



Micro infusion pump



SMP/IMS-310R User's Manual

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



Introduction

We would like to thank you for purchasing iPRECIO®.

iPRECIO® allows for accurate intracorporeal administrations of small-volumes over extended durations.

The iPRECIO® User's Manual for programming and operation of iPRECIO®.

The iPRECIO® is prohibited for human use.

When using iPRECIO®, please follow all appropriate guidelines, processes, and protocols mandated by the institution at which experimentation is performed.

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 connecting the 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. 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.

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

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.

IC:24730-SMP310R2019, IC:24730-UCDX10R2019

IC WARNING

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Caution

The Data communication unit UCD-X10R shall be installed at least 20cm away from users and the micro infusion pump SMP-310R shall be used at least 20cm away from human users when installed on mouse.

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



For more information:
PRIMETECH CORPORATION
TEL : +81-3-3816-0851 E-mail : iprecio@primetech.co.jp
URL : www.iprecio.com

Table of contents

INTRODUCTION	2
TABLE OF CONTENTS	4
ABOUT iPRECIO®	6
THE WORLD'S FIRST IMPLANTABLE, PROGRAMMABLE, INFUSION PUMP	6
BENEFITS OF iPRECIO®	7
PRODUCT COMPONENTS	7
STRUCTURE OF THE iPRECIO® SYSTEM: SMP-310R/UCD-X10R	8
WORKFLOW	9
PRODUCT WARRANTY.....	12
INFUSION VOLUME/BATTERY LIFE GUIDELINE.....	13
HOW TO SAVE BATTERY LIFE	13
DETECT AND PROGRAMMING TIME GUIDANCE	14
INSTALLATION OF MANAGEMENT SOFTWARE	15
PREPARATION BEFORE START	15
INSTALL iPRECIO® MANAGEMENT SOFTWARE	15
CABLE CONNECTION OF DATA COMMUNICATION DEVICE: UCD-X10R	18
TCP/IP CONNECTION BETWEEN DATA COM UNIT AND CONTROL PC.....	19
SOFTWARE SET-UP	20
RUN THE MANAGEMENT SOFTWARE.....	20
USER REGISTRATION	21
ENABLE ACCESS CONTROL	22
NETWORK SETTING.....	22
CUSTOMIZE INFORMATION	23
BEFORE STARTING A NEW STUDY	24
CREATE <INFUSION PROFILE> / GROUP ID.....	25
EXAMPLES FOR <DEFAULT ACTIVATION>&<SCHEDULED ACTIVATION>	26
KVO & DEAD VOLUME SETTING IN GROUP ID.....	29
PRELIMINARY IMPLANTATION PREPARATION FOR SMP-310R PUMPS.....	30
START STUDY	31
START NEW STUDY.....	31
PUMP DETECTION	32
CATHETER CONNECTION AND PUMP FILLING, TIMING DEPENDENT ON:-	33
A) DEFAULT ACTIVATION : COMPLETE THIS BEFORE <START ALL> PROGRAMMING	33
B) PROGRAMMED SCHEDULED ACTIVATION: COMPLETE THIS BEFORE ACTIVATION	33
SWITCHING ON PUMP WITH MAGNET -OUTSIDE BLISTER PACK	35
SWITCHING ON PUMP WITH MAGNET -INSIDE BLISTER PACK	35
SCHEDULED PROGRAMMED ACTIVATION TIME. (NOT DEFAULT SETTING)	35
INFUSION PROTOCOL SETTING	37
START INFUSION PROTOCOL	39
PUMP ACTIVATION IMMEDIATELY AFTER PUMP PROGRAMMED (DEFAULT SETTING IN INFUSION PROFILE-GROUP ID)	41
PUMP ACTIVATION -SCHEDULED ACTIVATION PROCESS	41
(SCHEDULED SETTING IN INFUSION PROFILE-GROUP ID -1 TO -48 HRS).....	41
ADD PUMP AFTER START OF INFUSION PROTOCOL.....	42
INDIVIDUAL <ABORT> PUMP AND THEN RE-PROGRAM.....	43
MONITOR THE PUMP STATUS	45

REPLACE AND/OR REFILL THE TEST ARTICLE	47
END OF STUDY	48
SAVE STUDY FILE	49
EXPORT STUDY FILE	49
REVIEWING SAVED STUDY DATA WITH MONITOR FUNCTION.....	50
HOW TO CHECK IF ALL THE PUMPS LOG DATA WERE COLLECTED.....	50
HOW TO RE-PROGRAM A PUMP.....	52
UTILITY SOFTWARE.....	52
CHANGE PUMP CONDITION/ STATUS	52
UTILITY BASESTATION MANAGER2.....	53
UTILITY PUMP DATABASE MANAGER2.....	54
PRODUCT SPECIFICATIONS	55
APPENDIX A: TABLE OF COMMANDS	57
APPENDIX B: MODIFY THE IP ADDRESS OF DATA COMMUNICATION DEVICE	59
APPENDIX C: HOW TO CONFIRM IF THE UCD-X10R IS WORKING CORRECTLY ..	61
APPENDIX D: COMMUNICATION AVAILABILITY.....	62
APPENDIX E: HOW TO USE THE LOG DATA	65
APPENDIX F: PUMP STATUS: EXAMPLE IN INFUSION PROTOCOL SETTING WINDOW	70
APPENDIX G: DETAILED PUMP STATUS	71
APPENDIX H: RECOMMENDED ORIENTATION OF UCD-X10R AND SMP-310R PUMPS	72
APPENDIX I: SMP-310R/300 COMPATIBILITY TEST	73

About iPRECIO®

The world's first implantable, programmable, infusion pump

iPRECIO® SMP-310R model is the successor to the SMP-300 model which was the world's first completely implantable, programmable, wirelessly programmable micro-infusion pump system for experimentation in small laboratory animals such as mouse. The pump has a built-in microprocessor which can be programmed to administer small volumes, in vivo, for extended durations. Additionally, the pump houses a septum designed for percutaneous access, through which filling and exchange of solutions is made possible. The iPRECIO® system's highly precise, in vivo capabilities uses a patented, high accuracy, mechanical pump technology, the "Rotary Finger Method". This method is a unique form of peristalsis. The precise "micro-stick" pushes a rubber tube in the pump in a uniform and sequential manner. This was developed by Primetech.

SMP-310R pumps are wirelessly programmed using proprietary technologies incorporated in the UCD-X10R programming station, application software and pumps. Using these technologies, the IMS-310R system, may be programmed to have maximum battery duration or maximum responsiveness. Maximum battery duration would mean the pumps would be available less often for re-programming/communicating. Maximum responsiveness would mean the pumps would be available more often for reprogramming but battery life significantly reduced. See Table on page 14 and Appendix D: Communication Availability for more detailed description. **Once wirelessly programmed, the iPRECIO SMP-310R Pumps will infuse as programmed until completed or aborted.**

In addition to infusing independently once programmed, the pumps will also provide logs to confirm certain operations of the pump. At each event, a log is created with a Timestamp. These logs include <Received a Schedule>, <Activation Start>, <Activation End>, <Start of Infusion- Step 1>, <Flow-rate change>, <Finished>, <Complete> etc. More details can be found in Appendix D and E. **Appendix E: How to use the Log Data** shows an example of Log Data from an infusion.

- During the study, these logs may be exported to have a permanent record of the study as it progresses. **See <Export Study File> on page 65.**

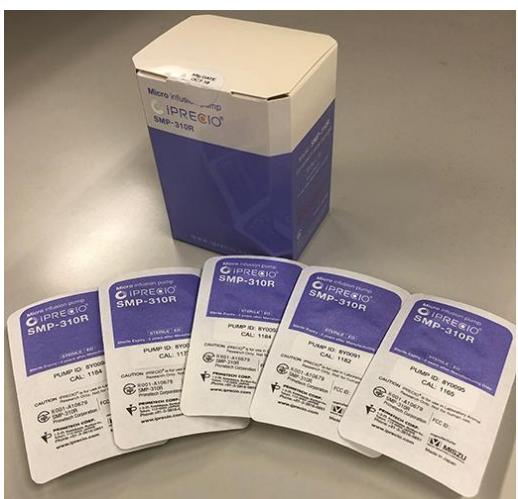
Benefits of iPRECIO®

- Highly precise delivery
 - Unique peristaltic mechanism
 - Patented Rotary Finger Method
 - Every pump is factory tested and calibrated
 - Better than +/-5% accuracy
- Totally implantable into subcutaneous space
- Programmable (requires PC with Windows 7 Professional or Higher or windows 10 Pro/Enterprise/Education, LAN port and USB2.0 or higher port for power to UCD-X10R)
- Refillable percutaneously through a septum
- Wireless Communication
- Battery life of up to 67 days (with continuous infusion of flow rate as 0.1uL/hr and communication interval setting as <none>)

Product Components

iPRECIO® system configured with the following parts:

- iPRECIO® Micro-Infusion Pump SMP-310R
- iPRECIO® Management System IMS-310R
 - Data Communication Device UCD-X10R (including USB power cable, LAN cable, magnet for SMP-310R pump ON/OFF)
 - iPRECIO® Management Software Installation CD
- iPRECIO® User's Manual

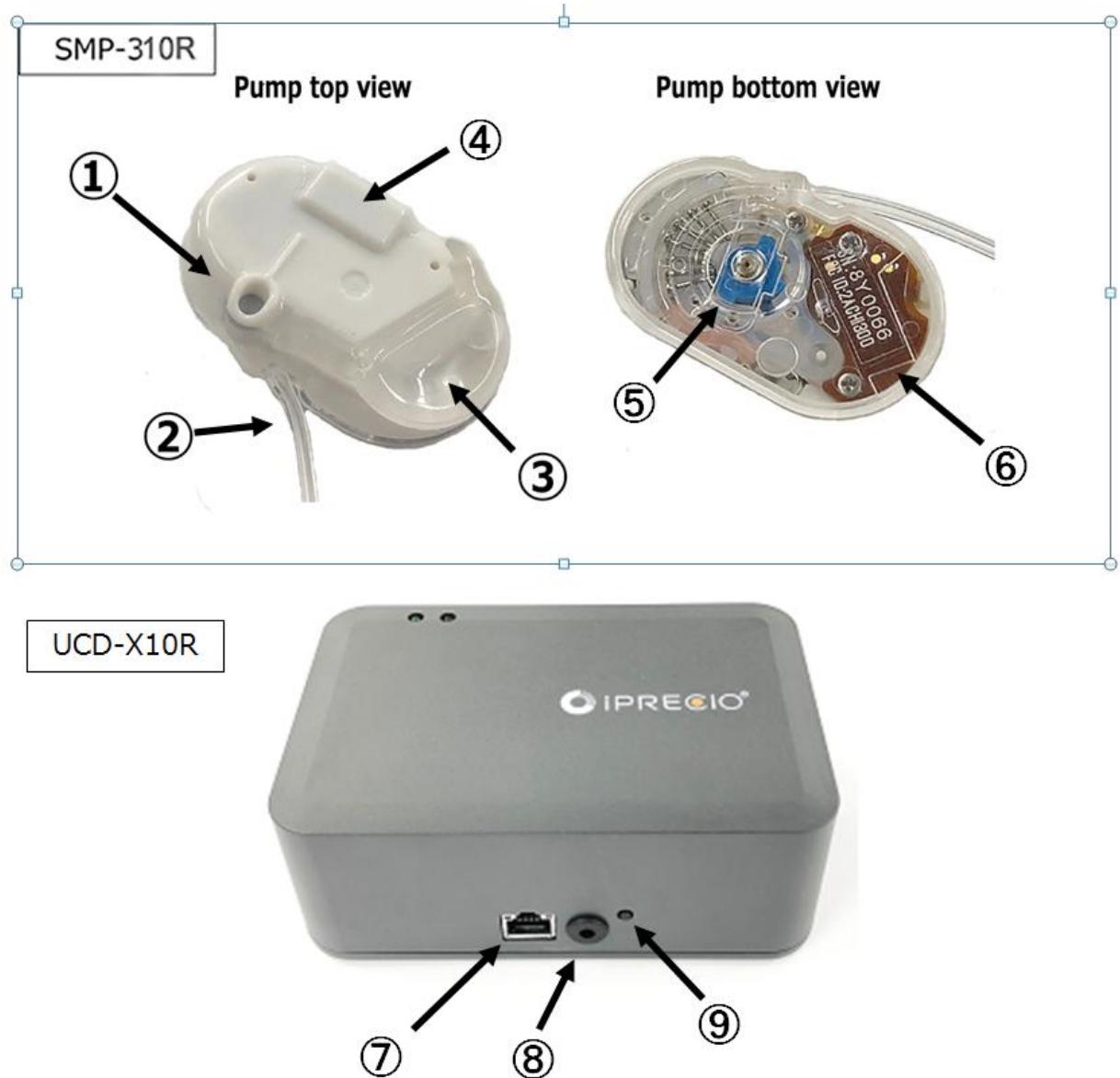


SMP-310R sterile pump 5pcs/box



UCD-X10R, USB power cable, LAN cable, magnet

Structure of the iPRECIO® System: SMP-310R/UCD-X10R



Number	name
①	Septum Port
②	Outlet tube
③	Reservoir
④	Magnetic Switch (South Pole - ON North Pole - OFF)
⑤	Micro Cam
⑥	Pump ID label
⑦	LAN cable connect port
⑧	DC Power Input (USB supply)
⑨	Reset Switch for UCD-X10R

①	Septum Port
②	Outlet tube
③	Reservoir
④	Magnetic Switch (South Pole - ON North Pole - OFF)
⑤	Micro Cam
⑥	Pump ID label
⑦	LAN cable connect port
⑧	DC Power Input (USB supply)
⑨	Reset Switch for UCD-X10R

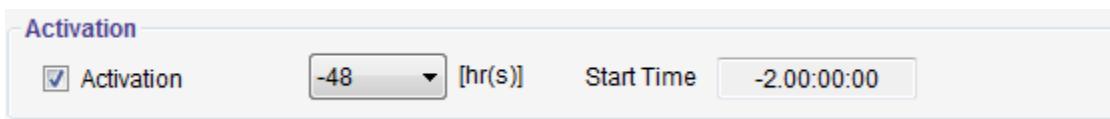
Workflow

You should begin implantation of the iPRECIO® according to the following workflow. Make sure there is sufficient time to switch ON, detect, fill, program, and activate all pumps prior to implantation. Detailed and comprehensive information are in the relevant sections of the User Manual. This workflow gives a high level view of considerations. All study plans should have been decided prior to starting. Infusion Profiles (Group Profile/ID) decided and prepared in advance to switching ON and detecting pumps. Once switched ON, pumps will start consuming power at the <Every Minute> communication availability rate. Ideally, pumps should be programmed shortly after being switched ON to minimize power consumption or wastage.

In default pump activation timing, all pumps should be filled prior to Programming of all the pumps with <Start All> as activation will begin immediately after the pump is programmed. <Start All> is in the Infusion Protocol Status Window. Blister pack containing the sterile pump would need to be opened to fill them.

 Study Start StartAll

Alternatively, pump scheduled activation start time may be programmed with reference to the pump start time. Pump start time is either the pump KVO Start Time or the Administration Start Time. This is will be described in detail in the Infusion Profile Section. This option gives flexibility to the workflow based on number of animals in the study and surgery related preparation and actual study start date and times. A maximum of -48 hours or 2 days before pump start time may be programmed. In this case, the blister pack containing the sterile pump may be opened and filled later in the process.



1. Installing the iPRECIO® Management System

Install the iPRECIO® Management Software that is required for the iPRECIO® Management System.

LAN Interface Arrangement

Set a connection between the data communication device, UCD-X10R, and the software.

User Registration

Certify the system by setting a study director and management software users upon initial setup of the software.

Software Customization

Customize the Infusion Protocol Setup header screen's pull-down menus: Section Name, Animal Species, Animal Strain, and Administration Route by adding or deleting the default pull-down menu options.

2. Before Starting a new Study, It is important to create a <Infusion Profile>/Group ID and decide on the key parameters.
3. Preliminary implantation guidelines – Low Flow Rate Standard Operating Procedure (SOP) -Pg. 30
4. Starting a new Study

Input general information about the study in the <Study Header> and <Pumps and Animals setting>. (Study name, animal ID, weight, species, strain, ..etc) Number of Animals/Pumps for the study is also decided here. Modify to requirements, click <Set> and start the detection process with <Detect>. This is done to optimize the detection process as a newly switched ON pump will be available to respond to the detection process immediately after it's start-up sequence. (Pump is only available for communication 5s in every minute for power saving and repeats every minute until programmed otherwise.)

Animals	Number of Animals	7	<input type="button" value="Set"/>
<input type="button" value="Copy"/> <input type="button" value="Paste"/> <input type="button" value="Delete"/> <input type="button" value="Detect"/>			

Pump Detection continues until total number of animals/pumps <Set> are detected. <Abort> will cancel the procedure and this will take no longer than 1 minute. **See Appendix H for Recommended orientation of UCD-X10R/SMP-310R.**

Switch ON Pump(s) – **Ideally switch ON pumps only when all preparations completed. (Infusion Profiles, Scheduled Activation Time, Start Time, where all parameters already decided)**

Switch ON Pump(s) with magnet provided with IMS-310R Management System. 5s per pump and organizing pumps by switch ON sequence so that it will be easy to find the pump if required. If pumps are switched ON by SN of pumps sequentially, this process can be more straight forward.

When Using Default Activation Settings –Fill Pumps Before Programming

Filling the test article (TA) or saline (MA) into the reservoir and catheter

Fill the TA or MA into the reservoir with 27G syringe prior to programming the pumps with <Start All> in Infusion Protocol Status Window.

When Using Optional Scheduled Activation Settings –Fill Pumps Before Activation Time

Filling the test article (TA) or saline (MA) into the reservoir and catheter

Finish filling the TA or MA into the reservoir with 27G syringe prior to selected activation start time and this is usually after programming the pumps with <Start All>.

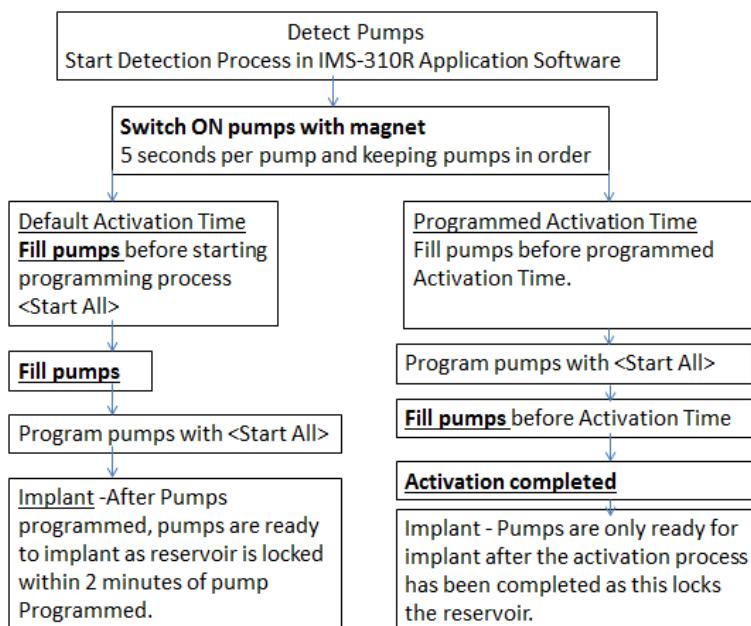
5. Start Infusion Protocol

Program <Infusion Profile> or choose infusion Group name from Group ID pull down menu and set the administration start time. If using KVO, this is programmed here; setup infusion flow rate for KVO, flushing flow rate and <dead volume

setting> for accurate flushing of dead volume. <Communication Availability>, <Activation> Timing, Test Article (TA) concentration are setup here.

Animal ID	Weight [g]	Pump ID	Pump Start Time	Start	Abort	Status
8Z0019	22	8Z0019	2019/06/10 09:30	Start	Abort	Programmed
910062	22	910062	2019/06/10 09:30	Start	Abort	Programmed
910063	22	910063	2019/06/10 09:30	Start	Abort	Programmed (0.1m delayed)
8Z0021	22	8Z0021	2019/06/10 09:30	Start	Abort	Programmed
8Y0073	22	8Y0073	2019/06/10 09:30	Start	Abort	Programmed
8Z0022	22	8Z0022	2019/06/10 09:30	Start	Abort	Programmed

Make sure there is sufficient time to program all the pumps to <Programmed> Status. Ideally, this will be <Programmed> Status in light green or dark green. This will mean that the programmed pumps will start at the programmed start time. In skyblue and deep skyblue, it is already sure that the pump start time has already elapsed or cannot be completed in time. **See Appendix F for more details on pump status.**



6. Implantation

Implant pumps only after all the pumps have been completely programmed as described in step 4 and the activation process has been completed with the reservoir of the pumps locked by the fingerpins. More care is required when Default Activation Setting was not used. These are Scheduled Activation Time and No Activation.

7. Status Management

The management software will predict the administration schedule based on the programmed protocol and will provide a filling time based on an empty reservoir. It is recommended to fill pumps when remaining volume is around 30ul.

Product Warranty

Primetech Corporation ("Primetech") warrants to the customer of iPrecio™ products (including the iPRECIO™ Micro Infusion Pump and the iPRECIO™ Management System and related products) that, for the warranty periods set forth below, the iPrecio™ products that Primetech and its authorized distributors have sold to the customer shall be free from defects in materials and workmanship. Primetech does not warrant that its products will meet the customer's requirements or will operate in the combinations (including with products not supplied by Primetech) which may be selected for use by the customer.

Customer's sole and exclusive remedy under the foregoing limited warranty is that Primetech will repair or replace, at the Primetech's option, any iPrecio™ product which is defective in materials or workmanship during the warranty periods set forth below at no cost to the customer, so long as such defect is not caused in transit or by customer's negligence, alteration, operation contrary to instructions, misuse, abuse, or parts or accessories not supplied by Primetech. Any defective product must be returned to Primetech for repair or replacement, transportation prepaid, and must be accompanied by a returned equipment declaration with RMA number supplied by Primetech.

Warranty Period:

iPRECIO® Micro Infusion Pump SMP-310R: 16 months after manufacture

iPRECIO® Management System IMS-310R: 12 months after shipping date

The foregoing limited warranty is in lieu of all other warranties, express or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

Limitation of Liability

Primetech's liability for damages to the customers of iPrecio™ products for any cause whatsoever, regardless of the form of action, whether in contract or tort, including negligence, shall be limited to the amount the customer paid for the product or products directly related to or which are the subject matter of the claim for damages. In no event shall Primetech be liable for any loss or damage resulting in lost profits, or other consequential, incidental, special or indirect damages of its customers of iPrecio™ products, even if Primetech has been advised of the possibility of such damages, or for any claim against its customers of iPrecio™ products by any other party. This warranty is null, void, and of no effect if the customer, its agents or employees, or any third party, uses the warranted iPrecio™ product for a use other than the intended use of that product, which is for use in animals.

Infusion volume/battery life guideline

The battery life is up to 43.3 days at a Flow Rate of 0.1uL/hr with communication availability of 6 hours. Please refer to the **Appendix D** for more detail about communication availability. As a guide, see the table below. **The specified (pump specifications) battery life is calculated by Application Software of IMS-310R system when setting up the <Infusion Profile/Group ID>. Use the IMS-310R Application as the definitive guide for battery life. Battery Lifetime of 1628 hours cannot be exceeded.** When maximizing infusion durations, ensure that that negative remaining battery is not displayed in the Group Profile. See page 28.

