

User manual

LLS-1 Single Shot Long-Length Imaging Rev.: 14-01-2022 draft





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User Manual: LLS-1



List of revisions

Equipment	LLS-1
Document	User manual
Document number	ODB-118-5070ENG

revision	Date	Comment	
00	05-12-2017	First version	
01	12-02-2018	Add new wall locking system	
02	07-09-2018	Correction of WEEE symbol	
03	17-06-2019	Add Name Single Shot Long-Length, warning label, alignment instructions, specs and small text updates	
04	14-01-2022	Update to MDR storage temp, Add specs Grid, ODB-118-0070ENG	

Legal manufacturer



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User Manual: LLS-1



Preface

Identification

Manuals are identified by a part number.



The part number is printed at the bottom of the title page. Numbers printed on other pages are for internal revision control and may differ.

CE Classification

Product meets the relevant provisions of the European MDR (EU 2017/745 - Medical Device Regulation); this is based on conformity of the products and the quality system according to ISO 13485:2016.



Symbols

Symbol	Meaning	Remarks
Location: Near or on the type identification plate.	Symbol for separated collection of electrical and electronic equipment per Directive 2002/96 of the European Parliament and the Council of the European Union (Directive on Waste of Electrical and Electronic Equipment - WEEE). If applicable to the type of device, it indicates legally imposed obligations within EU member states, Iceland, Norway and Switzerland when the equipment is disposed of, at the end of its life-time.	Owners of marked equipment should contact the organization that imported the equipment into their country, when they want to dispose of the equipment, at the end of its lifetime. The Directive prioritizes re-use of equipment over re-use of components over re-use of materials over disposal as waste. Article 5 part 2d allows producers to decline the return of any used equipment that is or may be biologically or radiologically contaminated.
MD	Medical device	
	Legal manufacturer	
	Date of manufacture	
SN	Serial number	
UDI	UDI code	Unique Device Identification
	This mark indicated that this is CLASS II Equipment according to EN60601-1.	
济	This mark indicated that this is a Type B Applied Part according to EN60601-1.	
\triangle	Consult Instructions for Use	
	Consulting the accompanying documents is a mandatory action.	
<u>^!</u>	General warning sign	Placed together with a supplementary symbol or text. The text associated shall be an affirmative statement (i.e., a safety notice) describing the principal risk(s) foreseen (e.g. "Causes burns", "Risk of explosion", etc.).
CE	The CE Mark is a declaration by the manufacturer that the product complies with the requirements of the applicable European Union (EU) medical device directive and that the product has been subject to conformity assessment procedures as provided in that directive.	



Conventions

The LLS-1 has been designed to meet all safety requirements applicable to medical equipment. However, anyone using the LLS-1 must be fully aware of potential safety hazards. The information contained in this chapter is provided to help users to operate the LLS-1 safely.

Throughout this manual certain conventions are used. These are Warnings, Cautions and Notes. They provide a means of prioritizing information to be brought to the attention of the user. Warnings, Cautions and Notes will also be used throughout this manual in the following manner:

WARNING:	Indication of an important warning that is to be obeyed to eliminate the risk of personal injury or an incorrect clinical diagnosis.
CAUTION:	Indication of important information to avoid serious system equipment damage.
Note:	Additional information for reader understanding or simplification of a task.

Precautions

The user is expected to use the product (soft and hardware) in accordance with the instructions given in this manual, which must be read before the system is used. Any unauthorized deviation from the procedures laid down in this manual can affect the contractual obligations between purchaser and vendor.

WARNING:	This product was designed and manufactured to ensure maximum safety of use. It should be installed and serviced in strict compliance with safety instructions described in this Document.
WARNING:	Do not use the system before carefully study the user manuals, it is assumed that the operator is a professional and trained X-ray user or service engineer, who has gained sufficient knowledge to operate the system safely.
WARNING:	Never attempt a shortcut to procedures which may degrade the safety considerations of the system.
WARNING:	Electrical protection class: Class II MD, to avoid the risk of electric shock, this equipment is double isolated (two levels of protection). Connection to a supply main with protective earth is not required.
WARNING:	The user shall take care that potential electromagnetic or other interferences between the unit and other equipment is avoided. If necessary certain actions must be taken.





Do not modify any part of Oldelft Benelux supplied hardware, software or software configuration. Any modification, installation or running an application that has not explicitly been approved by Oldelft Benelux may compromise patient safety and will result in termination of all warranty and service contracts.

