

PHILIPS

Test and Research Programme Update

Tuesday, 16th May 2023

Introduction

Leandro Mazzone

Head of IR, Royal Philips

Operator

Welcome to the Royal Philips analyst conference call on Tuesday, 16th May 2023. During the call hosted by Mr Roy Jakobs, CEO, and Mr Abhijit Bhattacharya, CFO, all participants will be in a listen-only mode. After the introduction, there will be an opportunity to ask questions. Please note that this call will be recorded and replay will be available on the investor relations website of Royal Philips. I will now hand the conference over to Mr Leandro Mazzone, Head of Investor Relations. Please go ahead, sir.

Welcome

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 polyester-polyurethane sound abatement foam. We appreciate that you could join our call on short notice.

Agenda

I'm here with our CEO, Roy Jakobs; our CFO, Abhijit Bhattacharya; and Steve Klink, who's the spokesperson for the test and research programme. Roy and Steve will take you through today's updates and after that, there will be an opportunity for Q&A. We ask that you – that your questions be limited to the test and research programme.

The press release, slide deck and frequently asked questions on the topic were published at 8.00am CET on our Investor Relations website this morning. The full transcript of this call will be made available on the website as well.

Over to you, Roy.

Overview

Roy Jakobs

CEO, Royal Philips

Today's update

Thank you, Leandro. Hello, everyone, and thank you for joining us this morning. Today, we are providing an update on the latest testing results regarding the safety of the sleep therapy devices affected by the June 2021 field safety notice.

Before I discuss the results in more detail, I would again like to take this opportunity to reiterate how important patient safety and quality are to Philips. As a company, we are driven by a purpose to improve people's health and well-being through meaningful innovation. This is at the heart of everything we do every day.

Encouraging complete test results for DreamStation1 devices

Now let me turn to the set of results we are reporting today. After a thorough and comprehensive process, we now have a complete set of test results for the first generation

DreamStation devices, including tests and analysis for devices that have been exposed to ozone cleaning.

The tests and analysis show that the exposure to VOC emissions for devices exposed to ozone is unlikely to result in appreciable harm to health in patients, which is very encouraging. This is based on assessment of ozone-induced degradation from up to 500 cleaning cycles.

This means that the outcome of all of the testing of the first-generation DreamStation devices is that the PE-PUR foam degradation, should it occur, is unlikely to result in appreciable harm to health in patients, which is very encouraging.

In addition, test and analysis has now been completed for System One and DreamStation Go devices and showed an exposure to foam particles and VOCs is unlikely to result in appreciable harm to help in patients in those devices as well.

We're also completing the analysis for System One and DreamStation Go devices treated with ozone cleaning. Based on results today, we do not expect different results compared to the first generation DreamStation devices. Let me remind you that these devices contain the exact same of PE-PUR foam as the DreamStation1 devices.

Together, first generation DreamStation, System One and DreamStation Go represent approximately 95% of the devices affected by the recall globally. At this time, the overall guidance for healthcare providers and patients using devices that have not been remediated yet remains unchanged.

The relevant competent authorities globally, including the FDA, are still reviewing the extensive data and insights gathered over the last 24 months. We have incorporated their feedback today and will of course address any feedback and questions that these competent authorities may have.

I will now pass it over to Steve to talk about the testing processes and latest findings in more detail.

Testing Process & Latest Findings

Steve Klink

Philips Global Press Office, Royal Philips

Introduction

Thank you, Roy, and hello, everyone. I would like to start with a closer look at the outcomes of the testing of the first-generation DreamStation devices.

Today's set of results build on the previous updates we gave in December 2021, June 2022 and later December 2022, and on this slide, you can see an overview of the previous test results.

We previously communicated to you that the prevalence of visible foam degradation is low. It's 0.5% in the inspected devices in the US and Canada; 0.04% of the inspected devices in Europe, and none of the inspected devices in Japan.

We also shared with you that both new and used first-generation DreamStation devices passed volatile organic compounds and particular matter emission testing. And in our last date in December 2022, we announced the completion of the biocompatibility tests for these devices. Exposure to particulates is unlikely to result in an appreciable harm to health in patients.

