lion alcolmeter® 500

[500 Instrument (Mk IV) with Printer Option]

User Handbook

Book Product Code - RM50737

CE 0086

WEEE Directive

English

Do not throw away or dispose of in landfill site - return to local distributor or manufacturer

Francais

Ne pas jeter ou ne pas s'en débarrasser dans un site d'enfouissement de déchets – retourner au distributeur local ou au fabricant.

Italiano

Non disperdere nell'ambiente o gettare nei rifiuti urbani - ritornare al distributore locale o al fabbricante

CONTENTS

Supervisor Functions

PLEASE!

Read this User Handbook carefully, ***BEFORE*** using the instrument to test a subject's breath for the first time.

1: Introduction

This version of the **lion alcolmeter® 500** is the latest in Lion's range of breath alcohol measuring instruments for breath alcohol testing applications in traffic law enforcement, commercial health and safety programs, and in medicine. This instrument version incorporates a memory to record the data from each subject's breath test, with the relevant date and time. This data can then be downloaded to a central computer for management use in statistics gathering and compilation for various applications.

When used for Medical purposes the **lion alcolmeter® 500** is intended to be used as a portable handheld device for rapid measurement of the alcohol concentration in the breath. The users of the device will be health service professionals with the necessary skill and training associated with such a position who will use the resultant measurement for diagnostic assessment purposes. Comprehensive instructions are provided with the device to ensure a clear understanding of the principles behind the operation of the unit and its function. Due to the nature of its construction the device is intended to be used in an environment as stated in this operating manual. If the device is used as intended then the patient or user cannot influence the result or harm themselves.

An optional printer unit is also available: this enables a permanent record of each test to be produced, at the relevant time.

Simple to use, the **lion alcolmeter® 500** allows a complete breath test procedure to be conducted on a subject, and their alcohol reading noted, all in around one minute.

This handbook explains the following aspects of the instrument, so please read it carefully:

- basic principles of operation
- how to run a breath test
- interpretation of results
- care and basic maintenance
- calibration checking
- calibration adjustment
- basic maintenance

Handbook Part A:
OPERATOR Functions

2: Instrument Description

Please note the following user features of the instrument:

1.	Disposable Mouthpiece
2.	Function Switch A [**FSA**] Small button
3.	Function Switch B [**FSB**] Large button
4.	Display
5.	Beeper [internal]
6.	Printer, Communications and Charger Port

2.1 Function Switch A

The smaller button, bearing a red power symbol and located directly above the display, is Function Switch **A** [**FSA**]. This switches the instrument **ON**: simply press **FSA** and release.

FSA may also be used at certain stages in the **500's** operation to switch it **OFF**. However, for operational reasons, this action cannot occur once a breath test sequence has been started.

This button is also used in situations where the subject fails or refuses to supply a specimen of their breath into the instrument.

2.2 Function Switch B

Located directly above **FSA**, the larger button is Function Switch **B** [**FSB**]. It is used for manual breath sampling [if this feature is active in the particular instrument's software], as well as during calibration checking and adjustment.

Do NOT press either of these two button very hard: a gentle but positive finger or thumb action is all that is required !

2.3 Graphics Display

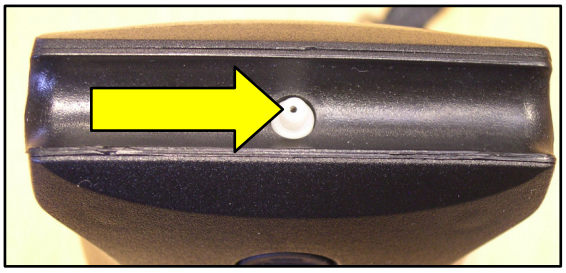
The illuminated display instructs the user during data-logging and breath sampling, and shows the subject's alcohol reading. The small icon at the bottom right shows battery charge level.

2.4 Beeper

This provides various audible tone messages to the instrument operator, and to the subject.

2.5 Breath Sampling Port

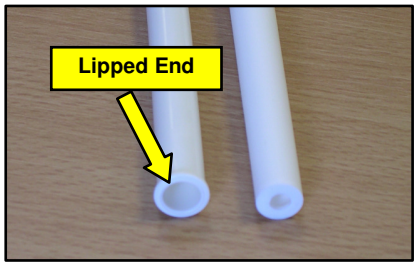
The small white port located in the top channel of the instrument is the entrance to the fuel cell alcohol detector and to the breath flow sensor. ***Do not allow fluids to enter this port, or serious damage to the instrument may result.***



2.6 Disposable Mouthpiece

The disposable mouthpiece is supplied packed in individual, hygienic wrappers. It is fitted to the instrument by locking its sampling port into the

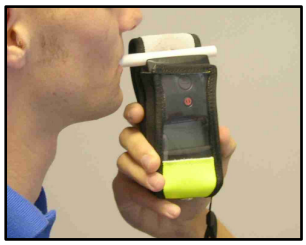
small hole in the side of the tube: it may be attached either way round, whichever is more convenient to you, the subject or the situation. But the subject ***MUST*** blow through the wide-bore, ***lipped*** end, or the instrument's automatic sampling system will not operate.



A NEW mouthpiece MUST be used for each complete breath test: but it NEED NOT be changed for repeated blows by the same subject in the same procedure

NOTE: the mouthpiece used with the **500 MK 4** is the same as that supplied for use the **lion alcolmeter® S-D2** and earlier **500** versions.

2.7 Leather Pouch



This protects the instrument from most levels of shock likely to be encountered during operational use, and is fitted with a mouthpiece storage pocket. The **500** should normally be left in place, in its pouch, during use:

2.8 Power Unit

The power unit is located in the rear of the instrument. It holds 2 x **AA** batteries: these should provide enough power for ***at least*** seven hundred and fifty breath tests [depending on operating conditions].

DO NOT USE RECHARGEABLE AA BATTERIES

The **500** is also available for use with a rechargeable battery, but this must be specified at the time of ordering. A **500** manufactured for use with AA batteries cannot then be used with a rechargeable battery and vice versa.

For **500** with rechargeable battery, the lower power warning message appears when there is enough power for about twenty more breath tests [depending on conditions of usage].

The power unit can be recharged from either the mains or 12 volts DC, using the appropriate charger as supplied.

2.9 Printer, Communications and Charger Port

This port is used to connect the **500** to the printer. It is also used for downloading stored breath test data to a PC, and for instrument system configuration.

