Acacium Group

Safe Use of Medical Devices Policy

Policy Reference | CLIN 12

Version | V2.1

Policy Name	Safe Use of Medical Devices Policy
Purpose of Document	To inform all Acacium Group workers of their responsibilities in regard to the safe usage of medical devices/equipment in order to ensure compliance with national policy and procedure.
Target Audience	All Acacium Group workers
Version	V2.1
Author	Karen Matthews-Shard
Date of Approval	January 2014
Published Date	January 2014
Lead Director	Karen Matthews-Shard
Review Frequency	3 yearly
Last Reviewed	February 2024
Next Review Date	February 2027
Risk and Resource Implications	
Associated Strategies and SOPs	CLIN 03 Medicines Management Policy CLIN 07 Infection Prevention and Management Policy CLINE 14 Health Records Management CORP11 Risk Management Strategy ORG 04 Incident Reporting Policy
Equality Impact Assessment (EIA) Form	Acacium Group is committed to Equality, Diversity and Inclusion and in line with our values, we strive to ensure that everyone that is part of the Acacium community is not disadvantaged or discriminated against given their individual need or characteristics. To support this, an Equality Impact Assessment has been undertaken on this policy/procedure. This information is held centrally and can be requested from the Clinical Governance Team.
About Acacium Group	Details of all Acacium Group trading companies that this policy applies to are detailed within Appendix A
Legislation	Legislation and Guidance pertinent to this policy can be found within Appendix B

Document History			
Version	**Date**	**Changes made/comments**	**By whom**
V1	Oct 2017	Annual review.	KMS/SJ
V1	Mar 2018	Updated front sheet to include new review frequency date. Changed reference list format.	KMS/MS
V1	May 2018	Updated 'CAS' to 'Safety alerts'	LW
V1.1	Nov 2018	Updated in relevance to training	KMS/SJ
V1.2	Jan 2020	Updated to new Policy	CCR
V1.3	Feb 2021	Clinical Advisory Group review	CAG
V1.3	Oct 2020	Update re Rebrand	CCR/CC
V1.4	Jan 2021	Update re Rebrand	CC
V1.5	Feb 2021	Clinical Advisory Group review	CAG
V1.6	Apr 2021	Added CHS brand	CC
V2.0	Jan 2024	Rebrand	Clinical Advisory Group
V2.1	Feb 2024	Reviewed and updated	Clinical Advisory Group

Table of Contents

1. Introduction

1.1 The Policy sets out how medical devices/equipment should be managed within Acacium Group. This document defines the scope of the Policy, definitions, responsibilities, accountability and the procedures for effective management.

1.2 Medical device (equipment) is any instrument, apparatus, appliance, material or other article, whether used alone or in a combination. This includes the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment or alleviation of a compensation for an injury or handicap.
- Investigation, replacement or modification of the anatomy or of physiological process.
- Control of conception and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

2. Purpose and Policy Statement

2.1 The purpose of this Policy is to inform all Acacium Group workers of their responsibilities in regard to the safe use of medical devices/equipment in order to ensure compliance with national policy and procedure.

2.2 This Policy aims to provide service users (inclusive of patient and client) and their families with confidence in how Acacium Group ensures that the devices/equipment they use is well maintained, checked and safe to use, as well as ensuring all workers are competent to use them.

2.3 The use of medical devices/equipment can influence the quality of care given to the service user. The use of such devices/equipment can present risks for the service user and Acacium Group workers. It is important to have robust policies and procedures in place to ensure the effective management of medical devices/equipment.

2.4 All Acacium Group workers are expected to comply with this Policy and local policies of clients at all times and in all places of work.

Acacium Group nurses and carers who are unsure at any time of what action to take should contact their Line Manager immediately for advice.

