STAT*IM* 2000/5000 G4

CASSETTE AUTOCLAVE™

- Operator's Manual
- Manuel de l'utilisateur
- Manuale per l'operatore
- Manual del Operador
- Manual do Operado - USB
- 操作手册 - USB
- Інструкція користувача - USB
- Руководство пользователя
- Uživatelská příručka - USB
- Betjeningsmanual - USB
- Kezelői kézikönyv - USB
- 사용자 설명서 - USB
- Gebruikershandleiding - USB
- Podręcznik obsługi - USB

EN13060 Fully Compliant

SciCan | Your Infection Control Specialist™

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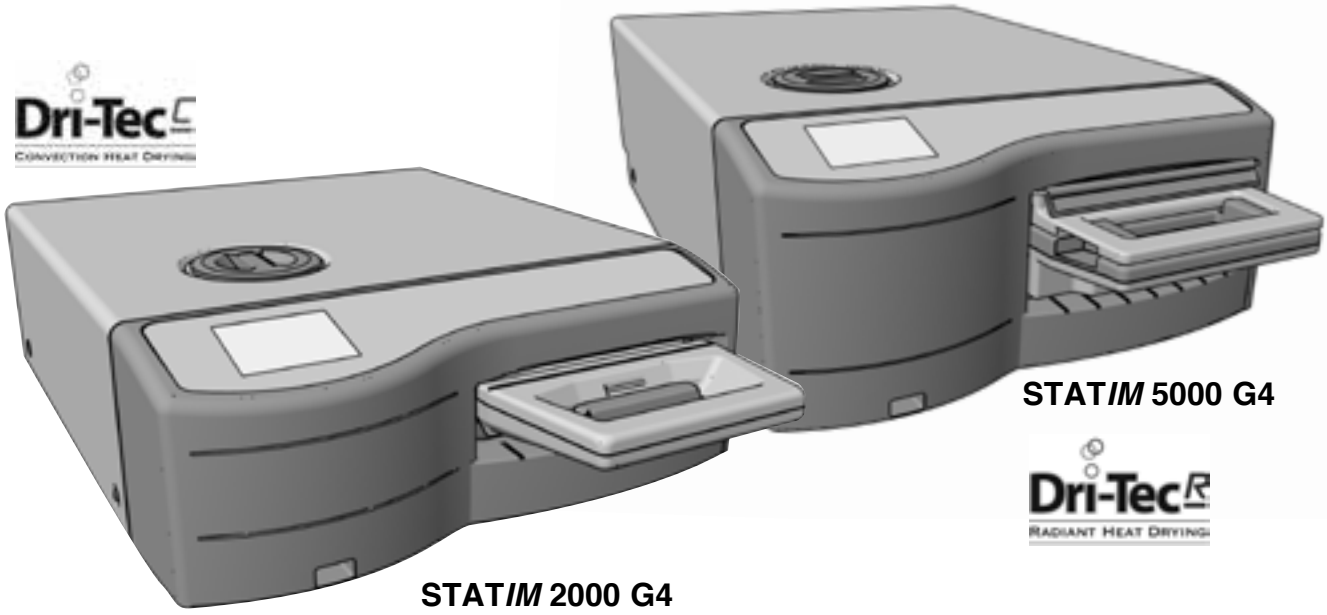
1 Introduction



Congratulations on selecting the STAT*IM*® Cassette Autoclave. The STAT*IM* is a compact, countertop unit that is suitable for steam sterilization. This STAT*IM* G4 Cassette Autoclave is fully compliant with EN13060.

The details of installing, operating and maintaining your STAT*IM* are all contained within this operator's manual. Please read these instructions before operating this unit and keep them for future reference. Operational, maintenance and replacement instructions should be followed. Contents of this manual are subject to change without notice to reflect changes and improvements to the STAT*IM* product.

The STAT*IM* is suitable for the sterilization of dental and medical instruments that are validated to be sterilised by steam. Refer to the Test Protocol section Type Testing for reference examples of instruments that have been validated in the STAT*IM* via micro biological testing. The STAT*IM* has not been designed to sterilize liquids, cloth loads, bio-medical waste or materials not compatible with steam sterilization. The processing of such loads may result in incomplete sterilization and / or damage to the autoclave.
For more information about instrument suitability for steam sterilization, consult the instrument manufacturers' reprocessing instructions.

2 Important Information

2.1 Disclaimers

Use only steam-process distilled water in your STAT*IM.* Deionized, demineralized, or specially filtered water should not be used. Never use tap water.

Do not permit any person other than certified personnel to supply parts, service or maintain your STAT*IM.* SciCan shall not be liable for incidental, special or consequential damages caused by any maintenance or services performed on the STAT*IM* by a third party, or for the use of equipment or parts manufactured by a third party, including lost profits, any commercial loss, economic loss, or loss arising from personal injury.

Never remove the cover of the unit and never insert objects through holes or openings in the cabinetry. Doing so may damage the unit and / or pose a hazard to the operator.

IMPORTANT: Follow local guidelines governing verification of the sterilization procedure.

Drying Performance

The STAT*IM* 2000 G4 and 5000 G4 have been designed to provide a complete sterilization solution for your unwrapped and wrapped instrument needs: rapid sterilization balanced with rapid drying, by using the SciCan Dri-Tec Drying Technology.

The STAT*IM* 2000 G4 uses convection heat to dry instruments by utilizing the remaining heat in the system after the sterilization phase. Heat is captured and released in the cassette to rapidly dry a properly loaded STAT*IM* cassette.

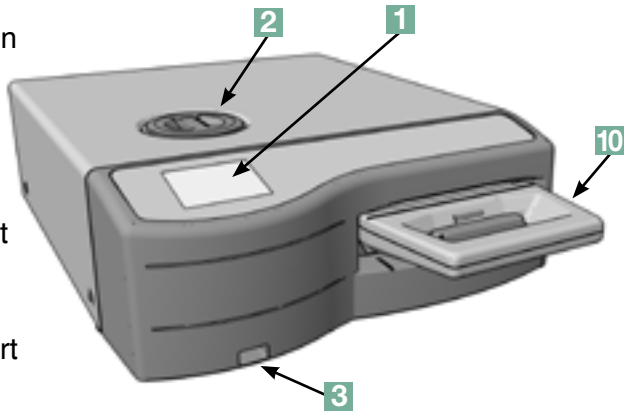
The STAT*IM* 5000 G4 uses heat generated by the sterilization phase which is absorbed by the drying plates. The heat is transferred from drying plates directly to the load resulting in accelerated, rapid drying of a properly loaded STAT*IM* cassette.

Please refer to this operator's manual for instructions on the proper arrangement of instruments in the cassette and the use of drying plates (STAT*IM* 5000 G4). By carefully following these directions on how to properly load the cassette chamber, rapid drying of the load will be achieved.

2 Important Information 2000 G4

2.2 STAT*IM* 2000 G4 — Unit Overview

1. LCD touchscreen
2. reservoir cap/ water filter
3. USB port
4. power switch
5. power cable port
6. leveler feet
7. Ethernet port
8. exhaust tube port
9. compressor
10. cassette
11. biological filter
12. RS232 port



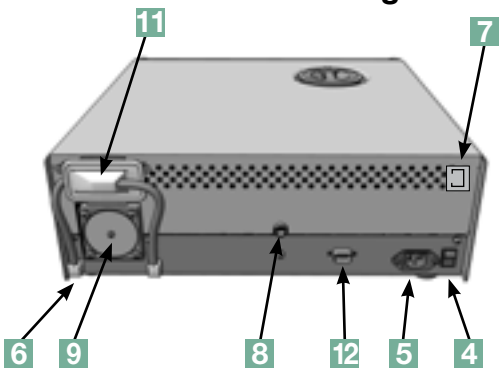


Figure 1

The following symbols appear in the margins of this book.

A potential hazard to the operator.

A situation which may lead to a mechanical failure.

Important information

The following symbols appear on the unit:

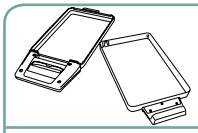
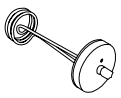
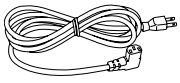
Caution: Hot Surface and/or Hot Steam

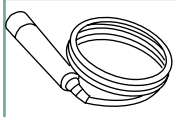
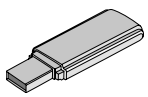
Caution: Refer to manual for details

Caution: Risk of electrical shock. Disconnect supply before servicing.

Steam distilled water only

When you receive your STAT*IM* 2000 G4, the items listed below will be included.
If any of the items are missing, contact your dealer immediately.

	**Cassette Tray and Lid**
	Instrument Rack
	Waste Bottle
	**Bottle Lid Fitting**
	Tube Mounting Hardware
	**Power Cord**

	Operator's Manual
	Exhaust Tube
	STAT-DRI PLUS
	**P.C.D. + 20 SciCan Sterilization Emulators**
	**USB Memory Stick**

2.3 STAT*IM* 5000 G4 — Unit Overview

1. LCD touchscreen
2. reservoir cap/ water filter
3. USB port
4. power switch
5. power cable port
6. leveler feet
7. exhaust tube port
8. biological filter
9. cassette
10. RS232 port
11. Ethernet port

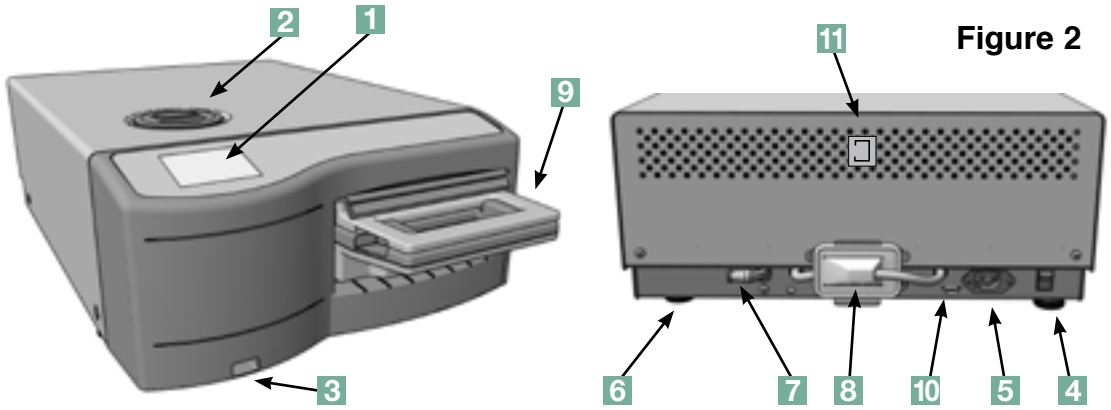


Figure 2

The following symbols appear in the margins of this book.

A potential hazard to the operator.

A situation which may lead to a mechanical failure.

Important information

The following symbols appear on the unit:

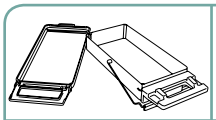
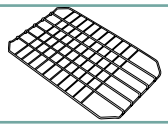
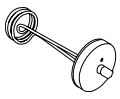
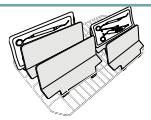
Caution: Hot Surface and/or Hot Steam

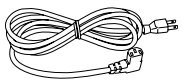
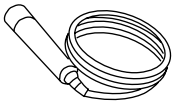
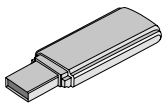
Caution: Refer to manual for details

Caution: Risk of electrical shock. Disconnect supply before servicing.

Steam distilled water only

When you receive your STAT*IM* 5000 G4, the items listed below will be included. If any of the items are missing, contact your dealer immediately.

	**Cassette Tray and Lid**
	**Unwrapped Instrument Rack**
	Waste Bottle
	**Bottle Lid Fitting**
	Tube Mounting Hardware
	**Rack with Drying Plates**

	**Power Cord**
	Operator's Manual
	Exhaust Tube
	STAT-DRI PLUS
	**P.C.D. + 20 SciCan Sterilization Emulators**
	**USB Memory Stick**

