Operating Precautions and Limitations of Use

IMPORTANT: Hygiena's products are designed and constructed to be safe and without risk to health when properly used in accordance with the supplied documentation and when the operating precautions outlined in this manual are fully observed.

<div style="border:2px solid black; padding:1em;">

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 BEFORE ATTEMPTING TO OPERATE THE UNIT.

IF THE UNIT IS USED IN A MANNER WHICH IS NOT SPECIFIED BY THE MANUFACTURER, THE PROTECTION PROVIDED BY THE EQUIPMENT MAY BE IMPAIRED.

</div>

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 Ultrasnap 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 vapours.

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 or operator the unit in 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 Ultrasnap Devices

CAUTION: Refer to the Ultrasnap data sheet and kit insert for details before using the device, and observe all federal, state and local environmental regulations.

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

CAUTION: Ensure that the Ultrasnap 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 warrantee.

WEEE Directive Compliance

The SystemSURE Plus unit should be disposed of in accordance with the European Union WEEE 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. Please contact your local distributor for details of how to correctly dispose of this product.

Regulatory Limitations of Use

The SystemSURE Plus 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	• EN 61000-4-2:1995 + A1

The SystemSURE Plus unit is manufactured under ISO 9001 controls.

Declaration of Conformity

The SystemSURE Plus 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 harmonisation 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 SystemSURE Plus 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)
Radiated Emissions	(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 SystemSURE Plus is intended to help the operator demonstrate due diligence and compliance with HACCP and other Hygiene regulations by allowing simple hygiene monitoring via the use of an ATP bioluminescent test.

The SystemSURE Plus system consists of two elements: the disposable Ultrasnap device and the handheld reader unit.

This Operator's Manual provides a detailed description of how to use the SystemSURE Plus unit, and how to handle maintenance and troubleshooting.

For full details on the Ultrasnap device, please refer to the Ultrasnap data sheet and kit insert.

For any additional technical assistance, please contact your local distributor.

1.1 Key Unit Features

The main features of the SystemSURE Plus unit are:

- ♦ Small and lightweight reader
- ♦ Large clear liquid crystal display
- ♦ Highly sensitive luminometer
- ♦ Short measurement time – just 15 seconds
- ♦ Internal calibration self-check light source
- ♦ 251 user programmable result thresholds
- ♦ Large 2000 test result memory
- ♦ 20 test plans of up to 251 locations each
- ♦ 50 User IDs
- ♦ 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 local distributor for details of unit accessories and consumables.

1.3 Principle of Operation

The Ultrasnap 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 SystemSURE Plus unit to produce both a quantitative and qualitative result.
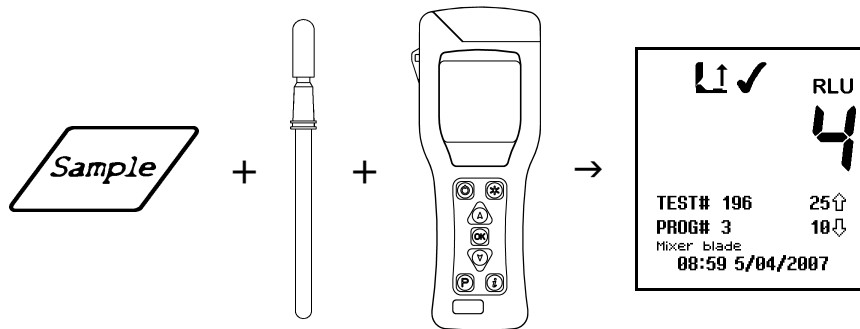
The quantitative result is a number in the range 0 to 9999, expressed in terms of Relative Light Units (RLUs).

Although RLUs are not a recognised 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 (✓), caution (!) or fail (✗) result.

PLEASE NOTE

The SystemSURE Plus 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.
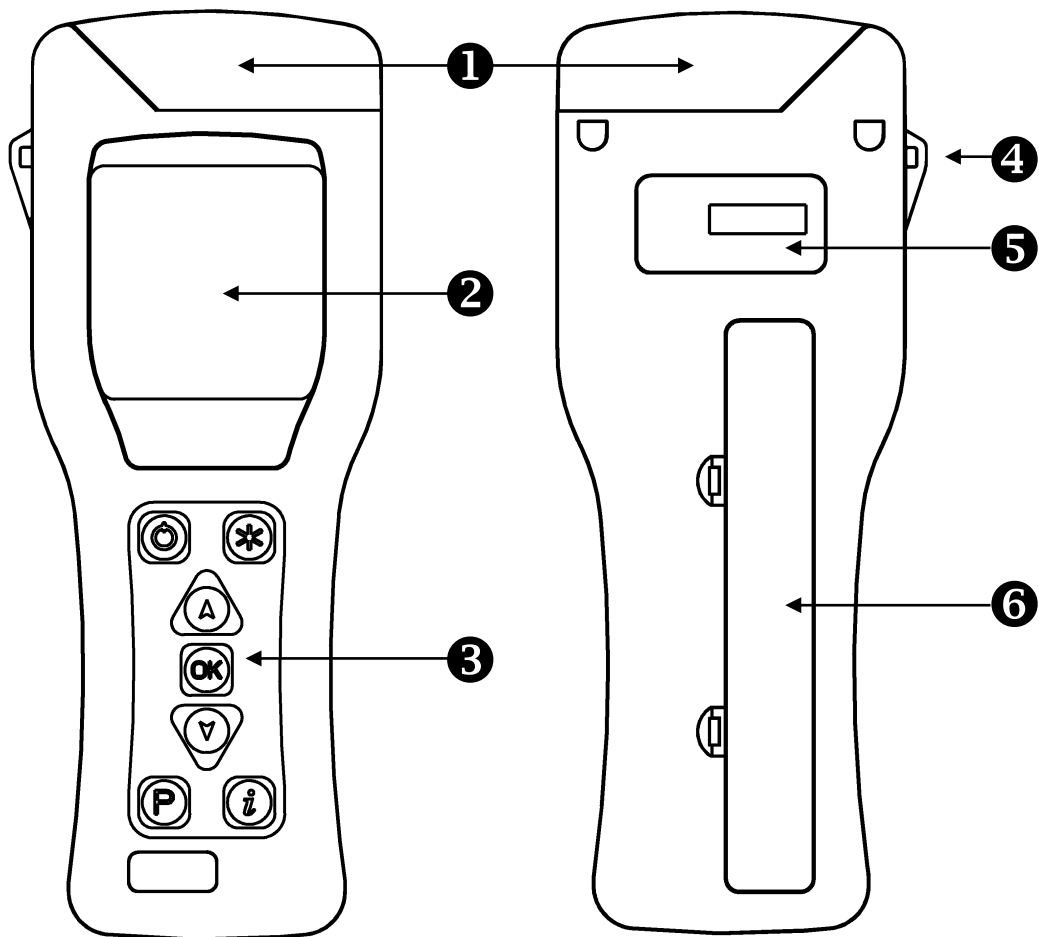
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2. Basic Unit Operation

