MODULITH® SLX-F2
Installation Preparation

(Version 2015 / 0R.xxx & 1M.xxx)

Table of content

1 General Information

This document describes the installation process and contains information for preparing a room for installation of a STORZ MODULITH SLX-F2 system (0R) with C-MX (1M).
Only reading this document does not replace direct cooperation between customer, distributor and manufacturer.

The manufacturer STORZ MEDICAL AG reserves the right to change this document or parts of it without notice to incorporate technical improvements.

NOTE:

Please consider to comply with local regulations regarding:

- Electrical installation, clinical gas supply and air conditioning in medical facilities
- Structural calculation
- Radiation protection and fire protection

STORZ MEDICAL assumes no responsibility apart from manufacturer's responsibilities. However, STORZ MEDICAL will provide assistance in establishing suitable procedures, if required.

2 Project Management

To build an effective corporation between STORZ MEDICAL and its clients, information about responsible persons on both sides need to be exchanged. Therefore the contact data fields on specific questionnaires, at the end of this document, have to be filled out.

As well please provide as much information as possible, like a construction plan, floor heating, parquet flooring, air conditioning, sloping ceiling and so on to STORZ MEDICAL service department, to enable our service engineers to plan the installation as perfect as possible.

During the following chapters, there are a lot of tasks which need to be completed by local technicians before installation can start. For example it is necessary to check the floor loading capacity. Please find more details in the separate chapters. Also note that the electrical installation should fit in accordance with the requirements in this document.

At the end of this document there are some questionnaires and confirmation sheets. Please complete this sheets and send them back to STORZ MEDICAL as soon as possible, at least **6 weeks before** installation. The installation preparation confirmation must be send back at least 2 weeks before installation.

The client's project manager is responsible to obtain all necessary official permissions for installation and application in time.

2.1 Installation Plan

STORZ MEDICAL can provide a true-to-scale installation plan based on client information asked in questionnary A. Any desired changes should be sent immediately to the Service Department of STORZ MEDICAL.
If there is no feed back from client, installation plan will be assumed as accepted. If further changes are required at a later date, delays in the installation can not be excluded.

2.2 Radiation Protection Plan

If requested, STORZ MEDICAL will assist in determining sufficient radiation shielding. For this purpose, please use the questionnaire located in Annex B (Questionnaire Radiation Protection).

2.3 Installation

STORZ MEDICAL requires a written confirmation of the planned installation at least 14 days before installation date. The signed Installation Preparation Confirmation (Annex E) must be attached. This letter should confirm that all preparations have been completed. Please keep in mind, that visa procedures may delay the installation schedule.
STORZ MEDICAL estimates that installation will take 5 work days, not including acceptance test or technical inspections by local authorities. It is expected to have one or two local technicians available for assistance during installation.
On completion of installation, the customer and STORZ MEDICAL finally sign an "Acceptance Declaration" form. If there are still technical problems or uncertainties on scope of delivery, this must be recorded on the form.

A service engineer certified by STORZ MEDICAL will perform the installation. It will be very helpful to allocate following tools. They are basically required during first 2 days of installation.

- Manual hydraulic fork lifter, respectively palette lifter
- Pneumatic drilling machine
- Crowbar
- Vacuum cleaner

The following list shows some equipment and installations which are recommended for smoothly workflow during installation, operation and maintenance. These articles can be purchased locally.

- Wash basin
- Cabinet for measuring instruments, expendable material and documentation
- Room lighting, infinitely variable
- X-ray warning light at the entrance door
- Electrical outlets in the vicinity of the MODULITH SLX-F2 system for various additional devices
- Potential equalisation bar for additional devices
- Exhauster unit for medical gasses
- Instrument table, anaesthetic trolley
- Lockable cabinet for medicaments and instruments
- Radiation protection aprons (minimum 3)
- Holder for radiation protection aprons
- X-ray film viewer
- Desk with swivel chair for physician
- Swivel stool for operator
- Telephone
- network connector

2.4 Application training

If stipulated by contract an application training will be provided by an application specialist of STORZ MEDICAL close after installation is completed. Scope of training concentrates on measures required for lithotripsy and endourological treatments to be performed on this system, even if single devices of the system could be used for further applications like mentioned in their separate operating manuals.

