

# Manufacturing What Matters

A few examples of products GMI manufactures for OEMs





#### Large, Complex Assemblies

GMI excels in complex assemblies that require the highest attention to detail and quality.

- High mix, low volume complex manufacturing
- · Power control & distribution assemblies
- Panel wiring and testing
- Cooling system manufacturing and test
- Isolation transformer integration
- Balance of custom and COTS hardware
- High voltage electronics assemblies
- Management of highly complex test procedures
- Cable management and serviceability improvements implemented through DFM review
- Safety controls & shut off circuitry
- High voltage testing capabilities (120/240/480v)

We embrace extremely complex products with challenging manufacturing requirements for critical applications. We have developed a series of processes and systems to enable these products to be built to our OEM customers' exact requirements while offering the convenience of a single part backed wholly by GMI's support team.

#### **Medium Volume Critical Assemblies**

Sensitive assemblies and small component integration are no challenge for our top notch manufacturing team. Whether it is safe handling of optical assemblies in a cleanroom or customer-facing assemblies with Class A finish requirements, we have the experience to build what you need.

- Build-to-print of various assemblies up to 50,000/year
- System-critical with extreme quality requirements
- Can assume customer's supply chain and inventory
- Clean environment manufacturing
- Modular class 10,000 clean room

## **Certifications that Matter**

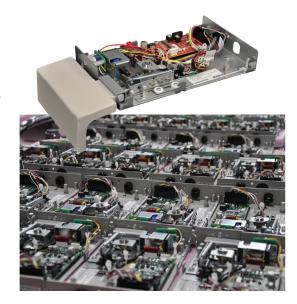
GMI has the certifications that matter to OEMs. We have been working with some of the largest OEMs in the world, and our systems and processes have been built ground-up to accommodate those requirements.



ISO 13485 certified USA and China facilities









## **Medical Imaging and Treatment Control Cabinet**

Complete manufacturing, DFM, testing and logisitics services.

Transfer of manufacturing to GMI involved assumption of BOM, build process, ongoing improvement to both logistics and final product.





- MRI guidance system for Radiation Oncology
- High criticality system requiring extreme quality
- Complex component list with over 1200 items
- Accommodation for 480V testing
- Complete assembly from schematic level documents
- Test process and fixture operation development
- Overall BOM management, including make/buy for specific components
- Custom PCB and Cable management
- Balance of custom and off-the-shelf parts
  - Mechanical assemblies
  - Electronic components
  - Cabling
- Custom test fixture validation
- Part consumption management
- Tooling management







#### HIFU (High-Intensity Focused Ultrasound)

Utilizing focused ultrasound combined with ultrasound-based imaging and assessment technology, The Sonablate system provides a minimally invasive approach to delivering precise and focused ablation treatment.

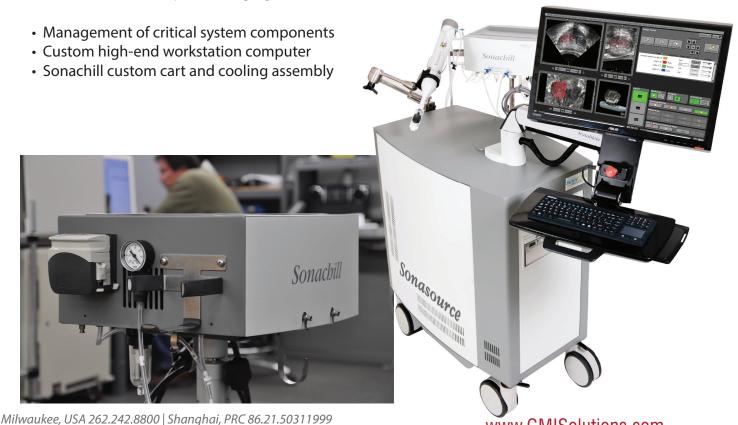
- Complex precision assembly
- Turnkey integration and test of complete medical device
- Utilization and management of customer-specified components and vendors

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• DHR documentation support

#### **Complete System-Level Management of Components**

Sonasource, in combination with Sonachill, acts as the foundation for all of SonaCare Medical's HIFU probes. Sonasource is comprised of several integrated programmable hardware and software modules that are used to drive and control SonaCare Medical's probes. The console includes all electronics required for user interaction with all probe imaging and treatment functions.





## Complete System-Level SPECT Imaging System

The customer asked GMI to manufacture the full assembly with the desire for DFM savings to be realized immediately. The transfer process involved customer-owned suppliers, consignment inventory and GMI-managed suppliers, all coming together to ensure the highest quality backed entirely by GMI.



