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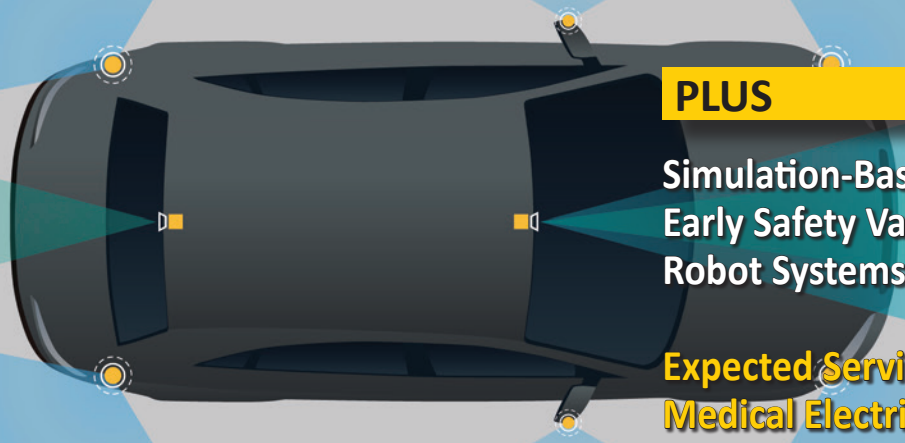

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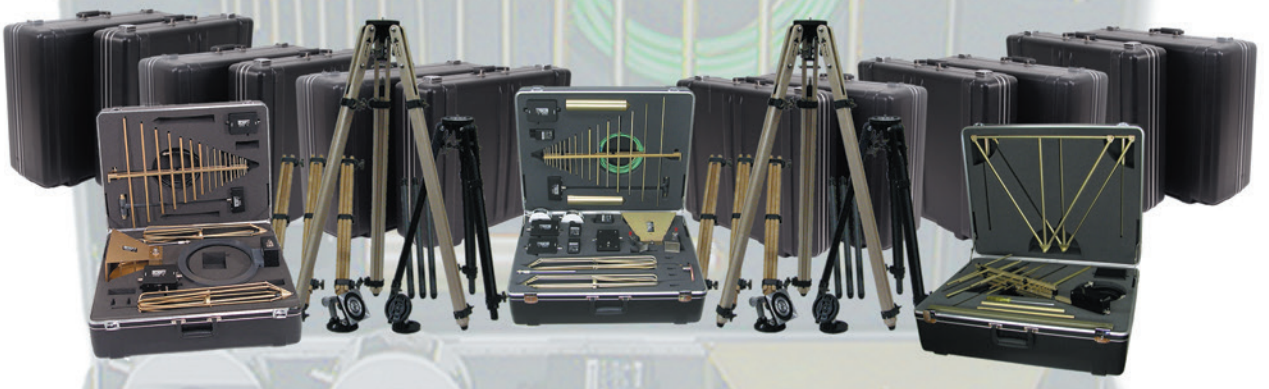

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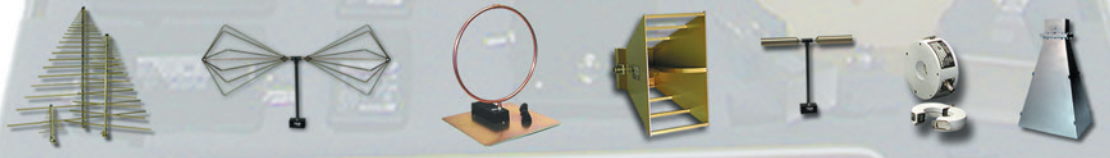

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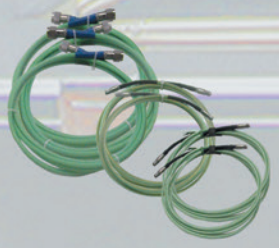

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CONTENTS

FDA Publishes List of Approved AI/ML-Enabled Medical Devices

The U.S. Food and Drug Administration (FDA) has published its first list of authorized medical devices incorporating software based on artificial intelligence (AI) and machine learning (ML) technologies.

Posted to its website, the FDA's list of AI/ML-enabled medical devices provides detailed submission information on nearly 350 separate medical devices that have been reviewed and authorized by the agency under its 510(k), De Novo, or PMA routes.

AI/ML-enabled medical devices have the potential to generate significant amounts of healthcare data, which can be used by healthcare providers and researchers to improve the delivery of healthcare and improve patient outcomes. The FDA says that its release of the list of authorized devices provides both industry and the general public with important information on innovations and developments in this growing segment of the medical device industry.

UK Seeks Overhaul of AI, Software as a Medical Device

In the wake of its exit from the European Union, the United Kingdom is working to update regulations applicable to medical devices that use software based on artificial intelligence (AI).

The UK's Medicines and Healthcare products Regulatory Agency detailed its plans in a recently released Guidance, "Software and AI as a Medical Device Change Programme." The Guidance maps out 11 different "work packages" that would implement changes across the entire medical device lifecycle, from initial product qualification to post-market surveillance.

The Guidance work packages also address issues specific to AI-enabled medical devices, including cybersecurity issues, mobile health and applications, alternative approval routes for innovative technologies, and the interpretability of AI data.

Wearable Fitness Trackers the Target of a Data Breach

More than 61 million records from Apple, Fitbit, and other fitness tracker brands have reportedly been exposed in a massive data breach.

According to an investigation conducted by WebsitePlanet and independent security researchers, the breached records contained user data that include user names, date of birth, key physical characteristics such as height, weight, and gender, and geographic location. A sampling of the breached records indicates that Apple's Healthkit application represented the original source of the majority of the records.

WebsitePlanet's investigation traced the breach to GetHealth, a company that accesses and synchronizes health and wellness data from wearables, medical devices, and other medical applications. GetHealth has reportedly confirmed that the affected data has been secured subsequent to the original breach.

EU Commission Moves to Require USB-C Charging

In a move that will have significant consequences for developers of a wide range of portable electronic devices, the Commission of the European Union (EU) has proposed the adoption of uniform charging capabilities in smartphones, tablets, and other consumer electronics.

Under a formal proposal, the Commission is seeking to amend EU Directive 2014/53/EU (also known as the Radio Equipment Directive, or RED) to harmonize charging technologies by standardizing the use of USB-C charging ports. The proposal would also harmonize supported speeds of charging devices and unbundle the sale of chargers from the sale of electronic devices.

The Commission's move is reportedly part of its overall effort to reduce consumer inconvenience and electronic waste created by the use of different and incompatible charging technologies for electronic devices. The Commission estimates that the average consumer owns three mobile phone chargers to ensure reliable access to compatible charging technologies, and that disposed chargers constitute 11,000 metric tons of e-waste every year.

The Commission's proposal must now be adopted by the European Parliament and the Council. Assuming that the proposal is accepted, it is expected that manufacturers will have a transition period of 24 months to take the steps necessary to comply with the amended RED requirements.

Clive Sinclair, Computing Pioneer, Dies

Clive Sinclair, a technology entrepreneur and the developer of one of the first home computers, died in September following a decade-long battle with cancer.

Born near London in 1940 into a family of engineers, Sinclair is credited with creating the world's first electronic calculator in 1972. His first mass-market home computer, the Sinclair Model ZX80, was released in 1980 in the United Kingdom (his home country), and sold for just under £80 in kit form, and for less than £100 fully built. The ZX80 and its successor model the ZX81 quickly ranked among the best-selling home computer models in the UK and the U.S.

Later in his career, Sinclair also actively explored the development of other advanced electrical and electronic technologies, including smartwatches and battery electric vehicles, and even a folding bicycle intended for commuters.

Sinclair was knighted by Queen Elizabeth in 1983 and was made a fellow by the Imperial College of London in 1984. He was 81 years old at the time of his death.

UK MHRA Launches Medical Device Regulatory Consultation

The United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) has initiated a public comment process on issues to be addressed in that country's medical device regulatory framework.

According to a press release posted to the UK Government website, the 10-week public consultation seeks views from the medical device and healthcare industries, including medical practitioners, patients, and the wider public. The consultation is intended to cover a broad range of regulatory issues, including requirements for conducting clinical investigations, assessing medical device safety, importer and distributor responsibilities, and post-market surveillance activities.

The MHRA says that the public consultation on the UK's medical device regulatory framework has been launched in the wake of the UK's departure from the European Union, and the opportunity to create a "world-leading regime" that supports medical device innovation, streamlines the device approval process, and prioritizes patient safety.

EU Commission Updates List of Harmonized Standards for MDR

The Commission of the European Union (EU) has updated its list of harmonized standards applicable to medical devices to reflect the latest available technical and scientific information.

According to Commission Implementing Decision (EU) 2021/1182, five additional standards can now be used to demonstrate compliance with applicable requirements of the EU's Medical Device Regulation, (EU) 2017/745. These are:

- EN ISO 10993-23:2021, the standard for "Biological evaluation of medical devices – Part 23: Tests for irritation"
- EN ISO 11135:2014 and EN ISO 11135:2014/A1:2019, the amended standard for "Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices"
- EN ISO 11137-1:2015 and EN ISO 11137-1:2015/A2:2019, the amended standard for "Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices"
- EN ISO 11737-2:2020, the standard for "Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process"
- EN ISO 25424:2019, the standard for "Sterilization of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical devices."

Under Commission rules, compliance with an EU harmonized standard confers a presumption of conformity with the corresponding essential requirements in EU harmonization legislation once the standard has been published in the Official Journal of the European Union.

NIST Model Develops Spectrum Sharing Model

The U.S. National Institute of Standards and Technology (NIST) has reportedly developed an innovative modeling technique to assist developers in the configuration of wireless communications devices to share transmission frequencies more efficiently.

According to an article posted on the NIST website, the new model reduces the number of measurements needed to determine the most reliable wireless configurations. Under testing, the use of the model results in a significant reduction in the number of required measurements, potentially by as much as 33%.

NIST says that the model was developed specifically for two-way coexistent testing, which is intended to evaluate two separate wireless systems under various transmission scenarios to identify the configurations that allow both systems to meet essential performance requirements. The model uses a sequential series of experiments that select a transmission configuration based on a limited set of previously collected coexistence data.

The NIST spectrum sharing model should be useful for testing up to 10 devices operating simultaneously. And NIST researchers are reportedly using machine learning and artificial intelligence (AI) technologies to investigate other spectrum sharing modeling techniques.

Standards Council of Canada to Develop National Standards Strategy

The Standards Council of Canada (SCC) has launched an effort to ensure that Canadian standards development efforts continue to focus on areas of strategic importance while helping to keep the country economically competitive on the global stage.

According to a recent press release, the SCC's National Standards Strategy (NSS) is intended to help the SCC and its stakeholders ensure that efforts to improve Canada's system of standardization are strategic, focused, and deliberate. The Strategy is also expected to help clarify Canada's standardization priorities in the international standards-setting process.

The National Standards Advisory Committee will spearhead the NSS consultation effort and is comprised of representatives from the SCC and other standards development organizations, government, and industry. The development of the NSS is scheduled to commence in the Fall and is expected to take about 10 months to complete. The process will also include opportunities for public input to ensure transparency in the deliberative process and that the final product reflects a wide range of perspectives.

According to Chantal Guay, CEO of the SCC, the NSS "will create unparalleled opportunities to boost Canada's economic competitiveness, drive innovation, and enhance health and safety across sectors."

You Can't Make This Stuff Up: 2021 Ig Nobel Prizes Announced

The 31st First Annual (not a typo!) Ig Nobel Prize ceremony was held virtually last month. Not to be confused with the Nobel Prizes scheduled to be announced in early October in Oslo, Norway, the Ig Nobel Prizes are intended to "honor achievements that first make people laugh and then make them think."

This year's Ig Nobel Prize award winners include:

- For biology, a team of researchers from Sweden and Ireland for their investigation into the variations in purring, meowing, squeaking, hissing, and growling in cat-human communications;
- For ecology, researchers from Spain and Iran for using genetic analysis to identify different species of bacteria found in wads of discarded chewing gum stuck on pavements in various countries;
- For chemistry, a team from Germany, the UK, New Zealand, Greece, Cyprus, and Austria for their efforts to determine the connection between odors found in airborne samples taken in movie theatres and the levels of violence, sex, drug use, and antisocial behaviors in the movie being watched;
- For transportation, researchers from the U.S., South Africa, and Namibia for their investigation of the safety of the airborne transportation of rhinoceros in an upside-down position (!!!); and, finally
- For economics, researchers from France, Switzerland, Australia, Austria, the UK, and the Czech Republic for research that found a potential correlation between the obesity of a country's politicians and the extent of that country's corruption.

To read more about this year's Ig Nobel Prize winners, go to https://www.improbable.com/2021-ceremony/winners.

ASSESSING ADVANCED DRIVER ASSISTANCE SYSTEMS (ADAS) IN VEHICLES

Testing Can Help to Ensure Effectiveness and Safety

Ralph Buckingham is Intertek's director of transportation technologies and also manages the daily operations requirements of The American Center for Mobility proving grounds. He participates on various standard development committees, contributing to the evolution of telematics, connected vehicle, and autonomous vehicle testing procedures. Buckingham can be reached at ralph.buckingham@intertek.com.

By Ralph Buckingham

The National Highway Traffic Safety Administration (NHTSA) estimates that 94% of traffic accidents are caused by driver error and the leading cause of these is recognition mistakes.[1] Advanced driver-assistance systems (ADAS) can help decrease accidents, injuries, and fatalities by reducing these errors using electronic technologies. In fact, ADAS is one of the fastest-growing sectors in the automotive industry, with expectations that the ADAS market will see a compound annual growth rate (CAGR) of 11.6% by 2027.[2]

ADAS are designed to increase the safety of vehicles by assisting motorists with driving and parking functions. They use automated technology, such as sensors, cameras, software, lighting, and audio components to detect obstacles and errors, then respond accordingly. ADAS technologies can range from passive to active, alerting drivers to problems, implementing safeguards, and/or taking control of the vehicle.

