GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

December 14, 2000

Materials Safety and Inspection Branch
United States Nuclear Regulatory Commission
White Flint North MS78F5
11545 Rockville Pike
Rockville, MD 20852

Attn: Mr. Ujagar S. Bhachu

Mr. Bhachu,

This is in response to your July 18, 2000 request for additional information on our Model V-TransACT application.

I believe you will find the response to all of your questions in the attached. Please reopen our application and proceed with the review. Contact me if you need anything else.

Regards,

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Jean-Paul Bouhnik, Ph.D. • Physicist • Tel: 972-4-8563673 • Email: Jean-Paul_Bouhnik@ELGEMS.COM

Dear Dave,

Find in the following document my answer to the question related to the V-TransAct NRC submission.

1. **Ball bearings**: We have ball bearing in the shutter mechanism. The statement in page 10 of the application will be corrected. Find in appendix A.1the corrected page 10.

2. **Page 1-11**: Find in appendix A.2 the corrected page.

3. **Other devices**: There is no other device attached to the gantryh

4. **Sensing switches**: There are two devices that give information on the position of the rod unit: the zero optocoupler and the encoder on the motor that moves the rod.
   The zero optocoupler is a reference point that permits the reset of the rod position each time the rod reach this point. This reduces eventual error in the rod position information. The encoder on the motor gives the information on the rod position respectively to the zero position.
   Another device that permit adequate mechanical function of the motion mechanism is the limit switches. See drawing number ASM 000 792, appendix A.3.

5. **Integrity of the option**: The following sentence will be added to the service manual page 1-2 under **Transportation and Unpacking**: ' Establish the integrity of the device and the sources respectively to the Option Contents page 2-3 part 2.1.1. Find in appendix A.4 the corrected page.

6. **Proprietary**: The information included in the VtranAct NRC submission can be released to public access. The most important feature related to the VtranAct transmission unit device are patented.

7. **Leak test**: The following sentences will be added to the service manual page 3-19 under 3.2.8 **Radiation Leakage Test** and also under the Maintenance page 5-12 of the Operation manual see updated page in appendix A.5 and A.6:

   Caution ***: Do not directly touch the surface of the rod unit with your hands either before or after obtaining the sample for the leakage test.***

   1. Ensure that the shutter is closed and locked
   2. Visually examine a piece of dry filter paper and verify that the paper is nit torn.
   3. Using dry filter paper, thoroughly wipe all surfaces of the sealed Rod Units (see Figure 3-10).
   4. After wiping the potentially radioactive surfaces of the Rod Units, check that the paper is not torn and measure the radioactive content. (If a piece of paper is missing it must be found and disposed of properly).

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5. If the radioactive content of the filter paper is less than 5 nCi, the machine is considered non-leaking.
6. Following the completion of the test, dispose of the filter in a container for radioactive waster materials.

8. **Source registration certificate**: This is the latest version that we received.

9. **Source shipping container**: The source holder is inserted by Dupont (the source manufacturer).The sources lead shipping container is manufactured by Elgems and provided to Dupont for this purpose. The QA/QC requirements for the shipping containers is the following:

   QA/QC at Elgems:
   1. All the part of the lead shipping container are inspected according to the production engineering draws.
   2. After completion of the assembly, the unit is inspected before sending it to Dupont .
   3. Elgems products are manufactured in accordance to FDA's Good Manufacturing Practices (GMP), ISO 9001 (quality system standard) and EN46001 (quality system standard for medical devices).

   QA/QC at Dupont:
   After the source is loaded into the source holder and the lead shield (shipping container), the following quality control check are performed:
   1. The orientation of the source is confirmed to be correct.
   2. A wipe test of the surface of the shield is performed and the acceptance limit is 0.0005 uCi.
   3. A visual inspection for accuracy of the source label and inserts is performed.

   The carton box (the shipping box) is manufactured by Dupont.
   QA/QC:
   After the source and the shield are packaged in the shipping box, the following checks are performed:
   1. The DOT label is properly applied (DOT label: Symbol of radioactive material, contents and activity).
   2. The external radiation level is within regulatory limits.
   3. A manufacturing report is included into the carton box.

   Details as to how the thin source is supported inside the shipping container:

   The thin source is glued to a groove on the source holder (see the submission for detail on the glue an the test on the glue performance). The source holder is inserted in the shipping container with any degrees of freedom.

10. **Requirement and Qualifications for the device users**: All handling of the V-transact rod unit, including removal replacement installation and repair must be performed only by qualified service personnel authorized by the Vendor. Disposal of the used line sources must be in accordance with the regulatory procedures. Only GE trained

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personnel or someone licensed by NRC Agreement State are considered suitable for source disposal. The activation of the VtransAct rod should be done by radiation worker after full training.

