

Oralix® AC

Operator manual

Manuale dell'operatore

Manuel de l'opérateur

Manual del usuario

X-ray Systems • Digital Systems • Intraoral Camera Systems

GENDEX®

Oralix AC

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This manual in English is the original version.

1 Introduction

Oralix ® AC is a system for radiography of teeth in conjunction with an intraoral detector (intraoral film or electronic x-ray image sensor). It can provide radiographs useful for observing the formation and condition of deciduous and permanent teeth and of the surrounding bone structure, for the diagnosis of tender areas of teeth and gums, for locating impacted and supernumerary teeth, for root canal therapy, and in other conservation work. Oralix AC can also be used for certain radiographic procedures with extra-oral detector used in dento-maxillo-facial radiography, such as transcranial projection of the TMJ and submento-vertex or lateral projection of the mandible with extra-oral film-screen cassette.

- The Oralix AC system consists of:
- The Oralix AC dental X-ray tubehead, i.e. a radiographic generator comprising a X-ray tube and a high-voltage transformer assembled in the same enclosure that also includes various provisions for X-ray shielding and filtering, high voltage insulation, heat convection and sinking, and safety devices;
- A Beam Limiting Device (BLD) and Position Indicating Device (PID), also commonly known as a dental "cone";
- An articulated suspension arm;
- A rigid extension arm;
- A wall support (except in the case of dental unit mount and of mobile assemblies);
- A microprocessor-controlled timer, either DENS-O-MAT or SECONDENT, that provides all necessary controls for the operation and the emission of x-rays. Note that one DENS-O-MAT timer could control the operation of two tubeheads (if the relevant option has been installed).

Oralix AC provides high quality X-ray irradiation by means of state-of-the-art technology. The diagnostic value and quality of the radiographic images obtained ultimately depends as well upon good positioning, on the detector used (film or electronic sensor) and on the subsequent image processing (either chemical or electronic), on compliance with the appropriate radiographic procedure, and, last but not least, on proper viewing technique.













This manual is intended to assist the user in the safe and efficient operation of the equipment described.



The equipment must be used in accordance with the procedures contained in the manual and must not be used for purposes other than those which are described herein.

The equipment should only be used by persons having recognised qualification and, if relevant, having adequate training on the particular equipment, especially regarding protective measures such as radiation protection. It is the responsibility of the user to ensure that the applicable regulations regarding installation and operation of the equipment are observed. Incorrect operation, or failure of the user to maintain the equipment in accordance with the scheduled maintenance, relieves the manufacturer or his agent from all responsibility for consequent non-compliance, damage, injury, defects and/or other malfunction.

1.1 Explanation of symbols

-  **0051** The CE symbol ensures that the product here in specified, and manufactured from 1998 onwards, meets the provisions of European Council Directive 93/42 EEC concerning medical devices.
-  Consult Written Instructions (this Operator's Manual)
-  Device emitting x-rays.
-  Type B equipment (IEC 601.1 - 1988)
-  Focal spot
-  Filtration, Al equivalent
-  X-ray tube
-  Stand-by
-  X-rays on, for SECONDEMENT timer
-  X-rays ready, for DENS-O-MAT timer
-  **Warning (in this Operator Manual)**
-  Note (in this Operator's Manual)

See page 12 for other symbols description.

2 Operation

2.1 General principles of operation



The tubehead-based dental X-ray system is a simple type of x-ray generator.

Essentially, it consists of a high-voltage transformer that elevates the voltage taken from the mains supply up to an extremely high value (e.g. 65 kVp = 65000 V peak), and applies it across a x-ray tube. The x-ray tube acts as a voltage rectifier and lets current pulses (the mA) flow through in correspondence with every half mains phase.

Inside the x-ray tube, the highly energetic electrons during the current pulses hit the tungsten surface of the anode and cause it to emit x-rays photons of various energies, the highest ones corresponding (in the keV unit of measurement) to the peak electron-accelerating voltage across the x-ray tube. Note that the higher the average energy of the x-ray photons, the more penetrating the x-ray beam is.

X-rays are only present during the very moment of the irradiation. They travel along a straight direction and cannot be deflected or reflected. When they pass through solid matter, or strike against a surface, they momentarily bring about a certain amount of secondary and less energetic x-rays, respectively called scattered and back scattered radiation.

The high-voltage transformer and the x-ray tube are soaked in dielectric oil both for electrical insulation and for convection of the intense heat generated in the x-ray tube. All around the x-ray tube there is lead shielding that effectively blocks x-rays in all directions, except through a small output window. This window also incorporates an Aluminium filter to remove the useless, less penetrating photons from the x-ray beam.

