Diagnose and monitor hygiene across the hospital

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1 Measuring cleanli and hygiene

Introduction
The purpose of this document is to address the issues around the measurement of cleaning and its impact on the control of hygiene, infections, and the quality and cost of service delivery.

Existing methods are inadequate and there is a need for simple, rapid, objective methods.

A proven measurement system is described with substantiating data and real case study experience for several applications in many different healthcare settings.

We will discuss:
- Existing methods and their limitations;
- An instant objective measurement system;
- Infection control and environmental hygiene;
- Sterile services and endoscopy;
- Multiple applications across many hospital departments.

Problem
- Healthcare relies almost entirely on visual assessment;
- NHS cleaning manual defined clean as "the absence of blood, spillages, stains and sticking plaster";
- Poor definition and very subjective that means different things to different people;
- Not a quantitative measure of cleanliness
- Not objective
- Gives poor quality management information
  - "Looking clean (e.g. shiny, dust-free, good smell)";
  - This implies that cleaning activity has occurred but…
  - It gives no information about how well the cleaning was performed.
- The National Institute of Health Research – "NHS places great reliance on visual assessment of surface cleanliness. However, reliance on observational evidence in judging cleaning efficacy is subjective and may be of questionable validity…"

- Steve Davis (Cardiff University review for Unison, 2009) stated that visual assessment resulted in "…misleading over-estimate of cleaning in hospital units and is therefore potentially undermining infection control strategies."
- Visual assessment is subjective and unreliable. Carling and Bartley (2010) state that:
  - 89% of hospitals use visual assessment of cleaning… but this can only detect gross lapses in practice.
  - Only 34-40% of surfaces are actually cleaned in accordance with policies
  - Monitoring and interventions improves the thoroughness of cleaning from 40% to 82%.

This also means that there is a lost opportunity for better control and potentially 60% wasted effort.

In the UK, the NHS spends £725m per year on cleaning, and 90% of the cost of that cleaning is labour. The NHS productivity review (2016) concluded that savings of £93m are achievable in cleaning alone.

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Solution

The National Institute of Health Research stated that…"the ideal test for cleaning efficiency then is a test for organic matter itself. The use of ATP bioluminescence can provide this, giving an instant indication of total surface contamination and importantly an objective assessment of cleanliness. ATP detects invisible contamination and tells us that the surface has been cleaned."

The ATP test has been used for >30 years as a direct objective rapid test to verify cleanliness and is recognised by the NHS Research Institute, Department of Health and Health Protection Agency's Rapid Review Panel, CDC in USA and Danish and Swedish Standard for Hospital cleaning and Infection control DS 2451-10 2011. Many published papers show the benefit of using the ATP to verify cleanliness in healthcare including decontamination services.

H James Harrington said:

"Measurement is the first step that leads to control and eventually to improvement.

If you can't measure something, you can't understand it.

If you can't understand it, you can't control it.

If you can't control it, you can't improve it."

Table 1. Benchmarks for cleanliness standards based on ATP Bioluminescence

Location	Pass	Caution	Fail
Public areas	100	101-200	>200
Near patient areas	50	51-100	>100
High care areas	25	26-50	>50
Sterile services	10	11-30	>30
Ambulances Driver cab Patient saloon	 50 50	 51-200 51-100	 >200 >100

Unit of measurement are Relative Light Units (RLU) and are equivalent to ƒ mols ATP

1 Measuring cleanli and hygiene

What is Adenosine Triphosphate (ATP)?
ATP is the universal energy carrier present and is a common component of all living cells; animal, insect, plant and microbes).

Test methods based on ATP
The ATP bioluminescence test is a biological test that uses the enzyme luciferase to generate light, and the amount of light is directly proportional to the amount of ATP present. The test is specific for ATP and it is extremely sensitive being able to detect down to 2.5 picograms (pg) of ATP and giving results in 15 seconds.

It detects ATP from all sources, but cannot differentiate between different sources of ATP. It is a direct objective test for total organic soil and cleanliness.

