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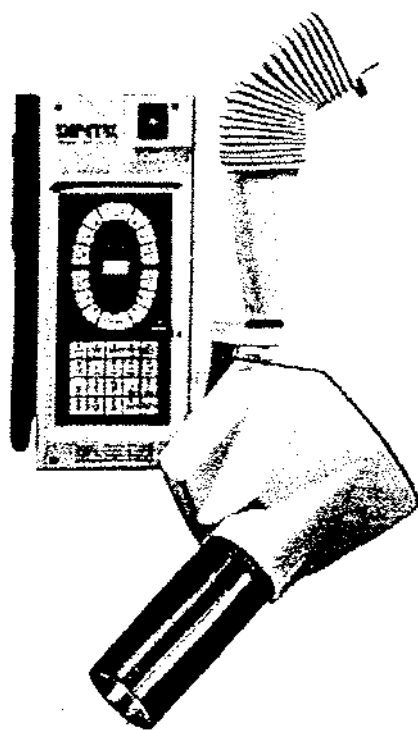


de Götzen's Quality System



*"Developing Excellence Since 1972"*

# image-x70



**Intraoral Diagnostic X-Ray Unit  
 With Anatomical Timer Control**

*The Reason For Change*



## REVISION RECORD

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# ***Introduction***

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## Main Description

The image-x70 System is designed for intra oral radiography. It is manufactured according to the international and U.S. regulations in force relevant to ionizing radiation protection as well as mechanical and electrical safety for electromedical equipment: IEC 601-2-7 (1987) and DHHS 21 CFR Sub Chapter J.

The image-x70 System consists of:

- 1) The image-x70 Tubehead.
- 2) One (1) ea. Long Cone and Short Cone for 12" and 8" S.S.D. respectively.
- 2) The articulating positioning arm with 82.5 cm (32 1/2") extension arm and wall mount.
- 3) The x-mind micro processor controlled console.

## Safety

### General

It is vitally important that everyone associated with X-Ray work be familiar with the recommendations of the Department of Health, National Bureau of Standards, and the National Council on Radiation Protection. The control of diagnostic dental X-Ray equipment varies in detail from state to state. However, in general, all of the states adhere strictly to the established recommendations of the NCRP. It is not practical to list all the relevant recommendations in this manual. Therefore, prior to operation, be sure that all personnel who are authorized to operate the X-Ray system are familiar with the established regulations of the authorities named above. Also, they should be monitored to assure that they conform to the recommendations. Current sources of information include:

*National Council on Radiation Protection Report No. 33 (Medical X-Ray and Gamma Ray Protection for Energies up to 10 MEV -- Equipment Design and Use.*

*National Bureau of Standards Handbook No. 76 (Medical X-Ray Protection up to Three Million Volts) Refer to MCRP Report No. 33.*

*Current recommendations of the International Committee on Radiation Protection.*

Although X-Ray radiation is hazardous, X-Ray equipment does not pose any danger when it is properly used. Be certain that all service and operating personnel be properly informed on the hazards of radiation. Also, those responsible for the system must understand the safety requirements for X-Ray operation. Study this manual for each component in the system to become aware of all the safety and operational requirements.

## Maximum Permissible Dose (MPD)

Various studies of the effects of X-Ray radiation have provided a foundation for establishing the maximum permissible dose (MPD) of X-Ray radiation. The results of these studies have been used by the NCRP and the ICEP to develop recommendations for MPD.

ICRP recommends that the MPD to the most critical organs (heart, lungs, liver, kidney, brain, etc.) accumulated at any age shall not exceed five rems multiplied by the number of years beyond 18:

$MPD = 5 \times (N-18)$  rems  
where N = age in years

However, in no case shall the exposure exceed three (3) rems in any period of 13 consecutive weeks.

For hands, forearms, feet and ankles, the recommended MPD is 75 rems in any one year.

## WARNINGS

### Manufacturer's Liability

As a manufacturer of electro-medical products, we can assure responsibility for safety-related performance of the equipment only if:

- 1) Assembly, calibration, modification, maintenance and repairs are carried out only by us or people we have authorized for this purpose.
- 2) The electrical installation is in compliance with I.E.C. standards.
- 3) The unit is used in accordance with the instructions.

Performance related to electric and electronic circuits as well as mechanical parts have to be carried out by agents authorized by the manufacturer only, under penalty of immediate revocation of manufacturer liability and warranty.