Passive systems simply give an alert but require the driver to act. Examples might be systems that make noises or vibrate when an object, such as another vehicle or pedestrian, is sensed in a blind spot or as the car drifts into another lane without a turn signal activated. With the warning, the driver needs to take corrective action. On the other hand, active ADAS not only sense the danger, but also automatically activate the required corrective action, such as emergency braking when an obstruction is sensed.

While the systems today are becoming more sophisticated and widely adopted, the general concept of ADAS is not new. The roots of ADAS go back nearly 70 years to anti-lock braking systems (ABS), and today include blind spot information systems, 360-degree cameras, adaptive cruise control, lane departure warnings, traction control, night vision, adaptive lights, collision warning, parking assistance and more. As technology quickly evolves and the industry increasingly moves toward autonomous vehicles, the possibilities for ADAS seem limitless.

ADAS TESTING IS ESSENTIAL TO OVERALL SAFETY

Yet, as ADAS technology is incorporated into vehicles at such an astonishing pace, it is essential to properly evaluate the systems through testing programs that can provide valuable information in developing the advanced technology.

Testing ADAS systems involves exposing a vehicle to situations that trigger the system to intervene, then measuring the outcome to assess system performance. An example of this might be using a mannequin to simulate a pedestrian to test whether the ADAS triggers emergency braking or using simulated cars to determine if collision warning or parking assistance systems are functioning as intended. The testing is monitored, and variables are controlled to ensure the consistent, repeatable application of each test method. Additionally, factors such as weather, dirt, or less optimal road conditions (i.e., lane line deterioration or potholes) can be added to the testing to ensure that the ADAS system goes beyond requirements and provides more robust, usable results.

The methods used to assess and evaluate ADAS come from a variety of sources. For example, the Insurance Institute for Highway Safety (IIHS) includes guidance for automatic emergency braking (AEB) and for AEBs and pedestrians. The European New Car Assessment Programme (NCAP) offers guidance on car-to-car AEB, vulnerable road user AEB, lane support systems, and speed assistance systems. In the U.S., the NHTSA

ADAS testing requires facilities and equipment capable of exposing the vehicle to the scenarios that trigger the engagement of those systems. Assessments can be done in the lab, on the road, and/or on proving grounds.

has several guidelines in development covering active parking assistance, blind-spot detection and intervention, intersection and opposing traffic safety assistance, pedestrian AEB, rear automatic braking, traffic jam assists, and heavy vehicle forward collisions warning (FCW). While the NHTSA guidelines have not been finalized, manufacturers and their testing partners can use the draft guidance for product development and assessment.

ADAS system testing provides valuable data that can be used for a variety of needs: validation to OEM standards and requirements, benchmarking to establish design baselines, R&D information, and data for ratings from organizations or programs like IIHS or NCAP. These insights can be quite significant for this increasingly used technology. For example, testing during the R&D and validation phase can help to reduce system redesigns and even the number of formal qualification tests required. Benchmark testing can assess the performance of systems being offered by many manufacturers to set performance requirements and goals. And for programs like NCAP or IIHS, preliminary testing can reduce formal testing and speed up compliance and time to market. The testing can vary from basic (monitoring velocity, direction, location, and response) to intermediate (basic with the addition of audio/video recording) to advanced (adds the capture of the vehicle bus messages for a complete understanding of vehicle behavior and intended response).

THE BENEFITS OF MULTIPLE TEST SETTINGS

ADAS testing requires facilities and equipment capable of exposing the vehicle to the scenarios that trigger the engagement of those systems. Assessments can be done in the lab, on the road, and/or on proving grounds. Each setting offers its own benefits and drawbacks, and often a combination of these test locations provides the best results.

Here are some of the benefits of each assessment approach:

- Laboratory testing allows for rigorous testing in a highly controlled environment. Engineers can evaluate products for safety, interoperability, functionality, connectivity, overall performance, and controlled environmental exposure to elements such as ultraviolet (UV) light, dust, water intrusion, and more.
- On-road testing uses real-world conditions (including unexpected and random situations) to subject systems to elements like weather, geography, light, infrastructure, obstacles, human activity, and more. Road tests can assess ADAS over an extended period, providing a realistic view of lifespan and functionality.
- Proving ground analysis evaluates products on the road, in a predictable, safe, controlled, and repeatable setting. This method ensures specific elements are included in the evaluation, such as direct sunlight, weather conditions, tunnels, on-ramps, and other potential obstacles. Testing can be configured to duplicate real-world environments and applications, depending on the design and capability of the proving ground.

A thorough test plan will integrate testing in multiple environments to provide robust, comprehensive data and actionable results. Some equipment and components will require lab assessments for items such as electrical safety, electromagnetic compatibility (EMC), performance, and other considerations. These same pieces of equipment and the overall system can then be sent to the proving ground for realistic, on-road assessments to see how they perform in action. Additional lab testing may then be required to help assess how the equipment has responded to those scenarios. For example, it may illustrate whether on-road usage impacts electrical safety or overall system functionality.

Assessing how ADAS functions in a traffic jam will be more complex than assessing how it interacts with a pedestrian. More components will be needed to simulate the traffic jam, thus more equipment is used and more data collected.

ADAS TESTING EQUIPMENT REQUIREMENTS

The equipment used to evaluate ADAS can vary both in type and number of testing systems and devices needed. For example, assessing how ADAS functions in a traffic jam will be more complex than assessing how it interacts with a pedestrian. More components will be needed to simulate the traffic jam, thus more equipment is used and more data collected. ADAS assessments will commonly include the use of several types of equipment, as follows:

- *Inertial measurement systems capable of real-time kinematics, or RTK:* These are used to assess things like speed, position, force, angular rate, and orientation. Because data needs to be pulled as the car is in motion and as systems are reacting, real-time kinematics are important for accuracy.
- *Guided soft targets:* Used to simulate other cars, guided soft targets are self-propelled platforms and aerodynamically stable. However, because they are "soft" targets, when they come into contact with a vehicle, they will break apart and not cause damage to the test car and on-board systems.
- *Other soft targets:* Used to simulate people (both adults and children) who are moving or static, as well as bicycles and other obstacles. They replicate the size, shape, and, when needed, the motion of the object to assist in evaluating the response to encountering these objects.
- *Driving robots:* Driving robots, such as steering robots, pedal robots, provide repeatable, accurate control of the vehicle and use RTK for speed and position corrections for accurate path following. The use of robots versus humans allows for multiple evaluations with less variability to factors like speed, control, path, angles, and impact.
- *Controller Area Network (CAN) decoding/ recording equipment:* CAN equipment allows for communication, data gathering, and recording

As the automotive industry seeks to find better ways to help ensure the safety of drivers, pedestrians, property, and vehicles, ADAS offers the technology and ability to reduce driver error and, as such, accidents.

without a host computer. Commonly used for in-vehicle communications since the 1980s, it provides low-cost, lightweight networks for the communication of data and information.

- *Additional rear-vehicle targets:* Simulates items such as buildings, lighting, signs, and other obstacles a car may encounter in reverse.
- *Various road and intersection types:* Used to assess systems such as AEB, blind-spot detection, and testing for intersections and traffic jams. These include different surfaces and speeds to ensure more comprehensive data.
- *Different test environments:* Varying environments, such as parking lots, highways, traffic jams, cities, rural roads, and more, are important to assess various systems such as AEB, parking assistance, lane keep/centering, customized tests, and more.

A COMPREHENSIVE TEST PLAN IS ESSENTIAL

Given the variety of test settings and equipment that can be used, it is important to establish a comprehensive test plan before evaluations begin. Start the process with the end goal in mind: Why are you testing? What information do you need? Then proceed to identify the best way to get the information needed. This will determine where the testing needs to be done, when, what equipment and environmental conditions are required, what data is needed, and how the data will be collected and, ultimately, analyzed. Once a test plan is in place, the ADAS evaluation can begin.

ADAS testing begins with preliminary set up and practice days, which can be beneficial for reducing downtime and completing the tests in a time-efficient manner. At this stage, engineers can map test surfaces and create different routes to ensure that the necessary test environments, lane configurations, and test targets are accounted for.

This preliminary phase can also include other recommendations to ensure time-effective testing. This might include planning and scheduling remote software resources for immediate updates, pre-testing software subroutines, and ensuring maintenance tools and lifts are available to fix any mechanical issues. Validating test system set up, confirming test equipment like RTK systems function properly, and making sure proper technical support is on hand to

troubleshoot any challenges is always a high priority to limit downtime once testing begins.

After this preliminary stage, testing can be completed. It may take a few days to gather all the necessary data, especially if the test plan includes a combination of lab evaluations and on-road/proving ground analysis. Test set up and completion could also take time, especially as simulations are conducted. As with any testing, it is important to be prepared for the reality that test runs, data collection, compilation, and analysis can be a lengthy process. In the end, though, the information provided is invaluable in ensuring the quality, performance, and safety of ADAS and the vehicles where they are present.

CONCLUSION

As the automotive industry seeks to find better ways to help ensure the safety of drivers, pedestrians, property, and vehicles, ADAS offers the technology and ability to reduce driver error and, as such, accidents. They also provide consumers with the benefits of convenience and safety. As the technology and use of these systems continue to advance at a high rate, ensuring their functionality and safety is critical. It is important to know the requirements in place for these systems, as well as the supplemental assessments that apply to ADAS.

Knowing what information is needed and how to find it, then partnering with experienced, knowledgeable engineers to prepare and execute a test plan, can help provide valuable information for R&D, benchmarking, marketing, regulatory purposes, and more. Safer ADAS can mean safer vehicles and safer transportation for everyone.

ENDNOTES

1. National Highway Traffic Safety Administration, Traffic Safety Facts, https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812115.
2. Globe Newswire, May 6, 2021, "Advanced Driver Assistance System (ADAS) Market Size Worth Around US$ 142 bn by 2027," https://www.globenewswire.com/en/news-release/2021/05/06/2225177/0/en/Advanced-Driver-Assistance-System-ADAS-Market-Size-Worth-Around-US-142-bn-by-2027.html.

SIMULATION-BASED TESTING FOR EARLY SAFETY VALIDATION OF ROBOT SYSTEMS

The authors are with the Intelligent Process Automation and Robotics Lab at the Institute of Anthropomatics and Robotics (IAR-IPR) at Karlsruhe Institute of Technology.

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By Tom P. Huck, Christoph Ledermann, and Torsten Kröger

Editor's Note: *The paper on which this article is based was originally presented at the 2020 IEEE International Symposium on Product Safety Engineering held virtually in November 2020. It is reprinted here with the gracious permission of the IEEE. Copyright 2020 IEEE.*

Industrial human-robot collaboration (HRC) promises a more flexible production and more direct support for human workers [1]. In HRC applications, human and robot work in close vicinity or even in direct collaboration. Safety fences, which have traditionally been used to ensure the safety of human workers, are (at least partially) absent. Instead, sensor- and software-based safety measures, such as laser scanners, light curtains, velocity limitation, and collision detection, are used to ensure that the robot system does not pose any hazard to human workers. Safety flaws in the configuration of these safety measures can lead to hazards. Thus, a thorough safety validation is required. Furthermore, ISO 10218-2, the safety standard for industrial robot systems, specifically states that prior to commissioning, a risk assessment must be conducted to identify and assess potential hazards [2].

The sooner a hazard is uncovered in the development process, the fewer corrective changes to the system have to be made later. Since early changes require smaller iterations in the development process and thus are less costly (see Figure 1), it is desirable to identify hazards as early as possible. In early development stages, there is usually no physical implementation available that could be used for this purpose. Instead, early development stages typically rely on simulation models, e.g., for planning the cell layout or optimizing the workflow. It would be beneficial to use these simulation models also for the early identification of potential hazards. However, to find hazards in simulation, one must overcome a major challenge: In many cases, hazards are *hidden*. This means that there are certain safety-critical flaws in the design of the system which may result in hazards, but only become manifest in specific situations. In a dynamic simulation, it can be very difficult to find simulation sequences that uncover these hazardous situations, especially when the simulation is highly detailed.

A recent promising approach to this problem is the concept of adaptive stress testing (AST) [3]. AST exposes hazards with a reinforcement learning agent that creates adversarial testing conditions. AST was successfully applied in several safety-critical domains

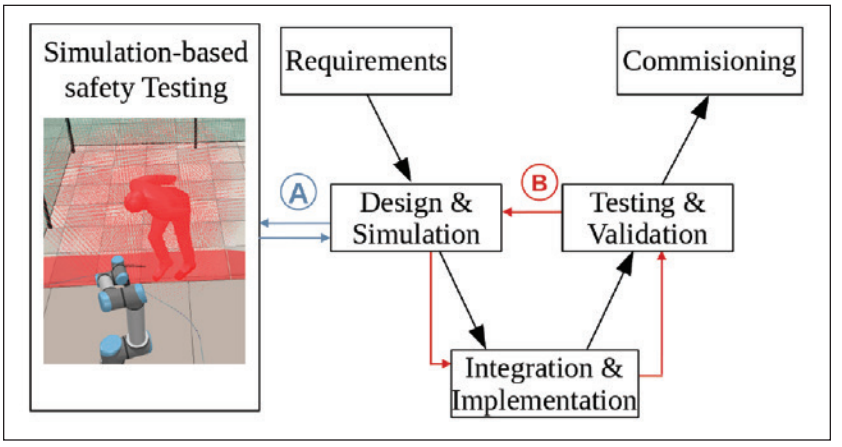

Figure 1: Simplified model of a development process to illustrate the benefits of simulation-based testing: Hazards identified early through simulation-based safety testing (A, blue) require smaller (and thus, less costly) iterations in the development process than hazards identified in the testing and validation phases (B, red). Although simulation-based testing cannot replace the testing and validation phase, it can reduce the need for costly iterations in the development process.

