BIODOT

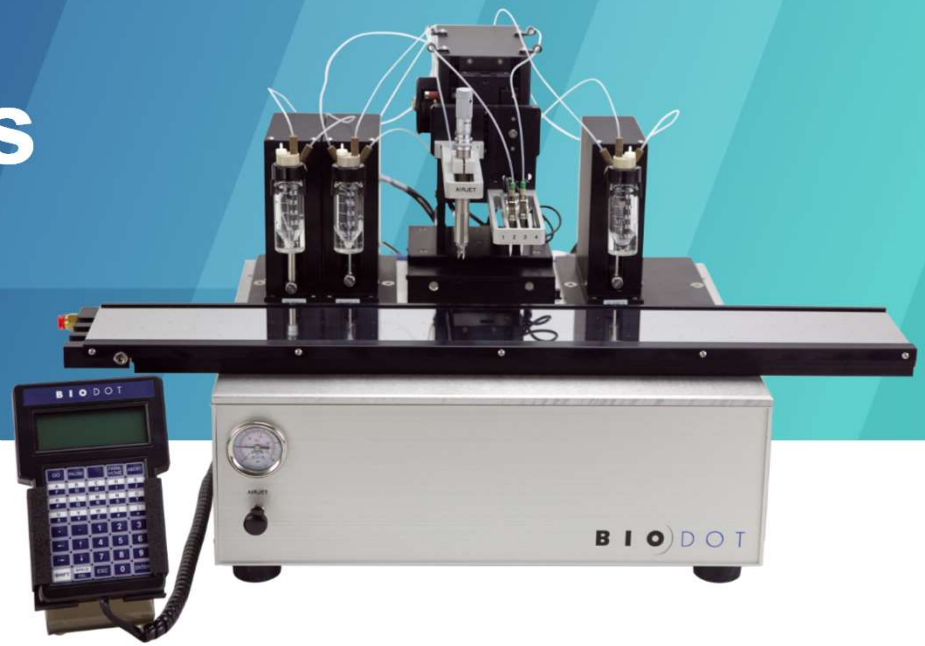
AN ATS COMPANY

Advances in Automation for the Manufacturing Lateral Flow Devices

Presented by:
Rob Rich
Director of Sales, America

August 11, 2025

Equipment and Solutions Provider for Lateral Flow Devices



BioDot Global Locations

BIODOT US

- 70 employees – 22,000 sq ft floor space
- Demo and feasibility facilities
- Innovation core focused on dispensing fluidics and miniaturization of science

BioDot
Irvine, CA

BioDot UK
Chichester, UK

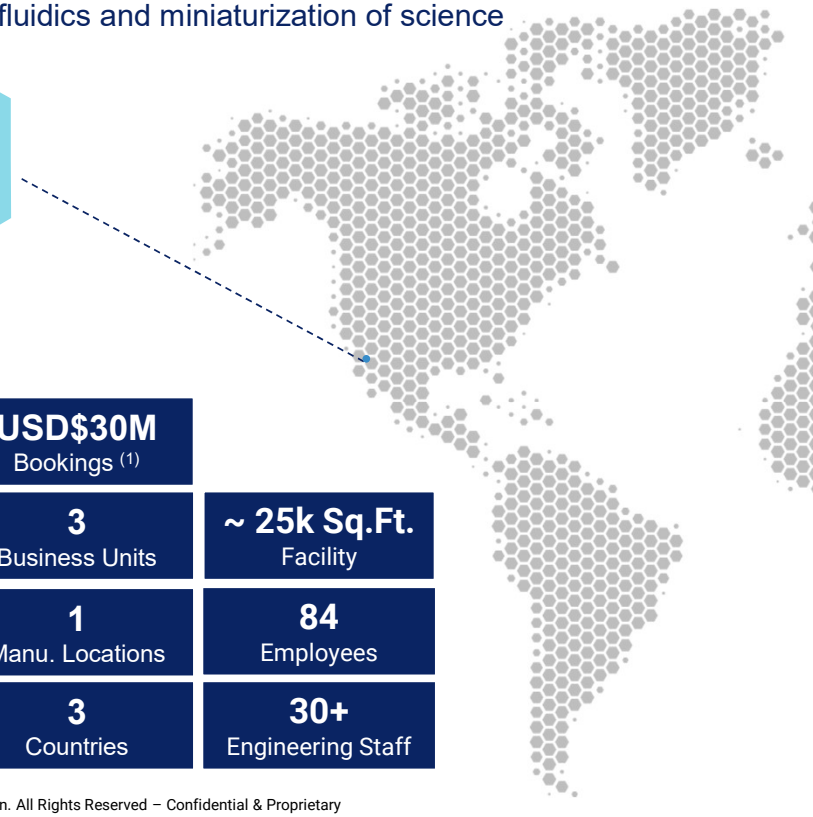
BIODOT UK, EMEA

- 10 employees – 5,000 sq ft floor space
- Demo and feasibility facilities
- Premium sales and support of scientists and manufacturers throughout EMEA

BioDot China
Shanghai, China

BIODOT CHINA

- 4 employees –2,000 sq ft floor space
- Demo and feasibility facilities
- Premium sales and support of scientists and manufacturers throughout China



USD$30M Bookings (1)	
3 Business Units	**~ 25k Sq.Ft.** Facility
1 Manu. Locations	**84** Employees
3 Countries	**30+** Engineering Staff

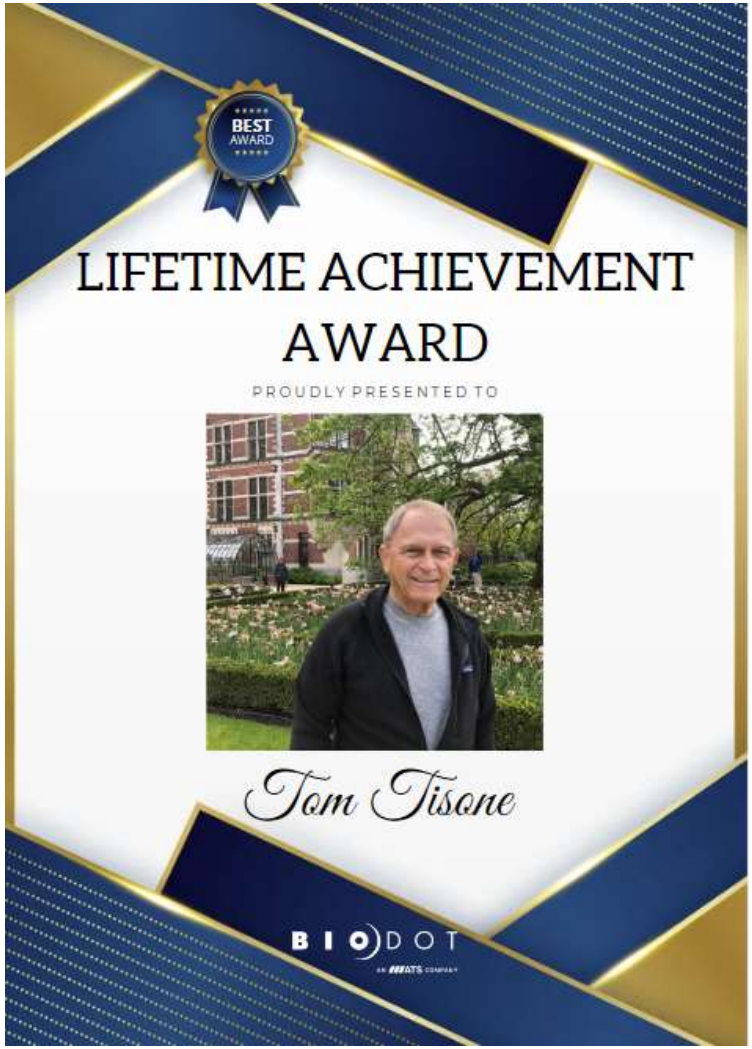
(1) F25


Davis, Sarah
Sankar, Ash
Winter, Thomas
Darban, Holly
Cui, Julia
Kirk, Brian
Kraft, Kelly
Karimi, Azad
Thacker, Simon
Winter, Thomas
Rich, Rob
Severino, Michael
"We are **creating a world** where every **scientist's vision** is met with the **precision** it deserves"

