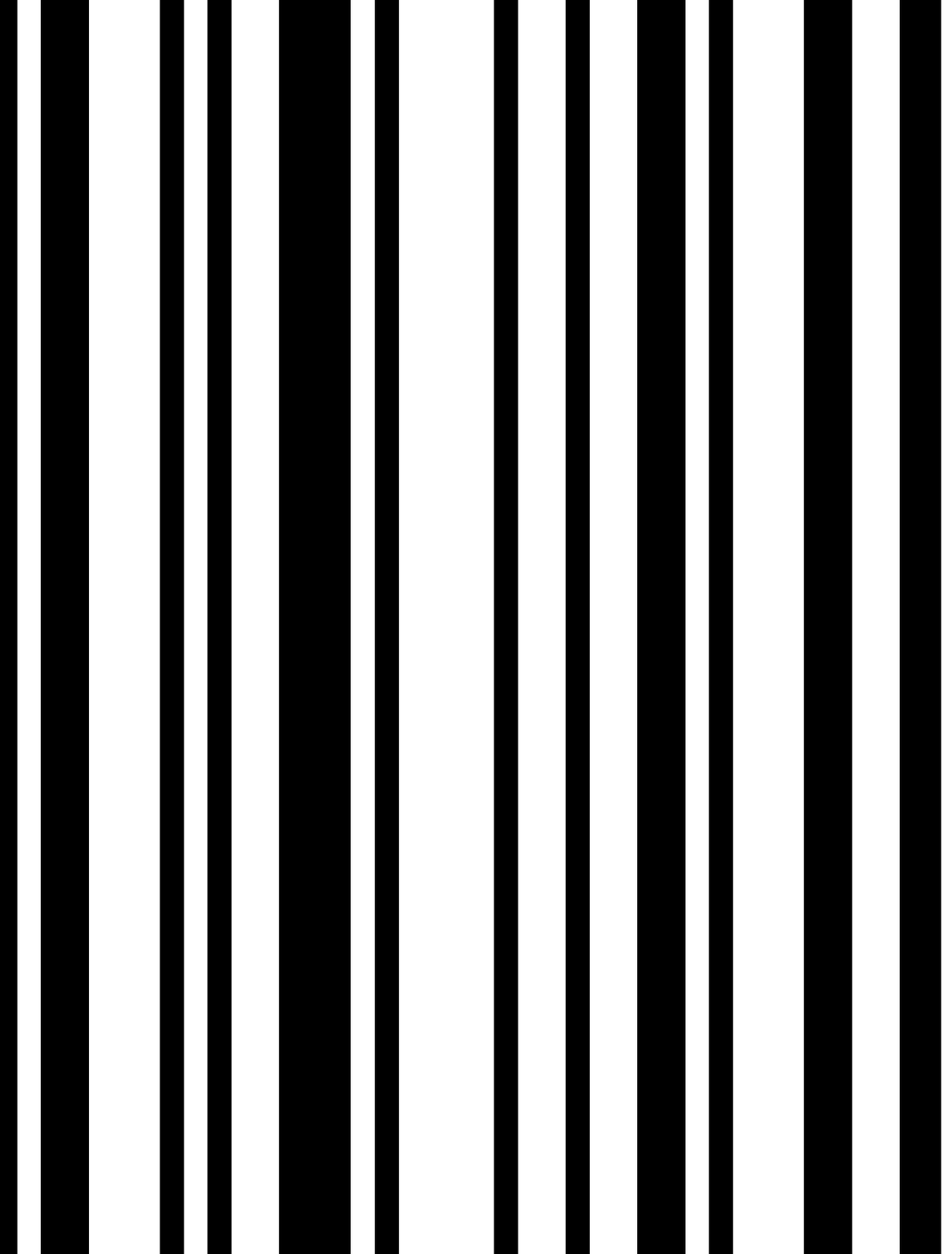
Life Savers and Game Changers:

The Story of Labels in Healthcare

40 YEARS

Computype™



Supporting the Big Decisions

Important decisions are made in healthcare every day. Questions about the effectiveness of a new drug, the accuracy of a cancer diagnosis, or the availability of a transplant option. Big decisions – sometimes life-or-death decisions – depend on data provided by research labs, clinical trials, and blood banks.

How is all this information tracked and made available to help assist in these big decisions? Barcodes!

At Computype, we understand how monumental these decisions can be, so we've spent the last 40 years ensuring that our labeling technologies and solutions live up to the demands of the healthcare industry.

From drug discovery to diagnostic screening, to blood collection, we've produced billions of labels and barcodes that have assisted in making tough decisions.

And as the healthcare industry continues to evolve, so will our solutions that help to support it.

Computype™

The healthcare barcoding and labeling timeline

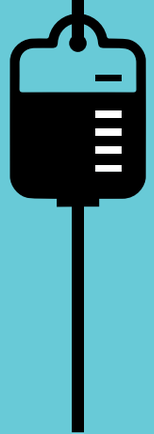
Believe it or not, barcodes and labels weren't always used to track samples or enable automation in healthcare. Let's take a look back at how the industry and its preferred method of tracking has evolved over the years

1973

Industry leaders determine a single standard for product identification for industries like healthcare, food service, and transportation. Still in use today, UPC was the first and original GS1 barcode

1977

The blood banking industry was one of the first in healthcare to begin using barcodes on collected product as they needed a way to reduce errors and ensure expiration dates weren't exceeded



1983

The Health Industry Bar Code (HIBC) standards were established to instill a uniform labeling standard for all products shipped to hospitals

1989

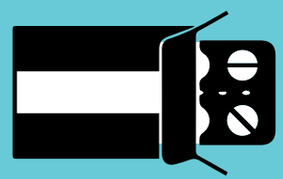
The international blood bank community began their transition from Codabar to Code 128 as the standard symbology. This 'upgrade' provided more flexibility, space for data, and security

1990s

Diagnostic companies began utilizing chemical-resistant barcode labels in conjunction with new technologies for automated histology slide staining

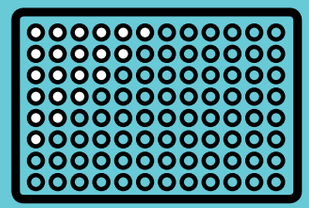
1999

Early adopters in hospitals began utilizing barcode technology for improved medication administration processes



2000

One of the first successful attempts is made to integrate barcodes and microwell plate labeling automation into a plate handling work cell



2004

In the United States, the FDA ruled that a 10-digit barcode must be used on all human medications to ensure a National Drug Code (NDC) reside on either the package or the label

2006

The International Society of Blood Transfusion (ISBT) created a task force to study the potential of utilizing RFID technology in blood transfusion

One of the first RFID –enabled barcode labels is utilized to track the quality and quantity of expensive reagents used in analytical test equipment

2013

The US FDA announces the Unique Device Identifier (UDI) regulation, mandating that all medical devices have a unique product identifier

2016

Used for drug discovery, billions of compounds & biologics stored in libraries all over world are now automatically tracked and utilized via linear and 2D barcodes

Barcodes in Healthcare

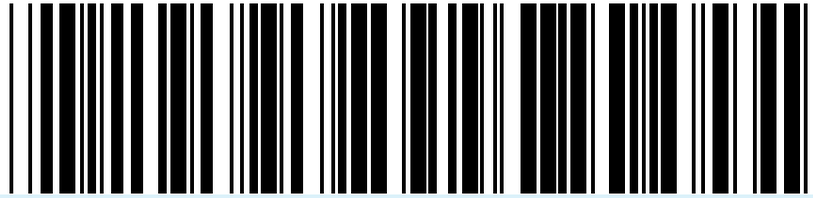
As small in size as they sometimes are, barcodes play a big role in making sure research, testing, and tracking is accurate.

- When affixed to a blood bag, Donation Identification Sets & ISBT labels help track important information about collection date, donor blood type, cell counts, and lab testing results. This means when a unit of blood is needed, the recipient is guaranteed a safe transfusion with compatible blood
- When used in a pathology lab, the barcode travels with the biopsy all the way from the point of collection to viewing under a microscope. This audit trail ensures proper chain of custody & accurate patient diagnosis. You wouldn't want to be wrongly diagnosed because samples got mixed up!
- Barcodes are relied upon in drug discovery for tracking of compounds and biologics. Each compound held by a pharmaceutical or biotechnology firm can range in value from $10 - $10,000, and hold even more value when combined. Since most libraries store over one million samples, it's imperative that each one is uniquely identified so as to ensure research can progress and money isn't lost

In all our time spent helping the healthcare industry identify, track, and manage their work, we've made some advances to improve the -tried-and-true barcode:

- We've engineered labels for microscope slides and tubes to include protective laminates and clear tabs that adhere over the image, so the barcode itself is never directly exposed to any harsh chemicals or temperatures
- A 'bullet' shaped label accommodates a conical tube to ensure the barcode can be properly scanned
- When a pre-printed label is required, we ensure each and every code is unique, has been pre-scanned, and isn't duplicated

Barcodes come in many shapes and sizes, and can even contain color!



Linear Codes: A good old fashioned barcode

It's all about bars and the spaces in between.

- **Start and stop characters** – these grouped patterns of bars and spaces tell the scanner where the code starts and ends. They also tell the scanner which symbology is to be scanned.

- **Check characters** – these are placed in the barcode at a predetermined position (usually at the end). They're related mathematically to the rest of the characters, and help confirm that the correct data has been decoded

- Perfectly-printed codes are necessary for blood banking applications as a duplicate or non-readable code can be a matter of life and death
- In applications like drug discovery or clinical trials, linear barcodes can be essential for ensuring proper chain of custody and patient confidentiality

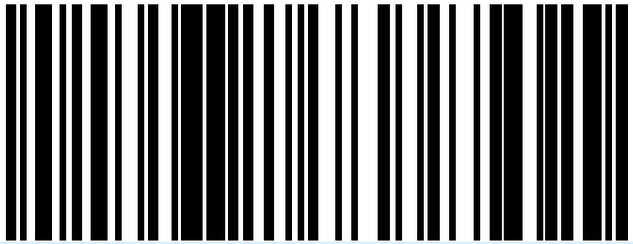
Code 39

Code 39 was the first alphanumeric code to be developed. Back in 1981 it became the official standard for US Department of Defense, and the overall government symbology standard. It's also the code recommended by the Automotive Industry Action Group and the Health Industry Business Communications Council.

- A discrete code must be read in an identical fashion to a continuous code from the standpoint of the scanner. The difference is that characters in discrete codes 'stand alone', and require a space between each pair of adjacent characters. This means they are slightly less space-efficient than a continuous code
- Alphanumeric – uses numbers 0-9, capitals A-Z and seven special characters
- Two element widths – narrow and wide
- Variable length
- Can be concatenated

AKA Code 3 of 9

Code 39 is sometimes called Code 3 of 9, and is widely used in industrial, medical, electronics, telecoms, shipping containers, commercial and government applications.



Code 128

Code 128 is a high density symbology that can be used for alphanumeric and numeric-only barcodes. It's often chosen ahead of Code 39 because of its density, and because it has a much bigger selection of characters available. Basically, Code 128 can carry a whole lot more information.

- A continuous code with no inter-character gaps
- Alphanumeric, can use the full ASCII 128 character set
- Variable length
- Has four element widths
- A high density code
- Can be concatenated

Good for blood

A customized version of Code 128 allows blood products around the globe each to be given a unique donation identification number.

Is it a fence or a ladder?

Barcodes can be orientated in two different ways:

Picket fence – where the code is arranged vertically, like a picket fence.

Step ladder – you guessed it, when the code's bars lie horizontally, it's called a step ladder.
In healthcare, you'll see both fences and ladders:

- **Fence**
  Microwell plate barcodes
  Microscope slide barcodes
- **Ladder**
  On the sides of tubes and vials

Two Dimensional Barcodes

Time definitely equals money in the healthcare industry, and reducing costs can come from speeding up processes, reducing waste and outsourcing to increase productivity.

