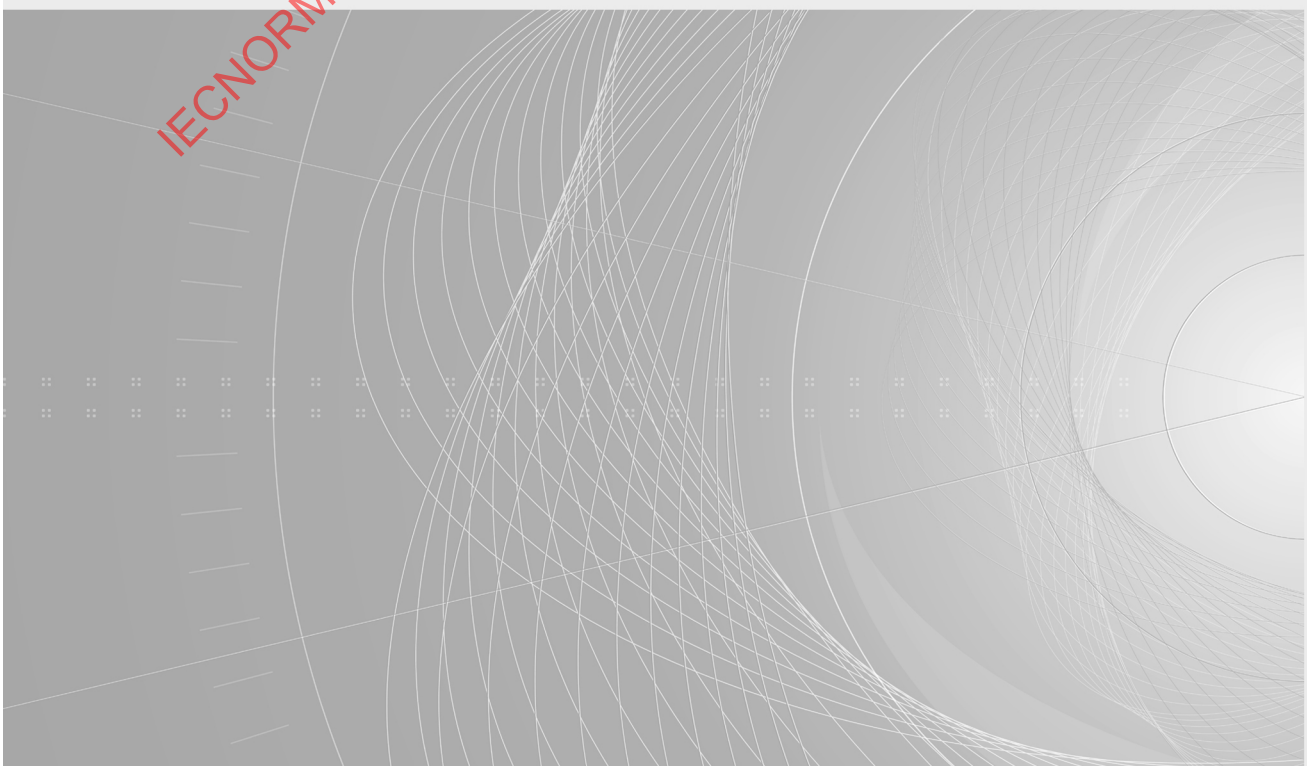
IEC TR 61289

Edition 2.0 2019-05

TECHNICAL REPORT

colour inside

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



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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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:

– 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- withdrawn,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.

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

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.

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.

