



Czech Republic



EXPORT FOMA

FOMA BOHEMIA spol. s r.o. (Ltd.)
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FOMA 2016



www.foma.eu



FOMA® DENTAL PROGRAM:

- intraoral films DENTIX®
- extraoral films DENTIX® PANORAMIC
- processing chemicals



FOMA BOHEMIA

established manufacturer with tradition since 1921

Having its own R&D and unique formulas, complete coating & finishing facilities as well as full technical support FOMA remains one of the last original producers of photosensitive material not only in Europe but all around the world.

At present, FOMA manufacturing program consists of: dental X-ray films, industrial X-ray films (NDT), Personal monitoring films (PMF), Black and White photographic materials including processing chemicals for all items.



FOMA since 1921

TRADITION OBLIGES



ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSchechische REPUBLIK
INSTITUT ELECTROTECHNIQUE DESMABIS - REPUBLIQUE Tcheque
ELECTROTECHNISCHE PRÜFANSTÄLLE DER TSCHECHISCHEN REPUBLIK

Pod Lázní 126, 171 02 Praha 8 - Troja

The Electrotechnical Testing Institute Certification Body No. 3004 for certification of management systems, accredited by the Czech Accreditation Institute, s.p.s. in accordance with ČSN EN ISO/IEC 17021, grants the

CERTIFICATE

No.: 8130166

for the Quality Management System in accordance with

EN ISO 13485:2012

to the Firm

FOMA BOHEMIA spol. s r.o.

Jana Krusinky 1737/6, 500 02 Hradec Králové, Czech Republic

in localities -

because it ascertained that the Quality Management System of the Firm in localities and processes:

Development, production and sale of imaging and recording materials (medical X-ray films, thermoluminescent and recording materials, processing baths).

complies with all requirements of the above mentioned Standard documented by the Report No.: 303983-01 of: 22.10.2013

The validity of the Certificate is limited till: 29.10.2018

The Certified Organization is subject to annual check-ups carried out by the Certification Body. Any change within the organization concerning the certification shall be followed up and approved by the Electrotechnical Testing Institute. The validity of this Certificate may be suspended or cancelled in the event of non-compliance with the Standard on the basis of which the Certificate was issued.

Certifikat dlevo: 30.10.2013
Certifikat na: 17.12.2014

Prague



Miroslav Sedláček
Head of Certification Body



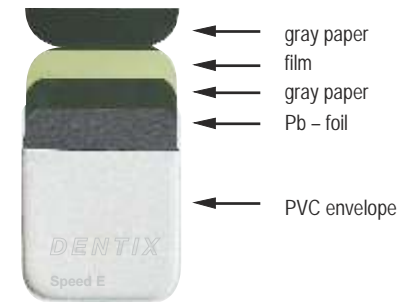
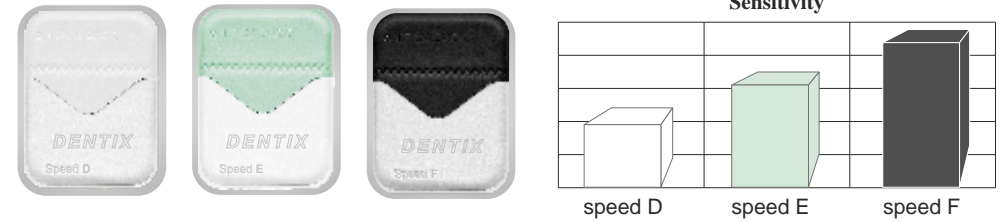
Stamp



303983-01

Intraoral films

Intraoral films DENTIX are manufactured in three types differing in their sensitivities: speed D (DENTIX D), speed E (DENTIX E), speed F (DENTIX X-Stream).



