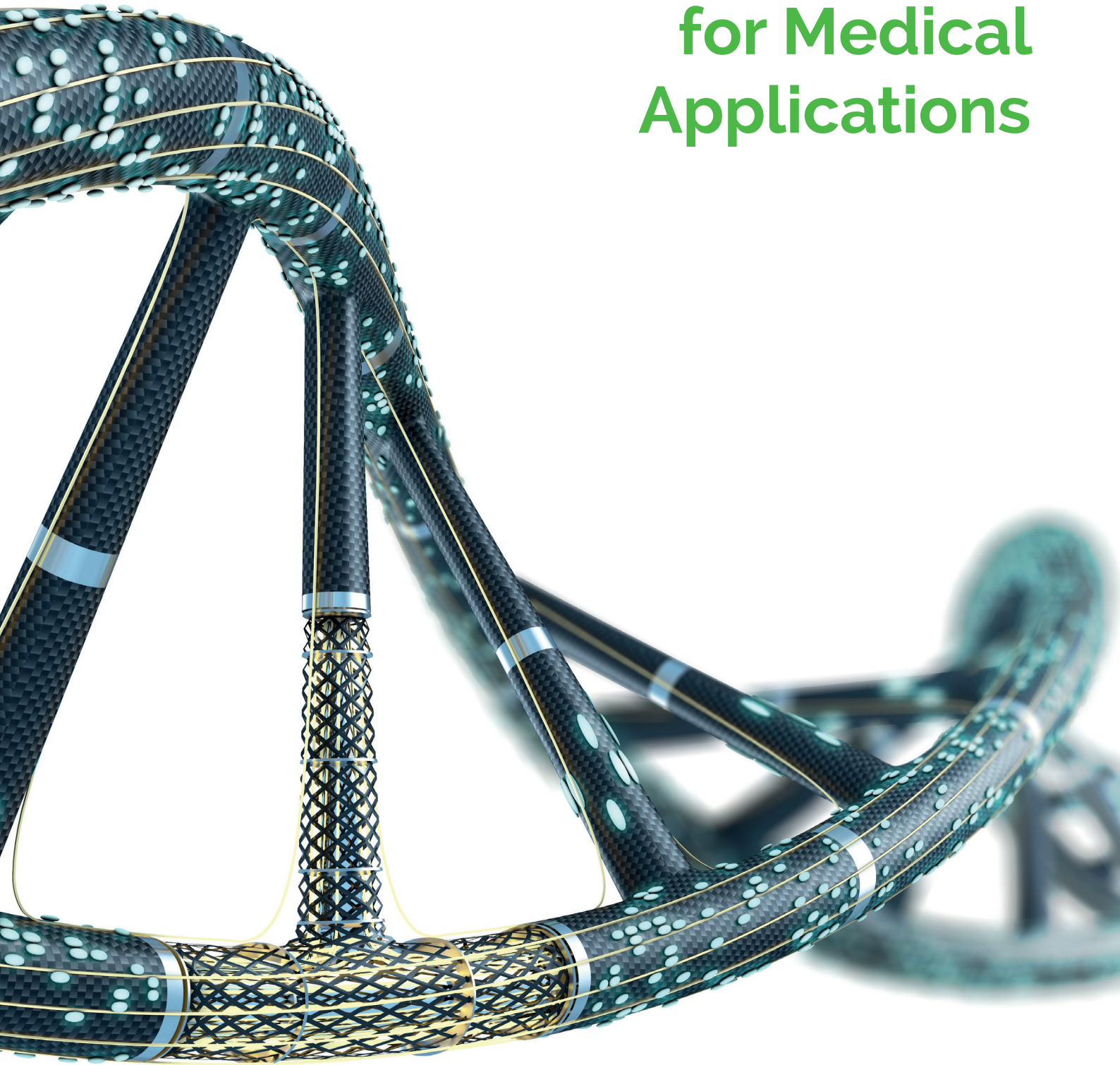




Innovative Interconnect for Medical Applications



Medical

www.lorom.com

Complete Medical Component Design, Prototyping, Manufacturing & Value Engineering

Lorom's medical business unit is a leading supplier of medical cable and cable systems for a variety of critical applications within the medical industry, including;

- **Patient monitoring**
- **Invasive products**
- **Equipment cable systems and harnesses**
- **Hospital grade power-cords**
- **Medical grade networking cables and human to machine interface**
- **Miniature ultrasound cable assemblies**
- **Audiological cables**

Our on-going collaboration with technology leaders and user organisations enables us to offer our customers comprehensive expertise in systems and applications such as medical diagnostics, patient monitoring, therapy and clinical solutions.

