Participant Information Sheet

Long title of study: An evaluation of clinical usability-related safety of Adaptive Templates Fitting System (ATFS) to support prosthetic socket design.

Short title: Clinical usability evaluation of an Adaptive Templates Fitting System for socket design.

We would like to invite you to take part in this two-stage research study. Before you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve.

Please take your time to read the information below carefully and ask questions if anything is not clear, or if you would like more information before you decide to take part in the study. You may like to discuss it with others, but it is your choice whether to take part. If you are happy to participate you will be asked to sign a consent form by the Clinical Investigation team.

What is the purpose of the study?
Prosthetic socket comfort and fit is important in ensuring people can get the greatest benefit from their prosthetic limb. Researchers from the University of Southampton and Radii Devices Ltd (a spin-out company from the University of Southampton) are developing a new tool intended to support you in the design of prosthetic sockets. Based upon analysis of historical fitting data including previous socket designs, various limb shapes, and clinical outcomes, we are developing adaptive 'templates'. Our aim is to deliver a more evidence-based approach to reach optimal socket fit and comfort, faster. The findings from this study will be used to develop software that, at the end of this study, can then be used in clinic.

The Adaptive Templates Fitting System (ATFS), developed with Opcare, suggest rectifications for a new patient based on previous socket designs that led to comfortable outcomes for patients with similar demographics and limb characteristics. The templates are a sequence of rectification visualisations that can be ignored or adjusted in shape/size as required and then applied, prior to subsequent free-form design changes.

The objective of this study is to evaluate the clinical usability of the Adaptive Templates Fitting System. This will be achieved by first understanding the strengths and limitations of the ATFS usability when used in-clinic to inform further development. The second stage of this study will be to test the in-clinic usability of the developed ATFS to support prosthetic socket design. Design time

data will also be captured to compare with the standard socket design process that represents your routine practice at your clinic.

Why have I been invited?
You have been invited to take part in the study because you are a prosthetist working at the Bristol Opcare NHS Prosthetics Clinic, which is part of this study.

To take part in the study, you also need to meet the following criteria:

- You are working with patients over 18 years old with a transtibial amputation who require a new socket.
- You are willing to design a socket using the Adaptive Templates Fitting System.

Exclusion criteria:

- Not familiar with using CAD software technologies for socket design.
- You are unwilling to design a socket using the Adaptive Templates Fitting System.

This study will be carried out in two stages:

- **Stage One** of this study will explore the strengths and weaknesses of the Adaptive Templates Fitting System and any unanticipated issues. This testing will be iterative and will overlap with the development of training materials and the software itself.
- **Stage Two** of this study will test the in-clinic usability of the final developed Adaptive Templates Fitting System. Data will also be captured to compare times taken for design using the Adaptive Templates Fitting System versus the standard TracerCAD software used for socket design in your clinic.

We would like to know about your experiences of designing sockets using the ATFS, as well as comparisons against your usual TracerCAD design workflow used in your prosthetics centre. We are also interested to know your views on any barriers or facilitators to using the ATFS in-clinic. Listening to your views and experiences will give us important insight that will help to guide development of the software.

Do I have to take part in the study?
No, you do not have to take part in this study. It is up to you to decide.
Please ask any questions to your clinic lead for this study (Jack Kitchen – Bristol NHS Opcare prosthetics services clinic, jack.kitchen@nbt.nhs.uk) or the study researchers (contact details are provided on the last page). Then if you are happy to take part, we will ask you to complete a consent form to show your agreement to participate.

What will taking part involve?
There are two stages to this study, and you can take part in both Stages One and Two, or just Stage One, or just Stage Two.

You will be invited to attend an in-person training session at your clinic carried out by the study researchers to introduce you to the Adaptive Templates Fitting System and guide you through an example case. The objective of the training session will be to ensure you feel comfortable to use the software as an aid in designing a socket for a patient. You will also receive a printed and electronic 'Quick Reference Guide' and be shown the in-software information videos.

