CE 2265

MATERIALS FOR MEDICAL USE

DENTIX® E

DENTAL RADIOGRAPHIC FILM – **INSTRUCTIONS FOR USE**

Characteristic

DENTIX E is a double-emulsion high speed non-screen X-ray film (ISO Class E) with a high contrast and fine grain that provides high image quality with outstanding detail definition. The film is intended for direct-exposure routine intraoral radiographs.
The used appliances enables the correction of exposure times as well as dose values (impulses).

Film base

DENTIX E is coated on a dimensionally-stable bluish 0.175 mm thick polyester film base. The film is provided, on both sides, with protective and antistatic layers preserving the film against mechanical damage and eliminating the static charge.

Packing

Each sheet of film is enclosed in a light-tight plastic envelope.

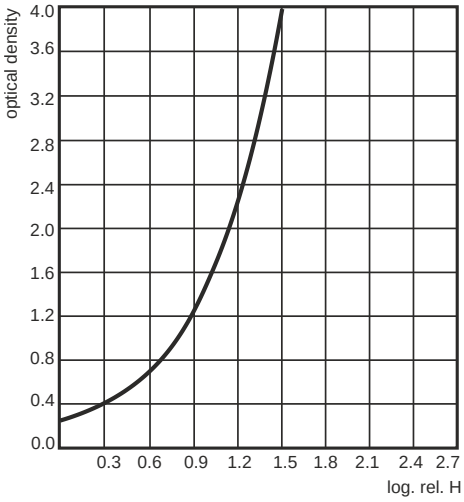
size ISO	size [mm]	number of films in one packet	number of packets in one packing
0	22.0x35.0	1	100
2	30.5x40.5	1	150
2	30.5x40.5	2	130

A packet is made up from a light-tight plastic envelope containing the quantity of films stated above.

This soft and hygienic packaging protects the patient, facilitates manipulation with the film and enables disinfecting the cover with common disinfectants.

Every film packet is protected with a lead sheet on the side opposite to the radiation source (marked on the back-side of the packet). Each film is provided with a protruding dot located near the edge of the film that serves as an identificator for the radiation side on the processed film. Its raised portion indicates the side facing the radiation source.

Characteristic curve



Darkroom illumination

The film is processed with at safety illumination with a wavelength of 590 nm and higher. The Length of exposure and distance of the processed material from the illumination source should be tested.

Processing

DENTIX E can be processed manually or in processors. The FOMADENT concentrated solutions are recommended for processing the film to obtain the best results, however, any other processing chemicals of well-known brands can be used too. It is recommended to follow the producer's instructions while processing in processors. It is necessary to test the ideal setting of a specific device (the bath temperature, the movement speed etc.) in practice.

Information according to Article 33 of REACH: The product DENTIX contains lead. This substance is included in the list of substances (for possible inclusion in Annex XIV). After handling, hygiene rules must be followed. More information at www.foma.eu.

automatic processing processing cycle/temperature	manual processing – developing developing time/temperature
4.5–5.0 min / 25 °C	5.0 min / 20°C 4 .0 min / 22°C 3.5 min / 24 °C 1.5 min / 28 °C
	Time of fixing/Temperature
	Not less than 2 min / 15–30°C

Note: It is necessary to wash the film in clean water at the end of manual processing.

Exposure conditions for DENTIX E

X-ray apparatus adjustment: 50 – 70 kV and 7 – 15 mA
(use correct values recommended by the apparatus manufacturer)

Adjustment: 65 kV, 8 mA, 20 cm focus-film distance			
Maxillary	Exposure	Mandibular	Exposure
Incisor Premolar Molar	0,18 s 0,23 s 0,25 s	Incisor Premolar Molar	0,14 s 0,14 s 0,18 s
For making exposures to children reduce the exposure time by approx. 33%. For making exposures of empty patches reduce the exposure time by approx. 25 %. For obtaining the best possible results all necessary changes of exposure parameters (i.e. exposure time, mA, kV or any changes of the focus-film distance) shall be reflected in other parameters. For X-ray devices with a DC generator, reduce exposure by about 33%.			

Storage

Films should be stored in original packaging at 10-25 °C and rel. humidity 40-60%, out of ionizing radiation and aggressive gases. The same conditions apply to shipping. If this is not otherwise possible due to technical reasons, the temperature and / or humidity can be exceeded up to 50 °C resp. 80% during the transport for a total period of up to 168 hours; the same applies to lowering the temperature and / or humidity up to -15 °C resp. 10%. For long-term storage, it is recommended to store the films at 0-10 °C. If the difference between the storage temperature and the film use temperature is higher than 15 °C, the film should be allowed to adjust to the target temperature for at least 3 hours before its use.

Warning

1. *The product is not sterile ; in accordance with the hygienic rules the disinfection of individual film packagings (each packet) must be applied before and after use and the procedure intended for specific healthcare department must be obeyed.*
2. *Usage and processing of the DENTIX film result in waste that is classified as hazardous waste and for this reason an ecological liquidation and recycling is necessary.*

   Classification of the waste:

Polyvinylchloride waste	*waste of developers*
Lead waste	*waste of fixing bath*

3. *The manipulation with the waste should be in accordance with valid statutory instruments.*
   It is necessary to work with individual packets carefully, not to flex them nor to push them down using nails or sharp tools. The film inside the packet is sensitive to pressure and the excessive pushing can cause pressure records which may complicate the picture evaluation.
4. *Do not use if the packaging is damaged*

The product has CE marking and has been produced and marketed in conformity with the requirements of the Directive 93/42/EEC.

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