



io[®] Instrument

Operator Manual



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General Information

Intended Use

The binx health *io* Instrument catalog number 3.001.001 is part of the binx health *io* diagnostic system. The *io* Instrument is required to process *io* Cartridges. Please refer to the Instructions For Use (IFU) supplied with the *io* Cartridges for specific information on each test type.

This instrument is intended for use in point-of-care (clinic, doctors' office) or clinical laboratory settings. It is not intended for use near RF surgical environments or other special electromagnetic environments.

The *io* Instrument is an *in vitro* diagnostic (IVD) medical device and conforms to the applicable requirements of the Directive on *in vitro* diagnostic medical devices (IVDD), 98/79/EC, October 27, 1998 and the requirements of the US Code of Federal Regulations Title 21, part 820, Quality System Regulation.

Technical Specifications

Dimensions	277mm x 275mm x 384mm (H x W x D)
Weight	10.2 kg
Electrical Rating	250W 100-240V AC 50/60Hz external power supply 24V 250W DC inlet to instrument
Operating Environment	Optimum Performance: 10°C to 35°C 0% to 80% Relative Humidity (RH) between 10°C and 31°C, decreasing linearly to less than 59% RH at 35°C Safe Operation: 5°C to 40°C Less than 80% RH up to 31°C decreasing to less than 50% at 40°C In accordance with international standard IEC 61010 definition of NORMAL CONDITIONS. See page 46 for details of the Electromagnetic Compatibility (EMC) environmental conditions tested.
Ports	1 x Ethernet (8P8C type) 1x Wireless (Digital Transmission System, currently dormant): WAN 2.4GHz 150Mbps IEEE802.11 b/g/n 2400MHz ~ 2483.5MHz / 20dBm 3 x USB 2.0

Shipping & Storage	For shipping use the original cardboard/foam packaging provided -5°C to 40°C Less than 80% RH up to 31°C decreasing linearly to less than 50% at 40°C Allow 1 hour to acclimatize from cold shipping or storage conditions before use
Associated Products	Barcode Scanner (Cat. No. 3.002.020) Replacement Power Supply (Cat. No. 3.002.100) Printer (Cat. No. 3.002.010)

Warnings and Precautions

Carefully read this Operator Manual before operating the *io* Instrument. When using *io* Cartridges, observe the Warnings and Precautions stated in the relevant Cartridge Instructions For Use (IFU).

1. Only use the *io* Instrument for the purposes and applications described in this Operator Manual.
2. Use only materials and equipment supplied as part of the *io* System or specified in the Cartridge IFU to perform a test procedure.
3. The *io* Instrument must only be used with binx health *io* Cartridges.
4. Do not use the *io* Instrument outside the optimum performance operating environment (see Technical Specifications).
5. Ensure there is a 50 mm gap between the *io* Instrument and walls or other objects at the rear and sides of the machine for ventilation.
6. Position the *io* Instrument on a stable, flat surface which is free from vibration.
7. Never make modifications to the *io* Instrument such as removing covers or parts. Any alterations to the instrument will invalidate the instrument warranty and may compromise user safety.
8. Cartridges and specimens used in conjunction with the *io* Instrument must follow local or national regulations governing *in vitro* diagnostic products for human use.
9. Cartridges and specimens used in conjunction with the *io* Instrument may be infectious. Appropriate precautions for handling and disposal of biohazardous materials should be established in accordance with local or national policies and practices.
10. Wear gloves when handling specimens and test materials. Wash hands thoroughly after handling specimens.
11. Avoid touching the instrument's screen with gloves that have been in contact with biohazardous material.
12. Remove Cartridges from the *io* Instrument as soon as possible once the test has finished.
13. Do not eat, drink or smoke in areas where this test is being performed or specimens are being handled.
14. Work surfaces around the *io* Instrument, where Cartridges are prepared and specimens are handled, should be thoroughly cleaned on a regular basis.

15. For *io* Instrument cleaning and decontamination procedures, please refer to the Cleaning & Maintenance section of this manual.
16. **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
17. **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the *io*, otherwise degradation of the performance of this equipment could result.
18. The requirements of IEC 60601-1-2:2014 have been tested and show that the instrument can run *io* CT/NG Assay Cartridges and report results. Note that under some electromagnetic environments, the instrument may terminate testing and reset. There is no residual risk of harm to the user, and any result affected will be invalidated.
19. Avoid using GMRS/FRS UHF radio near the *io*. The instrument may terminate testing and reset. There is no residual risk of harm to the user, and any result affected will be invalidated.
20. Some Ethernet cables may cause the instrument to become sensitive to some RF environments. This sensitivity is limited to causing the instrument to shut down.

Key to Symbols used on Product Labeling



in vitro diagnostic medical device.



European Community declaration of conformity.



Details of the manufacturer of the device.



User to consult the *io* Instrument Operator Manual or the IFU supplied with the *io* Cartridges.



Catalogue number for the binx health *io* Instrument.



Unique Serial Number assigned to the binx health *io* Instrument. This number should be quoted for service issues.



Do not dispose of in ordinary waste. binx health can arrange for disposal in accordance with the WEEE Directive. Contact your representative for details.



Biohazard. Traces of patient sample may be present.



Federal Communications Commission declaration of conformity.

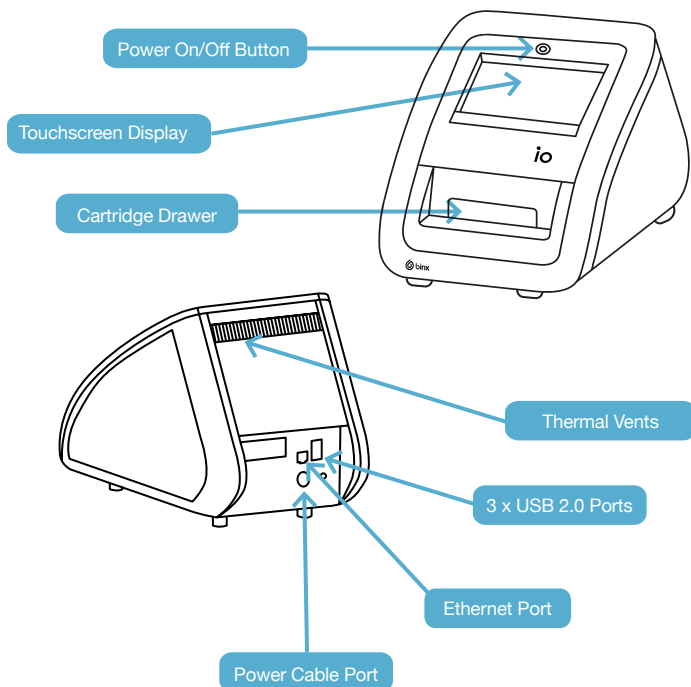
The binx health *io* Instrument

Contents

The following items should be present when unpacking the *io* Instrument for the first time.

Quantity	Item
1	<i>io</i> Instrument
1	Main Power Cable with Plug
1	External Power Supply
1	<i>io</i> Instrument Operator Manual
1	<i>io</i> Instrument Repackaging Instruction Sheet

Features of the *io* Instrument



Compliance and Approvals

The *io* Instrument has been designed, manufactured and tested to comply with European Union Directive on *in vitro* Diagnostic Medical Devices (IVDD), 98/79/EC, October 27, 1998, EMC Directive 2014/30/EU, Medical Devices Directive 93/42/EEC, RED Directive 2014/53/EU and 2007/47/EC. Additionally, the *io* instrument has been designed, manufactured and tested to comply with the US Code of Federal Regulations Title 21, Part 820, Quality System Regulation (21 CFR § 820). This requires compliance with all relevant aspects of the following standards:

- **BS EN 61010-1:2020** 2010 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements.
- **UL/EN/IEC 61010-2-101** Safety requirements for electrical equipment for measurement control, and laboratory use - Part 2 - 010: Particular requirements for laboratory equipment for the heating of materials.
- **UL/EN/IEC 61010-2-101** Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2 - 101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment.
- **EN/IEC 61326-1:2021** Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.
- **EN/IEC 61326-2-6:2021** Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements – *in vitro* diagnostic (IVD) medical equipment.

