PD IEC TR 61289:2019

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High frequency surgical equipment and high frequency surgical accessories - Operation and maintenance

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The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical 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 2019

ISBN 978 0 580 99925 3

ICS 11.040.01

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This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2019.

Amendments/corrigenda issued since publication

Date	Text affected

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IEC TR 61289

Edition 2.0 2019-05

TECHNICAL REPORT

colour inside

High frequency surgical equipment and high frequency surgical accessories – Operation and maintenance

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

ISBN 978-2-8322-6885-8

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

HIGH FREQUENCY SURGICAL EQUIPMENT AND HIGH FREQUENCY SURGICAL ACCESSORIES – OPERATION AND MAINTENANCE

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IEC 61289, which is a technical report, has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2011. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) general adaption to IEC 60601-2-2:2017;
b) refinement and additions to the defined terms;

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c) separation of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES;

d) consideration of the HIGH CURRENT MODE;

e) update of symbols.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62D/1652/DTR	62D/1662A/RVDTR

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

– TERMS DEFINED IN CLAUSE 3: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

This document gives guidelines to personnel in charge of operation of equipment covered by IEC 60601-2-2:2017 to enable them to attain the best conditions of safety for their PATIENTS and themselves.

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HIGH FREQUENCY SURGICAL EQUIPMENT AND HIGH FREQUENCY SURGICAL ACCESSORIES – OPERATION AND MAINTENANCE

1 Scope

This document contains guidelines for medical and nursing personnel regarding the safe and effective operation of HIGH FREQUENCY SURGICAL EQUIPMENT and HIGH FREQUENCY SURGICAL ACCESSORIES (also referred to as HF SURGICAL EQUIPMENT in this document). It is also of use to scientific/technical staff who have responsibility for the maintenance of this equipment.

The application guidelines in this document deal with the safe operation of HIGH FREQUENCY SURGICAL EQUIPMENT constructed according to the safety requirements of IEC 60601-1 [1][1] and IEC 60601-2-2 [4].

Not all existing HIGH FREQUENCY SURGICAL EQUIPMENT meets the minimum requirements of current international standards, however, the guidelines in this document is still helpful in utilizing these devices.

2 Normative references

There are no normative references in this document.

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
ACCESSORY
additional part for use with equipment in order to:

– achieve the INTENDED USE,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipment

[SOURCE: IEC 60601-1:2005, 3.3]

3.2
ACTIVE ACCESSORY
HF SURGICAL ACCESSORY intended for manipulation by the OPERATOR to produce an effect by electrical conduction adjacent to the ACTIVE ELECTRODE at the intended site on the PATIENT,

[1] Numbers in square brackets refer to the Bibliography.

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generally comprising an ACTIVE HANDLE, the cord of an ACTIVE ACCESSORY, ACTIVE CONNECTOR and ACTIVE ELECTRODE

[SOURCE: IEC 60601-2-2:2017, 201.3.201]

3.3
ACTIVE CONNECTOR
part of an ACTIVE ACCESSORY intended for connection to an ACTIVE OUTPUT TERMINAL, which may include additional terminals for connection of a FINGERSWITCH to a SWITCH SENSOR

[SOURCE: IEC 60601-2-2:2017, 201.3.202]

3.4
ACTIVE ELECTRODE
part of an ACTIVE ACCESSORY extending from the ACTIVE HANDLE to the surgical site and intended to pass HF current into body tissue

[SOURCE: IEC 60601-2-2:2017, 201.3.203]

3.5
ACTIVE HANDLE
part of an ACTIVE ACCESSORY intended to be held by the OPERATOR

[SOURCE: IEC 60601-2-2:2017, 201.3.205]

3.6
ACTIVE OUTPUT TERMINAL
part of HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to an ACTIVE ACCESSORY and for delivery of HF current thereto

[SOURCE: IEC 60601-2-2:2017, 201.3.206, modified – The notes have been deleted.]

3.7
APPLIED PART
part of ME EQUIPMENT that in normal use necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

[SOURCE: IEC 60601-1:2005, 3.8, modified – The notes have been deleted.]

3.8
ASSOCIATED EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT other than HF SURGICAL EQUIPMENT that may be electrically connected to the PATIENT circuit

[SOURCE: IEC 60601-2-2:2017, 201.3.207]

3.9
BIPOLAR
method of applying HF current to a PATIENT between two or more ACTIVE ELECTRODES without the need for a separately connected NEUTRAL ELECTRODE (or the need to use the PATIENT'S body capacitance to earth) in which an effect is intended in tissue near one or more ACTIVE ELECTRODES

Note 1 to entry: The BIPOLAR method includes devices energizing pairs of ACTIVE ELECTRODES as well as devices energizing groups of ACTIVE ELECTRODES where the HF current source and return may have different numbers of electrodes.

[SOURCE: IEC 60601-2-2:2017, 201.3.208]

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