and Installation

Tissue-Tek® Xpress® x120 Accessories

Confirm that the following accessories are provided with the instrument.

	Description	Quantity
	Paraffin Scraper (Product Code 1550)	1
	Trimming Knife Blades, 130mm* (Product Code 4785)	1 pack of 10
	Trimming Knife Handle* (Product Code 4786)	1
	Scalpel Handle* (Product Code 4791)	1
	Scalpel Blades, #62* (Product Code 4793)	1 pack of 20
	Grossing Wells (Product Code 4802)	1 set
	Grossing Wells, Left Handed (Product Code 4848)	1 set
	Grossing Fork, 1.5mm (Product Code 4803)	1
	Grossing Fork, 2.0mm (Product Code 4804)	1
	Grossing Fork, 2.5mm (Product Code 4807)	1
	Basket w/ Handle and Lid, 40-cassette (Product Code 7103)	8
	Tray Liners (Product Code 7106)	1 pack of 20
	Loading Station Container w/ Lid (Product Code 7108)	1
	Basket Transportation Tray (Product Code 7109)	1
	Drip Tray (Product Code O71-169-01)	1
	Reagent Bottle Tray (Product Code O71-355-00)	1
	Retort Cleaning Pipette (Product Code D9-01-0102)	1
	Retort Mesh Filter Removal Tool (Product Code O71-692-00)	1
	Sight Tube Cleaning Brush (Product Code O71-697-00)	1
	Spill Tray (Product Code O71-491-00)	1
	Unloading Station Container (Product Code F60-153-00)	1
	Container Kit (Product Code 7190)	1
	Operating Manual (Product Code 0004398-01)	1

*Not applicable to Model 7721

Missing or Damaged Items?

Check the contents of all shipping cartons and boxes carefully for all of the listed items. If any items are visibly damaged, or are missing, call 1-800-725-8723 or 1-310-972-7800 (U.S. Customers only). When located outside the U.S., contact the nearest Sakura instrument distributor.

CUSTOMIZATION OF SETTINGS

General Information

The Tissue-Tek® Xpress® x120 allows for the customization of a number of system options and operating parameters to suit the user requirements of a given installation. The UTILITIES menu provides the means of viewing the current system settings, of selecting and configuring system options, and specifying the desired values for user-configurable operating parameters.

This section provides the procedures to perform initial setup of the Tissue-Tek Xpress x120 system settings. Factory default settings for each parameter are listed where applicable.

Perform the following setup procedures before routinely using the Tissue-Tek Xpress x120 system. In addition, perform these procedures as needed to reset the clock, add or remove users, change automatic, start-up, and shut-down times, etc.

NOTE: Refer to *"Control Panel (Figure 1-O)"* on page 1.12 for a description of the controls and indicators used in performing setup procedures.

Accessing the UTILITIES Menu

NOTE: Login as an Administrator in order to modify system settings through the UTILITIES menu. Logging in with an Operator's password allows "read-only" access to the UTILITIES menu (current system settings may be viewed, but cannot be changed).

To access the UTILITIES menu:

1. From the WARMING UP SYSTEM screen, MANUAL START screen or AUTO START screen, touch the **LOG ON** button.
   - The INPUT PASSWORD dialog displays.
   - Use the keypad to enter the password, then touch the **ENTER** key.

NOTE: The password is displayed on the screen, as entered, as a series of asterisks.

- If the login is *unsuccessful*: When password is incorrectly entered, the message "INCORRECT PASSWORD ENTERED" displays. Reenter the password, then press the **ENTER** key to resubmit the login request.
- If the login request is *successful*: The WARMING UP SYSTEM screen displays while the system warms up, then the MANUAL START or AUTO START screen displays, as appropriate. Press the **UTILITIES** key to display the UTILITIES menu (Figure 3-A).

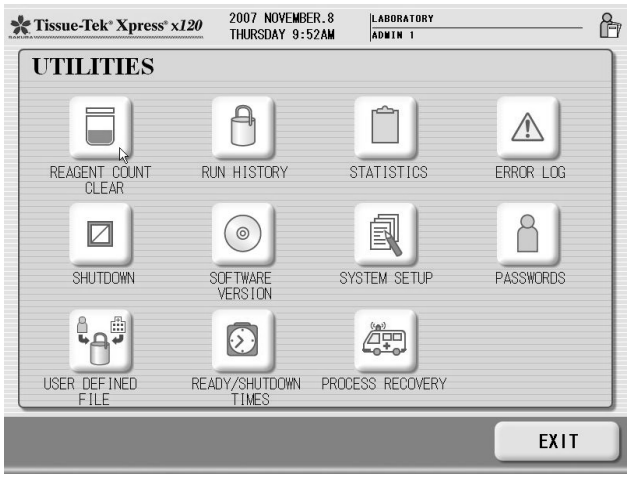


Figure 3-A

2. From the UTILITIES menu, select to perform the following operations:

REAGENT COUNT CLEAR – clears the cumulative cassette or run count when replacing reagents (see *"Reagent Replacement"* on page 7.4 for details).

RUN HISTORY – displays a status listing for *each* completed processing run initiated (see "*Viewing Run History*" on page 4.14 for details).

STATISTICS – displays statistics on the number of cassettes/runs/days processed for a selected time period (see "Viewing Statistics" on page 4.14 for details).

ERROR LOG – displays a log of errors that have occurred in monitored operations, systems or components (see "*Viewing the Error Log*" on page 4.16 for details).

SHUTDOWN – facilitates manual shutdown of the instrument when configured for MANUAL START operation (see "*System* Shutdown" on page 4.10 for details).

SOFTWARE VERSION – displays information related to instrument software and firmware versions and serial number (see "*Viewing the Software Version*" on page 4.14 for details).

SYSTEM SETUP – allows for the configuration of "user-selectable" options and operating parameters (see "*Configuring System Settings*" on page 3.2 for details).

PASSWORDS – allows for the addition, modification, and removal of system users (see "*Setting Names and Passwords*" on page 3.4 for details).

USER DEFINED FILE – allows for the addition, modification, and removal of assignable "identifiers" for use as sorting criteria for the Run History File and Statistics (see "*Managing the User Defined File*" on page 3.6 for details).

READY / SHUTDOWN TIMES – establishes the start-up and shut-down times for automatic operation of the system (see "*Setting Ready / Shutdown Times*" on page 3.7 for details).

PROCESS RECOVERY – allows for initiation of a "recovery process" for baskets in Retorts #3 and #4 when processing is interrupted (aborted) due to an error condition (see "*Section 5, Recovery Process*" for details).

NOTE: The **PROCESS RECOVERY** button is enabled only during the WARMING UP SYSTEM cycle.

Configuring System Settings

The SYSTEM SETUP option allows changes to "user-selectable" and "user-specified" system settings and parameters.

To change system settings:

1. From the UTILITIES screen, touch the **SYSTEM SETUP** button.
   - SYSTEM SETUP screen, page 1, displays (Figure 3-B), showing the currently selected parameters for the instrument (selected parameters are indicated by a "gray" background).

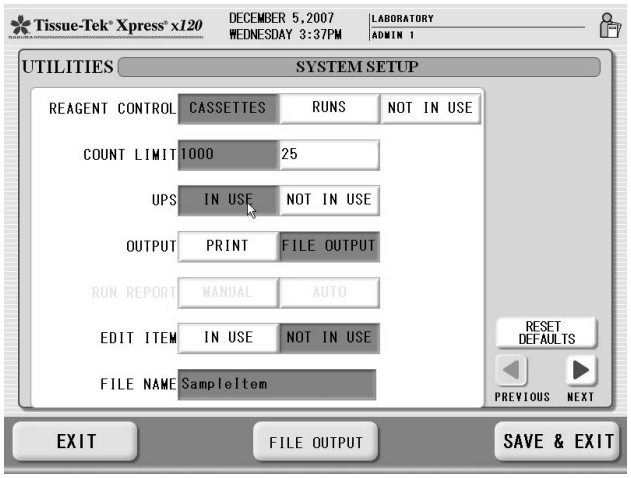


Figure 3-B

NOTE: The SYSTEM SETUP screen is a *multi-page* display screen.

- Use the **PREVIOUS** and **NEXT** buttons in the lower right-hand corner of the screen to toggle between pages.

2. Make changes to the following system settings /parameters on SYSTEM SETUP, page 1, as desired:
   - **REAGENT CONTROL** – sets the units by which reagent use is calculated (a cumulative count of the selected units is shown on the WARMING UP SYSTEM screen, MANUAL START screen and AUTO START screen).

     Touch the desired option field, either **CASSETTES** or **RUN**.

     The factory default setting for **REAGENT CONTROL** is **CASSETTES**.

NOTE: To not use the **REAGENT CONTROL** function, select the **NOT IN USE** option.

- **COUNT LIMIT** – sets the count limit for the associated **REAGENT CONTROL** options (the **COUNT LIMIT** indicates the maximum number of cassettes/runs that may be processed before reagent replacement is necessary).

  Touch the desired field to display the data entry keypad. Enter the desired value, then touch the **ENTER** key to close the keypad.
  The factory default settings for **COUNT LIMIT** are 1000 cassettes and 25 runs.

- **UPS** – indicates whether or not an external Uninterruptible Power Supply (UPS) is connected to the instrument.

  Touch the appropriate option field, either **IN USE** or **NOT IN USE**.

  The factory default setting for **UPS** is **IN USE**.
- **OUTPUT** –To determine method to export various data that Tissue-Tek Xpress x120 system recorded.

  Touch the desired option field, either **PRINT** or **FILEOUTPUT.** The factory default setting for **OUTPUT** is **FILE OUTPUT**. (See "To Print System Setting" on page 3.4 for more information).
- **EDIT ITEM** – indicates whether or not the USER DEFINED FILE option is enabled (see "*Managing the User Defined File*" on page 3.6 for more information).

  Touch the appropriate option field, either **IN USE** or **NOT IN USE**.

  The factory default setting for **EDIT ITEM** is **NOT IN USE**.
- **FILE NAME** – indicates the file name for the USER DEFINED FILE.

  The factory default setting for **FILE NAME** is **SampleItem**.

3. Touch the **NEXT** button to display the SYSTEM SETUP screen, page 2 (Figure 3-C). Make changes to the following system settings/parameters on SYSTEM SETUP screen, page 2, as desired:

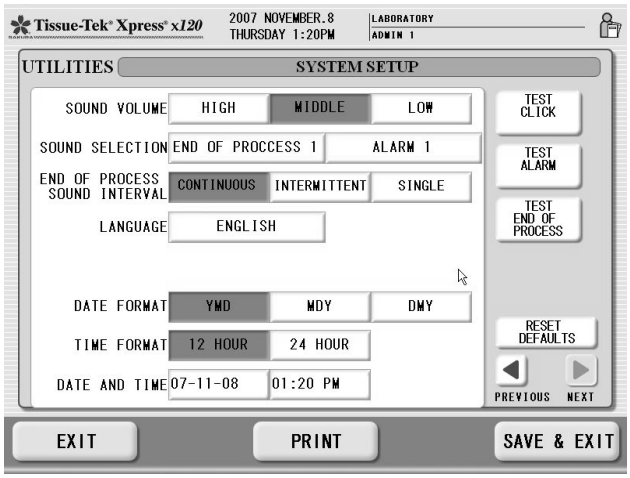


Figure 3-C

- **SOUND VOLUME** - sets the volume for "key clicks" and the audible "end of process" and "alarm" indications.

  Touch the desired option field, either **HIGH** (audible within 100 feet of instrument), **MIDDLE** (audible within 50 feet of instrument) or **LOW** (audible within 10 feet of instrument).

  The factory default setting for **SOUND VOLUME** is **MIDDLE**.

NOTE: Touch the **TEST CLICK**, **TEST ALARM**, or **TEST END OF PROCESS** button to test the selected **SOUND VOLUME**.

- **SOUND SELECTION** – allows for selection of the desired "end of process" and "alarm" sounds from one of seven available options.

  Touch the desired field to display a drop-down menu of available options, then select the desired option.

  The factory default settings for **SOUND SELECTION** are **ENDOFPROC1** and **ALARM1**.

NOTE: Touch the **TEST ALARM** or **TEST END OF PROCESS** button to test the selected **SOUND SELECTION**.

- **END OF PROCESS SOUND INTERVAL** – selects the interval at which the "end of process" sound is repeated.

  Touch the desired option field, either **CONTINUOUS**, **INTERMITTENT**, or **SINGLE**.

  The factory default setting for **END OF PROCESS SOUND INTERVAL** is **CONTINUOUS**.
- **LANGUAGE** – selects the display language for the instrument display screens.

  Touch the desired field to display a drop-down menu of available options, then select the desired option.

  The factory default setting for **LANGUAGE** is **ENGLISH**.
- **DATE FORMAT** – sets the format for the date display shown at the top of all instrument display screens.

  Touch the desired option field, either **YMD**, **MDY**, or **DMY**.

  The factory default setting for **DATE FORMAT** is **MDY**.

- **TIME FORMAT** – sets the format for the time display shown at the top of all instrument display screens.

  Touch the desired option field, either **12 HOUR** or **24 HOUR**.

  The factory default setting for **TIME FORMAT** is **12 HOUR**.
- **DATE AND TIME** - establishes the current calendar date and time-of-day shown on all instrument display screens.

  Touch the desired field to display the data entry keypad. Enter the appropriate value, then touch the **ENTER** key to close the keypad.

NOTE: Be sure to enter the date using the same format as selected for the **DATE FORMAT**. For example, if **YMD** is selected as the **DATE FORMAT**, enter March 10, 2002 as "02/03/10".

4. When all desired system settings/parameters have been changed, touch the **SAVE & EXIT** button to save the new settings to memory and return to the UTILITIES screen.

NOTE: To return to the UTILITIES screen *without* changing the SYSTEM SETUP, press the **EXIT** button.

To return to the factory default settings:

1. From the UTILITIES screen, touch the **SYSTEM SETUP** button.
   - SYSTEM SETUP screen, page 1, displays (Figure 3-B), showing the currently selected parameters for the instrument (selected parameters are indicated by a "gray" background).
2. Touch the **RESET DEFAULTS** key to return system settings to the factory default values.
3. The system returns to the UTILITIES screen.

To print system settings:

NOTE: The **PRINT** option allows users to export a file to a USB memory stick.

- **FILE OUTPUT**-exports a CSV file to a USB memory stick
- **PRINT**-exports a PDF file to a USB memory stick.

1. From the UTILITIES screen, touch the **SYSTEM SETUP** button.
   - SYSTEM SETUP screen, page 1, displays (Figure 3-B), showing the currently selected parameters for the instrument.
2. Touch the **PRINT** button.

Setting Names and Passwords

The PASSWORDS option performs the following functions:

- Set the Institution Name shown on all Tissue-Tek Xpress x120 display screens
- Add, edit, or delete names and passwords for up to 4 Tissue-Tek Xpress x120 system Administrators
- Add, edit, or delete names and passwords for up to 20 Tissue-Tek Xpress x120 system Operators

Passwords determine the features and functions available to Tissue-Tek Xpress x120 users. Operator passwords limit access to routine operations of the system. Administrator passwords allow access to all system functions and user-programmable features.

NOTE: A default Administrator's name "ADMIN 1" and password "100000" are provided to allow access to setup functions for initial configuration of the system. The default password should be replaced with a unique password to prevent unauthorized access to the system.

To access the PASSWORDS function:

1. From the UTILITIES screen, touch **PASSWORDS** button.
   - The PASSWORDS screen displays (Figure 3-D), showing the current Institution name, and Administrator and Operator names and passwords.

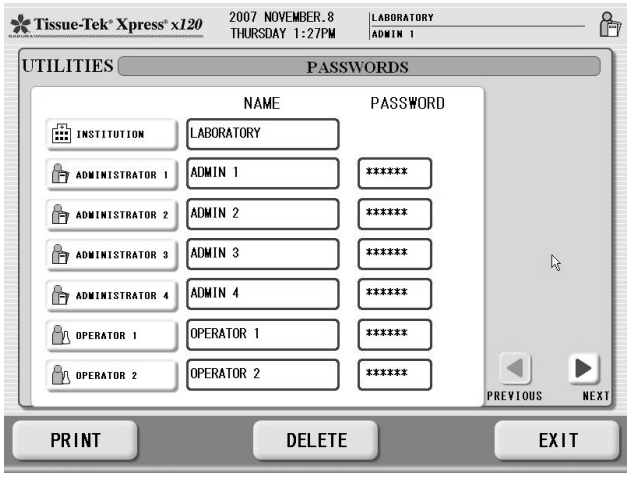


Figure 3-D

NOTE: The PASSWORDS screen is a *multi-page* display screen.

2. Use the **PREVIOUS** and **NEXT** buttons in the lower right-hand corner of the screen to scroll through other pages of the display.

To add or edit users:

1. Touch the **NAME** field of the user chosen for edit.
   - The EDIT NAME AND PASSWORD screen displays (Figure 3-E).

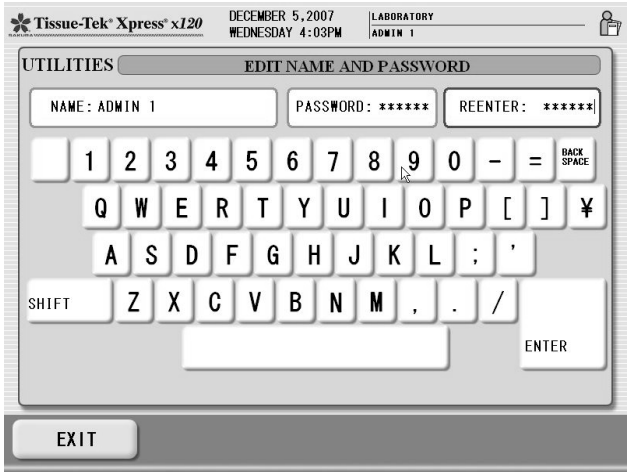


Figure 3-E

NOTE: Use the backspace key to edit a currently entered name.

2. Touch the **NAME** field, then use the keyboard to enter the desired user name.
3. When the desired name has been entered in the **NAME** field, press the **ENTER** key.

NOTE: When editing the Institution name, the **PASSWORD** and **REENTER** fields are not displayed.

4. Touch the **PASSWORD** field, then use the keyboard to enter the desired password. The password displays as a series of asterisks when entered.

NOTE: The password must be a six-digit numeric password. *DO NOT* use alphabetic characters in the password.

5. When the desired password has been entered in the **PASSWORD** field, press the **ENTER** key.
6. Touch the **REENTER** field, then use the keyboard to reenter the password as entered in step 4.
7. When the password has been reentered in the **REENTER** field, press the **ENTER** key.
8. When the desired name and password for the user have been entered, press the **EXIT** key to return to the PASSWORDS screen.
9. Repeat steps 1 through 8 to add or edit name and passwords for other users.
10. When all desired user names and passwords have been edited, press the **EXIT** button to return to the UTILITIES screen.

To delete users:

1. Touch the **ADMINISTRATOR** or **OPERATOR** button for the user chosen for deletion, then press the delete key. The screen refreshes with the selected user **NAME** and **PASSWORD** deleted.
2. Repeat step 1 to delete other users.
3. When all desired users have been deleted, press the **EXIT** button to return to the UTILITIES screen.

Managing the User Defined File

The USER DEFINED FILE function allows for creating "identifiers" that can be assigned to a basket or Paraform magazines on loading. The "identifiers" can then be used as sorting criteria for the run History File and Statistics. The USER DEFINED FILE can contain *any* "identifiers" that are appropriate to installation and workflow (such as doctor's names or hospital departments).

For example, specimens that are for the same doctor can be grouped in a single basket, and the doctor's name assigned to the basket or sets of Paraform magazines during setup and loading.

NOTE: The **EDIT ITEM** option in SYSTEM SETUP *must* be set to **IN USE** to enable this function (see "*Configuring System Settings*" on page 3.2 for details).

To access the USER DEFINED FILE function:

1. From the UTILITIES screen, touch the **USER DEFINED FILE** button.
   - USER DEFINED FILE screen displays (Figure 3-F), a listing of the current items (identifiers) in the file.

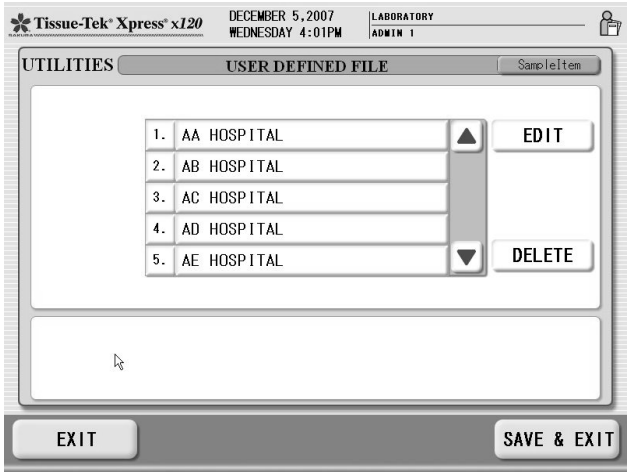


Figure 3-F

   - Use the scrollbar to view the complete list.
   - Up to 99 items can be entered.