Comms Avail.	Every Minute	Every 2hrs	Every 6hrs	Every 24hrs	None
Flow Rate (uL/hr)	Drive Time (hrs)				
0.1	157	528	1063	1542	1628
1.0	153	428	742	959	991
5.0	137	263	344	357	362
8.0	127	207	243	243	245
10.0	121	178	196	200	201

Please note that the conditions below reduce the battery life of pumps:

- ⌚ **If you do not use the pump immediately/rapidly after power on.** After power on, internal circuit becomes active and starts to use battery power by standby power requirement. Comms Avail. default setting is every minute.
- ⌚ **If you do not store under proper conditions.** When pumps/batteries are subject to frequent temperature swings and/or exposed to high temperatures outside storage temperature range, self-discharge of batteries are increased.

How to Save Battery Life

- Prepare everything in advance prior to switching ON SMP-310R pumps so that they can be detected and programmed rapidly.
- **It is recommended to use communication availability of <every 24 hours>.** This can save the battery life significantly compared to <every minute>, <every 1 hour>, <every 2 hours>, <every 4 hours>, <every 6 hours>, <every 12 hours>, and <every 24hours> will give almost same duration as <None> setting. This <every 24 hours> setting also provides the time for the pump logs to be collected.
- The table above and the **Application Software <Infusion Profile>/Group ID** function will help the user select based on flow-rate requirements, required durations and requirements for logs and programming.
- Infusion duration should be prioritized.

Detect and Programming Time Guidance

When the management system is communicating with the pumps, a certain amount of time will be required to complete the different processes. The exact time would be dependent on the wireless conditions (noisy or clear), distance of pumps from management system, number of pumps, the <Infusion Profile/Group ID> etc.

The table below is a theoretical example in a relative clear or clean wireless environment where there are no directly interfering wireless signals.

In noisy environments and non-ideal conditions, it has taken up to several hours to program pumps. If this occurs, contact your authorized distributor or Primetech Corporation. Note that the table below is based both on ideal wireless conditions and nosier environments. Use of Faraday Box should be considered. See troubleshooting section.

Pumps to be within 1 meter of UCD-X10R and according to recommended orientation
Check for additional guidance documents and/or contact authorized distributor or
Primetech Corp. iprecio@primetech.co.jp or call +81-3-3816-0851

SMP-310R (Pumps)	Detect (minutes)	Pump Status Programmed (Dark Green) 5 step profile	Pump Status Programmed (Dark Green) 6 to 15 step profile	abort
1-10	2 to 5	5 to 30 minutes	25 to 90 minutes	immediate
11-20	4 to 10	10 to 60 minutes	50 to 180 minutes	immediate
21-30	5 to 20	20 to 90 minutes	100 to 270 minutes	immediate

- See Appendix H for Recommended orientation of UCD-X10R/SMP-310R.
- Delete pumps from UCD-X10R memory before each new study. Delete all pumps using Utility Pump BaseStation Manager 2. See Pg 52 <Recommended Procedure for re-using pumps>.
- If detection reliability not good enough, use Faraday Cage. See Troubleshooting in iPRECIO Installation CD, "Faraday Cage to try to see if interference is the issue to date.pdf"
- Pump: On power ON - wake up 5 sec/min when communicating <Comms Avail>. **Once programmed, pump wakes up 5 sec every 2 minutes to save power during communication interval.**
- Management System: 3 sec interval call -20 calls per second for 1 second then 2 seconds in receive mode.
- Maximum steps in an <Infusion Profile/Group ID> is 15. If <Infusion Profile/Group ID> is more than 5 steps, programming will take longer.
- Abort does not mean that the pump(s) has stopped.
*UCD-X10R will send the abort signal but there is no way to confirm if the pump will receive the stop signal or not.

Installation of Management Software

Preparation before start

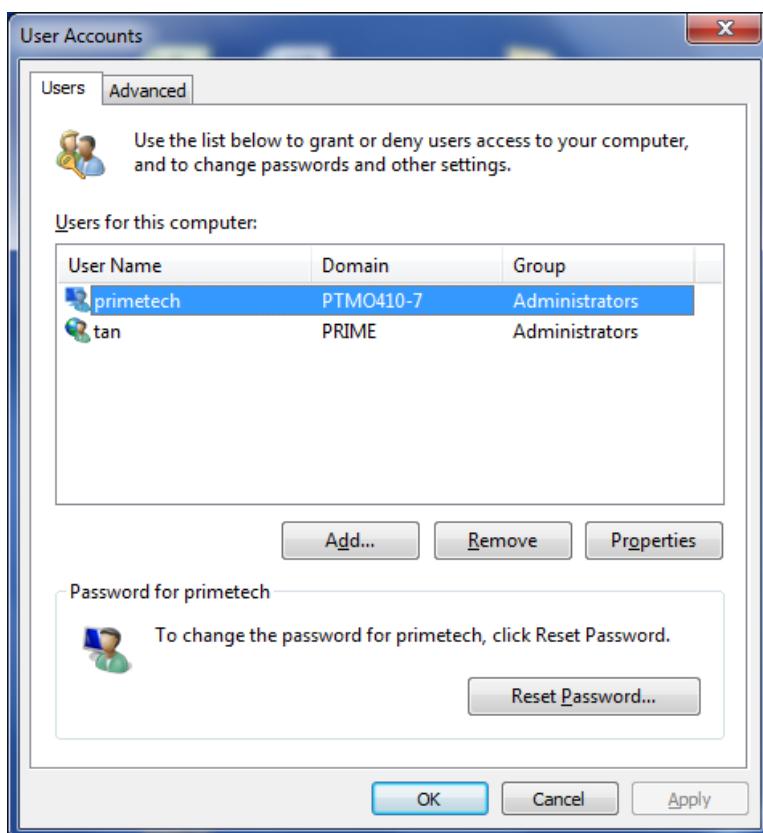
- iPRECIO® Management software install CD
- Windows 7 Professional or Higher, Windows 10 Pro/Enterprise/Education installed and LAN port ready PC
- Data communication unit UCD-X10R (data communication unit)
 - UCD-X10R
 - USB Power Cable for UCD-X10R
 - LAN cable (Cross over cable with Ferrite core)

Install iPRECIO® management software

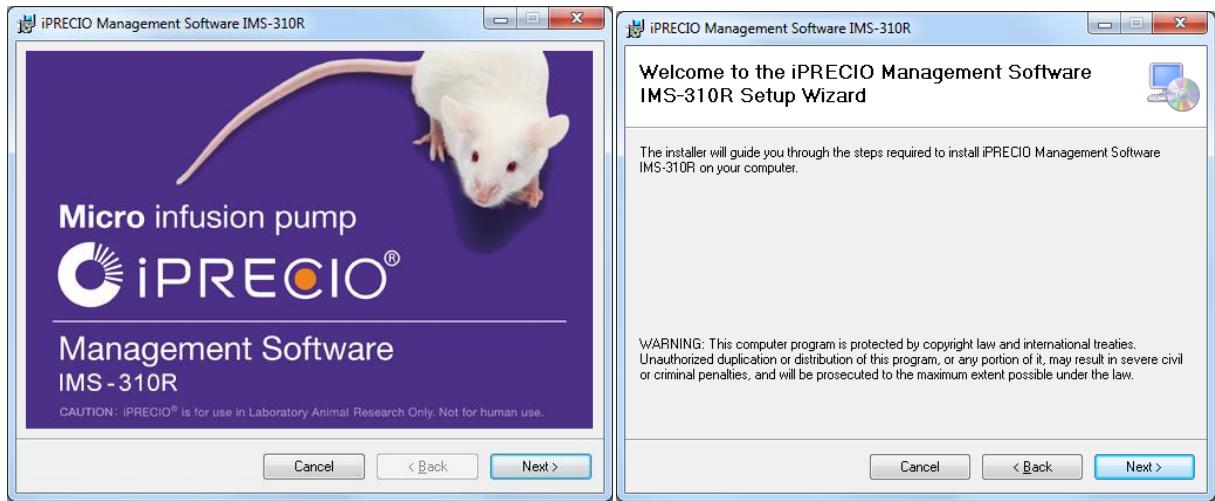
If the Application is closed, PC is switched off, sleeps, LAN disconnected or power supply to UCD-X10R Management System is lost, the Application software cannot recover to monitor study status. Pumps will continue to infuse as programmed.

Recommended PC settings:

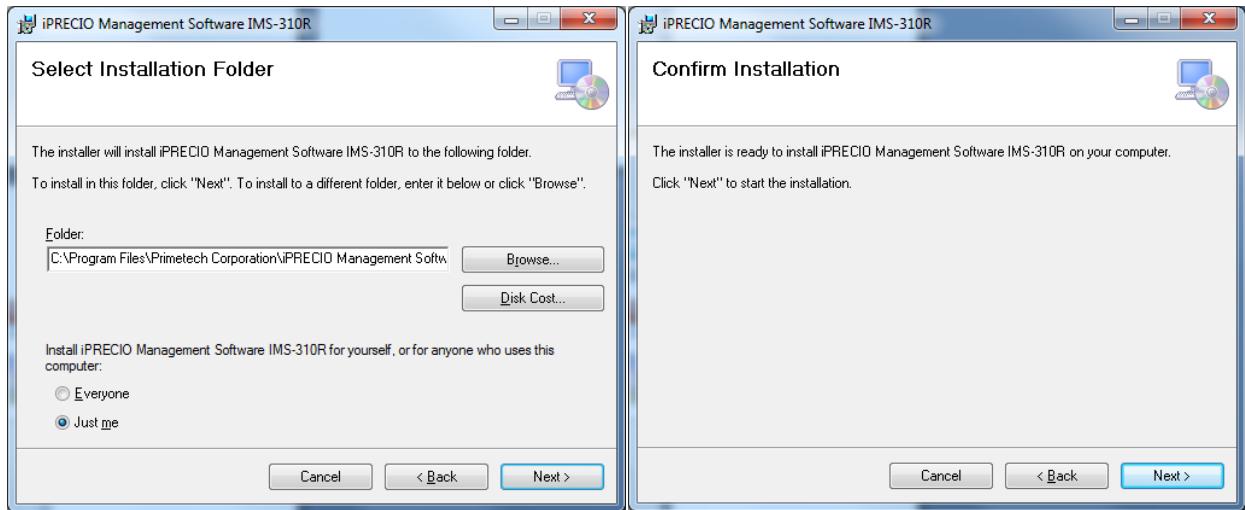
- Please TURN OFF the screen saver.
- Go to control panel and change the Power option as “Never Sleep Mode”.
- Please set the user account as “Administrators” (see picture below).
- Windows Update: Change settings to download updates but let me choose whether to install them.



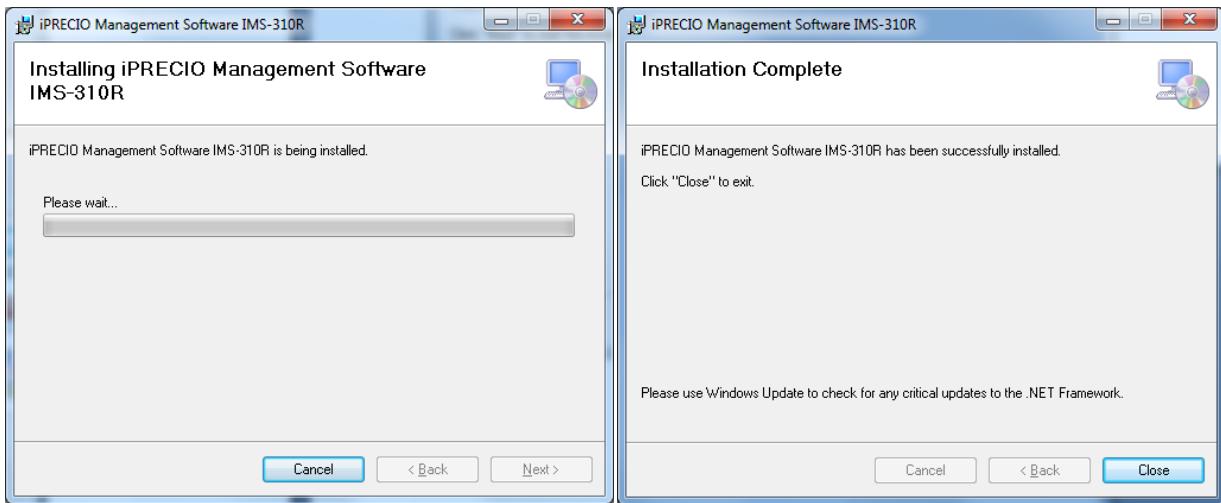
1. Run the "**setup.exe**" in an install CD.
2. When the startup window appears, click <**Next**> and follow instructions. Basically, following the next few steps. <**Next**> at Setup Wizard window.



3. Choose the default program files folder and click <**Next**> or modify as appropriate. Subsequently the confirmation screen opens, click on <**Next**> to start the installation.



4. When installation complete window appears, click <**Close**>.



5. Click on the start menu <All Programs> <iPRECIO Management Software IMS-310R> to confirm that the following 3 Programs were installed:-
 - iPRECIO® Management Software IMS-310R
 - Utility Base Station Manager2
 - Utility Pump Database Manager2

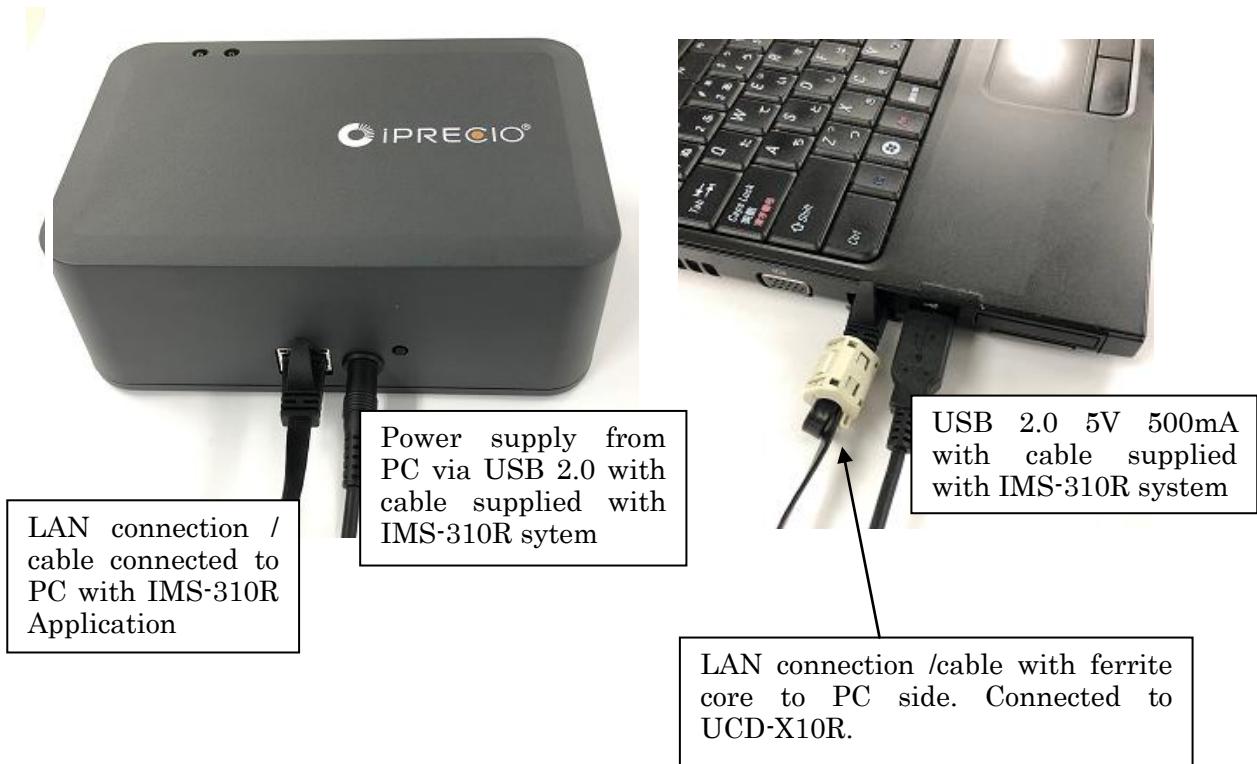
Usage of 3 Programs will be described within User Manual. All 3 will be required for correct operation.

6. If installation was successful, all 3 programs will be available in <iPRECIO Management Software IMS-310R>. Create shortcuts to Desktop if required for all 3 programs.

Cable connection of data communication device: UCD-X10R

 Connect USB port with supplied cable from PC to DC input of UCD-X10R. Connect the UCD-X10R and PC with LAN cable. If necessary, refer to Appendix C to confirm if the UCD-X10R is working correctly.

Connect LAN cable to management device and software installed PC



Ferrite core attached end must be connected to PC side.

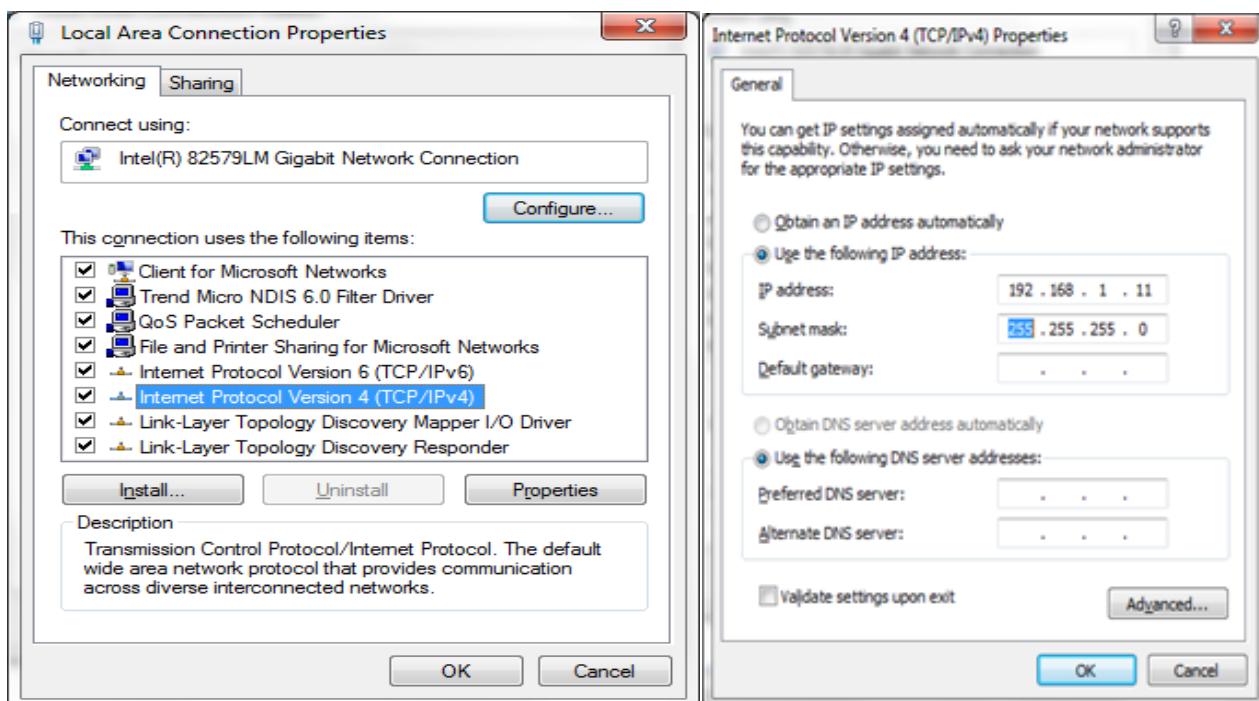
TCP/IP connection between data com unit and control PC

1. Connect data com unit (UCD-X10R) 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 Properties.
4. Select Internet Protocol version 4(TCP/IPv4) property and input the following IP address

IP Address: 192.168.1.11

Subnet mask: 255.255.255.0

Then press "OK".



The Data communication unit factory default IP address configuration is 192.168.1.10. If IP address does not work in default configuration due to conflict etc., change the IP address in accordance with **"Appendix B: How to change IP address of the Data communication unit"**

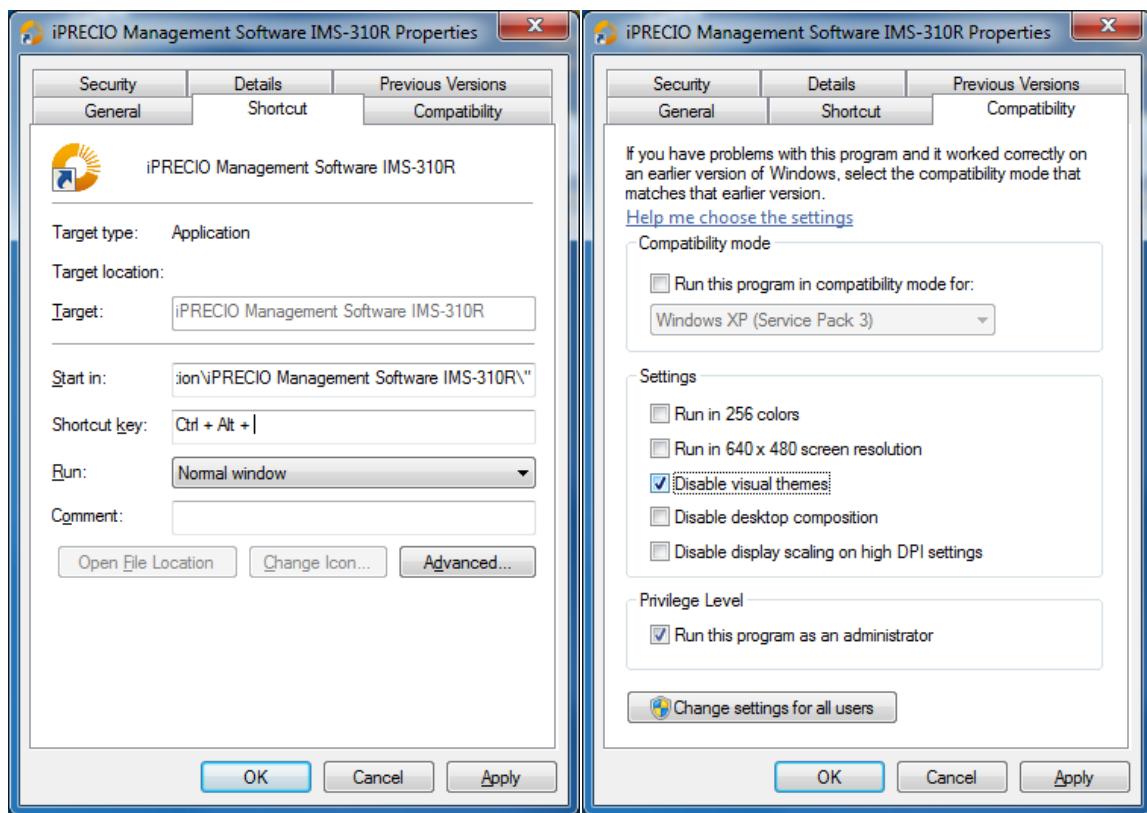
5. Once the Data communication device and control PC is connected by Internet Protocol, network connection <Network Setting> can be made in the management software.

Software Set-Up

Run the management software

Before running the software, put the cursor on the iPRECIO icon and right click to open below window.

