



**Koninklijke Philips N.V.
- Test and Research
Programme
Respironics' PE-PUR
sound abatement foam**

Wednesday, 21st December 2022

Introduction

Welcome

Thank you, and good morning, everyone. Welcome to today's conference call to update you on the Philips Respiroics' Test and Research Programme for the polyester polyurethane sound abatement foam. We appreciate that you could join our call on short notice.

I'm here with our CEO, Roy Jakobs; our CFO, Abhijit Bhattacharya; and Steve Klink, who is the spokesperson for the test and research programme.

The press release, slide deck, infographic and frequently asked questions on the topic were published at 8.00 AM 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.

Opening Remarks

Roy Jakobs

CEO, Philips NV

Welcome

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 and ventilators affected by the June 2021 field safety notice.

Field safety recall

Before I discuss the results in more detail, I would like to reiterate how important patient safety and quality are to Philips. We are driven by our company purpose to improve people's health and well-being through meaningful innovation. This is at the heart of everything we do every single day. Our commitment to addressing all facets of the Philips Respiroics' recall is a vital part and priority in this.

I understand how important these sleep therapy devices and ventilators are to patients and how they improve their lives every day and every night. We have disappointed the many patients who rely on them as well as those caring for them, for which I say again today, I'm deeply sorry.

Test results

Now let me turn to the set of results we are reporting today. Over the past 18 months, Philips Respiroics has conducted a very rigorous test and research programme with the support of five independent certified testing laboratories in the US and Europe, which was reviewed and validated by third-party toxicologists, as well as an independent external medical panel. The complexity of the tests and the time taken to analyse the data per device category and condition is substantial and impacts throughput time for each test.

Today's update focuses on the latest results for the first generation DreamStation devices, which represent more than two thirds of the registered affected devices globally. Following the

update in December of last year and June of this year, we now have a complete set of results for these devices. This provides greater clarity on the health risks compared to the limited insights we had in June 2021. We previously communicated to you that the prevalence of visible foam degradation is low. We also shared with you that both new and used first-generation DreamStation devices passed volatile organic compounds and respirable particulate emission testing.

The latest third-party chemical evaluation and toxicological risk assessment has concluded that exposure to particulates from degraded foam in these devices is unlikely to result in appreciable harm to health in patients. This is encouraging. We are sorry that patients had to wait this much time, but the scientific processes had to be done thoroughly and could not be rushed.

At this time, the guidance for healthcare providers and patients remains unchanged as the regulators work through their analysis. The relevant competent authorities globally, including the FDA, are still reviewing the extensive data and assessments that we provided. We share the same objective to ensure patient safety and quality in delivery of health care. We are therefore committed to working closely with these agencies as we continue to complete the test and research programme and the remediation of the affected devices.

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

Testing Process Overview

Steve Klink

Global Press Office, Philips NV

Overview of testing process

Thank you, Roy, and hello, everyone. I would like to start by giving more background on the rigorous methodology of the testing.

The applied test methods comprising test planning, test execution and interpretation of the results for the completed risk assessments are in accordance with applicable ISO 18562 and ISO 10993 industry standards. The design of the applied test methods was further scientifically underpinned based on the very thorough consideration and mitigation of the testing limitations that are inherent to any test standard or scientific research.

Extensive test and research programme completed for DreamStation 1 devices

Now, on the biocompatibility testing that we have completed for the first generation DreamStation devices, including the chemical characterisation and toxicological risk assessment that we are publishing today. These tests are relevant, as we have previously reported that lab-degraded foam failed genotoxicity, cytotoxicity and irritation tests under laboratory conditions. And as indicated by the ISO 10993 standard, the chemical characterisation and toxicological risk assessment were performed to determine the actual health risk if degraded foam particles were to reach the patient under normal use conditions.

Thorough consideration and mitigation of testing limitations that are inherent to any test standard and/or scientific research

The laboratories ran a fairly conservative toxicological risk assessment to assure confidence in the results. Worst case scenarios, so worst case assumptions, were considered. For example,

assuming that the per patient is exposed to a theoretical 100% of the foam, and this is a fairly conservative assumption, because even in the inspected devices that were returned to us and that had the most degradation, still foam was present in the device.