NOTE: The USER DEFINED FILE is *unsorted*. Items are listed in the order in which they were entered.

To edit an item in the file:

1. Touch the name of the item chosen for edit in the USER DEFINED FILE list, then touch the **EDIT** button.
   - The EDIT USER DEFINED ITEM screen displays (Figure 3-G).

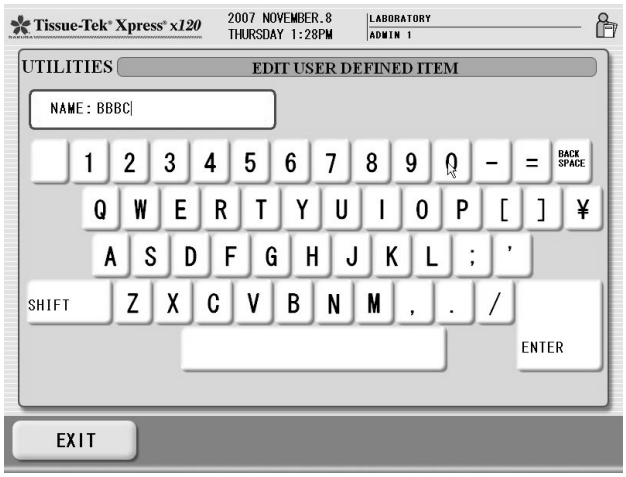


Figure 3-G

NOTE: Use the backspace key to edit a currently entered name.

2. Touch the **NAME** field, then use the keyboard to edit the current item (identifier) name.
3. When the item **NAME** has been edited as desired, touch the **ENTER** key.
4. Press the **EXIT** key to return to the USER DEFINED FILE screen.
5. Repeat steps 1 through 4 to edit *additional* items in the list.
6. When all desired items have been edited, touch the **SAVE & EXIT** button to save the changes and return to the UTILITIES screen.

NOTE: To return to the UTILITIES screen *without* changing the USER DEFINED FILE, press the **EXIT** button.

To delete an item from the file:

1. Touch the name of the item to delete from the USER DEFINED FILE list, then touch the **DELETE** button.
   - The screen refreshes with the selected item removed from the list.
2. Repeat step 1 to delete *additional* items from the list.
3. When all desired items have been deleted, touch the **SAVE & EXIT** button to save the changes and return to the UTILITIES screen.

NOTE: To return to the UTILITIES screen *without* changing the USER DEFINED FILE, press the **EXIT** button.

Setting Ready / Shutdown Times

The **READY / SHUTDOWN TIMES** option sets the automatic warm-up (ON) and automatic shutdown (OFF) times for the Tissue-Tek Xpress x120 for days on which the system will *normally* be used (see "*Setting Days Off*" on page 3.8 for more information). READY/SHUTDOWN times may be set individually for each day of the week, or the same times may be set for all days of the week. It is also possible to indicate days on which the system is not in use (automatic warm-up and shutdown is not performed).

To access the READY / SHUTDOWN TIMES function:

1. From the UTILITIES screen, touch the **READY / SHUTDOWN TIMES** button.
   - The READY/SHUTDOWN TIMES screen displays (Figure 3-H), showing the current system **ON TIME** and **OFF TIME** for each day of the week.

NOTE: When entering **ON / OFF TIME**, be sure to enter the desired times using the appropriate format, either 12-hour or 24-hour, as established in **SYSTEM SETUP** (see "*Configuring System Settings*" on page 3.2 for more information).

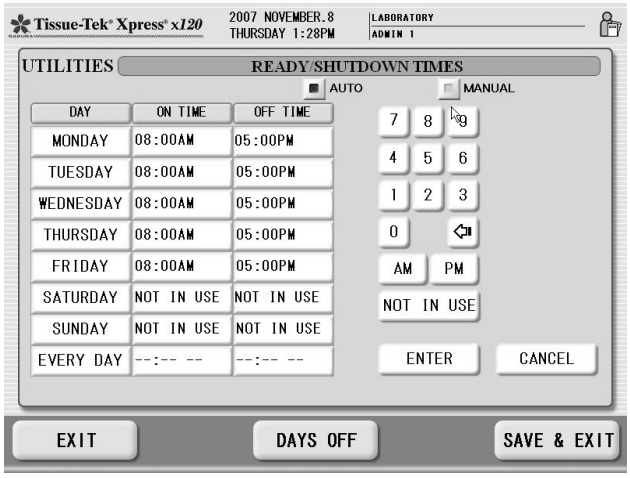


Figure 3-H

To set on/off times for a single day:

1. Touch the **ON TIME** or **OFF TIME** field for the desired day of the week (**MONDAY** through **SUNDAY**).

NOTE: Use the backspace key to edit a currently entered time.

2. Use the keypad to enter the desired "on" time (the time at which the instrument should be ready to begin processing) or "off" time (the time at which the instrument should *normally* shutdown).
3. When the desired time has been entered in the active field, press the **ENTER** key.
4. Repeat steps 1 through 3 to set the **ON TIME** and **OFF TIME** for the remaining days of the week.
5. When all desired on/off times have been entered or edited, touch the **SAVE & EXIT** button to save the changes and return to the Utilities screen.

NOTE: To return to the UTILITIES screen *without* changing on/off times, press the **EXIT** button.

NOTE: On/off times will repeat weekly, unless "days off" are specified (see "*Setting Days Off* on page 3.8 for more information).

To set the same on/off times for all days:

1. Touch the **EVERYDAY - ON TIME** or **EVERY DAY - OFF TIME** field

NOTE: Use the backspace key to edit a currently entered time.

2. Use the keypad to enter the desired "on" time (the time at which the instrument should be ready to begin processing) or "off" time (the time at which the instrument should *normally* shutdown).
3. When the desired time has been entered in the active field, press the **ENTER** key.
4. When the desired **EVERY DAY** on/off times have been entered or edited, touch the **SAVE & EXIT** button to save the changes and return to the Utilities screen.

NOTE: To return to the UTILITIES screen *without* changing on/off times, press the **EXIT** button.

NOTE: EVERY DAY on/off times will repeat daily, unless "Days Off" are specified (see "*Setting Days Off*" on page 3.8 for more information).

To set A "Not In Use" day:

NOTE: "Not In Use" days should be set *only* for days on which the instrument will not normally be operated.

1. Touch the **ON TIME** or **OFF TIME** field for the desired day of the week (**MONDAY** through **SUNDAY**).
2. Touch the **NOT IN USE** key, then press the **ENTER** key.
3. When the desired "Not In Use" days have been set, touch the **SAVE & EXIT** button to save the changes and return to the Utilities screen.

NOTE: To return to the UTILITIES screen *without* changing on/off times, press the **EXIT** button.

To determine the mode of operation for the Tissue-Tek Xpress x120 system:

Touch the desired option field, either **AUTO** (instrument is started and shutdown automatically, according to the scheduled READY/SHUTDOWN TIMES) or **MANUAL** (instrument must be started manually before use and shutdown manually after use)

Setting Days Off

The DAYS OFF option overrides the normal on/off time settings for *selected dates* on which the instrument will not be used, such as holidays, vacation days or other scheduled days off.

To access the DAYS OFF function:

1. From the UTILITIES screen, touch the **READY / SHUTDOWN TIMES** button.
   - The READY/SHUTDOWN TIMES screen displays (Figure 3-H), showing the current system **ON TIME** and **OFF TIME** for each day of the week.
2. Touch the **DAYS OFF** button.
   - The DAYS OFF screen displays (Figure 3-I), showing the "days off" calendar for the current month. Currently specified "days off" are indicated by a red circle around the date.
   - The **DAYS OFF LIST** lists all currently specified "days off", in chronological order.
   - Days off can be selected by using the calendar.
   - Days off can be deselected by using either the calendar or the DAYS OFF LIST.

To use the "days off" calendar:

1. Use the **PREVIOUS** and **NEXT** buttons at the top of the screen to scroll the calendar to the desired month.

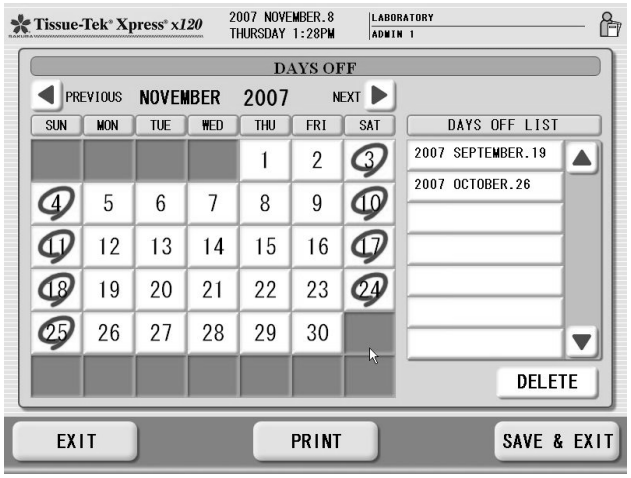


Figure 3-I

2. To *add* a "day off", touch an *unselected* day on the calendar. The screen refreshes to display a red circle around the selected day, and the selected date is added to the **DAYS OFF LIST**.
3. To *remove* a "day off", touch a *selected* day on the calendar. The screen refreshes with the red circle removed from the selected day, and the selected date is deleted from the **DAYS OFF LIST**.
4. When all desired "days off" have been specified, touch the **SAVE & EXIT** button to save the changes and return to the READY/SHUTDOWN TIMES screen.

NOTE: To return to the READY/SHUTDOWN TIMES screen *without* changing "days off", press the **EXIT** button.

To use the DAYS OFF LIST:

The **DAYS OFF LIST** shows a *complete* listing of all currently specified "days off."

1. Use the scrollbar to scroll through the **DAYS OFF LIST**.
2. To *remove* a "day off", touch the desired date in the **DAYS OFF LIST**, then touch the **DELETE** key.
3. Touch the **SAVE & EXIT** button to save the changes and return to the READY/SHUTDOWN TIMES screen.

NOTE: To return to the READY / SHUTDOWN TIMES screen *without* changing "days off", press the **EXIT** button.

OPERATING INSTRUCTIONS

Initial Setup

Ensure that initial setup procedures have been performed in accordance with the requirements of Section 3, Customization of Settings, prior to operating the Tissue-Tek® Xpress® x120 instrument.

Understanding the Control Panel Display

The Control Panel provides the controls and indicators necessary to initiate a processing cycle, monitor the status of individual baskets or Paraform® magazines during processing, configure system setting, manage user, and view statistical reports.

Process Monitor Screen

The Process Monitor screen (Figure 4-A) is displayed when the system is ready for processing, and during processing cycles. The Process Monitor screen is comprised of a screen header, process monitor window, information window, and button bar.

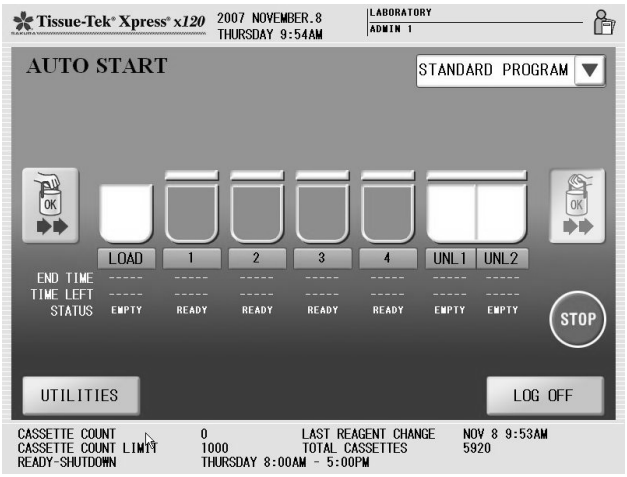


Figure 4-A

- The screen header shows the current date and time, the name of the hospital, laboratory, or institution where the instrument is installed, and the name of the currently logged on user (if no user is currently logged on, the field is blank).
- The process monitor window provides a pictorial representation of the Loading Station, Microwave and Vacuum retorts, and Unloading Station, and provides tabular data related to the status of baskets currently being processed (see "*Process Monitoring*" on page 4.8 for details). The currently selected operational mode (MANUAL START or AUTO START) is shown in the upper left-hand corner of the window. The currently selected processing program (STANDARD PROGRAM or EXTENDED PROGRAM) is shown in the upper right-hand corner of the window.

The process monitor window also provides status indicators for the Loading Station and Unloading Station access doors. The indicators show when the associated access door can be opened to load or unload baskets or Paraform magazines, as follows:

Access Permitted Icon – Indicates the associated access door may be opened to allow loading or unloading, as applicable.

NOTE: The Loading Station **Access Permitted Icon** is active only when a user is logged on to the instrument.

Access Denied Icon – Indicates the associated access door may not be opened.

When displayed for the Loading Station, one of the following conditions exists:

- A basket or magazine set is currently in the Loading Station retort.
- The Transfer Arm is in motion.
- A reagent shortage is detected.

When displayed for the Unloading Station, one of the following conditions exists:

- The Transfer Arm is in motion.

- The information window provides the following information:

  CASSETTE or **RUN COUNT** – The number of cassettes or runs processed since the last reagent change.

  CASSETTE or **RUN COUNT LIMIT** – The total number of cassettes or runs that may be processed, as applicable, before it is necessary to replace the reagents.

  LAST REAGENT CHANGE – The date and time at which the reagents were last replaced and the reagent counter was cleared.

  TOTAL CASSETTES or **RUNS** – The total number of cassettes or runs, as applicable, that have

been processed since the instrument was installed.

READY-SHUTDOWN – When the instrument is configured for Auto Start / Shutdown, shows the start and shutdown times for the current day. When the instrument is configured for Manual Start / Shutdown, shows the word **MANUAL**.

- The button bar provides the controls to log on and log off the instrument, and to access the UTILITIES menu (see *Section 3, "Customization of Settings"* for details).

Preparation for Processing

The Tissue-Tek Xpress x120 instrument supports the use of standard cylindrical baskets, or Paraform magazines (for use in conjunction with the Tissue-Tek® AutoTEC® Automated Embedding System).

Using the Standard Basket

The Standard Basket (Figure 4-B) is a cylindrical basket designed to hold up to 40 cassettes. The upper band (maximum limit rim) of the basket indicates the maximum height at which cassettes in the basket may be placed.

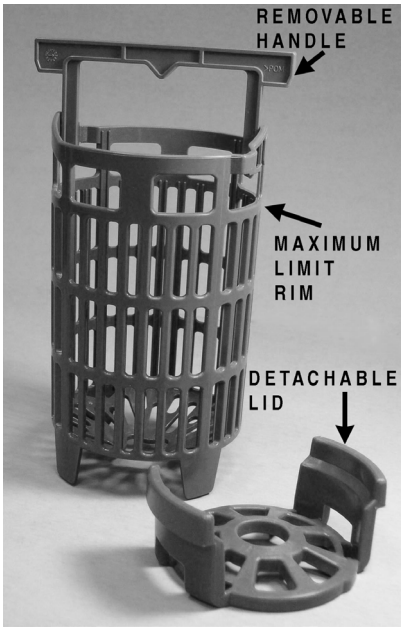


Figure 4-B

CAUTION: Do not use cassettes that contain any metal or use metal lids. When placing cassettes into the basket, do not allow any cassettes to extend above the maximum limit rim. Cassettes placed above the maximum limit rim will not be fully immersed in the reagents, and will not be processed properly.

The Standard Basket incorporates a removable handle and lid to allow for easy loading and positioning of cassettes in the basket.

To remove the basket handle (Figure 4-C):

1. Press down on the basket handle until the handle releases from its locking slots.
2. Turn the handle clockwise until it is aligned with the recesses in the basket, then pull the handle free from the basket.

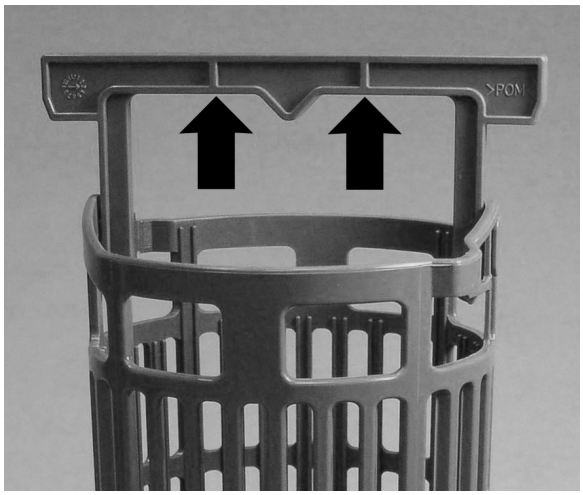


Figure 4-C

To install the basket handle (Figure 4-C):

1. Insert the basket handle into the recesses in the basket.
2. Turn the handle counterclockwise until it stops, then pull up on the handle to engage the locking slots.
3. The lid can be placed inside the basket prior to processing.

Using Paraform Magazines

If the embedding process is performed by the Tissue-Tek® AutoTEC® Automated Embedding System, a special handle is supplied with the Tissue-Tek AutoTEC. This handle allows two Tissue-Tek Paraform magazines to be

linked together by sliding the magazines into the handle slots. Each magazine can hold up to 20 Paraform cassettes.

Preparing the Tissue Specimens

The specific procedures to be used when preparing tissue specimens for processing using the Tissue-Tek Xpress x120 instrument depend on tissue type, specimen size, and other factors.

Detailed instructions for preparing tissue samples prior to processing using the Tissue-Tek Xpress x120 instrument are provided in Appendix A.

CAUTION: Failure to follow the appropriate pre-processing procedures may result in improper processing of the specimens.

System Start Up

The Tissue-Tek Xpress x120 instrument may be configured for either automatic start / shutdown at preprogrammed times, or for manual start (see "*Configuring System Settings*" on page 3.2 for details). Following startup, the instrument enters a WARMING UP SYSTEM cycle, where the various reagents are warmed to the appropriate temperatures for processing operations. Once the WARMING UP SYSTEM cycle is concluded, the instrument is ready to perform processing.

Auto Start

WARNING: WHEN THE INSTRUMENT IS CONFIGURED FOR AUTO START, IT IS NECESSARY TO PERFORM THE "PRE-START CHECKS" FOLLOWING SHUTDOWN OF THE INSTRUMENT IN ORDER TO ENSURE THE INSTRUMENT IS READY TO START AT ITS PREPROGRAMMED TIME.

The Auto Start / Shutdown feature allows the instrument to be configured to *automatically* start up and be ready for processing by a specified "ready" time. When auto start is enabled, the instrument is started prior to the desired "ready" time in order to allow the WARMING UP SYSTEM cycle to be completed by the desired time.

When the Auto Start / Shutdown feature is enabled, the Auto Start / Shutdown indicator on the User Interface is illuminated at all times that power is applied to the instrument (see Control Panel (Figure 1-O) on page 1.12 for details).

NOTE: If it is necessary to start the instrument *prior* to its programmed "ready" time, use the "Manual Start" procedure to manually start the instrument. Starting the instrument manually will not affect the auto shutdown cycle for the current day, and auto start will occur at its next scheduled start time.

Manual Start

When the instrument is configured for Manual start, the instrument must be started manually.

To perform a Manual start of the instrument:

1. Make sure the "Pre-Start Checks" have been performed, and the instrument is ready to start.
2. If necessary, apply Main Power to the instrument.

NOTE: The instrument is designed to remain powered continuously. In most cases, it will be necessary to apply Main Power to the instrument only following initial installation, or when it has been turned off for servicing or repair.

3. Press the **START** button on the right side panel above the power switch. The operating software loads, and the Tissue-Tek Xpress x120 Startup screen displays (Figure 4-D). The Transfer Arm moves to its "home" position, and the instrument enters the WARMING UP SYSTEM cycle.

