Atomic Energy of Canada Limited
L'Énergie Atomique du Canada, Limitée

Commercial Products
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VIA REGISTERED MAIL

1981 November 4

File: Q2.9.3
RA81-11-183

Director,
Office of Inspection & Enforcement,
U.S. Nuclear Regulatory Commission,
Washington, D.C. 20555

Dear Sir,

- 10 CFR 21 NOTIFICATION -
REPORTED INCIDENTS OF CERTAIN AECL-CP
TELETHERAPY UNITS

In accordance with the requirements of 10 CFR 21.21 we have to notify you that there have been reports of two types of incident occurring on AECL-CP teletherapy units which are equipped with an AECL-CP Digital Treatment Timer A102409-654.

These incidents and the corrective action plan have also been reported to BRH/USFDA. AECL-CP is currently beginning a "firm initiated medical device recall action".

Details of this 10 CFR 21.21(3) notification are as follows:

(i) Informant

Eric F. Ridout, Manager,
Regulatory Affairs Branch,
Quality Assurance,
Atomic Energy of Canada Limited,
Commercial Products (AECL-CP),
P.O. Box 6300,
Ottawa, Ontario, Canada.
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(ii) Identity of Equipment Involved

Unit Models affected are:

Theratron 60, Theratron 80, Eldorado 6, Eldorado 8, Theratron 780, and Eldorado 78.

Our current records indicate that there are 24 serials in the above model range currently in use in the USA which utilize an AECL-CP Digital Treatment Timer.

(iii) Manufacturer

Atomic Energy of Canada Limited, Commercial Products.

Address as in Item (i).

(iv) (a) Nature of Defect or Failure to Comply:

Affected sub-system is the AECL-CP Digital Treatment Timer Model A102409-654 (G72-00).

(1) In the first reported incident the treatment timer did not cause the radiation source to return to the fully shielded position after the prescribed treatment time had elapsed. An investigation into the cause of the incident indicated that this was caused by an improper connection between a printed circuit board and the mother board located inside the timer enclosure; the board was not properly installed.

(2) In the second reported incident, the treatment timer shut-down, the digital display turned off and the radiation source could not be moved into the treatment (exposed) position. An investigation into the cause of this incident indicated that the operating temperature rise within the timer assembly adversely affected the efficiency of the storage battery pack which in turn reduced the power supply voltage.

(iv) (b) Potential Safety Hazard or Consequences of Non-Compliance

Case (iv) (a) (1) may cause the timer to stop counting with the source in the exposed position and potential unplanned radiation exposure of a patient may occur.

Case (iv) (a) (2), a non-compliant condition would exist in that the timer would not continue to display the elapsed treatment time for the patient record.

(v) Date Incident Assessment Completed

In both cases, the AECL-CP Medical Device Hazards Assessment Committee completed their investigations and initiated Class III recall activities (FDA classification scale) on 13 October, 1981. The corrective action plan was completed on 2 November, 1981, and is being mailed to all users of the affected units on 4 November, 1981.

A copy of the recall plan with supporting documents is attached for your examination.

(vi) Number and Location of Affected Equipments

A copy of the listing of affected units in the U.S.A. is included in the attached recall plan.

(vii) Corrective Action

(1) All users of record of the affected units are currently being advised (registered mail) via AECL-CP Warning Notice WN-81-1, dated 2 November, 1981, of the nature of the problem, the potential consequences and the corrective actions which are to be implemented by the user on receipt.

(2) AECL-CP is responsible for the recall action; each user is responsible to carry out the recommended inspections and additional administrative controls described in the Warning Notice and supporting documents.

(3) The effectiveness of the recall will be monitored by AECL-CP via Compliance Certificates CC.PL-81-1 which is to be completed by the user and returned to AECL-CP in Ottawa. We expect all users to respond immediately on receipt of the Warning Notice.

(viii) Additional Advice to Users

No additional advice to users is required.

We trust this Notification meets the intent of the Regulations under 10 CFR 21. If we can be of further assistance to you in these matters, please contact this office at your convenience.

Yours sincerely,

E.F. Ridout,
Manager,
Regulatory Affairs,
Quality Assurance.

