

RIGGTEK



2011

RIGGTEK

The Evolution in Dissolution Testing

aktuelle Information 08/2011

DissoPrep X8
häufig gestellte Fragen (FAQ)

RIGGTEK



*Sie haben weiterführende Fragen über
unsere Mediumtankstelle DissoPrep X8?*

*... die FAQ's beantworten die häufigsten
Fragen! Natürlich stehen auch wir Ihnen
immer gerne zur Verfügung!*



DISSOPREP X8 FAQ 's

ID 20100927 REV 3

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The FAQ´s should give you a short summarize of the most often asked questions concerning the DissoPrep X8. This list not exhaustive. If you have further questions, we are available by phone or email service@riggtek.de .

I Questions concerning the investment of the DissoPrep X8:

I.1 What is the main advantage of the DissoPrep X8 in comparison with its competitors? (gravimetric principle)

The main advantage of the DissoPrep X8 is, that he uses as unique feature the gravimetric principle for mixing and dispensing the media. That means, that the DPX8 weighs the inlet media and the additive for mixing, and he weighs the outlet media at dispensing. So the DPX8 fulfills the USP requirements for the media preparation and achieves absolute precise results for all kinds of media.

Measuring the weight for mixing and dispensing a media is the only correct way, because different media have different volumes at different temperatures and pressures. Only the weight of a liquid is not changing when warming it or changing the pressure! According the USP, the wished volume is to dispense at standard condition - this is 25°C – and then afterwards the liquid has to be heated up. So in accordance with the USP e.g. 900ml dispensed at 37°C into a vessel weigh 897,4g, what is the mass of 900ml at 25°C!

So it would be wrong to measure warm media in a volumetric flask or device calibrated at 20°C. And it would be also wrong to use the specific weight (density) for gravimetric volume measuring of the media at e.g. 37°C. With this gravimetric principle a calibration of the DPX8 for each media and each temperature is NOT necessary!

Further information concerning the correct media preparation (incl. degassing) you will find in the RIGGTEK article “The correct Media Preparation” on our webpage www.riggtek.de → products → DissoPrep X8 → Information.

I.2 What are the further advantages of the DissoPrep X8?

- precise and repeatable mixing of the media: Mixing Accuracy < 0,5% of ratio 1:3 to 1:100, typically 0,2%, monitored
- precise and fast dispensing of the media directly into the vessels: Dosing Accuracy < 1% at 500-8.000g, typically 2g; 8L of dissolution media is ready in *less than 15 minutes* (12 minutes with prepared media without mixing), Dispensing Rate 2L/min, total Throughput: 24-32L/h
- timesaving warming of the media: Preheating 20 – 45°C
- degassing of the media with high efficiency and low costs : measured after dispensing into the vessels typ. 3 - 5ppm O₂ , degassing with vacuum
- documentation of the media preparation: All internal dosage processes are accurately controlled and monitored by a Precision Load Cell. The individual dosage processes are documented and can be printed on an external printer or administrated with PC (Option: RC Software). After each DISPENSE cycle the DissoPrep X8 provides a “DISPENSE Protocol” containing the weights, the mixing ratio, the vacuum and the temperature. Also a “CALIBRATION Protocol” is provided.

- USP, EP, FDA, GLP/GMP conformity: DissoPrep X8 fulfills all requirements of the media preparation according to the demanded rules of the USP and EP, as well as according to the recommendations of the FDA and of the GLP/GMP
- Reproducibility of the results: Reproducibility of the test results is independently of the operators (a result of the automation of the media preparation).
- Safety in the Laboratory: By automating the process - particularly the acid preparation and media dispensing - the risk to laboratory personnel is minimized
- easy handling: The user-interface of the DissoPrep X8 is quite simple with only a few buttons. The Remote Control Nozzle simplify the dispensing into the vessels.
- space saving: The dimensions of the DissoPrep X8 are W 30cm x H 66cm x D 59cm quite compact to fit in every lab.
- Simplification of administrative documentation: With the optional available Remote Control Software all methods can be administrated and all protocols which are generated with the DissoPrep X8 can be transmitted in a PC network "21CFR Part 11 compliant".
- Further information you will find in the „DPX8 Additional Information Sheet“, all chapters are separately available on our webpage www.riggtek.de → products → DissoPrep X8 → Information.

