



IEC TR 61289

Edition 2.0 2019-05
REDLINE VERSION

TECHNICAL REPORT



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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01

ISBN 978-2-8322-6934-3

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	2
1 Scope.....	7
2 Normative references	7
3 Terms and definitions	7
4 General information regarding HF SURGICAL EQUIPMENT	12
5 Recommended practices before use	13
5.1 Inspection of HF SURGICAL EQUIPMENT and hf surgical accessories before use.....	13
5.2 Preparation	14
5.3 Handling of NEUTRAL ELECTRODES, HF SURGICAL ACCESSORIES, cables and connections	14
5.4 PATIENTS with active implants (active implantable electronic medical devices)	15
5.5 Simultaneous use of two items of HF SURGICAL EQUIPMENT	15
5.6 Instructions for use	16
6 Recommended practices during use	16
7 Recommended practices after use	16
8 Nature of HAZARDS	17
8.1 General.....	17
8.2 HF SURGICAL EQUIPMENT related HAZARDS	17
8.2.1 Incompatible combinations	17
8.2.2 Electromagnetic compatibility	17
8.2.3 Misconnection of ACTIVE ACCESSORIES.....	17
8.2.4 Specialty HF SURGICAL EQUIPMENT.....	17
8.3 ACTIVE ACCESSORY related HAZARDS	18
8.3.1 Incompatible combinations	18
8.3.2 Environment of use.....	18
8.3.3 Misuse.....	19
8.4 OPERATOR-related HAZARDS	19
8.4.1 OPERATOR not reading and /or following the instructions for use	19
8.4.2 OPERATOR selecting inappropriate power or mode settings	19
8.4.3 OPERATOR using an ACTIVE HF SURGICAL ACCESSORY in an inappropriate manner	19
8.5 NEUTRAL ELECTRODE related HAZARDS	20
8.5.1 General	20
8.5.2 Inadequate contact area of a NEUTRAL ELECTRODE.....	20
8.5.3 Inappropriate application	20
8.5.4 Surgical procedures utilizing high currents and /or long duty cycles	21
9 Safety provisions of, and symbols on, HF SURGICAL EQUIPMENT	23
9.1 General.....	23
9.2 Colours of indicator lights	23
9.3 Markings on HF SURGICAL ELECTRICAL EQUIPMENT	24
9.4 Protection against electric shock and burns	26
9.4.1 Method of protection	26
9.4.2 Degree of protection	26
9.5 HF SURGICAL EQUIPMENT not properly marked.....	27
9.6 Monitoring the effectiveness of the NEUTRAL ELECTRODE	27

9.7 Output indicators 27

10 Accompanying documents 28

11 Preventive maintenance 28

Annex A (informative) Concerns regarding high current surgical procedures or high duty cycles..... 29

Bibliography..... 30

Figure 1 – Symbol used on Class II equipment 26

Figure 2 – Symbol used with an earth referenced PATIENT circuit 27

Figure 3 – Symbol used with an HF ISOLATED PATIENT CIRCUIT 27

Table 1 – Colours and significance of indicator lights according to IEC 60601-2-2 24

Table 2 – Symbols used on HF SURGICAL EQUIPMENT 25

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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.

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.

¹ Numbers in square brackets refer to the Bibliography.

TECHNICAL REPORT



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

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references	7
3 Terms and definitions	7
4 General information regarding HF SURGICAL EQUIPMENT	12
5 Recommended practices before use	13
5.1 Inspection of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES before use	13
5.2 Preparation.....	13
5.3 Handling of NEUTRAL ELECTRODES, HF SURGICAL ACCESSORIES, cables and connections	14
5.4 PATIENTS with active implants (active implantable medical devices)	14
5.5 Simultaneous use of two items of HF SURGICAL EQUIPMENT.....	15
5.6 Instructions for use	15
6 Recommended practices during use	15
7 Recommended practices after use.....	16
8 Nature of HAZARDS	16
8.1 General.....	16
8.2 HF SURGICAL EQUIPMENT related HAZARDS	16
8.2.1 Incompatible combinations	16
8.2.2 Electromagnetic compatibility	16
8.2.3 Misconnection of ACTIVE ACCESSORIES.....	16
8.2.4 Specialty HF SURGICAL EQUIPMENT.....	17
8.3 ACTIVE ACCESSORY related HAZARDS	17
8.3.1 Incompatible combinations	17
8.3.2 Environment of use.....	17
8.3.3 Misuse.....	18
8.4 OPERATOR-related HAZARDS	18
8.4.1 OPERATOR not reading or following the instructions for use	18
8.4.2 OPERATOR selecting inappropriate power or mode settings	18
8.4.3 OPERATOR using an HF SURGICAL ACCESSORY in an inappropriate manner	18
8.5 NEUTRAL ELECTRODE related HAZARDS	19
8.5.1 General	19
8.5.2 Inadequate contact area of a NEUTRAL ELECTRODE.....	19
8.5.3 Inappropriate application	19
8.5.4 Surgical procedures utilizing high currents or long duty cycles.....	19
9 Safety provisions of, and symbols on, HF SURGICAL EQUIPMENT	22
9.1 General.....	22
9.2 Colours of indicator lights	22
9.3 Markings on HF SURGICAL ELECTRICAL EQUIPMENT	22
9.4 Protection against electric shock and burns	24
9.4.1 Method of protection	24
9.4.2 Degree of protection	24
9.5 HF SURGICAL EQUIPMENT not properly marked.....	25
9.6 Monitoring the effectiveness of the NEUTRAL ELECTRODE	25

9.7	Output indicators	25
10	Accompanying documents	26
11	Preventive maintenance	26
Annex A (informative) Concerns regarding high current surgical procedures or high duty cycles.....		27
Bibliography.....		28
Figure 1 – Symbol used on Class II equipment		24
Figure 2 – Symbol used with an earth referenced PATIENT circuit		25
Figure 3 – Symbol used with an HF ISOLATED PATIENT CIRCUIT		25
Table 1 – Colours and significance of indicator lights according to IEC 60601-2-2		22
Table 2 – Symbols used on HF SURGICAL EQUIPMENT		23

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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.

¹ Numbers in square brackets refer to the Bibliography.