Getinge SafeStep ATP Monitor

Operator's Manual

GETINGE

Operating Precautions and Limitations of Use

IMPORTANT: Getinge's products are designed and constructed to be safe and without risk to health when properly used (in accordance with the supplied documentation, etc) and when the operating precautions outlined in this document are fully observed.

IMPORTANT:
IT IS ESSENTIAL THAT THE USER OF THIS MANUAL IS AWARE OF THE POTENTIAL HAZARDS ASSOCIATED WITH THE UNIT AND ITS ACCESSORIES. ALL OPERATORS SHOULD BE FAMILIAR WITH THE SAFETY PRECAUTIONS AND WARNINGS GIVEN IN THIS SECTION PRIOR TO ATTEMPTING TO OPERATE THE UNIT. IF THE UNIT IS USED IN A MANNER NOT SPECIFIED BY THE MANUFACTURER, THE PROTECTION PROVIDED BY THE EQUIPMENT MAY BE IMPAIRED.

The following symbol is used in this manual:

⚠ Description: CAUTION / WARNING

The precautions to be observed relate to the transportation and use of all types of solid state electrical/electronic instrumentation and to the handling of the Test® Swab and Test® InstruSponge devices.

These precautions are outlined below:
Operating Environment and Electrostatic Precautions

⚠ WARNING: Do not use the unit in any area which has been, or is thought to have been, exposed to explosive or flammable gases or vapors.

⚠ CAUTION: Avoid operating the unit in direct sunlight, as this may affect its performance. Never leave the unit in direct sunlight, even when turned off.

⚠ CAUTION: Do not expose the unit to extremes of temperature (see section 10), and minimise any exposure to electrostatic charges.

Unit Handling and Use

⚠ CAUTION: Care should be taken not to drop the unit or subject it to any form of rough physical handling, both during normal use and during storage and transportation.

⚠ CAUTION: To avoid the risk of injury or choking, never use the unit neck strap in situations where it could get caught in machinery, etc.

Batteries

⚠ WARNING: Use only non-rechargeable alkaline batteries, or rechargeable NiMH or NiCD batteries, of types specified in section 10.

⚠ WARNING: Do not use batteries with individual cell voltages greater than 1.65V, as this will cause permanent damage to the unit.

⚠ CAUTION: All batteries should be disposed of in accordance with your local regulations.

Use and Insertion of Test® Swab Devices and Test® InstruSponge Devices

⚠ CAUTION: Refer to the instructions for details before using the device, and observe all federal, state and local environmental regulations.

⚠ CAUTION: Do not force Test® Swab devices into the unit. Do not attempt to insert any object other than an approved Test® Swab device into the unit.

⚠ CAUTION: Ensure that the Test® Swab device is clean and dry before inserting it into the unit.

Keypad Buttons

⚠ CAUTION: Do not use excessive force when pressing any of the buttons on the unit's keypad.

RS232 Connector

⚠ WARNING: Computer equipment connected to the RS232 connector at the top of the unit must conform to BS EN 60950/IEC950 standards.

Unit Casework and Serviceability

⚠ WARNING: There are no Operator serviceable parts inside the unit. Removal or opening of the unit's casework will void the warranty.

WEEE Directive Compliance

The Getinge SafeStep ATP Monitor unit should be disposed of in accordance with the European UnionWEEE Directive 2002/96/EC, on Waste Electrical and Electronic Equipment.

⚠ WARNING: Do not dispose of this product into unsorted municipal waste or a public landfill.

Regulatory Limitations of Use

The Getinge SafeStep ATP Monitor unit has been designed to meet the following general, safety and EMC requirements:

General
- Low Voltage Directive 73/23/EEC
- EMC Directive 89/336/EEC

Safety
- BS EN 61010-1:2001, IEC 61010-1:2001
- UL 61010B-1
- CAN/CSA C22.2 1010.1-92

EMC
- EN 55022:1998 – Class B
- FCC CFR47 Pt15.109 – Class B
- EN 61000-4-3:1996

ESD
- N 61000-4-2:1995 + A1

The Getinge SafeStep ATP Monitor unit is manufactured under ISO 9001 controls.

Declaration of Conformity
The Getinge SafeStep ATP Monitor unit has been designed in accordance with, and satisfies the requirements of, article 11 of the Low Voltage Directive 73/23/EEC as realigned by 93/68/EEC on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, to the essential requirements of BS EN 61010-1:2001.

The Getinge SafeStep ATP Monitor unit has been type tested by EMC Projects Limited (a UKAS and CAA approved test facility and UK appointed Notified Body), and issued with a Certificate of Compliance No. 6349/07 to the following EMC standard:
EN61326 : 1997

Covering:
- Radiated Emissions (EN 55022:1998 – Class B)
- Electrostatic Discharge (FCC CFR47 Pt15.109 – Class B)
- Radiated Immunity (EN 61000-4-3:1996)
- Electrostatic Discharge (EN 61000-4-2:1995 + A1)

Satisfying the EMC Directive(s) 89/336/EEC and 92/31/EEC as realigned by 93/69/EEC.

Table of Contents

1. Introduction

The Getinge SafeStep ATP Monitor is intended to help the operator demonstrate due diligence and compliance with surgical instrument and scope reprocessing and other hygiene regulations by allowing simple hygiene monitoring via the use of an ATP bioluminescent test.

The SafeStep ATP Monitor system consists of three elements: the Test Swab device, Test Sponge device and the handheld reader unit.

This Operator's Manual provides a detailed description of how to use the Getinge SafeStep ATP Monitor unit, and how to handle maintenance and troubleshooting.

For full details on the Test Swab and Test Sponge devices, please refer to the Product Specification and kit insert.

For any additional technical assistance, please contact Getinge USA. Inc.

1.1 Key Unit Features

The main features of the Getinge SafeStep ATP Monitor unit are:

- Small and lightweight reader
- Large clear liquid crystal display
- Highly sensitive unit
- Quick results – just 15 seconds
- Internal calibration self-check light source
- 5000 user programmable result thresholds
- Large 2000 test result memory
- 200 programmable users
- RS232 interface for results uploading to a PC
- Uses two standard or rechargeable batteries
- Replaceable protective sample pocket

1.2 Accessories and Consumables

Please contact your Getinge representative for details of unit accessories and consumables.

1.3 Principle of Operation

The Test Swab device uses a bioluminescent chemistry technology to convert an invisible concentration of ATP present in the sample into a visible light output.

This extremely low-level light output is measured by the Getinge SafeStep ATP Monitor unit to produce both a quantitative and qualitative result.

The quantitative result is a number in the range 0 to 9999, expressed in terms of Relative Light Units (RLUs).