In front of this window and rigidly attached to the tubehead, there is an open-end Beam Limiting Device and Position Indicating Device (BLD/PID), that is a device including a lead diaphragm that collimates the x-ray beam field to the required shape and size, and means to apply such field to the required position. This device is also known as a "cone" (short for "coning device").

There are two types of cone that can equip your Oralix tubehead, depending on the option chosen, both providing a Source Skin Distance (SSD) of 20 cm:

A round BLD, consisting of a near-focus collimator and an open-end cylindrical spacer, with a circular irradiated field of 6 cm diameter. The tip of the cone includes a lead shielding for protection against back-scattered radiation.

A rectangular BLD, made out of metal, providing an irradiated field of 3.5x4.5 cm. It can be rotated so to align the x-ray field with the film.

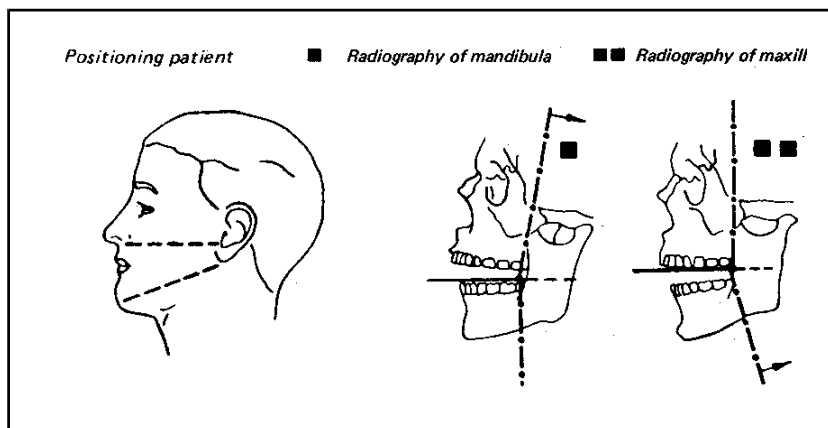
The cone can be removed and interchanged by turning it anti clockwise.

The rectangular BLD requires a more accurate operation than the round one (and re-takes may occasionally be required). However, the integral imparted dose using rectangular BLD is less than half than with round BLD (due to the smaller irradiated area). Also, the image quality thus obtained benefits from the less scattered radiation.

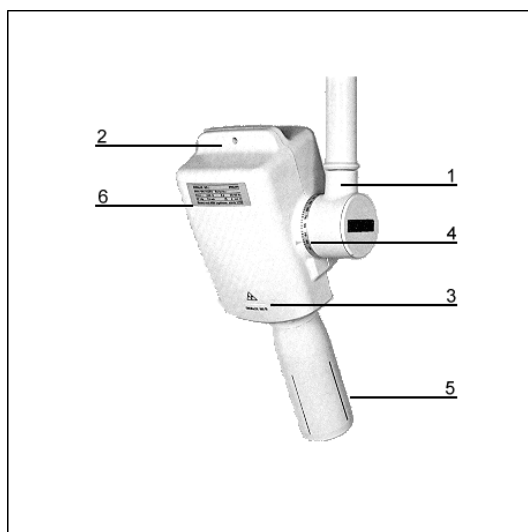
2.2 Preparation and positioning for an intraoral radiograph

Detailed operation may slightly vary among different types of image detector (film or electronic sensor). Instructions for using and positioning the detector in the mouth are normally provided with the detector itself. In the following instructions it is assumed that a conventional x-ray film is being used, unless otherwise specified.

Seat the patient on a dental chair, or any other accommodation providing appropriate support for the head, and tilt his or her head to the proper inclination. Always position the patient with the sagittal plane vertical. For upper jaw exposure, place the upper occlusal plane horizontal. For lower jaw exposures, place the lower occlusal plane horizontal.



Set the required exposure time on the timer. Refer to the next chapters for operation of the dental timer and selection of the proper exposure time.



1. Trunnion
2. Handgrip
3. Indication for the position of focal spot
4. Scale for the angle
5. Interchangeable cone
6. Label with technical data

Rotate the tubehead in its trunnion, by holding the cone and the handgrip, to proper angle depending on the radiograph to be made. The tubehead angle can be read on the graduated scale on the side of the tubehead.

Please note that the tubehead can be rotated continuously around the horizontal axis (the vertical pivoting shaft), and for 270° vertically (around the horizontal axis of the trunnion). Make sure that you are using the proper (that is middle) part of the 270° range.

Position the film into the patient's mouth in the proper position, either by using a holder or a by free hand (in the latter case the film must be hold in position by the patient's index finger, not the operator's!).