Test and analysis have now been completed for first generation DreamStation devices that have been exposed to ozone cleaning. The results published today indicate that potential patient exposure to foam particulates and VOCs from the PE-PUR foam in these devices is unlikely to result in an appreciable harm to health in patients.

This builds on our previous findings that exposure to particulates from degraded foam with self-reported ozone use is unlikely to result in an appreciable harm to health in patients. Therefore, although ozone cleaning exacerbates foam degradation, the test and analysis show that ozone-treated foam is unlikely to result in an appreciable harm to health in patients.

We continue to advise patients to follow Philips Respironics instructions and recommended cleaning and replacement guidelines for the sleep therapy devices and accessories. Ozone and UV-light cleaning products are not currently approved cleaning methods for sleep therapy devices or masks and should not be used.

Encouraging test result for System One and DreamStation Go

Moving on to the System One and DreamStation Go devices. Comprehensive third party risk assessments have concluded that potential patient exposure to VOCs and particulate emission is also unlikely to result in appreciable harm to health in patients. This is based on particulate matter testing, according to the ISO 18562-2, standard VOC testing according to the ISO 18562-3 standard, as well as a bioassay evaluation, chemical characterisation, and toxicological risk assessment, according to the ISO 10993 standard.

As Roy said, we're also completing the analysis for System One and DreamStation Go devices treated with ozone cleaning. Based on the results to-date, we do not expect different results compared to the first generation DreamStation devices.

Comprehensive and rigorous process to ensure patients and physicians have accumulated information

I would like to spend a minute on the rigorous methodology of the testing. We received a lot of questions from you on this topic, so it's important to explain it again. The test and research programme has been conducted with five independent certified testing laboratories in the US and Europe and the results have been reviewed and assessed by third party qualified experts, as well as by an external medical panel.

The testing laboratories conducted tests in accordance with the international Good Laboratory Practice or GLP standard, and they're making their own independent scientific assessment of the test results. The applied test methods comprising test planning, test execution and interpretation of the results for the completed risk assessments are in accordance with the applicable ISO standards. The design of the applied test methods was scientifically underpinned based on a thorough consideration and mitigation of test limitations that are inherent to any test standard and scientific research.

The laboratories and / or qualified third-party experts ran very conservative toxicological risk assessments to assure confidence in the results. Worst case, assumptions were considered. For example, assuming the theoretical consideration that all the foam is degraded, and the patient is exposed to all of the degraded foam.

When we inspected more than 65,000 devices, in none of the devices all of the foam was gone. So in all of the devices, there was still foam in the device.

Next steps

The VOC and particulate matter tests were conducted under different flow rate conditions. The VOC emission has the highest concentration at the lowest clinically relevant flow rate. Particulates are however stirred up via high flow rates, thus the maximum clinically relevant flow rate was used for dose tests. Therefore, a 17 litres per minute flow rate was used for the VOC emission test and a 90-litre per minute flow rate for the particulate matter emission tests.

We also checked testing at other flow rates and they did not yield higher VOC or particulate matter concentrations and ozone-induced degradation was tested up to 500 cleaning cycles. This resulted in foam degradation that was in line with a degree of degradation that we have observed in the expected use – in the inspected used devices with self-reported ozone. And let me please clarify that when we did the cleaning cycles, we have measured the VOCs and the particulates at various stages, for example, at zero, 20, 50, 60, 70, 80, and I can continue so and then up to 200, 300, 400, 500, and even one at 1,300 cleaning cycles. And at each time, the VOCs that were emitted were well below the safety limit, and at any time, it was almost a factor of 10 below the safety limit, which was taken fairly conservatively.

Large sample size

Another important topic is that the sample size is not small at all for this type of study. We have spent 24 months inspecting thousands of devices and conducting hundreds of tests. As I indicated earlier, we have visually inspected approximately 61,000 returned devices from the US and Canada, 2,500 devices from Europe, and approximately 2,000 devices from Japan.

For the devices from the US and Canada, where the user indicated they have not used ozone cleaning, only 164 out of 36,341 of these devices, that is 0.5%, showed significant visible degradation. So to do meaningful measurements on foam degradation, we need to primarily focus on those 164 devices and not so much on the other 36,177 devices. So automatically, you start with inspecting a big sample of devices of many thousands and then zoom in on the devices that showed significant degradation.

