



Memorandum

Date SEP 20 1996

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of Medirex, Inc's
Tripter-X1 Series Extracorporeal Shock Wave Lithotripters
(Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact)

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Kimber C. Richter
Kimber Richter, M.D.

Attachments

Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Russell P. Pagano, Ph.D., CDRH, HFZ-472, 09-09-96, 594-2194

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

[DOCKET NO. _____]

Medirex, Inc.; PREMARKET APPROVAL OF TRIPTER-X1 SERIES

EXTRACORPOREAL SHOCK WAVE LITHOTRIPTERS (TRIPTER-X1,

TRIPTER-X1 NOVA, and TRIPTER-X1 COMPACT)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medirex, Inc., Wellesley Hills, MA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Medirex, Inc. Tripter-X1 Series Extracorporeal Shock Wave Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact). FDA's Center for Devices and Radiological Health (CDRH) notified the applicant on September 20, 1996, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Russell P. Pagano, Ph.D.,
Center for Devices and Radiological Health (HFZ-472),
Food and Drug Administration,
9200 Corporate Blvd.,
Rockville, MD 20850,
301-594-2194.

SUPPLEMENTARY INFORMATION: On September 29, 1993, Medirex, Inc., Wellesley Hills, MA 02181, submitted to CDRH an application for premarket approval of the Tripter-X1 Series Extracorporeal Shock Wave Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact). These devices are indicated for use in the fragmentation of urinary tract stones (i.e., renal calyceal, renal pelvic and upper ureteral stones).

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On September 20, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act, (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may

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request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number



found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 1996

Ms. Yael Rubin
Medirex, Inc.
49 Walnut Park, Bldg. 4
Wellesley, Massachusetts 02181

Re: P920034
Tripter-X1 Series Extracorporeal Shock Wave Lithotripters
(Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact)
Filed: September 29, 1993
Amended: December 29, 1993; November 21, 1994; June 7,
September 28 and 29, and October 16, 1995; February 27 and July 17,
1996

Dear Ms. Rubin:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Tripter-X1 Series Extracorporeal Shock Wave Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact). These devices are indicated for use in the fragmentation of urinary tract stones (i.e., renal calyceal, renal pelvic and upper ureteral stones). We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements in the enclosure, you have agreed to participate in the National Electrical Manufacturers Association's study, "A Controlled Study of the Effect of Extracorporeal Lithotripsy on Blood Pressure Secondary to Nephrolithiasis," to fulfill the postapproval study requirements. The postapproval reports shall include a summary of your progress regarding the completion of the postapproval study requirements, including any available results.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by

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requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

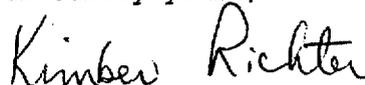
You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Russell P. Pagano, Ph.D., at (301) 594-2194.

Sincerely yours,



Kimber Richter, M.D.
Deputy Director, Clinical and
Policy Review
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SUMMARY OF SAFETY AND EFFECTIVENESS DATA:
MEDIREX TRIPTER-X1 SERIES LITHOTRIPTERS

I. GENERAL INFORMATION

DEVICE GENERIC NAME: Extracorporeal Shock Wave Lithotripter

DEVICE TRADE NAME: Tripter-X1 Series Lithotripters
(Tripter-X1, Tripter-X1 Nova, and
Tripter-X1 Compact)

APPLICANT: Medirex, Inc.
49 Walnut Park, Bldg. 4
Wellesley Hills, Massachusetts 02181

PREMARKET APPROVAL
APPLICATION (PMA) NUMBER: P920034

DATE OF NOTICE OF APPROVAL
TO THE APPLICANT: SEP 20 1996

II. INDICATIONS FOR USE

The Tripter-X1 Series Extracorporeal Shock Wave Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact) are indicated for use in the fragmentation of urinary tract stones (i.e., renal calyceal, renal pelvic, and upper ureteral stones).

III. DEVICE DESCRIPTION

The Tripter-X1 Series Extracorporeal Shock Wave Lithotripters consist of three distinct models, the Tripter-X1, the Tripter-X1 Nova, and the Tripter-X1 Compact. These models are very similar and differ primarily in the layout of the control panels. All of the internal components (e.g., ellipsoid reflector, high voltage generator, high voltage supply, electrode, and the coupling membrane) are identical for all three versions. These devices (hereafter referred to collectively as the Tripter-X1) utilize shock waves generated, by electrohydraulic means, outside the patient's body to fragment urinary calculi within either the kidney or upper ureter. The device consists of a Shock Wave Generator (SWAG) and a Motorized Floating Treatment Table (MFT). The Tripter-X1 does not provide imaging or monitoring functions, but does contain dedicated interfaces for requisite fluoroscopic imaging and ECG monitoring.

The SWAG is comprised of five modules: (1) a high voltage module, (2) a reflector module, (3) a control module, (4) a water module, and (5) a chassis module. The control module consists of controls, indicators, and interfaces to the SWAG and to an ECG monitor.

The MFT is used to support and position the patient. The MFT positions the patient in three coordinate axes and also provides access to the patient's lumbar area through an opening in the table. This opening permits the patient's lumbar area to contact an oil coated membrane that acoustically couples the patient with the water system. Specifications for compatible fluoroscopy units are provided in the labeling. Any ECG monitor that provides a 1-volt TTL R-wave sync or defibrillation sync output signal can be used for required synchronization of the Tripter-X1 with a patient's heartbeat.

As stated, the differences between the three versions of the device only involve very minor design changes. The three device versions are sufficiently similar to allow for pooling of data. Additionally, they are sufficiently similar to allow for a judgement of safety and effectiveness on all three. This decision was based on the fact that all of the components which could affect safety and effectiveness are unchanged between the three versions.

Stone Localization

An X-ray fluoroscopy system is used to visualize the stone. Before treatment, the SWAG and the fluoroscopy system must be aligned so that the shock wave focus (F2) is at a known position relative to the fluoroscopy system. The alignment procedure is performed using an alignment sight. The sight is referred to as the SWAG pointer and is detachable from the SWAG. When attached, it produces an X-ray shadow on the fluoroscopic monitor that appears at a location that coincides with a projection of the shock wave focus.

Under fluoroscopic guidance and using independent table controls, the patient is moved in three directions so that the stone's position coincides with the focal point of the shock waves. To assure 3-D localization, a verification procedure is performed prior to patient positioning from two viewing angles in two projections, AP and OBLIQUE. The two projections are achieved by rotating the fluoroscopic arm around its axis and thus successively obtaining two separate views. After verification, the "projection" of F2 is marked on the screen.

Using the X-ray fluoroscopy unit, the calculus is identified and positioned at F2 with the aid of the MFT by causing the projection of the stone to coincide at all projection angles with the "projection" of F2 already marked on the screen.

Shock Wave Generator

The shock waves of the Tripter-X1 are generated when an electrical spark is discharged between the tips of the spark gap electrode. This electrode is located, inside of the SWAG's water filled reflector, at the focus (F1). Vaporization of the fluid occurs at the location of the spark and produces spherical shock waves. The reflector focuses these waves to converge at F2.

The electrical discharge of the SWAG is synchronized to the ventricular refractory period of the patient's heart. The controls of the Tripter-X1 allow the high voltage module to discharge shockwaves only when the patient's heart is in its refractory phase (the QRS wave of the ECG). The Tripter-X1 controls further limit the rate of shock wave delivery to 100 shocks per minute.

IV. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS

The labeling for the Tripter-X1 contains the following Contraindications, Warnings, and Precautions:

Contraindications for the Tripter-X1 are:

1. Patient has a coagulative abnormality as indicated by

abnormal prothrombin time (PT), partial thromboplastin time (PTT), or bleeding time, including a patient that is receiving an anti-coagulant (including aspirin).

2. Patient has an obstructive uropathy distal to the stone, such that fragments might not pass spontaneously.
3. Patients in whom pregnancy is suspected.
4. Patient's stone cannot be imaged or positioned in the focal area.
5. Patient has renal artery calcification or aneurysm on the side to be treated.
6. Patient is a high risk for general or epidural anesthesia.

Warnings for the Tripter-X1 are:

1. Although patients with infected stones and/or acute urinary tract infection have been successfully treated with shock wave therapy, experience is limited and safety and effectiveness have not been demonstrated. Due to the possibility of systemic infection from pathogen bearing calculus debris, use of prophylactic antibiotics should be considered whenever the possibility of stone infection exists.
2. Bilateral treatment of renal stones should not be performed in a single treatment session because total urinary tract obstruction by stone fragments may result. Patients with bilateral renal stones should be treated using separate treatment sessions for each side. In the event of total urinary obstruction, corrective procedures may be needed to assure drainage of urine from the kidney.
3. Care should be taken to ensure that the shock waves are not applied to air filled areas, i.e., intestines or lungs. Shock waves are rapidly dispersed by passage through an air-filled interface which can cause harmful side effects.
4. Although children have been treated with the Tripter-X1, its experience is limited and safety and effectiveness in the treatment of children have not been demonstrated. Studies indicate that there are growth plate disturbances in the epiphysis of developing long bones in rats subjected to shocks, however, the significance of this finding in relation to humans is not known.
5. Although patients with calculi in the mid and lower ureter have been treated with the Tripter-X1, such cases are limited and, therefore, safety and effectiveness have not

been demonstrated. The treatment of lower ureteral stones in women of childbearing age should specifically be avoided because treatment of this patient population could possibly result in irreversible damage to the female reproductive system and to the unborn fetus in the undiagnosed pregnancy.

Precautions for the Tripter-X1 are:

1. Patients should be ECG monitored during treatment for cardiac effects. Additional caution must be used in treating patients with cardiac abnormalities. These precautions are necessary because the use of extracorporeal shock wave lithotripsy is known to cause ventricular cardiac arrhythmias in some patients and limited information is available on the effect of the Tripter-X1 on cardiac rhythm.
2. Extreme caution must be used in the treatment of patients with high risk of heart failure, pacemakers, pneumonia, or very low diaphragms. Although patients with cardiac pacemakers have been treated with shockwave therapy¹, the safety of using the Tripter-X1 to treat persons with cardiac pacemakers and other implanted devices, whose function could be affected by shock waves, has not been studied.
3. Extracorporeal shock wave lithotripsy procedures have been known to cause damage to the treated kidney. The potential for injury, its long-term significance, and its duration are unknown; but lithotripsy is believed to be less damaging than the persistence of the disease or alternative methods of treatment.
4. Radiographic follow-up examination is necessary until the patient is either stone free or there are no remaining stone fragments which are likely to cause a silent obstruction and loss of renal function.
5. While fluoroscopic imaging is used, the patient's radiation exposure should be kept to a minimum. This can be performed at a low current which minimizes exposure. Increased contrast images require higher current and expose patients to higher dosages. In certain cases, contrast dye may be administered.
6. No safety and effectiveness information is available regarding the treatment of patients with staghorn calculi.
7. In order to achieve successful fragmentation of a stone, the stone to be treated should not be impacted or embedded in tissue. The stone to be treated should be in direct contact with urine. Experience in treating impacted stones has shown limited success, therefore, alternative or auxiliary

procedures are recommended.

8. The number of shocks used for complete stone fragmentation should be minimized. All treatment sessions should be limited to a maximum of 2400 shocks.
9. Where retreatments are indicated for successful stone fragmentation, at least 1 month should elapse between consecutive treatments. Patients should not be treated more than three times.
10. Due to noise associated with the shock wave generation, both patient and staff should wear ear protection during the treatment.

V. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

Adverse effects reported in association with the use of extracorporeal lithotripters include: pain, nausea and vomiting, cardiac events, skin bruise, hematuria, muscle soreness, colic, renal hematomas, fever, infection, hydronephrosis, obstruction, and hypertension. More detailed information on these events can be found on page 17 of this document.

VI. ALTERNATE PRACTICES AND PROCEDURES

Urinary tract stone treatment has been based predominantly on the symptomatology and location of the stone. Treatment varies with the type and size of stone and the condition of the patient. The most common treatment for kidney stones is dietary restriction and consumption of large amounts of fluid. Soft ammonium-magnesium phosphate and uric-acid calculi may be dissolved in some instances by irrigation through ureteral catheters. Calculi of small size may be removed from the lower ureter by means of instruments passed through the urethra into the ureter to snare the stone.

Patients with stones in the kidney and the proximal ureter with persistent and significant symptoms have historically been treated with open surgery, including partial nephrectomy and ureterolithotomy².

In recent years, percutaneous stone removal techniques have been developed for use on patients who were poor surgical candidates or had undergone open surgery in the past³. Percutaneous stone removal is now being used on patients who have not had previous operations because it is felt to be less invasive than open surgery and, in general, requires shorter hospitalization.

Other currently marketed extracorporeal shock wave lithotripters that have the same or broader indications for use offer another

alternative.

VII. MARKETING HISTORY

Since 1987, a total of 300 Tripter-X1 lithotripters have been sold in 30 countries (including Japan and Europe). The device has not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

VIII. SUMMARY OF STUDIES

1. NON-CLINICAL STUDIES

a. Evaluation of Shockwave Pressure

Testing was conducted to characterize the shock wave generated by the Tripter-X1 using a number of pressure transducers. These include hydrophones constructed from polyvinylidene fluoride (PVDF) and piezoelectric ceramic. Although the PVDF hydrophone transducers had higher frequency responses, the piezoelectric pressure transducers were more durable and, therefore, the spatial experiments were conducted mostly with the piezoelectric transducer.

The peak positive pressure for the typical (20 kV) voltage setting was 30 MPa and the peak negative pressure was 4.2 MPa. The typical rise time of the shock wave pulse was 0.2 (+0.2, -0.1) μ sec and the pulse width was 0.55 (\pm 0.27) μ sec.

The recorded amplitude and dimensions at the focal area for the available range of lithotripter power settings are listed in the following table:

Pressure Measurement Data			
Power Setting	Peak Positive Pressure (MPa)	Focal Area Axial (mm)	Focal Area Lateral (mm)
14 kV	20	13	50
20 kV	30	13	48
24 kV	36	13	48

b. Animal Studies

Four animal studies were conducted to evaluate the effects of treatment with the Tripter-X1.

The first animal study examined the effect of shock wave lithotripsy on rats using a prototype of the Tripter-X1 system.

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In the second animal study, eight kidneys of five dogs were implanted with human kidney stones and treated with the Tripter-X1 to determine the acute and subacute effect of shock wave lithotripsy on dogs. In the third animal study, four kidneys of three dogs were implanted with human kidney stones and exposed to shock waves generated by 20 kV volt discharge to determine the effect of shock wave lithotripsy on dogs. The fourth animal study was similar to the third study, however, four dogs were used.

These studies found that successful fragmentation of stones occurred in the animals with implanted human kidney stones. The tissue effects observed were found to be dependent on the number of shock waves and voltage level. These effects were mild to moderate and reversible without intervention. These results are consistent with reported literature of shock wave therapy on the treatment of dogs. In summary, these studies demonstrated that the Tripter-X1 could be used to safely and effectively fragment human kidney stones which had been surgically implanted in the kidneys of dogs with minimal tissue damage to the animal.

2. CLINICAL INVESTIGATIONS

Clinical investigations with the Tripter-X1 were conducted between October 1988 and December 1991 at three primary sites. The intent-to-treat (complete) cohort consisted of a total of 305 patients (311 kidneys) with a total of 200 patients (204 kidneys) included in a primary cohort for evaluation.

Two other sites discontinued treatments very early in the study. Because of the extremely small number of patients treated at these sites, these data were not included in the complete or primary cohorts. However, they were presented as additional information.