Product benefits:

- extra soft edged vinyl packets
- unique formulas providing excellent detail & contrast
- compatible with well-known processing chemicals
- full research & development support

Sizes

size ISO	size [mm]	number of films in one packet	number of packets in one packing
0	22.0 x 35.0	1	100
2	30.5 x 40.5	1	150
2	30.5 x 40.5	2	150

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

Processing

DENTIX intraoral films can be processed manually or in processors.



DENTIX D DENTAL RADIOGRAPHIC FILM

Characteristic

DENTIX D is a double-emulsion, non-screen X-ray film of medium speed (ISO Class D), high contrast and fine grain, providing high image quality and outstanding detail definition. This general-purpose film is intended for direct-exposure routine intraoral radiographs.

Film base

DENTIX D 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 damages and eliminating the static charge.

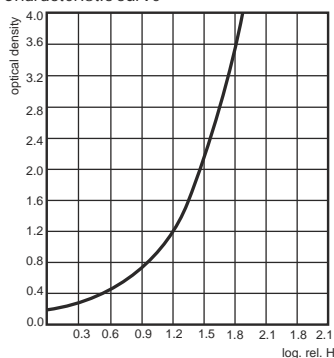
Packing

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

This soft and hygienic packing 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 radiation source (marked as back-side on the packet). Each film is provided with an embossed dot located near the edge of the film that serves as an identifier of 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 at safety illumination with wavelength of 590 nm and higher. Length of exposure and a distance of the processed material from the illumination source should be tested.

Processing

DENTIX D 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.

automatic processing	manual processing – developing
processing cycle/temperature	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 D

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	0,30 s	Incisor	0,25 s
Premolar	0,40 s	Premolar	0,28 s
Molar	0,45 s	Molar	0,30 s

For making exposures of children reduce the exposure time approx. by 33 %.
For making exposures of empty patches reduce the exposure time approx. by 25 %.
For obtaining the best possible results all the 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.
On X-ray devices with a DC generator, to reduce exposure by about 33%

Storage

DENTIX D should be stored in its original packaging in a cool dry place at a temperature from 10°C to 25°C and a relative humidity of 40–60 % protected from damaging fumes, gases and ionizing radiation. It is recommended to keep the film in a refrigerator with the temperatures between 5 and 8 °C in case of a long-term storage. Before use, the film in the intact original packaging should be allowed to adjust to room conditions for at least 2–4 hours.

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 E 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

Baths for intraoral films

for manual processing – liquid

The FOMADENT set includes:

- concentrate of developer FOMADENT D, 4x 250 ml, for preparation of 4x1 l of working solution
- concentrate of fixer FOMADENT F, 4x250 ml, for preparation of 4x 1 l of fixer working solution.

for machine processing – liquid

The FOMADENT M set is delivered in packaging of two types:

FOMADENT M 1,75 – the set includes 5x500 ml of concentrate of FOMADENT MD developer and 5x500 ml of concentrate of FOMADENT MF rapid fixer.

The set is intended for preparation of 5x1.75 l of developer working solution and 5x 1.75 l of rapid fixer working solution.

FOMADENT M 2,5 – the set includes 2x1 l of concentrate of FOMADENT MD developer and 2x1 l of concentrate of FOMADENT MF rapid fixer. The set is intended for preparation of 2x2.5 l of developer working solution and 2x2.5 l of rapid fixer working solution.



Baths for extraoral films

for manual processing – powder

- FOMA DP – two-part powder developer
- FOMA DP-R – two-part replenisher of developer
- FOMAFIX P – three-part powder rapid acid fixer

for manual processing – liquid

- FOMA LP-T – one-part liquid developer
- FOMA LP-TR – one-part liquid replenisher of developer
- FOMAFIX – one-part rapid fixer

for machine processing – liquid

- FOMA LP-D – developer/replenisher
- FOMA LP-DS – developer starter
- FOMAFIX + FOMAFIX H – set of liquid hardening fixer concentrates



DENTIX PANORAMIC Green EXTRAORAL RADIOGRAPHIC FILM

Characteristic

DENTIX PANORAMIC Green is green-sensitive X-ray film of a high-quality, high-contrast and low-fog designed for use with green-emitting intensifying screens. The film is suitable for all extraoral radiographic techniques.