Contents of application training are:

- Introduction to the MODULITH SLX-F2 and its concept (lithotripsy and endourological treatments)
- Functional tests of the MODULITH SLX-F2 system
- Operation of the system during lithotripsy and endourology
- Patient positioning for lithotripsy and endourology
- Localization of stones (with ultrasound and/or x-ray)
- Radiation protection
- Treatment strategies and recommendations
- Auxiliary measures
- Confirmation of the training completion

The first treatments after application training will be assisted by the applications specialist. Please take care about having 3 - 4 patients per day available for treatment.

2.5 Service

In case of any issues later on, please contact your local STORZ MEDICAL representative or directly:

STORZ MEDICAL AG
Service Department
Lohstampfestrasse 8
8274 Tägerwilen
Switzerland

Tel.-No: 0041 (0) 71 677 45 87
Fax.-No: 0041 (0) 71 677 45 09

E-mail: service@storzmedical.com

3 MODULITH SLX-F2 system

3.1 Room Planning

3.1.1 Introduction

STORZ MEDICAL recommends the preparation of an installation plan, which shows the location of all components prior to the installation. This ensures that final positions of MODULITH SLX-F2, x-ray device and accessories meet all needs of operators.
For providing an installation plan, the STORZ MEDICAL Service Department needs a true to scale construction plan of installation site. If a remote control room is requested, it must be included although. This construction plan should show as a minimum the following:

- Dimension of installation site and location of non-movable elements like columns, stairs etc.
- Location and dimension of all doors and windows
- Location of any kind of existing or installed interior (e.g. wash basin, surgical light,anaesthetic equipment, X-ray film viewer etc.)
- Location and dimension of all existing under floor installations (cable ducts, drainage, under floor heating etc.).

Based on the information mentioned above, the STORZ MEDICAL Service Department can create an installation plan, which shows the location of MODULITH SLX-F2 and its components in the prospective treatment room. In order to use this installation plan for the upcoming installation, it has to be approved by the responsible person on client site.

3.1.2 Example room plan

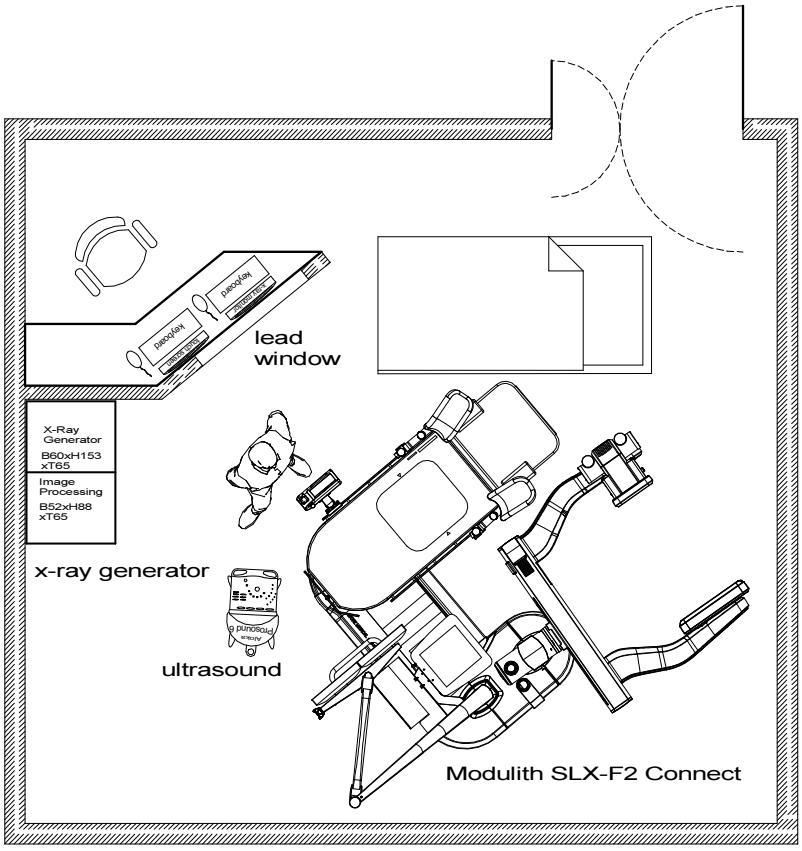

Fig. 1-1 Example room plan

3.2 Room Requirements

3.2.1 Room Dimensions

In order to ensure a safe and convenient treatment, a minimum space of 4,5 m x 5,0 m (after deduction of furniture inside the room) as well as a room height of 2.50 m is required for the MODULITH F2 connect system.