- a. If this equipment is modified, repaired or maintained, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- b. Do not leave problems unattended that may affect the safety of the product. In case you have doubts concerning the LLS-1 save operation, call the service number of your vender for further instructions.
- c. The LLS-1 stand should be cleaned regular to prevent the accumulation of dust. The contact surface should be cleaned after each patient for hygienic reasons.



The Oldelft Benelux products are designed for use and maintenance using only parts available from Oldelft Benelux. No liability for failure can be accepted by Oldelft Benelux through the use of parts obtained from other suppliers unless written permission is obtained from Oldelft Benelux.

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Concerning this Publication

Information contained in this publication is subject to change without notice. Whenever the equipment is delivered with a documentation medium such as a CD or DVD, the user shall always check the medium for latest information. This information is part of Release Notes and Document Upgrade files.

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This manual was originally drafted in the English language.

Note:

Any serious incident with the user and/or patient that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

User Manual: LLS-1



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User Manual: LLS-1



1 Introduction

1.1 About this manual

This user manual is a guide for the operator of the LLS-1, a Long-Length X-ray system. In this manual it is assumed that the operator is a professional and trained X-ray user, who has gained sufficient knowledge to operate LLS-1 safely.

In particular this document describes the daily operation.

1.2 Classification

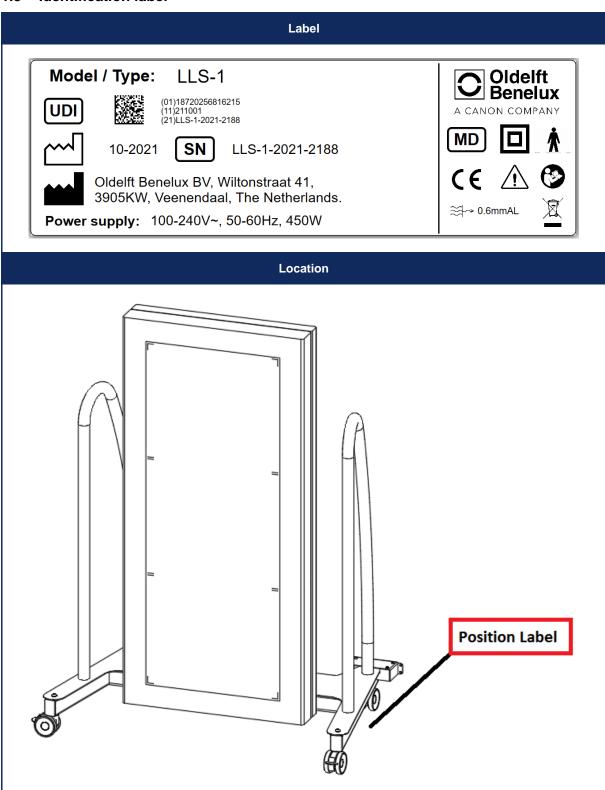
LLS-1 is classified according to Class I type B.

This mark indicated that this is CLASS II Equipment according to EN60601-1.	Equipment with two levels of protection against electrical shock double insulation of live parts and touchable conductive casing.
This mark indicated that this is a Type B Applied Part according to EN60601-1.	No Electrical contact with patient and the patient can be immediately released from the LLS-1.

The system meets the relevant provisions of the European Medical Device Regulation (EU) 2017/745 (MDR).



1.3 Identification label





2 General description

2.1 Description of the device

Product / Trade name: LLS-1

The LSS-1 is also referenced as:

- One Shot Long-Length imaging Stand
- Single Shot Long-Length Imaging Stand

The LLS-1 is available in two variations.

- Detectors CXDI 410C
- Detectors CXDI 710C

Product description

The LLS-1 is a single product, produced by Oldelft Benelux B.V.

The LLS-1 is a positioning stand that forms with an X-ray tube / generator, three flat panel detectors and acquisition computer a Long-Length X-ray system.

The system will be used as a Long-Length X-ray system with only the possibility to move the detector up and down depending on the length of the patient.

Typical application of Long-Length X-ray imaging is imaging of the total length of the spine or the legs. No stitching of three separate images is longer required. The x-ray image can be taken in one shot.

