SPECIFICATIONS

■ Basic Specifications

Flow Rate	0.1 - 10.0 mL/sec (Increment of 0.1)
Volume	0.1 - 60 mL (Increment of 0.1)
Maximum pressure	150psi (1034kPa)
Scan Time	0 (OFF) - 30 min （Increment of 1 min)
Memory	400 memories (5 User)
Injection Mode	Body Weight Input Mode、Single Mode、Dual Mode、Drip mode
Pressure Limit	10 - 200psi (100 - 1372kPa)

■ Safety functions

Over Flow Rate	○	Protocol Checking	○
Over Volume	○	Switch Error Warning	○
Over Pressure	○	Adapter Check Warning	○
Self checking function	○	Communication Error Warning	○

■ Electrical ratings

Electrical input/frequency	AC100-240V 50/60Hz
Power consumption	200VA (Main Unit) / 45VA (Console)
Protection Class	Class I
Protection Degree	Type CF

■ Standard function

Automatic Syringe Plunger Detection
One-Touch Syringe Adapter
Scan Timing
Body Weight Input Mode
Drip Infusion Mode
Power Head Indication Lamps

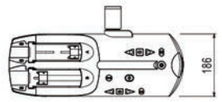
■ Acceptable Syringes

Product Name	Size (Capacity)
Disposable Syringe	50mL Syringe
OMNISCAN	10/15/20mL Pre-Filled Syringe
Magnevist iv inj. Syringe	10/15/20mL Pre-Filled Syringe
Gadovist IV inj, 1.0mol/L Syringe	7.5/10mL Pre-Filled Syringe
Multihance	10/15/20mL Pre Filled Syringe
ProHance	10/15/17mL Pre-Filled Syringe
DOTAREM	10/15/20mL Pre-Filled Syringe

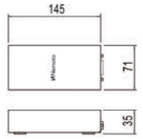
External View / Dimension / Weight

① Powerhead
② Remote Stand
③ Console
④ Power Supply Unit
⑤ Switch Box
⑥ Joint Box

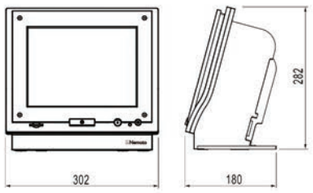
① Powerhead Weight : 7.5 kg

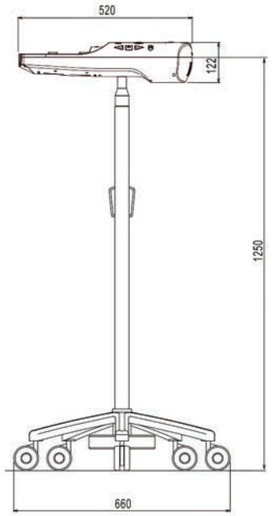


⑥ Joint Box Weight : 240 g

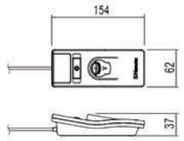


③ Console Weight : 6.0 kg

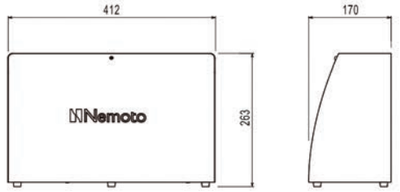




⑤ Switch Box Weight : 264 g



④ Power Supply Unit Weight : 6.4 kg



② Remote Stand Weight : 10.2 kg

Brand name / SONIC SHOT 7

The specification of this pamphlet are as of April in 2015 .

©Nemoto Kyorindo Co.,Ltd. 2015 All rights reserved.

- This product design and specifications may change without prior notice
- SONIC SHOT®7 is a Registered Trademark of Nemoto Kyorindo Co.,Ltd.
- This product requires specific installation and maintenance procedures.

