

VistaScan Plus Image Plates

EN



Operating Instructions



9000-618-78/02



 **DÜRR
DENTAL**

2102V002

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EN ! Important information

1 About this document

These operating instructions form part of the product.

 If the instructions and information in these operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the product.

The German version of the operating instructions is the original manual. All other languages are translations of the original manual.

These operating instructions are valid for the following image plates:

Article number:

- 2130-040-04
- 2130-041-04
- 2130-042-04
- 2130-043-04
- 2130-044-04
- 2130-040-05
- 2130-042-05
- 2130-050-02
- 2130-051-02
- 2130-052-02
- 2130-053-02
- 2130-054-02

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:

 General warning symbol

The warnings are structured as follows:

SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

- Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

- **DANGER**
Immediate danger of severe injury or death
- **WARNING**
Possible danger of severe injury or death
- **CAUTION**
Risk of minor injuries
- **NOTICE**
Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the product:

 Note, e.g. specific instructions regarding efficient and cost-effective use of the product.

 Refer to the accompanying electronic documents.

 Order number

 Lot designation

 Health Industry Bar Code (HIBC)

 Medical device

 Manufacturer

 CE labelling with the number of the notified body

 Search

 Keep away from sunlight

 Keep dry



Upper temperature limit

1.2 Copyright information

All circuits, processes, names, software programs and products mentioned in this document are protected by copyright.

The operating instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürre Dental.

2 Safety

Dürre Dental has developed and designed the product in such a way that dangers are effectively ruled out if the product is used in accordance with the Intended Use.

Despite this, the following residual risks can remain:

- Personal injury due to incorrect use/misuse
- Personal injury due to mechanical effects
- Personal injury due to electric shock
- Personal injury due to radiation
- Personal injury due to fire
- Personal injury due to thermal effects to skin
- Personal injury due to lack of hygiene, e.g. infection

2.1 Intended purpose

The reusable image plates are used to store intraoral or extraoral x-ray images in dental applications.

2.2 Intended use

The image plates can be reused multiple times after being erased.

Use the image plates solely in combination with image plate scanners manufactured by or branded with Dürre Dental and light protection covers manufactured by or branded with Dürre Dental. Images plates should be read out immediately, in order to avoid loss of image quality.

For image plate preparation refer to installation and operating instructions of the image plate scanners manufactured by or branded with Dürre Dental.

2.3 Improper use

Any use of this appliance / these appliances above and beyond that described in the Installation and Operating Instructions is deemed to be incorrect usage. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.

Especially if:

- Using the image plates in veterinary medicine and industrial NDT (Non Destructive Testing) applications
- Using scratched or damaged image plates
- Using intraoral image plates on the patients without light protection covers
- Cleaning the image plate differently than instructed in this operating instructions

2.4 General safety information

- › Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this product.
- › Check the function and condition of the product prior to every use.
- › Do not convert or modify the product.
- › Comply with the specifications of the Installation and Operating Instructions.
- › The Installation and Operating Instructions must be accessible to all operators of the product at all times.

2.5 Specialist personnel

Operation

Product operating personnel must ensure safe and correct handling based on their training and knowledge.

- › Instruct or have every user instructed in handling the product.

Installation and repairs

- › Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.6 Notification requirement of serious incidents

The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to the competent authority of the Member State in which the operator and/or patient is established/resident.

2.7 Only use original parts

- › Only use accessories and optional items that have been recommended or specifically approved by Dürr Dental.
- › Only use only original wear parts and replacement parts.

2.8 Disposal

The image plate contains barium compounds.

- › Dispose of the image plate properly in accordance with the locally applicable regulations.
- › In Europe, dispose of the image plate in accordance with waste code 20 03 01 "Mixed municipal waste".



Product description

EN

3 Overview

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

Plus image plate, size 0	
2 x 3 cm (2 pcs.)	2130-040-50
Plus image plate, size 1	
2 x 4 cm (2 pc.)	2130-041-50
Plus image plate, size 2	
3 x 4 cm (4 pcs.)	2130-042-50
Plus image plate, size 2	
3 x 4 cm (12 pcs.)	2130-042-55
Plus image plate, size 3	
2.7 x 5.4 cm (2 pcs.)	2130-043-50
Plus image plate, size 4	
5.7 x 7.6 cm (1 pc.)	2130-044-50
Plus ID image plate, size 0	
2 x 3 cm (2 pcs.)	2130-040-60
Plus ID image plate, size 2	
3 x 4 cm (4 pcs.)	2130-042-60
Image plate for OPG	
12.7 x 30.5 cm	
inc. Foil cassette, extraoral	2130-050-00
Image plate for OPG	
15 x 30 cm	
inc. Foil cassette, extraoral	2130-051-00
Image plate for Ceph	
18 x 24 cm	
inc. Foil cassette, extraoral	2130-052-00
Image plate for Ceph	
24 x 30 cm	
inc. Foil cassette, extraoral	2130-053-00
Image plate for Ceph	
20 x 24 cm	
inc. Foil cassette, extraoral	2130-054-00

