i-STAT Alinity v

FOR VETERINARY USE ONLY

USER MANUAL

ABAXIS
GLOBAL DIAGNOSTICS

Abbott

Contents

The User Manual contains information that describes several functional pathways of the i-STAT Alinity v Analyzer. The i-STAT Alinity v Analyzer is intended for veterinary use only. Additional information regarding the use of the i-STAT Alinity v Analyzer and i-STAT test cartridges can be found at www.abaxis.com. An Abaxis Technical Support personnel can also be reached 24 hours a day, 7 days a week, at 1-800-822-2947 (toll-free phone) for USA and Canada. International Technical Support is available from 8:30 am to 5:00 pm CET at +49 6155 780 210.

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Contains Transmitter Module
FCC ID: 2AAEX-SDABGN
IC: 7228C-SDABGN

Intertek
108952

R-NZ

60°C
140°F
-10°C
14°F

Abbott

APOC Artwork #755229-01 Rev. B
Rev Date: 19-Jan-2018

The i-STAT Alinity system complies with applicable regulations.

Safety Regulations:	
USA	UL 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1: General Requirements
Canada	CAN/CSA C22.2 No. 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1: General Requirements
European Union (EU)	IEC 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1: General Requirements
European Union (EU)	IEC 62133: Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
International	UN Manual of Tests and Criteria "Recommendations on the Transport of Dangerous Goods," Section 38.3 "Lithium Batteries"
EMC Regulations:	
USA	FCC 47 CFR Part 15, Subpart B, Class A (Unintentional Radiators)
Canada	CAN ICES-001 Class A, Industrial, Scientific and Medical Radio Frequency Radiators
European Union (EU)	IEC 61326-1: Electrical Equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.
Radio/Telecommunication Regulations:	
Angola	INACOM Instituto Angolano das Comuinicacoes Equipment Type Model Number: 189
Antigua & Barbuda	ABTD Antigua & Barbuda Telecommunications Division Type Approval Certificate Number 25-TAC2513000853

Armenia	Conforms to: Technical Regulations of radio equipment and telecommunication terminal equipment approved by RA Government Regulations Decree of 15 December 2005 No 2228-N
Aruba	Approved for use in accordance with article 4 of the Telecommunication Regulation. DTZ/910/2017/IZ, Pet nr. 3745
Australia 	Complies with Australian Communications and Media Authority as required by the following Notices: • Radiocommunications (Compliance Labelling-Devices) Notice 2014 made under section 182 of the Radiocommunications Act 1992; • Radiocommunications Labelling (Electromagnetic Compatibility) Notice 2008 made under section 182 of the Radiocommunications Act 1992; • Radiocommunications (Compliance Labelling-Electromagnetic Radiation) Notice 2014 made under section 182 of the Radiocommunications Act 1992; and • Telecommunications (Labelling Notice for Customer Equipment and Customer Cabling) Instrument 2015 made under section 407 of the Telecommunications Act 1997.
Bahamas	Utilities Regulation & Competition Authority (URCA) Type Approval UCRA_TA/2017_023 FCC ID: 2AAEX-SDABGN
Bahrain	Telecommunications Regulatory Authority, SPECT/0617/COM/150
Barbados	Complies with GOVERNMENT OF BARBADOS, TELECOMMUNICATIONS UNIT, Division of Energy & Telecommunications. MED Approval Number: 1905
Belize	Complies with Telecommunications Act, 2002 Type Approval per SI 152 OF 2002: PUC/APC/0182017/BZE
Bonaire - Sint Eustatius – Saba	Agentschap Telecom, Minisceñe van Economische Zaken Complies with articles 23 and 56 of the Besluit radio-elektrische inrichtingen BES and article 2 of the Regeling vrijstelling telecommunicatiemachtiging BES 2016 Type Approval 2017/008/AT and 2017/008a/AT
British Virgin Islands	Telecommunications Regulatory Commission Granted Equipment Type Approval for FCC Identifier 2AAEXSDABGN in accordance with section 42 of the Telecommunications Act 2006. Type Approval Number: VRGTA/011/2017
Brunei	AITI Authority for Info-communications Technology Industry of Brunei Darussalam Equipment Registration Certificate DRQ-D-BRUSIN-03-1998-7494-LPD-39421

Burkina Faso	ARCEP Type Approval 2017-000031 Autorite de Regulation des Communications Electroniques et des Postes Authority of Regulations of Communications Electronic and Posts
Canada	Industry Canada RSS 210: Licence-Exempt Radio Apparatus: Category I Equipment Certification No.: 7228C-SDABGN
Cayman Islands	Utility Regulation and Competition Office GRANT OF EQUIPMENT AUTHORISATION IN THE CAYMAN ISLANDS Certificate. No: KY1504003
Colombia	Communications Regulatory Commission (CRC) - Exempt
Curacao	Director Bureau Telecommunicatie en Post Type Approval Nos. 2017/054/TA and 2017/054a/TA
Dominica	National Telecommunications Regulatory Commission (NTRC) Type Approval No. DMA-0217-0539p
Dominican Republic	Istituto Dominicano de las Telecomunicaciones (INDOTEL) Type Approval 17003658
Egypt	NTRA National Telecom Regulatory Authority
European Union (EU)	DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 EN 300 328: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU. EN 301 893: 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU.
Grenada	National Telecommunications Regulatory Commission EQUIPMENT TYPE APPROVAL NTRC REGISTRATION NUMBER: CL 1090 | 17 – TA
Honduras	CONATEL Comision Nacional De Telecomunicaciones 20161024HM32
Hong Kong	CERTIFICATE OF TYPE APPROVAL per HKCA 1039 Issue 6, June 2015
India	Ministry of Communcations & IT Equipment Type Approval, ETA Certification No: ETA – 3319/16-RLO(WR)
Japan R 208-160178	Article 2 Section 1 No. 19, 19-3, 19-3-2 Radio Type Approval, Construction Designed Certificate No: 208-160178 当該機器には電波法に基づく、技術基準適合証明等を受けた特定無線設備を装着している。

Kuwait	CITRA Communication and Information Technology Regulatory Authority Type Approval Certificate
Lebanon	Ministry of Telecommunications Approval 1031-16-041
Lesotho	Lesotho Communications Authority Lesotho Communications Authority Act 2012, Section 5
Libya	General Authority for Communications Type Approval Certificate No. 343-C1-2017
Madagascar	Autorite de Regulation des Technologies de Communication (ARTEC) No 17/026/ARTEC/DG/DHCT/SSS/test
Mauritius	Information & Communication Technologies Authority (ICTA) Type Approval Certificate Reference Number: TA/2017/0214
Morocco AGREE PAR L'ANRT MAROC Numéro d'agrément : MR 12797 ANR 丁 2016 Date d'agrément : 11/11/2016	Numéro d'agrément : MR 12797 Date d'agrément : ANRT 2016
Mozambique	Instituto Nacional das Comunicacoes de Mocambique (INCM) Telecommunication and Radiocommunications Agreements approved by Decree 37/2009 of 13 August No. 1/R/IMS/2017
New Zealand R-NZ	Conforms to: Ministry of Business, Innovation & Employment, Radio Spectrum Management as required by notices under: • Section 134 (1) (g) of the New Zealand Radiocommunications Act 1989
Oman	Telecommunication Regulatory Authority, Approval Number: TRA/TA-R/4501/17
Pakistan Approved by PTA 2017 PTA Pakistan Telecom Authority	Pakistan Telecommunication Authority (PTA), Type Approval Certificate TAC NO: 9.197/2017
Peru	Ministerio De Transportes Y Comunicaciones, Certificado De Homologacion, Code: TRSS39479, Report: 2158-2017-MTC/29.CGH.CH Applied Technical Standard: PNAF-R.M. No. 187-2005-MTC/03, pub. 04/03/2005 – R.M. No. 777-2005-MTC/03, pub. 11/05/2005
Philippines	National Telecommunications Commission Type Acceptance Certificate No. ESD-1714467C
Qatar	Communications Regulatory Authority Certificate of Type Approval CRA/SA/2016/R-5837

Saudi Arabia	Ministry of Communication and Information Technology (MCIT) Conformity Certificate TA 24012017-24012019-18944
Singapore Complies with IMDA Standards DA00949	Info-communications Media Development Authority Regulation 20(6) of the Telecommunications (Dealers) Regulations (Cap 323, Rg 6) Registration Number: N0123-17 (5 GHz) Registration Number: N0074-17 (2.4 GHz)
Sri Lanka	Telecommunications Regulatory Commission of Sri Lanka, TRC/SM/MISC/00041/17/WIFI-106
St. Lucia	National Telecommunications Regulatory Commission (Saint Lucia) Telecommunications (Terminal Equipment and Public Networks) Regulations, No. 10 or 2002 Certification of Type Approval, Certificate No.:LCT/AP17.118D
St. Maarten	Bureau of Telecommunication and Post Type Approval Certificate no 2017/018-b/TA
St. Vincent & the Grenadines	National Telecommunications Regulatory Commission Telecommunications (Terminal Equipment and Public Networks) Regulations, No. 13 of 2002 Certificate of Type Approval, Certificate No.: SVG_050520171055
Turks and Caicos	Turks and Caicos Islands Telecommunication Commission Approval Certification under TCITC Ordinance PART V
United Arab Emirates هيئة تنظيم الاتصالات TRA TELECOMMUNICATIONS REGULATORY AUTHORITY TRA REGISTERED No: ER53962/17 DEALER No: 203829	Telecommunications Regulatory Authority Telecom Equipment Registration Certificate ER53962/17 under Law No.3 of 2003
Uganda	Uganda Communications Commission Type Approved
USA	FCC 47 CFR Part 15, Subpart C - Intentional Radiators FCC 47 CFR Part 15, Subpart E - Unlicensed National Information Infrastructure Devices FCC ID: 2AAEX-SDABGN

Vietnam 	Ministry of Information and Communications Type Approval Certificate No: C0031280217AE01A2
Yemen	Ministry of Telecommunications and Information Technology Type Approval
Zambia 	Zambia Information and Communications Technology Authority (ZICTA) Certificate of Type Approval ZMB/ZICTA/TA/2017/4/18 per ICT Act No. 15 of 2009
Zimbabwe	Postal & Telecommunications Regulatory Authority of Zimbabwe (POTRAZ) Certificate of Type Approval No POZ521

SAR / RF Exposure Regulations:

USA	FCC 47 CFR Part 2 Subpart J - Equipment Authorization Procedures, Section 2.1093, Radiofrequency Radiation Exposure Evaluation: Portable Devices. FCC OET-65C: Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields
Canada	Industry Canada RSS 102 Radio Standards Specification 102, Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)
European Union (EU)	EN 50360: Product standard to demonstrate the compliance of mobile phones with the basic restrictions related to human exposure to electromagnetic fields (Frequency range of 300 MHz - 3 GHz) EN 62209-1: Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from handheld and body-mounted wireless communication devices - Part 1: Devices used next to the ear (Frequency range of 300 MHz to 6 GHz) EN 62209-2: Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (Frequency range of 30 MHz to 6 GHz)

Environmental Regulations:

European Union (EU)	RoHS Directive 2011/65/EU
European Union (EU)	WEEE Directive 2012/19/EU
European Union (EU)	REACH Regulation 1907/2006/EC
European Union (EU)	Packaging and Packaging Waste Directive 94/62/EC

Federal Communications Commission (FCC) Statement

(United States only)

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the Federal Communications Commission (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the user manual, can cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case you will be required to correct the interference, at your own expense.

Changes or modifications not expressly approved by the manufacturer could void your authority to operate the equipment.

Canadian Department of Communications Industry Canada Notice

(Canada only)

This Class A digital apparatus complies with Canadian ICES-001.

FCC Part 15 / Industry Canada Information:
This device complies with Part 15 Subpart C and Subpart E of FCC Rules and Industry Canada licenceexempt
RSS-210 standard(s). Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference, including interference that may cause undesired operation of this device.

This product contains transmitter module:
FCC ID: 2AAEX-SDABGN
IC: 7228C-SDABGN

SAR / RF Exposure Notice:
This equipment complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement C to OET-65 and RSS-102 of the IC (Industry Canada) radio frequency (RF) Exposure rules.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other

users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This radio transmitter (identify the device by certification number, or model number if Category II) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

For product available in the USA/Canada market, only channels 1-11 can be operated. Selection of other channels is not possible.

If this device is to be operated in the 5.15-5.25 GHz frequency range, it is restricted to indoor environments only.

Antenna: Laird Technologies, Mini-NanoBlade

Antenna gain information: Embedded Antenna: 2.5dBi (2.4 GHz), 4.8dBi (5 GHz)

Frequency Tolerance: +/-20ppm

Wireless Labeling

The i-STAT Alinity v Analyzer includes the FCC mark and FCC module identifier.

Table for Wireless Specification for the i-STAT Alinity v Analyzer

Wireless Characteristic	i-STAT Alinity v Analyzer	
Network Standard	IEEE 802.11a, IEEE 802.11b, IEEE 802.11g, IEEE 802.11n (1-stream)	
Maximum RF Power	200mW	
Typical Maximum SAR	765 mW/kg at 0cm	
Wireless QoS Requirements	None. Best-effort delivery service is sufficient.	
Radio Band Center Frequencies	802.11 b/g/n 802.11 a/n	2.412 – 2.472 GHz 5.180 – 5.825 GHz
Modulation Types	OFDM DSSS DSSS-OFDM	(64QAM, 16QAM, QPSK, BPSK) (CCK, DQPSK, DBPSK) (64QAM, 16QAM, QPSK, BPSK)

Table 1: Analyzer/Power related

Symbol	Definition/Use
	Keep away from sunlight.
	Model number. The model number will appear adjacent to this symbol.
	Printer
	Humidity limitation
	On/Off
	Direct current power supply
	Alternating current power supply

Table 2: Regulatory and Safety Related; Miscellaneous

Symbol	Definition/Use
	Biological risks
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Serial number. The serial number will appear adjacent to this symbol.
	Catalog number, list number, or reference
	USB
	Do not reuse.