Safety engineering typically relies on methods like "Hazard and Operability Analysis" (HAZOP), "Failure Modes and Effects Analysis" (FMEA), or "Systems-Theoretic Process Analysis" (STPA) to identify hazards.

such as aerospace engineering [4] and autonomous driving [5]. In this paper, we show how AST can be applied to find hazards in robot systems. We use a Monte Carlo Tree Search (MCTS) algorithm to control a virtual human model which we place in a simulation model of the robot system. The MCTS acts as an optimization algorithm that adapts human behavior to maximize a risk metric, thereby creating high-risk situations which are more likely to uncover hazards. In other words, the human model exposes hazards by *learning to provoke hazardous situations* in simulation. Although this approach cannot guarantee to find all existing hazards, it can help to uncover hazards that would have been overlooked otherwise, especially those that only become apparent in very specific situations.

RELATED WORK

Safety engineering typically relies on methods like "Hazard and Operability Analysis" (HAZOP) [6], "Failure Modes and Effects Analysis" (FMEA) [7], or "Systems-Theoretic Process Analysis" (STPA) [8] to identify hazards. These methods are semi-formal, that is, they define a certain hazard identification procedure but largely rely on human reasoning. They can be applied to a wide range of safety-critical systems.

There are also several novel approaches that are specifically aimed at robotics: Guiochet proposed the use of HAZOP-UML, a HAZOP extension that uses UML diagrams, for analysis of robot systems [9]. Marvel et al. have proposed a task-based method that supports risk assessment using an ontology of HRC tasks [10]. Awad et al. have developed a rule-based expert system for risk assessment of HRC workplaces [11]. Their tool allows the user to model the workplace using a model of products, processes, and resources ("PPR model"). The PPR model properties are mapped to hazards based on a set of pre-defined rules. The method "SAFER- HRC," developed by Askarpour et al. [12]–[14] and Vicentini et al. [15], uses formal verification methods for safety verification of HRC systems.

While all of these methods are suitable to identify hazards in robot systems, they do have some limitations: semi-formal methods rely largely on human reasoning and domain-specific knowledge and thus can be difficult to apply to novel and complex systems. Formal and rule-based approaches require a specific system model like the formal language description from [12] or the PPR model from [11] which must be obtained specifically for the purpose of hazard identification. Furthermore, these models typically require significant modeling simplifications.

An alternative approach that avoids these problems is simulation-based safety testing. In the field of robotics, simulation-based safety testing is typically done on a component level, e.g., for testing safety-critical control code.

Examples of this are seen in the works of Araiza-Illan et al. [16], [17], Bobka et al. [18], and Uriagereka et al. [19]. In contrast, the use of simulation-based testing to identify hazards on a system level is still relatively unexplored.

PROPOSED APPROACH

Objective, Assumptions, and Basic Idea

This paper explores a novel concept that uses simulation to find hazards in robot systems. As explained in the introduction, a major challenge is that in many cases hazards only manifest themselves in specific situations. In a dynamic simulation environment, the number of possible simulation sequences can be vast. Thus, it can be difficult to create specifically those simulation sequences that lead to situations where existing hazards are uncovered.

Our approach relies on the assumption that the behavior of the robot system is deterministic for a given human behavior. This means that if there are inherent hazards in the system, then there are certain human behaviors for which these hazards manifest themselves in form of an unsafe state, that is, an accident or near-accident. This assumption leads to the basic idea behind our approach: To expose hazards by creating high-risk human behavior that provokes accidents. To achieve this, we draw on the concept of AST [3]: we use the MCTS Algorithm from [3] to control a virtual human model which is placed in a simulation model of the robot system under test. By optimizing the behavior of the virtual human to maximize a risk metric, the algorithm provokes unsafe situations. As our proof of concept will show, this approach can significantly increase the chance of finding hazards in simulation.

Problem Formulation

Formally, the approach can be framed as a search problem where the goal is to find sequences of human actions that result in unsafe states. The search problem is described in a 5-tuple:

$$(S, U, A, \phi, s_0) \quad (1)$$

where S is a set of simulation states that describe the combined configuration of the human model and the robot system model (including not only the robot itself but also other safety-related components, e.g., sensors). U is a user-defined subset of S that includes unsafe states, that is, states that violate a certain safety condition formulated by the user. The set A consists of the actions which can be performed by the human model in simulation. Note that in the following proof of concept example, A is a set

If an unsafe state is reached, the simulation stops, and the user can examine the hazard by replaying the simulation sequence that has led to the unsafe state.

of simple human movement primitives. However, A does not necessarily have to consist only of movements. It could also include other human actions that are relevant to the system under test, such as operator commands to the system. The function ϕ is a transition function that returns the next state given the current state and a human action: $s' = \phi(s, a)$. This function is implemented by the simulation, that is, the next state is obtained by simulating the interaction between the human and robot system for a given human action. Starting from the initial simulation state s_0, the goal is to find sequences of human actions $a_1, a_2, \ldots a_n$ which, when simulated in interaction with the robot system, result in an unsafe simulation state $s \in U$. The difficulty is that U is only known implicitly: While it is easy for the user to define certain high-level safety constraints (e.g., *"all collisions with the robot must be avoided"*), it is unknown what the specific system states are in which these constraints are violated, and which action sequences lead to them.

Search Procedure

We solve this search problem with an iterative search procedure as shown in Figure 2: the MCTS algorithm iteratively selects a human action which is then carried out by the human model in interaction with the robot system model. After each action, the current simulation state s is evaluated in a safety check to determine if an unsafe state $s \in U$ is reached. Furthermore, a reward R is calculated and fed back to the MCTS algorithm. This reward is designed in a way that encourages dangerous behavior and thus accelerates the finding of hazards. If an unsafe state is reached, the simulation stops, and the user can examine the hazard by replaying the simulation sequence that has led to the unsafe state. The user can then eliminate the hazard by implementing appropriate safety measures and restart the search with an updated simulation model to find further hazards. If desired, this process can be repeated throughout the whole system design stage.

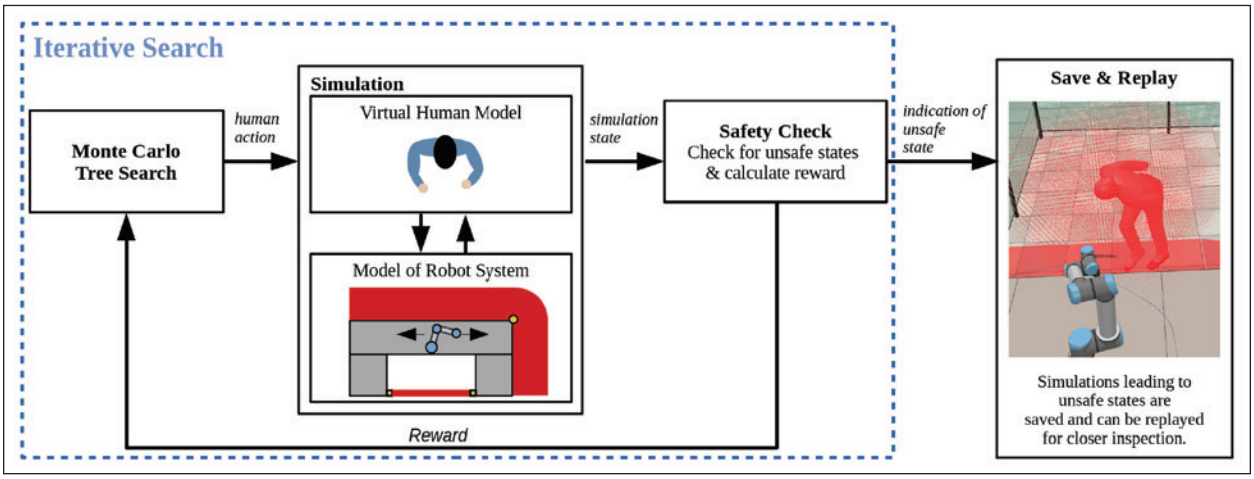

Figure 2: Iterative Search Procedure: The Monte Carlo Tree Search (MCTS) algorithm selects human actions which are carried out by a virtual human model in conjunction with a model of the robot cell. In each iteration, it is checked if the current simulation state is unsafe with respect to a user-defined set of safety criteria, and a risk metric is calculated. By rewarding the occurrence of unsafe states, this risk metric guides the MCTS algorithm towards creating dangerous situations in which unsafe states are likely to occur.

Note that the set U of unsafe states depends on the safety condition that is defined by the user. Depending on the context of the application, one might define conditions based on criteria like velocity and distance (e.g., "*all contact between human and robot must be avoided while the robot is moving with a velocity greater than X*") or on collision characteristics like collision force and affected body part. (e.g., "*all collisions that subject body part X to a collision force greater than Y must be avoided*"). For reasons of computational complexity, the following proof-of-concept example will use a simple velocity/distance criterion. In the future, we will also include a collision force estimation into our method to allow for more sophisticated safety criteria.

PROOF OF CONCEPT

This section presents our proof-of-concept example: We use the MCTS algorithm of [3] and the simulator CoppeliaSim (formerly known as V-REP [20]) to implement the search procedure from Figure 2. We then use this implementation to find hazards in an industrial robot cell. It should be noted that being a proof of concept, the presented implementation contains several simplifications which we will address in our future work.

Implementation

Human Model: We use a simple human model from CoppeliaSim and augment it with additional joints so that it can perform a set of basic motions (five walking- and six upper-body motions, amounting to an action space of 30 combined motions):

$$\mathcal{A}_{Walking} = \{(\text{walk forward}), (\text{turn left } 45^\circ), (\text{turn left } 90^\circ), (\text{turn right } 45^\circ), (\text{turn right } 90^\circ)\} \quad (2)$$

$$A_{UpperBody} = \{(\text{move body upright}), \quad (3)$$
(bend forward), (bend left),
(bend right), (bend forward and right),
(bend forward and left)}

$$A = A_{Walking} \times A_{UpperBody} \quad (4)$$

$$|A| = 5 \cdot 6 = 30 \quad (5)$$

Note that in our example, A does not include arm motions. Arm motion is quite complex and representing it via explicit actions would likely lead to an explosion of the search space. Instead, we use an octree based on a reachable arm workspace computation [21] to determine if the robot is within human reach. The parameters of the human model are shown in Table 1.

Parameter	Value	Source
Body Height	1.78 m	Test person measurement
Upper arm length l_U	0.30 m	Test person measurement
Lower arm length l_L	0.31 m	Test person measurement
Hand length l_H	0.18 m	Test person measurement
Walking speed	1.6 m/s	Specified in [22]
Max. Angle forward flexion	55°	Derived from [22]
Max. Angle lateral flexion	35°	Specified in [23]

Table 1: Human model parameters

Algorithm: To control the human model, we use the MCTS algorithm from [3]. For reasons of brevity, we only give a simplified explanation of the algorithm here. For a full explanation, we refer to [3]. The algorithm iteratively samples sequences of human actions from A and executes them in the simulation. In keeping with the terminology of [3], we call these action sequences *episodes*. After each action, it is checked if an unsafe state $s \in U$ has been reached. If this is the case, or if a maximum number of actions is reached, the episode terminates. The simulation is then set back to the initial state s_0 and a new episode begins. With each episode, the algorithm incrementally expands a search tree, in which the edges correspond to human actions and the nodes to simulator states.

We employ two variations of this algorithm: one basic version, which we call MCTS1, and one variation, which we call MCTS2. Whereas MCTS1 always starts its search at the initial simulation state s_0, MCTS2 commits to the most promising action after a certain number of episodes and uses the resulting simulation state as a new starting point. This results in a more exploitative search behavior.

Reward: After each action, the algorithm receives a reward R. Based on the reward, a state-action value function is estimated which is used to adapt sampling of actions in future episodes. The reward should increase the chance of finding hazards by encouraging a more dangerous behavior of the virtual human. Thus, the occurrence of dangerous situations should be rewarded, whereas the occurrence of safe situations should be penalized. To quantify the level of danger that a situation holds, we define a safety index c_S:

$$c_S = (d^2_{HR} + 1) \cdot e^{-v_R} \quad (6)$$

where d_{HR} is the human-robot distance and v_R is the cartesian velocity of the fastest robot joint. The value of c_S is large for *safe* configurations (i.e., large distance, low speed). Since we want to encourage *unsafe* situations, we give the inverse $\frac{1}{c_S}$ as a reward after each action. Additionally, we give the negative safety index c_S as penalty at the end of an episode when no unsafe state has been found. Thus, in total, the reward function is:

$$R = \begin{cases} \frac{1}{c_S}, & \text{if } k < n \\ -c_S, & \text{if } k = n \text{ and } s \notin U \end{cases} \quad (7)$$

where k indicates the current step within the episode and n is the episode length. (Note that the reward structure differs from [3], where there is also a component that rewards the probability of actions. We changed this as we are interested in finding hazards independently of their probability.)

Test Scenarios

As a basis for the proof-of-concept tests, we chose the industrial robot cell shown in Figure 3. This cell combines typical safety features of industrial robot systems: Safety fences, a laser scanner, and a light curtain. In the center of the cell, there is a U-shaped table on which the robot is mounted. The robot imitates a pick-and-place task between the two

sides of the table. To intervene in the process, e.g., to refill parts, workers can approach the table either by walking through the laser scanner field or by passing through a light curtain at the back of the cell. Areas not monitored via laser scanner or light curtain are closed off by the fences. Upon detection of a worker, laser scanner and light curtain send a stop signal to the robot. Note that due to the response time of the sensors, the stop signal is delayed. Furthermore, the robot needs a certain stopping time to reach a standstill. The cell is designed to satisfy the following safety condition: *"Contact between human and robot must not be possible unless the robot stands still."* Thus fences, laser scanner, and light curtain are configured in a way that even with the sensor delay and the robot stopping time, the worker cannot reach the robot before it has stopped [22], [24]. Since these safety measures should avoid any contact between human and robot while the robot is moving, the set of unsafe states U in our example is defined as follows:

$$U = \{s \mid v_R > 0,\ d_{HR} = 0\} \qquad (8)$$

By altering the original cell layout and deliberately introducing safety-critical design flaws, we created three test scenarios where unsafe states are possible, each scenario containing a specific collision hazard. The scenarios are shown and explained in Figure 3 and Table 2.

