REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						nemoto			
DM000073759	ACCESORIU LA INJECTOR DE CONTRAST PENTRU TOMOGRAFIE COMPUTERIZATĂ (CT)		CEILING MOUNT POWERHEAD ARM*		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	A07.PS-01.Rg04-75	20-03-2018
DM000073763	INJECTOR DE CONTRAST PENTRU TOMOGRAFIE COMPUTERIZATĂ (CT)		SNARTSHOT ALPHA		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	A07.PS-01.Rg04-75	20-03-2018
DM000073755	ACCESORIU LA INJECTOR DE CONTRAST PENTRU TOMOGRAFIE COMPUTERIZATĂ (CT)		CONSOLE		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	A07.PS-01.Rg04-75	20-03-2018
DM000073760	ACCESORIU LA INJECTOR DE CONTRAST PENTRU TOMOGRAFIE COMPUTERIZATĂ (CT)		CABLES		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	A07.PS-01.Rg04-75	20-03-2018
DM000073753	INJECTOR DE CONTRAST PENTRU TOMOGRAFIE COMPUTERIZATĂ (CT)		DUAL SHOT ALPHA 7		Japonia	NEMOTO KYORINDO CO., LTD.	INTERMED S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Digitally signed by Chicu Natalia
Date: 2022.12.16 18:24:35 EET
Reason: MoldSign Signature
Location: Moldova

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

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

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

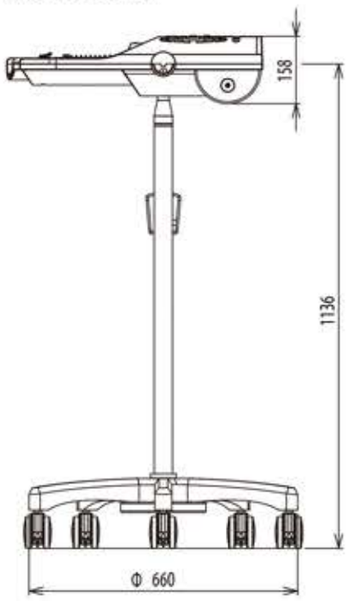
Electrical input/frequency	100-240VAC 50/60Hz
Power consumption	160VA Max
Protection Class	Class I
Protection Degree	Type CF

Approved Consumables

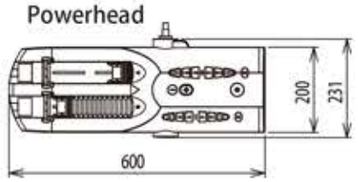
Product Description	Part No.
Dual 200mL Syringe/Y-set w1CV/Spike	C855-5408
Dual Syringe/Y-set w1CV/Spike	C855-5308
Dual Syringe/Y-set w1CV/J-Tube	C855-5304
Single Syringe/ 60" Coiled Line/Spike	C855-5206
Single Syringe/ 60" Coiled Line/J-Tube	C855-5202
200mL Syringe w/J-Tube	C855-5201
100mL Syringe w/J-Tube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

SYSTEM CONFIGRATION

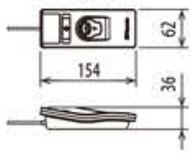
Remote Stand



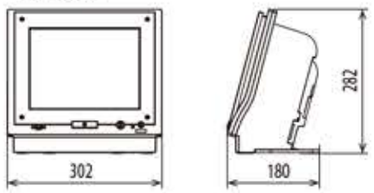
Powerhead



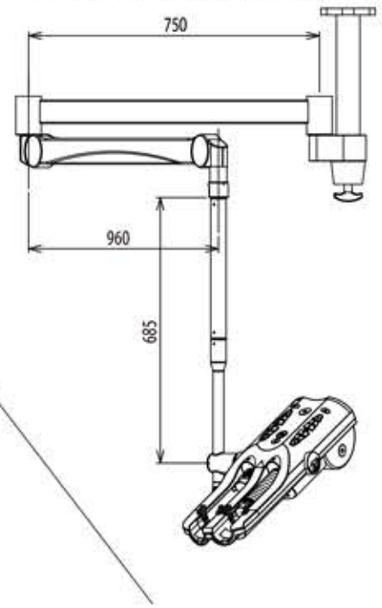
Switch Box



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

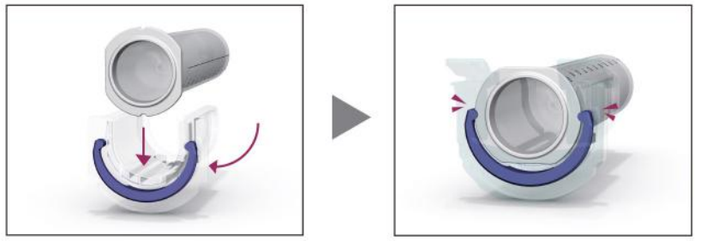
Looking for the injector that makes effective contrast imaging easier?

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

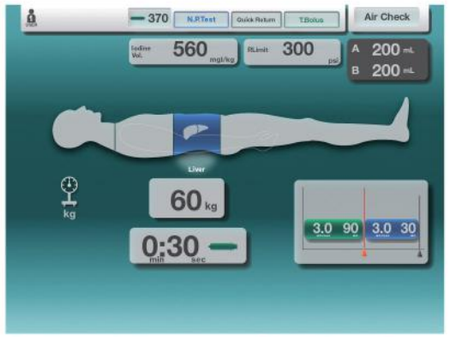
The alpha7's One Touch adapter has flexibility and strength. The One touch adapter makes syringe installation simple, plus gives audible snap sound when locked into place.

Console

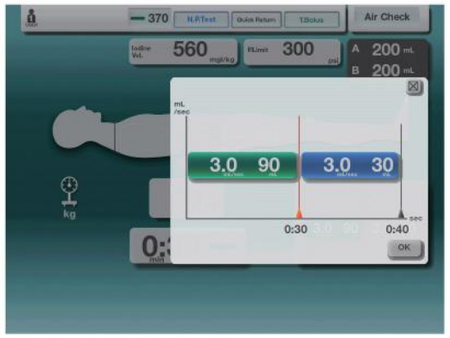
To make a high-resolution 3D image, high quality images are required

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.



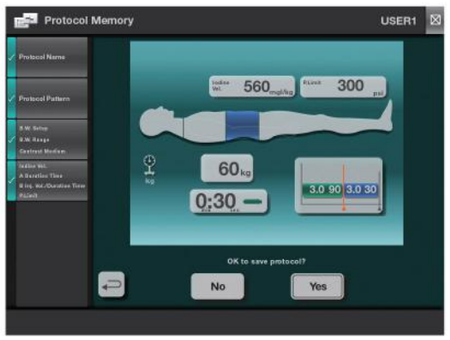
Input your date once, and from there the alpha7 will calculate the injection rate automatically. Just selecting an anatomic region,the alpha7 can calculate the contrast media volume required for your protocol.



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

Possibilities

Customize the injector functions the way you prefer



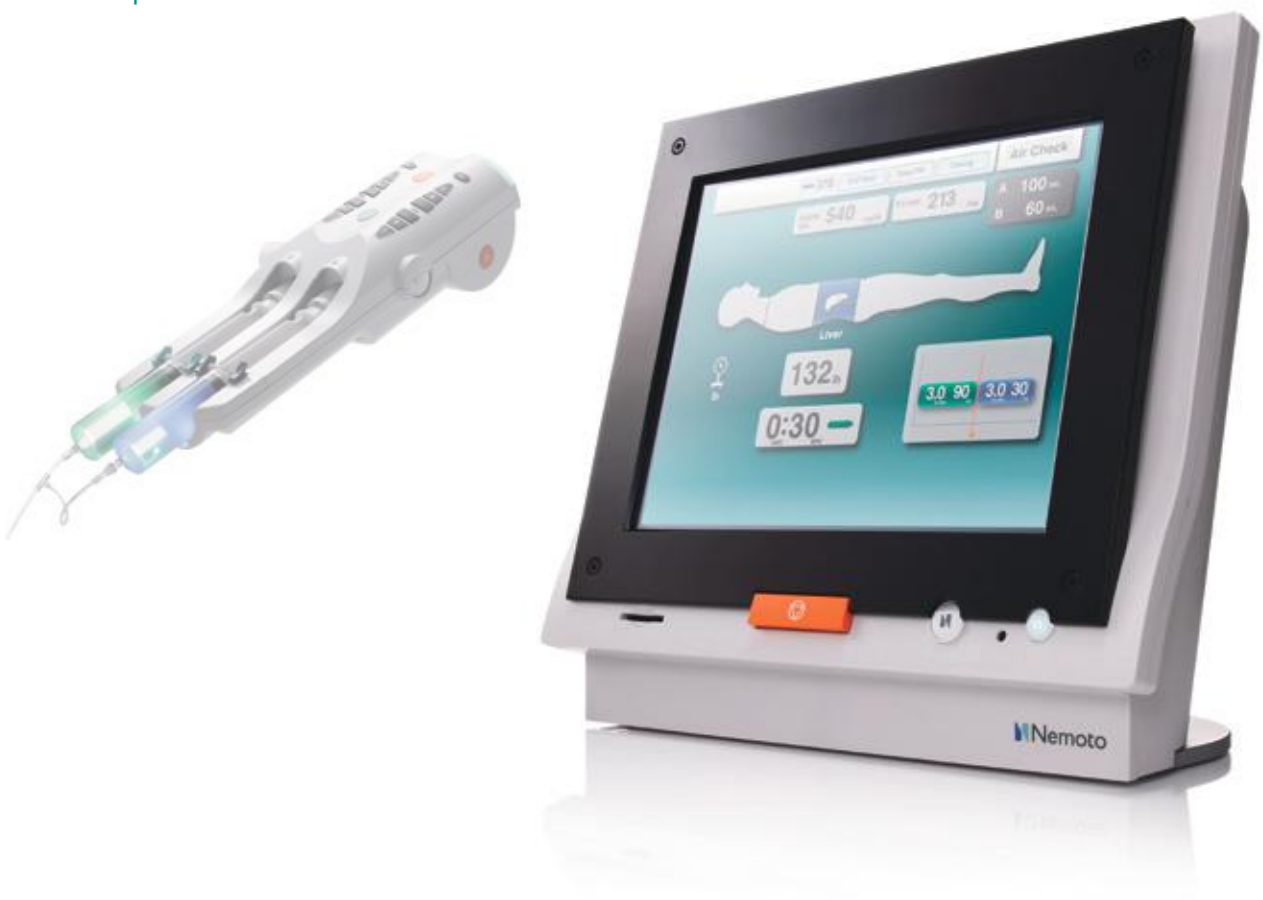
We listen to our customers voice. With alpha7 easy configuration of protocols, on screen help and multi-user,up to 5, capability is possible.

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.

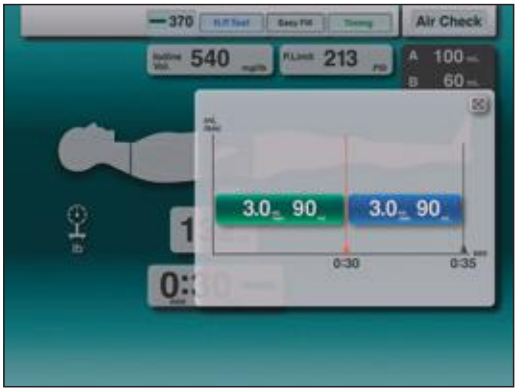
Console

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.

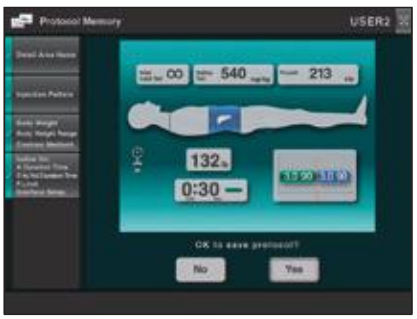


Thumbnail style display –
Quickly view injection time and volume and confirm protocol settings visually.

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

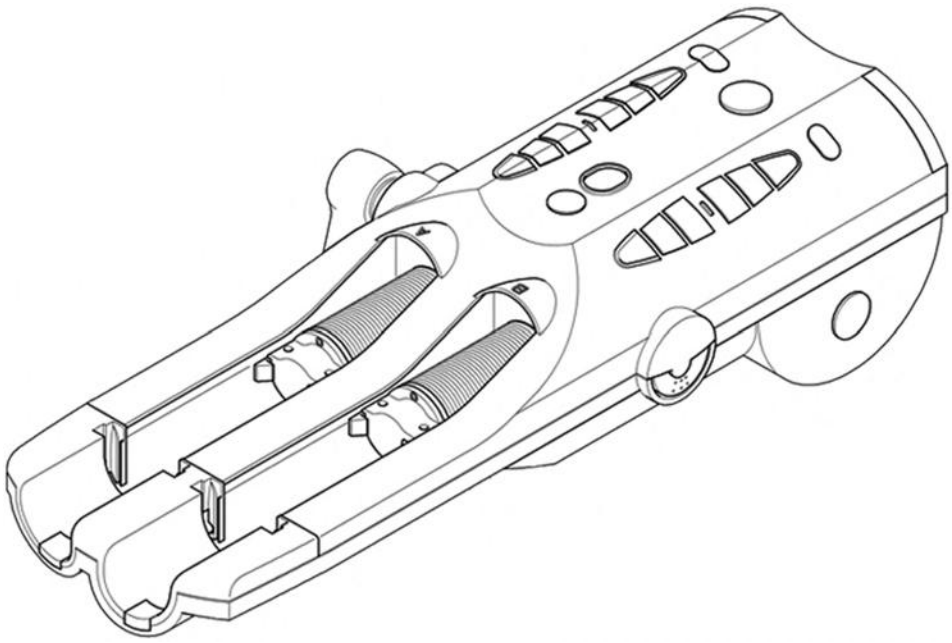
CR20121016

w840-100193.06(eng)

6th edition

Contrast Delivery System

DUAL SHOT alpha7 Operation Manual



This injector is the contrast medium injector system working with CT scanner.

RoHS Compliant

Nemoto Kyorindo Co., Ltd.
2-27-20 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
9/3/2014

THE POINT OF THE
Contrast Delivery System
DUAL SHOT alpha7

- The Contrast Delivery System DUAL SHOT alpha7 CT injector is intended for use by a medical practitioner to inject the contrast media into humans for the purpose of performing CT examination procedure.
- The Contrast Delivery System DUAL SHOT alpha7 CT injector is designed user friendly to allow the user to be able to operate without any specific training.
- Injection Protocols could be selected from the accustomed examination area.
- Flow Rate and the Volume could be set to any value.
- Numeric value could be set by two methods, up/down keys and the accustomed 10 key pad.
- The Console is easily seen with the large 10.4inch SVGA LCD.
- Setting could be set by the Touch Panel intuitively.
- The caster wheels are provided to be able to put aside when it is not to use.

1. Introduction

Thank you for purchasing our Contrast Delivery System DUAL SHOT alpha7.

- To ensure safe, reliable and proper use of the device please read this Operators Manual thoroughly.
- Keep this Operators Manual in a convenient location for easy reference.
- Observe all Danger, Warning and Cautions provided in this Operators Manual to prevent hazardous situation for users or patients and to reduce the likelihood of any damage to the device.

2. Markings

Markings used in this Operator Manual and their descriptions are as follows.

Danger	This symbol indicates hazards which will directly lead to serious personal injury, death or malfunction of the device.
Warning	This symbol indicates hazards which will indirectly lead to serious personal injury, death or malfunction of the device.
Caution	This symbol indicates hazards which could lead to personal injury, device malfunction or property damage.

2.1. Instruction Markings

The following symbols are used on the Contrast Delivery System DUAL SHOT alpha7.

Symbol	Description
	Caution, pinch point
	Caution!
	Keep away from sunlight
	Keep dry
	Handle with care
	Keep upright
	Temperature limitation
	Date of manufacture

Symbol	Description
	"ON" (power)
	"OFF" (power)
	"ON/OFF" (push-push)
	Protective Earth
	Alternating current
	Direct current
	Hazardous voltage
	Start of injection
	Stop of injection
	Type CF applied part
	Forward advance at slow speed
	Forward advance at medium speed
	Forward advance at fast speed
	Backward retraction at slow speed

Symbol	Description
	Backward retraction at medium speed
	Backward retraction at fast speed
	Licensed by TÜV Rheinland, indicates the product complies with UL and CSA standard in US and Canada. TÜV Rheinland is a Nationally Recognized Testing Laboratory (NRTL) by the Occupational Safety and Health Administration (OSHA).
	Indicates conformance to European 93/42/EEC Medical Device Directive.
	Indicates conformance to 2011/65/EU RoHS Directive.
	Indicates that wastes of electric and electronic equipment must be disposed of in accordance with your local laws and regulations. Please contact an authorized representative of the manufacturer regarding the proper disposal of your equipment.
	Symbol for "CONSULT OPERATION MANUAL"
	Serial Number
	It shows this system is the medical equipment working with CT scanner.
	This shows prohibition to bring this system into the room where MRI system is installed.
	Used to access the HOME screen.

3. Read Before Use

- INTENDED USE: The DUAL SHOT alpha7 is intended for use by a medical practitioner to inject contrast medium and physiological saline into humans for the purpose of performing radiography procedures. This device is not approved for any other purpose than its INTENDED USE.
- Do not use the device in connection with equipment that has not been approved or specified by Nemoto. 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.
- Modifications may be made to this Operation Manual without notice.
- Please contact us if you need clarification or further information regarding the DUAL SHOT alpha7. Contact information can be found at the end of this Operation Manual.
- The DUAL SHOT alpha7 complies with IEC60601-1-2:2007. This system uses electro-magnetic energy for its internal function only and does not transmit electro-magnetic energy to the patient. However, note that even small amounts of leakage of electro-magnetic energy may damage nearby sensitive equipment.
- This system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communications equipment can affect this system.
- The spare part with this system other than those specified may result in increased emissions or decreased immunity of this system.
- This system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this system should be observed to verify normal operation in the configuration in which it will be used.
- This system is not intended to be sterilized or disinfected. Do not apply any sterilization or disinfect process.

4. Precautions during Use

- To ensure safe, reliable and proper use of the device please read this Operators Manual thoroughly.
- Keep this Operators Manual in a convenient location for easy reference.
- Aside by all Danger, Warning and Cautions in the labeling of this product.
- Follow all instructions for use, cautions, warnings, etc. when using contrast media that are provided by the respective contrast media manufacturers.

⚠ Danger

- Do not bring this system into MR room. It is extremely dangerous because this system shall be suddenly and strongly pulled to MRI equipment due to strong magnetic field.
- To insure correct and safe operation of the DUAL SHOT alpha7, the installation shall be performed by someone trained and qualified for Medical Device installation. If reinstallation is required please contact Nemoto or your authorized representative.
- This device must not be used by anyone other than qualified and trained persons.
- To ensure safe and reliable operation this device must be installed and set up in accordance with all installation instructions provided in our Installation Manual.
- This device must only be used in conjunction with equipment specifically approved by the manufacturer. Use with any unapproved equipment may lead to misdiagnosis, user or patient hazards or equipment damage.
- This device must only be used with the approved list of consumables (Reference Section 5). Use with any unapproved consumables may lead to misdiagnosis, user or patient hazards or equipment damage.
- To avoid the risk of possible electrical shock, observe caution when connecting and disconnecting power, e.g. using wet hands, pulling on cable, etc. Only permit device housings to be removed and service to be performed by trained and qualified personnel.
- There is a risk of possible fire or electrical shock if usage is continued under any abnormal conditions. In the event of smoke or unusual smell(s) please discontinue use immediately and contact the manufacturer or authorized representative.
- Please use only the Nemoto approved consumables (syringes, tubing, and needles) and make certain to follow all instructions for use and cautions listed in the instruction manual and consumables package.

Warning

- Before initiating any injection protocol, always check to make certain the proper protocol parameters have been programmed into the injector.
- Before injections make certain syringe, tubing, stop-cocks, valves, etc. are open or correctly positioned for injection. In the event a blocked-line injection occurs take precautions to make certain the pressure is relieved before clearing line. Disconnect line from patient if necessary to relieve pressure.
- This device is not equipped with functions that will automatically detect or remove air. Before injection observe good clinical practice and remove all air from syringe and tubing.
- Disconnect tubing from patient before removing the syringe(s).
- Before using the Auto-Return function, disconnect tubing from patient and remove syringes. Failure to take these precautions may lead to air injection or possible contamination from reusing an empty syringe.
- To avoid the risk of electrical shock, this equipment must only be connected to a supply main with protective earth.
- Modification to this device by non-qualified persons, or without authorization and instructions from the manufacturer are strictly prohibited and could result in personal injury, patient injury and damage to the device.

⚠ Caution

- “Federal law restricts this device to sale by or on the order of a physician,” per 21CFR 801.109(b)(1) for USA.
- In the event of device failure, only permit repair by trained and qualified personnel. Contact the manufacturer or authorized representative for assistance.
- To ensure safe and reliable operation of the device do not change or alter its design, assembly, and installation or operate other than as specified by the accompanying document.
- In the event liquid ingresses into the device, discontinue use and remove power to avoid risk of fire or electrical shock. Contact an authorized representative for service and repair.
- When the syringe is filling or pulling in the reverse direction, do not remove or disconnect the syringe from the Powerhead ram. This may result in a sudden pressure relief causing the syringe to break, or move forward at a rapid rate.
- Be sure to confirm the pressure limit setting with all consumables (syringe, tubing, etc.) being used at the time of injection. Improper setting of the pressure limit may lead to leakage or bursting of consumable product.
- The real time pressure curve is provided to show the profile of the injection in process. It should not be used, as it has not been approved, as a means of detecting extravasations.
- Be sure the syringe, and adapter if applicable, is properly installed before starting an injection protocol. Incorrect installation may lead to interrupted procedure, leakage of syringe, damage to syringe or injector, etc.
- To correctly stop an injection use a stop button located on the Powerhead or Remote Switch Box. Do not use a stop-cock to stop an injection in process.
- Use caution when installing and removing syringes as this is a pinch-point area.
- Leakage from tubing may occur after purging due to siphoning effects. Keep tubing blocked or higher than syringe tip to prevent leakage.
- Exposure to shocks, dropping, falling over, etc. outside that seen in normal use, may lead to internal damage. Contact the manufacturer or authorized representative for device inspection.
- Do not forcefully bend, twist, pull, apply heat or place heavy objects on the power cable as this may lead to damage of the cable. To avoid risk of fire or electrical shock, replace damaged cables immediately.
- When using this device in combination with other non-stationary equipment e.g. C-arm or other similar diagnostic imaging equipment, please prevent accidental contact as it may result in equipment damage or personal injury.

⚠ Caution

- Maintenance
  - Follow all manufacturer recommended inspections and preventative maintenance specified in this manual.
  - If the device has not been used for an extended period of time it is recommended a qualified person inspect the device for proper operation before use.
- Disposal of Device
  - Dispose of this device in accordance with all local, state and federal laws and regulations. Please contact the manufacturer or its authorized representatives regarding the proper disposal.

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

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

6.4.7. Dimensions

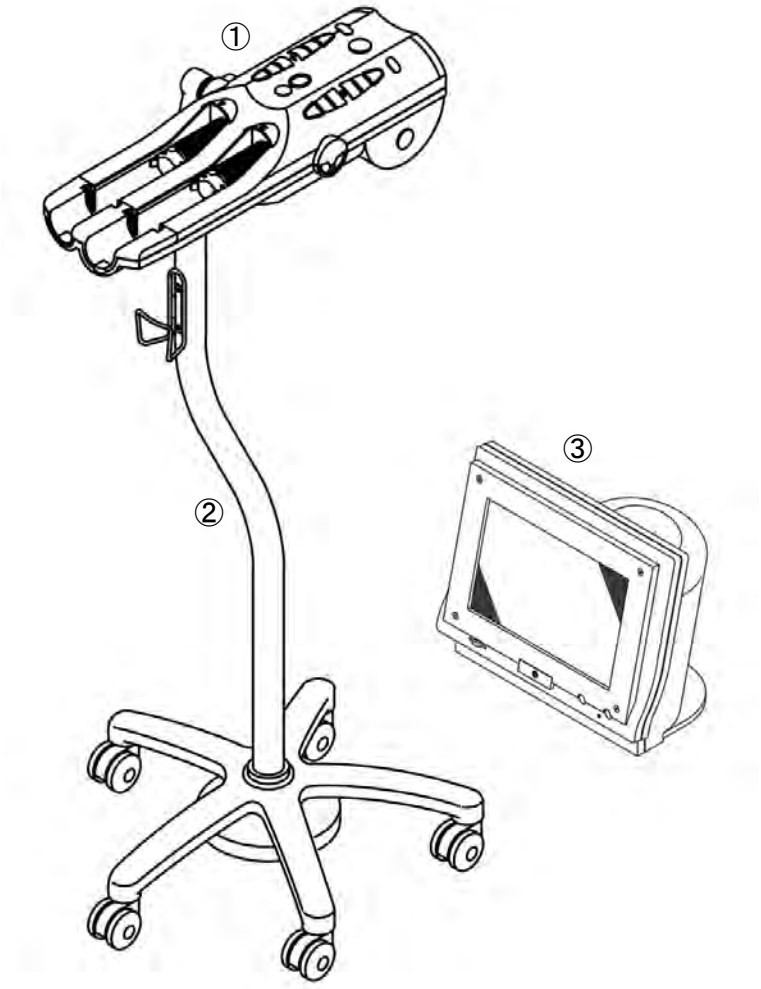
Powerhead	23.62 x 4.41 x 7.09 in.	600 x 112 x 180 mm
Control Console	4.21 x 10.63 x 9.76 in.	107 x 270 x 248 mm
Remote Stand	23.62 x 23.62 x 47.24 in.	600 x 600 x 1200 mm

6.4.8. Weights

Powerhead	18.75 lb.	8.5 kg
Control Console	8.16 lb.	3.7 kg
Remote Stand	25.35 lb.	11.5 kg

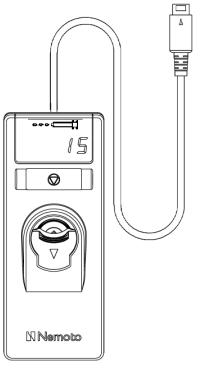
7. System Overview

7.1. System Components



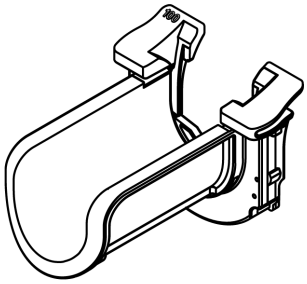
①	Powerhead
②	Remote Stand Optional at the time of shipment. Note : This is not included with the ceiling mount type.
③	Console

7.2. Other Components



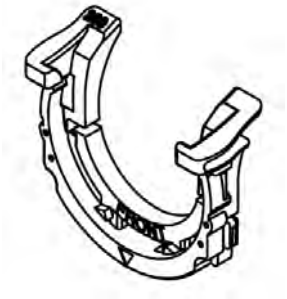
Switch Box

Used to start an injection from the Control Console



Syringe Adapter, 100mL

Used with the 100mL syringe



Syringe Adapter, 200mL

Used with the 200mL syringe

Power Cable

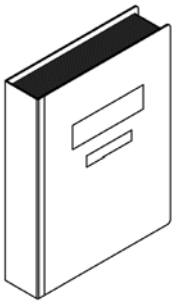
Used to connect the AC Power to the injector.

Powerhead Extension Cable

Used for extending the length of the Powerhead cable.

Ceiling Mount Powerhead Arm (optional at time of shipment)

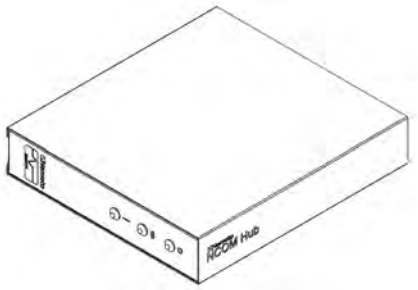
Used to mount the Powerhead to the ceiling suspension column.



Operation Manual (this book)

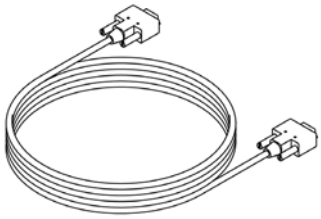
Describes how to properly operate the DUAL SHOT alpha7 contrast delivery system.

