NOVAERUS
Airborne Infection Control

# Validation Process

While there is a huge body of science and independent testing proving the efficacy of Novaerus, along with numerous successful clinical studies in live healthcare facilities, there are still those who are reluctant to make the final step in purchasing Novaerus.

We are often faced with the questions like ‘How long will it take to clean a room? How do I know it’s working? or the ‘try before you buy’ scenario.

Here is a guide on how to handle these situations and how to set realistic expectations when it comes to trials and air sampling.

# How long will it take to clean a room?

What we need to remember is that Novaerus is a **risk mitigation technology.** We are continuously reducing the bioburden in the air by treating the air 24/7 and creating a cleaner environment; thereby reducing the risk of spread of infection.

**We are not claiming to 'sterilize' the room!** In theory, our devices would be able to 'sterilize' a sealed room with no air inlet or outlets over time. However, this type of scenario is not what is experienced in a normal live environment. We have continuous sources of contamination releasing and spreading pathogens around the room.

Luckily our devices are completely safe to use 24/7, with people present in the room. However, we must remember that these people are very often the biggest source of contamination in the room. Humans are continuously emitting pathogens into the air by breathing, talking, walking, shedding skin cells, sneezing etc. So, when we have people in the room we have a constant source of contamination into the environment and can never create a sterile environment.

We also must consider that these rooms are obviously not 'sealed' environments – i.e air currents can enter/leave the room via windows/doors taking with them new sources of external contamination into the room and potentially removing the 'clean' air that has just been treated by our device out of the room.

Let us imagine this scenario. We are trying to walk down an escalator that is going up. It is difficult and we must walk and work all the time to try to reach the bottom. Now imagine that the escalator speeds up. We are walking at the same speed so we move slightly back up the escalator. But we do not stop walking down! We work 24/7 to try to continue to reach the bottom of the escalator. Eventually the escalator returns to its normal speed and we gradually continue to move down the escalator.

This is what Novaerus is doing – working (walking) 24/7 to try to treat the air and lower the bioburden in the room. When new sources of contamination are introduced (the escalator speeds up) and we move slightly up the escalator. After time the escalator returns to normal speed and we gradually work out way back down the escalator.

So, we need to move away from the idea that our devices will 'sterilize' a room in a live healthcare environment. This may be achievable for technologies such as H2O2 misting, however these technologies are point in time solutions, and cannot be used with people present in the room. The room will be sterile but only for that specific moment in time. As soon as new air currents or people enter the room contamination continues to increase.

Let's return to our escalator. Imagine we can turn the escalator off (i.e. there are no people/sources of contamination in the room, and no way for air to get in or out). We can easily walk down and reach the bottom of the escalator in one go. We have reached the ground floor (the room has been sterilized). So, we stop walking and stop working. But as soon as the escalator is switched back on (and people/air enters the room) we are moved all the way back up to the top. And because we have stopped walking/working we have no way of even trying to make our way back down to the bottom! This is what happens when we have a point-in-time solution for treating the air e.g. H202.

What Novaerus does is far more effective. We clean the air 24/7 and continuously reduce the bio-burden in the room at the most important stage…when people are present!

# How do I know it's working?

We are often faced with the difficult question in relation to Novaerus technology… 'How do I know it's working'. One of the most obvious effects will be the improvement in air quality and reduction in odour. This will occur within a few hours/days (depending on the level/sources of odours in the room). Over time there will be an overall reduction in the spread of infection.