Where applicable, this port is also used to recharge the power unit, using one of the two chargers supplied [mains or 12 volts DC]:

3: Subject Breath Test Procedure

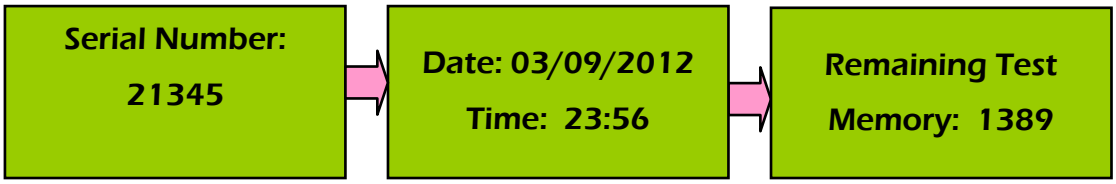
3.1 Step by Step …

STEP 1 - *Preliminary Questions to the Subject*

As far as possible, ensure the subject has taken ***NOTHING*** by mouth [alcoholic or otherwise] in the last ***TWENTY*** minutes; and has not smoked in the last ***TWO*** minutes. ***If necessary - WAIT.***

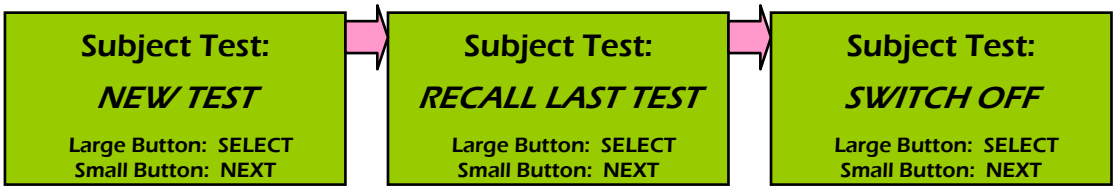
STEP 2 - *Switch On*

Press **FSA** until you hear the beep, then release. The instrument serial number is displayed. This is followed by the date and time, and then a review of the remaining memory capacity:



STEP 3 - *Function Selection*

Now scroll through the menu using the small button [**FSA**], to select what you want to do: there are three options. The menu option line, shown in these diagrams in *ITALICS,* flashes to indicate that the user may select this function from the available menu:



As instructed, press the large button [**FSB**] to **Select** the displayed option, or the small button [**FSA**] to go to the **Next**.

The first option enables you to start a new subject test: if you select **NEW TEST** then you cannot switch the instrument off until either a breath sample has been taken and analysed, or you have logged a *'fail to provide'*. The second option recalls [and prints] the result of the last breath test. The third option switches the **500** off. If the instrument is not used for a pre-set time (usually 5 minutes), it switches off automatically.

STEP 4 - *Attach a New Mouthpiece*

If you chose to breath test a new subject, [**NEW TEST]** this proceeds as follows.

The mouthpiece must be attached in a hygienic manner, or the subject could justifiably object to putting it in their mouth. Tear open the wrapper from the non-lipped end, and peel back far enough to expose the hole in the side. Now, holding the mouthpiece through the wrapper around the blowing [lipped] end, push the side hole over the **500's** sampling port, so it locks firmly into place. You may attach it either way round, whichever is more convenient. Now remove the wrapper completely [or have the subject do this themself].

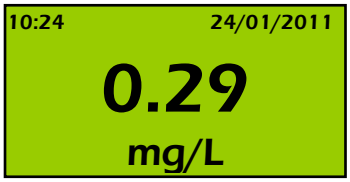
STEP 5 - *Instruct the Subject*

Instruct the subject to take in a deep breath, hold it, form a seal around the lipped-end of the mouthpiece with their lips; and then blow steadily and continuously until ***YOU*** say stop. He or she does ***NOT*** have to blow ***VERY HARD***: a ***LONG, MODERATE BREATH*** is all that is required. The subject must keep his or her hands away from the instrument, so they cannot hide the display from your view. Also, if relevant, warn the subject not to try to *'beat the instrument'*.

STEP 6 - *Take the Breath Specimen*

The subject now blows into the lipped-end of the mouthpiece, ***HARD*** enough to bring on the message **Breath Flow** and to sound the continuous beep tone; and then for ***LONG*** enough for the sample to be taken into the sensor for analysis. This successful sequence of events is indicated by the following screens, and a double beep:

STEP 7 - *Analysis and Alcohol Reading*

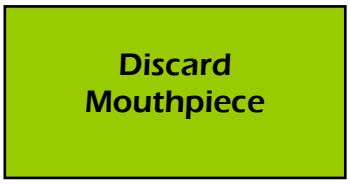


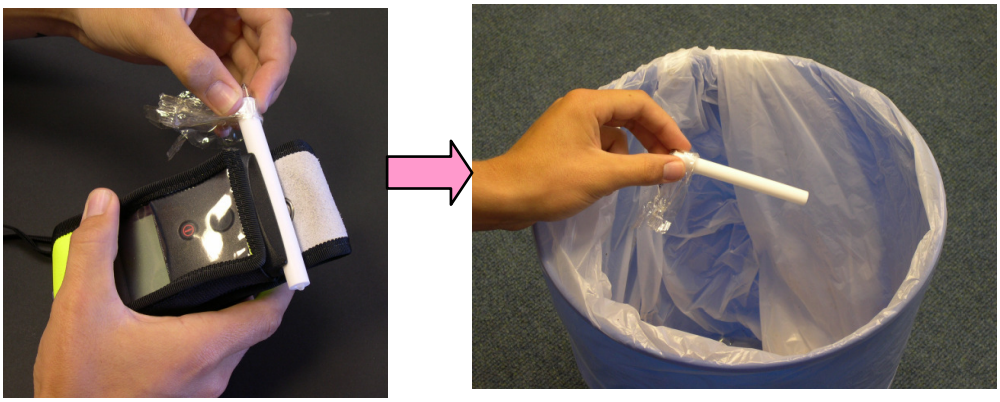
The fuel cell sensor in the **500**, along with its controlling electronic and software-based systems, now determine the alcohol level in the specimen. The result is then displayed, along with the time and date when that specimen was actually taken. This data is also then printed [assuming a printer is attached to the instrument and switched on]:

NOTE: During the analysis stage it is not possible to switch the instrument off

STEP 8 - *Discard Mouthpiece*

When instructed, remove and discard the mouthpiece, with the wrapper. ***DO NOT re-use the mouthpiece, except in the case of a repeat blow by the same subject for the same specimen.***





STEP 9 - *Test Next Subject, or Switch Off*

The system software now returns to **STEP 3**.