The ATP test requires an integrated sample collection and testing device (UltraSnap) and an instrument (Luminometer) to measure and record the light output.

It is simple and easy to use by anyone, anywhere, anytime.

Recognition of the benefits of ATP monitoring in Healthcare
The ATP test has been evaluated for >10 years in several healthcare settings.

It has been shown to be more sensitive, quantitative and faster than a protein test for the measurement of cleanliness, and benchmarks have been established in several healthcare settings (see Table 1).

- Benchmarks have been established and verified (Lewis and Griffiths, 2008; Mulvey et al, 2011)
- Revised NHS cleaning manual also recognises the potential benefit of the ATP test to monitor cleanliness in the near patient environment.
- Highest recommendation from UK Dept. of Health and Public Health England's Rapid Review Panel (2009)
- CDC (USA) HAI Tool Kit (2010); Level II; Appendix B, Objective Methods of Evaluating Environmental cleaning.
- Danish Standards DS 2451-10 2011 sets acceptable levels of ATP after cleaning in both high and low risk patient environments

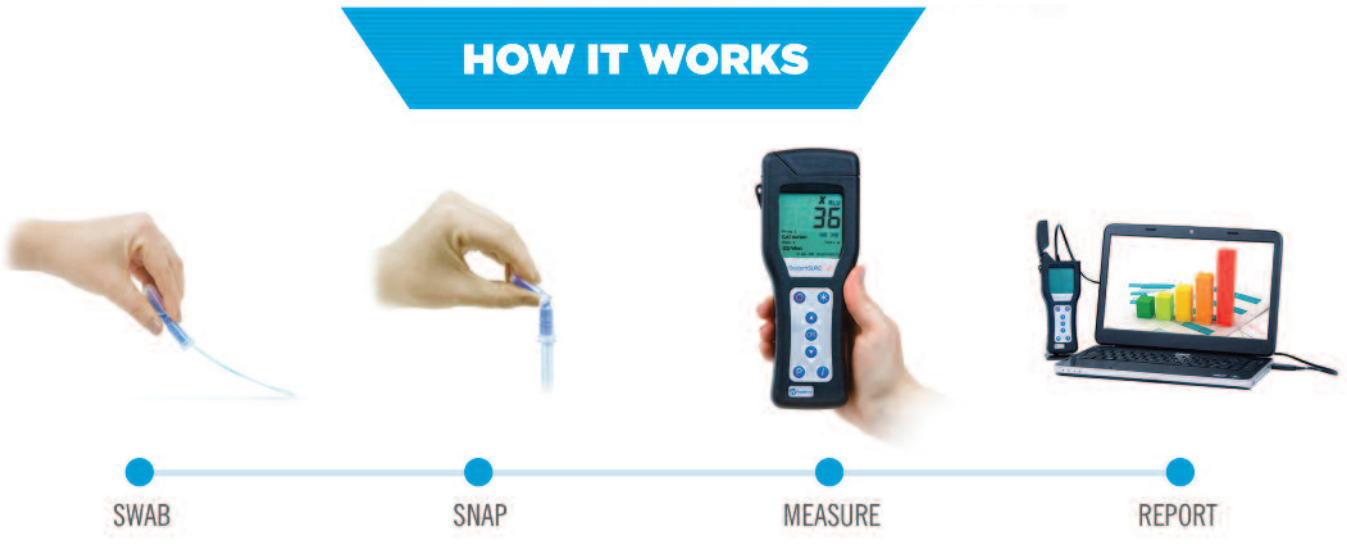

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Figure 2. Comparison of ATP Fail Levels with bacterial contamination
(Lewis and Griffiths 2008)

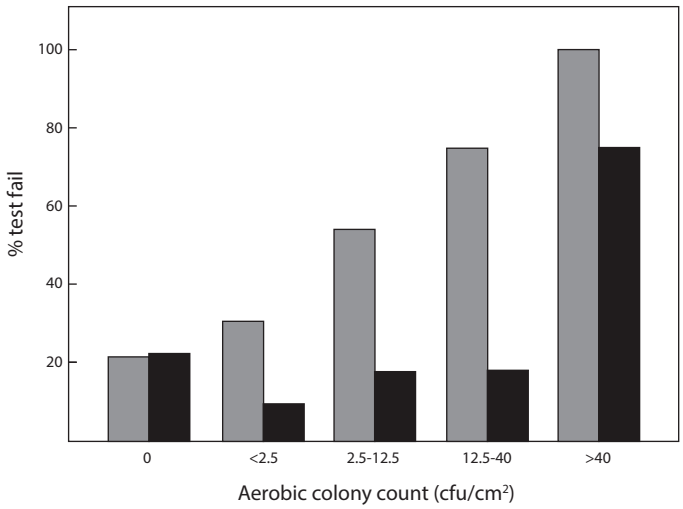
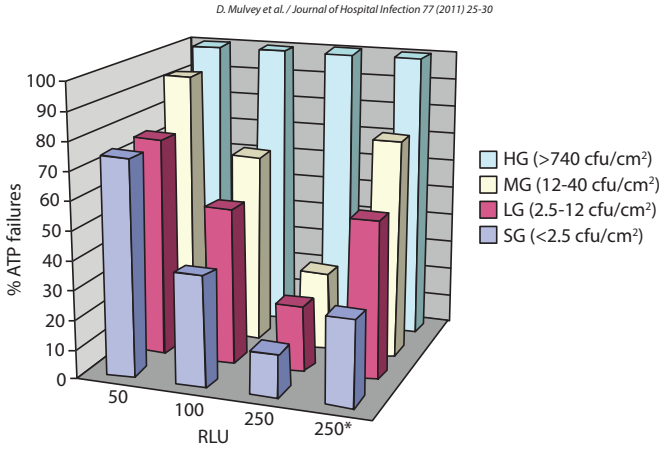


Figure 3. Comparison of ATP Failures with bacterial contamination levels
(Mulvey *et al*, 2011)



Percentage hygiene failures for three ATP benchmarks according to microbial growth categories. RLU, relative light units; SG, scanty growth; LG, light growth; MG, moderate growth; HG heavy growth. *Data from Lewis *et al*, with permission.[5]

ATP indication of microbial contamination

In its simplest form, the standard ATP test detects all ATP present in the sample and it cannot differentiate different sources of ATP i.e. it cannot differentiate microbial from non-microbial ATP. However decontamination processes are designed to remove all sources of contamination i.e. both body fluid and microbes. Thus there is a direct and concurrent relationship between ATP and bacterial contamination. Evidence shows that as the percentage of ATP failures increase there is a corresponding increase in bacterial contamination; see Figures 2 and 3.

Summary

- Cleaning is key to infection prevention and control
- Cleaning has a very high cost (mostly labour)
  - Inconsistently delivered; poorly monitored and controlled
  - Large waste and unnecessary risk
- Visual assessment methods of cleaning are subjective and of “questionable value”
- ATP bioluminescence provides a rapid objective detection systems
  - Simple convenient and easy-to-use
  - Well proven technology giving instant objective results; many applications
  - Makes the invisible visible; set quantifiable standards
  - Gives meaningful measurements of cleanliness that aides communication
- Better management information enables better targeting and focussing of resources to provide more control that drives an improvement in
  - Cleaning standards and delivery
  - Value for money
  - Compliance,
  - Infection rates
  - Patient care
  - Efficiency; Less waste

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2 Infection Control & Environmental Hy

Problem

Healthcare Associates Infections (HCAI) and WHO statistics

- Europe HCAI prevalence 7.1%
- 4.1 million patients
- €7 billion costs
- 37,000 deaths
- Equal to 7 Jumbo jet crashes every month
- HCAI are preventable

The patient environment recognised as a reservoir of contamination

- Hayden *et al* (2006)
  - "Decreasing environmental contamination helps to control the spread of antibiotic resistant bacteria in hospitals"
- 20-40% HCAI from unclean surfaces and hands of healthcare workers
- Bacteria can survive up to 60 days on surfaces
  - 78-93% telephone and computer keyboards contain coliforms and Staphylococcus.
- Superbugs continue to emerge.
- Traditional antibiotics have lost their efficacy.