3. Scope of Policy

3.1 The Policy has been developed to demonstrate how Acacium Group addresses its obligations in meeting the legal requirements of the Safe Medical Devices Act 1990, guidance issued by the Medicines and Healthcare products Regulatory Agency (MHRA), and the NHS Improvement

3.2 The Policy applies to any medical device used within Acacium Group for the provision of care.

3.3 This Policy is to be followed by ALL workers working for Acacium Group.

4. Definitions

Term	Definition
Policy	A high level, overall statement of intent, embracing general principles and the steps the organisation expects to be followed in order to achieve them. Policies are enforceable and failure to comply may result in disciplinary action.
Procedure	A formal set of steps to follow in order to achieve specific outcomes, which are specifically agreed for designated workers. Any deviation from the steps is acceptable if this can be justified and the rationale for doing so documented appropriately.
Competence	Should be acquired through general professional training, attending educational workshops, observation and supervised practice in the clinical setting. Competence can be examined by questioning knowledge, observing practice and reflective practice journal.
Registered Practitioner	Refers to nurses, midwives, and specialist community public health nurses who are registered on the Nursing and Midwifery Council Register
Carers	A trained care worker who has relevant and current experience.
Healthcare Professionals	All Acacium Group workers that provide clinical care
Medical Devices/Equipment	The Medicines and Healthcare products Regulatory Agency (MHRA), defines a medical device as "any instrument; apparatus; appliance; material or health care product; (excluding drugs), used for a service user for the purpose of; diagnosis, prevention, treatment or alleviation of disease, monitoring, treatment or alleviation of or compensation for, an injury or disability investigation; replacement or modification of the anatomy or a physiological process; control of conception. See **Appendix A** for an illustrative list of medical devices/equipment. This list is provided to help Acacium Group personnel understand what medical devices/equipment are but is not exhaustive.
Clinical Audit	Evaluation of clinical performance against standards or through comparative analysis, with the aim of informing the management of services.

5. Roles & Responsibilities

5.1 **Organisational**

5.1.1 **Workers training and continuing professional development**

5.1.2 Acacium Group will provide service user specific on the job training and assessment of competence on any medical devices/equipment to be used in the service user's home as part of the individual's shadow shifts in the service user's home. This will be an essential requirement upon commencement of employment with Acacium Group and as part of the service user specific training provided on shift in the home. Acacium Group workers are also expected to attend any formal training which is specific to the devices/equipment they use. The training will be proportionate, and relevant to the roles and responsibilities of each staff member.

- Take part in voluntary training, including attending updates so that they maintain their skills and are familiar with procedures
- Ensure they provide appropriate information and training about the use of medical devices/equipment to service users to ensure effective daily use.

- Training needs have been identified and acted on

5.1.3 Acacium Group requires all staff to participate in on the job training in the safe use and management of medical devices/equipment to ensure they are competent, have reached an agreed standard of proficiency and are certificated as competent to use the device unsupervised. This will form part of the training required to work with a specific service user. The training will be proportionate, and relevant to the grade, roles and responsibilities of each staff member. The delivery of training is the responsibility of the operational teams. The MHRA stipulates that "before a medical device is issued to a service user or carer they should receive training in how to use the device". This should be supported by written guidance which will be in the Care Plan. The manufacturer's instructions should provide some information, but this should be tailored to the needs of the individual service user or carer.

5.2 **Supervision and support**

5.2.1 Acacium Group recognises the importance of providing supervision and support to workers.

5.3 **Safe recruitment and vetting procedures**

5.3.1 Acacium Group has in place robust recruitment and vetting procedures for all workers, in line with national and local guidance. This includes thorough checks being carried out as part of the recruitment process. Gaps in employment history are checked and accounted for. Qualifications are also checked, with references always taken up, and followed up, if necessary.

5.3.2 All workers will also be subject to periodic checks during their assignment.

5.4 **Robust complaints procedures**

5.4.1 Acacium Group has in place robust complaints and whistleblowing procedures. Acacium Group guarantees that workers and service users using these procedures appropriately will not prejudice their own position, and prospects.