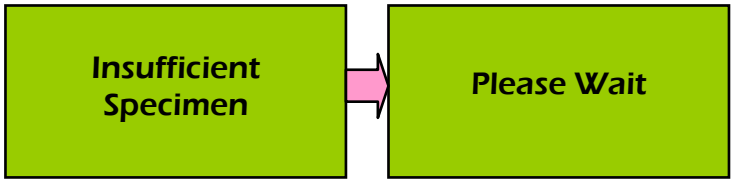
If you elect to run another breath test, wait for the **500** to go through its diagnostics first. This includes a temperature check, plus a test that the system is clear of alcohol:

3.2 The Breath Test Procedure Summarised

STEP	ACTION
1	Ask Preliminary Questions
2	Switch **On** the Instrument
3	Select **New** Function
4	Attach a New Mouthpiece
5	Instruct the Subject
6	Take Breath Specimen
7	Note Alcohol Reading
8	Discard Mouthpiece
9	Test Next Subject, or Switch **Off**

3.3 Invalid Breath Samples: Logging a Failure

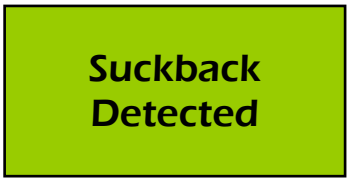
If the subject does not blow long enough, or sucks back before the breath specimen is taken into the fuel cell sensor for analysis, then, no sample is actually taken. The display shows the following:



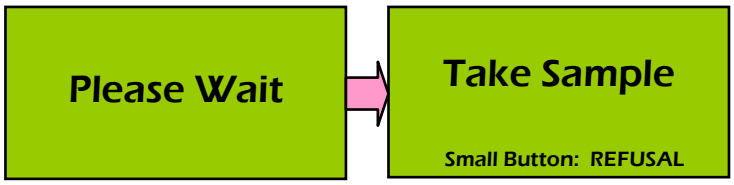
… then, when the system is again ready for the subject to blow:

Re-instruct the subject to blow into the instrument. ***There is no need to change the mouthpiece for this repeat attempt, though you may of course do so if you wish.***

If the subject blows properly, but then sucks back just as the breath sample is taken for analysis, the following message appears:



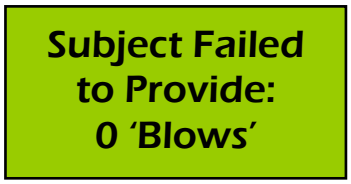
There is no alcohol reading, and after a short pause the screen invites a further attempt. If you wish to offer the subject one, it is advisable to re-instruct them to blow properly, without sucking back:

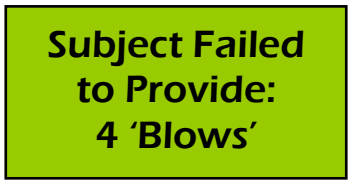


If the subject sucks back when the analysis is underway [ie after the **Sample Taken** message has appeared] then there is no effect on the alcohol measurement, so the alcohol reading will be given as normal.

NOTE: you do NOT have to change the mouthpiece for repeated attempts by the same subject in the same test procedure.

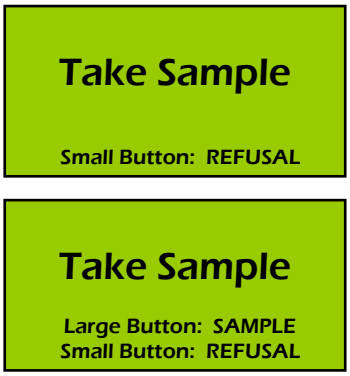
If the subject ***refuses*** to blow into the instrument, or by his actions and perhaps after one or more 'attempts' at blowing into it it is clear that he or she is not going to provide a proper specimen, then you may terminate the procedure by ***logging a refusal***. To do this press and continue to hold down the small button [**FSA**] until the beeper sounds and the screen shows a message such as the following:





The number in the above screens is a record of how many detectable but insufficient blows the subject made into the device.

3.4 Manual Breath Sampling

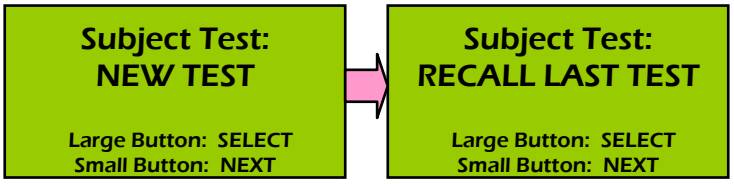


If your **500** has been so configured by your ***Supervisor***, then it is possible to take a sample **Manually** for analysis, by pressing the large button [**FSB**]. If this feature is ***NOT*** enabled, then the display inviting the subject to blow will appear as shown above. However, if this facility ***IS*** enabled then the screen will be as below.

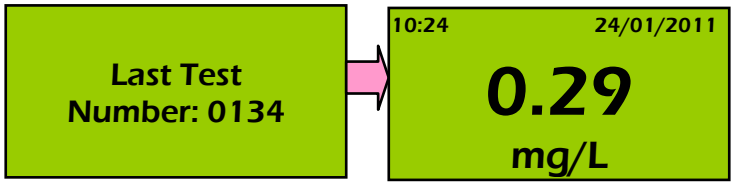
Press the Large Button to take the breath sample when the subject is still blowing, but almost at the end of expiration.

3.5 Last Test Recall

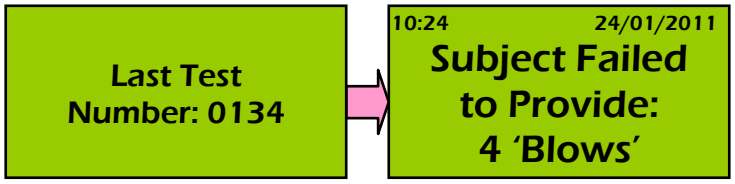
If you wish to recall the result of the last subject test - perhaps to show the subject or someone else concerned with the procedure - select the **Recall Last** option from the screen that appears just after instrument switch on; or at the end of each breath test procedure:



This brings up two screens: the first shows the **Test Number**; this is followed by the actual result with the relevant time and date, such as:



...or:



This may be repeated as often as required, until the **NEW** option is selected [to run another breath test]. Once a **NEW** test is started, it is no longer possible to recall the result of the last breath test.

3.6 The Auto Power Down Function

If the **500** is left switched on but no action is then taken for five minutes it will automatically switch itself off, to conserve battery life. This is preceded by a series of ten warning beeps.

