

i-STAT® 1 Analysers PHC Remote Guideline

Target Audience	All Clinical Employees
Jurisdiction	Primary Health Care Remote CAHS; Primary Health Care Remote TEHS
Jurisdiction Exclusions	N/A
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Purpose

To provide Primary Health Care remote staff with a guideline on the management, including operator training requirements, checks, maintenance and supply of consumables, of the i-STAT® 1 Analyser used in remote health centres.

Guideline

1. General Information

The Abbott i-STAT® Analyser is a portable medical device used for point-of-care (POC) pathology testing for a range of pathology tests including electrolytes, urea, creatinine, blood gases, PT/INR and cardiac Troponin I. The i-STAT® Analyser is designed to operate as a networked system allowing the electronic download of client and Quality Control (QC) results from the device and the upload of software to the device. The i-STAT® Analyser is standard equipment in Northern Territory (NT) remote health centres.

The NT Point-of-Care Testing (POCT) Program provides a framework for i-STAT POCT for the care of clients with both acute and chronic diseases across a network of almost 80 remote health centres in the NT. The Program is delivered through a formal partnership between the NT Department of Health (DoH) and Flinders University International Centre for Point-of-Care Testing (ICPOCT) with governance provided by the [NT POCT Management Committee](#).

Although the i-STAT® Analyser is relatively easy to operate there are potential risks to this valuable equipment, and the quality of results, if misused. This, coupled with the need to appreciate the quality management and supply issues surrounding the use of the analysers, dictates that staff must be appropriately trained and certified as a Qualified i-STAT Operator, before using the equipment. **Use by non-certified staff is not authorised.**

Information in this document includes:

[Temporary Operator ID to use the i-STAT Analyser](#)

[When to Perform a Test](#)

[How to Perform a Test](#)

[Point of Care Testing \(POCT\) Training and Competency](#)

[Quality Management](#)

[Technical and Other Support Information](#)
[Medicare Claiming](#)
[Ordering Consumables](#)
[Storage of Cartridges and Quality Controls](#)
[Maintenance / Cleaning / Location](#)

2. Definitions

Central Data Station (CDS): a specific i-STAT database located at the ICPOCT, capable of electronically storing real-time patient and quality testing data / results of QC testing, as well as performing other system management functions for the i-STAT network.

Downloader: a desktop electronic IT device capable of facilitating transmission of data between the i-STAT[®] Analyser and the CDS, via the internet. Some downloader's also have a recharger function.

Electronic Simulator: a device used to perform an external quality check on the analyser's electronic signal-reading function.

ICPOCT: Flinders University International Centre for Point-of-Care Testing. A specialist POCT provider, with experience in the delivery of POCT services to rural and remote health services around Australia and Internationally.

i-STAT Cartridge: a small, single use, disposable pathology test kit.

Qualified i-STAT Operator: clinical staff who have successfully completed the required training and hold a current ICPOCT i-STAT Competency Certificate.

POCT Resource Staff: clinical staff who have successfully completed primary training and hold a current ICPOCT i-STAT Competency Certificate, who have demonstrated advanced competency skills for client and quality testing, who participate in regular 'skill update' sessions provided, and who are able to provide training support to others.

NT POCT Management Committee: the management committee, comprising representatives of the DoH, Aboriginal Medical Services Alliance NT (AMSANT), ICPOCT and other stakeholder groups, responsible for the overseeing the NT POCT Program for i-STAT and DCA Vantage Analysers.

3. Responsibilities

3.1 Clinical Staff

- Request a temporary operator ID to use the i-STAT as appropriate. See [Section 4.1](#).
- Undertake training and achieve competency in the use of the i-STAT[®] Analyser

3.2 Qualified i-STAT Operator

- Perform POCT according to the [i-STAT Clinical Protocol](#)
- Maintain the security of the unique Operator ID Number
- Ensure Medicare Benefit claiming following i-STAT POC haemoglobin testing
- Perform routine quality management processes for POCT

3.3 Point-of-Care Testing (POCT) Resource Staff

- Successfully complete relevant training
- Demonstrate advanced competency skills for client and quality testing
- Maintain POCT competency and current Certificate
- Provide support for Qualified i-STAT Operators at participating health centres
- Identify operator, device, technical or supply issues at participating health centres and report these back to the PPN or ICPOCT

3.4 Primary Health Care Manager (PHCM)

- Ensure that POCT is performed by Qualified i-STAT Operators only
- Inform new clinical staff members of the requirement and process to request a temporary operator ID to use the i-STAT as appropriate. See [Section 4.1](#).
- Ensure maintenance, data downloads and software updates are completed as recommended
- Ensure Qualified i-STAT Operators adhere to Medicare claiming processes as appropriate
- Manage POCT stock levels and storage
- Download the i-STAT Essential Checks Forms and QC Result Sheets each month and place in the i-STAT Essential Checks Folder
- Ensure all i-STAT operators are familiar with the i-STAT Essential Checks Folder
- Perform / delegate POCT quality management tasks to relevant Qualified i-STAT Operators
- Evaluate and take action to correct issues identified through quality management activities
- In conjunction with the PPN, identify an on-site POCT Resource person

