

SECTION FOUR CARE AND MAINTENANCE

INTRODUCTION

This section of the manual is designed to inform the operator of basic care and maintenance of the instrument. If a problem occurs on the instrument, call the Alcon Technical Services Department and give details of the breakdown circumstances and effects. From these elements, a specialized technician will evaluate the problem and determine the maintenance requirements.

For optimum performance, it is the user's responsibility to schedule preventive maintenance service on the system and its accessories at least two times each year. Alcon's Field Service Engineers are trained and equipped to provide the highest quality of workmanship.

CAUTION

There are no operator replaceable parts, including the illuminator lamps. Contact Alcon Technical Services for all servicing issues.

WARNING!

The Constellation® Vision System battery can only be serviced by a factory-trained Alcon service personnel. Access by untrained personnel can lead to injury.

CARE AND CLEANING

The following recommendations are for proper care of the *Constellation®* Vision System:

- Follow cleaning and maintenance schedules outlined in this section of the manual.
- Periodically check chassis appearance.
- Pay attention to correct operation of controls, connectors, and indicators.
- Damaged hardware must be replaced to ensure safe operation. Call Alcon Technical Services for assistance.

WARNING!

A qualified technician must perform a visual inspection of the following components every twelve months:

- Warning Labels (see section one of this manual)
- Power Cord

In case of a deficiency, do not use the system; call Alcon Technical Services.

A qualified technician must check ground continuity for leakage current every twelve months to ensure they are within the applicable standards (for example: EN60601-1/IEC601-1). Values must be recorded, and if they are above the applicable standards, do not use the system; call Alcon Technical Services.

REVISION HISTORY		
REV	ECN	DATE
D	20100276	2/24/10
E	20100947	6/17/10
F	20102120	12/10/10
G	CN014548ECN	2/23/11
H	CN015512ECN	3/10/11

DECLARATION OF CONFORMITY
for the
Medical Device Directive 93/42/EEC

FOR
CONSTELLATION[®] VISION SYSTEM

By: John Underwood	Date: 8-30-08
Checked: Paul Pynckel	Date: 8/30/08
Approved: Roger Thomas	Date: 8/30/08

Alcon[®]
IRVINE, CALIFORNIA

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DECLARATION OF CONFORMITY
for the
Medical Device Directive 93/42/EEC

Annex II <input checked="" type="checkbox"/>	Annex III / V <input type="checkbox"/> Annex VII / V <input type="checkbox"/>	Annex VII <input type="checkbox"/>	Article 12 <input type="checkbox"/> Article 12 / Annex V <input type="checkbox"/>
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Date of Issuance: March 10, 2011	Supersedes Declaration Dated: February 22, 2011
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Manufacturer: Alcon Laboratories Inc., 6201 South Freeway, Fort Worth, Texas 76134-2099, U.S.A.

Authorized European Union Representative: Alcon Laboratories (U.K) Ltd., Boundary Way, Hemel Hempstead, Hertfordshire, HP2 7 UD, United Kingdom

Product: See the attached list for the Catalog Number, MDD Class, and Item Description.

EC Certificate Category: Surgical Devices and Electrosurgical Products for use in Ophthalmologic Procedures (Cataract, Vitreoretinal, Laser, and Imaging)

Technical File Title: CONSTELLATION[®] VISION SYSTEM

This declaration is applicable to all products listed and manufactured after the date of issuance of this declaration of conformity.



We hereby declare under our sole responsibility that the listed device(s) and quality system conform to:

MDD 93/42/EEC:1993 *as amended*

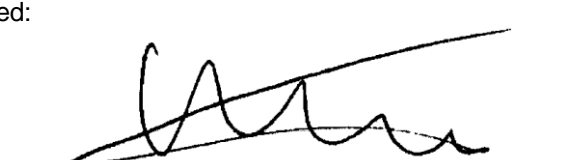
Annex II Certificate: (Applicable only if declaration is under Annex II): TUV SUD Product Service, Ridlerstr. 65, D-80339 Muenchen, Germany

Standards Applied: Refer to Technical File Index section 2.
ISO 13485:2003

Article 12 [Check for systems (e.g. Kits) / Procedure Pack(s)]:
We have verified the (a) mutual compatibility of the devices in accordance with the manufacturer(s) instructions and carried out our operations in accordance with these instructions. We have (b) packaged the product and supplied relevant information to users incorporating relevant instructions from the manufacturer(s). (c) The whole activity is subject to appropriate methods of internal control or inspection. (d) If the device(s) is sterilized, it was processed in accordance with Annex V of the MDD and the manufacturer(s) instructions.

Signed: 	Signed: 
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Dan Modi SIR&D Quality System Management Representative Alcon Laboratories, Inc. 6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.	Linda Howe Garriz Site-Wide Quality System Management Representative Alcon Laboratories, Inc. 6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.
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Signed: 	Signed: 
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Bruno Dacquay Surgical Instrumentation R&D Head Alcon Laboratories, Inc. 6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.	Martin Kaufman ITC Regulatory Affairs Alcon Laboratories, Inc. 6201 South Freeway, Fort Worth, TX 76134-2099, U.S.A.
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**Attachment to the
DECLARATION OF CONFORMITY
for the Medical Device Directive 93/42/EEC
FOR
Constellation[®] Vision System**

Item #	Catalog Number	MDD Class	GMDN Code	Item Description
1	8065751145	IIb	45073	Constellation [®] Vision System with PurePoint [®] Laser
2	8065751147	IIb	45073	Constellation [®] Vision System without Laser
3	8065751150	IIb	45073	Constellation [®] Table Top
4	8065751450	IIb	N/A*	Constellation [®] Embedded Laser
5	8065751451	IIb	N/A*	Constellation [®] Base
6	8065751452	IIb	N/A*	Constellation [®] Aux Illuminator
7	8065751539	IIb	N/A*	Constellation [®] Tray Arm Assy
8	8065751540	IIb	N/A*	Constellation [®] Ballast
9	8065751541	IIb	N/A*	Constellation [®] Support Column
10	8065751548	IIb	45073	Constellation [®] XT
11	8065751549	IIb	45073	Constellation [®] LT
12	8065751550	IIb	45073	Constellation [®] LXT
13	8065751551	IIb	45073	Constellation [®] LX
14	8065751552	IIb	45073	Constellation [®] B
15	8065751553	IIb	45073	Constellation [®] X
16	8065751554	IIb	45073	Constellation [®] L
17	8065751558	IIb	45073	Constellation [®] T
18	8065751536	IIb	45073	Constellation [®] Table Top China
19	8065751598	IIb	45073	Constellation [®] XT China
20	8065751601	IIb	45073	Constellation [®] LXT China
21	8065751597	IIb	45073	Constellation [®] B China
22	8065751594	IIb	45073	Constellation [®] L China
23	8065751559	IIb	N/A*	Constellation [®] Tray Arm Kit
24	8065750968	IIb	36362	Constellation [®] Remote Control
25	8065750977	IIb	36336	Constellation [®] Footswitch
26	8065751694	IIb	N/A*	Constellation [®] Pneumatic Pressure Hose
27	8065751817	IIb	45073	Constellation [®] Table Top Japan
28	8065752041	IIb	45073	Constellation [®] XT Japan
29	8065752042	IIb	45073	Constellation [®] LT Japan
30	8065752043	IIb	45073	Constellation [®] LXT Japan
31	8065752044	IIb	45073	Constellation [®] T Japan

*The indicated catalog numbers are accessories/modules integrated into the Constellation[®] Vision System.

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