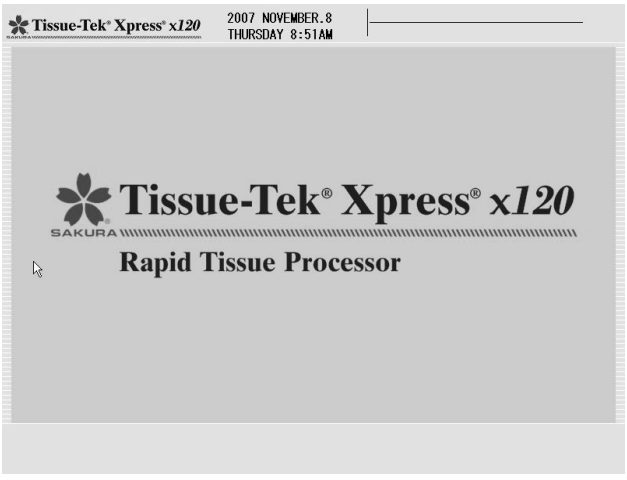


Figure 4-D

System Warm Up (Figure 4-E)

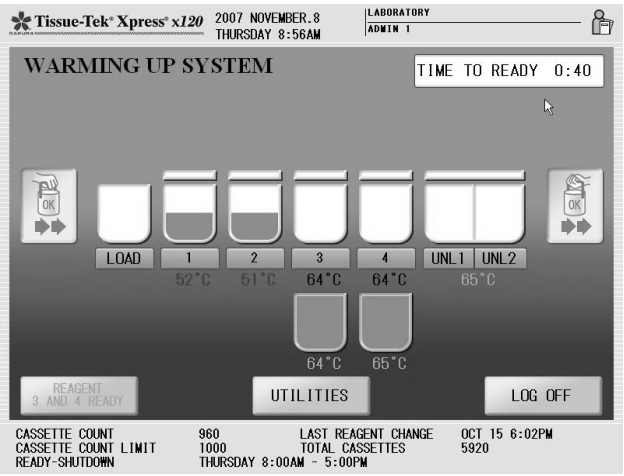


Figure 4-E

The WARMING UP SYSTEM cycle allows all reagents to warm to the appropriate temperature prior to automatic processing. Depending on the state of the system before starting, the time required to complete the WARMING-UP SYSTEM process may be as long as 4.5 hours. The **TIME TO READY** field in the upper right-hand corner of the display shows the time remaining until the cycle is complete.

During the WARMING UP SYSTEM cycle, the control panel display changes to indicate the current status of the cycle. Current temperatures for the retorts, Unloading Station, and paraffin ovens are displayed, in ºC, and are periodically updated as the cycle progresses.

Once the WARMING UP SYSTEM cycle has completed, reagents in retorts #1 and #2 are maintained at the correct temperature until a basket or magazine set is loaded and processing begins.

Logging On

Log on to the system before initiating processing operations or accessing the UTILITIES menu. Only one user may be logged on to the instrument at any time. It is possible to log on to the instrument during the WARMING UP SYSTEM cycle, or when the instrument is in the MANUAL or AUTO START process monitor mode.

To log on to the instrument:

NOTE: If another user is current logged on to the instrument, the **LOG OFF** button is shown in the lower right-hand corner of the screen, and the name of the user is shown at the top of the screen. The system will not allow logging on to the instrument until the current user has logged off.

1. Touch the **LOG ON** button located in the lower right-hand corner of the screen. The PASSWORD dialog displays (Figure 4-F).

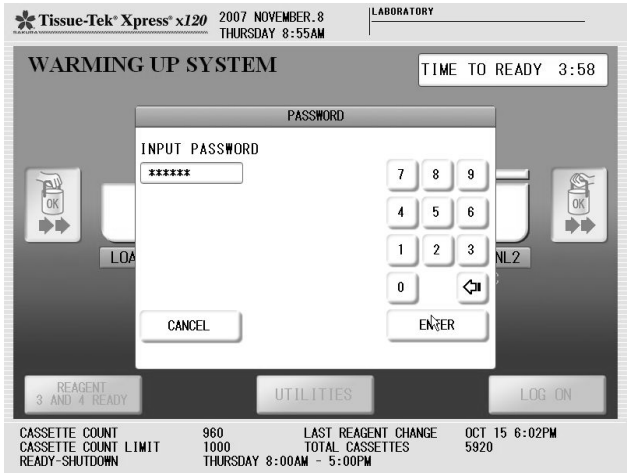


Figure 4-F

2. Use the keypad to enter the six-digit password in the **INPUT PASSWORD** text box.

NOTE: If needed, use the backspace key to correct errors when entering the password. Touch the **CANCEL** key to delete *all characters* from the **INPUT PASSWORD** text box.

3. When the correct password has been entered, touch the **ENTER** button to complete the log on process. The PASSWORD dialog closes, and the previous screen refreshes to show the user name at the top of the screen.

NOTE: To cancel the log on process, make sure the **INPUT PASSWORD** text box is empty, then touch the **ENTER** key. The PASSWORD dialog will close and the system will return to the previous screen.

Logging Off the System

NOTE: After loading a basket and initiating a processing cycle, it is recommended to log off the instrument if individual passwords have been assigned to users. This ensures that the next user must log on before initiating a processing cycle, and helps maintain an accurate history of processing by each user.

To log off of the instrument:

Touch the **LOG OFF** button in the lower right-hand corner of the screen. The screen refreshes, and the user name is removed from the top of the screen to confirm a successful log off.

System Operation

System operation is comprised of four phases:

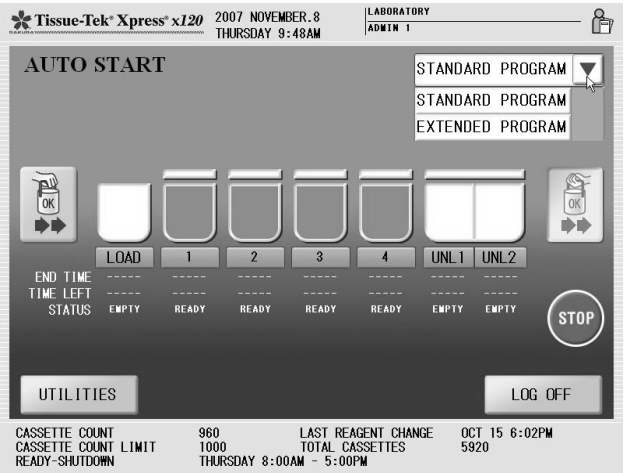


Figure 4-G

- **Loading Tissue Specimens** – A prepared basket or magazine set of specimens is placed in the Loading Station retort, and the information necessary to initiate the processing cycle is entered using the Control Panel.
- **Preprocessing** –Tissue samples processed on the Tissue-Tek® Xpress® *x*120 require proper preparation and handling to ensure optimal results. An optional online step is available to pretreat tissue specimens prior to tissue processing. Pre-Processing Solution (PPS) Product Code 7115 is used in the loading station. Users have the ability to set the onboard preprocessing time between 0-60 minutes. Once a preprocessing cycle has been initiated, the preprocessing operation is performed automatically, under the control of the scheduling software and based on the selected preprocessing time. The Control Panel displays a "process monitor" screen that allows tracking the status of a basket or magazine set through the preprocessing cycle.

NOTE: Do not transport or leave specimens in PPS overnight as this is a timed solution and over exposure will compromise the tissue samples.

- **Process Monitoring** – Once a processing cycle has been initiated, all processing operations are performed automatically, under control of the scheduling software, and based on the currently selected processing program. The Control Panel displays a "process monitor" screen that allows tracking the status of a basket or magazine set through the processing cycle.
- **Unloading Processed Specimens** – Once automated processing is completed, the processed basket is placed in the Unloading Station for unloading and for transfer to an embedding station.

NOTE: The user must be logged on to the instrument to load tissue specimens and initiate a processing cycle (see "*Logging On*" on page 4.4 for details). It is not necessary to log on in order to unload processed specimens.

Two programs can be selected in the program selection pull down list. The STANDARD program immerses the specimens for 15 minutes in each retort. The EXTENDED program immerses the specimens for 30 minutes in each retort. Touch the drop down arrow to view the two programs and then touch the desired selection (Figure 4-G).

NOTE: The program selection can only be made when the instrument is ready, but not processing specimens.

Setting Onboard Preprocessing Times

If this optional online preprocessing step is selected during setup, processing times will be altered accordingly. A basket cannot move to the next retort until the set preprocessing time expires and/or a retort is available.

NOTE: Only administrators have the ability to change the onboard preprocessing times.

CAUTION: Do not transport or leave specimens in PPS overnight as this is a timed solution and over exposure will compromise this tissue samples.

1. Touch the Loading Station icon.
   - A PREPROCESSING SETTINGS window displays (Figure 4-H).

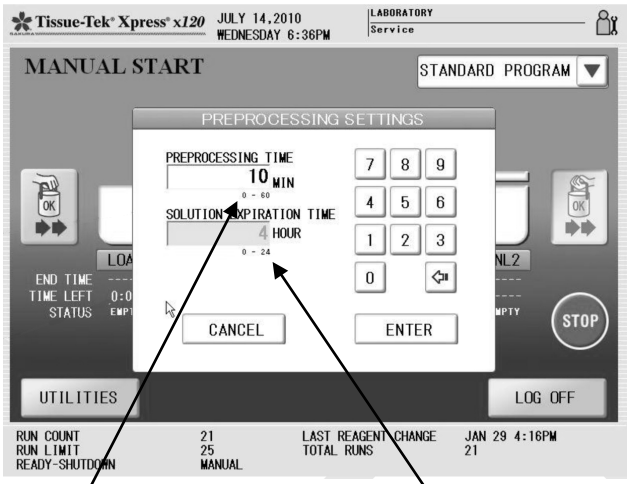


Figure 4-H

Preprocessing Time Range

Solution Expiration Time Range

2. Tap inside the PREPROCESSING TIME field box. Use the keypad to enter a time between 0 and 60 minutes.
   - If zero minutes are entered, the function is disabled.
3. Tap inside the SOLUTION EXPIRATION TIME field box. Use the keypad to enter a time between 0 and 24 hours.
   - If zero hours are entered, the function is disabled.

NOTE: It is recommended to change the onboard preprocessing solution every 3 hours.

4. Touch **ENTER**.

Loading Tissue Specimens and Initiating a Processing Cycle

After the WARMING-UP SYSTEM cycle has completed, the Control Panel displays the PROCESS MONITOR screen (see "*Process Monitor Screen*" on page 4.1 for details). The instrument is now ready to process specimens.

To load a basket or magazine set and initiate a processing cycle:

1. Verify the instrument is ready to accept a basket or magazine set by observing the following conditions:
   - The Loading Station **Access Permitted Icon** is displayed on the left-hand side of the screen.
   - The Loading Indicator is illuminated.

   NOTE: If the instrument is not ready to accept a basket, and a basket or magazine set is loaded into the instrument, the processing cycle will not be started, and a message will display on the Control Panel screen. Remove the basket from the Loading Station and wait until the instrument is ready to accept a basket or magazine set.
2. Log on to the instrument if necessary (see "*Logging On*" on page 4.4 for details).

NOTE: The user must be logged on to the instrument to initiate a processing cycle. If the user is not logged on when a basket or magazine set is loaded into the instrument, the processing cycle will not be started, and a message will display on the Control Panel screen.

3. Open the Loading Station Access Door (Figure 4-I). If necessary, remove the cover from the Loading Station retort.

Figure 4-I

4. Place the basket or magazine set directly into the Loading Station retort (Figure 4-J). Close the Loading Station Access Door.

Figure 4-J

CAUTION: The Loading Station retort has slots (1, Figure 4-K) positioned at the front and rear of the retort. Make sure the tabs of the basket handle engage these slots when the basket or magazine set is placed in the retort. If the basket is not positioned properly, the Transfer Arm will not be able to grasp it firmly.

Figure 4-K

5. Close the Loading Station Access Door.
   - If **REAGENT CONTROL** is set to **CASSETTES**, the CASSETTE COUNT data entry dialog displays (Figure 4-L). Use the keypad to enter the number of cassettes contained in the basket or magazine set to be processed in the **INPUT NUMBER OF CASSETTES** text box.

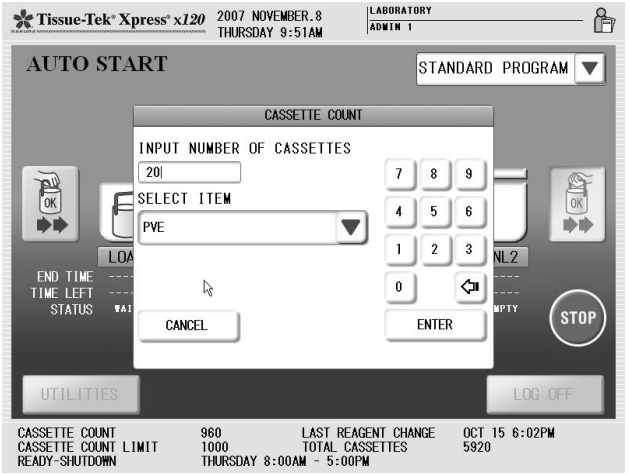


Figure 4-L

NOTE: If needed, use the backspace key to correct errors when entering the number of cassettes. Touch the **CANCEL** key to delete *all characters* from the **INPUT NUMBER OF CASSETTES** text box. If *no value* is entered in the **INPUT NUMBER OF CASSETTES** box, the system will default to 40 cassettes.

- If **REAGENT CONTROL** is set to **RUN** or **DAY,** the system counts each basket or magazine set as a run and a day is automatically accounted for; no user entry is required.
- Select the appropriate user-defined item (location, department, or doctor's name) for which the cassettes are being processed from the **SELECT ITEM** menu.

NOTE: If the USER DEFINED FILE is not enabled (see *Configuring System Settings* on page 3.2 for details), the **SELECT ITEM** menu will not be available.

6. When the necessary information has been entered, touch the **ENTER** button to complete the processing cycle setup. The CASSETTE COUNT dialog closes.
7. The instrument begins the processing cycle.
   - If the preprocessing option is chosen, the basket or magazine will remain in the loading station for the predetermined time before transferring to Station #1.
   - Once the basket or magazine set has been transferred from the Loading Station to Retort #1, another basket or magazine set may be loaded into the instrument for processing. The start time for the next basket or magazine set depends on the

set preprocessing time and/or the availability of Retort #1.

NOTE: If not processing additional baskets or magazine sets at this time, logging off the instrument is recommended (see "*Logging Off the System*" on page 4.5 for details). This ensures that the next user must log on before initiating a processing cycle, and helps maintain an accurate history of processing by each user.

NOTE: As mentioned on page 4.4, processing will not begin if no operator is logged in, there is insufficient reagent in Retort #1, an error condition is present, the robotic arm is in motion or is scheduled to move within the next 30 seconds, or all retorts are occupied. As applicable, the system will guide with prompts to take care of these conditions. Refer to Section 8 Troubleshooting for more details.

NOTE: Processing will not start if the left or right door is ajar. An audible alarm indicating the doors are open will sound to alert the user.

If the preprocessing SOLUTION EXPIRATION TIME is reached, the following message is displayed (Figure 4-M) and the Loading Station icon changes from blue to yellow.

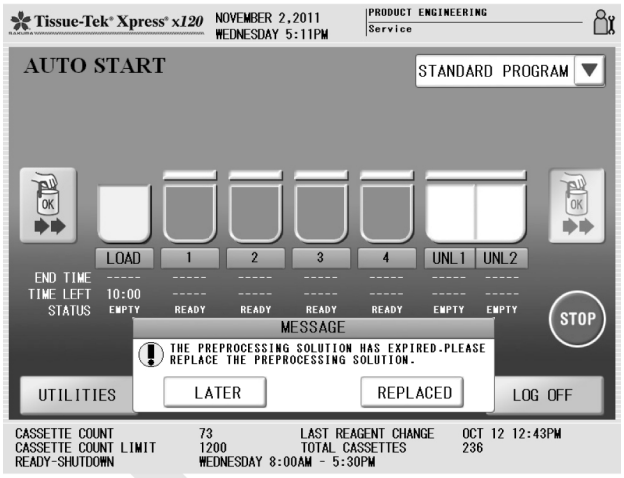


Figure 4-M

Touch **REPLACE** after replacing the Pre-Processing Solution, the loading station icon changes back to blue and the SOLUTION EXPIRATION TIME is reset.

Touch **LATER** to continue without replacing the Pre-Processing Solution, the loading station icon remains yellow and the above message is displayed every 10 minutes until the solution is replaced.

NOTE: Overuse of Pre-Processing Solution could lead to tissue artifacts on the stained slide.

Process Monitoring

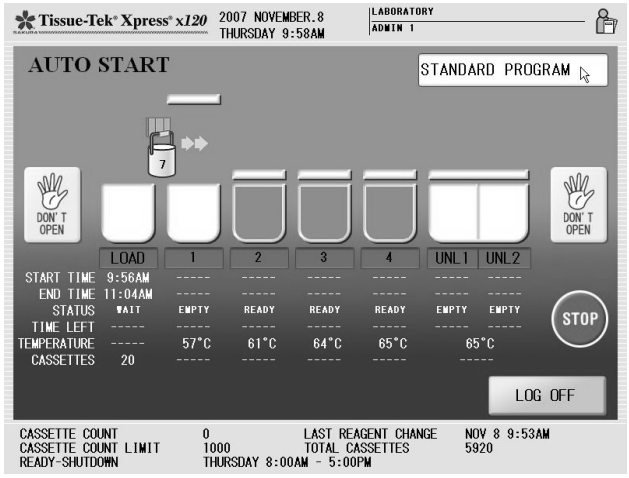


Figure 4-N

During a processing cycle, the Process Monitor screen (Figure 4-N) provides a graphical display of the status of each basket being processed. Icons shown in the graphical display are illustrated and described below

Basket/Magazine Icon – represents a basket or magazine set currently in processing. Each basket or magazine set being processed is identified by a system-assigned sequence number to aid in tracking.

Transfer Icon – indicates a basket or magazine set is being transferred from one retort to the next.

Loading Station Icon (Empty) – indicates the Loading Station is currently empty, and is ready to accept a basket or magazine set.

Loading Station Icon (Wait) – indicates a basket or magazine set is currently in the loading station, and is undergoing preprocessing or awaiting transfer to Retort #1 under control of the instrument's scheduling program.

Retort Icon (Ready) – indicates the associated retort is ready to accept a basket or magazine set.

Loading Station Icon (Yellow) – indicates the Preprocessing Solution Time has expired.

Retort Icon (Emptying) – indicates reagent is being drained from the associated retort prior to receiving a basket or magazine set.

Retort Icon (Filling) – indicates a basket or magazine set has been transferred to the retort, and the retort is being supplied with reagent.

Retort Icon (Emptying) - indicates reagent is being drained from the associated retort prior to transferring the basket or magazine set to the next retort.

Retort Icon (Processing) – indicates the basket or magazine set in the retort is currently undergoing processing.

Unloading Station Icon (Empty) – indicates the associated Unloading Station is currently empty, and is ready to accept a basket or magazine set.

Unloading Station Icon (Complete) – indicates a basket or magazine set has been transferred to the associated Unloading Station, and the processing cycle for the basket or magazine set is complete.

Tabular data shown below the graphical display provides additional information related to the current status of the basket(s) or magazine set(s) being processed. The following information is provided:

- **START TIME** – shows the time at which the basket or magazine set was picked up from the Loading Station and transferred to a retort. This field is blank if a basket or magazine set is not currently in the associated retort.
- **END TIME** – shows the time at which the basket or magazine set is scheduled to be transferred into the Unloading Station, completing processing.
- **STATUS** – identifies the current state of the associated retort, as follows:

LOADING STATION STATUS	
EMPTY	The Loading Station is currently empty and is ready to accept a basket or magazine set.
WAIT	A basket or magazine set is currently in the loading station, and is undergoing preprocessing or awaiting transfer to Retort #1 under control of the instrument's scheduling program.
RETORT STATUS	
READY	The associated retort is ready to accept a basket or magazine set.
EMPTYING	Reagent is being drained from the associated retort prior to receiving a basket or magazine set.
EMPTY	Reagent has been drained from the associated retort, and the retort is ready to receive a basket or magazine set.
FILLING	A basket or magazine set has been transferred to the associated retort, and the retort is being supplied with reagent.
PROCESS	The basket or magazine set in the associated retort is currently undergoing processing.
SHORTAGE	Indicates there is insufficient reagent volume to process the next basket or magazine set.
UNLOADING STATION STATUS	
EMPTY	The associated Unloading Station is currently empty, and is ready to accept a basket or magazine set.
COMPLETE	A basket or magazine set has been transferred to the associated Unloading Station, and the processing cycle for the basket or magazine set is complete.

The following information is available when the operator touches the associated icon.

- **TIME LEFT** – shows the time remaining until the associated basket or magazine set is transferred to the next station.
- **TEMPERATURE** – shows the current temperature of the associated retort. This field is blank for the Loading Station.
- **CASSETTES** – shows the number of cassettes contained in the basket or magazine set in the associated retort if **REAGENT CONTROL** is set for **CASSETTES**.

NOTE: If **REAGENT CONTROL** is set to **RUN**, the number "40" will display in this field.

Unloading Processed Specimens

When a basket or magazine set is transferred to the Unloading Station, processing is complete, and the basket or magazine set is ready for transfer to a paraffin embedding station. When a basket or magazine set is ready for unloading, the following indications are provided:

- The Unloading Station **Access Permitted Icon** is displayed on the right-hand side of the screen.
- The Unloading Indicator is illuminated.
- An audible alarm sounds briefly.

