IPEM
Institute of Physics and Engineering in Medicine

IPEM Position Statement:

PHOTOTHERAPY, post service maintenance and handover

The IPEM UNISIG have been made aware of multiple incidents of alterations to phototherapy equipment that either affected patient treatment or had the potential to do so. Incidents were enabled by inadequate communication between those carrying out work on ultraviolet phototherapy equipment and the responsible medical physics personnel, normally resulting from an underdeveloped equipment handover process. Instances have included maintenance or repair by manufacturers, routine calibrations, and bulb replacement by external or internal employees.

"The aim is to mitigate against the risk of inadvertent changes in dosimetry caused by inconsistent methods, equipment used or calibrations"

In accordance with British Association of Dermatologists standards, this IPEM statement recommends written local procedures detailing a handover process, and the appointment of a designated medical physicist or staff member trained and authorised by a medical physicist expert in UV protection[1]. The aim is to mitigate against the risk of inadvertent changes in dosimetry caused by inconsistent methods, equipment used or calibrations.

POSITION STATEMENT

SUMMARY RECOMMENDATIONS

1. Phototherapy centres should ensure safe and consistent phototherapy treatments by adopting a handover process to involve their own appointed medical physicist or a suitably trained member of staff with any intervention (Appendix 1).
2. Practical measurements should be undertaken after any interventions that could significantly impact accuracy or uniformity of UV irradiance, prior to acceptance back into clinical use.

PURPOSE OF STATEMENT

The purpose of this statement is to highlight risks posed to ultraviolet phototherapy patients following adjustment of UV sources. If performed outside of the locally agreed governance process, adjustments could lead to unintended consequences, including reduced efficacy of phototherapy treatments or increased likelihood of erythema.

The responsibility for safe treatment of patients is retained by the healthcare provider operating the equipment. This statement sets out recommendations for the management of a handover process that, if adopted, will ensure that any adjustments to phototherapy equipment are made only with the knowledge and authorisation of the designated medical physicist (or a staff member trained and authorised by a medical physicist with expertise in UV protection) employed by the organisation responsible for treating patients and registered with the relevant national care regulator.

APPLICABLE STANDARDS

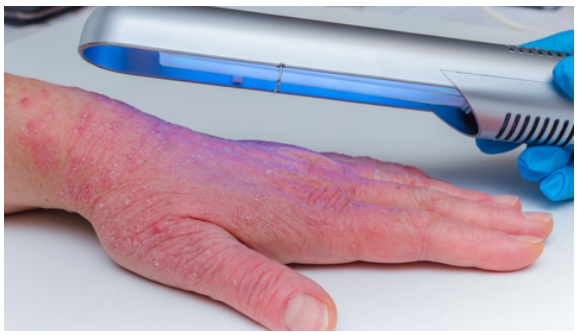
Phototherapy units operating within the UK health care system can reduce risk and harm by meeting standards set out within the British Association of Dermatologists (BAD) NICE accredited guidelines (British Association of Dermatologists 2022). Section 5, 'Equipment and Facilities' sets out responsibilities, including regular calibration traceable to national standards, and regular checks to ensure equipment remains within limits.

The standard is explicit that a Medical Physicist, or appropriately trained staff member, should be designated by each centre. The physicist will oversee measurements and ensure that local treatments are delivered to an acceptable level of accuracy.

RESPONSIBILITIES AND LIABILITIES

There are differences in the retained responsibilities and liabilities of both the manufacturers supplying phototherapy equipment and the phototherapy centre treating patients.

Equipment supplier: Devices purchased for clinical use in UK healthcare settings may be subject to specific manufacturer requirements in terms of dosimetry calibration, with warranties at risk if local calibrations are carried out. Efforts at procurement to establish manufacturer calibration conditions or specific requirements resulting from device approval would be prudent.



"Devices purchased for clinical use in UK healthcare settings may be subject to specific manufacturer requirements in terms of dosimetry calibration"

Employer: The registered healthcare employer retains responsibility for the safe treatment of patients and operation of equipment. Only the healthcare employer will have the information needed to ensure that patients are managed and treated with a known and consistent dose. For example, MED testing with an external device may require linking to the dosimetry of a cabin. A change in the dosimetry circuits of the cabin without consideration of the MED tester could result in unintended consequences in treatment delivery.

