

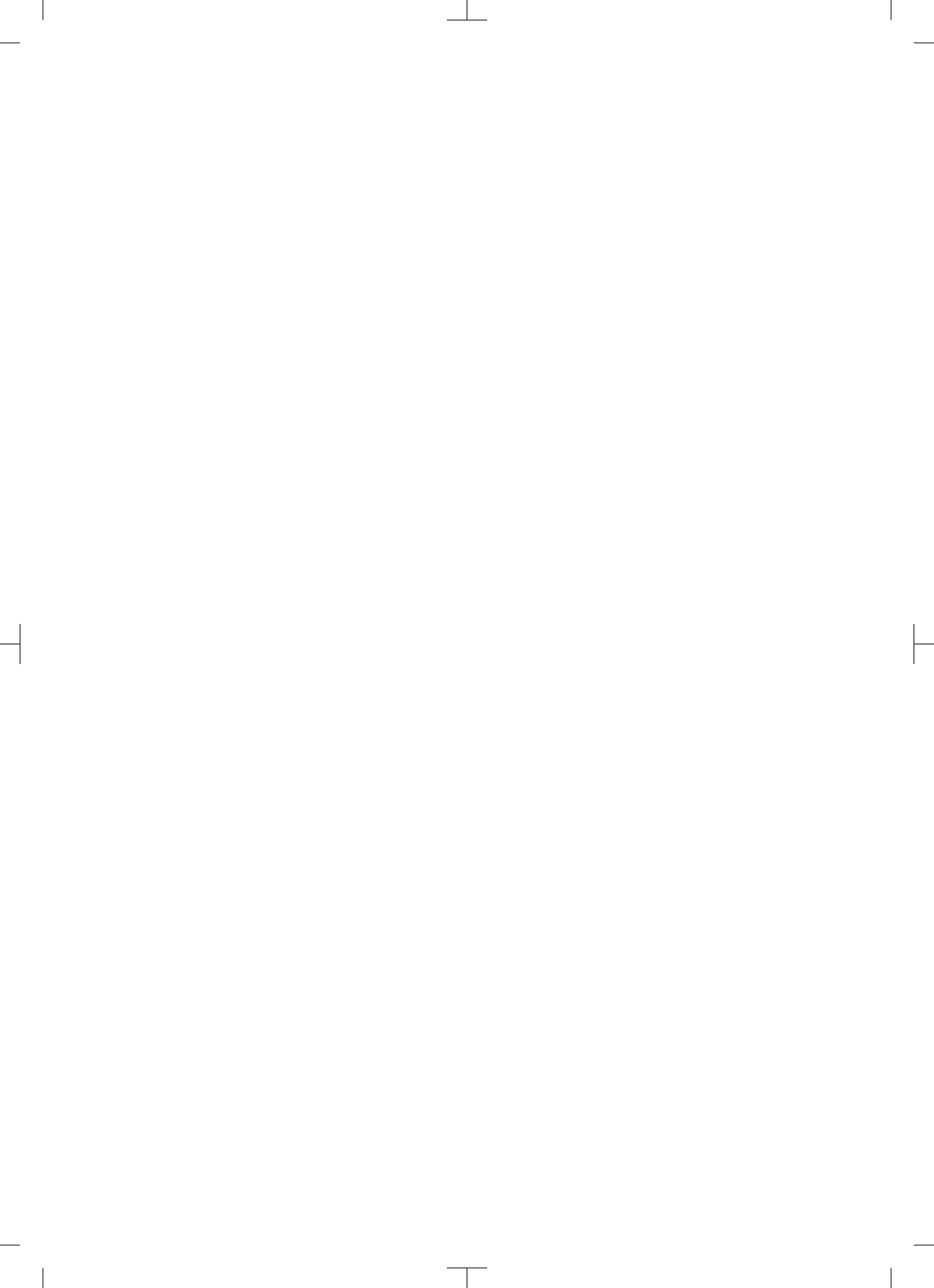
Phosphor storage plate



EN-US Operating instructions



2130100334L29 73481 2312V004



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! Important information

1 About this document

These operating instructions are an integral part of the product.

 The manufacturer shall not be held liable and offers no guarantees of the safe and smooth operation of this product you fail to comply with notes and instructions contained in these Installation and Operating Instructions.

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 phosphor storage plates:


- 2130214001 Phosphor Storage Plate S0
- 2130214101 Phosphor Storage Plate S1
- 2130214201 Phosphor Storage Plate S2
- 2130214301 Phosphor Storage Plate S3
- 2130214401 Phosphor Storage Plate S4

1.1 Warnings and symbols


Warnings

The warning notes in this document highlight possible injury to persons or damage to machinery.

They are marked with the following warning symbols:

 General warning symbol

The warnings are structured as follows:


 **SIGNAL WORD**
Description of 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 different levels of danger:

- **DANGER**
Direct 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

Miscellaneous 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.

 Take note of the accompanying electronic documents.

 Part number


 Batch name

 Health Industry Bar Code (HIBC)


 Medical device

 Manufacturer


 Distributor

 CE^{xxxx} CE labeling with the number of the notified body

 Search

 Keep away from sunlight during storage

 Keep dry

 ^{xx}% Note the upper humidity threshold

 ^{xx} 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 authorization from the manufacturer.

2 Safety

The product has been developed and designed appropriately such that hazards are largely excluded if it is used in accordance with its 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 use

The reusable phosphor storage plates are designed for recording intraoral and extraoral X-ray images in dental applications.

2.2 Normal use

The phosphor storage plates can be reused multiple times after being erased.

Use phosphor storage plates solely in combination with phosphor storage plate scanners manufactured by or branded with Air Techniques and barrier envelopes manufactured by or branded with Air Techniques.

Phosphor storage plates should be read out immediately, in order to avoid loss of image quality.

For phosphor storage plate preparation refer to installation and operating instructions of the Air Techniques phosphor storage plate scanner.

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 phosphor storage plates in veterinary medicine and industrial NDT (Non Destructive Testing) applications
- Using scratched or damaged phosphor storage plates
- Using intraoral phosphor storage plates on the patients without barrier envelopes
- Cleaning the phosphor storage plate differently than instructed in this operating instructions

2.4 General safety information

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

2.5 Specialist personnel

Operation

The personnel using the product must ensure the safe and appropriate handling of the product 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 the manufacturer or by qualified personnel specifically approved and authorized by the manufacturer.

2.6 Notification requirement of serious incidents

The operator/patient has to report any serious incident related the product to the manufacturer and the competent authority of the Member State, in which the operator and/or patient is established/resident.

2.7 Only use genuine parts

- Only use accessories and optional items that have been recommended or specifically approved by the manufacturer.
- Only use original working parts and spare 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 PSP in accordance with waste code 20 03 01 "Mixed municipal waste".



Product description

3 Overview

3.1 Accessories

The following articles are need for use of the product, depending on the actual application:

Barrier envelopes

- Barrier envelope, size 0
- Barrier envelope, size 1
- Barrier envelope, size 2
- Barrier envelope, size 3
- Barrier envelope, size 4

3.2 Optional items

The following items can be used with the product as an option:

Transfer box 73470

3.3 Consumables

The following materials are consumed during the use of the product and need to be reordered separately:

Barrier envelopes

- Patented, easy-to-open barrier envelope, size 0 (100 pcs.) 73248-0
- Patented, easy-to-open barrier envelope, size 1 (100 pcs.) 73248-1
- Patented, easy-to-open barrier envelope, size 2 (300 pcs.) 73248-2
- Patented, easy-to-open barrier envelope, size 2 (1000 pcs.) 73248-2K
- Patented, easy-to-open barrier envelope, size 3 (100 pcs.) 73248-3
- Patented, easy-to-open barrier envelope, size 4 (50 pcs.) 73248-4
- Barrier envelope Size 0
2 x 3 cm (100 pcs.) G8511-0
- Barrier envelope Size 1
2 x 4 cm (100 pcs.) G8511-1
- Barrier envelope Size 2
3 x 4 cm (300 pcs.) G8511-2
- Barrier envelope Size 2
3 x 4 cm (1000 pcs.) G8511-2K
- Barrier envelope Size 3
2.7 x 5.4 cm (100 pcs.) G8511-3

Barrier envelope Size 4
5.7 x 7.6 cm (50 pcs.) G8511-4

Cleaning and disinfection

Phosphor storage plate cleaning wipes
(50 pcs.) B8910

3.4 Wear parts and spare parts

- Phosphor storage plate size 0
(2 pieces) 73445-0
- Phosphor storage plate size 1
(2 pieces) 73445-1
- Phosphor storage plate size 2
(4 pieces) 73445-2
- Phosphor storage plate size 3
(2 pieces) 73445-3
- Phosphor storage plate size 4
(1 pieces) 73445-4

4 Technical data

4.1 Phosphor storage plate

Classification

Medical Device Class (MDR)	IIa
FDA classification (CFR Title 21)	I

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 phosphor storage plates

S0	mm	22 x 35
	in	0.87 x 1.38
S1	mm	24 x 40
	in	0.94 x 1.57
S2	mm	31 x 41
	in	1.22 x 1.61
S3	mm	27 x 54
	in	1.06 x 2.13
S4	mm	57 x 76
	in	2.24 x 2.99

5 Function



Detailed information about the compatibility of various types of phosphor storage plates with various types of phosphor storage plate scanner models from Air Techniques is available in the Downloads area at www.airtechniques.com (document-no.: G3602).

5.1 Intraoral



- | | | |
|---|---------------|--|
| 1 | Inactive side | Black, "back" and the size and manufacturer data printed on it |
| 2 | Active side | Light blue, with positioning aid a |

Positioning aid **a** is visible on the x-ray image and makes orientation easier during diagnosis.

To save space, the size and type of the phosphor storage plate are abbreviated.

The number indicates the size of the phosphor storage plate. Here, e. g. 2 indicates that this is a phosphor storage plate of Size 2.

Usage

6 Correct use of phosphor storage plates

WARNING

Risk of cross contamination when not using the barrier envelope or when using the barrier envelope more than once

- › Do not use an phosphor storage plate without a barrier envelope.
- › Do not re-use the barrier envelope (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 phosphor storage plates without either a barrier envelope 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.
- › Phosphor storage plates must only be read using a phosphor storage plate scanner that is approved by the manufacturer.

CAUTION

Phosphor storage plates (PSP) are toxic

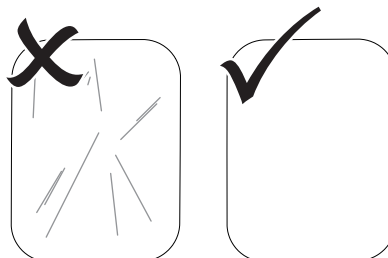
PSPs that are not used with a barrier envelope can lead to poisoning when placed in the mouth or swallowed.

- › Only place PSPs in the patient's mouth in a barrier envelope.
- › Do not swallow the PSP or parts of it.
- › If the PSP or parts of it have been swallowed, consult a specialist doctor immediately and remove the PSP.
- › If the barrier envelope was damaged in the patient's mouth, rinse the mouth thoroughly with copious amounts of water. Do not swallow the water in the process.

1. Phosphor storage plates must only be read using a phosphor storage plate scanner that is approved by the manufacturer.
2. Phosphor storage plates are flexible like X-ray film. However, the phosphor storage plates should not be bent.



3. Do not scratch the image plates. Do not subject the phosphor storage plates to pressure from hard or pointed objects.



4. Do not soil the image plates.

5. Protect the image plates against sunlight and ultraviolet light. Store image plates in a barrier envelope of the correct size.
6. Image plates will be pre-exposed on exposure to natural radiation and stray X-ray radiation. Protect erased and exposed phosphor storage plates from X-ray interference. If the image plate has been stored for more than one week, erase the image plate prior to use.
7. Do not store image plates under hot or damp conditions. Note the ambient conditions.
8. When used properly, image plates can be exposed, read and erased several hundred times provided there is no mechanical damage. Replace the phosphor storage 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.
9. Phosphor storage plates bearing a production or packaging defect will be replaced by the manufacturer in the same quantity. Claims can only be accepted within 30 working days after receipt of the goods.
10. Clean the phosphor storage plates properly.

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:

The manufacturer recommends the phosphor storage plate cleaning wipe (see "Cleaning and disinfection"). This is the only product that has been tested for its material compatibility by the manufacturer.

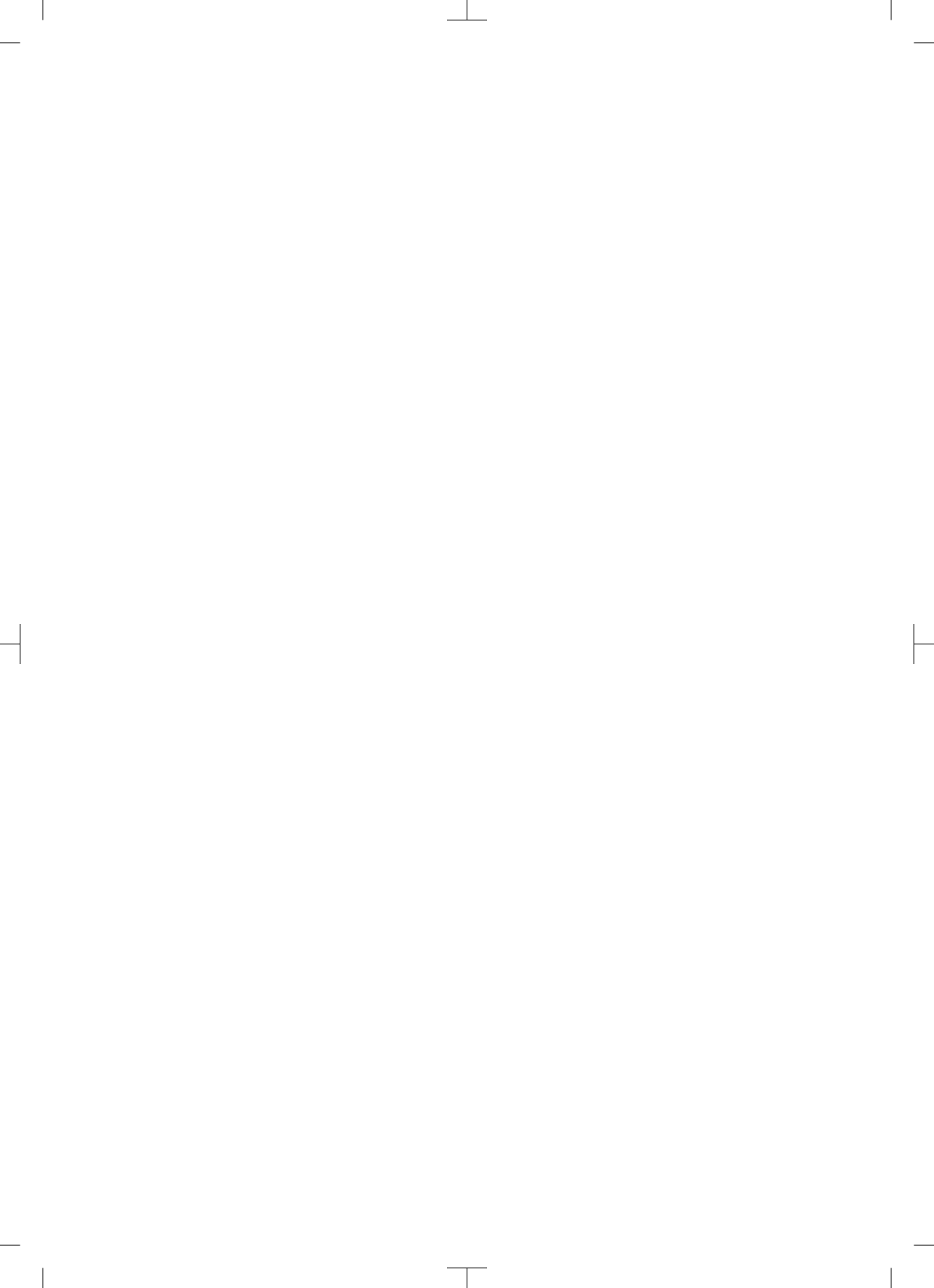


