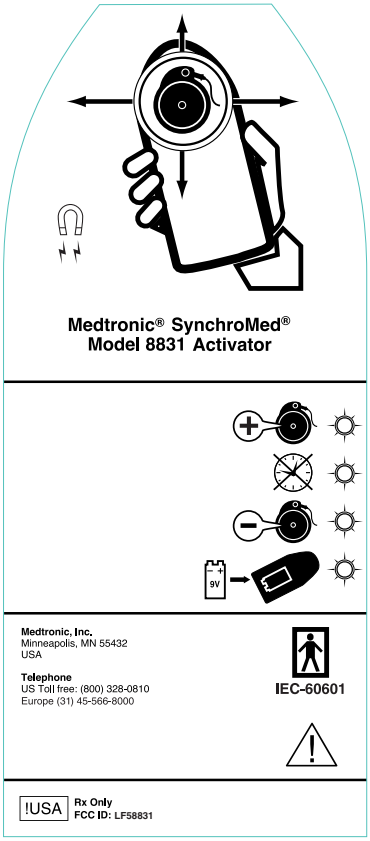


US Commercial

PN 220179-002

UC200101210a EN

Rx on Label refers to Prescription

SynchroMed® Activator

PN 220333-001
UC200101213 EN

Label Placement - Back

The following documentation includes a letter from the FCC accepting that the compliance statement for a product similar to this product (FCC ID: LF57435) was not on the label, but in the User's Manual.

If this is not acceptable by the TCB for the unit we are currently submitting application for (FCC ID: LF58831), please request a ruling from the FCC.

Medtronic *When Life Depends on Medical Technology*	NEUROLOGICAL DIVISION	CONTROLLED DOCUMENT/RECORD

MODEL OR BUCKET NO.	RECORD NO.	REV. NO.	RECORD DESCRIPTION	PROJECT NO:
7434	~~600013~~ 600016 (600 053 7/1/99)	01	FCC Approval Letter for Labeling Exemption	N1019

TYPE OF RECORD: DHF ☒ PMR ☐ PHR ☐

AUTHOR: Federal Communications Commission SUBMITTED BY: J. Grevious

ASSOCIATING RECORD:

Models Affected: 7435, 7436, 3031A, 3032A.

DOCUMENT/RECORD HISTORY:

FCC approval letter with attached letter of request submitted to FCC to support design of universal labels for Patient Programmers.

AUTHORIZATION SIGNATURES

FUNCTION TITLE	NAME	SIGNATURE	DATE
Design	John Grevious	John Grevious	July 12, 1999

NOTIFICATION OF COMPLETION

NAME	NAME
Eric Bonde	
Wynee Igel	

FEDERAL COMMUNICATIONS COMMISSION
Laboratory Division, Equipment Authorization Branch
7435 Oakland Mills Road, Columbia, MD 21046
Telephone: (301) 362-3027, Facsimile: (301) 344-2050
July 1, 1999

TO: John Grevious
ORGANIZATION: Medtronic, Inc.

PHONE NUMBER: 612-514-5210 **FAX NUMBER**: 612-514-5612

FROM: Richard Fabina **TITLE**: Acting Chief, Equipment Authorization Branch
NO. OF PAGES: 1

Please direct inquiries, if any, to the sender at the telephone number above.

Dear Mr. Grevious:

The following is in response to your faxes of May 28 and June 30, 1999, regarding proposed labeling changes to a device identified by FCC ID: LF57435. In the referenced communication, you ask if it is permissible to move the compliance statement required by Section 15.19(a)(3) of the FCC Rules from the label of the device to the user's manual. I apologize for the delay in answering this simple question. Apparently, the May 28th incoming correspondence was lost in our volume of paperwork.

Yes, it is acceptable to place the compliance statement in the user's manual of a device in accordance with Section 15.19(a)(5) of the Rules when the device is so small, or it is not practical, to place the compliance statement on it. We concur that this device meets this criteria to permit the compliance statement to be located in the user's manual.