- **FCC Rules 47 CFR § 15** Radio frequency devices.

(Note that the io Instrument contains a Digital Transmission System component, for which the original equipment manufacturer has been granted the following FCC ID: TE7WN725N. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. The OEM has also declared compliance with the following directives: Directives 1999/5/EC, Directives 2006/95/EC, Directives 1999/519/EC, Directives 2011/65/EU and standards: IEEE 802.11n, IEEE 802.11g, IEEE 802.11b, IEEE 802.1x, IEEE 802.11e, IEEE 802.11i. Although currently not used by the instrument (i.e. dormant) its operation has been included in EMC testing detailed later in this document, to ensure compatibility when future software revisions enable its usage.)

- **EN ISO 18113-1:2009 Part 1** *In vitro* diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements.
- **EN ISO 18113-1:2009 Part 3** *In vitro* diagnostic medical devices. Information supplied by the manufacturer (labelling). *In vitro* diagnostic instruments for professional use.
- **BS EN 62366-1:2015+A1:2020** Medical devices. Application of usability engineering to medical devices.
- **IEC 60601-1-2:2014** Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
- **ANSI C63.4-2014** American National Standard For Methods Of Measurement Of Radio-Noise Emissions From Low-Voltage Electrical And Electronic Equipment In The Range Of 9 KHz To 40 GHz.
- **IEC 61000-4** Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test.

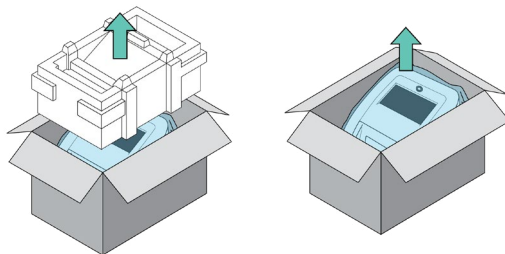
- **ETSI EN 301 489-1 V2.2.1:2019** ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility.
- **BS EN 55011:2016+A2:2021** Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics. Limits and methods of measurement.
- **ETSI EN 300 328 V2.1.1:2016** Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU.

The instrument has been developed in accordance with ISO 14971:2019 (Medical devices - Application of risk management to medical devices), ISO 62304:2006 (Medical device software – Software life cycle processes) and ISO 13485:2016 (Medical devices – Quality management systems – Requirements for regulatory purposes).

Unpacking the *io* Instrument

The *io* Instrument must be unpacked and installed following the steps outlined in this guide.

1. Check the packaging to ensure there are no visible signs of damage during shipping.
2. With the box open in the upright position, remove the power supply and the main power cable from the top of the packaging and set aside. Remove the top packaging from the cardboard box.
3. Carefully remove the instrument from the box.



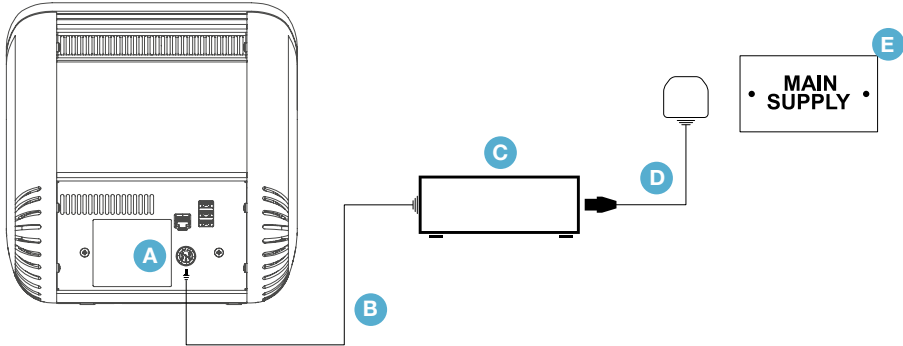
4. Remove the instrument from the anti-static bag.
5. Place the instrument upright on a flat stable surface, free of vibration with sufficient space, ensuring that there is at least a 50 mm gap at the sides and rear of the instrument for ventilation.
6. **IMPORTANT: Retain the packaging for future transportation.**

During transportation, the instrument may have experienced temperatures outside of those defined as optimum. Therefore, it should be left for a minimum of 1 hour to equilibrate before the power is switched on.

Installation of the *io* Instrument

Once equilibrated to ambient conditions perform the following steps to prepare the system for use.

1. Connect the main power cable to the external power supply block.
2. Connect the DC power supply (the integrated cable leading from the power supply block) to the power cable port at the rear of the *io* Instrument.



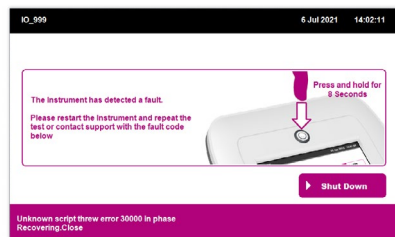
- A** *io* Power Cable Port **B** DC power supply cable **C** DC power supply
D Main power cable **E** Main supply

3. Connect the plug on the main power cable into the main socket.
4. The power on/off button will flash to show that the instrument is ready for use.

- Press the power on/off button to turn the instrument on. The light on the on/off button will remain constantly illuminated and after about 15 seconds the following screen will appear, showing that the instrument is initializing.



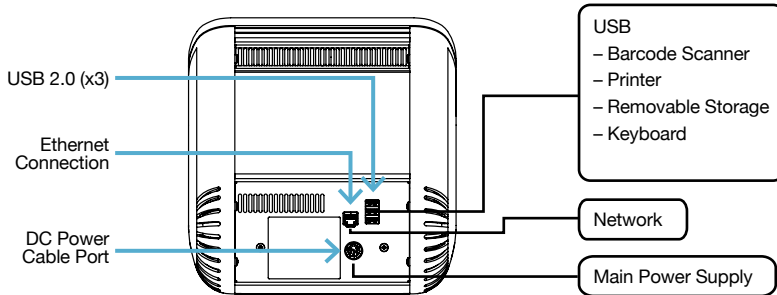
- Once initialized, the Log In screen will be displayed. If the instrument fails to initialize, turn off the power at the main and repeat steps 1-6. If after several attempts the instrument still fails to initialize, contact your representative or binx health Customer Support.



When contacting Customer Support, please quote the fault message at the bottom of the screen.

Connectivity and Peripheral Devices

The *io* Instrument provides connections at the rear for connection to a data network and for optional peripheral devices.



Ethernet

The instrument has a single Ethernet port which can be used to connect to a server for upload and storage of test results.

Wireless

The instrument contains a dormant Digital Transmission System component which, when activated, will be capable of wireless connection at up to 150Mbps, at a frequency of 2.4 ~ 2.4835GHz, supporting security measures 62/128-bit WEP, WPA/WPA2, WPA-PSK/WPA2-PSK. Future software updates will enable this utility, at which point updated user instructions will be provided which will also include information on safety and effective usage and coexistence with other devices.

Removable Storage

A removable USB storage device (not provided) can be connected to be used for local output of test results, Administrator logs and for instrument software updates. It may take a few seconds for a device to register on the instrument.

Barcode Scanner

A barcode scanner is available as a separate item (Cat. No. 3.002.020) and connects via USB. The barcode scanner can be used instead of the touch screen keyboard for Specimen and Patient ID entries where printed barcodes are used.

Printer

A printer is available as a separate item (Cat. No 3.002.010) and connects via USB. The printer can be used to print any selected test results from the instrument.