So – and then testing was subsequently performed on a smaller sample size, comprising multiple-use devices with differing amount of patient uses – usage and observed visible foam degradation. And on top of that, we have done tests on lab-aged foam that has been intentionally degraded to different degrees, and to a degree that was worse than any of the devices that we have inspected.

And this way, we have included the worst case scenario for our measurements and we have combined that, as I've already mentioned before, with fairly conservative assumptions for the risk assessments. So for example, that means that we have chosen fairly low safety levels.

Following the December 2022 update, the Dutch competent authorities stated on their website that the research was conducted thoroughly and that the test design is apprehensible and the methodology is adequate.

With regard to next steps for the Trilogy 100/200 and OmniLab Advanced Plus ventilator devices, the VOC and particulate matter testing continues, as well as the chemical evaluation and toxicological risk assessment. We expect to provide an update on this in the third quarter of this year as we indicated before.

As a reminder, the device has passed VOC and particulate matter testing, as well as several biocompatibility tests.

New and lab-aged Trilogy 100/200 foam failed the ISO 10993 genotoxicity testing under laboratory conditions, and therefore, a weight of evidence assessment is ongoing to confirm or exclude potential risks for patients under the expected usage of these devices.

I hope that you found the information that I just presented useful. And with that, I would like to give the floor back to Roy.

Conclusion

Roy Jakobs

CEO, Royal Philips

Summary

Thank you, Steve. Let me thank our patients and customers for their patience, and our suppliers and partners for their continued support. The new test results reported today are again positive and reassuring and as such, we're happy to present them.

This means that the outcome of all of the testing of the first generation DreamStation devices is that PE-PUR foam degradation, should it occur, is unlikely to result in appreciable harm to health in patients, which is very encouraging. The completion of the testing programme, as well as the remediation, remain our highest priorities.

And with that, we will now take your questions. Thanks.

Q&A

Operator: Thank you, sir. If any participant would like to ask a question, please press the star followed by two-times one on your telephone. Due to the time, please limit yourself to one question with maximum of one follow-up question. This will give more people the opportunity to ask questions. There will be a short pause while participants register for a question. We'll now take the first question. The first question comes from Ms Veronika Dubajova from Citi. Please state your question.

Veronika Dubajova (Citi): Hi, guys. Good morning and thank you for taking my question, please. Just would love to get a bit of insight to what the feedback has been from the FDA, as you have shown them this data, what their kind of thoughts have been? And when would you expect to have something more formal from them in terms of how they are perceiving

this data and whether it's satisfactory to maybe alter some of the language around the recall and the risk assessment? Thank you.

Roy Jakobs: Yeah. Thank you, Veronica. Along the whole process of testing, we have kept the FDA informed as we also shared earlier, and that also led to the inclusion of the notion that they are still studying the results. I also mentioned that, that we are now 24 months in the testing programme. This is a very extensive testing programme and as such, there are a lot of data involved.

Now what I alluded to earlier is that it's important to know that FDA is, of course, not a testing house. So it's not necessarily expected that they will qualify the data or that they will kind of give them a formal stamp of approval. But they are, of course, looking into the data and if they have further commentary, we can expect that they will provide that to us.

So that's the latest of the FDA, and before publication of today's results, we have reached out to them, we have kind of included their commentary, and that's what we also did last time.

Veronika Dubajova: Okay. And can I just ask a follow-up, Roy? Just sort of surprised by some of the stats that you presented at the outset of the call about the proportion of devices where you've seen degradation. I'm just really surprised by the geographic difference, there are none in Japan, one in Europe and then so many in the US. Just are you confident with the data? And what explains it in your mind? Because humidity cannot be the only thing and I'm just a bit surprised by that variability. It's quite striking. And then I'll go back into the queue. Thank you.

Steve Klink: Hi, Veronika. This is Steve. The – so indeed for the US, it's a 0.5%, for Europe is 0.04%. What I must mention is that for the US it's self-reported no ozone use. And what we suspect is that among those that have – that ozone has been used, because – and that leads to a higher prevalence compared to Europe and compared to Japan.

I would say that Europe and Japan are similar, 0.04% or 0%. Yeah, that is fairly close. And what we've also seen from Europe is that we have tested or we have inspected devices from various ages from between one and five years and from various parts of Europe, from France, Spain, Italy, the Netherlands, the Nordics. So all types of climates are in there and that did not have an impact on the degradation of the foam. And that is in line with our current understanding of the degradation process.

Roy Jakobs: So in short, Veronika –

Veronika Dubajova: So you think it's just ozone?

Roy Jakobs: Sorry, yeah, I think maybe to build on it, as we have said before, ozone use does have an impact, and that you have seen being used much more in the US. That's actually where you see the difference from. That's also why today's presentation of the results is so important, because despite that ozone was used and as a result, more degradation happened, even with that use of ozone actually, it's not leading to any appreciable harm for our patients.

So I think that is why today's update is really relevant, and was an important step to kind of complete the whole test results from DreamStation One on.

Veronika Dubajova: Thanks. I appreciate it.

Operator: Thank you. We will now take the next question from the line of David Adlington from JP Morgan.

David Adlington (JP Morgan): Hey guys, thanks for taking the question. Just to follow up on Veronika's question there, just in terms of the sentiments stated on the call, you've incorporated the FDA's feedback today. I just wonder what you meant by that, some sort of clarity and some further colour about what their feedback has been and how it's been incorporated in today's release? And sort of following on from that just the phrase 'appreciable harm', what do you mean by appreciable harm? Could it still cause some harm? Or how should we be interpreting that phrase appreciable harm? Thank you.

Roy Jakobs: Yeah, may be starting with the latter. So 'appreciable harm' is I think the formal term that's used also as part of the standard. It in essence means extremely low probability that there's any harm done. So this is the technical term that's being used in case that your evidence shows that, in essence, there's no evidence found.

Then on the inclusion of the FDA's request, that is that they may come to different conclusion based upon the ongoing study that they do. So that's what they have shared. And as you have seen earlier, we also included the limitations of our test results. And that was also kind of established together with the FDA. So we have this one-pager, I think also in the presentation, and that shows that kind of any test has kind of limitations. We have also taken countermeasures against those limitations, which then also kind of led to an inclusion into these results. So I think that's the slide 10 of the slide deck for the investor relation page.

So those are the two elements that came back from the FDA.

David Adlington: Okay. That's clear. Thank you very much.

Operator: Thank you. Once again, if you would like to ask a question, please press the star followed by two-times one on your telephone keypad. And we will now take the next question from the line of Sezgi Oezener from HSBC. Your line is open, madam. Please go ahead.

Sezgi Oezener (HSBC): Hi, thanks for taking my questions. Congratulations on delivering the test results. One question on the number of devices remediated. You've said you've remediated 4.3 million globally and the large part of this, 2.2 I believe, in the US. When do you expect to complete the remediation globally? And can we now be certain about the total number of devices involved?

Roy Jakobs: Yeah. So indeed we shared the 4.3 and the 2.3 that are with patients. So what we see is that actually, we are making good progress. We shared earlier that kind of we have more than 95% produced. And depending on the country that we look at, we also are above 95% of remediated and back in hands of patients.

But there are variances in it. And what we see is that we – as we get now to the back of the remediation, there are certain patients or devices that are registered and that actually do not respond anymore to our outreach to replace the device. And that might not be too surprising, as we know that 35% of the population actually drops out of therapy after one year.

So it might be that we never get to that full number that we initially reported as total registered number of devices, but we do all our efforts to kind of reach these patients and to kind of make sure that they get it. We have them at hand, right? We have them produced,

so we can send and install. But we do need of course to get the patient to share his details, both of the address as well as therapy. And that's kind of taking this last stretch.

Now, as we shared earlier, we expect that in Q2, we would really further focus on this in a significant manner, and then thereafter, there might still be some really tail-end patients that might step forward in a later date, and then of course, we will at any time remediate, as we have promised to do.

Sezgi Oezener: Thanks very much. Just as a follow up, do you have an estimate of the number of people that may have dropped out after registering the devices initially?

Roy Jakobs: No, we don't have an exact estimate because that's kind of – it's as hard to speculate on how many people do not return. But we do see that, in certain areas, we see less responsiveness certainly coming in. Yeah. And then, of course, you start to kind of further look for contact, but that doesn't then come back. So we will keep attempting, but currently, we do see that there's a certain number that doesn't reply.

And give you an example, for the Netherlands, we're now at kind of – we had more than 100,000 to remediate. We have now 97,000 remediated. Yeah. And then it's the last few thousand that are hard to reach. So that's kind of where we are in these last percentiles, that kind of we need to either reach or we will find that might – they might never come to us. Yeah, and then we don't need to remediate them.

Sezgi Oezener: Thanks very much. And if you don't reach these patients, you've had – you've set aside the provision, assuming that you will replace all of their devices registered. So if these people don't come back, is there a possibility that you might reverse some of that?

Abhijit Bhattacharya: Yeah. Hi, Sezgi. We will have to see at that point of time, because the machines would have been remediated. So it would be either a repaired machine or a new machine. If it's a new machine, we probably would be able to sell it. If it's a repaired machine, maybe not. So these are things that we will have to estimate closer to the time of this thing coming to an end.

Sezgi Oezener: Perfect. Thanks very much.

Operator: Thank you. We will now take the next question from Mr Robert Davies from Morgan Stanley. Please ask your question.

Robert Davies (Morgan Stanley): Yeah, thanks for taking my questions. You covered a couple. One was just on terms of remaining testing. What's actually sort of left to do, what data are you're waiting to still get?

And then the second part is just in terms of the options here from a legal standpoint, how these testing results are going to impact the potential settlement or provision that you're setting aside? Has this – has the outcome of this kind of testing had any impact on the size of the provision that's being set aside in your mind? Thank you.

Steve Klink: So this is Steve. For the ongoing testing, so we are in the process of completing the testing for System One and DreamStation Go devices that have been treated with ozone cleaning, but they contain the exact same foam as DreamStation1 devices, so we do not expect different results there.

And then, of course, we need to complete the testing for the Trilogy 100/200 and the OmniLab Advanced Plus ventilator devices. So that is among say that the last 5% of the devices that are under the recall.

A large part of these tests have already been done, but there are still a number of tests that needs to be done and we expect to provide an update on that in the third quarter.

Abhijit Bhattacharya: Robert, on the provision already set aside, the provision that we have set aside is for the economic loss. So it is not related to the test results. The provisions that we do not make or we – that we have not been able to make a reasonable estimate is on personal injury and that we will – that will come as we have said next year. So the existing provision of 575 will not change because of the test results.

Roy Jakobs: And this is, of course, very important news for the patients because we can assure them that that there is no appreciable harm done to their health, regarding use of the device. Of course, if there are cases where people then claim differently, we will use this data to kind of have the dialogue around it.

Robert Davies: I see. Okay. Thank you very much.

Operator: Thank you. We'll now take the next question from the line of Wim Gille from ABN ODDO. Please go ahead with your question.

Wim Gille (ABN ODDO): Yes, very good morning. This is Wim Gille from ABN AMRO ODDO. Taking into account that no appreciable harm was done to at least 95% of the patients in scope, can you give us a bit of feeling on if we – if there is any need to do with respect to a potential outcome on the consent decree and the personal injury class action that is still out there? I.e., what do your lawyers tell you what the impact of these test results might be on a positive outcome on these two outstanding reports as well? Thank you.

Roy Jakobs: Yeah, Wim, thank you for the question. Yeah, as we said earlier, it's hard to speculate on outcome both on consent decree as well as on personal injury claims. It's too early for that. The consent decree is not in essence anything to do with the testing, the consent decree is a follow up on the 43 that was given by the FDA after their findings of site visits and that's been worked into a wider set of measures. So that's a separate topic.

Then on the personal injury, as said, that's very hard to speculate on. So we will not do that in terms of what this will mean in or for any of these cases.

As I said before, of course, the fact that this is not having any health effect for patients, that's the big news of the day that we're very happy to share. And therefore, yeah, it was important to complete the ozone part of the testing of DreamStation One so that we now have very rigorously tested all separate pieces, over many, many devices, across the different test houses and with the independent views on it. So we feel very encouraged to be able to share those and then also take them forward.

Wim Gille: Thank you very much. And then as a follow up, taking into account that the use of ozone has basically increased the degradation of the foam quite substantially, is there any, let's say, lawsuit or legal process going on against the company that is actually promoting this ozone cleaning? Or is that still not in progress?

Roy Jakobs: No, it's – we will not comment on that. I think we tested the ozone impact. So this was about the best results and therefore, we're very happy to say that the amount of outcome was that there is no impact on patient safety and we will not kind of further involvement on any regulatory or litigation action with other companies.

Wim Gille: Thank you very much.

Operator: Thank you. We will now take the next question. It's from line of Falko Friedrichs from Deutsche Bank. Please ask your question.

Falko Friedrichs (Deutsche Bank): Thank you and good morning. I have a few follow ups, please. The first one is, so is it now fair to assume that in Q3 of this year, you should have the full conclusive test results for 100% of the affected devices?

Then my second follow up. When do you expect this more formal response from the FDA on today's announced test results? And my third follow-up, is can you provide your latest update or latest thinking on when you expect to finalise the consent decree? Thank you.

Roy Jakobs: So on – so Falko, on the testing, so what we said is we expect to come forward in Q3 with further Trilogy data. Then there is still remaining piece of the OmniLab that we will, kind of, have to complete and that we will probably present in Q4. So we'll aim to, kind of, conclude all of the testing in 2023 of all devices that, kind of, have been undergoing the recall with, then, different phasing in Q3. And then, when we have Trilogy, of course, that's 3%, and then you get in the real tail end of the recall for the last piece.

And then the expectation on the consent decree. Yeah, as I discussed earlier, also in the Q1 results, we are in continuous discussion. I also expect it to be in Q2. I still hope that it also is going to be Q2, but I also mentioned that we are not in control of the timeline, that's, of course, something that ultimately is the hands of the FDA. We're working closely together on it, but that is something that is determined on that end. So I cannot give any definitive date, but I can assure you that we're working through this with the FDA.

Falko Friedrichs: Okay, thank you. And by when do you expect the FDA to, essentially, sign off on today's announced test results? How long could that take?

Roy Jakobs: Yes, yeah. So as I said earlier, so I think we need to be very – we need to understand, also amongst the members of this call that there might be never a date that they sign off, because it's not their role to sign off on test data. So they will study it, they might comment on it, but they might never come forward with a definitive, kind of, opinion on it. They have a right, and that's also what they said, to reach different conclusions and that right they preserve, that right they have been preserving themselves throughout the whole process, right? So as we've been saying that every step along the way.

So that's nothing new, that is there since we started to share the results. And that maybe also indicates, kind of, a position that they hold, that, kind of, yes, they will study it, they might comment, but I think we should not, maybe, expect that there will be a certain date in time that they will say, 'And now we've looked into everything and now we sign it off,' because they're not a test house. And there's also a very comprehensive process that we have been going through that they might not want to repeat. So I think that's important to understand.

Falko Friedrichs: Okay, thank you.

Operator: Thank you. We will now take the next question from the line of Graham Doyle from UBS. Please ask your question, sir.

Graham Doyle (UBS): Morning. Thank you, guys. So, just can I ask one question on the ozone testing. In previous interactions we've had, you've kind of acknowledged that the cycle testing isn't necessarily – well, it's not – it doesn't really replicate real-world use, i.e. one hour of use for one clean, and in my estimate you'll probably use the machine for six to eight times longer than that. So do you think it's really fair to say that you can draw a conclusion for this test that using the device with ozone cleaning is still safe for patients? Because presumably most patients will have used the device for a lot longer, which therefore brings a risk of greater degradation. And just one follow-up in a second. Thank you.

Roy Jakobs: No, that is absolutely not correct. We have designed the test so that it can, say, mimic real-world use. So we have run the device for a certain amount of time, done – then done an ozone cleaning, and that is one cycle. And we have simply repeated that for a number of times and we have – at various intervals we have measured both the volatile organic compounds and the particulate matter, and at all times, even at 1,300 cycles, the VOC or particulate emissions were well below the safety limit.