Images: LLS-1







LSS-1 Stand - 45°







LSS-1 Stand with UP/Down Movement

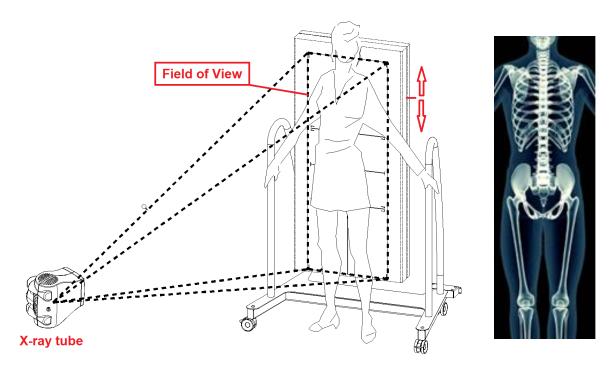
LSS-1 Docking incl. 3 detectors

The Canon Detectors 3x (42x43cm) or 3x (35x43cm) don't need any interfacing with the X-ray generator. The detector system is equipped with Ultralight Automatic Exposure Detection (AED) for automatically triggering and acquire the image during the X-ray procedure.



2.2 Principles of operation of the device

principles of operation of the device: The LLS-1 stand is intended to hold three Canon detectors in order to be able to make a Long-Length X-ray image in one shot, and to support the patient retaining a stable vertical position.



To perform a Long-Length X-ray image in one shot the LLS-1 needs to be positioned against the wall in the X-ray examination room. The X-ray beam must be able to cover the whole Field of View on the LLS-1. The Film Focus Distance (FFD) must be > 2.0m, depending of the used collimator. Normally this is around ~2.5m.

On this position wall brackets must be mounted on the wall, so next time the LLS-1 is positioned properly and stable due the fixation on the wall.

The patient is positioned in front of the stand and can hold onto the handles to stand stable and as still as possible to avoid motion blur. The Hight of the Docking and X-ray beam can be adjusted to the Field of Interest. The x-ray image can be taken in one shot. The images from the three different X-ray detectors are automatically combined to a one-shot image.

The Canon Detectors 3x-CXDI 410C Wireless (42x43cm) or 3x CXDI-710C Wireless (35x43cm) don't need any interfacing with the X-ray generator. The detector system is equipped with Ultralight Automatic Exposure Detection (AED) for automatically triggering and acquire the image during the X-ray procedure.

Accessory:



2.3 Intended purpose and patient population

Intended Purpose: The LLS-1 stand is intended to hold three Canon detectors

in order to be able to make a Long-Length X-ray image in a single shot, and to support the patient retaining a stable

vertical position.

Variants: The LLS-1 is available in two versions.

CXDI 410C Wireless (42x43cm).CXDI-710C Wireless (35x43cm).

There are no accessories

Intended indication: General Radiography.

For taking X-rays images where the Field of View (FoV) is greater than the FoV of one detector and it's important that there is no movement while the X-ray is being taken.

Making and merging of separately taken X-rays images is no longer necessary because the image can be taken in

one shot.

If the patient moves while recording the image, "moving blur" will be introduced into the image. The LLS-1 provides a stable position for the patient during an X-ray procedure

for patient picture improvement.

Intended Users: Trained professional radiographers.

Patient Population: There are no restrictions in patient population.

Duration: Transient. Even when the device is used more than once

on the same patient, the total duration will not exceed

transient use.

Intended environment: Dedicated X-ray room, in medical institutions.

Non-invase device: The device is non-invasive by its nature.

Active medical device: The device is an active medical device.



3 Instructions for Installation

WARNING:	This product was designed and manufactured to ensure maximum safety of use. It should be installed and serviced in strict compliance with the instructions described in this Document.
WARNING:	If the Stitch Frame U package is open or damaged inspect the product on damage and inform the distributor.
WARNING:	If the Stitch Frame U seems to be broken or damaged DO NOT install or use it.

3.1 Material required

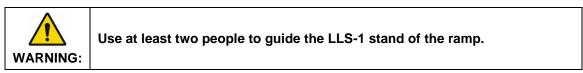
No special materials required	
-------------------------------	--

Tools required

Measuring tape	5m
Spirit level	
marker	
Drill & Drill bit	8mm
screwdriver set	

3.2 Unpacking and commissioning the LLS-1

Procedure



Remove the top and marked side panel of the case containing the LLS-1 stand. Unpack all additional items and check if all items are included. Use the marked side panel as ramp to the floor level. Use at least two people to guide the LSS-1 of the ramp.

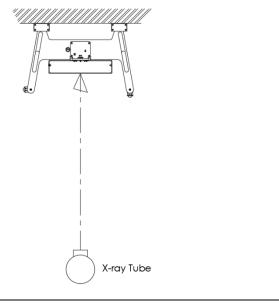
Please contact your distributor immediately if parts are missing or damaged.