<div style="border:1px solid black;">

<u>IMPORTANT</u>

Please ensure that you have read and understood all of the "Operating Precautions and Limitations of Use" at the beginning of this manual before continuing any further.
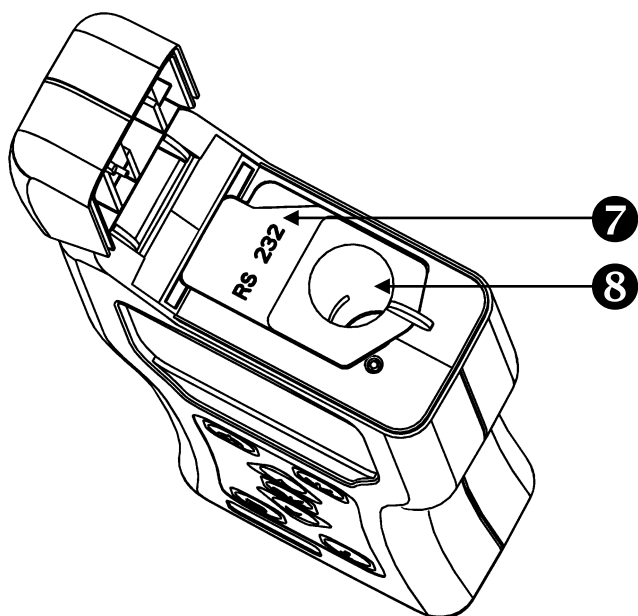
</div>

2.1 Unit Description

The unit has the following front and rear external features:

❶	Unit lid	❹	Neck strap anchor
❷	Liquid crystal display	❺	Serial number label
❸	Keypad	❻	Battery compartment

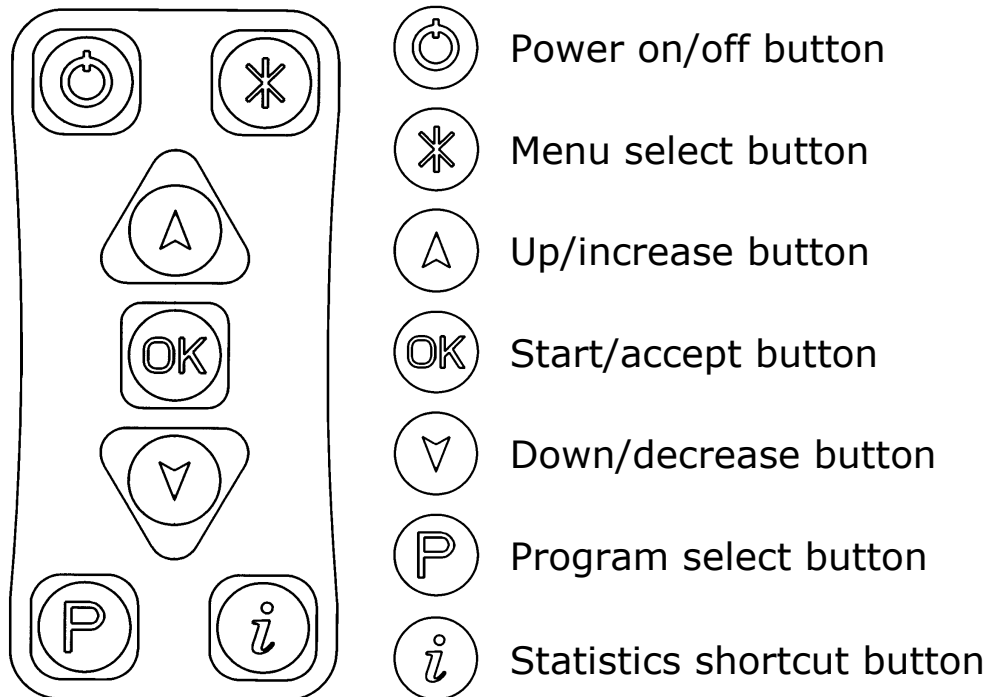Opening the lid reveals the following internal features:

➐   RS232 connector cover

➑   Protective pocket and sample insertion port

For details on the RS232 connector and protective pocket, refer to sections 5 and 6.3 respectively.

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 functions of these buttons are explained in detail in the following sections of this manual.

TIP: Pressing and holding down the Ⓐ or Ⓥ button will make it auto-repeat. The longer you hold it down, the faster it goes.

2.3 Display Layout and Icons

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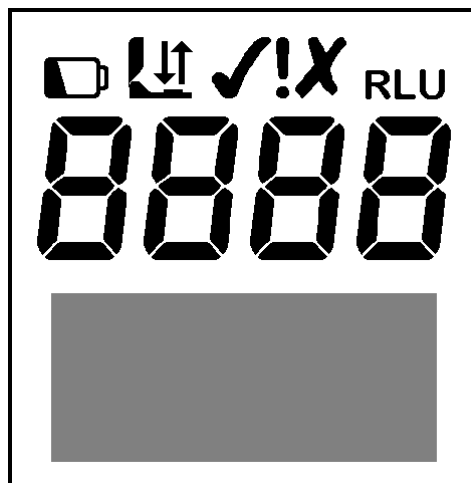
The upper half of the display contains the status icons and the large RLU result digits:

Icon	Description
🔋	Low battery warning icon
∟	Lid icon - flashes when the lid needs to be closed
⬇	Insert icon – arrow flashes when the Ultrasnap device should be inserted
⬆	Remove icon – arrow flashes when an Ultrasnap device needs to be removed
✓	Pass result icon
!	Caution result icon
✗	Fail result icon
8888 RLU	Sample measurement reading in Relative Light Units (RLUs)
Ⓡ (boxed R)	Retested icon – identifies the failed test result as having been retested
Ⓡ (circled R)	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	1.5V	1.0
NiMH	1.2V	0.6
NiCD	1.2V	0.5

The unit requires two batteries of 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 cover on the back of the unit, and inserting both batteries with their positive terminals (✚) pointing towards the top of the unit:
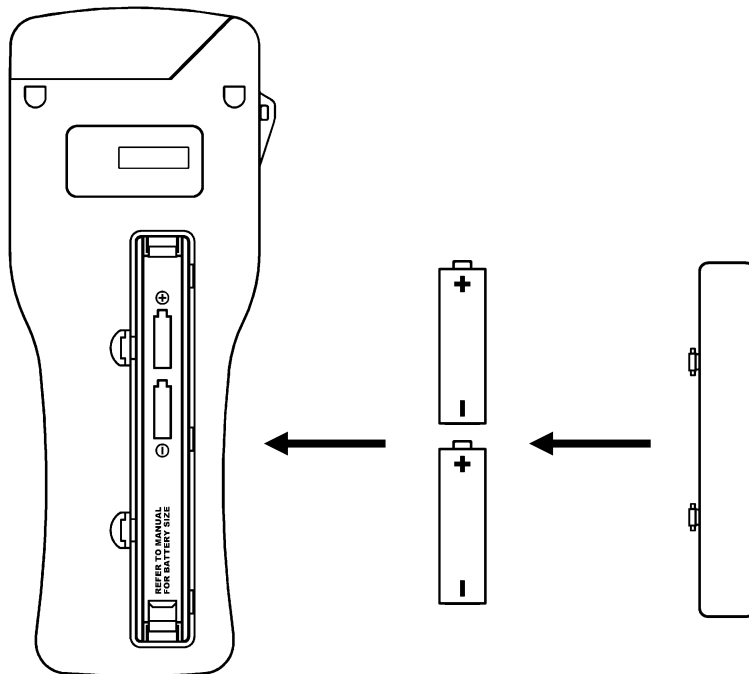
(1) Remove cover   (2) Insert batteries   (3) Replace cover

⚠ **CAUTION**: Take care not to insert the batteries the wrong way round, as this may cause permanent damage to the unit's internal electronics.

When the batteries are inserted correctly, the unit will automatically turn on and enter the clock set-up mode. Refer to section 4.7 for how to set the time and date.

