NOTIFICATION

Addendum

A translation of the Ministerial Order attached to document TBT/Notif.84.94 is reproduced below.

MINISTRY OF INDUSTRY AND ENERGY

22013 CORRIGENDUM to the Order of 31 May 1983 implementing Royal Decree 1231/1983 of 20 April, which makes electromedical apparatus for monitoring the intensive care of patients subject to technical standards.

There is an error in the above Order as published in the "Boletin Oficial del Estado", No. 145, of 18 June 1983. It should be corrected as follows:

In the Annex to the Order, in Section 5, second paragraph, last line, replace the words "frequencies higher than 1 mHz" by the words "frequencies higher than 1 MHz".

MINISTRY OF INDUSTRY AND ENERGY

17046 ORDER of 31 May 1983 implementing Royal Decree 1231/1983 of 20 April, which makes electromedical apparatus for monitoring the intensive care of patients subject to technical standards.

Royal Decree 1231/1983, of 20 April, makes mandatory compliance with technical standards, to be established by the Ministry of Industry and Energy, for the sale or installation throughout the national territory of electromedical apparatus for monitoring the intensive care of patients.

* English and French only

1 Published in the Boletin Oficial del Estado (Official Gazette) of 15 August 1983.

2 Published in the Boletin Oficial del Estado (Official Gazette), No. 145, of 18 June 1983.
Consequently, it is necessary to provide for a standard, as well as type approval, compliance with the standard and an approval mark - all in accordance with Royal Decree 2584/1981, of 18 September.

In virtue whereof, this Ministry has deemed it appropriate to order as follows:

First - 1. An electromedical apparatus for monitoring the intensive care of patients, whether manufactured in Spain or imported, is subject to the standard described in the specifications set out in the Annex hereto and to type or model approval and certification of conformity of the product to the approved model, in accordance with the provisions of the General Regulations of Procedure of the Ministry of Industry and Energy, approved by Royal Decree 2584/1981 of 18 September and Royal Decree 1231/1983 of 20 April, which makes electromedical apparatus for monitoring the intensive care of patients subject to technical standards.

2. It is prohibited to sell or install in any part of the national territory an apparatus of the kind referred to in the preceding paragraph if it is of a type that has not been approved or if, being a reproduction of a model that has been approved, it lacks the product-conformity certificate issued by the Supervision and Certification Commission of the Ministry of Industry and Energy.

3. An apparatus conforming to the approved model shall display the appropriate product-conformity mark issued by the above-mentioned Commission.

Secondly - 1. For approval and for certification of conformity of an electromedical apparatus for monitoring the intensive care of patients, compliance shall be required with the technical specifications appearing in the Annex to this Order and tests shall be made with respect to those specifications.

2. The required tests and analyses shall be made in laboratories accredited by the Directorate General for Industrial Innovation and Technology of the Ministry of Industry and Energy.

Thirdly - 1. Applications for type approval shall be addressed to the Director-General for Electronics and Computer Technology of the Ministry of Industry and Energy in accordance with the provisions of Chapter 5, Section 2, of the General Regulations approved by Royal Decree 2584/1981 of 18 September.

2. Among the documentation that must accompany the application, that specified in (5.2.3 (c)) of the above-mentioned General Regulations shall be presented in the form of a project, signed by a competent technical expert, which shall include diagrams, lists of components and all the instructions necessary for the manufacture, maintenance and utilization of the equipment.
3. If the decision on the application is affirmative, a copy of the
documentation referred to in the preceding paragraph, signed and sealed by
the Director-General for Electronics and Computer Technology shall be
returned to the applicant and must be preserved by the manufacturer for
possible inspections for product conformity.

Fourthly - 1. Applications for certification of conformity of products
that reproduce a previously approved model shall be addressed to the
Supervision and Certification Commission of the Ministry of Industry and
Energy and shall comply with the provisions of Chapter 6 of the General
Regulations approved by Royal Decree 2584/1981 of 18 September.