11. It will be take in consideration.

12. **User**: The devices will only be distributed to users licensed to 10 CFR 35.11 or equivalent Agreement State regulations.

13. **CFR**: See the updated page 2-13 of the Operation and Service Manual according to your remarks on the CFR. We replaced all the sections by section 10 CFR 35.49. The other section 10 CRF 35.500 is related to therapy device and not attenuation correction device, see updated label in appendix A.7, A.8 and A.9.

DEVICE TYPE: **Attenuation Correction System**

The device is powered from the gantry and does not have its own separate power supply. After each gantry activation or resetting, the device shutter mechanism is tested.

Reliability and diagnostic test:
The report results of the shutter mechanism reliability, diagnostics and power failure safe-fail can be found on appendix G, V_TransACT Shutter test report. Data sheet on the solenoid can be find in appendix G.

The failure rate acceptance criteria for the slotted switch is zero.
The life test, performed on the shutter of a similar device (see solenoid history below) with 207555 times open/close cycle, equals to 56 years life without failure (10 patients/day for 365 days and during 56 years = 204400 times cycle). The expected useful life of the device is only 10 years.

The solenoid chosen, dynamic component (see attached in appendix G data sheet, RE Type – Extended life: 10 million cycles) will provide a life expectancy of more than 10 years since the operation conditions complies with the manufacturer recommendation.

The solenoid shutter mechanism is a normally closed. The shutter is opened under electrical power and closed by spring. The shutter mechanism is inside closed case to prevent dirt and obstacles from interfering the smooth motion of the shutter.

Solenoid history of usage:
This component and similar shutter arrangement was include in a similar product device named MG ATC Rod Unit (p/n ASM 000415) which was approved in December 1999 by NRC (NR-1049-D-102-S).

The shutter mechanism based on solenoid (different type) was also used in a similar device named TransACT Rod Unit (NRC registration n°. NR-1032-D-101-S).

In case of failure, specific instructions are provided to the user to close and locked the shutter and call service personnel.

Reference :
Appendix A, Engineering drawing A8
Appendix B, Operation Manual , p 4-5, 4-6
Appendix G, Prototype Testing , Shutter Mechanism & Diagnostics Test Report.

A.2

1.8 REGULATORY INFORMATION

The equipment complies with the IEC 601-1 standard.

This equipment generates and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices and to radio communications. To provide reasonable protection against such interference, the camera complies with the emission limits for a Group 1, Class A Medical Devices as stated in IEC 601-1-2. However, there is no guarantee that interference will not occur in a particular installation.

The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized change or modifications to this equipment.

Unauthorized change or modifications could void the user's authority to operate the equipment.

To comply with the regulations on electromagnetic interference for a Group 1, Class A Medical Device, all interconnect cables to peripheral devices must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the local regulations.

Due to installation in less favorable environment, this equipment may be exposed to electromagnetic and electrostatic interference. To ensure a high level of reliability when exposed to such interference, this equipment complies with the immunity requirements as stated in IEC 601-1-2. for immunity Class 1. The operating conditions are classified on the basis of performance criteria as defined in IEC 801-2.

The equipment complies with the following standards:

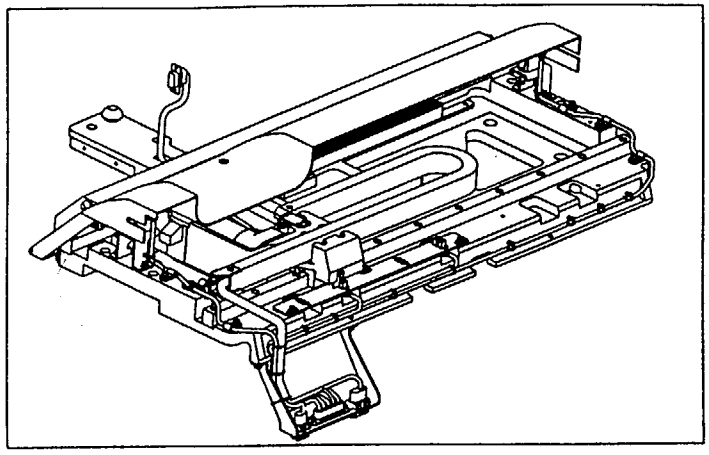
10 CFR Part 19 "Notices, Instructions and Reports to Workers: Inspections and Investigations"

