



PROS & CONS OF MOBILE PCS IN A PRODUCTION ENVIRONMENT

Sam Russem & Jan Thriene
ISPE Boston Product Show – Foxborough, MA
September 26, 2018

Booth W94

Speaker Biography

Sam Russem, Director of Smart Manufacturing Practice Grantek Systems Integration

Sam Russem is the Director of Smart Manufacturing Practice at Grantek. Sam graduated from the University of Pennsylvania and has been with Grantek for over 9 years. During his time at Grantek he has executed Automation and Manufacturing IT projects and taken on several roles within the organization.

Sam has a strong background in Smart Manufacturing. Most recently, Sam was a Senior Project Manager in Grantek's Enterprise PMO and has been integral in the execution of several prominent projects with key enterprise customers.



Speaker Biography

Jan Thriene, Business Development Manager Systec & Solutions

Jan Thriene is the Business Development Manager at Systec & Solutions, a Karlsruhe, Germany based manufacturer of best in class GMP-IT hardware for clean room production environments.

Mr. Thriene has over 7 years' experience providing HMI solutions in the pharmaceutical, food and cosmetics industries. Prior to his work with Systec & Solutions, Mr. Thriene held management roles in China and throughout Europe for various American firms.



EXPERIENCE, ISSUES OF CONCERN & STANDARDS

Tablets and Mobile - Regulatory

- > Tablets (and somewhat mobile trolleys) are reliant on battery power and wireless LAN
- > Additional controls may be needed for regulatory compliance
 - ICH Q7 Section 5.4
 - » 5.43 – “There should be controls to prevent omissions in data (e.g., system turned off and data not captured)”
 - » 5.48 – “If system breakdowns or failures would result in the permanent loss of records, a back-up system should be provided”
 - FDA Draft Guidance “Data Integrity and Compliance with cGMP” – April 2016
 - » Must document or save data at the time of performance to create a record in compliance with cGMP requirements
- > Loss of Wi-Fi signal or a dead battery can lead to data integrity issues

Tablets and Mobile - Regulatory

- > If a tablet leverages mobile OS, additional concerns arise regarding security, confidentiality and data integrity
 - FDA Guidance “Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Q and A” – June 2017
 - » Access Controls must be as per any other kind of regulated computer system
 - » All regulated data must be traceable to its origin: the user or the mobile device itself
 - » Additional checks are required such as a “heart beat” to ensure continuous device connectivity
 - » Data is considered “source data” only when recorded in a permanent manner, not in mobile device memory or temporarily resident in a vendor’s cloud
 - Encryption, digital signatures and/or biometrics required in “open systems” as classified by 21 CFR Part 11
 - » For mobile devices, disabling “remote wiping”, restricting the installation of certain apps, disabling automatic updates, and removing sensitive data prior to re-allocating the device should be implemented
 - » Additional validation to ensure the mobile device reliably transmits data to permanent storage system
 - » Additional personnel training on mobile technologies may be required

Tablets and Mobile – Line of Sight Control

- > If a tablet is used in a production environment during Aseptic Processing, Line of Sight Control must be considered throughout production
 - Potentially the most vital component to Clean Room Design, is the line of sight between the operators and the systems and components they are working with
 - » In the past, Line of Sight Control assumed an operator would be in the same location while entering data for the entire duration of their shift
 - » Tablets and Mobile Devices allow for mobility but also allow for the device to be positioned at various distances from operator, increasing opportunities for Line of Sight Control to be compromised
 - » The difficulty of ensuring an exact location and angle for the operator to consistently hold the Tablet or Mobile Device makes Line of Sight Control an equally difficult best practice to enforce
 - » When not in use, the concern for where a Tablet or Mobile Device is put to rest can also be a concern

About Us

System & Solutions GmbH

- > Experts for GMP-IT hardware solutions
- > Fully mobile or fix installed HMI solutions for clean rooms and hygienic areas
- > Full service offering around standard & customer specific products and solutions
- > Products used for MES, DCS, OEE, KPI and environmental monitoring applications
- > Globally used by Pharmaceutical, Biotech, F&B and Cosmetics industry
- > Applied by 15 out of the 20 largest Pharma companies worldwide
- > Based in Karlsruhe, Germany
- > DIN ISO 9001:2015 certified



