

# CERTIFICATE OF QUALITY

Date of issue: 2001-03-20

## General Radiography Films

### 1. Types

Blue MEDIPHOT X-90/RP  
Ortho MEDIPHOT X-O/RP  
MEDIPHOT X-OL/RP

### 2. Test method

To expose medical standard X-ray film, these conditions are comparable with the ANSI PH2 48-1981 specifications for sensitometry of medical standard X-ray film.

For blue sensitive film a corning No 5850 type filter is used.

For green sensitive film a corning No 4010 type filter is used.

Speed The speed is measured at density D 1.00 above fog level.

Average gradient The average gradient is measured between densities D = 0.25 and D = 2.00, above fog level.

The figures mentioned for all the films have been obtained in regular 90 sec. processing cycle using MEDIPHOT chemistry.

Developer Seasoned MEDIPHOT E90 at 33°C

Fixer Seasoned MEDIPHOT F90 at 30-33°C

### 3. Specifications and tolerances

Film type	Base + fog (D)	Speed (logE) tolerance	Average gradient tolerance	Max. density (D)
MEDIPHOT X-90/RP	≤0.220	1,4± 0.07	2,5± 10%	≥ 3.30
MEDIPHOT X-O/RP	≤0.220	1,7± 0.05	2,7± 7%	≥ 3.60
MEDIPHOT X-OL/RP	≤0.220	1,7± 0.05	2,3± 7%	≥ 3.35

Storage conditions Average temperature between 18°C and 21°C (max. 25°C – min. 4°C). Max. 28°C for 3 successive weeks per year. No relative humidity control.

Transport conditions Max. temperature 30°C for max. 4 weeks.

The specifications of fresh material are valid at the date indicated on this document. They can be changed without notice at any time according to the rules set forth in the Quality Assurance system.

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# Product specification for MEDIPHOT X-90/RP

Date of issue: 2001-03-22

## 1. Product name and type

MEDIPHOT X-90/RP; Blue sensitive screen film

## 2. Product class

Class II A, according to Medical Device Directive 93/42/EEC,

## 3. Distributor's name and address

COLENTA Labortechnik GmbH & Co. KG, Neunkirchner Strasse 117, 2700 Wiener Neustadt, Austria

## 4. Product description

Double coated x-ray film for the intended use of medical x-ray exposure in combination with blue emitting light intensifying screens.

## 5. Shelf life

For unexposed films, shelf life is 30 months from manufacturing date. Expire date is stamped on each box.

For exposed films, shelf life is at least 20 years if the film is processed according to the manufacturer's specifications.

## 6. Technical data

Films are available in the following standard sizes:

Metric size (cm): 13x18, 15x30, 15x40, 18x24, 18x43, 20x40, 24x30, 30x40, 30x90, 30x120, 35x35, 35x43, 40x40

Inch size ("): 8x10, 10x12, 11x14, 12x15, 14x36

Film thickness: 180 µm

For sensitometric data, see the certificate of quality.

## 7. Manufacturing process

The photographic emulsion is made by dissolving silverbromide in a gelatine-based solution. Sensitizers are added and the emulsion is subject to a maturing process. Hardener is added to the emulsion right before it is coated on a polyester base.

The coating process is followed by a drying phase where the emulsion layer is hardened. A top-coating layer is added for the protection of the light-sensitive emulsion layer. The process is repeated on the other side of the polyester base.

After the coating process, the rolls are being cut in standard film sizes, packed in cardboard boxes and labelled.

## 8. Packaging

100 sheets of film are packed in lightproof black polyethylene plastic bags, and put into cardboard boxes. Each box is stamped with the emulsion number and expire date.

## 9. Storage and transport conditions

See certificate of quality

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## 1. Product name and type

MEDIPHOT X-O/RP; Green sensitive screen film

## 2. Product class

Class II A, according to Medical Device Directive 93/42/EEC,

## 3. Distributor's name and address

COLENTA Labortechnik GmbH & Co. KG, Neunkirchner Strasse 117, 2700 Wiener Neustadt, Austria

## 4. Product description

Double coated x-ray film for the intended use of medical x-ray exposure in combination with green emitting light intensifying screens.

## 5. Shelf life

For unexposed films, shelf life is 36 months from manufacturing date. Expire date is stamped on each box.

For exposed films, shelf life is at least 20 years if the film is processed according to the manufacturer's specifications.

## 6. Technical data

MEDIPHOT X-O/RP is a high contrast green sensitive film.