Practical implementation: Operators should be aware that there could be a conflict in calibration method and manufacturers expectations if they are involved in post-sale service or maintenance. Healthcare organisations appoint registered healthcare professionals to accept responsibility for the safe treatment of patients. 5A.2 of the BAD guidelines requires that written protocols are in place, and 5A.1 requires that local measurements are undertaken and that changes in dosimetry are understood. Ultimately, the dosimetry of phototherapy equipment is the responsibility of the healthcare organisation operating the equipment. Phototherapists operating the equipment must demonstrate suitable training in the operation of their equipment, including the verification of delivered doses. Measurements after any engineer intervention may be necessary to maintain safety.

HANDOVER PROCEDURE

Any intervention, including external maintenance, should only be undertaken with the knowledge and consent of the phototherapy centre operating the equipment. A handover form for ultraviolet phototherapy equipment is a useful tool in ensuring process and maintaining safety. The principles are that a responsible person(s), the designated medical physicist (or staff member trained and authorised by a medical physicist expert in UV protection), should be informed of the details of an intervention prior to its occurrence. Depending on the intervention being undertaken they may choose to be present. Following intervention, the responsible person (or delegated individual) must approve the reintroduction of equipment into clinical use. They may wish to undertake practical measurements if the intervention could impact the accuracy or uniformity of UV irradiance. A useful document to record this process is the modified AXREM handover form in Appendix 1 (AXREM 2019).

“A handover form for ultraviolet phototherapy equipment is a useful tool in ensuring process and maintaining safety”

REFERENCES

AXREM. 2019. “General Equipment (Non X-Ray) Handover Form.” https://www.axrem.org.uk/resource/general-equipment-handover-form/.

British Association of Dermatologists, BAD. 2022. “Service Guidance and Standards for the use of Phototherapy.” https://cdn.bad.org.uk/uploads/2022/09/14144343/Phototherapy-Guidance-and-Services-Standards-2022.pdf.

APPENDIX

Equipment Handover Form - PHOTOTHERAPY

Part 1: CUSTOMER - Handover of (non-ionising radiation) equipment to Company Representative

FACILITY:	ROOM/AREA: EQUIPMENT:
CALL REFERENCE NO:	COMPANY CARRYING OUT THE WORK:
REASON FOR WORK:	
Identify any known hazards that exist with the equipment or environment such that the company carrying out the work is able to perform the necessary risk assessments.	
If ticked, the customer also hands control of the room / area identified above to the company representative, who may exclude all others from this area as a safety measure.	O

As an authorised representative of the customer, I hereby handover the above equipment / room for the reason stated above.

Customer Representative	Signature	Date	Time

The person named below accepts responsibility for the identified equipment on behalf of the company carrying out the work.
Risk assessments will be performed based on the information exchanged, as identified above, before commencement of work.

Company Representative	Signature	Date	Time

Part 2: COMPANY REPRESENTATIVE -Handover of equipment/room back to Customer

CATEGORYOFWORKCOMPLETED (tick all those applicable)

	Routine service		Modification
	Repair		Hazard (Safety) notice response
	Fault diagnosis		Incident response (e.g. fire, flood)
	Other (please specify)		Upgrade (Hardware or Software)

Equipment Status	O	Equipment operational and ready for handover, subject to appropriate customer acceptance testing.
	O	Equipment ready for handover. Further work required; please refer to the service report for details. Any return to operation should be subject to appropriate customer acceptance testing.
	O	Equipment is not operational. Please refer to the service report for details.

Company Representative	Signature:	Date:	Time:

Important: Please consult your quality management system and / or clinical procedures to determine and perform appropriate checks / tests before returning this equipment to normal use.

Customer	Signature:	Date:	Time:

Part 3: CUSTOMER - Returning equipment to use

I have completed all of the procedures necessary to return this equipment to use.

Equipment returned to use?		Yes O	No O
~~Name~~	Signature	Date:	Time: