EVERGREEN RADIOLOGY ASSOC., P.A.
220 HAMBURG TURNPIKE
WAYNE, N.J. 07470

DEPARTMENT OF RADIOTHERAPY
HIGH DOSE RATE REMOTE AFTERLOADING
HDR (OMNITRON)
OPERATION PROCEDURES

Radiation Safety Officer. Armand Fiore M.D. July 15, 1992

Radiation Oncology Sung H. Lee M.D. 7/15/92

Radiation Oncology. Stanley J. Brown M.D. 7/15/92

HDR

1. Initial Preparations
2. Simulation
3. Pre-treatment
4. Treatment Planning
5. Programming and Operation of Treatments
6. Second Physics Check
7. Quality Assurance - Daily/Weekly/Source Change
8. Calibration
9. Emergency

1. Initial Preparation:

A) Attending Physician decides on the course of treatment and fractionation and determines the volume to be treated from the CT and/or radiographic films, consults with the physicist qualified dosimetrist to determine the number of catheters needed.

B) Attending phyeician, dosimetrist, and qualified technologist coordinate to make the arrangement for simulation and treatment of the patient.

During the treatment, the presence of the attending Radiation Oncologist is required.

C) Qualified technologist/physicist reviews the status of the HDR unit and installation, according to the operating procedures and makes arrangements for repairs, if necessary.

2) Simulation:

After placing the appropriate afterloading applicator in the patient and securing them to prev[illegible]ifting:

1) The location of the afterloading device to the tumor volume will be assessed radiographically.

2) Where possible a marker wire will be inserted into the afterloading device and passed beyond the distal tumor margin.

3) In those cases where patiens will receive hyperfractionated/ multiple treatment applications:

   a) If the afterloading applicators are fixed (by button, prong, suture, etc.) visual inspection will be sufficient to confirm the position (after an initial simulation has been performed).

   b) If the afterloading applicator is to be inserted anew for each treatment - radiographs will be obtained to confirm position (after initial simulation has been performed)

4) If more than one catheter is required for the prodedure, steps 1 - 3 may be repeated.

5) A set of orthogonal radiographic films are obtained. The attending physician/physicist/qualified technologist examines the films.

6) The attending Radiation Oncologist draws the volume that is to be covered by the prescribed isodose line.

7) The films are taken to the treatment planning area. The markers are removed from the afterloading applicator(s). All the markers, wires, guide wires, check markers not used are then collected and kept on the HDR cart.

8) The petient is transferred onto a strectcher with proper care to ensure that the catheter(s) positioning is preserved.

3) PRE-TREATMENT Q.A.

1) Verify patient file name.

2) Verify source activity on printout.

3) Check dwell times from Tx. plan and afterloader printout

4) Check dwell positions.

5) Multiple channel: Verify correct catheter to corresponding channel.

6) Catheter(s) connection to afterloader

7. Catheter(s) fully seated to Quick-Connector(s).

8) Tight curve check.

4. Treatment Planning:

The simulation films (orthogonal set) are used by the physicist/ dosimetrist to obtain a computer treatment plan for the patient. Treatment planning is done using the Omnitron computer treatment planning program. The steps involved are specified in the physics procedures for the HDR Remote-Afterloading unit. After the treatment plan is approved by the attending Radiation Oncologist, the results are saved on a 3.5" Diskette, which is subsequently used to treat the patient.

5) Programming and Operation of Treatment:

The omnitron console operator (qualified technologist/physician)

1) Must have the key.

2) Must know the machine password in order to have access to the patient file.

3) Must have the patient's treatment plan file on a 3.5" computer diskette. Notice that there is no connection between the two P.C. computers (treatment planning and control console); the diskette is carried by the operator between the two systems.

4) The operator, under the guidance of the physician, calls the patient's file on the control console monitor, answering the prompts (Pt. name, DOB, M.D., treatment,...). All the desired treatment information (catheter #, dwell position, dwell time) that has been entered should be saved. The operator may then press the ESC key.

