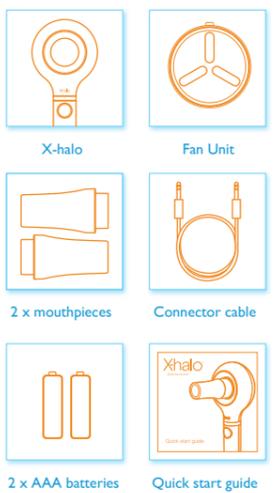
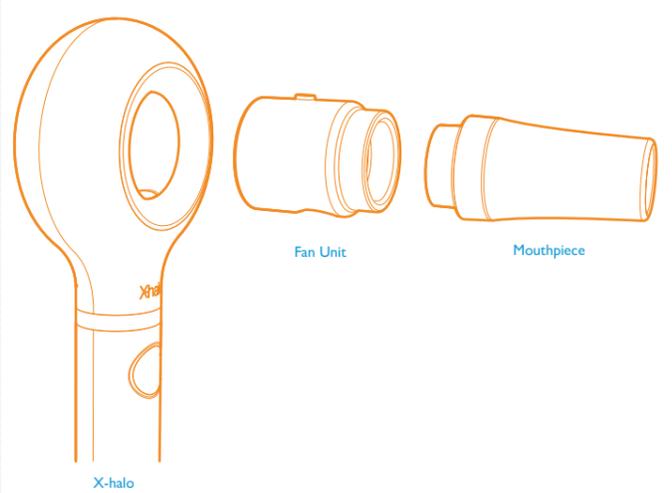


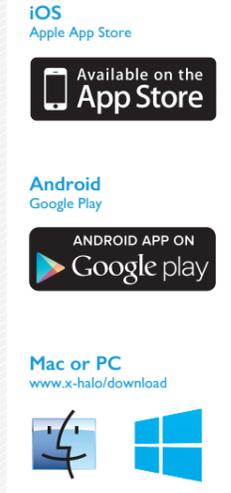
## 1 Open the box



## 2 Assemble your X-halo



## 3 Download the app



## 4 Get Started!



Need help? Go to [www.x-halo.com/quickstart](http://www.x-halo.com/quickstart)



### WELCOME

Welcome to X-halo, the future of home asthma management. X-halo allows you to track airwayinflammation (AI) levels quickly and easily at home in just a few minutes per day.

Three out of four asthma attacks are preceded by increased airway inflammation levels which until now were almost impossible to detect at home.

X-halo when used correctly on a daily basis as part of your asthma management routine, will revolutionise the way you manage your asthma at home.

### INTENDED USE

The X-halo™ Breath Thermometer is a medical device intended for the measurement of Exhaled Breath Temperature (EBT) and aids in the management of airway inflammation in conjunction with the actions and prescription(s) of the physician.

### INDICATIONS

The essence of the technology is a controlled environment where a thermal sensor measures the temperature of the air at each exhalation until equilibrium. To use the device, the user inhale through the nose and exhale through the mouth into the device via a mouthpiece.

The non-invasive device is to be used on a daily basis as part of a lifestyle routine. The user is not to consume any drugs based on the results of the measurement of EBT without consulting a qualified physician. The device is reusable and has to be cleaned and disinfected before each usage.

The medical device is for use in the management of airway inflammation in asthma.

### A. Specifications

Power supply: 2 AAA batteries  
 Battery life: 120 measurements or 2 months under normal use  
 Connections: Connects to your smart phone, tablet, PC or Mac through an audio jack  
 App: Available free from the App store or google play and downloadable from [www.X-halo.com](http://www.X-halo.com) for your PC or Mac  
 Measurement: Range: 25-42°C  
 Accuracy: Sensor accurate to 0.1°C in the temperature range specified  
 Storage: Temperature range: -20- 60°C; Humidity range: 10-90%RH  
 Usage: Temperature range: 10-35°C; Humidity range: 30-80% RH  
 Characteristics: Non-predictive, no measurement offset and no calibration necessary

### B. Contraindications

High AI readings can also occur under the following circumstances

- Fever caused by urinary or digestive tract infection.
- Strenuous exertion (such as running) just before performing the measurement.
- Prolonged exposure to high temperatures (you should wait for at least 1 hour in a cool environment before taking your measurement.
- Ingestion of high calorific value foods (chocolates, fizzy drinks, etc). You should wait for at least 1 hour to take your measurement.

### C. Measurement

- You should be sitting down comfortably.
- Inhale through your nose until your lungs are completely full of air then breathe out gently until your lungs are completely empty. Keeping your mouth to the nozzle at all times.
- Repeat this process for the WARM UP phase and the MEASUREMENT phase until X-halo tells you that your measurement is complete.

