PHILIPS

Test and research program Respironics' PE-PUR sound abatement foam

Tuesday, 28th June 2022

Welcome

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Thank you, and good morning, everyone. Welcome to today's conference call to update you on the Philips Respironics test and research programme for the PE-PUR sound abatement foam. We appreciate that you could join our call on short notice. I'm here with our CEO, Frans van Houten; our CFO, Abhijit Bhattacharya; the Business Leader for Connected Care, Roy Jakobs; and the spokesperson for the Test and Research programme, Steve Klink.

The press release, slide deck, frequently asked questions, as well as other supporting materials on the topic were published at 8.00 CET this morning on our Investor Relations website. A report containing more detailed information and context of the findings discussed today is also available on the Recall website, and you should refer to that as well as to our answers today.

The full transcript of this call will be made available on the website. After today's update, there will be an opportunity for Q&A with the team, which will be chaired by Frans. Over to you, Frans.

Opening Remarks

Frans van Houten

CEO, Philips

Extensive Test and Research Programme Launched In June 2021

Yeah. Hello, everyone, and thank you for joining this morning. Today, we are providing an update on the extensive test and research programme that we launched in June 2021 for the Respironics field safety notice for CPAP, BiPAP and certain other ventilator devices.

I've asked Roy Jakobs and Steve Klink to join me to provide important context on the testing results, and also an update on the Repair and Replacement programme. Roy is member of the Executive Committee for Philips and leads Philips Connected Care business, which also includes Philips Respironics. Roy oversees the remediation programme and other aspects of the field action.

As Leandro mentioned, Steve Klink is the spokesperson for the test and research programme. He also has a PhD in chemistry.

Before we go into the detail, I want to emphasise that patient safety is our absolute number one priority. Improving the health and wellbeing of people is at the heart of our company's purpose. We pride ourselves on the fact that people all over the world use our products, our services, our solutions to live healthier lives and to care for patients. And I know how important these sleep apnea devices are to our patients and how they improve their lives.

Let me then also say that I'm personally deeply sorry for the concern and the inconvenience experienced by patients, but also clinicians and caregivers. We have worked hard and we are working hard to fix the problems that have surfaced. That has been a very complex effort. We are making good progress, but the process takes a very significant amount of time.

Also, the test and research programme is comprehensive and lengthy. This is to ensure the patients and physicians have accurate information, but also reliable information on hand. At this stage in the programme, we can observe that the phenomena of foam degradation is rare. And the chemical characterisation of foam degradation is complex.

We have, in the meantime, performed hundreds of tests, and we have inspected over 63,000 devices. The results to-date for the DreamStation1, which represents the majority of the affected devices, are encouraging and insightful. Let me give you five main findings.

Overview of Testing Process

First, there is a very low prevalence of visible foam degradation in the thousands of devices that we have inspected. In the United States, we observed that only 0.5% of the devices with self-reported no use of ozone cleaning, showed visible foam degradation. None of the inspected devices from Europe or Japan showed visible foam degradation. It is clear, however, that ozone cleaning vastly exacerbates foam degradation. 7% of the devices with self-reported ozone cleaning use showed foam degradation.

Of the devices inspected, 422 were linked to a reported visible particle complaint, of which only 4% actually showed foam degradation. The VOC emissions of the devices are within established ISO limits and exposure is not anticipated to result in long-term health consequences for patients.

Particulate Matter testing shows that foam degradation did not contribute to appreciable elevated levels of respirable particles in the devices tested. In fact, the level of respirable particles is within the ISO norm, also for systems that show foam degradation.

When the foam degrades, it becomes moist, sticky and loses volume, becomes more dense. As such, even when visible particles – particulates are formed by foam degradation, these are likely to accumulate and stick inside the blower and air pathway compartment of the device and may not be emitted by the device. Importantly, biocompatibility testing and assessment of the degraded PE-PUR foam is still ongoing. And this is relevant as we had previous – as we have previously reported, that lab-degraded form foam failed genotoxicity, cytotoxicity and irritating – irritation testing thresholds.

PE-PUR Foam – Additional Testing

So in order to fully assess potential patient risk, we are still conducting tests to answer four questions. One, does the foam in used devices reach the same level of degradation as lab-aged foam? Two, can degraded foam particles actually reach the patient? And three, if so, how much of these foam particles would reach the patient? And finally, what is then the level of toxicity of such particles if these were to reach the patient?