5) The patient file must now be printed and reviewed. The randomly generated password to execute treatment for the patient file is on this printout.

6) After entering this password, the system then prompts for each channel, executes a "dummy" treatment using the inactive applicator wire and alarms if any obstruction(s) is encountered. If the dummy treatment is successful, then the afterloader will automatically treat that channel with the active Ir-192 source wire. This process is repeated until all channels have been treated and will print out the treatment record for the patient.

Note 1: An error condition occurs when STOP key is depressed on the control console, treatment room door panel, or afterloader. After error(s) are cleared by depressing the RESET (yellow Button) the afterloader determines it would be safe to continue the treatment. The operator will be asked to verify resuming treatment by entering the patient's password.

Note 2: A physician must monitor the treatment at all times.

Note 3: Only Closed End Applicators will be used with the HDR.

6) Second Physics Check:

At the completion of the treatment planning and prior to the patient treatment, whenever possible the physician/physicist/ qualifiedidosimetrist uses the method outlined in the physics prodedures for the HDR unit to verify the correctness of the BOT as calculated by the Omnitron Treatment Planning Program.

HDR QUALITY ASSURANCE
DAILY/WEEKLY

DAILY Q.A.

1) INTERLOCKS: testing to insure that the machine will not operate and/or the active wire should retract, that if (A or B):

   A) Room Door Open,
   B) Catheter not connected or fully seated in connector.

2) DISPLAY PANEL:

   A) LED indicators on door panel
   B) Lamp test
      (press STOP while machine is inactive, will light all LED)

3) EMERGENCY STOP:

   A) PRESS STOP BUTTON
      on console or door panel during simulated treatment.

4) VIDEO SYSTEM:

   A) T?V. monitor system check.

5) AUDIO SYSTEM

   A) Two-way conversation

6) RADIATION MONITOR:

   A) Monitor outside

   B) Monitor inside

WEEKLY Q.A.

1) TIMER ACCURACY:

   A) Stop Watch

2) SOURCE POSITIONING ACCURACY:

   A) Autoradiograph

Q.A. FOR SOURCE CHANGE:

1) Source Calibration: Activity Check

2) System Obstruction: Test for kink or knot (intentionally make kink or knot to check the unit's ability to detect an obstruction and retract wire).

3) Emergency Retract System:
(during a test treatment while the active source is extended, switch off the UPS red switch removing power from the afterloader)

4) Radiation Survey:
(while the source is parked and shielded, measure the surface of the unit)

5) Site Survey:
(Treatment room and all accessible areas with source at WORST position$)

8) Calibration:

After each source change the qualified physicist will calibrate the source and determine the activity of the new Ir-192 source. Also, the source transit time is measured by a qualified physicist. All measurements should be performed using calibrated instrumentation (chambers/electrometers). The method of performing these measurements are outlined in the physics procedures for the HDR remote afterloading machine.

EMERGENCY PROCEDURES

A) Failure of Source Wire to Retract:

1) Wear pocket dosimeter and enter the treatment room with a stop-watch type timer.

2) Turn the emergency retract handle located on the side of the Omnitron Afterloader.

3) When the source is returned to "safe", record the estimated treatment time and inform the person(s) listed in the Emergency numbers.

B) Failure of Source Wire to Retract after the Above Procedure has been performed:

4) Disconnect the applicator from the unit and pull the unit away from the patient. This pulls the source out of the applicator. Set the unit as far from the patient as is possible.

5) Assist the patient from the room.

6) Using the pair of forceps (located in the table drawer at the console) quickly slide the source into the lead-lined emergency storage safe (located at the table in the treatment room).

7) Close the door, post the sign "NO ENTRY" (located in the table drawer at the console). Record the estimated treatment time and inform the relevant person(s) listed in the Emergency numbers.

