VAL*ID*ATE™ Permanent Marking for Glass Vials and Syringes

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Topics Covered

> Why the VAL*ID*ATE ™ solution ?

> VAL*ID*ATE ™ marking solution, product mark characteristics

> VAL*ID*ATE ™ production solutions

Why VAL*ID*ATE™ Solution is needed?

> Counterfeiting is an increasing problem
> No competing marking solution offers a simple way for end users (consumers) to validate authenticity
> RFID requires extensive infrastructure to implement
> Ink jet technology can typically be copied by counterfeiters
> RFID tags are still an expensive solution and not ideal for all products
> Ink jet marks are erasable and messy in production
> Ink jet printers with UV flourescent inks are cleaning intensive
> Marking glass with lasers is slow, potentially damaging to the glass and provides a low contrast image

Counterfeiting Protection

> Anti-Counterfeiting Marking System Needs

- On-line in production facility
- Tamper proof once marked
- Must allow variable data to be marked with some legible features
- Human and machine readable features
- Verification of authenticity at end user point of use
- Must allow electronic batch and lot acquisition
- Supply chain control to provide maximum difficulty for counterfeiters to duplicate mark features on counterfeit product.
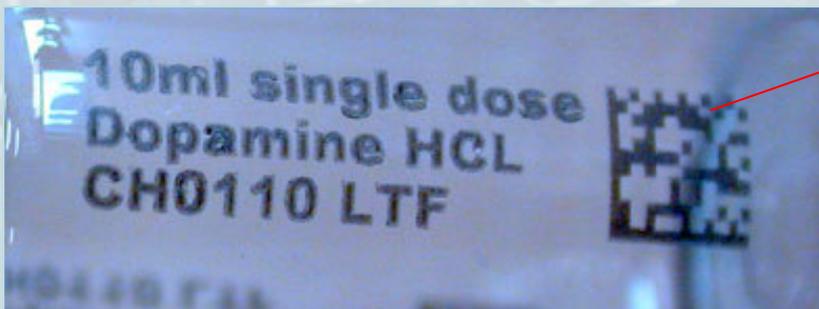
ATS/TESA VAL*ID*ATE™ Marking Solution

