

i-STAT CONVERSION GUIDE

The *i-STAT Conversion Guide* will help customers transition an existing testing platform to the *i-STAT System*. Information in this document will assist in identifying components to convert to the *i-STAT System*. Supply orders, pricing, and service agreements can be finalized with an Abbott Point of Care (APOC) *i-STAT* Sales Specialist.

INVENTORY

Verify required i-STAT equipment and supplies are onsite and ready for use before starting implementation. Local i-STAT representative can assist with ordering new or replacement items.

HARDWARE

- i-STAT 1 analyzer
- Simulator
- Printer
- Downloader (downloader cable connections)

DOWNLOADERS

- Are downloaders currently installed?
- Is reprogramming needed?
- Are downloaders labeled/ identified for location assignment?

CONSUMABLES

- Cartridges
- Controls & Calver
- Dispensing Tips
- Collection device (review appropriate collection device in IFU)

NOTE: Confirm consumables and pricing are loaded in ordering system with accurate part numbers

PERFORMANCE VERIFICATION (PV)

Follow internal policy and procedures approved by Laboratory Director; direct follow-up questions to accrediting organization.

APOC PV Support | APOC resource will schedule a Performance Verification review to discuss a plan to verify the *i-STAT* System. Performance Verification is not a manufacturer's requirement, therefore, APOC will assist with the protocol approved by the laboratory director.

i-STAT Supply Calculator | *i-STAT* supplies will be calculated according the number of analyzers, precision levels, method comparison and calibration replicates. Optional QC training cartridges and any additional cartridges will be calculated at the customer's request.

Data Collection Worksheets | Worksheets will be supplied by an APOC resource at the request of the customer. If a performance verification report is needed, submit request to an APOC representative.

POLICY & PROCEDURE

Review policy and procedures and identify changes needed, then obtain required signatures to revised policy.

- Review new blood collection requirements
- Evaluate existing use model and establish changes as needed
- Review sample types and implement accordingly
- Assess new reportable ranges and update systems
- Instructions For Use and Cartridge Test Information for cartridges available for use on the *i-STAT 1* and *i-STAT 1 Wireless* can be found in the *i-STAT 1* support area at www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12">www.globalpointofcare.google-bullet-number-12"

- Individualized Quality Control Plan
- Evaluate risk assessment
- Ensure controls are done in accordance with IQCP
- Review QC Plan
- Confirm signature and date is updated with changes



PROFICIENCY TESTING

Laboratories performing non-waived testing generally enroll in an approved program for each specialty for which they seek certification.

NETWORKING

Contact IT resources for network assignment changes; an APOC resource can provide guidance.

- · Ports and power outlets available for assigned locations
- IP's/VLANs still assigned for i-STATs

DATA MANAGEMENT/INTERFACING

Contact Data Manager vendor to determine if any changes are required for Data Management System. If testing is not currently interfaced and will not be interfaced in the conversion, the interfacing section does not apply.

- Verify order sets, power plans, and test batteries are still active.
- · Identify if order changes are needed
- If not active contact resource to enable or re-add
- LIS updates for reportable or critical ranges
- · Interface testing may be required

DE Customization Changes | Contact APOC resource to assist with changes to DE customization

- DE Customization training modules are available on the Abbott Point of Care website:
 DE Training Modules
- Customization instructions found in <u>i-STAT 1 System Manual</u> section 9.

SOFTWARE UPDATES

Due to the continuous manufacturing process improvements to the *i-STAT System*, it is necessary to update standardization values to maintain long-term consistency of performance. *i-STAT 1* software updates are released twice a year.

Verify CLEW/JAMS software is updated.
 See i-STAT 1 Software Updates

CLINICAL AWARENESS TRAINING

Inform clinicians and departmental leads of any changes (i.e. reportable range changes).

- New staff/department training requirements
- Competency and training documents up to date
- Interactive Remote Training is available. Your APOC resource can provide schedules.
 Your APOC resource can also assist with customized trainings.

i-STAT FOR IN VITRO DIAGNOSTIC USE ONLY. THIS MATERIAL IS INTENDED FOR A U.S. AUDIENCE ONLY.