Although RLUs are not a recognized international unit of light measurement (such as lux), they do provide a real measure of the amount of light output by the ATP bioluminescent test.

In this application, 1 RLU is roughly equivalent to 1 fmol of ATP.

The quantitative RLU reading is then compared against user programmable thresholds to provide an overall qualitative pass (✓) or fail (✖) result.

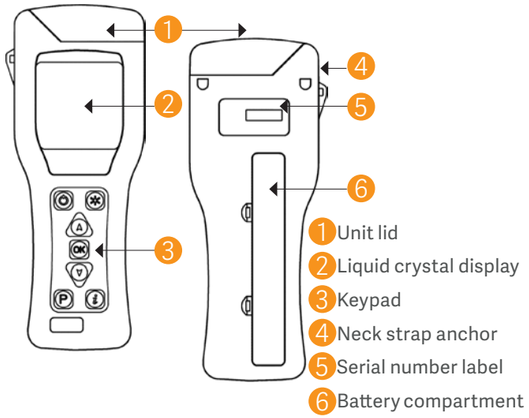
PLEASE NOTE
The Getinge SafeStep ATP Monitor unit is a highly sensitive and delicate measurement device. To avoid damage and degradation in performance, the unit should be treated with the utmost care and respect at all times.

2. Basic Unit Operation

IMPORTANT: Please ensure that you have read and understood all the "Operating Precautions and Limitations of Use" section at the beginning of the manual before continuing any further.

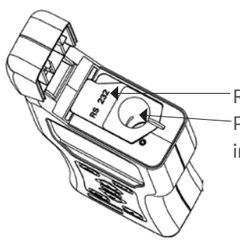
2.1 Unit Description

The unit has the following external front and rear features:



1. Unit lid
2. Liquid crystal display
3. Keypad
4. Neck strap anchor
5. Serial number label
6. Battery compartment

Opening the lid reveals the following internal features:

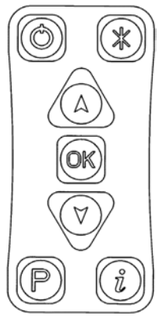


RS232 connector cover
Protective pocket and sample insert port

For details on the RS232 connector and protective pocket, refer to section 6.3.

2.2 Keypad Symbols

The keypad is arranged with the following buttons:



- Power on/off button
- Menu select button
- Up/increase button
- Start/accept button
- Down/decrease button
- Program select button
- Statistics shortcut button

The function of the buttons is explained in more detail in the following sections.

TIP: Holding down the "Up" or "Down" button will make it automatically repeat. Holding down this button scrolls through all functions rapidly.

2.3 Display Layout and Icons

The liquid crystal display (LCD) has the following layout. The upper half of the display contains the status icons and the large RLU result digits.

The following is a list of icons and their definitions.

Low battery warning icon

Lid icon - flashes when the lid needs to be closed, or the RS232 connector cover needs to be properly tucked under the lid

Insert icon – arrow flashes when the testing device should be inserted

Remove icon – arrow flashes when an testing device needs to be removed

Pass result icon

Caution result icon

Fail result icon

Sample measurement reading in Relative Light Units (RLU)

Retested icon – identifies the failed test result as having been retested

Retest result icon – identifies the Program location or test result as a retest result

2.4 Fitting the Batteries

The unit is designed to operate from both non-rechargeable alkaline batteries and rechargeable Nickel Metal Hydride (NiMH) or Nickel Cadmium (NiCD) batteries:

Battery Technology	Nominal Cell Voltage	Relative Capacity
Alkaline	1.5 V	1.0
NiMH	1.2 V	0.6
NiCD	1.2 V	0.5

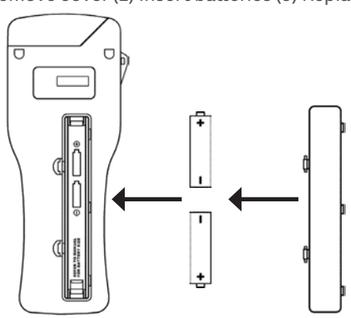
The unit requires two batteries of the size AA, LR6 or E91.

TIP: For best results, always use a quality brand of Alkaline battery and replace them as soon as they become flat (see section 2.6).

WARNING: Do not mix batteries of different technologies, or use recharged alkaline batteries as these are prone to overcharging and leaking, which may cause permanent unit damage and malfunction.

The batteries are fitted by unclipping the battery compartment cover on the back of the unit, and inserting two batteries with the positive ends (+) towards the top of the unit:

(1) Remove cover (2) Insert batteries (3) Replace cover



CAUTION: Batteries should not be placed into the ATP Unit in the wrong direction, as this may cause permanent damage to the internal electronics.

When the batteries are inserted correctly, the unit will automatically turn on and enter the clock set-up mode. Refer to section 4.8 for how to set the time and date.

2.5 Turning On the Unit

To turn the unit on, press the button. The unit will beep once and display the power-up self-check display:

NOTE: If the batteries are too flat, the unit may turn on and back off again automatically, or may not turn on at all. If this happens, replace the batteries immediately.

The unit will then perform its internal calibration self checks (see section 2.7 below).

NOTE: If the clock is not set, the unit will automatically enter the time and date set-up mode (see section 4.8) before performing its calibration self-check.

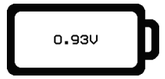
Important Tip: When the battery is replaced, the date and time need to be set.

2.6 Low Battery Indicator

The low battery icon indicates the state of the batteries:

Icon	Battery State
Not Visable	Good
Visable	Low- replace batteries soon
Flashing	Flat- replace batteries now!

When the batteries are completely flat, the unit will flash the icon, beep three times, and automatically turn off:



CAUTION: Never leave flat batteries in the unit, as they are prone to leaking/corrosion, which will damage the unit.

TIP: Always store the unit in a cool dry place when not in use, as elevated temperatures will shorten the battery life.

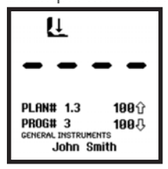
2.7 Internal Self-Calibration

When the unit is turned on, it performs an internal calibration, as the display counts down from 15 to 0 seconds.

NOTE: During the self-check sequence, there must not be a Test® Swab device in the unit and the lid must remain closed. If the icon is shown with the arrow flashing, open the lid and remove the Test® Swab device from the unit. If the icon is flashing, close the lid.

TIP: The "Menu Select" button can be pressed at any time to access the set-up menu options. Refer to section 4 for further details.

When the calibration self-checks are complete, the unit is ready to perform a sample measurement:



NOTE: When the unit is ready to perform a measurement, with the lid closed and no Test® Swab device present, the unit will automatically perform a zeroing cycle under any of the following circumstances:

- The unit is turned on for a prolonged period of time (typically 30 minutes).
- The unit is used in an environment where the temperature changes significantly (typically 5°C).
- The user presses and holds down the "OK" button for 1 second.

