



Rapid Surface Cleanliness Verification Using Swab Sampling and Capillary Electrophoresis.

**Mostafa A. Atia¹, Ria Marni Amuno¹, Umme Kalsoom²,
Samantha Ollerton², Alan Rhoden³, Paul R Haddad¹, Michael C.
Breadmore¹**

¹Australian Centre for Research on Separation Science (ACROSS), School of Natural Science, University of Tasmania, Private Bag 75, Hobart, Tasmania 7001, Australia.

² GreyScan, Port Melbourne, Australia.

³ Pfizer Global Technology & Engineering Manufacturing Intelligence, Peapack, NJ, United States.

Mostafa.Adel@utas.edu.au

Cleaning verification is mandatory in pharma production

- Required between each batch to ensure no cross contamination.
- Two ways:
 - **Collect and analyse rinse solution**
 - Easier, more repeatable, more representative to the whole system, but doesn't mean the surface is clean (**things stick**)
 - **Swab-based analysis**
 - Not as repeatable, but is better for things that stick and hardly reach sites.
- Both **require samples to be sent to the laboratory** for analysis
- This can **take hours to days** with significant loss in production capability until cleanliness has been verified.



At-site analysis

- Analysis of residue at-site would be quick and convenient
- Currently limited to optical spectroscopy methods
 - Mainly **IR and Raman spectroscopy** (although benchtop MS instruments are becoming more viable)
 - Point-and-shoot systems user friendly, they typically have a small '**field of view**'
 - low sensitivity and selectivity ($\text{LOD} \leq 1\mu\text{g}/\text{cm}^2$).
- Despite this, most samples are **still sent to the lab** for analysis



We know when speed is important...

2019 Christmas list

“‘five of the best’ relate to some of the most exciting technologies I have seen that could enhance the security arsenal for any airport.”
Philip Baum, Editor ASI



AVIATION SECURITY INTERNATIONAL
www.asi-mag.com

THE GLOBAL JOURNAL OF AIRPORT & AIRLINE SECURITY

Screening Technologies: from A to Z

DOWNLOAD YOUR ASI APP FOR THE IPAD/PHONE NOW

ALSO:
X-RAY TRAINING
CYBERTERRORISM
DISCRIMINATION
SECURITY THEATRE

CHO HYUN-AH, MACADAMIA NUTS SEE PAGE 12

ADELAIDE AIRPORT: FRONT OF HOUSE SEE PAGE 18

Body Search 2015 (UK) JUN

FEBRUARY 2015 VOLUME 21 ISSUE 1

STOCKING FILLER TECHNOLOGIES: ALL I WANT FOR CHRISTMAS

by Philip Baum

LEAD EDITORIAL

It is often said that aviation security is reactive in nature and that it takes a major incident for the system to change and for new technologies to be embraced and deployed. The traditional checkpoint still consists of archway metal detectors and X-ray machines, with those in the developed world also utilising explosive trace detection technology. Sure, the detection capabilities of all these devices are much improved, but we have not witnessed any radical re-think of how we screen people and their baggage.

We are gradually seeing the deployment of computed tomography (CT) for cabin baggage screening, an increase in the capability of automated threat detection software for X-rayed bags and more widespread installations of advanced imaging technology (body scanners) for either random searches or the performance of secondary screening. That said, we're still trying to identify the same threat items and substances as we did a decade ago and are not much nearer to being able to detect some of the more challenging explosive compounds or chemical, biological or radiological substances. That's not to say the technological capability is not out there – it is. But we are resistant to demanding such technologies being deployed in an environment which has not (yet) witnessed the use of such weapons. Complacency, however, is to be avoided.

CCTV systems and access control solutions have become increasingly more powerful in detecting and recording intrusions, whilst management systems have created a more robust security environment, especially in the area of cyber security. Furthermore, given the disruption now regularly being caused by drone-related incidents, counter-drone technology manufacturers are flourishing. But back in the world of passenger and bag screening, perhaps because of regulation, innovation is more muted.

Last December, my lead editorial highlighted my five pet poses with airports, air travel and hotel accommodations. This year, in a more positive vein, my 'five of the best' relate to some of the most exciting technologies I have seen that could enhance the security arsenal for any airport. Having recently attended the International Security Expo at London Olympia, I found that there were a number of products which both could, and even should, find their place within the security technology array that protects aircraft and those who fly in them. Refreshingly they are from various countries around the globe: Australia, South Korea, Israel, Belgium and Belarus.

