

Type:	UES06WV UES06WNCP
Model:	UES06WV-050100SPA UES06WNCP-050100SPA
Power Input:	100 - 240 V / 50 – 60 Hz
Power Output:	5 VDC / 1000 mA
Internal Battery	
Type:	Secondary Battery
Chemistry:	Li-ion Polymer Battery
Capacity:	1350mAh

9.2 Aerosol characteristics

The particle size and output rate of the FOX MOBILE were measured according to EN 13544:2007+A1:2009 Respiratory therapy equipment – Part 1: Nebulising systems and their components. The stated values may not be valid for medications with high viscosity or suspensions. In these cases please gather information from the medication supplier. Aerosol data are available from Vectura upon request.

Aerosol Output Rate: ¹	>0.24 ml/min
Mass Median Aerodynamic Diameter MMAD ² :	4.91 µm

9.3 Accessories and Spare Parts

Description	Reference number
FOX MOBILE Inhalation Set	08CD0004

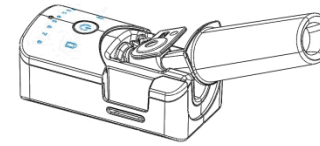
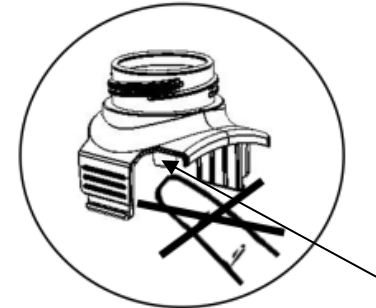


Figure 4: Attach the Mouthpiece to the FOX MOBILE Base Unit. The mouthpiece must be latched into the base unit.



Caution: Do not touch the metal parts (membrane), as it may be damaged easily.

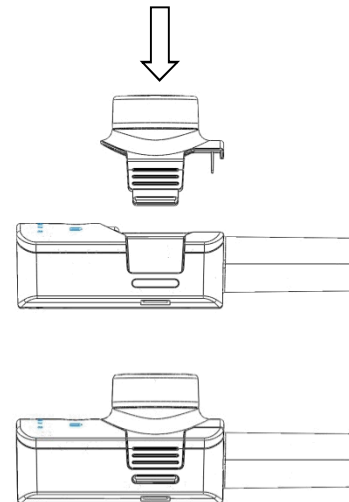


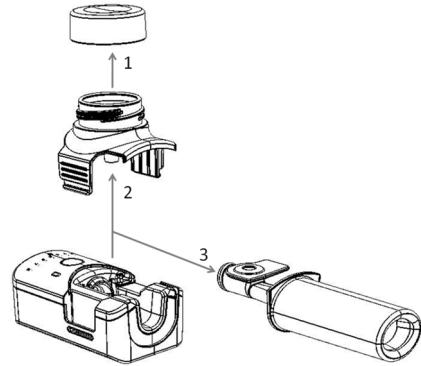
Figure 5: Attach the Nebuliser Reservoir to the Base Unit. Ensure the arms are clipped in place on both sides.

Figure 6: Fully assembled device.

¹ Filling: 2 ml Sodium fluoride dilution 1,0 %, Flow rate: 12 l/min

² Filling: 3 ml Sodium fluoride dilution 2,5 %, Flow rate: 15 l/min

6.3 Disassembly



*Figure 7: Disassembly instructions:
1. Remove the Nebuliser Reservoir
2. Remove the Mouthpiece*

Caution: The FOX MOBILE Base Unit must not become wet. Do not disassemble the FOX MOBILE Base Unit.

6.4 Switching ON / OFF

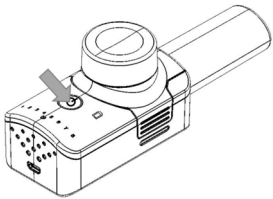
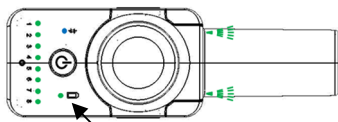


Figure 8: On/Off key



Power LED

Figure 9: Auto-test procedure

- Press the On/Off key.
- Wait for the device to perform the auto-test. All LEDs are illuminated during the auto-test.
- The auto-test is finished when only the power LED is illuminated. The FOX MOBILE clicks twice at the end of the auto-test.

Caution: Do not inhale during auto-test.