Stage One:
The patient pathway will not change for this clinical investigation. During the study we will ask you to do the following:

- When you have an eligible patient (over 18 years old, with transtibial amputation requiring a new socket) who has consented to participating in the study, you will capture their residual limb shape as normal (with a 3D scanner) during the assessment appointment.
- You will then access the Adaptive Templates Fitting System, via a web-browser, with details provided by the study research team.
- You will upload the limb shape file and use the software to support designing a socket for your patient.
- You will be asked to think aloud while using the Adaptive Templates Fitting System.
- You will be recorded as you use the software, and a member of the study research team will be available to help where required. Recording will be via screen-capture with audio.
- You will then send the designed socket file for manufacture as per your clinic's normal process.

As per normal care, later you will:

- Carry out a fitting appointment for the patient, taking and recording standard outcome measures (e.g. socket comfort score, Key Performance Indicators (KPIs) for their clinic, etc.).
- Discuss the socket fit with the patient and make minor/major socket adjustments as required - using the Adaptive Templates Fitting System software, or just your usual socket design software, where digital adjustments are needed, leading to delivering the definitive socket for the patient. The study research team will be on-call to help where required.
- Be asked to share socket comfort scores taken during any fitting appointments with the study research team.

The study research team will arrange to conduct a 30-minute semi-structured interview with you after delivery of the definitive socket to the patient, about your

experience creating a socket using the Adaptive Templates Fitting System. You will have the choice of an in-person, virtual, or telephone interview.
Training materials on using the Adaptive Templates Fitting System will also be evaluated through the semi-structured interviews.
For the iterative development of the software being carried out at this stage, you may be asked to carry out Stage One at least once more.

Stage Two:

You will be asked to design a socket for an eligible patient using the Adaptive Templates Fitting System. You will use the Adaptive Templates Fitting System **independently** while being recorded but without thinking aloud. Recording will be via screen-capture with audio. You will then send the designed socket file for manufacture as per your clinic's normal process.

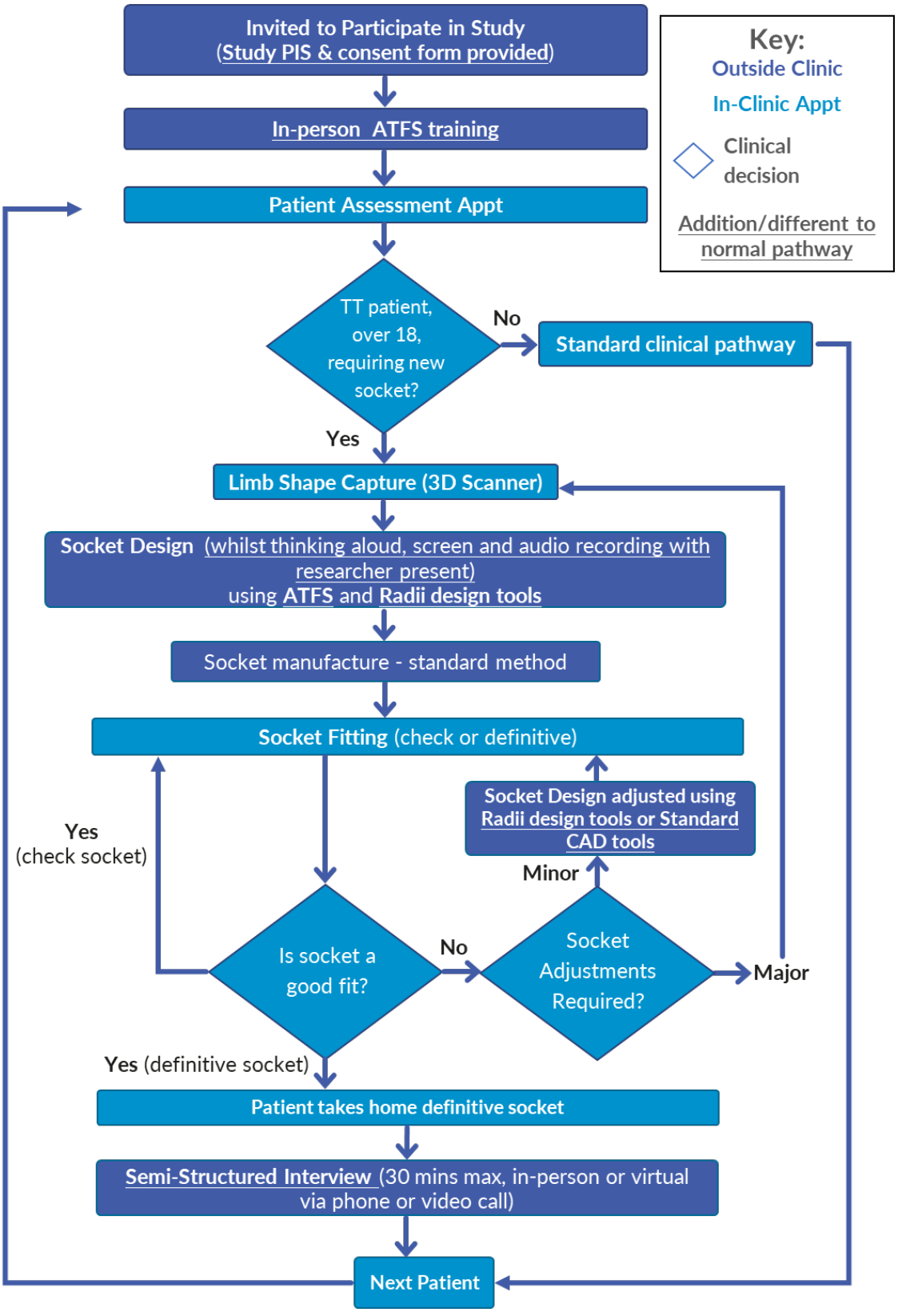
As in Stage One, as per normal care, later, you will carry out a fitting appointment for the patient, taking and recording standard outcome measures (e.g. socket comfort score, Key Performance Indicators (KPIs), etc.). You will discuss the socket fit with the patient and make minor/major adjustments as required - using the Adaptive Templates Fitting System software where digital adjustments are needed, leading to delivering the definitive socket for the patient. The study research team will be on-call to help, if required. You will be asked to share socket comfort scores taken during any fitting appointments with the study research team.