I referenced explosive detection technology. The problem is that there is no single explosive compound. Many of the solutions deployed offer a high degree of accuracy and detection capability – but primarily for the five traditional ingredients of the military grade improvised explosive devices. We know that homemade explosives pose a much greater challenge and that a multitude of readily available inorganic compounds are undetectable.

A long-term server on the editorial advisory board of this journal, Michael Bredmore, may be the man behind one of the industry's game changing technological innovations. On show in London, manufactured in Melbourne, Australia, yet with its roots slightly further away in the chemistry labs of the University of Tasmania, was the GreyScan FTD-100. The product can aid in the detection of the more accessible (i.e. inorganic) explosive substances.

I look forward to visiting the commercial factory manufacturing GreyScan, and its new CEO, Samantha Orlerton, in Melbourne this December (albeit after this issue of Aviation Security International goes to press).

Many a product on display at the Expo claimed to be AI (artificial intelligence) enabled. With computer science enabling the development of technologies that are able to perform tasks which, to date, would have required human intelligence, and the industry determined to ensure that machines sound alarms rather than individual intuition, AI is set to be the buzzword of the next decade, whether one is looking at CCTV or screening solutions.

South Korea's JLK Inspection was one such company providing AI security solutions. Their XINSPECTOR utilises AI as a tool to evaluate X-ray images, claiming to minimise human error due to operator fatigue by automatically signalling potential threats. But JLK was also marketing an innovative method of screening unattended bags and that was what caught my eye.

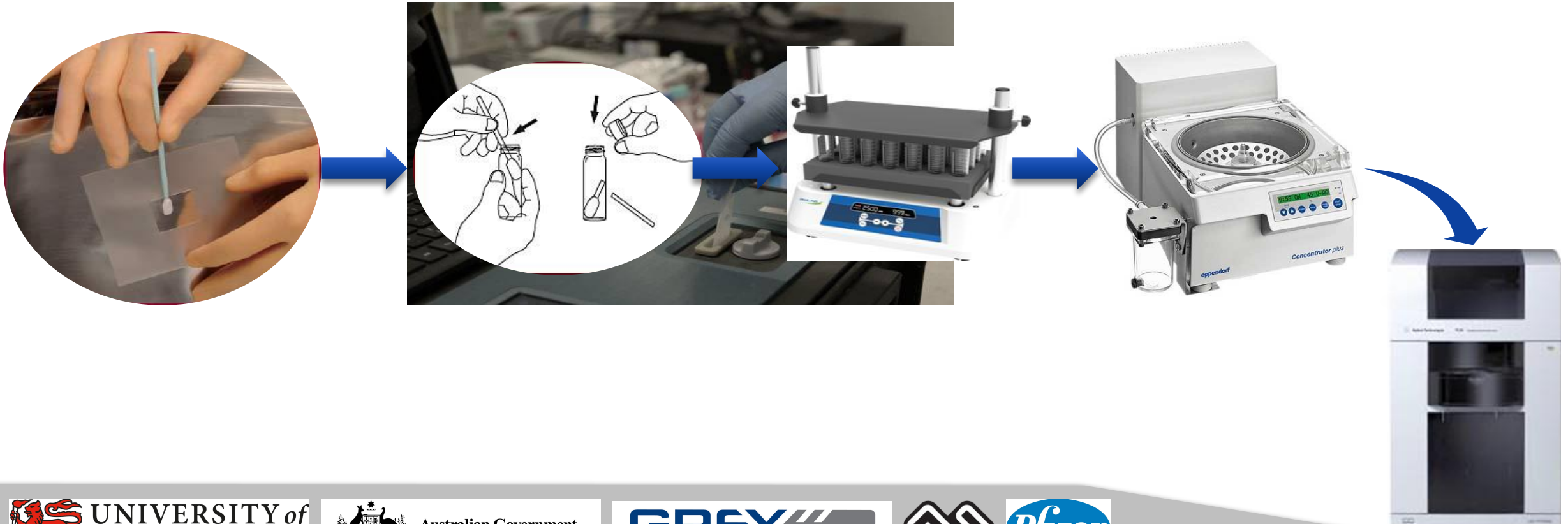
The XPEKI is an AI-based solution integrated into a handheld, and therefore portable, X-ray camera. It enables security teams to move around airport terminals, external courtyards and car parks, and X-ray any bag or item causing concern using low-dose radiation. The XPEKI looks like a camera and takes images like a camera. The images are analysed within a couple of seconds using JLK Inspection's unique AI algorithms which highlight potential threats.