So we now have a very thorough understanding of foam degradation, both with and without ozone cleaning. And when we did the risk assessments, then we have taken very conservative safety limit and what is more important, even if you have a look at – in our ozone tests and even at 1,300 cycles, then that is still not the worst case that we have seen and also tested in other conditions. For example, we have always said that we are also testing lab-degraded foam, that is artificially-degraded foam. And even after 1,300 cycles of ozone testing, the amount of VOCs is well below what we see after lab – after doing a lab-degraded foam test, and, again, that is well below the safety limit. So we are absolutely confident that we have looked at the worst case situation and we have full confidence in the ozone cleaning tests.

Graham Doyle: Okay. But, I mean, I still – the point would stand though, one hour of use, regardless, it is not the same as how a patient will use it, so we don't quite know how that will react. It's just an inference, I suppose. Is that ...?

Roy Jakobs: But that is not –

Graham Doyle: Have you done that test also?

Roy Jakobs: So what you're mixing up is the actual cycle to mimic ozone cleaning and then the toxicological risk assessment, because the toxicological risk assessment then assumes – that looks at the amount of VOC that was measured, and then, in the calculation, we use a normal use of the device. So the calculations are done based on the actual use of the device, and the cycles are just there to induce the ozone degradation.

Graham Doyle: Sorry, I don't think I am mixing up. I'm just trying to – what I'm trying to understand is, are those cycles, essentially, the best way of mimicking real-world use? Because previously that's not what you said is true. I'm just trying to understand that, because presumably there will be tests where it mimics real-world use and, whilst they might

say the same thing, results or risk, but they don't say the same thing. So that's what I'm trying to understand, is the cycle meant to mimic real-world use or not?

Roy Jakobs: Yes. Because we also know that it's about the exposure to the ozone and that you, in there, have a period of time where the system is simply being used. Again, this is just to mimic the degradation of the foam. When we do the toxicological risk assessment, we take into consideration that that device is used for the – depending on the use case, for six to eight hours a night. So in the calculations, we have the full use case.

Graham Doyle: Okay. So I'm still a bit confused, but let's leave it there. Thank you very much.

Roy Jakobs: And maybe just a final comment, Graham, just to clarify. So we have tested devices that have been used in the field, so this is not only theoretical test. We have been testing on user, kind of, devices that have been using ozone and have been further testing them to see what kind of VOC and particulate matter emission there was. So we have both, kind of, pristine foam that, kind of, we tested, we have lab-aged foam and we have real-life devices that we tested. So we tested the full population.

Graham Doyle: Okay, okay. Thank you.

Operator: Thank you. We will now take the last question. It's a follow-up from Veronika Dubajova from Citi. Please ask your question, madam.

Veronika Dubajova: Excellent. Thank you, guys. Just a follow-up. I mean, given that there clearly is a link between ozone and foam degradation, just wondering if you're doing any other work around the particle risk beyond the sizes that you've looked at? In particular, I'm thinking the patients here have significant lung damage to begin with, often asthmatic or COPD. Any testing in what you're doing on that front that you might be sharing with us, or is this not something that you're working on at the moment? Thank you.

Roy Jakobs: Yeah. We have already done it. So, essentially, so we have looked at multiple ways, if – whether there would be any particles coming from the device, and we have not seen that. So we have not seen a difference between new or used devices in terms of the particulates coming out or anything coming out of the device.

So what we are simply seeing is that, yeah, if there is any particulates coming from the device then it's well below the safety limits, and they've been taken, again, fairly conservatively. And even theoretically, if you would – were to assume that all of the foam degrades and all of the foam ends up in the patient, then still there is no harm to health in patients.

But you also should keep in mind that for DreamStation there is 5 grams of foam in there and foam contains air pockets. If you were to take the air pockets out and compress the foam to a solid, then you would only be left with 5 millilitres of the material and that is a teaspoon. So there is a finite amount of foam only present in a DreamStation device. And what we have even seen in the worst case, that there is always foam present in the device. So that's why we have confidence in the results.

Veronika Dubajova: Yeah, I appreciate you've done the lab testing, but, I guess, I – and it's a two-part question and some of it touches upon what Graham had asked, right? So, I mean,

one, particulate exposure can be cumulative, as opposed to in time, and so I'm curious if you've done any work on the cumulative particle accumulation? And then, obviously, patients with lung disease are at higher risk to health harm from particulate exposure than patients without lung disease, and the standard, at least as far as I understand it, is just one single standard. So I'm just curious if you're doing work in either one of those two things?

