

MydCombi™ Base Unit

Charging Instructions & Safety Manual

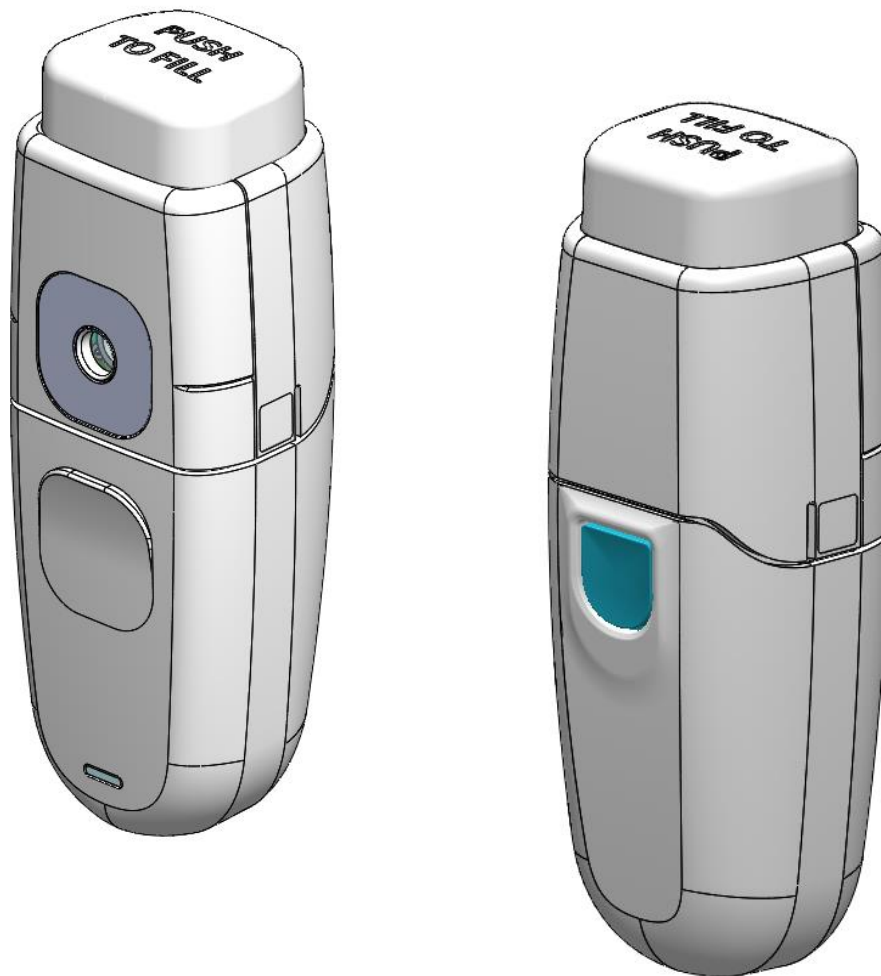


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MydCombi™ Base Unit

Charging Instructions

1. NOTES ON SAFETY:

WARNING	Contains Lithium-Ion Battery
MydCombi™ Base Unit contains a Lithium-Ion Battery. Damage to Base Unit can cause fire. Do not puncture Base Unit. Do not expose Base Unit to excessive heat ($\geq 50^{\circ}\text{C}$). Check with all governing travel bodies (e.g. The Transportation Security Administration) for current requirements before flying.	
WARNING	Do not use after expiration date
Expiration dates are published on the back label for the MydCombi™ Base Unit. Use of Base Units should be discontinued if the expiration date has passed.	
WARNING	Inspect for device damage
Do not use if package has been previously opened or damaged. Do not use the MydCombi™ Base Unit if there is evidence of damage. Doing so could result in injury.	
WARNING	Tampering of parts in the MydCombi™ Base Unit
Do not tamper with or attempt to open up the parts of the MydCombi™ Base Unit. Doing so could cause damage to the unit and result in personal injury.	
WARNING	Risk of usage
Failure to use the MydCombi™ Base Unit in accordance with these instructions could result in complications during dose dispensing. If the MydCombi™ Base Unit has been idling for an extended amount of time, a waste dose shot should be dispensed. The MydCombi™ Base Unit must be kept in the upright position during use.	
WARNING	Risk due to insufficient user training
Training is required prior to use of the MydCombi™ Base Unit. The user should be adequately trained in handling the MydCombi™ Base Unit prior to use. The MydCombi™ Cartridge is designed to solely interface with the MydCombi™ Base Unit. Refer to the MydCombi™ Cartridge instructions for use.	
