



DISSOPREP FAQ 'S

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

1 Questions concerning the investment of the DissoPrep:

1.1 What is the main advantage of the DissoPrep in comparison with its competitors? (precision of the gravimetric principle)

The main advantage of the DissoPrep is, that it uses as unique feature the gravimetric principle for mixing and dispensing the media. That means, the DissoPrep weighs the used media and the additive for mixing, and it weighs the dispensed media. So the DissoPrep fulfills the USP requirements concerning volume precision 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, which 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 DissoPrep 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 → Information.

1.2 What are the further advantages of the DissoPrep?

- 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; with DPX8 8.000g of dissolution media is ready in **less than 15 minutes** or with DPX15 15.000g of dissolution media is ready in **less than 25 minutes**, 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 provides a "DISPENSE Protocol" reporting the weights, the mixing ratio, the vacuum and the temperature. Also a "CALIBRATION Protocol" is provided.

- USP, EP, FDA, GLP/GMP conformity: DissoPrep fulfils 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 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 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 can be transferred 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 → Information.

1.3 How fast is the amortization of the DissoPrep investment?

The saving of time is considerable. DissoPrep prepares up to 8.000g (DPX8) 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 900g) 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€ labour 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 (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 DissoPrep” available on our webpage www.riggtek.de → products → DissoPrep → Information.

2 Questions concerning the specifications of the DissoPrep:

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 8.000g (DPX8) or 15.000g (DPX15)?

The volume of 8.000g (DPX8) is sufficient to fill all vessels of one dissolution bath or 15.000g (DPX15) to fill all vessels of two 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.

2.3 Why is the gross - volume of the tank 11L or 15L? What does this mean?

For prefilling the unit (tubings and death volume of the tank) an additional volume is required as well as for mixing media in the right concentration. This is why the tank has an actual volume of 11.000g (DPX8) or 18.000g (DPX15), but only 8.000g (DPX8) or 15.000g (DPX15) are for net use.

The prefill volume is approximately 1.000g.

2.4 Of which material is the tank?

The tank is made of PP (Polypropylen).

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

The prefill – volume is 1.000g. This volume is needed to prefill (filling tubings etc.) the unit incl. the Flush-volume at the beginning of the dispensing.

2.6 How does the DissoPrep degass the media?

The DissoPrep is degassing while exposing the media to vacuum, typically < 100mbar pressure absolute. The vacuum is monitored and documented on the protocol.

2.7 What is the degassing efficiency of the DissoPrep?

The degassing efficiency depends generally on

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

For a normal routine the interaction of heating, stirring and degassing (vacuum exposure) generates an effective de-aeration of the medium e.g. for water with typically 3 - 5ppm residual 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“, available on our webpage www.riggtek.de → products → DissoPrep → Information.

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

The DissoPrep 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 prepare in one hour? What is the preparation time for the media?

The throughput of DissoPrep 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 g/min. So for 6000g you can calculate with approximately 10-15min.

If the media is prepared and ready for dispensing, the dispensing rate is 2L/min. So typically a vessel with 900g is filled in 25 sec. So for 6 vessels with 900g you can calculate with approximately 2,5 min.

The timings depend on the degassing time settings and the selected temperature – without mixing approximately 10 min for 37°C up to 15 min with mixing and higher temperature

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

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

2.11 What is the minimum increment on dispense volume setting? Which dispense volume can I enter?

The minimum increment setting is 1g – the dispense volume can be entered from 100 – 8.000g (DPX8) or 15.000g (DPX15).

2.12 Why is the filtration pore size 20 micron, although the USP guidelines are 0,45 micron?

The USP recommends for the manual degassing procedure a 0,45micron filter, because the degassing at the manual process is highly depending on the filter size. For the process with the DPX8 it is not necessary for the degassing to use such a filter. It is good enough for degassing, filtering dust (clean DI-water should be used anyway) and the filter is all of PP and so capable for little acid media (0,5% hydrochloric acid). The 0.45 micron filter are of other materials.

3 Questions concerning the use of the DissoPrep:

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

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

During PREFILL, FILL and DISPENSE, the DissoPrep 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 from the mains power supply after state FILL. So it is not possible to prepare a media and then move the DissoPrep towards individual baths. After disconnecting from the mains power during FILL or DISPENSE and switching it on again, the DissoPrep 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 mains power supply / voltage.

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

The DissoPrep 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 specific 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 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 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/mass 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, which is the mass of 900ml at 25°C.