Films are available in the following standard sizes:

Metric size (cm): 12x30, 13x18, 15x30, 15x40, 18x24, 18x43, 20x40, 24x30, 30x30, 30x35, 30x40, 30x90, 30x120, 35x35, 35x43, 40x40

Inch size ("): 5x12, 8x10, 10x12, 11x14, 12x15, 14x36

Film thickness: 180 µm

For sensitometric data, see the certificate of quality.

## 7. Manufacturing process

The photographic emulsion is made by dissolving silverbromide in a gelatine-based solution. Sensitizers are added and the emulsion is subject to a maturing process. Hardener is added to the emulsion right before it is coated on a polyester base.

The coating process is followed by a drying phase where the emulsion layer is hardened. A top-coating layer is added for the protection of the light-sensitive emulsion layer. The process is repeated on the other side of the polyester base.

After the coating process, the rolls are being cut in standard film sizes, packed in cardboard boxes and labelled.

## 8. Packaging

100 sheets of film are packed in lightproof black polyethylene plastic bags, and put into cardboard boxes. Each box is stamped with the emulsion number and expire date.

## 9. Storage and transport conditions

See certificate of quality

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# Product specification for MEDIPHOT X-OL/RP

Date of issue: 2001-03-22

## 1. Product name and type

MEDIPHOT X-OL/RP; Green sensitive latitude screen film

## 2. Product class

Class II A, according to Medical Device Directive 93/42/EEC,

## 3. Distributor's name and address

COLENTA Labortechnik GmbH & Co. KG, Neunkirchner Strasse 117, 2700 Wiener Neustadt, Austria

## 4. Product description

Double coated x-ray film for the intended use of medical x-ray exposure in combination with green emitting light intensifying screens.

## 5. Shelf life

For unexposed films, shelf life is 36 months from manufacturing date. Expire date is stamped on each box.

For exposed films, shelf life is at least 20 years if the film is processed according to the manufacturer's specifications.

## 6. Technical data

MEDIPHOT X-OL/RP is a medium to high contrast latitude film.

Films are available in the following standard sizes:

Metric size (cm): 15x30, 18x24, 20x40, 24x30, 30x40, 35x35, 35x43, 40x40

Film thickness: 180 µm

For sensitometric data, see the certificate of quality.

## 7. Manufacturing process

The photographic emulsion is made by dissolving silverbromide in a gelatine-based solution. Sensitizers are added and the emulsion is subject to a maturing process. Hardener is added to the emulsion right before it is coated on a polyester base. The coating process is followed by a drying phase where the emulsion layer is hardened. A top-coating layer is added for the protection of the light-sensitive emulsion layer. The process is repeated on the other side of the polyester base. After the coating process, the rolls are being cut in standard film sizes, packed in cardboard boxes and labelled.

## 8. Packaging

100 sheets of film are packed in lightproof black polyethylene plastic bags, and put into cardboard boxes. Each box is stamped with the emulsion number and expire date.

## 9. Storage and transport conditions

See certificate of quality

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## 1. Product name and type

Mediphot PHN/RP for 633 nm laser printers (HeNe laser)  
Mediphot PL/RP for 670 nm laser printers (red light diodes)  
Mediphot PIR/RP for 820 nm laser printers (infrared light diodes)

## 2. Product class

Class II A, according to Medical Device Directive 93/42/EEC,

## 3. Manufacturer's name and address

COLENTA Labortechnik GmbH & Co. KG, Neunkirchner Strasse 117, 2700 Wiener Neustadt, Austria

## 4. Product description

Single coated x-ray film for the intended use of hard copy printouts from laser printers in medical radiology.

## 5. Shelf life

For unexposed films, shelf life is the following for each type of laserfilm:

Mediphot X-PHN/RP 24 months

Mediphot X-PIR/RP 18 months

Mediphot X-PL/RP 36 months

from manufacturing date.

Expire date is stamped on each box.

For exposed films, shelf life is at least 20 years if the film is processed according to the manufacturer's specifications.

## 6. Technical data

Mediphot Laser films (Mediphot X-PHN/RP, Mediphot X-PIR/RP, Mediphot X-PL/RP) are fine grain emulsion films with high contrast.

Sensitivity to light has the maximum for the following wavelengths:

Mediphot X-PHT/RP 633 nm, Mediphot X-PL/RP 670 nm, Mediphot X-PIR/RP 820 nm

Each film sheet is marked with a notch to mark the emulsion side of the film.

For sensitometric data, see the certificate of quality.