EMERGENCY NUMBERS

Physicist:	Vahid W. Jalayer	Number: (516) 794-0422
Oncologist:	Sam I. Brown, M.D.	Beeper#:(201) 881-2007
	Sung I. Lee, M.D.	Beeper#:(201) 670-5808
Omnitron:	Service Personnel (24 Hour)	Number: (713) 666-7198

EMERGENCY SITUATIONS:

1) In the event that the "Active" source becomes detached from it's housing, the following procedures will be instituted:

   A) The M.D. in attendance will enter the room with the appropriate devices necessary (i.e. dosimeter, forceps, scissors, etc.) to manually remove the afterloading device from the patient.

   B) The manual timer will be activated upon the discovery of error until the source is deemed safe in the portable carrier.

   C) Immediately upon exiting the treatment room, the recorded exposure on the pocket dosimeter will be noted and logged.

2) In the event of excessive patient dose due to mechanical malfunction, the attending physician will be notified when relatively accurate dose calculations are made to estimate dose received.

3) In the event of a life threatening situation having ensued, it will be strongly suggested that the patient be observed closely and/or hospitalized. This procedure will also apply to any personnel who may have received excessive exposure. Appropriate reports will be filed to the Nuclear Regulatory Commission as is required by regulation.

EQUIPMENT AVAILABLE FOR HDR TREATMENT

1) Survey Meter(s)

2) Anatomical Lead Markers

3) Coupling for Catheters

4) Long tweezers/forceps

5) Test Program Card

6) Source Position Check Ruler

7) Lead Container

8) Calibrated Pocket Dosimeter

Ir-192 Source Calibration Report

I. Site

Evergreen Radiology Associates
220 Hamburg Turnpike
Wayne, New Jersey 07470

II. Source Information

Source Type:	Ir-192 sealed; Active length of 10 mm attached to a 2201 mm stainless steel wire.
Source Model:	Omnitron International Model SL-777
Serial Number:	01-01-9239-001-051892-08680-69
Stated Activity:	8680 mCi at 5/18/92

III. Calibration Information

Chamber Type:	Well-type (Re-Entrant)
Manufacturer:	Standard Imaging Inc.
Model Number:	HDR-1000
Serial Number:	A912336
Calibration Date:	1/15/92

Electrometer Type:	Keithley Instruments
Model Number:	602
Serial Number:	224905
Calibration Date:	8/2/90

IV. Calibration Results

Calibration Date:	6/6/92
Measured Activity:	7568 mCi
Recorded in Data book:	CAL #2, pp 44-50

Comments: The measured activity of 7568 mCi is 4.0% greater than the stated activity of the source, when decayed to the calibration date.

Calibrated by: Abolghassem Jamshidi, Ph.D., Radiation Oncology Physicist

Abolghassem Jamshidi

3. **Data Precision Digital Multimeter**

   Model Number: 255
   Serial Number: 2677
   Calibration Date: 11/8/90

4. **Exradin Ion Chamber**

   Model Number: A3
   Serial Number: 163
   Calibration Date: 4/31/90

5. **Barometer**
6. **Thermometer**
7. **Exradin Ion Chamber Stand Jig**

Tests Performed

A. Radiation Survey of the HDR Housing

1. The unit was surveyed for the leakage using a Victoreen model 450 survey meter. The survey was done at several points around the unit, both in contact with the surface and at 1 meter distance from the afterloader.

2. **Results**: •The survey of the unit shows a maximum reading of about 0.55 mR/hr (above the Co-60 background of 0.47 mR/hr) at the front-top surface.

   •At 1 meter distance from the afterloader, the readings were less than 0.10 mR/hr.

B. Survey of Radiation Levels Outside the Treatment Room

1. Locations around the Co-60 teletherapy room (Figure 2),where the Omnitron unit is used for patient treatment, and areas above the treatment room (Figure 3) were surveyed for background radiation level with both the Co-60 and the HDR unit in off mode.

