Abbott

SoToxa™

ORAL FLUID
MOBILE ANALYSER

FOR FORENSIC & WORKPLACE USE ONLY

Contents

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The SoToxa™ Oral Fluid Mobile Analyser is intended to be used in conjunction with the SoToxa™ Oral Fluid Test Kit to screen for the presence of drugs of abuse and/or their metabolites in oral fluid.

A positive test result should be confirmed by a second test method such as GC-MS (Gas Chromatography-Mass Spectrometry) or LC-MS (Liquid Chromatography-Mass Spectrometry).

The results obtained using the SoToxa™ Oral Fluid Mobile Test System are intended to be used to monitor compliance with drug testing programmes and regulations, such as in a workplace setting or for use by law enforcement agencies. The product is not for home use or for use within a clinical, diagnostic or therapeutic setting.

Please read this user guide and the test kit instructions for use carefully, prior to using the analyser.

REF TOX500P | TOX500SFWOIND | TOX500SFWOEU | TOX500SFWOUS | TOX500SFWOAUS | TOX500SFWOUK | TOX500SFWOBRA | TOX500SFWOJPN | TOX400P | TOX400SFWOUK | TOX400SFWOAUS | TOX400SFWOUS | TOX400SFWOEU | TOX400SFWOBRA | TOX400SFWOJPN | TOX400SFWOKOR

IMPORTANT: Some menus and features described in this user guide may not be available on all SoToxa Oral Fluid Mobile Analysers. If you have any questions, please reach out to Customer Services.

1. Introduction

1.1 Intended use

The SoToxa™ Oral Fluid Mobile Analyser is intended to be used in conjunction with the SoToxa™ Oral Fluid Test Kit to screen for the presence of drugs of abuse and/or their metabolites in oral fluid.

A positive test result should be confirmed by a second test method such as GC-MS (Gas Chromatography-Mass Spectrometry) or LC-MS (Liquid Chromatography-Mass Spectrometry).

The results obtained using SoToxa™ Oral Fluid Mobile Test System are intended to be used to monitor compliance with drug testing programs and regulations, such as in a workplace setting or for use by law enforcement agencies. The product is not for home use or for use within a clinical, diagnostic or therapeutic setting.

1.2 Test principle

1.2.1 The SoToxa Oral Fluid Mobile Test System (system) consists of the SoToxa Oral Fluid Mobile Analyser (analyser) and the SoToxa Oral Fluid Test Kits (test kit/s) which contain the SoToxa™ Oral Fluid Test Cartridge (test cartridge) and the SoToxa™ Oral Fluid Collection Device (collection device).

1.2.2 The analyser is a digital imaging device which uses advanced image processing algorithms to accurately determine the line intensity on the test cartridge.

1.2.3 The test cartridge is a chromatographic immunoassay. This is a single use, disposable cartridge that contains dried reagents and a liquid buffer solution.

1.2.4 The test cartridge is inserted into the analyser and is warmed by the analyser to optimum testing temperature.

1.2.5 Oral fluid is collected using the collection device supplied within the test kit. This is a single use, disposable collection device. The donor must actively swab the collection device around the gums, tongue and inside the cheek, until the sample presence indicator starts to turn blue.

1.2.6 The collection device is then inserted into the test cartridge.

1.2.7 During the testing process, the oral fluid is combined with a buffer solution, mixed and then incubated before being applied to the immunoassay test strips housed within the cartridge.

1.2.8 The oral fluid flows by capillary action along the test strips, carrying with it labelled anti-drug antibodies which are released from pads on the strips and in the sample reservoir.

1.2.9 At designated zones on the strips, drug protein conjugate has been applied in bands which are invisible to the human eye. In the absence of a drug in the sample, the anti-drug antibodies will bind to the drug protein conjugate to form a line. In the presence of a drug the formation of this complex will be diminished, forming a weaker line.

1.2.10 On receipt of the analyser by the user, the analyser is already configured by the manufacturer to read specific cartridge types. Additional cartridge types can be added by the user by application of cartridge updates (see section *8.4 Installed cartridges and updating cartridge types*).

1.2.11 The analyser 'reads' the line intensity on the test strips. The detected line intensity is compared with a predetermined threshold derived from equivalent concentration curves, to report qualitative results.

1.2.12 Test results are displayed on the analyser screen and can be printed using the printer.

1.2.13 The test cartridge is then removed from the analyser and disposed of in accordance with local and national regulations.

1. INTRODUCTION

1.3 Analyser specifications

ANALYSER	
Dimensions (mm)	L 222 x W 88 x H 61
Weight	Approximately 680g
Detection system	Digital imaging device.
Controls	Test cartridge and collection device sensors. Test cartridge recognition using 2D barcodes for identifying cartridge type, ID, batch and expiry date. Sensor providing feedback on angle of inclination of analyser. Test cartridge heating with temperature control. Internal start-up checks and process controls during testing. Quality control test cartridges.
Display	LCD colour screen 3.2".
User interface	Five way navigation key, left and right select keys, power button, reset button.
Electrical rating	15V 2.6Amax (via external PSU). The analyser should only be charged/powered by the supplied PSU and cables.
Languages	English (EN), Spanish (ES), French (FR), Czech (SK) , Danish (DA), German (DE), Indonesian (ID), Italian (IT), Dutch (NL), Norwegian (NO), Polish (PL), Portuguese (PT), Russian (RU), Swedish (SV), Turkish (TR), Japanese (JP) and Vietnamese (VI).
Memory	Data storage capacity of over 10,000 tests, the last 100 results can be accessed on the analyser.
SD card	SD card connectivity for firmware and test cartridge updates and export of analyser test and diagnostic data.
Connectivity	Bluetooth - Communication with Bluetooth enabled accessories when provided and applicable.
Bluetooth frequency range	2.402GHz to 2.480GHz
Printer	Connection to Martel MCP7810 printer for printing test reports.
USB Interface	To communicate with a PC via the micro USB cable provided.

OPERATING CONDITIONS	
Temperature	Operational temperature is dependent on the test cartridge in use, please refer to the Instructions For Use (IFU) provided with the test kits. NOTE: the rated safe electrical operating temperature of the analyser is 0°C to 40°C. Test cartridges must not be at -5°C for more than 10 minutes.
Relative humidity	20 to 80% non-condensing.
Storage temperature	-20°C to 45°C
Environment	Protect the analyser from direct sunlight, humidity and dust. Pollution degree: 2.

POWER RATINGS	
Analyser	15V DC 2.6Amax
Mains adapter	100-240V AC 50-60Hz 1.1Amax (Voltage fluctuations: +/-10%)
Car adapter	10 to 15V DC
Battery	3.2Ah 11.1V lithium

Note: Supplied mains adapters may be rated for 2.6A to 3A output, all of which provide the same performance.

PRINTER	
Dimensions (mm)	L 150 x W 80 x H 50
Weight	636.5g
Controls	Power button

* Operation within the temperature range of 5°C to 35°C will be tested at 20 to 80% RH, however due to testing limitations it is not possible to accurately control humidity below 10°C. The analyser is operational down to 5°C at unquantified relative humidity.

1.4 Transport and unpacking

The analyser and its accessories are supplied in a convenient Carry Case, and all have been fully inspected and tested. Upon receiving the system, immediately inspect the contents of the case for any transportation damage or missing items (see list of accessories). If any sign of damage is found, or if any items are missing, contact Customer Service.

The case is designed to allow the analyser and accessories to be used from within the case, however the analyser can be removed if required. It is recommended that the analyser is operated and transported in the case, and is secured by the velcro straps to prevent movement when in transit.

1.5 Accessories

The following items are supplied with the analyser:

- Carry Case.
- Micro USB cable for connection to a PC.
- Power supply unit and power cable may be supplied as individual or integrated parts.
- QC test cartridge set (PQC and NQC).
- Printer and RJ12 printer cable.

The following optional items may also be supplied with your analyser:

- Car power supply.

The following item may be required, but is not supplied with the analyser:

- Small Phillips head screwdriver. This tool is required to access the SD card. Refer to section *2.9 SD card slot.*

1.6 Special features

- The analyser guides the user through the testing process with a series of on-screen messages and prompts and also has an on-board 'Help' function providing on the spot support if required.
- The analyser automatically performs a series of start-up checks along with process controls during testing to ensure correct operation. The analyser will not allow a test to be carried out or be continued if a malfunction is detected.
- The analyser is provided with a positive and negative quality control test cartridges (PQC and NQC). It is recommended that these performance checks are carried out at least once on each day of testing. The QC Tests can be enforced at defined time intervals. Please refer to section *7 QC Tests*, for further information.
- The analyser has internal sensors to detect the presence and position of the test cartridge and collection device. If the test cartridge and collection device are not detected, are detected at the wrong time in the test protocol, or are removed from the analyser prematurely, the test may be abandoned.
- The analyser reads and stores cartridge information from the test cartridge barcode. If the test cartridge has expired, the test will not be continued.
- New test cartridge types must be installed on the analyser via the SD card. Updates will be provided by the manufacturer.
- The analyser should be positioned horizontally and kept flat when in use. User feedback on the tilt angle of the analyser is provided on the screen. If the analyser is tilted out of the operational range, the test may be abandoned. Refer to section *2.8 Tilt sensor* for more information.
- The analyser detects and monitors test cartridge temperature and uses a heating element to warm the test cartridge to optimum temperature for testing.
- The analyser is now Bluetooth enabled which means in the future it will allow connectivity to accessories when provided and applicable.

1.7 Data handling

- The analyser is now Bluetooth enabled which provides greater flexibility from a data handling and management perspective in the future.
- The analyser is capable of capturing donor information via the donor questionnaire. Test cartridge identification via the test cartridge barcode, storage of test data and connectivity to the printer, PC and SD card.
- All results are stored in an on-board archive and may be retrieved and viewed on the analyser at any time after the test.
- Test results can be printed using the printer. Results can be printed immediately following the test and can be reprinted from the archive at a later date.
- Firmware upgrades and new test cartridge configurations can be uploaded to the analyser from an SD card, when these are released by the manufacturer.

1.8 Safety warnings and precautions

- WARNING: The analyser and test cartridges generate a weak magnetic field, which may interfere with the operation of cardiac implant devices such as pacemakers. Always maintain a safe distance of separation between the system and any implanted device. If you feel unwell whilst using the analyser, stop using the system and consult your physician.
- Only use the power supply unit (PSU), printer, USB and other associated cables supplied with the analyser. Contact Customer Services if in any doubt regarding power supplies and cables for use with the system.
- Only use the power supply unit (PSU), printer, USB and other associated cables as described in this user guide. If any part of the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
- Please ensure that the mains supply cable for the power supply unit is appropriately rated and approved as per the applicable national requirements.
- As with any electrical instrument or equipment, care is required when handling the analyser to ensure that it is not subjected to heavy shocks or dropped from any height. Never exert undue force on the surface of the display, or expose any part of the analyser to sharp or abrasive objects.
- Use the analyser indoors when connected to AC power.
- When the analyser is connected to the mains it should be placed in such a way to allow for easy disconnection of the power source.
- Do not open the analyser. The analyser contains no user serviceable parts. Any unauthorized opening of the analyser can cause hazards and will invalidate warranty claims.
- The test cartridges are designed for single use only – do not attempt to re-insert a used test cartridge into the analyser.
- Handle all oral fluid specimens as if they are potentially infectious. It is advisable to wear Personal Protective Equipment (PPE) such as gloves throughout the sample collection and testing process.