BIODOT 30 YEARS
AN ATS COMPANY

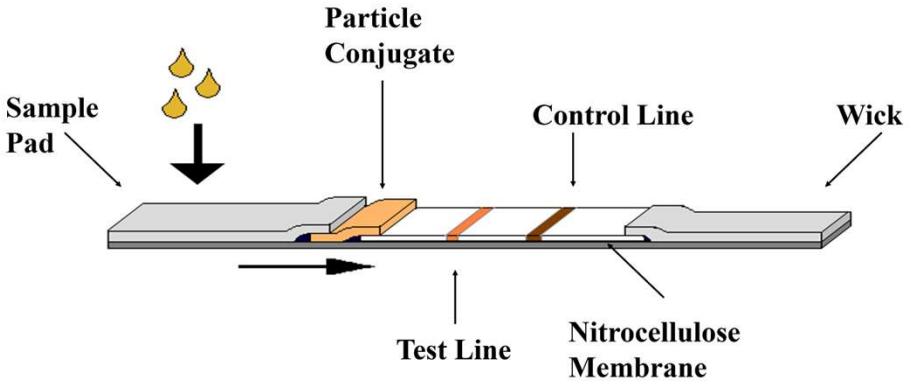
Celebrating 30 Years of Innovation and Success.

- **Lifetime Achievement Award.**
  DCN Dx is honored to present this award to **Thomas Tisone,** founder of BioDot, Inc. whose enduring contributions have left an indelible mark on our industry.
- Thomas Tisone's vision and leadership continue to inspire us as we strive to make a positive difference in the world.



Manufacturing of Lateral Flow Devices

- **Dispensing Technologies**
  - Membrane Test and Control
    - Lines & Dots
  - Sample Pad
  - Conjugate Pad
- **Batch Vs. In-line (Reel-to-Reel)**
  - Why & When
- **Other Manufacturing Strategies to Consider**
  - Tech Transfer
  - CDMO's?
  - Looking to the Future
    - Modularity
- **Are you doing something that is Non-Standard?**



Lateral Flow

Summary of Processes

1. Application of reagents
- Dispense: Test, control, conjugate
- Coat: Conjugates, blocking, other pad treatments

2. Dry
- Objective is to reduce water content to less than 4 % level.
- Used after reagent application processes.

3. Lamination
- Individual layers are attached, using thin layers of adhesive.
- Adhesive layers are prelaminated to plastic backing and cover layers.

4. Inspection / Marking
- Dispensing defects
- Material defects
- Lamination alignment defects

5. Cutting
- Separate into individual test strips: 3-10 mm
- Remove bad parts marked in inspection process

6. Quality Control
- Sample testing of manufacturing lot for functionality

7. Packaging
- Seal test strip in foil pouch with desiccant, pipette, etc

Dispensing Technologies for Lateral Flow

Membrane Test and Control

Non-Contact

BIOJET

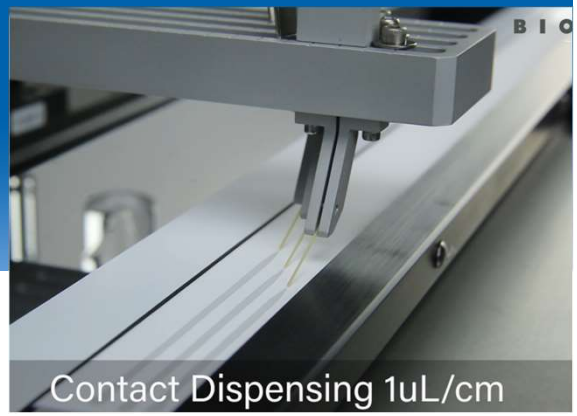
Solenoid valve synchronized with a syringe pump and motion platform.
Drops in the nL to uL.
Lines are created by overlapping drops.

RAINMAKER

Piezoelectric dispensing synchronized with a motion platform.

Prints drop in the pL to nL.
Typically used in multiplexed arrays.

Contact



FRONTLINE

Needle tip contacting membrane surface.

Dispensing Technologies for Lateral Flow

Spray and Dip Coating

Spray

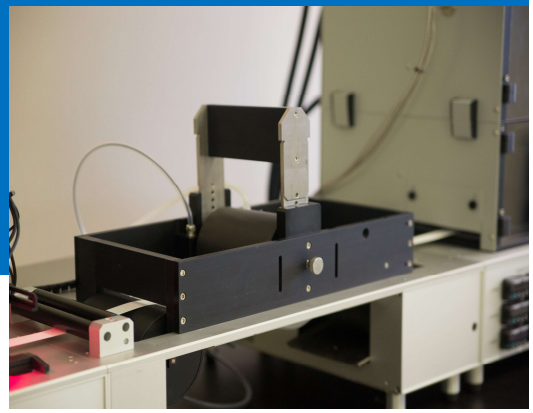
AIRJET

Aerosol spray typically used for conjugate deposition or reagents with larger particles.(line volume= 0.1-24 µl/cm)

Dip Coating

Manual Tray

Immersion track for soaking conjugate pad for batch processing



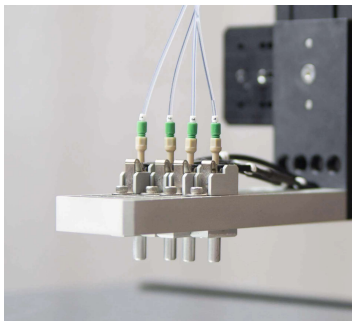
DIPTANK

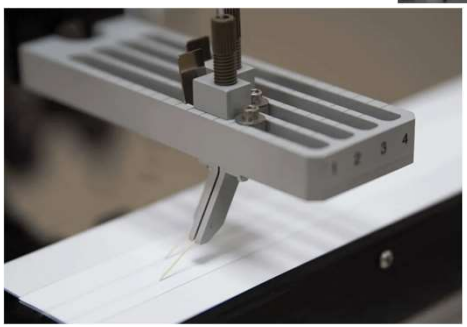
Immersion tank for in-line processing.

