GTS Management / ITC T/S Management

Preventative Maintenance

7. Establishes and defines the Preventative Maintenance in the applicable Service Test Procedure for each product based upon R&D input.
   a. The Preventative Maintenance cycle is typically a minimum of once every twelve (12) months, but can vary based upon the system configuration, product use, or environmental conditions.
   b. Customers are not typically billed for preventative maintenance during the system warranty period.
   c. The number of preventative maintenance cycles per year, is shown in Table 1 below and the parts to be replaced are defined in the applicable Service Test Procedure.

TABLE 1

PRODUCT	***PREVENTIVE MAINTENANCE***
3000LE™	1
ARGOS MOVU	1*
Centurion®	1
CONSTELLATION®	2
INFINITI®	1
LAUREATE™	1
LenSx®	2
Luxor® / QVue® Microscope	1
LX3 Microscope	1
Ngenuity	1
OCUSCAN® RxP	1
ALL ORA VerifEye, VerifEye+™ and VLynk	1
PurePoint™	1
SL1000 Slit Lamp	1
WaveLight® Allegretto Wave® Eye-Q (1010)	2
WaveLight® Allegretto Wave® (1007/1008/1009)	2
WaveLight® Allegro Analyzer® I & II (1070/1071/1073)	2
WaveLight® Allegro® OB820 (BioGraph) (1088)	2
WaveLight® Allegro Oculyzer® I & II (1074/1077)	2
WaveLight® Allegro Topolyzer® (1075/1076)	2
WaveLight® Allegro Topolyzer Vario® (1029)	2
WaveLight® EX500® (1016)	2
WaveLight® FS200® (1025)	2
Verion™	1**

* Per ARGOS Service Manual

➔ d. Periodic maintenance of the instrument is not required by the user. Maintenance of the machine is required when the machine does not pass its function check (Daily Calibration process). When the function check is not successful (Figure 179), the user is prompted to contact technical service or the distributor.

NOTE: PM's are optional and can be used for sites with contracts including annual

** Per Verion STP, under "Purpose and Scope"

➔ e. All functional tests "described by this instruction" and "documented by the checklist" includes the requirements for Preventive Maintenance. No separate activities are defined or required to perform a PM. Using this functional test for PM purposes is optional and can be used for sites with contracts including annual PM.

Digitally signed by Vidiborschii Vladimir
Date: 2024.02.23 17:54:54 EET
Reason: MoldSign Signature
Location: Moldova

Alcon Romania S.R.L.
B-dul Barbu Văcărescu nr. 301-311, Etaj 5
Sector 2, București, România
T: +40 372 195 001
www.alcon.com

Data: Septembrie 2020

De la: Ovidiu Tănăsescu Alcon Romania

Subiect: Plan de mentenanță (revizii) pentru aparatul de chirurgie vitreo-retiniana Alcon model Constellation® Vision System

În atenția persoanelor interesate,

Confirmăm prin prezenta, că planul de mentenanță (revizii) pentru aparatul de chirurgie vitreo-retiniană Alcon model Constellation® Vision System include 2(două) revizii / an, de obicei, odată la 6 luni calendaristice.

Revizia aparatului Constellation® Vision System include următoarele operații:

- Verificare stare aparat (să nu aibă lovituri, crăpături, starea şuruburilor şi prinderilor roţilor, etc.);
- Verificare parametrii tensiune de alimentare (tensiune, împământare, verificare întrerupători, etc.);
- Verificarea protecţiilor interne care asigură funcţionarea în condiţii de siguranţă ale aparatului;
- Verificare conectori şi cabluri;
- Măsurarea tensiunii din sursa de alimentare şi din bateria de back up;
- Măsurarea rezistenţelor diferitelor ansamble ale aparatului;
- Verificare şi curăţare filtre;
- Verificare modul pneumatic (verificare mecanism pompă şi pistoane de acţionare asupra casetei, verificare mecanism de prindere al casetei);
- Verificare şi curăţare ventilatoare de răcire;
- Verificarea presiunii cu casetă uscată (la diferitele praguri de măsurare a presiunii şi vacuumului);
- Verificare recunoaştere casetă;
- Testare la priming a casetei;
- Verificare rezistenţă a instrumentelor de măsura;
- Verificare infuzie cu flowmeter
- Verificare injecție și extracție
- Verificare coagulare la cele trei praguri;
- Verificare parte de phaco prin măsurarea amplitudinale și torsionale;
- Verificare vitrectomie la 5000 cpm, 7500 cpm și 10000 cpm
- Verificare si calibrare ecran;
- Verificare iluminator(intensitate luminoasa, durata de viață lampă)
- Verificare laser (energie, lumină de țintire)
- Descărcare fişiere de loguri şi erori;
- Verificare pedală (funcţionare continuă şi uşoară);
- Verificare sonde client (hand piece, sonde I/A şi sonde coagulare,fragmatom);

