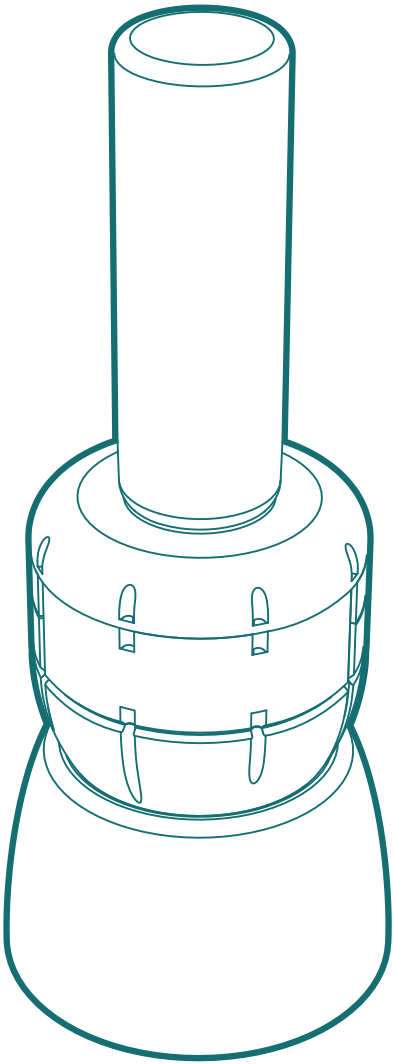
Solids Dispenser **SDM-1**

MANUAL



INSTRUMENTS

Contents

1. Volumetric Dispensing

1.1 Principle

The SDM-1 dispenser is based on the principle of volumetric dispensing. It is the improved and highly precise equivalent of a measuring spoon, portioning the volume, not the mass of the material.

Since powder doses are typically specified in mass, these specifications need to be converted to volume via the bulk density, which takes the voids around the particles into account and depends on granule size. Bulk density is different from solid density of a material, which is often listed in data sheets. The bulk density is generally much lower. It can be established by weighting a specific volume of powder, e.g. in a beaker or syringe barrel, without tapping or compressing the material.

1.2 Dosing

The dispensing disks in our equipment are permanently calibrated to a specific volume according to the target dose and material (bulk density). To change the single dose value of the dispenser, the disk needs to be replaced with one of a different calibration. Disks are calibrated according to customer specifications to a dose target in a specific materials; either nominally with bulk density value or based on testing with material samples.

1.3 Dosing Error

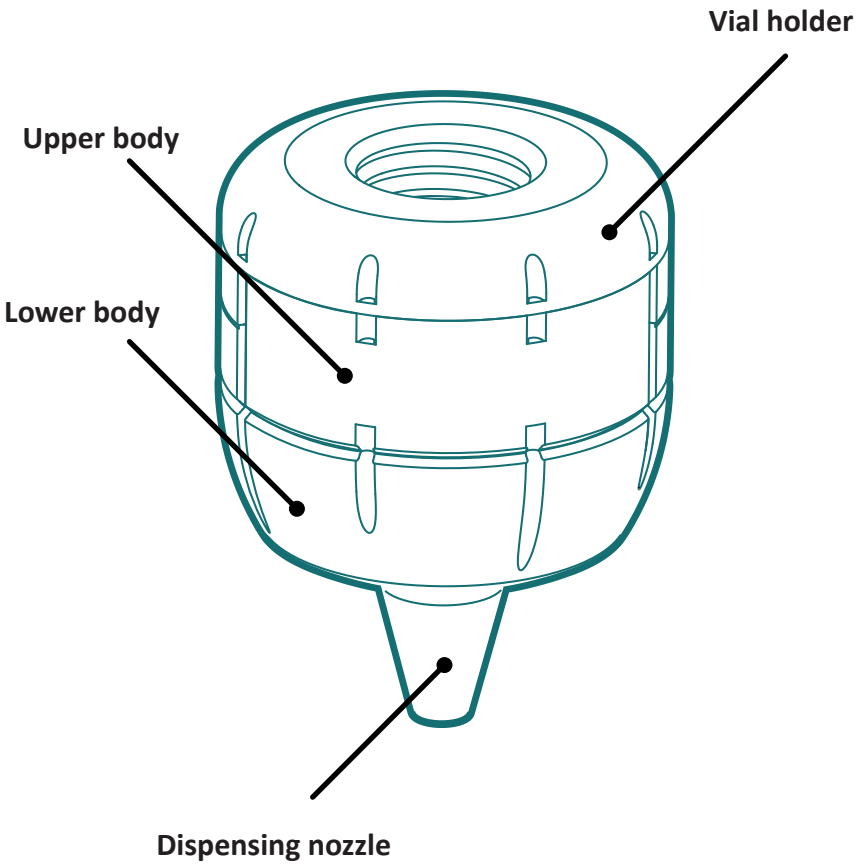
Volumetric dosing has a natural variation in dose mass depending on material properties and dose size (larger doses dispense relatively more stable). The expected precision of the dosing for a given material and dose size needs to be established in tests.