Technology Type Considerations

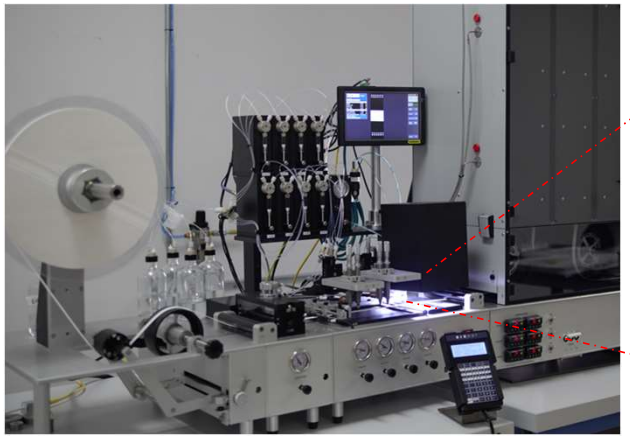
Non-contact vs. Contact

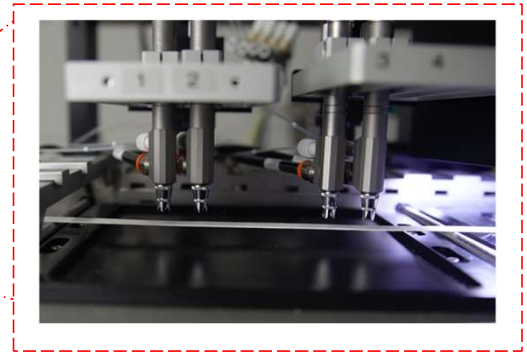
- Comparing non-contact and contact printing
- Non-contact has shown
  - Higher signal in quantitative tests
  - Higher sensitivity

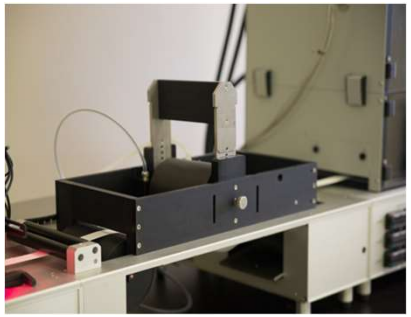




Spray vs. Dip Coating

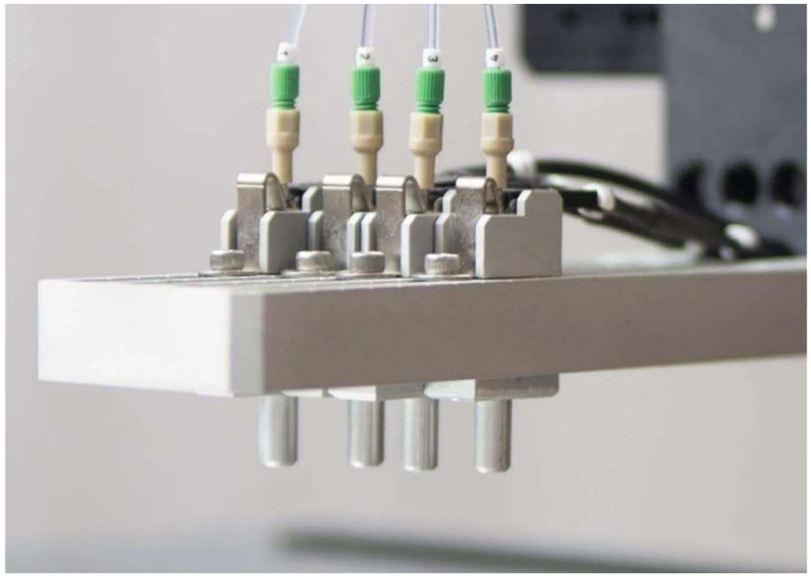




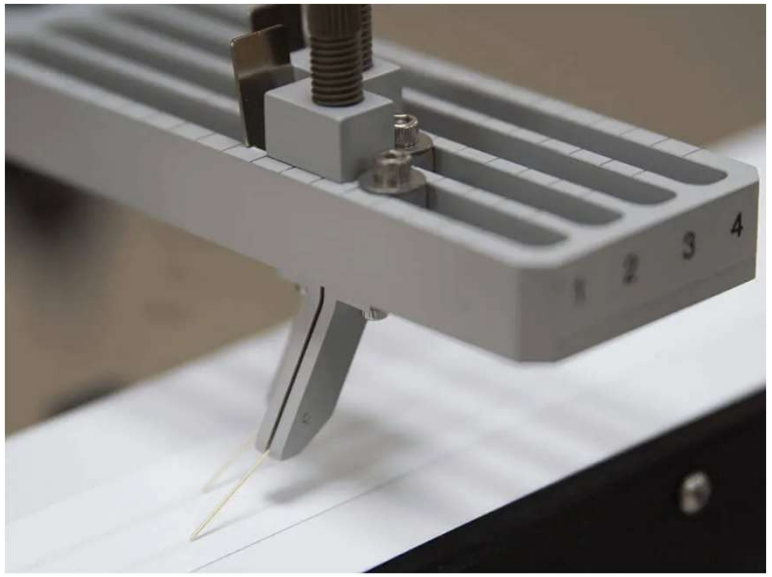


Comparing Non-Contact Vs. Contact Dispensing

Pro's & Con's



- Typically delivers higher sensitivity than contact dispensing
- Requires an ILD (more reagent)
- More complex set-up and cleaning

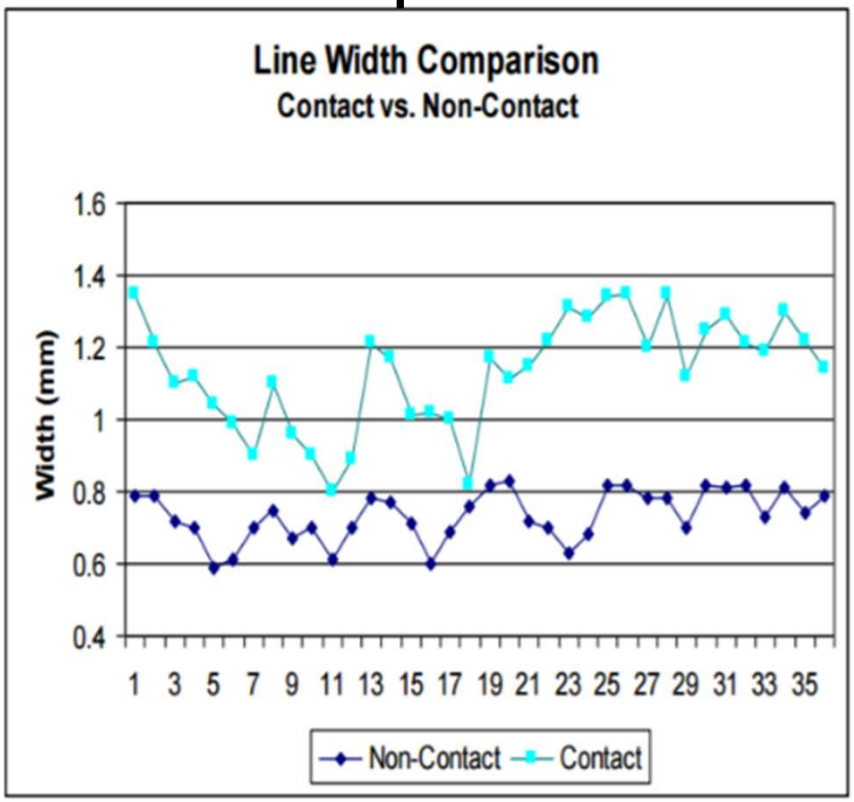


- Easier to use for R&D
  - Allows for use of less reagent for half card or single card runs
- Easier set-up and operation and cleaning
- Can score the surface of the membrane and deliver less consistent line widths