Although this equipment incorporates protection against X-Ray radiation other than the useful beam, practical design cannot provide complete protection. Equipment design does not compel the operator or his assistants to take adequate precautions, nor does it prevent the possibility of improper use which results in authorized or unauthorized persons from carelessly, unwisely or

## Manufacturer's Liability, (Cont'd)

unknowingly exposing themselves or others to direct or secondary radiation. Allow only authorized, properly trained personnel to operate this equipment. This equipment is sold with the understanding that DENT-X, its agents and representatives, do not accept any responsibility for over exposure of patients or personnel to X-Ray radiation.

No responsibility will be assumed for any machine that has not been serviced and maintained in accordance with the system manual, or which has been modified or tampered with in any way.

## Radiation Protection

Because exposure to X-Ray radiation may be damaging to health, use great care to provide protection against exposure to the primary beam. Some of the effects of X-Ray radiation are cumulative and may extend over a period of months or years. The best safety rule for X-Ray Operators is, ***avoid exposure to the primary beam at all times.***

Any object in the path of the primary beam produces secondary (scattered) radiation. The intensity of the secondary radiation is dependent upon the energy and intensity of the primary beam and on the atomic number for the object or material struck by the primary beam. Secondary radiation may be of greater intensity than that of the radiation reaching the film. Take protective measurements to safeguard against it.

An effective protective measure is the use of lead shielding. To minimize dangerous exposure, use such items as movable lead screens, lead impregnated gloves and lead impregnated aprons. These protective devices must contain a minimum of 0.25 millimeter thickness of lead or equivalent. Use such protective devices for all personnel exposed to radiation fields of 5 milliRoentgens per hour or more.

### **WARNING**

**WHILE SERVICING OR OPERATING X-RAY EQUIPMENT, DO NOT EXPOSE HANDS, WRISTS, ARMS OR OTHER PARTS OF THE BODY TO THE PRIMARY BEAM.**

## Monitoring of Personnel

Monitoring of personnel to determine the amount of radiation to which they have been exposed provides a valuable cross check to determine whether or not safety measures are adequate. It may reveal inadequate or improper radiation protection practices and potentially serious radiation exposure situations. The most effective method of determining whether or not the existing protective measures are adequate is the use of instruments to measure the exposure in rads. This measurement should be taken at all locations where the operator, or any portion of his/her body may be during exposure. Exposure must never exceed the accepted tolerable dose.

A frequently used, but less accurate, method of determining the amount of exposure is the placement of film at strategic locations. After a specified period of time, develop the film to determine the amount of radiation. Fluorescent screens (used in a darkened room) may also be used to detect excessive radiation.

A common method of determining whether personnel have been exposed to excessive radiation is the use of film badges. These are x-ray sensitive film enclosed in a badge which incorporates metal filters of varying degrees of transparency to x-ray radiation. Even though this device only measures the radiation which reaches the area of the body on which it is worn, it does furnish an indication of the amount of radiation received.

## CDRH Compliance

The DENT-X Corporation image-x70 intraoral X-Ray system complies with Department of Health and Human Services Radiation performance standards per *Title 21 CFR, Chapter 1, Subchapter J, Section 1020*.

Underwriters' Laboratory (UL) listing is pending.

Certified components covered by this manual are listed below:

Tube Housing Assembly	IX70-THA
X-Ray High Voltage Generator	IX70-THU
X-Ray Control	x-mind
Beam Limiting Device (31 cm...12" SSD)	BLD31
Beam Limiting Device (20 cm....8" SSD)	BLD20

