CONSENT TO PARTICIPATE IN RESEARCH STUDY

Comparative testing of ultrasound devices in monitoring venous gas emboli

IRB #023-20-20 (expiry: January 24, 2021)

SUMMARY
The purpose of this study is to compare three different ultrasound devices in healthy divers used to monitor post-dive venous gas emboli (VGE). The devices are two 2D-ultrasound devices and one sub-clavicular doppler device.

Participants in this study will have ultrasounds of the heart and subclavian vein performed pre- and post-dive. Your participation is complete once all ultrasound scans have been performed.

Risks associated with SCUBA diving are ear and sinus squeezes, nitrogen narcosis, abdominal discomfort, lung overexpansion injury, oxygen toxicity, loss of consciousness, decompression sickness, and drowning. The spectrum of ultrasound used in this study has not been reported to induce biological or medical damage. Some individuals may experience slight discomfort during continuous exposure of ultrasound due to the pressure of the probes applied on their ribs.

If you are interested in learning more about this study, please continue to read below.

INTRODUCTION
You are asked to volunteer for a research study to collect ultrasound recordings of the heart pre- and post-dive and subclavian doppler. In order to decide whether or not you wish to be in the study, you will need to know about benefits or risks that you may experience as a result of your participation. It is important that you understand this information so that you can make an informed choice about being a part of this research study. You will be given or sent a copy of this consent form. You can ask any questions you might have at any time. This study is being sponsored by Divers Alert Network, and portions of the research team’s salaries are being paid by the Divers Alert Network (DAN).

PURPOSE OF THE STUDY
The purpose of this study is to collect pre- and post-dive heart ultrasounds and subclavian doppler with three different ultrasound devices (Butterfly iQ, Vivid q, and O-Dive). The Vivid q device is most commonly used to scan the heart for gas bubbles in dive research, the Butterfly iQ and O-Dive are new technologies that have not been compared to the Vivid q. This study seeks to clarify whether the DCS-risk classification obtained from recordings of the Butterfly iQ and the O-Dive are comparable to those obtained with the Vivid q.

BACKGROUND
Decompression sickness (DCS) is a known risk of SCUBA diving. Inert gas from the compressed breathing air is absorbed by the body in larger amounts when the body is under pressure. When a diver begins to surface, the surrounding pressure decreases. The decrease in pressure forces the absorbed inert gas from the tissues into the bloodstream, forming bubbles which have been linked to increased risk of DCS. The bubbles that form can be counted or graded using 2D ultrasound imaging of the heart or

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ultrasound doppler of venous blood vessels. This study aims to collect ultrasound recordings pre- and post-dive with three different ultrasound devices in order to compare the associated high- or low-grade classifications obtained from their recordings.

**HOW THE STUDY WORKS**

You must be 18 years of age or older, and hold, at minimum, an advanced open water diver certification with a minimum of 50 logged open water dives. All genders are eligible to participate. We anticipate to recruit between 20 and 50 subjects.

You will be asked to read and sign the consent form and will have the opportunity to ask any relevant questions.

Before your dive, two ultrasound scans of your heart and two subclavian doppler recordings will be performed with three different ultrasound devices to serve as a baseline measurement in preparation for bubble detection after the dive. These pre-dive measurements will take approximately 10 minutes. After the dive, you will be monitored for bubbles every 20 minutes for 60 to 100 minutes. Scans will stop when bubbles can no longer be seen in the heart.

You will be asked to attach a dive profile tracker to your dive gear before you dive and return it after completion of the dive.

**RISKS TO YOU**

**Confidentiality**

Although there is a risk of loss of confidentiality, DAN will abide by Federal privacy regulations that provide safeguards for privacy and secured and authorized access to data. We will not record any of the data that could identify you. Your dive will be assigned a random ID number, and all your VGE measurements related to that dive will be labeled with that ID number. The link between your name and that number will be destroyed immediately after your last VGE measurement.

**Diving**

As you are a certified diver, you are aware that diving exposes you to a number of risks unrelated to your participation in this study. These risks are generally well known and accepted by all divers. Possible risks of diving exposure include ear and sinus squeeze (barotrauma), nitrogen narcosis, abdominal discomfort from expansion of intestinal gas, complications from lung overexpansion injury (including air under the skin and/or arterial gas embolism [AGE]), convulsions due to oxygen toxicity, and loss of consciousness due to excess carbon dioxide in breathing gas, and decompression sickness. As all aquatic activities, diving also includes a risk of drowning.