Non-Contact has Shown

Study conducted by DCN Dx

Dispense Method : Effect on Line Width

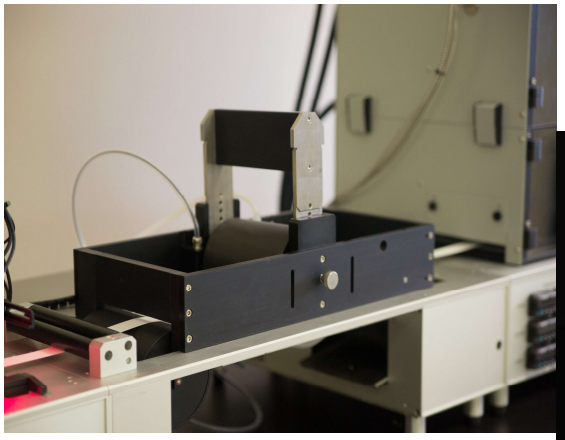


	Non-Contact	Contact
Mean	0.74 mm	1.13 mm
St. Deviation	0.07	0.15
% C.V.	9.5	13.6
Minimum	0.61 mm	0.83 mm
Maximum	0.83 mm	1.35 mm

Comparing Spray Vs. Dip

Pro's & Con's

- Quantitative
- Reduced waste
- Controlled delivery



- Dwell time based
- Uneven distribution
- Qualitative
- Can be good for blocking

Technology Type Considerations

Example

Spray vs. Dip Coating

Materials:

7 mm fiberglass conjugate pad
10 mm blocking paper
Conjugates A and B
Blocking buffer

Methods:

Currently dipping -move to spraying
(2) AirJet 3000s
(2) Dry towers
Ultra-Low tension configuration

Blocking Paper

Pad	Region 1	Region 2	Region 3	Region 4	Region 5	Avg.	STDEV	% CV
1	0.2841	0.2985	0.2913	0.3184	0.3005	0.2986	0.0128	4.30
2	0.3118	0.2932	0.3191	0.3012	0.2871	0.3025	0.0131	4.33
3	0.2896	0.2955	0.3115	0.3095	0.2966	0.3005	0.0095	3.16
4	0.2975	0.2810	0.3024	0.2885	0.3070	0.2953	0.0105	3.56
5	0.2896	0.3091	0.3101	0.3265	0.3175	0.3106	0.0136	4.39
6	0.3055	0.3154	0.3132	0.3124	0.3128	0.3119	0.0037	1.20
7	0.2987	0.2876	0.2947	0.3141	0.3174	0.3025	0.0128	4.23

Technology Type Considerations

Example

Spray vs. Dip Coating

Results:

1. Elution values comparable
   - Conjugate A
   - Conjugate B
   - Blocking buffer
2. Sufficient drying
   - High throughput
3. Material handling sufficient
   - Successful tracking
   - No breaking
   - No tearing
4. Reduced reagent consumption
5. Controlled delivery

Conjugate Pad

Pad	Region 1	Region 2	Region 3	Avg.	STDEV	% CV
1	0.1100	0.1148	0.1099	0.1116	0.0028	2.51
2	0.1085	0.1093	0.1070	0.1083	0.0012	1.08
3	0.0942	0.0889	0.0942	0.0924	0.0031	3.31
4	0.1026	0.0945	0.0926	0.0966	0.0053	5.50
1	0.2821	0.2880	0.2886	0.2862	0.0036	1.25
2	0.3169	0.3024	0.3234	0.3142	0.0108	3.42
3	0.2925	0.2889	0.2821	0.2878	0.0053	1.83
4	0.2485	0.2523	0.2448	0.2485	0.0038	1.51

Lateral Flow Manufacturing Equipment

BATCH

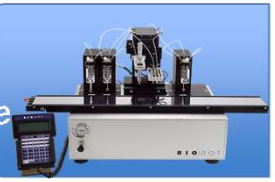
Pre-cut materials

IN-LINE

Roll format materials

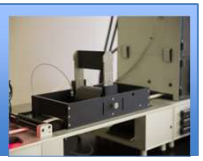
Batch Process Line Layout

XYZ3060
T&C / Conjugate



Inspect/Mark

Dip Tank
Block



Oven
Dry

LM5000
Laminate Master Strip

LM5000
Laminate Cover

Inspect/Mark

CM5000
Cut / Sort

AR3000
Assembley Roller

Assemble

Assemble

Assemble

Seal

Seal

Seal

QC

Final QC

Batch Manufacturing

- Lower Capital Equipment Cost
- Flexibility for Research & Development
- Scales Easily via Duplication
- Manual Quality Control (usually)

XYZ3060

CM5000

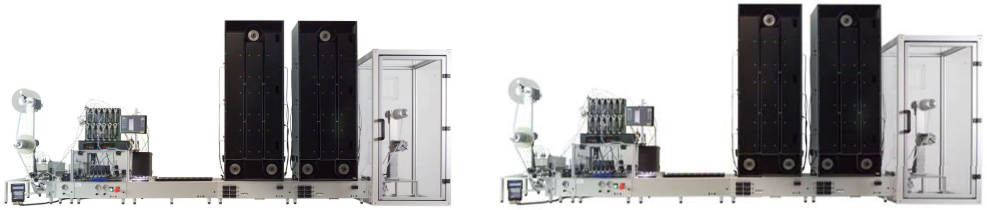
LM5000

Lateral Flow Device Manufacturing

Batch Scenario

- Materials in pre-cut lengths
  - 30cm typical
- Laminated or unlaminated to backing card
- R&D to low volume production (500K-1MM/yr typical)
- Process strips in groups
- Process time is noncritical
- Poor process symmetry
- High labor content