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]

3.10
COAGULATION
use of HF current to 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 60601-2-2:2017, 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 60601-2-2:2017, 201.3.211]

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

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

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

[SOURCE: IEC 60601-2-2:2017, 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 60601-2-2:2017, 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 60601-2-2:2017, 201.3.220]

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 60601-2-2:2017, 201.3.223, 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 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 60601-2-2:2017, 201.3.224]

3.21
HF SURGICAL MODE
any of a number of OPERATOR selectable HF output characteristics intended to provide a specific 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 60601-2-2:2017, 201.3.225]

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 60601-2-2:2017, 201.3.228]

3.26
MONOPOLAR
method of applying HF output current to a PATIENT via an ACTIVE ELECTRODE and returning via a separate 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 60601-2-2:2017, 201.3.229]

3.27
NEUTRAL ELECTRODE
NE
electrode intended to provide a return path for the MONOPOLAR application of HIGH FREQUENCY current with such a low current density in the PATIENT'S tissue that 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 60601-2-2:2017, 201.3.230]

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 60601-2-2:2017, 201.3.232]

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 60601-2-2:2017, 201.3.233]

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 60601-2-2:2017, 201.3.234]

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.

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 connection point, 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 gas or saline solution 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 or more.

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;
– integrity of the equipment;
– an effective maintenance scheme;
– safety of the installation. This document assumes that the HIGH FREQUENCY SURGICAL EQUIPMENT has been installed in a healthcare facility that meets national and local regulations.

5 Recommended practices before use

5.1 Inspection of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES before use

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

– Inspect the mains plug, connectors and cables, including handles for ACTIVE ACCESSORIES and any NEUTRAL ELECTRODES, for visible damage. If damaged, do not use. Damaged instruments or cords may lead to injury to the PATIENT or OPERATOR.
– Check that HF SURGICAL ACCESSORIES, NEUTRAL ELECTRODES, and cables are compatible with:
  - each other;
  - with the HF SURGICAL EQUIPMENT;
  - the output mode;
  - the output power setting;
  - the output voltage that will be used.

  Information should be available in the respective instructions for use.
– Check that the selected NEUTRAL ELECTRODE is compatible with the weight of the PATIENT.
– Check that the EQUIPMENT has no visible damage.
– Check that warning signs and other markings on the EQUIPMENT are readable.
– Check that all indicating lamps and audible tones are in working order.
– Conduct any additional checks or inspections as recommended by the manufacturer.

Warning: Do not try to test the HF SURGICAL EQUIPMENT by sparking against metal parts or the NEUTRAL ELECTRODE.

5.2 Preparation

Before application of the NEUTRAL ELECTRODE, check the positioning of the PATIENT.

- The PATIENT, including their extremities, shall be isolated from earthed metal parts.
- Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry towel.
- The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are suctioned or scavenged away.
- Use non-flammable agents for cleaning and disinfection wherever possible.
- Before the application of HF surgery, check for pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina.
- Before using HF SURGICAL EQUIPMENT, after cleaning or disinfection, remove visible volume, dry the area and allow evaporation of any residual flammable agents used for cleaning or disinfecting, or as solvents of adhesives from all PATIENT and non-PATIENT surfaces as well as cavities.
- Assess for the danger of ignition of endogenous gases, e.g., bowel gas methane.
- Be aware that some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the HF SURGICAL EQUIPMENT.
- Avoid placement of a NEUTRAL ELECTRODE over poorly vascularized areas such as: bony prominences, skin lesions, skin folds, and scars.

5.3 Handling of NEUTRAL ELECTRODES, HF SURGICAL ACCESSORIES, cables and connections

NEUTRAL ELECTRODES and connections shall be placed with care. Special attention shall be paid to the following.

- The entire area of NEUTRAL ELECTRODES should be reliably in contact with the PATIENT'S body.
- When HF SURGICAL EQUIPMENT and physiological monitoring equipment are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the ACTIVE ELECTRODES. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting devices are recommended.
- For NEUTRAL ELECTRODES that use a detachable cord, ensure that the tab of the NEUTRAL ELECTRODE is fully inserted into the connector so that no metallic surface is exposed.

The selection of ACTIVE ACCESSORIES should take into account their compatibility with HF SURGICAL EQUIPMENT.

The HF SURGICAL EQUIPMENT leads should be positioned in such a way that contact with the PATIENT monitoring or other leads is avoided.

Temporarily unused ACTIVE ELECTRODES should be stored in a non-conductive location that is isolated from the PATIENT, for example in a holster or quiver.