NOTE: If unable to remove the basket or magazine set immediately, the Unloading Indicator will flash continuously until the basket or magazine set is removed.

To unload a basket or magazine set:

WARNING: PROCESSED BASKETS OR MAGAZINE SETS MAY CONTAIN SOME FLUID PARAFFIN RESIDUE. USE THE TRANSPORT TRAY WHEN UNLOADING AND TRANSFERRING PROCESSED BASKETS OR MAGAZINE SETS TO PREVENT PARAFFIN DRIPS FROM FALLING TO THE FLOOR.

NOTE: It is not necessary to log on to the instrument to unload a basket or magazine set.

1. Press the Unloading Indicator to open the lid of the unloading station.
2. Open the Unloading Station Access Door (Figure 4-O).

Figure 4-O

3. Remove the basket or magazine set from the Unloading Station and place the basket or magazine set on the transport tray for transportation to the paraffin embedding system (Figure 4-P).

Figure 4-P

4. Close the Unloading Station Access Door. The lid of the Unloading Station will close automatically.

NOTE: If a basket or magazine set remains in the Unloading Station, closing the Unloading Station Access Door will reopen the lid of the Unloading Station.

System Shutdown

The Shutdown process should be performed at the end of the day for efficiency. Shutting down the system saves power and reagent. If the system is not shutdown, reagents in Retorts #1 and #2 remain heated and will slowly evaporate overnight.

When the instrument is shutdown, the following processes occur:

Reagent Drainage

- Reagents in Retorts #1 and #2 and in the preheating chambers are drained into the reagent bottles.
- Paraffin in Retorts #3 and #4 is drained into the paraffin oven.

Temperature Control

- The heaters for Retorts #1 and #2, the preheating chambers, and the Unloading Station are turned off.

NOTE: The heaters for Retorts #3 and #4, the paraffin oven, and all associated plumbing remain on to keep the paraffin in a melted state.

Computer (Controller)

- The computer switches to "sleep mode" after completing all reagent drainage.
- The Control Panel display screen powers off.

NOTE: Shutdown cannot occur until all processing cycles are completed, and all processed baskets or magazine sets have been removed from the instrument.

Auto Shutdown

The Auto Start / Shutdown feature allows the instrument to be configured to *automatically* shutdown at a specified time. When auto shutdown is enabled and the instrument is idle (no baskets or magazine sets are being processed), the instrument enters the Shutdown cycle at a specified time.

When the Auto Start / Shutdown feature is enabled, the Auto Start / Shutdown indicator on the User Interface is illuminated at all times that power is applied to the instrument (see *"Control Panel (Figure 1-O)"* on page 1.12 for details).

NOTE: If it is necessary to shutdown the instrument *prior* to its programmed shutdown time, use the "Manual Shutdown" procedure to manually shutdown the instrument. Shutting down the instrument manually will not affect the auto start cycle for the next day, and auto start will occur at its next scheduled start time.

Manual Shutdown

NOTE: The user must be logged on to the instrument to perform a manual shutdown (see "*Logging On*" on page 4.4 for details).

To perform a manual shutdown of the instrument:

1. From the Process Monitor screen, touch the **UTILITIES** button.
   - The UTILITIES screen displays.
2. Touch the SHUTDOWN button.
   - A confirmation dialog displays the message "ARE YOU SURE YOU WANT TO SHUT DOWN?" (Figure 4-Q).

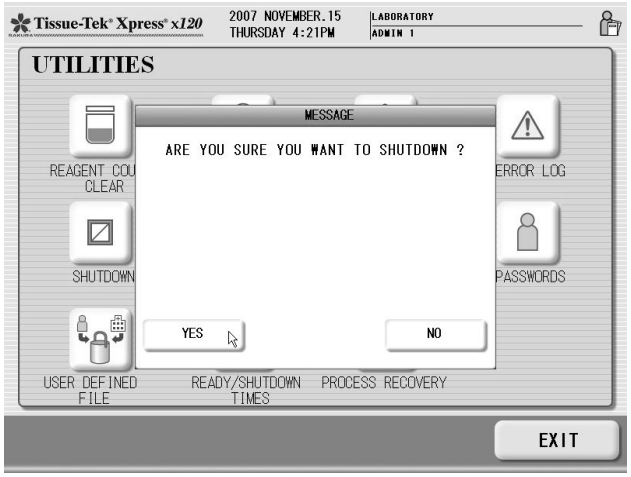


Figure 4-Q

3. Touch the **YES** button to initiate a shutdown of the instrument.
   - The SHUTDOWN screen displays, showing the status of the reagent draining process (Figure 4-R).

   NOTE: The reagent draining process takes approximately four minutes to complete.

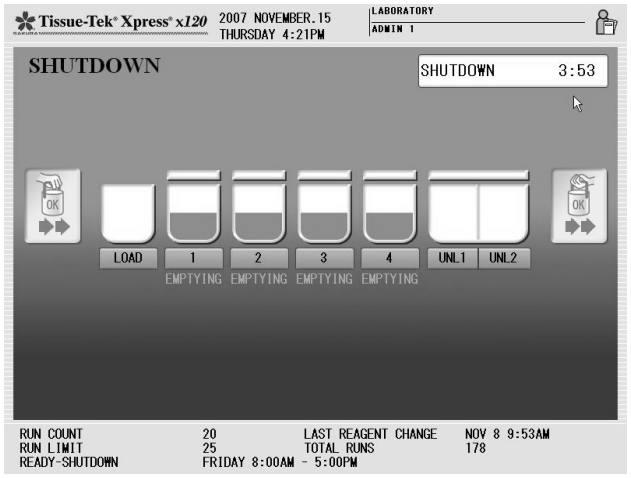


Figure 4-R

Special Conditions and Considerations

Understanding the Process Scheduler

In order to achieve continuous processing, the instrument's scheduling software internally calculates a process schedule to efficiently process and transfer the specimen basket or magazine set. Depending upon the immersion times and number of baskets or magazine sets simultaneously in process, the instrument's internal process scheduler may create a delay to prevent baskets or magazine sets from immersing too long in Retorts #1 or #2 if baskets or magazine sets in the Unloading Station are not removed.

For example, if four baskets or magazine sets are processed simultaneously, and the duration of the immersion time is 15 minutes for each of the four processing stations, the start of processing for the next basket or magazine set in the Loading Station may be delayed even though Retort #1 is READY. This is not an error. The basket or magazine set in the Loading Station will be transferred within 20 minutes.

Reagent Volume Monitor

Each time a basket or magazine set is transferred, the instrument checks the reagent volume when the reagent is pumped into retort. If the instrument detects that the reagent level is not sufficient for the next basket or set, the word, "SHORTAGE" displays in the **STATUS** row on the Process Monitor screen. The instrument will continue processing the basket(s) or magazine set(s) that are already in process, however, the instrument will not accept any new baskets or magazine sets until the shortage is corrected.

If a "SHORTAGE" occurs, proceed as follows:

1. Allow all baskets or magazine sets currently being processed to complete their processing.
2. Remove the baskets or magazine sets from the Unloading Station when processing is completed.
3. Perform a manual shutdown of the instrument (see "Manual Shutdown" on page 4.11 for details).
4. After the shutdown process has completed, replace all reagents (see "*Pre-Processing Solution Replacement*" on page 7.3 for details).

On board Pre-Processing Solution must be replaced on condition (after a specified number of hours) to ensure proper preprocessing. The instrument can be configured to count the number of hours the solution has been in the instrument to aid in determining when to replace the Pre-Processing Solution (see "System Operation", page 4.5).

NOTE: Depending on the types of tissues processed the Pre-Processing Solution should be replaced every 3 hours.

To replace the Pre-Processing Solution:

WARNING: THE PREPROCESSING CONTAINER MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF THE CONTENTS IN ACCORDANCE WITH LOCAL REGULATIONS.

1. Open the Loading Station Door.
2. Remove the loading Station Container.
3. Discard the Pre-Processing Soution per local regulations.
4. Wipe the inside of the loading station container with gauze.
5. Perform a manual start of the instrument (see "*Manual Start*" on page 4.3 for details).
6. When the WARMING UP SYSTEM cycle is completed (see "*System Warm Up (Figure 4-E)*" on page 4.4 for details), the user may resume processing.

Door Open

To prevent the risk of injury due to contact with the Transfer Arm while in motion, the Transfer Arm stops moving *immediately* when any Access Door (Loading Station Access Door, Retort Access Door or Unloading Station Access Door) is opened during processing. The instrument resumes processing when the door is closed.

Performing an Emergency Stop

The Process Monitor screen includes an emergency **STOP** button to stop the motion of the Transfer Arm and all processing actions in case of emergency.

To perform an emergency stop:

1. Touch the **STOP** button in the lower right-hand corner of the screen.
   - The Transfer Arm stops moving *immediately*, and a confirmation dialog displays the message "ROBOT ARM IS TEMPORARILY DISABLED. SELECT 'RESUME' OR 'ABORT'."
2. To cancel processing, touch the **ABORT** button on the confirmation dialog.
   - A confirmation dialog displays the message "ALL RUNS WILL BE ABORTED. ARE YOU SURE YOU WANT TO ABORT ALL RUNS?"
3. To abort all runs, touch the **YES** button on the confirmation dialog.
   - A shutdown dialog displays the message "REMOVE ALL BASKETS FROM RETORTS. THEN SELECT 'GO TO STANDBY' OR 'SHUTDOWN'."
4. Touch the **SHUTDOWN** button to shut down the instrument.

NOTE: If baskets were in Retort(s) 3 or 4, they may be reprocessed using the "recovery" process (see *Section 5, "Recovery Process"* for details).

Viewing Reports and Statistics

The UTILITIES menu provides access to historical and statistical reports and information screens intended to aid in monitoring instrument usage and in monitoring and maintaining the system.

NOTE: The user must log on to the system as an Administrator in order to access all features and functions available through the UTILITIES menu (see "*Logging On*" on page 4.4 for details).

To access the UTILITIES menu:

- From the WARMING UP SYSTEM, MANUAL START or AUTO START screen, press the **UTILITIES** key to display the UTILITIES menu (Figure 4-S).

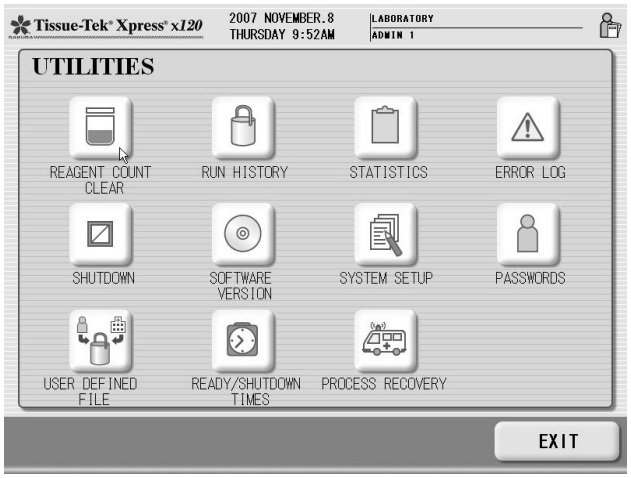


Figure 4-S

Viewing the Software Version

The SOFTWARE VERSION screen displays information related to instrument software and firmware versions, and the instrument's serial number.

To view the software version:

1. From the UTILITIES screen, touch the **SOFTWARE VERSION** button.
   - The SOFTWARE VERSION screen displays (Figure 4-T).
2. The SOFTWARE VERSION screen shows the main, master CPU, slave CPU1, slave CPU2 software version numbers, and the instrument serial number.
3. Touch the **EXIT** button to return to the UTILITIES screen.

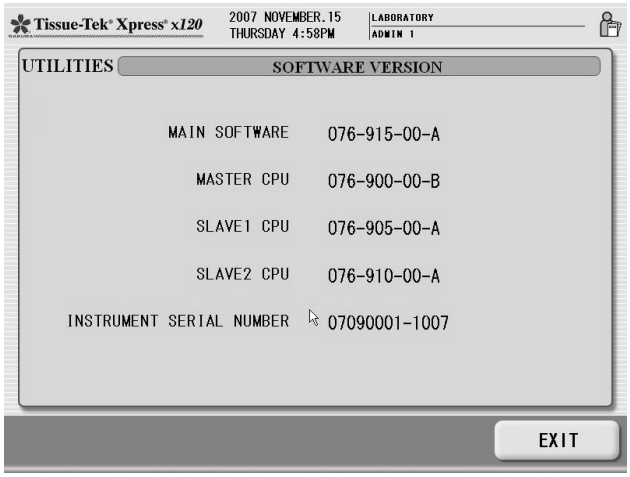


Figure 4-T

Viewing Run History

The system records and stores historical data related to each processing run. This information is retrieved and viewed using the **RUN HISTORY** function. The system stores run history for the previous 30 days.

NOTE: This feature is available to System Administrators only.

To access run history:

1. From the UTILITIES screen, touch the **RUN HISTORY** button.
   - The RUN HISTORY screen displays (Figure 4-U). In this example, the User Defined File has been defined as "**Location**".

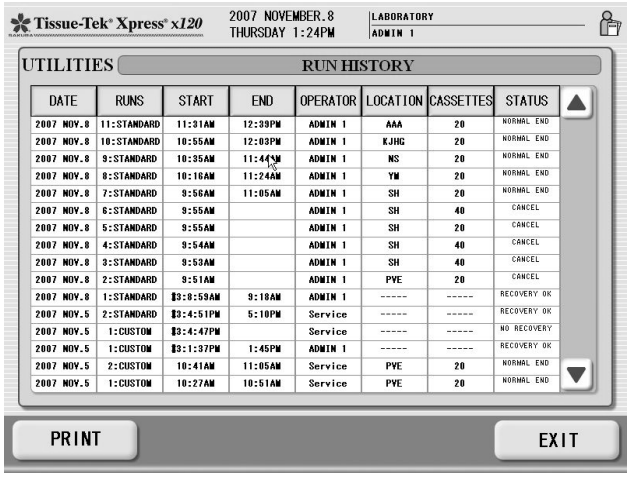


Figure 4-U

To view run history:

- The RUN HISTORY screen is comprised of a series of data lines. There is one for each run (basket or magazine set) processed by the instrument.
- The RUN HISTORY screen provides the following information:

DATE	The date on which the run was processed.
RUN	The system-assigned number for the run. Each basket or magazine set is assigned a unique number indicating the order in which it was processed.
START	The time at which the processing run was initiated.
END	The time at which the processing run concluded.
OPERATOR	The operator that initiated the processing run.
User Defined File ("LOCATION" in this example)	The location for which the run was processed, as selected from the "SELECT ITEM" menu during setup. **NOTE:** If an item was not selected during setup for a given run, the **LOCATION** field for that run will be blank. If no items are specified in the USER DEFINED FILE for installation, or if the USER DEFINED FILE is not enabled, the **LOCATION** field will *always* be blank.
CASSETTES	The number of cassettes processed in the run, as entered during setup.
STATUS	A brief description indicating the final status for the run.

- Use the scrollbar to scroll through the entire report.

- Sort the RUN HISTORY screen chronologically by **DATE**, or alphabetically by **OPERATOR,** or **LOCATION (User Defined File)**. To re-sort the RUN HISTORY screen, touch the column head chosen to use as a sort key.
- Touch the **EXIT** button to return to the UTILITIES screen.

To print run history:

NOTE: Two **PRINT** options are available, **MANUAL** and **AUTO**. Both options allow users to export a CSV file to a USB memory stick. **MANUAL** allows users to generate reports as needed. **AUTO** generates a report every time a process is completed. The factory default setting is **MANUAL**.

1. From the UTILITIES screen, touch the **RUN HISTORY** button.
   - The RUN HISTORY screen displays (Figure 4-U).
2. Touch the **PRINT** button.
3. Select the print period from the list.

Viewing Statistics

The system records and stores statistical data related to the number of runs and cassettes processed. This information is retrieved and viewed using the **STATISTICS** function. The system stores statistical information for the prior one-year period.

Statistical information can be a useful as a managerial tool to aid in evaluating operator activity, or in determining workloads for hospitals/clinics from which specimens were received for processing.

Statistics can be viewed for a selected daily, weekly, or monthly period.

To access statistics:

1. From the UTILITIES screen, touch the **STATISTICS** button.
   - The STATISTICS PERIOD SELECTION screen displays (Figure 4-V).

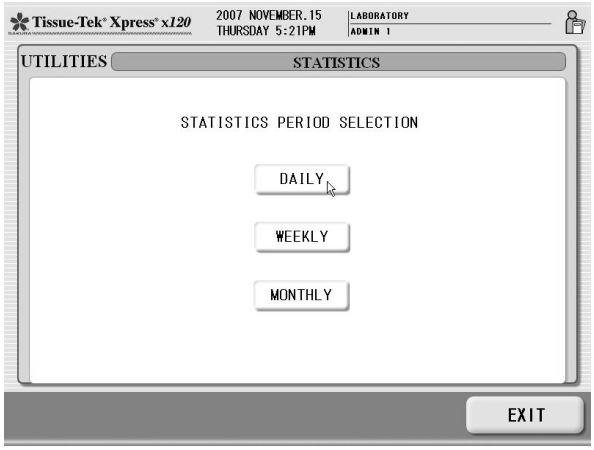


Figure 4-V

2. Select the period for which to view statistics, either **DAILY** (for the prior seven days), **WEEKLY** (for the prior 7 weeks), or **MONTHLY** (for the prior 24 months).
   - The screen refreshes to display the selected DAILY STATISTICS (Figure 4-W), WEEKLY STATISTICS (Figure 4-X) or MONTHLY STATISTICS (Figure 4-Y) screen.

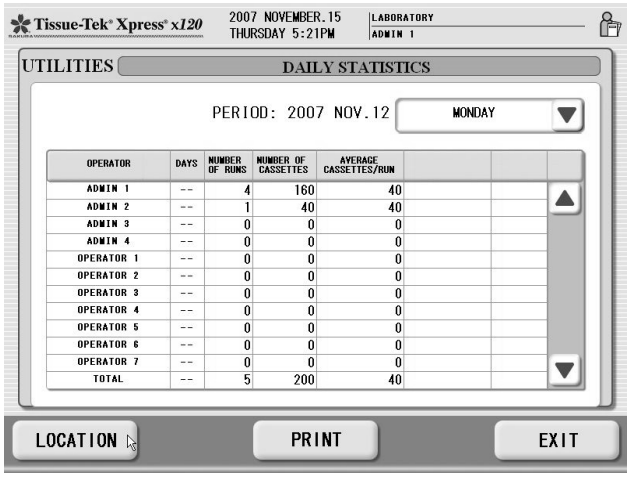


Figure 4-W

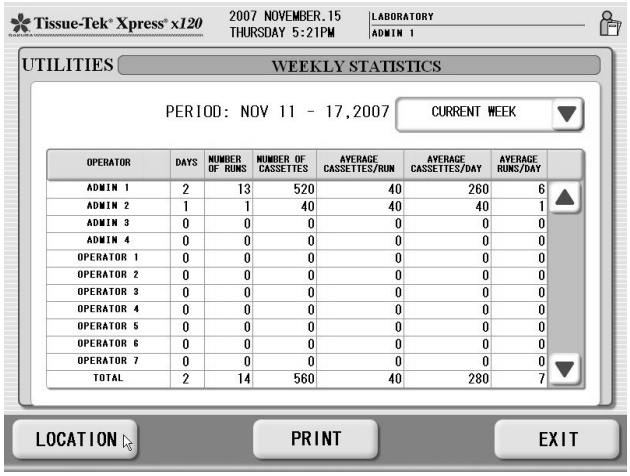


Figure 4-X

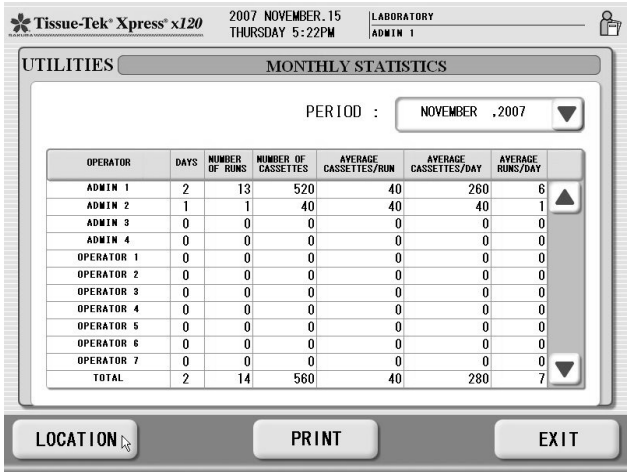


Figure 4-Y

To view statistics:

- The STATISTICS screen is comprised of a series of data lines; one for each instrument operator (ADMIN 1 THRU 4, OPERATOR 1 thru 20) when viewing by **OPERATOR**, or for each user-defined item currently defined in the USER DEFINED FILE (see *Configuring System Settings* on page 3.2 for details) when viewing by location.
- The STATISTICS screen provides the following information:

ITEM	DEFINITION	SHOWN ON REPORT		
		DAILY	WEEKLY	MONTHLY
PERIOD	The calendar date and day or week for which statistics are displayed.	X	X	
MONTH	The month and year for which statistics are displayed.			X
OPERATOR	The operator with whom the statistics are associated. (The **OPERATOR** field is shown *only* when viewing statistics by operator.)	X	X	X
User Defined File ("LOCATION" in this example)	The location with which the statistics are associated. (The **LOCATION** field is shown *only* when viewing statistics by location.)	X	X	X
DAYS	The number of days included in the report period.		X	X
NUMBER OF RUNS	The number of processing runs initiated *by* the associated operator (when viewing by **OPERATOR**) or *for* the associated location (when viewing by **LOCATION**) for the currently selected period.	X	X	X
NUMBER OF CASSETTES	The total number of cassettes in all processing runs initiated *by* the associated operator (when viewing by **OPERATOR**) or *for* the associated location (when viewing by **LOCATION**) for the currently selected period.	X	X	X
AVERAGE CASSETTES/RUN	The average number of cassettes-per-run processed *by* the associated operator (when viewing by **OPERATOR**) or *for* the associated location (when viewing by **LOCATION**) for the currently selected period.	X	X	X
AVERAGE CASSETTES/DAY	The average number of cassettes-per-day processed *by* the associated operator (when viewing by **OPERATOR**) or *for* the associated location (when viewing by **LOCATION**) for the currently selected period.		X	X
AVERAGE RUNS/DAY	The average number of runs-per-day processed *by* the associated operator (when viewing by **OPERATOR**) or *for* the associated location (when viewing by **LOCATION**) for the currently selected period.		X	X

- The STATISTICS screen initially displays statistics for the current period (day, week, or month, as appropriate), by operator. To view statistics by location (in this example), touch the LOCATION button; the screen refreshes to display statistics for the current period, by location. Touch the **OPERATOR** button to return to the previous display.

