CERTIFICATE OF COMPLIANCE

FOR

INHALATION DEVICE

MORA ELLIPSE

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1 RELEASE FUNCTION SPECIFICATION / CHANGE INDEX

Version	Date	Author	Clearance	Changes
0.1	21.03.2018	Markus Mezger	Markus Mezger	First version
0.2	06.02.2019	Markus Mezger	Markus Mezger	Change in some dimensions, addition of weight and updated pictures
0.3	15.05.2019	Rahul Murkute	Markus Mezger	Respiratory test; cleaning and recycling
0.4	24.10.2019	Rahul Murkute	Markus Mezger	General rework
0.5	08.01.2020	Stefan Verbakel	Markus Mezger	General rework of layout, corrections of spelling and content
1.0	12.01.2020	Stefan Verbakel	Markus Mezger	First release

2 REFERENCE DOCUMENTS

Dokument /-herkunft	Version	Datum
First submission by Markus Mezger	0.1	21.04.2015
URS Mora Ellipse	1.0	22.11.2019
FMEA Mora Device	1.0	24.09.2019

3 ABBREVIATION

General Abbrevation

ABS	Acrylnitril-Butadien-Styrol
API	Active Powder Ingredient
CFR	Code of Federal Regulations
COA	Certificate of Analysis
COC	Certificate of Conformation
DIN	German Institute for Standardization
DPI	Dry Powder Inhaler
EN	European Norm
FDA	Food and Drug Association
FMEA	Failure Mode and Effect Analysis
GMP	Good Manufacturing Practice
IEC	International Electro technical Commission
IPPC	International Plant Protection Convention (Euro pallets)
MDPI	Multi Dose Dry Powder Inhaler
PE	Poly Ethylene
POM	Polyoxymethylen
PP	Polypropylen
21 CFR 11	Title 21 Code of Federal Regulations Part 11
URS	User Requirement Specification (Benutzeranforderung)

3.1 Project Specific Abbreviations

Active Ingredient	The part of the formulation with therapeutic effect.
Delivered Dose	The mass of active ingredient received by the patient during a single inhalation. This can also be known as the Emitted Dose.
Device	The fully assembled inhaler (excluding all packaging).
Device Pressure Drop	A pressure drop created through the device by an inspiratory flow rate.
Dose Content Uniformity	The repeatability of the delivered dose during the lifetime of a device and between devices. Abbreviated to DCU.
Fine Particle Dose	The mass of active ingredient with an aerodynamic diameter of 5 microns or less received by the patient during a single inhalation. Abbreviated to FPD.
Fine Particle Fraction	The percentage of delivered dose with an aerodynamic particle size of 5 microns or less. Abbreviated to FPF.
FMECA	Failure Mode, Effects and Criticality Analysis – a bottom up risk management technique / design tool that systematically identifies failures that lead to hazardous conditions.
Formulation	The active ingredient stored in the inhaler and its associated lactose carrier.
FTA	Fault Tree Analysis – a top down risk management technique / design tool that uses hazardous conditions to systematically identify device or system failures.
Inhalation Path	The path of air into and out of the device and into the patient's mouth.
Metered Dose	The mass of active ingredient removed from the bulk reservoir during normal operation or for discrete dose devices - the mass of active ingredient contained in a discrete dose chamber. The metered dose for the capsule device is the capsule itself.

Nominal Dose	The label claimed delivered dose per normal operation, which is equal to the nominal, delivered dose.
Normal Operation	The operation of the device performing all the operating steps in the correct operating sequence and generating a device pressure drop of 4kPa. A 4kPa pressure drop represents a medium resistance inhaler as defined by the EP and USP. Where a low or high resistance inhaler is being specified the pressure drop values will need to be altered accordingly.
Patient	The person who uses the device to receive the formulation.
PIF	Median Peak Inspiratory Flow (PIF)
Particle Size Distribution	The distribution of particle sizes in the delivered dose.
RSD	Relative Standard Deviation = 100 x (Standard deviation / Mean).
Secondary Packaging	All external packaging surrounding the device during pre-sale storage.
Shot weight	The mass of formulation delivered from the device on a single actuation during normal operation.
S.G.	Specific Gravity = density of a substance / density of water at 4°C (1000 kg/m^3).
Specification	A dose is defined as being delivered to specification if its fine particle dose is within ±20% of the fine particle dose during normal operation.

4 INTRODUCTION

This document has been written as a detailed description for a dry powder inhaler (DPI) Mora Ellipse device.
This document contains regulatory requirements and industry standards present at the time of writing. A careful check of all current requirements should be made prior to issuing the specification for a product. Where no regulatory or industry standards exist, Mematec Solutions has used other source materials and its experience of DPI design to set requirements.

4.1 Objective of the document

The objective of this document is to describe the Mora Ellipse dry powder inhaler. It provides the full set of description against which the system will be validated. The basic information of the documents is provided from the valid URS and FMEA.

5 REFERENCED DOCUMENTS

These documents only form requirements to the extent explicitly stated wherever they are referenced in this document.

[ACPS]	Parametric tolerance Interval test for Delivered Dose Uniformity" Advisory Committee for Pharmaceutical Science October 2005
[ADULTDATA]	Adultdata: The handbook of adult anthropometric and strength measurements (Published by Product Safety and Testing Group (PSTG), 1998).
[BATT]	Directive 2006/66/EC of the European Parliament and of the Council on batteries and accumulators and waste batteries and accumulators
[BIO]	Draft Guidance for Industry - Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action: FDA, 2003
[CHILDDATA]	Childdata: The handbook of child measurements and capabilities (Published by PSTG, 1995).
[CHOKING]	BS EN 71-7:2002 - Safety of toys. Finger paints. Requirements and test methods. ASTM F963-07e1- Standard Consumer Safety Specification on Toy Safety.
[CYTO]	ISO10993-parts 1 to 18: 1997-2008 - Cytotoxicity.

[DOSE COUNTER] Guidance for Industry - Integration of Dose-Counting Mechanisms into MDI Drug Products: FDA, 2003.

[DROP] IEC 60068-2-32:1975 Environmental Testing- Tests.Test Ed: Free fall

[ELEC SAFETY] IEC 60601-1 Medical electrical equipment.General requirements for safety.

IEC 60601-1-1 Medical electrical equipment, collateral standard. Safety requirements for medical electrical systems.

IEC 60601-1-4 Medical electrical equipment, collateral standard. General requirements for programmable electrical medical systems

[EMC] IEC 60601-1-2 Medical electrical equipment, collateral standard. Electromagnetic compatibility:requirements and tests

IEC 61000-4-2 2001 Electromagnetic compatibility: Testing and measurement techniques – electrostatic discharge immunity tests

IEC 61000-4-2 2001 Electromagnetic compatibility: Testing and measurement techniques – Radiated , radio frequency, electromagnetic field immunity test.

[EMEA1] Note for Guidance on Dry Powder Inhalers: CPMP, 1998.

[EMEA2] Guideline on the pharmaceutical quality of inhalation and nasal products: CHMP, 2006

[EP] European Pharmacopoeia, Sixth Edition, 2008

[EPAG] Summary of test methods for use and misuse of inhalers: EPAG. Available from www.epag.co.uk/Inuse.htm

[GUIDANCE] Draft Guidance for Industry - Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products: FDA,1998.

[IPAC-RS] A Parametric Tolerance Interval Test for Improved Control of Delivered Dose Uniformity of Orally Inhaled and nasal Drug Products: IPAC-RS, Nov. 2001.

[ISO13485] BS EN ISO 13485: 2003 - Quality Systems - Medical Devices - particular requirements for the application of EN ISO 9001.

[ISO20072]	Draft BS ISO 20072 2007 Aerosol drug delivery devices design verification – Requirements and test methods
[ISO9001]	Quality Systems, BS EN ISO 9001: 2000 (will be updated 2008
[ITI]	ISO10993-1-17: 1992-2007 – Intracutaneous Toxicity or Irritation.
[LABEL]	Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA reviewers: FDA, 2001.
[LIGHT]	BS 2782-5, Method 540G:1995: Methods of testing plastics. Optical and colour properties, weathering. Methods of exposure to laboratory light sources. Open flame carbon-arc lamps.
[MDD]	Medical Device Directive, 93/42/EEC, 1993. Essential requirements Annex 1/93/42/EEC
[PARTICULATES]	"Best Practises for Managing Quality and Safety of Foreign Particles" J Blanchard et al Pharmaceutical Research 24.3 2007 471-479 "Measurement and Identification of Foreign Particles in a QbD Environment Streamlining with Efiicient Analytical Methods" O.Valet and M. Lankers Respiratory Drug Delivery 2008 "Proposal for Foreign Particles Testing in Orally Inhaled and Nasal Drug Products" J. Hart Respitory Drug Delivery 2004
[OLDERADULT]	Older Adultdata: The handbook of Measurements and Capabilities of the Older Adult (Published by PSTG,2000).
[QSR]	Current Good Manufacturing Practice (cGMP) for Medical Devices & In Vitro Diagnostic Products - Quality Systems Regulation, 21 CFR Part 820, FDA, April 2008.
[RECYCL]	ISO 14021:1999 Environmental Labels and Declarations
[ROHS]	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the "Restriction of the Use of certain Hazardous Substances in electrical and electronic equipment"
[Control]	Directive 21CFR 820.30 for US required Design controls
[SENS]	ISO10993-1-17: 1992-2007 – Sensitization.
[USP]	United States Pharmacopoeia 31, 2008.