3.2.2 Room Lights

Lighting and reflections have strong impact on image display quality on monitors. The lighting in rooms witch are used for diagnostics on display units must meet the following requirements:

- Adjustable, glare-free and reproducible setting of illuminance (dimmer with scale)
- No reflections from windows, lamps and viewing boxes when the monitors are in their standard operating position. (According to DIN 6868-57)

3.2.3 Room Temperature

The room temperature during operation should be between 20° C to 30° C. Lower temperatures are uncomfortable for staff and patients. Higher temperatures can lead to early shutdown of the system. Therefore calculate accordingly the right configuration of heating and cooling system (air conditioning).

3.2.4 Installation Area

For technical reasons, the installation of base frames is necessary. They provide a proper levelling of the MODULITH SLX-F2 system. The base frames get directly mounted on the existing ground surface (plaster, concrete, parquet etc.), if the surface is plane and able to bear the load. For mounting the base frames to the ground, holes must be drilled. Drilling template are included in scope of delivery.
Installation area must be prepared as requested in installation preparation confirmation (annex E).

3.2.5 Floor Load Capacity

It is recommend to review the floor load capacity in the "lithotripter room" by a structural engineer. Responsibility for structural design of building remains with client. Please refer to chapter **3.4 Technical Data**, regarding footprint and weight of the MODULITH SLX-F2 system. The floor load capacity must be adequate. For installing the devices on a floor system ("double floor", "raised floor") take care of maximum load capacity, or better install the MODULITH SLX-F2 system on a separate construction (fundament, base, stand).

3.2.6 Floor Material

The unit must be installed on a solid base with adequate load bearing capacity.
In case of self-levelling ground, having the required load-bearing capacity, it's possible to do the installation directly on self-levelling floor.

Other types of flooring without sufficient load bearing capacity should be removed and replaced with an appropriate floor construction.

Depending on national regulations, for operating theatres, a conductive floor material is recommended.

3.2.7 Cable Duct

For electrical connection of components over longer distances, a cable duct is absolutely necessary. We recommend an under floor cable duct with a cross section of at least 20 cm x 10 cm between the MODULITH SLX-F2 and the X-ray cabinet(s) and with a cross section of 5 cm x 10 cm between MODULITH SLX-F2 and the remote control room. The installation plan will indicate the required routing of the cable duct(s). For maintenance or any other service work after installation the cable ducts must be accessible always.

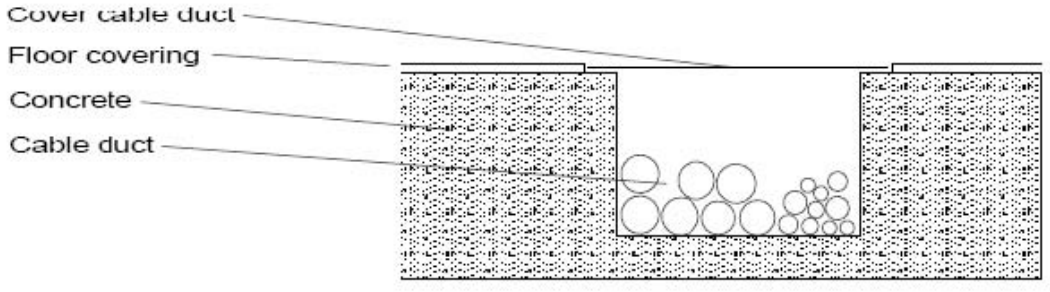

Fig. 1-2 Cable duct

In order to define the positions of the various components in the room plan, the free cable length in between these components has to be taken into account. The free cable length determines the length of the corresponding cable duct.
Free cable length is measured from outlet of "source device" until not connected end of cable.

from	to	free cable length
MODULITH SLX-F2 connect (x-ray components)	x-ray cabinets	11 m (ca. 1,5 m required inside x-ray cabinet !)
MODULITH SLX-F2	remote room	10 m (video connections via CAT-6e cables can be extended)
x-ray cabinets	remote room	10 m

Table 1-1 Free cable length

3.2.8 Water Supply

No direct or permanent connection to a water supply or drain is required. During installation and maintenance of the lithotripsy system water is needed, a tap in the vicinity of the lithotripsy system will be sufficient.