DO NOT attempt to switch off the 500 by simply removing the batteries. Such an action is recorded in the system memory.

4: Breath Test Record Printouts

Assuming a printer is connected to your **500** then at the end of breath analysis procedure the instrument will automatically switch it on and generate a relevant printed record.

In the first printout example [shown on page 28], at 12:37:06 on 01 March 2012 the subject provided a valid specimen of breath into the **500**. This was analysed and found to contain alcohol at a level of 0.65mg/L. In the second example, on 01 March 2012 the subject blew three [3] times into the **500**, but none of these were sufficient for analysis. At 14:01:10 the operator terminated the procedure by pressing **FSA** to log the fact that the subject had failed to provide a suitable specimen of breath for analysis.

There is space on the document for additional details [of the operator, subject, test witness and location] all to be entered by hand.

Additional copies may be obtained by calling up the **RECALL LAST TEST** option in the menu that appears at the end of the test. Connect the printer when **LAST TEST RECALL** is flashing, then press Select. The printer turns on automatically.

The printer uses rechargeable batteries only: these are recharged using a different charger system to that used with the rechargeable power supply option in the instrument itself.

Paper Saving Tip !

If you are conducting breath tests on a large number of people, most of who are likely to have no alcohol in their breath, and you wish to print out a record only in cases where alcohol ***IS*** present, then the following may assist.

Carry out the breath testing ***without*** the printer attached. Then, if alcohol is found to be present in a subject, connect the printer and select the **RECALL LAST TEST** option , then SELECT.

LION ALCOLMETER 500
Instrument Serial Number: 12345
Last Calibration Check:
16:54 on 01/12/2011

SUBJECT BREATH TEST
Time: 12:37:06
Date: 01/03/2012
Test Number: 0004

Blank Check: 0.00mg/L
Breath Result: 0.65mg/L

……..
Subject Name

……..
Subject Signature

……..
Operator Name

……..
Operator Signature

……..
Witness Name

……..
Witness Signature

……..
Location

LION ALCOLMETER 500
Instrument Serial Number: 12345
Last Calibration Check:
16:54 on 01/12/2011

SUBJECT BREATH TEST
Time: 14:01:10
Date: 01/03/2012
Test Number: 0004

Blank Check: 0.00mg/L
Breath Result: NO SAMPLE [3]

……..
Subject Name

……..
Subject Signature

……..
Operator Name

……..
Operator Signature

……..
Witness Name

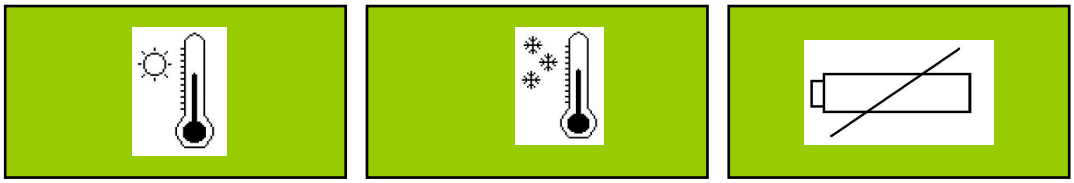
……..
Witness Signature

……..
Location

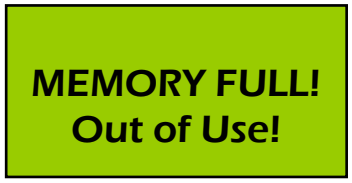
5: Warning Messages

5.1 Fatal Error Messages

If a ***FATAL*** message is shown, the **500** automatically powers down and cannot be used until the appropriate remedial action has been taken. The most likely occurring examples of such a message are:



Instrument Too Hot **Instrument Too Cold** **Change/Charge Battery**



The **Error Code X** messages are explained in the following table. If any of these occurs, please contact service personnel for attention.

lion alcolmeter© 500: Error Code Messages	
Code	**Meaning/Significance**
2	Fuel cell amplifier signal is too high
3	Fuel cell output too low during instrument calibration
4	Gas flow rate applied during breath flow sensor calibration was too low
5	Charge pump did not generate the required voltage
6	Temperature below -6℃
7	Calibration or checking attempted below 10℃
8	Calibration or checking attempted above 30℃
16	Fuel cell offset voltage has drifted too low
17	Blockage in sampling system
18	Used in Factory Mode only
19	Used in Factory Mode only

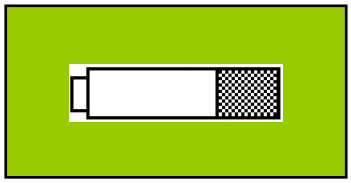
5.2 Non-fatal Error Messages

If a ***NON-FATAL*** message appears, the instrument can still be used, with no effect on its operation or accuracy.

There are two such messages:

Low Power:

Either ***change*** the disposable batteries as described in the following Section, or ***recharge*** the rechargeable unit.

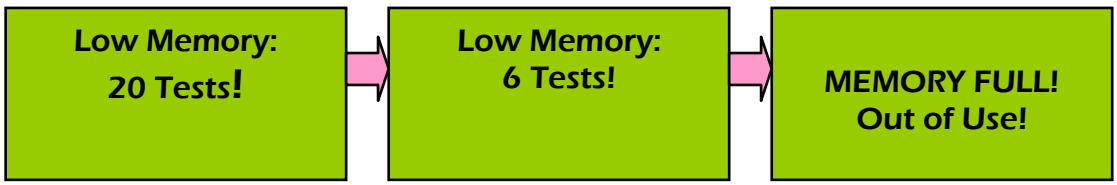


The rechargeable power unit, when fully charged, should provide enough power for ***at least*** five hundred complete breath tests [depending on conditions of usage].

Charge the system when this low power warning message appears, as there is enough power for only about twenty more complete breath test procedures [also depending on conditions of usage]. The power unit can be recharged from either the mains or 12 volts DC, using the appropriate charger as supplied.

Low Remaining Test Memory:

The **500** records in its memory the complete file of data from around 2,500 subject breath tests. This memory can then be down-loaded to a PC. In the unlikely event that the memory becomes full, the following sequence of messages will appear. **MEMORY FULL** is fatal, in that the instrument cannot be used for breath analysis until the stored data has been downloaded and the memory cleared:



6: Care and Maintenance: Batteries

To ensure optimum performance, follow these simple instructions:

6.1 Cleaning the Instrument

Simply wipe over with a ***LIGHTLY DAMPENED cloth***.