- Do not insert fingers or objects other than the test cartridge into the test cartridge slot. This may result in harm to the user or damage to the analyser.
- Do not use dirty or damaged test/QC cartridges as this may damage the analyser or cause an invalid test result.
- Do not use the analyser or any of its electrical accessories if these appear to be damaged. Contact Customer Service to arrange for replacement parts.
- Do not use the analyser near a magnetic source.
- Do not ingest the silica gel packs.
- Do not open power supply casing for the scanner or printer.
- Allow the analyser to reach ambient temperature before use. If moving the analyser between storage and operating environments of different temperatures or humidities, this may take at least 30 minutes.
- If climatic differences are significant, allow more than 30 minutes for the analyser to acclimatise.
- It is the responsibility of the user to ensure the date and time settings are correct.
- Physically secure the analyser in an access controlled area to prevent unauthorised physical access to the device.

1.9 Calibration

The analyser is factory calibrated and does not require any further calibration by the user.

However, it is recommended to carry out a regular performance check using the quality control test cartridges provided with the system (see section *7 QC Tests*).

1.10 Maintenance and cleaning

If required, the exterior of the analyser and its accessories can be wiped with a lint free cloth or a damp cloth with mild detergent. Wipe away any spillages immediately. Do not use abrasive cloths or other material, and do not allow the unit to come into contact with any potentially corrosive substances. If using a damp cloth, ensure the analyser is turned off and disconnected from mains AC power.

⚠️ **DO NOT try to clean inside the analyser or open the analyser for cleaning.**

The analyser does not contain any user serviceable components. If a fault is suspected or routine factory maintenance is required, then please contact Customer Service.

1.11 Servicing

The analyser does not require regular servicing to maintain performance, however, local contractual requirements may require servicing at fixed and agreed intervals. When servicing is required, the analyser and accessories should be returned to the manufacturer or authorised servicing facility where the service will be completed by a qualified service engineer.

For analysers where servicing is required, the date that the next service is due can be viewed in the Analyser Summary screen. Additionally, the analyser will automatically display the service symbol in the status line when service is due in less than one month. If the analyser is not serviced within this time, the symbol will turn from white to orange.

Note: Service status (OK, due or overdue) will also be displayed in the test details for each test and printed on test reports.

To view the date when the next service is due:

Step 1: From either of the main menus, select the **Analyser Summary** option.

Step 2: The following screen will display the servicing status, scroll down to view the due date of the next service:

Step 1   Step 2
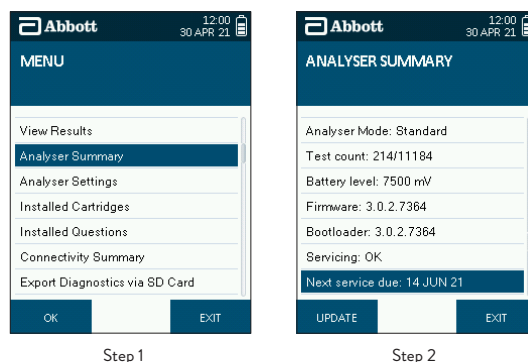
Please contact Customer Service to arrange servicing when required. The analyser and accessories must be returned in the Carry Case for protection in transit.

1.12 Lifetime

If the analyser is used as defined within the user guide and correctly maintained, the lifetime of the analyser is not limited.

1.13 Warranty

The analyser is covered by an initial 12 month manufacturer's guarantee. The guarantee covers all mechanical or electrical faults and firmware or hardware failures. The manufacturer's guarantee does not cover the systems for loss, theft or damage caused by the user.
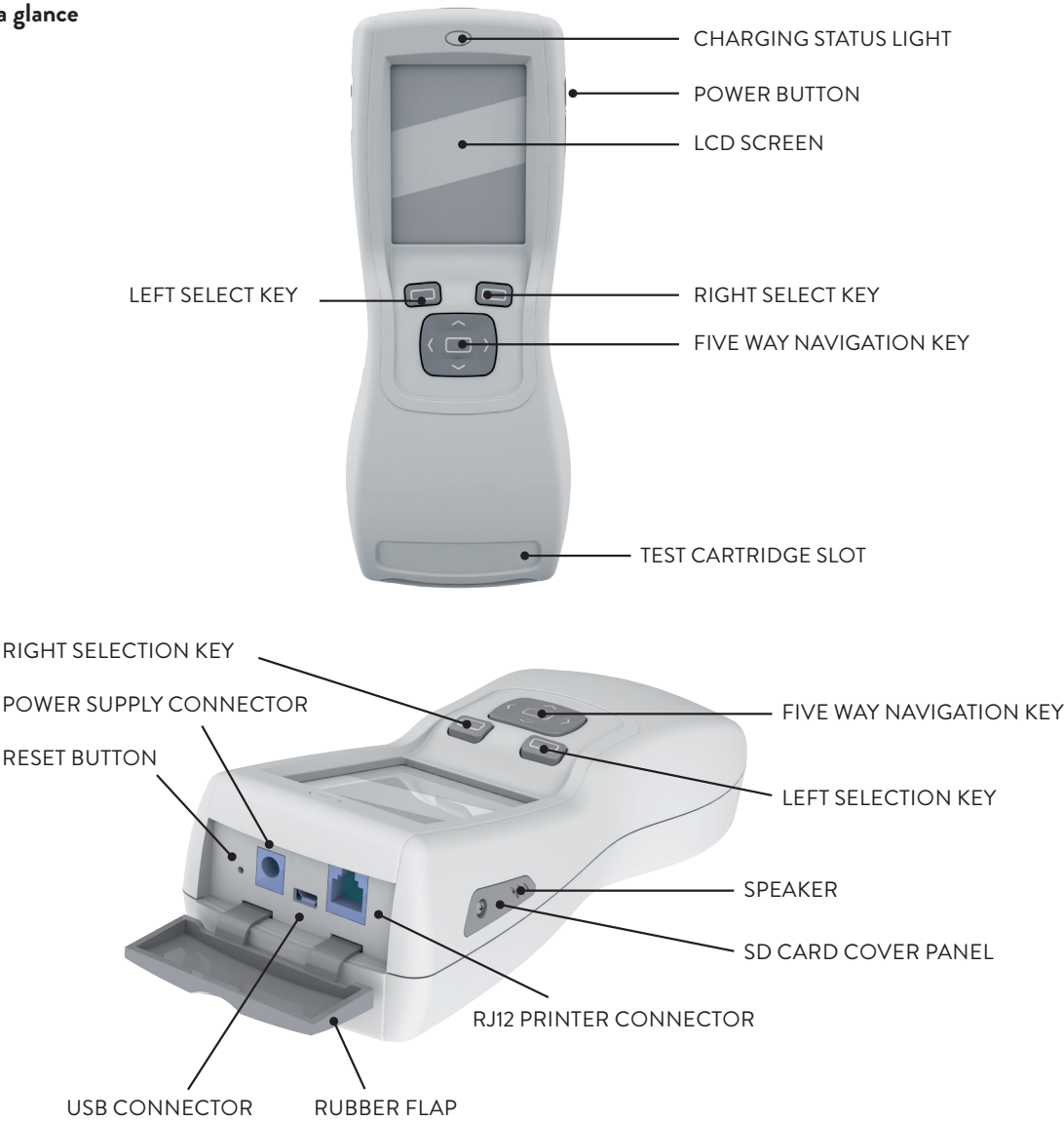
Following the expiration of this warranty, we recommend taking advantage of an extended warranty option for your analyser. Please contact Customer Service for details.

1.14 Drug abbreviations

DRUG ABBREVIATIONS	
Abbreviation	**Drug Name**
AMP	Amphetamine
BZO	Benzodiazepines
COC	Cocaine
MAMP	Methamphetamine
OPI	Opiates
THC	Cannabis

2. Getting Started

2.1 Analyser at a glance

CHARGING STATUS LIGHT
POWER BUTTON
LCD SCREEN
LEFT SELECT KEY
RIGHT SELECT KEY
FIVE WAY NAVIGATION KEY
TEST CARTRIDGE SLOT

RIGHT SELECTION KEY
POWER SUPPLY CONNECTOR
RESET BUTTON
FIVE WAY NAVIGATION KEY
LEFT SELECTION KEY
SPEAKER
SD CARD COVER PANEL
RJ12 PRINTER CONNECTOR
USB CONNECTOR
RUBBER FLAP

2.2 User interface and symbols

The analyser has a colour screen which will display graphics and text to guide the user through the test process, give feedback on the status of the test and the analyser and alert the user to any errors that may occur during use. The analyser also has a speaker and will produce various sounds as alerts or to tell the user when a test is complete. See section *8.3 Analyser settings*, for more information on how to alter the screen backlight and volume settings of the analyser.

The analyser screen displays date and time at all times. You will also see symbols appearing on the screen from time to time giving more information on the status of the analyser. These symbols will be displayed in the status line at the top of the screen, alongside the date and time.