WARNING	Risk due to battery leakage
If there is any sign of battery leakage, do not use the MydCombi™ Base Unit	
WARNING	Keep Dry
The MydCombi™ Base Unit should not be exposed to water and should be kept dry.	
WARNING	Transportation and Storage
Do not store or transport the MydCombi™ Base Unit where it can encounter sharp or metallic objects.	
WARNING	Risk of electrical leakage
Non-hazardous voltage is present during normal use.	
WARNING	Do not use with other equipment
Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.	
WARNING	Do not use with non-certified USB Charger
Device is intended to be recharged using MicroUSB cable (not included). Use of USB charger other than those specified or provided in the recommended USB Charger list could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.	

CAUTION	For professional use
Federal law restricts this device to sale by or on the order of a physician (21 CFR §801.109(b)(1)).	
CAUTION	Radiation Emission
This equipment emits radiation.	

2. OPERATION:

NOTE: If the packaging is opened or damaged, do not use the contents. Instead, contact Eyenovia at admin@eyenoviabio.com

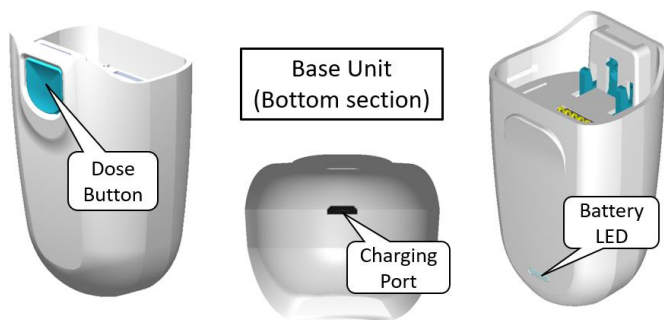
HOW TO STORE the MydCombi™ Base Unit

Store in a secure location at room temperature 59-85°F (15-30°C) away from direct sunlight and excessive heat.

- **Do not** heat or freeze the MydCombi™ Base Unit
- **Do not** get the MydCombi™ Base Unit wet or expose to fluids.
- **Do not** tamper with or attempt to open the parts of the MydCombi™ Base Unit.

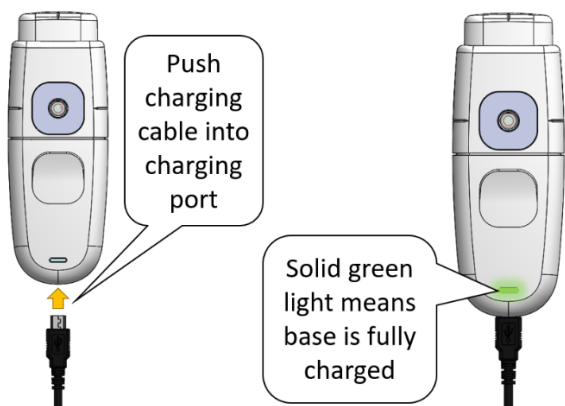
The MydCombi™ Base Unit contains a lithium ion battery¹.

