



Major article

Failure analysis in the identification of synergies between cleaning monitoring methods



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Background: The 4 monitoring methods used to manage the quality assurance of cleaning outcomes within health care settings are visual inspection, microbial recovery, fluorescent marker assessment, and rapid ATP bioluminometry. These methods each generate different types of information, presenting a challenge to the successful integration of monitoring results. A systematic approach to safety and quality control can be used to interrogate the known qualities of cleaning monitoring methods and provide a prospective management tool for infection control professionals. We investigated the use of failure mode and effects analysis (FMEA) for measuring failure risk arising through each cleaning monitoring method. **Methods:** FMEA uses existing data in a structured risk assessment tool that identifies weaknesses in products or processes. Our FMEA approach used the literature and a small experienced team to construct a series of analyses to investigate the cleaning monitoring methods in a way that minimized identified failure risks.

Results: FMEA applied to each of the cleaning monitoring methods revealed failure modes for each. The combined use of cleaning monitoring methods in sequence is preferable to their use in isolation.

Conclusions: When these 4 cleaning monitoring methods are used in combination in a logical sequence, the failure modes noted for any 1 can be complemented by the strengths of the alternatives, thereby circumventing the risk of failure of any individual cleaning monitoring method.

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Cleaning in health care settings is a manageable activity that can be audited for consistency and quality.¹ The processes of cleaning environment surfaces within hospitals can be monitored by 4 distinct methods: visual inspection, microbial recovery, rapid ATP bioluminometry detection, and use of fluorescent marker (FM) technologies.² Each of these monitoring methods generates a distinct type of information that is difficult to integrate into a single monitoring result.^{3,4}

Although cleaning has the goal of removing soils and pathogens, the monitoring methods used for management and supervision of cleaning have a distinct quality assurance role.⁵ The goal of any monitoring method is to provide feedback on cleaning failure to assist in the management and improvement of environment cleaning within health care settings.⁶⁻⁹

The sampling approach taken for the monitoring of environment surfaces within health care settings is a constant problem.^{10,11}

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The apparently random distribution of soils, including dry surface biofilms and pathogens, presents a challenge for any sampling plan investigating the nature of environment contamination, and is complicated by the presence high-touch objects.¹²⁻¹⁴ Health care environment cleaning protocols are management tools that set out the practical steps to achieving the goal of removing soils and improving the quality of environment surface hygiene.^{15,16}

Health care cleaning processes are designed on a risk-based format with the highest risk areas requiring the most frequent or highest-intensity cleaning.¹⁷ The secondary process of cleaning monitoring is intended to ensure that soil removal goals are met with optimal efficiency and efficacy.¹⁸

If the cleaning monitoring method is flawed due to uncontrolled or unrecognized failure, then the data on cleaning outcomes will also be flawed and unreliable. This compromises the management goal of ensuring that the primary process of cleaning has been achieved.

We focused on the failure of cleaning monitoring methods and not on the actual processes of cleaning. Failure mode and effects analysis (FMEA) is a reliable safety and quality management risk-assessment tool that identifies potential failure conditions or errors that may cause failure for products or processes.¹⁹ The FMEA

applied here investigated if current cleaning monitoring methods could be optimized to reduce cleaning failures as a type of medical error.^{20,21}

Within this management context, FMEA as a risk tool can add value by systematically examining failures to mitigate or minimize their influence on the cleaning process being undertaken.²² An ultimate aim is the identification of failure modes within cleaning monitoring systems as a quality improvement process in health service provision.²³

FMEA is typically conducted on products or processes, through the application of existing information on identified failures or failure modes to anticipate failure events. A failure mode is defined as a "loss of intended function" under normal operating conditions. FMEA was selected as a suitable method for prospective risk assessment of the 4 monitoring methods due to its applicability as a forecast model and as a risk-assessment tool that is frequently used in the context of medical devices.²⁴

A risk-assessment team of 3 individuals with collective skills in FMEA and cleaning monitoring using each of the 4 methods was formed, with the following aims:

- To identify a modified approach for the application of FMEA in failure analysis relating to the 4 commonly used cleaning monitoring methods,
- To test the feasibility of the approach by carrying out a preliminary assessment of the 4 monitoring methods using the modified FMEA approach and to identify areas of commonality and work toward a monitoring model that could include the 4 methods in an integrated monitoring approach, and
- To identify strategies for the development of potential synergies during an integrated application of the 4 cleaning monitoring methods.

