| Northern Ireland Blood Transfusion Service | STANDARD OPERATING PROCEDURE (Operational Copy) |

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Document Title: **ADMINISTRATION AND MAINTENANCE OF ELLAB THERMAL MONITORING EQUIPMENT**	
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CROSS REFERENCES

This SOP refers to the following documents:

Doc. Type	Doc. No.	Title
SOP	VL:016	To run a session using Ellab TS Pro Probes
SOP	VL:017	Result retrieval and analysis using Ellab Probe Data
		Ellab ValSuite User Manual
		Ellab Equipment Log
		Guidelines for the Blood Transfusion Services in the UK, (7th Ed)

Key Change from Previous Revision:

General minnor changes
Responsibility section updated, Access for administrators updated, Error codes updated.

1   RESPONSIBILITY

1.1   Validation Officer or deputy is responsible for ensuring Ellab equipment is maintained in validated state and calibrated and updated on Q Pulse and in Equipment Log.

1.2   Validation Officer and Compliance Officer are responsible for packaging and shipping Ellab equipment for calibration, maintenance and repair.

1.3   Validation Officer and Compliance Officer responsible for carrying out battery and other 'in house' maintenance/calibration checks.

1.4   The Validation Officer or deputy has access to the ValSuite system as administrators and as Master. The Master can set/edit the administration profiles of all others, administrators and users and can deactivate/activate administrators and users. An administrator can set/edit the administration profile for a user and deactivate/activate users only.

2   INTRODUCTION

2.1   GENERAL

2.1.1   Current regulations and the MHRA require that along with continuous temperature monitoring, all areas storing GMP critical items will be temperature mapped; empty and full or operational when new or after significant change or repair and thereafter operationally at least annually.

NIBTS purchased Ellab equipment and software to use for temperature and RH mapping for use throughout the Service, to permit full compliance with the current regulations. Data can be collected, analysed, displayed and reported by the Ellab ValSuite Pro system.

The system consists of a Master module and one Slave module each with four TS Pro logger slots, which would allow 8 loggers to be read at one time, however a session can control more than 100 loggers. The loggers are not linked to a specific position on the master or slave modules therefore a logger can be started in position A and read in position B. It is possible to run many different sessions at the same time, limited only by the loggers and sensors available.

This SOP explains how to assemble and maintain the Ellab equipment, how to send it for repair or maintenance as well as a troubleshooting guide on what action to take with an error message.

Use of the Ellab system to run a temperature mapping session is explained in SOP:VL:016 To Run a Session using Ellab Probes. Help with data analysis of results obtained is found in SOP:VL:017 Ellab Probe Result Retrieval and Analysis.

NIBTS use the password option at login. An administrator can set the password to be changed at next login for users. The Master can set the password to be changed at next login for administrators and users.

2.2   CLINICAL RELEVANCE/ PURPOSE OF EXAMINATION

Not Applicable

2.3   PRINCIPLE OF EXAMINATION

Not Applicable

3   HAZARD AND SAFETY PRECAUTIONS

3.1   The maintenance and administration of Ellab Thermal Monitoring Equipment poses no significant health and safety risks.

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4   MATERIALS

4.1   EQUIPMENT AND SPECIAL SUPPLIES

4.1.1   PC/ Computer system with ValSuite Pro software
4.1.2   Ellab TrackSense Pro X Data Logger
4.1.3   Ellab Single Rigid Temperature Sensors
4.1.4   Ellab Single Flexible Teflon Sensors
4.1.5   Ellab RH ($\pm$ 2%) with internal temperature sensors
4.1.6   Ellab Multi TrackSense Pro reader station
4.1.7   Ellab TrackSense Pro Slave reader station

4.2   SPECIMEN REQUIREMENTS AND MEANS OF IDENTIFICATION

Not Applicable

4.3   REAGENTS, STANDARDS OR CALIBRANTS AND INTERNAL CONTROL MATERIALS

Not Applicable

5   CALIBRATION

Not Applicable

6   PROCEDURE

6.1   Administrator Functions

6.1.1   The ValSuite Pro software is designed for three levels of user:

Master

Responsible for the security of the program, has access to all ValSuite Pro functions. The Master creates the first user and administrators and can deactivate administrators and users.