9 Technical data

9.1 General

FOX MOBILE Base Unit

Minimum Fill:	0.1 ml
Maximum Fill:	4.0 ml
Inhalation Flow:	15 l/min
Weight:	128 g
Dimensions (WxHxD):	154 x 55 x 51 mm
Sound pressure level:	<80 dBA
Electrical Protective Class:	II Type BF
Ingress Protection:	IP22

Solid particle protection:
Protected against fingers or
similar objects > 12.5 mm

Liquid ingress protection:
Protected against dripping water
when tilted at 15°

Charging interval:	Weekly
FCC ID	QOQWT12

Charger

Manufacturer:	XP Power LLC
Type:	VER05 VEL05
Model:	VER05US050-UB VEL05US050-EU-UB
Power Input:	100 - 240 V / 50 – 60 Hz
Power Output:	5 VDC / 900 - 1000 mA

Charger (Alternative)

Manufacturer:	UE Electronics
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Error	Possible Causes and Solution
Wireless Communication	
The wireless connection LED is flashing quickly and the Mouthpiece LED is orange. The device turns off.	<ul style="list-style-type: none"> As described in section 7.4, FOX MOBILE has the capability to connect to an App via Wireless Connection, however this feature is currently not available. If the Wireless Connection mode is ON, turn the device OFF and back ON again.

If after following these instructions the error persists, contact your clinic or study centre, who will contact Vectura at fox.mobile@vectura.com immediately.

8.2 Hardware reset

If the device does not respond to any key pressing, a hardware reset may be required. In order to do a hardware reset, press the “On/Off” key and the “inhalation time” key simultaneously. Use a pen to press the “inhalation time” key. The configuration of your FOX MOBILE is not changed. Make sure that the device is charged, a reset will not work if the battery is fully depleted.

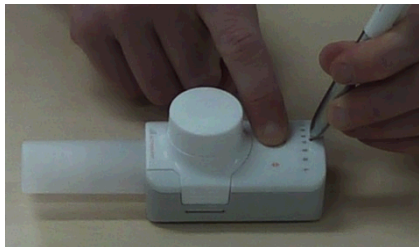











Figure 15: Press the “On/Off” key and the “inhalation time” key simultaneously using a pen to press the “inhalation time” key.

The next time you turn your device on the reset will take effect.

Caution: If the Mouthpiece LED flashes orange  and the base unit beeps, refer to section 8.

- Keep the On/Off key pressed for 2 seconds to switch the FOX MOBILE off.

The following table shows the different light modes while switching the device On/Off:

Name	Colour	Indication
Inhalation time LED		Green: Device is switched ON
		Green flashes (once): Device performing auto-test and the selected treatment time is showing
Charging LED		Green: Device performing auto-test and it is fully charged
		Constant orange: Device performing auto-test and needs to be charged within the next day
		Flashing orange: Device performing auto-test and needs to be charged before the next treatment
Mouthpiece LED		Green flashes (once): Device switched ON
		Green permanent: Device performing auto-test
Wireless Connection LED		Blue: Device performing auto-test

6.5 Hygienic Preparation and Maintenance

6.5.1 General

To avoid risks to health from a contaminated device, it is essential to comply with the following hygiene rules:

- Only use a device which has been cleaned according to section 6.5.2 Cleaning.
- Replace the FOX MOBILE Inhalation Set after service life is completed. Refer to section 9.4.

Caution:

- Ensure adequate drying after cleaning. Condensation or residual moisture can present an increased risk of bacterial growth.
- Check the parts of your nebuliser regularly and replace any defective (broken, deformed or discoloured) parts.
- If several medications are to be inhaled in turn within the scope of inhalation treatment, remove the remaining medication solution from the nebuliser and rinse it briefly with distilled water.

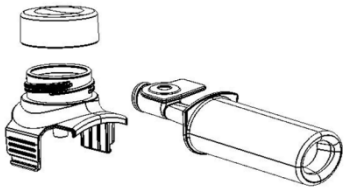


Figure 10: Parts, which require cleaning: Nebuliser Cap, Nebuliser Reservoir and Mouthpiece.

6.5.2 Cleaning

Warning: Do not use a dish washer or steriliser to clean or disinfect this device.

Follow the instructions below to clean and disinfect the device.

Inhalation Set Cleaning - Step 1: Rinse immediately after use

Disassemble the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece from the device. Remove visible dirt. Rinse the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece with distilled water for a minimum of 20 seconds. When rinsing the Nebuliser Reservoir make sure that all remaining medication is removed.