EFR/EB

Enclosures

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FILE: Q2.9.1
RA81-11-171

VIA REGISTERED MAIL

1981 November 2

- IMPORTANT -

MEDICAL DEVICE RECALL ACTION

AECL-CP WARNING NOTICE WN-81-1

To all users of beam teletherapy unit models Theratron 60, 80, 730 and Eldorado 6, 8 and 78 fitted with a Digital Treatment Timer (A102409-654) and manufactured by Atomic Energy of Canada Limited, Commercial Products (AECL-CP), address as above. Affected unit models and serials are listed by location in Appendices 'A' and 'B' attached to this notice.

We have received reports of two types of incident involving the use of the Digital Treatment Timer specified above.

In the first incident the treatment timer did not cause the radiation source to be returned to the fully shielded position after the prescribed treatment time had elapsed. An investigation into the cause of this incident indicated that there was an improper connection between a printed circuit board (PCB) and the board socket located inside the timer enclosure.

In the second incident, the treatment timer shut down, the digital display turned off and the radiation source could not be moved into the exposed position. An investigation into the cause of this incident indicated that the temperature rise within the timer assembly reduced the power supply voltage.

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AECL-CP has assessed these reported incidents and has developed a corrective action plan which, on completion, will reduce the probability of recurrences. Each user is requested to implement the plan as described below.

The corrective action consists of an inspection to be undertaken by the user and additional administrative controls; these are itemized as follows:

1. Inspection of the timer and installation of labels as described in Appendix 'C' attached to this Warning Notice. The labels and an Allen screw key required for removal of the timer cover are provided in a separate envelope within this Recall package.

2. Provision of replacement pages to those users of "70 Series" unit models with unit Operating Manuals covering digital timer use. These users are requested to insert these pages into their existing unit Manuals and to destroy the original pages.

   In summary, Section 5.6.4 or 5.6.5 as appropriate, which deals with treatment timer routine maintenance, has been modified to indicate that care should be taken to properly re-install the battery PCB after periodic battery replacement and to remove all references to the timer cover. Subsequent pages in these Sections, which are affected by the expansion of the text, have been included for continuity purposes.

3. Provision of replacement pages to those users of earlier unit models who have discrete copies of a Digital Treatment Timer Operating Manual. These users are requested to insert these pages into their existing Digital Treatment Timer Manuals and to destroy the original pages.

   In summary, Section 3.1.1, which deals with Digital Treatment Timer battery replacement, has been modified to indicate that care should be taken to properly re-install the battery PCB after periodic battery replacement and to remove all references to the timer cover.

4. Provision of an AECL-CP Compliance Certificate, CC-PL.81-1 (in triplicate) which users are requested to complete and sign after implementing the changes. Users are requested to mail the completed white and pink copies of the Certificate to the attention of Mr. D.W. Whitfield, Medical Products Service Department, at the above address, and to retain the remaining copy for record purposes.

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We wish to thank you for your assistance and co-operation in this regard.

This Warning Notice is being simultaneously issued to all users of the affected equipments; to the AECB, MDB/H & W and RPB/H & W in Canada; and the USNRC and BRH/US-FDA in the USA.

Yours sincerely,

E.F. Ridout, Manager
Regulatory Affairs
Quality Assurance

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Enclosures

Enclosures: Appendix 'A' (1)
Appendix 'B' (1)
Appendix 'C' (1)
Warning Label (1)
New CSA Certification Label (1) - A102409-654
New CSA Certification Label (1) - G7200
Allen Screw Key (1)
Replacement Manual Pages (2 sets each)
Compliance Certificate (1) - CC-PL.81-1

APPENDIX 'A'

Tabulation of digital timers (Model G-7200) installed on therapy units in clinical service in Canada:

Model	Serial Number	Location
Theratron 780	305	Calgary, Alberta
Theratron 780	1X	Toronto, Ontario
Theratron 780	43	Ottawa, Ontario
Theratron 780	188	Ottawa, Ontario
Theratron 780	300	Hamilton, Ontario
Theratron 780	310	Charlottetown, Prince Edward Island
Theratron 780	253A	Sherbrooke, Quebec

APPENDIX 'B'