So you have to enter always the weight of your wished media 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 volume at standard condition – RIGGTEK calls 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. Consequently 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 → 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 1.000g 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 1.000g media for each vessel, the maximum dilution ratio of 1:3 means a maximum of 333g of additive
Enter "Volume Vessel = 1000" and "Volume Additive = 333,3".
- If you want to have 1.000g media for each vessel, the minimum dilution ratio of 1:100 means a minimum of 10g of additive.
Enter "Volume Vessel = 1000" and "Volume Additive = 10,0".

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

No, this is not necessary, because the DissoPrep uses a calibrated pondering cell to weigh any arbitrary mass (volume) / the gravimetric principle (see question 1.1)!

Compared to all other competitive instruments, the DissoPrep 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 for degassing only to the temperature of my dissolution test – e.g. 37°C - and not to 41°C as the USP is recommending?

RIGGTEK has made some tests with water, which are proving, that the degassing efficiency at 45,5°C is only 0,5ppm (total 3,09ppm) better than at 36,7°C (total 3,59ppm). You have to consider, that in case of water with a temperature of 20°C and an ambient air pressure of 1bar, there are 9,08ppm oxygen and further air components dissolved, in case of 37°C it's 6,72ppm oxygen, the increase of degassing efficiency when overheating the media is not reasonable better.

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 0,5ppm 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”, available on our webpage www.riggtek.de → products → DissoPrep → 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 allowed 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, but 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. Some internal parts are not usable (inert) for alcohol.

3.11 When using SLS (surfactant), how is foam being prevented from entering the dispense tubing?

When using SLS media, the foam is at the top of the tank. The outlet for dispense is at the bottom of the tank and because of the prefill volume, the foam will never get out.

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

No, the PREFILL itself 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. The total sucked in additive is also in relation to the prefill-volume.

Because the tubings of the DissoPrep have to be prefilled, you need more additive as the additive which would be needed for the wished concentration. For safety, 150% of the normal amount should be provided at the additive-line.

3.13 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" correctly and so we trust that the DPX8 has produced the right mixing ratio.

In case you will prove the realistic mixing amounts, you have to measure the weight of the INTAKEN water and additive. Therefore

- make a full run (PREFILL, FILL, DISPENSE) with your wished additive and water to fill all tubings
- measure the weight of the reservoirs of water and additive
- 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 also of the additive-reservoir before and after
- with the differences of the water and additive you can calculate your mixing ratio.

It is not recommended to check the correct mixing ratio with ph-value or UV-marker.

3.14 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 has to be prefilled, so you need more media concentrate. How to use the concentrates:

- Fill a few bottles of the concentrate in a larger bottle (because the prefilling needs a uncertain volume - depending on length of the sucking-tube and the Flush Volume before dispensing) and connect it to the additive-inlet-tube of the DissoPrep,
- 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
- 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
- enter in both weights "Volume Additive" and "Volume Vessel" at the DissoPrep
- 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 concentrated Hydrochloric Acid is ready to dilute to 6L media as a 0.01N HCl.

- 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 Liter – 38,46ml = 961,54 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 $958,7\text{g (water)} + 38,46\text{g (additive)} = 997,16\text{g}$
- 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.

3.15 How often do I have to clean the DissoPrep? How to clean it?

A regular cleaning of DissoPrep should be done to prevent a possible contamination with bacteria. 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
- the total volume of media that is prepared with the DissoPrep

The DissoPrep 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 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 2.500ml 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 3.21)

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 keeping it 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!

3.16 How much time does the AUTOWASH-function take?

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

3.17 How is the cleaning performed for validation by RIGGTEK or the authorized distributor?

The cleaning is NOT performed for validation, because every customer is using different media and it is not possible for RIGGTEK to proof each combination of media change. You (the customer) has to verify yourself, which amount of wash cycles, with which volume and cleaning additive is to be used, so that there is no cross contamination between different medias. The recommendation of RIGGTEK see in the operation manual and in question 3.15.

3.18 Is the AUTOWASH-function able to clean the DissoPrep 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 guarantee an AUTOWASH setting for all different media.

But with the AUTOWASH-function, the DissoPrep 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 contents 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.

3.19 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 wetted materials are clean, see question 3.14

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

This is normal - if you perform 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 will force you to EMPTYING (the tank) before starting a new method.

3.21 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 that harmful particles can enter, and 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 gases are re-aerated in the media while dosing into the vessels. Recommendation:

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

3.22 Does the unit alarm when the remaining filter life time is elapsed?

Yes, the DPX8 suggests a filter change in the display, if the predefined filter volume capacity ("Remaining Filter Capacity") is expired. 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.