Due to extended throughput times of testing, we hope to come back to you on this assessment in the coming months.

We also referenced the Canadian study published in the *American Respiratory Journal* and the French study published in the *European Respiratory Journal* that we highlighted in recent months. These studies were done with thousands of PAP users, and should be reassuring for patients as they show – as they do not show any correlation between the occurrence of cancer and the use of Respironics devices.

We also looked at 10 other studies that we are aware of, and none of these lead to different conclusions.

Steve Klink will talk about the testing processes and findings in more detail in a moment. And we will continue to provide regular updates as new test results and assessments become available. At this time, the advice to patients remains unchanged.

The Repair and Replacement programme will continue at full speed and Roy Jakobs will go into this in more detail later this morning. We are working very hard to overcome challenges from the disrupted global supply chain and execute 90% of the programme in 2022. We will provide regular updates on the repair-and-replacement efforts to patients and healthcare providers.

I will now pass it over to Steve.

Overview of the Testing Process

Steve Klink

Spokesperson, Test and Research Programme, Philips

Thank you, Frans, and hello, everyone. I would like to start by giving an overview of the testing processes – process that we have been undergoing.

Affected CPAP, BiPAP and mechanical ventilator devices

We focused the test and research programme on the devices affected by the field safety notice, which are the CPAP, BiPAP and certain ventilator devices.

95% of the registered devices are CPAP and BiPAP devices. The products were divided into five categories, with the largest being the DreamStation1 and SystemOne accounting for 68% and 26% of the affected devices, respectively. Our initial concern when the field safety notice was initiated, was with any emission of VOCs and particulate matters, which might be released if the foam degrades.

So within each device category, we study the characteristics of foam and the operation of the devices in detail. We evaluated pristine foam in unused new devices, as well as lab-aged foam and foam in devices that had been used by patients.

Comprehensive and lengthy process to ensure patients and physicians have accurate information

I will take you through the following tests and analyses:

- Visual inspection and assessment of the foam in used devices to assess the prevalence of visible foam degradation;
- VOC testing to identify and quantify organic compounds that may be inhaled by during use;
- Particulate Matter testing to determine concentrations of respirable particulates, i.e., particulates below 10 microns or micro metres;
- Additional physical, chemical and biological testing of the PE-PUR foam related to patient risks, if patients were to contact the foam material.

We have worked and we are working with several third parties to ensure comprehensive results. The tests were conducted by five certified independent testing laboratories in the US and Europe, and we have leveraged multiple outside experts with regulatory experience. The tests were done in accordance with ISO 18562 and ISO 10993 standards. The test plan and approach have been presented to and discussed with the FDA and the Agency's feedback was taken into account.

The time taken to test and analyse the data per product category and situation is substantial and impacts throughput time for each test. The complexity of the test results also adds to the throughput time. We're talking about hundreds of tests, and each with a throughput time of many months. We can, of course, do many tests in parallel, but the testing capacity is finite, and some of the tests must take place sequentially.

PE-PUR Foam – Visual Inspection

Let's take a closer look at the outcomes of the testing to-date starting with official inspection, which was conducted according to a specific protocol as part of the repair process.

We have assessed over 63,000 DreamStation1 devices from the US, Canada and various countries in Europe and Japan for signs of visible foam degradation and/or volume reduction. This is important because only degraded foam would emit particulates. We also asked the users of these devices to report whether they used ozone cleaning or not.

0.5% of DreamStation1 devices with (self-reported) no Ozone use had significant visible foam degradation

In the US and Canada, we observed that only 0.5% of the devices with self-reported no ozone use showed visible foam degradation. None of the more than 2,200 assessed devices from Europe or Japan, which is our second – which are our second and third biggest markets, showed visible foam degradation. In those devices with visible foam degradation, it was observed that the foam becomes hydroscopic, which means that it absorbs moisture and it becomes sticky. It also loses significant volume and increases density as the structure changes from a foam to a viscous liquid material.

As such, even when particulates are formed by degradation, they are likely to stick and accumulate within the internal device air pathway, hence – and hence may not be emitted by the devices.

Also very important, we assessed the sample of 422 devices linked to a reported visible particle complaint. Only 4% of those devices actually showed foam degradation.

