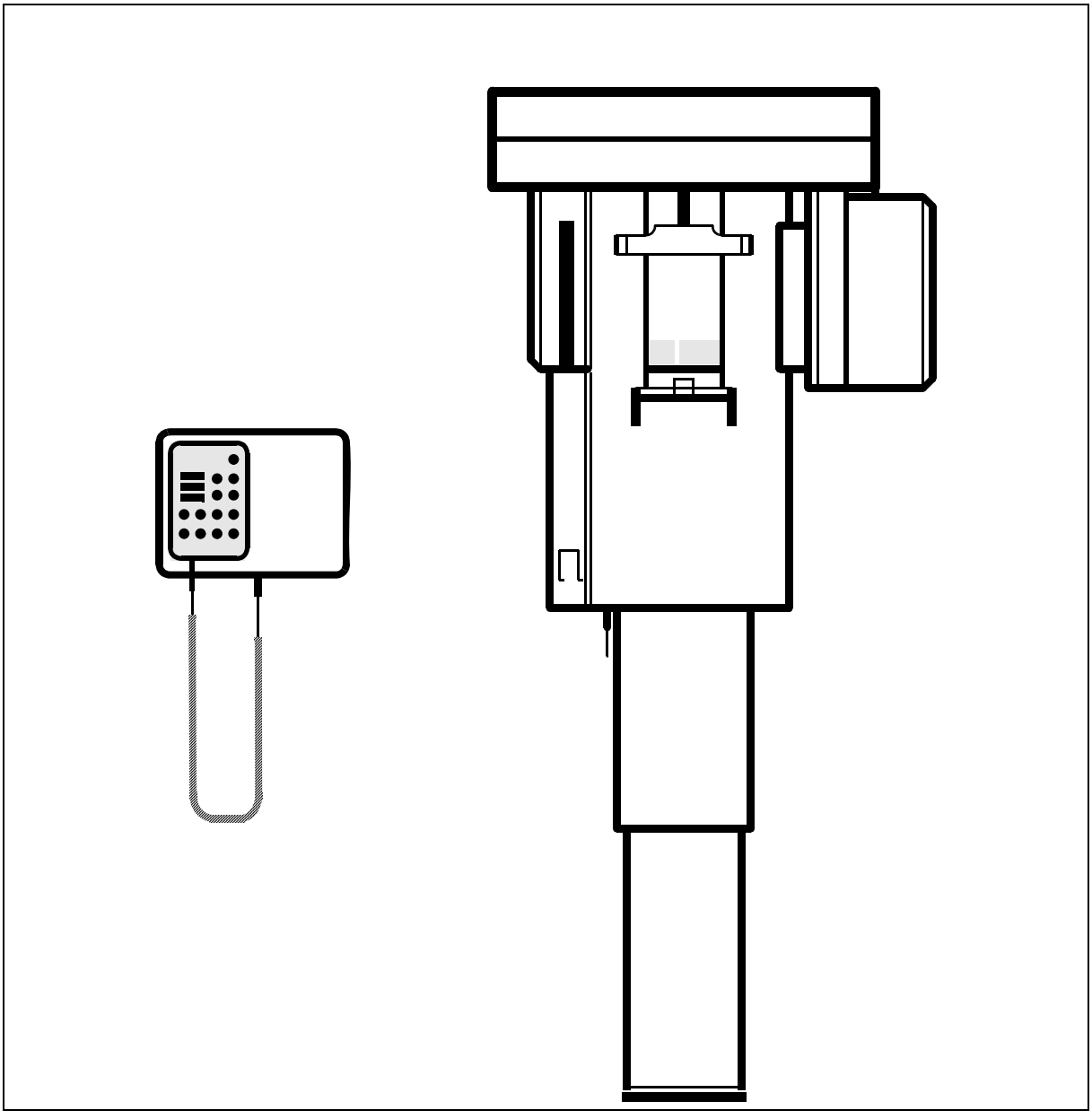
New since: 11.2005

sirona
The Dental Company

ORTHOPHOS Plus

Installation Instructions

English



ATTENTION

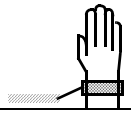
Interference with electromedical devices by radio telephones:
To guarantee the operational safety of electromedical devices, the operation of mobile radio telephones in the medical practice or hospital area is prohibited.

ATTENTION

When opening the equipment:
Please observe the safety measures for handling PC boards. Touch a ground point to remove any personal electrostatic charge before touching the components.

ATTENTION

Use an ESD arm band.
Connect this with the protective ground wire.



New since: 11.2005

Modification compared with last edition: 11.2001

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6 Remote Control 12

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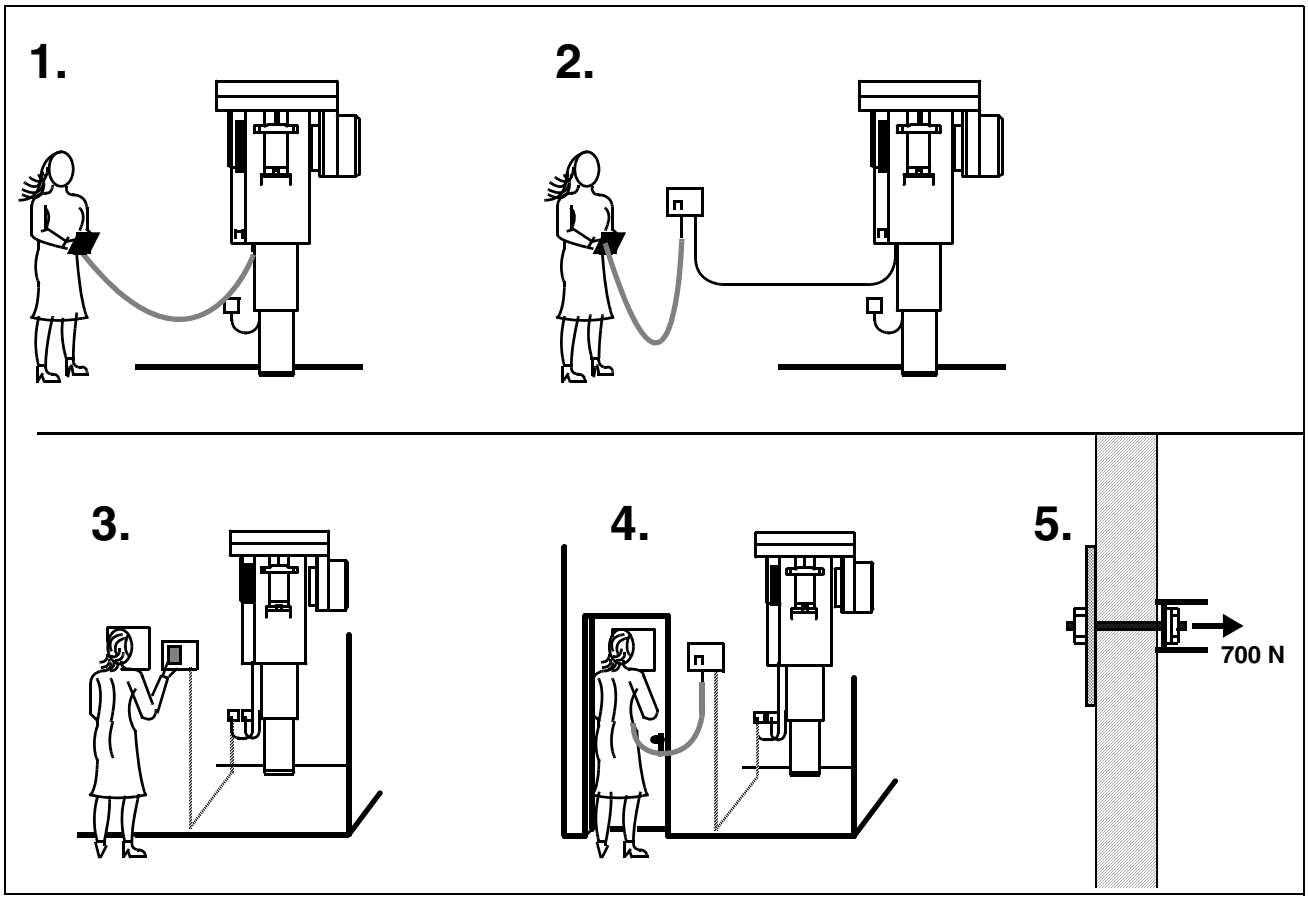
1 Possibilities of Installation



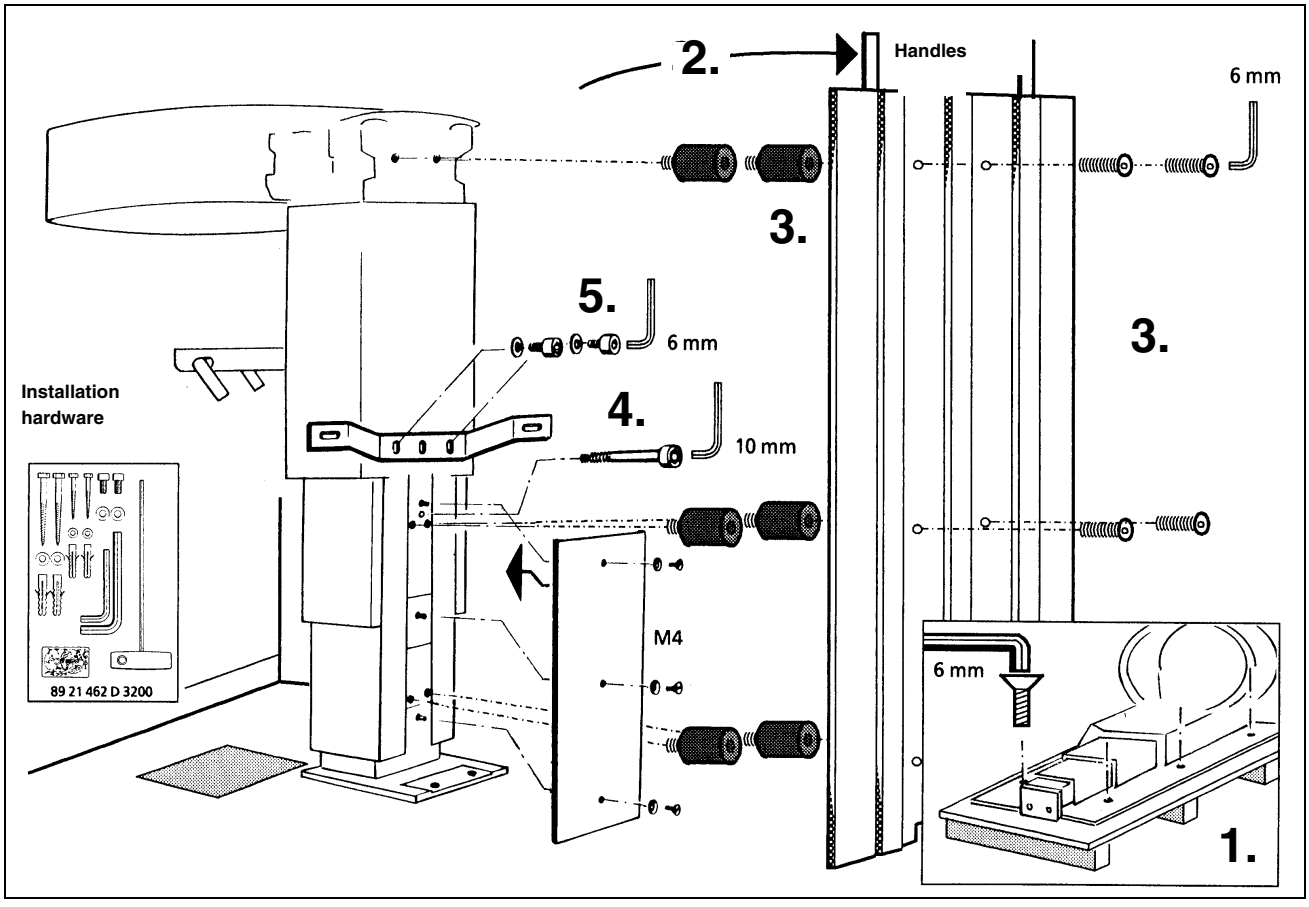
1. ORTHOPHOS® Plus **without** remote control in the treatment room.
2. ORTHOPHOS Plus **with** remote control in the treatment room.
   Length of supplied special control cable about 15 meters (591”/49 feet).
3. ORTHOPHOS Plus with remote control outside of X-ray room, **without coiled cable** at the Multitimer control unit.
   Length of supplied control cable about 15 meters (591”/49 feet).
4. ORTHOPHOS Plus with remote control outside of X-ray room, **with coiled cable** at the Multitimer control unit.
   Length of supplied control cable about 15 meters (591”/49 feet).

ATTENTION

Each wall plug must withstand a pull of 700 N (70 kp/155pounds).

Depending on the construction of the wall, suitable special wall plugs must be obtained or an anchor plate made.

2 Installing the Unit



NOTE

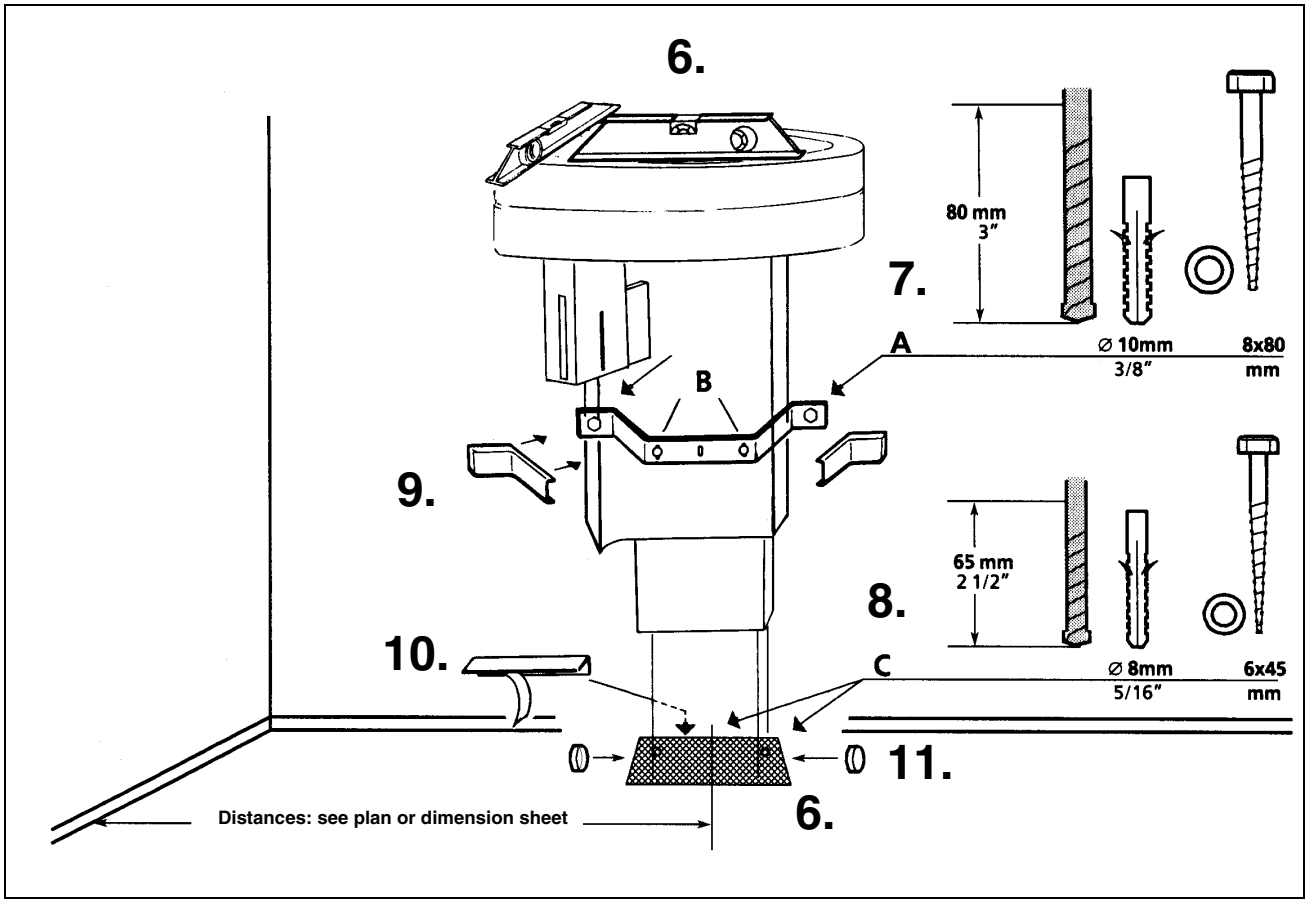
The power and control cables[1] must have a play of at least 0.75 m vertically behind the column, so that system motion during operation is unhindered.

