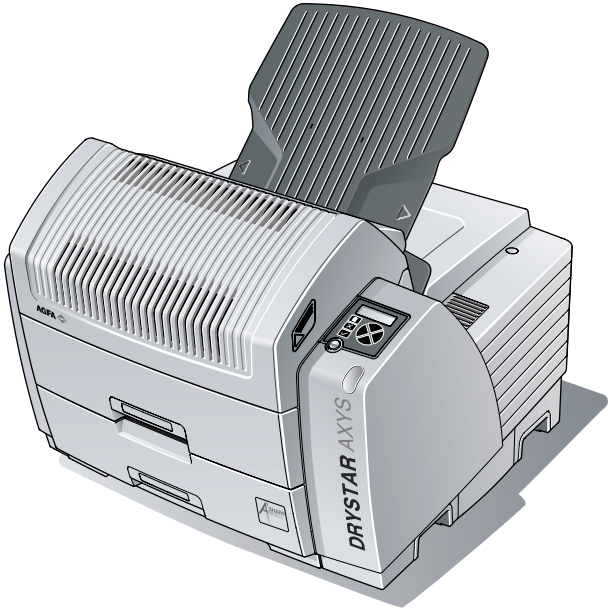
Drystar AXYS

User Manual



2852 A EN 20070205

AGFA

CE
0413

No parts of this document may be reproduced, copied, adapted or transmitted in any form or by any means without the written permission of Agfa-Gevaert N.V.

Agfa-Gevaert N.V. makes no warranties or representation, expressed or implied, with respect to the accuracy, completeness or usefulness of the information contained in this document and specifically disclaims warranties of suitability for any particular purpose. Agfa-Gevaert N.V. shall under no circumstances be liable for any damage arising from the use or inability to use any information, apparatus, method or process disclosed in this document.

Agfa-Gevaert N.V. reserves the right to make changes to this document without prior notice.

Agfa-Gevaert N.V., Septestraat 27, B-2640 Mortsel, Belgium.

Windows® and Windows® XP are trademarks of Microsoft Corporation.

The Drystar AXYS uses software developed by the Apache Software Foundation (http://www.apache.org/licenses/LICENSE).

Drystar AXYS is a trademark of Agfa-Gevaert N.V., Belgium.

Agfa and Agfa-Rhombus are trademarks of Agfa-Gevaert N.V., Belgium or one of its affiliates.

For more information on Agfa products and Agfa HealthCare products, please visit www.agfa.com.

© Agfa-Gevaert N.V. 2007.

1 Introduction 7

Introduction to this Manual **8**
Scope of this Manual 8
Warnings, Cautions, Instructions and Notes 9
Disclaimer 10
Introduction to Drystar AXYS **11**
Intended Use 11
Intended User 11
Configuration 12
Main Components 12
Functional Description 13
Film Formats 14
Operation Controls 15
Overview of user interface controls 15
The status indicator LED 16
The control buttons 16
System Documentation 17
Options and Accessories 18
Training 20
Product Complaints 20
Compatibility 21
Compliance 22
Directive 22
Quality Control 22
Standards 23
Additional standards for documentation 25
Harmonization 25
Performance 26
Connectivity 27
Network features 27
Network configuration 28
Installation 29
Connections 30
Transport after installation 31
Changing the film format of the trays 32
Messages 35
Labels 36
Patient Data Security 39
Node authentication, certificates and Certification Authority 39
Maintenance 40

Environmental protection 41
Waste Disposal and Environmental Regulations 41
Restriction of the Use of Certain Hazardous Substances (RoHS) 42
Safety Directions 43

2 Getting Started 45

Drystar AXYS Basic Features 46
Switching on the Drystar AXYS 48
Drystar AXYS Basic Workflow 50
Controlling the Working of the Drystar AXYS 50
Operator mode 51
Key-operator mode 51
Service mode 51
Specialist mode 52
Administrator mode (also known as Security) 52
Working with the keypad 53
The display 55
General display features 56
Operator mode 57
Key-operator mode 58
Data entry 58
Audio signals 59
Working with Compact flash cards (CF-card) 60
Cooling down the Drystar AXYS 62
Switching off the Drystar AXYS 63

3 Basic operation (Operator mode) 65

Overview of operator functions 66
Managing the print queue 67
Checking the print queue 67
The local print queue screen 68
Pausing the print queue 69
Viewing the film count info 70
Viewing the printer status 71
Deleting print jobs 72
About Drystar AXYS consumables 73

Labeling the input trays 74
Loading films 76
When the Drystar AXYS is printing or calculating and an input tray is empty 77
When the Drystar AXYS is in the ready state and an input tray is empty 78
Film loading procedure 79
Checking the correct position of a film in the input tray 83

4 Advanced operation (Key-operator mode) 85

Overview of key-operator functions 86
Quality Control for general radiography applications (DT 2 B & DT 2 C) 87
Establishing the reference values and verifying image quality for general radiography applications (DT 2 B and DT 2 C) 88
QC test image for general radiography applications (DT 2 B and DT 2 C) 90
Establishing the daily operating reference density levels for general radiography applications (DT 2 B and DT 2 C) 91
Establishing the image geometry reference values for general radiography applications (DT 2 B and DT 2 C) 95
Verifying Acceptable Spatial Resolution, Artifact Levels and Low Contrast Visibility for general radiography applications (DT 2 B and DT 2 C) 96
Performing quality control (QC) tests for general radiography applications (DT 2 B and DT 2 C) 98
Performing the daily QC test for general radiography applications (DT 2 B and DT 2 C) 99
Performing the Weekly QC tests for general radiography applications (DT 2 B and DT 2 C) 101
Performing the Annual QC tests for general radiography applications (DT 2 B and DT 2 C) 103
Quality control for mammography application (DT 2 Mammo) (optional) 104
Establishing the reference values and verifying image quality for mammography application (DT 2 Mammo) (optional) 105
QC test image for mammography applications (DT 2 Mammo) (optional) ... 107
Establishing the daily operating reference density levels for mammography application (DT 2 Mammo) (optional) 108
Establishing the image geometry reference values for mammography application (DT 2 Mammo) (optional) 112
Verifying Acceptable Spatial Resolution and Artifact Levels and Low Contrast Visibility for mammography application (DT 2 Mammo) (optional) 113
Performing quality control (QC) tests for mammography application (DT 2 Mammo) (optional) 115

Performing the daily QC test for mammography application (DT 2 Mammo) (optional) 116
Performing the Weekly QC tests for mammography application (DT 2 Mammo) (optional) 118
Performing the Annual QC tests for mammography application (DT 2 Mammo) (optional) 120
Preventive maintenance schedule 121
Safety guidelines 121
Cleaning the exterior 122
Cleaning the print head 123
Troubleshooting checklist 127
Clearing of film jams 129
Film input tray jams 130
Film transport jams (clearing from the top) 133
Unauthorized opening of the printer 136
Film identification problems 137
No identification code detected 138
Invalid content of Film Identification tag 141
Film overrun from current pack 141

A Equipment information sheet 143

Specifications 144
Viewing the system info area on a film 148

B Quality Control Charts 149

Charts for general radiography QC 150
Charts for mammography QC (optional) 155

1 Introduction

This chapter covers the following topics:

- Introduction to this Manual
- Introduction to Drystar AXYS

Introduction to this Manual

Scope of this Manual

This manual contains information for the safe and effective operation of AGFA Healthcare products.

This manual contains all instructions for the key-operator or any other skilled person, to work easily and correctly with the Drystar AXYS.

Warnings, Cautions, Instructions and Notes

The following samples show how warnings, cautions, instructions and notes appear in this document. The text explains their intended use.

WARNING: Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.

Figure 1: Safety icons

The purpose of the safety icons shown above is to indicate at a glance the type of warning or danger.

Caution: Cautions are directions which, if they are not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

Instruction: This sign is typically used in combination with the warning sign when providing a specific instruction. If it is followed exactly, it should avoid the subject of the warning

Note: Notes provide advice and highlight unusual points. A note is not intended as an instruction.

Disclaimer

Agfa assumes no liability for use of this document if any unauthorized changes to the content or format have been made.

Every care has been taken to ensure the accuracy of the information in this document. However, Agfa assumes no responsibility or liability for errors, inaccuracies, or omissions that may appear in this document.

Agfa reserves the right to change the product without further notice to improve reliability, function or design. This manual is provided without warranty of any kind, implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Introduction to Drystar AXYS

Intended Use

The Drystar AXYS is a dry digital tabletop printer for producing medical diagnostic images. It can print multiple formats (8x10", 10x12", 11x14", 14x14" and 14x17") of blue-based (Drystar DT 2 B) and clear-based (Drystar DT 2 C) film and offers crisp, dense grayscale images. The Drystar AXYS can be used for general radiography and optionally for the mammography application. It is designed for high-throughput and for use as a central printer.

Intended User

This manual is written for trained users of Agfa products. Users are considered as the persons who actually handle the equipment as well as the persons having authority over the equipment. Before attempting to work with this equipment, the user must read, understand, note and strictly observe all warnings, cautions and safety markings on the equipment.

Configuration

Main Components

The figure below illustrates the main components of the printer

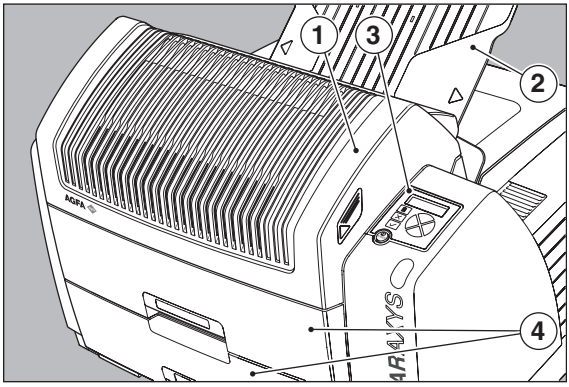


Figure 2: Front view

1. Top cover
2. Output tray
3. User interface (refer "Overview of user interface controls" on page 15
4. Input tray

Functional Description

The Drystar AXYS consists of two functional blocks: a controller and a print engine.

- The controller

  The controller captures the incoming data and stores the image.

  The controller composes the different images and generates the appropriate print engine control signals.

- The print engine

  The print engine receives the image data from the controller, drives the film through the device and produces black & white hardcopy prints.

  The figure below illustrates how the film is transported through the printer

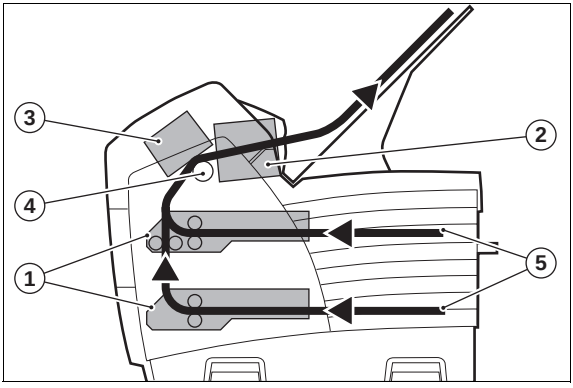


Figure 3: Film transport

1. Film pick up unit
2. Output module
3. Print head module
4. Drum
5. Film path

Film Formats

Multiple film formats (8x10”, 10x12”, 11x14”, 14x14” and 14x17”) can be used. Any combination of two film formats can be used “online”. Both input trays can be adjusted for all film formats.

Operation Controls

The Drystar AXYS interfaces with the user via the following controls:

- Power/Reset button;
- a keypad and a display;
- a status indicator;
- audio signals.

Overview of user interface controls

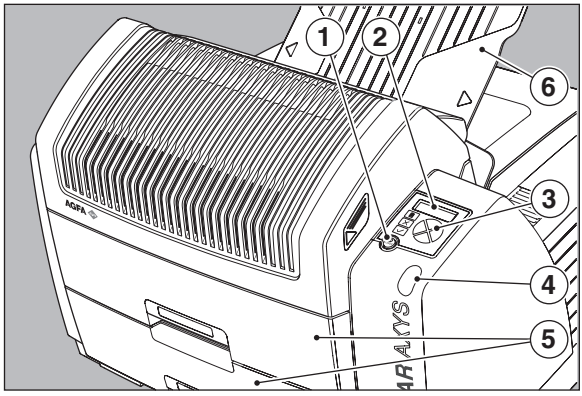


Figure 4: User interface controls

1. Power/Reset button
2. Display
3. Keypad
4. Status indicator LED
5. Film input trays
6. Film output tray

WARNING: Never try to open the printer when the Drystar AXYS is printing a film. Always follow the instructions on the display!

The status indicator LED

On the right side of the display, an LED indicates the status of the Drystar AXYS.

Colour/Light		Status	Action
Green	Constant	Ready (stand-by)	Proceed
	Blinking	Busy or in key-opertor mode	Wait
Red	Constant	Warning status	Check the display for messages. Refer to "Checking the status indicator LED" on page 241 of the Reference manual.
	Blinking	Error status	

Table 1: Status indicator LED

The control buttons

One control button has been provided:

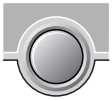
	**Power/Reset** button	• To power on or off the printer. • To reset the printer.

Table 2: Control buttons

WARNING: Do NOT press the Power/Reset button without first following the procedure to stop printing when the Drystar AXYS is printing a film. Refer to "Switching off the Drystar AXYS" on page 63

System Documentation

The documentation shall be kept with the system for easy reference. Technical documentation is available in the product service documentation that is available from your local support organisation.

The documentation consists of:

- Reference Manual (English only), this document.
- User Manual, document 2852.
- Plug & Play Manual, document 2851 & 2855.
- Mobile installation Kit, document 2854.
- Packing slip, document 2850.
- Documentation CD

Options and Accessories

ABC Ordering Codes

The table below lists the ordering codes for the Drystar AXYS and possible options.

Description	ABC code	Remark
Drystar AXYS	EYZ4E	A#sharp technology is included
Mammo option for Drystar AXYS	EY8RN	A#sharp technology is included The Drystar AXYS can be used for printing mammography application films. For this option, a license has to be activated by an Agfa service technician. The feature comes with a QC procedure that complies with the NEMA Standards Publication XR 23-2006. For more information, refer to "Quality control for mammography application (DT 2 Mammo) (optional)" on page 104. Contact your local service organization for more information.
Cleaning roller tissue	EQU6Y	
Mobile / Earthquake provision	EX2DV	The installation kit allows you to use the Drystar AXYS in a van, or to use it in unstable environment. It contains the necessary equipment to fix the printer onto a table, and has provisions for easy service access. The mobile/earthquake installation kit is delivered with the necessary mounting instructions. No additional software for mobile/earthquake use is required.

Table 3: ABC ordering codes

Available Software codes

The table below lists the available software versions and the type of printer they require.

Software version (SW)	**Printer**
1.60	Drystar AXYS RoHS compatible

Table 4: Software version

Consumables

The Drystar AXYS can handle DRYSTAR DT 2 B and DRYSTAR DT 2 C consumables (both are general radiography film types) in multiple formats (8x10” up to 14x17”) and optionally DRYSTAR DT 2 Mammo (mammograpy film type) consumables, available in the formats 8x10”, 10x12” and 11x14”.

Training

The user must have received adequate Agfa training on the safe and effective use of the product before attempting to work with it. Training requirements may vary from country to country. The user must make sure that training is received in accordance with local laws or regulations that have the force of law.

Your local Agfa representative can provide further information on training.

The user must note the following information in the preliminary section of this manual:

- Intended Use
- Intended User
- Safety Directions

Product Complaints

Any health care professional (for example a customer or a user) who has any complaints or has experienced any dissatisfaction in the quality, durability, reliability, safety, effectiveness, or performance of this product must notify Agfa.

If the device malfunctions and may have caused or contributed to a serious injury of a patient, Agfa must be notified immediately by telephone, fax or written correspondence to the following address:

Agfa Service Support - local support addresses and phone numbers are listed on www.agfa.com
Agfa - Septestraat 27, 2640 Mortsel, Belgium
Agfa- Fax +32 3 444 7094

Compatibility

Drystar AXYS must only be used in combination with other equipment or components if these are expressly recognized by Agfa as compatible. A list of such equipment and components is available from Agfa service on request.

Changes or additions to the equipment must only be carried out by persons authorized to do so by Agfa. Such changes must comply with best engineering practice and all applicable laws and regulations that have the force of law within the jurisdiction of the hospital.

Drystar AXYS is a Dicom printer and can therefore be connected to Agfa equipment and all modalities supporting Dicom. Although, to ensure optimal operation and image quality, Agfa has made the effort to test and release the Drystar AXYS with most of modalities on the market. For the complete list or if you want to check on a specific modality, contact your Agfa representative.

Compliance

This paragraph sums up the directives, standards and harmonization initiatives Drystar AXYS complies with.

Directive

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ No L 169/1 of 1993-07-12)

- ANNEX I - ESSENTIAL REQUIREMENTS - GENERAL REQUIREMENTS
  The devices are designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users.
- ANNEX II - EC DECLARATION OF CONFORMITY
  Full quality assurance system ISO 13485
- ANNEX X - CLINICAL EVALUATION
  The clinical evaluation follows a defined and methodologically sound procedure.

Quality Control

- The Quality Control test procedure for general radiography applications (refer to “Quality Control for general radiography applications (DT 2 B & DT 2 C)” on page 87complies with the grayscale reproduction constancy test, according to the international standard IEC 1223-2-4.
- The Quality Control test procedure for the optional mammography application (refer to “Quality control for mammography application (DT 2 Mammo) (optional)” on page 104) complies with the NEMA Standards Publication XR 23-2006

Standards

- ISO 14971:2000, Medical devices - Application of risk management to medical devices
- IEC 60601-1-2 It specifies the manufacturer of the medical equipment or medical system. It also provides information to the responsible organization that is essential in determining the suitability of the medical equipment or medical system for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the medical equipment or medical system to maintain basic safety and provide its essential performance without disturbing other equipment.
- Seismic (earthquake) requirements
  The printer meets the CA (Californian) requirements.

Safety standards

- IEC 60601-1, Ed. 3: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1 + A1 + A2
- EN 60601-1 + A1 + A2
- UL 60601-1
- CSA 22.2 No. 601.1-M90
- GB4943-2001 (for CCC-Mark)

EMC

- FCC Rules 47 CFR part 15 subpart B
- IEC 60601-1-2
- CISPR 11, class A
- CISPR 22, class A
- IEC 61000-4-3

- IEC 61000-4-4
- IEC 61000-4-5
- IEC 61000-4-6
- IEC 61000-3-2
- IEC 61000-3-3
- IEC 61000-4-11
- ETSI 300330
- GB9254-1998(Class A) (for CCC-Mark)
- GB17625.1-2003 (for CCC-Mark)

- USA: This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the Drystar AXYS Reference manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at its own expense. If required, contact your local service organization.
- Canada: This class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.
- EC: This is a class A product. In a domestic environment this product may cause radio interference in which case the user may be required to take adequate measures.

Additional standards for documentation

IEC 62079 Ed. 1: Preparation of instructions - Structuring, content and presentation

Harmonization

- Global Harmonization Task Force (GHTF) www.ghtf.org

  This document been has prepared to comply with Study Group 1 guidance document of the Global Harmonization Task Force (GHTF). To assist development of a consistent, harmonized definition for a medical device that could be used within a global regulatory model would offer significant benefits to the manufacturer, user, patient or consumer, and to Regulatory Authorities and support global convergence of regulatory systems.

- IECEE CB SCHEME www.iecee.org

  The IECEE CB Scheme is the world's first truly international system for acceptance of test reports dealing with the safety of electrical and electronic products. It is a multilateral agreement among participating countries and certification organizations. Agfa has produced a CB test report and claims national certification in all other member countries of the CB Scheme.

Performance

- The direct thermal printing system provides grayscale images with high quality: 508 pixels per inch resolution, each pixel with 12 bit contrast resolution and an average density of 3.2 for general radiography applications and an average density of 3.8 for optional mammography application (measured with an X-Rite densitometer).
- Multiple film formats (8x10”, 10x12”, 11x14”, 14x14” and 14x17”) can be used. Any combination of two film formats can be used “online”. Both input trays can be adjusted for all film formats.

Connectivity

The Drystar AXYS is a standard network printer. This means that you can just plug it into the (existing) ethernet network without any additional options or accessories. Drystar AXYS is also a native DICOM printer. Therefore the standard DICOM protocol can be used as network protocol, and again without any additional options or accessories the printer will be able to process and print the DICOM jobs.

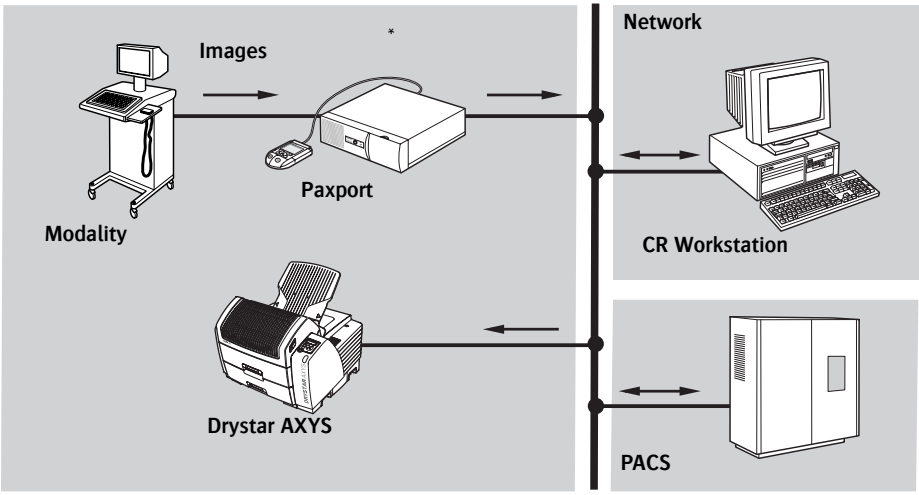
Network features

- The modular design offers optimal application functionality for your specific networking requirements.

  In a network configuration, the Drystar AXYS is fully compatible with all other AGFA imaging system components, including the CR digitizers, CR workstations, image buffer components, Paxport and the entire line of Impax stations. For more information, contact your Agfa representative

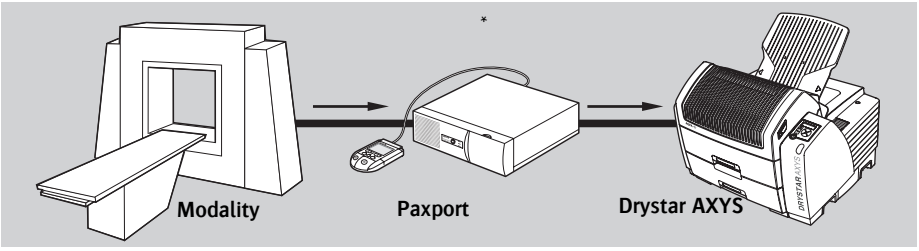
- The modular design offers optimal application functionality for your specific networking requirements.
- The functionality of the Drystar AXYS is completely controlled via the network.
- You can control the working of the Drystar AXYS via the local keypad or via a remote PC with a functioning web browser.

Network configuration



Example of Drystar AXYS in a network configuration

Figure 5:



Example of Drystar AXYS in a point-to-point configuration

Figure 6: Network configuration

* A Paxport is required if the modality is not a DICOM modality.

Installation

Drystar AXYS installation and configuration is performed by Agfa. (A limited number of configuration tasks can also be performed by the customer after an Agfa training course has been provided.) Contact your local support organization for more information.

For more information about the installation, refer to the Drystar AXYS Plug & Play installation manual and/or the Drystar AXYS Mobile Kit installation manual.

Connections

At the rear side of the printer, one slot and three connectors are available:

1	CF-card slot	To insert an external CF-card for software installation, back-up, etc.
2	Network connector	To connect to the hospital network.
3	Input/output connector	To connect a terminal PC (used by the Service engineer).
4	Power connector	To connect the printer power cord.

The figure below illustrates the back-to-back connections of the printer

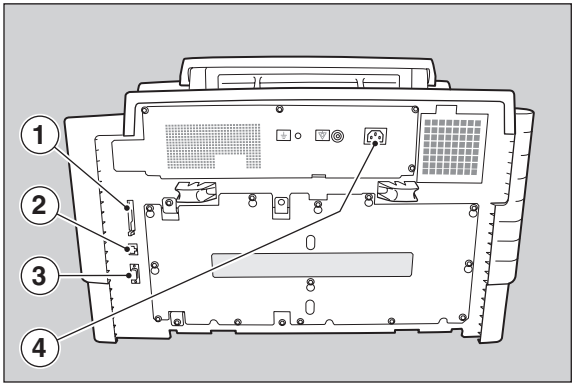


Figure 7: Rear view

1. CF-card slot
2. Network
3. RS-232 =>Service PC
4. Power connection

Transport after installation

The Drystar AXYS is quite compact, so moving the printer over a short distance - if required - can be done in a convenient way.

Always keep in mind the following safety guidelines:

Note: Refer to "Safety Directions" on page 43.

WARNING: The Drystar AXYS should be transported by 3 persons or if not possible with 2.

WARNING: The Drystar AXYS must only be transported with all covers closed.

WARNING: Always lift the Drystar AXYS by gripping the handles, situated at front, left and right side. Do not lift the Drystar AXYS by the output tray.

WARNING: When transporting the Drystar AXYS, the stability and the structure of the tabletop have to be taken into account.
The printer should not be placed on a soft surface, since this might prevent appropriate ventilation and cause overheating.
Make sure the printer is placed on a stable, hard surface table.

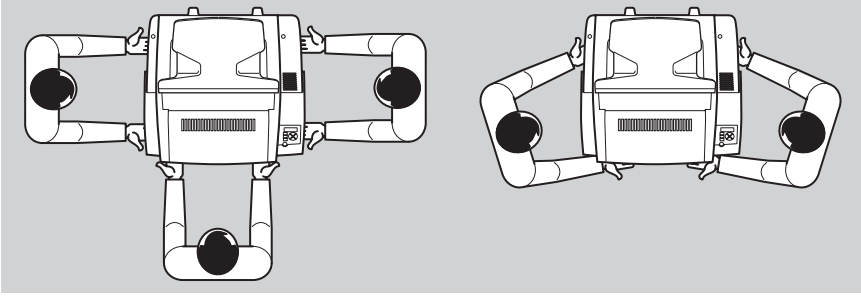


Figure 8: Transport posibilities

Procedure:

1 Switch off the Drystar AXYS (refer to "Switching off the Drystar AXYS" on page 63).

2 Disconnect the cables.

3 Move the Drystar AXYS to its destination (with 2, preferably 3 persons!).

4 Reconnect the cables.

5 Switch Drystar AXYS on (refer to "Switching on the Drystar AXYS" on page 48).

Changing the film format of the trays

The key-operator can adjust the film size setting of both input trays (8x10" up to 14x17" film sizes).

Before a different film format can be loaded, the film format settings of the tray has to be changed. After this modification, the 'film format' parameter is automatically read from the Film Identification tag when the new film pack is loaded.

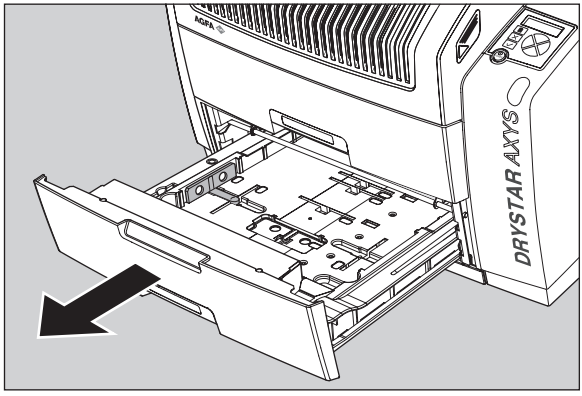
Note: Never load another film format when the input tray is not empty. Intermediate changing of film formats increases the risk for dust, which can damage the thermal print head (TPH).

Note: The system performs an automatic calibration when the film format has been changed.

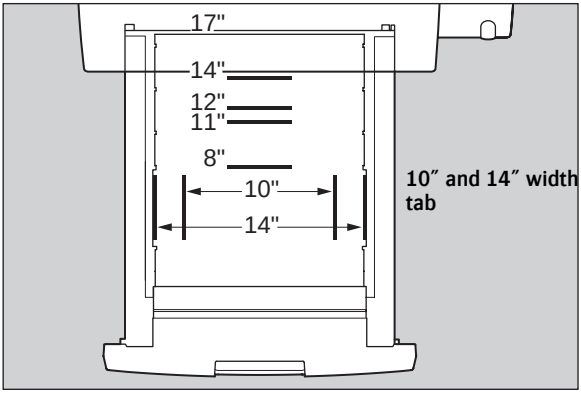
Proceed as follows to perform the mechanical modification:

1 Make sure that the printer is in 'Ready' mode.

2 Open the input tray you want to adapt and remove eventually loaded films.

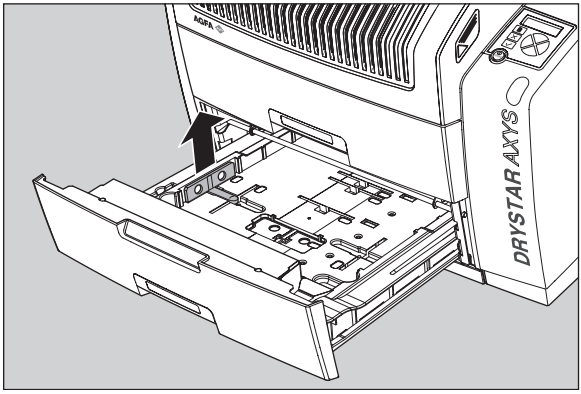


3 Locate the correct tab position for the desired film format.

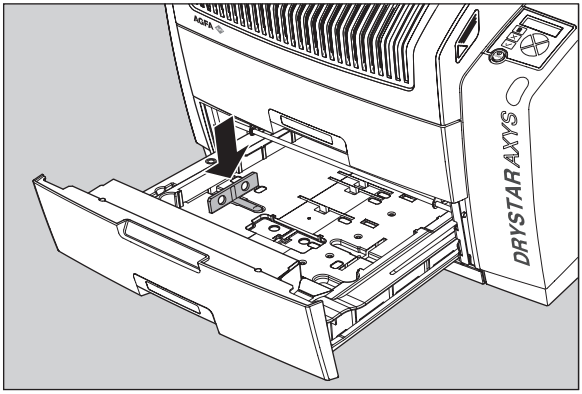


Note: Note that there is a screw to secure the position of the 10" and 14" width format tabs. The format tabs positioned in the depth are not provided with a screw.

4 Remove the film position tab.



5 Put the filmion tab in place and push it down until it locks. Tighten the screws of the width format tabs.



6 Load a new film pack. Refer to “Loading films” on page 76.

Messages

Under certain conditions the red LED on the right side of the display lits up and a warning or error message is shown on the display. This message informs the user that either a problem has occurred or that a requested action cannot be performed.

Colour/Light		**Status**	**Action**
Red	Constant	Warning status	Check the display for messages. Refer to "Checking the status indicator LED" on page 241 of the Reference manual.
	Blinking	Error status	

Table 5: Red status indicator LED

The user must read these messages carefully. It will provide information on what to do from then on. This will be either performing an action to resolve the problem or to contact the Agfa service organization. Details on the contents of messages can be found in the service documentation which is available to Agfa service personnel.

Labels

[The following samples illustrate some of the warning labels (ISO 3864 Safety Signs define the design principles for international safety signs) that may appear on the medical equipment.]

Symbol	Explanation
 Figure 9: Radiation Warning	Radiation Warning Indicates the possibility of increased levels of radiation.
 Figure 10: High Voltage Warning	High Voltage Warning Indicates the presence of high voltage.
 Figure 11: Laser Warning	Laser Warning Indicates the presence of a laser device.
 Figure 12: Hot Surface Warning	Hot Surface Warning Indicates that touching the part indicated can cause burns.
 Figure 13: Do not sit Warning	Do not sit Warning Indicates that sitting on a component can cause damage to the equipment.

Always take into account the markings provided on the inside and outside of the printer. A brief overview of these markings and their meaning is given below.

Symbol	Explanation
 Figure 14: Caution hot:	Keep hands clear from the thermal print head.
 Figure 15: High voltage	In order to reduce the risk of electric shock, do not remove any covers.
 Figure 16: Type B equipment:	Indicates that the Drystar AXYS complies with the limits for type B equipment.
 Figure 17: Supplementary protective earth connector:	Provides a connection between the Drystar AXYS and the potential equalization bus bar of the electrical system as found in medical environments. This plug should never be unplugged before the power is turned off and the power plug has been removed.
 Figure 18: Intergrounding connector:	Provides a connection between the printer and other equipment, which might exhibit minor ground potential differences. These differences may degrade the quality of communication between different equipment. Never remove connections to this terminal.
 Figure 19: Protective earth (ground):	Provides a connection between the printer and the protective earth of the mains. Do not remove this connection, because this will have a negative influence on the leakage current.
 Figure 20: Power button	Note that the power cord has to be disconnected from the wall outlet in order to disconnect the unit entirely from the mains.

The Drystar AXYS carries the CE, TÜV, cULus and CCC labels.

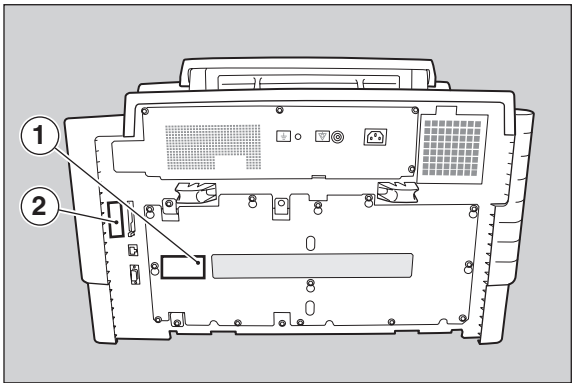


Figure 21: Location CE, TÜV, cULus and CCC label

1. CCC label
2. CE, TÜV and cULus label

Patient Data Security

It is the responsibility of the hospital to ensure that the patients' legal requirements are met and that the security of the patient records is:

- maintained and tested,
- audited,
- administered locally to cover risks from third party access and
- how the availability of the services is to be maintained in the event of disaster.

It is the responsibility of the hospital to ensure that types of access are identified, classified and reasons for access are justified.

Node authentication, certificates and Certification Authority

Each device - connected to a network - will receive a unique identifier: the X.509 certificate, a digital passport. Any device on the network is only allowed to communicate with another node of which it is holding the certificate in a 'communication allowed' table.

A Certification Authority (CA) is responsible for creating a certificate. The CA can be the hospital, Agfa or a third party.

This CA distributes the certificate to the hospital security responsible or service technician, who for his part:

- Imports the device certificate, created by the CA.
- Imports the certificates of all peer devices with which communication is authorized, i.e. creates the list of 'communication allowed' device certificates.

Maintenance

Print head cleaning must be done when image quality problems occur. For more information, refer to "Cleaning the print head" on page 123.