In the following discussions, some variations in the number of patients, kidneys, and treatments occur due to patients lost to follow-up and incomplete reporting. However, the data collected were determined to be adequate to evaluate safety and effectiveness.

The design of the clinical investigation of the Tripter-X1 is consistent with the recommendations that were made by the Gastroenterology and Urology Devices Panel members at their October 20, 1989, meeting. Specifically, the panel recommended that PMAs for renal extracorporeal shock wave lithotripters be based on a clinical study involving at least three investigational sites, each of which have enrolled a minimum of 50 patients who were followed for at least 3 months post-lithotripsy.

A list of the primary sites, investigators, and number of

patients evaluated in the primary and complete cohorts are presented in the following table.

Site	Principal Investigator	# of Pts Primary Cohort	# of Pts Complete Cohort
Calumet Out-Patient Surgery Center 7847 Calumet Avenue Munster, IN 46321	F. Portney, M.D.	58	79
Beth Israel Hospital 330 Brookline Avenue Boston, MA 02215	B. Saltzman, M.D.	75	143
Univ. of Oklahoma Health Sciences Center Oklahoma Mem. Hospital 940 Stanton L. Young Blvd. Oklahoma City, OK 73190	P. Mosca, M.D., Ph.D.	67	83
	TOTAL	200	305

In all of the following discussions, the data are pooled because there were only minor differences in the results from the three sites. The Oklahoma City site did have a lower rate of successful outcome (61% to 75%), however, this was attributed to an undetected device malfunction in the high voltage generator. Patients treated at Oklahoma City, after the device was repaired, experienced outcomes similar to those seen by patients at the other sites. Differences in the rate of some adverse events were also reported. These differences only pertained to less serious events such as pain, skin bruise, and hematuria. These differences were explained by a variety of factors, including different sedation/analgesia philosophies and differences in the tone of investigator questioning. There were no significant differences between sites for more serious events, especially those detected using objective means (e.g., ultrasound). Since there were no major effectiveness or safety rate variations seen from the data, a complete pooling of the sites was justified.

a. Subject Selection and Exclusion Criteria

Patients eligible for inclusion in this study were adults who had upper urinary tract calculi with individual stone size limited to less than 30 mm. There was no limit on the number of stones. Eligibility included being a candidate for an alternative surgical procedure for removal of the stone(s) and study patients being in reasonably good health.

Exclusion criteria included patients who:

- i. had an untreated renal or urinary tract obstruction or stenosis distal to the stone location,
- ii. had translucent or staghorn stones,
- iii. had only one functioning kidney,
- iv. were pregnant,
- v. had anatomy which did not permit focusing of the device in the area of the kidney stone,
- vi. had an aortic aneurysm or renal artery calcification on the affected side,
- vii. had a pacemaker,
- viii. had bleeding or clotting disorders or were receiving treatment with aspirin or anticoagulants,
- ix. were diagnosed as high risk.

Before enrollment in the study, patients were evaluated for suitability for lithotripsy. Information used in the evaluation included medical history and physical examination, laboratory work-up, and X-rays (including a Kidney, Ureter, and Bladder X-ray (KUB) and intravenous pyelogram). Those patients who met the entrance criteria signed an informed consent form and were enrolled in the study.

b. Study Population

Of the 343 kidneys that were treated in the Tripter-X1 clinical study, 204 are included in a primary cohort, and 311 are included in the intent-to-treat (complete) cohort. Data from both the primary cohort and the complete cohort have been used as the basis of the safety and effectiveness claims of this application.

The cohorts consist of patients from the three primary sites. The primary cohort consists of patients who had complete follow-up and all critical lab tests performed. All patients who entered the clinical trials came in for some follow-up. Eight percent of the patients did not return for complete follow-up in the primary cohort and 33% did not return for long-term follow-up (3-month) in the complete cohort. There were additional patients who, although they came in for complete follow-up, did not have all of the necessary tests as stated in the protocol.

Patients who were considered to have complete data were included in the primary analysis cohort. Data from the patients without all elements of the protocol were included in the complete cohort.

Complete data were available on 200 patients (204 kidneys) in the primary cohort. A total of 105 patients (107 kidneys) were missing one or more elements of the protocol. These patients were, in fact, carefully followed, but did not meet the requirements for "completeness" as defined in the protocol.

An analysis of the circumstances surrounding the reasons for the missing data identified seven major conditions which caused incompleteness.

<u>CAUSE OF INCOMPLETENESS OF PATIENTS</u>	<u>% of TOTAL PATIENTS</u>
1) Patient missed appointment and returned later:	12
2) Partial data collected:	10
3) Patient refused to return for follow-up:	8
4) Patient had follow-up, but data were pending at time of analysis:	5
5) Patient referred to other therapy:	2
6) Patient changed domicile or unable to be located:	1
7) Patient died:	<1

The patients of the primary and complete cohorts are further subdivided into those that had their immediate blood tests within 48 hours post-treatment and those that had their immediate blood tests between 48 hours and 1 week post-treatment.

Immediate post-treatment laboratory data are reported in 2 groups. One group had laboratory data measured within 48 hours of treatment and the second group had laboratory data measured at 1 week following treatment. At 1 week, there was no significant differences in the laboratory data for the 2 groups. More detailed information on these events can be found on page 19 of this document.

c. Patient Demographics

The complete cohort demographics were very similar to the primary cohort demographics. Of the 305 patients treated, 57% were males and 43% were females. The mean age was 44 years (range 18 to 86 years), mean height was 5' 6" (range 4' 8" to 6' 5"), mean weight was 169 lbs. (range 83 to 390 lbs.), and mean body mass index was 26 kg/m² (range 15 to 48 kg/m²).

The ratio of men to women in this study is similar to the ratios

reported in similar studies, i.e., between 56% - 67% men and 33% - 44% women. The general patient population in this study is also comparable to the general populations reported in other studies, with similar demographic data reported for mean age, weight, etc.

d. Stone Characteristics

The complete cohort study population contained 311 kidneys whose largest stone sizes ranged from 3 mm to 30 mm. Of the 311 treated kidneys, 230 (74%) had single stones, 42 (14%) had two stones, 38 (12%) had three or more stones and one was not reported. One hundred and thirty-six (44%) of the treated kidneys were on the right side of the patient, 174 (56%) were on the left, and the location of one was not reported. Largest stone sizes, stone burdens, and stone locations were distributed as follows:

SIZE OF LARGEST STONE (mm)	
0-4	13 (4%)
5-9	129 (41%)
10-14	92 (30%)
15-19	33 (11%)
≥20	43 (14%)
Not Reported	1 (<1%)
<hr/>	
Total	311 (100%)
Mean (S.D.)	11 (6)
Min.-Max.	3-30

STONE BURDEN (mm)	
0-4	11 (4%)
5-9	99 (32%)
10-14	95 (31%)
15-19	41 (13%)
≥20	64 (21%)
Not Reported	1 (<1%)
<hr/>	
Total	311 (100%)
Mean (S.D.)	14 (10)
Min.-Max.	3-86

LOCATION OF PRIMARY STONE	
Renal Pelvis	90 (29%)
Calyces	
Upper	27 (9%)
Middle	30 (10%)
Lower	97 (31%)
Ureter	64 (21%)
Not reported	3 (<1%)
<hr/>	
Total	311 (100%)

Patients whose largest stones were 4 mm or less in size were treated

if the patient was symptomatic and the investigator believed it to be clinically beneficial to the patient. For determining effectiveness, these patients were not considered to be successfully treated unless the stones were fragmented to a smaller size.

e. Treatment Characteristics

In the complete cohort, the 311 kidneys evaluated in the study underwent 430 treatment sessions. The average treatment lasted 35.1 minutes (range 2.7 to 90 minutes) with a mean of 1653 shocks (range 167 to 2400 shocks) delivered with an average maximum voltage setting of 21 kV (range 16 to 24 kV). Anesthesia and/or analgesia were employed according to the investigator's discretion. The majority of patients (65%) received general anesthesia.

Retreatments

Of the 305 patients evaluated, 61 (20%) underwent two treatments, 11 (4%) underwent three treatments, 2 (<1%) underwent four treatments and 4 (1%) underwent five treatments. There were a total of 50 treatments performed within 1 month of a previous treatment. Based on the data from the above patients, the recommended retreatment schedule calls for a maximum of three treatments at a minimum interval of 1 month.

It was found that patients with more stones, larger stones, and larger stone burdens were more likely to require multiple treatments.

f. Auxiliary Procedures

Stenting was the most frequently used auxiliary procedure and was employed in 228 of the 305 patients evaluated. Other pre-treatment auxiliary procedures included stone manipulation, nephrotomy tube placement, catheter placement, and ultrasonic lithotripsy. Stone manipulation was employed in 12% of the patients. All other pre-treatment auxiliary procedures combined were employed in less than 9% of the patients.

Following lithotripsy treatment, stents were placed in 19 patients to help clear debris. Thirty patients had one or more of several adjunctive procedures (e.g., nephrectomy, ureterolithotomy, meatotomy, nephrotomy tube placement, removal of calcified stent and attempted stent placement) before completing the protocol, and, if there was any suspicion that the procedure may have affected treatment outcome, these patients were considered failures for the evaluation of device effectiveness.

g. Results

The effectiveness of treatment with the Tripter-X1 was evaluated by KUB to determine the presence and dimensions of remaining kidney stones or stone fragments after treatment. KUB's were performed

immediately post-treatment and at subsequent follow-up visits. Successful cases consisted of those patients who were stone free or had stone fragments less than or equal to 4 mm in size at follow-up. Patients whose largest stones were 4 mm or less in size were retreated if the patient was symptomatic and the investigator believed it to be clinically necessary for the patient. For determining effectiveness, these patients were not considered to be successfully treated unless the stones were fragmented to a smaller size. Unsuccessful cases included cases where there was no fragmentation and cases where there remained stone fragments greater than 4 mm.

In the primary cohort, 204 kidneys were entered into the study for evaluation and resulted in a treatment success rate of 52% at the immediate post-treatment period. At long-term follow-up, the success rate was 75%. This increase in success rate could be expected since patients spontaneously passed stone fragments during this period. In the complete cohort, 311 kidneys were entered into the study for evaluation and 281 patients were accounted for at the immediate post-treatment phase of therapy. These patients exhibited a treatment success rate of 63% at the immediate post-treatment period and a rate of 78% at the long-term follow-up. The results are shown in the following tables.

Results of Immediate Post-Treatment KUB for
Primary PMA Cohort (n=204) and Complete Cohort (n=311).

Status	No. of kidneys (%) Primary Cohort	No. of kidneys (%) Complete Cohort
Stonefree	56 (33%)	65 (24%)
≤4 mm Fragments	32 (19%)	109 (39%)
Total Success	88 (52%)	174 (63%)
>4 mm Fragments	62 (37%)	75 (27%)
No Fragmentation	19 (11%)	26 (10%)
Total Not Success	81 (48%)	101 (37%)
Total Evaluable	169 (100%)	275 (100%)
KUB Not Readable	35	36
TOTAL	204	311

Results of 3 Month Follow-up KUB for
 Primary PMA Cohort (n=204) and Complete Cohort (n=311)

Status	No. of kidneys (%) Primary Cohort	No. of kidneys (%) Complete Cohort
Stonefree	125 (63%)	166 (67%)
≤4 mm Fragments	24 (12%)	26 (11%)
Total Success	149 (75%)	192 (78%)
>4 mm Fragments	36 (18%)	42 (17%)
No Fragmentation	13 (7%)	13 (5%)
Total Not Success	49 (25%)	55 (22%)
Total Evaluable	198 (100%)	247 (100%)
KUB Not Readable	6	64
TOTAL	204	311

The effects of selected patient characteristics on treatment outcome (including body mass index, age, sex, stone size, location, total stone burden, and site) were evaluated to determine if these characteristics could be used to predict which patients best benefited from treatment. The treatment outcomes were analyzed using the Pearson chi-square statistical analysis method.

The number of treatments was the only characteristic found to have a statistically significant effect on successful treatment outcome. Upper calyx stones were found to have an effect on treatment outcome in the primary cohort population. Patients with stones located in the upper calyx had significantly higher success rates than patients with stones in other locations. It is not clear why a better result was obtained in the upper calyx stones, but this result is not believed to be clinically significant. There was a clear trend toward lower successful outcome for larger stone size, greater total stone burden, and larger number of stones.

Gender had no affect on treatment outcome. Age may have an effect on the rate of hydronephrosis, hematoma, colic and obstruction. That is, there is a higher rate of occurrence of hydronephrosis, colic and obstruction in elderly patients, and a lower rate of hematoma. The sex of the patient also has an affect on hematuria and hematoma. That is, more hematuria was found in males and a higher rate of hematoma in women. Very obese patients were found to have a higher rate of hematoma.

The maximum voltage setting of 24 kV had an influence on the rate of

occurrence of hematuria, with less hematuria in those patients treated with the higher voltage.

The clinical trials were limited to the following ranges of patient and stone characteristics. Patients with characteristics outside of this range have not been studied with the Tripter-X1.

Characteristics	Limits
Weight	390 lbs
Body Mass Index	66 kg/m ²
Size of Largest Stone	26 mm
Stone Burden	47 mm
Number of Stones	7

h. Adverse Reactions and Complications

Adverse effects reported in the study are similar to those reported for other lithotripters and are described below. Most studies report adverse events after the last treatment, however, Medirex chose to report these events as they occurred after the first treatment. A comparison of the adverse event rates after the first treatment versus the rates after the last treatment showed no significant difference, therefore, for this device, this reporting method is acceptable. Information about the effects of retreatment on a particular adverse event are included in the following discussion only if the results are significant.

Summary of Adverse Events by Phase of Therapy After 1st Treatment

	During Treatment	Immediate Post	10 - 60 Days Post	3-Month Follow-Up*	1 Year Follow-up
Complication/ Adverse Event	n = 305	n = 278	n = 261	n = 203**	n = 92**
Hematuria	2 (<1%)	73 (26%)	40 (15%)	8 (4%)	1 (1%)
Pain	18 (6%)	66 (24%)	51 (20%)	20 (10%)	4 (4%)
Skin Bruise	47 (15%)	65 (23%)	16 (6%)		
Muscle Soreness		20 (7%)	17 (7%)	5 (3%)	
Colic		16 (6%)	18 (7%)	5 (3%)	1 (1%)
Renal Hematoma		14 (5%)	3 (1%)	1 (<1%)	1 (<1%)
Hydronephrosis		7 (3%)	9 (3%)		1 (1%)
Nausea/ Vomiting		6 (2%)	3 (1%)	1 (<1%)	
Fever		6 (2%)	3 (1%)		
Infection		3 (1%)	6 (2%)	3 (2%)	1 (1%)
Obstruction		1 (<1%)	4 (<2%)	3 (2%)	2 (2%)
Cardiac Event	1 (<1%)				
Other	3 (1%)	6 (2%)	9 (3%)	8 (4%)	2 (2%)

*Includes the period of 60-150 days post-treatment

**Includes patients that were stone free at earlier follow-up

Hematuria: The most consistent, clinically apparent effect noted following lithotripsy (200 or more shock waves) is gross hematuria^{4,5}. The hematuria associated with the Tripter-X1 generally resolved in 24 - 48 hours with no further treatment (transfusion, etc.) required. Follow-up reports of hematuria were associated with stents or other procedures, continued presence of stones, stone passage and retreatments. Following two treatments, the 3-month follow-up showed a slight increase (4/40, 10%) in the rate of hematuria.