3.2.9 Ceiling

CAUTION !

In the movement range of the monitor arm no other ceiling mounted devices should be present.

For standard configuration of MODULITH SLX-F2 connect system no ceiling construction is required.

3.2.10 Radiation Protection

On request STORZ MEDICAL will provide a radiation shielding calculation for radiation protection according to German or Swiss standards. Please use the questionnaire located in Annex B (Questionnaire Radiation Protection) for this purpose. National regulations must be complied in every case.

If system is used for interventional x-ray treatments a separate shielding for operator(s), standing close to x-ray devices and patient, is required. For example so called Overhead Suspension Shields can be used.

3.2.11 Remote Control Room

WARNING !

While working from remote control room an unobstructed view towards the patient and the MODULITH SLX-F2 connect must be possible.

Depending on individual x-ray configuration, a remote room for control of complete MODULITH SLX-F2 system can or must be installed. The remote control room has to match the following requirements:

- The remote control room should have a minimum dimension of 2 m x 2 m, normal room height
- It has to be equipped with a radiation shielding window (recommended size not smaller than 80 cm x 60 cm), which allows an unobstructed view towards the patient at every time.
- The wall towards the X-ray source has to provide sufficient shielding up to a height of 2,20 m.
- A voice communication with the patient from the remote control room is essential.
- Connections for power and LAN are required

Please consider as well chapter **3.2.7 Cable Duct** for connections to lithotripter and x-ray components. A customer specific version of the remote control table is recommended to suit the individual demands. The table should be big enough to carry all equipment (monitors, keyboard, ...). And below the table there should be possibilities to hide cables, plugs and power supplies.

3.3 Electrical Preparation / Requirements

Please observe all national regulations regarding line safety switches and residual current protected devices (RCD's) used in medical facilities. The customer is responsible for professional realisation of electrical installations in accordance with all national regulations. The customer must provide appropriate connections for SLX-F2, X-ray system and optionally ordered devices.