ATTENTION

Screw down the red transportation stabilization screw with the unit in vertical position before removing the unit from the wall!

1. Separate unit with carrying plate and handles from the transport palette by removing the six screws.
2. Move the carrying plate close to the installation location and set it up.
   CAUTION: Use only the **handles of the carrying plate.**
3. Unscrew the carrying plate and vibration buffer.
4. Unscrew the red transportation stabilization screw from the back (keep with **Adjustment Set**).
   Connect the cover with three M4 countersunk screws.
   Use the enclosed Allen wrench.
5. Attach the wall spacer with two M8 Allen screws and washers, but do not screw tightly yet.

1. Control cable for remote control only.



- Note the information on wall condition on page 5.

6. Move the unit to the desired location taking hold of the unit **only** at the rotation ring **and/or column.**
Align it vertically **for both sides** with a water balance on the rotation ring.

7. Mark two holes **A** and drill holes.
Insert dowels.
Connect the unit with screws, and recheck alignment with the water balance. Then tighten screws **A** and **B**.

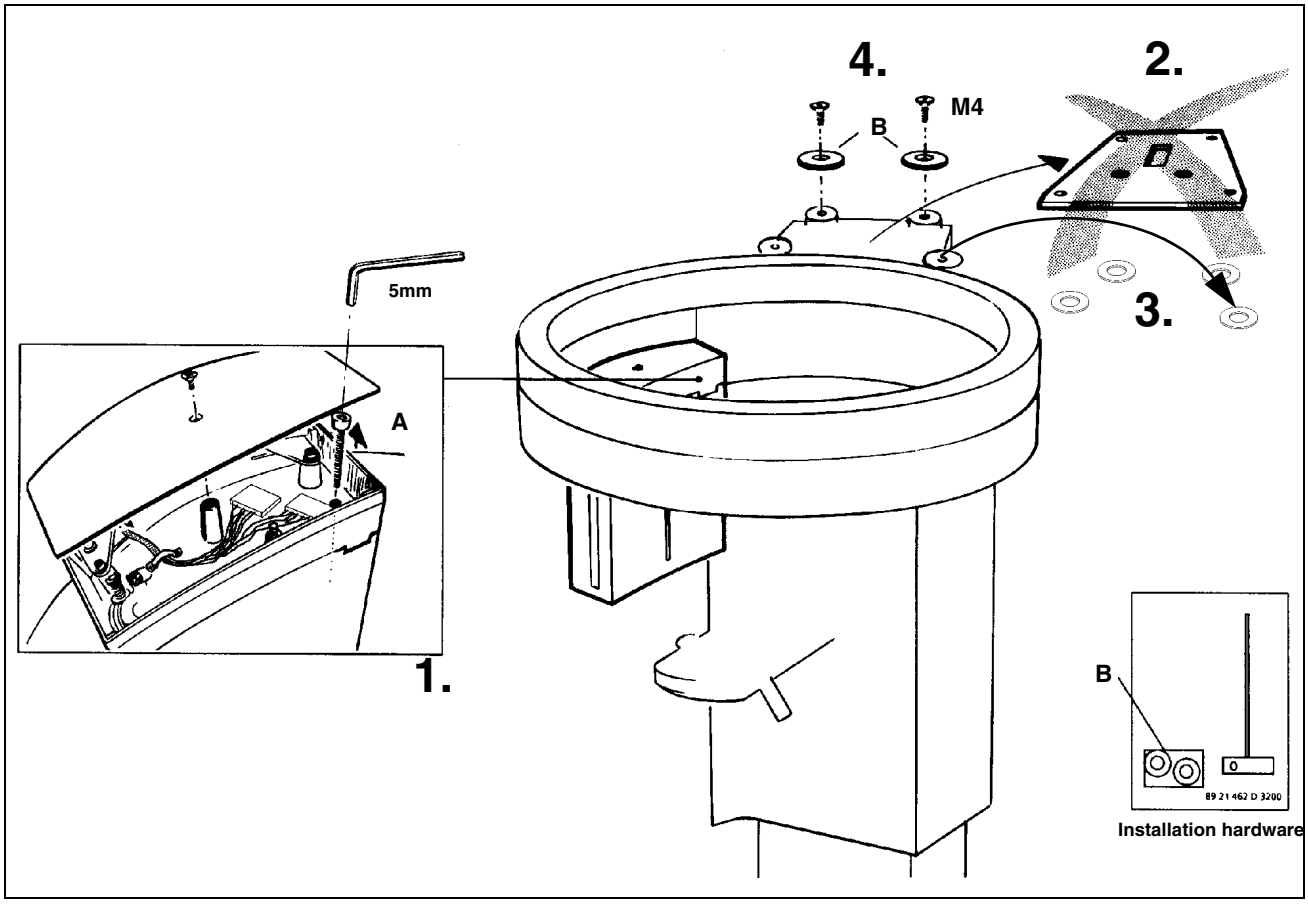
8. Drill fixing holes **C** through the floor cover. Insert dowels.
Tighten the unit.

9. Place the two covers on the wall spacer.

10. Remove the protective cover of the adhesive tape on the floor plate cover. Place the floor plate cover on the floor plate and press down tightly.

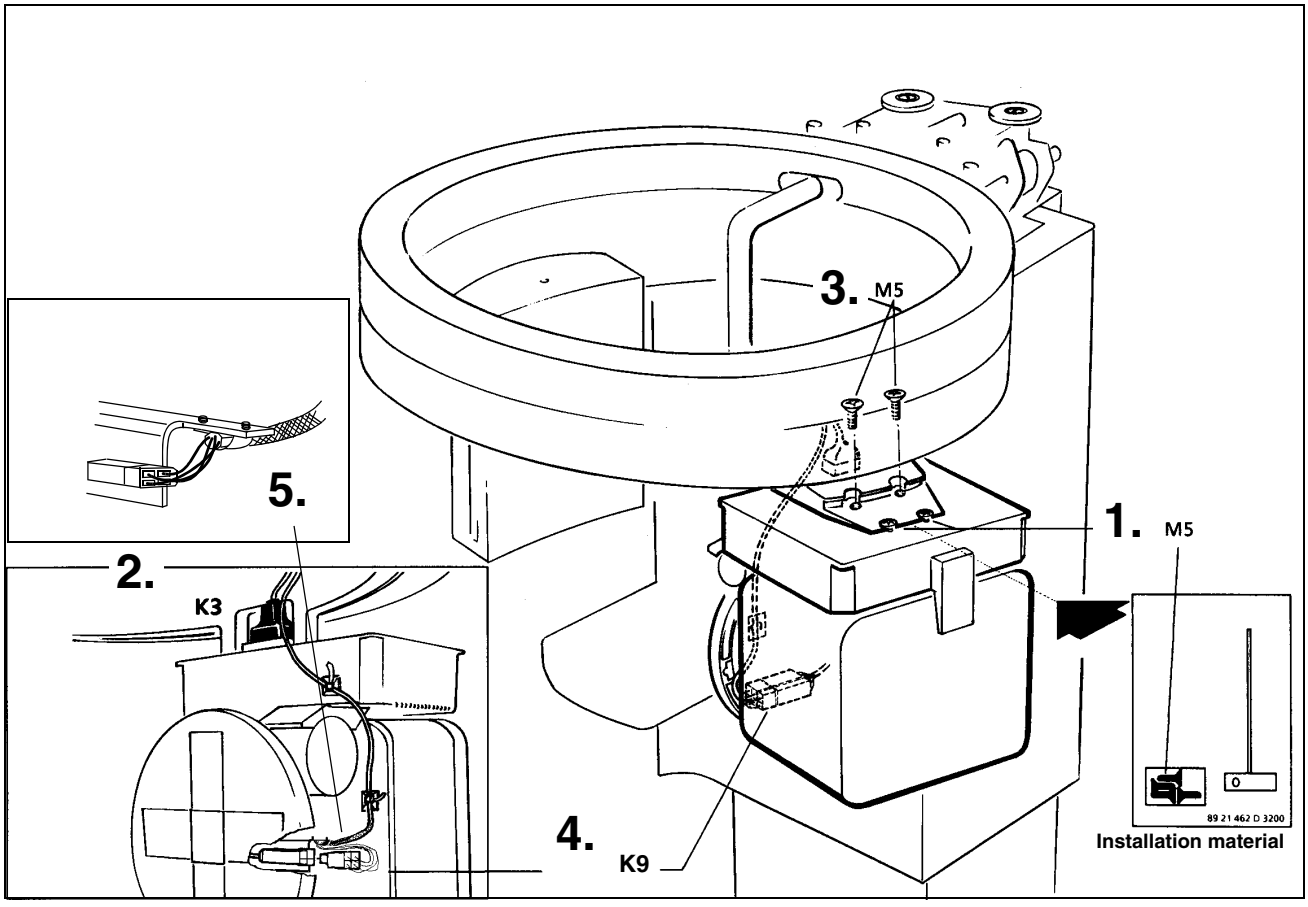
11. Remove the protective cover of the adhesive tape and put on two caps.

3 Removing Transport Fixings



1. Unscrew cassette holder cover.
   Unscrew transportation stabilization screw **A**, and keep it in the adjustment kit and screw cassette holder cover back on.
2. Unscrew transportation stabilization plate. Remove plate upwards.
3. Remove four washers.
4. Attach the two large washers **B** from the mounting hardware with two countersunk screws M4.

4 Installing the X-Ray Tube Assembly



1. Screw two Philips countersunk screws M5 into the threaded holes.

ATTENTION

When screwing in, be sure the tube assembly can be inserted into the slot all the way to the stop.

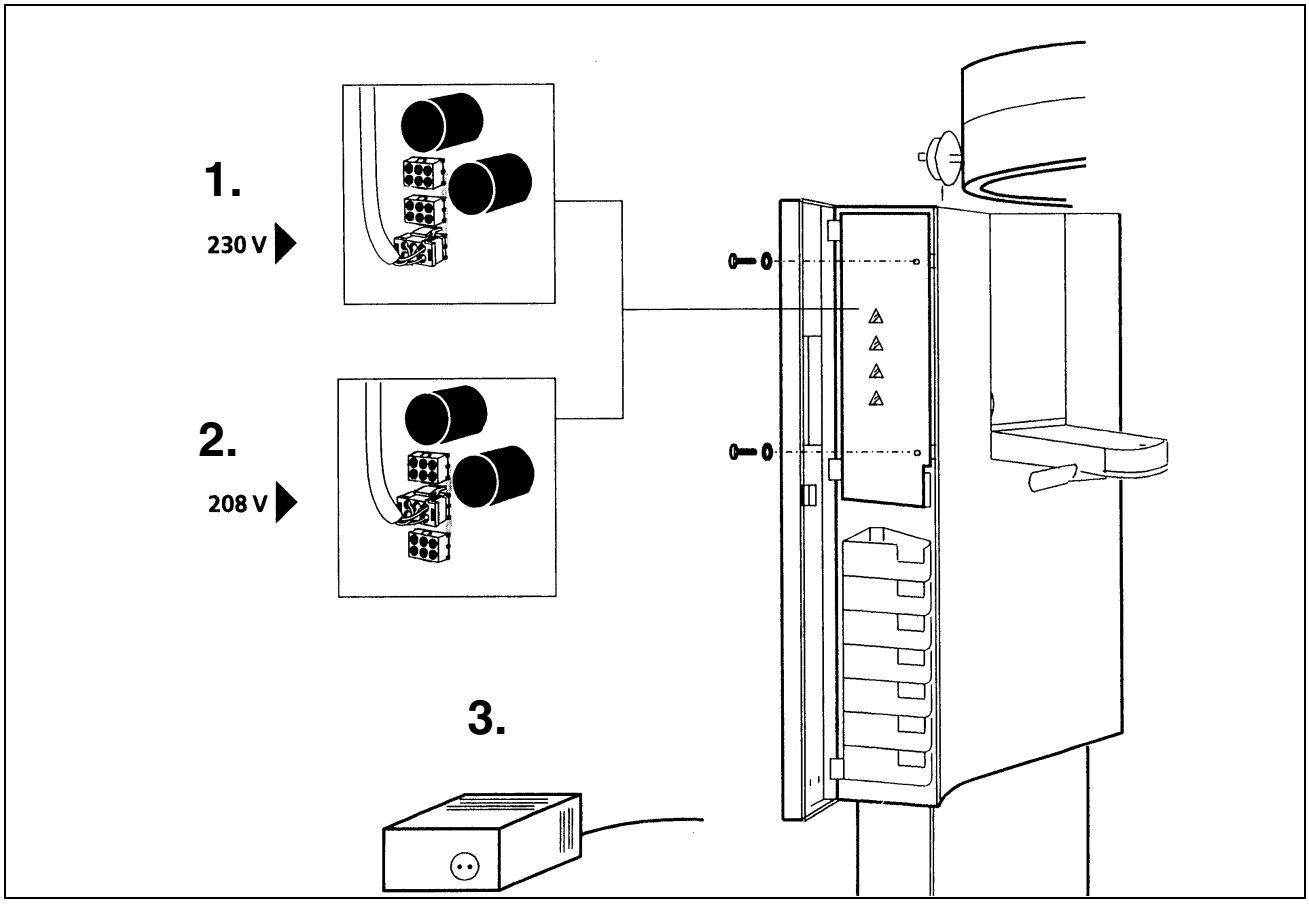
2. Pull plug K3 down from the rotating ring and plug it in. Engage x-ray tube assembly. Tighten 2 screws lightly.

3. Screw in another two M5 countersunk screws for the x-ray tube assembly.
Then tighten all four screws cross-wise!

4. Thread cable through the two cable tie loops and affix. Connect plugs **K9** together.

5. Attach cable lug with cable clip to support plate (2 screws).

5 Line Voltage



ATTENTION

Replug the line voltage only with the unit switched off.

1.

