Policy/Procedure Name:	AT Bespoke Equipment Procedure		
Policy/Procedure Number:	ICT 006		
Date of Approval:	20th		
Effective Date:	October 2018		
Revised Date:	October 2020		
Review by Date:	October 2022		
Policy/Procedure Author:	Head of Assistive Technology		
Policy/Procedure Owner:	Head of Technology		
Management Committee Approved By:	SMT		
Governor Committee (where appropriate) Approved By:	Not applicable		
For Action By:	All staff		
For Information to:	All students and parents		
Approval requested to upload on the Treloar Website:	Yes ☐ (tick if requested)		
Who is carrying out EIA?	SMT	Date of EIA?	23rd Oct 2018
Have we shown due regard for the 9 protected characteristics within the policy/procedure?	Yes ☑ No ☐		
Are all opportunities to promote equality taken within the policy/procedure?	Yes ☑ No ☐		
Refer Policy/Procedure to EDI Co-ordinator for further assessment	Yes o No ☑		

1. Procedure Aim

To ensure that Medical Devices legislation is followed with regard to bespoke equipment made by Assistive Technology
To enable students to have access to suitable adapted equipment across the Treloar campus and during off campus activities (as required)

2. Policy/Procedure Details

2.1 Medical Devices Legislation

The manufacture and distribution of medical devices is regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). This will continue post Brexit, with new legislation expected in 2023.

According to the Medical Devices Directive (MDD), a medical device is described as any instrument, apparatus, appliance, software, material or other article used alone or combined for humans to:

- diagnose, prevent, monitor, treat or alleviate disease
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- investigate, replace or modify the anatomy or a physiological process
- control conception

Adaptations or engineering solutions made by Treloar Assistive Technology (AT) are often classed as Medical Devices because they alleviate or compensate for an injury or handicap.

Assistive Technology is not registered to make mass produced medical devices, but complies with the legislation by manufacturing custom-made medical devices. It is also able to make some more generic devices 'in-house', meaning that they cannot be used outside of the Treloar campus.

2.2 Custom Made Devices

A custom made device is defined by the Medical Devices Regulations 5 (1) as:

- manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification, which gives under his responsibility, specific characteristics as to its design and
- intended for the sole use of a particular patient

The majority of devices and adaptations made by Treloar AT fit into this category. The therapist's referral into AT and any further details they provide are the prescription for the device.

Commonly requested custom made devices include:

- adaptations to Sam Hall turners
- desk extensions
- transfer boxes with/without turntables

- wheelchair armrest extensions

On making a custom-made device, AT will:

- Complete a risk assessment
- Label the device according to the MHRA standards with:
    - the name or trade name and address of the AT department
    - the details strictly necessary for the healthcare professional to identify the device e.g. the full student name, and AT reference number
    - the words 'custom-made device'
- Label the device with a unique Treloar TIN number and record this and the device details on the equipment log in Sharepoint
- Create a record on Caresys in YPP - Equipment and Medical Devices
- Provide an equipment instruction sheet and attach that to the above Caresys record

2.3 Re-issuing Custom Made Devices

Custom made devices can only be re-issued to a different student with a new referral (prescription) to AT.

On receiving a referral stating that a specific AT made device meets the needs of a different student, AT will:

- Check the device and complete any required maintenance
- Review the risk assessment
- Label the device according to the MHRA standards with:
    - the name or trade name and address of the AT department
    - the details strictly necessary for the healthcare professional to identify the device e.g. the full student name, and AT reference number
    - the words 'custom-made device'
- Check the device has a Treloar TIN number and update the allocation details on the equipment log in Sharepoint
- Create a record on Caresys in YPP - Equipment and Medical Devices
- Provide an equipment instruction sheet and attach that to the above Caresys record

Re-issuing any custom made device without following this procedure is a breach of the MHRA regulations.

2.4 In-house Devices

In-house manufacture refers to medical devices that are made in a healthcare establishment to be used for patients within that establishment. These are exempt from the MHRA regulations.