2.4 Touchscreen Overview

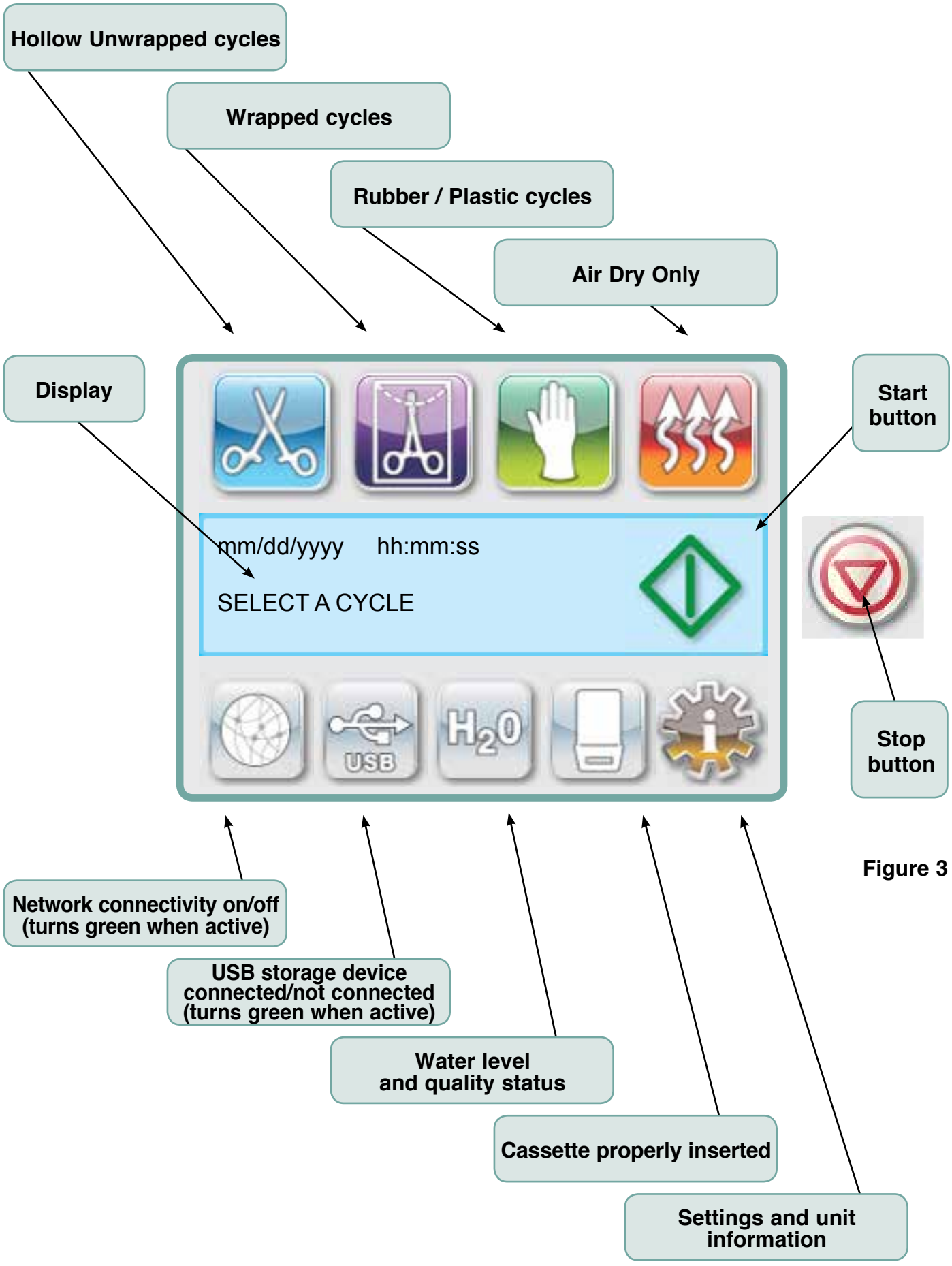
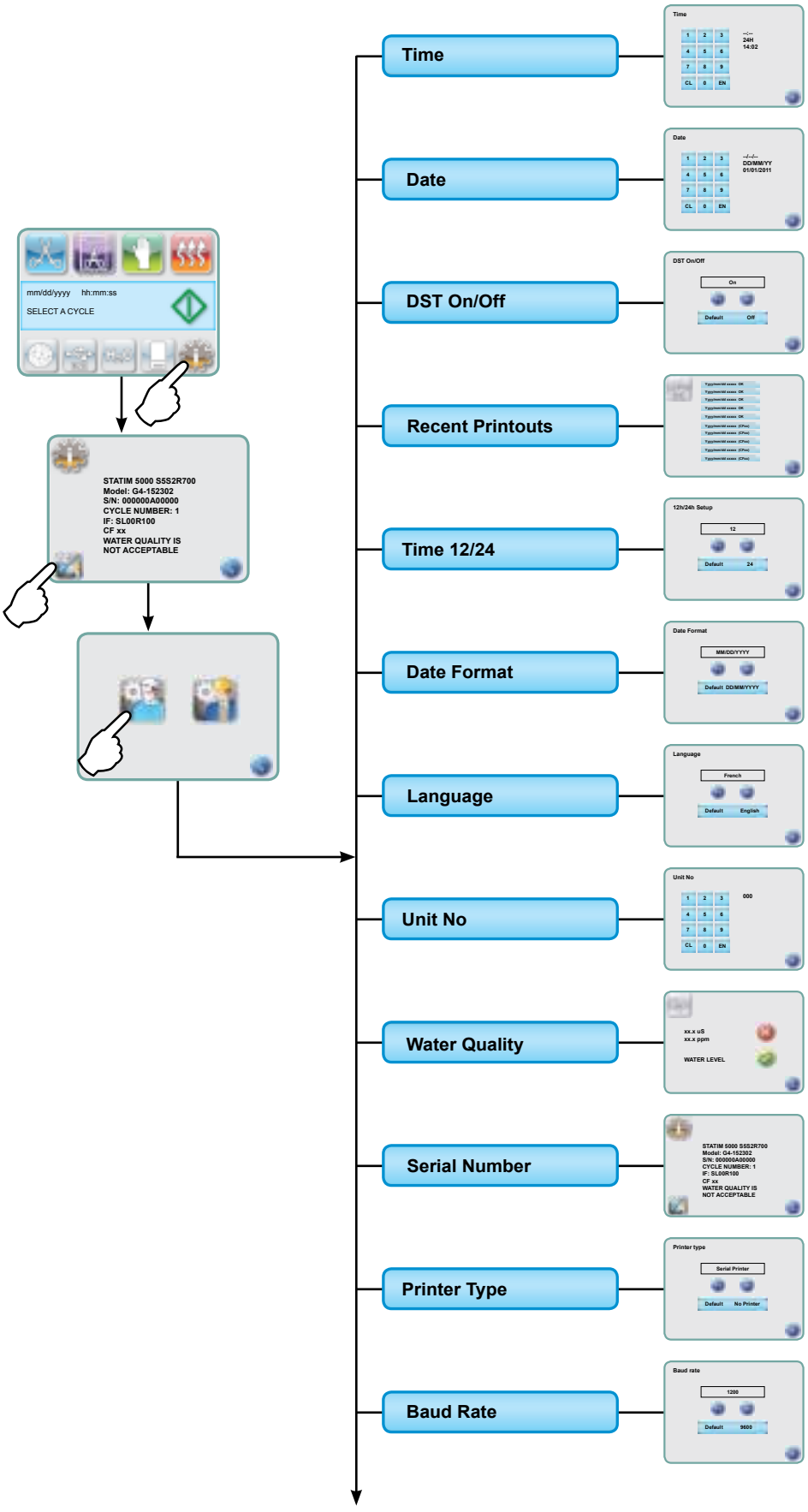
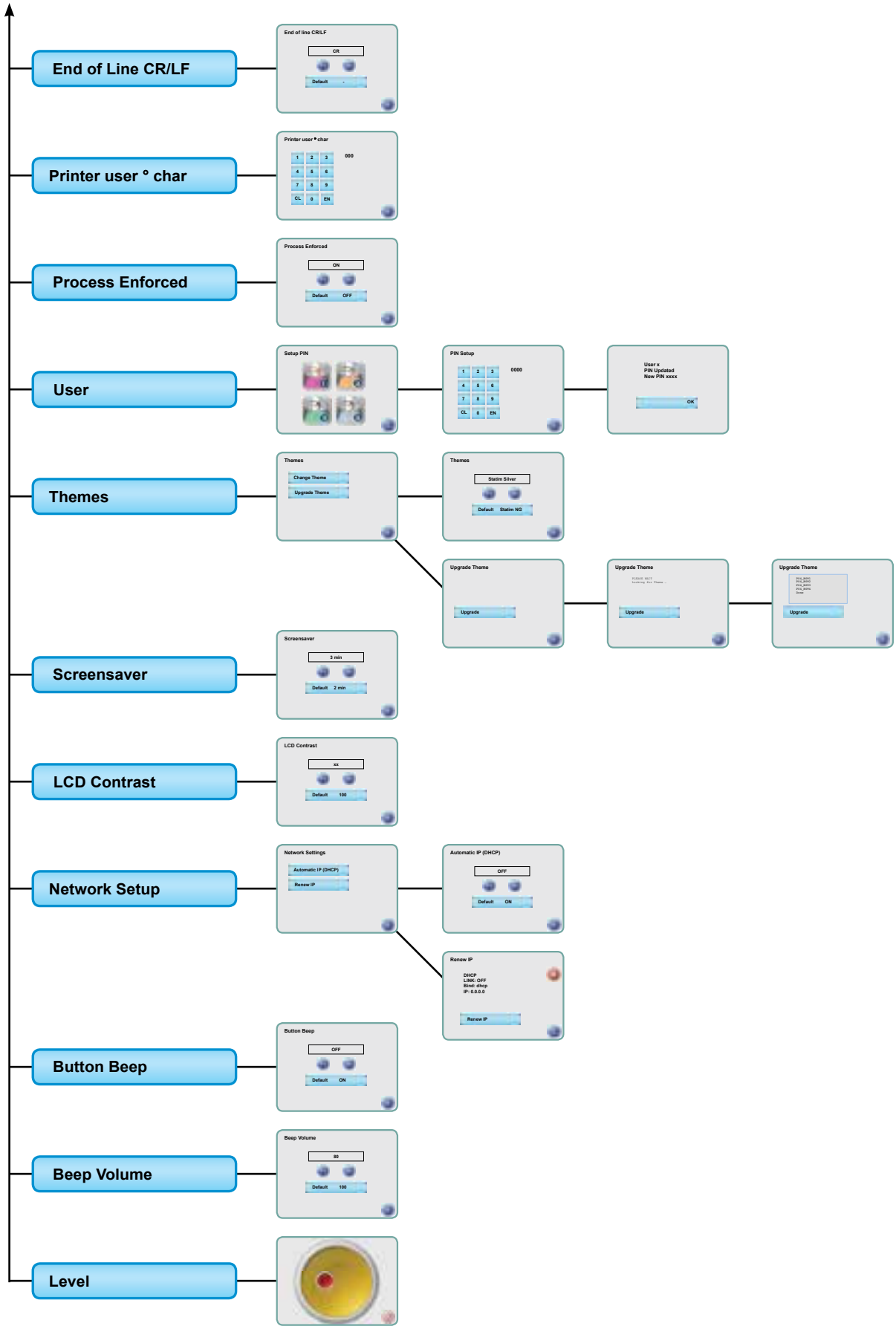


Figure 3

2.5 Set Up Menu Overview



2.5 Set Up Menu Overview con't



3 Setting up your STAT*IM*

3.1 Positioning and Powering your Unit

Positioning your Unit

There are several factors that may affect the performance of your STAT*IM.* Please review these factors, and select a suitable location in which to install the unit.

- **Temperature and Humidity**

Avoid installing your STAT*IM* in direct sunlight or close to a heat source (e.g. vents or radiators). The recommended operating temperatures are 15-25˚C with humidity of 25-70%.

- **Spacing**

The vents and openings on your STAT*IM* should remain uncovered and unobstructed. Leave a minimum of 50 mm between the top, sides and back of the unit and any wall or partition. For more detailed information on clearances, see Specifications.

- **Venting**

Your STAT*IM* should be operated in a clean, dust free environment.

- **Work Surface**

Your STAT*IM* should be placed on a flat, level, water-resistant surface.
Never install and operate the unit on a sloped surface.

- **Electromagnetic Environment**

Your STAT*IM* has been tested and meets applicable standards for electromagnetic emissions. While your unit does not emit any radiation, it may itself be affected by other equipment which does. We recommend that your unit be kept away from potential sources of interference.

- **Electrical Connection**

To power your unit, use properly grounded and fused power sources with the same voltage rating as indicated on the label at the back of your STAT*IM.* Avoid multiple outlet receptacles. If using a surge suppressor power bar, connect only one STAT*IM* to it.

Powering your Unit

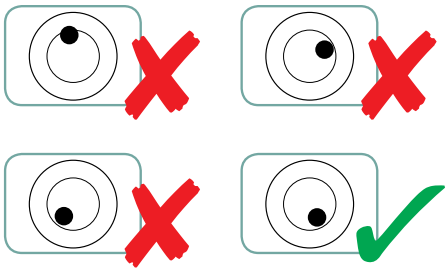
To power your STAT*IM,* connect the power cord to the A.C. inlet receptacle at the back of the unit. Ensure the power switch is in the OFF position and connect the unit to your power source.

3 Setting up your STAT*IM*

3.2 Levelling your Unit

When placing your unit on a counter top, ensure it is stable and that all four feet are securely in contact with the counter surface. This will prevent the unit from moving freely. Next, use the level indicator bubble function in the settings menu to adjust the three leveler feet so that the unit drains properly. To access the level indicator bubble from the main screen, follow these steps:

1.
2. Scroll to **Level** and select.
3. Adjust the leveler feet to move the bubble. Position the bubble in the bottom right quadrant of the target. This will ensure that the unit drains properly. Press STOP to exit and return to the cycle select menu. When the unit is properly leveled, the bubble level will change from red to green.



3 Setting up your STAT*IM*

3.3 Connecting the Waste Bottle

The waste bottle 1 is used to collect the wastewater after it has been converted to steam and then drained from the cassette. To connect the waste bottle to the STAT*IM,* follow these steps (see Figure 4):

1. Insert the exhaust 2 tube into the fitting 3 on the back of the unit and pull gently to confirm a tight fit.
2. Cut the tube to length and slide the waste bottle fitting 4 into place.
3. Place the free end of the tube into the hole in the lid of the waste bottle and hand-tighten the fitting.
   Do not coil the exhaust tube.
4. Unscrew the lid and copper condenser coil 5 assembly from the waste bottle. The lid and coil should come out together.
5. Fill the waste bottle with water to the MIN line and replace the lid and copper condenser assembly.
   Empty the waste bottle often to avoid unpleasant odors and discoloration of the contents. (A low-level disinfectant, prepared according to the manufacturer's instructions, may be added to the waste bottle to remedy this situation). As a minimum, empty the waste bottle each time you refill the reservoir.
6. Place the waste bottle near the unit. Store the bottle below the unit.
   The tube can be routed through a hole, (8 mm in diameter) in the countertop and secured with the provided nylon clamps.

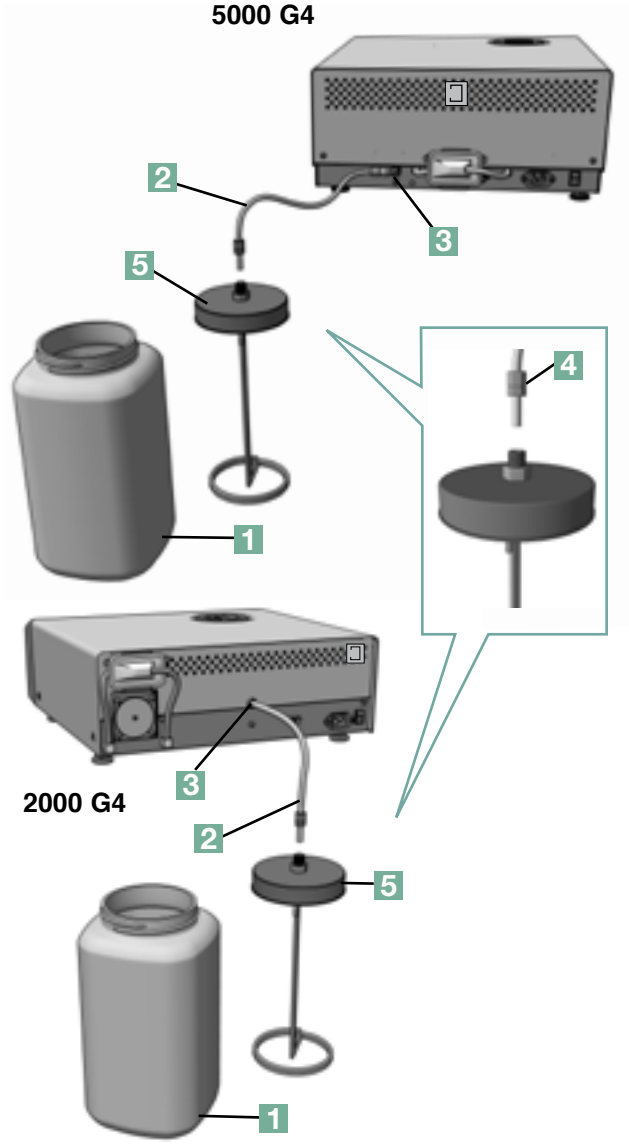


Figure 4

3 Setting up your STAT*IM*

3.4 Filling the Water Reservoir

When filling the reservoir, ensure you only use steam processed distilled water containing less than 5 ppm total dissolved solids (having conductivity of less than 10 μS / cm). The impurities and additives in other water sources will cause an error reading on the LCD. To fill the reservoir, follow these steps (see Figure 5):

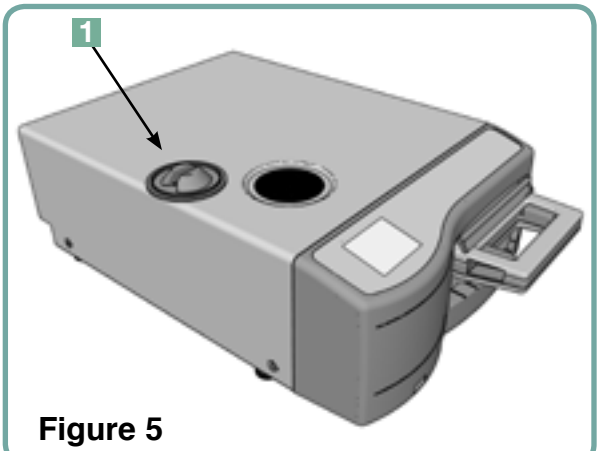


Figure 5

1. Remove the reservoir cap 1 .
2. Pour steam-process distilled water into the reservoir until almost full (a maximum of 4L). Use a funnel to avoid spillage.
3. Replace and secure the cap.