ATTENTION

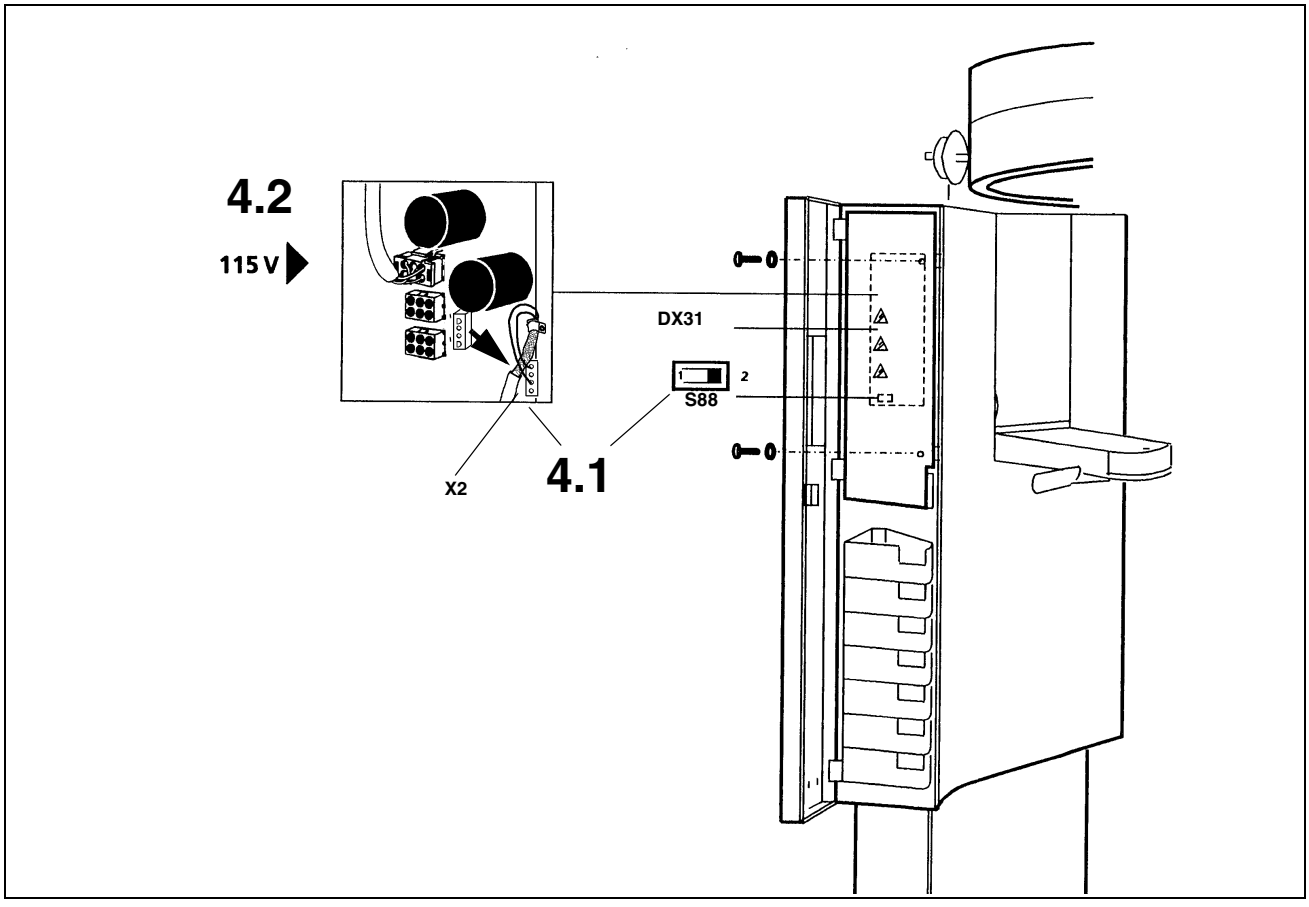
The unit is factory-wired for a nominal line voltage of 230 VAC (plug on PCB DX31, X5).
For exhibitions, follow point 4.1.

2. At nominal line voltage of 208 VAC
Swing out the door and unscrew the transformer cover.
Plug in the plug as shown for 208V (X6).
For exhibitions, follow point 4.1.
Reattach cover (two screws with washers) and close the door.

3. Other nominal line voltages
For other voltages a matching transformer (autotransformer) with the following specifications is required:

- **Input** : nominal line voltage
- **Output** : 230 V
- **Rating**: 1 kVA continuous
- Max. **voltage drop** at 10 A ohmic load: ≤6V.

Purchase a matching transformer which complies with these specifications in the destination country.
For exhibitions, follow point 4.1.



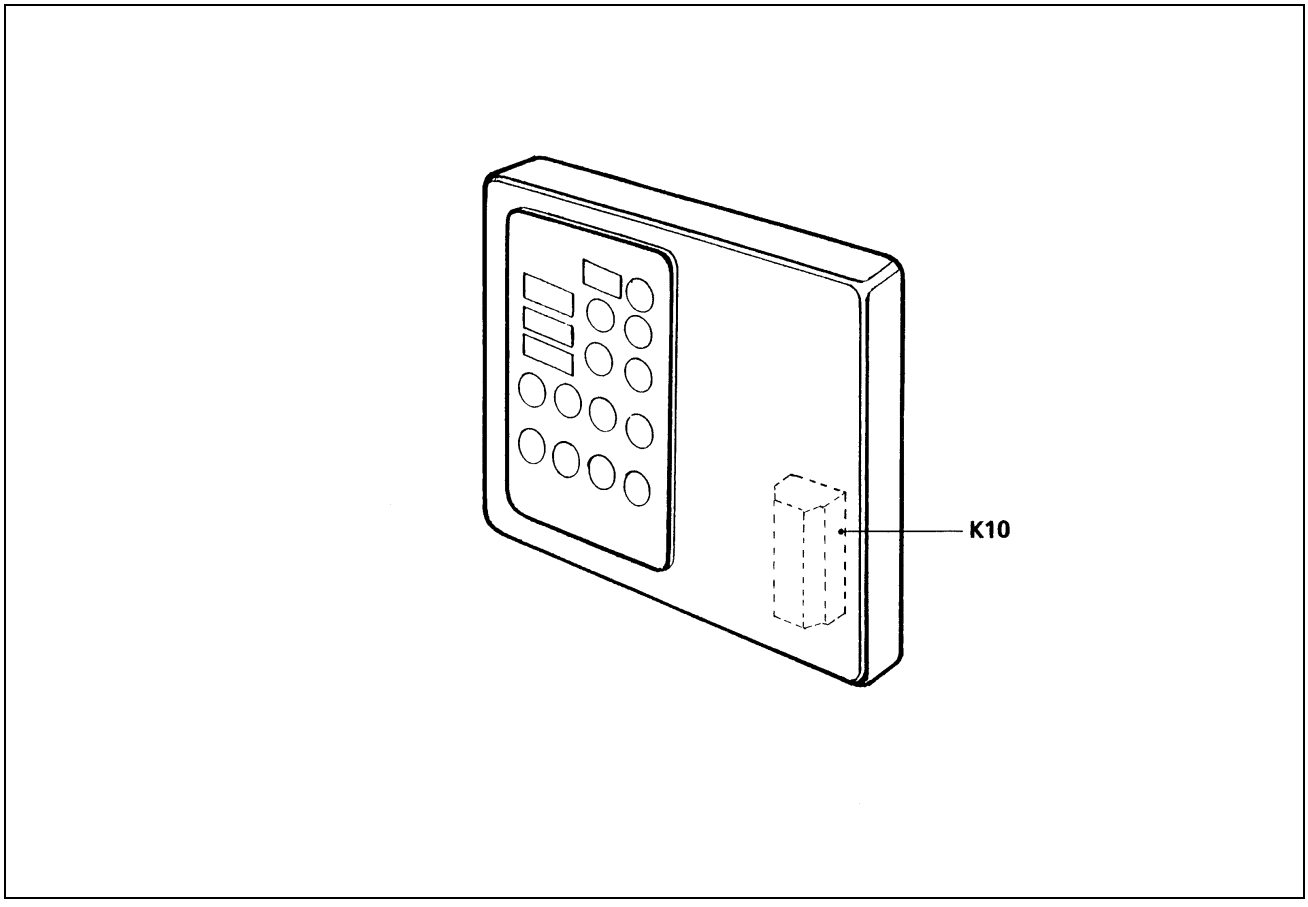
4.1 For exhibition only, without radiation !
On board DX31, set switch **S88** to position **2**.
Disconnect plug X2 and fix as shown.

4.2 For exhibition only in USA/Canada, nominal line voltage 115V, without radiation! (No transformer required).
On board DX31, set switch **S88** to position **2**.
Disconnect plug X2 and fix as shown.
Plug in the plug as shown for 115V (X7).
Reattach cover (two screws with washers) and close the door.

ATTENTION
Should the unit be required for later operation in a dental practice, undo all the measures taken for exhibition.

NOTE
If the position of switch S88 is changed during operation, the display S88 is shown on the Multitimer.

6 Remote Control



NOTE

If a door contact is required, connect to K10 according to Wiring References.

6.1 First installation possibility: Multitimer without spiral cable

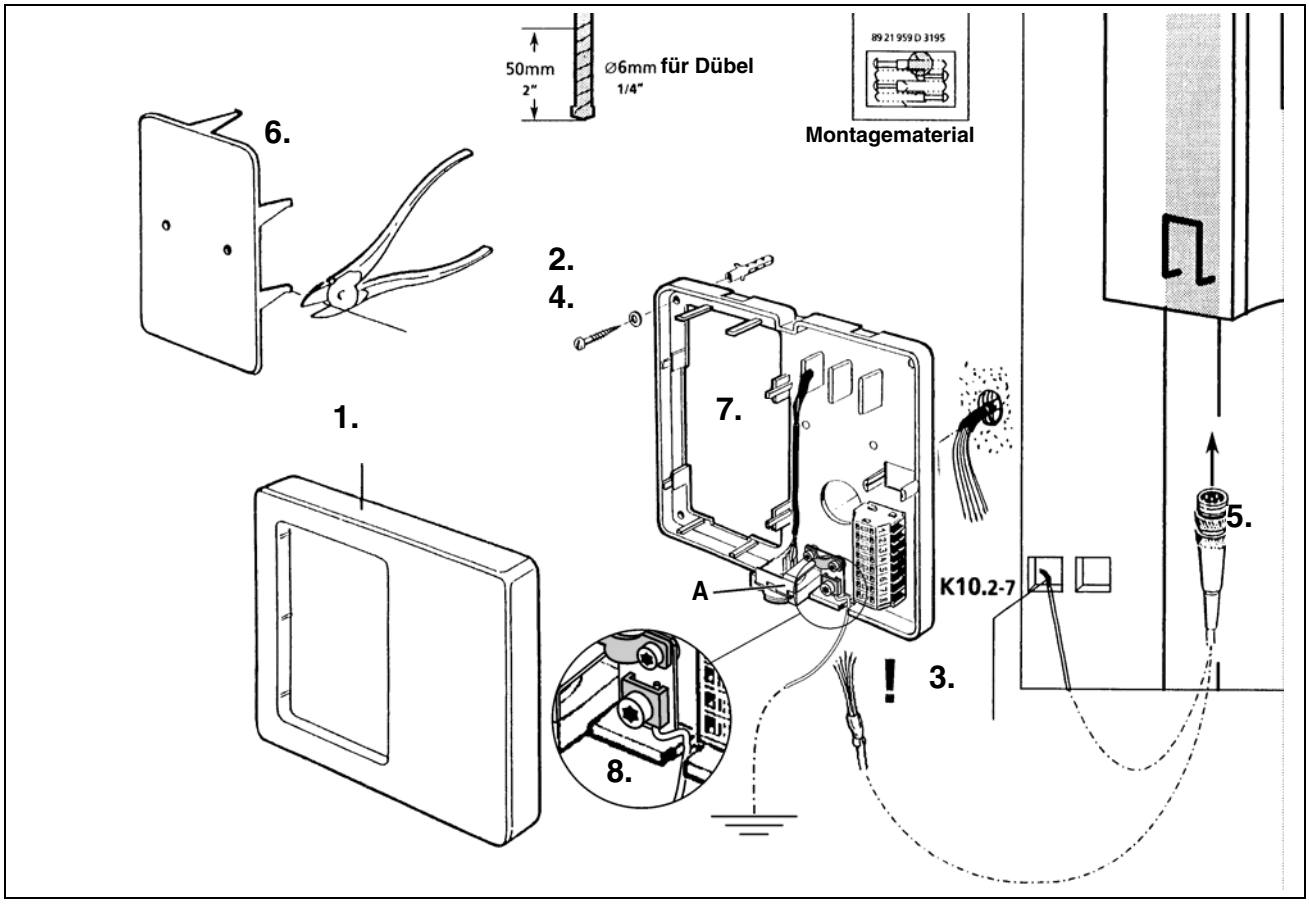
ATTENTION

The Multitimer with spiral cable is temporarily connected to the unit's carriage for start-up.

- Therefore the installation described on the following page cannot be performed until **after** the ”Phantom Radiograph” section.
- After installing the Multitimer without spiral cable, another functional check is required:
  Take and evaluate a phantom radiograph.

ATTENTION

Keep the spiral cable left over after installation at the customer's for later service use.



1. Remove the engaged cover.

2. Mark and drill four holes for chassis.
Insert four wall plugs.

3. Run the control cable

ATTENTION

If the control cable is interrupted the shielding must be bypassed!

- With concealed installation of control cable:
Pull control cable into tubing up to green marking and affix cable.
Thread the cable into the chassis from the wall.
- *With free-hanging control cable*:

ATTENTION

Engage cable from below.
Minimum distance from floor of 1m.

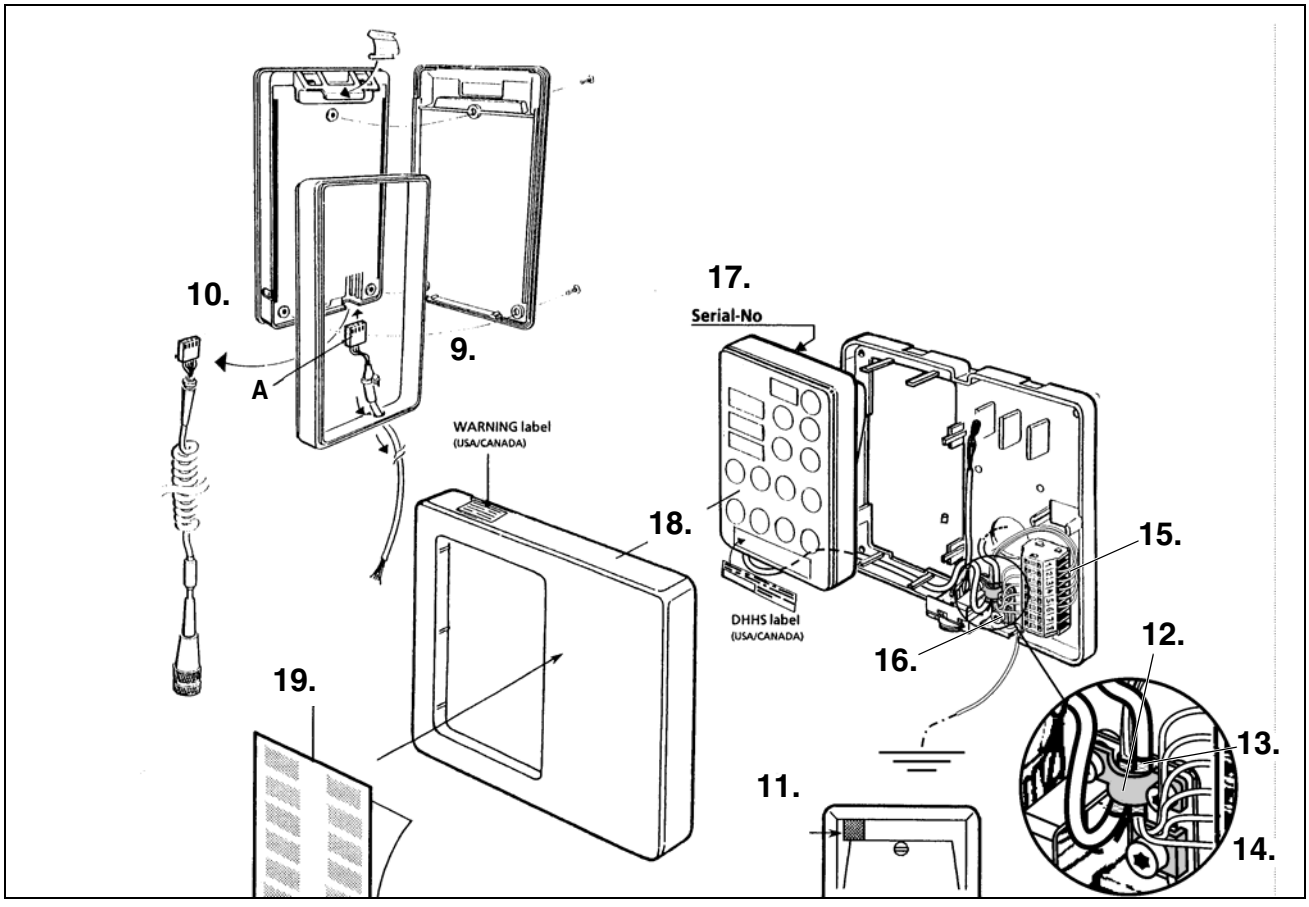
4. Fasten the chassis using four screws and washers.

