



Connecting the Real World to the Digital World

Developing a System of Unique Device Identifiers
FDA Docket 2006N-0292
November 8, 2006

Background

InfoGlyph USA Inc. is a provider of a closed system used for the identification, authentication and tracking of items. We connect the real world to the digital world through the technology. Our customers use the technology in various fields and applications, including automated pathology applications, automotive marking and tracking and security applications with an emphasis on authentication. The technology is robust and provides users with many features, permitting them to achieve key business objectives. The technology can be deployed via a wide range of delivery systems from direct printing to laser, the latter including both engraving and the use of laser marking materials. The recovery operation can be based on an inexpensive web camera and various hand held devices. To enable global deployment we have developed Internet based operations which only require a web camera and Internet access.

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

Careful consideration must be given to the system and the identifiers to insure that the multiple dimensions of the system architecture are fully considered. Future growth in new devices can be added to the system without causing problems for the system or its deployment. An identifier that reliably connects the device to its associated data under a wide range of conditions that the device will see over the life cycle of the system must be required.

The device should be identified to the level of common use. This means that how it may be deployed or used should determine the level of identification. This approach would apply to an implant device, medical instrument or item of support equipment used with the patient.

2. What should be the role, if any, of the FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

Certainly, the FDA should be involved, but its exact role must be clearly defined ahead of time to insure that potential suppliers are fully informed. And since no specific guidelines for marking and tracking have been established for the myriad items that are in question, it is paramount that the decision maker on the FDA