Miniaturization means being able to perform the same number of tests and functions but by using smaller quantities of 'stuff'. Smaller amounts are housed in smaller containers, and therefor require a smaller label – a perfect job for the 2D barcode!

2D codes are capable of holding more information in a small, compact amount of space

- 2D codes are being used more and more often in healthcare applications on the bottoms of small containers in conjunction with a linear code or human readable information on the side
  - These are especially helpful when the tube/vial needs to go through an automated scanning process
- The Transfusion Medicine Industry is currently looking at the use of 2D codes for the labeling of blood products

Datamatrix: Small is beautiful

Datamatrix is a 2D code that packs an amazing amount of data into a small space. It's been specifically designed to be read using vision-based scanning readers, in any direction and angle.

Each symbol is made up of:

- A perimeter 'quiet zone'
- A border comprising two solid edges and two dashed edges
- Data cells inside the board which are dark or light

There are two types of Datamatrix code:

ECC-000 to ECC-140 – this has an odd number of modules running along each square side.

ECC-200 – this features an even number of modules on each side. Its maximum data capacity is 3116 numeric digits, or 2335 alphanumeric characters, in a symbol 144 modules square.

Color labels:

While we do love black and white barcodes, every once in a while we like to add a hint of color.

Customers in all corners of healthcare are finding clever ways to use color for at-a-glance ease-of-use and to increase accuracy:

- Company identification, logos and branding, product differentiation
- Warning and spotlighting of information – like GHS compliance
- Color matching and coding with other containers or instructions for collection kits
- Extended content labels to separate the information on a label using color fonts or color "tabs"
- Color coding a tube or vial so the user knows when to use it or that it is used for a specific process/sample/reagent

Barcodes:

held by adhesive or permanently attached?

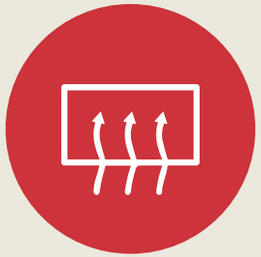
The answer is either! Depending on customer applications, environments, processes, and the material to which the barcode is attached, there are all kinds of ways to get a barcode affixed...

Gets the job done, but won't live forever:

Pressure sensitive
The good traditional adhesive label is still the most popular means of barcoding in healthcare. Engineered to withstand a variety of chemicals and environments, it sticks, and simply gets the job done. Its most commonly used to track microwell plates, plastic tubes and vials, and blood products

Fun fact:
Unlike a pressure sensitive label, containers that are permanently marked won't change weight over time - which is especially helpful when storing precious chemical compounds or biologics for years on end!

Permanent solutions:



Ceramic
A barcode is actually fired onto the container using high heat, and as a result becomes part of the component itself. Most typically used on glass containers that require a long-term, permanent barcode ID

Direct Imaging
The image or barcode is printed right onto the item using specialized inks and curing processes

Laser Etching
Via laser heat and evaporation the laser impresses an engraved barcode to the material surface