2.5 Turning the Unit On

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

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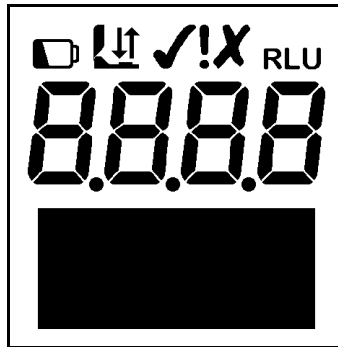
The unit will then perform its internal calibration self-checks (see section 2.7 below).

NOTE: If the clock is not set, the unit will automatically enter the time and date set-up mode (see section 4.7) before performing its calibration self-check.

2.6 Low Battery Indicator

The low battery 🔋 icon indicates the state of the batteries:

🔋 Icon	→	Battery State
Not visible	→	Good
Visible	→	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:
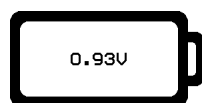
⚠ **CAUTION**: Never leave flat batteries in the unit, as they are prone to leaking/corrosion, which will damage the unit.

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 Calibration Self-Checks

When the unit is turned on (see section 2.5), it performs a series of internal calibration self-checks, as the display counts down from 60 to 0 seconds:
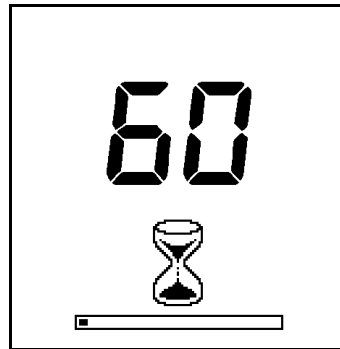
NOTE: During the self-check sequence, there must not be an Ultrasnap device in the unit and the lid must remain closed. If the ▌↑ icon is shown with the arrow flashing, open the lid and remove the Ultrasnap device from the unit. If the ▌_ icon is flashing, close the lid.

TIP: The ⊛ 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:
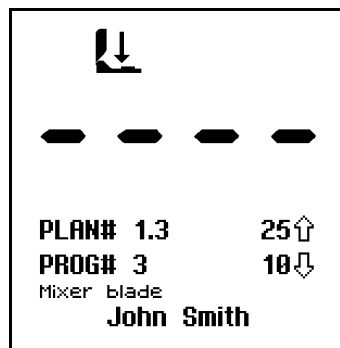
Please refer to section 3 for details of how to perform a sample measurement.

NOTE: When the unit is ready to perform a measurement, with the lid closed and no Ultrasnap device present, the unit will automatically perform a *zeroing* cycle under any 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 ⟳ button. The unit will beep once and the display will go blank.

NOTE: To avoid accidental turn off, the ⟳ 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 10 minutes, it will automatically enter a power saving standby mode and the display will go blank.

To exit standby mode and turn the unit back on, simply press the ⟳ button, as per section 2.5.

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:
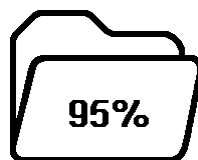
When the memory becomes completely full, no more tests can be performed until the memory is either erased or uploaded to the PC. Refer to sections 4.5 and 5 respectively.

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	↧	
	━ ━ ━ ━	*Ready for new test*
Test Plan and step	PLAN# 1.3 25⇧	*Upper threshold*
Program location	PROG# 3 10⇩	*Lower threshold*
User ID	Mixer blade John Smith	
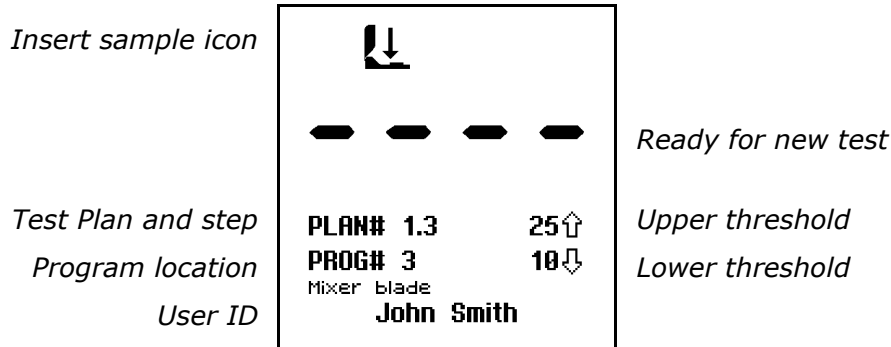
Various keypad options are now available, as detailed in each of the following sections:

Button	Action	Section
✳	Access set-up menu options	4
✳ *User ID*	Select different User ID	4.1
✳ *Test Plan*	Select different Test Plan	4.2
Ⓟ	Select program number	3.1 / 3.2
OK *1 Second*	Perform *zeroing* cycle	2.7
OK *+Sample*	Start new measurement	3.3
△ ▽	View previous test results	4.4
ⓘ	Show statistical result data	4.6
◎	Turn unit off	2.8

3.1 Programmable Test Locations

The unit can store up to 251 individual programmable test locations (numbered **PROG# 0** to **PROG# 250**).

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**, **Caution** or **Fail** result:

RLU Banding		Result
Reading $\leq$ lower threshold (⇩)	✔	Pass
Reading $>$ lower threshold (⇩) but $\leq$ upper threshold (⇧)	!	Caution
Reading $>$ upper threshold (⇧)	✗	Fail

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

To set-up the Program thresholds, refer the section 4.3.

To select a Program location press the Ⓟ button, then use the Ⓐ and Ⓥ buttons to change the Program **PROG#** to the desired Program location, followed by the ⓄⓀ button to accept the new location, or the Ⓟ button to cancel the selection.

```
                          25⇧
PROG# 3            10⇩
Mixer blade
   11:19 5/04/2007
```
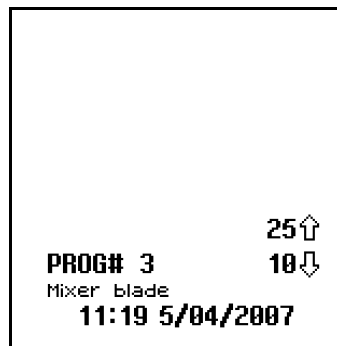
TIP: Whilst selecting a **PROG#**, the display also shows the time and date that the Program location was last tested.

NOTE: If the selected Program location does not have any thresholds defined, they must be set-up using the **PROGRAM** menu option (see section 4.3) before the Program can be used.

3.2 Using Test Plans

The unit can also store up to 20 individual Test Plans (numbered **PLAN# 1** to **20**), each consisting of a list of up to 251 Program locations, specified in the order in which each location should be tested.

An example set of Test Plans for a typical week might be:

PLAN# 1 Monday	PLAN# 2 Tuesday	PLAN# 3 Wednesday	PLAN# 4 Thursday	PLAN# 5 Friday
PROG#1	PROG#1	PROG#2	PROG#3	PROG#4
PROG#2	PROG#7	PROG#8	PROG#9	PROG#5
PROG#3	PROG#6	PROG#5	PROG#4	PROG#6
PROG#7		PROG#10		PROG#9
PROG#8				PROG#8
PROG#9				PROG#7
PROG#6				PROG#3
PROG#5				PROG#2
PROG#4				PROG#1
PROG#10				

Test Plans are defined by using the **SureTrend** Windows software. Please refer to the separate SureTrend User's Manual for full details.

To select a Test Plan, use the **TEST PLAN** menu option, as described in section 4.2.

NOTE: If Test Plan **PLAN#0** is selected, or no Test Plans have been defined, any of the 251 Program locations can be selected, as detailed in section 3.1.

