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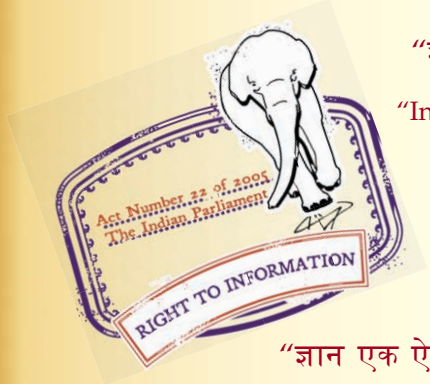



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( पहला पुनरीक्षण )

*Indian Standard*

# MEDICAL ELECTRICAL EQUIPMENT — HIGH FREQUENCY SURGICAL EQUIPMENT — SPECIFICATION

*( First Revision )*

UDC 615·846

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
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## FOREWORD

This Indian Standard ( First Revision ) was adopted by the Bureau of Indian Standards, after the draft finalized by the Electromedical Equipment Sectional Committee had been approved by the Medical and Hospital Planning Division Council.

This standard was first published in 1974. This revision has been carried out to align it with IEC 601-2-2 ( 1982 ) 'Medical electrical equipment: Part 2 Particular requirements for the safety of high frequency surgical equipment' issued by the International Electrotechnical Commission ( IEC ).

High frequency surgical equipment is used for surgical operations, such as, cutting and coagulation by means of high frequency current.

The use of frequencies above 0·3 MHz avoids the unwanted stimulation of nerves and muscles which result from the use of low frequency current. Normally, frequencies above 5 MHz are not used in order to minimize the problems associated with high frequency leakage currents. However, higher frequencies may be used in the case of bipolar techniques.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values ( *revised* )'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Indian Standard*

# MEDICAL ELECTRICAL EQUIPMENT — HIGH FREQUENCY SURGICAL EQUIPMENT — SPECIFICATION

*( First Revision )*

## 1 SCOPE

**1.1** This standard specifies safety and performance requirements of high frequency surgical equipment used in medical practice.

**1.2** Equipment having a rated output power not exceeding 50 W ( for example, for micro-coagulation, or for use in dentistry, or ophthalmology ) is exempted from certain requirements of this standard. These exemptions are indicated in the relevant requirements.

## 2 REFERENCES

The following Indian Standards are necessary adjuncts to this standard:

| *IS No.* | *Title* |
|---|---|
| 302 : 1979 | General and safety requirements for household and similar electrical appliances ( *fifth revision* ) |
| 1885 ( Part 43 ) : 1977 | Electrotechnical vocabulary: Part 43 Electrical equipment used in medical practice |
| 6842 : 1977 | Limits for electromagnetic interference ( *first revision* ) |
| 8607 ( Sec 1 to 10 ) | Medical electrical equipment — General requirements for safety ( *first revision* ) ( *under preparation* ) |

NOTE — Till such time the standard under preparation is published, the matter shall be as agreed to between the concerned parties.

## 3 TERMINOLOGY

**3.1** The following definitions, in addition to those given in IS 1885 ( Part 43 ) : 1977, shall apply.

### 3.2 Applied Part

Output circuit including active, neutral and bipolar electrodes.

### 3.3 Coagulation

Sealing of small blood vessels or body tissues caused by the passage of high frequency current at the active electrode ( *see* **3.5** ).

### 3.4 Cutting

Section of body tissue caused by the passage of high frequency current of high current density at the point of the active electrode ( *see* **3.5** ).

### 3.5 Electrode, Active

Electrode intended to produce certain physical effects required in electrosurgery, for example, cutting and coagulation.

### 3.6 Electrode, Bipolar

Assembly of two active electrodes on the same support and so energized that the current flows mainly between these two eletrodes.

### 3.7 Electrode, Neutral

Electrode of relatively large area for connection to the body of the patient 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 — The neutral electrode is also known as plate electrode, passive or dispersive electrode.

### 3.8 High Frequency ( hf ) Surgical Equipment

Medical electrical equipment including its associated accessories intended for the performance of surgical operations, such as, cutting or coagulation of biological tissues by means of high frequency ( hf ) current.

### 3.9 Rated Output Power

Maximum high frequency power which can be fed into a non-reactive load resistor having a resistance between 50 and 2 000 ohms in case of a monopolar output circuit and between 10 and 1 000 ohms in case of bipolar circuit.

## 4 GENERAL REQUIREMENTS

Relevant provisions of IS 8607 ( Sec 1 to 10 ) shall apply.

## 5 GENERAL REQUIREMENTS FOR TESTS

**5.1** Provisions of IS 8607 ( Sec 1 to 10 ) shall apply except additional routine tests ( *see* **11.12** ).

**5.2** Where reference is made in test specifications to electrode cables and/or electrodes, those

supplied or recommended by the manufacturer shall be used.

**5.3 Sequence**

The test called for protection against the effects of defibrillator discharge shall be performed prior to the leakage current and dielectric strength tests.

## 6 CLASSIFICATION

The equipment shall be of Class I or II, and Type BF or CF.

## 7 IDENTIFICATION, MARKING AND DOCUMENTS

**7.1 Marking**

Each apparatus shall be marked indelibly and clearly with the following information on a plate fixed firmly to it:

a) Indication of the source of manufacture,
b) Type designation,
c) Fabrication number,
d) Supply voltage or voltage range,
e) Current in amperes,
f) Operating frequency in MHz,
g) Phase, and
h) Rated output power in watts and the load resistance at which this power is available.

**7.1.1** *Marking on the Outside*

If relevant, the symbol indicating the type of protection against electric shock shall also indicate that protection against the effects of defibrillator discharge is incorporated.