2.8 Turning the Unit Off

To turn the unit off, press the "Power On/Off" button. The unit will beep once and the display will go blank.

NOTE: To avoid accidental turn off, the "Power On/Off" button is disabled whilst the unit is performing a sample measurement.

2.9 Power Saving Standby Mode

If the unit is on but has not been used for 19 minutes, it will beep every 10 seconds for 1 minute and then automatically turn off, and the display will go blank. If any key is pressed during that time the unit will reset the Standby Mode countdown. You can change the Standby Mode settings (see section 3.4).

To turn the unit back on, simply press the "Power On/Off" button.

2.10 Low Memory Warning

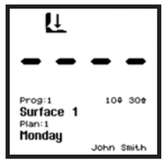
The unit can store up to 2000 test results in its internal memory. When the memory is more than 95% full (i.e. less than 100 tests remaining) the following warning symbol is displayed:

When the memory becomes completely full, no more tests can be performed until the memory is either erased or uploaded to the PC. Refer to section 5.

3. Sample Measurements and Test Results

With the unit turned on, and having completed its internal calibration self-checks, it is then ready to perform a new sample measurement, and the display shows the following details:

Insert Sample Icon



Program Number and Location

Plan Number and Name

Upper & Lower Threshold

User Name

Various keypad options are now available, as detailed in each of the following sections:

Button	Action	Section
✱	Access set-up menu options	4
✱	Select different User ID	4.1
P	Select program number	4.2
✱	Select different Test Plan	4.3
OK	Perform calibration	2.7
OK	Start new measurement	3
▲ ▼	View previous test results	4.5
i	Show statistical result data	4.6
⏻	Turn unit off	2.8

3.1 Programmable Test Locations

The unit can store up to 5000 individual programmable test locations (numbered PROG# 0 to PROG# 4999).

Each location is assigned a pair of upper (↑) and lower (↓) result threshold values, plus an optional location name.

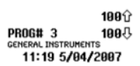
When a sample measurement result is displayed, the RLU reading is compared against the selected Program thresholds to determine the overall Pass or Fail result:

Banding	Result
Reading ≤ lower threshold (↓)	✔ Pass
Reading > upper threshold (↑)	✖ Fail

For details of how to determine the appropriate program thresholds for your particular operating procedures, please contact your Getinge representative.

To set-up the Program thresholds, refer the section 4.2.

To select a Program location press the “P” button, then use the up and down buttons to change the Program PROG# to the desired Program location, followed by the “OK” button to accept the new location, or the “P” button to cancel the selection.



TIP: While selecting a PROG#, the display also shows the time and date that the Program location was last tested.

NOTE: If the selected Program location does not have any thresholds defined, they must be set-up using the PROGRAM menu option (see section 4.2) before the Program can be used.

3.2 Taking a Sample Measurement

IMPORTANT: Please refer to the Test Swab and Test Sponge Product Specification and Kit Inserts for full details of how to use the Test Swab and Test Sponge device.

NOTE: Always allow the unit sufficient time to acclimatise to any change in environment, temperature or humidity before taking sample measurements.

To perform a sample measurement, follow the steps below:
For Flat Surfaces Using the Test® Swab

- Swab the sample area and activate the Test® Swab device (see Kit Insert for complete useage details)
- Open the unit lid, insert the Test® Swab device into the unit, and close the lid
- Press the “OK” button and wait 15 seconds for the result to be displayed

For Scopes and Cannulated Instruments Using the Test Sponge and Test Swab

- Pass Test Sponge through channel. (See Kit Insert for complete useage details)
- Cut off tip of Test Sponge into the Test Swab tube
- Swab outside surface of scope or instrument and activate Test® Swab device
- Open the unit lid, insert the Test Swab device into the unit, and close the lid
- Press the “OK” button and wait 15 seconds for the result to be displayed

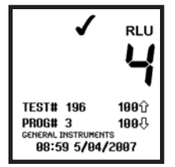
WARNING: Always ensure that the exterior of the Test® Swab device is clean and dry before inserting it into the unit. Never insert anything other than a Test® Swab device into the unit. Never insert a device into the unit when the protective pocket is removed (refer to section 6.3).

While the measurement is being performed, the display counts down from 15 to 0:

NOTE: For consistent results, always keep the unit upright and steady while it is performing a measurement to ensure that the liquid in the Test® Swab device is at the bottom of the tube.

When the measurement is complete, the test result and overall pass/fail result are displayed:

Pass/Fail



Test number
Program location
Test time

Upper threshold
Lower threshold
Test date

TIP: A failed test result (✖) can be selected for retesting by pressing the “P” button, followed by the “OK” button to select the Program location. See section 3.3 for details.

Now remove the Test® Swab device and dispose of it.

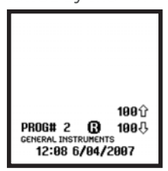
NOTE: For best results, and to prevent dust and dirt ingress, always keep the unit lid closed when not inserting or removing a Test® Swab device.

Previous test results can be viewed by pressing the up and down buttons (see section 4.5), or the results statistical data can be obtained by pressing the i button (see section 4.6).

TIP: The unit can be re-zeroed by removing the Test® Swab device, closing the lid and then pressing and holding down the “OK” button for 1 second. The unit will then perform a 15-second zero measurement.

3.3 Performing a Retest

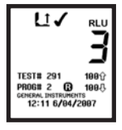
When viewing a failed (✖) test result (see section 4.5), the program location can be selected for retesting by pressing the “P” button, followed by the “OK” button:



NOTE: It is only possible to select a program location for retest if the most recent test result for that location was a failure (✖).

Having selected retest mode (signified by the Ⓡ icon next to the PROG#), perform the sample measurement in the usual way, using a new Test Swab device.

Once the retest measurement is complete, the original failed test result is marked with the Ⓡ icon, and the new test result is tagged with the Ⓡ icon:



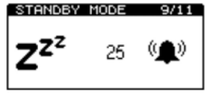
NOTE: Retest mode is automatically deselected once the new measurement is complete, or can be manually cancelled by pressing the “P” button and selecting a new program location (see section 4.2).

3.4 Standby Mode

The Standby Mode is used to control when the unit should automatically turn off when not in use. This is designed to conserve battery power.

The default is 20 minutes. If no buttons are pressed within the time period, the unit will turn off. If any button is pressed, or a reading is performed, the Standby Mode countdown timer is reset to zero.
If the bell icon is enabled the unit will begin beeping every 10 seconds for 1 minute as a warning before turning off. For example, if the Standby Mode time is set to 20, then if the unit is not used for 19 minutes it will start to beep every 10 seconds for 1 minute. If no action is taken the unit will turn off. If any button except the power button is pressed the countdown will restart.