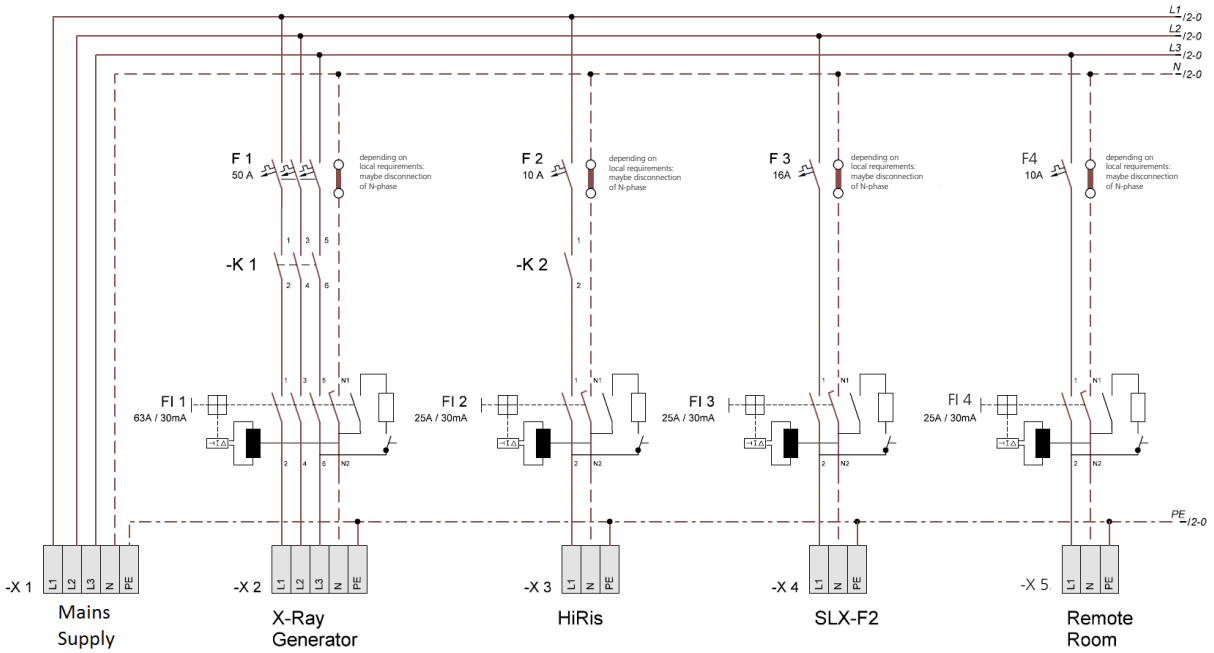

Fig. 1-3 Electrical sub-distribution for SLX-F2 connect, part a

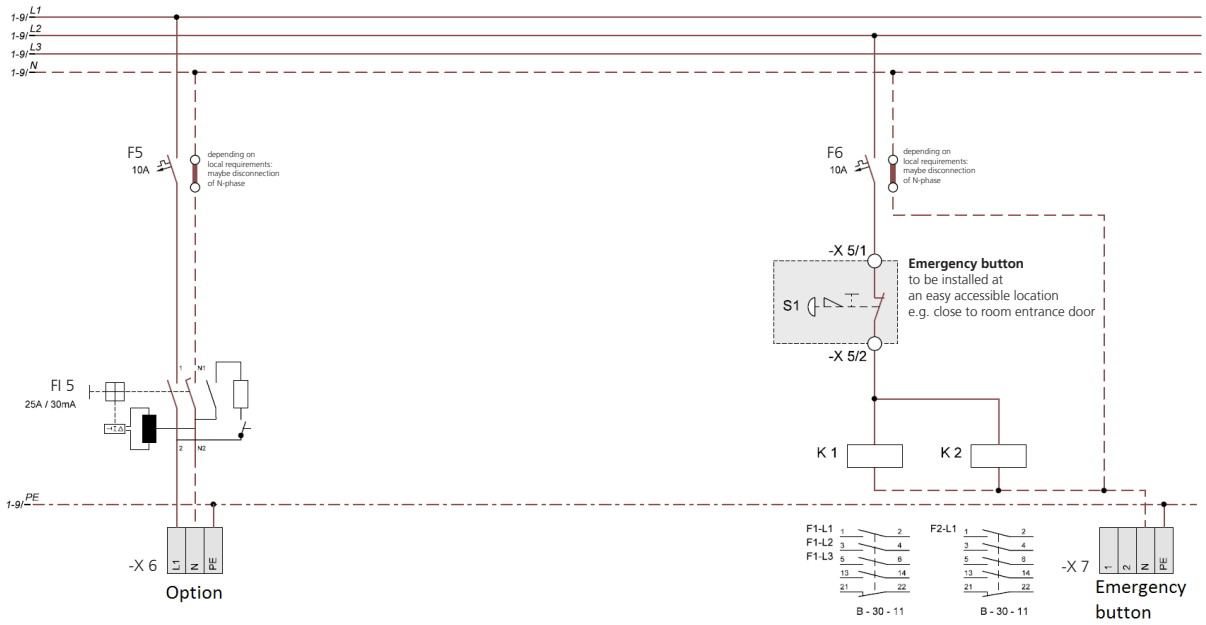

Fig. 1-4 Electrical sub-distribution for SLX-F2 connect, part b

WARNING !

The customer must provide the electrical installations for all components in accordance of national regulations.

The position of the wall distributor or a wall junction box should be close to the x-ray generator cabinet(s).

3.3.1 Modulith SLX-F2

Find below the minimum requirements for electrical connection of MODULITH SLX-F2.

