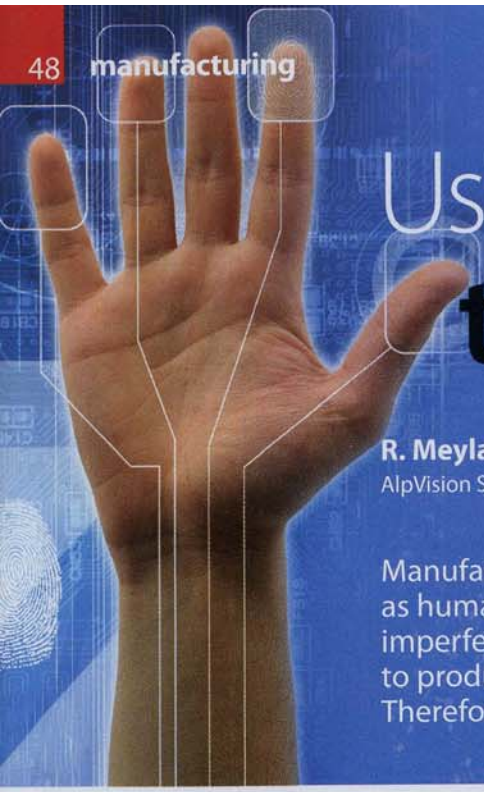

Using Manufacturing Marks to Identify Counterfeits

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Manufactured objects can now be identified by individual characteristics, just as humans can be identified by their irises or fingerprints. Using microscopic imperfections generated by the manufacturing process and the raw materials used to produce an object, digital imaging technologies can generate a unique "imprint." Therefore, it is possible to identify and to trace a medical device during its entire life.

The technological background

Images of distant planets are received on Earth even though they are sent by extremely low power transmitters millions of kilometers away. During its journey to Earth, which could last several minutes or even hours, the imaging information is polluted by an enormous amount of "noise," which is generated by billions of electromagnetic cosmic sources. The intensity of this "noise" is therefore much greater than the original image signal.

Today, high-tech digital imaging technology is so powerful that it is capable of extracting the useful image out of the mass of noise. Specialists say that the technology can analyse a signal with low signal-to-noise ratio even though it is like finding an extremely small needle in a big haystack!

Figure 1: Image of a metallic ring taken by a standard digital camera. Parts of this "noise" are significant imaging elements, which characterise the uniqueness of this object.

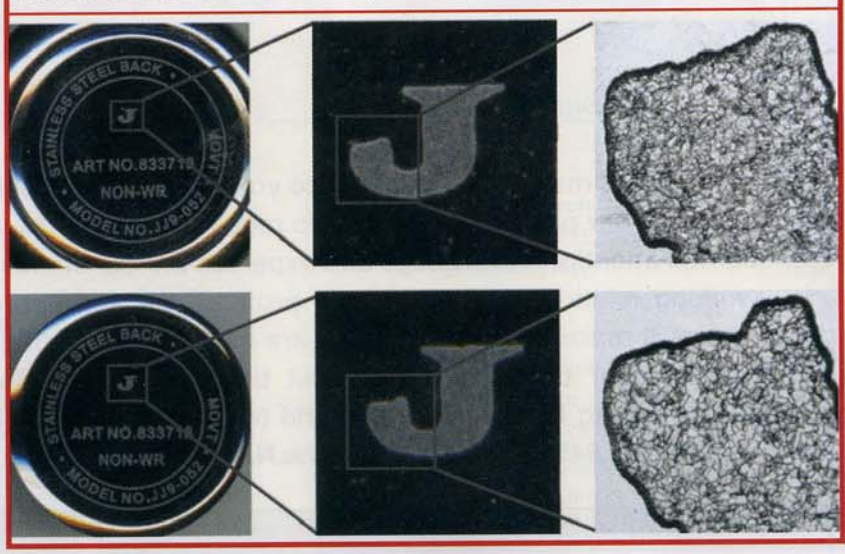
Identifying a manufactured object

Machining or moulding leaves unique "imprints" related to the tooling and the raw material (plastics, metals) used to produce an object. These microscopic differences can be used to identify the object, if there is a technical means to capture them. In fact, they are as identifiable and unique as human fingerprints or iris patterns.