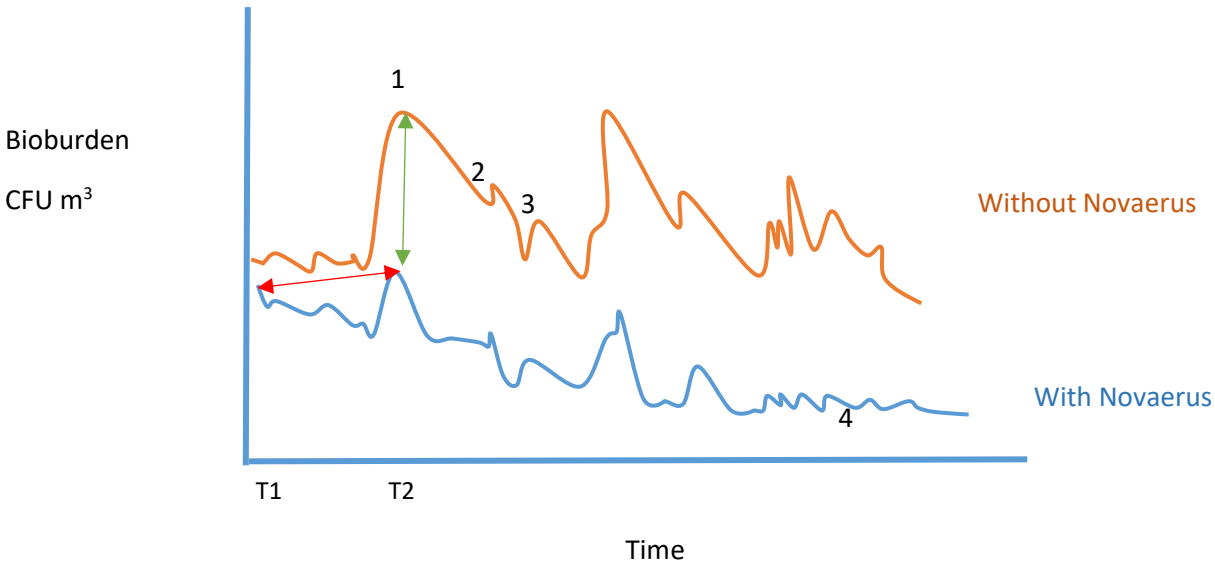
However, as these outcomes are either subjective or long term people will often require to see a quicker tangible, scientific results. As it is virtually impossible to see the direct tangible results in a live environment, in real time, answering this questions can prove challenging.

In effect, we are creating an absence…the absence of bio-burden, and therefore the reduction in spread of infection. So how do we go about showing this?

One method of doing this is by collecting air samples from the environment with and without Novaerus. This is done using air sampling instrument, which collects a specific amount of air (in litres) and impacts it onto a petri dish containing a specific culture media (soy agar) for bacteria or mould growth. The dishes are incubated for 24-48 hours and the number of Colony Forming Units (CFU) per $m^3$ is calculated – thereby giving us a representation of air quality.

This all sounds very simple however we must remember that we are dealing with a live healthcare environment, and not a controlled laboratory one. There are many variables that will affect that air quality at any point in time. Let's think back to our escalator – and event, which may be a sneeze/cough/flushed toilet or even just an increase in the number of people in the room will naturally result in an increase the bioburden in the air…and 'speed up the escalator'. So, if we were to collect 1 air sample at this moment in time, and compare it with our initial air sample at T0, we would expect an increase in CFU count. This is not to say that the Novaerus unit is not working…it is just that it can be difficult to understand the real effect using a limited sample set in a n environment with a lot of uncontrollable and unpredictable variables.

Let us look at the below animation that will help us to better understand the everyday events that cause airborne bioburden to continuously fluctuate…and how this will affect air sampling trials.



1. Everyday activities such as talking, breathing, opening curtains etc. results in a **constant emission and circulation of pathogens into the air**.
2. Cleaning activities such as surface cleaning, H2Os misting etc. will reduce this bioburden to a certain extent, but only for a short period of time – as they are **a point in time solutions**. Once that cleaning procedure has been completed new contaminants are introduced to the environment and continue to grow and spread minute by minute, hour by hour.
3. For this reason – **airborne bioburden is continuously fluctuating**. The constant activity and flow of air currents in a room can make it difficult to treat airborne and environmental bioburden all the time.
4. By using Novaeurs you are treating the air 24/7…thereby continuously reducing the bioburden in the entire environment.

You will naturally see some increases in bioburden while using Novaerus (as we are in a live environment) however the increases will be less than what would be expected without Novaerus and will also be reduced quicker.

Limitations to short term air sampling trials:

As mentioned earlier, if we were to collect and air sample at T1 and then another air sample at T2 while using Novaerus we would actually see a slight increase in bioburden. So…does this means our machines do not work!? No…let's think about it logically. In reality this delta is not showing the true impact of Novaerus. It is only showing airborne bioburden at 2 snapshot points in time – without considering the external variables and activities that are occurring within the room at that point in time. It is obvious that at T2 some sort of unpredictable event has occurred in the room, something which cannot be controlled in a live trial.

