SPECIFICATIONS

Basic Specifications

Flow Rate	0.1 - 10.0 mL/sec (Increment of 0.1)
Volume	1mL - Syringe Size (Increment of 1)
Pressure Limit	10 - 300psi (100 - 2058kPa, 1.0 - 21.0kg/cm^2)
Interphase Delay	0 (OFF) - 480sec (Increment of 1)
Ramp-Up Time	OFF: 0sec, ON: 2sec
Injection Mode	Body Weight Mode, Flow Rate Mode
Foward Jog Speed	0.5mL/sec (Low), 1.5mL/sec (Medium), 8.0mL/sec (High)
Reverse Jog Speed	0.5mL/sec (Low), 4.0mL/sec (Medium), 8.0mL/sec (High)
Protocol Memory	Maximum Protocols 420 (84 x 5 Users)
User Memories	Maximum 5
Injection Result Record	Maximum 100

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

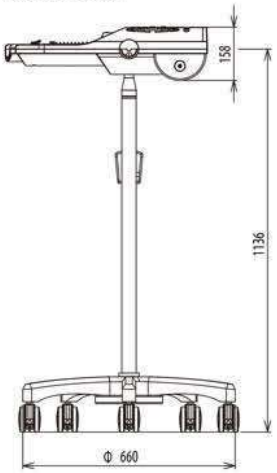
Electrical input/frequency	100-240VAC 50/60Hz
Power consumption	160VA Max
Protection Class	Class I
Protection Degree	Type CF

Approved Consumables

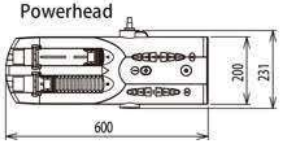
Product Description	Part No.
Dual 200mL Syringe/Y-set w1CV/Spike	C855-5408
Dual Syringe/Y-set w1CV/Spike	C855-5308
Dual Syringe/Y-set w1CV/J-Tube	C855-5304
Single Syringe/ 60" Coiled Line/Spike	C855-5206
Single Syringe/ 60" Coiled Line/J-Tube	C855-5202
200mL Syringe w/J-Tube	C855-5201
100mL Syringe w/J-Tube	C855-5101
200mL Syringe Only	SYPET-200
100mL Syringe Only	SYPET-100

SYSTEM CONFIGRATION

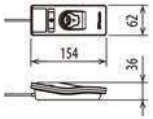
Remote Stand



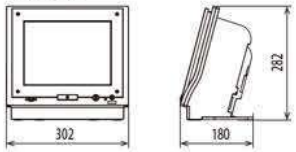
Powerhead



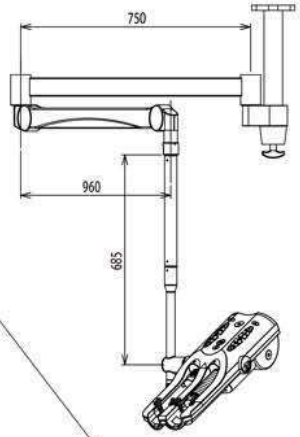
Switch Box



Console



Ceiling Mount type (Option)



Dimensions and Weights

Powerhead	W600 x D231 x H158mm / 8.4kg
Console	W302 x D180 x H282mm / 6.5kg
Remote Stand	Φ660 x H1136mm / 11.0kg
Switch Box	W62 x D154 x H36mm / 264g

2016.01

Brand name / DUAL SHOT alpha7

- This product design and specifications may change without prior notice
- 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

Nemoto
www.nemoto-do.co.jp

DSA70001.02E

HOSPINIAGA
TIME for LIFE

Nemoto

DUAL SHOT alpha7

CT Contrast Delivery Systems

Looking for the injector that makes effective contrast imaging easier?

Answer

The DUALSHOT alpha7 includes a variety of built-in protocols, including our unique body weight protocol. Our injector takes into consideration imaging time, contrast concentration and other factors to customize a protocol to result in a constant TDC with excellent enhancement. Based on these factors the injector can calculate the protocol.

Power Head

Simplified syringe loading, with positive indication of correct placement

One Touch adapter with snap lock

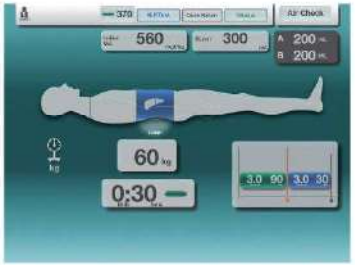
The alpha7's One Touch adapter has flexibility and strength. The One touch adapter makes syringe installation simple, plus gives audible snap sound when locked into place.

Console

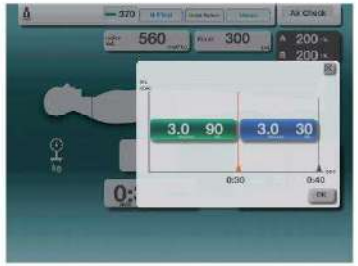
To make a high-resolution 3D image, high quality images are required

Our new simplified interface, QS4

Our new QS4 interface further simplifies the alpha family operation. Via the main screen protocols can be selected quickly, and the injector can be configured the way you prefer.



Input your date once, and from there the alpha7 will calculate the injection rate automatically. Just selecting an anatomic region,the alpha7 can calculate the contrast media volume required for your protocol.



Thumbnail style display –
Quickly view injection time and volume and confirm protocol settings visually.