For each of the identified failure modes, literature support was required as part of the process of identification and consideration of mitigation for each major failure mode.

METHODS

The initial step in the FMEA process was for the FMEA team members to identify all possible causes of failure (loss of intended function) for each of the 4 cleaning monitoring methods.²⁴ Each identified failure mode was substantiated by relevant material in the literature. Where similar, multiple, or overlapping causes of failure were identified, these were gathered under a common failure mode. A comprehensive list of failure modes was noted for each cleaning monitoring method.

The risk associated with each of the failure modes was then assessed individually by each of the FMEA team members. Each of the failure modes was graded against 3 distinct categories with associated risk criteria. These categories were first graded for the likely frequency of occurrence of that failure mode during normal use, second for the severity of the effect of this failure mode on the validity of the information produced, and finally the assessment was also graded for whether the failure mode had any detectability in the normal course of its use. The grading system applied for this study is shown in Table 1. It uses a 3-tiered scoring approach similar to the 3-tiered risk criteria that are used in Australian Infection Prevention.²³ In the FMEA method used in our study, each category was assigned a score of 1-3 (low to high).

After the grading of each failure mode against each of the 3 categories (frequency, severity, and detectability), the grades for each failure mode were multiplied to produce a single score known as the risk priority number (RPN). The RPN is an overall indicator as to whether the failure mode requires further consideration or

Table 1

Ordinal conversion table for assigning values to identified failure risk cofactors

| Failure risk cofactor and criteria | Descriptor | Value |
|--|-------------|-------|
| Frequency | | |
| The failure mode is unlikely to occur, or cannot occur, during normal monitoring operations | Low risk | 1 |
| The failure mode is fairly likely to occur during normal monitoring operations | Medium risk | 2 |
| The failure mode is highly likely to occur, or always occurs, during normal monitoring operations | High risk | 3 |
| Severity | | |
| Occurrence of the failure mode will have minimal or no effect on the monitoring results, or on the associated cleaning outcome | Low risk | 1 |
| Occurrence of the failure mode will have some effect on the monitoring results, or on the associated cleaning outcome | Medium risk | 2 |
| Occurrence of the failure mode will have considerable or extreme effect on the monitoring results, or on the associated cleaning outcome | High risk | 3 |
| Detectability | | |
| Occurrence of the failure mode is easy to detect. Feedback is likely to inform immediate monitoring-failure mitigation | Low risk | 1 |
| Occurrence of the failure has a possibility of being detected. Feedback may inform early monitoring-failure mitigation | Medium risk | 2 |
| Occurrence of the failure mode is difficult or impossible to detect. Feedback is unlikely to inform monitoring-failure mitigation | High risk | 3 |

mitigation to minimize the identified failure risks. Whereas some authors have suggested use of weighting to accentuate critical failures, for the purposes of simplicity no weighting of the RPN was used in our study.²⁵ Using the 3-point grading system outlined in Table 1, there are only 10 possible RPN scores, with a minimum score of 1, a median of 7, and a maximum score of 27. The RPN for each failure mode was noted and ranked from high risk to low risk of the nominated failure occurrence.

Following the establishment of each RPN a structured dialogue was conducted to arrive at a common view on the RPN score using a modified Delphi approach.²⁶ The FMEA team members then reconfirmed each identified failure mode through the published literature and where no published evidence in support of the failure mode was available then that failure mode was discarded.

The RPN scores were finally ranked and divided into 3 classes based on a low, medium or high risk classification.²³ For ease of interpretation, the failure modes with RPN scores less than the median of 7 were accepted as low risk. Scores >7 and <13 were set as medium risk. Scores >13 were accepted as high risk.

The combined FMEA results were then considered to investigate whether combinations of the cleaning monitoring methods would provide mitigation of the effects of failure modes. This allowed for the FMEA team members to identify any novel approaches that could provide an enhanced approach to cleaning monitoring. This step allows for mitigation to be used as a form of redundancy whereby a reduction of the overall risks arising from cleaning failure is practically achieved by reducing the risks of failure of the cleaning monitoring methods. Thus the risk assessment approach is used as predictive tool to improve practice in advance of failure. This will lead to further research opportunities.