Role	Responsibility
Global Clinical Director/Group Chief Nurses	Responsible for ensuring that all policies, standard operating procedures (SOPs), protocols, training, and competencies, are in place to support workers or care in the safe delivery of safe and effective care provision.
Nominated Divisional Lead	The lead is responsible for ensuring that medical device alerts are produced on Datix and for ensuring that Acacium Group personnel have actioned any appropriately.
The Operations Board:	Ensure that the Directors have management, and accountability, structures that deliver safe and effective services.
Team leaders and senior nurses / managers:	• demonstrate leadership, be informed about and take responsibility for the actions of their workers • maintain the confidentiality of all service users in their care • ensure that workers report incidents • ensure their workers access voluntary training, supervision, and support, relevant to their roles and responsibilities • check that equipment is maintained in good operational condition • report any defects or deficiencies to the commissioning organisation

	• ensure their workers are clear about their professional roles and responsibilities • ensure their workers keep comprehensive and accurate records • facilitate and / or undertake regular audits of practice • ensure that safe use of medical devices/equipment is identified in appraisal and Personal Development Plans
Individual workers members:	• Be aware of Acacium Group policies, procedures, and guidance, for the safe use and management of medical devices/equipment to ensure compliance with them • Take part in voluntary training, including attending updates so that workers maintain their skills and are familiar with procedures • Ensure they provide appropriate information and training about the use of medical devices/equipment to service users to ensure effective daily use • Abide by any workers group's professional standards • Check that equipment is maintained in good operational use • Report any defects or deficiencies to the commissioning organisation via the Line Manager • All practitioners, registered and non-registered, should access regular supervision and support in line with local procedures • All workers should maintain accurate, comprehensive and legible records, with records being stored securely in line with Acacium Group policy.
Clinical Advisory Group (CAG)	Review polices associated documents and training content for the Group. To support high clinical standards and quality improvement agendas in line with the Groups vision, strategic aims.

6. Assessment of Risk

6.1 Assessment of risk and planning are integral to safe use and management of medical devices/equipment. All Acacium Group workers will be expected to contribute to these processes. This is not a laborious process.

7. Choice of Medical Device

7.1 As medical devices/equipment are commissioned from local health services, Acacium Group may have limited access to the device of their choice. However, Acacium Group may be able to influence the decision in regard to what to use. Below are the main three points for Acacium Group to consider:

- Technical Support – what level of aftercare does the company offer
- Reliability – have other organisations used this model or have the MHRA published an evaluation of it
- Maintenance costs

8. Conformity Assessment Mark

8.1 The United Kingdom Conformity Assessment Mark, or UKCA Mark for short, is a replacement for the CE Mark.

8.2 With the UK having left the EU, the CE Mark will cease to be a valid indicator of conformity with UK Product Safety Regulations.

8.3 The link below will give an overview and specific details in the different areas that this relates to and how the legislation applies in Great Britain.

https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk

8.4 **Summary of key requirements for placing a device on the Great Britain market**

8.4.1 Since 1 January 2021, there have been a number of changes, introduced through secondary legislation, to how medical devices/equipment are placed on the market in Great Britain (England, Wales and Scotland). These are:

- CE marking will continue to be recognised in Great Britain until 30 June 2023
- certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
- the EU no longer recognises UK Notified Bodies
- UK Notified Bodies are not able to issue CE certificates (other than for the purposes of the "CE UKNI" marking, which is valid in Northern Ireland) - and have become UK Approved Bodies
- a new route to market and product marking is available for manufacturers wishing to place a device on the Great Britain market
- since 1 January 2021, all medical devices/equipment, including in vitro diagnostic medical devices/equipment (IVDs), placed on the Great Britain market need to be registered with the MHRA.

https://www.technologyinternational.co.uk/ukca-mark-regulations?gclid=EAIaIQobChMIz7X1sIOF7wIVyweICR1yfw0OEAAYBCAAEgIqPvD_BwE

9. Who can Decide which Medical Device to Use?

9.1 Acacium Group or the commissioners/service users will decide which is the most appropriate medical device to commission and use. However, where the care to be provided is highly technical, Acacium Group may advise that the decision of what to commission and use should be made by a more highly trained professional.