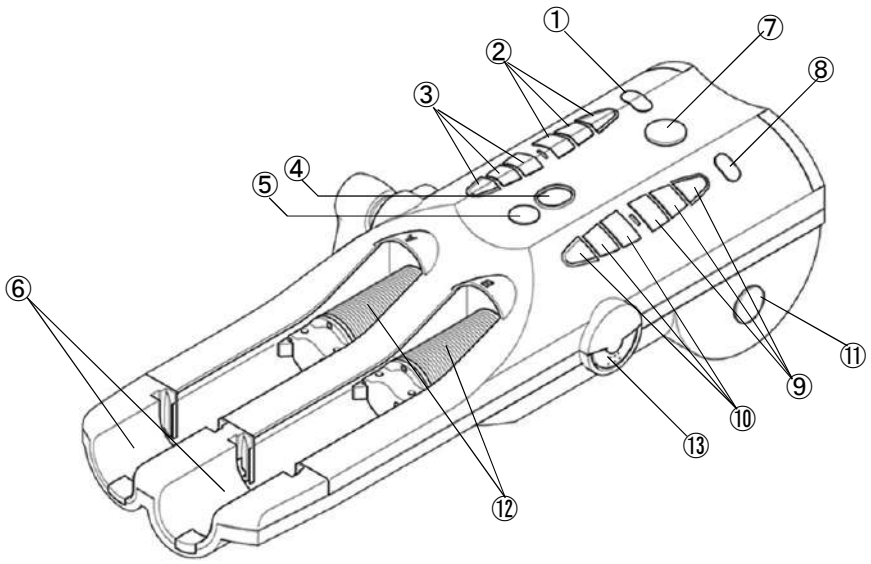
Possibilities

Customize the injector functions the way you prefer

We listen to our customers voice. With alpha7 easy configuration of protocols, on screen help and multi-user,up to 5, capability is possible.

8. Names of Individual Parts

8.1. Powerhead



① A-Side Auto Return Button
Press and hold for 2 or more seconds to automatically retract the A-side ram.

② A-Side Reverse Buttons
Retract the A-side ram.
Fast Medium Slow

③ A-Side Forward Buttons
Advances the A-side ram.
Fast Medium Slow

④ Start Button
Pressing this button while "Start OK" is displayed will start the injection.

⑤ Check Button
Press this button after confirming no air is contained in the syringe and connection tubing. The injection cannot be started unless no air has been confirmed with Check Button.

⑥ Syringe Holder
Recessed areas for securing syringes or adapter. Also location of integrated heating elements.
This item is an Applied Part as defined by IEC60601-1.

⑦ Stop Button
Pressing this button will stop ram motion.

⑧ B-Side Auto Return Button
Press and hold for 2 or more seconds to automatically retract the B-side ram.

⑨ B-Side Reverse Buttons
Reverse the B-side ram.
Fast Medium Slow

⑩ B-Side Forward Buttons
Advances the B-side ram.
Fast Medium Slow

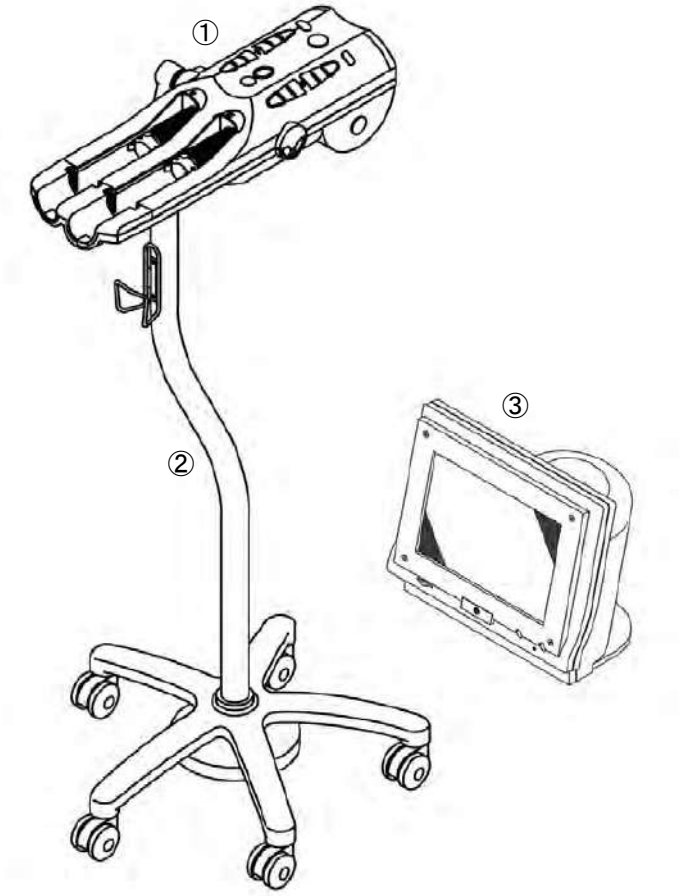
⑪ Stop Button
Pressing this button stops ram motion.

⑫ Powerhead ram
Pushes or pulls the syringe plunger forward or reverse.

⑬ Quick Purge Button (US Version)
Pressing this button will start Quick Purge function.

7. System Overview

7.1. System Components

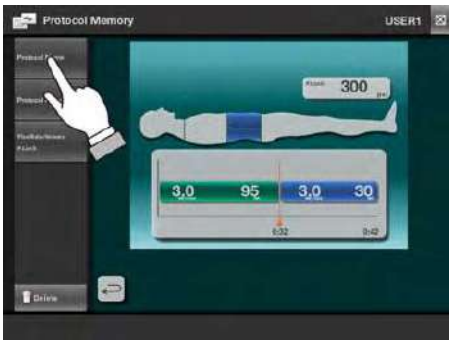


①	Powerhead
②	Remote Stand Optional at the time of shipment. Note : This is not included with the ceiling mount type.
③	Console

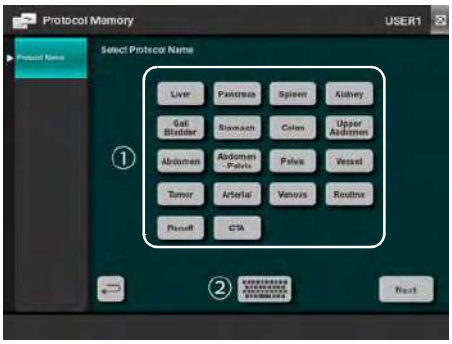
13.3.1. Modifying the Protocol Name

The selected protocol summary screen will be displayed.

