

## Dear friends and team mates!



There are quite a lot of frustrated customers on the European market that are now waiting for their JJ-CCR rebreathers locked up in our warehouse. Trust us, we are very frustrated as well!

Please take some time and read "The unvarnished truth of the CE odyssey" on the following pages to get picture of our journey through the CE-process so far.

Best regards Jan Petersen / JJ-CCR ApS

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# The unvarnished truth of the CE odyssey

A journey full of danger, sustained effort, unexpected setbacks and arbitrariness

When you follow some discussions about CE on the Internet, most of them are showing a completely wrong picture about the CE certification process and the work, which is involved. You could get the wrong impression that the people behind JJ-CCR ApS prefer to drink coffee the whole day in the office instead of working on the CE, or they don't have any interest to move the project forward, or just don't have a clue how to achieve this CE certification. Especially as it seems, that they are not able to provide at least an estimated date when it is done or just add one month more each time you are talking with them.

A CE certification for a rebreather is not like a technical inspection of your car. You can't just go to a notified body, wait some time and they will give you the CE certification. As soon as something is handed over the notified body, everything is out of your control and you can only wait until they are coming back with a review which is successful or not. But this is only a small part of the CE odyssey....

# A long time ago at JJ-CCR ApS...

End of 2012 we did the very first test dives with a DiveCAN prototype lid. It used a DiveCAN enabled Shearwater Predator and the prototype of the DiveCAN mainboard was ways too big for the lid. At this time, the DiveCAN HUD was not available either.

In the middle of 2013 we got the first DiveCAN HUD and in the meantime the final version of the DiveCAN mainboard was smaller and we could design a new lid, which allowed us to add the additional electronics. A lot of test dives followed to make sure everything is working as expected.

In September 2013 we had everything ready (test units, user manual, technical documentation etc.) to talk with the notified body about the changes on the rebreather.

# Ready for the CE Odyssey....

In October 2013 we arranged a meeting with all responsible persons at the notified body headquarter. During the meeting we made them clear why we needed to switch to another electrics – simply because Shearwater set the analog system (Predator and HUD) end of life and there is no other way than switch to the DiveCAN version as well in order to produce and sell JJ-CCR rebreather in the future. They got a detailed presentation of the new electronics including a detailed comparison against the analog version. They also got a full documentation about it. We agreed to handle the new DiveCAN lid as an upgrade of the electronics and change the corresponding part of the current modular CE certification to add it.

We only had some minor open points after the meeting:

- Which testing in detail is needed for the new DiveCAN lid.
- A quote for this project including an updated CE certification
- Find a date to start with this project and send over a complete unit.

After leaving the meeting we had the impression that everything was ready to start and the updated CE for the DiveCAN version is just a matter of time. Afterwards It turned out that we just got our first unexpected setback..



## How time flies and you can't do anything....

The time passed and we got nothing from our notified body. No proposal for the required tests, quote or a project plan to have a timeframe. When we tried to contact them, no answer was given or something completely useless came back. There are points, which seems to be valid for mainly all companies in this business: You are treated as supplicant and not a customer, which would like to spend a huge amount of money. Secondly as more pressure you are putting on them to get something, as slower they are working. We only got the OK to deliver a test unit beginning of January 2014 and nothing else.

## Merry Christmas 2013!

End of 2013 we got the short information that the responsible person retired and another person will take over in January 2014. We really hoped that it would be a smooth transmission of the project.

#### Nice to see you here - but....

As agreed in December 2013 we went in January 2014 at the agreed date and time to the notified body test center to handover a complete rebreather with Sofnolime, gases etc. It turned out that our contact completely forgot our appointment and he was totally surprised to see us. It also turned out, that he had not a clue of what to do with the rebreather. Anyway we handed over the unit and hoped the situation will be cleared up very soon...

#### How time flies again....

Even we tried to move the project forward as much as possible; there was no progress at all in January 2014.

#### Sorry - EN 14143:2013 is now in place..

End of January 2014 we got the information from the notified body that the new standard EN:14143:2013 is now in place and therefore we can no longer do an upgrade / change against the old standard. No proposal has been made how to move forward with the pending project.

To fulfill the requirements of the new EN14143:2013 was a complete new situation for the people at JJ-CCR ApS which are working on the CE. First we needed to figure out all changes and afterwards we started to update the technical documentation and to collect all additional certifications, documents etc. form the suppliers. Everything was done without any support from the notified body. Everything was handed over to the notified body in order to get now a proposal, project plan etc. But we have to say - as usual – nothing move forward.

#### **ANNEX B: Safety critical software!**

One big difference to the old EN 14143:2003 is the annex B: Safety critical software. In very short words this annex B requires the manufacturer to put the complete software development of every safety critical software used inside the rebreather (E.g. design, testing, implementation, etc.) on the table. Bruce Partridge (CEO Shearwater Research Inc.) is part of the committee for the EN 14143 standard and we got a complete safety case documentation with more than 350 pages. This safety case documentation does not only fulfill all requirements of the annex B, the level is even higher. Even a non-functional safety specialist can figure this out by reading the first 10 pages.