NOTE: If the USER DEFINED FILE is not enabled (see *Configuring System Settings* on page 3.2 for details), the **LOCATION** option for viewing statistics will not be available.

- Use the scrollbar to view the entire statistics report.
- To view statistics for another period, select the desired period from the **PERIOD** (for DAILY or WEEKLY statistics) or **MONTH** (for MONTHLY statistics) drop-down menu.
- Touch the **EXIT** button to return to the UTILITIES screen.

To print statistics:

NOTE: The **PRINT** option allows users to export a file to a USB memory stick.

- **FILE OUTPUT**-exports a CSV file to a USB memory stick
- **PRINT**-exports a PDF file to a USB memory stick

1. From the UTILITIES screen, touch the **STATISTICS** button.
   - The STATISTICS PERIOD SELECTION screen displays (Figure 4-V).
2. Select the period for which to print statistics, either **DAILY**, **WEEKLY**, or **MONTHLY**.
   - The screen refreshes to display the selected DAILY STATISTICS (Figure 4-W), WEEKLY STATISTICS (Figure 4-X) or MONTHLY STATISTICS (Figure 4-Y) screen.

3. If necessary, use the **PERIOD** (for DAILY or WEEKLY statistics) or **MONTH** (for MONTHLY statistics) drop-down menu to select the desired report period.
4. Touch the **PRINT** button to export data to a USB stick.

Viewing the Error Log

The instrument maintains a log of errors that occur in monitored systems, subsystems or processes. This information serves as an aid in diagnosing equipment malfunctions, and in determining whether service is required.

To access the error log:

1. From the UTILITIES screen, touch the **ERROR LOG** button.
   - The ERROR LOG screen displays (Figure 4-Z).

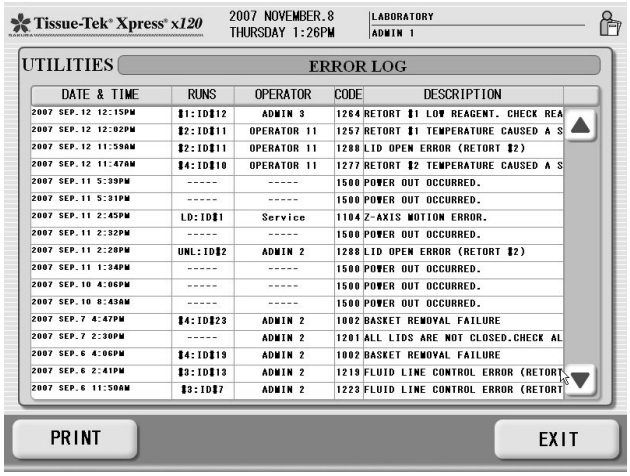


Figure 4-Z

To view the error log:

- The ERROR LOG screen is comprised of a series of data lines. There is one for each error that occurred in a monitored system, subsystem, or process.
- The ERROR LOG provides the following information:

DATE & TIME	The date and time at which the associated error was logged.
RUN	The identification number for the run that was in process when the associated error occurred. If the associated error occurred while the instrument was idle, this field is blank.
OPERATOR	The name of the operator (ADMIN 1 THRU 4, OPERATOR 1 THRU 20) logged into the instrument when the associated error occurred. If the associated error occurred while no operator was logged in, this field is blank.

1. Use the scrollbar to scroll through the entire log.
2. Touch the **EXIT** button to return to the UTILITIES screen.

To print the error log:

NOTE: The **PRINT** option allows users to export a file to a USB memory stick.

- **FILE OUTPUT**-exports a CSV file to a USB memory stick
- **PRINT**-exports a PDF file to a USB memory stick

1. From the UTILITIES screen, touch the **ERROR LOG** button.
   - The ERROR LOG screen displays (Figure 4-Z).
2. Touch the **PRINT** button.

RECOVERY PROCESS

Overview

This section describes the recovery process for any operation that is suspended due to an error condition. If an error occurs during processing, the UTILITIES SCREEN provides a means of initiating the recovery procedure detailed in this section. In addition, it enables the operator to abort and restart any baskets that may have been suspended in Retorts 3 or 4. See "*Section 8, Troubleshooting*" for specific troubleshooting procedures for a given error.

It is important to note that not all conditions causing an error are immediately recoverable. Some error conditions require a service technician to diagnose the problem and may require service attention. In this case, please contact the Sakura Technical Support Department at 800-725-8723, option 2, (U.S. customers only), or the nearest authorized Sakura instrument distributor or representative.

Detecting an Error Condition

When the instrument has detected an error during processing, a message window displays automatically. *Write this message down*. Then note the time left for the basket(s) in Retorts 3 and/or 4 for reference during recovery process setup. The window presents two options from which to choose, **RESUME** or **ABORT** (Figure 5-A).

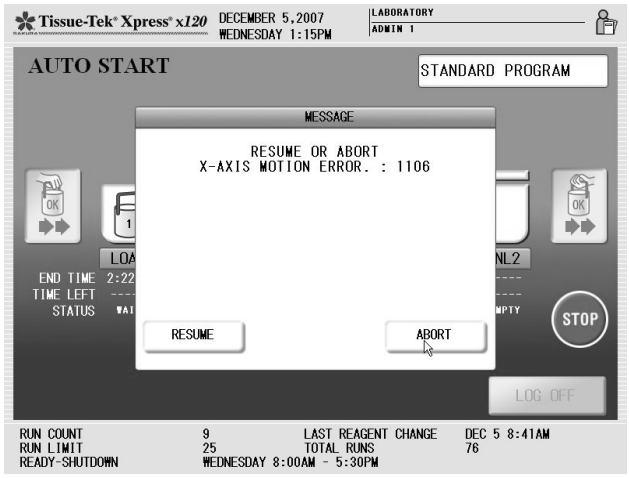


Figure 5-A

- If the **RESUME** button is pressed, and the error is a condition from which the instrument can immediately recover, the error is cleared and the Xpress x120 process resumes where it left off.

NOTE: If the error that occurred is such that it prevents the system from resuming processing, it may be necessary to shutdown the instrument and provide service attention.

- If the **ABORT** button is pressed, a confirmation screen displays (Figure 5-B). Press the **YES** button to continue with the abort process; press the **NO** button to cancel the abort.

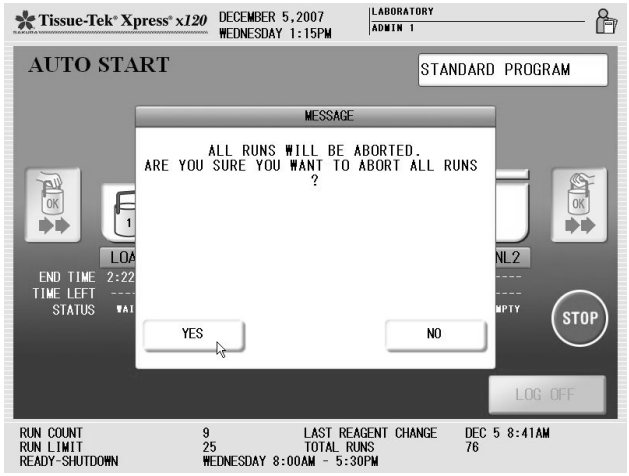


Figure 5-B

- If the **NO** button is pressed, the system returns to the prior display (Figure 5-A).

- If the **YES** button is pressed, an advisory message displays (Figure 5-C). All baskets must be removed from the system, and one of two options, **GO TO STANDBY** or **SHUTDOWN** can be selected.

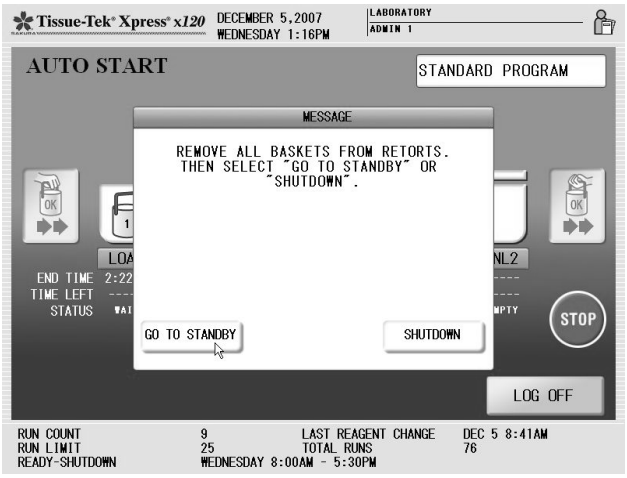


Figure 5-C

- If the **SHUTDOWN** button is pressed, the system will shut down. The main power switch can also be turned off if it appears that the instrument will require service.
- If the **STANDBY** button is pressed, the instrument will revert to the standby mode and the WARMING UP SCREEN will display. The warming up screen ensures that the reagents are at the proper temperature to continue processing. It is not possible to override this procedure. Once the warming up process is completed, the instrument will go into the STANDBY mode and is again ready for processing.

Starting a Processing Run in Retort 3 or 4

It may be necessary to reprocess a specimen or group of specimens beginning in Retort 3 or 4 due to an error condition that suspended processing, or because of a technical processing issue.

NOTE: There are no special recovery methods for those specimens that may have been suspended in Retorts 1 or 2. These specimens can be reprocessed by placing them back into Retort 1 without compromising specimen integrity.

NOTE: If the Tissue-Tek Xpress x120 will be down for longer than 1 hour, place the tissue specimens in Molecular Fixative until instrument is operational. Preprocessing does not have to be repeated prior to reprocessing. If Molecular Fixative is not available place the tissue specimen in 10% NBF. Once the instrument is operational the preprocessing steps must be repeated prior to reprocessing.

To reprocess specimens starting in Retort 3 or 4:

1. From the UTILITIES screen, touch the **PROCESS RECOVERY** button.

NOTE: The **PROCESS RECOVERY** button is enabled only during the WARMING UP SYSTEM cycle.

- The PROCESS RECOVERY screen displays (Figure 5-D).

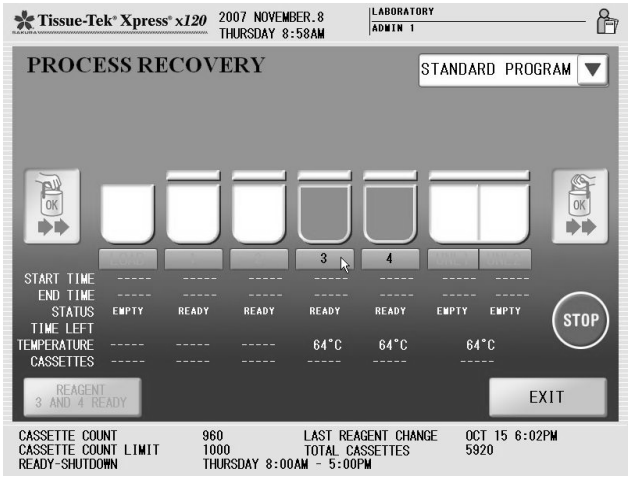


Figure 5-D

- The PROCESS RECOVERY provides the following information/functions specific to process recovery:

TIME TO READY	Shows the time remaining until the reagents for Retorts 3 and 4 are completely melted. If the instrument was shut down following an abort, 4:00 hours will be displayed (this is the amount of time required to completely melt the reagents).
REAGENT 3 AND 4 READY	If the regents for Retorts 3 and 4 have completely melted, but the **TIME TO READY** timer has not expired, pressing the **REAGENT 3 AND 4 READY** button will override the timer and allow processing to begin immediately. **NOTE:** Be certain that the reagents for Retorts 3 and 4 are completely melted before pressing the **REAGENT 3 AND 4 READY** button.
Pull down list	To select the desired program from pull down list. The process recovery program is made from this selected program.
3 (Retort 3)	Opens the lid for Retort 3 and displays the PROCESS TIME entry dialog.
4 (Retort 4)	Opens the lid for Retort 4 and displays the PROCESS TIME entry dialog.
STOP	Aborts the process recovery operation. The system returns to warm-up mode, then reverts to normal operation.

2. Once the reagents for Retorts 3 and 4 are at proper temperature (the button text changes from red to black), and the Retorts are filled, touch the **3** (Retort 3) or **4** (Retort 4) button, as appropriate.
   - The lid for the selected Retort opens, and the PROCESS TIME dialog displays (Figure 5-E). The Retort for which process time is being set is shown in the upper left corner of the dialog.

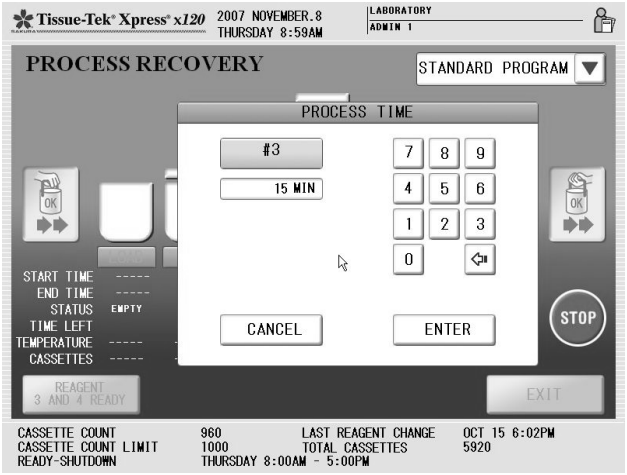


Figure 5-E

3. Place the basket to be processed in the Retort.
4. Use the keypad on the PROCESS TIME dialog to set the amount of time for which processing will occur (the amount of processing time that remained when processing was aborted). Touch the **ENTER** key to begin processing. The Retort lid closes automatically.

NOTE: Reprocessing can be cancelled by pressing the **CANCEL** key. When the **CANCEL** key is pressed, the lid for the corresponding Retort closes.

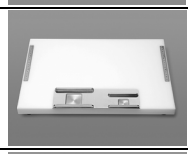
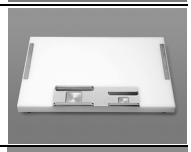
5. Repeat steps 2 through 4, if needed, to set process recovery time for the remaining Retorts.

When process time for Retort 3 is completed, the basket is transferred to the Retort 4 for the programmed time. If a basket is currently in Retort 4, and the process time has not completed, the basket in Retort 3 will remain until processing for the basket in Retort 4 has completed.

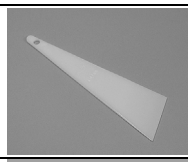
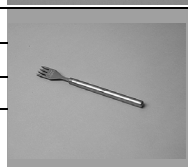
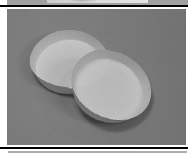
When reprocessing is complete, the basket is transferred to the Unloading Station, and the system alerts the operator with an “End of Process” sound. The system performs a self check then enters into warm-up mode followed by normal operation mode.

CONSUMABLES AND ACCESSORIES

Consumable Materials

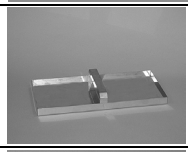
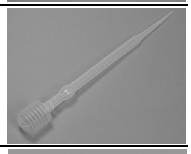
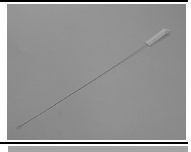
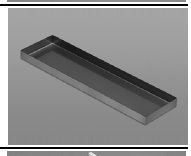
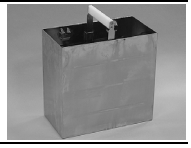
Product Code	Description	
4295	Neutra-Pads (100/pk)	
4785	Trimming Knife Blades, 130mm (50/pk)*	
4786	Trimming Knife Handle*	
4791	Scalpel Handle*	
4792	Scalpel Blades, #61 (20/pk)*	
4793	Scalpel Blades, #62 (20/pk)*	
4800	Grossing Board Kit • Grossing Board • Instruction Sheet • Tampers (2 pcs) • Gauge Set (4 pcs)	
4801	Grossing Board, Large • Grossing Board • Instruction Sheet • Tampers (2 pcs) • Gauge Set (4 pcs)	
4802	Grossing Wells • Grossing Wells • Instruction Sheet • Tampers (2 pcs) • Gauge Set (4 pcs)	
4848	Grossing Wells, Left Handed • Grossing Wells • Instruction Sheet • Tampers (2 pcs) • Gauge Set (4 pcs)	
7730	Reagent Set, (set of 4)	
7115	Pre-Processing Solution (4 x 3.8L)	
7117	Pre-Processing Fixative (4 x 3.8L)	
7120	Molecular Fixative(4 x 3.8L)	

Standard Accessory Items

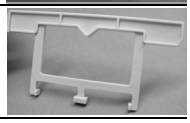
Product Code	Description	
1550	Paraffin Scraper	
4803	Grossing Fork (1.5mm)	
4804	Grossing Fork (2.0mm)	
4807	Grossing Fork (2.5mm)	
4814	Grossing Fork Cleaning Brushes (10/pk)	
7103	Basket w/ Handle, and lid, 40-Cassette (8 pcs)	
7106	Tray Liners (100/pk)	
7107	Fume Filter (2/pk)	
7108	Loading Station Container w/ Lid	
7109	Basket Transportation Tray	
7190	Container Kit	

*Not applicable to Model 7721

Maintenance & Service Items

Product Code	Description	
O71-169-01	Drip Tray	
O71-355-00	Reagent Bottle Tray	
D9-01-0102	Retort Cleaning Pipette	
O71-692-00	Retort Mesh Filter Removal Tool	
O71-697-01	Sight Tube Cleaning Brush	
O71-491-00	Spill Tray	
F60-153-00	Unloading Station Container	
0004389-01	Operating Manual	

Accessory Items for Compatibility with the Tissue-Tek® AutoTEC® Embedding System

Product Code	Description	
7006	20-Cassette Tissue-Tek® AutoTEC® Magazines (4/case) Includes 4 adapters, and 4 lids.	
7007	Tissue-Tek® AutoTEC® Magazine Handles (6/case)	
7139	Uninterruptible Power Supply (UPS)	
7145	Uninterruptible Power Supply, Extended Use (UPS)	
AI8-IF-001	Service Manual	

Where to Call to Order Consumables and Accessories

If located within the United States, contact the Order Management Department of Sakura Finetek U.S.A, Inc., or by calling toll-free: 1-800-725-8723. Alternately, or in countries other than the United States, contact the nearest authorized Sakura distributor.

CARE OF THE INSTRUMENT

General Information

This section provides information on how to care for and maintain the Tissue-Tek® Xpress® x120. The system must be maintained correctly to ensure proper operation.

Read this section carefully before attempting to perform maintenance. Follow all instructions carefully.

