Micro infusion pump

iPRECIO®

SMP/IMS-300 **User's Manual**

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

PRIMETECH
CORPORATION

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-300 only)
The provided LAN Cable with a ferrite core shall be used when connecting the UCD-300 to a PC and do not replace the LAN cable with other LAN cable.

FCC WARNING
FCCID: 2ACHIUCD300/2ACHI300

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.

CE1780

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

INFORMATION TO THE DIGITAL DEVICE USER REQUIREMENT by FCC (For Model UCD-300 only)

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

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

Table of contents

About iPRECIO®

The world's first implantable, programmable, infusion pump

iPRECIO® SMP-300 model is 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-300 pumps are wirelessly programmed using proprietary technologies incorporated in the UCD-300 programming station, application software and pumps. Using these technologies, the IMS-300 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 12 and Appendix D: Communication Availability for more detailed description. **Once wirelessly programmed, the iPRECIO SMP-300 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>, <Start of Infusion>, <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 44.**

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 Windows 7/ 8/ 8.1 and LAN port)
- Refillable percutaneously through a septum
- Wireless Communication
- Battery life of up to 46 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-300
- iPRECIO® Management System IMS-300
  - Data Communication Device UCD-300 (including AC adapter, LAN cable)
  - iPRECIO® Management Software Installation CD
- iPRECIO® User's Manual

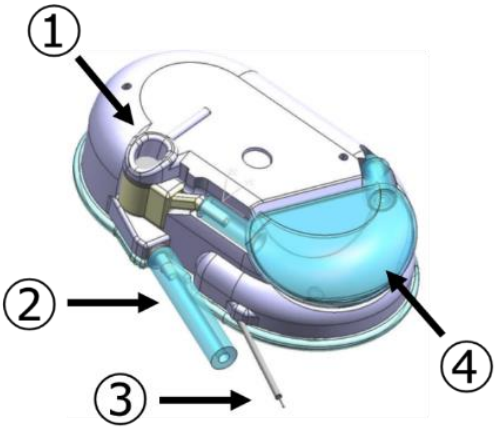
(L) SMP-300 sterile pump 5pcs/box

(R) UCD-300 including AC adaptor, LAN cable

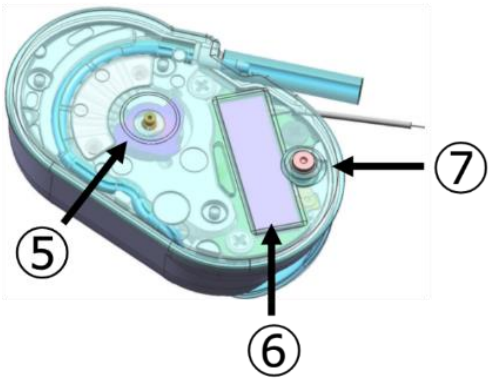
Structure of the iPRECIO® System: SMP-300/UCD-300

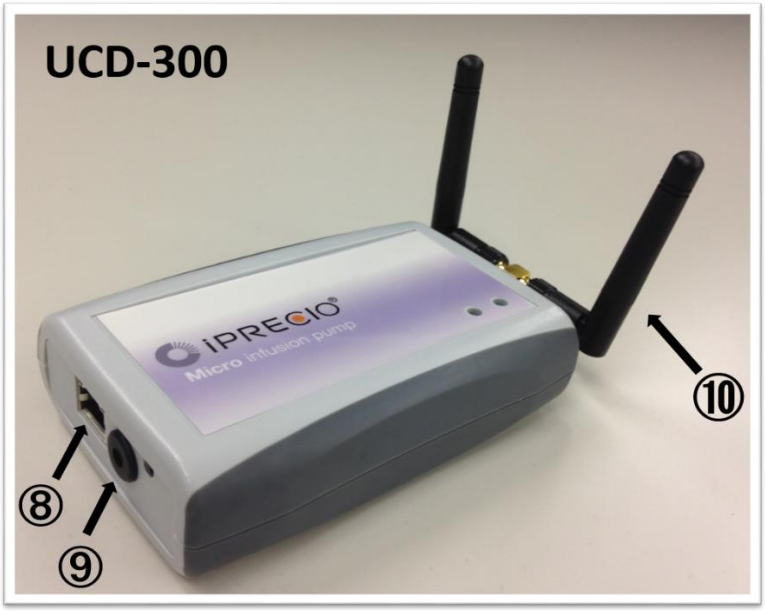
SMP-300

Top view



Bottom view





Number	name
①	Septum Port
②	Outlet tube
③	Wire Antenna
④	Reservoir
⑤	Micro Cam
⑥	Pump ID label
⑦	Power Switch
⑧	LAN cable connect port
⑨	AC Adaptor connect port
⑩	Dual Antennae (full length of antenna 5 cm)

Workflow

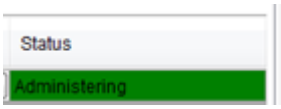
You should begin implantation of the iPRECIO® according to the following workflow. Make sure there is sufficient time to fill, activate and program all pumps prior to implantation.

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-300, 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. **Starting a new Study**
   Input general information about the study
   (Study name, animal ID, weight, etc.)
   Filling the test article (TA) or saline (MA) into the reservoir and catheter
   Fill the TA or MA into the reservoir with 27G syringe.
   Activate the Pump
   Use blunt-nosed forceps to press down firmly the black power button switch to switch ON and activate pump
   Pump Detection
   Click Detect button to detect the pumps.

3. **Start Keep Vein Open (KVO) and setup dead-volume protocol**
   If using KVO, setup infusion flow rate for KVO and <dead volume setting> for accurate flushing of dead volume and Click <KVO Start>. Use <Skip KVO> if not required prior to drug infusion.

4. **Start Infusion Protocol**
   Program <Infusion Profile> or choose infusion Group name from Group ID pull down menu and set the administration start time. Make sure there is sufficient time to program all the pumps (dark green status (green)) before infusion start time. Click <Start All> or <Start> for each pump to start the programming process.



5. **Implantation**
   Implant pumps only after all the pumps have been completely programmed as described in step 4. (<Administrating> dark green status)

6. **Status Management**
   The management software will predict the administration schedule based on the programmed protocol and will suggest when the pump needs refilling.

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-300: 12 months after manufacture

iPRECIO® Management System IMS-300: 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 42 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 guaranteed battery life is calculated by Application Software of IMS-300 system when setting up the <Infusion Profile/Group ID>. **When maximizing infusion durations, ensure that that negative remaining battery is not displayed in the Group Profile. See page 31.**

Comms Avail.	Every Minute	Every 2hrs	Every 6hrs	Every 24hrs	None
Flow Rate (uL/hr)	Drive Time (hrs)	Drive Time (hrs)	Drive Time (hrs)	Drive Time (hrs)	Drive Time (hrs)
0.1	403	907	1025	1104	1139
1.0	352	681	745	785	803
5.0	243	362	379	389	394
10.0	169	218	224	227	228

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

- **It is recommended to use communication availability of <every 24 hours>.** This can save the battery life significantly compared to <every minute>, <every 2 hours>, <every 6 hours> and <every 24hours> will give almost same duration as <None> setting. This 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.

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 for a <2 hour communication availability> with an <Infusion Profile/Group ID> for 5 steps.

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.

Pumps to be within 1 meter of UCD-300 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

	Detect (minutes)	Programmed **Pump Status: <Administrating (dark green)>**	abort	Log (2 hour Comms Avail)
1-10 pumps	1 to 10	20 minutes to 2 hours	immediate	1 to 2 hours
11-20 pumps	3 to 20	40 minutes to 3 hours	immediate	2 to 4 hours
21-30 pumps	5 to 30	80 minutes to 4 hours	immediate	4 to 6 hours
31-50 pumps	8 to 50	120 minutes to 6 hours	immediate	6 to 8 hours

- Delete pumps from UCD-300 memory before each new study. Delete all pumps using Utility Pump BaseStation Manager. See Pg 48 <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: wake up 5 sec/min when communicating <Comms Avail>
- Management System: 3 sec interval call
- Pumps communicating time is automatically staggered to reduce waiting time.
- 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-300 will send the abort signal but there is no way *to confirm if the pump will receive the stop signal or not.*
  *During KVO step, use <Abort All> to go to the next step if required. If <Abort> is used to stop the pump individually, the pump and log will no longer be available.

Installation of Management Software

Preparation before start

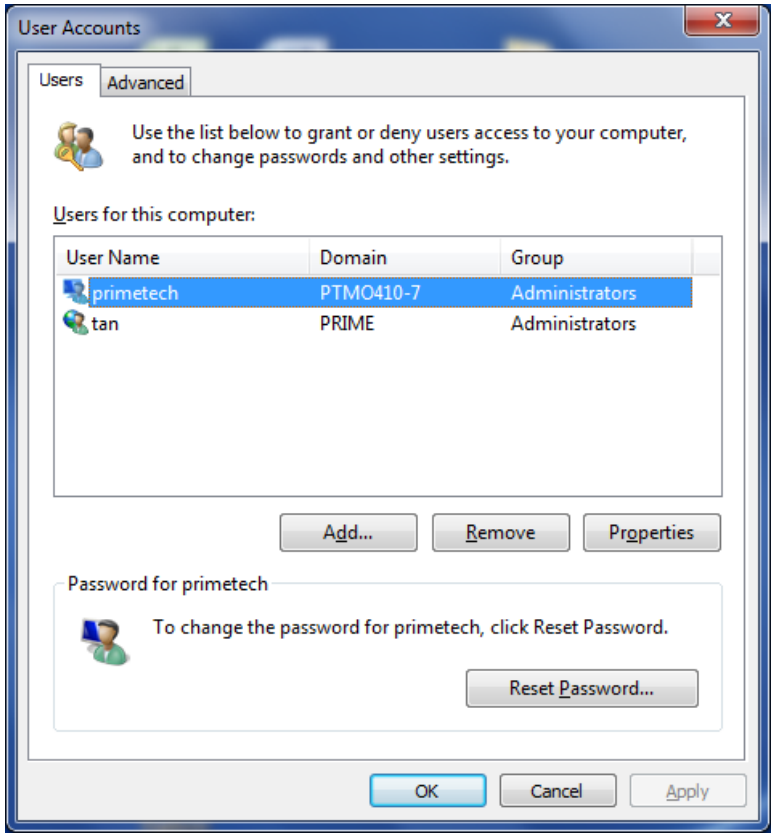
- iPRECIO® Management software install CD
- Windows 7/8/8.1 (32bit or 64bit OS) installed and LAN port ready PC
- Data communication unit UCD-300 (data communication unit)
  - UCD-300
  - AC adapter
  - LAN cable (Cross over cable with Ferrite core)

Install iPRECIO® management software

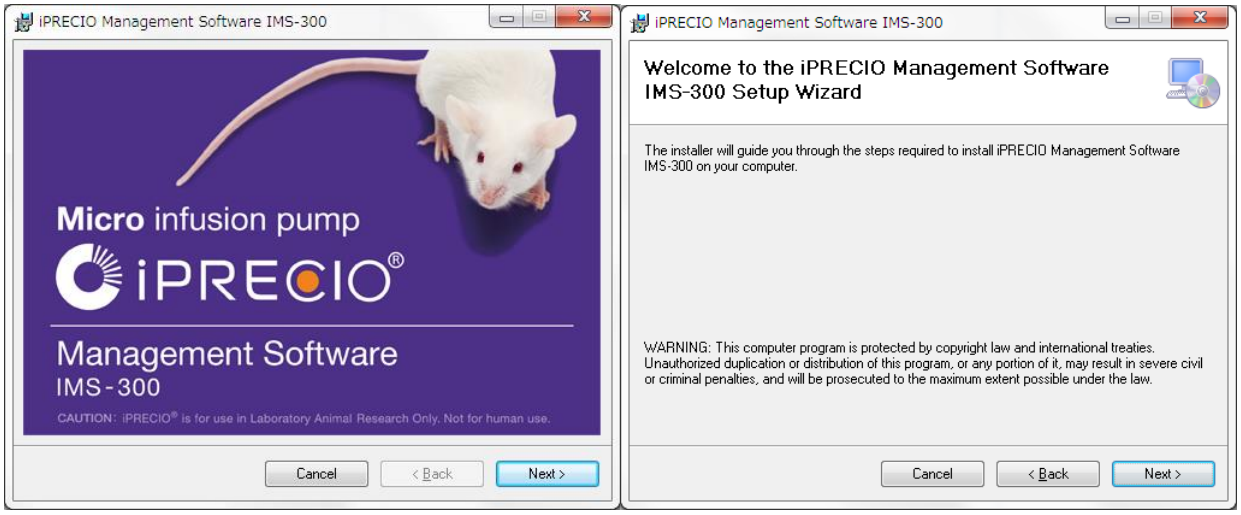
If the Application is closed, PC is switched off, sleeps, LAN disconnected or power supply to UCD-300 Management System is lost, the Application software cannot recover to monitor study status. Pumps will continue to infuse as programmed.

Recommended PC settings:

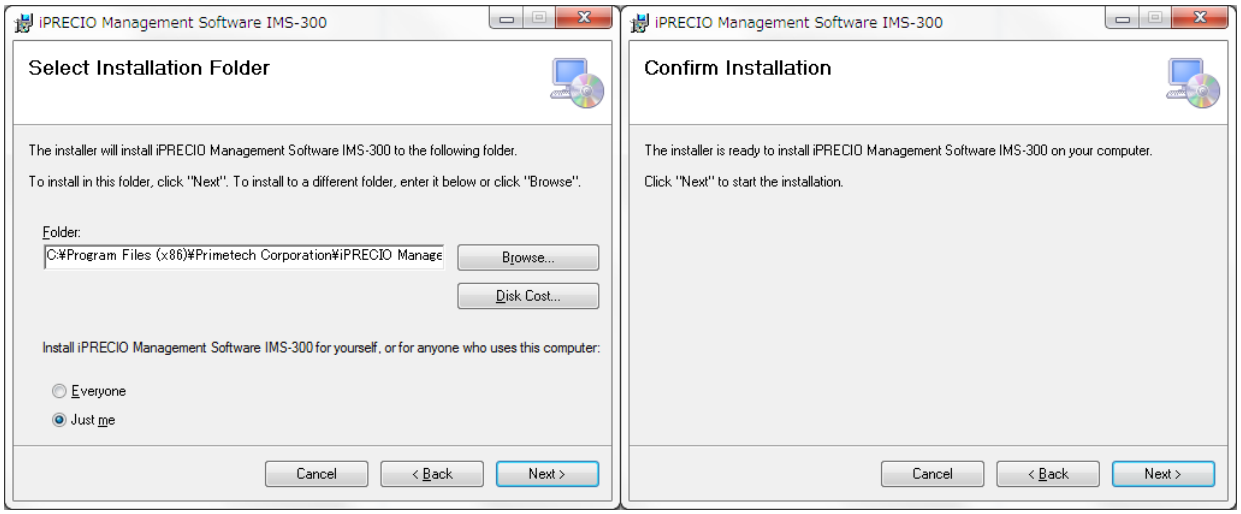
- **Please TURN OFF the screen saver.**
- **Go to control panel and change the Power option as "Never Sleep Mode".**
- **Please set the user account as "Administrators" (see picture below).**
- **Windows Update: Change settings to download updates but let me choose whether to install them.**



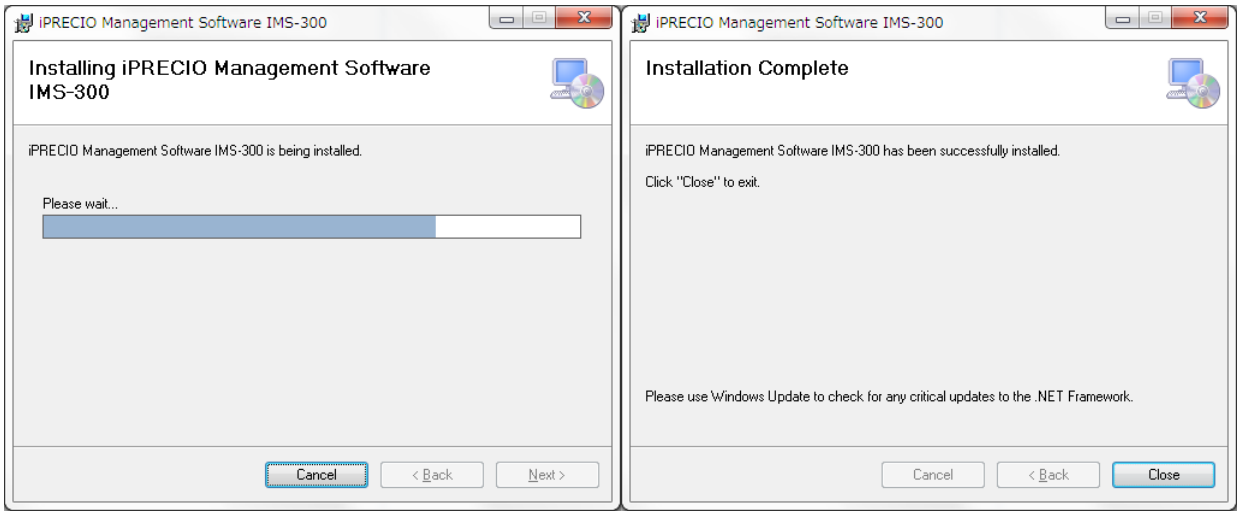
1. Run the "**setup.exe**" in an install CD.
2. When the startup window appears, click <**Next>** and follow instructions. Basically, following the next feel steps. <Next> at Setup Wizard window.