10 CFR Part 20 "Standards for Protection Against Radiation"

10 CFR Part 32 "Specific Domestic Licences to Manufacture or Transfer Certain Items Containing By-product Material"

10 CFR Part 35 "Medical Use of By-product Material"

FOR ECO SEE PAGE 1



	NAME	DATE
DESIGNER	ILAN.S	26.1.00
DESIGN CONTROL	ILAN.S	26.1.00
CHECKER	BENNY.H	26.1.00
APPROVAL	ACHION.Y	26.1.00

EUROPEAN PROJECTION. DEFAULT DIMENSIONS : MM.
FINISH
TOL. NOT SPECIFIED :

EQUIPMENT: VG

ASSEMBLY NAME: VTRANSACT ASSY
No. ASM-000836

SCALE: 1.0:1.0

NAME: VTRANSCT-MOTION RIGHT (VG)

DWG. SIZE: 2

DRAWING No.

A3

1.1.2 Transportation and Unpacking

1. Any damage discovered during shipment should be immediately reported to the Vendor.
2. During unpacking and installation, the system should be handled with great care, to avoid damage.
3. During unpacking and transportation, do not leave the equipment unsupervised.
4. Verify that all packages are empty after the unpacking process.
5. Before assembly, clear the area of packaging material, nails, hazardous metal pieces, dirt and rubbish.
6. Verify that all of the Option Contents (as described in Section 2.1.1) were received and that the contents are free of damage.

1.2 SAFETY DEFINITIONS

Warnings, Cautions and Notes are used throughout this manual. The identified hazards are surrounded by a frame, and are used in the following way.

	**DANGER** **Danger** is used to identify conditions or actions for which a specific hazard is known to exist which **will** cause severe personal injury, or substantial property damage if the instructions are ignored.

	**WARNING** **Warnings** are used to identify conditions or actions for which a specific hazard is known to exist, which may cause severe personal injury, death or substantial property damage if the instructions are ignored.

	**CAUTION** **Cautions** are used to identify conditions or actions for which a potential hazard may exist, which will or can cause minor personal injury, or property damage if the instructions are ignored.

3.2.8 Radiation Leakage Test

The camera should be checked for radiation leaks at least once a month or earlier if stipulated by local safety regulations. The radiation leak test should be performed according to the requirements of the American National Standard, Publication N542, Appendix A: Dry Wipe Test.

⚠	**CAUTION** Do not directly touch the surface of the rod unit with your hands either before or after obtaining the sample for the leakage test.

The radiation leak test is carried out as follows:

1. Ensure that the shutter is closed and locked.
2. Visually examine a piece of dry filter paper and verify that the paper is not torn.
3. Using the dry filter paper, thoroughly wipe all surfaces of the sealed Rod Units (see Figure 3-10).
4. After wiping the potentially radioactive surfaces of the Rod Units, check that the filter paper is not torn and measure the radioactive content. (If a piece of the paper is missing it must be found and disposed of properly).
5. If the radioactive content of filter paper is less than 5ηCi, the machine is considered non-leaking.
6. Following completion of the test, dispose of the filter paper in a container for radioactive waster materials.

A.6

Radioactive Contamination Test

The camera should be checked for radiation leaks at least once every six months or earlier if stipulated by local safety regulations. The radiation leak test should be performed according to the requirements of the American National Standard, Publication N542, Appendix A: Dry Wipe Test.

CAUTION

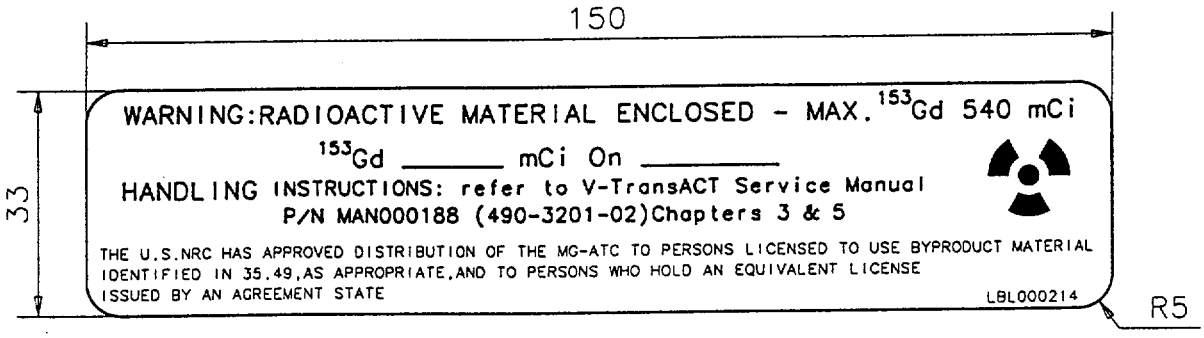
Do not directly touch the surface of the rod unit with your hands either before or after obtaining the sample for the leakage test.