10. Upon Delivery of Medical Device

10.1 It is important to check the medical device for safety including cleanliness before its use. Acceptance should be based on:

10.2 **The following paperwork checks:**

- Is the device compatible with the specification set out in the original order?
- Has all the relevant information been included; such as user, repair and maintenance manuals, plus all necessary compliance and calibration certificates
- Are the instructions for use appropriate?

10.3 The following visual inspections:

- Is the product clean?
- Is the outer packaging intact and undamaged?
- Is there any damage apparent to the device on inspection?
- Is there a CE marking and is the quantity available as required?

10.3.1 Additionally, the manufacturer's instructions may specify particular testing, calibration or adjustment before a medical device is used for the first time.

10.4 Single use

10.4.1 A medical device that is intended for only one episode of use on one service user only. Note: the international symbol, which is a figure '2', with a diagonal line drawn through it, may be used on medical device packaging to indicate 'Do Not Reuse' and may replace any wording. There are instances where the company may decide to use a 'Single Use Only' item on more than one occasion on the same service user. In such circumstances, a risk assessment will be undertaken, and a local guideline developed to ensure that the service user is not put at risk.

10.5 Single service user use only

10.5.1 medical device that is intended for more than one episode of use on one service user only. The device may go through some sort of processing between each use.

10.6 Re-usable medical device

10.6.1 A medical device that may be re-used on either the same or a different service user after it has been through decontamination processing or reprocessing. Note: some accessories of re-usable medical devices/equipment may be either for single use or single service user only use.

11. Servicing / Maintenance

11.1 The owner of the medical device is responsible for servicing and maintenance. Where appropriate, the following checks will take place. More extensive checks will be performed by specialist workers for complex or specialist equipment:

- Does the device function in line with the manufacturer's information?
- Are accessories or parts included and compatible?
- Is the servicing/calibration in date usually found on a sticker on the device?
- Do indicators and displays function correctly in line with the manufacturer's information when powered up?
- When powered up, does the device start when it should and do the dials, and switches, do what they say?
- Are the mains leads, plugs and other connectors undamaged?
- Where appropriate, use the test device to check:
  - Accuracy of physiological measurements
  - Dose delivery
  - Energy delivery
  - Accuracy of other outputs.

11.2 Tests should be carried out by an adequately trained and appropriately qualified person.

11.3 Within the community setting, the service user's care plans and equipment lists should detail who is responsible for servicing the equipment and the frequency it is required.

11.4 Report any concerns or servicing issues to the owner of the device/equipment

12. Devices/Equipment on Contract from Local Health Services

12.1 Any medical devices/equipment Acacium Group use are provided on contract to the service user from local health services or personally owned by the service user.

12.2 The maintenance contracts with suppliers of equipment remain the responsibility of local health services.

13. Third Parties Knowledge of Devices/Equipment

13.1 There will be times when the families or service users or other third parties will use the medical devices/equipment. In this case, the family, service user or other third party should have undergone training to use the device. If the worker has any concerns, they must report it to the clinical lead. If the equipment fails, they must follow the correct protocol written in the care plan and or contingency and the process of escalation. This needs to be fully documented in the service user's records.

14. Using Equipment for the First Time

14.1 When a piece of equipment needs to be installed, there will be an agreed procedure for commissioning the installation and programming.

14.2 This usually applies when any of the following occurs:

- Substantial assembly work will be required on-site
- There are permanent plumbing, electrical and gas pipeline connections
- The device needs to be permanently fixed in place.

14.3 Under the Medical Devices Regulations, suppliers must provide instructions for installing a device and bringing it into use. Where appropriate, these instructions should include specifications for safety and performance checks.