Paralleling Technique

Paralleling technique produces the most accurate image of the teeth as it follows the principles of accurate shadow casting (more closely than the bisecting technique does). An accurate shadow casting is obtained when the long axis of the tooth is placed parallel to the film. The undesirable enlargement of the object can be avoided by using a "parallel" x-ray beam. With the Oralix AC an SSD of 20 cm is used. At this distance, conditions are suitable for applying the paralleling technique. In order to escape the restrictions of the oral anatomy, the film must be positioned further away from the tooth. The radiographic enlargement will be approx. 15%. In order to place the film parallel to the tooth axis, film holders can be used.

The Oralix AC is thus positioned in relation to the film holder. As a consequence of the technique applied, a smaller tubehead angle is used than with the bisecting technique.

Bisecting Technique

With the bisecting technique, the radiographic enlargement is selected so that of the tooth axis equals the length on the radiograph. This is obtained by placing the central ray perpendicular to the bisector of tooth axis and film. The radiographic enlargement due to the different film-object distance along the length of the tooth is acceptable.

Grab the tubehead from behind, and move it close to the patient's head. Direct the tubehead and gently bring it to the patient's head until the cone tip touches the patient skin at the area to be examined. Finally check the angle again.

Please note that, in order to ensure the required mechanical stability, the folding arm needs to be open at least 10°. Smaller angles may cause the arm to drift to zero, i.e. completely folded, thus impairing stability and position of the x-ray source.

Make an exposure by keeping the exposure handswitch firmly pressed.



During an exposure all personnel must stay away from path of the primary x-ray beam, preferably behind the tubehead and at least 2.5 m from the patient's head, in order to ensure that the potential exposure to direct and scattered radiation be less than the limit indicated in the applicable international standards.

The value of a radiograph depends not only on the amount of details it reveals but also on the accuracy with which the film and object have been positioned, in relation to the x-ray beam. Therefore, the use of positioning devices is encouraged, in order to properly position and align the detector in relation with the radiographic object (e.g. the tooth to be radiographed) and the cone.

3 SECONDENT Timer

SECONDENT ® is a fully microprocessor-controlled dental timer, featuring sophisticated internal design in order to achieve very simple operation.

