

# Sentinel

## *Technical Specification*

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## **Document History**

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### **Released Versions**

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# 1 Introduction

## 1.1 Purpose

The purpose of this document is to document specifications, classifications and standards compliance for the Sentinel System Release 3.

## 1.2 Scope

The scope of this document is the complete Sentinel system.

## 1.3 Definitions and acronyms

Term	Description

## 1.4 References

Ref	Document ID	Description
[1]	IEC 60601-1 second edition 1988	Medical electrical equipment- General requirements for safety
[2]	LVFS 2003:11	Swedish Medical Products Agency: "Läkemedelsverkets föreskrifter om medicintekniska produkter", transposing the European Medical Device Directive 93/42/EEC
[3]	IEC 60601-1-2	Medical electrical equipment, General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
[4]	IEC 60825-1	Safety of laser products – Part 1: Equipment classification, requirements and user's guide.
[5]	21CFR 1040.10	Laser products

## 2 Product description

### 2.1 Intended use

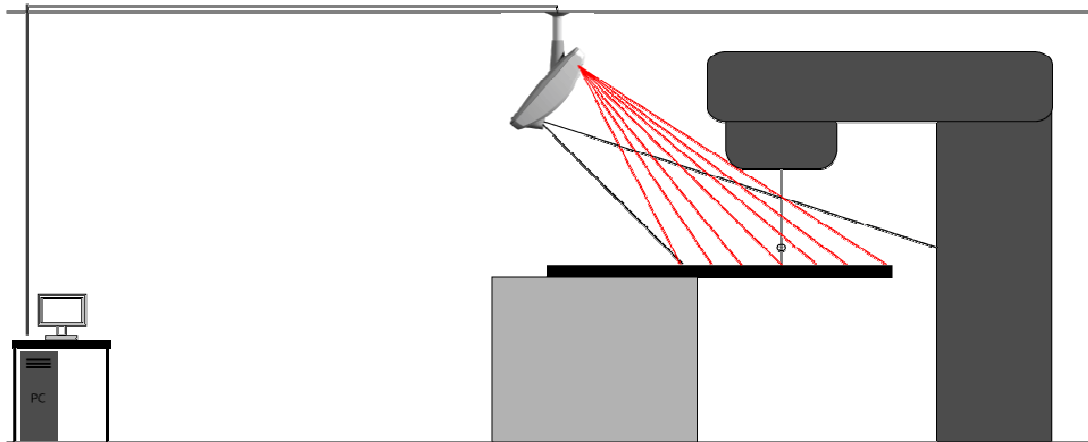
The Sentinel system is intended for use in radiation therapy clinics to accurately position patients in a reproducible way, prior to treatment and to monitor the patient continuously during treatment. The system provides information about a patient's position and the adjustments required in order to position the patient as close as possible to a reference setup. During monitoring, the system reports deviations in the patient's position during treatment.

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments.

### 2.2 System description

The Sentinel system consists of a scanner unit (LS200) and a Windows based application (Sentinel c4D). Some basic functions of the application software can be controlled from the treatment couch via an infrared remote control. The LS200 scanner unit is mounted in the ceiling of treatment rooms, simulation rooms or diagnostic rooms.

The system is non-invasive and uses visible laser light (635nm) to project lines on the patient. The ceiling height is typically around 3m above the floor and the distance from the laser source to the patient is approximately 2-3 m.



The laser-camera scans a 3D surface by projecting a series of laser lines which are recorded by the camera. From each camera recording a 3D contour of the measured object is calculated using triangulation technique and by adding the contours a full 3D surface image is achieved.

Sentinel includes two application modules, cPosition for fast and accuracy patient positioning and cMotion for motion detection during the treatment delivery procedure. Patient positioning before the actual treatment begins, together with subsequent motion detection, ensures that the patient's position is correct both before and during the whole treatment delivery.

## **2.3 User characteristics**

The system shall only be used by hospital personnel, qualified to work in radiation therapy or diagnostics departments. Training on the use of the system will be given to users at the time of installation, but is not required in order to operate the equipment.