### D. Power on & off modes

- Press the power button once for less than 1 second to power on X-halo. Only do this once the fan unit has been inserted unless you are cleaning the sensor.
- If you want to enter CLEAN mode power on X-halo by pressing the power button for more than 2 seconds. Make sure that you only do this WITHOUT the fan unit installed. The temperature sensor stalk will be raised to allow for cleaning. To take a measurement you must power off the device by holding the power button down for less than 1 second the LED will blink rapidly, insert the fan unit and power up the device again.

- If X-halo has not been used for 90 seconds the device will go into sleep mode, all of the LEDs will be switched off except for the power button LED which will pulse.
- To power on from sleep mode, press power button once for less than 1 second.
- If the X-halo is not used for a further 30 seconds it will go into power off mode, the temperature sensor stalk will be lowered and all LEDs switched off.

### E. Getting Started

1. Assembly

- Open the battery compartment of X-halo and insert two AAA batteries.
- Align nub on fan unit with groove on the X-halo and push until a click is heard.
- Attach nozzle to the fan unit.
- Attach one end of the connector cable to your smart phone, tablet or computer and the other to the X-halo. DO NOT turn the X-halo on yet only do so when you have registered.

### 2. Downloading the app

- Make sure that your smart phone, tablet or computer is connected to the internet. Now go to the app store (Apple products), Google play (for Android products) or to our web-site [www.X-halo.com](http://www.X-halo.com) to download the PC or Mac version of the application and download the X-halo app. IMPORTANT your X-halo will not work without this.

### 3. Registration

- The app will guide you through the registration process. It consists of a personal information section and an asthma questionnaire.

### 4. Baseline

- X-halo needs to know your normal baseline AI so that it can accurately track the changes in this level.

### F. Tracking your AI with X-halo

5. Measurement

- X-halo recommends that you measure your AI, every day, once a day before breakfast.

### 6. Interpreting Results

- X-halo will analyse your AI reading and give you several traffic light based explanations

**Red:** Your AIR is high, if it remains high for 24 hours see your physician and or follow your AAP. Caution if you have symptoms of a digestive tract infection or a urinary tract infection, this may cause your AIR to be raised due to an increase in your core body temperature. Visit your physician and inform him of your symptoms.

**High Yellow:** Your AIR is higher than normal, if it remains high for 48 hours see your physician and or follow your AAP. High Yellow AIR readings could be caused by mild inflammation of your airway lining or by other factors such as, exertion before taking your measurement or ingestion of high calorific value foods or drinks.

**Low Yellow:** Your AIR is lower than normal, if it remains low for 48 hours see your physician. Low AIR readings can be caused by a build up of mucous within your lungs, this normally follows inflammation of the airway lining.

**Green:** Your AIR reading is normal, it is within 2 standard deviations of your ten point moving average (95% confidence level).

### 7. Charts & reports



## Instructions for Use

### G. Cleaning and care of X-halo

8. After taking a measurement remove the nozzle and fan unit. Clean by rubbing the parts with a soft cloth which has been immersed in a solution of warm water and mild disinfectant or 70% ethyl alcohol. Make sure that both parts are dry for the next measurement.

### 9. For disinfection see the table below

Disinfectant	Dilution with water	Method
Ethanol	70 - 80%	wipe with probe with a cloth moistened with the disinfectant
Isopropyl Alcohol	70 - 90%	
Glutaraldehyde	0.5 - 2%	
Alkylpolyaminoethyleglycine	0.05 - 0.2%	
Benzylkonium Chloride	0.1%	
Benzathonium Chloride	0.1%	immerse the probe for 30 minutes
Gluconate Chlorhexidine	0.1 - 0.5%	
Sodium Hypochlorite	0.02 - 0.05%	

10. The sensor can be gently cleaned by rubbing with a soft cloth which has been immersed in 70% ethyl alcohol.

11. The X-halo should not be immersed in water at any time.

12. The X-halo although robust is a precise medical device and so should be treated with care.

13. Children under the age of 12 should only use the device under the supervision of an adult. Each nozzle contains a one way valve, if this valve breaks or stops functioning you should purchase a new nozzle.

### H. Beyond X-halo

14. Asthma Management

- <http://hpb.gov.sg/HOPPortal/dandc-article/774>

### 15. Asthma Action Plan

- [http://www.moh.gov.sg/content/moh\\_web/home/Publications/guidelines/cpg/2008/management\\_of\\_asthma.html](http://www.moh.gov.sg/content/moh_web/home/Publications/guidelines/cpg/2008/management_of_asthma.html)

### I. Warranty

This X-halo is guaranteed for one year from the date of purchase against manufacturer's defect under conditions of normal use. Following the directions closely will ensure years of dependable operation. If the x-halo does not function properly, first check the battery, replace it if necessary. Observe the applicable regulations when discarding the device and batteries.

### J. Manufacturer & Authorised Representatives

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