 Updated processes & procedures to maintain quality while gaining productivity and reducing lead time

• DFM work completed using existing "gold" unit

 Manufacturing support, device history records and DFM engineering

Turnkey manufacturing services







#### **Patient Input Devices**

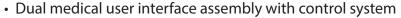
Big or small, we can do it all! Whether we are working with Hall Effects Generators, custom plastics, cables or even higher volumes then GMI is your partner. Custom build patient response systems and other system critical assemblies are a perfect fit for our high quality manufacturing.

- Build-to-print of 10,000+ pieces/year
- Assumed all of customer's supply chain and existing inventory
- 20 line item BOM custom build with ESD sensitive electronics
- Thorough test process



#### **Gantry-based Operator Interface System**

GMI Solutions was able to substantially reduce overall system size and cost while adding exactly the functionality the customer needed. This single PCB solution replaced an audio card, USB to serial adapter, USB GPIO card, and LCD power module; all with a simple, single card solution.



- Custom assembled display with touch screen
- Consolidated design for price, life cycle improvement and certifications





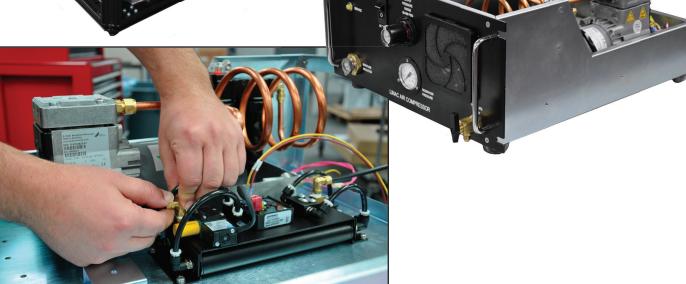




### **Treatment Cooling Systems**

We are not your typical contract manufacturing partner. We provide DFM review and manufacturing efficiencies to all of our customers. The mechanical rack assembly with a high capacity chiller coupled with the custom built air compressor that we manufacture is an example of an assembly that is not typical as well. We do fluidic and gas line pressure testing as well as electronic integration into a single assembly.

- Cooling system for the linear accelerator in a high-end radio surgery system
- Started as build-to-print utilizing the OEM's existing supply chain
- GMI provided DFM feedback
- Improvements, changes, increased efficiencies
- · Lead time, assembly time, test time are all managed
- Extreme quality control and copy-exact production
- Fluidic flushing and gas line pressure testing

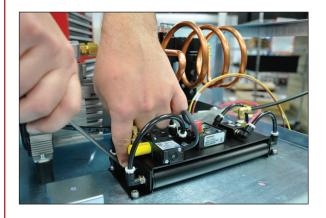




## **Cooling Solutions for Critical OEM Applications**

GMI offers manufacturing and test of cooling solutions for capital equipment, including critical applications.

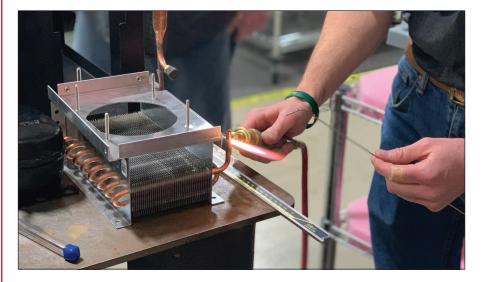
- Medical device cooling solutions
- Extreme durability
- · Small to large
- Pressure testing capabilites
- Embedded applications
- Build-to-print applications





## **Extreme Dependability with Economical Cost**

- DfMA for pecise manufacturing of copper components
- System charging services
- Nitrogen-based testing process to ensure quality
- · Positive pressure systems to avoid particualtes



## Complete set of capabilities

- System refigeration charging
- Copper brazing
- · Pressurized hold leak testing
- Duty cycle testing
- System level record keeping





#### **RF Generation System**

Precision manufacturing of control systems for RF generation devices is a specialty. Non-standard integration and gas line pressure testing of custom cables for highly regulated medical cryoablation device typify the precise assemblies GMI excels at. Managed through our ISO 13485 process and device history records we can ensure you receive the highest quality products every time.

- Custom electronic design by GMI Solutions
- Manufacturing process development
- Testing hardware and process development
- Global logistics for localized support
- Legacy system support for extreme lifecycle
- Custom electronics for critical system operation
- Specialty fine-pitch soldering and testing

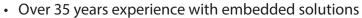






#### **Embedded Computer Solutions**

GMI offers complimentary computer services for OEMs that manufacture capital equipment for critical applications.