2. The above locations were surveyed with the high dose rate Ir-192 source in treatment position (the Omnitron unit in on mode). Each measurement was performed by placing the Ir-192 source closest to the point of measurement. A bronchial catheter was used for these surveys.

3. A Victoreen survey meter, model number 450, was used. The source [illegible] at the time of the survey [illegible] 58 mCi

4. **Results**: •With the HDR source in treatment mode a maximum radiation level of 1.96 mR/hr was measured at a position (#9, Figure 1) located in the hallway/north on the treatment floor, at a height of 1.0 meters above the floor. The background radiation at this point, with the CO-60 and Ir-192 units off was [illegible] mR/hr

1.

Transit Time and Radiation Survey Report

Site

Evergreen Radiology Associates
220 Hamburg Turnpike
Wayne, New Jersey 07470

Unit

Omnitron High Dose Rate remote afterloading system

Manufacturer:	Omnitron International, Inc.
Model Number:	2000
Serial Number:	109

Source Information

Source Type:	Sealed Ir-192
Source Length:	10 mm attached to source wire
Source Wire:	2201 mm stainless steel
Outer Diameter:	0.0135 in.
Wall Thickness:	0.004 in.
Source Model:	Omnitron International SL-777
Serial Number:	01-01-9239-001-051892-08680-69

Equipment/Materials

1. **Survey Meter**

Manufacturer:	Victoreen
Model Number:	450
Serial Number:	1447
Calibration Date:	7/15/91

2. **Electrometer**

Manufacturer:	Keithley Instruments
Model Number:	602
Serial Number:	[illegible]

3.

C. **Verification of Source Transit Time**

1. A spherical Exradin ion chamber model A3 was used with a Keithley 602 electrometer. A Mick RadioNuclear stand Jig was used to place the chamber at a precise (to within ±0.1 mm) distance from a bronchial catheter.
2. **Results**: •The transit time measured is 5.26 ± 0.02 seconds.

CONVERSATION RECORD

TIME ~3PM

DATE July 16, 1992

TYPE

☐ VISIT ☐ CONFERENCE ☐ TELEPHONE

☒ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Dr Brown	Evergreen	

ROUTING

NAME/SYMBOL	INT

SUBJECT

CAL dated 6/5/92

SUMMARY

Dr Brown stated that all commitments of CAL have been completed:

(1) terms of conditions of licenses have been reviewed + training provided plans to make change to relieve them of requirement to have physicist present during HDR source changes through amendment

(2) operating procedures were developed + reviewed + training was provided

(3) HDR was calibrated + survey was performed.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Mary Cahill	Mary Cahill	7/16/92

ACTION TAKEN

SIGNATURE	TITLE	DATE

NOV 25 1992

Docket Nos. 030-10074
030-32352

License Nos. 29-02023-05
29-02023-06

Evergreen Radiology Associates
ATTN: Sam I. Brown, M.D.
220 Hamburg Turnpike
Wayne, New Jersey 07470

Dear Dr. Brown:

Subject: Routine Inspection Nos. 030-32352/92-001 and 030-32352/92-001

This refers to your letter dated July 23, 1992, in response to our letter dated June 24, 1992.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:

Mohamed M. Shanbaky, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey
Armando F. Leone, M.D., Radiation Safety Officer

H/3

EVERGREEN.RL OFFICIAL RECORD COPY Pg 1 October 16, 1992

RETURN ORIGINAL TO
REGION I

IE:07

9212080348 1P.

Evergreen Radiology Assoc., PA
220 Hamburg Tpke.
Wayne, NJ 07470
(201) 942-1202 Fax (201) 942-0781

July 23, 1992

Sam I. Brown, M.D.
Sung IL Lee, M.D.
Stewart A. Berkowitz, M.D.
Rajmohan H. Shetty, M.D.

