

TECHNICAL REPORT

High frequency surgical equipment – Operation and maintenance

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IEC/TR 61289:2011

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**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

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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.

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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]