Earlier adopters such as North Tees and Hartlepool Trust have shown a consistent and marked improvement in cleanliness and reductions in infection rates since its introduction in 2008. The results have shown a >20% improvement in pass rates and a large reduction in fail scores to fewer than 5% with a corresponding decrease of 35% in C. difficile cases and a 39% reduction in infections per 10,000 occupied bed days. Monitoring officers, independent from nursing and environmental services staff, are assigned to act as project champions for individual facilities, reporting to departmental managers wherever poor cleaning was discovered and where corrective action is required. Monthly reports are circulated for cross-functional team meetings of nursing, facilities and infection control staff. This allows for open discussions on all cleaning and maintenance related issues and stimulates actions for improvement.

The Hygiena SystemSURE Plus received the highest recommendation for the Dept of Health and Public Health England's Rapid Review Panel in 2009. It has many different applications within hospitals including the routine testing of patient room, identification of hotspots and hazard management, training of cleaning staff, and hand wash training and verification.

The benefits of the ATP cleaning verification system include a dramatic improvement in hospital cleanliness, optimised cleaning performance and personnel training, increased productivity commitment and morale of cleaning staff and reduced infections rates. The NHS Productivity Review (2016) showed that there are savings of £93m to be made from cleaning alone.

Southport and Ormskirk NHS Trust have been using the ATP technology for >5 years for several applications and departments from medical equipment library, ITU, IP&C, domestic services, planned care, catering and operating theatres. It is also used for hand hygiene training and compliance monitoring. Andrew Chambers explained: "We also use Hygiena ATP monitoring when we may have had an incidence of VRE, for example. After a clean, the area might look clean but a number of spot ATP tests might show that the area is, in fact, not clean.

"ATP gives you a clean hospital," said Val Hulme (Team leader Domestic Services). "When you're doing a deep clean the staff know they are going to be tested but they do everything to a very high standard now. ATP has helped us to achieve that. "When you have a number – like the ATP machine gives you – it's more objective than subjective. You can't argue with it."

"ATP makes the staff competitive. They all want to score five or below. And ideally zero."

Andrew explained: "The results of the ATP monitoring are incorporated into the weekly

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ygiene

PREVALENCE OF HCAI IN DEVELOPED COUNTRIES IS **3.5-12%**

USA
4.5% prevalence
1.7 million patients
99,000 deaths
$6.5 billion costs

EUROPE
7.1% prevalence
4 million cases
37,000 deaths
16 million extra bed days
€7 billion costs

UK
6.4% prevalence
300,000 patients
£1 billion costs

infection prevention and control performance report, which is circulated trust-wide. It includes a breakdown of the results of commode cleanliness, amongst a range of other items, area by area."

"This adds a competitive edge and drives the staff to achieve a low score."

"It's there to encourage people, to make them aware. If they're doing a good job, it's a low number and the staff are delighted."

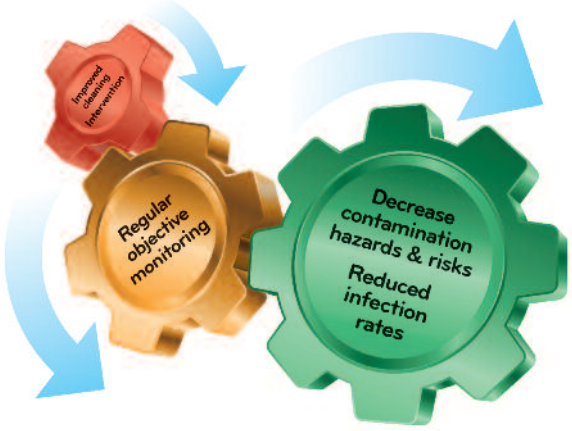
"If we have an area of concern with a particular infection or organism – we use ATP as part of the investigation. The benefit is that with ATP we can react immediately to the results on site and put any necessary interventions into immediate effect. That way we're safeguarding patients, which is what it's all about." Andrew added: "Low numbers mean it's a safe environment for patients to be in."