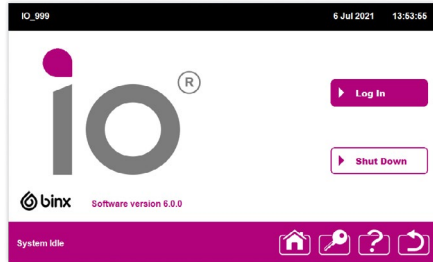
USB Keyboard

A USB keyboard can be used to aid with the entry of alphabetic and numerical data. binx health does not supply USB keyboards.

Log In and Set Up

The *io* Instrument is supplied with a default Administrator login. The default Administrator User ID is admin; no password is required.

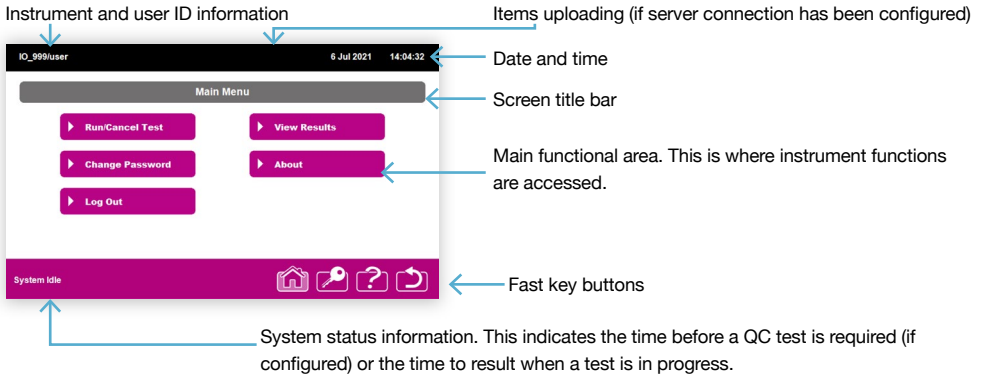
To log in to the instrument, press the **Log In** button. A new screen with **User ID** and **Password** fields will appear. User IDs and passwords are case sensitive.



Pressing on these fields will bring up the on-screen keyboard. Enter the required User ID and Password, then press **Log In** again to access the main menu.

Note that the **Main Menu** will be different for 'User' and 'Administrator' accounts.

User Interface



Fast Keys



Home

Select to go to the Main Menu screen.



Log In/Log Out

Log into the instrument or log out of a current session.



Help

Use this to get help on the current displayed screen.



Back

Use this to go back to a previous screen or to exit the current screen without saving changes.

Buttons and Data Entry Fields



Buttons are indicated by a box containing text denoting the function of the button with a white triangle against a pink background. These are activated by pressing any part of the button on the touchscreen.



Data entry fields are indicated by a box containing two sections, a pink section with white text showing the name of the field and a white section with a pink triangle and black text describing the data to be entered. Press the touchscreen anywhere in the white section to enter data into this field.

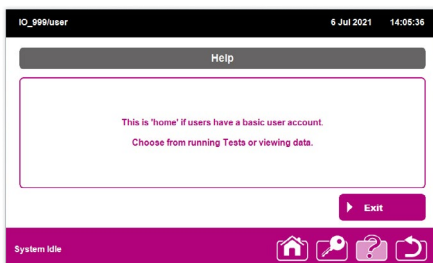
On-Screen Keyboard

The on-screen keyboard automatically appears when there is a requirement to enter information.



Help Screen

Pressing the **Help** fast key will display an information screen relating to the active screen at the time the **Help** fast key was pressed.

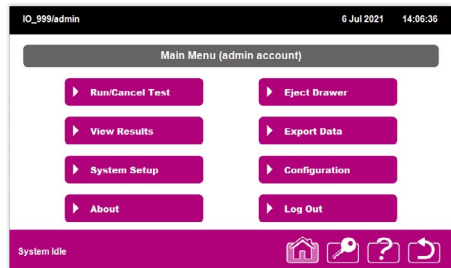
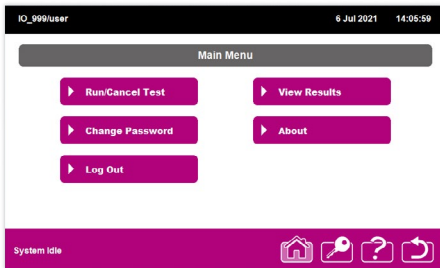


Test Procedure

Certain screens differ slightly when viewed through a User account or an Administrator account. Illustrations in this manual show both account type screens when these differ.

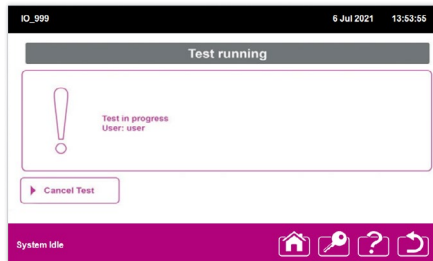
This test procedure assumes the operator has already logged in to the instrument.

1. From the **Main Menu** screen press the **Run/Cancel Test** Test key on the touchscreen.



If a test is currently in progress, you will be alerted and given the option to cancel the current test.

The rights to cancel a current test will depend on the type of account. Those with a User account can only cancel a test which was started from their own account. An Administrator can cancel a test started by any account.



If you wish to cancel the current test press the **Cancel Test** button, then confirm by pressing the **Yes** button. If you do not wish to cancel the test press the **Back** fast key and await the completion of the in progress test.

If no test is running continue with the following Test Procedure.

2. Enter a unique specimen identification by either (a) entering the Specimen ID manually via the Specimen ID field on the touchscreen, (b) scanning a barcode on the Specimen Collection tube using a handheld barcode scanner or (c) leaving the specimen ID field empty and allowing the instrument to automatically assign a unique Specimen ID.

The Administrator may configure the *io* Instrument so that some of these options for entering the Specimen ID are not available.



A unique Specimen ID is mandatory and provides traceability to the test result.

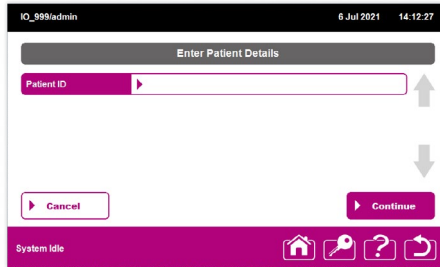
If the local Administrator has enabled automatic Specimen ID generation and the Specimen ID field is left empty the *io* Instrument software will ask you to confirm you would like the instrument to generate a Specimen ID and if confirmed will do so.

If the local Administrator has enabled automatic Specimen ID generation and a Specimen ID that has already been used is entered the *io* Instrument software will ask you to confirm you would like the instrument to append an incremental number suffix to the Specimen ID and if confirmed will do so.

If the local Administrator has not enabled automatic Specimen ID generation and the Specimen ID field is left empty or a Specimen ID that has already been used is entered the *io* Instrument software will indicate that a unique Specimen ID must be entered and will not continue until one is entered.

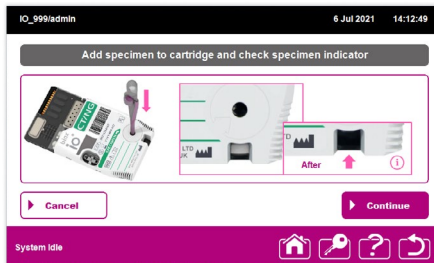
- If the Administrator has configured the instrument so that specific patient details are required, the **Enter Patient Details** screen will appear. If not, the instrument will go to Step 4. To enter patient details, press the relevant box on the touchscreen, add the details using the keyboard and press **Enter**. A USB keyboard or barcode reader may also be used in this step.

Press the **Save Changes** button on the touchscreen when all Patient Details fields are complete.



- The instrument will prompt the loading of the specimen on to the Cartridge.

Please note, the instrument drawer will open automatically at this prompt screen.



For full instructions on Cartridge handling and specimen loading please consult the Instructions For Use (IFU) supplied with the *io* Cartridges.