2. The documentation required for such certification, as specified in
6.1.1 of those General Regulations, shall be submitted at intervals of not
more than one year for Spanish manufacturers, and at the time of
importation of each lot, for imported products.

3. As regards small manufacturing series and small imported lots, the size
of the sample to be tested shall be one specimen of the product and, for
the purposes of 6.1.1(b) of the General Regulations referred to in the
preceding paragraph, shall be selected by a Co-operating Entity operating
in the field of standardization and type approval.

4. If, in connection with approval of the type, the specimen of the
product sent to the testing laboratory has been selected by a Co-operating
Entity, it will not be necessary to send another specimen in order to
secure certification of product conformity for the first annual period or
for the imported lot, as the case may be.

Fifthly - 1. The inspection services of the Ministry of Industry and
Energy, and the Autonomous Communities and Pre-Autonomous Entities to which
competence has been transferred, shall ensure that all electromedical
apparatus for monitoring the intensive care of patients that are installed
after the entry into force of the present Order are displaying the
product-conformity mark, and shall report cases that might be doubtful to
the Director-General for Electronics and Computer Technology for
verification.

2. Violation of the provisions of the present Order shall be deemed a
breach of standardization and type-approval rules and shall be punishable
in accordance with the provisions of Chapter 9 of Royal Decree 2584/1981,
of 18 September.

Madrid, 31 May 1983

SOLCHAGA CATALAN
ANNEX

Specifications to be met by Electromedical Equipment for Monitoring the Intensive Care of Patients

1. OBJECT

To determine the general technical conditions that must be complied with by equipment for monitoring the intensive care of patients and to describe the way in which certain tests are to be made to verify such compliance.

2. DEFINITIONS

The following definitions apply to the present standard:

2.1 Electromedical apparatus for monitoring the intensive care of patients - An electromedical instrument designed for the continuous or semi-continuous observation of the critically ill by means of sensing, processing and (alpha-numerical and/or graphic) display of parameters and/or biological symptoms of the patient through connections to the patient.

2.2 Leakage - Non-functional current which passes through an insulation. The following leakages are defined below: earthed leakage, casing leakage, and patient leakage.

2.2.1 Earthed leakage - Current which flows from the power source through the insulation to the earthed neutral conductor.

2.2.2 Casing leakage - Current which passes from the casing or one of its parts to earth, or to another part of the casing, through an external connection different from the connection for the earthed neutral conductor.

2.2.3 Patient leakage - Current which passes from any insulated connection (or applicable part thereof) to the patient (see 4.1 below) to earth through the patient (excluding any functional current from the patient) or which passes from the patient to earth through an insulated connection to the patient, type F (floating), and is created by the fortuitous presence, near the patient, of voltage from an external source.

2.3 Normal operation - State of operation in which all the elements provided for protection against risks are intact.

2.4 Single-fault operation - State of operation in which only one of the elements of protection against risks is defective.

One of the following cases applies for the purposes of the present standard:
- gap in earthed neutral conductor;
- presence of external voltage in an insulated patient-connection.

3. GENERAL CONDITIONS OF THE EQUIPMENT

3.1 The construction of the equipment in question, both mechanical and electrical, shall meet the quality criteria generally accepted in practice, and in particular must comply with what is specified in Chapter 9.1 of Standard UNE-20514/78.

3.2 The controls shall be easy to operate and their number reduced to the minimum necessary for maximum simplicity of operation. The function of each one of them, as well as of measuring instruments and indicators, shall be clearly shown by means of immediately understandable symbols and labels in Spanish, except for universally accepted indications, so as to prevent wrong manipulation which might endanger the patient.

3.3 The apparatus shall indicate in a conspicuous place the characteristics of its power supply and shall have a place reserved for the number of the type-approval decision in the form "Homol. No. ...", and for the emblem representing the product-conformity mark.

3.4 The manufacturer shall provide instruction manuals, both for use and for installation and maintenance of the apparatus, in Spanish, in order to prevent improper installation, mainly as regards use of the apparatus in combination with other equipment.