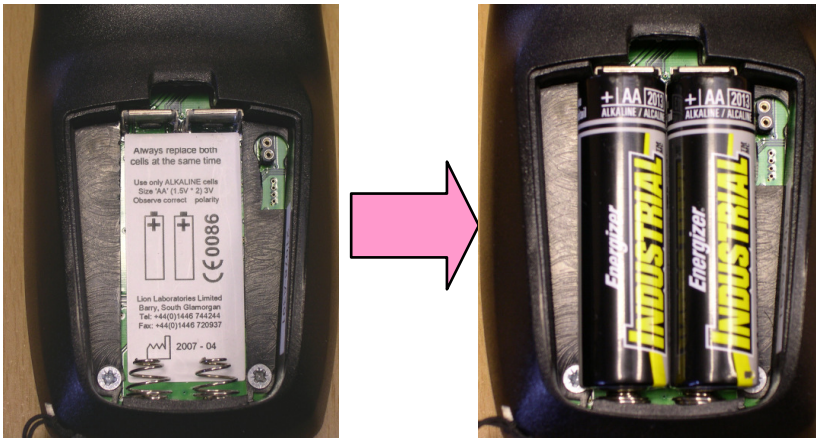
Do not use chemical solvents, abrasives or excess water to clean this instrument: these could damage the case material, and possibly the various internal sensors

6.2 Changing the Batteries

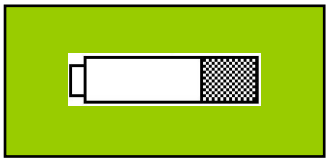
The standard power supply unit used with the **500** [and unless otherwise specified at the time of ordering] is two **AA** cells. These should give enough power for at least 750 breath tests, depending on the conditions of use.

When the low power warning screen appears it is recommended that you change these batteries as soon as possible. When so doing please remember the following:

- Change both batteries together; and
- Ensure that each is fitted with its positive end ***UPwards***



6.3 Recharging the Power Unit



The rechargeable power unit [an instrument option], when fully charged, should provide enough power ***for at least*** five hundred tests.

Charge the system when this low power warning message appears, as there is enough power for only about twenty more complete breath test procedures. The power unit can be recharged from either the mains or 12 volts DC, using the appropriate charger as supplied. This connects to the instrument via the small port on the lower-left side. Make sure that the instrument is switched **ON** for charging, so that the charge status icon is displayed. This scrolls during the actual recharging process.

A fully discharged power unit will take around 60 minutes to recharge, at which time the icon stops scrolling.

In-vehicle, 12 volt

Mains charger unit

7: The Calibration CHECK Procedure

7.1 Why Calibration CHECKS?

Your instrument is set up for use with a dry gas alcohol vapour standard. IF A WET VAPOUR STANDARD IS TO BE USED, THIS CAN ONLY BE DONE AFTER CONTACTING LION AND RETURNING THE INSTRUMENT TO LION'S FACTORY.

To ensure the **500** remains fully operational and accurate, its calibration must be CHECKED periodically; such as every two months. The CHECK procedure is carried out using a known alcohol vapour standard - the **AlcoCal®.**

Instrument calibration ***ADJUSTMENT*** is needed when the ***CHECK*** procedure produces a reading that is greater than 0.03mg/L away, in either direction, from the known value of the **AlcoCal®** standard.

As a guide, because of the high stability of the alcohol sensor and electronics used in the **500,** recalibration should not be needed more often than every six months.

7.2 The AlcoCal® Standard

The **lion alcolmeter® 500** is checked for accuracy by means of an alcohol vapour of known concentration. This standard is a mixture of alcohol in air at a known proportion. This known mixture is then compressed into a cylinder suitable for long-term 'field' use.

The breath alcohol standard so supplied by Lion is called **AlcoCal®**.

The alcohol level in this gas is precisely known and is shown in units of mg/L. The label also carries an expiry date, beyond which the gas must not be used.

Please follow the instructions for use of whichever breath alcohol standard you are using to check the **500**, including making any relevant adjustment for local altitude.

7.3 The AlcoCal® Connector Tube

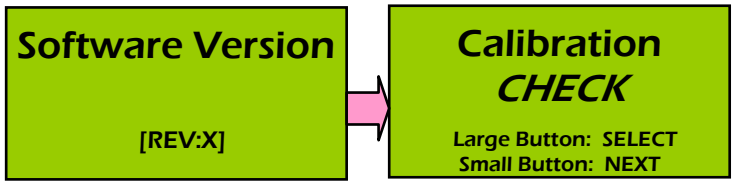
Place one of these on the cylinder outlet tube, as shown here. The mouthpiece on the instrument is then placed over this tube so as to sample the alcohol vapour from the cylinder during the checking procedure.

Replace the **Connector Tube** if it is cracked or split. Each **AlcoCal®** cylinder is supplied with a pack of ten tubes [**product code: SA10040**].

7.4 Calibration CHECK Mode

This mode enables you to take the gas sample manually, irrespective of how the **500** is set up for breath analysis. This is necessary as the gas flow rate from an **AlcoCal®** or breath simulator will generally be too low to activate the **500's** automatic sampling system.

Calibration CHECK Mode also ensures the instrument is in its proper temperature range for checking purposes. A screen message will appear if its temperature is below +15°C or higher than +30°C. To enter **Calibration CHECK Mode**, press and release **FSA**, then, just after you hear the click, press and hold down **FSB** until the serial number screen appears, then release **FSB**.

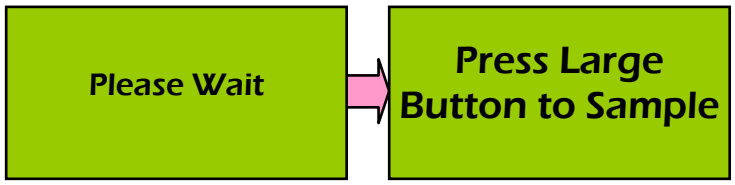


Press **FSB**. again to select **Calibration CHECK Mode**, or **FSA** to move on to the ***Supervisor Menu***.

7.5 The Calibration CHECK Procedure

Firstly, the instrument to be checked should not have analysed any sample containing alcohol in the last 30 minutes. Now, follow the instructions above to enter **Calibration CHECK Mode**.

