

Hangzhou XinHan Optoelectronics Technology Co., Ltd. is a specialized medical equipment company, which develops, produces, sales or provides medical services, our company has developed the TMT medical infrared thermal imaging system, which is widely used in health examination, traditional Chinese medicine, pain, bone, breast, anorectal, sports, features and other fields.

TMT medical infrared thermal imaging technology is a new type of functional imaging technology, it has a unique advantage of evaluation of human health, disease screening for early warning information, follow-up observation and efficacy of traditional Chinese medicine. TMT medical infrared thermal imaging technology has become an excellent complement modern clinical tests.

TMT-9000P medical infrared thermal imager is a high-tech product integrating infrared thermal imaging technology, computer control technology, computer image processing technique, electronic

technology and fine optical instrument. It changes the thermal distribution state of the object into visual image, displays it on the instrument in pseudo-color, and measures the temperature of the target on the infrared image as well.

Its basic working principle is: all objects in the nature higher than absolute zero (that is -273°C) emit infrared radiation all the time, but radiation peak wavelength of the normal temperature object is in far-infrared wave band beyond the visual range of human. Therefore, the self-radiation characteristics of normal temperature object cannot be seen by human eyes directly. TMT-9000P medical infrared thermal imager gathers the infrared radiation emitted from human body through its optical and mechanical system on the detector sensitive to infrared radiation (infrared detector) and turns it into electrical signal. After that, it amplifies the electrical signal and turns into digital signal, inputs it into computer to reconstruct the infrared radiation image of the object in gray or pseudo-color. which reflects the thermal distribution state of human body. In this way, it turns the invisible temperature information of the object into visual image, presenting human body skin temperature and thermal distribution Image.



- Working wavelength range : $8\mu\text{m}\sim 14\mu\text{m}$
- Temperature measurement range : $30^{\circ}\text{C}\sim 42^{\circ}\text{C}$
- Working distance : $0.5\text{m}\sim 5\text{m}$
- Temperature measurement correctness : $\delta\leq 0.4^{\circ}\text{C}$
- Temperature resolution : $\text{NETD}\leq 0.1^{\circ}\text{C}$
- Medical infrared thermal imager is available for power-driven focus
- Medical infrared thermal imager has the function of looking up, stooping down and moving around from left and right
- Medical infrared thermal imager is available for thermography generation, emperature measurement, image processing and report creation, etc
- **Power condition**
 - ☆ Rated supply voltage: AC 110V/220V
 - ☆ Rated supply frequency: 50Hz
 - ☆ Input power: $\geq 300\text{VA}$



Certificate

No. Q6 104072 0001 Rev. 00

Holder of Certificate: **Hangzhou Xinhan Photoelectric Technology Co.,Ltd**
Room 502A, No.22, Xinyan Road
Yuhang Economic And Technological Development Zone
Yuhang District
310000 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Hangzhou Xinhan Photoelectric Technology Co.,Ltd
Room 502A, No.22, Xinyan Road, Yuhang Economic And
Technological Development Zone, Yuhang District, 310000
Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of
Medical Infrared Thermal Imager**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH19154801

Valid from: 2019-09-20
Valid until: 2022-09-19

Date, 2019-09-20

Stefan Preiß
Head of Certification/Notified Body