The Master can set/edit the administration profiles of all others, administrators and users.

The Master can set the password to be changed at next login for administrators and users.

Administrator

Creates users, has access to all run functions in ValSuite Pro software. An administrator can set/edit the administration profile for a user. An administrator can set the password to be changed at next login for users.

User

User has access to running ValSuite Pro function.
User can change their own password
The Master or Administrator defines all access.

6.2   Adding Users to the Ellab system.

6.2.1   The Administrator must add users to the system to enable them to access the ValSuite Pro software and run sessions.

6.2.2   To add a user go to Tools, Administrator, Access Manager as shown on the screen dump below.
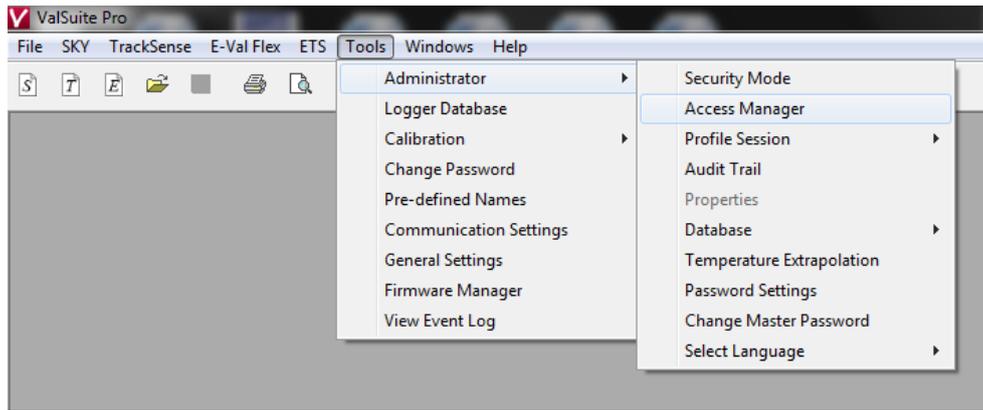
Note: the Master login must be used to add and edit Administrators. Administrators can add and edit users, not administrators. An individual administrator can edit their own general info. There is no profile option for administrators; they all have the same access
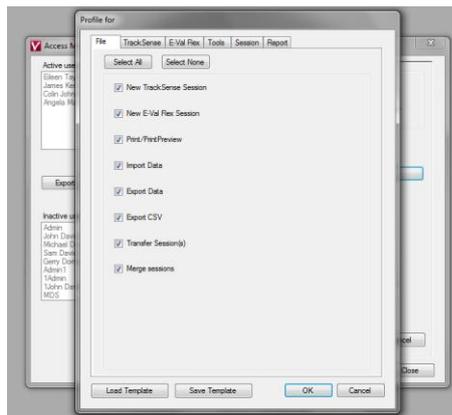
6.2.3   The Access manager window opens
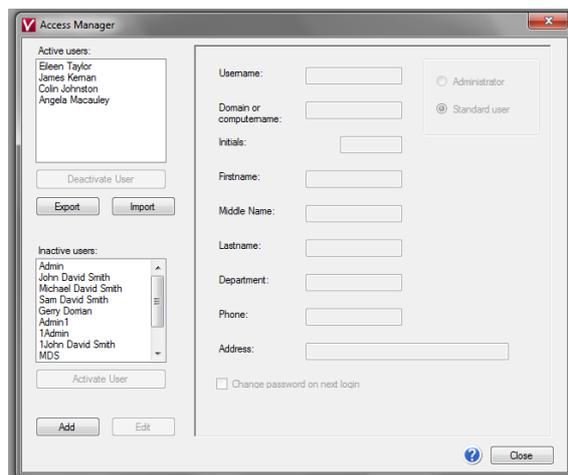
6.2.4   Click on Add and the window below opens to be completed with the general details of the user. Remember to checkmark 'Change password on next logon'
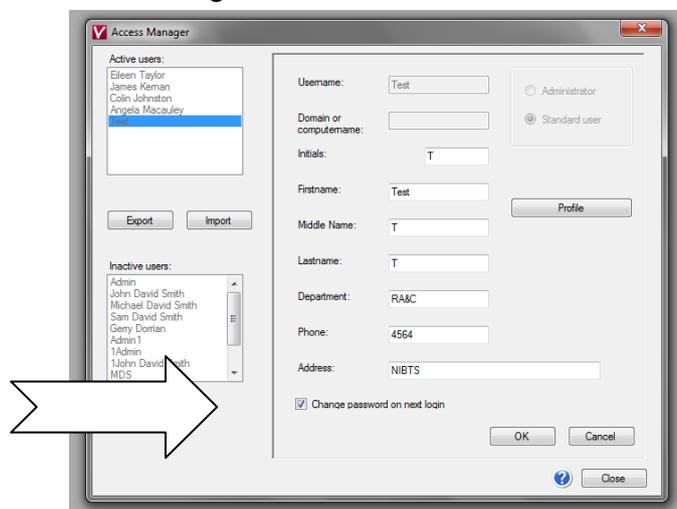
6.2.5   Click on the profile button to open the profile window and select what access the user is to have.