United States Nuclear Regulatory Commission
ATTN: Mary Cahill
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Ms. Cahill:

This is in response to your lettter citing violations referrring to our License Nos. 29-02023-05 / 06. It is my understanding that you havc been verbally assured by our office that these matters have been corrected, I would like this letter to serve as officical confirmation of the corrective actions taken to date:

In response and correction to these items:

A. Until ammended in future, at each Ir-192 source change, the responsible physicist will be in attendance. Verification of Output and source travel time will be measured at each source change.
B. Survey of the source housing of the HDR brachytherapy unit and all areas adjacent to the treatment room will be done at each source change.
C. Effective 7/1/92 monthly spot checks on the teletherapy unit will be performed, with timer constancy, linearity, on-off error, and output measured and recorded.
D. An indicator light above the treatment room door is scheduled to be installed by Aug. 1, 1992.
E. In future, all leak tests of sealed sources will be signed by the Radiation Safety Officer.

Should you need further information, please do not hesitate to contact me.

Thank you for your consideration in this matter.

Sincerely,

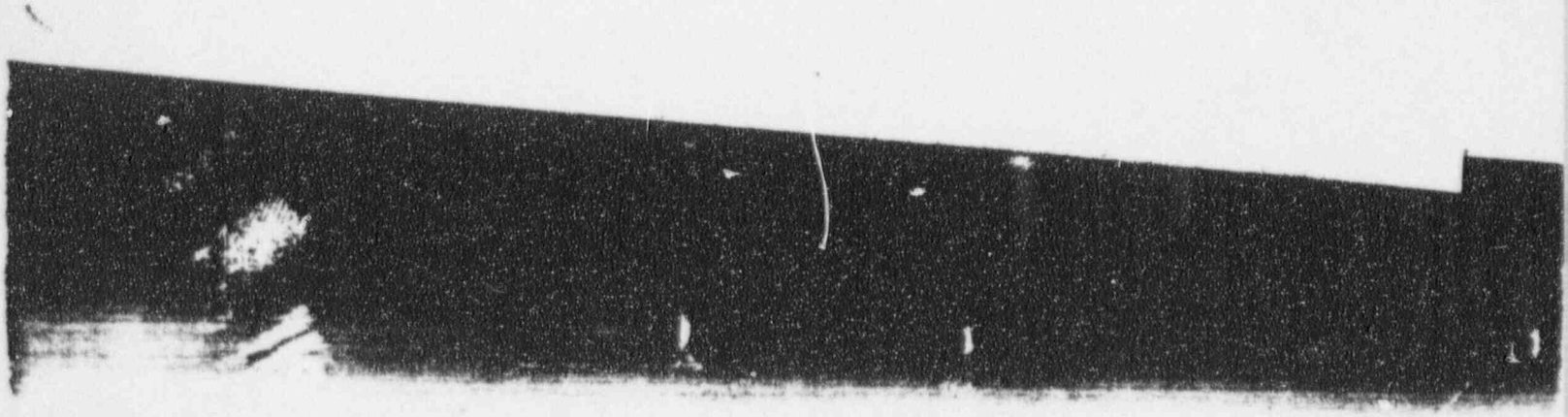
Vahid W. Jalayer, MS
Radiation Phycisist

Richard Conte MD RSO

9212080337 12 pp

INSTRUCTION MANUAL

OMNITRON HIGH DOSE RATE REMOTE AFTERLOADER



INTRODUCTION

The Omnitron remote afterloading radiation therapy device is a versatile single source, 10 channel, high dose rate afterloading machine with a built in inactive wire which tests all connections before an actual treatment run is allowed. The Omnitron uses a patented source wire that measures 0.59 millimeters in diameter and contains an Iridium-192 source of 370 Gbq (10Ci). The Iridium source measures 0.343 millimeters in diameter and 10.0 millimeters in length and is encapsulated in a homogeneous stainless steel wire so there are no joints or welds to snag, break, or cause stiff spots in the wire. The small diameter applicator wire allows the use of 20 gauge applicator tubing and needles, resulting in minimal patient discomfort.

