

BATTLE CARD

PULSED FIELD ABLATION

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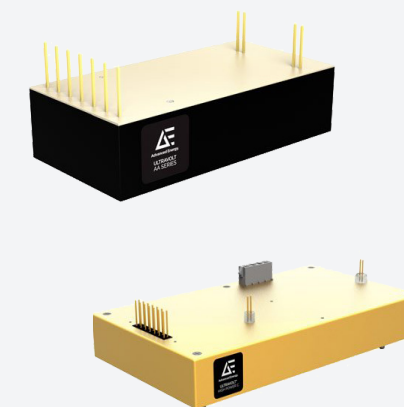


SOLUTION OVERVIEW

Pulsed Field Ablation (PFA) or Irreversible Electroporation (IRE) is driving new treatments for tumors and atrial fibrillation. PFA is a technique where a HV electrical field is applied to cells culminating in cell death. The voltage required is typically in the range of 1 to 3 kV with some applications requiring up to 5 kV with currents up to 65 mA. Pulse widths are typically in the range of 100 ns to 100 μs with burst mode frequencies up to 5 MHz. The associated slew rates for the pulse are both significant and challenging.

Ultravolt High Power C is a compact, reliable HVPS providing tightly regulated output power and features fast rise-times ideal for pulsing applications. It is suitable for high-energy pulsers, amplifiers, and discharge devices with large capacitance, fast repetition rates, and high current loads.

In certain use cases, the customer may require a lower power HVPS for the purpose of a stimulation pulse application during the ablation procedure. This may be in the 20 to 30 W range at <50 V where the UltraVolt AA Series is a recommended choice of product.



Target Markets/Customers

Medical Device companies focused on electrosurgery for atrial fibrillation or tumor ablation. The following are some companies that are developing pulsed field ablations systems:

- Abbott St Jude
- Acutus Medical
- Adagio Medical
- Affera, Inc
- AngioDynamics
- Argá Medtech
- Atrian Medical
- Boston Scientific
- Creo Medical

- Field Medical
- Galvanize Therapeutics,
- Igea Medical
- Intelligent Health Medical
- J&J Biosense Webster
- Kardium Medic Vancouver
- Kossel MedTech
- Medtronic Mounds
- Mirai Medical

Where to Avoid

- Low volume custom solutions - they can be pushed to our standard product offerings

Audience – who to engage and when

- Focus on OEMs and ODMs of electrosurgery medical devices
- Functions: Engineering Manager, Principle Electrical Design Engineer, Sourcing Manager, R&D Director
- Functions: Product (line) management, Engineering, Technical Purchasing
- Seniority levels: Director, Manager
- When to engage: When prospects are in early design stages (++) or have completed their designs (+) and start to look for the required components

Business Benefits

- Quick turnaround for delivery
- Proven and highly reliable
- Broadest medical power portfolio - preferred vendor
- Highest performance and quality
- Best in class QMS
- Dedicated medical engineering and customer support
- Standard off-the-shelf and full-custom solutions
- Lowest total cost of ownership

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INTERNAL CONTACTS



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Qualifying Questions

Qualifying questions to ask when engaging with a potential customer.

- What is the application?
- What are input and output voltages?
- How much ripple? (ripple is the noise on the High Voltage output line)
- How much high voltage power is needed?
- How many different high voltage outputs are needed?
- What type of mounting method is preferred? Chassis or PCB?
- Polarity: negative, positive or positive & negative output voltages?
- How do they want to control it?
- Ask the customer for a block diagram to uncover cross sell opportunities



Customer Challenges

1. Pulsed electric fields in the sub-microsecond range are increasingly used in biomedical and biotechnology applications because it is both faster and more precise, causing less unnecessary damage than RF or cryoablation
2. Demand for high-voltage and high-frequency pulse generators with enhanced performance and pulse flexibility is pushing the limits of pulse power solid state technology

3. Long lead times and lack of customer support delay time to market

Generator Considerations:

- Pulse shapes, from unipolar to bipolar pulses
- Symmetric or asymmetric modes
- Voltage range typically from 1 kV up to 5 kV
- Pulse width from 100 ns to 100 μ s
- Burst mode up to 5 MHz
- Overcurrent & output arc protection, current, and voltage monitoring.