5. Plug connector into unit and screw it tight.

6. Remove cover (cut 6 connections).

7. Remove cable at terminal strip **K10** and insulate the flexible leads.

8. Run and connect the ground wire
A white or gray cable (D 1.5mm² , max. 10m long) must be run from the chassis to a suitable grounding contact (e.g. the grounding contact of the ORTHOPHOS).
Screw this cable down onto plate **A** in the chassis.



9. Undo the 3 screws on the back of the Multitimer and open the Multitimer.

10. Pull the helical cable off the Multitimer and connect the short cable A.
Complete the Multitimer.

11. Stick on rubber spacer.

12. Loosen the clamp.

13. Remove the cable tie and the shrinkdown plastic tubing from the control cable.
The shielding of the control cable must be visible.

14. Slide short cable **A** under the clamp from **below**.
Slide the control cable under the clamp from **above**.
The shielding must lie underneath the clamp.
Screw the clamp down tight.

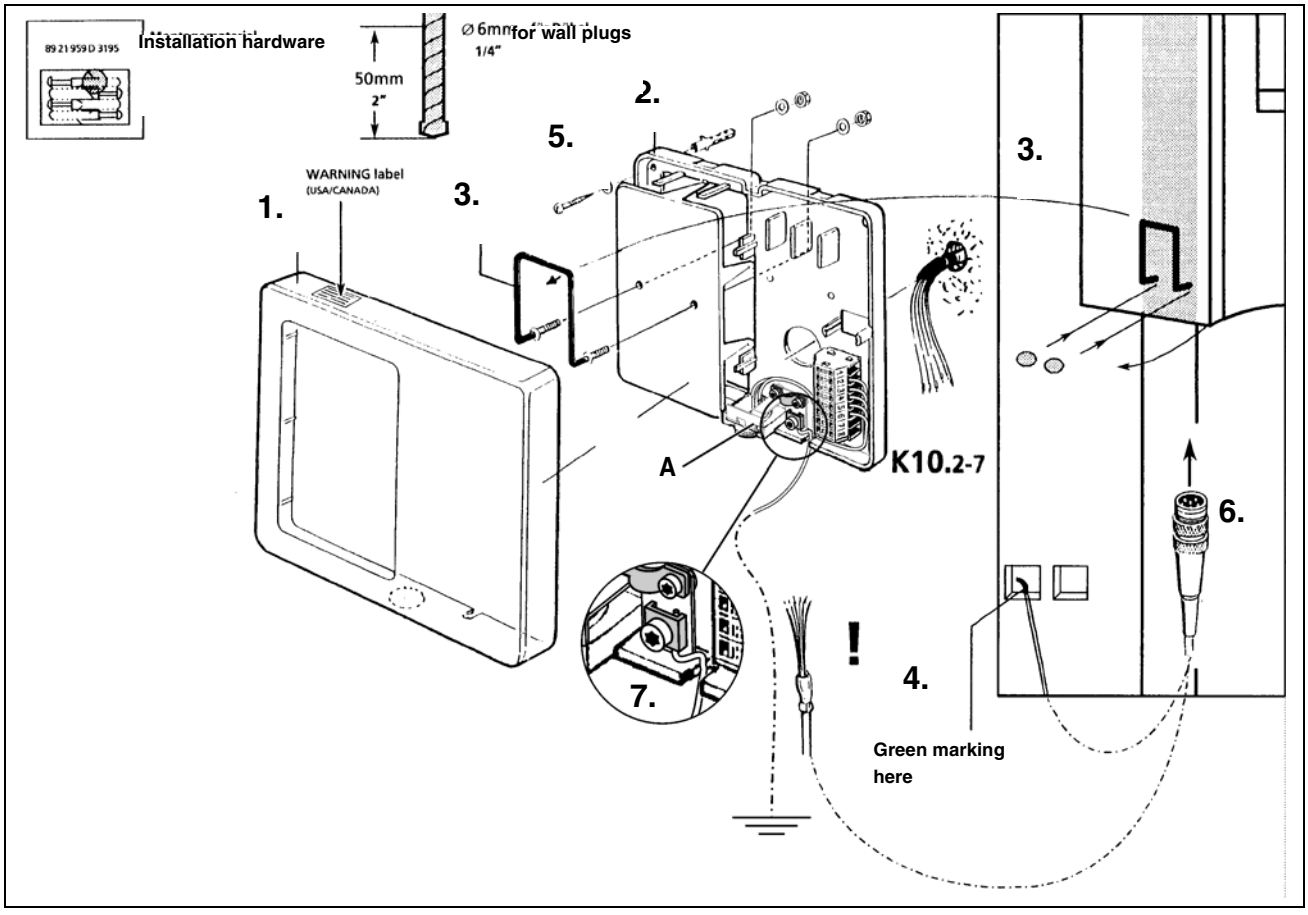
15. Connect the short cable to **K10.2-6.**

16. Connect control cable (6 leads) to terminal K10.2-7.

17. Record serial no. for the **Warranty Passport.**

18. Fit Multitimer into chassis and engage cover.
USA/CANADA only: Stick on WARNING and DHHS labels.

19. Stick program foil in place.



6.2 Second installation possibility: Using the Multitimer with spiral cable

1. Remove the engaged cover.

2. Mark and drill four holes for chassis.
Insert four wall plugs.

3. Swing out unit cover and unscrew bracket.
Attach bracket to remote chassis.
Seal drill holes on unit with dummy caps.

4. Run control cable

ATTENTION
If the control cable is interrupted the shielding must be bypassed!

- With concealed installation of control cable:
Pull control cable into tubing up to green marking and affix cable. Thread the control cable into the chassis .

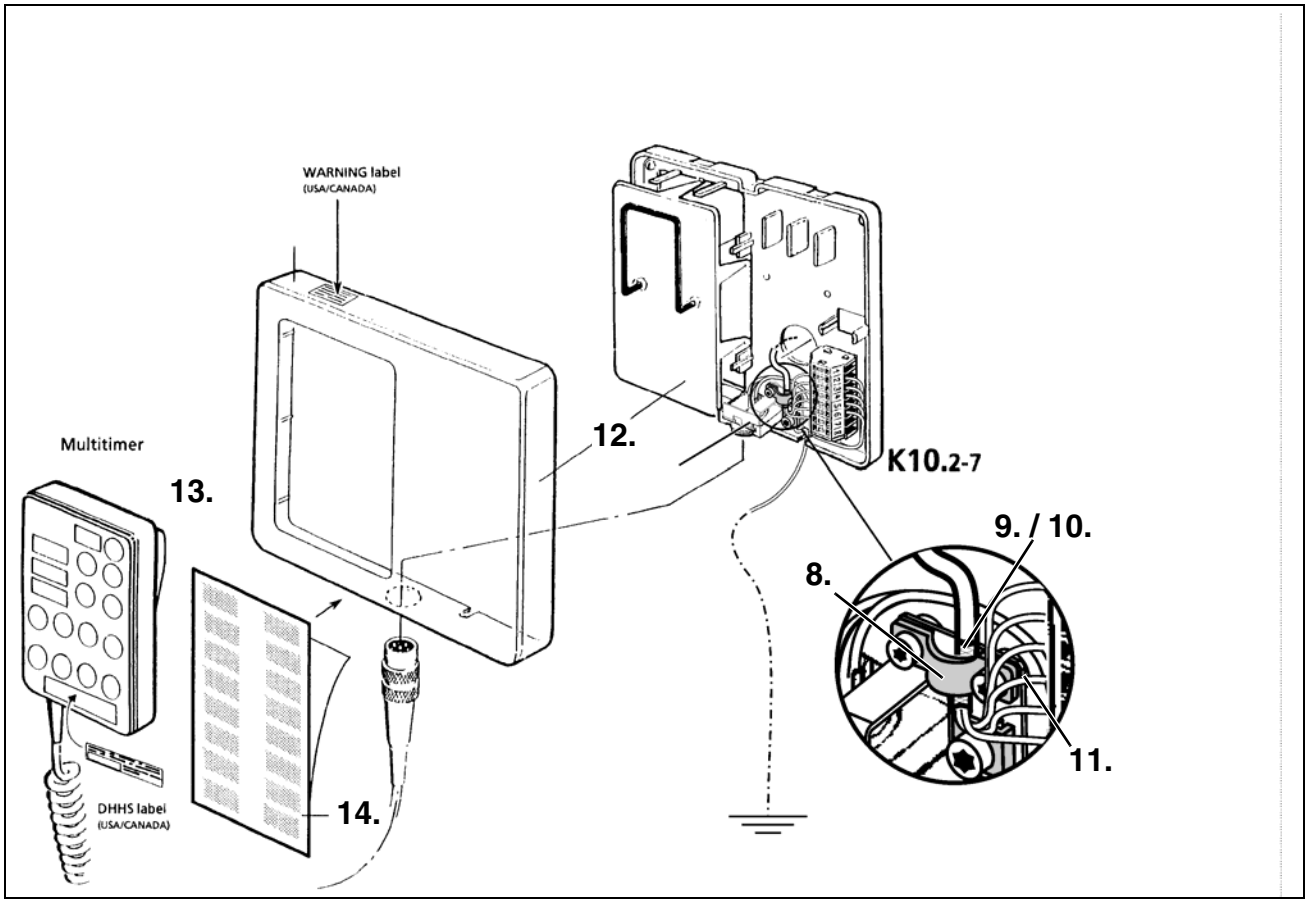
- With free-hanging control cable:

ATTENTION
Engage cable from below.
Minimum distance from floor of 1m.

5. Screw chassis down tight using four screws and washers.

6. Plug connector into unit and screw it tight.

7. Run and connect ground wire
A white or gray cable (D 1.5mm² , max. 10m long) must be run from the chassis to a suitable grounding contact (e.g. the grounding contact of the ORTHOPHOS).
Screw this cable onto plate **A** in the chassis.



8. Loosen the clamp.

9. Remove the cable tie and the shrinkdown plastic tubing from the control cable. The shielding of the control cable must be visible.

10. Slide the control cable under the clamp from **above**. The shielding must lie underneath the clamp. Screw the clamp down tight.

11. Connect control cable (6 leads) to terminal K10.2-7.

12. Engage cover.
USA/CANADA only: Stick on WARNING and DHHS label.

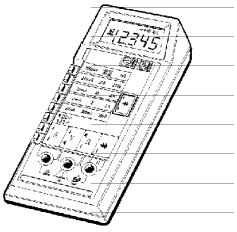
13. Attach the Multitimer control panel, insert plug and screw on.

14. Stick program foil in place.

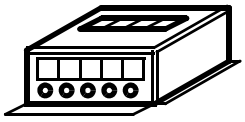
7 Starting-up, Measurements and Controls for USA/Canada only

Required Measuring Instruments

1. Digital multimeter Fluke 8000 A, Philips PM 2816 rms or equivalent.



2. Electromechanical pulse counter KESSLER ELLIS, KT 203±1 pulse, or equivalent.

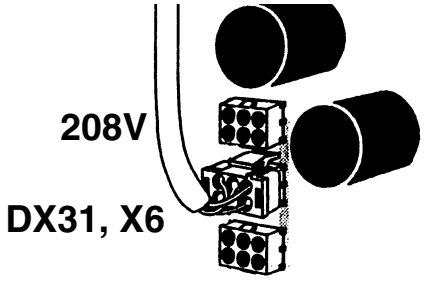


Radiation Protection

Observe the radiation protection guide lines as outlined in the Operating Instructions manual.
X-radiation is emitted as long as the exposure key on the Multitimer is depressed.
The **X-ray** indicator must light up on the Multitimer during radiation. An acoustic signal must also be heard.

Line Voltage

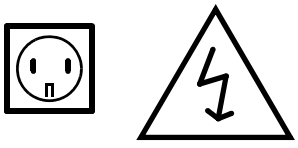
Be sure the plug on PCB DX31 is plugged according to nominal line voltage as outlined on page 10.



Power Supply Adequacy

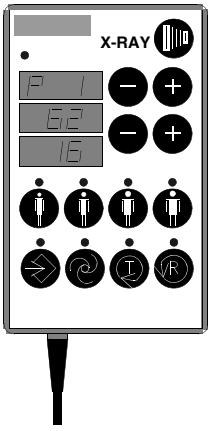
To assure that the ORTHOPHOS system performance is in accordance with Sirona specifications, an adequate power supply is essential.

The Federal Performance Standard for diagnostic X-ray units, code of Federal Regulations, title 21 CFR, subchapter J, mandates an adequate power supply.



Multitimer

For measurements and controls the remote installed Multitimer must be connected directly to the unit's carriage instead of the control cable's plug.



Duty Cycle

Between exposures maintain at least a cool-off time (automatic exposure blocage, see Operating Instructions manual).

Operating Instructions

During measurements and controls it is necessary to energize or de-energize the unit. For all operating steps please refer to the Operating Instructions manual.

CAUTION with PC - Boards!

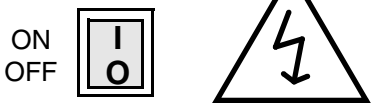
All PC-boards are fitted with electronic components sensitive to electrostatic discharge (ESD). In an environment of moving people electrostatic charges are unavoidable due to friction of clothing, carpeting etc.

ATTENTION

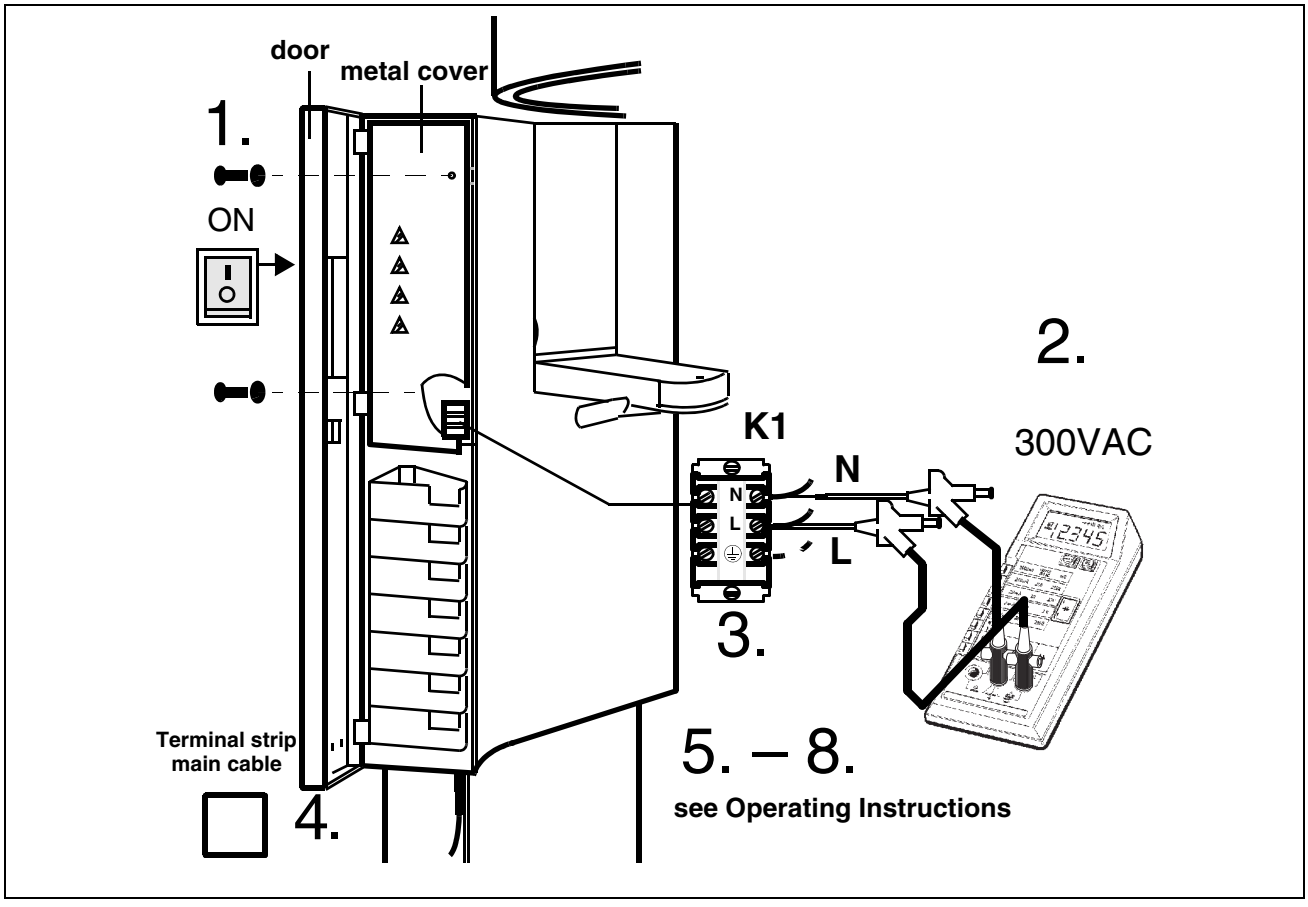
To prevent damage of electronic chips do not touch same. Always handle circuit boards by the edge of same.