Pain: Sixty-six (24%) of the patients experienced pain during the immediate follow-up period, most of which was general post-procedure pain. Pain was also attributed to stents, hydronephrosis/obstruction, and spinal headache. Sixteen percent of the patients with immediate post-treatment pain required medication.

At the 10-60 day follow-up, 51 (20%) patients reported pain. Twenty (10%) patients reported pain at the 3-month follow-up. Pain was attributed to residual fragments, passing fragments, retained stones, stents, stones on the untreated side, general post-treatment pain, and

back pain. During retreatments, a lower rate of pain was reported "during treatment" (0%) than that reported for patients who had only one treatment (6%).

Skin Bruise: The above table reports the rate of skin bruises or abrasions at the contact point between the membrane and the patient's skin. These were all minor and resolved by the 3-month follow-up period. For patients who received four treatment sessions, a higher rate of skin bruise (4/6, 67%) was reported. This was attributed to increased skin sensitivity from multiple treatments.

Muscle Soreness: As shown in the table, muscle soreness was reported in 20 patients (7%) immediately following treatment, and in five patients (3%) at 3-month follow-up.

Colic: Renal colic following treatment was apparently secondary to passage of stone fragments, and typically resolved with elimination of fragments. Colic at the immediate post-treatment follow-up was associated with stone passage, stents and residual stones/fragments. One (<1%) patient required pain medication.

The colic reported at the 3-month follow-up was associated with stone passage, stents, stone manipulation, residual stones/fragments and stones in the opposite side. Two (<1%) of these patients received medication for the pain and one patient was hospitalized. This patient passed several large stone fragments 2 days after hospitalization and was discharged.

Hematoma: Renal hematomas were reported in 14 (5%) patients following lithotripsy. Eight of these cases involved small (<3 cm) hematomas, and all but one resolved without intervention by the 3-month follow-up. The one remaining patient underwent several retreatments and the hematoma remained visible at the 3-month and 1-year (from original treatment) follow-up. By the 2-year follow-up, the hematoma was no longer visible.

Hydronephrosis: Hydronephrosis following treatment was apparently secondary to unpassed large stone fragments. The hydronephrosis resolved spontaneously with the passage of the fragments or following either an auxiliary procedure or a retreatment.

A higher rate of hydronephrosis was recorded in retreatment patients (during treatment). This condition was seen in 1% (1/78) of patients receiving two treatments, 6% (1/17) of patients receiving three treatments, and 17% (1/6) of patients receiving four treatments. In all of the cases, unpassed fragments passed spontaneously following the retreatment, and the hydronephrosis resolved.

Nausea/Vomiting: Six patients (2%) reported nausea/vomiting immediately following treatment due to the analgesics/sedatives used. One patient (<1%) reporting nausea/vomiting was re-hospitalized the day after treatment due to colic and hematuria. One patient (<1%)

reported some nausea/vomiting during the follow-up period due to unknown causes.

Fever: Fever (>100°F) was reported immediately post-treatment in six (2%) of the patients. No patient required hospitalization for this complication.

Infection: Urinary tract infections were generally diagnosed within the first week post-treatment, and resolved with normal antibiotic therapy.

Obstruction: Obstructions were noted in four (1.5%) patients between discharge and the 3-month follow-up. All obstructions resolved spontaneously or with the use of auxiliary measures.

Cardiac Events: One (<1%) cardiac event was reported in this population. This event was related to anesthesia and treatment was continued following the episode. The patient was asymptomatic, held for 2 days observation, and given appropriate medication.

Hypertension: Hypertension was reported as an adverse event in 9% of patients post-treatment. In 80% of these patients, this was a transient elevation in blood pressure that resolved at subsequent follow-up. Six patients (2%) were referred for treatment of hypertension during the clinical study, although in five of these patients the hypertension seemed to be related to the patients' underlying disease and condition rather than secondary to treatment.

The relationship between extracorporeal shock wave lithotripsy and hypertension is not fully understood and continues to undergo investigation.

Renal Injury: Renal injury to the treated kidney has been known to occur with extracorporeal shockwave lithotripsy, although the potential for injury, its long term significance and its duration are unknown.

i. Laboratory Values

Following is a summary of the blood laboratory values for the complete cohort patient population as measured at the pre-treatment baseline, immediate post-treatment (48 hours), and long-term follow-up.

Bleeding

The hematocrit was obtained both pre- and post-treatment to evaluate potential blood loss. A slight downward trend in mean hematocrit was observed immediately post-treatment (48 hours), likely reflecting transient hematuria. At long-term follow-up, the mean was observed to increase to pre-treatment value. None of the patients required

treatment for bleeding.

Renal Function

BUN and creatinine levels were obtained before and following treatment to evaluate renal function. The mean creatinine baseline value was 1.10 mg/dl and dropped to 1.05 mg/dl at 48 hours post-treatment. Mean BUN values were 14.64 mg/dl at baseline and dropped to 12.89 mg/dl at 48 hours. At long-term follow-up, the mean creatinine and BUN returned to approximately their baseline levels (i.e., 1.08 and 15.35 mg/dl). These trends are consistent with published lithotripsy data⁶ and may be attributed to relief of a partial obstruction.

A sub-study was carried out in which patients were monitored for significant decreases in renal function following treatment with the Tripter-X1. Renal function was measured by either Glomerular Filtration Rate (GFR) or Estimated Renal Plasma Flow (ERPF) and a significant decrease was defined as a decrease in function of greater than 10% in the baseline value of the percent function of the treated kidney.

Out of 34 evaluated patients, 30 experienced no significant decrease in renal function subsequent to lithotripsy. Three of the patients experienced a significant short term decrease in renal function and subsequent return to baseline at 90 days. One patient had a significant decrease in renal function at 30 days and did not return to baseline at 90 days. It was concluded that the decrease in function for this patient was unrelated to the lithotripsy. Both functionally normal and abnormal kidneys gave similar results in the study.

Hepatic trauma

Total bilirubin, SGOT, alkaline phosphatase, and LDH levels were obtained pre- and post-treatment to evaluate for possible liver damage. Mean bilirubin values rose from a baseline value of 0.61 mg/dl to 0.68 mg/dl at 48 hours post-treatment and decreased back to a mean value of 0.56 mg/dl at long-term follow-up. This trend, along with the downward trend in hematocrit, has been discussed in the lithotripsy literature as possibly reflecting some degree of blood cell hemolysis⁷. Mean SGOT values increased from a baseline of 21.38 IU/L to 30.33 IU/L at 48 hours and decreased back to 20.93 IU/L at follow-up. Mean LDH levels went from 172.53 IU/L to 227.35 IU/L and 182.09 IU/L during the same respective periods. These mean values were all within normal ranges.

Pancreatic Trauma

Mean amylase values varied during follow-up by statistically insignificant amounts and remained within normal range.

j. Device Failures

During the clinical trials there were 15 incidents of device failures which required repair or replacement of functional components. These failures are categorized by type and discussed below. No patient was injured or suffered any complications as a result of these device failures.

High voltage module failures

During the clinical trials, high voltage generators were replaced four times as a result of producing asynchronous (three times) or no (one time) shock waves. Although one treatment was interrupted due to high voltage generator failure, there was no deleterious effect to the patient. In response to these failures, it was determined that the high voltage meter was not displaying the correct voltage and causing generator breakdown. There were no injuries or any increase in the rate of complications secondary to treatment as a result of the over-voltage. Subsequently, additional testing procedures were developed in order to check high voltage display calibration.

Control module failures

A control board of the unit was replaced once after causing a reduced rate of shock wave generation. There was no effect on patient treatment.

Cardiac gating

The ECG interface connector broke twice requiring replacement. Although one treatment was interrupted due to high voltage generator failure, there was no deleterious effect on the patient.

Treatment table

There were four incidents of treatment table failures where table movement was disabled. In three instances, the table did not move in the horizontal plane. This was repaired by replacing the table piston, which had apparently been damaged while moving the table from one location to another. Subsequently, a locking procedure that protects against piston damage was developed for shipping and transport. The written procedure is attached to the table and included in the operator's manual. In one instance, the table movement control box was damaged due to being dropped on the floor and was replaced.

Water leakage

There were two incidents of water leakage. In one case this was due to a defective electrode which was replaced. In the second case, the leakage situation was unable to be detected or reproduced by the manufacturer's service technician. Operator error was suspected as

the cause and a careful review of the procedure was given to the operator. It is noteworthy that there are limit switches in the water system that activate a pump to replace water in the case of a low water level and to automatically shut the system down when the water gets below a predetermined level.

Membrane ring

A ring which attaches the elastic membrane to the SWAG head was replaced on two occasions due to randomly occurring deformation defects.

IX. CONCLUSIONS FROM THE STUDIES

The laboratory, animal, and clinical data provide reasonable assurance of the safety and effectiveness of the Tripter-X1 Series Lithotripters for the treatment of urinary tract stones (i.e., renal calyceal, renal pelvic, and upper ureteral stones).

X. PANEL RECOMMENDATION

Pursuant to section 515(c)(2) of the Food, Drug, and Cosmetic Act (the act) as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Gastroenterology and Urology Devices Panel, an FDA advisory panel, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

XI. CDRH DECISION

An FDA inspection of the Medirex, Inc., manufacturing facility was completed on June 4, 1996, and determined that the manufacturer was in compliance with the device Good Manufacturing Practices Regulation.

Based upon a review of the data contained in the PMA, CDRH determined that the Tripter-X1 Series Lithotripters are safe and effective for the indications of fragmentation of urinary tract stones (i.e., renal calyceal, renal pelvic and upper ureteral stones). Furthermore, the applicant agreed to participate in the postapproval study "A Controlled Study of the Effect of Extracorporeal Lithotripsy on Blood Pressure Secondary to Nephrolithiasis" to determine whether a relationship exists between lithotripsy and hypertension.

CDRH issued an approval order for the stated indication for the applicant's PMA for the Medirex Tripter-X1 Series Lithotripters (Tripter-X1, Tripter-X1 Nova, and Tripter-X1 Compact) on

SEP 20 1996

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XIII. Approval Specifications

1. Instructions for Use: See labeling;
2. Hazards to Health from Use: See indications, contraindications, warnings, precautions, and adverse events sections of labeling;
3. Postapproval Requirements and Restrictions: See approval order.

TRIPTEER-X1
NOVA
and
COMPACT

OPERATOR'S MANUAL

CONFIDENTIAL

Version 6.08 - June, 96

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SAFETY WARNINGS

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician trained and/or experienced in the use of this device as outlined in the required training program..

Cautions, warnings and notes are prominently displayed throughout the text where appropriate. In particular, the following safety considerations should be heeded:

- Always observe standard safety precautions during operation of these systems.
- Tripter-X1 *Nova* and *Compact* designs have high voltage circuits active, when connected to a mains power supply.
- The enclosure should be opened only by qualified personnel in order to avoid the possibility of electrical shock.

The Tripter-X1 *Nova* and the *Compact* designs incorporate many safety features. However, it is especially important that the physician treat only patients that are indicated for treatment.

Only Medirex Inc. appointed qualified service Engineer may perform any service acting on the device.

NOTICE

The Medirex Lithotripter Designs: Tripter-X1 *Nova* and *Compact* must not be used unless the user has a thorough understanding of this manual. Read the entire manual prior to operation.

This manual contains confidential information that is proprietary to Medirex Inc. and is subject to contractual restrictions on the use and disclosure hereof. No part of this publication may be reproduced without prior written approval from Medirex Inc.

The information contained herein is intended for the sole and exclusive use of customers of Medirex Inc. in connection with the Tripter-X1 *Nova* and the *Compact* designs. Any other unauthorized use of this manual or any of the information it contains is prohibited.

No representations for fitness for any purpose, other than those specifically mentioned in this manual, are made either by Medirex Inc. or its agents.

Medirex Inc. reserves the right to revise this publication without undertaking any obligation to notify anyone of such revisions.

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CHAPTER 1 - GENERAL INFORMATION

1.1 INTRODUCTION

The Tripter-X1 *Nova* and *Compact* designs are mobile extracorporeal shock wave lithotripsy systems which are used for the treatment of urinary stones. The systems include a shock wave generator (SWAG) including a control module and a motorized floating treatment table (MFT).

Neither design provides imaging or monitoring functions, but contain the necessary interfaces for fluoroscopy imaging and ECG monitoring.

A detailed description of the Tripter-X1 *Nova* and *Compact* designs is provided in Chapter 3 below.

This manual is organized such that all figures, graphs and tables are included in the appendices.

CHAPTER 2 - INFORMATION FOR THE CLINICIAN

2.1 INTRODUCTION

This chapter is intended to provide information for the clinician. It includes indication and usage, contraindications, warnings, precautions, clinical study information and potential adverse effects for the usage of the Tripter-X1 *Nova* and *Compact*.

2.2 INDICATIONS

The Tripter-X1 *Nova* and *Compact* are indicated for use in the fragmentation of urinary tract stones i.e., renal calyceal, renal pelvic, and upper ureteral stones.

2.3 CONTRAINDICATIONS

Contraindications for the Tripter-X1 *Nova* and *Compact* are:

1. Patient has a coagulative abnormality as indicated by abnormal prothrombin time (PT), partial thromboplastin time (PTT), or bleeding time, including a patient that is receiving an anticoagulant (including aspirin).
2. Patient has an obstructive uropathy distal to the stone, such that fragments might not pass spontaneously.
3. Patients in whom pregnancy is suspected.
4. Patient's stone cannot be imaged or positioned in the focal area.
5. Patient has renal artery calcification or aneurysm on the side to be treated.
6. Patient is a high risk for general or peridural anesthesia.

2.4 WARNINGS

Warnings for the Tripter-X1 *Nova* and *Compact* are:

1. Although patients with infected stones and/or acute urinary tract infection have been successfully treated with shock wave therapy, experience is limited and safety and effectiveness have not been demonstrated. Due to the possibility of systemic infection from pathogen bearing calculus debris, use of prophylactic antibiotics should be considered whenever the possibility of stone infection exists.
2. Bilateral treatment of renal stones should not be performed in a single treatment session because total urinary tract obstruction by stone fragments may result. Patients with bilateral renal stones should be treated using separate treatment sessions for each side. In the event of total urinary obstruction, corrective procedures may be needed to assure drainage of urine from the kidney.
3. Care should be taken to ensure that the shock waves are not applied to air filled areas, i.e., intestines or lungs. Shock waves are rapidly dispersed by passage through an air-filled interface which can cause harmful side effects.
4. Although children have been treated with the Tripter-X1 *Nova* and *Compact*, its experience is limited and safety and effectiveness in the treatment of children have not been demonstrated. Studies indicate that there are growth plate disturbances in the epiphysis of developing long bones in rats subjected to shocks, however, the significance of this finding in relation to humans is not known.
5. Although patients with calculi in the mid and lower ureter have been treated with the Tripter-X1 *Nova* and *Compact*, such cases are limited and, therefore, safety and effectiveness have not been demonstrated. The treatment of lower ureteral stones in women of childbearing age should specifically be avoided because treatment of this patient population could possibly result in irreversible damage to the female reproductive system and to the unborn fetus in the undiagnosed pregnancy.

