RTS TECHNOLOGY, INC.
A Company of the Sauerwein Group

6 June 1991

RTS TECHNOLOGY, INC.
35 Flagship Drive
North Andover, MA 01845
Telephone 508-683-5211
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Mr. Stephen Baggett
Medical, Academic & Commercial Use Safety Branch
Division of Fuel Cycle, Medical, Academic & Commercial Use Safety
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Baggett,

Enclosed is an application for Health and Safety Review and Registration of GammaMed 12it High Dose Rate Remote Afterloading Device. This device is manufactured by Isotopen-Technik Dr. Sauerwein, GmbH, Bergische Str. 16, D-5657 Haan, Germany, and is distributed in the United States by RTS Technology, Inc. This device is designed for use as a remote controlled radionuclide applicator system. It is used in conjunction with RTS Technology, Inc. Model 721 Source Assembly, which has been previously registered with your organization

We ask that you review this application and deem this device acceptable for licensing purposes. In accordance with 10 CFR 170.31, Item 9.A, we are enclosing a check for $2,600 as the fee for this review.

We trust that this application is satisfactory. Your prompt review would be greatly appreciated. If we can provide any additional information, please contact us.

Sincerely,

John J. Munro III
Managing Director

Appendices

Technical Description of GammaMed 12it

Associated Approvals

Registration NY 453 D 105 S for GammaMed 12i
FDA Letter K891131/A for GammaMed 12i
NRC Registration NR-555-S-104-S for Model 721 Source

Brochures

Drawings

Type A Transport Evaluation

RTS Technology, Inc. Quality Assurance Program Approval

Operating Manual

RTS TECHNOLOGY , INC.
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GammaMed Model 12it
Remote Afterloading Brachytherapy Device

1. Introduction

The GammaMed Model 12it is designed for use as a Transportable Remote Afterloading Brachytherapy Device. It is designed and manufactured by Isotopen-Technik Dr. Sauerwein, GmbH., Bergische Str. 16, D-5657 Haan, Germany. The device is distributed in the United States by RTS Technology, Inc., a subsidiary of Isotopen-Technik Dr. Sauerwein, GmbH. The GammaMed Model 12it is designed to house a single source assembly. The nominal capacity of the device is 10 curies of iridium^{192} with a maximum rated capacity of 12 curies of iridium^{192}.

The source assembly to be used in conjunction with this device is the RTS Technology, Inc. Model 721, which has been previously registered with the US Nuclear Regulatory Commission.

The GammaMed Model 12it is very similar to the GammaMed Model 12i Remote Afterloading Brachytherapy Device which has been previously registered with the US Nuclear Regulatory Commission through the State of New York under Registration Number NY 453 D 105 S. A copy of this certification is enclosed in the Appendix.

The GammaMed Model 12i would only be used by persons specifically licensed by the USNRC or by an agreement state.

2. General Description

The GammaMed 12it is a transportable remotely controlled afterloading brachytherapy device used for the treatment of cancer by intracavitary, interstitial, intraluminal and and intraoperative irradiation. The unit is designed to provide a predetermined dose of radiation to tissues and organs by means of manipulating a radioactive source from a shielded position within the device into an applicator, which has been previously implanted within a patient.

The GammaMed 12it high-dose rate brachytherapy device is designed to deliver a high dose of radiation from within a cancerous site. High dose treatments are generally given in several fractions. The individual treatment time is usually less than 30 minutes. These high dose rate units have been used in the treatment of brohchial (intraluminal), gynecological (intracavitary), head and neck, and breast (interstitial) cancers. Patients may be treated as an out-patient, a hospital in-patient, or as a patient of a free-standing medical practice. Units in operation are generally located in properly shielded rooms to protect staff and personnel from unnecessary radiation exposure. The unit's control and computer systems are located outside the treatment room, thereby reducing radiation exposure to the operating personnel when the source is in the exposing, or treatment, position inside the treatment room.

