PD IEC/PAS 63077:2016

BSI Standards Publication

Good refurbishment practices for medical imaging equipment

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National foreword

This Published Document is the UK implementation of IEC/PAS 63077:2016.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Published by BSI Standards Limited 2016

ISBN 978 0 580 95743 7
ICS 11.040.55

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 November 2016.

Amendments/corrigenda issued since publication

Date	Text affected

IEC PAS 63077

Edition 1.0 2016-11

PUBLICLY AVAILABLE SPECIFICATION

PRE-STANDARD

Good refurbishment practices for medical imaging equipment

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.55

ISBN 978-2-8322-3761-8

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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FOREWORD

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IEC PAS 63077 has been processed by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this PAS is based on the following document:	This PAS was approved for publication by the P-members of the committee concerned as indicated in the following document
Draft PAS	**Report on voting**
62B/1022/PAS	62B/1030/RVC

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INTRODUCTION

Keeping up with the latest innovations in medical technology often involves replacing equipment in medical practice before it reaches the end of its expected service life. This is because innovation cycles for medical technology are much shorter than the functional lifecycle of capital equipment. As a result, a sustainable resource management model is required: early replacement of installed medical imaging equipment by newer technology is more economically feasible if the residual value of the existing medical imaging equipment is utilized.

Conserving assets is a fundamental principle of ecological thinking in a recycling economy. Several medical imaging equipment companies have already set up quality management systems to refurbish used medical imaging equipment and have delivered this refurbished equipment across the healthcare sector for many years. Refurbishment addresses the high demand for affordable and reliable products. Customers of this used equipment are not only small hospitals with limited budgets but also leading medical institutes. The EU and the US represent by far the two largest markets for refurbished medical equipment. Refurbishment of used medical imaging equipment is a well-established element of the healthcare economy.

If used medical imaging equipment is not accurately maintained according to requirements defined by the manufacturer, it may result in additional risk for patients and operators. Consequently, some countries have imposed bans on the importation of used medical imaging equipment to protect public health. These bans fail to distinguish between quality-assured refurbished medical imaging equipment and second-hand medical imaging equipment of undefined quality, with the effect that patients may be denied access to the safe and economical medical imaging equipment they need.

Safety and effectiveness are the most important aspects to consider with medical imaging equipment, including used equipment. To ensure safety and effectiveness, used medical imaging equipment has to be refurbished in a highly specialized and quality-assured way.

GOOD REFURBISHMENT PRACTICES FOR MEDICAL IMAGING EQUIPMENT

1 Scope

This document describes and defines the process of refurbishment of used medical imaging equipment and applies to the restoring of used medical imaging equipment to a condition of safety and effectiveness comparable to that of new equipment. This restoration includes actions such as repair, rework, software/hardware updates, and the replacement of worn parts with original parts. This document enumerates the actions that must be performed and the manner consistent with product specifications and service procedures required to ensure that the refurbishment of medical imaging equipment is done without changing the finished medical imaging equipment's performance, safety specifications, or intended use according to its original or applicable valid registration.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13485:2016, *Medical devices – Quality management systems – Requirements for regulatory purposes*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
expected service life
time period specified by the manufacturer during which the medical electrical equipment or medical electrical system is expected to remain safe for use (i.e. maintain basic safety and essential performance)

Note 1 to entry: Maintenance can be necessary during the expected service life.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.28]

3.2
intended use
intended purpose
use for which a product, process, or service is intended according to the specifications, instructions and information provided by the manufacturer