Key Features & Specs (high-level differentiators)

The High-Power C Series of regulated DC-to-DC converters are designed for high voltage capacitor charging applications that demand fast rise times with controlled voltage overshoot.

1. Regulated high voltage outputs ranging from 125V to 60kVDC maximum
2. Positive or negative polarity models
3. 60, 125, or 250W maximum power (dual polarity 60 or 125W maximum power)
4. 24VDC input
5. Output ripple performance <1%
6. Controlled high voltage overshoot enhances longevity of external load components
7. Temperature coefficient 50ppm/ $^{\circ}$ C
8. Simplified integration with available 0 to 5VDC or 0 to 10VDC interface for constant voltage or constant current mode operation
9. Reliable modular, fanless design

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COMPETITIVE ANALYSIS

Competitor	Type A	Type B	Type C
Their Positioning & Selling Points	<ul style="list-style-type: none"> Leading independent supplier of precision DC high voltage power supplies. Privately head company, making them highly price competitive. Specializes in partnering with OEMs for each system and market segment. 	<ul style="list-style-type: none"> All their high voltage power supplies are clones of UltraVolt’s core products; this can enable them to pursue our existing customer base. Their go-to-market model is broad and more product-focused with little to no targeted applications or markets. 	<ul style="list-style-type: none"> Virtually their entire line appear to be copies of other HVPS manufacturer’s products, including Ultravolt They do have a “product by application” section, including a medical section, but no mention of electrosurgery
Our Differentiation	<ul style="list-style-type: none"> Globally recognized name in high voltage with unmatched customer support. We are also just as likely to engage with medical start-ups and academia as much as we are to work with large, well-established corporations. They are more selective and will gravitate toward well-established device manufacturers. Our global footprint and access to capitol allows us to more effectively control our costs. 	<ul style="list-style-type: none"> AEI has a strong background in HVPS design with an emphasis on medical applications, coupled with a team of application-specific technology directors guiding our medical product roadmap. They do not focus on any aspect of the medical market. They make no mention of this field on their website. 	<ul style="list-style-type: none"> Advanced Energy is a globally recognized name in high voltage with unmatched customer support. Their footprint is largely Asia-focused, with less penetration in other geographical regions.
Comparative Positioning	<ul style="list-style-type: none"> AEI has a deep understanding of the electrosurgery field (including PFA and IRE technology) and can tailor precision power solutions to individual requirements. We are currently engaged with numerous electrosurgery customers. To date, their website yields zero hits on the term “electrosurgery” despite them having cloned UltraVolt’s High Power C Series, which we are already selling to several electrosurgery customers. This alludes to their lack of penetration in that medical market segment. 	<ul style="list-style-type: none"> AEI can lead medical customers toward dedicated solutions for their respective segment of the medical industry. They can only offer broad technical support for specification-based requirements, not market or application based. Their series is a clone of our “HP-C” series units 	<ul style="list-style-type: none"> AEI is well-known for designing and manufacturing robust and fully traceable HV products which are our own team’s design, based upon decades of HVPS design experience. Their penchant for copying existing products raises concerns about the capabilities of their own design team and the true depth of their knowledge of high voltage power supply design. Their series is a clone of our “HP-C” series units