When complete click OK, the window closes.

6.3   Calibration / Maintenance / Repair

6.3.1   NIBTS Ellab sensors are returned to Ellab headquarters in Denmark for recalibration, maintenance or repair. The Ellab equipment log and Q-PULSE must be updated if the status of the equipment is altered.

6.3.2   In the event that Ellab equipment requires calibration, maintenance or repair:

- Contact Ellab UK giving details as required and obtain a returns number for shipping equipment to Ellab Denmark for work to be carried out. Obtain a written quotation for work to be carried out, except for repairs as costs are not known in advance.

- Complete a Non-Stock requisition to be approved by the Quality Manager or a nominated deputy. This order is then passed to NIBTS Stores for further processing. Provide a written quotation and service report containing the details of equipment for calibration/maintenance or repair from Ellab with the requisition for stores.

- Equipment for return to Ellab is to be packed suitably and shipped by a courier which is selected according to the amount of insurance required. This is arranged through NIBTS Reception or when necessary by the validation officer.

- Inform Ellab UK when shipped.

- Update the NIBTS Ellab Equipment log & Q-PULSE.

- On return to NIBTS the equipment must be verified as working and the printouts placed in the equipment log. Calibration certificates must be signed-off and placed in the equipment log.

- Update equipment log and Q-PULSE as appropriate giving the equipment status.

6.3.3   Periodically check calibration on the single rigid sensors. Place all probes into a controlled temperature dry incubator for 1 hour after equilibration. Verify REES and Ellab both in air are ±1°C from each other, sign–off the print-out and file at the front of the equipment log. Note the calibration check on the calibration sheet for single rigid sensors. If the results do not meet the acceptance criteria repeat the comparison using a 'slush bath'. If the results are not acceptable return out of specification sensors to Ellab for calibration.

The RH and flex sensors are not calibration checked as these are only used once per year.

6.4   TrackSense Pro Battery Management

Note: Only Ellab high performance batteries may be used.

6.4.1   The batteries for the loggers are identified by a number. Each battery will be assigned to a specific logger and must only be used in that logger. This logger/battery list is available in the electronic Ellab folder on the 'I' drive and is updated when new batteries are assigned to loggers. The batteries are only removed from the loggers if they are to remain unused for 4 weeks or longer.

6.4.2   The high performance lithium battery for TrackSense Pro loggers is designed for use within a temperature range of –80°C and +150°C. When new or if unused for 4 weeks or more the battery must be placed in an activator unit for 1hour, but no longer, which prevents draining the battery, prior to use with the TrackSense Pro loggers. The diagram on the activation unit itself shows the required orientation of the battery within the unit.
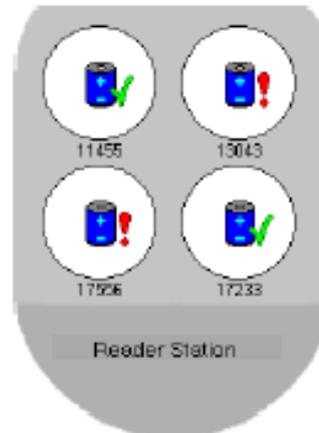
Activator Unit and battery

