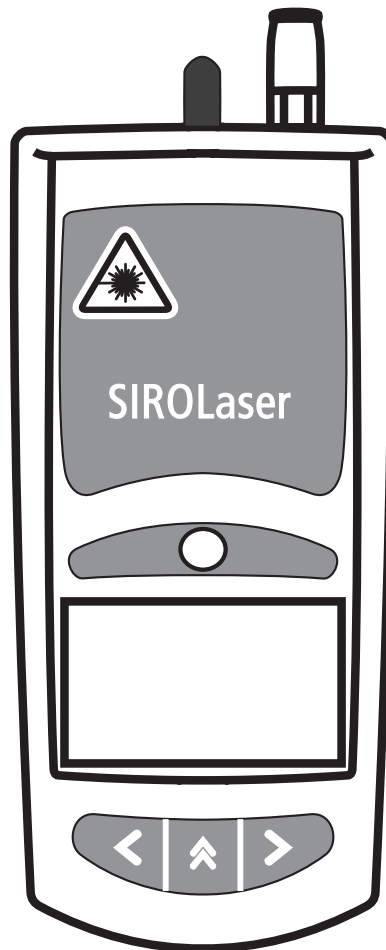


# SIROLaser

Safety Test Service Manual

English



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SIROLaser is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices (MDD). Compliance is determined based on the following standards: IEC 60601-1: 1998, IEC 60601-1/A2: 1998 and IEC 60601-2-22: 1997.



ME20



MEDICAL ELECTRICAL EQUIPMENT  
WITH RESPECT TO ELECTRIC SHOCK  
FIRE, AND MECHANICAL HAZARDS ONLY  
IN ACCORDANCE WITH UL2601-1/CAN/CSA C22.2 No. 601.01  
58EA

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# 1 Warning and safety information

## 1.1 Before you begin

---

### NOTE

Technical information concerning parts requiring repair will be supplied by Sirona only to authorized agents whose technical personnel have completed a corresponding product training course. **No maintenance or repairs may be performed on the SIROLaser without the corresponding product training.**

---

### NOTE

Knowledge and understanding of the operating instructions is required to operate the unit. Please read the operating instructions prior to startup to familiarize yourself with the operation of the SIROLaser.

---

### CAUTION

Perform maintenance only on a cleaned and disinfected unit.

---

### 1.1.1 Preparation for testing

Testing may be performed only by authorized personnel. If deviations from the specified values are detected during the tests, their cause must be determined immediately.

### 1.1.2 Laser protection

---

### NOTE

**Laser protection:** Observe the relevant national regulations and ordinances when repairing and/or servicing the SIROLaser.

Regarding the installation and startup of the SIROLaser, Sirona Dental Systems GmbH requires in particular:

- Compliance with IEC 60825-1 including all annexes.

*If you have any further questions, please contact your laser protection officer.*

---

Testing of the SiroLaser may be performed only in a room that complies with the relevant laser protection requirements

The testing personnel must be properly instructed by the laser protection officer.

During testing, suitable safety goggles must be worn as soon as the laser is switched on.

Noone except for persons directly involved with the testing may be located in the laser testing room.

### 1.1.3 Measuring equipment

The following measuring equipment is required for the test run:

- Tester for leakage current tests acc. to IEC 60601-1
- Optical power meter 0.1 – 10 W for 970 nm with accuracy of  $\pm 5\%$
- Good as new optical fiber reserved for calibration, dia. 320  $\mu\text{m}$  (Mat. No.: 60 53 578)

## 1.2 Highlighting of warning and safety information

To prevent any personal injury or material damage, please observe the warning and safety information provided in the present operating instructions. The information is highlighted as follows:

---

**i NOTE**

for additional information,

---

**! CAUTION**

if there is any risk of damage to the laser unit,

---

**! WARNING**

if there is any hazard to the life or health of persons.

- This symbol indicates that you have to take action.
- ☞ This symbol indicates that a certain result will occur.

## 1.3 Intended use



---

**i NOTE**

*SIROLaser is intended for surgery and coagulation of oral soft tissue in periodontal pockets and root canals. This laser unit may only be used by trained and qualified personnel in compliance with the applicable occupational safety regulations and accident prevention measures as well as the operating instructions and the present service manual.*



---

**i NOTE**

*The SIROLaser is also suitable for surgical interventions and for stopping bleeding in soft tissue. This laser device may be operated only in a dental practice by trained persons who are familiar with the labor protection laws and accident prevention regulations and have read the present maintenance and operating instructions.*

---

**i NOTE**

*Users are obliged to use only faultless materials, to ensure correct application and to protect themselves, the patient and other persons against hazards.*

---

**! WARNING**

*This laser unit is not intended for operation in areas subject to explosion hazards or in the vicinity of flammable materials or substances.*

---

**! WARNING**

*Public legal provisions may include special safety regulations for the protection of persons against laser radiation. These regulations must be complied with.*

---

---

 **WARNING**

*WARNING: Using controls or settings or performing procedures other than those specified in this manual may result in hazardous radiation exposure.*

---

## 1.4 Wireless phone interference

---

 **CAUTION**

*To ensure safe operation of medical electrical equipment, the use of mobile wireless phones in practice or hospital environments must be prohibited.*

---

## 1.5 Disposal

If you plan to discontinue the use of your SIROLaser and intend to dispose of the unit, make sure to observe the applicable legal provisions.