Miliran Ltd. has a lengthy history of supplying innovative defensive products. Established in 1950, and based in Israel, the company manufactures a broad-range of anti-terror products from guard posts to fencing and from barriers to explosive-proof blast and fragment decompression flight simulator chambers. The latter was a one time staple demand of the aviation industry, and Miliran is one of the few companies which continues to manufacture such systems to check cargo for the presence of barometric devices. One such system is installed at Tel Aviv's Ben Gurion International Airport.

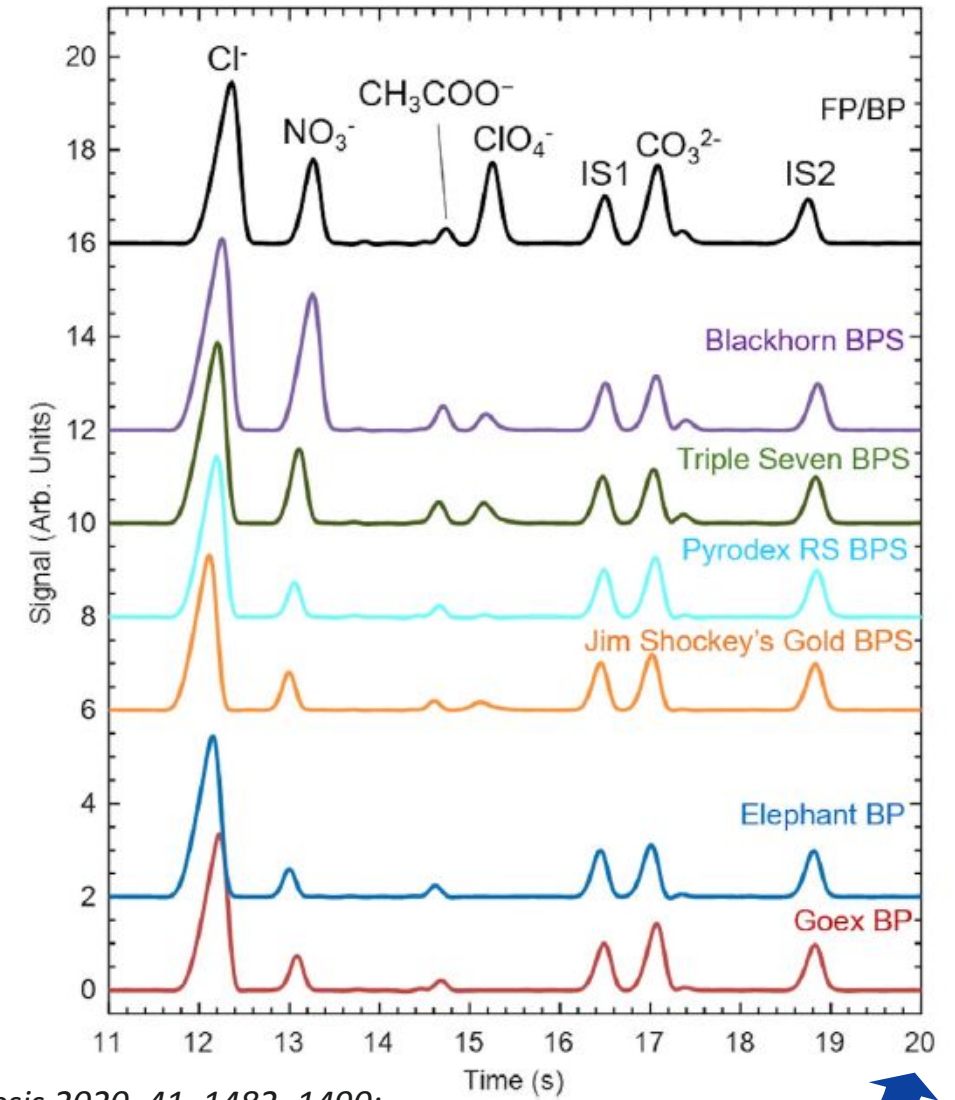
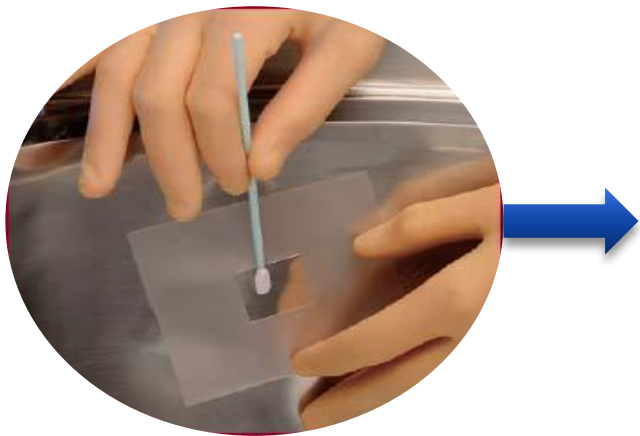
However, in terms of innovation, it is Miliran's MVB 3XTM barriers that seem to be an absolute necessity for any facility

