Medical Devices Training and Monitoring

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Introduction

BCUHB Medical Device Training Policy (MP03) outlines the strategy for ensuring all relevant staff are suitably trained in the safe use of medical devices.

Medical Devices encompass equipment used for diagnosis, treatment, prevention and monitoring in healthcare.

The departmental Audiology Standard Operating Procedure (SOP) was rolled out in July 2022.

This presentation outlines the elements that make up that SOP.

Standard 2.9 of the Health and Care Standards for Wales (2015)

- *"all health service settings should have an on-going program of medical device competency training"*

MP02: BCUHB Medical Device and Equipment Management Policy (2020)

- *'all staff are expected to undergo suitable medical device training and that managers ensure that staff are appropriately trained and competent with medical devices used'.*

MP03: BCUHB Medical Device Training Policy (2022)

- *"sets out a 'risk based approach' to staff training: ie. that training should be in proportion to the risk of harm from user error. This approach is aimed at maximising the benefit to patients, and optimizing the support to staff"*

BCU Audiology Medical Devices Training SOP (2022)

- *"outlines the strategy that should be adopted by Secondary Care and Area Teams to ensure that all relevant staff are suitably trained in how to use medical devices safely and effectively for the benefit of patients in their care."*

Green/Low Risk: These devices are those devices that are unlikely to cause any serious consequences, meaning the user can continue in a safe and sensible manner, referring to the manufacturer's instructions as needed.

Amber/Medium Risk: These devices would have significant impact in patient care or cause temporary adverse health consequences should they be misused or fail. The device must only be operated by a user who is deemed competent in the use of the device following a formal written self-assessment, to be completed every 3 years. The user must take advice and instruction from a senior, knowledgeable colleague, and read the manufacturer's Instructions For Use if they have any queries about the device.

Red/High Risk: These devices are those that have the potential to cause serious adverse consequences or death should they be misused or fail. Any high-risk device carries a 'STOP' element, meaning that the device MUST NOT be used unless the user has received formal training to do so.

Equipment Risk Assessment

Equipment was risk assessed by departmental Health & Safety and Equipment Teams.

Classification was based on the Risk Classification System defined in policy MP03. This is different to the routine 5 x 5 matrix Risk Assessment.

Under these definitions the majority of Audiological equipment was classified as **LOW** risk.

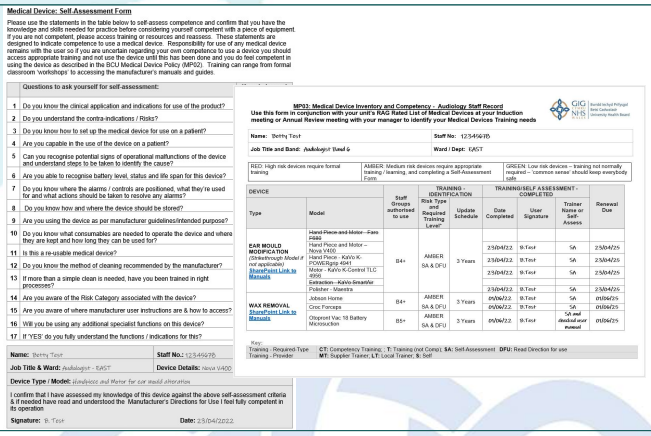
A few devices were assigned **MEDIUM** risk.

Self-Assessment Checklist and Staff Compliance Record

Staff complete a Self-Assessment Checklist for each Amber/Medium Risk device every 3 years.

An Individual Competency Record form summarises each staff members competency and this is reviewed annually at PADR.

Links to electronic equipment manuals available on Microsoft SharePoint are on the Individual Competency Records for ease of reference.



Medical Device: Self Assessment Form

Please use the statements in the table below to self-assess competence and confirm that you have the knowledge and skills needed for practice before considering yourself competent with a piece of equipment. If you are not competent, please access training or resources and reassess. These statements are designed to indicate competence to use a medical device. Responsibility for use of any medical device remains with the user so if you are uncertain regarding your own competence to use a device you should access appropriate training and not use the device until this has been done and you do feel competent in using the device as described in the BCU Medical Device Policy (MP02). Training can range from formal classroom 'workshops' to accessing the manufacturer's manuals and guides.