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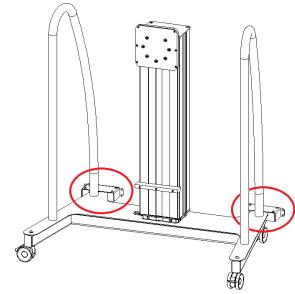
item	Description		Details
1	LSS-1 Assembly	1x	
2	Power Cord	1x	
3	Hand Controller	1x	
5	Wall bracket LLS-1 stand	2x	To lock the stand
6	Mounting material Wall brackets LLS-1 stand	1 set	
7	Wall brackets Grid	1 set	To hang the grid when not used in the docking.
8	Mounting material Wall brackets Grid.	1set	



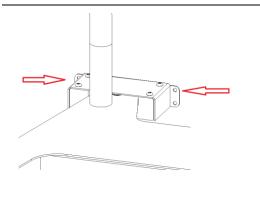
Setting up of the Wall bracket LLS-1 Stand



- Position the LLS-1 on the supposed position and center the LLS-1 stand in relation to the X-ray tube.
- FFD > 2.0m, depending of the used collimator.



 Position the Wall brackets between the LLS-1 stand and the wall.

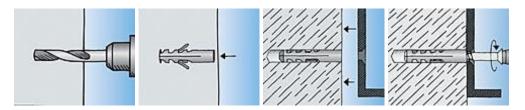


- Place temporally a spacer of 2mm between the stand and the wall brackets to ensure the stand can move in and out smooth.
- Level the wall brackets.
- · Mark holes on the Wall.

Note: check before drilling that the stand can move in and out smooth without touching the upper side of the wall brackets.

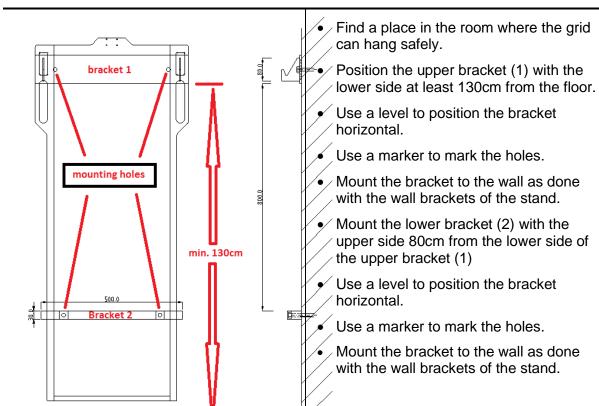


- Remove the LLS-1 brackets and drill the Holes with an 8mm stone bit.
- Clean all the dust and debris from the holes and floor.
- Install Nylon Fixing Plugs into the holes and mount the wall brackets to the wall.



- Finally: Install the LLS-1 and check the centering in relation to the X-ray field.
- Position the LSS-1 stand in the wall brackets and lock the front wheels from the stand.
- Check the fixation of the stand in the wall brackets to be sure that the stand stands stable.

Setting up of the Wall bracket grid



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Install Detectors in the Docking

- The LLS-1 stand is prepared to work with two types Canon detectors.
 - o CXDI-410C Wireless detector.
 - o CXDI-710C Wireless detector.
- The following steps needs to be done to mount the detectors in the right way.



While closing the LLS-1 door after mounting the detectors or grid frame keep hands clear.





- Unlock and open the LSS-1 docking, using the two latches on the backside.
- Rotate the latches a half turn CW.
- Open the Docking.
- Rotate the latches a half turn CCW. When closing the Docking again this will automatically locked.



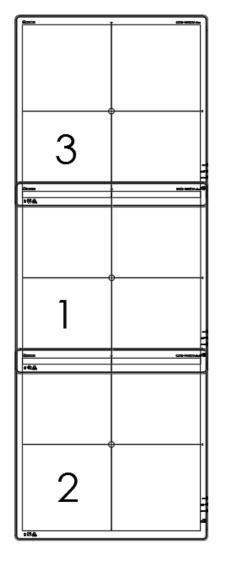
Open all detector latches as shown on the image.

- Install the detector with the lower side in the Bay.
- If the lower side fits in the bay rotate the detector totally in the bay and lock it with the detector latch.









- Install the detectors in the right order starting with
 - o 1 (middle)
 - o 2 (lowest)
 - 3 (highest)

It's advised to use the systems preferred detector location. Each detector is designated for a specific location within the frame. Labeling the detectors with "middle", "upper" and "lower" is recommended.



4 Instructions for Use

4.1 Precautions

The user is expected to use the product (soft and hardware) in accordance with the instructions given in this manual, which must be read before the system is used. Any unauthorized deviation from the procedures laid down in this manual can affect the contractual obligations between purchaser and vendor.