2.5 PRECAUTIONS

Precautions for the Tripter-X1 *Nova* and *Compact* are:

1. Patients should be ECG monitored during treatment for cardiac effects. Additional caution must be used in treating patients with cardiac abnormalities. These precautions are necessary because the use of extracorporeal shock wave lithotripsy is known to cause ventricular cardiac arrhythmias in some patients and limited information is available on the effect of the Tripter-X1 *Nova* and *Compact* on cardiac rhythm.
2. Extreme caution must be used in the treatment of patients with high risk of heart failure, pacemakers, pneumonia, or very low diaphragms. Although patients with cardiac pacemakers have been treated with shockwave therapy (M.F. Goldsmith, 1987), the safety of using the Tripter X1 *Nova* or *Compact* to treat persons with cardiac pacemakers and other implanted devices, whose function could be affected by shock waves, has not been studied.
3. Extracorporeal shock wave lithotripsy procedures have been known to cause damage to the treated kidney. The potential for injury, its long-term significance, and its duration are unknown; but lithotripsy is believed to be less damaging than the persistence of the disease or alternative methods of treatment.
4. Radiographic follow-up examination is necessary until the patient is either stone free or there are no remaining stone fragments which are likely to cause a silent obstruction and loss of renal function.
5. While fluoroscopic imaging is used, the patient's radiation exposure should be kept to a minimum. This can be performed at a low current which minimizes exposure. Increased contrast images require higher current and expose patients to higher dosages. In certain cases, contrast dye may be administered.
6. No safety and effectiveness information is available regarding the treatment of patients with staghorn calculi

7. In order to achieve successful fragmentation of a stone, the stone to be treated should not be impacted or embedded in tissue. The stone to be treated should be in direct contact with urine. Experience in treating impacted stones has shown limited success, therefore, alternative or auxiliary procedures are recommended.
8. The number of shocks used for complete stone fragmentation should be minimized. All treatment sessions should be limited to a maximum of 2400 shocks.
9. Where retreatments are indicated for successful stone fragmentation, at least 1 month should elapse between consecutive treatments. Patients should not be treated more than three times.
10. Due to noise associated with the shock wave generation, both patient and staff should wear ear protection during the treatment.

2.6 CLINICAL TRIAL

Study Design

Clinical investigations were conducted between October 1988 and December 1991 at three primary sites. In these investigations, the patients served as his/her own control. Patients were eligible for inclusion into the study if they were adults with upper urinary tract calculi with no individual stones 30 mm or larger in size. Patients were excluded if they:

- i. had an untreated renal or urinary tract obstruction or stenosis, distal to the stone location,
- ii. had translucent or staghorn stones,
- iii. had only one functioning kidney,
- iv. were pregnant,
- v. had anatomy which did not permit focusing of the device in the area of the kidney stone,
- vi. had an aortic aneurysm or renal artery calcification on the affected side,

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- vii. had a pacemaker,
- viii. had bleeding or clotting disorders or were receiving treatment with aspirin or anticoagulants,
- ix. were diagnosed as high risk.

A primary cohort of 200 patients (204 kidneys) and a complete cohort of 305 patients (311 kidneys) were analyzed during the trial. The primary cohort consisted of patients with complete follow-up. The patients in the complete cohort, but excluded from the primary cohort, were also carefully followed but did not meet the requirements for "completeness" as defined in the protocol.

Effectiveness

The treatment was considered a success if the patient was stone free or had fragments ≤ 4 mm in size at follow-up. At the three month follow-up visit, 75% of the primary cohort and 78% of the complete cohort patients were either stone free or had ≤ 4 mm fragments. Of the 305 patients evaluated, 61 (20%) underwent 2 treatments, 11 (4%) underwent 3 treatments and 6 (2%) patients underwent 4 or 5 treatments. Based on the data from the retreated patients, a retreatment schedule of 3 treatments with a minimum of 1 month between treatments is recommended.

Analysis of the results of clinical trials carried out for a variety of patient and stone characteristics (e.g., height, weight, stone size and location) did not show any statistically significant dependence of outcome as related to patient or stone characteristics. Stones located in the upper calyx were found to have a significantly higher rate of success, but no clinical significance is attached to this finding. A weak relationship (not statistically significant) was found between size of the largest stone as well as stone burden and successful outcome with larger stones and larger stone burdens tending to have a lower rate of successful

outcome. The clinical trials were limited to the following ranges of patient and stone characteristics. Patients with characteristics outside of this range have not been studied with the Tripter-X1 Nova or Compact.

CHARACTERISTICS	LIMIT
Weight	390 lbs
Body Mass Index	66 kg/m ²
Size of Largest Stone	26 mm
Stone Burden	47 mm
Number of Stones	7

Safety

Hematuria, Pain, Skin Bruise, Muscle Soreness, Renal Colic, Renal Hematoma, Hydronephrosis, Nausea and Vomiting, Fever, Infection, Obstruction, Cardiac Events, Hypertension, and Renal Injury may occur with extracorporeal shock wave lithotripsy of upper urinary tract calculi.

Summary of Adverse Events by Phase of Therapy After 1st Treatment

Complication/ Adverse Event	During Treatment n=305	Immediate Post n=278	10 - 60 Days Post n=261	3 - Month Follow-Up * n=203 **	1 - Year Follow-Up n=92 **
Hematuria	2 (<1%)	73 (26%)	40 (15%)	8 (4%)	1 (1%)
Pain	18 (6%)	66 (24%)	51 (20%)	20 (10%)	4 (4%)
Skin Bruise	47 (15%)	65 (23%)	16 (6%)		
Muscle Soreness		20 (7%)	17 (7%)	5 (3%)	
Colic		16 (6%)	18 (7%)	5 (3%)	1 (1%)
Renal Hematoma		14 (5%)	3 (1%)	1 (<1%)	1 (<1%)
Hydronephrosis		7 (3%)	9 (3%)		1 (1%)
Nausea/Vomiting		6 (2%)	3 (1%)	1 (<1%)	
Fever		6 (2%)	3 (1%)		

	During Treatment	Immediate Post	10 - 60 Days Post	3 - Month Follow-Up *	1 - Year Follow-Up
Complication/ Adverse Event	n=305	n=278	n=261	n=203 **	n=92 **
Infection		3 (1%)	6 (2%)	3 (2%)	1 (1%)
Obstruction		1 (<1%)	4 (<2%)	3 (2%)	2 (2%)
Cardiac Event	1 (<1%)				
Other	3 (1%)	6 (2%)	9 (3%)	8 (4%)	2 (2%)

* Includes the period of 60 - 150 days post-treatment

** Includes patients that were stone free at earlier follow-up

Hematuria

The most consistent, clinically apparent effect noted following ESWL therapy (200 or more shock waves) is gross hematuria (Chaussey et al., 1984; Kaude et al., 1985). Gross hematuria is not specific to shock wave lithotripsy and is observed in other procedures related to treatment of patients with renal calculi.

A total of 73 patients (26%) reported hematuria immediately after treatment, and 8 patients (3.9%) reported hematuria at follow-up. The hematuria associated with lithotripsy generally resolved in 24-48 hours and no further treatment (transfusion, etc.) was required. Follow-up reports of hematuria were associated with stents or other procedures, continuing presence of stones, stone passage and retreatments.

Following two treatments, a slight increase in hematuria (4 cases, 10%) was reported, during the three month follow-up.

Pain

Sixty six (24%) of the patients experienced pain during the immediate follow-up period of which most were general post-operative pain. Pain was also attributed to stents, hydronephrosis/obstruction, and spinal headache. 16% of the patients with immediate post-treatment pain required medication.

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During the 10-60 days follow-up phase of therapy, 51 patients (20%) reported pain. Twenty patients (10%) were reported with pain at three month follow-up. Following three treatments, a small increase in pain (4 cases, 40%) was reported, during the 10-60 days follow-up. Pain was attributed to residual fragments, passing fragments, retained stone, stents, stones on the untreated side, general post-treatment pain, and back pain

During retreatments, a lower rate of pain was reported "during treatment" (0%), than for patients who had only one treatment (6%).

Skin bruises

Skin bruises or abrasions at the contact point between the membrane and the patient's skin was reported in a total of 112 cases (36.7%). These were all minor and resolved quickly. All cases of skin bruise were resolved by the follow up period

During retreatment, a slightly higher rate of skin bruise was reported (67%, 4 cases), following four treatments, due to skin sensitivity following multiple treatments.

Muscle Soreness

Muscle soreness was reported in twenty patients (7%) immediately following treatment, and in five patients (2.5%) at follow-up.

Renal colic

Renal colic following treatment was apparently secondary to passage of stone fragments and typically resolved with elimination of fragments.

Colic was reported in sixteen patients (6%) at the immediate post-treatment follow-up and was associated with stone passage, stents and residual stones/fragments. 1 (<1%) patient required pain medication for the colic.

Five (2.5%) patients reported colic during the follow-up period. The colic was associated with stone passage, stents, stone manipulation, residual stones/fragments and stones in the opposite side. 2 (<1%) of these patients received medication for the pain and 1 (<1%) patient was hospitalized. This patient passed several large stone fragments two days after hospitalization and was discharged.

Renal Hematoma

Renal hematomas were reported in fourteen (5%) of the patients following lithotripsy. Eight of these cases involved small (<3 cm) hematomas, and all but one resolved without intervention by the 3 month follow-up. The one remaining patient underwent several retreatments and the hematoma remained visible at the 3 month and 1 year (from original treatment) follow-up. By the 2 year follow-up, the hematoma was no longer visible.

Hydronephrosis

Hydronephrosis developed in seven patients (3%) post-treatment and resolved by the three month follow-up. Hydronephrosis following treatment was apparently secondary to unpassed large stone fragments. The hydronephrosis resolved spontaneously with the passage of the stones, or following an auxiliary procedure or following a retreatment of the unpassed stones. A higher rate of hydronephrosis was recorded in retreatment patients during treatment. 1% (1 case) in patients who underwent two treatments, 6% (1 case) in patients who underwent three treatments and 17% (1 case) in patients who underwent four treatments. The hydronephrosis in retreatment patients was due to unpassed large stone fragments and in all cases passed spontaneously following the retreatment.

Nausea/Vomiting

Six patients (2%) reported nausea/vomiting immediately following treatment due to the analgesics/ sedatives used during treatment. 1 patient (<1%) reporting nausea/vomiting was rehospitalized the day after treatment due to colic and hematuria. 1 patient (<1%) reported nausea/vomiting during the follow-up period due to unknown causes.

Fever

Fever (>100 F) was reported immediately post-treatment in six (2%) patients. No patient required hospitalization.

Infection

Infection was noted in a total of six (1.5%) patients between discharge and follow-up. Urinary tract infections were generally diagnosed within the first week posttreatment and resolved with normal antibiotic therapy.

Obstructions

Obstructions were noted in a total of four (1.5%) patients between discharge and follow-up. All obstructions resolved spontaneously or with the use of auxiliary measures.

Cardiac Event

Only one cardiac event was reported in our study (<1%). This event was related to anesthesia and treatment was continued following this episode. The patient was asymptomatic, held for two days for observation and given medication.

Hypertension

Hypertension was reported as an adverse event in 9% of patients post-treatment. In 80% of these patients this was a transient elevation in blood pressure that resolved at subsequent follow-up. Six patients (2%) were referred for treatment of hypertension during the clinical study, although in five of these patients the hypertension seemed to be related to the patients' underlying disease and condition rather than secondary to treatment.

The relationship between extracorporeal shockwave lithotripsy and hypertension is not fully understood and continues to undergo investigation.

Renal Injury

Renal injury to the treated kidney has been known to occur with extracorporeal shockwave lithotripsy, although the potential for injury, its long term significance and its duration are unknown.

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CHAPTER 3 - DESCRIPTION OF SYSTEM

3.1 INTRODUCTION

The Medirex Inc., Tripter-X1 *Nova* and *Compact* designs, are mobile Extracorporeal Shock Wave Lithotripsy devices which consist of a Shock Wave Generator (SWAG) including a control module and a Motorized Floating Treatment Table (MFT). The Tripter-X1 *Nova* and *Compact* do not provide imaging or monitoring functions, but contain the necessary interfaces for fluoroscopy imaging and ECG monitoring. Both Tripter-X1 *Nova* and *Compact* are small and mobile and can be used in any room equipped with the proper anesthesia equipment. A typical room layout of the Tripter-X1 *Nova* and the *Compact* are shown in Figures 1 and 2, respectively.

3.2 BACKGROUND AND PRINCIPLE OF OPERATION

A high energy spark, which can be controlled within defined limits, is generated by a special electrode placed within a reflector. The shock wave generated by the spark is focused through water and through the body to converge on the calculus. The shock waves must be generated and transmitted through liquid to assure that sufficient energy is delivered to the stone. A series of the focused shock waves is used for the stone disintegration. The number of shocks in such a series should not exceed the allowed number of 2,400.

The mobile SWAG includes a high voltage module, control module, a reflector module and a water module. The control module consists of controls, indicators and interfaces to the ECG monitor. The Treatment Table, for patient support and positioning, is a motorized floating table which can be moved electrically in all three axes. It supports the patient and enables line up of the stone in the therapeutic focus of the SWAG reflector. Any adequate mobile X-Ray fluoroscopy unit (as defined in Appendix A) can be used for imaging.

The X-Ray and fluoroscopy unit and the SWAG are first aligned using imaging sights on the SWAG. The patient is then positioned with the aid of the moveable table top to precisely position the stone in the focal point of the SWAG under fluoroscopic guidance.

3.3 TRIPTER-X1 NOVA AND COMPACT MAJOR COMPONENTS:

3.3.1 The Lithotripter:

The Lithotripter systems consist of 2 major components, the SWAG (ShockWave Generator) and MFT (Motorized Floating Table):

3.3.1.1 Shock Wave Generator (SWAG):

The purpose of the SWAG is to convert electrical energy into mechanical energy of shockwaves. A high enspis generated between the tips of an underwater electrode. The electrode is positioned so that the spark is generated at the (F1) focal point of an ellipsoidal reflector. Vaporization of the water occurs at the location of the spark producing spherical shock waves.

The shock waves are generated in and transmitted through an aqueous solution contained in the space enclosed by the reflector and the flexible membrane.

The shock waves generated by the spark at the (F1) focal point are focused by the semiellipsoidal reflector to converge at the therapeutic focal point (F2). The patient is positioned such that the calculus is at the therapeutic focal point.

Using an X-ray fluoroscopy unit, the calculus is identified and positioned with the aid of the MFT at the therapeutic focal point, by causing the projection of the stone to coincide at all projection angles with the "projection" of F2 already marked on the screen.

The patient's flank is brought into contact with the lubricated membrane covering the water filled reflector. The patient is coupled to the SWAG and the shock waves are transmitted via the membrane.

The SWAG is connected to the ECG monitor and synchronizes the shock waves with the ventricular refractory period of the patient's heart (the R-wave of the ECG QRS-complex). The shock waves are controlled so that they are only delivered when the heart is in the refractory phase.

Tripter-X1 *Nova* and *Compact* designs of the SWAG are shown in Figure 3 and 4, respectively.

3.3.1.2 Treatment Table (MFT):

The MFT is pictured in Figure 7. The table is a motorized floating table which can be moved electrically in all three axes. The patient is placed on the MFT and by utilizing an X-ray fluoroscopy unit and the 3 dimensional electrical motion of the MFT, the calculus is positioned at the therapeutic focal point.

The MFT has four wheels to allow manual movement, and has side railings for standard stir-ups.

3.3.2 Required Equipment not Provided:

3.3.2.1 ECG Monitoring:

An ECG monitor must be provided for synchronization of the shock wave generation to the patient's refractory phase. The ECG monitor should provide an R-wave synchronization, or defibrillator SYNC, output signal of 1 volt minimum, for proper reception and proceeding of the ECG signal. See Appendix A - peripheral equipment

A shock wave is generated per each heartbeat for a low pulse rate and once every second heartbeat for a pulse rate over 100 pulses/minute. The changeover is carried out automatically within the control module.

