

TECHNICAL REPORT

High frequency surgical equipment – Operation and maintenance

Witholdam



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TECHNICAL REPORT

High frequency surgical equipment – Operation and maintenance

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

HIGH FREQUENCY SURGICAL EQUIPMENT – 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 first edition of IEC 61289 cancels and replaces IEC 61289-1:1994 and IEC 61289-2:1994, of which it constitutes a technical revision and combination.

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

Enquiry draft	Report on voting
62D/929DTR	62D/956/RVC

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.

Certain terms are used with a defined meaning and these are given in the text in SMALL CAPITALS. The definitions of these terms are provided in Clause 2.

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- withdrawn,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.

A bilingual version of this publication may be issued at a later date.

Withdrawn

INTRODUCTION

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

Withdrawn

HIGH FREQUENCY SURGICAL EQUIPMENT – OPERATION AND MAINTENANCE

1 Scope

This technical report contains guidelines for medical and nursing personnel regarding the safe and effective operation of HIGH FREQUENCY SURGICAL EQUIPMENT (also referred to as HF SURGICAL EQUIPMENT in this document). It will also be 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 and IEC 60601-2-2 (see Bibliography).

Not all existing HIGH FREQUENCY SURGICAL EQUIPMENT meets the minimum requirements of current international standards, however, the guidelines in this report will still be 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 Terms and definitions

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

2.1

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, definition 3.3]

2.2

ACTIVE ACCESSORY

HF SURGICAL ACCESSORY intended for manipulation by the OPERATOR to produce surgical effects at the intended site on the patient, generally comprising an ACTIVE HANDLE, cord of an ACTIVE ACCESSORY, ACTIVE CONNECTOR and ACTIVE ELECTRODE

[SOURCE: IEC 60601-2-2:2009, definition 201.3.201]

2.3

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, definition 201.3.202]

2.4

ACTIVE ELECTRODE

part of an ACTIVE ACCESSORY extending from the ACTIVE HANDLE to the surgical site

[SOURCE: IEC 60601-2-2:2009, definition 201.3.203]

2.5

ACTIVE HANDLE

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

[SOURCE: IEC 60601-2-2:2009, definition 201.3.205]

2.6

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, definition 201.3.206]

2.7

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, definition 3.8]

2.8

ASSOCIATED EQUIPMENT

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, definition 201.3.207]

2.9

BIPOLAR

method of applying HF output current to a patient via multiple-pole ACTIVE ELECTRODES

[SOURCE: IEC 60601-2-2:2009, definition 201.3.208]

2.10

COAGULATION

use of HF current to elevate the temperature of tissue, e.g. to reduce or terminate undesired bleeding

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

[SOURCE: IEC 60601-2-2:2009, definition 201.3.210]

2.11

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

[SOURCE: IEC 60601-2-2:2009, definition 201.3.211]

2.12

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, definition 201.3.212]

2.13

CUTTING

resection or dissection 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, definition 201.3.214]

2.14

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, definition 201.3.216]

2.15

HAZARD

potential source of harm

[SOURCE: IEC 60601-1:2005, definition 3.39]

2.16

HIGH FREQUENCY

HF

frequencies generally greater than 200 kHz

[SOURCE: IEC 60601-2-2:2009, definition 201.3.218]

2.17

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 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.

[SOURCE: IEC 60601-2-2:2009, definition 201.3.221]

2.18

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

[SOURCE: IEC 60601-2-2:2009, definition 201.3.222]

2.19

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

[SOURCE: IEC 60601-2-2:2009, definition 201.3.223]

2.20

LEAKAGE CURRENT

current that is not functional

[SOURCE: IEC 60601-1:2005, definition 3.47]

2.21

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 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, definition 3.63]

2.22

MONITORING NE

NE intended for use with a CONTACT QUALITY MONITOR

[SOURCE: IEC 60601-2-2:2009, definition 201.3.225]

2.23

MONOPOLAR

method of applying HF output current to a patient via an ACTIVE ELECTRODE and returning via a separately-connected NE or via the patient's body capacitance to earth

[SOURCE: IEC 60601-2-2:2009, definition 201.3.226]

2.24

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 HIGH FREQUENCY current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided

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

[SOURCE: IEC 60601-2-2:2009, definition 201.3.227]

2.25

OPERATOR

person handling equipment

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

2.26

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, definition 201.3.229]

2.27

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, definition 201.3.230]

2.28

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, definition 201.3.231]

3 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.

The current is conducted to and from the patient in the following ways:

- in MONOPOLAR application with an ACTIVE ELECTRODE of a small area and a large NEUTRAL ELECTRODE;
- in MONOPOLAR application of HF SURGICAL EQUIPMENT with a RATED OUTPUT POWER less than 50 W and not provided with a NEUTRAL ELECTRODE, the circuit for the HIGH FREQUENCY current being completed through the capacitive coupling between the patient and the earthed environment;
- in BIPOLAR application with a BIPOLAR electrode only, for example forceps where the legs are electrically insulated from each other;
- in multipolar application where a multitude of ACTIVE ELECTRODES are present. In this type of application the current passes from one or more of the ACTIVE ELECTRODES to either a large NEUTRAL ELECTRODE in a MONOPOLAR-like arrangement or to one or more small area electrodes in the immediate vicinity in a BIPOLAR-like arrangement;
- in an application where the current delivery is augmented by the use of argon or saline between the ACTIVE ELECTRODE(S) and the target tissue.

The output power may vary considerably depending on the intended use, from a few watts for special procedures, for example in ophthalmology, up to 300 W or more for some equipment. The peak output voltage from some equipment may be as high as 6 000 V.

The use of HIGH FREQUENCY (HF) current is a possible HAZARD to the patient, the OPERATOR and other personnel present and to the surroundings. Other equipment connected to the patient may be affected. The safe operation of HIGH FREQUENCY SURGICAL EQUIPMENT depends mainly on the following factors:

- safe use, which depends on:
 - OPERATOR's knowledge of the safe methods of use of the equipment,
 - OPERATOR's knowledge of safety characteristics of the equipment,
 - availability and readability of accompanying documents;
- safety of the equipment;
- an effective maintenance scheme;
- safety of the installation;

4 Recommended practices

4.1 Inspection of HF SURGICAL EQUIPMENT before use

Before surgery the OPERATOR should check the HF SURGICAL EQUIPMENT and ACTIVE ACCESSORIES as listed below.