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TECHNICAL REPORT

colour inside

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

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

FOREWORD

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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;
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:

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- reconfirmed,
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- amended.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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.

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.

~~This report assumes that the electrical installation of HIGH FREQUENCY SURGICAL EQUIPMENT meets national and local regulations for medically used rooms.~~

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]

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1 Numbers in square brackets refer to the Bibliography.

3.2
ACTIVE ACCESSORY
HF SURGICAL ACCESSORY intended for manipulation by the OPERATOR to produce ~~surgical effects~~ an effect by electrical conduction adjacent to the ACTIVE ELECTRODE at the intended site on the PATIENT, generally comprising an ACTIVE HANDLE, the cord of an ACTIVE ACCESSORY, ACTIVE CONNECTOR and ACTIVE ELECTRODE

[SOURCE: IEC 60601-2-2:~~2009~~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:~~2009~~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:~~2009~~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:~~2009~~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:~~2009~~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 ~~and not intended for independent use~~

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.207]

3.9
BIPOLAR
method of applying HF ~~output~~ current to a PATIENT ~~via multiple pole~~ 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:~~2009~~2017, 201.3.208]

3.10
COAGULATION
use of HF current to ~~elevate the temperature of tissue, e.g. to reduce or terminate undesired bleeding~~ induce a thermal effect, e.g. to control or prevent bleeding, induce tissue destruction, or induce tissue shrinkage

Note 1 to entry: COAGULATION may take the form of contact or non-contact COAGULATION.

Note 2 to entry: FULGURATION, desiccation, spray, forced, swift, soft and argon beam (plasma) COAGULATION are all names of COAGULATION types.

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.210]

3.11
CONTACT QUALITY MONITOR
circuit in HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to a MONITORING NE providing an alarm in the event that NEUTRAL ELECTRODE (NE) contact with the PATIENT becomes insufficient

Note 1 to entry: A CONTACT QUALITY MONITOR is functional only when used with a MONITORING NE.

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.211]

3.12
CONTINUITY MONITOR
circuit in HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to an NE, ~~except MONITORING NE,~~ providing an alarm in the event of electrical discontinuity in the NE cable or its connections

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.212]

3.13
CUTTING
~~resection or dissection~~ division of body tissue caused by the passage of HIGH FREQUENCY current of high current density at the ACTIVE ELECTRODE(S)

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.214]

3.14
FINGERSWITCH
device generally included with an ACTIVE ACCESSORY which, when manipulated by the OPERATOR, enables HF output to be produced and, when released disables HF output

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.216]

3.15
HAZARD
potential source of harm

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.39]

3.16
HEATING FACTOR
a value equal to $I^2 \times t$ where I is the MONOPOLAR current in amperes and t is the duration of the current flow in s

Note 1 to entry: The HEATING FACTOR is expressed as A^2s (amperes squared seconds).

[SOURCE: IEC 60601-2-2:2017, 201.3.218]

3.17
HIGH CURRENT MODE
MONOPOLAR output mode whose INTENDED USE (MAXIMUM OUTPUT CURRENT and maximum DUTY CYCLE) results in a HEATING FACTOR of greater than 30 A^2s in any 60 s period

[SOURCE: IEC 60601-2-2:2017, 201.3.219]

3.18
HIGH FREQUENCY
HF
frequencies less than 5 MHz and generally greater than 200 kHz

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~218~~220]

3.19
HIGH FREQUENCY SURGICAL ACCESSORY
HF SURGICAL ACCESSORY
ACCESSORY intended to conduct, supplement or monitor HF energy applied to the PATIENT from HF SURGICAL EQUIPMENT

Note 1 to entry: HF SURGICAL ACCESSORIES include HF surgical application electrodes, including cords and connectors for attachment to HF SURGICAL EQUIPMENT, as well as other ASSOCIATED EQUIPMENT intended for connection to the HF surgical PATIENT circuit.

Note 2 to entry: Not all accessories used with HF surgical equipment are HF SURGICAL ACCESSORIES.

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~221~~223, modified – In Note 1, replacement of "active electrodes" by " HF surgical application electrodes".]

3.20
HIGH FREQUENCY SURGICAL EQUIPMENT
HF SURGICAL EQUIPMENT
~~MEDICAL ELECTRICAL EQUIPMENT, including its associated ACCESSORIES, intended for the performance of surgical operations such as the CUTTING and COAGULATION of biological tissue by means of HIGH FREQUENCY (HF) currents~~
MEDICAL ELECTRICAL EQUIPMENT which generates HIGH FREQUENCY currents intended for the performance of surgical tasks such as CUTTING or COAGULATION of biological tissue by means of these HIGH FREQUENCY currents

Note 1 to entry: HF SURGICAL EQUIPMENT is also variously known as surgical diathermy, electrosurgical equipment, electrosurgical generator, RF generator or HF generator.