7% of devices with (self-reported) Ozone use had significant visible foam degradation

Moving to the next slide. When we consider the impact of ozone cleaning, 7% of the devices with self-reported ozone use showed foam degradation. This is 14 times more likely to have visible foam degradation than those with self-reported no ozone use, which was 0.5%. As mentioned before, ozone cleaning is not an authorised cleaning method for these devices.

PE-PUR Foam – VOC Testing

We also performed detailed VOC testing to quantify VOC emissions from the devices and assessed the toxicological risk associated with exposure to quantify concentrations of those VOCs.

In December of 2021, we already informed you that VOC emissions in DreamStation1 devices are below established limits based on the ISO 18562-3 testing and evaluation of new lab-aged and new devices. And today, we provided an update on the new DreamStation Go, SystemOne, Trilogy 100/200, and new and used OmniLab devices for also passing VOC testing under the applicable standards.

Testing to assess the impact of repeated ozone cleaning on VOC emission is ongoing and we intend to provide regular updates.

PE-PUR Foam – Particulate Matter Testing

Turning to particulate matter. We performed the testing to quantify particulate matter emissions from devices and to assess where the concentration is – whether the concentration detected is less than thresholds provided in the relevant standard. Today, we are announcing the positive outcome that new and used DreamStation1 devices were tested and were all found to be compliant with the ISO18562-2 limits for respirable particulate emissions.

Importantly, this included used devices with visible foam degradation. New DreamStation Go, SystemOne, Trilogy 100/200, and OmniLab devices also passed Particulate Matter testing. Particulate Matter testing is ongoing for the used OmniLab devices. Testing to assess impact of repeated ozone cleaning on particulate matter emissions is ongoing.

As Frans mentioned, Philips Respironics expects to complete the remaining VOC and particulate matter testing for the CPAP and BiPAP devices, as well as the degraded foam toxicological risk assessment in accordance with ISO 10993 in the coming months. Philips Respironics will also continue with a test to assess the impact of repeated ozone cleaning on foam degradation in these devices.

Silicon Foam Testing – in Response to FDA Request in November 2021

Moving on to the silicone foam used in DreamStation2 and the repaired DreamStation1 devices. In November 2021, the FDA requested that Philips retained an independent laboratory to perform additional testing to determine what, if any, potential safety risks may be posed to patients by silicone-based foam. Philips Respironics engaged independent testing laboratories to perform additional VOC testing. Based on the draft reports, Philips Respironics has not identified any safety issues. The assessment is being completed and the final reports are subject to FDA review, which are expected in the coming months.

Independent Literature and Epidemiological Studies

To conclude, I would like to spend a minute on the existing literature and independent studies on the risk of health risks and CPAP use globally. We have engaged a team of external scientists to review these studies. All 12 studies available to-date show no correlation between the occurrence of cancer and the use of Respironics PAP devices.

Two of these studies have a robust methodology and high statistical quality according to experts. And these are the Canadian study published in *American Respiratory Journal* and the French study published in the *European Respiratory Journal* that we have highlighted in recent months. These were done with thousands of PAP users and should be reassuring for patients.

All other studies available to-date have major methodological and reporting limitations. For example, the Swedish study that has been discussed by the financial community recently, relies on county level ecological data on type of CPAP use without any individual patient level data on

CPAP use or smoking history. These limitations are also partly highlighted by the authors of the study themselves.

I hope you find the information presented useful. And with that, I would like to hand over the call to Roy.

Repair and Replace Programme Update

Roy Jakobs

Chief Business Leader Connected Care, Philips

Welcome

Thank you, Steve, and hello, everyone. I'm Roy Jakobs, Head of Connected Care here at Philips; that includes Philips Respironics. First, I want to say how passionate I am about what Philips does, and how we help improve the health and wellbeing of our patients. That's also why I feel so much for patients and caregivers who are affected by the recall. I know that this has been a worrying and frustrating time, particularly for patients who rely on these devices for the health and quality of life.

I would like to spend a few minutes to update you on our Repair and Replacement efforts, which are underway globally. We have produced 2.7 million repair kits and replacement devices to-date. And we more than tripled our production capacity compared to before the recall. We mobilised more than 1,000 people working on the recall day in and day out.

I would like to remind you that we started to work with the regulatory authorities to get the recall programme and the devices approved for release. So we were able to start the shipments towards the final part of 2021. As mentioned in April, we target to execute around 90% of the Repair and Replacement programme by the end of 2022. We are working to that schedule. But we are dealing with some headwinds related to supply of materials and logistics due to the recent lockdown in China.