5.4 PATIENTS with active implants (active implantable medical devices)

PATIENTS with active implants, for example pacemakers, implantable neurostimulators, implantable pumps, implantable defibrillators, or implanted electrodes, may be affected by the application of HF SURGICAL EQUIPMENT. The effects could be irreparable damage to the active implant or impairment of its function. The manufacturer of the active implant should be consulted prior to the surgery. Simultaneous monitoring of such PATIENTS using suitable monitoring equipment is also recommended.

NOTE Currents induced in the implanted electrodes due to the use of HF SURGICAL EQUIPMENT can cause irreversible changes in the tissue around the electrodes, causing malfunctioning of the implant.

The following guidelines should be taken into account:

– the selected output power should be as low as possible for the intended application;
– the current path in the body should be at right angles to the leads of the active implant;
– whenever possible, the use of BIPOLAR technique should be considered.

5.5 Simultaneous use of two items of HF SURGICAL EQUIPMENT

In some applications, it may be necessary to use two separate pieces of HF SURGICAL EQUIPMENT, for example when simultaneously operating on two different parts of the body. In these cases, additional technical advice should be sought.

The choice of equipment that provides the lowest clinical risk is the use of two BIPOLAR HF surgery generators. If this is not clinically appropriate, then use of one BIPOLAR and one MONOPOLAR generator is the next lower risk option. If the clinical circumstances justify it, two MONOPOLAR generators can be used. Both should be of the HF isolated type shown by the F symbol as described in 9.4.2.2. The NEUTRAL ELECTRODE for each generator should be positioned appropriately for the surgical operating site of that generator, taking account of manufacturers' recommendations and good clinical practice. The NEUTRAL ELECTRODES should not be positioned close together and the NEUTRAL ELECTRODE leads should be kept well separated. Whenever possible, ensure that the current path from ACTIVE ACCESSORY 1 to NEUTRAL ELECTRODE 1 does not pass through the same part of the PATIENT'S body as the current path from ACTIVE ACCESSORY 2 to NEUTRAL ELECTRODE 2.

Further technical advice can be sought from the equipment manufacturers or from the local clinical engineering department.

5.6 Instructions for use

Users should read and understand the instructions for use provided by manufacturer(s). Modes, options and operating characteristics may not be consistent across manufacturers.

6 Recommended practices during use

When using HF SURGICAL EQUIPMENT caution is necessary, therefore observe the following rules:

– The HIGH FREQUENCY power should be set as low as possible for the application in question. Reference should be made to the manufacturer's recommended setting for the procedure being carried out.
– Insufficient power at the customary control setting may be caused by, for example, bad contact of the NEUTRAL ELECTRODE, bad contact in connectors or a broken cable under the insulation. These items should be checked before a higher power setting is used.
– After repositioning the PATIENT, or if someone trips on the NE cable, the application of the NEUTRAL ELECTRODES and the NE cables should be inspected. For NEUTRAL ELECTRODES that use a detachable cord, ensure that the tab of the NEUTRAL ELECTRODE is still fully inserted into the connector so that no metallic surface is exposed.
– The functioning of the HF SURGICAL EQUIPMENT should not be tested by sparking against metal parts or the NEUTRAL ELECTRODE.
– When operating in parts of the body having a small cross section, the application of BIPOLAR technique may be preferable in order to avoid unwanted tissue damage.
– Flammable agents for skin cleaning, grease removal and disinfection shall be completely evaporated before the application of the HF SURGICAL EQUIPMENT. The HAZARD of igniting endogenous gases shall also be considered.

– Be aware that electromagnetic interference emanating from HF SURGICAL EQUIPMENT may influence other MEDICAL ELECTRICAL EQUIPMENT, for example ECG monitors, blood pressure monitors, infusion pumps, cardiac pacemakers, etc.

– The HF SURGICAL EQUIPMENT should be activated only when the HF SURGICAL ACCESSORY is in position and the intended clinical effect is desired.

7 Recommended practices after use

After each use, the HF SURGICAL EQUIPMENt should be cleaned as indicated in the instructions for use. Reusable HF SURGICAL ACCESSORIES should be cleaned and sterilized according to local policy and the manufacturer's recommendations.