3. Chose 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-300> to confirm that the following 3 Programs were installed:-
   - iPRECIO® Management Software IMS-300
   - Utility Base Station Manager
   - Utility Pump Database Manager

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-300>

Cable connection of data communication device: UCD-300

Plug the AC Adapter to data communication device. Connect the communication device and PC with LAN cable. Refer to Appendix C to confirm if the UCD-300 is working correctly.

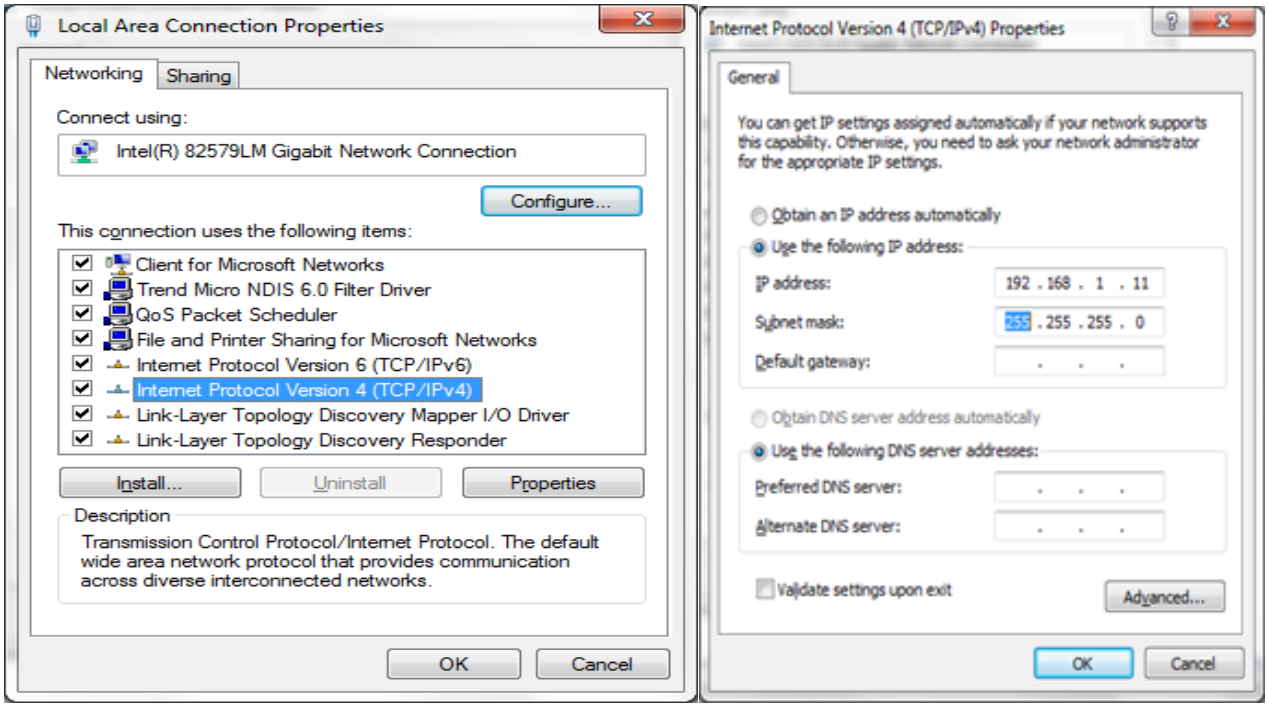
Connect LAN cable to management device and software installed PC

Plug the AC Adapter to outlet power source:
100-240V, 50/60Hz

Ferrite core attached end must be connected to UCD-300 side.

TCP/IP connection between data com unit and control PC

1. Connect data com unit (UCD-300) 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**"

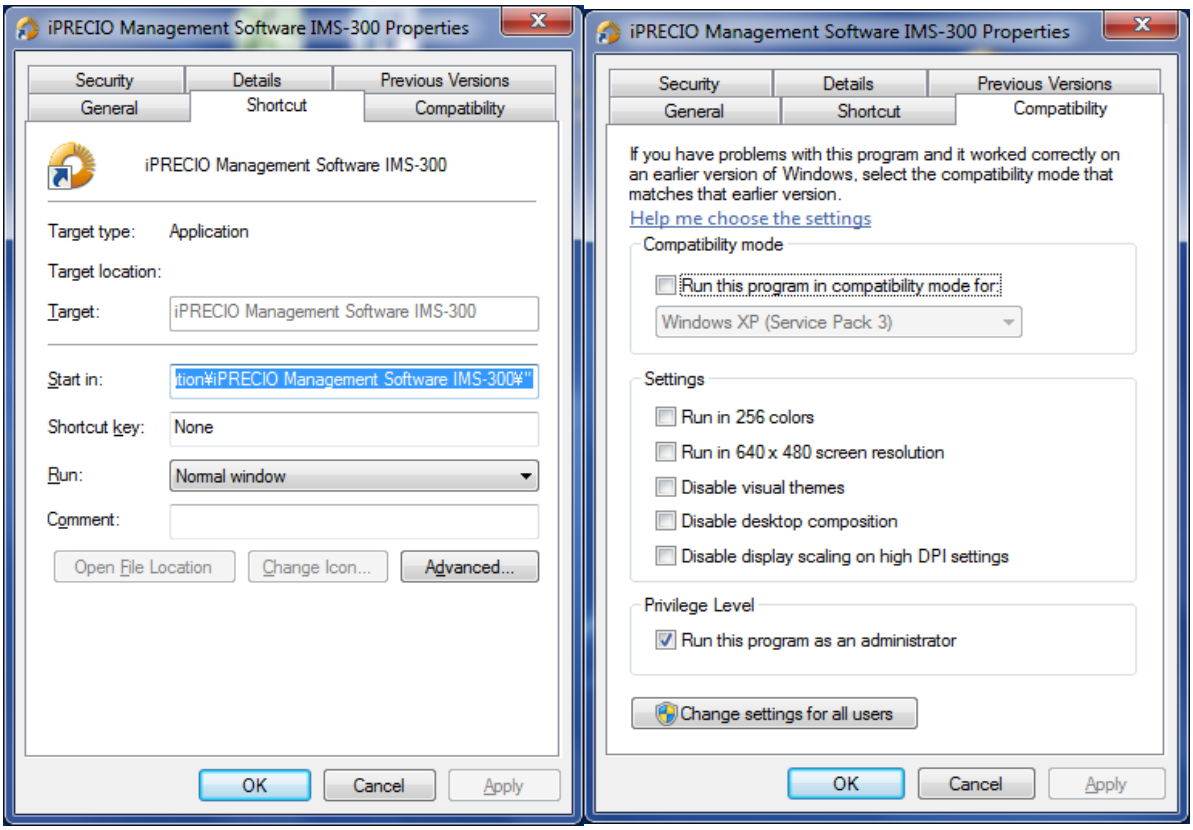
5. Once the Data communication device and control PC is connected by Internet Protocol, network connection <Network Setting> can be made in the management software.

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.

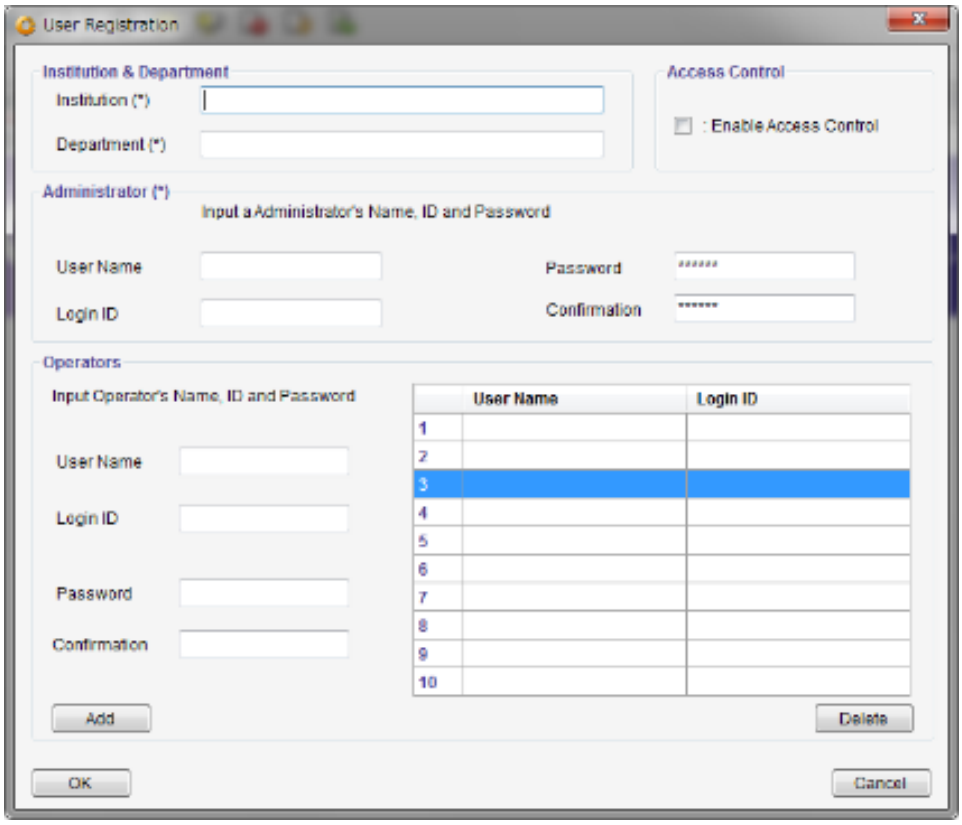
User Registration

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.

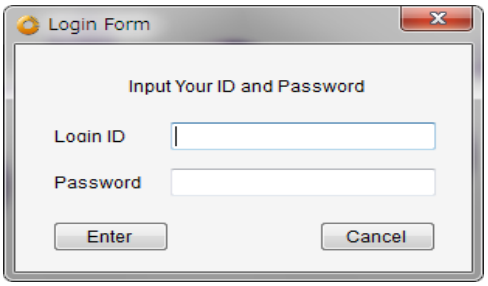


Enable Access Control

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.

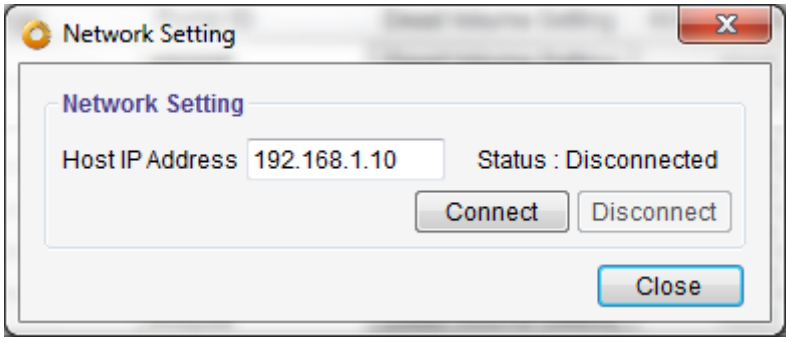
Please record Login ID and Password carefully. Without username and password, access to software will not be possible.



Network Setting

Connects IMS-300 Application Software to UCD-300.

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".



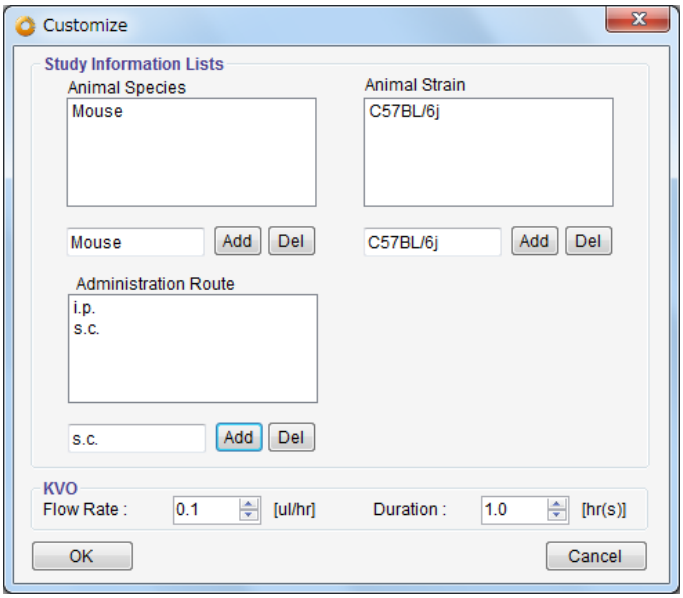
Customize information

Pull down menu for registration and management for Study Information, Keep Vein Open (KVO) flow-rate default setting. 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 <Del>at their respective controls below each list.
4. Input the required default KVO Flow-Rate and Duration.
5. 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>.

KVO parameters may be modified in the KVO setting window. See page 28 for more details on KVO.



Start Study

Start New Study

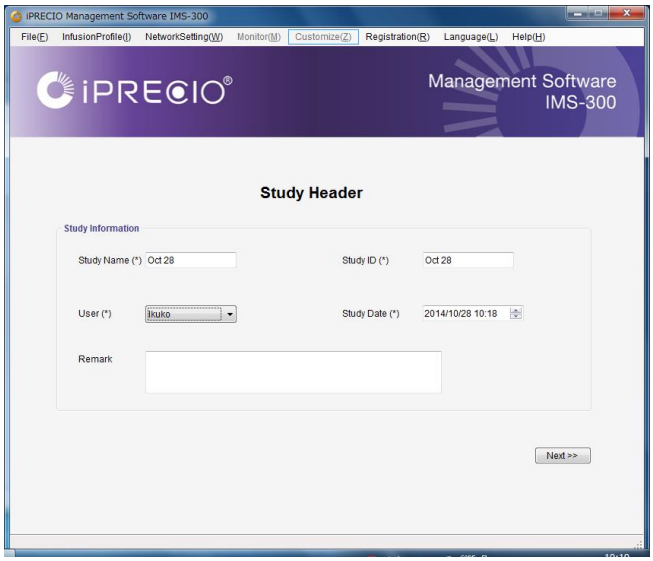
iPRECIO® Management software has a function to abort individual animals/pumps during KVO and also during administration phase. For example, it is possible to exclude animal(s) from a study by using <abort> for that animal(s). Also, during Administration phase it is possible to deselect individual animals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

IMPORTANT NOTICE

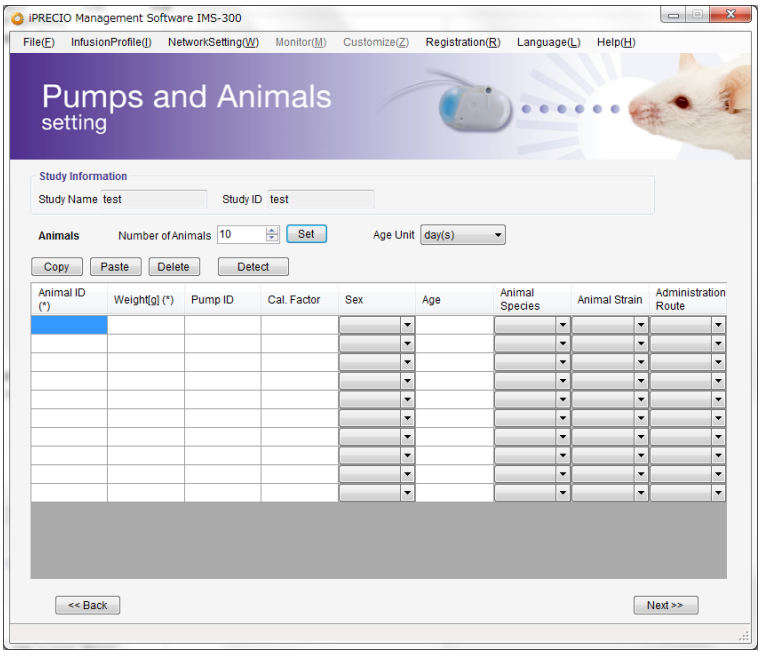
The Data access Radio system of iPRECIO® is not a Broadband version. Therefore, the management system can only communicate/detect/program one pump at a time. It will sequentially communicate with each pump in the study design. Depending on wireless conditions and number of pumps, programming may take more time than expected. Refer also to <About iPRECIO®>on page 6 and table on page 13: Ideal Wireless conditions: Time to detect, program pumps etc. See also FAQ for more details.

