

Micro infusion pump



IMS-310R User's Manual

The World's First, Smallest, High precision, Wirelessly controlled, Programmable Implantable Micro Infusion Pump for Mice



Read me

Thank you for choosing iPRECIO[®], programmable infusion pump for Lab animal for your research/experiments.

This quick guide show you how to use iPRECIO® pump and operate iPRECIO® management software.

(1) Caution

The iPRECIO® is for use in Laboratory Animal Research ONLY. Not for human use.

(1) Caution

Please obey the Guide for the Care and use of laboratory animal by your organization and or institute when use iPRECIO[®].

NOTICE TO THE USER

One or more of the following statements may be applicable for this equipment.

Notice (For Model UCD-X10R only)

The provided LAN Cable with a ferrite core shall be used when connect UCD-X10R to a PC and do not replace the LAN cable with other LAN cable.

FCC WARNING

FCC ID: 2ACHIUCDX10R, FCC ID:2ACHI310R

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

(**(** IC:XXXXX-2ACHI310R, IC:XXXXX-2ACHIUCDX10

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.



For more information:

PRIMETCH CORPORATION

URL: www.iprecio.com

INFORMATION TO THE DIGITAL DEVICE USER REQUIREMENT by FCC (For Model UCD-X10R only)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- -Reorient or relocate the receiving antenna.
- —Increase the separation between the equipment and receiver.
- —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- —Consult the dealer or an experienced radio/TV technician for help.

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About iPRECIO®

A subsequent of the first radio programmable infusion pump

iPRECIO[®] SMP-310R model is the world first programmable pump which is complete implantable into a laboratory mouse.

Utilize high precision mechanical pump technology that was unique developed and controlled by built in microprocessor. An administration protocol can be programmed with dedicated management application software and pump will be work by the programmed protocol with accurate low flow rate (μ L/H order) medical solution infusion. In addition the medical solution in the reservoir can be complimented and or replace through septum by transcutaneous even after implanted in an animal.

Accessories which included in iPRECIO® STD System

iPRECIO[®] system configured with the following accessories.

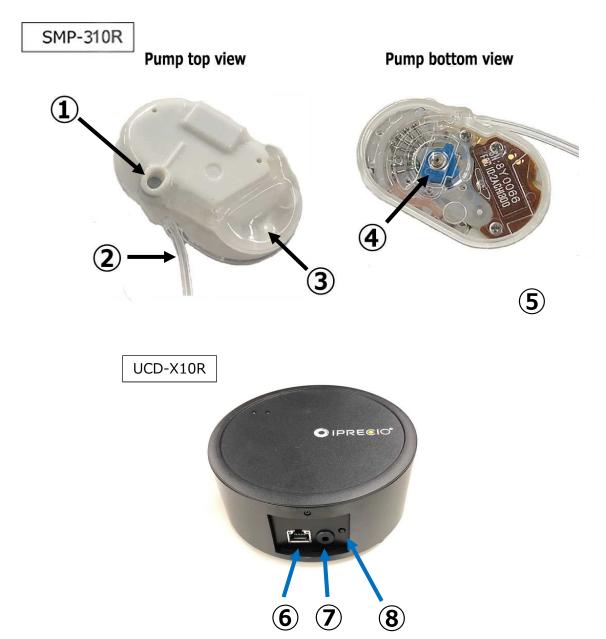
- Small Lab animal micro infusion pump iPRECIO® SMP-310R
- iPRECIO[®] management system IMS-310R
- Data communication unit UCD-X10R (USB Power Adapter*, LAN cable* included)
- Management Software IMS-310R
- iPRECIO Quick guide (this guide)



(L) Pump in pre-sterilized pack and 5pcs box. (R) Included parts with UCD-X10R

^{*}The attached LAN cable and USB power Adapter cable with a ferrite core shall be used.

iPRECIO[®] System construction



Number	name
1	Refill septum
2	Outlet tube
3	Reservoir
4	Micro cam
(5)	Pump ID print mark
6	LAN cable connect port
7	USB power adopter connect port
8	Reset switch

Product Warranty

PRIMETECH CORPORATION (hereinafter PRIMETECH) guarantee the product and it's material are free from defect within the below period which was distributed through the official sales channel.