The radiation leak test is carried out as follows:

1. Ensure that the shutter is closed and locked
2. Visually examine a piece of dry filter paper and verify that the paper is not torn.
3. Using the dry filter paper, thoroughly wipe all surfaces of the sealed Rod Units.
4. After wiping the potentially radioactive surfaces of the Rod Units, check that the filter paper is not torn and measure the radioactive content. (If a piece of the paper is missing it must be found and disposed of properly).
5. If the radioactive content of filter paper is less than 5ηCi the machine is considered non-leaking.
6. Following completion of the test, dispose of the filter paper in a container for radioactive waster materials.

A.7

ZONE	DESCRIPTION	APPR.	DATE	REV	CHANGE ORD.
	NEW DOCUMENT			AA	



1. MATERIAL - LEXAN 0.3 MM
2. FONT - DARK GRAY PANTONE 446
3. BACKGROUND LIGHT GRAY PANTONE 427
4. ⊠ - TRANSPARENT
5 ADHESIVE: MAC-TAC COVER BY PAPER

Q.C.

TESTS OF 15 SECONDS RUBBING WITH WATER, ISO-PROPANOL AND METHANOL
AFTER ADHESION INSPECT THAT THE TEXT IS READABLE AND CLEAR AND THAT THE BORDERS OF THE LABEL ARE NOT FOLDED

	NAME	DATE
DESIGNER	Evgeny M.	25.12.99
DESIGN CONTROL	Evgeny M.	25.12.99
CHECKER	Benny H.	25.12.99
APPROVAL	YOSSI H.	25.12.99

EUROPEAN PROJECTION. DEFAULT DIMENSIONS : MM.
FINISH
√
TOL.NOT SPECIFIED :

EQUIPMENT: V-TransACT
ASSEMBLY NAME
No. :
SCALE: 1.0:1.0
NAME: WARNING LABEL

DWG.SIZE: 1
DRAWING No.: LBL-000214-01
VERSION
SHEET 1 OF 1

ELGEMS R&D
POB 170 Tirat Hacarmel 30200 ISRAEL

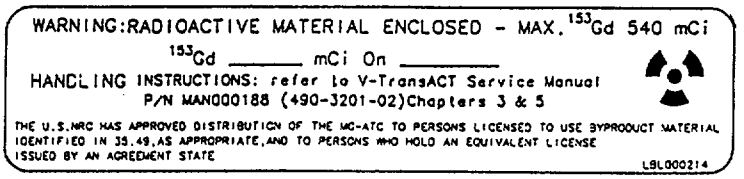
LAST OP.
NEXT OP.

Project : BENNYHA, Item : LBL000214-01, 10-10-100 17:20:52

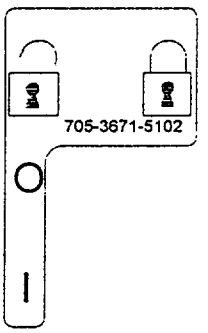
Old Partnumber : NEW PART

Table 1-1. Safety Labels

1



2 **Shutter Status Label**

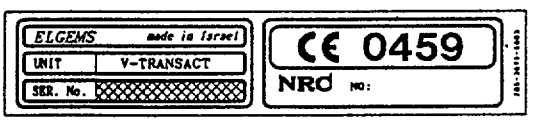


3

WARNING:
DO NOT LET FINGERS, HAIR, OR CLOTHING GET CAUGHT IN THE OPENING

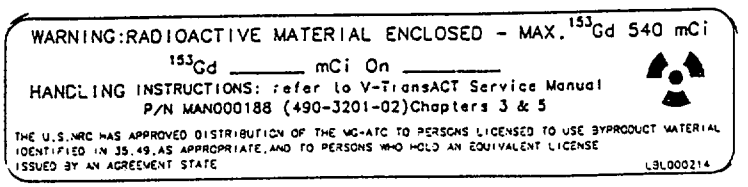
705-3671-0802

4

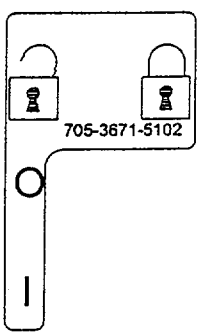


A:9

1



2 **Shutter Status Label**



3

WARNING:
DO NOT LET FINGERS, HAIR, OR CLOTHING GET CAUGHT IN THE OPENING

705-3671-0802

4