Similar improvements are seen in USA where the CDC also recommends the use of ATP as part of the monitoring tool kit for environmental cleaning. The Environmental Services (EVS) manager (Gomez) at Deaconess Rehabilitation Hospital in Evansville, Indiana said "Realizing that our surfaces were not as clean as we thought was – quite honestly – a slap in the face. But it was a good wakeup call for everyone, especially me. As EVS leaders we sometimes think our processes are flawless and we don't make mistakes because we've been in the industry for so long. We become overly confident – and that can be our worst quality. We have to be open to the idea that we are bound to make mistakes. How we respond from those mistakes and improve our processes is what will help us to become confident and assertive leaders."

"ATP testing has truly helped us become aware of our cleaning techniques," Gomez says. "We now hold educational meetings to discuss the program's success and areas where we still have trouble – to make sure we're quick to correct any problems that consistently show up in our 'fails' report."

A review by an independent company rated the Evansville healthcare system the highest score for cleanliness among the more than 600 facilities the company surveyed. ATP testing played a significant role in that achievement.

The EVS department also reports results of ATP inspections to the infection control specialist and committee. "Our infection control specialist has actually watched us do our inspections to see how staff performs that duty. Our infection rates are very low – and that's a credit to everyone."



3 Sterile service and endoscopy

The concept of testing to monitor the efficacy of decontamination processes is well established in sterile services. Historically, protein tests have been used to monitor the cleanliness of surgical equipment.

Definition

- Decontamination is the process of cleansing to remove contaminants such as micro-organisms or hazardous materials;
- Decontamination can be a combination of processes, including cleaning, disinfection and sterilisation;
- Cleaning is the first step;
- Failure of cleaning compromises sterilisation procedures.

Problem

NHS Medical equipment and Failure:

- £500m annual spend on capital equipment and consumables;
- Additional 30-50% cost for maintenance due to improper use;
- 20-40% equipment is under-utilised (WHO);
- 13,000 reported incidents in 2013 due to faulty instruments;
- 1400 deaths.

Limitation of protein tests

Visual assessment and protein tests have been used for decades for assessing the decontamination of surgical equipment and washer disinfectors. The subjectivity and inaccuracy of visual assessment is recognised and a call for more objectives methods of assessment has been made (Heathcote and Stadelmann, 2009).

Protein residues being a common component of body fluids have been used historically to monitor cleanliness in sterile service facilities and are still promoted in the regulation (BS 15883), HTM 2030 and CFPP 01-01 and 01-06.

The target level for detection has been 2mg protein per square meter or better which means the detection range for a typical swab area (10 x 10cm = 100cm^2 = 0-20µg protein per swab. For smaller surface areas 10cm^2 = 0-2µg protein per swab.