To access this function refer to *page 64 "13.3.Edit / Delete Protocol"* section.



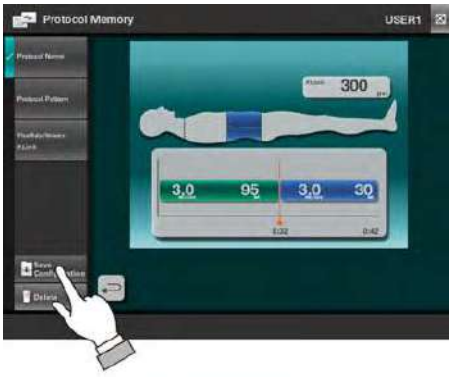
- Select the Protocol Name from the left-side menu.



Pressing the Protocol Name key will cause the Select Protocol Name screen to appear.

- To set a new name for the protocol select a standard name from the list (1) or use the keyboard (2) to enter a custom name.

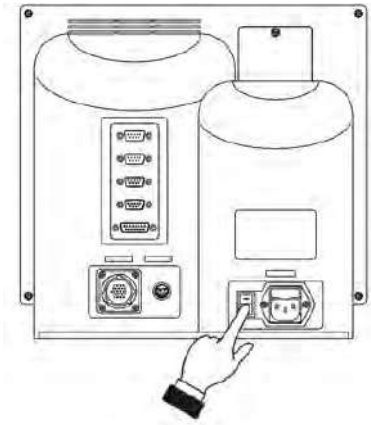
  For information on using the keyboard function, refer to *page 77 "13.5.Alphabetic Keyboard Overview"* section.
- Press the Next key to return to the protocol summary screen.



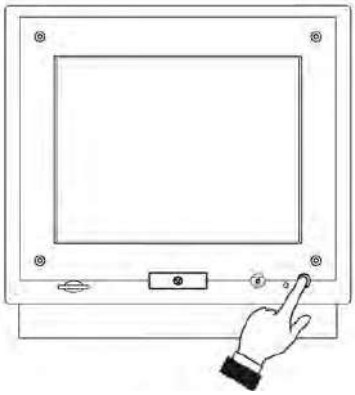
- Press the Save Configuration key on the left-side menu as shown.

9. Basic Procedures

9.1. How to Turn On the Injector



1) Turn on the main power.
Press the main power switch on the back side of the console to turn ON (" | " side).



2) Turn on the console.
Press the power button on the front side of the console to turn on.

3) "Self-checking…."
The above message will appear on the display.

4) Initial Screen
The initial screen will be displayed in a few seconds. The alarm "Switch Confirmation" may be displayed. At that time, press any key on the Powerhead to continue.

Do not insert or remove the power cable or Powerhead cable when the power is ON.
Power is not applied if the main power of the Power Supply Unit is OFF.

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						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

24. Guidance and manufacturers declaration

The following functions of the DUAL SHOT alpha7 are deemed as Essential Performance and were tested for electromagnetic compatibility in compliance with IEC60601-1-2:2007.

Essential Performance:

Inject the liquid contained in the Syringe mounted on the device with controlling the flow rate and the volume.

Guidance and manufacturer's declaration - electromagnetic emissions		
The DUAL SHOT alpha7 is intended for use in the electromagnetic environment specified below. The customer or the user of the DUAL SHOT alpha7 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions EN 55011 CISPR 11	Group 1	The DUAL SHOT alpha7 uses RF energy only for its internal function. Therefore, its RF emissions are very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions EN55011 CISPR 11	Class A	The DUAL SHOT alpha7 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2 IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions EN 61000-3-3 IEC 61000-3-3	Not applicable	

DoC. Number : EU108-11

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: **CT Contrast Delivery Systems DUAL SHOT alpha7**

Valid from: Starting from serial number QCB31072G/QCU30034G/QCBS3429G/QCUS3067G 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 +AC:2018+A11:2021	Medical devices-Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019+A11:2021	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+A2:2021	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 62366-1:2015+A1:2020	Medical devices – Application of usability engineering to medical devices
EN ISO 20417:2021	medical devices -Information to be supplied by the manufacturer
EN ISO 15223-1:2021	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: **December 19, 2022**