1.3 How fast is the amortization of the DPX8 investment?

The saving of time is considerable. DissoPrep X8 prepares up to 8L of dissolution media automated in less than 15 minutes (12 minutes with prepared media). The fast and precise dosage by a tube into the individual vessels (~25 seconds for 900ml) saves time-consuming handling steps. The preheated media saves up to 45 minutes for media heating with a conventional water bath dissolution tester.

If you calculate with:

- 180€ full costs of a manual test (135€ labor costs for at least 1,5h manual work + 15€ consumables to prepare the media + 30€ raw material for the media),
- 30€ costs of a test with the DissoPrep X8 (30€ raw material for the media) and
- an investment of 14.544,05€ for a DPX8,

the ROI will already be reached after 90 tests!

Further information you will find in the „DPX8 Additional Information Sheet“, chapter “Profitability Analysis of DPX8” available on our webpage www.riggtek.de → products → DissoPrep X8 → Information.

2 Questions concerning the specifications of the DissoPrep X8:

2.1 What is the meaning of a gravimetric dosing principle?

A gravimetric dosing principle means dosing “by weight” or “by mass”. For further information see question 1.1

2.2 Why is the volume of the tank only 8L? Is a bigger tank available?

The volume of 8L is sufficient to fill all vessels of one dissolution bath. It is not being the correct way to prepare media on stock, because the resaturation of gases happens very quickly. So the degassing would be useless, if the media is prepared on stock and not just “fresh” before use.

At the moment, a 15L tank is planned for year 2012. This tank is foreseen for those customers, who want to prepare always to dissolution baths at the same time with “fresh” media.

2.3 Why is the brutto - volume of the tank 11L? What does this mean?

For prefilling the unit (tubings and tank) an additional volume in tank is required as well as for mixing media in the right concentration. This is why the tank has an actual volume of 11L, but only 8L are for use.

2.4 Of which material is the tank?

The tank is build from PP (Polypropylen).

2.5 How big is the prefill-volume? How much DI-water is required for prefilling the unit?

The prefill – volume is 1.500mL. This volume is needed to prefill (filling tubings etc.) the unit.

2.6 How does the DissoPrep X8 degass the media?

The DissoPrep X8 degass the media with a vacuum typically < 100mbar pressure absolute. The vacuum is monitored.

2.7 What is the degassing efficiency of the DissoPrep X8?

The degassing efficiency of the DissoPrep X8 depends on

- the size of the vacuum
- the time the media is exposed to the vacuum
- the temperature of the media
- the mixing of the media

For a normal routine the interaction of heating, mixing and degassing generates an effective de-aeration of the medium e.g. for water with typically 3 - 5ppm end oxygen (measured after filling into the vessel).

Further information you will find in the „DPX8 Additional Information Sheet“, chapter “Dissolution Media Degassing Efficiency Investigation with DissoPrep X8”, available on our webpage www.riggtek.de → products → DissoPrep X8 → Information.

2.8 How is the DissoPrep X8 ensuring the mixing of the media?

The DissoPrep X8 is mixing the media with a magnetic stirrer continuously in the tank. The magnetic stirrer is functionally monitored to ensure a continuously mixing of the media.

2.9 How much media can the DissoPrep X8 prepare in one hour?

The throughput of DissoPrep X8 is 24 – 32 L/h, depending on the selected temperature, additional degassing time, mixing of additive and numbers of dispensed vessels. Throughput is in the meaning of preparing the media (sucking in the raw material, degassing, mixing, warming) and dispensing into the vessels. This is equal to 400-533 mL/min.

If the media is prepared and ready for dispensing, the dispensing rate is 2L/min. So typically a vessel with 900ml is filled in 25 sec.

2.10 Are there any restrictions for the DissoPrep X8 concerning the laboratory environment?

The DissoPrep X8 is prepared to work in an environment of 18 – 30°C and maximum 85% humidity.