# 2 Glossary, symbols and abbreviations

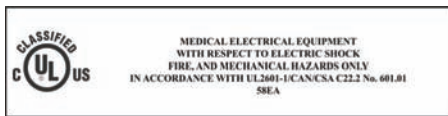
## 2.1 Symbols on the SIROLaser



CE mark in accordance with Council Directive 93/42/EEC, stating the manufacturer's recognized certifying body (depending on the Sirolaser SW)



GOST Certificate for Russia (depending on the Sirolaser SW)



UL/CSA Certificate for the USA/Canada (depending on the Sirolaser SW)



01-2005

Date of manufacture (January 2005)



01-2007

Best-before date: Do not use after January 2007



0123 / 12 / 05

Batch number (consecutive number/month/year)



Type B applied part according to IEC 60601-1



Please refer to manual first



Refers to directive 2002/96/EC and EN 50419  
Do not dispose with domestic waste

DC IN    Optical fiber    INTERLOCK/  
SWITCH



Socket for DC input from Sinpro MPU50–105 switching power supply

Socket for optical fiber

Socket for interlock connector

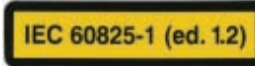


Laser radiation warning

## 2 Glossary, symbols and abbreviations



Specification of laser output power and wavelength of IR and aiming beam (see also Chapter "Technical data")



States the compliance of the SIROLaser with IEC 60825-1, edition 1.2



Warns of potential laser radiation hazards when opening the unit



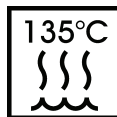
Warns of class 4 laser radiation hazards when using the laser unit



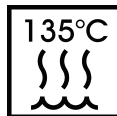
"LASER STOP" button: Press this button in case of an emergency



Operate the laser unit exclusively with the Sinpro MPU50-105 power supply



Can be sterilized in an autoclave with saturated water vapor at 135 °C (275 °F), 3 min. holding time and 2.13 bar (30.89 PSI)



Can be sterilized in an autoclave with saturated water vapor at 132°C (270 °F), 3 min. holding time and 1.87 bar overpressure (27.12 PSI)



### 2.2 Glossary

CONTINUOUS EMISSION	Continuous laser emission
PULSED EMISSION	Pulsed laser emission (chopped mode)
FREQUENCY	Number of laser pulses per second
HERTZ	Unit of measure for frequency
INTERLOCK	Safety device that stops laser radiation when the door of the treatment room is opened
JOULE	Unit of measure for emitted energy
WATT	Unit of measure for laser power
STOP	End of treatment or treatment break
TIME	Treatment time setting mode

### 2.3 Abbreviations

cm <sup>2</sup>	Square centimeter
Hz	Hertz
s	Seconds
W	Watt
mW	Milliwatt (one thousandth of a Watt)
J	Joule
nm	Nanometer
V	Volt
IR	Infrared diode
NOHD	Nominal Ocular Hazard Distance according to EN 60825-1: 2003

# 3 Maintenance and service

## 3.1 Checking the calibration

### 3.1.1 Calibration check with an external power meter

- Connect an optical fiber to the SIROLaser.
- Aim the optical fiber at the measuring head of the power meter. Keep a minimum distance of 20 mm between the optical fiber and the surface of the measuring head. This will prevent damage to the measuring instrument due to the high energy density resulting from the small diameter of the optical fiber.
- Wear the laser protective goggles and verify that the entrance to the room where the calibration is being performed is controlled by an interlock device or is locked.
- Switch on the SIROLaser and go to the "MANUAL SETTING" area.
- Select "MANUAL SETTINGS NO. 1".
- Check to see that the optical fiber is neatly cut and that the laser beam projects a red circle. The circle must be as well defined as possible.

The first test is performed at 0.5 W.

- Press the "ENTER" key until the "W" are highlighted.
- Select the required power level with the "RIGHT ARROW" key or the "LEFT ARROW" key.
- You can quit the "MANUAL SETTINGS" area once again by pressing the "ENTER" key.

The test is performed in the following steps: 0.5 W, 1 W, 2 W, 3 W, 4 W, 5 W, 6 W, 7 W (see "Calibration/Optical power measurement" table).

#### Test at 0.5 W

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.