Our Engagement & Commitment

Conception Phase

- Assessment of technical challenge
- Intended purpose and function
- Team selection , know how needed

Team Website

- Joint collaboration web site
- "Live" data 24/7 accessible
- Sharing project time-lines, milestone data-concepts, specification, etc

First Design Review

- Formal process evaluation of engineering level requirements,
- Materials , regulatory requirements etc

Second Design Review

- Blueprints, Test Specifications, SOP, Maytreila review, intended manufacturing process specifications etc

Prototype

- Tooling/machinery development
- First built
- Verification and test that all requirements are met

Design Approval

- Ensuring that we are ready for mass production

Design Transfer

- R&D / project team initiates creation jointly with QM
- Training of staff/operators
- QC inspection

With over 500 engineers dedicated to offering solutions in development, design, processing & qualification. Lorom are providing our customers with all the support they need.



Ultrasound has become one of the most widely used diagnostic tools in healthcare, subsequently the design needs to be both functional and practical. Lorom has developed a variety of customized products for ultrasound including moulded assemblies and connectors.

Our manufacturing portfolio includes a full range of ultrasound applications, including:

- **Ultrasonic endocavity probes for real-time volumetric imaging**
- **High-frequency phased arrays for paediatric and neonatal applications**
- **Portable ultrasound machines**
- **Traditional ultrasound machines**

Lorom's products are used in market-leading ultrasound applications including high-quality color-power portable ultrasound machines.

Our Technology Platform:

| | |
|------------------------|---|
| Conductor: | Silver-plated copper alloy center |
| Conductor size: | 36 AWG to 50 AWG. |
| Dielectric: | Polyolefin, FEP or low density ePTFE) |
| Shielding: | Braid, round or flat Silver plated copper, tin-plated copper. |
| Shielding: | Spiral helix round or flat Silver plated copper tin-plated copper |
| Element Jacket: | FEP or other material on request. |

Maximum elements:

| | |
|-----------------------|----------------------|
| Conductors: | 126 |
| Coaxial: | 126 |
| Twisted Pairs: | 126 (252 conductors) |

- **Specialty high flexible AWG46 micro coaxial cable**
- **Custom PCB-A fine pitch development**
- **Automatic soldering of micro coaxial cables**
- **Autoclave able medical grade jacket material**
- **Specialty over moulding**
- **Clean and free microbial contamination on surfaces**
- **ISO 13485**

INSTRUMENT HARNESS

Our vertical engineering approach provides significant value in solving complex issues commonly found in wire harness design that incorporate many direct wired connectors, such as routing, installation & wire protection.

Our experience in design, prototyping & software development allows us to reduce the development time significantly while pre-production 3D mockups proves the design concept and eliminates costly errors.

Our wire harnesses are extensively used in the medical and specialty instrumentation markets such as; MRI, CT scanners and often utilise hybrid cables that have been designed to take into consideration extreme requirements for both flex life and flexibility.

An engineered and custom solution ensures optimal performance. We will assist in the selection of materials which will perform in the desired environmental condition i.e. extreme temperature; flex cycles, space and routing requirements, durability etc.

After initial concept reviews, design and solution proposals are presented with extensive evaluation data. Following is a thorough first article evaluation to guarantee application



performance. Finally in-house testing of all engineering considerations and application parameters to ensure a long life span of the final product.

Our cable harnesses are designed and built to IPC WHMA- A-620 Class 2 Dedicated Service Electronics Products, and critical harnesses are built to Class 3 criteria for High Performance Electronic Products.

Workmanship criteria is also customized and documented for many assemblies to eliminate special process concerns that are not fully addressed in the industry standards.

With our flexible manufacturing system we can accommodate any volume capacity, from small runs to high-volume production.



Patient Monitoring cable assemblies transmit signals from electrodes or sensors placed on the patient's body to the monitoring instrument that processes the signals.

Our products provide reliable connectivity of patients to performance critical equipment measuring a wide variety of physiological parameters such as:

- Electrocardiogram (ECG)
- Blood oxygen saturation (SpO₂)
- Blood pressure
- Temperature
- Neurological monitoring
- Sleep diagnostics/monitoring
- EEG
- EMG/MEP/SSEP
- Portable multi-parameter patient monitors
- IOM (Inter Operative Monitoring)
- ECG

What percentage of the manufacturing processes does your supplier actually control....?

In order to rise above the standard, LOROM have found it necessary to develop processes and equipment not currently available on the market and in doing so we were able to develop processing and manufacturing skills in every component in our medical devices and interconnects.

We recognise the continued demand for miniaturisation and chemically resistant products, that's why we have invested in equipment that lets us extrude cables as small as 50awg

Our on-going cooperation with technology leaders and user organisations enables us to offer our customers comprehensive systems expertise in applications such as medical diagnostics, patient monitoring, therapy and clinical solutions.

PCB-A

LOROM has invested significantly over the last 10 years in PCB assemblies to be able to offer our customer complete turnkey solutions and one stop shopping.

CLEAN ROOM

Our state-of-the-art clean facility includes a process class 8 clean room, which meets both the US federal standard 209E class 100 and China standard YY0033-2000.

DIE CAST

Our unique high-speed multi-slide die-casting process lends itself to the manufacture of intricate three dimensional connector housings and assemblies.

EQUIPMENT

LOROM have a wide capability in producing silicone & rubber tubes & hoses, all produced to customers specific requirements in a controlled environment.

INJECTION MOULDING

We assist and help guide our customers through a technical process of selecting the best-suited polymers for the injection moulded parts necessary to meet their application.

CABLE

Our cable manufacturing capability is unrivalled. All our medical cables are produced within a controlled environment.

CHEMICAL LAB

Fully equipped chemical lab enables functions such as Rheometry, X-ray, gas chromatography & spectrometry

AUTOCLAVE

For autoclave sterilization, LOROM manufactures products in materials such as thermoplastic & silicone. We also proof test using our own autoclaves.

CABLE ASSEMBLY

LOROM has a capability in the manufacture of cable assemblies & harnesses that is second to none. The highly controlled environment required for such processes fits with the LOROM methodology and attitude to get things right.



DENTAL CARE



We support a full range of technologies ranging from complex hybrid wire harnesses to board to board PCB interconnect for the dental care industry.

Our FDC (flat panel display) cables are available in a 0.5mm, 1.00mm & 1.25mm pitches and with multiple conductor counts. Our Flat Panel Display Cable assemblies exceeds international strict standards such as:

- **Video Electronics Standards Association (VESA)**
- **Flat Panel Display Interface (FDPI-1)**
- **LVDS protocol**
- **V-By-One® HS for HD displays**
- **3D display specifications**

FDC-flat cable assemblies are ready-to-plug flexible connections.

High Flex life, extremely flexible bulk cable configurations incorporating pneumatic tubes, mixed signals, and power distribution as well as customized interconnect.

Our cable solutions are designed with ergonomically optimized strain relief, flexibility and weight saving in mind, making it easier for the dentist to do his job.

Our in-house compound R&D enables to offer various options for sterilization, ranging from medical grade PVC, TPE, TPR, TPU, Silicone rubber, and co-polymers.



Our high performing cables and assemblies have been developed to offer above standard performance for invasive applications and include miniaturized single and multi-wire constructions. Features include biocompatible & antimicrobial compounds for patient safety, including cosmetic adaptability for maximum patient comfort.

Our cables are used in catheters featuring various types of conductors & plating, including high strength alloys, stainless steel etc. Products Available in AWG sizes from 20 to 48 – with up to 36 conductors or in shielded or unshielded twisted pair constructions. Smaller cross-section cables such as wires used in pacemakers are also available ranging from AWG 28 - AWG 46.

To ensure conformity with the highest standards for invasive cables, our wires are built in a contamination free manufacturing unit using equipment dedicated to producing miniature shielded and un-shielded wires.

Invasive cables are tested extensively according to customer specifications. Tests carried out include: electrical performance, bending and

flexibility (to match user movement), salt-water tests to simulate behaviour in blood environments, neutrality and biocompatibility to support extreme temperatures and shock during transportation & storage.

Lorom has installed dedicated extrusion lines within a controlled environment that have been fitted with a state-of-the-art water purification system.

Advanced application such as :

- **Laparoscopy**
- **Endoscopy**
- **Single port access (SPA)**
- **Natural orifice transluminal endoscopy (NOTES) surgery**

AUDIOLOGY

Audiology science covers studies in hearing, balance, & related disorders.

Our cable assembly technology helps the audiologist to evaluate and determine if a patient can hear within the normal range and if not, what area of hearing (high, middle, or low frequencies) are affected and to by what degree

By employing various testing with sophisticated instruments allows the audiologist to conduct hearing tests, otoacoustic emission measurements, videonystagmography, and electrophysiologic tests.

The Triboelectric Effect

Triboelectric charging is a type of contact electrification in which elements such as conductors and shields with insulation materials become electrically charged during frictive contact with a different material.

The polarity and strength of the charges produced differ according to the materials, surface roughness, temperature, strain, and other properties.

Triboelectric effect is not very predictable, and only broad generalizations can be made as well as low noise transmission line suppressing triboelectric noise induced noise by flexing when the audiologist is positioning and moving cables during test of the patient

A combination of measurement requirements, physical limitations, and environmental conditions usually determines the best choice of cable type.

We provide a wide variety of high-quality cables and interconnect ensuring optimal electrical connections throughout the measurement setup.



Our products employ a combination of a ePTFE insulation system, triboelectric suppression tapes or insulation systems combined with ergonomically optimized medical grade jacket materials providing advantageous properties such as low coefficient of friction, mechanical strength, excellent dielectric insulation, wide temperature range, low gas permeability, and chemical and flame resistance.

Our fine wire capabilities enables highly flexible, precise and durable cables and cable systems for critical applications with in the audiological market.

With material science and fine wire manufacturing we have a solution for any complex challenge in designing and developing cable and interconnect incorporating e.g. mixed signal, pneumatic tubes.



Reliable connectors for medical applications

We design and manufacture custom connectors for many of the most critical systems in the medical device industry, ranging from critical applications in patient monitoring to MRI and CT Scanners.

Connector reliability is a concern for performance-critical medical device and specialty instrumentation assemblies. Often, critical components are separately evaluated, validated and approved prior to their use in final assemblies. Our design review process and detailed product validation will ensure that key contact resistance; compatibility and durability concerns are consistently met.

We furthermore customize "off the shelf standardized connectors" in adding mixed signals, pneumatic tubes, add /remove pins, increase mating cycles, etc.

Our engineering team in close partnership with our QM and supply chain can recommend cost effective, equivalent connectors with increased reliability while maintaining critical performance.

No matter what your requirements are, we look at all sourcing options to ensure the most value for our customers. Whether your connector needs are very specific or just a standard product with a twist on a custom element or test provision.

Our local application engineering teams assist in determining and suggesting an optimal solution that exceeds all requirements at the lowest cost.

We like challenges and thrives of solving critical interconnect problems.

INTERCONNECT



The Feel of the Jacket & Cable Flexibility

In addition to the appearance of the cable jacket, the feel to the user often implies a great deal about the quality of the cable assembly. Different materials offer a different tactile feel and more significantly softer grades of even the same material feel different.

Silicone is the softest and most flexible material used for medical cable jackets. In addition to being soft and flexible, silicone can withstand a high number of sterilization cycles by autoclave.

As uncoated silicone cables are “tacky” and easily accumulate dirt, LOROM has a developed coating technology addressing this issue.

The LOROM dispersion/coating technology gives the cable jacket a silky texture enabling easy to cleaning.

As alternatives to Silicone LOROM offers rubberized polyvinylchloride as a soft material.

Available in medical grades meeting FDA and ISO biocompatibility requirements as well as being RoHS compliant.

Our specialized rubberized PVC jackets will be more durable than one made of silicone for the same wall thickness, they can be very flexible and offer a cost advantage.

Balance between durability & Flexibility of Cable Jackets

The durability of a cable jacket is not only a function of the compound material as described previously, but also of the hardness of the material and wall thickness of the jacket.

Increasing the wall thickness of the cable jacket increases the durability, but conversely reduces the flexibility of the cable, irrespective of the material.

Providing Additional Strength

Additional strength and protection of cable terminations can be achieved by employing a robust cable jacket that is mechanically clamped to the internal components. If this method is used, the stronger and thicker the cable jacket, the greater the protection of terminations is.

Polyurethane is the most durable material commonly used for medical cable jackets and can add significant strength to the cable assembly. Silicone, while having other advantageous properties, offers the least amount of added strength or protection. A thermoplastic elastomer, TPE-R is stronger than silicone and typically more flexible than polyurethane.

Cleaning and Disinfection

Before selecting a material it should be determined what methods can be used to clean and disinfect a cable. Standardization ANSI/AAMI EC53 describes minimum for cleaning and disinfection of ECG Cables and Lead wires. Section 4.3.1 of the standard details cleaning and disinfection requirements with the following solutions:

- **Green soap or alcohol-free hand soap**
- **2% glutaraldehyde solution**
- **Sodium hypochlorite (bleach) solution 10% in water**

Alcohol based solutions are often used in clinical settings. The following table offers guidance in the selection of both cable jacket and over mould resins based on how the cable assembly will be cleaned or disinfected:

| Material | Sodium hypochlorite bleach | Isopropyl Alcohol | Glutaral-dehyde |
|----------|----------------------------|-------------------|-----------------|
| PVC | Good | Good | Fair |
| TPE-R | Excellent | Excellent | Excellent |
| TPU | Poor | Poor | Good |
| Silicone | Good | Excellent | Good |

Sterilization

Elimination of all micro-organisms by sterilization, the selection of a suitable cable jacket material becomes even more significant. Of the three most common methods: steam autoclave, low-temperature hydrogen peroxide or peracetic acid steam autoclave is the most challenging for many materials used for cable jackets and over moulding. Of the materials commonly used for medical cable jackets, only silicone can withstand hundreds of autoclave cycles.

| Material | Autoclave | Gamma | Ethylene oxide | Low temp hydrogen peroxide | Paracetic Acid |
|----------|-----------|-----------|----------------|----------------------------|----------------|
| PVC | Poor | Excellent | Excellent | Good | Good |
| TPE-R | Fair | Excellent | Excellent | Good | Good/Excellent |
| TPU | Poor | Excellent | Excellent | Good | Good |
| Silicone | Excellent | Excellent | Good | Excellent | Good/Excellent |

CLEAN ROOM



Our manufacturing facility features an ISO 8 (equivalent to GMP requirements 100,000) 600 m² Clean room assembly area which meets China Standard YY0033-2000, our clean room is Bio burden monitored and controlled.

Our assembly area is staffed with our best and most experienced operators (app 80) and includes automatic termination equipment, Nissei precision scientific injection over moulding machines as well as Branson high performance ultrasonic welding machines which enables us to offer medical cable assemblies intended for use in surgical theatres, as well as invasive cable systems.

- **Automatic precise rotary stripping equipment**
- **Automatic laser stripping machines**
- **In house positioning tools and jigs**
- **Dual head hot bar welding systems (direct attach weld to PCB 0.3 mm pitch).**
- **Automatic soldering systems**
- **Automatic test equipment and benches**

The cables incorporated within our assemblies are produced in a “semi-clean” environment with saline additives as part of the water cooling process, insuring the highest level of sanitation.



Quality Management

- DIN ISO 9001 and DIN EN 9100
- ISO 13485:2003
- TS 16949:2009
- AS 9100: B

Environmental Management

- DIN ISO 14001

Electrical Test Equipment

- 40 GHz VNA
- TDR 30ps Risetime
- High-voltage test
- Insulation test
- Bio Burden
- Pin assignment check
- EMC/EMI Chambers
- Corona Testing

Mechanical Test

- Drag chain test
- Flex life
- Flexibility
- Micro sectioning lab, 40x electron microscope
- Tensile strength test
- Vibration
- Tensile & Elongation
- Optoelectronic measurement systems

Environmental

- IP 67 watertightness test
- Fire and flame test VW-1 IEC etc
- Halogen content
- Salt Spray, Sand & Dust
- Temperature & humidity

Chemical lab

- Rheometry
- X-Ray
- Spectrophotometers
- Gas Chromatography / Mass Spectrometry
- Microwave Digestion/Extract
- Energy Dispersive X-Ray Fluorescence
- UV Accelerated weathering tester



CLEAN ROOM



Simulating and testing real life exposure

Our test equipment enables us to perform both swept sine and random vibration inputs, therefore enabling us to assimilate real life product exposure in order to configure the test most representative of the products life cycle. In-house test chambers allow us to introduce and control temperature and humidity profiles during vibration testing, this enables us to simulate any environment conditions that the product may be subject to during its lifetime.

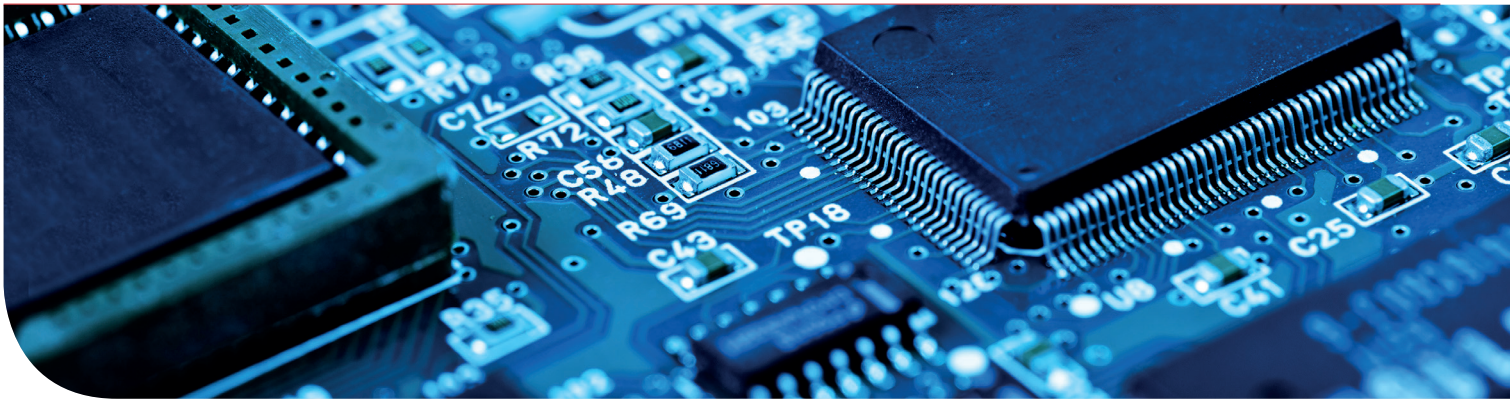
- **3 Axis Vibration Testing**
- **Frequencies up to 3500Hz**
- **High Frequency Testing at up to 30Kg Component Mass**
- **Combined Vibration, Temperature and Humidity Testing**
- **Life Assessments**
- **Performance Assessments During Vibration**
- **Weak-Link Analysis For Product Development / Improvements**

Fluids Testing

Our fluid testing capability covers a broad range of products and applications. from initial prototypes, first article functional testing, qualification testing, to compliance and verification testing.

Our fluid testing facilities are equipped with computerised data acquisition, reduction and analysis equipment for monitoring the functional characteristics of specimens during testing. Fluid tests capabilities include:

- **Hydraulic/Pneumatic - Static/Dynamic**
- **Flow - Gas, Liquid, Fuel, Propellant, Oxidizer, Chemical, Hazardous, Water, Steam**
- **Temperature - High/Low Gas Flows**
- **Cryogenic - Liquid Oxygen, Liquid Nitrogen, Liquid Hydrogen, LNG**
- **Bio-Burden testing**