3 Questions concerning the use of the DissoPrep X8:

3.1 Is it possible to use the DissoPrep X8 mobile, so that I can place it where I need it? Do I have to consider anything when moving the DissoPrep X8 from place to place?

The DissoPrep X8 can be used mobile (RIGGTEK offers a suitable cart – called LabCart – to place the DissoPrep X8 and all reservoirs etc. sure on it). But there are to consider some restrictions.

During PREFILL, FILL and DISPENSE, the DissoPrep X8 has to be placed on a stable base without any vibrations. And it is not allowed to move during these states. Otherwise the internal load-cell will be influenced and the mixing and dispensing results will be wrong.

Due to the power supply, it is not possible to move and disconnect the DissoPrep X8 from the power supply after state FILL. So it is not possible to prepare a media and then move the DissoPrep X8 to different baths. After disconnecting from the power supply during FILL or DISPENSE and switching it on again, the DissoPrep X8 will force you to EMPTYING the system.

To avoid this, there is an UPS (Uninterruptible Power Supply) available. Please ask us, if it is available for your power supply / voltage.

3.2 Do I have to enter the wished volume or the weight / mass per vessel?

The DissoPrep X8 uses a gravimetric principle (why? see question 1.1 or below), so you have to enter the wished weight / mass per vessel.

RIGGTEK is sometimes speaking from “volume per vessel”, because most customers want to have a special volume at first - e.g. 900ml – at a wished temperature – e.g. 37°C. According the USP, the wished volume is to dispense at standard condition - this is 25°C – and then afterwards the liquid has to be heated up. So the weight of this liquid at 37°C has to be the same weight as at 25°C. So for the wished “volume per vessel” has to be entered the weight at 25°C – RIGGTEK is speaking the from entering the volume per vessel in weight equivalents per vessel. How to make the needed Volume to Mass Conversion – see question no.3.3

3.3 Why do I have to do the Volume to Mass Conversion / enter the mass instead of the volume?

Measuring the weight for mixing and dispensing a media is the only correct way, because different media have different volumes at different temperatures and pressures. Only the weight of a liquid is not changing when warming it or changing the pressure! According the USP, the wished volume is to dispense at standard condition - this is 25°C – and then afterwards the liquid has to be heated up. So in accordance with the USP e.g. 900ml dispensed at 37°C into a vessel weigh 897,4g, what is the mass of 900ml at 25°C.

So you have to enter always the weight of your wished media and volume at standard condition (according USP 25°C) – RIGGTEK is speaking to enter the weight equivalents of your wished “volume per vessel”. Therefore you have to calculate what is the weight of your wished media and volume at standard condition – RIGGTEK call this “Volume to Mass Conversion”.

3.4 How do I have to do the Volume to Mass Conversion?

Most accurate and precise proportioning is performed when the “quantity of the mass” of a “stated volume” is weighed under “normalized conditions”. The density of the “normalized conditions” is inherently included.

If this is not possible you have to calculate the mass of the “normalized volume” with its known density at “normalized conditions”.

Example I:

You wish to dispense 900ml water per vessel.

According the standard conditions of the USP with 25°C and 1bar the density of water is 997,1g / L. So 1000ml H₂O weigh 997,1g and 900ml H₂O = 0,9L * 997,1g / L =897,4g.

You have to enter 897 g for the parameter „Volume Vessel“ for the wished 900ml..

Example II:

You want to mix 1000ml media of 0,1 N HCL diluted from 1 N HCL.

1 N HCL has a density of 1,02 kg/L.

Density of water is 0,997 kg/L (USP related at 25°C).

Dilution ratio is 1:10, because of dilution from 1 N HCL.

Calculate with the dilution ratio your volumetric mixture (900 mL water + 100 mL additive = 1000 mL media) and calculate the weight of the media for one vessel with the density:

$$0,9L * 0,997kg/L + 0,1L * 1,02kg/L = 897,4 g + 102 g = 999 g.$$

Enter "Volume Vessel = 999".

Enter "Volume Additive = 102".