ATTENTION

Electrical Shock Hazard!
Always turn unit OFF before connecting and disconnecting the test leads to the test points.



8 Power Supply Adequacy (for USA/Canada only)



To determine power supply adequacy, the line voltage drop during exposure must be measured.

1. Be sure power cord is not plugged in! Open door and remove metal cover (2 screws).
2. Select 300VAC line voltage range on multimeter.
3. Connect measuring leads to terminal **K1**, **L** and **N**.
4. Plug in power cord and switch unit ON, see Operating Instructions.
5. Press button **R** at the Multitimer to return X-ray tube head into the initial position.
6. Remove and reinsert the film cassette. The Ready LED at the Multitimer must now go out.
7. Select **P1** program and **90** kV/**8** mA at the Multitimer.
8.

ATTENTION

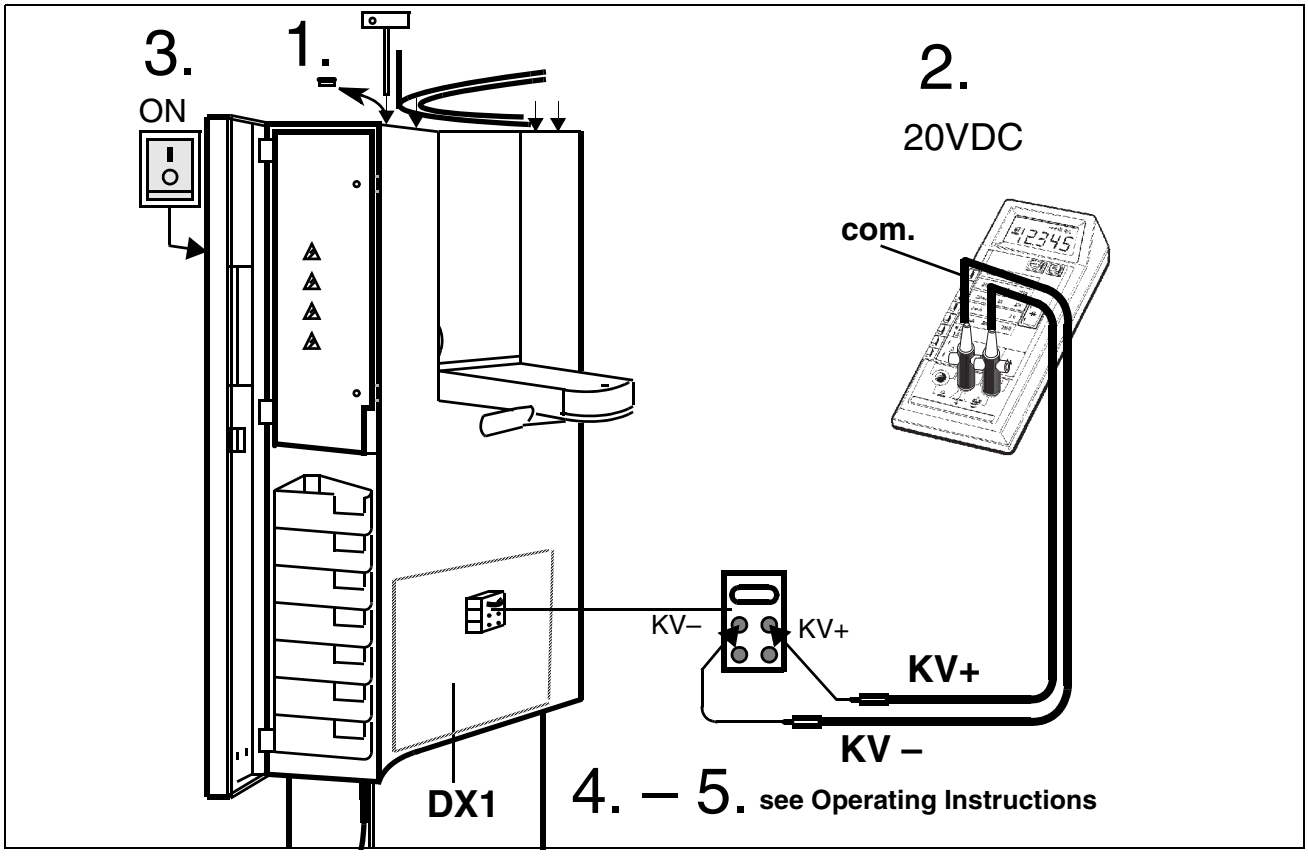
Depress the exposure button at the Multitimer until meter reading is obtained.

Line voltage no load:	**Max. permissible line voltage drop:**
187 – 200V	8V
201 – 220V	9V
221 – 240V	10V
241 – 264V	11V

Turn unit OFF and remove meter leads.

If the voltage drop is not within the specified range advise the customer, that an adequate power supply must be installed. Refer to Pre-Installation Instructions. Disconnect unit and do not release for use!

9 kV - Verification, kV-Ramp During Panoramic Exposure (for USA/Canada only)



- During exposure the kV is encreased in the central region depending on kV/mA selected up to 17%.
  This increase can be measured in VDC.

1. Remove covers. For details see Service Manual.

2. Connect digital voltmeter to KV+ and KV– and select range 20 VDC.

3. Switch unit ON. The X-ray head must be in the initial position (return button R), temple support fully open.

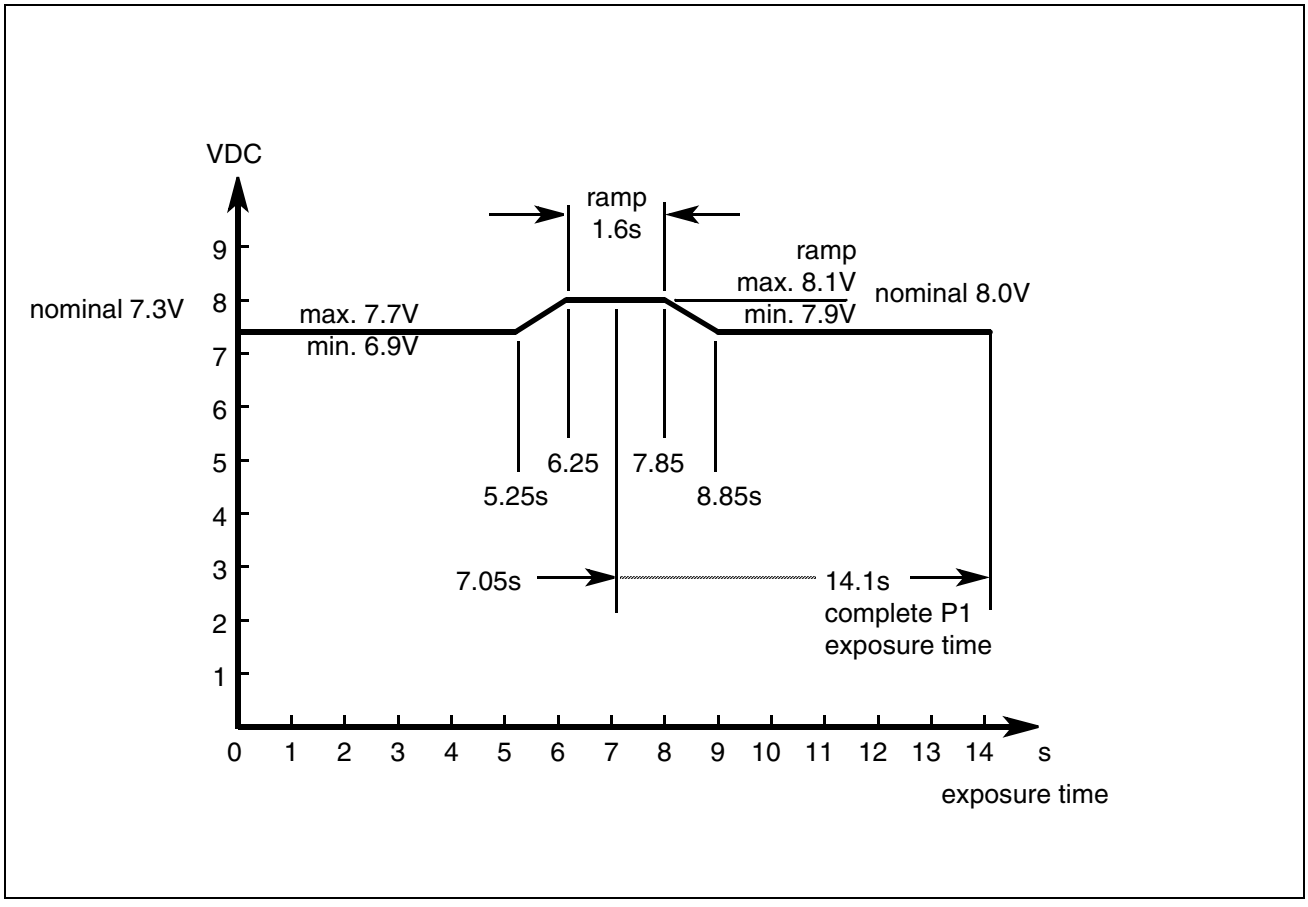
4. Select **P1** program and **73** kV/**15** mA at the Multitimer. Ready LED above button R must be out.

5.

ATTENTION

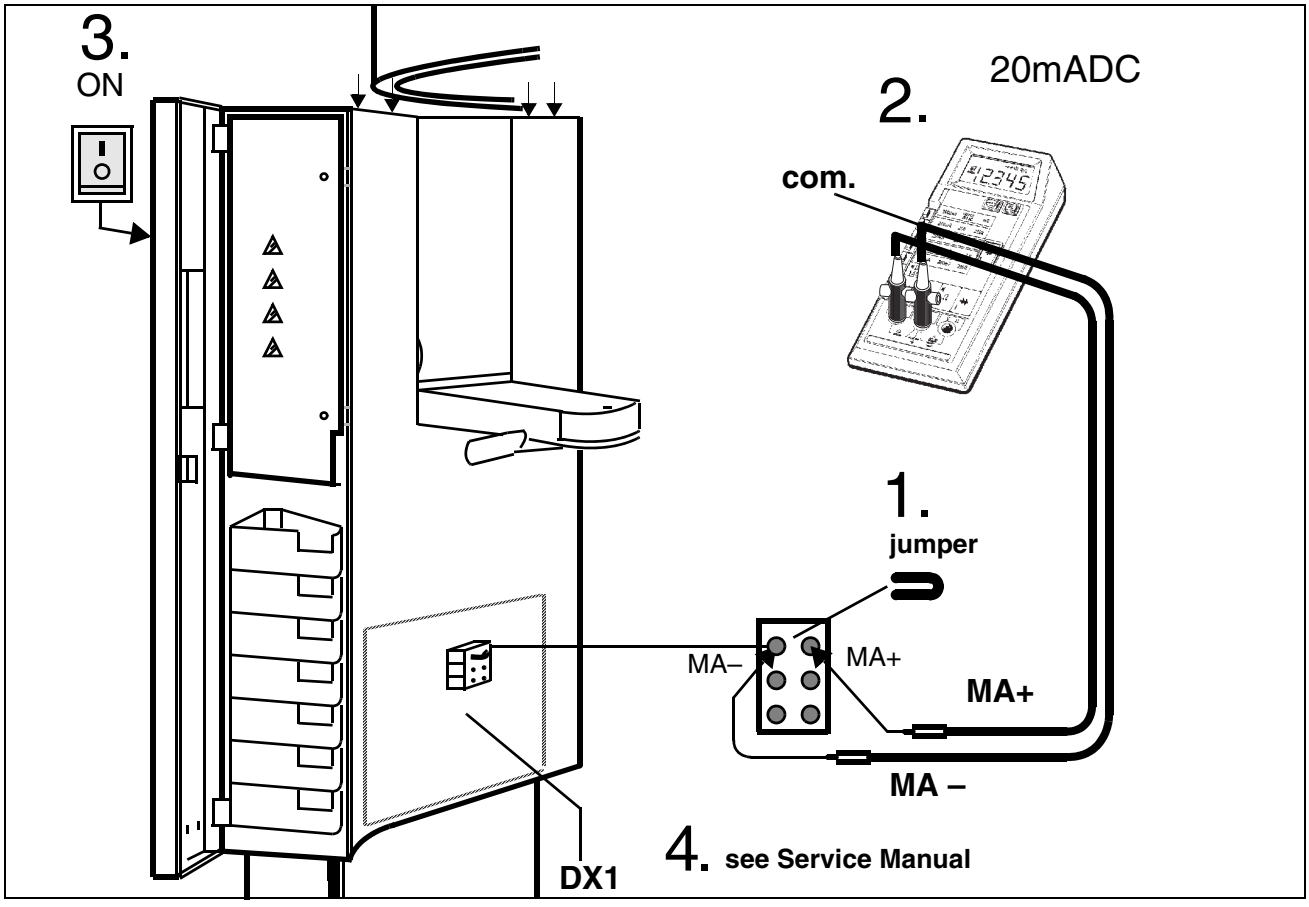
Depress the exposure button until the exposure terminates automatically.

- The following values must be obtained – see also diagram on next page.
  - up to 5.25 seconds: 7.3 V ± 0.4 V,
  - from 6.25 to 7.85 s: 8.03 V ± 0.1 V,
  - after 8.85 seconds: 7.3 V ± 0.4 V.
- Turn unit OFF and remove meter leads.
- If specified values cannot be obtained, see Service Manual, ”Radiographic Density in Vertebrae Region Incorrect”.



kV – ramp diagram
with program **P1** and **73** kV / **15** mA set on the Multitimer and temple support fully open.