ATTENTION: Be sure to read this manual thoroughly, plus any other related documentation to ensure safe and reliable operation.



NCOM Hub (Option)

For further details refer to the NCOM Operation Manual.



NCOM Hub Cable (Option)

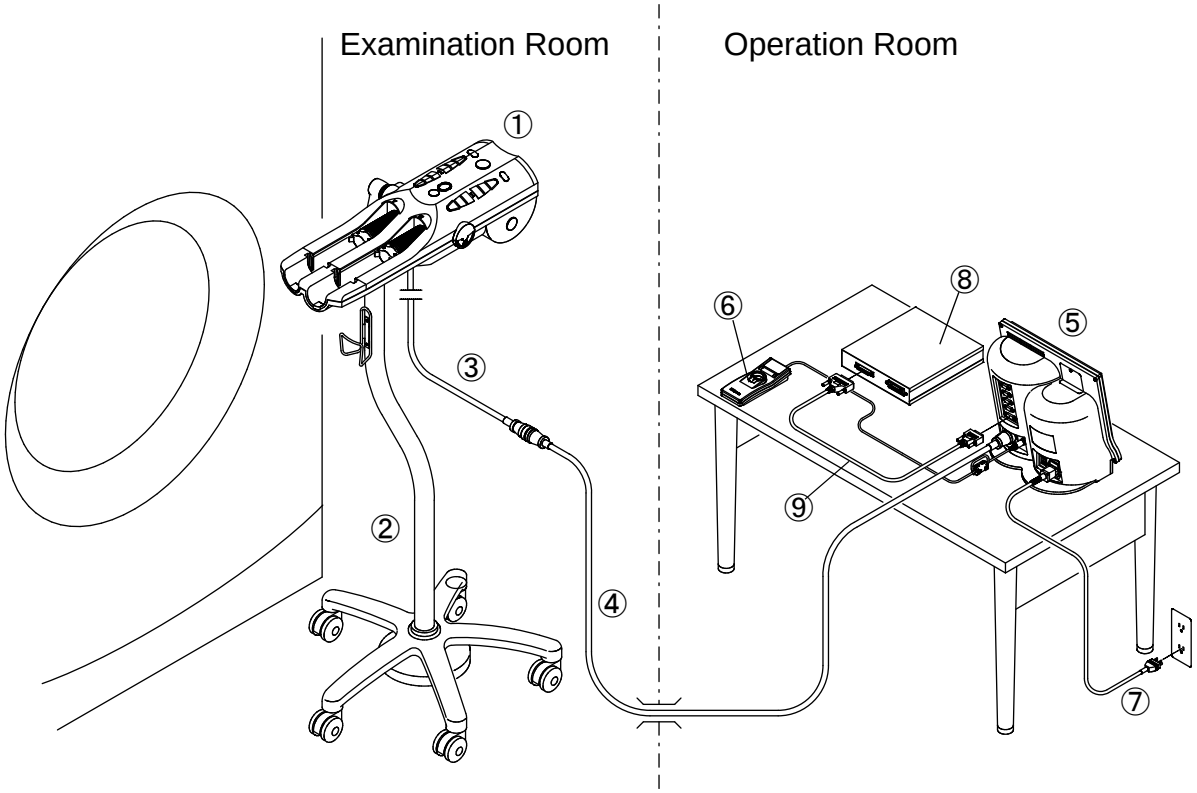
For further details refer to the NCOM Operation Manual.

7.3. Structure and Principal of Operation

⚠ Warning

To assure proper installation and operation of the unit, follow the installation and checkout procedures in the DUAL SHOT alpha7 Installation Manual. The following is provided for general information only and should not be used as complete installation and checkout instructions.

7.3.1. Basic Connection Diagram



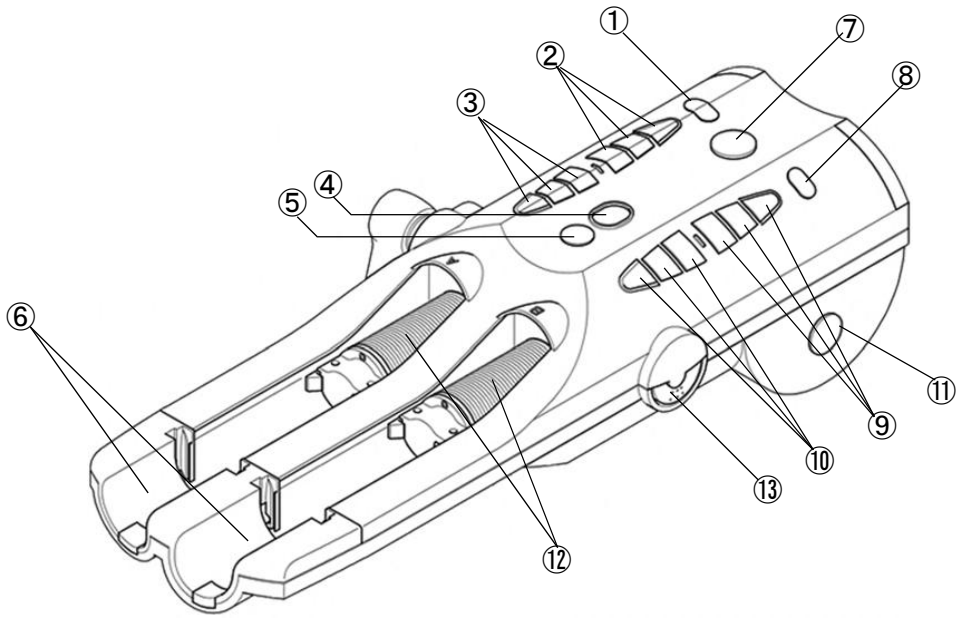
①	Powerhead	④	Powerhead extension cable	⑦	Power cable
②	Remote Stand	⑤	Console	⑧	NCOM Hub (Option)
③	Powerhead cable	⑥	Switch Box	⑨	NCOM Hub cable(Option)

7.3.2. Principle of Operation

The device accepts user inputs that will set the desired speed, movement and force that shall be used during operation. Upon initiation, the inputs shall be translated into electrical signals that cause the internal motor to rotate, turning the drive screw causing a linear motion. The linear motion will push the pressers A and B to expel the contrast and saline loaded into syringe A and B into the patient via the connected consumables.

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

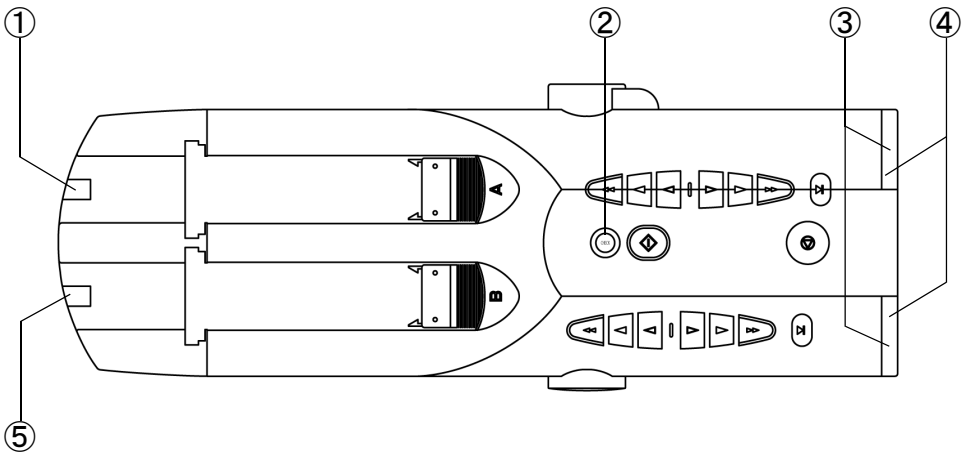
⑩ B-Side Forward Buttons
Advances the B-side ram.
Fast Medium Slow

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.

8.2. Powerhead LED Displays



① A-side Front LED
Indicates status of A-side operation. If A-side is selected for injection, the LED illuminates. While the A-side is injecting, the LED is blinking.

② Air Check LED
It indicates the status of air check. It also functions as an air check confirmation button. It illuminates when the air check button is pressed after user performs air check. It blinks when air check is cancelled.

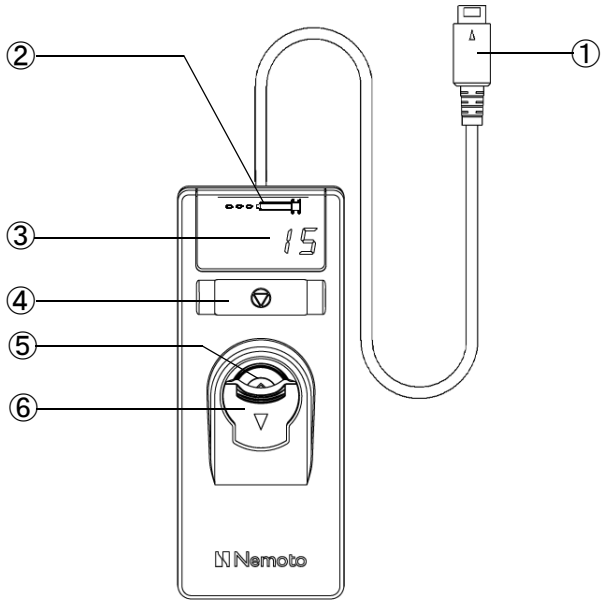
③ Rear LED (Green)
There are several indications available from the Rear LEDs. When both are on the status is"Start OK" meaning the injector is ready to inject. When both LEDs are flashing, an injection is in process.
When the LEDs are off, the injector is in an non-injecting state or an idle state.

④ Online LED (Blue)
It indicates the status of CT interlocking. It illuminates when the DUAL SHOT alpha7 and the CT equipment are in interlocked operation. (Optional interface must be installed)

⑤ B-Side Front LED
It indicates the status of the B-side operation. If B-side is selected for injection, the LED lights up. While the B-side is injecting, the LED is blinking.

Note: During the system power-ON sequence, all LEDs will illuminate briefly. If an alarm occurs, all LEDs will flash to indicate an alarm condition.

8.3. Switch Box



① Switch Box Connector
Connects the Switch Box to the Console.

② Operation Lamp
During an injection a syringe icon lights up.

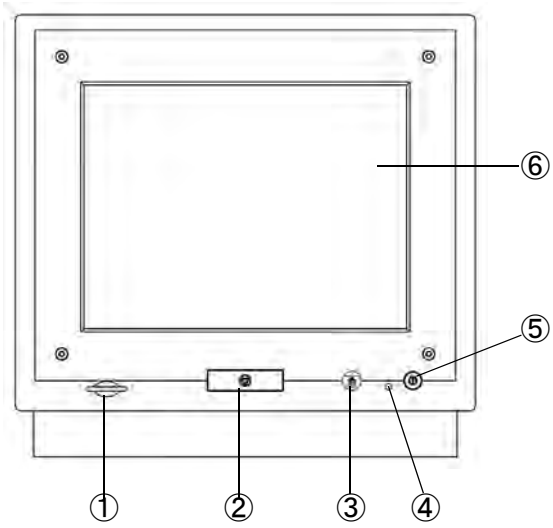
③ Injecting Time Display
Starts counting up simultaneously with the start of an injection.

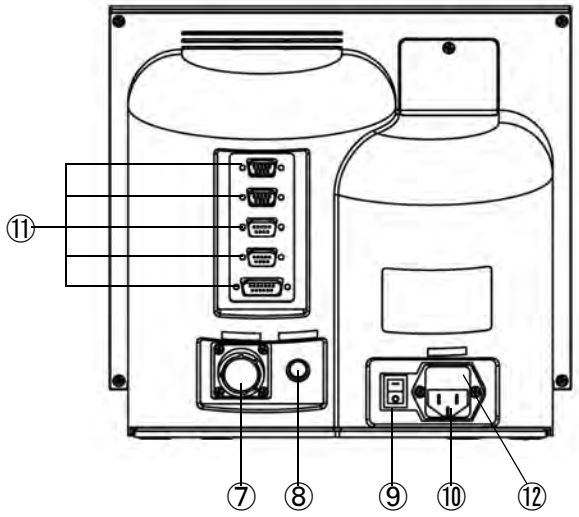
④ Stop Button
Stops an injection in progress.
NOTE: Pressing and holding for two seconds resets the injecting time to zero.

⑤ Start Button
Starts an injection.

⑥ Slide Cover
A protective cover to prevent against inadvertent activation of start switch.

8.4. Console





① SD Card Slot for update
Caution: Do not use.

② Stop Button
Stops an injection in progress.

③ HOME Button
Used to access the Home screen.

④ Adjustment Button

⑤ Power Button
Used to turn power on and off to the system.
NOTE: The Power Supply Unit must be turned on for this button to operate as indicated.

⑥ Touch Panel
Used to select and program injection parameters.
NOTE: Touching the touch panel during an injection will put the injection in HOLD.

⑦ Powerhead Cable Connector
Location for Powerhead cable connection.

⑧ Connector for the Switch Box
Connects to the Switch Box connector.

⑨ Power Switch
Main power ON and OFF switch.

⑩ Power Cable Connector
Location for power cable connection.

⑪ Connector for RS-232
Connector to connect the external device.

⑫ Fuse

Note:

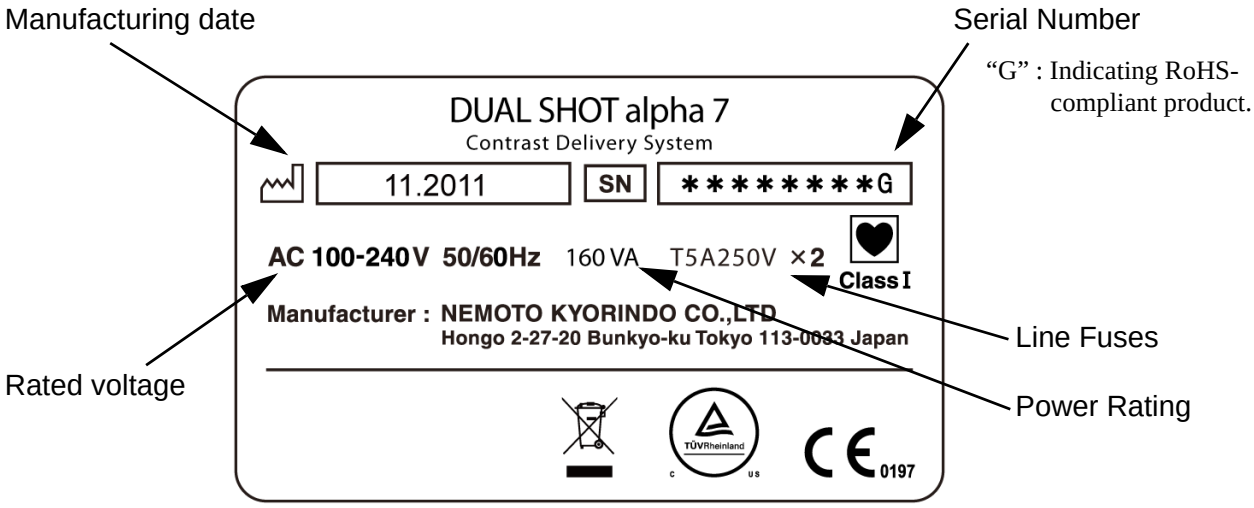
The interface connections are designed and tested to be used with only Nemoto approved external equipment. Contact Nemoto or an authorized representative for approved external equipment and to procure the Nemoto approved interface cable for connection.

⚠ Danger

This device must only be used in conjunction with equipment specifically approved by the manufacturer. Use with any unapproved equipment may lead to misdiagnosis, user or patient hazards or equipment damage.

⚠ Caution

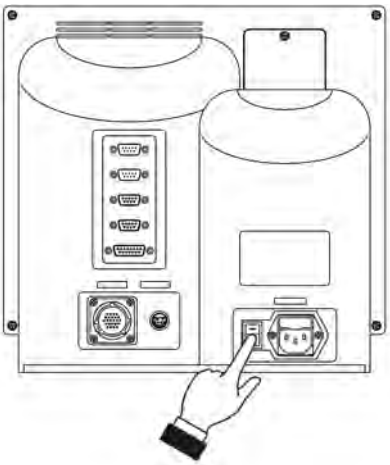
Main power fuse should only be changed by trained and qualified personnel. Use only the fuse designated by Nemoto.



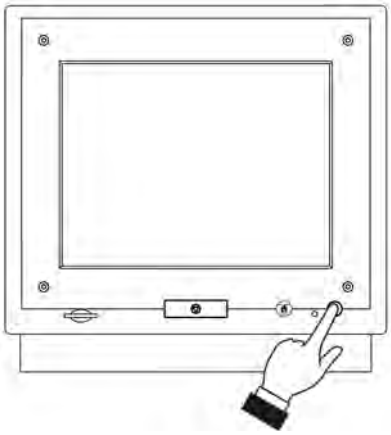
Example of Rating Label

9. Basic Procedures

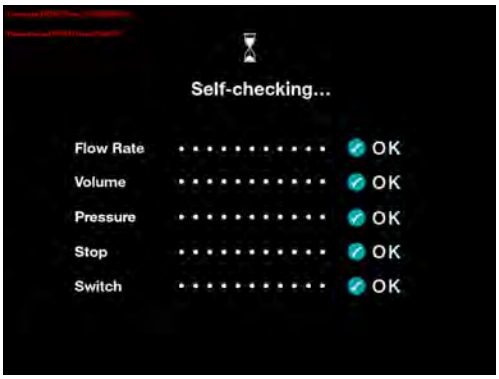
9.1. How to Turn On the Injector



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.

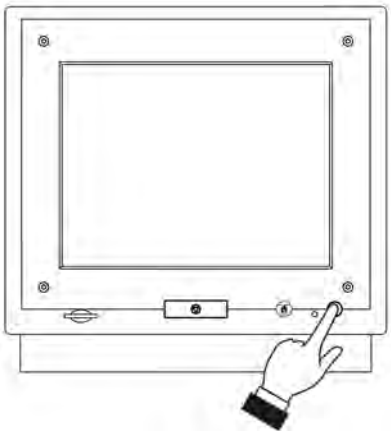


3) "Self-checking…."
The above message will appear on the display.

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.

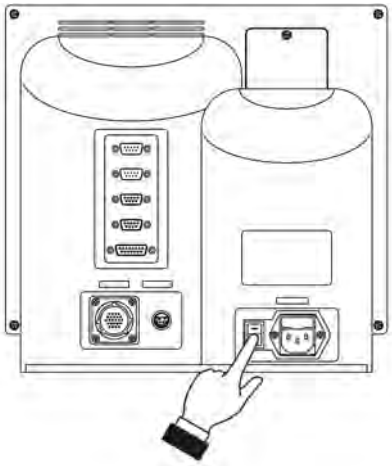
Do not insert or remove the power cable or Powerhead cable when the power is ON.
Power is not applied if the main power of the Power Supply Unit is OFF.

9.2. How to Turn Off the Injector



1) Turning OFF the power
Press the button identified on the Control Console. The LED of the power supply button will turn off.

Note: To preserve the backlight of the LCD, it is recommended that the Console be turned OFF when not in use.

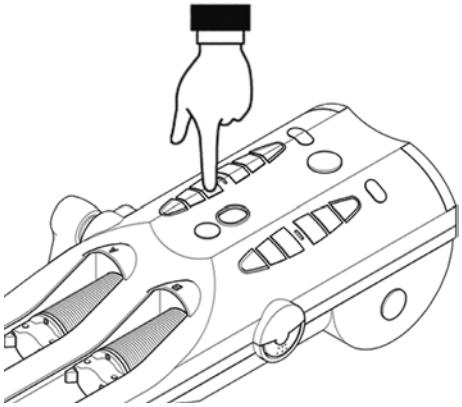


2) It is recommended to turn off the main power when not in use for an extended period. Press the power supply button on the Control Console. Then, turn off the main power switch on the rear side of the power supply unit by pressing the "O" side of the switch.

ATTENTION SERVICE PERSONNEL
CHANGING THE MAIN POWER FUSE

1. Turn off power and disconnect power cord.
2. Remove cover above inlet connector to remove fuses.
3. Replace fuses only with same fuse type and rating as specified by manufacturer.
4. Insert fuses and reinstall protective fuse cover.
5. Connect power cord and apply power.

9.3. Basic Operations



Forward Movement

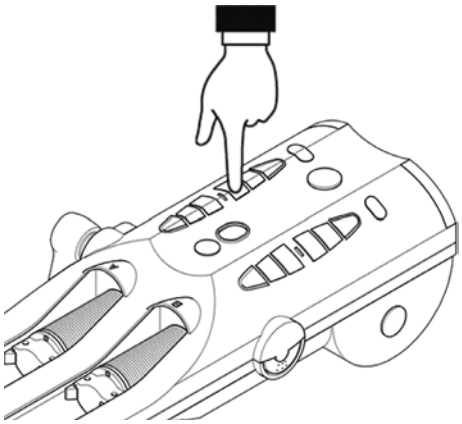
Pressing a forward button moves the ram forward at the selected speed.

◀◀ fast

If the pressure exceeds approximately 40psi when the ram is moving forward fast it will automatically stop.

◀ medium ◁ slow

(The ram stops automatically when 10mL have been injected at the slow or medium speed)



Reverse Movement

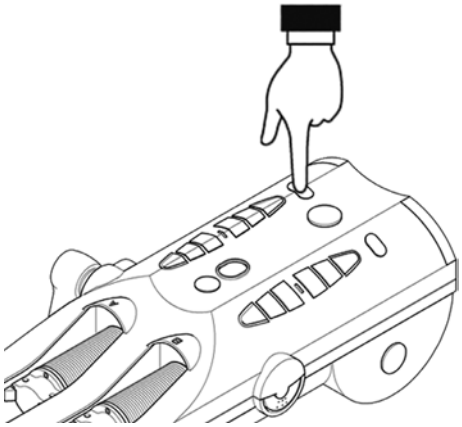
Pressing a reverse button moves the ram in reverse direction at the selected speed.

▶▶ fast

▶ medium ▷ slow

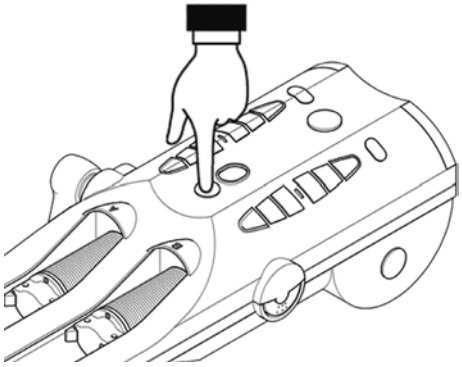
(The ram stops automatically when 10mL has been retracted at the slow or medium speed)

Note: To fill syringes take advantage of the Auto Return feature.



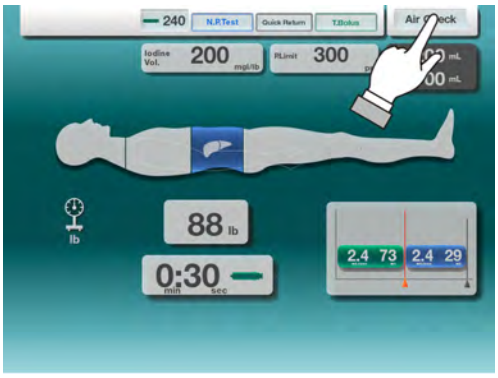
Auto Return

The rams automatically perform the filling sequence after this button is pressed for 2 or more seconds. The Quick Return volumes are programmable from the control console.



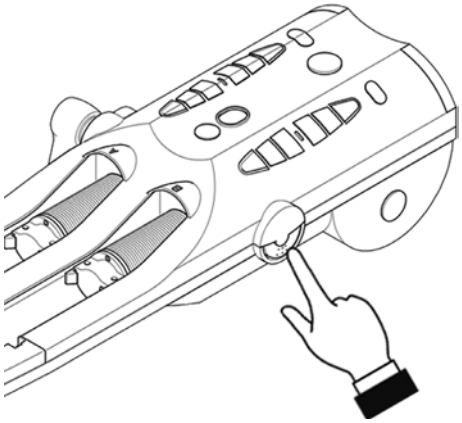
Air Check

Press this button after verifying no air is present in the syringe or tubing. If this button is not pressed, an injection cannot be performed.



Air Check (US Version)

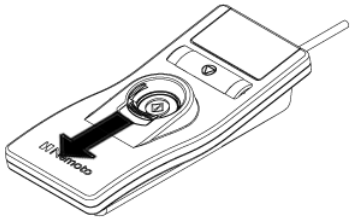
Pressing the Air Check button on the Console, as shown at left, shall also cause the Start OK to appear.



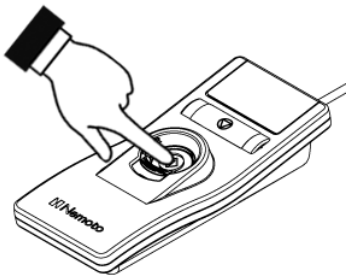
Quick Purge (US Version)

The Quick Purge feature will automatically move the Powerhead rams forward to assist in expelling remaining air. The Quick Purge is activated by pressing the button located on the side of the Powerhead as shown.

9.3.1. Starting injection from control room



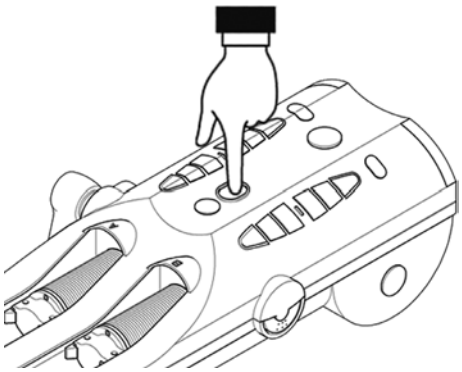
Position the Switch Box as shown, the slide the Start Button cover in the direction shown by the arrow.



Press the now exposed green Start Button to start the injection.

Note : Pressing the Start Button during an injection will cause the injection to stop. Pressing again will restart the injection.

9.3.2. Starting injection from examination room

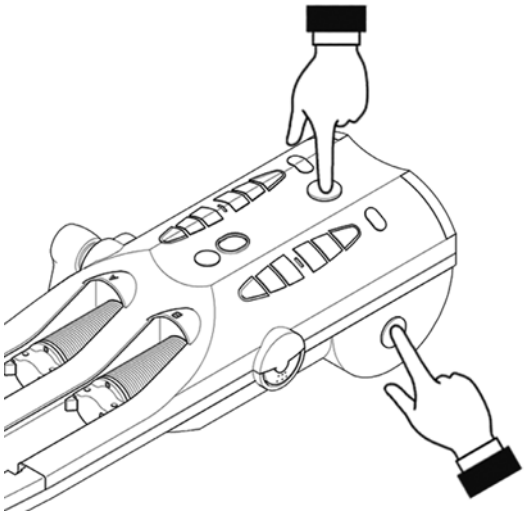


Powerhead start button

Press the start button on the Powerhead to start an injection.

Note : Pressing the start button during an injection, will stop the injection. Pressing again will restart the injection.

9.3.3. Stopping injection from examination room



Injection stop buttons are located on both sides and atop the Powerhead.

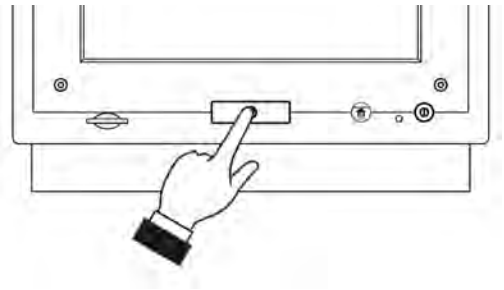
Pressing any Stop button during an injection shall cause the injection to Stop.

(If the STOP button is setup as a HOLD button, then pressing the STOP button during an injection will cause the injection to HOLD. Pressing a START button again, either on the Powerhead or Switch Box will cause the injection to re- start.

If STOP button is setup as a STOP button, then pressing the STOP button during an injection will cause the injection to Stop completely.)

Pressing any Powerhead button other than the "Stop" or "Start" button places the injection in HOLD.