Laser Imaging
Special materials are marked with the usage of a laser beam

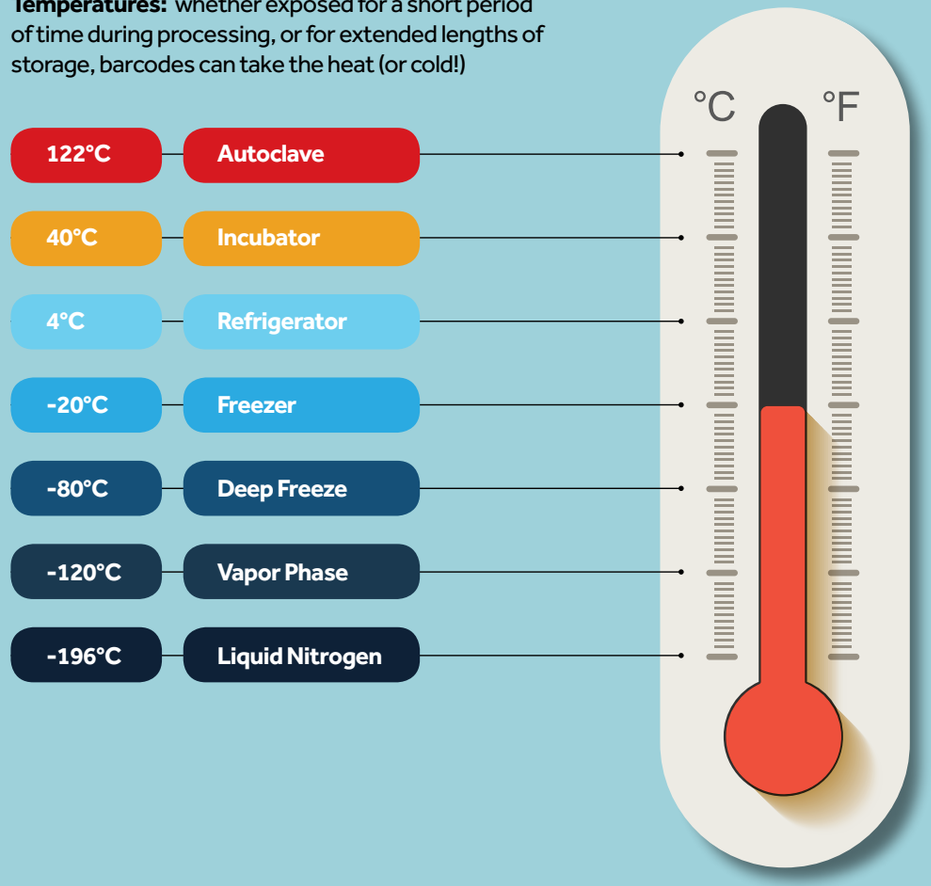
Laser Ink Removal
A laser removes the top coats, thus producing different colors of top coat and substrate. This technique is often used in cases where aluminum, metals, foils, and films need to be permanently marked

Custom molded plugs/ inserts
Already -barcoded plugs and inserts can be designed to fit with existing labware

Survival of the fittest

Sometimes in healthcare, samples and their associated barcode have to go through some crazy processes that involve nasty chemicals and extreme temperatures for lengthy periods of time. Luckily, barcodes and the way in which they are affixed have evolved over the years, and they're now stronger and more durable than ever.

Temperatures: whether exposed for a short period of time during processing, or for extended lengths of storage, barcodes can take the heat (or cold!)



Chemicals: whether submerged for hours or sometimes just wiped with a chemical cleaning agent, barcodes have to resist some pretty potent mixtures

Did you know....

- When it comes to processing and exposure, most labs consider water to be a chemical
- Some biologic samples are stored at -80C for years at a time!
- Cryogenic liquid nitrogen boils (liquefies) at -195.79C, and causes rapid freezing on contact with tissue

RFID

RFID technology is transforming the way we track and trace in healthcare

So goodbye barcodes? Not just yet...

Most experts agree that the barcode still has an important role to play in identification and tracking. In fact, RFID and barcodes are starting to work together in complementary ways.

Combining the barcode with RFID offers the safety of two data carriers – if one can't be read for whatever reason, the other provides back up.

As a result of our involvement in the global ISBT 128 standardization effort, we are now leading the way in the next wave of automatic identification within the healthcare community—RFID.

In 2006, the International Society for Blood Transfusion (ISBT) created a Task Force on Radio Frequency Identification (RFID) to study the potential of that technology in blood transfusion. The team highlighted two inherent advantages of RFID:

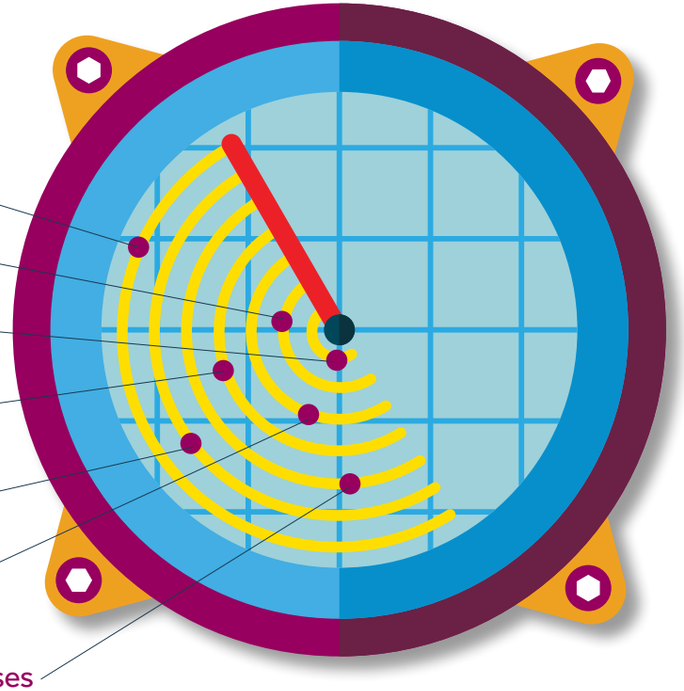
- RFID tags can be scanned without a line-of-sight. With the right combination of tags and readers, it's possible to read an entire carton of uniquely identified blood containers without even opening the box
- RFID chips can indicate, in real-time, the exact nature of the blood product; relabeling would still be required, of course, prior to distribution

The first comprehensive US effort to study RFID in blood banking was launched by the Blood Center of Wisconsin in 2009 when they received a grant from the National Institutes of Health. Using smart labels provided by Computype, a consortium of multiple blood centers and hospitals, along with the University of Wisconsin-Madison RFID lab, studied the usability, survivability, and safety of RFID in the blood supply chain.

After the ISBT agreed to standardize on HF (High Frequency; 13.56 MHz) RFID technology, and it was shown to the FDA to have no deleterious effects on blood products, two of the first comprehensive systems for the blood supply chain were developed. Real-world trials of RFID technology at blood center and hospital facilities followed, and in 2013 the first FDA 510(K) was issued for this group's blood center RFID system.

RFID is tracking all kinds of things in healthcare:

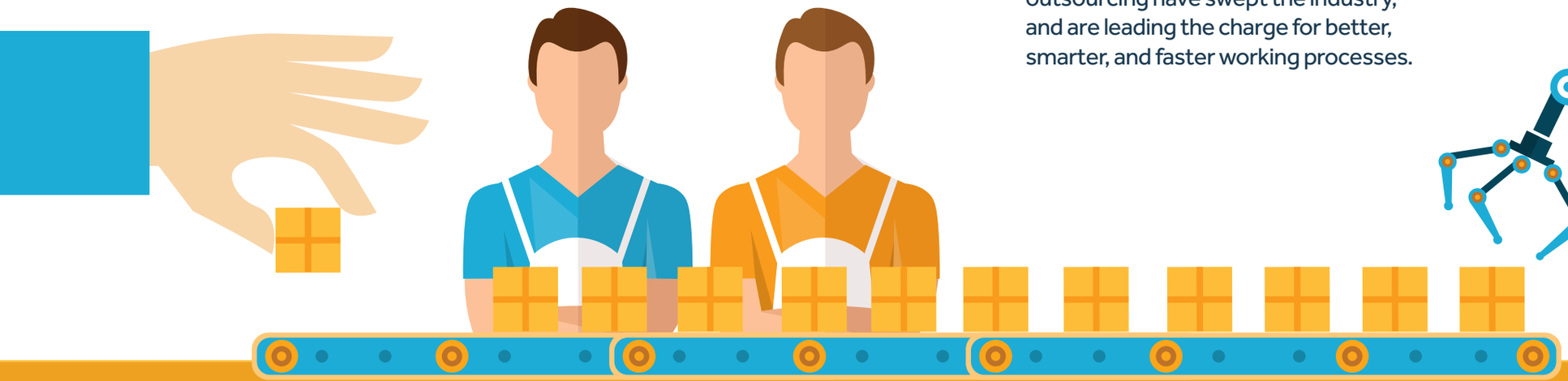
- Reagent usage and quality
- Location of surgical instruments
- Management of available hospital beds
- Patient treatment administration
- Status and processes related to sterilization
- Maintenance status & location of lab equipment
- Kitting and shipping processes



So Computype's growth—along with the evolution of auto ID in healthcare labeling—continues. While the conversion to RFID will not take place quickly, there is evidence of increasing interest in the technology among thought leaders in life sciences, diagnostics, and blood banking. And Computype is positioned to repeat our historical role of helping those leaders get the very most from automatic identification.

#Trending

As rapidly as the healthcare and medical industries have grown, they are changing and evolving equally as fast. Miniaturization, automation, and outsourcing have swept the industry, and are leading the charge for better, smarter, and faster working processes.



Miniaturization:

In healthcare, labs are now able to perform tests and carry out processes using smaller quantities of material – saving money and space as a result. This means containers are smaller, and they need labels to match. 2D barcodes are particularly suited to this miniaturization. Performing a test may have taken a liter of substance five years ago, now can be performed using only 10mL

As the requirement for using less increases, so then does the importance of barcode labels and automation that support these initiatives

'Lab on a chip', nanotechnology, microfluidics, and lab automation are all outputs of this miniaturization trend, and automation equipment has even adapted to accommodate these miniaturized tests & smaller volumes

Outsourcing:

When automation or equipment can't be justified, or a 3rd party can accomplish tasks better than internal processes allow, outsourcing is often considered. Lots of tasks can be outsourced, from sample management to logistics, to clinical trial kitting to barcoding. Companies all over the healthcare industry rely on each other's expertise to ensure that their facility runs smoothly.

Several benefits can be realized when processes or tasks are outsourced:

- Additional flexibility
- Shared equipment
- Additional knowledge
- Expanded capacity
- Time savings

Automation:

Flexibility, accuracy, and tighter controls are all benefits associated with automation in the lab.

- Total Lab Automation (TLA) means an entire process is automated where automation equipment is available for the workflow
- Workstation Automation means that a single function, task, or work center is automated

Automation reduces the risk of human error, ensures consistency, and allows for work to be easily replicated if needed.

All over the healthcare industry from blood banks to compound libraries to pathology labs and plasma collection, automation is being used to ensure both reliable and prompt results.

Most automated systems rely on (you guessed it!) barcodes! Linear or 2D codes are typically what keep the system flowing smoothly and ensure that downtime is minimized, samples are processed accurately, and errors are avoided.

Microwell plates used to have 32 wells as standard, but now it is not uncommon to see plates with 96, 380, or even 1536 wells

The Future is Bright

Research tells us that the Healthcare Industry will continue to grow, and we believe that the usage of barcodes and automatic ID technology is here to stay. That being said, both the industry and its means of identifying and tracking will continue to evolve and adapt.

As systems become more integrated and globally connected, research progresses, and as 'things' become smarter, the possibility for greater efficiencies, accuracy, and precision sure are bright...

- RFID may be used to track diagnostic samples through the entire process and link all collected samples from a particular patient
- Direct mark technologies will reduce the chance of labeling issues such as flagging
- Barcodes will become even smaller!
- RFID will provide real-time location information on a sample being evaluated and reduce the risk of sample loss
- Automation in diagnostics could move from a large, single lab to patient bedside
- Point of care diagnostics (Lab-on-a-chip) will speed up the diagnostic process and improve the personalization of treatment
- Automation will become smaller, more condensed, and more accurate to the point of needing a fraction of the sample size
- In Compound Management, RFID will enable libraries to know which samples are available and identify their location faster and with little to no impact on storage temperatures
- The sharing of global technology will speed up the development of drugs and diagnostic test accuracy
- Personalized medicine will diagnose and treat each patient as an individual

Discover the discoverers

Automation, outsourcing services, precisely printed barcodes, and RFID systems - these are our strengths, and we'd be pleased to discuss their many benefits for your facility.

The most important piece of work we do is discovery. Discovering your current process, future goals, the holes in your workflows, and opportunities for improvement. Without this discovery process, we would be just another label supplier, and that's not how we do business. Each niche of the healthcare industry is different and has unique challenges, which is why each barcode, label, automation system, & outsourcing solution is tailored to meet the demands of your process and environment.

To find out more, please contact us at **contactus@comptuype.com** or visit **www.computype.com**

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Notes

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