The symbols used by the analyser and their meaning, are shown below:

| ANALYSER SYMBOLS	
Symbol	**Meaning**
	Bluetooth symbol: The appearance of this symbol indicates that there is a connection established through Bluetooth technology between the analyser and a host device. Note this will not appear when connected to a peripheral such scanner or printer. Refer to section *8.6 Connectivity summary*.
	Memory symbol (white): The appearance of this symbol indicates that the analyser is close to reaching maximum storage capacity for stored test results. Contact Customer Services to discuss options on how to download test data to make more memory space available. To view how much memory space is remaining, refer to section *8.2.1 Results storage capacity*.
	Memory symbol (orange): When memory storage capacity is reached, the white memory symbol will turn orange. The oldest tests stored on the analyser will be overwritten with new test results. Contact Customer Services to discuss options on how to download test results and make more space available.
	QC Lockout symbol: The appearance of this symbol indicates that the Quality Control (QC) checks with the PQC and NQC cartridges have not been successfully completed in the defined time period. No further drug tests can be initiated until the quality control checks have been completed. Refer to section *7 QC Tests* for more information.
	Tilt warning symbol: The appearance of this symbol means that the analyser has been tilted beyond the acceptable range for testing. This symbol is accompanied by a beeping sound (if the analyser sound is switched on). The analyser must be returned to horizontal immediately and kept flat during testing. If the analyser is tilted beyond the acceptable range for too long, this may result in a test error or damage to the analyser. Refer to section *2.8 Tilt sensor* for more information.
	Power connection symbol: This symbol is shown when the internal battery is fully charged and the analyser is connected to an electrical outlet via the power cable. If the internal battery is not fully charged, then the battery charging symbol will be shown. If this symbol, or the battery charging symbol does not appear when connected to an electrical outlet, check that the power cable connections are secure and that the electrical outlet is active. Refer to section *2.5 Power connection* for more information.
	Battery status symbol: This symbol is displayed to show that the analyser is operating from battery, rather than the electrical outlet. If the analyser is not connected to an electrical outlet, the battery status symbol will be displayed. The level of battery power remaining is indicated by the number of shaded blocks. When all the blocks are shaded, the battery is full.
	Critical battery level: The battery status symbol will change to a red outline with the last block shaded red when the battery reaches a critical level. The analyser will need to be connected to an electrical outlet and charged.
	Battery charging symbol: This is the same symbol as the battery status symbol but the number of shaded blocks will increase and decrease to indicate charging. This symbol will be displayed when the analyser is connected to an electrical outlet and is charging. The analyser will automatically begin to charge when connected to the electrical outlet, if the battery is not full. Once the battery is charged, this symbol will be replaced by the power connection symbol. Refer to section *2.7 Charging the analyser* for more information.
	Service symbol (white): This symbol will appear on the status line when the annual service date for the analyser is due in less than one month. To view the service due date, refer to section *1.11 Servicing*. Contact Customer Service to arrange a service for the analyser.
	Service symbol (orange): When service is overdue, the service symbol will turn orange. Contact Customer Service to arrange a service for the analyser.

2.3 Control keys

The analyser has a five-way navigation button and the left and right soft keys. Please see section *2.1 Analyser at a glance*, which shows the location of these buttons.

The left and right selection keys can be used to select the corresponding on-screen buttons which will appear at the bottom left and right hand corners of the screen when input is required from the user. For example, if the screen below appears, pressing the left selection key would take the user to the menu while pressing the right selection key would take the user to the help function associated with this step.

The five way navigation key can be used to scroll up, down, left and right by pressing the top, bottom, left or right edge of the button respectively. For example, if the screen below appears, the five way navigation key can be used to move the highlighter bar up and down through the list of test results. Pressing the center of the five way navigation key selects the option that is highlighted on the screen and can be used instead of the left and right selection keys for 'OK' and 'Enter'.
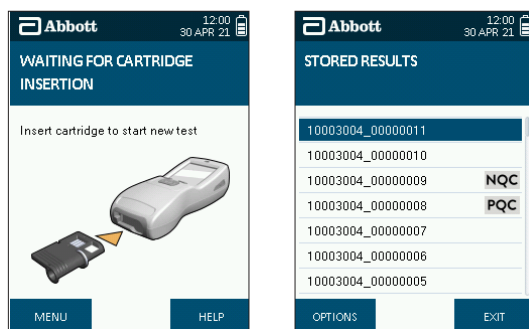
2.4 Setting up

The analyser does not require any installation steps. The analyser can be connected to mains power, to the printer using the cables provided in the system Carry Case. Use only the connections and printer provided. Alternative connections and printers should not be used as these may be unsafe or incompatible with the analyser.

2.5 Power connection

The analyser can be powered from a power outlet or by its internal batteries. To connect the analyser to the power outlet:

Step 1: Insert the AC power cable into the power supply unit.

Step 2: Connect the power supply unit to the power supply connector, located at the top of the analyser.

Step 3: Connect to the corresponding AC power socket.

Step 4: Turn on the analyser by pressing the power button.

Step 5: If a power outlet is connected when the analyser is running from batteries, the analyser will switch to the outlet as a power source. When the analyser is connected to a power outlet the power connected symbol will be displayed in the status line:

⚠️ **Do not use cables or power supply units that are damaged as there may be risk of electric shock.**

⚠️ **If the analyser battery requires charging, the battery charging symbol will be displayed when the analyser is connected to the power outlet.**

2.6 Battery power

The analyser will automatically operate from the battery when turned on if not connected to a power outlet. If outlet power is lost or interrupted, the analyser will switch to battery power automatically. To switch to battery power when in use, simply disconnect the analyser from the power outlet.

When running the analyser on battery power, the battery charge level is displayed by the battery status symbol within the status line as shown below:

The number of tests that the analyser can perform from one full battery charge will vary depending on the type of test cartridge that is being used, the environmental conditions, the age of the analyser, whether results are printed and whether the questionnaire function is being used.

If the battery level reaches critically low level the screen will display a nearly empty battery symbol with the final bar red. The battery symbol in the status bar will have a red outline. The screen will appear for a few seconds before the analyser turns off.
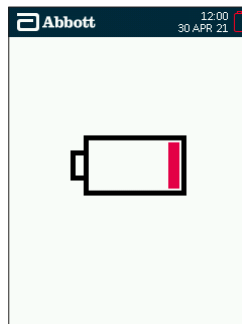
See the following section *2.7 Charging the analyser*, for how to charge the analyser when the batteries are low.

2.7 Charging the analyser

The analyser is supplied with a partially charged battery which is secured within the analyser. To charge the battery, connect the analyser to an electrical outlet as follows:

Step 1: Insert the AC power cable into the power supply unit.

Step 2: Connect the power supply unit to the power supply connector port located at the top of the analyser.

Step 3: Connect to the corresponding AC power socket.

Upon connecting the power outlet the charging status light above the display will illuminate. A red light means the battery is charging, a green light indicates the battery is fully charged.

⚠️ **The charging status light will only be illuminated when connected to an electrical outlet.**

⚠️ **In order to ensure maximum battery life, charge the analyser battery for a minimum of 5 hours before running the analyser on battery power.**

It is recommended to charge the printer every time the analyser is charged; if the system is in storage, the analyser and printer should be charged every 2-3 months to ensure the batteries remain in good condition.

2.8 Tilt sensor

The analyser should be used in a horizontal plane, and once the collection device has been inserted it must be kept as still and flat as possible throughout testing to prevent disruption to the test. The analyser has a built-in tilt sensor which will display a warning on the screen when the analyser is tilted beyond the acceptable range. If tilting is not corrected immediately, this may result in a test error.
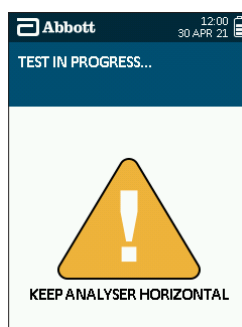
2.9 SD card slot

The analyser has a microSD card slot. Refer to section *2.1 Analyser at a glance* for the location of the SD card cover panel. The SD card socket can only be accessed by unscrewing the SD card cover panel. For this, a small Phillips head screw driver is needed. This tool is not supplied with the system. Please contact Customer Service if access to the SD card is required.

The SD card can also be used for applying firmware updates to the analyser, adding new test cartridge types or versions to the analyser and exporting of diagnostic data from the analyser to the card. Information on how to use the SD card for updating information on the analyser is covered in section *8.2.2 Updating firmware and exporting of data is covered in section 8.7 Exporting diagnostic data.*

2.10   Silica gel packs

Each foil wrapped test cartridge is packed with a silica gel packet. The silica beads are designed to change in colour when moist and act as an indication that the test kits have been stored correctly and have not been exposed to water vapour in the air. The silica packs are made from an environmentally friendly, synthetic silica indicating gel that is impregnated with a colour changing agent.

The silica gel packs are yellow/orange when dry, indicating that the kit has been stored correctly and has not been exposed to the external environment. When moisture has been absorbed, the silica packs will turn to light green, indicating that water vapour has entered the packaging.

The silica gel pack should be checked each time a test cartridge is opened. If the silica gel pack is green, discard the test cartridge and contact Customer Service, as the performance of the product may have been compromised. If the silica gel has burst, discard the test cartridge and contact Customer Service.

Slight discolouration of the silica beads is normal. When the majority of the beads within the pack are green, the test cartridge should not be used.

3.   Printer

The analyser is configured and the printer port set for the printer that has been provided: Martel MCP7810 (wired). Please refer to section *8.3.9 Printer port* for full details if required.

3.1   Connecting the printer

To connect the analyser to the printer attach the RJ12 connector cable to the base of the printer and to the RJ12 printer connector on the top of the analyser, behind the rubber flap. Refer to section *2.1 Analyser at a glance* for the location of connections. Switch the printer on by pressing the power button on the top of the printer. The green status light on the printer will then come on. To turn the printer off, press the power button again so that the status light goes off.

3.2   Loading paper

The printer is supplied with one roll of paper already loaded. To load a new roll of paper into the printer, open the paper cup lid and remove the spool and any remaining paper. Reel off a few inches from the new roll of paper and hold approximately 2 inches of paper outside of the printer. Place the new roll into the paper reservoir with the paper feeding forwards from the bottom of the roll and the leading edge over the tear bar. Close the lid by applying equal amounts of pressure on each side of the paper cup lid until the lid is in the locked position.

Please contact your distributor or Customer Service to order replacement printer paper rolls.

3.3   Charging the printer

The printer will only charge when it is offline and connected to the analyser via the RJ12 printer cable and when the analyser is powered by the mains. This is indicated by the printer's green LED status light flashing every 1-2 seconds.

The printer will not charge if it is online, indicated by the printer status light remaining on; or if the analyser is not connected to the mains.

The printer will take approximately 2-3 hours to charge.

See section *2.5 Power connection*, for more information on how to connect the analyser to the mains.

4.   Start-up

Important – Please read the instructions for use in full provided with the test kit, prior to commencing a test.

Turn on the analyser by pressing on the power button situated on the right hand side. The analyser will complete a series of checks during the start-up process to make sure it is in a good operating condition. During this testing, the start-up screen will be displayed:
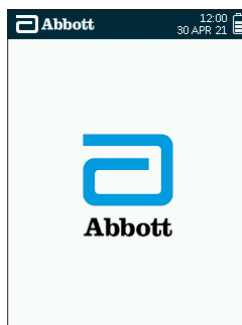
⚠ **The analyser will not be able to run start-up checks if a test cartridge is already inserted. Please remove the test cartridge before switching on.**

⚠ **The operational temperature range for running a test is between 5°C to 35°C. Outside of this range the following message will be displayed:**
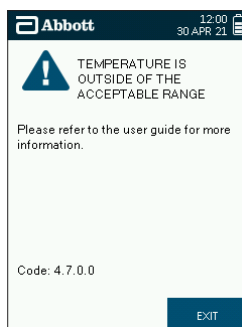
⚠ **Allow the analyser to reach ambient temperature before use. If moving the analyser between storage and operating environments of different temperatures or humidities, this may take at least 30 minutes. If climatic differences are significant, allow more than 30 minutes for the analyser to acclimate.**

5.   Using the Help Function

The analyser will display instructions and prompts on the screen to guide the user through the test process. When an action or user input has been completed, these screens will update automatically to lead on to the next step.