RESULTS

For the 4 cleaning monitoring methods 32 failure modes were identified and risk-assessed. Table 2 shows the 15 failure modes

ultimately found to be associated with the highest RPNs and associated failure risk.

The consideration of mitigation identified a novel combination of the 4 cleaning monitoring methods. This was particularly crucial for the high and medium risk failure modes. The new model for cleaning monitoring is outlined in [Figure 1](#).

Costs were considered on a desktop basis for the purposes of cost consideration on both individual basis and as a combination of all 4 methods.

The high and medium risk failure modes identified using FMEA for each of the cleaning monitoring methods is noted below for each of the cleaning monitoring methods.

Visual inspection

The highest RPN was for visual inspection. Although a surface may look clean, human vision cannot detect microscopic-level contamination.¹¹ This method is the current standard approach for normal cleaning monitoring within Australian and American health care settings.^{27,28}

Similarly, visual inspection cannot detect nonpathogenic soils that can be left in situ due to a flawed cleaning method, or a lack of cleaning.^{6,7,12}

Visual triggers for cleanliness have a major behavioral effect and cannot be discounted as important.²⁹ The usefulness of visual inspection is that it is the only cleaning monitoring method that assesses the visual appearance of the hospital, which is also seen by patients, their families, and the other noncleaning staff members. Visual inspection is the only cleaning monitoring method that matches the appreciation of hospital cleanliness with all of the stakeholders and that provides a representative outcome of the hospital aesthetics. It is also noted that visual inspection carries only an existing cost overhead in terms of staff time used.

Mitigations noted for visual inspection included each of the other cleaning monitoring methods.

Microbial recovery (environmental Swabs)

A high RPN and high risk classification was also associated with the delay between microbial sampling and reading results, which frequently takes longer than 48 hours.^{27,28} This delay renders cleaning monitoring results to low relevance because the patient, the cleaning processes, and the environment may have changed several times in the interim.¹⁰

Medium and high risk was associated with technical swabbing issues and poor sampling planning.¹¹ Sampling planning is particularly vulnerable to statistical error in terms of representative sampling due to the low level of sampling and the high surface area for potential contamination, even with high-touch objects or surfaces. Using a validated sampling and recovery method can mitigate many of these failures. Sampling plans should also take into account the risks of pathogenic viruses where appropriate because bacterial recovery methods will not work.³⁰ The presence of biofilm-mediated pathogens presents yet another challenge that was assessed as a medium risk failure mode.¹³ Interference due to disinfecting solutions use can also be overcome through the use of validated protocols with appropriate robustness.¹⁰

As noted in [Table 2](#), the use of the other cleaning monitoring methods (ATP bioluminometry and FM) can mitigate the time failure mode and assist in targeting the environmental surfaces that require samples collection for microbial recovery.

Rapid ATP detection

Since use of rapid ATP testing was first suggested, many technical problems have been described with regard to its use within

health care settings.^{6,31-33} The failure modes identified from our FMEA, which are categorized as medium risk, are noted in [Table 2](#).

The 3 highest RPN and medium risk scores came from unrepresentatively low ATP readings due to a failure of ATP detection.³² The correlation between high ATP bioluminometry readings and microbes has been established, but there does not appear to be any ATP level (in relative light units) that correlates with nosocomial pathogens at low levels, nor with viruses present on surfaces.³⁴⁻³⁷ The lack of correlation with specific pathogens is not recognized as a failure insofar as the setting of an appropriate alert level noting that none of the brands of ATP bioluminometers claim direct correlation with known pathogenic microbes, particularly at low concentrations on surfaces.^{8,36,37}

Difficulties interpreting the results of ATP are a medium risk failure mode that underscores the importance of validation and training.^{16,31,33}

Mitigations noted against ATP testing are the adjunct use of microbial recovery methods and FM to indicate the frequency of cleaning on relevant environment surfaces, a validated sampling plan, and appropriate levels of training in the use an interpretation of ATP readings.³²