## Warranty

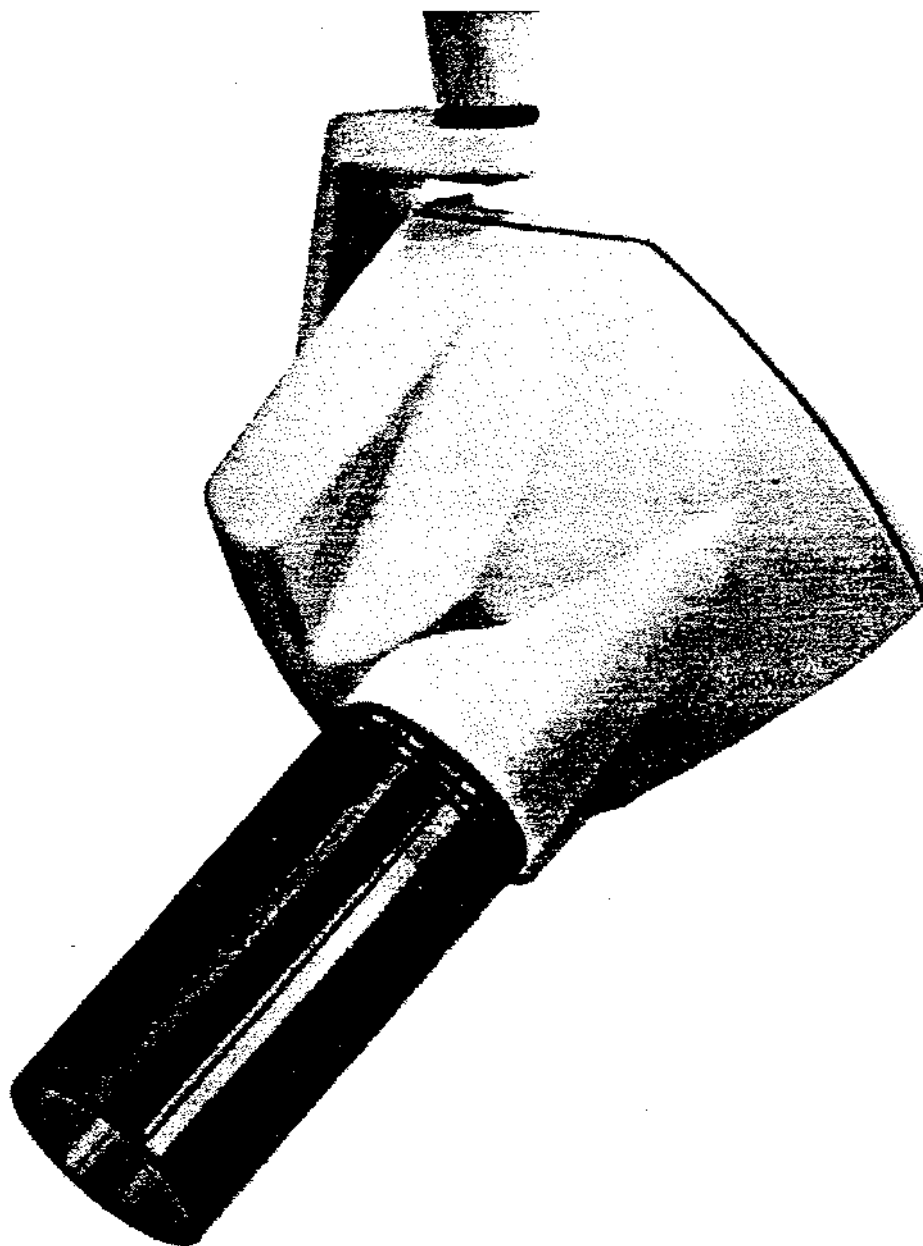
- 1) Damage incurred due to improper wiring or connections are excluded.
- 2) The installation must be carried out by authorized personnel.
- 3) The installation must be completed in accordance with the diagrams supplied by the manufacturer.
- 4) The neutral wire, even if grounded, cannot be used for protection.

**Important:** An electrical source must be provided with + or - 10% regulation which includes a fuse or circuit breaker rated for 120 VAC, 20 Amps.

# ***Tubehead***

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Tubehead



# Tubehead

## Description

The image x-70 tubehead is an integrated design, constructed of die-cast aluminum. It is painted with age resistant and antiabrasion dry epoxy.

Two beam limiting devices for the primary X-Ray beam are designed for two stage collimation.

The indestructible makrolon cones adapt to every type of centering situation. The degree of angle displayed in the window of the articulating support arm, together with the infinite degree of rotation around the vertical axis (as made possible by the electrical concentric pin), provide for perfect positioning every time regardless of what diagnostic technique is used.

Technological innovations allow for recessing of the tube, which makes possible a source to skin distance of 31 cm, (12") or 20 cm, (8") while utilizing a cone of only 20 cm, (8") or 10 cm, (4") of actual length respectively. This helps maximize the use of internal shielding for protection while providing a more compact design. Filtration of the central beam is via a pure aluminum window.