WARNING:	This product was designed and manufactured to ensure maximum safety of use. It should be installed and serviced in strict compliance with safety instructions described in this Document.
WARNING:	Do not use the system before carefully study the user manuals, it is assumed that the operator is a professional and trained X-ray user or service engineer, who has gained sufficient knowledge to operate the system safely.
WARNING:	Never attempt a shortcut to procedures which may degrade the safety considerations of the system.
WARNING:	Electrical protection class: Class II MD, to avoid the risk of electric shock, this equipment is double isolated (two levels of protection). Connection to a supply main with protective earth is not required.
WARNING:	The user shall take care that potentional electromagnetic or other interferences between the unit and other equipment is avoided. If necessary certain actions must be taken.



WARNING:	Before using the LLS-1 stand ensure the stability of the frame and locking to the locking mechanism of the wall brackets.
CAUTION:	Check if the LLS-1 stand can move up and down without bumping against any obstacles.
WARNING:	If the LLS-1 stand is broken or otherwise different than normal: DO NOT use it.
WARNING:	Before using the LLS-1 stand on patients check the alignment of the X-ray tube.
WARNING:	In case of equipment malfunction, bring the patient into safety and seek the assistance of a qualified technician.
WARNING:	For infection prevention is advised to disinfect the LSS-1 contact surface of the LLS-1 after each patient contact.
WARNING:	Always take radiation safety precautions

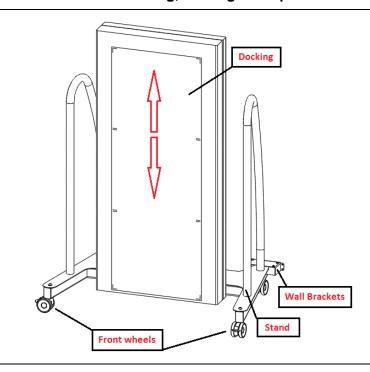
The LLS-1 stand in its construction is planned to be used as a stand together with an X-ray tube and 3 x-ray detectors. It is destined for transport in a clinic. Before transportation the docking must be parked in the lowest position.

The medical staff is responsible for a safe positioning of the patient. Before taking the image, make sure the patient is positioned correctly and in accordance to the local regulations, all parameters of generator are adjusted to size and body-part of the patient and all necessary actions for radiation safety were taken.

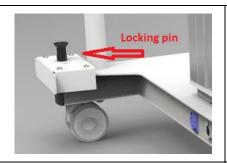


4.2 Use of the device

Instructions for Docking, moving/Transport the LLS-1 stand



Positioning the stand for use.



- Position the LLS-1 stand in the Wall brackets.
- Check the locking pin is positioned in the LLS-1 stand (in position) and fixates the LLS-1 stand to the wall (2x).
- Note: Rotating the locking pin can stop the pin from falling into the hole.



Front wheels

- Lock the front wheels to secure the LLS-1 stand (2x).
- Check the stability of the LLS-1 stand before starting the exam.

CAUTION:

Check the stability of the LLS-1 stand before starting the exam.



Instructions for Docking, moving/Transport the LLS-1 stand

Prepare the stand for moving / transport

- Move the Docking with the handset to the lowest position.
- To unlock the LLS-1 stand, pull the locking pin up and rotate the pin, so it stays in the upper position (2x).

Note: Rotating the locking pin can stop the pin from falling into the hole.

- Unlock the front wheels.
- The LLS-1 stand is ready to move.



Attach and remove the anti-scatter grid



- Unlock and open the LSS-1 docking, using the two latches on the backside.
- Rotate the latches a half turn CW.
- Open the Docking.



• Slide the grid frame into notch on the bottom of the frame.



Tilt the grid frame upwards towards the lock.



- Push the lock gently behind the lock bar
- Check if the grid frame is secured by the lock

• Removal of the grid frame can be done in reversed order.



Attach and remove the anti-scatter grid



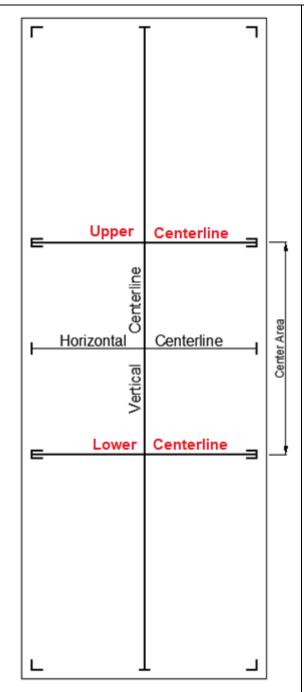
- To change the height of the LLS-1 stand:
- Press the appropriate button on the hand controller.