FM technologies

The data for FM technologies are impressive with excellent correlation with cleaning outcomes.³⁸ Failure modes noted for were only for unintended or detectable visibility (and preferential removal of FM marker) and for the lack of quantitative information provided through the removal of an FM marker. FM technologies in themselves only measure whether a surface has been attempted to be cleaned, and do not provide an indication of the quantitative hygienic status of a surface. If the FM spot is removed then the data generated are nominal (pass or fail) and are therefore qualitative, although the authors note the highly impressive value of the data and the evidence in favor of this cleaning monitoring method.^{4,8,39}

In [Table 2](#), the 2 medium risk failure modes can both be mitigated through the use of alternative cleaning monitoring methods. The visibility of the FM spots is a noted problem, and the additional problem of well-prepared cleaning staff (with their own fluorescent lights to identify the location FM spots) can be mitigated through the sequential or parallel use of rapid ATP detection.⁴⁰

Mitigation

The FMEA assessors considered the failure modes in combination with all 4 cleaning monitoring methods. The failure modes identified for visual inspection were given the classification of high and medium risk, but in each case the use of an alternative rapid method such as ATP bioluminometry could mitigate the risk rating. For microbial recovery, the use of a rapid method of testing, again such as ATP, could work well to mitigate the delay issues, given that correlation has been established with at least high levels of microbial contamination. The classification of medium risk for failure modes of ATP testing can in each case be mitigated through the concurrent use of FM or microbial recovery (during any outbreak of disease). The lack of quantitative information as a failure mode for FM can be mitigated easily through adjunct use of ATP.

[Figure 1](#) outlines a new theoretical approach that attempts to overcome the identified failure modes of the cleaning monitoring methods by using the strengths of 1 method to cover the weaknesses of another method. [Figure 1](#) demonstrates the potential synergy provided by using the cleaning monitoring methods concurrently and in sequence, rather than in isolation or in a parallel trial. When considered together as a bundle of solutions for cleaning monitoring, the 4 methods work best in combination, with

Table 2
Fifteen failure modes ultimately found to be associated with the highest risk priority numbers (RPN) and associated failure risk

| Cleaning Monitoring method | Failure mode | Frequency* | Severity* | Detectability* | RPN [†] | Risk classification [‡] | Mitigation suggestions |
|---|--|------------|-----------|----------------|------------------|---|---|
| Visual Inspection | Surface looks clean but is contaminated with pathogenic microbes ¹¹ | 3 | 3 | 3 | 27 | High | Testing of surfaces with a quantitative method for determining surface hygiene may indicate contamination (eg, ATP testing) |
| | Surface looks clean but is contaminated with non-visible soils ⁶ | 3 | 2 | 3 | 18 | High | Testing of surfaces with a quantitative method for determining surface hygiene may indicate contamination (eg, ATP testing) |
| | Surface looks clean but has not been subject to routine cleaning processes ¹² | 2 | 2 | 3 | 12 | Medium | Use of an FM technology will indicate surface cleaning frequency rate. ATP testing alone will not be sufficient to indicate cleaning frequency |
| Microbial recovery | Result from sampling is delayed by 48 h or more ²⁷ | 3 | 3 | 2 | 18 | High | Testing of surfaces with a rapid method (eg, ATP testing) can rapidly inform the sampling processes by indicating any loci of contamination |
| | Pathogenic bacteria are not detected on swab but are present on high-touch objects ¹⁰ | 2 | 2 | 3 | 12 | Medium | Validation of sampling methods with examination of different methods results can improve microbial recovery |
| | Viruses (pathogenic) are not detected by sampling methods ³⁰ | 2 | 3 | 2 | 12 | Medium | Selection of a virus-sensitive sampling and recovery method is required where cross-infection with viruses is a known risk factor |
| | Pathogenic bacteria are not detected due to poor environmental sampling plan or methodology ¹¹ | 2 | 2 | 2 | 8 | Medium | Validation of sampling methods with examination of the effect of different methods can improve microbial recovery. Adjunct use of rapid ATP detection can assist in identification of possibly contaminated environmental locations |
| ATP bioluminometry | Pathogenic bacteria are present in biofilms that are not recovered in normal sampling ¹³ | 2 | 2 | 2 | 8 | Medium | Swabbing techniques should utilize different approaches to dislodge resident organisms. Subsequent recovery techniques may be required for cultures to adjust for slower recovery dynamics |
| | Failure to detect the ATP present on contaminated surfaces (possible lysis failure by ATP consumables-reagent) ³² | 2 | 2 | 3 | 12 | Medium | Microbial recovery can be used for confirmatory quality control where FM indicates inadequate cleaning but low ATP readings do not reflect inadequate cleaning. A validated sampling plan will ensure testing is representative |
| | ATP swab fails to pick up sufficient bacteria to indicate surface contamination (falsely low ATP reading) ³² | 2 | 2 | 3 | 12 | Medium | Microbial recovery can be used for confirmatory quality control where FM indicates inadequate cleaning but ATP readings are in the low range and biofilm is suspected |
| | Failure to detect viruses due to absence of ATP ³² | 3 | 2 | 2 | 12 | Medium | Use of an FM technology is low cost and will indicate surface cleaning frequency in addition to use of rapid ATP detection. A suitable microbial recovery method for virus detection could also be used |
| | Similar before-and-after ATP readings that do not indicate that cleaning has or has not occurred ³¹ | 2 | 2 | 2 | 8 | Medium | Rapid ATP detection requires a carefully considered sampling plan to ensure that multiple readings are taken for proper interpretation of the results. Adjunct use of FM will indicate if cleaning has occurred |
| Incorrect interpretation of the ATP readings from the hospital surfaces ³³ | 2 | 2 | 2 | 8 | Medium | ATP readings are subject to both variability and sampling error. Careful validation of the sampling plan and use of ATP will reduce both types of error. Adjunct use of FM will indicate cleaning. Training in reading ATP results is essential | |