14.4 The Acacium Group worker providing a person's care, and / or their Line Manager should oversee the commissioning process if present and ensure where reasonably practicable that it has been completed and documented satisfactorily. If in any doubt, they should seek advice from the Line Manager.

15. Using A New Model of Equipment for the First Time

15.1 When a new model is first introduced, or when pre-use functional checks are completed workers should work together to ensure that:

- Checks are successfully carried out and documented
- Users have all the information that they need
- Training needs have been identified and acted on
- Users know how the device works, when functioning correctly.

16. General Safety Requirements

16.1 Medical devices/equipment should only be stored in appropriate ways as defined by the manufacturer.

16.2 No member of Acacium Group personnel should modify or alter the function, or capability, of a medical device without agreement from the supplier or prescriber that this will improve care for the service user, and certainly not cause a reduction in function and therefore care

16.3 Medical devices/equipment are not shared amongst service users. However, the cleaning of medical devices/equipment must be done in accordance with the manufacturer's instructions.

16.4 ***NEVER*** remove a device from the point of care unless it is required to go with the service user on trips or holidays and ***NEVER*** without having undergone full safety checks before and after removal and

before return to the usual environment. When removing for the purposes of trips or holidays, ensure mechanisms are in place in the case of failure and that emergency contact details are available.

16.5 Any member of staff adapting the use of a medical device, i.e. making it suitable for a particular service user without changing the manufacturer's intended use, must undertake a risk assessment where appropriate, which must be recorded in the service user's notes.

17. When Medical Device/Equipment is Found to be Unsafe

17.1 When a worker finds that a piece of Device/equipment is unsafe, it should they should report this to the Nurse in Charge/Line Manager and seek advice and suitable alternative equipment/device.

17.2 Where applicable inform the organisation from which the device is commissioned, requesting a replacement be sought or the equipment serviced.

17.3 Any medical equipment can fail. However, an increasing number of incidents which result in significant morbidity or mortality arise out of user / device interface problems or because of poor practice. Safety alerts highlight problems arising from the use or misuse of medical devices/equipment when health or safety, have been put at risk. These include Medicines and Healthcare Products Regulatory Agency (MHRA) and Department of Health (DOH) notices.

17.4 Where the Acacium Group healthcare professional feels that a serious failure has occurred they should report this as an incident. The Clinical Director may then request that the organisation from which it was commissioned informs the MHRA. To ensure this is not overlooked, the Clinical Director will also inform the MHRA. Ensure the incident report has the product number, serial number and description of device and failure noted.

18. In an Emergency / Out of Office Hours

18.1 Service users, their families and Acacium Group health professionals must have contact details of who to contact in the case of an emergency, such as device failure. This includes outside of office hours and bank holidays.

18.2 If the supplier or organisation that the device was commissioned from fails to act in a way that supports Acacium Group with the provision of care during an emergency failure, an incident must be reported **(see the Incident Reporting Policy) and the service users contingency applied as necessary.**

19. Management of Safety Alerts

19.1 A vital aspect of managing medical devices/equipment safely is the dissemination of safety alerts and actioning them promptly to minimise harm to service users and personnel.

19.2 Acacium Group will cascade relevant alerts via Datix. These will require action by healthcare personnel, their Line Managers and evidence of actions may be required. Actions must be recorded on the Datix system.

20. Medical Equipment Disposal

20.1 All medical equipment must be disposed of in a safe and appropriate manner. The disposal of medical equipment is currently not specifically covered under any legislation. However, it is incumbent on the

company / service user to ensure that any used medical equipment is disposed of correctly following any necessary local regulations or guidelines.

20.2 Equipment will be disposed of using the following method:

- Disposal via the Waste Electronic Equipment (WEE) Regulations (collection by manufacturer, waste collectors)

21. Record Keeping

21.1 All records must be kept in accordance with national requirements, such as the Data Protection Act 2018 (DPA), and Acacium Group 'information governance and record management' policies.

