Manufacturing, Packaging, and Transport

"The Age of Tissue Computing has Arrived™"
Brought to you by BCM Industries

One can design an amazing Tissue Computer but if that computer cannot be mass produced and delivered to customers at an affordable price, the Tissue Computing era would never materialize. BCM has specifically designed the first commercially available Tissue Operating Device (TOD™) to be mass producible, extremely dependable, and affordable.

The public and commercial desire for access to a Tissue Computer, with blazing processing speed, massive throughput, near infinite data storage capacity, and lightning data transfer network services is well known.

This Article is directed at presenting the manufacturing, packaging, and delivery process and systems used by BCM to make and deliver TOD™ and all the associated components, including the Tissue Computer. This Articles presumes the information presented in the two Articles: "Introduction to TOD™ and Tissue Computing," and "Design, Components, and Architecture," have already been reviewed and absorbed by the reader.

Specifics addressing installation procedures and process in delivery of the TOD™ tower model, and the floor and rack models, the TOD™ configured laptop computer, and the Tissue Computer are available in the Article: "Installation and Operations."

As discussed in the referenced Installation Article, physical delivery and install of every TOD™ Model is by a TOD™ Support Team. All packaging and transportation issues are therefore between the BCM production faculty and the TOD™ Support Team.

The packaging and transport of the TOD™ components, excluding the Tissue Computer, uses standard computer equipment packaging and shipping. Packaging and transporting of the Tissue Computer which includes millions of neurons, live nerve cells, requires special procedures.

Tissue Manufacturing

The Tissue Computer is filled with neuron populated tissue structures. Because this Computer contains many millions of living neurons, the manufacturing processes must be totally performed within a medically sterile Lab Environment.

The process includes first manufacturing of the TC Disk tissue scaffolding. Next the growth and propagation of the Disk structure with approximately one million new living neurons. This newly created and fully populated TC Disk is then processed through a battery of tests and validation procedures. These tests assess the levels of TC Disk functionality and performance.

In parallel, to this TC Disk production activity, is a process to produce TC Cords. Manufacturing a TC Cord is a three-step serial process. First, the exterior of the tube structure is manufactured. Next, is the manufacturing of the Cord's interior tissue scaffolding. Last is the process which grows and populates the Cord's interior scaffolding structure with many newly grown neurons. Each newly created TC Cord is then repeatedly evaluated to assess effectiveness of data transfer functionality and performance.

Each approved TC Disk and TC Cord is them packaged and placed into a medically sterile Lab Environmental warehouse to await an allocation to a specific TOD™ customer order. Figure 1 is an image of the sterile temporary storage and warehousing container used to assure each newly manufactured TC Disk and TC Cord produced remains fully compliant with medical grade sterile manufacturing procedures.

Manufacturing Quality

In the tissue manufacturing process, BCM utilized only bovine source material that meets or exceeds all U.S. FDA recommended "Guidelines as to Pedigree and Handling" procedures for materials to be used in medical devices. BCM's controlled sourcing process assures a pure material that contains no growth stimulating hormones or GMO products are used in the birthing and raising of the bovine herds.

All BCM processing and manufacturing is performed under strict Standard Operating Procedures and are cGMP ("current good manufacturing practice") compliant, and compliant with the USDA and FDA regulations. These operating controls, procedures and qualified processes enable BCM to provide the highest quality and purity of materials used in the manufacture of each Tissue Computer.

Order Processing

Upon acceptance of a TOD™ purchase order, and authorization to proceed with manufacturing, the required number of TC Disks and TC Cords are withdrawn from the warehouse. Within a medically sterile Lab Environmental these components are arranged into the processing array configuration required for the TOD™ Model ordered.

Upon completion of the construction phase of the array manufacturing, all the TC Disk and TC Cord in the architectural array structure, including the internal TC Cord network and the special TC Cord external data ports, are cell growth bonded into the final deliverable Tissue Computer.

The packaging and shipping of the tested and approved Tissue Computer to the TOD™ Support Team for delivery and install at the customer site, uses the BCM proprietary live tissue transporter, named Steff.