3.2 Accessories

The following articles are necessary to operate the product, depending on the actual application:

Light protection covers

- Light Protection Cover Plus, size 0
- Light Protection Cover Plus, size 1
- Light Protection Cover Plus, size 2
- Light Protection Cover Plus, size 3
- Light Protection Cover Plus, size 4
- Light Protection Cover Plus, size 0, white
- Light Protection Cover Plus, size 2, white

Extraoral foil cassettes

Extraoral foil cassette, OPG	
12.7 x 30.5 cm	2130-021-00
Extraoral foil cassette, OPG	
15 x 30 cm	2130-022-00
Extraoral foil cassette, Ceph	
18 x 24 cm	2130-023-00
Extraoral foil cassette, Ceph	
24 x 30 cm	2130-024-00
Extraoral foil cassette, Ceph	
20 x 24 cm	2130-025-00
Extraoral foil cassette, Ceph	
13 x 18 cm	2130-026-00

3.3 Optional items

The following optional items can be used with the product:

Bite protector, size 4 (100 pcs) . . .	2130-074-03
Storage box	2141-002-00
Copper dot set, self-adhesive . . .	2130-006-00
Lead letters	2130-005-00

3.4 Consumables

The following materials are consumed during operation of the product and need to be re-ordered separately:

Light protection covers

Light Protection Cover Plus size 0	
2 x 3 cm (100 pcs.)	2130-080-00
Light Protection Cover Plus size 1	
2 x 4 cm (100 pcs.)	2130-081-00
Light Protection Cover Plus size 2	
3 x 4 cm (300 pcs.)	2130-082-00
Light Protection Cover Plus size 2	
3 x 4 cm (1000 pcs.)	2130-082-55

- Light Protection Cover Plus size 3
2.7 x 5.4 cm (100 pcs.) 2130-083-00
- Light Protection Cover Plus size 4
5.7 x 7.6 cm (100 pcs.) 2130-084-00
- Light Protection Cover Plus size 0,
white
2 x 3 cm (100 pcs.) 2130-080-50
- Light Protection Cover Plus size 2,
white
3 x 4 cm (300 pcs.) 2130-082-50

Cleaning and disinfection

- Image plate cleaning wipes
(10 pcs.) CCB351B1001

4 Technical data

4.1 Image plate

Classification

Medical Device Class	IIa
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Ambient conditions during operation

Temperature	°C	18 - 45
	°F	64 - 113
Relative humidity	%	< 80

Ambient conditions during storage and transport

Temperature	°C	< 45
	°F	< 113
Relative humidity	%	< 80

Dimensions of intraoral image plates

Size 0	mm	22 x 35
	in	0.87 x 1.38
Size 1	mm	24 x 40
	in	0.94 x 1.57
Size 2	mm	31 x 41
	in	1.22 x 1.61
Size 3	mm	27 x 54
	in	1.06 x 2.13
Size 4	mm	57 x 76
	in	2.24 x 2.99

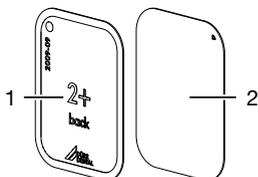
Dimensions of image plates extraoral

OPG 12.7 x 30.5	mm	125 x 286
	in	4.92 x 11.26
OPG 15 x 30	mm	148 x 298
	in	5.83 x 11.73
Ceph 18 x 24	mm	178 x 227
	in	7.01 x 8.94
Ceph 20 x 24	mm	202 x 241
	in	7.95 x 9.49
Ceph 24 x 30	mm	238 x 298
	in	9.37 x 11.73

5 Operation

i Detailed information about the compatibility of various types of image plate with various types of image plate scanner model by Dürr Dental is available in the Downloads area at www.duerredental.com (document-no.: 2130100177).

5.1 Intraoral

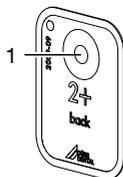


- 1 Inactive side Black, printed with the word "back" and the size and manufacturer's information
- 2 Active side Light blue, with positioning aid

The positioning aid is visible on the X-ray image and makes it easier to align the image correctly during diagnosis.

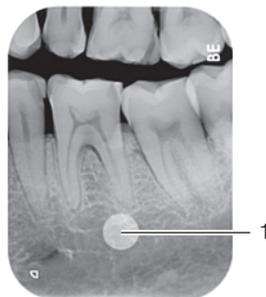
Exposure from the wrong side (image plates Plus ID only)

A marker is attached to the inactive side of the image plate.



- 1 Marker

If the image plate has been exposed from the wrong side, the marker is visible as a shadow in the X-ray image.



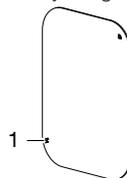
1 Marker visible as a shadow
The image can be corrected by mirroring it in the software. If a diagnosis is not possible in the area of the marker then the image will need to be acquired again.

i With the aid of the copper dots set you can retrospectively add a marker to image plates (see "3.3 Optional items").