CHARGING the MydCombi™ Base Unit



Before beginning:

1. If packaging is opened or damaged, do not use the contents. Instead, get a new package.
2. A USB Cable is required to charge the MydCombi™ Base Unit.
 - The cable can be connected either to a wall outlet plug or to a USB port.
3. The MydCombi™ Base Unit must be charged before first use.
 - Charging may be performed either before or after cartridge assembly attachment.



Perform these steps to charge Optejet base:

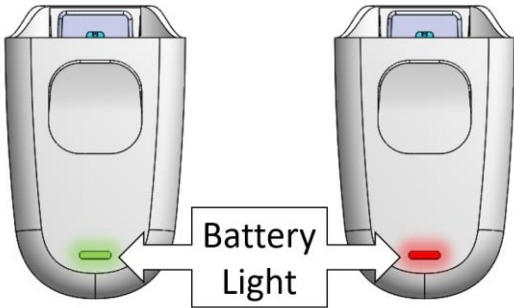
1. Push USB cable into charging port.
2. Connect opposite end of USB cable to wall outlet plug or USB port.
 - Battery light **BLINKS GREEN** while charging.
3. Charge until battery light turns **SOLID GREEN** and remove charging cable from base.

Note: Excessive charging may decrease the battery life. Weekly charging or charging once the LED light starts blinking red (signaling a low battery), is preferable.

MydCombi™ Base Unit BATTERY INDICATORS

	If you see...	It means...
	Mirror Light AND Battery Light SOLID BLUE	Ready to dose
	Battery Light BLINKING GREEN	Battery is charging
	Battery Light SOLID GREEN	Battery is fully charged
	Battery Light BLINKING RED	Battery is low
	Battery Light SOLID RED	Charge MydCombi™ Base Unit
	Mirror Light AND Battery Light BLINKING BLUE	Warning for automatic medicine discharge

¹ Damage to the base can cause fire. Do not puncture base unit or expose to excessive heat (≥ 50° C), Li-Ion batteries may pose environmental and safety hazards and should be disposed of in accordance with all applicable Federal and State Law. Check with all governing travel bodies for current requirements before air travel.

	<p>This happens if you do not use the medicine within 1 minute after it is loaded</p>	
	<p>Mirror Light BLINKING BLUE AND Battery Light BLINKING RED</p> <ul style="list-style-type: none"> - This happens after automatic medicine discharge 	<p>Press Mist Button to reset Dispenser</p>
<p>NOTE: Device does not require maintenance by user.</p>		

3. SPECIFICATIONS:

Parameter	Specifications
Operating power	4.1VDC
Power source	Internally powered, Lithium-Ion Battery
Instrument make / model	Eyenovia / Micro Dose Dispenser (MiDD)
Dimensions	50 length, 120mm height, 40mm width
Weight (system)	< 100g
Allowed operating temperature range	15°C to 30°C
Allowed shipping and storage temperature range	15°C to 35°C at relative humidity of 15% to 90% RH, non-condensing >35°C to 60°C at water vapor pressure up to 50hPa
Allowed operation, storage, and shipping humidity range	15°C to 30°C at relative humidity of 15% to 90% RH, non-condensing
Allowed operation, storage, and shipping atmospheric pressure	700hPa to 1060hPa
Electrical shock protection - Classification / Degree	Internally powered Class I
Product life	1 year
Battery life	2-4 weeks, if used as indicated.
Shelf life	12 months
Software version	Software version number can be found by calling the manufacturer.