3.5 Priming the Pump

To prime the STAT*IM* pump, follow these steps:

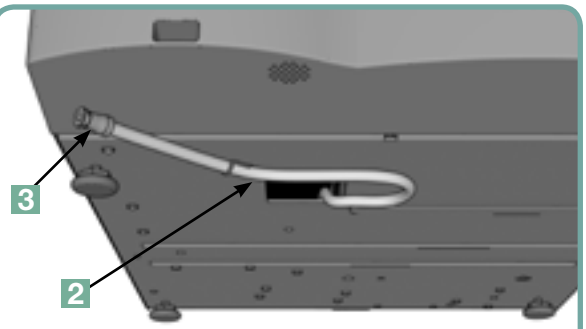


Figure 6

1. Move the unit to the edge of the work surface. The front leveler feet should be approximately 12 mm from the edge.
2. Lift the front left corner of the unit upward and remove the drain tube 2 from the clip located on the underside of the unit.
3. Pull the drain tube outward so the free end can be positioned over a water container.
4. Fill the reservoir with steam-process distilled water.
5. Remove the plug 3 from the end of the drain tube and allow water to drain from the tube into a container for 30 seconds. When the water flows in a steady stream, replace the stopper.
6. Lift the front left corner of the unit upward and reinsert the tube into the clip on the underside of the unit. Push the excess length of tubing back into the space provided.

! Make sure the plug in the drain tube is secure.

3 Setting up your STAT*IM*

3.6 Setting the Time

1.
2. Scroll to Time and select.
3. From the TIME screen, use the keypad to set the time. Press EN to save and to return to the Setup menu.
4. To change your unit to display 12-hour time format (24-hour time format is the default setting), go to the Setup menu and use to scroll to TIME 12/24, select it and toggle to 12. Press to save and return to the Setup menu.
5. To activate daylight savings time (DST), which is recommended if you have connected your unit to a network, go to the Set up menu and use to scroll to DST ON/OFF and select. Use to toggle DST ON or OFF and press to save and return to the Setup menu.

3.7 Setting the Date

1.
2. Scroll to Date and select.
3. From the DATE screen, use the keypad to set the date. Press EN to save and to return to the Setup menu.
4. To change the format in which the date appears, return to the Setup menu and use to scroll to DATE FORMAT. Select it, and follow the prompts to have the date displayed in the desired format. Press to save and return to the Setup menu.

3.8 Setting the Language

The messages displayed by your STAT*IM* can be presented in a number of different languages. To change the current language, follow these steps:

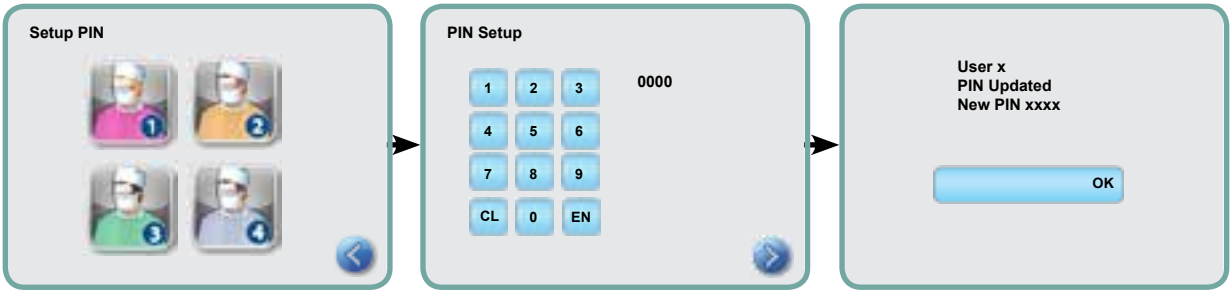
1.
2. Scroll to Language and select.
3. From the LANGUAGE screen, press to scroll through the list of languages. When you have found the desired language, press to save your selection and return to the Setup menu.

3.9 Assigning Unit Identifier Number

1.
2. Scroll to **Unit No** and select.
3. Using the keypad, select a maximum of 3 digits to be used as the unit's identifier number. Press EN to save and to return to the Setup menu.

3.10 Creating a User ID and PIN

1.
2. Scroll to **User** and select.
3. From the SETUP PIN screen, you can assign up to four PINs. Select one of the User icons to assign a PIN.
4. Using the keypad, assign a PIN of up to four digits and press EN to save and to move to the confirmation screen.



5. If all of the information presented in the confirmation screen is correct, press OK to be returned to the PIN USER screen. To make a correction, select the PIN User you want to change and repeat the process described above.

3.11 Setting Up Process Enforced Usage

When process enforced usage is activated, users are required to enter a PIN both at the beginning and at the end of a cycle. For Process Enforced usage to function, User IDs and PINs must first be assigned. To set up User ID and PINs, refer to section 3.10 Creating a User ID and PIN. To activate process enforced usage, follow these steps:

1.
2. Scroll to **Process Enforced** and select.
3. Use to toggle Process Enforced function ON or OFF. Press to save your selection and return to the Setup menu.

NOTE: Any user can stop a cycle and remove the cassette even with Process Enforced usage ON. However, the cycle data will record that an unauthorized user has stopped the cycle and/or removed the cassette.

3 Setting up your STAT*IM*

3.12 Changing the Touchscreen Display Themes

Your STAT*IM* G4 touchscreen themes (i.e., icons and background colours) can be changed to one of the preset options or you can upload additional themes, as they become available from SciCan, using the USB port. To change themes follow these steps:

1.

2. Scroll to **Themes** and select.

3. From here, you can either select **Change Theme** for a menu of preloaded themes or **Upgrade Theme** to access a new theme that can be loaded using the USB port.

4. In the **Change Theme** screen, use to scroll through your available options. As you scroll, each theme will display on the touchscreen. Press to select your theme and return to the Setup menu.

5. To upgrade a theme available from SciCan, download the theme onto your computer's desktop and save the files onto a portable USB storage device. Insert the device into your STATIM's USB port and, from the UPGRADE THEME screen, press **Upgrade** .

5.1 The unit will load the files directly from the USB storage device. Do not remove the USB storage device while files are loading (this could take as long as 10 minutes). When it is complete, the screen will display the 'Done' message. This new theme will now be accessible from your THEMES menu.

5.2 Press to select this theme and return to the Setup screen.

3.13 Adjusting the Screensaver Delay

To change the length of time before your inactive touchscreen activates the screensaver, follow these steps:

1.

2. Scroll to **Screensaver** and select.

3. Use to scroll through your time options. When you have found the amount of time you require, press it. Press to save and return to the Setup menu.

3 Setting up your STAT*IM*

3.14 Adjusting the Screen Contrast

The STAT*IM* G4 touchscreens are calibrated for the lighting condition of most sterilization centres. Should you need to adjust the contrast for your office, follow these steps:

1.
2. Scroll to **LCD Contrast** and select.
3. Use to scroll through your contrast options. When you have found the contrast you require, press it. Press to save and return to the Setup menu.

3.15 Turning the Button Sound ON or OFF

The STAT*IM* G4 is preset to beep when a button is pressed. If you would like to turn the button sound off, follow these steps:

NOTE: Turning OFF the button sound does NOT turn off other alarms and cycle notification beeps.

1.
2. Scroll to **Beep ON/OFF** and select.
3. Use to scroll through your ON or OFF options and select it by pressing it. Press to save and move back to the Setup menu.

3.16 Adjusting the Button Beep Volume

If you would like to adjust the beep volume, follow these steps:

1.
2. Scroll to **Beep Volume** and select.
3. Use to scroll through to scroll through the volume settings. Select the one you want by pressing it. Press to save and move back to the Setup menu.

3 Setting up your STAT*IM*

3.17 Setting up and Using your STAT*IM* G4 Web Portal

The STAT*IM* G4 web portal is a direct connection to the STAT*IM* on your local area network. It is protected by your firewall and not accessible to outside users (unless they have a Remote Access Code. For more information, see Section 7. Retrieving a Remote Access Code). The web portal provides real-time cycle information and archived sterilization records unique to this unit. From here, you can print reports, set up email notification and search cycle histories. To set up your web portal follow the instructions available on the portal's 'HELP' tab.

3.18 Connecting to a Network

The STAT*IM* G4 has a 10/100Base-T Ethernet port located at the back of the unit.
To connect your STAT*IM* to a network using a router, follow these steps:

1. Connect your network cable to the Ethernet port at the back of the unit. If your office uses a router, the router should automatically assign the unit an IP address. You will know the IP address has been assigned when the red X over the Network icon disappears.

NOTE: In some circumstances, where you do not have a router, for example when using Windows Network Sharing, you may have to assign a dedicated or 'static' IP address.
To assign a static IP address, contact your local network administrator.

2. From the main screen, press the Network icon. The Network screen displays information about your STAT*IM*'s connectivity, including its IP address.

3. Type the IP address displayed on the touchscreen into the browser of any web enabled device to access your unit's web portal. You will know that an IP address has been assigned when the red X over the Network icon disappears. When the Network icon is active (for example when sending email) it will turn green.

NOTE: Use QR code if connecting to a mobile device.

NOTE: Connection time will vary depending on your network speed, and making an initial connection can take longer.

3.19 Connecting to a Wireless Network

The STAT*IM* G4 can be configured for wireless use by connecting the Ethernet port to an external wireless bridge / access point. SciCan currently recommends the use of the D-Link® DAP-1522 Xtreme N® Duo Wireless Bridge. Contact your network administrator to learn more about setting up a wireless bridge.

3.20 Reserving an IP Address for your STAT*IM*

When your STAT*IM* is connected to a router on your network, it is assigned a unique IP address. If the connection between your STAT*IM* and the router is lost (e.g. power failure, STAT*IM* or router was restarted), the re-established connection may be a different IP address. This may cause any previously saved bookmarks or other saved links to become invalid.

To set a 'permanent' IP address (also known as establishing a DHCP/IP/Address Reservation), follow these steps:

1. Select the Network icon From the STAT*IM* G4 touchscreen and write down the numbers found for the GATE (Router Local IP). Enter this GATE number in the address bar of your web browser to access your router settings. (NOTE: You will need your network password to change the settings.)

NOTE: Accessing this screen will vary for each router, please consult your router's User Manual or contact your network administrator for more detailed instructions. SciCan currently recommends D-Link DIR-615 Wireless N router.

2. Use the 'DHCP/IP/Address Reservation' function to assign your STAT*IM* a 'permanent' IP address. (**NOTE:** Each manufacturer may use different nomenclature; this setting may be called: HCP Reservation, IP Reservation, or Address Reservation.)
3. You will have to select the appropriate device to apply this setting. Your unit's default name will be: 'statim_###'.

IMPORTANT: Please contact your network administrator for more detailed instructions.

3.21 Preparing Unit for Use

Once the unit is installed and before any instruments are sterilized, run two Hollow Wrapped (3.5 min) Cycles (see section 5.2 - Running a Cycle). Remove the cassette once it has cooled. Clean the top (lid) and bottom (tray) sections using a soft cloth to wipe the inside surfaces and then rinse thoroughly with tap water. Once the cassette is clean and dry, coat the inside surfaces with STAT-DRI PLUS.

4 Using Cassettes and Preparing Instruments

4.1 Using the STAT*IM* 2000 G4 Cassette

When removing the cassette after a cycle, exercise caution as the metal areas will be hot and the cassette may contain hot steam.

Opening the Cassette:

1. Hold the cassette handle with your thumbs facing inward on the cassette latch.
2. Push downward on the cassette latch.
3. Raise the cassette lid upwards and disengage the hinge.
4. Rest the lid on its outer surface.

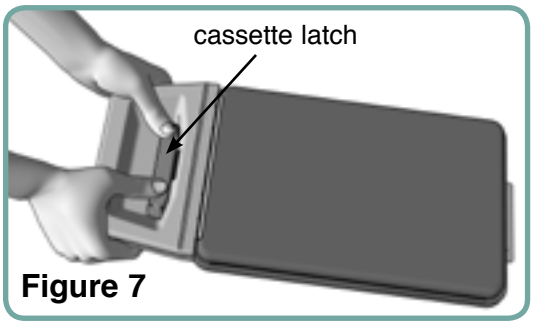


Figure 7

Closing the Cassette:

1. Align the hinge tab on the cassette lid with the hinge slot on the rear of the bottom tray.
2. As you begin to close the lid, the hinge tab and slot will engage.

Inserting the Cassette into the STAT*IM* 2000 G4:

1. Place the end of the cassette into the unit.
2. Gently push inward until you hear a “click” sound and check the LCD icon for change from to .

Never force the cassette into the STAT*IM* as the interior components could be damaged.

NOTE: The main menu screen will display if the cassette is not properly inserted in the unit.

Removing the Cassette:

1. Grasp the handle with two hands and pull away from the unit.
2. Pull the cassette clear of the unit and set down on a firm surface.

Disengaging the Cassette:

When not in use, the cassette should be disengaged. To disengage the cassette, grasp the handle and pull the cassette out until there is a 15 mm to 20 mm ($^{1}/_{2}$ to $^{3}/_{4}$”) gap between the front of the STAT*IM* and the cassette handle.

Using the STAT-DRI PLUS Drying Agent

Treatment of the interior surfaces of the cassette with the STAT-DRI PLUS drying agent, provided with your unit, will enhance the drying process. (Replacement bottles are available from SciCan, order number 2OZPLUS, 8OZPLUST, 32OZPLUS).

4.2 Using the STAT*IM* 5000 G4 Cassette

When removing the cassette after a cycle, exercise caution as the metal areas will be hot and the cassette may contain hot steam.

Opening the Cassette:

1. Push the carry handle 2 into the open position.
2. Put your hands on either side of the cassette handle 1 .
3. Insert your forefingers in the slots and place your thumbs on the thumb pads.
4. Press down with your thumbs and pull up with your forefingers until the lid opens.
5. Raise the cassette lid and disengage from the tray. Rest the lid on its outer surface.

Closing the Cassette:

1. Align the hinge tab on the lid with the hinge slot on the tray.
2. As you begin to close the lid, the hinge tab and slot will engage.
3. Place the carry handle 2 into the closed position.

