

# Intraoral Dental X-ray film sensitivity E

(further film)

## TECHNICAL LIST – INSTRUCTION FOR USE

### Product Characteristics

The film speed E High-quality double-emulsion intraoral X-ray film of high speed (ISO class E), high contrast and fine grain, providing high image quality and outstanding detail definition. This film is intended for intraoral X-ray diagnostics only.

### Film Base

Bluish 0.175 mm thick polyester provided with double-sided protective and antistatic layer which protects the film against mechanical and electrostatic damage (ESD).

### Technical Properties

- standard exposure time
- soft plastic envelope with rounded corners
- easy opening and manipulation
- disinfectable package
- sheet of lead foil on the back side of the film (the side is marked as „back“ on the packet)
- easy sides recognition provided by embossed dot in the top corner of the packet (its raised portion indicates the side facing the radiation source/front side)

RECOMMENDED EXPOSURE TIMES*			
Adjustment: 65 kV, 8 mA. Focus film distance = 20 cm			
Maxilla	Exposure (s)	Mandible	Exposure (s)
Incisor	0.18	Incisor	0.14
Premolar	0.23	Premolar	0.14
Molar	0.25	Molar	0.18
For making children´s exposures reduce the exposure time by approx. 33 %			
For making exposures of empty spaces reduce the exposure time by approx. 25 %			
For the best possible results it is necessary to reflect all the changes (exposure, mA, kV, focus film distance) in other parameters.			

### Warning

\* Indicated parameters are tentative! For correct exposure adjustment use the values recommended by the manufacturer of your X-ray machine. It is better to test the film with different adjustments first.

\* The film is not sterile; in harmony with hygiene regulations is necessary before and after use to disinfect the individual packages of films (sheets) according defined process for the given medical centre.

### Processing

The film can be exposed in daylight. Exposed films can be processed either manually or in processors. The manual processing should be carried out in a darkroom under indirect dark-red or olive-green safelight. Recommended safelight filters are, for example: Kodak GBX-2, Agfa R1 (dark-red), Agfa G7 (olive-green) and its analogies. It is possible to use any liquid good-quality trademarked chemicals for processing. It is NOT recommended using tablet or powder chemicals.

Manual processing	Automatic processing
developing times/temperature	processing times/temperature
5.0 min/20 °C	5.0 min/27 °C 4.5 min/28 °C 4.0 min/29 °C
4.5 min/21 °C	
4.0 min/22 °C	
fixing times	
2.0 min/15 – 30 °C	

### Packing and Sizing

Dental films are packed in a tropical vacuum wrapping and put inside paper boxes to prevent all possible kinds of damage.

ISO size	Film dimensions (mm)	Films in one packet	Number of packets in one box
2	30.5 x 40.5	1	150

### Storage

Film should be stored:

- in the original packing in a dry and cool place
- at a temperature +10 up to 25 °C and relative humidity of 40 – 60%
- protected from damaging fumes, gases and ionizing radiation
- For long-term storage the film should be stored in a refrigerator. In such case the film in the intact original

Table 4	Temperature	Humidity	Storage time
warehouse	<25°C	<60 %	Until date of expire
	25< <30°C	60< <80 %	within 30 days
	30< <40°C	80< <90 %	within 10 days

packing should be allowed to adjust to room conditions for at least 2 – 4 hours.

Film speed E is necessary to storage:

- in original package in dry and cool place
- in temperature from +10 to +25°C and relative humidity 40 – 60%
- out of reach the harmful vapours, gases and ionizing radiation
- In case of long-term storage is recommended to store the films in the refrigerator, but before use is necessary to adopt the film in the room temperature for the period of 2 – 4 hours
- For storage in other than determined status without the influence on the durability of the dental film SKYDENT see Table 4.