The 70 kV, 8mA output together with a small focal spot of .7mm provides for superior grey scale gradations on the radiograph.

Leakage radiation is extremely low @ less than 28mR/hour at a distance of one meter.

The image x-70 tubehead together with the x-mind timer make use of the smooth and balanced movement of the articulating extension and positioning arms for comfort and increased ergonomics.

## Bisecting Angle and Paralleling Techniques

With the short cone (20 cm - 8 inch S.S.D.) installed, swivel the tubehead so that the central X-Ray beam is perpendicular to the tooth/film bisecting angle (bisecting technique).

With the long cone (31 cm - 12 inch S.S.D.) installed, swivel the tubehead so that the central X-Ray beam is perpendicular to the film (paralleling technique).

## Contrast

To increase the contrast (obtain a clearer image of appliances, amalgams, etc.), reduce the exposure.

To decrease the contrast (obtain more overall density), increase the exposure.

## Technical Data - 115VAC/60Hz

### Dental X-Ray Equipment with Grid Circuit

CLASSIFICATION:	Electromedical Equipment. Class 1, Type B.
LINE VOLTAGE:	Single-Phase AC @ 115 Volts
FREQUENCY:	60 Hz
ABSORBED POWER AT 115V:	1320 VA
RESISTANCE OF THE LINE:	.34 $\Omega$
MAINS FUSE (F3):	8A, 250V, 5 X 20 mm, Fast Blow
TUBEHEAD FUSES:	
X-RAY 2 (F1)	8A, 250V, 5 X 20 mm, Fast Blow.
X-RAY 1 (F2)	8A, 250V, 5 X 20 mm, Fast Blow.
FUSE PROTECTION FOR THE ELECTRONICS:	F5 - .63A, 125V axial mini-fuse F6 - .5A, 125V axial mini-fuse (Both fuses are placed on the secondaries of the timer transformer.)
X-RAY TUBE:	Toshiba DG-073B
HIGH VOLTAGE:	70KV (With mains voltage fluctuations of + or - 5%, high voltage fluctuations will be + or - 9%)
ANODE CURRENT:	8 mA
GENERATOR ACTIVE POWER:	0.415 kW
FOCAL SPOT:	0.7mm
TUBE INHERENT FILTRATION:	Equivalent to 0.8mm Al
TOTAL FILTRATION:	Equivalent to 2.5mm Al
RADIATION LEAKAGE:	Less than 28 mR/hour maximum allowed at a distance of 1 meter from the focal spot.
DUTY CYCLE:	1:32 - (32 seconds of cooling time required for every second of exposure.)

## Technical Data - 220VAC/50/60Hz

### Dental X-Ray Equipment with Grid Circuit

CLASSIFICATION:	Electromedical Equipment. Class 1, Type B.
LINE VOLTAGE:	Single-Phase AC @ 220 Volts
FREQUENCY:	60/50 Hz
ABSORBED POWER AT 220V:	720 VA
RESISTANCE OF THE LINE:	.5 $\Omega$
MAINS FUSE (F3):	5A, 250V, 5 X 20 mm, Fast Blow
TUBEHEAD FUSES:	
X-RAY 2 (F1)	5A, 250V, 5 X 20 mm, Fast Blow.
X-RAY 1 (F2)	5A, 250V, 5 X 20 mm, Fast Blow.
FUSE PROTECTION FOR THE ELECTRONICS:	F5 - .63A, 125V axial mini-fuse F6 - .5A, 125V axial mini-fuse (Both fuses are placed on the secondaries of the timer transformer.)
X-RAY TUBE:	Toshiba DG-073B
HIGH VOLTAGE:	70KV (With mains voltage fluctuations of + or - 5%, high voltage fluctuations will be + or - 9%)
ANODE CURRENT:	8 mA
GENERATOR ACTIVE POWER:	0.415 kW
FOCAL SPOT:	0.7mm
TUBE INHERENT FILTRATION:	Equivalent to 0.8mm Al
TOTAL FILTRATION:	Equivalent to 2.5mm Al
RADIATION LEAKAGE:	Less than 28 mR/hour maximum allowed at a distance of 1 meter from the focal spot.
DUTY CYCLE:	1:32 - (32 seconds of cooling time required for every second of exposure.)