side of the equation should be fully versed in the technical aspects of the various solutions that will be recommended

3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?

There are a variety of incentives for the adoption of unique device identifiers. A major incentive would be improved inventory management at the hospital and better warranty management of equipment at the hospital or clinic level. Recall management by manufactures would be better managed at lower cost by knowing the specific items to be recalled. One only has to look at the Ford Firestone tire fiasco to see how billions of dollars were lost by an inability to manage a recall. It should be noted that the after-market for tires fares little better with about 4% of new tires being properly registered. With a UDI system in place the location of the device can be known by the management systems of both the manufacturer and the hospital deploying the device. This provides a clear chain of custody insuring better opportunities to protect patients.

4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

- Symbology/information and data conveyance and capture

A major issue here is the extent to which the symbology must provide for survivability in a variety of potentially destructive environments and the length of time during which symbols must be recoverable after they are written. For example, if a symbology defines a portion of the area of a symbol to be the area for clock marks, then if that portion of the symbol is destroyed (or partially destroyed) by the action of the environment over time, then the symbol may not be readable, even if the data encoded in it contains forward error correction codes or other forms of redundancy.

- Different device types – definition of and identifying those that are critical to patient safety

No comment from InfoGlyph

- Different surfaces and difficulty in marking/labeling the myriad of surfaces.

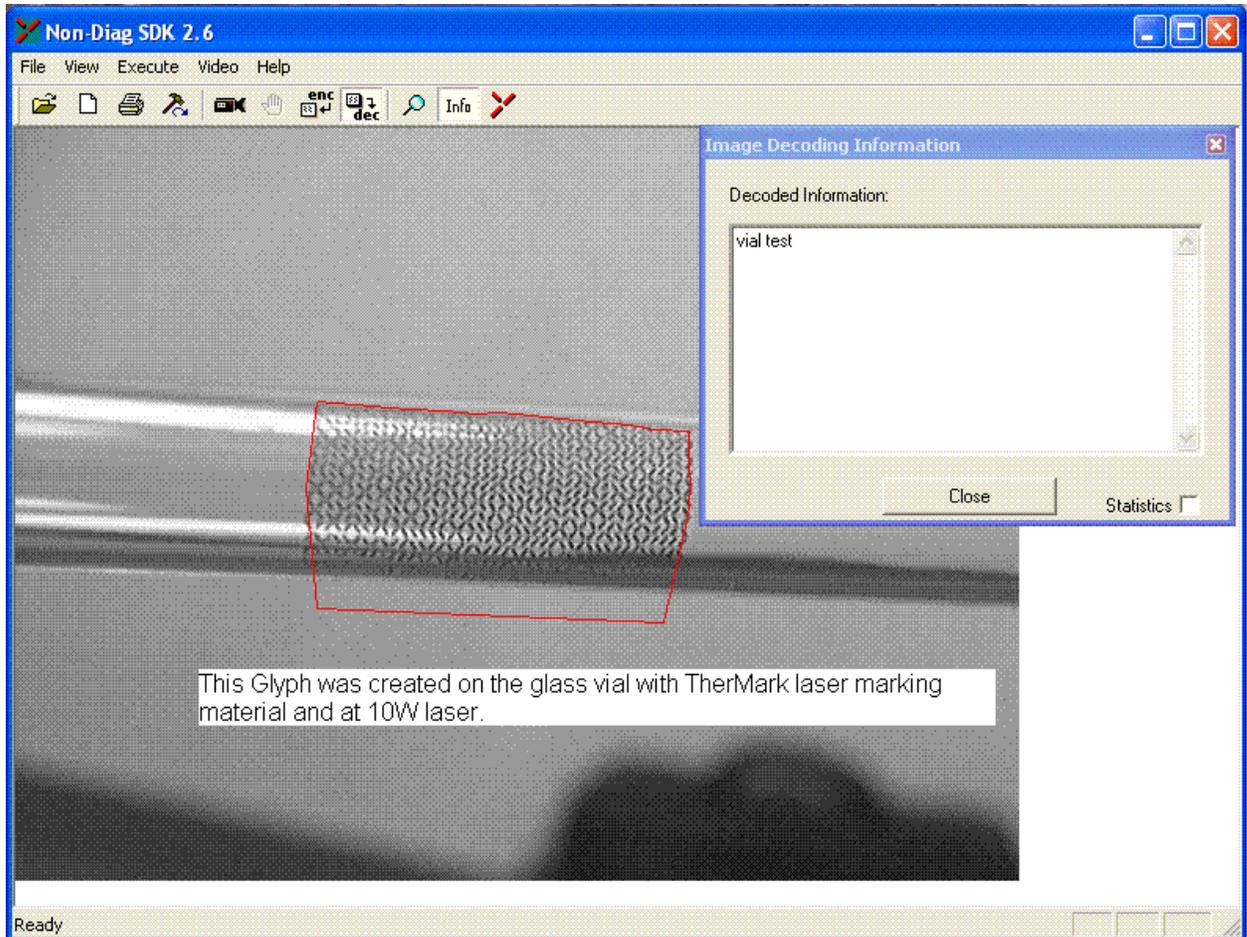
The ability of a symbol to be read depends on many factors, including the specification of the symbology, the quality of the writing equipment, the surface on which the symbol was written and the lighting conditions and