To select a location within the Test Plan, press the Ⓟ button and use the Ⓐ and Ⓥ buttons to change the **PLAN#** and associated Program location **PROG#**, followed by the ⓄⓀ button to accept the new location, or the Ⓟ button to cancel the selection.

```
PLAN# 1.3        25⇧
PROG# 3          10⇩
Mixer blade
   11:19 5/04/2007
```
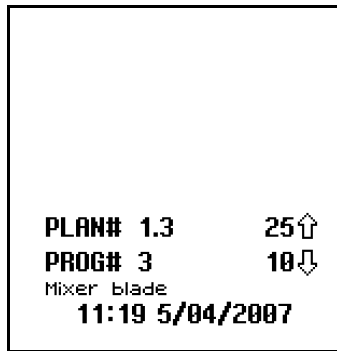
TIP: Whilst selecting a **PROG#**, the display also shows the time and date that the Program location was last tested.

NOTE: If the selected Test Plan Program location does not have any thresholds defined, they must be set-up (see section 4.3) before the location can be tested.
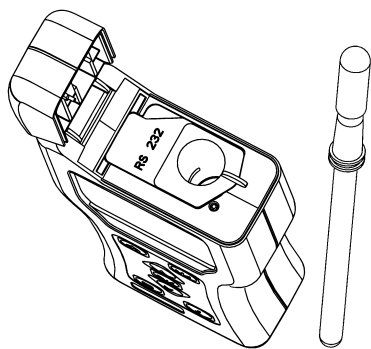
3.3 Taking a Sample Measurement

IMPORTANT: Please refer to the Ultrasnap data sheet and Kit Insert for full details of how to use the Ultrasnap 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:

- ❑ Swab the sample area and activate the Ultrasnap device (see Kit Insert for details)
- ❑ Open the unit lid, insert the Ultrasnap device into the unit, and close the lid
- ❑ Press the ⓞⓚ button and wait 15 seconds for the result to be displayed

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

Whilst the measurement is being performed, the display counts down from 15 to 0:
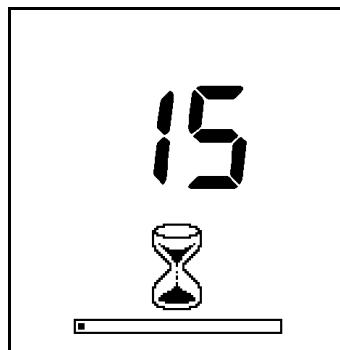
NOTE: For consistent results, <u>always keep the unit **upright and steady** whilst it is performing a measurement</u> to ensure that the liquid in the Ultrasnap device is at the bottom of the tube.

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

TIP: A failed test result (✗) can be selected for retesting by pressing the Ⓟ button, followed by the ⓄⓀ button to select the Program location. See section 3.4 for details.

Now remove the Ultrasnap 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 an Ultrasnap device.

Previous test results can be viewed by pressing the Ⓐ and Ⓥ buttons (see section 4.4), or the results statistical data can be obtained by pressing the ⓘ button (see section 4.6).

TIP: The unit can be *re-zeroed* by removing the Ultrasnap 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.
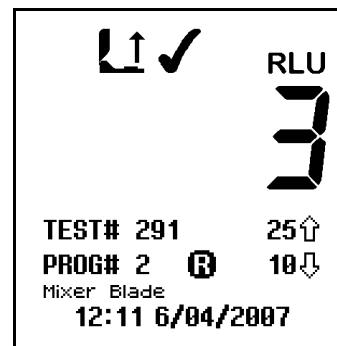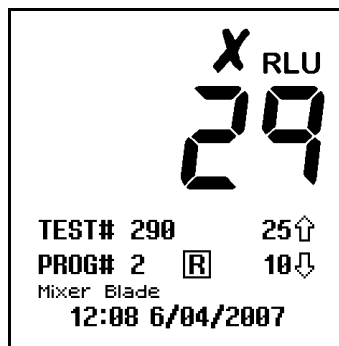
3.4 Performing a Retest

When viewing a failed (✗) test result (see sections 4.4 and 4.6), the program location can be selected for retesting by pressing the (P) button, followed by the (OK) button:

```
                          25⇧
      PROG# 2    ®    10⇩
      Mixer Blade
          12:08 6/04/2007
```
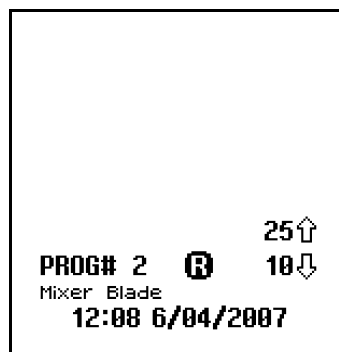
NOTE: It is only possible to select a program location for retest if the most recent test result for that location was a failure (✗).

Having selected retest mode (signified by the ® icon next to the **PROG#**), perform the sample measurement in the usual way, using a new Ultrasnap device, as described in section 3.3.

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:

```
        ✗ RLU                        ⌐↑✓ RLU

       29                              3

   TEST# 290      25⇧           TEST# 291      25⇧
   PROG# 2  ☒   10⇩            PROG# 2   ®   10⇩
   Mixer Blade                  Mixer Blade
       12:08 6/04/2007              12:11 6/04/2007
```
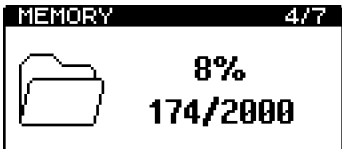
NOTE: Retest mode is automatically deselected once the new measurement is complete, or can be manually cancelled by pressing the (P) button and selecting a new program location (see sections 3.1 and 3.2).

4. Set-up Menu Options

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

The following seven menu options are then available:

USER ID 1/7 — USER# 1 — John Smith	Select User ID
TEST PLAN 2/7 — PLAN# 1 — Monday	Select Test Plan
PROGRAM 3/7 — PROG# 0 — 10⇩ 30⇧	Define Program limits
MEMORY 4/7 — 8% — 174/2000	View stored test results
STATISTICS 5/7	View statistical data
CLOCK 6/7 — 08:50 — 5/04/2007	Set clock time and date
LCD CONTRAST 7/7 — 0	Adjust LCD contrast

Use the ⒶA and ⒱V buttons to scroll through the menu list, and then press the ⓄⓀ button to select the required menu option, or the ✳ button the exit the menu.

4.1 Selecting a User ID

The unit can store a list of up to 50 User IDs, allowing each test result can be tagged with the ID of the individual test operator.

PLEASE NOTE: The User ID list can only be defined by using the **SureTrend** Windows software. For further details, please refer to the separate SureTrend User's Manual.

Having selected the **USER ID** menu option (see section 4), use the Ⓐ and Ⓥ buttons to scroll through the list of User IDs, then press the ⓄⓀ button to select the new User ID, or the ✳ button to cancel the selection.

TIP: **USER#0** is the default selection if no User ID list has been defined. This allows **Any User** to operator the unit.

4.2 Selecting a Test Plan

The unit can be loaded with up to 20 different Test Plans, (numbered **PLAN# 1** to **20**) each consisting of between 1 and 251 test locations, specified in the order in which they would normally be tested.

PLEASE NOTE: Test Plans can only be defined by using the **SureTrend** Windows software. Please refer to the separate SureTrend User's Manual for further details.

Having selected the **TEST PLAN** menu option (see section 4), use the Ⓐ and Ⓥ buttons to scroll through the list of Test Plans, and then press the ⓄⓀ button to select the new Plan, or the ✳ button to cancel the selection.