Because dry gas is used for this checking procedure, for technical reasons the instrument temperature ***MUST*** be in the range +15 to +30°C. If this condition is not met then calibration checking is not possible. Assuming the temperature is in range, the display shows:



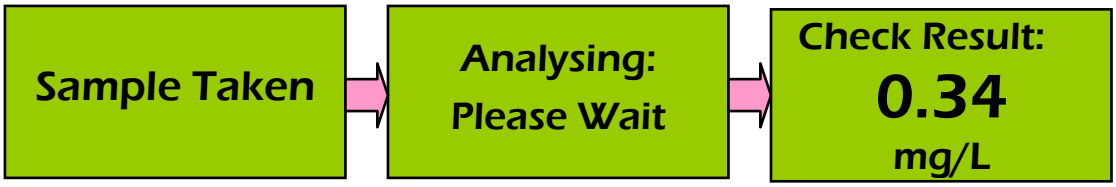
Prepare the **AlcoCal®** for use: check the expiry date has not passed, that the gauge shows there is enough gas; and the altitude, if relevant. If the cylinder has not been used in the last two hours, hold

down the push-button for a few seconds to flush the regulator of any 'stale' gas. Firmly attach the **Connector Tube** to the outlet port, and attach a clean, ***dry*** mouthpiece to the sampling port on the **500**.

This mouthpiece *MUST* be *DRY*: do *NOT* blow through it!

Now push the lipped end of the mouthpiece on the **500** over the **Connector Tube,** to form a tight fit. Then hold down the **AlcoCal®** control button to allow gas to flow through the mouthpiece. After at least five seconds of flow, press and release **FSB** to take the sample. It is important that the gas then flows at least a further second, ***after*** pressing **FSB**, ***before*** releasing the **AlcoCal®** button.

Once the **AlcoCal®** sample has been taken, observe the display:



Calibration CHECK Mode remains in use for further checks, if needed, until switch off or auto-power down.

Did the reading agree with the **AlcoCal®** value? If it was outside the acceptable range, the **500** needs **Calibration ADJUSTMENT**.

7.6 What Is An Acceptable CHECK Value?

A satisfactory CHECK result is generally one that is within ±0.03mg/L of the value of the **AlcoCal®** gas standard.

So if the alcohol value of the standard is 0.35mg/L, then a CHECK result between 0.32 and 0.38mg/L inclusive should be acceptable.

7.7 Last Calibration CHECK: Time and Date

The date and time of the last calibration ***CHECK***, but ***not*** the alcohol reading actually obtained [because the value of the alcohol standard that was used is not defined to the instrument], is stored automatically by the **500**, and will be shown on all subsequently produced subject breath test printouts.

8: Do's and Don'ts

……. Do's

DO...Press **FSA** and **FSB** ***GENTLY*** **!**

DO...Change or charge batteries when **Low Battery** appears.

DO...When changing batteries, replace ***BOTH*** cells.

DO...Use the correct mouthpiece for this instrument.

DO...Use a clean, new mouthpiece for each ***COMPLETE*** breath test.

DO...Ensure the subject blows into the lipped end of the mouthpiece.

DO...Read this handbook carefully, and comply with its contents.

DO...Use a ***DRY*** mouthpiece for calibration checking.

……. Don't

DO NOT...Test the subject if you think he may have drunk or taken ***ANYTHING*** by mouth in the last 20 minutes

DO NOT...Test the subject if he has smoked in the last 2 minutes.

DO NOT...Let the subject hyperventilate before supplying breath. This cools the mouth and upper airways, so that alcohol is lost [by condensation] from the breath on expiration, and so produces a falsely low reading of the body alcohol loading. If necessary, wait a minute or so before proceeding to take the breath sample, after any such action by the subject.

DO NOT...Store the **500** in extremes of temperature, hot or cold.

DO NOT...Subject the **500** to violent shock. Treat it with respect!

DO NOT...Clean the case with chemical or abrasive products.

DO NOT...Allow the sampling port to become blocked.

DO NOT...Block or restrict the end of the mouthpiece while the subject is blowing. This can seriously damage the instrument.

DO NOT...Re-use mouthpieces, for hygiene ***and*** accuracy.

DO NOT...Open the case: this will invalidate the warranty/service.

DO NOT...Deviate from the instructions in this handbook.

Handbook Part B:
SUPERVISOR Functions

9: The Supervisor Access Level

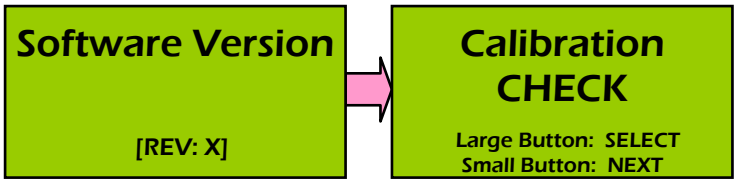
9.1 The Supervisor Utilities

As standard the utilities contained in this menu can be accessed by all personnel. It is possible for the ***Supervisor Menu to be PIN-protected, but this can only be done at Lion's factory so this requirement must be specified at the time of ordering***. The functions accessible at this higher user level are:

- Viewing and printing stored breath test data
- Calibration of the alcohol measuring system
- Setting the date and time
- Activating / deactivating the **Manual Sampling** option

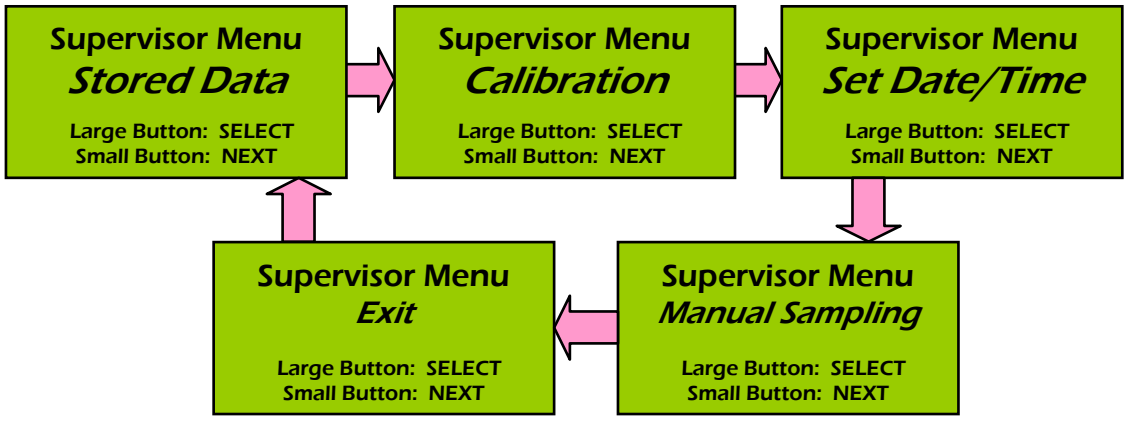
9.2 Accessing the Supervisor Menu

1. Switch on the **500**, by pressing and releasing **FSA** [the smaller, red button], then after the click press and release **FSB**. The following screens appear:



2. Now select **NEXT**, by pressing and releasing **FSA** [the smaller, red button]. This brings up:

3. Now select **NEXT**, by pressing and releasing **FSA** [the smaller, red button]. This brings up:

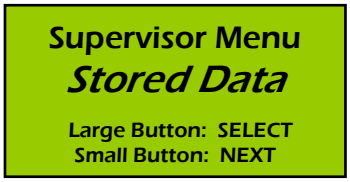


The **Exit** option returns to the **Calibration CHECK** menu page.