21.2 It is best practice to document the medical devices/equipment used for a service user in their nursing records. The detail and complexity of the records will depend on the type of device and usage during its lifetime.

21.3 Ensure that your records provide evidence of:

- A unique identifier for the device, where appropriate
- A full history, including the date of receipt and, where applicable, when it was put into use, deployed or installed
- Where it was deployed / installed
- Scheduled maintenance
- Maintenance and repairs
- The end-of-life date.

21.4 Records will also show that users:

- Know how to use the device safely
- Users including service users, and their family, can carry out routine checks and maintenance
- Service users and their families have been trained and had relevant refresher training.

22. Reporting Breaches in Policy

22.1 Acacium Group supports the use of a thorough, open and multi-disciplinary approach to investigating adverse events, where improvements to local practice can be discussed, identified and disseminated.

22.2 It is important that an open culture exists in order to encourage the immediate reporting of errors or incidents.

22.3 All errors and incidents require a thorough and careful investigation at a local level. Context, circumstances and the position of the practitioner involved need to be taken into account. Such incidents require sensitive management, and a comprehensive assessment of all the circumstances before a professional, and managerial, decision is reached on the appropriate way to proceed.

22.4 If any Acacium Group worker makes or identifies an error or incident, they should inform their Line Manager or the complaints and incidents team, as soon as possible, after the event.

22.5 All errors (service user safety incidents and information management) and "near misses" should be reported through the Acacium Group incident reporting system.

22.6 The Clinical Director would then make the decision to report the incident to the Medicines and Healthcare products Regulatory Agency (MHRA).

22.7 When considering allegations of misconduct, the Clinical Director and / or Line Manager will identify if the error was the result of reckless or incompetent practice, and / or was concealed. If the error is identified as such, the result may be disciplinary action and external reporting to the professional bodies.

22.8 Acacium Group may still suspend a worker or take local disciplinary action where it is considered to be necessary if errors or incidents are the result of other causes, such as the serious pressure of work, even where there was immediate, honest disclosure in the service user's interest.

22.9 Lessons learnt from errors and incidents will be reviewed by the Governance Committee and disseminated across the organisation.

22.10 Any outcomes from serious untoward incidents (SUIs), where it was demonstrated that Acacium Group could have performed better, will be taken very seriously. Acacium Group will set up their own internal review process and implement the necessary policy changes.

See also 'Section 20 – When equipment is found to be unsafe'.

23. Training

23.1 Acacium Group will enable staff to participate in training as appropriate, in particular, caring for people in an anti-discriminatory way. Where appropriate, this will be included in local induction programmes. The training will be proportionate, and relevant, to the roles and responsibilities of each staff member. The delivery of training is the responsibility of the operational teams. It is the responsibility of the central training team to organise and publicise educational sessions, and to keep records of attendance. All training provided will be mapped to the requirements of individual care packages, the appraisal process and noted in the personal development plan.

23.2 The MHRA stipulates that "before a medical device is issued to a service user or carer, they should receive training in how to use the device." This should be supported by written guidance. The manufacturer's instructions should provide some information, but this should be tailored to the needs of the individual service user or carer. Written guidance should cover the following:

- The name of the device
- The operation and control of the device
- Checking of the device while in use
- Recognition of a device failure or fault
- Action to be taken in the event of a device failure or fault
- Individuals to be contacted in an emergency.

24. Audit / Monitoring

24.1 Acacium Group will regularly audit its safe use of medical devices/equipment practices for compliance with this Policy.

24.2 Processes for monitoring the effectiveness of the Policy include:

- Audits of specific areas of practice
- Evidence of learning across the organisation
- Incident reporting procedure
- Appraisal and Personal Development Plan (PDP).