10 Tube Current Verification (for USA/Canada only)



1. Remove jumper from MA+/MA – test points.

2. Connect digital ammeter to MA+ and MA– and select range 20 mADC.

3. Switch unit ON. Wait for self-adjustment of the unit.

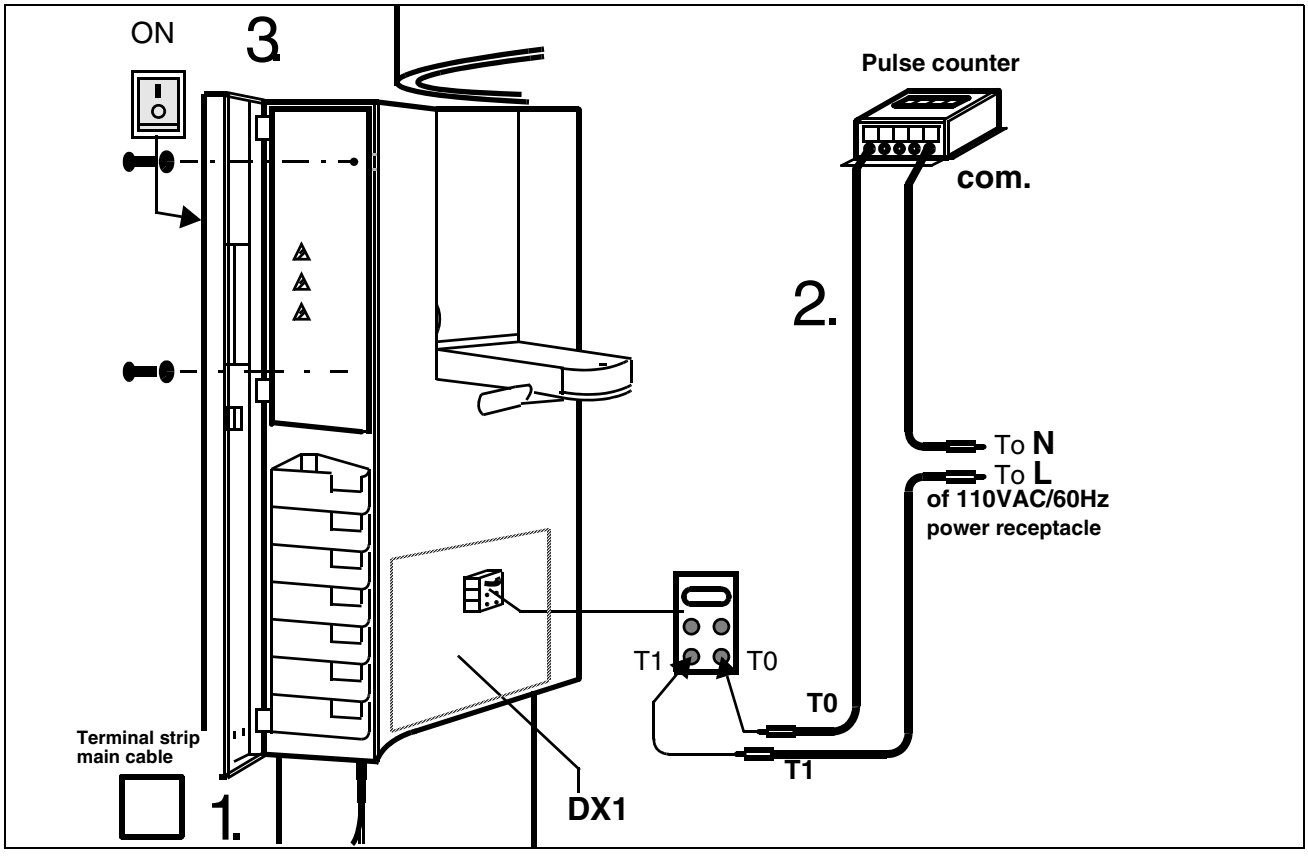
4. Select service routine S.01.

- First measurement (1.)
  - Select **P1** program and **60**kV / **9**mA at the Multitimer. The Ready LED must be out.
  - **CAUTION RADIATION!** Depress the exposure button and hold depressed until meter reading is obtained.
  - The multimeter shall indicate **9mA ±0.5mA**.
- Second measurement (2.)
  - Select **P1** program and **90**kV / **12**mA at the Multitimer. The Ready LED must be out.
  - **CAUTION RADIATION!** Depress the exposure button and hold depressed until meter reading is obtained.
  - The multimeter shall indicate **12mA ±0.5mA**.

Switch unit OFF.

Remove meter leads and replace jumper! If specified values cannot be obtained, see Service Manual, ”Checking theTube Current”.

11 Exposure Time Verification for Panorama Exposure (for USA/Canada only)



1.

ATTENTION

Switch the unit OFF. Switch off the AC power at the on-site cabinet.

2. Connect pulse counter according to the connection diagram above.

3. Switch power ON and unit ON. Wait for self-adjustment of the unit. Move the X-ray tube unit to the start position (press the R key). **Set diaphragm 1.**

- **VERY IMPORTANT!** Open temple support fully, see Operating Instructions.
- At the Multitimer: Select **73**kV/**9**mA with **P1** program.

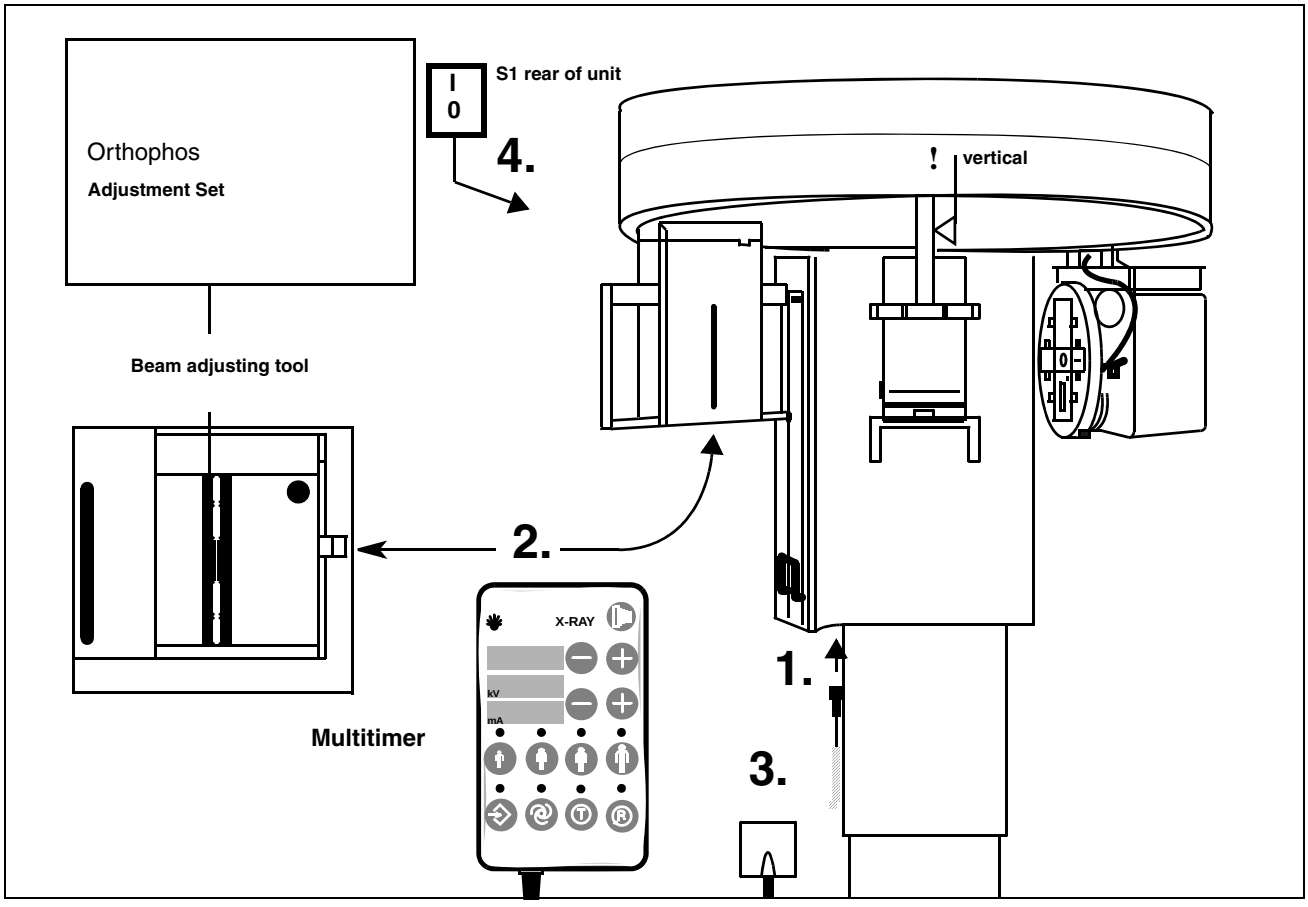
ATTENTION

Press the exposure key until the X-ray display switches off automatically (complete rotation).

- The exposure time must be **14.1s**±0.7s.
  nominal **14.1** sec.= **846** pulses±38 at 60Hz

If specified value cannot be obtained, see Service Manual "Checking Exposure Times".

12 Checking and Adjusting the X-Ray Beam



- The supporting tube of the forehead support must be vertical. Check with spirit level and correct if necessary.

1. Connect the Multitimer plug to the unit's carriage and tighten.

2. Place adjusting tool in the cassette carriage and insert behind the secondary collimator.

3. Connect unit power cable.

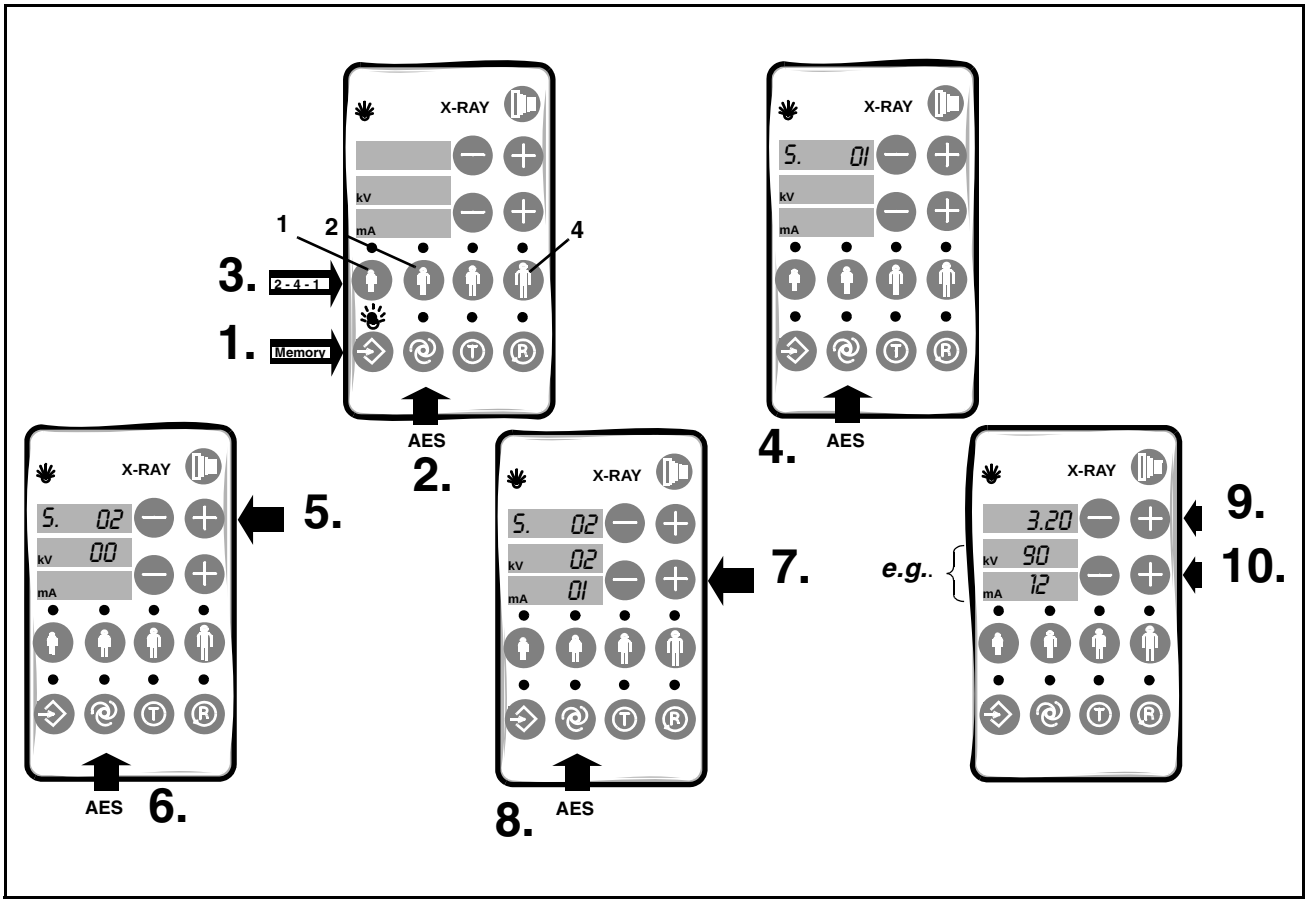
4. Turn on switch S1 located on the back of the carriage. Various exposure parameters will light up on the Multitimer (see Operating Instructions).

- Darken the room.
- **IMPORTANT NOTES**
  Observe the x-ray protection guide-lines for the following tests. Please refer to the Operating Instructions.
  X-radiation is emitted as long as the exposure button is depressed.
  The X-ray indicator must light up the entire time, and an acoustic signal must also be heard.

ATTENTION

Be certain to observe 20 second cooling break for each second of exposure.

13 Selecting the Service Routine S.02



- Following the self-adjustment routine of the unit, perform Service Routine **S.02** on the Multitimer (no rotational movements, no movement of the cassette carriage).

1. Press **Memory** button. (LED above button flashes).

2. Then press the **AES** key until the digital displays disappear (approx. 4s) .

3. **Within 3s:**
Press the **patient symbol** keys in the sequence **2 – 4 – 1** The service mode is now selected..

- If the sequence is not observed when selecting the service routine, if a wrong key is pressed or the time (see 3.) is exceeded, the system switches automatically to normal mode.

4. Press **AES** key.
Service routine **S.0 l** appears on the digital display.

5. With the "**+**" button (program selection) select Service Routine **S.02**.

6. Press **AES** key.
00 is shown in the kV display.

7. Actuate the "**+**" **(kV/mA)** button several times, until Service **02** is shown in the display.
This step must be performed for safety reasons during all service routines which could entail danger.

NOTE

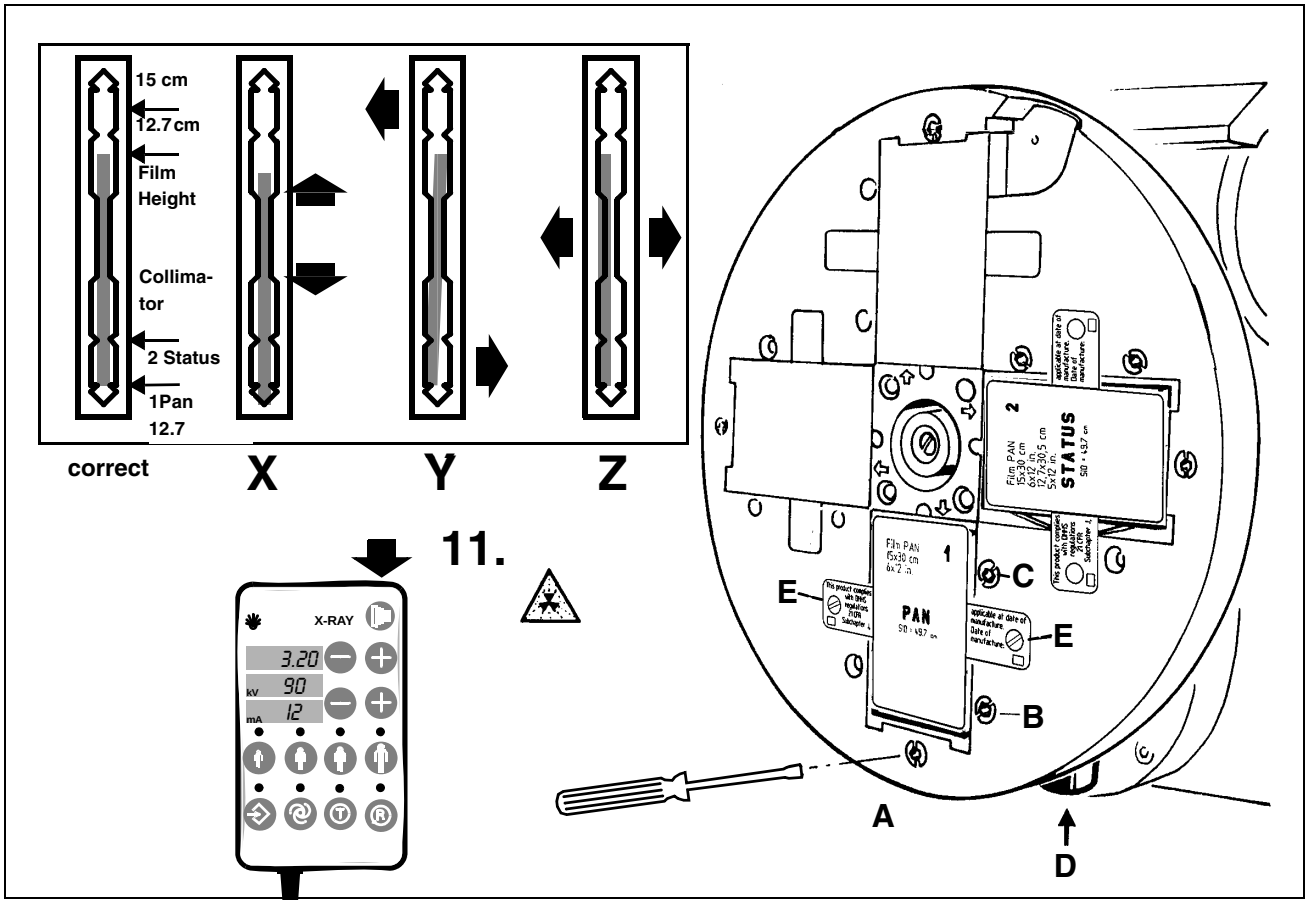
The service code correspoinds to the number of the service routine selected
e.g.:
Service Routine S.02 →Service-Code 02
Service Routine S.26 →Service-Code 26

- Test step **01** is shown in the mA display.