December 2013/January 2014 Aviation Security International 2

The GreyScan ETD-100



The GreyScan ETD-100



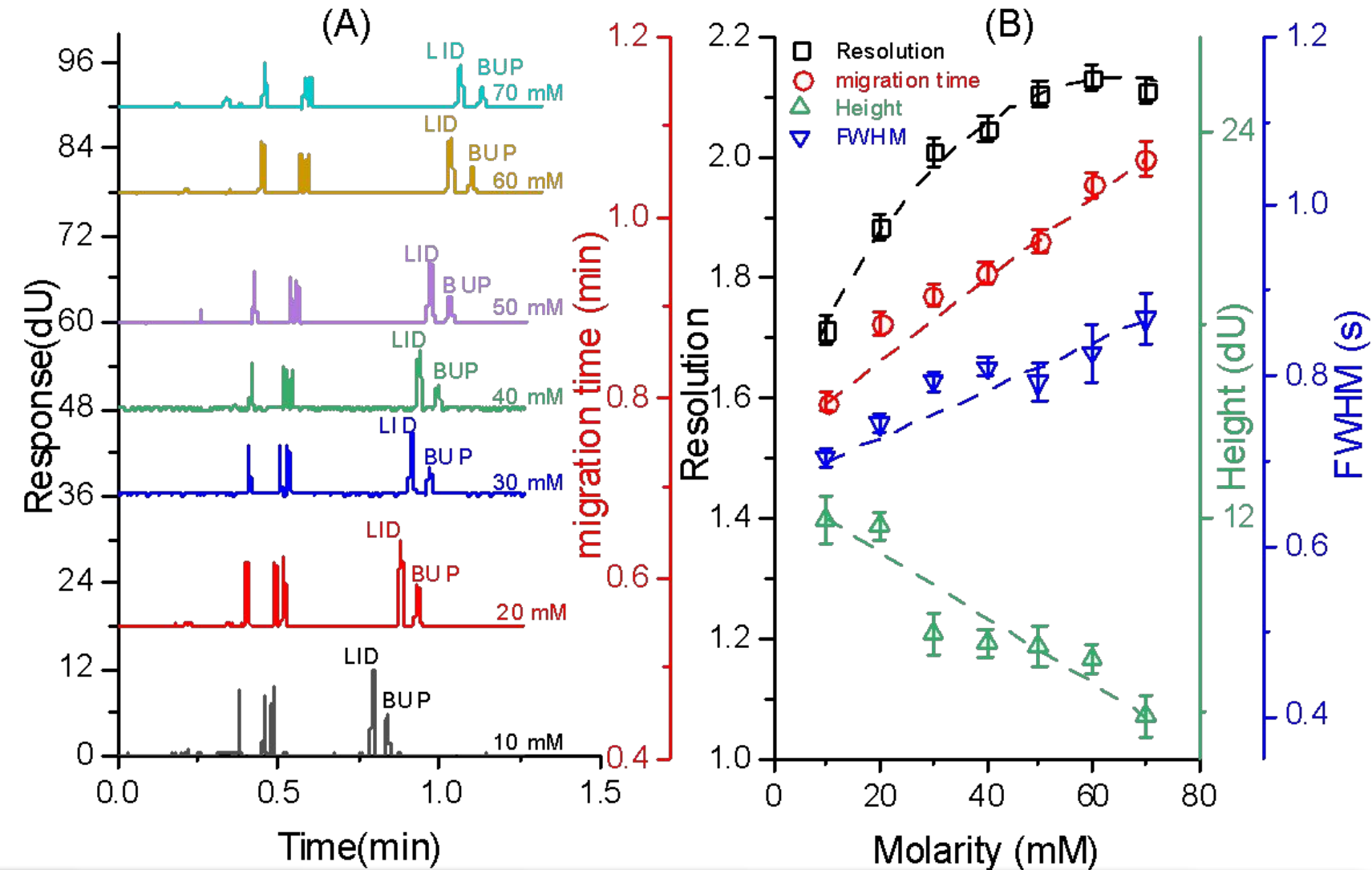
Krauss et al, *Electrophoresis* 2020, 41, 1482–1490;



