

IEC SYSTEM FOR CONFORMITY TESTING AND  
CERTIFICATION OF ELECTRICAL EQUIPMENT (IECEE)  
CB SCHEME

SYSTEME CEI D'ESSAIS DE CONFORMITE ET DE CERTIFICATION  
DES EQUIPEMENTS ELECTRIQUES (IECEE)  
METHODE OC

## CB TEST CERTIFICATE CERTIFICAT D'ESSAI OC

Product  
Produit

Waveform Analyzer

Name and address of the applicant  
Nom et adresse du demandeur

Percussionaire Corporation  
1655 Glengary Bay Rd., P.O. Box 817  
Sandpoint, Idaho 83864, U.S.A.

Name and address of the manufacturer  
Nom et adresse du fabricant

Percussionaire Corporation  
1655 Glengary Bay Rd., P.O. Box 817  
Sandpoint, Idaho 83864, U.S.A.

Name and address of the factory  
Nom et adresse de l'usine

Percussionaire Corporation  
1655 Glengary Bay Rd., P.O. Box 817  
Sandpoint, Idaho 83864, U.S.A.

Rating and principal characteristics  
Valeurs nominales et caractéristiques principales

Input: 100-240 V ac, 50-60 Hz, 30 W, 60 VA

Trademark (if any)  
Marque de fabrique (si elle existe)

Not applicable

Model / Type Ref.  
Ref. de type

Monitron II (Part # F00007-1)

Additional information (if necessary)  
Information complémentaire (si nécessaire)

The CB Test Report comprises 5 Enclosures.

A sample of the product was tested and found  
to be in conformity with  
Un échantillon de ce produit a été essayé et a été  
considéré conforme à la

### PUBLICATION EDITION

IEC 601-1 (1988) Second Edition with Amdt 1 (1991) and 2 (1995)  
except Clause 36, EMC and Clause 48, Biocompatibility not evaluated.  
EN 60601-1: 1990 + A1: 1993 + A2: 1995, except EMC limitations, EN60601-2; and  
Biocompatibility, ISO 10993-1, additionally evaluated to National Differences for USA  
(UL 2801-1), Canada (CAN/CSA-C22.2 No. 601.1-M00 + S1:1994 + A2:1998).

as shown in the Test Report Ref. No.  
which forms part of this Certificate  
comme indiqué dans le Rapport d'essais numéro  
de référence qui constitue partie de ce Certificat

E191360-V1-S2

This CB Test Certificate is issued by the National Certification Body  
Ce Certificat d'essai OC est établi par l'Organisme National de Certification



Underwriters Laboratories Inc. ®

Underwriters Laboratories Inc. / International Compliance Services  
333 Pfingsten Road, Northbrook, IL 60062-2096  
United States of America  
TEL INT\* 1-847-272-8800, Ext. 43008 FAX INT\* 1-847-272-9562  
email: wroblewskaj@ul.com

Date: Issued: 17 December 1999

Signature:

  
Jolanta M. Wroblewska

# Percussionaire Corporation

1655 Glengary Bay Road  
Sagle, ID 83860

Underwriters Laboratories Inc.® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

## ISO 9002:1994

EN ISO 9002:1994; BS EN ISO 9002:1994; ANSI/ASQ Q9002:1994

for the following scope of registration

**3842 (US) : Orthopedic, Prosthetic, and Surgical Appliances and Supplies**

**The manufacture and repair of pneumatically served aeromedical devices and the procurement and supply of supplemental accessory equipment such as battery back-up systems and waive form analysis equipment.**

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of Underwriters Laboratories Inc. ®.

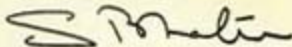
File Number: A3965

Volume: 1

Issue Date: January 22, 1997

Revision Date: January 27, 1999

Renewal Date: January 22, 2001



S. Joe Bhatia  
Vice President  
Follow-Up Services



Accreditatie  
Raad voor  
Accreditatie



# CERTIFICATE

## CE MARKING OF CONFORMITY

### MEDICAL DEVICES

Number: 76931CE01

Issued to:

**Percussionaire Corporation**

Box 817 Glengary Bay Road  
Sandpoint, ID 83864  
U.S.A.

For the product category:

**Pneumatically powered ventilators and accessory monitoring equipment**

KEMA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the Type described in the EC Type-Examination Certificate and meeting the provisions of the EC-Directive which apply to them:

**0344**

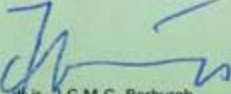
Documents, that form the basis of this certificate:

**Certification Agreement 76931, initial dated December 31, 1997**

**Certification Notice 76931CN, initial dated December 31, 1997**

KEMA hereby declares that for the above mentioned product category the Conformity Assessment Procedure Annex VI for combination with Annex III is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate. This certificate is valid for three years under the conditions of the agreement belonging to this Certificate.

This certificate is issued: December 31, 1997

  
d.r. J.C.M.C. Borburgh  
Managing Director

Integral publication of this certificate is allowed.

CECMA35.4R1

N.V. KEMA  
KEMA Medical

Utrechtseweg 310, 6812 AR Arnhem, P.O.Box 9035, 6800 ET Arnhem, The Netherlands  
Telephone +31 26 356 2828. Telefax +31 26 351 6708

# CERTIFICATE

## EC TYPE-EXAMINATION

### MEDICAL DEVICES

Number: **76931TE02**

Issued to:

**Percussionaire Corporation**

**Box 817 Glengary Bay Road  
Sandpoint, ID 83864  
U.S.A.**

For the product category:

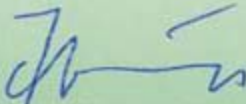
**Intensive care ventilators (Class IIb)**

Documents, that form the basis of this certificate:

**Certification Agreement 76931, initial dated December 31, 1997**  
**Certification Notice 76931CN, initial dated December 31, 1997**  
**CE Marking of Conformity Certificate 76931CE01**

KEMA hereby certifies that the products falling within the product category mentioned above, conforms to the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, in accordance with Annex III of this Directive. The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate. This certificate is valid for three years under the conditions of the agreement belonging to this Certificate.

This certificate is issued: **December 31, 1997**



dr. J.C.M.C. Borburgh  
Managing Director

\* Integral publication of this certificate is allowed.

TECMDA35.2R1