Symbol	Definition/Use
	Date of manufacture
	Manufacturer
	Consult instructions for use or see System Manual for instructions.
	Note the following information.
	Denotes conformity to specified European directives.
	ETL product safety listing mark for U.S. and Canada
	Electrical hazard
	**ATTENTION:** See instructions for use.
	**CAUTION:** Indicates a hazardous situation, which if not avoided, could result in minor or moderate injury or damage to the equipment.
	**WARNING:** Indicates a hazardous situation, which if not avoided, could result in serious injury or death.
	Separate waste collection for this electrical/electronic item indicated; Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).

1. **i-STAT Alinity v Analyzer:** Used to perform cartridge testing, reviewing test results, and conducting quality control (QC) testing.
2. **i-STAT Alinity Rechargeable Battery:** Provides main power source to the analyzer.
3. **i-STAT Alinity Base Station:** Used to recharge the battery installed in the i-STAT Alinity v Analyzer.
4. **i-STAT Alinity Test Cartridges:** Contains sensors and reagents for all patient and quality testing.
5. **i-STAT Alinity Portable Printer:** Used to print records stored in the analyzer.
6. **i-STAT Alinity Electronic Simulator:** Provides an independent check on the analyzer's thermal controls and success of software updates.

Intended Use
The i-STAT Alinity v Analyzer is an analytical, point of care device designed for veterinary use only.

The i-STAT Alinity v Analyzer with i-STAT test cartridges is intended for use in point of care or clinical laboratory settings. The i-STAT Alinity system is intended for the quantitative measurement of various analytes in arterial, venous and capillary whole blood.

Principles of Operation
The design enables it to be taken to a convenient location near the point of care. The analyzer requires i-STAT single-use cartridges containing sensors to perform quantitative diagnostic testing on whole blood. After the insertion of a filled test cartridge, the analyzer carefully monitors and controls the testing process. The only user intervention is in the form of data entry. Data entry is performed via the touchscreen or by barcode capture. Throughout the cycle, the analyzer performs a series of quality checks. These checks are designed to monitor the status of the analyzer and the quality of the cartridge. The analyzer and cartridge together allow the user to perform clinical testing and administrative tasks related to the quantification of various analytes in a whole blood sample.

The i-STAT Alinity v Analyzer includes the following subsystems:

- analytical measurement module: interfaces with the i-STAT single-use test cartridges and controls execution of the measurement test cycle
- user module: a central computing unit with embedded firmware that controls the user interaction with the device and supports communication with outside peripherals
- user interface: allows data input, display of information, audio and visual alerts
- rechargeable battery

Precautions and Limitations
For best results, observe the following precautions to prevent damage to the i-STAT Alinity v Analyzer and its peripherals, to ensure the safety of the operator and the integrity of the results.

DO:
- Only use Abaxis supplied accessories, power supplies, power cables, and consumables specified for the i-STAT Alinity system (includes analyzer, printer and base station).
    - Always use the Base Station for charging the i-STAT Alinity v Analyzer.
    - Connect only the i-STAT Alinity printer to the Base Station printer port.

- Always place the Analyzer, Base Station, and Printer on a level and stable surface or in a location where they will not cause injury if dropped.
    - Falling equipment may cause injury.

- Be sure to install all cables and power supplies so they do not pose a trip hazard. Mount equipment so cables and accessories stay clear of walkways.

- Allow the analyzer temperature to stabilize to operating temperature and humidity specifications prior to use.

- Check temperature strip for each new shipment of cartridges.
    - Verify that the temperature in transit was maintained by reading the temperature strip included in each shipping container.

- Keep the test cartridge and the analyzer at the temperature of the room where they are to be used.
    - Condensation on a cold cartridge can prevent proper contact with the analyzer.

- If a printout appears inconsistent with a patient's clinical assessment, verify that the correct patient record was selected (patient ID, date and time of test, etc.). If the record is not correct, select the correct record and print. If the printout still does not match the data in the analyzer, the printer needs service and the printed results must not be used. If another printer is available, retry.

- Clinical settings that demand fail-safe testing should have a backup analyzer or test source available.

- Follow site specific guidelines for integration of wireless devices into the facility/facility environment.

- Check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

- Attempt to remove a test cartridge during the testing cycle. The force that would be necessary to do so could damage the analyzer.

- Place metal objects on or near the exposed charging contacts on all peripherals.

- Store batteries in such a manner that they may short circuit each other, or allow metal objects to touch the battery contacts.

- Expose the battery to heat or fire. Avoid storage in direct sunlight.

- Try to connect any non-electrically isolated equipment to the i-STAT Alinity Base Station.

- Connect the i-STAT Alinity Base Station to unauthorized medical devices or other equipment.

- Disturb the analyzer or the printer until printing is complete, since this will interrupt the printout. If printing is interrupted, realign the analyzer and the printer, or replace the analyzer in the Base Station to resume printing.

- Use the analyzer in environmental conditions that exceed the operating temperature and humidity specifications.

- Make any unauthorized repairs or modifications to this product as this may cause personal injury or damage to the unit.

NOTE

- The analyzer and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.

- In the event of a battery leaking, do not allow any leakage to come into contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

- The analyzer can become contaminated with blood during use. Operators should use standard precautions whenever handling the analyzer, cartridge, and peripherals to protect themselves from blood-borne pathogens and pathogens from other body substances. Standard precautions, such as the wearing of gloves, are designed to protect personnel from blood-borne pathogens and pathogens from other body substances.

Preparing for Use
For setup instructions on using the i-STAT Alinity v Analyzer and Rechargeable Battery, Base Station, Printer, and External Simulator, please refer to the Getting Started Guides enclosed with each item. Contact Abaxis Technical Support if additional support is needed.

System Specifications — i-STAT Alinity v Analyzer

Operational range - Temperature and humidity:	16 to 30ºC (61 to 86ºF) for clinical testing 10 to 40ºC (50 to 104ºF) other than clinical testing 10 to 90% non-condensing relative humidity, with maximum saturation temperature of 34ºC (93.2ºF)
Testing Environment:	Indoors, on a dry, clean, horizontal, stable surface. Avoid nearby vibration equipment such as centrifuges. Avoid direct sunlight.
Altitude:	Up to 3,048 meters (10,000 feet)
Storage range - Temperature and humidity:	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 50ºC (122ºF)
Power source:	Lithium Ion Rechargeable Battery, 3.65 (nominal) VDC, 19.3 Wh

i-STAT Alinity Rechargeable Battery*

Electrical rating:	3.65 VDC 19.3 Wh (nominal)
Operational range- Temperature and humidity:	10 to 40ºC (50 to 104ºF) 10 to 90% non-condensing relative humidity, with maximum saturation temperature of 34ºC (93.2ºF)
Storage range- Temperature and humidity:	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 50ºC (122ºF)
Altitude:	Up to 3,048 meters (10,000 feet)

**This Lithium-Ion rechargeable battery is designed for use only with the i-STAT Alinity v Analyzer. Keep a spare, charged battery on hand at all times and store charged battery in the original packaging.*

i-STAT Alinity Base Station*

Communication Interface:	Ethernet 10/100 base t, RS-232, USB 2.0 LED Indicators: Color: Blue Status: Power
Operational range-Temperature and humidity:	10 to 40ºC (50 to 104ºF) 10 to 90% non-condensing, with maximum saturation temperature of 34ºC (93.2F)
Testing Environment:	Indoors, on a dry, clean, horizontal, stable surface. Avoid nearby vibration equipment such as centrifuges. Avoid direct sunlight.
Altitude:	Up to 3,048 meters (10,000 feet)
Storage range-Temperature and humidity:	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 34ºC (93.2F)
External Power Supply Unit:	Input: 110-240 VAC, 50-60 Hz, 1.5A Output: 5.3V DC, 6.6A

**The Base Station is intended for use only with the i-STAT Alinity v Analyzer. Use only the power supply shipped in the box with the Base Station. Attempting to use a different type of manufacturer's adapter could damage the unit and cause fire or explosion hazards.*

i-STAT Alinity Printer*

Power ratings (AC adapter):	Input: 100-240 VAC, 50/60Hz, 1.1 A Output: 12 VDC, 3.0 A
Power ratings (battery pack):	4.8 V
Operational range-Temperature and humidity:	15 to 40ºC (59 to 104ºF) 20 to 90% Non-condensing relative humidity
Storage range-Temperature and humidity:	-20 to 50ºC (-4 to 122ºF) 10 to 90% Non-condensing
Communication link:	Infrared or Serial/RJ12
Paper:	Black print thermal paper 5.7 cm wide (Available from Abaxis)

**Attempting to print from an i-STAT Alinity v Analyzer to any printer other than an i-STAT Alinity printer may be unsuccessful. Use only a rechargeable battery pack purchased from Abaxis designed for the i-STAT Alinity printer.*

i-STAT Alinity Electronic Simulator*

Operational range-Temperature and humidity:	16 to 30ºC (61 to 86ºF) 10 to 90% non-condensing, with maximum saturation temperature of 34ºC (93.2ºF)
Storage range-Temperature and humidity:	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 34ºC (93.2ºF)
Altitude :	Up to 3,048 meters (10,000 feet)

**Electronic Simulator is designed for use only with the i-STAT Alinity v Analyzer.*

LED: Indicates status of the analyzer.

- **Green**: Analyzer is starting up or test results are complete.
- **White**: Cartridge is processing.
- **Red**: Requires immediate attention.
- **Blue**: Battery is charging.

Display Screen

Barcode Capture Button: Press and hold button in order to capture a barcode. Audible cues indicate successful and unsuccessful barcode captures.

Power Button: Press and hold button for 2 seconds to power up or power down the analyzer.

Cartridge Port: Cartridge or Electronic Simulator is inserted into the cartridge port to initiate testing.

Rechargeable battery is the sole power source for the analyzer.

Camera and IR Port: Camera is activated by pressing and holding the barcode capture button. The display screen displays the object within the cameras view. The IR port sends information from the analyzer to the portable printer.

After the power button is pushed and the analyzer starts the power-up sequence, the LED light will turn green, and i-STAT Alinity will appear briefly on the display screen. During the power-up sequence, the i-STAT Alinity v Analyzer performs a series of self checks.

If all the self checks pass, the analyzer will display the Home Screen. See page 20.

If one or more self checks fail, the analyzer will display the Alerts Screen. See page 21.

If all self checks pass at start up, the analyzer will display the Home Screen.

Anatomy of the Home Screen which contains:

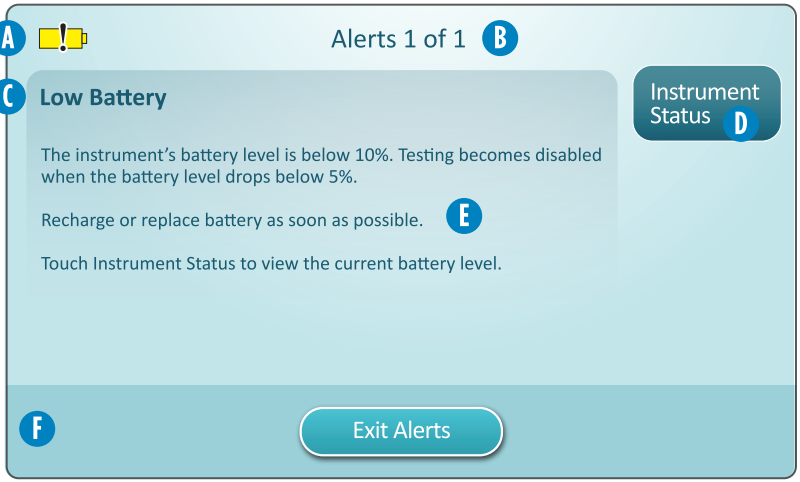
A Header:
- Date/Time
- Wireless/Wired Status*
- Battery Status*

B Body:
- Buttons provide access to pathways
  - Perform Patient Test
  - More Options

C Footer (left):
- Home Button

D Footer (right):
- Software Pending Installation Button
  - Displays only when software has been downloaded but not installed on the analyzer

* See Page 23 for screen icons and their meanings.



If one or more start up self checks fail, the analyzer will display the Alerts Screen as shown in the **example** above.

Anatomy of Alerts Screen:

A Warning or Lockout Icon:
Indicates status of alert.

Analyzer is locked until requirement is satisfied

or Analyzer warning

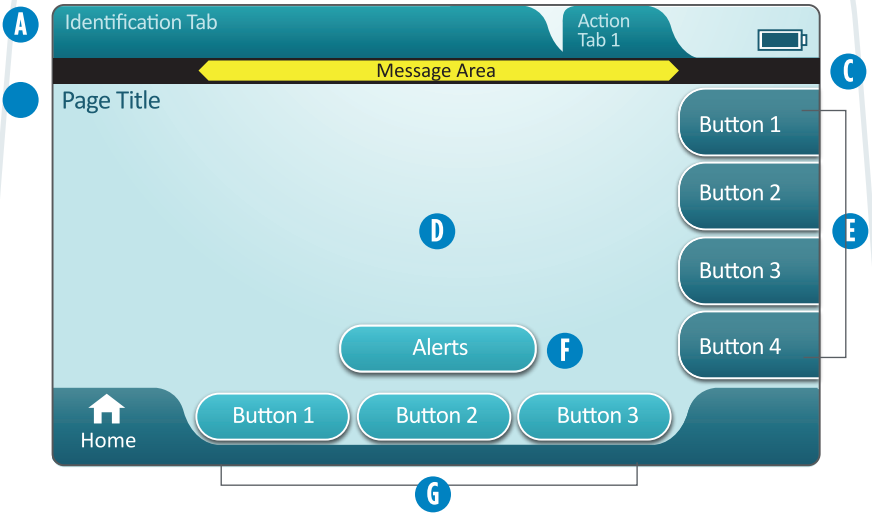
B Alerts Indicator:
Displays number of alerts

C Alert Title

D Corrective Action Button:
Displays corrective action pathway

E Alert Description:
Displays cause and resolution

F Action Buttons:
Displays options for screen navigation



A generic pathway screen is shown in the **example** above.