Can the ETD-100 be used for trace pharmaceutical detection?

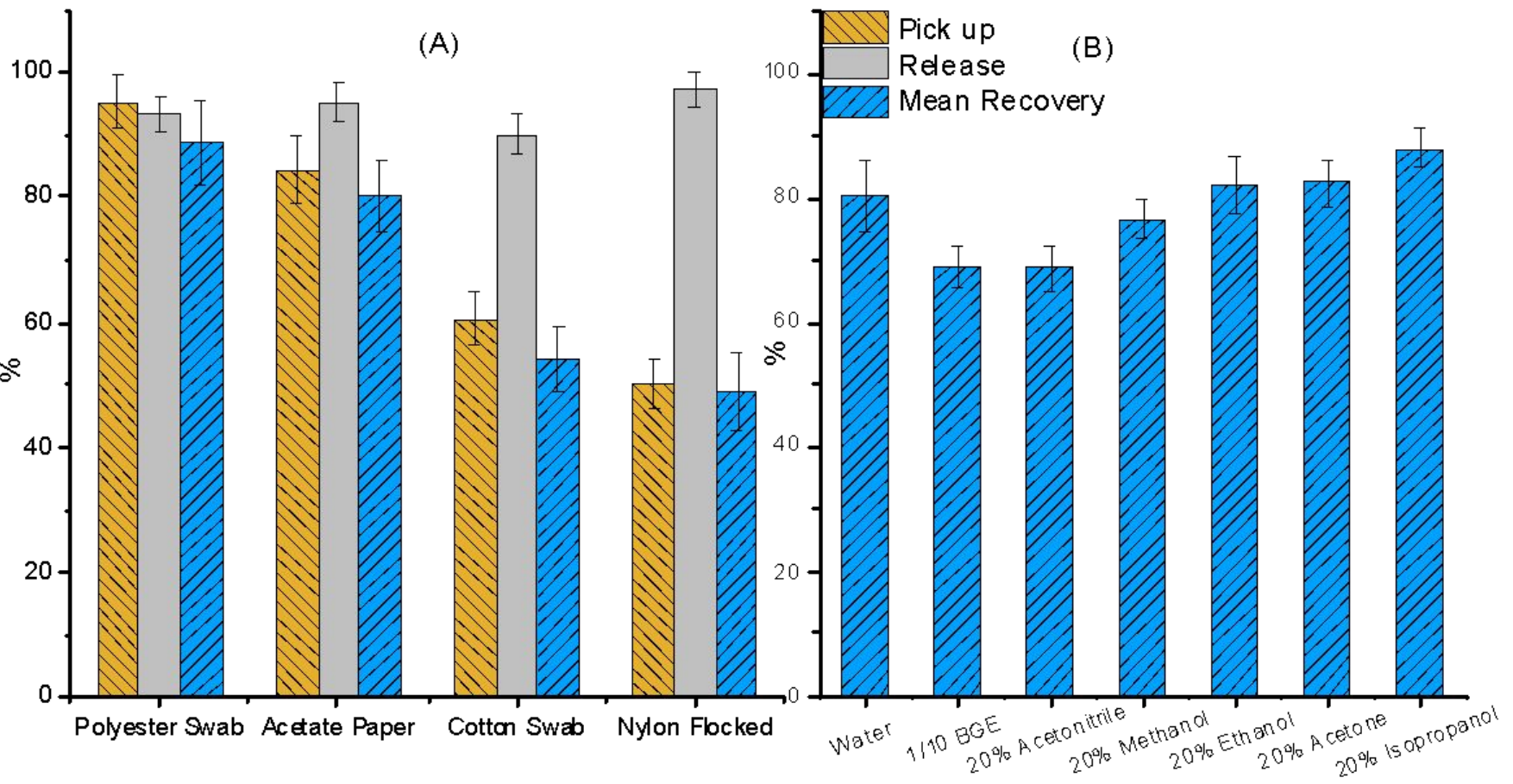
- Many papers on CE of pharmaceuticals
- Limitations of the ETD-100
 - C4D detection (charged drugs)
 - Some current components are not compatible with organic solvents
 - Single type of swab (acetate paper)
 - Destructive analysis (swab residue cannot be reanalysed)
- Benefits of the ETD-100
 - Portable system that can operate off battery for 6 hours
 - Completely integrated extraction system with the CE
 - Time saving with **1-2** min outcome after inserting the swab, Potential for 2-5 min turnaround on analysis
 - Has **large surface coverage** unlike other portable handheld techniques.