I trust that this has answered your questions. However, if you have any additional questions about this matter, please contact me at the address or telephone numbers above.

Medtronic

Medtronic Neurological
800 53rd Avenue NE
P.O. Box 1250
Minneapolis, MN 55440-9087
Internet: www.medtronic.com
Telephone: (612) 514-5000
Toll Free: 1-800-328-0810
FAX: (612) 514-5078

Richard Fabina
Federal Communications Commission
Washington, D.C. 20554

May 28, 1999

Dear Mr. Fabina:

The purpose of this letter is to determine if we may be exempted from placing the FCC part 15 statement ("This device complies with...") on the labels of our hand held patient programmers. These programmers are best categorized as inefficient radiators that use short-range inductive coupling (i.e. within a few inches) at 175 kHz to communicate to implanted medical devices.

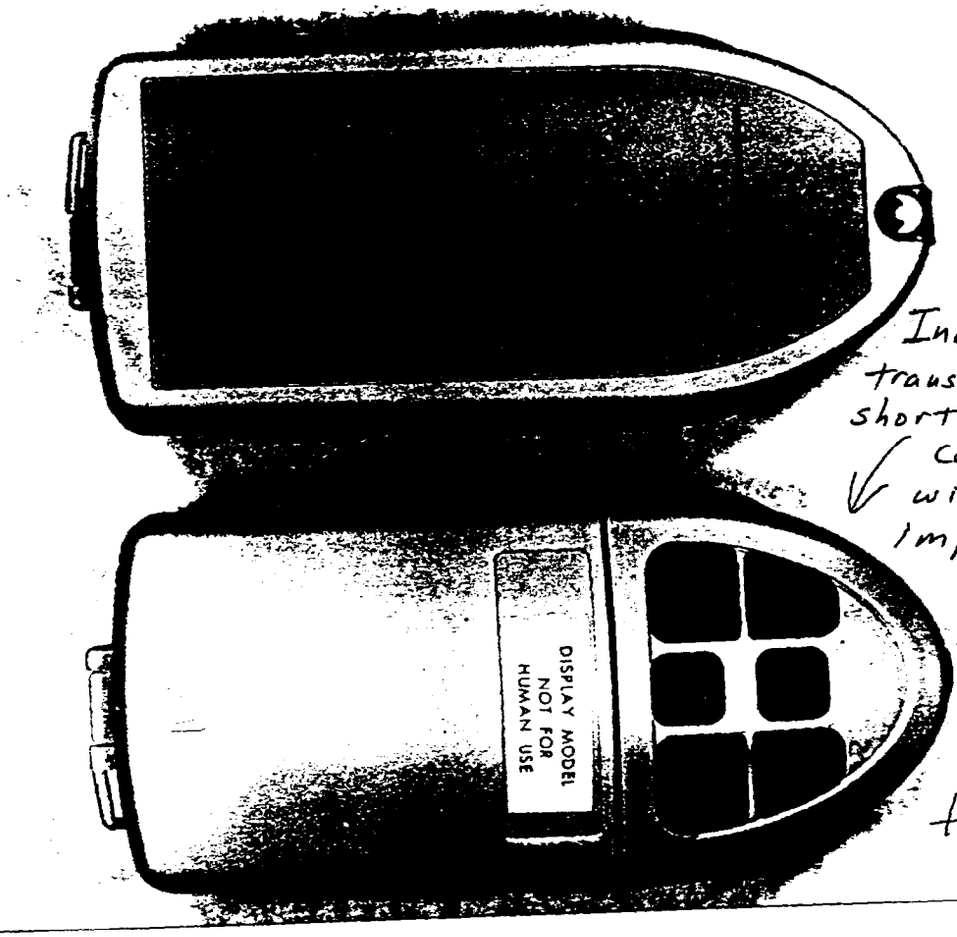
Presently we print both the FCC ID# and the FCC part 15 statement on both the device label and in the manual. We wish to make a universal label for worldwide use. The label designers require more print space on the label to accomplish this task. I understand such exemptions can be applied to other devices such as hearing aids where obvious space/size restrictions become an issue. In our case we have maximized the label size and use it for both user instruction and industry standards information. Please refer to the attached edited drawings (A, B, C1, C2, D) for an overview of this product and to better understand this request.