Makoto Yasuda

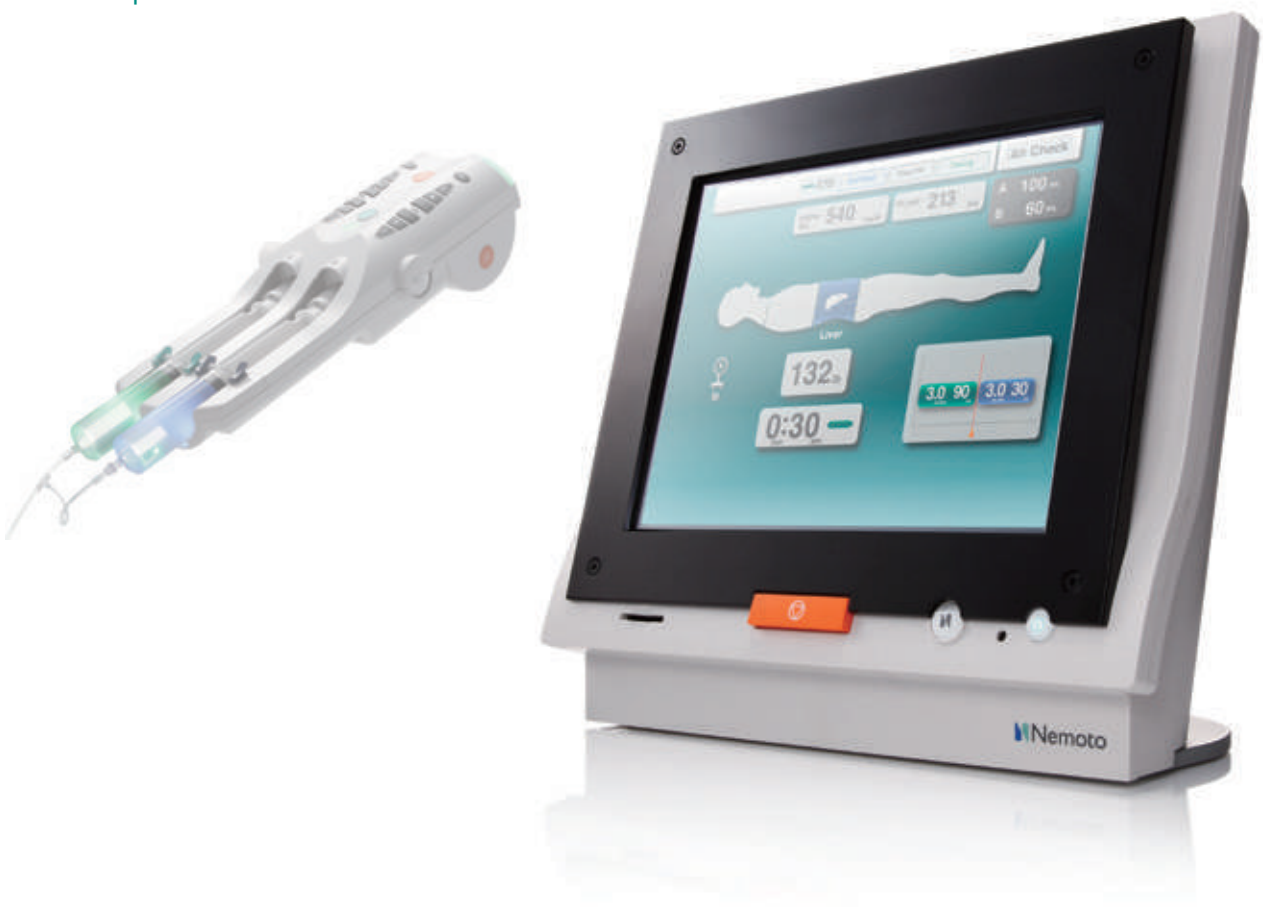
Makoto Yasuda
General Manager

Nemoto

Looking for the injector that makes effective contrast imaging easier?

The Answer

The Dual Shot alpha7 includes a variety of built-in protocols, including our unique body weight protocol. Our injector takes into consideration imaging time, contrast concentration and other factors to customize a protocol to result in a constant TDC with excellent enhancement. Based on these factors the injector can calculate the protocol.



The answer is Nemoto's

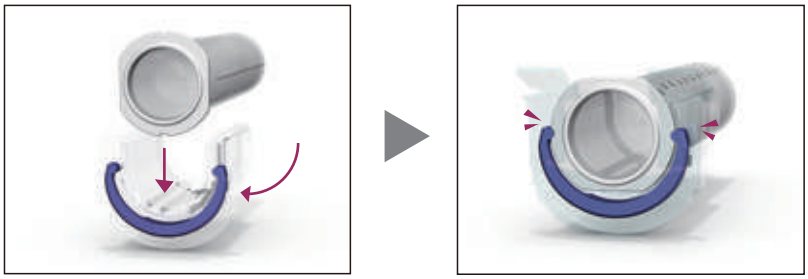
NEW

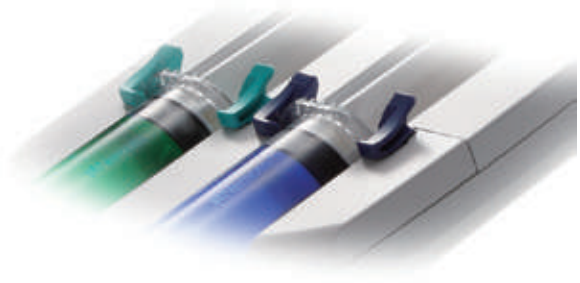
DUAL SHOT alpha7

Contrast Delivery System

Power Head

Simplified syringe loading, with positive indication of correct placement





One Touch adapter with snap lock

The alpha7's One Touch adapter has flexibility and strength. The One touch adapter makes syringe installation simple, plus gives an audible snap sound when locked into place.

Console

To make a high-resolution 3D image, high quality images are required

Our new simplified interface, QS4

Our new QS4 interface further simplifies the alpha family operation. Via the main screen protocols can be selected quickly, and the injector can be configured the way you prefer.

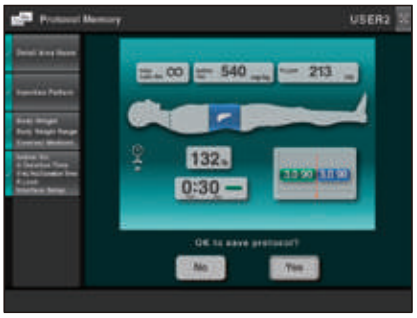
Input your data once, and from there the alpha7 will calculate the injection rate automatically. Just selecting an anatomic region,the alpha7 can calculate the contrast media volume required for your protocol.

Thumbnail style display –
Quickly view injection time and volume and confirm protocol settings visually.

Possibilities

Customize the injector functions the way you prefer

Using the SD Card brings flexibility and longevity to the alpha7.
With the SD Card feature, new feature software updates, new protocols and new modes of operations can easily be added in the future.



We listen to our customers. With the alpha 7, easy configuration of protocols, on screen help and multi-user capability, up to 5 users, is possible.