Films are available in the following standard sizes:

Metric size (cm): 35x43

Inch size ("): 8x10, 11x14

Film thickness: 250 µm

## 7. Manufacturing process

The photographic emulsion is made by dissolving silverbromide in a gelatine-based solution. Sensitizers are added and the emulsion is subject to a maturing process. Hardener is added to the emulsion right before it is coated on a polyester base. The coating process is followed by a drying phase where the emulsion layer is hardened. A top-coating layer is added for the protection of the light-sensitive emulsion layer. The backside is coated with an anti-halation layer. After the coating process, the rolls are being cut in standard film sizes, packed in cardboard boxes and labelled.

## 8. Packaging

100 sheets of film are packed in lightproof black polyethylene plastic bags, and put into cardboard boxes. Each box is stamped with the emulsion number and expire date.

## 9. Storage and transport conditions

See certificate of quality

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## 1. Product name and type

Mediphot X-IM/RP, Medical recording film

## 2. Product class

Class II A, according to Medical Device Directive 93/42/EEC,

## 3. Manufacturer's name and address

COLENTA Labortechnik GmbH & Co. KG, Neunkirchner Strasse 117, 2700 Wiener Neustadt, Austria

## 4. Product description

Single coated x-ray film for the intended use of printouts from video imaging and monitors in medical radiology.

## 5. Shelf life

For unexposed films, shelf life is 36 months from manufacturing date. Expire date is stamped on each box.

For exposed films, shelf life is at least 20 years if the film is processed according to the manufacturer's specifications.

## 6. Technical data

Mediphot X-IM/RP is a fine grain emulsion film with high contrast.

The film is orthochromatic with maximum sensitivity in green light.

Each film sheet is marked with a notch to mark the emulsion side of the film.

For sensitometric data, see the certificate of quality.

Films are available in the following standard sizes:

Metric size (cm): 35x43

Inch size ("): 8x10, 11x14

Film thickness: 250 µm

## 7. Manufacturing process

The photographic emulsion is made by dissolving silverbromide in a gelatine-based solution. Sensitizers are added and the emulsion is subject to a maturing process. Hardener is added to the emulsion right before it is coated on a polyester base. The coating process is followed by a drying phase where the emulsion layer is hardened. A top-coating layer is added for the protection of the light-sensitive emulsion layer. The backside is coated with an anti-halation layer.

After the coating process, the rolls are being cut in standard film sizes, packed in cardboard boxes and labelled.

## 8. Packaging

100 sheets of film are packed in lightproof black polyethylene plastic bags, and put into cardboard boxes. Each box is stamped with the emulsion number and expire date.

## 9. Storage and transport conditions

See certificate of quality

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## Medical Recording Films

1. Type

Mediphot X-IM/RP

2. Test method

To expose medical standard X-ray film, these conditions are comparable with the ANSI PH2 48-1981 specifications for sensitometry of medical standard X-ray film.

For Medical recording film a coming No 4010 type filter is used.

Speed                      The speed is measured at density D 1.00 above fog level.

Average gradient      The average gradient is measured between densities D = 0.25 and D = 2.00, above fog level.

The figures mentioned for all the films have been obtained in regular 90 sec. processing cycle using Mediphot chemistry.

Developer                Seasoned Mediphot E90 at 33°C  
Fixer                        Seasoned Mediphot F90 at 30-33°C

3. Specifications and tolerances

<b>Film type</b>	<b>Base + fog (D)</b>	<b>Speed (logE)</b>	<b>Average gradient</b>	<b>Max. density (D)</b>
Mediphot X-IM/RP	≤0.21	± 0.09	± 11%	≥ 3.50

Storage conditions      Average temperature between 18°C and 21°C (max. 25°C – min. 4°C). Max. 28°C for 3 successive weeks per year. No relative humidity control.

Transport conditions    Max. temperature 30°C for max. 4 weeks.

The specifications of fresh material are valid at the date indicated on this document. They can be changed without notice at any time according to the rules set forth in the Quality Assurance system.

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# CERTIFICATE OF QUALITY

Date of issue: 2002-03-20

## Mammo Films

1. Type

Mediphot X-MA/RP

2. Test method

To expose medical standard X-ray film, these conditions are comparable with the ANSI PH2 48-1981 specifications for sensitometry of medical standard X-ray film.

For Mammo film a corning No 4010 type filter is used.

Speed                      The speed is measured at density D 1.00 above fog level.

Average gradient      The average gradient is measured between densities D = 0.25 and D = 2.00, above fog level.

The figures mentioned for all the films have been obtained in regular 90 sec. processing cycle using Mediphot chemistry.