24.3 The audit will:

- Identify areas of operation that are covered by this Policy

- Set and maintain standards by implementing new procedures, including obtaining feedback where the procedures do not match the desired levels of performance
- Highlight where non-conformance to the procedures is occurring and suggest a tightening of controls, and adjustment, to related procedures
- The results of audits will be reported to the Executive Management Team via the Governance Committee.

25. Associated Policies / SOPs

Policies

CLIN 03 Medicines Management Policy
ORG 03 Health & Safety
CLIN 07 Infection Prevention and Management Policy
CLIN 14 Health Records Management
ORG 02 Risk Management Strategy.
ORG 04 Incident Reporting Policy

26. References

- Provision and Use of Work Equipment Regulations 1998.
- The Medical Devices Regulations 2002.
- Nursing and Midwifery Council, 2015. *The Code: Professional standards of practice and behaviour for nurses and midwives.* NMC.
- MHRA, November 2006. *Device Bulletin: Managing Medical Devices DB2006(05).*
- NHS Bassetlaw, 2009. *Safe use of medical devices.*
- Medical Devices Agency, 2002. *MHRA MDA SN 2002(17): Management of loaned medical devices, equipment or accessories from manufacturers or other hospitals.* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/965010/Managing_medical_devices022021.pdf
- MHRA, March 2011. *Medical Device Alert MDA/2007/001 – Device bulletin: 'Reporting adverse incidents and disseminating medical device alerts.*
- Alerts and recalls for drugs and medical devices - https://www.gov.uk/drug-device-alerts
- https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-medical-technologies-guidance
- https://www.england.nhs.uk/patient-safety/patient-safety-alertshttps://www.hse.gov.uk/work-equipment-machinery/index.htm

Appendix A: About Acacium Group

Acacium Group consists of a number of trading companies, each providing services within core niche areas of the health and social care industries. Therefore, as this document is a Group Policy, the Policy herein applies to all trading companies detailed below:

GP World Part of Acacium Group	pulse Part of Acacium Group	Proclinical Part of Acacium Group
Bank partners	espirita	INGAGE multistaffing | one solution
Liquid Healthcare Part of Acacium Group	Thornbury Nursing Services Part of Acacium Group	Scottish Nursing Guild Part of Acacium Group
Thornbury Community Services Part of Acacium Group	Hobson Prior Part of Acacium Group	maxxima Part of Acacium Group
xyla health & wellbeing Part of Acacium Group	xyla health & social services Part of Acacium Group	xyla elective care Part of Acacium Group
xyla digital therapies Part of Acacium Group	CHS Healthcare Part of Acacium Group	DRA DUNN REGULATORY ASSOCIATES Part of Acacium Group