**7.2 Marking of Controls**

The output control shall additionally have a scale and/or associated indicator showing relative units of high frequency output. The figure 'O' shall not be used unless no power is delivered in this position.

**7.2.1** Graduation of the output power control scale in 10 major intervals is recommended.

**7.3** The location of all components shall be marked for easy identification or re-location during maintenance/repair.

**7.4 Indicators, Push Buttons and Audio-Visual Device**

**7.4.1** *Colours of Indicator Lights and Push Buttons*

Where indicator lights are incorporated, they shall have the following colours and provide the indications shown against each:

a) *Green* — Power supply switched on;
b) *Yellow* — Output circuit energized but where cutting and coagulation output may be separately selected, two lights may be incorporated and if so, they shall have the following colours:

*Yellow* : Cutting, and

*Blue* : Coagulation.

Alternatively, knobs may have the same colour code as stated above.

**7.4.2** *Audio-Visual Device*

A fail safe audio-visual device shall be provided to indicate fault condition in patient circuits.

**7.5 Accompanying Documents**

Each apparatus shall be provided with the instructions for use and a technical description giving the following details:

a) Rated voltage;
b) Frequency of supply;
c) Symbol for protection class;
d) Details of trolley ( *see* **9.11** );
e) Degree of radio interference;

NOTE — Limits of interference field strength and interference voltage for electromedical apparatus have been laid down in IS 6842 : 1972.

f) Rated output and corresponding load resistance;
g) Rated working frequency ( nominal generated frequency in MHz for short-wave and in RHz for surgical units );
h) Nominal output in watts ( maximum high frequency output given by the apparatus );
j) Manual containing operating instruments;
k) Maintenance/service manual;
m) Parts list; and
n) Circuit diagram.

**7.5.1** Instructions for use shall additionally contain:

a) Information concerning the compatibility of high frequency cables in order to prevent the use of unsuitable cables; and
b) Notes on the application of high frequency surgical equipment. These shall draw the attention of the user to certain precautions which are necessary in order to reduce the risk of accidental burns.

**7.5.1.1** In particular, advice shall be given on the following:

a) The neutral electrode should be reliably attached with its entire area to the patient's body and as close to the operating field as possible.

b) The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth ( for example, operating table, supports, etc ). The use of antistatic sheeting is recommended for this purpose.

c) Skin-to-skin contact ( for example, between the arms and the body of the patient ) should be avoided, for example, by insertion of dry gauze.

d) When high frequency surgical equipment and physiological monitoring equipment is used simultaneously on the same patient, any monitoring electrode not incorporating protective resistors or high frequency chokes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.

e) The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided.

f) For surgical procedures on parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.

g) The output power selected should be as low as possible for the intended purpose.

h) Apparent low output or failure of the surgical equipment to function correctly at normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.

j) The use of flammable anaesthetics and nitrous oxide ( $N_2O$ ) and oxygen should be avoided if a surgical procedure is carried out in the region of thorax or the head unless these agents are sucked away or anaesthetic-proof equipment is used. Flammable agents used for cleaning or disinfecting or as solvents of adhesives should be allowed to evaporate before the application of high frequency surgery. There is a risk of pooling of flammable solutions under the patient or in body depressions, such as the umbilicus and in body cavities, such as, the vagina. Any fluid pooled in these areas should be mopped up before the equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example, cotton wool and gauze, when saturated with oxygen, may be ignited by sparks produced in normal use of the equipment.

k) For patients with cardiac pacemakers or pacemaker electrodes, a possible hazard exists because interference with the action of the pacemaker may occur or the pacemaker may be damaged. In case of doubt, reference should be made to the cardiology department for advice.

m) The possibility of interference to other medical electrical equipment due to the operation of high frequency surgical equipment.

**7.5.2** The technical description shall contain the following output data:

a) Diagrams showing the power output at full- and half-setting of the output control over the range of load resistance 50 to 2 000 ohms for the following operating modes, if available,

1) Cutting,

2) Coagulation, and

3) Blend, any variable; 'Blend' control being set to the maximum position;

b) Diagrams showing the power output versus the output control setting at a specified load resistance in the range 50 to 2 000 ohms for the operating modes listed above; and

c) Designation of the applied part(s) ( *see* **11.2** ).

## 8 SAFETY REQUIREMENTS

**8.1** The equipment shall satisfy the relevant safety requirements of IS 8607 ( Sec 1 ).

**8.2** To avoid safety hazards, the following considerations should be taken into account:

a) Minimizing the distance between the operating field and the neutral electrode reduces the load resistance, and for a given power at the site of the active electrode, the power output required from the equipment and also the high frequency voltage across the patient so as to reduce the hazard of unwanted burns;

b) Small area contacts with objects having a low impedance to earth at high frequencies may result in high current densities and hence unwanted burns;

c) There may be some high frequency voltage difference between these parts of the patient's body which may cause an unwanted current to flow;

d) The current flowing to the leads of the monitoring equipment may cause burns at the site of the electrodes;

e) The capacitance between the electrode cable and the patient may result in some local high current densities;

f) Specially where bony structures and having a relatively high resistance are involved, bipolar techniques can avoid unwanted tissue damage;

g) Output power shall be minimum required;

h) Techical description, output data and diagram shall be provided. These diagrams should enable the user to judge the suitability of an equipment for a particular purpose; and

j) It should be made clear to the user whether the applied part is completely floating or referenced to earth at high frequency.

## 9 CONSTRUCTION

**9.1** Provisions of IS 8607 ( Sec 10 ) shall apply except as stated below.

### 9.2 Switches

In addition to the mains switches, an output switch ( finger or foot switch ) shall be provided requiring continuous activation to energize the output circuit.

**9.2.1** The switching circuit shall be supplied from a power source isolated from the mains part and from earth and having a voltage not exceeding 12 V if a conductive connection to the applied part exists, and 24 V ac or 34 V dc in other cases.

**9.2.2** Under single fault condition, this circuit shall not cause low-frequency patient leakage current(s) exceeding the allowable limits.

**9.2.3** Compliance shall be checked by inspection, functional check, and measurement of voltage and leakage current(s).

### 9.3 Cord Connected Foot Switches

The force required to actuate the foot switch shall be between 10 and 15 N.

### 9.4 Monitoring Circuit

Equipment having a rated output power of more than 50 W and an applied part not isolated from earth at high frequencies to the degree required in this standard shall be provided with a circuit arranged so as to de-energize the output and to give an audible alarm when an interruption of the neutral electrode cable or its connections occurs. The audible alarm shall meet the sound level requirements of **9.5.2** and shall not be externally adjustable.

NOTE — An additional visible warning should be provided consisting of a red indicator light.

### 9.5 Output Indicator

A device shall be incorporated which gives an audible signal when any output circuit is energized by the operation of an output switch or as a result of a single fault condition. The sound output shall have its major energy content in the band of frequencies between 100 and 1 000 Hz. The sound source shall be capable of producing a sound level of at least 65 dBA at a distance of 1m from the equipment. An accessible sound level control may be provided but shall not reduce the sound level below 45 dBA.

**9.5.1** In order to enable the user to distinguish between the audible alarm called for in **9.4** and the signal specified above, either the former shall be pulsed or two different frequencies shall be employed.

**9.5.2** Compliance shall be checked by functional check and measurement of the sound level.

### 9.6 Neutral Electrode

**9.6.1** Except for any output circuit intended only for connection to a bipolar electrode, equipment having a rated output power in excess of 50 W shall be provided with a neutral eletrode.

**9.6.1.1** Compliance shall be checked by inspection.

**9.6.2** The neutral electrode should be so designed that it provides, with a margin of safety an adequate area of contact with the body and allows a return path for the high frequency current with such a low current density in the body tissue that adverse physiological or physical effects are avoided.

**9.6.3** The neutral electrode of equipment having a rated output power of not more than 50 W may be capacitively coupled to the patient.

**9.6.4** The neutral electrode shall be reliably connected to the cable. Any current used for monitoring electrical continuity of the electrode cable and its connections shall pass through a section of the electrode.

**9.6.4.1** Compliance shall be checked by inspection and test of the electrical continuity.

### 9.7 Neuromuscular Stimulation

To minimize the possibility of neuromuscular stimulation, the dc resistance between active and neutral electrode terminals or between the terminals of a bipolar output circuit shall be not less than 2 MΩ.

**9.7.1** The effective series capacitance should not exceed 5 000 $\mu$F.

**9.7.2** Compliance shall be checked by inspection of dc resistance between the output terminals.

### 9.8 Cooling Fans

**9.8.1** Cooling fans, if incorporated, shall be so arranged that in normal use, any draught is directed away from the patient.

**9.8.2** Generally, the use of cooling fans should be avoided.

**9.8.3** Compliance shall be checked by inspection of the equipment and the accompanying documents.

### 9.9 Anaesthetic-Proof High Frequency Surgical Equipment

**9.9.1** At least the applied part of equipment specified for use with flammable anaesthetics shall be anaesthetic-proof and marked 'AP' and shall comply additionally with the following requirements.

**9.9.1.1** Cutting or coagulation electrodes shall be provided with a holder equipped with a means for directing a stream of inert gas towards the operating site. The arrangement shall be such as to ensure that the inert gas flow is started at least 1 second before the output is energized and the gas flow is stopped only after the output is de-energized.

NOTE — Inert gas, for example, nitrogen or carbon dioxide, at flow rate of 3 to 5 l/min have proved adequate in practice.

**9.9.2** Compliance shall be checked by the test of **11.4**.

### 9.10 Rated Output

The equipment set up to deliver its rated output power into a resistive load using the electrode cables is operated for 1 hour with a duty cycle as specified by the manufacturer but minimum with an operating time of 10 seconds and resting time of 30 seconds.

### 9.11 Spillage

The equipment shall be placed on a trolley, approximately 600 mm in height, so that the liquid spillage in normal use does not wet electrical insulation or other components which, when wetted, are likely to affect adversely the safety of the equipment.

The relevant test shall be carried out only on the front panel of the equipment and switch to conform to the protection of internal device during normal operation.

### 9.12 Ingress of Liquids

The electrical switching parts of foot switches for high frequency surgical equipment intended for use in operating rooms shall be of watertight construction.

### 9.13 Human Errors

**9.13.1** Where a double foot switch assembly is used to select cutting and coagulation output modes, the arrangement shall be such that when viewed by the operator, the 'cut' pedal is on the left and the 'coagulate' pedal on the right-hand side.

**9.13.1.1** Compliance shall be checked by inspection.

**9.13.2** Where the active electrode holder incorporates two finger switches, the switch nearer to the electrode shall activate the cutting mode and the switch further from electrode shall activate the coagulation mode.

**9.13.2.1** Compliance shall be checked by inspection.

**9.13.3** Operation of a single output switch shall not result in the simultaneous energizing of more than one active electrode.

**9.13.3.1** For the purpose of this requirement, a bipolar electrode is considered to be one active electrode.

**9.13.3.2** Compliance shall be checked by inspection and functional check.

**9.13.4** Connectors for active and neutral electrode shall not be interchangeable.

**9.13.4.1** Compliance shall be checked by inspection.

### 9.14 Electromagnetic Compatibility

The equipment shall comply with the requirement specified in CISPR Publication 11 'Limits and methods of measurement of radio interference characteristics of industrial, scientific and medical ( ISM ) radio-frequency equipment excluding surgical diathermy apparatus' when the equipment is energized but the output switch is not activated.

