

Summative Human Factors Testing



Test Locations include USA, UK & Germany

Simulated & actual use environments

Ethics & IRB approvals

Participant Recruitment

FDA, CE & MHRA Compliance

Future-proofing medical devices





Summative Human Factors Testing

Validating the design and use safety of your medical devices.

THAY Medical is an ISO13485 accredited company and a natural choice of partner when developing medical devices, where world-class usability and human factors are required. We specialise in collaborating with organisations to provide the human factors and usability engineering elements that are now critical in maximizing device safety, by performing human factors testing.

For compliance to the US-based FDA human factors guidance, the UK MHRA human factors guidance and IEC 62366-1:2015, performing a summative human factors test is essential, and has to be performed well. It has to cover not just the device or system, but also the instructional documents such as IFU's and User Manuals, and any training regimes. For compliance to the European MDR, a summative human factors test is evidence to show acceptable use safety.

Creating evidence of usability together

Being the best at summative Human Factors Testing.

THAY Medical are focused on performing summative Human Factors tests to a world-class level. Our customer feedback proves we do this. Our ISO 13485 certified Quality System enables us to do this. We engage with our clients to really understand their medical device, its intended use and all previous development performed on it. In addition, our experience in performing Human Factors and usability tests means we have real expertise in understanding how users are likely to use the device once launched.

We work to all country specific regulations and always perform ethically to the highest standards achievable to give the best quality of data. The test data we produce is minimally biased and trustworthy—purely because we continuously improve our test methods. We are known for high quality Human Factors documentation and compliance to the regulations.

THAY Medical are able to perform all aspects of a summative Human Factors test, or can assist your organisation with specific parts of it—as part of a test team. As a leading service provider in Human Factors Engineering, we excel in performing summative Human Factors tests. We are the partner of choice of many medical organisations, and we can be your partner for summative Human Factors testing.

If you have any devices you wish to test, please contact us for a FREE quotation.

More details on testing..

Test Locations we use:



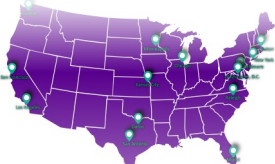
11 UK Locations



7 European Locations



4 Australian Locations



13 US Locations

Participant Recruitment:



2 weeks +



HOME



CLINICS



AMBULANCES



HOSPITALS

- 15-125 test participants
- ALL worldwide locations



- Healthcare Professionals of all types.
- Patients and Lay Users.
- Pharmacists and Specialty Healthcare Professions.



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THAY Medical Limited is a company registered in England and Wales, Company number **9211177**, with the registered office at the above address.

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