MODULITH SLX-F2 - electrical connections	
Line connector	Single-phase + N + PE
Line frequency	50 or 60 Hz (± 1%)
Line voltage	200 – 210 V_{AC} (± 10%) 220 – 230 V_{AC} (± 10%) 240 V_{AC} (± 10%)
Power consumption (max.)	2 kVA (2,3 kVA)
Device input fuse	10 A
Line protection / RCD	16 A / 30 mA

Table 1-2 Electrical connection SLX-F2

3.3.2 X-ray system

Regarding x-ray safety requirements it is recommended to install an **external x-ray warning light** outside the treatment room close to the entrance of the room. Depending on local regulations for some installations **door contacts** (switching off radiation exposure when door gets opened) are required. Different generators provide direct or relay contacts to connect external warning lights and/or door switches.
In this case it would be helpful to have the cables (3 x 1,5 mm^2) available from external warning light and/or door contact close to the generator, with a free cable length of about 3 m.

Type of x-ray generator	X-ray warning light	Door contact
Spellmann HFe x01	terminal for 230 V terminal for 24 V	yes

Table 1-3 Connectors for external x-ray warning light and door contact

If required the generators can be equipped with additional electronic circuits to provide also a opportunity to connect warning lights for indicating preparation of radiation exposure.

X-ray generator HFe - electrical connections		
Generartor	HFe 501	HFe 801
Line connector	Three-phase + N + PE	
Line frequency	50 or 60 Hz (± 1Hz)	
Cross-section mains connecting cable	16 mm² flexible core	
Line voltage	400 V_{AC} +10%, -10% @ 400 V	
with additional pre-transformer (option)	208 V, 420 V, 440 V, 480 V	420 V, 440 V, 480 V
Line resistance per phase	< 0,3 Ω	< 0,12 Ω
Power consumption (max.)	50 kW	80 kW
Device input fuse, slow blow	35 A	50 A

Table 1-4 Electrical connection X-ray generator HFe x01

3.3.3 Remote Control

As an option, the MODULITH SLX-F2 connect can be operated from a remote control room. The remote control room has to match the following requirements:

- Electrical connections for ordered devices
- Network connection – in case of ordered DICOM option(s)

3.3.4 Hospital Network / DICOM

In order of DICOM options it is important to complete the questionnaire in Annex C. Please attache as well the DICOM conformance statements of all DICOM devices (PACS, worklist server, printer) involved in communication with OR1 control. This can help to avoid any trouble during installation of network.

NOTE:

It is very helpful to have the responsible persons of IT Department, Printer Company etc. available while performing the installation or system setup on client site.

3.3.5 Video signal

The SLX-F2 connect system is providing and processing digital video signals. Usually only DVI- and HDMI-connectors will be used. Analogue video signals are not supported. Via a video matrix processor (option) different video signals can be assigned to various monitors. Details must be clarified with STORZ MEDICAL Service department.

If analogue signals should be used client is responsible for A/D-conversions, and has to provide all necessary devices for conversion.

3.4 Technical Data

The following table summarizes technical information of SLX-F2 system which are required for room preparation.

Room size (recommended) Size of SLX-F2 (rectangular footprint)	4,5 m x 5 m 1,26 m x 1,95 m
Footprint of base frames	1,7 m²
Room height (required)	2,50 m
Room temperature	+15° / +30°C
Relative room humidity for SLX-F2 in combination with x-ray system	20% - 75%
Max. heat emission of SLX-F2 (complete system incl. x-ray)	approx. 2500 W
Weight MODULITH SLX-F2 system with x-ray components and patient	approx. 1600 kg
Weight x-ray cabinets	approx. 250 kg

3.5 Transport to final location

3.5.1 MODULITH SLX-F2

The MODULITH SLX-F2 will be transported within a hospital by means of a fork lifter. Prior to delivery of the equipment, the entire transport route starting from the position of delivery up to the installation site has to be checked for obstacles or impassable points. The width of MODULITH SLX-F2 in transport position is 0,90 m. Therefore all doors, floors and passages must have at least this width (e.g. narrow passages at doors, fitted furniture in corridors, narrow corridor corners, thresholds, steps as well as lifts).