To change the Standby Mode setting, select the STANDBY MODE menu option by pressing the ✳ button. Scroll to “STANDBY MODE” and press “OK” button. Then use the up or down button to increase or decrease the Standby Mode duration, followed by the “OK” button to store the new setting. Standby Mode duration can be from 5 to 60 minutes in increments of 5 minutes. Then use the up or down button to enable or disable the warning beeps. This will toggle the bell icon from enabled 🔔 to 🔕 disabled . Press the “OK” button to accept the settings:

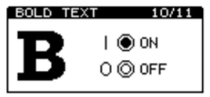


Ⓐ Ⓥ increase or decrease duration (5 to 60)
OK set duration
Ⓐ Ⓥ enables or disable warning beeps
OK set warning state

3.5 Bold Text

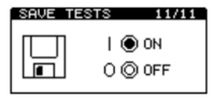
The unit displays key information on the LCD is bold to improve legibility. In some cases the number and size of the text will exceed the allotted space on the LCD. If bold is set to OFF all text on the unit will be displayed normally. This will allow all text to be displayed even if the text is maximum and all wide characters.

To change the Bold Text setting, select the BOLD TEXT menu option by pressing the ✳ button. Scroll to “BOLD TEXT” and press “OK” button to switch between ON and OFF:



OK OFF
OK ON
✳ EXIT

menu option by pressing the up button. Scroll to “SAVE TESTS” and press “OK” button to switch between ON and OFF:



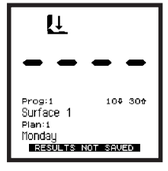
OK OFF
OK ON
✳ EXIT

3.6 Save Tests

By default any test performed on the unit is recorded to the unit’s non-volatile memory. Even if you take the batteries out the results of the test are retained in the unit’s memory.

In some cases, such as training, calibration checks, etc. users may want to discard test results. If Save Test is set to OFF, all tests taken in this mode will not be recorded.

NOTE: The Save Tests mode will be set back to ON when the unit is turned off and back on again. When Save Tests mode is set to OFF “RESULTS NOT SAVED” will appear at the bottom of the LCD.



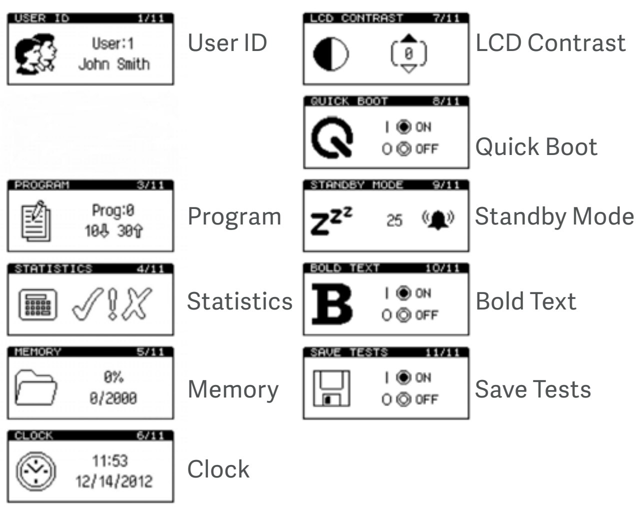
To change the Save Tests setting, select the SAVE TESTS

4. Set-up Menu Options

With the unit turned on, the Set-up Menu can be accessed by pressing the button.

Use the up and down buttons to scroll through the menu list, and then press the “OK” button to select the required menu option, or the button the exit the menu.

The following 11 menu options are then available:



NOTE: Getinge SafeStep ATP Monitor software is required for sections 3.1 to 3.3. For further details, refer to the separate Getinge SafeStep ATP Monitor User’s Manual located on the Getinge SafeStep ATP Monitor software CD that comes with the unit.

4.1 User ID

The unit can store (0 to 200) User Ids. Each test result will be tagged with the currently select User Id.

Select the User ID menu option, then use the up and down buttons to scroll through the list of User IDs, then press the button to select the a User ID, or the “OK” button to cancel the selection.

TIP: User:0 is the default selection if no User ID list has been defined.

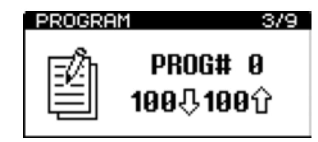
4.2 Setting up Program Test Points and Pass/Fail Limits

The unit has the ability to store a list of 5000 unique Program test points (Prog# 0 to 5000), each with its own upper and lower pass/fail result threshold values.

Program test point location names can only be programmed to the unit through the Getinge SafeStep ATP Monitor software. Program pass/fail thresholds can either be set-up on the unit, or set using the Getinge SafeStep ATP Monitor software. If a location name is entered and threshold set in the Getinge SafeStep ATP Monitor, and then downloaded to the unit, the threshold values can’t be changed via the unit. This is a security feature and prevents inadvertent changes to the thresholds after they have been set.

TIP: Prog:0 has a special function, whereby the threshold values defined for Prog:0 are used as the initial values when setting-up the other Prog thresholds. Thus setting Prog:0 with your typical threshold values will save time when setting-up the other Programs. The unit comes with pass/fail thresholds of 100 RLU for pass and 100 RLU for fail. These pass/fail thresholds were determined based on a comprehensive study looking at ATP, food residue, and microorganism samples. To receive the report or more information on setting up pass/fail thresholds contact Getinge USA, Inc.

To set the Program result thresholds on the unit, first select the PROGRAM menu option by pressing . Scroll to “PROGRAM” and press “OK”. Then use the up and down buttons to scroll through the list of Programs, followed by the “OK” button to select the Program to be changed:



PROG# OK

To select a Program location press the “P” button, then use the up and down buttons to change the ProgramProg: to the desired Program location, followed by the “OK” button to accept the new location, or the “P” button to cancel the selection.

TIP: When selecting a Prog:, the display also shows the time and date that the Program location was last tested.

NOTE: If the selected Program location does not have any thresholds defined, they must be set-up using the PROGRAM menu option before the Program can be used.

4.3 Establishing ATP Pass/Fail Limits

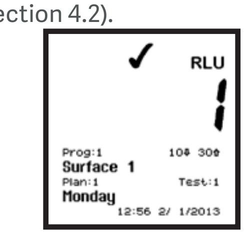
For instructions on establishing Pass/Fail limits, refer to the implementation guide included with your system, or visit the resources available on www.getinge.com.

4.4 Viewing Stored Test Results

The unit can indefinitely store a maximum of 2000 test results in its internal memory, even when the batteries are low or removed.