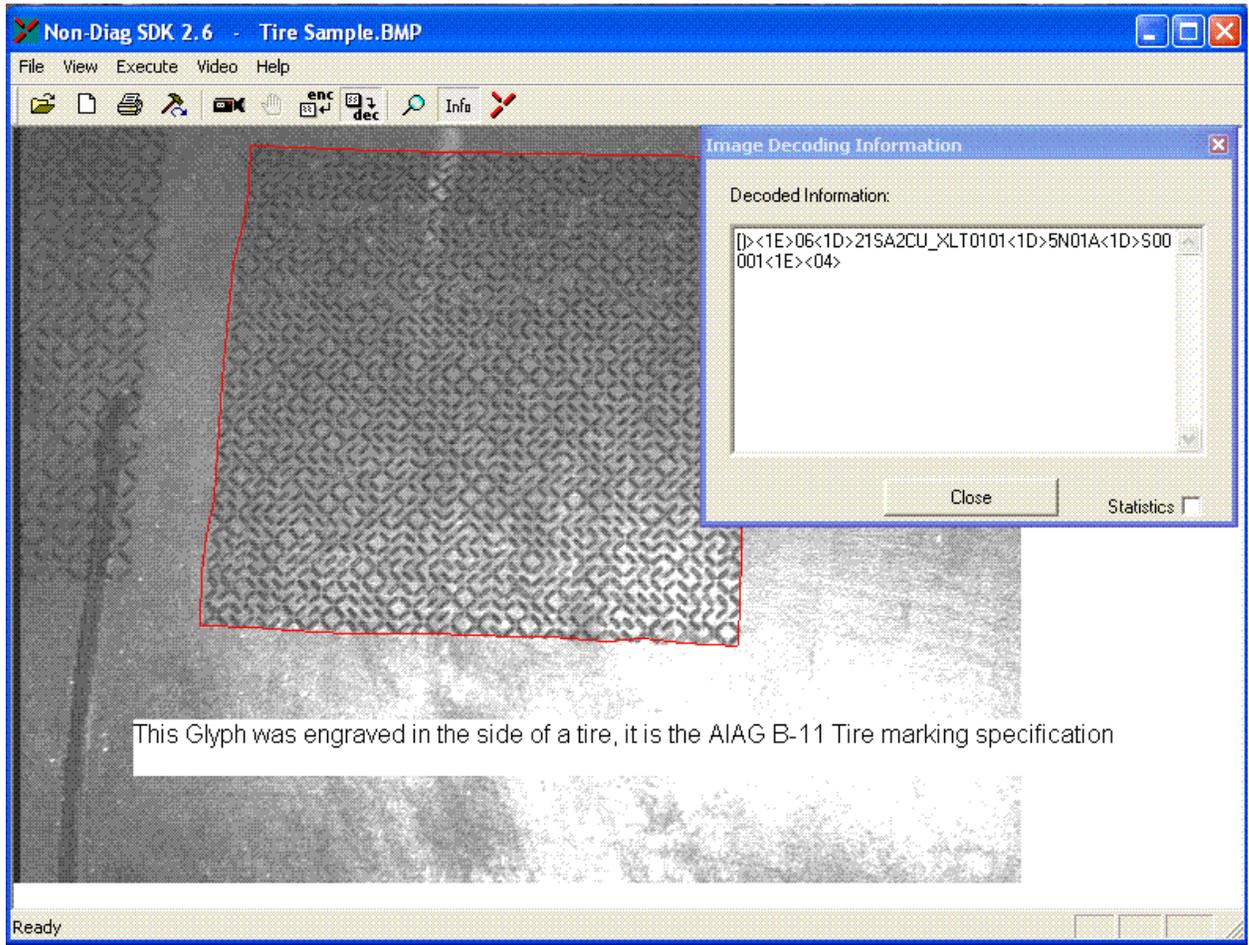


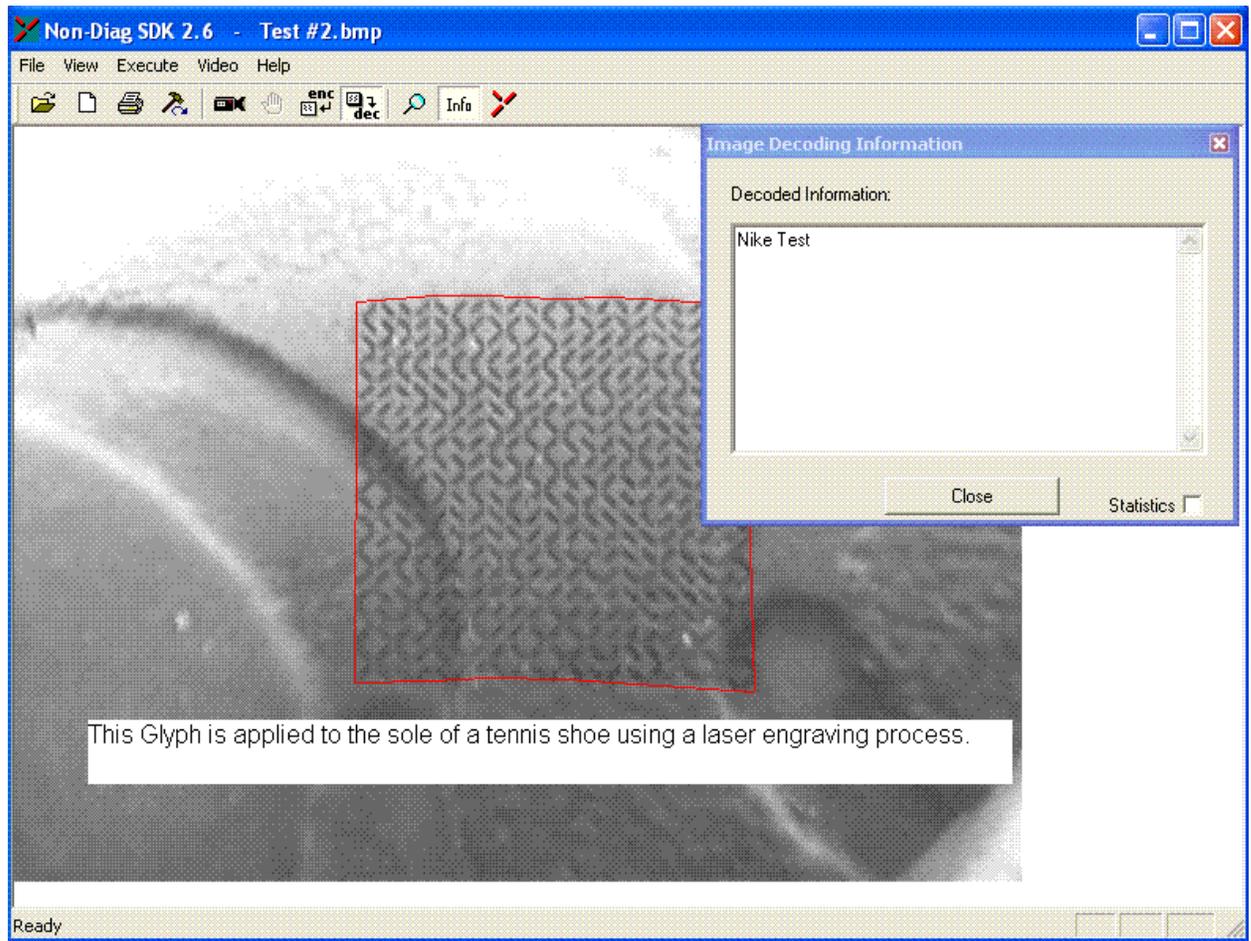
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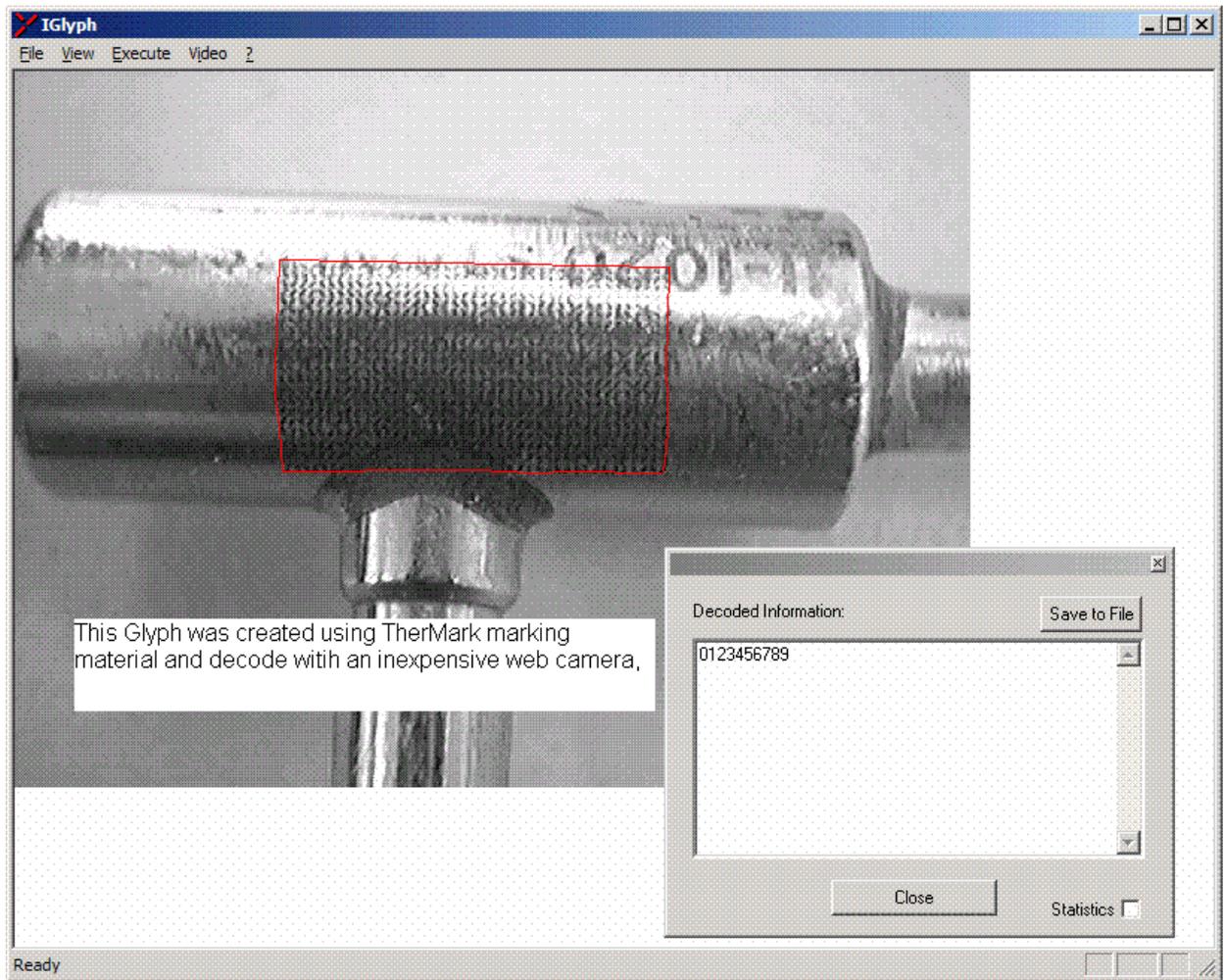
equipment in effect when the symbol is read. The system requirements should specify the range of all these constraints, including surfaces,