Inhalation Set Cleaning - Step 2: Full Cleaning Procedure for Inhalation Set immediately after rinsing:

- Fill a clean bowl with distilled water (room temperature). Add standard manual washing-up liquid to the water. Use a concentration as specified by the manufacturer of the washing-up liquid.
- Place the Nebuliser Reservoir, Nebuliser Cap, and Mouthpiece into the cleaning solution. The components need to be fully submerged. The opening of the Nebuliser Reservoir needs to face upwards. Make sure that the components do not touch the membrane.

Error	Possible Causes and Solution
It is not possible to change the inhalation time.	<ul style="list-style-type: none"> • Reset the device (section 8.2) • Device error: Contact support
During treatment	
The Mouthpiece LED flashes orange.	<ul style="list-style-type: none"> • Release the Mouthpiece at exhalation phase as described in section 7.2. • Make sure that you do not try to exhale into the device at the end of an inhalation. • Make sure that you do not exhale into the device before starting an inhalation. • If the inhalation time of each single breath is too long or too short, please adjust the inhalation time according to instructions section 7.3, if permitted. • Make sure that the Nebuliser Reservoir and Mouthpiece are correctly attached.
The Mouthpiece LED is constant orange.	<ul style="list-style-type: none"> • Make sure that you do not inhale too fast according to instruction section 7.2
The Mouthpiece LED is constant orange and device switches into charging mode.	<ul style="list-style-type: none"> • During inhalation charging is not possible. Note: You cannot charge the device while taking a treatment.
Longer than usual treatment time. Drug in mouthpiece.	<ul style="list-style-type: none"> • Check whether the nebuliser membrane at the Nebuliser Reservoir is damaged (i.e. the drug is leaking directly into the mouthpiece). Replace the Nebuliser Reservoir if necessary, and contact support if you do not have a replacement Nebuliser Reservoir.

Error	Possible Causes and Solution
The device does not trigger and does not respond to keys.	<ul style="list-style-type: none"> • Make sure the device is charged. See section 6.1 for charging instructions. • Reset the device (section 8.2) • Device error: Contact support.
Mouthpiece LED flashes orange and all inhalation time LEDs are illuminated. Device shuts off after showing the error.	<ul style="list-style-type: none"> • Ensure that the device is used within the allowed temperature range (refer to chapter 9.5.1 “Environmental Conditions for use”). Allow a few minutes for the device to acclimatize, when transferring from hot or cold conditions. • Contact support if the error persists.
After switching on	
The device beeps, the Mouthpiece LED flashes orange and the device shuts off.	<ul style="list-style-type: none"> • Check whether the Nebuliser Reservoir is properly connected to the device. If it is not properly connected, connect it according to section 6.2 and restart the device. • Check whether the Nebuliser Reservoir is filled. If it is empty (and you have not just completed a treatment), fill the Nebuliser Reservoir according to instructions in section 7.1 and restart the device. <p>Note: when you restart your device an auto-test will be repeated. Do not try to inhale during the auto-test.</p>
The Mouthpiece LED turns orange and the device changes into charging mode.	<ul style="list-style-type: none"> • Disconnect Charger. <p>Note: You cannot charge the device while taking a treatment.</p>

- Leave the components in the solution for a minimum of five minutes and agitate gently. If necessary use a soft dish cloth and wipe carefully the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece with exception of the membrane.
- Rinse all components with distilled water for at least one minute. Pay attention that the inside of the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece is rinsed intensively.
- Shake all components thoroughly to remove excess water, paying attention to areas where moisture may be trapped.
- The cleaning procedure is complete. After you have cleaned the components, continue with drying. Please refer to chapter 6.5.3 Dry the components.

Base Unit Cleaning:

- To clean the FOX MOBILE Base Unit, wipe the exterior of the housing with a damp cloth or a disinfecting cloth.

Caution:

- Do not touch the membrane or try to clean it with a brush or any other object, as it can be easily damaged.
- Use standard washing-up liquid (for manual washing-up, neutral pH between 6 and 8) without disinfection properties and without skincare additives (e.g. balsam).
- Use the recommended dilution as specified by the manufacturer of the washing-up liquid.
- Use of other cleaning detergents may damage the device (e.g. disinfectants, detergents with skin care additives and detergents to be used in dishwashers)
- Do not use tap water as any calcification can damage the Nebuliser Reservoir and reduce its service life
- The FOX MOBILE Base Unit must not become wet. Do not disassemble the FOX MOBILE Base Unit.
- Ensure FOX MOBILE is rinsed immediately after use.
- Do not use any methods for cleaning or disinfection other than those described here.

