IMPLEMENTATION GUIDE

Choosing an On-Demand Label Printer

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance for users who wish to procure on-demand label printers.

1.2 Scope

This document provides background information on the laboratory and hospital use of thermal transfer and thermal direct printers for blood product container labels. It provides supplementary information only and is therefore intended to be used in conjunction with the *ISBT 128 Standard Technical Specification.*

1.3 Intended Audience

This document is intended for staff (management, laboratory, quality, validation and information technology) of facilities using ISBT 128, software developers, and manufacturers of labels for blood, cellular therapy, and tissue products.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (found at www.iccbba.org)

ISO/IEC 15416:2000(E): Information technology—Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols (http://www.iso.org/iso/en/prods-services/ISOstore/store.html)

1.5 Other Reference

US FDA 21 CFR 175.105

1.6 Background

The last 30 years has seen tremendous growth worldwide in the use of bar codes across all industries and in a broad range of applications. This has fueled a corresponding growth in the popularity of thermal technology because of its capabilities to produce reliably scannable symbols on a wide variety of media. In fact, thermal printing technology was developed specifically to produce bar code labels.

Thermal label printers are capable of producing bar code symbols with sharply-defined edges. With the right type of print-head (discussed below), they can produce high-density symbols that meet the minimum requirements outlined in bar code symbology specifications.

Linear (one-dimensional) bar code symbols—such as those required by ISBT 128—can be produced via thermal printing. In addition, two-dimensional symbols designed for use on small cellular therapy containers can also be reliably produced with that same

thermal printing technology. While not designed for page printing, thermal printing is suitable for bar codes, text, and one-color graphics on labels or on tag stock.

Indeed, it is precisely the quality of the symbols generated, as well as symbol durability, that has positioned thermal printers as the overwhelming choice of blood banks and transfusion services around the world. The purpose of this paper is to help transfusion medicine professionals make informed and objective choices regarding ISBT 128 label printing.

2 Thermal Printing Technology

There are two types of thermal printing—thermal direct and thermal transfer.

Thermal direct printing requires the use of heat-sensitive label stock. The print-head, which is typically mounted above the label stock in a printer, activates the heat-sensitive coating on the material, which blackens where it was exposed to heat. Thermal direct printers use no ink, toner, or ribbon.

Thermal transfer printing uses a ribbon from which ink is transferred under heat and pressure to the label stock. The graphics below depict the mechanical similarities and differences.

Figure 1 Thermal Direct

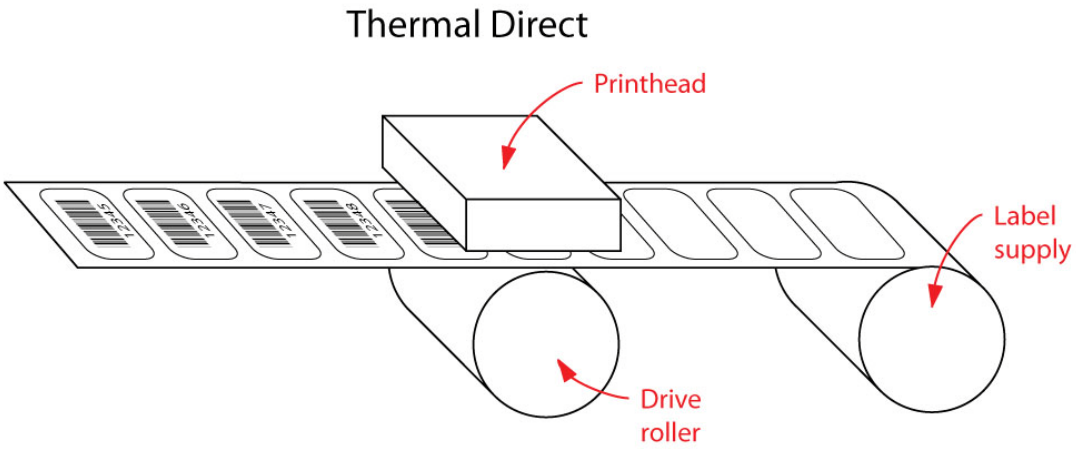
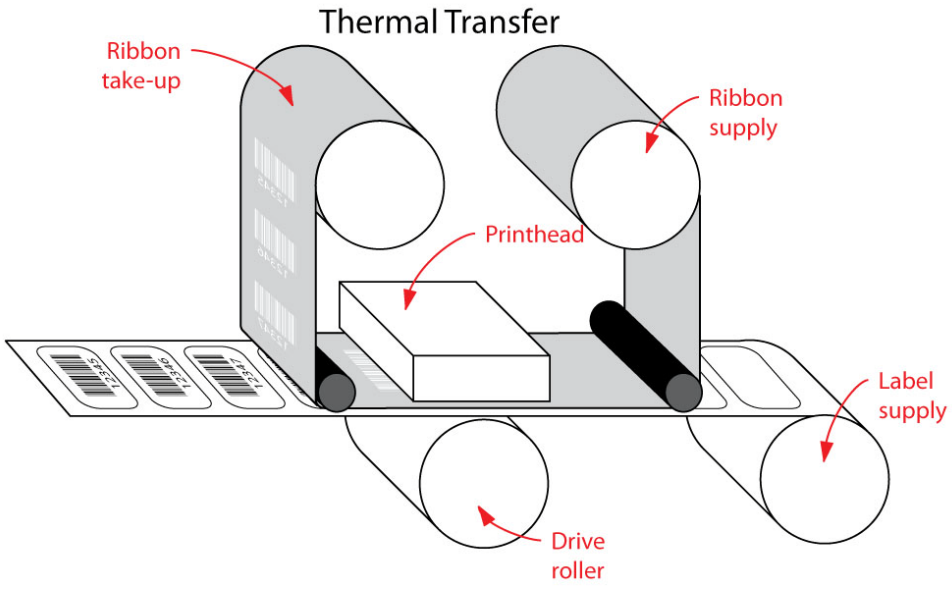