Static charge can affect dosing consistency as well. In many cases it leads to a 'coating' of the surfaces in the powder path with material. Due to this effect the first 5 doses of a series can be under dispensed. It is recommended to eliminate these first shots from a batch. The severeness of static depends on ambient humidity; it is most pronounced in entirely dry conditions. Dispensing disks in antistatic material are available to improve performance for such sensitive materials and environments.

A volumetric dose can be affected in its mass by humidity. While the mass may vary with moisture content, the volume will be largely constant. The dose volume is in these cases often the more relevant measure, since it ignores the humidity weighted in addition. While weighting doses (gravimetric dosing) might seem in such cases very precise, it could actually mask this error (with higher moisture content less material will be dosed for the same mass in gravimetric dosing). The volumetric dispensing will still provide quite a stable dose of the actual material in such cases.

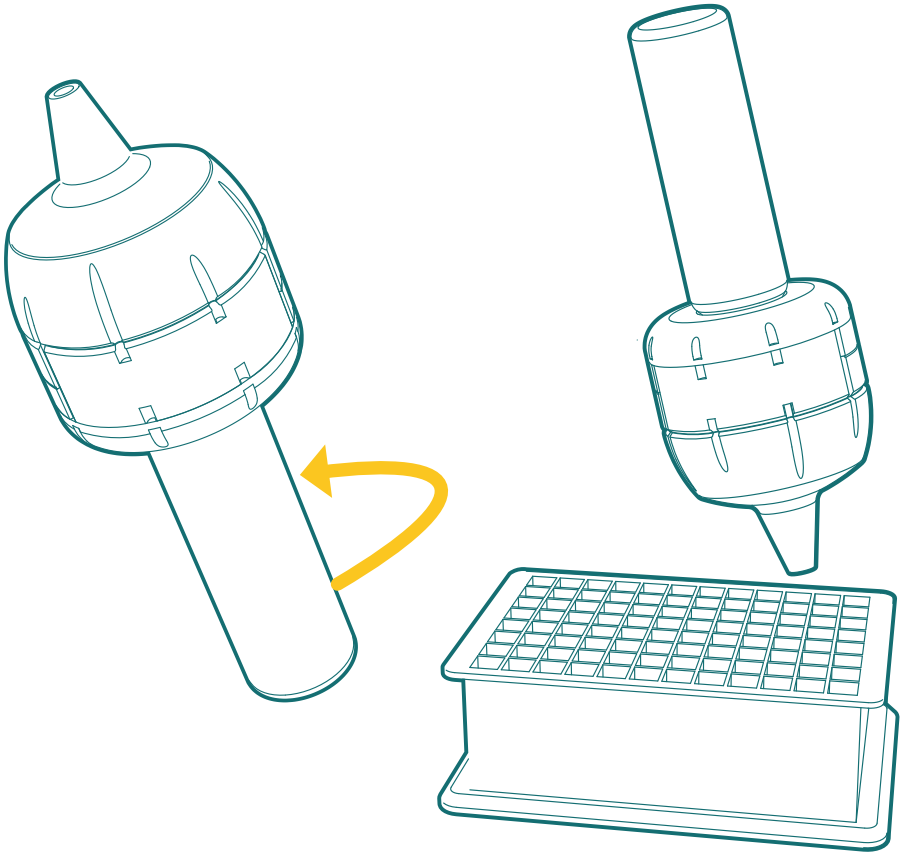
2. Overview

The SDM-1 dipsenser consist of Vial holder, which is locked onto the Upper body and the lower body. The upper body rotates relative to the lower body in quarter turn increments.