Inserting the Cassette into the STAT*IM* 5000 G4:

1. Hold the cassette handle in one hand and the carry handle in the other as shown in Figure 8.

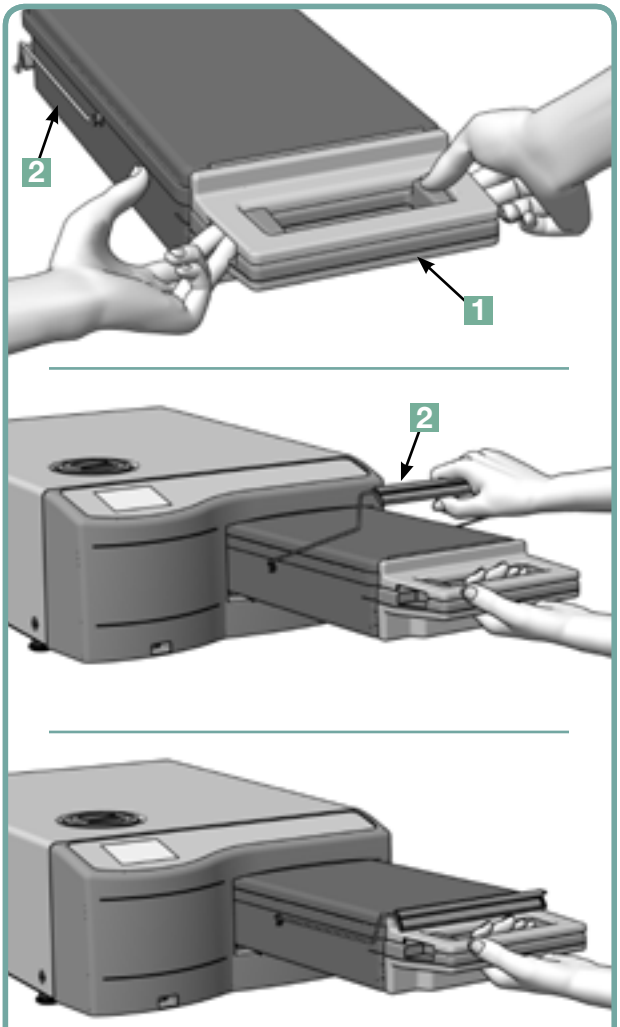


Figure 8

2. Place the end of the cassette into the unit and drop the carry handle into its closed position.
3. Gently push inward until you hear a “click” sound and check the LCD icon for change from to .

Never force the cassette into the STAT*IM* as the interior components could be damaged.

NOTE: The main menu screen will display if the cassette is not properly inserted in the unit.

4 Using Cassettes and Preparing Instruments

Removing the cassette:

1. Grasp the cassette handle with one hand and pull out from the unit.
2. As the cassette emerges from the unit, grasp the carry handle with your free hand and lift it upwards.
3. Pull the cassette clear from the unit and set down on a firm surface.

Disengaging the cassette

When not in use, the cassette should be disengaged. To disengage the cassette, grasp the handle and pull the cassette out until there is a 15 mm to 20 mm ($^{1}/_{2}$ to $^{3}/_{4}$") gap between the front of the STAT*IM* and the cassette handle.

4.3 Using Drying Plates with the STAT*IM* 5000 G4

The STAT*IM* 5000 G4 cassette comes with two racks, one with drying plates affixed and another without. Use the rack with drying plates to enhance the drying process for wrapped instruments.

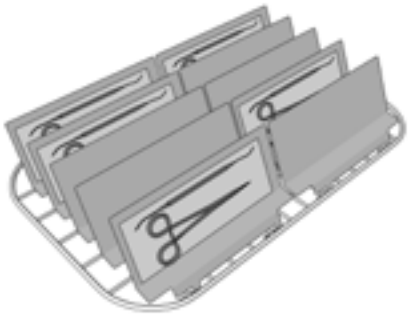


Figure 9

4.4 Preparing and Loading Instruments

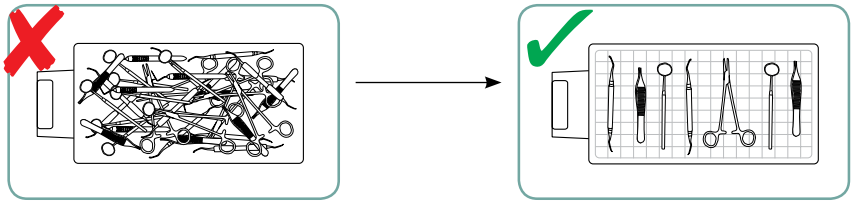
Before loading any instruments into the STAT*IM,* consult the manufacturer's reprocessing instructions.

Clean Instruments

Clean and rinse all instruments before loading them into the cassette. Disinfectant residues and solid debris may inhibit sterilization and damage the instruments, the cassette, and the STAT*IM.* Lubricated instruments must be wiped thoroughly and any excess lubricant should be removed before loading.

Unwrapped Instruments

Arrange unwrapped instruments on the rack spreading them out as evenly as possible.



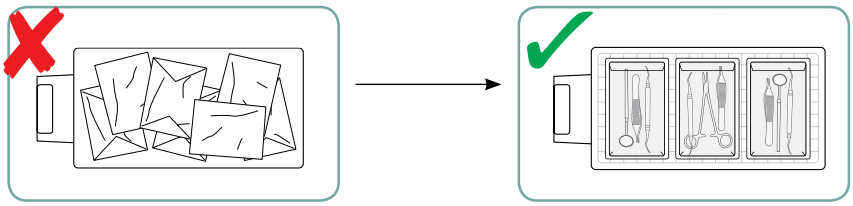
4 Using Cassettes and Preparing Instruments

Wrapped Instruments (single wraps)

Place the instruments into single layer autoclave bags according to the manufacturer's instructions. Orient the instrument rack in the cassette to ensure that wrapped instruments rest approximately 6 mm / 0.25" above the cassette base. Place the wrapped instruments on the rack and arrange them to avoid overlap. Ensure that all wrapped loads are dry before handling and /or storage to maintain sterility.

Care must be taken to ensure that the combined weight of the loaded bags does not exceed 1.5 kg (3.3 lbs) for STAT*IM* 5000 G4 or 1.0 kg (2.2 lbs) for STAT*IM* 2000 G4.

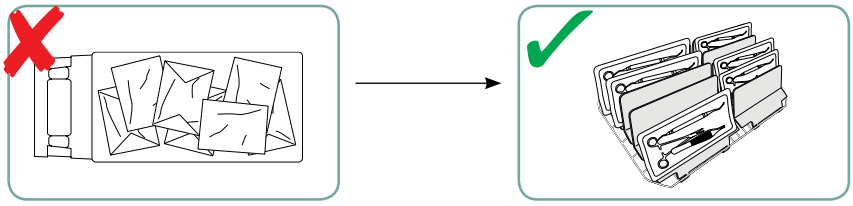
For STAT*IM* 2000 G4:



! The use of cloth wraps in the STAT*IM* is not recommended.

SciCan recommends the use of paper / paper and plastic / paper autoclave bags manufactured in accordance to EN 868. Loosely pack instruments in the bags to allow steam penetration to all instrument surfaces.

For STAT*IM* 5000 G4:



The instrument rack fitted with a maximum of 10 drying plates will hold 10 autoclave bags.

Rubber and Plastic Instruments

The following materials can be sterilized in the STAT*IM:*

Nylon, polycarbonate (Lexan™), polypropylene, PTFE (Teflon™), acetal (Delrin™), polysulfone (Udel™), polyetherimide (Ultem™), silicone rubber, and polyester.

! When loading rubber and plastic instruments in the tray, leave a space between the instruments and the cassette walls. This ensures that steam reaches all surfaces, and will promote drying.

4 Using Cassettes and Preparing Instruments

The following materials **cannot** be sterilized in the STAT*IM:*

Polyethylene, ABS, styrene, cellulosics, PVC, Acrylic (Plexiglas™), PPO (Noryl™), latex, neoprene, and similar materials.

Use of these materials may lead to instrument or equipment damage. If you are unsure of your instrument's material or construction, do not load into your STAT*IM* until you have checked with the instrument manufacturer.

All Instruments

The STAT*IM* is **NOT** intended for sterilizing textiles, liquids or biomedical waste. Instruments will remain sterile after a successful cycle until the cassette is disengaged from the unit. Unwrapped instruments, once exposed to ambient or external conditions, cannot be maintained in a sterile state. If sterile storage is desired, wrap the instruments to be sterilized in autoclave bags, according to the instrument manufacturer's instructions. Then allow the wrapped cycle to run until the air-dry phase is complete.

Best Practice Tip: Allow instruments (wrapped or unwrapped) to dry completely prior to handling. Wrapped or pouched instruments must not touch each other to promote drying and enable effective sterilization.

SciCan recommends users carefully choose the most appropriate sterilization cycle according to the recommendations of their leading infection control authorities and local regulatory guidelines / recommendations.

Note for Ophthalmology Use

In the field of ophthalmology, proper wrapping or pouching of surgical instruments will reduce the exposure of instruments to any process residues during the sterilization cycle. Due to the highly sensitive nature of some types of surgery (particularly in ophthalmology), SciCan recommends that all instruments be routinely packaged or wrapped and processed through the wrapped cycle of the sterilizer. This practice is the suggested approach for the majority of sterile surgical procedures and is referenced in most leading infection control publications and guidelines.

4.5 Using Biological and Chemical Indicators

Chemical process indicators suitable for steam sterilizers should be included in or on each package or load being sterilized. In addition, the weekly use of biological indicators, which allow you to ascertain whether the instruments have been exposed to sterilization conditions, is recommended.

4 Using Cassettes and Preparing Instruments

4.6 Instrument Weight Guide

Instrument	Typical Instrument Weight
Scissors	30 g / 0.96 oz
Dental scalers	20 g / 0.64 oz
Forceps	15 g / 0.48 oz
Dental handpiece	40 to 60 g / 1.29 to 1.92 oz
Wrapped instrument rack	260 g / 8.35 oz
Unwrapped instrument rack	225 g / 7.23 oz
Suction cannula	10 g / 0.32 oz
Plastic mouth mirror	8 g / 0.25 oz
Impression tray	15 to 45 g / 0.48 to 1.45 oz
Plastic x-ray positioning ring	20 g / 0.64 oz

NOTE: The above weights are to be used as reference only.
For exact weights of your instruments, consult the manufacturer's specifications.

5 Using your STAT*IM*

Before using your STAT*IM* for the first time, make sure the reservoir is full and the pump is properly primed. Refer to sections ***3.4 Filling the Reservoir and 3.5 Priming the Pump*** for detailed instructions.

5.1 Selecting a Cycle

The STAT*IM* 2000 G4 and 5000 G4 have seven sterilization cycles, each designed to sterilize using the parameters specified. Each cycle can be selected by pressing the UNWRAPPED, WRAPPED or RUBBER / PLASTIC cycle buttons.

The types of instruments, sterilization requirements and a graph depicting each cycle characteristics are described over the following pages. Load size requirements are listed in the 'Test Protocol' section.

5.1.1 Unwrapped Cycles

The STAT*IM* 2000 G4 and 5000 G4 feature two 134˚C type S and one 134˚C type N UNWRAPPED sterilization cycles. At the end of the cycle's sterilization phase, air drying will commence for one hour. The type S cycles are used to sterilize solid and hollow metal instruments such as dental handpieces.

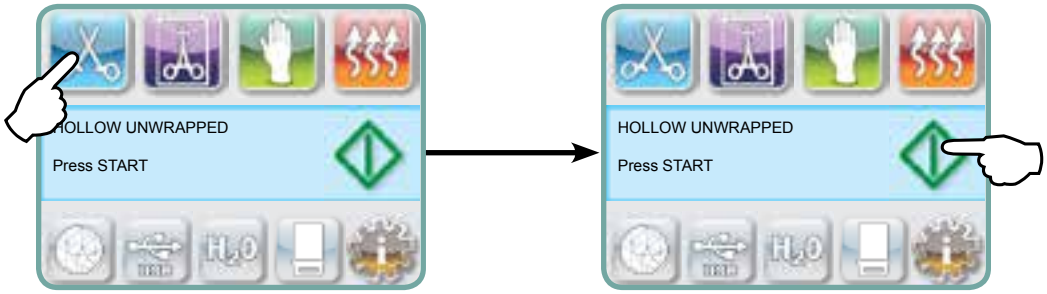
HOLLOW UNWRAPPED (S) 134˚C / 3.5 min

HOLLOW UNWRAPPED (S) 134˚C / 18 min

The type N cycle is used to sterilize solid metal instruments such as pliers, burrs, scalers and forceps.

SOLID UNWRAPPED (N) 134˚C / 3.5 min

To select one of these cycles: Press the UNWRAPPED cycle button to scroll through the available cycles.



Once the desired cycle has been selected, press the **START** button.

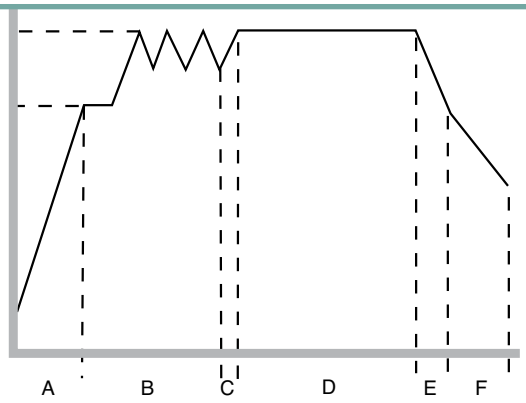
The STAT*IM* G4 will remember the last Unwrapped cycle type selected and will display it when you select the Unwrapped icon.

NOTE: If Process Enforced usage is enabled (where users must enter a PIN to Start and Stop a cycle), a PIN screen will appear after you have pressed START. Enter your PIN to start the cycle.

5.1.1 Unwrapped Cycles cont'd

HOLLOW UNWRAPPED (S) 134˚C / 3.5 min

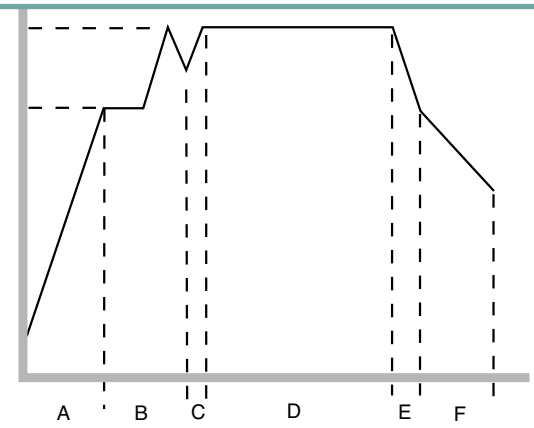
HOLLOW UNWRAPPED (S) 134˚C / 18 min



A 100˚C / 101 kPa
B 3 purges (Conditioning) peak at 133˚C / 295 kPa vent to 115˚C / 169 kPa
C Pressurizing
D Sterilizing 134˚C / 304 kPa - 138˚C / 341 kPa
E Venting
F Air Drying

(Type S)

SOLID UNWRAPPED (N) 134˚C / 3.5 min



A 100˚C / 101 kPa
B 1 purge (Conditioning) peak at 133˚C / 295 kPa vent to 115˚C / 169 kPa
C Pressurizing
D Sterilizing 134˚C / 304 kPa - 138˚C / 341 kPa
E Venting
F Air Drying

(Type N)

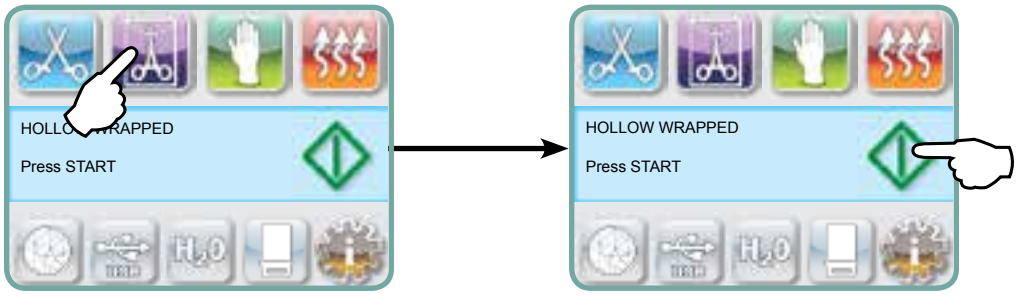
5.1.2 Hollow Wrapped Cycles

The STAT*IM* 2000 G4 and 5000 G4 feature two WRAPPED 134°C type S sterilization cycles.These cycles are used to sterilize solid and hollow metal instruments which have been sealed in paper/paper or paper/plastic autoclave bags.