Anatomy of a Pathway Screen

A Header:
- Identification Tab
  - Displays details such as patient ID, cartridge name, liquid quality control name
- Header Action Tabs
  - Provide options for screen navigation

B Page Title

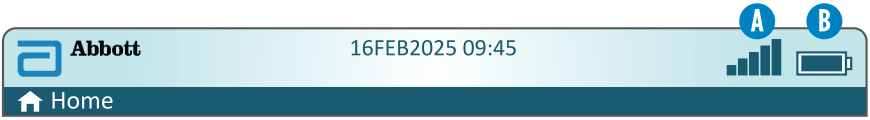
C Message area

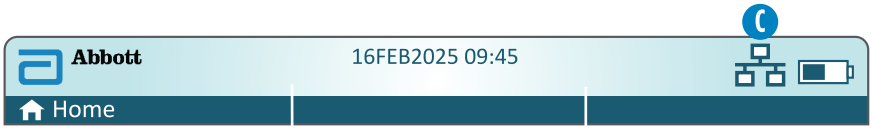
D Body:
- Buttons in this area provide access to pathways, OR
- Location of details such as data entry field, help graphics, selection options

E Side Action Tabs:
- Provide access to area or action indicated

F Alert Button:
- Provides access to Alerts description

G Action Buttons:
- Provide options for screen navigation



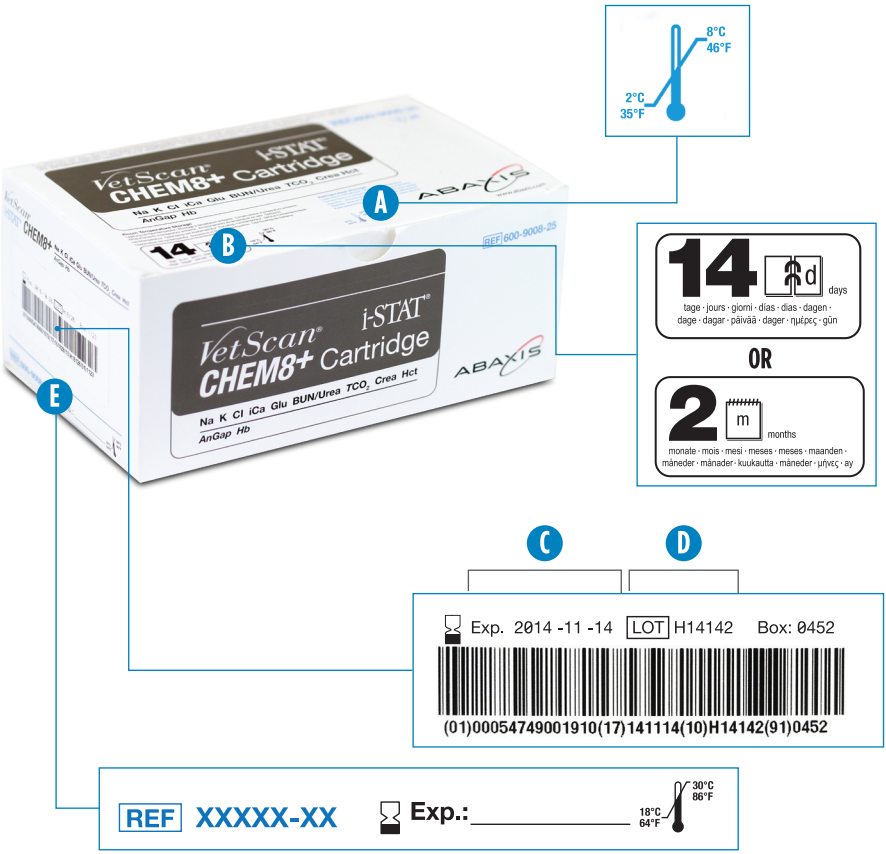


A Wireless Status	
	Best
	Very Good
	Good
	Fair
	Poor
	No Signal
	No Connection
	Wireless Disabled
	Wireless Connecting
	Wireless Not Allowed

B Battery Status	
	Fully Charged
	Approximately 1/2 Charged
	Charge Needed Soon
	Charge Immediately
Battery Charging	
	Bolt Indicates Actively Charging
	Bolt Indicates Actively Charging
	Bolt Indicates Actively Charging

C Network Status	
	Connected
	Disabled
Alert Icons	
	Pass
	Fail
	Warning
	Analyzer Locked
	Information
	Low Battery

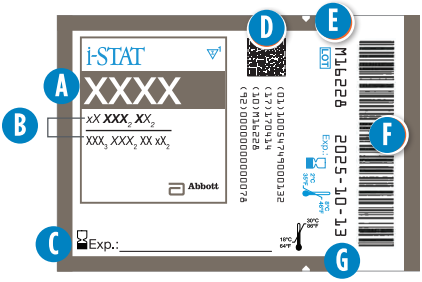
Instructional Icons	
	Mandatory
	Software Pending Installation



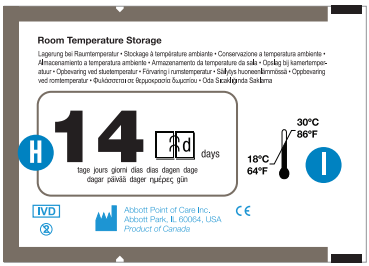
Anatomy of a Box:

- (A) Refrigerated storage temperature indicator: 2-8°C (35-46°F)
- (B) Indicates shelf life when stored at room temperature
- (C) Refrigerated storage expiration date
- (D) Cartridge LOT number
- (E) Location to record room temperature expiration date

Pouch Front



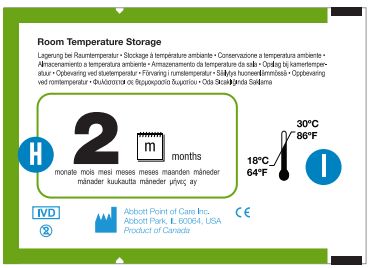
Pouch Back



OR

Pouch Front

Pouch Back



Anatomy of a Pouch:

- (A) Cartridge name
- (B) Analytes – measured and calculated
- (C) Location to record room temperature expiration date
- (D) 2D barcode for manufacturing quality control; not scannable
- (E) Cartridge LOT number
- (F) Cartridge pouch barcode
- (G) Refrigerated storage expiration date
- (H) Indicates shelf life when stored at room temperature
- (I) Room temperature storage range

Cartridge can be stored refrigerated or at room temperature

Cartridges stored in refrigerator:

- Temperature must be 2-8°C (35-46°F)
- Cartridges expire on the date printed on the pouch

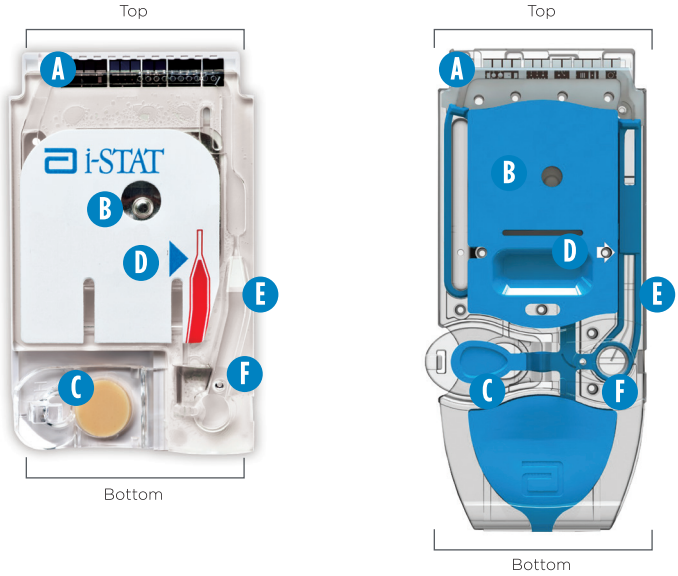
Cartridges stored at room temperature:

- Temperature must be 18-30°C (64-86°F)
- Pouched cartridge must be at room temperature for 5 minutes before use
- Box of cartridges must be at room temperature for 1 hour before use
- Once cartridge is at room temperature the expiration date changes:
    - Cartridge pouch displaying the  indicates the cartridge expires in 14 days

      Example: *cartridge reaches room temperature on 2025-10-13; new expiration date is 2025-10-27*
    - Cartridge pouch displaying the  indicates the cartridge expires in 2 months

      Example: *cartridge reaches room temperature on 2025-10-13; new expiration date is 2025-12-13*
    - Room temperature expiration date cannot exceed manufacurer's printed expiration date
- Cartridge should not be returned to the refrigerator once out for more than 5 minutes

Cartridge Front



Anatomy of a Cartridge

- **A Sensors (Do Not Touch)**
- **B Calibrant Pack (Do Not Touch)**
- **C Closure**
- **D Fill to Mark**
- **E Sample Chamber**
- **F Sample Well**

- Always handle cartridges by the sides or the bottom. Do not touch the sensor area at the top of the cartridge or the calibrant pack area in the middle of the cartridge. Improper handling may damage the cartridge and result in a Cartridge Quality Check Failure instead of results.
- Dispose of used cartridges as biohazardous waste. Follow facility policy for disposal.

*For Cartridge & Test Information sheets, please visit: **www.pointofcare.abbott***

Acceptable Sample Types:

Crea	CG8+	CG4+	Chem8+	*E3+	EC8+	G	6+

Follow manufacturer's recommendation for filling the following:

- **Venous whole blood**
  - Collect in a lithium heparin tube
  - Collect in a syringe containing balanced heparin
- **Arterial whole blood**
  - Collect in an arterial blood gas syringe containing balanced heparin
- **Capillary whole blood**
  - Collect in a balanced heparin capillary tube
    - Recommend 150 µl capillary tube

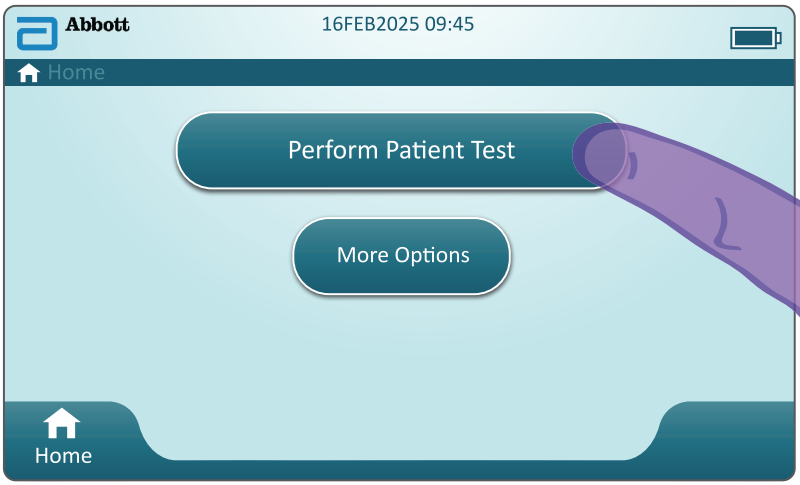
Sample Handling

Crea	CG8+	CG4+	Chem8+	*E3+	EC8+	G	6+

- **Venous and arterial samples**
  - Always mix sample **immediately** before removing for testing
  - Graphics on the analyzer instruct on proper mixing technique
- **Capillary samples**
  - Fill cartridge **immediately** after sample collection

**The VetScan E3+ cartridge containing test for Chloride (Cl) which runs on the VetScan i-STAT 1 is not currently supported and will not run on the i-STAT Alinity v Analyzer.*

Not all cartridges are available in all regions. Contact Abaxis Technical Support for availability in specific markets.



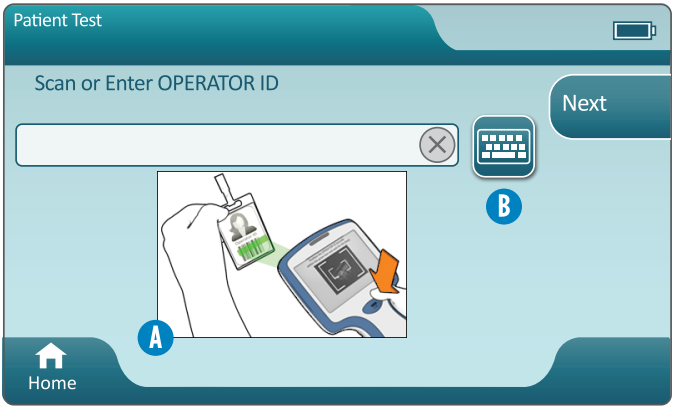
From the Home screen, touch **Perform Patient Test**. This initiates the patient testing pathway.

- When the analyzer is customized by the System Administrator, the pathways may present screens not displayed in this guide.
    - It is essential to follow the prompts on the analyzer screen.
    - On screen graphics and text are provided to assist the user.
- This guide does not include instruction on blood collection. Follow facility-specific guidelines.

Standard precautions should be used when handling materials that may contain transmissible infectious agents.

