

## **Package leaflet: Information for the user**

### **Yanimo Respimat 2.5 microgram/2.5 microgram, inhalation solution** tiotropium/olodaterol

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Yanimo Respimat is and what it is used for
2. What you need to know before you take Yanimo Respimat
3. How to take Yanimo Respimat
4. Possible side effects
5. How to store Yanimo Respimat
6. Contents of the pack and other information

#### **1. What Yanimo Respimat is and what it is used for**

##### **What Yanimo Respimat is**

Yanimo Respimat contains two active substances called tiotropium and olodaterol. These belong to a group of medicines called long-acting bronchodilators. Tiotropium belongs to the subgroup of anticholinergics; olodaterol belongs to the subgroup of long acting beta<sub>2</sub> agonists.

##### **What Yanimo Respimat is used for**

Yanimo Respimat helps adult patients who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a long-term lung disease that causes shortness of breath and coughing. The term COPD is associated with the conditions chronic bronchitis and emphysema.

Yanimo Respimat helps to open your airways and make it easier to get air in and out of the lungs. Regular use of Yanimo Respimat can also help you when you have on-going shortness of breath related to your disease, and will help to minimise the effects of the disease on your everyday life. As COPD is a long-term disease you should take Yanimo Respimat every day and not only when you have breathing problems or other symptoms of COPD.

#### **2. What you need to know before you take Yanimo Respimat**

##### **Do not use Yanimo Respimat**

- if you are allergic to tiotropium or olodaterol or any of the other ingredients of this medicine (listed in section 6)

- if you are allergic to atropine or substances related to it, e.g. ipratropium or oxitropium

## **Warnings and precautions**

### **Talk to your doctor or pharmacist before using Yanimio Respimat**

- if you have asthma (you should not use Yanimio Respimat for the treatment of asthma).
- if you have diseases of the heart.
- if you have high blood pressure.
- if you have epilepsy.
- if you have a specific thyroid gland problem called thyrotoxicosis.
- if you have an abnormal widening of an artery called aneurysm.
- if you have diabetes.
- if you have severe hepatic impairment.
- if you have renal impairment.
- in case of a planned surgery.
- if you have an eye problem called narrow-angle glaucoma.
- if you have prostate problems or have difficulty passing urine.

### **During treatment with Yanimio Respimat**

- **Stop using the medicine and tell your doctor immediately** if you get tightness of the chest, coughing, wheezing or breathlessness immediately after using the medicine. These may be signs of a condition called bronchospasm (see section 4).
- If your breathing has got worse or if you experience rash, swelling or itching directly after using your inhaler, stop using it and tell your doctor immediately (see section 4).
- If you experience any side effects affecting your heart (increase in pulse rate, increase in blood pressure and/or increase in symptoms like chest pain), tell your doctor immediately (see section 4).
- If you experience muscle spasm, muscle weakness or abnormal heart rhythm, consult your doctor as these may be related to low blood levels of potassium (see section 4).

When taking Yanimio Respimat take care not to let any spray enter your eyes. This may result in eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes (i.e. narrow angle glaucoma). Eye symptoms may be accompanied by headache, nausea or vomiting. Wash your eyes in warm water, stop using Yanimio Respimat and immediately consult your doctor for further advice.

Yanimio Respimat is indicated for the maintenance treatment of your chronic obstructive pulmonary disease. **It should not be used to treat a sudden attack of breathlessness or wheezing.**

Do not use Yanimio Respimat together with certain medicines containing long-acting  $\beta$ -adrenergic agonists, like salmeterol or formoterol.

If you regularly take certain medicines called short-acting  $\beta$ -adrenergic agents, like salbutamol, continue to use these only to relieve acute symptoms like breathlessness.

Dry mouth which has been observed with anti-cholinergic treatment may in the long term be associated with dental caries. Therefore, please remember to pay attention to oral hygiene.

Do not take Yanimio Respimat more frequently than once daily.

### **Children and adolescents**

Yanimio Respimat **should not** be given to **children or adolescents (below the age of 18 years)**.

### **Other medicines and Yanimio Respimat**

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines.