3.5.2 C-MX

The C-MX will be transported within a hospital by means of a fork lifter. Prior to delivery of the equipment, the entire transport route starting from the position of delivery up to the installation site has to be checked for obstacles or impassable points. The width of C-MX in transport position is 0,90 m. Therefore all doors, floors and passages must have at least this width. (e.g. narrow passages at doors, fitted furniture in corridors, narrow corridor corners, thresholds, steps as well as lifts).

3.5.3 Common

If a transport between different floors is necessary, a lift of adequate size and lifting capability must be present. Keep in mind that lifts of older generation slightly sag under load. Any height differences exceeding 1 cm should be bridged or bypassed.
If the MODULITH SLX-F2 system has to be stored prior to installation, please observe the environment conditions as stated below.

	Storage and Transport	Operation
Temperature	0°C / + 50°C (water circuit emptied)	+15°C / +30°C
Relative air humidity	20% - 90%, non-condensing	20% - 75%, non-condensing
Atmospheric pressure	500 hPa - 1060 hPa	700 hPa - 1060 hPa

Table 1-5 Transport and storage conditions of SLX-F2 connect

The complete SLX-F2 system, including X-ray, will be delivered in several wooden cases and boxes. Depending on individual configuration of the system, these cases will have different sizes and weights.

Transport - Boxes	W x L x H / weight
SLX-F2 - Box (for 0R.xxx)	126 x 227 x 135 cm / approx 830 kg (wood case)
C-arm - Box (for 1M.xxx)	126 x 227 x 160 cm / approx. 760 kg (wood case)
C-arm accessories (for 1M.xxx)	230 x 120 x 85 cm / approx. 365 kg (wood case)
Generator - Box (HFe)	60 x 79 x 112 cm / approx. 150 kg
Imageprocessor - Box (HiRis)	60 x 79 x 112 cm / approx. 160 kg
HITACHI-ALOKA Ultrasound	68 x 109 x 160 cm / approx. 135 Kg

Table 1-6 Transport - Boxes

Transport measures (unpacked)	W x L x H / weight
MODULITH SLX-F2	90 x 140 x 100 cm / approx. 590 kg
C-MX x-ray & accessory column	160 x 90 x 140 cm / approx. 350 kg
C-arm accessories (for 1M.xxx)	different parts / up to 50 - 60 kg (Σ = 225 kg)
X-ray generator HFe	52 x 66 x 88 cm / approx. 120 kg
Imageprocessor HiRis	52 x 66 x 88 cm / approx. 130 kg
Ultrasound (maximum size for all available units)	62 x 84 x 150 cm / approx. 100 - 110 kg

Table 1-7 Transport measures

4 Questionnaires & Confirmations

On following pages you will find:

- Annex A - Questionnaire Installation
- Annex B - Questionnaire Radiation Protection
- Annex C - Questionnaire IT-Infrastructure
- Annex D - Questionnaire video distribution
- Annex E - Installation Preparation Confirmation

4.1 Questionnaire Installation (Annex A)

Hospital name: _____

Hospital address: _____

_____

_____

Contacts	Distributor	Project leader (distributor)	Project leader (hospital)
Name			
Phone			
Fax			
Email			

Room location

Building _____
Floor _____
room identifier _____

Room size

Length _____ m
Width _____ m
Height _____ m

Floor carrying capacity _____ kg/m²

Line voltage ☐ Single phase (P+N+PE) ☐ 3-Phase (3P+N+PE)
Voltage value (measured) _____ V_{AC}

Construction plan attached ☐ Yes ☐ No

Cable duct ☐ Underfloor ☐ On-floor

Lift necessary ☐ Yes ☐ No

Lift

Length of cabin _____ cm
Door width _____ cm
Door height _____ cm
Carrying capacity _____ kg

Transport route

Smallest width _____ cm
Smallest height _____ cm

_____ _____
Location / Date Signature

Please fax the completed questionnaire back to:
STORZ MEDICAL AG, Service Department, Fax.-No: 0041 (0) 71 677 45 09
or send it via email to service@storzmedical.com

4.2 Questionnaire Radiation Protection (Annex B)

Hospital name: _____

Hospital address: _____

_____

_____

Contacts	Distributor	Project leader (distributor)	Project leader (hospital)
Name			
Phone			
Fax			
Email			

Room location

Building _____
Floor _____
room identifier _____

Room size

Length _____ m
Width _____ m
Height _____ m

Construction plan attached ☐ Yes ☐ No

Please list all neighbouring areas and their type of occupancy inclusive the space above and below the room concerned. Add as well the material the walls, floors and ceilings are made of.