As reference, Figure 2 is a picture of Steff after successfully delivering BCM created ARTR™ organ repair tissue to the Hayatabad Medical Complex, Peshawar, Pakistan. Steff has successfully demonstrated the ability to sustain cell populated living tissue for over 20 days, without the need for any internal or external power.

Steff has also successfully survived many unplanned air courier drop tests, being lost in an airfreight warehouse for over a week and being left on a hot airport runway for an extended lunch break. In simple terms, Steff is amazing.

Volume Tissue Production

Manufacturing a TOD™ computer is complex and challenging. However, BCM has previously, and repeatedly performed all these manufacturing steps and maliciously validated all the processes, equipment, and procedures. The latest tissue production system validation was in the manufacturing, and delivery of multiple sets of Autologous Regenerative Tissue Replacement (ARTR™) organ repair tissue units in support of human kidney repair clinical trials. To learn more, review the ARTR™ data at the BCM website.

A key element in an ability to deliver high-volume manufacturing of tissue products is a BCM designed tissue production machine known as Cliff. Illustrated in Figure 3, with extremely limited manual supervision, a single Cliff unit produces up to 120 TC Disk units per week, or 6,000 per year. All BCM tissue manufacturing machines, including Cliff, are modular and can be quickly expanded to increase production based upon market demand.

For example, by installing 2,000 Cliff units into a TOD™ manufacturing facility, annual production will exceed 12 million TC Disks. A modified version of Cliff can manufacture TC Cords at the same annual production rates. The use of 2,000 Cliff units is an example only, there are no physical limits to the number of Cliff units that can be added to the BCM manufacturing facility production lines.

For additional data, review the TOD™ Articles posted on the BCM website or contact a TOD™ sales and support representative.

The Three Referenced Figures Follow

Figure 1

Medically Sterile Storage and Transport Packaging
TC Disk and TC Cord Sterile Storage Unit

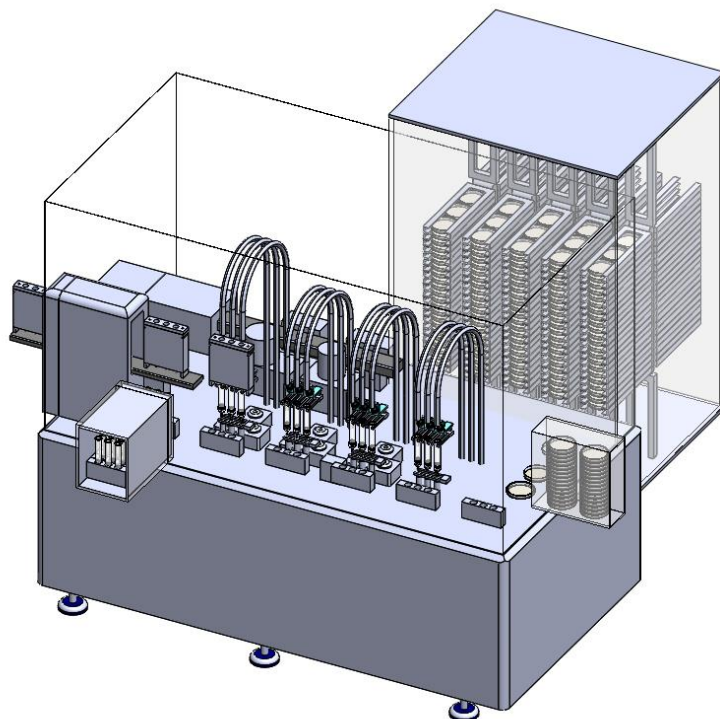# Figure 2

Steff - Tissue Computer Transporter

Environmentally Sterile Extended Duration Tissue Shipper

Figure 3

Cliff - Fully Automated Tissue Manufacturing Unit

High-Volume Manufacturing of TC Disk and TC Cord Units

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Additional Available Articles

Introduction to TOD™ and Tissue Computing

Nine Available TOD™ Models

Design, Components, and Architecture

Programming and Controlling a Tissue Computer

Installation and Operations

TOD™ Processing Applications

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