To meet the FCC labeling requirements and achieve our universal labeling needs we are requesting allowance to apply the FCC information per attachment D for our patient programmer products. Thank you for your time to review this request.

Sincerely,

John Grevious
Principal Engineer
Medtronic, Inc.
Phone: (612) 514-5210
Fax: (612) 514-5612
e-mail john.grevious@medtronic.com

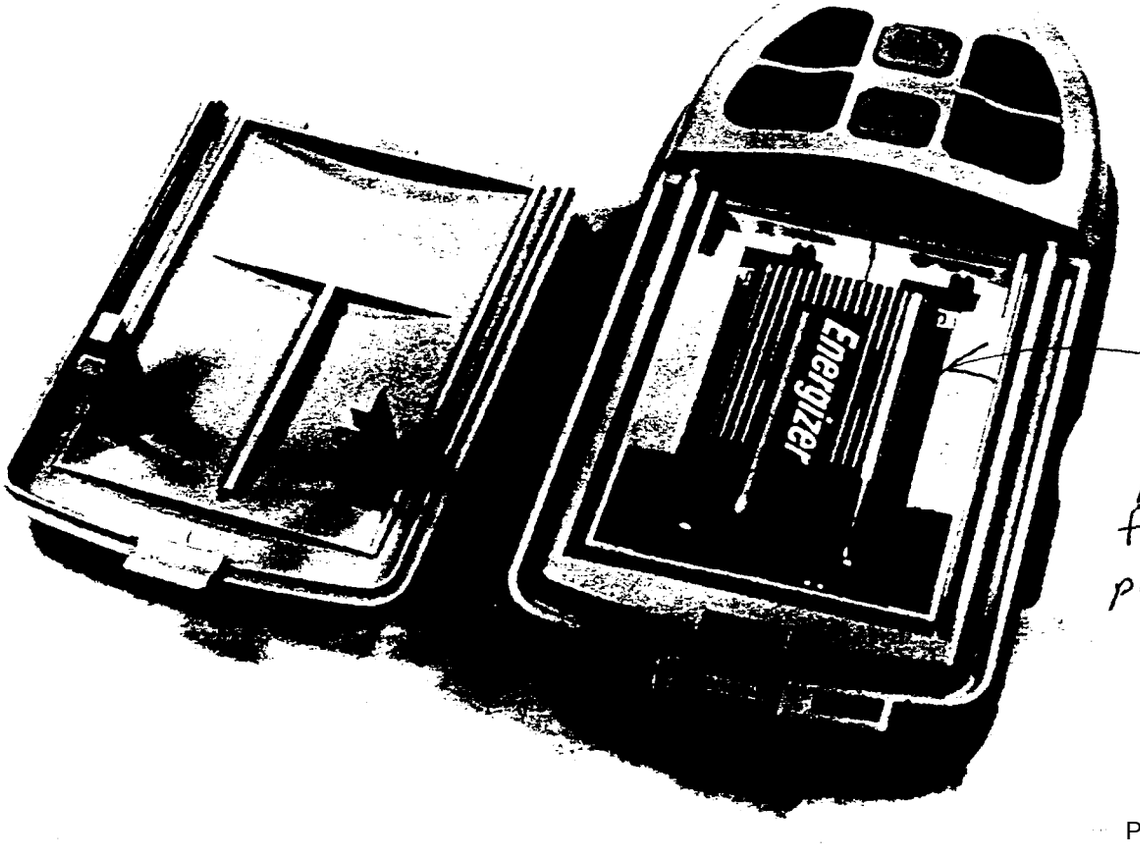
(A)



Inductive Coupled transmitter for short range (<1 ft) communication with medically implanted products

