



# Digital Manufacturing for Medical Applications



# Table of Contents

<b>Introduction</b>	4
---------------------	---

<b>Attributes of a Quality Medical Manufacturer</b>	5
---	---

<b>The Five Stages of Manufacturing in Protolabs' Digital Thread</b>	6
--	---

Iterative Design  
Rapid Prototyping  
Early Production  
Full Production  
End-of-life Production

<b>Working with Protolabs for Medical Parts</b>	8
---	---

<b>Secondary Options for Your Parts</b>	10
---	----

<b>Why This Matters: Factors Driving the Growth of Medical Manufacturing</b>	11
--	----

Aging Population  
Healthcare Spending  
Emerging Markets  
Technological Advancements

<b>The Protolabs Advantage</b>	11
--------------------------------	----

# Medical manufacturing is one of the fastest growing industries.

Medical manufacturing is critically important because every component has the potential to save lives. That's why ensuring the quick, reliable delivery of high-quality parts is a priority for us. With decades of experience, Protolabs is committed to bringing our expertise to every medical part we produce.

To learn about the factors driving the expansion of medical manufacturing, go to "**Why This Matters: Factors Driving the Growth of Medical Manufacturing**" on page 11.



# Attributes of a Quality Medical Manufacturer



It's likely that you have worked with both traditional and digital manufacturers. If you're in the medical vertical, the difference between the two can mean the difference between a rapid go-to-market strategy and one that leaves you on your heels waiting for your parts. The reasons for working with a digital manufacturer are considerable and directly relate to the medical sector's need for speed, quality, compliance, and the ability to work with high requirement parts, such as those needing expanded manufacturing capabilities.

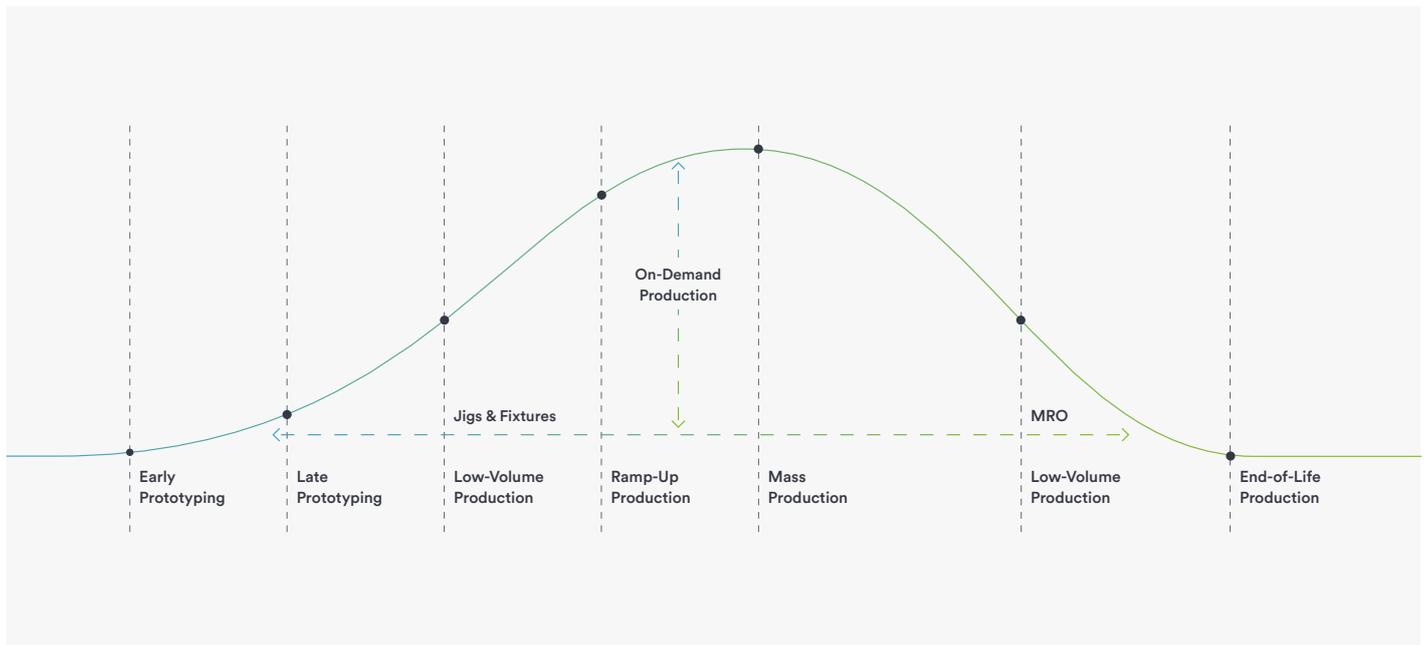
## Comparing Traditional and Digital Production Methods

Traditional	Digital
Focuses on older manufacturing processes	Leverages AI, machine learning, IoT, and more to optimise workflow
Data input, process monitoring, and material handling all manual	Automation informs and improves efficiency, productivity, and quality
Linear workflow with minimal—if any—real-time adjustments	Integrated sensors provide metrics for data analysis while monitoring manufacturing in real-time, enhancing opportunities to adjust design to address issues
Tasks tend to be siloed, rather than informing part of a process	Protolabs' digital thread is a workflow that is purely digital. From CAD and quote to production and shipment, it's possible to do almost everything within the cloud, yielding higher consistency, reducing back-and-forth, and maximising speed at all stages
Focus is on mass production, not iteration	From prototyping to production quantities, the digital manufacturing workflow is essentially the same
Ingrained internal processes make it difficult to react to technological trends and changes in customer demand	Nimble and responsive to customer and industry changes

# The Five Stages of Manufacturing in Protolabs' Digital Thread

All of our manufacturing services— injection moulding, 3D printing and CNC machining— benefit from our digital thread. To that end, the fastest and most streamlined way to partner with Protolabs is straight through from the early stages of design iteration, through prototyping and production, followed by end-of-life production.

While all of Protolabs' services are accelerated through the digital thread, we will first focus on the benefits of digital manufacturing for injection moulding, which continues to be a vital offering for medical device customers. Working with us through the following product development stages ensures seamless transitions through the lifecycle of your part.



## Iterative Design

- Instant quoting with mouldability analysis
- Hundreds of plastics and LSR materials
- Enhanced finishing and post-processing options

It takes time to design parts so they work for your application. Our digital quoting platform offers nearly instantaneous design-for-manufacturability (DFM) feedback, bringing any potential issues to the front end. Also, Protolabs offers broad options with an array of materials as well as post-processing and finishing options. For parts with additional requirements, we offer pad printing, threaded inserts, part cleaning, and others.

## Rapid Prototyping

- Moulded parts in hand within days
- Form, fit, and function testing for agile development
- Move with ease from 3D printing and machining to moulding

Medical parts often have very stringent requirements that must be addressed during the prototyping phase. Our rapid prototyping techniques mean that you can have your mould cut and parts in hand in just days, which is precisely the kind of speed necessary to jump out the gate and quickly fill a need. All the parts we make are measured against your most critical specifications, ensuring the parts we ship will perform as designed.

Another prototyping technique we offer is to iterate parts using 3D printing and then move that final CAD to injection moulding. This pairing can speed up the process even further and cut down on the expense of cutting new moulds for each iteration. Working with our applications engineers to ensure that your parts follow DFM rules for both 3D printing and injection moulding is crucial. Through our free Consultative Design Service (CDS), you can avoid what can sometimes be a difficult transition from printing to moulding by working with our experts.

## Early Production

- Cost-efficient bridge tooling before production
- Pilot runs and market testing to validate design
- No minimum order quantities (MOQs)

The mould we cut for you can last quite a while. If you aren't ready to commit to mass production for a particular product, bridge tooling becomes the perfect means to test a part and the product with an eye toward validation. Best of all, should you choose to move forward with full production, we will apply the cost of your prototyping mould to pay for your on-demand manufacturing tool, which has unlimited mould life. In the meantime, you have a functional production solution, and the quantity of parts ordered is your choice.

## Full Production

- Dedicated account manager with production expertise
- Up to 1 million moulded parts possible
- ISO 9001: 2015 and ITAR registered in the U.S.

Obviously, the jump into full production carries risk for any company, especially if you need 1 million parts or more. We want to eliminate those risks. It comes down to communication: We work with you through a dedicated account manager who understands your questions about design. Yes, even though we are a digital manufacturer with ecommerce capabilities, we know each production order is unique. Our experienced account team works with you offline to ensure we meet the requirements of your procurement process. In the end, you should feel assured that you will be working with validated manufacturing processes that comply with medical industry regulations and standards.

## End-of-life Production

- Reduced cost with parts on demand and as needed
- Resourcing for maintenance, repair, and operations (MRO)
- Transition into new product introduction (NPI) for extensions

Earlier, we mentioned we have no MOQs. That helps you at multiple stages in your product lifecycle, but for many companies it's especially crucial when your product is approaching end-of-life. With Protolabs, you can get the parts you need on-demand whenever you need them, keeping a tight rein on costs.

Also helpful is that we can manage all production aspects of a given product's ramp-down to ensure that you can still order the quantities you need and avoid maintaining an inventory of unneeded parts. Simply put, we are there for you to help transition to a revised part design for your existing product or for new product introductions.

It's important to note that when you work with us through these five stages, you know the parts made at production quantities will be of the same quality as your approved prototype. Our digital thread collects manufacturing data continuously, and it allows us to adapt learnings from each stage to improve quality while accelerating our processes, gaining consistency along the way. All of these are critical qualities for medical manufacturing.

# Working with Protolabs for Medical Parts

The process starts in our digital quoting systems, where you can submit your CAD file along with any specific needs for your part(s), such as finishing. Sometimes, parts require more detailed information than you can easily put into a CAD, so to maintain the clarity of what you need us to manufacture, you can include drawings/prints that provide those details.

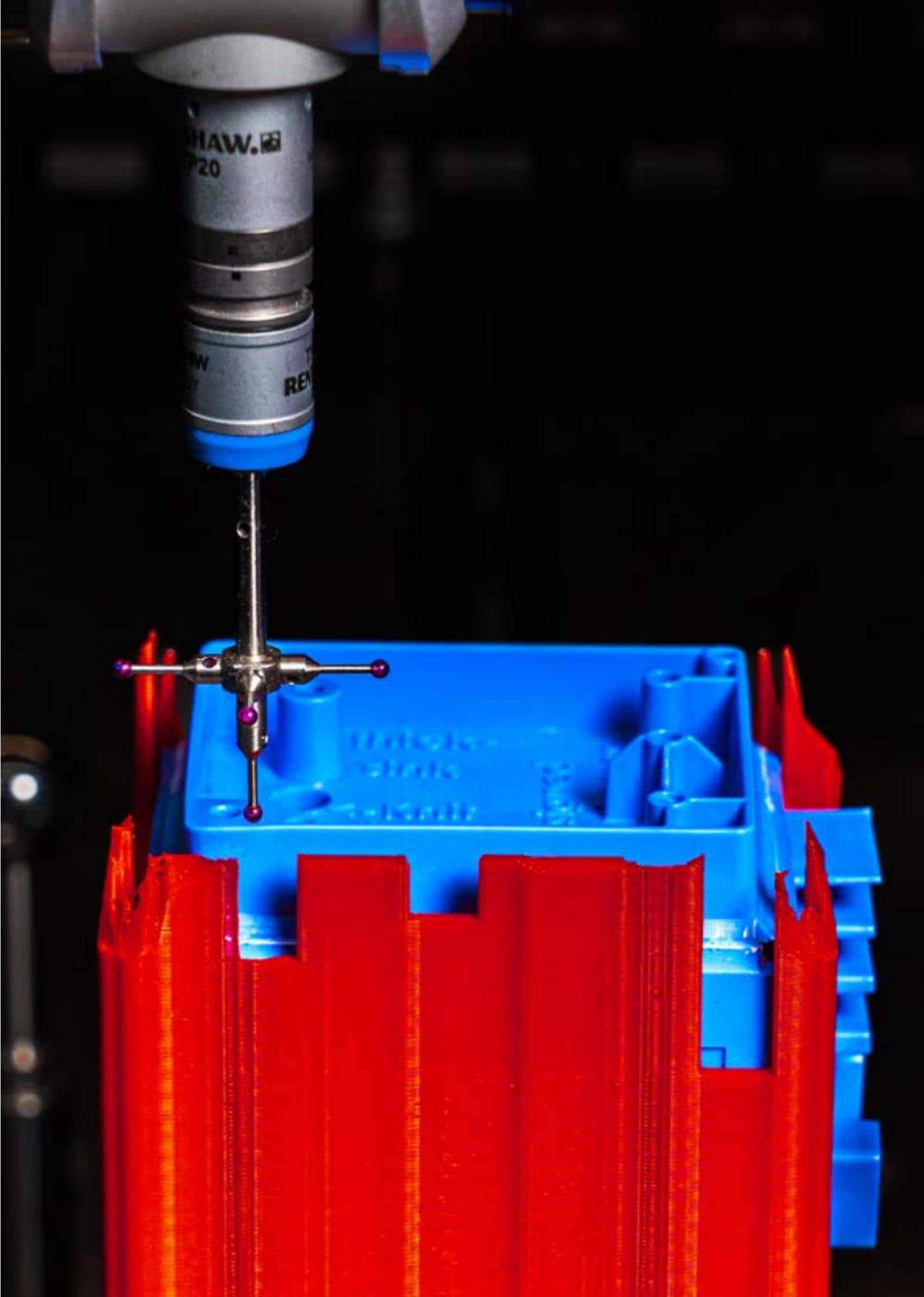
If you forget to do that in this phase—no problem. Just chat with a helpful Protolabs applications engineer or your sales representative. We want this to be a team effort that delivers the parts you need, whether you are prototyping, in low-volume production, or large production quantities.

Speaking of production quantities, Protolabs offers decades of manufacturing knowledge, and an optimised workflow through our digital thread. We have massive capacity and scalability thanks to the combination of multiple factories and our network of manufacturing partners.

**Also, we offer a variety of reporting options, such as:**

- Critical to Quality (CTQ) with Partial First Article Inspection (FAI)
- CTQ with Capability Study
- Digital Inspection Reports with Full FAI
- Production Part Approval Process (PPAP)
- Customised reporting available upon request





# Secondary Operations for Your Parts

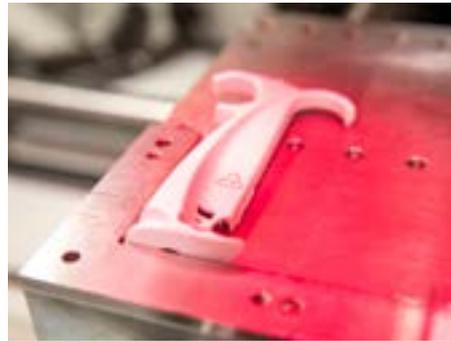
Some people say that parts aren't finished—until they are finished. Protolabs has that covered, too. Furthermore, Protolabs is adaptable to your project. For example, sometimes it's helpful to use our CNC machining capabilities to add certain geometries to moulded parts via milling that would otherwise be difficult or time consuming in a pure moulding environment.

Got a bigger project? If we are manufacturing several parts that go together, you can request assembly. If you don't need assembly, you can ask for specialised packaging with parts identified with barcodes, sterilised labels, and QR codes.

Choose from a wide selection of secondary operations for moulding that strengthen parts, improve cosmetic appearance, provide customisation, and other benefits.



**Mould Texturing and Engraving**



**Laser Engraving**



**Pad Printing**



**Part Cleaning**



**UV Printing**



**Threaded Inserts**

# Why This Matters: Factors Driving the Growth of Medical Manufacturing

## Aging Population

Increasingly, senior citizens are working to improve and extend their lives with devices to help maintain mental acumen and physical capabilities. Traditional assistive devices such as wheelchairs and walkers will always be in demand, but more technical products are driving rapid innovations in the sector. For example, hearing aids—which are now an over-the-counter product—are a growth area, as are devices to assist with chronic conditions such as heart disease, arthritis, and diabetes. To address these needs, medical equipment companies are designing technologically advanced monitors to evaluate blood glucose levels, your heart, and other measurable physical metrics.

## Healthcare Spending

A Kaiser Family Foundation study forecasts a 50% increase in healthcare spending through 2032. While people are spending more each year on medical care of all sorts, inflation, rising insurance premiums, and more expensive cutting-edge testing technology all play a part in the rapid rise.

## Emerging Markets

One factor that is crucial to consider is the growth of wealth in countries outside the West, and their citizens' needs/desires for improved healthcare systems, for people at all economic levels. For example, according to India's National Health Accounts Estimates, the Global Health Expenditure as a percentage of GDP increased 39% between 2013 and 2022. Other countries experienced similar rises. More spending globally brings more money into the healthcare manufacturing sector.

## Technological Advancements

While medical innovations certainly improve outcomes for people requiring prosthetics, hip/knee replacements, 24/7 monitoring of vital signs, and more, companies designing medical devices pay for that innovation, which repays for itself over time.

The process of rapidly iterating critical parts (prototyping) before moving to production quantities is not inexpensive, but it is fundamental to a product's success in the marketplace. Digital manufacturing provides a go-to-market pathway moving from rapid innovation to consumer product in half the time of a traditional manufacturing route.

## The Protolabs Advantage

We don't believe in standing still, and we have a reputation to uphold as the fastest and highest quality manufacturer in the world. We're always adding and improving the capabilities we offer you.

This guide provided an overview of our offer but to get a granular perspective, contact a member of the applications engineering team at [customerservice@protolabs.co.uk](mailto:customerservice@protolabs.co.uk) or [+44 \(0\) 1952 683047](tel:+44201952683047). We look forward to working with you.

This document contains trade secrets or otherwise confidential information owned by Proto Labs, Inc. Access to and use of this information is strictly limited and controlled by Proto Labs, Inc. This document may not be copied, distributed, or otherwise disclosed without permission from Proto Labs, Inc. This document may not be used in any way not expressly authorised by Proto Labs, Inc.



**Contact Us**

Halesfield 8,  
Telford,  
Shropshire,  
TF7 4QN  
United Kingdom

**Phone** +44 (0) 1952 683047  
**Email** [customerservice@protolabs.co.uk](mailto:customerservice@protolabs.co.uk)