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| Policy/Procedure Name: | AT Bespoke Equipment Procedure | | |
| Policy/Procedure Number: | ICT 006 | | |
| Date of Approval: | October 2018 | | |
| Effective Date: | October 2018 | | |
| Revised Date: | April 2026 | | |
| Review by Date: | April 2029 | | |
| Policy/Procedure Author: | Assistive Technology Manager | | |
| Policy/Procedure Owner: | Finance and Resources Director | | |
| Management Committee Approved By: | TLT | | |
| 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 ϒ (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 þ | | |

## 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).

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

Assistive Technology is not currently registered to make medical devices, but is able to make small adaptations or non-medical devices.

### 2.2 Modifying Devices

The Medical Device Regulation 2002 apply whenever a device has been modified to such an extent that it can be considered as a new device. The modifications could include:

- deviations from the instructions for use that alter the function, performance or purpose of the device
- modifying a device for a new purpose
- altering the sample types, accessories or components or combining devices not specified by the manufacturer

The modification and use of the device should be verified against the original device when used as intended by the manufacturer to demonstrate and document whether the function, performance or purpose has been altered. Where a modified device is treated as a new device, the entity that modifies the device will be regarded as the manufacturer and will need to comply with the MDR 2002.

In accordance to the above, Assistive Technology will not make adaptations that make any equipment a new device.

### 2.3 Maintenance of Devices

Prior to legislation changes, AT was able to make bespoke devices. AT will continue to 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 is recorded on the Medical Devices Log.

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.

### 2.4 Use of Custom Made Devices After Leaving Treloar's

Prior to legislation changes, AT made custom devices to be used within the Treloar environment. This was reflected in the instruction sheet and risk assessment.

Small, low risk adaptations that are not medical devices (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.

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.

### 2.5 Audit

There is 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.

A member of the team inspects each device in use within the specified area to ensure it is in safe working condition, and records against the Sharepoint equipment register.

## 3. Implications of Policy/Procedure

### 3.1 Training Requirements

No further training required.

### 3.2 Communication Requirements

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| How will the Policy/procedure | Sharepoint<br>Team meetings<br>School and College briefings |

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|---|---|---|
| be communicated: | | |
| Who will ensure the above communication is carried out: | AT Manager<br>Heads of Therapy<br>Residential Managers<br>Head of School<br>Head of College | |
| Do the changes made to this policy/procedure affect any other policies/procedures?<br>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

Medical devices – how to comply with the legal requirements:
https://www.gov.uk/guidance/medical-devices-how-to-comply-with-the-legal-requirements
Updated Jan 2025

In-house manufacture of medical devices:
General information on the Health Institution Exemption - GOV.UK
Updated Jan 2026

## 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 |
| 3.2 | Removal of staff names | Jane Hayden | 17.01.2023 |
| Whole document | Full update with regard to changes in legislation | Hannah Hunt | 29.04.2026 |
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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.