Further examples and information you will find in the „DPX8 Additional Information Sheet“, chapter "Volume to Mass Conversion", available on our webpage www.riggtek.de → products → DissoPrep X8 → Information.

3.5 How do I have to enter the wished additive?

The parameter "Volume Additive" determines the portion, e.g. acid, in gram for one vessel (setting in 0,1g digits) and has to be within the specification from 1:3 to 1:100 dilution ratio and is not allowed to exceed 1000g per vessels. So the required volumes have to be entered in weight equivalents per vessel.

3.6 What is the meaning of the dilution ratio 1:3 to 1:100?

The parameter "Volume Additive" has to be within the specification from 1:3 to 1:100 dilution ratio and is not allowed to exceed 1000g per vessels.

Example:

- If you want to have 1000g media for each vessel, the maximum dilution ratio of 1:3 means, that you need at minimum 300g of additive
Enter "Volume Vessel = 1000" and "Volume Additive = 300,0".
- If you want to have 1000g media for each vessel, the minimum dilution ratio of 1:100 means, that you need at minimum 10g of additive.
Enter "Volume Vessel = 1000" and "Volume Additive = 10,0".

3.7 Do I have to calibrate the DissoPrep X8 for each different media and temperature?

No, this is not necessary, because the DissoPrep X8 uses the gravimetric principle (see question 1.1)!

So despite to all other units, the DissoPrep X8 prepares and dispenses the media according the weight and not according the volume. The weight is specific for each media and is not changing for different temperatures (see also question 1.1).

3.8 Why should I heat the media only to the temperature of my dissolution test – e.g. 37°C - and not to 41°C as the USP is recommending for a better degassing efficiency ?

RIGGTEK has made some tests with water, which are showing, that the degassing efficiency at 45,5°C is only 0,5ppm (total 3,09ppm) better than at 36,7°C (total 3,59ppm). If you consider, that in case of water with a temperature of

20°C and an ambient air pressure of 1 bar, there are 9,08 ppm oxygen and air components dissolved (in case of 37°C it's 6,72 ppm), the increase of degassing efficiency when heating the media more is not deciding.

But when cooling down the media from e.g. 41°C to the dissolution test temperature of e.g. 37°C the resaturation of gases to the "normal" value of 6,72 ppm will be much more than this 0,5 ppm difference. So RIGGTEK does not recommend to increase the temperature due to a theoretic better degassing efficiency.

Further information and the test results on the degassing efficiency you will find in the „DPX8 Additional Information Sheet“, chapter “Dissolution Media Degassing Efficiency Investigation with DissoPrep X8”, available on our webpage www.riggtek.de → products → DissoPrep X8 → Information.

3.9 Is it possible to degas and heat a ready mixed hydrochloric acid-solution?

Yes, it is possible. Instead of DI-water you can connect the ready mixed acid-solution to the water-inlet-channel. But the maximum possible acid concentration at the water-inlet and the outlet-channel is 0,5% hydrochloric-acid.

3.10 Is it possible to use SLS (surfactant), buffer (basic reagent), acid and organic / alcoholic media?

It is possible to use SLS (surfactant). There are no general problems known, although it is foaming.

Buffer and acid is possible. For Acid the maximum acid concentration at the additive input line is 36% hydrochloric acid, for the medium-/ water-input-line and the output-line the maximum hydrochloric acid concentration is 0,5%.

Organic / alcoholic media is NOT usable (NOT allowed)! The sucked in organic / alcoholic media flows through a heater – there you have the risk of an explosion. All internal parts are not usable (inert) for alcohol.

3.11 Does PREFILL also need additive from the additive-line? How much additive is needed?

No, the PREFILL is just to prefill the tank to the Minimum Switch with DI-water (from the water-inlet-line), the additive will be only sucked in during the FILL state.

Because the tubings of the DissoPrep X8 has to be prefilled, you need more additive as the additive which would be needed for the wished concentration. Normally 150% of the normal amount are needed / are to allocate at the additive-line.

3.12 How to verify, that the proportion of water and additive is correct, if the dispensed liquid is always a mixture of them?