#### Test at 1 W

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.

#### Test at 2 W

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.

### Test at 3 W

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.

### Test at 4 W

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.

### Test at 5 W

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.

### Test at 6 W

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.

### Test at 7 W

---

#### **i** NOTE

*The maximum value for a setting of 7 W is 6.5 W.*

---

- Trigger the foot or finger switch until the power meter displays a stable value.
- Check whether the reading displayed on the power meter is within the permissible range. Acc. to the standard, the maximum deviation is +/- 20 %. However, Sirona Dental Systems GmbH recommends performing recalibration if the deviation is +/- 5 %.
- Quit the calibration menu by pressing the "ENTER" key.

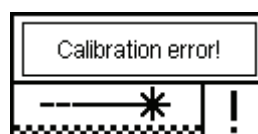
If the process is completed without errors and the values measured with the power meter are within the permissible range, the calibration of the SIROLaser has been tested successfully.

Enter the values in the attached certificate (see page 15).

Enter the measured values in the medical product log.

### 3.1.2 Error message and incorrect parameter values

If the following screen appears during one of the three calibration tests:



Repeat the test from the beginning. If the error persists, do not continue working with the unit in any case. Please contact our Service in Bensheim.

### 3.2 Function check

#### 3.2.1 Visual inspection

Damage and completeness check

Perform a completeness check according to the current SiroLaser Operating Instructions.

#### **i** NOTE

*If the laser including all accessories is not complete, the visual check must be regarded as passed only to a limited degree. Missing parts must be entered in the test certificate and in the medical product log.*

*If the customer demands a test of an incomplete unit this also must be documented.*

If any parts are damaged or missing, the resulting safety impairment must be calculated and entered in the test certificate.

Example: A deep scratch in the paint job of the foot switch is not safety impairing. A deep scratch in the glass of the safety goggles is safety impairing.

Enter the defects in the attached certificate (see page 15).

#### 3.2.2 General function check

- Switch the unit on and check each key for proper functioning.
- Select an indication and check the corresponding functions one after the other:
- 4 green diodes are flashing.
- Red pilot beam is ON.
- **Check readiness for exposure.**

Pull off the interlock connector: The laser emission is terminated immediately and the message

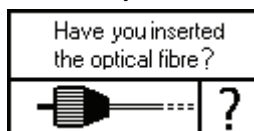


appears on the display.

Reconnect the interlock connector: The display indicates the start parameter and the laser is ready for operation again.

- **Check of fiber optic cable connection**

Pull off the fiber optic cable connection: The laser emission is terminated immediately and the message



appears on the display.

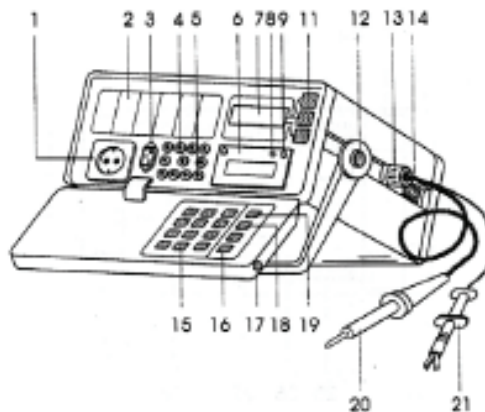
Reconnect the fiber optic cable: the display indicates the start parameter and the laser is ready for operation again.

- 4 yellow diodes flash when the laser is ON.
- Activate the buzzer in the "Settings" menu.  
Check the the buzzer for proper functioning.
- Check the the finger switch for proper functioning.
- Perform a complete test treatment in any case and check the power parameters: The power must not fluctuate by more than  $\pm 20\%$  throughout the entire treatment (However, Sirona Dental Systems GmbH recommends recalibration if the deviation exceeds  $\pm 5\%$ ).
- Enter the items in the attached certificate (see page 15).

### 3.3 Electrical safety test

Before you run the test, familiarize yourself with the tester using its operating instructions.

#### 3.3.1 Tester setup based on the Bender tester



- 1) Power outlet for test object
- 4) Sockets for patient electrodes
- 11) Selection keys
- 15) Alphanumeric keyboard
- 16) Program control keys
- 18) Function key
- 20) Test prod
- 21) Test terminal

### 3.3.2 Test setup and performance

- Perform this test with the leakage current tester.