8. Press the **AES** key again. The digital displays begin flashing.

9. With the "**+**" (program selection) button, select a tradiation time of **3.2 s**.

10. With the "**+**" (kV/mA) button, select the largest possible kV/mA combination.
Observe the warmup time. When the flashing LED above the Return button goes out, the unit is ready for radiation release.



- Adjust the primary collimators 1 and 2 on the collimator wheel, one after the other.
- To move the collimator wheel, press button **D**.
  X-radiation will only be activated when button **D** is engaged.
- When adjusting the
  primary collimator 1 and 2, move the x-radiation position to the indicated mark.

11.

ATTENTION

Activate x-RADIATION.
Activate x-radiation only for as long as you need to recognize the x-radiation position.

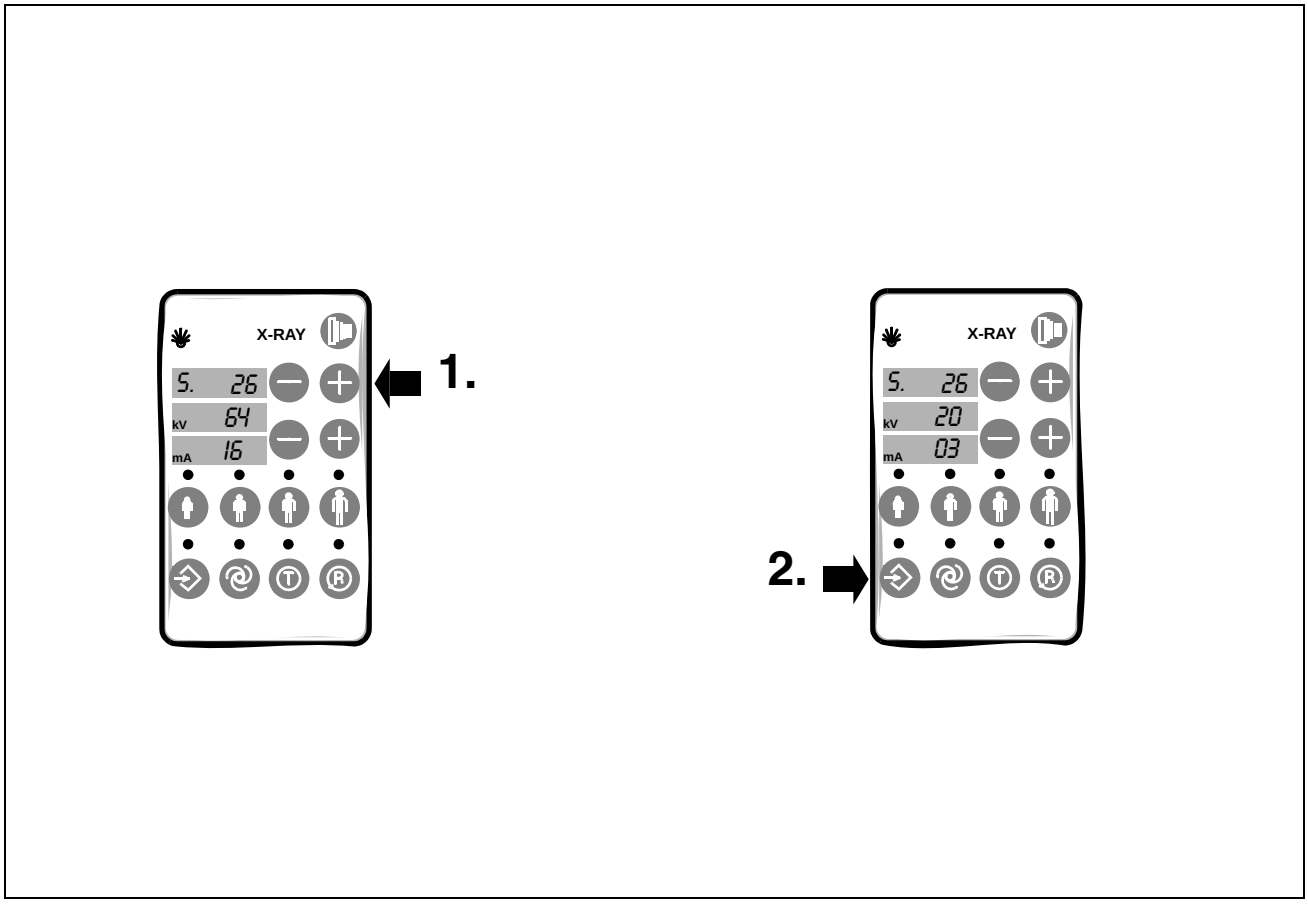
X Set beam correction to '**High - Low**'
Loosen two screws **E** by one turn.
Set beam correction via Allen screw A (eccentric).
Retighten screws **E**.

Y Set beam correction to '**Vertical**' and

Z Set beam correction to '**Right - Left**'
Loosen two screws E by one turn.
Set beam correction via Allen screws **B** and **C** (eccentrics).
Retighten screws **E**.

- Final check of beam position is performed under Phantom Radiograph.

14 Checking the AES (Automatic Exposure Selection)



14.1 Set Service-Routine S.26

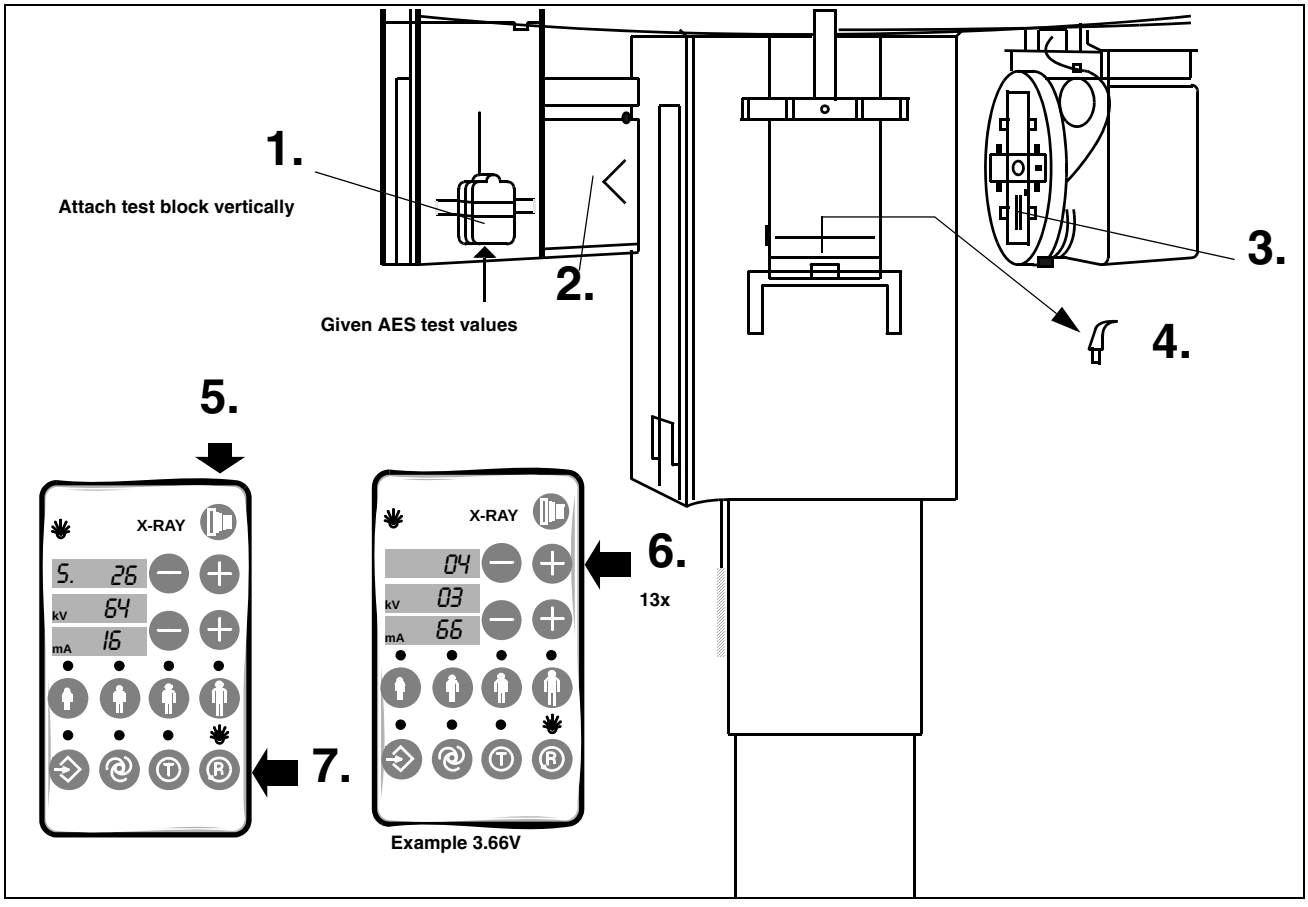
1. Set Service-Routine S.26 on the Multitimer (procedure analogous to that on page 25).

- In the digital display the values
  61 kV/16 mA oder 64 kV/16 mA flash, according to the film-screen system setting.
  All LEDs above the patient symbols light up.

2. Press the Memory button. Control the film-screen (FiSc) system and the position of the black-level switch.
Required values:
kV FiSc-System: check factory setting[1]
mA 03: basic setting of film density switch

- These values are displayed for app. 2 s. In case of deviations, they must be corrected using Service Routine S.25 (see Service Manual) or with the film density switch.

1. film-screen systems approved acc. to country (e.g. 20; 33)



14.2 Perform phantom exposure

1. Attach special **test block** delivered as **part of this unit** to bottom of secondary collimator with adhesive tape. **Check that test block is exactly vertical.**
2. Insert a loaded film cassette until it locks in place. Details see Operating Instructions.
3. On diaphragm wheel, swing in **PAN 1** diaphragm.

- Unit must not be irradiated by a striong light source.

4. **Remove** any bite blocks from holder.

- The **film density switch** on Multitimer must be in position **03**!
- Prepare unit for exposure, see Operating Instructions.
- **Ring must be in start position**.

5.

ATTENTION

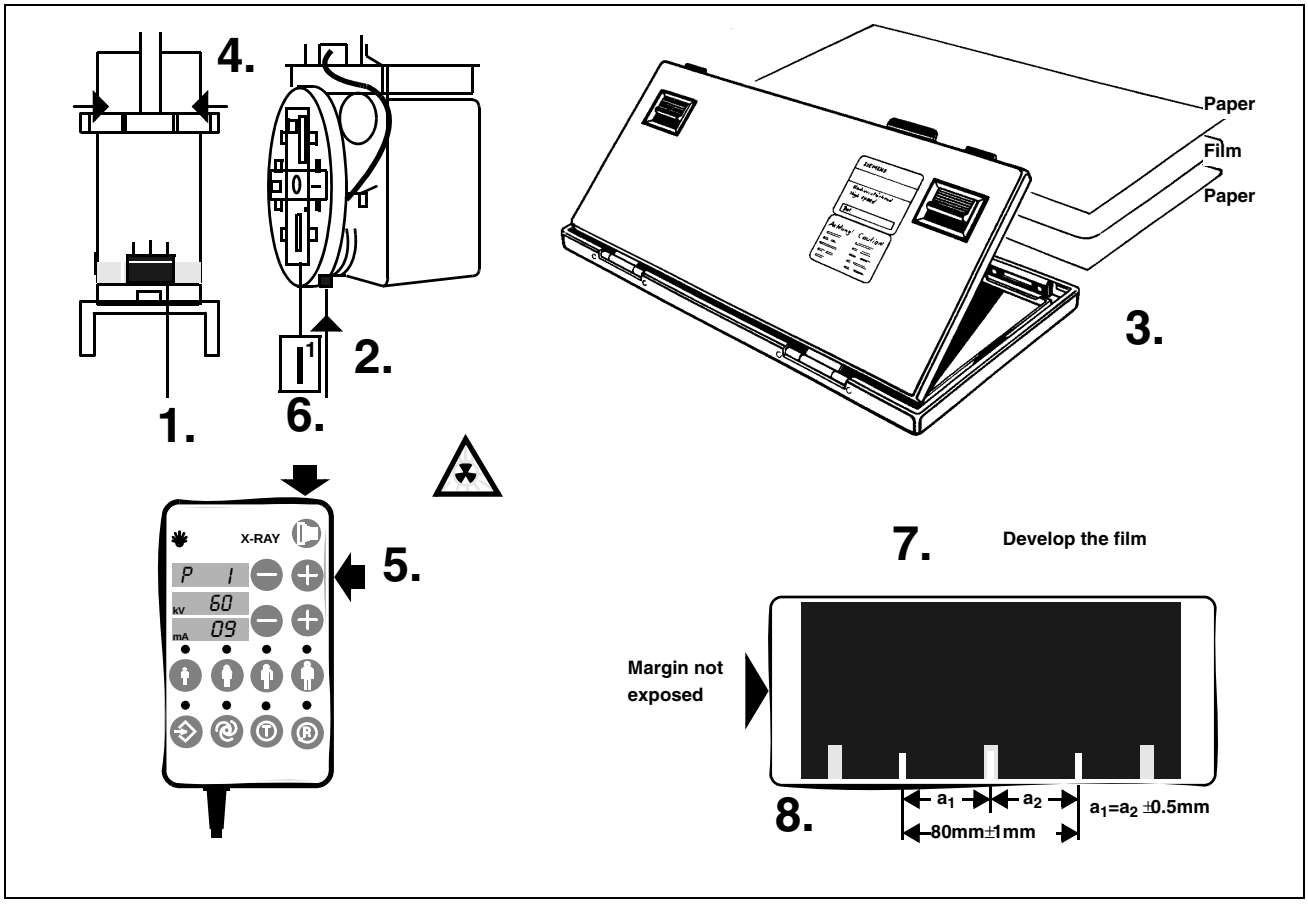
Release a phantom exposure and hold pressed until radiation switches off (app. 1 s).

6. Then check displays on Multitimer.
   Program display: test step (10 steps in total)
   kV/mA display: AGC voltage value (10 test values)

   Press the "**+**" button (program selection) a total of 13 times.
   1 - 10 :Test values
   11: Black-level switch (e.g. 03).
   12: AGC pointer (e.g. 3).
   13: Correction value (e.g. 7).
7. Press the **R** button (the flashing LED goes out).

