Eye & Health Care
NIDEK CO., LTD.
34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
TEL +81-533-67-8895 FAX +81-533-68-1320
URL http://www.nidek.com
e-mail info@nidek.co.jp

Document No.: DOCCV-9000EU13

DECLARATION OF CONFORMITY

Manufacturer's name	NIDEK Co. Ltd.
Manufacturer's address	34-14 Maehama, Hiroishi-cho, Gamagori, Aichi 443-0038, Japan
European Representative	NIDEK s.a. Europarc, 13 rue Auguste Perret, 94042 Créteil, France
Identification of device	Ophthalmic Surgical System
Model No.	CV-9000
Classification(Annex Ⅸ, MDD)	Ⅱb
Category (for RoHS)	8

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer. The supporting technical documentation is also retained at NIDEK s.a., Europarc, 13 rue Auguste Perret, 94042 Créteil, France.

General applicable directives	Notified Body	Date CE Mark was affixed
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices.	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany Certificate : G1 18 04 23653 195 (Annex Ⅱ, Section 3 of MDD)	February 6, 2012 CE 0123
COUNCIL DIRECTIVE 2011/65/EU of 8 June 2011 concerning restriction of the use of certain hazardous substances.	N/A	June 30, 2014 CE

Place: Aichi, Japan
Signed by

H. Torii

Hiroyuki Torii
Director,
Top Management,
NIDEK Co., Ltd.

Effective date : July 24, 2018

Date of signature : June 1, 2018

Digitally signed by Bejenari Serghei
Date: 2019.04.11 15:03:37 EEST
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Traducere autorizată din limba engleză

Servicii produs

CERTIFICAT

Nr. Q1N 13 10 23653 129

Titular certificat: **NIDEK CO., LTD.**
34-14 Maehama, Hiroishi-cho, Gamagori Aichi
443-0038 JAPONIA

Unitate (unități): **NIDEK CO., LTD., Hiroishi Plant**
34-14 Maehama, Hiroishi-cho, Gamagori, Aichi, 443-0038 JAPONIA

NIDEK CO., LTD., Hamacho Plant
67-4 Hama-cho, Gamagori, Aich i, 443-0036 JAPONIA

Marcaj certificare:

Domeniu de aplicare: Design și Dezvoltare, Producție și Distribuție de echipamente laser cu uz oftalmologic și chirurgical dermatologic, Echipament cu ultrasunete cu uz oftalmologic, Echipament diagnosticare uz oftalmologic și chirurgical, Aparate optometrice, Software procesare date oftalmologice, lentile intraoculare.

Standard(e) aplicabil(e): EN ISO 13485:2012 + AC:2012
Dispozitive medicale - Sisteme de management al calității - Cerințe în scop de reglementare (ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Organismul de certificare al TUV SUD Product Service GmbH certifică faptul că societatea mai sus menționată a implementat și menține în vigoare un sistem de management al calității, care întrunește cerințele standardului(lor) menționat(e). A se consulta și informațiile de pe verso.

Nr. raport.: **OAQ235012226A**

Valabil din: **2017-04-01**
Valabil până la: **2020-03-31**

590672

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

Data,

2017-03-08

TRADUCATOR - INTERPRET AUTORIZAT ZBRAVOZ IRINA Engleză - Italiană ROMÂNIA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 11 23653 179

Holder of Certificate: **NIDEK CO., LTD.**
34-14 Maehama, Hiroishi-cho, Gamagori
Aichi
443-0038 JAPAN

Facility(ies):

NIDEK CO., LTD., Hiroishi Plant
34-14 Maehama, Hiroishi-cho, Gamagori,
Aichi, 443-0038 JAPAN

NIDEK CO., LTD., Hamacho Plant
67-4 Hama-cho, Gamagori, Aichi, 443-0036
JAPAN

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Ophthalmic Surgical Lasers, Ophthalmic Ultrasound Equipment, Ophthalmic Diagnostic and Surgical Equipment, Optometric Equipment, Ophthalmic Data Processing Software, Intraocular Lenses**

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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). See also notes overleaf.