We know how important these devices are to patients and we are working extremely hard to get them to them as quickly as we can. This is Philips' number one priority.

Thank you for listening, and now I'll hand back to Frans.

Conclusion

Frans van Houten

CEO, Philips

Yeah, thanks, Roy. We have outlined the encouraging results so far and the next steps in our test and research programme, as well as progress of our Repair and Replacement programme. Before we conclude, I would like to provide a quick update on litigation related to the recall, as I know this is also a question in your mind.

Over a year into the recall, approximately 200 personal injury cases have been filed against Philips Respironics. And many of these personal injury cases, alleged injuries consistent with the use of ozone-based cleaning of the devices such as cough, difficult breathing, nasal

irritation, headaches, asthma attacks and other breathing complaints. We are aware that as a result of the extensive advertising, so far a little over 50,000 individuals in the United States have registered with lawyers.

Let me observe that precedent shows it is not likely that all of these individuals will file suit. As mentioned before, we will continue to share information in a transparent and timely manner as the situation evolves.

Let me conclude by thanking our patients and customers for their patience and our suppliers and partners for their continued support. I also want to say a special thanks to our employees for their fantastic contribution through a year of often very difficult circumstances.

And with that Roy, Steve and I will take your questions. Thanks.

Q&A

Operator: Thank you, sir. If any participants would like to ask a question, please press the star followed by the one on your telephone. If you wish to cancel this request, please press the star followed by the two. Please limit yourself to one question with a maximum of one follow-up. This will give more people the opportunity to ask questions. If you are using speaker equipment today, please lift the handset before making your selection. There will be a short pause while participants register for a question.

Our first question today comes from Hassan Al-Wakeel of Barclays. Please go ahead.

Hassan Al-Wakeel (Barclays): Thank you for taking my questions. I have two, please. Firstly, could you walk us through the Ames genotoxicity tests that failed with lab-aged foams? I believe this was the case last year. What is driving this? And how are you thinking about further tests and potential outcomes, should further testing corroborate this? And is the FDA concerned by this?

Secondly, could you talk us through whether the FDA has approved these tests or what the degree of oversight has been, given some recent commentary in the 518(b), as an example around testing methods that they did not find persuasive. So any clarification here would be great. Thank you.

Frans van Houten: Yeah. Hi. Good morning. I will pass it to Steve Klink in a moment. But let me emphasise that when we went out last year with the field safety notice, it was for two reasons. One, it was that we found the fail on genotoxicity and cytotoxicity, and the other one was the VOCs. Right? And we have in the meantime proven that the VOCs are not an issue. And so when you refer to genotoxicity test, that is not new news, and I'll let Steve talk more about it in a moment.

The efforts by the FDA to propose the 518(b) process can, in my view, be explained by the desire to advance as fast as possible the recall completion. I think everybody in this world, including regulators and Philips, we all want the recall to be finished as fast as possible. The 518(b) process requires a high hurdle to actually make it and I see communication in that context as preparing for that case. We have responded to the 518(b) process. There's no resolution or conclusion on it that's outstanding.

Now, then on your point, has the FDA approved the test methodologies? We have been very transparent ever since last year for all the tests that we do, all the test houses that we do, all the experts that are advising us. We have also shared that and presented that to the FDA on several occasions.

We've also shared with the FDA, and other competent authorities, the test results in advance of today's publication. I don't think we can expect regulators to approve of results. But certainly, we have been very transparent all along the way.

Steve, could you please comment further?

Steve Klink: Yes. Thanks, Frans. So the insight that lab-degraded foam – so that is foam that has been exposed to 90 degrees Celsius and 95% relative humidity, so that is a very harsh lab condition – the fact that that foam fails an Ames test, that was already known last year. And as Frans indicated, that was one of the limited information that we had at that time. And based on that, we started the recall notification.

In the meantime, we have, on the one hand, repeated the test for increased confidence in the result. And at the same time, we're conducting various tests to, first of all, assess whether or not a situation in lab-degraded foam, whether that is a measure for what's actually happening in the field. So we need to establish whether or not foam that is in the field can actually degrade to the same degree as lab-degraded foam. So that is one element.

And then another element is, of course, we first need to establish whether or not that foam will be in contact with the patient. So those tests are ongoing.