Since up to 20 dwell positions are allowed per treatment channel and the source can be moved in 1.1 cm minimum steps, a treatment distance of at least 21 cm per channel is possible. Each dwell position has a selectable dwell time of up to three minutes in 0.1 second increments.

Up to ten treatment channels are available, with all of the above parameters applying to each channel.

5. Dummy Parked (Green LED) - Indicates that the dummy wire is in the parked position.

6. Diagnostic Mode (Amber LED) - Indicates the diagnostic mode is activated allowing direct control of the afterloader wire movement functions via the console. This mode can be accessed only by Omnitron personnel.

7 Armed (Amber LED) - Indicates that all keylocks and security codes have been set to allow a treatment to progress.

8. In Progress (Amber LED) - Indicates that a treatment is in progress.

9. Error (Red LED) - Indicates an internally detected error condition which will prevent extension of the active wire or cause an automatic retraction if the active wire is extended. The exact cause of the error can be determined from the control console.

10. Door Open (Red LED) - Indicates that the treatment room door is open.

11. Manual Retract (Red LED) - This indicator will be accompanied by an audible alarm, indicating that the afterloader has determined that a manual retraction is required.

REMOTE AFTERLOADER

The remote afterloader contains all the components necessary to safely store the active and dummy wires and to move and track the wires during treatment.

The active wire is stored with the radioactive tip located in a lead safe. This safe is sized to keep radiation levels below 0.1mr/hr at a distance of 1 meter from the afterloader.

The wires are moved via stepping motors controlled by the afterloader CPU as instructed by the main console. Wire tracking is done with independent optical encoders that are immune to any possible drive system slippage.

A battery operated emergency retract system is provided to bring the active wire back to the parked position in the event of a malfunction of either the remote afterloader or the main console. This system is independent of the main movement and tracking system. The system consists of a DC electric motor driving the wire via a friction roller system and controlled by a mechanical switch indicating the wire is in the parked position. If the afterloader CPU is still functional when an emergency retract is triggered, it will record the date, time, and possible cause of the retract.

Because the main console is used for most operator interface requirements, only a few status lights and push button controls are located on the remote afterloader status panel. The following items are on the afterloader status panel as shown in Figure 2:

1. SAFE (Green LED). This indicates that the active wire is parked and a manual retract is not required.

2. DUMMY PARKED(Green LED). This indicates the dummy wire is parked.

3. ARMED (Amber LED). This indicates that all keylocks and security codes have been set to allow a treatment to progress.

4. IN PROG (Amber LED). This indicates that a wire or turret movement function is in progress.

5. ERROR (Red LED). This indicates an internally detected error condition which will prevent extension of the active wire or cause an automatic retraction if the active wire is extended. The exact cause of the error can be determined from the console. This also indicates any errors detected during a treatment.

6. MAN RETRACT (Red LED). This indicator will be accompanied by an audible alarm, indicating that the afterloader has determined that a manual retract is required.

7. DIAG MODE (Amber LED). This indicates the diagnostic mode is activated, allowing direct control of the afterloader wire movement

ACTIVE WIRE PARKING

For safe storage, the active portion of the treatment wire must be parked in the lead safe. This is accomplished by returning the fixed length active wire back into the storage path. The path is sized so that when the inactive tail of the wire is at the park switch sensor, the center of the active source is located at the center of the lead safe.

After treating a channel, the stepper motors park the active wire. Successful parking is determined by a mechanical switch located at the end of the wire travel path. When the switch is tripped, the active portion of the wire at the other end is in the lead safe. If the parked condition is not detected after a preset time/step limit, an emergency retract is initiated. Should this ever fail, a manual retract alarm will sound.

WIRE LENGTH CHECK

The length of the wires is checked just before parking to make sure than no length errors have occurred during treatment. This is done by comparing the wire position when the home sensor is activated during extension to the position when the home sensor is deactivated during retraction. Any length errors are reported to the operator at the main console, and will cause a manual retract alarm to sound.