HOLLOW WRAPPED (S) 134˚C / 3.5 min

HOLLOW WRAPPED (S) 134˚C / 18 min

From the main menu, press the WRAPPED icon to scroll through the available cycles.



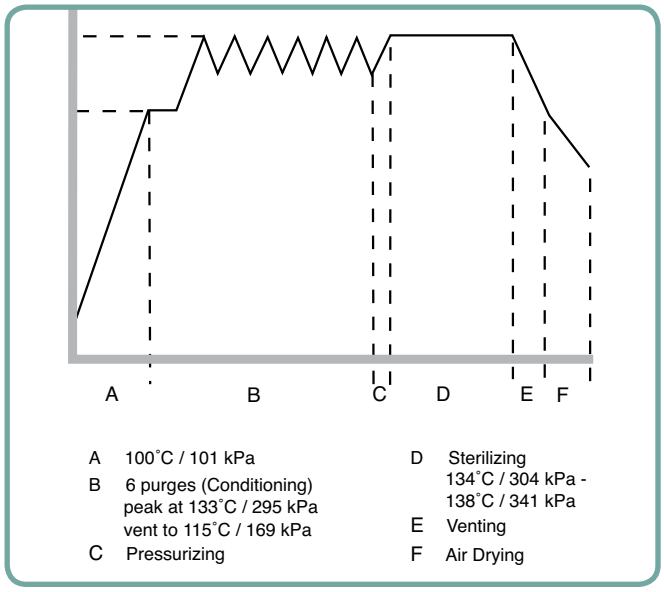
Once the desired cycle has been selected, press the **START** button.

The STAT*IM* G4 will remember the last Hollow Wrapped cycle type selected and will display it when you select the Hollow Wrapped icon.

NOTE: A Process Challenge Device (PCD) is available for validation of HOLLOW WRAPPED (S) 134°C/3.5 min cycle.

HOLLOW WRAPPED (S) 134˚C / 3.5 min

HOLLOW WRAPPED (S) 134˚C / 18 min



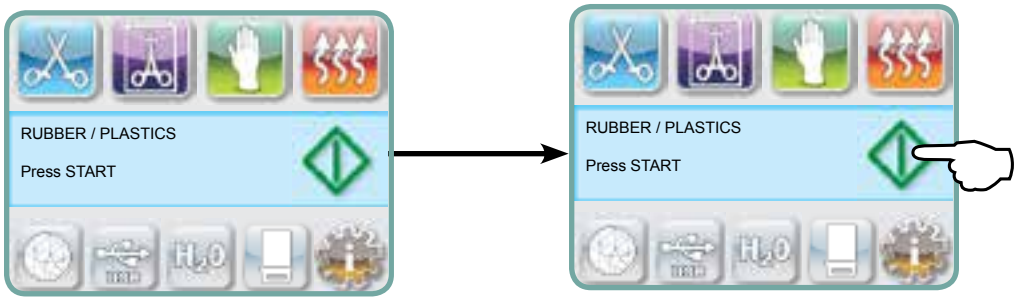
5.1.3 Rubber and Plastics Cycles

The STAT*IM* 2000 G4 and 5000 G4 feature two 121°C type S sterilization cycles used to sterilize solid unwrapped instruments constructed of metal or the materials listed in section ‘Preparing and Loading Instruments’.

RUBBER / PLASTIC (S) 121˚C / 15 min

RUBBER / PLASTIC (S) 121˚C / 30 min

From the main menu, press the Rubber / Plastics icon to scroll through the available cycles.

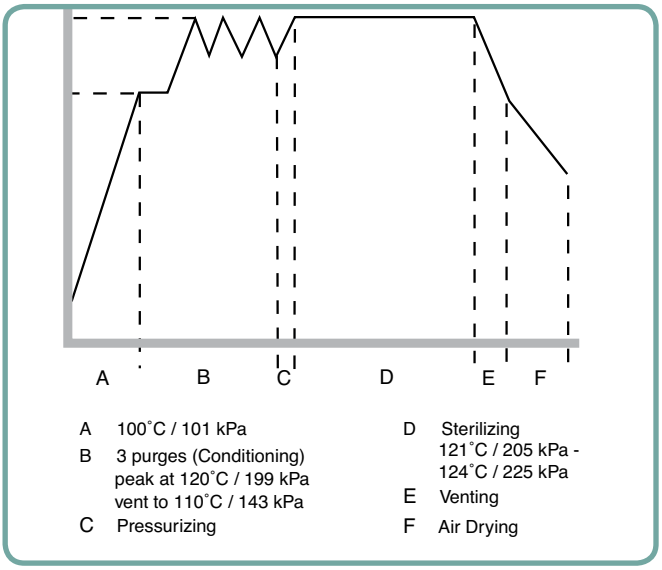


Once the desired cycle has been selected, press the **START** button.

The STAT*IM* G4 will remember the last Rubber / Plastics cycle type selected and will display it when you select the Rubber / Plastics icon.

RUBBER / PLASTIC (S) 121˚C / 15 min

RUBBER / PLASTIC (S) 121˚C / 30 min



5.1.4 Air Dry Only Cycle

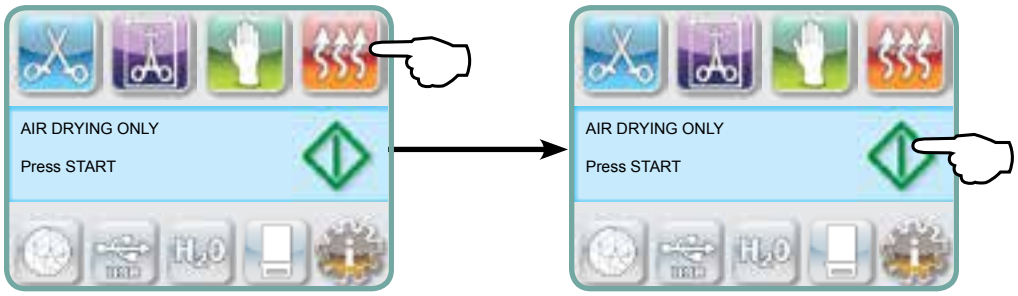
This is not a sterilization cycle.

The load is considered sterile after the successful completion of the sterilization phase of the cycle.

Air drying may be interrupted by pressing the STOP button anytime after the sterilization phase of the cycle is complete. Dryness is important for unwrapped instruments to prevent corrosion. For wrapped instruments, a dry wrap is required to maintain sterility.

If the STOP button is pressed during the air drying stage of the sterilization cycle, and the cassette has not been removed from the autoclave, the Air Dry Only cycle may be used to promote further drying. If the cassette has been removed from the autoclave, it may NOT be reinserted for the Air Dry Only cycle. If the cassette contains wrapped instruments and the wraps are not dry when the cassette is opened, the instruments must be handled in a manner that maintains their sterility and must be used immediately or resterilized.

NOTE: Sterilized instruments should only be handled once they are dry. Drying times can vary depending on the weight of the load, (refer to section ‘Preparing and Loading Instruments’ and ‘Maintenance’).



To start, press the Air Dry Only icon, then press the **START** button.

5.2 Running a Cycle

To operate each cycle, follow these steps.

1. Turn the power switch at the back of the unit to ON.

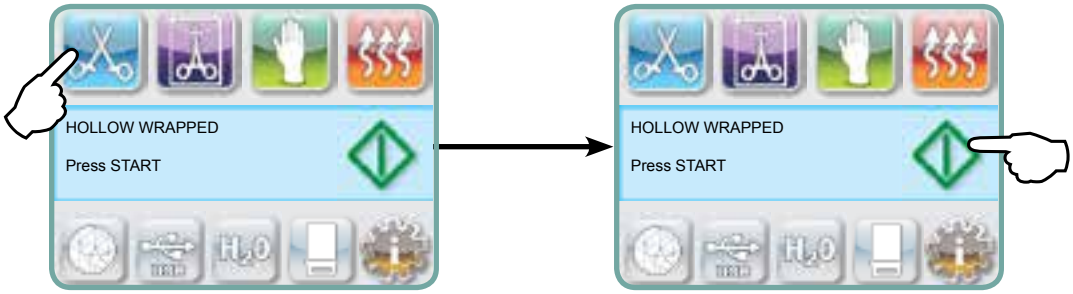
At start up, the unit will display the main menu.

2. Press the appropriate cycle button on the touchscreen to scroll through the available cycles.

The display will show the cycle name and parameters. The STAT*IM* G4 features seven different cycles:

HOLLOW UNWRAPPED (S) 134˚C / 3.5 min	HOLLOW WRAPPED (S) 134˚C / 3.5 min	RUBBER / PLASTIC (S) 121˚C / 15 min
HOLLOW UNWRAPPED (S) 134˚C / 18 min	HOLLOW WRAPPED (S) 134˚C / 18 min	RUBBER / PLASTIC (S) 121˚C / 30 min
SOLID UNWRAPPED (N) 134˚C / 3.5 min		

3. When you have found the cycle you require, press the **START** icon.



NOTE: If Process Enforced usage is enabled, a PIN screen will appear after you have pressed START. Enter your PIN to start the cycle.

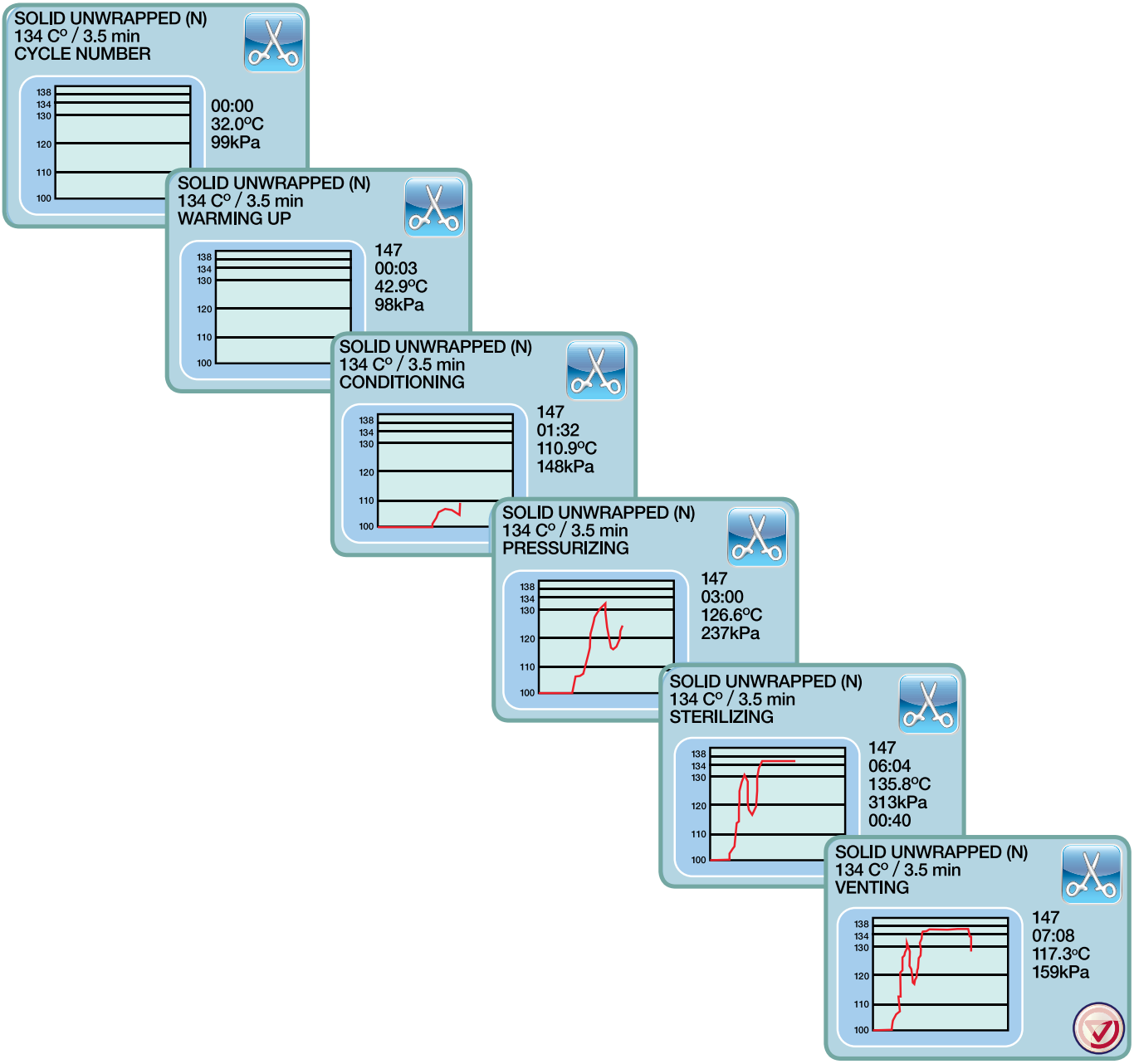
5.2 Running a Cycle cont'd

When the cycle starts, the cycle parameters are displayed at the top of the screen.

Below it is the current phase. The unit's cycle counter is displayed at right.

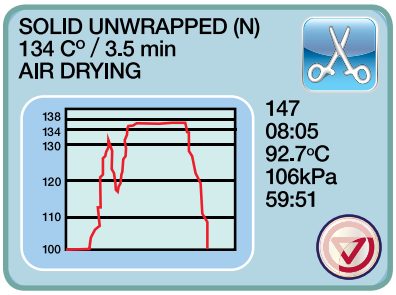
A graph charts the progress of the cycle while current cycle information is displayed at right.

As the cycle is running, various sounds will be heard. This is the normal functioning of the unit.

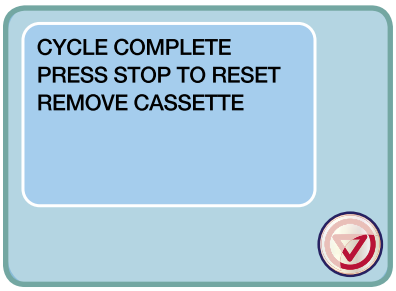


5.2 Running a Cycle cont'd

The buzzing noise during the air drying stage is the compressor operating. The air drying phase of the cycle may be interrupted at any time by pressing the **STOP** button.



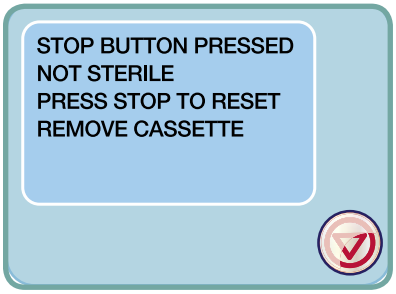
When the automatic air drying stage is finished and the sterilization cycle is successful, the touchscreen will display a Cycle Complete message and the reminder tone will sound until the **STOP** button is pressed or the cassette is removed from the unit.



Be careful. The metal parts will be hot and the cassette may contain hot steam.