Nowadays, consumer electronic devices such as flatbed scanners, digital cameras and camera phones are powerful enough to capture an image of an object in sufficient quality. Although at first glance images of a series of objects may seem identical, high-tech digital imaging can identify "hidden" significant differences by using mathematical algorithms similar to those used in identifying an image lost in cosmic "noise" (Figure 1).

To identify a specific object amongst millions, the digital image of an object can be compared with the original "imprint," which is captured when it exits the production line. This process identifies a

Figure 2: Details of two metallic objects that were initially evaluated as identical, but with visible differences seen under magnification performed by a standard flatbed scanner.



counterfeit object because its digital image will not be among the images produced by the original manufacturer. Because a genuine individual object can be identified, the process can provide full traceability of an object during its life. This patented solution was initially developed to help Swiss watch manufacturers fight against counterfeiting (Figure 2).

Medical devices are targets

Nowadays, any single object is a potential target for counterfeiting, it will have some value as an individual object or when mass produced. Many solutions have been developed to help manufacturers distinguish their genuine products from fake ones. Marking processes include radio frequency identification, laser engraved encrypted serial numbering and two-dimensional data matrix barcodes. Taggants such as chemical or material tracers can also be included in the manufacturing process. Unfortunately, the current criminal counterfeiting industry is as well equipped as genuine manufacturers. Therefore, these additional markings can also be duplicated. Additional security marking features also increase the cost of manufacturing. First, security manufacturing processes have to be implemented to manage the security elements. Second, production lines have to be modified to include these features in the process, which could be sensitive to heat, light or other environmental conditions. In the case of taggant or chemical tracers, the verification process requires specific tools or the costly involvement of forensic laboratories. Beyond this, add-on features applied to medical devices must also go through the medical certification approval.

Individual identification

The image of a medical device generates an equivalent of a family photo taken by a digital camera of approximately 1 mega pixel. Once compressed by digital imaging proc essing, it is reduced to 50 kilobytes. Therefore, today, an off-the-shelf personal computer equipped with 500 Gigabyte hard disk (disk priced approximately €150) is capable of storing 10 million images. This makes the storage of a digital image of each individual medical device or component highly achievable.

Some digital imaging acquisition processes use coherent (laser) light; others can use normal off-the-shelf scanning or camera devices. The ability to identify one image among these 10 million is again a digital imaging computing issue. Sophisticated mathematical and computational processes can retrieve the originals in seconds. If →

→ the image sent for checking is found not to have an original counterpart, the tested product is deemed to be a fake.

Mobile phones equipped with a digital camera are now adequate to photograph some objects for analysis.

Using the Swiss watch example

Because watches and medical devices are metal or plastic based, the solution developed to identify Swiss watches easily applies to many medical devices. The manufacturer simply captures a digital image of each manufactured object as it exits the production line, which has not had to undergo any modification. Once processed the captured images are stored on a secured computer server. Later, anyone in the field who wants to authenticate or identify an object can capture the digital image of the object using an off-the-shelf flatbed scanner or digital camera. This image is sent to the secured server via a secured Internet connection. Mobile phones equipped with a digital camera are now adequate to photograph some objects and send the image to the secured server for automated analysis. In only a few seconds, the mobile phone receives the return verdict: "genuine" or "counterfeit."

Technology to fight counterfeiting

Digital imaging technology is part of the numeric revolution that has already dramatically affected the way we consume films, images and music as well as how we are communicating and obtaining information worldwide. The constant progress of consumer electronics puts powerful tools in everyone's hands. The criminal industry of counterfeiters has perceived the potential of these technologies to develop their business. Now the same tools will also play an important role in fighting them worldwide. mdt

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