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York and Scarborough Teaching Hospitals NHS
Foundation Trust R&I Department
Standard Operating Procedure
DAISY/ IRAS 343550

Feasibility study to demonstrate patient acceptability and system performance of DAISY in the Emergency Department.

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise.

If you are reading this in printed form check that the version number and date below is the most recent one.

SOP Reference:	DAISY/IRAS No:343550
Version Number:	3.0
Author:	Anna Waine
Implementation date of current version:	6th May 2025

Approved by:	Name/Position:	Dr Ol'Tunde Ashaolu, Chief Investigator
	Date:	1st May 2025
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	1st May 2025

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	10th February 2025		
2.0	19th March 2025		
3.0	6th May 2025	Ol'Tunde Ashaolu Claire Brookes	Technical support telephone numbers and e-mails added. Signpost to technical issues log added. Contact numbers removed and request to refer to contact list in ISF added. Amendments made to reflect new location of DAISY system following ED move.

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1 Introduction, Background and Purpose

The purpose of this standard operating procedure (SOP) is designed to assist the "Interaction Observer" in process, procedure, and safety of DAISY – Diagnostic AI System for robotic and automated triage and assessment in the Emergency Department (ED) or Urgent and Emergency Care Centre (UECC). This is SOP is applicable to all those performing the following:

- Switch on Process
- Patient Interaction
- Post patient interaction

2 Who Should Use This SOP

It is the responsibility of the all staff who are consenting participants and/or performing the role of Interaction Observer for the DAISY study to adhere to this SOP and to ensure it is communicated to other clinical staff undertaking this role. This includes the Chief/Principal Investigator, Research Nurses, Research Practitioners, Clinical Trial Assistants, Urgent Care and Emergency Centre Team and other appropriately delegated staff. All training on this SOP should be documented in a study specific training log held by the Research Team.

3 When this SOP Should be Used

This SOP should be followed when preparing the DAISY system, consenting patients to the study, observing patients undergoing assessment by the DAISY system, in between patients' assessments and at the end of each session.

4 Procedures

4.1 Switch-on process:

- .The security code for the Clinical Research room is 54321.
- The DAISY robot must be switched on at all times. **Please DO NOT turn it off.**
- The tablet, android phone, SATS monitor, thermometer and BP machine are left out ready. The laptop is kept in the lockable drawer unit.
- Switch on the iPad using the top left button.
- Swipe up on the iPad screen and select the Purple Planet icon at the bottom of the screen.
- Select the NHS Daisy icon on the taskbar. The mode should always remain in "real" mode – developer mode should only be used on a spare tablet.
- Switch on the android phone using the power button on the right, below the volume button.
- Switch on the blood pressure machine using the power button at the back.

- Ensure that there is sufficient paper roll in the machine. Spare paper rolls are kept in the lockable drawer unit. To change the roll, push the button to the right of the paper roll dispenser and lift the cover. Take out anything that is left and replace it with the new roll. Pull out an inch of paper. Close the cover until it clicks.
- Ensure that there are plenty of cap covers available for the thermometer. Spare cap covers are kept in the lockable drawer unit.
- Ensure that there is a bin available near the thermometer for easy disposal of the cap covers by the participants.
- Switch on the laptop. The DAISY screen should appear.
- Wipe down all equipment including the machines, buttons, thermometer, inside the blood pressure cuff and all monitors using clean surface technique.
- Ensure posters are put up in the waiting room to advise patients that they may be approached for Research.

4.2 Patient Interaction:

- A Patient Information Sheet should be given to eligible patients who present to the Scarborough UECC or ED to read.
- A member of the research team will approach the patient to discuss the study.
- If the patient declines to participate, this must be documented on the screening log. If the patient offers a reason why they do not wish to take part this should also be documented on the log.
- If the patient is interested in participating in the study the research team should inform the UECC or ED reception and ensure that the patient is flagged so that they can be easily contacted if they are called to see the ED or UECC team.
- The patient should be taken to the Clinical Research room
- The patient will be consented in accordance with GCP by a researcher who is delegated to receive consent for the study.
- Make a note of the start time in the space provided on the Observer Feedback form.
- Using the laptop click on the “Welcome to Daisy” command. Daisy will welcome the participant, ask their first name and instruct them to press the green button on the tablet screen to begin the assessment.
- Allow the patient to work through the Daisy assessment.
- If the patient appears to need assistance, you should click the “Help” command on the laptop. Any interaction between observer and patient must be recorded on the Observer Feedback Form with an explanation.
- Make a note of the finish time in the space provided on the Observer Feedback form.
- At the end of the assessment click on the “Thank you” command on the laptop.