Charger Specifications (Micro-USB to USB Cable with Wall Plug):

Parameter	Specifications
Type	Switching Power Supply
Input	100-240V~, 50/60 Hz 200mA
Output	5V, 1A
USB Cable Minimum Requirements	5V, 1A
<p>Must be UL Listed. Must meet US Standard Level VI energy efficiency. Must meet DOE & CEC regulatory requirements.</p>	
<p>Example charging cable is UL number: E178074, Homespot Model S005AYU0500100</p>	

4. EMC COMPLIANCE:

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

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

Note: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the home healthcare environment in a residential area (CISPR 11 Class B), as specified below. The customer or the user of the device should assure that it is used in such an environment. The safety of the device will be ensured, refer to section 2 (notes on safety).		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	
RF emissions CISPR 11	Class B	
Harmonic Emissions IEC 61000-3-2	Class B	
Voltage Fluctuations/Flicker emissions IEC 61000-3-3	Complies	
Guidance and manufacturer's declaration – electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Performance Criteria		
Phenomena of a continuous nature.	Shall operate as intended. Shall be no degradation of performance. Shall be no loss of function.	
Phenomena of transient nature.	Functions shall be self-recoverable. Shall operate as intended after recovering. Shall be no degradation of performance,	
Power interruption exceeding a certain time.	Functions shall be recoverable by the operator. Shall operate as intended after recovering. Shall be no degradation of performance.	
Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines
Surge IEC 61000-4-5 EN/IEC 61000-4-3	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode
Surge IEC 61000-4-5 EN/IEC 61000-4-3	Radiated Immunity 3 V/m, 80 – 2700 MHz 80% AM at 1 kHz & Proximity Fields from RF Wireless Communications Equipment	Radiated Immunity 3 V/m, 80 – 2700 MHz 80% AM at 1 kHz & Proximity Fields from RF Wireless Communications Equipment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°
	Voltage Dips > 95% reduction, 0.5 period	Voltage Dips > 95% reduction, 0.5 period

	At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
	Voltage Dips > 95 reduction, 1 period At 0°	Voltage Dips > 95 reduction, 1 period At 0°
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Max. Power (W)	Distance (m)	Immunity test level (V/m)
385	380 – 390	TETRA 400	Pulse ^{b)} 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ± 5 kHz Deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse ^{b)} 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse ^{b)} 18 Hz	2	0.3	28
870						
930						
1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse ^{b)} 217 Hz	2	0.3	28
1845						
1970						
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse ^{b)} 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse ^{b)} 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because, while it does not represent actual modulation, it would be worst case.

Bluetooth Module		
Designation	Unit	Value
Transmit and receive frequencies	MHz	2402-2480
Antenna(s) & Gain	dBi	Internal Antenna, Gain: 0.5dBi
Transmission power	mW	0.79

Type of Modulation / Data Rate	-	GFSK / 1Mbit/s
Bluetooth FCC ID	-	2A2VJ-EyenoviaGen1

Note: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Recommended separation distances between portable and mobile RF communications equipment and the device, except for the distances indicated in the following table “Immunity to RF Wireless Communications Equipment”.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



5. DISPOSAL:













WARNING	Contains Lithium-Ion Battery
Lithium-Ion Batteries may pose environmental and safety hazards and should be disposed of in accordance with all applicable Federal and State law.	
WARNING	Electronic Equipment
Base Unit should be properly disposed of in accordance with all applicable State and Federal law.	

6. REPORTING TO MANUFACTURER AND AUTHORITIES:

If a serious incident occurs in connection with this medical device affecting the operator or another person, the operator (or person responsible) must report this serious incident to the manufacturer or seller of the medical device.

7. SYMBOLS USED IN LABELS ON THE MIDD BASE:

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	CAUTION, CONSULT ACCOMPANYING DOCUMENTS		USE BY (YYYY-MM: YEAR-MONTH)

	SEE INSTRUCTIONS FOR USE		ELECTRONIC EQUIPMENT. DO NOT THROW IN TRASH.
	CATALOG NUMBER		NON-STERILE
	BATCH CODE		KEEP DRY
	QUANTITY		LITHIUM ION BATTERY - TO BE APPROPRIATELY RECYCLED
	DATE OF MANUFACTURE (YYYY-MM : YEAR-MONTH)		MANUFACTURER
	WARNING: ELECTRICITY		CAUTION: FEDERAL LAW RESTRICTS THIS PRODUCT

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