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About Us

Grantek Systems Integration

- > Systems Integrator and Business Solution Provider
- > From the plant floor to the boardroom
- > Founded in 1980
- > 200 professionals across 17 Global offices
- > Serves the North American Pharma and Life Sciences industries
- > Member of CSIA (Control System Integrators Association)
- > Solution provider in Smart Manufacturing, Industrial Networking, Automation and Industrial Safety



PROS & CONS OF MOBILE PCS IN A PRODUCTION ENVIRONMENT

Hardware Solutions for a Demanding Industry

Tablets vs. Mobile vs. Fixed

- > Tablet PCs
- > TROLLEY Systems
- > WAVE/PILOT/CONTROL Systems



Customer Decision Based On:

> Cost 

> Handling 

> Design 

Tablets

> Tablet PCs



Tablets - Cost

Capex is low, Tablet PCs are usually cheap

Opex is high, Tablet PCs are short lived

| ADVANTAGE | DISADVANTAGE |
|-----------|----------------------------------|
| Low Capex | High Opex/Maintenance Cost |
| | Short Product Life Cycle |
| | Non-Rugged Designs |
| | Requalification Upon Replacement |

Tablets - Handling

Easy to move from Point to Point, excellent mobility

Easy to drop, but easy to replace

Battery powered solution only, severely limited usability during recharge

Must be carried by the operator for extended period of time

| ADVANTAGE | DISADVANTAGE |
|-----------------|-------------------------|
| High Mobility | Battery Operated |
| Lightweight | On Screen Keyboard |
| Easily Replaced | Weight During Operation |

Tablets - Design

Made for commercial applications, adopted to industrial use

Active fan, plastic surfaces, open interface connectors

No use without WLAN

Can be adopted to GMP requirements, but with limitations

| ADVANTAGE | DISADVANTAGE |
|-----------------|-----------------------------------|
| Many Interfaces | Difficult to Clean |
| | Cleaning Agents too Aggressive |
| | Interfaces Exposed to Environment |
| | Fan Outlet |

Trolleys

- TROLLEY LIGHT
- TROLLEY COMPACT
- TROLLEY MAXI
- TROLLEY INDUCTIVE



Trolleys - Cost

Capex is high, designed for pharma requirements

Opex is low, industrial grade components

| ADVANTAGE | DISADVANTAGE |
|-----------------------------|----------------------|
| Low Opex | High Capex |
| Industrial Grade Components | Maintenance Required |
| Long Product Life Cycle | |

Trolleys - Handling

Easy to move from Point to Point

Battery or AC powered solution

Useable during recharge

| ADVANTAGE | DISADVANTAGE |
|------------------------------------|--|
| High Mobility | “Parking Space” Required |
| Battery and Mains Powered | Maintenance on Wheels and Battery Required |
| Inductive Charging Available | Potentially Large Surface to Clean |
| Full Keyboard and Touchpad | |
| Large Screen Size with Multi Touch | |

Trolleys - Design

Made for use in pharma/clean room applications

Fully encapsulated design

No issues with common cleaning agents

WLAN or LAN connection

| ADVANTAGE | DISADVANTAGE |
|---|--------------|
| Easy to Clean | |
| Inductive Charging Possible | |
| Integration of 3 rd Party Equipment Possible | |

Fixed HMIs

- > WAVE Series
- > PILOT/PILOT OEM Series
- > CONTROL/CONTROL FM Series
- > VIEWSION Series



Fixed HMIs - Cost

Capex is moderate

Designed for pharma requirements

Opex is almost non-existent, industrial grade components

| ADVANTAGE | DISADVANTAGE |
|-----------------------------|----------------|
| Very Low Opex | Moderate Capex |
| Industrial Grade Components | |
| Long Product Life Cycle | |