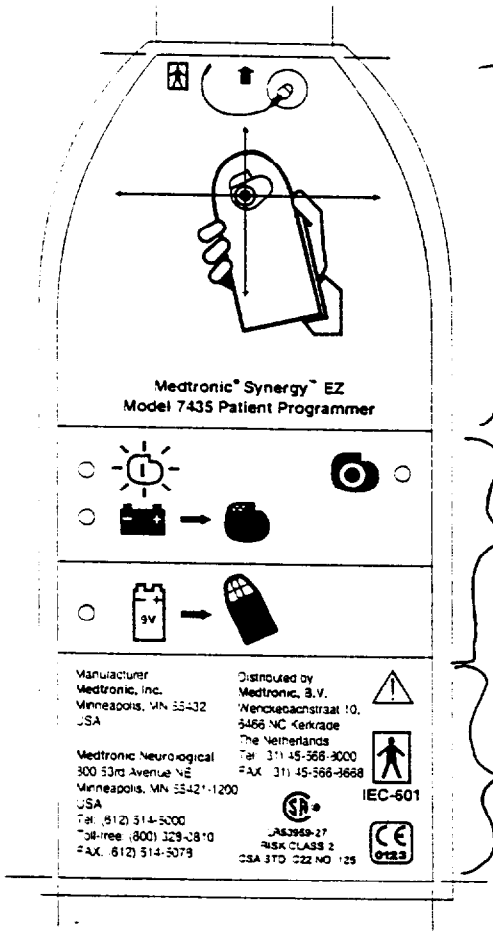
Reference:
FCC ID # LF57435
Conf # EA93061
for more details

Note: These photos depict a sample of the device (Patient Programmer) for which our labeling question applies.



9V Battery provides scale for these photo's

(B)



User Instruction Section

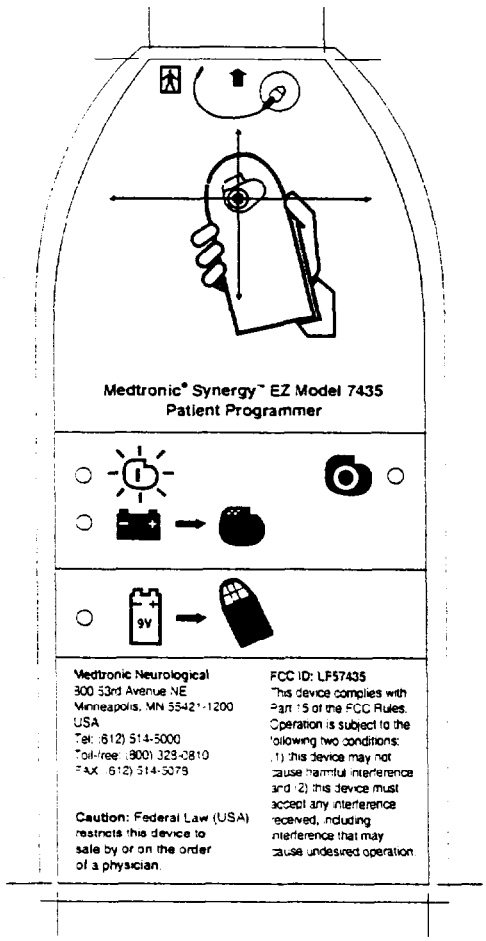
Operational Information Section

Industry Standards Section.

- Label for use outside U.S.