6.5.3 Dry the components

To dry the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece follow these steps:

- To remove left-over water, gently shake the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece.
- Tap the front end of the Mouthpiece carefully on a clean, dry and lint-free paper towel to remove left-over water.
- Press the back end of the Mouthpiece carefully on a clean, dry and lint-free paper towel to remove left-over water from the filter.

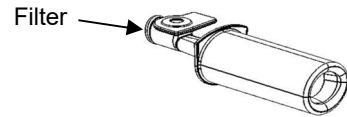


Figure 11: Filter

- Put the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece on a clean, dry and lint-free paper towel.
- Let the components dry adequately overnight, if possible.

Your device is now ready for the next treatment or for storage and transportation. For more details on how to store or transport the FOX MOBILE read chapter 6.5.4

All components must be dry after rinsing, cleaning and disinfection.

6.5.4 Disinfection

Disinfect the Nebuliser Reservoir and Mouthpiece after 7 days of use or 21 treatments, whichever comes first. Do not disinfect the Nebuliser Reservoir and Mouthpiece more than once during its service life. Refer to section 9.4 for details.

The components should be cleaned after every use and before disinfection. Refer to section 6.5.2 for details on how to clean FOX MOBILE.

Caution: Do not boil for longer than 10 minutes to prevent damage to the Nebuliser Reservoir and mouthpiece.

 **Warning:** Do not attempt to disinfect the Base Unit.

Caution: Do not use tap water as any calcification can damage the Nebuliser Reservoir and reduce its service life.

In order to disinfect the Nebuliser Reservoir and Mouthpiece, complete the following steps:

- Fill a pan with distilled water at room temperature

- If you hear the device “click” and the mouthpiece flashes orange while you are still inhaling, you have inhaled longer than intended.

Note: The adjusted inhalation time is stored even when you turn the device On/Off and this setting will be used on your next treatment.

7.4 Wireless Connection

Note: FOX MOBILE has the capability to connect to an App via Wireless Connection, however, this feature is currently not available.

Should the Wireless Connection light illuminate, refer to section 8 for troubleshooting.

8 Troubleshooting

8.1 Error Messages

Error messages are related to different light modes. Refer to sections 6.1, 6.4 and 7.2 for the different light modes.

Error	Possible Causes and Solution
General	
Charging LED is continuously orange	Low battery power: Charge the device after next treatment. When the charging LED is orange, the FOX MOBILE should be charged within the next day. See section 6.1 for charging instructions.
Charging LED flashes orange	Very low battery power: Charge the device before taking a treatment. See section 6.1 for charging instructions.
Device cannot be switched on. No LEDs light up.	<ul style="list-style-type: none"> • Battery is fully depleted: Charge the device before taking a treatment see section 6.1 for charging instructions. • If battery does not recover and error still remains contact support.

- Make sure that aerosol does not escape through your nose and do not inhale additional air through your nose during inhalation. If necessary, use a nose clamp.

7.3 Setting the Inhalation Time

The inhalation time can be adjusted in 0.5 seconds intervals between 1 second and 8 seconds. For the first use of the device set the inhalation time defined by your attending physician.

To change the inhalation time, use the tip of a pen as shown in Figure 13 and increase the inhalation time by 0.5 seconds. The eight inhalation time LEDs show the set inhalation time.

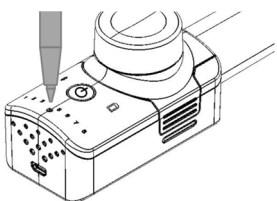


Figure 13: Use the tip of a pen to change the inhalation time.

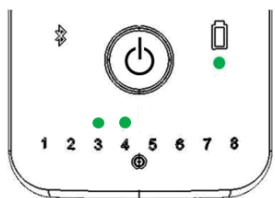


Figure 14: Example setting with an inhalation time of 3.5 seconds.

Whole second intervals are indicated by one light over one digit and half second intervals are indicated by two lights over two digits, as represented in Figure 14 where digits 3 and 4 are indicated, meaning that the inhalation time is set to 3.5 seconds.

Reduce the inhalation time if:

- You stop inhaling and then hear the device “click” and the mouthpiece flashes orange, you have inhaled for a shorter duration than intended.