TIP: **PLAN#0** allows any of the 251 test locations to be tested in any order, and is the default selection if no Test Plans have been defined or selected.

Please refer to section 3.2 for details of how to select each Program location within a selected Test Plan.

4.3 Defining Program Limits

The unit has the ability to store a list of up to 251 Program test points (numbered **PROG# 0** to **250**), each with its own upper (⇧) and lower (⇩) result threshold values and location name.

The Program result thresholds can either be set-up on the unit (see below), or downloaded using the **SureTrend** or **dataSURE II** Windows software.

PLEASE NOTE: The associated location names can only be defined by using the **SureTrend** software. Please refer to the separate SureTrend User's Manuals for further details.

For details of how to use the Program settings, please refer to section 3.1.

TIP: **PROG#0** has a special function, whereby the threshold values defined for **PROG#0** are used as the initially 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.

To set the Program result thresholds on the unit, first select the **PROGRAM** menu option (see section 4), then use the Ⓐ and Ⓥ buttons to scroll through the list of Programs, followed by the ⓄⓀ button to select the Program to be changed:

Ⓐ Ⓥ **PROG#** ⓄⓀ
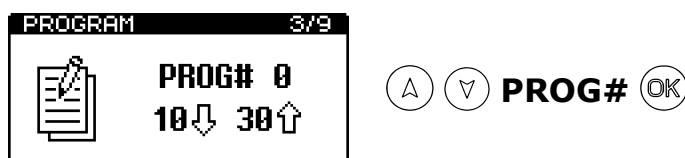
Next use the Ⓐ and Ⓥ buttons to first change the value of the upper threshold (⇧), followed by the ⓄⓀ button; and then to change the value of the lower threshold (⇩), followed by the ⓄⓀ button to store the new values:

Ⓐ Ⓥ upper threshold (⇧) ⓄⓀ
Ⓐ Ⓥ lower threshold (⇩) ⓄⓀ

TIP: Pressing the Ⓧ button at any point will exit this set-up mode, leaving both the **PROG#** and thresholds unchanged.

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 flat or removed.

To view these stored test results, select the **MEMORY** menu option (see section 4), then use the Ⓐ and Ⓥ buttons to scroll through the test results, pressing the Ⓞⓚ button to exit:

```
                ✓    RLU

                    4

TEST# 196        25⇧
PROG# 3          10⇩
Mixer blade
    08:59 5/04/2007
```
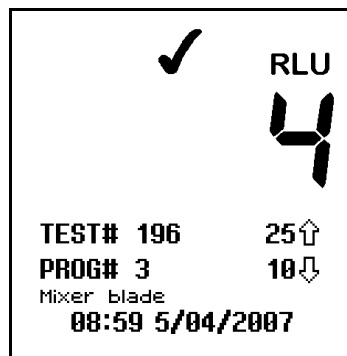
TIP: Whilst reviewing the stored test results, a failed (✗) Program location can be selected for retesting by pressing the Ⓟ button. Refer to section 3.4 for details.

4.5 Erasing the Test Results Memory

The entire test results memory can be cleared using the **MEMORY ERASE** function, by first selecting the **MEMORY** menu option (see section 4.4) and then pressing and holding down the Ⓧ button <u>for 2 seconds</u>. The display will then show the total number of stored results to be erased:

```
            279

    MEMORY ERASE?
      📁 ➝ 🗑
```
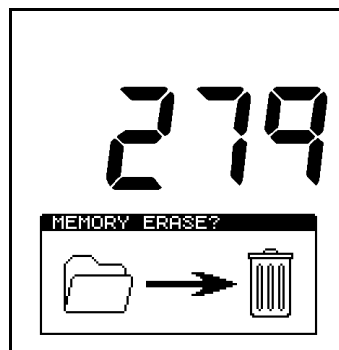
To accept and start the erase function, press and hold down the
(OK) button for 1 second, or press any other button to exit the
option.

WARNING

Once the test results have been erased from memory they
are permanently deleted and can no longer be viewed or
uploaded to a PC.

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

4.6 Viewing Statistics Data and Test Failures

The test results database can be analysed by selecting the
STATISTICS menu option (see section 4) to display a simple
comparison of all the stores results:
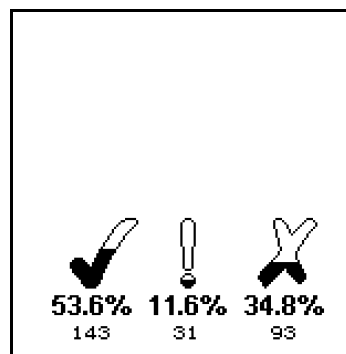
TIP: The (i) button also provides a direct shortcut to this
function.

The (A) and (V) buttons can then be used to scroll through all of
the failed (✗) test results, pressing the (OK) button to exit:
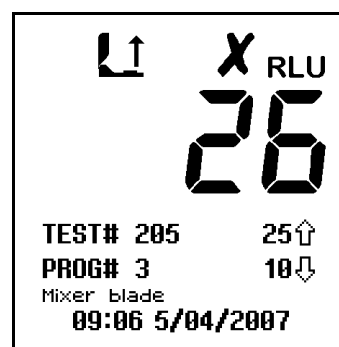
TIP: Whilst reviewing the failed test results, a Program location can be selected for retesting by pressing the ⓟ button. Refer to section 3.4 for details.

4.7 Setting the Clock Time and Date

To set or change the clock time, date, and format, select the **CLOCK** menu option (see section 4). Then use the Ⓐ and Ⓥ buttons change each time and date value, followed by the ⓄⓀ button to accept each new value in turn.

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

```
CLOCK
       08:50
        24H
```
Ⓐ Ⓥ **AM**, **PM** or **24H** ⓄⓀ
Ⓐ Ⓥ hours ⓄⓀ
Ⓐ Ⓥ minutes ⓄⓀ
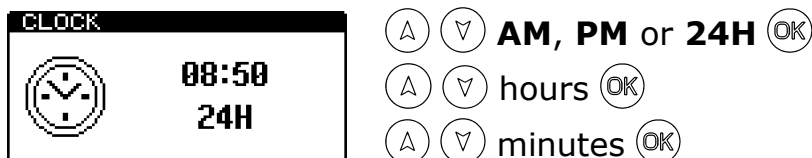
Next the date is set (format → date/month → month/date → year), which can be configured for either European format (select **D/M/Y** for date, month, year) or American format (select **M/D/Y** for month, date, year):

```
CLOCK
      D/M/Y
    5/04/2007
```
Ⓐ Ⓥ **D/M/Y** or **M/D/Y** ⓄⓀ
Ⓐ Ⓥ date (D/M/Y) or month (M/D/Y) ⓄⓀ
Ⓐ Ⓥ month (D/M/Y) or date (M/D/Y) ⓄⓀ
Ⓐ Ⓥ year ⓄⓀ
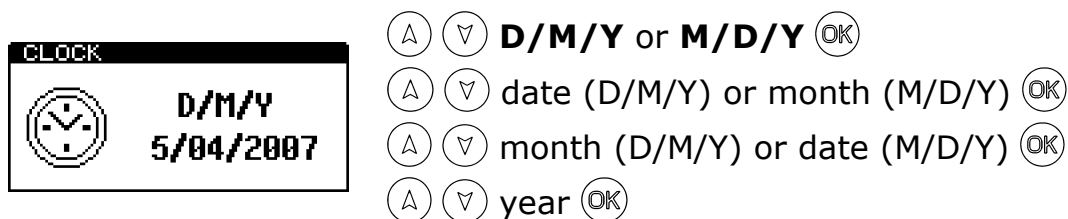
TIP: Pressing the ✳ button at any point will exit the clock set-up mode, leaving the time and date unchanged.