To view these stored test results, select the MEMORY menu option by pressing the button. Scroll to “MEMORY” and press “OK”. Then use the up and down buttons to scroll through the test results, pressing the “OK” button to exit.

TIP: After reviewing the stored test results, a failed Program location can be selected for retesting by pressing the button (see section 4.2).



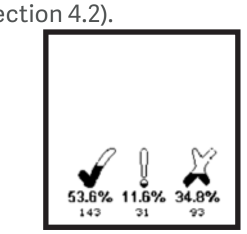
TIP: While reviewing the stored test results, a failed (×) Program location can be selected for retesting by pressing the “P” button. Refer to section 3.3 for details.

4.5 Viewing Statistics Data and Test Failures

The test results database can be analysed by selecting the STATISTICS menu option by pressing the button. Scroll to “STATISTICS” and press “OK”. This will display a simple comparison of all the stored results. The button also provides a direct shortcut to this function.

The up and down buttons can then be used to scroll through all of the failed (×) test results. Press the button to exit.

TIP: When reviewing the failed test results, a Program location can be selected for retesting by pressing the “P” button (see section 4.2).



4.6 Erasing the Test Results Memory

WARNING: Once the test results have been erased from memory they are permanently deleted and can no longer be viewed or uploaded to the Getinge SafeStep ATP Monitor unit.

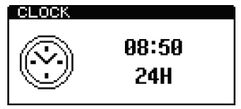
NOTE: Once started, the erase function cannot be stopped, and will take about 30 seconds to erase a full 2000 results.

The entire test results memory can be cleared using the MEMORY ERASE function, by first selecting the ✱, the using the up or down arrows to select the MEMORY menu option, then press "OK" to select, and then pressing and holding down the ✱ button for 2 seconds. The display will then show the total number of stored results to be erased. To accept and start the erase function, press and hold down the "OK" button for 1 second, or press any other button to exit the option.

4.7 Setting the Clock Time and Date

To set or change the clock time, date, and format, select the CLOCK menu option by pressing the ✱ button. Scroll to "CLOCK" and press "OK" . Then use the up and down buttons to change the time and date value, followed by the "OK" button to accept each new value.

First the time is set (style–hours–minutes), which can be configured as either a 12-hour clock (selectAM or PM) or a 24-hour clock (select 24H):



▲ ▼ AM, PM or 24H OK
▲ ▼ Hours OK
▲ ▼ Minutes OK

Next set the date format, which can be configured for either European format, select D/M/Y for day, month, year, or American format, select M/D/Y for month, day, year):

▲ ▼ D/M/Y or M/D/Y OK
▲ ▼ date (D/M/Y) or month (M/D/Y) OK
▲ ▼ month (D/M/Y) or date (M/D/Y) OK
▲ ▼ year OK

TIP: Pressing the ✱ button at any point will exit the clock set-up mode, leaving the time and date unchanged.

NOTE: The clock does not have automatic daylight saving adjustment. If this is required, the time must be manually changed when necessary.

4.8 Adjusting the LCD Contrast

The contrast of the LCD screen is factory set at its optimum level for normal operating conditions. However, in extremes of temperature the display may appear too dark or light.

This setting can be manually adjusted by selecting the LCD CONTRAST menu option by pressing the ✱ button. Scroll to "CONTRAST" and press "OK". Then use the up or down button to increase or decrease the contrast level, followed by the "OK" button to store the new setting:

▲ darker (+1 to +5)
normal (0)
▼ lighter (-1 to -5)

4.9 Quick Boot

The unit will turn on when you press the ⏻ button. The unit will perform a standard calibration in 15 seconds and will be ready to perform readings. Quick Boot can be turned off and the unit will perform a more in-depth system check the next time it is turned on. The more in-depth system check takes 60 seconds.

NOTE: The more in-depth system check is typically used for diagnostic purposes and not necessary for normal use.

To change the Quick Boot setting, select the QUICK BOOT menu option by pressing the ✱ button. Scroll to "QUICK BOOT" and press "OK" button to switch between ON and OFF:

OK OFF
OK ON
✱ Exit

5. Uploading Test Results to a PC

The test results stored in the unit's memory can be uploaded to a PC using the Getinge SafeStep ATP Monitor Results Upload Utility. This utility is supplied on the CD-ROM with the unit.

5.1 Conditions of Use

As Getinge USA, Inc has no control over the specification, state or use of any computer equipment on which this software is installed or used, the following Conditions of Use apply:

IMPORTANT
The software is provided "as is" without warranties of any kind either expressed or implied including warranties of merchantability or fitness for a particular purpose.

Getinge USA, Inc. shall not be liable for any loss of profit, loss of use, loss of software, loss of data, interruption to business, nor for indirect, special, incidental or consequential damages of any kind whether under this agreement or not.

5.2 System Requirements

System Requirements – Windows XP or later, 2 GB or more RAM recommended, and 2 GB free hard drive space (actual installation size dependent on data retained). Admin rights are required to install the software. The following item affects the availability of the software features. An ATP handheld device is required as well as an available com port or USB to com port converter. Please contact your Getinge representative if you do not have any of these components.

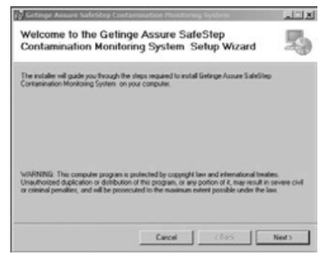
5.3 Installing the Software

Step 1. Step 1. Start Windows, and then insert the Getinge SafeStep ATP Monitoring software disc into your CD-ROM drive.

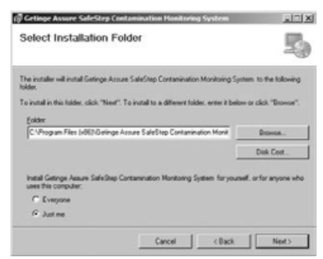
NOTE: Do not connect the handheld at this time. If the software installation does not start automatically, open your cd-drive (ex <d:>) double click setup.exe and follow the installation steps that follow.