3.23 Why is there only one method modifiable at the DissoPrep?

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 with a User-Login to modify any method. This is the reason why the DissoPrep 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 an 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.

If there are users who use many methods very regularly and alternately, they should use the Remote Control Software, where they can adjust and store up to 50 methods in a very easy and clear way. RIGGTEK or the distributor can also store for him the wished methods. Of course, such methods can't be modified.

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

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

3.25 The RC-Software is "RFC 21 Part 11 compliant" – what does this mean?

"RFC 21 Part 11 compliant" means, that data from the DPX8 (such as protocols) can't be manipulated from the user before printed out. Also any user login or any handling step is documented in a log-file.

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

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

3.27 The temperature of the first batch is sometimes lower than setted?

At the first batch, the internal tank must be temperature conditioned. Therefore we recommend (see Operation Manual chapter 6..5.2 Prefill, page 19) to waste the first batch. 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 wasted.

The inlet water should be at least 15°C, and the minimum volume should be 5.000g to reach temperature specification of +/- 1,5°C at setted temperature of 32°C - 37°C for more than 5.000g.

3.28 The setted temperature is not reached?

The temperature accuracy is 1,5°C at setted temperature of 32°C - 37°C for more than 5.000g. 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 that RIGGTEK or your distributor has done the correct instrument presettings ("TINI file is for 100V or 115V).

3.29 When calibrating the DissoPrep, 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 and compares only an arbitrary amount. Therefore the calibration compares only the internal load-cell measure against the external reference measure. Any deviation to the setted volume is not relevant for the calibration. Finally the dispensing accuracy will then be proofed in the performance run..

3.30 Is it possible to connect the media-inlet directly to the faucet?

No, it is not possible to connect the inlet tube directly to the faucet! The pressure is to high and the principle of the DissoPrep of sucking in the media is not working then anymore. Besides the valves would be destroyed. As option RIGGTEK offers the "Water-Interface" (article-no. DPX-WI2), which you connect between the faucet and the DissoPrep. The Water-Interface is like a tank which is filled up automatically. Because the installation has to do with the building equipment (maybe a pressure reducer is necessary), the installation has to be done by the building service of the customer and there is no guarantee from RIGGTEK´s side for the long-time function (because it depends on the water-pressure of the faucet). We also strongly recommend to install a shut-off valve, which is too use, when no person is in the room.

3.31 Is there any possibility to avoid an AUTOWASH when changing the media to save time. So is there any possibility to flush the system without doing a PREFILL?

No, you can´t flush the system without "flushing out" = emptying all the existing media. The PREFILL is necessary then.

3.32 Is it possible to use water for the PREFILL and prepared media afterwards for the FILL?

No, it is not possible to use water for the PREFILL and the prepared media for the FILL. The water as PREFILL-media would be mixed with the prepared media and would change the concentration and density of the prepared media.

3.33 Is it possible to use detergent as SLS, SDS and do the bubbles influence the accuracy of the dispensing?

Yes, some customers use it, there are no problems known. So no, the bubbles should not influence the accuracy of the dispensed media.

3.34 When entering e.g. 43,8 g for the additive, the display shows 44 during the preparation. Does the unit take 43,8g or 44 g for each vessel?

The unit takes 43,8, the displayed value is only rounded up because of the limited place on the display.

3.35 Is the maximum volume of 8L or 15L limiting the possible volume entry (weight equivalents) per vessel? E.g. is it possible to enter 1003g per vessels for 8 vessels, which is a total volume of 8.024g?

For firmware versions > 7.113 you can enter "Volume Vessel" (weight equivalents) that are in sum for all vessels (Total Volume) $\leq 9.000\text{g}$ (DPX8) or $\leq 15.000\text{g}$ (DPX15). If it is higher, you will get an error message "TotalVol tooHigh" and the LED "Message" will light when starting the method and you have to press the button STOP for returning to adapt the method. Then you have to reduce the volume per vessel or the number of vessels, so that the total volume is $\leq 9.000\text{g}$. At firmware versions ≤ 7.113 only DPX8 it is NOT allowed to enter volumes per vessel (weight equivalents) that are in sum for all vessels (Total Volume) $>8.000\text{g}$, because there is a security limitation. But be careful, there is no warning message or a limitation for the volume entry! You can start the method, but then only the volume for one vessel will be prepared. So after the first dispensed vessel, air will be dispensed and the DissoPrep will not stop to dispense air. You have to shut down the unit.

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