In particular, please tell your doctor if you are using:

- any medicines that may be similar to Yanimio Respimat (contain similar active substances, such as anticholinergic drugs or  $\beta$ -adrenergic agents). You may be more likely to get side effects.
- medicines called beta blockers that are used for high blood pressure or other heart problems (such as propranolol), or for the eye problem called glaucoma (such as timolol). This may result in loss of the effect of Yanimio Respimat
- medicines that lower the amount of potassium in your blood. These include:
  - o steroids (e.g. prednisolone),
  - o diuretics (water tablets),
  - o medicines for breathing problems such as theophylline.If you use these medicines together with Yanimio Respimat you may experience symptoms of muscle spasm, muscle weakness or abnormal heart rhythm.
- medicines called tricyclic antidepressants or monoamine oxidase (MAO) inhibitors (like selegiline or moclobemide), that are used to treat neurological or psychiatric disorders like Parkinson's disease or depression; the use of these drugs will increase the likelihood that you get side effects affecting your heart.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not use this medicine unless specifically recommended by your doctor.

### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed.

If you feel dizzy or if blurred vision occurs while taking Yanimio Respimat, do not drive or use any tools or machines.

## **3. How to take Yanimio Respimat**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Yanimio Respimat is for inhalation use only.

## **Dosage**

The recommended dose is:

Yanimo Respimat is effective for 24 hours so you will need to use Yanimo Respimat only **ONCE A DAY**, if possible at the same time of the day. Each time you use it take **TWO PUFFS**.

As COPD is a long-term disease take Yanimo Respimat every day and not only when you experience breathing problems. Do not take more than the recommended dose.

### **Use in children and adolescents**

There is no relevant use of Yanimo Respimat in the paediatric population (under 18 years).

Make sure that you know how to use your Yanimo Respimat inhaler properly. The instructions for use of the Yanimo Respimat inhaler are provided on the other side of this leaflet.

### **If you take more Yanimo Respimat than you should**

You may be at a higher risk of experiencing a side effect such as dry mouth, constipation, difficulties passing urine, blurred vision, chest pain, high or low blood pressure, faster or irregular heartbeat or feeling of heart beat, dizziness, nervousness, difficulty in sleeping, anxiety, headache, shaking, muscle cramps, nausea, fatigue, malaise, low blood levels of potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm), high blood sugar, or too much acid in your blood (which may cause symptoms of nausea, vomiting, weakness, muscle cramps and more rapid breathing).

### **If you forget to take Yanimo Respimat**

If you forget to inhale a dose, inhale just one dose at the usual time the next day.

Do not take a double dose to make up for a forgotten dose.

### **If you stop using Yanimo Respimat**

Before you stop taking Yanimo Respimat, you should talk to your doctor or your pharmacist. If you stop taking Yanimo Respimat the signs and symptoms of COPD may worsen.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Immediate allergic reactions such as rash, nettle rash (urticaria), swelling of the mouth and face or sudden difficulties in breathing (angioneurotic oedema) or other hypersensitivity reactions (such as sudden reduction of your blood pressure or dizziness) may occur individually or as part of severe allergic reaction (anaphylactic reaction) after administration of Yanimo Respimat. If any of these occur, **please stop using this medicine** and consult your doctor immediately.

The side effects described below have been experienced by people taking this medicine and they are listed according to frequency.

**Common (may affect up to 1 in 10 people)**

- dry mouth

**Uncommon (may affect up to 1 in 100 people)**

- dizziness
- difficulty in sleeping (insomnia)
- headache
- hypertension
- irregular heart beat (atrial fibrillation)
- feeling your heartbeat (palpitations)
- faster heart beat (tachycardia)
- cough
- constipation

**Rare (may affect up to 1 in 1,000 people)**

- nasopharyngitis
- sore throat (pharyngitis)
- inflammation of the larynx (laryngitis)
- inflammation of the gums (gingivitis)
- hoarseness (dysphonia)
- nosebleed (epistaxis)
- fungal infections of the oral cavity and throat (oropharyngeal candidiasis)
- blurred vision
- rapid heartbeat (supraventricular tachycardia)
- feeling sick (nausea)
- joint pain (arthralgia)
- back pain
- difficulties passing urine (urinary retention)
- painful urination (dysuria)
- hypersensitivity, including immediate reactions
- serious allergic reaction which causes swelling of the mouth and face or throat (angioneurotic oedema)
- itching (pruritus)
- nettle rash (urticaria)

**Not known (frequency cannot be estimated from the available data)**

- seeing halos around lights or coloured images in association with red eyes (glaucoma)
- increase of the measured eye pressure
- tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- inflammation of the tongue (glossitis)
- dental caries
- inflammation in sinuses (sinusitis)
- inflammation of the mouth (stomatitis)
- difficulties swallowing (dysphagia)
- heart burn (gastroesophageal reflux disease)
- blockage of intestines or absence of bowel movements (intestinal obstruction, including ileus paralytic)
- rash
- severe allergic reaction (anaphylactic reaction)
- dryness of the skin
- infections or ulcerations of the skin
- depletion of body water (dehydration)

- infections of the urinary tract
- swelling of joint

You may also experience side effects which are known to occur with certain medicines for breathing problems similar to Yanimio Respimat (beta-adrenergic agents). These may be irregular heartbeat, chest pain, low blood pressure, shaking, nervousness, muscle cramps, fatigue, malaise, low blood levels of potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm), high blood sugar, or too much acid in your blood (which may cause symptoms of nausea, vomiting, weakness, muscle cramps and more rapid breathing).

