Thank you for acquiring the SGL SmartRay System, V4.0

Please read through this User Guide carefully to ensure safe usage

If you have any technical issues contact Spinal Guides Labs Technical Support Center via support@spinalguideslabs.com

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1. Introduction

Indication for Use

SGL SmartRay System, V4.0 is an accessory to a stationary X-ray system and is indicated for acquiring X-ray images for measurements in the orthopedic field (spinal segments, skeleton) with control of optical distortions.

Caution:

Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Warning:

- a. Calibrate before use SmartRay System according to the manufacturer's specification,
 otherwise the measured values of length and angles will not be correctly red by the System
- b. Do not spray, pour or spill any liquid on the sensors or components of the System
- c. Do not use any organic solvent or chlorine bleach on the System
- d. Do not work the System between -10 C and +60 C
- e. Do not operate in the environment between -20 C and +70 C
- f. Do not drop or give strong impact to the sensors of the System
- g. Do not dismantle of modify the product
- h. Do no use any sterilizer such as an Autoclave
- i. To disinfect any part of the System, wipe with a soft cloth damped with ethyl alcohol
- j. Avoid transport of the System, or sensors, whichever case may be without designated for that purpose special packaging
- k. Avoid damaging the BSS-1 cable

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2. Precautions for Safe Use:

- a. Do not run any other software program on the computers of the System
- b. Use third party computer hardware with the System according to the SGL Radiology System requirements listed in each individual module under "Hardware Requirements"

3. Manufacturer's Declaration

Applicable Standard

1. FSS Standard

Title 47: Telecommunication

Part 15- RADIO FREQUNCY DEVICES

Subpart C- Intentional Radiators

Paragraph 15.247 Operation within the bands 902-928 MHz, 2400-2483.5 MHz and 5725-5850 MHz

2. The manufacturer includes with purchase scheduled training sessions. Please call 718-880-2086 to schedule a session with one of our trainers.

4. FCC Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

RF warning statement:

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.