Report No.: **JAQ235026669**

Valid from: **2017-04-01**
Valid until: **2020-03-31**

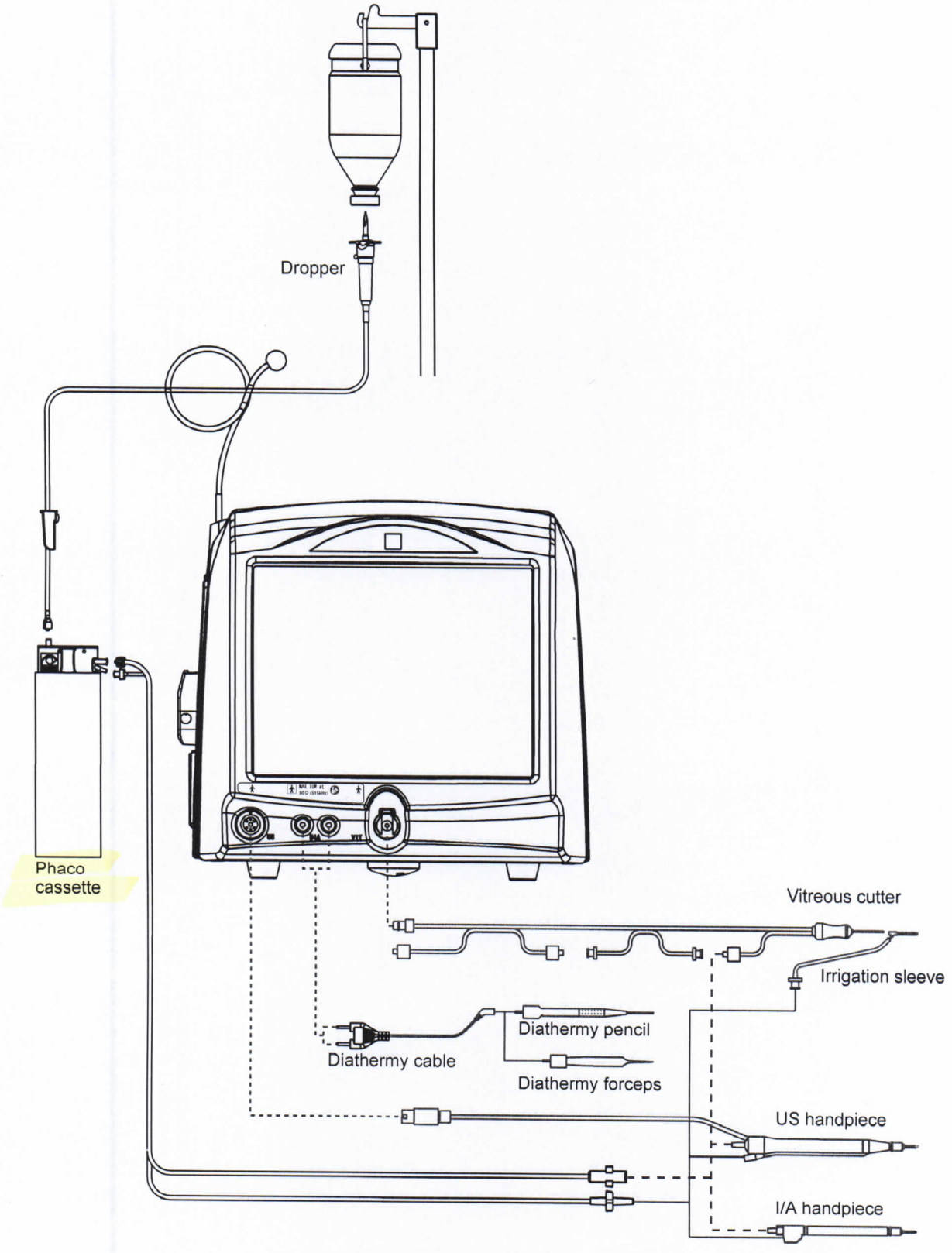
Date, 2017-03-08

Stefan Preiß

04052767790805

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

4.2 Setups and Tests



7.2.2 Optional accessories

○ General

Product	REF	Quantity	Remarks
Multi-function type foot pedal	18602-2000	1 unit	
Up-and-down movable tray arm (with tray)	18601-0086	1 unit	
Aspiration enlarge pack	18602-0021	1 unit	Propedal, APS, US Restart, Flow Restart
US enlarge pack	18602-0022	1 unit	VIS, Burst
Aspiration enlarge pack plus US enlarge pack	18602-0023	1 unit	Propedal, APS, US Restart, Flow Restart, VIS, Burst
Stand with motorized pole	Ask NIDEK.	1 unit	
Video overlay	18601-5402	1 unit	