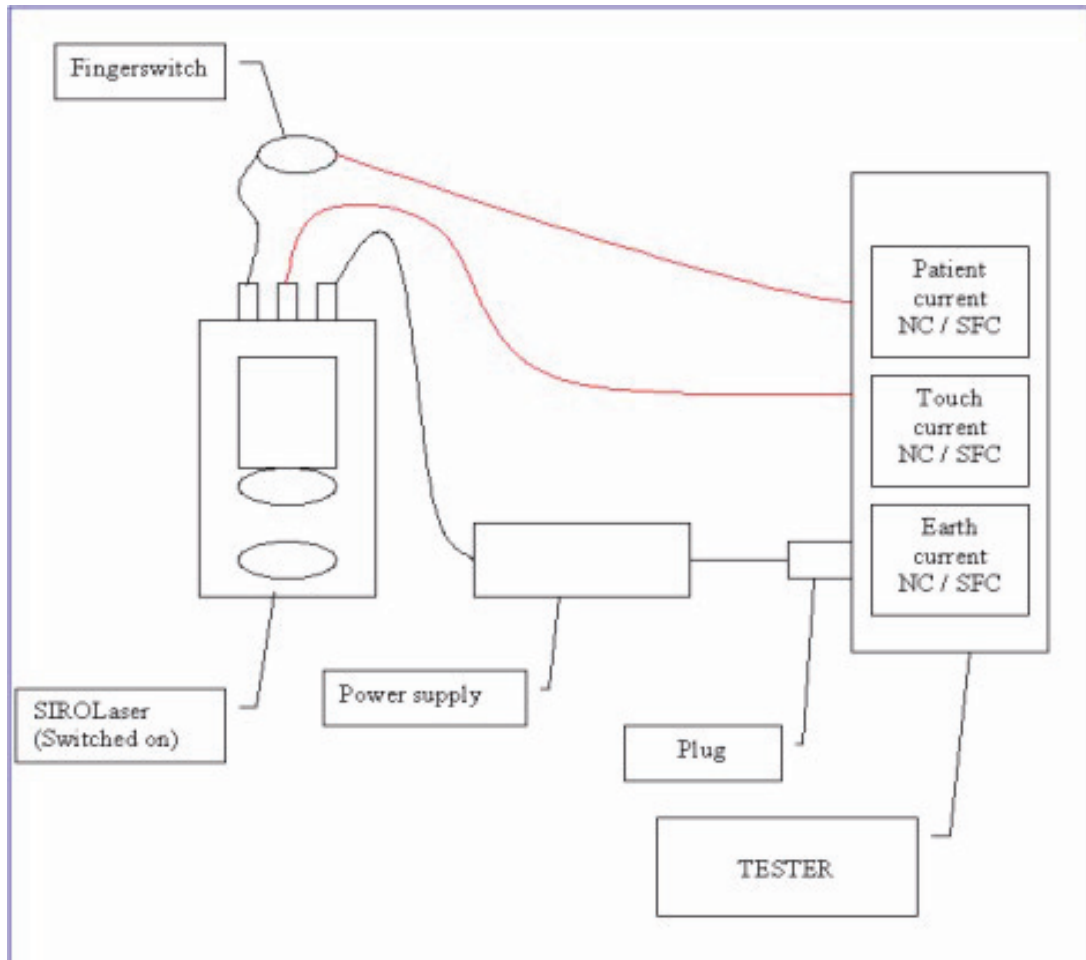


Fig. 1: Cable connections of the SIROLaser to the leakage current tester

1. Plug the connector of the SIROLaser power supply into the socket of the tester (1) provided for that purpose.
2. Connect the finger switch to the patient electrode (4).
3. Connect the metallic SMA socket of the laser to the test terminal (21).
4. Switch the laser on.
5. Perform the measurement
  - of the patient leakage current acc. to IEC 6060 1-1 (NC, SFC)
  - of the housing leakage current acc. to IEC 60601-1 (NC, SFC) and
  - of the earth leakage current acc. to IEC 60601-1 (NC, SFC)as specified by the Tester Operating Instructions.
6. During an STK, enter the values in the medical product log of the laser if it is available.

Enter the values in the attached certificate (see page 15).

### 3.4 Repair test certificate

<input type="checkbox"/>	SIROLaser (DE, EN, FR, ES, IT)	60 46 960
<input type="checkbox"/>	SIROLaser (EN, DK, SV, FI, NO)	60 46 978
<input type="checkbox"/>	SIROLaser (EN, FR, ES, NL, PT)	60 46 986
<input type="checkbox"/>	SIROLaser (EN, RUS, PL, TR, GR)	60 46 994
<input type="checkbox"/>	SIROLaser (USA)	60 88 749
<input type="checkbox"/>	.....	
<input type="checkbox"/>	.....	