UC9700819cEN/194733-004

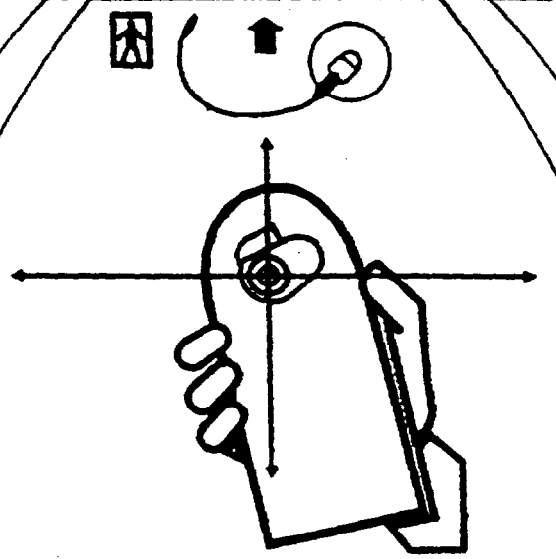
C1



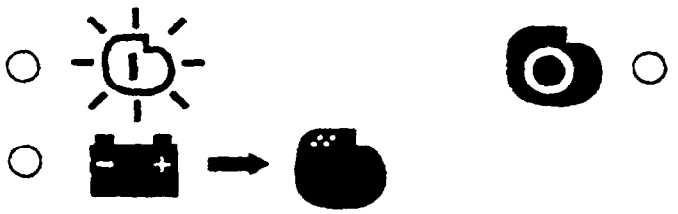
Example of Cable used for products within the U.S.

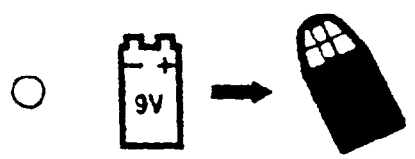
UC9900344EN/220183_001

C2



Medtronic® Synergy™ EZ Model 7435
Patient Programmer





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800 53rd Avenue NE
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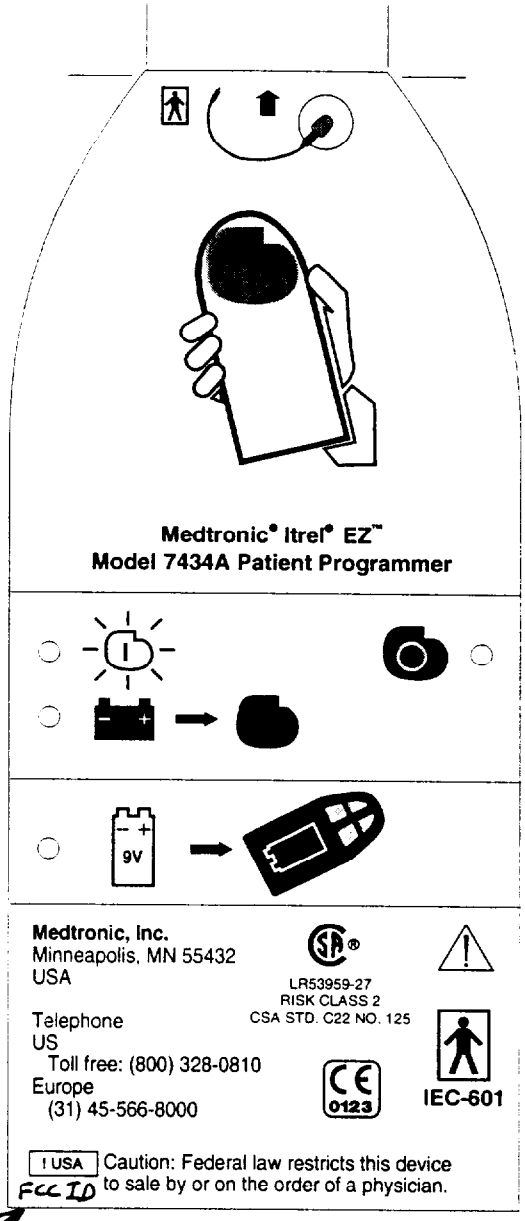
Tel: (612) 514-5000
Toll-free: (800) 328-0810
FAX: (612) 514-5078

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

FCC ID: LF57435
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

- Our product label designers need more label space to achieve a universal label design.
- This statement is also provided in the device manual.

(D) A prototype DRAFT of a "universal label"



FCC ID: LF57435

Our request is to do the following:

- FCC ID # on external label.
- FCC ID# and full FCC statement [redacted] printed in the device manual.

Draft

UC9900371 EE/220181-001