Figure 2 Thermal Transfer



3 Differences Between Thermal Direct and Thermal Transfer

Clearly, thermal direct printing and thermal transfer printing are similar. They both use thermally-sensitive materials—either ribbon (thermal transfer) or the label stock itself (thermal direct)—and use the same type of print-head to create the image. They both create scannable bar code symbols efficiently and effectively; that is primarily what they were designed to do.

The most obvious difference, as mentioned above, is the use of a ribbon in thermal transfer where none is required in thermal direct. In fact, most thermal transfer printers can also print on thermal direct materials; this is often referred to as 'dual mode'. In thermal direct mode, the print-head images directly onto the thermally-sensitive stock, and the ribbon supply and take-up reels are simply not used.

3.1 Thermal Direct

Because thermal direct printing requires heat-sensitive label stock, it is prone to fading over time, as it is exposed to heat and/or light (UV radiation). Exposure to harsh chemicals might also cause the image to fade which, unfortunately, might render the bar code symbol or text unscannable or unreadable. This is unacceptable within transfusion medicine, which relies heavily on bar code identification of products that might require long-term storage such as rare blood units.

In a hospital setting, thermal direct printing might be acceptable for the short-lived label requirements of unit-dose packaging, bar-coded patient wrist bands, and so on. In addition, many receipts, shipping labels, and tickets can be economically printed via thermal direct printers, as well as pick tickets, coupons, name tags, and visitor passes. Thermal direct printers only print in black, unless a special stock is used which allows the production of 'spot color' only in pre-defined and consistent locations on the label. The printing is not as crisp as that of thermal transfer ribbon printing. Over time the labels will darken, particularly when subjected to heat and sunlight. Thermal direct printing is popular in the food industry, because most items are stored away from heat and sunlight, and the label shelf life is typically quite short. The primary benefit is the potential of an overall lower cost because ribbon is not required.

3.2 Thermal Transfer

A thermal transfer printer is capable of printing on a much wider range of label stock than thermal direct printers, because there is no need for the stock to be heat-sensitive. More durable materials—such as polyesters, polypropylenes, and other synthetics—provide much better resistance to adverse environmental conditions than most thermal direct stocks.

Thermal transfer ribbons can be different colors, although black is required for the best bar code scannability. If the user desires to print multiple colors simultaneously, special printers are available that accommodate multiple ribbons. The cost of these printers is higher than a standard thermal transfer printer, which uses one ribbon.