**For Women of Childbearing Potential**

Being a part of this study while pregnant may expose the fetus to significant risks. Pregnant women will not be included in the study population. We do not test for pregnancy; however, if you know yourself to be pregnant, please exclude yourself from diving activities and participation in this study.

**Ultrasound measurements:**

Some individuals may experience slight discomfort during continuous exposure of ultrasound due to the pressure applied to their ribs. The spectrum of ultrasound used in this study is not expected to induce biological or medical damage or expose the subject to any additional risk, if however, a subject
experiences any unforeseen symptoms or discomfort, the measurements will immediately be stopped and
the incident will be reported as an adverse event to the PI and the DAN IRB.

Unforeseen risks:
The research procedures may involve a risk that is currently unforeseeable. Any new risks that we may
learn about during the course of your participation will be shared with you.

PHYSICIAN AVAILABILITY
There will be no physicians available on site.

BENEFITS TO YOU
There are no direct benefits to you participating in the study. However, your participation will help DAN
improve our ability to assess decompression stress and DCS risk following a dive.

WITHDRAWALS
You can withdraw from this study at any time, without penalty or loss of benefits to which you
are already otherwise entitled. The investigators also have the right to stop your participation at
any time. After the link between the dive ID and your name has been deleted, it will not be
possible to identify and remove your data from the study.

CONFIDENTIALITY
All of these tests are being done only because you are in this study.

The records of your participation, except your signed informed consent, do not contain your identification
data and cannot be traced back to you.

The de-identified data will be saved indefinitely in DAN research data repository. The electronic copy of
your informed consent will be kept on a protected server at DAN for ten years. Your name will not be
used in journal articles or at meetings when the results of this study are reported.

Photographs are taken to demonstrate protocols used in research studies. You will be asked if you agree to
be photographed before any are taken. If taken, such photographs might be presented at meetings
describing the research, in which case a black square will be placed in the photograph over your face to
make the photograph less identifiable. You will not be identified nor will your individual results be
discussed in such cases.

Please read the sentence below and put your subject initial next to your choice. You may participate in the
study, without allowing your photograph to be taken.

[    ] "Yes, I agree to be photographed."

[    ] "No, I do not agree to be photographed."

COMPENSATION/COSTS
You will not receive any compensation for this study.

All dives being performed will be voluntary. You will be responsible for planning and executing these
dives on your own accord. You will also be responsible for any costs associated with the dive itself: gear,
lodging, and transportation costs. DAN will cover the cost of consumables and testing materials needed for data collection, and postage associated with correspondence with the subjects.

RESTRICTIONS
In accordance with DAN guidelines, participants should not fly in an airplane for 18 hours after completion of the study.

YOUR RIGHTS
It is necessary that you read and understand several general principles that apply to everyone who takes part in this study:
1. Taking part in this study is entirely voluntary. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes. You may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal, and data already de-identified), but you must do this in writing. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled. If you do decide to withdraw, we ask that you contact Dr. Frauke Tillmans (ftillmans@dan.org) personally or in writing and let her know that you are withdrawing from the study. At that time we will ask your permission to continue using all of your information that have already been collected as part of the study prior to your withdrawal.
2. There will not be a charge to you for taking part in this study.
3. Research records are maintained according to confidentiality requirements, but authorized reviewers such as representatives from the OHRP (Office of Human Research Protection) and/or DAN IRB may examine your records. Thus, complete confidentiality cannot be guaranteed.
4. If you sustain acute injuries during participation in this research study there will not be provision for free medical care or monetary compensation for such injury by the study organization. There are not any provisions for chronic conditions or injuries sustained after the completion of the study. You are responsible for your emergency plan and all possible costs that may arise in case of your injury.

QUESTIONS
Should you have any questions with regard to this research, you are urged to contact the principal investigator, Dr. Frauke Tillmans (ftillmans@dan.org). Information concerning the rights of subjects in research can be obtained from the DAN IRB (919-684-2948; irb@dan.org).

AUTHORIZATION
The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask the questions I have, and my questions have been answered to my satisfaction. I have been told whom to contact if I have additional questions. I have fully disclosed my complete medical history. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed copy of this consent form.

__________________________________________       Date
Signature of subject

__________________________________________
Printed name of subject

__________________________________________       Date
Person obtaining consent