10: Data Management

10.1 Option and Sub-option Selection

The ***first*** available item appearing in the ***Supervisor Menu*** is:

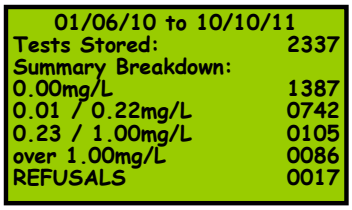


This option brings up the choice whether to **View Summary,** or to view and print a line-by-line summary of **All Tests**, or to **Clear Data** from the memory, or to **Exit** back to the ***Supervisor Menu***:

Selecting the **NEXT** option after the Clear Data screen takes you to **Stored Data EXIT** screen.

10.2 View Summary

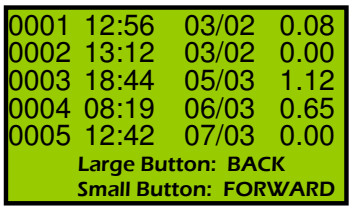
This utility displays a single screen summary of all breath test records held in memory. This page is also sent to the printer, if this is connected to the instrument:



This screen is shown for ten seconds, following which the system automatically reverts back to the **View Summary** screen.

10.3 View All Tests

Selecting this utility displays a line-by-line record of each subject breath test that is held in memory:



The data is displayed from the beginning of the series, in block of five records. Use the two buttons to go back and forwards, as instructed.

NOTE: pressing **BACK** at the start of the series takes you to show the most recent test.

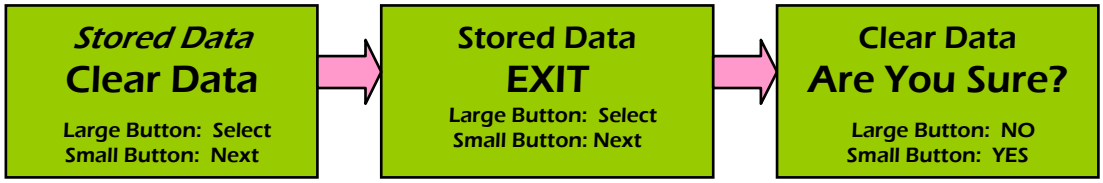
This screen is shown for ten seconds, following which the system automatically reverts back to the **All Tests** screen.

10.4 Data Down-loading to a PC

This can only be carried out using a PC loaded with the bespoke software utility **Data-500™**, available only from Lion. Please initially refer to the instructions issued with that software product, ***before*** using it for the first time.

10.5 Clear Data

This enables the ***Supervisor*** to erase all data from memory:



11: Instrument Calibration

11.1 General Information

Your instrument is set up for use with a dry gas alcohol vapour standard. IF A WET VAPOUR STANDARD IS TO BE USED, THIS CAN ONLY BE DONE AFTER CONTACTING LION AND RETURNING THE INSTRUMENT TO LION'S FACTORY.

You may use any alcohol vapour standard in the range 0.20 to 0.40mg/L to calibrate the **500**. The alcohol level in the standard does ***NOT*** have to be at any other particular value - ***provided that its actual value is known.***

You may use either a wet-bath simulator, or dry-gas standard such as the **Lion AlcoCal®** product. However, for technical reasons, the instrument ***MUST 'KNOW'*** which type of standard is to be used [**Wet** or **Dry**] - as well as its actual alcohol concentration value.

IMPORTANT:

Please read the instructions in this section carefully, and be sure you understand each part, ***BEFORE*** attempting to calibrate an instrument for the first time.

11.2 Calibration ADJUSTMENT Mode

In **Calibration ADJUSTMENT Mode**, which is the second option in the ***Supervisor Menu***, the digital display does not show the measured value of the alcohol value of the standard vapour [as it would during breath analysis]. Instead the value of the standard is

initially set by the user into the instrument as the final value, and then the reading obtained on analysing the standard vapour is made to correspond with that setting. This then ensures that during subsequent breath testing all digital readings are accurate.

NOTE: When using a dry-gas standard, the **500's** temperature must be in the range 15 - 30°C.

11.3 Use of the AlcoCal® Standard

Please follow the instructions for its preparation and use as given in **Section 7** of this ***User Handbook***.

11.4 The Calibration ADJUSTMENT Procedure

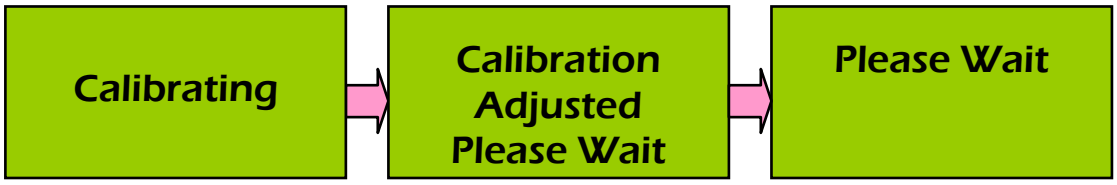
1. Switch on and access the **Calibration ADJUSTMENT** option of the ***Supervisor Menu***, as described above.

2. The instrument temperature must be in the range 15 - 30°C. Assuming this condition is met, the next screen to appear will be:

3. Use **FSA** to change the displayed number to agree with the known alcohol standard [after making any allowance for altitude for a dry-gas]; then press **FSB** to **ENTER**.

4. When the instrument is ready, take a sample of the gas:

5. The instrument now calibrates itself, fully automatically:



….. and then switches off. The process is now complete.

6. Before returning the **500** to service, you may wish to ***CHECK*** its accuracy of calibration [**Section 7** of this **User Handbook**], to verify that the above process has been carried out satisfactorily. Make a record of the process.