Step 2. Accept the terms

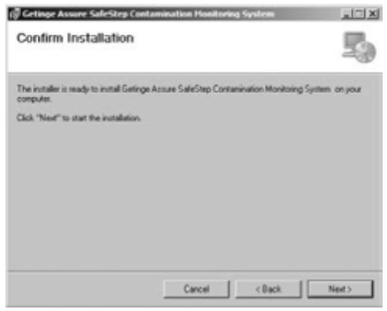
Step 3. Click Next



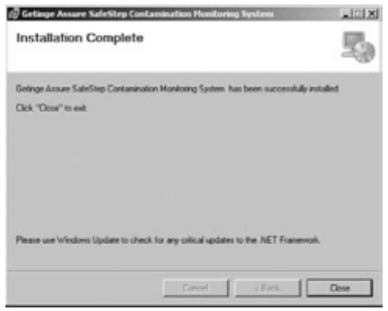
Step 4. Choose Everyone if you would like the software available for all users on the computer otherwise choose Just me. You can change the default directory to your choice of locations by hitting the Browse button. Click Next Step



Step 5. Microsoft .Net Framework 4 isrequired to be installed for the software to run. If the software is not installed, the installer will automatically install the needed software and any patches. Click Next



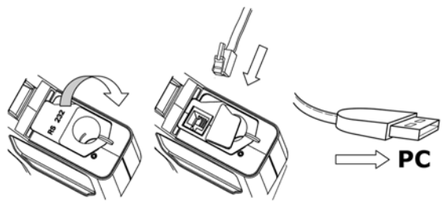
Step 6. The install of the drivers for the handheld drivers will begin. Follow the on screen prompts and the ATP install will continue to completion. Do not click to restart the computer until the installation completed. Click Close



Step 7. Click Next then finish. (Do not click to restart the computer until the installation completed.)

Step 8. Step 8. Prior to turning on the handheld unit make sure the flap is sealed over the RS232 port, and the top of the handheld is closed. Press the power button and the device will self-calibrate for 15 or 60 seconds.

To connect the handheld device please follow these simple instructions: Open the top of the device, and gently move the rubber flap back until you see the RS232 socket. Place the RJ10 plug into the RS232 socket, and connect the other end of the cable to your PC's USB port.



1. Fold back rubber cover to access RS232 socket
2. Insert small RJ10 plug into unit's RS232 socket
3. Connect other end of cable to PC's USB port

Step 9. Double click this icon to start the software.

Step 10. The first time you run the software, the default user name Admin and password 1234 will be needed and may be changed in the software users' form. This is the default Admin account so the password should be changed if you choose so.

Step 11. Hit the Enter Key after you enter your login credentials. If your ATP device was already connected prior to opening the software the serial port should be recognized and you can press Enter to continue. If the serial port is not recognized automatically, you can choose the port from the drop down list. To see what port your Getinge SafeStep ATP handheld device is connected to, follow the instructions below. The system will tell you whether the port is a valid port on the system.

a. Go to the Device Manager:
   - Windows XP: Start -> Control Panel -> System -> Hardware -> Device Manager
   - Windows 7/Vista: Start -> Control Panel -> System -> Device Manager (Top Left Panel)

b. Click on the plus sign (+) next to "Ports." If the device is installed properly, you will see Prolific USB to Serial Com Port with the port number (Ex (Com 4).

5.4 Software Functions

The Main Screen allows you to upload data, download data, run reports and manage users and hand held devices. You must be an admin to manage devices and users. All users can perform upload and download functions.

For all the functionality of the software to work, a device must be connected and the user must be an admin. If a device is not connected and the user is an admin, the features available will be admin tools & reports. If the user is not an admin, the only features available will be the reports. If the device is not registered within the software you must do so.

5.5 Registering Handheld Devices

To register a new device, login in as an administrator on the main screen and choose the Admin Tools button on the Menu Bar. You must perform the following tasks after choosing the handheld tab in Admin Tools;

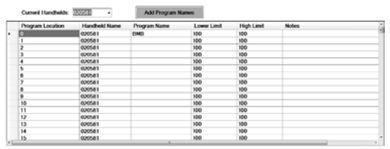
a. Click the button labeled Get Factory Data. This will register the device serial number with the database.
b. Drop down the Current Date and set the date for the handheld device.
c. Choose Default Upload Template or Current Handhelds to set the program points for the handheld. The Default Upload Template creates 5000 blank program points depending on the model of the device you have purchased. If you would like to transfer data from one hand held unit to another you can choose that handheld from the drop down list.
d. Optional description fields are available to define device properties.
e. Choose Load Handheld To Database to write the selected information to the new handheld.
f. You may delete a handheld from the database; however the recorded records will remain in the database.

a. The User management tab allows the Admin to add/ delete users from the program. Fill in the users' information and choose whether they will be an admin or user account. Assign a user name and password for each new user. You may also modify an existing user's information as well.

b. The handheld control is for diagnostic purposes only. Choose the program numbers tab to assign program names and the upper/lower limits as well as notes for the device. To do this with the device attached choose the handheld number from the current handhelds drop down box. Upon choosing the handheld you will see the records populate see below. At this time you can update the program names, lower and higher limits and notes. Upon completion of your updates click the Add Program Names button to commit to the database.

5.6 Results Data File Format

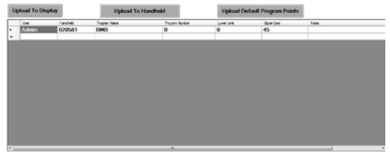
The Main Screen allows you to upload data, download data, run reports and manage users and hand held devices. You must be an admin to manage devices and users. All users can perform upload and download functions.



You can Upload and Download data to and from the handheld to the database for reporting needs.

Click the upload button in the menu bar with the ATP device connected.

a. With the handheld connected choose the Upload To Display button to see which program points have been configured and prepared for upload to the handheld. Only records modified from the Admin Tools – Program Numbers records will be uploaded.



b. Choose Upload To Handheld to commit the records displayed to the hand held device.

NOTE: The Upload Default Program Points will reset the device record and clear all the data including limits and program names. Once you do this you will need to enter the data again.

Downloading

Connect the serial interface cable (as supplied with the unit) between the Getinge SafeStep ATP Monitor handheld device and one of the USB ports on your PC.

Click the download button in the menu bar with the ATP device connected.

*Note: It is recommended downloads be done either bi-weekly or monthly.

When you click the Download button the records on the handheld will be downloaded. The system will confirm you want to download the records. You can choose to cancel the import if you choose. If you commit the records they will be written to the database and the handheld's data will be deleted.

Prior to writing the records to the database you may add notes to any of the downloaded records. Upon completion of your edits you must choose the update comments database button which will write the data to the database.

You only need to comment on the records you choose.

To access the reporting function on the software click the report button on the main screen. Reports are created based on the criteria you select including units, user and date ranges.

You can generate the report to export to excel or to print by choosing the print check box besides the generate report button.

Choose the date range from the drop down calendar and click generate report to display the data.

Choose any or all from the drop down choices to display the data you are looking to review, export or print. You can choose by unit, user, department, test status (pass or fail) and program names or numbers. You can choose to view as a graph, an export or print view. The export prints in landscape and the print is portrait.

Admin tools include handheld, user and program management. This feature is only available to admin users.

