

## **Useful Q&A on Soteria AI platform:**

**Q: How many OSA cases are being operated by Soteria platform for AI system training at the moment [September 2022]? Is there any post-operative feedback optimization training?**

A: Soteria AI system training is currently based on a total of 6872 cases (Taiwan 6840, the UK 20, the Netherlands 12).

When the amount of cases had reached 200, the OSA Report accuracy rate reached 88%. Then Soteria successfully passed the TFDA and CE certification.

The missing percentage is mainly mild OSA cases, since it's challenging to collect data from patients with mild symptoms.

The accuracy rate of post-treatment optimization training is currently 90% (published at the 2018 Asian Sleep Conference).

**Q: How many patients have been successfully assisted by Soteria AI platform at the moment? How did it become possible to predict post-treatment improvements with such high efficacy?**

A: Soteria has registered 6840 patients' upper airways improvement, based on provided clinical feedback in Taiwan.

Initially, for the purpose of TFDA and CE certification, Soteria has participated in 200+ PSG diagnostics in sleep centers. PSG complete output data was fed to the AI program together with pre-treatment CT images of the same patients to detect corresponding information.

Post-treatment CT images of the same patients followed up feeding the AI program to further 'teach' it to recognize results and predict them with just the input of CT images only.

Since then, by fulfilling the contract, Kaohsiung Medical University Hospital (Kaohsiung city, Taiwan) is continuing to provide pre- and post-treatment detailed clinical feedback to Soteria to refine and advance our medical software.

Also, this key corresponding information uncovered by the system can't be seen by a doctor on a CT scan, it can only be simulated and calculated by the AI and offered as visual colorful image of airflow pressure and velocity.

Basically, now a doctor only needs to input CT image, and receive complete+ gold standard diagnostic result without asking a patient to stay in a sleep center.

**Q: Will the treatment methods/ standard definitions/ rehabilitation definitions be different in different countries and regions? Will the above definitions or methods have a certain influence on the judgment capability of Soteria AI platform?**

A: For OSA, these treatment methods/ standard definitions/ rehabilitation definitions in different countries are all guided by the criteria of the American Sleep Society and the European Sleep Society, so there is no difference.

At present, there are no differences detected among different human races in the OSA test results conducted in the Netherlands and the UK.

Due to the uniqueness of Soteria AI+CFD technology, the analysis result is based on breathing pressure and breathing speed, not on the conventional respiratory tract volume and cross-sectional area.

Thus, belonging to a different human race creates zero influence on Soteria OSA evaluation capability. In other words, the software can be efficiently applicable for any patient.

**Q: In addition to the FDA and CE certification, does the AI platform have any exclusive doctor/university certification?**

A: Currently, thoracologists, otolaryngologists, and neurologists in Taiwan are all Soteria platform users and have published medical journal papers for certification.

**Q: Are there any requirements for CT scanning while standing/lying down, or leaning forward/backward/sideways, etc.?**

A: When scanning while lying down, patient should lie flat horizontally. When scanning while standing, patient should stand up straight. Patient shouldn't move/tilt his/her head. Patient should completely exhale, then radiologist starts scanning.

**Q: How many times CT scans are usually performed for different recommended solutions? If the same case requires multiple scans and analyses, is the cost being also charged for a single case?**

A: There are mainly these 3 different treatment plans:

1.Respirator (CPAP): only needs to scan once —> single charge.

2.Oral Sleep Device: two shots before treatment —> one case —> single charge.

3.Orthodontic/Laryngeal Surgery (MMA): once before the operation, once after the operation —> the cost of the case is charged twice.

**Q: What level of details can AI platform possibly provide with the guidelines/risk warning? For example, will it only be "Surgery is required", or something like "Tracheal dilation surgery is required (the cut part is marked in the red area of the image), pay attention to the adhesion of the lower part" and the like?**

A: Soteria report mainly provides the location of the respiratory tract obstruction, the severity of the obstruction, and the cause of the blockage.

The detailed guidelines (as in the example above) will not be recommended by AI platform. The physician proposes the final solution with the help of all information provided in the report.

**Q: Is it convenient to provide a test account to understand the entire platform operation process?**

A: Sure. Just click [https://lydata.com.tw/lydata\\_soteriablo/admin/index.html](https://lydata.com.tw/lydata_soteriablo/admin/index.html) and give us a call to get your login and password.

**Q: Is it convenient to provide instructions for making standard CT images for reference?**

A: Sure. Please refer to the corresponding file.

**Q: Will there be some public information, brochures or posters that can be provided to the hospitals to exhibit/post/introduce to patients?**

A: Yes, Soteria can provide you with digital copies for printing.

**Q: If patient needs to use oral sleep device, does Soteria also provide them, or can the local hospitals make these braces themselves?**

A: Soteria can also provide oral sleep devices, which in turn require intraoral scan files and CT files, and additional business negotiations and a whole new business setup. Or the local hospitals can make their own braces.

**Q: If patient has undergone surgery and the trachea is in unnatural state, does the postoperative situation apply to this AI evaluation?**

A: Yes, it is applicable. AI platform can also provide an analysis report on the degree of narrowing of the respiratory tract, and the rest of the information in the same way as for a natural state.

**Q: Will the AI platform store records of patient data? If so, where will they be stored (server location)?**

A: No, Soteria doesn't store records of patient data.

In accordance with medical regulations and ISO13485 regulations, the uploaded image files will first be stored in a cloud company that meets the information security specifications.

European data is stored in Amsterdam (Netherlands), Taiwanese data is stored in Hsinchu (Taiwan).

Patient OSA analysis data (Report) will be automatically deleted in two days after it has been downloaded by the hospital.