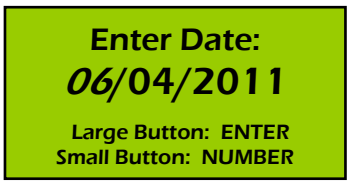
11.5 The Calibration ADJUSTMENT Date

This is not normally stored or printed, but only that information relating to the last ***Calibration CHECK***.

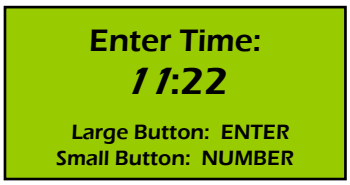
12: Setting the Date and Time

The ***third*** available item appearing in the ***Supervisor Menu*** is:

This option brings up the **Enter Date** screen, in **dd/mm/yyyy** format:

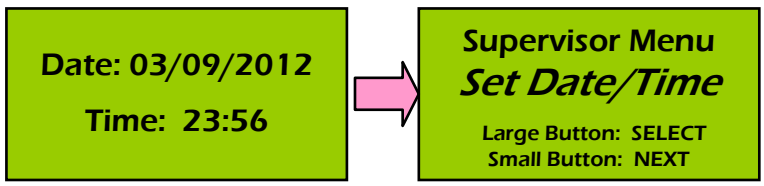


Increment the flashing number and then **ENTER** this, as instructed.
This then brings up the **Enter Time** screen:



Repeat the process for the time [24 hour clock]. The clock starts from when you hit **ENTER**, so for utmost accuracy enter the minute in advance of the actual current, and then press **ENTER** when the actual real time catches up to agree with this displayed value.

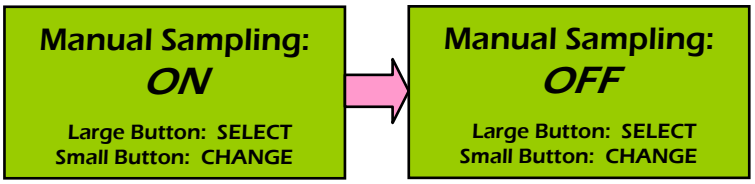
Following entry the two settings are displayed: the system then automatically returns to **Set Date/Time** in the ***Supervisor Menu***:



13: The Manual Sampling Option

The ***fourth*** and final available item in the ***Supervisor Menu*** is:

In general, before dispatch from Lion, the instrument is configured with Manual Sampling OFF. This option brings up the review / change screen for this setting:



Change the setting, as required, and then **ENTER** this, as instructed. This then brings back the initial utility option screen :

14: PIN-code

1. If the **PIN-code** option is configured, , selecting the ***Supervisor Menu*** brings up the **PIN-code** entry screen:

2. Each digit is a number from 0 to 9. Press **FSA** [**NUMBER**] to select the required value for each digit, then **FSB** to **ENTER** and move to the next. [The **PIN-code** factory setting is **1111**].

3. If the **PIN-code** is not entered correctly in three attempts the instrument automatically switches off.

4. If you entered the **PIN-code** correctly, you may now ***change*** it if you wish to do so:

Press **FSA** [**YES**] and follow the display instructions if you wish to do this [the factory setting of **1111** is then invalid].

Responding **NO** at the above screen, or after changing the **PIN-code** moves you on to the ***Supervisor Menu*** itself:

Appendix I: Technical Details

Alcohol sensor: Lion fuel cell.

Breath sampling: automatic, on deep-lung air only.

Analytical response time: normally within 30 seconds, but within 5 seconds at the 'zero' alcohol level.

Recovery time: around 22 seconds at 0.35mg/L.

Certified operating temperature range [for breath]: 0 to +40ºC.

Disposable mouthpiece: simple disposable 'pressure-type' tube.

Temperature range for calibration checking and adjustment [using dry gas standards]: +15 to +30ºC.

Storage temperature: -20 to +65ºC.

Power: Two disposable **AA** cells provide enough power for at least 750 complete subject breath test procedures.

Optional, rechargeable, lithium-ion power unit gives at least 500 tests, when fully charged. Two-stage warning of low power condition [20 then 0 remaining tests]. Mains and car chargers available.

Humidity: 10 - 95%, non-condensing.

Barometric pressure: 600 to 1,300hPa.

Calibration check: ***recommended*** every two months.

Display: backlit LCD, 45mm x 21mm, 128 x 64 pixels.

Warm-up time: none.
Memory: the result of the last subject's breath test is stored for later recall. Around 2,500 breath test files English language; date, time and test result can be stored in memory, for downloading to a PC. Two stage low memory warning [20 remaining tests, then **Memory Full**].

RFI certification [emission and immunity]: meets general Police requirements in respect of EMC immunity [including Airwave].

Vibration and shock: meets relevant specification requirement.

Case material: impact resistant ABS.

Dimensions [instrument only]: 120 x 60 x 30mm.

Weight [instrument only] : around 160g, with batteries.

Appendix II: EMC Requirements

1. Requirements

All Medical Electrical Equipment require special precautions to be taken regarding EMC and the **500** needs to be used according to the EMC information provided in this appendix.

Portable and mobile RF equipment can affect medical electrical equipment.

The Medical Equipment System described in this appendix comprises a **500** instrument powered by AA batteries alone, or a **500** instrument powered by AA batteries, attached to a thermal printer (RM40800) via a printer cable (RM50871).

The printer and printer charger meet international standards for EMC and are determined to be 'Not Medical Electrical Equipment' and therefore exempt from inclusion in this appendix.

Use of a printer or printer cable other than those specified by the manufacturer may result in increased emissions or decreased immunity of the system.

The **500** should not be used adjacent to other equipment and that if adjacent use is necessary, the **500** should be observed to verify normal operation.

2. EMC Declaration

Guidance and Manufacturers Declaration – Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **500** system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **500** system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Exempt	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Exempt	

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 KV Contact ±8 KV Air	±6 KV Contact ±8 KV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, then the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4		Exempt	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5		Exempt	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11		Exempt	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8		Exempt	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

Guidance and Manufacturers Declaration – Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3Vrms 150 KHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the **500**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = (3.5/V_1)\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = (1.2)\sqrt{P}$ 80 MHz to 800 MHz $d = (2.3)\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended

			separation distance in metres (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (celluar/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **500** is used exceeds the applicable RF compliance level above, the **500** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the **500**. [b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the 500

The **500** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **500** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **500** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3. Guidance Notes

1. When storing the **500** for long periods (greater than 1 month) or during transport between sites the batteries should be removed.