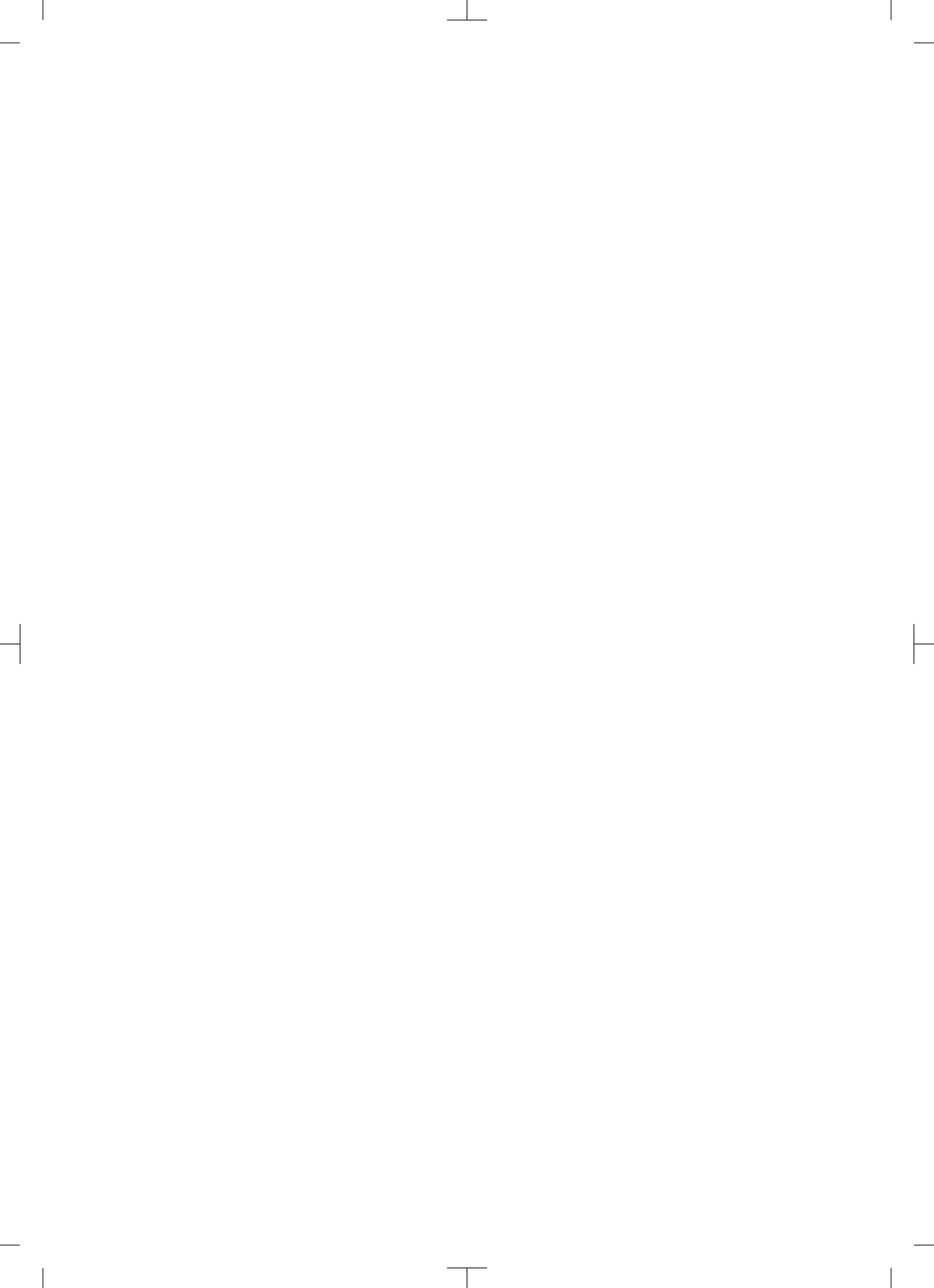
NOTICE

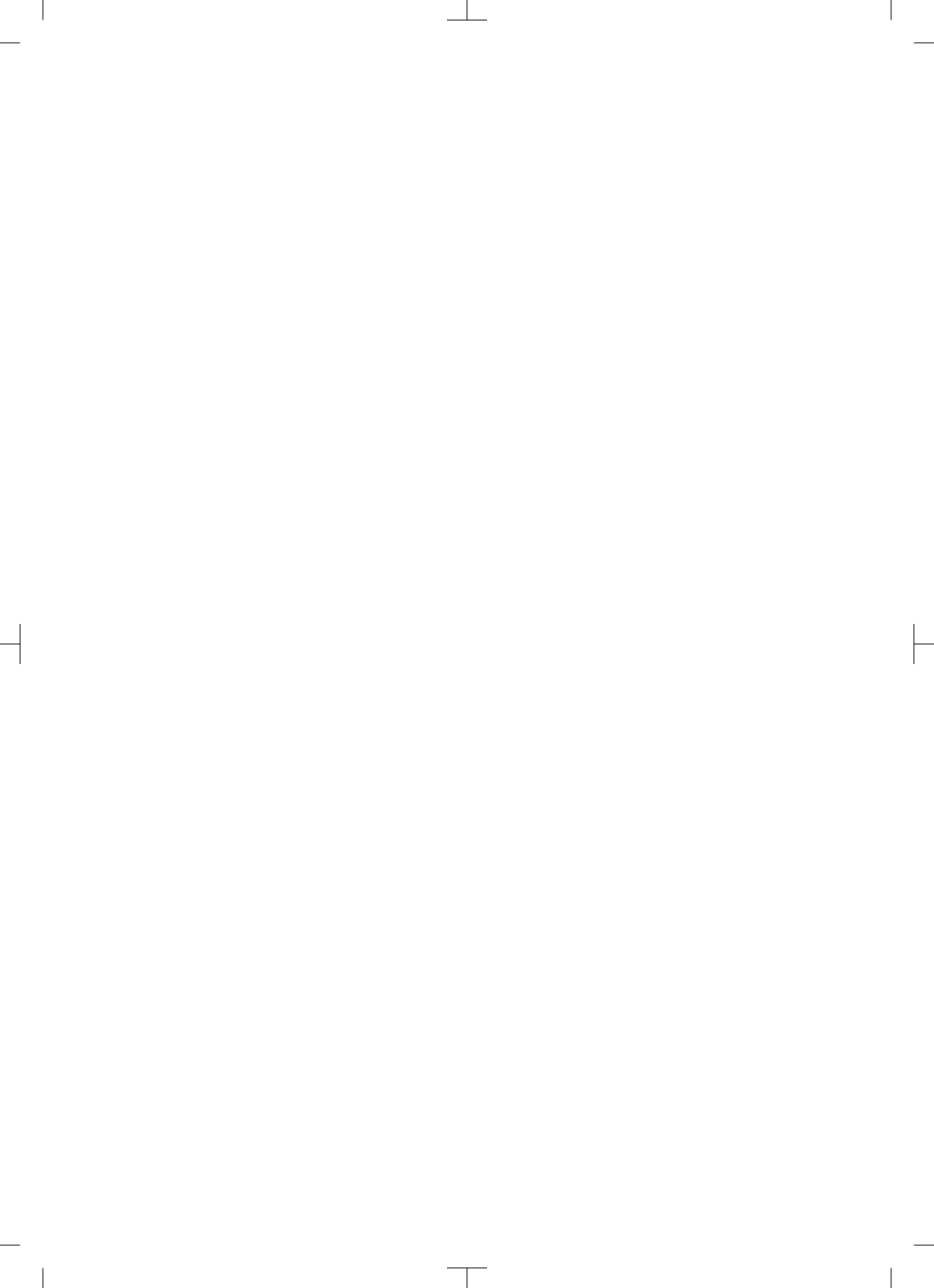
Heat or humidity damage the phosphor storage plate