Note that the movement of the robot, the sensor delays, and the robot stopping time make the scenario *dynamic*. Although the dynamic effects here are relatively simple, they show that the method is able to find hazards in dynamic simulations and not only in static environments.

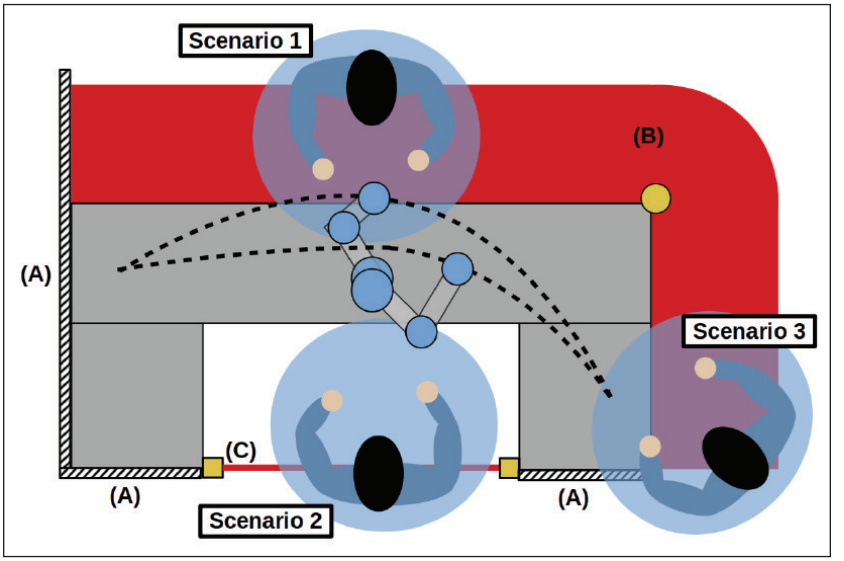

Figure 3: Top view of the robot cell, featuring safety fences (A), the laser scanner detection zone (B), and a light curtain (C). By introducing safety flaws into the cell design, three collision hazards (Scenario 1-3) were created (see Table 2).

Test Scenario	Safety Flaw	Resulting Hazard
Scenario 1: Reduced width of laser scanner zone	The width of the laser scanner protective field is reduced. Although the worker can still be detected by the laser scanner, the reduced field is too small to ensure that the robot stops completely before the worker can reach it.	A collision is possible if the worker approaches the table at the point where the robot path is closest and leans into the path as the robot passes (see Figure 3, Scenario 1).
Scenario 2: Altered robot path and position	Position and path of the robot are altered in such a way that the robot's elbow joint protrudes into the maintenance bay. Due to the protruding elbow joint, the distance between the light curtain and the robot is not sufficient anymore to stop the robot in time.	A collision is possible when the worker enters the maintenance bay (Figure 3, Scenario 2).
Scenario 3: Partly removed safety fence	A part of the safety fence is removed. While the table itself is still closed off by the fence, the edge of the laser scanner field is not.	A collision can occur when the worker leans over the laser scanner field to reach around the remaining part of the safety fence (see Figure 3, Scenario 3).

Table 2: Description of proof-of-concept test scenarios

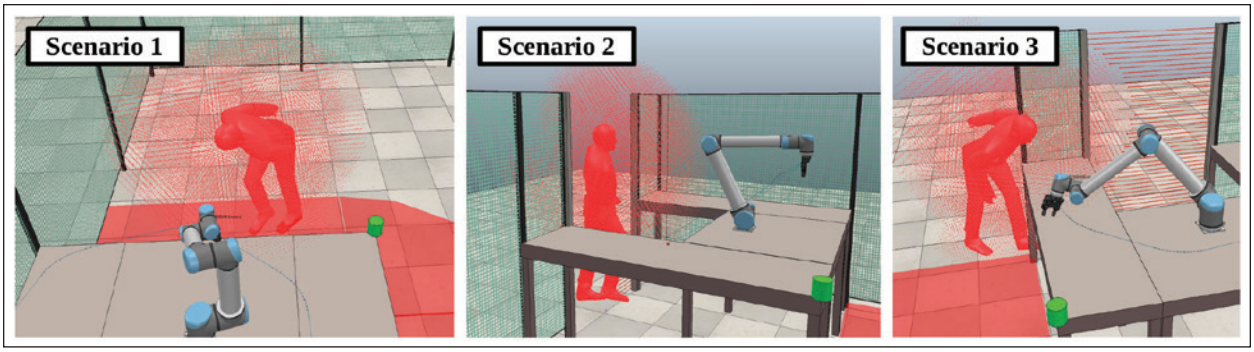

Figure 4: Hazard situations found in the three test scenarios (corresponding to Figure 3). The red cloud indicates the volume reachable by the human. In all three situations, the human is able to reach the robot while it is moving, and thus, the safety condition is violated.

Test Runs

Setup: Test runs are performed in CoppeliaSim with simulation timesteps of 50 ms. Each human action has a duration of four timesteps and each episode consists of eight actions. Test runs are conducted from two different starting points, one on the upper end of the cell for scenario 1 and one on the lower end of the cell for scenario 2 and 3 (compare Figure 3 for the test scenarios and Figure 4 for examples of corresponding hazard situations). Although this may seem like a convenient simplification, it is justifiable from a practical perspective since a user would certainly select meaningful starting points and not place the human model at random. Each test scenario is performed with both MCTS1 and MCTS2. To show that our approach does indeed increase the chance of finding hazards, we conduct a random search for comparison in which episodes are assembled by sampling actions from a uniform distribution over A. For each combination of test scenario and algorithm, ten test runs are conducted with different random seeds. Each test run is limited to 200 episodes.

Results: Results are shown in Table 3. The first row shows the success rates, i.e., in how many of the test runs the hazard was found. If no hazard is found within 200 episodes, a test run is considered unsuccessful. The second row shows the runtime, that is, the average number of episodes until the discovery of the hazard (unsuccessful test runs are counted with a maximum of 200 episodes). It can be seen clearly that the two MCTS variants perform significantly better than the random search, both in terms of success rate and run time, which indicates that the adaptation of human behavior does indeed increase the chances of finding hazards. However, it can also be seen that hazards can be missed. This is not only the case for the random search but also for both MCTS algorithms (although much less frequently). Meanwhile, comparing the MCTS variants with each other shows no clear advantage for either of them, especially given the small number of test scenarios. More tests will be conducted in the future to investigate potential differences in performance.

DISCUSSION

As the proof of concept has shown, the method can identify hazards in a realistic, industry-like robot system. Compared to a random search, it finds hazards significantly quicker and with a higher success rate. However, being in a proof-of-concept phase, there are several limitations to its applicability, especially the simplistic human model. Furthermore, in its current implementation, the method can only find one hazard at a time. In a practical application, the user would have to eliminate the found hazard by updating safety measures and then repeat the search to find further hazards. While this avoids the problem of local minima (i.e., discovering the same hazard repeatedly),

	Algorithm	Scenario		
		1	2	3
Success rate	Random	3/10	3/10	8/10
	MCTS1	10/10	8/10	10/10
	MCTS2	10/10	9/10	10/10
Avg. number of episodes	Random	166.8	150.4	81.1
	MCTS1	70.0	63.3	34.9
	MCTS2	49.7	80.4	38.0

Table 3: Results of the test runs

it is impractical. Another, more fundamental limitation comes from the fact that the method is based on falsification of safety conditions. This means it cannot give a safety guarantee, it can only find counterexamples of situations where safety conditions are violated. Thus, it should be seen as an addition to existing methods rather than a replacement.

The major advantage of the method is that it can find hazards autonomously while reducing the required amount of prior knowledge about the system to a minimum. Furthermore, it can be easily integrated into common robot simulator models which are widely used and do not require building a system model specifically for hazard analysis. These properties are highly desirable for the analysis of novel and complex systems. Since the proof-of-concept implementation is relatively simple, the full extent of these advantages may not be visible yet. However, we believe that there is great potential in this approach and that it could provide a powerful, scalable, and flexible tool for testing various types of complex robot systems, not only in the industrial context.

FUTURE WORK

Currently, the method's limitations mainly result from simplifications in modeling and implementation. Especially the fact that we use a static octree for the arm workspace rather than an articulated arm model limits the types of hazards that can be identified. This will be addressed by augmenting the reachability model with an articulated arm model. Moreover, a collision force estimation will be incorporated. This will allow the method to test systems not only against velocity- and distance-based safety criteria but also against collision force limits. Another aim is to enable a search for multiple hazards in one run. This will require adaptations to the MCTS to avoid convergence in local minima. To enable a widespread practical application, it should also be investigated how the method can be implemented in other common robot simulators, for example, *Visual Components*, *ProcessSimulate*, etc.

CONCLUSION

A simulation-based method for safety testing of robot systems was proposed and evaluated. The method uses a human model and Monte Carlo Tree Search to find unsafe system states in simulation, which enables

an automated hazard identification and reduces the reliance on prior system knowledge. A proof of concept has shown promising results, but the current implementation is still relatively simple and requires further development. Since the method is based on falsification of safety conditions, it cannot give a safety guarantee. Thus, it should be seen as an addition to existing methods rather than a replacement.

ACKNOWLEDGMENTS

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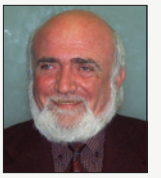
EXPECTED SERVICE LIFE OF MEDICAL ELECTRICAL EQUIPMENT

Clarifying Confusion Around “Life” Definitions

Steli Loznen has over 40 years of experience in compliance issues associated with medical electrical equipment and participates in the IEC standardization as WG Convener and Project Leader. In 2017, he received the IEC's "1906 Award" in recognition of his efforts to advance the work of the IEC. Loznen is also a member of the Experts Evaluation Team of the European Commission, a member of the Board of Governors of the IEEE-PSES, and a vice-president for IEEE-PSES technical activities. He can be reached at sloznen@ieee.org.



By Steli Loznen

The main purpose of mandatory regulations is to obtain marketing authorization to enter global markets. Consequently, a manufacturer must demonstrate that all safety-related aspects, including compliance with relevant standards for basic safety, essential performance, risk management, usability, etc., have been reviewed, that all applicable requirements have been met, and that a quality system mechanism has been implemented.

With regard to medical devices included within the field of the medical electrical equipment (MEE), it is striking to observe how the clauses describing these specific concepts vary among applicable EU Directives, guidelines, regulations, IEC, ISO standards, and other requirements applicable to design, regulatory compliance, marketing, and health professionals.

Moreover, the concept of "expected service life" (ESL) for MEE comes on top of the already existing standards. Thus, due to an incomplete definition of ESL, there is a long chain of misunderstandings regarding the analysis and assessment required to determine compliance with MEE requirements.

In this article, we'll attempt to clarify this confusion through a discussion of the standard definition of ESL found in IEC 60601-1 and the requirements applicable to MEE at the end of their ESL.

WHAT DOES "EXPECTED SERVICE LIFE" MEAN?

With reference to the ESL of medical devices, applicable regulatory documents specify many life-related terms, including "service life," "shelf life," "useful life" (or "practical life"), "lifetime" (or "life span"), and "life cycle." (Don't confuse the use of these terms in the context of a device's safety or performance with warranty-related issues, which is a commercial consideration.)

An explanation of the meaning of the following "life" terms should help to provide a better understanding of the issues we seek to address in this article:

a. The term "service life" includes the time of use that a device is intended to remain functional after it has been manufactured, put into service, and maintained as specified.

b. "Shelf life" is the term or period during which a device or accessory remains suitable for the intended use, whether it is stored or used. The termination of shelf life is represented by the expiration date, after which the device may no longer function as intended.[1]

   The EU Guidance document in the medical devices vigilance system MEDDEV 2.12/1[2] requires that the service life and the shelf life must be specified by the device manufacturer and included in the master record (technical file) and, where appropriate, in the instructions for use (IFU) or labeling, respectively.

   For "life-sustaining" equipment, the failure rate should approach zero within the labeled shelf life.

   To determine if a particular piece of equipment requires a shelf life and be assigned an expiration date, several parameters must be considered, including susceptibility to degradation that would lead to functional failure (e.g., implantable devices) and the level of risk that the failure would present.

   If parts or accessories with a specified shelf life are used in a device, their shelf life must be carefully considered in relation to the shelf life of the whole device.

In general, "useful life" is defined as an estimation of the average number of years an asset is considered usable before its value is fully depreciated.

Examples

1. The patient could not be defibrillated due to insufficient contact of the defibrillator pads with the patient's chest because the labeled shelf life of the pads was exceeded.
2. The patient is given a blood glucose test, receives a faulty diagnosis, and is given an incorrect insulin dosage because the test strip used for the blood glucose test was beyond the expiration date specified by the manufacturer.

c. In general, the "useful life" is defined as an estimation of the average number of years an asset is considered usable before its value is fully depreciated. Specifically, for an electrical device, IEC 60050 defines "useful life" as the time interval beginning at the start of use (a given moment in time) and ending when the failure intensity becomes unacceptable or when the item is considered to be unrepairable as a result of a fault.[3]

   Another similar definition is the time interval from first use until user requirements are no longer met due to economics of operation and maintenance or obsolescence.