In addition, in common with all inhaled medicines, some patients may experience an unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (bronchospasm).

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

### **Ireland**

HPRA Pharmacovigilance

Earlsfort Terrace

IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

### **Malta**

ADR Reporting

[www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

## **5. How to store Yanimio Respimat**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the inhaler label after EXP. The expiry date refers to the last day of the month.

Do not freeze.

Yanimio Respimat inhaler should be discarded at the latest 3 months after first use.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Yanimo Respimat contains**

The active substances are tiotropium and olodaterol. The delivered dose is 2.5 microgram tiotropium (as bromide monohydrate) and 2.5 microgram olodaterol (as hydrochloride) per puff.

The delivered dose is the dose which is available for the patient after passing the mouthpiece.

The other ingredients are:

Benzalkonium chloride, disodium edetate, purified water and hydrochloric acid for pH adjustment

### **What Yanimo Respimat looks like and contents of the pack**

Yanimo Respimat is composed of one cartridge with inhalation solution and one Respimat inhaler.

The cartridge has to be inserted into the inhaler before the first use.

Single pack: 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)

Double pack: 2 single packages, each containing 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)

Triple pack: 3 single packages, each containing 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)

Eight pack: 8 single packages, each containing 1 Respimat inhaler and 1 cartridge, providing 60 puffs (30 medicinal doses)

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

The marketing authorisation holder for Yanimo Respimat is:

Boehringer Ingelheim International GmbH  
Binger Straße 173  
D-55216 Ingelheim am Rhein  
Germany

The manufacturer for Yanimo Respimat is:

Boehringer Ingelheim Pharma GmbH & Co. KG  
Binger Straße 173  
D-55216 Ingelheim am Rhein  
Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**Austria, Liechtenstein:** [Yanimo Respimat 2,5 Mikrogramm/2,5 Mikrogramm – Lösung zur Inhalation](#)

<b>Belgium, Luxembourg:</b>	Yanimo Respimat 2,5 microgrammes/2,5 microgrammes/ inhalation, solution à inhaler
<b>Bulgaria:</b>	Yanimo Respimat Янимо Респимат
<b>Cyprus, Greece:</b>	Yanimo Respimat
<b>Croatia</b>	Yanimo Respimat 2,5 mikrograma/ 2,5 mikrograma, otopina inhalata
<b>Czech Republic:</b>	Yanimo Respimat 2,5 mikrogramů/2,5 mikrogramů
<b>Denmark:</b>	Yanimo Respimat
<b>Estonia:</b>	Yanimo Respimat
<b>France:</b>	Yanimo Respimat 2,5 microgrammes/2,5 microgrammes/dose, solution à inhaler
<b>Germany:</b>	Yanimo Respimat 2,5 Mikrogramm/2,5 Mikrogramm pro Hub, Lösung zur Inhalation
<b>Hungary:</b>	Yanimo Respimat 2,5 mikrogramm/2,5 mikrogramm inhalációs oldat
<b>Iceland:</b>	Yanimo Respimat
<b>Ireland, Malta, UK:</b>	Yanimo Respimat
<b>Italy:</b>	Yanimo Respimat 2,5 microgrammi/2,5 microgrammi, soluzione per inalazione
<b>Latvia:</b>	Yanimo Respimat 2,5 mikrogrami/2,5 mikrogrami šķīdums inhalācijām
<b>Lithuania:</b>	Yanimo Respimat 2,5 mikrogramo/2,5 mikrogramo/išpurškime įkvepiamasis tirpalas
<b>Netherlands:</b>	Yanimo Respimat 2,5 microgram/2,5 microgram, inhalatieoplossing
<b>Norway:</b>	Yanimo Respimat
<b>Poland:</b>	Yanimo Respimat
<b>Portugal:</b>	Yanimo Respimat
<b>Romania:</b>	Yanimo Respimat 2,5 micrograme/2,5 micrograme soluție de inhalat
<b>Slovakia:</b>	Yanimo Respimat
<b>Slovenia:</b>	Yanimo Respimat 2,5 mikrogramov/2,5 mikrogramov/vdih raztopina za inhaliranje
<b>Spain:</b>	Yanimo Respimat 2,5 microgramos/2,5 microgramos solución para inhalación
<b>Sweden:</b>	Yanimo Respimat

**This leaflet was last revised in 02/2016.**

---



## Instructions For Use

### Introduction

Yanimo Respimat (tiotropium bromide and olodaterol). Read these Instructions for Use before you start using Yanimo Respimat.