8 Nature of HAZARDS

8.1 General

The currents and voltages generated in HF SURGICAL EQUIPMENT may present a HAZARD to the PATIENT or the OPERATOR by the nature of its use or by its electrical interference with other equipment in the vicinity of, in contact with, or implanted within the PATIENT. The generation of sparks or arcs between the ACTIVE ELECTRODE and tissue or, between the ACTIVE ELECTRODE and metal objects, may be a source of low frequency components in the output current which may cause neuromuscular stimulation. The following subclauses give some examples of HAZARDS that are associated with the use of HF SURGICAL EQUIPMENT.

8.2 HF SURGICAL EQUIPMENT related HAZARDS

8.2.1 Incompatible combinations

Although it may be possible to physically connect different pieces of HF SURGICAL EQUIPMENT or HF SURGICAL ACCESSORIES, the combination may not always work in the expected manner. OPERATORs should always confirm the compatibility of different pieces of HF SURGICAL EQUIPMENT or HF SURGICAL ACCESSORIES with all of the manufacturers involved. This includes correct operation, possible changes in the electromagnetic compatibility of the combination, and electrical safety. For example, identical looking footswitches from different manufacturers may not be electrically identical resulting in unexpected, unintended and potentially harmful results.

8.2.2 Electromagnetic compatibility

When in use, HF SURGICAL EQUIPMENT will generate electromagnetic disturbances. A disturbance may be radiated through the air, conducted through the PATIENT or conducted through the mains power cord or PATIENT cables. This may impact other MEDICAL ELECTRICAL EQUIPMENT in the vicinity of or connected to the PATIENT. OPERATORs should follow the recommendations of the manufacturer(s) regarding this situation. This includes the manufacturer of any active implanted, body worn, or semi-implanted device. There may be techniques for cable placement, equipment setup or output mode/power setting that will help mitigate this HAZARD.

8.2.3 Misconnection of ACTIVE ACCESSORIES

Some ACTIVE ACCESSORIES may be physically connected to HF SURGICAL EQUIPMENT in a manner not intended by the manufacturer. An example might be a BIPOLAR ACTIVE ACCESSORY incorrectly connected to a MONOPOLAR receptacle through the use of an adapter or non-conforming cord. OPERATORs should always consult the instructions for use for the correct connection information.

8.2.4 Specialty HF SURGICAL EQUIPMENT

Certain types of specialty HF SURGICAL EQUIPMENT may have risks associated with their use that are different from traditional HF SURGICAL EQUIPMENT. These risks may not be obvious. The instructions for use will list the warnings and cautions particular to that HF SURGICAL EQUIPMENT. An example is argon-enhanced HF SURGICAL EQUIPMENT where the risks associated with the use of argon gas should be understood by the OPERATOR. Another example is HF SURGICAL EQUIPMENT that has a HIGH CURRENT MODE where there are risks associated with heating under the NEUTRAL ELECTRODE.

8.3 ACTIVE ACCESSORY related HAZARDS

8.3.1 Incompatible combinations

An ACTIVE ACCESSORY may not be compatible with every cord that can be physically connected to it. The incompatibility may be electrical where the voltage or current that will be used is too high. The incompatibility may be in the physical connection itself where the mating parts are not the same size or tolerance, potentially causing the connection to become hot or come apart during surgery. The connection may be incomplete with uncovered bare metal allowing unintended current to injure the PATIENT or OPERATOR.

An ACTIVE ACCESSORY may not be compatible with every ACTIVE ELECTRODE that can be physically connected to it. The incompatibilities and the consequences are likely to be the same as described above.

An ACTIVE ACCESSORY may not be compatible with every HF SURGICAL MODE, power or voltage to which it could be exposed. OPERATORS should consult the instructions for use of both the ACCESSORY and the HF SURGICAL EQUIPMENT for compatibility information and maximum voltage ratings. An HF SURGICAL MODE or power setting that delivers a peak voltage greater than the maximum peak voltage rating of an ACTIVE ACCESSORY is an example of this HAZARD and should be avoided. The maximum peak voltage rating is also known as the RATED ACCESSORY VOLTAGE within the IEC 60601-2-2.