Lateral Flow Reel to Reel Process



RR120

Reel-to-Reel Dispense with Coat/Dry

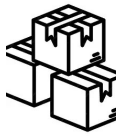
T/C & Conjugate, Dry, Inspect/Mark

LM9000

Laminate/Inspect/Mark

Package

Cut/ Assemble



Package

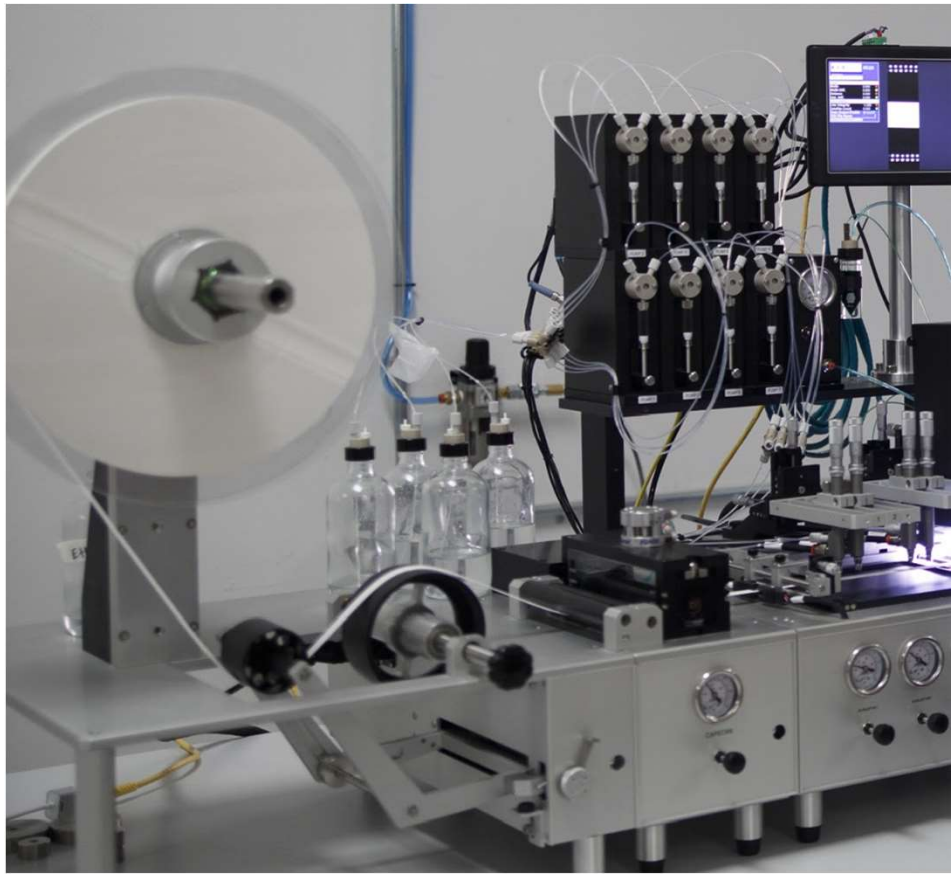
Cut /Assemble

In-Line Manufacturing

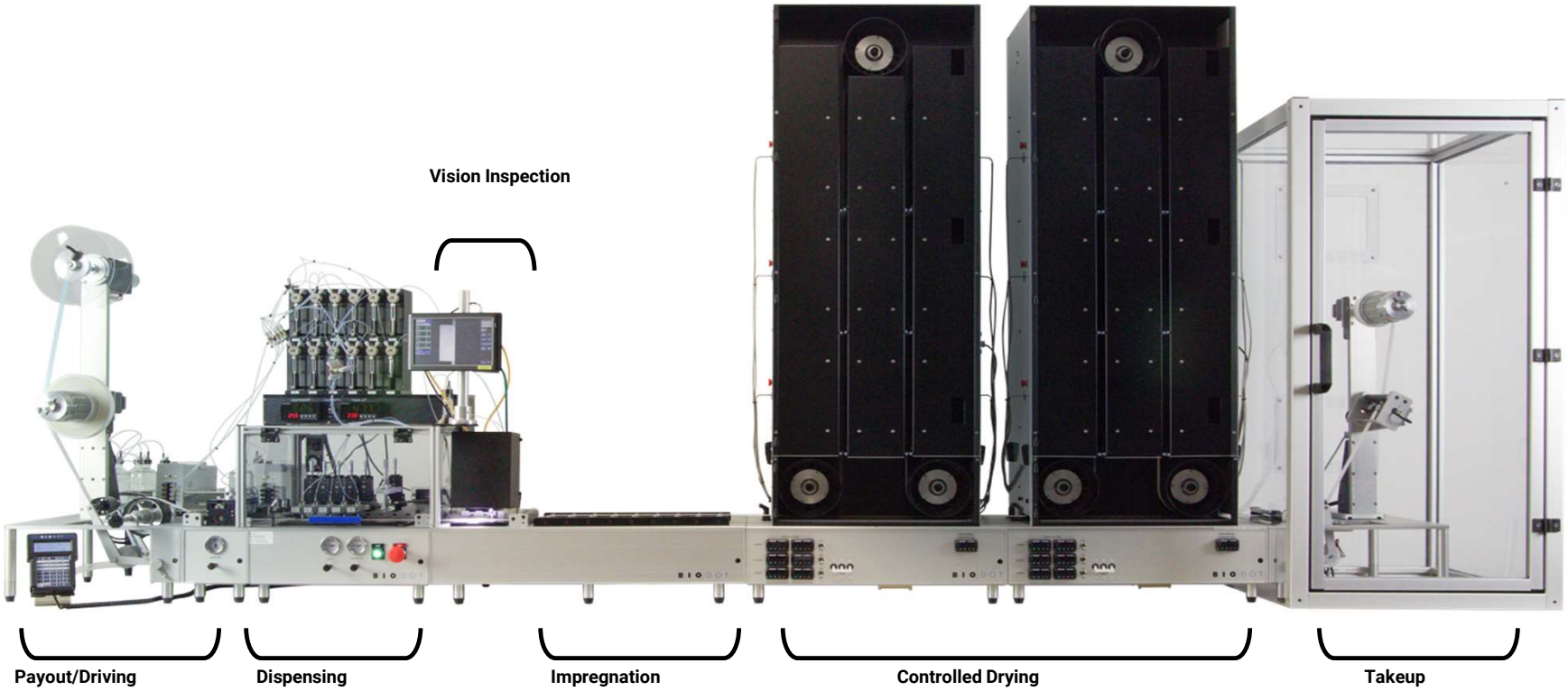
- Increase in Quality / Decrease in Human Error
- Cost Reduction from Correction of Inefficiencies
- Cost Reduction from Less Waste
- Reduction in overall Production Time

In-Line Manufacturing

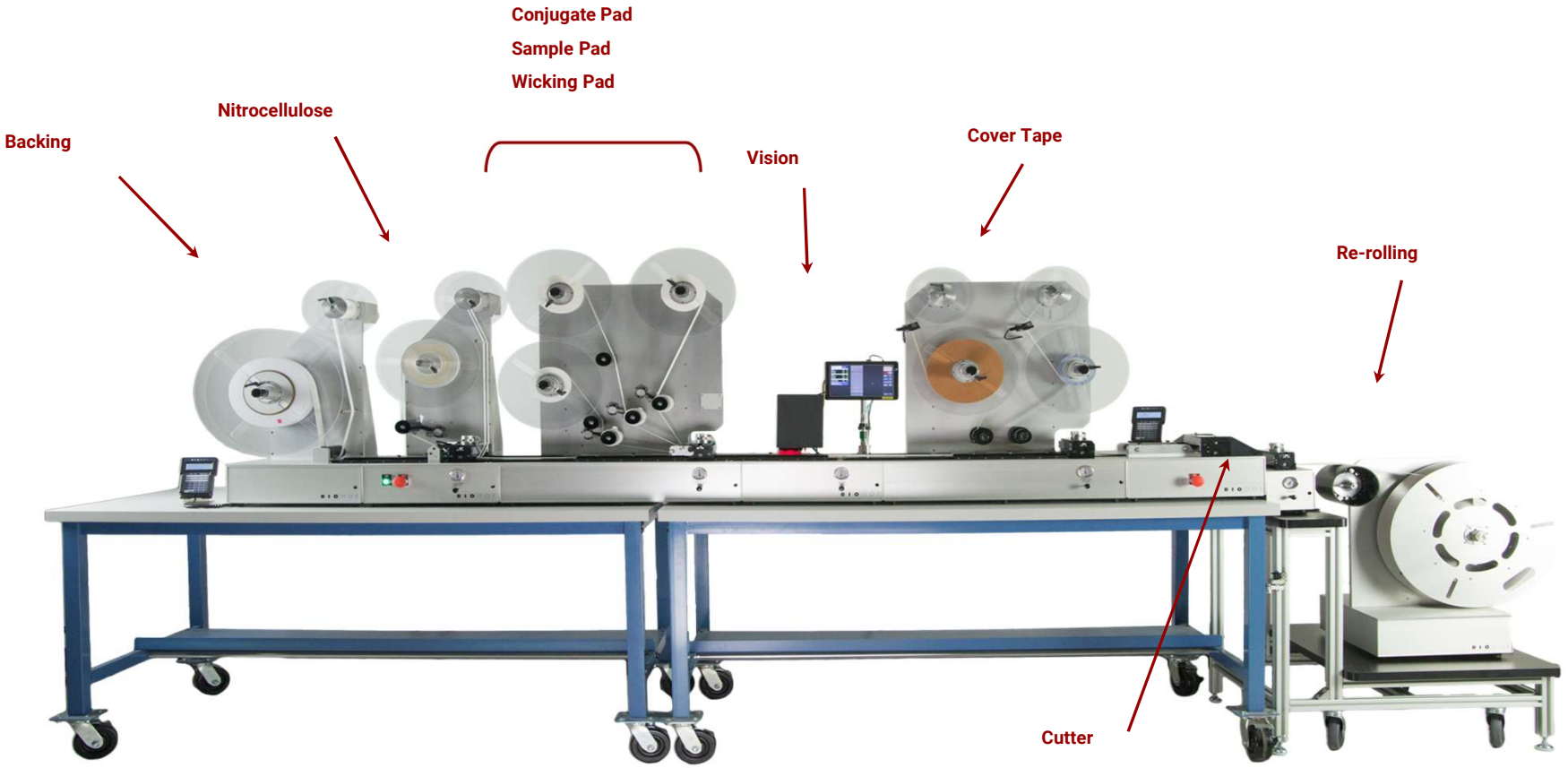
- Materials feed continuously through the process
- Provides greater process controls
  - Continuous drying via forced air dry towers
  - In line QC with vision and bad part marking
  - Precision alignment
- Higher volume production capabilities
  - >10 MM/yr
- Built in environmental controls
  - Humidity control (high) in dispense area
  - Humidity control (low) after drying



RR120 - Modular Web Handling Platform

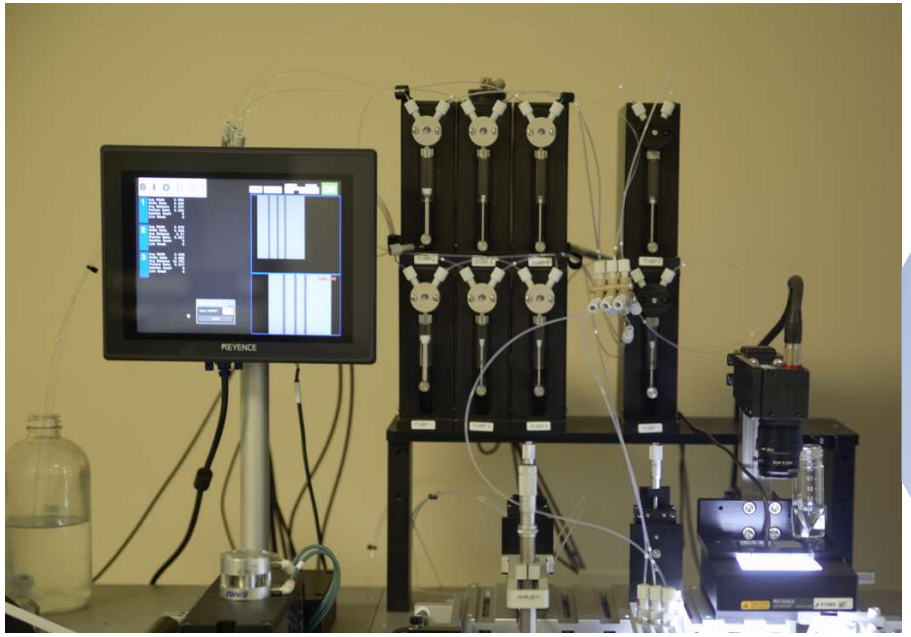


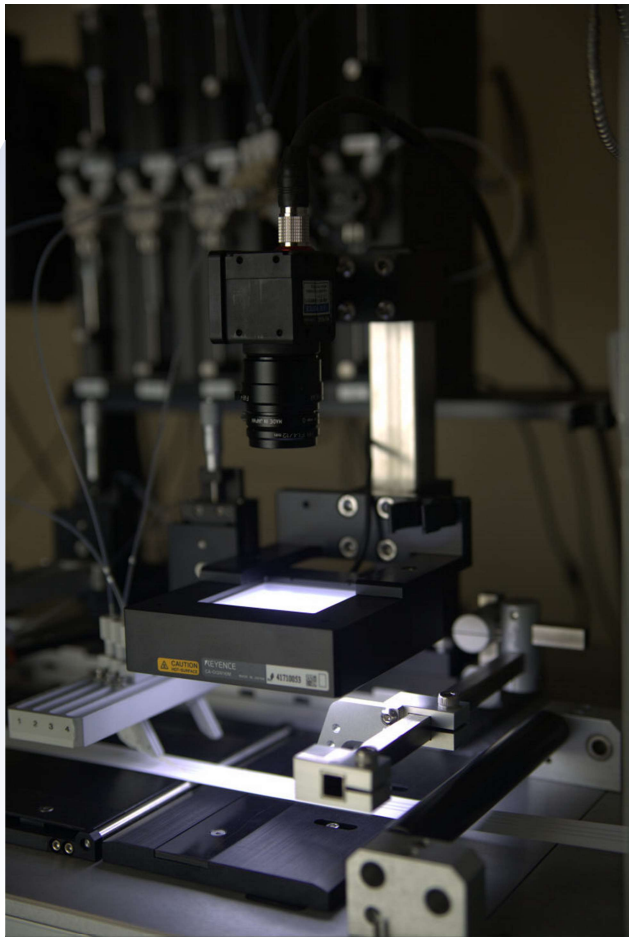
LM9000 AutoLamination System



Advanced Vision Inspection (dispensing and lamination)

Vision system software (RR and LM)





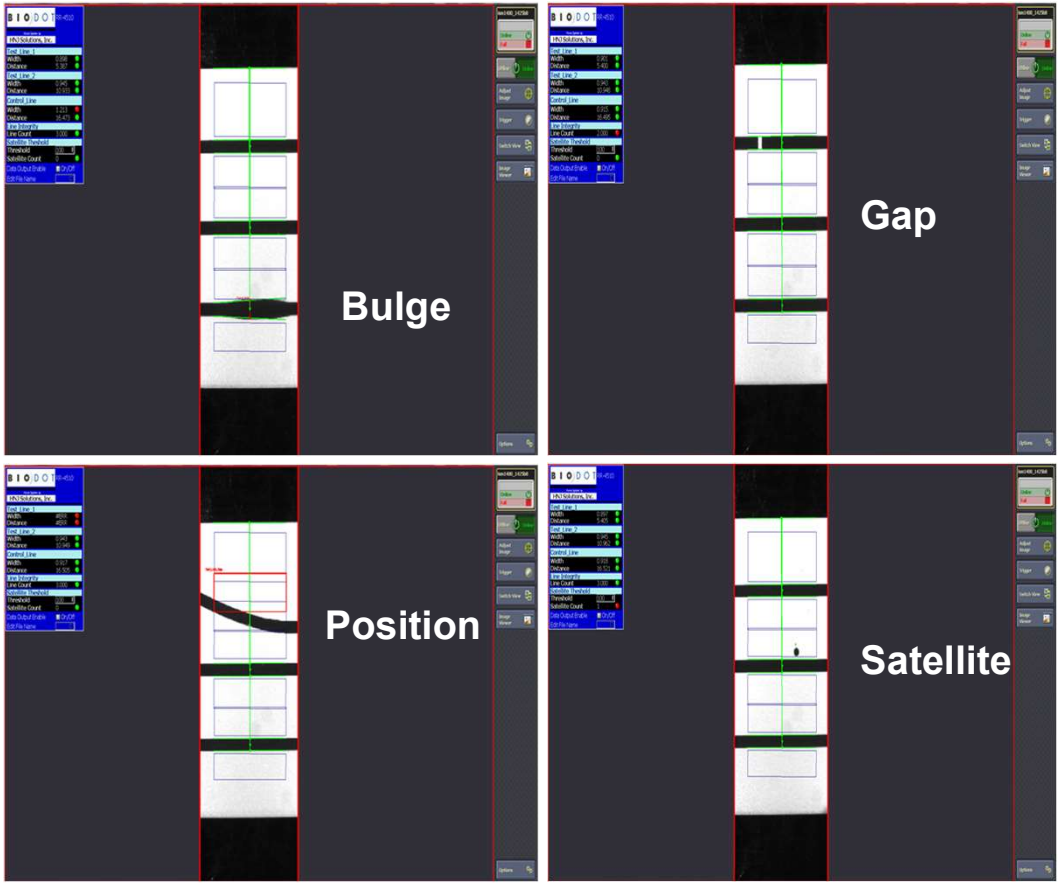
Advanced Vision Inspection (dispensing and lamination)

Vision system software (RR and LM)

- High Precision
- Error Detection
- Quality Control
- Increased Throughput
- Reduced Waste
- Flexibility (Programmable and adaptable)
- Data Logging and Traceability
- Process Optimization
- Compliance and Documentation

Image of strip passing underneath the camera.

Lateral Flow Device Manufacturing



Equipment Calculation

One (3) RR120 and one (2) LM9000 will conservatively yield you 75M tests annually on a single shift

RR120

	Process Used in Calculation?	Roll Length (m)	Scrap Per Roll (m)	Web Speed (mm/s)	Seconds/Roll	Total Time per Roll (seconds)	Lunch/Break (minutes)	Hours per Day	Number of Rolls/Day	Good Material/Day (mm)	Test Width (mm)	Tests/Day	Days/Year	Tests/Year
T/C	Yes	100	5	60	1,667	1,667	60	7.5	14	1,333,800	4	333,450	220	73,359,000
Block	No	100	5	25	4,000	0	60	7.5	0	0	4	0	220	0
Conjugate	Yes	100	5	30	3,333	3,333	60	7.5	7	666,900	4	166,725	220	36,679,500
Block	No	100	5	25	4,000	0	60	7.5	0	0	4	0	220	0
Total						**5,000**	**60**	**7.5**	5	**444,600**	**4**	**111,150**	**220**	**24,453,000**

LM9000

Process		Roll Length (m)	Scrap Per Roll (m)	Web Speed (mm/s)	Seconds/Roll	Setup Time (minutes)	Clean/Wash (minutes)	Total Time per Roll (seconds)	Lunch/Break (minutes)	Hours per Day	Number of Rolls/Day	Good Material/Day (mm)	Test Width (mm)	Tests/Day	Days/Year	Tests/Year
Lamination		100	5	60	1667	10	10	2867	60	7.5	8	775465	4	193,866	220	42,650,581.40

Batch vs. Continuous

Recap

Batch

- Card format for material and lamination: 30cm card length typ.
- Process strips in groups
- Process time is noncritical
- Poor process symmetry
- Low to medium production R&D
  - 1,000's to 1 million tests per year
- High labor content

Continuous

- Roll format for material and laminate: 100 meter roll length
- Process rolls in continuous process
- Process time is critical and limited by web speed and equipment size
- Excellent process symmetry
- Medium to high volume
  - 1 million to + 1 billion tests per year
- Low labor content

Manufacturing Strategy Considerations

Examples

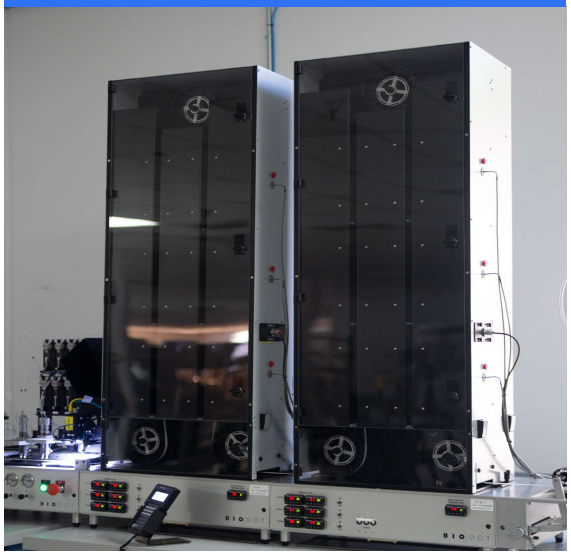
Do Your Material Choices Transfer Well in Manufacturing?

Low tensile strength materials

Unbacked 10 mm nitrocellulose on Payout Module, Ultra-Low Tension configuration

Do Your Processes Transfer Well to Manufacturing?

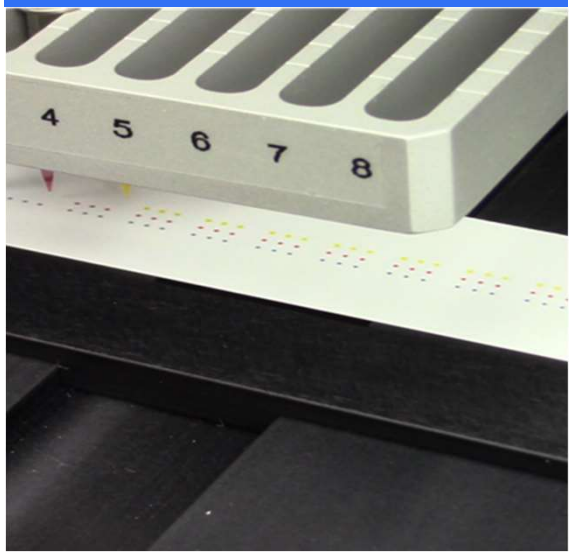
Overnight or 1 hour (lunch break) Drying Times



Forced Air Drying In-Line

Do Your Technologies Transfer Well to Manufacturing?