Serial number.:	
Software version:	

### 3 Maintenance and service

## Safety tests

Performed by: \_\_\_\_\_, Date: \_\_\_\_\_

Test:	Passed Y/N	Remarks:																
<b>1. Visual inspection of unit and accessories for mechanical damage</b>																		
<b>2. General function check</b>																		
<b>3. Check of the audible and visual indicators</b>																		
<table border="1"> <thead> <tr> <th>4. Measured values according to EN 60601-1: 1990</th> <th>Limit value<sup>1</sup></th> </tr> </thead> <tbody> <tr> <td>Earth leakage current NC: _____ mA</td> <td>0.5</td> </tr> <tr> <td>Patient leakage current NC: _____ mA</td> <td>0.01</td> </tr> <tr> <td>Housing leakage current NC: _____ mA</td> <td>0.1</td> </tr> <tr> <td>Earth leakage current SFC: _____ mA</td> <td>1</td> </tr> <tr> <td>Patient leakage current SFC: _____ mA</td> <td>0.05</td> </tr> <tr> <td>Housing leakage current SFC: _____ mA</td> <td>0.5</td> </tr> </tbody> </table>	4. Measured values according to EN 60601-1: 1990	Limit value <sup>1</sup>	Earth leakage current NC: _____ mA	0.5	Patient leakage current NC: _____ mA	0.01	Housing leakage current NC: _____ mA	0.1	Earth leakage current SFC: _____ mA	1	Patient leakage current SFC: _____ mA	0.05	Housing leakage current SFC: _____ mA	0.5				
4. Measured values according to EN 60601-1: 1990	Limit value <sup>1</sup>																	
Earth leakage current NC: _____ mA	0.5																	
Patient leakage current NC: _____ mA	0.01																	
Housing leakage current NC: _____ mA	0.1																	
Earth leakage current SFC: _____ mA	1																	
Patient leakage current SFC: _____ mA	0.05																	
Housing leakage current SFC: _____ mA	0.5																	
<b>5. Laser power measurement<sup>2</sup> with calibrated measuring instrument in the range of 0.5 to 7 W</b> <table border="1"> <tbody> <tr> <td>0.5W:</td> <td>.....</td> </tr> <tr> <td>1W:</td> <td>.....</td> </tr> <tr> <td>2W:</td> <td>.....</td> </tr> <tr> <td>3W:</td> <td>.....</td> </tr> <tr> <td>4W:</td> <td>.....</td> </tr> <tr> <td>5W:</td> <td>.....</td> </tr> <tr> <td>6W:</td> <td>.....</td> </tr> <tr> <td>7W:</td> <td>.....</td> </tr> </tbody> </table>	0.5W:	.....	1W:	.....	2W:	.....	3W:	.....	4W:	.....	5W:	.....	6W:	.....	7W:	.....		
0.5W:	.....																	
1W:	.....																	
2W:	.....																	
3W:	.....																	
4W:	.....																	
5W:	.....																	
6W:	.....																	
7W:	.....																	

1. If the limit values are exceeded, the laser must be repaired by Sirona or by an authorized dealer.  
 2. If one of the tests is not passed, the laser must be repaired by Sirona or by an authorized dealer.

\_\_\_\_\_  
 Signature



### 3.5 Final work

- Switch unit off and pull power plug
- Enter readings in "test certificate"
- If a medical product log is present, it must be filled out
- Complete as required by the customer if necessary

Accessories completed at the customer's request	<input type="checkbox"/> Yes	<input type="checkbox"/> No
STK performed and parameters entered in medical product log or supplementary attached sheet (repeated measurement)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Test certificate completed and attached to laser	<input type="checkbox"/> Yes	<input type="checkbox"/> No

### 3.6 Technical support

Technical information concerning parts requiring repair will be supplied by Sirona only to authorized agents whose technical personnel have completed a corresponding product training course. Please contact your local dental depot or authorized service center for technical support.

Please always use the original packaging when shipping the laser unit. Please disinfect and sterilize the laser unit according to the relevant Operating Instructions before shipping it.

# 4 Technical data

Laser system	Class IV (according to DIN EN IEC 60825-1: 2003)
Equipment classification	Class IIb (according to Council Directive 93/42/EEC)
IP degree of protection	Laser unit: IP20; foot control: IPX5
Wavelength	970 nm +/- 15 nm
Power max.	Approx. 7 W CW
Aiming beam	635 or 650 nm, 1 mW max.
Emission mode	CW (continuous wave) or modulated 1 to 10 kHz
Pulse (chopped mode)	Single or repeated pulse
Pulse duration	100 ms to 60 sec in steps of 50 ms
Optical fiber thickness	200 µm, 320 µm and 400 µm, NA >= 0.22
Start	Electrical foot control/finger switch plus electronic access key
Adapter	External, 90 - 264 VAC, 47 - 63 Hz
Insulation class	Class 1, type B
Performance data displays	On graphic display
Dimensions	Approx. 87 x 54 x 190 mm (3.43 x 2.1 x 7.48 in.)
Weight	Approx. 0.45 kg (1 lb)
Power supply	The SIROLaser may only be operated with the Sinpro MPU50-105 power supply
NOHD (Nominal Ocular Hazard Distance)	Approx. 1.5 m for 10 s radiation exposure of the unprotected eye (numerical aperture of the optical fiber NA = 0.22)

# 5 Appendix

## 5.1 Appendix A – Certification

The unit is manufactured in compliance with the provisions of Council Directive 93/42/EEC concerning medical devices.