**Technical Data  
(Cont'd), - 115/220VAC**

<p><b>COLLIMATOR:</b></p> <p style="padding-left: 40px;">long cone:</p> <p style="padding-left: 40px;">short cone:</p>	<p>A cylinder with double lead (Pb) diaphragms for 2-stage collimation.</p> <p>Focus to cylinder tip distance = 31 cm (12")</p> <p>Focus to cylinder tip distance = 20 cm (8")</p>
<p><b>IRRADIATED FIELD AT THE SKIN:</b></p>	<p>6 cm (2 3/8") diameter</p>
<p><b>WEIGHT:</b></p>	<p>8 Kg (17.6 Lbs)</p>
<p><b>GENERATING CIRCUIT:</b></p>	<p>Single-phase self-rectifying</p>
<p><b>TIMER:</b> (See page 4-3 for information on taking exposures for digital radiography)</p>	<p>Regular exposure time adjustable from .08 to 3.2 seconds, deferred for a preheating time of 0.15 seconds (50Hz) or 0.13 seconds (60 Hz). Digital exposure time available as 1, 2, or 3 pulses. Accuracy: 4ms. @ microprocessor</p>
<p><b>SPECIFIC CONFORMITY RANGE:</b></p>	<p>Long Cone: From 0.16 seconds to 3.2 seconds (full range)</p> <p>Short Cone: From 0.08 seconds to 1.6 seconds</p>
<p><b>X-RAY EMISSION CONTROL:</b></p>	<p>A "Dead Man" switch is provided with a 9' coiled cable.</p>
<p><b>ENVIRONMENTAL CONDITIONS:</b></p>	
<p style="padding-left: 40px;"><b>TEMPERATURE:</b></p>	<p>Between 15°C (59° F) and 35°C (95° F)</p>
<p style="padding-left: 40px;"><b>RELATIVE HUMIDITY:</b></p>	<p>Between 30% and 75%</p>
<p style="padding-left: 40px;"><b>ATMOSPHERIC PRESSURE:</b></p>	<p>Between 700mbar and 1060 mbar</p>



**ATTENTION!**

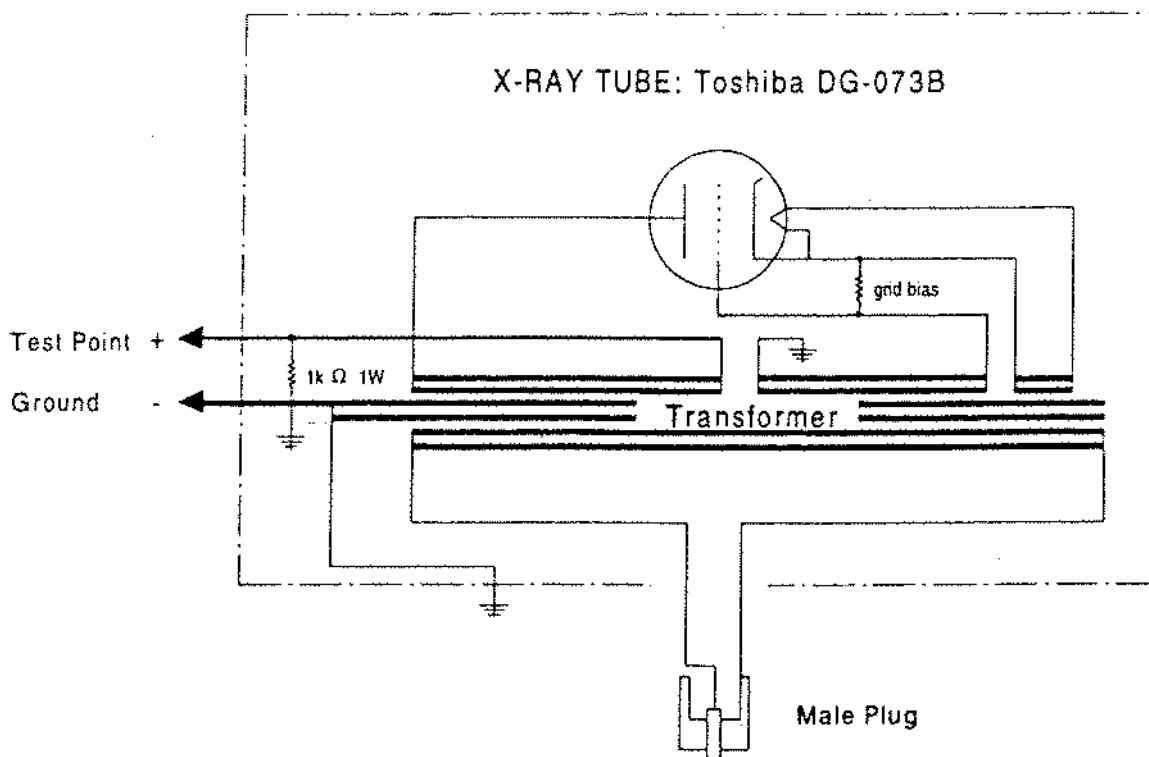
This X-Ray unit could be dangerous for the patient and the operator as well if the instructions are not strictly observed.