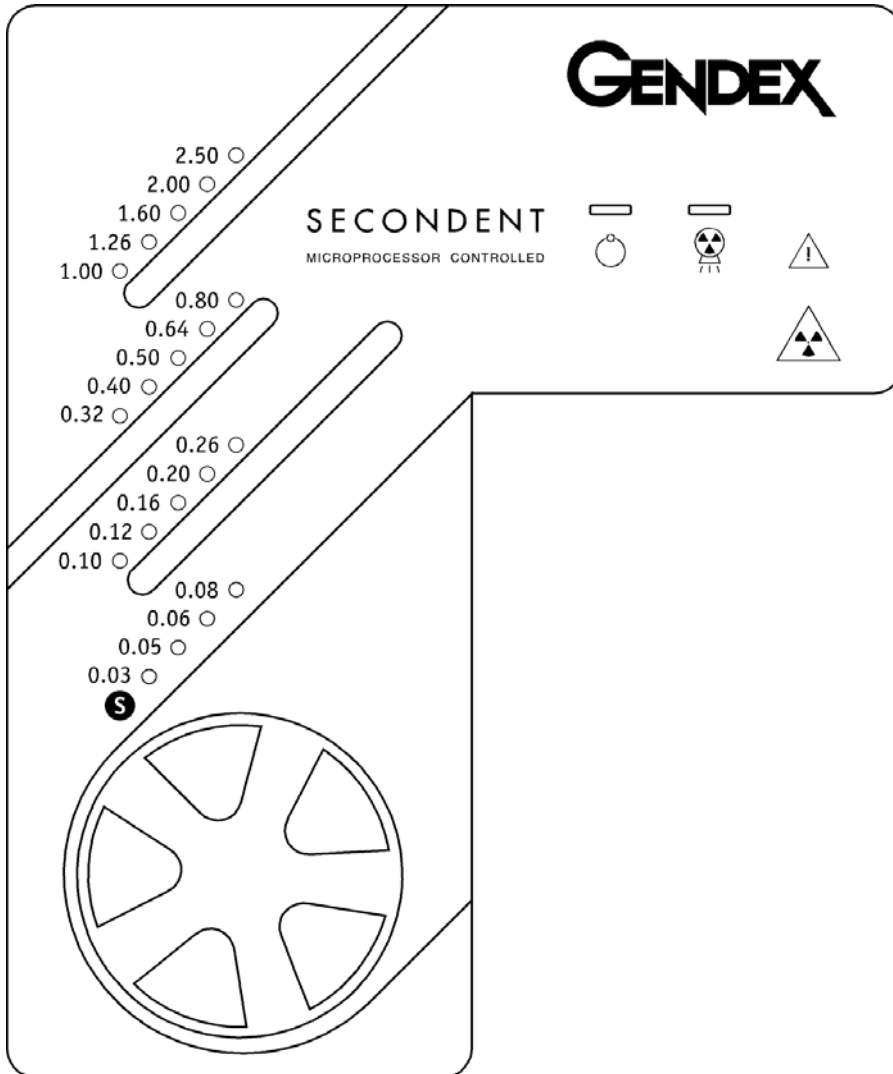



As the actual value of the mains voltage keeps fluctuating during the day, so does the kV applied to the x-ray tube and the resulting imparted x-ray dose rate (i.e. the flow of x-ray photons emitted). In a given system, the dose rate depends on the kV to a very large degree, and a difference of a few percent in the mains supply may well imply a twofold change in dose rate.

SECONDENT continuously adjusts the actual exposure time in order to ensure that the dose imparted in a given exposure is independent from such mains voltage fluctuations. For any selected nominal exposure time, the actual exposure time is automatically shortened or lengthened in such a way that the overall imparted dose is the same that would occur if the mains supply voltage was at nominal value (i.e. 230V).

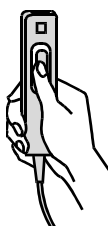
Therefore, the actual exposure time corresponds to the nominal selected exposure time only when the line mains voltage is exactly at its nominal value of 230V.


To disable the time vs. voltage compensation (e.g. for test purpose) pls refer to the Technical Service Manual.



Power on the system by the mains switch. Green mains lamp  must light up, the timer is in stand-by mode.

Select the required exposure time with the 24-steps time selector rotary knob. The nominal selected exposure time will light up on the front panel. Use the table here under as a reference to select the exposure time as a function of the tooth. The exposure times given apply for an average patient and paralleling technique. It may be necessary to use different exposure times depending on the specific tooth and jaw thickness or density, the age of the patient, the efficiency of the film processor, the personal preferences of the observer of the radiograph, in case of bisecting technique, and if a film of different speed is used.



An exposure is made by means of the handswitch. The coiled cable of the handswitch can be stretched up to 2.5 m, to ensure the required distance between operator and x-ray source (the tubehead). During the exposure the yellow lamp  lights up and a warning tone is buzzed, indicating that x-rays are being emitted.

Press the handswitch push-button to start the exposure and keep it pressed until the lamp goes out and the warning tone stops. If the handswitch is released during exposure, the same will be interrupted (this is called "dead-man" operation).

EXPOSURE CHART









Object	Exp. time (s) D-type film	Exp. time (s) E-type film	Exp. Time (s) Digital sensor
molars, upper jaw	0.8	0.4	0.20
premolars, upper jaw	0.64	0.32	0.16
canines, upper jaw	0.5	0.26	0.12
incisors, upper jaw	0.4	0.2	0.1
molars, lower jaw	0.5	0.26	0.12
premolars, lower jaw	0.4	0.2	0.1
canines, lower jaw	0.4	0.2	0.1
incisors, lower jaw	0.32	0.16	0.08
Occlusal. , post., upper jaw	1.6	0.8	0.4
Occlusal. , ant., upper jaw.	1.25	0.64	0.32
Occlusal. , post., lower jaw	1.0	0.5	0.26
Occlusal. , ant., lower jaw.	1.0	0.5	0.26
Interproximal, posterior	0.64	0.32	0.16
Interproximal, anterior	0.5	0.25	0.12

Children: reduce times by two settings i.e. approx. 40%

Edentulous mouth: reduce times by one setting i.e. approx. 25%.