One of InfoGlyph's strengths is marking and reading on a wide variety of substrates. InfoGlyph has been applied to a wide range of substrates from tires to metal, glass and ceramic surfaces. It can be applied to curved and rough finishes and decode reliably.

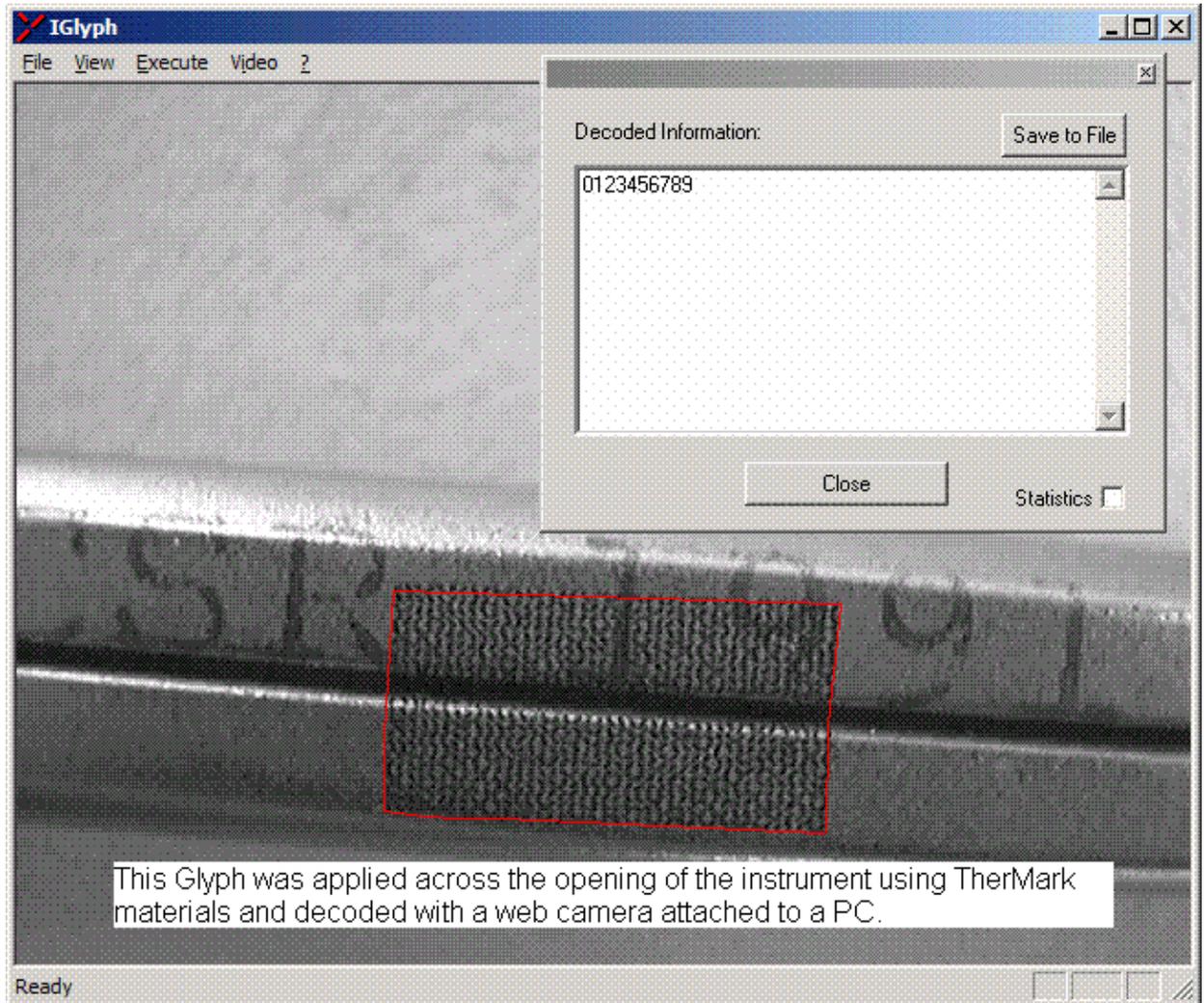




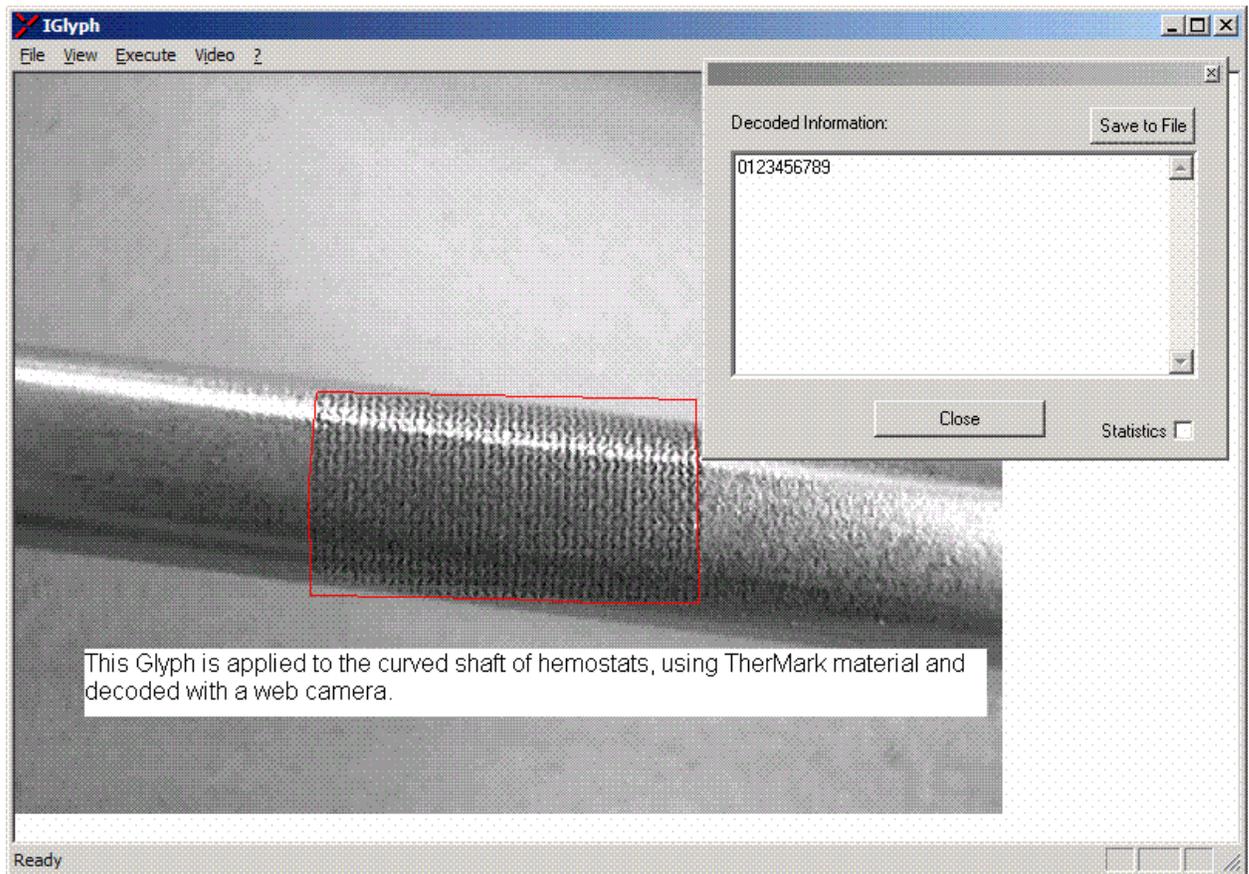




Medical Instrument



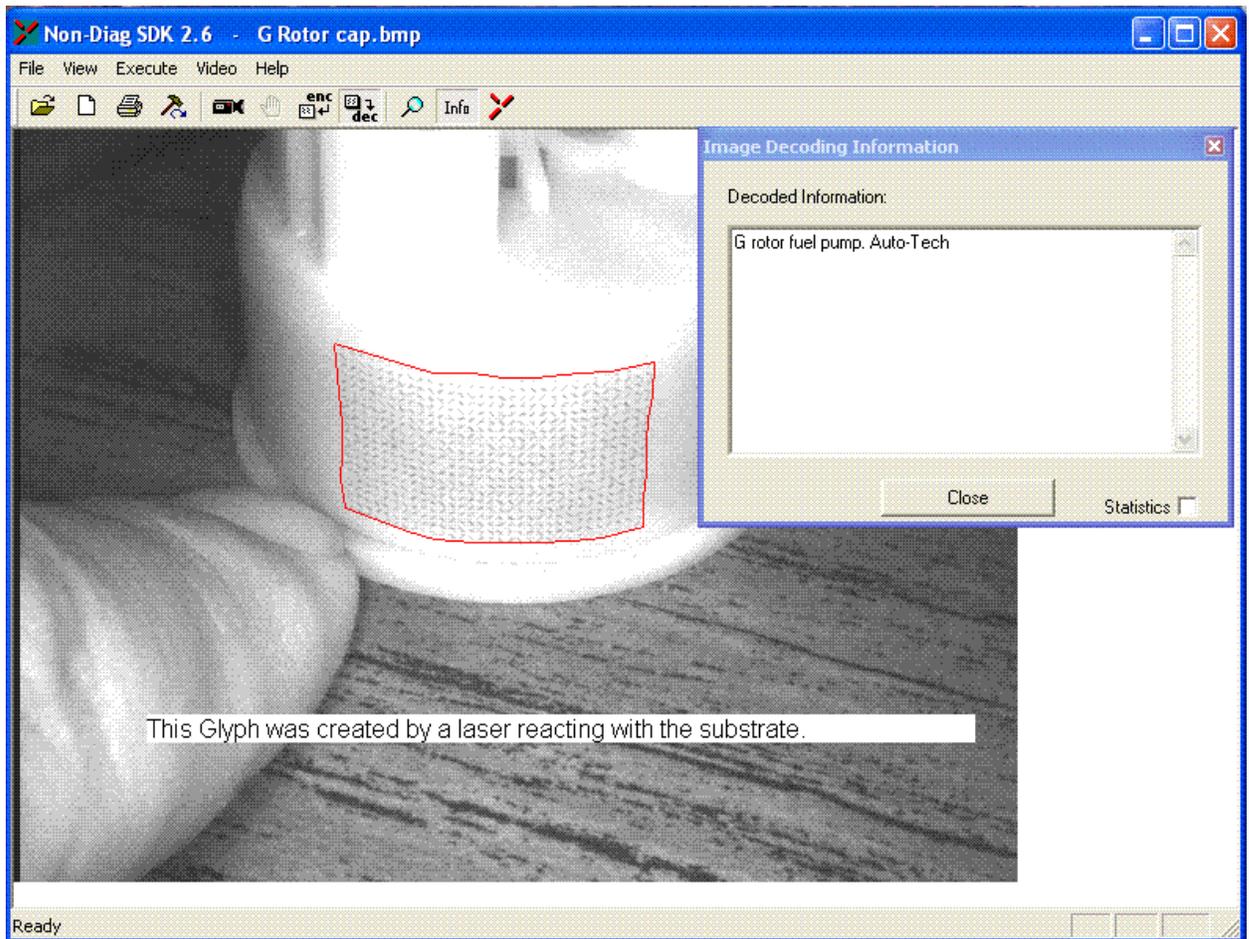
Medical Instrument

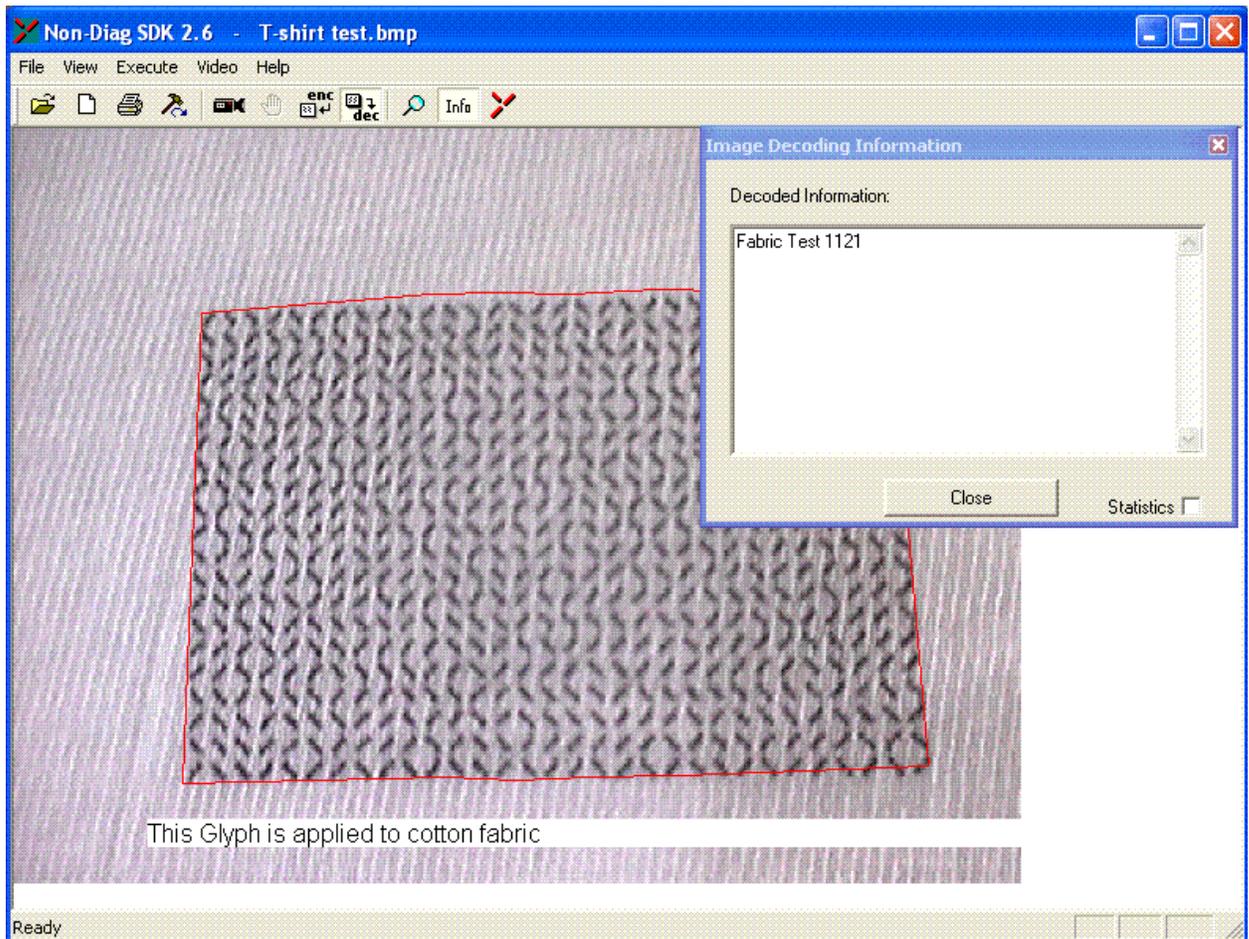


InfoGlyph can be used with a range of marking technologies from printing to laser marking and laser engraving see the attached images for samples of the various surfaces that have been marked and read with the InfoGlyph technology.