3.5 Professional Practice Nurse (PPN)

- Maintain asset inventory data base of i-STAT POCT equipment
- Maintain appropriate levels of consumable stock
- Manage the distribution of stock orders to health centres
- Contribute to training and competency assessment for clinical staff as required
- Provide technical and telephone support where appropriate
- Coordinate repairs, maintenance and software updates (where necessary) for DoH health centres
- Provide advice re repairs, maintenance and software updates (where necessary) for Aboriginal Community Controlled Health Services

3.6 Medical Practitioner

- Knowledge of POCT according to the [i-STAT Clinical Protocol](#)
- Provide clinical direction for the interpreting and actioning of POCT results, as needed
- Participate in i-STAT Operator training
- Optimise Medicare Benefit claiming for POCT as appropriate

3.7 Flinders University International Centre for Point-of-Care Testing (ICPOCT)

- Oversee and coordinate the NT POCT Program
- Process [Applications for Temporary i-STAT Emergency Operator ID](#)
- Issue Temporary ID and i-STAT Operator instructions
- Provide i-STAT training for groups as required
- Determine training program content and resources
- Maintain the [NT POCT Program](#) website
- Conduct competency assessment of i-STAT Operators
- Maintain a Competency Register of Qualified i-STAT Operators and POCT Resource Staff (including their unique Operator ID number)
- Provide update training sessions where possible
- Co-ordinate and manage the Quality Management program for the i-STAT
- Provide feedback reports to PHCMs / health services
- Provide telephone support hotline for remote health centres from 9am to 5pm weekdays
- Maintain a Device Asset Register for all i-STATs in use in the NT
- Manage the Central Data Station network for the i-STAT devices

- Collect and analyse data for research purposes subject to direction of Management Committee
- Organise and participate in meetings of the NT POCT Management Committee
- Prepare monthly reports to the NT POCT Management Committee
- Prepare NT POCT Program newsletter when required

Note: [NT POCT Governance](#) summarises the responsibilities and relationships of stakeholders.

4. Procedure

4.1 Temporary Operator ID to use the i-STAT Analyser

Clinicians who have not previously undertaken POCT training or those who do not have a current Operator ID must apply for a temporary i-STAT emergency operator ID which allows them to use the i-STAT Analyser in **emergency situations only**.

The [Application for Temporary i-STAT Emergency Operator ID](#) must be completed and submitted to ICPOCT who will issue a Temporary ID and i-STAT Operator instructions to PHCM and staff member within 24 hours of receipt of the application. The i-STAT Operator instructions must be read and understood prior to using the i-STAT.

It is important to note that the Temporary ID will expire two weeks from date of issue. During this two week period staff must complete i-STAT training and achieve competency to be assigned an ongoing standard Operator ID. If training and competency is not successfully completed within the two week timeframe, the applicant should liaise with ICPOCT re extension / alternative arrangements.

4.2 When to Perform a Test

Use of the i-STAT analyser is restricted to qualified i-STAT Operators only.

Due to the operational cost of POCT, discriminate use of the i-STAT is essential. Therefore criteria for use has been established, which will directly or indirectly involve authority from a Medical Practitioner. i-STAT tests are used for the assessment and management of both chronic and acute clinical conditions. Where i-STAT analysers are available they must be used instead of other alternative POCT equipment.

The [i-STAT Clinical Protocol](#) provides criteria for use of each cartridge type. Outside of these criteria, routine channels for laboratory pathology testing should still be utilised despite the presence of an i-STAT® Analyser.

4.3 How to Perform a Test

The unique i-STAT Operator ID must only be used by the person it is assigned to.

Qualified i-STAT Operators are required to enter their unique Operator ID when preparing the i-STAT to perform a test.

There are different cartridges for different tests. All the cartridge types share similar features and the test procedure for performing any test on the i-STAT is essentially similar.

To perform a POC test on the i-STAT, refer to the poster [How to do a Patient Test on the i-STAT](#) for a quick step-by-step guide. Also see the [i-STAT Training Manual](#).

4.3.1 Results

i-STAT Analysers have the capacity to store 1000+ records so future checking or retrieval of results may be accessed from the analyser. Thermal printers are also available for use with i-STAT® Analysers, however staff must be aware that the printed image will fade over time.

All test results must be recorded into the client's health record. See the relevant Electronic Health Record (EHR) User Reference Guide on recording i-STAT results.