The study research team will arrange to conduct a 30-minute semi-structured interview with you after delivery of the definitive socket to the patient, about your experience independently designing a socket using the Adaptive Templates Fitting System, as well as your views on comparisons against your standard TracerCAD design workflow. You will have choice of a one-on-one, virtual, or telephone interview.

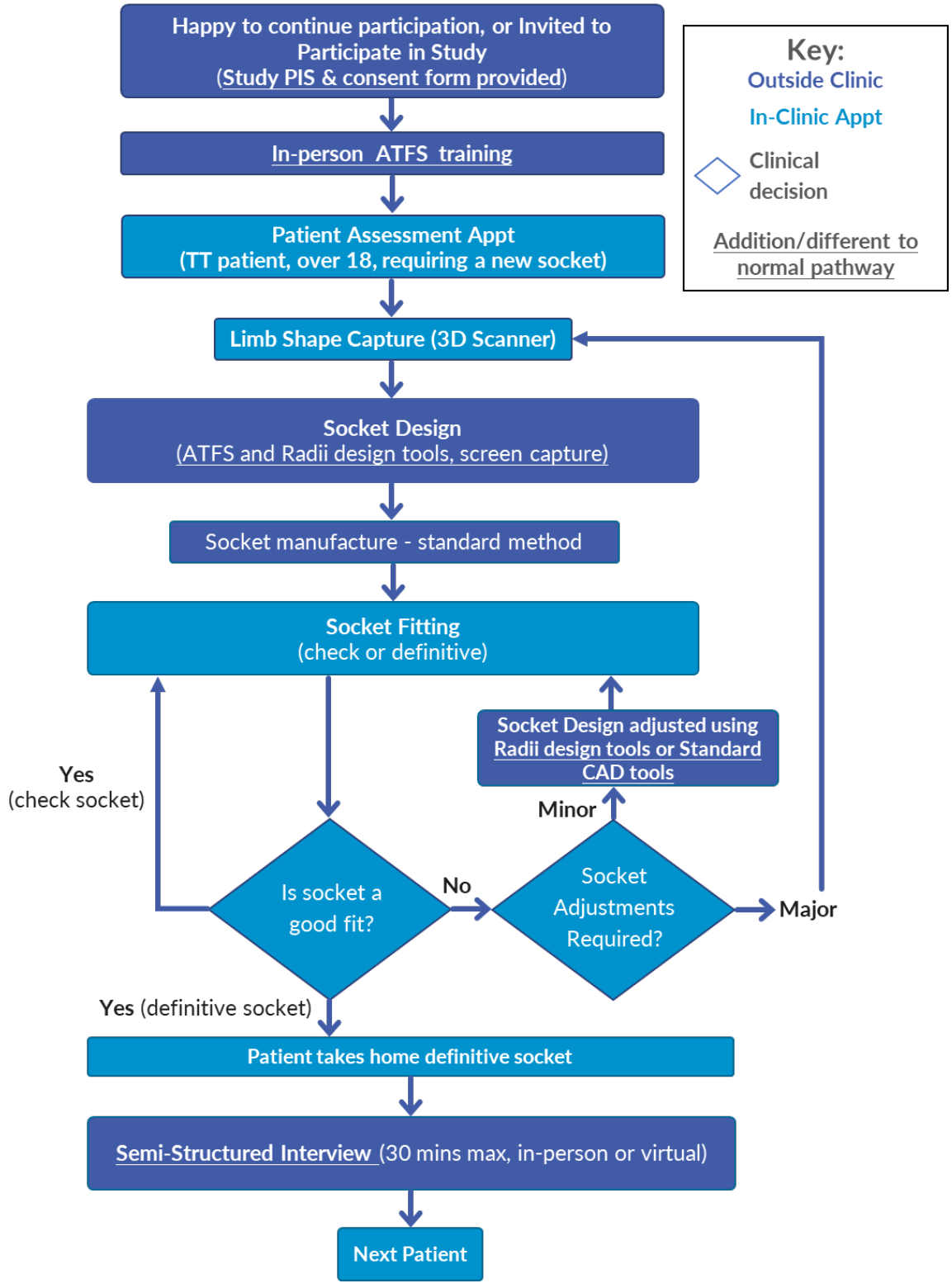
Follow-up care for participating patients to address any concerns following their fit/delivery appointment will be through existing normal standard of care pathways, i.e., planned review appointments or the patients contacting the clinic directly.

Flow charts showing what will happen during this study:

Stage One (Formative) testing - 081222



Stage Two (Summative) testing - 081222



What are the possible benefits of taking part?

There are no direct benefits from taking part in the study other than being able to use the Adaptive Templates Fitting System to support your socket design. However, if you do take part, you will be contributing to advancing knowledge

regarding digital socket design, and informing further development and clinical integration of the Adaptive Templates Fitting System.

What are the possible harms of taking part?
We aim to minimise your time involvement by having only two to three 30-minute interviews in total throughout the 6-month study, and the booking of these can be flexible to work around your schedule. Aside from this time cost we do not anticipate any elevated harms from taking part.

What will happen if I decide not to take part?
You do not have to take part in this study. If you decide not to take part you will not be affected in any way.

What will happen if I don't want to carry on with the study?
It is very important for you to understand that your participation is voluntary and you may withdraw from the study at any time, without giving any reason. Your withdrawal will not affect your legal or any other rights in any way. If you wish to withdraw please contact the study researchers using the details provided below.

What if there is a problem?
If you have a concern about any aspect of this study, the study researchers will answer your questions. If you remain unhappy and wish to speak to someone else, you can contact Jenny Bramley (Radii Devices, Clinical Lead), your clinic lead for this study (Jack Kitchen, jack.kitchen@nbt.nhs.uk), or other contacts provided on the final page.

Will my taking part in this study be kept confidential?
Your personal information will remain anonymous, and we will not share your information with any other organisation or party outside of the study research team and/or relevant NHS Trusts. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All these people have a duty to keep your information, as a research study participant, strictly confidential.