5.3 Stopping a Cycle

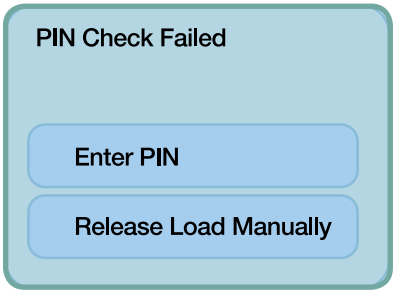
To stop a cycle, press the **STOP** icon at the bottom right of the touchscreen. If the **STOP** button is pushed, the cassette is removed, or the unit detects a problem while operating, the cycle will stop. Once a cycle has been stopped, the **STOP** button must be pressed before another cycle can be started. The display will show:



If the display shows the message, CYCLE FAULT or NOT STERILE, the cassette contents are not sterile! See Section 10 Troubleshooting for more information.

If the air drying stage of the cycle is interrupted, do not store wrapped instruments that were in the cassette unless they are dry.

NOTE: If Process Enforced usage is enabled, a PIN screen will appear after you have pressed **STOP**. To release the load manually, press EN on the PIN screen. On the next screen, select RELEASE LOAD MANUALLY.



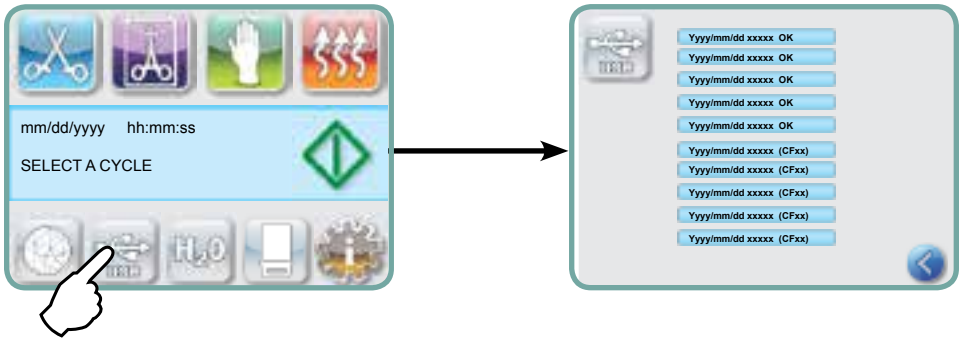
6 Storing and Retrieving Cycle Information

The STAT*IM* G4 has an internal Data Logger capable of storing all cycle data on every cycle, whether successful or incomplete, for the lifetime of the unit. You can access this information through the touchscreen, through the web portal, using a USB storage device or by attaching a printer.

6.1 Retrieving Cycle Information Using the Touchscreen

1. From the main menu, press the USB icon.
2. The unit will record the last five successful cycles and the last five incomplete cycles. If you select a cycle from the list, it will display cycle information in a format similar to how it would be printed.
3. Use the arrow keys to scroll through and read.

NOTE: Regardless of whether you have a USB storage device attached to the unit or not, you can always see the last five successful cycles and the last five incomplete cycles. Use the STAT*IM* G4 Web Portal to access all the cycle information stored on your STAT*IM* from your computer. To connect your STAT*IM* to a network consult the separate manual titled STAT*IM* 2000/5000 G4 – Setting Up and Using Your Web Portal.



6.2 Retrieving Cycle Information Using the USB Data Back Up

The USB storage device can be used to transfer cycle information stored in the unit to a computer. Best practice suggests this should be done once a week. To transfer data using the USB port, follow these steps:

1. Plug the USB storage device into the USB port.
2. The STAT*IM* keeps track of what data has already been transferred to the USB storage device and will automatically load only new data.

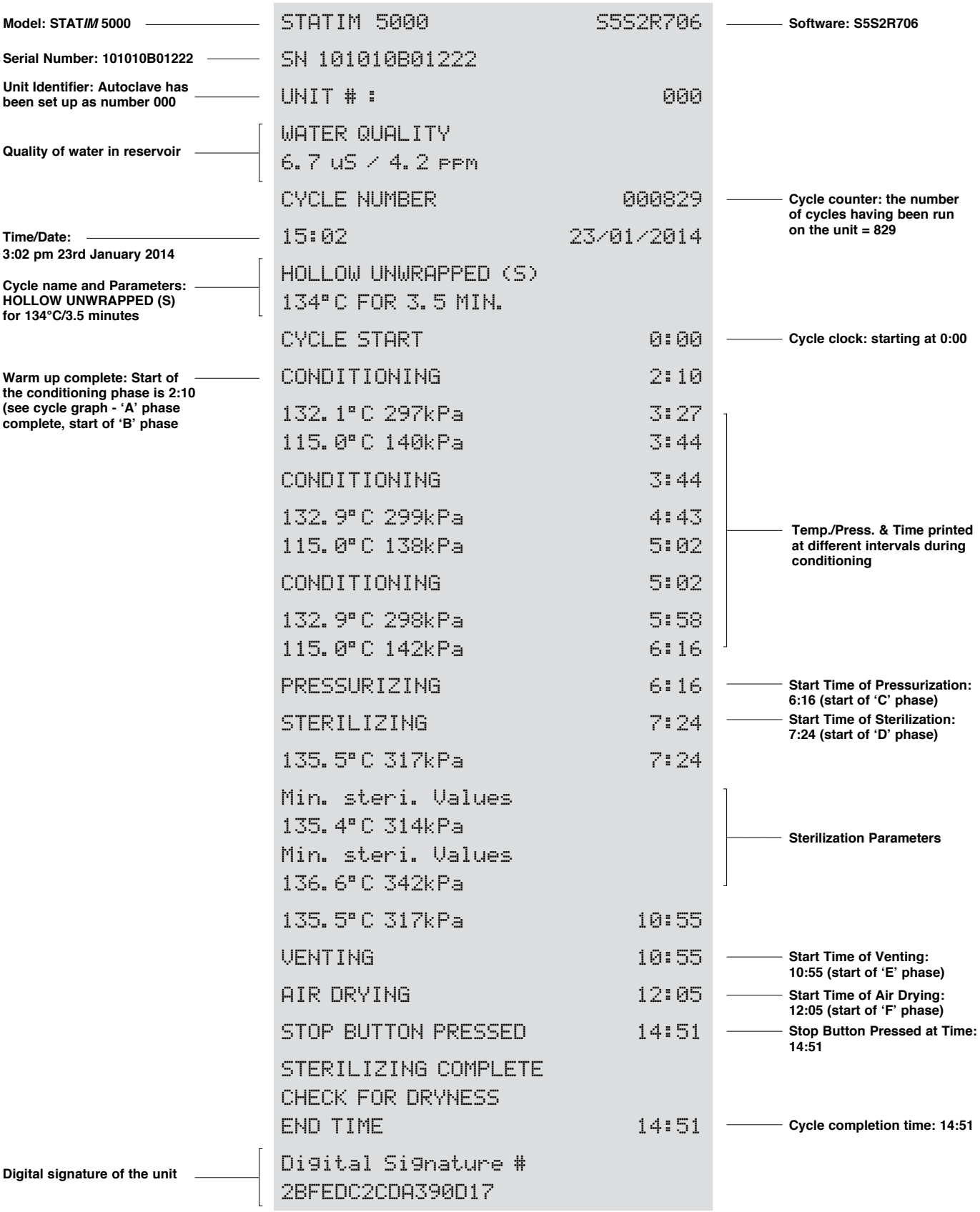
! Data stored in the internal memory of the STAT*IM* can only be copied once. Data that has been previously transferred will not be resaved onto a new USB storage device. Access to previously transferred information can be made from the Web Portal.

3. When the activity light on the provided USB storage device stops blinking or the USB icon on the LCD turns from a flashing green to a solid grey, remove the USB storage device and transfer the information to your computer.

NOTE: If you select the USB storage device icon from the main menu, you will only be able to view the last five complete cycles and the last five incomplete cycles. To view all the cycles stored on the USB storage device, you must use your computer.

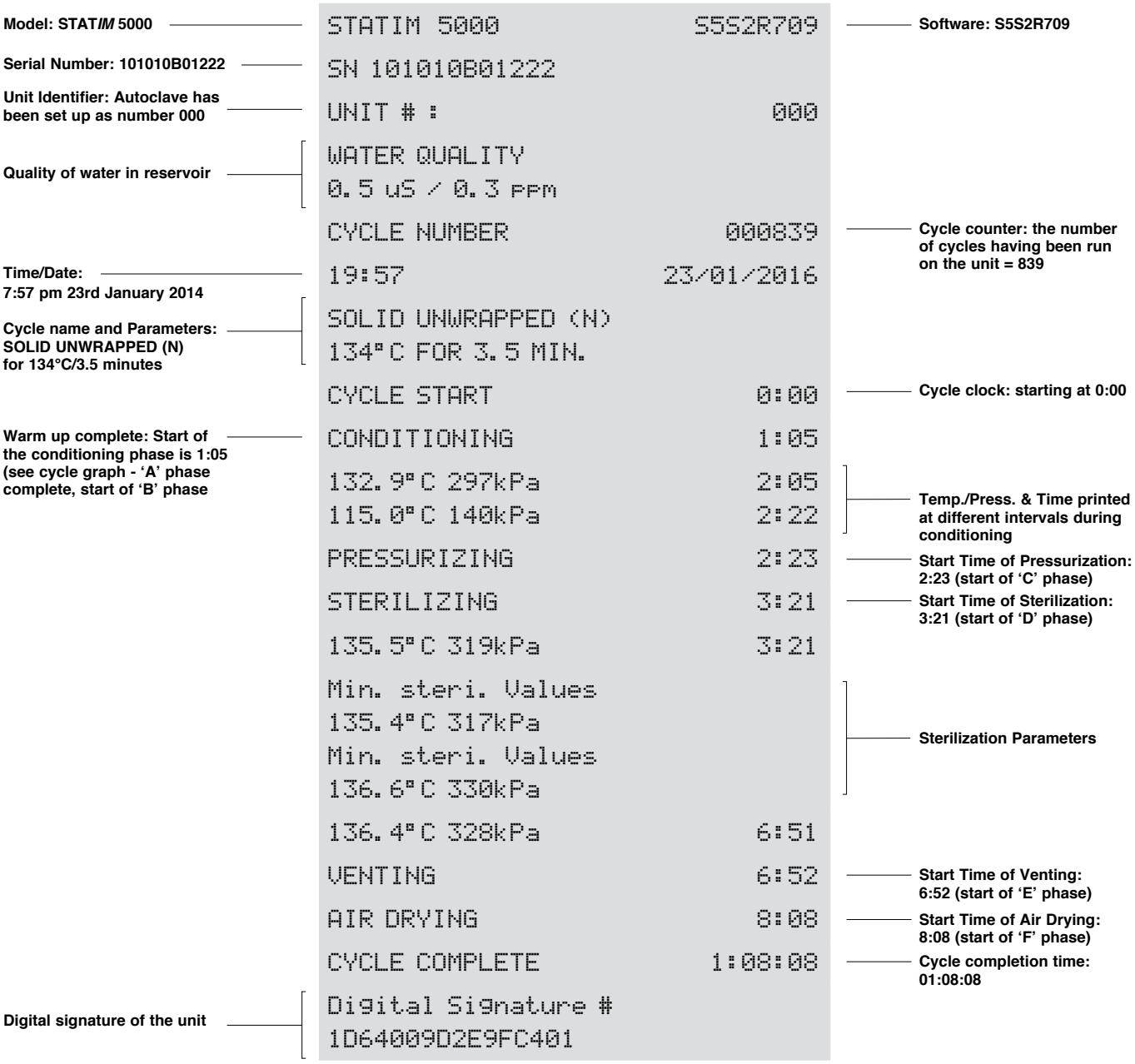
6 Storing and Retrieving Cycle Information

6.3 Cycle Printout Overview – Cycle with Stop button pressed



6 Storing and Retrieving Cycle Information

6.3 Cycle Printout Overview – Full Cycle



***Note: Time Format**

Time displayed as mm:ss (e.g. 3:27) for software revision 708 and lower; h:mm:ss (1:01:42) for software revision 709 and higher

Acceptable Tolerances:

Sterilization time: "Sterilization time" (e.g. 3.5 mins) -0/+1%

Saturated Steam Pressure: 304kPa - 341kPa for Unwrapped/Wrapped cycle (205kPa - 232kPa for Rubber and Plastics cycle)

Sterilization Temperature: "Specified temp" -0/+4 (134°C-138°C) (121°C -125°C for Rubber and Plastics cycle)

*data on Cycle Printout should fall within these ranges

7 Retrieving a Remote Access Code

To allow access to external persons to gain remote access to the STAT*IM* G4, you will need to provide a security token to the person requesting access. To obtain this code follow these steps:

1.
2. Scroll to **Remote Access** and select.
3. Press **Enable** and wait a few seconds for a security token to be provided. Once displayed, provide the token to the person requiring Remote Access.

NOTE: This token will be valid for only 2 hours, at which time the remote session will automatically disconnect. Should you wish to end the session earlier, select **Disable** from the same menu to disable the token.

8 Printing Cycle Information

The STAT*IM* G4 is equipped with an RS232 serial port to allow you to connect it to an external printer. (For a list of recommended printers, see the table below.)

8.1 Connecting to a Printer

To connect the printer, follow these steps:

1. Connect the external printer to the STAT*IM* G4's RS232 port using the serial printer cable supplier with your printer.
2. Power on the printer.
3.
4. Scroll to **Printer Type** and select.
5. Use to toggle to the Serial Printer option and select. Press to save and move back to the Setup menu.

8.2 Adjusting your Print Settings

The STAT*IM* G4 allows for several printer adjustments. You can access these settings from the user setup menu (see instructions above). Use the table below or your printer's operator manual to make the correct adjustments to your printer's **Baud Rate** , **End of Line CR/LF** and **Printer User Char.** .

8.3 External Printers and Specifications

Suggested External Printers by SciCan	End Of Line CR/LF	Serial Port Bitrate	Printer user ° char
Epson TM-U220D(C31C515603)	CR/LF	9600	248 [0xF8]
Citizen IDP-3110-40 RF 120B	CR	9600	N/A
Star Micro SP212FD42-120	CR	9600	210 [0xd2]
Star Micro SP216FD41-120	CR/LF	9600	210 [0xd2]
Star Micro SP512MD42-R	CR/LF	9600	210 [0xd2]

Under normal storage conditions, a thermal document will remain legible for a minimum of 5 years. Normal storage conditions include avoiding direct sunlight, filing in office temperatures below 25 degrees Celcius and moderate humidity (45-65% relative humidity) and not next to incompatible materials including plastic, vinyl, hand lotion, oil, grease, alcohol-based products, carbonless paper and carbon paper.

9 Maintaining your STAT*IM*

9.1 Cleaning the Cassette

Keeping the STAT*IM* cassette clean is good clinical practice and assists in the proper functioning of the unit. SciCan recommends that the interior surface be cleaned at least once a week. Cleaning the inside of your cassette is very important if you regularly sterilize lubricated instruments.

1. Use dishwashing soap or a mild detergent that does not contain chlorine.
2. Scrub the inside of the cassette with a cleaning pad designed for use with Teflon™ coated surfaces.
3. After scouring, rinse thoroughly with water to remove all traces of the detergent.

Coating the entire inside surface with STAT-DRI PLUS drying agent induces water to form an even coat on the inside surface, without beading. The water in contact with the hot cassette surfaces also evaporates much more efficiently. Spotting is minimized and instruments dry much better. STAT-DRI PLUS should be applied every 10 cycles, and after every cassette cleaning.