Tabulation of digital timers (Model G-7200) installed on therapy units in clinical service in the U.S.A.:

Model	Serial No.	Location
Eldorado 8	28	Los Angeles, California
Eldorado 6	25R	Tampa, Florida
Eldorado 78	63	Joliet, Illinois
Theratron 780	297	Kankakee, Illinois
Theratron 780	296	Prairie Village, Kansas
Theratron 780	308	Louisville, Kentucky
Theratron 780	306	Augusta, Maine
Eldorado 78	61	Bethesda, Maryland
Theratron 60	132	Detroit, Michigan
Theratron 60	4	Duluth, Minnesota
Theratron 780	302	Minneapolis, Minnesota
Theratron 780	299	Jackson, Mississippi
Theratron 780	307	Columbia, Missouri
Theratron 780	323	Bronx, New York
Eldorado 78	3	Bronx, New York
Theratron 780	322	Kisco, New York
Eldorado 78	62	Schenectady, New York
Theratron 80	69	Toledo, Ohio
Theratron 80	200	Canton, Ohio
Theratron 780	289	Philadelphia, Pennsylvania
Eldorado 78	60	Columbia, Tennessee
Theratron 780	311	Danville, Virginia
Theratron 780	314	Bluefield, West Virginia
Theratron 60	40	Marshfield, Wisconsin

APPENDIX C
AECL-CP WARNING NOTICE WN-81-1

DIGITAL TREATMENT TIMER G7200 INSPECTION

1. Turn off the power at the main isolating switch.

WARNING

IF POWER IS NOT TURNED OFF, ELECTRIC SHOCK MAY CAUSE INJURY OR DEATH.

2. (i) On the Theratron 60 and 80 and the Eldorado 6 and 8, release the fastening screw near the top center, and pull out the front panel; it is hinged at the bottom.

   (ii) On the Theratron 780 and Eldorado 78, remove the control console cover.

   (iii) On the stand-alone model, remove the upper and lower outer covers.

3. The digital timer serial number is on the timer cover. Transfer the serial number to the new nameplate label (provided), Model A102409-654, and affix it to the underside of the timer. Ball-point pen or typewriter may be used for applying the serial number to the new label. See Fig. 1.

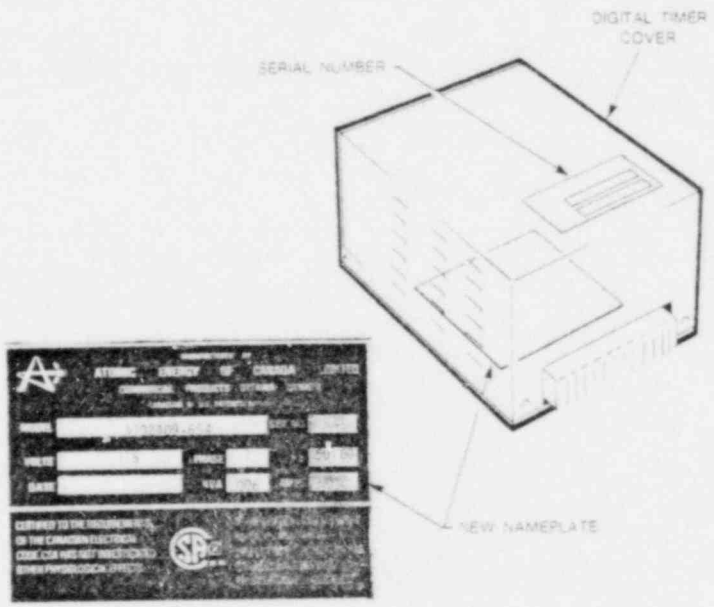

Fig. 1. Location New Nameplate Label (Model A102409-654)

4. (i) On the stand-alone model, affix the new nameplate label, Model G7200, and the warning label (both provided) to the lower console cover. Do not affix to rear surface where they would interfere with the ventilation openings. See Fig. 2.

