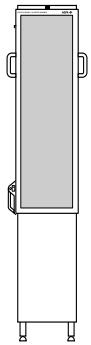
EASYLIFT

6009/100

User Manual



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AGFA

Contents

Legal Notice

CE

Agfa NV, Septestraat 27, B-2640 Mortsel - Belgium

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implied or expressed, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Note: *In the United States, Federal law restricts this device to sale by or on the order of a physician.*

Scope of this Manual

This manual contains information for the safe and effective operation of the EASYLIFT.

About the safety notices in this document

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

DANGER:
A danger safety notice indicates a hazardous situation of direct, immediate danger for a potential serious injury to a user, engineer, patient or any other person.

WARNING:
A warning safety notice indicates a hazardous situation which can lead to a potential serious injury to a user, engineer, patient or any other person.

CAUTION:
A caution safety notice indicates a hazardous situation which can lead to a potential minor injury to a user, engineer, patient or any other person.

An instruction is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

A prohibition is a direction which, if it is not followed, can cause damage to the equipment described in this manual or any other equipment or goods and can cause environmental pollution.

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

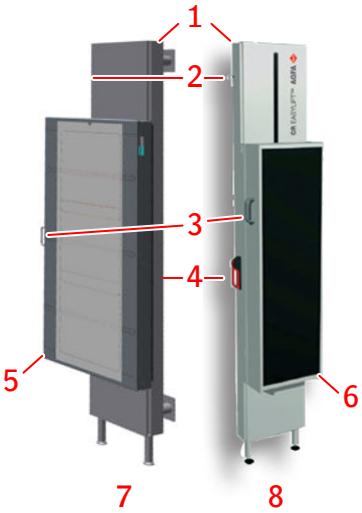
Intended Use

The intended use of the EASYLIFT is lifting up and lowering down the attached cassette holder (CR Full Leg Full Spine application) or the attatched detector holder (Full Leg Full Spine DR Retrofit System).

Intended User

This manual is written for trained users of Agfa products and trained clinical personnel. 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



1. EASYLIFT
2. Lever of the locking mechanism
3. Handle to adjust height
4. Release clamp
5. DR detector holder
6. CR cassette holder
7. Configuration for DR Full Leg Full Spine Retrofit System
8. Configuration for CR Full Leg Full Spine application

The position of the release clamp is configurable and can be mounted to the left or right side of the EASYLIFT at installation by the trained service engineer.

Compliance

Topics:

General

- The product has been designed in accordance with Regulation (EU) 2017/745 on medical devices (MDR)
- ISO 14971

Safety

- IEC 60601-1
- AAMI ES 60601-1
- CSA C 22.2 No.60601-1

Environmental Compliance

- European Council Directive 1907/2006 (REACH)
- European Council Directive 2011/65/EU (RoHS 2)

Equipment Classification

Per EN/IEC60601-1, this device is classified as following:

Table 1: Equipment classification

Water Ingress	This device does not have protection against ingress of water.
Cleaning	See section on maintenance and cleaning.
Disinfection	See section on maintenance and cleaning.
Continuous Operation	The unit is suitable to run continuously.
Expected service life	Minimum 7 years.

Training

The user must have received adequate training on the safe and effective use of the system 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 or dealer representative can provide further information on training.

The user must note the following information in the system documentation:

- 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 with the quality, durability, reliability, safety, effectiveness, or performance of this product must notify Agfa.

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Manufacturer 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

System Documentation

The documentation shall be kept with the system for easy reference. The most extensive configuration is described within this manual, including the maximum number of options and accessories. Not every function, option or accessory described may have been purchased or licensed on a particular piece of equipment.

Refer to the System User Documentation before using the Full Leg Full Spine application:

- User Manual of the DR system and related user documentation
- NX User Manual

The most recent version of this document is available on *http://www.agfahealthcare.com/global/en/library/index.jsp*

Installation

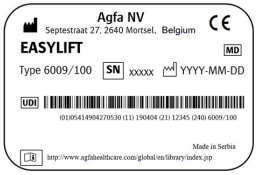
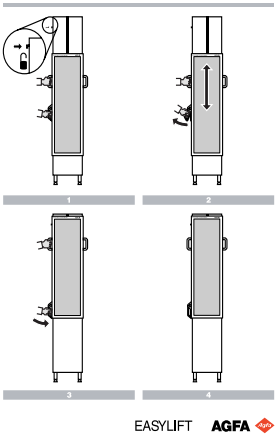
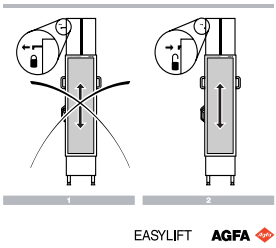
Installation and configuration is performed by an Agfa trained and authorized service engineer. Contact your local support organization for more information.

Compatibility

The system 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.

Labels

CE	This mark shows compliance of the equipment with Regulation 2017/745 (for European Union).
 **Figure 1: Example of type label**	Type label
	Instruction card
	Lock-unlock instruction card
	Pinch Points

Cleaning and Disinfecting

All appropriate policies and procedures should be followed to avoid contamination of the staff, patients and equipment. All existing universal precautions should be extended to avoid potential contaminations and to avoid patients coming into (close) contact with the device. The user is responsible for selecting a disinfection procedure.

Topics:

Cleaning

To clean the exterior of the equipment:

Wipe the exterior of the device with a clean, soft, damp cloth. Use a mild soap or detergent if required. Do not use any corrosive, dissolving or abrasive cleaning or polishing agents. Make sure no liquid gets in the device.

