

Thinking Ahead Thermally:

A Guide to Thermal Management Considerations for Medical Devices

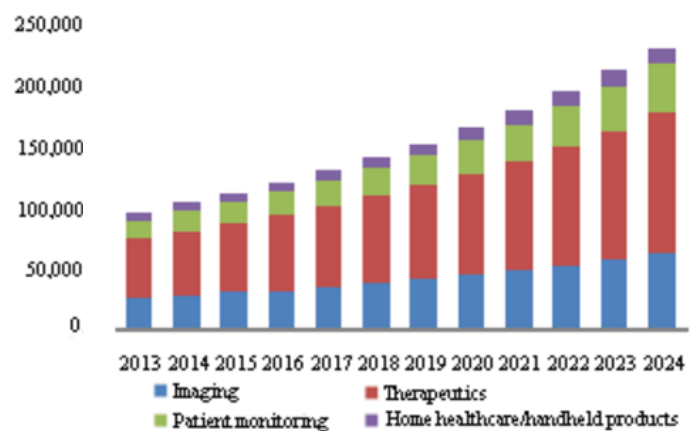
The medical device and engineering industry continues to grow and evolve year over year. As technology improves, the population expands, and the depth and breadth of medical knowledge and treatments grow, so does our need for better devices and equipment. As such, current trends that span all industries, such as electronics getting smaller and more powerful, as well as increased focus on improved customer experience, have greater implications and challenges for the medical industry. Should a device fail, a patient's well-being could be endangered. Additionally medical devices need to be portable, costs need to be judiciously managed so that treatment can be made available to the populace, and reliability is crucial.

Boyd has been designing and manufacturing thermal solutions for over 50 years and has worked with medical design partners across the globe ranging from large corporations to small startups. In doing so, we have identified and assessed the major design flaws that lead to poor thermal management and product performance. Not planning for your thermal solution can cost time, money, and resources as well as cause a large amount of rework or even massive device failures.

Planning ahead during your initial product design to allow for appropriate cooling will make a significant difference to your device's success. This paper evaluates key thermal considerations to take into account during the development process to ensure that your design is safe and effective.

Estimated US Medical Electronics Growth in USD.

Image Source: Grand View Research, Inc. 2016



Start with the End User in Mind

As with most electronics, the number one priority is the end user. This is especially true for the medical device and equipment industry, as the health and safety of both caregivers and patients are at stake. Engineers must determine exactly who will be using the device and how. Usage dictates requirements which heavily impact your thermal management choices.

Questions to address:

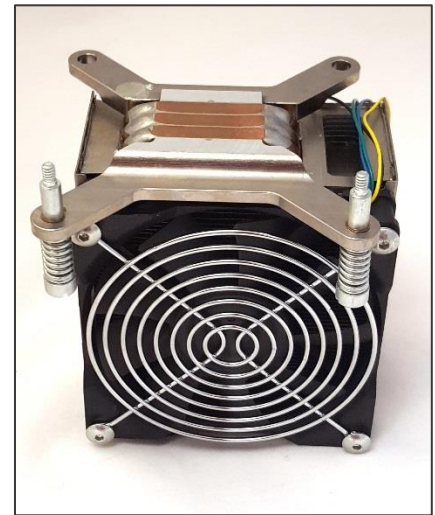
Will the patient or caregiver be in direct contact with the device? If so, will they be near enough to the heat source to feel it?

This is perhaps the most obvious consideration. If they touch the device or are exposed to it while running will it be uncomfortably hot or even burn them? Finding a safe heat dissipation path and moderating touch temperatures are

imperative if the end user will be in close contact with the device. In these cases, you will need to set your requirements to account for safety and comfort rather than the device's operating limits.

For example, if a device were to feature a power intensive sensor that comes into proximity with the patient, heat pipes might be a requirement to quickly and safely remove the heat from the device, even if the device itself can handle the heat load.

For higher power electronics, no matter where the heat is being dissipated, one must account for the user's safety. If using an enclosure, heat must be dissipated through one of the sides or through a heat exchanger. The user should be prevented from contacting these surfaces by use of a guard that still allows airflow but prevents wayward fingers from contact.



Fan with Finger Guard

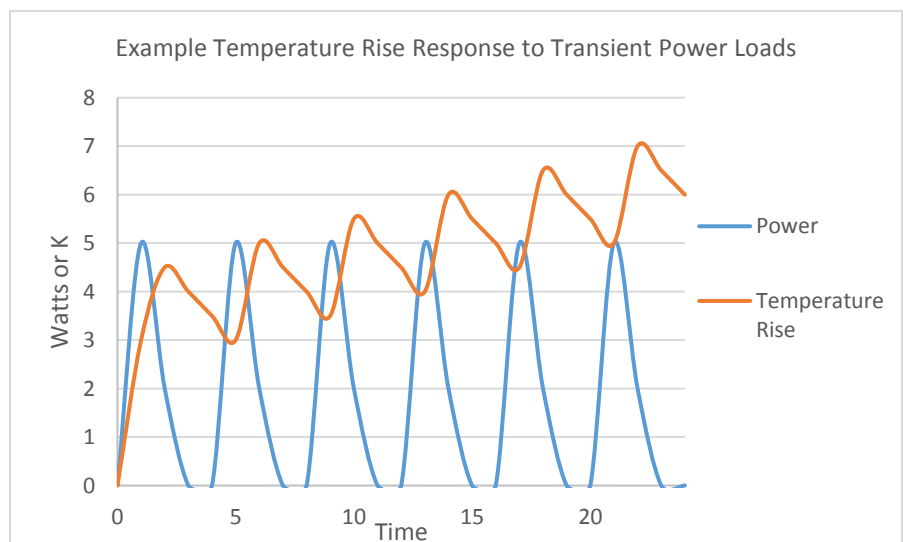
How often and for how long will the equipment be in use?

Equipment use must be carefully considered in conjunction with the device's rejected heat. Devices that are used for longer stretches of time or with more frequency will likely need more powerful cooling. Constant use devices are likely going to need active thermal solutions as the device will consistently be generating heat with little to no cooldown period. Devices used intermittently but often will have a very different set of thermal requirements; as will devices used infrequently but with high heat loads that need to be cooled quickly.

With smaller heat loads, even if used regularly, a thermal mass might be all that is necessary to conduct the heat away from the device and dissipate the heat slowly and naturally. If the heat load is considerable, the device will require a more complex system to dissipate the heat as quickly as possible. High, instantaneous loads may be too much for a typical thermal solution to handle before the device reaches maximum junction or case temperatures. Heat pipes or higher power cooling systems, such as liquid solutions, may be required to safely dissipate these loads.

With intermittent use devices, frequency is also a key consideration. When a device is operated so frequently that it does not have time to fully cool down

between uses, inconsistent power dissipation must be taken into account. This is when the heat essentially adds up over time, causing a higher average operating temperature than what the device should be exposed to. These transient loads are often overlooked in the design phase and result in inadequate cooling. Additional analysis may be required prior to solution design and product layout if there is the potential for high transient heat loads. The final cooling solution may be drastically different when these are taken into account.



Does the device need to be portable? How much so and how will it be powered?

Although size and weight requirements are always important, there are varying degrees of limitations based on portability. For stationary equipment, larger or heavier solutions may be used and trade-offs between forced convection and passive cooling can be considered. If a caregiver needs to transport the device, weight, shape, and size must be controlled but may be less of a priority. You must also consider if the device will need to be stackable and if so, how this affects the locations of power supply within the device and the associated ventilation.



*Example of a Portable Medical Device –
ActiVox Portable Oxygen Generator*

If the patient or caregiver must carry or wear the device, these factors are crucial. Weight requirements will heavily impact material choices. For example, while more conductive, copper is 3X heavier than aluminum. Device shape dictates heat sink shape and vice versa. Heat sink shape then impacts fin type and geometry. Size, weight, and shape all impact each other and your technology choices. Further analysis is often required to examine the design trade-offs between these key factors in determining your ideal thermal solution.

Additionally, fully portable devices are powered by batteries, which generate their own waste heat and require charging. Therefore, if active cooling is to be used, you must take into account the balance between how much it is cooling and how much power the solution is consuming. Using too much power to cool the device drains the battery and results in constant recharging and potential field use failure.

What sort of environment will the device be used in?

All environments pose their own unique thermal challenges, including the controlled environment of a lab. In any environment, engineers will need to consider touch temperature, ambient temperature, noise considerations, and robustness.

Touch temperature tends to be a bigger issue when the device is used outside of an office or a lab, especially in areas such as a patient's home where pets, children, and other untrained individuals may come into contact with the device. Finger guards can help prevent potential accidental contact with hot surfaces. Plastic, if appropriate for the application, can also be used as an alternative material as skin can withstand higher touch temperatures on plastic (about 85°C) compared to metals (60°C). This is due to metal having a higher conductivity and therefore transferring the heat faster to the skin.

Ambient temperatures are typically more easily controlled in labs than in other environments where it becomes a particularly limiting factor. Ambient temperature effects the operating temperature of the device, but the device can also increase



*Example of a Portable Medical
Device in Plastic Enclosure with
Ventilation – Aqueduct Medical
Cold Therapy Device*

the room temperature causing the environment to become uncomfortably hot for the user. This is especially true if the user is in close proximity to the device. Proximity makes the location of ventilation openings extremely important, so that hot air is not dispelled directly on to the patient or caregiver.



*Device Used During Sleep –
CPAP Machine*

Noise considerations are also key to patient comfort, especially for a device that is used on children or is in constant or frequent use. Loud noises often cause patient distress, even if infrequent. Fans, while essential to providing higher airflows and heat transfer in smaller spaces, can produce noise. Noise may not be a concern in some environments, such as labs. But for a device that is with a patient at night either at home or a hospital room, even lighter noise can be irritating or disruptive to sleep and the healing process. Larger heat sink surface areas are required to increase heat transfer if fans are not a viable option.

Environment plays the largest role in how robust the device and solution must be. The equipment may need to operate in a stationary, climate controlled lab, in an unstable war zone, or anywhere in between. Devices operated by the patient daily outside of a controlled environment will require a certain amount of ruggedness to withstand day-to-day usage. Dust, shock and vibration, foreign debris, and liquid ingress are all potential issues that must be taken into account for your thermal solution.

If the device will be carried around in a case, it will need to be able to withstand higher temperature fluctuations as well as the other limiting factors like reduced air flow. This will affect your technology choices, especially in regard to fans. The electronics enclosure may be embedded in alternative materials, such as foam, which may totally block any airflow to the devices. In these cases, initial brainstorming and creative problem solving may be required to find a solution to keep device at safe and reliable temperatures.

Is the device critical to life?

Life sustaining medical devices go through much more rigorous testing and certification processes. They also typically require redundant systems. Based on design, the redundant system may require its own thermal solution or the thermal solution must be developed to accommodate both systems. For example, heat pipes can be utilized as a reliable way to transfer heat from the redundant system to the cooling solution rather than maintaining an entirely separate solution for the system or relying on an active switch.

There is a high correlation between how cool electronics are kept and the longevity of the device. Keeping your electronic device as cool as possible increases its safety, reliability, and lifetime. This is crucial in cases when a patient's life is supported by the function of the device. Device failure due to poor thermal management is not an option.

Additional Considerations

Although the user is paramount, there are other key considerations for your product and thermal solution design. These include regulations, development and manufacturing costs, and maintenance.

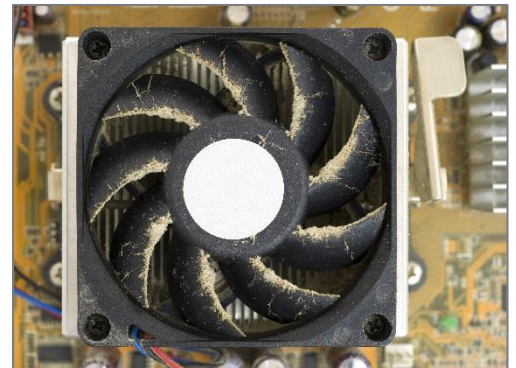
Does it meet regulations? IP Rating, USP Class Rating, ISO 10993, or additional necessary requirements?

In general, medical devices must meet higher safety and reliability standards than most other types of electronics because of their impact on users' health and safety.

IP ratings (Ingress Protection) are crucial if devices are going to be used in an environment with limited control. Fans and enclosure openings are determining factors for the IP rating of a device. If there are any solid particle protection or liquid ingress requirements, fan selection and establishing opening sizes of your enclosure are critical.

Your thermal solution affects how large your enclosure openings will need to be which directly affects your IP rating. If you find that you need larger openings to enable enough heat transfer, finger guards may need to be designed in to maintain an IP rating of 2X.

For sensitive equipment or devices, a higher IP rating may be required, which would necessitate the use of filters to protect from dust. Filters directly impact flow resistance and pressure drop within an air cooled system and the fan must be chosen appropriately to function in those conditions.



Unprotected Fan with Dust Collected

For the even higher IP 6X ratings, which require a vacuum tight seal, the device will need to be fully within an enclosure, which might mean that the external surfaces will need to dissipate the heat. And, if those external surfaces are to exceed touch temperatures, protection should be provided to the end user from accidental contact. This level of rating would be preferred for more rugged applications, especially for devices that are going to be outside a medical facility, whether it be at home, out in the field, in emergency situations, etc.



IP Rating (Liquid Ingress) Test Setup
Image Source: KLED

Depending on the application, full waterproofing may or may not be a key concern, but in any case, liquid ingress due to cleaning and sterilization must be factored in. If a device is simply wiped down for cleaning, lower IP ratings would be acceptable. If there are full and extensive cleaning processes with powerful waterjets, any sort of openings devoted to heat transfer should be heavily scrutinized. If liquid is able to get into the device and the device requires an IP rating of X5 or above, some sort of waterproofed coating should be considered for the electronic devices. Conformal coatings, such as thermally conductive silicones or epoxies, can seal the electronics from liquid, but still enable heat transfer away from the device.

Additionally, take-home medical treatment devices should have a minimum IP rating of X4. Day-to-day activities, at home cleaning, and spills are all legitimate concerns.

Material selection is critical in considering USP Class ratings (if the device is used in manufacturing any ingestible products, such as medicines, food ingredients, supplements etc.) or ISO 10993 for physical devices that will be implanted, mounted, or in contact with the patient in any way.

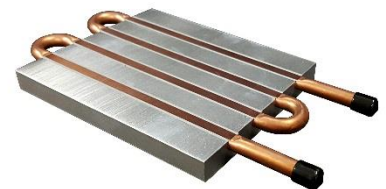
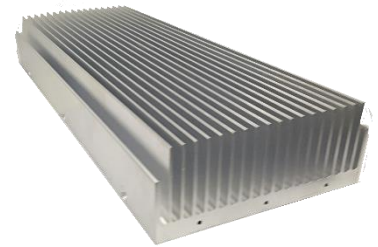
Plastics are a large concern in these two standards due to outgassing and potential chemical leeching. If part of your solution utilizes a thermally conductive plastic, the plastic's properties in relation to biocompatibility must be determined prior to finalizing the product design.

Metals may also be an issue depending on the level of corrosion resistance as well as potential allergies patients may have to particular metals, especially nickel, which is a common plating for corrosion resistance. Certain types of surface treatments, such as hard anodize for aluminum products, clear coats for copper, or conformal coating for most other components can be potential resolutions that will still work in conjunction with your thermal solution.

Is affordability a key concern?

If the costs of the device are going to be passed off to either the facility or patient, affordability of the end product can be a determining factor for thermal solution selection. Some technologies are more expensive than others, such as a liquid cooling system compared to a standard extruded heat sink. A fully custom system may also be out of the question if the product requires low costs.

Finding the balance between meeting strict thermal and regulatory requirements and keeping costs feasible is much easier when the thermal solution is considered very early in the design process. The earlier you consider cooling the more efficient and cost-effective your solution will be. When thermals are considered too late in the process, more expensive or less effective cooling might be the only remaining option. Some may even find that they need to go back and completely redesign the product, costing more money and time.



*Top: Large Extruded Heat Sink
Bottom: Hi-Contact™ Liquid Cold Plate*

How will the device be serviced?

Your thermal solution should not hinder the maintenance of the product. Therefore it should either be placed out of the way or designed to be easily removed and replaced without risk to the integrity of the device. If it will need to be removed, mounting hardware selection becomes more important if the heat sink needs to be repeatedly mounted. For example, spring loaded pins wear down with repeated removal and become less viable.

As stated previously, cleaning may also be an issue and must be considered.

Final Thoughts

Your thermal solution has a significant impact on your device's safety and success, but far too many engineers consider cooling late in the design process. The sooner you evaluate your thermal needs, the better you can accommodate them and ensure that you have a fully optimized and cost-efficient solution and end product design. From small portable devices to huge pieces of equipment, all medical electronics require proper thermal management to ensure they operate to meet the high standards of the industry. The safety, health, and comfort of patients, families, caregivers, and health care professionals rely on these devices every day.

How Can Boyd Help?

Although this paper highlights key considerations for product design and cooling, this is just the beginning.

Boyd offers standard and customizable solutions across all applications and technologies as well as custom systems and engineering services as early on as concept development and as late as a full retrofit. Our engineers can provide continuous support throughout the entire product development cycle from concept to manufacturing and future generations. By bringing in Boyd at the beginning, not only can your team avoid the consequences of insufficient thermal management, we can ensure that your product is fully optimized for success.

Boyd also offers testing and reliability services to ensure that your device meets the high regulatory and user standards of the medical industry.

For Questions, Quotes, Or More information

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More About Boyd Design

Boyd employs over 300 engineers worldwide and maintains Design Centers in the US, Europe, India, and Asia. Boyd Design offers innovative, cost effective product design, testing, and prototyping services across all industries, with customers ranging from Fortune 500 companies to pioneering technology startups. Our engineers work to provide the best solution to fit your requirements. From finding the right current standard part to developing custom systems utilizing integrated design solutions, Boyd Design can help.

DESIGNING YOUR THERMAL SOLUTION

Boyd determines the needs of a customer based on the evaluation of six key factors affecting your product:

USABILITY

Surface
Temperatures
Feature Set

MATERIAL SELECTION

Metals or Plastics
Manufacturing
Processes

AESTHETICS

Texture
Finish
Venting
Perforations

PERFORMANCE

Acoustic
EMI/Radio
Power
Environment

COST

BOM Cost
Assembly Cost

FORM

Size
Weight
Architecture
Footprint

Based on your specific needs, Boyd Design will provide the best solution in one of three ways:

1

SELECTING THE BEST EXISTING OPTION

from our catalog of standard thermal solutions

2

DESIGNING A CUSTOM COMPONENT SOLUTION

3

DEVELOPING A CUSTOM SYSTEM UTILIZING BOYD'S INTEGRATED DESIGN SOLUTIONS

Thermal Design
Mechanical Design
Electrical Design

Industrial Design
Prototyping
Testing & Verification

About Boyd

For over 50 years we have consistently brought the most innovative new cooling solutions to market while also improving the efficiency and availability of conventional cooling technologies. In doing so, we have developed the widest array of cooling products and services in the industry. Boyd provides thermal solutions across all industries and for any application on a global level. Decades of experience and expertise combined with an unwavering dedication to unique problem solving allows us to meet any requirements and resolve any thermal challenges.

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