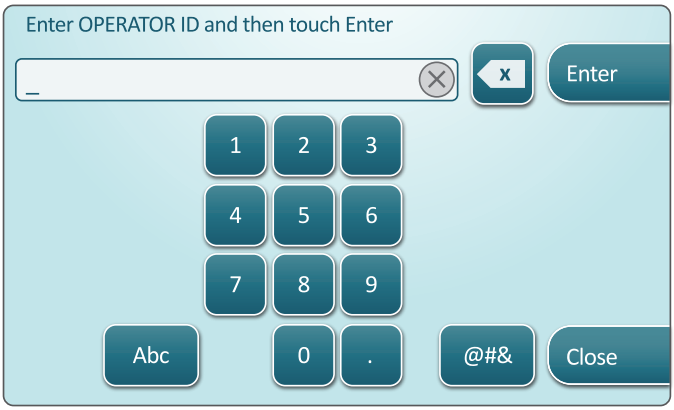
Patient Testing Pathway

The next step in the pathway is **Scan or Enter OPERATOR ID**



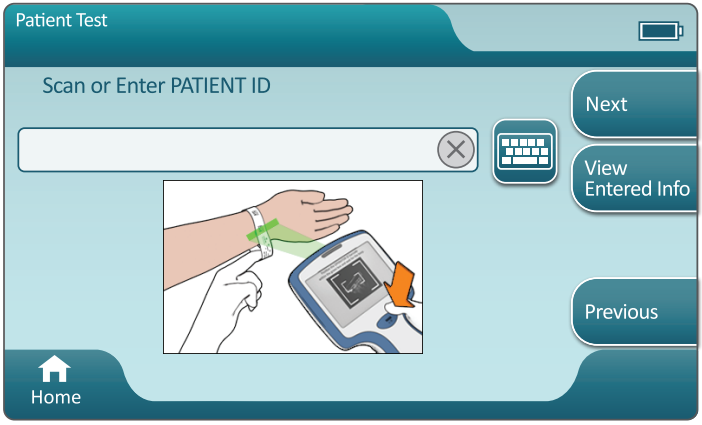
A On-screen graphic assists with scanning. After scanning is complete, the analyzer will advance to the next step in the pathway.

B To enter information manually, touch icon. A numeric keyboard displays automatically. For alpha, touch the **Abc** button. After entering the information, touch Enter and the analyzer will advance to the next step in the pathway.



Patient Testing Pathway (Cont.)

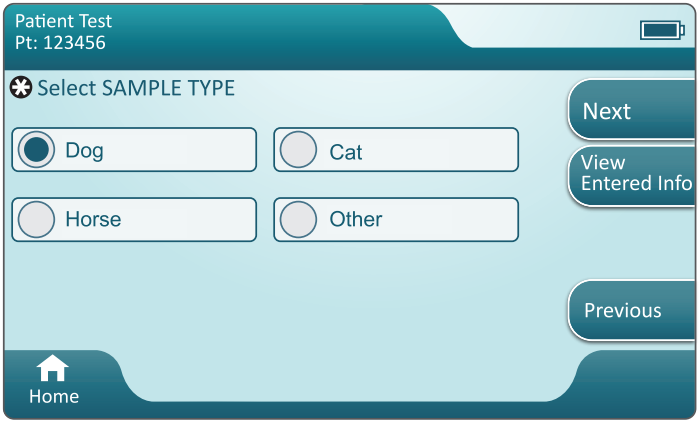
The next step in the pathway is **Scan or Enter PATIENT ID**



After patient ID is entered, the analyzer advances to **Select SAMPLE TYPE**.

Choose the **SAMPLE TYPE**, then touch **Next**.

When the text is preceded by a ✱, the information is mandatory.

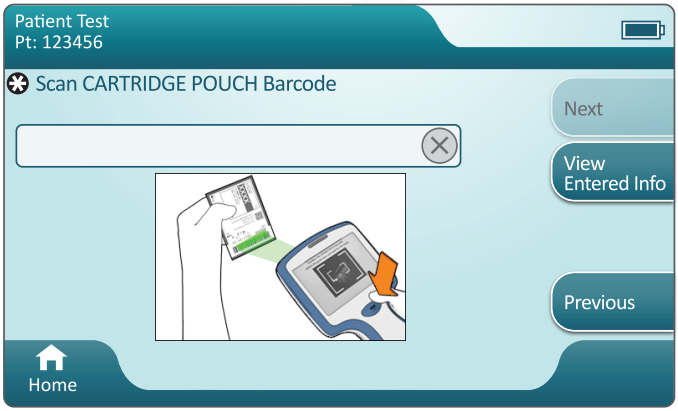


Important Warning: *Interpreting the patient result is dependent on selecting the correct sample type.*

Patient Testing Pathway (Cont.)

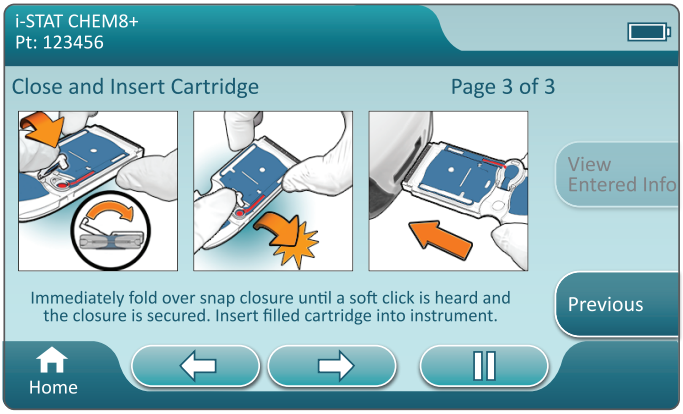
Scan cartridge pouch barcode

Scanning is required. You must scan the barcode on the cartridge pouch. This information cannot be entered manually.



*If an **Invalid Cartridge Type** window is displayed, contact Abaxis Technical Support for additional assistance.*

After the analyzer successfully scans the barcode, help screens will be displayed on how to insert the cartridge.

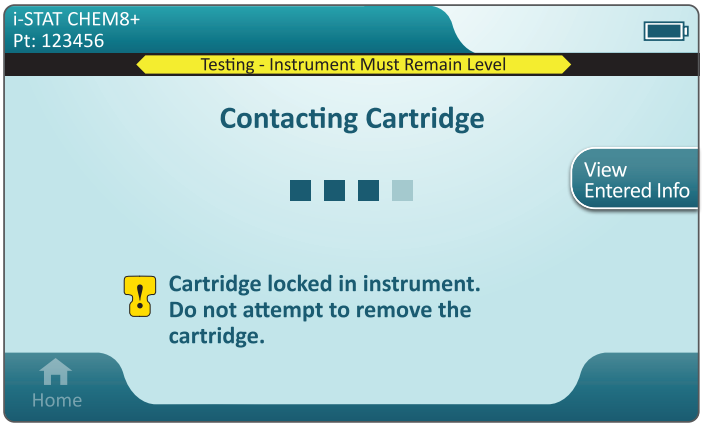


The help graphics on this screen vary based on the sample type previously selected. The action buttons at the bottom of the screen allow forward, backward and pause functionality.

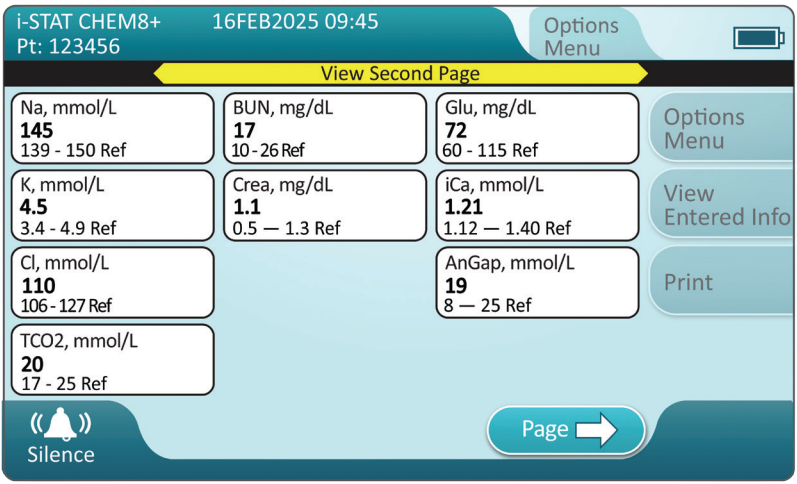
For experienced users, the help screens may be bypassed by inserting a filled cartridge.

Patient Testing Pathway (Cont.)

Once the cartridge is inserted, **Contacting Cartridge** will display followed by the countdown bar. This allows the user to estimate the time to results. Alerts such as **Cartridge Locked and Analyzer Must Remain Level** are also displayed.



Patient Testing Pathway (Cont.)



When the test is complete, the test results are displayed as in the **example** above.

Results

- An audible cue will be heard when results are ready. Touch **Silence** or remove cartridge to silence the audio.
- The blinking page button at the bottom of the screen appears when there is more than one page of results. All action tabs are inactive until the second page of results has been viewed.
- Occasionally numeric results will be replaced with the following symbols. When displayed, a new test must be performed.

  <> – Analyzer cannot calculate the result.

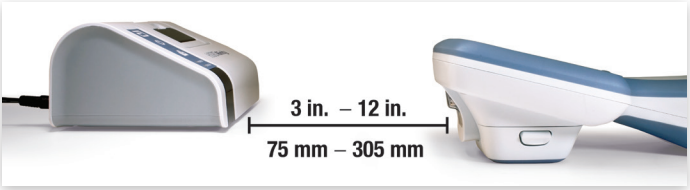
  *** – Analyzer is unable to determine a result.

A sample may also yield results that are preceded by a greater than (>) or less than (<) symbol. These results are outside the analyzer's measurement range. In order to determine the exact numeric result, the sample must be analyzed by a different method.

Printing

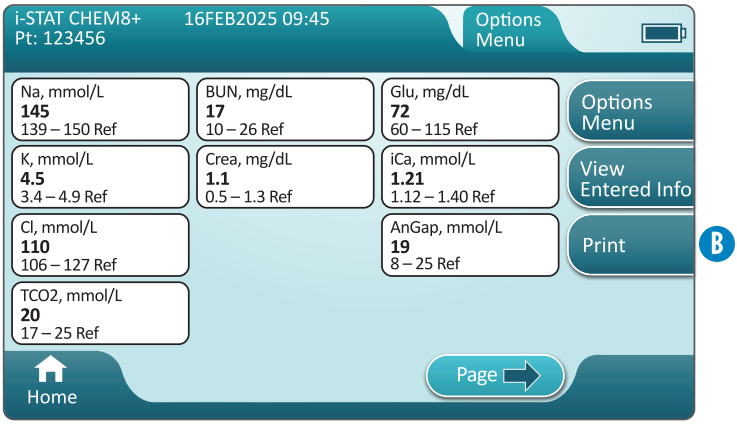
A Determine printing method:

Wireless



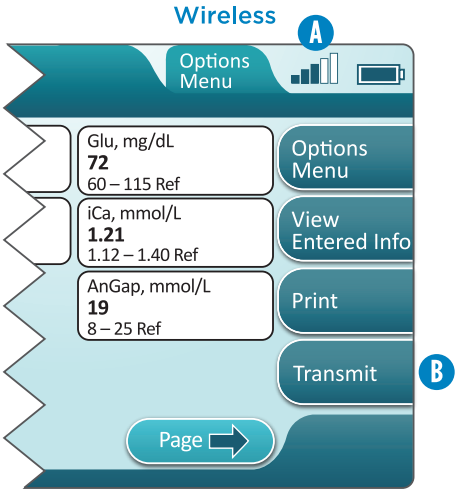
Wired to Base Station

B With analyzer and printer powered up, and the results on the screen, touch Print



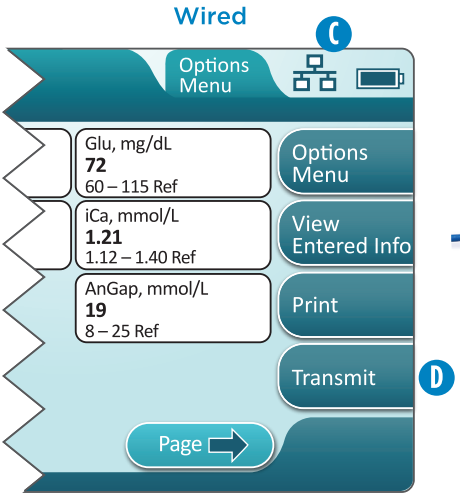
Transmitting

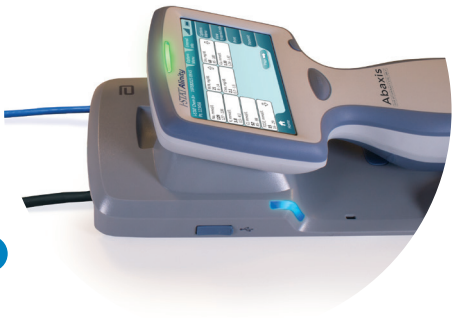
Determine transmission method:



Ⓐ A signal strength of 3 bars or higher is recommended

Ⓑ To initiate transmission, touch Transmit

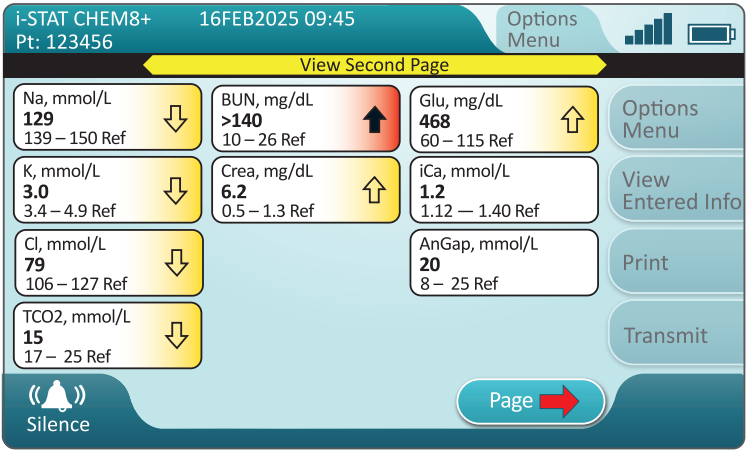




Ⓒ Symbol indicates analyzer is connected to the network

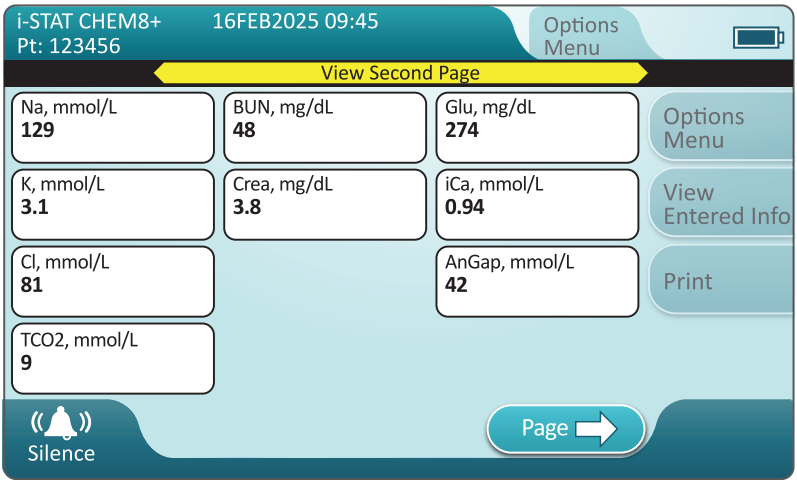
Ⓓ To initiate transmission, touch Transmit

Best Practice Example



Results

- An audible cue will be heard when results are ready.
  Touch **Silence** or remove cartridge to silence the audio.
- Results outside of the reference range will be highlighted:
  - **Yellow** in the result area indicates that the result is outside of the reference range, known as an abnormal result. The arrow indicates if the result is high (⇧) or low (⇩).
  - **Red** in the result area indicates that the result is not within the system range. The arrows indicate if the result is high (⬆) or low (⬇).
  - **Yellow arrow** in page button - indicates one or more results on second page are outside the reference range.
  - **Red arrow** in page button - indicates one or more results on second page are not within the system range.
  - **White arrow** in page button - indicates all results on second page are within the reference range.



* When running a sample selected under "Other", reference ranges will not be displayed. Result will appear with no highlighted indicators.

Resetting the analyzer to Factory Default or deleting the current profile will display results without reference ranges or highlighted indicators.

Test Reference Ranges and System Range

		Units	System Range	Reference Range		
				Canine	Feline	Equine
Hematology	Hematocrit (HCT)	% PCV	15 – 75	35 - 50	24 - 40	30 - 45
	Hemoglobin (HGB)	g/dL	5.1 – 25.5	12.0 - 17.0	8.0 - 13.0	10.0 - 15.0
Chemistry	Blood Urea Nitrogen (BUN)	mg/dL	3 – 140	10 - 26	15 - 34	11 - 27
	Creatinine	mg/dL	0.2 – 20.0	0.5 - 1.3	1.0 - 2.2	0.4 - 2.2
	Ionized Calcium (iCa)	mmol/L	0.25 – 2.50	1.12 - 1.40	1.20 - 1.32	1.25 - 1.75
	Glucose (Glu)	mg/dL	20 – 700	60 - 115	60 - 130	62 - 134
Electrolytes	Chloride (Cl)	mmol/L	65 – 140	106 - 127	112 - 129	100 - 111
	Sodium (Na)	mmol/L	100 – 180	139 - 150	147 - 162	128 - 142
	Potassium (K)	mmol/L	2.0 – 9.0	3.4 - 4.9	2.9 - 4.2	1.9 - 4.1
Acid Base	pH		6.5 – 8.2	7.35 - 7.45	7.25 - 7.40	7.35 - 7.45
	PCO_2	mmHg	5 – 130	35.0 - 38.0	33.0 - 51.0	36.0 - 46.0
	HCO_3	mmol/L	1.0 – 85.0	15.0 - 23.0	13.0 - 25.0	25.0 - 30.0
	TCO_2	mmol/L	5 – 50	17 - 25	16 - 25	24 - 32
	Anion Gap	mmol/L	(-10) – (+99)	8 - 25	10 - 27	5 - 15
	Base Excess	mmol/L	(-30) – (+30)	(-5) - 0	(-5) - (+2)	(-5) - (+5)
Blood Gas	PO_2	mmHg	5 – 800	85 - 100	90 - 110	90 - 110
	sO_2	%	0 -100	>90	>90	>90
Specialty	Lactate	mmol/L	0.30 – 20.00	0.6 - 2.9	0.5 - 2.7	0.3 - 1.5

Highlighted cells reflect ranges for arterial samples. No venous reference ranges are yet available.

These normal intervals are provided only as a guideline. The most definitive reference intervals are those established for your patient population. Test results should be interpreted in conjunction with the patient's clinical signs.

Cleaning

i-STAT Alinity v Analyzer, Base Station, Printer, Rechargeable Battery and Electronic Simulator

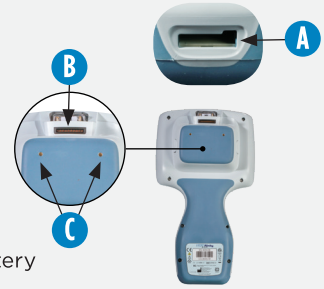
It is recommended that the i-STAT Alinity v Analyzer, base station, printer, and electronic simulator be cleaned periodically or whenever visibly soiled. Standard precautions should be taken whenever working with blood or blood products.

1. When cleaning the i-STAT Alinity v Analyzer with a lint-free tissue or cloth, power off the analyzer and place it on a level surface. Do not clean or disinfect the analyzer while it is in the Base Station. The Base Station does not need to be unplugged when it is being cleaned.
2. Remove a new disposable wipe from the container and squeeze to remove excess solution.
3. Gently wipe all outside surfaces (noting the "Sensitive Areas") until all visible soil is removed.
4. Inspect all surfaces. If necessary, repeat until all visible soil is removed.
5. Wipe with dry gauze until dry.

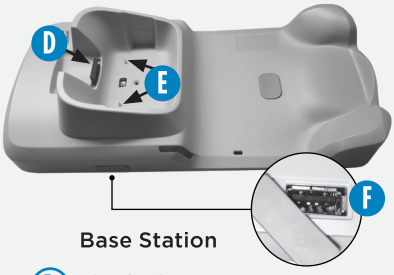
Sensitive Areas

Avoid forcing liquid into these areas:

i-STAT Alinity v Analyzer



- A Cartridge Port
- B 10-Pin Connector under the camera
- C Gold contacts (2) on the outside of the battery

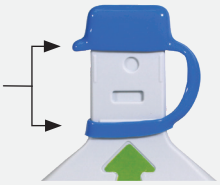


Base Station

- D 10-Pin Connector
- E Gold contact pins (2)
- F USB Port

G Electronic Simulator

Area between protective cap retaining ring and white sensor area



Disinfecting

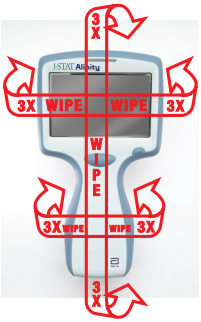
i-STAT Alinity v Analyzer

The disinfection process must begin **IMMEDIATELY** after the cleaning procedure is complete. Standard precautions should be taken whenever working with blood or blood products.

1

Remove a wipe from the container and squeeze out any excess fluid before you begin to wipe the surface.

2



Wipe all surfaces three times. This includes front, back, sides, top and bottom.

3

Allow all surfaces to remain wet for **3 minutes**.

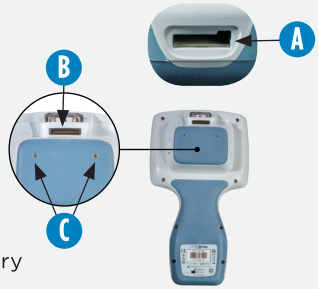
4

Wipe with gauze until dry.

Sensitive Areas

Avoid forcing liquid into these areas:

i-STAT Alinity v Analyzer



- **A** Cartridge Port
- **B** 10-Pin Connector under the camera
- **C** Gold contacts (2) on the outside of the battery

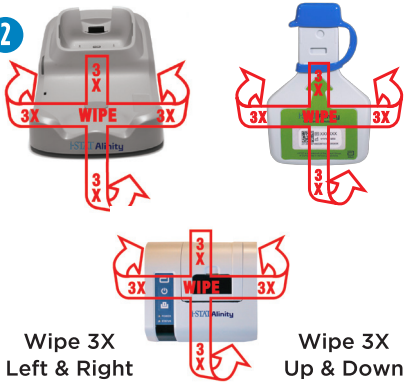
Disinfecting (Cont.)

Base Station, Electronic Simulator and Printer

1

Remove a wipe from the container and squeeze out any excess fluid before you begin to wipe the surface.

2



Wipe 3X Left & Right **Wipe 3X Up & Down**

Wipe the front as shown, flip products on back side and repeat.

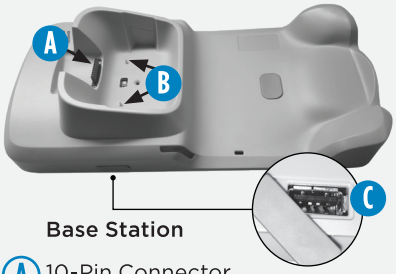
3

Allow all surfaces to remain wet for 3 minutes.

4

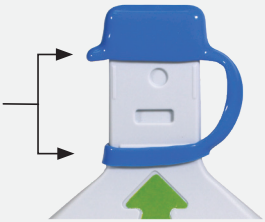
Wipe with gauze until dry.

Sensitive Areas *Avoid forcing liquid into these areas:*



Base Station

- (A) 10-Pin Connector
- (B) Gold contact pins (2)
- (C) USB Port



(D) Electronic Simulator

Area between protective cap retaining ring and white sensor area

Precautions

- Analyzers used with multiple patients may require more frequent cleaning and disinfecting. Cleaning is necessary for the removal of visible organic soil. Disinfecting is intended to kill microorganisms.

- Due to the portability of the i-STAT Alinity v Analyzer, it may be subject to splatter or splash of bodily fluids when used in proximity of patients. Failure to wear clean gloves will result in contamination of the analyzer.

APPROVED DISINFECTANT PRODUCTS

CaviWipes
EPA #46781-13

Super Sani-Cloth
EPA #9480-4

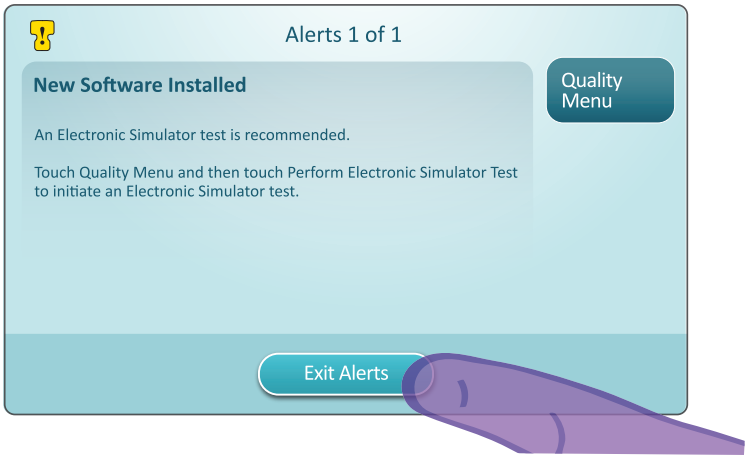
Analyzers (New, Repaired and Replacement) will be delivered with CLEW software and application software installed. Upon receipt of analyzer, check the expiration date of the CLEW software and the version of the application software by navigating to **More Options > Instrument Status**.

Software updates to the i-STAT Alinity v Analyzer are delivered twice a year. Each software update contains two elements in a single package: CLEW software and application software.

These updates may be downloaded and installed either by a network connection to the Abbott Managed Cloud or from the Abaxis Website via a USB memory device.

• Software update and installation using USB memory device via Base Station is a two-step process. It requires downloading the software from the Abaxis website onto a USB memory device, and then downloading and installing the software onto the analyzer via the Base Station.

• Software update and installation via Abbott Managed Cloud with a wired or wireless network connection requires the operator to check for software update using the analyzer, and then initiate the software download onto the analyzer. Once the analyzer has received the software, an install confirmation will be displayed. The operator can choose to install the software at a later time. If the operator cancels the install confirmation, the analyzer will display an icon on the home screen indicating the software is available for installation. The software icon will display until installation is complete.

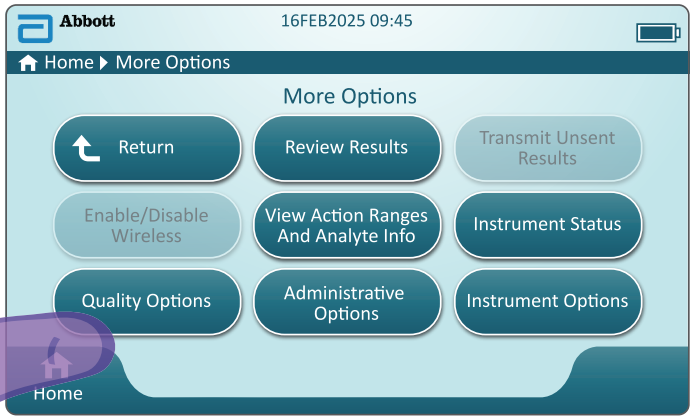


• It is recommended that Electronic Simulator Test be completed immediately following a software update. This is not required, select **Exit Alerts** to resume normal operation of the analyzer.