## 10 ACCURACY OF OPERATING DATA AND PROTECTION AGAINST INCORRECT OUTPUT

### 10.1 Accuracy of Operating Data

**10.1.1** Equipment shall incorporate means ( an output control ) to enable the output power to be reduced to not more than 5 percent of the rated output power or 10 W, whichever issmaller ( *see* **7.2** ). In the load resistance range 100 to 1 000 Ω, the output power shall increase with the increase of the output control setting.

**10.1.2** For output powers in excess of percent of the rated output power, the actual power as a function of load resistance and output control setting shall not deviate from that shown in the diagrams specified in **7.5.2** by more than ±20 percent.

### 10.2 Protection Against Incorrect Output

**10.2.1** The rated output power shall not exceed 400 W for any operating mode averaged over any period of 1 second.

**10.2.1.1** Compliance shall be checked by inspection of marking and output power-load resistance curves.

**10.2.2** When the equipment is switched off and again switched on, the mains supply is interrupted and re-established, the following requirements shall be complied with:

a) The output power for a given setting of the output control shall not increase by more than 20 percent, and

b) The mode of operation shall not be changed except to a stand-by mode in which no output is produced.

**10.2.2.1** Compliance shall be checked by measurement of output power averaged over a period of 1 second and the observation of the operating mode:

a) with repeated operation of the mains switch of the equipment; and

b) with interruption and re-establishment of the mains supply, the switch in the equipment being left in the 'on' position.

## 11 TESTS

### 11.1 High Voltage and Insulation Resistance Test ( Routine Tests )

**11.1.1** *High Voltage Test*

**11.1.1.1** High voltage test shall be carried out in accordance with Annex A. The test voltage between output circuit and any other terminal of the unit having $U$ as their working voltage shall be $2\ U + 500\ V$.

**11.1.1.2** The surgical apparatus is operated with 110 percent of the rated supply voltage for 30 minutes and after this operation, the high frequency insulators shall be checked for no change and satisfactory operation.

**11.1.2** *Insulation Resistance Test*

The insulation resistance test is performed with direct voltage of approximately 500V immediately after the humidity treatment specified in **4.10** of IS 8607 ( Sec 1 ) the measurement being made one minute after the application of the voltage and heating elements, if any, being disconnected. The insulation resistance is measured. The measured value between live parts and the casing shall not be less than those stated below:

a) For functional insulation : 5 M Ω, and

b) For reinforced insulation : 7 M Ω.

NOTE — The term 'casing', as used above, includes all accessible metal parts, shafts of carrying handles and knobs and similar components, and a metal foil not larger than 200 mm × 100 mm which lies on the surface of the external parts of insulating material. The metal foil shall have the largest area possible that can be placed for the test on the surface of the apparatus to be tested, but shall not be larger than the dimensions stated above.

### 11.2 Test for High Frequency Leakage Current

**11.2.1** The applied part shall, depending on its design, comply with the relevant section of the following requirements:

a) *Neutral electrode reference to earth* — The applied part is isolated from earth but the neutral electrode is referenced to earth at high frequencies by component ( for example, a capacitor ) satisfying the requirements of Type BF equipment. When tested as described below, the hf leakage current flowing from the neutral electrode through a non-inductive 200 Ω resistor to earth shall not exceed 150 mA.

Compliance shall be checked by the following tests:

*Test 1* — The test is performed on the equipment with the electrode cables and electrodes as shown in Fig. 1. The cables are spaced 0·5 m apart on an insulating surface 1 m above the floor or any conducting plane. The output is loaded with 200 Ω and the equipment is operated at maximum output setting in each operating mode. The hf leakage current flowing from the neutral electrode through a non-inductive resistor of 200 Ω to earth is measured.

*Test 2* — The equipment is set up as for Test 1 but the 200 Ω load resistor is connected between the active electrode and the protective earth terminal, of the equipment as shown in Fig. 2. The hf leakage current flowing from the neutral electrode is measured.

b) *Neutral electrode isolated from earth at high frequency* — The applied part is isolated from earth at both high and low frequencies and the isolation shall be such that the hf leakage current flowing from each electrode through a 200 Ω non-inductive resistor to earth does not exceed 150 mA when tested as described below:

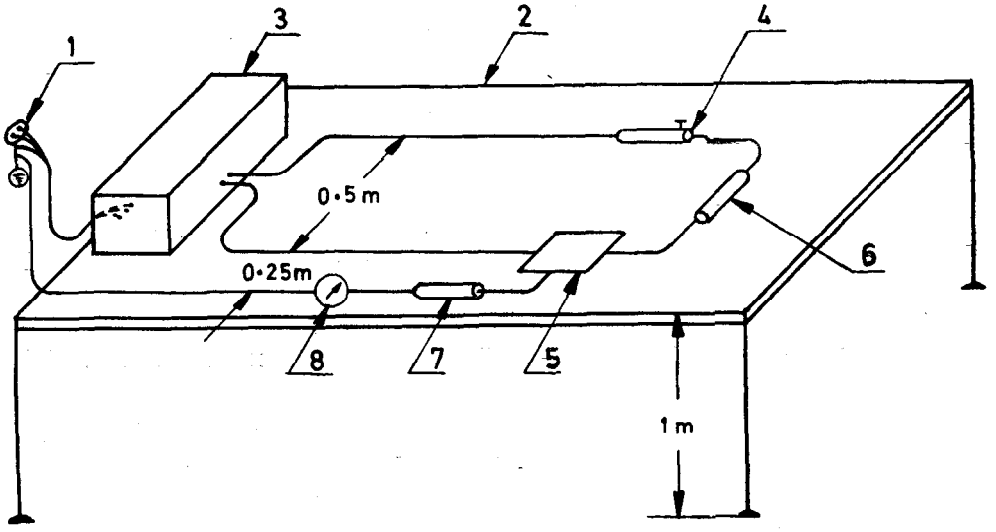
The equipment is set up as described in **11.2.1** (a) Test 1, the output being unloaded. Any metal enclosure of Class II equipment and internally powered equipment shall be connected to earth. Equipment having an insulating enclosure shall be positioned on earthed metal having an

area at least equal to that of the base of the equipment during this test ( *see* Fig. 3 ). The hf leakage current is measured from each electrode in turn while the equipment is operated at maximum output setting in each operating mode.