In the meantime, we have learned some very valuable insights as to the prevalence of foam degradation. As we indicated earlier, if no ozone is used, then in the sample size that we inspected, 0.5% shows foam degradation. And then Europe and Japan, it was, say, none of the devices that we inspected.

And then – so first, it's important, it's very rare. And then we have also learnt very important insights that if you look at respirable particulate, then the degraded foam does not add to respirable particulates, that's one. And the other one is that if foam degrades, so in the rare instance that it happens, the foam becomes moist, sticky and we see an accumulation of that sticky material within the device. So it's likely that it will stay in the device. We are testing that further.

So to recap, the fact that lab-degraded foam fails an Ames test, that was known last year. We have done many repeat tests for consistency. And at the same time, we're doing all the other tests to establish whether or not that outcome is relevant or not.

Hassan Al-Wakeel: That's helpful. And if I could just follow up on the 518(b), I mean, it also talked about the potential for refunds. Can you talk about how you think about this, potentially in light of some of the data and how discussions are trending with the regulator on this topic?

Frans van Houten: Yeah. Hassan, I mentioned that we have made our proposal to the FDA in the process of the 518(b), but not have further response on that. So I cannot speculate as to the outcome of the 518(b) process. However, I do want to underline that for the sake of the patient, a refund is not a resolution. We all know that there is a lack of capacity in the industry. The best way and the fastest way forward for a patient to receive a remediated device that they

can fully trust, that is equipped with silicone foam, is actually the Repair and Replace programme, whereas a partial refund does not help the patient to get a new machine.

Now, as we are focused on the Repair and Replace programme, and have produced over 2.7 million units and repair kits to date, we have been able to increase capacity of the Repair and Replace programme by a factor of three from our original capacity. And this underpins the ability to complete 90% of the production volume by the end of the year. And so basically in the coming six months, we aim to get very, very, very far in the completion of the programme, and we think, back to the question of 518(b), that that is a far more feasible resolution than going into – into refund options.

Hassan Al-Wakeel: Perfect. Thank you.

Frans Van Houten: You're welcome Hassan.

Operator: Thank you. The next question comes from David Adlington from JP Morgan. Please state your question.

David Adlington (JP Morgan): Hi guys, yeah, just a follow-up question on [inaudible], just in terms of the genotoxicity studies and the follow-ups that you're doing in non-lab-based foam degradation, so, real-life field studies. I'm just wondering when you expect to get that data, and if it confirms the lab-based studies, what implications that has from here.

And then just a follow-up in terms of the recall. It seems to me like you're emphasising that you're facing additional supply chain challenges. I just wondered if that was the right reading of the situation on what the implications were for you completing that recall. Thanks.

Frans Van Houten: Yeah. In my introduction, David, I mentioned that in the ongoing bio-compatibility testing, we really want to answer four questions. Does the foam in used devices reach the same level of degradation as lab-aged foam? Steve mentioned that lab-aged foam is tested in a very harsh environment. Such a harsh environment of 90^0 Celsius temperature, and very high humidity, does not happen in the field, so, we really need to understand whether used devices show the same level of degradation as lab-aged foam.

And secondly, can degraded foam particles actually reach the patient? There, we said that the process of degradation actually makes the foam sticky and moist, and we have observed individual inspection that most of these particles – that these particles do not seem to exit the machine, right, but we want to make that a very reliable conclusion.

And then thirdly, if, in the situation that the particle actually reaches the patient, to what degree or volume, or how many would that be?

And finally, then, what is the level of toxicity of such particles? And it was mentioned that the Ames test, as such, is not answering that.

So, that, I think is very important to understand what we expect to get out of it. Now, we mentioned the coming months, we are – they're also dependent on the external experts. Steve, is there anything you want to add to this?

Steve Klink: No. That's complete, and you always need to look at the big picture. There are many, many factors, and then, of course, zooming out completely, then there are also the epidemiological studies that we certainly also need to take into account.

Frans Van Houten: Yeah. Maybe – I may zoom out a little bit and then ask Roy to come back to your question of supply chain. So, I'm not forgetting that, David. Maybe still to highlight a few other things, right? So, we have observed that foam degradation is rare, right? Of the inspected devices of users that have self-declared not to use ozone, it happens in 0.5% of the cases in United States, and we have not seen any machines in Europe and Japan with foam degradation. I want to emphasise that all the machines passed the VOCs as well as the respirable particle emission tests according to the ISO standards.

But probably even more importantly is if you look at that selection of inspected devices, there are over 60,000 units in the US, and you correlate that to complaints on file, we found that of those 60,000+ machines, we had 422 complaints registered by people who allege foam degradation. But interestingly, when you open up these machines, only 4% of those 422 machines actually showed foam degradation, right, which, of course, implies or begs the question, well, what is it then that people have observed or complain about? And one of the things that we have seen is that the level of cleanliness of the device varies greatly, and that could just be confusing to a patient.

So, all of that is very encouraging. Now, Roy, temporary supply chain challenges in China, lockdown, tell us about it.

Roy Jakobs: Yeah. So, indeed we mentioned that. I think we all know what happened in recent months. Our programme, as said, is still targeting the 90% by end of year. It's a daily battle. There is also still time in which we will do all we can to catch up on the challenges that we encountered in Q2. So, this is something that we will work daily with, as I said, the 1,000 people that are on this. Yes, we are dependent on our suppliers and certain logistic challenges to, kind of, take into account, but we will continue on a path to remediation. And as Frans said, we have 2.7 million now produced. We have the production capacity installed to actually deliver all of that, and then 90% within the year, and we will continue on that, with all force that we have.

David Adlington: Thank you.

Operator: Thank you. Our next question comes from James Vane-Tempest of Jefferies. Please state your question.

James Vane-Tempest (Jefferies): Good morning, and thanks for taking my questions. The first one, I was just curious, why do you think 0.5% of devices showed visual foam degradation even with no ozone cleaning?

And my second question is, you mention, 50,000 individuals who already registered with lawyers, which seems like a lot. I know you mentioned some might not file, but do you have a sense of the scope of potential injuries of those potential claimants, to help us just understand the materiality of that? Thank you.

Frans Van Houten: Yeah. Well, as I said, the – whether people use ozone or not to clean a device is a self-declaration, right, and – so, we cannot be 100% sure that the class of the devices in the 0.5% bucket, whether, indeed, there is no ozone usage there at all, or maybe there is some, right? That could be – that may still explain the difference between Europe, Japan, and US. Still, it's a marked difference between the 0.5% and the 7% where people do admit to the use of ozone.

The question around claims, I mentioned that a large proportion of the claims actually talk about…. I'm looking it up, breathing – which page is it? Yeah, so many of the personal injury cases allege injuries consistent with ozone, namely, cough, difficult breathing, nasal irritation, headaches, asthma attacks, and other breathing complaints. When you look up the FDA advisory back of 2020, these are exactly the same. And when you look in, let's say, the complaints in – registered with the FDA by users of ozone cleaning devices, these are the symptoms that are given there. So, let's not forget that ozone is an aggressive gas and cleaning agent that may cause these irritations in the respiratory process.

Many of the 50,000 people that have registered, could actually be about economic loss, and not about personal injury. The claims that we are aware of that have personal injury claims are 200 patients. 200 only. And it's very likely that many of the 50,000 actually will look for economic loss compensation, or may never file, as I said, in my introduction.

Yeah, then, is it a lot or not? Over the lifetime of production, of course, we have produced so many devices that our impression, actually, that all the advertising has not necessarily yielded that many registrants.

James Vane-Tempest: Thank you. And if I can just follow up to David's question, I understand what you're trying to show with the biocompatibility test, but this seems to be the most important test, which is outstanding. I'm not wanting you to speculate on the outcome, but can you help us understand the implications if the biocompatibility studies also fail?

Frans Van Houten: Well, the biocompatibility test, first of all, do particles actually reach the patient? If so, how many? And then, what is the level of toxicity, if any? All right, the fact that there are signals coming out of the Ames test show a potential, but does not necessarily confirm toxicity, and that needs to be completed. At this time, I cannot exclude that it does, but I find the fact that the process of degradation makes the foam sticky and moist, and that visual inspection shows an accumulation of particles within the machine, I find that very encouraging.

And let's not forget that this is then the base station of the machine to which you then attach a humidifier, and then you attach a long hose. And we are, of course, testing whether from the base station where, today, we see the accumulation of sticky particles, whether those sticky particles will actually leave the machine, pass through the humidifier, through a long hose reaching the patient in a degree and volume that would then be dangerous, if the test shows toxicity, right? So there are still various hurdles to overcome, and we don't want to speculate on that outcome, it takes time. But we are quite encouraged by the fact that the stickiness of the particles do not make them easily airborne and, therefore, hard to make that entire journey through the humidifier, through the tube, all the way into the – into patient lungs.

