

# Remote Care Platform for Medical Device Manufacturers



## Collecting, Securing and Leveraging Medical Device Data

Medical device manufacturers are rapidly transforming from capital sales device vendors to smart, connected pay-per-use service providers. This IoMT (Internet of Medical Things) trend requires privacy and cybersecurity of patient data, creating low-cost home-care devices, remote patient monitoring, and value-based care.

However, future IoMT solution providers are challenged by protecting patient data, efficient offloading of processing from device to cloud, designing digital products and managing patient adherence to the medical device protocol. Mastering the intersection of regulated medical software + IoT + cybersecurity + cloud is hard for any company, even harder for science / hardware companies.



## The bio-T Solution Remote Care Platform for Medical Device Manufacturers

bio-T™ is a remote clinical care platform for medical device manufacturers enabling them to securely connect their device to the cloud, manage the generated data and facilitate clinical care. Through HIPAA/GDPR compliant, cybersecured clinical features, bio-T promotes patient interaction and data sharing.

As an off-the-shelf product, bio-T™ accelerates the transformation of medical device manufacturers from capital sales vendors into smart, connected, pay-per-use service providers. As a battle-trained tool, bio-T™ reduces cyber and regulatory compliance risks, while retaining manufacturer ownership over the data and providing complete flexibility via code-level customization.

## Benefits

bio-T provides out-of-the-box patient care features, guaranteed security & privacy compliance, OPEX savings, and customization flexibility:



### Smart Patient Care

- Real-time remote patient monitoring
- Clinical follow-up
- Patient-device adherence



### Guaranteed Security and Privacy

- Constantly adapting to changing threats and regulations, bio-T signs HIPAA BAA and GDPR DPA commitments for offloading liability from manufacturers



### OPEX Cost Savings

- Cloud OPEX Optimized using 8-year sharpened microservice technology.
- Compression of biomarker data



### 100% Customizability

- Designed for code-level customization, any medical device and any bespoke solution could be implemented using bio-T

## bio-T on AWS

Working together since 2011 and pioneering the early private Alpha release of AWS IoT back in 2015, the bio-T platform has perfected the best practices of delivering connected medical device solutions with AWS, both from the security standpoint and the cloud OPEX standpoint. Using the HIPAA-eligible AWS IoT core and AWS Kinesis, bio-T supports multiple data ingestion protocols with maximum security. Leveraging advanced AWS APIs for asynchronous programming and DynamoDB transactions bio-T is able to utilize AWS with the highest efficiency, thus minimizing the monthly cloud bill. In 2019, bio-T was accredited the AWS Well-Architected status with high honors.

## Features



### Consent Management

Consent Management provides the level of privacy governance required by international regulations such as GDPR and HIPAA. **Supported functions:**

- a. Multiple Consent types. EULA (end-user license agreement), T&C (terms and conditions), etc.
- b. Fine-grained management according to revisions and locales for each Consent.
- c. Consent tracking. Consent Management keeps track of each and every user signature.



### Adherence Management

Adherence Management is a bio-T microservice responsible for ensuring that the medical device is used as prescribed. It compares the given plan per patient with the actual usage (time/day, session length, etc..) and provides tools for enhancing adherence. The tools include diary adherence views for the patient and the caregiver, alert/notification when the patient is not in compliance and more.

Adherence Management leverages several AWS storage services.

## Case Study: Theranica Bioelectronics



### Challenges

Theranica needed to connect its migraine therapeutic device for collecting migraine data. Born in hardware, Theranica had technology gaps around issues like patient data privacy, implying financial risks in a heavily regulated industry.



### Solution

Theranica integrated its device with the bio-T platform forming a solution with web and mobile applications for patients and caregivers. Theranica is leveraging many bio-T features such as Consent management and EDC integration.



### Results

In a record time for the medical device industry, Theranica leveraged its FDA De Novo approval to quickly launch a complete, remote patient monitoring system that collects migraine data, in hopes that big data analytics will enable finding the root cause for migraine.

## Get started with bio-T solutions

[www.biot-med.com](http://www.biot-med.com)