The system may be permanently or temporarily placed in an adequately shielded room with temperatures not to exceed 40° C. The unit should be operated by properly trained personnel in accordance with the conditions of the institution's license.

The GammaMed 12it is a technically advanced afterloading device which has been developed based on the principles and experiences accumulated from its predecessors, the GammaMed II (NY 453 D 101 S), the GammaMed III (NY 453 D 201 S), and the GammaMed 12i (NY 453 D 105 S). Each of these devices have been previously registered and found to be acceptable for licensing purposes within the United States. Principles such as incremental source motion, dwell times, and the accuracy of source positioning are retained while additional features, herein described, add to the versatility, flexibility, and safety of the equipment. More than ten years of experience with these High Dose Rate afterloading devices and close contact with physicians using this equipment have led to the development of this new device.

A wide range of applicators assures the widest possible range of treatment for intraluminal, interstitial, intracavitary, and intraoperative brachytherapy.

More than 100 GammaMed units are in operation world-wide and product reliability is remarkably high. No major incidents have been reported since the first installation.

3. Description of the GammaMed 12it

The GammaMed 12it consists of the GammaMed Exposure Device with its associated trolley (the treatment unit) and the GammaMed Operator Console, with its associated computer.

The GammaMed Model 12it Exposure Device is 900 millimeters (36 inches) long, 400 millimeters (16 inches) wide, and 450 millimeters (18 inches) high. The total mass of the exposure device is 60 kg (130 pounds). The exposure device contains the radioactive source, the shield, the drive motors, indexer and position encoders for the source, electronic control circuit boards, the battery pack and power supply.

The radioactive material is sealed inside a stainless steel source capsule. The source capsule is attached to the source cable to form the source assembly. The source cable is also fabricated from stainless steel. The source assembly is housed inside a source tube. The source tube assembly is surrounded by depleted uranium metal which is used as shielding material. The mass of the uranium shield assembly is 12 kg (26 pounds). The uranium shield assembly is encased in a metal housing. Additionally, a tungsten S-channel cylinder is located in front of the depleted uranium shield to prevent leakage of radiation. Radiation intensities in the vicinity of the GammaMed 12i exposure device, when containing a source of the maximum capacity, have been measured as:

40 µSv/h (7.75 cm from source)
10 µSv/h (10 cm from source)
0.6 µSv/h (100 cm from source)

Since the shielding properties of the GammaMed 12it are identical to those of the GammaMed 12i, it is expected that the radiation intensities in the vicinity of this device will be equivalent.

A mechanical/electrical key lock is provided to prevent actuation of source.

The source guide tubes attach to the exposure device by means of a special quick connector to facilitate connection. The source may be exposed through a particular channel only if the source guide tube is properly attached to this channel. The applicators to be employed in a particular treatment are connected to the GammaMed 12it indexer by way of the source guide tubes. Use of the wrong tubes is precluded by the matching quick connectors.

The exposure device also contains a simulator source assembly. This simulator source assembly is identical to the actual source assembly except that it does not contain radioactive material. The simulator source makes it possible to test the condition and location of the source guide tube and the applicators and their connections before carrying out the actual treatment. The device is equipped with 24 access channels, through which the single iridium^{192} source can be sequentially manipulated. The source exit port can be raised or lowered into a position that is optimal in relation to the particular patient. A wide range of flexible and rigid applicators is available for a wide variety of brachytherapy techniques.

The exposure device is equipped with an emergency hand crank to permit the emergency retraction of the source. The hand crank is a "one way" hand crank which allows only retraction of the source. It is not possible to expose the source using this hand crank.