5. Before starting the test, confirm that the specimen has been loaded correctly by observing the specimen addition Indicator window on the Cartridge. If the specimen has not been loaded or has been incorrectly loaded a light area will be visible. After the specimen has been correctly loaded, the light area will turn dark.

If the specimen addition indicator suggests the specimen has not been loaded or has been loaded incorrectly, load the specimen again.

The *io* Cartridge is capable of accepting a second specimen volume without impacting function or the test result. However, if you believe you have attempted to load the specimen on to the Cartridge twice **do not** attempt to load the specimen on to the Cartridge a third time. Discard this Cartridge and start the test procedure again with a new Cartridge.

Once you are satisfied the specimen has been loaded correctly, either press the **Continue** button on the touchscreen or proceed directly to Step 6.

If you press the **Continue** button the following screen will be displayed.



6. Insert the Cartridge into the drawer, ensuring the Cartridge is seated correctly in the recess and push the drawer closed.
7. The instrument will recognize the test type and display the details of the test to be run including Specimen ID and any Patient ID information. Check this information is correct then press the **Run Test** button.

IO_999/admin 6 Jul 2021 14:13:37

Review Test Input

Patient ID 1

Specimen ID 268578741

Selected Test CTNG

QC Test

Cancel Edit Details Run Test

System Idle

If the test you are about to perform is a QC test, designate a QC Test by selecting the **QC Test Check box**. Please refer to the QC Testing section of this document for further details about QC testing.

If the test is not recognized, the following screen will be displayed because the software required to run the test is not installed.

IO_999/admin 6 Jul 2021 15:10:47

New Cartridge Type Detected

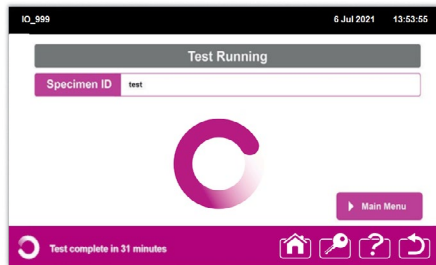
? The detected cartridge is new to this instrument.
Would you like to install this test software?

Cancel Add Test

System Idle

To install the software required to run the test refer to **Software Installation for New Test Types** or the **Add Test** section under Administrator Functions of the Operator Manual.

If the barcode on the Cartridge was not successfully read, you will be offered the opportunity to eject the Cartridge and try again.



8. Once initiated the **Test Running** screen will appear and remain whilst the test is in progress.

This screen will display the progress of the test using two rotating graphics. The outer ring spins quickly to indicate that the test is in progress, the inner circle will turn pink to indicate the progression of the test. For example, when half the circle is pink the test is halfway through.

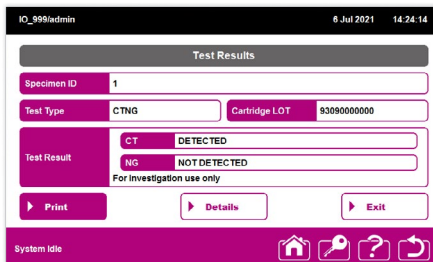
In addition, an estimate of how long until the test is complete in minutes is provided in the bottom left corner of the screen.

9. Following completion of the test, the screen will update to a **Test Complete** summary and the instrument drawer will open. The used Cartridge should be removed immediately and disposed of in accordance with local or national policies on disposal of biohazardous materials.



To maintain patient confidentiality, the result will not be automatically displayed on screen upon completion of the test.

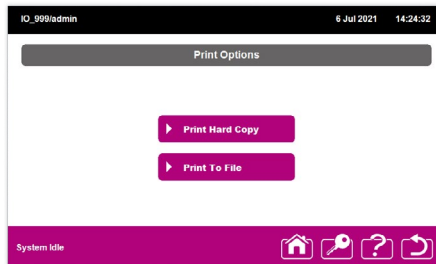
10. The test result can be viewed by pressing the **View Results** button on the touchscreen. To run a new test immediately from the Test Results screen, press the **Back** fast key to return to the previous screen and press the **Run New Test** button.



For full details of test results please consult the Instructions For Use (IFU) supplied with the io Cartridge.

To maintain patient confidentiality the Patient ID (if one has been entered) will never be displayed on the same screen as the test result.

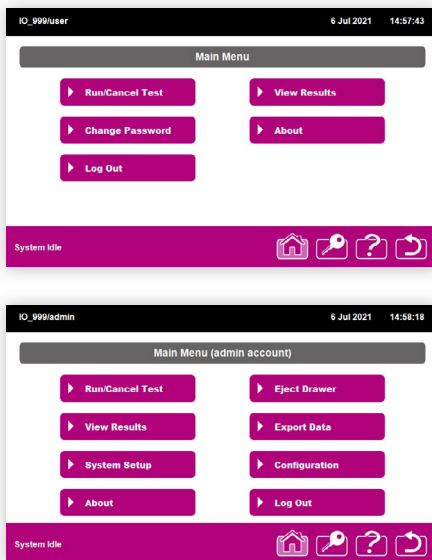
11. To immediately print or save this test result, select **Print**, then either **Print Hard Copy** or **Print to File** to save to a USB storage device. You will need the optional USB printer or a USB storage device connected to a USB port at the rear of the instrument.



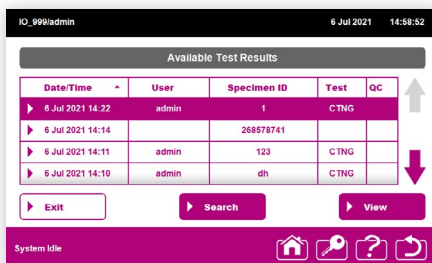
Retrieval of Test Results

Previous test results are stored on the system and can be retrieved when required.

1. From the **Main Menu** screen press the **View Results** button.

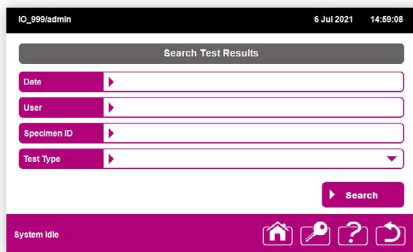


2. The **Available Test Results** screen appears. Use the scroll buttons to find the test result you are searching for.



The test results can be sorted in ascending or descending order by any of the column headings. Press the heading of the column you wish to sort by until the arrow points upwards (for ascending) or downwards (for descending).

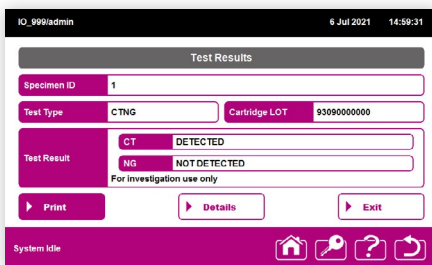
Alternatively press the **Search** button on the touchscreen. The **Search Test Results** screen will appear.



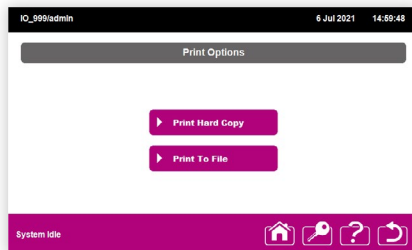
A search can be performed on one or multiple fields by pressing the appropriate search field box and either entering the search criteria using the touchscreen keyboard or by selecting from the available options in the dropdown box. Once the search criteria have been entered press the **Search** button on the touchscreen.

The **Available Test Results** screen will show the filtered results based on the search criteria. Use the scroll buttons to find the test result you are searching for.

3. Select the result you wish to view by pressing anywhere on the result line and pressing the **View** button.
4. To maintain patient confidentiality the Patient ID (if one has been entered) will never be displayed on the same screen as the test result.



5. To print or save this test result, select **Print**, then either **Print Hard Copy** or **Print to File** to save to a USB storage device. You will need the optional USB printer or a USB storage device connected to a USB port at the rear of the instrument.



QC Testing

The *io* Instrument performs a range of self-checks upon initialization at start-up and prior to running a Cartridge to confirm the instrument is functioning correctly. Additionally, every *io* Cartridge contains an Internal Process Control (IPC) which undergoes exactly the same process steps as the specimen. The detection of the IPC at the end of the test verifies that the test has worked. If the IPC is not within an acceptable range the test will be invalid and no test result will be reported.

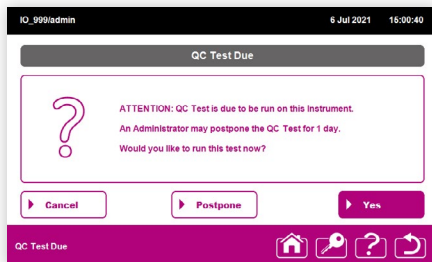
In addition, users may be required to perform periodic QC testing, where QC samples of a known status are tested. Please refer to the appropriate site, local or national policies on Quality Control.

The instrument may be configured to support periodic QC testing and will prompt the user to run a QC test to demonstrate the instrument is performing as expected.

The local Administrator can configure the *io* Instrument to define the frequency at which QC testing should be carried out. This is described in the QC Test Setup section.

QC Testing Following Prompt

If a QC test is due, the **QC Test Due** message will be displayed when a User or Administrator attempts to run a test. It is recommended that the QC test is run at this point.



If an Administrator has set the QC Test Due State to **Unlocked** then non-QC tests can still be performed by pressing **No**. All test results will be reported with a QC Test Due comment and the QC Test Due screen will continue to appear until a QC test is performed.

If an Administrator has set the QC Test Due State to **Locked** then non-QC tests cannot be performed until a QC test is performed.

Pressing **Postpone** will postpone the QC test for 1 day allowing non-QC tests to be performed as normal. Postponing a QC test requires an Administrator account. If a User presses **Postpone** then a prompt for Administrator authorization will appear to authorize the postponement.

To perform a QC test, press the Yes button.

The QC test will now run and follows the same process as described in the **Test Procedure** section of the Instrument Operator Manual with the exception that a QC Specimen ID is requested instead of a Patient Specimen ID.

At the Review Test Input screen, the QC Test check box will automatically be checked.

QC Testing Without Prompt

A QC test can be performed at any time. The process for performing a QC test without a prompt is the same process as described in the **Test Procedure** section of the Instrument Operator Manual except that at the **Review Test Input** screen a QC test needs to be designated by manually selecting the **QC Test** check box.

QC Test Results

QC test results are shown and accessed in the same manner as normal test results. The results show whether a target was detected or not but also indicate that this was a QC test on printouts and electronically stored results.

IO_999/admin 6 Jul 2021 15:07:44

QC Test Result

Specimen ID QC:1

Test Type CTNG Cartridge LOT 9309000000

Test Result

CT DETECTED

NG NOT DETECTED

QC Test Due, For investigation use only

Print QC Passed EXIT

QC Test Due

The instrument does not interpret or compare QC results with an expected result, and you will need to compare the result with the expected result of the QC sample in accordance with your own QC procedures. Pressing **QC Passed** will record that a successful QC test was performed, and the next QC test will become due according to the **QC Duration** rules set by the Administrator. Passing a QC test requires an Administrator account. If a User presses **QC Passed** then a prompt for Administrator authorization will appear to authorize the pass.

IO_999/user 6 Jul 2021 15:08:35

Authorise

User ID

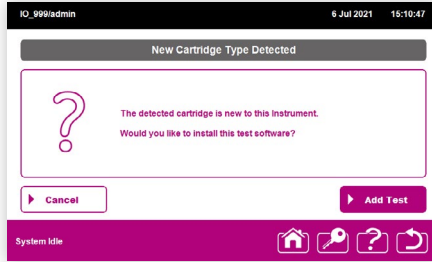
Password

Cancel Authorize

QC Test Due

Software Installation for New Test Types

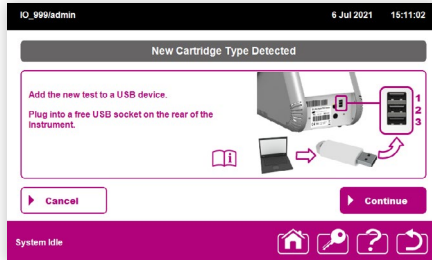
If a new type of Cartridge is inserted into the instrument without the software required to run this test being installed, the instrument will automatically request that the software to perform this test is installed.



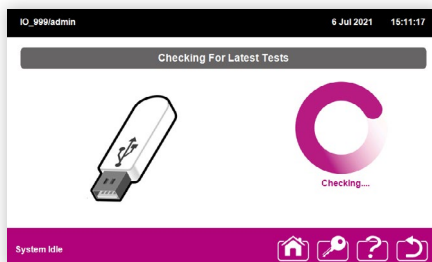
Under these circumstances both Users and Administrators can add new test software, as this does not require access to the **Configuration** menu. A USB storage device containing the new test software is required.

New test software may be made available from binx technical support, or your local representative.

Press the **Add Test** button. A screen will be shown describing the process for updating the test software.



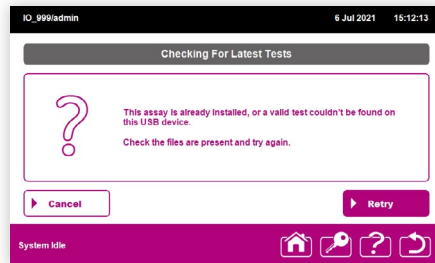
Once you have inserted the USB storage device containing the new test software into a USB port at the rear of the instrument, press **Continue**. The Instrument will search the USB storage device.



If the correct test software is available on the USB device, it will be installed immediately and the test process will continue.

Software Update Not Found

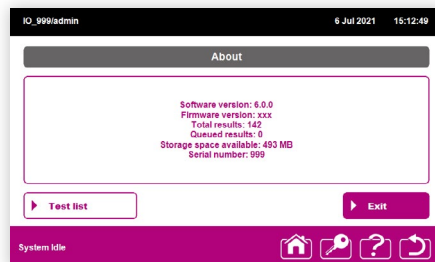
If the appropriate new test software is not found, the following screen will be displayed.



Cancel the update by pressing **Cancel**. This will result in aborting the current test and ejecting the Cartridge.

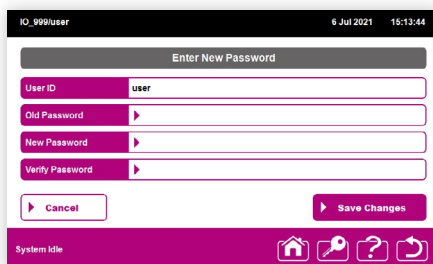
About

Pressing the **About** button will display an information screen listing the current firmware and software versions, the number of stored results, internal storage space available and the serial number of the *io* Instrument. Press **Exit** to return to the previous menu. Pressing **Test List** shows all the test types installed on the system.



Change Password

A User can change their password at any time by pressing the **Change Password** button on the **Main Menu** screen and completing the fields. Administrators can change their passwords through the **User Management** Administrator function.



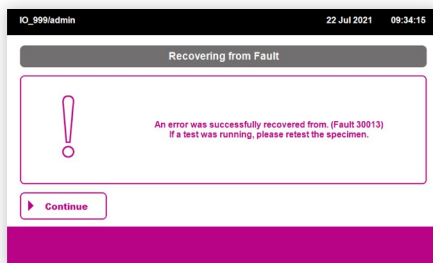
The screenshot displays the 'Enter New Password' interface. At the top, the header reads 'Enter New Password'. Below this, there are four input fields: 'User ID' (containing 'user'), 'Old Password', 'New Password', and 'Verify Password'. Each field has a right-pointing arrow icon. At the bottom of the form area, there are two buttons: 'Cancel' and 'Save Changes'. The top status bar shows 'IO_999/user', '6 Jul 2021', and '15:13:44'. The bottom navigation bar shows 'System Idle' and icons for home, user, help, and refresh.