8.3.2 Environment of use

Sparks generated at the ACTIVE ELECTRODE during normal use may cause a fire or explosion if flammable anaesthetic or cleaning agents are present or the HF SURGICAL EQUIPMENT is used in an atmosphere enriched by endogenous gases, oxygen or nitrous oxide.

Low-frequency voltages caused by sparks or electrical arcs may cause neuromuscular stimulation. The PATIENT may have excitable tissue stimulated, especially if there is a fault in the insulation in endoscopes or resectoscopes between the ACTIVE ELECTRODE and the shaft. For example, during plastic surgery, especially on the face, neuromuscular stimulation may occur due to arcing from tips of ACTIVE ELECTRODES.

Arcing to a metal instrument or retractor may accentuate the possibility of neuromuscular stimulation. It can also increase the amount of current flow in unexpected and undesired ways.

Surgical gloves do not adequately insulate against the output of HF SURGICAL EQUIPMENT. For example when coagulating tissue or vessels using non-insulated forceps, the OPERATOR may experience an electrical burn.

Use of HF current on or near metallic implants may cause high current density resulting in undesired heating. Arcing to a metallic implant may cause damage to the implant and may negatively impact the performance or functionality.

The sparking and current flow during normal use causes the ACTIVE ELECTRODE to become hot during use. After use, the ACTIVE ACCESSORY should always be placed safely away from the

PATIENT, the surgical team and flammable materials to prevent the possibility of an unintended burn or fire.

Use of an ACCESSORY in an inappropriate medium or solution may be hazardous. For example, conductive solutions used for distension may cause an unexpected and increased amount of current to be delivered by the HF SURGICAL EQUIPMENT. It could also cause current dispersion at the targeted tissue leading to a need to increase the power resulting in even more current. This would cause the total current flowing through the NEUTRAL ELECTRODE to be much higher than in a traditional surgical procedure. In addition, current dispersion through conductive media may result in unintended tissue damage. OPERATORS should always consult the instructions for use for the ACTIVE ACCESSORY, the HF SURGICAL EQUIPMENT and the NEUTRAL ELECTRODE prior to use.

8.3.3 Misuse

HF ACCESSORIES which are modified by OPERATORS may be hazardous. After modification, the HF ACCESSORY may not be compatible with the expected voltages, its switching or control configuration may be incorrect or it may result in an undesired part becoming live. Examples of this HAZARD are the use of a red rubber catheter to insulate the shaft of an ACTIVE ELECTRODE and cutting a NEUTRAL ELECTRODE to make it smaller.

The reuse of an HF ACCESSORY marked for single use may be hazardous. The re-sterilization process may not be effective, may degrade the insulation resulting in a fire or injury to the PATIENT or OPERATOR or may degrade product performance resulting in increased risk to the PATIENT.

Inappropriate cleaning and sterilization of a reusable HF ACCESSORY may be hazardous. The process may not result in a sterile HF ACCESSORY and may degrade the insulation resulting in a fire or injury to the PATIENT or OPERATOR

A reusable HF ACCESSORY should be discarded at the end of its useful life. Continued use may be hazardous and could result in a fire or injury to the PATIENT or OPERATOR. The instructions for use should be consulted for the recommended number of uses or the proper inspection procedure to determine end of useful life.

8.4 OPERATOR-related HAZARDS

8.4.1 OPERATOR not reading or following the instructions for use

The use of HIGH FREQUENCY current is a possible HAZARD to the PATIENT, the OPERATOR and other personnel present. All personnel that may setup or use these types of devices should read and follow the instructions for use included with the EQUIPMENT, the ACCESSORIES and the NEUTRAL ELECTRODE (if applicable). This includes all warnings, cautions and recommended clinical use information.

8.4.2 OPERATOR selecting inappropriate power or mode settings

The use of inappropriate power or mode settings may be hazardous. Increasing the output power beyond that normally used for a procedure may indicate a problem that should be investigated. Inappropriate power or mode settings may subject the ACCESSORY to voltages for which it was not designed. It may also result in unanticipated tissue effects.