| | | | | | | | |
|-----------------|---|---|---|---|----|--------|---|
| FM technologies | FM spots are visible to cleaning staff and are preferentially removed ⁴⁰ | 2 | 3 | 2 | 12 | Medium | Testing of surfaces prior to use of FM will indicate surface suitability for use of FM |
| | FM assessment does not indicate a quantitative level of cleanliness has been achieved by the cleaning process, even when the cleaning process is conducted as intended ⁸ | 3 | 2 | 2 | 12 | Medium | Validation of the cleaning processes should be conducted to ascertain the quantitative contribution of the cleaning method to the primary purpose of soil removal as a primary aim. ATP measurement will provide an adjunct measurement of surface cleanliness that is semiquantitative |

FM, fluorescent marker.

⁴⁰1 = low, 2 = medium, and 3 = high.

⁸RPN = Frequency × severity × detectability.

³High = RPN 15, medium = RPN > 8 < 15, and low = RPN < 7.

system redundancy built in to the process of monitoring through carefully considered and adjunct use of each of the available methods.

The costs attached to cleaning monitoring method are a substantial concern, but these do vary by geographic region, commercial availability, and local practices. The individual cost components on any 1 cleaning monitoring method are outside of the range of this study and will require further investigation and quantitation. The opportunity for cost-efficiency in the mixed monitoring approach outlined in Figure 1 should be further investigated to find the balance between cost and efficiency in the supervision of cleaning services.

In an integrated study using the 4 monitoring systems in parallel, costs could be managed in a very different manner to suit the location of the monitoring and the specific infection control circumstance.

DISCUSSION

The worst of all failure modes observed from the 4 cleaning monitoring methods was for visual inspection.⁶ The use of microbial recovery through environmental sampling has a major failure mode due to the delay in receiving results.¹⁰ Clearly FM is a simple tool that provides excellent quality data on the frequency of non-cleaning; that is, the qualitative question of how often the cleaning is not conducted as intended.³⁸ There is also a need for a monitoring process that has the role of quantitation of cleaning performance in terms of surface cleanliness, and rapid ATP testing could be developed to fill this void, subject to interpretation and validation issues.^{8,31-36}

Not 1 of the current cleaning monitoring methods could overcome all of the potential failure modes that were identified for that monitoring method when considered in isolation.