In the implemented Performance Qualification Test, RIGGTEK trust the before calibrated pondering cell, that it is measuring the added "additive" right and so we trust that the DPX8 has reached the right mixing ratio.

But this is not sufficient and you want to proof the mixing result independently, you have to measure the weight of the INTAKEN water and additive. Therefore

- make a full run (PREFILL, FILL, DISPENSE) with your wished additiv and water to fill all tubings

- measure the weight of the reservoirs of water and additive you take the water and additive from
- note the weights of both tanks. Be careful - do not shake the inlet-tubings when taking them out of the tank for measuring the reservoirs, otherwise the result will be wrong
- make a second full run
- measure the weight of the reservoirs again
- calculate the differences of the water-reservoir before and after and of the additive-reservoir before and after
- with the differences of the water and additive you can calculate your mixing ratio.

Another way to check the right mixing ratio is to measure the ph-value or make an analysis (UV or HPLC).

3.13 Is it possible to use prepared media concentrates?

Yes, it is possible. But one bottle, which is normally ready for a certain volume of media, is not sufficient for exactly one media preparation. Because the tubings of the DissoPrep X8 has to be prefilled, so you need more media concentrate – normally 150% of the normal amount. How to use the concentrates:

- Fill a few bottles of the concentrate in a larger bottle (because the prefilling needs a uncertain volume - depending of length of the sucking-tube etc.) and connect it to the additive-inlet-tube of the DissoPrep X8,
- you have to know / measure / calculate the weight of your concentrate at ambient temperature (USP 25 °C), for entering it as “Volume Additive” at the DissoPrep X8
- you have to know / measure / calculate the weight of the ready mixed media at this temperature, for entering it as “Volume Vessel” at the DissoPrep X8
- enter in both weights “Volume Additive” and “Volume Vessel” at the DissoPrep X8
- DPX8 is mixing, warming, degassing and dispensing the wished media

Example:

using the product “DMC020-06, HCl 0.01N, dilute to 6L, 1 btl.”, in the meaning, that one bottle with 230,8ml Hydrochloric Acid 0.01N is ready to dilute to 6L media.

- Take e.g. 2 bottles of this in a larger bottle
- If the concentrate has e.g. a specific weight of (supposed !!!) 1.0g/L at 25°C then the content of 38,46 ml of the concentrate in 1 Liter weighs $230,8\text{ml} / 6\text{L} = 38,46\text{g}$
- weight of ready mixed media of wished 1 Liter per Vessel is
 - $1\text{ Liter} - 38,46\text{ml} = 961,54\text{ ml water}$
 - $961,54\text{ml} * 0,997\text{ kg/l} = 958,7\text{g of water}$

- plus your 38,46g of your concentrate
- is for 1 Liter of your ready mixed media 958,7g (water) + 38,46g (additive) = 997,16g
- Data entry in DPX8 is 38,5 g for “Volume Additive” and 997g for “Volume Vessel” to achieve 1L per vessel of your 0,01N HCL media.
- DPX8 is mixing, warming, degassing and dispensing the wished media

So it's of course possible to use the concentrates, but not emptying one bottle exactly for one mixing / preparation.

3.14 How often do I have to clean the DissoPrep X8? How do I have to do the cleaning?

A regular cleaning of DissoPrep X8 should be done to prevent a possible contamination. The cleaning intervals depend on the following individual factors:

- the type of media (especially in the use of foaming media the cleaning interval should be shorter)
- the frequency of use of the DissoPrep X8
- the total volume of media that is prepared with the DissoPrep X8

The DissoPrep X8 can be cleaned with very effective 0,2% Sodium-Hypo-Chlorid or more compatible 5% Hydrogen-Peroxid. For the filter cartridge at the inlet tubing, the cleaning medium is as safe as for the transparent PVC tubings, which could get milky. DI water for rinsing the DissoPrep X8 is recommended.

The cleaning can be done in two complete runs (PREFILL, FILL, DISPENSE, EMPTYING).

- In the first run with the washing media as input medium.
- In the second run with DI water as input medium for rinsing.