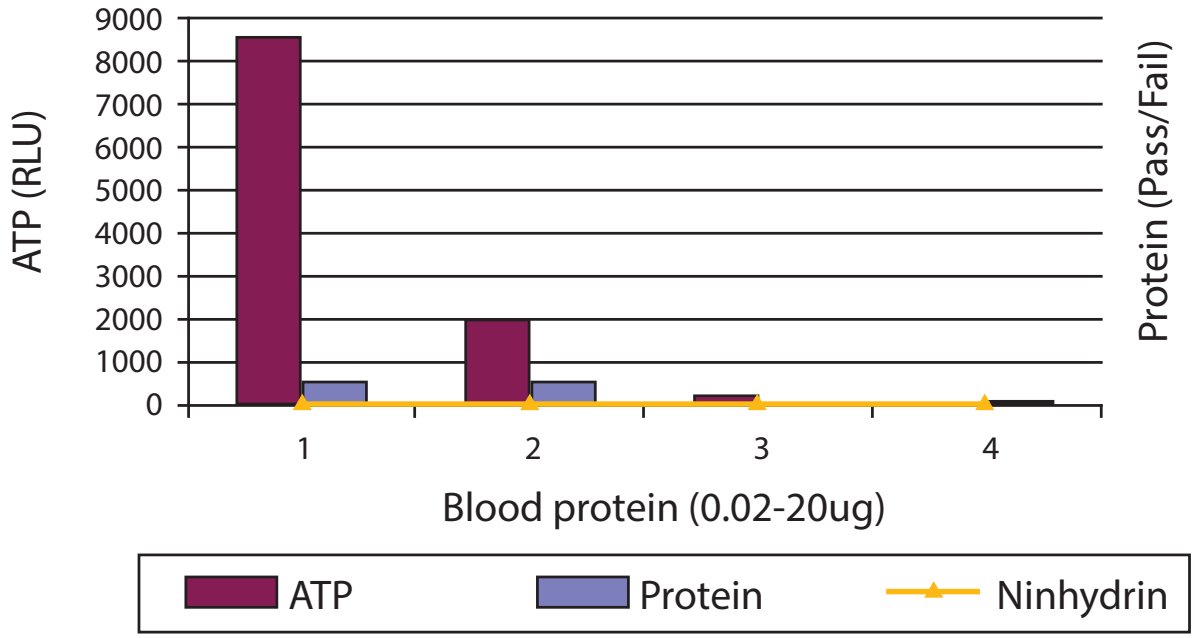
The sensitivity of these protein tests is running at the limits of detection (1-3µg protein for the Biuret protein test) and the variable nature of sample size means that the results is a presence or absence test at best. However the ninhydrin protein test is not as sensitive.

Vassey et al (2011) assessed residual protein on dental instruments cleaned in general dental practice by manual, manual plus ultrasonic and automated washer disinfector (AWD) processes. They showed no correlation between visual assessment and residual protein data, and demonstrated several shortcomings in cleaning chemistries and operation of automated washer disinfectors. Manual washing combined with ultrasonic cleaning was significantly less effective than either manual washing alone or automated washer disinfectors. The median detectable residual protein contamination of 72% of 1304 instruments subjected to a cleaning process was 10.25µg.

Lipscomb et al (2006) found that Biuret test was more sensitive than the Ninhydrin test but both were insensitive compared to their epifluorescence microscopy method.

Studies by Murdock et al (2006) have shown that 17% (35/206) of cleaned and sterilised surgical instruments exceeded the threshold of 200µg protein whereas certain items had 5 or 10 fold greater levels of contamination at 1-2mg protein. Clearly, inadequate cleaning procedures represent a direct cross contamination hazard that could compromise patient safety.

Figure 4. Detection of fresh blood by ATP and Protein tests



Technical Memorandums recommend tests for residual soil that…
"The method will detect a broad spectrum of residuals from body fluids and is thus suitable for detecting residual contamination."

The ninhydrin protein test adopted decades ago in the absence of other suitable methods but it has been shown to lack sensitivity and performance which has prompted the quest for alternative methods including alternative protein test or tests for other common components of body fluids such as the detection of enzymes in blood cells. More recently specific protein test for prion proteins have been requested.

Both HTM 2030 and CFPP 01-01 and 01-06 recognise the need for better test methods and state that… "Alternative systems/kits may be commercially available. Use of these should demonstrate resolution and accuracy at a similar level to that of the technique described above."

Adenosine triphosphate (ATP) is the universal energy carrier found in all living cells. It satisfies the requirement because it is a common component of all body fluids and enables the detection of a 'broad spectrum of substances'.

It also offers other benefits by being more sensitive than protein tests by at least 2-3 orders of magnitude, and gives a numerical quantitative result in 15 seconds that can be stored electronically with track and trace capability for due diligence.