Note: The inhalation time will always increase towards the 8 second setting, before returning back and beginning again at 1 second.

Increase the Inhalation time if:

- You realise that you could easily inhale for a longer time, or

- Place the Nebuliser Reservoir, Nebuliser Cap and Mouthpiece in the pan, ensuring they are fully submerged
- Put the pan on the stove
- Turn on the heat and allow the water to reach boiling point with the components in it
- Boil the distilled water with the Nebuliser Reservoir and Mouthpiece for 10 minutes.
- Turn off the heat
- Place the pan on a heat-proof surface
- Use tongs to remove the components from the pan
- Place hot components on a clean, dry, lint-free paper towel
- Let the components cool down for 10 minutes

Caution: Do not touch the hot components or boiling water. As this can lead to serious scalds.

After disinfection is complete, allow the components to dry. Refer to section 6.5.3 for detail on how to dry the Nebuliser Reservoir.

6.5.5 Storage and Transportation

The FOX MOBILE Inhalation Set must be cleaned and dried before storage (refer to section 6.5.2).

For storage and transportation:

- Store and transport the Base Unit, Nebuliser Reservoir, Nebuliser Cap and Mouthpiece in the carry case.
- Store the carry case with the components in a dry and dust-free environment.
- Do not store the carry case with the components in direct sunlight.

Store and transport the components within the temperature range described in section 9.5.2.

7 Operating instructions

7.1 Fill the Nebuliser Reservoir

Before every treatment, check that the FOX MOBILE is correctly assembled and the air inlet slots at the back of the FOX MOBILE Base Unit are not blocked.

- Disconnect the Charger from the FOX MOBILE Base Unit.
- Assemble the device according to section 6.2.
- Remove the Nebuliser Cap.

- Fill the Nebuliser Reservoir with the quantity of medication prescribed by your physician.
- Close the Nebuliser Cap
- Continue with the Inhalation immediately.

Caution:

Please ensure that the medication level is below the rim at the top of the Nebuliser Reservoir. If it has been overfilled, discard the complete filled medication and clean the nebuliser (see section 6.5). Once clean and dry, re-start the filling steps.

7.2 Inhalation

The device will guide you to achieve an optimal inhalation flow rate to achieve good lung deposition, via the lights in the mouthpiece.

- Green full brightness: Optimum inhalation speed
- Green lower brightness: Incorrect inhalation speed, try to inhale faster or more slowly. Full brightness indicates the optimum inhalation speed
- ⚠ Orange flashing: If the mouthpiece flashes orange, you have inhaled longer or shorter than intended. Refer to troubleshooting section 8
- ⊘ Green flashing (5 seconds): End of treatment

Note: LEDs will appear more clearly when the device is used out of direct sunlight.

In order to start your treatment:

- Switch the device on.

Caution:

While switching on the device, the Mouthpiece shall not be placed in the mouth. The Mouthpiece shall not be blocked.

Caution:

Keep the device horizontal during inhalation.

- Sit in a relaxed and upright position.
- Place the mouthpiece between your teeth and enclose the mouthpiece with your lips.

- Inhale slowly through the Mouthpiece. The air channel opens and you will hear a click. While inhaling, watch the mouthpiece LED to ensure correct inhalation speed.
- When you have reached the end of the chosen inhalation time, the air channel will close (with a clicking sound). Inhale until you feel the inhalation channel has closed.

Note: If you cannot comfortably reach the end of the inhalation time when the air channel closes, you should consider reducing the inhalation time setting, as described in section 7.3. If you can comfortably reach the end of your inhalation time, you can consider extending your inhalation time setting.

- Remove the Mouthpiece from your mouth and exhale normally through your mouth or nose.



Figure 12: Inhalation

Caution: Do NOT exhale into the mouthpiece.

- You can pause for breath between inhalations, if necessary. The FOX MOBILE will stay active for 5 minutes and you can continue your inhalation at any time during this time period. Try not to pause longer than 5 minutes between inhalations. In case the FOX MOBILE has switched off, press the ON/OFF key to continue the inhalation session.
- Continue with inhalation until the device flashes slowly green to indicate that the treatment has finished.
- The FOX MOBILE switches off automatically at the end of the treatment.
- Proceed with section 6.5 hygienic preparation and maintenance.

General advice during treatment:

- Place the Mouthpiece between your teeth and enclose it completely with your lips.
- Do not block the Mouthpiece with your tongue during inhalation.