[VENTILATION]	BS 7272-1:2000 - Writing and marking instruments. Specification for safety caps.
[VIBRATION1]	IEC 60068-2-64: 1993- Environmental testing. Test methods. Test Fh. Vibration, broad band random (digital control) and guidance IEC 60068-2-27: 2008 Environmental testing.Test Ea and guidance: Shock
[VIBRATION2]	IEC 60068-2-6: 2008- Environmental testing. Test methods. Test Fc. Vibration (sinusoidal). IEC 60068-2-7: 1993 - 60068-2-7: 1983 - Environmental testing. Test methods. Test Ga and guidance. Acceleration, steady state. IEC 60068-2-29: 1993 - Environmental testing. Test methods. Environmental testing procedures. Tests. Test Eb and guidance. Bump. US Standards: ASTM D3332-99 (2004)– Standard Test Methods for Mechanical-Shock Fragility of Products, Using Shock Machines. ASTM D3580-95 (2004)– Standard Test Methods for Vibration (Vertical Linear Motion). ASTM D5112-98 (2003)– Standard Test method for Vibration (Horizontal Linear Sinusoidal Motion) Test of Products. Electrical Standards: IEC 60601-1: 2005 Medical Electrical Equipment- Part 1: General Requirements for Safety.
[WEEE]	Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on "Waste Electrical and Electronic Equipment"
[FDA]	Draft Guidance from 22. June 2011. Applying Human Factors and usability engineering to optimize medical device design

6 GENERAL DESCIPTION

The Originator Devices for the development of the capsule device are the "BreezeHaler" from Plastiabe manufactured in Italy for the API "Foradil" and the "HandiHaler" from Boehringer Ingelheim for the API "Tiotropium bromide".
The BreezeHaler is a Low Resistance Device. The HandiHaler is a High Resistance Device. Both devices are designed for capsule size 3. It is a so-called Monodose Inhaler. Both devices have weaknesses. The handling of both devices is not optimal. The BreezeHaler does not work in all orientation positions. Furthermore, the pullback force of the needle of both Devices is done by a spring. Due to cohesive active substances, the capsule is sometimes jammed when the needle is retracted. Therefore the device cannot be used. The de-agglomeration of the powder is better with a horizontally rotating capsule than with a horizontal capsule. Therefore the Mora Ellipse device will have a horizontally rotating capsule.
The impaction, i.e. the separation of active substance and carrier material in the device, is dependent on the respiratory path resistance.

The device is the entry into inhalation for many customers. Compared to an MDPI, a capsule device is an inexpensive alternative to inhalation.
Mematec will develop and manufacture the device itself. Sales will also be handled by Mematec. It is intended to increase the company's profile in order to level the market for the existing inhalers (MDPI).

6.1 Area of Use:

The Device can be used for Tiotropiumbromid (Spiriva), Foradil (Fluticasone) or any other powder blend delivered in capsule size 3.
The Mora Ellipse device is available as a "Low resistant, Medium Resistant and High resistant" Device. The Device is modular built. The Mouthpiece and the Body Base are adapted to the device resistant.
The recommended capsule is the HPMC Capsule of any capsule supplier.

7 PATENTS

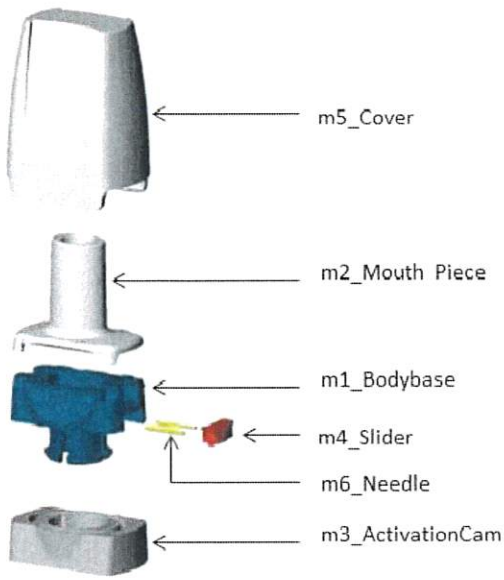
"Geschmacksmuster" 004524205-0001
Basic function: 10 2017 008 238.3
Addition function: 10 2018 008 344.7

Main class: A61 M / A61K9/72 Subclass: A61K31/14

3 Patents are registered:

- Patent no. 1 (No. 004524205-0001) is protecting the design of the Mora Ellispe
- Patent No. 2 (No. 10 2017 008 238.3) is going to protect the basic function of the device
- Patent No. 3 (No.10 2018 008 344.7) is going to protect the orientation and perforation of the device

8 MODULAR STRUCTURE

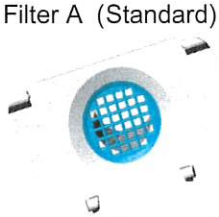


The picture shows the Mora Ellipse device with all components. The device is modular built. Mouth Piece and the Body Base are dedicated to the device resistance. As a variant the Body Base is available for high- medium- and low-resistant.
The Mouth Piece is adapted to the device resistance with the integrated filter.

Standard:
Article type: Mora Low Resistant, MC-P086-50_LR
Article type: Mora Medium Resistant, MC-P086-50_MR
Article type: Mora High Resistant, MC-P086-50_HR

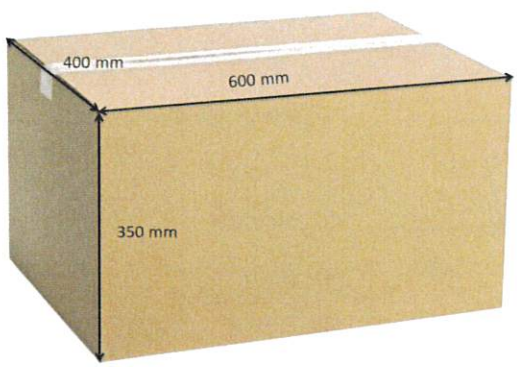
Options:
Engraving, labelling or printing of Cover

Variants: Device Resistance

Device Resistant at 4 kPa Measured without capsules	Filter A (Standard) 	Filter B (Nesat) 	Filter C (High Volume) 
Low resistant Body Base 	106 l/min ± 15% Standard version	95 l/min ± 15%	n.a.
Medium resistant Body Base 	65 l/min ± 15%	62,5 l/min ± 15% Standard version	n.a.
High resistant Body Base 	45l/min±15%	40l/min ± 15%	n.a.

9 PACKAGING

The Mora Ellipse device will be delivered fully assembled in PE-bags. The number of devices per PE-bag is 500. Each PE-bag will be placed in one carton. The Dimension of the standard carton is 35x40x60 cm (dimension can be varied from customer to customer). The weight of 1 filled carton is 17,5 kg.



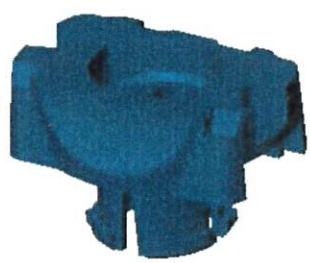
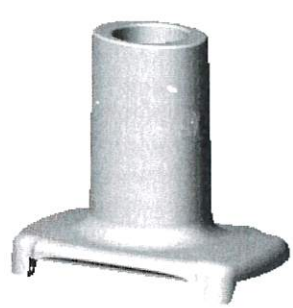
10 SHIPMENT OF THE DEVICE

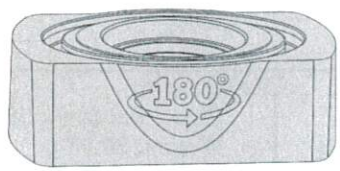
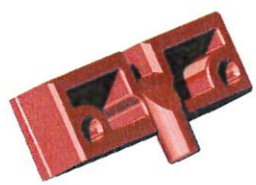
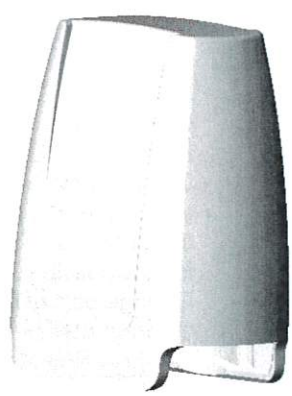
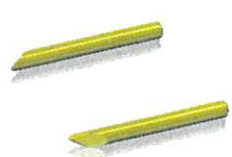
Our Euro pallet complies with the IPPC standard (ISPM15). Up to 16 cartons will be placed on each pallet. The total weight is 26 kg for the pallet plus 280 kg for 8000 Mora.

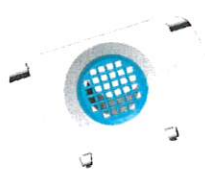
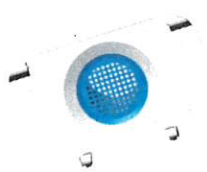
11 STABILITY OF THE DEVICE

The Device and its selected materials are designed for a time of storage under standard conditions of minimum 2 years.

12 DESCRIPTION OF THE DEVICE AND COMPONENTS

Mora Ellipse Device consisting of : 1. Body Base 2. Mouthpiece 3. Activation Cam 4. Slider 5. Cover 6. Needles x2		Description: - Size: 28,9 mm x 58,5 mm 44,61 mm - Weight: 30,46 g - Material: POM/PP/ABS/1.4301 all FDA approved - Tolerances are defined in Mematec parts drawings - Ambient conditions: 23°C ±5 Temperature for the device in use, RH 50%
Body Base with respiratory path in 3 versions: • Low Resistant • Medium Resistant • High Resistant		Description: - Size: 25,1 mm x 27,24 mm x 40,72 mm - Weight: 6,3 g - Volume: 5950,64 mm^3 - Material: ABS - Colour: depending on API: Blue - RAL: 5005 / Green - RAL: 6005 - The Body Base must have a catch. It must lock in the end position of the piercing. A click noise signals the user that inhalation is now possible. - Change part of the Body Base with 3 different device resistors. High, Medium and Low Resistance.
Mouthpiece with filter variants: A: Standard B: Nesat C: High Volume		Description: - Size: 36 mm x 40 mm x 24,99 mm - Weight: 6,2 g - Volume: 5843,4 mm^3 - Material: ABS - Colour: White - RAL: 9003 - Surface polished. - Integrated plastic filter. The mouthpiece must snap securely into the bodybase. - The catch must be torsion-proof. - The mouthpiece must be elliptical to allow intuitive use; with horizontal inhalation position the longest side of the ellipse is horizontal.

Activation Cam		Description: - Size: 12,6 mm x 42,12 mm x 27,24 mm - Weight : 5,2 g - Volume : 4850,72 mm^3 - Material: ABS - Colour: White - RAL: 9003 - Stroke of the groove curve: about 4,3 mm - The pin of the needle must disappear completely in the capsule and in the Body Base. The drill holes of the needle must be closed during inhalation.
Slider		Description: - Size: 15,4 mm x 8,1 mm x 6,13 mm - Weight: 0,56 g - Volume: 277,35 mm^3 - Material Slider: POM - Colour: Red - RAL 3003
Cover		Description: - Size: 57,7 mm x 44,61 mm x 29,80 mm - Weight: 12,2 g - Volume : 11345,66 mm^3 - Material: PP - Colour : White - RAL: 9003 - The Cover has space for fixed and variable data to be printed, labled, engraved or laser batched.
Needles x2		Description: - Diameter: 1,5mm - Length: 15,5mm - Material 1.4301 stainless steel - Weight: 0,18g (x2) - Distance between needles: 12.20 ±0.05 - Mounting depth:3,2mm - Needle length pressed in: 12,3-0.1 - Needle must close tightly in guiding direction to avoid air leakage - Needles must be pressed in at a defined length. - Needles have to be pressed in parallel to each other without any need for intervention. - Needles need a press fit - The needle tips need to be in orientation

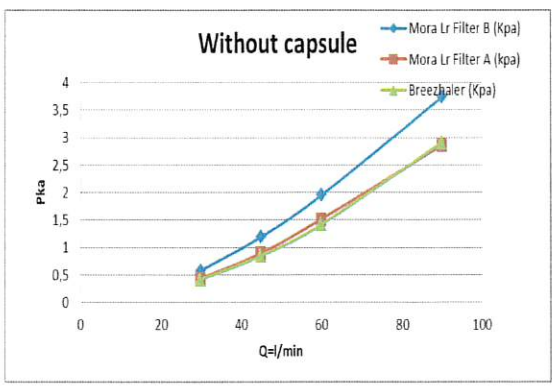
Capsule Capsule size 3		Description: - Hard Gelatin or better HPMC capsules consisting of two parts. Upper part and lower part. The lower part is inserted into the upper part. - Manufacturer: Qualicaps, Capsulgel and ACG Description of the Tolerances Qualicaps: - Tare weight: 50mg ±5mg - Size tolerance: l:15,8mm ±0,3mm (closed) - Outer ø: lower part: 5,56mm upper part: 5,82mm Capsugel: - Tare weight: 49mg ±4mg - Size tolerance: l:15,5mm ±0,3mm (closed) - Outer ø: lower part: 5,57mm upper part: 5,83mm
Filter A: Standard **Filter B**: Nesat **Filter C**: High Volume	  	Description: - Material: Same as mouthpiece - filter is molded together with mouthpiece - Colour : Same as mouthpiece Filter A: Use: standard in Low Resistant device Filter B: Use: standard in Medium- and High- Resistant device Filter C: Use: Backup solution for very cohesive powders

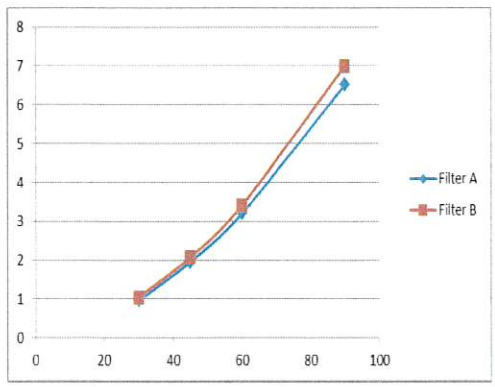
13 RESPIRATORY DEVICE RESISTANT DATA

Device resistant without capsules:

Flow rate [L/min]	Mora lr Filter B (Kpa)	Mora lr Filter A (kpa)	Breezhaler (Kpa)
30	0,53	0,40	0,41
45	1,08	0,80	0,84
60	1,80	1,32	1,41
90	3,67	2,68	2,91

Flow rate [L/min]	Mora hr Filter A (kpa)	Mora hr Filter B (kpa)
30	0,96	1,04
45	1,96	2,07
60	3,21	3,41
90	6,51	6,98

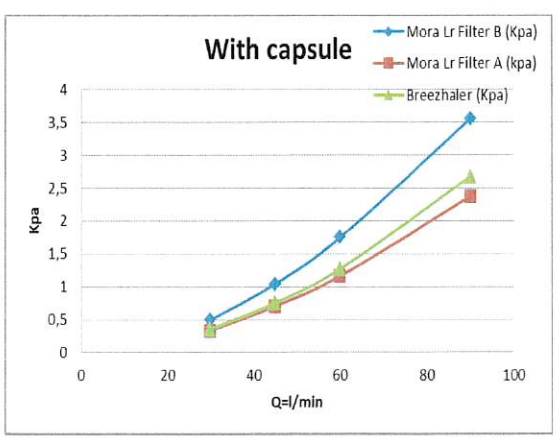


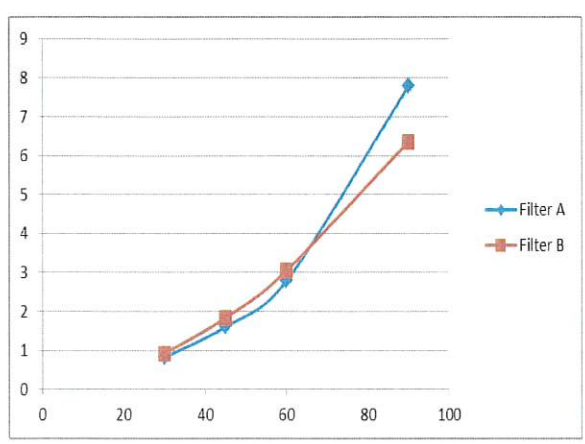


Device resistant with capsules:

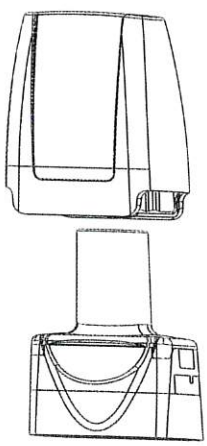
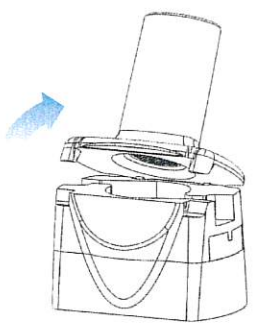
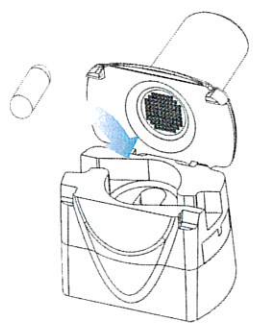
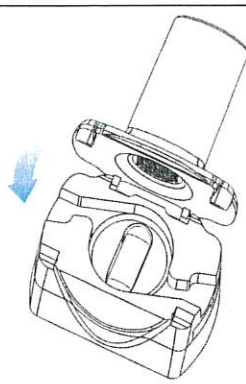
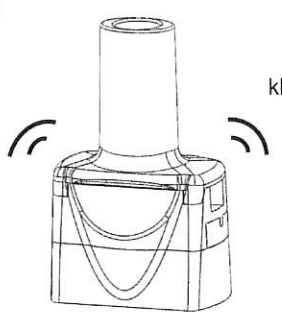
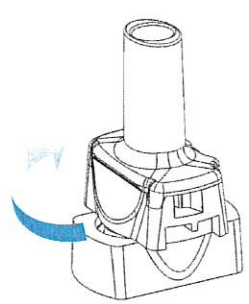
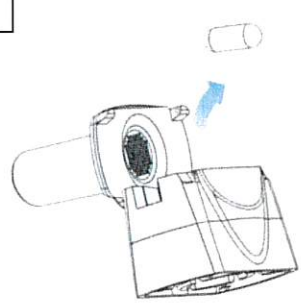
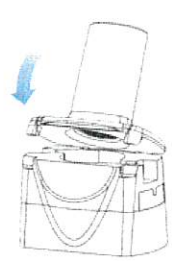
Flow rate [L/min]	Mora lr Filter B (Kpa)	Mora lr Filter A (kpa)	Breezhaler (Kpa)
30	0,48	0,32	0,35
45	0,97	0,65	0,74
60	1,63	1,07	1,27
90	3,35	2,20	2,67

Flow rate [L/min]	Mora hr Filter A (kpa)	Mora hr Filter B (kpa)
30	0,82	0,92
45	1,61	1,84
60	2,79	3,05
90	7,79	6,35





14 USER DESCRIPTION

1  The Cover is pulled up from the device.	2  The Mouthpiece is folded backwards.	3  The capsule is inserted
4  The Mouthpiece is folded back	5  *A "click"* signals that the device is closed.	6  The Body Base is turned 180° (clock- or anti clock wise), the capsule is pierced
7  Ready for Inhalation A clack in the interior signals that the capsule rotates in the interior and thus, the active substance is released.	8  After you finish taking the dose, open the Mouthpiece and throw out the capsule by gravity	9  Close the Mouthpiece and Cover for storage of your Mora Ellipse device

Additional information:

Occasionally, very small pieces of the capsule can get past the screen and enter your mouth. If this happens, you may be able to feel these pieces on your tongue. It is not harmful if these pieces are swallowed or inhaled. The chances of the capsule shattering will be increased if the capsule is accidentally pierced more than once (step 6). Do not pierce the capsule more than once.

14.1 Cleaning and Recycling

Purpose of cleaning your inhaler:

Mora Ellipse has a cleaning instruction for the device to prevent powder build-up and blockage. Below are some basic instructions on how to clean your Mora Ellipse inhaler.

Cleaning instructions:

Step1: Open the Cover of the device

Step 2: Open the Mouthpiece of the device.

Step 3: Look in the center chamber or at the mouthpiece filter for capsule pieces or powder buildup. If seen, tap it out.

Step 4: Rinse your Mora Ellipse device with warm water, by rotating the activation cam for few times so that the center chamber and the piercing needle is under the running water. Check that any powder buildup or capsule pieces are removed.

Step 5: Dry your Mora Ellipse device well by tipping the excess water out on a paper towel. Air dry the device afterwards while leaving the cover and mouthpiece open.

⚠ Do not use a hair dryer to dry your Mora Ellipse device.