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

1. Click <New> from 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-300 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.



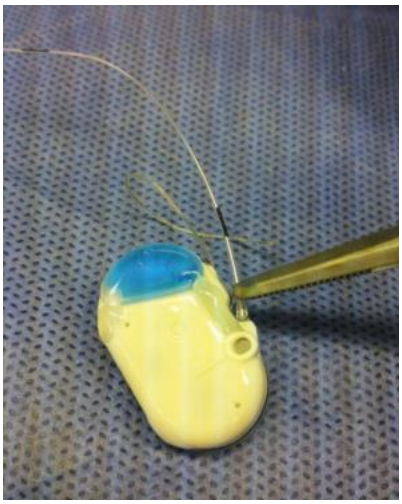
6. After filling the first row, it may be copied to other rows. Use Copy and Paste for repetitive inputs. It copies data from the different columns for age, strain, etc. Then modify as appropriate. Pump ID and Cal Factor are not copied.

Catheter connection and Pump activation.

Add/cut catheter to length, fill, and activate the pump by switching ON pump. Once pump is on and activated, communications are enabled. Default setting on Power ON <1 minute> communications availability.

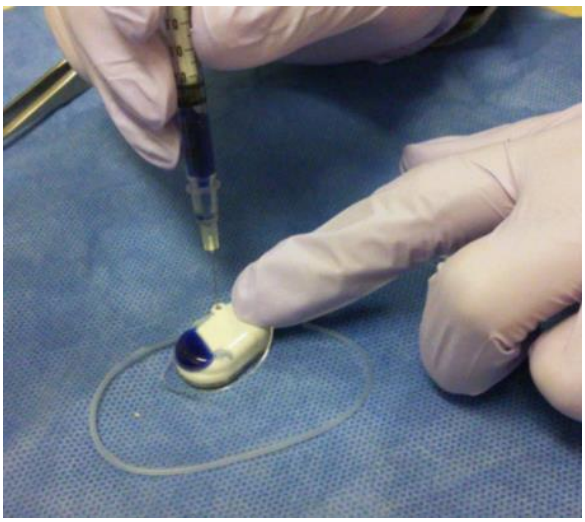
iPRECIO Pumps are delivered with all fingerpins down to facilitate filling where air escapes through open catheter. Fill Saline or Test Article till distal end of catheter before power on. On Power ON, activation process starts and the CAM rotates until fingerpin locks the tubing. Once locked, liquid 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 during the Power ON process. 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.

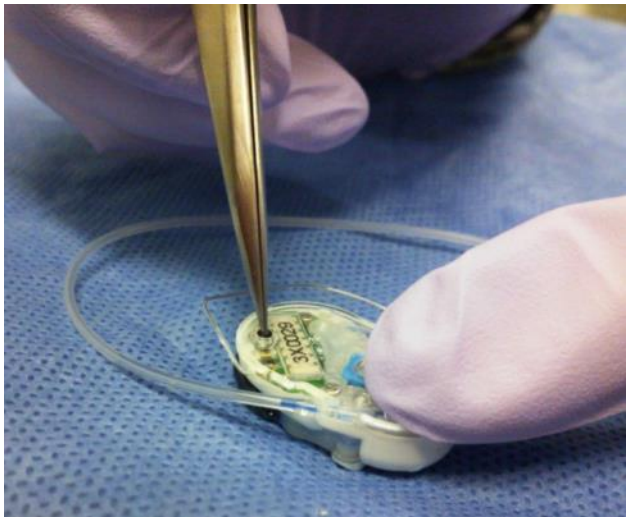


Each pump's dead volume is calculated with KVO setting. Final tube length, inner diameter or measured dead volume will be required. If not known, measure and record accurately.

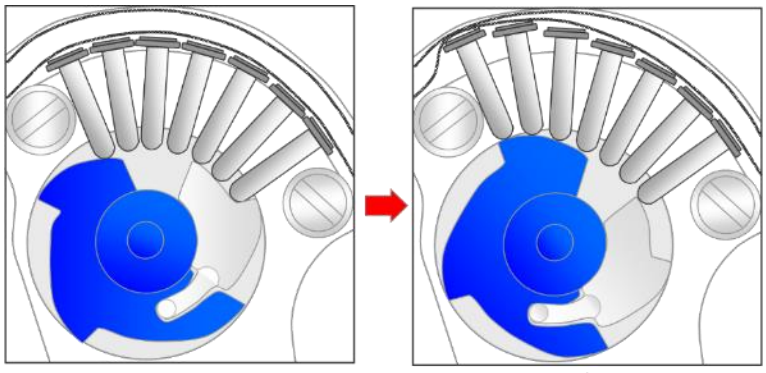
3. Fill saline/test article to distal end of tube with 27G syringe needle through septum port. Then carefully turn over pump to access Power ON switch.



4. Firmly hold pump down with finger(s). Then, press down firmly to Power ON pump. If the pump moves/rocks during this process, solution will be pushed out of the reservoir. A blunt pointed tool like forceps is ideal. Take care not to damage silicon coating. **Once pumps are turned ON, they cannot be switched off.**



5. When Power On successful, activation starts, and the inner cam rotates for about a 100 seconds where the rear most pin completely blocks the tube. This is for a new un-activated pump. Check by verifying CAM position or that reservoir is locked after 2-3 minutes.



Factory-configured Block tube mode

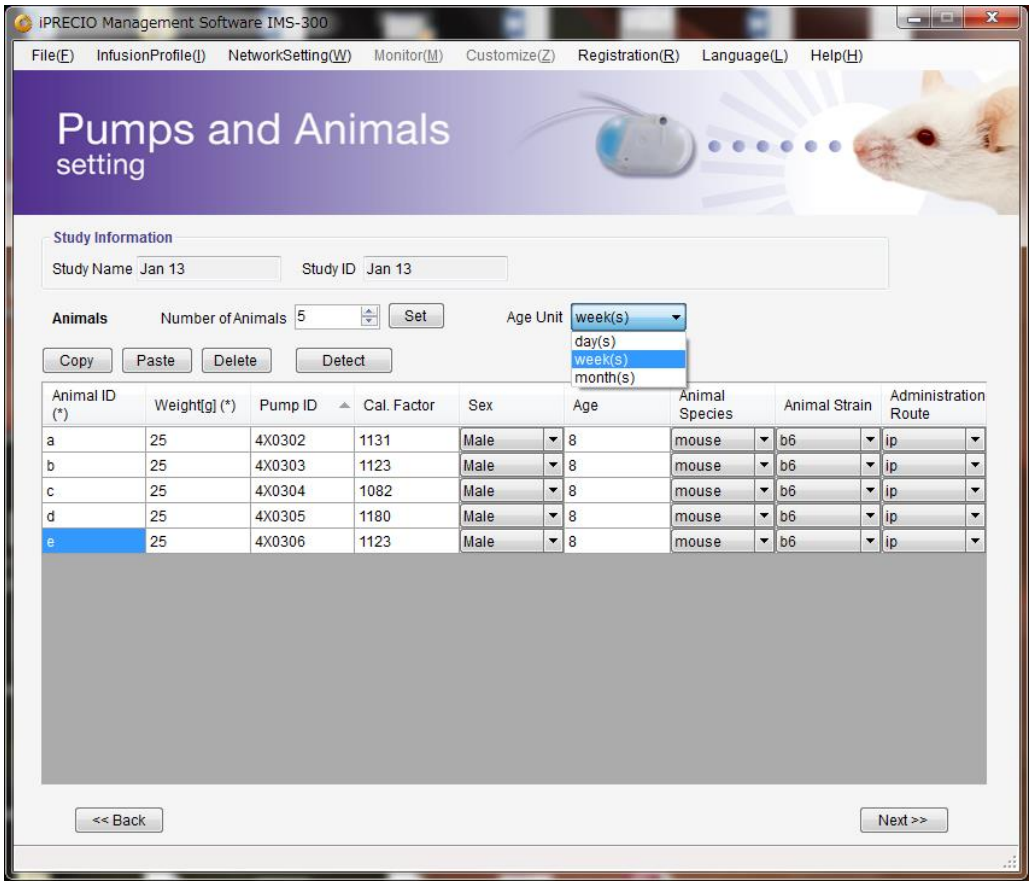
6. After activating with Power ON, the pumps are ready for detecting <Detect>, <Programming> and then for implanting.

Once pumps are turned ON, they cannot be switched off. Activation starts and the pump starts consuming power at <every minute> communication availability rate.

- **Pumps are only switched ON once /activated once.**
- **Only way to save battery life would be to program greater than <every minute> communication availability and 0.1 uL/hour.**
- **If programmed to <None> communication availability, no further communications (including programming/abort/etc.) possible until end of that protocol.**

Pump detection

1. Place the pumps and data com device, UCD-300, within 1 m range.
2. Enter <Number of Animals> or number of pumps for the study.
3. Click <Detect> to start detecting pumps. 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 13 for detection and programming time guidance.**
- **It may take long time to detect pump due to radio wave background environment.**
- **Verify PC and UCD-300 connected properly. For details, refer to "TCP/IP connection between data com unit and control PC" and "Network Setting".**
- **Verify pump activation. For details, please refer "Catheter connection, and pump activation".**
- **See also the step by step trouble shooting guide in the installation CD.**

4. 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.

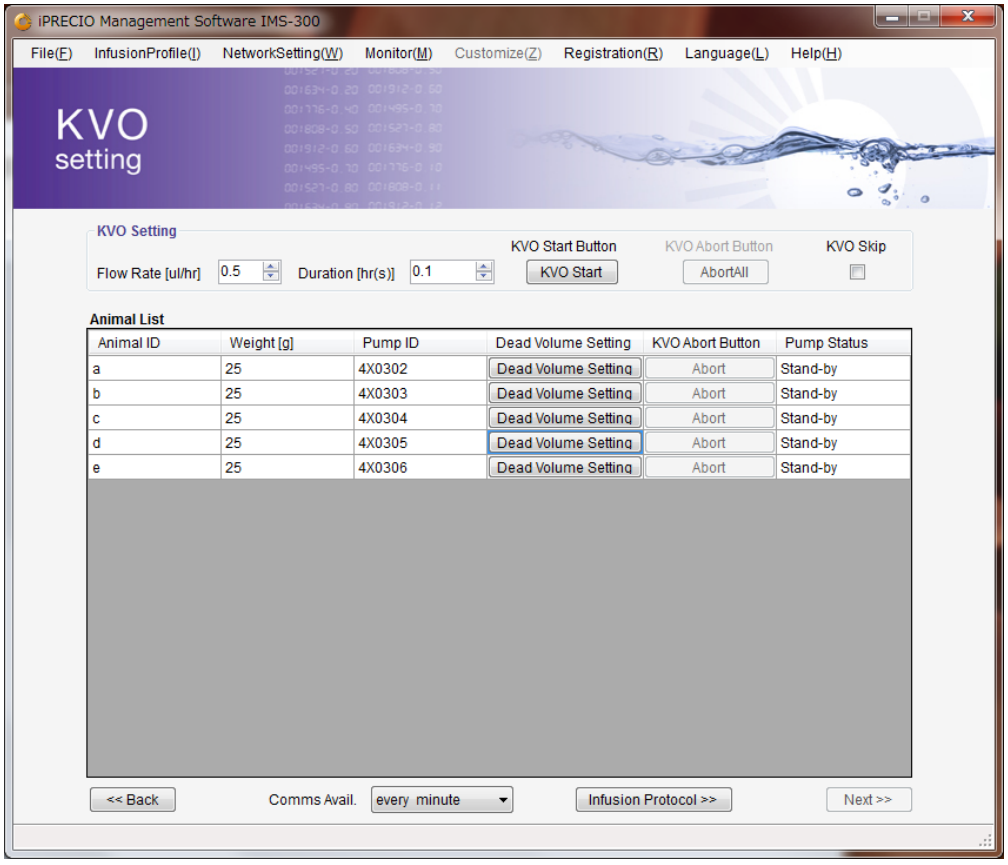
KVO setting, Dead Volume Setting, start and complete

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.

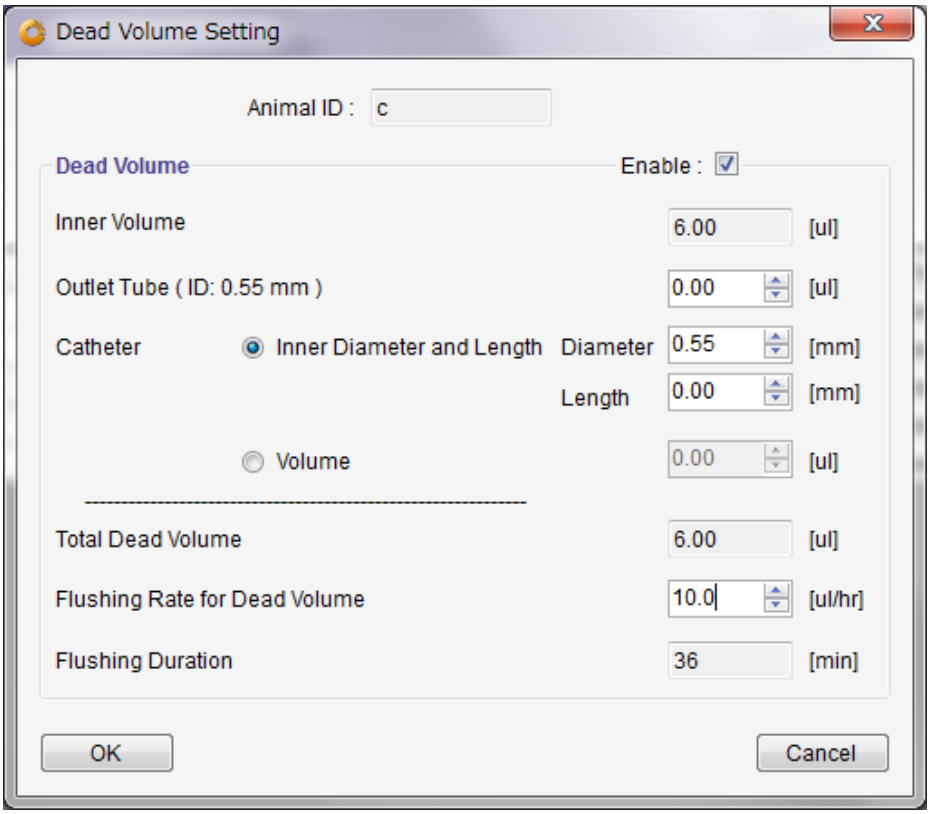
Important Note. Primetech recommends that the KVO and flushing steps are included within <Infusion Profile>/Group ID to allow full pump programming prior to implantation. Note that it is important to review this section to understand the concept behind KVO, dead volume and flushing durations. See < There are two options for KVO settings> later.

1. KVO setting window appears. If KVO is not required, then check <**skip KVO**> and click <**Next>** or click **< Infusion Protocol>** button to go on to the infusion settings.