#### Continued on next page



#### ...ANNEX B, continued from last page

We were convinced that with this documentation in place every discussion about annex B is no longer needed. Our notified body had a very different opinion. First of all it took several attempts via phone and/or email from different persons at JJ-CCR ApS before they even look into the introduction document, which is only around 60 pages. We also need to say that after the former responsible person retired, we no longer had a clear contact person and they moved us from one to another person. After a long time, we got an unbelievable feedback: They requested a complete audit of the Shearwater safety case! Including access to the source code and when needed an on site audit/visit at Shearwaters headquarter. Needless to say that Shearwater already did an external audit of its safety case.

#### Springtime is coming...

Mid of March 2014 we got the first official quote for the project, based on our meeting in October 2013 from our notified body. They requested only for the test of the safety critical software documentation from Shearwater 150 working hours. 150 hours for something, which is absolutely not needed. Additionally they added some tests. The overall offered price was so far away from any acceptable amount, that we in this case really needed to sit down and drink a very strong cup of coffee.

#### We pressed the emergency stop button....

We already discussed this step earlier internally, but we always thought we would find a way to move forward. Middle of March 2014 we terminated any business relationship with the current notified body. A company, which requires 6 months for a quote, has no experience in rebreathers and puts the focus to a functional safety instead of looking into the product itself, is the wrong partner. They more and more gave us the feeling to be an unwanted customer. We never ever have been treated so badly and wrong from any other company before. We've spent half a year with hundreds of working hours just for nothing.

#### Heading for new shores....

After the disaster with the old notified body we now had the problem to find another one. There are not so many notified bodies in Europa you can choose. The big task was to find one you can work together and more important which already has some practical knowledge in rebreather design to avoid having some basis design discussions with them. It required some additional time to get in contact with them and to make a decision.

## Sorry – In English please....

The former notified body as a German company got all CE related documents in German. It was the easiest way for the responsible persons on both sides. The new notified can't work with the German documents therefore the author of these documents needed to translate everything into English. Even with 24 hours a day working on it, some time was needed as we are talking about more than 250 pages.

#### Initial audit with new notified body....

End of March 2014 the initial audit with the new notified body was finished. For a first audit we got only a few points, which needed to be clarified. In the first view it looked like a short task to provide the requested information. Most of them were related to some test results. As we did all these tests earlier with the old notified body, we asked them to give us the data. They refused to give us the data. They even refused to sell it to us. Instead of just send over the data, we have been forced to do all the tests for this data again. A rebreather needed to be sent to the test facility and we needed some time before they had a slot for testing. Afterwards some time was needed to summarize the test result and put them on paper.



## A small change can have a large impact...

Some tests within the standard include several tests, but they are grouped together and count as one. This means you need to pass all tests otherwise you will not pass this section of the standard. So far the JJ-CCR rebreather passed all requirements of the new EN14143:2013 without any modifications, which is in our opinion a very good sign for the quality and design. But some numbers slightly changed on the new standard and one result within such a group of tests was just a little bit out of the required range. Some additional tests came out with the same result. To pass this single test a modification on the rebreather was needed. There was no time to develop something completely new. Therefore we investigated into a solution, which can fulfill the requirements and can be added without any problems. Of course, it required some tests as well.

#### Land in sight....

Since the 25.6.2014 the updated technical file is at the notified body for a second audit. In our eyes the fully updated version should solve all open points on the first audit. As we mentioned in the beginning – After something is handed over the notified body we have no influence at all. You will need to wait until the report of the audit is coming back with one of the conclusions "Granted, Continued, Withheld until...". And you don't know whether they are coming up with something completely new or not. The only thing, you can do is crossing you fingers and hope the best. Even the audit is granted it will take some time for the notified body to issue the certification.

#### Our wish for an updated EN14143 standard!

The way in which the EN14143 standard is done allows too much interpretation. We noticed it clearly after switching to another notified body. To speed up the CE certification process and to avoid unnecessary discussions, we would like to see a standardized certification checklist. These checklist needs to summarize all requirements into a simple fulfilled or available yes and no table. Hopefully the members of the committee will add some like this when they are working on a new version.

## Final word from the JJ-CCR CE Team

We hope that this text made you clear that we did everything possible to get the CE for the JJ-CCR DiveCAN version as soon as possible. It is our highest interest and priority to start shipping the CE 2014 edition as fast as we can. We drink a lot of coffee, not because we find nothing better do to – it helps us to survive very long working days with only a few hours of sleep.

We also hope that you understand the fact that the CE certification requires a lot of work and most of the process is out of your influence. Therefore we are not able to provide any useful timeframe. The new CE can be done within days or when they are coming back with something new or different it can take longer. How long – Sorry we can't even estimate it – But you can be sure that we will do our very best to make it happen as soon as possible.

There are numerous JJ-CCR rebreathers in stock and they will be shipped out to expecting customers the same day that the CE-certification arrives!

Your JJ-CCR CE TEAM

Jan Petersen Dave Thompson Dietmar Inäbnit