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

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

CR20121016

Nemoto

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Nemoto Kyorindo Co., Ltd.
Manufacturer address and contact details	2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
Single Registration Number (SRN) (if available)	JP-MF-000004827

Authorised Representative name (if applicable)	Medicor International NV
Authorised Representative address and contact details	Wingepark 5B-101 3110 Rotselaar Belgium
Single Registration Number (SRN) (if available)	BE-AR-000003308

Notified body name (if applicable)	☑ See attached schedule
Notified body number (if applicable)	☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☑ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☑ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name Nemoto Kyorindo Co., Ltd.

Location & Date Tokyo, Japan / 2023-08-25

Signature, Print Name, Title Makoto Yasuda / Makoto Yasuda / Plant Manager, PRRC

Contact Details (at least email) m_yasuda@nemoto-do.co.jp

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
CT Contrast Delivery Systems DUAL SHOT alpha7	**MDD Certificate number; HD 60134044 0001**	**Expiry date; 2023-11-07**	**TÜV Rheinland LGA Products GmbH** **NB Number; 0197**	**BSI Group The Netherlands B.V.** **NB Number; 2797**	**2028-12-31**	—
CT Contrast Delivery Systems SmartShot alpha	**same as above**	**same as above**	**same as above**	**same as above**	**same as above**	—
MR Contrast Delivery Systems SONIC SHOT 7	**same as above**	**same as above**	**same as above**	**same as above**	**same as above**	—
Angiography Contrast Delivery Systems PRESS DUO elite	**same as above**	**same as above**	**same as above**	**same as above**	**same as above**	—
Extravasation Sensors LD	**same as above**	**same as above**	**same as above**	**same as above**	**same as above**	—

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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.

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

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

BSI Scheme Manager

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

Confirmation Letter Revision History

Date	Action
2023/08/25	Initial issue

6. Specifications

6.1. Electric Rating

	Powerhead	Console
Rated voltage	AC100 - 240V 50/60Hz	
Power output or consumption	160VA Max	
Type of protection	Class I	
Level of protection	Type CF	
Drip-proof construction	Yes	-
Classification by operation mode	Continuous operation	
AP - APG support	Not supported	

6.2. Safety Device

6.2.1. Warning and Alarm Messages

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

6.2.2. Ceiling Mount (optional)

The ceiling mount arm that attaches to the ceiling suspension system and supports the DUAL SHOT alpha7 Powerhead is equipped with an internal safety mechanism. The safety mechanism installation is described in the DUAL SHOT alpha7 Installation Manual. In the event of failure the safety mechanism will catch and support the Powerhead. If a failure occurs discontinue use of the ceiling suspension and contact the manufacturer or authorized representative for repair.

6.2.3. Fuse

Control Console T5A250Vx2

6.3. Environmental Conditions

Transportation and storage	Temperature: -40°C - 70 °C
	Humidity: 5% - 95%
	Atmospheric pressure: 500hPa - 1060hPa
Operating	Temperature: 5°C - 40 °C
	Humidity: 10% - 90% (Non-Condensing)
	Atmospheric pressure: 680hPa - 1060hPa

6.4. Programming Range

6.4.1. Volume Programming Range

A side

200mL syringe	1 - 200mL (1mL increments)
100mL syringe	1 - 100mL (1mL increments)

B side

200mL syringe	1 - 200mL (1mL increments)
100mL syringe	1 - 100mL (1mL increments)

6.4.2. Flow Rate Programming Range

A side

200mL syringe	0.1 - 10mL/sec (0.1mL/sec increments)
100mL syringe	0.1 - 10mL/sec (0.1mL/sec increments)

B side

200mL syringe	0.1 - 10mL/sec (0.1mL/sec increments)
100mL syringe	0.1 - 10mL/sec (0.1mL/sec increments)

6.4.3. Pressure Limit Programming Range

200mL syringe	10 to 300 PSI (10 psi increments) 100 to 2058 kPa (100kPa increments) 1.0 to 21.0kg/cm2 (0.1kg/cm2 increments)
100mL syringe	10 to 300 PSI (10 psi increments) 100 to 2058 kPa (100kPa increments) 1.0 to 21.0kg/cm2 (0.1kg/cm2 increments)

6.4.4. Pause Time

Range 0 to 300 seconds (1 second increments)

6.4.5. Inject Delay Time

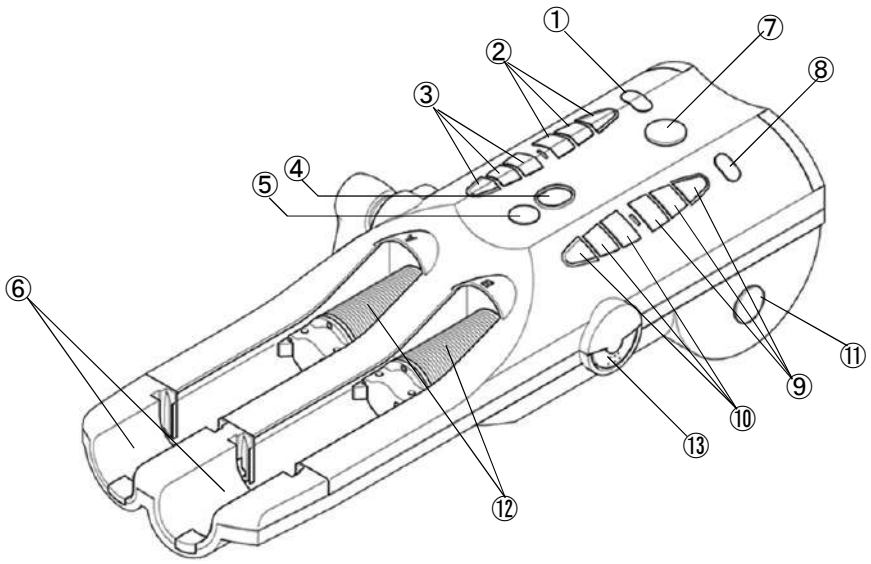
Range 0 to 300 seconds (1 second increments)

6.4.6. Ramp-Up Time

0 or 2 seconds

8. Names of Individual Parts

8.1. Powerhead



① A-Side Auto Return Button
Press and hold for 2 or more seconds to automatically retract the A-side ram.