Developer                Seasoned Mediphot E90 at 33°C  
Fixer                        Seasoned Mediphot F90 at 30-33°C

3. Specifications and tolerances

Film type	Base + fog (D)	Speed (logE) Tolerance	Average gradient tolerance	Max. density (D)
Mediphot X- MA/RP	≤0.21	± 0.05	± 7%	≥ 3.50

Storage conditions      Average temperature between 18°C and 21°C (max. 25°C – min. 4°C). Max. 28°C for 3 successive weeks per year. No relative humidity control.

Transport conditions    Max. temperature 30°C for max. 4 weeks.

The specifications of fresh material are valid at the date indicated on this document. They can be changed without notice at any time according to the rules set forth in the Quality Assurance system.

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# CERTIFICATE OF QUALITY

Date of issue: 2001-10-01

## Laser Hard Copy Films

### 1. Types

Mediphot X-PHN/RP  
Mediphot X-PIR/RP  
Mediphot X-PL/RP

### 2. Test method

To expose laser hard copy film the exposure is made on a special sensitometer designed by AGFA, using laser light with the appropriate wavelength and scanning configuration for faithful reproduction of the practical exposure conditions in a laser imaging camera.

Speed                      The speed is measured at density D 1.00 above fog level.  
Average gradient      The average gradient is measured between densities D = 0.40 and D = 1.00, above fog level.

The figures mentioned for all the films except for Mediphot X-PL/RP (45 sec. processing), have been obtained in regular 90 sec. processing cycle using Mediphot chemistry.

Developer                Seasoned Mediphot E90 at 33°C or 38°C for 45 sec. processing.  
Fixer                      Seasoned Mediphot F90 at 30-33°C or 38°C for 45 sec. processing.

### 3. Specifications and tolerances

Film type	Base + fog (D)	Speed (logE)	Average gradient
Mediphot X-PHN/RP	≤0.20	± 0.06	± 12%
Mediphot X-PL/RP	≤0.20	± 0.06	± 12%
Mediphot X-PIR/RP	≤0.20	± 0.08	± 12%

**Storage conditions**      Average temperature between 18°C and 21°C (max. 25°C – min. 4°C). Max. 28°C for 3 successive weeks per year except for infrared films (Mediphot X-PIR/RP) where the average temperature must be between 8°C and 10°C with max. 14°C for 1 week.  
No relative humidity control.

**Transport conditions**    Max. temperature 30°C for max. 4 weeks except for infrared films (Mediphot X-PIR/RP) where the max. temperature is 10°C and max. 32°C for one week (total transport period).

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## 1. Product name and type

Mediphot X-MA/RP, Mammography Film

## 2. Product class

Class II A, according to Medical Device Directive 93/42/EEC,

## 3. Manufacturer's name and address

COLENTA Labortechnik GmbH & Co. KG, Neunkirchner Strasse 117, 2700 Wiener Neustadt, Austria

## 4. Product description

Single coated x-ray film for the intended use of medical x-ray exposure in combination with green emitting light intensifying screens in mammography applications.

## 5. Shelf life

For unexposed films, shelf life is 36 months from manufacturing date. Expire date is stamped on each box.

For exposed films, shelf life is at least 20 years if the film is processed according to the manufacturer's specifications.

## 6. Technical data

Mediphot X-MA/RP is a fine grain emulsion film with high contrast.

It is sensitive to green emitting light.

Each film sheet is marked with a notch to mark the emulsion side of the film.

For sensitometric data, see the certificate of quality.

Films are available in the following standard sizes:

Metric size (cm): 18x24, 24x30

Film thickness: 250 µm

## 7. Manufacturing process

The photographic emulsion is made by dissolving silverbromide in a gelatine-based solution. Sensitizers are added and the emulsion is subject to a maturing process. Hardener is added to the emulsion right before it is coated on a polyester base. The coating process is followed by a drying phase where the emulsion layer is hardened. A top-coating layer is added for the protection of the light-sensitive emulsion layer. The backside is coated with an anti-halation layer.

After the coating process, the rolls are being cut in standard film sizes, packed in cardboard boxes and labelled.

## 8. Packaging

100 sheets of film are packed in lightproof black polyethylene plastic bags, and put into cardboard boxes. Each box is stamped with the emulsion number and expire date.

## 9. Storage and transport conditions

See certificate of quality

The specifications of this document are valid at the date indicated on this document. They can be changed without notice at any time according to the rules of set forth in the Quality Assurance system.

COLENTA Labortechnik GmbH & Co. KG

Wiener Neustadt, Austria

Johann Lacher  
Quality Manager

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