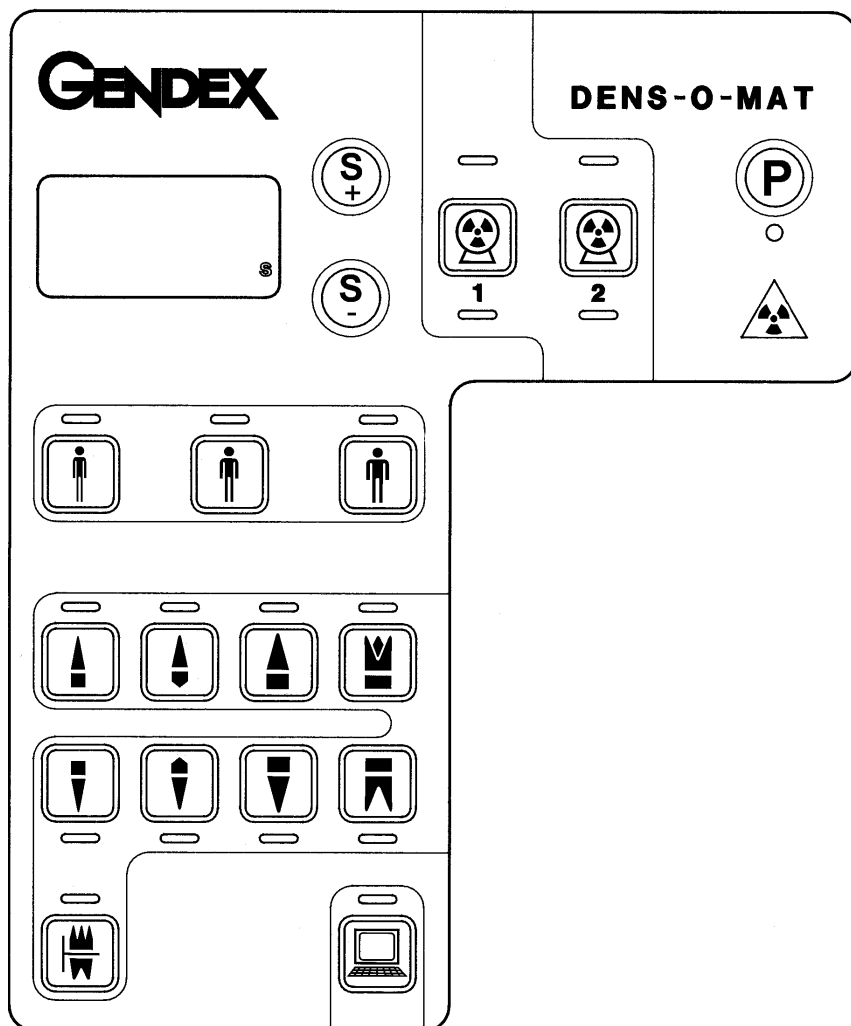
3.1 Anomalies & Alarms Chart

Even during normal operation, irregular conditions or any other anomalies might occur. In this case an alarm signal is generated and a lamp lights up.

Anomaly	Signal	Consequence
The actually-required exposure time (corrected because of mains voltage fluctuations) is less than the minimum (< 0.03 s).	Time selected lamp on 0.03 s lamp flashing	Exposure time is forced to 0.03 s (the lower limit).
The actually-required exposure time (corrected because of mains voltage fluctuations) is more than the maximum (> 2.5 s).	Time selected lamp on 2.5 s lamp flashing	Exposure time is forced to 2.5 s (the upper limit).
The mains voltage fluctuates beyond the allowed range ($\pm 10\%$).	 lamp flashing  lamp flashing	Exposure is inhibited until the mains returns within voltage range.
An exposure was attempted during the cooling time (to prevent tubehead overheating, exposure is disabled during cooling down).	 lamp flashing	Lamp flashing is reset at the end of cooling time, or by selecting a shorter exposure time.
The exposure was prematurely stopped by operator ("dead man" function)	 lamp flashing	Exposure is inhibited. Reset by actuation of the rotating knob.
No power supply	No lamp lights up	Refer to Service Manual (note: fuse # 3 could be blown).
Technical Alarms (See Service Manual)	 lamp flashing,  turned off, or  lamp flashing ,  turned on	Exposure is inhibited. Turn off the timer, wait a few seconds and turn on again. If problem persists, contact your Gendex dealer.

4 DENS-O-MAT Timer

Dens-O-Mat ® is a microprocessor-controlled dental timer, featuring object-oriented



operation.

If the relevant option has been installed, two tubeheads can be connected to Dens-O-Mat. Selection of the tubehead to be controlled and operated is done via keys ☼1 and ☼2, and the relevant lamp lights on. At power on, tubehead ☼1 is selected by default.



Tubehead selection is only possible if DENS-O-MAT automatically detects the relevant connection.

All DENS-O-MAT functions are independent and separate for either tubehead, e.g. the programmable modalities described further on (film speed adjustment, time scale customisation, digital sensor mode), or the tubehead overheating control.

In object-oriented operation, the exposure time is automatically set in accordance with the selected technique, that is the choice of object (tooth) and patient size done at the keyboard panel, and depending upon the pre-set film speed and other eventual customisations. This is called "Pre-Programmed Mode".