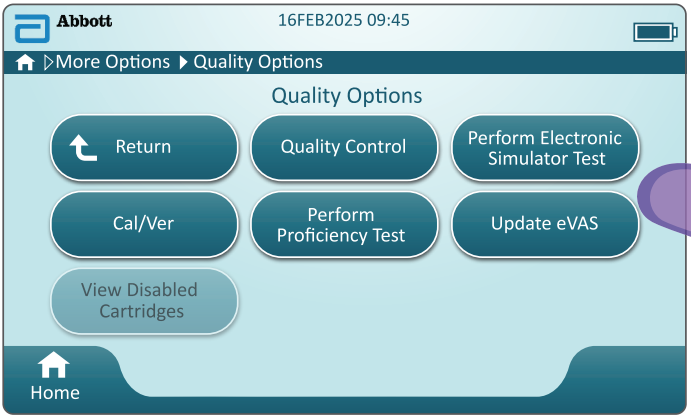
Please contact Abaxis Technical Support if assistance is needed.

How to Perform Quality Testing – Electronic Simulator

Starting from the **Home Screen** touch **More Options** then **Quality Options**.



Next, touch the **Perform Electronic Simulator Test** button.

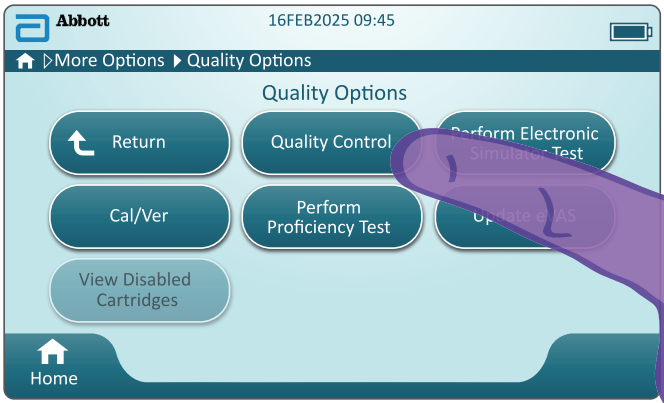


By carefully observing the text and graphic instruction, the user will be able to successfully complete an Electronic Simulator test. In the event that the test does not pass, follow the prompts on the screen.

Use care when handling the Electronic Simulator. Avoid touching the sensor area.

How to Perform Quality Testing – Liquid Quality Control

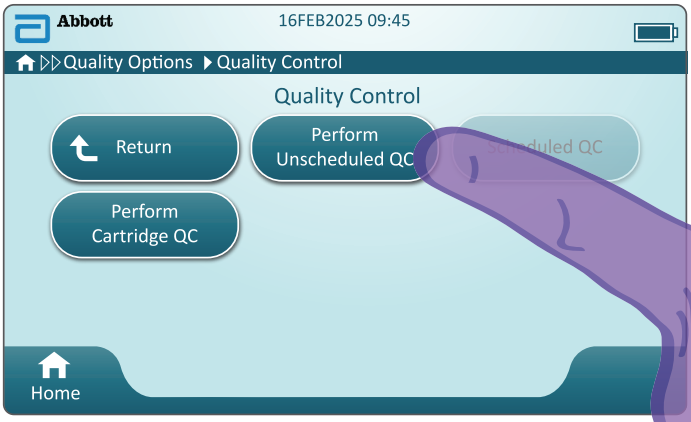
Starting from the **Home Screen** touch **More Options** then **Quality Options** then **Quality Control**.



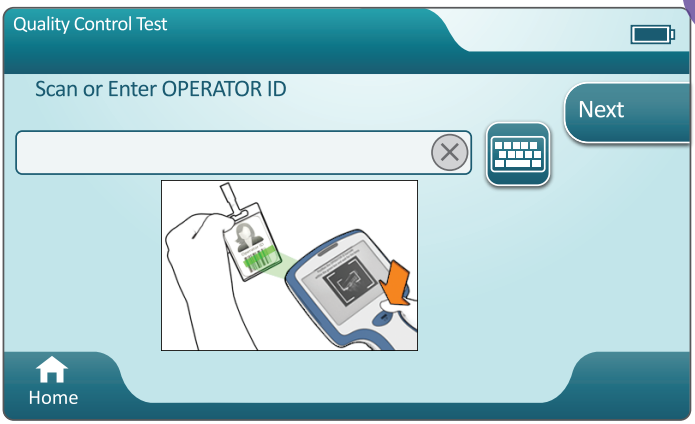
- When using either i-STAT Control or i-STAT Tri-Control materials, refer to the package inserts for handling instructions.
- When the analyzer is customized by the System Administrator, the Quality Control Pathway may present screens not displayed in this guide.
    - It is essential to follow the prompts on the analyzer screen.
    - On screen graphics and text are provided to assist the user.

How to Perform Quality Testing – Liquid Quality Control (Cont.)

The next step in the pathway is **Perform Unscheduled QC**



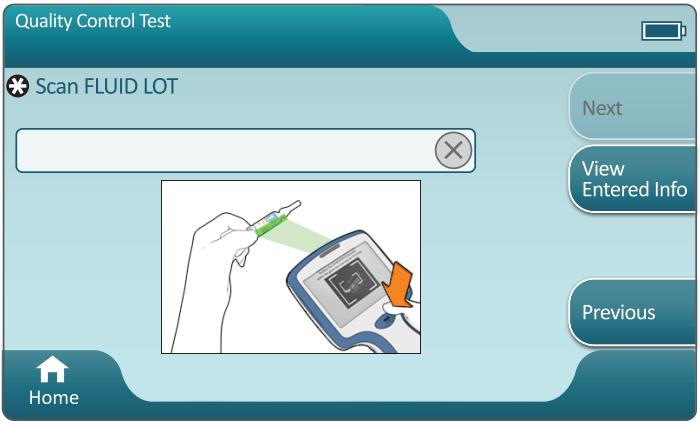
The next step in the pathway is **Scan or Enter OPERATOR ID**



How to Perform Quality Testing – Liquid Quality Control (Cont.)

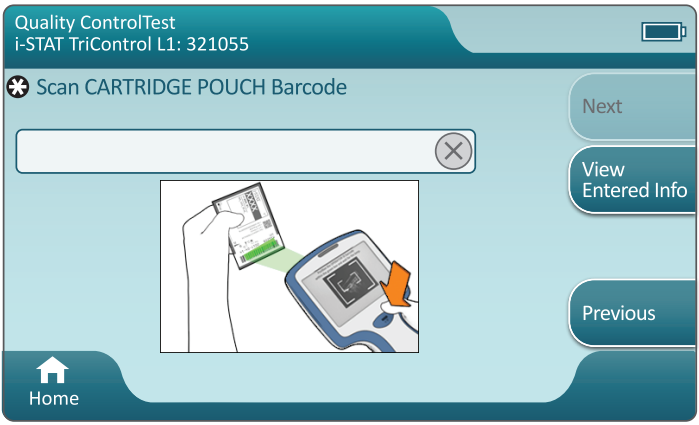
Scan FLUID LOT barcode on control vial. Manual entry is not an option. Scanning is required.

When the text is preceded by a , the information is mandatory.



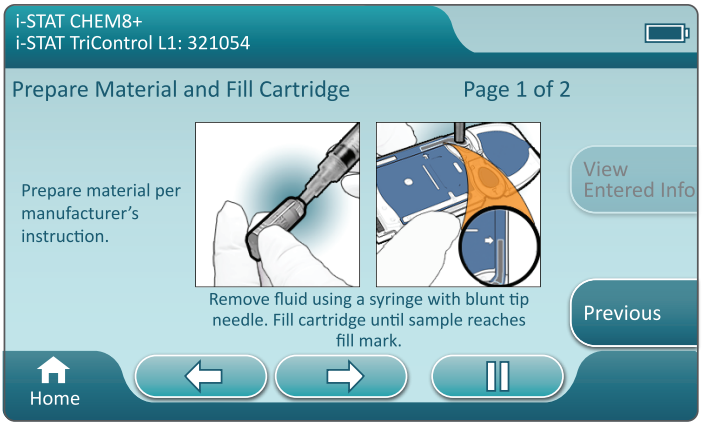
When using i-STAT material, the barcode on the ampule contains the control level being tested. Barcode on the ampule must be scanned before the ampule is opened.

Scan CARTRIDGE POUCH barcode. Scanning is required. You must scan the barcode on the cartridge pouch. This information cannot be entered manually.



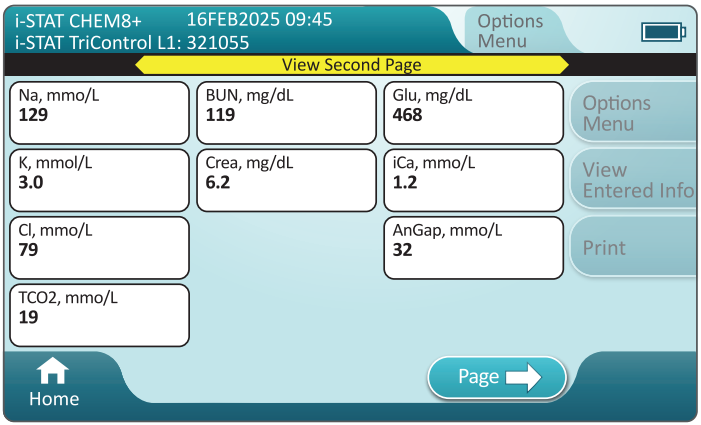
How to Perform Quality Testing – Liquid Quality Control (Cont.)

After the analyzer successfully scans the barcode, help screens will be displayed.



For experienced users, the help screens may be bypassed by inserting a filled cartridge.

Once the cartridge is inserted, **Contacting Cartridge** will display followed by the countdown bar. This allows the user to estimate the time to results. Alerts such as **Cartridge Locked and Analyzer Must Remain Level** are also displayed.



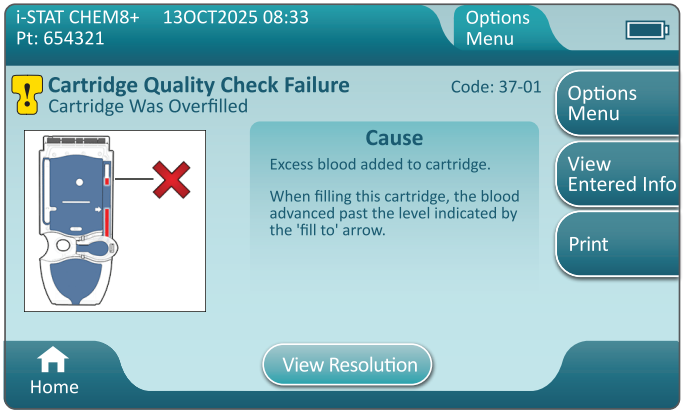
Results

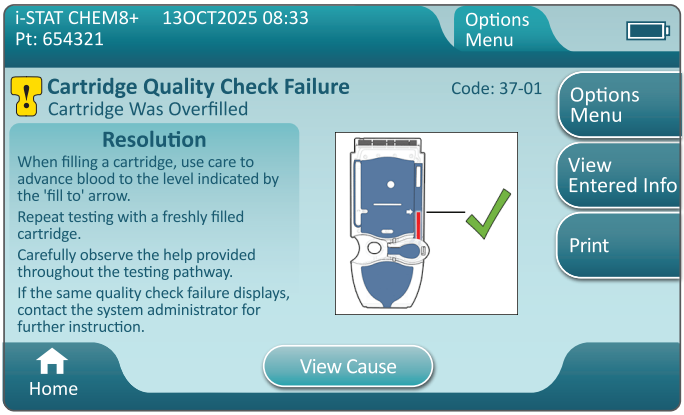
Use Value Assignment Sheet to determine if results are in range. Follow facility policy if results are outside the assigned range.

The i-STAT Alinity v Analyzer is programmed to perform quality checks throughout the testing cycle.

The analyzer has several methods of notifying operators of failed quality checks.

1. **Quality Check Failures**
   - Are displayed when the analyzer identifies a problem while running a cartridge or simulator
   - There are 4 types of quality check failures:
     1. **Analyzer**
     2. **Cartridge**
     3. **Sample**
     4. **Software**
   - Screen displays the type of failure and instructions for resolution





2. **Startup Alerts**
   - Displayed before the Home Screen appears
   - Screen displays instructions for resolution
3. **Alerts**
   - Alert button provides access to Alerts description
   - Indicates a change in analyzer status during testing

Quality Check Failure Codes

For analyzer issues, follow the instructions on the display. If the analyzer has been powered down, the Quality Check Failure (QCF) code will be stored in Review Results. To retrieve it: Power on the analyzer and touch **More Options > Review Results > Quality Results > Quality Check Code Results.**

Use the following tables to find the **Quality Check Failure** code and determine the cause and resolution.

1. In the table below, in the first column, find the **QCF code** as found in **Review Results.**
2. Identify the pathway in which the failure occurred, and
   - in the **Cause** column find the cause number, then see *Quality Check Failure Causes* for the description
   - in the **Resolution** column find the resolution letter, then see *Quality Check Failure Resolutions* for corrective action.

Table of Quality Check Failure Codes

An empty cell indicates that there is no applicable information for that pathway and code.