Fixed HMIs - Handling

Individual mounting options

IP65 protection grade

No external cables

| ADVANTAGE | DISADVANTAGE |
|------------------------------------|------------------------------|
| Fully Encapsulated Design | Single Location Installation |
| Accessories Easily Mounted | |
| Internal Cable Mount | |
| Full Keyboard and Touchpad | |
| Large Screen Size with Multi Touch | |

Fixed HMIs - Design

Made for use in pharma/clean room applications

Fully encapsulated design

No issues with common cleaning agents

| ADVANTAGE | DISADVANTAGE |
|-----------------------------|-------------------------------------|
| Easy to Clean | Limited Design Flexibility |
| Integrated Installation | Replacement Difficult in Clean Room |
| Best Use of Available Space | |

Which Product is Best for My Application?



Tablet

Tablet allows for independent and mobile use and can store and access information.

Tablet is not well suited for applications where you need to operate continuously.

Tablet is best suited for application where a limited amount of data needs to be displayed for a limited period of time with limited interaction.



TROLLEY

TROLLEY allows for independent and mobile use, can store and access information.

TROLLEY is well suited for applications where Data must be entered, changed or visualized.

TROLLEY is best suited for temporary or mobile applications.



Fixed HMI

Fixed HMI allows for continuous use, can store and access information.

Fixed HMI are well suited for applications where Data must be entered, changed or visualized.

Fixed HMI are best suited for applications where continuous access is needed.



Product Selection Based on Application



| APPLICATIONS | TABLET PC | TROLLEY | FIXED HMI |
|-------------------------|-----------|---------|-----------|
| DCS Visualization | | | |
| MES Visualization | | | |
| ERP System | | | |
| Paperless Documentation | | | |
| Batch/Track & Trace | | | |

Ergonomics, Health & Safety

For how long can an Operator carry a Tablet PC?

Do you want an Operator to move through your production area:

- > With both hands full (Tablet PC & Scanner)?
- > With eyes on the tablet screen (distracted)?

Where do you charge your Tablet PCs?

How do you prevent Tablet PCs from being misplaced?

Ergonomics, Health & Safety

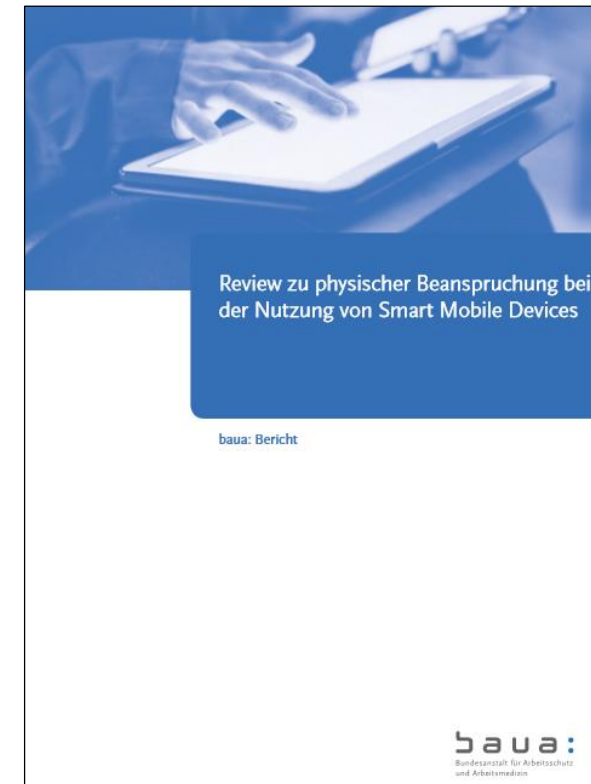
Review based on 41 scientific studies with focus on biomechanical parameters

Findings of the review:

- > Increased risk on physical strain for neck, shoulder and thumb
- > Body movement to prevent light reflection on display leads to disadvantageous body position
- > Use of thumb and index finger increases risk of tendinopathy

Recommendations of the review:

- > Short use of Tablet PCs only
- > Weight and display size key criteria depending on application
- > Non-reflecting displays if possible
- > External keyboard for longer use of Tablet PC



Questions

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