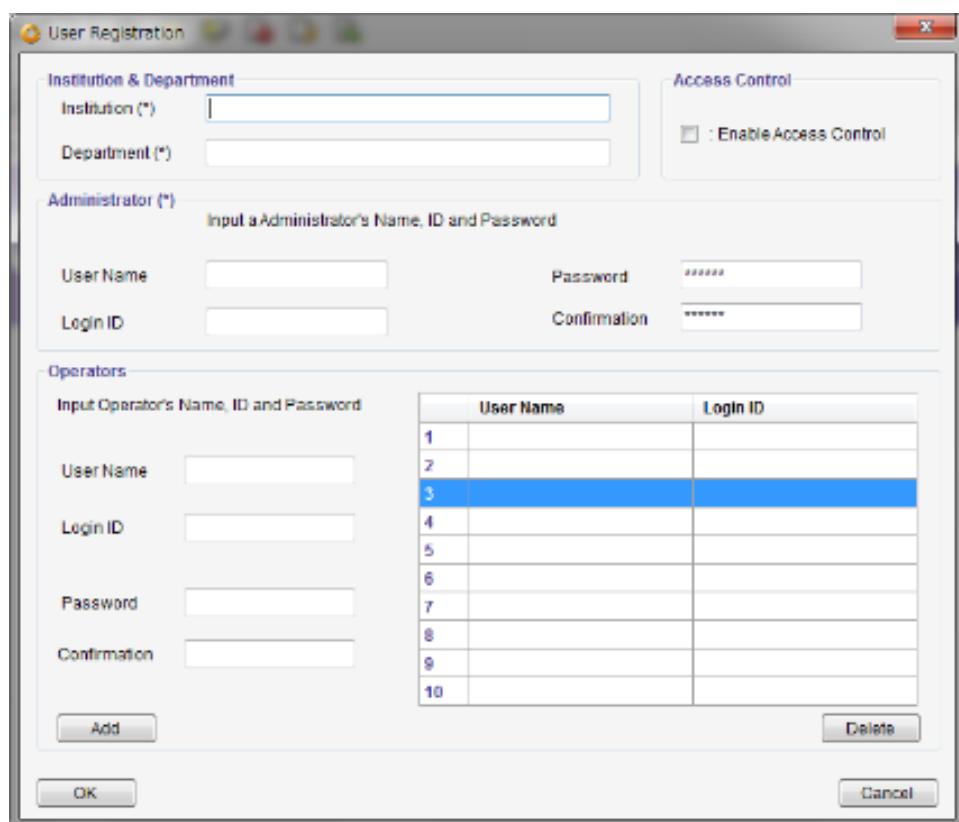
Go to Compatibility to check “use as an administrator” box.



The first time the management software is used, the user registration window will open automatically. Register user information, user management and access control as appropriate.

User Registration

1. Input required information in the user registration window. The asterisk (*) marked column must to be filled.
 - Institution & Department
 - Administrator
2. In addition, at least one operator registration is required. Input operator's User Name, Login ID and Password (Confirmation required), then click on <**Add**>. The operator will then be listed in the table. Add as appropriate.
3. To use Access control, check the "**Enable Access Control**" check box. Detail of Access Control function, refer to the next page, "Access control of software".
4. Fill all required information then, click <**OK**> to finish the registration process.

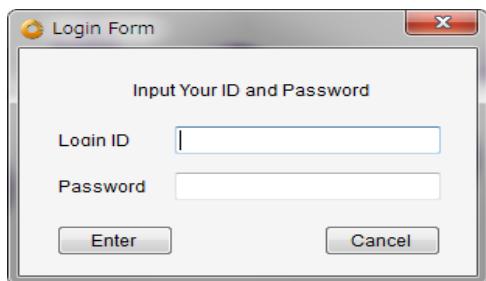


Enable Access Control

When using <Access Control Function>, the administrator can restrict and/or control user access to the management software. To use this function, check the “**Enable Access Control**” in the user registration window.

Once <Access Control Function> is active, Login ID and Password is required every time the software is used.

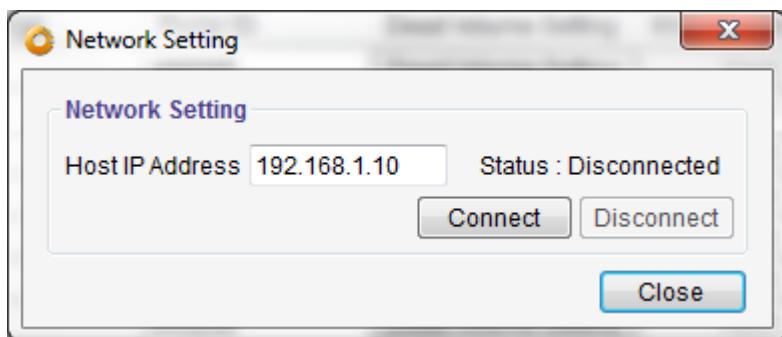
Please record Login ID and Password carefully. Without username and password, access to software will not be possible.



Network Setting

Connects IMS-310R Application Software to UCD-X10R.

1. Click **network setting** menu in toolbar.
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 confirming Status as <**Connected**>, 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”.

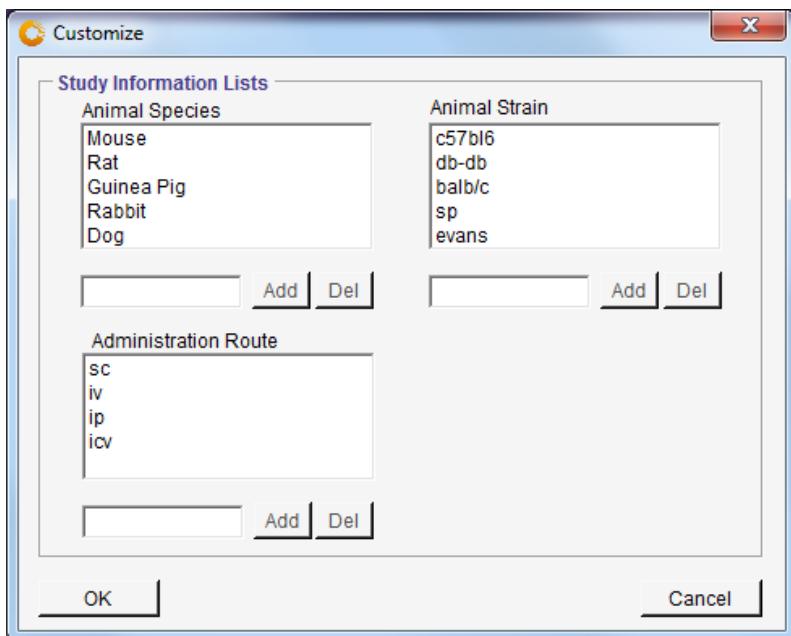


Customize information

Pull down menu for registration and management for Study Information. Modify default setting if required.

1. Open customize window from “**Customize (Z)**” menu in the tool bar.
2. Input the desired information in **the Animal Species, Animal Strain and Administration Route lists**, then click <Add> at their respective controls.
3. To delete existing information, select information and click at their respective controls below each list.
4. To complete and save, click <OK> in the left bottom corner of the Window.

Customize <Study Information List> before starting a new Study. Once a new Study is open, it will not be possible to customize and add to the list. It will be necessary to close the Study or proceed without the <Study Information Lists>.



Before Starting a new study

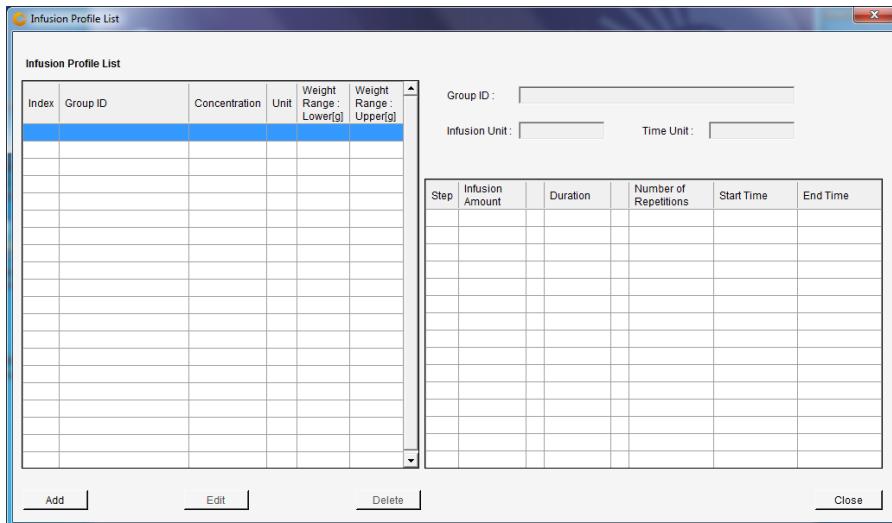
Before starting a new study, probably the most important function of iPRECIO® IMS-310R is to understand and decide on the Infusion Profile or Group ID. Infusion flow rates, durations, activation setting, communication availability, concentration of drug are all setup here. Use of Keep Vein Open (KVO) is also decided here.

Important Glossary (covered in more detail in relevant sections) –

Function	Details
Group ID <i>In Group Profile/Group ID</i>	Infusion Profile Information
Keep Vein Open (KVO) <i>In KVO & Dead Volume Setting</i>	Impacts KVO start time. Starts prior to Administration Start Time. Total Duration is KVO duration, Exchange Duration and Flushing Duration. Total Duration used to calculate KVO start time. See also <KVO Start Time> in Infusion Protocol Setting. Usually saline is filled in the reservoir and this is infused during the animal recovery period after surgery.
Exchange <i>In KVO & Dead Volume Setting</i>	Impacts KVO start time and duration for extracting and refilling reservoir. See also <Drug Exchange Period> in Infusion Protocol Setting.
Flushing Flow Rate <i>In KVO & Dead Volume Setting</i>	Impacts KVO start time and duration for flushing
Flushing Duration <i>In KVO & Dead Volume Setting</i>	Automatically calculated based on Total Dead Volume and Flushing Flow rate. See also <Flushing Start Time>
Total Dead Volume <i>In KVO & Dead Volume Setting</i>	Includes Dead Volume in Pump (inner volume), remain tube length and additional catheter (if added)
Flushing Duration <i>In KVO & Dead Volume Setting</i>	Automatically calculated based on Total Dead Volume and Flushing Flow rate
Step 1 to 15 or Step 1 to 12 if KVO used. <i>In Group Profile/Group ID</i>	Step(s) flow rate and duration is the Drug Administration (Administration) Infusion Profile.
Activation <i>In Group Profile/Group ID</i> -Default -Scheduled activation -1h to -48h -None or no activation Important key differences should be clearly understood.	Activation is the process where the pump's CAM rotates for 2 minutes where the rear most pin completely blocks the tube. This locks the reservoir and saline/vehicle/test article/TA in the reservoir can no longer be pushed out. Pumps may only be implanted after activation process is completed. No activation may be programmed if pump already implanted and previously activated.
Comms Avail (Communication Availability) <i>In Group Profile/Group ID</i>	SMP-310R communication with UCD-X10R consumes significant amount of power. Reducing communications increase significantly infusion flow rate durations. Every minute Comms Avail. Should only be used when absolutely required. Recommend is Comms Avail. of 12 hours or 24 hours. No communication or <None> should also be considered.
Remaining Battery Life <i>In Group Profile/Group ID</i>	Remaining battery calculation helps ensure that infusion protocol will be completed correctly. Should not be negative or red.
Pump Start Time <i>In Infusion Protocol Status</i>	KVO start time (if programmed) or Drug Administration (Administration) start time. If programmed, KVO start time is always the pump start time.

Create <Infusion Profile> / Group ID

The <Infusion Profile> / Group ID will define the iPRECIO Micro Infusion Pump infusion protocol. The pumps will infuse/administer test article (TA) or vehicle/saline in the reservoir according to the programmed <Infusion Profile>. In <Infusion Profile>/Group ID, Compound Name, concentration, flow-rate/dose settings, animal weight range, Communication Availability <Comms Avail.>, and battery life calculations are made. Keep Vein Open (KVO) parameters, Dead Volume and Pump Activation Settings are also decided here. These Profiles are usually created in advance and re-used.



1. Open <Infusion Profile> menu.
2. <Infusion Profile> list window opens up.
3. Add new <Infusion Profile>/Group ID, click “Add”.
4. Group profile window will be opened. See next page for full window.
5. One of the most important choices to make is related to whether to use Default Activation Time or modify it to fit your ideal workflow. This will decide when the pump(s) need to be removed from the blister pack to be filled before the activation process. Activation locks the reservoir so that pumps may be implanted.
6. Default Activation (pump activates immediately after being programmed). In this case, fill pump before <Start All> programming process.
7. Activation time of -1 to -48 hours (1 hour resolution) before to pump start time. In this case, make sure that pump is filled before activation start time. In example below pump(s) must be filled at least 6 hours before pump start time. Once activated pumps are much harder to fill correctly.
8. No Activation (usually used only when pump already in-vivo and previously activated)

Activation			
<input checked="" type="checkbox"/> Activation	Default	[hr(s)]	Start Time

Activation			
<input checked="" type="checkbox"/> Activation	-6	[hr(s)]	Start Time
-06:00:00			
Activation			
<input type="checkbox"/> Activation	Default	[hr(s)]	Start Time
No Activation			

Different workflows depending on Default Activation or Scheduled Programmed Activation Timing. In both cases pump(s) must be filled to distal end of catheter prior to activation.

1. **Default Activation** starts as soon as pumps are programmed and takes 2 minutes to complete.
2. **Scheduled Programmed Activation** may be programmed to be between -1 hour to -48 hours of Pump Start Time. Pump start time is either KVO start time (if programmed) or Administration Start Time.

Default Activation	Programmed Activation
<input checked="" type="checkbox"/> Activation <input type="button" value="Default [hr(s)]"/> Start Time <input type="button" value="..."/>	<input checked="" type="checkbox"/> Activation <input type="button" value="6 [hr(s)]"/> Start Time <input type="button" value="-06:00:00"/> -6 hrs <-1 to -48 hrs
<p>1) Start <Detect> Process on IMS-310R Application.</p>	
<p>2) Prepare Sterile Environment Remove pump(s) from blister pack Catheter connection preparation Fill Pumps</p>	
<p>3) Switch ON pump with <u>sterile magnet</u> Sequentially switch ON required pumps 5secs. South Pole (ON) to pump magnetic switch. Pumps should start to be detected in IMS-310R Application (1)</p>	
<p>4) Program Pumps <Start All> As pumps Programmed Default Activation starts (2mins to complete) Pumps may be implanted after activation completed</p>	
<p>5) Pump Starts at programmed Time</p>	
<p>6) Pump Starts at programmed Time</p>	

Examples for <Default Activation>&<Scheduled Activation>

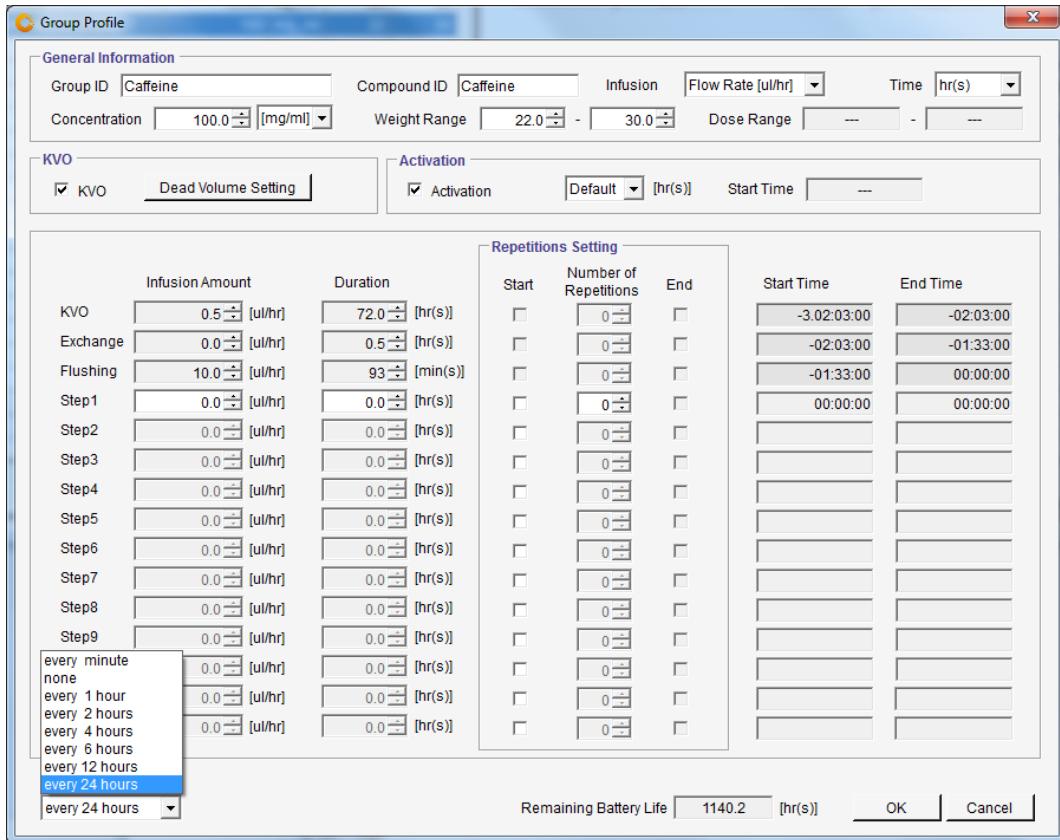
Study n=10, SC administration, No KVO, 15-20 minutes per surgery. (3hrs 20 mins surgery duration) – Surgery time here is for an experienced surgeon.

Example for Default Activation:

1. At the very latest, planning to <Start All> for Tuesday 1pm with 5pm Start Time.
2. Before 1 pm Tuesday, all pumps must have been prepared with catheter (if required) and pump filled to distal end of catheter. At 1pm <Start All> where it should take around 30 minutes to detect and program all 10 pumps.
3. Surgery starting from around 130pm after pumps programmed in Dark Green.
4. 2 minutes after pump programmed correctly (light/dark green), implant.

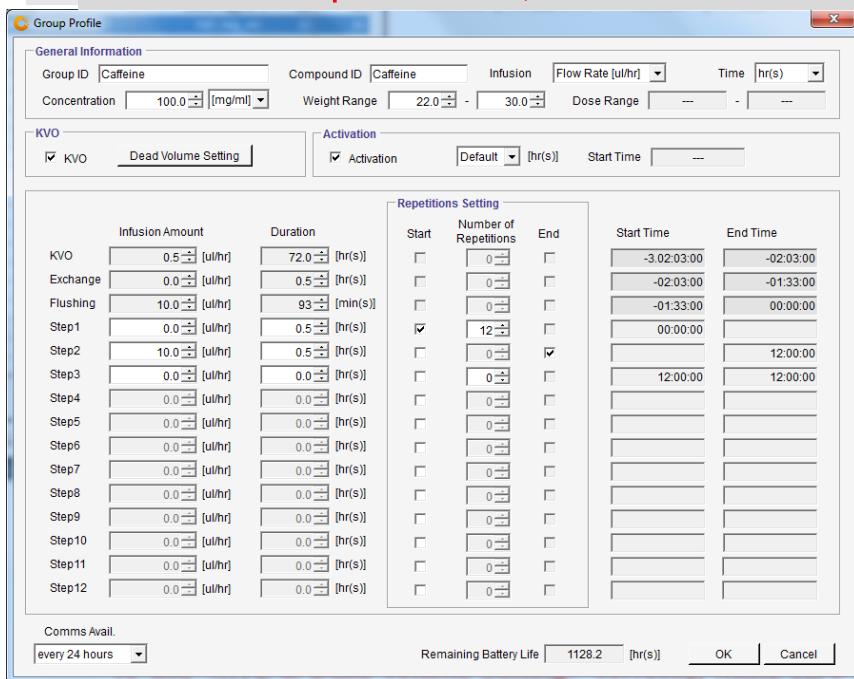
Example for Scheduled Programmed Activation of -6 hours

1. Start time programmed for 5pm Tuesday and activation of pumps will begin at 11.00am Tuesday. (-6 hours relative to start time)
2. All 10 pumps may be detected and fully programmed (Dark Green) the day before (Monday) with the pumps in the blister pack taking around 30 minutes.
3. Before 1100am Tuesday, all pumps must have been prepared with catheter (if required) and pump filled to distal end of catheter. At 1100am, activation starts.
4. At 1102am Tuesday, pumps may be implanted in animals after activation completed.
5. At 500pm Tuesday, pumps start.



9. Input or select the basic information. To set the infusion amount in Dose, select the unit : **$\mu\text{g/kg/hr(Dose)}$** or **mg/kg/hr(Dose)** . **Animal weight range and concentration of test article** must be filled when using this setting. Flow-rate in **$\mu\text{l/hr}$** may also be programmed.
 10. To get the correct remaining battery life calculation when programming the steps, select the correct **<Comms Avail.>** setting first. Default setting **<every minute>** gives max responsiveness of pumps. Maximum duration is achieved with **<None>** for communication availability. **<every 12 hours>** may be a good trade-off. **When maximizing infusion durations, it may be necessary to adjust/enter durations several times to ensure that negative remaining battery life is not displayed. Usually most important is the study duration with the required flow rates. Reduce communication availability to make sure Remaining Battery Life is positive and not negative in red**
 11. Input dose/flow-rate amount and duration from Step 1 onwards as required to create the infusion profile/schedule. This is a good time to decide whether to use KVO & Dead Volume Setting or not. See next section (KVO & Dead Volume Setting) for full details as it will take the first 3 steps and this is shown above. If KVO is not required, uncheck the Check Box and all 15 steps will be available for programming.
 12. Input the value for each step in each box and press **<Enter>** to finalize dose/flow-rate. The starting time and finish time will be shown in elapsed time with all the steps (including Repeat if used) accumulating in duration. The battery life shown in the bottom of window indicates the expected battery life for a new pump (new battery). It will help to create an **<Infusion Profile>/Group ID**.

13. To repeat the same schedule, use <Repeat Setting>. Check <Repeat Start> and <Repeat End> box at the appropriate steps in the infusion schedule. Input the number of cycles in <Times> box. It will count each loop/sequence as a repeat. Therefore, to have an infusion sequence to be run 12 times in total, enter twelve (12) like in the example below. Loop Step 1 & 2 is run 12 times to give total duration of 12 hours; [Step 1 Step 2] = [Step 1 Step 2] x 12. **When using step 1 with repeat but without KVO, step 1 duration must be at least 3.1 hours or longer or battery life calculation may be incorrect. When step 1 is on row 4, like in ex. below there is no limitation of duration with repeat.**



⌚ Remaining Battery calculation is fairly complex as it has to take into account both pump operation, communication availability (wireless battery consumption), logs etc. Therefore it may be necessary to input duration a number of times especially when needing to reach maximum duration.

⌚ For re-programming, see <How to re-program a pump> section.

14. After all information has been programmed, click <OK> to save new Infusion Profile. <Group ID/Infusion Profile> will be registered in the Infusion Profile list.

15. To modify/change the existing Infusion Profile, select intended Infusion Profile and click <Edit>. After modification, re-save by clicking <OK> to save or modify name and save under new name.

To eliminate the existing Infusion Profile in the list, select the intended Infusion profile to delete and click the <Delete> button.