The exposure device is installed onto a trolley. The GammaMed trolley consists of a rectangular chassis with four large casters for easy movement of the equipment. It has a manually operated brake that reliably maintains its position during treatment. It also contains a hydraulically operated scissors type jack for elevating the exposure device to the proper vertical position for treatment. The position of the exit port of the exposure device can be varied from 500 millimeters (20 inches) above the floor to 1050 millimeters (42 inches) above the floor. The dimensions of the exposure device mounted on its trolley are 1050 millimeters (42 inches) long, 520 millimeters (21 inches) wide, and 900 millimeters (36 inches) high. The total mass of the exposure device and its associated trolley is 112 kg (250 pounds).

The GammaMed Model 12it Control Console is built into a table which contains the control console and its associated computer, and can be integrated with the GammaMed 12it Exposure Device and its associated trolley for transportation. The control console dimensions are 700 millimeters (28 inches) long, 540 millimeters (22 inches) wide, and 900 millimeters (36 inches) high. The total mass of the control console is 31 kg (68 pounds).

The GammaMed 12it is computer controlled. The menu-driven software allows the operator to enter all radiation parameters into the computer memory. Patient specific data is either entered manually through the computer keyboard or automatically loaded from the treatment planning program. Data describing the radiation treatments are automatically stored in the computer memory and can be displayed at any time. The decrease in the activity of the iridium ^{192} source due to decay is automatically compensated by an internal clock in the computer. The data characterizing a radiation treatment in progress are concurrently displayed on the computer screen and printed. Operator error or equipment malfunction are highlighted on the computer screen and emphasized in the printout.

Tamperproof seals are provided during shipment of this device.

Drawings of the GammaMed Model 12it Exposure Device are presented in the Appendix.

The components used in this exposure device were selected for their durability and resistance to corrosion. The source changer is designed to minimize the entry of dirt, water, and other foreign matter. The device can be readily and safely cleaned. Temperatures normally encountered in use will have no adverse effect on the device. The materials in close proximity to the source will not be adversely affected by radiation.

No moving parts are in direct contact with the uranium shield.

4. Security of the Source Assembly

The source assembly is secured in the proper storage position by means of the friction drive wheel. Additionally, source movement is precluded by means of a fixed end stop in the RETRACT direction and a storage plug inserted through an applicator channel in the EXPOSE direction. Demonstration of the security of this device was made during the tests for Type A packages. At the conclusion of these tests the source assembly was properly secured in the proper shielded position in the exposure device.

5. Operational Features

The GammaMed 12it exposure device is designed to be used in conjunction with a variety of applicators for intraluminal, intracavitary, interstitial and intraoperative brachytherapy. These applicators are attached to the exposure device by means of source guide tubes. Each source guide tube is attached to one of the exit ports on the exposure device. As many as 24 source guide tubes and applicators may be used at one time. The single iridium^{192} source would be sequentially manipulated through each of the attached guide tubes and applicators to perform the intended treatment. In each applicator, the source may be stopped at as many as 40 positions to perform the intended treatment.

In operation, the treatment plan would be entered into the computer of the operating console. This would be accomplished by manually entering the dwell positions and dwell times for the source in each applicator, or by automatically downloading this data from a computerized treatment planning computer program, such as the GammaDot which is described below.

Unauthorized operation of the GammaMed 12it is prevented by the key-operated switch. Once the key switch is activated, and before any radiation treatment can be initiated, the GammaMed 12it will conduct a completely automatic diagnostic self-test of all components which relate to safe operation. This diagnostic program checks the limit sensor status, battery backup capacity, electronic controls, internal clock, and component connections. Safety lamps illuminate when the GammaMed 12it is ready to operate, indicating external power on, battery ready, iridium-192 source retracted, operating mode normal, and ready.

Once the treatment plan has been entered and the applicators and connectors are properly attached, treatment can be initiated by pressing the START button. The exposure sequence begins with the source position indexer checking that the source guide tubes are properly connected to each exit port through which the treatment program requires the source to traverse. This is accomplished by means of a proximity switch. If a necessary source guide tube is not in position, an error message indicating the missing source guide tube is displayed on the computer terminal. The program cannot be continued until a source guide tube is introduced into that channel and the START button is again actuated. The source cannot be advanced until all the necessary source guide tubes are in place. If source guide tube becomes loose during operation, the source retracts and the error message "INTERRUPT: SOURCE GUIDE TUBE" appears. Once the unit has assured that all source guide tubes are in place, the source position indexer is positioned to the appropriate exit port.