CAUTION:

Check if the LLS-1 stand can move up and down without bumping against any obstacles.



Alignment patient, LLS-1 and the X-ray beam



- Align the X-ray center beam on the vertical centerline in the middle of the stand (left-right)
- Position the patient in front of the LLS-1 stand.
- Adjust the LLS-1 stand horizontal centerline in the middle of the target area. Use the up-down buttons from hand control to adjust the proper height of the stand.
- Align the X-ray center beam on the horizontal centerline in the middle of the stand (move the X-ray tube up or down).
- Collimate the target area.

Note:

To prevent overlap artefacts, stay in between the <u>center area</u> with the X-ray center beam.

 FFD > 2.0m, depending of the used collimator. Normally this is around ~2.5m

Note:

When using only 2 detectors:

 Align the X-ray center beam on horizontal line in the middle of the two used detectors. (Upper or lower Centerline)

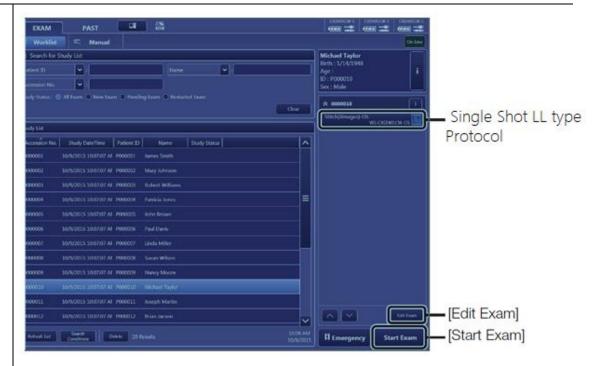
Note:

To prevent overlap artefacts, stay in between the <u>center area</u> with the X-ray beam center.



Capturing Single Shot Long-Length images

1



- Select a target study order that includes a Single Shot Long-Length type protocol.
- 2 Start the examination
 - Click [Start Exam].
- Select the Single Shot LL type protocol.

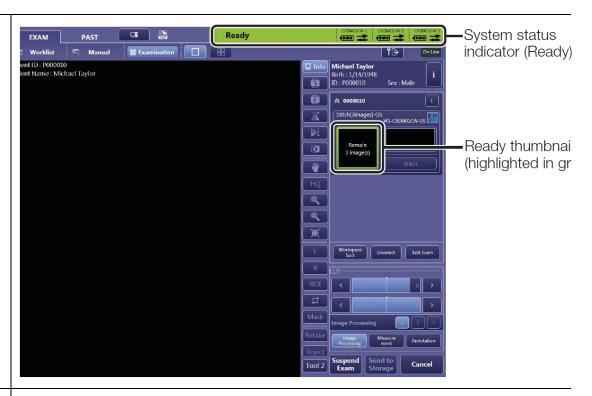
Confirm that the **Waiting...** indicator changes to **Ready** in the system status Indicators, and that a ready thumbnail appears in the target protocol.

If the Not Ready and indicators appear in the system status indicator, check that.

Note:

- The detectors are attached to the stand.
- The cables are securely connected.
- The power boxes are turned on.





5 Arrange the patient in the correct posture.

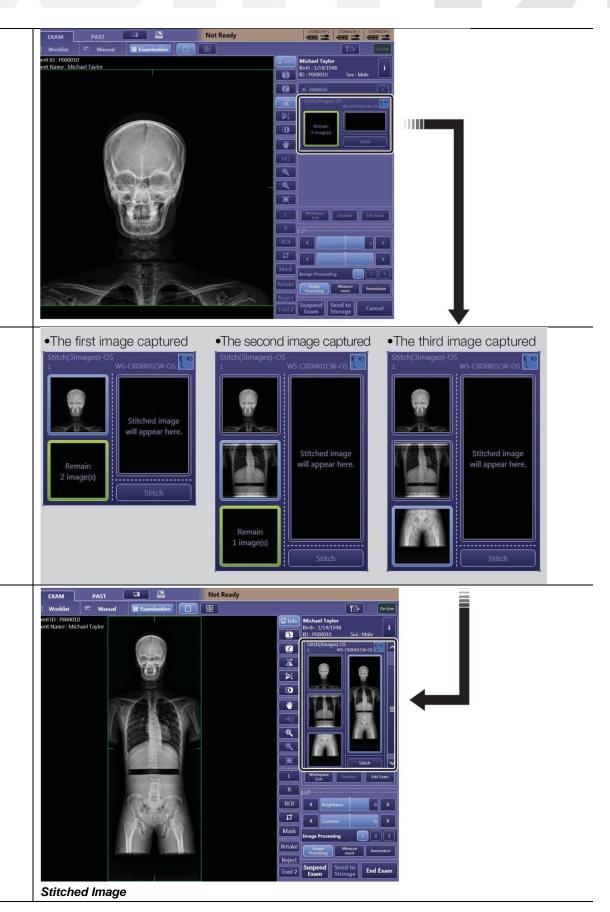
Adjust the patient's posture so that the target body part fits appropriately in the irradiated field. See also: *Alignment patient, LLS-1 and the X-ray beam.*