16. Close the Infusion profile window by clicking <Close> button.

Note:

- Minimum Repeat <Times> per sequence/loop is 2 and the Maximum Repeat <Times> per loop is 254. Each count is a repeat.
- A minimum of 2 steps per loop is required. One step for <Repeat Start> and another step for <Repeat End>.

Number of steps in the <Infusion Profile>/Group ID will define the number of pump logs created. See Appendix D. iPRECIO SMP-310R pumps has an internal memory to hold a maximum of 20 logs. These logs will be over written if not downloaded before. When Infusion Profile or Group ID is in use, it will be greyed out in Infusion Profile List.

KVO & Dead Volume Setting in Group ID

KVO is abbreviated from **K**eep **V**ein **O**pen. KVO is used to maintain the infusion line. This is carried out by continuously infusing saline or vehicle. Continuous infusion helps prevent or delay the catheter or infusion from being clogged.

After animal surgery pump implantation with pump, saline is infused from reservoir to allow recovery and also maintaining the infusion line. After the recovery period, saline in the reservoir may be replaced by test article through the septum port without additional surgery. With accurate information on remaining iPRECIO catheter tube, dead volumes can be calculated to ensure that test article hits animal at programmed administration time.



KVO Setting			
Infusion Amount	Duration		
KVO	0.5 [uL/hr]	72.0 [hr(s)]	
Exchange	0.0 [uL/hr]	0.5 [hr(s)]	
Flushing	10.0 [uL/hr]	93 [min(s)]	
Dead Volume Setting			
Inner volume	6.00 [uL]		
Remaining tube			
Inner diameter	0.55 [mm]	Sub total	
Length	40.0 [mm]	9.50 [uL]	
Additional catheter			
<input type="radio"/> Calculated dead volume	Inner diameter	0.55 [mm]	Sub total
<input checked="" type="radio"/> Actual dead volume	Length	100.0 [mm]	23.76 [uL]
Total dead volume		15.50 [uL]	
Flushing flow rate		10.0 [uL/hr]	
Flushing duration		93 [min(s)]	
<input type="button" value="OK"/>		<input type="button" value="Cancel"/>	

In Group Profile, click on **<Dead Volume Setting>** to open the KVO window. Then fill in the required parameters for **KVO flow rate & Duration**. These are in **uL/hr** and **hours** respectively. Then fill in the **Exchange Duration**. During this duration the pump stops for maximum accuracy. Saline or vehicle in the reservoir is extracted or removed and then refilled with Test Article (TA) or Drug. Next, fill in the correct Remaining Tube Length in mm (Remain length). In default setting it has 140mm of length. This is usually cut to length for the Administration Route. Additional catheters may also be added for IV or ICV infusion. In the above example, Remain Tube Length is 40mm. This automatically transferred to the Group Profile when selected as shown below. Start Time is shown as negative as the TA or Drug Administration time is Step 1 with time T= 0

To use **<KVO & Dead Volume Setting>** correctly, make sure the checkbox is selected and the information is accurately filled. If not accurately filled, the dead volume calculation will not be correct and this will impact when the Drug or Test Article(TA) hits the animal.

Group Profile					
General Information		Activation		Time	
Group ID	Caffeine	Compound ID	Caffeine	Flow Rate [uL/hr]	[hr(s)]
Concentration	100.0 [mg/mL]	Weight Range	22.0 - 30.0	Dose Range	---
KVO		Activation		Time	
<input checked="" type="checkbox"/> KVO	<input type="checkbox"/> Dead Volume Setting	<input checked="" type="checkbox"/> Activation	<input type="button" value="Default [hr(s)]"/>	<input type="button" value="Start Time [hr(s)]"/>	<input type="button" value="Time [hr(s)]"/>
Repetitions Setting					
Infusion Amount	Duration	Start	Number of Repetitions	End	Start Time
KVO	0.5 [uL/hr]	72.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	-3:02:03:00
Exchange	0.0 [uL/hr]	0.5 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	-02:03:00
Flushing	10.0 [uL/hr]	93 [min(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	-01:33:00
Step1	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	00:00:00
Step2	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	00:00:00
Step3	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step4	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step5	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step6	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step7	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step8	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step9	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step10	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step11	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Step12	0.0 [uL/hr]	0.0 [hr(s)]	<input type="checkbox"/>	<input type="checkbox"/> 0	
Comms Avail.					
every 24 hours					
Remaining Battery Life 1140.2 [hr(s)]					
<input type="button" value="OK"/>		<input type="button" value="Cancel"/>			

- The remaining <Catheter> length of the iPRECIO pump. Diameter of 0.55mm already filled by default.
- Total Dead Volume must be accurate to calculate flushing duration and ensure that the Drug/TA hits the animal at the programmed time.
- Data filled and calculated here would then fill the first 3 steps of the Group Profile.
- It is shown as negative time relative to step 1 for the Administration Step.

Preliminary Implantation Preparation for SMP-310R Pumps

This step is carried out 3 days before start of implantation surgery.

Low Flow Infusion Standard Operating Procedure (SOP) [0.1µl/hour to 3µl/hour]

In general, you should condition the SMP-310R pumps in a 45°C incubator for 3 days to obtain maximum accuracy of pumps. Ideally, they are conditioned in their blister packs for maintaining sterility. Low Flow Infusion SOP is recommended especially if you plan to infuse at flow rates of between 0.1µl/hour to 3µl/hour. Special care should be taken to check Flow Rates when using the dose option.

Ideally, place the iPRECIO pumps in their unopened blister packages into 45°C air incubator for 3 days prior to implantation surgery.

1. Please ensure that the pump temperature is maintained until implantation, fill and re-fill with warmed solution, syringe and needle at warmed condition. (38°C)
2. Sterility of solutions and pumps must always be maintained as iPRECIO® pumps are designed to contain solutions for as long as 68 days.
3. Sterility must be maintained during first fill, exchange and each subsequent extract/refill procedure.

Start Study

Start New Study

iPRECIO® Management software has a function to abort individual animals/pumps during KVO and also during administration phase. For example, it is possible to exclude animal(s) from a study by using <abort> for that animal(s). Also, during Administration phase it is possible to deselect individual animals for any reason.

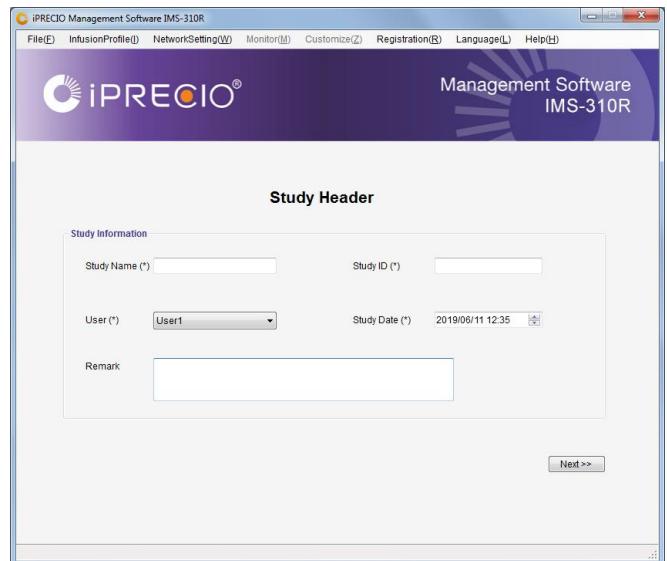


IMPORTANT NOTICE

The Data access Radio system of iPRECIO® is not a Broadband version. Therefore, the management system can only communicate/detect/program one pump at a time. It will sequentially communicate with each pump in the study design. Depending on wireless conditions and number of pumps, programming may take more time than expected. Refer also to <About iPRECIO®> on page 6 and table on page 14: Ideal Wireless conditions: Time to detect, program pumps etc. See also FAQ for more details.

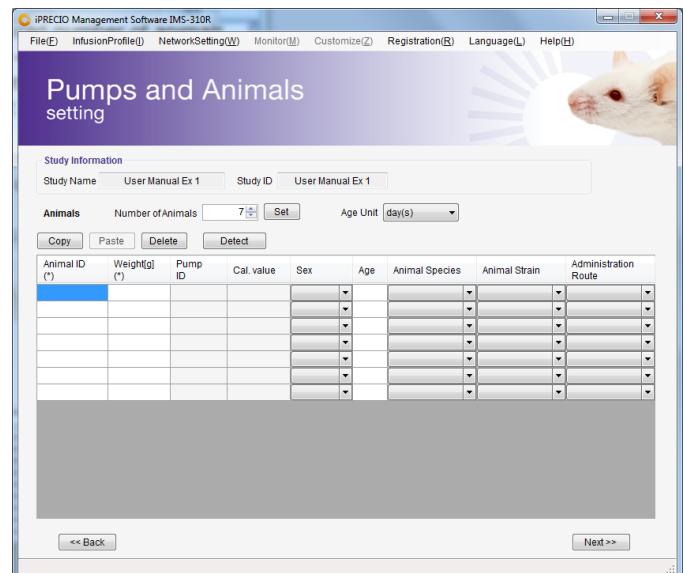
- Pump detection
- Program pumps with <Start All>
 - Infusion Profile which contains up to 15 flow steps
 - With and without repeat mode
- Abort is possible anytime but subject to wireless conditions and also programmed communication availability,
- Finish Infusion Profile
- Extract executed study log

1. Click <New> from the File Menu Bar.
2. Study Header window opens. (*) marked items are mandatory.
3. After filling required information, click <Next>.



4. Pumps and Animals setting window opens. Input the required number of animals (pumps) for the study in the **Number of Animals** and click <Set>. Default Number of Animal is 20. (20 rows in the table in this case) This will set the number of pumps the IMS-310R Application software will try to detect/find. It will continue to detect until all pumps set here are found or until <Cancelled>

5. **Pump ID and Calibration Factor** will be automatically filled during the <Detect> phase. Input animal ID, and weight. Then select with pull down menu for Animal Species, Animal Strain and Administrative Route.



6. After filling the first row, it may be copied to other rows. Use Copy and Paste for repetitive inputs. It copies data from the different columns for age, strain, etc. Then modify as appropriate. Pump ID and Cal Factor are not copied.

Pump detection

Pump detection is in IMS-310R Application software is started prior to switching ON the pumps to optimize the detection process.

Default Activation will be used in Infusion Profile (Group ID). Next step will be catheter connection, pump filling and switching ON pump(s)

Catheter connection and pump filling. Timing dependent on:-

- A) Default Activation : Complete this before <Start All> programming.**
B) Programmed scheduled activation: Complete this before activation.

Add/cut catheter to length, fill, and switch ON the pump with a sterile magnet. Once pump is on, communications are enabled. Default setting on Power ON is <1 minute> communications availability. Time in this setting must be minimized to save battery.

iPRECIO Pumps are delivered with all fingerpins down to facilitate filling where air escapes through open catheter. Fill Saline or Test Article till distal end of catheter before pump activation. Timing of activation process is dependent on (A) or (B) and at that time, the CAM rotates until fingerpin locks the tubing. Once locked, liquid or air from the reservoir cannot be pushed out. Before locking of the tube by the fingerpins is complete, it is important that reservoir is not accidentally compressed. If not, solution will be pushed out of the reservoir.

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



Each pump's dead volume is calculated with KVO setting. Final tube length, inner diameter or measured dead volume will be required. If not known, measure and record accurately.

3. Fill saline/test article to distal end of tube with 27G syringe needle through septum port.



4. Prepare all pumps for the study or for the surgery session. See also pg. 30 -
5. Switching ON pump is the next step. **Once pumps are switched ON, it is very important that the exact and correct procedure is followed to switch OFF. If not, the pump may actually be still ON and all the battery will used up. The only way to verify it is OFF is by detecting to see if the pump is ON or OFF. Unable to detect a pump does not mean that it is OFF. It could be radio interference or incorrectly set-up hardware and application software.**

See Appendix H for Recommended orientation of UCD-X10R/SMP-310R.

Notes:

Catheter preparation and filling of pump needs to be done before the pump activation process. See workflow below as reminder.

- A) Default Activation will mean pumps will be outside blister pack before the programming process to attach catheter and fill reservoir
- B) Programmed activation means pumps can be in blister pack until completely programmed but before the activation process.

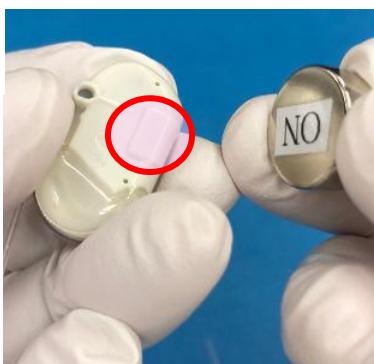
Default Activation		Programmed Activation	
<input checked="" type="checkbox"/> Activation <input type="button" value="Default"/> [hr(s)] Start Time _____		<input checked="" type="checkbox"/> Activation <input type="button" value="-6"/> [hr(s)] Start Time -06:00:00	
1) Start <Detect> Process on IMS-310R Application.		1) Start <Detect> Process on IMS-310R Application.	
2) Prepare Sterile Environment Remove pump(s) from blister pack Catheter connection preparation Fill Pumps		2) Switch ON pump(s) in blister pack with magnet. Sequentially switch ON required pumps 5secs. South Pole (ON) to pump magnetic switch. Pumps should start to be detected in IMS-310R Application (1)	
3) Switch ON pump with <u>sterile magnet</u> Sequentially switch ON required pumps 5secs. South Pole (ON) to pump magnetic switch. Pumps should start to be detected in IMS-310R Application (1)		3) Program Pumps <Start All> Fill Pumps before activation starts -6 hrs	
4) Program Pumps <Start All> As pumps Programmed Default Activation starts (2mins to complete) Pumps may be implanted after activation completed		4) Prepare Sterile Environment Remove pump(s) from blister pack. Catheter connection preparation. Fill Pumps	
5) Pump Starts at programmed Time		5) Activation starts -6 hrs <-1 to -48 hrs> before Pump Start Time Pumps may be implanted 2mins. After activation complete	
		6) Pump Starts at programmed Time	

Switching ON pump with magnet –outside blister pack

It is important to make sure that IMS-310R and UCD-X10R connected and working together prior to switching ON the SMP-310R pumps. IMS-310R Application should already be in <Detecting> mode.

Power On	Pump is switched ON magnetically. (S Pole -ON & N Pole - OFF) magnetic strength > 100mT. 5 seconds directly above the Magnetic Switch location as shown below to switch ON or OFF. Remove the magnet perpendicularly away from the top of the pump. After switching ON, wait at least 10 seconds before switching OFF. If there is any doubt, repeat procedure to switch ON or switch OFF with the exact procedure.
----------	--

Switching ON pumps which are outside the blister pack are shown below.



Magnet should be sterilized prior to use. Alternatively, use a sterile surgical drape or sterile plastic wrap around magnet to keep the pump sterile. Switch ON pumps sequentially, 5s per pump directly above magnetic switch. **Remove the magnet perpendicularly away from the top of the pump.** Keep the pumps in switching ON order by the UCD-X10R. As the pumps are switched ON, they will

start to communicate with UCD-X10R.

Important Notes.

Switching ON pump with magnet –inside blister pack Scheduled Programmed Activation Time. (not default setting)

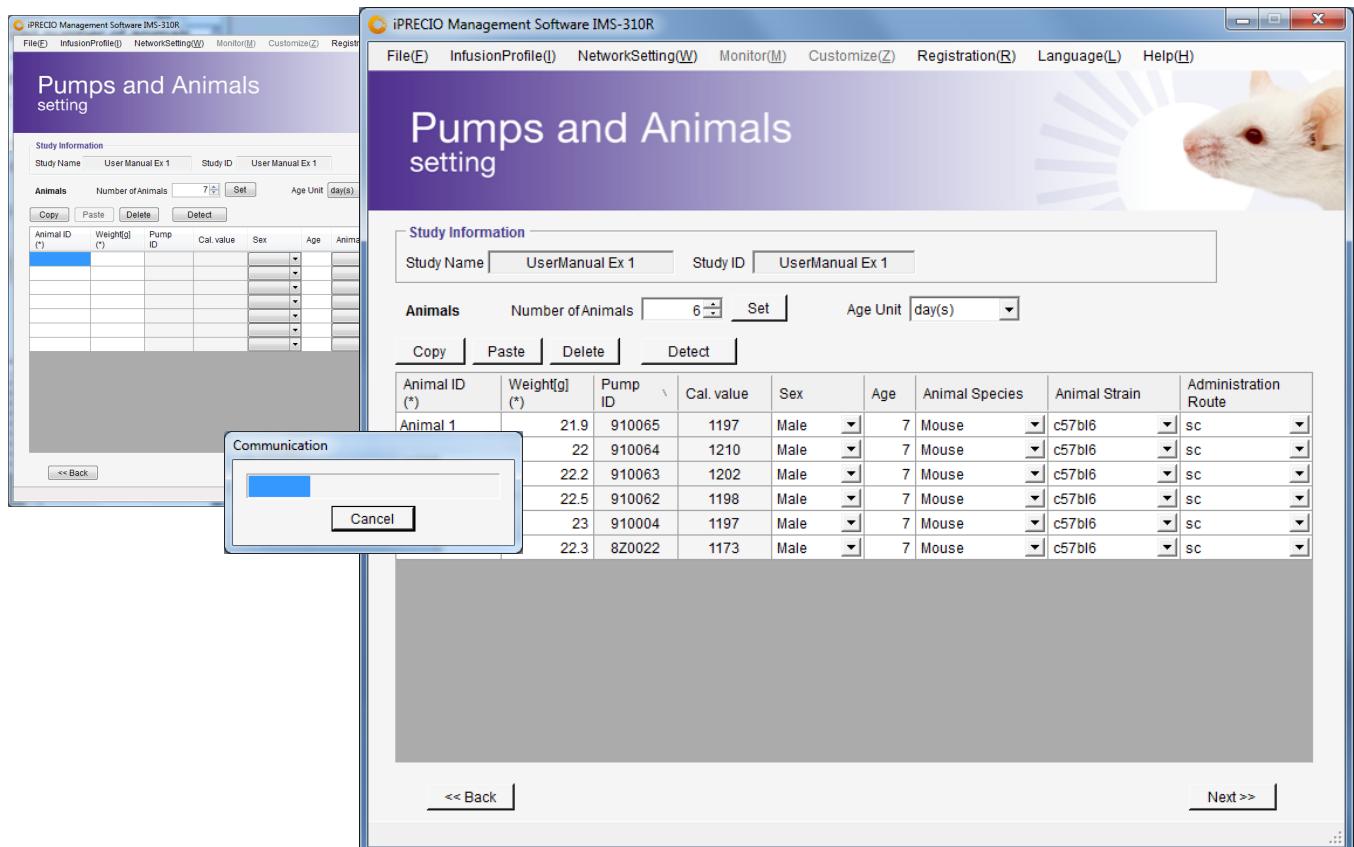
When activation time of pump is programmed, switch ON, detecting and programming may be completed with the pump in the blister pack. Important to make sure to <Add Catheter Connection and Pump filling> before programmed scheduled activation time.

In their blister packs, pumps are switched ON by aligning the ON side of the magnet towards blister pack as shown. The magnet should be left in place for 5s to be sure to switch ON the pumps. Ideally only switch ON when everything is ready. **To switch OFF, this is also very important to follow the procedure to be sure that they are OFF.** 5s OFF side of the magnet facing the blister pack/pump. **Remove the magnet perpendicularly**



away from the top of the pump/Blister Pack.

6. When Power On successful, pumps will be detected correctly by IMS-310 Application where pumps are displayed every 1 minute interval until correct number of pumps are detected. Place the pumps and data comms device, UCD-X10R, within 1 m range. <Number of Animals> or number of pumps for the study.
7. Progress bar is displayed and will continue until all pumps detected. <Cancel> if required to stop detecting. Pump ID and Cal Factor will be automatically filled from the pumps memory.



If there is no response from the pump(s), please check the following:

- ⌚ Table on page 14 for detection and programming time guidance.
- ⌚ It may take long time to detect pump due to radio wave background environment.
- ⌚ Verify PC and UCD-X10R connected properly. For details, refer to “TCP/IP connection between data com unit and control PC” and “Network Setting”.
- ⌚ Pump Switched ON. For details, please refer to Section <Switching ON pump with magnet>
- ⌚ See also the step by step trouble shooting guide in the installation CD.

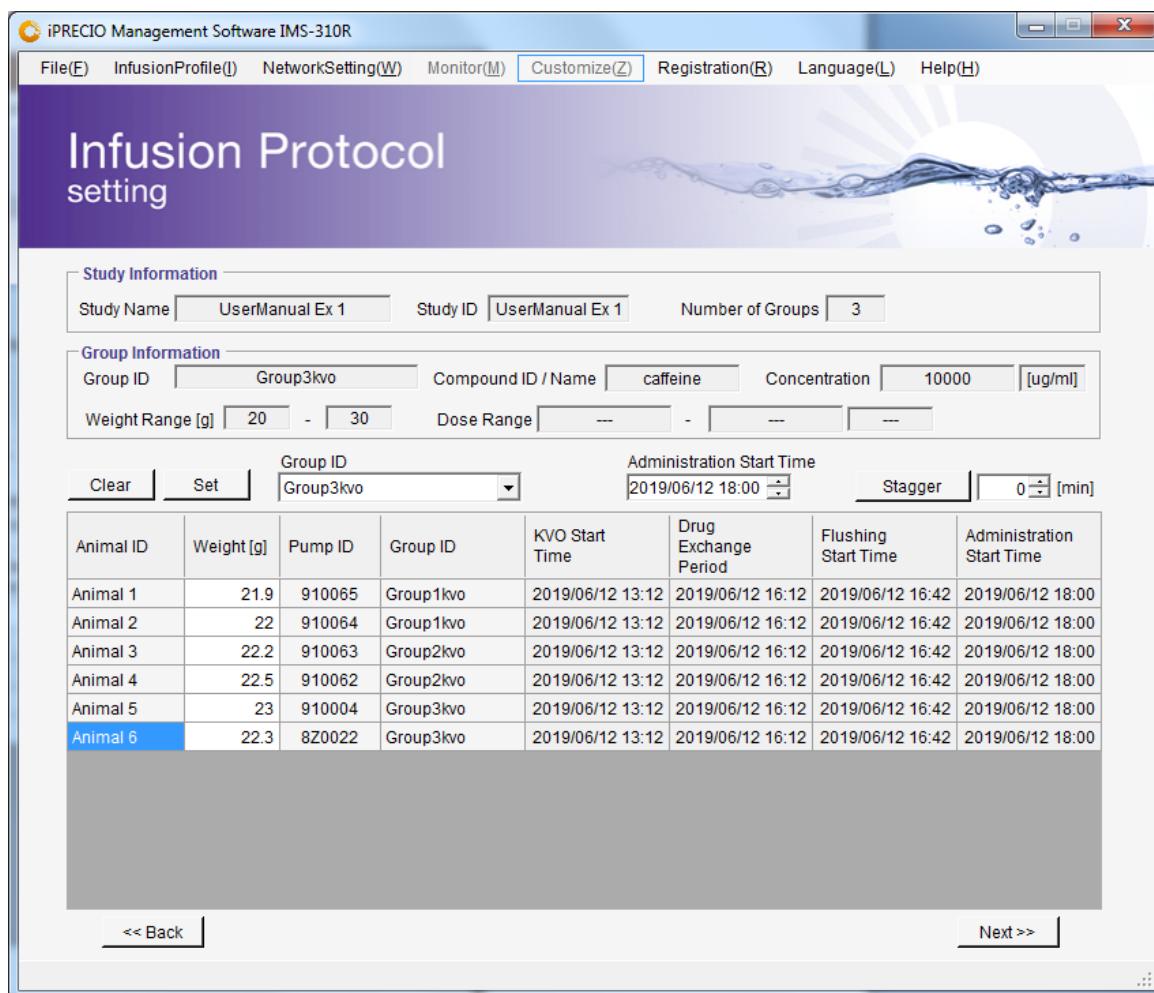
8. After all pumps detected, click <Next>.