## 5.2 Appendix B – Label positions

The following figures show the positions of the labels on the SIROLaser.

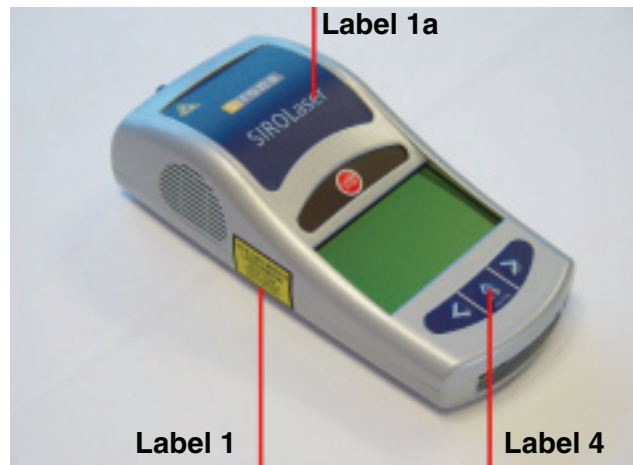


Fig. 2: Label positions, top view



Fig. 3: Label positions, bottom view

## B2 – Label list

The following labels are attached to the SIROLaser:



Label 1a

CU<sup>1</sup>

**SICHTBARE UND UNSICHTBARE LASERSTRAHLUNG**  
BESTRAHLUNG VON AUGE ODER HAUT  
DURCH DIREKTE ODER STREUSTRALUNG VERMEIDEN  
LASER KLASSE 4

**VISIBLE AND INVISIBLE LASER RADIATION**  
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION  
CLASS 4 LASER PRODUCT

**RADIATION LASER VISIBLE ET INVISIBLE**  
EVITEZ L'EXPOSITION DIRECTE OU DIFFUSEE SUR LES YEUX ET LA PEAU  
LASER CLASSE 4

**RADIACIÓN LÁSER VISIBLE E INVISIBLE**  
EVITAR LA EXPOSICIÓN DE OJOS O PIEL A LA RADIACIÓN DIRECTA O DIFUSA  
EQUIPO LASER DE CLASE 4

**RADIAZIONE LASER VISIBLE E INVISIBLE**  
EVITARE L'ESPOSIZIONE DELL'OCCHIO O DELLA PELLE ALLA RADIAZIONE DIRETTA O DIFFUSA APPARECCHIO LASER DI CLASSE 4

CN<sup>1</sup>

**VISIBLE AND INVISIBLE LASER RADIATION**  
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION  
CLASS 4 LASER PRODUCT

**SYNLIG OCH OSYNLIG LASERSTRÅLNING**  
UNDVIK BESTRÅLNING AV ÖGON ELLER HUD GENOM DIREKT ELLER SPRIDD STRÅLNING  
LASER AV KLASSE 4

**SYNLIG OG USYNLIG LASERSTRÅLING**  
UNNGÅ BESTRÅLING AF ØJNE OG HUD MED DIREKTE ELLER STRÅLING  
KLASSE 4 LASER

**SYNLIG OG USYNLIG LASERSTRÅLING**  
UNNGÅ DIREKTE BESTRÅLING ELLER STRÅLING AV ØYNE ELLER HUD  
LASER KLASSE 4

**NÄKYVÄÄ JA NÄKYMÄTÖNTÄ LASERSÄTEILYÄ**  
VÄLTÄ SUORAA TAI EPÄSUORAA SÄTEILYÄ SILMIIN JA IHOLLE  
LASERLIUOKKA 4

SA<sup>1</sup>

**VISIBLE AND INVISIBLE LASER RADIATION**  
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION  
CLASS 4 LASER PRODUCT

**RADIATION LASER VISIBLE ET INVISIBLE**  
EVITEZ L'EXPOSITION DIRECTE OU DIFFUSEE SUR LES YEUX ET LA PEAU  
LASER CLASSE 4

**RADIACIÓN LÁSER VISIBLE E INVISIBLE**  
EVITAR LA EXPOSICIÓN DE OJOS O PIEL A LA RADIACIÓN DIRECTA O DIFUSA EQUIPO LASER DE CLASE 4

**ZICHTBARE EN ONZICHTBARE LASERSTRALING**  
BESTRALING VAN OGEN OF HUID DOOR RECHTSTREEKSE STRALING OF STROOISTRALING VERMUDEN  
LASER KLASSE 4

**RADIAÇÃO DE LASER VISIVEL E INVISIVEL**  
EVITAR A INCIDÊNCIA DIRECTA DOS RAIOS DO LASER NO OLHO OU NA PELE POR RADIAÇÃO DIFUSA  
LASER CLASSE 4