2. Successively program the dead volume setting for each animal.

3. Input the required information for dead volume calculation and click OK button.



To use <Dead Volume Setting> correctly, make sure the <Enable> 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.

- **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.**

4. Verify/modify KVO flow-rate and duration then click <**KVO start**>. The pump status will display **KVO** after KVO start. Pump status color will change in accordance with communication status, from Red →Yellow→Green. When the color changes to Dark Green (green), infusion starts at the programmed rates. Dark Green (green) means that the pumps are correctly programmed and confirmed. Infusion in KVO starts immediately after this.
   *To confirm if the KVO step starts correctly, check the color code of the box which states KVO.
   - **Red color**: Application software is sending the schedule to UCD-300.
   - **Yellow color**:UCD-300 has been received the schedule from application software.
   - **Dark Green (Green) color:** Pumps have received the KVO flushing schedule and have started KVO flushing.

Once the study with iPRECIO pumps have started, make sure that the Application software and UCD-300 are always ON to ensure that the study can be completed with all the required information collected and saved in the IMS-300 Application Software. Otherwise, the data will be lost and cannot be recovered. Note that once programmed, the pumps are independent of the UCD-300 and Application software.

5. When the pre-set KVO duration ends, the pumps will stop. The Pump status also changes to **Finished**. Click <**Next>**, for the administration schedule setting. When all of the animals have fully recovered before pre-setting KVO period, you can abort all KVO by clicking <**abort all>** and start administration schedule. If some animal do not recover during KVO, these animals can be removed from the study. Use the <**abort>** from individual animal column.
   *Abort All: UCD-300 send the stop schedule to the pumps and UCD-300 will wait to receive the stop log from the pumps.
   *Abort Individually: UCD-300 send the stop schedule to the pumps but UCD-300 will not wait to receive the stop log.

After KVO stopped, check that the Pump status displays <Finished>. Depending on the communication condition, <Finished> status may appear with a delay even if the pump has already stopped. Logs will have the actual start and stop timestamps. Logs are usually received some time later and dependent on <Communication Availability>, number of pumps and communication availability.

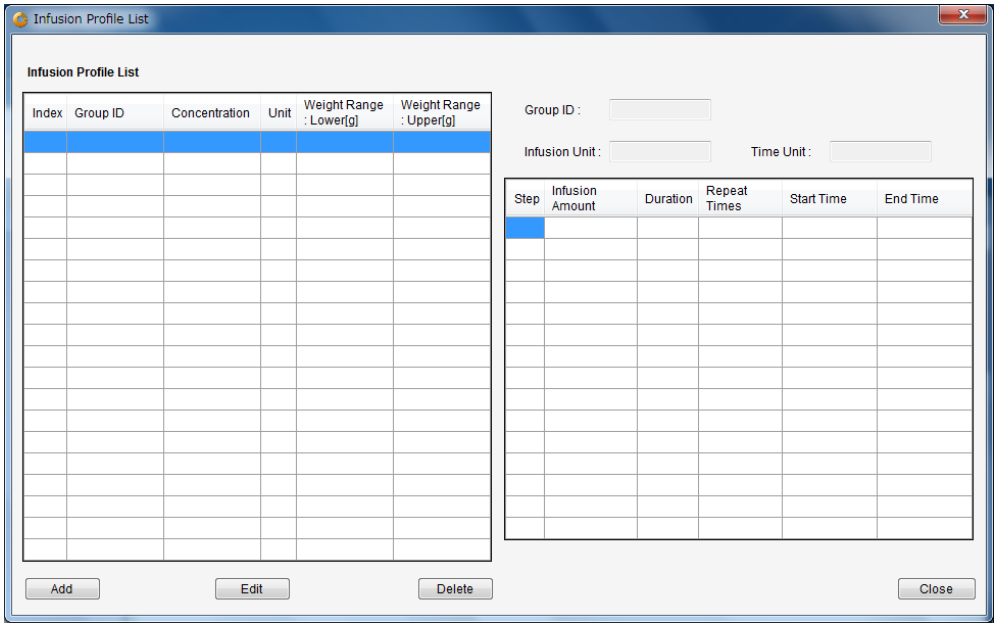
Important Note. Primetech recommends that the KVO and flushing steps are included within <Infusion Profile>/Group ID to allow full pump programming prior to implantation. See < There are two options for KVO settings> later.

If KVO function used, KVO flow-rate/duration, and dead volume flushing will consume battery power. This is automatically calculated by the application software when creating <Infusion Profile>/Group ID in the <Infusion Protocol Setting> Window. If KVO function not used (skipped), then full battery life will be available for <Infusion Profile> programming.

Create <Infusion Profile> / Group ID

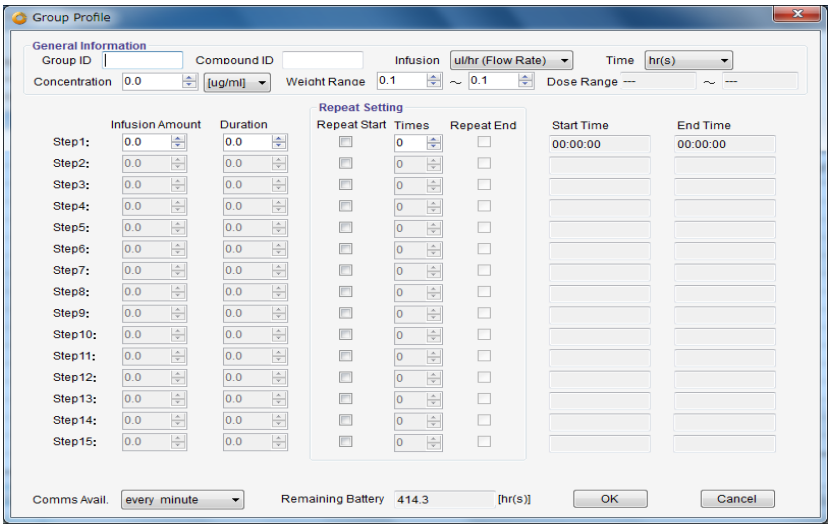
The <Infusion Profile> / Group ID will define the iPRECIO Micro Infusion Pump infusion protocol. The pumps will infuse/administer test article (TA) or vehicle/saline in the reservoir according to the programmed <Infusion Profile>. In <Infusion Profile>/Group ID, Compound Name, concentration, flow-rate/dose settings, animal weight range, Communication Availability <Comms Avail.>, and battery life calculations are made. These Profiles may be 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.



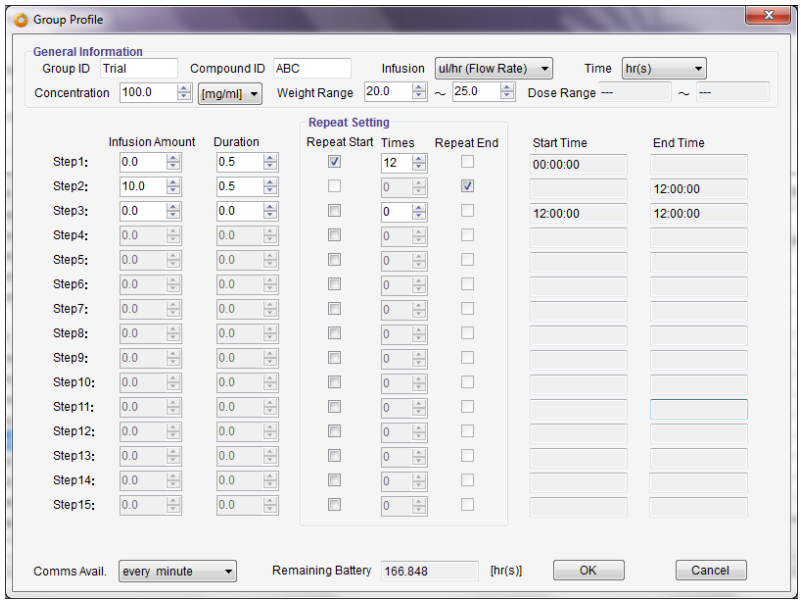
5. Input or select the basic information. To set the infusion amount in Dose, select the unit : **μg/kg/hr(Dose)** or **mg/kg/hr(Dose)**. **Animal weight range and concentration of test article** must be filled when using this setting. Flow-rate in **μl/hr** may also be programmed.
6. To get the correct 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 6 hour>** 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.**
7. Input dose/flow-rate amount and duration from Step 1 onwards as required to create the infusion profile/schedule. 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.

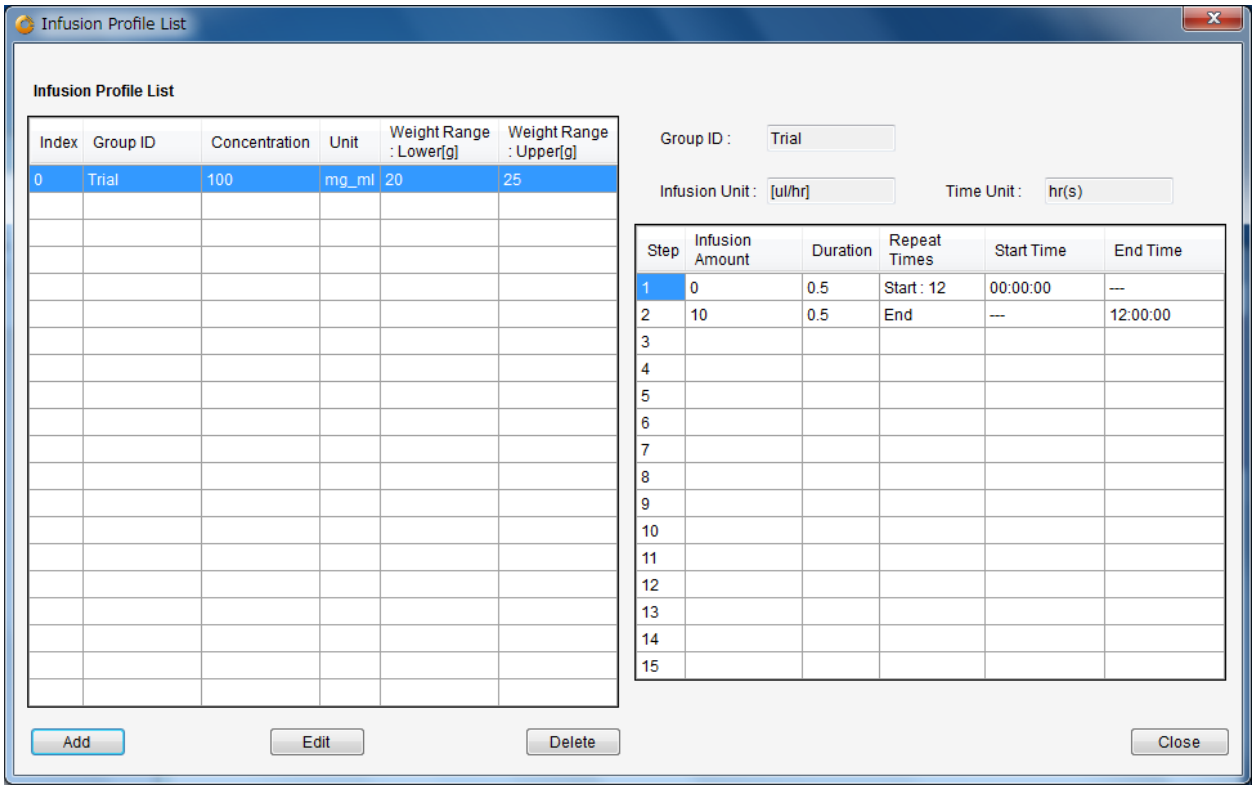


- **Remaining Battery calculation is fairly complex as it has to take into account both pump operation, communication availability (wireless battery consumption), logs etc. Therefore it may be necessary to input duration a number of times especially when needing to reach maximum duration.**
- **For re-programming, see <How to re-program a pump> section. Note that manual calculation of battery life will be required. See FAQ.**

8. 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] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] [Step 1 Step 2] = [Step 1 Step 2] x twelve (12)



9. 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.



10. 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.

11. 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 250. 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 under section <iPRECIO SMP-300 pumps has an internal memory to hold a maximum of 28 logs>.

There are two options for KVO settings

1. <KVO> with <Dead Volume Setting> enabled *(described in a previous section and briefly again hereafter)*

2. Programming KVO, exchange and dead-volume flushing within <Infusion Profile/Group ID>.

Refer also to Workflow Guide provided separately and Important Notes on page 36

◆ **<KVO> with <Dead Volume Setting> enabled** *(described in last section)*

Pros

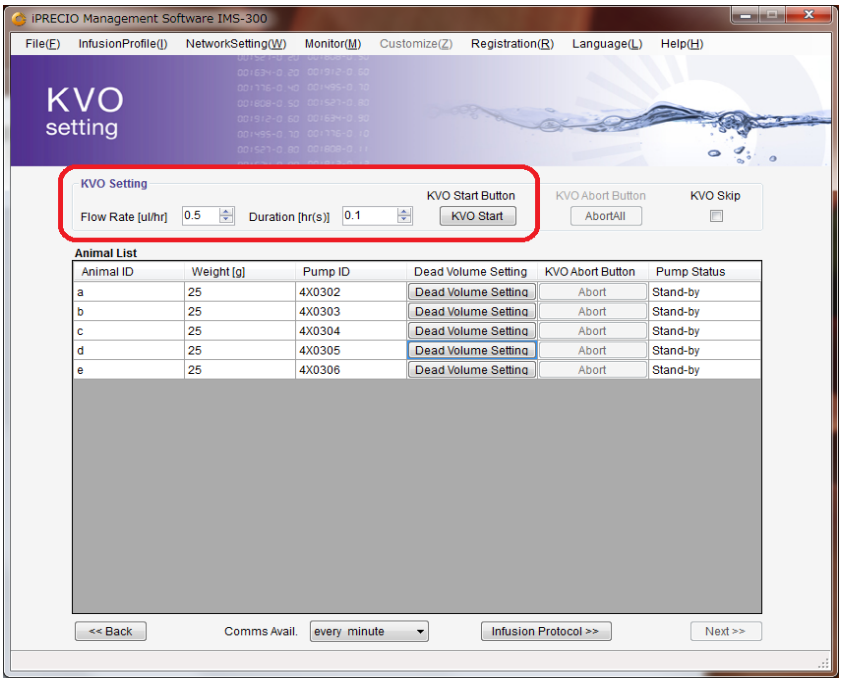
1. Easy to use with <Dead Volume Setting>
2. Most efficient way to program all the pumps to start and finish as quickly as possible
3. Does not use any steps in <Infusion Profile/Group ID>

Cons

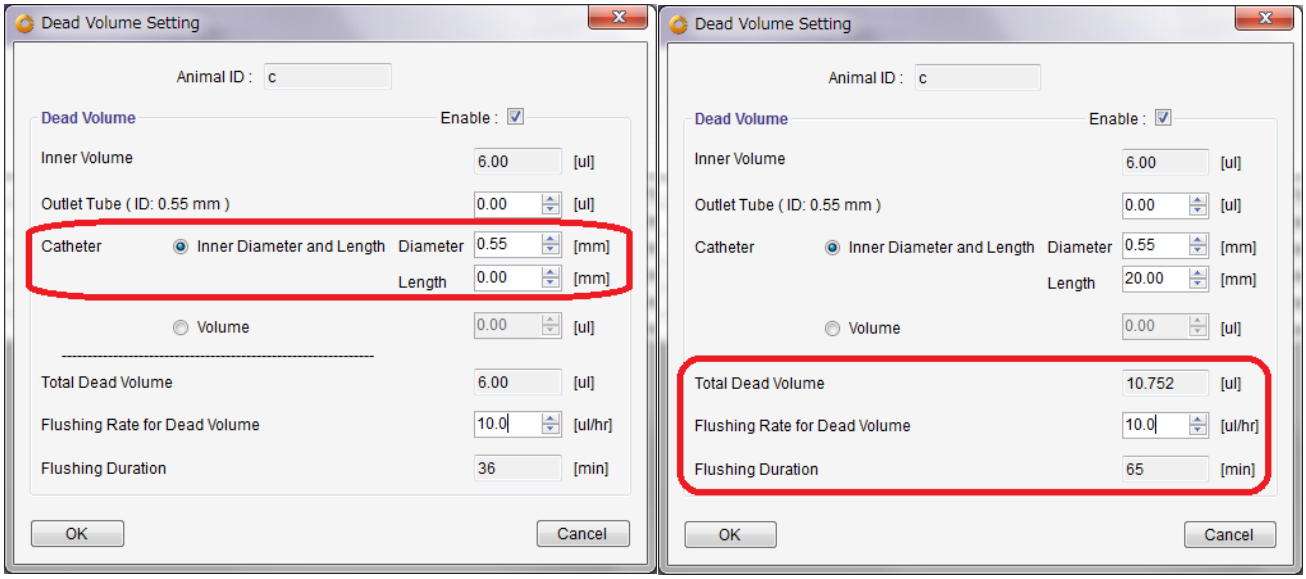
1. Programming with Infusion Protocol required after KVO step
2. Need to wait until last programmed pump has finished KVO before able to program <Infusion Profile/Group ID> unless <Abort All> is used
3. Pumps start as soon as KVO programmed and stop after duration reached.
   *KVO programmed = Pumps received schedule from UCD-300

Procedure:

➢ Fill in the KVO "Flow Rate" and "Duration" in KVO Setting window.