6.4.3   It is possible to test the battery before running a session.
Right click on one of the logger positions marked blue and select **Battery Test.**
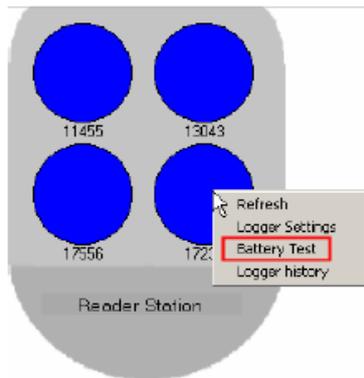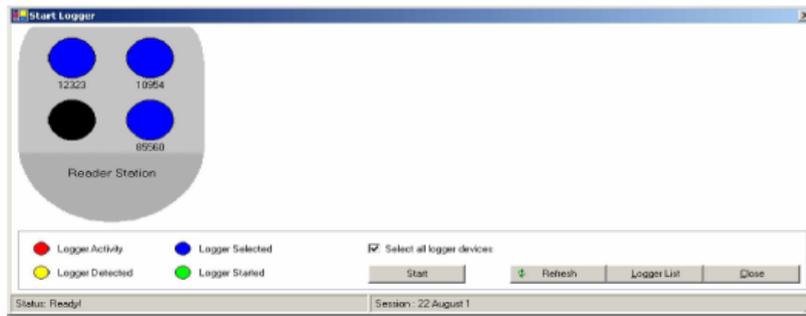
The test takes one minute and a bar indicates the time consumption.

The test result may look like below.
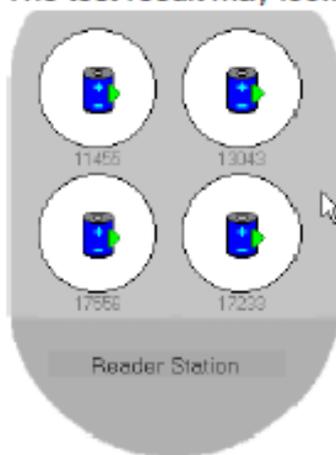
Waiting symbol

Battery Status:

The battery condition is excellent!

The current battery is fully operational.

Checkmark indicates battery status is acceptable.

Battery Status:

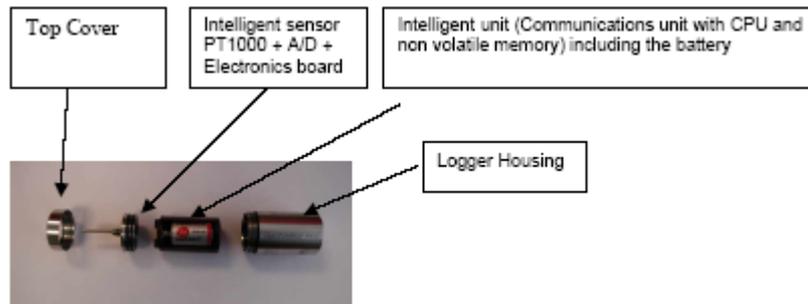The battery is empty!

The current battery must be replaced.

17556

Battery Status:

The battery status is unknown!

The battery test could not be done!

10857

When finished, continue with starting loggers or click **Close.**
Please change battery if the status is low or critical.

6.5   The TrackSense Pro logger system

   6.5.1   The TrackSense Pro logger system consists of four parts.

| Top Cover | Intelligent sensor PT1000 + A/D + Electronics board | Intelligent unit (Communications unit with CPU and non volatile memory) including the battery |

Logger Housing

   6.5.2   First disassemble the logger by unscrewing the top cover and removing
            the logger unit and sensor, if present, from the logger housing, using the
            tool provided. Check the battery is the correct number assigned to that
            logger and is inserted in the correct orientation i.e. facing the base).
            (See 6.4.1)

6.6   How to position the tool to unscrew the logger
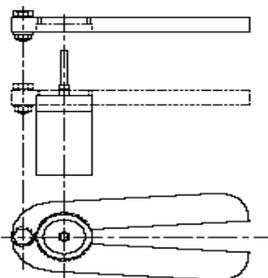
6.7   How to position the tool to release the Sensor
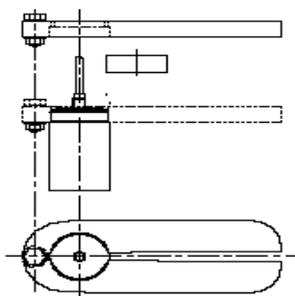
6.8   Assembling the logger