Application

Film is used for all extraoral radiographic techniques, as

- Panoramic tomography
- Cephalometry
- Radiography for orthodontic diagnostics

Film is to be used in combination with intensifying screens, emitting in green regions of spectrum. Film can be used with all standard intensifying screens of well-known producers (e.g. AGFA, CAWO, MCI OPTONIX, KODAK, FUJI etc.) emitting in above mentioned regions of spectrum. E.g. screens AGFA CP-G (400), Rarex Green Medium (200), Rarex Green Regular (400) can be used.

Packaging

Film is supplied in 15x30 cm or 5"x12" (12,7x30 cm) sizes in a cardboard box containing 100 sheets of film NIF.

Darkroom illumination

The film is processed at yellow or diode safety illumination with wavelength of 660 nm and higher. Length of exposure and a distance of the processed material from the illumination source should be tested.

Processing

DENTIX PANORAMIC Green can be processed in roller processors in 90 seconds cycle time (or longer), or manually in tanks, using common chemicals. Optimum result is reached with FOMA LP-D Developer and FOMAFIX + FOMAFIX H rapid fixer for automatic processing and FOMALP-T Developer and FOMAFIX rapid fixer for manual processing.

Storage

Unexposed film should be stored in an intact original packing (the boxes should stand in the vertical position) at temperatures of 10 – 25°C and relative humidity of 40 – 60 %, away from harmful fumes, gases, X-ray and other ionizing radiation. The inventory should rotate.



DENTIX E DENTAL RADIOGRAPHIC FILM

Characteristic

DENTIX E is a double-emulsion high speed non-screen X-ray film (ISO Class E) with high contrast and fine grain that provides high image quality and outstanding detail definition. The film is intended for direct-exposure routine intraoral radiographs.

The used appliances enable the correction of exposure times as well as dose values (impulses).

The used appliances enable to correct exposure times as well as dose values (impulses).

Film bas130e

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 damages and eliminating the static charge.

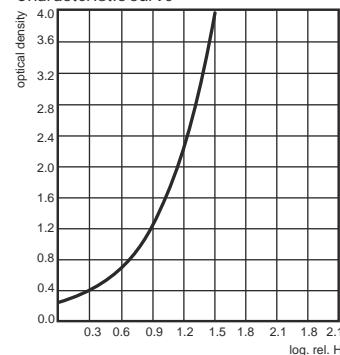
Packing

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

This soft and hygienic packing 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 radiation source (marked as back-side on the packet). Each film is provided with an embossed dot located near the edge of the film that serves as an identifier of 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 at safety illumination with wavelength of 590 nm and higher. Length of exposure and a 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.

automatic processing	manual processing – developing
processing cycle/temperature	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	0,18 s	Incisor	0,14 s
Premolar	0,23 s	Premolar	0,14 s
Molar	0,25 s	Molar	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

DENTIX E should be stored in its original packaging in a cool dry place at a temperature from 10°C to 25° and a relative humidity of 40–60 % protected from damaging fumes, gases and ionizing radiation. It is recommended to keep the film in a refrigerator with the temperatures between 5 and 8°C in case of a long-term storage. Before use, the film in the intact original packaging should be allowed to adjust to room conditions for at least 2–4 hours.

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 E 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

DENTIX X-Stream DENTAL RADIOGRAPHIC FILM

Characteristic

DENTIX X-Stream is a double-emulsion extra high speed non-screen X-ray film (ISO Class F) with high contrast and low fine grain. The film has perfect image quality and outstanding detail definition. The film is intended for direct-exposure routine intraoral radiographs.

This extra high speed of the film enables to reduce the X-ray dose by approximately 50% in comparison with the dental films of D class and by 20% in comparison with E class.