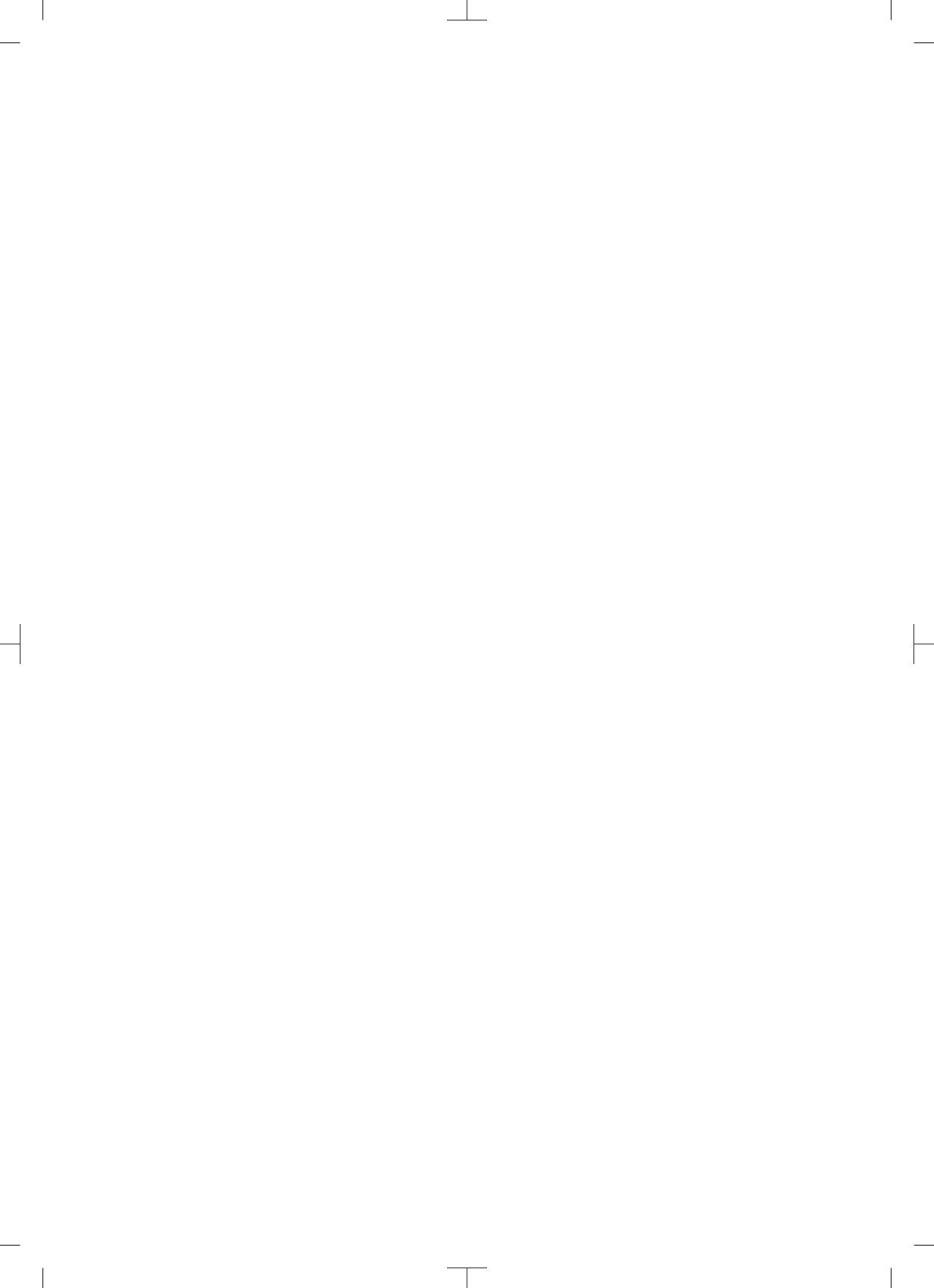
- › Do not steam sterilise the image plate.
- › Do not immersion-disinfect the image plate.
- › Only use cleaning agents that are compatible with the materials.

1. Soiling on both sides of the image plate should be cleaned off with a soft, lint-free wipe prior to every use.
2. Remove stubborn or dried-on dirt with the phosphor storage plate cleaning wipe. When doing this, observe the instructions for use for the cleaning wipe.
3. Allow the image plate to completely dry before using it.











Manufactured for / Distributed by:

Air Techniques, Inc.
1295 Walt Whitman Road
Melville, New York 11747-3062, USA
Phone: 800-247-8324
Fax: 888-247-8481
www.airtechniques.com



Hersteller / Manufacturer:

DÜRR DENTAL SE
Höpfigheimer Str. 17
74321 Bietigheim-Bissingen
Germany
www.duerrdental.com

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