    6.8.1   Add the battery to its housing unit (ensuring correct battery orientation).

    6.8.2   Fit the sensor by carefully connecting the male and female connectors at the base of the sensor and the top of the logger. Take care not to damage the connector pins. Ensure the serial number on the logger unit and the logger housing are the same. Slip this unit into the logger housing by gently pressing the sensor down until the O-rings at the sensor base are no longer visible.

    6.8.3   Add a very thin coating of the supplied lubricant to the O-rings. Screw on the top cover finger-tight. Never use tools to do this and do not over-tighten, as this might damage the threads.

6.9   Maintenance of Loggers and Sensors

- Do not use the probes outside the measuring range listed in the technical specification.

- The loggers are to be stored with the batteries removed if not used regularly.

- The loggers and sensors are to be kept clean and stored in boxes in a cool dry area.

- The loggers and sensors are sensitive electronic equipment and must be treated with care.

- Frequently lubricate the O-rings with silicone and when necessary change the O-rings.

NOTE: If a defective sensor is connected to a logger, the logger will start the first time it is used without an error message. An error message will appear when the logger is next read. It is recommended to test new sensors on receipt, to avoid this problem.

6.10   Using the Ellab equipment

    6.10.1   To use the Ellab equipment to run a session refer to SOP:VL:016.NIBT To Run a Session using Ellab TS Pro Probes.

6.11   Corrective Action

A list of possible error messages and actions are listed below

TS Pro Error Codes from the ValSuite 2.8 Edition User Manual page 375-380
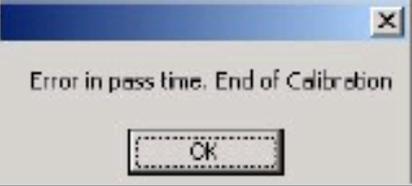
Info.	Error message	Action	Output
Message Start	"Invalid data in logger memory"	If the error persists, please send the logger for factory inspection.	*Start logger [YES] / [NO]*
	"Invalid data in logger memory"	If the error persists, please send the logger for factory inspection.	Start logger [YES] / [NO]
	"Invalid data in sensor memory"	If the error persists, please send the logger and sensor for factory inspection.	Start logger [YES] / [NO]
	"Hardware error in logger memory"	If the error persists, please send the logger for factory inspection.	Start logger [YES] / [NO]
	"Hardware error in logger memory"	If the error persists, please send the logger for factory inspection.	Start logger [YES] / [NO]
	"Hardware error in sensor memory"	If the error persists, please send the logger and sensor for factory inspection.	Start logger [YES] / [NO]
	"Low battery warning"	Battery voltage has become low and the battery should be replaced. If the battery has been replaced this warning will disappear after the next logger start.	Start logger [YES] / [NO]
	"Low battery critical warning"	Battery voltage has become extremely low and the battery MUST be replaced now. If the battery has been replaced this warning will disappear after the next logger start.	Start logger [YES] / [NO]
	"Hardware error in logger clock"	If the error persists, please send the logger for factory inspection.	Start logger [YES] / [NO]

Info.	Error message	Action	ValSuite Output Button
Message start	"Incomplete measuring cycle"	Remove battery, reinsert after 10 seconds. If the error persists, please send the logger and sensor for factory inspection.	Start logger [YES] / [NO]
	"Hardware error in sensor"	If the error persists, please send the logger for factory inspection.	Start logger [YES] / [NO]
	The application or DLL C:\WINDOWS\System\OLE2.DLL is not valid Windows image. Please check this against your installation diskette.	Install USB drivers in to the PC.	[OK]
	Only VISTA error: Access to path: C:ProgramData\ELLAB \Device.TrackSensePro. StartLoggerSettings.xml is denied	In User Account, Unclick Use User Account Control (UAC) to help protect your computer.	[OK]
	"Sensor exposed to maximum temperature limit applied for this sensor. Physical damage could have occurred!"	This warning will disappear after the next logger start.	Start logger [YES] / [NO]
	"Sensor exposed to maximum temperature limit applied for this logger. Physical damage could have occurred!"	This warning will disappear after the next logger start.	Start logger [YES] / [NO]
	"Sensor exposed to maximum temperature limit applied for this product. Physical damage could have occurred!"	This warning will disappear after the next logger start.	Start logger [YES] / [NO]
Message Read	"Invalid data in logger memory"	Logger session invalid, no data will be transferred to data file. If the error persists, please send the logger for factory inspection.	[OK]