When the cleaning monitoring was considered in a single flowchart (Fig 1), it became clear that use of the monitoring methods in combination offered the opportunity to mitigate the effect of failure modes through the synergistic value of the cleaning monitoring methods were used both in parallel and in sequence. The strength of visual inspection was maximized, whereas the high-risk failure modes are mitigated through use of both FM and ATP bioluminometry. A highly targeted (adjunct) use of microbial recovery, particularly during an outbreak, can be used to provide quantitative information against any specific pathogens of concern where timely feedback is less of a concern.^{27,28,37}

When using both FM and ATP testing for cleaning monitoring, health care providers must set a suitable acceptable level of pass or fail using the data generated.⁸ For example, FM will indicate the frequency of cleaning for surfaces and infection control professionals (ICPs) should consider the acceptable level of success before any intervention on the quality of the cleaning service provided.⁴ Similarly for rapid ATP, the appropriate level of pass or fail for the brand of ATP device should be carefully considered before implementation of use of rapid ATP detection, so that intervention on the quality of cleaning service provided is appropriate.³⁶

The issue of cost of monitoring is the subject of ongoing studies, and costs will vary by location and commercial issues. The outline considered in Figure 1 demonstrates that by using an integrated approach, costs of monitoring can be managed to achieve the lowest potential cost to yield the greatest likelihood of successful cleaning performance.

This work is intended as an exemplar on the use of FMEA, and is by no means fully comprehensive. The failure modes identified by our FMEA assessors are subjective and may not fully reflect all of the potential failures in cleaning monitoring methods. However,

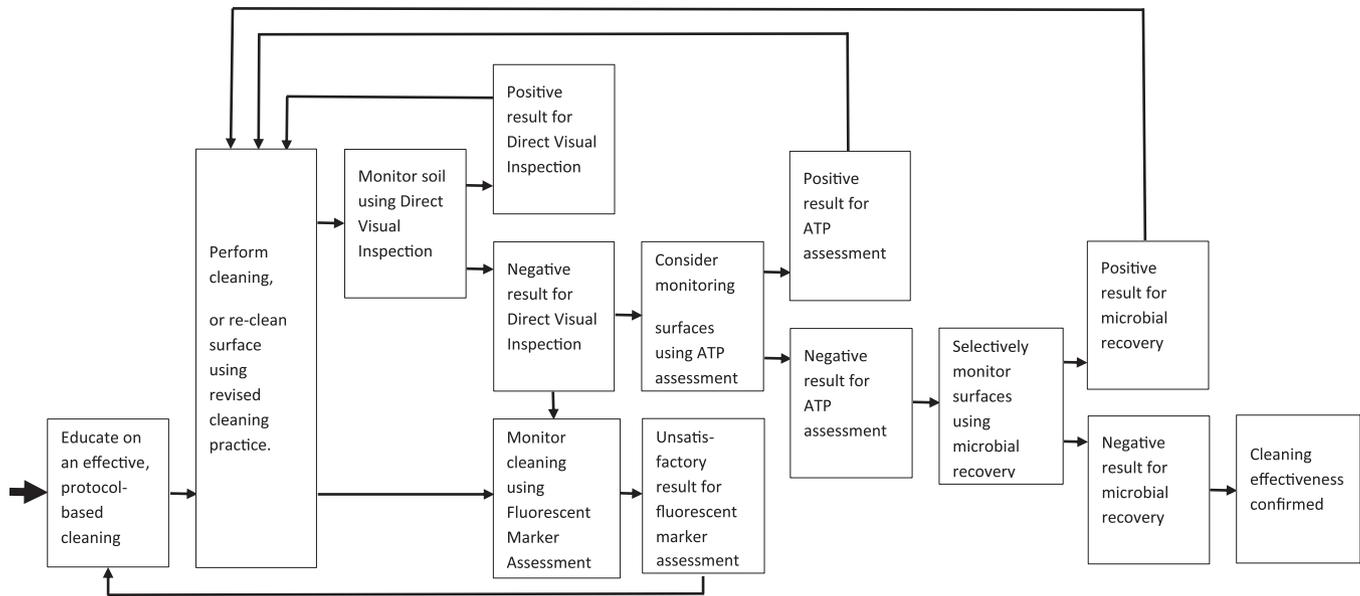


Fig 1. Model for cleaning monitoring.

the work in reconstructing the approach of cleaning monitoring using all 4 available methods does offer ICPs a new approach to drive quality improvements in environmental cleaning processes through more reliable data collection in ongoing studies. Further studies are underway to investigate and confirm the findings of this FMEA-based risk assessment study.

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