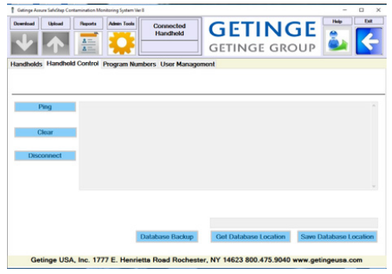
Manage users under admin tools by clicking the User. Management tab. In this tab you can set the users name, department, user name and password. You have the ability to make the user an admin. You can also delete user accounts as well.

The handheld management tab is for adding/deleting and managing the handheld devices. In the device management you can delete devices by clicking the delete handheld device. The systemtime and date can be set by the drop down for date and time. Get factory default allow you to reset the device to the factory default. Load handheld to database puts the device information in the handheld database. There is a default template upload to put a default data set into the handheld itself. Data will be downloaded from a device that is not registered, however all devices must be registered for reports to be created.

If you would like to change the path to where the data resides to another local folder or a network folder, you can modify the location in this tab by clicking the Get Database Location button and modifying that location. You must move the database folder to the new location specified.

An additional database backup is available to copy the database to a USB drive, network drive or a flash drive.

The ping, clear & disconnect commands are for testing the characteristics of a device with support.



The program numbers tab allows admins to assign program numbers to each device set. The handheld can handle 5000 program points. You can assign a template that may be assigned to another device by checking “Default Upload Template.”

Contact your Getinge representative for installation or software assistance.

Click the back arrow on the top right to close the software.

We can assist with software or hardware issues with the hardware or software that we supplied.

6. Operator Maintenance

The Getinge SafeStep ATP Monitor unit does not require any specific routine operator or service engineer maintenance.

6.1 Cleaning the Casework

Clean the unit casework when required using a dry or slightly damp cloth only.

WARNING: Never clean the unit using a wet cloth, or by washing it under running water.

CAUTION: Do not use solvents or other strong cleaning solutions as these may attack and deform the unit’s plastic components, and seriously degrade its performance.

6.2 Replacing the Batteries

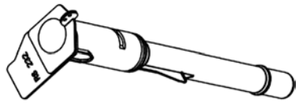
For best results, the batteries should replaced when the low battery warning icon is flashing.

Refer to section 2.4 for how to fit new batteries – taking care not to mix the old batteries with the new ones.

IMPORTANT: Always dispose of old batteries in accordance with your local authority regulations.

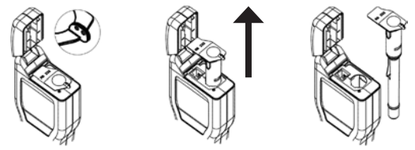
6.3 Cleaning and Replacing the Protective Pocket

The unit is designed with a special protective pocket, which can be removed for cleaning or replacement if required.



WARNING: Always turn off the unit before removing the protective pocket.

To remove the protective pocket, open the unit’s lid, tightly grasp the finger grip of the pocket, gently pull the pocket upwards, and remove it from the unit.



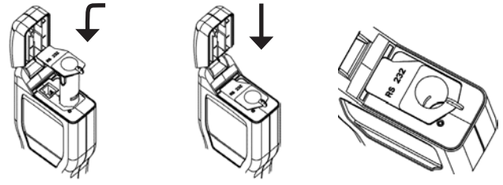
1. Grasp finger grip. 2. Pull pocket upwards. 3. Remove pocket.

CAUTION: Great care should be taken when removing the pocket not to damage it or the surrounding casework. Do not use excessive force. Never use a tool to pull the pocket out.

Carefully clean the interior of the pocket using water or a very mild detergent solution – ensuring that the pocket is completely dry and clean before placing it back into the unit.

WARNING: Do not use solvents or other strong chemicals as these will degrade the clear optical section of the pocket and affect the performance of the unit.

To replace the pocket, carefully insert the pocket ensuring that it is correctly orientated, and then push it fully down until it clicks into position.



1. Insert pocket in the orientation shown. 2. Push fully down until it clicks into place. 3. Push RS232 cover back under lip.

WARNING: Do not use excessive force when replacing the pocket. If the pocket jams during insertion, remove it fully, check for obstructions or damage, and then try again.

Finally ensure that the black rubber RS232 cover is pushed down and that the lid can be fully closed – see section 6.3.

7. Troubleshooting

This section lists typical problems that might be encountered when using the unit, and their possible causes.

Some problems and causes can be rectified by the operator, while others may require technical assistant:

Severity	Action Required
✔	This indicates a cause which can be rectified by the operator.
✖	This indicates a cause which may require technical attention for rectification. Contact your Gteinge representative

7.1 Unit Beeps

During normal use, the unit emits a variety of different beeping sounds:

Beep Type	Possible Causes
Short high-pitched tone	✔ Unit turned on or off ✔ Sample measurement started ✔ Communications established with PC ✔ Results memory being erased
Long high-pitched tone	✔ Unit self-calibration complete ✔ Sample measurement complete ✔ Results memory erase complete
Long low-pitched tone	✔ Invalid date entered ✔ Program thresholds not set-up ✔ Invalid program threshold limits entered ✔ Attempting to select a non-failed (pass/caution) result for retesting
Two short high-pitched tones	✔ Self-calibration required – remove Test® Swab device and close the lid
Three short high-pitched tones	✔ Clock set-up required ✔ Batteries are flat ✔ Memory full warning ✔ Memory erase requested ✔ Unit error (see section 7.3)

7.2 Troubleshooting Tips

If the unit appears to be malfunctioning for any reason, carry out a thorough check for any obvious damage to the case, LCD display, lid, etc., caused by dropping or excessive physical mishandling.

The following table lists typical symptoms and their possible causes.