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ADDITIONAL REFERENCES

Cross Selling Opportunities

Power Factor Correction

- Artesyn AIF - PFC SERIES

AC/DC power supplies

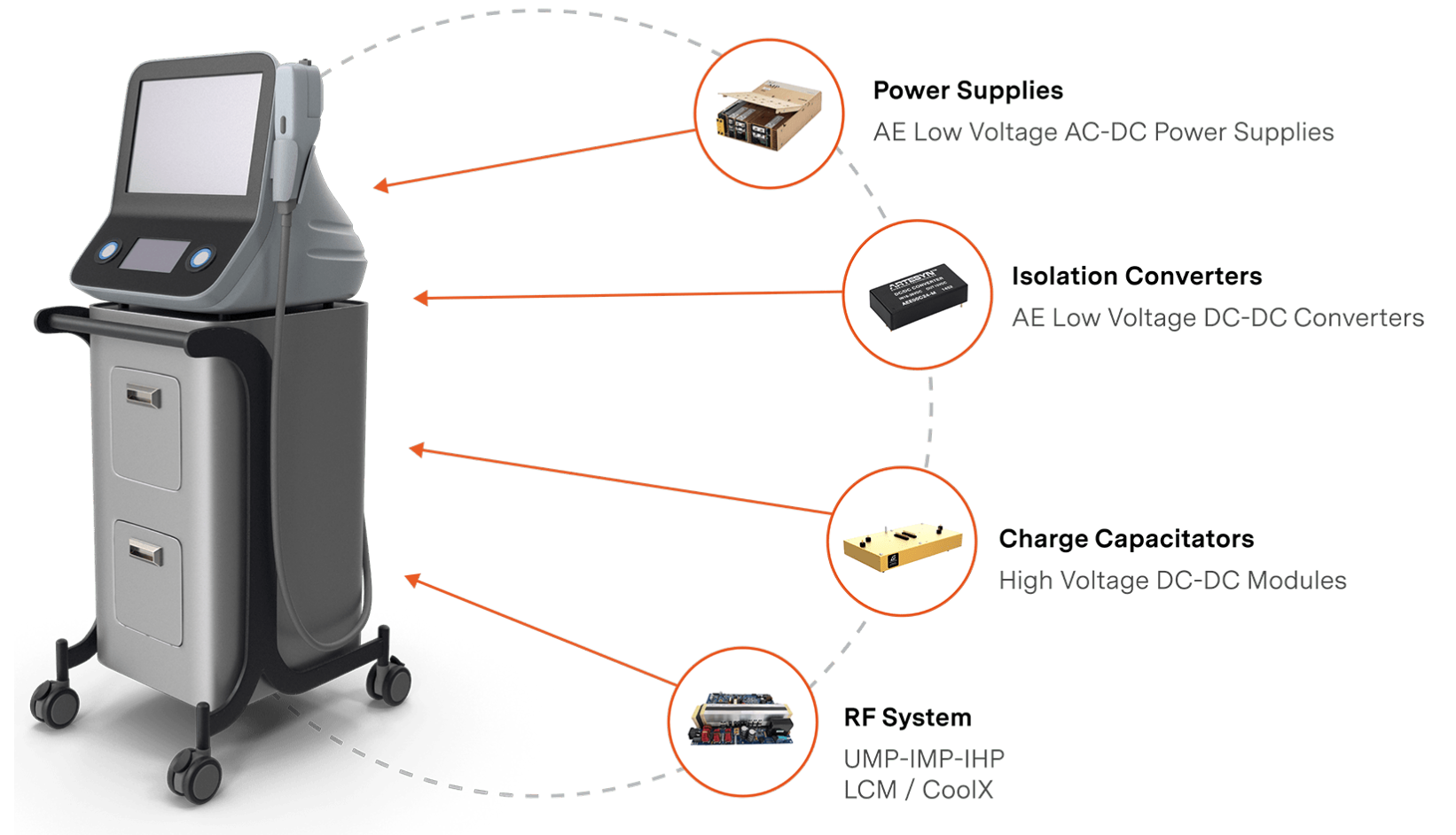
- Artesyn LPS360-M Series
- Excelsys CoolIX600 Series
- SL Power NGB425

Pulsed Electric Field is an emerging therapy segment. Research and development into pulsed field ablation (PFA) is of particular interest as the ultra-short pulses increase therapeutic effects while minimizing thermal issues. However, you must be able to deliver high voltage (HV) electrical energy accurately while these systems need to meet varied parameters without compromising precise control.