4.4 Point-of-Care Testing (POCT) Training and Competency

The use of i-STAT® Analyser is restricted to appropriately trained staff. Having only competent staff performing POCT is an important feature of ensuring the reliability of results obtained from these devices.

It is recommended that all clinical staff become qualified i-STAT Operators. To be recognised as a qualified i-STAT Operator, an individual must undertake training and complete a competency assessment process.

Training sessions and competency assessment processes are coordinated by ICPOCT. Following completion of the [Application for Temporary i-STAT Emergency Operator ID](#) applicants will be notified of training sessions and requirements. Training is usually conducted weekly via GoToMeeting and teleconference with notification of the date and time and equipment required by the ICPOCT.

If both written and practical assessments are acceptable, ICPOCT will issue a Competency Certificate and an individual Operator ID will be assigned.

Note: Should the trainee fail either step of the competency process, any shortfalls in knowledge will be addressed by further instruction and reassessment.

Staff are required to update their competency every two years or as deemed necessary by the ICPOCT.

[i-STAT Training Resources](#) and [i-STAT Training Videos](#) produced and supplied by ICPOCT are available to support training.

4.4.1 POCT Resource Staff

POCT Resource Staff are able to access training resources and written competency assessment forms from ICPOCT and provide training support for aspiring and qualified i-STAT operators at participating health centres.

Staff interested in becoming a POCT Resource person should liaise with the ICPOCT Team for further information.

4.5 Quality Management

An essential part of conducting routine POCT is the regular monitoring or 'checking' of the precision and accuracy of the analyser. Quality procedures are integral components of the quality management system and include:

- [i-STAT Essential Checks](#)
- [Quality Control Checks](#)
- [Software Updates](#)

Performing these quality procedures is critical; without them there can be no assurance that results generated by POCT devices are sufficiently accurate for client care. Quality procedures are also an important component of maintaining a high level of i-STAT Operator competency. Quality procedures may only be performed by a Qualified i-STAT Operator.

The forms should be downloaded from the [i-STAT Key Paperwork](#) webpage. Once the procedures are completed both the [i-STAT Essential Checks Form](#) and the appropriate [QC Result Sheet](#) is to be signed and returned as instructed on the form.

4.5.1 i-STAT Essential Checks

The required checks are summarised on the [i-STAT Essential Checks Form](#) and grouped into weekly and fortnightly tasks. Checks should be completed and signed off on the i-STAT Essential Checks Form and fax or e-mail to ICPOCT during the first week of the next month.

4.5.2 Quality Control (QC) Checks

QC checks on the i-STAT involve the testing of an artificial sample that is produced by the manufacturer. This sample has an assigned, or 'target' value, for each POC test being measured, and limits for acceptable performance around that target are set by the ICPOCT unit (consistent with those used in laboratories). The results of QC testing can be compared to the assigned values and limits on the [QC Result Sheet](#) for acceptable performance and an immediate assessment made of the quality of the device's performance. If QC results are outside acceptable limits, then patient testing should stop until the reason for poor performance has been rectified through consultation with the ICPOCT.

QC Checks are required for each type of cartridge used for patient testing. For information on how to perform a QC check please refer to the [How to Complete a Quality Control Test on the i-STAT](#) for a quick reference step by step guide or the [i-STAT Training Manual](#).

Refer to the [i-STAT Quality Control Action Sheet](#), which summarises the interpretation of QC results.

QC checks are completed fortnightly and staff must ensure that the 'Lot Number' on the control solution and 'QC Result Sheet' match. Each time a QC test is completed, results should be recorded on the relevant [QC Result Sheet](#) and faxed or emailed to the ICPOCT.

4.5.3 Software Update

The i-STAT® Analyser requires regular software updates every 6 months. If an update is not performed, then the Analyser will cease to function until the update occurs. Software updates can be performed in several ways. In most instances, the software update will be conducted in the health centre by following some simple instructions issued by the ICPOCT, and involves placing the i-STAT® Analyser in the downloader at the appropriate time. Health centres with satellite IT connections may experience slower connection speeds, thus requiring an alternative process. For example emailing software packages & instructions to the health centre or transferring software analyser-to-analyser. Alternatively, sending the i-STAT® Analyser to the CA / TE PPN. For instructions on performing software updates please see the [i-STAT Training Manual](#). Technical support to perform software updates is also available, see point 4.6 below.

4.6 Technical and Other Support Information

If a test fails, the i-STAT® Analyser will display an error code. Information on the [i-STAT Common Error Codes](#) provides a description of the error and suggests actions which may resolve the issue. If the issue cannot be resolved, a telephone support service is available for assistance. Contact details are provided on the [Key Contacts for Support Services](#) (participant login required).