James Vane-Tempest: Thank you.

Frans Van Houten: You're welcome, James.

Operator: Thank you. Our next question comes from Julien Doumergue from BNP Paribas. Please go ahead.

Julien Doumergue (BNP Paribas): Hi, good morning, gentlemen. Thanks for taking my question. It's not directly related to the test result but more as to when you would now expect to resume production and sales of Respironics. I think you previously indicated that Q1 2023

was a potential target. Do the additional testing changes anything to that target, that we now expect more something in the mid-2023 timeframe, for instance?

Frans Van Houten: Yeah. Since I have Roy Jakobs next to me, who is in charge of Connected Care, and therefore Philips Respironics, I'll let him answer the question.

Roy Jakobs: Yeah, thanks, Julien. As I said, we continue our programme at full force. Actually, the testing is not expected to have an influence on our production, as such. So that, we will go in at full, and we are targeting the 90% completion of the programme by the end of the year, so that is still the plan we are working towards.

I also mentioned that there are supply and logistic challenges to deal with, and we know that that's a battle of every day, and not only for this remediation programme, but at large, and we will keep working that. And therefore also, the earlier plans – resumption of sales into the market, remains, as we are targeting, in the early 2023 timeframe.

Julien Doumergue: Thank you very much.

Operator: Thank you.

Frans van Houten: Yeah, maybe, Julien, just to be transparent, there may of course, also be a relationship to potential enforcement action by the FDA, that we also need to await, and that is something that is today not yet clear.

Operator: Thank you. Our next question now comes from Graham Doyle of UBS. Please go ahead.

Graham Doyle (UBS): Great. Thanks a lot for taking my questions. Just two from me. Firstly, we spent a lot of time talking about the lab-aged foam and degradation, but in the detailed results today, it looks like you failed on the cytotoxicity side in terms of new foam. So could you maybe just talk a little bit about that, and why you think that's happening, and if there's any impact from that?

I know you spoke about some of the injuries from some of these cases, it sounds a lot like ozone-related injuries. But to me, they also sound a lot like the worsening of lung disease, which is something we saw within the Swedish paper, which I know you pushed back on. But ultimately, what will be interesting is if you guys are going to come out with some sort of similar data, which maybe addresses that particular injury, given the potential scale of injured patients from that. Thank you.

Steve Klink: Yes. So, for the failed cytotoxicity, there was one test where it passed, and one element, indeed, it failed. For this one, it's important that this is new foam, so that will not – and new foam does not emit particulate, so, in that sense, the chance that it will come in contact with the patient is not relevant. Nevertheless, we will look into this in detail.

So, and then, if you look at the Swedish study, so, this study has several limitations that is also admitted or acknowledged by the authors themselves. They indicate that they did not take, let's say, the personal situation of the patients into account. And that significantly limits, say, the conclusions of that study. That goes for, on the one hand, when they looked at, say, the correlation with cancer. In the end, there is no significant correlation. And it also goes for the correlation with other diseases, there, the same limitation applies.

Graham Doyle: Maybe just a quick follow-up on that. So are you pretty confident that the data, or at least the signal shown in that particular study around lung function and your device is that there is no such signal, and you're not worried about that? And will you have data to support that view?

Steve Klink: So, we look at all the studies. So there were 12 – there were two high quality studies in the sense that they have very robust methodology. And all of the studies, whether or not they were robust, or less robust, they all point, from a cancer perspective, that there is no increased risk of cancer. The Swedish one also specifically looked at other diseases. But there was, as I indicated, a significant limitation that the authors themselves also acknowledged.

Graham Doyle: In terms of the lung function – so separate the cancer risk, and the questions around that – in terms of the lung function, have you any data yourselves, or any reason to believe that there is no risk there?

Steve Klink: We have no reason to believe that there is a risk there.

Graham Doyle: Okay, perfect. Very clear. Maybe just a quick follow-up, and this will be the last one. Just you mentioned a potential enforcement action from the FDA. Can you maybe sort of elaborate to what sort of things you've been thinking about, running scenarios on that front, if that's possible?

Frans van Houten: Yeah, I agree, and that was me – I just wanted to be transparent. I mean, because today, we are publishing very encouraging news. And we're very happy and excited about that. But, of course, that potential enforcement action is still possible.