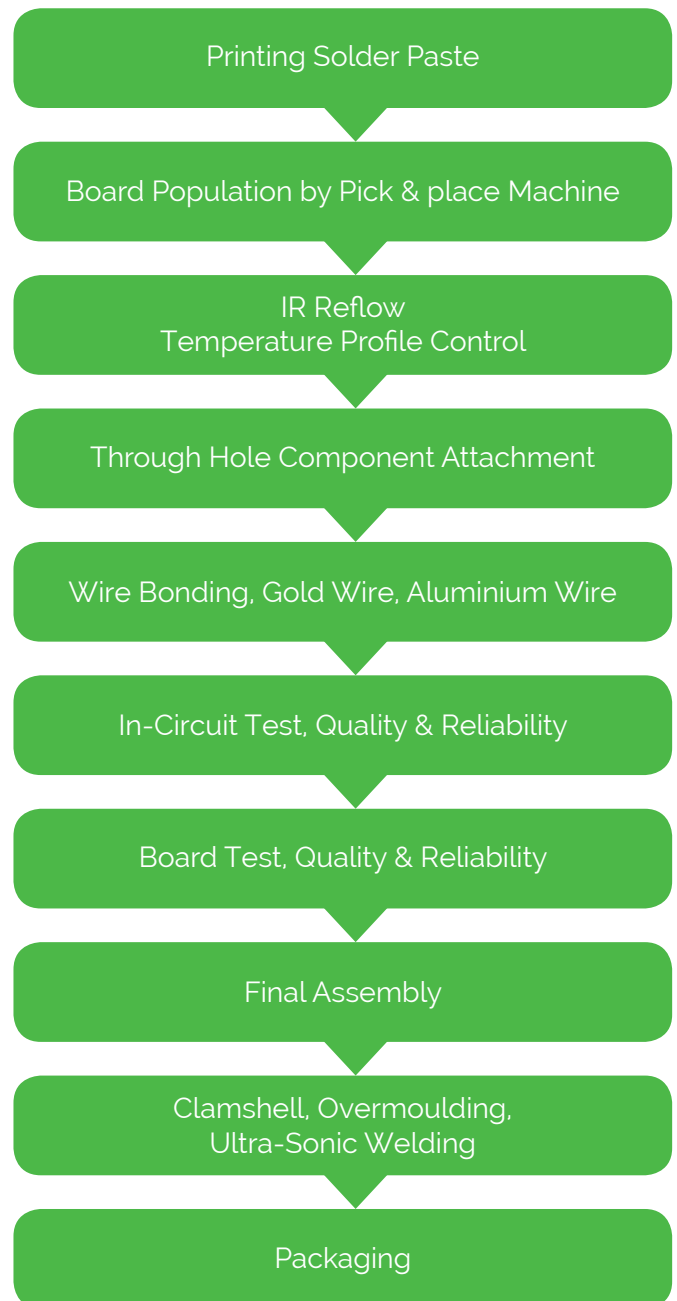


Efficient development gives every new product the best possible start and plays a major part in rolling out production configurations that are cost-optimized right from day one.

Using a DFM Designed For Manufacturing focus from the outset ensures that each product is designed so that it can be produced at lowest practical cost and as swiftly and efficiently as possible to minimize time to market.

Lorom manufacture PCB assemblies to compliment our own cable assemblies/systems, as well as complex interconnects and harnesses. Vital know-how is applied in terms of optimization of Signal integrity, EMC, termination methodology and mechanical and electronic packaging.

“Clean-room” PCB-A facilities in both our Shenzhen and Hangzhou facility comprise a total of 8 complete state of the art assembly lines. In-house designed and custom-built automated test systems ensures consistent and world class quality.



ASSEMBLY



- **Automatic Cut & Strip of cable**
- **Stripping insulation/dielectrics/insulation**
 - Laser stripping
 - Automatic and semi automatic stripping
 - Automatic and semi automatic stripping in Steps
- **Wire Cutting / Prep**
 - Fan out optimization
- **Termination**
 - Soldering
 - Automatic
 - Infrared
 - Hot bar, single / dual
 - Reflow air
- **Laser soldering**
 - Welding - Direct attach- resistance welding
 - Crimping
 - IDC
- **EMI-EMC techniques**
 - 360 Degree soldering
 - 360 Degree Tip&Dip solder wicking
 - Crimp rings
- **Inner mould & Over mould**
- **Ultra sound**
 - Housing
 - Injection moulded shells
- **Die-cast Back Shell**
 - ZAMAK, Aluminium
- **Strain Relief**
 - Over mould,
 - Pneumatically attached grommets



Flat Planar cables

- Extruded or laminated
- Ribbon Cable
- FFC Cable

Differential transmission lines

- AWG46 to AWG000
 - Twisted Pair Flat Cable
 - Twisted Pair Cable, Shielded /unshielded
 - Parallel Pairs, shielded in excess of 30GHz
 - X-Linked materials

Single ended

- Coaxial Cable
 - AWG46 to AWG12
 - Low loss dielectric, ePTFE, F-FEP/PFA-F-PE/PE
 - X-Linked materials
 - Solid dielectric, PP/PE, PFA/FEP, PTFE,
 - Round/flat 16/24/36 carrier braid

Jacket

- Autoclave sterilization resistant materials
 - Hyperlon, Neoprene, Rubber
 - Silicone
 - TP-U,TP-E,TP-R
 - Flourpolymers
- PVC,PE,FEP
- Polyamide

Hybrid Cable

- Pneumatic tubes
- Mixed signal
- Fibre optic incorporated
 - High flex life application, tugged applications
 - Ergonomically design, for flexibility, and durability

Our controlled FFC manufacturing area is maintained at a positive pressure so if any leaks occur, air leaks out of the chamber instead of unfiltered air coming in.

The area is equipped with a clean room HVAC system to keep the humidity to controlled levels. Ionizers are used to prevent electrostatic discharge problems.



Medical



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