4.7 Medicare Claiming

A Medicare rebate is claimable for a haemoglobin measurement using the i-STAT Chem8+ cartridge (Medical Benefit Schedule item number [73802](#)). In addition, if the patient is the holder of a Commonwealth concession card the incentive item number [74991](#) may also be claimed. See: [Medicare Overview](#).

4.8 Ordering Consumables

Testing Cartridges, QCs and batteries can be ordered and faxed to the PPN (number on form) using:

Point-of-Care Consumables Order (Central Australia) PHC Remote Form	DoH Health Centres Only
Point-of-Care Consumables Order (Top End) PHC Remote Form	
i-STAT Consumables Order (Community Controlled Health Service) PHC Remote Request Form (Atlas Link: https://hdl.handle.net/10137/6945)	Community Controlled Health Services

Note: Stock levels should be kept to a minimum to avoid wastage. When receiving new stock it should be placed behind existing / older stock so that stock at the front of the refrigerator shelf is the oldest stock and therefore used first.

4.9 Storage of Cartridges and Quality Control Solutions

i-STAT cartridges and QCs should be stored in a purpose built temperature controlled refrigerator that is separate to the vaccine refrigerator. Where this is not available, a dedicated domestic refrigerator with temperature monitoring may be used to store these consumables.

i-STAT Cartridges and QCs are to be kept refrigerated at 2 – 8°C until product expiry date. During transportation they should be packed in the same way as vaccines (with an ice brick and cold chain monitor in an esky).

If the cartridges are removed from refrigeration or exposed to room temperature, they should continue to be stored at room temperature (18 - 30°C) and *not* returned to the fridge. When stored at room temperature, cartridge life is shortened to:

- two (2) months for CG4 and
- 14 days for all other cartridge types.

The cartridges should be labelled with a handwritten new expiry date. Once past the new expiry date the cartridge should be discarded or clearly labelled and may be used for training purposes. See [Cold Chain](#) for more information.

4.10 Maintenance / Cleaning / Location

On-site maintenance is minimal, essentially summarised in the weekly check component of the [i-STAT Essential Checks Form](#).

The downloader should always be connected to an active network port and preferably the analyser routinely placed in the downloader when not in use.

If the analyser becomes soiled, it should be wiped with a slightly damp soft cloth, using mild general-purpose detergent / warm water. Avoid using excessive fluid.

The analyser must be stored in a dust-free location in an air-conditioned room in the health centre within a 16 - 30°C temperature range. Outside of this temperature range the analyser will disable client and quality testing capabilities. Transport of the analyser for off-site use should utilise a dedicated insulated bag, taking care to prevent the device being subject to temperature extremes. (Transport of cartridges requires maintenance of the [cold chain](#)).

Document Quality assurance

	Method	Responsibility
Implementation	Document will be accessible via the Policy Guidelines Centre and Remote Health Atlas	Health Policy Guidelines Program
Review	Document is to be reviewed within three years, or as changes in practice occur	Atlas Development Officer, Primary Health Care CAHS
Evaluation	Evaluation will be ongoing and informal, based on feedback.	Atlas Development Officer, Primary Health Care CAHS

Key Associated Documents

Forms	<p>DoH Health Centres Only:</p> <p>Point-of-Care Consumables Order (Central Australia) PHC Remote Form</p> <p>Point-of-Care Consumables Order (Top End) PHC Remote Form</p> <p>Community Controlled Health Services:</p> <p>i-STAT Consumables Order (Community Controlled Health Service) PHC Remote Request Form</p> <p>Application for Temporary i-STAT Emergency Operator ID</p> <p>Flinders University International Centre for Point-of-Care Testing - NT Program homepage</p> <p>i-STAT for Participants Only webpage: Note: Participant log in is required to access the following i-STAT Key Paperwork documents:</p> <ul style="list-style-type: none"> - i-STAT Essential Checks - i-STAT Quality Control Result Sheet - Fortnight 1 - i-STAT Quality Control Result Sheet - Fortnight 2
Key Legislation, By-Laws, Standards, Delegations, Aligned & Supporting Documents	<p>Cold Chain PHC Remote Guideline</p> <p>Medicare Overview PHC Remote Guideline</p> <p>PCIS User Reference Guide - Recording of i-STAT results</p> <p>Flinders University International Centre for Point-of-Care Testing - NT Program homepage</p> <p>i-STAT for Participants Only webpage: Note: Participant log in is required to access the following i-STAT webpages:</p> <p>i-STAT Key Paperwork</p> <p style="padding-left: 40px;">Key Contacts for Support Services</p> <p>i-STAT Training Resources</p> <p>i-STAT Training Videos</p> <p>Remote Primary Health Care Manuals</p> <p>Central Australian Rural Practitioners Association (CARPA) Standard Treatment Manual</p>
References	As above

Evidence Table

Reference	Method	Evidence level (I-V)	Summary of recommendation from this reference
N/A	N/A	N/A	N/A