*Click “Animal ID” or “Pump ID” to sort lines into ascending/ descending order.

***Use “Delete” button to erase a complete row**

Infusion Protocol setting

1. Group information window appears.
2. Choose infusion Group ID (Infusion Profile) from **Group ID** pull down menu and set **Administration Start Time**. Confirm that there is sufficient time to program the pumps before the <KVO Start Time>. If <KVO Start Time> is missed the <Administration Start Time> will also be missed. During this process, if time has already elapsed, the times are highlighted in red as shown below.
3. Animals may be assigned different Group IDs. They may have the same or different infusion protocols. Each group ID will be shown in a separate tab in the following window.

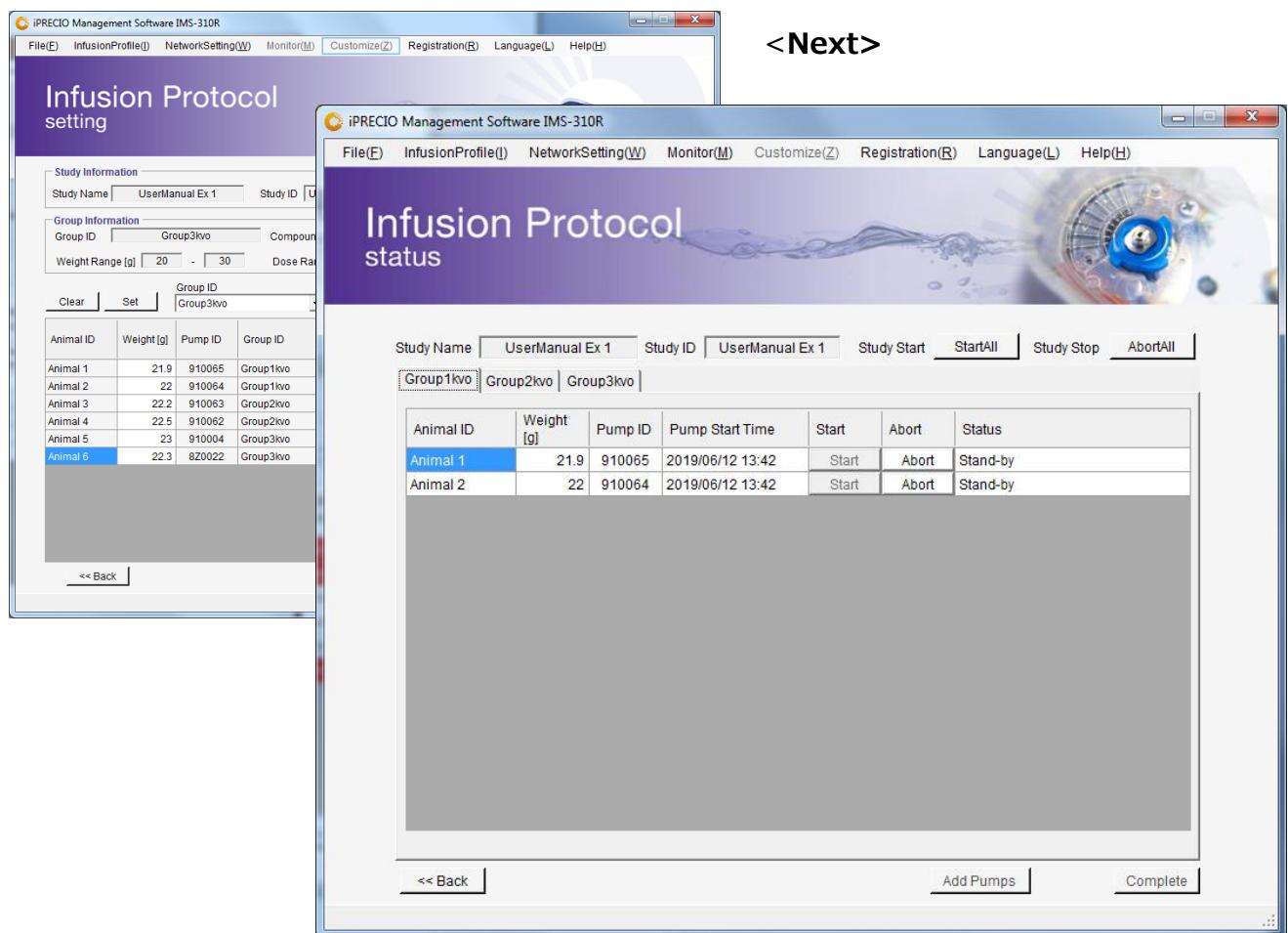


Animal ID	Weight [g]	Pump ID	Group ID	KVO Start Time	Drug Exchange Period	Flushing Start Time	Administration Start Time
Animal 1	21.9	910065	Group1kvo	2019/06/12 12:12	2019/06/12 15:12	2019/06/12 15:42	2019/06/12 17:00
Animal 2	22	910064	Group1kvo	2019/06/12 12:12	2019/06/12 15:12	2019/06/12 15:42	2019/06/12 17:00
Animal 3	22.2	910063	Group2kvo	2019/06/12 13:12	2019/06/12 16:12	2019/06/12 16:42	2019/06/12 18:00

4. If stagger is required, click <Stagger>, the administration will be staggered from set time with that value.
5. If the proper infusion group name not found, then create new one. Please refer

"Create Infusion Profile".

6. After all animal are assigned to profile group and Administration Start Time, click <Next> to go to the Infusion Protocol status from the Infusion Protocol setting window.
7. Make sure that there is sufficient time to program the pumps. **If the pumps are not programmed before the <KVO Start Time> and/or <Administration Start Time>, the protocol will start immediately after programming and there will be a delay versus what was programmed. This will result in the pumps status to be Deep skyblue or skyblue. See next section and Appendix F.**

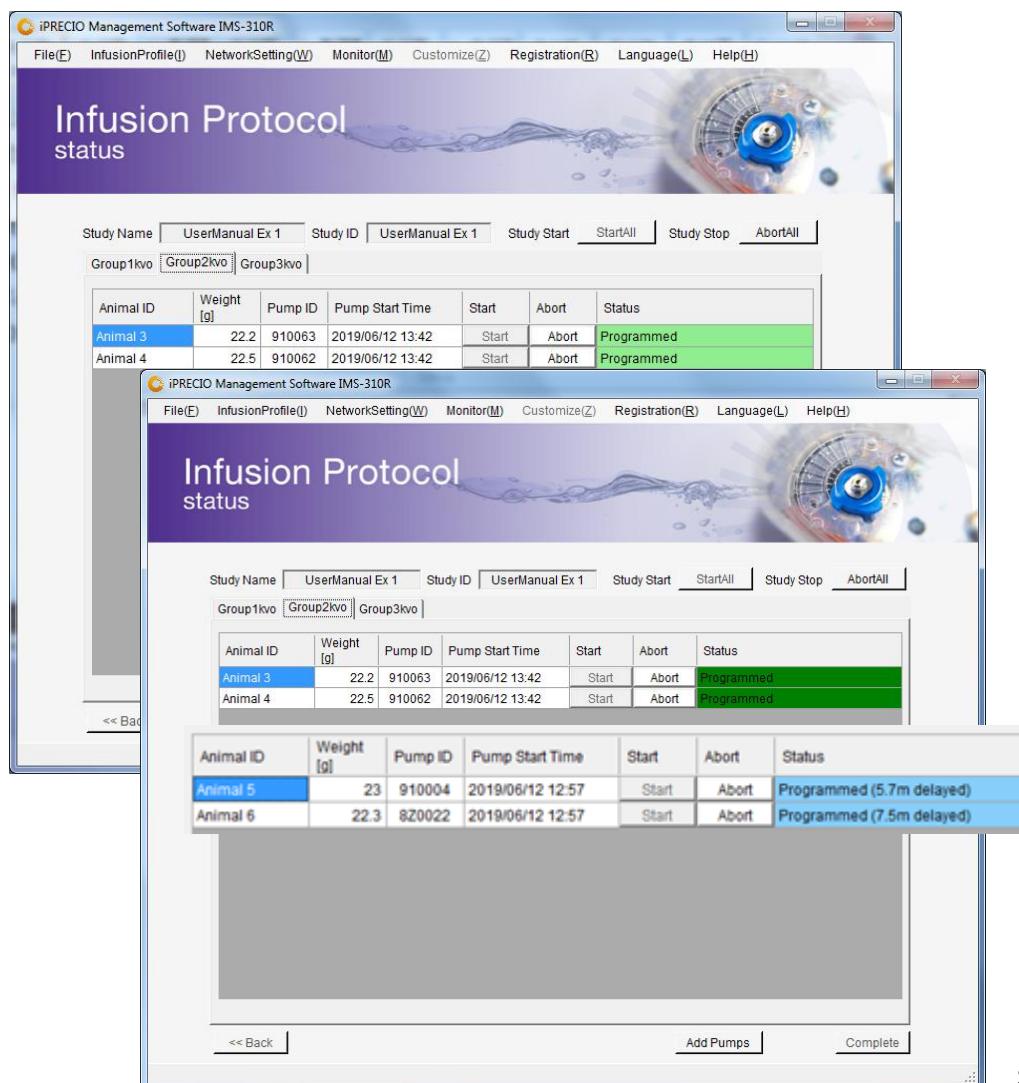


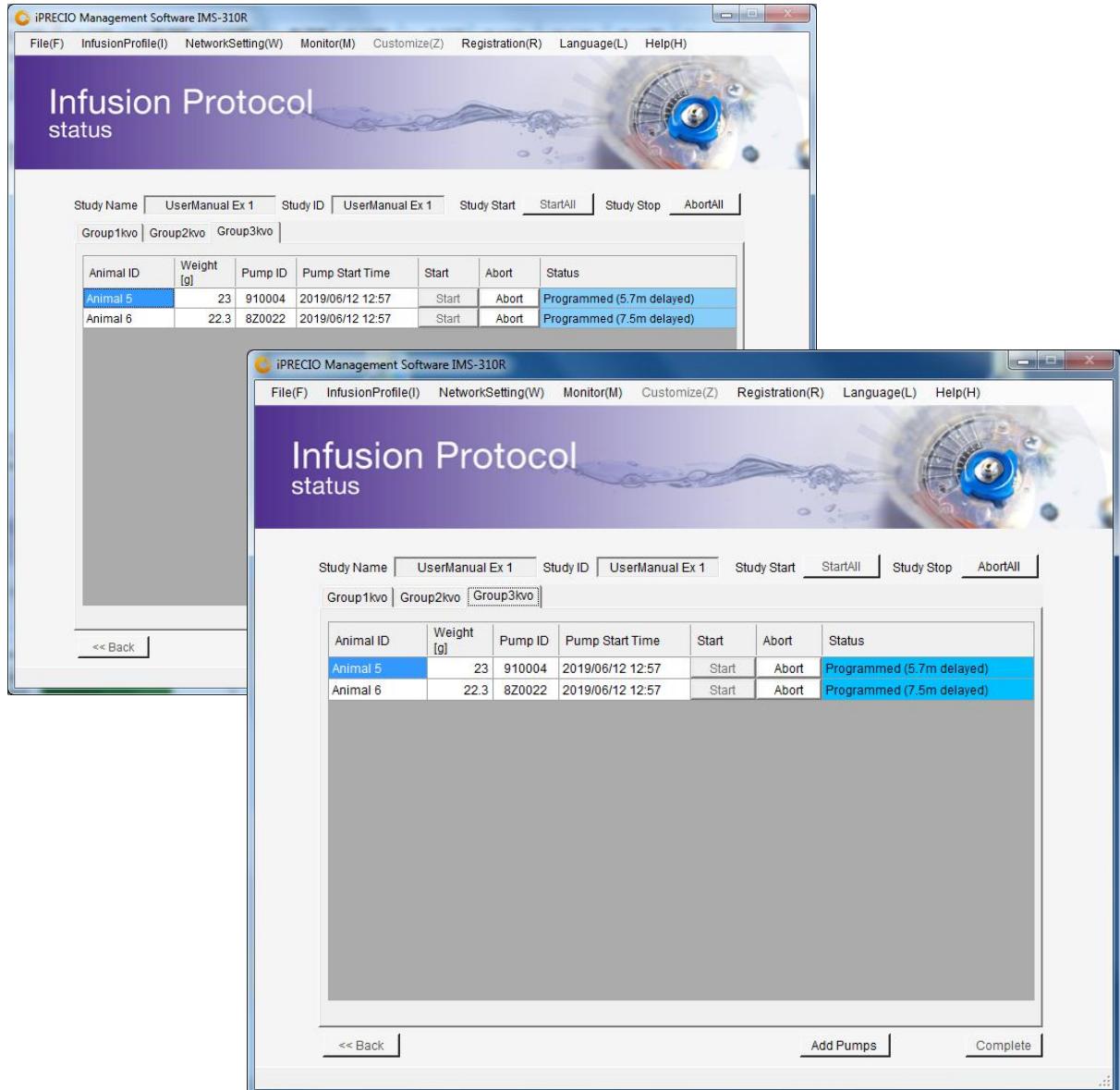
Start Infusion Protocol

See Table on Page 14 for Detect and Programming Time Guidance to allow sufficient time to program the pumps. If insufficient time is given, infusion profiles may start with a delay and the only way to correct for this is to abort and re-start the study. There is the option of using <Add Pumps> but best to plan sufficient time. **As a reminder, if using Default Activation, pumps should already be filled & catheter prepared. See pages 26 & 33 if this is unclear.**

1. Infusion Protocol window comes up.
2. Click **Start all** or click start for individual animal to start Infusion Protocol.
3. When all pumps have been programmed, Status shown as <Programmed>.

*To confirm if the pumps work correctly, check the color of the box which states <Programmed>. When <Programmed (Light/Dark Green)>, it means that pumps will start infusing as programmed at the required start time. When <Programmed (Light Green)> pumps will start on time but <Received a Schedule> has not been received. If the pump was not programmed in time and started after the <Start Time>, the pump status will be shown as <Programmed> in deep skyblue or skyblue. Pumps may be implanted when pump status shows <Programmed> and the **activation procedure to block the reservoir has completed**. See Appendix F for pump status. See FAQ to see how to check if reservoir has been blocked.





- Light Green <Programmed> - Pumps will start infusing as programmed but <Received a schedule> log has not been received.
- Dark Green (Green) <Programmed> Pumps will start infusing as programmed and <Received a schedule> log has been received.
- Deep Sky Blue <Programmed> - Pumps started infusing with delay with <Received a schedule> log received.
- Sky Blue <Programmed> - Pumps started infusing with delay with but <Received a schedule> log has not been received.

The only way to correct for the delayed pumps (deep sky blue sky blue) would be to Abort the pumps and reprogram or abort the full study and re-start the study with sufficient programming times. There is the option of using <Add Pumps> with How to Re-Program a Pump on pg 52.

For advanced and more detailed feedback on pump status see Appendix F & G.

If the Application is closed, PC is switched off, sleeps, LAN disconnected or power supply to UCD-X10R Management System is lost, the Application software cannot recover to monitor study status. Pumps will continue to infuse as programmed.

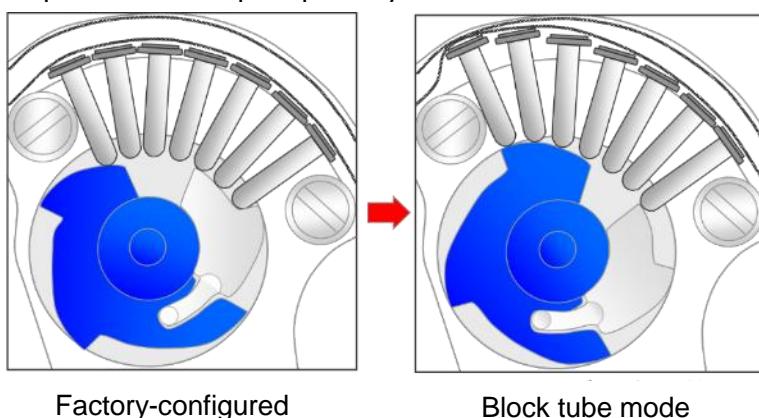
List of Active IMS-310R commands are listed/summarized in Appendix A.

Pump Activation immediately after pump programmed (Default Setting in Infusion Profile-Group ID)

As soon as pump(s) programmed (Status Programmed in light/dark green or skyblue or deep skyblue), pump activation starts. Therefore before <Start All> make sure all pumps already prepared correctly and filled. Activation is completed 2 minutes after Status shows Programmed as below.

5sMinDMin1							
Animal ID	Weight [g]	Pump ID	Pump Start Time	Start	Abort	Status	
Animal 1	22	8Z0021	2019/06/14 15:00	Start	Abort	Programmed (0.2m delayed)	
Animal 2	22	910064	2019/06/14 15:00	Start	Abort	Programmed (1.3m delayed)	
Animal 3	22	910063	2019/06/14 15:00	Start	Abort	Programmed	
Animal 4	22	8Z0019	2019/06/14 15:00	Start	Abort	Programmed	
Animal 5	22	8Z0022	2019/06/14 15:00	Start	Abort	Programmed (0.5m delayed)	
Animal 6	22	910062	2019/06/14 15:00	Start	Abort	Programmed (0.6m delayed)	
Animal 7	22	910004	2019/06/14 15:00	Start	Abort	Programmed (0.7m delayed)	
Animal 8	22	910065	2019/06/14 15:00	Start	Abort	Programmed	
Animal 9	22	8Z0016	2019/06/14 15:00	Start	Abort	Programmed	

Activation Process: From Factory-configured to Block tube mode. Pumps may be implanted after pumps fully activated and in Block tube mode.



Factory-configured

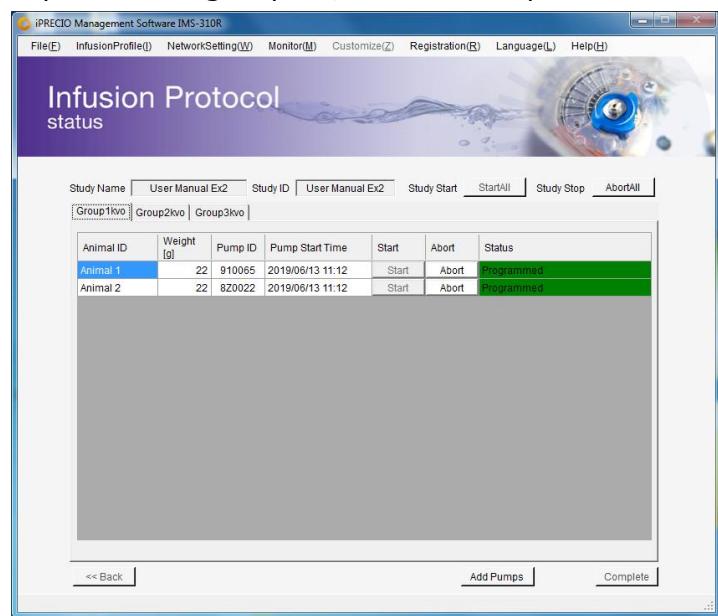
Block tube mode

Pump Activation -Scheduled Activation Process (Scheduled Setting in Infusion Profile-Group ID -1 to -48 hrs)

Activation Process is the same for Scheduled Activation: From Factory-configured to Block tube mode. Pumps may be implanted after pumps fully activated and in Block tube mode. Main difference is timing on when Activation occurs between Default and Scheduled.

Add Pump after Start of Infusion Protocol

This feature allows for additional animals to be added to an on-going study. If a new Group ID or Group Profile required and not programmed before, create before using <Add Pump>. Using the function <Add Pumps>, Pumps and Animals Setting window opens with a choice of number of pumps to add. This is similar to when starting a study. Pumps and Animals setting is open. Select number of pumps (animals) to be added. Detect pumps, fill information and related to animals. Next in the Infusion Protocol setting window assign the Group ID and start time. It can be a Group ID already in the study or it can be a new Group ID. If Group ID already in use, new animal is added to that group. For new group ID, new tab is opened.



Added pump/animal Group ID is already in study, animal is added to that Group ID tab-Group1kvo.

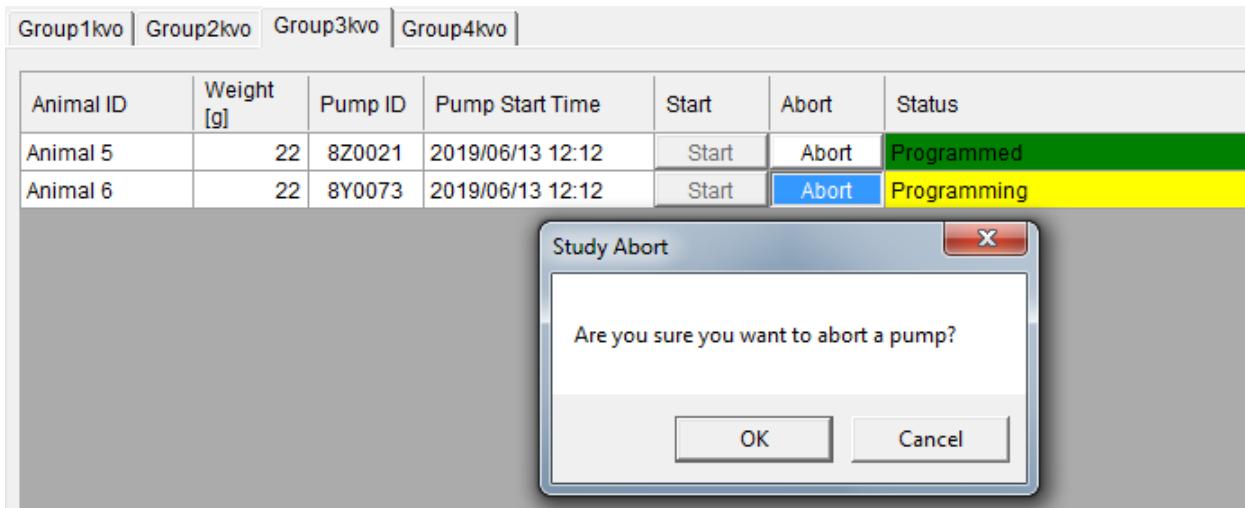
Group1kvo Group2kvo Group3kvo Group4kvo						
Animal ID	Weight [g]	Pump ID	Pump Start Time	Start	Abort	Status
Animal 1	22	910064	2019/06/13 12:12	Start	Abort	Programmed
Animal 2	22	910065	2019/06/13 12:12	Start	Abort	Programmed
Animal 8	23	8Z0019	2019/06/13 15:12	Start	Abort	Programmed

Added pump/animal not already in the study, animal is added to new Group ID tab-Group4kvo.

Group1kvo Group2kvo Group3kvo Group4kvo						
Animal ID	Weight [g]	Pump ID	Pump Start Time	Start	Abort	Status
Animal 7	23	8Z0016	2019/06/13 15:12	Start	Abort	Programmed

Individual <Abort> pump and then re-program.