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 (see section 4) and using the Ⓐ or ⓥ button to increase or decrease the contrast level, followed by the ⓄⓀ button to store the new setting:
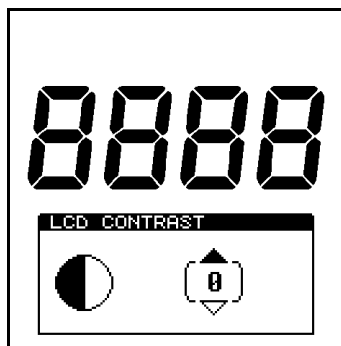
Ⓐ darker   (**+1** to **+5**)

⇅ normal   (**0**)

ⓥ lighter   (**-1** to **-5**)

5. Uploading Test Results to a PC

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

NOTE: Although the screen shots in this section relate to Windows XP, the software can also be used on other versions of Microsoft Windows, such as Windows 98 and 2000.

5.1 Conditions of Use

As Hygiena LLC 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:

<u>IMPORTANT</u>

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.

Hygiena 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 Installing the Results Upload Utility

IMPORTANT: By installing this software, you are deemed to be in acceptance of the Conditions of Use specified in section 5.1 above. Do not install this software if you are not in agreement with these conditions.

NOTE: If you already have a previous version of the Results Upload Utility installed on your PC, it is highly recommended that you uninstall it <u>before</u> installing the new version. See section 5.5 for details.

The software is installed onto your computer by inserting the CD into your CD-ROM drive and following the installation script screen prompts. If the install script does not automatically start, open the CD-ROM folder from the **My Computer** icon on the PC desktop and run the **Install** application.

Once installed, the new software is run by clicking on the SystemSURE Results Upload Utility shortcut from the Windows *start* menu:
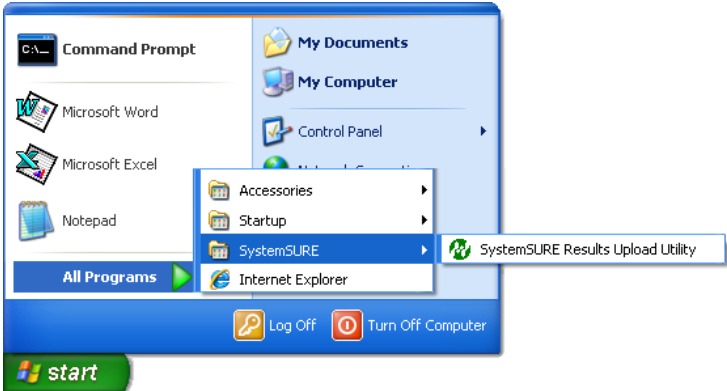
TIP: This software can be used with both the SystemSURE Plus and systemSURE II units.

5.3 Using the Results Upload Utility

Running the upload utility from the Windows *start* button brings up the following software dialogue box:
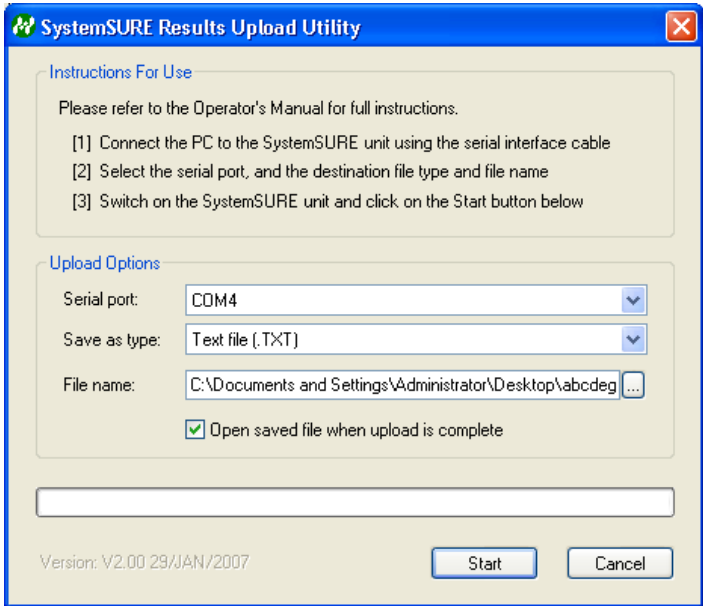
Now connect the serial interface cable (as supplied with the unit) between the SystemSURE Plus unit and one of the RS232 or USB ports on your PC:
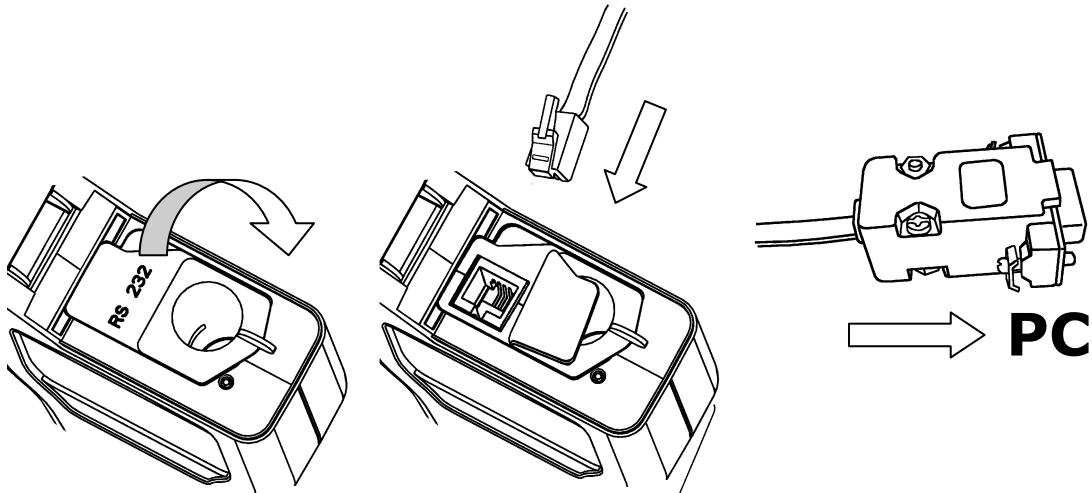
(1) Fold back rubber cover to access RS232 socket

(2) Insert small RJ10 plug into unit's RS232 socket

(3) Connect other end of cable to PC's COM port

NOTE: Select the appropriate RS232 or USB cable most suitable for your PC. A USB-to-RS232 adapter or USB Smart cable can also be used.

See section 11; Appendix on page 43 for instructions for the installation and connection of SystemSURE USB Smart Cable. Please contact your local distributor for further details.