STAT-DRI PLUS is available from SciCan in a 2-ounce bottle (SciCan Part # 2OZPLUS) or an 8-ounce bottle (SciCan Part #8OZPLUS) or a 32-ounce bottle (SciCan Part #32OZPLUS).

9.2 Cleaning the Water Reservoir Filter

This water reservoir filter should be cleaned at least once a week or when required.
The filter can easily be removed and cleaned by placing the filter upside down under running water to wash away the particles until clean, and then placed back into the reservoir opening.
If a replacement water reservoir filter is required, order part number 01-109300S.

9.3 Cleaning the Water Reservoir

Check the reservoir for dirt or particles. The reservoir may be cleaned by draining followed by cleaning and rinsing with steam process distilled water ONLY. Use of chemicals or cleaning agents is not recommended and could damage the unit.

9.4 Cleaning the Exterior Surfaces

Use a soft cloth moistened with soap and water to clean all exterior surfaces.
Do not use harsh cleaning chemicals or disinfectants.

9 Maintaining your STAT*IM*

9.5 Changing the Air Filter and the Bacteria Retentive Filters

The filters should be replaced every six months or after 500 cycles to maintain an adequate supply of clean air during the air drying cycle.

To change the bacteria retentive air filter on the STAT*IM* 2000 G4 and 5000 G4, follow these steps:

1. Power the STAT*IM* **OFF**.
2. Disconnect tube A 1 from the bacteria retentive filter 2 and remove the filter from the filter bracket 3 . As you remove the filter from the bracket, note the orientation of the arrow mark on the filter.
3. When the filter is free of the bracket, carefully disconnect tube B 4 from the filter.
4. Before installing the replacement bacteria retentive filter 2 (SciCan order no. 01-102119S) check that the arrow mark on the filter matches the direction of the arrow on the bracket. Push the left hand filter fitting into tube B 4 .
5. Gently press the replacement filter into the filter bracket 3 . The arrow mark of the filter should be facing out and pointing to the left.

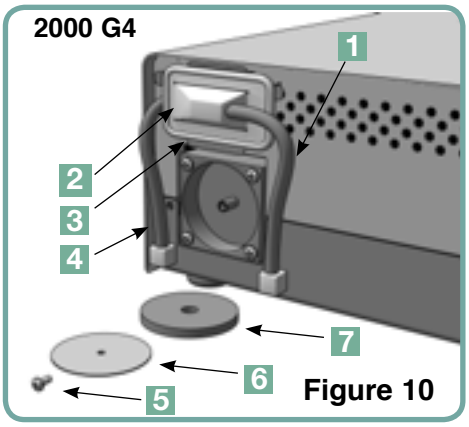


Figure 10

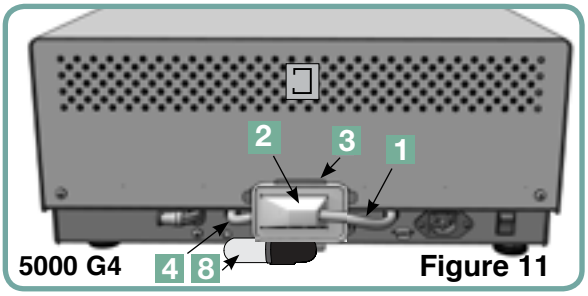


Figure 11

6. Re-connect tube A 1 to the right hand filter fitting.

To change the air filter on the STATIM 2000 G4, follow these steps:

1. Turn the power switch at the back of the unit OFF.
2. Remove and discard the old foam air filter 7 .
3. Install the new filter (SciCan part no. 01-100207S).
4. Secure the filter plate 6 to the back of the compressor using the screw 5 retained during the disassembly procedure.

To change the air filter on the STAT*IM* 5000 G4, follow these steps:

1. Unscrew the cylindrical air filter 8 in a counter-clockwise direction.
2. Discard the old filter.
3. Screw the new filter (SciCan part no. 01-101652S), finger tight only, into place.

9 Maintaining your STAT*IM*

9.6 Replacing the Cassette Seal

To ensure optimum performance of your STAT*IM* cassette autoclave, change the cassette seal every 500 cycles or every six months, whichever comes first. Replacement seals are available from SciCan (order number 01-100028S for the STAT*IM* 2000 G4 and 01-101649S for the STAT*IM* 5000 G4).

To change the cassette seal, follow these steps:

Place the cassette lid and the new seal on a clean work surface. Examine the position of the old seal in the cassette lid and arrange the new seal in the same orientation, next to the lid.

Remove the old seal and discard. Clean any residue out of the seal channel and flush out the channel with distilled water.

Lubricate the new seal with the liquid seal lubricant provided.

Insert the rounded edge of the seal under the round lip of the lid. Align the holes in the new seal with the holes in the lid.

NOTE: At every corner and at the holes in the lid, two square nibs should be visible. The nibs should fit flush with the lid's outer surface.

Ensure the seal is completely inserted. Feel around the periphery to ensure the seal is securely in place.

NOTE: During a cycle, steam may appear between the lid and the tray. If this persists, remove the cassette and check that the seal is correctly installed.

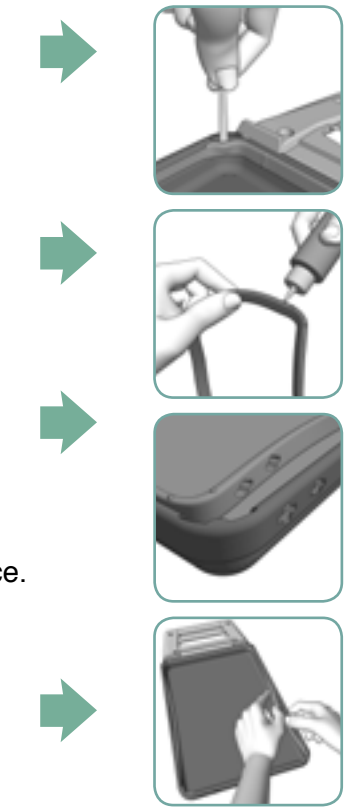


Figure 12

Be careful. The metal parts will be hot, and the cassette may contain hot steam.

9 Maintaining your STAT*IM*

9.7 Maintaining Fluid Levels

1. The water reservoir level is continually monitored by your STAT*IM.* If the reservoir is low, a red X will appear on the water icon of the cycle select screen. Press the icon to go to the next screen to confirm that it is a water level issue and not a water quality issue.
2. If the reservoir is low, a will appear next to WATER LEVEL.
3. To fill the reservoir, remove the cap from the top of the unit and fill the reservoir. We recommend using a funnel to minimize spills. Each time you refill the reservoir, empty the waste bottle and refill with water to the MIN line. Empty the waste bottle often to avoid unpleasant odors and discoloration of the contents. (A low-level chlorine-free disinfectant, prepared according to the manufacturer's instructions, may be added to the waste bottle to remedy this situation).

9.8 Reading Water Quality

1. The water quality is continually monitored by your STAT*IM.* Use only steam-process distilled water containing less than 5 ppm total dissolved solids (having conductivity of less than 10 µS / cm) in the STAT*IM.* If the water quality is beyond these tolerances, a red X will appear on the water icon of the cycle select screen. Press the icon to go to the next screen to confirm that it is a water quality issue and not a water level issue.
2. If the water quality not suitable, will appear next to micro S. and parts per million values.
3. Using the drain tube (see section 3.5 Priming the Pump, Figure 6) empty the contents of the reservoir into the water container and replace with steam-process distilled water containing less than 5 ppm total dissolved solids (having conductivity of less than 10 µS / cm).

9.9 Using On-Screen Instructions

The STAT*IM* G4 on-screen help instruction can be viewed by following these steps:

1.

2. Scroll to **Instructions** and select.

3. Choose the Instructions you would like to view and select.

9.10 Preventative Maintenance Schedules

To ensure trouble-free performance, both the operator and the dealer must follow a preventative maintenance schedule.

NOTE: Please refer to your National, Regional, State or Safety laws for any additional reoccurring user testing that may be required.

The schedules below describe the necessary actions.

Operator		
Daily	Water Reservoir	• Drain after each working day.
	Waste Bottle	• Empty the waste bottle every time you refill the reservoir. Fill with tap water up to MIN line. • You can also add some chlorine-free disinfectant.
	Unit	• To ensure optimal performance of the STAT*IM* autoclave, SciCan recommends that a full sterilization cycle, which must include the full Air Drying phase, be completed at the end of each day of use. This is especially important when the unit is left idle over the weekend or for any extended period of time.
Weekly	Cassette	• Wash the interior of the cassette with chlorine-free dishwashing detergent or soap. Rinse thoroughly with water to remove all traces of the detergent and treat interior surfaces of the cassette with the STAT-DRI™ Plus drying agent to enhance the drying process. Order more STAT-DRI ™ Plus from SciCan quoting 2OZPLUS, 8OZPLUS, or 32OZPLUS.
	Water Filter	• Check the water reservoir filter every week and clean if necessary. Replace only if necessary.
	Biological and/or Air Filter	• Check the filter for dirt and moisture. Replace if dirty. Call for service if wet.
Every 6 months	Air Filter	• Replace every 500 cycles or six months (whichever comes first).
	Biological Air Filter	• Replace every 500 cycles or six months (whichever comes first).
	Cassette Seal	• Replace every 500 cycles or six months (whichever comes first).
Extended Period of NON-USE	Unit	• If the STAT*IM* is not going to be in use for a week (or more), ensure that a full sterilization cycle, which must include the full air drying phase, is completed before the period of non-use. After the period of non-use and before any instruments are sterilized, run three wrapped cycles. Remove the cassette once it has cooled. Clean the top (lid) and bottom (tray) sections using a soft cloth to wipe the inside surfaces and then rinse thoroughly with tap water. Once the cassette is clean and dry, coat the inside surface with STAT-DRI PLUS.

	Technician	
Once a year	Cassette	• Check the tray, lid and seal for damage. Replace if necessary.
	Biological Filter	• Inspect the biological filter for moisture.
	Solenoid Valve	• Inspect the valve and clean if dirty. Replace the plunger if defective.
	Pump	• Clean the filters, replace if dirty.
	Check Valve	• Remove the exhaust tube from the back of the unit during the air drying phase. Check for air coming from the fitting. • Remove the air compressor tube from the check valve inlet while running a cycle. Make sure no steam is leaking from the valve. Replace if there are any leaks.
	Water Reservoir	• Check the reservoir for dirt. Clean and rinse with steam process distilled water if necessary.
	Calibration	• Calibrate the unit.

9.11 Shipping the Unit / Draining the Reservoir

Before you move the unit, you will need to drain the reservoir. To do so, follow these steps:

1. Place a water container below the unit.
2. Using the drain tube (see Section 3.5 Priming the Pump, Figure 6) empty the contents of the reservoir into the water container.
3. Remove any remaining water from the reservoir with a non-linting, absorbent towel.
4. Screw-in the three leveler feet found underneath the unit.
5. Repack the unit in the original packing materials and include all accessories originally included with the unit.
6. Specify heated and insured shipping.

10 Troubleshooting Your STAT*IM*

Problem	Solution
Unit does not power **ON**.	Check that the unit is plugged into a properly grounded outlet and that the power cord is firmly seated at the rear of the machine. Try another circuit. Power unit **OFF** for 10 seconds and then power **ON** again. Check the condition of the line circuit breaker or fuse.
There is water under the machine. 	Check that water was not spilled when refilling the reservoir. Make sure the plug in the exhaust tube is secured. Remove and reinsert the cassette. Attempt another cycle. Be careful. The metal parts will be hot, and the cassette will contain hot steam. The cassette is leaking. If water drips from the underside of the unit during operation, check the cassette seal for misalignment or damage and replace the seal if required. Be careful. The metal parts will be hot, and the cassette will contain hot steam. Attempt another cycle. If it still leaks attempt another cycle using a different cassette if possible. If the leak persists, turn the unit **OFF**, remove and unload the cassette, unplug the unit, and call your dealer.
Instruments do not dry.	Best drying occurs when the cycle continues to completion. Allow the cycle to finish. Make sure the instruments are loaded correctly in the cassette. Refer to section 4. Using Cassettes and Preparing Instruments. Check the unit leveling. Check air/biological filters and replace if dirty. Clean the inside of the cassette and treat with STAT-DRI Plus drying agent. Refer to section 8.1 Cleaning the Cassette. Examine the exhaust tube (tube to the waste bottle) for kinks.

10 Troubleshooting Your STAT*IM* con't.

Problem	Solution
Instruments do not dry con't	If kinked, straighten the tube. If the tube cannot be straightened, remove it from the push-in fitting attached to the STAT*IM.* Depress the collar on the fitting and with the other hand pull firmly on the tube. Once the tube is free of the fitting, cut the damaged section of tubing away using a sharp instrument. Be sure that you leave enough tube to reach the unit when you re-attach the tube to the exhaust fitting. If the tube is too short to remove a section, contact your SciCan dealer for a replacement. Make sure the compressor is working. To check, remove the exhaust tube from the waste bottle. Start the Air Drying Only Cycle, and place the free end into a glass of water. If there is not a strong, steady flow of bubbles, the compressor is not functioning properly. Contact your SciCan dealer.
Cycle interrupted — NOT STERILE, Cycle aborted — NOT STERILE and CYCLE FAULT messages.	Wait a few minutes and attempt another cycle before proceeding to the next solution. Remove the cassette. Be careful. The metal parts will be hot and the cassette will contain hot steam. Inspect the cassette to ensure that the holes in the back of the seal are perfectly aligned, and that the flexible lip of the seal is completely free. Check the exhaust tube for kinks or obstructions. If kinked, straighten the tube. If the tube cannot be straightened, remove it from the push-in fitting attached to the STAT*IM.* Depress the collar on the fitting and, with the other hand pull firmly on the tube. Once the tube is free of the fitting, cut the damaged section of tubing away using a sharp instrument. Be sure that you leave enough tube to reach the unit when you re-attach the tube to the exhaust fitting. If the tube is too short to remove a section, contact your SciCan dealer for a replacement. Check that the STAT*IM* has not inadvertently been exposed to any electrical interference. Refer to section 3.1 Positioning your Unit. Try running another cycle. If the problem persists, record the cycle fault message number and contact your dealer.

10 Troubleshooting Your STAT*IM* con't.

Problem	Solution
Excessive steam issuing from the front of the machine.	Remove and reinsert the cassette. Attempt another cycle. Remove and check the cassette seal for misalignment or damage. Replace the seal if required. Be careful as the metal parts will be hot and the cassette will contain hot steam. If the leak persists, turn the unit **OFF**, remove and unload the cassette and contact your SciCan dealer.
Machine will not start and touchscreen shows:	Press on the icon to confirm whether it is a water level problem or a water quality problem. If it is a water quality problem, you have likely used water which is not steam-process distilled or is improperly distilled. Empty the reservoir and refill with steam-process water containing less than 5 ppm total disolved solids (having conductivity of less than 10 μS / cm). If you have the water conductivity meter, check the quality of the water before refilling the reservoir. To empty the reservoir, see section 8.11 Shipping the unit / Draining the Reservoir.
Machine will not start and touchscreen shows:	Press on the icon to confirm whether it is a water level problem or a water quality problem. If the level of the water in the reservoir is low, refill the reservoir. Refer to the steps described in section 3.4 Filling the Reservoir.
The printer does not work.	Make sure that the printer cable is connected securely with the connector on the back of the STAT*IM.* Make sure that the printer is powered **ON**. Power unit **OFF** for 10 seconds and then power **ON** again.
Time and date are incorrect.	The time and date have not been set. See Section 3. Setting up your STAT*IM,* for time and date instructions.