PRIMETECH do not responsible with any problem that caused by using with other company product. Also the product performance is not guaranteed when a customer uses it beyond the original specification.

The defect part will be replaced and or repair by free of charge except, in-transit accident, customer's fault, breakage caused by abnormal/improper use and damnification cause by PRIMETECH recommendation of use.

Any defect parts back to PRIMETCH for replace, always need the RMA format and ship back through original sales channel.

Duration of guarantee

iPRECIO® Micro Infusion Pump SMP-310R: 18 months after manufacturer

iPRECIO® Management System IMS-300: 12 months after shipping date

This warrantee represent any other warrantee and include an implied consent of merchantability and dedicated fitness for purpose, but not limited to.

Liability Limitation

Except the warrantee describe in above, PRIMTECH do not responsible any direct, indirect and special loss caused by violence of use condition within the maximum LAW protection. This includes any return loss and or opportunity loss (includes profit loss by contract) with direct, indirect, and damage.

This warrantee will be no longer valid when customer (include stuff, member and any other bystander) use $iPRECIO^{®}$ for any other purpose against PRIMETECH sales conditions.

Battery life

iPRECIO[®] SMP-310R can continuous operate time below table during product warranty period (After 16 months from manufacturing date)

Flow rate (µl/hr)	Battery life (hr)
0.1	408
0.5	384
1.0	360
5.0	216
10.0	144

Please note that below condition makes shorter battery life. :

- In case of kept certain period of time without use after power on. (After power on, internal circuit becomes active and consume battery power by standby power requirement)
- In case of not storage under proper circumstances. (Under frequent temperature swing or exposed in over storage temp range in spec may cause increasing self-discharge of battery)

Install management application

Preparation before start

- iPRECIO[®] Management software install CD
- Windows 7/Windows8/Windows 10 installed and LAN port ready PC
- Data communication unit UCD-X10R (data com unit)
 - ➤ UCD-X10R main body
 - USB to DC adapter
 - ➤ LAN cable (Cross over cable with Ferrite core)

Install iPRECIO® management software

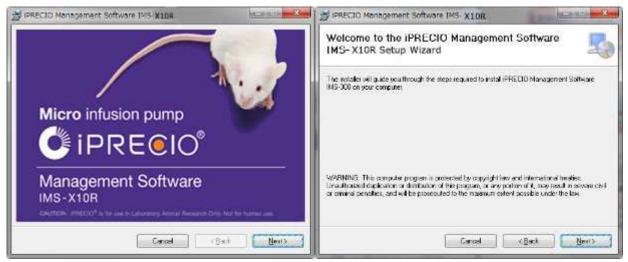
(1) Caution

PC setting should be:

- Off the screen saver
- Get into the control panel Power option of "Change when PC sleep" and set "Put the computer to sleep" = "Never"

Procedure

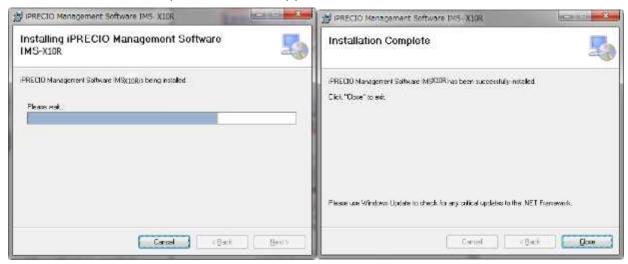
- 1. Run the "setup.exe" in a install CD.
- 2. When the startup window appeared, click "Next>". Then setup wizard window comes up, click "Next>" again.



3. Chose the program files store folder and click "Next>". Subsequently confirmation screen open, then click "Next>". For this step the installation will be started.



4. When install complete windows appears, click "Close".



- 5. Check start menu that the following software installed.
 - iPRECIO® Management Software IMS-X10R
 - Utility Base Station Manager
 - Utility Pump Database Manager
- 6. Three of those software has been installed, then the management software install is successful.

Cable connection of data communication unit UCD-X10R

1. Plug in the AC Adapter to data communication unit and connect with the PC which the management software installed by cross-over type LAN cable.

Connect to LAN port of UCD-X10R

Connect to LAN port of Control PC









Plug in the USB Adapter to a PC USB port (USB 2.0 or later)

Plug in the power plug to a UCD-X10R power in port.