Symptom	Possible Causes
Unit will not turn on when the button is pressed	✔ Batteries are flat ✔ Batteries are the wrong type ✔ Batteries inserted incorrectly ✖ Unit or keypad damaged or faulty
Unit will not turn off when the button is pressed	✔ Unit is busy performing a reading or self-calibration operation ✔ Unit lockup – remove the batteries for 10 seconds, then insert them again ✖ Unit or keypad damaged or faulty
Unit turns off unexpectedly	✔ Batteries are flat ✔ Batteries are loose within the battery compartment ✔ Unit dropped or subjected to shock or vibration ✔ Unit not used for 10 minutes and automatically turns off into standby mode ✖ Unit damaged or faulty
Unit beeps when turned on, but nothing is displayed	✔ Batteries are flat ✖ Unit or display damaged or faulty
The real time clock reverts to 12:00 01/01/2000	✔ Batteries have been replaced ✔ Batteries are flat ✔ Batteries are loose within the battery compartment ✔ Unit dropped or subjected to shock or vibration ✖ Unit or display damaged or faulty
The display appears washed out or very dark	✔ Unit is too hot or too cold ✔ LCD contrast incorrectly adjusted (see section 4.6) ✔ Unit is being used in inappropriate lighting ✖ Unit or display damaged or faulty
Display segments missing or garbage displayed	✔ Display window is dirty ✖ Display window is scratched or dented ✖ Display or unit damaged or faulty
Keypad button has no effect when pressed	✔ Some buttons only work when electing particular unit functions ✔ Lid not fully closed ✖ Keypad or unit damaged or faulty
Unit lid will not close properly or springs open during use	✔ Protective pocket incorrectly or not fully inserted ✔ RS232 connector cover is interfering with the lid (see section 6.3) ✔ Test® Swab device incorrectly or not fully inserted ✖ Lid or unit casework damaged
Measurement result is always zero RLU, or is much lower than expected	✔ Incorrect use of Test® Swab device ✔ Unit being used in an unstable ✔ Unit not in upright position when measurement taken ✔ Test® Swab device is out-of-date ✔ Unit being used in an unstable thermal environment – turn the unit off and back on again ✔ Protective pocket or Test Swab device not fully inserted into unit ✔ Protective pocket dirty or severely scratched ✖ Protective pocket damaged ✖ Unit damaged or faulty
Measurement result is higher than expected	✔ Incorrect or inconsistent use of the Test® Swab device ✔ Lid not fully closed ✔ Unit being used in an unstable thermal environment – turn the unit off and back on again ✖ Unit casework or lid damaged or faulty
RS232 interface does not appear to be working	✔ Wrong interface cable being used ✔ Cable connector incorrectly inserted into unit ✔ Cable connected to wrong port on PC ✔ Wrong PC software being used ✔ PC software incorrectly installed or wrong options selected ✖ Cable or connectors damaged or broken ✖ PC serial port or system software faulty ✖ Unit damaged or faulty

7.3 Unit Error Codes

During normal operation, the unit performs various self-checks on its internal components. If a problem is detected, the display will show an error number:

TIP: Most problems are likely to be transitory, and can be cleared by pressing the button, or by removing the batteries for 30 seconds and then reinserting them.

If any problem persists, please contact your Getinge representative for technical assistance, giving full details of the error code.

Error Code	Possible Causes
E1	Not applicable on the Getinge SafeStep ATP Monitor unit
E2 Temperature out of range	✔ The unit is being used outside of the specified operating temperature range (see section 10) ✔ The unit has been stored in an environment which is outside of its specified operating temperature range –allow unit to acclimatise before use ✖ Unit damaged or faulty
E3 Erratic measurement	✔ Unit environment unstable or used in an area of high electromagnetic noise ✔ Unit tilted whilst measurement being performed ✔ Unit lid damaged and allowing light in ✔ Protective pocket dirty or severely scratched ✖ Unit damaged or faulty
E4 User settings undefined	✔ The user configurable settings are undefined - check and re-set the CLOCK format, USER#, PLAN# and PROG# data
E5 Program or User ID undefined	✔ Program thresholds not defined, and have been reset to the default values (100↑ and 100↓) ✔ User ID not defined
E6 Calibration self-checks failed	✔ Unit operating environment unstable ✔ Protective pocket dirty or severely scratched ✔ Lid not fully closed ✖ Lid seal damaged ✖ Protective pocket damaged ✖ Unit damaged or fault
E7 Internal memory failure	✔ Batteries are flat or loose ✖ Unit's memory damaged or faulty
E8 Internal reader fault	✔ Batteries are flat or loose ✖ Unit's sample reader is damaged or faulty
E9 Internal error	✔ Batteries are flat or loose ✔ Unit dropped or subjected to shock or vibration ✖ Unit's damaged or faulty

8. Unit Warranty and Returns

The Supplier warrants the Getinge SafeStep ATP Monitor unit, when purchased new, to be free from defects in materials and workmanship, and will repair or replace, at their discretion, any SafeStep ATP Monitor unit which, used under proper conditions, exhibits such defects.

Under the terms of this warranty, the product must be returned in the original packaging, transportation prepaid, with a copy of the Proof of Purchase, to your local distributor.

Contact Getinge USA, Inc to receive authorisation to return the instrument, and enclose a detailed description of the problem.

8.1 Warranty Duration

This warranty is provided to the original purchaser for one year from the date of purchase.

In no event will Getinge USA, Inc be liable for indirect, incidental or consequential damages; the original user's remedies being limited to repair or replacement of the unit at the manufacturer's option.

8.2 Particular Exclusion

Unauthorised modification of any part of the SafeStep ATP Monitor unit or the use or attachment of any peripheral not supplied or specified by Getinge USA, Inc will void this Warranty.

WARNING: Use only the accessories and consumables supplied by Getinge USA, Inc. The use of any non Getinge USA, Inc supplied accessories and consumables will invalidate the warranty.

9. Glossary of Terms and Abbreviations

ATP	Adenosine Triphosphate – energy carrier molecule
Device	The Test® Swab sample collection and chemistry reaction device
EMC	Electro-Magnetic Compatibility
fmol	Femtomole (10-15 moles)
HACCP	Hazard Analysis Critical Control Point
LCD	Liquid Crystal Display
NiCD	Nickel Cadmium rechargeable batteries
NiMH	Nickel Metal Hydride rechargeable batteries
PC	IBM compatible personal computer of Pentium 1 specification or higher, running Windows 98 or later
Reading	Measurement value in RLUs
Result	Measurement pass (✔), fail (✖) or caution (!)
RLU	Relative Light Units (unit of measurement)
RS232	Serial communications protocol for connecting the unit to a PC, used for uploading test results data
USB	Universal Serial Bus used to connect computer peripherals to a PC
Unit	The Getinge SafeStep ATP Monitor unit

10. Technical Specifications

General:

Unit dimensions (W x H x D)	72mm x 191mm x 32mm
Unit weight (including batteries)	approx. 260g
Operating temperature range Relative Humidity range	5°C to 40°C 20 - 85%, non-condensing
Storage temperature range Relative Humidity Range	-10°C to 40°C 20 - 95%, non-condensing

Unit Details:

Measurement range	0 to 9999 RLUs
Measurement resolution	1 RLU
Measurement time	15 seconds
Measurement noise	±5% or ±5 RLUs
Programmable result thresholds	251 programs
Programmable location names	251 names of 20 characters
Results memory size	2000 tests
Serial interface	EIA-232 compatible

Batteries:

Battery Size (2 off)	AA, LR6 or E91
Battery Types Non-rechargeable Rechargeable (externally charged)	 nom. 1.5V Alkaline nom. 1.2V NiMH or NiCD
Battery Capacity (for 2600mAh) Standby mode (at 20°C) Continuous reading	 min. 6 months min. 500 tests

REVA

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