The use of this unit should be limited to authorized personnel only.

Make certain that the small ventilation hole on the rear panel of the tubehead is not blocked.

Not to be operated in environments having a risk of explosion, temperature extremes, or pressure.

CLEANING AND DISINFECTING: The tubehead and collimators may be cleaned with warm water and mild detergent (optional), using a soft cloth. Disinfect with a disinfectant such as "Cavicide" or equivalent. Take care not to get any of these on the X-Ray port.

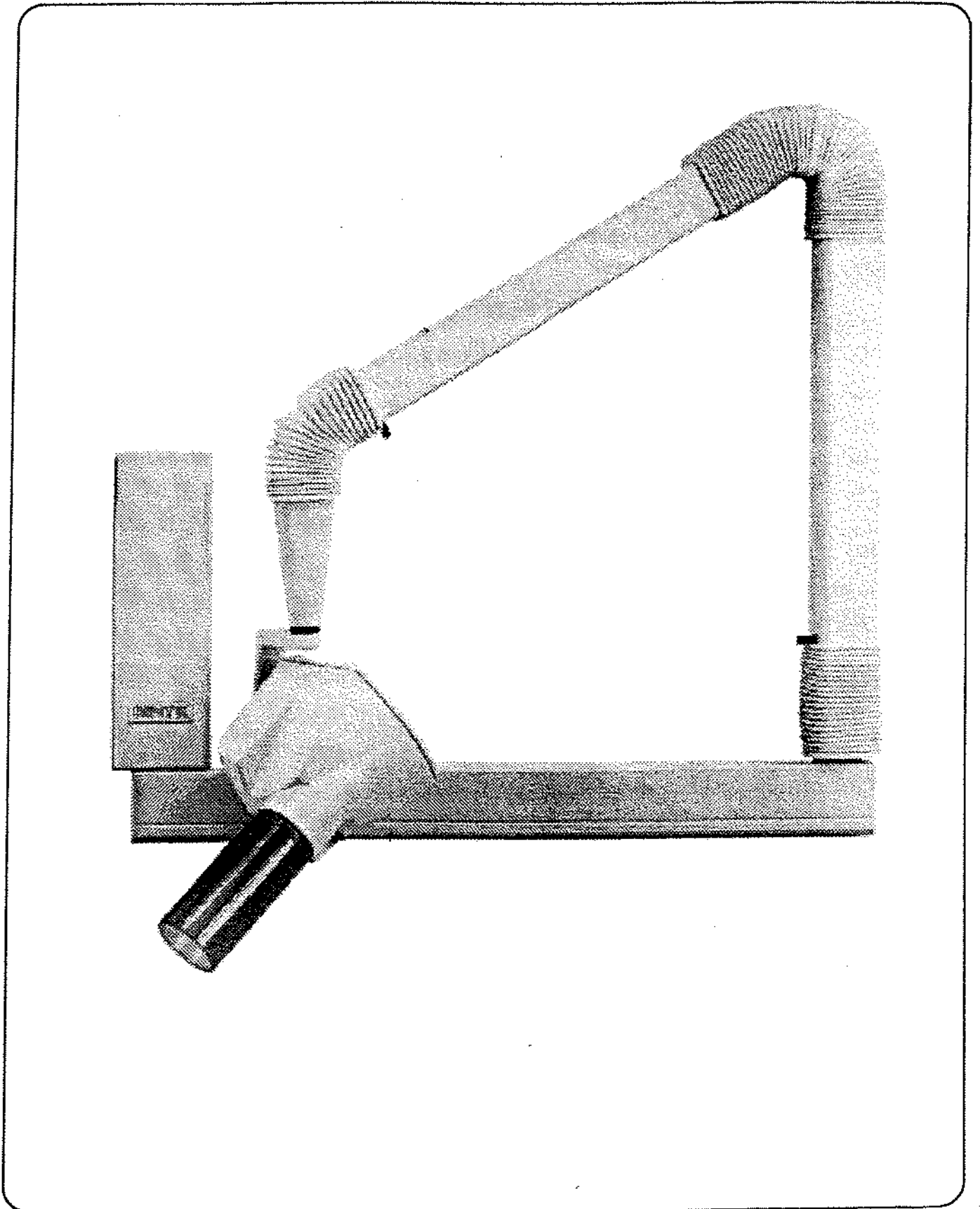


*Tubehead Schematic*

# ***Articulating Arm***

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Articulating Arm



## Description

The unique design of the articulating arm allows a wide range of movement. It can be adjusted for height and depth and assures you smooth, accurate