3. Operating Instructions

1. Load sample material into glass vial, and screw glass vial onto the dispenser (holding dispenser upside down).
2. With one hand holding the upper body, use other hand to rotate the lower body in a clockwise or anti-clockwise manner. One dose is released at each quarter-turn, recognizable by a light ‘click’ sound and locking into place.
3. Allow for priming (1-4 shots).



4. Disassembly and Cleaning

4.1 Disassembly of Dispenser

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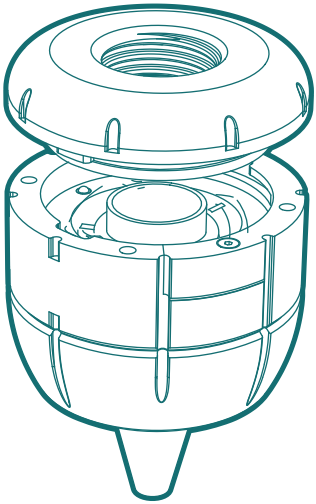
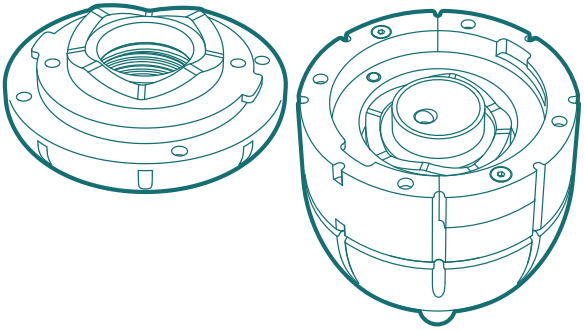


Open the dispenser and clean:

1. Unscrew glass vial from vial holder for cleaning. Turn top ring about 20 degrees counter-clockwise.
2. Lift top ring off main body. Remove the dispensing disk inside the housing by pushing the dispensing disk out of its seat with a pin, e.g. allen key.
3. Use compressed air or brush to clear out any powder inside the dispenser.

2



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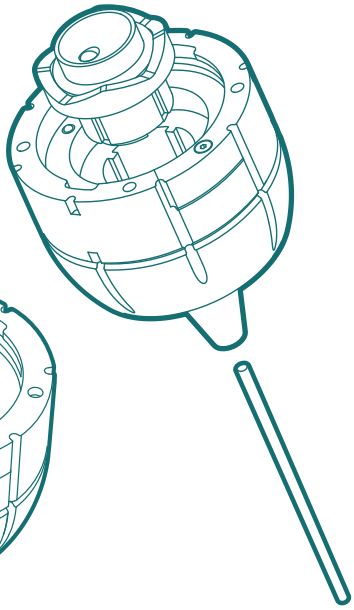
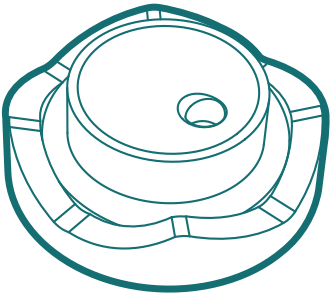
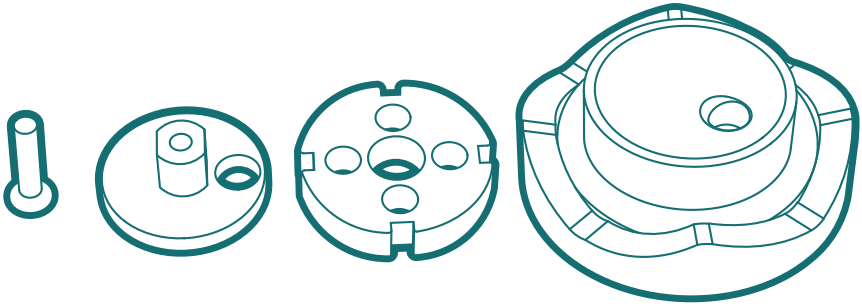


4.2 Cleaning and Disassembly of Small dispensing disk

The dispensing disk can be cleaned externally by blowing compressed air through it, or brushing, wiping with agents such as Isopropyl alcohol or detergent. Rotate the volume disk to access all 4 apertures. For more thorough cleaning of the dispensing disk it can be dismantled:



For more thorough cleaning of the dispensing disk it can be dismantled:

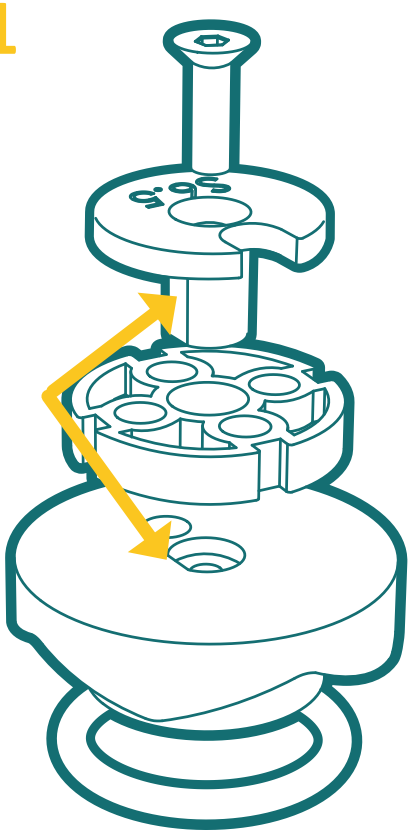


Remove the pan head screw on the underside of the dispensing disk to separate three parts (right) & and clean all parts by using compressed air, brushing or wiping.

4.3 Re-assembly of Dispensing Disk

Slide bottom disk part into volume disk. Then insert into top disk by while aligning the D-indexing feature. Insert screw.

1



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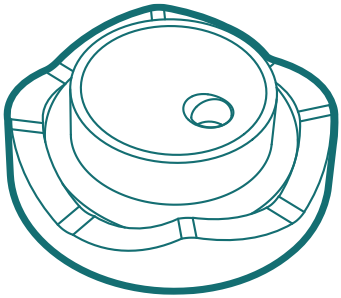


Tighten the screw in a manner that the disk can rotate smoothly with some slight friction. Light tightening is sufficient, don't overtighten.

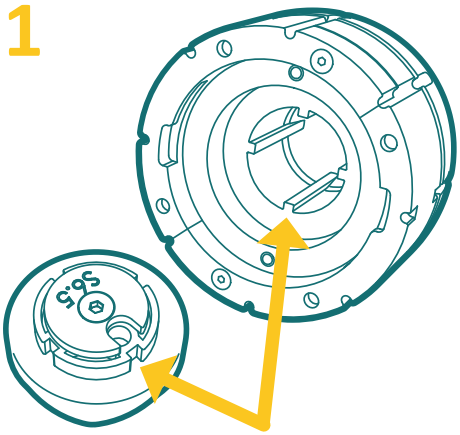
4.4 Re-assembly of Dispenser

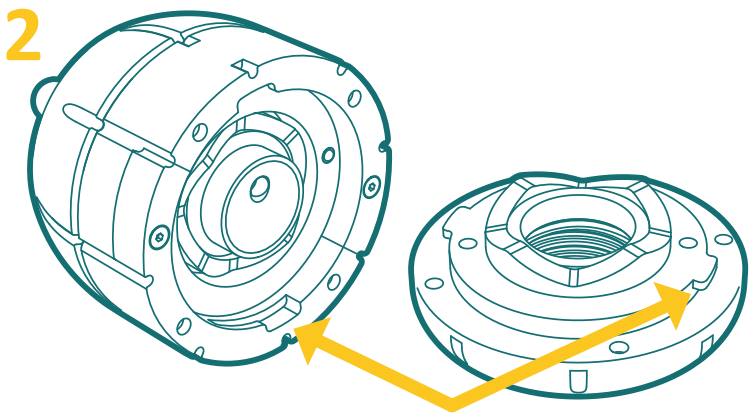
Re-assemble in reverse order

Assembly:

1. Place the disk back into the funnel with the screw towards funnel tip. Carefully align notches in the disk with ribs in the funnel (indexing), before pressing the disk into the funnel seat (2).

2. Place the vial holder onto the dispenser upper body while aligning the fastening tags with the corresponding pockets in the dispensing body





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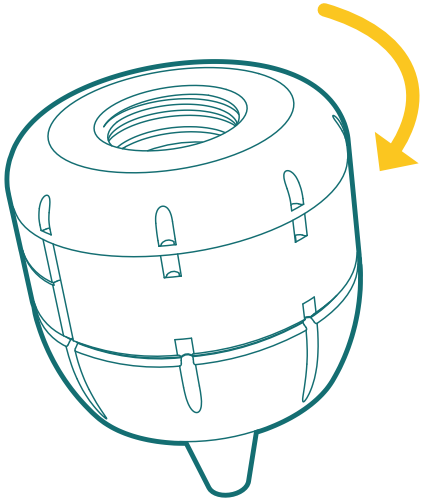
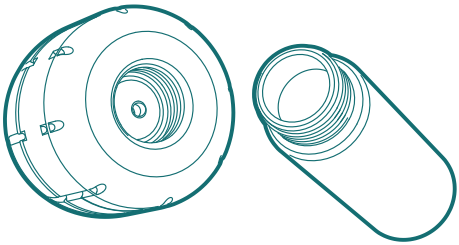


Insert vial holder by aligning tags and turn ring about 20 degrees clockwise to fasten. The groves will align once fully tightened.