Always consult the Agfa Service documentation and the Agfa trained service personnel for complete maintenance schedules.

Environmental protection

Waste Disposal and Environmental Regulations

WEEE Notice

The Directive on Waste Electrical and Electronic Equipment (WEEE), which entered into force as European law on 13th February 2003, resulted in a major change in the treatment of electrical equipment at end-of-life. The purpose of this Directive is, as a first priority, the prevention of WEEE, and in addition, to promote the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste.

The WEEE logo on the product or on its box indicates that this product must not be disposed of or dumped with household waste. The owner of the equipment is liable to dispose of all electronic or electrical waste equipment by delivering it to the specified collection point for recycling of such hazardous waste. Collection and proper recovery of electronic and electrical waste equipment at the time of disposal will allow the producer to help conserve natural resources. Recycling of the electronic and electrical waste equipment will ensure safety of human health and the environment. For more information about electronic and electrical waste equipment disposal, recovery and collection points, please contact your local waste disposal service or producer / distributor of this equipment.

If your equipment contains removable batteries or accumulators please dispose of these separately according to local regulations.

Figure 22: The WEEE logo EN 50419: 2005

Restriction of the Use of Certain Hazardous Substances (RoHS)

The RoHS (Restriction of Hazardous Substances) Directive No 2002/95/EC of the European Union focuses on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Member States of the European Union (EU) shall ensure that, from 1 July 2006, new electrical and electronic equipment put on the market (EU countries), does not contain the following substances above specified concentrations at the homogeneous material level:

- Cadmium (0.01%)
- Hexavalent chromium (0.1%)
- Lead (0.1%)
- Mercury (0.1%)
- Polybrominated biphenyls (PBB) (0.1%)
- Polybrominated diphenyl ethers (PBDE) (0.1%)

At the date of preparation of this manual, Medical Devices are exempted of the RoHS Directive.

However Agfa HealthCare is committed to meet the requirements of the European RoHS Directive in case the exemption is cancelled.

If there is a RoHS label at the rear of the printer it means that the printer is RoHS compliant and does not contain the above listed substances above the mentioned concentrations at the homogeneous material level.

In case of questions or more detailed information do not hesitate to contact your local sales organization.

Safety Directions

- Observe the following general safety guidelines:

WARNING: Strictly observe all warnings, cautions, notes and safety markings within this document and on the product.

WARNING: Safety is only guaranteed when trained personnel have installed Drystar AXYS.

WARNING: All Agfa medical products must be used by Agfa trained and qualified personnel.

WARNING: [The user is responsible for judging image quality and controlling environmental conditions for diagnostic softcopy or print viewing.]

WARNING: [Any error (crash/ lock up) leading to an image processing failure can cause loss of diagnostic information.]

Caution: Position the Agfa product so that it is possible to disconnect the mains power connection if required.

Caution: Changes, additions or maintenance to the Agfa products carried out by persons without appropriate qualification and training as well as using unapproved spare parts may lead to serious risk of injury and damage to the equipment as well as making the warranty void.

- When operating or maintaining the Drystar AXYS, always observe the following safety guidelines:

WARNING: The Drystar AXYS must only be operated according to its specifications and its intended use. Any operation not corresponding to the specifications or intended use may result in hazards, which in turn may lead to serious injuries or fatal accidents (for example electric shocks). AGFA will not assume any liability whatsoever in these cases.

WARNING: All images created using any image technology can show artifacts, which could be mixed up with diagnostic relevant information. If there is any doubt that the diagnostic information could not be absolutely true, additional investigations must be performed to get a clear diagnostic.

WARNING: Have electrical or mechanical defects repaired by qualified personnel only!

WARNING: Always switch off the Drystar AXYS and disconnect the power cord from the outlet before carrying out any maintenance work.

WARNING: Do not override or disconnect the integrated safety features

Caution: Ventilation openings should not be covered.

- [In the United States, Federal law restricts this device to sale, distribution and use by, or on order of, a licensed physician.]

WARNING: (U.S.A. only): In accordance with U.S. Law, this device can only be sold to or ordered by a licensed physician.

WARNING: Printed images should be treated as patient records and should only be viewed by authorized personnel.

WARNING: It is advisable to do a reprint when film artifacts are present in the image.
In case of general image quality degradation, please refer to "Maintaining image quality and resolving image quality problems" on page 258 (Reference manual).

Caution: (USA only): Make sure that the circuit is single-phase center-tapped, if the printer is connected to a 240 V/60 Hz source instead of a 120 V/60 Hz source.

2 Getting Started

This chapter covers the following topics:

- Drystar AXYS Basic Features
- Switching on the Drystar AXYS
- Drystar AXYS Basic Workflow
- Cooling down the Drystar AXYS
- Switching off the Drystar AXYS

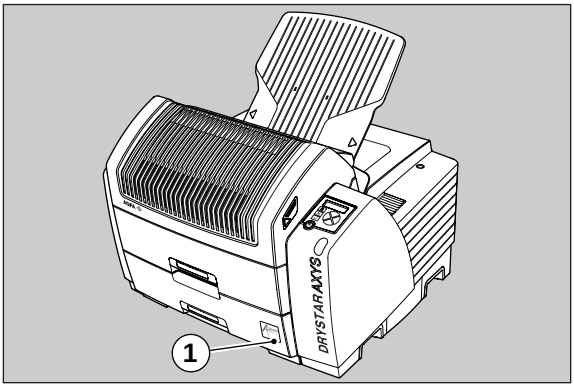
Drystar AXYS Basic Features

The Drystar AXYS offers the following features:

- The Drystar AXYS is a Dicom-only network printer
- Dry technology for printing diagnostic quality hardcopies in full daylight offers important advantages: no chemistry, no wet processing, simple cleaning procedures, no time-consuming adjustments, no darkroom and no chemical disposal costs. The consumables can be loaded in full daylight.
- With its compact design, the Drystar AXYS needs little workspace and allows easy customer access. Maintenance and service activities are reduced to a minimum.
- The input trays of the Drystar AXYS are equipped with an RF-tag reader, which automatically traces the films used in the printer and protects the printer when detecting non-identified media.
- Number of input trays: The Drystar AXYS is equipped with 2 input trays. Both input trays can use multiple formats (8x10" up to 14x17") of Drystar DT 2 B and DT 2 C and optionally Drystar DT 2 Mammo (8x10", 10x12" and 11x14").
- Number of output trays: The Drystar AXYS is equipped with 1 output tray, which is suitable for the multiple formats without any adjustment.
- A Quality Control software module is available for the key-operator.
  The QC procedure for general radiography applications has been designed to comply with the grayscale reproduction constancy test, according to the international standard IEC 1223-2-4.
  The QC procedure for the optional mammography application has been designed to comply with the NEMAStandards Publication XR 23-2006.