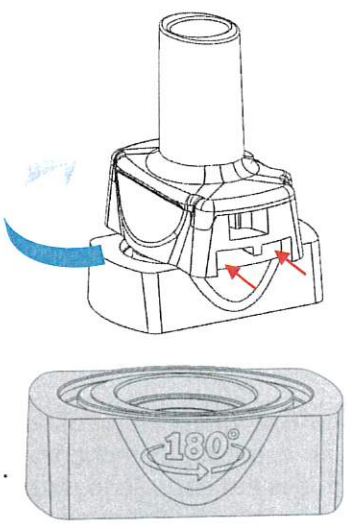
Step 6: Do not use your Mora Ellipse device when it is wet. If needed, you may clean the outside of the mouthpiece with a clean damp cloth.

Disposal or recycling of the inhaler:

All used inhalers should be returned to a pharmacy to be disposed of safely. They can be disposed of by the pharmacist with other drugs waste. This is then thermally treated to destroy the greenhouse gases. This environmentally safe disposal route is available at all pharmacies.

The inhaler provided with each new prescription should be used. The inhaler in each pack should be disposed of after all capsules in that pack have been used. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

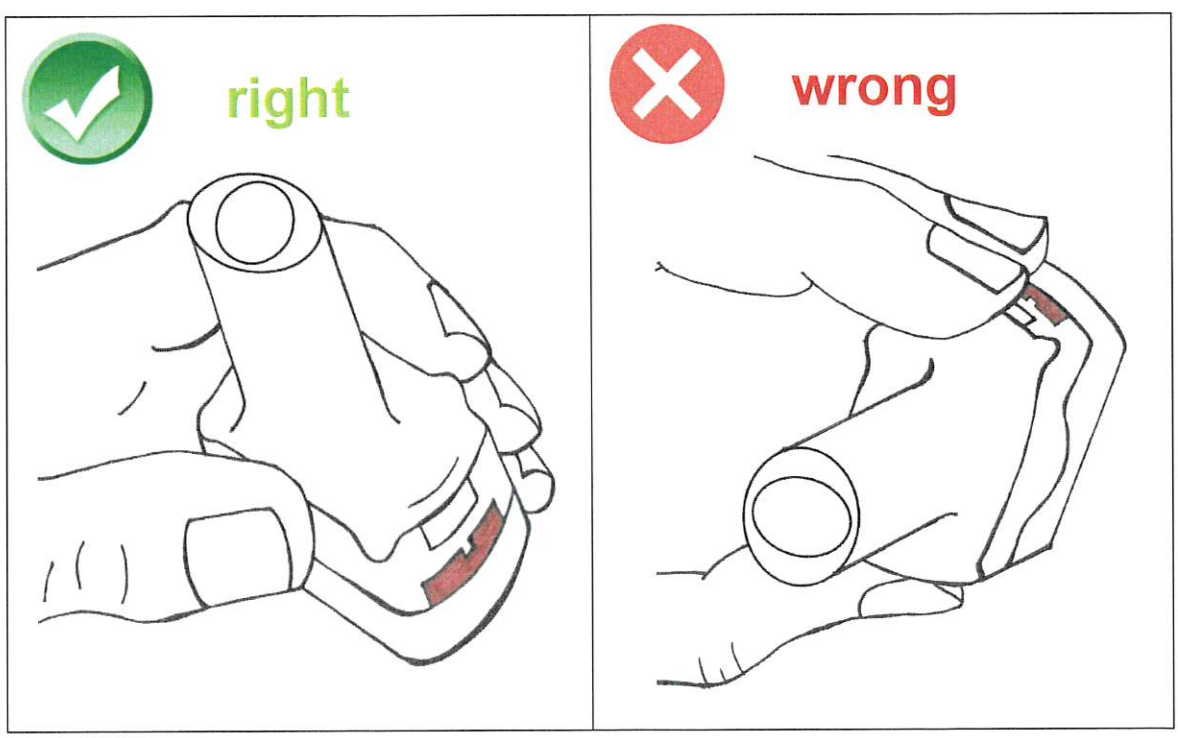
15 FUNCTIONAL DESCRIPTION PIERCING / PERFORATION



The Activation Cam has to be turned by 180°. Both turning directions are possible, clock wise or alternative anti clock wise. During the turn the Slider will be activated and during the activation the capsule will be perforated with 2 needles. Each needle has a diameter of 1,5 mm.

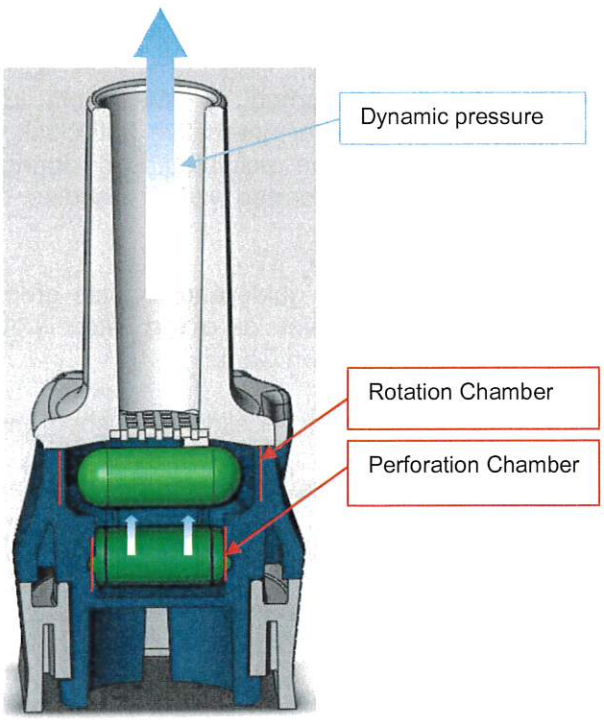
The slider is guided via the needle guide and a guide groove in the Body Base. The cam on the underside of the Slider is guided in the elliptical groove of the Activation Cam.