c) *Bipolar application* — Any applied part specifically designed for bipolar application shall be isolated from each and from other applied parts at both high and low frequencies.

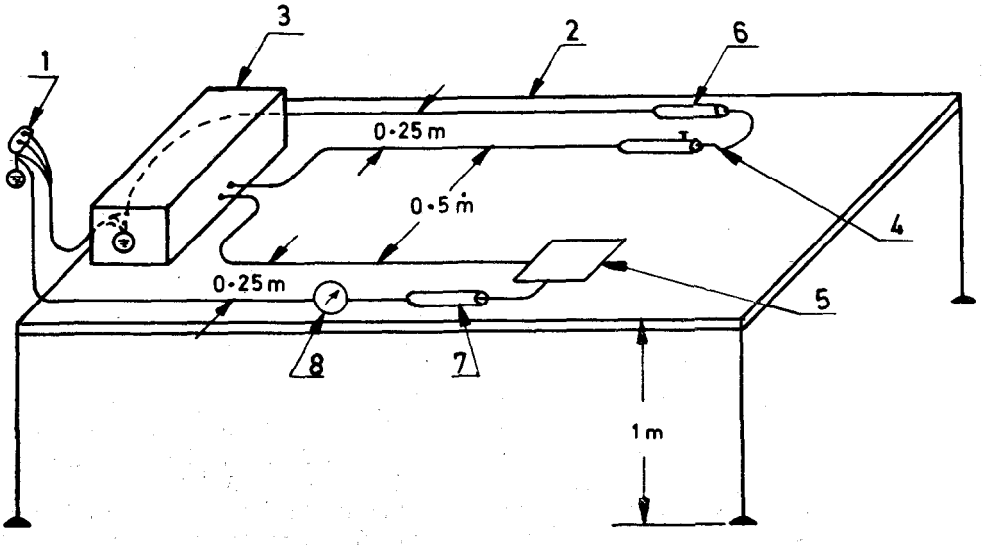
**11.2.1.1** The hf leakage current requirements are under consideration.

**11.2.1.2** In the case of equipment, specified for permanent installation, the tests shall be carried out with the equipment fitted with mains supply cord having a length of 3 m.



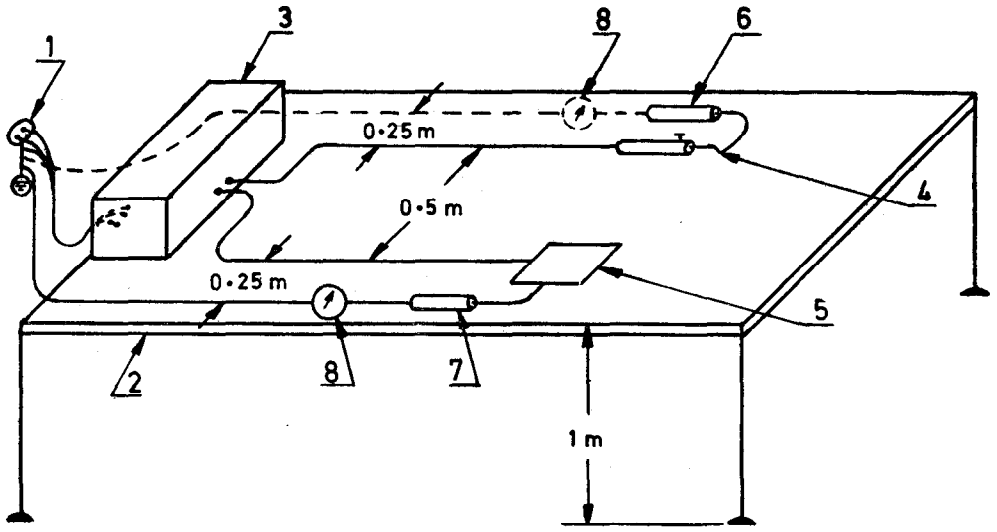

1 — Supply mains
2 — Table made of insulating material
3 — hf surgical equipment
4 — Active electrode
5 — Neutral electrode, metallic or in contact with metal foil of the same size
6 — Load resistance, 200 ohms
7 — Measuring resistance, 200 ohms
8 — hf current meter

FIG. 1 MEASUREMENT OF hf LEAKAGE CURRENT, EARTH REFERENCED, LOAD BETWEEN ELECTRODES




For legends 1 to 8, *see* Fig. 1.

FIG. 2 MEASUREMENT OF hf LEAKAGE CURRENT, EARTH REFERENCED, LOAD FROM ACTIVE ELECTRODE TO EARTH




For legends 1 to 8, *see* Fig. 1.