Rotate the dispenser upside down, insert and screw vial tight.

2



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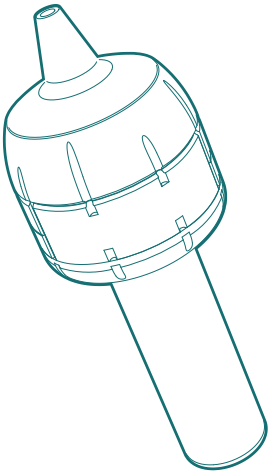
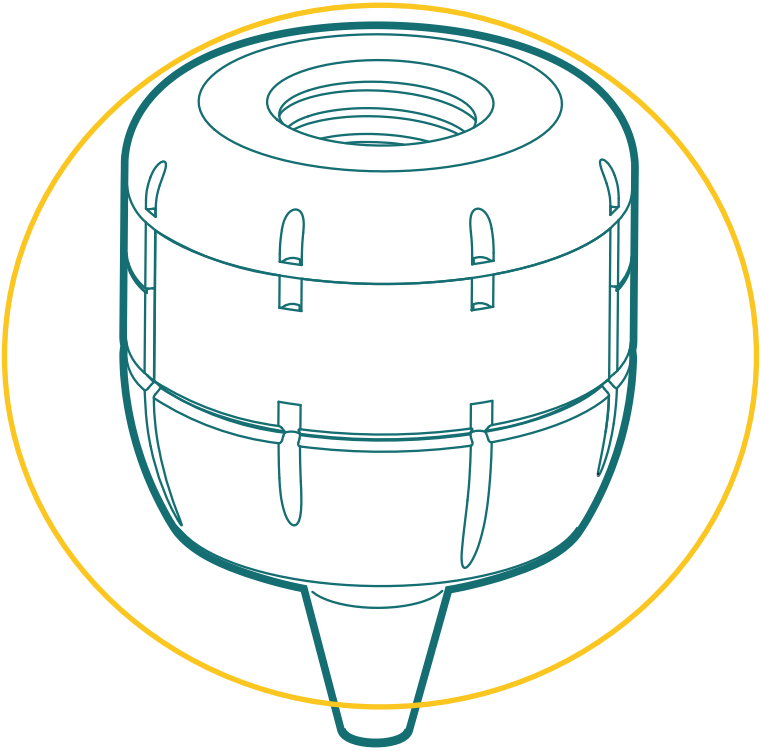


5. Cleaning of Main Unit

The dispensing disk and its parts, as well as all internal surfaces can be cleaned and disinfected normally.

Painted surfaces of the exterior should not be cleaned with bleach, alcohol, IPA or any harsh chemicals. Mild disinfectant soap can be used on these painted surfaces.

Painted surfaces are are the outside surfaces of the dispenser



6. Calibration

9.1 Initial Calibration

In calibration the dispensing disks are machined for a specific, definite dose volume of the dosing chambers.

Depending on what is most practicable, the chamber size can be defined in several approaches:

9.1.1. Based on specification of a dose volume

The dispensing disk will be prepared with the chamber size according to the volume specification

Volume range: small disk: 2.3mm^3-300mm^3

9.1.2. Based on specification of dose mass with samples

The dispensing disk will be adjusted in testing until the mean of a test dosing string is very close to the target

9.1.3. Based on specification of dose mass with bulk density

The dispensing disk will be prepared nominally to a volume that corresponds to the dose mass based on the bulk density of the material. The bulk density value is either obtained from the powder material manufacturer or established by weighting a specific volume of the material (e.g. 50ml e.g. in a syringe barrel).

9.2 Volume Calculation

The calibrated volume corresponding to a dose target in mass can be calculated as follows:

Dose target (g) / Bulk density (g/ml)= Dose volume (ml)

The disk can be calibrated with this value.