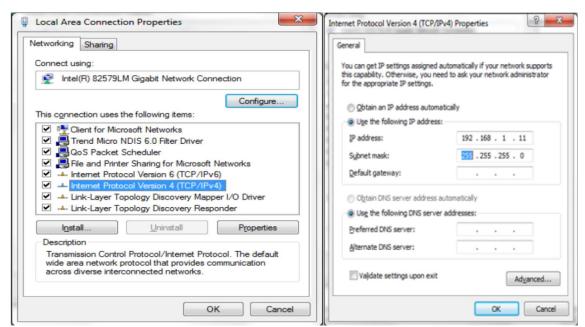
- *LAN cable Ferrite core attached end shall be connected to UCD-X10R.
- *USB power Adapter cable Ferrite core attached end shall be connected to PC.

TCP/IP connection between data com unit and control PC

Procedure

- 1. Connect data com unit and control PC with LAN cable
- 2. Open Network and Sharing Center from control panel.
- 3. Click Change adapter setting, then right click on the data com Local Area Control and open Property.
- 4. Open Internet Protocol version 4(TCP/IPv4) property and input IP address below

IP Address: 192.168.1.11 Subnet mask: 255.255.255.0



Then press OK to finalize.

(1) Caution

The Data communication unit factory default IP address configuration is 192.168.1.10. If IP address doesn't work by usage environment with default configuration, please change IP address in accordance with "Appendix A: How to change IP address of the Data communication unit"

5. With that the Data communication unit and control PC is connected by Internet Protocol. Subsequently network connection should be made in the management software.

Preparation before software use

For the first time execute management software

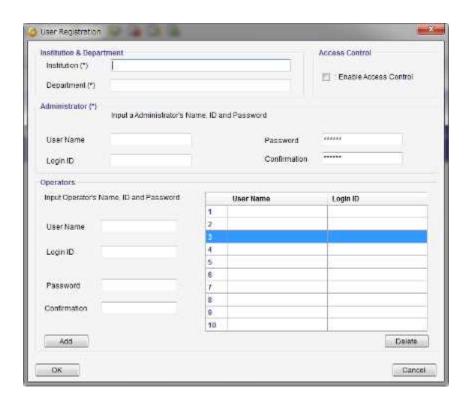
For the first time run the management software, the user registration window will open automatically. To register user information, user management and access control function will be available.

The language default setting is in English and after user registration the language selectable function will be active to change.

User Registration

►) Procedure

- 1. Input required information in the user registration window. The asterisk (*) marked item below are mandatory.
 - Institution & Department
 - Administrator
- 2. In addition, at least one operator registration required at this time. Input operator's User Name, Login ID and Password (Confirmation required), then click on Add tab. The operator will be listed in right table.
- 3. To use Access control, check the "**Enable Access Control**" check box. Detail of Access Control function, please refer the nest page "Access control of software".
- 4. After all fill in required column, click **OK** to finalize.



Access Control of software

To utilize Access Control function, administrator can confine and or control of user who can reach the management software. To permit to access the software, check the "Enable Access Control" in the user registration window.

Once use control function is active, every time Login ID and Password is required whenever the software executed.

(1) Caution

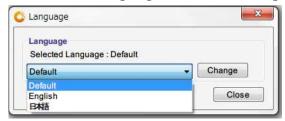
Please note Login ID and Password. When forgot password, then software access will be denied.



Change Language

Procedure

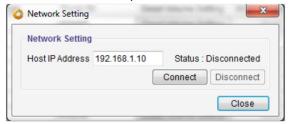
- 1. Click Language menu
- 2. Select language from pull down menu, then click **Change**.
- 3. Now the language has been changed.



Network Setting

► Procedure

- 1. Click **network setting** menu in tab.
- 2. Input default IP address(192.168.1.10) in the **Host IP address** column for the data com unit.
- 3. Click "connect"
- 4. After confirm "Status: connected", then close the window.
- 5. If the status column shows "disconnected", check the IP address setting. Please refer the "TCP/IP connection between data com unit and control PC".