8.4.3 OPERATOR using an HF SURGICAL ACCESSORY in an inappropriate manner

Many HF SURGICAL ACCESSORIES are designed for a specific procedure or for use on specific tissue types. Disregarding the recommendations of the manufacturer in this matter may result in inadequate or unexpected clinical effect. Examples include the following:

– use of an HF SURGICAL ACCESSORY in a way that is outside the scope of its INTENDED USE;

NOTE Always consult the manufacturer's instructions for use to determine if the ACCESSORY is approved for the intended procedure.

– use of an HF SURGICAL ACCESSORY in a location where the current flowing towards the NEUTRAL ELECTRODE is concentrated along a narrow path resulting in undesired tissue damage or destruction (e.g. fallopian tubes);

– use of an HF SURGICAL ACCESSORY or HF SURGICAL EQUIPMENT with activation duty cycles in excess of the recommendations of the manufacturer resulting in a PATIENT burn under the NEUTRAL ELECTRODE;

– OPERATOR modification of the HF SURGICAL ACCESSORY;

– activation of a MONOPOLAR endoscopic HF SURGICAL ACCESSORY when not in position to produce the intended clinical effect (e.g. activation when the tip of the endoscopic ACTIVE ELECTRODE is not in view of the OPERATOR). This can increase the risk of an unintended burn by:

  • direct contact of the ACTIVE ELECTRODE with tissue that is not targeted,

  • direct contact with other metallic instruments.

8.5 NEUTRAL ELECTRODE related HAZARDS

8.5.1 General

These HAZARDS relate to MONOPOLAR procedures where a NEUTRAL ELECTRODE is used.

8.5.2 Inadequate contact area of a NEUTRAL ELECTRODE

Inadequate contact area of the NEUTRAL ELECTRODE may be hazardous resulting in a PATIENT burn. Application should always follow the instructions for use provided by the manufacturer. Inadequate contact area can result from the following:

– NEUTRAL ELECTRODE contact area too small for the application;

– NEUTRAL ELECTRODE not in complete contact with tissue;

– NEUTRAL ELECTRODE insulated from the skin by hair, non-conducting material or interposition of surgical drapes, bedding or clothing.

8.5.3 Inappropriate application

A hazardous situation may be created if the site preparation or location recommendations of the manufacturer are not followed. A poorly vascularized application site may not be able to dissipate the heat normally generated under a NEUTRAL ELECTRODE. Poor site preparation may degrade the desired contact area or contact impedance resulting in increased heating. The NEUTRAL ELECTRODE should not be placed adjacent to metallic implants or other orthopaedic hardware.

A single use NEUTRAL ELECTRODE should not be used if the packaging has been damaged. A single use NEUTRAL ELECTRODE should not be used beyond the "use by" date on the package.

8.5.4 Surgical procedures utilizing high currents or long duty cycles

8.5.4.1 General considerations

It is important for OPERATORS (and more specifically, the surgeons using the HF SURGICAL EQUIPMENT) to understand that some HF SURGICAL EQUIPMENT and ACTIVE ACCESSORIES may be capable of producing more current than a single conventional NEUTRAL ELECTRODE (i.e. one which is not suitable for use in a HIGH CURRENT MODE) can safely handle, and as a result there may be an increased risk of a burn at the NEUTRAL ELECTRODE site. For more information, see Annex A.

8.5.4.2 High current risk identification

To prevent PATIENT injuries, the hospital personnel need to recognize the types of equipment and procedures that are most likely to result in the delivery of high current levels that can overwhelm a NEUTRAL ELECTRODE. The following factors pose the greatest risk as they may result in delivery of high current levels, have long activation times or low surgical impedance.

a) Ablation or other procedures.
   1) Tumour ablation.
   2) Cardiac ablation.
   3) Liver ablation or resection.
   4) Endoscopic ablation.
   5) Bulk tissue ablation such as roller ball ablation.