- The value printed on the film-screen system used (± 0.05 V) must appear in the kV/mA display as the tenth voltage value measured.
  e.g. for type 20 film-screen system: read out voltage value of 250
  for type 33 film-screen system: read out voltage value of 400
- If this value is not displayed, carefully check “Adjust X-Ray Beam” again. See Chapter Checking and Adjusting the X-Ray Beam”.
  Turn the diaphragm slightly if required (maximum one detent).
- Release another phantom exposure. See Point **5.** on the previous page.
- If the AES test value printed on the test body is still not displayed, you must check the AES setting. See Service Manual, Chapter “**Checking the AES Setting**”.

15 Phantom Radiograph



- The unit must be in Panorama mode. Exit the service routine by switching OFF and then ON again.

1. Fit the needle phantom up to stop.

2. Adjust primary **diaphragm 1** at the diaphragm wheel.

3. Cut out two paper strips as large as the film size.
Place the film between the paper strips **in the dark room**.
– Making sure film and paper strips are level with bottom of cassette! (The paper strips are needed to neutralize the intensifying screens).
Attach film cassette to the unit's cassette holder (for details see Operating Instructions).

4. Close temple support fully!

5. Select program **P1** and lowest kV value at the Multitimer.
The rotating unit must be in start position!

6.

ATTENTION

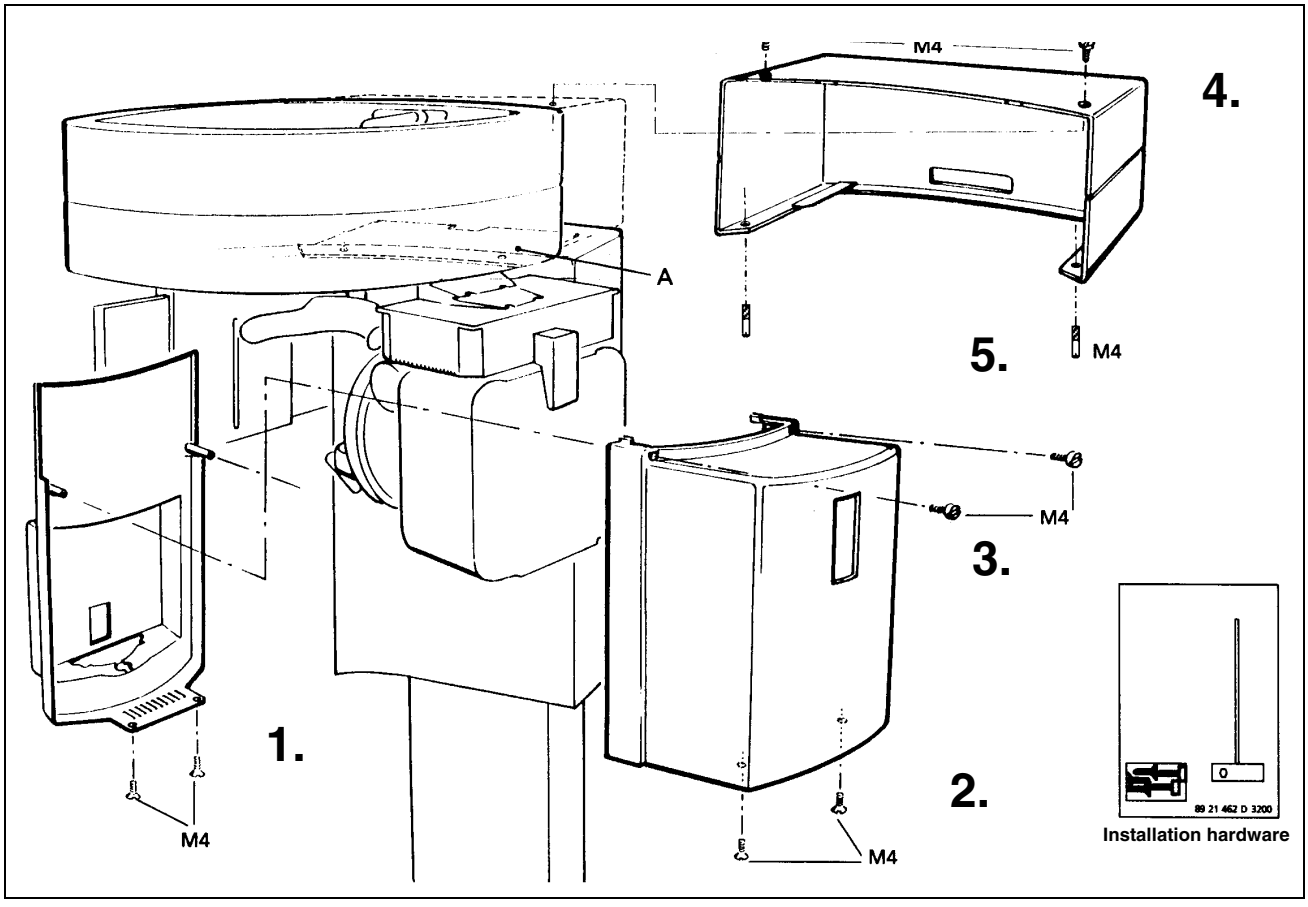
Initiate the exposure for a complete rotating cycle.

7. Process the film.

8. Check the film.
Measure the line distances on the film.

If distance is 88 mm, temple support is open. Close temple support and make another exposure.
If the distances exceed the above tolerances, the actuators M2/M3 must be readjusted – see Service Manual.

16 Final Work



- Attach cover. Be sure to follow the correct sequence.

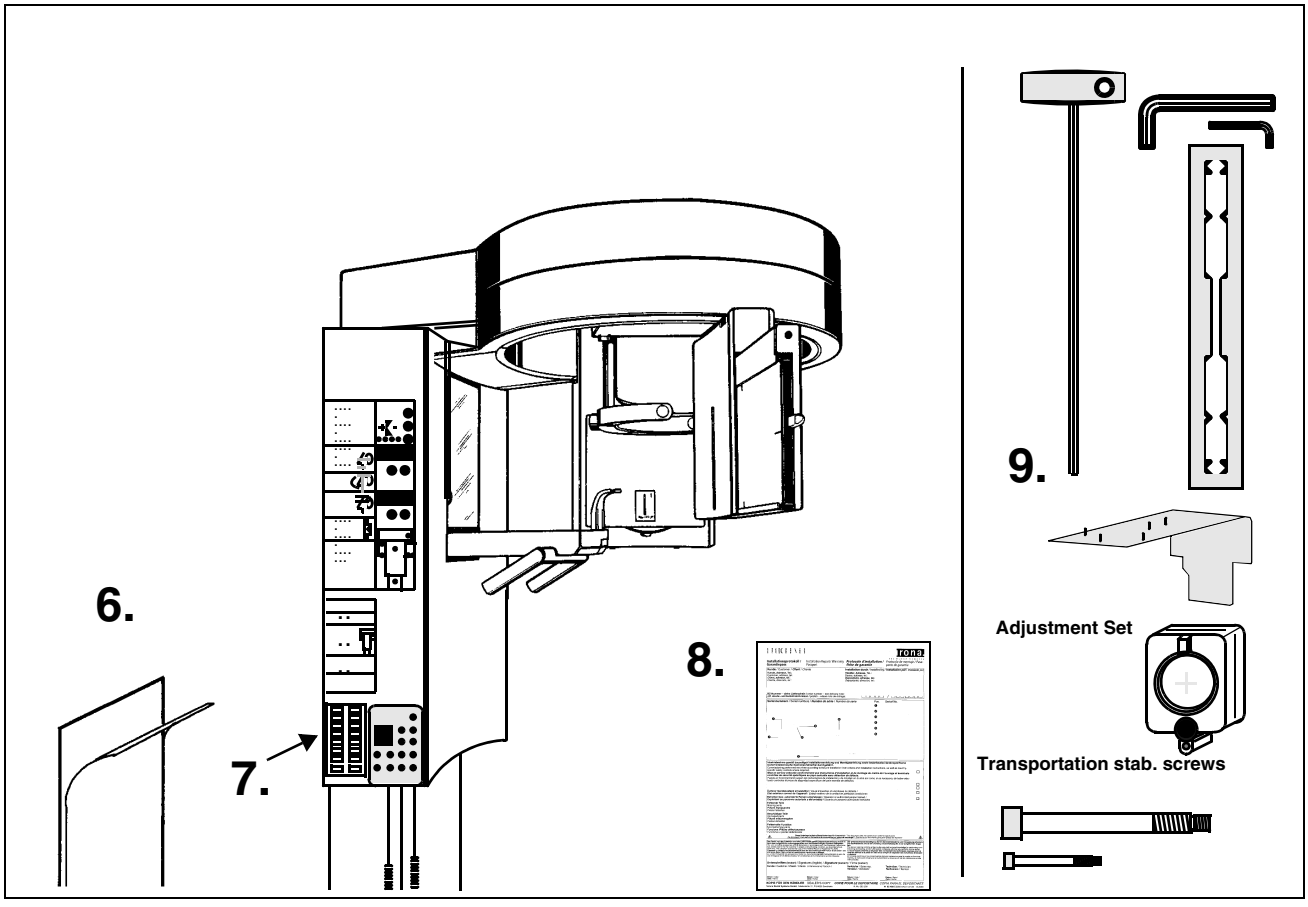
1. Place the front cover
over the diaphragm wheel and attach from below with the two **countersunk screws M4.**

2. Shift the back cover
over the X-ray head and screw on from below with the two **countersunk** screws M4.

3. Connect both covers
with the two **cylinder head screws M4.**

4. Position the upper cover,
aligne with the lower cover **A** and screw on with two **cylinder head screws M4** from above.

5. Screw in two **screws M4** from below.



6. The operating labels in English, French and Spanish are contained in the package.
Remove the German label, make certain that the surface is free of grease and residue from the label, and affix the English label.

7. Stick program foil in place if no remote control is installed.

8. Installation Report / Warranty Passport

- Fill in **Serial-Nos**. and **Software Version** in the enclosed Warranty Passport.
  Fill out remaining fields together with the customer.
  Send the filled out Form to Sirona.
- **FOR THE CUSTOMER**
  remains in possession of customer.
- **FOR THE DEALER**
  remains in customer file of Technical Service.

9. Adjustment Set
The supplied **needle phantom, beam alignment tool, test block and special wrench** are part of the unit and are thus to be handed out to the customer in the corresponding packing for Adjustment Set.
The supplied **technical documents** also are part of the unit and are thus to be handed out to the customer.

The unit is now ready for operation.

17 Attention Installer (for USA/Canada only) !

- Proper shielding of room and operator position is essential.
  Since these requirements vary from state to state it is the assembler's / installer's responsibility that all local radiation safety requirements are met.
- Form FD 2579:
  It is the responsibility of the Dealers, Distributors, Assemblers, Installers of Certified Diagnostic X–Ray Equipment to fill out and distribute the Federal Form FD 2579, upon completion of an installation. It is also your obligation to inform the end user "purchaser" of the use, care and recommended yearly maintenance.
  Forms may be acquired from:
  FDA
  2098 Gaither Rd.
  Rockville, MD 20850
  (301) 594–4520
  Sample of a filled out form see next page.
- The Model - Nos of the certified components are printed and the Serial - Nos have been recorded by you, the installer, on the Warranty Passport.
- Familiarize the user with the proper operation of the unit.
- Advise the user / customer of the manufacturer's recommended Yearly Maintenance.
- Hand over the adjustment tools
  and special wrenches for future yearly maintenance.
- All manuals are part of the unit and are the customer's property.
- Additional copies of the manual scan be purchased for service use and / or customer use at our cost price, a P.O. via dealer must be sent to the address indicated on the rear of this manual.
- This unit is now ready for use!

18 Sample of a Filled out Form (for USA/Canada only)

FOR FDA USE ONLY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM

Form Approved OMB No. 0910-0213
Expiration Date November 30, 1994
See reverse for OMB statement

D 197009

1. EQUIPMENT LOCATION

a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED: Dr. John Doe
b. STREET ADDRESS: 1111 State Street
c. CITY: Anywhere
d. STATE: USA
e. ZIP CODE: 01994-0002
f. TELEPHONE NUMBER: (000) 111-2222

2. ASSEMBLER INFORMATION

a. COMPANY NAME: Dental Company
b. STREET ADDRESS: 5555 City Street
c. CITY: Anywhere
d. STATE: USA
e. ZIP CODE: 01994-0002
f. TELEPHONE NUMBER: (000) 111-3333

3. GENERAL INFORMATION

a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE *(Check appropriate box(es))*
- [x] NEW ASSEMBLY-FULLY CERTIFIED SYSTEM
- [ ] REASSEMBLY-FULLY CERTIFIED SYSTEM
- [ ] REASSEMBLY-MIXED SYSTEM *(Both certified and uncertified components)*
- [ ] REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM
- [ ] AN ADDITION TO AN EXISTING SYSTEM

b. INTENDED USE(S) *(Check appropriate box(es))*

[ ] GENERAL PURPOSE RADIOGRAPHY	[ ] PODIATRY	[ ] CT HEAD SCANNER	[x] DENTAL PANORAMIC
[ ] GENERAL PURPOSE FLUOROSCOPY	[ ] UROLOGY	[ ] CT WHOLE BODY SCANNER	[ ] RADIATION THERAPY SIMULATOR
[ ] TOMOGRAPHY *(Other than CT)*	[ ] MAMMOGRAPHY	[ ] HEAD-NECK *(Medical)*	[ ] C-ARM FLUOROSCOPIC
[ ] ANGIOGRAPHY	[ ] CHEST	[ ] DENTAL-INTRAORAL	[ ] DIGITAL
	[ ] CHIROPRACTIC	[ ] DENTAL-CEPHALOMETRIC	[ ] OTHER *(Specify in comments)*

c. THE X-RAY SYSTEM IS *(Check one)*
- [x] STATIONARY
- [ ] MOBILE

d. THE MASTER CONTROL IS IN ROOM: #4

e. DATE OF ASSEMBLY: 04 (mo.) 03 (day) 98 (yr.)

4. COMPONENT INFORMATION *(If additional space is needed for this section use another form, replacing the preprinted number with this Form Number and complete Items 1, 4, and 5 only)*

a. THE MASTER CONTROL IS
- [x] A NEW INSTALLATION
- [ ] EXISTING *(Certified)*
- [ ] EXISTING *(Non-certified)*

b. CONTROL MANUFACTURER: SIRONA
c. CONTROL MODEL NUMBER: 46 80 364 D3297
d. CONTROL SERIAL NUMBER: — — — —
e. SYSTEM MODEL NAME *(CT Systems Only)*:

Complete the following information for the certified components listed below which you installed. For beam limiting devices, table, and CT gantries enter the manufacturer and Model number in the indicated spaces. For other certified components, enter in the appropriate blocks how many of each you installed in this system.

f. SELECTED COMPONENTS

	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED
BEAM LIMITING DEVICE	SIRONA	1888 408 D3200	— — — —
BEAM LIMITING DEVICE	SIRONA	1888 382 D3200	
TABLES			
TABLES			
CT GANTRY			

g. OTHER CERTIFIED COMPONENTS *(Enter number of each installed in appropriate blocks)*

[x] X-RAY CONTROL	[ ] CRADLE
[ ] HIGH VOLTAGE GENERATOR	[ ] FILM CHANGER
[ ] VERTICAL CASSETTE HOLDER	[ ] IMAGE INTENSIFIER
[ ] TUBE HOUSING ASSEMBLY *(Medical)*	[ ] SPOT FILM DEVICE
[x] DENTAL TUBE HEAD	[x] OTHER *(Specify)*

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.

a. PRINTED NAME: John Smith
b. SIGNATURE: John Smith
c. DATE: 04.03.98

6. COMMENTS

'other' ORTHOPHOS PLUS D3287 Unit-Model # D3287
X-rayhead Model# 59 68 573 D3200

FORM FDA 2579 (5/94) PREVIOUS EDITION IS OBSOLETE

White Copy - FDA, HFZ-353, 5600 Fishers Lane, Rockville, MD 20857

We reserve the right to make any alterations which may be due to technical improvements.

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