Or the cleaning is done with the AUTOWASH function

RIGGTEK recommends generally a monthly cleaning with 5 l of 5% hydrogen peroxide as washing media for

- a full run (PREFILL, FILL, DISPENSE, EMPTYING) at 37 ° C or
- the AUTOWASH function with two wash cycles and 2500ml flushing volume

Afterwards RIGGTEK recommends for rinsing 5l DI water in another full run at 37 ° C or to make a further run of the AUTOWASH function with two wash cycles and 2500ml flushing volume.

If the input and outlet hoses are not clean after the cleaning, we also recommended changing all tubing's (see also question 3.19)

In case that there is a Water Interface (optional) in use, it is to clean regularly, so that the float valve is free moveable and so keep fully functional. All sediments incl. limescale / calcium carbonate are to be removed. Please consider the following hint for the Water Interface. The Water Interface is not part of the Installation and maintenance of the

RIGGTEK GmbH. The Installation and cleaning / maintenance has to be organized / done by the customer himself. A not fully functional Water Interface can cause overflowing water!

3.15 How much time does the AUTOWASH-fuction take?

It depends on the setted volume and the amount of cycles at the AUTOWASH-function. E.g. one cycle with 1500ml takes round about 7-10min.

3.16 Is the AUTOWASH-function able to clean the DissoPrep X8 completely? Even when SLS was used?

The user has to specify and verify for himself how often, with which cycle-volume and with which amount of cycles they have to use the AUTOWASH-function for the used media. There are too many different media and user habits, so that RIGGTEK can not recommend or even garantuee an AUTOWASH setting for all different media.

But with the AUTOWASH-function, the DissoPrep X8 is able to clean all the internal components. It is not necessary to open the tank etc. for cleaning.

To verify the setted AUTOWASH-function, the user has to make a full run with DI-water after AUTOWASH and analyze the possible remaining ingredients of the previous used media. E.g. the user should use a normal method 6 Vessels, 900g DI- Water, 0g Additive, 37°C. After the DPX8 is ready for dispensing the user should fill up a beaker with media and take a sample of the media for analyzing it with HPLC or UV. So they can find out if there are some rests of additives in the dispensed water after AUTOWASH.

3.17 If I want to prepare different medium in the same day, do I always need to do an AUTOWASH between preparing different media?

If you don't switch to different additive, but only change the concentration of the additive, you don't have to use the AutoWash.

If you change the additive, you should do an AUTOWASH. How to verify, that the internal components are clean, see question 3.13

3.18 After AUTOWASH the unit starts from PREFILL – is this normal?

This is normal - if you made an AUTOWASH, the unit is totally empty and starts with PREFILL (so there is even no Prefill- / reserve-volume in the tank). That is the best starting position every morning - a total empty and clean unit.

If you will switch off the unit after FILL, the tank is full and the DissoPrep X8 will force you to EMPTYING (the tank) before starting a new method.

3.19 When or how often do I have to change the inlet-filter, tubings and the outlet-frit?

The regular / periodical exchange of the filter (filter capsule) prevents the DissoPrep X8 that harmful particals can enter and together with the regular exchange of the tubings bacterial growth is avoided.

The regular / periodical exchange of the frit (outlet) secures the precision of the dosing and that low gases are re-aerated in the media while dosing into the vessels. Recommendation:

- complete inlet tubing incl. filter (= filter capsule) – **exchange every 12 months** – article-no. DPX-INLETMED-C
- filter – **exchange every 6 months or 5.000 liter** – article-no. SAR-559132P5-OO
- additive inlet tubing – **exchange every 12 months** – article-no. DPX-INLETACID-C
- outlet tubing (also for Remote Control Nozzle) – **exchange every 12 months** – article-no. DPX-INLETACID-C
- frit – **exchange every 6 months or 5.000 liter** – article-no. DPX-OUT-FRIT

3.20 Does the unit alarm when the remaining filter life time is used up?

Yes, the DPX8 suggests a filter change in the display, if the predefined filter volume capacity ("Remaining Filter Capacity") is exhausted. You have to reset the remaining filter capacity in the AUXILLARY-Mode after the filter-change. The "Remaining Filter Capacity" is always shown on the printer protocols, so that it is possible to order a new filter in advance.

