EESTI STANDARD EVS-EN 864:1999

# Elektrilised meditsiiniseadmed. Inimestel kasutatavad kapnomeetrid. Erinõuded

Medical electrical equipment - Capnometers for use with humans - Particular requirements

EESTI STANDARDIKESKUS

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

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|---|---|
| Käesolev Eesti standard EVS-EN 864:1999 sisaldab Euroopa standardi EN 864:1996 ingliskeelset teksti. | This Estonian standard EVS-EN 864:1999 consists of the English text of the European standard EN 864:1996. |
| Standard on kinnitatud Eesti Standardikeskuse 23.11.1999 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas. | This standard is ratified with the order of Estonian Centre for Standardisation dated 23.11.1999 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation. |
| Standard on kättesaadav Eesti standardiorganisatsioonist. | The standard is available from Estonian standardisation organisation. |



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EUROPEAN STANDARD

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Descriptors: electromedical equipment, capnometers, men, safety requirements, accident prevention, detail specifications, protection against electric shocks, protection against mechanical hazard, radiation protection, explosion proofing, fire protection, performance evaluation, tests, marking



English version

# Medical electrical equipment - Capnometers for use with humans - Particular requirements

Appareils électromédicaux - Capnomètres pour utilisation chez l'homme - Prescriptions particulières

Medizinische elektrische Geräte - Kapnometer für die Anwendung am Menschen - Besondere Anforderungen

This European Standard was approved by CEN on 1996-09-14. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

**CEN**

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

**Central Secretariat: rue de Stassart,36 B-1050 Brussels**

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**Annexes**

**Foreword**

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1997, and conflicting national standards shall be withdrawn at the latest by June 1998.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive (s).

For relationship with EU Directives, see informative annex ZA, which is an integral part of this standard.

Annexes AA,BB and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

## Introduction

This European Standard is one of a series based on European Standard EN 60601-1:1990.

In EN 60601-1 this type of European Standard is referred to as a "Particular Standard". As stated in 1.3 of EN 60601-1:1990, the requirements of this European Standard take precedence over those of EN 60601-1:1990. Clauses and subclauses additional to those in EN 60601-1:1990 are numbered beginning '101'. Additional annexes are lettered beginning 'AA'. Additional figures are numbered beginning '101' and additional tables are numbered beginning '101'. Additional items in lettered lists are lettered beginning 'aa)' .

The measurement of carbon dioxide in a gaseous mixture has become an increasingly common practice in many areas of clinical medicine, such as anaesthesia, respiratory therapy, paediatrics and intensive care. The minimum safety requirements given in this European Standard are based on parameters that are achievable within the limits of existing technology.

Annex AA contains a rationale for the most important requirements. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this standard. Clauses and subclauses marked with R after their number have corresponding rationales contained in annex AA.

## Section one. General

### 1 Scope

Clause 1 of EN 60601-1:1990 applies except that 1.1. is replaced by the following:

**1.1** This European Standard specifies requirements for the safety of capnometers as defined in 3.6 of this standard.

It applies to capnometers used with adults, children, and neonates. It does not apply to devices intended for use as transcutaneous monitors.

Capnometers intended for use in laboratory research applications are outside the scope of this standard.



### 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Appendix L of EN 60601-1 : 1990 applies with the following additions:

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|---|---|
| EN 475 | Medical devices. Electrically-generated alarm signals. |
| prEN 737-3 | Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum - Basic requirements |
| prEN 740:1992 | Medical electrical equipment - Anaesthetic workstations and their modules - Particular requirements |
| prEN 1281-1 | Anaesthetic and respiratory equipment - Conical connectors - Part 1 : Cones and sockets |

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|---|---|
| EN 1281-2 | Anaesthetic and respiratory equipment - Conical connectors - Part 2 : Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified) |
| EN 60601-1 : 1990 | Medical electrical equipment - Part 1 : General requirements for safety |
| EN 60601-1-2 | Medical electrical equipment - Part 1 : General requirements for safety - Collateral standard : Electromagnetic compatibility - Requirements and tests |
| EN ISO 3744 | Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering method in an essentially freefield over a reflecting plane (ISO 3744:1994) |
| IEC 79-4 | Electrical apparatus for explosive gas atmospheres - Part 4 : Method of test for ignition temperature |
| IEC 651 | Sound level meters |
| IEC 801-2 | Electromagnetic compatibility for industrial-process measurement and control equipment - Part 2 : Electrostatic discharge requirements |



## 3 Terminology and definitions

Clause 2 of EN 60601-1:1990 applies with the following additions:

**3.1 accuracy:** Quality which characterizes the ability of a device to give indications approximating to the true value of the quantity measured.

**3.2 alarm:** Signal that is activated when a monitored variable equals or crosses the alarm limit.

**3.3 alarm limit:** Reading of a monitored variable at which the alarm is first activated.

**3.4 alarm set point:** Setting of the adjustment control or display value which indicates the monitored variable's reading, at or beyond which the alarm is intended to be activated.

NOTE: Terms such as "alarm limits" or "alarm threshold" are frequently used to described the same function.

**3.5 alarm system:** Those parts of the capnometer which: