



Project: **SEAWave**

Human exposure system acceptance test

Work Package: WP7

Deliverable: D7.1

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Abstract

Deliverable 7.1 is related to the acceptance test of the exposure system for the work package 7 and its SEAWave-Clin clinical trial. The 5G system was built by IT'IS Foundation and certified by SPEAG. It was delivered to CHUV and tested.

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1 Introduction

To perform the SEAWave-Clin clinical trial programed by the WP7 of the SEAWave project, IT'IS Foundation built a sXh mm-wave Skin Exposure System and SPEAG certified it. Several meetings were necessary to optimize the system.

2 sXh mm-wave Skin Exposure System: Reception

Initially scheduled for July 2023, the sXh mm-wave Skin Exposure System was delivered by M. Capstick and his colleague from IT'IS Foundation, Zurich, to the CHUV- Hôpital de Beaumont, in Lausanne on October 2nd, 2023.

The sXh mm-wave Skin Exposure System is composed of several electronic equipments, a left exposure device, a exposure right device, a control unit, and a computer connected to the internet via a dongle. It has been installed on a trolley, so it is easy to move around.

3 Acceptance tests

3.1 Test 1: installation

02/10/2023: A test without any irradiation has been performed in the room dedicated to the clinical trial. The devices were installed on the arms of C. Pich-Bavastro. This test allowed the CHUV team to get familiar with the devices, the Velcro straps, and the right way to install the devices.

Test successfully passed.

3.2 Test 2: software use, blind exposure, difference between the two sources < 2°C, logbook transmission

02/10/2023: A test with a 20-minute irradiation session allowed the CHUV team to get familiar with the electronic equipment and the software. This test was performed with temperature gauges installed on the volunteer's skin.

Test results:

- Success of the use of the software and the blind exposure tests.

- A difference in temperature between the two devices above 2°C was noticed during this test. Test is considered as Failed.
- The logbook was not sent to IT'IS Foundation. Test is considered as Failed.

A 2nd visit by M. Capstick was then scheduled to correct these issues.

Both issues are now resolved, see point 3.3, 3.4 and 3.5.

3.3 Test 3: correction of logbook transmission

11/10/2023: I. Alonso, from IT'IS Foundation, took remote control of the computer to do some additional tests.

Test failed.

This issue is now resolved, see point 3.4.

3.4 Test 4: correction of equipment temperature and logbook transmission

12/10/2023: M. Capstick came back to CHUV to adjust the devices so that the difference of temperature could be lowered. He performed a new blind exposure test. During this test, I. Alonso also connected to the computer to finalize a few software corrections.

Test results:

- Logbook transmission test successfully passed.
- Blind exposure test failed: M. Capstick noticed a problem with the left equipment and took it back with him to Zurich for repair.

The blind exposure issue is now resolved, see point 3.5.

3.5 Test 5: correction of equipment temperature and logbook transmission

16/10/2023: M. Capstick came back to CHUV with the left equipment. He run the last blind exposure test, controlling the temperatures and the success of irradiation by the two devices. During this test, the temperature recorded were less than one degree apart. The volunteer could not tell the difference between the two devices and thus did not know which one was the active antenna.

Test successfully passed.

4 sXh mm-wave Skin Exposure System: Manual for the system operation

A sXh mm-wave Skin Exposure System manual was prepared and sent by M. Capstick to C. Pich-Bavastro and O. Gaide, to properly use the system. It is physically located in the Investigator Site File (ISF), under the heading “10 Appareillage et Equipement d’étude”. It can also be found in the electronic ISF, under the same heading.

5 Conclusions

The sXh mm-wave Skin Exposure System needed a few adjustments and corrections after its installation in CHUV. The last test shows the system works properly and is user-friendly.

The system is now installed in O. Gaide’s office while waiting for the start of the clinical trial.