

New as of:

07.2010

sirona.
The Dental Company

SIROLaser Advance SIROLaser Xtend

Medical product log

English



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1

Safety check

Only qualified service technicians trained by Sirona Dental Systems GmbH should be authorized to perform safety checks.

1. The medical device may be operated only with the accessories expressly listed in its operating instructions.
2. Each medical device must be subjected to a safety check every 24 months beginning on its date of delivery and following any repair which could influence its safety characteristics.

This check must be performed according to IEC 60601-1 in the following points:

- Visual inspection of the unit and its accessories for mechanical damage that might impair operation
- General function check
- Check of the acoustic and visual displays
- Earth leakage current
- Patient leakage current
- Housing leakage current

2 Master data of the unit

System owner:

.....

.....

Inventory No.:

Type/class of medical device active / 2 b

Type of medical device SIROLaser Advance ☐ SIROLaser Xtend ☐

UMDNS – BEZ / CODE Laser, other / 16-648

Serial number (SN):

Manufacturer / importer if applic.: Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim

Supplier:

Year of purchase:

Is a safety check (STK) required according to the manufacturer's requirements or pursuant to the provisions of § 6 or 11 of the MPBetreibV (German Medical Products Operator Ordinance)?

Interval for safety checks 24 months months

Are the operating instructions available? YES ☐ NO ☐

Service agreement? YES ☐ NO ☐

If "YES", contracting parties:

Acceptance certificate attached? YES ☐ NO ☐

3 Startup

3.1 Medical device: SIROLaser Advance / SIROLaser Xtend

Mode of operation:	Active medical device
Laser class:	IV
System class according to 93/42 EC:	IIb
Degree of protection:	1
Applied part (IEC 60601-1):	Type B

3.2 Initial startup

Measured values according to EN 60601-1

Earth leakage current NC:	_____ mA	Earth leakage current SFC:	_____ mA
Patient leakage current NC:	_____ mA	Patient leakage current SFC:	_____ mA
Housing leakage current NC:	_____ mA	Housing leakage current SFC:	_____ mA

Measuring devices used:

.....

Performed on _____ Company _____ Checked by _____

Startup/Functional check by qualified expert

.....

Performed on _____ Company _____ Checked by _____

4 Instruction

4.1 Instruction of authorized person(s)

for the medical device/by the manufacturer or supplier

NOTE

The responsible persons specified by the system owner(s) and instructed by the manufacturer/supplier are entitled to instruct other persons in the operation of the medical device. This instruction must be documented.

Date	Manufacturer/ supplier	Name of responsible person performing instruction	Name of authorized person	Signature (Medical Device Officer)

4.2 Instruction of personnel/users

by the Medical Device Officer (according to § 5, Par. 2) (see page 8).

Observe the operating instructions!

Date	Instructor (Medical Device Officer)	Name of instructed person	Signature (instructed person)

5 Repeated measurements

5.1 Safety checks (repeated measurement)

A printout/record of the measured results must be filed in the medical product log.

Performed by: _____, Date: _____

Safety check:	Passed Y/N	Remarks:																
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Comments on safety check:														

6 Maintenance measures

i NOTE

Only persons, companies or institutions possessing the expertise, qualifications and means required to perform these tasks properly may be authorized by the system owner to carry out maintenance (service, inspection, repair and conditioning) on medical devices.

Maintenance:	Other:						
.....	
months		months	months	months	months	months	months

Date	Performed by (person/company)	Short description of measures	STK performed
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO
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			<input type="checkbox"/> YES <input type="checkbox"/> NO
			<input type="checkbox"/> YES <input type="checkbox"/> NO

7

Malfunctions or repeated similar operator errors

Date	Description of type and results	Manufacturer / Type / REF / SN

8

Incidents reported to the manufacturer/authorities

Date	Report submitted to	Description of incidents

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

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