ETD-100 CE-C4D optimisation



(A) CE separation of 10 µg/swab Lidocaine (LID) and 5 ppm Bupivacaine (BUP) as at different concentrations of BGE
 (B) Effect of different concentrations of BGE on LID height, FWHM, Migration time and Resolution between LID and BUP.

Extraction characterisation and optimisation



Pick up



Release



ETD-100 performance metrics

Parameter	GreyScan ETD-100	Agilent 7100 CE
Range (µg/swab)	0.50 – 20	0.50 - 20
Intercept (a)±SD	0.398 ± 0.024	1.05 ± 0.029
Slope (b)±SD	2.632 ± 0.053	0.246 ± 0.002
LOD (µg/swab)	0.133	0.312
LOQ (µg/swab)	0.403	0.946
R ²	0.997	0.998
% RSD of Peak Height	2.21	1.62
% RSD of Migration Time	0.187	0.200
Number of Theoretical Plates (N)	517×10 ²	525×10 ²

Calculation for a Swab Sample:

$$1. \frac{\text{Lowest Dose (Product A)}}{\text{Safety Factor}} \times \frac{\text{Batch Size}}{\text{Max Daily Dose (Product B)}} - \text{Maximum Allowable Carryover (MAC)}$$

(Product A is the product being cleaned/Product B is the subsequent Product)

- MAC/Total Surface Area = Surface Residue µg/cm²
- Surface Residue/cm² × Area Swabbed = Residue on Swab (µg)
- Residue on Swab(µg)/Dilution Volume (mL) = Residue level in swab sample (ppm)