You will be assigned a participant number so that no data can be linked to you directly. Any information that we gather in relation to this study will be kept strictly confidential. All documents will be identified by code number (and not by any of your personal identifiable information) and kept securely, either under lock and key or via encrypted and password protected computers (in accordance with the General Data Protection Regulation and the UK Data Protection Act, 2018).

Anonymised direct quotations will be used for the software development and regulatory approval, and may be used in future publications for the purpose of sharing the research.

Encrypted recording devices will be used as you use the ATFS Software, when you are thinking aloud, and during the interviews. Recordings will be anonymised at-source and file-naming. A transcription service officially approved by the University of Southampton (collaborating on this study) will transcribe the recordings. There is a written agreement of confidentiality (SLA) between the transcription service provider and the University of Southampton. Once transcribed, your recording will be deleted from the recording device. The transcription data will be transferred to the study team via a secure, password-protected system.

Upon your consent, photographs may be taken during the use of the ATFS for the purposes of reporting the clinical investigation research findings publicly and for marketing the ATFS.

If you lose ability to give consent, you will be withdrawn from the study and identifiable data already collected with consent will be retained and used in the study. No further data will be collected, or any other research/study activities carried out in relation to you.

Radii Devices Ltd is the sponsor for this study and will act as the data controller, which means they are responsible for looking after your data and using it properly. It is expected that the anonymised collected data will be stored in the repository of Radii Devices Ltd for at least 10 years after the study. This repository is highly secure to protect the stored data. All files will be kept in compliance with the Company's Data Protection Guidelines prior to being deposited in the repository. More information on Radii Devices Ltd Data Protection Privacy Notice can be found here:
https://www.radiidevices.com/privacy

How will we use information about you?
We will need to use information collected about you for this study. This information will include your name and contact details. Your information will be used only during the study. To safeguard your rights, we will use the minimum personal-identifiable information possible.

People who do not need to know who you are will not be able to see your information. If you withdraw from the study, we will keep the information about you that we have already obtained with consent. No further information will be collected about you.
We will write our reports in a way that no one can work out that you took part in the study.
If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. You can find out more about how we use your information by asking one of the study research team members.

What will happen to the results of the research study?
If you wish, we will send you a summary of the findings of the full study upon completion. Post-analysis anonymised data will be used in publications and presentations to display the work, and to inform further development of the Adaptive Templates Fitting System. You will not be identified in any report or publication. If you would prefer your data to not be included in research publications at any time during or after the study, please inform the study researchers. After transcription, your recordings will be destroyed. However, once the data have been analysed we will be unable to withdraw your contribution.

Where can you find out more about how your information is used?
You can find out more about how we use your information
by asking one of the research team members, or by emailing Jenny Bramley, Radii Devices Clinical Lead (jenny@radiidevices.com).

Who is organising the research?
Radii Devices Ltd are the sponsor of the study, partnering with the University of Southampton **(ERGO 81419)** and Opcare Ltd. In the interests of transparency, involved academics Prof Alex Dickinson and Prof Peter Worsley are academic co-founders of Radii Devices Ltd and declare a small shareholding.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC) to protect your safety, rights, wellbeing and dignity. The London-Dulwich Research Ethics Committee has given a favourable opinion of the study. This has also been reviewed by the Medicines & Healthcare Products Regulatory Agency (MHRA), as it focussed on the evaluation of a medical software application, **IRAS 317901, REC reference 24/LO/0126**.

Further information and contact details:
For further information about this project please contact the study researchers detailed in this information sheet, or if you would like to find out more about being involved in the study, please contact:
Jenny Bramley, Radii Devices Clinical Lead Researcher
(jenny@radiidevices.com)
Or, if you are unhappy about anything to do with the study, please contact:
Jenny Bramley (Radii Devices, Clinical Lead Researcher):
Jenny@radiidevices.com
Professor Alex Dickinson (University of Southampton)
alex.dickinson@soton.ac.uk
NHS Trust R&D contact: Malcolm Dixon, 0117 414 9330, research@nbt.nhs.uk