EMERGENCY RETRACT SYSTEM

Two levels of emergency retract are provided in the Omnitron Afterloader. A software retract occurs when the wire is retracted by the stepper motors due to a self-detected error condition. This is done under control of the afterloader CPU, which can then log the error and inform the console of the nature of the event. A hardware retract occurs when the emergency retract motor is used to retract the wire. This is done if a software retract fails, if an afterloader CPU failure occurs, if the wire extended time-out occurs, or if the power fails.

In the event of failure in the main stepper motor system, the emergency retract system will bring the active wire back to the parked position. The system operates from a battery located in the afterloader.

SAFETY FEATURES

A primary goal of the Omnitron Remote Afterloader design is to insure the safety of the patient and the operator. This means insuring that the active wire is never inadvertently extended, or left extended for an excessive amount of time. To do this, a dual-processor architecture was chosen. This consists of the PC based console and a microcomputer controlled afterloader. The Control console is used for entering patient data and treatment prescription. The Remote Afterloader has sole overriding responsibility for safety.

There are essentially five levels of security provided by the design:

1. Treatment verification. The console program will verify each step of a treatment before allowing execution. This includes checking for excessive individual or total dwell times, inconsistent or duplicate treatment positions, and illegal wire or turret movement requirements.

2. Afterloader software and hardware verification. The afterloader acts as a second opinion on all requested wire movement functions. Like the console, it will check for illegal, excessive, or inconsistent wire movements. The afterloader software constantly monitors the hardware status. It measures power supply voltages, battery charge state, wire position and length, stepper voltage, and console communications. Hardware failures are self-detected, retracting the wire and reporting the error to the console. A battery backed memory holds error and service data, such as date installed, power on hours, treatment cycles, etc, and will prevent operation if any preset service limit is exceeded. In general, the afterloader is designed so that a multitude of items must be correct for the active wire to be extended, but any error will cause a retract or prevent extension.

3. Hard-wired logic circuitry. This circuitry acts independently of the afterloader processor, preventing illegal operations from occurring even if the processor should fail. For example, the logic will prevent extension of the active wire if the dummy wire is not parked.

4. Watchdog timers and power failure detect. Two redundant watchdog timers will time out in 100 milliseconds (0.1 seconds) if not reset by the correct sequence from the processor. Should the afterloader processor become 'locked up' or 'lost' this timer will detect this in 0.1 seconds and initiate an emergency retract. The second watchdog timer is set up to run whenever the active wire is not parked. This timer is programmed for the maximum reasonable total dwell time(approximately 20 minutes) for any one channel, and is independent of the processor. Should this timer ever expire, an emergency retract will be initiated. This timer can only be stopped if the active wire is parked. The hardware is designed so that power must be applied to keep the battery-backed retract motor from

2. Mechanical/electrical verification that all programmed treatment channels have properly connected and locked catheters.

3. Applicator wire lengths are checked each time the wires are retracted into the machine to ensure the entire wire has been retrieved with no breaks.

4. Position encoder checks turret position to verify turret rotation and prevent double treatment of any treatment channel. The turret is mechanically locked in position and an optical sensor verifies the mechanical lock.

5. Automatic treatment interruption and source retraction if the applicator wire is extended too far.

6. Manual retract hand wheel to allow source retraction in the event of main retract and emergency retract motor failures.

7. Fail-safe retract system which ensures that applicator wire has been fully retracted.

8. Position encoder tracks applicator wire to ensure source position accuracy to ±1.0 millimeters.

9. Inactive applicator wire executes programmed treatment to test for proper guide tube routing, programming, and to ensure there are no obstructions or kinks in the guide tubes. The inactive applicator wire is constructed of the same material and to the same dimensions as the active applicator wire.

10. All applicators are closed at the distal end.

11. Applicator wires always move in the same direction during treatment to ensure accuracy and eliminate errors due to wire bunching or sticking.