Proper periodic maintenance of the Tissue-Tek Xpress x120 is essential in maintaining the system in operational condition. Recommended periodic maintenance procedures are listed below along with the suggested frequency of performance. Maintenance procedures with a recommended frequency of "On Condition" should be performed whenever visual and/or functional inspection indicates the need.

NOTE: Depending on system use, it may be necessary to perform periodic maintenance procedures on a more frequent basis than recommended.

NOTE: A routine maintenance checklist can be found on the last page of Section 7.

PERIODIC MAINTENANCE

MAINTENANCE ACTION	FREQUENCY
Clean Baskets or Magazines	On condition (before each use)
Clean Overflow Bottle	On condition
Replace Pre-Processing Solution Loading Station	On condition (0-24 hours)
Replace Reagents	On condition
Replace Paraffin	On condition
Replace Drip Tray Liner	Daily
Perform Exterior Cleaning	Weekly
Perform Retort Cleaning	Weekly
Clean Retort Mesh Filters	Weekly
Clean Paraffin Oven Mesh Filters	Weekly
Clean Retort Sight Tubes	Weekly
Clean Preheating Chamber Sight Tubes	Weekly
Replace Fume Control System Activated Carbon Cartridge	Monthly

On Condition Maintenance

Basket / Magazine Cleaning

CAUTION: Using baskets or magazines with paraffin residue will cause clogging of the reagent transfer line and will result in instrument malfunction and improper processing of specimens.

A clean basket or magazine set MUST be used for each processing run.

Cleaning of Processing Baskets and Magazines

A minimal amount of paraffin remains on Tissue-Tek Xpress x120 baskets following immersion in Retorts #3 and #4. The paraffin *must* be removed from the surface of the basket, basket handle, and lid prior to reuse.

If the AutoTEC 20-cassette magazines are being used on the instrument, the magazine, lid, and adapter must also be free from paraffin.

Cleaning Method #1 for Tissue-Tek Xpress x120 Processing Baskets and Magazines

The use of an automatic dishwasher with water temperature set on **Hot** and the use of a detergent is the recommended cleaning method. The amount of paraffin that must be removed from the processing basket(s) is minimal and should not contribute to clogging of the laboratory drain pipes.

WARNING: THE PRESENCE OF WHITE, CHALKY RESIDUE INDICATES THAT PARAFFIN REMAINS ON THE SURFACE OF THE BASKET WHICH COULD CLOG THE TISSUE-TEK XPRESS x120 DRAIN FILTER.

Materials and Supplies:

- Recommended dishwasher soap (amount recommended by manufacturer)- Electrasol® Gelpac

Procedure:

Water temperature for washing basket must be HOT, at least 100°C or 212°F. It is recommended that hot water also be used to rinse the baskets after the hot soapy water wash.

1. Place basket(s) in to the dishwasher and place a pre-measured amount of detergent, (1 Gelpac) or the amount recommended by the manufacturer, into the dishwasher.
2. Check that the cycle is set for normal dishwashing (water temperature setting – HOT 100°C (212°F)).
3. Start the dishwasher.
4. The cycle time will depend on the setting selections available on the dishwasher.
5. Remove the baskets from the dishwasher at the completion of the dry cycle and inspect for the presence of paraffin on the surface of the basket and handle.
6. If the baskets are dry and free of paraffin, they are ready for use.

Cleaning Method #2 for Tissue-Tek Xpress x120 Processing Baskets and Magazines

If an automatic dishwasher is not available for use in the laboratory, Tissue-Tek Xpress x120 processing baskets, magazines, cover, and handle may be cleaned by the following method, which requires the use of hot soapy water.

Materials and Supplies:

- Hot plate
- Appropriate sized metal container (leak proof)
- Detergent
- Water

Procedure:

1. Set the hot plate temperature to High or Hot.
2. Using a leak-proof metal container, fill with tap water, and add detergent.
3. Allow the water and soap solution to heat up near boiling point.
4. Place empty processing baskets/magazines and handles in the container and allow to boil for at least five minutes.
5. Rinse the baskets/magazines with two changes of hot water, then allow the baskets to air dry completely prior to reuse.
6. Check each basket/magazine for residual paraffin. If the baskets are clean, they are ready for use.
7. Discard the soapy hot water solution down the drain. Rinse the container with a second hot water rinse. Discard soapy water down the drain.

Cleaning Method #3 for Tissue-Tek Xpress x120 Processing Baskets and Magazines

If an automatic dishwasher is not available for use in the laboratory, Tissue-Tek Xpress x120 processing baskets, magazines, cover, and handle may be cleaned by the following method, which requires the use of Xylene or a Xylene substitute.

Materials and Supplies:

- 1 metal Xylene-resistant container
- Xylene or Xylene substitute
- Absolute alcohol
- Detergent
- Hot water

Procedure:

1. Fill a Xylene-resistant container with solvent (Xylene or Xylene substitute).
2. Place empty processing baskets/magazines and handles in the container.
3. Allow the baskets/magazines to remain in the solvent container until the paraffin coating the surface of the baskets/magazines has been removed. The length of time required to remove any residual paraffin depends on the length of time the baskets/magazines were allowed to cool prior to cleaning. Agitating the baskets/magazines while immersed in the solvent will shorten the cleaning time required.
4. Remove the baskets/magazines from the solvent and place in a container containing absolute alcohol, for a minimum of 30 minutes.
5. Rinse the baskets/magazines in hot water containing detergent.
6. Rinse the baskets/magazines with two changes of hot water, then allow the baskets/magazines to air dry completely prior to reuse.
7. Check each basket/magazine for residual paraffin. If the baskets/magazines are clean and dry, they are ready for use.

Overflow Bottle Cleaning

The overflow bottles associated with Retort #3 and #4 serve as overflow receptacles in the event excess reagent (paraffin) is pumped into the associated retort. The overflow bottles should be cleaned as needed to remove any accumulated paraffin.

WARNING: THE OVERFLOW BOTTLES MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF CONTENTS IN ACCORDANCE WITH LOCAL REGULATIONS.

To clean the overflow bottles:

1. Open the Overflow Bottles Access Door (Figure 7-A).

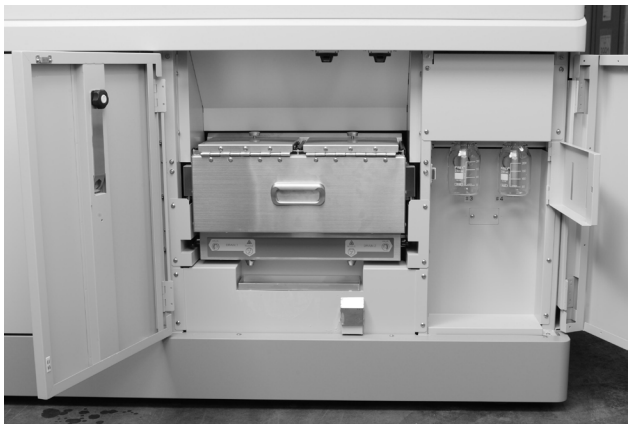


Figure 7-A

2. Loosen each overflow bottle by turning to the left, and remove the overflow bottles from the overflow bottle cabinet (Figure 7-B).

Figure 7-B

3. Discard accumulated paraffin in the overflow bottles in accordance with local regulations for biohazardous waste.
4. Clean any paraffin residue in overflow bottles using hot, soapy water, then rinse and wipe dry.

NOTE: The overflow bottles are labeled "#3" and "#4" to ensure reinstallation in the correct locations in the overflow bottle cabinet.

5. Reinstall the overflow bottles in the overflow bottle cabinet. Be sure to match the labels on the overflow bottles with the labels on the overflow bottle cabinet to ensure installation in the proper locations.
6. Tighten each overflow bottle by turning to the right.
7. Close the Overflow Bottle Access Door.

Pre-Processing Solution Replacement

Onboard Pre-Processing Solution must be replaced on condition (after a specified number of hours) to ensure proper preprocessing. The instrument con be configured to count the number of hours the solution has been in the instrument to aid in determining when to replace the Pre-Processing Solution (See "System Operation", page 4.5).

NOTE: Depending on the types of tissues processed the Pre-Processing Solution should be replaced every 3 hours.

To replace the Pre-Processing Solution:

WARNING: THE PREPROCESSING CONTAINER MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF THE CONTENTS IN ACCORDENCE WITH LOCAL REGULATIONS.

1. Open the Loading Station Door.
2. Remove the Loading Station Container.
3. Discard the Pre-Processing Solution per local regulations.
4. Wipe the inside of the loading station container with gauze.
5. Fill the Loading Station Container with 1.2L of Pre-Processing Solution.
6. Place the Loading Station Container inside the instrument.
7. Close the Loading Station Door.

Reagent Replacement

Reagent must be replaced periodically (after a specified number of runs or cassettes have been processed, or in the event an insufficient amount of reagent is available for processing) to ensure proper processing of tissue specimens. The instrument can be configured to count the number of cassettes processed, or the number of runs processed, as an aid in determining when to replace the reagents (see "*Configuring System Settings*" on page 3.2 for details). The "run" or "cassette" count is shown in the lower window of the WARMING UP SYSTEM, MANUAL START and AUTO START screens.

NOTE: Depending on the types of tissues processed and the hours of operation, the four-retort reagents set should be replaced after processing up to 1,500 specimens, up to about every 37 runs, or up to every 3 days, whichever comes first.

Following reagent replacement, the reagent counter status must be cleared to ensure proper tracking of the number of processed runs for the fresh reagents (see *"Clearing the Reagent Counter"* on page 7.7 for details).

CAUTION: To ensure proper processing of tissue specimens, reagent for Retorts #1 and #2, and paraffin for Retorts #3 and #4 MUST be replaced at the same time.

NOTE: Refer to *"Section 9, Service and Replacement Parts"*, for information on obtaining replacement reagents.

Retorts #1 and #2 Reagent Replacement

NOTE: Each reagent container is equipped with a two-piece cap/connector. The upper cap is used during shipment and storage of the container. The lower cap facilitates connection of the container to the Tissue-Tek Xpress x120 system.

WARNING: THE REAGENT CONTAINERS MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF CONTENTS IN ACCORDANCE WITH LOCAL REGULATIONS.

To replace Retorts #1 and #2 reagents:

1. Perform a system shutdown.
2. Open Retort #1/#2 Reagent Cabinet Access Door (Figure 7-C).

Figure 7-C

NOTE: The instrument utilizes a two-position locking lever to couple the reagent containers to the reagent supply system for Retorts #1 and #2.

3. Press each reagent container locking lever down to the "RELEASE" (lower) position, then allow the lever to return to the "UNLOCKED" (upper) position, uncoupling the reagent containers (Figure 7-D).

Figure 7-D

4. Remove the reagent containers from the reagent cabinet.
5. Invert the new reagent bottles 4-5 times to gently mix the solution, prior to placing on the instrument.

NOTE: Solely shaking the reagent bottle will not thoroughly mix the solution. The bottle must be inverted.

6. Remove the upper caps from the new reagent containers, and install the caps on the used reagent containers. Discard the used reagent containers in accordance with local regulations for biohazardous waste.
7. Remove the foil seal from each reagent container.
8. Place the new reagent containers in the reagent cabinet in the appropriate positions.
9. Press down on each reagent container locking lever until it engages the "LOCKED" position, coupling the reagent containers with the reagent supply system (Figure 7-E).

Figure 7-E

10. Close Retort #1/#2 Reagent Cabinet Access Door.

Retort #3 and #4 Paraffin Replacement

NOTE: Retain the shipping materials to drain used paraffin.

WARNING: DISPOSE OF USED PARAFFIN IN ACCORDANCE WITH LOCAL REGULATIONS FOR BIOHAZARDOUS WASTE.

To replace paraffin:

1. Perform a system shutdown.
2. Open the Paraffin Oven Access Door (Figure 7-F).

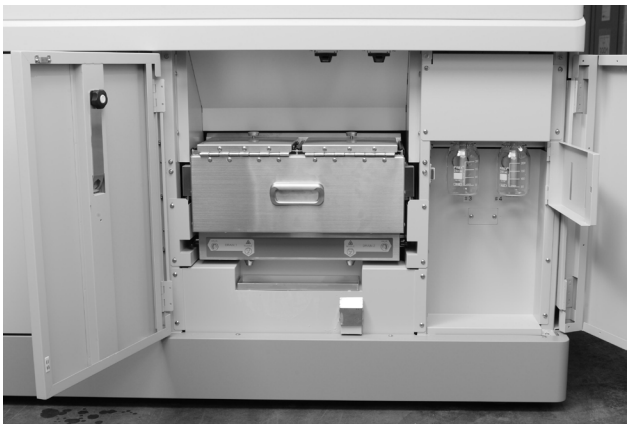


Figure 7-F

3. Remove the drip pan from the paraffin oven (Figure 7-G). If necessary, remove hardened paraffin residue from the drip pan using the paraffin scraper (see *"Section 6, Consumables and Accessories"* for details). Replace the drip pan on the paraffin oven.

Figure 7-G

4. Press in on the paraffin oven to unlatch, then slowly slide the oven out of the cabinet.

5. Using the shipping materials retained after the previous paraffin replacement, line the cardboard shipping carton with the plastic bags. Place the lined cartons under the drain port for the Retort #3 paraffin oven (Figure 7-H).
6. Rotate the left drain control knob for Retort #3 paraffin oven back, until the knob is vertical (Figure 7-I), opening the drain valve. Melted paraffin will begin to drain from the paraffin oven

Figure 7-H

Figure 7-I

7. After the melted paraffin has drained completely from the paraffin oven, rotate the drain control knob to close the drain valve.
8. Repeat steps 5 and 6 for Retort #4 paraffin oven (right drain control knob).
9. Seal the plastic bags securely. Allow the used paraffin to harden, then seal the containers. Discard the used paraffin in accordance with local regulations for biohazardous waste.
10. Turn the locking knob on the lid of the Retort #3 paraffin oven clockwise, then lift the lid to open (Figure 7-J).

Figure 7-J

11. Open the plastic shipping bag, and dispense the entire contents into the paraffin oven (Figure 7-K), then close the oven lid.

Figure 7-K

12. Repeat steps 9 through 11 for Retort #4 paraffin oven.

NOTE: Be sure to retain the paraffin shipping cartons and plastic bags for use during the next paraffin replacement.

13. Slowly push the paraffin oven back into the cabinet until the oven latches into place.
14. Close the Paraffin Oven Access Door.

NOTE: Following paraffin replacement, the instrument may require up to four hours to melt the paraffin and exit the WARMING UP SYSTEM cycle.

Unloading Station Paraffin Replacement

If desired, paraffin can be used in the Unloading Station retort container to ensure tissues are immersed in molten paraffin when processing is complete. Paraffin replacement should be performed at the same time the four-retort reagent set is replaced.

To replace paraffin:

1. Open the Unloading Station Access Door (Figure 7-L).

Figure 7-L

2. Grasp the container handle and lift the container out of the Unloading Station retort.
3. Pour the used paraffin into a suitable waste container.
4. Fill the container with fresh molten paraffin, and return the container to the Unloading Station retort.
5. Close the Unloading Station Access Door.

Clearing the Reagent Counter

The instrument can be configured to count of the number of cassettes processed, or the number of runs processed, as an aid in determining when to replace the reagents (see "*Configuring System Settings*" on page 3.2 for details). The "run" or "cassette" count is shown in the lower window of the WARMING UP SYSTEM, MANUAL START and AUTO START screens.

When reagent is replaced, the reagent counter must be cleared to maintain an accurate count for the next reagent replacement cycle.

To clear the reagent counter:

NOTE: The user must be logged on to the system as an Administrator in order to clear the reagent counter (see

NOTE: The user must be logged on to the system as an Administrator in order to clear the reagent counter (see "*Logging On*" on page 4.4 for details).

1. From the UTILITIES screen, touch the **REAGENT COUNT CLEAR** button.
   - A confirmation dialog displays (Figure 7-M).
2. Touch the **OK** button to clear the reagent counter. (Touch the **CANCEL** button to close the confirmation dialog *without* clearing the reagent counter.)
   - The confirmation dialog closes, and the reagent counter is reset to "0".

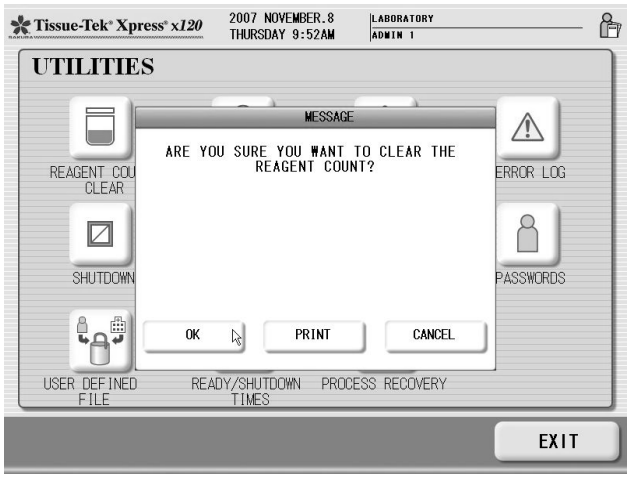


Figure 7-M

Daily Maintenance

Drip Tray Liner Replacement

NOTE: Depending on the number of runs performed on a given day, more frequent replacement of the drip tray liner may be necessary.

Replace the soiled drip tray liner from the transferring arm drip pan and the transport tray with a fresh tray liner daily or as needed.

If necessary, remove hardened paraffin residue using the paraffin scraper (see *"Section 6, Consumables and Accessories"* for details).

WARNING: MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF CONTENTS IN ACCORDANCE WITH LOCAL REGULATIONS.

NOTE: Refer to "*Section 6, Consumables and Accessories*", for information on obtaining drip tray liners.

Weekly Maintenance

Exterior Cleaning

Keep the exterior of the Tissue-Tek Xpress x120 cabinet free of dust and clutter. Generally, wiping with a clean cloth moistened with water is all that is needed to keep the cabinet dust free. Do not use solvents of any kind on the front of the control panel. To disinfect the keypad, wipe with 70% ~ 80% ethanol or isopropanol, and allow to air dry. The acrylic doors may be cleaned with a glass cleaner and soft cloth.

Retort Cleaning

WARNING: MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF CONTENTS IN ACCORDANCE WITH LOCAL REGULATIONS.

NOTE: Open the retort lids manually as necessary to facilitate cleaning operations. Be sure to close the lids when finished cleaning.

Clean the inside of Retorts #1 and #2 and the retort flanges with a lint-free cloth moistened with isopropyl alcohol, then wipe dry. After cleaning, manually close the retort lids.

WARNING: RETORTS #3, #4, AND UNLOADING RETORT HAVE HOT SURFACES.

Clean the inside of Retorts #3, #4, unloading retort, and the retort flanges with a lint-free cloth moistened with a xylene substitute, then wipe dry. After cleaning, manually close the retort lids.

Use the paraffin scraper (see *"Section 6, Consumables and Accessories"* for details) from the retort shelf inside the instrument. Clean excess paraffin residue from the retort shelf inside the instrument with a lint-free cloth moistened with a xylene substitute, then wipe dry.

Retort Mesh Filter Cleaning

WARNING: MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF CONTENTS IN ACCORDANCE WITH LOCAL REGULATIONS.

The retort mesh filters aid in ensuring that any debris generated during processing does not enter reagent containers or the paraffin ovens. If excessive debris accumulates, the filling and draining processes for the retorts may be affected.

To ensure proper filling and draining of all retorts, clean the retort mesh filters weekly.

To clean the retort mesh filters:

1. Open the Retort Access Door (Figure 7-N). The Access Door supports will retain the door in the open position.

Figure 7-N

NOTE: Open the retort lids manually as necessary to facilitate mesh filter removal for cleaning.

2. Insert the Retort Mesh Filter Removal Tool (see *"Section 6, Consumables and Accessories"* for details) into the retort and engage the hub in the center of the filter. Turn the removal tool counterclockwise to unlock the mesh filter, then pull the filter free from the retort (Figure 7-O).

Figure 7-O

CAUTION: Exercise care to avoid damaging the mesh filter during cleaning. Tears in the mesh may allow debris to enter the reagent containers or paraffin ovens, and result in improper processing of tissue specimens.

3. Clean Retorts #1 and #2 mesh filters using a soft-bristle brush and isopropyl alcohol. Ensure that the filters are completely free of debris. Allow the filters to air dry.
4. Clean Retorts #3 and #4 mesh filters using a soft-bristle brush and hot soapy water. Ensure that the filters are completely free of debris. Rinse the filters and allow to air dry.
5. Use the Retort Mesh Filter Removal Tool to engage the hub in the center of the mesh filter. Insert the filter into the appropriate retort, then turn the removal tool clockwise to lock the filter in place.
6. After installation, manually close the retort lids.
7. Close the Retort Access Door.