○ Cassette

Product	REF	Quantity	Remarks
Phaco cassette pack	18601-7510	1 box	10 units per box Phaco cassette, Tray cover, Gamma sterilized, Single use
Phaco cassette pack (without tubing)	18602-7610	1 box	6 units per box Phaco cassette including infusion tube (without tube for Phaco surgery), Sterilized, Single use
Phaco surgery tubing set	18602-7620	1 set	Reusable tube (for 18602-7610), Nonsterile, 5 times of autoclaving

○ Infusion tube

Product	REF	Quantity	Remarks
NIDEK infusion tube	18241-M026	1 box	Disposable, 50 units per box

○ US handpiece

Product	REF	Quantity	Remarks
US handpiece	18241-1600	1 unit	40 kHz, 500 times of autoclaving

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

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 023653 0198 Rev. 00

Manufacturer: **NIDEK CO., LTD.**
34-14 Maehama, Hiroishi-cho, Gamagori
Aichi
443-0038 JAPAN

EC-Representative: **NIDEK S.A.**
Europarc, 13 rue Auguste Perret, 94042 Créteil, FRANCE

Product Category(ies): **Ophthalmic Diagnostic Devices**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: **JAQ235034790**

Valid from: **2019-02-05**
Valid until: **2024-02-04**

Date, **2019-01-09**

Stefan Preiß

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

A4 / 07.17

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

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

TÜV®

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

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 023653 0198 Rev. 00

Facility(ies):

NIDEK CO., LTD., Hiroishi Plant
34-14 Maehama, Hiroishi-cho, Gamagori, Aichi, 443-0038 JAPAN

NIDEK CO., LTD., Hamacho Plant
67-4 Hama-cho, Gamagori, Aichi, 443-0036 JAPAN

-/-

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

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 023653 0197 Rev. 00

Holder of Certificate: **NIDEK CO., LTD.**
34-14 Maehama, Hiroishi-cho, Gamagori
Aichi
443-0038 JAPAN

Facility(ies):
NIDEK CO., LTD., Hamacho Plant
67-4 Hama-cho, Gamagori, Aichi, 443-0036 JAPAN

NIDEK CO., LTD., Hiroishi Plant
34-14 Maehama, Hiroishi-cho, Gamagori, Aichi, 443-0038 JAPAN

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:
Design and Development, Production and Distribution of Ophthalmic Surgical Lasers,
Ophthalmic Diagnostic Active Devices,
Ophthalmic Surgical Devices,
Optometric Equipment,
Ophthalmic Data Processing Software,
Intraocular Lenses,
Intraocular Lenses Preloaded into Inserters

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

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). See also notes overleaf.