Alcon Romania S.R.L.
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- Verificare parametrii de lucru conform procedurilor de service Alcon și întocmire STP (service test procedure).
- Verificare parametrii de protecție electrică conform SREN 60601/ SREN 62353

Vă mulțumim pentru interesul pentru aparatele Alcon și vă rog să nu ezitați să ne contactați în cazul în care aveți nevoie de informații sau detalii suplimentare.

Cu respect,

Ovidiu Tănăsescu
Technical Service Manager
301-311, Barbu Vacarescu Blvd., 020276 Bucharest, ROMANIA
T +40 21 203 93 21 | F +04 21 203 93 00 | M +04 0728 109 117

Alcon
SEE BRILLIANTLY

Alcon Pharmaceuticals Ltd.
Rue Louis d'Affry 6
Case postale, 1701 Fribourg, Switzerland
T +41 58 911 22 22 | F +41 58 911 32 22
www.alcon.com

TO WHOM IT MAY CONCERN

We, **Alcon Pharmaceuticals Ltd.,** located at Rue Lou is d'Affry 6, 1701 Fribourg, Switzerland ("**APL**") herewith confirm that **Alcon Romania S.R.L,** Romanian legal person having the legal form of limited liability company, incorporated and functioning in accordance with the laws of Romania, registered office in Romania, Bucharest, 301- 311 Barbu Vacarescu st. , 5[1] floor, office 001, District 2, is the authorized service provider in Romania and the Republic of Moldova for the medical devices manufactured by ALCON in U.S., IRELAND, GERMANY and SW ITZE RLAND, as follows:

Alcon
Laboratories
Inc.
6201 South
Freeway
Fort Worth, TX 76134

Alcon
Research,
Ltd. 9965
Buffalo
Speedway
Houston, TX
77054

Alcon
Research,
Ltd.
6065 Kyle
Lane
Huntington, WV 25702

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Alcon Research, Ltd. 1580 0 Alton Parkway Irvine, CA 92618

Alcon Laboratories, Inc. 250 I Discovery Drive Orlando, FL 32826

Alcon Laboratories, Inc. 714 Columbia Avenue Sinking Spring, PA 19608

Alcon Ireland B.V. Cork Busines s & Technology Park Mode l Farm Road Cork, Ireland

Alcon Grieshaber, Ltd. Winkelrieds trasse 52 CH-8203 Schaffhaus en Switzerland

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 020895 0393 Rev. 00

Manufacturer:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099
USA

Product Category(ies):

Ophthalmic Implants, Irrigating Solutions, Viscoelastics, Ophthalmic Surgical Disposable Products, Ophthalmic Surgical Procedure Packs, Contact Lens Care Products, Ophthalmic Cutting Instruments, Cannulas, Cystitomes, Surgical Sponges and Sutures, Ophthalmic Solutions and Gels, Surgical Devices and Electrosurgical Products for Use in Ophthalmic Procedures (Cataract, Vitroretinal, Laser and Imaging), Wavefront Technology Equipment for Ophthalmic Diagnostics and Ophthalmic Devices for the Treatment of Chronic Disease of the Eyelid, Sterile Soft Contact Lenses for Correction of Refractive Error and/or for Use as Bandage Lenses (Soft Corrective Contact Lenses, Extended Wear / Therapeutic Contact Lenses; Silicone Hydrogel Soft Contact Lenses, Corrective; Non-Silicone Hydrogel Soft Contact Lenses, Corrective)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 020895 0393 Rev. 00

Report No.: 713194570

Valid from: 2021-02-05
Valid until: 2024-05-26

Date, 2021-02-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 020895 0357 Rev. 02

Holder of Certificate: **Alcon Laboratories, Inc.**
6201 South Freeway
Fort Worth, TX 76134-2099
USA

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution, Marketing, Sales, Installation and Servicing of Ophthalmic Devices**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020895 0357 Rev. 02