Film base

DENTIX X-Stream 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 damages and eliminating the static charge.

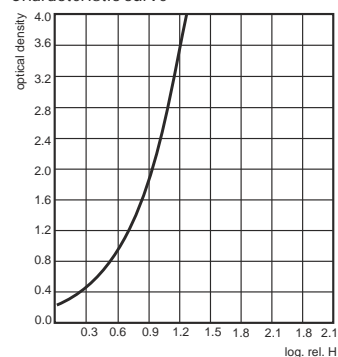
Packing

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

This soft and hygienic packing 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 radiation source (marked as back-side on the packet). Each film is provided with an embossed dot located near the edge of the film that serves as an identifier of 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 at safety illumination with wavelength of 590 nm and higher. Length of exposure and a distance of the processed material from the illumination source should be tested.

Processing

DENTIX X-Stream 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.

automatic processing	manual processing – developing
processing cycle/temperature	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 X-Stream

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	0.14 s	Incisor	0.11 s
Premolar	0.18 s	Premolar	0.12 s
Molar	0.20 s	Molar	0.14 s

For making exposures of children reduce the exposure time approx. by 33%.
 For making exposures of empty patches reduce the exposure time approx. by 25%.
 For obtaining the possibly best results all the 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.
 On X-ray devices with a DC generator, to reduce exposure by about 33%

Storage

DENTIX X-Stream should be stored in its original packaging in a cool dry place at a temperature from 10 °C to 25 °C and a relative humidity of 40–60 % protected from damaging fumes, gases and ionizing radiation. It is recommended to keep the film in a refrigerator with the temperatures between 5 and 8 °C in case of a long-term storage. Before use, the film in the intact original packaging should be allowed to adjust to room conditions for at least 2–4 hours.

Warning

- 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.
- Usage and processing of the DENTIX E 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
- 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.
- Do not use if the packaging is damaged

Extraoral films

DENTIX PANORAMIC Blue EXTRAORAL RADIOGRAPHIC FILM

Characteristic

DENTIX PANORAMIC Blue is blue-sensitive X-ray film of a high-quality, high-contrast and low-fog designed for use with blue-emitting intensifying screens. The film is suitable for all extraoral radiographic techniques.

Application

Film is used for all extraoral radiographic techniques, as

- Panoramic tomography
- Cephalometry
- Radiography for orthodontic diagnostics

Film is to be used in combination with intensifying screens, emitting in ultraviolet and blue regions of spectrum. Film can be used with all standard intensifying screens of well-known producers (e.g. AGFA, CAWO, MCI OPTONIX, KODAK, FUJI etc.), emitting in above mentioned regions of spectrum. E.g. screens Ultravision Fast Detail (200), Ultravision Rapid (400), Ultravision Blue Fast Detail (400) and Agfa Curix Blue 200 HC or Agfa Curix Blue 400 HC for blue part of spectrum can be used.

Packaging

Film is supplied in 15x30 cm or 5"x12" (12,7 x 30 cm) sizes in a cardboard box containing 100 sheets of film NIF.

Darkroom illumination

The film is processed at yellow or diode safety illumination with wavelength of 660 nm and higher. Length of exposure and a distance of the processed material from the illumination source should be tested.

Processing

DENTIX PANORAMIC Blue can be processed in roller processors in 90 seconds cycle time (or longer), or manually in tanks, using common chemicals. Optimum result is reached with FOMA LP-D Developer and FOMAFIX + FOMAFIX H rapid fixer for automatic processing and FOMALP-T Developer and FOMAFIX rapid fixer for manual processing.

Storage

Unexposed film should be stored in an intact original packing (the boxes should stand in the vertical position) at temperatures of 10 – 25 °C and relative humidity of 40 – 60 %, away from harmful fumes, gases, X-ray and other ionizing radiation. The inventory should rotate.