The local Administrator can configure the instrument to enforce password changes at defined intervals. The instrument will alert both Users and Administrators when a password is due to expire with a **Renew** button option.

The local Administrator also has the option to define a minimum password length. All passwords must conform to this minimum length.

Fault Screen

If the instrument encounters a fault the following screen will be displayed.



The screenshot displays the 'Recovering from Fault' interface. At the top, the header reads 'Recovering from Fault'. Below this, there is a large exclamation mark icon and the text: 'An error was successfully recovered from. (Fault 30013) If a test was running, please retest the specimen.' At the bottom of the message area, there is a 'Continue' button. The top status bar shows 'IO_999/admin', '22 Jul 2021', and '09:34:15'. The bottom navigation bar is partially visible.

Please try restarting the instrument to see if this resolves the issue, otherwise contact your representative or binx health Technical Support.

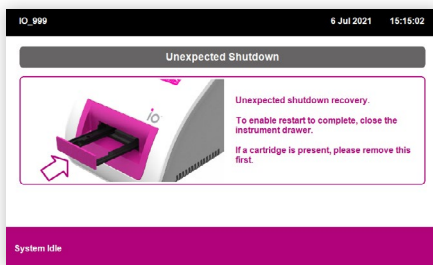
Turning the *io* Instrument Off



Under normal operation the *io* Instrument should be shut down using the **Log Out** button on the **Main Menu** screen or the **Log In / Log Out** fast key.

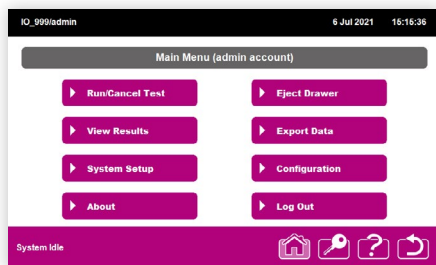
Both options will return the user to the **Log In / Shut Down** screen. To turn the instrument off press the **Shut Down** button.

If necessary, the instrument may be turned off at any time by disconnecting the main supply through switching the power off at the wall socket or by removing the power cable from the port at the rear of the instrument. If power is disconnected while a test is in progress, that test will be immediately aborted. The Cartridge will be invalidated and remain inside the instrument until the power is restored. When you restart the instrument, the following screen will prompt you to remove the aborted Cartridge.



Administrator Functions

When logged in as an Administrator, the **Main Menu** shows additional options over those available to a User.

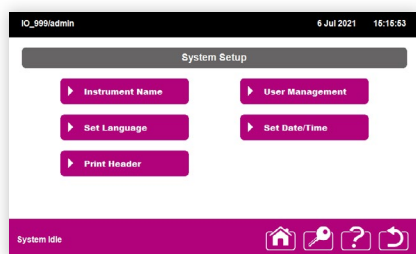


The **System Setup** and **Configuration** buttons allow an Administrator to access tools for configuring the *io* Instrument.

The **Export Data** button allows an Administrator to transfer locally stored results and the *io* Instrument audit log to a USB storage device.

System Setup

Press the System Setup button on the **Main Menu** to access the **System Setup** menu. The screen provides options to change settings related to the instrument.

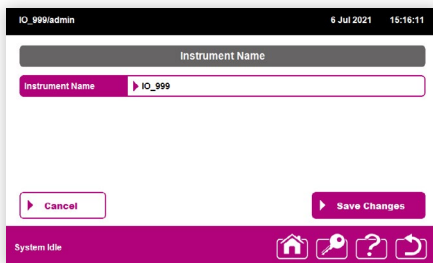


Instrument Name

This enables an Administrator to assign a unique name or identifier to this *io* Instrument, to distinguish it from other *io* Instruments at a location with multiple instruments.

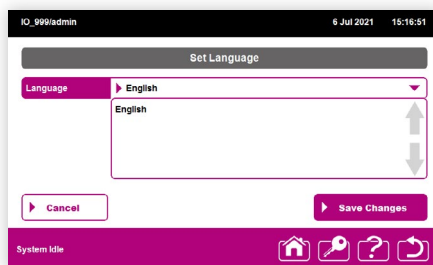
The name assigned to the instrument is displayed in the top left corner of the user interface and is recorded on all test results.

To edit the instrument name, press the **Instrument Name** field and then type in the chosen name using the on-screen keyboard. Press **Save Changes** to save and exit.



Set Language

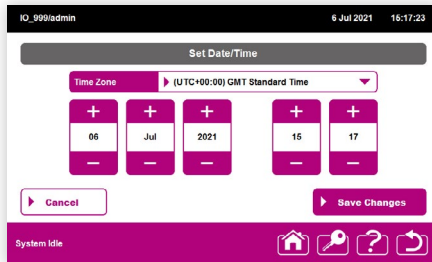
The language used on the user interface can be changed to other languages stored on the instrument. Languages are added automatically through software updates and do not require any additional action.



To change the language, press the **Language** field, then select the required language from the dropdown list and press **Save Changes** to save and exit.

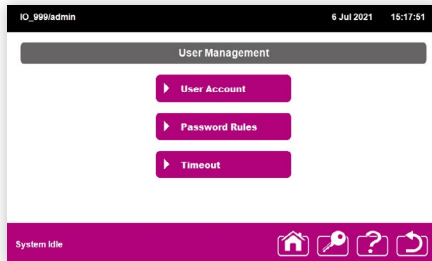
Set Date and Time

This sets the instrument internal time and date. Use the + and - buttons to adjust the date and time. Use the dropdown list to choose the time zone. Press **Save Changes** to save and exit.



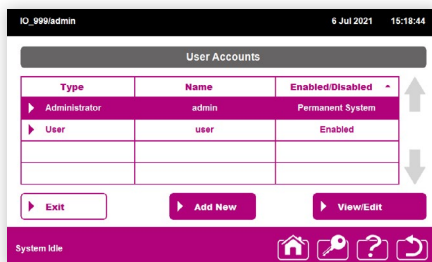
User Management

The Administrator can control **User Accounts**, including login details, password rules and the period of time before a user is automatically logged out.



User Accounts

This lists all current Administrator and User accounts, the account details and their status. Press on the table headings to sort by **Type**, **Name** or whether the account is enabled or disabled. Browse by scrolling up and down using the arrows to the right of the table.



Press the **View/Edit** button to show and edit the details of an existing account or the Add New button to add a new user account to the instrument. The data fields are the same for creating a new account or editing an existing account.

The screenshot displays the 'View/Edit User Account' interface. At the top, it shows the user 'IQ_999/admin' and the date/time '6 Jul 2021 16:19:07'. Below the title bar, there are two radio buttons: 'Administrator' (selected) and 'User'. The form contains three input fields: 'User ID' with the value 'admin', 'Password', and 'Verify Password'. At the bottom of the form are 'Cancel' and 'Save Changes' buttons. The bottom status bar indicates 'System Idle' and contains icons for home, user, help, and refresh.

Administrator / User buttons

The level of access associated with an account is chosen by selecting either the **Administrator** or **User** option buttons under the screen title bar.

• User ID

A User ID can be entered by pressing the **User ID** box and typing a new name using the touchscreen keyboard.

• Password

Press the **Password** box to set a password for an account. Type the password using the touchscreen keyboard. Passwords must comply with any password rules.

• Verify Password

Press the **Verify Password** box and re-type the password using the touchscreen keyboard. The password typed in this box must correspond to the password entered in the **Password** box.