CAUTION:
Clean the equipment with only a little moisture. Do not spray disinfectants or detergents directly on the equipment. Do not pour liquid directly on the equipment.

Using unsuitable cleaning agents or methods can damage the property when surface becomes dull and brittle (e.g. alcohol-containing agents).

Disinfecting

WARNING:
To disinfect the device, use only disinfectants and disinfection methods that are approved by Agfa and that correspond to the national regulation and guidelines as well as explosion protection.

If you plan to use other disinfectants, approval of Agfa is needed before use, as most disinfectants can damage the device. UV disinfection is also not allowed.

Perform the procedure following the instructions for use, the disposal instructions and the safety instructions of the selected disinfectants and tools and of the hospital.

Items contaminated with blood or body fluids, which may contain blood-borne pathogens, should be cleaned and then receive intermediate level disinfection with a product having an EPA-registered claim for activity against hepatitis B.

Approved disinfectants

Refer to the Agfa website for specifications on the disinfectants that have been found compatible with the cover material of the device and can be used on the outer surface of the device.

http://www.agfahealthcare.com/global/en/library/overview.jsp?ID=41651138

Safety Directions

WARNING:
Always use the EASYLIFT only for its intended use.

WARNING:
Always follow the instructions in the User manual.

WARNING:
Safety is only guaranteed when an Agfa certified field service engineer has installed the product.

WARNING:
Only qualified and authorized personnel shall operate this system. In this context 'qualified' means those persons legally permitted to operate this equipment in the jurisdiction in which the equipment is being used, and 'authorized' means those persons authorized by the authority controlling the use of the equipment. Full use must be made of all radiation protection features, devices, systems, procedures and accessories.

WARNING:
Improper changes, additions, maintenance or repair of the equipment can lead to personal injury and damage to the equipment. Safety is only guaranteed when changes, additions, maintenance or repairs are carried out by an Agfa certified field service engineer. A non certified engineer performing a modification or service intervention on a medical device, acts on his own responsibility and makes the warranty void.

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

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

WARNING:
System unavailability due to hardware failure. If the product is used in critical clinical workflows, a backup system has to be foreseen.

WARNING:
Operating the equipment when it is faulty includes the risk of injury to the patient and to the operator. Operate the equipment only in safe and fault-free conditions.

WARNING:
Do not connect the equipment with anything other than specified.

WARNING:
While every care has been taken, it is possible that minor errors still exist in the product. It is unlikely that a minor error could result in incorrect (unexpected) device operation.

WARNING:
To avoid risk of mechanical injuries, do not remove any covers. Changes, additions, maintenance or repairs must be carried out by an Agfa certified field service engineer.

WARNING:
Risk of heavy weight causing physical injury. The wall-mounted base must be installed and used according to the instructions.

WARNING:
Risks of falling masses. The EASYLIFT must be installed and used according to the instructions.

WARNING:
Never move the CR cassette holder or DR detector holder without having at least one hand on its handle.

WARNING:
Never lean or allow leaning on the EASYLIFT with attached CR cassette holder or DR detector holder.

WARNING:
Never use or allow to use the EASYLIFT with attached CR cassette holder or DR detector holder as a support.

WARNING:
Never put additional weight to the EASYLIFT with attached CR cassette holder or DR detector holder.

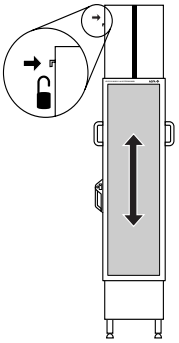
WARNING:
The CR cassette holder or DR detector holder can be brought to floor level by the EASYLIFT device. Take caution that no object or body part has been placed underneath or above the CR cassette holder or DR detector holder! In that case some serious risk of harm can be caused.

CAUTION:
Make sure your fingers are not squeezed during movement of the CR cassette holder or DR detector holder up and down. Also the release clamp mechanism may hurt your fingers, therefore take special care.

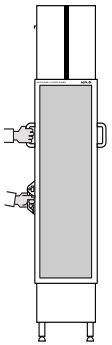
Basic workflow

1. Verify that the locking mechanism is in the unlocked position.

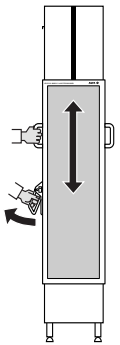
   The lever of the locking mechanism is pushed inward.



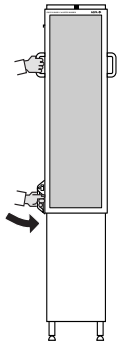
2. Take hold of the handle of the CR cassette holder or DR detector holder and of the release clamp.



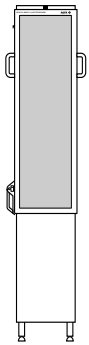
3. Pull the release clamp and move CR cassette holder or DR detector holder up and down.



4. Push back release clamp.



5. Let go of the handle of the CR cassette holder or DR detector holder.



Technical data

Table 2: EASYLIFT technical data

Type	6009/100
Dimensions	Width: 390 mm Height: 2300 mm Depth: 135 mm
Weight approx.	73 kg
Expected product lifetime	7 years

Table 3: EASYLIFT environmental requirements

Environmental requirements (operation)	
Room temperature	10°C to 35°C
Maximum temperature change	0.5 °C/min.
Relative humidity	30% to 75%
Atmospheric pressure	70 kPa to 106 kPa
Relative altitude	3000 m to 0 m
Environmental requirements (storage)	
Temperature	-20°C to +40°C
Environmental requirements (transport)	
Temperature	-20°C to +40°C