   (Note: In this context, "first use" excludes testing activities prior to hand-over of the item to the end-user. For the "useful life" of a medical device, the accepted definition is the duration of actual use, or the number and duration of repeat uses before some change results in the device's inability to achieve its intended function.)

d. The "lifetime" (life span) of a medical device refers to the time interval from design and development of the device to the decommissioning (proper disposal) of the MEE. The lifetime of the device could be how long the MEE is expected to be functional (i.e., fulfill his intended use) and remain safe (i.e., free from unacceptable risk) per IEC 60601-1 requirements.

e. The "life cycle" represents all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.[4]

f. The "expected service life" is defined in the third edition of IEC 60601-1:2005 as the "maximum period of useful life as defined by the manufacturer," but fails to provide an explanation or reference about the meaning of "useful life" (!).

   The needed clarification was achieved in IEC 60601-1, Amendment 1:2012 which clarifies the ESL definition as being the:

   > *"…time period specified by the manufacturer during which the ME equipment or ME system is expected to remain safe for use (e.g., maintain basic safety and essential performance); (Note: Maintenance may be necessary during the Expected Service Life.)"*

   Fortunately, Rationale Annex A4 provides a further explanation of the meaning of "safe for use," as follows:

   > *"The ESL is the time period during which the ME equipment or ME system is expected to remain suitable for its intended use, and all risk control measures remain effective ensuring that risks remain acceptable. The ESL needs to be determined by the manufacturer, as part of the risk management process, as a precondition for assessing compliance with many requirements of this standard, such as 4.5, 4.7, 7.1.3, 8.6.3, 9.8.2, and 11.6.6".*[5]

The "expected service life" is the anticipated and planned "safe for use" in-service life of the device. "Safe for use" means that the state of the device maintains both basic safety and essential performance. Therefore, it is critical to establish the ESL of a device regardless of the method chosen to verify it.

In reading these definitions, we find clear differences among various standards and specifications. Although all refer to the "life" of medical devices, the term means different things. Indeed, it seems that the terms "lifetime" and "life cycle" cover the most extended period of the "life" of a medical device.

But these varying terminologies and definitions are the source of many misunderstandings and

IEC 60601-1 specifies that the medical electrical equipment shall be decommissioned as a waste product at the end of its expected service life.

much confusion, especially now when the term ESL represents a compliance requirement within IEC 60601-1. However, the ESL requirement must be regarded as a safeguard equal to those addressing intended use (function), ratings, environmental conditions of installation and use, etc.

ESL AND IEC 60601-1

The inclusion of the ESL in the 3rd edition of IEC 60601-1 should be seen as a positive step since it is the manufacturer who has the responsibility and obligation to specify the time segment of the lifetime or of the life cycle for a medical device in which the basic safety and essential performance are maintained.

We are reaching a very sensitive point of our analysis: unequivocally, clause 7.9.2.15 of IEC 60601-1 ed.3.1 specifies:

> *"The instructions for use shall provide advice on the proper disposal of waste products, residues, etc. and of the MEE and accessories at the end of their expected service life."*

In other words, IEC 60601-1 specifies that the MEE shall be decommissioned as a waste product at the end of its ESL. According to the standard, the end of ESL represents the end of all other "lives."

However, in the real world, the situation may be different. For example, a medical device can finish its specified ESL (e.g., seven years) and, through sufficient refurbishing or re-manufacturing, start a new ESL period (e.g., three years) during which time its basic safety and essential performance requirements continue to be met. In theory, this cycle could continue until such time that a device can no longer be refurbished or re-manufactured. This is the real moment of the end of lifetime, life cycle, or useful life (or however you want to designate the whole "life" of the device!).

In using terms like "refurbished" or "re-manufactured," it is important to remember that there is no universal standard applicable to refurbished goods. Thus, the terms "refurbished," "re-manufactured," "renovated," and "reconditioned" are considered to be synonymous. All can be defined as the processes of restoring a used device to an "as-new" condition for performance and safety so that the device can again be safely placed on the market.

Maybe due to the misunderstanding of terms or misinterpretation of them, IEC 63077[6] defines the "refurbishment" as a:

> *"…process or combination of processes applied during the expected service life to restore used medical imaging equipment to a condition of safety and performance according to the specification of the manufacturer."*

But in the same standard, "used equipment" refers to "equipment that has been put into service." Mysteriously, it seems to indicate that if a problem arises with a device after just a week of use, the device must be "refurbished." Perhaps the standard's contributors considered the "maintenance" or "repair" processes, which are different from "refurbishment." During the ESL, safety and performance need to be maintained (as IEC 60601-1 requires), and there is no need to perform a "refurbishment." This kind of confusion can lead to difficult situations for a manufacturer and for a device user, since the necessity to replace one component or another doesn't mean a "refurbishment."

Of course, if at some point during the life of the device, the majority of components need to be replaced to keep the device functioning or to fulfill the ESL specified by the manufacturer, this should be considered the end of the original ESL of an MEE while leaving open the potential for a "refurbishment."

Estimated typical equipment lifetimes for healthcare technology can be found in published literature.[7,8,9] In general, the expected lifetime is estimated at a minimum of seven years. A few exceptions exist, such as cardiac laser units (three years), alarms oxygen depletion units (five years), ECG leads (two years), cell

Decisions related to device ESL can be made, in part, by controlling identified residual risks that can increase to unacceptable levels as the period of use of an MEE is extended.

counters (five years), cuffs (two years), duodenoscopes (five years, aneroid sphygmomanometers (five years) and infrared thermometers (five years).

HOW DOES A DEVICE MANUFACTURER DETERMINE EXPECTED SERVICE LIFE?

Decisions related to device ESL can be made, in part, by controlling identified residual risks that can increase to unacceptable levels as the period of use of an MEE is extended. The ESL is just one of the "inputs" of the risk management file that can affect the probability of occurrence of harm. Medical device ESL may be based on technical, legal, commercial, or other considerations.

The manufacturer, who needs to specify the ESL in their risk management file, needs tools to accurately determine this time period. The best way to determine the ESL of the equipment is through reliability analysis and tests. Using reliability engineering techniques such as accelerated life testing (HASS and HALT) analysis can help with estimating the potential for initial failures or projecting the average expected functional life (with random failures) or the point of expiration (wear-out failures), etc.

However, one needs to be careful with the use of such reliability information because safety and reliability are different product characteristics that are sometimes in conflict with each other. Reliable products are not necessarily safe, and safe products are not inherently reliable. In general, safety has a broader scope than failures, and failures may not compromise safety in all situations.

The Practical Guide for the implementation of ISO 13485 standard (formerly ISO 14969) does list a few things that may need to be considered when defining device "lives." The basis of the defined lifetime of the medical device should be documented. To assist in determining the lifetime of the medical device, the rationale for the determination should be recorded and may involve consideration of the following:

- Shelf life of the medical device
- Expiration date for medical devices or components which are subject to degradation over time
- Number of cycles or periods of use (frequency of use) of the medical device, based on life testing of the medical device
- Environmental conditions of use that can result in material degradation
- Stability of packaging material
- For implantable devices, the residual risk that results from the entire period of residence of the device inside the patient's body
- For sterile medical devices, the ability to maintain sterility
- An organization's ability/willingness or contractual or regulatory obligation to support service
- Spare parts cost and availability
- Legal considerations including liability

In addition, the following factors may also be considered:

- Intended use
- Experience and knowledge of the user
- Care and attention paid to use and operator maintenance
- Existence, capability, and cost of maintenance support
- Management of scheduled and unscheduled maintenance
- Availability and cost of replacement devices
- Business, safety risks, strategic, and political risks associated with continued or discontinued use
- Compliance with current codes and standards
- Technological or clinical redundancy
- Funding availability

A device many have completed its intended service and can no longer be serviced or maintained due to obsolete procedures, a lack of spare parts, or the cost of servicing.

Based on the above factors, a device manufacturer should have sufficient information to determine the ESL, which will be included in the risk management file and the accompanying documents. Additionally, Rationale Annex A4 of ed. 3.1 of IEC 60601-1 recommends:

> *"The accompanying documents should provide information to allow the responsible organization (e.g., hospital) to assess when the equipment is approaching the end of its expected service life. This could be given in terms of years of service or number of uses, or tests as part of preventative maintenance to allow the responsible organization to make an appropriate determination of ESL".*

To summarize, once the ESL is determined, it is expected that the device remains "safe for use during ESL" Basic safety and essential performance is maintained, and the user is informed about the "signs" of ESL end proximity. We will see in the next section the "fate" of the device after the period when ESL ends.

IS IT NECESSARY TO SUPPLY DECOMMISSION INFORMATION?

During the ESL period as declared by the manufacturer to be (e.g., seven years), an MEE which has undergone the recommended periodic maintenance as specified in the accompanying documents can be considered compliant with the basic safety and essential performance as required in IEC 60601-1. However, at the end of its ESL, is a device that is still compliant with the standard's requirements be decommissioned? The answer is a categorical no.

As we have previously discussed, the life cycle of an MEE ends when the user is forced to decommission it when it can no longer be used safely and or fails to meet its performance specifications. This point in time can occur either before or after the endpoint of the ESL.

For example, a device many have completed its intended service and can no longer be serviced or maintained due to obsolete procedures, a lack of spare parts, or the cost of servicing. So, instead of lasting seven years (for example), the device needs to be removed from service and decommissioned as a waste product. In other cases, a device can reach the specified end of its ESL in good condition and is able to continue to be used beyond its ESL if it is serviced or repaired as needed.

In such situations, based on the actual IEC 60601-1 requirements, a manufacturer can claim that they are no longer responsible for the product after the end of ESL and are not required to take steps to ensure that use of the device is discontinued. However, questions of product liability now come into sharper focus. It would be most helpful if the working group responsible for developing and updating IEC 60601-1 provided some clarification on this situation (for example, by issuing an Interpretation Sheet) or by including clarification in a 4th edition of the standard.

For device manufacturers, another ESL-related challenge is presented by the scope of basic safety and essential performance requirements found in IEC 60601-1. Specifically, only certain clauses in the standard refer to ESL, including 4.7 – Single Fault Condition; 7.1.3 - Durability of Markings; 7.9.2.15 - Environmental Protection; 8.6.3 - Protective Earth of Moving Part; 8.8.4.1 - Mechanical Strength and Resistance to Heat; 9.8.2 - Tensile Safety Factor; 11.6.6 - Cleaning and Disinfection of ME Equipment and ME Systems; and 15.3.7 - Environmental Influences. Shouldn't all other clauses in the standard be applicable during a device's defined ESL? "Yes" would be the logical answer, but the standard is unclear on that point.

WHAT EVIDENCE SHOULD A DEVICE MANUFACTURER PROVIDE TO A NOTIFIED BODY REGARDING EXPECTED SERVICE LIFE

Lifetime is mentioned twice in Annex I of the MDR:

- Paragraph 6: *"The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions".*
- Paragraph 23.4: *"The instructions for use shall contain all of the following particulars:*

  … "(k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

  - *"Details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,*
  - *"Identification of any consumable components and how to replace them,*
  - *"Information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime, and*
  - *"Methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices."*

Compliance with the above requirements should be demonstrated with objective evidence and documented in the device Technical File. These documents, together with the information used to determine the ESL, will then serve as the basis for a thorough and objective assessment of the basic safety and essential performance of an MEE during the ESL.

WHAT IS THE BEST WAY TO DEFINE THE EXPECTED SERVICE LIFE OF A DEVICE?

We believe that a small addition to the actual ESL definition found in Amendment 1 of IEC 60601-1 would provide the necessary clarification and help to eliminate future confusion. As such, the updated definition of "expected service life" would read as follows:

"Time period of the life cycle, *specified by the Manufacturer during which the ME Equipment or ME System is expected to remain safe for use (e.g., maintain Basic Safety and Essential Performance)."*

By adding "of the life cycle" to the ESL definition, it becomes clear that ESL is a time part of the life cycle of an MEE in which the expectation to be safe for use is present. This time part can be extended by refurbishing or remanufacturing until the MEE becomes obsolete from a performance point of view or cannot be put back into operation due to outdated technology, lack of parts, or economic reasons. This is the point at which the MEE is decommissioned from service and recycled, destroyed, or discarded as appropriate.

ENDNOTES

1. FDA, "Shelf Life of Medical Devices," 1991.
2. MEDDEV 2.12/1 rev.8, "Guidelines on a Medical Devices Vigilance System," 2013.
3. IEC 60050:2012, "International Electrotechnical Vocabulary," Chapter 191: Dependability and Quality of Service, Definition IEV 191-19-06.
4. ISO/IEC Guide 63:2019, "Guide to the development and inclusion of aspects of safety in International Standards for medical devices," definition 3.5.
5. IEC 60601-1: 2012, Ed.3.1, "Medical electrical equipment – Part 1: General requirements for basic safety and essential performance."
6. IEC 63077: 2019 "Good refurbishment practices for medical imaging equipment."
7. "Life span of Biomedical Devices," Biomedical Engineering Advisory Group SA, Australia, 2004.
8. "Estimated Useful Lives of Depreciable Hospital Assets," American Hospital Association, 1998.
9. "Personal Property Manual," State of Nevada, Department of Taxation, 2009.

PRODUCT Showcase

FORESEEABILITY: A CRITICAL ANALYSIS IN MINIMIZING PRE-SALE AND POST-SALE LIABILITY

When Is Misuse Reasonably Foreseeable?

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By Kenneth Ross

The law requires manufacturers to anticipate foreseeable uses and risks when designing products and providing warnings and instructions. In addition to foreseeable uses, manufacturers must also predict future conduct by users and consider what conduct constitutes foreseeable misuse.

But how far must a manufacturer go to anticipate unintended but foreseeable misuses of a product? How does a manufacturer make this determination while designing the product? What do courts regard as a foreseeable misuse, and what must a manufacturer do about it? Does an unforeseeable misuse become a foreseeable misuse if, after a product's sale, it comes to light that some people have actually misused the product?

These questions go to the core of a manufacturer's quest to provide a reasonably safe product before and after a sale. Unfortunately, the answers are unclear and, in most situations, are provided by a judge and jury after a trial.

PRE-SALE LAW

At the birth of product liability, the California Supreme Court in *Greenman v. Yuba Power Products, Inc.* limited the manufacturer's liability to a product that was "unsafe for its intended use." Section 402A of the Restatement (Second) of Torts, adopted shortly after *Greenman*, imposed no liability for injuries caused by consumer "mishandling," "over-consumption," and "excessive use."

The Restatement Third, Torts: Products Liability (1998) continued that precedent by confirming that a manufacturer is liable only when its product is put to "reasonably foreseeable uses." If a use and the harm occurring during that use are reasonably foreseeable, then the manufacturer must design the product to eliminate or minimize the risk of the foreseeable use. In addition, the manufacturer must warn of known or reasonably foreseeable risks that remain in the product.

However, consistent with case law as it developed after 1965, comments to sections 2(b) and 2(c) of the Restatement Third also provided that a manufacturer can be liable for "foreseeable product misuse, alteration, and modification" (hereinafter, generically, "misuse"). Accordingly, a manufacturer must also design its product and provide warnings so that it is safe for foreseeable misuse.

Injury caused by a misuse does not provide the injured party a separate theory of liability, but instead relates to the issue of whether a product is defective and whether a causal connection exists between the defect and injury. Misuse also is relevant to comparative fault, which can be used to reduce a manufacturer's liability based on the plaintiff's product misuse.

Setting aside the legal concept, though, the practical question for the manufacturer is what do the courts consider "misuse?" As one would suspect, the answers are all over the map. In fact, similar conduct has been deemed foreseeable misuse in one court and unforeseeable misuse in another court. But some common themes run through the cases that provide some guidance to manufacturers.

First, courts generally recognize that "nothing is unforeseeable" (especially in retrospect) and that the ways in which a product can be misused are "endless." To counter absolute liability for product-caused harms, however, courts have attempted to limit the foreseeability concept to what is "reasonable."

Recognizing this limitation, one court memorably stated: "Reasonably foreseeable … does not encompass

the far reaches of pessimistic imagination." While true, this limitation is not that helpful as a guide to manufacturers because an event must occur before a jury gets to decide whether it was foreseeable, reasonably or otherwise.

Certainly, though, foreseeable use (or misuse) is broader than "intended use." One state statute (Louisiana Rev. Stat. § 2800.53) defines "reasonably anticipated use" as any use or handling of the product that the manufacturer should reasonably expect of ordinary persons in the same or similar circumstances. In addition, a technical standard for machine tools defines "reasonably foreseeable misuse" as unintended conduct that may result from "readily predictable human behavior." *See* ANSI B11 (2008).

In some situations, the manufacturer may do something that increases the probability of unintended human behavior. For example, it may design a product in a way that increases the chance that the user will misuse or alter it because of some difficulty in using the product as originally configured. Or the product's marketing may invite misuse by showing unintended users using the product or intended users using it in an unintended and unsafe way. In both situations, the user and the use would arguably be considered "reasonably foreseeable."

IS THE RISK FORESEEABLE OR UNFORESEEABLE?

One court determined whether a misuse was reasonably foreseeable by asking if the use or handling was "so unusual that the average consumer could not reasonably expect the product to be designed and manufactured to withstand it?"

David Owen, in his treatise on Products Liability Law (3rd Edition, West Academic Publishing), gathered cases on this issue. The outcome of these cases illustrates how difficult it is to predict how a jury might react to a particular use:

- Hurling a beer bottle against a utility pole (unforeseeable);
- Teenagers scenting a candle by pouring cologne on it (foreseeable);
- A woman attempting suicide by getting in a car trunk, changing her mind, and then being unable to get out for 9 days (unforeseeable);
- Failing to maintain a machine (foreseeable);
- Disabling a machine's safety devices (foreseeable);
- A baby drinking furniture polish in a bright red container that looks like a soft drink (foreseeable);
- A youth tilting or rocking a soft drink vending machine, causing it to fall on and kill the youth (foreseeable and unforeseeable);
- A child playing with a gas can without a child-proof cap (foreseeable and unforeseeable).

An additional difficulty in predicting how a jury might react to some conduct is that other juries can rule the opposite way.

The difficulty is even greater in warnings cases. Is it foreseeable that a product user will ignore warnings and instructions? Of course, it is. Thus, safety engineering principles, some case law, and the Restatement Third (section 2, comment l) all encourage manufacturers to design out a hazard, guard against it or, as a last resort, warn against it.

But assuming that the manufacturer designed or guarded its product as safely as possible, can it rely on a warning if it is foreseeable that users will ignore the warnings? Thankfully yes, assuming that the warning was adequate. Judges and juries understand that manufacturers cannot make product users read and follow warnings. Any other answer would require manufacturers to sell products with no significant risk of harm based on their design and guarding. With most products, this is almost impossible to do.

Nevertheless, a plaintiff could still argue that it was reasonably foreseeable a user would ignore a warning because it is, for example, too hard to comply with, too detailed, or too small, or because there were too many of them or it was only in English. Users have many creative excuses for ignoring clear safety messages.

Likewise, another difficult issue is deciding whether a warning about a hazard in a label on the product or in the instruction manual could be considered an admission that the conduct that creates the hazard is also reasonably foreseeable. And, if so, what effect that would have on the risk assessment and final design decisions.

POST-SALE LAW

So far, this legal discussion has dealt with misuses that are reasonably foreseeable as of the time of sale. However, a separate issue—and a separate claim—arises for misuses that were unknown before sale but became known post-sale and the manufacturer failed to alleviate the risk by recalling or retrofitting the product or informing customers about the danger.

It is entirely possible for a manufacturer to be held not liable for selling a defective product but held liable for violating some post-sale duty. In the context of product misuse, a plaintiff could engage in conduct that would be deemed unforeseeable at the time of a product's sale but foreseeable by the time of the accident.

While the first incident of misuse may not make the misuse sufficiently foreseeable to require remedial action, the more misuses that occur, the more it can be argued that the misuse has become "reasonably foreseeable."

PREVENTIVE TECHNIQUES

So, given the state of the law and the vagueness of its application, what should a manufacturer do? They can't just decide who they want to be an intended user and what is the intended use. Nor can they just review case law and rely on past decisions to conclude that some misuse would not be deemed reasonably foreseeable.

The manufacturer needs to employ preventive techniques through risk assessment, either before or after product sale, to try to identify conduct that is a misuse and could be considered "reasonably foreseeable."

These techniques will differ when performed during initial product development and after the product is in the field. Pre-sale, the analysis will turn on whether the product is completely new to the manufacturer and/or consuming public or is an upgrade to an existing product made by that manufacturer or other manufacturers. Post-sale, the analysis depends on whether an accident is the first or the latest in a string of accidents where the same misuse has been observed?

Before the sale of a new product, every manufacturer should engage in a risk assessment of its product. Risk assessment has been described as

> *"… a tool for manufacturers to identify possible hazards and provide a basis for considering alternative designs to mitigate or control risks. A risk assessment offers the opportunity to identify hazards associated with intended uses and reasonably foreseeable misuses, and to take steps to eliminate or control them before an injury occurs. This process can be a key factor in successfully reducing risks to an acceptable level."* (Ross and Main, *Risk Assessment and Product Liability*, Defense Research Institute, For the Defense, April 2001.)

Risk assessment starts with identifying hazards during intended uses. There are many approaches to identifying hazards and many standards, technical guidelines, and safety specialists that can help in this regard. See https://www.designsafe.net for more information in this area.

By definition, risk is the probability of a harm occurring and the consequences of that harm if it occurs. When first identifying hazards that may give rise to a risk of harm, probability should not be considered. However, it does not follow that a completely unusual hazard should be considered during a risk assessment. Identifying something as a hazard and subjecting it to a probability-of-harm-and-consequences analysis could arguably be construed as an admission that the hazard is reasonably foreseeable.

Consequently, some screening of hazards at the beginning of a risk assessment is appropriate. If an unintended use or misuse has never or rarely happened or is an obvious hazard, it might not need to be included in the risk assessment. If in doubt, however, include it in the analysis. Then, when the risk is assessed, the manufacturer can indicate that it is not reasonably foreseeable or that the probability of harm is essentially zero.

However, one needs to be careful when omitting conduct from the risk analysis so that a plaintiff will not be inclined to allege that only intended uses were included, and that remote but possible misuses were ignored.

If a product is new to the manufacturer but has been sold by other manufacturers, searching the internet, and talking to trade associations, other manufacturers, and members of standards groups can be helpful in determining what misuses have previously occurred and should therefore be considered.

Since the goal is identifying misuses that might be reasonably foreseeable, it might be appropriate to interview potential product users or provide them a prototype to see how they would normally use and misuse the product. Certainly, this step is routinely taken with many children's products and toys.

TAKING THE NEXT STEPS

After a hazard is identified and included in the risk assessment process, the probability of harm and consequences must then be analyzed to determine whether the risk should be reduced by design, guarding, or warnings and instructions.

If a foreseeable misuse has serious consequences, probability analysis is critical to the decision on what risk reduction measures to implement. For example, if disabling a safety device is foreseeable misuse and the probability of disabling it is fairly high, then the manufacturer should consider incorporating a safety device that is difficult to disable and providing warnings and instructions about the hazards of disabling the device.

When a product has been used in the field without incident, that fact can be useful in determining what kind of risk assessment to conduct on a future model or similar product.

Conversely, when there have been prior misuses in the field, the manufacturer may need to reconsider whether that misuse is now reasonably foreseeable.

Or even on existing models, the manufacturer might want to issue a post-sale alert or warning that the conduct is a misuse that has resulted in serious accidents. While such misuse is open and obvious, the manufacturer would want to discourage it, and issuing such a notice to current product users may be the only feasible way of doing it.

Of course, issuing such a post-sale warning will be argued to be an admission that the misuse is "reasonably foreseeable" and that instead of issuing an "ineffective" warning, the product should have been recalled. Post-sale warnings, instead of recalls, have to be undertaken very carefully, and there are significant risks of issuing such a warning as well as not issuing one.

To help with the risk assessment, especially of products already in the field, a post-sale monitoring system with distributors, dealers, retailers, and consumers needs to be established to learn about field experience. The lack of misuses or lack of a particular misuse over time is probably the best evidence that some conduct is not reasonably foreseeable.

CONCLUSION

The defense in a significant number of product liability cases involves product misuse. Conducting an initial risk assessment can be critical to the successful defense of product liability actions. Unfortunately, the analytical techniques for conducting a proper risk assessment are not exact nor are the results definitive. All such techniques require predicting future behavior, which is by nature inexact and sometimes unknown and unknowable.

However, certain time-tested techniques and the use of experienced personnel can help with the process. Proof that a manufacturer employed state-of-the-art processes and experienced people to do the best job it could to anticipate reasonably foreseeable uses and misuses and implement appropriate risk reduction measures is the best defense against persons who sue regardless of misuse.

EVALUATION OF EMC EMISSIONS AND GROUND TECHNIQUES ON 1- AND 2-LAYER PCBs WITH POWER CONVERTERS

Part 6: PCB Layout Considerations

By Bogdan Adamczyk, Scott Mee, and Nick Koeller

In this article, we discuss the PCB layout considerations and the design of the reference return paths for the one- and two-layer boards.

1. INTRODUCTION

The PCB layout and the design of reference return connections (may also be referred to as grounding) play a critical role in the EMC performance of any circuit. This is especially critical for power converters, which are the focus of this series of articles. In circuit design, it can be easy to focus on power and signal trace connections while overlooking or not focusing enough attention on how circuit current returns. Proper reference return design can especially be challenging in single- and two-layer designs where best practices can't always be applied. It is important to understand and visualize the path of the return current so its entire loop area can be controlled by design. The complete loop area of each circuit tends to be the dominant factor when compared with other parasitic inductances associated with the components or vias. This inductance has a detrimental effect on the EMC performance.

Visualizing the loop areas allows the designer to identify ways to reduce the size and cross-sectional area of the loops, thus reducing the inductance and high-frequency impedance. In single-layer PCB designs, there is fierce competition for copper routing real estate as all routes need to be completed on a single layer. In this setting, we don't have the luxury of a reference return on the secondary side of the PCB. We rely on prioritizing the reference return connections between critical points and loop areas are often much larger than we would like to see. This can drive the need for additional decoupling capacitors, filter components and 'jumper' components to 'stitch' reference returns back together across other trace routes. Figure 1 shows an example of a jumper used to 'stitch' the ground areas back together across a signal trace route.

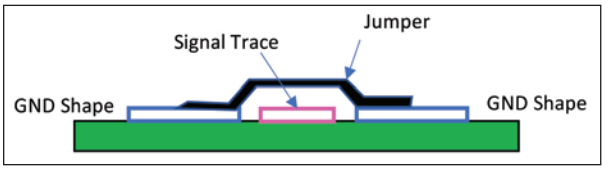

Figure 1: Example of GND stitching with jumper

In two-layer PCBs, there is more opportunity for proper reference return design as the additional layer of copper combined with return vias allows us to make a more consistent return path with smaller loop areas.

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Stitching ground areas together in single- and two-layer PCBs is important not only for better emissions performance but also aids in reducing immunity issues. Figure 2 shows an example of implementing vias connecting different 'ground floods' on the top and bottom layers to create a 'ground mesh' and improve the flow of return currents. Efforts should be made to reduce the number of signals on the secondary side to create a more solid reference return plane.

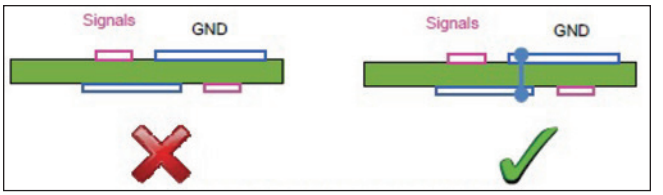

Figure 2: Two-layer example of ground connection

Device application notes can sometimes recommend introducing splits into reference returns for returns such as analog and digital circuits. There may be legitimate reasons for splitting the reference returns but in our experience, this almost always causes an increase in EMC emissions or immunity performance issues. When splits are introduced, efforts are required to 'reconnect' these separate shapes either with jumpers or with capacitors. Often the efforts to reconnect the separate shapes are not as effective as making the original solid connections in the PCB layout.

2. VISUALIZING COMPLETE FORWARD AND RETURN PATHS

In the design process, we recommend drawing the forward and return currents of all power and signal paths as a three-step process. Step 1: draw these complete paths (loops) on the electrical schematic itself. Step 2: draw these complete paths (loops) on the PCB board layout. Step 3: minimize the loop areas (and discontinuities) in the PCB layout.

During the design of the DC-DC Buck converter that has been discussed over the last three articles [x], the reference path design has been the main concern and will continue to be a concern of this study. The schematic and layout of this DC-DC Buck converter are shown in Figure 3. Figure 3a shows the power and signal traces as well as the reference return conductors (highlighted in green). Figure 3b shows the corresponding layout traces and the ground pads (highlighted in green).

All of the power and signal traces were routed on the top layer, and the reference return paths reside on the bottom layer which is a full solid plane. Implementing this circuit (power and signal traces) on the top layer serves two purposes. First, in later parts of this study this circuit will need to be constructed on a 1-layer PCB, and routing it on just the top layer now will help to keep the layouts similar between this PCB and the future one. Second, the full reference plane on layer two provides an ideal return path as it is not constrained. Such an unconstrained path is highly desirable, especially for the high-frequency currents. Without the solid reference plane, the effectiveness of the filtering on the board would be diminished and the loop areas involving the reference return would increase.

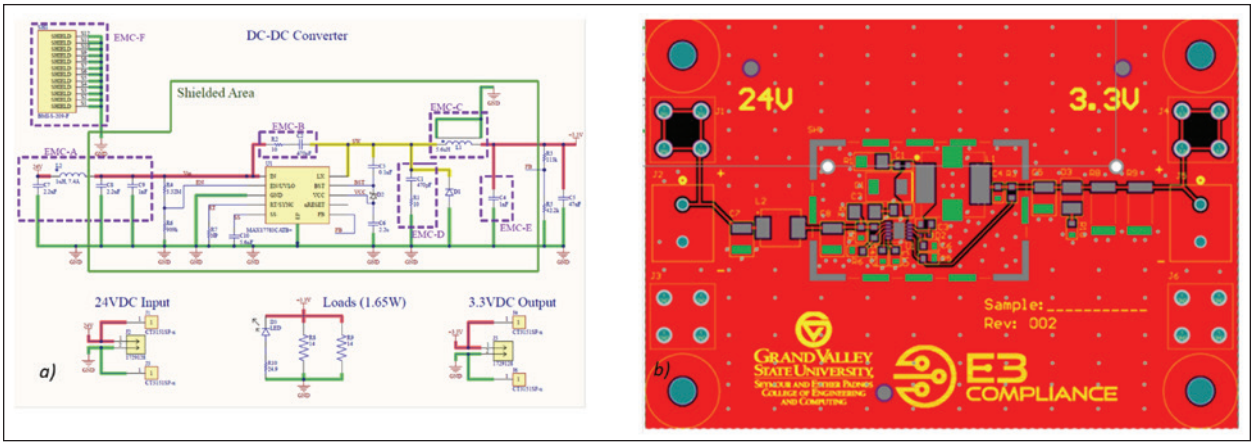

Figure 3: DC-DC Converter - a) schematic b) layout

Let's demonstrate this by looking at one of the output filtering capacitors shown in Figure 4. The forward path of the current is A-B-C-D, and the current return path is E-F-G.

Currents return to the source following the path of least impedance [x], at DC and low frequencies (below 100kHz or so) this is predominantly the path of least resistance. At higher frequencies, the return predominantly is the path of least inductance. This inductance is the inductance of the loop formed by the currents' forward and return paths. At the higher frequencies that we are concerned with in EMC, the loop inductance will be the dominating factor in the impedance, meaning the current will likely follow the path of least inductance to return to the source. This loop inductance is kept at a minimum when the return path is directly under the forward path. This means in a completely unbroken ground plane the current will likely flow directly under the forward path as depicted in Figure 4.

With a completely solid GND plane, the currents will have no issues returning directly under the forward path, but in many practical designs this is just not possible. Generally, at least a couple of traces may need to be routed in the GND plane, especially on a two-layer board. The output section of this DC-DC power supply was modified to allow us to analyze how the current might return to the source when the ideal return path is broken by a trace in the GND plane. This modified output section is shown in Figure 5 on page 44.

In this modified case, the feedback was routed on layer two as opposed to layer one. In this case, it would be expected that the current will initially follow the same path as it did in our original layout until it reaches the feedback trace that is routed in layer two. At this point, the current will have to go around the break in the ground plane and continue to return under the forward path back to the source. The loop area added to the currents path introduced by the cut-out in the return plane increases the inductance of the loop. This causes an increase in the radiation from the current loop [1]. Having a cut-out in the reference plane is therefore not desirable in more complicated designs where space is more a premium, this might be unavoidable.

Next, let's look at the input filtering section shown in Figure 6 on page 45.

As described in Section 1, the high-frequency current paths were traced. Because we are concerned with the high-frequency noise that is generated by the switching in U1, we assume the current path starts at the Vin of U1. However, in this case, there are multiple possible return paths for the high-frequency currents. The obvious and most likely three paths are

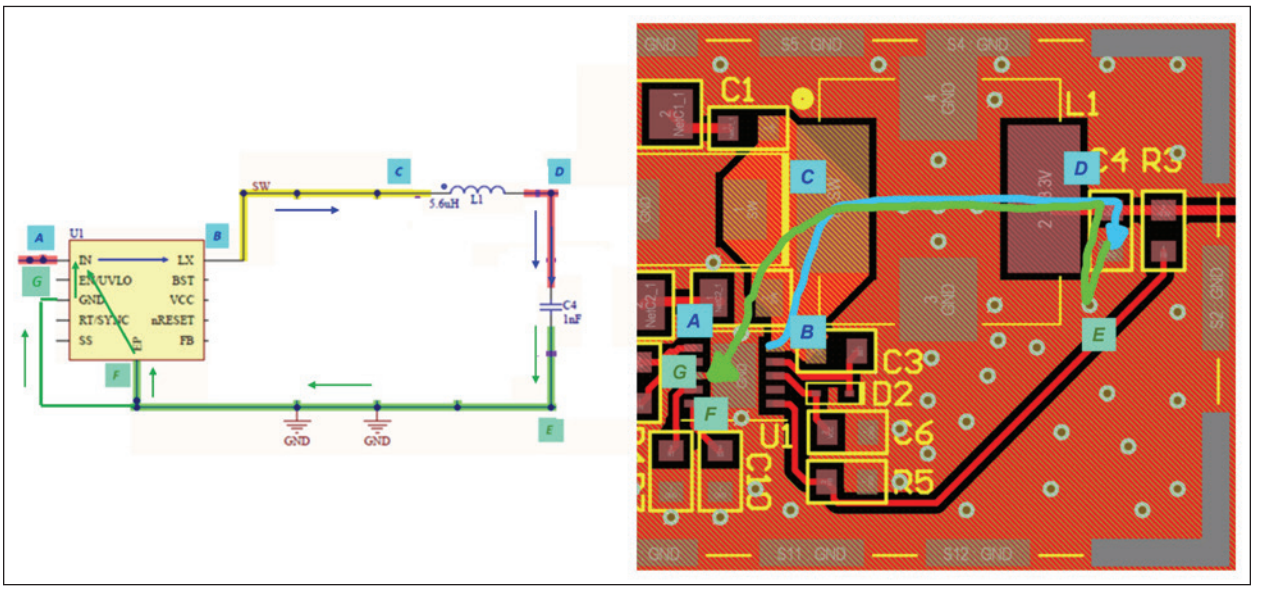

Figure 4: Output filtering section of PCB

through C7, C8, or C9, which are drawn in purple, green, and blue, respectively. To complicate things further, the loop that noise chooses to satisfy may also change with frequency. For example, noise at 100MHz may choose to go through the smaller capacitor, C9, and noise at a lower frequency, such as 500kHz, may choose to go through one of the larger capacitors, C7 or C8. Interrupting any of these return paths has the potential to generate a common mode noise due to increasing the size of the possible current loops if that current path is being used. It is not guaranteed that if one of these paths is interrupted there will be an emissions failure, but it becomes more likely.

As the circuit complexity increases, it becomes challenging to visualize all possible high-frequency current paths. What can be done then?

This is where the application of some good EMC rules of thumb can help. Here are several that we have identified over the years by working on power converters and solving EMC emissions issues:

1. Wherever possible, keep a solid reference plane on the secondary (or adjacent) layer
2. Place decoupling and by-pass capacitors as close to the IC pins as possible
3. Ensure short connections and provide adequate reference via connections adjacent to component reference (GND) pins to ensure a low impedance path (smallest loop area)
4. Place all high di/dt components on the same layer of the PCB and in close proximity
5. Place optional snubber components (series R C) across the internal switch and free-wheeling diode. Locate components in close proximity with short connections.
6. Fill with reference area fill beneath switching components (ICs, inductors, etc.)

All of these approaches reduce the current loop area and serve to reduce radiated and conducted emissions from the switched-mode power supply.

3. RETURN-PLANE SPLIT IN AC-DC CONVERTER

The next several articles will be focused on an AC/DC power supply that utilizes an Off-line Flyback circuit. For safety purposes, the primary side and secondary side circuits must be isolated. Figure 7 shows a part of the schematic for the Maxim MAX5022 Evaluation kit [2], with the current path on the primary side of the transformer shown on the left-hand side of Figure 7 whereas the path of the current flow on the secondary side of the transformer is shown on the right side of Figure 7. Forward currents in both loops are drawn in RED color and return currents are drawn in GREEN color. Note the dashed line

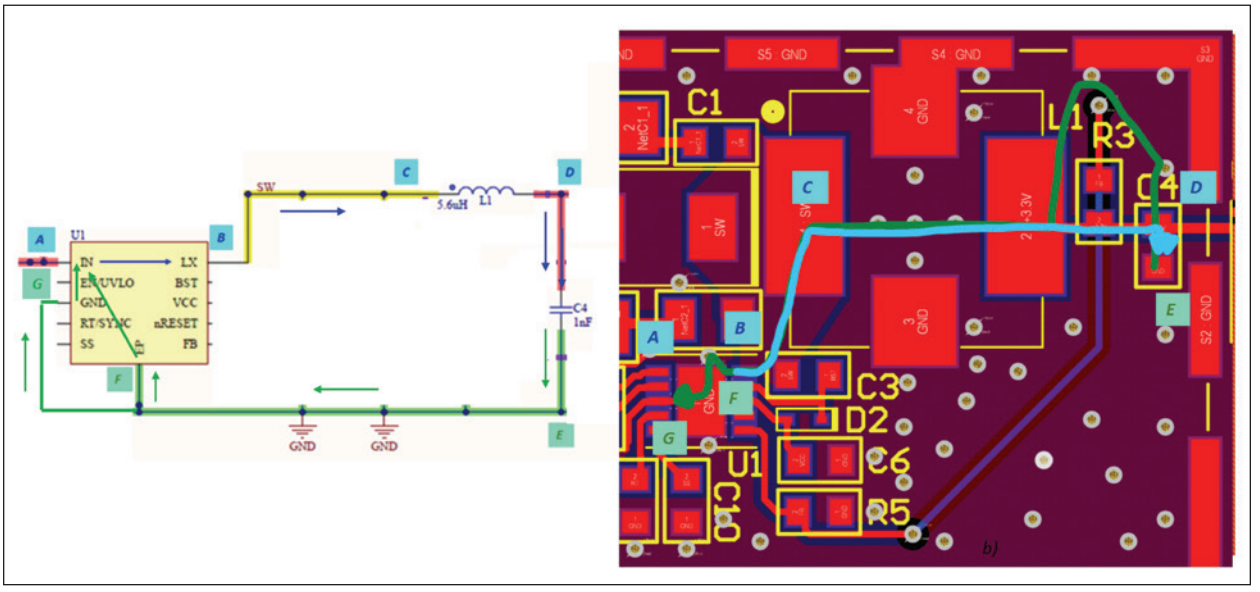

Figure 5: Modified output DC-DC converter

in parallel with C7 that denotes the current flowing back to the source from the secondary to the primary through a stitching capacitor that is safety rated. This capacitor provides a pre-determined path for the noise currents to return back to their source along the PCB surface rather than through the air, thus reducing radiated and conducted emissions.

The capacitor C7 stitches the two grounds together at high frequencies. Next, the return current flows through the current sense resistor (R7) back to the switching transistor completing the loop. The placement of the stitching capacitor impacts the size of the current loop, and therefore it should be placed as close to the transformer as possible. In some cases, a second stitching capacitor is needed so that a stitching capacitor can be provided above and below the body of the transformer. Total values of stitching capacitors must meet the required limitations imposed by isolation requirements.

FUTURE WORK

The next article will discuss the design of the AC/DC Off-Line Flyback Converter. We will present a schematic and PCB layout along with supporting design documentation.

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1. Adamczyk, B., "Alternative Paths of the Return Current," *In Compliance Magazine*, May 2017.
2. MAX5022 Evaluation Kit, MAX5022, Rev 3, Maxim Integrated, 2021, https://datasheets.maximintegrated.com/en/ds/MAX5022EVKIT.pdf.