Report No.: 72168932

Valid from: 2022-04-25
Valid until: 2025-04-24

Date, 2022-04-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 020895 0357 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Alcon Research, LLC
15800 Alton Parkway, Irvine CA 92618-3818, USA

Production and Distribution of Ophthalmic Surgical Disposable Products, Surgical Devices and Electrosurgical Disposable Products for Use in Ophthalmic Procedures (Cataract, Vitreoretinal, Laser and Imaging) - Wavefront Technology Equipment for Ophthalmic Diagnostics, and Ophthalmic Devices for the Treatment of Chronic Disease of the Eyelid

Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2099, USA

Management Oversight Responsibilities for the Design, Development, Manufacturing, Distribution, Servicing, and Installation of Ophthalmic Medical Devices

./.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Traducere din limba engleză

Sigla DAkks
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

Cod QR TÜV SÜD Product service

Certificat
Nr. Q5 020895 0357 Rev. 02

Titular certificat: **Alcon Laboratories, Inc.**
6201 South Freeway
Fort Worth, TX 76134-2099
STATELE UNITE ALE AMERICII

Marcaj de certificare:

Domeniul de aplicare al certificatului: proiectare și dezvoltare, producție, distribuție, marketing, vânzări, instalarea și întreținerea dispozitivelor oftalmice

Organismul de certificare al TÜV SÜD Product Service GmbH atestă că societatea menționată mai sus a instituit și menține un sistem de management al calității, care întrunește cerințele standardului (standardelor) enumerate. Îi revine obligația de a respecta toate cerințele aplicabile ale regulamentului de testare și certificare ale Grupului TÜV SÜD. Pentru detalii și valabilitatea certificatului, accesați: www.tuvsud.com/ps-cert?q=cert:Q5 020895 0357 Rev. 02

Raport nr.: 72168932

Valabil din data de: 25-04-2022
Valabil până în data de: 24-04-2025

Data 25.04.2022

Semnătură indescifrabilă
Christoph Dicks
Director organism notificat/de certificare

Sigla DAkks
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

Cod QR

TÜV SÜD
Product service

Certificat
Nr. Q5 020895 0357 Rev. 02

Standard(e) aplicat(e): EN ISO 13485:2016
Dispozitive medicale - Sisteme de management a calității - Cerințe în scopuri de reglementare
(ISO 13485:2016)
DIN EN ISO 13485:2016

Unitate/unități: Alcon Research, LLC
15800 Alton Parkway, Irvine CA 92618-3818, SUA

Producția și distribuția de produse chirurgicale oftalmice de unică folosință, dispozitive chirurgicale și produse electrochirurgie de unică folosință pentru utilizare în proceduri oftalmice (cataractă, chirurgia vitreoretiniană, laser și imagistică) - Echipamente cu tehnologie Wavefront pentru diagnosticare oftalmică și dispozitive oftalmice pentru tratamentul bolilor cronice ale pleoapei

Alcon Laboratories, Inc.
6201 South Freeway, Fort Worth, TX 76134-2099, SUA

Responsabilități de supraveghere a managementului în ceea ce privește proiectarea, dezvoltarea, producția, distribuția, întreținerea și instalarea dispozitivelor medicale oftalmice

Subsemnata, **BRONT MARIANA-VIORICA,** traducător autorizat, de Ministerul Justiţiei cu nr. 17220/2006, certific exactitatea traducerii cu textul înscrisului original din limba engleză în limba română.

Alcon®

Certificate of Completion

THIS IS TO CERTIFY THAT

Liviu POLAK

Has successfully completed the training course on

CONSTELLATION

and is fully qualified to provide installations and maintenance services on the above system while under the supervision of ALCON

Training dates : **October 4-5 & October 8-12, 2018**

Alcon
EURMEA Service Center

Bruno DEVIERCY, Service Center Manager EURMEA

Laurence ALBERTI, Instructor

Christophe SALOMON, Instructor

Alcon®

Certificate of Completion

THIS IS TO CERTIFY THAT

Raducu OPREA

Has successfully completed the training course on

CONSTELLATION

and is fully qualified to provide installations and maintenance services on the above system while under the supervision of ALCON

Training dates : **October 21-25 - 28-29, 2019**

Bruno DEVIERCY, Service Center Manager EMEA

Alcon

Christophe SALOMON, Instructor

Claire PETTOELLO, Instructor