3.3.2.2 Fluoroscopy unit:

The fluoroscopy unit supplied by the user must be suitable to the system. See Appendix A - peripheral equipment.

3.3.2.3 Consumables:

The consumables consist of the electrode and the flexible membrane. Significant shockwave degradation occurs at 3000 shocks; therefore, it is recommended that the electrode be replaced prior to each treatment. This practice will ensure that the maximum number of shocks per treatment (2400) will never exceed the life of the electrode.

In addition, the flexible membrane should not be used for more than 30,000 shocks.

CHAPTER 4 - SAFETY, RELIABILITY AND PROTECTIVE MEASURES

4.1 INTRODUCTION

The greatest possible care and attention must be given when handling this equipment in order to ensure the protection of the patient. The lithotripter may only be used by qualified specialists who fully observe the operating instructions and have the required technical training in radiation protection.

4.2 GENERAL

The safety, reliability and performance of the equipment can be assured only if:

- (1) Installation, adjustment, maintenance and modifications are performed by Medirex Inc. staff or persons authorized by Medirex Inc.
- (2) The electrical installations of the facility where the lithotripter is installed meet the appropriate facility regulatory requirements.
- (3) The equipment is used as specified in the operator's manual.
- (4) Medirex supplied spare parts are used.

WARNING: The system carries dangerous voltages when connected to the power supply.
Voltage-carrying equipment may only be opened by properly instructed staff.

Modifications of or supplementing to the equipment may only be performed upon written approval by Medirex Inc..

The system must not be operated in an explosive atmosphere, no matter what causes this atmosphere (anesthetics, cleaning and disinfecting agents).

The application of shock waves to air-filled areas (intestines, lungs) causes harmful side effects to the patient and must be avoided.

Prior to shock wave release, ensure that the ECG has no artifacts which could cause uncontrollable shock wave releases.

4.3 RADIATION PROTECTION

Applicable regulations for operator radiation protection and radiation safety must be observed when using a radiofluoroscopy unit with the lithotripter. It is the responsibility of the user to observe required regulations concerning the installation and operation of the X-Ray system. Protective working zones must be set out for the examiner, in which the examiner is especially protected against scattered radiation from the patient. Minimum dimensions and maximum dosages for these protective zones are set forth in standards recommended by the IEC, BRH and other regulatory bodies.

It is necessary for each hospital to determine the dosage rate of the individual working areas under practical conditions and to use this data as a basis for the determination of the radiation protection measures to be taken.

Radiation Safety

It is recommended that the user designate areas suitable for safe operation and service of the system. Consideration must be given to room (lead) shielding, ability of the floor, ceiling and walls to attenuate scatter radiation, choice and use of lead draping and any other room environment conditions necessary to protect personnel.

The system must be operated only by qualified personnel, who understand the use of fluoroscopy unit and radiation safety procedures.

The physician in charge of the radiological procedure must ensure that all personnel in the room wear approved protective clothing and radiation monitoring devices.

Radiation levels fall off as the inverse square law designates. The operator and all ancillary personnel should maintain the maximum distance possible from the fluoroscopy source during exposure.

Exposure of Personnel

Reduction of radiation exposure to an individual from external sources of radiation may be achieved by any one or any combination of the following measures:

- a. Increasing the distance of the individual from the source
- b. Reducing the duration of exposure
- c. Using protective barriers between the individual and the source

For medical X-ray equipment, shielding and distance are the factors most readily controlled. Protective shielding includes that incorporated into equipment; it may also consist of mobile or temporary devices used as the occasion demands, such as movable screens, or lead impregnated aprons and gloves; or it may comprise permanent protective barriers and structural shielding such as walls containing lead, concrete, or other materials in thicknesses sufficient to provide the required degree of attenuation. Structural shielding is an important part of installation planning.

Exposure of the Patient

Techniques employed in fluoroscopy should be those which achieve the desired objectives with minimum dose to the patient.

The following recommendations are presented for the guidance of physicians and others responsible for the exposure of patients.

1. The useful beam should be limited to the smallest area practicable and consistent with the objectives of the fluoroscopy examination or treatment.
2. Suitable protective devices to shield the parts of the patients body not to be exposed to fluoroscopy examination.



4.4 CONNECTION WITH OTHER EQUIPMENT

When the Tripter-X1 *Nova* or *Compact* are connected with other equipment, components or assemblies (e.g. ECG-unit) and the safe connection with these units, components or assemblies cannot be clearly established from the technical documentation, the user must ensure the necessary safety of the patients, operators and the environment is not affected in any way by the proposed connection, e.g. by contacting the respective manufacturers or by obtaining expert advice.

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CHAPTER 5 - SYSTEM PREPARATION

5.1 INTRODUCTION

The system is to be prepared for treatment in five stages: Preparation of water, SWAG setup, Fluoroscopy unit setup, alignment of fluoroscopy unit to SWAG, system hook-up and system simulation test.

5.2 PREPARATION OF WATER

A mixture of 8 liters of distilled water with 112 cc of saline (0.9% NaCl) is required for the *Compact* design.

A mixture of 10 liters of distilled water with 140 cc of saline (0.9% NaCl) is required, for the *Nova* design.

Fill the empty SWAG water tank with the prepared mixture.

5.3 SWAG SETUP

The Shock Wave Generator (SWAG) is positioned such that the reflector will be inside the notch of the treatment table (see Figures 1 and 2, for Tripter-X1 *Nova* and *Compact* designs, respectively). Lock the SWAG into position by locking all three wheels. The SWAG is locked to the MFT via a coupler, in the *Nova* design, to ensure that the MFT and the SWAG remain as positioned during the treatment procedure. The position of the patient on the treatment table is according to the patient's side to be treated, so that SWAG setup is independent of the side to be treated.

5.4 FLUOROSCOPY UNIT SETUP

The mobile Fluoroscopy unit is positioned perpendicular to the SWAG as shown in Figure 1 and 2, for the Tripter-X1 *Nova* and *Compact* designs, respectively. The fluoroscopy unit is moved into position such that the focal mark of the X-Ray tube is approximately underneath



the focal pointer of the SWAG. Once the fluoroscopy unit is positioned, all wheels are locked in place. The fluoroscopy unit is locked to the SWAG via a coupler, in the *Nova* design.

Note: Refer to the fluoroscope operation manual for further use.

5.5 SYSTEM HOOKUP

Verify that the system components (SWAG and MFT) are in the OFF position. Connect the power cables to the electrical outlets on the SWAG. Connect all the additional marked cables. Verify again that all cables are connected correctly, and the voltages are set according to the line voltage. Finally connect the power cable from the SWAG to a 110 volt electrical outlet.

5.6 ALIGNMENT OF FLUOROSCOPY UNIT TO SWAG

The initial alignment of the SWAG to the fluoroscopy unit is performed at installation. This alignment should be verified prior to each treatment day. The following procedure should be followed if re-alignment is needed. The fluoroscope/SWAG alignment is performed with the use of alignment sights on the SWAG. The lower sight is permanently mounted on the SWAG and it will appear as a "crossbar" on the fluoroscope image. The removable focal sight, pointing to the focal point, is positioned on the reflector plate and will appear as an "pointer" on the fluoroscope image.

The fluoroscope/SWAG alignment is performed using five moveable axes on the fluoroscopy unit: Wig-Wag axis; Boom axis; Pitch axis; Roll axis; and Up-down axis. The five axes are illustrated in Figure 8. The alignment procedure is as follows:

5.6.1 Initial positions of the fluoroscopy unit are as follows:

BOOM	Set fluoroscopy tube outlet approximately below the SWAG lower sight.
WIG-WAG	Set at 0 degrees.
ROLL	Set at 0 degrees.
PITCH	Set at 0 degrees.
UP-DOWN	Leave as is.

5.6.2 Procedure

1. Turn the fluoroscopy unit main switch on and make an exposure.
2. Move Boom and Wig-Wag axes to position the SWAG focal sight tip to the center of the fluoroscopy display monitor.
3. Using the fluoroscopy monitor controls ("Image Rotation", "Turn 180 deg.") align the SWAG focal sight to be positioned vertically in the lower portion of the monitor display and the "arrow" to the left side of the focal sight as shown in Fig. 9, "Alignment Sights as seen on Monitor".
4. Verify that the focal sight tip is still at the center of the monitor display.
5. Lock Boom and Wig-Wag axes in place.
6. Move the Roll and Pitch alternately until the crossbar (lower sight) and the focal sight tip are all set as shown in Fig. 9, "Alignment Sights as seen on Monitor" and mark the focal sight tip position on the display.
7. Lock Roll and Pitch in place.
8. Move the Roll to about a 30 degree angle.
9. Using the fluoroscopy unit "Up-Down" controls adjust the height of the fluoroscopy so that the mark on the display is at the tip of the focal sight.
10. Move Roll back to 0 degrees and check to make sure the crossbar and the focal sight tip are set as in step 6.
11. The fluoroscopy unit and the SWAG are now aligned

12. Remove the focal sight from the SWAG and place it aside gently.

5.7 SYSTEM SIMULATION TEST

- 1) Hook up the main power cable to the POWER connector on the SWAG.
- 2) Connect one end of the ECG self test cable to the ECG input connector and the other to the ECG "TEST" connector on the side panel of the SWAG.
- 3) Insert a new electrode into the reflector.
- 4) Ensure that the SWAG reflector is filled with the water mixture (as detailed in section 5.2 - Preparation of Water). Ensure that there is something placed against the membrane to absorb the energy, saline bags may be used.
- 5) Turn on the power switch and check to see if all the indicators are on, except the trigger indicator.
- 6) Turn the KV high voltage setting switch on the Control module front panel to see if there is movement on the high voltage meter on the Control module front panel.
- 7) Turn on the Trigger switch. The SWAG will fire and the green trigger indicator should flicker on every shockwave.
- 8) Turn the KV high voltage switch on the Control module front panel until reaching "0" on the high voltage meter, to complete the simulation test. Release one more shock and switch the trigger key off. Remove the ECG Self Test Cable. Remove the water from the reflector and switch the Power key off.

CHAPTER 6 - OPERATION

6.1 INTRODUCTION

The operation of the Tripter-X1 *Nova* and *Compact* is performed via the control panels.

6.2 CONTROL FUNCTIONS

The Control Module serves as the operator's station for presetting and controlling the treatment procedure.

Control functions are divided into the following main groups:

<u>NOVA</u>	<u>COMPACT</u>	<u>FUNCTION</u>
I. WATER CONTROL		
OUT-0-IN switch	WATER OUT button	Controls water flow from the SWAG container into and out of the membrane.
	WATER IN-OUT valve	
II. HIGH VOLTAGE CONTROL		
H.V. Meter	H.V. Meter:	Measures high voltage in KV.
H.V. LOW/HIGH	H.V. LOW/HIGH:	High Voltage setting switch.
H.V. 0/1		Turns high voltage ON/OFF.
III. TREATMENT CONTROL		
Treatment Counter	Treatment Counter	Counts number of SWAG shocks during treatment.
Trigger 0/1	Trigger 0/1	Turns trigger ON/OFF.
IV. GENERAL		
POWER 0/1:	POWER 0/1	System ON/OFF.
Cumulative Counter		Counts cumulative number of SWAG shocks (for maintenance)

Additional optional switches and switches for future use exist on the control panel, of the *Nova* design.

V. IMAGING & POSITIONING CONTROL:

- | | |
|-------------------|---|
| X-Ray/Echo: | For Future use. |
| Indicator H,V,R: | For future use. |
| Joystick; IN/OUT: | Three directional movement of the table for stone positioning (Up/Down, Right/Left and In/Out). |

The control mechanism allows the SWAG to be activated only when;

- (a) the Power switch is ON,
- (b) there is enough water in the reflector, and
- (c) the heart is in its refractory phase (QRS wave of the ECG).

The control panels of the *Tripter-X1 Nova* and *Compact* are pictured in Figures 5 and 6, respectively.

6.3 TRIPTER-X1 NOVA AND COMPACT OPERATING PROCEDURE

The operating procedure is divided into three stages:

- 1. Initial operation;
- 2. Daily Start Up;
- 3. Standard Operation.

6.3.1 INITIAL OPERATION

Use of the system for the first time following installation, refer to Section 5.0 - System Preparation.



6.3.2 DAILY START UP:

- 1) Assure that all systems are on, i.e. SWAG, MFT and Fluoroscope.
- 2) Mount SWAG focal sight.
- 3) Expose fluoroscope and confirm that the image of the focal sight tip is at the center of the screen. If not, perform "Alignment of Fluoroscope unit to SWAG", Section 5.6.
- 4) Ensure SWAG and fluoroscope unit are mechanically coupled.
- 5) Commence with standard operation.

6.3.3 STANDARD OPERATION:**6.3.3.1 Patient Positioning:**

After the SWAG and the fluoroscopy unit have been aligned and the patient has been prepared, place the patient on the treatment table such that the area to be treated is in the center of the table's notch and is out towards the SWAG as much as possible. The ECG monitoring equipment should then be connected to the patient and anesthesia or sedation of choice started.

Adjustment of the treatment table is performed using the MFT positioning switches, located on the hand remote control unit, or in the *Nova* unit also using the Joystick on the Control Panel.

6.3.3.2 Stone Positioning:

- 1) Move patient on the table so that the vertical stone projection is under the image intensifier center.
- 2) Press the "Fluoro" switch and make an exposure.
- 3) Obtain a fluoroscopic image of the stone to verify that it is near the focal point.

- 4) Use the MFT motion control switches and move the MFT so that the stone superimposes the focal point which is marked on the screen.
- 5) Press the "Fluoro" switch and make an exposure.
- 6) Obtain a fluoroscopic image to verify the stone location.
- 7) If the stone is not exactly at the focal point, use the MFT motion control switches under continuous fluoroscopic exposure and move the MFT until the stone is exactly at the focal point.
- 8) Rotate the fluoroscope arm to 30° C .
- 9) Obtain a fluoroscopic image to verify the stone location. If the stone is not exactly at the focal point, move the MFT under continuous fluoroscopic exposure until the stone is exactly at the focal point.
- 10) Rotate the fluoroscope arm to vertical position.
- 11) Press the "Fluoro" switch and make an exposure.
- 12) Obtain a fluoroscopic image to verify the stone location. If the stone is at the focal point, proceed with the treatment procedure. If not, repeat steps 7 to 9 and then proceed to treatment procedure.

6.3.3.3 Turn on water flow

After patient positioning is checked and the stone is localized, turn the water switch or valve (for *Nova* or *Compact*, respectively) to IN position to fill the reflector with water. Apply silicone oil to the membrane and to the patient on the side to be treated, while waiting for the reflector to fill with water. Once the membrane is filled, verify that the water indicator turns on. Also verify that the membrane is properly touching the patient, and that the stone is still on the marked therapeutic focal point.

6.3.3.4 Pre-treatment checklist

Verify that the cables are properly connected and that there is an ECG wave form on the ECG monitor.

Turn the Power key/switch of the control module panel, to the "1" (ON) position and check the indicator lights on the control panel, as follows

- (1) The Power indicator is on.
- (2) The Water indicator is on.
- (3) The ECG-R indicator is flashing on and off with the patient's R wave of the ECG wave form.