> ATS and TESA have partnered to provide a glass vial and syringe marking system

> Product Name: VAL*ID*ATE ™

> Characteristics

– Non-erasable mark allows end user verification of authenticity

– Imbedded capability to apply overt and covert security features

– Ability to mark glass without a separate label

– Can mark either circumference or the bottom of the vial

– Data traceability via 2D bar code

> Ideal stand alone or as part of a two tiered anti-counterfeiting solution

VAL*ID*ATE™ Mark Characteristics

> Black colour, non erasable
> Good contrast mark, easily human readable
> Pigment imbedded in glass molecular structure
> Human readable as well as 2D or RSS bar code
> Variable information can be printed (eg. lot/date code)
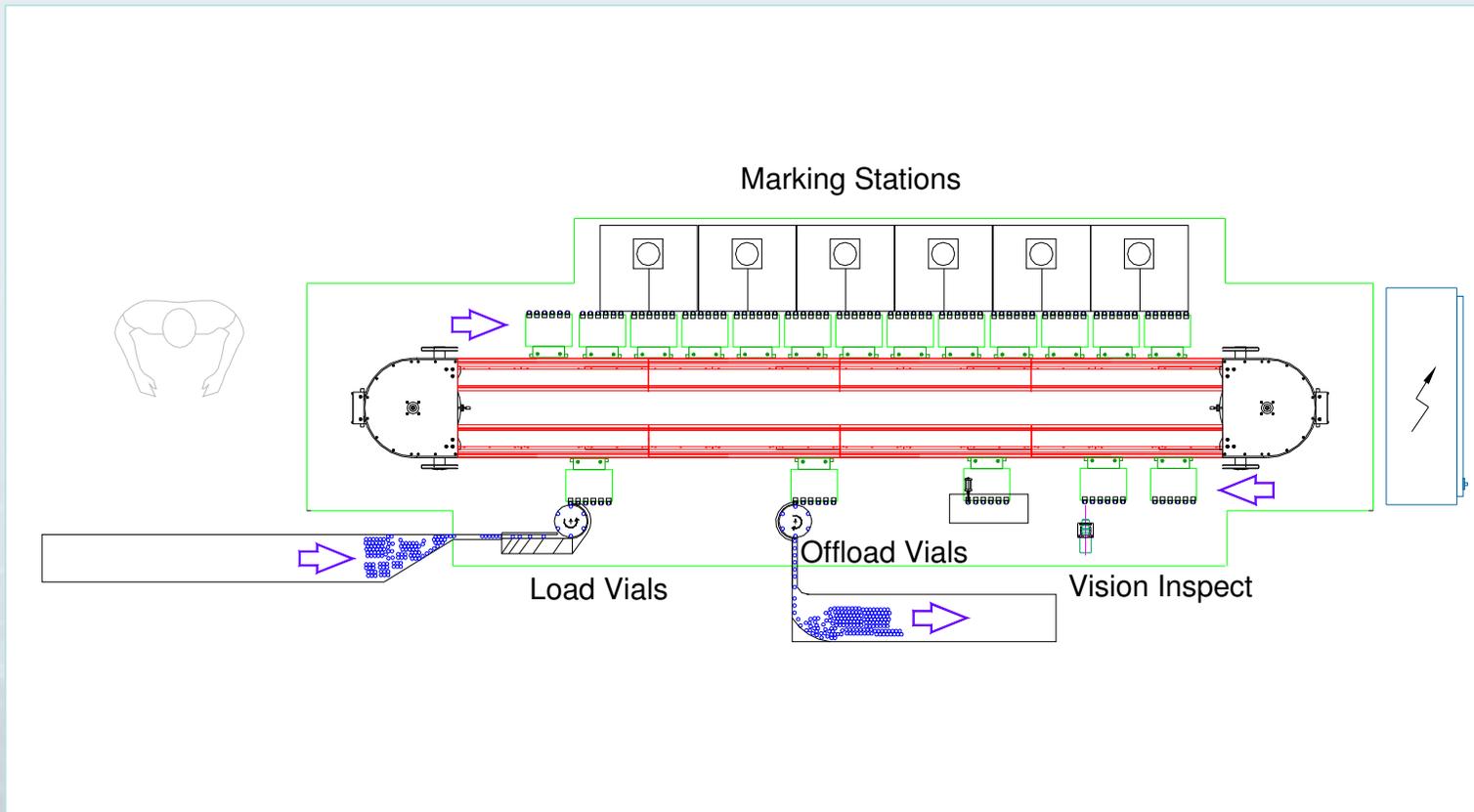> Company or drug logos can be printed
> Microscripting possible

Potential Applications

> Vial marking after filling and capping

> Integrated labeling station

> Vial or syringe marking prior to washing station

> Prefilled syringe marking including

   – Security markings

   – Label, logo etc.

> Glass syringe marking of graduation marks

> Mark can be put on side of vials/syringes or on bottom
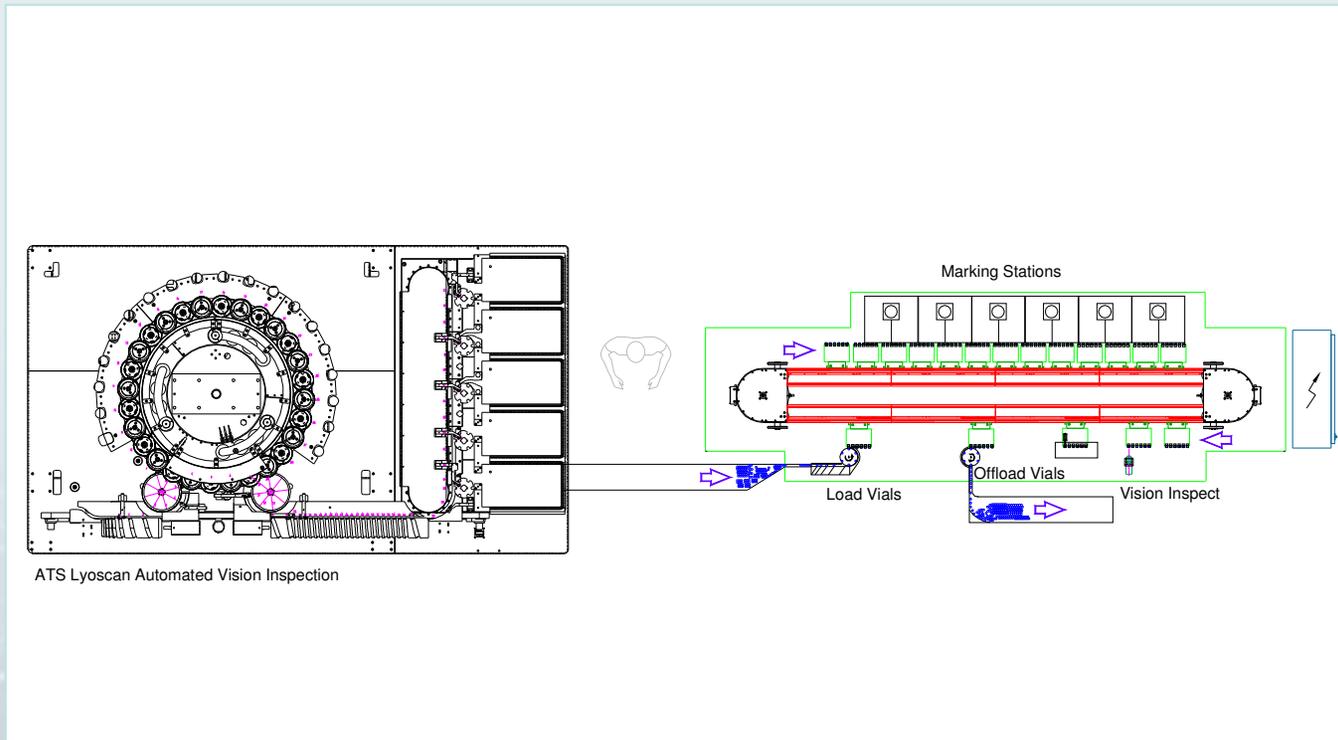
Sample VAL*ID*ATE™ Production Solution

Marking Stations

Load Vials

Offload Vials

Vision Inspect

➢ System concept configured for vials or syringes with marking on possible on many different glass areas

VAL*ID*ATE™ Production Solution Integration

Marking Stations

Load Vials

Offload Vials

Vision Inspect

ATS Lyoscan Automated Vision Inspection

➢ System concept integrates with upstream or downstream filling and capping equipment and from ATS automated vision inspection technology

VAL*ID*ATE™ Production Solution

Manufacturing Equipment

> Designed and built by ATS in North America and Europe.

> Line speeds of up to 400 per minute

> Information printed on the vial can be configured as the customer desires with lot, date and batch code tracking

> Marking speed: variable depending upon nature of mark

> **ATS Compliant Solutions** can provide up front consulting engineering for cGMP compliant manufacturing concept definition

> Solutions tailored to suit individual customer and product needs

> ATS Supertrak™or Rotary transfer solutions used for material handling

VAL*ID*ATE™ Production Solution

> Lyoscan vision inspection solution can be integrated with the valIDate marking solution

> Controls solutions: ATS MACS PC based or A-B ControlLogix

> Complete data tracking and CFR21 Part 11 compliance

> ATS provides complete cGMP compliant documentation and training

> Integrates directly into the vial fill-finish line
  – Inline concept
  – Off to the side concept
  – After capping and vision inspection or before washing

> System concept provides flexibility to handle variable line rates

> Labeling solution can be integrated into the system concept

ATS