6 Perform exposure.

Press and release the exposure switch of the X-ray generator. The **Ready** indicator changes to **Capturing**, and then to **Not Ready** in the system status indicator. The first image, the second image, and the third image are captured one after another. The partial images are aligned and stitched automatically. Then, a stitched image appears on the image view pane.







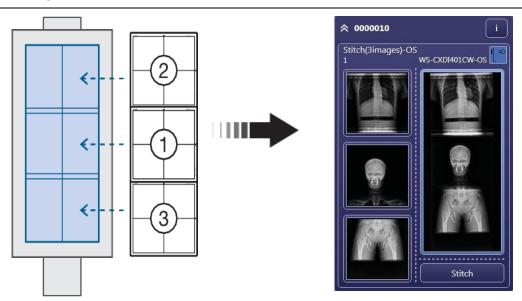


7	Check the automatically stitched image.
	Confirm that partial images are correctly aligned and stitched. If they are not aligned, realign them manually. Click [Stitch] and perform precise alignment on the Stitch Screen.
	Note:
	When the stitched image cannot be generated correctly after the detector receives some mechanical shock, the calibration for stitching boundaries by service engineer is required. Contact your sales representative or local Canon dealer for details.
8	Finish the examination.
	Click [End Exam]. The image data will be transferred to a preset destination such as storage servers (PACS).



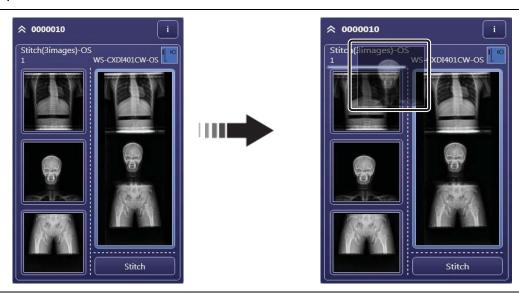
Correct wrong stitched image manually

When detectors are in the wrong positions in a stand accidentally, the stitched image is not generated correctly. You can rearrange partial images manually and regenerate the correct stitched image.



1 Rearrange partial images

Click the thumbnail of the image in the wrong position, drag it onto to the correct position, and release the mouse button.





2 A stitched image is regenerated.

After partial images are rearranged, a stitched image is automatically generated.



Preparing system for transportation

For transportation of the LLS-1 stand follow the following steps:

- Move the docking to their lowest position.
- Disconnect the power cord.
- Unlock the front wheels.
- The LLS-1 is now ready for transportation to another location



Before transporting the LLS-1 move the docking to their lowest position and disconnect the power cord.



5 Instructions for Maintenance

The LLS-1 is maintenance free but, to help ensure the safe operation of your LLS-1, there are checks that should be performed before using the frame.

Integrity checks

- a. Check overall condition of the LLS-1 stand.
- b. Check wheels for proper operation and any signs of damage and breakage.
- c. Check the wall brackets for any signs of damage and breakage.
- d. Check the cover of the docking for cracks or damage.
- e. Check the stability and fixation of the LLS-1 stand and wall brackets.
- f. Check smooth up/down movement without strange noises.

If you have reasons to assume that the safe operation is not possible any longer, take the LLS-1 stand out of operation immediately and protect it against inadvertent operation.

6 Cleaning

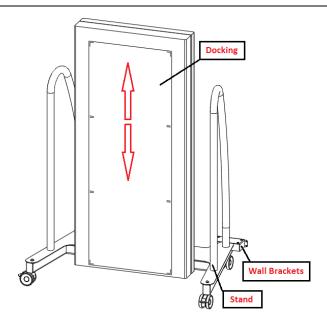
Stand

Wipe the LLS-1 stand with a piece of soft cloth soaked in water containing neutral detergent and wrung dry. DO NOT use abrasive or chemical agents as gasoline, benzene, acetone and carbon tetrachloride, de-icing fluids, lacquer thinner or detergents containing solvents.