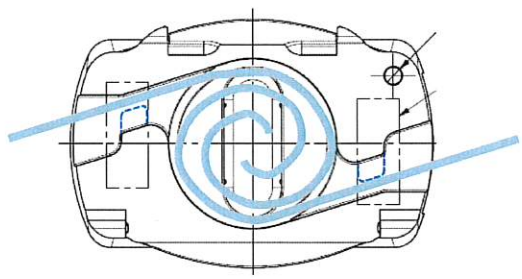
When the Activation Cam is turned, the slider is pushed inwards by the cam in the elliptical groove.
If the slider is pushed inwards, the needles enter the capsule chamber and pierce the capsule.
Between 90° and 180° the slider is brought back into its initial position after piercing.



As shown in the picture above, handling should be done in proper position to avoid air blockage with the fingers. Due to wrong handling air passage will block and there will be no proper inhalation.

15.1 Functional description of Respiration:

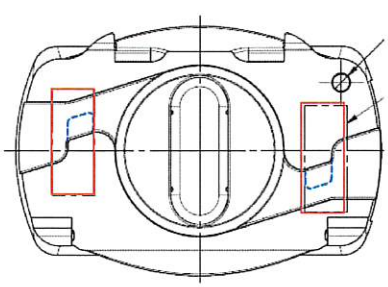




During inhalation, a vacuum is created in the rotation chamber, which lifts the capsule out of the capsule chamber.

The position of the flow channels causes a turbulence of the air in the rotation chamber. This turbulence causes the capsule to rotate. During rotation, the active ingredient powder is pressed out of the capsule and the agglomerates of the powder are destroyed.

15.2 Functional description High / Medium / Low Resistant



The difference between Body Base Low Resistant, Body Base Medium Resistant and Body Base High Resistant lies in the construction of the flow channels.
The Size of the two constrictions (see picture) change the respiratory path.
The constrictions increase the air resistance. More pressure (dynamic pressure / breathing power) is needed to lift the capsule out of the chamber and release the active substance.

16 REQUIREMENTS

The device should be handled in an environment of 18°C to 28°C at 25%R.H. to 75%R.H.
The device can be stored in an environment of 25+/- 3°C at 25% to 50%R.H.

16.1 GMP – Requirements / Hygiene

Device will not require cleaning during normal use. Cleaning of the device is possible using regular clean water
Device will have a Cover to protect the Mouthpiece of dust and dirt
Device will deliver a dose to specification immediately after the patient cleans the device as per cleaning instructions for the device [EPAG]. For example, cleaning the device with a cloth will not leave a static charge on it that would prevent the device from subsequently delivering a dose to specification.

16.2 Environment Protection of the Device

Fulfilled requirements: • Device will be RoHS confirm • Device will be Reach Declaration confirm • Device will be Packaging and Packaging Waste confirm • Device will be WEE- Declaration confirm

16.3 Moisture

Will deliver doses to specification if there is a delay of up to 60 seconds between actuation and inhalation.

16.4 Particulates

The device does not contain any removable parts that may be classified as a choking hazard as defined by the Small Parts Cylinder criterion detailed in [CHOKING].

The device is being designed that after inhalation according to Mematec operation manual and specification, no residual powder remains in the device.

16.5 Quality Systems

Device is, manufactured and distributed in accordance with the following reference documents: [QSR], [ISO9001], [ISO13585], [MDD].
Device is designed accordance with ISO 13485 (Design and manufacturing of medical devices)
Device is designed accordance with MDD 93/42/EWG from (Medical Device Directive)

16.6 Recycling Information

Device has appropriate recycling information marked on product as defined in URS
Device has appropriate colours according to the convention defined in URS

16.7 Manufacturing

Description and requirements of manufacturing the plastic parts:
Plastic parts to be molded in a non-specified clean room
Device is assembled a non-specified clean room.
Plastic parts will be final checked in a non-specified clean room.
Transport of device according to packing specification.
Molding tool material for mouth and product contaminated parts is done in stainless steel.
No lubrication and mold release agent are used for the molding process

16.8 Documents to be delivered

The following documents are available with the device Mora Ellipse.

- Layout Drawing of the device with the dimension
- Plastic Parts of the device with Material Certificates
- Metal parts with Material Specification
- COC
- COA

Operation Manual:

The handling of the device is shown in the handling instruction.
A handling video can be downloaded on the Mematec Solution homepage

Date released: 12.01.2020 **Date of next review 12.01.2021**

created by:	Stefan Verbakel	18.01.2020	Stefan Verbakel
	Mematec Solutions	Date	Signature
approved and released by:	Markus Metze	19.1.2020	
	Mematec Solutions - CEO	Date	Signature