➢ Open "Dead Volume Setting" window and put correct length of the catheter.
*You have to fill the correct length of catheter or dead volume will be automatically set as 6uL, flushing rate as 10uL/hr.



If an additional catheter is used, the volume should be entered. Alternatively, Use Application software to calculate based on Diameter of Additional Catheter and length. Unless Total Dead Volume is accurately filled/calculated, the dead volume flushing step will not be accurate.

- Click <KVO Start> button. Then, KVO will start individually for all the pumps.

◆ **Preprogrammed KVO with <Dead Volume Setting>**

KVO, exchange stop time and dead volume flushing programmed within <Infusion Profile/Group ID>

Refer also to Workflow Guide provided separately and Notes below

Pros

1. KVO, exchange time stop, flushing and <Infusion Profile/Group ID> in one programming step
2. Sure that once programmed within start time, infusion protocol will be followed without any additional programming

Cons

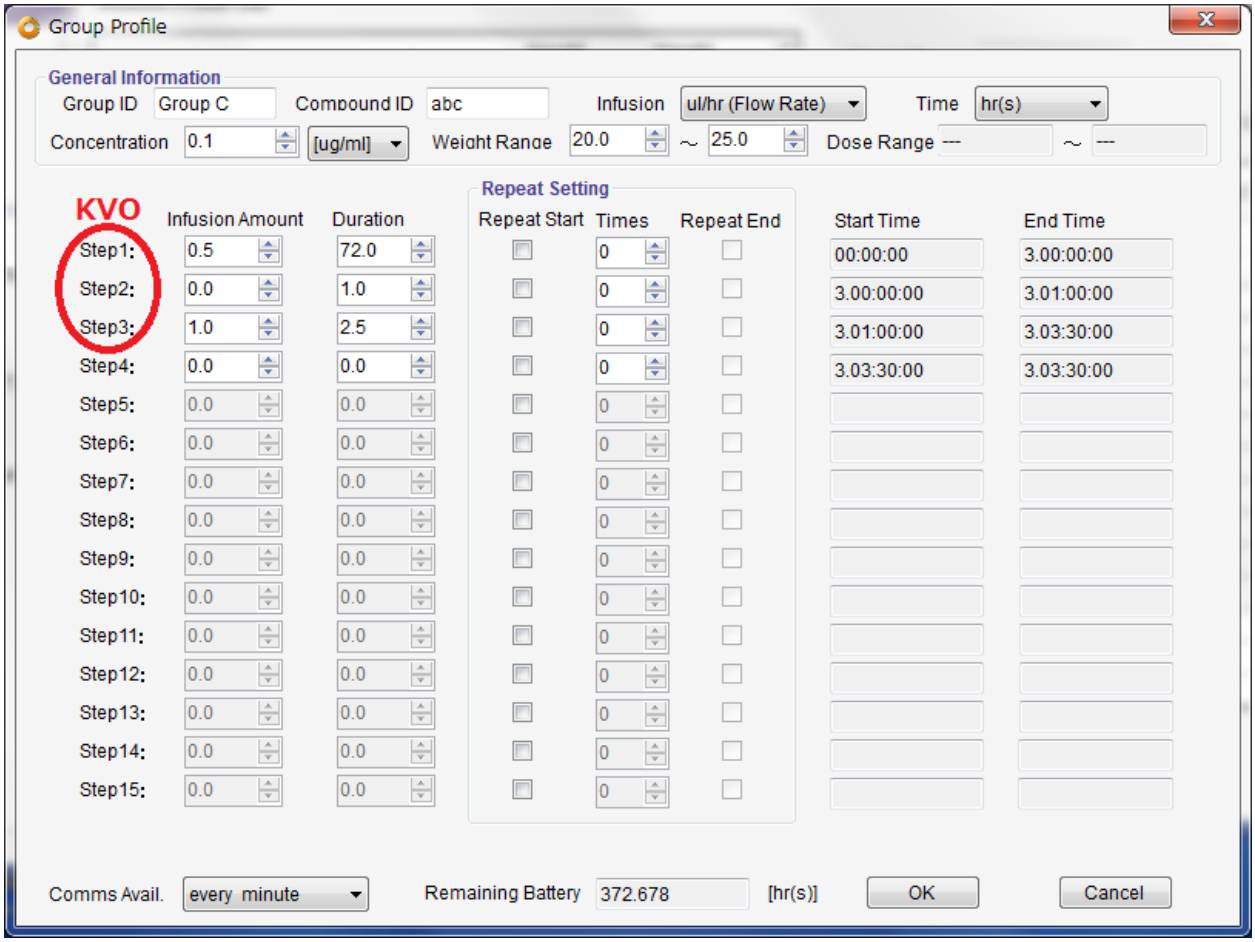
1. Uses 3 steps out of 15 from Profile steps for <KVO>, <exchange time> and <flushing duration>.

Important Notes:

- If pumps not programmed at the same time for KVO, they will stop at different times and will need to wait until KVO finished before exchanging reservoir solution and programming <Infusion Profile/Group ID> Infusion Protocol
- If pumps not programmed at the same time but before the programmed <Flushing Start Time>, then the pumps will start administration at the programmed time
- If start times are missed, the <Infusion Profile/Group ID> with start with a delay. Delay will be dependent on exactly when the pump is programmed
  - ✧ Very important that pumps are programmed before <Start Time> especially for Circadian, Intermittent (pulsatile), bolus or any infusion protocol other than continuous.
  - ✧ For continuous infusion, the stop time will be extended by the delay. Basically the new start time (delayed) + <Infusion Profile/Group ID> duration.

Procedure:

- ➢ Check <KVO skip> box or click <Infusion Protocol> button to go on to the Infusion Protocol setting screen.
- ➢ Assign the Group ID (Infusion Profile) and set the administration start time for each animals.
- ➢ If KVO flow rate is 0.5uL/hr, and Duration is 3 days (72hrs), input this into Step 1 in Group Profile.
- ➢ In Step 2, input the flow rate as 0.0uL/hr and duration at least 30min. or longer. For maximum accuracy for dead volume flushing, Exchange the KVO solution to Test Article (TA)/Drug within this stop duration. Take in consideration the number of pumps to be filled/exchanged and the number of people available to carry out the task for the stop duration.



Step1. KVO infusion flow-rate and duration
Step2. Exchange time 0 flow-rate and duration
Step3. Infusion flushing rate and duration

Step4 – Step15. Administration

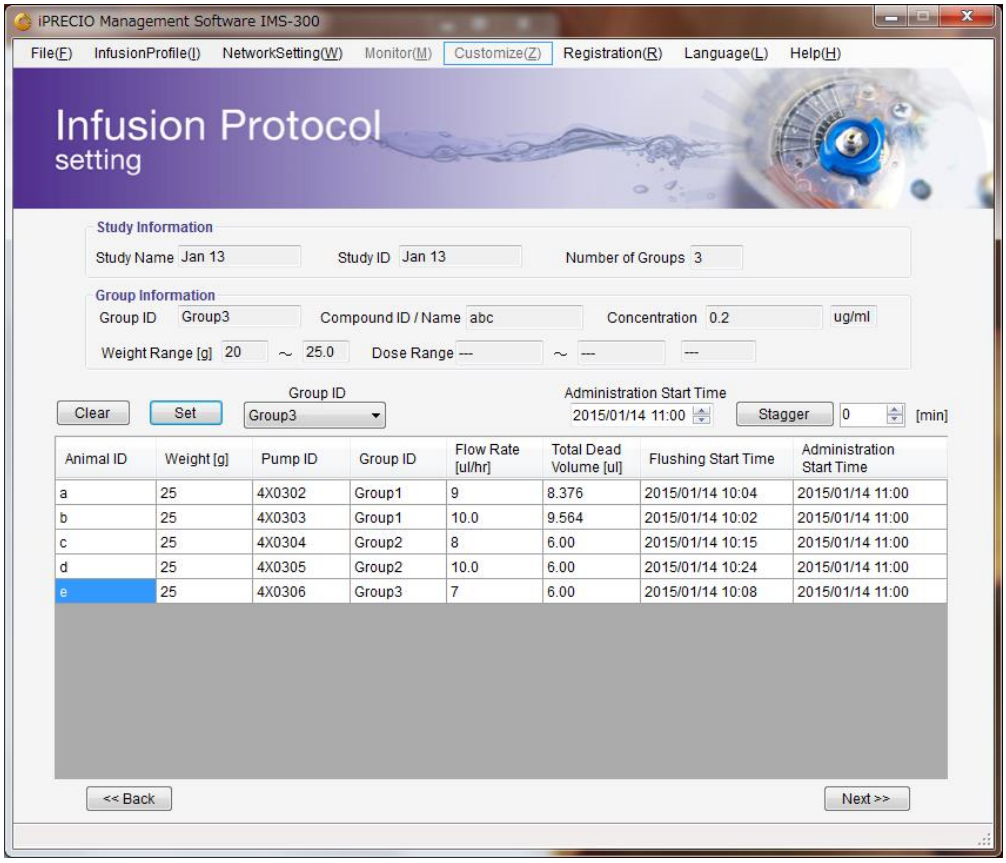
- Please calculate the dead volume using <Dead Volume Setting> in application software or excel file <Dead Volume Setting.xls> which is included in installation CD.

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.

Infusion Protocol setting

Following KVO function (if used), click <Next>. If KVO function not used, click **<Infusion Protocol>** to skip KVO function and dead volume flushing options.

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 <Flushing Start Time>**. If **<Flushing Start Time>** is missed the **<Administration Start Time>** will also be missed.
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.



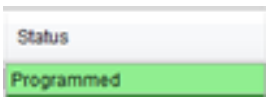
4. If stagger is required, click **<Stagger>**, the administration will be staggered from set time with that value.
5. If the proper infusion group name does not found, then create new one. Please refer "Create Infusion Profile".
6. After all animal are assigned to profile group, flushing rate and Administration Start Time, click <**Next>**.
7. Make sure that there is sufficient time to program the pumps. **If the pumps are not programmed before the <Flushing 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 Light Blue or Dark Blue. See next section and Appendix F.**

Start Infusion Protocol

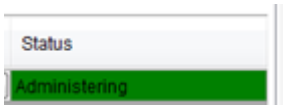
See Table on Page 13 for Detect and Programming Time Guidance to allow sufficient time to program the pumps. If insufficient time is given, infusion profiles may start with a delay and the only way to correct for this is to abort and re-start the study.

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, <Administrating> is shown in green.
   *To confirm if the pumps work correctly, check the color of the box which states Administrating. When <Administrating (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 communication availability setting not fixed. If the pump was not programmed in time and started after the <Start Time>, the pump status will be shown as <Administrating (Delay)> in blue. Pumps may be implanted when pump status shows <Administrating (Green)>

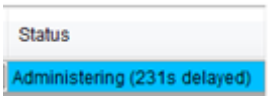
*Red ⇒ Yellow ⇒ light Green ⇒ Dark Green (Green)



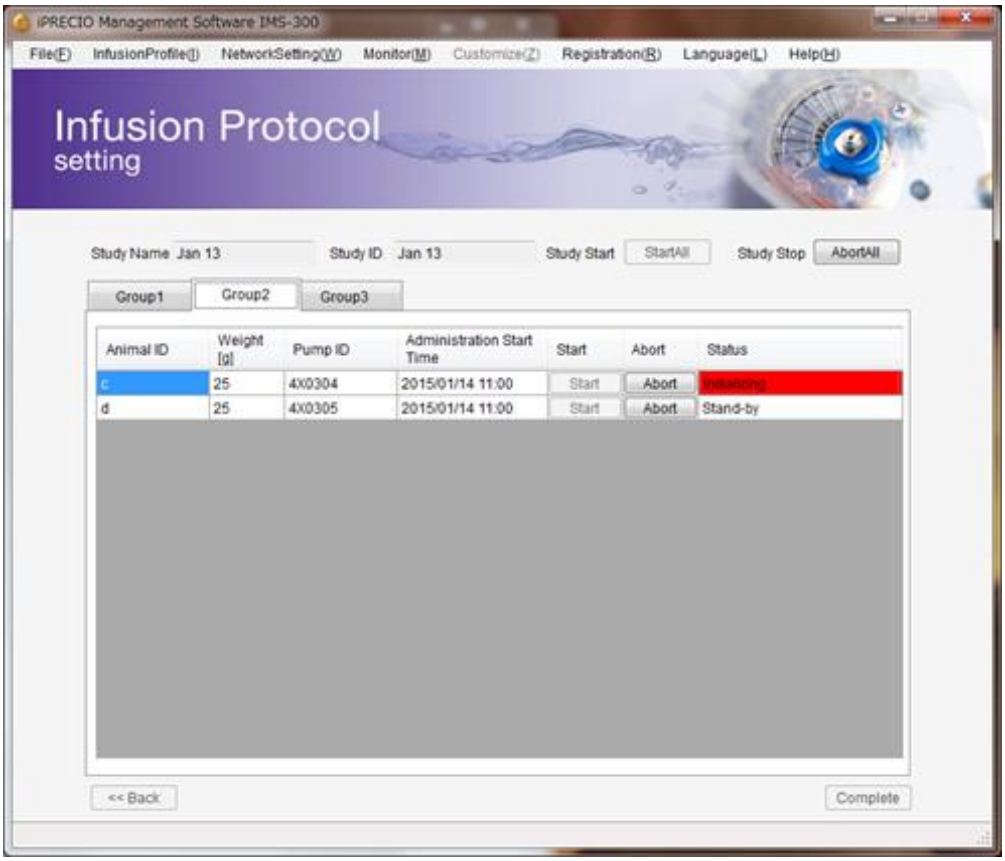
Light green



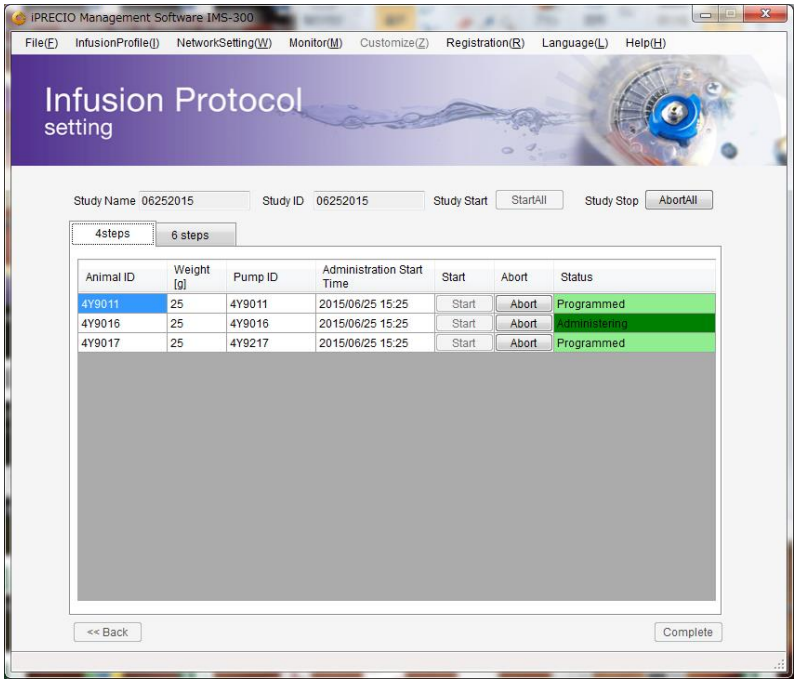
Dark Green (Green)



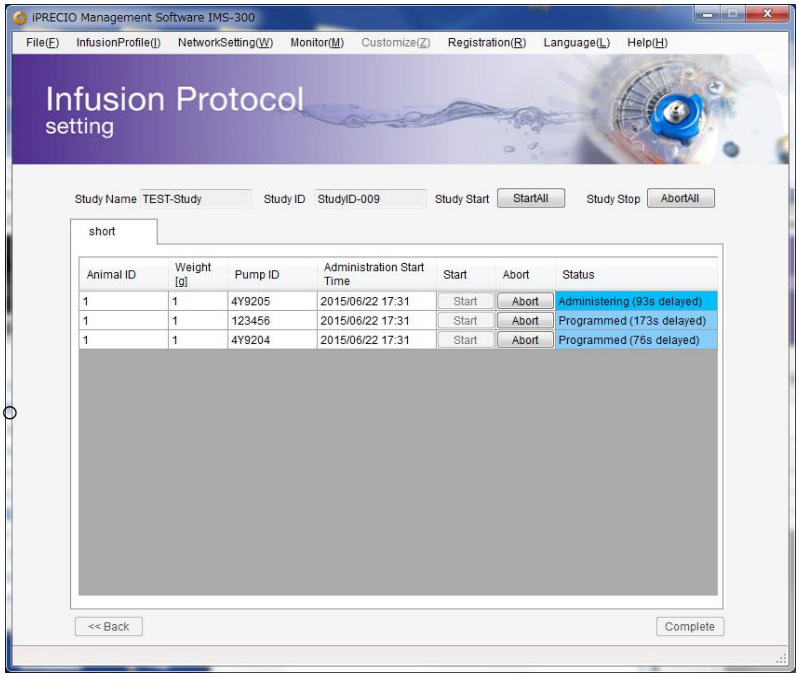
Dark Blue (Blue)



Red indicating that UCD-300 is being initialized for that pump



- Light Green <Programmed> - Pumps will start infusing as programmed with <Communication Availability> not finalized yet.
- Dark Green (Green) <Administrating> Pumps will start infusing as programmed with <Communication Availability> finalized.