9.3.4. Stopping injection from Control Console

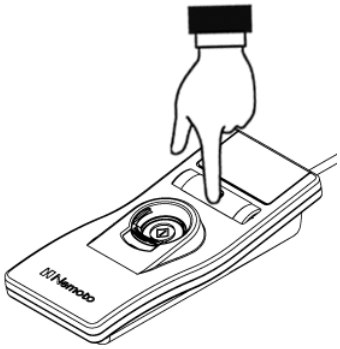


Pressing the "Stop" button on the Console during an injection stops the injection.

(If the STOP button is setup as a HOLD button, then pressing the STOP button during an injection will cause the injection to HOLD. Pressing a START button again, either on the Powerhead or Switch Box will cause the injection to re- start.

If STOP button is setup as a STOP button, then pressing the STOP button during an injection will cause the injection to Stop completely.)

9.3.5. Stopping injection from Switch Box



Pressing the Switch Box stop button stops the injection.

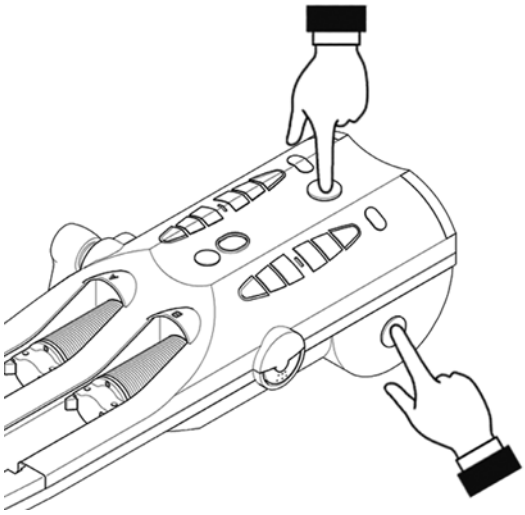
(If the STOP button is setup as a HOLD button, then pressing the STOP button during an injection will cause the injection to HOLD. Pressing a START button again, either on the Powerhead or Switch Box will cause the injection to re- start.

If STOP button is setup as a STOP button, then pressing the STOP button during an injection will cause the injection to Stop completely.)

9.3.6. Stopping Injection from Touchscreen

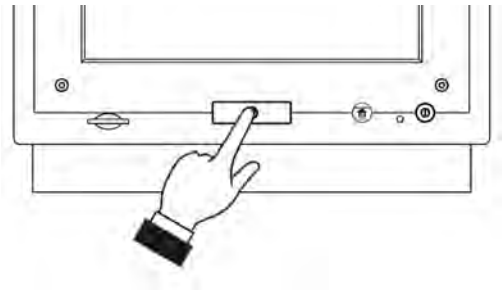
Touching any point on the Control Console touchscreen during an injection will put the injection into the injection HOLD status. Pressing a Start button on the Powerhead or the Switch Box will re-start the injection.

9.3.7. Air Check Cancel



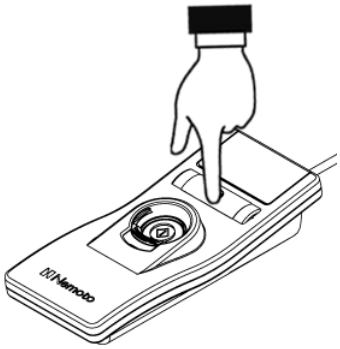
Air check cancel from the Powerhead.

Air check will be canceled when a Powerhead stop button or A-side reverse button is pressed, pulling the ram back.



Air check cancel from the Console.

Air Check will be cancelled when the stop button of the Control Console is pressed.



Air Check cancel from the Switch Box.

Air Check will be cancelled when the "Stop" button of the Switch Box is pressed.

- To resume injecting, press AIR CHECK, then START on Powerhead or Switch Box.
- When an injection is placed into HOLD, Console screen will display HOLD status.

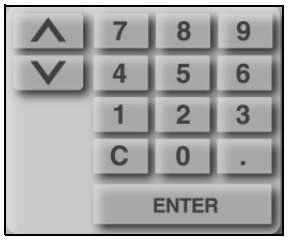
9.4. Console Operation

The Console displays consist of a color graphical user interface operated via a touchscreen interface.

9.4.1. Basic Operation

- Pressing any of the icon items on the user interface will cause the icon to highlight and become active.

9.4.2. 10-Key Keypad Operation

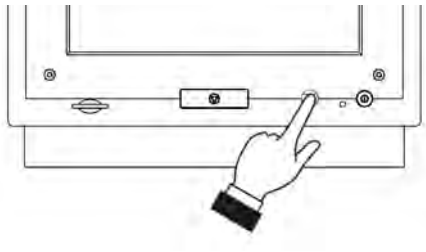


The keypad shown on the left is used for value entries.

Pressing the Up ^ arrow will cause the value to increase and pressing the Down v arrow will cause the value to decrease.

- Values can also be entered via the numeric keys. After the desired value is set, pressing the ENTER key will cause the new value to be entered.

9.4.3. HOME Screen



Pressing the HOME button on the Console front panel will cause the screen display to return to the Home screen shown in 9.4.1.

① User
The top row icons show the currently defined users for the system.

② Injection Results
Shows the history of the injections performed.
(⇒ *"18. Injection Results Screen on Page90"*)

③ Protocol Memory
Accesses the protocol memory
(⇒ *"13. Protocol Memory on Page56"*)

④ Injector Setup
Setup for date, time and sounds
(⇒ *"20. Injector Setup on Page97"*)

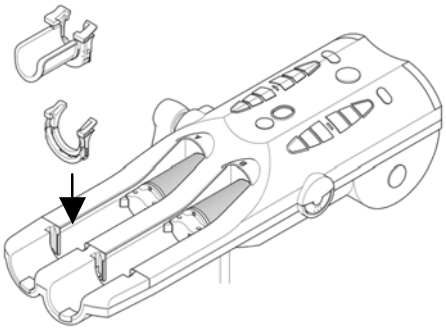
⑤ User Configuration
Setup configuration for each user
(⇒ *"14. User Configuration on Page78"*)

9.5. Insertion and Removal of a Syringe and Adapter

⚠ Warning

To prevent syringes from becoming disengaged during an injection make sure to follow all insertion and locking instruction described in this Operation Manual. Failure to follow the instructions provided may present a hazardous situation for the patient and operator and could lead to damage to the equipment.

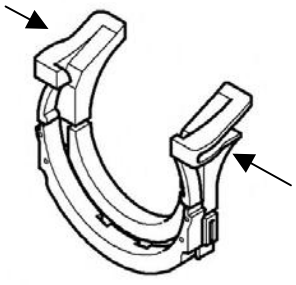
9.5.1. Insertion of Syringe Adapters



The syringe adapters of the DUAL SHOT alpha7 insert into the Powerhead identically regardless of whether it's a 200mL or 100mL adapter. The adapter simply slides into the Powerhead syringe pocket.

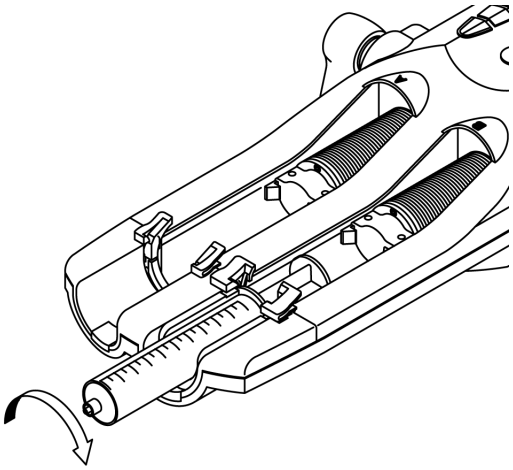
Ensure it is pressed down firmly until a clicking or latching sound is heard.

9.5.2. Removal of Syringe Adapter



To remove a syringe adapter, squeeze the adapter in the direction of the arrows as shown in the diagram on the left. After squeezing inward, lift the adapter from the syringe pocket area of the Powerhead.

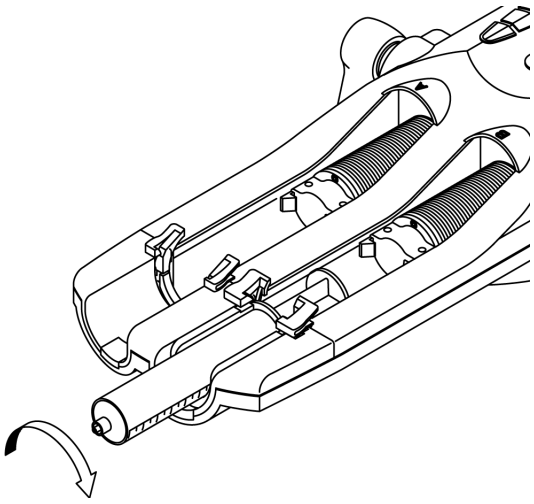
9.5.3. Insertion of Syringe into Adapter



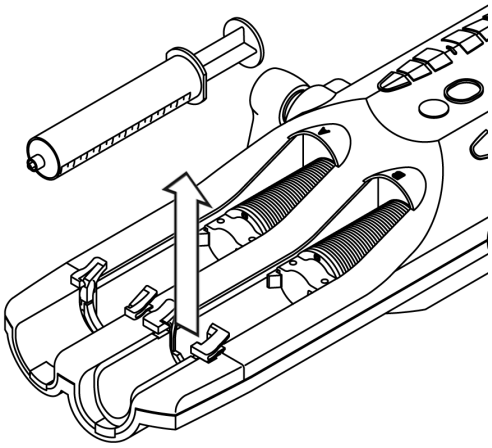
The syringe must be aligned and pushed into the slot of the adapter for proper insertion. Proper alignment consists of aligning the flat sides of the syringe with the adapter slots and ensuring the syringe notch is pointing upwards.

After the syringe is inserted into the adapter slots, rotate clockwise or counterclockwise until the syringe locks into place.

9.5.4. Removal of Syringe from Adapter

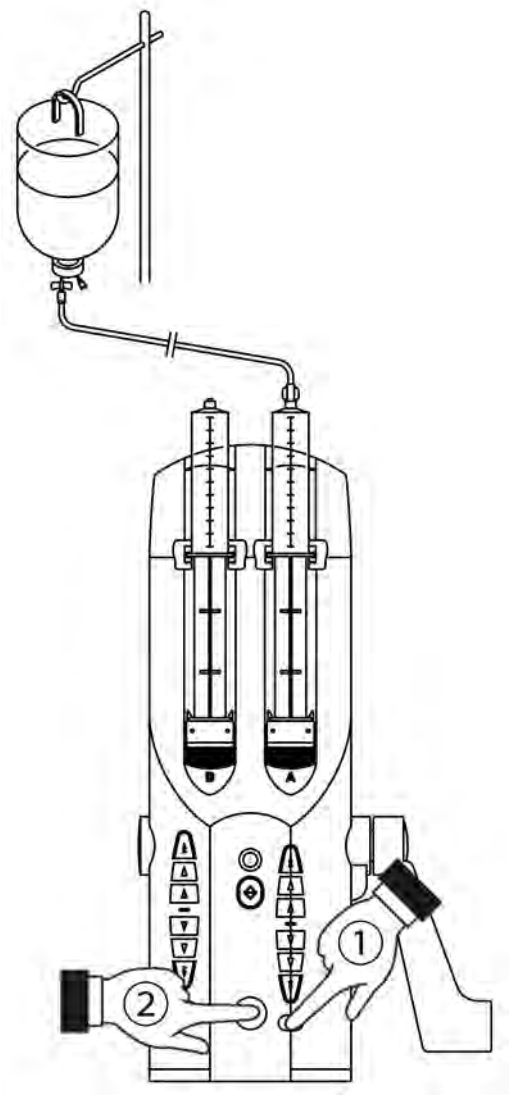


To remove the syringe from the adapter, first rotate the syringe either clockwise or counter-clockwise until the flat sides of the syringe are aligned with the adapter.



After aligning the syringe lift upwards and remove the syringe from the syringe pocket.

9.6. Syringe Filling



Filling of Contrast or Saline

Tilt the Powerhead so the syringe tips are pointing upward. Connect the syringes to the media supply.

Press the Auto-Return button ① for 2 or more seconds to start the Quick Return process.

Quick Return Process

Quick Return Process will automatically move and stop the ram movement to the preset filling volume setting.

For detail, refer to *"17. Quick Return on Page89"* for the Quick Return setting.

Press the "Stop" button ② at anytime to stop the ram motion.

Disconnect the tubing from the syringes when complete.

9.7. Connection of the injection line

After completing the filling sequence, connect the Y-tubing to the injector syringes as shown in the below diagram. After connecting tubing the air must be purged from the syringes and tubing. If the injection is for contrast only, a minimum of 6mL forward motion must be detected. In the case of contrast and saline injection, a minimum of 2mL forward motion on the A-side must be detected and 4mL on the B-side. The DUAL SHOT alpha7 provides two methods to assist users in purging air.

Quick Purge (US Version)

The Quick Purge sequence has been designed specifically for use with the manufacturers recommended consumables. The Quick Purge sequence can be used for either single syringe configurations or dual syringe configurations. To activate the Quick Purge sequence, press the button on the side of the Powerhead to start.

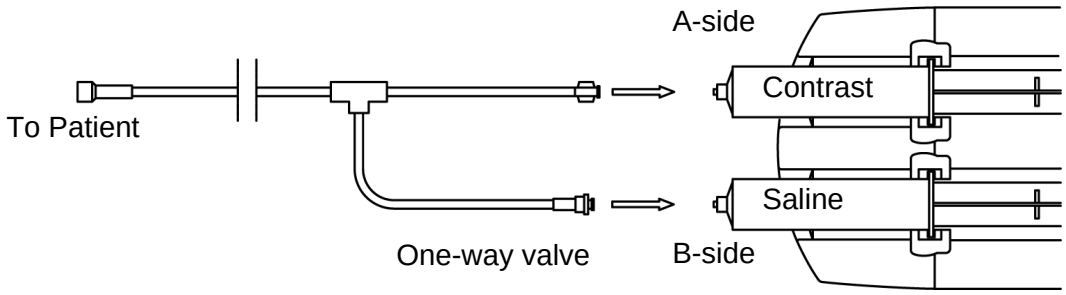
Quick Purge Sequence will move both A-side and B-side simultaneously to the preset volume. Refer to Configuration - *"20.9. Quick Purge Volume Set on Page100"* section for setting up the default values for the Quick Purge feature.

Manual Purging (US / EU Version)

1. A-side: After filling, connect the female connector of tubing to the syringe. Using the forward buttons to push contrast to the junction of the Y-connector.

2. B-side: After filling, connect the tubing with one-way check valve to the saline syringe. Using the forward buttons push saline, removing remaining air to the distal end of tubing.

Note: To properly remove air, be sure syringe tips are pointing upwards.



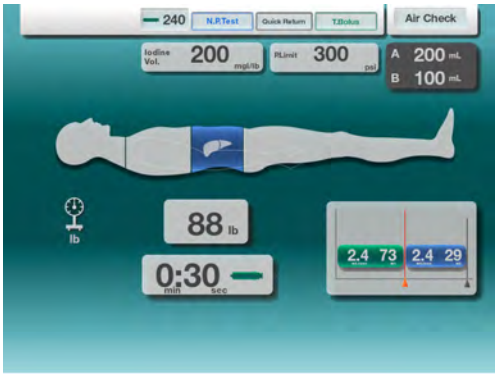
IMPORTANT:
Verify syringe and tubing connections are secure before proceeding. Unsecured connections may become disconnected if not properly secured.

⚠ Danger

Observe and practice good clinical technique to ensure sterility and removal of air from all syringe and tubing connections.

10. Operation Procedure

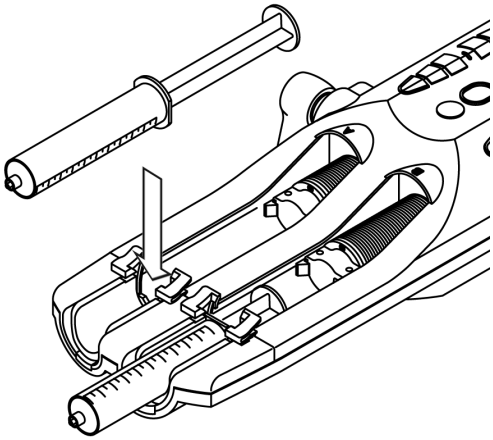
1) Setup injection protocol



Program the desired protocol for the examination.

For protocol mode programming explanations reference *page 41 "11. Body Weight Mode"* or *page 50 "12. Flow Rate Mode"*.

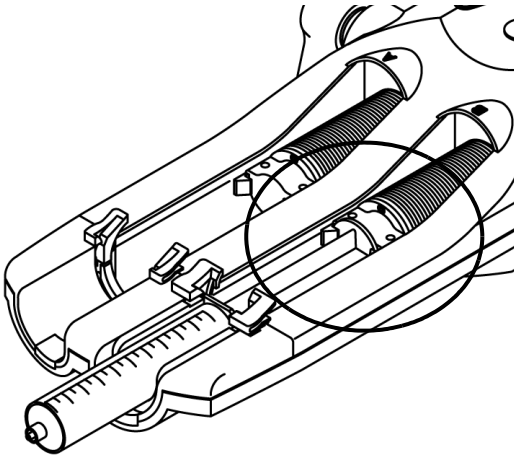
2) Prepare syringes and tubing for injection



An examination using both A and B sides is shown as an example.

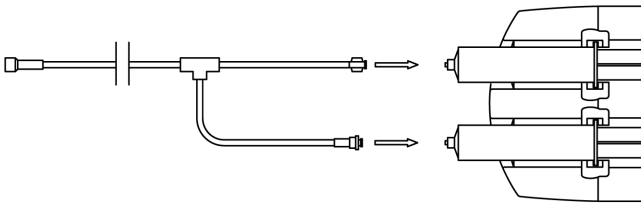
Using the techniques described earlier, install, fill and purge a contrast syringe on the A-side and a saline syringe on the B-side.

3) Secure the syringes in the Powerhead



Securely lock the ram clamper onto the syringe plunger. Closely contact the ram with the flange of the plunger.

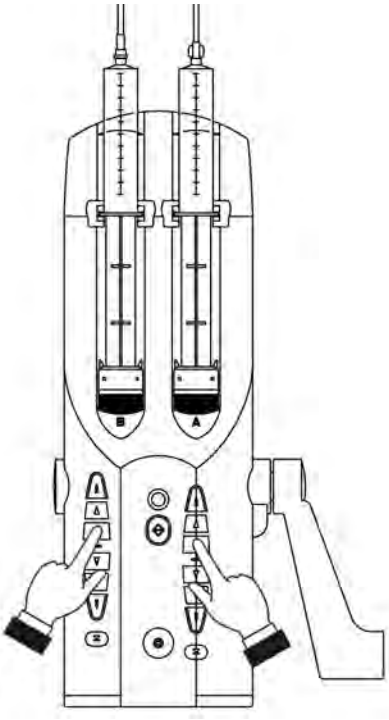
4) Connect the injection line.



Connect the injection line to the syringe.

Refer to "Connecting the Injection Line" for details.

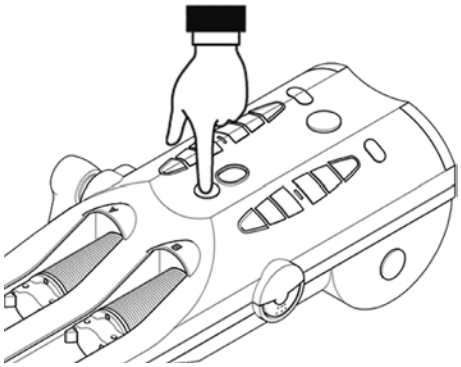
5) Purge the air in the syringe and tubing



Using the techniques described in the "Connection of the injection line" section purge and remove air from the syringes and tubing.

Whether the Quick Purge feature or manual method is used to evacuate air, remember these are only aids to good clinical practice.

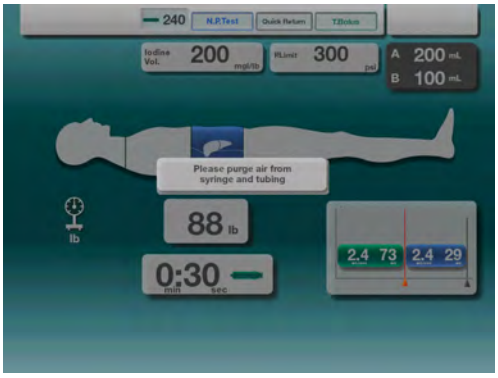
6) Confirmation of air removal



Inspect syringe(s) and tubing to verify that air has been removed. To confirm to the injector that you have removed air, press the Air Check button on the Powerhead.

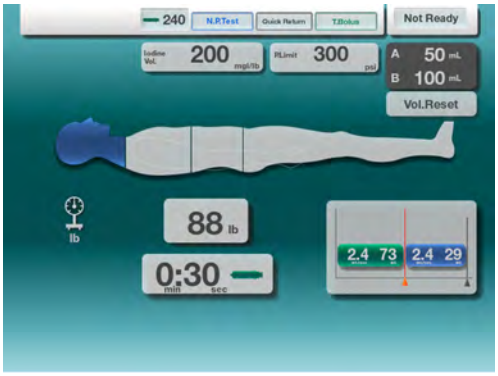
US VERSION

NOTE: If an air purge sequence, either manually or via the Quick Purge feature is not completed, the system cannot be made Ready for an injection.



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.

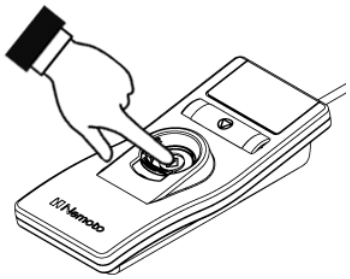
Confirm the status "Start OK" is displayed in the upper right hand corner of the Control Console display.

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.

9) Low Pressure Warning

A low pressure monitoring system is designed in the injector for the A-side and B-sides. The message at the left will be displayed when a low pressure condition exists. Low pressure sensing aids in detecting an empty syringe. Refer to the following table for understanding when a low pressure condition exists.

Low Pressure Warning

PRESSURE	FLOW RATE	ACTION
Low pressure	0.1 - 1.4 mL/sec	Warning message appears, injection continues
A-side < 4PSI	1.5 - 10.0 mL/sec	Warning message appears and injection stops after 10mL are injected
B-side <10PSI	0.1 - 1.9 mL/sec	Warning message appears, injection continues
B-side <10PSI	2.0 - 10.0 mL/sec	Warning message appears and injection stops after 10mL are injected
Caution: Low pressure warning feature for B-side is only active if the following conditions are satisfied. 1. Any injection mode in which a B-side injection follows a A-side injection. 2. When the actual pressure for the A-side exceeds 14 PSI.		

If a low pressure warning message is displayed, check the syringe, tubing and needle for air, proper connections, etc.

⚠ Danger

The injector does not automatically check for extravasations. Exercise good clinical practice and monitor the injection site. In the event extravasations are identified, stop the injection immediately and correct.

10) Injection in Process

During an injection a screen similar to the one on the left will be displayed. A real-time pressure graph will be shown during the injection.

In the event pressure limit is reached, a message will be presented indicating Pressure Limit is activated.

11) Injection Stopped

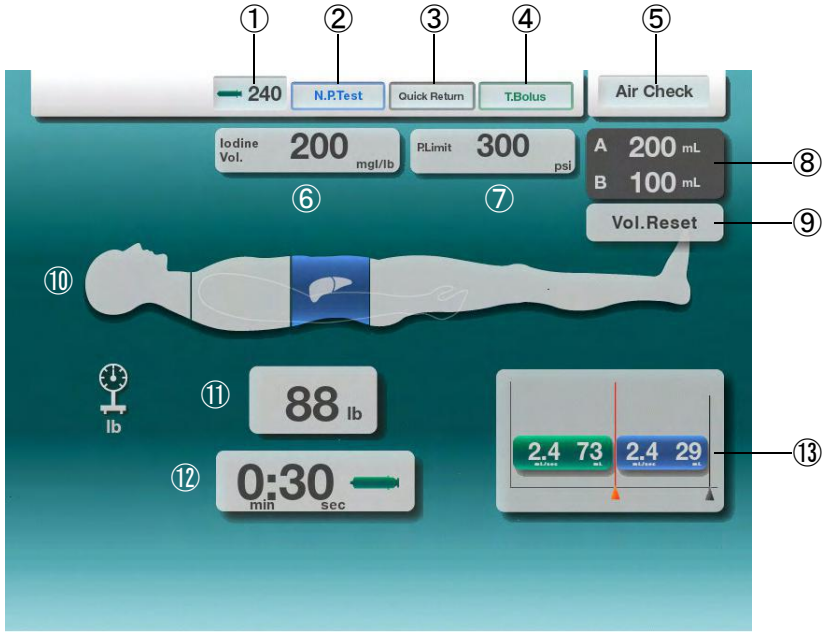
If the Stop button is pressed during an injection, the injection will stop.

Press "OK" to return to the idle screen.

11. Body Weight Mode

11.1. Screen Details

Setup Screen



① Contrast Concentration Setting Key
Select the contrast media concentration value.

② N.P. Test
Needle Placement Test. Press to access and perform test.

③ Quick Return
Press to access and program the Quick Return function.

④ T.Bolus
Press to access T.Bolus injection pop-up window and to perform T.Bolus injection.

⑤ Injection Status Indication
Indicates status such as Air Check, Start OK, etc.

⑥ Iodine Volume
Set value for amount of iodine per unit weight.

⑦ P Limit
Press to set the desired pressure limit for the injection protocol.

⑧ Syringe Information
Display of remaining volume and the syringe size for the A-side and B-side.

⑨ Vol.Reset
Sets the programmed volume of the injection protocol to the volume remaining in the syringe.
This key only appears when the remaining volume of the syringe is less than the programmed volume.

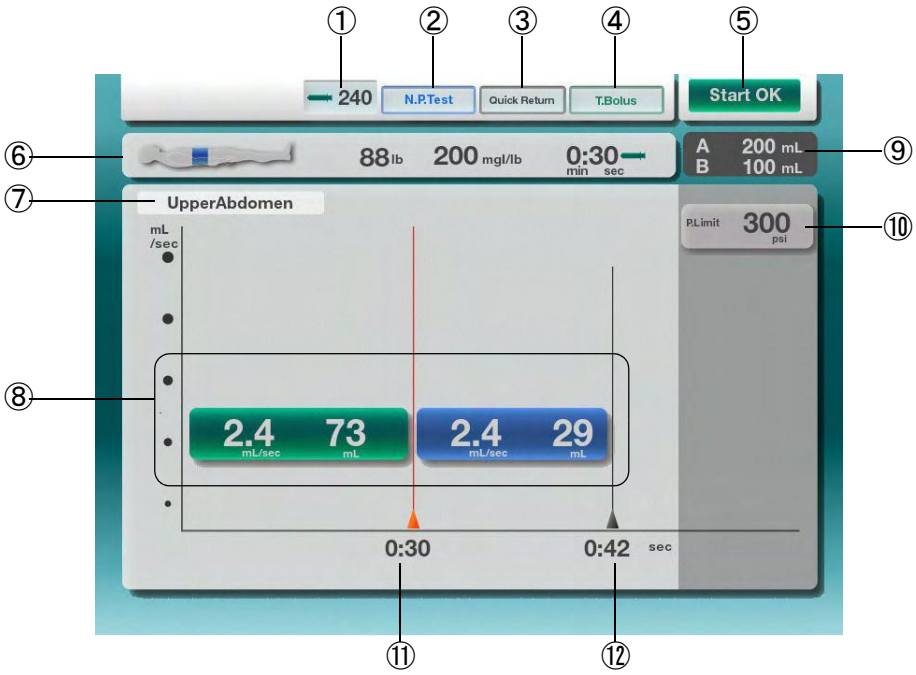
⑩ Examination Area
Select body segment for examination area.

⑪ Weight Key
Select / Enter patient weight.

⑫ Injection Time
Set the amount of time for the injection.

⑬ Injection Pattern
Display of the injection protocol.
Press parameters to alter values.

INJECTION READY SCREEN



① Contrast Concentration Setting Key
Select the contrast media concentration value.

② N.P. Test
Needle Placement Test. Press to access and perform test.

