FATRON

HEATING ELEMENT DESIGNS FOR MEDICAL DEVICES

Go ahead

Push the boundaries

Higher performance products that differentiate your business.

Expertise in Design for Performance, Design for Manufacturing and vast insights into the challenges you face. Heatron designs products based on intelligent combinations of materials and complex component integration. Proficient in a multitude of key thermal technologies, our products are engineered to withstand the extraordinary demands placed on them.

Heatron offers turnkey manufacturing solutions for products, subassemblies and components to lower cost of ownership and speed time to market. We continually reinvest in new technology while utilizing Lean Principals to streamline operations, eliminate variation and deliver a competitive advantage to our customers.

- Proven FDA and Safety Agency experience
- Quality Audited by Fortune 500 customers
- ISO 9001: Certified
- Class 10,000 Clean Room
- High velocity production experience
- Incredible throughput
- Best-in-class path planning and control



BLOOD ANALYZER

Heating Element

Dual HEATFLEX Kapton[®] /Polyimide bonded to two anodized plates

Heatron's Role

- **Regulatory Compliance:** performs to tightened NGSP protocol
- **Product Differentiation:** controlled, rapid heating maximizes test speed and throughput, reducing cost per test
- Design for Performance: distributed watt density ensures uniform, consistent surface temperature
- Design for Manufacture: integrated design eliminated a quality test from the process

Dependable results every time. This blood-glucose analyzer simplifies diabetes testing, enabling an immediate and effective treatment plan. A dual heater was designed for precise, controlled heat that meets tightened NGSP performance criteria.





SLEEP APNEA

Heating Element

HEATFLEX Kapton[®] /Polyimide bonded to anodized plate

Heatron's Role

- **Product Differentiation:** uniform, warm vapor experience preferred by most patients
- **Design for Performance:** integration of mounting and sensing components for patient-controlled vapor and air temperature
- Patient Safety: equipped with an over-temp safety cutoff
- **Regulatory Compliance:** rigorous quality controls that stand up to regulatory scrutiny

Designed to meet exacting medical standards and patient-controlled performance requirements, Heatron's heating solution allows customizable humidity control for optimal patient comfort. The heater is engineered to pass extreme test conditions, as well as easy attachment to the device in the assembly process.





DIALYSIS

Heating Element HEATROD Cartridge

Heatron's Role

- **Product Differentiation:** a more advanced heat transfer treatment at a lower cost
- **Patient Comfort:** designed with electronic controls to limit dialysate heating at re-entry to the appropriate temperature parameters
- Patient safety: equipped with an over-temp safety cutoff
- **Regulatory Compliance:** complies with UL safety requirement 60601-1 and Class 1 medical device current leakage

Precision performance measured in tenths of a degree. Dialysis therapy with controlled heat for blood warming to body temperature prior to re-entry, the temperature accuracy is $\pm 0.3^{\circ}$ C. Designed for a three-step thermal process to disinfect the blood, warm to body temperature and system cleanse at the end of operation.





DNA ANALYSIS

Heating Element

HEATFLEX Kapton[®] /Polyimide bonded with pressure sensitive adhesive

Heatron's Role

- **Product Differentiation:** unprecedented test speeds and output that lowers cost per test; tight tolerances and registration, temperature uniformity of ±0.5° C and ramp rate as fast as ±3.0° C/second
- **Design for Performance:** targeted, rapid thermal cycling to facilitate temperature-sensitive reactions with a confidence level of 99.7%
- **Design for Manufacture:** engineered with distributed wattage, integrated sensors and controls, and a simple Plug and Play interface
- First to Market: Heatron was the first in the market to design the 384-well format

Engineered from the ground up to support rapid thermal cycling, high-density PCR applications. This DNA Analyzer is optimized for superior yield, purity and integrity. Designed for uniform, optimum temperature across the 384-well block while rapidly cycling the reagents in each well.





HOME DIALYSIS

Heating Element

HEATFLEX Silicone rubber vulcanized to custom aluminum plate

Heatron's Role

• **Product Differentiation:** small footprint allows treatment at home or on the road; plugs into any standard electrical outlet



- Design for Performance: multi-purpose, simplified heat disinfection system
- **Regulatory Compliance:** FDA clearance for home and travel; CE mark approved for night time use
- Patient Safety: heat sensor monitors dialysate temperature and provides a short feedback loop for changes; equipped with thermistor alarm and over-temp safety cutoff

With the temperature accuracy of a healthcare facility, this portable home dialysis system improves patient survival and quality of life. The compact system uses controlled heat to assist in degassing treated water prior to blood warming to body temperature.



HOME DIALYSIS

Heating Element

Hybrid HEATROD Cartridge

Heatron's Role

• **Product Differentiation:** considerable savings in terms of clinician's time and work; same day results improve therapeutic success and patient outcome; targeted therapy lowers health care expenses



- **Design for Performance:** engineered for speed and efficiency, numerous temperature sensors ensure the system operates at an average temperature of 35.5° C, ±1° C for superior strain identification
- Design for Manufacture: domestic vertical design; lower cost of ownership

For crucial identification and resistance information, this completely automated system provides same day results. Heatron's heater controls the test card incubation while two remote precision thermistors continually monitor and control the temperature to specifications.



PATIENT WARMING BLANKET

Heating Element

4-up series of HEATROD Cartridge heaters

Heatron's Role:

- **Product Differentiation:** adjusts patient's temperature to the target temperature at an average rate of 1.63° C/hour
- **Design for Performance:** up to five times more thermal energy; efficient transfer rates allow target temperatures to be reached rapidly and precisely maintained
- **Regulatory Compliance:** FDA clearance in the U.S. and the European Union's CE Mark
- **Patient Safety:** adjustable minimum and maximum system temperature for patients with risk of skin injury; under- and over-temp safety limits

Critical care therapeutic temperature management. Fastest initiation of treatment for heart attack and stroke patients, this system offers more efficient cooling and automatic activation of rewarming, including the slow rewarming crucial to therapy.





CONVECTION OVENS

Heating Element

HEATFLEX Silicone rubber with pressure sensitive adhesive (PSA)

Heatron's Role

- **Product Differentiation:** obtain results with superior precision; high performance ovens for diverse analytical procedures
- **Design for Performance:** designed to operate between 100° C and 215° C; attain maximum temperature within thirty minutes; maintain uniform, even heat distribution
- **Regulatory Compliance:** 115 volt units meet UL and CSA requirements and 230 volt units are CE marked
- Safety: equipped with advanced over-temp safety cutoff
- **Design for Manufacture:** incorporated with an array of value added features, including sensors, bi-metallic thermostats and mounting

Versatile, reliable performance. Researchers can dry, sterilize, anneal, polymerize, evaporate and accelerate product age. Diagnostic studies are conducted with greater precision and efficiency.





ELECTROLYTE ANALYZER

Heating Element

HEATFLEX Kapton® /Polyimide with pressure sensitive adhesive (PSA)

Heatron's Role

- **Product Differentiation:** accurate, reliable heat within fully automated, self-monitoring analysis system helps allows operator to walk away from operation
- **Design for Performance:** highest assurance of precise, accurate temperature in self-calibrating system
- **Regulatory Compliance:** FDA labeling for in-vitro diagnostic use; meets IEC 61010, UL and CSA Standards
- Lower Total Cost of Ownership: component
 design lowers equipment and power costs

Fast, simple, accurate. Achieve whole blood stat analysis in less than 40 seconds; all day, all night. For high throughput, routine testing, this fully automated system procures up to 475 tests/hour while freeing up the operator for increased efficiencies.



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