Appendix B: Legislation

1 The following are the main acts affecting the safe use of medical devices/equipment:

Acts/national policies/guidance	Explanation
Health and Safety at Work Act 1974) HASAWA) and associated legislation	Defines the fundamental structure and authority for the encouragement, regulation, and enforcement, of workplace health, safety and welfare within the UK.
Management of Health and Safety at Work Regulations 1999 (MHSWR)	The main requirement of the Management of Health and Safety at Work Regulations is that employers must carry out risk assessments to eliminate and reduce risks. Employers with five or more employees need to record the significant findings of a risk assessment.
Management of Health and Safety at Work (Amendment) Regulations 2003	As above, with amendments.
'Managing Medical Devices' (MHRA, April 2014)	This guidance for healthcare and social services agencies covers England, Wales, Scotland, and Northern Ireland. It outlines responsibilities for employers and employees in choosing, and maintaining, medical devices/equipment in a safe manner.
Manual Handling Operations Regulations 1992 (MHOR)	These Regulations require employers to minimise the health risks associated with manual handling for example; activities involving lifting, carrying, moving, holding, pushing, lowering, pulling or restraining an object or person.
Reporting of Injuries Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)	Under these Regulations, certain work-related accidents are reportable by law to the Health and Safety Executive (HSE).
Provision and Use of Work Equipment Regulations 1998 (PUWER)	These Regulations set out the minimum standards for the use of all equipment at work.
Workplace (Health, Safety and Welfare) Regulations 1992 (WHSWR)	These Regulations deal with physical conditions in the workplace and require employers to meet minimum standards in relation to a wide range of matters.
MHRA (Medicines and Healthcare products Regulatory Agency)	'Safe use of bed rails': This bulletin identifies areas for safe practices, so that policies and procedures can be reviewed and put in place.
Provision and Use of Work Equipment Regulations (PUWER 1998). **Health and Safety Executive.**	Guidance stating that all equipment provided and used in the course of employment should be checked prior to its first use, and on a regular basis thereafter. The regularity will depend on the device or piece of equipment being used.
Lifting Operations and Lifting Equipment Regulations 1998. (LOLER). Health and Safety Executive	Guidance stating that all equipment used for lifting a person whether a hoist, or any other type of sling used, or lifts in buildings, must be checked by an appropriately qualified person / engineer every six months.
Data Protection Act 2018	Covers all recording, storage and sharing of personal information held on paper files or computer. All personal data must be recorded and shared lawfully. Investigating, assessing and responding to risk to adults are multidisciplinary, joint agency activities. They depend on the selective sharing of information which is normally confidential. Information sharing should comply with the Data Protection Act 2018.

Health and Social Care Act 2008 – updated 2014 (now Care Act 2014)	The relevant part of this Act to the Policy was the introduction of the Care Quality Commission (CQC) which is an integrated regulator for health and adult social care bringing together existing health and social care regulators under one regulatory body. The CQC has new powers to ensure safe and high-quality care for service users.

2 This Policy also respects all laws in relation to equality and diversity. Therefore, it respects the rights and dignity of all adults, children and young people regardless of their age, gender, ethnic origin, culture, faith, ability, or sexuality. People's rights will be positively promoted through service support and delivery.

3 It is important to seek legal advice about specific situations via the Acacium Group Management Team, if required.

4 Latex is classed as a hazardous substance which is covered by the Health and Safety Executive's Control of Substances Hazardous to Health (COSHH) Regulations 2002. Under the regulations, organisations have a duty to assess the risk, eliminate, substitute, and limit and control exposure to latex, unless there is a need to use it.

5 There is a requirement to report diagnosed cases of Occupational dermatitis (schedule 3) to RIDDOR (The Reporting of Injuries, Diseases and Dangerous Occurrences) Regulations 1995.

6 Equality and diversity

Under the Race Relation (Amendment) Act 2000 Acacium Group has a statutory duty to 'set out arrangements to assess and consult on how their policies and functions impact on race equality', in effect to undertake Equality Impact Assessments (EIA) on all policies and SOPs. The Equality Act October 2010 demands a similar process of Equality Impact Assessment in relation to disability. An EAI must be completed by the author of this policy using the checklist provided in Appendix A. See also Acacium Group Equality and Diversity policy.

Appendix C: List of Medical Devices/Equipment

The following list - produced by the MHRA - is not exhaustive, due to technology's constant development, but gives a sense of the wide range of products classed as medical devices/equipment.

- Dressings
- Gastrostomy tubes
- Nebulisers
- Peak flow meters
- Suction equipment
- Syringes and needles
- Sphygmomanometers
- Thermometers
- Urinary catheters
- Pumps, syringe drivers and controllers
- Domiciliary oxygen therapy systems
- Insulin injectors
- Acacium Group oximeters
- Ventilators used in the home
- Blood glucose measuring devices
- Specimen collection tubes
- Urine test strips
- Adjustable beds
- Lifting poles
- Hoists
- Pressures relief equipment
- Stoma care equipment
- Equipment used by people with disabilities
- Bathing equipment
- Commodes
- Hearing aids
- Incontinence aids
- Urine drainage systems
- Walking aids
- Wheelchairs and special support seating
- Feeding pumps
- Urine-testing machines.