Clear assignment of image plate to image (Image Plate Plus ID only)

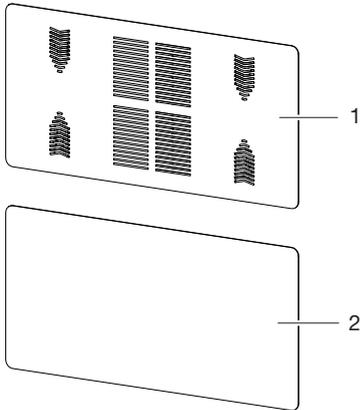
On the Image Plate Plus ID there is also a hexadecimal code on the image plate in addition to the marker. This code can be seen in the X-ray image.

This code allows you to clearly assign the correct image plate to the X-ray image.



- 1 Hexadecimal code

5.2 Extraoral (OPG, CEPH)



- | | | |
|---|---------------|--|
| 1 | Inactive side | black, with manufacturer's information printed on it
The surface is fitted with a "grip structure" which facilitates the insertion of the image plate from the foil cassette into the device. |
| 2 | Active side | White |

6 Correct use of image plates



WARNING

Risk of cross contamination when not using the light protection cover or when using the light protection cover more than once

- › Do not use an image plate without a light protection cover.
- › Do not use the light protection cover more than once (disposable item).



CAUTION

The image data on the image plate is not permanent.

The image data is altered by light, natural X-ray radiation and scattered X-ray radiation. This will lead to a reduction in diagnostic information and clarity.

- › Read the image data within 30 minutes of exposure.
- › Never handle exposed image plates without either a light protection cover or a foil cassette.
- › Do not subject an exposed image plate to X-ray radiation before or after the scanning process. Do not X-ray during the scanning process if the unit is in the same room as the X-ray tube.
- › Image plates must only be read using an image plate scanner that is approved by Dürer Dental.



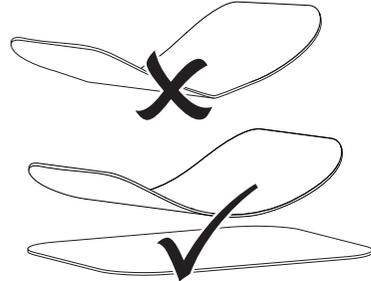
CAUTION

Image plates are toxic

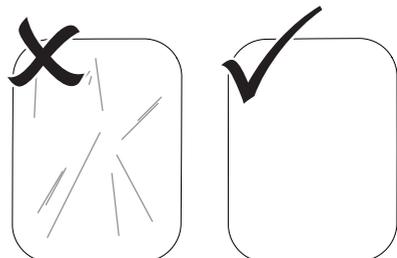
Image plates that are not packed in a light protection cover can lead to poisoning when placed in the mouth or swallowed.

- › Only place image plates in the patient's mouth in a light protection cover.
- › Do not swallow the image plate or parts of it.
- › If the image plate or parts of it have been swallowed, consult a specialist doctor immediately and remove the image plate.
- › If the light protection cover has been damaged in the patient's mouth, rinse the mouth thoroughly with lots of water. Do not swallow the water in the process.

- › Image plates are flexible like X-ray film. However, the image plates should not be bent.



- › Do not scratch the image plates. Do not subject the image plates to pressure from hard or pointed objects.



- › Do not soil the image plates.

- › Protect the image plates against sunlight and ultraviolet light.
Store image plates in a light protection cover or intraoral/extraoral foil cassette of the correct size.
- › Image plates will be pre-exposed on exposure to natural radiation and stray x-ray radiation. Protect erased and exposed image plates from X-ray interference.
If the image plate has been stored for longer than one week, erase the image plate prior to use.
- › Do not store image plates under hot or moist conditions. Observe the correct ambient conditions (see "4 Technical data").
- › When used properly, image plates can be exposed, read and erased several hundred times provided there is no mechanical damage. Replace the image plate if there are any signs of damage, e.g. if the protective layer is damaged or there are visible scratches that impair the quality of the diagnosis.
Also replace the image plate if the RFID tag is damaged or becoming detached.
- › Image plates that have a production or packaging defect will be replaced by Dürr Dental in the same quantity. Claims can only be accepted within 7 working days after receipt of the goods.
- › Clean image plates properly (see "7 Cleaning").

7 Cleaning

Cleaning and disinfection wipes are unsuitable for cleaning image plates and may cause damage to them.

Only use a cleaning agent that is compatible with the materials:

Dürr Dental recommends the image plate cleaning wipe (see "3.4 Consumables"). Only this product has been subjected to material compatibility testing by Dürr Dental.



NOTICE

Heat or humidity will damage the image plate.

- › Do not steam sterilise the image plate.
 - › Do not immersion-disinfect the image plate.
 - › Only use cleaning agents that are compatible with the materials.
- › Soiling on both sides of the image plate should be cleaned off with a soft, lint-free wipe prior to every use.
 - › Remove resistant or dried on dirt with the image plate cleaning wipe. When doing this, observe the instructions for use for the cleaning wipe.
 - › Allow the image plate to completely dry before using it.



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