Ideally, if we were to compare any two air samples to show the true impact of Novaerus it would be air sample T2 with Novaerus and T2 without Novaerus. i.e. ⟷

Looking at this delta would be impossible (unless we could build a time machine). So, we need to find another way to use air sampling to show our impact.

One of the best ways to do this is by collecting a larger sample set i.e more sample locations to get an average and more frequent sampling. That way we can better understand the overall impact of Novaerus and see how in the long term we are reducing bioburden.

Another way to show the effect is to introduce a control. It can be difficult to compare two separate rooms as there are different activities occurring in both rooms (e.g. different patients, staff, infections, visitors, air flow etc.) One way we have tried to introduce a control is by turning off the units and continuing with air sampling without any devices running. The general trend that has been observed is the bioburden will increase once the machines are switched off. (see report from Bucharest trial for more details).

So, as you can see we face many challenges when trying to prove the impact of Novaeurs in short time period. It is possible to do so with air sampling trials however we must be aware of the difficulties and unpredictability of testing in a live environment.

The most important thing here is to **educate the customer before even introducing the idea of running an air sampling trial.** The second step is to **set realistic expectations** as to what results they

can expect. Once the customer is educated in the process of the tiral realistic expectations can be set and it is also easier to explain unexpected peaks/dips during the trial.

**Step1**: Chosing a Location.

**Step 2:**

Collection of air samples using AirIdeal Air sampling device at T0.

**Step 3:** Installation of Novaerus devices throughout the area.


**Step 4**: Collection of Air samples after Novaerus installation

**Step 5**: Incubation of samples (petri dishes) in order to determine the number of CFU/$m^3$ before and after using Novaerus.

CFU/$m^3$ Before

CFU/$m^3$ After

These simple validation processes can be performed within a specific, controlled location inside your healthcare facility.

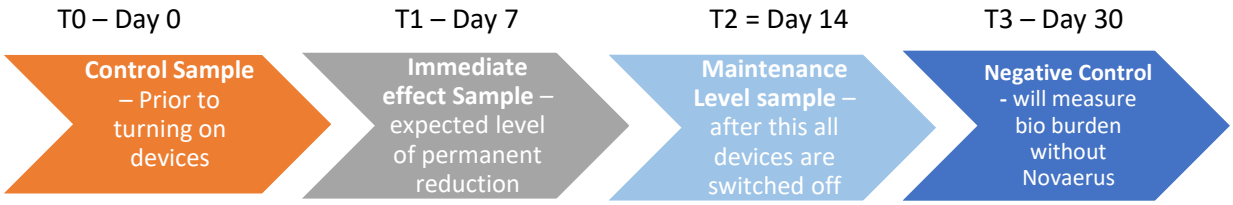
There are 3 critical components involved in conducting these validation protocols:

- Choice of Location – as few entrances/exits possible, limited sources of 'fresh air'.
- Uniformity of sampling times and locations – take sample at same time of day/location
- Methodology for taking and developing the samples

## 30 Day Protocol

The 30 day protocol has been designed not only to prove the efficacy of the system but also show what will happen when the system is not running. Half way through the trial machines are turned off in order to observe the effect without Novaerus and measure a 'Negative Control'.

SAMPLING TIMELINE




Novaerus recommends that you perform a minimum of 12 sample periods during the 30 day trial, across as many locations as possible within the trial location. No less than 5 sample points should be used, so that there are enough samples to give an average reduction across the indoor space.

## What is being tested?

Airborne bacteria and fungi samples are taken in order to determine the airborne bioburden.

## Air Sampler

We recommend using the Air Ideal Bio sampler. This device works by taking an air sample (60– 100 litres in 100 - 140 seconds) and impacting the sample onto a petri dish. The dishes are then sent to a laboratory (many hospitals will have their own micro lab on site) to be incubated for 2-3 days (depending on what is being tested). The number of colony forming units on the dishes is counted and the CFU per $m^3$ is calculated for before and after use of Novaerus.

The air sampling method has been proven to be far more reliable than the use of settle plates. Settle plates can easily become contaminated giving skewed results.