### Transportation

Film speed E is s necessary to transport:

- In original package in dry and cool place
- In temperature from +10 to +25°C and relative humidity 40 – 60%
- Out of reach the harmful vapours, gases and ionizing radiation
- For the transportation in other than determined status without the influence on the durability of the dental film see Table 5.

<u>Table 5</u>	<u>Temperature</u>	<u>Humidity</u>	<u>Storage time</u>
<u>Transport</u>	<25°C	<60 %	Until date of expire
	25< <30°C	60< <80 %	within 30 days
	30< <40°C	80< <90 %	within 10 days
	40< <50°C	90< <100 %	within 1 day

### Waste Management

The usage and processing of dental film result in production of wastes classified as dangerous. It is therefore necessary to provide its ecological liquidation and recycling. Waste management should be in compliance with local waste legislation of the film's processor.

**Particular Waste Categories:**

PVC	lead	developers	fixers
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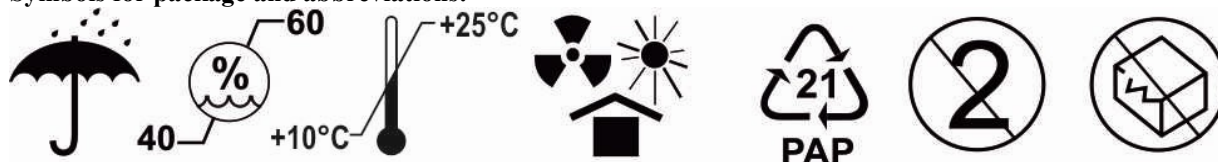
### Handling with waste

By use and processing the product came into being the dangerous wastes and is needed to ensure their ecological liquidation, resp. the recycling. The handling with these wastes modifies the Law on waste in valid wording of the particular state of the waste's processor.

**Individual kinds of wastes:**

PVC	lead	developing chemicals	fixing chemicals
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**Symbols for package and abbreviations:**



Keep in dry	Store in temperature and humidity 40 – 60%	Store temperature in 10 – 25 °C	Protect against temperature and radioactive sources	Recycling code – other paper	Do not use again	Do not use if package is damaged
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Lot number:



Expiration:



**Instruction for use see annex no. 1**

## **Annex no. 1 technical sheet – instruction**

### **– INSTRUCTION FOR USE –**

This annex no. 1 is an integral part of the Technical sheet – instruction films speed E. The individual values are based on sensitivity mentioned on the package and particular Technical sheet – instruction.

INSTRUCTION FOR USE DIVIDES INTO INDIVIDUAL POINTS:

- 1) Before the use of individual packet check if it's not damaged, especially individual welding point and adhesiveness of flip – in case of damage – DO NOT USE.
- 2) Always handle with the packet only with use of the protection gloves.
- 3) Before put the packet into patient's mouth, use the dental disinfection (see Package).
- 4) Always put the packet into patient's mouth that the side without sign (flip) would be in the direction to the source of radiation (by it, you ensure the correct use of the protective foil).
- 5) The equipment itself with the radiation source can be operated only by trained radiological technician.
- 6) After the exposition (according sensitivity and particular values in Technical sheet – instruction) the charged laboratory worker takes the packet who also follows the instruction in the technical sheet – instruction.
- 7) To unpack the packet itself after the exposition make solely in the space determined for it with the protective light (recommended wave length is 590 nm), after taking out of the exposed film, catch it by the particular instrument (clamps for the film's negative).
- 8) Insert the films into ahead prepared developer according the Technical sheet – instruction, following it, carefully rinse by the clear water, insert into the fixer according Technical sheet – instruction, following it, carefully rinse by the clear water and let it dry. By it, the film is prepared for the other use, for example for the inspection on the negatoscope.

***THIS TECHNICAL SHEET – INSTRUCTION IS ISSUED FOR ALL PRODUCTS  
FILM'S SENSITIVITY D MENTIONED IN ACTUAL (VALID) CE  
CERTIFICATE.***

**CE 2265**