Paraffin Oven Mesh Filter Cleaning

The paraffin mesh filters aid in ensuring that any debris generated during processing does not enter the paraffin ovens. If excessive debris accumulates, the filling and draining processes for Retorts #3 and #4 may be affected.

To ensure proper filling and draining of the retorts, clean the paraffin oven mesh filters weekly.

To clean the paraffin oven mesh filters:

1. Open the Paraffin Oven Access Door (Figure 7-P).

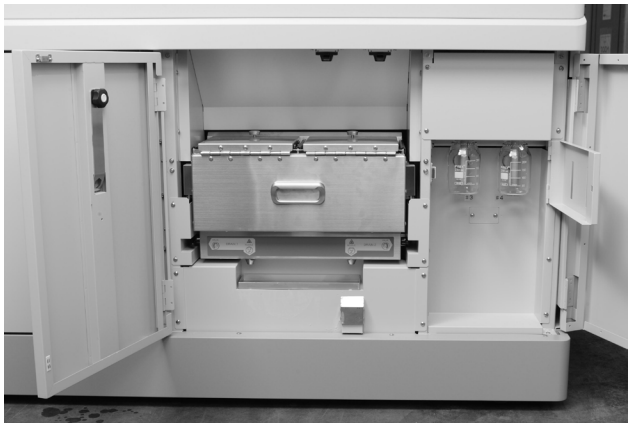


Figure 7-P

2. Press in on the paraffin oven to unlatch, then slowly slide the oven out of the cabinet.
3. Turn the locking knob on the lid of Retort #3 paraffin oven clockwise, then lift the lid to open (Figure 7-Q).

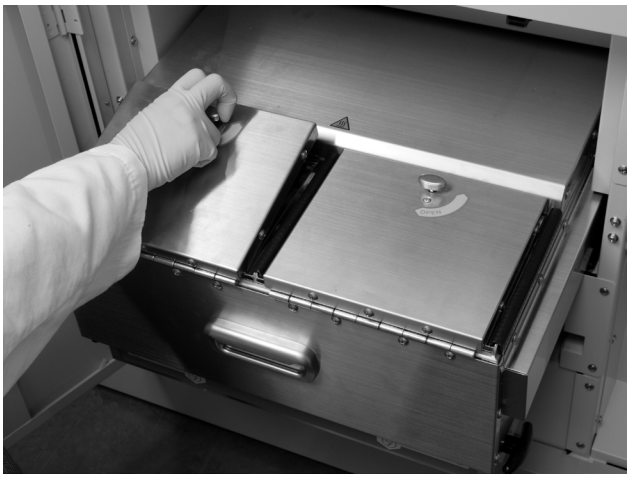


Figure 7-Q

4. Grasp the tab of the mesh filter, and pull up to remove the filter from the paraffin oven.

CAUTION: Exercise care to avoid damaging the mesh filter during cleaning. Tears in the mesh may allow debris to enter the retorts and result in improper processing of tissue specimens.

5. Clean the filter using a soft-bristle brush and hot soapy water. Ensure that the filter is completely free of debris. Rinse the filter and allow to air dry.
6. Hold the mesh filter by the tab, and replace the filter in the paraffin oven. Close the oven lid.
7. Repeat steps 3 through 6 for Retort #4 paraffin oven mesh filter.
8. When both filters have been cleaned, slowly push the paraffin oven back into the cabinet until the oven latches into place.
9. Close the Paraffin Oven Access Door.

Retort Sight Tube Cleaning

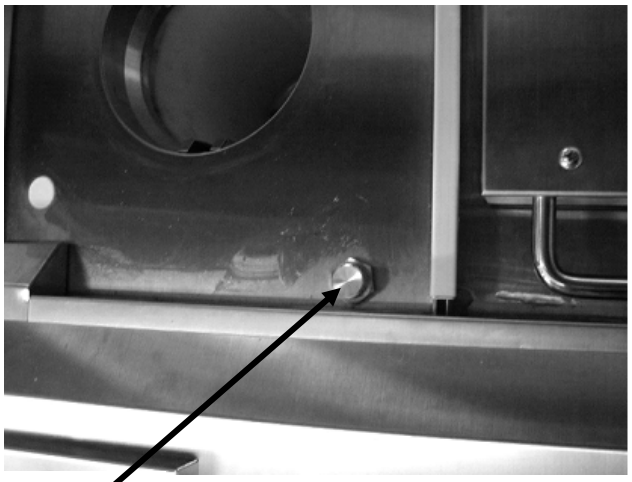
Retort Sight Tubes should be cleaned weekly to ensure reagent in Retorts #1 and #2 is filled and maintained at the appropriate levels for proper processing of tissue specimens, and to guard against reagent overflow.

To clean the Retort Sight Tubes:

1. Open the Retort Access Door (Figure 7-R). The Access Door supports will retain the door in the open position.

Figure 7-R

2. Remove sight tube screw (Figure 7-S)



Remove this screw

Figure 7-S

NOTE: Open Retort #1 and #2 lids manually, as necessary, to facilitate cleaning the retort sight tubes.

3. Insert the sight tube cleaning brush (see *"Section 6, Consumables and Accessories"* for details) into the sight tube, and scrub up and down several times to remove debris from the wall of the sight tube (Figure 7-T).

Figure 7-T

NOTE: Debris removed from the sight tube walls during cleaning will accumulate in the bottom of the sight tube. Be sure to use the retort cleaning pipette to extract and expel any accumulated debris.

4. Insert the retort cleaning pipette (see *"Section 6, Consumables and Accessories"* for details) into the trap at the bottom of the sight tube. Draw out the remaining reagent.
5. Remove the pipette from the sight tube and discard reagent.
6. Repeat steps 4 and 5 as needed to extract and expel all debris from the sight tube.
7. Repeat steps 2 through 5 for Retort #2.
8. Manually close the retort lids.
9. Close the Retort Access Door.

Preheating Chamber Sight Tube Cleaning

The Preheating Chamber sight tubes should be cleaned weekly to ensure reagent in Retorts #1 and #2 is filled and maintained at the appropriate levels for proper processing of tissue specimens, and to guard against reagent overflow.

WARNING: MAY CONTAIN BIOHAZARDOUS WASTE. DISPOSE OF CONTENTS IN ACCORDANCE WITH LOCAL REGULATIONS.

To clean the preheating chamber sight tubes:

CAUTION: Ensure the system shutdown has completed prior to opening the valve.

1. Open the preheating chamber access door on the left-hand side of the instrument.

NOTE: Prior to opening the valves, place a small container under the valves to catch any reagent within the site tubes.

2. Turn the sight tube access valve for the Retort #1 preheating chamber counterclockwise to open the valve (Figure 7-U).

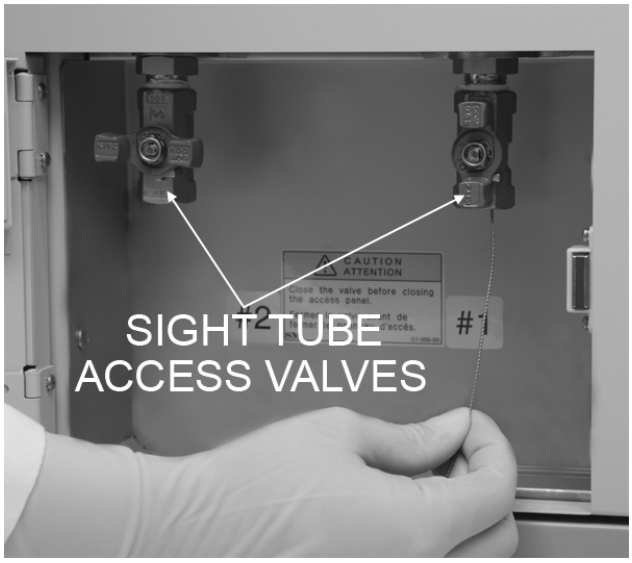


Figure 7-U

3. Insert the sight tube cleaning brush (see *"Section 6, Consumables and Accessories"* for details) into the sight tube, and scrub up and down several times to remove debris from the wall of the sight tube (Figure 7-V).
4. After cleaning, turn the sight tube access valve for Retort #1 preheating chamber clockwise to close the valve.
5. Repeat steps 2 through 4 for the Retort #2 sight tube.
6. Close the preheating chamber access door.

Figure 7-V

Monthly Maintenance

Fume Control System Filter Replacement

WARNING: AN ACTIVATED CARBON FILTER MUST BE INSTALLED IN THE INSTRUMENT AT ALL TIMES TO ENSURE PROPER FILTERING OF FUMES GENERATED DURING PROCESSING.

The fume control system serves to reduce acetone emissions generated by the instrument to acceptable levels. To ensure proper filtering and fume control, replace the fume control system filter monthly.

To replace the fume control system activated carbon filter:

1. Open the Fume Control System Access Door (Figure 7-W).

Figure 7-W

2. Release the latch securing the fume filter access door (Figure 7-X) and open the access door.

Figure 7-X

3. Unlock the latch securing the fume filter cover (Figure 7-Y) and lift the cover up.

Figure 7-Y

4. Slide the fume filter out of the instrument (Figure 7-Z).

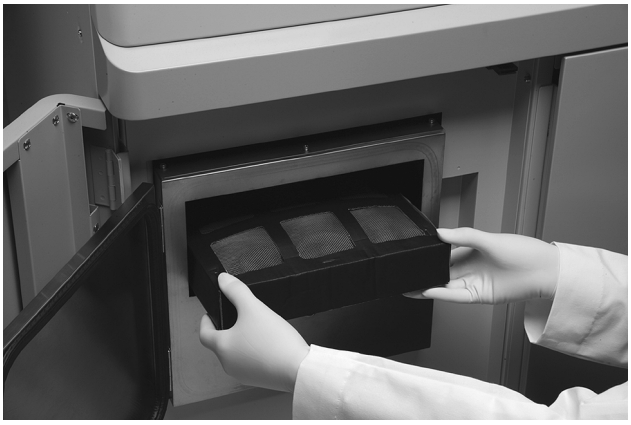


Figure 7-Z

5. Install a new fume filter in the instrument. Lower the fume filter cover and secure the cover latch.
6. Close the fume filter access door and secure the door latch (Figure 7-AA).

Figure 7-AA

7. Close the Fume Control System Access Door.

Tissue-Tek® Xpress® x120 Tissue Processor
Routine Maintenance Check List, Daily

Proper periodic maintenance of the Tissue-Tek® Xpress® x120 Tissue Processor is essential in maintaining the system in operational condition. Recommended periodic maintenance procedures and frequencies of performance are listed below. Keeping a running log of all routine maintenance preformed on the Tissue-Tek® Xpress® x120 Tissue Processor is advised. **MONTH:**_____

Daily Care Week 1							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace MF in load station	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Perform Exterior Cleaning							
Perform Interior Cleaning							
Replace Drip Tray Liner							
Check Reagent Bottle							
Check Overflow Bottle							
Clean Cassette Baskets							
Daily Care Week 2							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace MF in load station	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Perform Exterior Cleaning							
Perform Interior Cleaning							
Replace Drip Tray Liner							
Check Reagent Bottle							
Check Overflow Bottle							
Clean Cassette Baskets							
Daily Care Week 3							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace MF in load station	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Perform Exterior Cleaning							
Perform Interior Cleaning							
Replace Drip Tray Liner							
Check Reagent Bottle							
Check Overflow Bottle							
Clean Cassette Baskets							
Daily Care Week 4							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace MF in load station	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Perform Exterior Cleaning							
Perform Interior Cleaning							
Replace Drip Tray Liner							
Check Reagent Bottle							
Check Overflow Bottle							
Clean Cassette Baskets							
Daily Care Week 5							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace MF in load station	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Perform Exterior Cleaning							
Perform Interior Cleaning							
Replace Drip Tray Liner							
Check Reagent Bottle							
Check Overflow Bottle							
Clean Cassette Baskets							

Tissue-Tek® Xpress® x120 Tissue Processor
Routine Maintenance Check List, Weekly

MONTH:_____

Reagent Change Week 1							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace On Board Reagent Set	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Cassette Count							
Clean Microwave Retort Mesh Filter							
Clean Microwave Chamber Sight Tube							
Clean Paraffin Retort							
Clean Paraffin Retort Mesh Filter							
Clean Paraffin Oven							
Clean Paraffin Oven Mesh Filter							
Reagent Change Week 2							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace On Board Reagent Set	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Cassette Count							
Clean Microwave Retort Mesh Filter							
Clean Microwave Chamber Sight Tube							
Clean Paraffin Retort							
Clean Paraffin Retort Mesh Filter							
Clean Paraffin Oven							
Reagent Change Week 3							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace On Board Reagent Set	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Cassette Count							
Clean Microwave Retort Mesh Filter							
Clean Microwave Chamber Sight Tube							
Clean Paraffin Retort							
Clean Paraffin Retort Mesh Filter							
Clean Paraffin Oven							
Reagent Change Week 4							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace On Board Reagent Set	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Cassette Count							
Clean Microwave Retort Mesh Filter							
Clean Microwave Chamber Sight Tube							
Clean Paraffin Retort							
Clean Paraffin Retort Mesh Filter							
Clean Paraffin Oven							
Reagent Change Week 5							
Beginning Date_____	**Sun**	**Mon**	**Tues**	**Wed**	**Thurs**	**Fri**	**Sat**
Replace On Board Reagent Set	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#	Lot#
Cassette Count							
Clean Microwave Retort Mesh Filter							
Clean Microwave Chamber Sight Tube							
Clean Paraffin Retort							
Clean Paraffin Retort Mesh Filter							
Clean Paraffin Oven							

Replace Carbon Filter Date:_____ **Preheat Chamber Sight Tubes Date:**_____

TROUBLESHOOTING

General Troubleshooting Procedures

CAUTION: All the processes are interrupted during an Error. Therefore, please remove all the baskets from the instrument as soon as possible and protect specimens when an error occurs. If specimens are left in the instrument for a prolonged period, detrimental effects could result.

CAUTION: If any of the Access Doors are open, the Transfer System would be disabled and the baskets will not be transferred. Keeping an access door open for a prolonged period could result in detrimental effects on specimens.

The following Troubleshooting Chart contains general problems that could occur during operation of the Tissue-Tek® Xpress® x120 system. Probable causes and recommended remedies are included for each problem listed, to aid in diagnosis and correction.

If additional assistance is required concerning a Tissue-Tek Xpress x120 system problem, or if a problem cannot be corrected or is beyond the scope of this manual, contact the Sakura Finetek Technical Support Representative for information or assistance.

TROUBLESHOOTING CHART

PROBLEM	PROBABLE CAUSE	REMEDY
Power indicator is not illuminated.	1. Line cord is not plugged. Power failure.	1. Make sure power is available at the power source. Make sure the line cord is properly connected to the electrical power source.
	2. Main power switch (circuit breaker) is off.	2. Turn the main power switch ON
	3. UPS power switch is off.	3. Turn the UPS power switch ON.
	4. UPS outputs “power failure” signal.	4. Contact Sakura Technical Support.
Retorts #3 and #4 are not heated.	1. Line cord is not plugged. Power failure.	1. Make sure power is available at the power source. Make sure the line cord is properly connected to the electrical power source.
	2. Main power switch (circuit breaker) is off.	2. Turn the main power switch ON
	3. UPS power switch is off.	3. Turn the UPS power switch ON.
	4. UPS outputs “power failure” signal.	4. Contact Sakura Technical Support.
LCD display screen does not display when System Start Switch is pressed.	1. Line cord is not plugged. Power failure.	1. Make sure power is available at the power source. Make sure the line cord is properly connected to the electrical power source.
	2. Main power switch (circuit breaker) is off.	2. Turn the main power switch ON
	3. UPS power switch is off.	3. Turn the UPS power switch ON.
	4. UPS outputs “power failure” signal.	4. Contact Sakura Technical Support.
Retorts #3 and #4 have reached set temperature, but “warming-up” process does not proceed to the next step.	1. System is waiting until reagents #3 and #4 in paraffin oven are completely melted.	1. Ensure that reagents #3 and #4 in paraffin oven are completely melted and that all paraffin in plumbing reach appropriate temperature; then press “REAGENTS 3 AND 4 READY” button.
LCD screen turns on unexpectedly.	1. Power failure occurred.	1. No action is needed.
	2. System is in “Auto Ready/Shutdown” mode.	2. Change setting to “Manual Ready/Shutdown” mode.
	3. “ON TIME” and “OFF TIME” are set for the day in “READY/SHUTDOWN TIMES” screen.	3. Change setting to “NOT IN USE”.

PROBLEM	PROBABLE CAUSE	REMEDY
Warm-up or shutdown does not begin according to "Auto Ready/Shutdown" setting.	1. Instrument is in "Manual Ready/Shutdown" mode.	1. Change setting to "Auto Ready/Shutdown" mode.
	2. "NOT IN USE" is set for the day in "READY / SHUTDOWN TIMES" screen.	2. Set "ON TIME" and "OFF TIME".
	3. The day is specified as "holiday" in "DAYS OFF" screen.	3. Cancel holiday setting.
	4. Date setting is not correct.	4. Correct date setting.
	5. "ON TIME" set for the day in "READY/SHUTDOWN TIMES" screen is too late.	5. Set earlier "ON TIME".
Shutdown begins unexpectedly.	1. Instrument is in "Auto Ready/ Shutdown" mode.	1. Change setting to "Manual Ready/Shutdown" mode.
	2. "OFF TIME" set for the day in "READY/SHUTDOWN TIMES" screen is too early.	2. Set later "OFF TIME".
	3. Date setting is not correct.	3. Correct date setting.
Automatic warm-up operation ended approximately 30 minutes earlier than set time.	1. Since automatic warm-up begins one hour before "ON TIME" (in consideration of various environmental temperatures), warm-up ends earlier than set time.	1. Use instrument as it is, or set later "ON TIME".
Shutdown does not begin according to Ready/Shutdown Times setting (with instrument in "Auto Ready/Shutdown" mode).	1. One or more baskets are currently being processed.	1. Continue processing; remove basket(s) from unloading station when complete.
	2. One or more baskets are unloading station.	2. Remove basket(s) from unloading station.
	3. Instrument was started manually following an automatic shutdown (automatic shutdown will not begin until next "OFF TIME" occurs when the instrument has been started manually following automatic shutdown).	3. Shut the system down manually.
	4. "OFF TIME" setting is not correct.	4. Set correct "OFF TIME".
System started automatically and then shutdown began automatically after a time.	1. Power failure occurred.	1. No action is needed.

Monitored Errors

Certain components, operating parameters and system conditions are monitored while the system is powered on, and during operation, to ensure the instrument is in operational condition. When a monitored component or parameter falls outside the established limits or operating criteria, an alarm sounds continuously until the error is cleared, and an error number or warning message is shown on the Tissue-Tek Xpress x120 display. To cancel (turn off) the alarm, press the **EXIT** button on the warning message.

Each error that results in the display of an error number generates an entry in the system Error Log. The Error Log stores the 100 most recent errors, arranged by date, and provides a description of each error (see "*Viewing the Error Log*" on page 4.18 for details).

SERVICE AND REPLACEMENT PARTS

Service Information

When there is a Problem with the Instrument

When a problem occurs during operation of the Tissue-Tek® Xpress® x120 instrument, refer to Section 8, Troubleshooting, to determine the most likely cause of the malfunction and to obtain recommended corrective actions. (Avoid problems by carefully following the proper operation and maintenance procedures described in this manual). If the problem cannot be solved and an instrument failure is apparent, the Customer Support Department is available to assist.

Before calling for instrument service, please have **model number, installation date, and warranty period** ready for our Customer Support Representative. For convenience and reference, record this information in the blanks below.

Model Number _____

Serial Number _____

Installation Date _____

Warranty Period _____

Where to Call for Service

If located within the United States, contact the Customer Support Department of Sakura Finetek U.S.A., Inc. by calling toll free:

1-800-725-8723

In countries other than the United States, contact the nearest authorized Sakura instrument distributor or representative for service information and assistance.