Pump 8Y0073 for animal 6 may be aborted individually and then re-programmed. Click on <Abort> for that pump. <OK>.

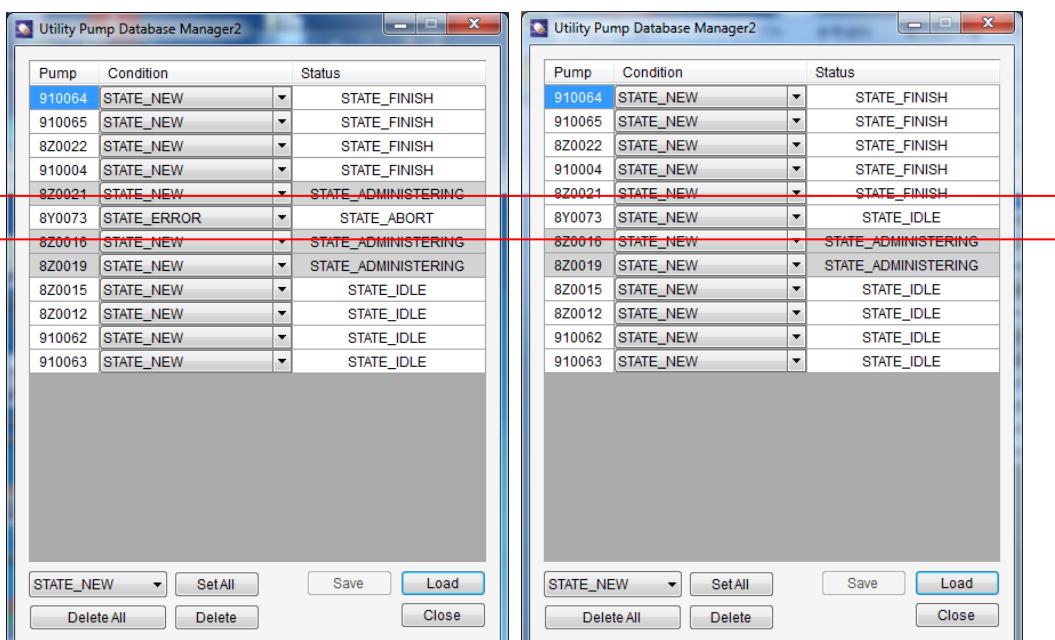


Pump 8Y0073 is then shown as aborted. It will then be necessary to use Utility Pump Database Manager2 to change the pump's status.

The screenshot shows the Utility Pump Database Manager2 window. It displays a table with columns: Pump, Condition, and Status. The table lists various pumps and their current status. Pump 8Y0073 is highlighted with a red box around its row. In the first version (left), its status is listed as 'STATE_ERROR'. In the second version (right), its status is changed to 'STATE_IDLE'. Other pumps like 8Z0021 and 8Z0016 also show changes in their status from 'STATE_ERROR' to 'STATE_IDLE'.

Pump	Condition	Status
910064	STATE_NEW	STATE_FINISH
910065	STATE_NEW	STATE_FINISH
8Z0022	STATE_NEW	STATE_FINISH
910004	STATE_NEW	STATE_FINISH
8Z0021	STATE_NEW	STATE_FINISH
8Y0073	STATE_ERROR	STATE_ABORT
8Z0016	STATE_NEW	STATE_ADMINISTERING
8Z0019	STATE_NEW	STATE_ADMINISTERING
8Z0015	STATE_NEW	STATE_IDLE
8Z0012	STATE_NEW	STATE_IDLE
910062	STATE_NEW	STATE_IDLE
910063	STATE_NEW	STATE_IDLE

Aborted pump 8Y0073 is shown with condition State_Error status <State_Abort>. To re-program, change Condition to State_New and save. Status is then shown as NEW and STATE_IDLE. After doing this, it is basically the same as adding a new pump or animal in previous section.



Then use <Add Pumps> in Infusion Protocol Status. <Add Pumps> open windows which allows detection of new pumps to add to Study. Fill as required, assign Group ID and finalize Administration Start making sure that there is enough time prior to KVO start. <Start All> will then start the process of programming the pumps.

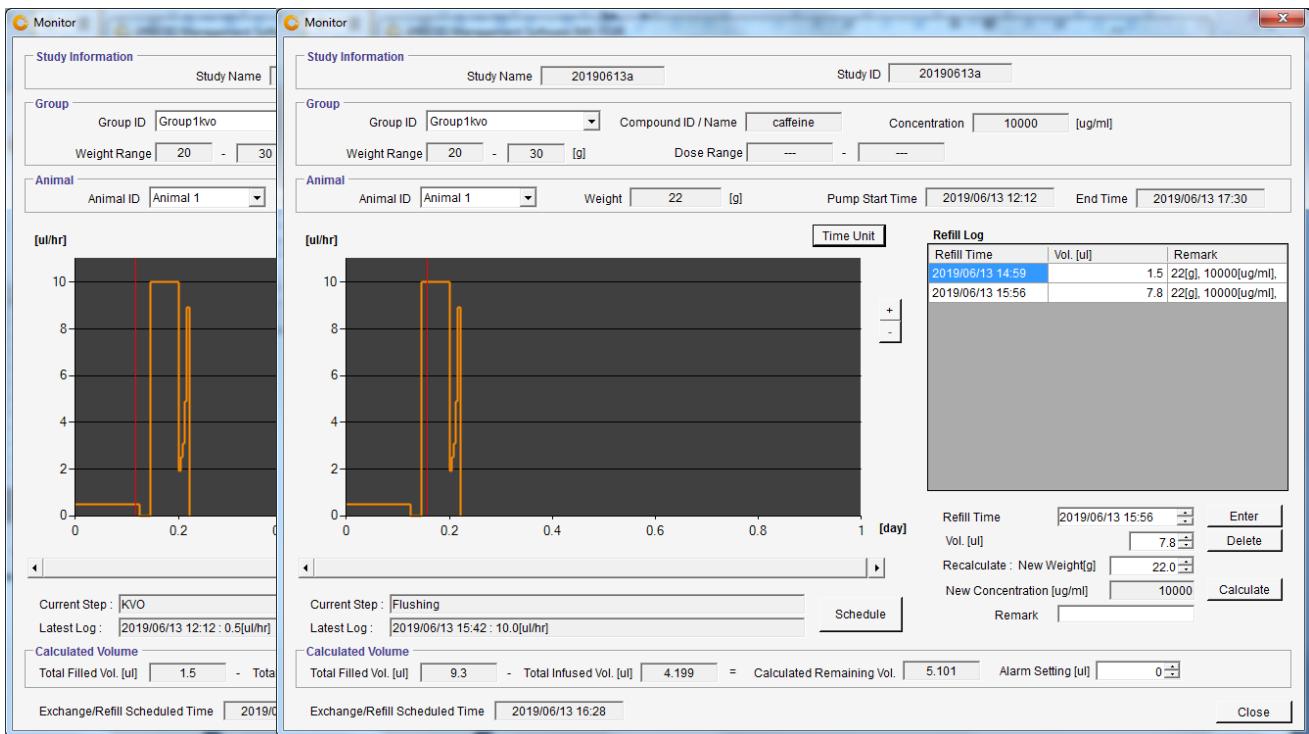
Pump 8Y0073 may be detected and then programmed again.

Animal ID (*)	Weight[g] (*)	Pump ID	Cal. value	Sex	Age	Animal Species	Animal Strain	Administration Route
Animal 6	22	8Y0073	1176	Male	7	Mouse	c57bl6	sc

<input type="button" value="Clear"/>	<input type="button" value="Set"/>	Group ID Group1kvo	Administration Start Time 2019/06/13 23:30	<input type="button" value="Stagger"/>	0 [min]		
Animal ID	Weight [g]	Pump ID	Group ID	KVO Start Time	Drug Exchange Period	Flushing Start Time	Administration Start Time
Animal 6	22	8Y0073	Group1kvo	2019/06/13 18:42	2019/06/13 21:42	2019/06/13 22:12	2019/06/13 23:30

Monitor the pump status

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



Orange Line: Programmed infusion profile. Red curser line current step.

Actual logs from pump(s) being monitored are shown in Latest Log <2019/06/03 12:12 : 0.5(ul/hr)> for start of KVO step <2019/06/03 15:42 : 10 (ul/hr)> for start of flushing. Receipt of the logs from the pumps is dependent on Infusion Profile, communication availability and wireless environment. Current Step <KVO> and <Flushing> information is based on PC Clock used for programming the pumps. When monitoring, best to use Current Step as indicator of pump infusion status as the pump is pre-programmed and not dependent on when the pump logs are received. See pg. 6 about iPRECIO 2nd paragraph. Pump logs may be delayed due to wireless conditions but this does not affect infusion protocol start, steps and finish when programmed correctly.

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 a <Refill Log Table> in the Right side. First input the Test Article or saline in Remark. Update Refill volume if required and click <Enter>. For details, refer to <Replace and/or refill drug solution>. (Next Section)

Study Information (Left Screenshot):

- Study Name: []
- Group ID: Group1kvo
- Weight Range: 20 - 30
- Animal ID: Animal 1

Current	Step	Infusion Amount [ul/hr]	Doses [ug/kg/hr]	Duration
-->	KVO	0.5	---	
	Ex.	0	---	0
	Flush	10.0	---	1
1		1.9	863.64	0
2		2.5	1136.36	0
3		3.1	1409.09	0
4		4.9	2227.27	0
5		8.9	4045.45	0

Current Step : KVO
Latest Log : 2019/06/13 12:12 : 0.5[ul/hr]
Calculated Volume
Total Filled Vol. [ul] 1.5 - Total Infused Vol. [ul] 0.509
Exchange/Refill Scheduled Time 2019/06/13 12:12

Study Information (Right Screenshot):

- Study Name: 20190613a
Study ID: 20190613a
- Group ID: Group1kvo
Compound ID / Name: caffeine
Concentration: 10000 [ug/ml]
- Weight Range: 20 - 30 [g]
Dose Range: --- - ---
- Animal ID: Animal 1
Weight: 22 [g]
Pump Start Time: 2019/06/13 12:12
End Time: 2019/06/13 17:30

Current	Step	Infusion Amount [ul/hr]	Doses [ug/kg/hr]	Duration	Number of Repetitions	Start Time	End Time
-->	KVO	0.5	---	3 hr(s)	0	2019/06/13 12:12	2019/06/13 15:12
	Ex.	0	---	0.5 hr(s)	0	2019/06/13 15:12	2019/06/13 15:42
-->	Flush	10.0	---	78 min(s)	0	2019/06/13 15:42	2019/06/13 17:00
1		1.9	863.64	0.1 hr(s)	0	2019/06/13 17:00	2019/06/13 17:06
2		2.5	1136.36	0.1 hr(s)	0	2019/06/13 17:06	2019/06/13 17:12
3		3.1	1409.09	0.1 hr(s)	0	2019/06/13 17:12	2019/06/13 17:18
4		4.9	2227.27	0.1 hr(s)	0	2019/06/13 17:18	2019/06/13 17:24
5		8.9	4045.45	0.1 hr(s)	0	2019/06/13 17:24	2019/06/13 17:30

Refill Log:

Refill Time	Vol. [ul]	Remark
2019/06/13 14:59	1.5	22[g], 10000[ug/ml]
2019/06/13 15:56	7.8	22[g], 10000[ug/ml]

Refill Time: 2019/06/13 15:56 Enter
Vol. [ul]: 7.8 Delete
Recalculate: New Weight[g]: 22.0 Calculate
New Concentration [ug/ml]: 10000
Remark:

Current Step : Flushing
Latest Log : 2019/06/13 15:42 : 10.0[ul/hr]
Calculated Volume
Total Filled Vol. [ul] 9.3 - Total Infused Vol. [ul] 4.241 = Calculated Remaining Vol. 5.059 Alarm Setting [ul] 0
Exchange/Refill Scheduled Time 2019/06/13 16:28 Close

Schedule is shown as text format. Has Current Step information and arrow indicating current status.

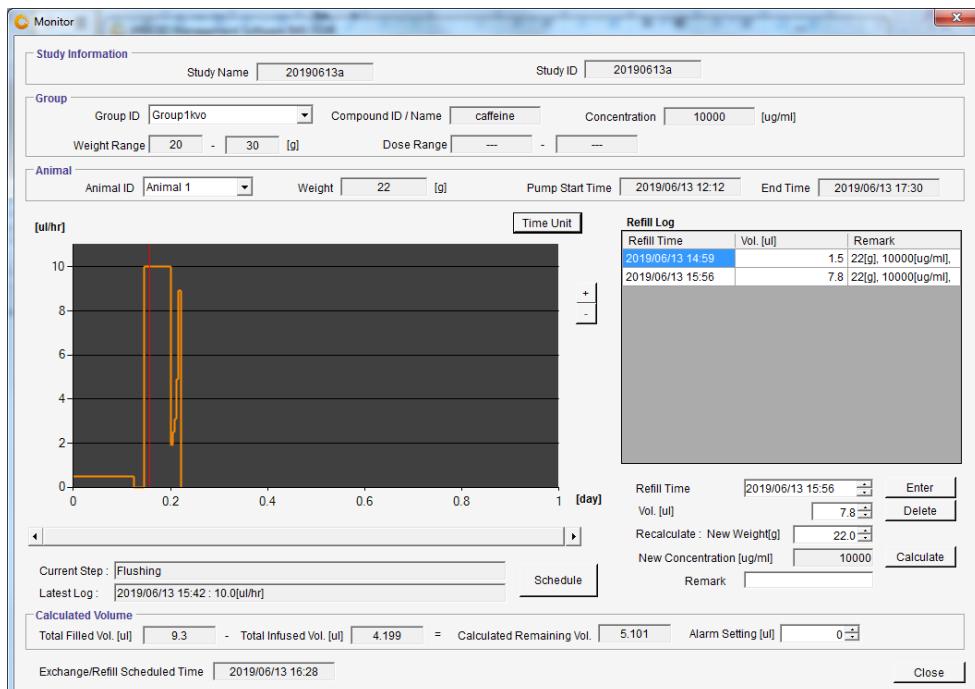
The estimated remaining volume is calculated from the infusion profile/schedule, elapsed time based on the PC clock and Total Filled Volume. The software alarm will appear when the calculated volume reaches the Alarm Setting volume.

4. The Infusion Profile Graph located on the left side of window. Clicking <Time Unit> upper right button, the Graph axis unit can be switched. Clicking <Schedule> bottom right button, the Infusion schedule table (text) can be shown. To return, click <Graph> button. **Orange Line shows programmed infusion profile.**

Note that log collection/missing logs do not affect the performance of the pumps. Once programmed, the pumps will infuse as programmed with or without the UCD-X10R and Application software.

Replace and/or Refill the test article

1. Open Monitor (M) window.
2. Verify the estimated remaining volume in the bottom area of window.
3. Anesthesia the animal with isoflurane or fast acting anesthesia.
4. If required, extract and measure the remaining volume in the reservoir with a 27G needle syringe through the septum port and then refill using the same syringe.
5. First input the Test Article or saline in Remark. Update Refill volume if required and click <Enter>. Add details as required in remark.



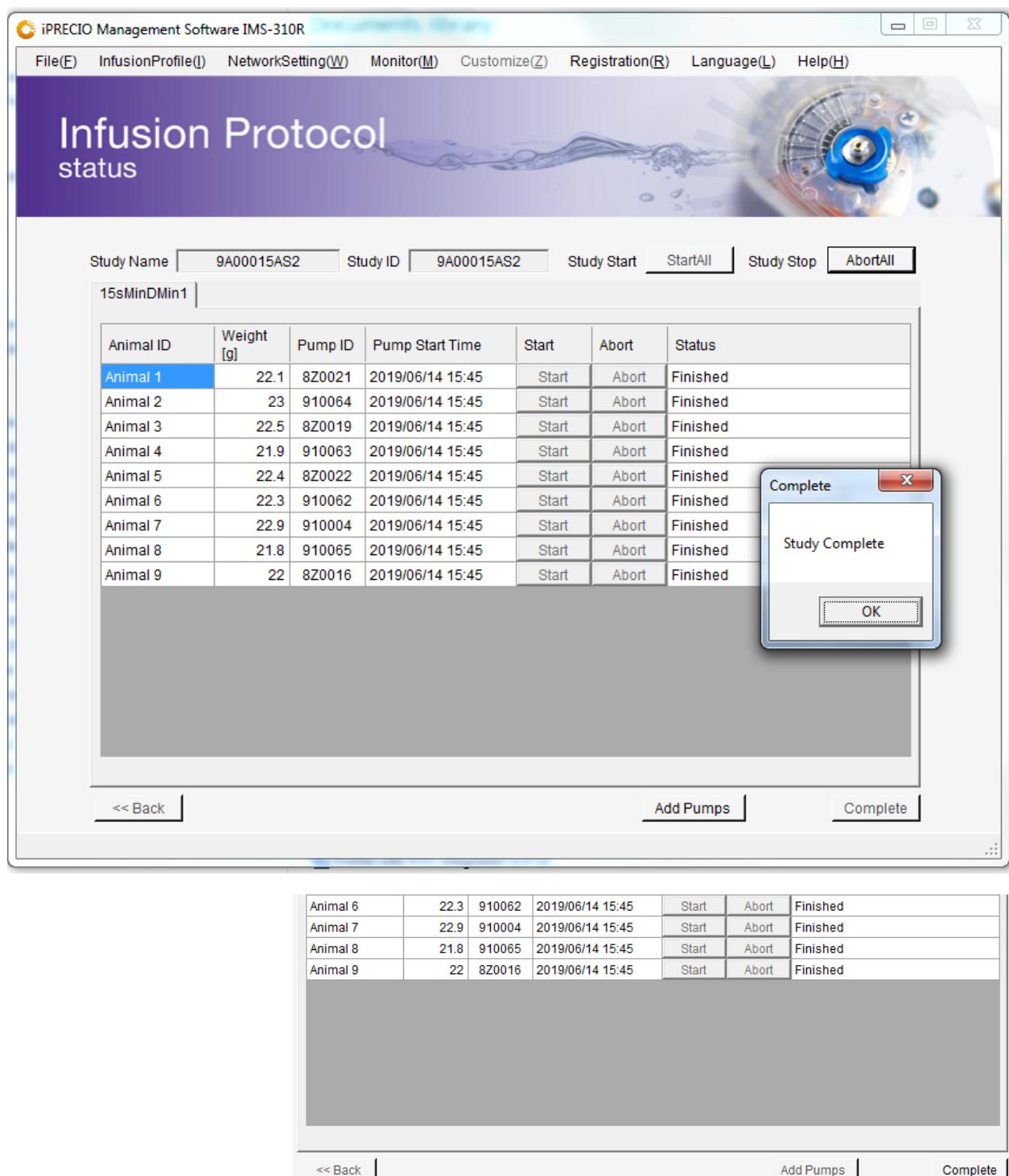
6. After logging the Refill Log with <Enter>, the table records automatically the Refill time, volume and comments (weight and density etc). To remove the refill log, select target refill log and click <**Delete**> button.

Important Notes:

When exchanging saline with test article (TA), it is recommended to extract remaining saline in the reservoir and then refilling with TA. It is recommended that TA is filled twice. Basically refilling, extracting and refilling. This will ensure that the concentration of TA in the reservoir is correct. Filling once only after saline extraction will mean a dilution of around 10% of TA. **Maximum accuracy of pump is obtained when reservoir level is between 30µl and 130µl. Refill the pump when the reservoir is ≤ 30µl. Calculated Remaining Volume is shown in Monitor Window.**

End of Study

After all infusion protocol finished, click **OK** for <**Study Complete**> and then <**Complete**>. Data from the study are automatically saved. If the study needs to be cancelled before the end, click <**Abort All**> then click OK for <**Study Complete**>



Save Study File

1. Click Save Study from the **File (F)** in menu bar. The data file stored in C:\Users\XXX\AppData\Local\iPRECIO2\study2
2. The save data can be loaded from "Open" in the File (F) in the menu bar.

Export Study File

Export maybe used at any time during the study to have detailed logs from pumps. It is recommended to Export Data from time to time during the study to have a record. A good time to export is after <Received a schedule> has been received by UCD-X10R.

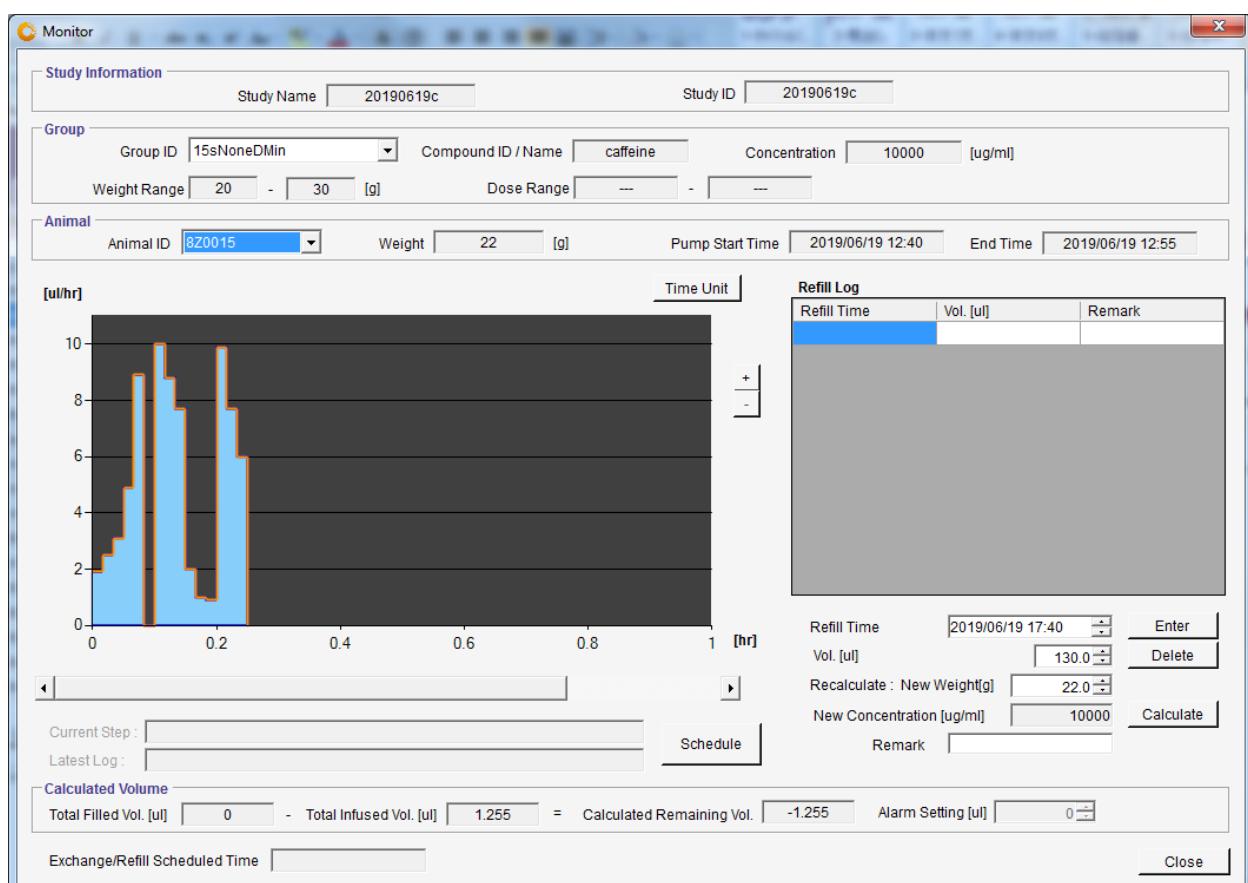
See Appendix E - <Infusion Log> for example of exported CSV file.