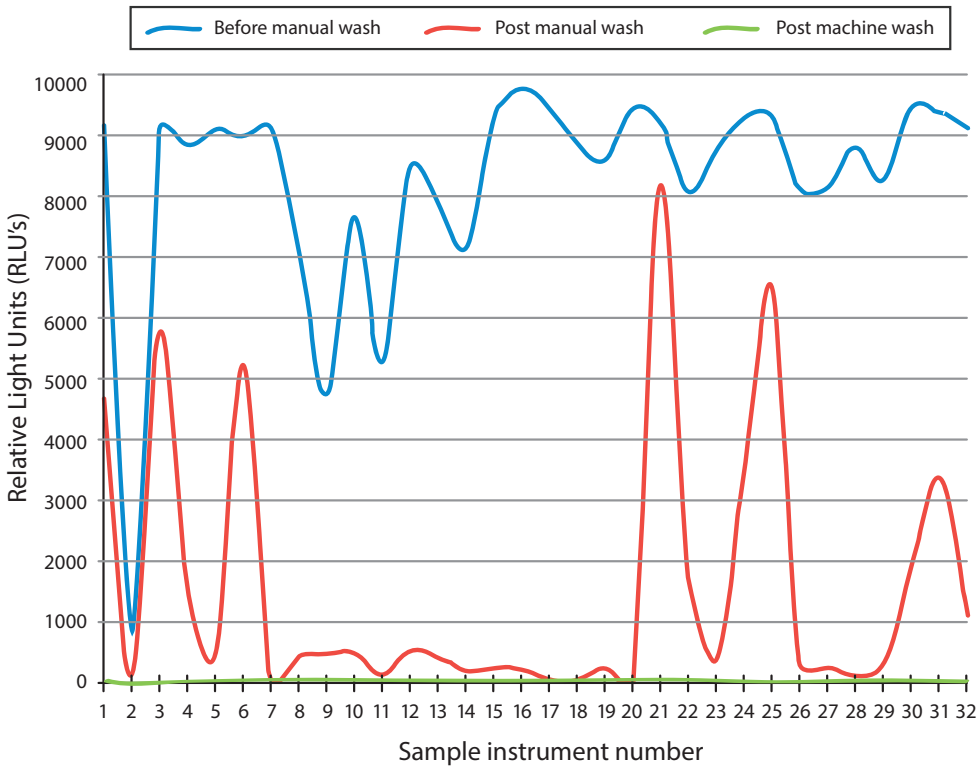
The ATP technology is well established and proven and therefore meets the requirement of both HTM and CFPP guidance documents.

Comparison of methods

Figure 4 shows the ATP test detects dilutions of blood < 1:100,000 dilution < 0.02µg. It gives results that are faster, easier to interpret and give objective numerical results:

Sterile service and endoscopy

Figure 5. Measured ATP bioluminescence results across the decontamination cycle
(From Heathcote and Stadelmann, 2009)



- Ninhydrin colour test did not detect <u>any</u> dilution of blood;
- Biuret protein test (MediCheck) clearly detected a 1:1000 dilution of blood (~ 2µg), but only under correct conditions of time/temperature (37˚C x 30mins).

Heathcote and Stadelmann (2009) (see Figure 5) used ATP bioluminescence to monitor AWD performance:

- 99.85% reduction in contamination:
  - Before cleaning = 8289 RLU
  - Manual cleaning = 1518 RLU
  - After AWD = 4

Endoscopes pose a more significant risk

Modern key hole surgery uses endoscopes that are very complex instruments and are difficult to clean – 30% are contaminated (Hansen et al 2004) and *APIC 40th Annual Conference 2013:*

- *<u>3 out of 20 scopes</u> used to examine GI tracts and colons improperly cleaned;*
- Screening at 5 US hospitals using the ATP test showed unacceptable levels of organic matter from a patient's body that could pose potential infection risk.
- 275 flexible duodenoscopes, gastroscopes, and colonoscopes analysed:
  - 30% duodenoscopes failed;
  - 24% gastroscopes failed;
  - 3% colonoscopes failed.