Within the Treloar environment, that means that devices such as shared transfer boxes, can be made by AT and used on the Treloar campus only. These should be labelled accordingly and only be used when identified as needed on a student's Young Person's plan or during assessment/treatment in a therapeutic setting; thereby following good practice standards.

These devices cannot be used off campus – i.e. at Alton College or on community based trips. A custom made box for that individual should be requested if needed.

2.5 Maintenance of Devices

AT will provide appropriate maintenance, repairs or replacements to adaptations and devices they have made when requested by a student or a member of their multidisciplinary team.

High risk devices, such as those supporting moving and positioning, will be checked by AT once yearly. This will be done in line with the Clinical Services annual review of care needs so as to coincide with a therapeutic review confirming the device still meets the student's needs.

In the event that the device needs repairing or replacing, AT will check with the treating therapist that this is still required (confirming the prescription) and then complete this work.

2.6 Use of Custom Made Devices After Leaving Treloar's

As standard, AT makes custom made devices to be used within the Treloar environment. This is reflected in the instruction sheet and risk assessment.

Small, low risk adaptations (e.g. minor adaptations to wheelchairs, switch mounts) can be taken with students when they leave Treloar's. The instruction sheet for the device will be included in the student's leavers pack, and includes the contact details for the AT department should any queries or issues arise.

High risk adaptations, including any involving moving and positioning of students, cannot be taken with students when they leave Treloar's. This ensures that they are only used in the specific environment assessed for by the prescribing therapist.

Should the student's new treating therapist feel they need the same adaptation or medical device, they should refer to AT through the Outreach pathway.

Treloar's therapists or MDT members should contact AT for clarification if they are unsure whether a bespoke device or adaptation should be taken when the student leaves.

2.7 Audit

There is already a Medical Devices Audit process within Treloar's. This includes bespoke adaptations/solutions made by AT as they are recorded on the Sharepoint equipment register.

In addition, the Assistive Technology department will complete an annual visit to:

- Each residential house
- A sample of classrooms
- A sample of shared bathroom facilities

A member of the team will inspect a sample of devices in use within the specified area and check against the Sharepoint equipment register and the student's record on caresys.

3. Implications of Policy/Procedure

3.1 Training Requirements

No further training required.

3.2 Communication Requirements

How will the Policy/procedure be communicated:	Sharepoint Team meetings School and College briefings
Who will ensure the above communication is carried out::	Head of AT (Hannah Golding) Heads of Therapy (Susan Bryan, Vicky Pitt, Sally Mosely) Residential Managers Head of School Deputy Head of College
Do the changes made to this policy/procedure affect any other policies/procedures? If yes, has this been communicated to the policy/procedure author/owner	No

3.3 Inclusive communications

If you require this document in an alternative format, such as large print, audio description or a colour background, please contact Jo Cox at jo.cox@treloar.org.uk

4. Monitoring and Review

This policy will be monitored through the audit process described in section 2.6, and reviewed by the Head of Assistive Technology.

5. Links to other related policies, procedures or documents (internal)

Policy and procedure for the management and decontamination of medical devices & other equipment – AT bespoke adaptations/solutions are still classed as medical devices and therefore should be maintained and decontaminated in accordance to this policy.

6. References

MHRA guidance on custom made devices:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/398428/Custom_made_devices.pdf
Published August 2013

Medical devices – how to comply with the legal requirements:
https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements

Published August 2013

In-house manufacture of medical devices:
https://www.gov.uk/government/publications/in-house-manufacture-of-medical-devices/in-house-manufacture-of-medical-devices
Published Sept 2014

7. Revision History

Listed below is a brief audit trail, detailing amendments made to this policy procedure in last 4 years

Page/para No.	Brief description of the change(s)	Change made by	Date
2/2.1	Updated to include note of expected change to national legislation	Hannah Hunt	05.10.2020

IMPORTANT NOTES:

It is essential for those with designated responsibilities to familiarise themselves with the sources of information, referred to above.

Policy documents describe mandatory minimum standards and will be subject to audit and review. Line managers are required to ensure suitable and sufficient arrangements are in place to meet policy requirements, including the provision of information and instruction to staff.