• Delete Account

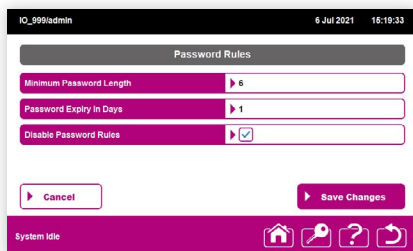
The **Delete Account** button is only visible when viewing an existing account and not when adding a new account. Press this button to remove a current account from the system. A confirmation screen will appear, press **Yes** if you wish to continue deleting the user account. You can edit but not delete the Permanent System account.

Save Changes

This will save any changes made to an existing account or create a new account.

Password Rules

For added security, an Administrator can define the Minimum Password Length and the frequency with which a password must be changed by setting a Password Expiry.



The screenshot shows the 'Password Rules' configuration screen. At the top, the user is identified as 'IQ_999admin' and the date/time is '6 Jul 2021 16:19:33'. The screen has a dark header with the title 'Password Rules'. Below the header, there are three settings, each with a right-pointing arrow icon:

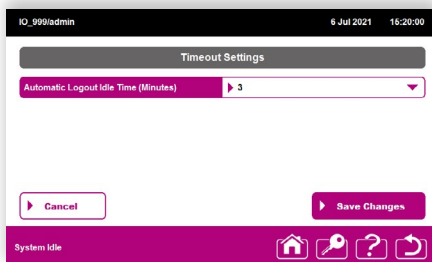
- Minimum Password Length:** Set to 8.
- Password Expiry In Days:** Set to 1.
- Disable Password Rules:** A checkbox that is currently checked.

At the bottom of the settings area, there are two buttons: 'Cancel' and 'Save Changes'. The bottom of the screen features a dark purple navigation bar with the text 'System Idle' and four icons: a home icon, a key icon, a question mark icon, and a refresh icon.

The password rules can be disabled at any time by ticking the check box. This will allow passwords of any length to be used and the instrument will never prompt for a password change.

Timeout

This setting controls how long the instrument will remain idle before logging out the current User.



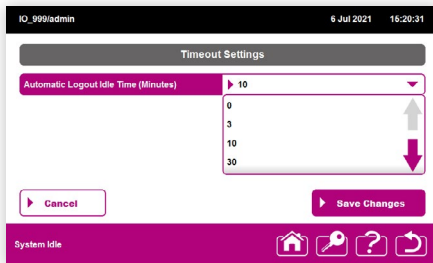
The screenshot shows the 'Timeout Settings' configuration screen. At the top, the user is identified as 'IQ_999admin' and the date/time is '6 Jul 2021 16:20:00'. The screen has a dark header with the title 'Timeout Settings'. Below the header, there is one setting with a right-pointing arrow icon and a dropdown arrow:

- Automatic Logout Idle Time (Minutes):** Set to 3.

At the bottom of the settings area, there are two buttons: 'Cancel' and 'Save Changes'. The bottom of the screen features a dark purple navigation bar with the text 'System Idle' and four icons: a home icon, a key icon, a question mark icon, and a refresh icon.

Press the **Automatic Logout Idle Time** data entry field then use the + and – buttons on the subsequent screen to adjust the timeout setting.

The options available are 0, 3, 5, 10, 30, 60 and 120 minutes. Press **Save Changes** to save this setting and exit the screen.



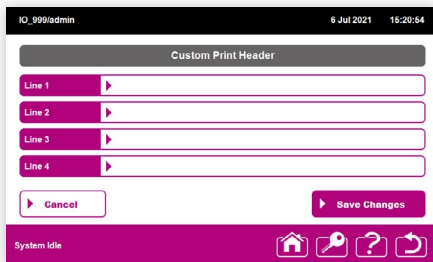
If the Timeout is set to **0 Minutes**, the instrument will never automatically log a user out and will require a user to log off manually.

Print Header

The instrument allows you to customise the text that appears in the header of a results printout.

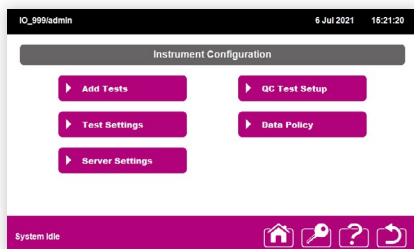
It should be noted that any text is common to all printouts irrespective of test result.

Press the **Print Header** button on the **System Setup** screen. The Custom Print Header screen will appear. Press the **Line** fields and enter up to 4 lines of text.



Configuration

Press the **Configuration** button on the main menu to access the **Instrument Configuration** menu. This screen provides the options to change settings related to tests.



Test settings

Test Settings are available for quickly configuring operation of the *io* Instrument in accordance with your local work practices.

Use Automatic Specimen ID Method

To speed up the test process the Administrator can allow Users to bypass entering a Specimen ID. As a **Specimen ID** is mandatory and provides the traceability to the test result the *io* Instrument will assign a unique **Specimen ID** if this option is checked.

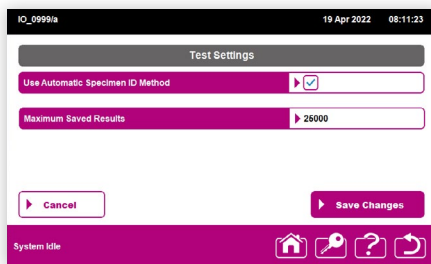
Set Maximum Test Result Storage

As a default, the *io* instrument will store 25,000 test results. **Once that limit is reached, the oldest test result will be deleted.**

Administrators can set the number of test results stored to any number between 1 and 25,000 in accordance with institutional cybersecurity and privacy policies. Only administrators are able to change this setting. This setting should only be adjusted under the guidance of the institution's cybersecurity and privacy compliance policies.

IMPORTANT: If the number of stored test results is reduced, the oldest results will be deleted if the number of results stored on the instrument exceeds the newly set limit. Following the next test run after changing the limit, the results stored will be reduced with the oldest results being deleted to meet the newly set limit.

This action cannot be undone. It is recommended that all results should be transferred to another storage system such as an EMR/EHR or LIS or similar repository before adjusting this setting.

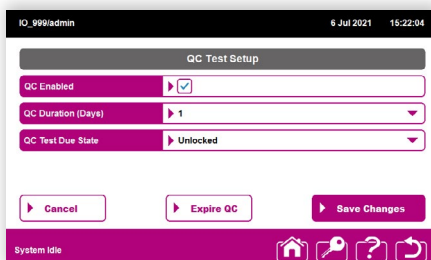


QC Test Setup

Local or national regulations or guidelines may require that tests using QC samples are run to demonstrate that the system is giving the correct results.

The *io* Instrument can be configured to either prompt or force a user to perform QC testing at defined intervals. It should be noted that the QC test results must be checked to ensure that a QC test returns the expected result. The instrument cannot determine what the correct outcome of a QC test should be or act on the basis of that outcome.

The instrument allows the Administrator to define how often a QC test should be performed and whether the QC Test Due State is Locked or Unlocked.



Press **QC Test Setup** on the **Configuration** menu to access the QC Test Setup screen.

- **QC Enabled**

The Administrator can disable QC test prompting if it is not required.

- **QC Duration**

If QC is enabled the Administrator can set the time period between QC tests. A QC test will become due the configured number of days after the last successful QC test. Use the dropdown menu to select the required period between QC tests.

- **QC Test Due State**

If QC is enabled the Administrator can set the status of the instrument when a QC test is due. If set to **Unlocked** then non-QC tests can still be performed when a QC test is due but test results will be reported with a QC Test Due comment. If set to **Locked** then non-QC tests cannot be performed when a QC test is due.

Pressing **Expire QC** will expire the last QC test pass which will result in the instrument entering the QC Test Due state immediately.

Add Test

When new tests become available an Administrator can update the *io* Instrument with the software required to run a new test type. This can be performed by an Administrator in advance of a user attempting to run a new Cartridge.

New test software may be made available from binx technical support, or your local representative.

You will require a USB storage device containing the appropriate software to install this on the instrument.

To update the instrument with the new software, insert the USB device into any free USB port on the rear of the instrument and select **Add Test** from the **Configuration** menu.