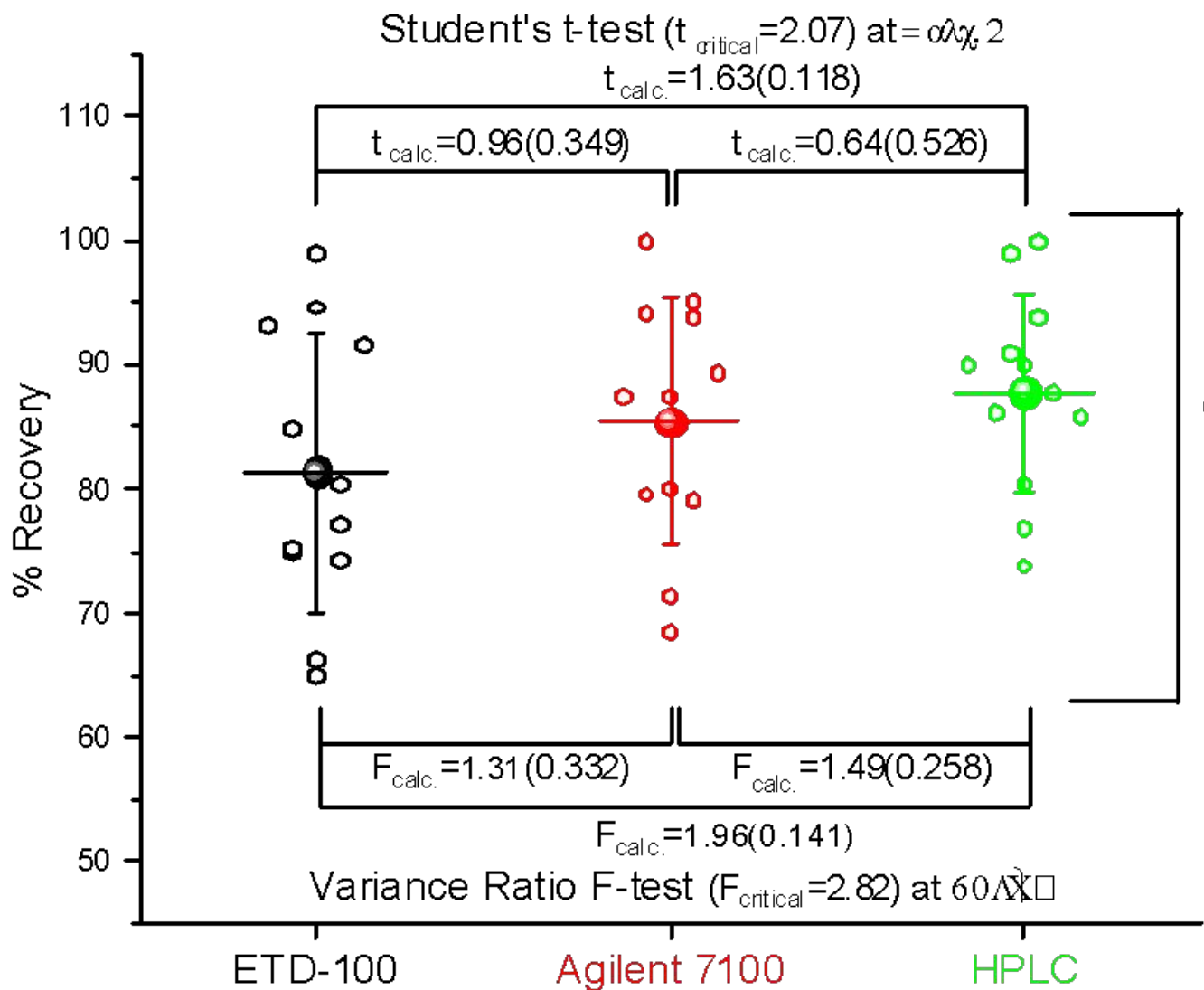
The table below shows the MAC values, Surface Residues, and PPM values in an Analytical Sample for all combinations of Lowest Dose (0.001 mg and 500 mg), Batch Size (15 kg and 50 kg), Maximum Daily Dose (0.05 gm and 5 gm), and total Surface Areas (1,000 cm² and 100,000 cm²). A swab area of 100 cm² and a swab recovery of 100% are assumed.

Lowest Dose (mg)	Batch Size (kg)	Max Daily Dose (gm)	MAC (mg)	Total Surface Area (cm ²)	Surface Residue (µg/cm ²)	ppm in 20 mL
0.001	15	5	0.003	100000	0.00003	0.0002
0.001	15	5	0.003	1000	0.003	0.02
0.001	1200	5	0.24	100000	0.0024	0.01
0.001	1200	5	0.24	1000	0.24	1
0.001	15	0.05	0.3	100000	0.003	0.02
0.001	15	0.05	0.3	1000	0.3	2
0.001	1200	0.05	24	100000	0.24	1
0.001	1200	0.05	24	1000	24	120
500	15	5	1,600	100000	15	75
500	15	5	1,500	1000	1,500	7,500
500	1200	5	120,000	100000	1,200	6,000
500	1200	5	120,000	1000	120,000	600,000
500	15	0.05	150,000	100000	1,500	7,500
500	15	0.05	150,000	1000	150,000	750,000
500	1200	0.05	12,000,000	100000	120,000	600,000
500	1200	0.05	12,000,000	1000	12,000,000	60,000,000

Table C: Calculation for a swab sample limit and simulated results

WALSH, A. *ETD-100*. *ETD-100*, 14-03.