- Lifecycle management to ensure controlled change
- · DFM (Design for Manufacturing) services
- · Complete testing expertise
- In and out of warranty depot repair services
- Depot refurbishment services
- · Record retention at system level
- Permanently archived manufacturing and service history



## Balance of Off-The-Shelf and Custom Components

- Management of off-the-shelf products
- Board-level component management
- EOL replacement discovery
- Automated test capabilities
- Software preload management

## **Critical Assembly Quality**

- 100 percent test and inspection
- Medical application
- TUV, CE, UL, CCC and other certifications
- In-process inspections as applicable
- Build-to-specification or copy exact







#### **Connected Health Kiosk**

If you are looking for a full turnkey manufacturing partner, then GMI Solutions can help. We support early stage OEMs and multinational OEMs with complete manufacturing, supply chain support and logistical advantages for turnkey projects. We provide the ability to drop ship globally from either of our manufacturing locations.

- Full turnkey patient vital screening devices
- Card reader technology
- Touch screen interface
- Takes weight through integrated and tested load cells
- User interface, patient O2, BP, weight, and more
- Upload info to selected healthcare provider
- Customer needed both build-to-print services and manufacturability analysis
- Fully tested and drop shipped to installation locations

### **Secure Locking Mechanism**

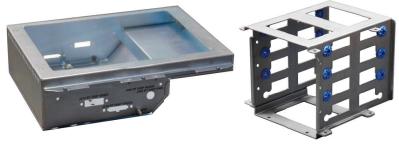
High volume manufacturing with cosmetic finish requirements are not an issue for GMI. We manufacture and test thousands of units that are used in critical medical dispensing applications around the world. We have these services through our US or China facility.

- Build to print project with DFM activity
- Manufacturing of CDC approved product
- Class A metal surface finish capabilities
- Custom plastic fabrication
- High volume automated testing setup for reliability and quality





#### **Metal Fabrication Service in China**



#### **Vertically Integrated Services**

Global logistics and vendor/component consolidation is one of many value-added services GMI can provide. Increasing system reliability by creating custom designed parts of systems to enhance your off the shelf parts is an example of that. GMI builds assemblies that fit your own manufacturing needs whether it is kitting, subassembly, assembly or even turnkey manufacturing.

- Metal fabrication and machined parts expertise
- Tight tolerances, high quality
- China cost advantages
- Direct shipments in Asia or globally
- Power supply and distribution products
- Custom cable manufacturing
- Cable assembly validation and production testing

## **Machined Part Management**



**Custom Cables** 



#### **Power Related Products**







## Panel and Large Cabinet-Level Wiring

Some contract manufacturers say they can do electronic assembly. We live it every day whether it is ESD sensitive manufacturing or customer specified panel wiring assemblies. Our robust and repeatable processes allow us to provide OEMs with the exact quality they require.

- Build-from-schematic capabilities
- Customer specific panel wiring
- Repeatable processes for non standard assemblies
- High quality results from highly trained technicians
- High voltage, low voltage panel wiring

## **Panel Wiring Services**





#### Why GMI Solutions is the Best Choice

#### **Stability**

- GMI has been in business since 1983 and has a long history of consistent, steady growth.
- Serving OEMs has been the sole focus of GMI since 1994, and we have developed a set of tools and processes to offer the very best product quality, consistency and timeliness possible.
- The Midwest region of the USA is centrally located and offers a stable workforce.
- The in-house systems for complete control are very efficient and highly automated, resulting in efficiency and competitive costs.
- Our OEM customers are partners, and engagements last for many years.
- Full business continuity plan in place.

#### **Global Locations**

- GMI has facilities in both the US and China, providing for:
  - Dual Hemisphere manufacturing.
  - Redundant manufacturing and supply chain capabilities with duplicate processes.
  - Seamless program migration (if desirable).
  - Manufacturing failover plan in case of catastrophic damage to facility.

#### Manufacturing

- As an ISO certified manufacturer for OEMs exclusively, GMI has the tools in place to ensure a consistent, extremely high-quality product flow.
- Skilled Midwest manufacturing workforce with competitive rates.
- Product consistency utilizing tools designed specifically for OEM manufacturing and product testing.
- ISO 13485 based processes with robust ECN/ECO process.
- We welcome learning new things and take training our team seriously. We add tools and processes to accommodate specific product manufacturing and testing requirements for OEM's regularly.

#### Quality

- Our manufacturing process controls are the 'Gold Standard' for Philips Healthcare CT Division as a direct result of their multi-day quality audit.
- Everything GMI does globally is under ISO 13485 certification.
- 100% of incoming components and outgoing products tested.
- Comprehensive data gathering and sharing results in collaborative product and process improvements.
- We welcome quality audits and use them as a vehicle for positive change.

#### **Full Team Support**

- The entire organization has been built to offer high-touch, top notch service to each and every customer.
- A dedicated group at GMI will support your team throughout the product cycle and into the next products or generations of product.
- Our goal is always to create a lasting partnership and become the supplier of choice for all product manufacturing requirements in the future.



## **USA Based with Facilities in China**

#### **GMI Solutions America:**

(Global Headquarters) 10202 North Enterprise Drive Mequon, WI 53092 USA



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