③ Quick Return
Press to access and program the Quick Return function.

④ T.Bolus
Press to access T.Bolus injection pop-up window and to perform T.Bolus injection.

⑤ Injection Status Indication
Indicates status such as Air Check, Start OK, etc.

⑥ Return Key
Press this key to return to the protocol setup.

⑦ Protocol Name Indication
This is the name of the currently displayed protocol if it has been saved.

⑧ Injection Pattern
Shows the protocol to be performed. Always shown in a flow rate and volume format.

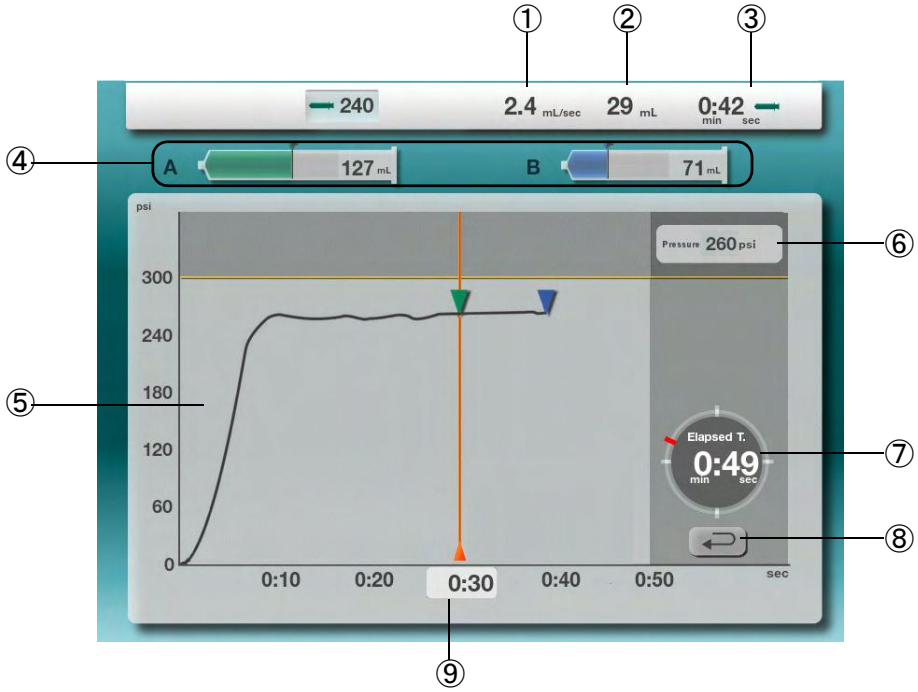
⑨ Syringe Information
Display of remaining volume and the syringe size for the A-side and B-side.

⑩ P.Limit
Displays current set pressure limit. Press to change the pressure limit setting.

⑪ Injection Time
Display of the time required to inject the contrast.

⑫ Injection Time
Total time expected for the contrast and saline injection.

INJECTING / RESULTS SCREEN



① Injection Flow Rate
Display the programmed protocol flow rate.

② Injection Volume
Display the programmed protocol volume.

③ Injection Time
Display the programmed injection time.

④ Syringe Information
Display of remaining volume and the syringe size for the A-side and B-side.

⑤ Real-Time Pressure Graph
Display injection pressure graph in real-time.

⑥ Real-Time Pressure Display
Numerical display of pressure in real-time.

⑦ Elapsed Time Display
Displays amount of time since the start of injection.

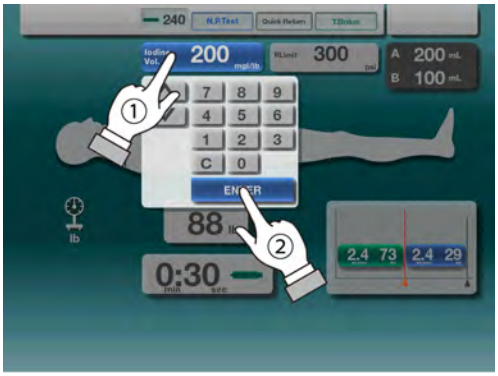
⑧ Return Key
Press to exit the injection result display. (Appears when injection is complete)

⑨ A-Side Injection Time Display
Display the injection time for the A-side.

11.2. Parameter Setup

11.2.1. Iodine Volume Setup

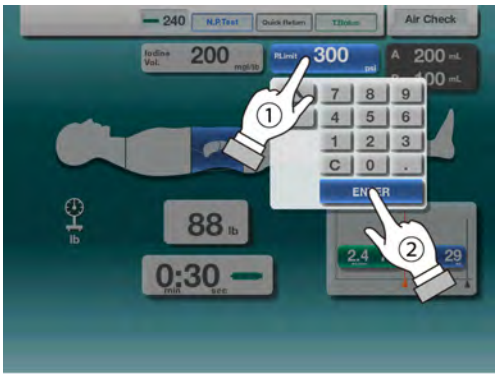
By setting the iodine volume first, the injection volume and flow rate will be calculated accordingly.



- Pressing the Iodine Vol. key will cause the 10-key keypad to be displayed. (1)
- Enter the desired value using the 10-key or the up/down arrow keys, then press the ENTER key. (2)
  (Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation).

Iodine Vol. 200 mgI/lb	For Standard mode injections, the Iodine volume is indicated as the milli-grams of iodine needed per kilogram or per pound of body weight. The injection volume is then calculated using the following formula: *Injection volume[mL] = I_{NEED} [mgI/lb] / I_{CM} [mgI/mL] * Body weight[lb]* I_{NEED} : Iodine volume needed per body weight 1lb I_{CM} : Iodine volume which is included in the CM. In this mode, even if the duration changes, the volume does not change.
Iodine Vol. 10.0 mgI/lb/sec	For Heart mode injections, the Iodine volume is indicated as the milli-grams of iodine volume needed per kilogram or per pound of body weight per second. The injection flow rate is then calculated using the following formula: *Injection flow rate[mL/sec] = I_{NEED} [mgI/lb/sec] / I_{CM} [mgI/mL] * Body weight[lb]* I_{NEED} : Iodine volume needed per body weight 1lb per 1sec I_{CM} : Iodine volume which is included in the CM. In this mode, even if the duration changes, the flow rate does not change.

11.2.2. Pressure Limit Setup



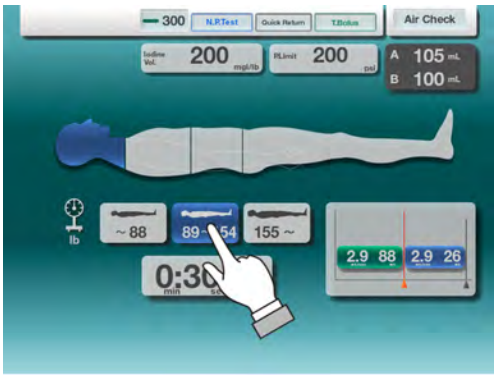
- Pressing the P.Limit key will cause the 10-key keypad to be displayed. (1)
- Enter the desired value using the 10-key or the up/down arrow keys, then press the ENTER key. (2)
  (Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation).

11.2.3. Body Weight Setup

By setting the Body Weight, the injection volume and flow rate will be calculated as described on *page 44 "11.2.1.Iodine Volume Setup"*.

Body Weight Range Input Method

The protocol setup is based on one of three body weight ranges. Detailed information regarding the range selection setup starts on *page 56 "13.Protocol Memory"* section.



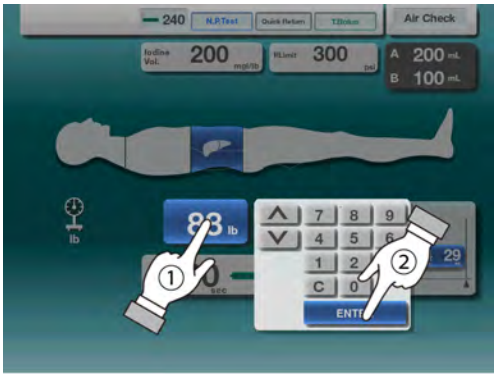
- Press the appropriate Body Weight Range Key for the protocol.

  The active range will remain highlighted.

NOTE: Pressing the same range key twice, will toggle to the Direct Mode.

Body Weight Direct Input Method

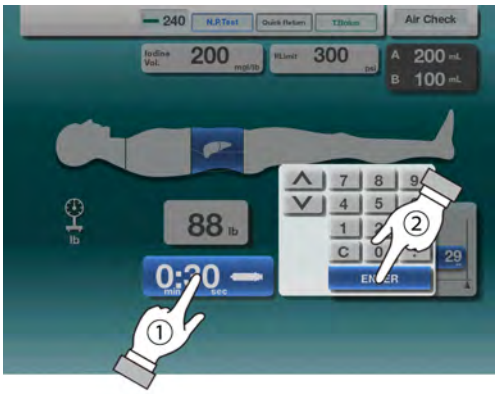
The protocol is setup based upon the direct input of the patient's body weight.



- Pressing the Body Weight Key (1) will cause the 10-key keypad to be presented to the user.
- Enter the patient's body weight using the 10-key numeric keys or using the UP/DOWN arrows. (2)
  Press the ENTER key to accept the value. Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation.

11.2.4. Injection Time Input Method

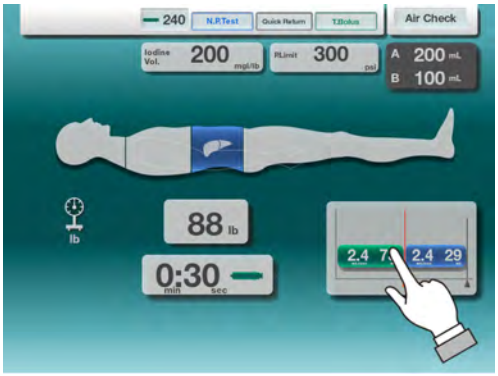
For heart protocols, the injection volume will be calculated and the flow rate will not change.
For standard protocols, the injection flow rate will be calculated and the volume will not change.
Refer to *page 44 "11.2.1.Iodine Volume Setup"*.



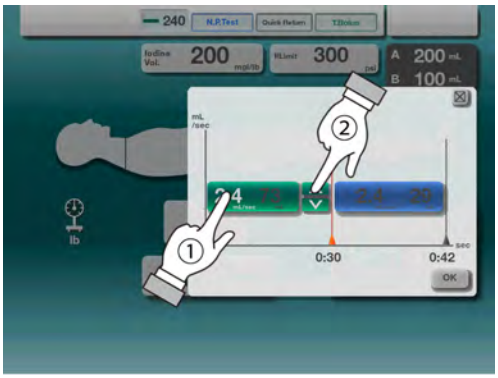
- Pressing the Injection Time (1) will cause the 10-key keypad to be presented to the user.
- Enter the desired injection time using the 10-key numeric keys or using the UP/DOWN arrows.
  Press the ENTER key to accept the value. Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation.

11.2.5. Flow Rate and Volume Input Method

Setting the flow rate or volume, the injection time will be maintained.



- Press the injection pattern area.



After pressing the injection pattern area, the pattern pop-up window will appear.

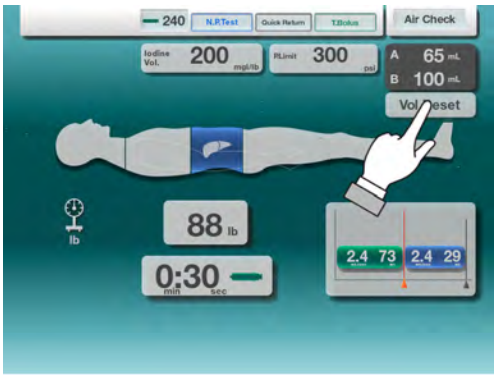
- First, press a parameter area to modify the value (as shown (1)).
- Use the up/down arrow keys (2) to change the value to the desired value.
  After the value is set, press the [OK] key to accept the value.

  Press the ⊠ key at anytime to close the pop-up. Any changes will be disregarded.

11.2.6. Volume Reset

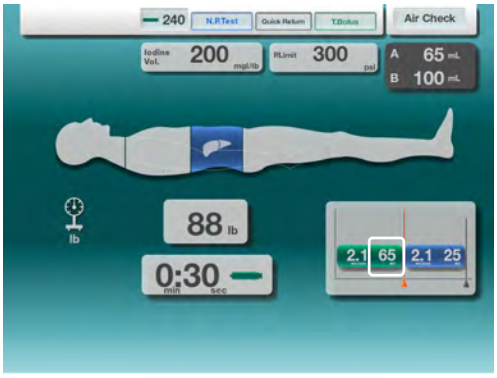
When the syringe volume is less than the programmed volume the Volume Reset key will appear.

- 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

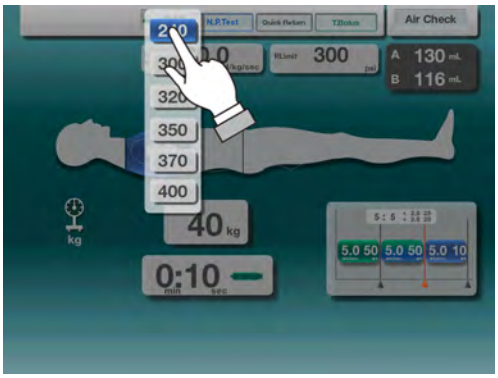
- Press the Vol.Reset key.



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

11.2.7. Contrast Concentration Selection Method

When using the contrast concentration selection method, the injection volume and injection flow rate will be selected automatically.



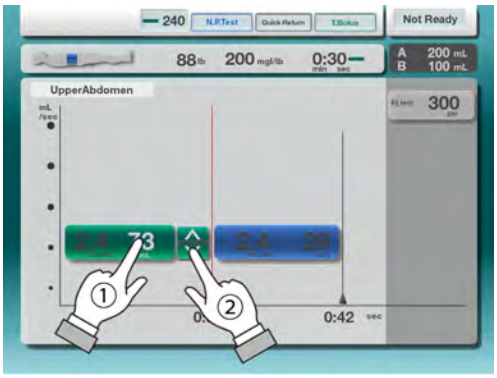
Press the Contrast Concentration Setting Key and the available options will shown in pop-up menu.

- Select the desired contrast concentration by pressing the appropriate key.

11.3. Protocol Changes on the Confirmation Screen

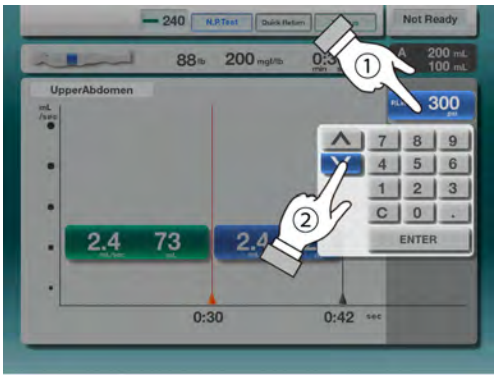
The injection confirmation screen permits changes to the injection volume, flow rate and the pressure limit.

11.3.1. Changing the Injection Volume and Flow Rate



- Press either the volume or flow rate parameter (1) and the up/down arrows will be displayed.
- Enter the new value using the up/down arrows, then press the parameter again or leave the arrows untouched for more than 2 seconds to accept the values.
  Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation.

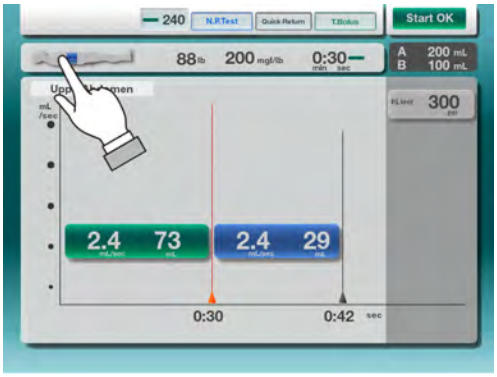
11.3.2. Changing the Pressure Limit



- Press pressure limit key / parameter (1) and the 10-key keypad will be displayed.
- Enter the new value numerically or using the up/down arrows, then press the ENTER key to accept the value.
  Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation.

11.3.3. Changing other Parameter Values

Only the volume, flow rate and pressure limit can be changed on this screen.



- In order to change other values, press the return key (as shown) to return to the protocol setup screen.
- The other parameters can be changed on the setup screen.

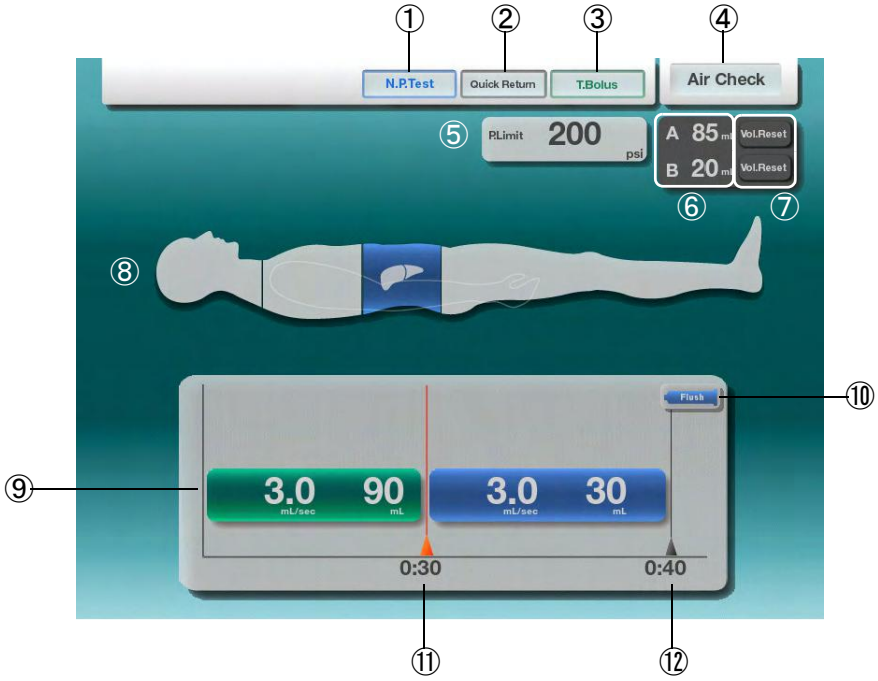
  If a parameter key is pressed, but no further action taken after 5 seconds, the function will de-activate and return to normal without changes.

  To confirm the parameter value change, press the parameter again or press the ENTER key on the 10-key keypad when available.

12. Flow Rate Mode

12.1. Screen Explanation

Setup Screen



① N.P. Test
Needle Placement Test. Press to access and perform test.

② Quick Return
Press to access and program the Quick Return function.

③ T.Bolus
Press to access T.Bolus injection pop-up window and to perform T.Bolus injection.

④ Injection Status Indication
Indicates status such as Air Check, Start OK, etc.

⑤ P Limit
Press to set the desired pressure limit for the injection protocol.

⑥ Syringe Information
Display of remaining volume and the syringe size for the A-side and B-side.

⑦ Vol.Reset
Sets the programmed volume of the injection protocol to the volume remaining in the syringe.
This key only appears when the remaining volume of the syringe is less than the programmed volume.

⑧ Examination Area
Select body segment for examination area.

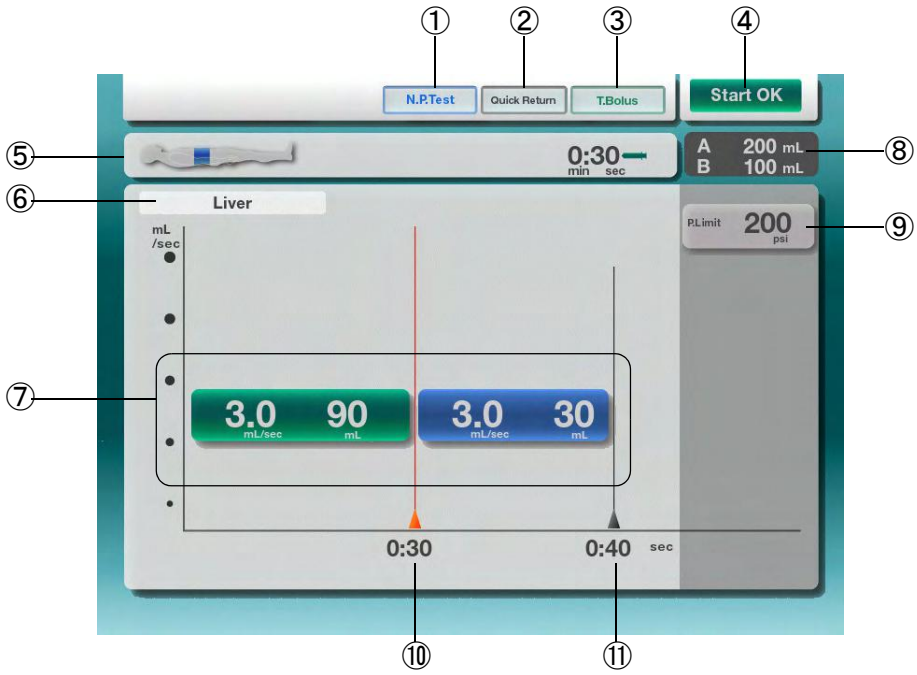
⑨ Injection Pattern
Display of the injection protocol.
Press parameters to alter values.

⑩ Flush
Touch "Flush", when saline is not necessary after the contrast injection.
Saline then will not be injected following a contrast injection.

⑪ Injection Time
Display of the time required to inject the contrast.

⑫ Injection Time
Total time expected for the contrast and saline injection.

INJECTION READY SCREEN



① N.P. Test
Needle Placement Test. Press to access and perform test.

② Quick Return
Press to access and program the Quick Return function.

③ T.Bolus
Press to access T.Bolus injection pop-up window and to perform T.Bolus injection.

④ Injection Status Indication
Indicates status such as Air Check, Start OK, etc.

⑤ Return Key
Press this key to return to the protocol setup.

⑥ Protocol Name Indication
This is the name of the currently displayed protocol if it has been saved.

⑦ Injection Pattern
Shows the protocol to be performed. Always shown in a flow rate and volume format.

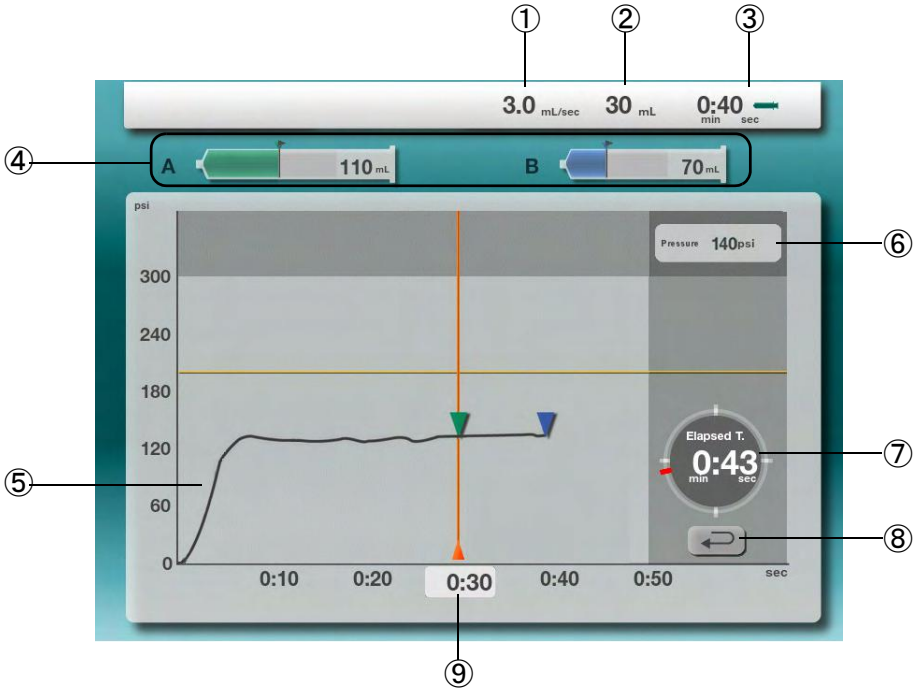
⑧ Syringe Information
Display of remaining volume and the syringe size for the A-side and B-side.

⑨ P.Limit
Displays current set pressure limit. Press to change the pressure limit setting.

⑩ Injection Time
Display of the time required to inject the contrast.

⑪ Injection Time
Total time expected for the contrast and saline injection.

INJECTING / RESULT SCREEN



① Injection Flow Rate
Display the programmed flow rate for the currently injecting phase.

② Injection Volume
Display the programmed volume for the currently injecting phase.

③ Injection Time
Display the expected injection time.

④ Syringe Information
Display of remaining volume and the syringe size for the A-side and B-side.

⑤ Real-Time Pressure Graph
Display injection pressure graph in real-time.

⑥ Real-Time Pressure Display
Numerical display of pressure in real-time.

⑦ Elapsed Time Display
Displays amount of time since the start of injection.

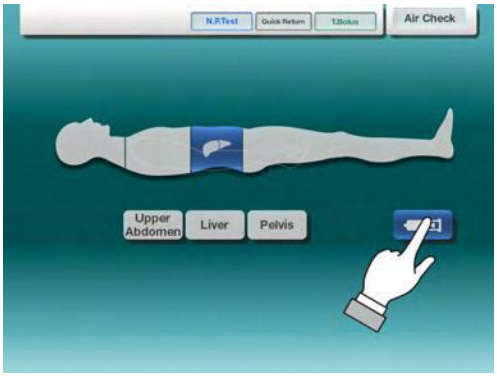
⑧ Return Key
Press to exit the injection result display. (Appears when injection is complete)

⑨ A-Side Injection Time Display
Display the injection time for the A-side.

12.2. Protocol Setup

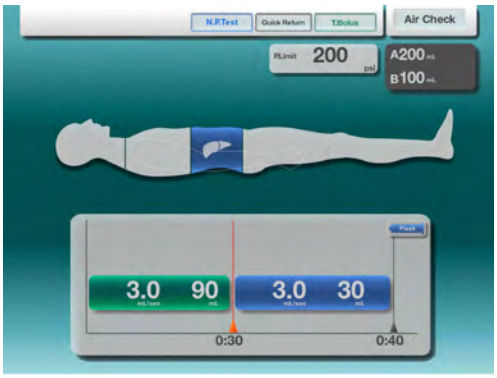
Protocol Setup Description.

12.2.1. Flow Rate Screen Selection



- To access the Flow Rate Mode programming, press the Flow Rate key as shown.

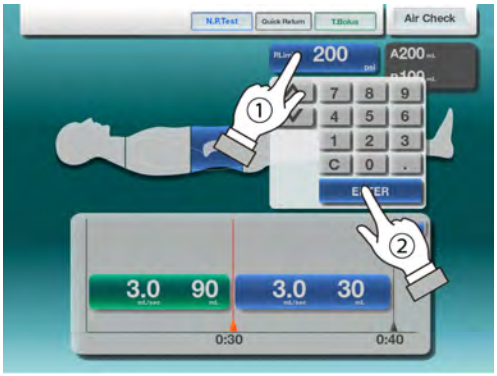
  The Flow Rate injection pattern will be selected based upon the body part selected.



The Flow Rate injection pattern will be presented as shown.

12.2.2. Pressure Limit Setup

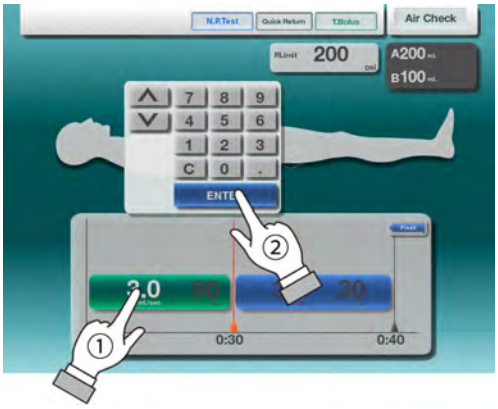
Setting up the injection Pressure Limit.



- Pressing the P.Limit key will cause the 10-key keypad to be displayed.
- Enter the desired value using the 10-key or the up/down arrow keys, then press the ENTER key.
  (Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation.)