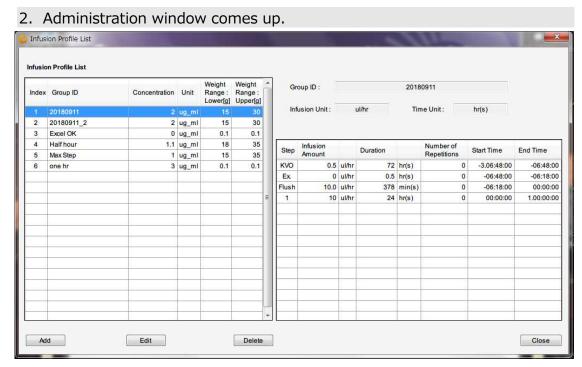


Create Infusion Profile

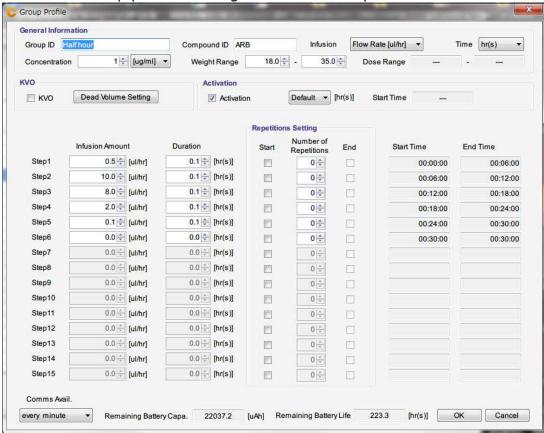
Administration protocol that perform in vivo pump of a subject animal of experiments, it is required create in the management software in advance and store as a "administration protocol". The administration profile should be determined by each group of dosing preparation and concentrations and assign administration schedule.

►) Procedure

1. Open Administration profile menu by clicking.



- 3. Add new administration profile, click "Add" button.
- 4. Group profile creating window will be opened.

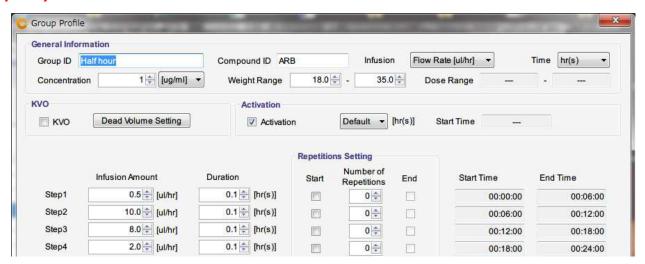


5. Input and or select basic information. When chose the injected amount unit as µg/kg/hr(Dose) or mg/kg/hr(Dose), amount set by dose. It is therefore the animal weight range and concentration input are mandatory.

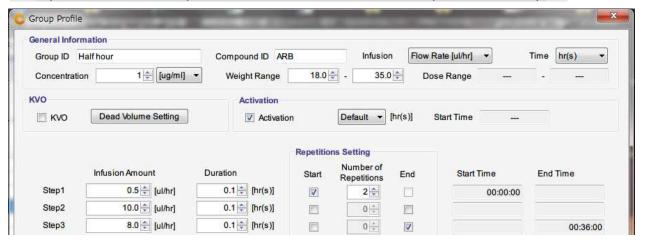
6. Input dose amount and duration from Step1 to create the infusion schedule. Input the value to the each boxes and press Enter to finalize dose. The starting time and finish time will be shown in elapsed time that accumulate the injection period. The battery life shown in the bottom of window indicate the expected battery life which calculated as a new battery. It may help to create an administration schedule.

(I) Caution

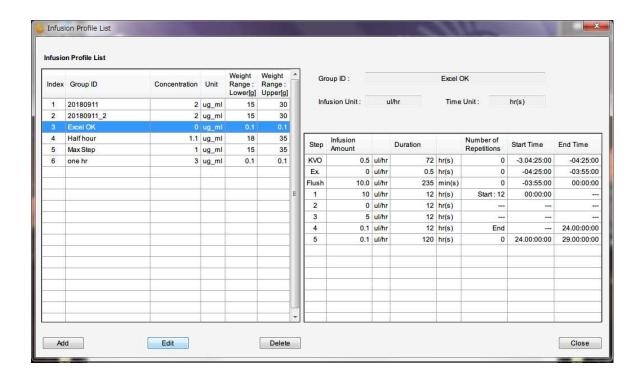
- Weight range should be input by maximum to minimum.
- Please do not forget to finalize the data by pressing "Enter" key.
- O not refer the battery life when the pump was re-use and or reprogramming. The indicated battery life was calculated from the battery capacity as a new one.