Docking

For infection prevention is advised to disinfect the cover of the Docking. Soak a piece of soft cloth with ethanol 80~90 %, or glutaraldehyde solution and wipe the surface thoroughly when an x-ray procedure for a patient has been finished. Also, avoid scouring compounds, gasoline, benzene, acetone and carbon tetrachloride, de-icing fluids, lacquer thinner or strong solvents.

Note: Test commercial cleaning to ensure there is no adverse effect on the cover.





7 Disposal

This device contains substances that can be hazardous to the environment and care should be taken when disposed of.

The device is marked with the following symbol:



Follow local regulations regarding disposal of devices that contain electronic parts.

8 Specifications

Specification	LLS-1 Stand						
Туре	Docking with Integrated light weight columns for X-ray tube and Detector						
	Suitable for Canon detectors:						
	• CXDI 410C						
	• CXDI 710C						
	Synchronized column movement allowing easy patient positioning (up/down)						
	Setup time < 2 minutes						
	Travel 60 cm						
Line power 100-240V~, 50-60Hz, 450W							
	Standby Power 0.1W						
Dimensions	107.4 x 69.1 x 144.3 ~ 204.3cm (LxWxH and 60cm travel range)						
Weight	92 kg						

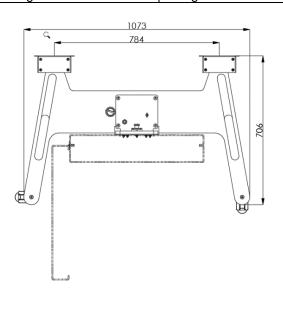
Specifications	GRID 1000 - ASS 43x122cm
Grid Ratio	10:1
Line	52 L/cm
Focal Distance	Parallel
Interspacer	AL

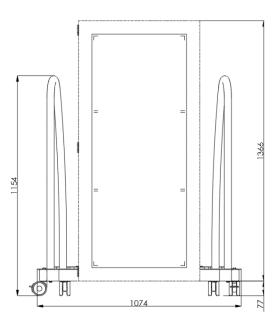
Environment conditions				
Operational	5°C to 40°C			
	20 - 90%, non-condensing (30°C)			
	800 to 1060 hPa (<2000m)			
Transport	0°C to +40°C			
	20 - 90%, non-condensing (30°C)			
	800 to 1060 hPa (<2000m)			
Storage	0°C to +40°C			
	20 - 90%, non-condensing (30°C)			
	800 to 1060 hPa (<2000m)			



8.1 Dimensions LLS-1 Stand

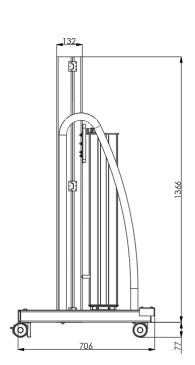
height	1344 mm (min) ~ 1944mm (max) travel range 600mm
length	1074 mm
depth	691 mm
weight	92 kg



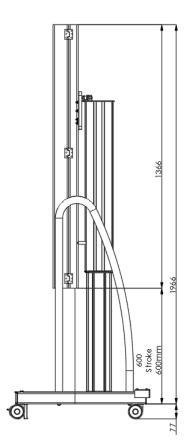


Top View

Front View



Side view - lower position



Side View - higher position

User Manual: LLS-1



8.2 Used materials

Used materials	product description							
Trespa®	 High Pressure Laminate (HPL) 3mm sheet material Very good chemical resistance / very high impact resistance Biocompatibility (skin contact) DIN EN 10993-5 - Non cytotoxic 							
Steel	 S 235 JR S – denotes the fact that it is Structural Steel 235 – related to the minimum yield strength of the steel (tested at a thickness of 16mm) 							at a
		C% 0.22max	Mn% 1.6max	P% 0.05max		0.05max	0.05max	
Stainless steel	 RVS 304 K320 1.4301 stainless steel is a variation of the 18% chromium – 8% nickel austenitic stainless steel, the most familiar and most frequently used alloy in the stainless steel family. This stainless steel be considered for a wide variety of application on good corrosion resistance, ease fabrication, excellent formability, and high strength with low weight. 							
	Materialnr.		IN 17006 5CrNi18-10		ASTM/AISI 304		UNS S30400	
Powder coating	 Alesta® IP / Polyester Industrieel IF Diverse IF05019000223 GREY Domestic and industrial appliances Indoor application e.g. shelving, office furniture, partitioning, white goods 							