	Area	Occupancy
1		
2		
3		
4		
5		
6		

_____ _____
Location / Date Signature

Please fax the completed questionnaire back to:
STORZ MEDICAL AG, Service Department, Fax.-No: 0041 (0) 71 677 45 09
or send it via email to service@storzmedical.com

4.3 Questionnaire IT-Infrastructure (Annex C)

Hospital name: _____

Hospital address: _____

_____

_____

Contacts	Distributor	Project leader (distributor)	Project leader (hospital)
Name			
Phone			
Fax			
Email			

DICOM Network

Ethernet connector (RJ 45) ☐ Yes ☐ No

network speed ☐ 10 Mbit/s ☐ 100 Mbit/s ☐ 1000 Mbit/s

assignment of IP-address ☐ DHCP ☐ fix IP address for "OR1 control"
(computer for lithotripter DICOM communication)
____ . ____ . ____ . ____

For pre-configuration of "OR1 control" we request following information:

PACS Server (SCP)

conformance statement attached ☐ Yes ☐ No

IP-address ____ . ____ . ____ . ____

AET _____

port _____ (default: 5678)

Worklist Server (SCP)

conformance statement attached ☐ Yes ☐ No

IP ____ . ____ . ____ . ____

AET _____

port _____ (default: 4004)

DICOM Printer (SCP)

conformance statement attached ☐ Yes ☐ No

IP ____ . ____ . ____ . ____

AET _____

port _____ (default: 7104)

note: The "OR1 control" is usually pre-configured with following values:

AET STORZ (calling AET)

port 2104 (for DICOM query retrieve)

_____ _____

Location / Date Signature

Please fax the completed questionnaire back to:
STORZ MEDICAL AG, Service Department, Fax.-No: 0041 (0) 71 677 45 09
or send it via email to service@storzmedical.com

4.4 Questionnaire video distribution (Annex D)

Hospital name: _____

Hospital address: _____

_____

_____

Contacts	Distributor	Project leader (distributor)	Project leader (hospital)
Name			
Phone			
Fax			
Email			

Video sources in treatment room:

Source purpose _____ ☐ HDMI ☐ DVI ☐ other

Source purpose _____ ☐ HDMI ☐ DVI ☐ other

Source purpose _____ ☐ HDMI ☐ DVI ☐ other

Source purpose _____ ☐ HDMI ☐ DVI ☐ other

Source purpose _____ ☐ HDMI ☐ DVI ☐ other

_____ _____

Location / Date Signature

Please fax the completed questionnaire back to:
STORZ MEDICAL AG, Service Department, Fax.-No: 0041 (0) 71 677 45 09
or send it via email to service@storzmedical.com

4.5 Installation Preparation Confirmation (Annex E)

Hospital name: _____

Hospital address: _____

_____

_____

Contacts	Distributor	Project leader (distributor)	Project leader (hospital)
Name			
Phone			
Fax			
Email			

	Yes	No
All necessary official permission for the installation and treatment present?		
Room preparation fully completed?		
Print of the prospective lithotripsy room enclosed?		
Electrical connection according to specification?		
Cable duct according to installation plan?		
All flooring work completed?		
Lighting system installed?		
Sanitary facilities available?		
Heating and / or air-conditioning working?		
Drilling machine or rotary hammer available?		
Smallest door frame width according to specification?		
Transport route free of obstacles, gaps and steps?		
Forklift truck available?		
Must components be moved between floors?		
Lift available according to maximum size and load of components?		
Shipment with lithotripter components at installation site on time? Storage location:		
3 radiation protection aprons present?		
Pictures / Photos of completed room(s) are attached (direction of view: from each corner to the centre of the room)		

_____ _____

Location / Date Signature

Please fax the completed questionnaire back to:
STORZ MEDICAL AG, Service Department, Fax.-No: 0041 (0) 71 677 45 09
or send it via email to service@storzmedical.com