7. When ditto the same schedule, the use the "Repeat Setting". Check the "Repeat Start" box for start of repeated schedule step then check the "Repeat End" box for termination ditto schedule. For number of cycle, input "Times" of "Repeat Start" column and finalize to press Enter key.



8. After all information input, press OK then new administration profile will be registered in the Infusion Profile list.



9. When to change the existing Infusion Profile, select intended Infusion Profile and click "Edit" button.

If want to eliminate the existing Infusion Profile on the list, select the intended Infusion profile to delete and click the "**Delete**" button.

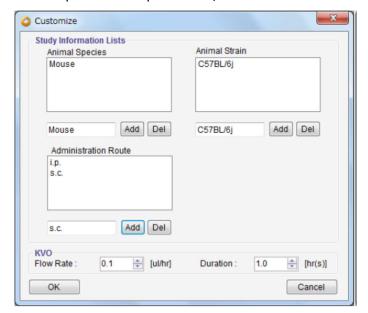
10. Close the Infusion profile window by clicking "Close" button.

Customize information

Pull down menu registration and elimination are possible for Study Setting. And KVO setting of flow rate and duration also set in advance.

► Procedure

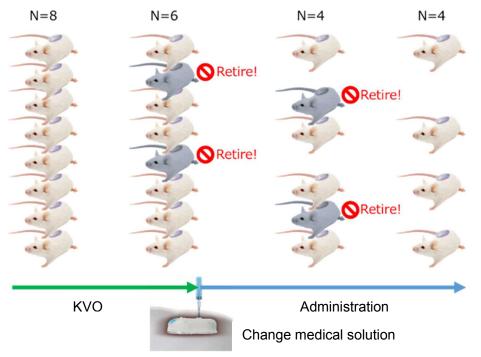
- 1. Open customize window from "Customize(Z)" menu in the tool bar.
- 2. Input a desire information in **the Animal Species, Animal Strain and Administration Route**, then click Add button in the below of each boxes.
- 3. If would like to delete existing information, select information and click Del button in the below of each boxes.
- 4. Input the numerical value of KVO Flow Rate and Duration.
- 5. To complete the input value, click OK button in the left bottom of the Window.



Start Study

Start New Study

iPRECIO[®] Management software has a function to abort the study during the KVO and Administration with pumps which implanted in under study animals. For example, to be able to except individual animal from study that is slow-healing than others during KVO. Also even during Administration to be able to deselect individual animal that is difficult to continue Administration by some trouble.



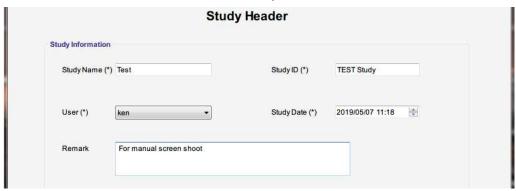
(1) Caution

The Data access Radio system of iPRECIO® is not Broadband type in use. For that reason, the management system can control only one pump in the same time, then it may require long time to complete the following data communication.

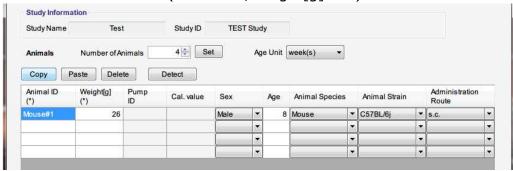
- Pump detection
- Start KVO
- Abort KVO
- Complete KVO
- Start Administration protocol
- Abort Administration protocol
- Finish Administration protocol
- Extract executed study log



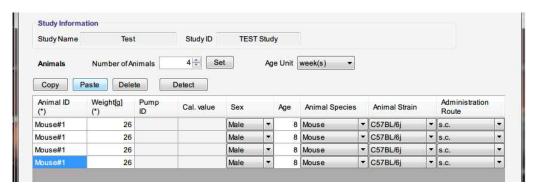
- 1. Click **New** from **file menu bar**.
- 2. Appear Study Header window. (*) marked items are mandatory.
- 3. Click **Next** after fill the information input boxes.