If the nominal bulk density is not available it can be empirically established by weighting a fixed volume of the sample (e.g. 50ml in tube, beaker or syringe barrel). The bulk density results then as follows:

Weight sample (g) / Volume weighted (ml) = Bulk density g/ml

9.3 Calibration Verification and Recalibration

The dispensing disks should be verified periodically by testing in a string of doses in comparison to the test results when the disk was new (mean of actual doses and standard deviation). The original test results were provided as part of the outgoing inspection of new dispensers or dispensing disks. These tests are typically repeated onsite to check for any deviation as part of the IQ/PQ process.

If during the periodic verification testing the values have drifted and variation has increased, the disk should be replaced with a new component of the same specifications (chamber diameter and height). The wear of disks will depend besides intensity of use on the abrasive character of the dispensed material.

The dispensing disks can be ordered to specifications from XQ Instruments and will come with a new test report.

9.4 Workflow

Our dispensing is volumetric, and we calibrate the dispensing disks (the dosing element) for a specific dose size as specified by the customer. With the calibrated dispensing disk this dose or multiples of it can be dispensed.

Dispensing multiple doses allows to dispense different dose sizes from the same dispensing disk, as long as they have a common denominator. However dispensing time will increase and there can be a stack up error.

To change the single dose values, or switch to a material with different bulk density, the dispensing disk needs to be swapped with one to a new value. This takes only a few seconds.

For different dose sizes and/or materials several dispensing disks can be kept at hand and switched quickly. Additional disks to new specifications can also be ordered from XQ Instruments at any time; e.g. when requirements change.

7. Quality Management

9.1 Calibration certificate

Our dispensers, dispensing heads and dispensing disks are supplied with calibration certificates for verification of performance and filing as quality records. The results on the calibration report are also the basis of comparison for IQ/OQ tests and subsequent periodic calibration tests.

9.2 IQ/OQ

Typically our customers repeat our outgoing functional and calibration test when they receive the equipment as part of their IQ/OQ. We can provide templates for recording the results.

9.3 Periodic calibration test

The functional dispensing test should be repeated periodically. The frequency depends on the abrasiveness of the dispensed material. The test consists of a series of doses with the actual material. If the mean and variation of the doses has not changed beyond limits, the dispensing disks can continue to be used and the test results can be filed as quality records. If there is a significant drift or inconsistencies, the dispensing disk should be replaced and a new one to the exact same specs as the initial one should be ordered. The new disk will come with a calibration certificate from XQ Instruments.

8. Troubleshooting

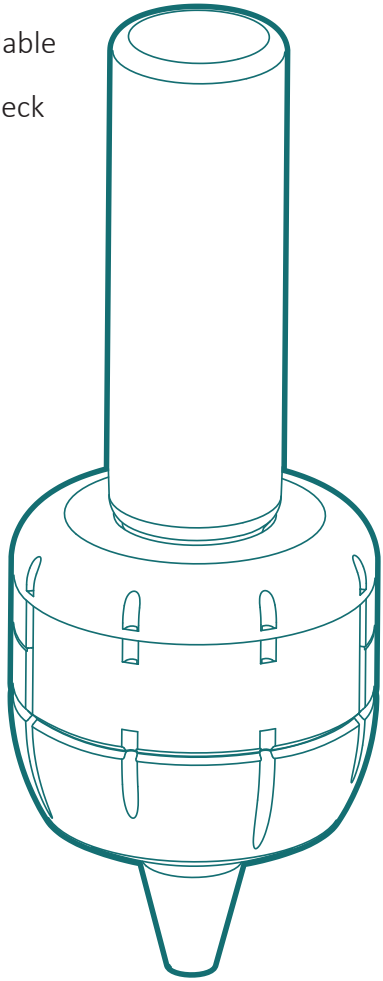
1. In case the powder clogs and jams the dispensing head, the device might get hard to turn.

2. Detach the vial and open the dispenser.

3. Follow usual cleaning procedures to dislodge any clogs. *(Refer to '4. Disassembly and Cleaning').*

9. Specifications

- Typical single dose size: 5 to 300 milligrams
- Accuracy: +/- 5%, depending on substances
- Sample vials (for small head): Diameter 28 mm glass screw thread, available in 40 or 60mls, 24-400 thread neck
- Size: Size: 58 (Dia) x 78 mm (H)
- Weight: 160 g
- Storage conditions-5°C – 40 °C, humidity 0-90%



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User Manual DP1803-281E