- Dark Blue (Blue) <Administrating> - Pumps started infusing with delay with <Communication Availability> finalized. (top row)
- Light Blue <Programmed> - Pumps started infusing with delay with <Communication Availability> not finalized yet. (2nd and 3rd row)
- The only way to correct for the delayed pumps (blue) would be to Abort the full study and re-start the study with sufficient programming times.

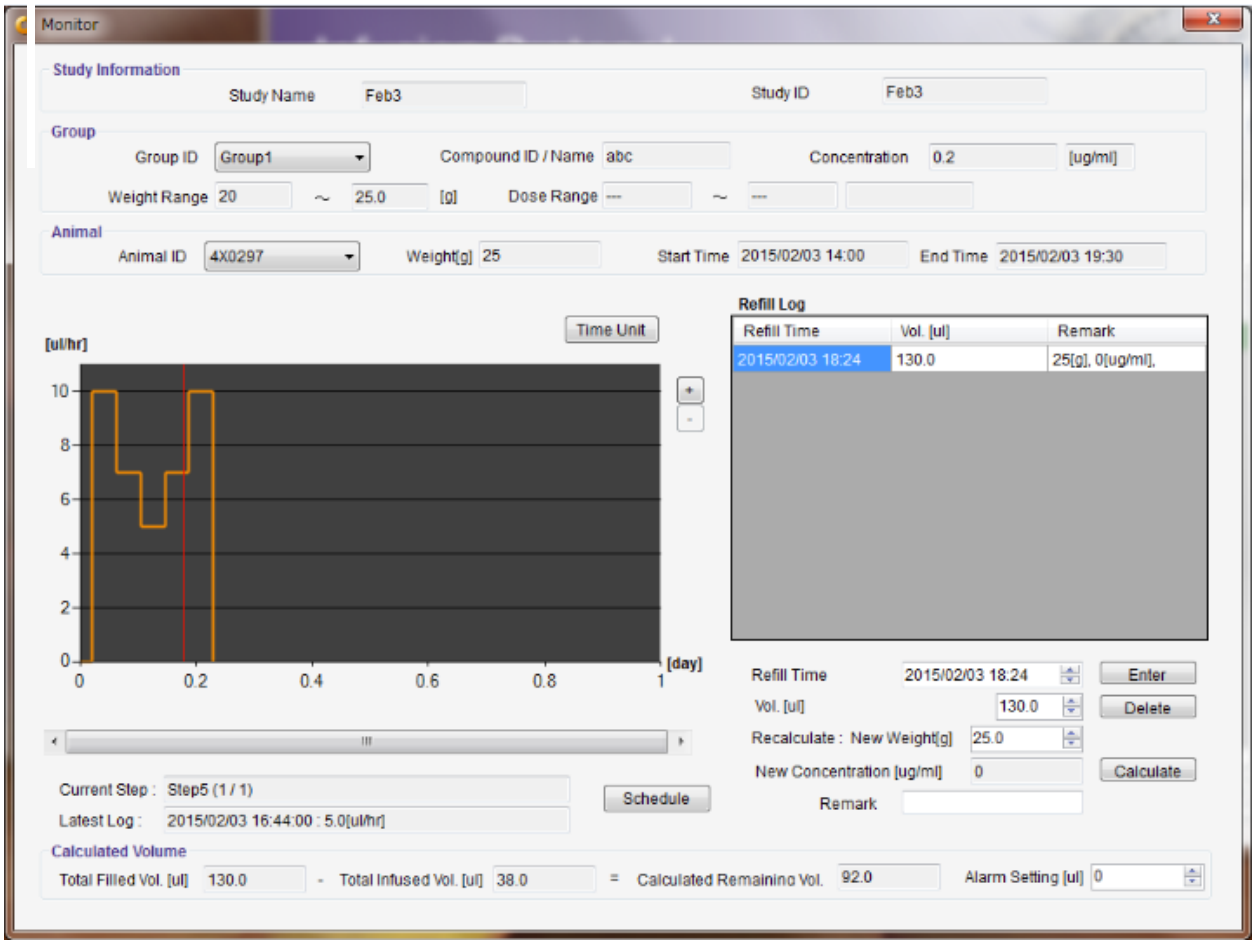
For advanced and more detailed feedback on pump status see Appendix G.

If the Application is closed, PC is switched off, sleeps, LAN disconnected or power supply to UCD-300 Management System is lost, the Application software cannot recover to monitor study status. Pumps will continue to infuse as programmed.

List of Active IMS-300 commands are listed/summarized in Appendix A.

Monitor the pump status

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



Actual logs from pump(s) being monitored are shown in **Latest Log <2015/02/03 16:44 : 5.0(ul/hr)>**. Receipt of the logs from the pumps is dependent on Infusion Profile, communication availability and wireless environment. **Current Step** <Step 5(1/1) 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 **refill time** and **volume**, then click <Calculate> and <Enter> button. For details, refer to <Replace and/or refill drug solution>. (Next Section)

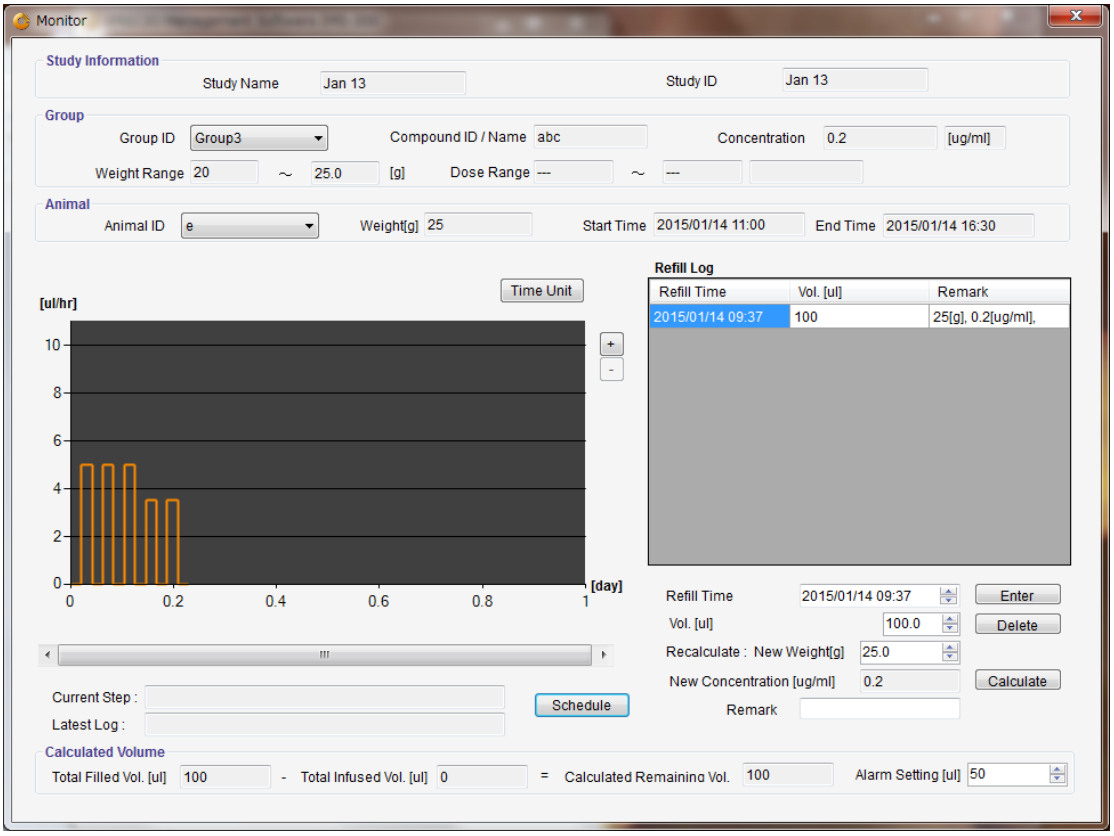
The estimated remaining volume is calculated from the infusion profile/schedule, elapsed time based on the PC clock and Total Filled Volume. The software alarm will appear when the calculated volume reaches the Alarm Setting volume.

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-300 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. Input **Refill Time** and **Volume**, click <**Calculate**> and <**Enter>** button. If required, refill with higher concentration drug to compensate for new weight. Calculator helps to calculate drug concentration to maintain dose at the same level.



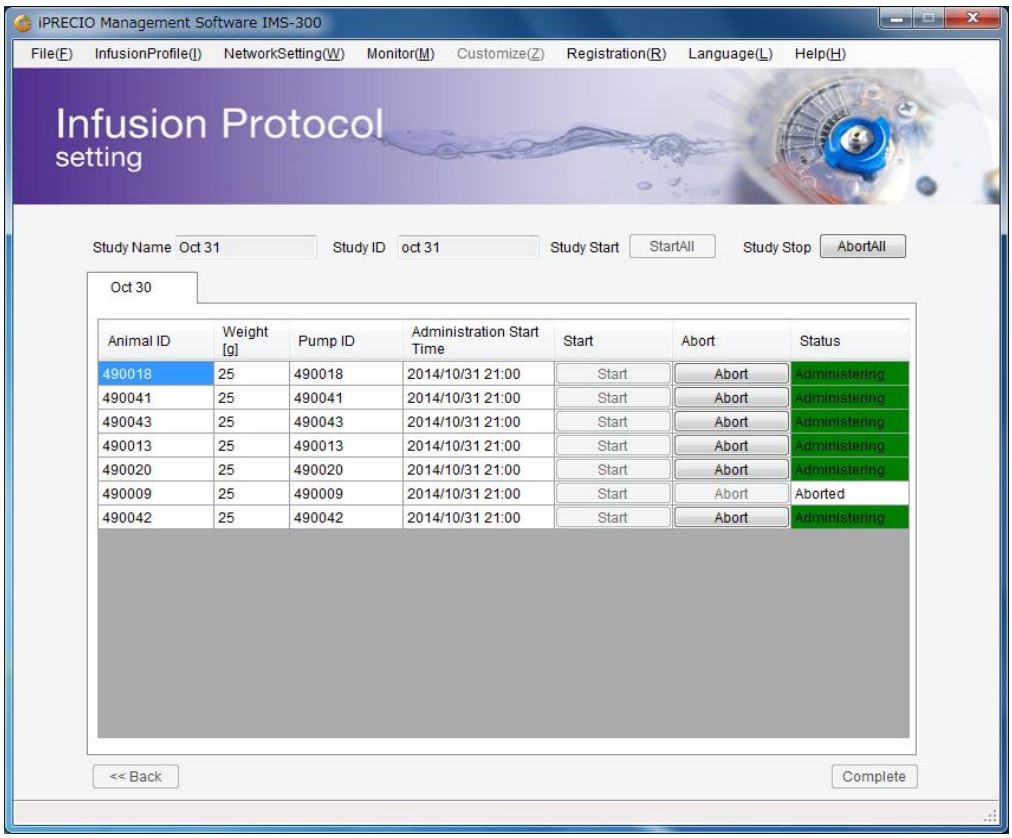
6. After logging the Refill Log with <Enter>, the table records automatically the Refill time, volume and comments (weight and density etc). To remove the refill log, select target refill log and click <**Delete**> button.

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 <**Study End**>, Data from the study are automatically saved. If the study needs to be cancelled before the end, click <**Abort All>** then click <Study End>. Make sure <Study End> is clicked before closing software to save all data collected.



Save Study File

1. Click Save Study from the **File (F)** in menu bar. The data file stored in C:¥Users¥XXX¥AppData¥Local¥iPRECIO¥study
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.

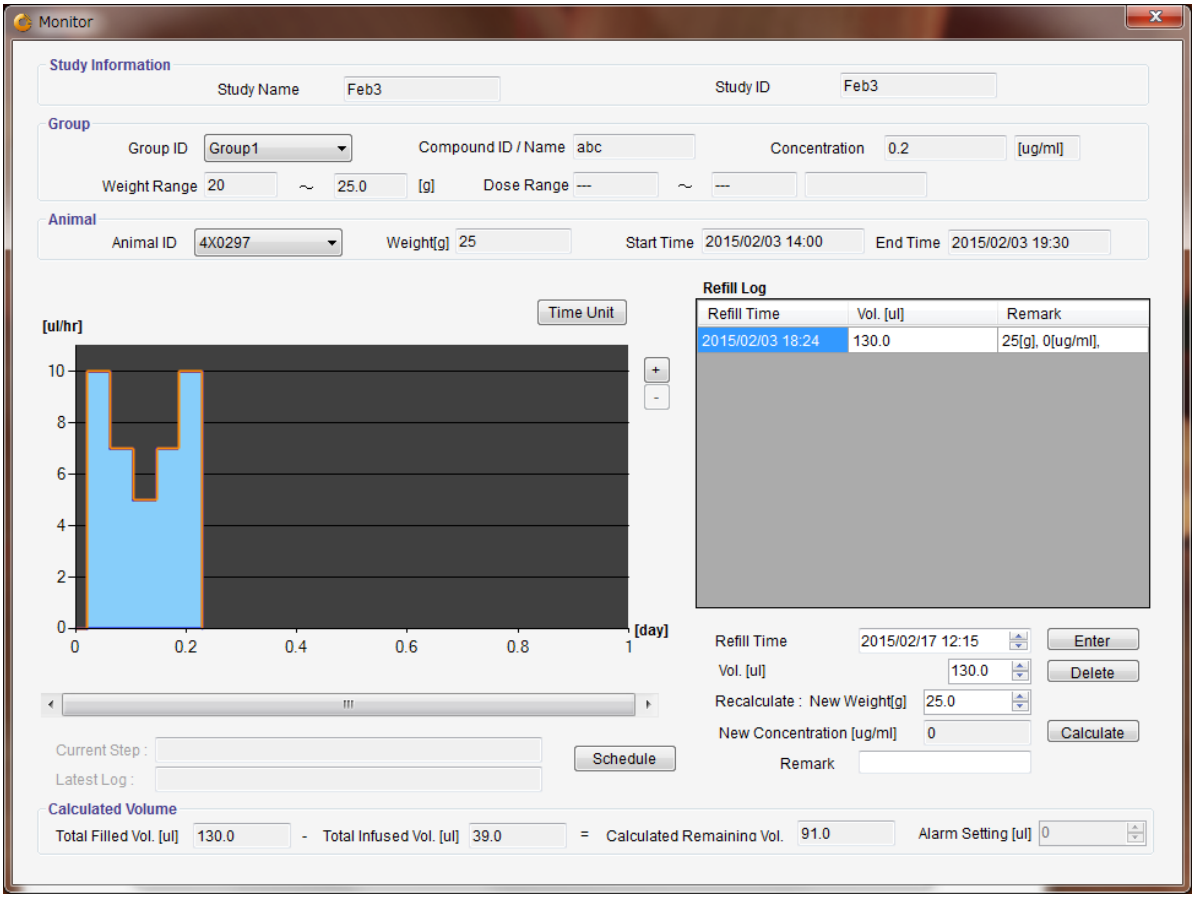
1. Chose <Export> from the **File (F)** in menu bar.
2. Select folder to export, save with file name.
3. The exported data format is "csv". To view the data, simply import it by regular spreadsheet program. This file contains all the information and logs from the completed study.