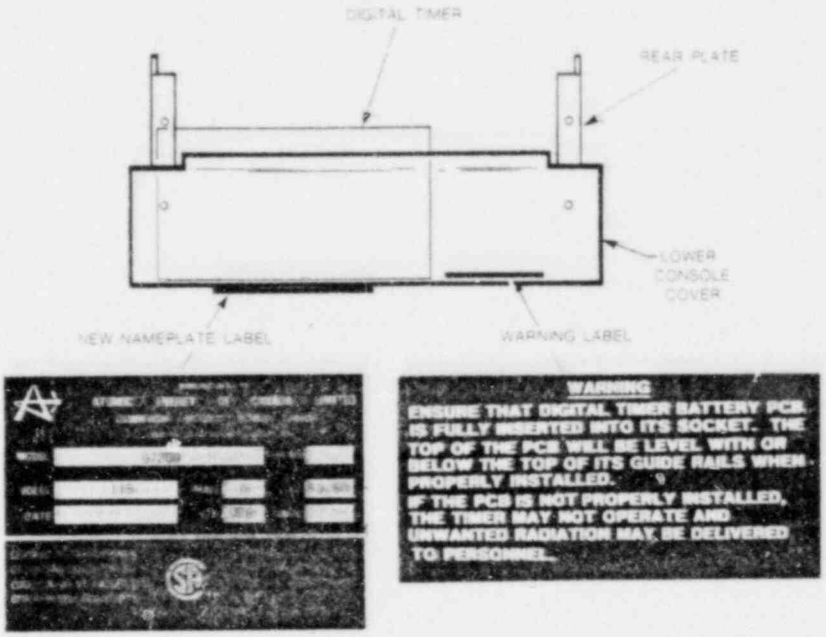

Fig. 2. Location of Nameplate Label (Model G7200) and Warning Label

(ii) On the Theratron 60, 80 and 780 and on the Eldorado 6, 8, and 78 console, affix the warning label (provided) to the exterior rear surface of the console. The new nameplate label, Model G7200, is not required.

5. Using the Allan key provided, remove and discard the four screws which retain the timer cover. Remove and discard the timer cover; DO NOT REINSTALL. See Fig. 3.

6. Ensure that the battery printed circuit board (PCB) is correctly installed; it must be fully inserted into its socket. The top of the PCB must be level with or below the top of its guide rails when properly installed.

WARNING

IF THE PCB IS NOT CORRECTLY INSTALLED, THE TIMER MAY NOT OPERATE PROPERLY AND UNWANTED RADIATION MAY BE DELIVERED TO PERSONNEL.

7. Replace the panel or covers removed in Step 2.

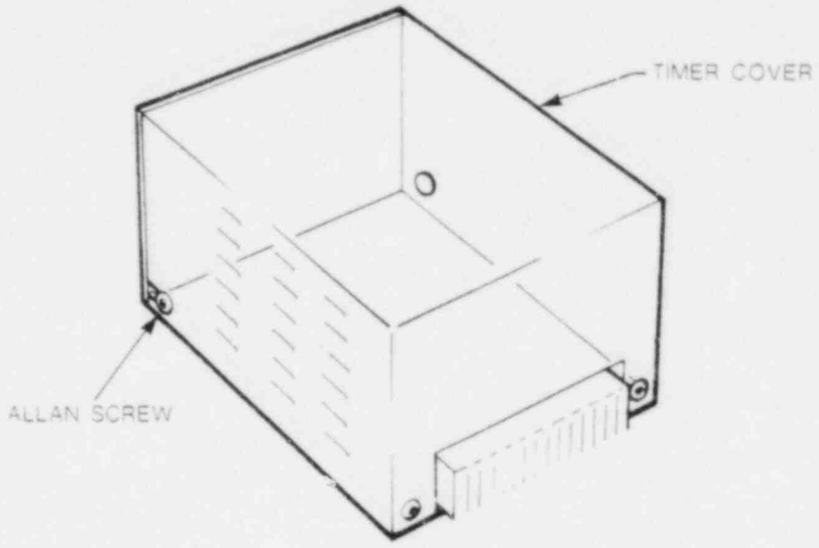

Fig. 3. Location of the Four Screws Retaining the Time Cover

8. Switch on the power at the main isolating switch.

9. The timer display may remain blank for a short time. When the display decimal points stop flashing and flickering, perform the routine test described in the Operator's Manual.