- Ask the patient to complete the Patient Feedback Form.
- Add the patient ID number (from the iPad screen) to the CRF **and** the ICF.
- Thank the patient for taking part and escort them back to UECC or ED waiting area.
- If during the assessment the patient withdraws consent or is called back to the UECC or ED waiting area visit should be terminated and this must be documented on the Observer Feedback Form and the enrolment log.

4.3 Once the patient has left the room:

- Ensure that the paper record of the BP result is retained and stapled to the CRF.
- Complete the Observer Feedback Form.
- Update the screening log and complete the recruitment log.
- Wipe down all equipment including the machines, buttons, thermometer, inside the BP cuff and all monitors using clean surface technique.

4.4 At the end of each day:

- Switch off all equipment, **except for DAISY**, which is to be left on.
- Remove posters from the waiting room area.
- Ensure that the door to the clinical research room is locked.
- Ensure all research paperwork is gathered and stored appropriately.

4.5 Data back-up arrangements

- Data collected by Daisy will be backed up at least once a week using a data cable to connect from the tablet to the laptop. As additional data storage security, this encrypted data will also be transferred and backed up on to a secured USB data stick. The USB data stick and the laptop will remain in the locked drawer in the lockable room where Daisy is located.

5 Related SOPs and Documents

For additional equipment instructions please refer to printed instructions for usage on the individual machines.

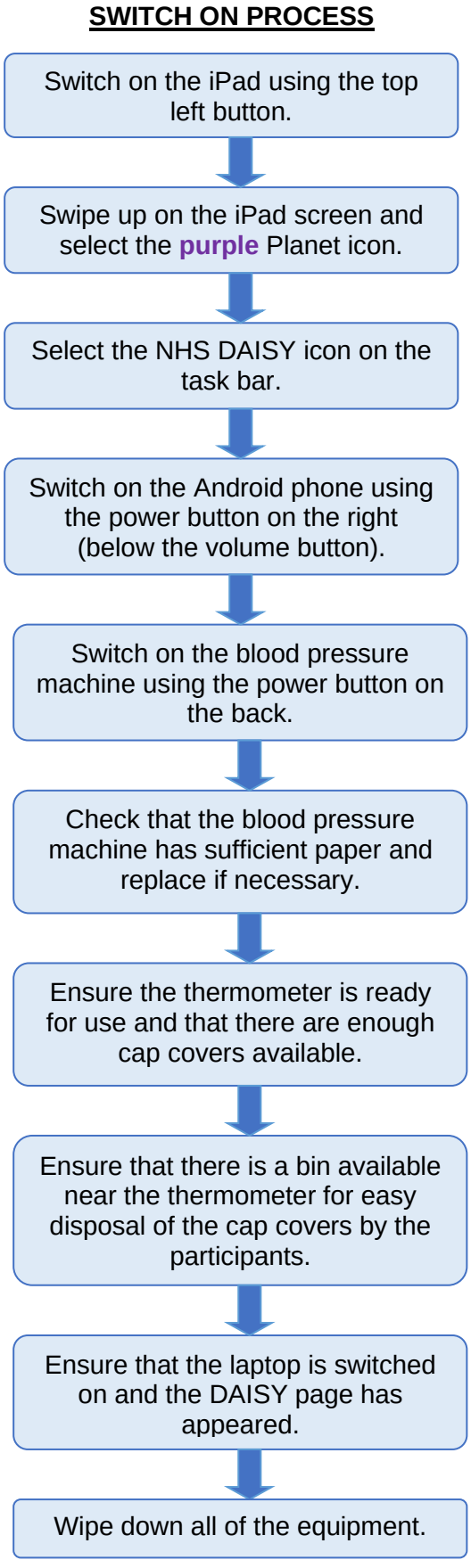
6 Technical support for DAISY

Should you encounter any technical issues with the DAISY system, please attempt to close down and re-open the iPad. The system may take some time to come back online. However, if this is unsuccessful, in the first instance, please contact Dr Tunde

Ashaolu. *Please refer to the contact details sheet found in the ISF for appropriate contact numbers*

Any technical issues should be logged on the DAISY technical issues log which is located in the site file (Section 13) in the Clinical Research Office, 3rd floor Woodlands House.

3. Appendix A- Switch on process



4. Appendix B- Study Visit