The operator can manually alter (increase or decrease) the set exposure time, by means of keys **s+** and **s-**, thus entering a so-called "Manual Mode".

In Pre-Programmed Mode, the exposure time is automatically corrected in order to compensate for mains voltage fluctuations, and to impart an exposure dose consistent for the selected technique. The actual exposure time is shown on the display.


In Manual Mode, time compensation vs. mains voltage fluctuation is disabled.






In Pre-Programmed Mode, it is possible to read the value of the uncompensated exposure time, that is the exposure time with the selected technique, that would be set if the mains voltage was at exactly the nominal value (230 V). To do so, keep pressed for at least 2 s the key corresponding to the selected object (whose lamp is already lighted on).

In Manual Mode, setting an internal jumper can enable exposure time compensation for mains voltage fluctuations, please refer to the instructions in the Technical Service Manual.










4.1 Operation


Power on the system by means of the mains switch. Green lamp  1 will light up, the timer is in stand-by mode.


Set patient size:


- Key  for children and toothless jaw.
- Key  for young adults of normal size.
- Key  for heavy or calcified jaw.

Select the key corresponding to the tooth to be radiographed:

- Key  upper molar (maxilla).
- Key  upper premolar (maxilla).
- Key  upper canine (maxilla).
- Key  upper incisor (maxilla).
- Key  lower incisor (mandible).
- Key  lower canine (mandible).
- Key  lower premolar (mandible).
- Key  lower molar (mandible).
- Key  bitewing.

When using DENS-O-MAT in connection with a digital intraoral sensor (e.g. Gendex Visualix ®), set key . This will decrease all exposure times by a number of steps (or a factor) which is selectable and is 4 steps by default (see Digital Mode Customisation).

An exposure is made by means of the handswitch. The coiled cable of the handswitch can be stretched up to 2.5 m, to ensure the required distance between operator and x-ray source (the tubehead). During the exposure the yellow lamp  lights up and a warning tone is buzzed, indicating that x-rays are being emitted.

Press the handswitch push-button to start the exposure and keep it pressed until the yellow lamp  goes out and the warning tone stops. If the handswitch is released during exposure, the same will be interrupted (this is called "dead-man" operation).

4.2 Customisation

Film Speed Adjustment

The general dose requirements for your specific x-ray system may differ depending on the speed of the film used, and on other factors (e.g. different cone length, or added filtration), therefore you may need to change the pre-set exposure time scale by a coefficient. This is done through the Film Speed Adjustment procedure:

Keep key **P** pressed at power on. The relevant lamp flashes, "FSA" is displayed for 2 s, after that the display shows the speed film coefficient (1 by default). Lamp **P** is flashing.

Using the **s+** and **s-** keys, you may change the speed coefficient of the time scale as follows (according to the R10 scale). The entire time scale is altered by shifting all nominal time values by the given number of steps.

Coefficient	0.32	0.4	0.5	0.64	0.8	1	1.26	1.6	2
Nr of steps	-5	-4	-3	-2	-1	-	+1	+2	+3

Recommended film speed coefficient is 1 for D type films (Kodak Ultra Speed), 0.5 for E type films (Kodak Ektaspeed Plus, Agfa Dentus M2 ^{Comfort}) and 0.32 for F type films (Kodak Insight).

Press key **P** to confirm the selected speed coefficient, and to exit the Film Speed Adjustment modality and enter the Time Scale Customisation modality.

Time Scale Customisation

Using this function it is possible to customise exposure times for each tooth/technique, (independently and separately for tubehead ① and ②).

After the Film Speed Adjustment modality, the Time Scale Customisation mode is initiated. The message TSC is displayed for 2 s and the lamp **P** lights on.

Select the tubehead of interest by the relevant key ①. If only one tubehead is connected then customisation of tubehead 2 is inhibited.

Select the tooth, and then change the set time via the **s+** and **s-** keys.



Customisation anyway maintains the one step separation between small-medium-large patient. The "medium" size is forced during this operation, the relevant lamp lights on, and the time is always displayed (the time vs. mains voltage compensation is disabled).


Default values (medium patient size, film speed coefficient =1):

Tooth mandible	Exposure Time
⚓: lower incisor	0.32 s
⚓: lower canine	0.40 s
⚓: lower premolar	0.40 s
⚓: lower molar	0.50 s
⚓ Bitewing	0.50 s





Tooth maxilla	Exposure Time
⚓ upper incisor	0.40 s
⚓ upper canine	0.50 s
⚓ upper premolar	0.64 s
⚓ upper molar	0.80 s

The lamp associated to a tooth, whose set time has been changed, lights on. Press key **P** to save and enter Digital Mode Customisation.