- 4. Pumps and Animals setting window comes up. Input intend animal number in the **Number of Animals** and click Set button. Default Number of Animal is 20. The information input column will be active in answer to input animal number.
- 5. Input and select by pull down for except **Pump ID** and Calibration Factor, such as individual information. (Animal ID, weight[g] etc.)



6. Can copy and paste of the column which already input individual information to another column.



Catheter connection, plomb admin liquid and activation.

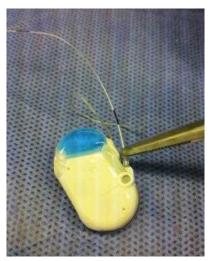
Activate the pump by switch on to communication enable. If required connect additional catheter as necessary.

(1) Caution

To fill administration liquid till the end of catheter before power on, because once a pump switched on, the internal cam will start moving to the initial position to block the inner tube.

►) Procedure

- 1. Open pump pre-sterilization pack in clean environment.
- 2. Cut, replace tube and/or catheter connection of pump as necessary.



① Caution

Each pump dead volume can be calculated in KVO setting, so keep final tube length and inner diameter or measured dead volume need to be recorded.

3. Fill the admin into the end of tube with 27G syringe needle through upper port.



4. Slide the south pole of a magnet (100mT or stronger) on the surface of the protracted area of a pump to power on the pump.



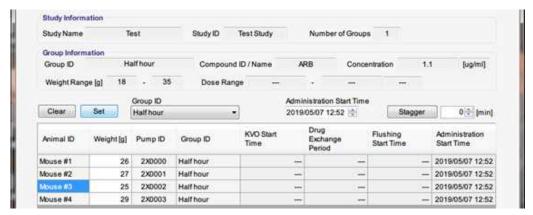


Under red marked area, magnet SW was built in.

Pump detection

Procedure

- 1. Place pumps by recommended position with a data com unit UCD-X10R.
- 2. Click Detect button. During Communication progress bar is shown, the powered on and communication enable pump will be detected. If a pimp is not detect wait a minute or over, please try the power on action (power on by magnet).





If there is no response from pump, please check the followings:

It may take long term to detect pump due to radio wave back ground

environment.

- Verify PC and UCD-X10R connect properly. For detail, please refer "TCP/IP connection between data com unit and control PC" and "Network Setting".
- Verify pump activation. For detail, please refer "Catheter connection, plomb admin liquid and activation".
- 3. After all pumps detected, then click **Next** button.

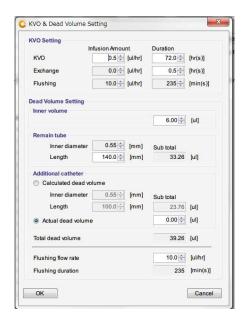
KVO setting, start and complete

KVO is abbreviate of Keep Vein Open, semantics to prevent the catheter edge clog by continuous liquid dosing by low flow rate. Be normally administrate biocompatible liquid such as saline as KVO by low flow rate after implant surgery and prevent clog of catheter end during animal healing period. After animal comeback form the surgery, the KVO liquid in reservoir can be replaced by medicine liquid from the septum. And acknowledge user the timing that when the medicine liquid will reach the catheter end by pump and appurtenant catheter dead volume calculation.

Procedure

- 1. Open desire Group profile and check the KVO check BOX and click the dead volume setting button. Then KVO setting window pops up. If KVO is not required, then remove check the KVO check box to skip KVO.
- 2. Click individual column dead volume setting.
- 3. Input the required information for dead volume calculation and click OK button.





(I) Caution

Even if there is no need to change dead volume setting, it need to open every animal dead volume setting and determine the dead volume choice. If this determine was lost, the dead volume and flash rate will not apply to the administration start schedule.

4. Check KVO flow rate and KVO duration and if it's ok then click to **KVO start**. The pump status will be **KVO** after start KVO. Pump status color will change in accordance with communication stats, red →Yellow→Green. When the color will be Green, then injection is started.

(I) Caution

During KVO is running, please DO NOT STOP the management software.

5. When the pre-set KVO period will end, pumps will stop and Pump status changes into Finished. Click Next>, the injection schedule setting. All of animal looks fully recovered before pre-setting KVO period, you can abort all KVO by clicking abort as a pack and start administration schedule. When some animal cannot heal enough during KVO period and need to terminate the experiment of that animal, then click the remove button from individual animal column.