## **2.4 System environment**

The system is intended to be used in radiation therapy clinics, where it will be installed in the ceiling of treatment rooms, simulator rooms or diagnostic (CT, MR, PET, etc.) rooms. These rooms are always well shielded since the equipment used in these rooms emit ionizing radiation, which means that the mounting of the device is very stable, i.e. no vibration or movements of walls or ceilings.

## **2.5 Principle of operation**

First, a reference surface image is acquired either by scanning the surface when the desired patient position has been determined, or by importing contours extracted from the CT data set (RT Structure Set) used for treatment planning. Scanning of a reference surface can either be done in the simulator room during simulation or in the treatment room during setup of a fraction when the setup is verified with an EPID system.

Prior to each treatment fraction the patient is scanned and the software compares the scanned image with the reference image and calculates the adjustments required in order to match the two images, thus positioning the patient in a similar way as when the reference image was acquired. The system calculates the adjustments in all six degrees of freedom, out of which four can normally be adjusted with the treatment couch (Lateral, Longitudinal, Vertical/Height and Isocentre rotation). The other two, pitch and roll, are related to patient posture, thus normally corrected by adjusting the patient manually on the couch.

cMotion monitors the movement of the patient during treatment delivery and automatically warns if the patient moves outside the allowed tolerances.

## **3 Classifications**

### **3.1 Medical device classification**

#### **3.1.1 MDD**

Class IIb according to rule 9 in appendix 9 [2].

#### **3.1.2 FDA**

Regulatory Class: II

### **3.2 Safety classifications**

#### **3.2.1 Protection against electrical shock**

Class I, basic insulation with connection of the equipment to the protective earth connector in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation. [1] § 2.2.4.

Type B, lowest degree of protection. [1] § 2.2.24

#### **3.2.2 EMC**

EMC Class A, [3].

#### **3.2.3 Laser**

##### **3.2.3.1 IEC-60825-1**

Laser Class 2M, [4].

##### **3.2.3.2 FDA 21 CFR 1040**

Laser Class II, [5].

## 4 Specifications

### 4.1 Product life time

The technical life time of the product is 10 years. Under this period C-RAD guarantees that the product is safe to use, provided that it is used and maintained according to C-RAD's recommendations.

### 4.2 Technical Data

#### 4.2.1 Physical dimensions

Size (L * W * H):	700 mm x 200 mm x 200 mm
Weight:	8 kg (18 lbs)

#### 4.2.2 Power

Input voltage:	100 – 240 VAC
Frequency:	47 – 63 Hz
Power consumption:	1.35 A

#### 4.2.3 Environment

Operating temperature	+10 °C to +40 °C (50 °F to 104 °F)
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#### 4.2.4 Laser

Power:	< 1 mW according to IEC-60825-1
Wavelength:	635 nm

#### 4.2.5 Camera

Type:	CMOS BGi4 LS
Resolution:	1280 X 1024 pixels

#### 4.2.6 Performance

Scan volume (X * Y * Z):	800 mm x 1300 mm x 700 mm.
Maximum no. of 3D data points:	360 000
Measurement resolution:	0.2 mm in Y- and Z-direction, 0.5 mm in X-direction
Measurement repeatability:	0.05 mm
Long term stability:	Better than 0.5 mm
Warm-up time:	10 minutes
Scan speed:	> 30 contours per second. Typically 1-2 s for a 40 cm scan.
Positioning accuracy (rigid body):	Within 1 mm

#### 4.2.7 Software requirements

Operating system	Windows XP SP2
Computer for Sentinel c4D Server / Sentinel c4D Standalone installation	Minimum requirements: 2GHz, 512 MB RAM, SXGA graphics, min 20G available space on the hard disk
Computer for Sentinel c4D Client	Minimum requirements: 2GHz, 512 MB RAM, SVGA graphics

## 4.3 Software

### 4.3.1 Overview

The Sentinel system can be installed as a multi-user networked system or a standalone system. In a networked installation all application data is managed by a central server and is shared across the network by client workstations that have the Sentinel c4D application installed.