4. SPECIAL ELECTRICAL SPECIFICATIONS

The monitoring apparatus shall comply, as regards current leakages, with what is indicated in this Order, both in normal operation and in the case of a fault in the earthed lead.

4.1 The terminals of the monitoring apparatus which are connected to the patient shall, as regards current leakages, comply with the specifications contained in Table 1 below and shall be termed "insulated patient-connections".

The insulated patient-connections shall be clearly marked as such so as to relate them to their appropriate connector points.

4.2 The monitoring equipment shall comply with the prescriptions concerning current leakages indicated in Section 5 below. Those prescriptions shall be complied with also for whatever assemblage results from connecting the monitoring equipment to the various accessories specified by the manufacturer.
5. **MAXIMUM VALUES OF CURRENT LEAKAGES**

The maximum values permitted for current leakages are given in Table 1. The measurements shall be made as indicated in Section 6 below.

For frequencies higher than 1 kHz, the values given in Table 1 shall be multiplied by the value of the frequency in kHz, 10 mA being the maximum value. This value is the absolute maximum for frequencies higher than 1 mHz. The total current leakages of an apparatus and of the accessories connected to it shall not exceed the values given in Table 1.

### TABLE 1

<table>
<thead>
<tr>
<th>Type of current leakage</th>
<th>Normal operation</th>
<th>Single-fault operation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mA</td>
<td>mA</td>
</tr>
<tr>
<td>Earthed leakage</td>
<td>0.5</td>
<td>1</td>
</tr>
<tr>
<td>Casing leakage</td>
<td>0.01</td>
<td>0.5</td>
</tr>
<tr>
<td>Patient leakage</td>
<td>0.01</td>
<td>0.05</td>
</tr>
</tbody>
</table>

6. **METHOD OF MEASUREMENT**

6.1 The apparatus shall be connected to a voltage 10 per cent higher than the highest power-source voltage specified by the manufacturer.

6.2 The measurements specified in 6.3 below shall be made after the equipment has reached its normal operating temperature.

6.3 Current leakage shall be measured between:

1. Each insulated patient-connection and the metal parts of the casing;
2. Each insulated patient-connection and earth;
3. The casing of the apparatus's and earth;
4. The various metal parts of the casing;
5. The terminal of the earthed neutral conductor of the apparatus and earth.

6.4 Each measurement shall be made under each and all of the following conditions and their possible combinations:

1. Normal and reversed connection to the mains;
2. On and off position of the apparatus's power switch;

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1 Including leakage in case of application of mains voltage at B in Fig. 2.
3. Normal operation and single-fault operation;
4. Insulated patient-connections connected in accordance with the manufacturer's specifications.

6.5 Load-impedance for test - All tests indicated in 6.3 and 6.4 above shall be made, using the load-impedance shown in Fig. 1.

![Fig. 1](image)

The test load-impedance shall be constructed with precision metal-film resistors so that the tolerance is $\pm 1$ per cent and with condensers having a tolerance of $\pm 5$ per cent.

6.6 Measurement diagram - The measurements referred to in paragraph 6.3.2 above shall be made in accordance with the diagram in Fig. 2. In the other cases, the measurements shall be made by introducing the test load-impedance, along with the associated voltmeter, between the points indicated.

When the type of apparatus to be tested so requires, the measurements shall be made through a saline-solution bath interposed as indicated in Fig. 2.

The voltmeter used in the measurements must be a truly efficient instrument.

6.7 In the case of apparatus that also operates on batteries, the above tests shall be made with the battery's charging device connected to the mains.
**POWER SOURCE**

Various terminals applied to patient transducers

Physiological saline solution

Fig. 2

A: Earthed (connected/normal operation
neutral conductor) disconnected/single-fault operation

Only one transducer is to be introduced in the saline solution for each measurement

B: Switch

(M = Normal operation
0 = Single-fault operation)