This indexer connects the emergent position of the shield to each of the exit port positions in the sequence indicated by the treatment plan. Prior to exposure of the actual source assembly, a simulator source assembly is manipulated through the source guide tube to the applicator and through the programmed movement sequence. Upon actuation, the simulator source assembly will move to the precise irradiation position and then attempt to advance 5 mm beyond. The purpose of this actuation is to assure that the correct source guide tube and applicator are attached. If, through this manipulation, the source does not sense the closed end of the applicator, the sequence will be aborted. The error message "Probe Tube too long" will appear and the program will be interrupted. If the source senses the end of the applicator, the exposure sequence will be performed by the simulator source assembly. As a safety precaution, the actual source assembly can be manipulated through the guide tube and applicator only if the simulator source assembly has be successfully manipulated through this sequence. In general, the simulator source assembly must reach the extreme position before the actual treatment begins. This is an important safety measure which assures that the path of source transit is free from any obstruction. If there is an obstruction, the source automatically retracts and an error message which identifies the problem is displayed.

The simulator source assembly serves several safety functions. In addition to checking for the presence of the proper source guide tube and applicator combination and a clear pathway, the simulator source can be used to established the distal source position which can be visual observed under fluoroscopy. The distal point coordinate is automatically stored in the computer. This set coordinate dictates the path to be travelled by the actual source.

The simulator source can also be manually activated and moved bidirectionally (in both the EXPOSE and RETRACT directions) by a remote controlled button located on the GammaMed exposure device. It provides a means for the physician to visually observe the source position under fluoroscopy and compare source location in relation to the tumor site. If desired, the treatment parameters can be changed.

Once the simulator source has completed the programmed sequence, the actual source begins the cycle.

Source motion is microprocessor controlled. Source position can be incrementally changed in steps of 5 mm or 10 mm. The source can be stopped at 40 stopping points in each channel. The dwell time for each stopping point can be up to 9999 seconds. Although the source must reach the end of the applicator in order to begin the exposure sequence, it is not necessary that the exposure sequence begin at that point. The first dwell point can be selected at any point in the path.

Control of source travel and step-distance is accomplished by the number of preprogrammed pulses emitted by the incremental encoder and verified by two additional limit switches (optical and mechanical). The preprogrammed source travel distance is extended by approximately 2 mm beyond the path of the limit switch. Once the source reaches this end point, the source cable is withdrawn in the opposite direction until it reaches the limit switch. This procedure establishes a distinct end-position and simultaneously removes any slack in the source cable, thus eliminating any backlash. The result is precise source positioning starting in the first treatment position. The precision of each increment, monitored by the encoder, is $\pm$0.22 mm. Bidirectional motion of the source is also controlled in relation to time. The source must reach the final destination in 7 seconds. If this does not occur, an error code will be indicated, and the source will automatically retract into the shield. The entire treatment plan is stored in the computer and in the control panel and they run synchronously. A deviation of 0.2 seconds will cause the treatment to be terminated.

Battery voltage is constantly monitored. The battery backup assures that the iridium ^{192} source can be retracted back into its shielding in the event of a power failure. It also provides the means for the data characterizing the current treatment to be stored. The exposure sequence cannot be started until main power is present and the capacity of the battery voltage is sufficient to assure that the source can be retracted. The overall controls constantly test the batteries capacity before and during the treatment. The program is interrupted if the battery capacity drops below a critical limit during exposure. If the computer or the main electronic controls fail, the battery backup comes into operation and retracts the iridium ^{192} source into its shielding.