1. Choose <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. This file contains all the information and logs from the completed study.

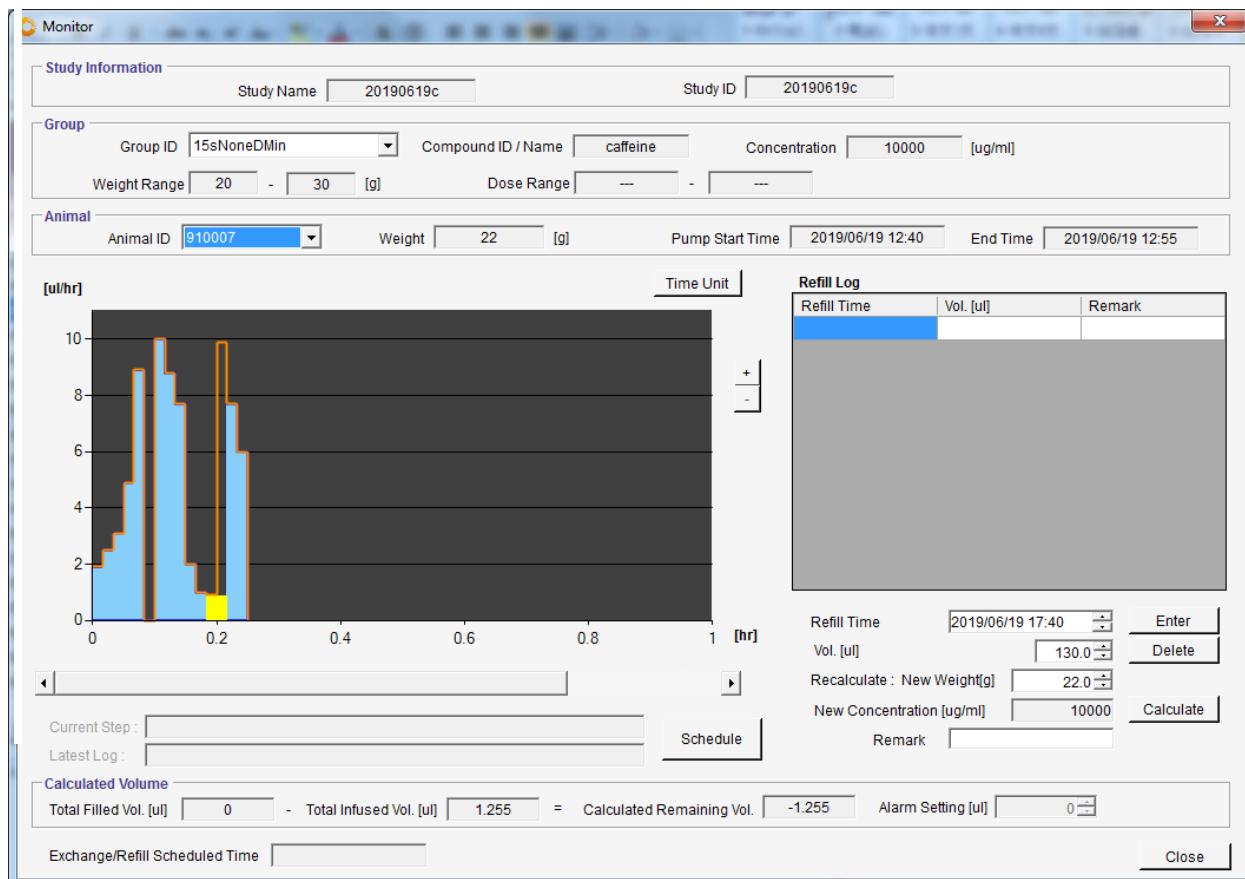
Reviewing saved Study Data with Monitor function

After the study, previous study data can be reloaded. This is done using the **Monitor** function. This can be done only if there is no study running or open. Click on <Monitor> and load the required <Study Name> or <Study ID>. All data collected from pumps, infusion schedule, Total Filled Volume, Total infused volume and Calculated Remaining Volume are available. Refill comments are also available. The <Export> function in **Monitor**, allows to export all the data to a csv file. This is the same as <Export Study File>.

How to check if all the pumps log data were collected



When all the log data were collected without any problems, the programmed infusion flow-rate and duration are filled with a blue color. Programmed infusion profile flow-rates and durations are shown as an orange line.



Incomplete study where not all logs collected.

When all the logs were not collected due to overwriting of the logs (logs skipped), Communication Availability, Wireless conditions etc., a yellow rectangle/box will be displayed. The yellow box will start from the last received log until the next log (received log). In the figure below, the yellow box signifies missing data.

Note that log collection/missing logs do not affect the performance of the pumps. Once programmed, the pumps will infuse as programmed with or without the UCD-X10R and IMS-310R Application software.

How to Re-Program a Pump

When you want to change the infusion profile after the original protocol is complete or after aborting the study, iPRECIO software allows you to change the status of the pumps to re-program them.

Utility Software

Please make sure you have below two utility software installed in your PC.
Open Start Menu to confirm.



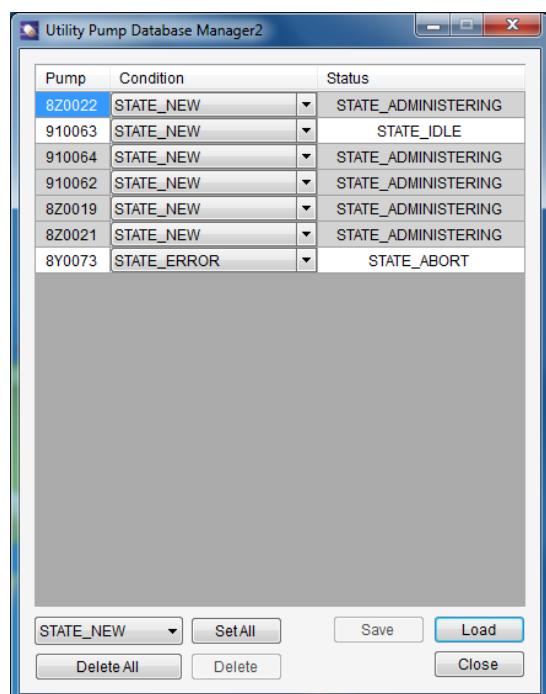
iPRECIO Management Software IMS-310R
 Utility BaseStation Manager2
 Utility Pump Database Manager2

Change Pump Condition/ Status

1. Open Utility Pump Database Manager2 and select <Load> to check the pump status.
2. Choose <STATE_NEW> from the pull down menu in the Condition column. **You cannot re-detect the pump until you change the pump status to new and save.**
3. Select the <Save> and close the window.
4. Now it is possible to detect the pump and re-program at <study settings> step. In example below pump 910063 may be re-programmed but not 8Y00763 which is still in STATE_ERROR and status shown as STATE_ABORT. Pump 910063 condition shown as New and status Idle. Pumps (Greyed out) are still in use and cannot be modified.

CONDITION	Details
STATE_NEW	Pump may be programmed
STATE_USED	Pump infused as programmed Change pump status if re-use required
STATE_ERROR	Pump aborted before infusion completed Change pump status if re-use required

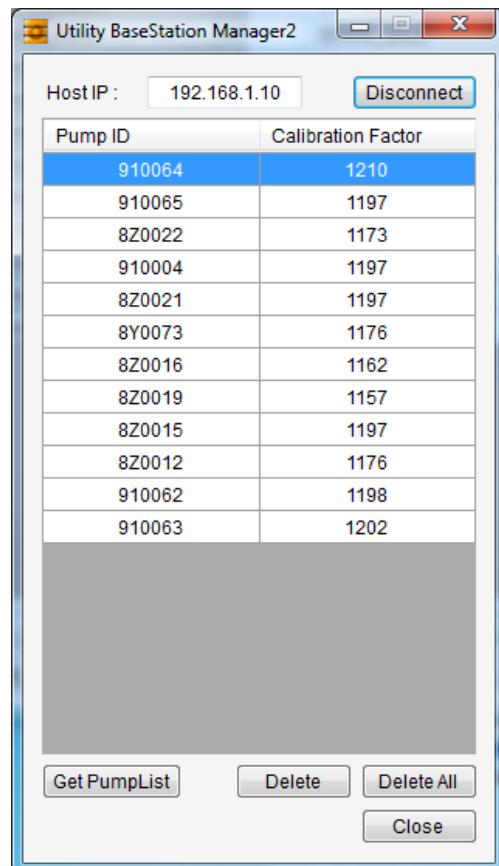
Summary of Pump Condition in Utility Database Manager2



<Recommended Procedure for re-using the pumps>

1. Open Utility Pump BaseStation Manager2 and click <Connect> and <GetPumpList>.
2. Click <Delete All> or <Delete> only the pumps which will no longer be used.

*If the old pumps' IDs are left in UCD-X10R, communication time will be assigned for all the pumps in memory. Therefore more time will be required for programing, log collection etc. Remove pumps by deleting as required. It is not always necessary to delete all the pumps when re-using. See FAQ



Important Tips:

<Utility BaseStation Manager2> and <Utility Pump Database Manager2> software applications which are used to confirm status of pumps which are being used.

Utility BaseStation Manager2

Utility BaseStation Manager2

Shown above

- Will contain details of all pumps which have been detected by the management system unless they have been deleted.
- When detecting pumps using IMS-310R Management Application, pumps which are new will be called by the management system during detect
 - These are pumps which are known and more easily detected.
 - New Pumps which have not been detected may take a little longer as they have to be identified by the management system during the detect procedure.
- It will be advantages to delete all pumps which have been USED before which will not be re-used. If not deleted, the management system (UCD-X10R) will assign time to communicate with these pumps and will cause large delays to the pump programming process.
- <Get Pump List> gets pump list from UCD memory after connected. All pumps may be deleted <Delete All> or individual pumps may be deleted by selecting and <Delete>

Utility Pump Database Manager2

Utility Pump Database Manager2

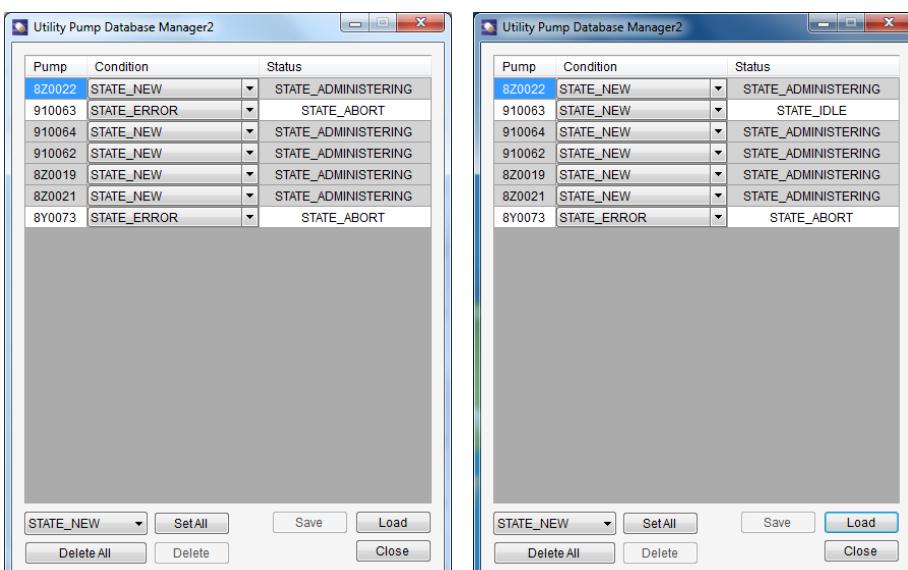
- Keeps track of status of all pumps. (used and being used) Management system would communicate to connect with Pumps which are New and Idle.
- Pumps which are labeled USED and ERROR will not be used or detected by IMS-310R Management Application.
- If you are planning to re-program a pump which has been used, it will be necessary to change the status from USED OR ERROR to NEW and make sure status is changed to idle.

CONDITION	Details
STATE_NEW	Pump may be programmed
STATE_USED	Pump infused as programmed Change pump status if re-use required
STATE_ERROR	Pump aborted before infusion completed Change pump status if re-use required

Summary of Pump Condition in Utility Database Manager

Pumps which are grey-ed out cannot be modified as the pumps are in use.

Pump Status	Details
STATE_IDLE	Pump available for use
STATE_STANDBY	Pump in use and waiting to be programmed
STATE_SETSCHEDULE	Programming Pump
STATE_ADMINISTERING	Pump in use and infusing
STATE_FINISHED	Pump finished infusing
STATE_ABORT	Pump has been aborted



Examples

Pumps 8Z0022, 910064, 910062, 8Z0019, 8Z0021 are in use and greyed out.

Pumps 910063 & 8Y0073 status may be modified and used for programming. 910063 changed to NEW and idle will be available but not 8Y0073 as condition is STATE_ERROR and STATUS_ABORT

Product Specifications

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

Administration method	Rotary finger type (Patented: Peristaltic mechanism)
Reservoir	130µL Built-in reservoir: (Material) Medical grade SIBS ※The Maximum capacity is 130 µL. ±5% flow accuracy when reservoir is filled between 30 to 130µL.
Tube	Inner Tube: (Material) Medical grade SEBS Outer Tube: (Material) Medical grade SEBS (3Fr) (Size) ID=0.55 mm, Length approx. 140mm
Replace/Refill port	φ2mm size refill port on top of pump with side location reference point (Recommend below 27Ga size needle)
Data communication	Wireless Frequency FCC: 923.1 MHz – North America / FCC CE: 865.5 MHz - Europe Com unit : Within 1 -6 m from UCD-X10R
Antenna	Embedded FPC pattern antenna inside pump
Programmable Flow Rate (FR)	0.0 - 10.0µL/hr. (setting resolution:0.1µL/hr) * Discharge flow by 360 degree roll of cam:3.2µL
Infusion accuracy	±5% (Under pressure 0~80cmH ₂ O) Reservoir volume 20µL to 100µL
Battery Life	Continuous driving life : FR 0.1µL/hr : 67.8 days, 8µL/hr : 10.2 days , FR 10.0µL/hr : 8.4 days for No-Comms mode Setting (none). FR 0.1ul/hr : 5.5 days, 8µL/hr : 5.2 days , 10ul/hr : 5 days for Comms Avail of 1 minute.
Power On & Activation Method	Pump is switched ON magnetically. (S Pole -ON & N Pole - OFF) magnetic strength > 100mT. Pump activation is programmed in Infusion Profile (Group ID)
Size	24.8(L) × 15.0(W) × 7.2 mm partially 8.2 (H) max mm
Weight	3.4g (Including outer catheter)
Solid content	2.26cc
Type of usage	Disposable (Not designed for re-use)
Package	EO Sterilized blister package (5 package/box)
Sterilization	2 years from manufacturing

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.
Wireless Communication	FCC: 923.1 MHz – North America / FCC CE: 865.5 MHz – Europe /CE ※Not broadband type. One –on one communication between Data com unit and individual pumps.
Number of pumps per unit	20~25
Required Power source (from PC running IMS-310R Application Software)	USB cable to DC out to UCD-X10R provided. USB 2.0 required from PC. (DC Output : 5V 0.5A) [Weight] 35g [Cable length] 1.1 m
Size and Weight Accessories included	145(L) × 95 (W) × 55 (H) mm · Approximately 320g 1 Ethernet cable (3m), USB DC adapter cable (1.1m)
Management software	
Supported OS	Windows 7 Professional or higher) Windows 10 Pro/Enterprise/Education Japanese and English with major PC manufacturers

Appendix A: Table of Commands

List of the active commands for IMS-319R software; their (1) Actions (2) Limitations and (3) Comments summarized.

Commands	Action	Limitations	Comments/ Recommendations
Detect	Continue to search for the number of pumps entered until found.	If pump not found, will continue until cancelled	
Administration <Start All>	Will attempt to start all pumps across all groups. Positive confirmation in Application software and in Exported logs.	Pump needs to be available for communication. Programmed start times must not be in the past. If not <Start> individually required.	Application software will show pumps which did not start on time with delay information.
Administration <Start> individually	Will attempt to start pump(s) individually <Started>. Positive confirmation in Application software and in Exported logs.	If <Start> time passed, new start time is when <Start> is clicked.	Will start pumps even if start time is in the past.
Add Pumps	Allows additional pumps/animals to be added to ongoing study.	Ideally, use only once all pumps in on-going study have been Programmed correctly.	May be used to sequentially add new groups or animals to on-going study.
Administration <Abort All>	Will attempt to abort all pumps across all groups. No positive confirmation to software from pump(s)	No positive confirmation from pump(s) and pump(s) will continue to infuse until aborted, protocol complete or out of battery or re-programmed	UCD-X10R will send the abort signal until unplugged.
Administration <Abort> individually	Will attempt to abort the selected pumps. No positive confirmation to software from pump(s)	No positive confirmation from pump(s) and pump(s) will continue to infuse until aborted, protocol complete or out of battery or re-programmed	UCD-X10R will send the abort signal until unplugged.

Commands	Action	Limitations	Comments/ Recommendations
Export	Exports Study information and log data. May be used anytime during the study to obtain detailed logs and have a permanent record.	<p>Logs from pumps are available from events like <Received a Schedule>, <Flow-rate step 1 duration 1> <Flow-rate step 2 duration 2>, etc. <Complete> and <Finished>. Timestamps are included in the logs.</p> <p>See Appendix E, page 65.</p> <p>Each pump can only store 20 logs and they will be overwritten if not downloaded/collected by UCD-X10R/Application Software</p>	<p>Logs usually available immediately after event completed but dependent on communication availability and wireless environment.</p>

Appendix B: Modify the IP address of Data Communication Device

Factory Default Network Settings

Factory Default Settings of UCD-X10R Management Device is below:

Headings	Default Settings
IP address	192.168.1.10
Network mask	255.255.255.0
Default Gateway	192.168.1.1
User Name	admin
Password	admin

Modify the Default Network Settings for UCD-X10R

This modification is only required when there is a conflict with the Default IP address setting.

1. Connect the UCD-X10R to the management PC and plug AC adapter to turn on.
2. Input the IP address of UCD-X10R in Web browser URL such as Internet Explore.
3. Input the User name and Password on the User Authentication Screen.



Modify the IP address of Data Communication Device

Manually Input a different IP address

1. Uncheck the check box of the '**use DHCP**' on the Network Settings Screen.
2. Input the IP address other than 192.168.1.10. (e.g. 192.168.1.12/ 192.168.1.15 etc)
3. Click '**Set**'
4. Wait for Network parameters successful updated and/or PC screen refreshed screen with new IP address.
5. Unplug the Data Communication Device to Re-Start it
6. Do not forget to update Network Settings in iPRECIO Application software from 192.168.1.10 to new address entered. (e.g. 192.168.1.12/ 192.168.1.15 etc)

Password Settings

It will allow you to restrict modifying the network settings, if you set the password.

1. Input the password in "**New password**" box which is in the Network Setting Window.
2. Re-type the password in "**Retype new password**" box.
3. Click "**Set**".

Resets the Network Settings of Data Communication Device

It is possible to reset the network settings to restore it to the factory default settings, if access to the data communication device is impossible due to wrong settings.

1. Unplug the AC adaptor to turn off the management device.
2. The black push button for reset is located to the right of the power connector.
3. Press and hold the Reset Button while replugging the AC adapter to turn on the management system. Continue to hold the Reset Button for 30s to start the Reset Procedure.
4. Network Setting is initialized following reset.
5. After reset complete, use initial settings for IP address in User Manual.

Appendix C: How to Confirm if the UCD-X10R is Working Correctly

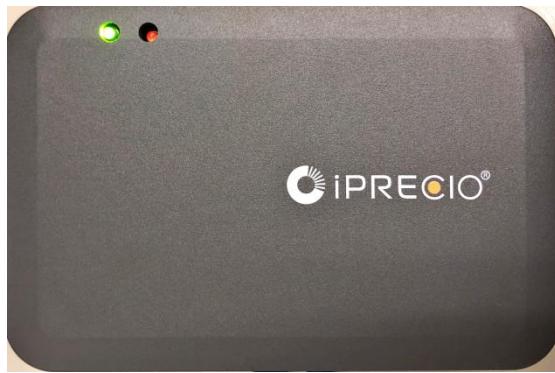


Green Light On: UCD-X10R is correctly plugged with power supply

Green Light Off: UCD-X10R is not plugged correctly or UCD-X10R is not working

Red Light On: If the red light is on for more than 5 mins, the UCD-X10R is not working properly. It will be necessary to reset the UCD-X10R

Press and hold the Reset Button while re-plugging the DC supply plug to switch on the management system. Continue to hold the Reset Button for 30s to start the Reset Procedure.



Red Light Off: UCD-X10R received no signals from PC/application software

Red Light Blinking: UCD-X10R is communicating with PC and pumps. This includes, Detecting, sending Study schedule to the pumps, collecting the logs from pumps, sending the logs to PC/application software.

Red Light on for 2-3 seconds then turn-off: This is normal or the expected operation. Basically, "resetting the polling command"

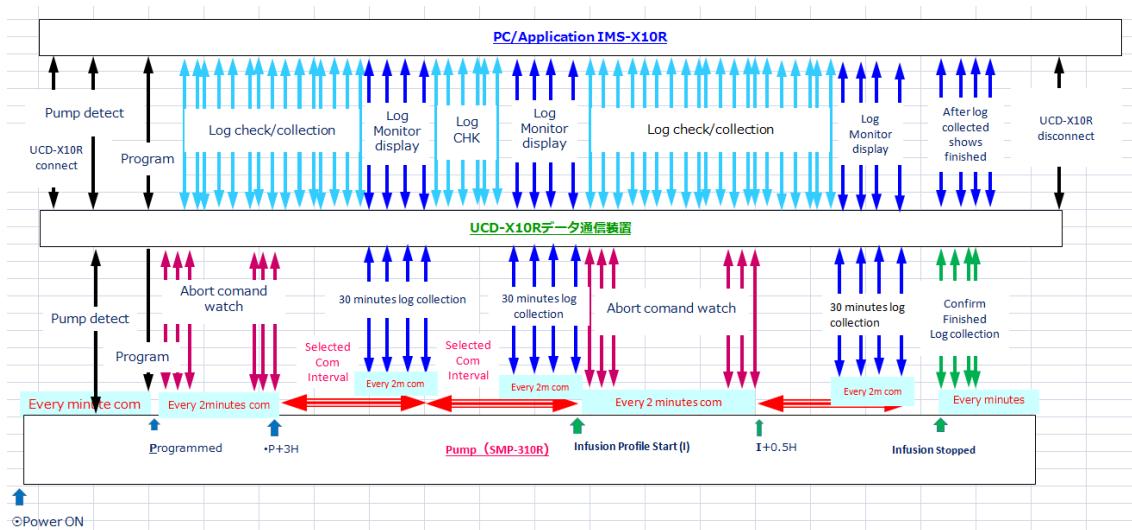
Appendix D: Communication Availability

Communication Availability <Comms Avail.>:

The figure below shows how Communication Availability works for programming and logs. Programming includes full infusion profile or Group ID.