12.2.3. Injection Flow Rate and Volume Setting

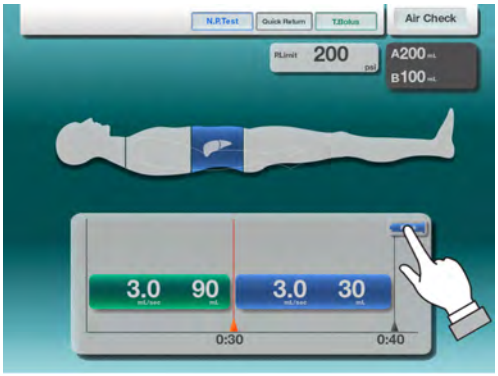
Setting up the injection Flow Rate and Volume.



- Pressing the Flow Rate area or Volume area will cause the 10-key keypad to be displayed. The selected value will highlight for easy identification.
- Enter the desired value using the 10-key or the up/down arrow keys, then press the ENTER key.
  (Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation.)

12.2.4. Flush Setup

Setting up a saline flush following the contrast injection.



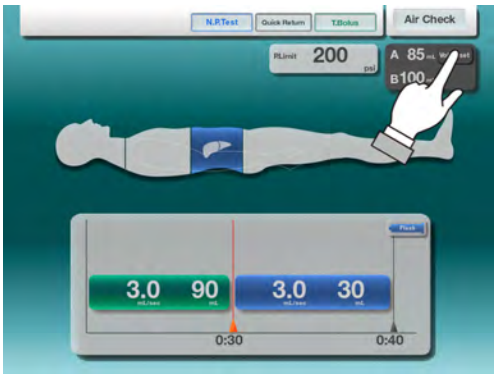
Pressing the Flush key as shown, will toggle the flush ON and OFF.

- When the Flush is ON, the key will be highlighted and the saline injection phase will be shown.
- When the Flush is OFF, the key will be dimmed and the saline injection will be hidden.

12.2.5. Volume Reset

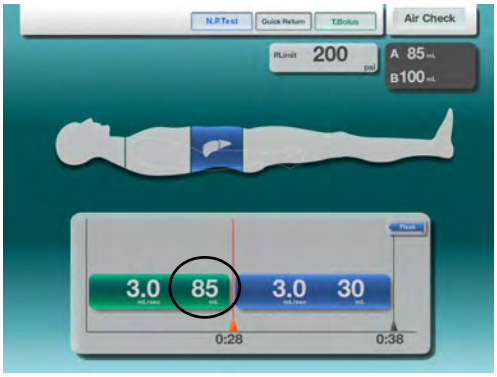
When the syringe volume is less than the programmed volume the Vol.Reset key will appear.

- Pressing the Volume Reset key when the syringe volume is less than the programmed volume will cause the programmed value to be set to the syringe volume.



A-syringe remaining volume: 85mL / Programmed Volume: 90mL

- Press the Vol.Reset key.

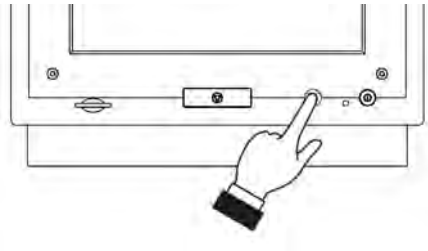


A-syringe volume and programmed volume are equal.

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

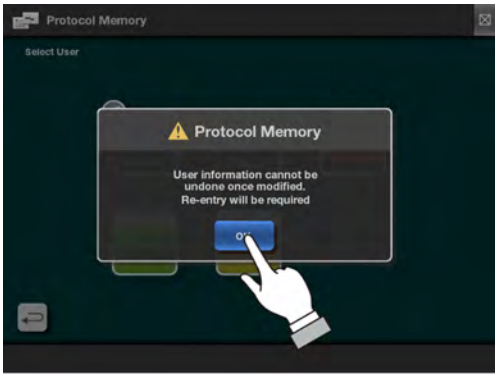
13. Protocol Memory

13.1. Accessing Protocol Memory Menu

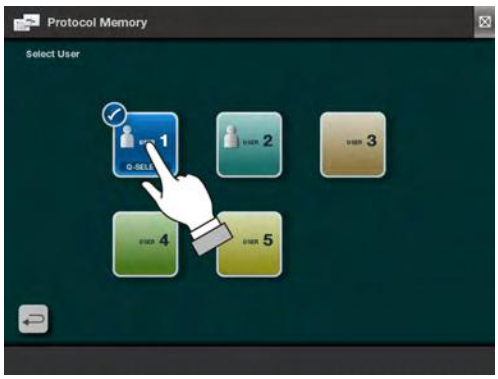


- Press the HOME button on the Console front panel.

- The HOME menu will be displayed. Press the Protocol Memory key.



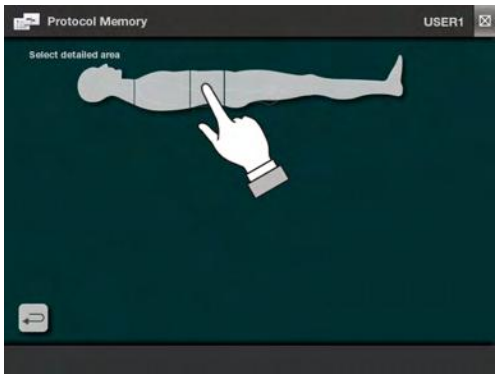
- An informational message will be presented, regarding changes to protocols. Press the OK key to continue.



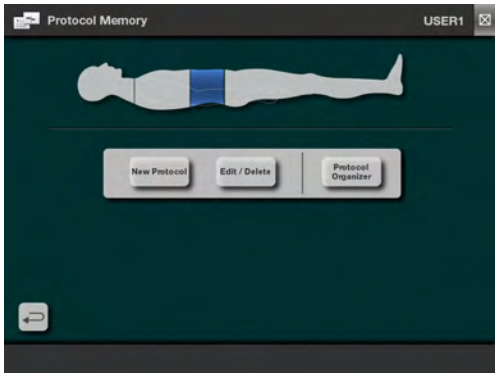
- To set the protocol, first select the desired User.

  To cancel at anytime and return to the HOME screen, press the ⊠ key in the upper right-hand corner.

  To return to the previous screen, press the Return key.



- After selecting the User, the Body Area Selection screen will be presented. Select the desired body area.

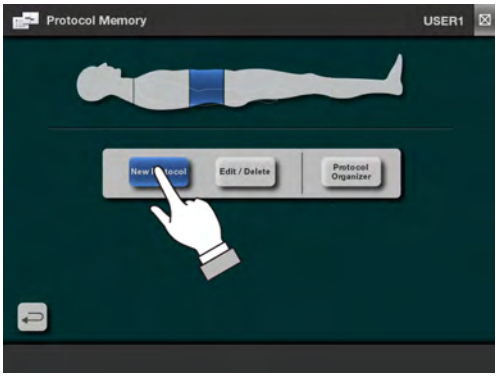


The Protocol Memory options (New Protocol, Edit/Delete, Protocol Organizer) will appear.

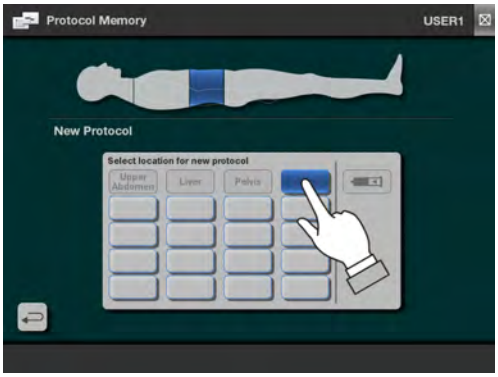
13.2. New Protocol

Setting up a new protocol for a selected body area.

Refer to *page 56 "13.1.Accessing Protocol Memory Menu"* for details on accessing this function.

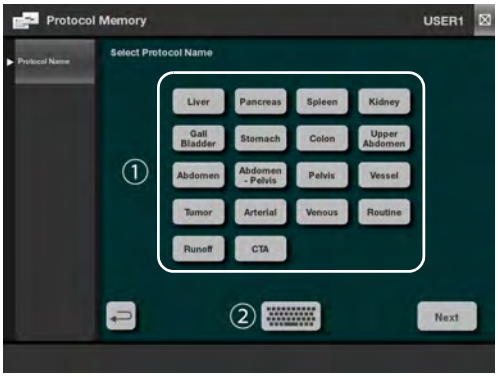


- To create a new protocol, press the New Protocol key on the menu.



After selecting New Protocol, the protocol location selection screen will appear.

- Select the desired location to store the new protocol.

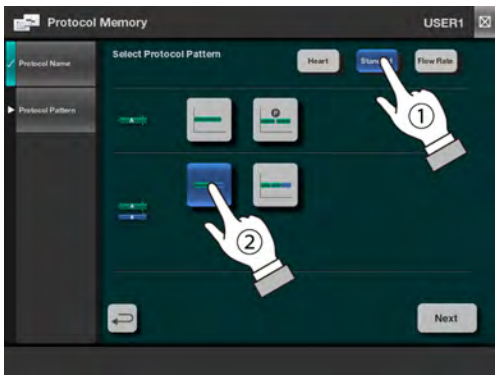


After selecting the desired location, the screen will change to allow the selection of a standard protocol name or will provide the option to enter a custom name.

- The standard list of protocol names will be as shown (1).

  To enter a custom protocol name, press the keyboard button (2). For detailed information regarding the keyboard, refer to *page 77 "13.5.Alphabetic Keyboard Overview"* section.

- After the protocol name is set, press the Next button in the lower right-hand of the display.

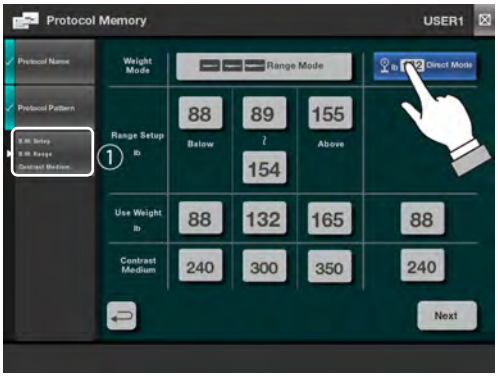


The Protocol Pattern selection will be presented after the protocol name is set.

- First, select the type of injection pattern from the top row of buttons. (Heart, Standard, Flow Rate)
  The various injection patterns will be shown below the type of injection pattern buttons. Choose the Standard type of protocol patterns from the group of icons presented. For Flow Rate type of pattern setup, refer to *page 62 "13.2.1.Flow Rate Protocol Setup"* section.
- Press the Next button to continue.

Injection Pattern List:

Mode	EU Version	US Version
Heart	A A → B A → A+B A → A+B → B	A A → B A → A+B A → A+B → B
Standard	A A → Pause → A A → B A → A → B	A A → Pause → A A → B A → A → B
Flow Rate	A A → A → A → A → A A → Hold → A A → B B → A → A+B → B A+B → B A → A → A → A → B A → Pause → A → B A → A+B A → A+B → B	A A → Pause → A A → B A+B A → Pause → A → B A → A+B → B A → A → B



- The left side menu will update to show the next step of the protocol definition. (The screen shown is for the Standard protocol type)

  There are two different types of Body Weight protocol available, range selection or direct entry. For each type the detailed setting will be shown, including the ranges with each use weight and contrast concentration.

  To adjust any of the detailed values shown, press the value then use the Up / Down arrows at the bottom center to increase or decrease the value.

- Press the Next button to continue.

- The left side menu will update to show the next step of the protocol definition. Each of the detailed items will be listed in the menu.

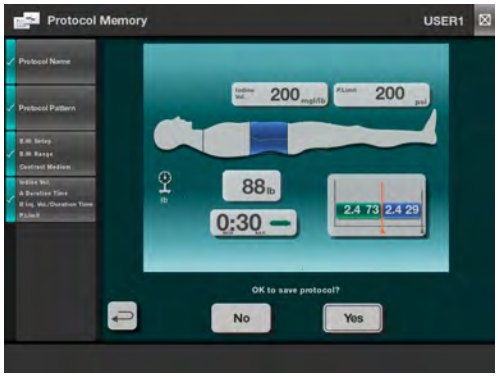
  To adjust any of the detailed values shown, use the corresponding Up/Down arrows to increase or decrease the value.

  For injection patterns that also use a B-side injection, the behavior of the B-side flow rate, volume and injection time are selectable using the selection button (1), to select the behaviors in shown in the table below.

B-side Behavior Settings:

Injection Pattern	Injection Flow Rate	Injection Volume	Injection Time
1	Same as A-side [1]	User Programmed [2]	Automatic [3]
2	Same as A-side	Automatic	User Programmed
3	Automatic	User Programmed	User Programmed

1. Same as A-side: B-side flow rate will be set to the A-side flow rate automatically
2. User Programmed: The user sets the desired value.
3. Automatic: Based on the other parameters, this value will be calculated.

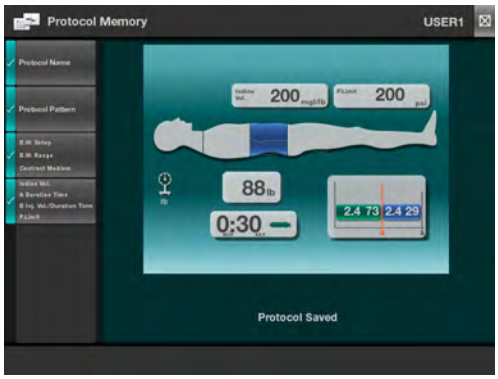


The final screen presented is the protocol confirmation and saving screen. The protocol will be presented as shown, and the option to save or not save will be at the bottom.

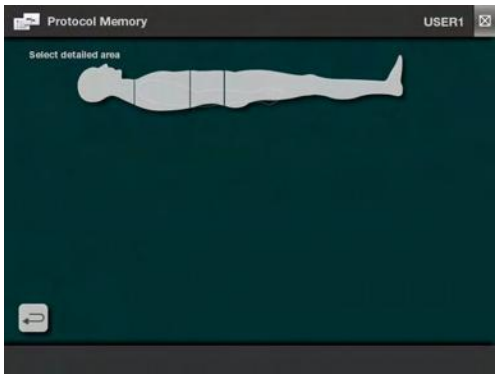
- To save the protocol, press Yes.

  To return to the protocol setup process, press No.

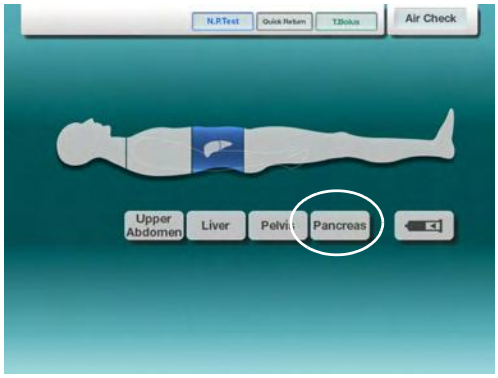
The protocol cannot be modified on this screen



- Pressing Yes (to save) on the previous screen will store the protocol in memory. A saved confirmation will be shown briefly.

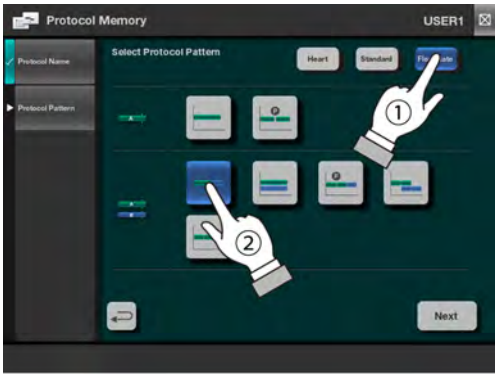


- The screen will then transition back to the initial protocol setup screen.
  Press the Return key to the main screen.

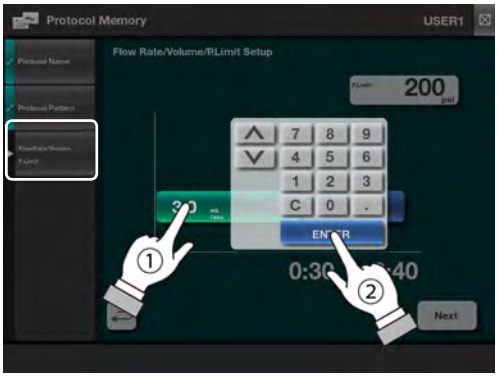


The newly created protocol will be shown. Press the corresponding button to access the protocol.

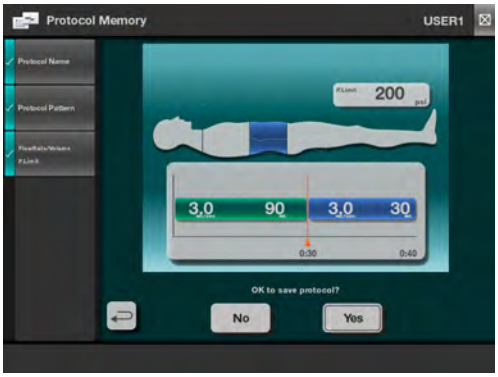
13.2.1. Flow Rate Protocol Setup



- Before this step, be sure to enter the protocol name as previously described.
- Select the Flow Rate type by pressing the Flow Rate button (1).
- Select the desired protocol pattern (2)
- Press Next button to continue.



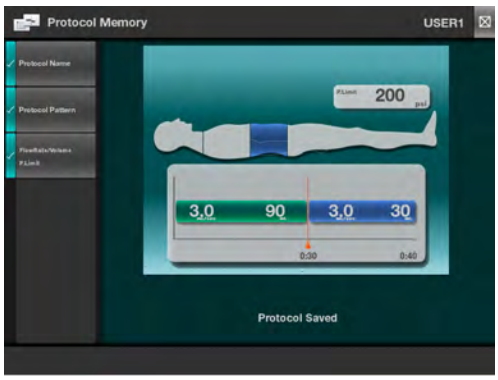
- Once the protocol pattern is fixed, the Flow Rate and Volume parameters can be set.
- Select the Flow Rate or Volume parameter by pressing the corresponding area. The 10-key keypad will appear. Enter the desired value using the 10-key or the up/down arrow keys, then press the ENTER key. (Refer to *page 30 "9.4.2.10-Key Keypad Operation"*).
- Press the Next key to continue.



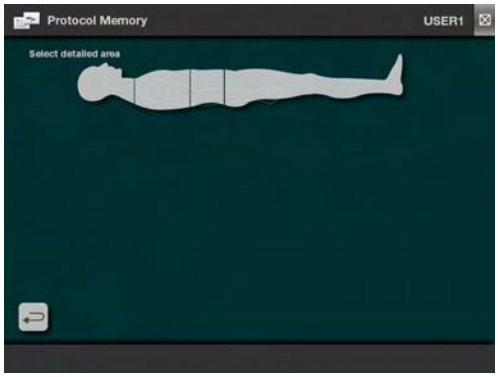
- The protocol confirmation screen will be presented before the protocol is saved
- To save the protocol, press the Yes key.

  Press the No key, to return to the protocol setup.

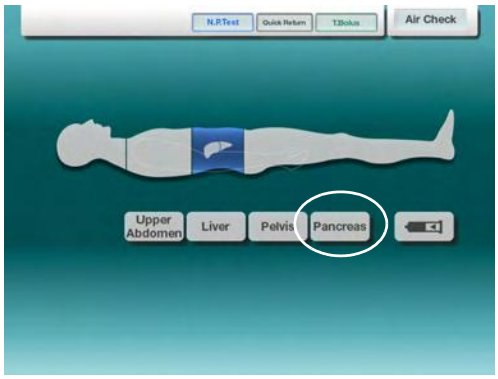
The protocol cannot be modified on this screen.



- Pressing Yes (to save) on the previous screen will store the protocol in memory. A saved confirmation will be shown briefly.



- The screen will then transition back to the initial protocol setup screen.
  Press the Return key to the main screen.

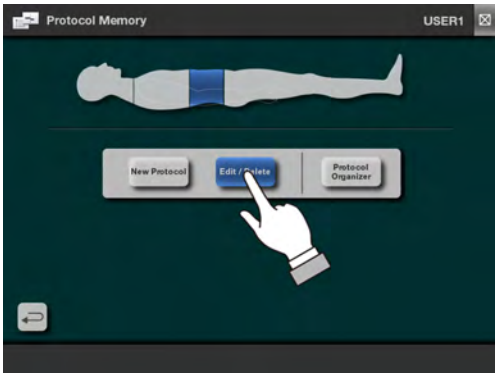


The newly created protocol will be shown. Press the corresponding button to access the protocol.

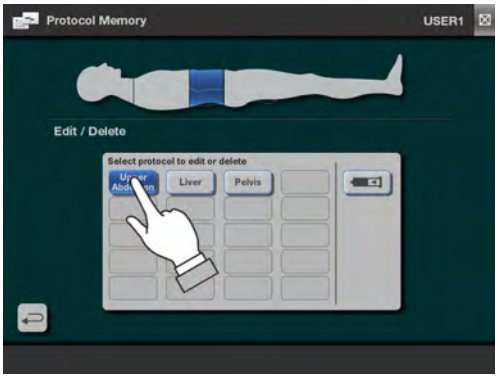
13.3. Edit / Delete Protocol

An existing protocol can be edited or deleted as follows.

To access Edit/Delete Protocol refer to *page 56 "13.1.Accessing Protocol Memory Menu"* section.

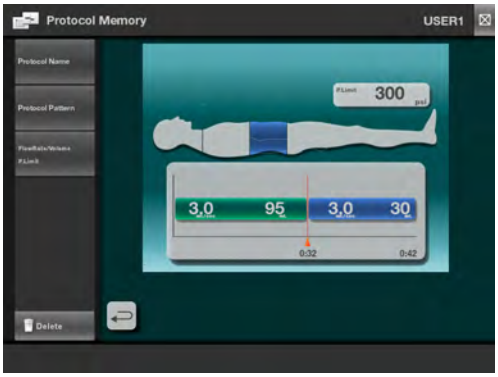


- Press the Edit / Delete key on the Protocol Memory menu.



The currently available protocols will appear.

- Select the desired protocol to edit or delete.



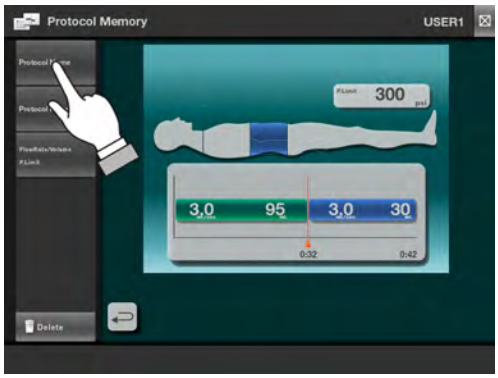
The selected protocol summary screen will be displayed. Based on the item that is desired to be modified press the appropriate menu item on the left.

- To modify the Protocol Name refer to *page 65*.
- To modify the Protocol Pattern refer to *page 67*.
- To modify the injection details refer to *page 70*.
- To delete an injection refer to *page 74*.

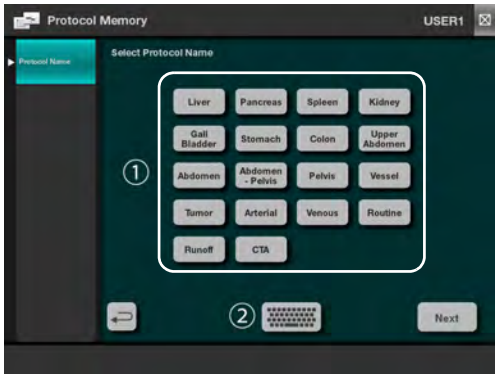
13.3.1. Modifying the Protocol Name

The selected protocol summary screen will be displayed.

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



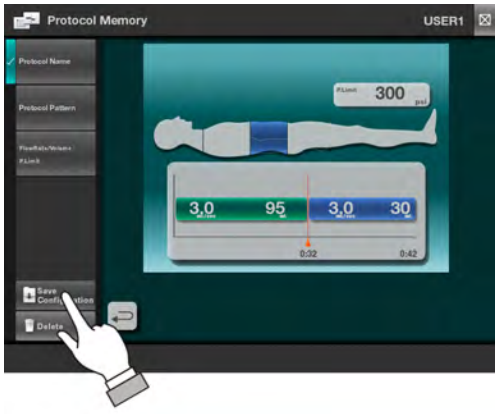
- Select the Protocol Name from the left-side menu.



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.



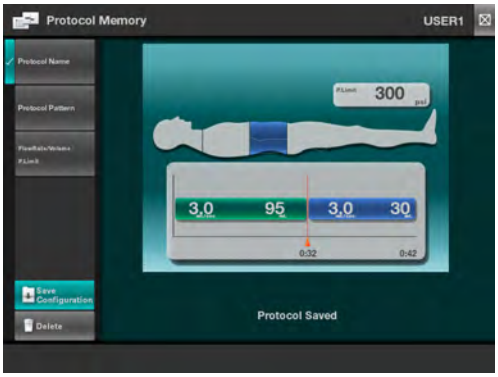
- Press the Save Configuration key on the left-side menu as shown.

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

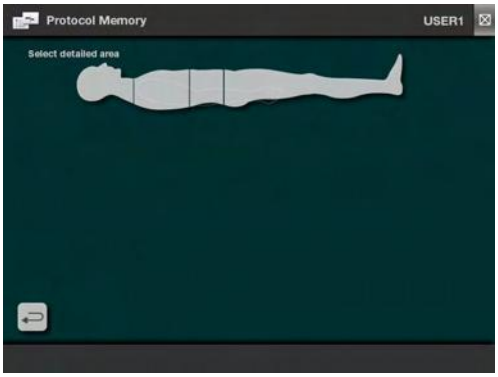
  To save the protocol, press the Yes key.
  Press the No key, to return to the protocol setup.

  Press Yes to confirm overwriting the previous version of the protocol.

Notice: This cannot be undone.



- A brief confirmation message of the saved protocol will be displayed then the screen will then transition back to the initial protocol setup screen.

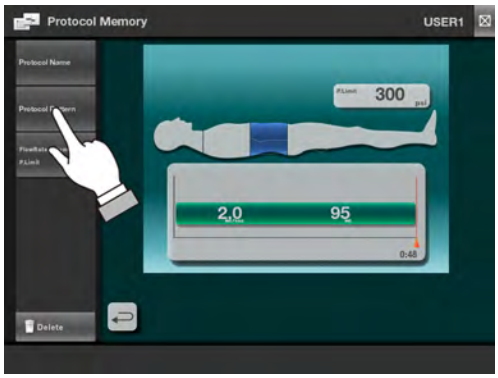


- The screen will return to the main protocol screen. Press the Return key to the main screen.

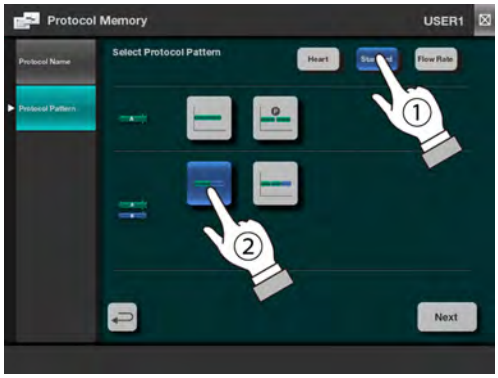
13.3.2. Modifying the Protocol Pattern

The selected protocol summary screen will be displayed.

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

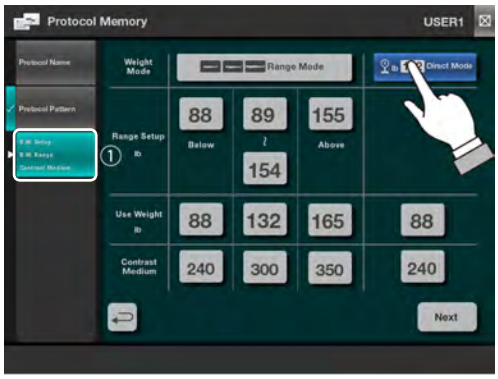


- Select the Protocol Pattern from the left-side menu.



Select the type of protocol pattern, Heart, Standard, and Flow Rate as shown (1).

- For Flow Rate type of pattern setup, refer to *page 62 "13.2.1.Flow Rate Protocol Setup"* section.
- Next, select the injection pattern as shown by (2).
- Press the Next key to continue.