Next select the correct **Serial port** from the available list:

26
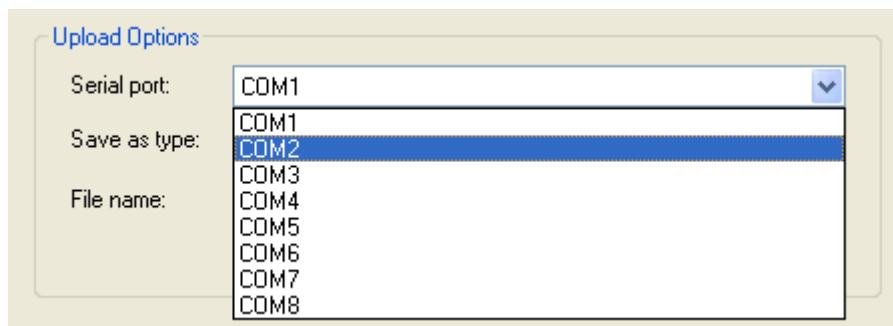
Then select the file **save as type**, depending on whether you want to create a Microsoft Excel data file or a plain text file:

File Type	Advantages
Excel workbook file	Generates a Microsoft Excel compatible file, which is more secure than a text file as the results data cannot be modified. This does <u>not</u> require Excel to be installed on the same PC.
Text file	Generates a simple text file, which should work on any PC. However, the data in the file is less secure and can be easily modified.
Excel file using DDE *This option provides compatibility with earlier versions of the Results Upload Utility*	Generates a secure Microsoft Excel file using Dynamic Data Exchange (DDE). However, Excel <u>must</u> be installed on the same PC. ⚠ **WARNING**: Do not *interact* with Excel whilst the data is being uploaded using DDE mode, as it may corrupt the data file format.

Next specify a suitable **File name** for the uploaded results to be stored in. This file name must be unique, as previously created file names cannot be reused or overwritten.

You also have the option whether you wish the upload utility to automatically open the saved data file for viewing once the results upload is complete:

Finally, turn on the SystemSURE Plus unit using the ◎ button, and begin the upload process by clicking the [Start] button.

The software then attempts to establish communications with the unit and, if successful, the unit display shows:
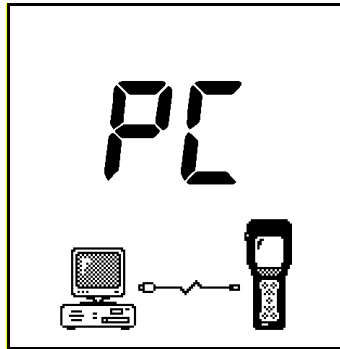
The results are then uploaded from the unit and stored in the specified data file on your PC's hard disk. This will take between 2 to 3 minutes to upload a full 2000 results.

Once the results have been uploaded and stored, you are given the option to erase all of the test results from the SystemSURE Plus unit.

⚠ **WARNING**: Please ensure that you can open and view the test results in the data file before clicking the [Yes] button to erase them from the SystemSURE Plus unit. Once erased from the unit, the results data cannot be re-uploaded to the PC.

If you choose not to erase the results from the SystemSURE Plus unit, they can be manually erased later by using the **MEMORY ERASE** function (see section 4.5).

When the upload is complete, turn off the unit and disconnect the serial cable from the SystemSURE Plus unit – ensuring that the black rubber RS232 cover is pushed back down and that the lid can be fully closed:

Push RS232 cover back under lip
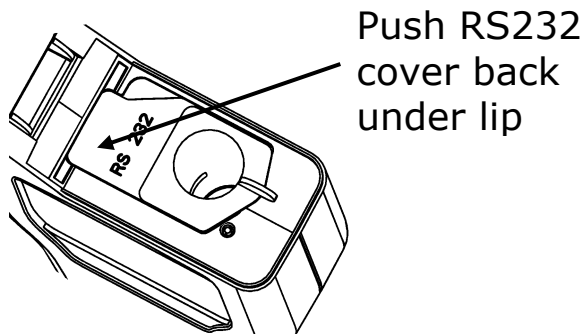
5.4 Results Data File Format

The uploaded test results data is stored in either an Excel file or a text file (see section 5.3 above). Both have the same format:

Unit#	Test#	Date	Time	Prog	Result	RLU	Lower	Upper	Comments
1721	1	12/05/03	08:04	0	Pass	26	100	200	
1721	2	12/05/03	08:05	0	Pass	35	100	200	
1721	3	12/05/03	08:08	1	Caution	172	150	400	*Re-cleaned*
1721	4	12/05/03	08:17	1	Pass	73	150	400	*Retest*
1721	5	12/05/03	17:42	0	Fail	257	100	200	*End of shift*
1721	6	12/05/03	17:44	1	Pass	141	150	400	

The data fields are:

- **Unit#** - the unit serial number (see unit rear label)
- **Test#** - the test number
- **Date** - the date the test was performed
- **Time** - the time the test was performed
- **Prog** - the PROG number used for the test
- **Result** - the overall Pass/Caution/Fail test result
- **RLU** - the test reading in RLUs
- **Lower** - the lower (⇩) program threshold
- **Upper** - the upper (⇧) program threshold
- **Comments** - additional field for user comments

TIP: The **Comments** field can be used to annotate each result with additional information, as required.

NOTE: When the results are uploaded using DDE mode (see section 5.3) the formats of the **Date** and **Time** fields are determined by Excel from your computer's **Regional** settings in the **Control Panel**, irrespective of the clock format set-up on the SystemSURE Plus unit.

5.5 Uninstalling the Results Upload Utility

To uninstall the Results Upload Utility from your PC, use the **Add or Remove Programs** option in the Windows **Control Panel**. Then select the SystemSURE Results Upload Utility from the list of currently installed programs and follow the on-screen prompts.

NOTE: Please copy off any test results data files you wish to keep <u>before</u> uninstalling the software.

6. Operator Maintenance

The SystemSURE Plus 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 <u>slightly damp</u> 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.
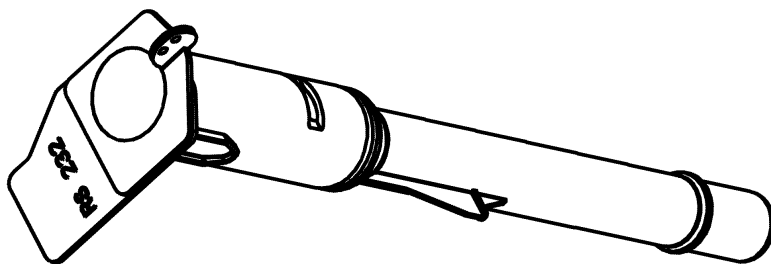
⚠ **WARNING**: Always turn off the unit before removing the protective pocket.

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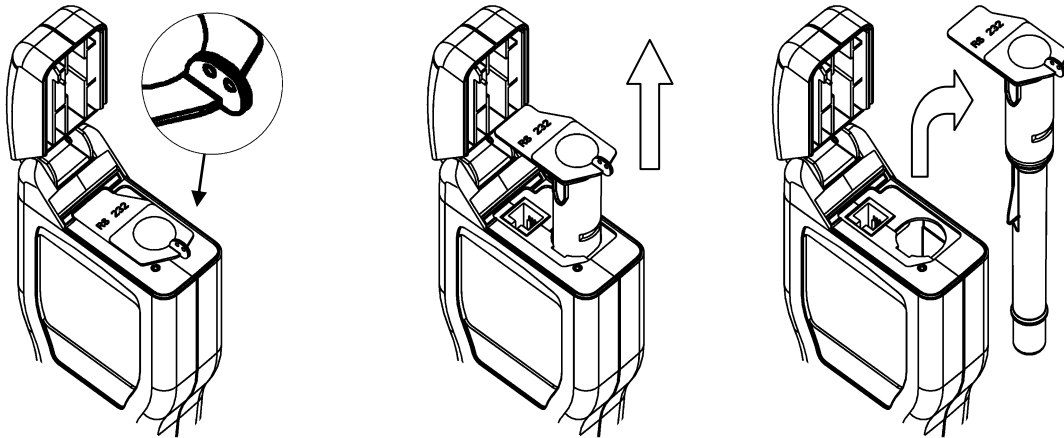
(1) Grasp finger grip   (2) Pull pocket upwards   (3) Remove pocket

⚠ **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 prise out the pocket.