- Integrated A#sharp technology.

  A#sharp is a technology that enhances image sharpness for the Drystar AXYS. An A#sharp label on the lower tray shows that the imager is equipped with this technology.



1. A#Sharp label

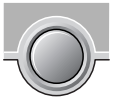
Switching on the Drystar AXYS

Note: Before switching on the Drystar AXYS, read the safety instructions. Refer to "Safety Directions" on page 43.

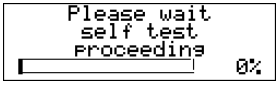
Follow the procedure below to ensure proper start-up of the Drystar AXYS and to check that everything is working correctly.

Procedure:

1 Check that the power cord is plugged in and then switch on the printer by pressing the Power/Reset button.



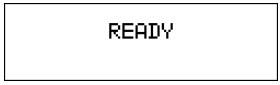
On the display, the following message is displayed. After a short while, a progress indicator will show the progress of the self-test.



If anything goes wrong during the self-test, refer to "Start-up errors" on page 256.

2 The printer is ready for operation:

If, on the front panel display, the READY message is shown, the status indicator LED is constantly green.



Note: It takes 9 minutes before the Drystar AXYS can start printing. After 4 minutes the READY message appears and from then on you can send print jobs to the printer, but it will take another five minutes for the printer head to heat up. When you send print jobs to the Drystar AXYS during this five minutes, the printer will use that time to calculate the print job and the display will inform you that the printer is warming up.

If, on the front panel display, the print queue screen is shown,

the status indicator LED is green and blinking.

3 Make sure that the printer is loaded with appropriate consumables.

Note: Refer to page for detailed information on loading films.

Note: If the job status displays a warning or error indication, refer to "Troubleshooting checklist" on page 127.

Drystar AXYS Basic Workflow

Controlling the Working of the Drystar AXYS

You can control the working of the Drystar AXYS via the local keypad or via a networked remote PC.

The Drystar AXYS can be operated in five modes: Operator mode, Key-operator mode, Service mode, Specialist mode and Administrator mode.

The table below gives an overview of the operating modes you can access locally and/or via the remote PC.

Local	Password protected	Remote	Password protected
Operator mode	No	Operator mode	Yes
Key-operator mode	No	Key-operator mode	Yes
—	—	Service mode	Yes
—	—	Specialist mode	Yes
—	—	Administrator	Yes

The manual describes the controlling of the Drystar AXYS via the local keypad. The menus for controlling the Drystar AXYS via a remote PC are structured in the same way and sometimes they offer even more possibilities. Refer to the chapter "Controlling the Drystar AXYS via a remote PC (with browser)" on page 219 of the Reference manual.

Operator mode

The Operator mode groups all basic functions that are intended for radiographers without special technical skills:

- Producing diagnostic usable hardcopies;
- Loading consumables;
- Ensuring normal operation of the printer.

The Operator mode is accessible by the keypad and by browser via a remote PC (password protected).

All functions of the Operator mode are described in both User and Reference manuals. Refer to the chapter "Basic operation (Operator mode)" on page 65.

Key-operator mode

The Key-operator mode groups advanced functions that are intended for technically skilled operators such as X-ray operators, network managers and service and hospital technicians.

The Key-operator mode is accessible by the keypad and by browser via a remote PC (password protected).

The Key-operator mode is menu-driven. The Key-operator functions are described in the Drystar AXYS Reference manual only. Refer to the chapter "Advanced operation (Key-operator mode)" on page 85.

Service mode

The Service mode functions are reserved for trained Service personnel. The Service mode is accessible by browser via a remote PC (password protected). Limited service actions (password protected) are also accessible by the keypad.

Specialist mode

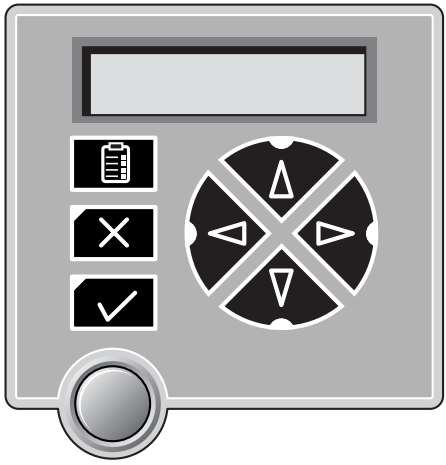
The specialist mode functions are reserved for trained service personnel of the Agfa Customer Support Center. The specialist mode is password protected and is only accessible by browser via a remote PC.

Administrator mode (also known as Security)

The Administrator mode functions are reserved for the System Administrator. The Administrator mode is password protected and is only accessible by browser via a remote PC.

Working with the keypad

The keypad is located below the display panel.



The Drystar AXYS keypad features the following keys:

	Key-operator key	To access the advanced functions of the key-operator mode. Refer to the chapter "Advanced operation (Key-operator mode)" on page 85.
	Escape key	To quit the current function or exit a menu without saving modifications.
	Confirm key	(In key-operator mode) • To select a menu. • To accept an entry in a menu
	Up key	• To move the cursor to the previous entry field. • To scroll upwards • To increment the number in a(n) (alpha) numerical entry field.

Table 6: Keypad keys