12. Programmed dwell and treatment times are continuously monitored and displayed.

DESCRIPTION OF A TYPICAL TREATMENT SEQUENCE

Under the guidance of a physician, the operator will determine the treatment positions and dwell times for each position. A patient treatment file is entered at this time by selecting either the "Edit Old Patient File", "Create New Patient File", or "Import Patient File" task and answering the prompts from the console requesting patient and treatment information. When all desired information has been entered, press the F10 key as prompted to SAVE the treatment information. The operator may then press <ESC> or select "Return to Main Menu Screen.

The patient file must now be printed and reviewed in order to determine the randomly generated Treatment Access Password for that patient file.

After the catheters have been attached to the afterloader, execute the treatment by selecting "Execute Patient Treatment" from the Main Menu Screen. Note: The Omnitron key must be in the TREAT position.

The system will ask the operator to verify that treatment is ready to begin by answering 'Y'(yes). The system will then prompt for the Omnitron Treatment Access Password to be entered. After this password is verified, the system will, for each channel, automatically execute a 'dummy' treatment using the inactive applicator wire and will alarm if any obstructions are encountered. If the 'dummy' treatment is successful then the Omnitron Afterloader will automatically treat that channel with the Ir-192 source wire and print out the treatment record for that channel. This process is repeated until (1) all channels have been treated, (2) an error condition occurs, or (3) the STOP key is depressed on either the Omnitron Control Console, Treatment Room Door Panel or the Omnitron Afterloader. If the afterloader determines it would be safe to continue the treatment after an error condition or the STOP key is pressed, then the operator will be asked to verify resuming treatment by reentering the Omnitron Treatment Access Password. The operator can cancel resuming the treatment by pressing ESC.

Before another treatment can be executed, the above programming and arming sequence must be repeated.

SPECIFICATIONS

Radioactive Source

Iridium-192

Cylindrical configuration, 0.343 millimeters in diameter, 10.0 millimeters active length

Initial intensity 370 GBq (10Ci)

Afterloader Shielding

Safe material - lead

Maximum storage capacity of safe - 370 GBq (10Ci)

Maximum Air Kerma Rate one meter from afterloader does not exceed 1 uGy/hour (0.1 mR/hour)

Radiation shielding conforms to International Electrotechnical Commission requirements and to I.C.R.P. codes

Room Shielding

Controlled by federal and local codes, approximately 4 centimeters of lead or 35 centimeters of concrete are required.

Electrical Power Requirements

120 volt, 50/60 Hz.

3.0 amp peak

Weight

Console: 67 lbs. (30.5 kg.)

Afterloader: 325 lbs. (148 kg.)

SYSTEM INSTALLATION GUIDELINES

Since the Omnitron Afterloader is small and mounted on casters, it can be rolled out of the way after use and can be installed in existing treatment rooms used for other forms of radiation therapy, such as cobalt treatments. Room shielding requirements are controlled by local and federal codes, however typical shielding requirements are 40 millimeters (1.6 inches) of lead or 350 millimeters (13.8 inches) of concrete.

The control console must be located outside of the treatment room. The console is interlocked with the treatment room door which, when opened, will prevent initiation of treatment or interrupt treatment if in progress.

A one inch penetration into the treatment room is recommended to accommodate wiring between the console and the afterloader. This penetration must be routed through the wall in such a way as to not allow a line of sight path through the shielding.

NOTE: Installation is to be performed only by factory trained technicians. Individual planning for installation will be provided upon purchase of the Omnitron system.

WARRANTY

Omnitron International, Inc. warrants that the product described herein possesses the characteristics represented on and in the labeling, and will perform as represented by Omnitron when used in accordance with the instructions issued by Omnitron. There are no warranties which extend beyond the description on the face hereof. All warranties of merchantability and fitness for particular purposes are hereby disclaimed and excluded by Omnitron. No other express or implied warranties are made with respect to the products described hereon.