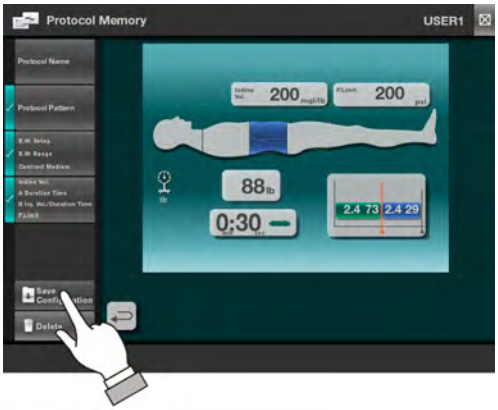
- The left side menu will update to show the next step of the protocol definition. (The screen shown is for the Standard protocol type)

  There are two different types of Body Weight protocol available, range selection or direct entry. For each type the detailed setting will be shown, including the ranges with each use weight and contrast concentration.

  To adjust any of the detailed values shown, press the value then use the Up / Down arrows at the bottom center to increase or decrease the value.
- Press the Next button to continue.

- The left side menu will update to show the next step of the protocol definition. Each of the detailed items will be listed in the menu.

  To adjust any of the detailed values shown, use the corresponding Up/Down arrows to increase or decrease the value.
  For injection patterns that use the B-side, refer to the table on page 60 for the behavior settings for B-side injections.



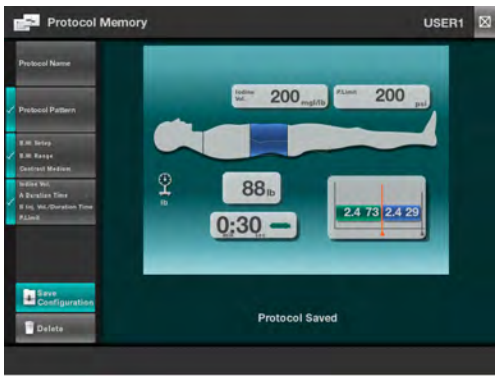
- Press the Save Configuration key on the left-side menu as shown.

- The protocol confirmation screen will be presented before the protocol is saved.

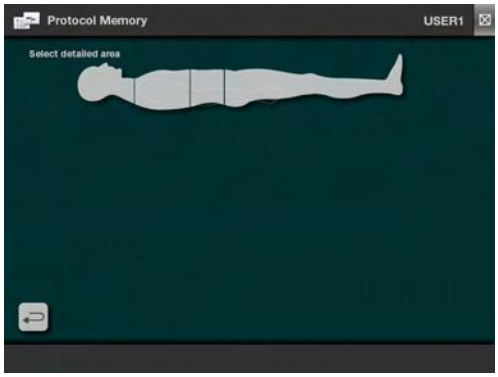
  To save the protocol, press the Yes key.
  Press the No key, to return to the protocol setup.

  Press Yes to confirm overwriting the previous version of the protocol.

Notice: This cannot be undone. The previous protocol data will be overwritten.



- A brief confirmation message of the saved protocol will be displayed then the screen will then transition back to the initial protocol setup screen.

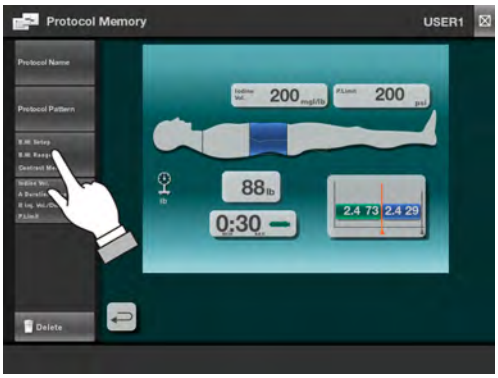


- The screen will return to the main protocol screen. Press the Return key to the main screen.

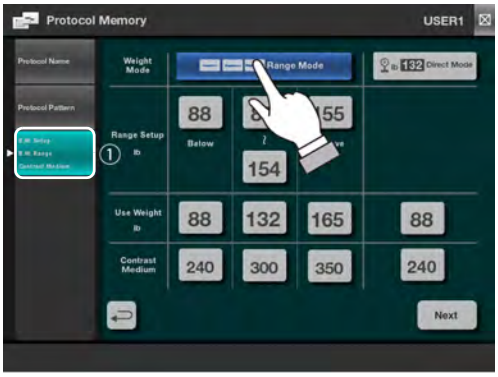
13.3.3. Modifying the protocol details

The selected protocol summary screen will be displayed.

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



- Select the body weight parameter settings from the left-side menu.



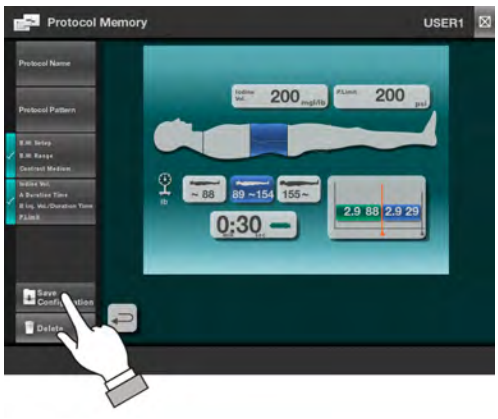
- Select the key (1) as shown in the left-side menu.

  There are two different types of Body Weight protocol available, range selection or direct entry. For each type the detailed setting will be shown, including the ranges with each use weight and contrast concentration.

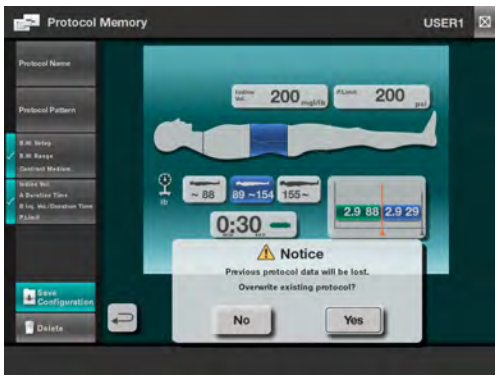
  To adjust any of the detailed values shown, press the value then use the Up / Down arrows at the bottom center to increase or decrease the value.
- Press the Next key to continue.

- The left side menu will update to show the next step of the protocol definition. Each of the detailed items will be listed in the menu.

  To adjust any of the detailed values shown, use the corresponding Up/Down arrows to increase or decrease the value.
  For injection patterns that use the B-side, refer to the table on *page 60* for the behavior settings for B-side injections.



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

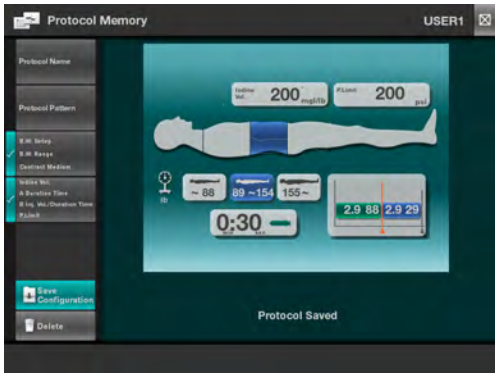


- The protocol confirmation screen will be presented before the protocol is saved.

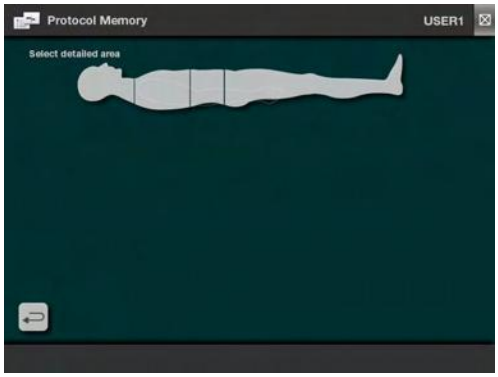
  To save the protocol, press the Yes key.
  Press the No key, to return to the protocol setup.

  Press Yes to confirm overwriting the previous version of the protocol.

Notice: This cannot be undone. The previous protocol data will be overwritten.

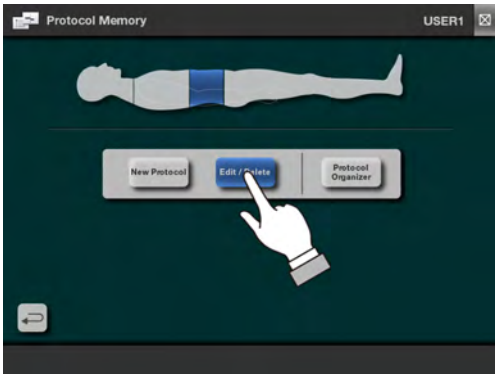


- A brief confirmation message of the saved protocol will be displayed then the screen will then transition back to the initial protocol setup screen.

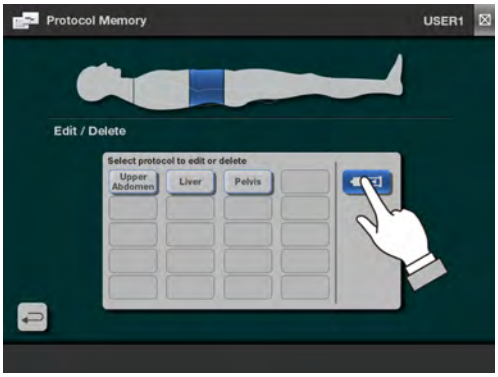


- The screen will return to the main protocol screen. Press the Return key to the main screen.

13.3.4. Flow Rate Mode

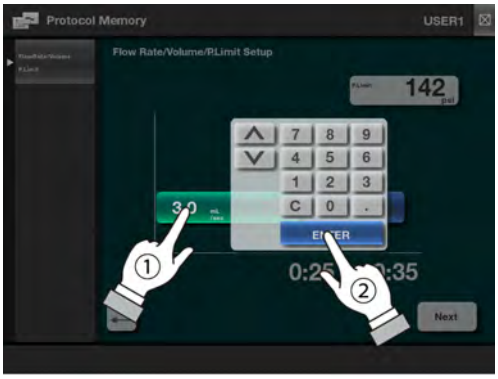


- Press the Edit / Delete key as shown.

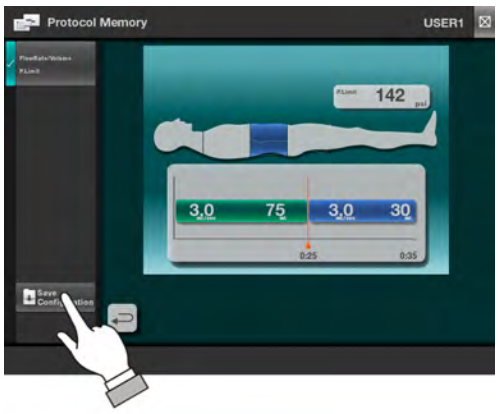


The protocol memory screen will appear as shown.

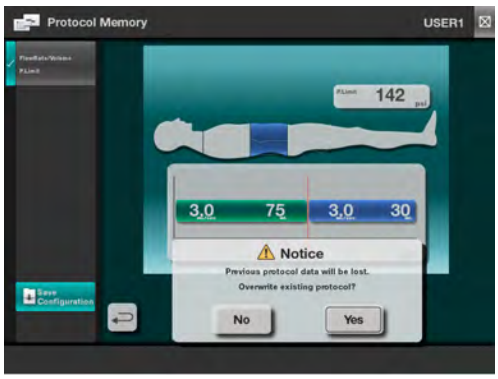
- Press the syringe icon key as shown to change to the Flow Rate protocol setup screen.



- The left side menu will indicate the values that are available for setup.
- Press either the volume or flow rate parameter (1) and the 10-key keypad will be displayed.
- Enter the new value numerically or using the up/down arrows, then press the ENTER key to accept the value. Refer to *page 30 "9.4.2.10-Key Keypad Operation"* for details of keypad operation.
- Press the Next key to continue.



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

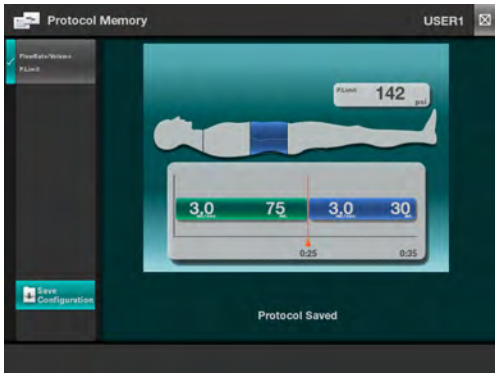


- The protocol confirmation screen will be presented before the protocol is saved.

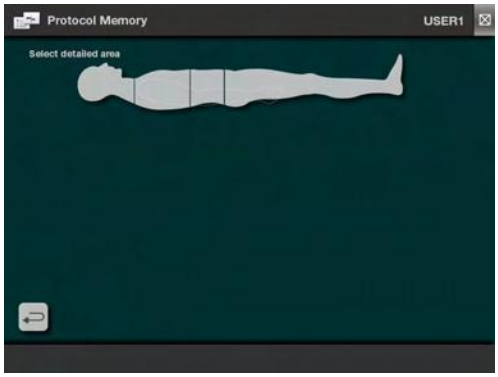
  To save the protocol, press the Yes key.
  Press the No key, to return to the protocol setup.

  Press Yes to confirm overwriting the previous version of the protocol.

Notice: This cannot be undone. The previous protocol data will be overwritten.



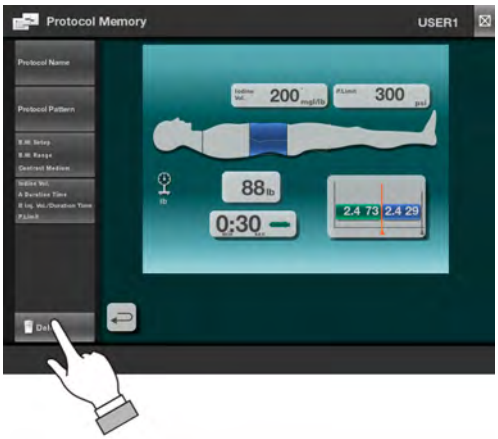
- A brief confirmation message of the saved protocol will be displayed then the screen will then transition back to the initial protocol setup screen.



- The screen will return to the main protocol screen. Press the Return key to the main screen.

13.3.5. Delete Protocol

Select the protocol to be deleted, the selected protocol summary screen will be displayed.
To access this function refer to *page 64 "13.3.Edit / Delete Protocol"* section.

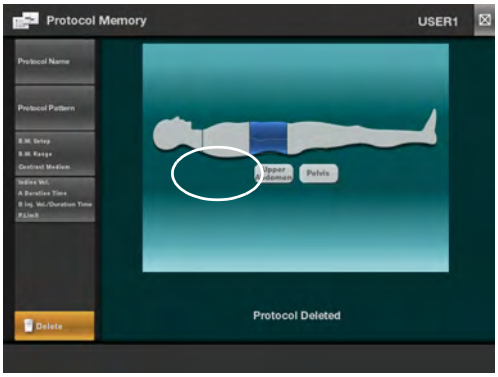


- Select the Delete key (1) as shown in the left-side menu.

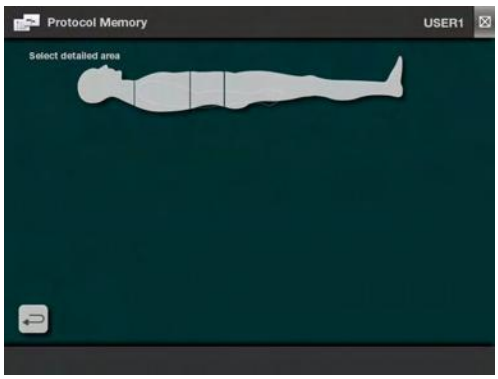
- Press Yes to delete the protocol.

  Press No to cancel and keep the protocol.

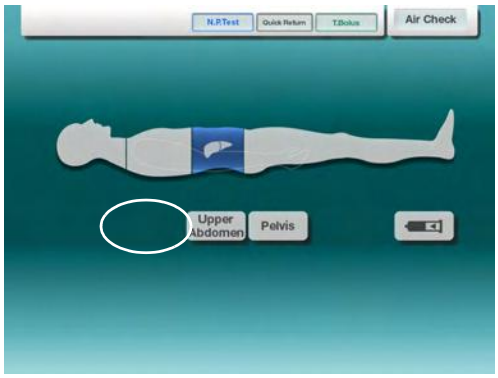
Notice: The delete protocol function permanently deletes the protocol from memory and it cannot be undone.



- The screen shown at the left will appear briefly indicating the Delete protocol is completed, and the protocol is removed from memory.



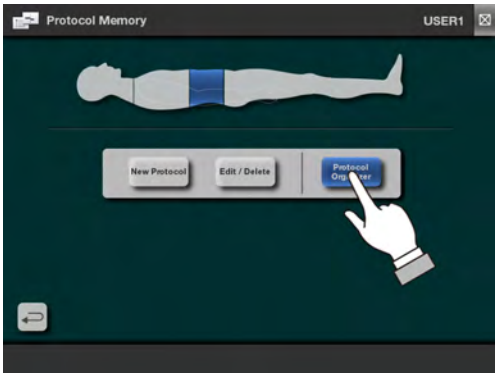
- The screen will return to the main protocol screen. Press the Return key to the main screen.



The selected protocol will be deleted.

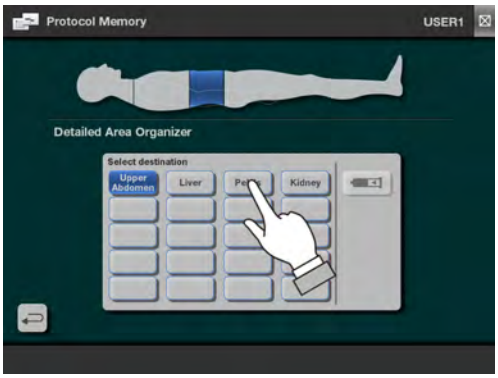
13.4. Protocol Organizer

Organizing the protocol memory.



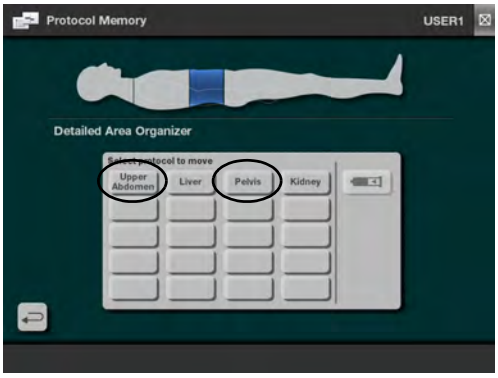
- Press the Protocol Organizer key on the menu as shown.

- The protocols available will appear in the menu. Select the desired protocol to move.



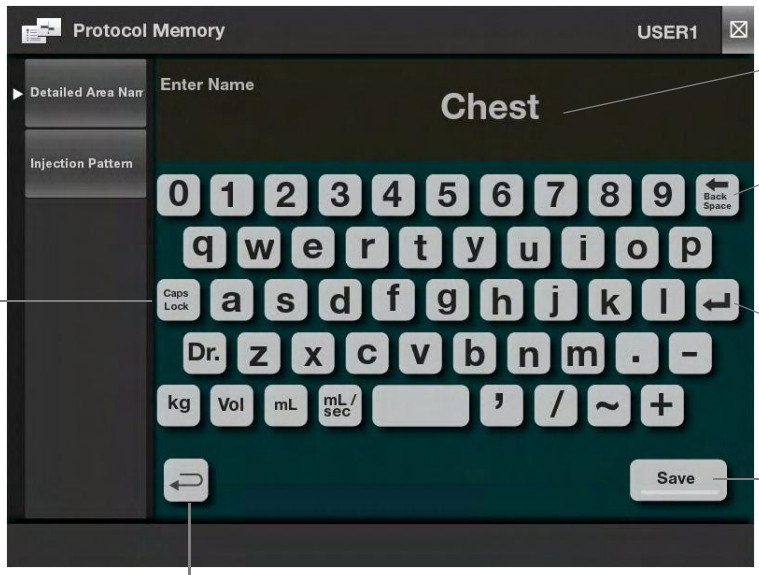
- To move the selected protocol, press another protocol or an empty location.

The protocols will switch locations. All protocol data will be move accordingly.



- The protocol menu will update showing the changes.

13.5. Alphabetic Keyboard Overview



- Typed characters will appear in the Protocol Name Area as entered.
- After the protocol name is entered, press the Save key to complete.

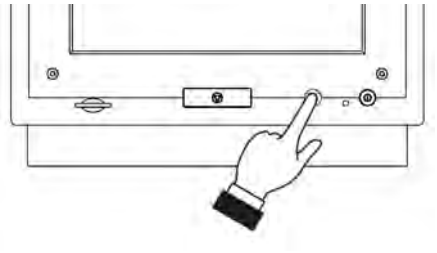
SUPPLEMENTAL EXPLANATION

- [Caps Lock] key allows changing between upper case and lower case characters.
- Enter key is used to create a second line of text for the protocol name
- The protocol name can have one or two lines, each having 16 characters.
- If an incorrect character is entered, use the Backspace key to delete the last character.
- To cancel the protocol name entry, press the Return key.

14. User Configuration

User configuration settings.

14.1. User Configuration Setup Description



To start, press the [HOME] button on the Console front panel.

The HOME screen will appear.

- Press the User Configuration key as shown.

A pop-up message will appear indicating that User Configuration changes cannot be undone.

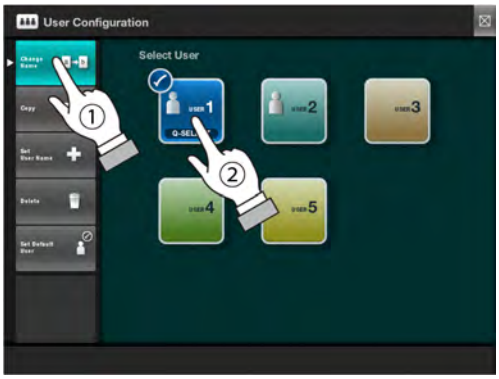
- Press [OK] to continue.

- The user configuration menu screen will appear after pressing OK.

  To cancel the user configuration process, press the ⊠ key.
- To change User name refer to *page 80*
- To copy a user refer to *page 81*
- To set user name refer to *page 82*
- To delete user refer to *page 83*
- To Set Default User refer to *page 84*

14.2. Change User Name

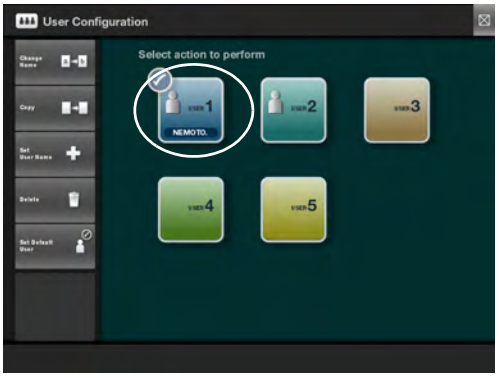
Use these steps to change the user name.



- To change the User Name, press the Change Name key (1).
- After that, select the user (2). A blank user cannot be selected.

- The screen will change to the keyboard with the current user name displayed.

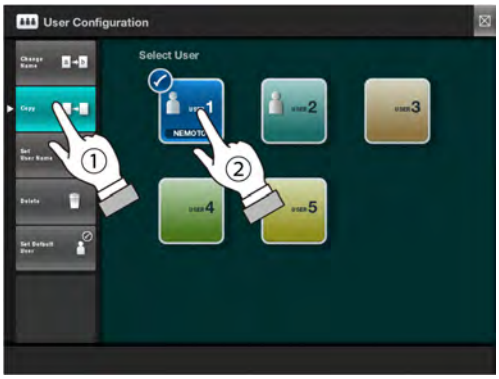
  For information on using the keyboard function, refer to *page 86, "14.8.Overview of User Name Keyboard"* section.
  Use the keyboard as required to update the name.
- Press the Save key when completed to save the changes.



The screen will return to the User Configuration main screen. The new name will be shown for the user.

14.3. Copy User

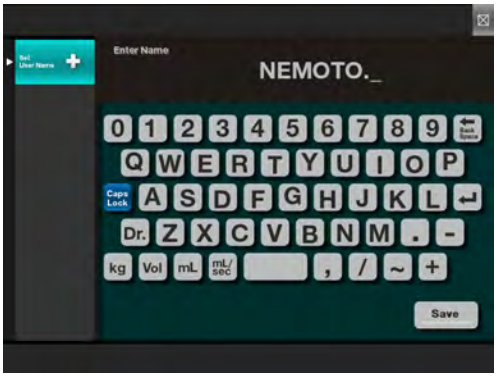
Use these steps to copy a User.



- To copy a user, press the Copy key (1).
- After that, select the user (2). A blank user cannot be selected.

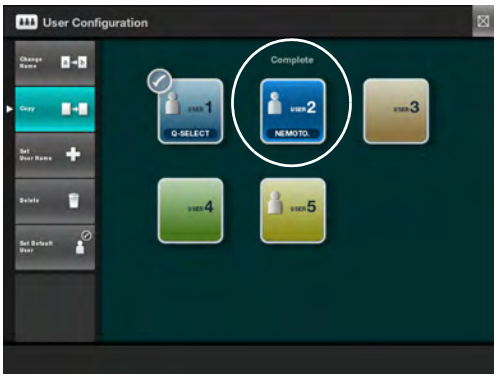
After selecting the user, arrows indicators will appear under the available locations to copy to.

- Press the desired location and the User will be copied. The original user data does not change.



- The screen will change to the keyboard with the current user name displayed.

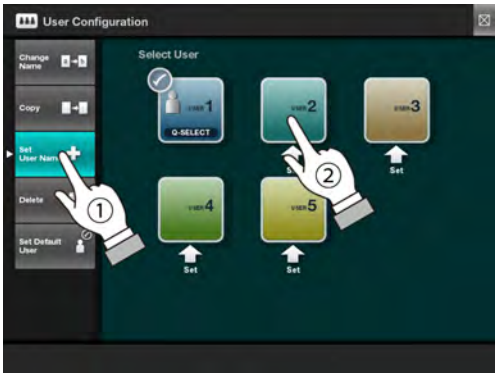
  For information on using the keyboard function, refer to *page 86, "14.8.Overview of User Name Keyboard"* section.
  Use the keyboard as required to update the name.
- Press the Save key when completed to save the changes.



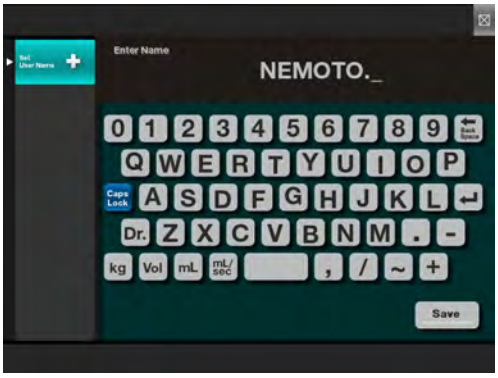
- The screen will return to the User Configuration main screen. The copied user will be shown.

14.4. Set User Name

Use these steps to set a new User name.

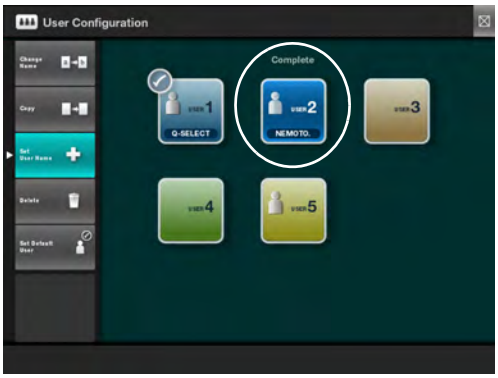


- To set user name, press the Set User Name key (1).
- After that, select the user (2). A blank user must be selected.



- The screen will change to the keyboard with the current user name displayed.

  For information on using the keyboard function, refer to *page 86, "14.8.Overview of User Name Keyboard"*section.
- Use the keyboard as required to update the name. Press the Save key when completed to save the changes.
- Press the Save key to save the User Name.