The analyser has an on-board help function which provides additional guidance. To access the help screens, press the **right** select key when the help button is displayed on the screen. The help option can only be accessed if the help button is shown – see the example below. If additional help is required, please contact Customer Service for assistance.
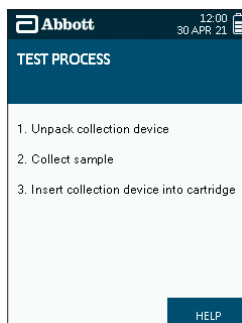
6. Running a Drug Test

6.1 Initiating a drug test

Ensure the instructions for use insert supplied with the test kit has been read carefully before beginning a test. If additional guidance is required please contact Customer Service.

Step 1: Refer to section *4 Start-up* to switch on the analyser.

Step 2: When the analyser is ready to begin a test, the screen below will appear:

6.2 Inserting the test cartridge

Step 1: Remove a new test cartridge from the foil wrapper. Testing should be initiated within 10 minutes of opening the foil wrapper.

⚠️ **The test cartridges and collection device are designed for single use only and must be disposed of after use.**
DO NOT re-insert a used test cartridge into the analyser or re-use the collection device.

Step 2: Check the silica gel pack is yellow. If the silica gel is green, discard the test as the performance of the product may have been compromised. See section *2.10 Silica gel packs*, for more information.

Step 3: Insert the test cartridge into the cartridge slot on the front of the analyser.

| Step 1 | Step 2 | Step 3 |

6.3 Test cartridge identification and verification of the expiry date

Following insertion of the test cartridge, the analyser will read the barcode to identify the test cartridge and verify that it is within its expiry date. The analyser will also check that the test cartridge type is installed on the analyser. If the test cartridge has expired, it must not be used and the testing process must be restarted with a new test cartridge that is within its expiry date.
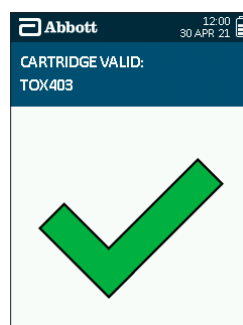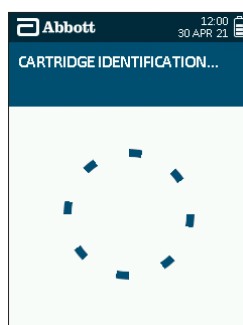
If the test cartridge is not valid, refer to section *10 Technical Support, Codes and Troubleshooting*.

6.4 Sample collection

Following test cartridge identification and verification of the expiry date, the screen below will be displayed. For additional guidance on each step of the test process, select the help function on the analyser screen or refer to the instructions for use insert supplied with the test kit.
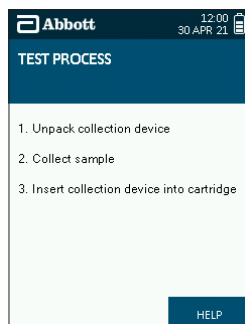
Step 1: Ask the donor to remove the collection device from the packaging, ensuring they hold the plastic stem of the collection device, and then place it in the mouth.

Step 2: The donor must actively swab the collection device around the gums, tongue and inside the cheek, until the sample presence indicator **starts** to turn blue.

Step 3: Insert the collection device into the test cartridge (this should already be inserted into the analyser). Gently push the collection device all the way into the test cartridge to the stop position. There may be some resistance experienced as the collection device punctures the test cartridge buffer foil. The sample should be processed immediately. Failure to process the sample within 30 seconds following collection may produce unreliable results.
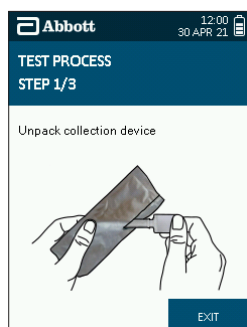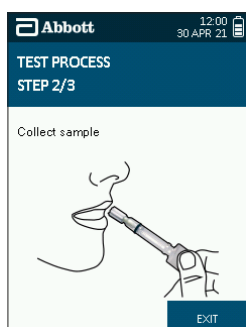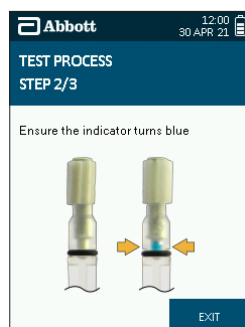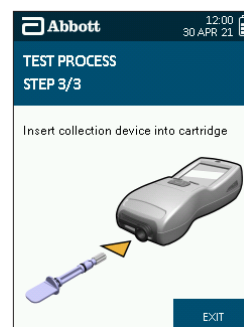
| Step 1 | Step 2 | Step 2 | Step 3 |

⚠️ **Once the sample collection device has been inserted, the analyser should be kept in a horizontal plane remaining as still as possible throughout testing. If the analyser is tilted beyond the acceptable range, this warning symbol will appear on the screen:**
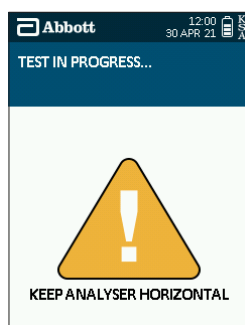
Correct the orientation of the analyser immediately to prevent disruption to the test. See section *2.8 Tilt sensor*, for more information about the tilt sensor.

6.5 Test in progress and interpretation of results

When the collection device has been inserted into the test cartridge in the analyser, the screen will display 'test in progress' and a countdown timer will appear. The time it takes to analyse results depends on the type of test cartridge being used.

When the analyser has finished processing the test, a results screen will be displayed. Results are displayed as positive, negative or lab test required against each drug group, depending on which results display option has been set up on the analyser. To change the results display, refer to section *8.3.5 Results display*. If the testing process has not been successful then an error message will be displayed on screen with a description of the issue encountered. Full details of all error messages can be found in section *10.2 Codes and troubleshooting*.
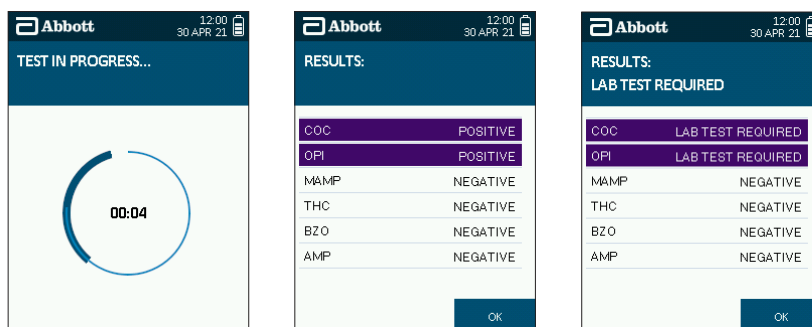
Select **OK** using the **right** select key to move onto the next screen.

On occasion prior to the results screen being displayed you may see an additional analysis screen which is shown below. This screen may be present for a maximum of 60 seconds.

6.6 Completing the questionnaire

The analyser allows additional donor information to be captured alongside the test result. If the questionnaire set has been enabled on the analyser, the questionnaire will be entered following the results screen. The questionnaire can be enabled or disabled by changing the Analyser Settings. Refer to section *8.3.6 Questionnaire* for instructions on how to enable and disable the questionnaire.

Step 1: Use the five way navigation key to scroll up or down to select the correct information.

Step 2: Any of the individual questions can be skipped by either selecting **Skip**, or scrolling through the options until **Skip** or – is reached.

Step 3: To make a selection, press **OK**.

Step 4: At the end of the questionnaire, a summary of the information entered will be displayed.
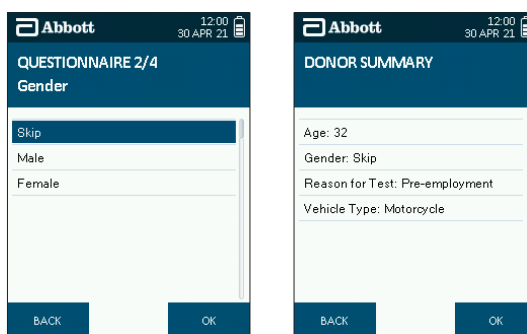
Step 3   Step 4

Step 5: If the information is correct, select **OK** using the **right** select key or if something needs to be changed, select **Back** with the left select key to return to the questions.

Step 6: Selecting **OK** will accept the questionnaire and move on to the next screen.

6.7 Printing results

If the results and questionnaire (if used) have been accepted, the analyser will give the option to print results.

Step 1: If not already connected, ensure that the printer is attached to the analyser (refer to section *3.1 Connecting the printer*) and ensure the printer is switched on.

Step 2: To print results, select **Yes** using the **left** select key.

Step 3: Failure to connect or switch on the printer will lead to the print failure screen. Check connections, switch on the printer and select **Retry** to return to the previous screen. Alternatively select **Cancel** to skip printing.

Step 4: After printing is complete, the print option screen will be displayed again to give you the choice to print additional copies of results.

Step 5: If printing is not required, select **No** on the print option screen.

Step 2	Step 2	Step 3
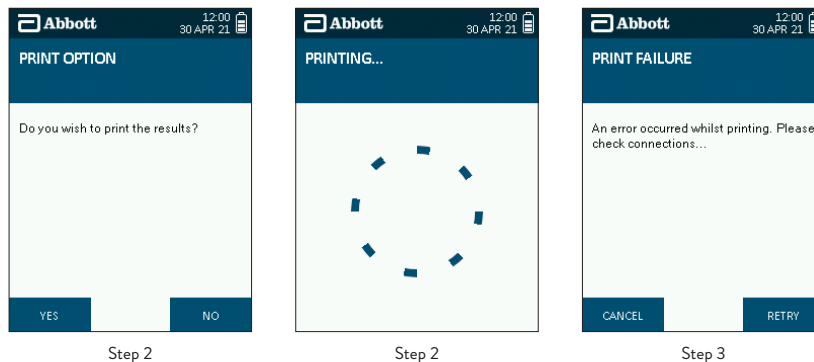
6.8 Completing the test

At the end of testing when results have been displayed and printed (if required), the analyser will prompt the user to remove the test cartridge. Do not remove the test cartridge by pulling the collection device and do not attempt to remove the collection device from the test cartridge.

⚠ **Dispose of the used test cartridge and collection device according to local and national regulations.**

⚠ **Take care when removing the test cartridge as the underside of the cartridge may be hot. Handle the test cartridge by the side edges.**

7. QC Tests

7.1 What are the QC tests?

QC stands for Quality Control. Two reusable QC test cartridges are supplied with the analyser:

- Positive Quality Control (PQC)
- Negative Quality Control (NQC)

These two QC test cartridges are tested in sequence to check that the analyser is interpreting test lines correctly. If the QC tests pass, this means that the analyser optical functionality is working correctly.

7.2 How often should the QC tests be carried out?

It is recommended that you carry out the QC tests once on each day that the analyser is used. If required, the QC tests can be enforced at defined time intervals. Refer to section *8.3.8 Periodic QC* for instructions on how to enable and disable QC Lockout.