10 Troubleshooting Your STAT*IM* con't.

Problem	Solution
Touchscreen is blank/white	Power was interrupted during a firmware upgrade. Power off the unit and power it on again. It can take up to 6 minutes before the main menu screen appears.
Touchscreen is blank/ dark	Check power source.
USB storage device does not contain the last print out	Re-insert the USB storage device and wait for the data to copy over again. If problem persists, back up all the information you have on the USB device and reformat it. **NOTE:** You can always access all your unit's cycle information through the unit's web portal.
Touchscreen shows:	An X over the connectivity icon means the unit is not connected to a network. If it is supposed to be connected to a network and the X is visible, it is because the unit is unable to acquire an IP address. To resolve the issue, try some of the following: • Check that the router is functioning properly • Check the LAN cable (try a new cable if possible) • Make sure your router assigns IP addresses automatically. • Renew the IP address by following these steps: 1. Scroll through the setup menu to NETWORK SETUP and select. 2. Select RENEW IP
Unit is not sending emails	Check email settings by using the TEST button on the unit's web portal. From the SETUP web page, select the TOOLS tab. Click on TEST to check your router, unit, and Internet connections. If all settings appear to be OK. Go to the unit's touchscreen and renew the IP address by following these steps: 1. Scroll through the setup menu to NETWORK SETUP and select. 2. Select RENEW IP
Not receiving emails from the unit	Check your spam filter. Be certain the unit has been identified as an accepted email source. Ensure that you have accepted the SciCan Privacy policy by putting a check mark in the box on the CONTACTS page of your web portal.

STATIM 2000/5000 G4	CYCLES						
Type Test	SOLID UNWRAPPED (N) 134°C / 3.5 min	HOLLOW UNWRAPPED (S) 134°C / 3.5 min	HOLLOW UNWRAPPED (S) 134°C / 18 min	HOLLOW WRAPPED (S) 134°C / 3.5 min	HOLLOW WRAPPED (S) 134°C / 18 min	RUBBER/PLASTIC (S) 121°C / 15 min	RUBBER/PLASTIC (S) 121°C / 30 min
Dynamic chamber		X	X	X	X	X	X
Empty chamber	X	X	X	X	X	X	X
Solid load – unwrapped	X	X	X	X	X	X	X
Solid load – single wrapped		X	X	X	X	X	X
Simple Hollow Item		X	X	X	X	X	X
Dryness, solid load – unwrapped	X	X	X	X	X	X	X
Dryness, solid load – single wrapped		X	X	X	X		
Residual air	X	X	X	X	X	X	X
Additional Tests							
STATIM 2000/5000 G4 PCD * (01-108341)				X			
Microbiological Tests							
For Specific Medical Devices - SEE LIST BELOW							

Maximum Load							
2000 G4	1 Kg.	1 Kg.	1 Kg.	1 Kg.	1 Kg.	0.4 Kg.	0.4 Kg.
5000 G4	1.5 Kg.	1.5 Kg.	1.5 Kg.	1.5 Kg.	1.5 Kg.	0.4 Kg.	0.4 Kg.

Make - Model	Cycle
Dental instruments	
KaVo GENTLEforce 7000C	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Kavo – Gentle Power Lux 25 LPA	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
W&H-Trend LS, WD-56	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
W&H-Trend HS, TC-95RM	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
KaVo Super-Torque LUX/640 B	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
KaVo-INTRAmatic LUX3, 20 LH	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
NSK-PANA Air	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
NSK-ATL118040	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
NSK – Ti-Max	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
STAR-430 SWL	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Sirona-T1 Classic, S 40 L	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Sirona-T1 Control, TC3	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Midwest-Tradition	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Bein – Air - Bora L	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
W&H – WS-75	HOLLOW / WRAPPED (S) 134°C / 3.5 min
W&H – WA-99 LT	HOLLOW / WRAPPED (S) 134°C / 3.5 min
W&H – TA-98 LC	HOLLOW / WRAPPED (S) 134°C / 3.5 min
B & L Ophthalmology instruments	
Gimble irrigating cannula 30g E4894	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Lasik cannula E4989	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Gillis irrigating-aspirating cannula E4932	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Nichamin hydrossection cannula 26g E4421 H	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Irrigating-aspirating handpiece MVS 1063C	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Rudolf Medizintechnik GmbH Endoscope accessories	
Trocar sleeve, arthroscopy, 2 rotating stop cocks,	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
1.7 mm dia x 104 mm length #10-0008-00	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Trocar sleeve, hysteroscopy diagnostic sheath, 1 fixed	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
stop cock, 2.7 mm dia x 302 mm length #10-0049-00	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Alcon ophthalmic handpiece	
NeoSonix Phaco handpiece	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Miltex medical instruments	
Frazier needle 26-778	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Yeoman biopsy forceps with rotating shaft 28-304	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Kerrison rongeur 18-1994	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Frazier-Ferguson tube 19-570	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Yankauer suction tube 2-104SS	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Menghini biopsy needle 13-150	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Becton Dickinson	
Needle, 30G1	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min
Medical Workshop	
Hockeystick Forceps, membrane peeling mw-1925	HOLLOW / UNWRAPPED (S) 134°C / 3.5 min

* 1. The PCD (Process Challenge Device) was designed exclusively for use in STATIMs that are compliant with EN13060.

2. The PCD is not for use with STATIMs which are not in compliance with EN13060 or with the extended cassette.

3. PCD specification available upon request.

4. Narrow Lumen test not applicable – rationale available upon request.

11 Test Protocols con't.

Cycle Name	Load	Sterilisation Temperature	Sterilisation Time	Cycle Time (mm:ss)*	
				Warm Start	Cold Start
SOLID UNWRAPPED (N)	2000: 1.0kg 5000: 1.5kg	134°C	3.5 min	2000: 6:45 5000: 8:45	2000: 9:15 5000: 13:15
HOLLOW UNWRAPPED (S)		134°C	3.5 min	2000: 8:05 5000:10:50	2000: 11:45 5000: 17:30
HOLLOW UNWRAPPED (S)		134°C	18 min	2000: 22:35 5000: 25:20	2000: 26:15 5000: 32:00
HOLLOW WRAPPED (S)**		134°C	3.5 min	2000: 10:40 5000: 15:30	2000: 15:35 5000: 24:00
HOLLOW WRAPPED (S)		134°C	18 min	2000: 25:10 5000: 30:00	2000: 30:05 5000: 38:30
RUBBER/PLASTIC (S)	0.4kg	121°C	15 min	2000: 18:40 5000: 20:20	2000: 20:15 5000: 22:50
RUBBER/PLASTIC (S)		121°C	30 min	2000: 33:40 5000: 35:20	2000: 35:15 5000: 37.50
AIR DRYING ONLY	Not a sterilisation cycle				

*Drying not included **Cycle for routine check (STAT*IM* PCD) test

12 Ordering Spare Parts

STAT*IM* G4 SPARES	
01-100028S	Cassette Seal (2000)
01-101649S	Cassette Seal (5000)
01-103865S	Seal Lubricant
01-1016528	Air Filter (5000)
01-100207S	Compressor Filter (2000)
01-102119S	Biological Filter
01-101783S	Reservoir Cap and Filter
01-109300S	Water Reservoir Filter Kit
01-100204S	Exhaust Tube
01-100724S	Condenser Bottle w / o Condenser
01-100735S	Waste Water Bottle Fitting
01-100780S	Bumper
01-100812S	Condenser Bottle
01-104093S	Exhaust Tube 3 m long
01-104343S	Plug - Drain Tubing
01-108340S	STAT*IM* PCD – spare parts
01-103945S	Rack-Tray Unwrapped Instr. Kit (STAT*IM* 2000)
01-112409S	Cassette Lid (2000 G4)
01-112410S	Cassette Handle - Lid (2000 G4)
01-112386S	Cassette Lid (5000 G4)
01-112387S	Cassette Handles Tray/Lid (5000 G4)
01-112388S	Cassette Handle - Lid (5000 G4)
01-112511S	Cassette Lid (5000 Ext G4)
01-112512S	Cassette Handles Tray/Lid (5000 Ext G4)
01-112513S	Cassette Handle - Lid (5000 Ext G4)
01-103557S	Power Cord Replacement Denmark (det.)
01-101766S	Power Cord UK
01-101768S	Power Cord Switzerland
01-101769S	Power Cord Italy
01-101779S	Power Cord Europe

STAT*IM* G4 SPARES	
01-101709S	Mesh Rack (5000)
01-106653	Mesh Rack - STAT*IM* 2000
01-112408S	Cassette Tray (2000 G4)
01-112407S	Cassette Tray with mesh rack (2000 G4)
01-112510S	Cassette Tray (5000 Ext G4)
01-112385S	Cassette Tray (5000 G4)
01-103935	STAT-DRI Plates (Qty 5) STAT*IM* 5000
01-103923	Condenser Additional Bottle

STAT*IM* G4 ACCESSORIES	
01-112406S	Cassette Complete (2000 G4)
01-112509S	Cassette Complete (5000 Ext G4)
01-112384S	Cassette Complete (5000)
01-106325	Container Endoscope Complete (STAT*IM* 5000)
2OZPLUS	STAT-DRI Plus 2 oz.
8OZPLUST	STAT-DRI Plus 8 oz.
32OZPLUS	STAT-DRI Plus 32 oz.
99-108332	Chemical Emulators (Class 6) 134°C/3.5min)
01-108341	PCD Final Assembly Kit

13 Warranty

Limited Warranty

For a period of one year, **SciCan** guarantees that the **STAT*IM* 2000 / 5000 G4**, when manufactured by **SciCan** in new and unused condition, will not fail during normal service due to defects in material and workmanship that are not due to apparent abuse, misuse, or accident.

The one year warranty will cover the performance of all components of the unit except consumables such as the cassette seal, the compressor filter and the microbiological filter, provided that the product is being used and maintained according to the description in the user's manual.

A two-year warranty will be applied specifically to the water pump, steam generator, and printed circuit board (PCB) provided that the product is being used and maintained according to the description in the user's manual.

In the event of failure due to such defects during this period of time, the exclusive remedies shall be repair or replacement, at **SciCan's** option and without charge, of any defective part(s) (except gasket), provided **SciCan** is notified in writing within thirty(30) days of the date of such a failure and further provided that the defective part(s) are returned to **SciCan** prepaid.

This warranty shall be considered to be validated, if the product is accompanied by the original purchase invoice from the authorized **SciCan** dealer, and such invoice identifies the item by serial number and clearly states the date of purchase. No other validation is acceptable.

After one year, all **SciCan's** warranties and other duties with respect to the quality of the product shall be conclusively presumed to have been satisfied, all liability therefore shall terminate, and no action or breach of any such warranty or duty may thereafter be commenced against **SciCan**.

Any express warranty not provided hereon and any implied warranty or representation as to performance, and any remedy for breach of contract which, but for this provision, might arise by implication, operation of law, custom of trade or course of dealing , including any implied warranty of merchantability or of fitness for particular purpose with respect to all and any products manufactured by **SciCan** is excluded and disclaimed by **SciCan**.

If you would like to learn more about **SciCan** products and features or register your warranty online, visit our website at **www.scican.com**.

14.1 STAT*IM* 2000 G4

Machine Dimensions:	Length: Width: Height:	50.0 cm 41.5 cm 16 cm
Cassette Size (External)**:**	Length: Width: Height:	41 cm (includes handles) 19.5 cm 4 cm
Cassette Size (Internal)**:**	Length: Width: Height:	28 cm 18 cm 3.5 cm
Sterilization Chamber Volume:		1.8 L
Reservoir Volume:		4.0 L
Weight (Without water)**:**		22 kg
Clearance required:	Top: Sides: Back: Front:	5 cm 5 cm 5 cm 48 cm
Minimum charge in the water reservoir:		550 mL
PRV value (pressure relief valve)**:**		Set at 43.5 PSI to release pressure in overpressure situations
Thermal Fuse:		Cuts power to boiler in event of overheat
Electrical Rating:		220 - 240 V, 50/60 Hz, 6 A
Ethernet Port:		10/100 Base-T
USB Port:		USB 2.0
Current:		AC
Protection Class:		I
Protection:		covered
Ambient Operating Temperature:		5˚C - 40˚C
Sound levels:		Mean - 56 dB, Peak - 65 dB
Humidity:		80% Max.
Max. Altitude:		2000 m
Ambient Operating Pressure:		70kPa - 106kPa
Max. Water Consumption:		268mL

14.2 STAT*IM* 5000 G4

Machine Dimensions:	Length: Width: Height:	60.0 cm 41.5 cm 19.0 cm
Cassette Size (External)**:**	Length: Width: Height:	49.5 cm (includes handles) 19.5 cm 8 cm
Extended Cassette Size (External):	Length: Width: Height:	56.5 cm (includes handles) 19.5 cm 8 cm
Cassette Size (Internal)**:**	Length: Width: Height:	38 cm 18 cm 7.5 cm
Extended Section (Internal)**:**	Length: Width: Height:	11 cm 13 cm 2.8 cm
Sterilization Chamber Volume: **Extended Sterilization Chamber Volume:**		5.1 L 5.5 L
Reservoir Volume:		4.0 L
Weight (Without water)**:**		34 kg
Clearance required:	Top: Sides: Back: Front:	5 cm 5 cm 5 cm 57 cm
Minimum charge in the water reservoir:		550 mL
PRV value (pressure relief valve)**:**		Set at 43.5 PSI to release pressure in overpressure situations
Thermal Fuse:		Cuts power to boiler in event of over heat
Electrical Rating:		220 - 240 V, 50/60 Hz, 6 A
Ethernet Port:		10/100 Base-T
USB Port:		USB 2.0
Current:		AC
Protection Class:		I
Protection:		covered
Ambient Operating Temperature:		5˚C - 40˚C
Sound levels:		Mean - 57 dB, Peak - 65 dB
Humidity:		80 % Max.
Max. Altitude:		2000 m
Ambient Operating Pressure:		70kPa - 106kPa
Max. Water Consumption:		564mL

15 Declaration of Conformity

Classification: Class IIa (MDD Annex IX, Rule 15)

Manufacturer: SciCan Ltd.

Manufacturer Address: 1440 Don Mills Road
Toronto, Ontario
M3B 3P9
Canada

Telephone (416) 445-1600
Fax (416) 445-2727

European Representative: SciCan GmbH
Wangener Straße 78
88299 Leutkirch
Germany

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards and that SciCan Ltd. has exclusive responsibility for the content of this Declaration of Conformity. All supporting documentation is retained at the manufacturer's premises.

DIRECTIVE

General Applicable Directive:
Medical Devices Directive: Council Directive 93/42/EEC of June 14 1993 concerning medical devices [MDD 93/42/EEC, Annex II, excluding (4)].

Standards:
Harmonized Standards (published in the Official Journal of the European Communities) applicable to this product are:

ISO 13485, EN 61010-1, EN 61010-2-040, EN ISO 14971, EN 62304, EN 13060.

Additional Product Specific Standards applicable to this product are:

EN 61326-1

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraß 65,
D-80339 München, Deutschland
Identification No. 0123

Date CE Mark was affixed: May 30, 2011