Digital Mode Customisation

The message diG is displayed for 2 s, after that the display shows the digital mode coefficient (0.4s by default). Lamp  is off and lamp **P** is flashing.

It is possible to set the timer for digital mode per default at start-up by following the instructions below.

Press the  key, the control LED lights up; press the **P**-key until "End" shows up in the display. As of now the digital mode is set per default when starting up the timer. This setting can be made for one or both tubeheads ( **1** and  **2**) controlled by the timer, should these be connected. To restore the original setting, press the  key, the control LED does not light up.

Using the **s+** and **s-** keys, you may change the coefficient of the time scale as follows (according to the R10 scale). The entire time scale is altered by shifting all nominal time values by the given number of steps. By default, the exposure time scale is shifted by -4 steps for the Digital Mode (0.4s on display).

Coefficient	0.32	0.4	0.5	0.64	0.8	1
Nr of steps	-5	-4	-3	-2	-1	-

Press key **P** to save the selected coefficient, and to exit the Digital Mode Customisation. The message End is displayed. Switch off the timer, wait few seconds and switch on again to use the timer with the customisation.



This procedure must be completed as described above to become effective, and is concluded only when "End" appears in the display.

4.2 Anomalies & Alarms Chart

Even during normal operation, irregular conditions or any other anomalies might occur. An alarm signal is then generated and the display shows an error message.

Anomaly	Signal	Consequence
The actually-required exposure time (corrected because of mains voltage fluctuations) is less than the minimum (< 0.03 s).	0.03 s flashing	Exposure time is forced to 0.03 s (the lower limit).
The actually-required exposure time (corrected because of mains voltage fluctuations) is more than the maximum (> 2.5 s).	2.5 s flashing	Exposure time is forced to 2.5 s (the upper limit).
Mains voltage fluctuates beyond the allowed range (+/- 10%) oU : above +10% uU : under -10%	"oU" flashing "uU" flashing	Exposure is inhibited until mains fall within voltage range.
An exposure was attempted during the cooling time (to prevent tubehead overheating, exposure is disabled during cooling down).	"-II-" flashing	Alarm status reset at the end of wait time or by pressing any key.
Exposure stop by dead man function.	Real exposure time displayed flashing.	Exposure is inhibited. Reset alarm by pressing any key.
Handswitch pressed at power on.	"PrP" flashing	Exposure is inhibited. Turn off the timer, wait a few seconds and turn on again.
No power supply	No lamp lights up	Please refer to Service Manual (note: fuse # 3 could be blown).
Technical Alarms (See Service Manual)	"BUT" flashing "trc" flashing "rSt" flashing "Int" flashing "EEP" flashing	Exposure is inhibited. Turn off the timer, wait a few seconds and turn on again. If problem persists, contact your Gendex dealer.

5 Maintenance, Cleaning and Disinfecting

Maintenance

No maintenance is normally required by user. Please refer to the Technical Service Manual for preventive and corrective maintenance, to be carried out by a trained technician.



In order to prevent interference during normal operation, the system should not be used in presence of strong electromagnetic fields.

Oralix contains non-environmental-friendly substances, in particular approx. 1 kg of dielectric oil in the tubehead. Therefore disposal of discarded parts must be done via a company specialised in industrial wastes.

Cleaning

Always disconnect the equipment from the mains supply before cleaning.

Do not allow water or other liquids to enter the equipment, as they may cause circuits and corrosion.

Enamelled parts must only be cleaned by wiping with a damp cloth and mild detergent, followed by rubbing down with a dry woollen cloth. Do not use abrasive polishes.

Disinfecting

Always disconnect the equipment from the mains supply before disinfecting. Do not allow water or other liquids to enter the equipment, as they may cause short circuits or corrosion.

The powered equipment, accessories and connecting cables can be disinfecting by wiping with a cloth dampened with a disinfectant solution.

Do not use solvent or corrosive disinfectants.

The equipment must not be exposed to gaseous disinfectants. Spray disinfectants are not recommended, as the disinfectant may enter the equipment causing short circuits or corrosion.

If sprays are unavoidable the following precautions shall be taken:

If the room in which the equipment is installed is to be disinfected by means of an atomiser, the equipment should be carefully covered with plastic sheet.

The equipment should be switched off and allowed to cool down well in advance in order to prevent convection currents drawing the disinfectant mist into the equipment.

After dispersal of disinfectant mist the plastic sheeting can be removed, and the equipment can be disinfected by wiping.

The equipment may not be used in the presence of disinfectants which vaporise to form explosive mixtures, and the vapour must be allowed to disperse before the equipment is returned to use.