7.3   Running the QC tests

Step 1:   Check that both QC test cartridges are clean and undamaged. If the QC test cartridges are marked, please contact Customer Service.

Step 2:   Insert one of the two QC test cartridges, the cartridge will be analysed automatically. The order in which the QC test cartridges are inserted is not important, as the analyser is able to recognise the cartridge that has been inserted and will analyse it accordingly.
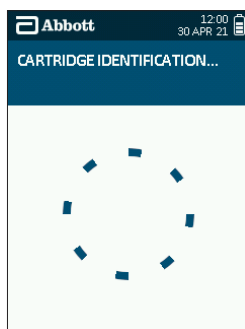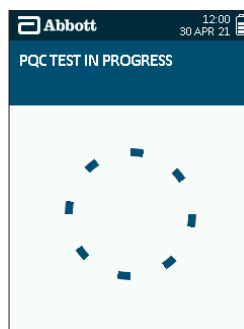
Step 2   Step 2

Step 3:   Once analysis of the first QC test cartridge is finished, the system will prompt you to remove the current cartridge and insert the other QC test cartridge. Note that if QC failed on the first cartridge, QC testing will be abandoned; see step 5.

Step 3

Step 4:   Following analysis of the second QC test cartridge, results of the QC test will be displayed as 'QC Results: Pass' or 'QC Results: Fail'.

Step 5:   If the QC tests have failed, contact Customer Service. Do not continue testing.

Step 6:   After acknowledging the results by selecting **OK**, the analyser will prompt you to remove the test cartridge, to complete the QC testing.
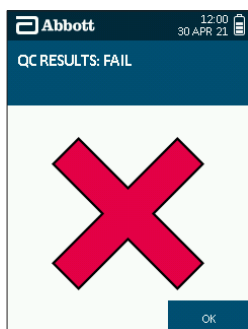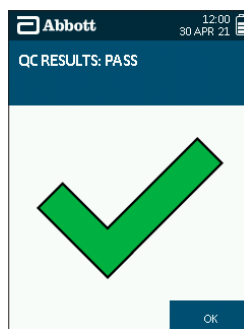
Step 4   Step 4   Step 6

Step 7:   If you wish to print the QC results, please select the **View Results** option from the main menu to print the individual QC tests. See section *8.1 Accessing Stored Results.*

7.4 QC lockout

If the PQC and NQC cartridges have not been successfully completed in the defined time interval, no further drug tests can be initiated until the quality control checks have been completed.

The following screen will be displayed when a test cartridge is inserted if the analyser is in lockout mode. The QC lockout symbol will also be displayed in the status bar.

Remove the inserted test cartridge and then insert either one of the two QC cartridges to initiate the QC testing as described in the section above.

8. Main Menu

The analyser main menu screen (shown on the right below) can be reached from the default screen (shown on the left below) by pressing the **left** selection key.

From this screen you can access stored results, view the analyser summary and settings and check the test cartridges that are installed on the analyser. See the following sections for more details.
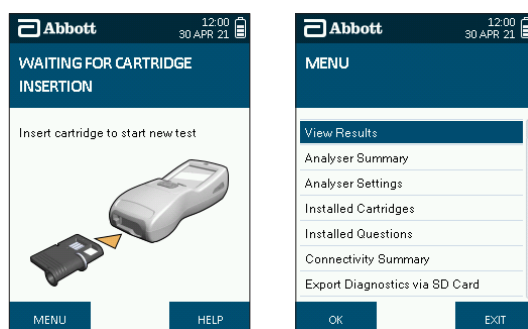
8.1 Accessing stored results

The analyser will store test information and results which can then be viewed and printed.

8.1.1 View results from memory

Step 1: From the Main menu, select the **View Results** option.
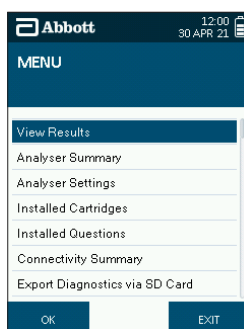
Step 1

Step 2: The Stored Results screen will display the last 100 tests performed. Select the test you wish to view using the five way navigation key to scroll up and down through the tests, then press the **Options** button using the left selection key. The most recent tests are at the top of the screen. Tests are identified by a unique test ID number. This number is also printed on the results printout.

Step 3: The Test Options screen will then be displayed. From this screen, you can view the test details by selecting **View Details** and pressing **OK**.
The screen will then display the following information about the selected test (this is an example test):

| Step 2 | Step 3 | Step 3 |
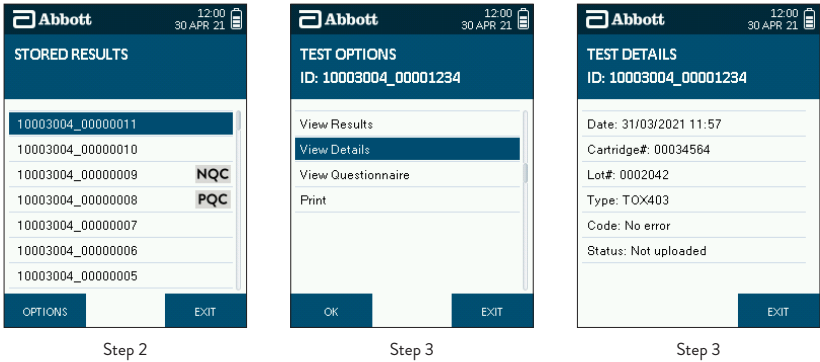
Step 4: Exit this screen to return to the Test Options screen.

Step 5: From the Test Options screen, highlight and select **View Results** to see test results.

Step 6: The results for the selected test are then displayed (this is an example test).

| Step 5 | Step 6 |
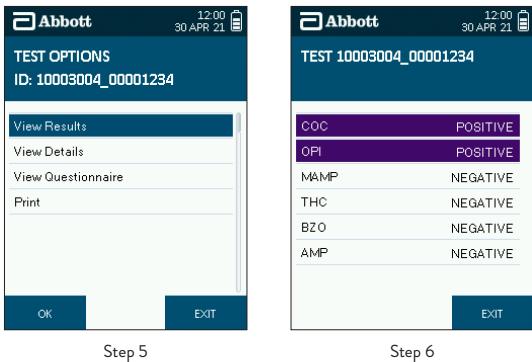
⚠ **If an error has occurred during the test, the results will not be available to view, so this option will not be displayed on the Test Options screen.**

Step 7: From the Test Options screen, you can view the questionnaire information by selecting **View Questionnaire** and pressing **OK**. The screen will then display the following information about the selected test (this is an example test).

| Step 7 | Step 7 |
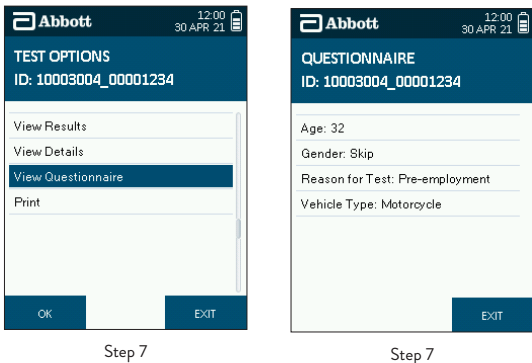
8.1.2 Print results from memory

Step 1: From the Test Options screen, highlight and select **Print**. Before selecting print, ensure that the printer is connected and online. See section *3.1 Connecting the printer*.

Step 2: Printing will then start.

Step 1   Step 2
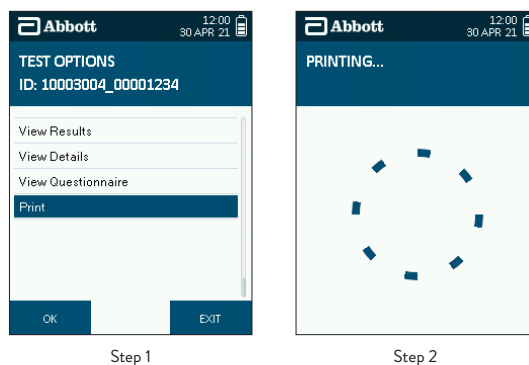
8.2 Analyser summary

An overview of the key settings and dates that are important to the use of the analyser can be viewed in the Analyser Summary screen.

Step 1: From the main menu screen select the **Analyser Summary** option.

Step 2: The Analyser Summary screen will then be displayed. Scroll down to see all elements of the screen.

Step 1   Step 2   Step 2
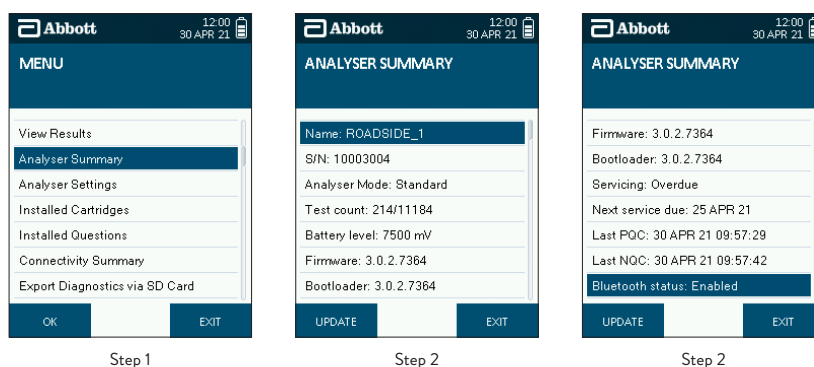
The information detailed on the screen is:

SCREEN DISPLAY	
Name	Name of analyser if provided.
S/N	Serial number of the analyser. Also stated on the label on the underside of the analyser.
Analyser Mode	Denotes the mode that the analyser is set to. In this instance it will be Standard.
Test Count	The number of tests completed expressed with the total test storage capacity. See section *8.2.1 Results storage capacity* for further information.
Battery Level	Current battery level in mV.
Firmware	Version that is loaded on the analyser. See section *8.2.2 Updating firmware* for further information.
Bootloader	Version that is loaded on the analyser. See section *8.2.2 Updating firmware* for further information.
Servicing	Stated as either OK, due soon or overdue, with 'due soon' meaning within a calendar month of the due date.
Next Service Due	Date that the analyser service is due if applicable.
Last PQC	Date of the last successfully completed PQC test.
Last NQC	Date of the last successfully completed NQC test.
Bluetooth status	Denotes as to whether the Bluetooth functionality is enabled or disabled. See section *8.6.1 Bluetooth status* for further information.