3.21 Why is there only one method modifiable at the DissoPrep X8?

According to the GLP (Good Laboratory Practice) only registered / legitimated users are allowed to adapt methods. So according to GLP the user should have to register at the DissoPrep X8 with a User-Login to modify any method. Because this is not according to the normal user requirements, the DissoPrep X8 allows only to adapt the Method 0 at the unit itself. For modifying any other method, the RC-software (installation on a connected computer) with a User-Login is required. So only the use of the Methods higher than Method 0 - which are only to adapt by the RC-software - is really according to GLP.

Normally the users use always one of e.g. 5 methods or they use every time a totally different method. So it's sufficient, that only one method is modifiable at the unit. If there are users who use e.g. 10 methods very regularly and alternately, they should use the Remote Control Software, where they can adjust up to 50 methods in a very easy and clear way. If the user has no computer in the lab or did not want to buy the software, RIGGTEK or the distributor can store for him the wished methods. Of course, he can not modify them without help.

3.22 How do I connect my computer with the RC-Software to the DissoPrep X8?

You will need a "Zero-Modem-Cable" (available everywhere or at RIGGTEK) to connect the DissoPrep X8 with the computer (COM-Port).

3.23 The RC-Software is "RFC 21 Part II compliant" – what does this mean?

"RFC 21 Part 11 complaint" means, that data from the DPX8 (such as protocols) can't be manipulated from the user before printed out - our software fulfills this requirement.

3.24 Is it possible to connect more than one DissoPrep X8 to one computer with the RC-Software installed?

Unfortunately it is not possible with the actual RC-Software to control more than one DissoPrep X8 from one computer (with the RC-Software installed). It is NOT possible to install the RC-Software several times to control several DissoPrep X8 connected to different COM-Ports.

3.25 Is it possible to connect more than one DissoPrep X8 to one computer with the RC-Software installed?

Unfortunately it is not possible with the actual RC-Software to control more than one DissoPrep X8 from one computer (with the RC-Software installed). It is NOT possible to install the RC-Software several times to control several DissoPrep X8 connected to different COM-Ports.

3.26 The temperature of the first batch is always lower than setted?

At the first batch, the tank, all tubings etc. have the room temperature. The temperature sensor is measuring the media near the heater before filling in the tank, afterwards due to the cold tank and tubings at the outlet side, the media is cooled down very much at the first time. That is one reason, why we recommend (see Operation Manual chapter 6.5.2 Prefill, page 19) to throw the first batch to the waste. Additionally, if you mix media with acid, all internal parts have to be conditioned to the new media, so that the first batch is also to be thrown away.

The inlet water should be at least 15°C, otherwise the heater is not strong enough.

After the first batch, the temperature accuracy is 1,5°C at setted temperature of 32°C - 37°C for more than 5000ml. If there is prepared less than 5000ml in total, it is possible, that the temperature is not reached, as well if the temperature should be higher than 37°C.

3.27 The setted temperature is not reached?

The temperature accuracy is 1,5°C at setted temperature of 32°C - 37°C for more than 5000ml. If there is prepared less than 5000ml in total, it is possible, that the temperature is not reached, as well if the temperature should be higher than 37°C.

If you are using a 100V or 115V power supply, please make sure (RIGGTEK or your distributor), that the TIN1 file is for 100V / 115V or that some parameters ("MVI Takt, MV2 Takt, Heizleistung, MaxHZG") are setted to the right values.

3.28 When calibrating the DissoPrep X8, the documented weight on the protocol is higher than the setted weight, but it is right according an external balance. Why is this?

The calibration run uses a virgin dispense control without the needed "OFFSET". If the internal load-cell measure the right dispensed mass, the reaction of the electronic components as the valves take still some time, so that more media will be dispensed.

So this higher mass at the calibration run than the setted mass is ok. Important for the calibration is only the comparison of the load-cell value and the value of the external reference balance. With these calibration datas, the OFFSET will be calculated in this calibration run. The dosing accuracy will then be proofed in the performance run.