Critical Sensing & Control

- Luxtron® Fiber Optic Temperature Sensors

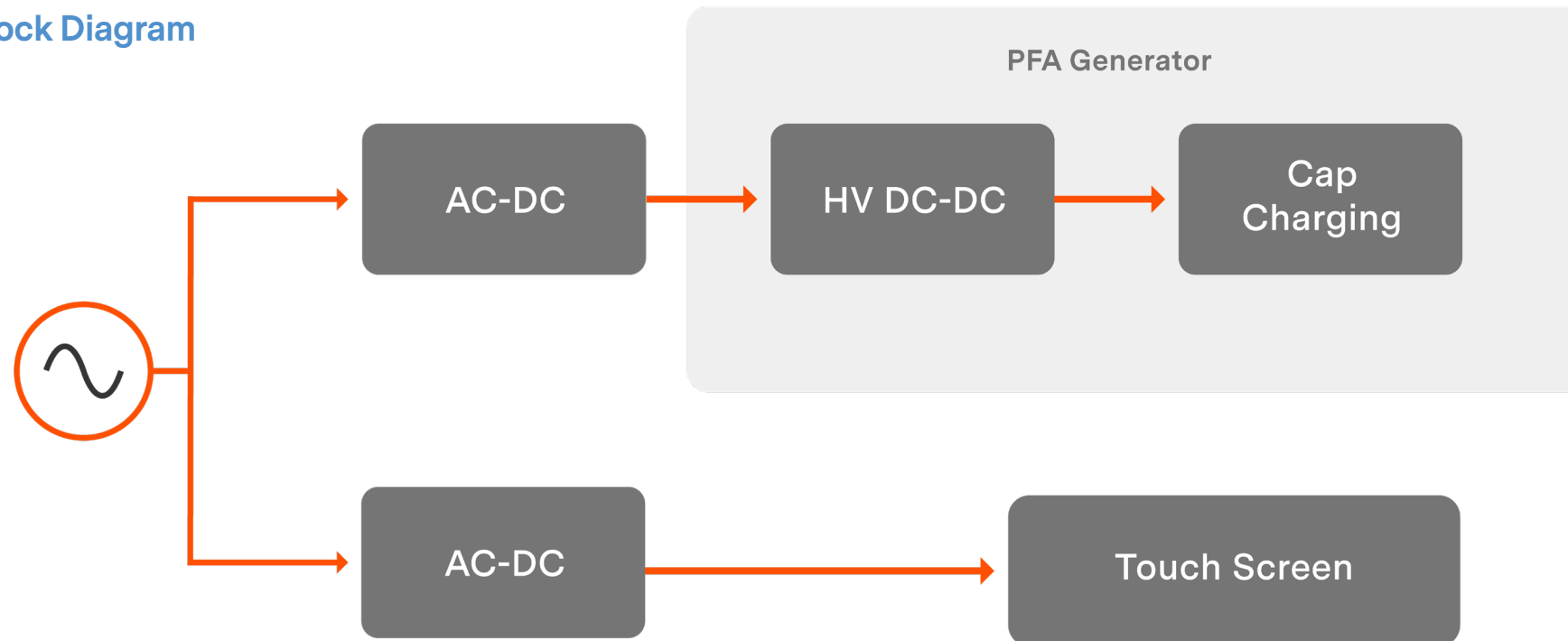
While PFA is a non-thermal tissue ablation therapy, medical device manufacturers use fiber optic temperature sensors during development to confirm safety when adjusting pulse parameters and to monitor for effects on adjacent tissue and structures. The FOT sensors from AE are safe and accurate for use in the electric fields created by PFA.



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ADDITIONAL REFERENCES

Block Diagram



Application	AE Products to be Offered
AC-DC	NGB Series, CPS Series, LPS Series, SLB Series
High Voltage DC-DC for Cap Charging	Ultravolt High Power C
AC-DC for Control Room Touch Screen	NPS Series, SLB Series, LPS Series