Carefully clean the interior of the pocket using water or a <u>very mild</u> detergent solution, ensuring that the pocket is completely dry and clean before putting 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, <u>carefully</u> insert it into the unit, ensuring that it is correctly orientated, and then push it fully down until it clicks into position:
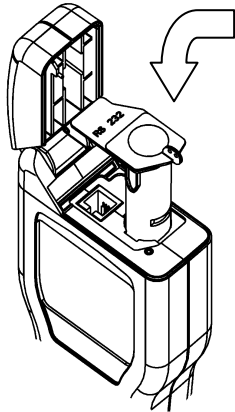
(1) Insert pocket in the orientation shown	(2) Push fully down until it clicks into place	(3) Push RS232 cover back under lip
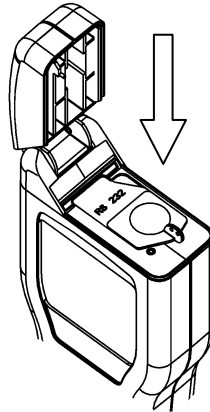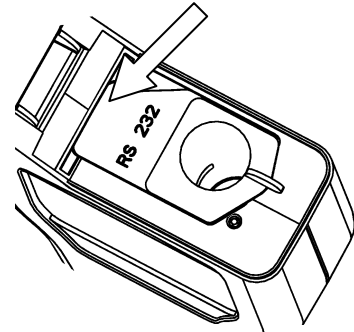
⚠ **WARNING**: Do not use excessive force when replacing the pocket. If the pocket jams during insertion, remove it fully, check for obstructions or damage, and then try again.

Finally ensure that the black rubber RS232 cover is pushed down and that the lid can be fully closed – see section 5.3.

7. Troubleshooting

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

Some problems can be rectified by the operator, whilst 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 local distributor for further assistance.

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 calibration self-checks 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	✓ Calibration self-checks required – remove Ultrasnap 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 below)

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, lid, LCD screen, battery contacts, 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 incorrectly inserted ✗ Unit or keypad damaged or faulty
Unit will not turn off when the ◎ button is pressed	✓ Unit is busy performing a reading or calibration self-check operation ✓ Unit lockup – remove the batteries for 30 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 enters standby mode ✘ Unit damaged or faulty
Unit beeps when turned on, but nothing is displayed	✓ Batteries are flat ✘ Unit or display damaged or faulty
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 damaged or faulty
The display appears washed out or very dark	✓ Unit is too hot or too cold ✓ LCD contrast incorrectly adjusted (see section 4.8) ✓ Unit is being used in inappropriate lighting conditions ✘ 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 selecting 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) ✓ Ultrasnap device incorrectly or not fully inserted ✖ Lid or unit casework damaged
Measurement result is always zero RLU or is much lower expected	✓ Incorrect use of Ultrasnap device ✓ Unit not in upright position when measurement taken ✓ Ultrasnap device is out-of-date ✓ Unit being used in an unstable thermal environment – turn the unit off and back on again ✓ Protective pocket or Ultrasnap 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 Ultrasnap 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:
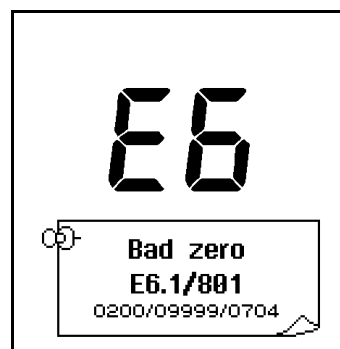
TIP: Most problems are likely to be transitory, and can be cleared by pressing the ⓄⓀ button, or by removing the batteries for 30 seconds and then reinserting them.

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

Error Code	Possible Causes
E1	*Not applicable on the SystemSURE Plus 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, Test Plan or User ID undefined*	✓ Program thresholds not defined, and have been reset to the default values (10⇓ and 30⇑) ✓ Test Plan data not defined ✓ 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 SystemSURE Plus unit, when purchased new, to be free from defects in materials and workmanship, and will repair or replace, at their discretion, any SystemSURE Plus 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 your local distributor 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 Hygiena 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 SystemSURE Plus unit or the use or attachment of any peripheral not supplied or specified by Hygiena will void this Warranty.

⚠ **WARNING**: Use only the accessories and consumables supplied by Hygiena. The use of any non Hygiena supplied accessories and consumables will invalidate the warranty.

9. Glossary of Terms and Abbreviations

ATP	Adenosine Triphosphate – energy carrier molecule
Device	The Ultrasnap 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 (✓), caution (!) or fail (✗)
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 SystemSURE Plus unit

10. Technical Specification

General

Unit dimensions (W x H x D)	72mm x 191mm x 32mm
Unit weight (including batteries)	approx. 260g
Operating temperature range	5°C to 40°C
Relative Humidity range	20% to 85% non-condensing
Storage temperature range	-10°C to 40°C
Relative Humidity Range	20% to 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
User IDs	50 IDs of 16 characters
Programmable result thresholds	251 programs
Programmable location names	251 names of 20 characters
Test plans	20 plans of 251 programs
Results memory size	2000 tests
Serial interface	EIA-232 compatible

Batteries

Battery Size (2 off)	AA, LR6 or E91
Battery Types	
Non-rechargeable	nom. 1.5V Alkaline
Rechargeable (externally charged)	nom. 1.2V NiMH or NiCD
Battery Capacity (for 2600mAh)	
Standby mode (at 20°C)	min. 6 months
Continuous reading	min. 2000 tests

11. Appendix

SystemSURE USB Smart Cable Driver Installation Instructions

Please follow these instructions to ensure the complete installation of the USB Smart Cable Driver.

Step 1: Remove all previous SystemSURE cables from the computer.

Step 2: Plug in the new USB Smart Cable into one of your USB ports.

Step 3: Allow Windows to detect the new hardware.

Step 4: When prompted for a driver, insert the CD supplied with the USB Cable. This will either start the installation or request a specific path in which case select the CD drive and the subfolder 'USB driver'.

Note: You may see a message stating that the USB Smart Cable has not passed the Windows logo test or verification test. If this occurs, click **"Continue Anyway"** as the software has been tested and does work on Windows Operating Systems.

Step 5: You will then see a message requesting you run the installation again. This is essential to complete the process, repeat the process in Step 4.

Step 6: Restart the computer if necessary.

Tip: Identifying the COM port Allocation
This is required in order to select the correct COM port when using the SureTrend or Result Upload Utility software.

Note: the USB Cable must be plugged in and the green light should be illuminated.

For Windows XP users:

Step 1: Right click on 'My Computer' and select 'Properties'.

Step 2: Select Hardware Tab.

Step 3: Click on Device Manager, expand the 'Port (COM & LPT) folder to reveal the SystemSure SMART USB Cable Serial Port. The COM port number is identified within the brackets e.g (COM19).

For Vista users:

Step 1: Open the Start menu.

Step 2: Type 'Device Manager' in the 'Start Search' box at the bottom and press enter. Expand the 'Port (COM & LPT) folder to reveal the SystemSure SMART USB Cable Serial Port. The COM port number is identified within the brackets e.g (COM19).

Note: the allocated COM number maybe any number from 1 to 128 dependant on hardware configuration. Note this number for future use with SureTrend or Result Upload Utility software configuration.