8.2.1   Results storage capacity

The analyser can store over 10,000 test results. When storage capacity is nearly reached, the white memory symbol will be displayed in the status line. When storage capacity is reached, the orange memory symbol will be displayed. Before saving the next test result, the memory full screen will be displayed. Select **Continue** to overwrite the oldest test with the new result, or select **Cancel**. Selecting cancel will mean the new test result is not saved.
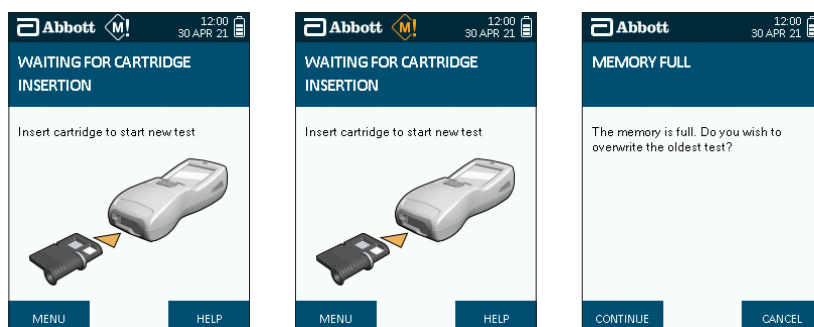
To determine remaining storage space, complete the following steps:

Step 1:   From the main menu, select the **Analyser Summary** option.

Step 2:   The following screen will display the number of tests performed under **Test count**:
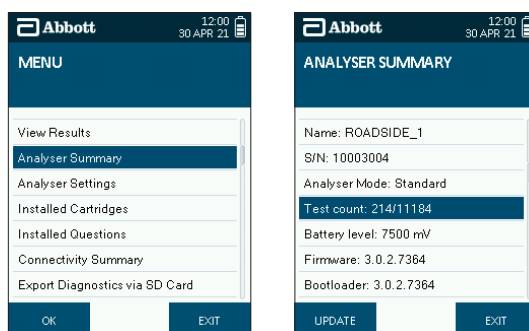
Step 1   Step 2

Contact Customer Services to discuss options on how to download test results and make more space available.

8.2.2   Updating firmware

When firmware updates are available these may be provided by the manufacturer by way of a replacement SD card.

⚠   **Data may be lost during the updating process. Where possible please ensure that data is backed up prior to completing the update.**

To update the analyser firmware using the SD card, follow these steps:

Step 1:   Ensure that the new SD card is inserted in the analyser before starting this procedure.

Step 2:   From the main menu, select the **Analyser Summary** option.

Step 3:   When in the Analyser Summary screen, press the **Update** button on the bottom left of the screen.

Step 4:   The analyser will display the list of files and folders carried on the inserted SD card. To open a folder, highlight the folder using the five way navigation key, then press the **Enter** button. To exit a folder, select the top folder marked with an arrow, then press the **Enter** button.
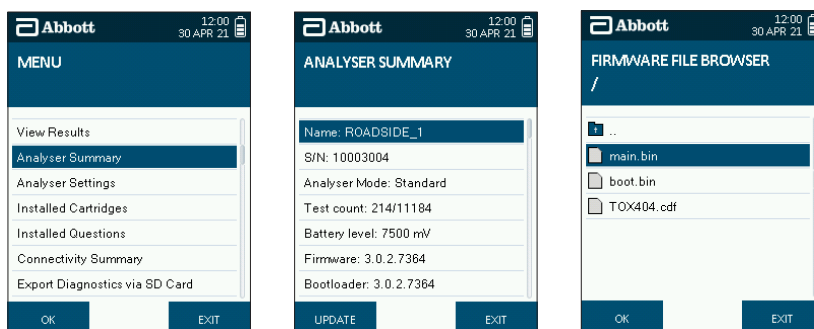
Step 2   Step 3   Step 4

Step 5:   Select the desired firmware file and press the **Enter** button.

Step 6:   If the firmware file is valid, the analyser will automatically update the firmware and restart.
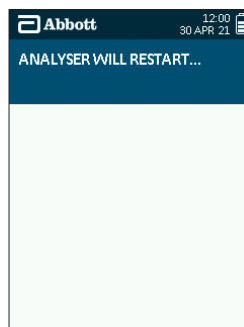
Step 6   Step 6

8.3   Analyser settings

The analyser has a number of settings you can update as follows.

8.3.1   Language settings

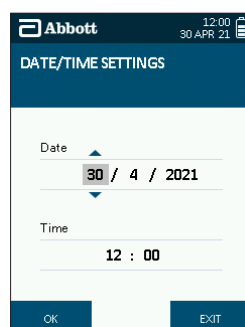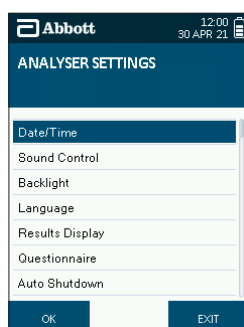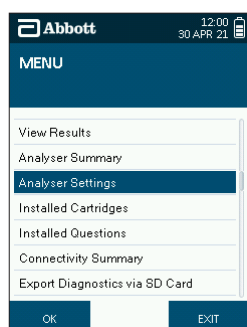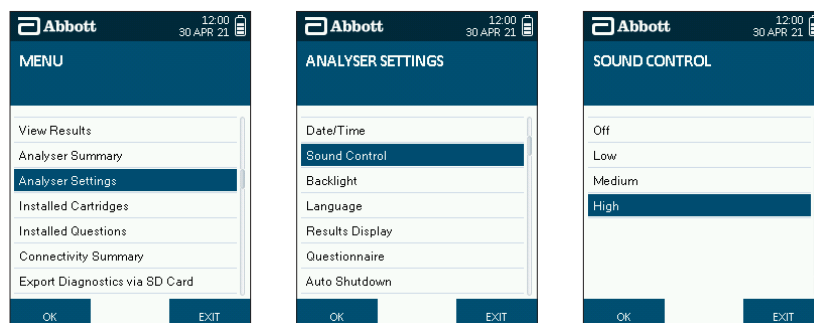To alter the language settings on the analyser, select the **Analyser Settings** option from the main menu, and then select the **Language** option.
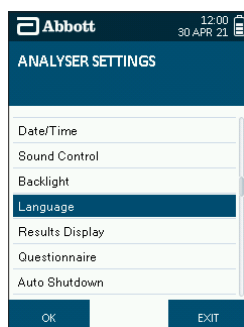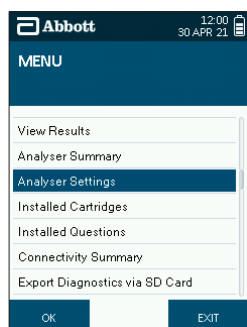
Use the five way navigation key to highlight the language required, and apply this to the analyser by selecting OK.

8.3.2   Setting the date and time

The analyser time and date are set to Greenwich Mean Time (GMT) by the manufacturer. To alter the date and time settings on the analyser, select the **Analyser Settings** option from the main menu, then in the Analyser Settings screen, select the **Date/Time** option.

Use the five way navigation key to select the time and date, then press **OK** to save the settings.

8.3.3 Changing the volume settings

To alter the volume setting on the analyser, select the **Analyser Settings** option from the main menu, then in the Analyser Settings screen, select the **Sound Control** option.

Use the five way navigation key to select the required volume setting, then press **OK** to save the settings.

8.3.4 Backlight settings

To alter the backlight setting on the analyser, select the **Analyser Settings** option from the main menu, then in the Analyser Settings screen, select the **Backlight** option.
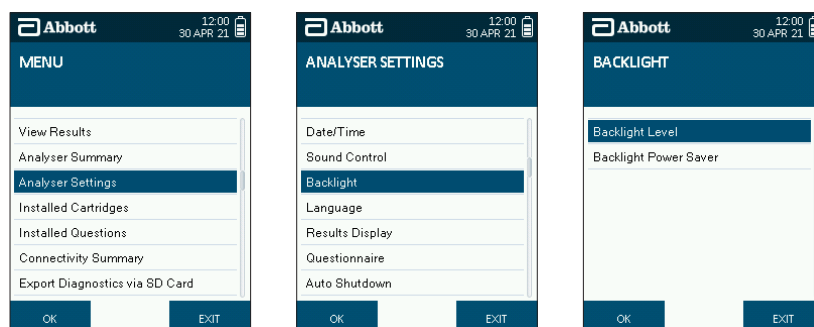
In the Backlight screen, the first menu item allows you to change the backlight level; the second one enables/disables the backlight power saver, where the backlight is turned off after 15 seconds of inactivity, to save battery power. Press **OK** to save the settings.
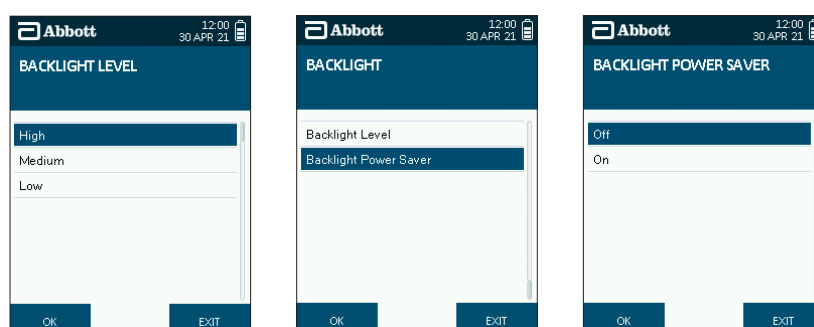
8.3.5 Results display

The analyser is a screening device and all positive screens should be confirmed by a second test method such as GC-MS (Gas Chromatography-Mass Spectrometry) or LC-MS (Liquid Chromatography-Mass Spectrometry). Both of these confirmatory methods are laboratory tests.

Test results can be displayed on the analyser in the following formats:

| RESULTS DISPLAY		
Results Display	**Meaning**	**Laboratory Confirmation Recommended**
Positive	The drug or metabolites of the drug have been detected in the sample at levels above the cut-off.	Yes
Negative	The drug or metabolites of the drug have been detected in the sample at levels below the cut-off.	No
Lab Test Required	The drug or metabolites of the drug have been detected in the sample at levels above the cut-off.	Yes

To carry out a confirmation test, a second sample must be collected from the donor using a laboratory test kit. Please contact Customer Service for more information of how to do this.