② A-Side Reverse Buttons
Retract the A-side ram.
Fast Medium Slow

③ A-Side Forward Buttons
Advances the A-side ram.
Fast Medium Slow

④ Start Button
Pressing this button while "Start OK" is displayed will start the injection.

⑤ Check Button
Press this button after confirming no air is contained in the syringe and connection tubing. The injection cannot be started unless no air has been confirmed with Check Button.

⑥ Syringe Holder
Recessed areas for securing syringes or adapter. Also location of integrated heating elements.
This item is an Applied Part as defined by IEC60601-1.

⑦ Stop Button
Pressing this button will stop ram motion.

⑧ B-Side Auto Return Button
Press and hold for 2 or more seconds to automatically retract the B-side ram.

⑨ B-Side Reverse Buttons
Reverse the B-side ram.
Fast Medium Slow

⑩ B-Side Forward Buttons
Advances the B-side ram.
Fast Medium Slow

⑪ Stop Button
Pressing this button stops ram motion.

⑫ Powerhead ram
Pushes or pulls the syringe plunger forward or reverse.

⑬ Quick Purge Button (US Version)
Pressing this button will start Quick Purge function.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo,
Bunkyo-ku,
Tokyo
113-0033
Japan

株式会社 根本杏林堂
〒113-0033
東京都
文京区
本郷2-27-20

Holds Certificate No: MD 767755

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design and Development, Manufacture, Distribution, Installation and Service of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors
CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの設計・開発、製造、販売、設置およびサービス

Transfer from TUV Rheinland Register Certificate Identity number: SX 60143975 0001

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-04-05
Latest Revision Date: 2022-08-05

Effective Date: 2022-11-08
Expiry Date: 2025-11-07

...making excellence a habit.™

Certificate No: MD 767755

Location	Registered Activities
Nemoto Kyorindo Co., Ltd. 2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033 Japan 株式会社 根本杏林堂 〒113-0033 東京都 文京区 本郷2-27-20	Distribution of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの販売
Nemoto Kyorindo Co., Ltd. Kawaguchi Plant 2-12-23 Aoki, Kawaguchi-shi, Saitama 332-0031 Japan 株式会社 根本杏林堂 川口工場 〒332-0031 埼玉県 川口市 青木2-12-23	Manufacture of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの製造
Nemoto Kyorindo Co., Ltd. Technical Center 2-12-4 Aoki, Kawaguchi-shi, Saitama 332-0031 Japan 株式会社 根本杏林堂 技術センター 〒332-0031 埼玉県 川口市 青木2-12-4	Design and Development of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの設計開発

Original Registration Date: 2022-04-05
Latest Revision Date: 2022-08-05

Effective Date: 2022-11-08
Expiry Date: 2025-11-07

Certificate No: MD 767755

Location	Registered Activities
Nemoto Kyorindo Co., Ltd. Test Site 1-4-18, Asahi, Kawaguchi-shi, Saitama 332-0001 Japan 株式会社 根本杏林堂 テストサイト 〒332-0001 埼玉県 川口市 朝日1-4-18	Installation and Service of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの付帯サービス
Nemoto Kyorindo Co., Ltd. Kawaguchi Warehouse 1-7-5, Asahi, Kawaguchi-shi, Saitama 332-0001 Japan 株式会社 根本杏林堂 川口倉庫 〒332-0001 埼玉県 川口市 朝日1-7-5	Storage of components of CT Contrast Delivery Systems, MR Contrast Delivery Systems, Angiography Contrast Delivery Systems and Extravasation Sensors CT 用造影剤注入装置、MR 用造影剤注入装置、アンギオグラフィ用造影剤注入装置および血管外漏れセンサーの部品の保管

Original Registration Date: 2022-04-05
Latest Revision Date: 2022-08-05

Effective Date: 2022-11-08
Expiry Date: 2025-11-07

w056-1SDc002.03(eng)

3rd edition

NCOM

(NCOM Integrated Injector)

Operation Manual

Please note this manual shows display images for reference only and the actual images may vary between injector models.
However, the operation of NCOM is the same between all models.

Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
2017-6-5

Applicable devices

Injectors : DUAL SHOT alpha7

CT Scanners : The NCOM feature is designed to operate with CiA DSP425 Part 2 Version 2.0.1 compliant CT scanners

*The both devices above shall comply with IEC60601-1-1.

1. Introduction

1.1. Overview

The NCOM interlocking feature provides the necessary components to connect a Nemoto contrast delivery system to a compatible CT scanner for the purpose of synchronizing a contrast injection with the CT scan.

To utilize the CANopen(CiA425) specification features, the NCOM Hub and required cabling must be connected between the injector and CT scanner. When operating in the Control Mode, the CT scanner will monitor and control the injector. When operating in the Monitor Mode, CT scanner only monitors the injector status and does not control the injector.

1.2. Disclaimer

Nemoto shall not be liable for any malfunction as a result of using the device outside its INTENDED USE or as a result of, but not limited to, the following:

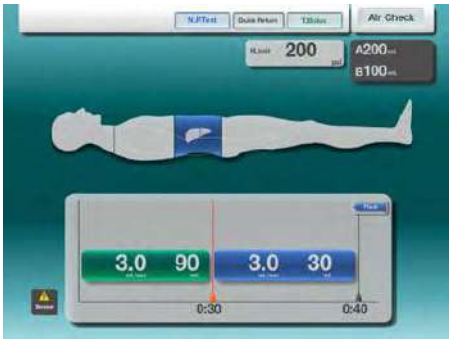
- Any malfunction or damage of this system resulting from not adhering to the Precautions for Use and operating instructions specified in this Operation Manual.
- Any malfunction or damage of this system resulting from the deviation of operating environment specified in the Operation Manual, such as power sources, installation conditions, etc.
- Any malfunction or damage of this system resulting from any natural disasters, such as fire, earthquake, flood, lightning, etc.
- Any malfunction or damage of this system resulting from use with products not approved or specified by Nemoto.

