



2020/02/21
Fujimori Kogyo Co., Ltd.

Our Total Thrombus-formation Analysis System, "T-TAS®01" has been approved by FDA as a Medical Device

T-TAS (hereinafter referred to as T-TAS ® 01 system) developed by Fujimori Kogyo Co., Ltd. (Location of HQ: Shinjuku-Ku, Tokyo, President: Eiji Fuyama) has obtained a FDA (Food and Drug Administration) clearance as a medical instrument on February 14th, 2020(U.S. time zone).

The T-TAS ® (Total Thrombus-formation Analysis System) is the world's first instrument for quantitatively observing thrombus-formation ability in the blood stream based on a new measurement principle developed independently by our company.

Developed for *In vitro* diagnosis use, the T-TAS ® 01 system is an assessment system for the analysis and evaluation of platelet thrombus formation (primary hemostatic function) in patients receiving antiplatelet therapy, including aspirin, clopidogrel, prasugrel and ticagrelor, and in patients with congenital platelet dysfunction, such as von Willebrand's disease and Glanzmann's thrombasthenia.

The system has been on the market in Europe by 7 sales agents covering 17 countries since March 2019, and has been highly evaluated by researchers and doctors in the field of thrombosis and hemostasis in European countries.

Following the approval of FDA for the medical devices, we plan to begin marketing the T-TAS ® 01 system in U.S. in this summer.

Our company will contribute to the improvement of the quality of medical care in the field of thrombosis and hemostasis by providing this instrument and chips to a wide range of clinical sites, and will also work on the development of medical equipment that can be used with greater peace of mind and comfort by medical professionals.

Device Name: T-TAS ® 01 system with PL-Chip

System Classification: Automated platform aggregation system

Classification: class II-

Application date: May 22, 2019

Approval Date: February 14, 2020

Product Introduction “T-TAS®01”



Reference Website: Product Information

<https://www.zacros.co.jp/products/ttas.shtml?c=15>

Special Site

<https://www.t-tas.info/>

Device Specification (Outline)

No.	Item	Description
1	Product Name	T-TAS® 01 Total Thrombus formation Analysis System
2	Rated Voltage	AC Adapter: AC100V to 240V 50/60Hz Instrument: DC12V (3.5A)
3	Rated power consumption	Less than 42W (Overall rated power consumption of system is 60W)
4	Dimensions	320(W)×247(H)×360(D)mm
5	Weight	6.0kg
6	Pressure detection range	-60kPa to 200kPa
7	Storage Temperature	5°C to 50°C In packed condition
8	Storage Humidity	10% to 90% No condensation In packed condition

9	Ambient operating temperature	20°C to 30°C
10	Ambient operating humidity	20% to 80% No condensation

Contact information for this product

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