and firm control for positioning the tubehead for all procedures. It is manufactured under strict quality guidelines and is in compliance with international regulations regarding mechanical and electrical safety.

The **positioning** and **extension arms** are corrosion proof with a scratch resistant electrostatic epoxy powder coating and plastic coverings.

The unit is designed to be wall mounted by means of a **wall mount bracket** with **extension arms** available in three different sizes. (See listings below) The wall mount bracket is provided with electrical terminals to insure quick and easy installation while complying to local electrical codes.

Short (Optional) Extension Arm: 41cm.

Standard Extension Arm: 82.5 cm.

Long (Optional) Extension Arm: 110 cm.

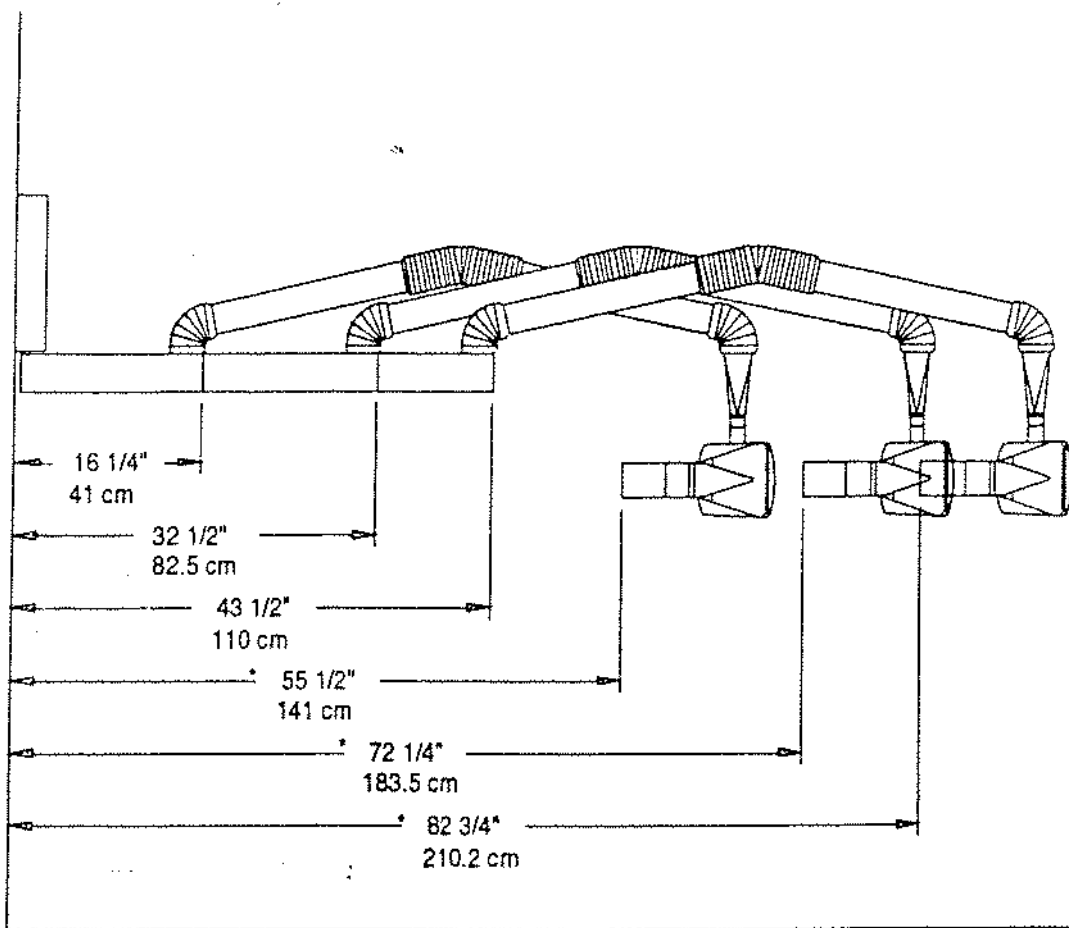
(See Figure 1, page 3-3)