- Different marking methods

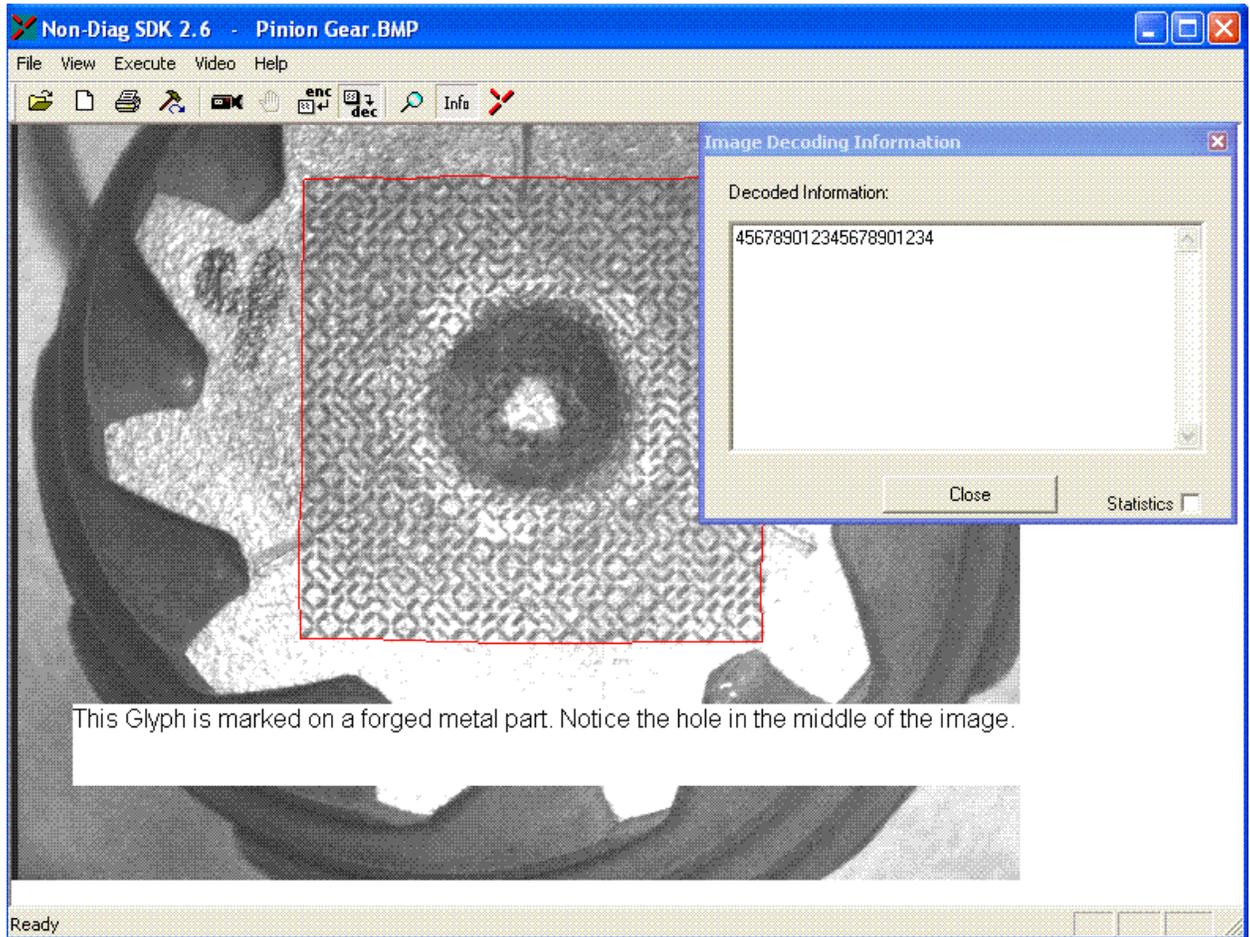
InfoGlyph can be delivered via a wide range of marking processes for printing to laser marking, laser engraving and magnetically. The images below were created via direct laser engraving, laser marking material, Thermal printing and magnetically.





This Glyph is applied to cotton fabric

Digital Printing on Fabric.



Laser engraved image.

- Cost – both capital investment and operating costs
No comment from InfoGlyph
- Manufacturing adoption and implementation timeline
No comment from InfoGlyph
- End user (hospitals, patient care facilities) adoption and timeline.
No comment from InfoGlyph



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5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided

Our customers deploy InfoGlyph technology integrated with their management systems. The general approach is to use a unique identifier, encoded within a glyph, to connect the item back to specific data at a centralized data repository. They deploy the technology via laser marking and Thermal printing

6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

No Comment from InfoGlyph.

7. At what level of packaging (that is, unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?

No Comment from InfoGlyph.

8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

No Comment from InfoGlyph.

Implementing Unique Device Identifiers

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

InfoGlyph believes that the readability of the Identifier is a critical requirement and that the data contained in the mark should be at least a unique identifier that will permit the recovery of the key and relevant data from the various systems. These systems should be structured to support a wide range of access methods with the appropriate security.

10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

The UDI minimum data would be characterized as its public face. This information can be made available to the public via an internet based service. This is enabled such that the user may only need an inexpensive imager device (web camera) connected to a PC to capture the data which is routed to a clearing house function which decodes the data to determine the manufacture of the device. The manufacturer responds with the public information. All other information is in a secure system, and the user must pass security checks to obtain any other information.

11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

The AIAG, and DOD are using the human readable data because current symbologies are not that reliable for reading. There will be space issues to be addressed in the deployment; that is why the appropriate technology for each device is selected to meet the requirements for reliable identification.

12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred, and if so, what type and why? Should the bar code be compatible" with those used for the drug bar code rule? If yes, why? If not, why not?

InfoGlyph believes that the requirements may dictate the best approach to the correct solution. Ideally it would be most efficient to use a single technology; however this may not be the case. It should be a critical requirement for readability over the life of the marked item with the most reliable technology. Insuring that information can be recovered over the life cycle must be a high priority requirement. If this objective is achieved perhaps other application can be migrated to this solution where appropriate.

UDI Benefits and Costs

13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event re-



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porting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

No comment from InfoGlyph

14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation, and use of a UDI system? Please submit detailed data to support these cost estimates.

No comment from InfoGlyph

15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

No comment from InfoGlyph.

16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?

No comment from InfoGlyph

17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?

No comment from InfoGlyph.

18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside bar-coding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?

No comment from InfoGlyph.

19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic in-



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ventory control and recall completion purposes? How costly are these advancements?

No comment from InfoGlyph.

20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?

No comment from InfoGlyph.