Additional chemical characterization and toxicological risk assessment (biocompatibility test for DreamStation1 devices)

Now let's take a closer look at the outcomes of the testing. The complete set of results published today with results of the new and repeat tests indicate that exposure to particulate matter emissions from degraded foam in DreamStation devices, including the potential respirable and non-respirable particulates, is unlikely to result in an appreciable harm to health in patients.

Completion of biocompatibility test for DreamStation 1 devices shows encouraging results

Moreover, the results indicate that the exposure to VOCs is not anticipated to result in long-term health consequences for patients. This is based on the ISO 18562-3 testing and is consistent with the results that we presented in December of 2021. We can also confirm that based on additional visual inspection of the foam in used DreamStation 1 devices, the prevalence of visible foam degradation was found to be low. Also these results are consistent with the results we presented in June of 2022.

Results to date on the impact of ozone cleaning on PE-PUR foam degradation – DreamStation 1 devices

We are also conducting ongoing testing on devices that has been exposed to ozone cleaning. Data available to date for DreamStation 1 devices shows that ozone cleaning, which is not an approved cleaning method, exacerbates foam degradation. We found that returned devices from the US and Canada with user-reported ozone cleaning are 14 times more likely to have significant visible foam degradation compared to devices with no user-reported ozone exposure.

This observation is consistent with laboratory testing, where first-generation DreamStation devices exposed to increasing cycles of ozone cleaning had increasingly more severe visual degradation.

It is important to note that testing and analysis regarding the risks associated with respirable and non-respirable particulates has been performed on devices with known ozone exposure. Third-party collective analysis concluded that exposure to particulates from degraded foam exposed to ozone cleaning in DreamStation 1 devices is unlikely to result in appreciable harm to health in patients. The VOC toxicological risk assessment of ozone-induced degradation is still being assessed.

Trilogy 100/200 devices

Now moving on to the new Trilogy 100/200 devices, which contain a different type of polyester polyurethane foam than the DreamStation 1 devices. The new Trilogy 100/200 devices passed VOC and particulate matter testing, as well as several biocompatibility tests. New and lab-aged Trilogy 100/200 foam failed ISO 10993 genotoxicity testing under laboratory conditions. Therefore, a weight of evidence assessment is ongoing to confirm or exclude potential risks for patients under the expected usage of these devices.

Silicone foam testing

And moving on to the silicone foam used in the DreamStation2 and the reworked DreamStation1 devices. In November of 2021, the FDA requested that Philips Respiroics retain an independent laboratory to perform additional testing to determine what if any potential safety risks may be posed to patients by the silicone-based foam. Philips Respiroics engaged independent test – engaged independent testing laboratories to perform additional VOC testing. And based on these tests and the final reports, no safety issues have been identified. And this is subject to FDA review.

Next steps

With regards to next steps, we are in the process of finalising the toxicological risk assessment of the VOC emissions resulting from ozone-induced foam degradation in DreamStation 1 devices. We are also completing testing for the SystemOne and DreamStation Go sleep therapy devices that contain the exact same polyester polyurethane foam as the DreamStation 1 devices. Based on the results to date, we do not expect to see different results for these devices compared to the DreamStation 1 devices.

Additionally, for the Trilogy 100/200 and OmniLab Advanced Plus ventilator devices, the VOC and particulate matter testing continues, as well as chemical evaluation and the toxicological risk assessment.

Philips Respiroics engaged external scientific experts to conduct a systematic review

I would like to spend a minute on the existing literature and independent studies on the health risks and CPAP usage globally.

Philips Respiroics engaged external scientific experts to conduct a systematic literature review of epidemiological studies. There were 13 identified studies, all of which found no consistent statistical association between use of PAP devices, that is, positive air pressure devices, including Respiroics devices, and the risk of cancer in patients with obstructive sleep apnoea.

Two of the studies are quite comprehensive and should be reassuring for patients, as they show no statistical difference in cancer risk between users of Philips Respiroics PAP devices and users of other brand devices, or even users – or even sleep apnoea patients that use no devices. 11 studies provided limited additional insight, but their results also suggested no excess risk of cancer associated with use of positive air pressure devices.

The 2022 study by Palm et al reported a more frequent prescription of respiratory relief medication among patients with both OSA and obstructive lung disease but there was no statistical difference observed in the hospitalisation for all among obstructive sleep apnoea patients and between the users of polyurethane, PEP foam and non-foam PEP.