Thermal transfer printers can print on paper, film, and even foil substrates. This enables labels produced via this technology to survive a wide variety of end-use environments. It is critical that the media (label stock) be carefully matched with the ribbon to ensure high quality and durable images. It is not the case that any ribbon can produce good quality results on any label stock. Ribbons come in three basic types: wax, wax/resin, and full resin. It is important to work with an experienced supplier when making material and ribbon choices. Within the blood bank application, any label stock destined for use on a blood bag may need to meet regulatory requirements. For example, in the United States label stock must comply with US FDA 21 CFR 175.105 to ensure adhesives do not leach into the blood bag with deleterious effects.

It is critical for the transfusion medicine professional to select the right combination of label stock and ribbon for optimal results. Working with an experienced label vendor can be a great value. It is possible for the right material/ribbon combination to withstand a fairly wide range of temperatures, along with exposure to UV, and chemicals used in cleaning up blood spills. With the right adhesive, labels will remain adhered to the blood container even through centrifugation, refrigeration, and freezing.

While there are similarities between the two print technologies, there are also subtle differences between them that need to be understood before a selection is made for the specific needs of the end-user.

Consider the following questions concerning your application. If the answer to any of them is 'yes,' it's likely that thermal transfer would be a better choice.

- Will you ever need to print labels in colors other than black?
- Do the labels need to be scannable or have a shelf-life of over one year?
- Will you be printing high density bar codes (module widths of 10 mils or less)?
- Will the labels be subjected to heat, sunlight, moisture, solvents, or abrasion?

4 Selecting the Right Printer

Once the decision is made regarding thermal direct vs. thermal transfer printing, the next step is to find the appropriate printer model. The following questions will help make the decision:

- What is the label usage per day? If usage is more than about 500 labels per day then an industrial printer (sometimes called a 'table top') should be considered. If usage is merely a couple of hundred labels a day, then a small (sometimes called a 'desk top') printer should be considered.
- What is the maximum label width and length? What is the minimum label width and length? Some printers can handle wide-width labels, but there's no reason to pay a premium for a 6" wide printer, for example, when the widest label required in your application is 4".
- Because ISBT 128-compliant labels contain small text (such as some FDA-required warnings), a 300 dot-per-inch (dpi) resolution is recommended. While these high-density printers may cost a few dollars more, the difference is minimal, and the difference in bar code and text quality justifies the small additional expense.
- Consider connectivity—does the printer need to be connected via USB, parallel, serial, or Ethernet? Some printers come with many of these connectivity alternatives as standard; others offer them only as an added-cost option.

Another issue is the operating mode of the printer itself (regardless of thermal direct vs. thermal transfer). There are three basic modes of operation for most thermal printers:

1. *Straight through*. In this mode, the printer runs the stock through the printer without any attempt to spool the result, or to separate adhesive labels from the backing. The result is a long strip of printed labels still affixed to the backing paper (called 'release liner);
2. *Self-strip*. Sometimes referred to as 'peel-and-present,' or 'dispense,' this mode individually ejects most of the adhesive-backed label from the printer after printing. This enables the user to easily take the label off the liner (which is typically wound up into the printer for later disposal), apply the label, and then remove the next one from the printer. Printing is inhibited until the previously-printed and presented label has been removed from the liner;
3. *Batch*. In this mode, the printer spools up the media after printing. After the entire roll of blank stock has been printed, it is removed from the printer.

Many blood banks label individual units one at a time; the label contains specific Product Code, ABO/Rh, and expiration date information intended only for that specific unit. The peel-and-present mode is often used in this situation. For this end-use, it is important to confirm that the label stock is sufficiently rigid to be removed easily from the release liner. Flimsy or excessively compliant stock may fall back onto the release liner prior to removal, especially when printing 4" x 4" labels. This makes removal difficult, and increases the likelihood of labels folding over and sticking to themselves.

5 Print Heads

All thermal printer providers agree that print heads should be considered a consumable, just like labels and ribbons. Regardless of print technology, print heads should be regularly cleaned, and then replaced as needed. Thermal direct labels, which directly contact the print head, will wear the head more quickly than thermal transfer because of their abrasiveness. Thermal transfer labels contact the ribbon directly, rather than the print head itself. The ribbons are slip coated to slide easier, create less abrasion on the print mechanism, thus reducing wear.