1.3. Device Disposal

Please refer to the injector Operation Manual for the proper disposal method of the NCOM device.

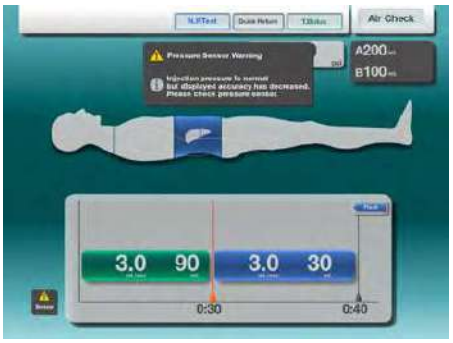
19.6. Pressure Limit Warnings

The DUAL SHOT alpha7 is equipped with redundant pressure protection systems, "primary pressure control" and "secondary pressure control".



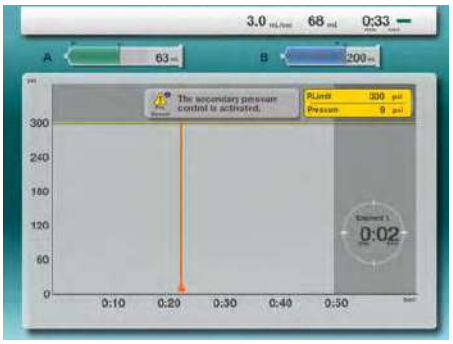
In the event the "primary pressure control" system detects a fault internally to it system, it will automatically switch the pressure protection elements to the "secondary pressure control" system.

If this occurs a pressure the icon will appear.



Pressing the icon will cause a message to appear stating the secondary pressure control is activated.

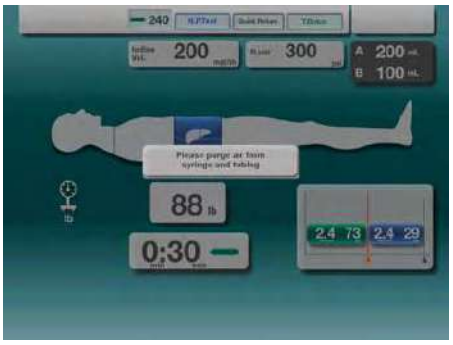
NOTE: When the secondary pressure control is activated, the pressure limit is fixed at maximum pressure limit of each syringe and cannot be changed.



If the secondary pressure control is activated the injection in process screen will operate slightly different.

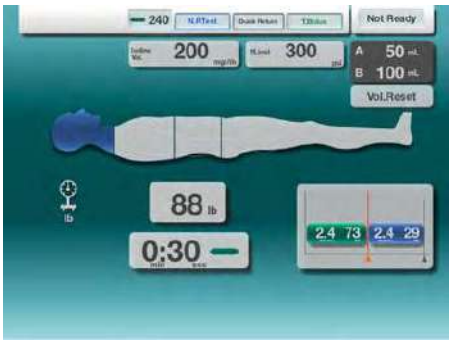
The real-time pressure graph will not be displayed during the injection. The actual pressure however will be displayed in real-time below the set pressure limit.

NOTE : When any of these conditions appears, your authorized service provider should be contacted for repair.



In the event the Air Check is attempted without first performing an air purge sequence the message on the left will be presented to the user.

7) Injector "Not Ready" and "Start OK"



After the user confirms no air is present in the system, it is still possible conditions are not sufficient for the injection to start. If "Air Check" has been pressed, but the injection cannot be performed, a "Not Ready" state will be presented to the user. The "Not Ready" state appears as a blinking "Not Ready" in the upper right corner of the display.

Note: In the example here, the volume is insufficient for the A-side injection.

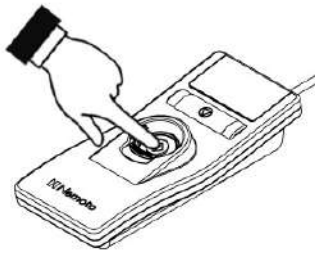
Confirm the status "Start OK" is displayed in the upper right hand corner of the Control Console display.

If "Start OK" is not displayed, check settings of injection protocol and syringe volumes.

The following operations will cancel the "Start OK" status prohibiting the injection start.

- Pressing a Reverse or Forward button
- Pressing an Auto-Return button
- Pressing a Stop button

8) Starting an Injection



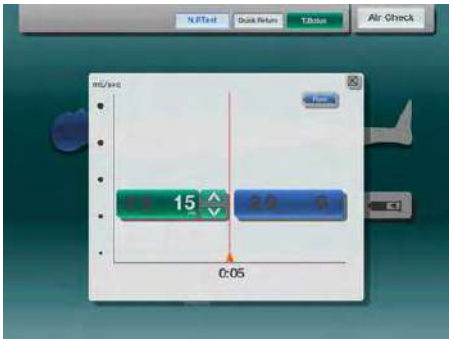
An injection can be started in the control room by pressing the Start button on the Switch Box or by pressing the Start button located on the Powerhead.

If the Start button is pressed during an injection, the injection will stop. When the start button is pressed again, the injection will continue.