Turn the high voltage up to 14-24 KV,(depending on the energy required to apply to the stone), using the High Voltage adjustment switch on the control panel, if the indicator lights indicate proper operation. When operating the *Nova* system, turn the H.V. switch to "1" (ON) position. The high voltage indicator light should be on.

WARNING: Do not turn on the Trigger key at this time since it will cause the machine to trigger and deliver shock waves.

CHAPTER 7 - TREATMENT

7.1 TREATMENT

Ear plugs should be worn by the patient and operator during treatment. Make certain that the TREATMENT counter is zeroed. Check to see if the HIGH VOLTAGE METER displays 14-24 kilovolts, if not adjust the voltage. Turn the TRIGGER key to the ON position, and the SWAG should begin firing.

NOTE: If the patient is not anesthetized it is recommended to start with a low HIGH VOLTAGE setting and increase slowly after a few shocks.
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The fluoroscope can be used from time to time, to verify the stone location and degree of disintegration. Set the fluoroscopy unit to pulsed fluoroscopy mode, if available. Immediately following the commencement of the shock wave treatment, press the fluoroscopy button and verify that the stone is in the proper position. Apply short fluoroscopy imaging exposures only every 300-500 shocks or when desired to check the stone status.

The physician should determine when the stone is sufficiently disintegrated, and the treatment should be terminated. Turn the TRIGGER key off, to terminate the treatment. Turn the HIGH VOLTAGE setting knob or switch (for *Nova* and *Compact*, accordingly) to the "0" KV position and allow the SWAG to fire one additional time. Turn the high voltage switch (HV 0/1) to "0" (off) position, in the *Nova* design.

7.2 POST-TREATMENT PROCEDURE

The MFT can be moved out of the way and its wheels locked, once the system is turned off. The patient may be transferred from the MFT.

Empty the water from the reflector by turning or pressing (for *Nova* and *Compact*, respectively) the water switch to the OUT position. The Water Valve should also be turned to OUT position, when operating the *Compact*.

Remove the water from the system water tank, at the end of each treatment day. The water is not reusable.

Clean and wipe dry the SWAG, the reflector and the membrane with a cloth.

7.3 MAINTENANCE

7.3.1 ELECTRODE REPLACEMENT

WARNING: SWAG CARRIES LETHAL HIGH VOLTAGE.

VERIFY THAT THE POWER SWITCH IS IN THE "OFF" POSITION.

Wait two minutes from the time that the power switch was turned off. Rotate the fluoroscope "Roll" to approximately a 30° angle. Use the reflector key to open the reflector. Remove the electrode. Replace the electrode with a new electrode. Fit the electrode in tightly, and close the reflector using the reflector key.

7.3.2 MEMBRANE CHECKING AND REPLACEMENT

Visually check to see if there are any holes in the membrane. The membrane must be replaced, if holes are visible.

Remove the membrane rubber rings, remove the membrane, place a new membrane, and tighten it to the reflector with the membrane rubber rings, to replace the membrane.

CHAPTER 8 - CLEANING**8.1 GENERAL**

WARNING: SWITCH THE SUPPLY VOLTAGE OFF, BEFORE CLEANING.

Water may be used for cleaning purposes. The SWAG should not be washed with excessive amounts of water in order to avoid water splashing on electrical system components.

Ensure that all the power cords are disconnected from the system, prior to cleaning. Do not clean the system with gaseous or spray disinfectants.

The SWAG and MFT are cleaned by wiping with a slightly moist soapy water cloth on a regular basis.

CAUTION: Do not use cleaning or disinfecting agents which when combined with air, create an explosive atmosphere.

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CHAPTER 9 - TROUBLESHOOTING: TRIPTER-X1 NOVA AND COMPACT SELFTEST

9.1 CONTROL MODULE SIMULATION - NOVA DESIGN:

- (1) Ensure TRIGGER and POWER switches are turned off. Hook up main power cable to the POWER connector on the control panel. Check that the "Power from" switch is on the "TCU" position.
- (2) Turn the "TCU" switch on the control panel to the TEST position.
- (3) Turn the ECG switch to INT (Internal) position.
- (4) Turn on POWER switch and check to see if on the control panel the power, water and exhale indicators are on and that the ECG-R indicator is flashing. If not, check power and ECG cable connections.
- (5) Check to see if the high voltage meter on the control panel moves by adjusting the "High Voltage" knob.
- (6) Turn on trigger switch and check to see if the trigger indicator is flashing, and the treatment counter is counting.
- (7) If after these steps the control module is not working, please contact your Medirex service man.
- (8) Turn off power and trigger switches, and return all the switches at the rear panel of the Control module to their normal working position. i.e. "Power From" switch back to SWAG position, "TCU" switch back to NORM position, "ECG" switch back to "EXT" position.

9.2 SHOCK WAVE GENERATOR (SWAG) SIMULATION - NOVA DESIGN:

- (1) Hook up the main power cable to the POWER connector.
- (2) Hook up the SWAG cable to the SWAG connector.
- (3) Turn the ECG switch at the rear panel of the control module to "INT" position.

- (4) Make sure the reflector is filled with water (a mixture of 10 liters of distilled water with 140 cc of saline (0.9%)). Ensure that there is something placed against the membrane to absorb the energy, saline bags may be used.
- (5) Turn on the power key and check to see if all the indicators turn on or flicker, except the trigger indicator.
- (6) Turn the High Voltage setting knob on the control panel to see if there is movement on the HIGH VOLTAGE METER.
- (7) Turn on Trigger key. The *Nova* will fire and the trigger indicator should flicker on every shock wave. If not, check all switches and indication lights. If system is still not working, contact the Medirex service personnel.
- (8) To complete the self-test turn the HIGH VOLTAGE knob down on the control panel until reaching "0" on the HIGH VOLTAGE METER. Release one more shock and switch the TRIGGER key off. Switch the POWER key off. Return all switches to normal working position. (see section 9.1 parag. 8). Remove water from the reflector.

9.3 SHOCK WAVE GENERATOR (SWAG) SIMULATION - COMPACT DESIGN:

- (1) Hook up the main power cable to the POWER connector.
- (2) Connect one end of the ECG self test cable to the ECG input connector and the other to ECG "TEST" connector on the control module panel.
- (3) Make sure the SWAG reflector is filled with water (a mixture of 8 liters of distilled water with 112 cc of saline (0.9%)). Ensure that there is something placed against the membrane to absorb the energy, saline bags may be used.
- (4) Turn on the power switch and check to see if all the indicators turn on or flicker, except the trigger indicator.
- (5) Turn the KV HIGH VOLTAGE setting switch on the control module panel to see if there is movement on the HIGH VOLTAGE METER on the control panel.

- (6) Turn on the TRIGGER switch. The SWAG will fire and the trigger indicator should flicker on every shockwave. If not, check all switches and indication lights. If system is still not working, contact your Medirex Inc. service personnel.
- (7) To complete the self-test, turn the KV HIGH VOLTAGE switch until reaching "0" on the HIGH VOLTAGE METER. Release one more shock and switch the TRIGGER switch off. Remove the ECG Self Test Cable. Remove water from the reflector. Switch the Power switch off.

APPENDICES



APPENDIX A: PERIPHERAL EQUIPMENT**1. ECG MONITORS SUITED TO OPERATE WITH THE TRIPTER-X1 *NOVA* AND *COMPACT*****Background**

The Tripter-X1 *Nova* and *Compact* generate the shock waves in synchronization with the patient's R-wave from the ECG signal. The sync signal is generated by the ECG monitor supplied by the user.

General requirement from the ECG monitor:

Any ECG equipment that has a sync (synchronization) or defibrillator sync output signal with an amplitude of at least 1 volt and is legally marketed in the U.S. is suited for the Tripter-X1 *Nova* and *Compact* operation.



2. FLUOROSCOPY UNITS SUITABLE TO OPERATE WITH THE TRIPTER-X1 NOVA AND COMPACT:Essential Requirements:

1. A mobile Fluoroscopy unit with a firm locking of the wheels.
2. Firm locking of the five moving axes: Boom, Wigwag, Roll, Pitch and Up/Down.
3. Rotating of the image on the monitor.

Dimensions:

See Fig. 10; "Requirements for Fluoroscopy Adaptability"

1. The distance "A" between the lowest point of the Image Intensifier and the rotating roll axis - should be at least 25 cm.
2. The distance "B" - between the highest point of the tube and the rotating roll axis - should be at least 25 cm.
3. The distance "G" - between the X-ray tube-line and the inner edge of the X-ray Tank - should be at most 25 cm.
4. The distance "C" - the width of the fluoroscopy unit - should be at most 14 cm.
5. The adjustable height "D" - between rotating roll axis and the floor should be less than 98 cm at minimum height, and more than 104 cm at maximum height.
6. The point "O" is the intersection of the fluoroscopy Roll Axis line and the central Image Intensifier-X-Ray Tube Line (This is the point where the system focal point will be placed). At 45 cm from "O" along the Roll axis (Point "P"), the following should measure:

- The distance "F" - from point "P" on the Roll axis to the upper inner side of the fluoroscopy should be at least 27 cm.
- The distance "E" - from point "P" on the Roll axis to the lower inner side of the fluoroscopy should be at least 24 cm.

Recommendation:

1. Possibility to freeze the last picture.
2. Memory of one or more pictures.

Examples of Mobile C-Arm's suited for use with the Tripter-X1 Nova and Compact:

The Mobile C-arm used with the Tripter-X1 Nova or Compact shall be legally marketed in the U.S..

1. Phillips - BV 25/BV 29
2. General Electric - Stenoscope / Polarix 2
3. Siemens - Siremobile 2N / 4E / 2000
4. Toshiba - SXT-60M / SXT-60F
5. CGR - Stenoscope
6. Acoma - MCA-501

APPENDIX B: FIGURES

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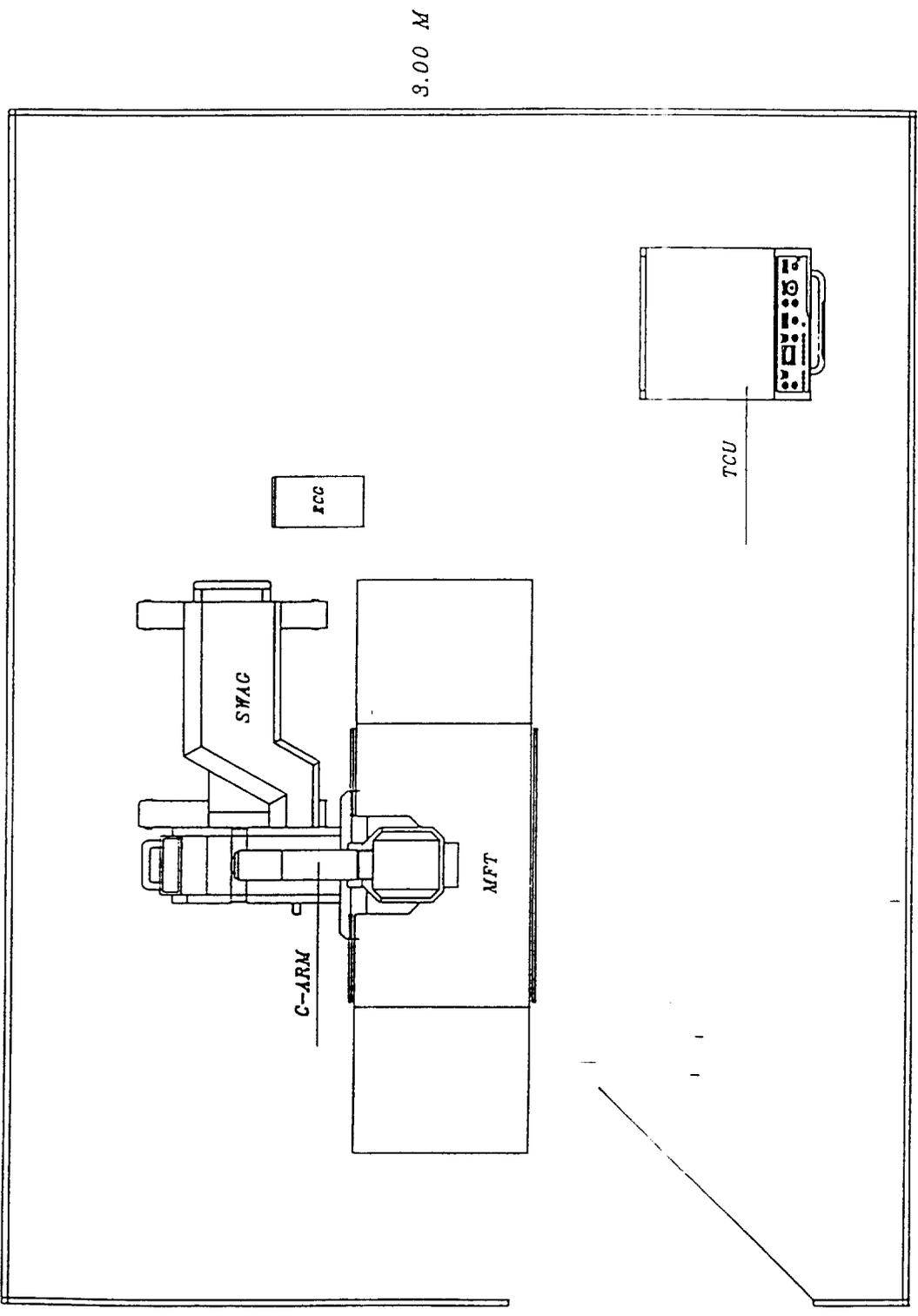


FIGURE 1: TRIPTER-X1 NOVA TYPICAL ROOM LAYOUT

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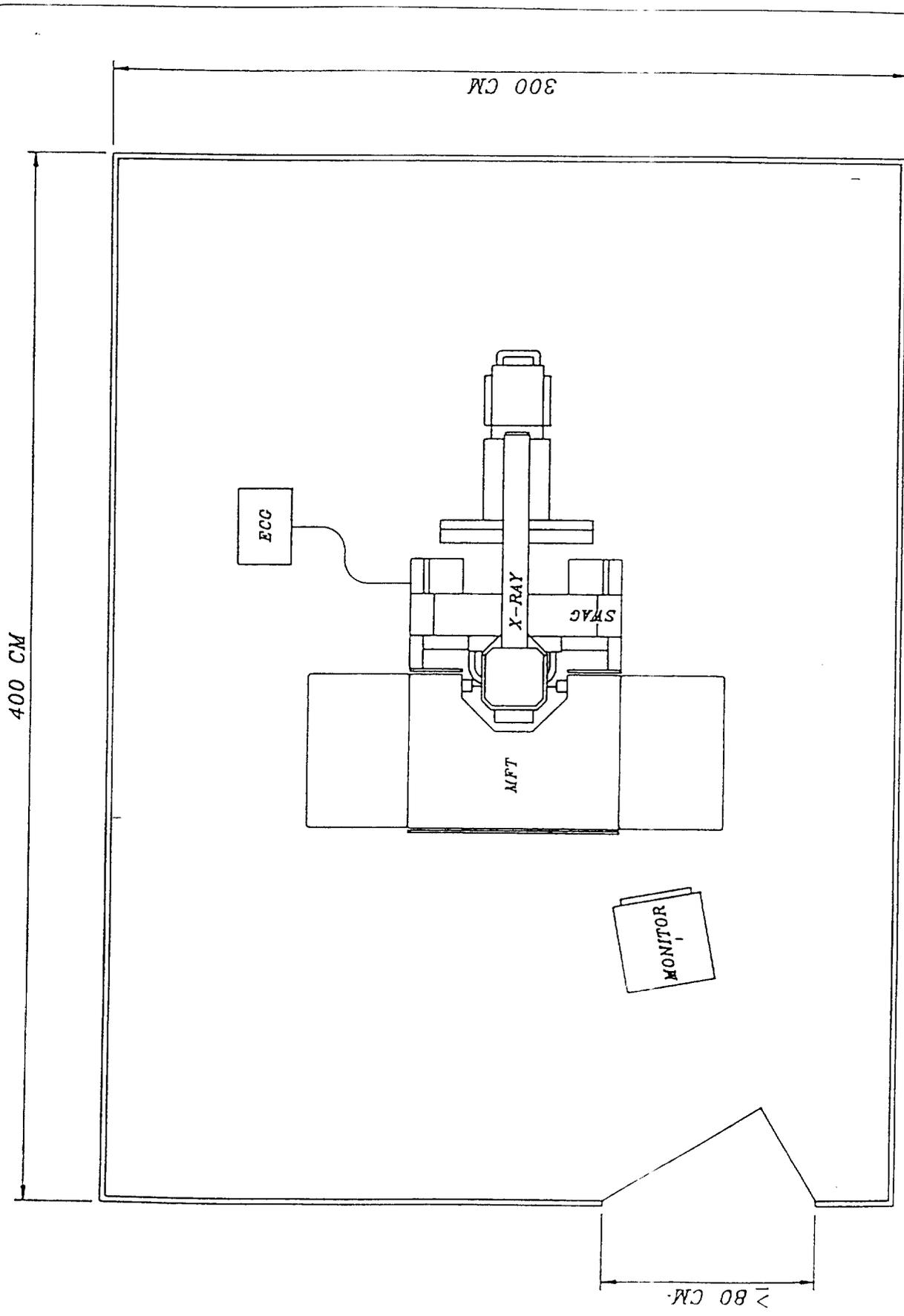