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>.

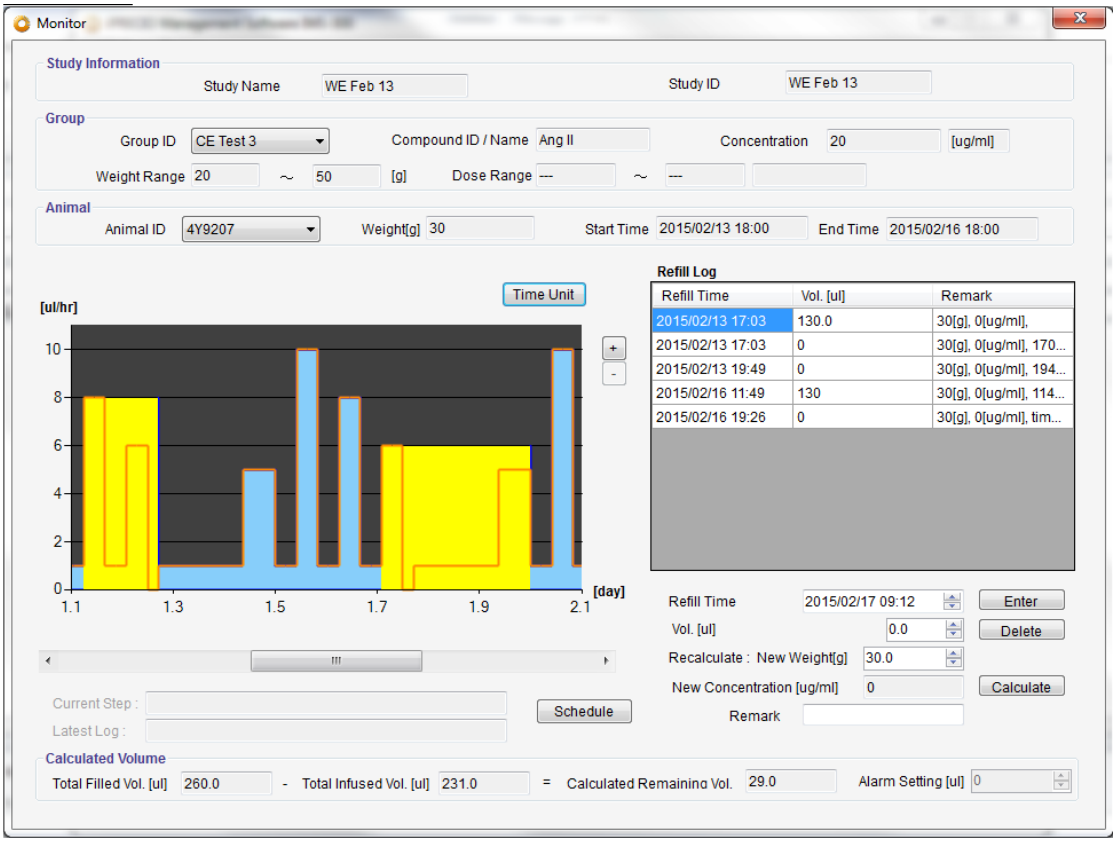
How to check if all the pumps log data were collected

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.



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 2 yellow boxes signifies missing data in between received logs (blue)

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-300 and Application software.

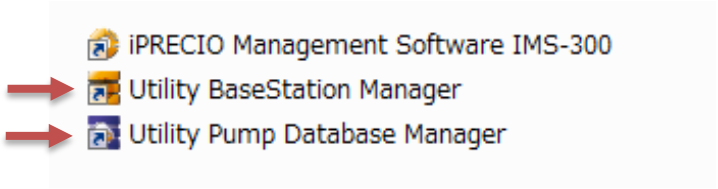


How to Re-Program a Pump

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.

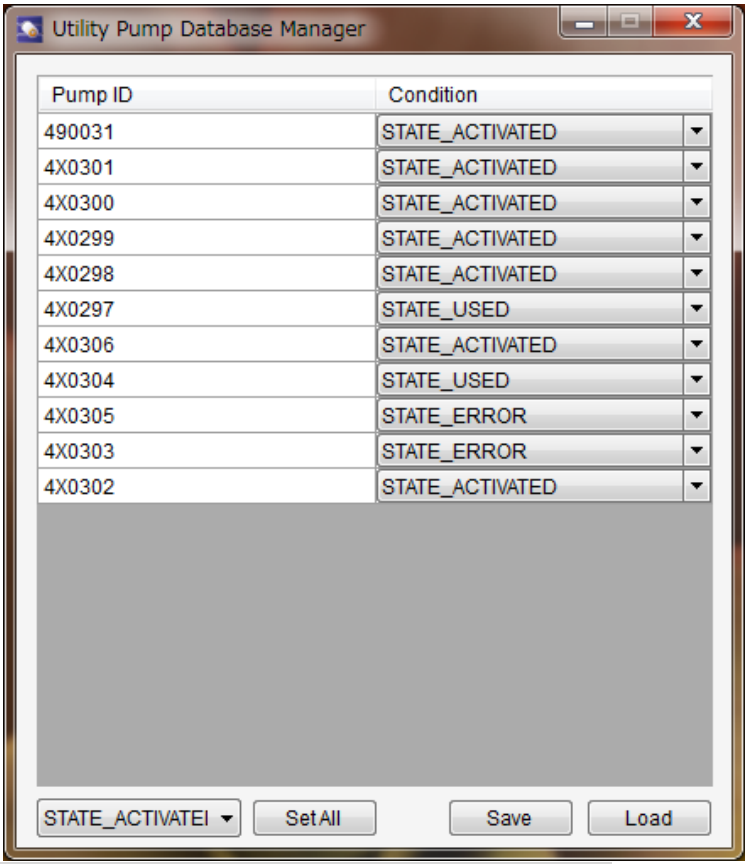


Change Pump Condition/ Status

1. Open Utility Pump Database Manager and select **<Load>** to check the pump status.
2. Chose **<STATE_ACTIVATED>** from the pull down menu in the Condition column. ***You cannot re-detect the pump until you change the pump status to activated.***
3. Select the **<Save>** and close the window.
4. Now it is possible to detect the pump and re-program at **<study settings>** step.

CONDITION	Details
STATE_NEW	Pump may be programmed
STATE_ACTIVATED	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

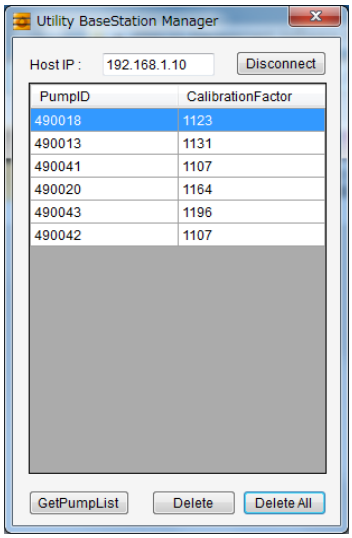
Summary of Pump Condition in Utility Database Manager



<Recommended Procedure for re-using the pumps>

1. Open Utility Pump BaseStation Manager 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-300, 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 Manager> and <Utility Pump Database Manager> software applications which are used to confirm status of pumps which are being used.

Utility BaseStation Manager

- Will contain details of all pumps which have been detected by the management system unless they have been deleted.
- When detecting pumps using IMS-300 Management Application, pumps which are New or Activated will be called by the management system.
  - 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-300) will assign time to communicate with these pumps and will cause large delays to the pump programming process.

Utility Pump Database Manager

- Keeps track of status of all pumps. (used and being used) Management system would communicate to connect with Pumps which are New and Activated.
- Pumps which are labelled USED and ERROR will not be used or detected by IMS-300 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 ACTIVATED.

Product Specifications

Micro infusion pump for small laboratory animal iPRECIO® (Model:SMP-300)

Administration method	Rotary finger type (Patented: Peristaltic mechanism)
Reservoir	130μL Built-in reservoir: (Material) Medical grade SIBS ※The Maximum capacity is 130μL. ±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, L>130mm ※Outer tube is detachable.
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: 916.15 MHz – North America CE: 864.35 MHz - Europe Com unit : Within 1 m from UCD-300
Antenna	Wire antenna with pump (L: ca. 50mm) ※Coating by Polyurethane(1.2Fr) Titanium wire(φ0.1mm)
Programmable Flow Rate (FR)	0.0~10.0μL/hr. (setting resolution:0.1μL/hr.) * Discharge flow by 360 degree roll of cam:3.4μL
Infusion accuracy	±5% (Under pressure 0~80cmH_2O)
Battery Life	Continuous motion FR 0.1μL/hr.: 16.7 days, FR 10.0μL/hr.: 1 week with communications availability every minute.
Power on Activation	By pressing down the power switch at the bottom of pump to pump start. (Co-instantaneously activated) ※Once activated, not reversible to switch off.
Size	24.8(L) × 15.0(W) × 7.2 (H) mm (Except accompanying catheter and wire antenna)
Weight	3.3g (Include accompanying catheter and wire antenna)
Solid content	2.15cc
Type of usage	Disposable
Package	EOG Pre-Sterilization pack (5 package/box)
Sterilization	2 years from manufacturing

Data com unit (Model UCD-300)

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: 916.15 MHz – North America CE: 864.35 MHz – Europe ※Not broadband type. One –on one communication between Data com unit and individual pumps.
Number of pumps per unit	20~25
Power source	AC adapter cable included. [Weight] 73g [Cable length] 1.85m [I/P] 100-240V 50/60Hz 25VA · [O/P] DC 5V 2A
Size and Weight	120(L) × 77 (W) × 31(H) mm · 167g
STD accessory	LAN cable with ferrite core (3m) × 1 cable

Management software

Supported OS	Windows XP · Windows 7, 8, 8.1 (32bit and 64 bit) Japanese · English with major PC manufacturers

Appendix A: Table of Commands

List of the active commands for IMS-300 software; their (1) Actions (2) Limitations and (3) Comments summarized.

	Action	Limitations	Comments/ Recommendations
Detect	Continue to search for the number of pumps entered until found.	If pump not found, will continue until cancelled	
KVO <Start All>	Will attempt to start all pumps across all groups. Positive confirmation in Application software and in Exported logs.	Pump needs to be active and available for communication	
KVO <Abort All>	Will attempt to abort all pumps across all groups. No positive confirmation in Application software.	Pumps and management system needs to be available for communication	
KVO <Abort> individually	Will attempt to abort selected pump(s). 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-300 will send the abort signal until unplugged.
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.

	Action	Limitations	Comments/ Recommendations
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-300 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-300 will send the abort signal until unplugged.
Export	Exports Study information and log data. May be used anytime during the study to obtain detailed logs and have a permanent record.	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. See Appendix E, page 59 Each pump can only store 28 logs and they will be overwritten if not downloaded/collected by UCD-300/Application Software	Logs usually available immediately after event completed but dependent on communication availability and wireless environment.

Appendix B: Modify the IP address of Data Communication Device

Factory Default Network Settings

Factory Default Settings of UCD-300 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-300

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

1. Connect the UCD-300 to the management PC and plug AC adapter to turn on.
2. Input the IP address of UCD-300 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 -300 is Working Correctly

Green Light On: UCD-300 is correctly plugged with power supply
Green Light Off: UCD-300 is not plugged correctly or UCD-300 is not working

Orange Light On: If the orange light is on for more than 5 mins, the UCD-300 is not working properly. It will be necessary to reset the UCD-300

Press and hold the Reset Button while re-plugging the AC adapter to turn on the management system. Continue to hold the Reset Button for 30s to start the Reset Procedure.

Orange Light Off: UCD-300 received no signals from PC/application software
Orange Light Blinking: UCD-300 is communicating with PC and pumps. This includes, sending KVO/Study schedule to the pumps, collecting the logs from pumps, sending the logs to PC/application software.
Orange Light on for 2-3 seconds then turn-off: This is normal or the expected operation. Basically, "resetting the polling command"

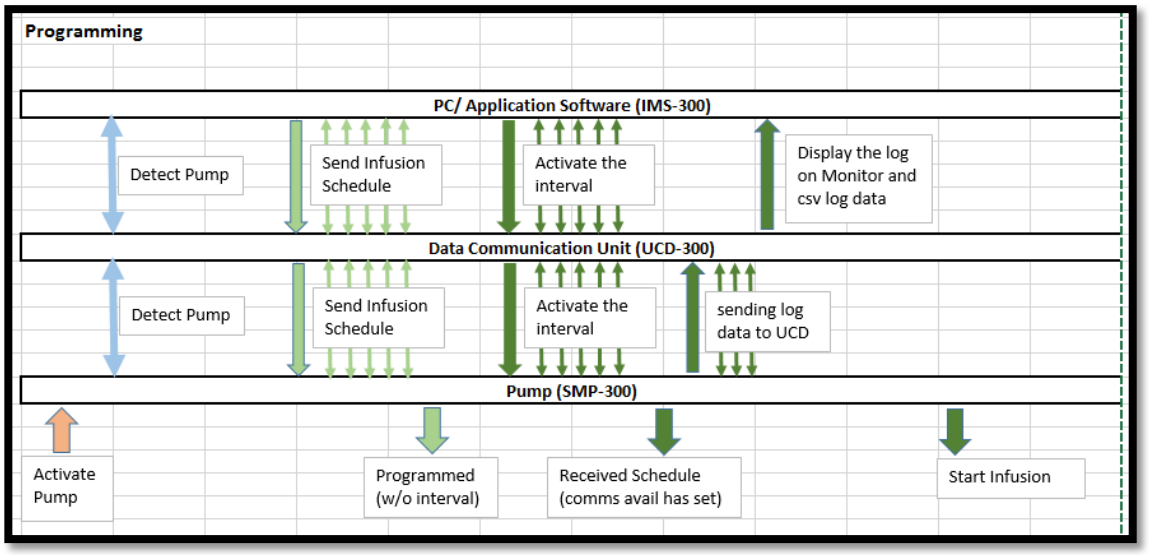
Appendix D: Communication Availability

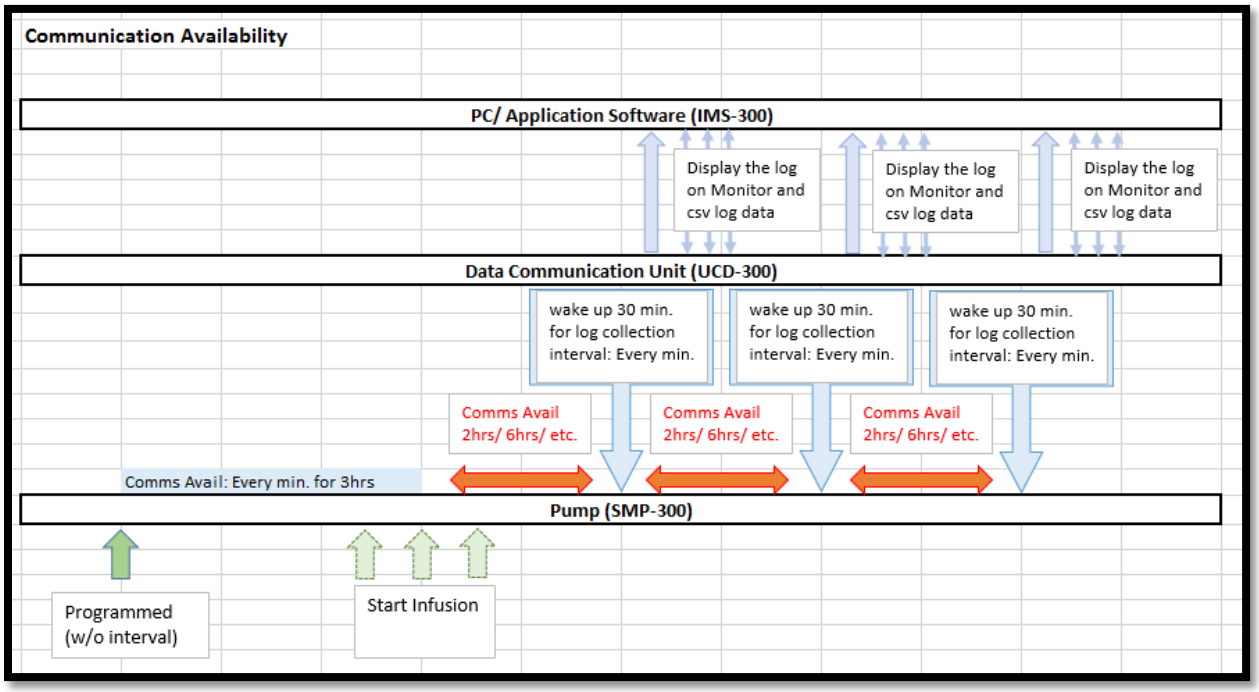
Communication Availability <Comms Avail.>:

The figure below shows how Communication Availability works for programming and logs. Programming includes detecting, KVO, Flushing, Administrating, Abort etc.