b) Application of high current to the PATIENT'S tissue.
   1) Use of a high-current or special purpose HF SURGICAL EQUIPMENT intended for large-volume tissue ablation.
   2) Use of ACTIVE ACCESSORIES such as a roller ablation electrode.
   3) Required use of multiple (2 to 4) NEUTRAL ELECTRODES at the same time.
   4) Required use of multiple ACTIVE ELECTRODES.

c) Application of current for an extended period of time to the PATIENT'S tissue.
   1) Use of a general purpose HF SURGICAL EQUIPMENT with either long-activation periods or little time between activations.
   2) Use of a special purpose HF SURGICAL EQUIPMENT or ACTIVE ACCESSORIES with long-activation periods.

d) Use of conductive solutions such as saline or lactated Ringer's which lowers the surgical impedance of tissue in contact with the solution.
   1) Use of an ACTIVE ACCESSORY that is designed to be used with or dispense saline or has a significant portion of its surface area in contact with a conductive medium such as saline.
   2) Use of an ACTIVE ACCESSORY that is fully immersed in flowing blood for extended periods of time (e.g., cardiac ablation).

8.5.4.3 High current risk mitigation

Hospital personnel may not recognize the risk associated with high-current, long-activation-time electrosurgical procedures or procedures that involve the use of conductive fluids (e.g., saline) for irrigation or distension. To minimize the risk of a burn at the NEUTRAL ELECTRODE site during such procedures, the following is recommended:

a) Recognize that HF SURGICAL EQUIPMENT and ACTIVE ACCESSORIES in your facility are capable of producing current levels that can exceed what a NEUTRAL ELECTRODE can withstand, in procedures involving any combination of high current, long-activation times or the use of conductive fluids for irrigation or distension.

b) Identify the electrosurgical procedures performed in the facility that may require the use of high current, long-activation times or the use of conductive fluids for irrigation or distension.

c) Educate operating room clinicians, surgeons, and risk managers on the increased risk of burns associated with high-current, long-activation electrosurgical procedures or procedures that involve the use of conductive fluids for irrigation or distension.

d) Educate operating room clinicians and surgeons about how burns occur, how to recognize when there is an increased risk of electrosurgical burns, and what to do to minimize the risk.

e) Require operating room clinicians to be familiar with the instructions for use and warnings of each piece of equipment – HF SURGICAL EQUIPMENT, ACTIVE ACCESSORIES, and NEUTRAL ELECTRODES.

f) Make sure that the NEUTRAL ELECTRODE is in full contact with the PATIENT and verify the manufacturer's instructions were followed regarding NEUTRAL ELECTRODE application.

g) Use the lowest possible power settings and shortest activation times to achieve the desired surgical effect. If long activation times are necessary, allow sufficient time off between activations to allow the tissue to cool under the NEUTRAL ELECTRODE. The amount of time off required will vary depending upon the amount of current used, the length of activation time and the individual characteristics of the PATIENT. This may require the time off to be equal or greater than the activation time.

h) Confirm the use of the appropriate irrigation/distension medium with the surgeon before any electrosurgical procedure. Use a non-conductive solution as the distension/irrigation medium unless specific medical reasons indicate otherwise or the manufacturer of the generator or ACCESSORY recommends otherwise. Numerous non-conductive fluids are available. Common ones include 1,5 % glycine, 3 % sorbitol, 5 % mannitol, and sterile water. Not all non-conductive media are appropriate for all procedures. Selection shall be based on the surgical procedure. For example, long procedures involving large volumes of media require that the PATIENT'S fluid balance be carefully monitored to avoid fluid overload which can lead to serious complications such as pulmonary edema, congestive heart failure, cerebral edema, hypotension, and electrolyte imbalance.

i) Avoid use of a roller ablation electrode with a conductive fluid, unless otherwise indicated by the electrode manufacturer, because a significant portion of its surface area will be in contact with the conductive medium, causing a loss of surgical effect. Increasing the power settings will increase the amount of current delivered to the NEUTRAL ELECTRODE. If high power is used for too long, the current may overwhelm the NEUTRAL ELECTRODE, resulting in a PATIENT burn.