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
2-01-1.1.1	1	A	1	A			2-01
2-02-1.1.2	1	A	1	A			2-02
8-01-2.1.8		I		I		P	8-01
11-01-2.13.32		B		B		D	11-01
13-01-1.6.1		S		S		S	13-01
19-01-6.2.5	2	E	2	F			19-01
20-01-3.1.1		G		F			20-01
21-01-3.1.3	3	G	3	F			21-01
22-01-6.1.3	4	G	4	F			22-01
22-01-6.1.5	4	G	4	F			22-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
22-01-6.1.8	4	G	4	F			22-01
22-01-6.1.9	4	G	4	F			22-01
22-01-6.1.10	4	G	4	F			22-01
22-01-6.1.11	4	G	4	F			22-01
22-01-6.1.12	4	G	4	F			22-01
22-01-6.1.15	4	G	4	F			22-01
23-01-3.3.2		G		F			23-01
24-01-3.1.5		G		F			24-01
25-01-6.1.13	5	G	5	F			25-01
25-01-6.1.14	5	G	5	F			25-01
26-01-6.2.1		G		F			26-01
26-01-6.2.2		G		F			26-01
26-01-6.2.3		G		F			26-01
26-01-6.2.4		G		F			26-01
27-01-4.1.1		G		F			27-01
28-01-4.1.2		G		F			28-01
29-01-4.1.3		G		F			29-01
30-01-6.1.4	6	H	12	F			30-01
30-01-6.1.7	6	H	12	F			30-01
30-02-4.1.4	6	H	12	F			30-02
31-01-4.1.5	7	G	7	F			31-01
31-02-6.1.16	7	G	7	F			31-02
32-01-4.1.6		G		F			32-01
33-01-4.1.8		G		F			33-01
34-01-4.1.11	7	G	7	F			34-01
35-01-4.1.7	8	H	13	F			35-01
36-01-4.1.10	8	H	13	F			36-01
37-01-4.1.9	6	H	12	F			37-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
38-01-4.1.12	9	G	9	F			38-01
39-01-6.1.6	9	G	9	F			39-01
40-01-3.3.3		G		F			40-01
41-01-3.1.2		G		F			41-01
42-01-3.1.6		G		F			42-01
44-01-6.1.1	5	G	5	F			44-01
46-01-6.1.2	5	G	5	F			46-01
47-01-2.1.7		N		N		J	47-01
48-01-2.13.2		B		B		C	48-01
49-01-3.3.1		G		F		C	49-01
50-01-2.1.1		G		F		C	50-01
50-01-2.1.2		G		F		C	50-01
50-01-2.1.3		G		F		C	50-01
50-01-2.1.6		G		F		C	50-01
51-01-2.1.4		G		F		C	51-01
51-01-2.1.9		G		F		C	51-01
52-01-2.1.5		G		F		C	52-01
53-01-2.9.3		T		T		T	53-01
57-01-2.4.1		B		B		D	57-01
59-01-4.5.1		B		B		D	59-01
60-01-1.6.2		B		B		C	60-01
63-01-2.9.1		D		D		D	63-01
63-01-2.9.2		D		D		D	63-01
66-01-2.2.1		B		B		D	66-01
66-01-2.2.2		B		B		D	66-01
66-01-2.2.3		B		B		D	66-01
68-01-2.4.2		B		B		D	68-01
69-01-4.6.1		G		F			69-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
69-01-4.6.2		G		F			69-01
69-01-5.6.1		G		F			69-01
69-01-5.6.2		G		F			69-01
69-01-6.6.1		G		F			69-01
69-01-6.6.2		G		F			69-01
69-02-4.6.3		K		K			69-02
69-02-4.6.4		K		K			69-02
69-02-5.6.3		K		K			69-02
69-02-5.6.4		K		K			69-02
69-02-5.6.5		K		K			69-02
69-02-6.6.3		K		K			69-02
69-02-6.6.4		K		K			69-02
69-03-7.6.1						C	69-03
69-03-7.6.2						C	69-03
69-04-7.6.3						L	69-04
70-01-1.6.3		B		B		D	70-01
72-01-2.1.10		D		D		D	72-01
72-01-2.1.11		D		D		D	72-01
79-01-2.3.1		G		F			79-01
80-01-3.4.1		G		F			80-01
80-01-3.4.2		G		F			80-01
80-01-3.4.3		G		F			80-01
80-01-3.4.4		G		F			80-01
82-01-1.2.1		B		B		D	82-01
82-01-2.10.3		B		B		D	82-01
87-01-3.2.1		G		F			87-01
88-01-1.6.33		B		B		C	88-01
89-01-2.7.32		B		B		C	89-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
90-01-2.4.3		D		D		D	90-01
90-01-2.4.4		D		D		D	90-01
90-01-2.4.5		D		D		D	90-01
90-01-2.4.6		D		D		D	90-01
90-01-2.4.7		D		D		D	90-01
90-01-2.4.8		D		D		D	90-01
90-01-2.4.9		D		D		D	90-01
90-01-2.4.10		D		D		D	90-01
90-01-2.4.11		D		D		D	90-01
90-01-2.4.12		D		D		D	90-01
90-01-2.4.13		D		D		D	90-01
90-02-2.4.14		B		B		C	90-02
90-02-2.4.15		B		B		C	90-02
90-02-2.4.16		B		B		C	90-02
90-02-2.4.17		B		B		C	90-02
90-02-2.4.18		B		B		C	90-02
91-01-2.6.32		B		B		D	91-01
92-01-2.10.1		B		B		D	92-01
92-01-2.10.2		B		B		D	92-01
93-01-2.5.32		B		B		D	93-01
93-01-2.5.33		B		B		D	93-01
94-01-1.6.32		B		B		D	94-01
95-01-1.7.1		R		R			95-01
99-01-2.13.1		G		F		C	99-01
99-02-2.2.4						C	99-02

Quality Check Failure Causes

Causes

1. The internal temperature is not within 16 to 30 °C (61 to 86 °F).
2. No clot was detected during testing.
3. Cartridge was rejected during the testing cycle. Probable causes:
   - Operator pressed too hard on the center of the cartridge
   - Used cartridge inserted
   - Cartridge was frozen and thawed before testing
4. Sample was rejected during the testing cycle. Probable causes:
   - Bubbles in the sample
   - Microclots in the sample
   - Used cartridge inserted
   - Snap closure not secure
5. Sample was rejected during the testing cycle. Probable causes:
   - Bubbles in the sample
   - Too little sample used to fill the cartridge
   - Clots in the sample
6. Excess blood was added to the cartridge. When filling the cartridge, the blood advanced past the level indicated by the 'fill to' arrow.
7. Sample was rejected during the testing cycle. Probable cause:
   - Snap closure not secure.
8. An insufficient amount of blood was used to fill the cartridge. When filling the cartridge, the blood did not reach the level indicated by the 'fill to' arrow.
9. Sample was rejected during the testing cycle. Probable causes:
   - Bubbles in the sample
   - Insufficient amount of sample used to fill the cartridge
10. Sample was rejected during the testing cycle. Probable causes:
    - Microclots in the sample
    - Snap closure not secure
11. Reserved for future use.
12. Excess sample was added to the cartridge. When filling the cartridge, the sample advanced past the level indicated by the 'fill to' arrow.
13. An insufficient amount of sample was used to fill the cartridge. When filling the cartridge, the sample did not reach the level indicated by the 'fill to' arrow.

Quality Check Failure Resolutions

Resolutions

A Navigate to the Home Screen, then touch More Options. Touch Instrument Status and assess the analyzer's temperature. Move the analyzer to an appropriate environment.

B Perform an Electronic Simulator test. If the test results in a PASS, the analyzer is ready for use otherwise contact system administrator for further instruction.

C Repeat Electronic Simulator testing. If the test results in a PASS, the analyzer is ready for use otherwise contact system administrator for further instruction.

D Contact the system administrator for further instruction.

E Do not collect the sample for this cartridge in a device that contains anticoagulant. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.

F Prepare a new bottle of material per the manufacturer's instruction. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.

G Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.

H When filling a cartridge, use care to advance blood to the level indicated by the 'fill to' arrow. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.

I Analyzer did not reset correctly. Perform an electronic simulator test. If the test results in a PASS, the instrument is ready for use otherwise contact system administrator for further instruction.

J The simulator was not fully inserted. Repeat testing. Make sure that the cover retaining ring does not interfere with Electronic Simulator insertion. Ensure the Simulator is fully inserted. The Simulator is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.

K Always scan the barcode found on the pouch that contained the cartridge in use. Scanning any other barcode can cause this error. Repeat testing

Quality Check Failure Resolutions

Resolutions (Continued)

with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.

L A cartridge was detected when an Electronic Simulator was expected. Repeat testing ensuring to insert an Electronic Simulator. Make sure that the cover retaining ring does not interfere with Simulator insertion. Ensure the Simulator is fully inserted. The Simulator is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.

M Reserved for future use.

N The cartridge was not fully inserted. Repeat testing with a freshly filled cartridge. Ensure the cartridge is fully inserted. The cartridge is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.

P The analyzer did not reset correctly. Repeat electronic simulator testing. If the test results in a PASS, the analyzer is ready for use otherwise contact the system administrator for further instruction.

R Test has been successfully cancelled.

S OSi software installation required. Contact the system administrator for further instructions

T Install the most recent OSi software. Contact the system administrator for further instructions.

Abaxis Technical Support can be reached as the system administrator.

The Network Connectivity utility for i-STAT (AlinIQ NCi) is used to configure the analyzer to connect to wired and wireless networks. The NCi utility package must be downloaded from the Abaxis website at www.abaxis.com. It is best practice to load NCi onto a computer that is installed behind the facility's firewall, and that has antivirus software installed on it.

The following is an overview of the steps required to perform the configuration:

1. Download the NCi online and install on a Windows PC.
2. Use the NCi to create NC (ancc) file that contains the network parameters and security credentials required by the analyzer to connect to the facility network.
3. Upload the ancc files to the analyzers.

Before beginning:

- Define how the analyzer is to connect (wired, wireless, both) to the network
- Define the network to which the analyzers are to connect (SSID, authentication protocol)
- Supply network access credentials for the network (that is, username, password, security certificates/keys)
- Identify connection details (proxy server, IP address and DNS server address modes, etc.)

Have available:

- i-STAT Alinity base station
- FAT32 formatted USB 2.0 memory stick

Some preformatted USB flash drives may not work with the i-STAT Alinity system. To avoid issues, reformat the drive using a Windows PC before using the USB flash drive with the i-STAT Alinity system.

- Computer running Microsoft Windows 7 or Windows 10 and Internet Explorer 11 or Edge browser

After securing all of the above:

- Download the NCi utility package from the Abaxis website to your computer. The package will download to your desktop, unless you specify otherwise.

When the installation of NCi completes, this icon will appear on the desktop:

To run NCi, double click the icon.

If additional assistance is needed, please contact Abaxis Technical Support.

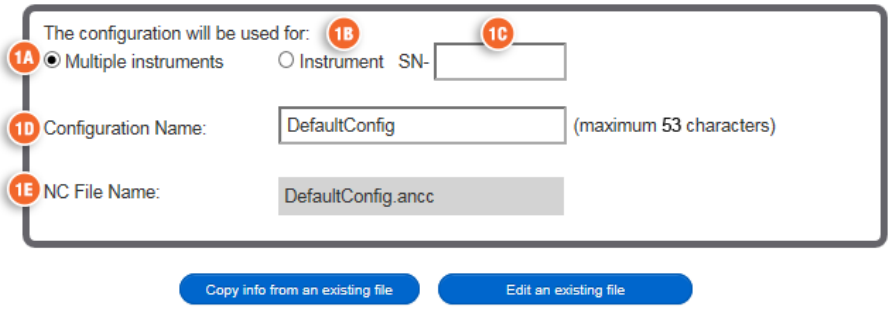
AlinIQ NCi - General Section

On the first section of the NCi screen, specify whether this NC file will be used for multiple i-STAT Alinity v Analyzers or a single analyzer. Unless your facility requires that each analyzer have its own unique security credentials, a single NC file may be used for all analyzers connecting to the same network.

Numbered labels (1A) are used in this section to highlight areas of the screen. These labels are for the purpose of this document only. They are not part of the actual NCi screen.

1. General

Enter information to customize the name you want to give your NC file.



The configuration will be used for:
Select one of these radio buttons:

1A Multiple analyzers
Use this NC file for multiple analyzers. This is the default.
This option may not be available if your facility requires individual Enterprise Security Certificates for each analyzer.

1B Instrument
This NC file will apply only to one analyzer. If this option is selected, the analyzer's serial number is required:

1C SNSerial
number of the analyzer to which this NC file applies. When a serial number is specified, the NC file name will include it, as shown here: `DefaultConfig.snnnnn.ancc`

1D Configuration Name
Name for the NC file. Specify up to 53 alphanumeric characters.

1E NC File Name
This field is automatically populated with the NC file name and cannot be changed.

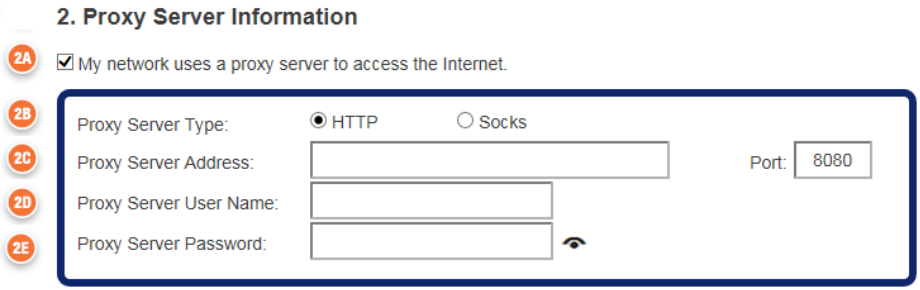
Copy info from an existing file
Click this option to open an existing NC file, copy its contents, and then save it to a new name. Navigate to the folder containing the NC file you wish to copy.
Attempting to rename an NC file causes unpredictable results. Instead, use the function Copy info from an existing file and save the file to a new name.

Edit an existing file
Click this option to edit an existing NC file. Navigate to the folder containing the NC file you wish to edit.