Report No.: JAQ235034768

Valid from: 2019-01-17
Valid until: 2022-01-16

Date, 2019-01-17

Stefan Preiß

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

TÜV®

NIDEK

Ophthalmic Surgical System

CV-9000

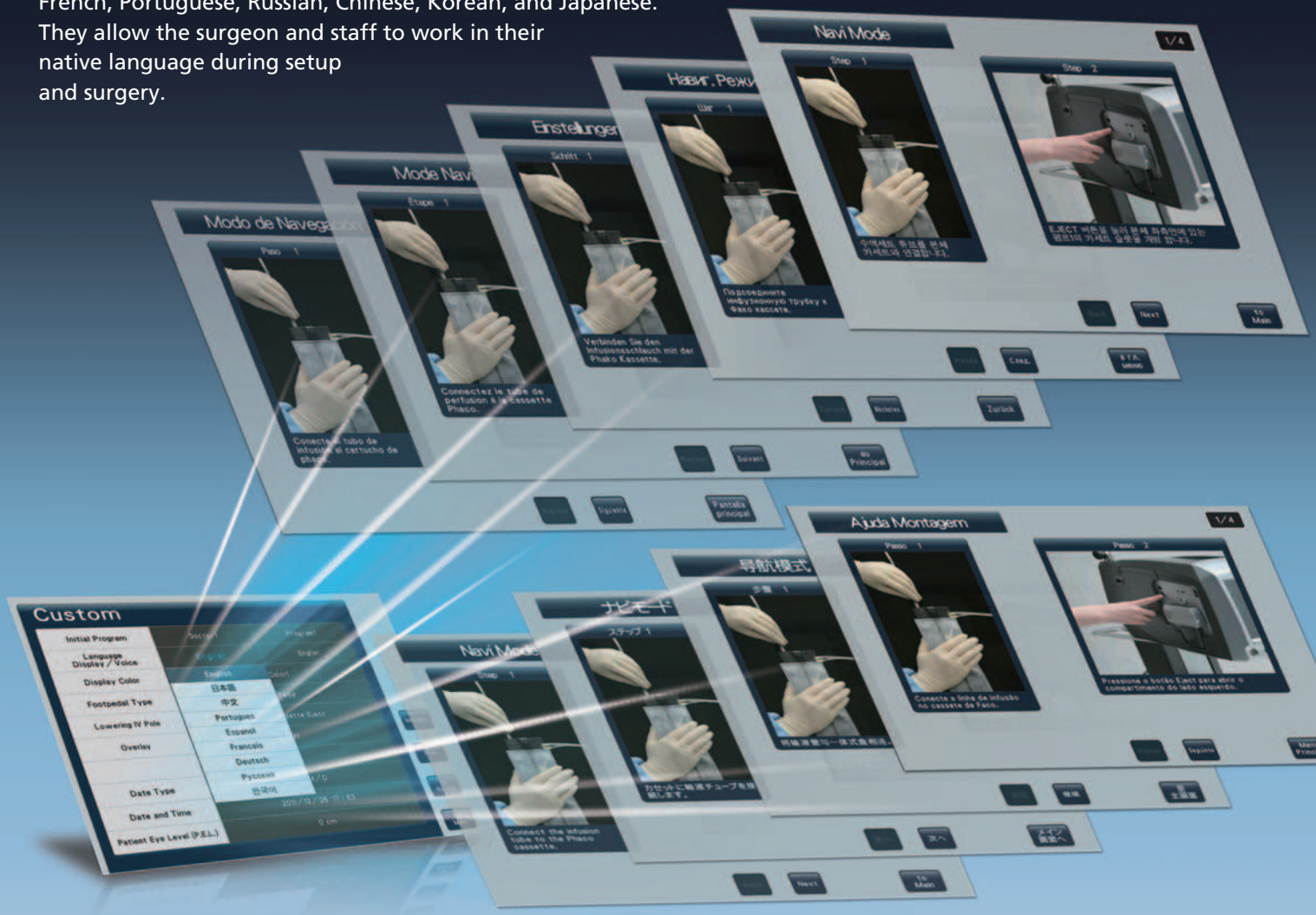
THE ART OF EYE CARE

Intuitive Graphic User Interface with Pop-up Window

The intuitive design of the graphic user interface provides easy and quick operation. The pop-up window appears once the menu, icon, or parameter is touched, and enables the surgeon to activate function or to customize parameters.

Nine Languages for Universally Easy-to-use Operability

Nine languages are available including English, Spanish, German, French, Portuguese, Russian, Chinese, Korean, and Japanese. They allow the surgeon and staff to work in their native language during setup and surgery.

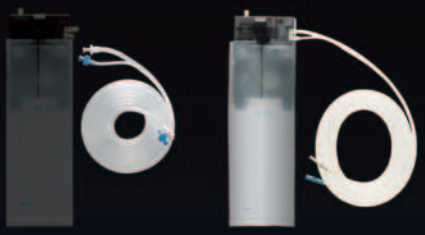


Newly Designed Handpiece

The newly designed handpiece allows easy intraoperative handling and enhanced durability.

Dual Tube Availability of Reusable and Disposable

Different cases may require reusable or disposable tubes. The CV-9000 is designed to work with both. The reusable tube can be autoclaved therefore minimize the costs associated with the disposable tube.