- 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 less responsive but significant battery life is saved. See table on page 12. For example, for 0.1 uL/hr with every minute <Comms Avail>, only 403 hours (16.8 days) of battery life available. For 24 hours <Comms Avail>, 1104 hours (46 days) Basically 2.7 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 2 hours>, <Every 6 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. 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.**

iPRECIO SMP-300 pumps has internal memory to hold a maximum of 28 logs.
If an <Infusion Profile/Group ID> will create more than 28 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.

- If KVO is used, 4 logs will be created
  - Timestamp : Received a Schedule (Pump programmed with KVO)
  - Timestamp: KVO flow-rate (start)
  - Timestamp: KVO Complete
  - Timestamp: KVO Finished
- For Administration following KVO, a dead volume flushing step will precede the <Start Administration> step
  - Timestamp : Received a Schedule

- Timestamp: Dead volume flushing flow-rate
- 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 that step.
2. The log before the aborted step will not be available also.
3. 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.**

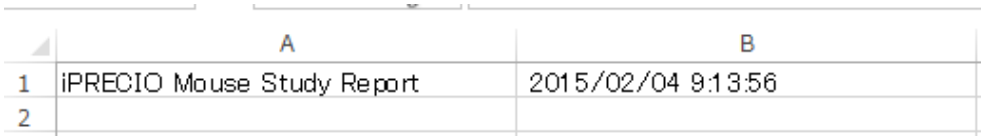
An example of log data file is provided in the installation CD. Refer to the exported log data as necessary ("Sample Log Data").

◆ 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)



	A	B
1	iPRECIO Mouse Study Report	2015/02/04 9:13:56
2		

<<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)

3	<<Basic Infomation>>	
4	Institution Name	Primetech
5	Department Name	International
6	Study Name	Feb3
7	Study ID	Feb3
8	Study Date	2015/02/03 10:02:22
9	User Name	Ikuko
10	Number of Groups	6
11	Total Number of Animals	8
12	KVO : Flow Rate[ul/hr]	0.1
13	KVO : Duration[hr(s)]	0.5
14	Remark	

<Group Information>>

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

Ex)

16		
17	<<Group Information>>	
18	Group ID	Group1
19	Compound ID / Name	abc
20	Consentration[ug/ml]	0.2
21	Weight Range[g]	20-25.0

<Animal Information>

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

Ex)

22				
23	<Animal Information>			
24	Animal ID	4X0297	4X0298	
25	Group ID	Group1	Group1	
26	Weight[g]	25		25
27	Sex	Male	Male	
28	Age[week(s)]	8		8
29	Species	mouse	mouse	
30	Strain	b6	b6	
31	Administration Route	ip	ip	
32	PumpID	4X0297	4X0298	
33	Cal. Factor	1090		1139
34	Start Date/Time	2015/02/03 14:00	2015/02/03 14:00	
35	End Date/Time	2015/02/03 19:30	2015/02/03 19:30	

<Infusion Schedule>

In this section the study profile is recorded.
Step 1 to 15 is the maximum. Example shows steps 1 to 6. No repeat functions is used. Repeat function is used in Group 2. Refer to the whole log data in the installation CD. Repeat times is shown in brackets () next to step number.
For example below, step 2 to 5 repeated 3 times.
2(3)
3(3)
4(3)

Ex)

36				
37	<Infusion Schedule>			
38	Program No./ Repeat Times (n)	1 (1)		1 (1)	
39	Step1 : Flow Rate[ul/hr]		0		0
40	: Duration[hr(s)]		0.5		0.5
41	: Doses[ug/kg/hr]		0		0
42	Program No./ Repeat Times (n)	2 (1)		2 (1)	
43	Step2 : Flow Rate[ul/hr]		10		10
44	: Duration[hr(s)]		1		1
45	: Doses[ug/kg/hr]		0.08		0.08
46	Program No./ Repeat Times (n)	3 (1)		3 (1)	
47	Step3 : Flow Rate[ul/hr]		7		7
48	: Duration[hr(s)]		1		1
49	: Doses[ug/kg/hr]		0.06		0.06
50	Program No./ Repeat Times (n)	4 (1)		4 (1)	
51	Step4 : Flow Rate[ul/hr]		5		5
52	: Duration[hr(s)]		1		1
53	: Doses[ug/kg/hr]		0.04		0.04
54	Program No./ Repeat Times (n)	5 (1)		5 (1)	
55	Step5 : Flow Rate[ul/hr]		7		7
56	: Duration[hr(s)]		1		1
57	: Doses[ug/kg/hr]		0.06		0.06
58	Program No./ Repeat Times (n)	6 (1)		6 (1)	
59	Step6 : Flow Rate[ul/hr]		10		10
60	: Duration[hr(s)]		1		1
61	: Doses[ug/kg/hr]		0.08		0.08

<KVO>

In this section, actual KVO start/ end time and calculated dead volume and flushing duration etc. There is no information about KVO flow rate in here, details are in <Basic Information> or <KVO log> section.

Ex)

62				
63	<KVO>			
64	KVO Start Date/Time	2015/02/03 10:21		2015/02/03 10:13	
65	KVO Duration[hr(s)]		0.5		0.5
66	KVO Stop Date/Time	2015/02/03 10:51		2015/02/03 10:43	
67	Flushing Flow Rate[ul/hr]		10		10
68	Flushing Duration[min]		65		65
69	Dead Volume[ul]		10.752		10.752

<Infusion Log>

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

Ex)

70			
71	<Infusion Log>		
72	TimeStamp : PumpLogData	2015/02/03 13:09:23 : Received a S	2015/02/03 13:09:45 : Received a Schedule
73			
74		2015/02/03 13:09:29 : 10.0[ul/hr]	2015/02/03 13:09:52 : 10.0[ul/hr]
75		2015/02/03 14:14:00 : 0.0[ul/hr]	2015/02/03 14:14:22 : 0.0[ul/hr]
76		2015/02/03 14:44:00 : 10.0[ul/hr]	2015/02/03 14:44:22 : 10.0[ul/hr]
77		2015/02/03 15:44:00 : 7.0[ul/hr]	2015/02/03 15:44:22 : 7.0[ul/hr]
78		2015/02/03 16:44:00 : 5.0[ul/hr]	2015/02/03 16:44:22 : 5.0[ul/hr]
79		2015/02/03 17:44:00 : 7.0[ul/hr]	2015/02/03 17:44:22 : 7.0[ul/hr]
80		2015/02/03 18:44:00 : 10.0[ul/hr]	2015/02/03 18:44:22 : 10.0[ul/hr]
81		2015/02/03 19:44:00 : Complete	2015/02/03 19:44:22 : Complete
82		2015/02/03 19:44:00 : Finished	2015/02/03 19:44:22 : Finished

<2015/02/03 13:09:23 : Received a Schedule>
When pump programmed

<2015/02/03 13:09:29 : 10.0[ul/hr]
Pump started at 2015/02/03 13:09:29 with a flow-rate of 10ul/hour

<2015/02/03 14:14:00 : 0.0[ul/hr]
Pump stopped infusion at 10ul/hour at this time and started with a flow-rate of 0.0ul/hour

<2015/02/03 14:44:00 : 10.0[ul/hr]
Pump stopped infusion at 0ul/hour at this time and started with a flow-rate of 10.0ul/hour.

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.

Ex)

86		
87	<Infusion Refil Log>	
88	TimeStamp : RefillVol[ul] : NewWeight	2015/02/03 18:24 : 130.0 : 25 : 0 :
89		

<KVO Log>
In this section, the exact time of KVO start/ end and KVO flow-rate are recorded. Same nomenclature as <Infusion Log>

Ex)

89			
90	<KVO Log>		
91	TimeStamp : PumpLogData	2015/02/03 10:21:39 : Received a S	2015/02/03 10:13:47 : Received a Schedule
92			
93		2015/02/03 10:21:47 : 0.1 [ul/hr]	2015/02/03 10:13:53 : 0.1 [ul/hr]
94		2015/02/03 10:51:46 : Complete	2015/02/03 10:43:53 : Complete
95		2015/02/03 10:51:46 : Finished	2015/02/03 10:43:53 : Finished

<KVO Refill Log>
In this section, refill logs during KVO are recorded. If data not filled during study, in the application software, no data will be available.

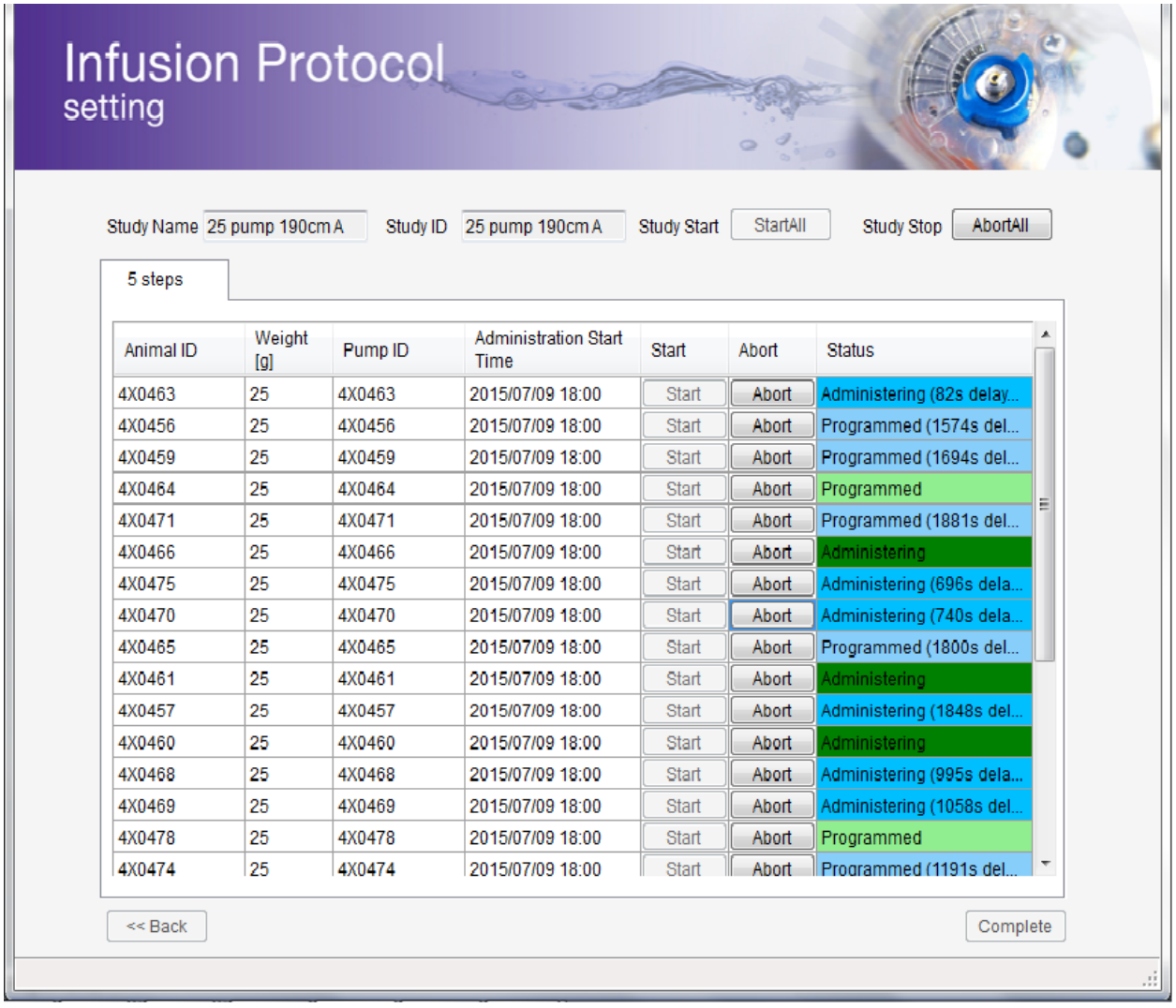
Ex)

96			
97	<KVO Refil Log>		
98	TimeStamp : RefillVol[ul] : NewWeight	2015/02/03 10:11 : 100 : 25 : 0 :	2015/02/03 10:11 : 110 : 25 : 0 :

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

Detailed explanation in Appendix G for advanced users.

Pump Status	Brief Details
Programmed *Light Green*	Pumps(s) will start as programmed but awaiting positive confirmation for <Communication Availability> programming
Administrating *Dark Green (Green)*	Pump(s) may be implanted
Programmed *Light Blue*	Pump(s) will start with delay respect to programmed start time but awaiting positive confirmation for <Communication Availability> programming
Administrating *Dark Blue (Blue)*	Pump(s) will start with delay respect to programmed start time



Appendix G: Detailed Pump Status

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 or finished on time** **if <Communication Availability> not set, study may finish early due to lack of battery.**	At start time, pump will start as programmed but no positive confirmation from <Received a schedule> Even if pump started and in absence of <Received a schedule>, Status will show as programmed <Communication availability> may have been confirmed but no positive feedback yet. *After 24 hours, UCD-300 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. Pumps may be administrating but not sure of exact status of <communication availability interval> and therefore battery life*

Pump Status	During Programming	Towards the end of Infusion Duration	Detailed Explanation
Programmed (xx delay with respect to programmed start time) *Light Blue*	**Will start with a delay or started with delay**	**Pumps will finish after study duration completed or finished after study duration completed** **if <Communication Availability> not set, study may finish early due to lack of battery.**	Within 1-2 minutes of being programmed, pump will start but no positive confirmation from <Received a schedule> Even if pump started and in absence of <Received a schedule>, Status will show as programmed <Communication availability> may have been confirmed but no positive feedback yet. After 24 hours, UCD-300 will stop calling these pumps. Therefore it is, no longer possible to collect logs and status will no longer change. Pump may be administrating but not sure of exact status of <communication availability interval> and therefore battery life
Administrating *Dark Green (green)*	**Pumps will start on time or started on time**	**Pumps will finish on time or finished on time**	Dark green means <communication availability> confirmed. <Received a schedule> received. Pump will finish on time but positive confirmation for <Finished> may be delayed in Application Software due to delay of receipt of <Finished> from pump due to wireless interferences etc. If <Received a schedule> received before start time, Status will show as <Administrating> even though pumps have not started administrating / infusing yet.

Pump Status	During Programming	Towards the end of Infusion Duration	Detailed Explanation
Administrating (xx delay with respect to programmed start time) *dark blue(blue)*	**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**	Dark blue means <communication availability> confirmed. <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.

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