The complete treatment plan is simultaneously stored in both the computer and in the GammaMed 12it controls. The two programs are tested for identity and, if any discrepancies are detected, the treatment is automatically discontinued. Treatment Plans are stored in a battery backed-up buffer memory and checked once per second. In case of power failure, and subsequently thereafter, the treatment plan can be recalled.

If any of the above ongoing tests reveals a malfunction, the treatment is immediately discontinued. It is also possible to manually discontinue treatment at any time by depressing the INTERRUPT button. Pressing the EMERGENCY button or opening the door into the treatment area will also terminate the procedure. The treatment parameters, up to the instant of interruption, and the cause of the interruption are stored in memory and can be retrieved once the equipment is turned on. The battery backup retains the memory in the event of a power outage.

In case of a power failure (failure of both main power and battery back-up), the operator can retract the iridium^{192} source back into its shielding with a manually operated one-way emergency crank. Since the crank is designed to operate in only one direction, it cannot be employed to advance the iridium^{192} source.

An illuminated panel on the control console contains a **RADIATION WARNING LIGHT** which indicates source "on" or "off" positions. This panel is clearly visible from the operator's position.

The radiation warning light is activated by an independent Geiger-Müller detector located in the exposure device. This built-in radiation detection system utilizes a variable alarm threshold (a potentiometer on the GamNet card). If the intensity at the detector exceeds approximately 3 mSv/h, the RADIATION signal on the control panel will illuminate. This lamp also illuminates when the GammaMed source leaves the shielding. When the RETRACT SOURCE command is initiated by an INTERRUPT or by an EMERGENCY at the control panel during normal operation (a situation sensed by the GammaMed by way of incremental monitoring and limit-switch controls), the controls determine whether the radiation detected by the counter has diminished within 2 seconds. If not, the RADIATION lamp illuminates and the error message "radiation" is displayed and printed out accompanied by an audible alarm. In this situation, either the source is still outside the shielded container or some other source is generating a radiation field in the vicinity of the device.

There is an EMERGENCY BUTTON on the top of the device. This large, mushroom type emergency button is clearly visible and easily accessible. The use of this button is only in the event of an emergency after all other safety back-up systems fail to retract the source. When pressing the emergency button, the source retracts within less than one second from the distal point to the shield.

The computer monitor constantly displays events which occur during the treatment. Any errors or malfunctions are highlighted on the screen and emphasized in the printout. The printer automatically documents the complete treatment, providing hard copy for the patient's file.

An manual brake system is provided to prevent machine dislocation during normal use.

6. Description of the GammaDot Treatment Planning System

The integrated GammaDot treatment planning system includes extensive and versatile optimization software for high-dose rate brachytherapy controlling an iridium ^{192} source. The system is designed to operate on an IBM PC-AT compatible computer. All functions are displayed and menu-controlled. The treatment parameters, patient records, control numbers, name, date, fraction and diagnosis are entered from an alphanumeric keyboard, with all other functions attainable through the function keys. The operator is provided with complete information assistance as to what parameters have to be entered. A CLINIC FILE contains all the specific clinical data which are utilized as defaults for calculating, displaying and printing.

Except for a few important parameters, type of source and computational formulas, etc., all values entered by the operator can be changed at any time.

Source dwell times, source positions and channel selections are entered into the computer by self-explanatory optimization software. Since the treatment parameters are constantly displayed on the monitor during the treatment, the operator has full supervision of source movement and timing. Any errors or malfunctions occurring during the treatment are instantly recorded on the screen and printed out by the printer.

In addition to performing calculations involving standard applicators, such as vaginal, vaginal/cervical, bronchial and other simple implants, whose geometries are included in the standard program configuration, the program permits the entry of source-stopping points and dose reference points through the keyboard or digitizer (orthogonal x-ray images). The use of standard applicators requires entry by reference to the type of applicator, the treatment length, diameter of applicator, dose reference point and the reference dose. Additionally, entries of up to 150 source stopping points (maximum of 20 needles) and 60 dose reference points can be made. The computer further checks the parameters entered to the matching source position coordinates.