FIG 2: TRIPTER-X1 COMPACT TYPICAL ROOM LAY OUT

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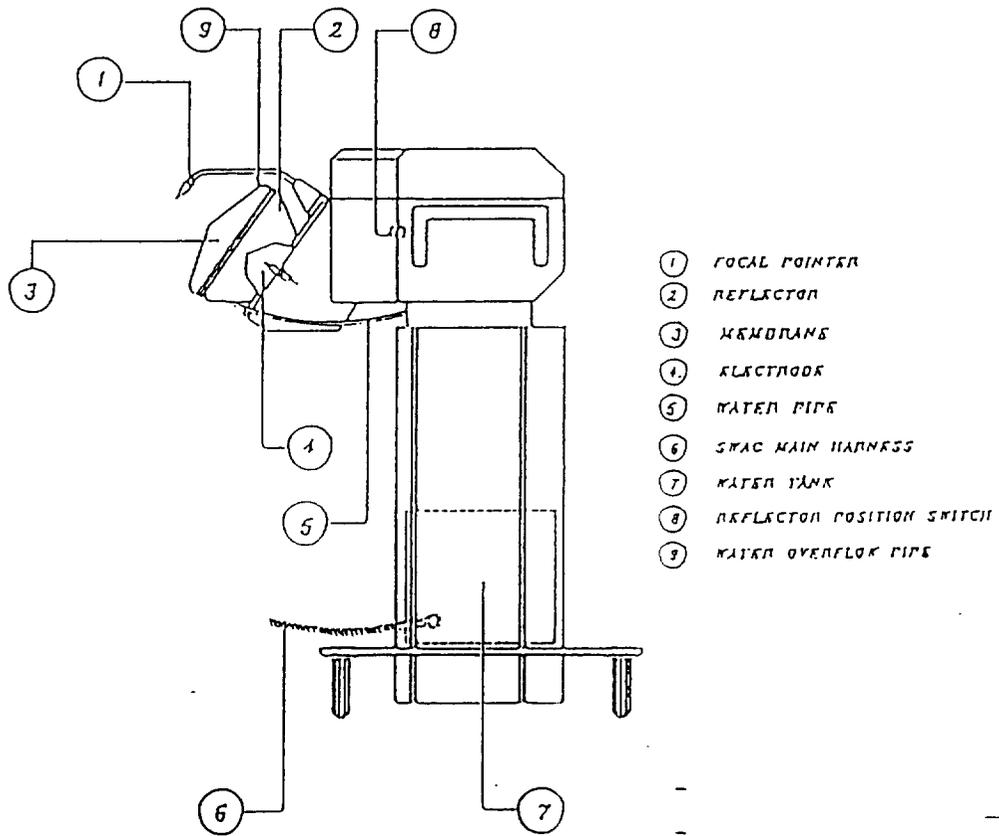


FIG 3: TRIPTER-X1 NOVA SHOCKWAVE GENERATOR (SWAG)

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- 1) CHASSIS
- 2) CONTROL MODULE
- 3) H.V. MODULE
- 4) WATER SYSTEM MODULE
- 5) REFLECTOR MODULE

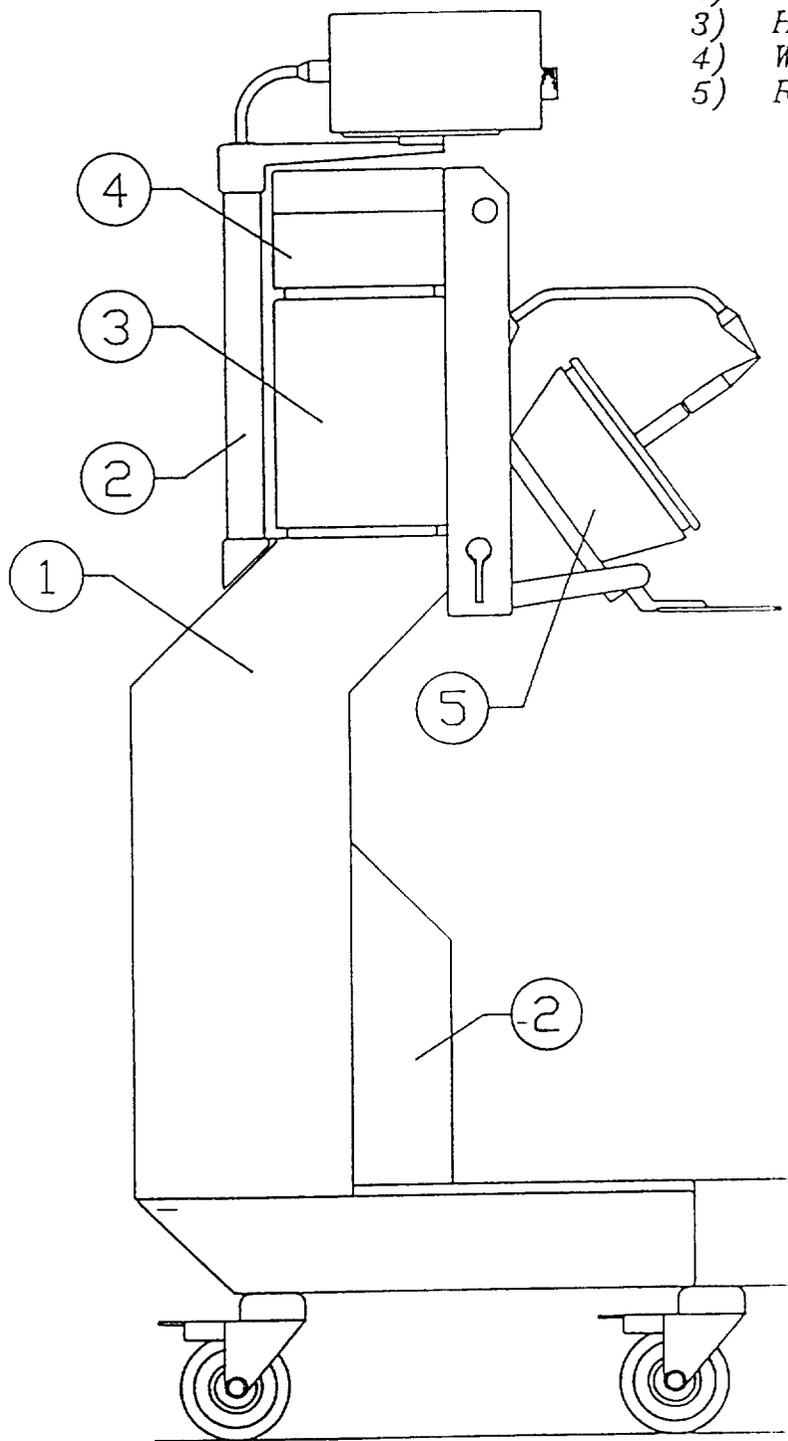


FIG 4: TRIPTER-X1 COMPACT SHOCKWAVE GENERATOR(SWAG)

80

- | | |
|-------------------------------------|---------------------------------|
| 1. TRANSFORMER SIMULATION INDICATOR | 12. POWER INDICATOR |
| 2. TCU SIMULATION INDICATOR | 13. CUMULATIVE COUNTER |
| 3. ECC SIMULATION INDICATOR | 14. TABLE POSITIONING JOYSTICK |
| 4. WATER INDICATOR | 15. FUTURE USE |
| 5. HIGH VOLTAGE INDICATOR - | 16. FUTURE USE |
| 6. EXHALE INDICATOR | 17. FUTURE USE |
| 7. ECC INDICATOR | 18. TRIGGER SWITCH |
| 8. TRIGGER INDICATOR | 19. TREATMENT COUNTER |
| 9. FUTURE USE | 20. HIGH VOLTAGE POWER SWITCH |
| 10. FUTURE USE | 21. HIGH VOLTAGE SETTING SWITCH |
| 11. POWER KEY SWITCH | 22. HIGH VOLTAGE METER |
| | 23. WATER FILL/EMPTY SWITCH |

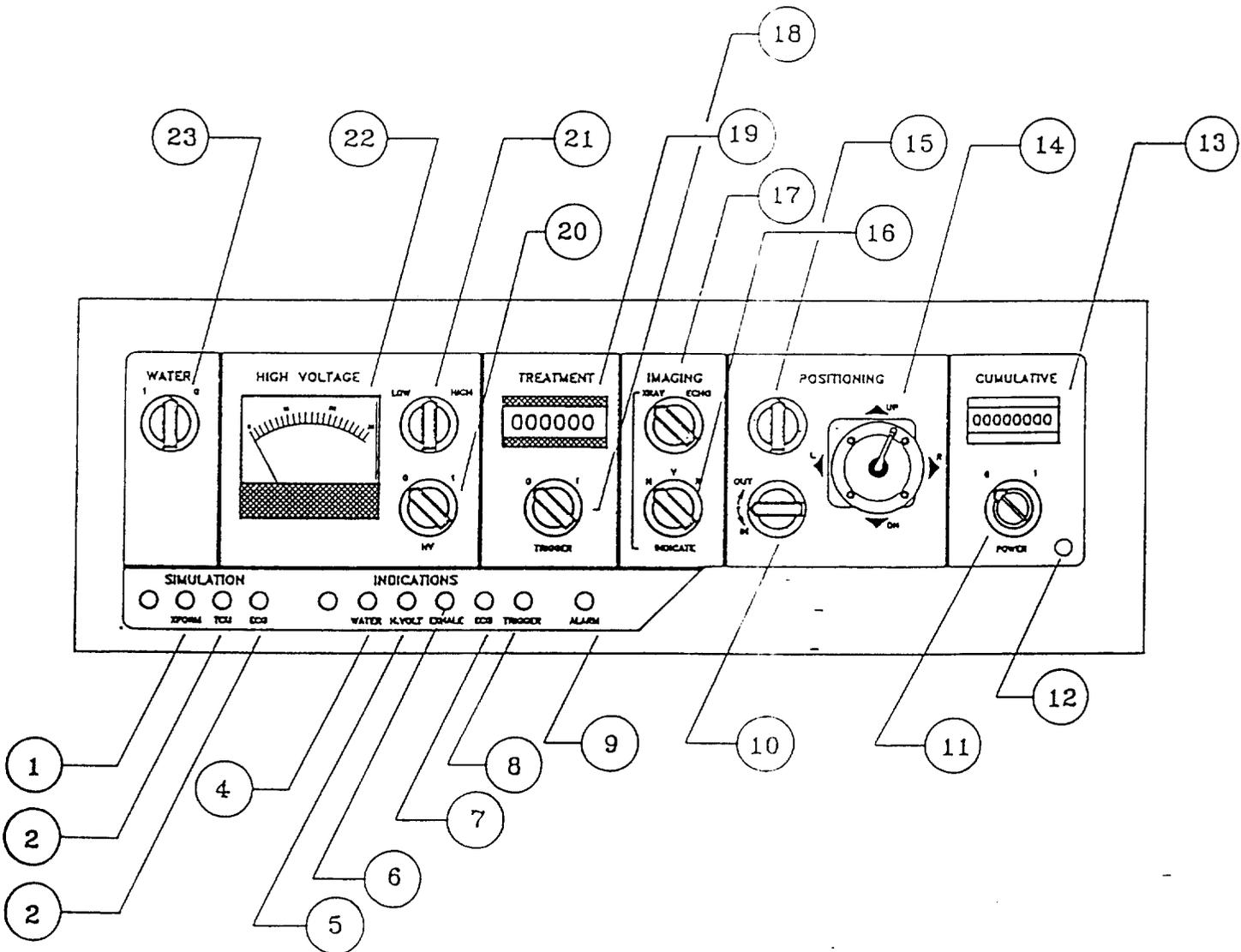


FIGURE 5A: TRIPTER-X1 NOVA TCU FRONT PANEL

- | | |
|-----------------------------------|---|
| 24. HIGH VOLTAGE INDICATOR SWITCH | 30. FUSE |
| 25. ECG FREQUENCY SWITCH | 31. POWER CONNECTOR |
| 26. COMPUTER CONNECTOR (OPTIONAL) | 32. MFT CONNECTOR |
| 27. ECG INPUT CONNECTOR | 33. EXHALE INPUT CONNECTOR |
| 28. POTENTIAL EARTH | 34. ECG EXTERNAL/INTERNAL SIMULATION SWITCH |
| 29. SWAG CABLE CONNECTOR | 35. TCU NORMAL/TEST SIMULATION SWITCH |
| | 36. SWAG/TCU POWER FROM SIMULATION SWITCH. |