j) Verify that the correct distension/irrigation medium has been selected if there is no surgical effect or less than a desired surgical effect. Inspect the NEUTRAL ELECTRODE to ensure that it is applied according to the manufacturer's instructions and is in full contact with the PATIENT before increasing the power setting on the HF SURGICAL EQUIPMENT.

k) Use two or more identical NEUTRAL ELECTRODES placed symmetrically and equidistant from the surgical site where there is a concern that the use of high current, extended activation times, or the use of a conduction irrigation/distension fluid may pose an increased risk of an electrosurgical burn at the NEUTRAL ELECTRODE site. Such placement will divide the current flow between the two NEUTRAL ELECTRODES and reduce the risk of a burn. Suitable placement sites include:

   1) the left and right anterior thigh;
   2) the left and right buttock; or
   3) the left and right bicep.

l) Avoid placing multiple NEUTRAL ELECTRODES in the following configurations because they will increase the risk of a burn:

   1) Placement of one NEUTRAL ELECTRODE below another NEUTRAL ELECTRODE on a single limb. With this placement, nearly all of the current will be collected by the NEUTRAL ELECTRODE closer to the surgical site, increasing the risk for a burn at the closer NEUTRAL ELECTRODE.
   2) Asymmetrical placement of NEUTRAL ELECTRODES on two limbs, such as the right thigh and left calf. With this placement, the current flow to the right thigh will be substantially more than the left calf.
   3) Placement of two NEUTRAL ELECTRODES directly next to each other. With this placement, the current will be more heavily concentrated at the edges of the NEUTRAL ELECTRODES closest to the surgical site, increasing the risk for a burn at this location.
   4) Placement of two NEUTRAL ELECTRODES on one limb, particularly if this placement causes the encirclement of an entire limb. If more than one NEUTRAL ELECTRODE is used on any limb and the current flow is very high, it is possible that the high level of current flow through the limb will increase the temperature of the entire limb.

m) Follow the NEUTRAL ELECTRODE manufacturer's instructions for NEUTRAL ELECTRODE placement if the instructions for use for HF SURGICAL EQUIPMENT or ACTIVE ACCESSORY call for the use of more than two NEUTRAL ELECTRODES. If the instructions for use do not include NEUTRAL ELECTRODE placement for two or more NEUTRAL ELECTRODES, contact the manufacturer and request written instructions for multiple NEUTRAL ELECTRODE placement.

9 Safety provisions of, and symbols on, HF SURGICAL EQUIPMENT

9.1 General

HF SURGICAL EQUIPMENT fulfilling the relevant IEC standards have safety provisions incorporated to ensure that the equipment is safe when used according to the instructions for use. To help the OPERATOR to utilize these provisions, symbols and colours are used.

9.2 Colours of indicator lights

The significance of colours of indicator lights for HF SURGICAL EQUIPMENT is according to Table 1.

Table 1 – Colours and significance of indicator lights according to IEC 60601-2-2

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required, for example, a fault in the PATIENT circuit
Yellow	CUTTING mode
Blue	COAGULATION mode
Green	Ready for use
Any other colour	Meaning other than that of red, yellow, blue or green

9.3 Markings on HF SURGICAL ELECTRICAL EQUIPMENT

Warnings, marking of controls, and other symbols are explained in the instructions for use. The important symbols are given in Table 2. More information about these symbols is given in the current versions of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-2-2:2017.

Table 2 – Symbols used on HF SURGICAL EQUIPMENT

Symbol	Meaning
 IEC 60417-5840 (2002-10)	Type BF (Not suitable for direct cardiac application)
 IEC 60417-5335 (2002-10)	Type CF (Suitable for direct cardiac application)
 IEC 60417-5841 (2002-10)	Defibrillation protected Type BF
 IEC 60417-5336 (2002-10)	Defibrillation protected Type CF
 ISO 7010-W012 (2011-05)	Dangerous voltage
 In older equipment ISO 7000-0434A (2004-01)	Attention, consult accompanying documents.
 In newer equipment ISO 7000-0434A (2004-01)	Caution