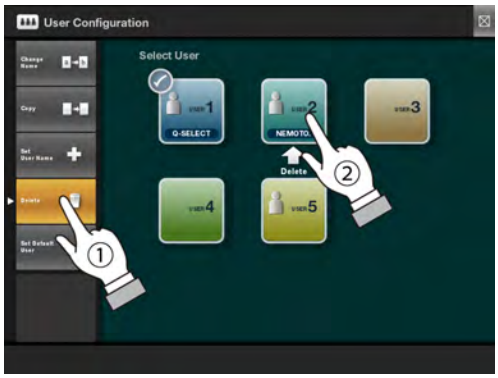
The screen will return to the User Configuration main screen. The new user name will be shown.

14.5. Delete User

Use these steps to delete a User.

IMPORTANT INFORMATION

- Once a user is deleted it cannot be undone. Information is lost.
- User 1 cannot be deleted, but the name can be changed.



- To delete a user, press the Delete key (1).
- After that, select the desired user (2).

Confirm the Delete function

- Press the Yes key to continue deleting the user.

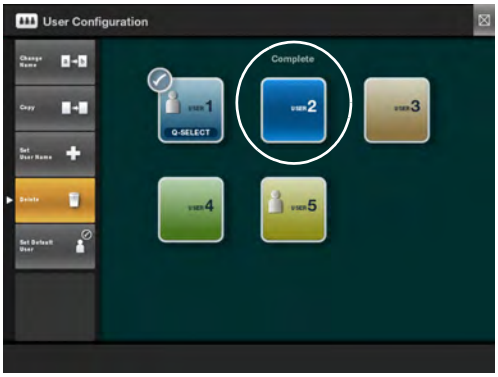
  Press the No key to abort and return to the User Configuration Main screen.

After pressing Yes on the previous screen a delete confirmation pop-up will be displayed.

- Press Yes to confirm deleting user.

  Press No to cancel and return to User Configuration main screen.

Caution: The Delete User function permanently deletes the user from memory and it cannot be undone.



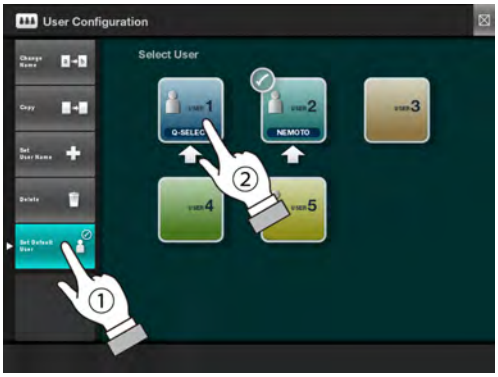
- The screen will return to the User Configuration main screen. A blank user will be shown in place of the previous deleted user.

14.6. Set Default User

The Default User is the user that is used upon startup of the device.

14.6.1. Setting the Default User

Use these steps to set the Default User.



- To set the default user, first select the desired user (1).
- Next, press the Set Default User key (2).

The new Default User to be set with a check mark in the upper left-hand corner. A confirmation message will appear at the bottom of the screen.

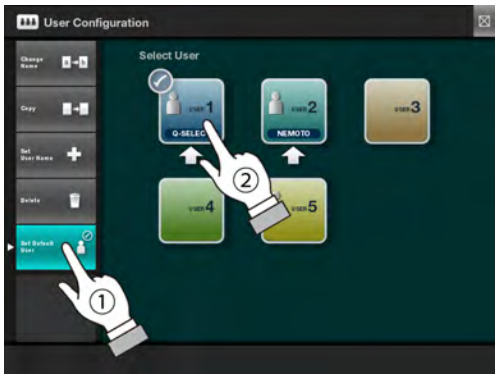
- Press Set Default key to confirm setting the new default user.

  Press Cancel key it abort and keep the current default user.

If the Set Default key was pressed on the previous screen, the new default user will be set and the User Configuration screen will appear.

14.7. Delete Default User

Use these steps to delete a Default User.



- Press the Set Default User key.
- Select a user to be deleted.

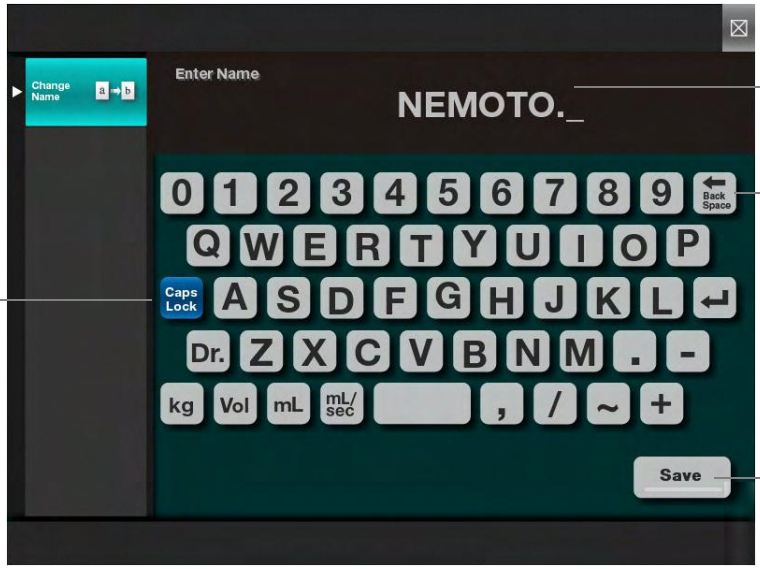
A confirmation message will appear at the bottom of the screen.

- Press "Delete" to delete the Default User.

  Press "Do not delete" to maintain and not delete the Default User.

If "Delete" was selected on the previous screen, the Default User will be deleted and the check mark in the upper left-hand corner will disappear from the user.

14.8. Overview of User Name Keyboard



User Name Area

Backspace Key
Use this key to delete one character at a time, starting from the last character typed.

Caps Lock Key
Press this key to make alpha characters capitalized.

Save Key
Press this key to save this name for the protocol.

- Typed characters will appear in the User Name Area as entered.
- After the protocol name is entered, press the Save key to complete.

SUPPLEMENTAL EXPLANATION

- [Caps Lock] key allows changing between upper case and lower case characters.
- Enter key is used to enter the user name, but does not save.
- The user name may be up to 16 characters
- If an incorrect character is entered, use the Backspace key to delete the last character.

15. Needle Placement Test

The Needle Placement Test (NPT) is provided as an aid to the medical professional for checking the patency of the vein, catheter, etc. before the injection process. To access the NPT press the N.P.Test key located at the top of the Console display.

The Needle Placement Test (N.P.Test) 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".

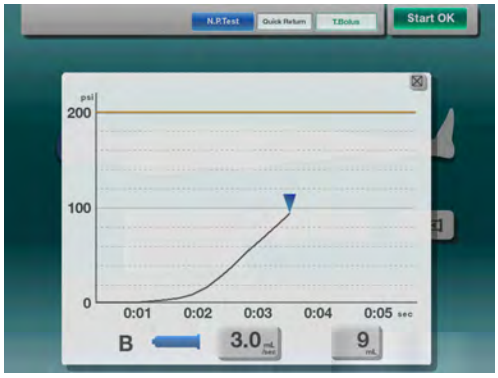
These parameters will be displayed for the user.

Pressing the N.P.Test key (without an injection first selected) will cause the Needle Placement Test pop-up window to appear. The NPT is available anytime saline is available.

B-side front and rear Powerhead LEDs will flash rapidly and simultaneously.

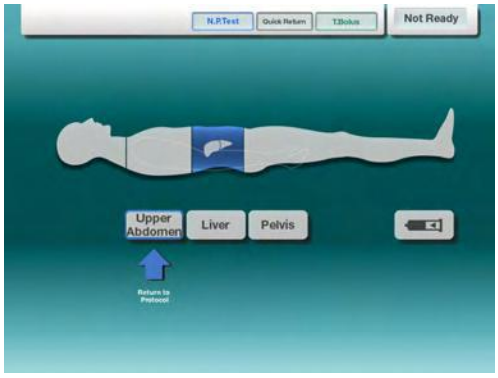
The flow rate can be set from 0.1mL/sec to 10mL/sec in 0.1mL/sec increments. The volume range is 1 - 100 or 200mL in 1mL increments.

To initiate the NPT, confirm there is no air in the syringe and tubing then press the Check Air button located on the Powerhead or Console (US Version). The Start OK status should appear.



Press a start button on the Powerhead or Remote Switch Box to start the NPT.

The NPT real-time pressure will be displayed during the injection. Press any key to stop the NPT process.



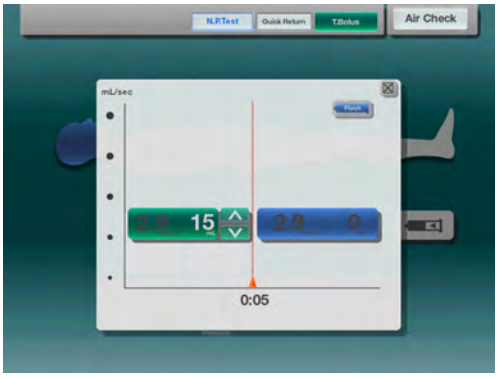
After the N.P.Test is finished or if the window closed and injection protocol was selected beforehand, a "Return to Protocol" message appears under the key previously selected. Press the indicated key to return to protocol.

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.

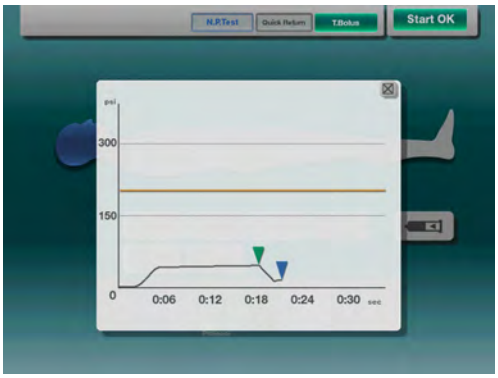
The T.Bolus values are automatically set to the values set on the Injector Setup screen for T.Bolus/ N.P.Test. Refer to page 99 "20.5.T.Bolus / N.P.Test".

These parameters will be displayed for the user.



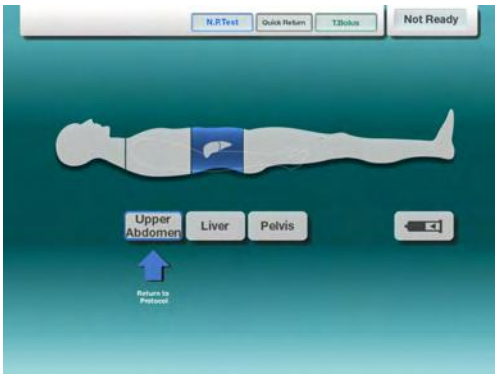
Pressing the T.Bolus key (without an injection first selected) will cause the T.Bolus pop-up window to appear.

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.

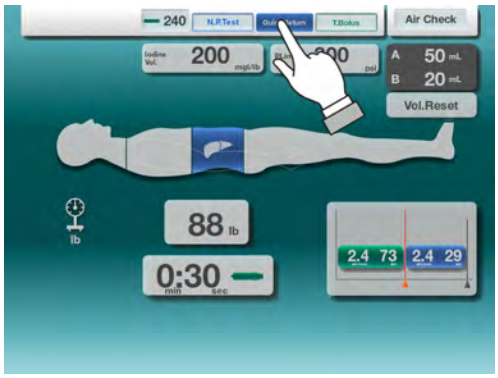


After the T.Bolus is finished or if the window closed and injection protocol was selected beforehand, a "Return to Protocol" message appears under the key previously selected. Press the indicated key to return to protocol.

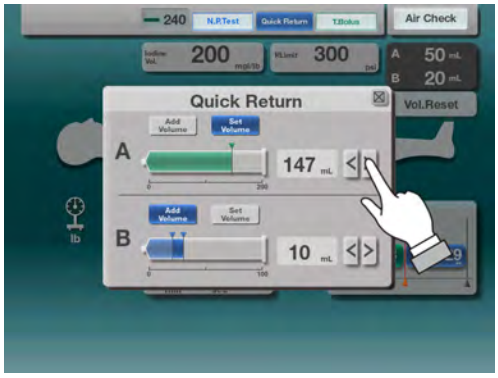
17. Quick Return

The Quick Return process is stopped after the set volume is filled.

Note: Before filling, remove air contained in the syringe. Otherwise, the total volume in the syringe will be less than the expected volume as it includes the volume of air.



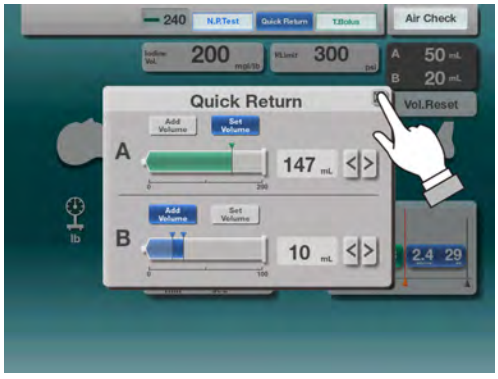
Touch the syringe icon "Quick Return" to access the set-up screen.



The "Quick Return" set-up screen is shown on the left.

When < is touched, the set value decreases.

When > is touched, the set value increases.



When Add Volume is selected, the amount indicated will be added to the syringe.

When Set Volume is selected the syringe is fill to the amount indicated.

Touch ☒ when set-up is complete.

18. Injection Results Screen

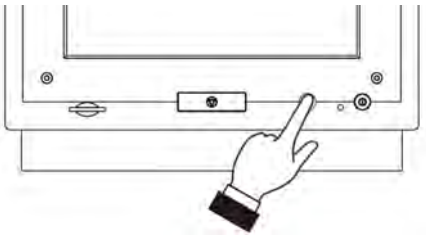
The Injection Results Screen enables the user to view previous injection results in a table or graph format.

Table View : The Protocol Pattern, peak flow rate, volume and pressure are shown. Results are displayed for the last 100 injections in chronological order.

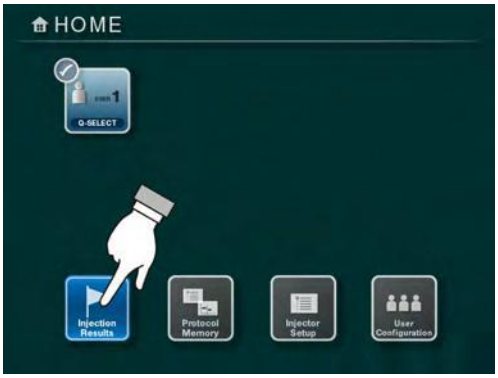
Graph View : Displays the pressure graph from start to end of the injection selected.

Regardless of Protocol Pattern, injection results are shown for the last 100 injections. Injections older than the last 100 are automatically removed from memory.

IMPORTANT : Pressure graphs are kept in memory even after power is removed.



To access HOME screen press the button as shown.

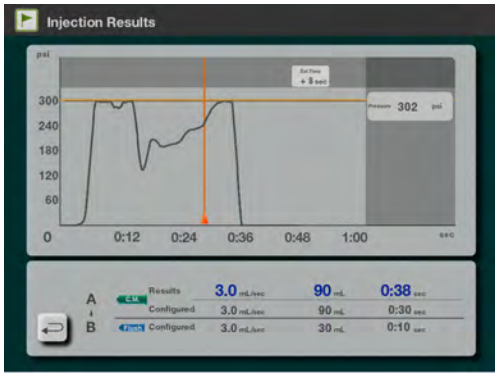


1) Touch the "Injection Results" key.

2) The latest 10 results will be displayed on the "Injection Results" screen.

   To scroll to additional results pages, touch the "Page Change" key.

   To see the pressure graph, press the Graph Key.



3) The pressure graph displays the pressure values throughout the injection protocol.

   Touch the "Return" key in the lower left corner of the screen to revert back to the "Injection Results" list screen.

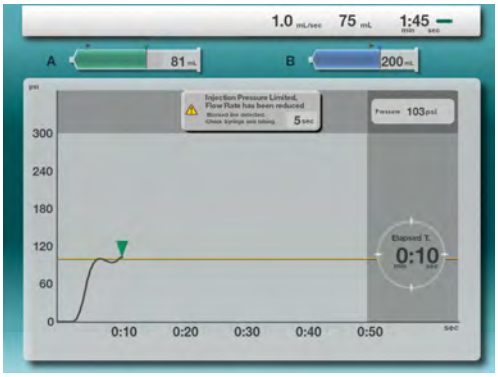
19. Warning and Information Screens

19.1. Blocked Line Warning

During an injection it is possible that a Blocked Line Warning message appears indicating that a Blocked Line condition exists. If this message appears, please check the following:

1. Check the injection line for occlusion, such as a kinked tubing or catheter, or closed stopcock. If an occlusion can not be detected it may be the flow rate is set too high for the pressure limit, try lowering the flow rate or using larger diameter catheter.

2. Please check the pressure limit setting. The pressure limit may be set too low for the programmed flow rate or the catheter bore size may be too small. To maintain the programmed flow rate without activating the pressure limit, use a larger diameter catheter, lower viscosity contrast media or warm the contrast media.



If the injection pressure reaches the pressure limit setting, the pressure limit function will activate and reduce the flow rate until the injection pressure is maintained at the pressure limit setting.

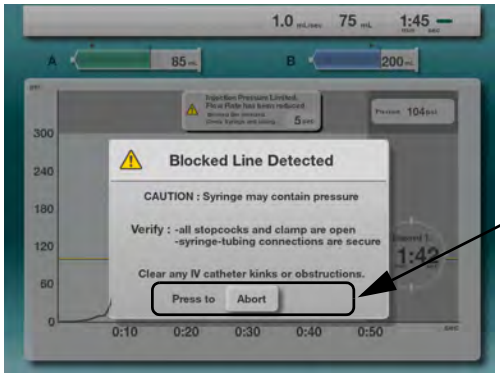
In the event the actual flow rate is reduced to 10% or less of its programmed value, the injector detects the condition as an occluded injection line and displays the message shown on the left, notifying the user of a line blockage.

If the condition continues for a period of 5 seconds, the injection will stop and the "**Blocked Line Detected**" message will appear.

However, during the 5 second period the injection will be resumed automatically if one of the following conditions occurs:

1. Injection pressure reduces below the pressure limit setting.
2. Flow rate increases to more than 10% of its programmed value.

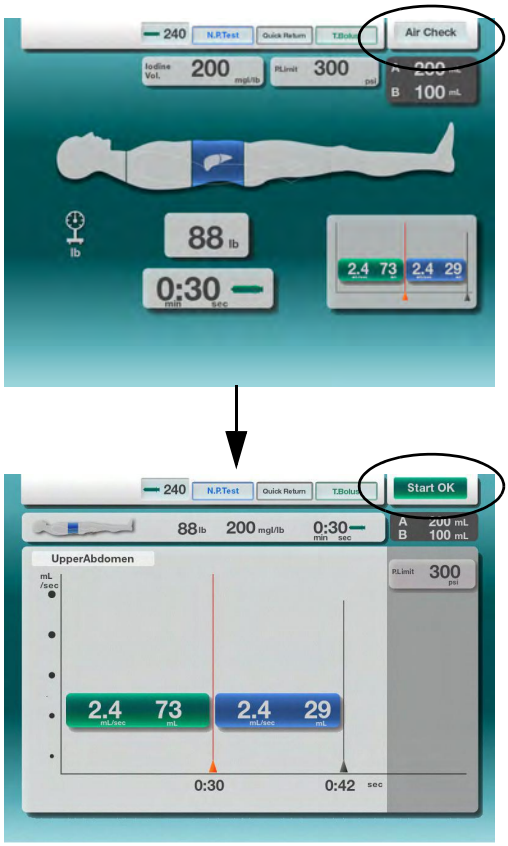
Refer to section "19.1.1.Resuming the injection" if the injection is resumed automatically.



If the injection is stopped due to a blocked line condition the message on the left will be displayed.

Injection will stop and injector rams will reverse slightly to reduce the pressure contained in the syringe. For the safety purpose, key functions will be inoperable for 3 to 5 seconds until the pressure is reduced. After reducing the pressure, the message “Press to Abort” will appear indicating it is safe to continue.

Pressing the "Abort" key will cause the screen to return to the Initial screen, no protocol is selected.



To start the injection again, press the "Air Check" button on the Powerhead after checking the injection line.

Confirm the button is changed from "Air Check" to "Start OK".

Pressing a "Start" key will start the injection again.

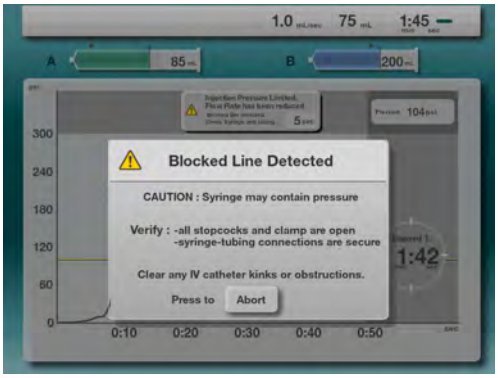
19.1.1. Resuming the injection

When the injection is completed, the warning message popup will reappear to notify the user the pressure limit was activated during this injection.

19.2. Switch Alarm at power up

During power up, if any button on the Powerhead, Console, or Switch Box is pressed an alarm message is generated. When the cause of the alarm is corrected, the setup screen will appear without cycling power.

19.3. Warning Screen



WARNING SCREEN EXAMPLE

When a warning screen is displayed, correct the cause of the warning and touch the "Abort" key.

The setup screen will appear.

19.4. Alarm Screen

ALARM MESSAGE EXAMPLE, Alarm 1 shown

An Alarm screen will appear when an error is detected. After review of the alarm number (①), turn off the power and remove the alarm cause.Power up the system again to verify the clearing of the alarm condition. If the alarm continues, contact the manufacturer or authorized representative for correction.Refer to the "Troubleshooting" section regarding the causes of alarms.

19.5. Syringe Adapter Warnings

If the Check Air button is pressed and a syringe adapter is not detected or properly installed the message at the left will appear.

If the adapter is installed or corrected the message will automatically disappear.

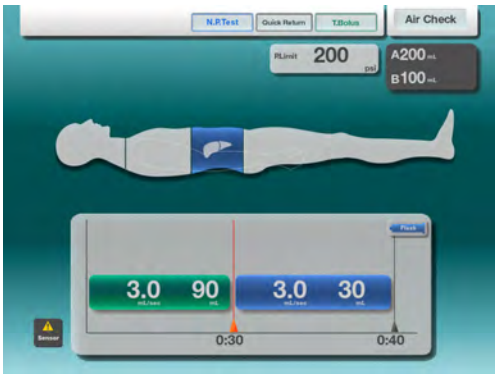
Pressing OK will override the message but a adapter must be detected before an injection can be executed.

In the event a syringe adapter is not installed or detected, a manual selection window will appear. Depending upon the type of protocol the option for the A-side or both sides will be presented.

Making a manual selection will permit an injection to be executed.

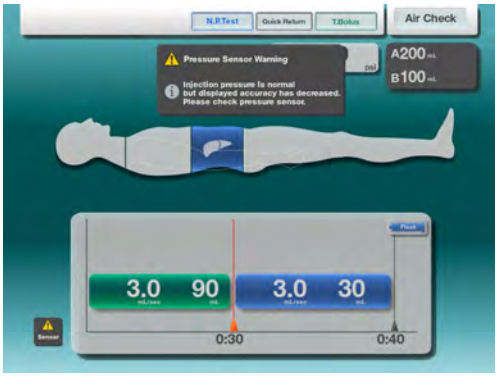
19.6. Pressure Limit Warnings

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



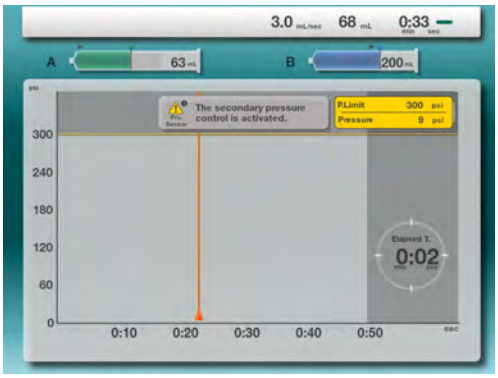
In the event the "primary pressure control" system detects a fault internally to it system, it will automatically switch the pressure protection elements to the "secondary pressure control" system.

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.



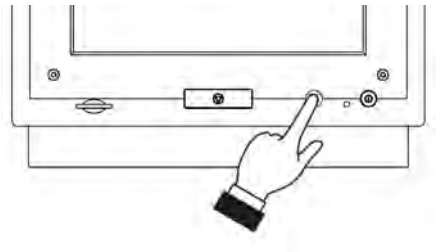
If the secondary pressure control is activated the injection in process screen will operate slightly different.

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.

20. Injector Setup

The Injector Setup screen is a user accessible function that enables setup and configuration of various parameters.



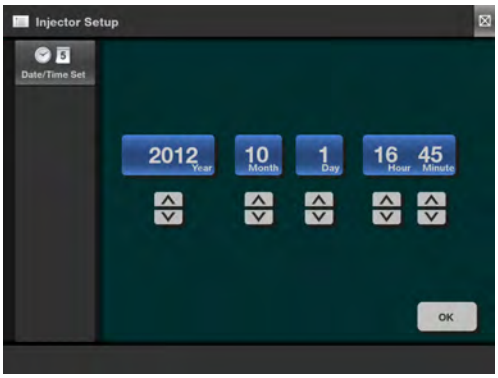
To access the HOME press the button as shown.

The HOME screen will be displayed.

- Press the Injector Setup Key as shown.

To make adjustments to any of the items listed, press the corresponding key and the setup screens will appear.

20.1. Date / Time Set



To adjust the date and time use the corresponding ^ and v keys located below each parameter.

After the date and time is set as desired, press the "OK" key to set the new date and time.

20.2. Sound Level

The sound level for the Console (display) or Powerhead (head) can be set independently. Use the ^ and v keys to set the desired volume.

The values can be set from 0 (mute) to 15 (maximum).

It is not recommended to mute the sound levels.

Press "OK" when complete.

20.3. LD Set

Set injector behavior when LD is activated.

Choose either STOP or Continue Injection.

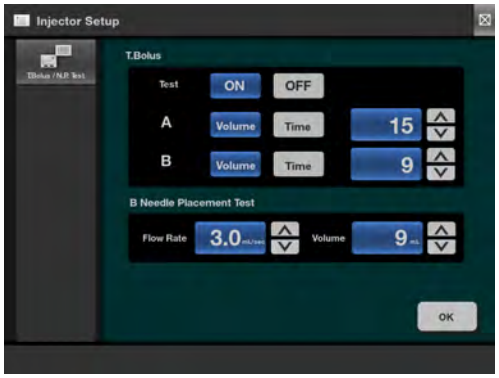
Press "OK" when complete.

20.4. Flow Rate Warning

Use the Up/Down arrows to set when the warning message will appear.

Press "OK" when complete.

20.5. T.Bolus / N.P.Test



Set default values for T.Bolus and N.P.Test.

Use Up/Down arrows to set the default values for manual entry.

Press "OK" when complete.

20.6. Results Display Time

Set if Auto-Return to Main Screen is desired.

Select ON or OFF.

If set to ON, set the time desired to show results before returning.

Press "OK" when complete.

20.7. Interface Setup

When CT and Injector become synchronized emit a sound.

ON = Sound Emits
OFF = No Sound

Press "OK" when complete.

20.8. Quick Return Speed

The Quick Return Speed Set determines the speed that will be used to fill the syringes when using the Quick Return (Auto-Return) sequence.

Use the corresponding [^] and [v] keys to set the desired speed.

The slowest speed is 1.5mL/sec and the maximum speed is 8.0mL/sec.

Press "OK" when complete.

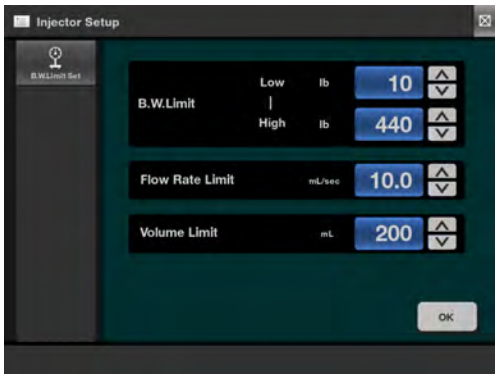
20.9. Quick Purge Volume Set

TheQuick Purge Volume Set sets the default values for the Quick Purge feature. The Single section sets the default purge volume when only the A-side is being used in the injection protocol.