## Preparation for Installation

Choose a location in your work space that will provide the widest range of movement. The wall mount bracket to which the extension and positioning arms will mount should be mounted on the wall central to the above area. Considerations should include clearance from any obstruction either in the extended or stored position. Refer to the **Installation Specifications** and other drawings in the **Illustrations** section of this manual before proceeding.

To avoid cable twisting, the 82.5 cm and 110 cm extension arms are provided with an anti-rotation retainer. This retainer is mounted on the top of the extension arm in a way that allows a stored position to the right of the wall plate. If storage is desired to the left of the wall plate, rotate the retainer 180 degrees.  
(See figure 2, page 3-5)

SIDE VIEW



WALL

\* ADD 4" (10cm) FOR  
8" S.S.D. CONE

Figure 1

## Preparation for Installation, Continued:

Figure 2a shows the unit in a stored position to the right of the wall mount bracket.

Figure 2b shows the position of the retainer for storing the unit to the right side.

Figure 2c shows the unit in a stored position to the left of the wall mount bracket.

Figure 2d shows the retainer rotated 180 degrees for storing the unit to the left side.

## Mounting Instructions

After determining the exact location of the wall mount bracket, proceed as follows:

(refer to figure 3, page 3-6)

Position the cardboard template so the bottom of the wall bracket is located 51 inches (130 cm) above the floor. Tape the template to the wall and mark where the holes are to be drilled. If an additional hole is needed for the incoming line from the timer, (top center of the template), mark it at this time. Make sure that the holes for the mounting bolts are exactly perpendicular to the floor. This is best done with a plumb line.

It is best to start with a 7 mm (1/4") drill and gradually increase in size to 12 mm (<1/2") to avoid breaking up the drywall or plaster, and to maintain the accuracy of the positioning. The 12 mm mollies that are provided are for installations on a wall made of concrete, concrete blocks, or brick.

Once the holes have been made, remove the template (Item 1), insert the mollies (Item 2), and remove the cap and sliding cover (Items 3 & 7). Make sure the ground wire to the sliding cover remains intact.

Move the bracket (Item 4) into position and insert the bolts and washers (Items 6 & 5). **It is important for the wall to be absolutely flat against the plate.** If it is not, insert washers in the appropriate areas to fill in any spaces. Tighten the bolts a little at a time, alternating among them to keep the tension even over the entire plate.

**Do not use plastic mollies for the installation.**

**At this point, make sure the power supply is turned off.**

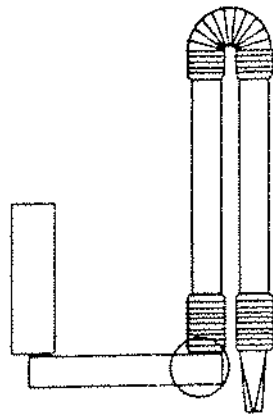


Fig. 2a

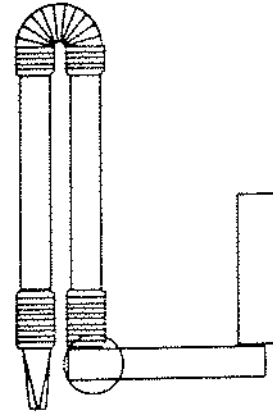


Fig. 2c

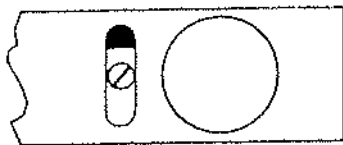


Fig. 2b

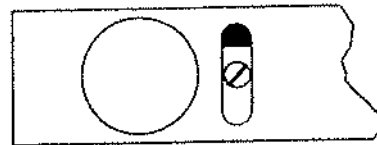


Fig. 2d

Figure 2