Reusable tube

Disposable tube and cassette

High-speed Cutter for Anterior Vitrectomy (1,000 cpm)

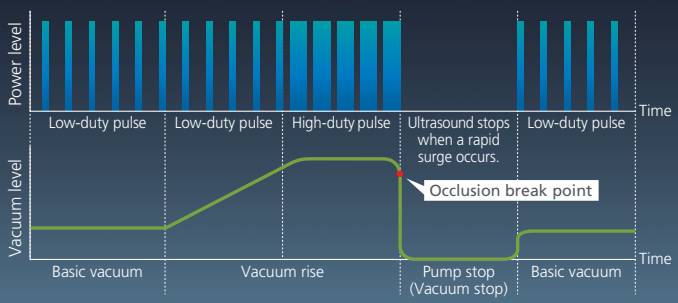
Anterior vitrectomy can be performed safely and efficiently with the high-speed vitreous cutter. It reduces risk of vitreous traction.

Enhanced Aspiration and Ultrasound with Optional Software

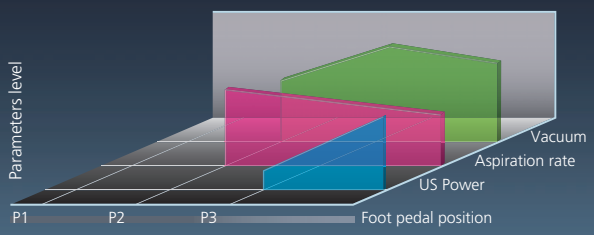
The CV-9000 provides three optional software packages, package A, package B, and package A + B, to enhance aspiration and ultrasound performance.

Package A (APS Plus and ProPedal)

The package A includes Auto Pulse System Plus (APS Plus) and ProPedal. The APS Plus automatically limits the duty of the ultrasound pulse to the optimum value for efficient emulsification and aspiration, reducing the risk of posterior capsule rupture. The ProPedal allows customized programming of the parameters for each foot pedal position.



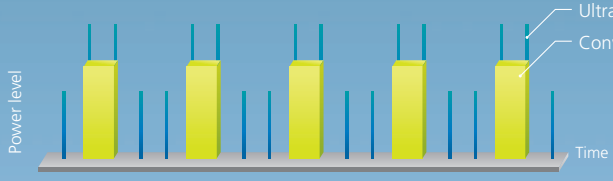
APS Plus - simulated graph of vacuum and power variation



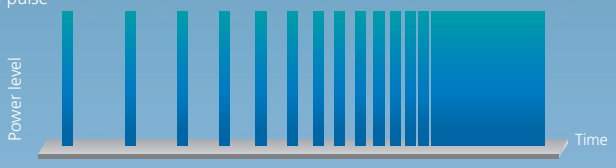
ProPedal - simulated graph of parameters variation

Package B (VIS and Burst mode)

The package B includes Variable Intervals and Strokes (VIS) and Burst mode. The VIS provides dual-oscillation of conventional and ultra-short duration pulses to enhance capture of the lens nucleus and efficient aspiration. The burst mode provides a burst of ultrasound power by controlling interval times between each oscillation.



VIS - simulated graph of dual-oscillation



Burst mode - simulated graph of interval time variation

Package A + B (APS Plus, ProPedal, VIS, and Burst mode)

The package A + B includes APS Plus, ProPedal, VIS, and Burst mode, and enables complete enhancement of aspiration and ultrasound.

CV-9000 Specifications

Application	Cataract surgery
Vacuum	
Pump type	Peristaltic pump
Vacuum setting	0 to 700 mmHg (I / A mode)
	0 to 650 mmHg (US mode and Vit mode)
Flow rate	0 to 60 mL / min
Ultrasound	
Transducer	Piezoelectric
Frequency	40 kHz
Pulse mode	1 to 100 pulses / s
Diathermy	
Frequency	515 kHz
Output	0.5 to 10 W (5 to 100%)
Vitreous cutter	
Cutting system	Pneumatic driven guillotine system
Cutting rate	100 to 1,000 cuts / min (with built-in air compressor)
Power supply	AC 100 to 230 V
	50 / 60 Hz
Power consumption	240 VA
Dimensions / Mass	317 (W) x 456 (D) x 295 (H) mm / 16 kg

Stand with motorized pole (optional)

Power supply	AC 100 / 115 / 230 V
	50 / 60 Hz
Power consumption	300 VA (including CV-9000's power consumption)
Dimensions / Mass	452 (W) x 607 (D) x 1,616 to 2,216 (H) mm / 38 kg

Specifications and design are subject to change without notice.

Eye & Health Care
NIDEK CO., LTD.

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94042 Créteil, France
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VEGETABLE OIL INK