- For <Every Minute> setting the system has the highest responsiveness where the pumps are available for programming and logs every minute.
- For <24 hour> setting, the system is much less responsive but significant battery life is saved. See table on page 13. For example, for 0.1 uL/hr with every minute <Comms Avail>, only 157 hours (6.5 days) of battery life available. For 24 hours <Comms Avail>, 1542 hours (64.3 days) Basically nearly times longer pump lifetime.

Availability for re-programming and logs are also dependent on the wireless environment, and infusion protocol set-up.



Communication availability options: <Every Minute>, < Every 1 hour>, < Every 2 hours>, < Every 4 hours>, <Every 6 hours>, < Every 12 hours>, <Every 24 hours> and <None>. Therefore if communication available of <None> is selected, the pump cannot be re-programmed until the infusion protocol is complete. Logs for the pumps will not be available until the infusion is complete. There is a 3 hour window following <Completion of Programming of each pump> to cancel and communication except for <None>. If < Every 2 hours> communication availability selected then pumps will be available every 2 hours for 30 minutes for reprogramming or for logs. The date/time stamp for <Received a schedule> is the reference for the start of the 3 hour window following <Completion of Programming of each pump> Following this 3 hour window, Communication Availability cycle starts. When pump starts infusion Profile, this start time resets the Communication availability cycle to the Pump Start Time to synchronize to pumps' start times rather than programmed date and time.

Summary Table of communication availability (comms avail) settings.
 (From above timing diagrams)

Comms Availability Interval (hr))	OFF (hr)	ON (hr)	P + 3Hr comms window	30 min infusion profile start comms window	Received schedule Log	Comments
every minute	every minute			Not applicable	Yes, wireless conditions	Minimum battery life Most responsive
1	0.5	0.5	Yes	Yes	Yes, wireless conditions	
2	1.5	0.5	Yes	Yes	Yes, wireless conditions	
4	3.5	0.5	Yes	Yes	Yes, wireless conditions	
6	5.5	0.5	Yes	Yes	Yes, wireless conditions	
12	11.5	0.5	Yes	Yes	Yes, wireless conditions	
24	23.5	0.5	Yes	Yes	Yes, wireless conditions	
None	Always	No	No	No	Yes, but only after infusion profile completion, wireless conditions	Maximum Battery Life No response after programmed until finished. Immediate sleep.

- Pump: On power ON - wake up 5 sec/min when communicating <Comms Avail>. **Once programmed, pump wakes up 5 sec every 2 minutes to save power during communication interval.**

iPRECIO SMP-310R pumps has internal memory to hold a maximum of 20 logs. If an <Infusion Profile/Group ID> will create more than 20 logs, then it will be possible that some of the logs are overwritten. This will be dependent on <Communication Availability>, the number of pumps in the study, and the wireless condition between the system and pumps. Extra special care should be taken for <24 hour communication availability> and <None communication availability> but remembering that once programmed the pump will infuse as programmed and the overwriting of logs will not affect pump performance.

- For Infusion Profile
 - Timestamp : Received a Schedule
 - Timestamp : Activation Start
 - Timestamp : Activation End
 - Timestamp: Infusion Profile/Group ID Step 1
 - Timestamp: Infusion Profile/Group ID Step 2
 - Timestamp: Infusion Profile/Group ID Step 3
 - Etc
 - Etc
 - Etc
 - Timestamp: Infusion Profile/Group ID Complete
 - Timestamp: Infusion Profile/Group ID Finished

Notes.

1. If the infusion is aborted in the middle of an infusion step, no event log will be available for the end of the aborted step. Only that start time log will be available.
2. Logs do not affect pump performance.

See appendix E for example logs.

For additional information refer to FAQ or contact Primetech Corporation or Authorized Distributor.

Appendix E: How to use the Log Data

csv log data may be exported during or after the study. All data collected will be exported. Data including all study parameters and logs<when the pump received the study schedule>, <start of infusion>, <when the study aborted from the log data> etc. **It is recommended that you export the log data from time to time as it will guarantee that you have at least part of the infusion study record.**

An example of log data file is provided in the installation CD. Refer to the exported log data as necessary ("Sample Log Data").

◆ Overview of Log Data

iPRECIO Mouse Study Report

In this section, the title is in the uppermost column of the exported csv log data. The exact date and time of export is recorded here.

Ex)

iPRECIO Mouse Study Report	2019/06/16 11:08
----------------------------	------------------

<<Basic Information>>

In this section, general information such as Institution Name, Department Name, Study Name, Study ID, Study Date, User Name, etc. are recorded.

Ex)

<<Basic Information>>	
Institution Name	Primetech Corporation
Department Name	Drug Delivery and Infusion Solutions Department
Study Name	20190614ON
Study ID	20190614ON
Study Date	2019/06/14 19:39
User Name	Admin
Number of Groups	1
Total Number of Animals	9
Remark	

<Group Information>

In this section, Group ID, Compound ID, Concentration and Weight Range are recorded.

Ex)

<>Group Information>>	
Group ID	15sMinDHR1
Compound ID / Name	caffeine
Concentration[ug/ml]	10000
Weight Range[g]	20-30
KVO	False
Activation	Default
Communication availability (Interval)	every minute

<Animal Information>

In this section, individual animal information such as Animal ID, Group ID, Weight, Sex, Age, Species etc. are recorded

Ex)

<>Animal Information>>	
Animal ID	Animal 1
Group ID	15sMinDHR1
Weight[g]	22
Sex	Male
Age[week(s)]	6
Species	Mouse
Strain	c57bl6
Administration Route	sc
PumpID	8Z0021
Cal. value	1197
Pump Start Date/Time	2019/06/14 20:00
End Date/Time	2019/06/15 11:00

<Infusion Schedule>

In this section the study profile is recorded.

Step 1 to 15 is the maximum.

Ex)

<Animal Information>	
Animal ID	Animal 1
Group ID	15sMinDHr1
Weight[g]	22
Sex	Male
Age[week(s)]	6
Species	Mouse
Strain	c57bl6
Administration Route	sc
PumpID	8Z0021
Cal. value	910064
Pump Start Date/Time	2019/06/14 20:00
End Date/Time	2019/06/15 11:00
<Infusion Schedule>	
Program No./ Number of Repetitions (n)	1 (1)
Step1 : Flow Rate[ul/hr]	1.9
: Duration[hr(s)]	1
: Doses[ug/kg/hr]	863.64
Program No./ Number of Repetitions (n)	2 (1)
Step2 : Flow Rate[ul/hr]	2.5
: Duration[hr(s)]	1
: Doses[ug/kg/hr]	1136.36
Program No./ Number of Repetitions (n)	3 (1)
Step3 : Flow Rate[ul/hr]	3.1
: Duration[hr(s)]	1
: Doses[ug/kg/hr]	1409.09
Program No./ Number of Repetitions (n)	4 (1)
Step4 : Flow Rate[ul/hr]	4.9
: Duration[hr(s)]	1
: Doses[ug/kg/hr]	2227.27
Program No./ Number of Repetitions (n)	5 (1)
Step5 : Flow Rate[ul/hr]	8.9
: Duration[hr(s)]	1
: Doses[ug/kg/hr]	4045.45
Program No./ Number of Repetitions (n)	6 (1)
Step6 : Flow Rate[ul/hr]	0
: Duration[hr(s)]	1
: Doses[ug/kg/hr]	0
Program No./ Number of Repetitions (n)	7 (1)
Step7 : Flow Rate[ul/hr]	10
: Duration[hr(s)]	1
: Doses[ug/kg/hr]	4545.45
Program No./ Number of Repetitions (n)	8 (1)
Step8 : Flow Rate[ul/hr]	8.8

<Infusion Log>

<Infusion Log>			
TimeStamp : PumpLogData	2019/06/14 19:47 : Received a Schedule	2019/06/14 19:48 : Received a Schedule	2
	2019/06/14 19:48 : Activation Start	2019/06/14 19:49 : Activation Start	2
	2019/06/14 19:50 : Activation End	2019/06/14 19:51 : Activation End	2
	2019/06/14 20:00 : 1.9[ul/hr]	2019/06/14 20:00 : 1.9[ul/hr]	2
	2019/06/14 21:00 : 2.5[ul/hr]	2019/06/14 21:00 : 2.5[ul/hr]	2
	2019/06/14 22:00 : 3.1[ul/hr]	2019/06/14 22:00 : 3.1[ul/hr]	2
	2019/06/14 23:00 : 4.9[ul/hr]	2019/06/14 23:00 : 4.9[ul/hr]	2
	2019/06/15 00:00 : 8.9[ul/hr]	2019/06/15 00:00 : 8.9[ul/hr]	2
	2019/06/15 01:00 : 0.0[ul/hr]	2019/06/15 01:00 : 0.0[ul/hr]	2
	2019/06/15 02:00 : 10.0[ul/hr]	2019/06/15 02:00 : 10.0[ul/hr]	2
	2019/06/15 03:00 : 8.8[ul/hr]	2019/06/15 03:00 : 8.8[ul/hr]	2
	2019/06/15 04:00 : 7.7[ul/hr]	2019/06/15 04:00 : 7.7[ul/hr]	2
	2019/06/15 05:00 : 2.0[ul/hr]	2019/06/15 05:00 : 2.0[ul/hr]	2
	2019/06/15 06:00 : 1.0[ul/hr]	2019/06/15 06:00 : 1.0[ul/hr]	2
	2019/06/15 07:00 : 0.9[ul/hr]	2019/06/15 07:00 : 0.9[ul/hr]	2
	2019/06/15 08:00 : 9.9[ul/hr]	2019/06/15 08:00 : 9.9[ul/hr]	2
	2019/06/15 09:00 : 7.7[ul/hr]	2019/06/15 09:00 : 7.7[ul/hr]	2
	2019/06/15 10:00 : 6.0[ul/hr]	2019/06/15 10:00 : 6.0[ul/hr]	2
	2019/06/15 11:00 : Complete	2019/06/15 11:00 : Complete	2
	2019/06/15 11:00 : Finished	2019/06/15 11:00 : Finished	2
Reason of Stop	Complete	Complete	C
Total Time	00:15:00	00:15:00	0
<Infusion Refill Log>			
TimeStamp : RefillVol[ul] : NewWeight[g] : NewConcentration : Remark			
<Time Stamps>			
Administration StartAll	2019/06/14 19:43	2019/06/14 19:43	2
Administration AbortAll			
Individual Start			
Individual Abort			

In this section, logs from the pumps are recorded. Time stamped information including programming of pump <Received a schedule> and pump logs are available

Ex)

2019/06/14 19:47 : Received a Schedule

When pump programmed

2019/06/14 19:48 : Activation Start

2019/06/14 19:50 : Activation End

When pump activation started and finished. In this example, Default Activation Setting of immediately after programmed was used.

2019/06/14 20:00 : 1.9[ul/hr]

Pump started infusion at 1.9 ul/hour at 20:00 2019/06/14

2019/06/15 11:00 : Finished

Pump finished infusion at 11:00 201/06/15

Etc.

<Infusion Refill Log>

In this section, refill logs of test article(s) are recorded. If data not filled during study, in the application software, no data will be available like shown below.

Ex)

<Infusion Refil Log>		
TimeStamp : RefillVol[ul] : NewWeight[g] :		
NewConcentration : Remark		
<Time Stamps>		
Administration StartAll	2019/06/14 19:43	2019/06/14 19:43
Administration AbortAll		
Individual Start		
Individual Abort		

Appendix F: Pump Status: Example in Infusion Protocol Setting Window

Status is dependent on wireless conditions. Once programmed, wireless conditions not critical.

Detailed explanation in Appendix G for advanced users.

Pump Status	Brief Details
Programmed Light Green	Pump(s) correctly programmed and will start on time/started on time. Pumps may be implanted if <Received a Schedule> log not required for a permanent record. User should consider to take screen shot of IMS-310R as record.
Programmed Dark Green	Pump(s) correctly programmed and will start on time/started on time <Received a Schedule> Log collected from pump by UCD-X10R. May be exported by csv file.
Programmed Skyblue	Pump(s) correctly programmed but started with a delay/will start with delay. Pumps may be implanted if <Received a Schedule Log> not required. User should consider to take screen shot of IMS-310R as record.
Programmed Deep Skyblue	Pump(s) correctly programmed but started with a delay/will start with delay. <Received a Schedule Log> collected from pump by UCD-X10R. May be exported by csv file.

5sMinDMin1						
Animal ID	Weight [g]	Pump ID	Pump Start Time	Start	Abort	Status
Animal 1	22	8Z0021	2019/06/14 15:00	Start	Abort	Programmed (0.2m delayed)
Animal 2	22	910064	2019/06/14 15:00	Start	Abort	Programmed (1.3m delayed)
Animal 3	22	910063	2019/06/14 15:00	Start	Abort	Programmed
Animal 4	22	8Z0019	2019/06/14 15:00	Start	Abort	Programmed
Animal 5	22	8Z0022	2019/06/14 15:00	Start	Abort	Programmed (0.5m delayed)
Animal 6	22	910062	2019/06/14 15:00	Start	Abort	Programmed (0.6m delayed)
Animal 7	22	910004	2019/06/14 15:00	Start	Abort	Programmed (0.7m delayed)
Animal 8	22	910065	2019/06/14 15:00	Start	Abort	Programmed
Animal 9	22	8Z0016	2019/06/14 15:00	Start	Abort	Programmed

Appendix G: Detailed Pump Status

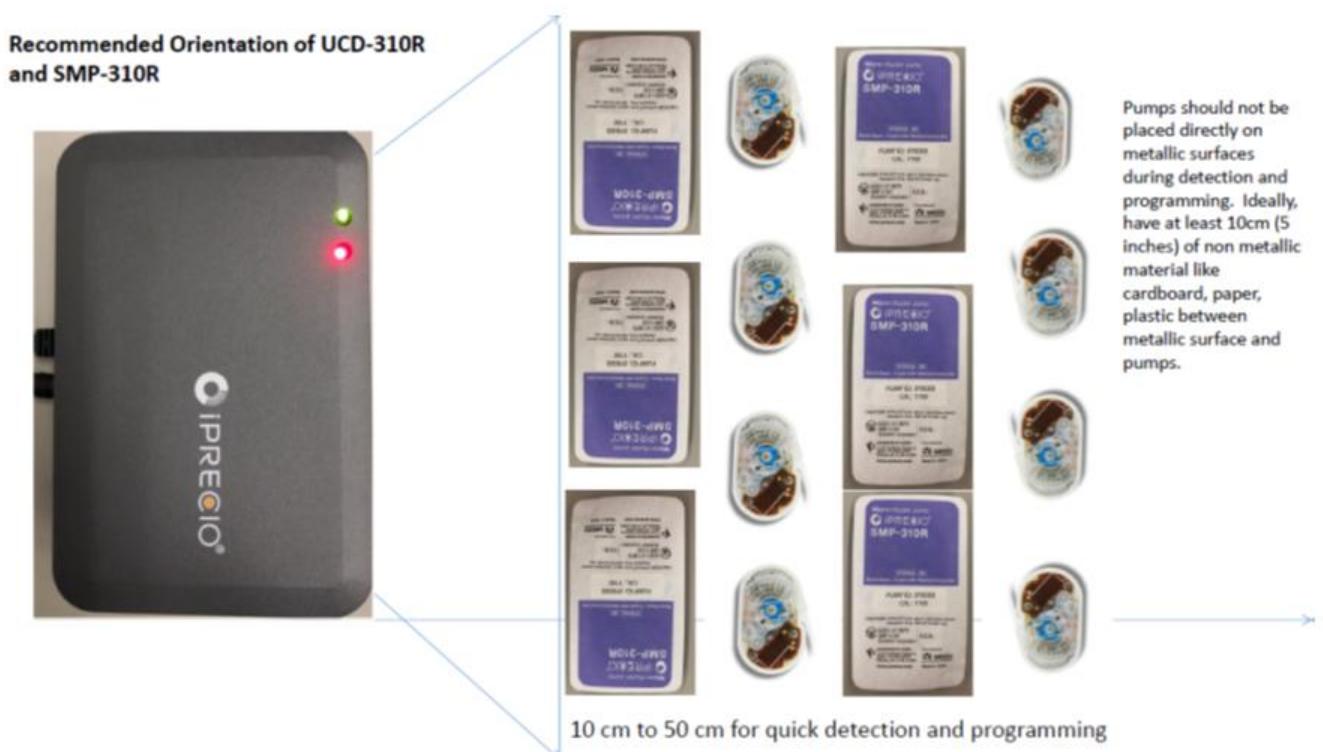
Status is dependent on wireless conditions. Once programmed, wireless conditions not critical.

Pump Status	During Programming	Towards the end of Infusion Duration	Detailed Explanation
Programmed Light Green	Pumps will start on time or started on time	Pumps will finish on time.	<p>Pumps programmed correctly but <Received a schedule> log not yet collected. Most likely reason is wireless conditions.</p> <p>For <No Communication> or <NONE> communication availability, status will always be shown as light green as the pumps goes to sleep immediately after being programmed.</p> <p>After 24 hours, UCD-310R will stop to call these pumps anymore (pumps without received a schedule log), therefore no longer possible to collect logs and status will no longer change. A workaround is to use <Add Pump> option and detect pump after infusion profile has completed. This will re-start the log collection process. This should be done shortly after infusion profile completed while battery life remains.</p>
Programmed dark green	Pumps will start on time or started on time	Pumps will finish on time.	<p>Pump(s) correctly programmed and will start on time/started on time</p> <p><Received a Schedule> Log collected from pump by UCD-310R. May be exported by csv file.</p>
Programmed (xx delay with respect to programmed start time) Skyblue	Pumps started (xx delay) with xx delay with respect to programmed start time	Pumps will finish after study duration completed or finished after study duration completed	<p>Within minutes of being programmed, pump will activate (if programmed) and then start immediately. <Received a schedule> not yet received.</p> <p>After 24 hours, UCD-310R will stop to call these pumps anymore (pumps without received a schedule log), therefore no longer possible to collect logs and status will no longer change. A workaround is to use <Add Pump> option and detect pump after infusion profile has completed. This will re-start the log collection process. This should be done shortly after infusion profile completed while battery life remains.</p>
Programmed (xx delay with respect to programmed start time) Deep skyblue	Pumps started (xx delay) with xx delay with respect to programmed start time	Pumps will finish after study duration completed or finished after study duration completed	<p>Pumps programmed correctly and <Received a schedule> received. Pump will finish after study duration completed after delayed start but positive confirmation for <Finished> may be delayed in Application Software due to delay of receipt of <Finished> from pump due to wireless interference etc.</p>

* xx Delay shown is with respect to <Activation Start> rather than actual pump start time. Start time will after <Activation Start> and <Activation End>.

5sMinDMin1						
Animal ID	Weight [g]	Pump ID	Pump Start Time	Start	Abort	Status
Animal 1	22	8Z0021	2019/06/14 15:00	Start	Abort	Programmed (0.2m delayed)
Animal 2	22	910064	2019/06/14 15:00	Start	Abort	Programmed (1.3m delayed)
Animal 3	22	910063	2019/06/14 15:00	Start	Abort	Programmed
Animal 4	22	8Z0019	2019/06/14 15:00	Start	Abort	Programmed
Animal 5	22	8Z0022	2019/06/14 15:00	Start	Abort	Programmed (0.5m delayed)
Animal 6	22	910062	2019/06/14 15:00	Start	Abort	Programmed (0.6m delayed)
Animal 7	22	910004	2019/06/14 15:00	Start	Abort	Programmed (0.7m delayed)
Animal 8	22	910065	2019/06/14 15:00	Start	Abort	Programmed
Animal 9	22	8Z0016	2019/06/14 15:00	Start	Abort	Programmed

Appendix H: Recommended Orientation of UCD-X10R and SMP-310R pumps



Appendix I: SMP-310R/300 Compatibility test

The parts of the pump (reservoir, catheter tube and connectors) which are exposed to the solution for infusion in an iPRECIO® Micro-infusion pump are made with medical grade SIBS, SEBS and PP. The solution is also in contact with the septum material. Current compatible and incompatible solvents are listed hereafter. Compatibility is based on Primetech's Testing Methods only.

For the most current list of compatible solvents, check www.iprecio.com or contact your nearest official distributor. **For studies longer than 2 months, contact your nearest official distributor to confirm compatible solvents.**

Last Updated December 3, 2015

Highlighted in yellow: Tested

Not highlighted: SMP-200 Pump (same materials and manufacturing process) and expected to be compatible when compatible. Also, not compatible when not compatible.

Compatible Solvents

Acids, with pH 2 or weaker

Bases, with pH less than 13

Buffered Phosphate Saline (PBS)

Culture Media (1% benzyl alcohol)

Cyclodextrin

Dextrose, up to 5% in water or saline

N,N-Dimethyl formamide (DMF), up to 25% in water

DMSO 50% and water or saline 50%

DMSO, up to 50% in ethanol ($\leq 15\%$) and water

DMSO 5% and PEG400 95%

50% DMSO + 50% Propylene Glycol

DMSO 50% and water 50%

DMSO 50% + 15% ethanol and 35% water

Dulbecco's Modified Eagle Medium (D-MEM) (1X), liquid

Ethanol, up to 50% in water

Glycerin, up to 75% in water

Glycerol 100%

1-Methyl-2-Pyrrolidone, up to 12.5% in water

Propylene Glycol

Ringer's solution (without lactate)

Saline, 0.9% (or other aqueous salt solution)

Triacetin, up to 5% in water

Tween 80, up to 2% in water

Water, distilled

PEG200 100%

Solutol® 15% in water

Viscosity up to 20 cp is ok. (Higher viscosity not tested due to the use of 27G needles. Difficulty to aspirate solution with 27G needle)

Last Updated December 3, 2015

Highlighted in yellow: Tested

Not highlighted: SMP-200 Pump (same materials and manufacturing process) and expected to be compatible when compatible. Also, not compatible when not compatible.

Short term use only (1 - 2month)

PEG300 100% (**< 45 days**)

PEG400 100%

Cremophor EL 25% in water (**< 30 days**)

PEG400/Propylene Glycol/Water 30:50:20 (**< 30 days**)

In-compatible Solvents

Acids, with pH less than 1.8

Bases, with pH higher than 14

Benzyl-alcohol >10% vol

Corn Oil

DMSO (100%)

DMSO 50% + ethanol 50%

DMSO 50% and PEG400 50%

DMSO 50% and PEG300 50%

DMSO 50% and PEG200 50%

Ethyl Oleate

Mineral Oil

Sesame Oil

Solutol® 30% in water

In-compatible Drugs/Molecules

Rotenone (CAS 83-79-4) ≥ 3µg/ml

Primetech Corporation recommends that a compatibility test be performed before using a pump to ensure the drug and solvent solutions are compatible with the materials used. Strong acids, strong alkalis and organic solvents may cause decomposition or denaturation of the materials comprising the pump. Drug compounds may also be absorbed by the materials.

Primetech is able supply the complete sub-assembly composing of SIBS reservoir, PP refill port with septum, PP connectors and SEBS catheter for evaluation of compatibility. For compatibility testing, add the solution in question into the reservoir and catheter sub-assembly (warmed to body temperature), in a controlled environment. Incubate for a period of time exceeding the expected study duration. After incubation, analyze the solution according to known analysis procedures.

A test kit containing the different materials used is also available for evaluation.

July 23 2019

www.iprecio.com

For support, please contact +81-3-3816-0851 or
E-mail:iprecio@primetech.co.jp

CAUTION

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

Made in Japan