The software of the Sentinel consists of a platform application and a number of interface and application modules.

- Sentinel c4D is the platform application that contains all basic functionality of the system, such as data base access, data export and import and tools for data analysis. The Sentinel c4D application must be installed on all workstations that shall have access to Sentinel data. You can run the application in Administrator and Advanced mode using this module.
- cPosition is the application module that performs the actual patient positioning task, i.e. acquires contours, creates a 3D surface, compares it with a reference surface and calculates the suggested corrections. The workstation to the scanner unit must have the cPosition module installed, in addition to the Sentinel c4D platform application.
- cMotion is the application module that performs motion detection before and during treatment. The patient's normal respiratory motion is first recorded and analyzed. The system will then begin to monitor subsequent motion and issue an alarm if it exceeds the initially measured limits by more than the configured threshold. The status of the current patient position will be displayed using a set of indicator lights in the control area, and also on the Sentinel c4D monitors in both the treatment room and control area.

In addition to this the system can be configured with the following interface modules for communication with external systems:

- cDICOM: Interface software for import of DICOM RT-Plan objects and RT-Structure Set objects. The RT-Plan objects are used for import of patient data such as name, id, etc., while RT-Structure Set objects are used for import of patient contours extracted from CT data, which can be used as reference surface.
- cVisir: Interface software for the Visir Record and Verify system from Nucletron. With this module you do not need to select patients in the Sentinel system, since this is automatically done when patient and field information is selected for treatment in Visir system.
- cElekta: Interface software for Elekta accelerators with iCOM software. With this module you do not need to select patients in the Sentinel system, since this is automatically done when the patient and field information is transferred from the R&V system to the accelerator. The current couch coordinates will also be read automatically.
- cVarian: Interface software for connecting to Varian 4D Console using the ADI protocol. With this module you do not need to select patients in the Sentinel system, since this is automatically done when the patient and field information is transferred from the R&V system to the accelerator. The current couch coordinates will also be

read automatically, and the new suggested couch coordinates will be sent back in order to enable auto-setup of the couch position.

The application modules and interface modules available for you are determined by the licenses that you have installed.

Several users can share the Sentinel c4D application data and conflicts can arise when two users tries to modify the same data set. The solution implemented in the Sentinel c4D application is called “optimistic concurrency” i.e. several users are allowed to work on the same data but only the changes committed by the first user will be accepted while the changes that other users try to save will be denied.

### 4.3.2 Functionality

The application has three different user interfaces, modes, each designed for its specific purpose:

- user interface for the daily clinical use (Clinical mode)
- rich user interface for more advanced functions (Advanced mode)
- rich user interface for system administration (Administrator mode)

The user interface in Clinical mode is work-flow oriented, i.e. the interface guides the user through the steps that shall be performed and only the minimum required information for each step is presented to the user.

The interface in Advanced and Administrator modes is of a more traditional type, e.g. Word, Excel, etc., where the user chooses the data-set to work with and then applies operations on the data-set from a selection of menu-items and dialogues.

The functions available in Clinical mode are:

- Perform a Daily Check.
- Perform Patient positioning.
  - Select patient manually or automatically via integration with R&V system.
  - Perform a scan. Initiated either with a remote control or by clicking on a software button on the monitor.
  - The system calculates and presents the required adjustments in patient position, in six degrees of freedom (X-, Y-, and Z-translation as well as rotation around the X-, Y-, and Z-axes).
  - Also, on the monitor a quality index is displayed that indicates how well the scanned image matches the reference image when the proposed adjustment is applied to the scanned image.
- Perform patient monitoring
  - Select patient manually or automatically via integration with R&V system.
  - Perform monitoring. The system reports the deviations outside allowed tolerances.

The functions available in Advanced mode are:

- Enter new patients to the system, either by importing via DICOM or by manual entry.