The next section of the NCi screen is for configuring a connection to a proxy server.

AlinIQ NCi - Proxy Server Connection

Use this section of the screen to supply information for connecting to the internet using a proxy server. Proxy server information is required if the analyzer is to connect to the internet via a proxy server. This may be required to download eVAS directly from Abbott Point of Care to the analyzer via the internet.



2A My network uses a proxy server to access the internet
Selecting this check box displays the following prompts:

2B Proxy Server Type:
Select either:
- HTTP HTTP proxy intercepts web access
- Socks Provides proxy service for UDP data and DNS look up operations in addition to web access.

2C Proxy Server Address:
Required. IP address of the proxy server
- Port: Port used by the proxy server. The default is 8080.

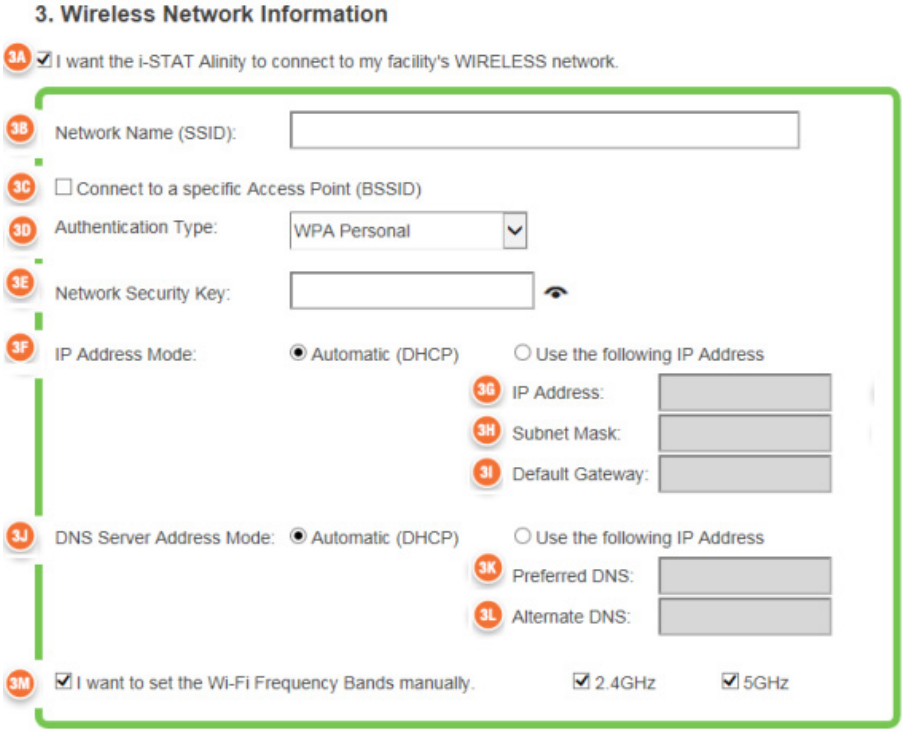
2D Proxy Server User Name:
Network name of the proxy server

2E Proxy Server Password:
Network password for the proxy server. By default, bullets (••••) are displayed as you type the password. To display the actual password after typing it, click this symbol:

The next section of the NCi screen is for connecting wirelessly.

AlinIQ NCi - Wireless Network Connection

This section of the screen is used to configure connectivity to a wireless network. Some of the options displayed on the screen depend upon the authentication type, and are noted as such.



3A I want the i-STAT Alinity v Analyzer to connect to my facility's WIRELESS network
Select this check box to configure wireless network connectivity.

3B Network Name (SSID):
Name of the wireless local area network (WLAN)

3C Connect to a specific Access Point (BSSID):
Select this check box to connect to a single wireless access point (WAP) by specifying its unique BSSID. Specify the BSSID address in this format: `DD-DD-DD-DD-DD-DD-DD-DD`, where `D` is a hexadecimal digit. Typically this is the media access control (MAC) address or hardware address of the WAP.

3D **Authentication Type:**
The selection of Authentication Type controls the WPA Type, Authentication Method, and Cipher Types as shown in this table:

Authentication Type	WPA Type	Authentication Method	Cipher Type	
			Groupwise Transient Key	Pairwise Transient Key
WPA Personal	WPA	PSK	TKIP	TKIP
WPA Enterprise	WPA	EAP	TKIP	TKIP
WPA2 Personal	WPA2	PSK	CCMP	CCMP
WPA2 Enterprise	WPA2	EAP	CCMP	CCMP
WPA2/WPA Mixed Personal	WPA2	PSK	TKIP	CCMP
WPA2/WPA Mixed Enterprise	WPA2	EAP	TKIP	CCMP

When one of the Personal Authentication Types is selected, the Network Security Key field will be enabled. When one of the Enterprise Authentication Types is selected, refer to the Options for Enterprise Authentication Types sections for the security credential fields that will be enabled.

3E **Network Security Key**
Enter the PSK passphrase, 8 to 63 characters, or 64-digit HEX key. By default, bullets (••••) are displayed as you type the key.

3F **IP Address Mode**
Select either:
- **Automatic (DHCP)** Obtain IP addresses and networking parameters automatically from a DHCP server.
- **Use the following IP address** Select this check box if you are using a static IP address. Specify values for:
  - 3G • **IP Address** IPv4 address of analyzer in decimal dot notation. Example: 172.16.254.1
  - 3H • **Subnet Mask** IPv4 mask that defines the Subnet in decimal dot notation. Example: 255.255.255.0
  - 3I • **Default Gateway** IP address for routing device that passes traffic between different subnets and networks in decimal dot notation. Example: 172.16.254.1
  - 3J • **DNS Server Address Mode** Select either:
    - **Automatic (DHCP)** Obtain IP addresses and networking parameters automatically from a DHCP server.
    - **Use the following IP address** Select this check box if you need to specify the DNS server address manually. Specify values for:
      - 3K • **Preferred DNS** IPv4 address of the server in decimal dot notation.
      - 3L • **Alternate DNS** IPv4 address of the server in decimal dot notation.

I want to set the Wi-Fi Frequency Bands manually.
Select this check box to configure the analyzer to use either the 2.4 or 5 GHz frequency band exclusively. When both values are selected, the analyzer will automatically select which band to use. Select one of the check boxes to limit the analyzer to that band only:
2.4 GHz
5 GHz

Options for Enterprise Authentication Types

When **Authentication Type** selected is WPA Enterprise, WPA2 Enterprise, or WPA2/WPA Enterprise, the options shown here are enabled:

EAP Method
Select one of the following:
TLS
TTLS/MSCHAPv2
PEAPv0/EAP-MSCHAPv2

Validate the Server Certificate
Select this check box to configure the analyzer to validate the server certificate. Unselect the check box if this is not required.

Server Name
Network name of the authentication server.

CA Certificate File
Name of the file that contains the Certificate Authority certificate.

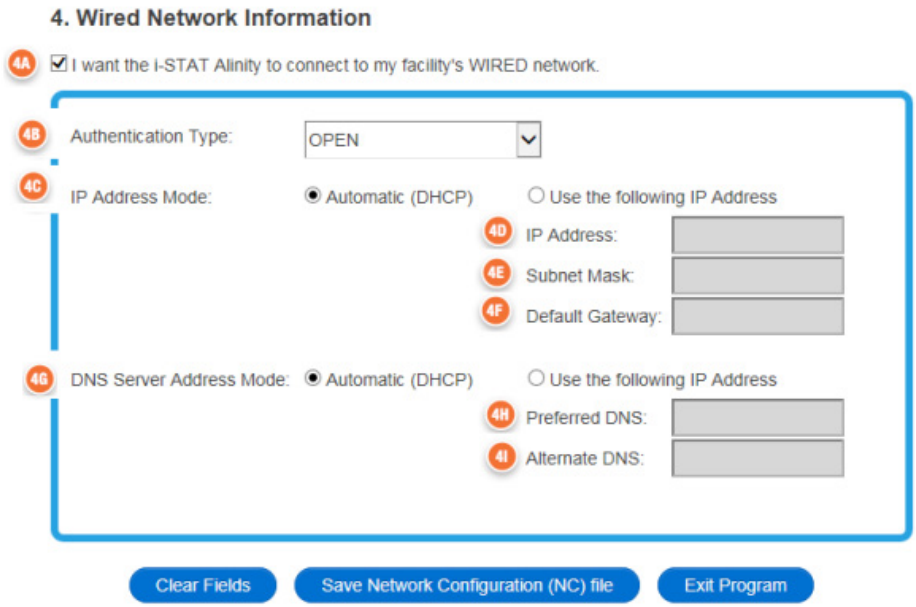
Client Certificate File
Name of the file that contains the client certificate.

Client Key File
Name of the file that contains the client key.

Client Key Password
Password for the client key.

Username/Identity
Username required by the authentication server.

AlinIQ NCi - Wired Network Connection



4A I want the i-STAT Alinity v Analyzer to connect to my facility's WIRED network
To configure connectivity for a wired network, select this check box and specify values for:

4B Authentication Type
OPEN (this value is not modifiable)

4C IP Address Mode
Select one of these values:
- Automatic (DHCP) - Obtain IP addresses and networking parameters automatically from a DHCP server.
- Use the following IP Address - Select this button to use a static IP address.

If you specify a static IP address you must also specify DNS addresses.

4D IP Address
IPv4 address of analyzer in decimal dot notation.

4E Subnet Mask
IPv4 mask that defines the Subnet in decimal dot notation.

4F Default Gateway
IP address for routing device that passes traffic between different subnets

4G and networks in decimal dot notation.

DNS Server Address Mode:

Select one of the following:

- Automatic (DHCP) - Obtain IP addresses and networking parameters automatically from a DHCP server.
- Use the following IP Address - Specify values for:

4H

Preferred DNS:

IPv4 address of the server in decimal dot notation

4I

Alternate DNS:

IPv4 address of the server in decimal dot notation.

You must specify DNS addresses if you specify a static IP address.

AlinIQ NCi - Save the Network Connectivity (ancc) file

After supplying the information for connectivity, you are prompted to save the ancc file. The saved file can then be loaded onto a USB memory stick, and then uploaded to an i-STAT Alinity v Analyzer.

At the bottom of the NCi screen, choose **Save Network Connectivity (ancc) File**, then click **Continue**.

Depending upon the browser in use the ancc file will be saved to the Downloads directory, or, at the bottom of the screen a banner may display with the prompts shown below.
Note: *Best practice is to select* ***Save*** *which will save the file to the Downloads directory. Opening NC (ancc) files in a text editor is not recommended.*

Do you want to open or save *filename.ancc*?

Open
Open the ancc file in a text editor.

Save
Save the file to the Downloads directory.

Save as
Save the file to a specified destination.
Note: *If you use this option make note of the destination where the file is saved. This information will be needed to load the ancc file onto the USB memory stick.*

Save and open
Not recommended.

Cancel
Do not save the file.

AlinIQ NCi - Copy NC (ancc) file onto a USB memory stick

NC files are uploaded to analyzers via USB memory stick as described in the next section.

The following rules apply to the number and type of NC (ancc) files that may reside on the USB memory stick:

- Any ancc file to be uploaded to an analyzer must reside at the top level of the directory structure of the USB memory stick. The ancc file should not be in a folder.
- The USB memory stick may contain multiple ancc files created with serial numbers, but the serial numbers must be unique (there cannot be more than one ancc file with the same serial number at top level).
- The USB memory stick may contain one and only one ancc file created without a serial number. If both serialized and non-serialized ancc files are placed on the USB memory stick at the top level, then upon upload to the analyzer, the analyzer will attempt to upload a serialized ancc file if it finds a serial that matches that of the analyzer itself, otherwise it will attempt to upload the non-serialized ancc file.

Use the following steps to copy the ancc file onto the USB memory stick:

1. Plug the USB memory stick into the USB slot of the computer. A message displays indicating that the operating system recognizes the drive and it is ready to use.
2. From the **Start** menu, click **Computer** > **Downloads**.
3. In the displayed list, find the *filename.ancc* file and right-click on it.
4. Click **Send to:** and press **Enter**. This loads the file onto the memory stick.
5. Repeat steps 3 and 4 for each ancc file to be copied.

AlinIQ NCi - Upload an NC (ancc) file to an analyzer

To upload an NC (ancc) file, an i-STAT Alinity base station and a USB memory stick that the NC (ancc) file resides on are needed.

Some preformatted USB flash drives may not work with the i-STAT Alinity system. To avoid issues, reformat the drive using a Windows PC before using the USB flash drive with the Alinity system.

Follow these steps:

1. Plug the USB memory stick into the USB slot of the base station.
2. Place the i-STAT Alinity v Analyzer in the base station.
3. Touch **More Options**
4. Touch **Instrument Options**
5. Touch **Network Settings**
6. Install **Network Settings**
7. Enter Operator ID, touch **Next**
8. Follow instructions on the i-STAT Alinity v screen.

AlinIQ NCi - Determining Success or Failure

After you have used NCi to configure connectivity, you can test the connection. Follow the steps shown here:

- To check a wired network connection, place the i-STAT Alinity v Analyzer in the base station that is connected to the facility's network and power on the analyzer. On the analyzer screen, in the upper right corner, the ethernet symbol displays indicating an active connection.

- To check a wireless network connection, remove the i-STAT Alinity v Analyzer from the base station. On the analyzer screen, in the upper right corner, the wireless internet symbol displays. This symbol represents a strong signal.

Some or all of the bars in the signal should be filled in, depending upon the signal strength in the location. A location that displays the symbol with all bars empty represents no signal. If the symbol displays with all bars empty, move the analyzer to a location closer to the wireless access point.

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Toll Free: +1 800 822 2947
Phone: +1 510 675 6500

Rest of World:
Email: techsupport@abaxis.de
Phone: +49 6155 780 210

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