US<sup>1</sup>

**VISIBLE AND INVISIBLE LASER RADIATION**  
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION  
CLASS 4 LASER PRODUCT

1. Software extension (CU, NU, SA, US)

Label 1

CU<sup>1</sup>

**VORSICHT**  
SICHTBARE UND UNSICHTBARE  
LASERSTRALHUNG KLASSE 4  
WENN ABDECKUNG GEÖFFNET  
BESTRAHLUNG VON AUGE ODER HAUT  
DURCH DIREKTE ODER STREUSTRALHUNG  
VERMEIDEN

**CAUTION**  
CLASS 4 VISIBLE AND INVISIBLE  
LASER RADIATION WHEN OPEN  
AVOID EYE OR SKIN EXPOSURE  
TO DIRECT OR SCATTERED RADIATION

**ATTENTION**  
RADIATION LASER VISIBLE ET INVISIBLE  
CLASSE 4  
LORSQUE L'APPAREIL EST OUVERT  
EVITEZ L'EXPOSITION  
DIRECTE OU DIFFUSEE  
SUR LES YEUX ET LA PEAU

**ATENCIÓN**  
RADIACIÓN LASER VISIBLE E INVISIBLE  
DE CLASE 4 EN CASO DE APERTURA  
EVITAR LA EXPOSICIÓN DE OJOS O PIEL  
A LA RADIACIÓN DIRECTA O DIFUSA

**ATTENZIONE**  
RADIACIONE LASER VISIBILE ED INVISIBILE  
DI CLASSE 4 IN CASO DI APERTURA EVITARE  
L'ESPOSIZIONE DI OCCHI O PELLE ALLA  
RADIACIONE DIRETTA O DIFFUSA

CN<sup>1</sup>

**CAUTION**  
CLASS 4 VISIBLE AND INVISIBLE  
LASER RADIATION WHEN OPEN  
AVOID EYE OR SKIN EXPOSURE  
TO DIRECT OR SCATTERED RADIATION

**VARNING**  
SYNLIG OCH OSYNLIG LASERSTRÅLNING  
AV  
KLASS 4 NÅR KÅPAN ÄR ÖPPNAD.  
UNDVIK BESTRÅLNING AV ÖGON ELLER  
HUD  
GENOM DIREKT ELLER SPRIDD STRÅLNING

**FORSIGTIG**  
SYNLIG OG USYNLIG KLASSE 4  
LASERSTRÅLING NÅR  
AFSKÆRMNINGEN ER ÅBEN.  
UNDGÅ DIREKTE ELLER SPREDT BESTRÅLING  
AF ØJNE ELLER HUD.

**FORSIKTIG**  
SYNLIG OG USYNLIG LASERSTRÅLING  
KLASSE 4 NÅR DEKSLET ÅPNER.  
UNNGÅ DIREKTE ELLER SPREDT STRÅLING  
SOM TREFFER ØYE ELLER HUD.

**VARO**  
NÄKYVÄÄ JA NÄKYMÄTÖNTÄ  
LASERSÄTEILYÄ,  
JOS SUOJUS ON AUKI (L.K. 4).  
VÄLTÄ SUORAA TAI EPÄSUORAA SÄTEILYÄ  
SILMIIN JA IHOLLE.

SA<sup>1</sup>

**CAUTION**  
CLASS 4 VISIBLE AND INVISIBLE  
LASER RADIATION WHEN OPEN  
AVOID EYE OR SKIN EXPOSURE  
TO DIRECT OR SCATTERED RADIATION

**ATTENTION**  
RADIATION LASER VISIBLE ET INVISIBLE  
CLASSE 4  
LORSQUE L'APPAREIL EST OUVERT  
EVITEZ L'EXPOSITION  
DIRECTE OU DIFFUSEE  
SUR LES YEUX ET LA PEAU

**ATENCIÓN**  
RADIACIÓN LASER VISIBLE E INVISIBLE  
DE CLASE 4 EN CASO DE APERTURA  
EVITAR LA EXPOSICIÓN DE OJOS O PIEL  
A LA RADIACIÓN DIRECTA O DIFUSA

**LET OPI!**  
ZICHTBARE EN ONZICHTBARE  
LASERSTRALING KLASSE 4 ALS  
AFDEKING OPEN IS.  
BESTRALING VAN OGEN EN HUID DOOR  
DIRECTE-OF STROOISTRALING VERMIJDEN.

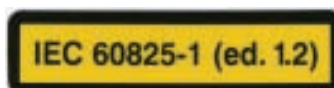
**ATENÇÃO**  
RADIÇÃO LASER VISÍVEL E INVISÍVEL  
CLASSE 4 QUANDO ABERTO.  
EVITE EXPOR DITERAMENTE NOS  
OLHOS E PELE.