16. T.Bolus

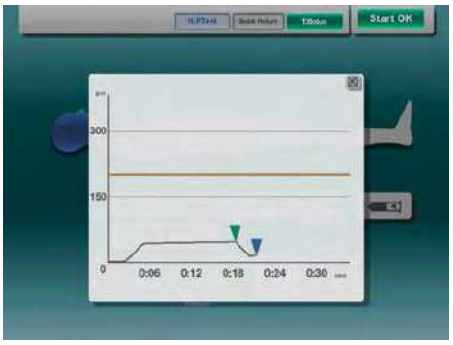
The T.Bolus function permits quick access and execution of an injection for determining the appropriate scan delay time. To activate, press the T.Bolus key located at the top of the Console display.

The T.Bolus values are automatically set to the values set on the Injector Setup screen for T.Bolus/ N.P.Test. Refer to page 99 "20.5.T.Bolus / N.P.Test".
These parameters will be displayed for the user.



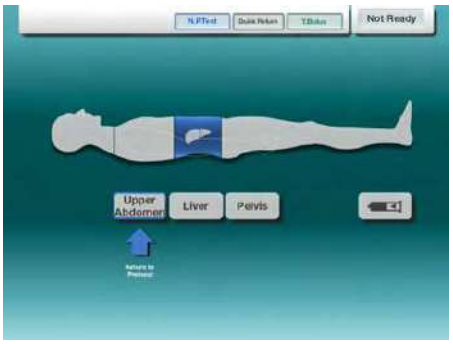
Pressing the T.Bolus key (without an injection first selected) will cause the T.Bolus pop-up window to appear.

NOTE: Pressing the Flush syringe on the T.Bolus pop-up window can be used to turn the flush on and off. The parameters will be maintained.



Press any START on the Powerhead or Switch Box to initiate the T.Bolus injection.

The T.Bolus injection real-time pressure curve will be displayed for reference.



After the T.Bolus is finished or if the window closed and injection protocol was selected beforehand, a "Return to Protocol" message appears under the key previously selected. Press the indicated key to return to protocol.

5. Consumables

- Do not use this system for any other purpose outside of its stated INTENDED USE.
- High pressures are generated during the injection procedure. Be certain to only use those consumables (syringes, tubing, etc.) that have been approved by Nemoto.

APPROVED CONSUMABLES

There may be a risk of leakage, breakage, etc. if consumables other than those approved by Nemoto are used.

Nemoto Approved Consumables

Nemoto Part #	Product Description
C855-5408	Dual 200mL Syringe/Y-set w1CV/Spike
C855-5308	Dual Syringe/Y-set w1CV/Spike
C855-5304	Dual Syringe/Y-set w1CV/J-Tube
C855-5206	Single Syringe/ 60" Coiled Line/Spike
C855-5202	Single Syringe/ 60" Coiled Line/J-Tube
C855-5201	200mL Syringe w/J-Tube
C855-5101	100mL Syringe w/J-Tube
SYPET-200	200mL Syringe Only
SYPET-100	100mL Syringe Only

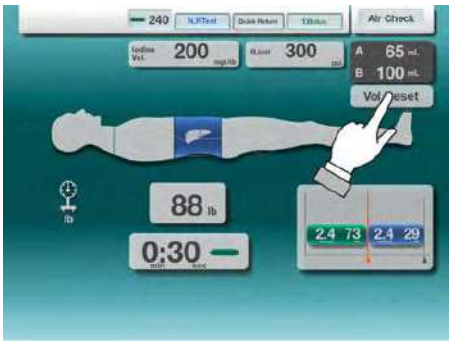
Remove power if any of the following alarms are displayed.

Alarm 2	
Problem	Over Volume
Cause	Internal error or using unapproved consumables. If the alarm continues, contact your service representative.
Alarm 3	
Problem	Abnormal Injection Flow Rate
Cause	More than 25% error tolerance of the preset flow rate value has occurred. If alarm continues, contact your service representative.
Alarm 6	
Problem	Abnormal Motor Stopping
Cause	Internal failure. If alarm continues, contact your service representative.
Alarm 7	
Problem	Hardware Trouble
Cause	This error will appear when trouble is detected with hardware for example, motor, memory, etc.
Alarm 11	
Problem	Encoder Trouble
Cause	Internal failure. If alarm continues, contact your service representative.
Alarm 13	
Problem	Trouble with Limit Sensor
Cause	Both forward and reverse limits activated at the same time. If alarm continues, contact your service representative.
Alarm 14	
Problem	Trouble with Powerhead
Cause	Improper rotation of the motor. If alarm continues, contact your service representative.
Alarm 16	
Problem	Communication Error
Cause	This error will appear if the communications between the Console and Powerhead is not operating correctly.
Alarm 18	
Problem	Slit-Pulse Error
Cause	This error will appear when the Slit Pulse counter does not change after there is a 5mL increase or decrease in the remaining volume.

11.2.6. Volume Reset

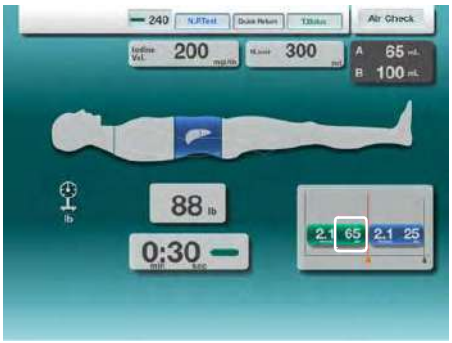
When the syringe volume is less than the programmed volume the Volume Reset key will appear.

- Pressing the Volume Reset key when the A-side syringe volume is less than the A-side programmed volume will cause the programmed value to be set to the syringe volume.
- When performing an A → B injection and the syringe volume is less than the programmed volume, the programmed volume will be set to the syringe volume.



A syringe remaining volume: 65mL / Programmed volume 73mL

- Press the Vol.Reset key.



- After pressing the Vol.Reset key, the programmed volumes will be adjusted in accordance with syringe volumes.