FIG. 3 MEASUREMENT OF hf LEAKAGE CURRENT, EQUIPMENT INSULATED AT hf

**11.2.1.3** The requirements in **11.2.1** (a), (b) and (c) apply for both Type BF and Type CF equipment.

**11.2.1.4** Requirements for hf enclosure leakage currents are under consideration.

### 11.3 Dielectric Strength Test

**11.3.1** Relevant provisions of IS 8607 ( Sec 3 ) shall apply.

**11.3.1.1** In addition, requirements and tests for electrode cables are given in **11.11**.

### 11.4 Test for Anaesthetic-Proof Equipment

Compliance for anaesthetic-proof high frequency surgical equipment shall be checked by the following tests:

a) Measurement of time interval between the commencement of the flow of inert gas from the electrode holder and the energization of the output ( *see also* **B-1.4** ).

b) Verification that the flow of inert gas is maintained as long as the output is energized ( *see also* **B-1.4** ).

c) A test for ignition is performed with the device shown in Fig. 4. The cotton wool plug in the trough (1) is wetted with a few millilitres of ether. The ether vapour flows via the gutter (2) on to the metal plate (3). The handle (5) with the electrode approximates the metal plate at a distance of about 150 mm from the end of the gutter. Sparking at the electrode shall not produce ignition of the ether mixture or air mixture. The test shall be performed with the equipment set to maximum output. Where selection 'cut or coagulate' modes is provided, the equipment shall be tested in each of these modes. The test shall be performed with all electrodes supplied for use with the equipment.

### 11.5 Output Test

**11.5.1** Requirements of **10.1** shall be verified by the following test:

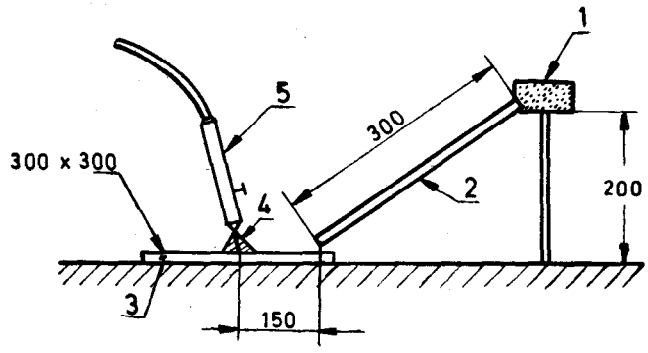
Measurement of output power as a function of output control setting at four values of load resistance in the range 100 to 1 000 ohms, for example, at 100, 200, 500 and 1 000 ohms. The electrode cables shall be used for connection of the load resistors. The high frequency current $I$ is measured through the known resistance $R$ and the output $W$ is obtained by the formula

$$W = I^2 R.$$

**11.5.2** Compliance of **10.1.2** shall be checked by performing the test of **11.5.1** but using appropriate values of load resistance.

### 11.6 Protection Against the Effects of Defibrillator Discharge

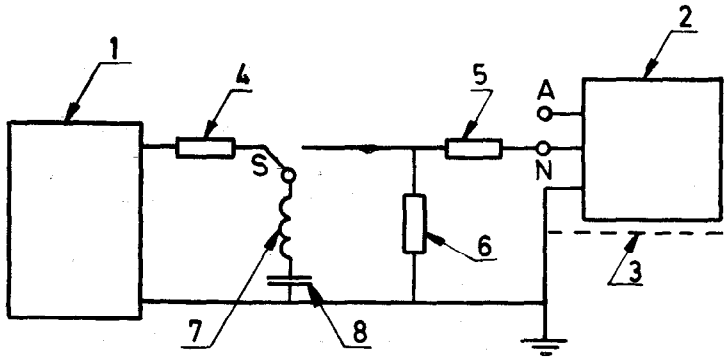
Equipment having a rated output power of more than 50 W shall be provided with protection against the effects of the discharge of a cardiac defibrillator tested 5 times at an output of 400 J from the defibrillator. Such equipment shall be permanently marked on the front panel to indicate that such protection is incorporated and this shall be confirmed in the accompanying documents.




1 — Trough with cotton wool plug
2 — Gutter
3 — Metal plate
4 — Cone of inert gas
5 — Handle with active electrode

All dimensions in millimetres.

FIG. 4 IGNITION TEST FOR ANAESTHETIC-PROOF EQUIPMENT




1 — DC voltage source
2 — High frequency surgical equipment
3 — Metal plate for equipment having an enclosure of insulating material
4 — Resistance, $R_L \leq 10$ ohms
5 — Resistance, 50 ohms
6 — Resistance, 100 ohms
7 — Capacitance, $C = 32\mu F$

FIG. 5 TEST FOR DEFIBRILLATOR PROOFNESS

### 11.7 Spillage

Compliance shall be checked by the following test:

A quantity of one litre of water is poured steadily on to the middle of the top surface of the equipment over a period of 15 seconds Equipment intended to be built into a wall or cabinet is test mounted as recommended by pouring water into the wall above the control panel. After this treatment, the equipment shall withstand the dielectric strength test and inspection shall show no trace of water on insulation for which creepage distances are specified in IS 8607 ( Sec 10 ).

### 11.8 Ingress of Liquids

Compliance shall be checked by the following test:

The foot switch shall be completely immersed in water to a depth of 150 mm for a period of 30 minutes. While immersed, it shall be connected in a circuit corresponding to its normal operation and actuated 50 times. After completion of this test, the switch shall be inspected. There shall be no evidence of entry of water and the switch shall pass the dielectric strength test specified in **11.3**.

### 11.9 Protection Against the Effect of Short-Circuiting of Electrodes

The equipment shall be capable of withstanding without damage, the effects of short-circuiting or open-circuiting the output when energized at maximum output setting.