Comparison with Normal CE and HPLC

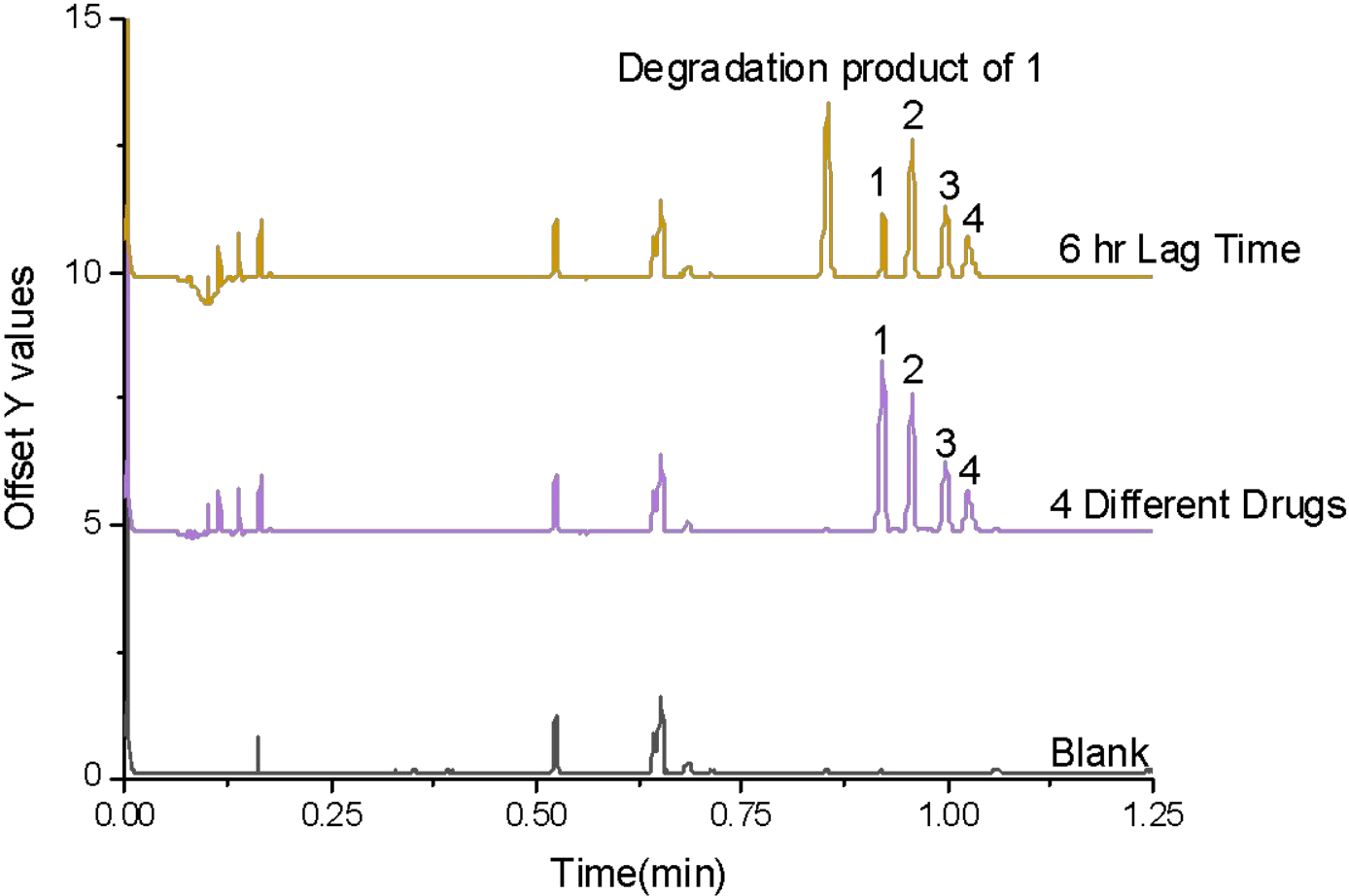


I SD
● Mean

One-Way ANOVA
 $(F_{critical} = 3.28)$ at τ
 $F_{calc.} = 1.35(0.274)$

The mean percent recovery for 12 spiked coupons with $5\mu\text{g LID} / 10\text{cm}^2$, using GreyScan ETD-100, Agilent 7100 CE and a reported HPLC method. The tabulated t and F values for Student's t-test, Variance ratio F-test and ANOVA are 2.07, 2.82 and 3.28 respectively at 95% confidence limit ($\alpha = 0.05$).

More Drugs... less time



Where are we now?

- Capability of the ETD-100 for trace pharmaceutical detection has been demonstrated.
- Can reach all but the highest requirements for cleanliness testing in 2-3 min at-site.
- On-line concentration will allow lower limits to be achieved.
- Potentially applicable to other applications
 - Illicit drugs
 - Bacteria
 - viruses

Thanks to...

- Supervision and advice from:
 - Prof. Michael Breadmore, Prof. Paul Haddad.
- Sponsorship and scholarship from:
 - ARC, UTAS, Pfizer® and GreyScan®.
- All my colleagues