**Q: How long are the Reports stored on the platform?**

A: In accordance with medical regulations and ISO13485 regulations, patient OSA analysis data (Report) will be automatically deleted in two days after it has been downloaded by the hospital.

As long as there's business with the hospital, hospital can choose to store used reports on the platform.

However, based on Soteria experience, hospitals rather prefer to keep downloaded reports (PDF format) in the hospital.

If business with the hospital is terminated, hospital will still be granted with some time to save all paid reports as PDF files, and then all relevant data will be deleted.

**Some straight-forward FAQs from doctors' perspective:**

**Q1: Sounds like you are trying to load me with something new, that requires to get studied, get used to... And I'm already way beyond busy!**

A1: On the contrary, Soteria is designed to UNLOAD your hectic schedule. Expert's time and direct attention to patients are most precious. The rest of the routine that required 1-3 days per visitor, now can be done in 1-2 hours. Just drag and drop CT scans to our online platform, and receive OSA analysis Report.

What Doctor DOES see on Soteria platform: it processes uploaded CT images and issues a Report with the same but colored CT images and detailed crucial data, exceeding PSG's.

What Doctor DOES NOT see on Soteria platform (it's background functioning): our system is "trained" to simulate the work of upper respiratory tract during sleep WITHOUT the need for the Patient to actually sleep in the laboratory.

The complete process is elegantly simplified for your ultimate convenience!

In other words, WHY should more and more Patients continue sleeping in laboratories, when thousands and thousands of other Patients with different degrees of OSA complexity have already slept before them?

WHY spending 1-3 days on one Patient, when for the same retail value and with great accuracy you can examine him/her in an hour or two? And our Report will show the result of simulation, how Patient's upper airways behaved while "sleeping".

**Q2: Are you trying to replace Doctors with AI? :)**

A2: No, it's illegal, and/or must be so. Doctor's expertise is INDISPENSABLE! The software does NOT make decisions INSTEAD of a doctor, it only analyzes big data by just being a "smart calculator".

The software removes 80% of work routine: collecting PSG/other measurements, data entry, simulation, calculation, analysis; and outputs visually intuitive (also patient-friendly) data.

20% of the work can only be done by an experienced doctor, relying on the Report to choose the best method of treatment. And these 20% are most important.

**Q3: We've (just) invested a ton in the best sleep center equipment! And now you want us to replace Gold Standard PSG with AI?**

A3: At that moment it surely was your best investment in business growth and service quality. Today, why not to have both at your disposal? You already have a certain number of beds in your sleep laboratory. How about "installing" more "beds", even more "sleep centers" with a small fraction of their cost?

These virtual "beds" DON'T require: space in your clinic, more equipment and consumables, maintenance, new training, qualified personnel, extra services for Patients during the whole procedure, extra attention from Doctors, etc.

INSTEAD, these virtual "beds" provide you with precise certified analyses AND attract largely underexamined Patients who did not want to come previously, because:

- clinics don't offer quick diagnosis,
- it takes long waiting time to finally get examined in the laboratory,
- they're busy and can't set aside as much as 1-3 days for this procedure,
- their OSA has unnoticeable or light form, which they believe is unworthy of 1-3 days spent in a hospital,
- they feel it's too complex and morally uncomfortable,
- they hesitate to visit any medical institution due to fear of Covid-19 or other contagious diseases,
- they are children (including: they're just too small; with lagging development; with hysterical behavior; underachieving pupils with ADHD; who require orthodontic treatment),
- they are old people, disabled (with caretakers), weak (Patients who need to identify whether OSA is one of the root reasons why they're sick for a long time, don't recover well, recover poorly after surgery).

All these categories of Patients are not even included in the clinical OSA studies, and thus this market is largely underpenetrated.

So, now you see how you can rethink your service quality and business EFFICIENCY with Soteria's improved approach. Our software helps to EXPAND your business without inserting a stick into the wheel of what has already been established by your esteemed clinic.

**Q4: Why do we need your AI system if Pulmonologist can see where the narrowing is on the CT scan, and whether surgery is needed or not?**

A4: Of course, complex and trouble-free cases are always obvious for Pulmonologist, but all in between – not so much.

Our system is especially good when it's difficult for a Doctor to determine by eye whether there is an OSA. That's why Soteria has created visual Reports: air flows are

highlighted in colors, how they move, where they get stuck, pressure, velocity, etc. – all during Patient's simulated "sleep".

Doctor can't possibly SEE how Patient's upper airways behave when he snores and suffocates. AI can. This process can only be "SEEN" with Computational Fluid Dynamics (CFD) simulation; with PSG/else – it's just a bunch of numbers (with some inconsistency).

In 2016–2017, the medical software Developer, together with leading Pulmonologists in Taiwan, conducted over 200 comprehensive measurements and studies in the sleep centers of Taiwan's leading hospitals to collect high quality big data from a wide variety of OSA cases, and "teach" AI to "see" all changes in the Patients' breathing patterns in their sleep.

Nowadays, the world's first patented and CE certified system is operating thousands of such cases, constantly self-learning and enhancing its Reports' precision beyond current 88%–91%.

**Q5: Can you provide contacts of Doctors who have already implemented your system? We'd like to personally hear their feedback.**

A5: Currently, there're over 15 hospitals, medical centers and clinics in Taiwan, Singapore, the Netherlands, and the UK, that are successfully using Soteria platform and satisfied with OSA Reports.

Please send us a message to [...@gmail.com](mailto:...@gmail.com) or give us a call at... (WhatsApp, Telegram), and we'll arrange a conversation with an available English-speaking doctor without breaching existing NDAs (Non-Disclosure Agreements).