CE 0197

Nemoto Kyorindo Co., Ltd.
Manufacturer：2-27-20 Hongo, Bunkyo－ku, Tokyo, 113 - 0033, Japan

Distributed by: Medicor Europe AG
www.medicor-international.com

Nemoto
www.nemoto-do.co.jp

SS70001.01E

Digitally signed by Chicu Natalia
Date: 2023.10.16 12:33:01 EEST
Reason: MoldSign Signature
Location: Moldova

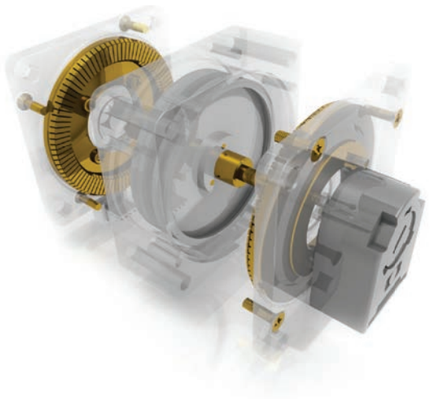
Nemoto

NEW SONIC SHOT® 7

MR Contrast Delivery System

SONIC SHOT 7 Sharpened Functionality

Each performance specification was honed to perfection, for safe and reliable contrast delivery.



Ultrasonic Motor

Completely non-magnetic design. Exclusive for MR, long-lifetime and trusting performance.

Powerhead Lamps

Quickly & Easily recognize injector operation.

Plunger Detection

Insert the syringe, and the injector will automatically detect the plunger position. No need to manipulate manually.

One-Touch Syringe Adapter

Exclusive adapters designed for pre-filled syringes. Easily inserted and removed with One-Touch design.

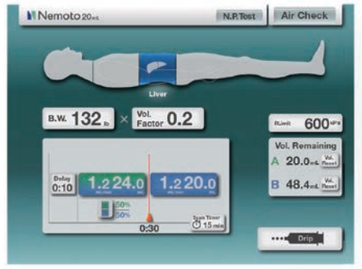
Operational Buttons

Powerhead buttons are designed for easy identification and ease of operation.

Powerhead

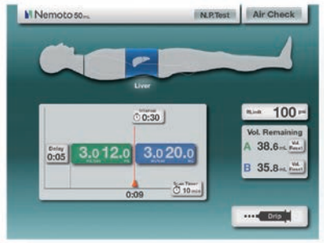
Completely non-magnetic structure, new features, and enhanced ease of use.

Body Weight Input Mode



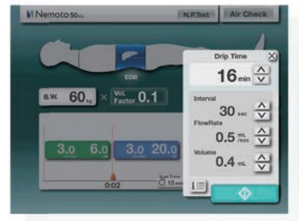
Injector will automatically calculate the protocol based only on patient weight.

Flow Rate Mode



Manually set desired injection parameters.

Drip Infusion

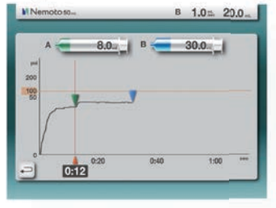


Simplified Drip Mode, easy access and easy to setup and use.

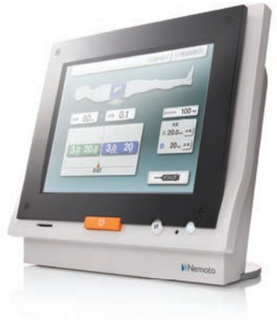
Scan Timing

Real-time information, Elapsed Time bargraph and audible sound indicate when to scan.

Injection



Real-time display of injection progress.



Console

Design for improved reliability and safety with Nemoto's advanced Body Weight Protocol.

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60134044 0001

Report No.: 12022660 007

Manufacturer:
Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo, Bunkyo-ku
Tokyo 113-0033
Japan

Products:
CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems, Extravasation Sensors

(see attachment for sites included)

Replaces Approval, Registration No.: HD 60103647 0001

Expiry Date: 2023-11-07

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-11-08

Date: 2018-11-07

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 1/1, Rev.1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60134044 0001
Report No.: 12022660 007

Manufacturer: Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo, Bunkyo-ku
Tokyo 113-0033
Japan

Sites included :

Nemoto Kyorindo Co., Ltd.
Test site
1-4-18 Asahi, Kawaguchi-shi, Saitama 332-0001, Japan
Manufacture

Nemoto Kyorindo Co., Ltd.
Kawaguchi Plant
2-12-23 Aoki, Kawaguchi-shi, Saitama 332-0031, Japan
Manufacture

