



## Hospital Bulletin

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### Manufacturer

Spectros MDI  
2211 Norfolk, # 1110  
Houston, Texas 77098  
Phone:(650) 851-4040  
Support:1(346) 398-7828

### U.S. Distribution

Advanced Ambulatory, Inc.  
Houston, Texas 77098  
Phone (713) 528-9998  
Support 1 (346) 398-7828

### Pricing & Catalogue Numbers

Please refer to current price list

### FDA Registration & Product Listing

510K Registration # **K192322**

Trade/Device Name:	T-Stat 2.0 Microvascular Tissue Oximeter
Regulation Number:	21 CFR 870.2700
Regulation Name:	Oximeter
Regulatory Class:	Class II
Product Code:	MUD

### Product Description

T-Stat is a VLS Tissue Oximeter that provides a continuous, non-invasive and localized measurement, sensitive to regional and global ischemia. T-Stat reports a capillary-weighted oxygen saturation which is closely related to a local venous saturation measure

### EU Distribution

IGZ Instruments  
Furtbachstrasse, Switzerland  
Phone +41 44 456 33 33

### T-Stat System

T-Stat Tissue Oximeter Monitor  
And a disposable T-Stat Sensor  
CTH-060-SUR  
CTH-060-ORA  
CTH-060-ENDO

### CE Mark Registration

#### Product Reimbursement

In the U.S. no specific HCPCS code for *additional* reimbursement exists for tissue oximetry. Standard reimbursement is covered as part of the **global fees** as outlined in each hospital's individual managed care contracts

#### For more information:

Please visit our website: [www.spectros.com](http://www.spectros.com)

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