The method of disinfecting used should comply with current regulations and recommendations, including those concerning the prevention of explosion hazards.

6 Safety



In the interest of the safety of patient and user, the following points should be observed:

Electrical Safety

Only qualified service representatives should be authorised to remove the covers, or otherwise obtain access to the powered circuits.

The equipment should preferably be used in rooms with provisions in compliance with the relevant national and/or international legislation and recommendations concerning electrical safety in rooms used for medical purposes, concerning provisions of an additional protective earth (ground) terminal for equipotential connection.

Always disconnect or switch the equipment off before cleaning or disinfecting

Mechanical Safety

Where complete safeguarding of the equipment is not possible due care must be taken to ensure that no part of the user's or patient's body or clothing can be trapped or injured by any part of the equipment.

In particular, make sure that fingers are not caught pinched in the articulated arm, when closing it.

Explosion Safety

The equipment is not suitable for use in the presence of flammable gasses or vapours.

Remember that some disinfectants vaporise to form explosive mixtures, and that if such disinfectants are used the vapour must be allowed to disperse before the equipment is returned to use.

Radiation Safety

Only qualified and authorised personnel may operate this equipment observing all laws and regulations upon Radiation Protection.

Operators are strongly urged to acquaint themselves with current recommendations of the International Commission on Radiological Protection.

Full use must be made of all radiation protection features on the equipment and of all radiation protection devices, accessories and procedure available to protect Patient and Operator from x-ray radiation.

The tubehead contains dielectric mineral oil, which is potentially injurious in case of ingestion or contact with skin or mucous membrane.

In case of damage, the oil can flow out of the tubehead. In that case, avoid contact with the oil or breathing any potential vapour. In case of a limited lost of oil, the oil can be wiped out, wearing impermeable gloves.

Mandatory reporting according to the European Directive 93/42 for medical devices

In order to fulfil the obligations foreseen for the CE marking, the user must report to the Health Authorities in charge any accident involving the medical device and any eventual alteration in its features or performances, including insufficient user's instructions, which could cause death, injuries or a health hazard to patient and/or operator. Such reporting must also be promptly notified to the manufacturer or his agent, in order to permit the fulfilment of the obligations foreseen in the a.m. European Directive for the manufacturer.

7 Technical Data

Mains power supply:	230 V - 50/60 Hz.
Maximum mains voltage deviation:	± 10%
Maximum frequency deviation:	± 2 Hz
Maximum current absorption:	5 A
Mains resistance:	0.8 Ω
 X-ray tube:	
Secondary voltage, nominal:	65 kVp
Secondary current, nominal:	7,5 mA mean
Maximum duty cycle ratio:	1:75
Permissible mean current:	360 mAs/hour
Focus (focal spot):	0,7 (IEC 336 - 1982)
Inherent filtration, minimum:	2 mm Al equivalent (IEC 522 1976)
Output dose rate (approximate, indicative):	5 mGy/s @ 20 cm from source (at cone tip)
HVL - Half Value Layer (approximate, indicative):	2 mm Al
SSD - Source (focus) to skin distance:	20 cm
Manufacturer	Gendex
Type:	800-0004G1
 X-ray field at tip of cone:	
	60 mm (round BLD) 35 x 45 mm (rectangular BLD)
Leakage radiation: (taking into account the 1:75 maximum duty factor)	less than 0.044 mGy/h @ 1 m from source
Reach:	1410 cm / 1860 cm
 Weights:	
tubehead (excluding cone):	6 kg
round cone	0,3 kg
rectangular cone	0,4 kg
articulated arm	7 kg
extension arm, 45 cm	2,3 kg
extension arm, 90 cm	3,8 kg
Timer (SECONDENT/ DENS-O-MAT)	2,4 kg

7.1 Storage and transportation conditions

	Temperature [°C]		Relative Humidity [%]		Pressure [hPa]	
	Min	Max	Min	Max	Min	Max
DENSOMAT	-40	70	10	95	500	1060
SECONDENT	-40	70	10	95	500	1060

7.2 Compliance with applicable standards

Oralix AC conforms to the following standards:

- IEC 601.1 (1988), Amendment Nr.1 (1991), Amendment Nr.2 (1995)
- IEC 601.1.2 (1993)
- IEC 601.1.3 (1994)
- IEC 601.1.4 (1996)
- IEC 601.2.7 (1987)
- IEC 601.2.28 (1993)
- 93/42 CEE, European Directive concerning medical devices

Oralix AC is a Class I, Type B equipment (IEC 601.1 - 1988).

GENDEX

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