Info.	Error message	Action	ValSuite Output Button
Message Read	"Invalid data in logger memory"	Logger session invalid, no data will be transferred to data file. If the error persists, please send the logger for factory inspection.	[OK]
	"Invalid data in sensor memory"	Logger session invalid, no data will be transferred to data file. If the error persists, please send the logger and sensor for factory inspection.	[OK]
	"Hardware error in logger memory"	Logger session invalid, no data will be transferred to data file. If the error persists, please send the logger for factory inspection.	[OK]
	"Hardware error in logger memory"	Logger session invalid, no data will be transferred to data file. If the error persists, please send the logger for factory inspection.	[OK]
Message Read	"Hardware error in sensor memory"	Logger session invalid, no data will be transferred to data file. If the error persists, please send the logger and sensor for factory inspection.	[OK]
	"Low battery warning"	Battery voltage has become low and the battery should be replaced.	[OK]

Info.	Error message	Action	ValSuite Output Button
Message Read	"Low battery critical warning, logger stopped!"	Battery voltage has become extremely low and the battery MUST be replaced now. Logger session partly invalid, only data collected before low-battery condition will be transferred to data file.	[OK]
	"Hardware error in logger clock"	Logger session invalid, no data will be transferred to data file. If the error persists, please send the logger for factory inspection.	[OK]
	"Incomplete measuring cycle"	Logger session invalid, no data will be transferred to data file. Remove battery, reinsert after 10 seconds. If the error persists, please send the logger and sensor for factory inspection.	[OK]
Message Read	"Hardware error in sensor"	Logger session partly invalid, only data collected up to the violation will be transferred to data file.	[OK]
	"Sensor serial number mismatch. Sensor has been replaced since logger start or sensor / logger could be defective."	Logger session partly invalid, only data collected up to violation will be transferred to data file.	[OK]

Info.	Error message	Action	ValSuite Output Button
Message Read	"Sensor exposed to the maximum temperature limit applied for this sensor. Physical damage could have occurred, logger stopped!"	Logger session partly invalid, only data collected up to violation will be transferred to data file.	[OK]
	"Sensor exposed to the maximum temperature limit applied for this logger. Physical damage could have occurred, logger stopped!"	Logger session partly invalid, only data collected up to violation will be transferred to data file.	[OK]
	"Sensor exposed to the maximum temperature limit applied for this product. Physical damage could have occurred, logger stopped!"	Logger session partly invalid, only data collected up to violation will be transferred to data file.	[OK]
	Algorithm Id = 5, is NOT supported ! (no. match found / not defined)	Contact Ellab to buy a newer version of ValSuite to support all logger types or firmware update.	[OK]
	An Error occurred when reading the logger(s).Please re-read logger.	Re-read loggers again if logger whit out the RF module. **Coved logger's with RF module:** Due not read logger again, the data is OK.	[OK]
Transfer / Auto transfer Message	Session already exists (session name)	The files are already in the database you shout at.	[OK]
	Unable to open connection to database Name\ELLAB.	You need to disable windows firewall, see control panels / security center.	[OK]

Info.	Error message	Action	ValSuite Output Button
SKY open	When start online mode Error message: No Data Series found session.	No SKY logger is started.	[OK]
Calibration error	Error in pass time. End of Calibration OK	Control water bath is stable, control stirring is on.	[OK]
Error when add validation report	Boodlan error.	Reinstall .NET, used ValSuite installation CD	[OK]
Session open error	Session Open	See chapter 9.6.2 Reset Access Status.	[OK]

6.12   LIMITATIONS OF THE EXAMINATIO

Not Applicable

7   **RESULTS**

Not Applicable