US<sup>1</sup>

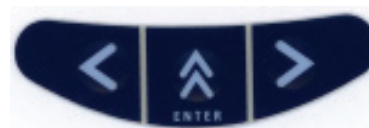
**CAUTION**  
CLASS 4 VISIBLE AND INVISIBLE  
LASER RADIATION WHEN OPEN  
AVOID EYE OR SKIN EXPOSURE  
TO DIRECT OR SCATTERED RADIATION

1. Software extension (CU, NU, SA, US)

Label 2



Label 3



Label 4



Label 5



Label 6

CU, US<sup>1</sup>



NU<sup>1</sup>



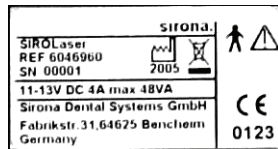
SA<sup>1</sup>



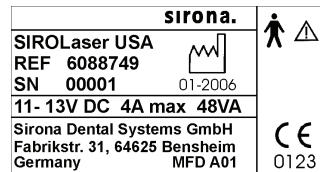
1. Software extension (CU, NU, SA)

Label 7<sup>1</sup>

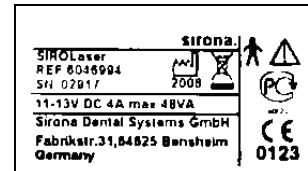
CU, NU, SA<sup>1</sup>



USA<sup>1</sup>



GUS<sup>1</sup>



1. Software extension (CU, NU, SA, USA, GUS)

Label 8

USA

Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50 dated July 26, 2001

SA (up to SN 4225)



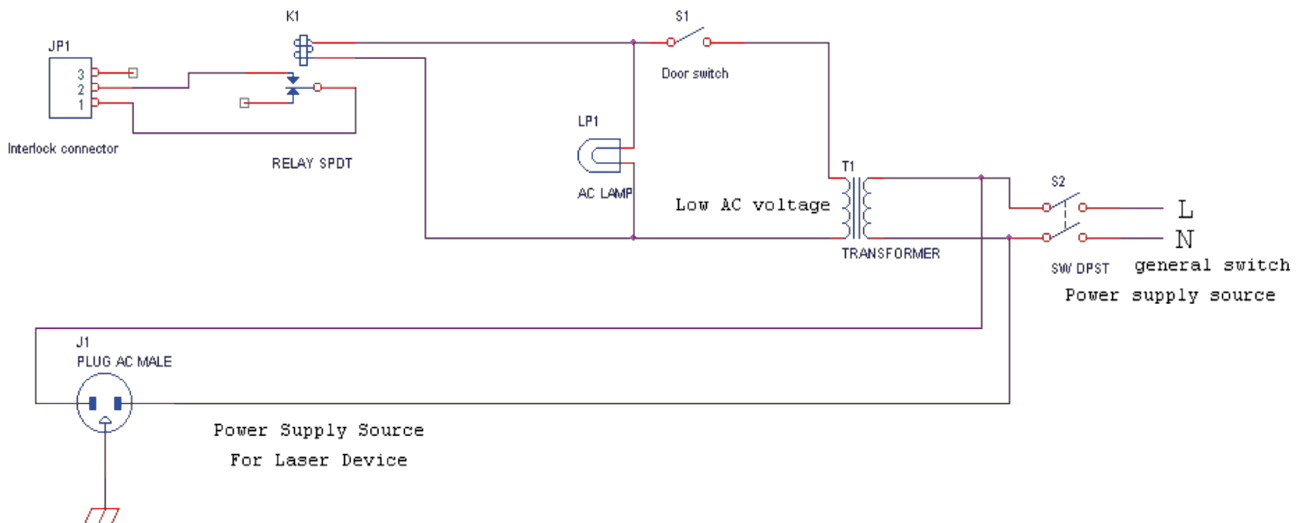
US/SA (from SN 4226)



Label 9

1. Dependent on the SIROLaser version

### 5.3 Safety circuit (interlock)



JP1	Interlock connection supplied with the SIROLaser (Insulate the jumper between pins 1 and 2; connect both of these pins to relay K1 with a two-core cable.)
K1	Low-level relay (AC)
Door switch S1	must close the interlock circuit when the treatment room door is closed
Lp1	Optional low-level lamp used as an optical warning while the laser is in operation
T1	Power transformer
S2	Main switch for power supply
J1	Possible power supply for the SIROLaser

#### **CAUTION**

*It is recommended to keep the distance between connection JP1 and relay K1 as short as possible.*

Units designed for this purpose are already available from various companies, however, are also unreasonably expensive in some cases. We recommend having the installation performed by a qualified electrician who is also responsible for the electrical system.







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We reserve the right to make any alterations which may be required due to technical improvements.

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