- Edit patient information.
- Create reference images, either by importing via DICOM or by performing a scan.
- Edit settings for a reference image. The reference image settings are then used in following scans coupled to the reference image, e.g. in Clinical mode.
- Setting up regions on reference images, e.g. to exclude areas that are affected by respiratory motion from being used for positioning of the patient.
- Inspect results from patient monitoring.
- Use of templates to pre-define settings for reference images customized for specific situations.
- Export of image data to text files in a comma separated format.
- Presentation of results for all registered scans.
- Generate reports on the Sentinel c4D application data.

The functions available in Administrator mode:

- User management.
- Room and scanner management.
- Archive and restore patients.

### **4.3.3 Interfaces**

#### **4.3.3.1 DICOM**

Import of patient and treatment plan data via DICOM RT-Plan objects.

Import of reference images, i.e. patient surface from CT data, via DICOM RT-Structure objects

#### **4.3.3.2 iCOM**

Synchronization with Elekta accelerators via Elekta iCOM protocol version 12.05.

#### **4.3.3.3 ADI**

Synchronization with Varian accelerators via the Varian ADI protocol.

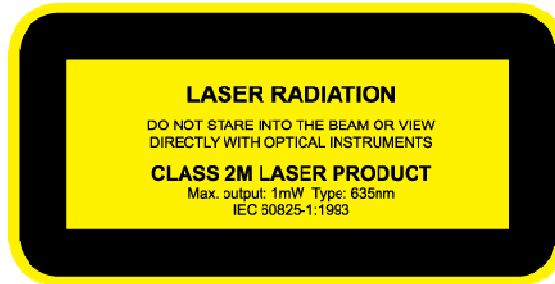
#### **4.3.3.4 Visir**

Synchronization with Nucletron Visir R&V system version 1.3a.

## 4.4 Labels

### 4.4.1 Laser Warning label

Labels on laser scanner



## 4.5 Standards compliance

The system complies with the following standards:

- IEC-60601-1 Medical electrical equipment, General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.
- CAN/CSA C22.2 601.1
- UL 60601-1
- IEC-60601-1-2 Medical electrical equipment, General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- EN/IEC-60825-1 Safety of laser products – Equipment classification, requirements and user’s guide
- Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007

### 4.5.1 IEC-60601-1-2

Cable specifications			
Description	Manufacturer	Model/Part number	Maximum length
Serial communication cable	GSI Lumonics Component Group	712-74214	7.1m
LVDS communication cable	C-Cam Technologies		6.8m
Power supply	XP Power	PCM50UD08	Voltage output: + 15 V DC, - 15 V DC, max 1m

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
The LS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the LS200 should assure that it is used in such an environment.		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The LS200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The LS200 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	


<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The LS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the LS200 should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / Burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 0.5 kV for signal lines	Mains power quality should be that of a typical commercial or hospital environment.  To reduce the environmental levels of disturbances on the signal lines to less than 0.5kV the signal lines should run no closer than 30cm from any high voltage line where the lines are parallel.
Surge IEC 61000-4-5	+/- 1 kV differential mode	+/- 1 kV differential mode	Mains power quality should be that of a typical commercial or

	+/- 2 kV common mode	+/- 2 kV for common mode	hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LS200 requires continued operation during power mains interruptions, it is recommended that the LS200 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields may be at levels up to ten times higher than characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.			

### Guidance and manufacturer's declaration – electromagnetic immunity

The LS200 is intended for use in the electromagnetic environment specified below. The customer or the user of the LS200 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the LS200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	<b>Recommended separation distance</b> $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz  where $P$ is the maximum output power rating of the transmitter in watts (W) according to the

			<p>transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol.</p> 
<p>NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.</p>			
<p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LS200 is used exceeds the applicable RF compliance level above, the LS200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the LS200.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m</p>			

<b>Recommended separation distances between portable and mobile RF communications equipment and the LS200</b>			
<p>The LS200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LS200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LS200 as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1,2	1.2	2.3
10	3,8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p><b>Note 1:</b> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p><b>Note 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			