The analyser can either display results as positive/negative or as lab test required/negative. To change the results display, select the **Analyser Settings** option from the main menu, then in the Analyser Settings screen, select the **Results Display** option. In the Results Display screen, use the five way navigation key to highlight the results display required, then press **OK** to save the settings.
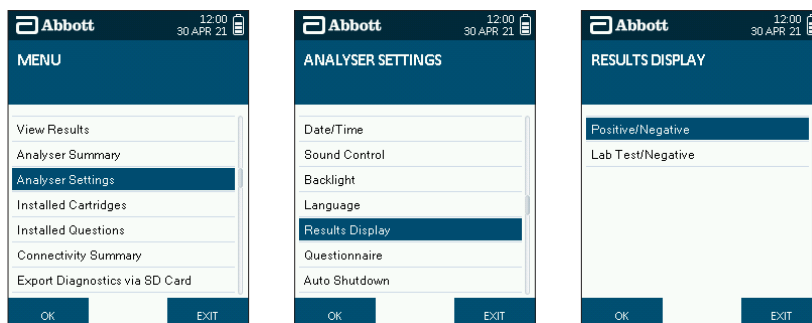
8.3.6 Questionnaire

To enable or disable the questionnaire, select the **Analyser Settings** option from the main menu, then in the Analyser Settings screen, select **Questionnaire**.
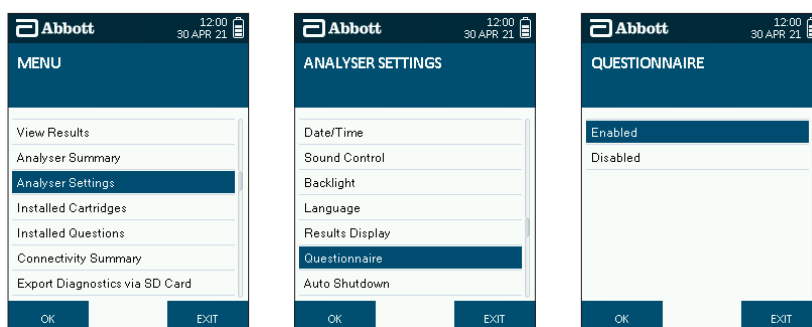
In the Questionnaire screen, the first option enables the questionnaire set and the second option disables it. Use the five way navigation key to select the required settings. Press **OK** to save the settings.

8.3.7 Automatic shutdown

The analyser can be set to automatically shutdown after a period of inactivity to save power. The automatic shutdown function can be set to on or off and the time period before shutdown can be selected.

Select **Analyser Settings** from the main menu, then in the Analyser Settings screen, select **Auto Shutdown**. In the Auto Shutdown screen, use the five way navigation key to highlight the required setting and press **OK** to save the setting.
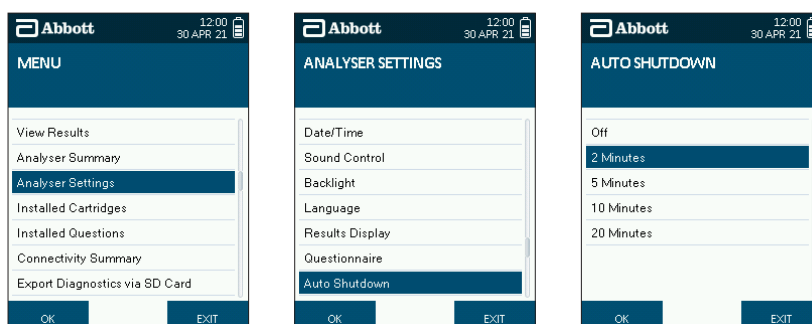
⚠️ **The analyser will not automatically shutdown while a test is in progress or if a test cartridge is inserted.**

8.3.8 Periodic QC

The analyser can be set to enforce QC testing at a defined time intervals.

Select **Analyser Settings** from the main menu, then in the Analyser Settings screen, select **Periodic QC**. In the Periodic QC screen, use the five way navigation key to highlight the required setting and press **OK** to save the setting.
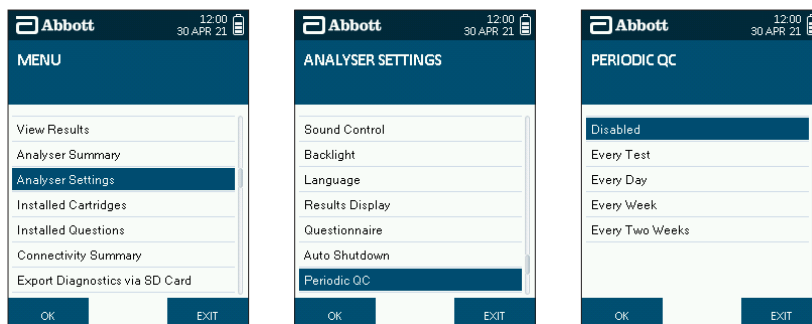
8.3.9 Printer port

The analyser printer port must be configured to enable printing to the required printer.
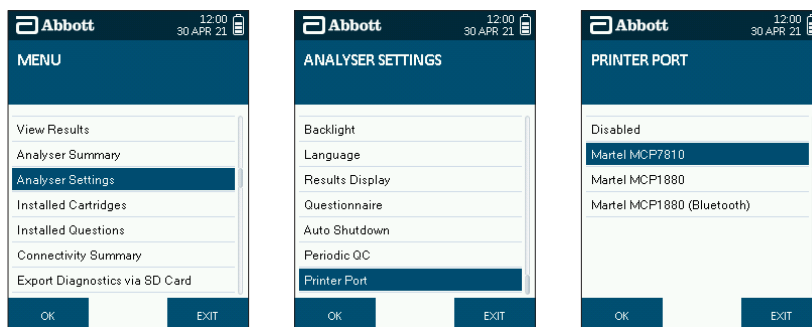
Select **Analyser Settings** from the main menu, then in the Analyser Settings screen, select **Printer Port**. In the Printer Port screen, use the five way navigation key to highlight the required setting and press **OK** to save the setting.

⚠️ **Ensure that the printer port selected reflects the printer that you want to use. The system will be supplied with the standard wired printer (MCP7810) and the port will be set to reflect this.**

8.4 Installed cartridges and updating cartridge types

To use a drug test cartridge on the analyser, the test cartridge type must be installed in order that the analyser recognises the test cartridge. New test cartridge types can be added to the analyser via the SD card.

To add a new test cartridge type using the SD card, follow these steps:

Step 1: Insert the SD card into the analyser before starting this procedure.

Step 2: From the main menu, select the **Installed Cartridges** option.

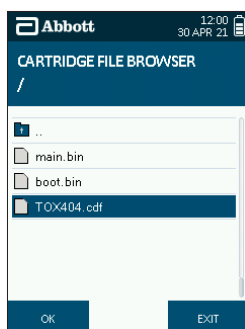**Step 3:** In the Installed Cartridges screen, press **Add**, on the bottom left of the screen.
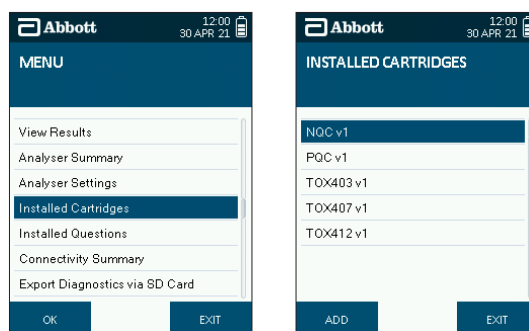
Step 2   Step 3

Step 4: The analyser will display the list of files and folders carried on the inserted SD card. To open a folder, select the folder, then press the **OK** button. To exit a folder, select the top folder marked with an arrow, then press the **OK** button.

Step 5: Select the desired test cartridge file and press the **Enter** button.
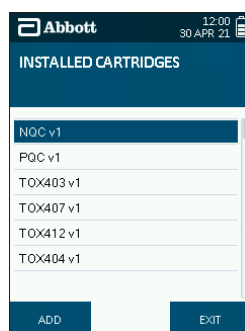

Step 5

Step 6: If the test cartridge file is valid, the analyser will update its test cartridge library and navigate back to the Installed Cartridges screen. The new test cartridge will now appear on the list of installed cartridges.
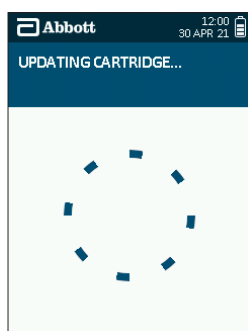
Step 6   Step 6

8.5 Installed questions

To view which questions are installed on the analyser and will be available at the end of a subject test, from the main menu select **Installed Questions**.
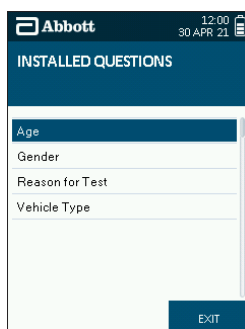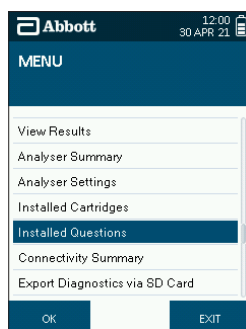
8.6 Connectivity summary

The analyser is now Bluetooth enabled which allows connectivity to appropriate accessories when provided.

8.6.1 Bluetooth status

The analyser will be supplied with Bluetooth enabled. To check the status, select the **Connectivity Summar**y option from the main menu, then in the Connectivity Summary screen, select the **Bluetooth Status** option.

In the Bluetooth Status screen, use the five way navigation key to select the required settings. Press OK to save the settings.

8.6.2 To pair with app

It is not possible to pair with a app at this time.

8.6.3 Pair with printer

A wired printer is supplied with this system, so the pairing with printer is not in use at this time.

8.6.4 Remove paired devices

To remove paired connections with the analyser, select the **Connectivity Summary** option from the main menu, then in the Connectivity Summary screen, select the **Remove paired devices** option.

The analyser will return to the menu screen and all paired connections will be removed.
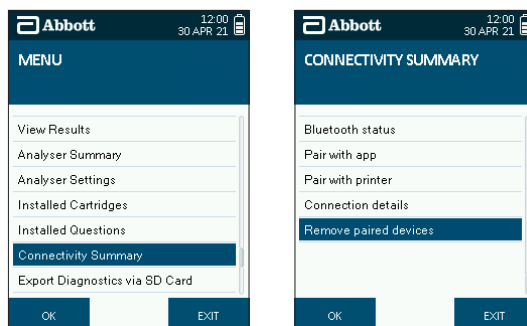
8.7 Export diagnostics via SD card

Diagnostics data can be exported from the analyser to an SD card, if required and instructed to by Customer Service on behalf of the manufacturer. This data can be used to aid with troubleshooting of a particular issue or as part of routine monitoring of how the system is working.

To export the diagnostics data to an SD card, follow these steps.

Step 1: Insert the SD card into the analyser before starting this procedure.

Step 2: From the Test Data Management menu, select the **Export Diagnostics via SD Card** option.

Step 3: A progress wheel will be displayed while the data is being exported. It may take several minutes to complete as it is dependent on the number of tests completed on the analyser.
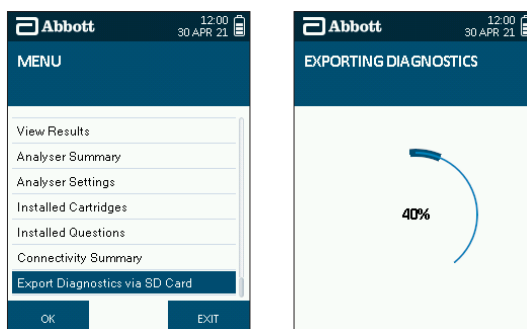
Step 2   Step 3

Step 4:   On completion of the export the main menu will be displayed.

Step 5:   Turn the analyser off and remove the SD card from the slot and return to Customer Service as instructed.