Printing arrays on webs for LF multiplexing

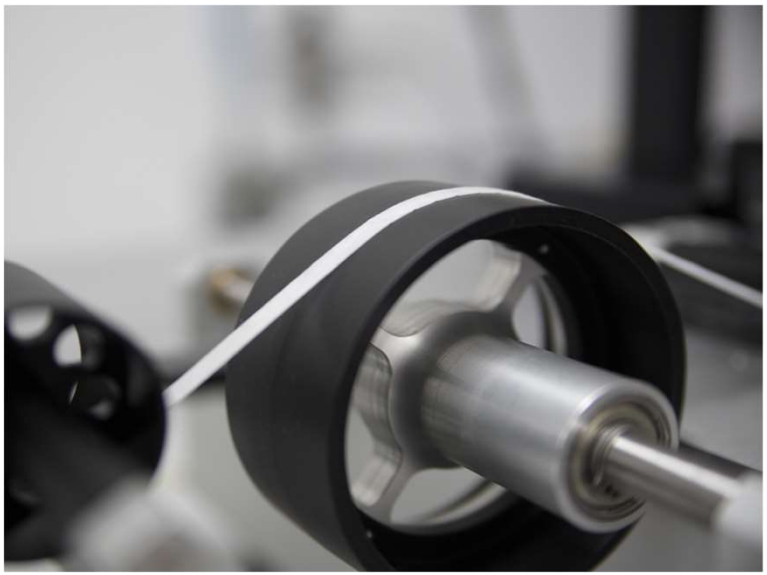


High Speed Array Printing

Manufacturing Strategies

It is helpful to include manufacturing considerations in the product design phase

- Select Materials with properties that allow for machine handling
  - ex: tensile strength for web handling
  - ex: plastic housing shaped to facilitate automation
- Design Processes that transfer easily to manufacturing
  - ex: drying by forced air vs. lyophilization
- Use equipment in development that can transfer to manufacturing
  - ex: use the same dispensing systems in R&D as in manufacturing
- Will you be scaling up production in-house or will you subcontract this out to a CMO?
  - ex: Does the CMO have the same equipment you developed on?



Ex: low tension web system is needed for low tensile strength materials

Lateral Flow Multiplex Array Device Manufacturing

Batch Scenario

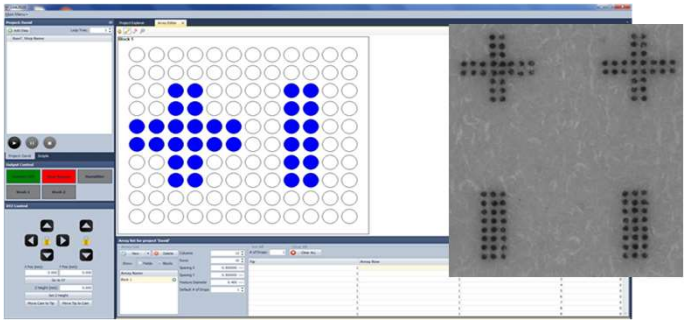
Step and Repeat

Locate Fiducial → Dispense 1 x Array → Repeat to end of card

On-The-Fly

Locate Fiducial → Dispense all Arrays on card → Load next card

LAMINATE → CUT → ASSEMBLE

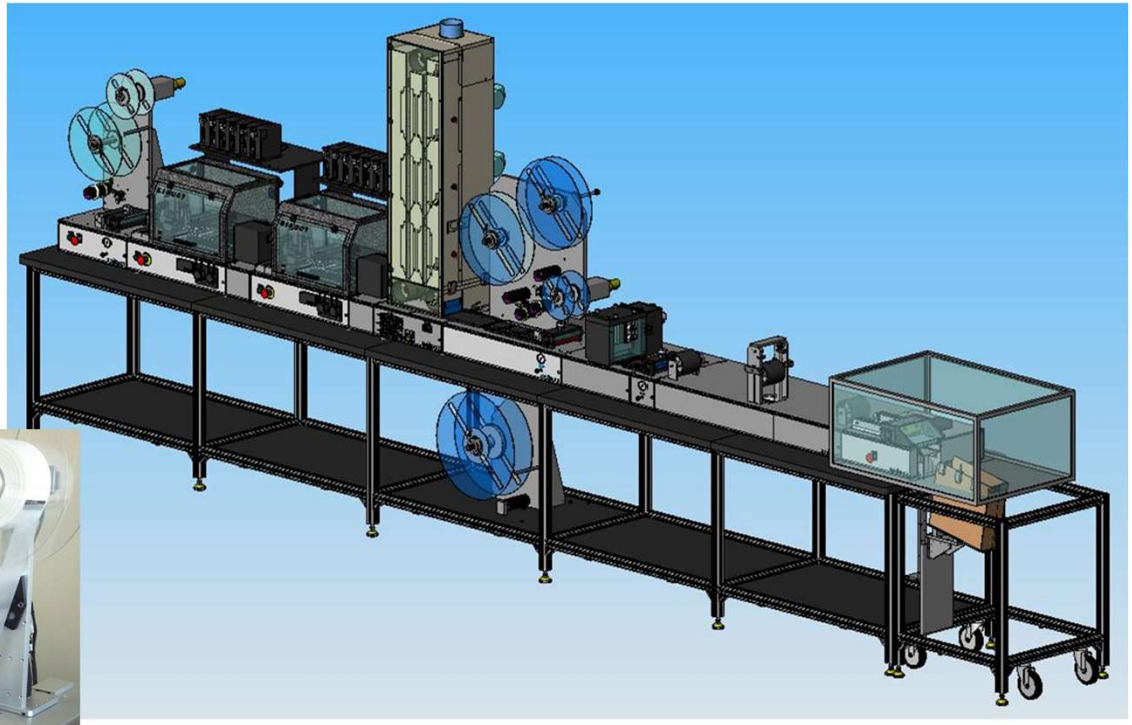


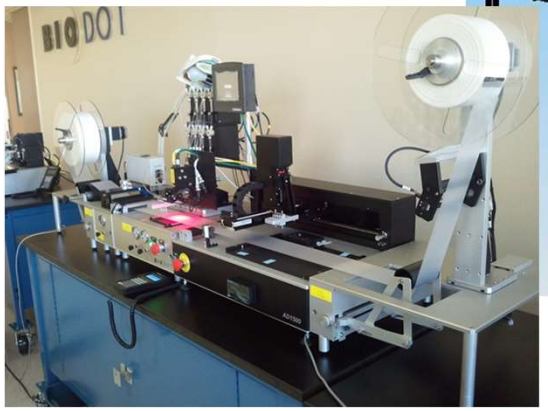
Vision Fiducial Offset Printing

Lateral Flow Multiplex Array Device Manufacturing

In-Line Scenario

- Array printing
  - Picoliter to Nanoliter
  - Indexing
- Drying
- Environmental control
- Vision
- Cutting





Thank you!

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