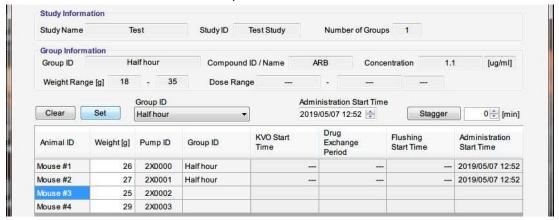
① Caution

After KVO stopped, please check the Pump status as "Finish". Demepnd on the communication condition, "Finish" status appears very slow after prompt to end KVO from management software due to communication condition.

Infusion Protocol setting

Procedure

- 1. Group information window appears.
- 2. Chose infusion group name (Profile) from **Group ID** pull down menu and set **Administration Start Time**, then click Set button.

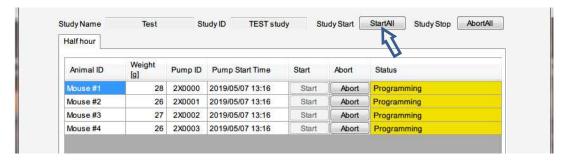


- 3. When click Stagger, the administration will be staggered from set time in that value.
- 4. If the proper infusion group name does not found, then create new one. Please refer "Create Infusion Profile".
- 5. After all animal are assigned to profile group, click **Next>>** button.

Start Infusion Protocol



- 1. Infusion Protocol window comes up.
- 2. Click **Start all** or click start for individual animal to start Infusion Protocol.



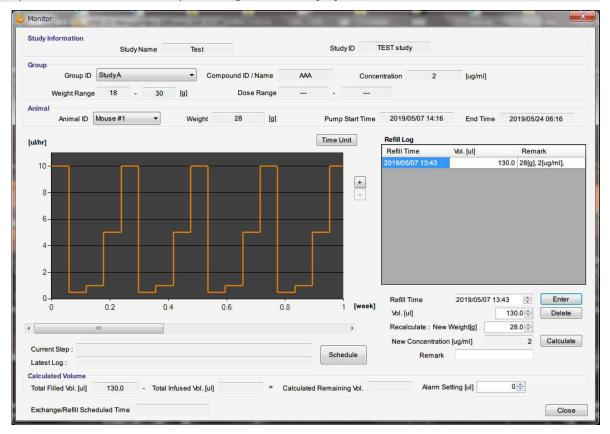
(1) Caution

During Infusion Protocol is running, please DO NOT STOP the management software.

Monitor the running pump status

► Procedure

1. Open Monitor window by clicking **Monitor (M)** from menu bar.

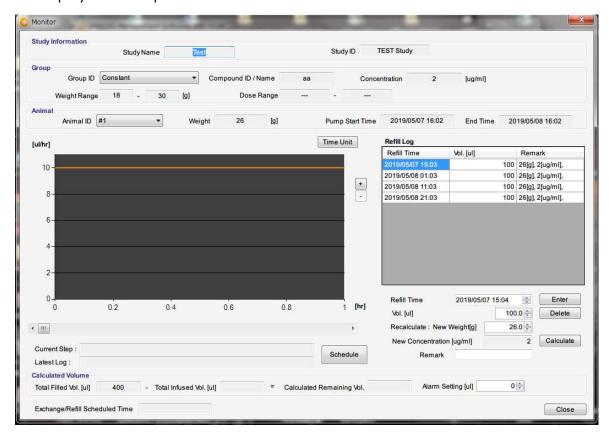


- 2. Upper part of window shows Study Name, Group and Animal. Select **Group ID** from pull down menu in Group column and **Animal ID** from Animal column.
- 3. There is Refill Log table in the Right side. At first input the medical solution **refill time** and **volume**, then click Enter button. For detail, please refer "Replace and/or refill drag solution". (Nest chapter)
- 4. The estimated remain solution volume is shown by calculated from infusion schedule and duration in the bottom of window. Also software alarm will be appear when the calculated volume reaches the Alarm Setting volume.
- 5. The Infusion Profile Graph locates in the left side of window. Clicking "**Time Unit**" button upper right, the Graph axis unit can be switched. Also clicking "**Schedule**" button bottom right, the Infusion schedule table will be shown. TO return, just click "**Graph**" button.