Note 2 to entry: A footswitch is an example of an associated ACCESSORY that is part of HF SURGICAL EQUIPMENT.

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~222~~224]

3.21
HF SURGICAL MODE
any of a number of OPERATOR selectable HF output characteristics intended to provide a specific ~~indicated surgical~~ effect at a connected ACTIVE ACCESSORY, such as CUTTING, COAGULATION and the like

Note 1 to entry: Each available HF SURGICAL MODE may be provided with an OPERATOR-adjustable output control to set the desired intensity or speed of the effect.

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~223~~225]

3.22
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

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.44]

3.23
LEAKAGE CURRENT
current that is not functional

[SOURCE: IEC 60601-1:2005, 3.47, modified – The note has been deleted]

3.24
MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT
electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

– provided with not more than one connection to a particular supply mains; and
– intended by its manufacturer to be used in the diagnosis, treatment, or monitoring of a PATIENT; or for compensation or alleviation of disease, injury or disability

Note 1 to entry: ME EQUIPMENT includes those ACCESSORIES as defined by the manufacturer that are necessary to enable the normal use of the ME EQUIPMENT.

[SOURCE: IEC 60601-1:2005, 3.63, modified – Notes 2 to 5 have been deleted]

3.25
MONITORING NE
NE intended for use with a CONTACT QUALITY MONITOR

Note 1 to entry: A MONITORING NEUTRAL ELECTRODE is also known as a split plate, dual plate, dual foil electrode or CQM electrode.

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~225~~228]

3.26
MONOPOLAR
method of applying HF output current to a PATIENT via an ACTIVE ELECTRODE and returning via a separate~~ly~~ PATIENT-connected NEUTRAL ELECTRODE (or via the PATIENT'S body capacitance to earth) in which an effect is intended only in tissue at or near the ACTIVE ELECTRODE

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~226~~229]

3.27
NEUTRAL ELECTRODE
NE
electrode ~~of a relatively large area for connection to the body of the patient,~~ intended to provide a return path for the MONOPOLAR application of HIGH FREQUENCY current with such a low current density in the ~~body~~ PATIENT'S tissue that ~~physical~~ effects such as excessive rise in temperature or unwanted burns are avoided

Note 1 to entry: The NEUTRAL ELECTRODE is also known as plate, plate electrode, electrosurgical pad, passive, return or dispersive electrode.

Note 2 to entry: To keep the current density low enough to prevent unwanted heating, the NEUTRAL ELECTRODE needs to have a large enough area.

Note 3 to entry: A NEUTRAL ELECTRODE is usually in contact with the PATIENT at a location that is separate from the MONOPOLAR ACTIVE ELECTRODE.

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~227~~230]

3.28
OPERATOR
person handling equipment

[SOURCE: IEC 60601-1:2005, 3.73]

3.29
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.76, modified – The note has been deleted.]

3.30
RATED ACCESSORY VOLTAGE
maximum peak HF output voltage which may be applied to a MONOPOLAR HF SURGICAL ACCESSORY with respect to an NE connected to the PATIENT. For a BIPOLAR HF SURGICAL ACCESSORY, the maximum peak HF output voltage which may be applied to pairs of opposite polarity

3.31
RATED LOAD
value of non-reactive load resistance which, when connected, results in the maximum HF output power from each HF SURGICAL MODE of the HF SURGICAL EQUIPMENT

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~229~~232]

3.32
RATED OUTPUT POWER
for each HF SURGICAL MODE set at its maximum output setting, the power in watts produced when all ACTIVE OUTPUT TERMINALS which can be activated simultaneously are connected to their respective RATED LOADs

[Source: IEC 60601-2-2:~~2009~~2017, 201.3.~~230~~233]

3.33
SWITCH SENSOR
part of HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT which controls activation of HF output in response to operation of a connected FINGERSWITCH or footswitch

[SOURCE: IEC 60601-2-2:~~2009~~2017, 201.3.~~231~~234]

4 General information regarding HF SURGICAL EQUIPMENT

HF SURGICAL EQUIPMENT is MEDICAL ELECTRICAL EQUIPMENT which delivers HIGH FREQUENCY currents to perform surgical modification of tissue. The most common forms of tissue modification are CUTTING and COAGULATION but may also include tissue ablation, lesioning, shrinkage, sealing or fusion.