You will need to use this inhaler only **ONCE A DAY**. Each time you use it take **TWO PUFFS**.



- If Yanimo Respimat has not been used for more than 7 days release one puff towards the ground.
- If Yanimo Respimat has not been used for more than 21 days repeat steps 4 to 6 under ‘Prepare for first use’ until a cloud is visible. Then repeat steps 4 to 6 three more times.
- Do not touch the piercing element inside the clear base.

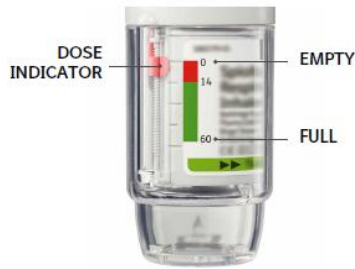
### How to care for your Yanimo Respimat

Clean the mouthpiece including the metal part inside the mouthpiece with a damp cloth or tissue only, at least once a week.

Any minor discoloration in the mouthpiece does not affect your Yanimo Respimat inhaler performance.

If necessary, wipe the outside of your Yanimo Respimat inhaler with a damp cloth.

### When to get a new Yanimo Respimat



- Your Yanimo Respimat inhaler contains 60 puffs (30 doses) if used as indicated (two puffs/once daily).
- The dose indicator shows approximately how much medication is left.
- When the dose indicator enters the red area of the scale you need to get a new prescription; there is approximately medication for 7 days left (14 puffs).
- Once the dose indicator reaches the end of the red scale, your Yanimo Respimat locks automatically – no more doses can be released. At this point, the clear base cannot be turned any further.
- Yanimo Respimat should be discarded three months after you have prepared it for first use, even if it has not been fully used or used at all.

### Prepare for first use

<p><b>1. Remove clear base</b></p> <ul style="list-style-type: none"> <li>• Keep the cap closed.</li> <li>• Press the safety catch while firmly pulling off the clear base with your other hand.</li> </ul>	
<p><b>2. Insert cartridge</b></p> <ul style="list-style-type: none"> <li>• Insert the narrow end of the cartridge into the inhaler.</li> <li>• Place the inhaler on a firm surface and push down firmly until it <b>clicks</b> into place.</li> </ul>	
<p><b>3. Replace clear base</b></p> <ul style="list-style-type: none"> <li>• Put the clear base back into place until it clicks.</li> </ul>	

<p><b>4. Turn</b></p> <ul style="list-style-type: none"><li>• Keep the cap closed.</li><li>• Turn the clear base in the direction of the arrows on the label until it clicks (half a turn).</li></ul>	
<p><b>5. Open</b></p> <ul style="list-style-type: none"><li>• Open the cap until it snaps fully open.</li></ul>	
<p><b>6. Press</b></p> <ul style="list-style-type: none"><li>• Point the inhaler toward the ground.</li><li>• Press the dose-release button.</li><li>• Close the cap.</li><li>• Repeat steps 4-6 until a cloud is visible.</li><li>• <b>After a cloud is visible</b>, repeat steps 4-6 three more times.</li></ul> <p>Your inhaler is now ready to use. These steps will not affect the number of doses available. After preparation your inhaler will be able to deliver 60 puffs (30 doses).</p>	

## Daily use

### TURN

- Keep the cap closed.
- **TURN** the clear base in the direction of the arrows on the label until it clicks (half a turn).