Nemoto Kyorindo Co., Ltd.
Technical Center
2-12-4 Aoki, Kawaguchi-shi, Saitama 332-0031, Japan
Design/ development

Nemoto Kyorindo Co., Ltd.
Kawaguchi Warehouse
1-7-5 Asahi, Kawaguchi-shi, Saitama 332-0001, Japan
Manufacture

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2018-11-07

M.Sc. M. Aihara

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod v
						NEMOTO				
DM000422607	SISTEM DE INJECTARE A MEDIULUI DE CONTRAST ANGIOGRAFIC		CT CONTRAST, SMART SHOT ALPHA		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	Rg04-000012	18-01-2023	
DM000422608	SISTEM DE INJECTARE A MEDIULUI DE CONTRAST ANGIOGRAFIC		PRESS DUO ELITE		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	Rg04-000012	18-01-2023	
DM000422600	SISTEM DE INJECTARE A MEDIULUI DE CONTRAST ANGIOGRAFIC		CT CONTRAST, DUAL SHOT ALPHA7		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	Rg04-000012	18-01-2023	
DM000422609	SISTEM DE INJECTARE A MEDIULUI DE CONTRAST ANGIOGRAFIC		MR CONTRAST, SONIC SHOT 7		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	Rg04-000012	18-01-2023	

Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo,
Bunkyo-ku,
Tokyo
113-0033
Japan

2023-08-25

Notified Body Confirmation Letter

Reference: EU2023-607/642255

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo,
Bunkyo-ku,
Tokyo
113-0033
Japan

SRN Number: JP-MF-000004827

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Takato Akimoto

Digitally signed by Takato Akimoto
Date: 2023.08.25 15:45:50 +09'00'

Takato Akimoto

BSI Scheme Manager

By Royal Charter

SUSTAINABLE DEVELOPMENT GOALS

Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable			

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CT Contrast Delivery Systems **DUAL SHOT alpha7** **456013848170AM**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate number: HD 60134044 0001 NB Number: 0197
CT Contrast Delivery Systems **SmartShot alpha** **456013848200A5**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate number: HD 60134044 0001 NB Number: 0197
MR Contrast Delivery Systems **SONIC SHOT 7** **456013848210A8**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate number: HD 60134044 0001 NB Number: 0197
Angiography Contrast Delivery Systems **PRESS DUO elite** **456013848260AP**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate number: HD 60134044 0001 NB Number: 0197
Extravasation Sensors **LD** **456013848130A9**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate number: HD 60134044 0001 NB Number: 0197

NB 0197

Confirmation Letter Revision History

Date	Action
2023/08/25	Initial issue

NB 2797

DoC. Number : EU112-08

Declaration of Conformity

Manufacturer: **Nemoto Kyorindo Co., Ltd.**
2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan

Authorized European Representative:
Medicor International NV
Wingepark 5B-101 3110 Rotselaar Belgium

Product: **MR Contrast Delivery Systems SONIC SHOT 7**

Valid from: Starting from serial number EMB30078G, and in conjunction with the release documents for the product.

We herewith declare that the above mentioned device meets all applicable provisions of the EC Directive 93/42/EEC.

The following Standards were applied:

EN ISO 13485:2016	Medical devices- Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN 60601-1:2006+A1:2013	Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment-Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304:2006	Medical device software – Software life-cycle processes
EN 62366:2008	Medical devices – Application of usability engineering to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements

Conformity Assessment Procedure:
Annex II (exclude Sec. 4) of the EC Directive 93/42/EEC.