Now, if you go back to, I think it was the January call, where I updated you on the response to the 483 that we had provided to the FDA, I think I mentioned there, explicitly, that we are treating this as if that would be an enforcement action. And we take very comprehensive action with regards to improvement of quality management, of all the various observations in the 483.

And I would imagine that if there is an enforcement action, that that, in any case, would make – would be integrally part of it. Other than that, I think this is not the day that we should speculate on the action. I merely tried to be transparent that this is outstanding.

Graham Doyle: That's completely fair. Thank you very much for taking my questions, guys.

Operator: Thank you. We're now moving on to Wim Gille of ABN AMRO ODDO, for our next question, please go ahead-

Wim Gille (ABN AMRO ODDO): Yes, very good morning. This is Wim Gille from ABN ODDO. If I look at the results of the study, it's pretty evident that there is a significant increase in all of the issues with – in relation to the ozone cleaning. Obviously, this is unauthorised and was also flagged by the FDA before the recall, that that was not the right thing to do. Do you have any intention after the entire replacement program has been completed, to basically go after the companies that actually promoted and sold the ozone cleaning [inaudible]? Thanks.

Frans van Houten: Yeah, hi, Wim. The particular company supplying these ozone cleaning devices is actually now included in the district litigation case and, therefore, will be integrally part of the court proceedings.

Wim Gille: And does that mean that you can't go after them to reclaim some of the costs that you have made? Or does that include that potentially, the individual injury cases or economic loss cases, whatever you refer to them to, of individuals in the United States, will fall in that [inaudible] bucket? Or how should I read that?

Frans van Houten: I realise I was maybe a little bit too short in my answer, apologies. The significance that the provider of ozone cleaning devices is part of the same court case means that we are able to transparently explain, let's say, what is our view to the origin of the acceleration of foam degradation, as well as a logical explanation of some of the respiratory complaints of patients. And when it comes to what extent is Philips to blame, or potentially another company to blame, we think that that is helpful.

Then, you have a second implied question, and that is, is there an economic damage to be gotten from somebody else? That is not where we are – I don't think that's, for us, the urgent question, right? Most importantly, priority number one, complete the recall; and then priority number two, is to provide clarity that – what is our responsibility in this litigation versus potential other actors.

Wim Gille: Thank you very much.

Frans van Houten: You're welcome. Of course, at this time, speculating about litigation is very difficult, right? This is also why I phrase everything very carefully, because that's really too early, but I understand why the questions are there.

Operator: Thank you. Our last question today comes from Falko Friedrichs of Deutsche Bank. Please go ahead.

Falko Friedrichs (Deutsche Bank): Thank you, good morning, everyone. I have two brief ones. The first one in terms of the timelines, and you said we should hear from the outstanding test results over the coming months. Is it realistic that we hear from you before the end of this year, or are you more alluding to early next year, when you say over the coming months?

And then, secondly, given the amount of suits that have been filed in the US, are there any litigation trials that could start over the near term, or have potentially already started? Thank you.

Frans van Houten: Yeah, hi, Falko. When we use the word 'months', it's still intended – it's still intended this year. We debated, is it this quarter, or could it be early next quarter, which is more the definition of the coming months.

We have learnt to be a bit careful, because we have been too optimistic in the past where testing time is always a bit longer than we had anticipated. And as we are dependent on external test houses, but also experts and toxicologists, and, in particular, this biocompatibility test will be heavily scrutinised by external specialists. We want to give this a little bit of leeway. But we still very much expect it to be this year. So we are not flagging this to move into next year at all.

Now then, on the lawsuit, look, the court preparations are already in motion, right? There's already this combination multi-district litigation court set up in – what is it? – the Western District of Pennsylvania. People have been appointed. All of that is clear. People are now making the preparatory steps towards hearings. All of that takes a lot of time. At this time, I cannot lay out the exact timeline or process. But certainly, preparations are in progress. The

moment we can say something about it, we will definitely try to share that in a transparent manner.

Falko Friedrichs: Okay. Thank you.

Frans van Houten: You're welcome. I think that was it from questions from you this morning. It's a lot of information that we published. I understand that there may be questions later on when some of the data has been digested. Of course, our team remains fully available to answer your questions. And we look forward to follow up on this dialogue.

Still, in conclusion, we find this news very encouraging, and I hope that we have been able to convey why that is. Thanks very much and have a great day.

[END OF TRANSCRIPT]