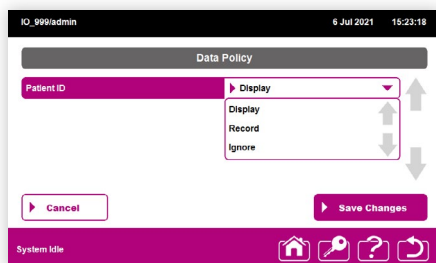
Uploading the new test software will take a few seconds during which time the following screen will be displayed.



When complete the instrument will then return to the **Configuration** menu. To add further software from the connected USB device, repeat this process.

Data Policy

The Data Policy allows the Administrator to control what information a User is requested to enter during the test set-up process and how this information is processed by the instrument. This also allows an Administrator to configure what information is recorded and displayed on screen for test identification and patient confidentiality.



Each field has three options:

Display	The instrument requests that the user enters this information and records this information with the test result. The instrument displays this information on the test results.
Record	The instrument requests that the user enters this information and records this information with the test result. The instrument does not display this information on the test results. This information is only shown when the data is exported or uploaded to the server.
Ignore	The instrument does not request the user enters this information, this data field will not be presented to the user during the test set up process, and therefore this information is neither recorded nor displayed by the instrument.

Server Settings

To enable the instrument to transfer test results to a server you will need to install the appropriate server plugin from a **USB storage device**. To discuss your connectivity needs please contact binx Customer Support.

Cleaning and Maintenance

The *io* Instrument has been designed to require minimal maintenance. When faults occur that require attention an error message will be displayed on screen.

Thermocycler Units

The *io* Instrument uses a thermocycling unit as part of the test process. With frequent usage, over time, these may lose efficiency resulting in the instrument displaying a notification message stating that the thermocycling unit may need replacing. The instrument can continue to be used but may eventually lead to regular **Invalid** test results due to failure of the Internal Process Control (IPC).

Replacement or service of the thermocycler unit is a simple procedure which can be performed by a binx health Service Engineer. Contact binx health Customer Support to arrange at your convenience.

Regular User Cleaning and Maintenance

Cleaning the *io* Instrument once a month is advisable, following the procedure described below.

1. Disconnect the main power supply from the rear of the instrument.
2. Wipe all external surfaces thoroughly with a clean cloth or absorbent towel moistened with 70% aqueous Isopropyl Alcohol (isopropanol). Avoid excessively wetting the instrument and avoid splashing fluid into the instrument's air vents.
3. After applying the cleaning solution, wait 1-2 minutes before wiping down with a clean cloth or absorbent towel moistened with clean water. Again, avoid excessively wetting the instrument and avoid splashing fluid into the instrument's air vents.
4. Wipe off any remaining excess water with a dry clean cloth or dry absorbent towel.

Spills and Leaks

If a specimen is spilled onto the surface of the Cartridge, it is possible that this could lead to infectious material remaining in the instrument after use. Spills or leaks of specimens or amplified test material can lead to incorrect test results.

Always clean up small spills on the surface of the Cartridge with clean tissue or a disposable absorbent towel prior to inserting the Cartridge into the instrument.

If the spill is significant, it is recommended you dispose of the Cartridge prior to inserting it into the instrument and use a new Cartridge.

If you suspect there has been a spill or leak inside the instrument, turn the instrument off and remove the main power supply. Leave the instrument to dry for at least 12 hours and call binx health Customer Support or your representative for advice.

Cleaning the Instrument for Return

If you need to return the instrument to binx health, please decontaminate the instrument in accordance with your local policies and procedures. If possible, please provide a record showing that the instrument has been decontaminated to your procedures.

If no local procedures exist, please contact your representative to notify us you are returning a decontaminated instrument and clean the instrument as described below.

1. Disconnect the main power supply from the rear of the instrument.
2. Wipe all external surfaces thoroughly with a clean cloth or absorbent towel moistened with 70% aqueous Isopropyl Alcohol (isopropanol). Avoid excessively wetting the instrument and avoid splashing fluid into the instrument's air vents.
3. After applying the cleaning solution wait 1-2 minutes before wiping down with a clean cloth or absorbent towel moistened with clean water. Again avoid excessively wetting the instrument and avoid splashing fluid into the instrument's air vents.
4. Wipe off any remaining excess water with a dry clean cloth or dry absorbent towel.
5. Allow the instrument to dry completely before re-packing in the *io* Instrument packaging and await collection.

EMC Testing

Further Technical Details: EMC testing conducted on the *io* Instrument (Emissions)

Test Type	Test Standard	Test Range	Criteria met	Result	Notes
Transmitter Spurious Emissions	EN300 328 V2.1.1	1GHz to 12.5GHz vertical & horizontal	N/A	Pass	n/a
Occupied Channel Bandwidth	EN300 328 V2.1.1	2.4000 to 2.4835 MHz	N/A	Pass	n/a
Eirp (Radiated)	EN300 328 V2.1.1	-10dBW 100mW 20dBm	N/A	Pass	n/a
	EN300 328 V2.1.1	10dBW 100mW 20dBm	N/A	Pass	n/a
Conducted Emissions	EN60601-1-2	150kHz to 30MHz	Class A	Pass	n/a
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				
	EN55011 Class A				
	IEC60601-1-2 FCC Part 15 Class A				
Radiated Emissions	EN60601-1-2	30 MHz - 1.0 GHz 1-GHz - 18GHz	Class A	Pass	n/a
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				
	EN55011 Class A				
	IEC60601-1-2 FCC Part 15 Class A	1GHz to 25GHz	Class A		
Harmonic Current Emissions	EN61000-3-2	0Hz to 0.002MHz	N/A	Pass	n/a
Voltage Fluctuation and Flicker	EN61000-3-3	<Pst, <0.65 Pit <3.3%Dc <4%Dmax <3.3% 500mSdt	N/A	Pass	n/a
Inrush Current	EN61000-3-3	Measure result	N/A	Pass	17.382A

Test specifications for Immunity to RF wireless communications

Test Type	Test Standard	Test Range	Criteria met	Result	Notes
Electro Static Discharge	EN61000-4-2	-15KV to +15KV	C	Pass	Sensitivity to $\pm 8KV$ & $\pm 15KV$ Instrument Screen may flicker or freeze instrument may cease to operate and require a power cycle.
	EN301 489-1				
	EN61326-1				
	EN60601-1-2				
	EN61326-2-1				
Radiated Immunity	EN6100-4-3	3 V/m to 28 V/m	C	Pass	Sensitivity to 385MHz Instrument may restart or turn off unexpectedly
	EN61000-4-3				
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				
Fast Transient Bursts	EN6100-4-4	1KV to 2KV @ 5KHz	A	Pass	n/a
	EN61000-4-4				
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				
Surges	EN6100-4-5	Phase 0 to 270° AC Mains @ -2 to +2 phase angle	A	Pass	n/a
	EN61000-4-5				
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				
Conducted Immunity	EN6100-4-6	150kHz to 80MHz	A	Pass	n/a
	EN61000-4-6				
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				
Voltage Dips & Fluctuations	EN6100-4-11	30% to 100% dip, 230V and 100v AC	C	Pass	Instrument may reset with repeated voltage dips in quick succession
	EN61000-4-11				
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				
Voltage interruptions	EN6100-4-11	60%, 230V and 100v AC	C	Pass	Instrument may reset with repeated voltage interruptions
	EN61000-4-11				
	EN301 489-1				
	EN61326-1				
	EN61326-2-6				

Contact and Support



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Product (Technical) Support

For Product Support in the United Kingdom please call the following toll-free number.

UK Product (Technical) Support: 0800 8407489

Product (Technical) Support

For Product Support in the United States please call the following toll-free number.

US Product (Technical) Support: 1-844-MYBINX-1

For Product Support enquiries outside of the UK and US, please contact your local distributor.

www.mybinxhealth.com