### OPEN

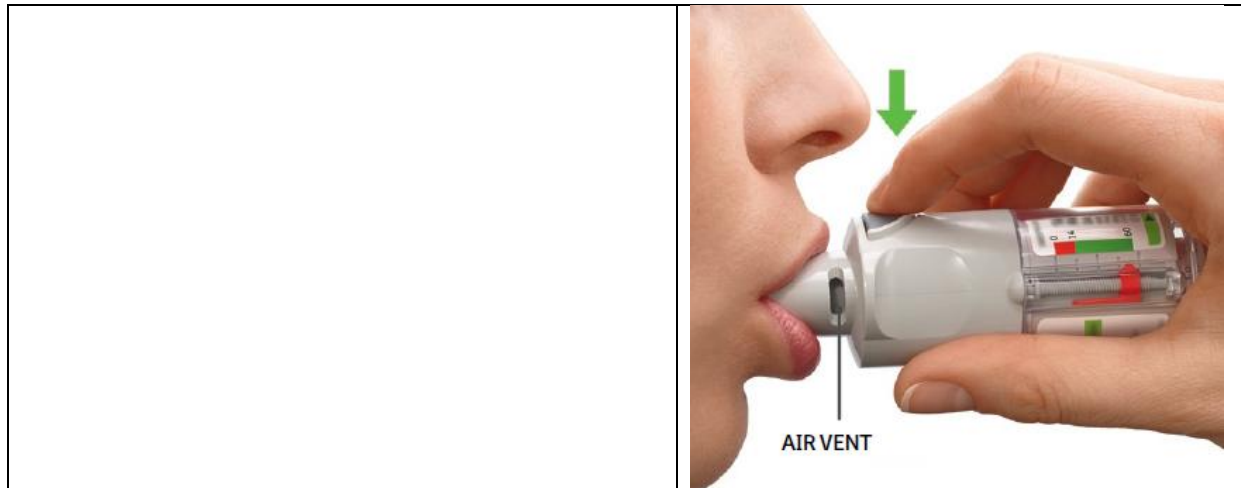
- **OPEN** the cap until it snaps fully open.



### PRESS

- Breathe out slowly and fully.
- Close your lips around the mouthpiece without covering the air vents. Point your Inhaler to the back of your throat.
- While taking a slow, deep breath through your mouth, **PRESS** the dose-release button and continue to breathe in slowly for as long as comfortable.
- Hold your breath for 10 seconds or for as long as comfortable.
- Repeat **TURN, OPEN, PRESS** for a total of 2 puffs.
- Close the cap until you use your inhaler again.





### Answers to Common Questions

#### **It is difficult to insert the cartridge deep enough.**

**Did you accidentally turn the clear base before inserting the cartridge?** Open the cap, press the dose-release button, then insert the cartridge.

**Did you insert the cartridge with the wide end first?** Insert the cartridge with the narrow end first.

#### **I cannot press the dose-release button.**

**Did you turn the clear base?** If not, turn the clear base in a continuous movement until it clicks (half a turn).

**Is the dose indicator on the Yanimo Respimat pointing to zero?** The Yanimo Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Yanimo Respimat inhaler.

#### **I cannot turn the clear base.**

**Did you turn the clear base already?**

If the clear base has already been turned, follow steps “OPEN” and “PRESS” under “Daily Use” to get your medicine.

**Is the dose indicator on the Yanimo Respimat pointing to zero?** The Yanimo Respimat inhaler is locked after 60 puffs (30 medicinal doses). Prepare and use your new Yanimo Respimat inhaler.

#### **The dose indicator on the Yanimo Respimat reaches zero too soon.**

**Did you use Yanimo Respimat as indicated (two puffs/once daily)?** Yanimo Respimat will last 30 days if used at two puffs once daily.

**Did you turn the clear base before you inserted the cartridge?** The dose indicator counts each turn of the clear base regardless whether a cartridge has been inserted or not.

**Did you spray in the air often to check whether the Yanimo Respimat is working?** Once you have prepared Yanimo Respimat, no test-spraying is required if used daily.

**Did you insert the cartridge into a used Yanimo Respimat?** Always insert a new cartridge into a NEW Yanimo Respimat.

#### **My Yanimo Respimat sprays automatically.**

**Was the cap open when you turned the clear base?** Close the cap, then turn the clear base.

**Did you press the dose-release button when turning the clear base?** Close the cap, so the dose-release button is covered, then turn the clear base.

**Did you stop when turning the clear base before it clicked?** Turn the clear base in a continuous movement until it clicks (half a turn).

**My Yanimo Respimat doesn't spray.**

**Did you insert a cartridge?** If not, insert a cartridge.

**Did you repeat TURN, OPEN, PRESS less than three times after inserting the cartridge?** Repeat TURN, OPEN, PRESS three times after inserting the cartridge as shown in the steps 4 to 6 under "Prepare for first use".

**Is the dose indicator on the Yanimo Respimat pointing to 0?** If the dose indicator points to 0, you have used up all your medication and the inhaler is locked.

Once your Yanimo Respimat is assembled, do not remove the clear base or the cartridge. Always insert a new cartridge into a **NEW** Yanimo Respimat.