Consumable Materials

Product Number	Description
4295	Neutra-Pads (100/pk)
7115	Pre-Processing Solution (4 x 3.8L)
7117	Pre-Processing Fixative (4 x 3.8L)
7120	Molecular Fixative
7730	Reagent Set (set of 4)

Replacement Accessory Items

Product Number	Description
1550	Paraffin Scraper
4785	Trimming Knife Blades, 130mm (50/pk)
4786	Trimming Knife Handle
4791	Scalpel Handle
4792	Scalpel Blades, #61 (20/pk)
4793	Scalpel Blades, #62 (20/pk)
4800	Grossing Board Kit
4801	Grossing Board, Large
4802	Grossing Wells
4803	Grossing Fork (1.5mm)
4804	Grossing Fork (2.0mm)
4807	Grossing Fork (2.5mm)
7103	Basket with Handle, 40-Cassette
7106	Tray Liners (100/pk)
7107	Fume Filter (2/pk)
7108	Loading Station Container with Lid
7109	Basket Transportation Tray

Service Accessory Items

Product Number	Description
O71-169-01	Drip Tray
O71-355-00	Reagent Bottle Tray
D9-01-0102	Retort Cleaning Pipette
O71-692-00	Retort Mesh Filter Removal Tool
O71-697-01	Sight Tube Cleaning Brush
O71-491-00	Spill Tray
F60-153-00	Unloading Station Container
0004389-01	Operating Manual

Optional Accessory Items

Product Number	Description
7139	Uninterruptible Power Supply (UPS)
7145	Uninterruptible Power Supply, Extended Use (UPS)
AI8-IF-001	Service Manual

Where to Order:

In the United States, the above Replacement Accessory Items may be ordered directly from:

Order Management
Sakura Finetek U.S.A., Inc.
1750 W. 214th Street
Torrance, CA 90501
1-800-725-8723

Or contact the nearest authorized Tissue-Tek distributor or representative.

Outside of the United States, contact the nearest authorized Sakura instrument distributor.

TISSUE-TEK® XPRESS® X120 RAPID TISSUE PROCESSOR APPLICATIONS MANUAL

Overview

Tissue Processing on the Tissue-Tek® Xpress® x120 Rapid Tissue Processor

Tissue samples that will be processed on the Tissue-Tek® Xpress® x120 Rapid Tissue Processor require proper preparation and handling to ensure acceptable results. Specimen preparation begins shortly after the specimen is excised from the patient. The tissue is sent to the pathology laboratory, either fresh or in an appropriate fixative, such as Molecular Fixative or Formalin. The Pathologist or Pathology Assistant grosses the tissue sample and places the desired selection in a cassette for processing. At the completion of the processing program, the tissue is embedded in paraffin, preparing it for microtomy and subsequent staining and coverslipping.

This Appendix provides guidelines and techniques related to the following critical areas:

- Preparation of appropriate-sized tissue samples for Tissue-Tek Xpress x120 processing, and selection of the appropriate immersion program
- Use of Molecular Fixative and its effect on routine and special staining and procedures
- Use of Pre-Processing Reagents
- Embedding practices for Tissue-Tek Xpress x120-processed tissue
- Microtomy practices for Tissue-Tek Xpress x120-processed tissue blocks
- Staining of Tissue-Tek Xpress x120-processed tissue slides
- Microscopic evaluation of Tissue-Tek Xpress x120-processed tissue slides
- Reprocessing of Tissue-Tek Xpress x120-processed tissue
- Reagent replacement and frequency
- Do's and don'ts
- Disposal of Tissue-Tek Xpress x120 processing reagents

Preparation for Processing

The Tissue-Tek Xpress x120 can be configured for operation using one of two immersion time settings for tissue processing based on the thickness of the grossed tissues: either 2 mm maximum or 3 mm maximum.

Use of Tissue-Tek Xpress x120 Pre-Processing Solution or Pre-Processing Fixative

Pre-Processing Solution is used to firm and pre-condition the tissue specimens prior to Tissue-Tek Xpress x120 processing. Some types of tissue (such as breast, skin, etc.) grossed at 2 mm may require a longer immersion time in the Pre-Processing Solution.

Pre-Processing Fixative is used for long term storage and transport or to precondition tissue specimens prior to Tissue-Tek Xpress x120 processing. Pre-Processing Fixative is more readily compatible with poorly formalin-fixed tissue specimens. Pre-Processing Fixative is not compatible with all molecular pathology techniques, it is however compatible with IHC techniques.

Use a container capable of holding at least 500 mL of reagent. Change the Pre-Processing reagents every 3 hours. If excessive debris or cloudiness occurs, change more frequently.

Tissue Preparation for the 2 mm (15min/station) Standard Immersion Program

Tissue specimens of up to 2 mm in thickness are processed using the 2 mm (15 min/station) Standard immersion program. The total processing time, including robotic transfer of the basket between stations, is approximately 67 minutes. The 2 mm Standard program is appropriate for use only with tissue samples that are not larger than 2 mm in thickness. The length and width of the tissue should allow for space between the tissue and cassette walls.

Fixed tissues that cannot be initially trimmed to 2 mm thickness must be grossed to a thickness no greater than 3 mm, placed in a cassette, and immersed in a container filled with the Pre-Processing Solution for a minimum of 15

minutes. Fatty tissue, lymphoreticular tissue and bloody tissue may require additional immersion time (30 – 60 minutes) in the Pre-Processing Solution prior to performing the final trimming of the specimen. Following the required immersion time in the Pre-Processing Solution, the cassettes are then removed from the solution, opened, and the tissue then trimmed to the final 2 mm in thickness. The tissue is then placed back in the cassette, and is immersed in 10% NBF for 1 hour.

CAUTION: Tissue Specimens are to be held in 10% NBF until they are ready to start the preprocessing step.

NOTE: It is recommended that tissue specimens are immersed in Pre-Processing Solution for a minimum of 45 minutes or in Pre-Processing Fixative for a minimum of 30 minutes prior to being processed by the Tissue-Tek Xpress x120.

Tissue Preparation for the 3 mm (30min/station) Extended Immersion Program

The 3 mm Extended immersion program is used for processing of tissue specimens of up to 3 mm in thickness. The total processing time, including robotic transfer of the basket between stations, is approximately 127 minutes. The length and width of the tissue should allow for space between the tissue and cassette walls.

The tissue is trimmed to 3 mm maximum in thickness, placed in cassettes, and is immersed in 10% NBF for 3 hours.

NOTE: All tissue must be immersed in Pre-Processing Solution for a minimum of 15 minutes prior to being processed by the Tissue-Tek Xpress x120.

CAUTION: Tissue specimens are to be held in 10% NBF until they are ready to start the preprocessing step.

Processing Tissue Specimens

CAUTION: The Loading Station retort should be filled with Preprocessing Solution to accelerate the dehydration process.

Additional processing baskets (with tissue samples) can be loaded into the Loading Station when the **Loading Indicator** lights steady "ON" and the Loading Station **Access Permitted Icon** displays on the Process Monitor screen.

At the completion of the processing program, the basket containing the processed cassettes may be removed immediately. The processed cassettes are then transported to the embedding center. Each processing basket must be thoroughly cleaned before reuse (see "*Cleaning of Processing Baskets"* on page 7.1 for details).

Use of Tissue-Tek Molecular Fixative

Use of Molecular Fixative is *mandatory* for tissue specimens that require certain studies, such as DNA, RNA, and protein. It is recommended that specimens for RNA studies be placed into Molecular Fixative *immediately* upon excision from the patient. The use of Molecular Fixative**:**

- Stops any further degradation of RNA that normally occurs
- Does not cause cross linking with proteins
- Preserves histomorphology
- Protects high quality DNA, RNA, and proteins at ambient temperature
- Can be used to transport the specimen to the laboratory
- Can be used for tissue specimen storage

NOTE: Pre-Processing Fixative is not as compatible with all Molecular Pathology techniques (it is however compatible with IHC techniques, the same as Pre-Processing Solution).

Hematoxylin and Eosin (H&E) and Special Stains:

- Tinctorial staining is slightly more intense with Molecular Fixative than with Formalin-fixed tissues.
- Tissue may stain more eosinophilic when using Tissue-Tek Molecular Fixative, which may require decreasing the staining time in Eosin (approximately 40%).
- Molecular-fixed tissue and Formalin-fixed tissue yields similar staining results for special stains.

Immunohistochemistry:

- Some types of Molecular-fixed tissue may not require Antigen Retrieval.
- Molecular Fixative does not cause cross-linking, which occurs with Formalin.
- Increased intensity of IHC staining can be anticipated with some types of antibodies when tissue is placed directly into Molecular Fixative.
- Tissue for Her-2 must be fixed in Formalin to comply with FDA approved protocols. Refer to the manufacturer's operating protocol for specific instructions on how to fix the specimens.

RNA:

- Molecular fixative preserves RNA from degradation, if tissue is placed directly into the solution immediately upon surgical excision.
- Finer nuclear detail can be expected with the use of Molecular Fixative.
- Molecular fixed tissues yield amplification curves similar to fresh specimens.

Do not process tissue for RNA studies in Formalin or expose tissue for RNA studies to any items that have come in contact with Formalin. RNase-free conditions of paraffin embedded tissue will yield intact RNA comparable to fresh tissue. If the Tissue-Tek Xpress x120 has been used for processing Formalin-fixed tissue, the Tissue-Tek Xpress x120 must be cleaned prior to use for RNA study (see *"Cleaning Instructions for RNA Tissue Processing"* on page A.3 for details).

DNA:

- Tissue treated with Molecular Fixative yields similar results to enzyme digested DNA extracted from fresh tissue (frozen).
- Crossing Threshold for Molecular-fixed tissue is comparable to DNA extracted from fresh tissue.
- Crossing Threshold measured after 24 hours yields results similar to DNA from fresh tissue.

PROTEIN:

- Molecular fixed tissue yields gel electrophoresis results similar to those seen from protein extracts from fresh tissue.
- Western Blot testing shows stronger distinct bands when compared with Formalin-fixed material.
- Time interval between surgical excision and tissue fixation in Molecular Fixative (usually 30 minutes), does not affect the quality of the extracted proteins.

Cleaning Instructions for RNA Tissue Processing

Description:

Processing of RNA tissue requires an RNase-free environment. If the Tissue-Tek Xpress x120 has been used for processing Formalin-fixed tissue, the Tissue-Tek Xpress x120 must be cleaned prior to use for RNA study. Failure to properly prepare the Tissue-Tek Xpress x120 prior to processing tissue specimens for RNA studies may cause the degradation of RNA.

Materials and Equipment Required:

- 0.1% diethylpyrocarbonate
- Sterile water
- Autoclave
- RNaseZap® Wipes (may be purchased from Ambion, Inc, TX, USA www.ambion.com)*
- Gloves
- Face mask

* RnaseZap® is a registered trademark of Ambionm Inc.

Procedure:

WARNING: WEAR PROTECTIVE PERSONAL EQUIPMENT WHEN CLEANING THE TISSUE-TEK XPRESS X120 PRIOR TO PROCESSING TISSUES FOR RNA STUDIES. USE OF A FUME HOOD IS RECOMMENDED FOR PREPARATION OF THE DECONTAMINATION SOLUTION AND THE CLEANING OF SMALL INSTRUMENTS.

1. Rinse all baskets and small instruments that come in contact with the tissue using 0.1% diethylpyrocarbonate dissolved in sterile water.
2. Leave items in the 0.1% diethylpyrocarbonate solution overnight.
3. Autoclave the items in the solution for 1 hour.
4. Wipe all parts of the instrument that come in contact with tissue using the RNAZap wipes.
5. Use gloves and a facemask when operating the instrument.

Embedding of Tissue-Tek Xpress x120 Processed Tissue

Tissue cassettes are placed into the holding chamber of the embedding center and embedded following laboratory protocol.

Please note that an acetic acid (vinegar) odor may sometimes be noted upon removal of the lid from the processed tissue cassette. This odor is present when tissue is cut too thick for proper processing or the on-board reagens are past their useful life.

NOTE: Improperly processed Tissue-Tek Xpress x120 and traditionally processed tissue may sometimes appear as white areas on the embedded paraffin blocks, and/or may show areas that appear sunken the day after microtomy.

Microtomy

Paraffin embedded Tissue-Tek Xpress x120 tissue can be sectioned on a Microtome. The tissue blocks usually do not require soaking. The blocks can be faced and allowed to cool face up on ice water for not more than 5 minutes prior to sectioning.

CAUTION: Avoid soaking of Tissue-Tek Xpress x120-processed paraffin blocks. Soaking may result in a water artifact on the stained slide or in the tissue section(s) "disintegrating" when floated on the surface of the water.

If the paraffin ribbon fails to stretch out properly, the waterbath temperature may need to be increased slightly to approximately 45°- 46°C.

Compression of the ribbon may be eliminated by cooling the block by spraying the paraffin block with a freezing spray just prior to ribboning or by adjusting the knife angle.

Staining

Tissue fixed in Formalin prior to Tissue-Tek Xpress x120 processing will stain similar to traditionally processed tissue.

Molecular-fixed tissue will stain slightly more intensely than Formalin-fixed tissue. The current laboratory staining protocols may require an adjustment to the staining time when using Hematoxylin and Eosin stains with tissue fixed in Molecular Fixative (see "Use of Tissue-Tek Molecular Fixative"on page A.2 for details).

Special stains performed on Tissue-Tek Xpress x120 processed tissue will appear similar to special stains performed on traditionally processed tissue regardless of the fixative used.

Microscopic Evaluation

Moderate swelling of red blood cells may be noted.

Artifact - A retraction artifact that may be observed between epithelial cells and the underlying connective tissue when tissue is placed directly into Molecular Fixative or if the tissue was insufficiently fixed. The artifact may appear as a halo that surrounds the tissue cell(s). The artifact may also be noted on tissues that have been processed using Formalin fixation. This artifact may appear more prominent on Molecular-fixed tissue.

Reprocessing of Tissue

Tissue-Tek Xpress x120-processed tissue may be reprocessed, if necessary, without adverse affects on the tissue. Tissue that has been trimmed too thick for proper processing can be reprocessed using the following reprocessing procedure.

Procedure:

1. Place tissue cassette in a 60°C oven or in the Tissue Embedding Center and allow the block to melt down.
2. Remove tissue and place in a cassette identified with the proper accession number. It is important to note the thickness of the residual tissue.
3. Place labeled cassette in solvent (xylene or xylene substitute) for 30 minutes (two changes).
4. Place cassette with tissue in a beaker containing absolute alcohol for 30 minutes (two changes).
5. Remove cassettes from the alcohol.
6. Retrim tissue to the correct thickness, as necessary.
7. Place tissue in processing basket, then place the basket in Pre-Processing container filled with Pre-Processing Solution for 15 minutes.
8. Place processing basket in the Loading Station, with the preprocessing step enabled and set for 30 minutes.
9. Depending on the thickness of the residual tissue, select the appropriate immersion program (2mm or 3mm).
10. Enter number of cassettes loaded, as required.
11. At completion of the processing program, remove and embed tissue as usual.

Tissue-Tek Xpress x120 Reagent Replacement Schedule

It is recommended that Tissue-Tek Xpress x120 reagents be replaced after processing up to approximately 1,500 cassettes, or up to every 3 days, whichever occurs first. Reagent integrity depends on the type of tissues processed. Reagents cannot be topped off or rotated. All reagents must be replaced at the same time to ensure proper processing of tissue samples.

NOTE: The user may want to change the reagent set more frequently depending on the tissue type or shifts of operation.

Pre-processing solution in the Loading Station should be changed every 3 hours.

Signs of reagent over-use are:

- The odor of vinegar is noted when opening the Paraffin Ovens lids.
- Paraffin feels slippery or oily when the tissue is embedded.
- White areas are noted on the majority of the uncut paraffin blocks.
- Tissue “disintegrates” when ribbon is floated on the waterbath.

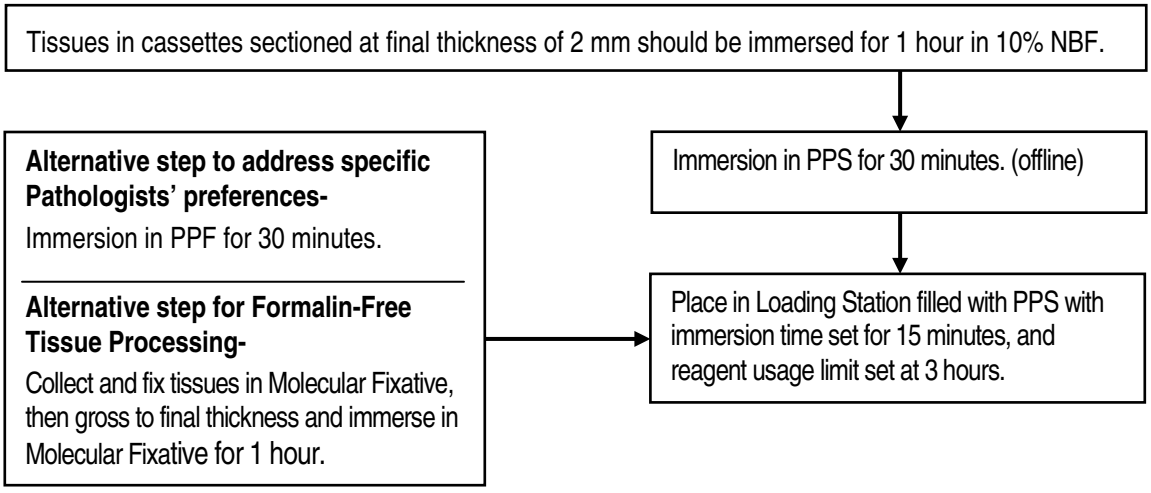
Do's and Don'ts

- DO leave breast or fatty tissue in Pre-Processing Solution 30 to 60 minutes to firm tissue prior to trimming.
- DO NOT use blue sponges for processing of tissue.
- DO use embedding bags, lens paper, etc.
- DO NOT process tissue for RNA studies with Formalin-fixed tissue or solutions that have been used for Formalin-fixed tissue.
- DO run RNA tissue after the processor is cleaned and solutions are all changed.
- DO NOT process tissue with O.C.T. compound (used for Cryotomy) residue in the Tissue-Tek Xpress x120.
- DO remove all O.C.T. compound (used for Cryotomy) from specimens by rinsing with water prior to placing in the Tissue-Tek Xpress x120.
- DO NOT process tissue thicker than 2 mm in thickness on the Standard program.
- DO process tissue that is more than 3 mm in thickness using the Extended program.
- DO NOT allow the faced tissue blocks to soak too long in water.
- DO face the block and allow the block to soak/or cool only for a short period of time.
- DO NOT use metal cassette lids.
- DO use plastic lids and remove metal staples and sutures from tissue prior to placement in the cassette.
- DO NOT top off reagents or rotate reagents.
- DO change the reagents and solution after 1,500 cassettes or every 3 days, whichever occurs first.
- DO seal blocks after Microtomy with a thin layer of paraffin if block will later be used for molecular studies

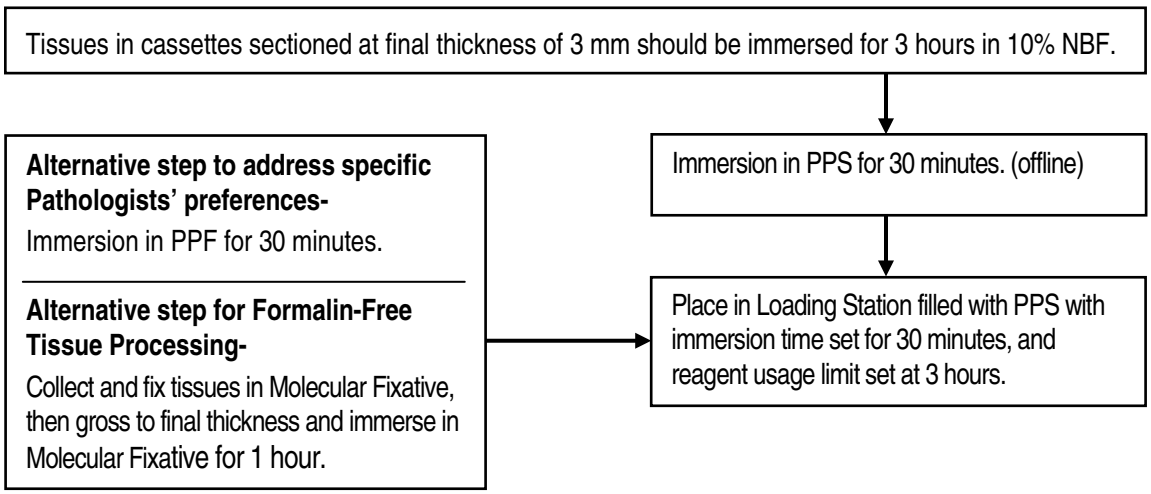
Disposal of Tissue-Tek Xpress x120 Processing Solutions

Refer to MSDS sheets. Disposal should be in accordance with Local, State and Federal regulations.

Tissue-Tek Xpress x120 Processing Flow Chart for Standard Program



Tissue-Tek Xpress x120 Processing Flow Chart for Extended Program



NOTES:

- As needed, tissue difficult to section, can be immersed in PPS for 15 minutes to firm up.
- Some immersion times can be significantly reduced for small biopsies. The above baseline procedure creates optimal conditions for the Xpress technology.
- Breast, placenta, lymph nodes, and other fatty tissues may require longer immersion times in PPS (60 minutes).
- PPS to be changed every 3 hours.
- For Breast tissues requiring IHC testing, time in 10% NDB must be a minimum of 6 hours to satisfy the ASCO guidelines.