Planning a typical gynecological treatment takes approximately 10 to 11 seconds for the computer calculation once the treatment parameters have been entered. It takes approximately one minute to compute five stopping points in each of nine needles.

The isodose distributions are displayed on the screen in a variety of colors at any desired isodose level. Specific isodose levels can be entered. The number and the value of the isodoses can be selected by the operator. The scale of presentation on the screen and at the printer can be freely selected. Calculations are based on a point or linear source with corrections undertaken for self-absorption and attenuation from source capsule.

All calculated isodose distributions are automatically stored in a patient directory which can be recalled at any time. The patient directory can be recalled by entering the date, the patient's name, or the patient's identification number. The data retrieved can directly be transferred into the GammaMed control panel. The number of stored treatment plans is limited only by the capacity of the Winchester drive. Treatment plans can be deleted from the directory or copied onto disks by way of the menu.

7. Transportation of the Device

The GammaMed Model 12it is designed to be transported as a DOT Specification 7A, Type A package. The device is designed to satisfy the requirements for a Type A package in accordance with 10 CFR 71. A report of an evaluation of the device's compliance with the Type A requirements and the results of tests performed on a prototype device are presented in the Appendix.

The device is designed to be transported to a site and placed into operation without the necessity of recalibration of source intensity or position.

8. Quality Assurance

The GammaMed Model 12it is designed and manufactured by Isotopen-Technik Dr. Sauerwein, GmbH., Bergische Str. 16, D-5657 Haan, Germany. The device is designed, manufactured and tested under their quality assurance program which is in accordance with the requirements of the German government for devices containing radioactive material. The GammaMed Model 12it is tested and serviced in the United States under our quality assurance program, which has been approved by the USNRC. A copy of the approval certificate, Number 0642, is enclosed in the Appendix.

Prior to delivery of the GammaMed Model 12it and again at the time of delivery, the GammaMed Model 12it is inspected and tested following the specific instructions for this device. Records of this inspection are maintained in accordance with our Quality Assurance Program.

9. Labeling

The GammaMed 12it will be labeled with a sign bearing the radiation caution symbol, in magenta on a yellow background, and the words "Caution, Radioactive Material" It will also be labeled with the name of the manufacturer, the model number, the serial number, the radionuclide and the capacity of the container.

10. Source Exchange

Sources in the GammaMed 12it shall only be performed by persons specifically licensed by the NRC or an agreement state. RTS Technology, Inc. offers its users the performance of sources exchanges as a service. The procedures for source exchange are included in the operating manual for the device.

The iridium 192 source can be changed semi-automatically in a special operating mode from the control console, reducing the risk of radiation exposure to the operator. Access to this mode is secured with a key switch. Source-specific data, i.e. activity and reference date, can be changed only in this mode.

Replacement sources are transported in the GammaMed Source Changer (drawing B 8319-1). This source changer is the same as that used in conjunction with the GammaMed IIi and the GammaMed 12i, and has been previously deemed acceptable for licensing purposes.

11. Installation and Service

RTS Technology, Inc. offers its users a complete line of service associated with this device, including installation, repair, technicians for performing source exchanges at the user's facility, leak testing, periodic inspection and maintenance, training of the user personnel in the operation and maintenance of this device and technicians for response to a radiological emergency involving this device.

12. Instructions for Use.

A copy of the operating instructions for the GammaMed 12it is included in the Appendix.

APPROVALS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 7

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

Re: K891131/A
GammaMed 121
Dated: May 25, 1989
Received: May 26, 1989
Regulatory class: II

Mick Radio-Nuclear Instruments, Inc.
Attn: Felix W. Mick
P.O. Box 99
Bronx, New York 10465

Dear Mr. Mick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

George C Murray

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology,
and Radiology Devices
Office of Device Evaluation
Center for Devices and
Radiological Health