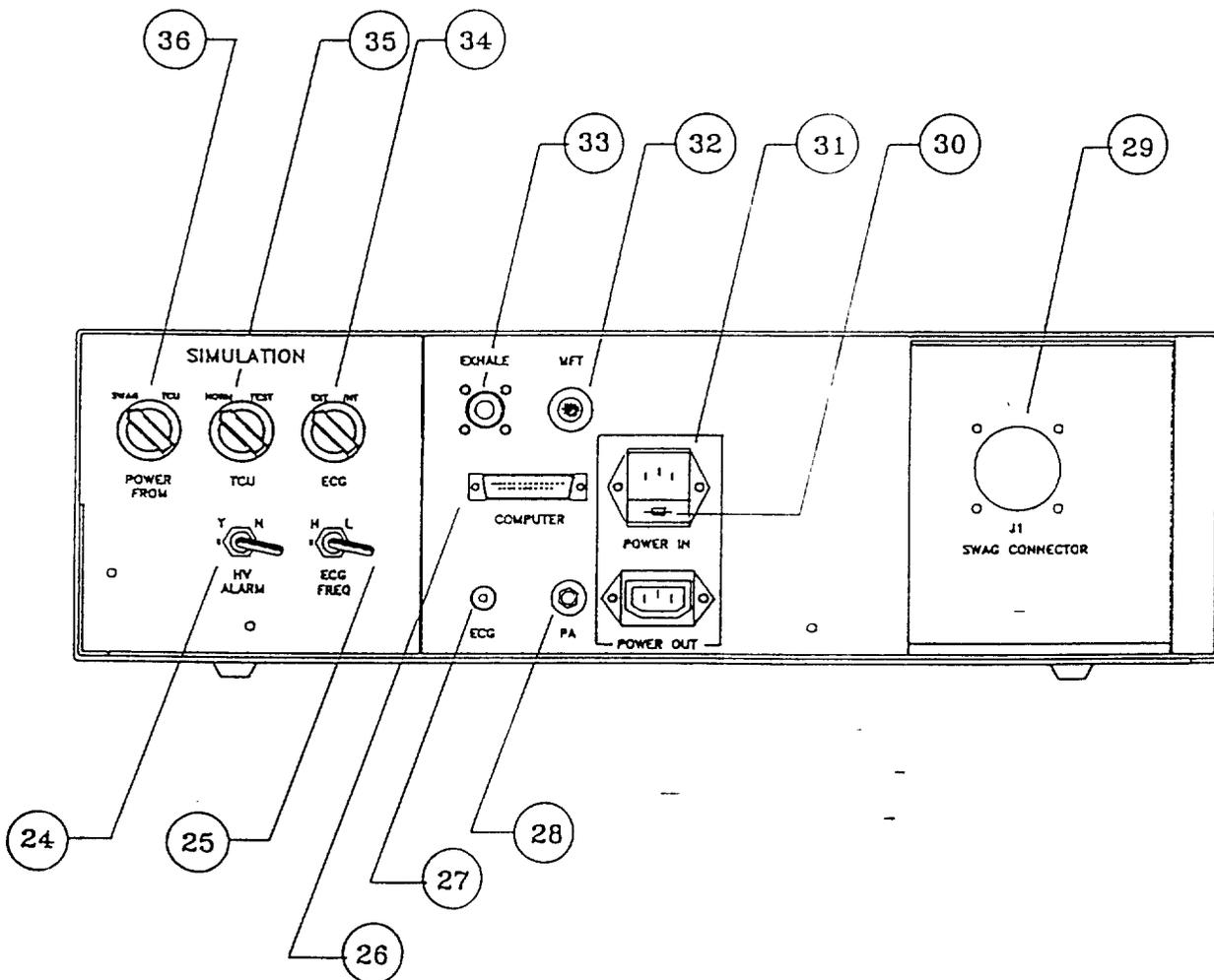
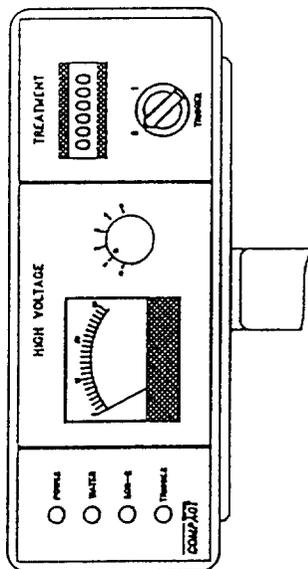
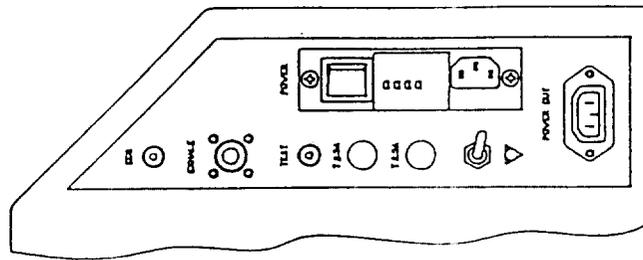


FIGURE 5B : TRIPTER-X1 NOVA TCU REAR PANEL

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FRONT PANEL



REAR PANEL

FIG 6 : TRIPTER-X1 COMPACT FRONT AND REAR CONTROLS PANELS

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/com.000

100

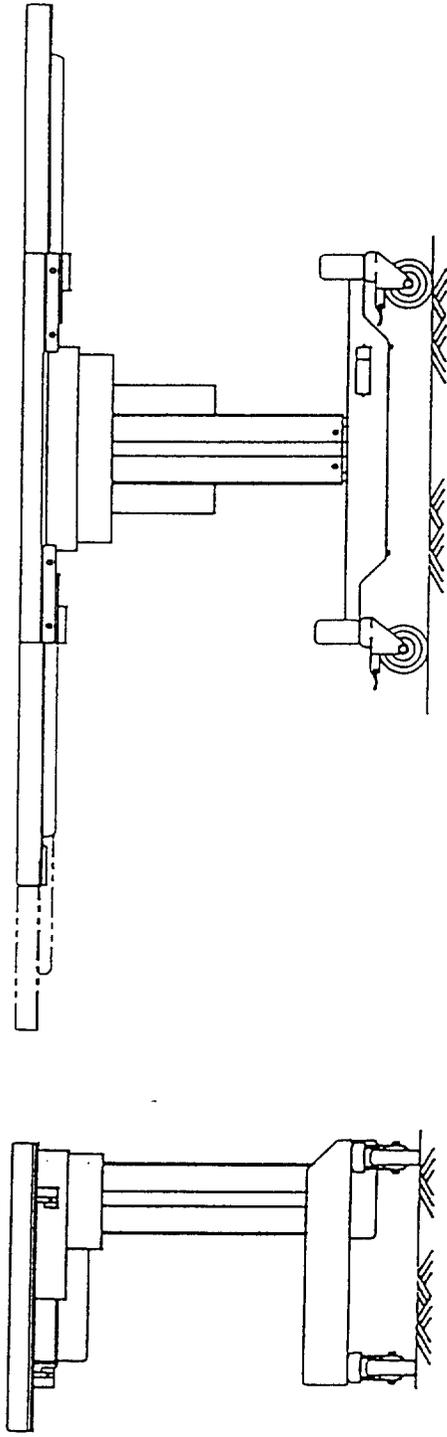
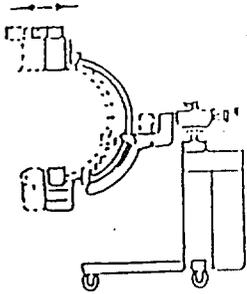
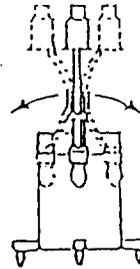


FIGURE 7: THREE DIRECTIONAL FIGURE OF
MOTORIZED FLOATING TREATMENT TABLE (MFT)

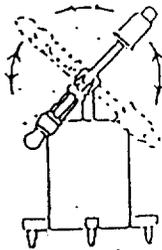
FIGURE 8: TYPICAL C-ARM MOVEMENTS



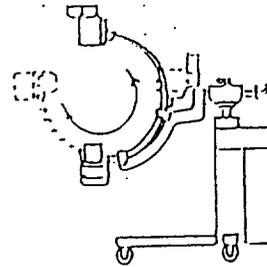
BOOM AXIS
HORIZONTAL MOVEMENT OF 20 CM



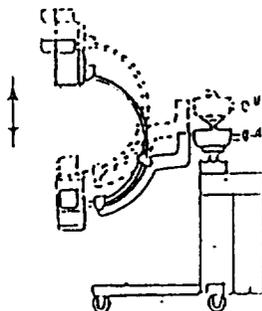
WIG-WAG AXIS
SCANNING IN HORIZONTAL PLANE $\pm 12^\circ$



ROLL AXIS
ROTATION OF THE C-ARM



PITCH AXIS
ORBITAL ROTATION



UP DOWN
VERTICAL TRAVEL MOTORIZED
HEIGHT ADJUSTMENT

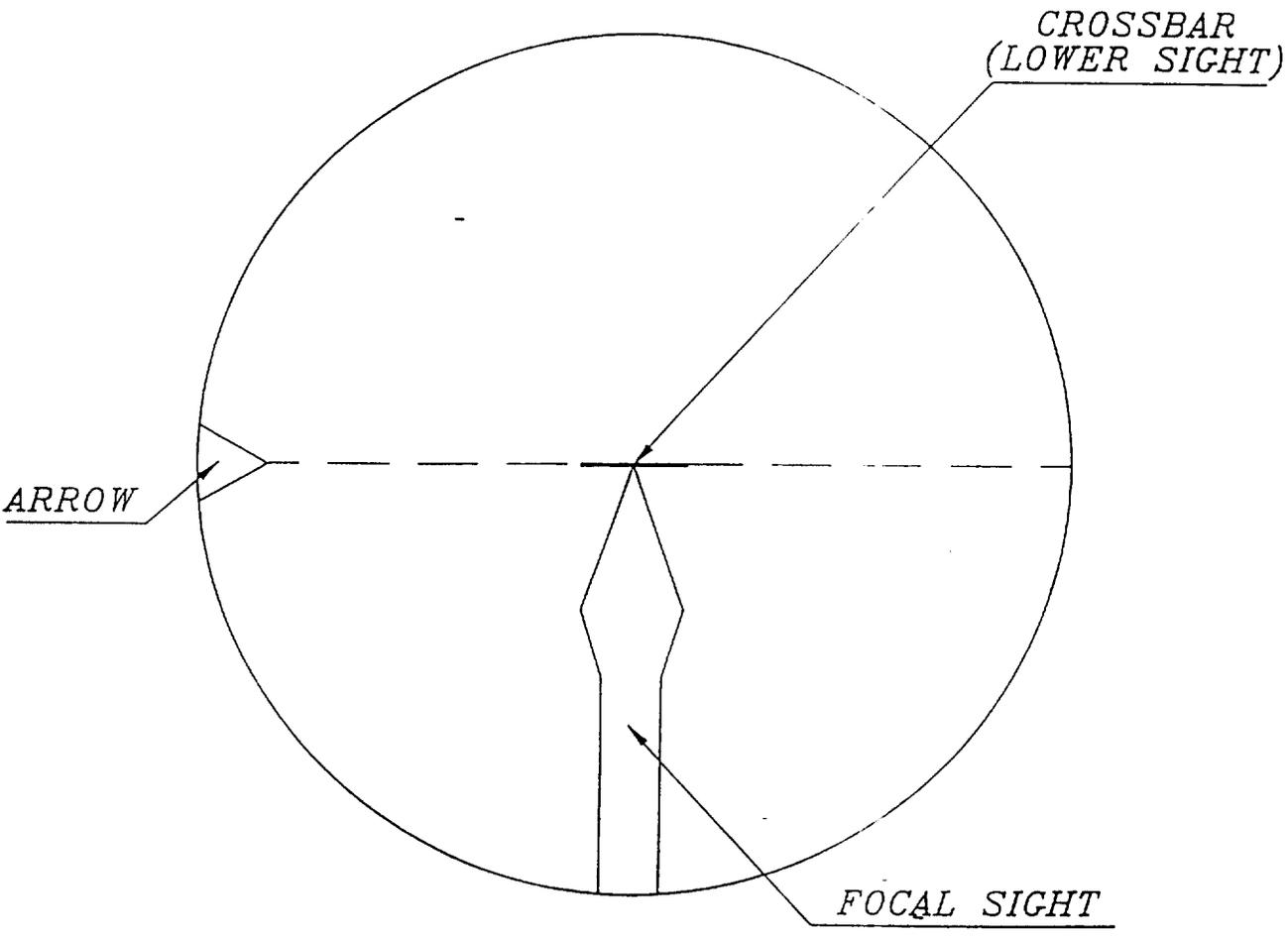
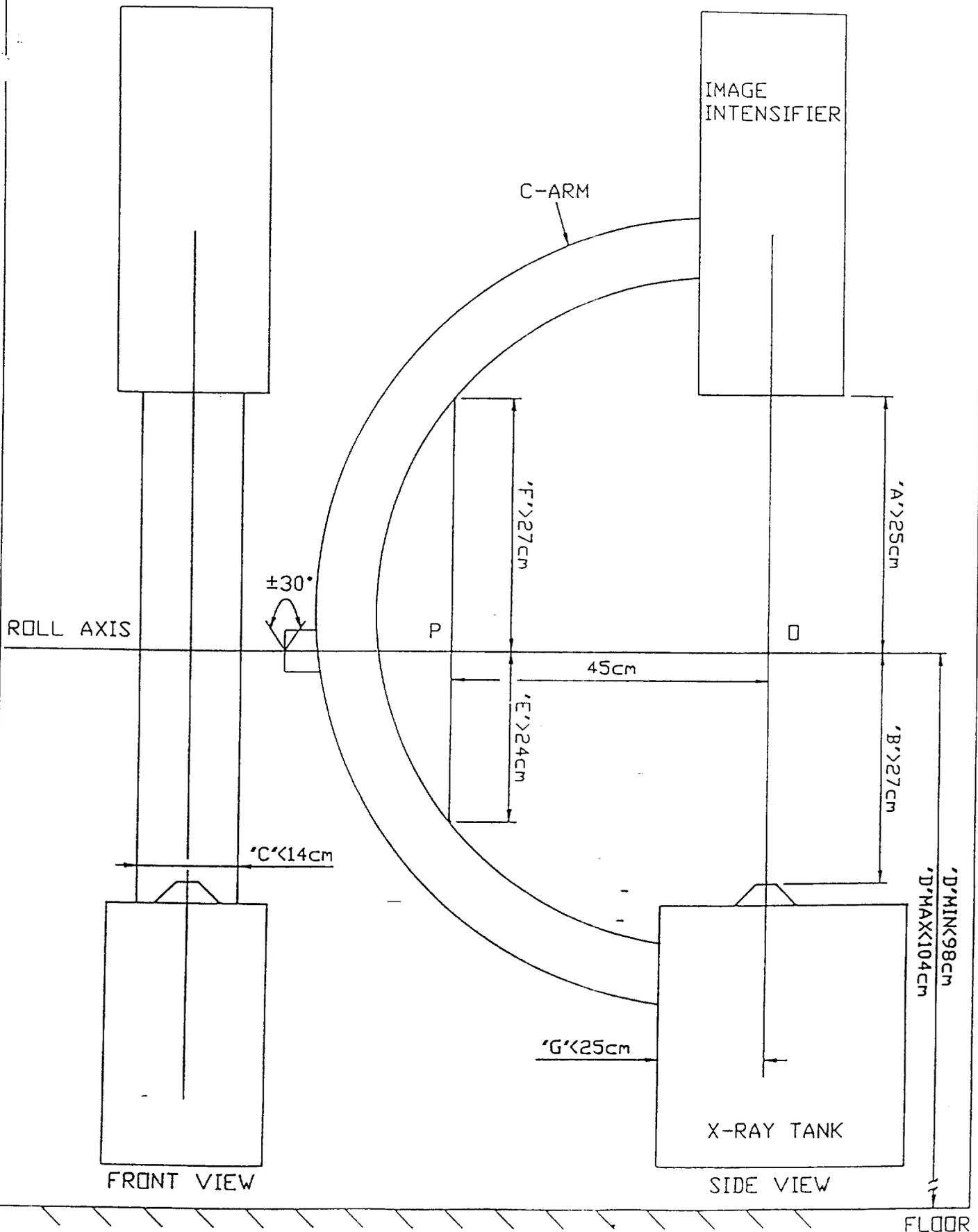


FIG 9: ALIGNMENT SIGHTS AS SEEN ON MONITOR

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FIG 10 : REQUIRMENT FOR FLUOROSCOPY ADAPTABILITY



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