Roy Jakobs: So, yeah, we have already done it. So we have considered different patient populations, and again, we have taken the most conservative standards or safety limits and at all times it was well within the safety limits. So we have done everything that you've discussed and we have taken that into consideration in the risk assessments. We were just –

Steve Klink: Yeah.

Roy Jakobs: – very brief about it.

Steve Klink: So for any patient population, Veronika, whether it's somebody who has (just) sleep apnoea or has multi-morbidity, so various problems, the outcomes hold and there are no health effects coming from the use of the sleep apnoea device, neither from a sleep apnoea device that was cleaned with ozone. And I think that's very good news because it also means that even now for completing the recall, there is no patient out there currently that has been using our devices that has been exposed to health harm risks as a result of it. And I think that is really important and kind of, that's also why we core stress-test that to extreme conditions. And that is for any patient population that is out there.

Veronika Dubajova: Okay. So you've simulated five years of particle accumulation?

Steve Klink: Yes.

Veronika Dubajova: Okay, okay. Thanks guys.

Operator: Thank you.

Roy Jakobs: No problem.

Operator: We will now take the next question from the line of Hugo Solvet from BNP Paribas Exane. Please ask your question.

Hugo Solvet (Exane BNP Paribas): Hi, hello. Thank you taking my questions. I have just two follow-ups. First, Roy, you mentioned that the FDA is carrying out their own studies. Just wanted to clarify, are they basing their assessment on your results or carrying a separate, sort of, trial and lab testing? And, if yes, have you been provided with any timeline on when they will have the results and if there are any differences in the methodology being used, i.e. for example, will they focus only on newer devices or anything else?

And, second, can you repeat just the total number of devices that you have inspected by geographies? Thank you.

Roy Jakobs: So on the first, as I said earlier, actually the FDA is looking into the data. We are not privy to inside that; they are doing their own studies. So that's something I cannot, kind of, comment on or speculate about. Actually, what we've – we are not aware of that. So, actually, they have been using and looking into our data and our methodology, and as I said before, you would also not necessarily expect to them to do own testing because they are not a test house. They will also not come, necessarily, with conclusive, kind of, outcomes

on testing because testing for them is one part of looking into patient safety, but that's not something they do themselves.

So that's something that we keep in dialogue on. But, yeah, we might, maybe, never get a final opinion on it, or we might and then, the moment we get further opinion, of course we will share as we have been doing that today.

And then the second question, if I understood well, was you asked for the number of devices that we have looked into per region. So, regionally, how many –

Hugo Solvet: Per region, yeah.

Roy Jakobs: – how many we tested or remediated, what was the exact question?

Hugo Solvet: Inspected, I think you mentioned 65K, but not sure I got that right.

Abhijit Bhattacharya: Inspected.

Steve Klink: Oh, yeah, yeah. So with the number of inspected devices, so it's around 61,000 from the US and Canada, it's something like 2,500 from Europe and 2,000 from Japan. Yeah.

Abhijit Bhattacharya: Yeah.

Roy Jakobs: Was that clear, Hugo?

Hugo Solvet: Yes, perfect. Thank you.

Roy Jakobs: Okay, great.

Operator: Thank you. Due to the time, that was the last question. Please continue for any points you would like to raise.

Roy Jakobs: Thank you all for dialling in on short notice, as Leandro said. We were really pleased to be able to come forward today with the final and complete test results on DreamStation One, including the ozone testing, and with the very important outcome for the patient that actually what we have seen from all our extensive testing, which was done very rigorously with the scientific methods that, kind of, we developed for it with external parties and external medical panels, and that there is no appreciable harm for health in patients that we have been seeing, as the result of the use of a sleep apnoea device. So that is something that we very much value as an outcome and we're happy to share with you.

Thank you for your time and I wish you a great day.

Operator: This concludes the Royal Philips Analyst Conference Call on Tuesday, 16th May 2023. Thank you for participating, you may now disconnect.

[END OF TRANSCRIPT]