The Dual section sets the purge volume when both A-side and B-side syringes are installed and required by the injection protocol.

Use the corresponding [^] and [v] keys to set the desired volumes. The values programmed when received are based upon the manufacturer's consumables.

20.10. B.W Limit Set



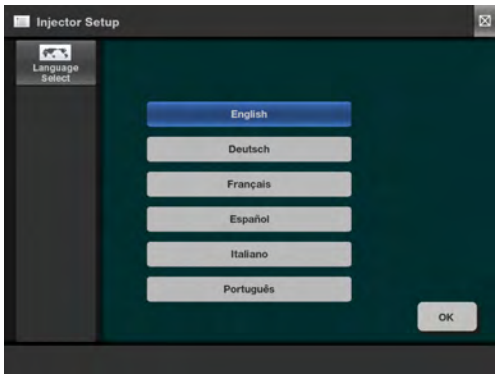
When using the Body Weight protocol, these values will establish the minimum and maximum weights that may be entered for the patient.

Use the corresponding ^ and v keys to set the desired weight.

Press "OK" when complete.

20.11. Language Select

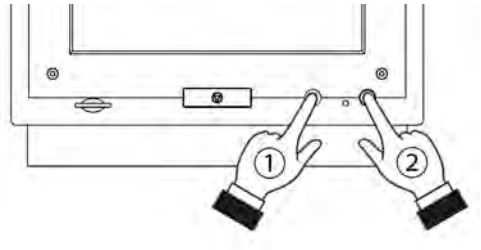
The Language Select feature permits changing the user interface language to the user's preferred language.



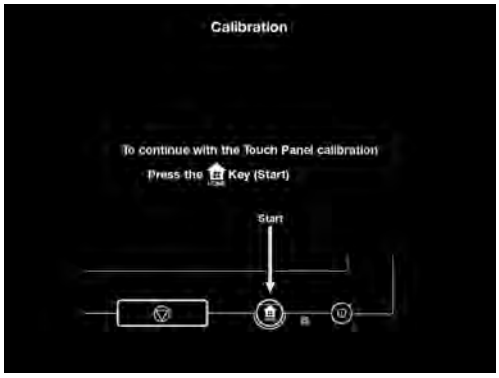
The blue highlighted button identifies the current language setting. To change the language, select the desired language then press the "OK" button.

20.12. Calibration

If a Touch Panel Location Error occurs, calibrate according to the following process.



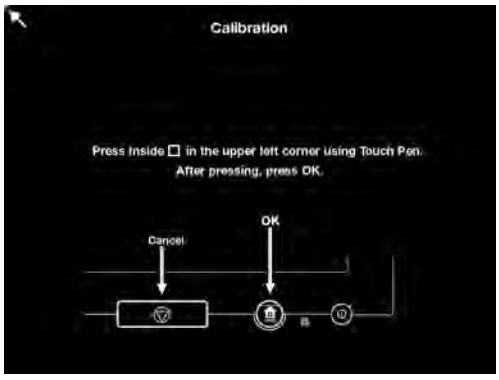
Hold down the HOME button (①) and turn on the console (②) .



The calibration screen is displayed.

Perform the calibration according to the process indicated on the screen.

Press the "HOME" button of the console.



After the following screen is displayed, touch the inside of the red square in the upper left corner with the touch pen.

When the square is selected properly, it will turn green.

If the square does not turn green, try again.

Press the "HOME" button of the console after the square turns green.

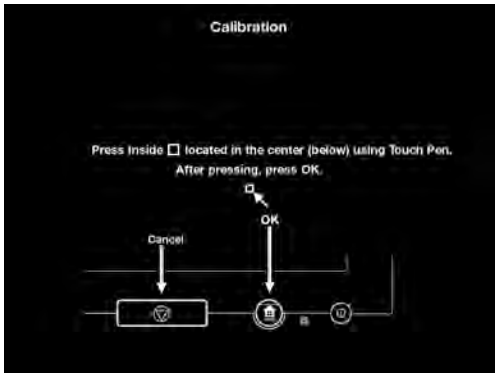
Press the "Stop" button of the console to cancel the calibration, and the screen will return to the screen above.

After the following screen is displayed, touch the inside of the red square in the lower right corner with the touch pen.

When the square is selected properly, it will turn green.
If the square does not turn green, try again.

Press the "HOME" button of the console after the square turns green.

Press the "Stop" button of the console to cancel the calibration, and the screen will return to the screen above.

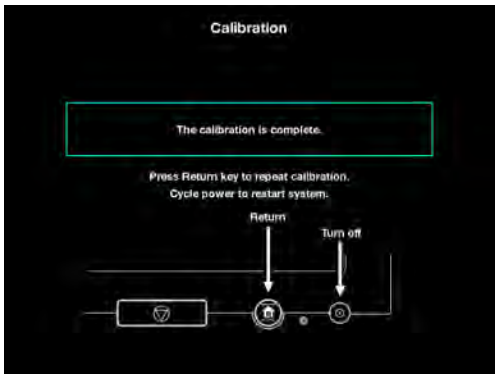


After the following screen is displayed, touch the inside of the red square at the center of the screen with the touch pen.

When the square is selected properly, it will turn green.
If the square does not turn green, try again.

Press the "HOME" button of the console after the square turns green.

Press the "Stop" button of the console to cancel the calibration, and the screen will return to the screen above.



The following screen will be displayed after the calibration is completed.

Turn off the power with the power button pushed and reboot to finish the calibration.

20.12.1. When the calibration is not completed properly

When the calibration is not completed properly, the following screen will be displayed.

Press the "HOME" button of the console to perform the calibration one more time after the following screen is displayed.

20.13. RTC Check Function (Date/Time Set Check Function)

The clock and calendar of this system are operated by the lithium battery contained in.

A full-charged battery works for about 2 months.

The clock or calendar might get out of order if it does not be operated for long period. In that case, reset the "Date / Time set" screen will appear automatically before operating.

After the "Date/Time Set" screen is displayed, touch the ∧ or ∨ key to set the date and time.

Touch the "OK" key after setting.

The date and time are saved and the power is automatically shut off.

21. Daily and Periodic Inspections

Daily inspections and maintenance are recommended to maintain the function of the DUAL SHOT alpha7 contrast delivery system. The following schedule is recommended:

DAILY: Clean and check each component of the system.

MONTHLY: Clean and check operation of each part of the system.

21.1. Daily Inspection

Always perform the recommended inspections before using the system.

If any malfunction is identified, prohibit use of the system and contact the manufacturer or an authorized representative.

21.2. System Inspection

1. Before use, check movement of the Powerhead rams by moving them completely back and forth at maximum speed, and without a syringe installed.
2. Check that all displays and lamps illuminate.
3. Check that no flaws, wear or tear are found on the connecting cables of the system.
4. Check that cables are properly connected.
5. Check that no unapproved equipment is connected to the system.
6. Visually check the system and the parts for damage.
7. Use of unapproved parts may cause malfunction of the system or harm to the patient. Verify the system is used with only approved devices and consumables.

21.3. Powerhead and Remote Stand Inspection

1. Visually check that no damage such as cracks, are found on the Powerhead cover.
2. Check that the Powerhead and the Powerhead arm rotate freely and the Powerhead rotates more than 180 degrees, but less than 270 degrees in the vertical direction.
3. Check that the casters of the Remote Stand move smoothly and the locking mechanism operate properly.
4. Check the support of the Remote Stand moves up and down smoothly.
5. Check that no damage such as cracks, are found on the Remote Stand. Verify all fasteners are secure.

21.4. Ceiling Suspension Inspection (optional)

1. Visually check for cracks, bends, wear and tear or loose fasteners on ceiling suspension system.
2. Check that the support can be moved up and down lightly without bending.
3. If any defects are identified, prohibit the operation and contact the manufacturer or an authorized representative for correction.

21.5. Cleaning

⚠ Caution

- To avoid electrical shock, always remove power and disconnect power cable before cleaning the system.
- A main cause of malfunction can be the build up of contrast media on the Powerhead. Cleaning the Powerhead after each use will significantly reduce the likelihood of failure.
- Never use any organic solvents, such as thinners or benzene as they may damage the equipment. Organic solvents are not effective in removing contrast.
- To clean the Powerhead use gauze or paper towel dampened with our recommended disinfectants below. Gently wipe the Powerhead then use a dry cloth to remove any remaining disinfectant.

  Recommended Disinfectants

Chlorhexidine gluconate	0.1 - 0.5% solution
Benzalkonium chloride	0.1 - 0.2% solution

- Care should be used when disinfecting the product. The above disinfectants are recommended using only as advised by the manufacturer. Please be certain to follow the manufacturers directions for use, and your healthcare facility procedures for disinfecting and decontamination of product as well as body fluid spills, blood, etc.

21.6. Operation Check

1. Check movement of the Powerhead rams by moving them completely back and forth at maximum speed without a syringe mounted.
2. Move the Powerhead ram forward by pressing the forward key without a syringe mounted, and check that the Powerhead ram stops in 10mL increments automatically with medium and slow buttons.
3. Check that all displays and lamps illuminate.
4. Start an injection using a programmed protocol and check that values of the protocol are displayed on the Console display and that the system operates properly.

22. Planned Maintenance

The injector will continue to perform six years later just as it did when first installed.

The planned maintenance should be performed once annually, and must be performed by a trained and qualified representative of the manufacturer. The items included in the annual preventative maintenance check are:

- Repeat of daily and monthly inspections
- Perform pressure calibration check
  - Re-calibrate if necessary
- Perform system performance checks
- Perform required system upgrades
- Perform safety circuit check

23. Troubleshooting

This system incorporates an automated diagnostic function to ensure a high level of safety in consideration of the various possible malfunctions. When an abnormality occurs, this function activates and displays the description and the Alarm number on the Console display.

This automated diagnostic function will aid in troubleshooting the system's operation and its connections.

In some cases, such as damage of external appearance of the system, abnormal noise and other malfunctions which are unpredictable in nature, the automated diagnostic function may not be effective.

Depending on the malfunction, up to 10mL may be injected before the system can detect and stop the injection.

Pressure limit warning is indicated during an injection	
Problem	Pressure limit is activated. The flow rate is decreased from programmed flow rate.
Cause	The pressure limit setting is too low for the programmed flow rate. The injection line (needle, tube, catheter, etc.) is too small or obstructed.
Low pressure warning is displayed during an injection	
Problem	No pressure is detected
Cause	The syringe does not contain contrast or saline. Syringe may not be installed.
Check Point	Check the syringe or injection check

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.

Alarm 20	
Problem	Unacceptable Protocol
Cause	This error will appear when the protocol parameters are not within valid ranges or if different between Powerhead and Console.
Alarm 30	
Problem	Invalid Device Type
Cause	This error will appear if the Console and Powerhead versions are not compatible with each other.
Alarm 50	
Problem	Power-Supply Undefined
Cause	This error will appear, if during the power-on checks, the Console and Powerhead cannot establish a connection with each other.

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	

Guidance and manufacturer's declaration - electromagnetic immunity			
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.			
Immunity test	**EN 60601 / IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2 IEC 61000-4-2	± (2, 4, 6) kV contact ± (2, 4, 8) kV air	± (2, 4, 6) kV contact ± (2, 4, 8) kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN 61000-4-4 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5 IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11 IEC 61000-4-11	< 5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	5 % UT (> 95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DUAL SHOT alpha7 requires continued operation during power mains interruptions, it is recommended that the DUAL SHOT alpha7 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8 IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

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.

Immunity test	EN 60601 / IEC60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the DUAL SHOT alpha7 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF EN61000-4-6 IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = 1{,}2\sqrt{P}$
Radiated RF EN61000-4-3 IEC61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 : At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorptionand reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DUAL SHOT alpha7 is used exceeds the applicable RF compliance level above, the DUAL SHOT alpha7 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DUAL SHOT alpha7.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the DUAL SHOT alpha7

The DUAL SHOT alpha7 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DUAL SHOT alpha7 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DUAL SHOT alpha7 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 2,5 GHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Maximum Cable Length Information

Following table shows the maximum length for our specified cables.
Do not use the cable other than those specified in the below table.
It may result in increased emission or decrease immunity with the Electromagnetic Compatibility of the system.

No.	Cable	Maximum length	Shield
HC-005	Powerhead extension cable	15m	Shielded
HC-006		20m	
AC-002	Power Cable (CE)	2.5m	— — —
AC-003	Power Cable (FDA)	5m	— — —
AC-004	Power Cable (SDA)	2.5m	— — —

25. Contact Information

If there are any questions or concerns relating to this information please consult the Operation Manual or the Service and Parts Manual. Please feel free also to contact the manufacturer or any of its authorized representatives:

Manufacturer

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

Telephone: +81-3-5842-8571
FAX:+81-3-5842-8589

Authorized Representative (EU)

Medicor International NV
Timmerik 2
3020, Herent
Belgium

Telephone: +32 16 27 18 18
E-mail: info@medicor-international.com

CE 0197

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.

2. Marking

Markings used in this Operator Manual and their descriptions are as follows.

	This symbol indicates hazards which could lead to personal injury, device malfunction or property damage.

2.1. Instruction Marking

The following symbols are used on this system.

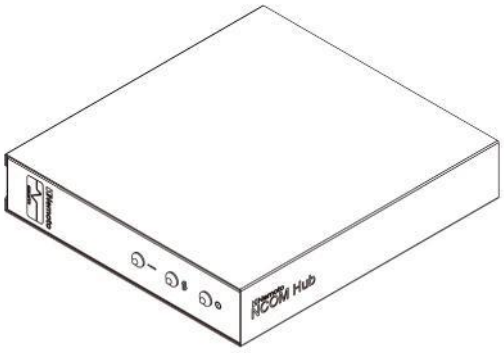
Symbol	Description
	Symbol for "CONSULT OPERATION MANUAL"

3. Precautions during use

⚠ Caution

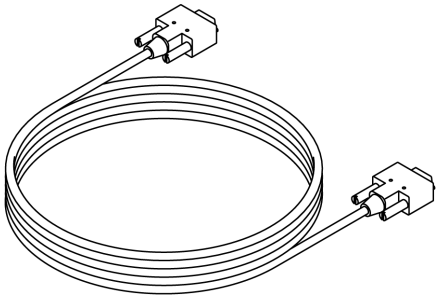
- The NCOM interlocking feature is specifically designed to connect with CT scanners that are specifically designed to conform to CANOpen CiA 425. Connections of the NCOM feature to CT scanner can only be performed by those trained and authorized by Nemoto. Connection by unqualified persons, third parties, etc. is strictly prohibited as this may result in equipment malfunction, incorrect data transmission, display or processing.
- If any of following occur, please contact the manufacturer or an authorized representative.
  - Installing, replacing or updating the NCOM.
  - Changes implemented to authorized equipment connected to the NCOM.
  - Any malfunction during use of the NCOM
- Modification to this device are strictly prohibited. Electric shock may occur if you touch the inside.
- In the event of device failure, only permit repair by trained and qualified personnel.
  Repair by other than trained or qualified personnel may result in patient or operator harm or may result in equipment damage.
- There is a risk of possible fire or electrical shock if usage is continued under any abnormal conditions. In the event of smoke or unusual smell(s) please discontinue use immediately and contact the manufacturer or authorized representative.
- This device must only be used in conjunction with equipment specifically approved by the manufacturer. Use with any unapproved equipment may lead to misdiagnosis, user or patient hazards or equipment damage.
- During the Control Mode operation of the NCOM, the start of the CT scan will also initiate the start of the contrast injection, however once the injection is initiated the injection will operate independently of the CT scanner. In the event the injection is stopped, the CT scan will continue and vice versa, if the CT scan is stopped at the scanner the injection will continue.

4. System Components



NCOM Hub

Network interface according to CANopen.



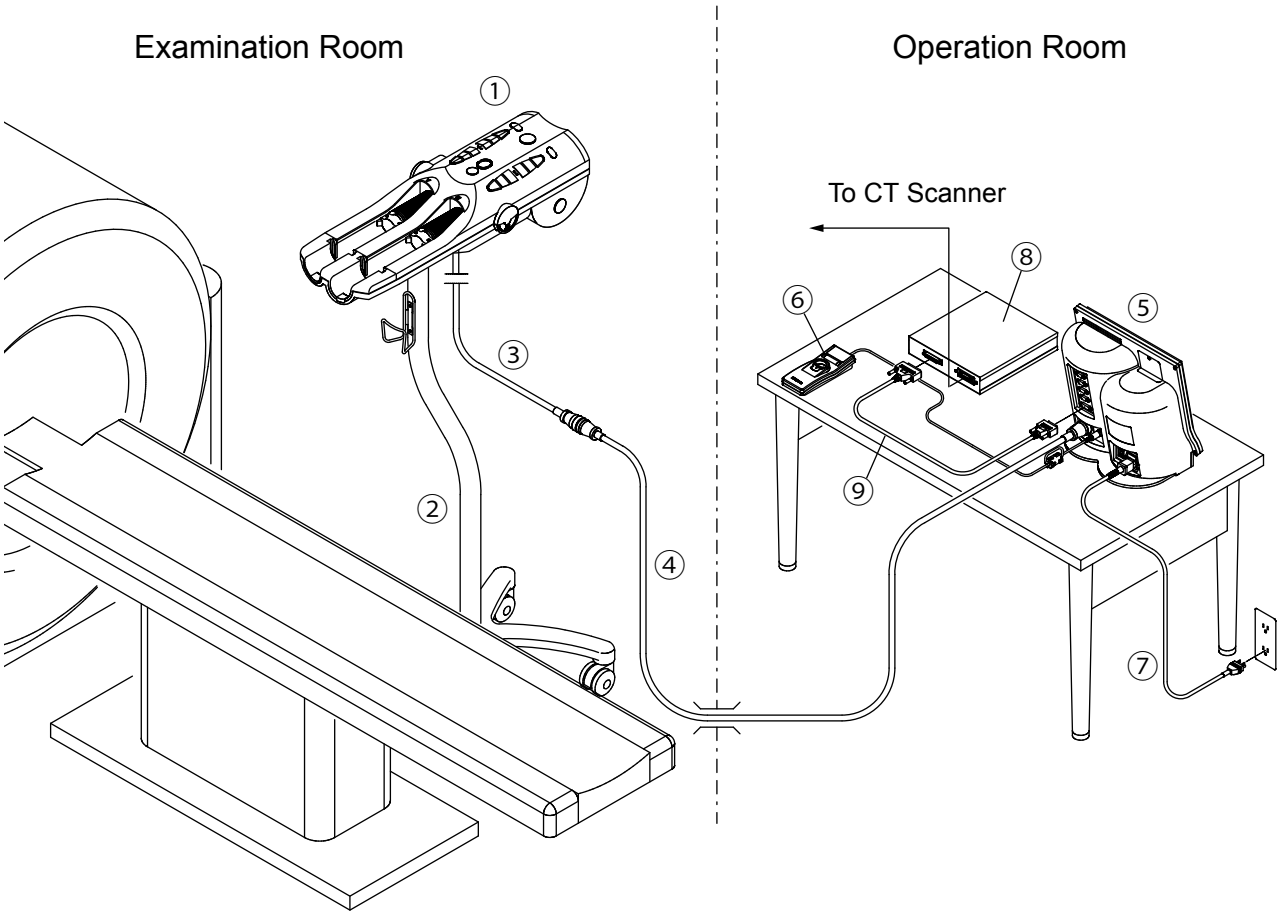
NCOM Hub Cable

Used to connect the Console and NCOM Hub.

5. Basic Connection Diagram

⚠ Caution

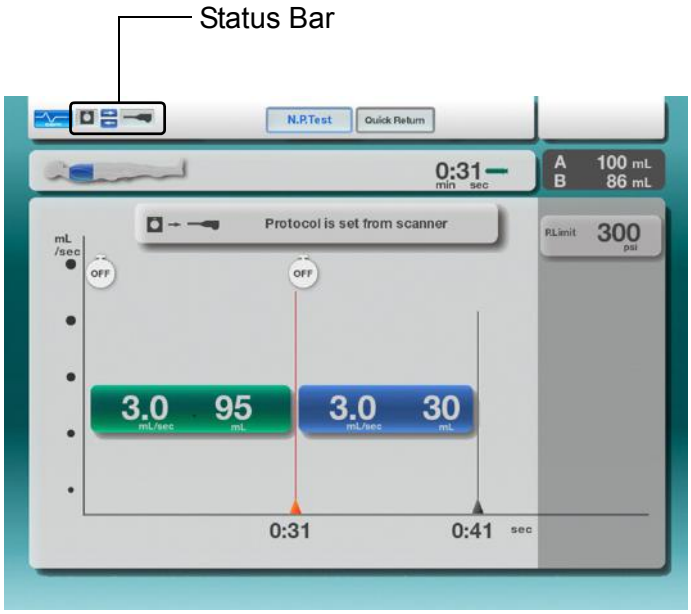
- This device follows a controlled installation procedure. The installation shall be performed by personnel trained and qualified for medical device installation. If reinstallation is required please contact Nemoto or your authorized representative.
  Installation by other than trained or qualified personnel may result in injury to the patient, operator or result in equipment damage.



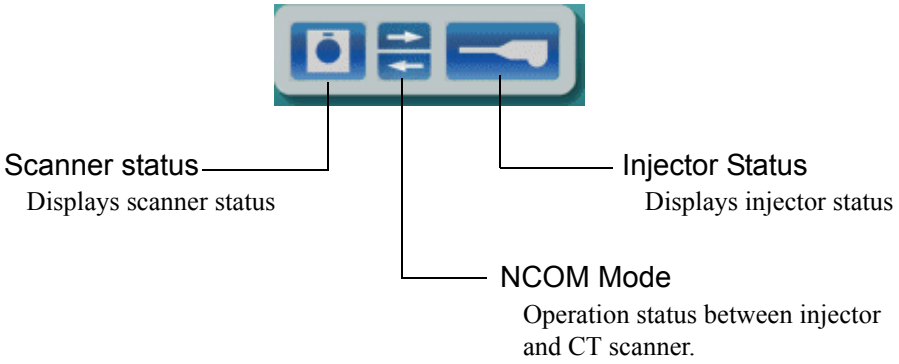
① Powerhead
② Remote Stand
③ Powerhead Cable
④ Powerhead Extension Cable
⑤ Console
⑥ Switch Box
⑦ Power Cable
⑧ NCOM Hub
⑨ NCOM Hub Cable

6. NCOM Status Bar

The NCOM Status Bar will be displayed when NCOM functions are active. Then, injector status can be observed by the status bar indication.



【 Details of status indication 】

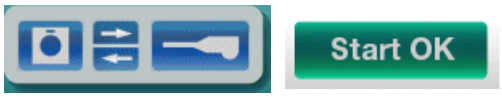


【 Explanation of icon color 】

Ready status

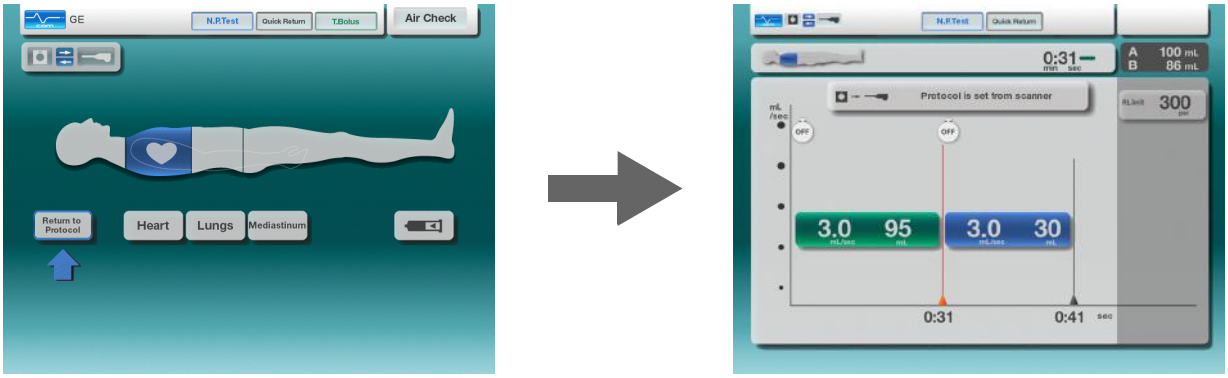
Not ready status

Control Mode Indications

Status Bar	Status
	[Injector: Ready] [CT Scanner: Ready] Injection start is ready
	[Injector: Not Ready] [CT Scanner: Ready] Injection start is not ready Causes: - Air Check has not been pressed - Protocol parameters are unacceptable
	[Injector: Ready] [CT Scanner: Not Ready] Injection start is not ready Cause: - CT scanner is not ready to start scan
	[Injector: Not Ready] [CT Scanner: Not Ready] Injection start is not ready Cause: - CT scanner is not ready to start scan - Air Check key has not been pressed - Protocol parameters are unacceptable

7. N.P. Test

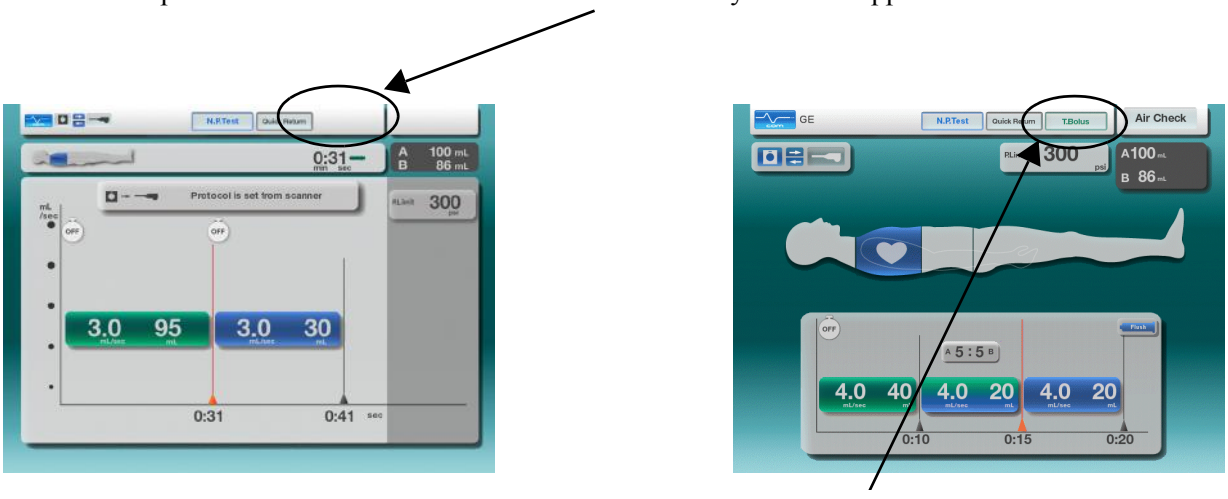
The N.P.Test injection can be accessed even if the protocol has been set from the CT scanner.
Upon completion of a N.P.Test injection, the current protocol will be concealed.
Pressing the "Return to Protocol" button, the previous protocol will appear again.



8. T.Bolus

The operation of the T.Bolus function with NCOM is different from the standard Dual Shot Alpha7 T.Bolus.
The following description applies to the T.Bolus when used with NCOM.

- If the protocol is set from the scanner the "T.Bolus" key does not appear.



- If the protocol is configured during the Body Weight Mode "T.Bolus" appears.
- The CT scanner will recognize "T.Bolus" as a protocol. It is not differentiated as a separate function.

9. Message Screen

When an abnormality exists between the Console and the NCOM Hub, the message on the left is displayed.

- Pressing "Return" will cause the injector to work in standalone mode.
- To resume NCOM operations with CT scanner, correct problem and cycle injector power.

10. Contact Information

If there are any questions or concerns relating to this information please consult the Operation Manual or the Service and Parts Manual. Please feel free also to contact the manufacturer or any of its authorized representatives:

Manufacturer

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

Telephone: 81-3-5842-8571
FAX: 81-3-5842-8589

Authorized Representative (EU)

Medicor International NV
Wingepark 5B - 101
3110 Rotselaar
Belgium

Telephone: +32 16 27 18 18
E-mail: info@medicor-international.com