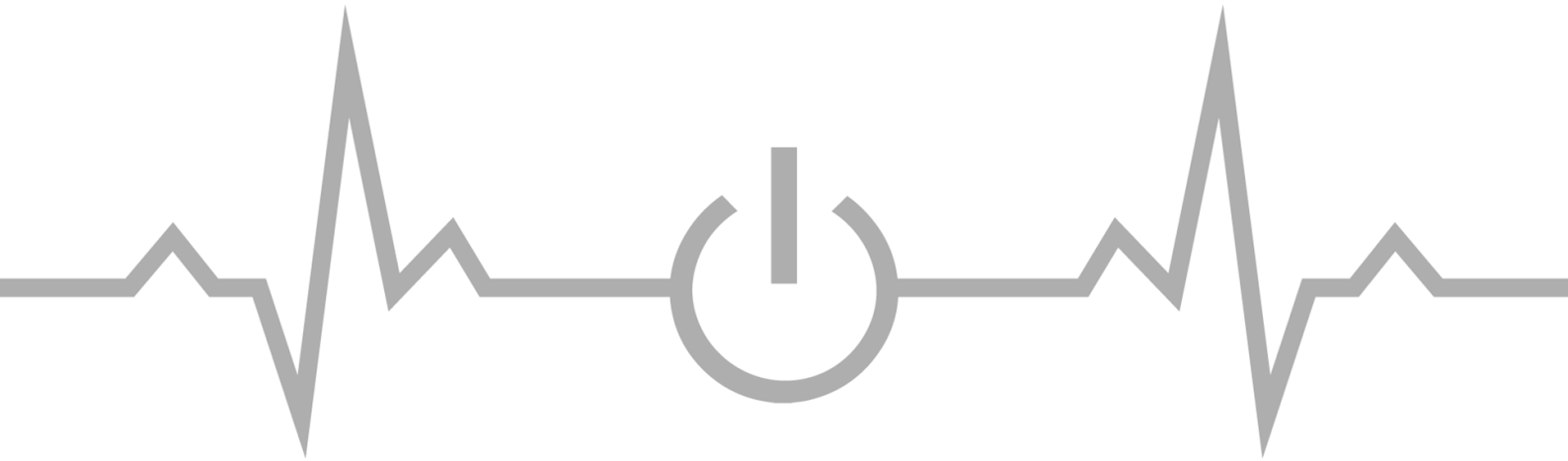
Choosing a Medical Power Supply

Since modern medical equipment heavily leverages advances in the computing and electronics fields, it is increasingly critical to select the right power supply to meet functional and regulatory requirements. This paper will discuss the unique design requirements for medical power supplies, and how to select the right medical power supply for your application and product.



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Modern medical equipment requires advanced power conversion technology to meet functional and regulatory requirements.

Advances in switching power supplies for medical equipment have yielded greater energy-efficiency, higher power-density and smaller footprint standard products. This allows the OEM medical product designer greater flexibility, selection and shorter time -to-market that will enhance their end product.

Selecting the right power supply is critical to the success of the end product. It must meet the electrical, AC leakage, mechanical and medical safety requirements such as IEC 60601-1.

Power supplies can be broadly split into two types – AC-DC and DC-DC - and within the AC/DC category there are linear and switching. The focus of this paper is on the switching AC-DC category. Within the modern medical environment, most of the focus is on switching medical power supplies that provide electronic components requiring DC voltage and current including such devices as CPUs, transistors, FETs, ICs, relays and motors.

Safety for Medical Power Supplies

Safety is a critical consideration in power supply design and selection.

There are two main safety approvals for power supplies - IEC 60950-1 for ITE (information technology equipment) and IEC 60601-1 for medical equipment. Both protect against electrical shock and, as medical equipment may come into contact with a patient, IEC 60601-1 therefore has a higher level of safety.

Some power supply manufacturers offer standard power supplies that offer both ITE 60950-1 and medical 60601-1.

IEC is the International Electrotechnical Commission, a leading international standard organization that manages safety standards for power supplies.

IEC 60601-1

The IEC 60601-1 standard defines the general safety requirements for equipment that has not more than one connection to a particular supply mains and is intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient.

It provides requirements for evaluating electro-medical products and uses a similar evaluation approach as that of IEC 60950 for ITE equipment. Medical power supplies have both electrical and mechanical requirements to reduce hazards under normal and single-fault conditions.

IEC 60601-1 applies to equipment in medical, dental and laboratory environments. Examples range from small items of equipment such as thermometers, infusion pump controls, and endoscopic cameras, through to larger systems such as dialysis machines, MRI scanners and gamma imaging systems.

It has worldwide adoption by the various international safety agencies but may have regional deviations and is identified internationally by - for example - UL/AAMI for the USA, CSA for Canada, EN for Europe, and JIS for Japan – as outlined in Figure 1.

Common deviations include the requirements of the electrical code of the particular country, another national standard that may apply to the product type or its components, and different national component requirements, such as modified labeling.

To facilitate the approval of the medical end-product device, components such as power supplies should be certified within safety standards.

Country / Region	Approval Agency	Standard adapted from IEC 60601-1
United States	Food and Drug Administration (FDA)	ANSI / UL ES 60601-1 (formerly UL 2601-1)
Canada	Therapeutic Product Directorate (TPD)	CAN/CSA C22.2 No.606.1
European Union	Various Notified Body – compliance to Medical Device Directive 93/42/ECC	EN 60601-1 (BS EN 60601-1 in United Kingdom)

Figure 1 shows the main international agencies and adapted standards related to IEC 60601-1

What is AC Leakage Current?

AC leakage occurs when current flows through an alternate path such as a human body. This can cause potential electrical shock to medical patients.

Leakage tests simulate a human body coming into contact with medical equipment. The measured leakage current measurements must be low enough to be safe and the leakage current limits are set by the safety specification.

Subjects		IEC 60950-1	IEC 60601-1	
Creepage distance / clearance distance Working voltage: Max. 250 Vrms	Basic insulation	2.5mm / 2mm	4mm /2.5mm	
	Supplementary insulation	5mm / 4mm	8mm / 5mm	
Electric strength test	Basic insulation	1500 Vac	1500 Vac	
	Supplementary insulation	3000 Vac	4000 Vac	
Leakage current	Class I	Handheld: 075 mA	----	
		Others: 3.5 mA	Leakage current of grounding	0.3 mA
			Leakage current of case	0.1 mA
	Class II	0.25 mA	Leakage current of case	0.1 mA
Number of AC fuses		1	2	

Figure 2 details the key differences between the ITE and medical safety standards

Third Edition

The third edition of the IEC 60601-1 standard makes a distinction between operator and patient with the introduction of MOOP, which refers to the Means of Operator Protection, as opposed to Means Of Patient Protection or MOPP. Since patients are involved, MOPP has stricter requirements.

Insulation	MOOP			MOPP		
	Air clearance	Creepage distance	Test voltage	Air clearance	Creepage distance	Test voltage
Basic (1 X MOP)	2.0 mm	2.5 mm	1500 Vac	2.5 mm	4.0 mm	1500 Vac
Double or reinforced (2 X MOP)	4.0 mm	5.0 mm	3000 Vac	5.0 mm	8.0 mm	4000 Vac

Figure 3 shows the differences between MOOP and MOPP as introduced by Edition 3 of the IEC 60601-1 standard

No	Description	Insulation category from sec.20.1 or 20.2	Working voltage, U, from sec.20.3	Test voltage from table V sec. 20.3	Air clearance from table XVI sec. 57.10	Creepage distance from table XVI sec. 57.10
1	Primary to secondary 2 x MOPP	A – e Double	125 Vrms < U < 250 Vrms	4 KVac	5 mm	8 mm
1	Primary to secondary 2 x MOPP	A – e Double	250 Vrms < U < 400 Vrms	4 KVac	7 mm	12 mm
2	Primary to protective earth 1 x MOPP	A – a1 Basic	240 Vrms	1.5 KVac	2.5 mm	4 mm
3	Primary to primary 1 x MOPP	A – f Basic	240 Vrms	1.5 KVac	1.6 mm	3 mm
5	Secondary to protective earth NA	A – a1 Basic	U < 36 Vdc	500 Vac	1 mm	2 mm

Figure 4: An insulation diagram and table to illustrate compliance with IEC 60601-1 Edition 3

EMC for Medical Power Supplies

Electromagnetic compatibility (EMC) is also a critical consideration in power supply design and selection.

EMC requirements for medical electrical (ME) equipment and ME systems are stated in IEC 60601-1-2, a collateral standard to IEC 60601-1.

Under this medical EMC standard, power supplies are classified as 'non-ME equipment' and therefore are technically required to comply only with IEC EMC standards applicable to that equipment (e.g., ITE immunity standard EN 55024), provided that the power supply will not result in the loss of basic safety or essential performance of the ME system in its intended environment. Essential performance is determined by the ME system manufacturer.

Given that there is no specified performance criteria for the non-ME equipment itself, the ME system manufacturer should determine whether the EMC performance of a given power supply is adequate for the specified application.

Fourth Edition

The latest edition of the IEC 60601-1-2 standard, the fourth edition, comes into force in the USA and EU from December 31, 2018. This expands the risk management requirements of the standard and provides guidance for the determination of the immunity test levels for special environments and guidance identifying the immunity pass/fail criteria.

Compliance is checked by inspection of the risk management file prepared by the ME system manufacturer in relation to the basic safety and essential performance of the ME system.

The electromagnetic compatibility (EMC) requirements move away from equipment categories, such as 'life-supporting,' and instead considers 'intended use environments.' In the past, it may have been possible to exclude sources of interference from sensitive medical environments, such as hospitals, but with more and more medical equipment now intended to operate in home and other environments, that approach
no longer works. The fourth edition defines:

Professional healthcare facility environment
The traditional use of medical equipment in hospitals, clinics and similar places where medical staff are often present are mostly considered to have a controlled EM environment against fixed electromagnetic sources, these facilities are assumed to not be connected to the public mains network.

Home healthcare environment
Covers both the requirements of non-specialist users as well as more diverse EM environments with electromagnetic disturbances which are less well-controlled than for the professional healthcare facility environment (e.g., when connected to the public mains network).

Special environment
A category for environments which are neither

professional healthcare nor home healthcare that may have higher levels of electromagnetic disturbance, including industrial locations or settings such as a radiotherapy treatment room, or which may require special considerations of mitigation.

The key to meeting these more rigorous test specifications is providing immunity from the sources of interference these environments may create. The differences between the third and fourth edition of the IEC 60601 standard are

IEC 61000-4-2: ELECTROSTATIC DISCHARGE		
Test	3rd Edition	4th Edition
Contact Discharges	±2, 4, 6 kV	±2, 4, 8 kV
Air Discharges	±2, 4, 8 kV	±2, 4, 8, 15 kV
IEC 61000-4-3: RADIATED RF IMMUNITY		
Test	3rd Edition	4th Edition
Enclosures	3 V/m, Life Support: 10 V/m 80% AM at 1 kHz or 2 Hz, 80 ~ 2500 MHz	3 V/m, Home: 10 V/m 80% AM AT 1 kHz or risk frequency 80 ~ 2700 MHz
IEC 61000-4-4: ELECTRICAL FAST TRANSIENTS		
Test	3rd Edition	4th Edition
Ac Mains or Dc Input	±2 kV, 5kHz PRF	±2 kV, 100kHz PRF
Input/Output Ports	±1 kV, 5kHz PRF	±1 kV, 100 kHz PRF
IEC 61000-4-11: VOLTAGE DIPS, DROPOUTS AND INTERRUPTIONS		
Test	3rd Edition	4th Edition
Voltage Dips (16 A)	>95% dip, 0.5 periods 0° and 180° 60% dip, 5 periods 30% dip, 25 periods	100% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods

Figure 5: Key changes to immunity test levels from 3rd edition to 4th edition of IEC 60601-1

Selecting a Medical Power Supply

Choosing or designing an AC-DC power supply for a medical product involves all the usual considerations from overall power budget, electrical and mechanical requirements, conversion efficiency, and control and monitoring functions, through to set-up or programmable features, cost, environment, regulations and safety. On top of this comes the need to determine if a standard 'off-the-shelf' medical power supply will meet your requirements or if a custom medical power supply is required.

Selecting a Custom Medical Power Supply

Custom medical power supplies are designed and manufactured to your specification. Many power supply vendors offer technical support to help develop the specification. The advantages of this include getting exactly what you want, engineering change control, determining the life of the power supply program, it can be modified and/or changed, ownership of the design, and potential cost savings with high volume and/or long life.

The main disadvantages are: paying for the development cost, non-recurring engineering (NRE) fees, tooling and safety, a development time of typically 8-12 months, and single sourced unless another vendor is to be paid again for development.

Selecting a Standard Medical Power Supply

Standard medical power supplies are available in a wide variety, offered by many manufacturers. Again, the advantages of this approach include the wide variety in industry standard voltages and packaging, immediacy of availability and safety pre-approval. They can also be modified by many manufacturers and distributors, from multiple sources and there is no upfront cost for NRE or safety.

The disadvantages could be that the customer must use an existing standard product offering, it may not be the ideal solution for your medical product and there is little control over changes and life of the product.

Figure 6 shows a typical OEM product offering of standard medical power supplies, which ranges from high power configurable units, wall or desktop adapters, medium power open frame or enclosed.

High Power	Bulk Power	Medium Power	Low Power	Conduction Cooled	External Adapters
1000W-4920W 1-24 outputs Configurable	350W-18kW Single output Cost-effective	400W-1500W 1-21 outputs Configurable	25W-500W 1-4 outputs High reliability	250W/600W Fanless	
					

Figure 6: There is wide range of standard off-the-shelf medical power supplies

If your product requires low power AC-DC, there is a decision to be made between a power supply embedded in the end product or an external unit such as an adapter. The factors in Figure 7 will help you make that decision.

External Power	
Advantages	Disadvantages
Reduces safety needs of end product	Limitations on worldwide acceptance due to multiple plug standards
Eliminates power supply generated heat and EMI inside the product	Often requires post regulation inside product
Minimizes size of end product	Increased clutter outside end product
Usable on many end products	Only available in low wattage
Embedded Power	
Advantages	Disadvantages
Available in higher power ranges	End product requires full safety and EMI approvals
Allows for multiple voltages without additional post DC/DC regulators	Requires larger physical space inside end product
Single power cord minimizing external clutter	Power supply heat and EMI inside end product

Figure 7: Decision making chart for low power standard medical power supply

If your product requires medium or high power AC-DC, here are some considerations:

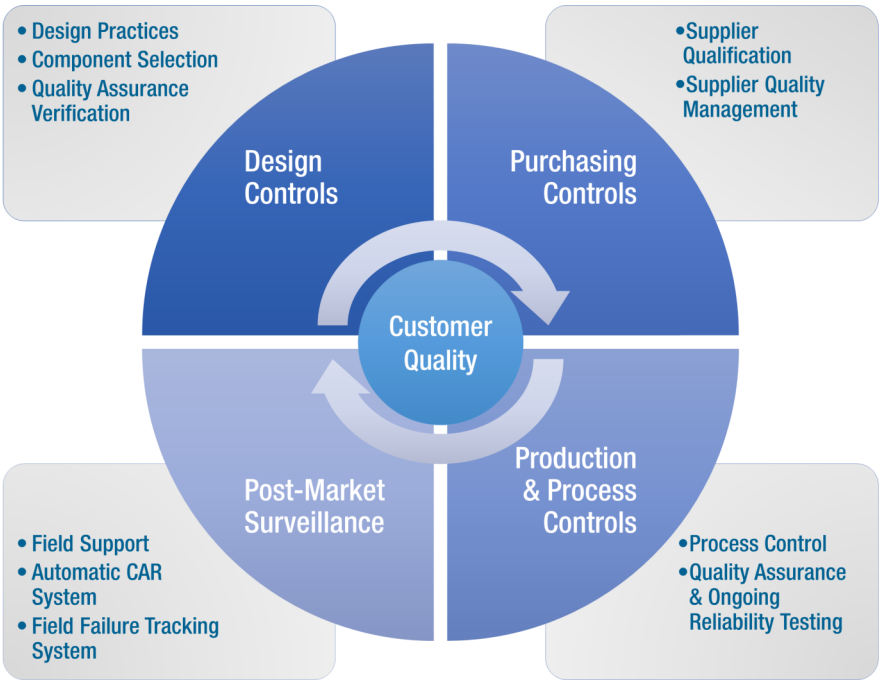
- Generally enclosed with fan cooling
- Offered in single and three phase input
- Available with or without intelligence

For multiple outputs, configurable power supplies offer great flexibility with millions of output voltage combinations with safety approvals.

Quality Questions for Your Power Supply Vendor

Beyond the safety and regulatory issues, medical equipment designers have to mitigate any risks associated with selecting a component such as a power supply by ensuring their supplier has a quality system that, at a minimum, meets the requirements of the relevant ISO standard. For example, Figure 8 shows the Artesyn quality system, which goes beyond the usual prescriptions of ISO quality systems and promotes quality from the viewpoint of the customer, focusing on

- Design Controls - Design Practices, Component Selection and Quality Assurance Verification
- Purchasing Controls - Supplier Qualification and Supplier Quality Management
- Production and Process Controls – Process Control and Quality Assurance & Ongoing Reliability Testing
- Post-Market Surveillance - Field Support, Automatic CAR System, Field Failure Tracking System



By the same token, the FDA's final rule on Current Good Manufacturing Practice (CGMP) includes design controls and purchasing controls and harmonizes those with ISO 9001. The goal of design controls is to optimize the quality of the power supply early in the design phase, aiming for minimal failures and better reliability over its life while the goal for purchasing controls is to extend quality control to vendor partners, thereby catching and correcting problems directly at the component sources.

As with most electronics, there is an expected failure rate at the customer side. These failures are usually caused by component reliability issues, escaping the normal screens and tests. In the electronics industry, this is simply charged to warranty cost for return and replace. In the medical device industry, such failures, particularly in a power supply, will raise a flag in the Medical Device Reporting (MDR) database or some other adverse reporting mechanism.

The Artesyn quality and reliability initiatives listed above are designed to drive down that failure rate.

Another key aspect in addressing customer quality, particularly for medical device manufacturers, is field support. Either directly or through Artesyn's sales distribution partners, field failures are tracked and catalogued. Failed units undergo intensive failure analysis down to the component level at Artesyn's component analysis laboratory or trusted third-party centers. The resulting corrective and protective actions are implemented and monitored while the corresponding quality metrics and databases are updated to further alert related issues.

What are the key considerations in the design process?

The term 'medical-grade' is used for a wide variety of power supplies that may look no different to their commercial-grade counterparts.

However, medical-grade power supplies have been specially designed to meet the IEC60601-1 medical equipment safety standard, which influences the internal power supply design.

However, safety is not the only factor that distinguishes medical-grade power supplies from commercial models. Medical equipment typically requires longer design cycles than other types of equipment and medical equipment designers often require enhanced design support from the power supply vendor. In addition, medical equipment usually has greater life expectancy than other equipment. Therefore, power supplies designated as medical-grade generally need to be supported by the power supply vendor for many years.

Beyond the volts, amps and safety approval considerations that are common to the selection of almost any power supply for OEM equipment, here are some design considerations that can make it easier for customers to select the right medical power supply:

- Define and specify the power requirements as early in the design process as possible
- Use a standard off-the-shelf medical power supply if possible and consider configurable solutions before jumping straight to the custom design option
- Evaluate your potential suppliers' quality system
- Consider your second source strategy

To speak with a medical power supply expert, please visit www.artesyn.com/power.

Specifying a Medical Power Supply

Here is a checklist of considerations to help you when specifying a medical power supply.

Electrical Requirements

- ☐ Input/output requirements DC-DC or AC-DC
- ☐ Class I (3 wire AC input) or Class II (2 wire AC input)
- ☐ Number of outputs
- ☐ Voltage and current of each output
- ☐ Output wattage of each output W = V x A
- ☐ Calculate total power supply wattage by adding all the output's wattage
- ☐ EMC/EMI (radiated and conducted)
- ☐ Efficiency
- ☐ Holdup time
- ☐ Control and monitoring functions

Mechanical Requirements

- ☐ Physical Size L x W x H, weight
- ☐ Mounting requirements
- ☐ Cooling, forced air, convection or conduction
- ☐ Thermal considerations, airflow, temp. rise
- ☐ Shock and vibration requirements
- ☐ Electrical connections, input and output of power supplies
  - ▪ Type of mating connectors, wiring harness, etc.
- ☐ Acoustics, especially in noise sensitive applications
- ☐ Reliability
  - ▪ MTBF, Life and QAV

Environmental/Safety/Regulations

- ☐ Hospital/clinic/in-home/portable/fixed
- ☐ Airborne/ship/ambulance
- ☐ Ambient temp requirements
- ☐ Altitude
- ☐ Medical safeties
  - ▪ 60601-1
  - ▪ Patient contact/vicinity (MOPP/MOOP)
- ☐ RoHS2 (Removal of Hazardous Substances)
- ☐ WEEE (recycling)
- ☐ REACH

Appendix 1

Classification of Medical Equipment

Protection against electrical shock

Class I – reliable protective earth is provided such that all metal parts cannot become live in case of insulation failure (3-pronged AC plug – live, neutral and electrical ground).

Class II – no protective earth and where double or reinforced insulation is relied upon against electric shock (2-pronged AC plug – live and neutral only).

- Class I or II when external power source is used. Classification does not apply if internally powered by battery
- Protective Earth – ground conductor in the power cord, also known as chassis ground

Degree of protection against electrical shock (applied parts)

An applied part is any part of the electrical medical equipment that comes in contact with the patient.

Type B = 'Body' – Sometimes considered 'patient vicinity'. No electrical contact with the patient and usually earth-grounded. Least stringent classification and is used for applied parts that are normally not conductive. Examples are LED operating lighting, medical lasers, MRI body scanners, hospital beds and phototherapy equipment.

BF = 'Body Floating' - More stringent than 'B' but less stringent than 'CF', and generally used for applied parts that have conductive contact with the patient but not directly to the heart. Floating ground. Examples are blood pressure monitors, incubators and ultrasound equipment.

CF = 'Cardiac Floating' - Electrically connected to the heart of the patient. Floating ground. Most stringent classification and is used for applied parts that may come in direct contact with the heart, such as a dialysis machine.

Appendix 3

Medical Power Supply Advances

Switching power supplies have experienced tremendous advances in the last 20 years and this has resulted in dramatic increases in efficiency from 70% to over 90%. Other advances include switching topology and increased switching frequency to allow much smaller magnetics and components.

Packaging advances, from through-hole to surface mount devices have resulted in the miniaturization of components.

Using planar magnetics has improved power supply profiles by enabling lower height as well as improving leakage inductance, mechanical integrity and thermal characteristics.

In addition, the adoption of multilayer PCBs has enabled smaller units with higher density, more functionality, and greater reliability.

The integration of processors lowers part count, as well as semiconductor advances and new materials such as gallium nitride and silicon carbide.

Key Technology Improvements

There have been a number of key technology improvements over recent years:

- Semiconductors with lower on resistance (Rds_{on}), faster switching and lower gate capacitance, and silicon carbide diodes
- Topology improvements such as enhanced soft switching converters
- Magnetic material improvements through higher frequency and lower loss

In addition to this, there has been improved magnetic construction where integrated planar transformer-rectifiers can reduce the volume by up to 50% as well as significantly lowering parasitic interconnection resistances and inductances to reduce component stress.

Digital Control for Power Supplies

Digital control is now used as the feedback loop for many power supplies using communications channels such as I2C and PMBus™, as opposed to the older, analog type of feedback control. Advantages of digital control include lowering the parts count and greater flexibility.

There are also particular advantages in productivity. During development, power supply design bugs can be fixed by firmware patches, thus eliminating multiple PCB re-spins.

In addition, firmware and software can be upgraded in the field via the internet without physically attending the system, and modular code can be re-used.

Data Logging

Current digital power supplies contain a history log which enables backtracking of failures with failure modes including PMBus™ /IPMM defined events such as over voltage (OVP), over current (OCP), etc.

To assist in field failure analysis, additional events can be recorded by the digital controller, such as:

- Runtime of power supply (power-on-hours)
- Actual maximum load
- Actual maximum ambient
- Actual maximum input

Parameters in Intelligent Power

Digital control also enables the use of a graphical user interface (GUI) as an aid to engineers. It is a visual tool for debugging and modifying a range of power supply issues such as input thresholds, output settings, delay times, switching frequency, loop response and other parameters.

Figure 9 shows Artesyn's Universal PMBus GUI

Artesyn's Universal PMBus GUI also enables enhanced power management features, including:

- *Accurate monitoring and reporting functions* - reporting of power supply input parameters such as voltage, current, and power allows better system manipulation for optimum efficiency
- *Future failure prediction capability* – the ability of the power supply to self-diagnose for potential failures or weakened parts by monitoring and comparing specific parameters against nominal values
- *History logging* - event logging of power supply environment conditions such as input voltage surge and sag, AC recycles, maximum ambient, internal temperatures, and failure logging to backtrack failures
- *Fan speed optimization* – the system has the capability to determine fan operating speed based on load and ambient temperature such that maximum efficiency at specific loads can be attained

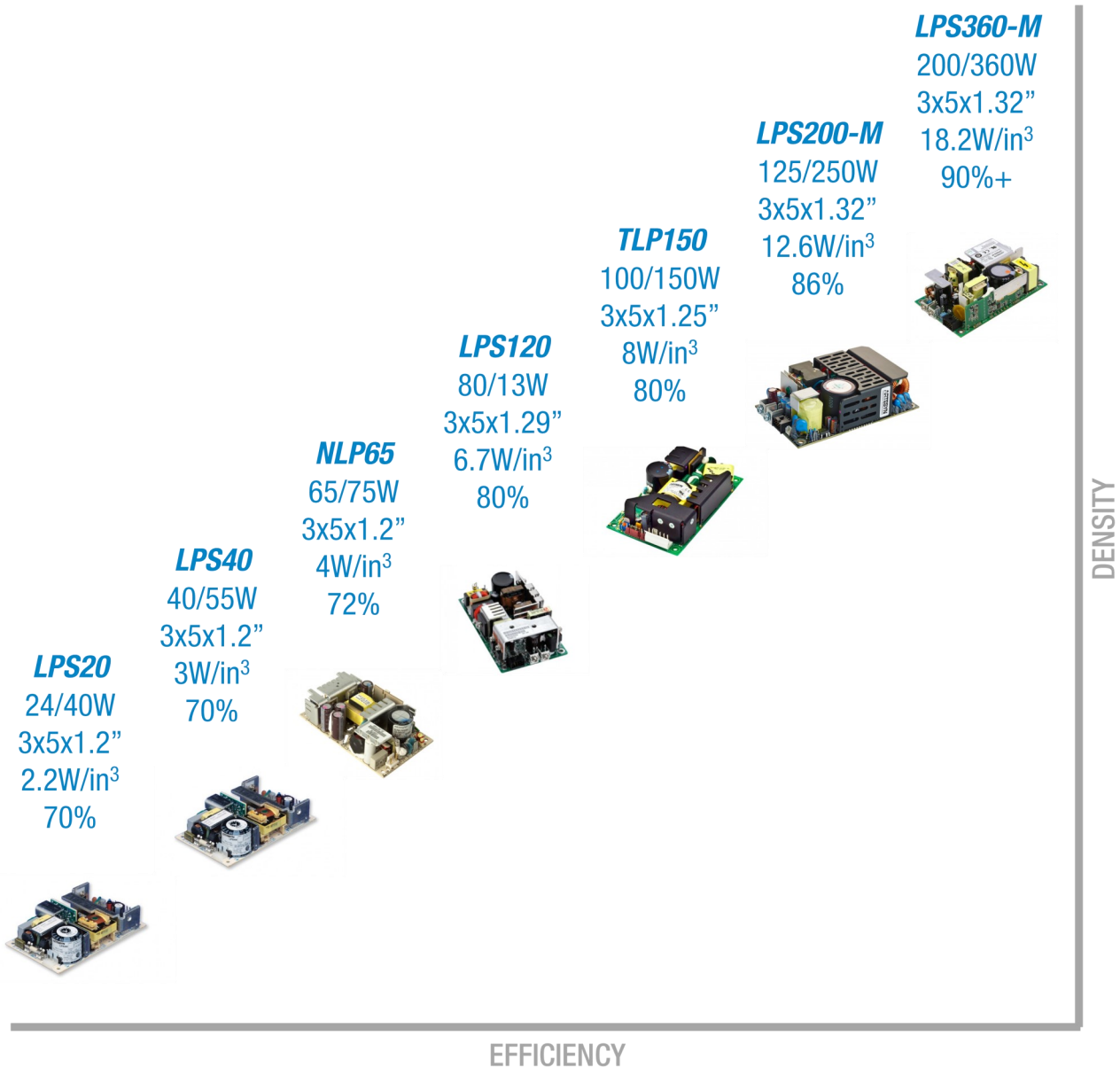


Figure 10 reveals how power, and efficiency have changed on the same footprint. It shows the dramatic increases in power density over almost 25 years.

About Artesyn Embedded Technologies

Artesyn Embedded Technologies is a global leader in the design and manufacture of highly reliable power conversion solutions for a wide range of industries including communications, computing, consumer electronics, medical, aerospace and industrial automation.

Artesyn is one of the world's largest and most successful power supply companies, embracing the well-known Astec brand. The company's extensive standard AC-DC product portfolio covers a power range of 3 watts to 24 kilowatts and includes open-frame and enclosed models, highly configurable modular power supplies, rack-mounting bulk front end units, DIN rail power supplies, external power adapters and power supplies for LED lighting. Many of these products are available in medically approved versions and many of the higher power models feature extensive built-in intelligence.

As an industry leader in distributed power applications, Artesyn produces an exceptionally wide range of DC-DC power conversion products. These include isolated DC-DC converters, covering industry-standard sixteenth- to full-brick form factors with power ratings from 3 watts to 800 watts. Artesyn also offers three application-optimized families of non-isolated DC-DC converters, non-isolated memory power, and processor voltage regulator modules (VRMs).

As a pioneer in low power switch mode adapters, Artesyn has designed and manufactured solutions for almost every major mobile phone supplier. With well over one billion chargers shipped from its best-cost facilities, Artesyn has aligned itself to meet the demands for the next billion chargers through new platforms, automated manufacturing methodology and unsurpassed quality and reliability.

For more than 40 years, customers have trusted Artesyn to help them accelerate time-to-market and shift development efforts to the deployment of new, value-add features and services.

Headquartered in Tempe, Arizona, Artesyn has over 16,000 employees worldwide across multiple engineering centers of excellence, wholly-owned world-class manufacturing facilities, and global sales and support offices.

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