Notified Body: **TÜV Rheinland LGA Products GmbH CE 0197**

Registration No.: **HD 60134044 0001**

Classification: **IIb according to Annex IX of MDD, Rule 11, Sub-clause 1, Indent 1**

Nemoto

Place: **Tokyo, Japan**

Date: **February 18, 2019**

Makoto Yasuda

Makoto Yasuda
General Manager

26. Specifications

26.1. Electric Rating

	Power Supply Unit	Console
Rated voltage	100-240VAC 50/60Hz	
Power output or consumption	200VA	45VA
Fuse	-	T5AL 250V×2
Type of protection	Class I	
Level of protection	Type CF	
Classification by operation mode	Continuous operation	
AP - APG support	Not supported	

26.2. Dimensions

External Dimensions (W x D x H)

Powerhead	186×520×122mm
Console	302×180×282mm
Power Supply Unit	170×412×263mm
Switch Box	62×154×37mm
Remote Stand	Φ660 (Stand Base)×1250mm

26.3. Safety Device

Warning and Error Messages

The device is equipped with several warning and error message indications. Warning messages, when present require user intervention before operation can continue. An error message requires power to be cycled. If the error message persists, contact your authorized representative. Refer to the Troubleshooting section of this manual for additional information.

26.4. Environmental Conditions

Electrical safety

This device is designed to comply with IEC/EN 60601-1 (safety) and IEC/EN 60601-1-2 (EMC).

Earth-resistance

Earth resistance shall be less than 0.1Ω when measured between the earthing pin on the AC power cord and any metallic surface on the device Console.

Environment

	Non-Operating (Transportation and storage)	Operating*
Temperature	-40 – 70 ℃	5 – 40 ℃
Humidity	5 – 95%	10 - 90% (Non-Condensing)
Atmosphere pressure	500 - 1060hPa	680 - 1060hPa

*. Make sure to operate this device under specified conditions.

26.5. Programming Range

Flow Rate Programming Range(mL/sec)

	Syringe size	Programming Range	Increment	Accuracy
A-side	50mL	0.1 - 10.0	0.1	±15%
	Magnevist 10mL	0.1 - 4.0		
	Magnevist 15 / 20mL	0.1 - 6.0		
	Gadovist 7.5 / 10mL	0.1 - 4.0		
	Gadovist 15 / 20mL	0.1 - 6.0		
	OMNISCAN 10 / 15 / 20mL	0.1 - 6.0		
	Multihance 10 / 15 / 20mL	0.1 - 6.0		
	ProHance 10 / 15 / 17mL	0.1 - 6.0		
	DOTAREM 10mL	0.1 - 4.0		
	DOTAREM 15 / 20mL	0.1 - 6.0		
B-side	50mL	0.1 - 10.0		

Volume Programming Range(mL)

	Syringe size	Programming Range	Increment	Accuracy
A-side	50mL	0.1 - 60.0	0.1	±2.0mL
	Magnevist 10mL	0.1 - 10.0		
	Magnevist 15 / 20mL	0.1 - 20.0		
	Gadovist 7.5 / 10mL	0.1 - 10.0		
	Gadovist 15 / 20mL	0.1 - 20.0		
	OMNISCAN 10 / 15 / 20mL	0.1 - 20.0		
	Multihance 10 / 15 / 20mL	0.1 - 20.0		
	ProHance 10 / 15 / 17mL	0.1 - 17.0		
	DOTAREM 10mL	0.1 -10.0		
	DOTAREM 15 / 20mL	0.1 - 20.0		
B-side	50mL	0.1 - 60.0		

Pressure Limit Programming Range(psi)

	Syringe size	Programming Range	Increment	Accuracy
A-side	50mL	10 - 150	10	±19psi
	Magnevist 10mL	10 - 200 *		
	Magnevist 15 / 20mL	10 - 200 *		
	Gadovist 7.5 / 10mL	10 - 200 *		
	Gadovist 15 / 20mL	10 - 200 *		
	OMNISCAN 10 / 15 / 20mL	10 - 200 *		
	Multihance 10 / 15 / 20mL	10 - 200 *		
	ProHance 10 / 15 / 17mL	10 - 200 *		
	DOTAREM 10mL	10 - 200 *		
	DOTAREM 15 / 20mL	10 - 200 *		
B-side	50mL	10 - 150		

*. The maximum value of pressure limit can be programmed up to the lower value of A or B side. So since the maximum pressure limit of B side is 150 psi, this value should be the maximum one.

Programming Range for each unit of Pressure Limit

psi		kg/cm^2		kPa	
Programming Range	Increment	Programming Range	Increment	Programming Range	Increment
10 - 200	10	1.0 - 14.0	0.1	100 - 1372	100