**11.9.1** Compliance shall be checked by the following test:

The electrode cables and electrodes are connected to the equipment and the output control set to the maximum position. The output is then switched on and the active and neutral electrodes are short-circuited for a period of 5 seconds and then open-circuited for a period of 15 seconds. The output is then switched off for a period of 1 minute. The above cycle is repeated for a total of 10 times.

**11.9.1.1** After this test, the equipment shall comply with all the requirements of this standard.

### 11.10 Test for Monitor Circuit

Compliance shall be checked by the following test:

A circuit consisting of 1 000 ohm resistor in parallel with a switch is connected in series with the neutral electrode lead. The equipment is operated so as to deliver the rated output power into a resistive load and the switch is closed and opened five times. The alarm shall operate and the high frequency output shall be disabled at each opening of the switch.

NOTE — Care should be taken to see that under normal conditions, the monitoring circuit does not introduce any interfering voltage ( for example, at mains frequency or its harmonics ) at the neutral electrode which can adversely effect the operation of any patient monitoring equipment.

### 11.11 Test for Electrode Cables, Connectors and Handles

**11.11.1** The insulation of electrode cables whether or not specified for re-use, shall be capable of withstanding a mains frequency voltage of 3 000 V rms and a high frequency voltage of twice the maximum open-circuit high frequency voltage of the equipment.

**11.11.2** High frequency dielectric strength test for the active electrode handle is under consideration.

**11.11.3** Compliance shall be checked by the following tests:

a) *Main frequency* — Approximately 200 mm of the cable to be tested is formed into a loop by joining suitably bared conductors at each end. It is lowered into water, the conductivity of which has been increased by the addition of a small amount of salt until a total length of 100 mm of insulated cable has been immersed. The cable shall remain in water for at least 24 hours following which the test voltage shall be applied for 5 minutes between the conductor or conductors and the water.

b) *High frequency* — A test sample of the cable is prepared and immersed as in test at **11.11.3**(a). A quantity of transformer oil is then added, just sufficient to produce a visible continuous film on the water surface ( this technique reduces the curvature of the meniscus ). High frequency voltage produced by the equipment via a 1 : 2 set-up high frequency transformer is applied between the cable conductor and a bare conductor in water while the equipment is operated in each output mode in turn at the maximum setting of the corresponding control for 30 seconds.

**11.11.3.1** During these tests, no breakdown or flashover shall occur.

**11.11.4** The handle for the active electrode and its cable shall fulfil the relevant requirement of IS 8607 ( Sec 7 ) regarding sterilization.

**11.11.5** Any connector provided for attachment of the neutral electrode to its cable shall be so designed as to prevent conductive contact with the body of the patient in the event of inadvertent disconnection.

Compliance is checked by the following test:

Any cable to neutral electrode connector is disconnected from the electrode and using the standard test finger shown in IS 8607 ( Sec 3 ), it is verified that contact with conductive parts of the cable connector is not possible.

**11.12** Additional routine tests are given in Annex B.

# ANNEX A

( *Clause* 11.1.1 )

## HIGH VOLTAGE TEST

**A-1** High voltage is made with alternating voltage of substantially sine wave form and having a frequency of 50 Hz after the humidity treatment specified in IS 302 : 1979 and when the apparatus has attained its operating temperature.

**A-1.1** In order to prevent circuit-making impulses, the test voltage is increased within 10 seconds from 500 V to its final value and then maintained for one minute.

**A-1.2** During this test, breakdown or flashover shall not occur; no objection shall be made to corona phenomena. The magnitude of test voltage and the points for high voltage test are stipulated in Table 1.

**A-2** If it is not possible to make interruptions in circuits without damaging the apparatus for the test, the manner in which the purpose of this test can be achieved by other means, shall be subject to agreement between the manufacturer and the testing authority. In intermediate circuits separated from the mains part and within the applied part, the high voltage test is only made if by bypassing the insulation between the live parts, danger may occur to the operator, the patient or the surroundings, or if currents over 300 $\mu$A ( peak ) or voltages over 24 V can be transmitted to the applied part.

**A-2.1** The operation of a series-connected overcurrent protective part or an overload protection device in the apparatus may constitute a danger within the meaning of this specification.

**Table 1 Test Voltage**

( *Clause* A-1.2 )

| Sl No. | Voltage | Test Voltage (*V*) | |
|---|---|---|---|
| | | Protection Class I | Protection Class II |
| (1) | (2) | (3) | (4) |
| i) | Between all parts having a conducting connection with the mains ( mains part ) on the one hand and the applied part and the casing on the other hand. | 1 $U$ + 1 000<br>2 000, *Min* | 2 $U$ + 3 000<br>4 000, *Min* |
| ii) | Between parts within the mains part ( input part ) or within the applied part ( output part ), between which occurs a voltage $U$: | | |
| | a) $U$ up to 24 V | 500 | 500 |
| | b) $U$ over 24 V | 2 $U$ + 1 000<br>1 500, *Min* | 2 $U$ + 1 000<br>1 500, *Min* |
| iii) | Between parts of Class II apparatus: | | |
| | a) Between the mains part and non-accessible metal parts ( functional insulation ) of the Class II apparatus | — | 1 500 |
| | b) Between non-accesible metal parts and casing ( supplementary insulation ) of a Class II apparatus | — | 2 500 |
| iv) | Insulating linings, knobs and lead entries: | | |
| | a) Between metal casings having an insulating lining and metal foil on the inner surface of the lining when the clearance between functionally insulated parts which are subjected to mains voltage and the metal casing smaller than the clearances specified in IS 302 : 1979. | 1 500 | 2 500 |
| | b) Between metal foils on actuating part ( knobs, handles and similar components ) and their spindles when these spindles can become live in the case of a fault. | 1 500 | 2 500 |
| | c) Between metal casings and either of the metal foil wrapped round the fixed connection lead inside inlet guard. | 1 500 | 2 500 |

NOTE — The insulation between live parts in accordance with item (ii) is tested only insofaras doubt with regard to high voltage arises after inspection.