	Questions to ask yourself for self-assessment:
1	Do you know the clinical application and indications for use of the product?
2	Do you understand the contra-indications / Risks?
3	Do you know how to set up the medical device for use on a patient?
4	Are you capable in the use of the device on a patient?
5	Can you recognise potential signs of operational malfunctions of the device and understand steps to be taken to identify the cause?
6	Are you able to recognise battery level, status and life span for this device?
7	Do you know where the alarms / controls are positioned, what they're used for and what actions should be taken to resolve any alarms?
8	Do you know how and where the device should be stored?
9	Are you using the device as per manufacturer guidelines/intended purpose?
10	Do you know what consumables are needed to operate the device and where they are kept and how long they can be used for?
11	Is this a re-usable medical device?
12	Do you know the method of cleaning recommended by the manufacturer?
13	If more than a simple clean is needed, have you been trained in right processes?
14	Are you aware of the Risk Category associated with the device?
15	Are you aware of where manufacturer user instructions are & how to access?
16	Will you be using any additional specialist functions on this device?
17	If 'YES' do you fully understand the functions / indications for this?

Name: Betty Test | Staff No.: 123456/B

Job Title & Ward: Audiologist - EAST | Device Details: Nova V400

Device Type / Model: Handpiece and Motor for ear mould alteration

I confirm that I have assessed my knowledge of this device against the above self-assessment criteria & if needed have read and understood the Manufacturer's Directions for Use I feel fully competent in its operation

Signature: B. Test | Date: 25/04/2022

MP03: Medical Device Inventory and Competency - Audiology Staff Record

Use this form in conjunction with your unit's RAG Rated List of Medical Devices at your induction meeting or Annual Review meeting with your manager to identify your Medical Devices Training needs

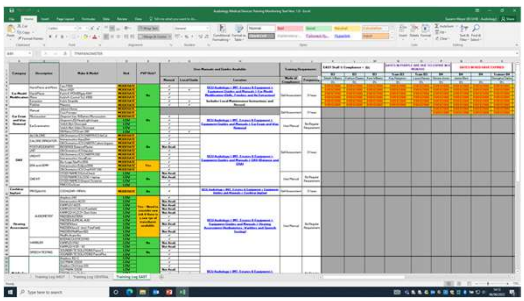
Name: Betty Test | Staff No.: 123456/B

Job Title and Band: Audiologist Band 6 | Ward / Dept.: EAST

RED: High risk devices require formal training | AMBER: Medium risk devices require appropriate training / learning, and completing a Self-Assessment Form | GREEN: Low risk devices – training not normally required – 'common sense' should keep everybody safe

DEVICE		Staff Groups authorised to use	TRAINING - IDENTIFICATION		TRAINING/SELF ASSESSMENT - COMPLETED			
Type	Model		Risk Type and Required Training Level	Update Schedule	Date Completed	User Signature	Trainer Name or Self-Assess	Renewal Due
EAR MOULD MODIFICATION (Breakthrough Model if not applicable) SharePoint Link to Manuals	Hand Piece and Motor – Kaltenbach & Voigt Nova V400	B4+	AMBER 5A & DFU	3 Years	25/04/22	B.Test	5A	25/04/25
	Hand Piece - KaVo K-POWERgrip 4041 Motor - KaVo K-Control TLC 4995 Extraction - KaVo SmartAir				25/04/22	B.Test	5A	25/04/25
					25/04/22	B.Test	5A	25/04/25
	Polisher - Maestro				25/04/22	B.Test	5A	25/04/25
WAX REMOVAL SharePoint Link to Manuals	Jobson Horne	B4+	AMBER 5A & DFU	3 Years	09/04/22	B.Test	5A	01/04/25
	Croc Forceps				09/04/22	B.Test	5A	01/04/25
	Otoprint Vac 10 Battery Microsuction	B5+	AMBER 5A & DFU	3 Years	09/04/22	B.Test	5A and checked wax removal	01/04/25

Key: Training - Required Type | Training - Provider | CT: Competency Training; T: Training (not Comp.); SA: Self-Assessment DFU: Read Direction for use | MT: Supplier Trainer; LT: Local Trainer; S: Self



Compliance Monitoring

The Monitoring Tool Spreadsheet is used to track service level compliance

The Monitoring Tool returns individual staff % compliance, as well as automatically highlighting competencies that have either expired or are due to expire in the next 6 months.

It also monitors overall service % compliance which is reported via Governance functions up to Trust Level Leadership.

Implementing a process for training and monitoring the use of medical devices is essential to ensure good governance and to comply with national guidance.

References:
NHS Wales (2015) Health and Care Standards. Available at: Health standards framework english (gov.wales)

Gwasanaeth Awdioleg Gogledd Cymru
North Wales Audiology Service

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Betsi Cadwaladr University Health Board