Step 6:   Re-screw the card cover into place.

Please note that if the battery is too low, then the warning message shown below will appear when you start to export the data. Either charge the analyser or simply connect to the mains before starting the export again.
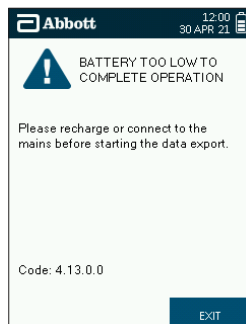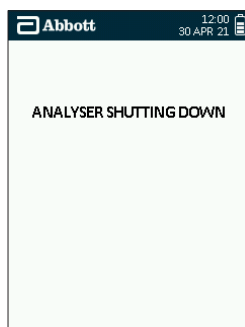

9.   Shutdown Procedure

9.1   Turning the analyser off

Step 1:   Remove any test cartridges from the analyser.

Step 2:   Press the power button on the right hand side of the analyser.

Step 3:   The screen will read 'Analyser Shutting Down'.

Step 4:   When the screen turns dark, the analyser has switched off.

Step 3

⚠️   **The analyser cannot be switched off if a test is in progress or if a test cartridge is inserted.**

9.2   Automatic shutdown

In order to save power, the analyser can be set to automatically shutdown after a period of inactivity. Refer to section *8.3.7 Automatic shutdown*.

⚠️   **The analyser will not automatically shutdown if a test is in progress.**

10. Technical Support, Codes and Troubleshooting

10.1 Technical support

In the event of an incomplete test or analyser issue on-screen feedback will be provided, in most cases, to the user to assist with diagnosis and resolution of the issue. In some cases, the analyser will report specific codes – please refer to the list of codes on the following pages for interpretation. If the issue cannot be resolved using this guide, please contact Customer Service.

Examples of screens:
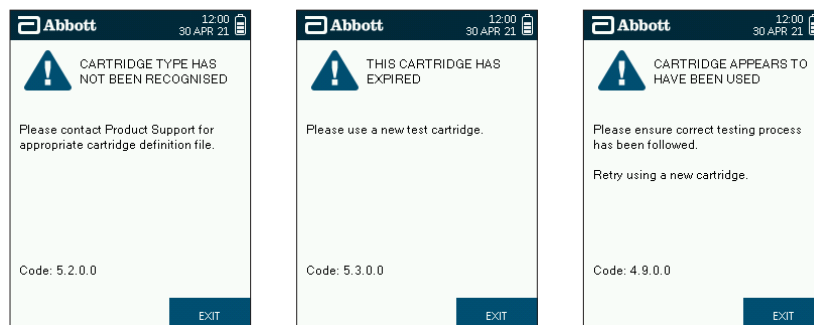
10.2 Codes and troubleshooting

Please note, the codes listed below are examples. When displayed by the analyser, the characters denoted by 'X' will be numbers. The first and second numbers are used to denote the type of code.

CODES AND TROUBLESHOOTING			
Code	**Description**	**Possible cause**	**Solution**
1.1.X.X to 1.5.X.X	**Cartridge analysis incomplete.**	The test cartridge was not detected correctly. Can be due to dirty optics, a damaged test cartridge or a hardware fault.	Initiate a QC test, if the QC test fails contact Customer Service. If the QC tests pass complete the test.
1.6.X.X	**Insufficient sample.**	The reference band has not been detected; the sample has not run on the test cartridge.	Ensure that the test process has been correctly followed.
1.7.X.X	**Insufficient sample.**	The sample has not run sufficiently on the test cartridge. Can be due to insufficient sample collection, incorrect test process.	Ensure that the test process has been correctly followed.
1.8.X.X to 1.10.X.X	**Cartridge analysis incomplete.**	The test cartridge was not detected correctly. Can be due to dirty optics, a damaged test cartridge or a hardware fault.	Initiate a QC test, if the QC test fails contact Customer Service. If the QC tests pass complete the test.
2.1.X.X to 2.6.X.X	**Cannot read barcode.**	During the barcode analysis the analyser has detected a fault this could be due to the cartridge/barcode being damaged, dirty optics or a hardware fault.	Initiate a QC test. If the QC test passes, verify that the inserted test cartridge is not used and its barcode is not damaged. If the test cartridge or its barcode is damaged, dispose of the test cartridge and start a new test with a new test cartridge. If the QC test fails, contact Customer Service.
2.7.X.X	**Barcode not valid.**	The barcode data cannot be interpreted into valid cartridge information. The barcode may have been tampered with or a newer barcode version has been introduced.	Please contact Customer Service for assistance.
3.1.X.X	**Issue detected with hardware.**	Analyser hardware issue.	Unable to complete test process. Please contact Customer Service for assistance.
3.3.X.X	**Analyser calibration required.**	The analyser appears not to be calibrated or has lost its calibration settings.	Tests cannot be completed until the analyser is calibrated. Contact Customer Service for assistance.
3.4.X.X and 3.5.X.X	**Test result inconclusive.**	Issue detected during the test analysis, analyser unable to interpret the result.	Restart analyser and start test process again if applicable.
3.6.X.X	**Start-up checks have failed.**	The analyser has detected a fault during the initial checks and will not be able to complete a test.	Unable to complete test process. Contact Customer Service for assistance.
3.7.X.X	**Analyser has shutdown unexpectedly.**	The analyser has either been reset by the Operator, the battery has run out or the analyser was unable to complete the test analysis.	Press **Exit** to continue. Contact Customer Service for assistance if the problem persists.
4.1.X.X	**Do not remove cartridge during the test.**	Test cartridge was removed during the test process.	Initiate a new test, making sure that the test cartridge is not removed until the test result is displayed.

CODES AND TROUBLESHOOTING

Code	Description	Possible cause	Solution
4.2.X.X	**SD card not detected.**	SD card is not present within the analyser.	Insert a valid SD card into the analyser.
4.3.X.X	**The selected file is not valid.**	Incorrect file has been selected while trying to install a new cartridge file.	The file selected is not a valid test cartridge file. Make sure a valid test cartridge file is selected to be updated. See section *8.4 Installed cartridges and updating cartridge types*.
4.4.X.X	**The selected file is not valid.**	Incorrect file has been selected while trying to install a new software (firmware) version.	The file selected is not a valid software (firmware) file. Make sure a valid firmware file is selected to be updated. See section *8.2.2 Updating firmware*.
4.5.X.X	**Incorrect QC cartridge inserted.**	Incorrect QC cartridge has been inserted.	During QC testing, the second cartridge inserted was incorrect. Make sure the PQC and NQC cartridges have been used, not drug test cartridges. Ensure the same cartridge has not been inserted twice.
4.6.X.X	**Cartridge appears to be used.**	Collection device detected before prompt indicating cartridge could be used, optical detector has been compromised or buffer within test cartridge is opaque or foaming.	Ensure the correct testing process has been followed. Dispose of used test cartridge, start a new test making sure that the inserted test cartridge is new and not used. If the problem persists please contact Customer Service for further assistance.
4.7.X.X	**Temperature is outside the acceptable range.**	The analyser detected that the ambient and test cartridge temperature are out of the accepted operating range for testing.	Ensure that the test cartridge and analyser are within the 5°C to 35°C, and start test again with a new test cartridge.
4.8.X.X	**Could not install cartridge file.**	An issue occurred whilst storing the cartridge definition file.	Try to install the cartridge file again.
4.9.X.X	**Cartridge appears to be used.**	The analyser has detected that the cartridge could have already been used or an issue with the analyser optics.	Ensure the correct testing process has been followed. Dispose of used test cartridge and repeat test with a new test cartridge. If the problem persists please contact Customer Service for further assistance.
4.11.X.X	**Cartridge inserted unexpectedly.**	Cartridge was inserted whilst analyser was in a menu screen.	Ensure the correct testing process has been followed. Remove the test cartridge, return to the Waiting for Cartridge Insertion screen and re-insert the test cartridge.
4.12.X.X	**Cartridge not compatible.**	An old cartridge version has been used.	Unable to complete the test process. Contact Customer Service for assistance.
4.13.X.X	**Battery too low to complete operation.**	Low battery could interrupt the export of data and corrupt the file system on the SD card.	Recharge the analyser or connect to the mains prior to starting the export of data.
4.14.X.X	**Low space on SD card.**	Insufficient space on the SD card to allow the export of data.	Free space on the SD card being used before proceeding.
4.15.X.X	**Cannot write file to SD card.**	SD card has been removed or the card could be faulty.	Restart analyser and reinsert the SD card.
4.16.X.X	**Cartridge analysis disrupted.**	analyser was tilted beyond the acceptable range.	Retry using a new cartridge, keeping the analyser level.
4.17.X.X	**QC Lockout.**	A QC Lockout has occurred due to no successful QC tests being completed within the enforced timescale.	Please complete QC tests before proceeding.
5.1.X.X and 5.2.X.X	**Cartridge type has not been recognised.**	The barcode of the inserted cartridge indicates a cartridge type or version that is not recognised by the analyser.	Contact Customer Service for the appropriate cartridge definition file.
5.3.X.X	**This cartridge has expired.**	The inserted test cartridge has expired.	Dispose of the used test cartridge. Start a new test with a new test cartridge, checking the date on the wrapper to make sure that it has not expired.
6.1.X.X to 6.4.X.X	**Start-up checks have failed.**	The analyser has detected a fault during the start-up checks.	Ensure the cartridge is fully removed and press **Restart** to try again. If issue persists contact Customer Service.
6.5.X.X	**Start-up checks have failed.**	The analyser has detected a fault during the start-up checks but the Operator has continued and initiated a test by inserting a test cartridge.	Ensure the cartridge is removed and press **Restart** to try again. If issue persists contact Customer Service.
6.6.X.X to 6.7.X.X	**Start-up checks have failed.**	The analyser has detected a fault during the start-up checks.	Ensure the cartridge is fully removed and press **Restart** to try again. If issue persists contact Customer Services.

10.3 Symbols glossary

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
⧖	Use by	∑ (inverted triangle)	Contains sufficient for <n> tests	SN	Serial Number
5°C–35°C	Temperature limit	REF	Catalogue number	CE	CE Mark
(factory)	Manufacturer	☀	Keep away from sunlight	(glass)	Fragile, handle with care
UDI	Unique Device Identifier	☂	Keep dry	[i]	Consult instructions for use www.globalpointofcare.eifu.abbott
(date)	Date of Manufacture	⊘2	Do not re-use	UKCA	UK Conformity Assessed
(RCM)	Regulatory Compliance Mark	⚠	Caution Symbol		

11. End of Operational Life

11.1 Return of components

At the end of operational life, the analyser and its electrical or electronic peripherals including the power supply units (PSUs), and printer, should be returned to the manufacturer. Please contact Abbott to make arrangements for return.

No electrical or electronic equipment may be disposed of in conventional domestic or commercial waste systems.

12. Customer Service

For additional technical support and advice please contact Customer Services on the details below:
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