**A-2.2** The insulation between the contacts of microswitches, thermostats, thermal cut outs, relays, etc, and the insulation of capacitors are not tested.

**A-3** In the case of Class II apparatus which has been reinforced and double insulated, care should be taken that the voltage applied to the reinforced insulation does not overstress the functional or supplementary insulation. When testing insulating coating, the metal foil may be pressed against the insulating material by means of a sand bag of such a size that the pressure is approximately 0·005 N/mm$^2$.

**A-3.1** Care should be taken to ensure that the metal foil is positioned in such a manner that flashover does not occur at the edges of the insulation.

**A-4** High voltage test may be limited to places where the insulation is likely to be weak, for example, where there are sharp metal edges under the insulation.

**A-4.1** If possible, insulating linkings shall be tested separately.

## ANNEX B

( *Clauses* 11.4 *and* 11.12 )

### TESTING DURING MANUFACTURE AND/OR INSTALLATION

### B-1 ADDITIONAL ROUTINE TESTS

**B-1.1** Measurement of dc resistance between the active and neutral electrode terminals or between the two terminals for a bipolar electrode, respectively ( *see* **9.7** ).

**B-1.2** Functional test of any monitoring circuit.

**B-1.3** Measurement of rated output power.

**B-1.4** For anaesthetic-proof equipment, the following test is required to be carried out.

**B-1.4.1** The test is performed with the device shown in Fig. 6. Instead of the inert gas normally used, compressed air is fed with a flow of 3 to 5 litres per minute through the handle. The supply pipe is connected to bottle having a capacity of approximately one litre which contains 700 ml of an aqueous solution of ammonia. The handle with electrode is directed towards the plate which is covered with a suitable indicator paper ( for example, universal *p*H indicator paper, range 1-10 ) which has been moistened with water.

The air/ammonia mixture will produce a change in the colour of the indicator paper corresponding to the area of the gas flow surrounding the active electrode. The test should be repeated with all active electrodes supplied for use with the equipment, the hf output control may be set to minimum power throughout the test.

In each case, the entire electrode shall be within the stream of gas as shown by the indicator paper. The test may be used to check compliance with the requirement that the inert gas flow is started before the output power is switched on and that the gas flow stops after the output power is switched off.

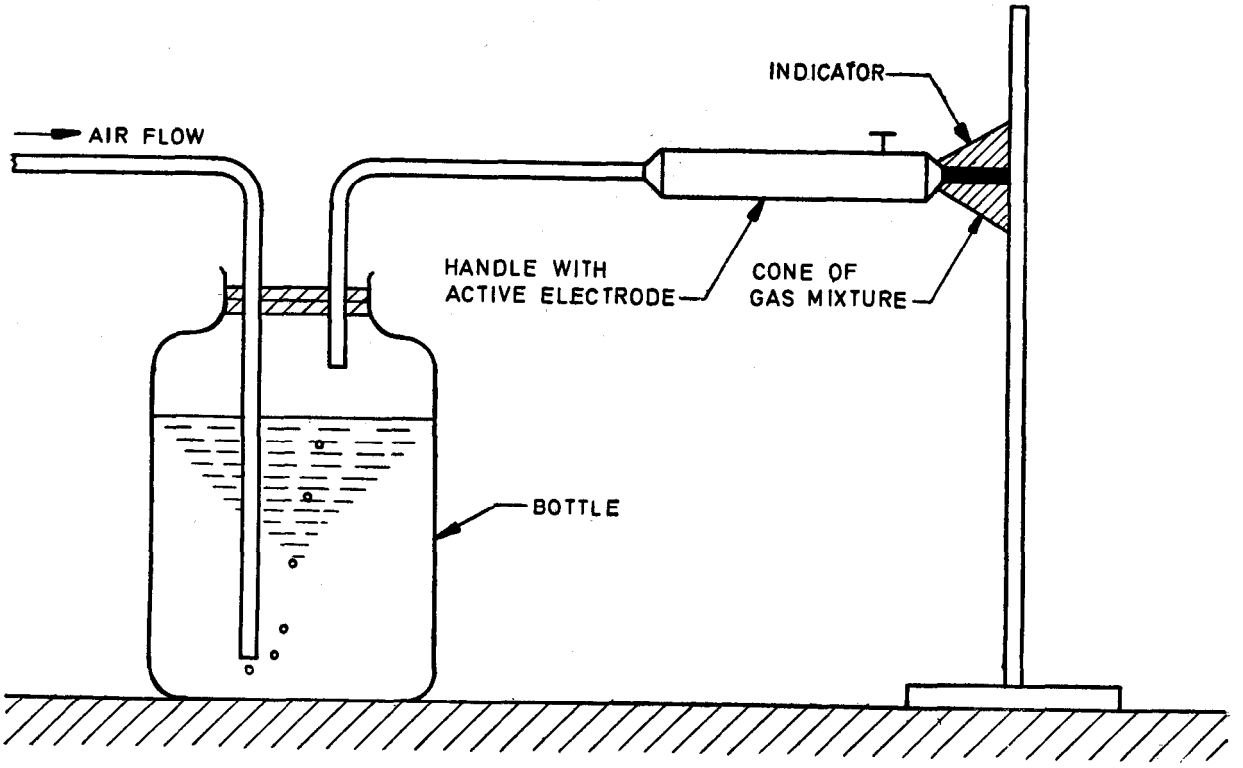



FIG. 6 ADDITIONAL ROUTINE TEST FOR ANAESTHETIC-PROOF EQUIPMENT

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