Hansen et al 2004 compared the ATP bioluminescence and microbiological methods to check hygiene of the reprocessing procedures;

- 108 flexible endoscopes were tested;
- 28 endoscopes showed bacterial growth;
- 28-67 endoscopes were contaminated (depending on the acceptance level of ATP).

These Authors stated that:

"A clean endoscope should not only show fewer viable organisms but also a less amount of all organic contamination and ATP sources."

"The presence of any ATP source may indicate an infectious risk for consecutively examined patients and should be avoided irrespective of viable bacteria."

"We conclude that ATP bioluminescence does not replace routine microbiologic methods but it should be applied additionally to check endoscope reprocessing."

"In contrast to microbiologic methods results of ATP bioluminescence are available at once and can indicate the need for checking the reprocessing practice immediately."

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Endoscopy Case Study

Gastro-scope No.44 was consistently generating readings that were much higher (e.g. 178 RLU) than the rest of his gastro-scopes.

Further investigation discovered that gastro-scope No.44 had damage to its surface which was making it more difficult to clean.

As a result it was taken out of circulation.

Previously very high reading of 258 RLU on a gastro-scope used on machine No.9 after reprocessing twice it came down to 9 RLU.

Scopes tested in
- machine No. 7 = 16 RLU;
- machine No. 9 = 48 RLU;
- machine No. 10 = 22 RLU.

All passed using the ninhydrin test which is less sensitive.

4 Other Application Hygiena SystemS

Water Quality
Water borne pathogens such as Legionella are covered by regulation and other opportunistic pathogens such as Pseudomonas are known to cause infections and deaths in hospital. The control of biomass and biofilm with water supply systems requires control and monitoring. The reduction of biofilm and removal of stagnant water is a primary control together with effective water treatment. The Hygiena SystemSURE Plus and AquaSnap test device are used to monitoring water quality in many application from cooling towers, sluice rooms, sterile services to hydrotherapy pools.

Emergency vehicles
Ambulances (both ground and air) and patient transport vehicles provide an opportunity for cross contamination particularly in emergency situations when spillages and open wounds can compromise vulnerable patients and the healthcare worker. The Hygiena SystemSURE Plus is used by many ambulance groups and services providers to ensure the cleanliness of their equipment and vehicles.

Forensic services also use the ATP hygiene systems to verify cleanliness after crime scene incidents.

Catering
Hygiene is an essential pre-requisite to ensure food safety which is critical to health and wellbeing. This is particularly important for the young, elderly and infirm whose natural resistance and immunity is compromised by a clinical conditions.

The hygiene of food preparation and serving areas as well as personal hygiene of food handler is regulated by law, and compliance is enforced by government food hygiene inspectors (who also use Hygiena SystemSURE Plus). The use of rapid hygiene test systems ensure high standards of hygiene are implemented and provides evidence of due diligence and compliance to inspectors.

Training
The ‘Clean your hands’ campaign has been a major plank in the WHO strategy to reduce HCAI, and it is also a fundamental requirement of food hygiene. Hygiena SystemSURE Plus is used to both train and monitor hand wash technique, as well as demonstrate the importance of the correct cleaning procedure in the patient environment, medical equipment and high touch surfaces.

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Dental
The sterility of dental surgical equipment and water supply are critical to dental treatment and surgery. The potential for the cross infection from equipment, high touch surfaces and aerosols in the patient environment is similar to that in the hospital environment where high standards of hygiene are required. The Hygiena SystemSURE Plus is also used in dental surgeries to monitor hygiene levels and demonstrate compliance and best practice during hygiene inspections.

Care homes
Maintaining good hygiene in care homes for the elderly and infirm is equally important. High standards of personal hygiene, as well as efficient management of catering facilities, the environment and any equipment in use are required.

The Hygiena SystemSURE Plus can be used to monitor hygiene levels, train staff and demonstrate compliance and best practice anywhere that hygiene matters.

Diagnose and monitor hygiene levels across the hospital

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