Replace and/or Refill the medical solution

Procedure

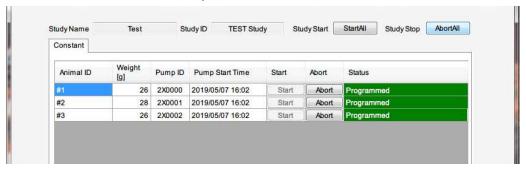
- 1. Open Monitor (M) window.
- 2. Verify the estimated remain volume in the bottom area.
- 3. Make pump implanted animal immobilization by weak anesthesia or retention.
- 4. When replace the solution, aspirate remain fluid in reservoir by 27G syringe needle through the skin to port. Subsequently fill the replacing solution into syringe and refill it to reservoir. To restock the drag solution, just fill the solution in a loaded syringe through the skin to port.
- Input Refill Time and Volume, click Enter button. When executed by dose mode, input new weight and click Calculate button, recast New Concentration result will be displayed to keep dose condition.



6. After fix the Refill Log, the table record automatically the Refill time, volume and comments (weight and density). To remove the refill log, select target refill log and click "**Delete**" button.

End of Study

After all infusion protocol finished, click "**Study End**" makes automatically record study date and finish study. If study should be abort during infusion schedule, click "**AbortAll**" then click "Study End"



Save Study file

► Procedure

- 1. Click Save Study from the **File (F)** in menu bar. The data file stored in C:\u00e4Users\u00e4XXX\u00e4AppData\u00e4Local\u00e4iPRECIO\u00e4study
- 2. The save data can be loaded from "Open" in the File (F) in the menu bar.

Export Study file

►) Procedure

- 1. Chose "Export" from the File (F) in menu bar.
- 2. Select folder to export, save with file name.
- 3. The exported data format is "csv". To view the data, simply import it by regular spreadsheet program.

Product Specification

Micro infusion pump for small laboratory animal iPRECIO® (Model:SMP-310R)

Administration method Rotary finger type (Patented: Peristaltic mechanism)

130µL Built-in reservoir: (Material) Medical grade SEBS Reservoir

> *The Maximum capacity is 130 µL, but out of accuracy guarantee range. To keep accuracy, only within 100µL is

guaranteed.

Tube Inner Tube: (Material) Medical grade SEBS

Outer Tube: (Material) Medical grade SEBS (3Fr)

(Size) ID=0.5mm, L=140mm

Replace/Refill port φ2mm size refill port stick out in the pump.

(Recommend below 27Ga size needle)

Data communication ISM band radio (Frequency: 916.2, 923.1, 926.1MHz)

Com unit: Within 3m from UCD-X10R

Built in pattern antenna. **Antenna**

*Material: Polyamide FPC

Programmable Flow Rate 0.1~10.0µL/hr. (setting resolution:0.1µL/hr.)

(FR) * Discharge flow by 360 degree roll of cam:3.2µL

Infusion accuracy ±5% (Under pressure 0~80cmH2O) Battery Life

Continuous motion FR 0.1µL/hr.: 19days,

FR 10.0µL/hr.: 7 days

Power on By applying the magnet force to power on.

Size $25.6(L) \times 15.8(W) \times 8.2 (H) \text{ mm}$

(Except accompanying catheter)

Weight 3.4g (Include accompanying catheter)

Solid content 2.4cc Type of usage Disposable

Package EOG Pre-Sterilization pack (5 package/box)

Sterilization TTL 2yrs (*Built in batter causes self-discharge during storage)

Data com unit (Model UCD-X10R)

Interface with control PC LAN (Cross type cable with ferrite core)

*Control through Ethernet by setting fixed IP address to the

Data com unit.

Communication way with ISM band radio (Frequency: 916.2, 923.1, 926.1MHz)

pump

*Not broadband type. One-on one communication between

Data com unit and individual pump.

unit controllable 20~25 pumps (Theoretical value without time expense)

pump number

USB DC adapter cable included.

Power source [Weight] 35g [Cable length] 1.2m

Size and Weight ϕ 140 × 60(H) mm · 347g STD accessory Anchorage to cage(Velcro) \cdot LAN cable with ferrite core

 $(3m) \times 1$ cable

Management software

Supported OS Windows 7/Windows 8/Windows 10 Japanese · English