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

Conclusion

Roy Jakobs

CEO, Philips NV

Completing around 90% of the required production in 2022

Thank you, Steve. Before we conclude, I would like to provide an update on the progress of our remediation efforts, which are underway globally.

We have quadrupled our production capacity compared to before the recall and we mobilised more than 1,000 people working on recall day in and day out. We will complete around 90% of the required production by the end of this year, despite dealing with headwinds related to supply of materials and logistics throughout the process.

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. 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 encouraging and reassuring. 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 time, please limit yourself to one question. This will give more people the opportunity to ask questions. There'll be a short pause while participants register for questions. The first question comes from Ms Veronika Dubajova from Citi. Please go ahead, madam.

Veronika Dubajova (Citi): Hi, guys. Good morning and thank you for doing this call today. A big picture question for me, I guess. Obviously, we've seen some encouraging data, I guess. What do you need to see to change your own risk assessment of the recall? Because I've noted that the language there has remained unchanged. And what do you think the regulators need to see to agree with that revised risk assessment, whenever you're ready, just to start those conversations? And I guess, what is the timeline for that? I know, it's a very big picture question but just trying to get to the heart of – we have some encouraging data today, but obviously, the bigger question is, is the risk assessment all in, and we have not yet seen a change to your thinking on that front. Thank you.

Roy Jakobs: Thank you, Veronica. Maybe a twofold answer. First, we do come out with visuals today that do show that actually the use of the DreamStation 1 is within safety limits. So the prevalence is low, VOC and particulate emission is within the safety limit. So that actually is very encouraging, reassuring.

In terms of the process that we are in, and we are also connected to a potential change of the advice to use, that of course has to happen in alignment with the regulator. Now, as we have shared today, we have taken 18 months to get to these results, because this is a scientific,

elaborate process that needs to be done very thoroughly. And we have put ample amount of resources, tons of researchers; you saw the independent laboratories on it.

Now, we shared this very comprehensive data set with the regulator, but they have this only a few weeks whilst we have been studying it for 18 months. So I think it's fair to say that they need the time to work through this, of course, at their own leisure. They also therefore uphold the right to kind of draw those conclusions. I can say that we have stayed in very close contact with the regulator. So they have been seeing the data up to date, they have been giving input. They also gave input even to today's release in terms of some of the text that you have seen. So we are in very close contact.

And after the alignments with the regulator, and when they have made their assessment, then also we can change, for example, the field safety notice that we have out there that also comprises all the devices that we have out there. So we, of course, gave the test results today of DreamStation 1, which is the vast majority, 68%. And we hope to come shortly back with the DreamStation – or with SystemOne and DreamStation Go results and then we cover 95%. And if we have all the devices covered, and we have the regulator outcome, then you can also kind of change your advice that is in the FSN.

Veronika Dubajova: Got it, Roy. And apologies, if I can just squeeze in a follow up. In terms of the ozone-exposed machines, when do you expect to provide data on that? That would be – when can we expect that?

Steve Klink: Hi, Veronika. This is Steve. Yes, we can expect that in the coming months. We are in full process of doing or finalising the tests. And then the next step is the assessment of the results. So in the coming months.

Veronika Dubajova: Okay. That's great. Thank you, guys.

Operator: Thank you. We will now go to our next question. And the next question comes from Mr David Adlington from JP Morgan. Please go ahead and ask your question. Hello, David, is your line on mute?

David Adlington (JP Morgan): Morning guys. Thanks for the question. Just on the Trilogy 100/200. I just wondered firstly – hello, can you hear me?

Roy Jakobs: Yes, we can.

David Adlington: Hello?

Steve Klink: Yes, David, we can hear you.

David Adlington: Hello?

Roy Jakobs: Yes, we can hear you.

David Adlington: Can you hear me?

Roy Jakobs: Yes, David, we can hear you.

David Adlington: Yeah, perfect. Yeah, just on Trilogy 100/200. I wondered how many units – we have a very long lag. On Trilogy 100/200, I just wondered how many units were affected? And in terms of the genotoxicity failure rate, I just wondered what the potential risks were there, and the potential implications around that data? Thank you.

Steve Klink: Hi, David. This is Steve. Yeah. So the Trilogy 100/200 devices, they make up approximately 3% of the 5.5 million registered devices. So it's around 170,000. And yes, so we have started or we made a good progress with the testing. And the new devices passed VOC testing as well as several biocompatibility tests. And yes, new and lab-degraded foam failed the genotoxicity test under lab conditions. But that means that we still need to find out if – whether – if a compound or material fails on the lab conditions, it doesn't mean that it also fails under the actual usage.

For example, if you take water, water can also be toxic if the concentration is high enough. And the same you should look here. So yes, we found that the compound or that the material was toxic under lab conditions. But by now we need to do the full assessment to see whether it's an actual risk in real life.

We have the same situation with DreamStation 1. We went through the whole process. And at the end, it turned out that it was all within the safety limits. Now, because it was a good outcome for DS1, it doesn't automatically mean that it's also good outcome for Trilogy 100/200. But it's just a step that you need to take and it's too early to say to make a statement on that.

Operator: Thank you. We will go to our next question.

David Adlington: Okay, thank you. And then just a follow up –

Operator: And the next question comes from James Vane-Tempest from Jefferies. Please go ahead.

James Vane-Tempest (Jefferies): Yes. Good morning. Thanks for taking my question. [Inaudible] the discussions with the FDA are ongoing, and you mentioned that may reach conclusions. Just wanted to know with your ongoing dialogue, if you can give any sense in terms of which tests or areas are open to the greatest interpretation? Thank you.

Roy Jakobs: Could you repeat, James?

Steve Klink: Sorry, the line is not very strong. Can you repeat once more your question, James?

James Vane-Tempest: Yes, is that better?

Roy Jakobs: Yeah, much better. Yeah. Thank you.

James Vane-Tempest: Thank you. Obviously, discussions with the FDA are ongoing. Just wondering, obviously, you mentioned they may reach different conclusions. So with your dialogue, are there any sort of particular tests or areas which you feel are open to the greatest areas of interpretation?

Roy Jakobs: No, I think what I can say is that, actually, we have not gotten any substance or substantive feedback back on the results. What they have provided feedback on, and you have also seen that actually in our release, is that they also found out the limitations that there are to testing. And as you also describe, of course, with any test, there are limitations, but then it's about what you can do to mitigate that. That's also why we have put in additional testing to actually address mitigations that have been pointed out.

So that's what they are kind of currently further studying. Of course, we don't know what they will come out with further, but to date, and that's also what we have included, that's what I

shared before, the feedback that have been given is be explicit about limitations, because that's – the testing that we're doing is novel. There was no developed testing method for degraded foam, so, of course, we are developing that as we speak. We're doing that with the best scientists to make sure this is really rigid, sound, scientifically proven. That's also what we have worked through.

And that's the same rigour, of course, that the FDA expects in the interest of the patient. So they're kind of stress testing that and that's also where we expect that they will continue to come back if they have concerns or questions and the ones that they had to date, we have all included and are part of the press release that you have seen as well.

James Vane-Tempest: Thank you.

Operator: Thank you. I will now go back to David Adlington from JP Morgan. I'm just going to open your line, sir. Please, can you turn off the webcast and use the phone to prevent any delay. David, if you can hear me okay, if you can turn off the webcast and use the phone line to prevent any delay? David, your line is open.

David Adlington: Yeah. I'm on the phone line, so I'll try my questions. So I was under the impression that you weren't going to release this data – hello, can hear you me? Hello?

Steve Klink: Yeah, now we can hear you.

David Adlington: Okay. Yeah. Let me try again. So I was under the impression that you weren't going to sign – release this data until it had been signed off by the regulators. And obviously, they're – you're now releasing this data before sign-off from the FDA. I just wondered what had changed that made you decide to release this data now, rather than waiting till the regulators had given their view?

Roy Jakobs: So as said – I think we said before that we are in dialogue with the regulator, but also what is important also in the patients' interest, of course, to share the test results that we have found. We are in dialogue with the regulator, as I just shared, and very close contact. They have also given feedback on it. So that's also why we felt we could go out, is also they have seen what we come out with. They have the test results. So it's in alignment with them.

But I think it's fair to also give them the appropriate time to actually work through this at pace. And as we didn't want to wait too much longer to share these results because they're very important for patients, we have come out with all the inputs that they wanted to give into this. So that's kind of where it was important for us to come out at this point in time, include their input, but also make sure that we go out, and also the – as said, the regulator knows that we are going out because we have been in close contact with them on it.

Operator: Thank you. We'll now take our next question. And the next question comes from the line of Graham Doyle from UBS. Please go ahead and ask your question, sir.

Graham Doyle (UBS): Morning. Thanks for taking the questions. It's just on the – obviously, the testing on the non-ozone cleaned device. It looks quite positive from biocompatibility. We're waiting for the ozone testing to complete. I suppose I'm just wondering, where would the liability lie? Or how do you feel about your position on ozone? Because I just noted in 2020, you actually responded to HME News where you basically said you do tend to honour warranties related to machines that had used ozone cleaning. So – and obviously, we saw the

FDA in the 518(b) talk about the impact of ozone cleaning, but it's not been something that was explicitly prohibited up until recently. So I suppose to just get your sense of what sort of level of protection you think you have in relation to those devices? Thank you.

Steve Klink: Hi, Graham. This is Steve. Let me give you a little bit of a perspective from the testing point of view. So if we quickly look at the devices that were not exposed to ozone, then we see that there is a fairly low prevalence, so 0.5% of the devices in the US and Canada, one out of 2,500 in Europe, and none from Japan.

And so there is a low prevalence of degradation. And then even if degradation occurs, then the VOCs and particulate matter that are associated with it are within the safety limits. And we have taken the most conservative safety limits possible. So we have a lot of confidence in those results.

Now, if we switch to ozone cleaning, then we see again from visual inspection, that the occurrence is 7%. So it's – so yes, it is higher than the 0.5% if there is self-reported no ozone, but with ozone cleaning, it is 7%. So it is not 100%. So that is one thing.

And then we need to investigate. So if ozone cleaning leads to degradation, which seems to be the case in 7% of the devices, then we know now that the particulates that come – that are emitted, are within the safety limits. So that is, I think, an encouraging data point and a very important data point.

And then now the next thing that is still there and that is ongoing, so we need to determine whether the VOCs that are associated with foam that is degraded or damaged by ozone, whether or not that is within the safety limits. And that's ongoing, and we expect to have those results within the coming months.

So I think it's important to have that context of that, yeah, if degradation occurs, that it does not necessarily mean that there is a safety risk. So we need to wait for the complete set of results, also for ozone cleaning.

Graham Doyle: Sure. So I suppose the question was more around what difference does it make? I mean, you – obviously, you're pointing out that ozone cleaning is – it potentially does make a difference to degradation and therefore could have an effect on VOCs. But let's just say for a moment that it did, from your perspective, do you think Philips is in a position whereby you're not liable for this, because I suppose you've never actually actively condoned the use of ozone cleaning? That – that's more my question.

Steve Klink: Yes, but we cannot speculate on that. And again, we have confirmed that ozone cleaning exacerbates degradation. But again, we need to first assess whether or not that leads to a health risk or not. So – and but before we have that outcome, I think we cannot speculate on the what-if.

Graham Doyle: So I'll try one last thing and I'll promise I'll leave you alone. Either way, do you feel you have an obligation to patients and users of machines if they have used ozone cleaning in the same way that you do to patients if they have not?

Roy Jakobs: I think if I look at it, so we are addressing all machines regardless, right? So if you look to the recall and remediation, we are addressing all machines in the field and we're replacing them regardless of cleaning method or not.

Then in determining any safety risk that is related or has related to the use of it, that's where we are giving the update today that actually, we have encouraging results that actually on the DreamStation 1 complete set now shows that for non-ozone used actually, it's within safety limits. For ozone used, particulate emission is within safety limits. VOC, we need to still conclude to also see whether that's within safety limits.

Of course, we have said before that ozone is not an approved cleaning method, as also being said by the regulator and others. So that still stands. And of course, all data points that we are gathering will be used in any further discussion on this. Let me also be clear on that. But let me also leave it there because otherwise it would get very speculative.

Graham Doyle: Yeah. That's perfectly fine. I appreciate it. Thank you very much.

Operator: Thank you. Once again, if you would like to ask a question, please press the star followed by one and one on your telephone. We will now take our next question from Sezgi Oezener from HSBC. Please go ahead, madam.

Sezgi Oezener (HSBC): Hi. Thanks for today's information and taking my question. My questions relates to the ozone-cleaned devices. We know that there has been issues or there can potentially be issues with self-reporting. Is there any way you can prove whether ozone was used for a device or not? And also the potential impact on the outcome of any legal case, whether that tips the case for you in your opinion or not? I know this will sound speculative, but I'm just asking about the theoretic outcome.

Steve Klink: Yeah, so I can – let me say a few things on the ozone tests. As I said before, so we know that ozone cleaning or repeated ozone cleaning exacerbates the degradation of the foam. I think it's important to also know that the results show that the particulates that are associated with foam that is degraded by ozone are within the safety limits. That's one element. And what is ongoing is the VOC testing or the VOCs that are associated with ozone-degraded foam.

We are in the middle of that analysis and we're looking into whether there are say specific chemicals that are associated with ozone cleaning that can be considered a marker, if you will, of a device that has been cleaned with ozone. But yeah, we will be able to say more about it at our next test update, which can be expected when the results are done in the coming months.

Sezgi Oezener: And in terms of the remaining testing days, what kind of a time frame are we looking at potentially? Should we more expect three months, six months? Or would it take another, hopefully not, 18 months?

Steve Klink: If you just look at the testing, then it should be a few months. But of course, we also have the initial interactions on any new results with the competent authorities. And at the very least, we always want to take the initial feedback on board as we have done here. So that is also something that we need to take into consideration.

Sezgi Oezener: Thanks very much, Roy. That's very helpful.

Operator: Thank you. We will now go to the next question. And the next question comes from the line of Delphine Le Louët from Société Générale. Please go ahead and ask your question, madam.

Delphine Le Louët (Société Générale): Hello. Hi, good morning, everyone. Two questions on my side. The first one I was wondering if – this one regards the silicones foam that is used. I was just wondering if all the trials, all the testing are done? And – because you mentioned in the press release the final results. So I was wondering and just willing to validate that everything has been set regarding this silicone foam use.

Then regarding the federal courts in Pittsburgh, I was wondering if you had more timelines to give us regarding any hearings? Thank you. Very appreciated.

Steve Klink: Hi, Delphine. This is Steve. So regarding the silicone foam testing, so as we indicated in November of last year, FDA requested Philips Respirationics to do additional testing, especially to have a look at, say, the variability or the variance of test outcomes. So Philips Respirationics engaged that test lab, and they did quite a lot of additional testing. And there, we did not see any safety issues.

So – and what was also important to note that all the tests that have been done to date and that have been submitted to, for example, FDA related to DreamStation 2 and reworked DreamStation 1, they all already showed good test results.

Delphine Le Louët: Okay, definitive. Okay.

Roy Jakobs: Yeah. And on the court. So we don't have any specific updates now. Indeed, this is starting, but we have not been given any specific timings on that. So we will, of course, keep you posted once we have specific relevant news on that.

Delphine Le Louët: All right. Thank you very much.

Operator: Thank you. We will now go to our next question. And the next question comes from the line of Robert Davis from Morgan Stanley. Please go ahead, sir. Your line is open.

Robert Davis (Morgan Stanley): Yeah, morning. Thanks for taking my question. The first one I had was just around the potential timeline for some feedback from the FDA. You mentioned Phillips has obviously been looking at the data for 18 months. You've only just given it to the FDA. Have they given you any indication of a timeline of what – how long before they get back to you?

And then the second one was just around – I just was wondering on the FDA side, are they running independent tests? You mentioned some of your tests were sort of novelly constructed, because there was no sort of standardised methodology here. What's the risk of them doing something different or outside of the scope of what you've already done? Or are they incorporating your data at all in their analysis? Thank you.

Roy Jakobs: Yeah, maybe on the first, let me take the first on the timeline. As I said before, at their leisure, right, so we cannot speak on their behalf and also, they will take their time. So I don't have a specific date on that. I know they are working through it. They will do that with the rigour that they need to do it. So we respect that process and have to wait until they are ready. So no specific timing on it.

So maybe on the – Steve, you can go on –

Steve Klink: Yeah. So when we talk about that these are new tests or a new method, it's more in the detail because if you zoom out and you look at what are the two main alleged risks, that is, say, the volatile organic compounds and the particulate matter, then if you look at the

industry standard, then it's clear that you need to use the ISO 18562 for testing of VOCs and particulate matter. But the 18562 only looks at, say, the size of the particulates to see if there is a risk associated with the size of the particulates. And that's why for the things that we need to investigate, you also need to look at ISO 10993.

So the fact that we use those two standards, that is – forgive me saying standard. It's in the details, how you apply the standards, how you develop the protocols, that you ensure that you look at all the details and don't overlook anything. So that's why we also engage with a third-party qualified expert that help us develop all the protocols, and that we assess whether there are any limitations that we need to mitigate.

And so it's a very thorough process to – if there is a limitation, then you have, on one hand the mitigation, so for example, an additional test. And on top of that, we always use the most stringent, say, safety limit that is possible, just to make sure that we can have full confidence in the results. And we have extensively described that in the press release, for example, and also in the full update.

Robert Davis: Okay. That's great. Thank you.

Steve Klink: Sorry, to the best of our knowledge, FDA is not doing their own independent tests. They provide feedback on our test, and we incorporated and for – and if they in the past have requested additional tests, then we have done that. So that is kind of the way it works with the competent authorities, not just the FDA, is that they come back to us with feedback. And it's not just when we come with an update, but that's kind of a – yeah, let's say, constant and regular dialogue.

Robert Davis: Thank you. Maybe just one follow up. Just to be clear on the DreamStation 1, are there any remaining outstanding tasks or queries that the FDA is asking you to do? Or is still requesting from you?

Steve Klink: No. To the best of my knowledge, no. So we have this complete test programme that is ongoing. We have completed one part. And we are in the process of completing the other part, which is the ozone testing. And in that sense, FDA is fully knowledgeable of our test approach. And also the tests that have been done and the tests that are still being done.

Robert Davis: Okay. Thank you for your time. Thank you.

Operator: Thank you. We will now go to our next question. And the question comes from the line of Falko Friedrichs from Deutsche Bank. Please go ahead, sir. Your line is open.

Falko Friedrichs (Deutsche Bank): Thanks very much. Good morning. So my question is whether you can provide an update on this consent decree and the timelines around it when we can expect to hear from that? And then my follow-up is if you can provide an update on the census registry, the number of people in the US that have registered there, and also the number of people that have registered with the lawyer in the US? Thank you.

Roy Jakobs: Thank you, Falko. So, on the consent decree, as I also shared last time, these are ongoing dialogues with the FDA. We are not kind of privy to the timeline of that because that ultimately is also in the hands of the regulator. So I cannot provide you with any specific date. I can only share that we are in dialogue, and we remain in dialogue. Of course when we

have any outcome there, we will immediately come forward with those to share it with you at large.

And on the census register, currently, latest update that we have is that we have around 60,000 people in there, but only 7,500 registered with lawyers.

Falko Friedrichs: Okay, thank you.

Operator: Thank you. We will now take the last question, which is a follow-up from Veronika Dubajova from Citi. Please go ahead. Your line is open, madam.

Veronika Dubajova: Hi guys. I'm actually okay. My thoughts have already been covered. So I'm good. Thank you.

Operator: Thank you. Thank you, gentlemen. That was the last question. Please continue.

Roy Jakobs: Okay, then I want to thank you all for your attendance. Important update today, where we shared the complete test results with DreamStation 1, where we shared that after the earlier findings that there was low prevalence. Now also, VOC and particulate emission testing was found within safety limits, was very reassuring, encouraging.

As I said, we will continue, of course, with all our efforts and resource to further complete the testing, to further complete the remediation and to work collaboratively with regulators through these processes.

Steve Klink: And if I may, I would like to stress the, say, the extensiveness of the testing. In the past 18 months, we have inspected thousands of devices, more than 60,000. We have done hundreds of tests. And they were conducted by five of the largest testing laboratories in the world, where we have something like, yeah, hundreds of people working on it. So it is a very extensive programme. And we have taken a very rigorous approach when it comes to the test methods.

Roy Jakobs: Okay. Thank you, Steve. And thank you all and already happy holidays for the ones that are going to enjoy them later. Thank you so much.

[END OF TRANSCRIPT]