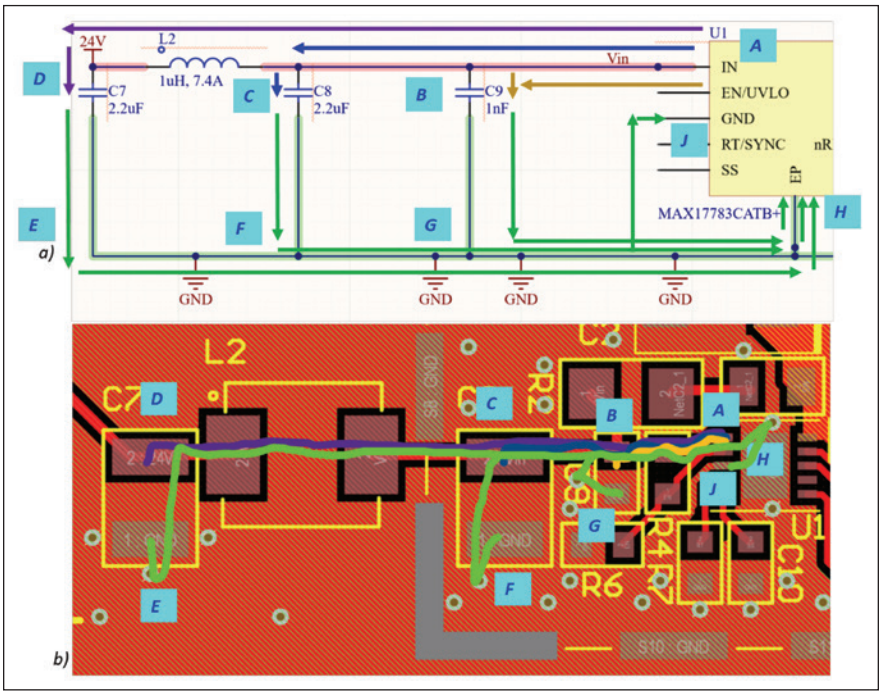

Figure 6: Input filtering section of buck regulator PCB

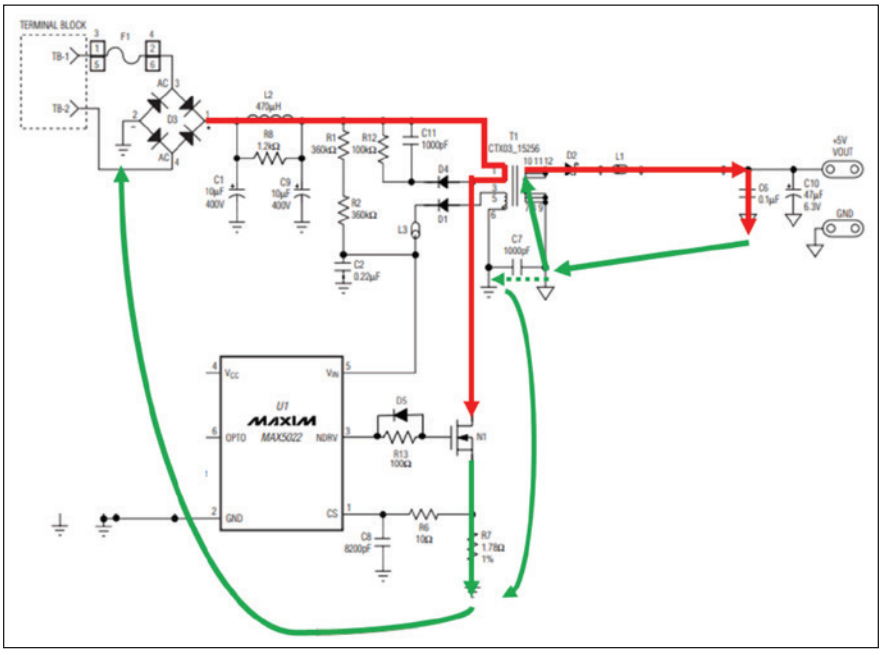

Figure 7: MAX5022 EV kit schematic

UNDERSTANDING FOOTWEAR AND FLOORING IN ESD CONTROL

By Dr. Jeremy Smallwood for EOS/ESD Association, Inc.

I have a floor that complies with IEC 61340-5-1 and ANSI/ESD S20.20, and buy footwear that also complies, so that's sorted then?

Well, not really. It's a good starting point, but you need to know that the flooring and footwear work together. Unfortunately, I've seen cases where they don't. If that happens, you're fooling yourself if you think you've got human body ESD risk under control. I've seen a person wearing footwear that measures about 10 MΩ, standing on a floor that measures about 10 MΩ, but their resistance from body to ground was over 1 GΩ, and a body voltage test while walking showed well over 100 V.

Hang on – how can that be? If the footwear and flooring were both about 10 MΩ, surely the resistance from body to ground should have been about 20 MΩ?

In an ideal world, you might think so – but there's another factor – contact resistance between the footwear and the floor.

So how does a footwear and flooring system work, and why does it sometimes not work?

Footwear and flooring work together as a system to ground the person wearing the footwear. For grounding to work, you need a continuous connection between the body and ground. The ESD control footwear, say a shoe, makes the connection between the person's body and the sole of the shoe. The ESD control floor makes a connection between the floor surface and ground. When the shoe is in contact with the floor, we have contact from body through footwear and flooring to ground. At least, that's the plan.

But many types of floors rely on small amounts of conductive material to form the connection through a sea of high resistance material. So, another question is, how well does the conductive material in the footwear contact with the conductive material in the floor? If both footwear and floor materials rely on relatively small amounts of conductive materials, or there's another reason they don't easily make contact, maybe the answer is "not so well!"

Dr. Jeremy Smallwood is an independent consultant, trainer, and researcher specializing in electrostatics and electrostatic discharge (ESD) protection and control. Jeremy is the author of "The ESD Control Program Handbook" published by Wiley in 2020.

But surely as long as the resistances are within the ANSI/ESD S20.20 and IEC 61340-5-1 limits, we're ok?

Life's not so simple, and that's why both standards insist we must qualify each type of footwear we use in combination with each type of floor we will use it with. A circuit model, as shown in Figure 1, can help us understand why this might be. It might look complicated, but it's actually much too simple, and only the left foot circuit is shown - the right foot circuit is similar.

Let's imagine that the body is like a capacitor C_b. While walking, this capacitance gets charged and discharged via the body resistance R_b and the shoe R_s, because charge is generated by shoe-floor contact. While the shoe is in contact with the floor there is a contact resistance R_c and lifting the foot acts as a switch breaking contact. With the foot in contact with the floor, discharge is through the contact resistance R_c and the floor R_f.

Charge is generated by shoe-floor contact. Let's assume this actually charges a foot-floor capacitance C_{ff} while there is contact. C_{ff} is a highly variable capacitance, which varies from a high value when there is shoe-floor contact, to a low value when lifted. Assuming that at the moment of lifting there is some

charge Q on C_{ff}, a voltage is produced which increases as C_{ff} reduces ($V_{ff} = Q/ C_{ff}$). It's this voltage that charges C_b via R_s and R_b and produces the peaks seen in a body voltage walking test.

Assuming the person is walking, C_b discharges at the same time through the other foot circuit via R_b, R_s, R_c and R_f. The rate of discharge depends on the total of these resistances. The higher this total, the greater the voltage produced by a given current flow. To stop the body voltage from increasing, the current flow through the discharging part of the circuit must be greater than the charging current from the reducing capacitance of the opposite foot lifting.

So, this model tells us some useful things. It tells us that there are many factors other than shoe and floor resistance that contribute to the body voltage waveform in a walking test. This can include things like shoe size and the way we walk, as this affects C_{ff} and the way it changes as the foot is lifted.

The charge on C_{ff} is affected by the way the footwear and floor materials charge against each other – high charging material combinations would be expected to give a higher charge on C_{ff} on lifting the foot. So, two sets of footwear and flooring with otherwise identical resistance characteristics (including contact resistance) can give different charge generation and therefore different body voltages.

Importantly, the footwear-floor contact resistance can differ for footwear-floor combinations that have otherwise similar footwear and floor resistance characteristics. If this contact resistance is greater than the footwear and flooring resistance, it can dominate the total resistance and charge dissipation characteristics and give a much higher body voltage for the same charge generation.

So, if you really want to know whether your footwear and flooring are working together, measure the resistance from the wearer via footwear and flooring to earth (ground). Then, do a walk test to show what body voltage is produced. And, yes, do this for every combination of footwear and flooring you plan to use. And, by the way, be careful how you clean your floors – surface contaminants like cleaning materials and polishes can change both the contact resistance and charge generation characteristics of the footwear-flooring combination. In manual component handling, all of this gets more important as the components you handle get more sensitive (lower withstand voltage), especially below 100 V HBM.

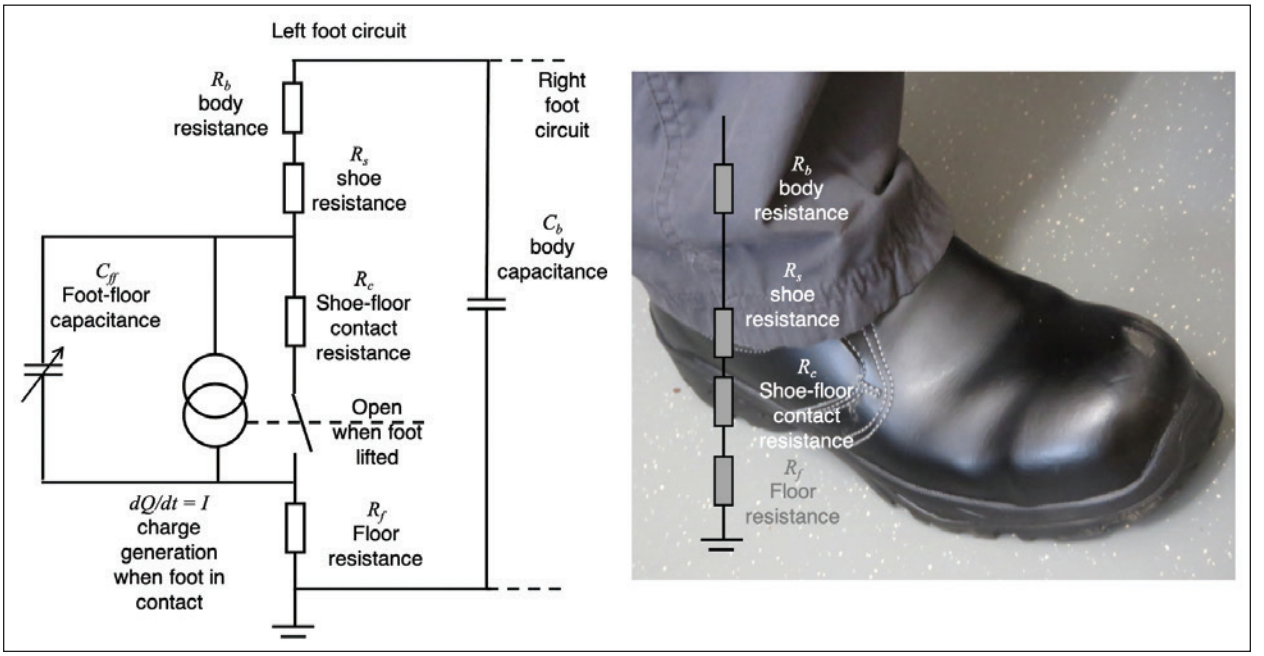

Figure 1: Flooring – footwear circuit model and illustration

Banana Skins

354 Marine mains supply harmonic distortion problems solved

The Ocean Challenger is a very high bollard pull cableship of UT746C dual role design, equipped with a Rockplough that allows for simultaneous cable lay and burial to 1.0m depth in fractured rock, 2.2m in sand/clays and 3.0m in soft soils. The Ocean Challenger's trenching operation is performed by a 2MW Remotely Operated Pipe-line Trenching Vehicle, referred to as the ROV PT1, which is capable of operating in depths of up to 2000m. The PT1 is fitted with ten 30kW electric thrusters for manoeuvring and four 300kW Jet Sword high volume flow rate electric pumps.

The electric thrusters and pumps are independently speed controlled via AC PWM VFD's (Variable Speed Drives) mounted in the surface module. These 400V AC drives are equipped with sinus output filters and 400V to 3300V step-up transformers. From the surface module the 3300V is fed down an umbilical cable to the 3300V thrusters and pump motors. The step up in voltage is required due to the voltage drops associated with very long cable runs extending as much as 2000m.

All individual PT1 drives on the ship were fitted with 3% AC line reactors to partially attenuate the harmonic currents they generate. When connected to the ship's normal power supply, the 1.5MW of AC drives produced too high a harmonic voltage distortion on the two 2800kVA shaft generators. This was partially due to the fact that generator power is more susceptible to voltage distortion than shore-based transformer power, because generators typically have much higher source impedance. With transformers, the impedance (Z) is usually in the order of 5% to 6% whereas for generators the subtransient reactance (Xd") is typically 12% to 20%. The higher the percentage source impedance, the higher the voltage distortion (and the worse its effects) for a given harmonic load.

Historically, to operate the ROV PT1 and its 1.5MW of drives, two deck mounted external generators have had to be rented in order not to breach the Det Norske Veritas (DnV) harmonic voltage maximum limitation of 5% and to prevent possible damage to the generators. This was an expensive proposition in respect to both financial outlay and required deck space.

CTC Marine Projects asked cable handling specialists, Parkburn Precision Handling, to provide a tailored solution, and Parkburn proposed the use of Lineator™ wide spectrum filters. These high performance harmonic filters are manufactured by Canadian company Mirus International Inc. who are represented in Europe by Harmonic Solutions Co. in the UK. The Lineator™ is a patented, multi-limbed reactor with a relatively small capacitor bank whose output, when connected to AC or DC drives, produces a trapezoidal voltage which forces the input rectifier devices to conduct for a longer time period and with smaller peak currents. This has the effect of reducing the 'total harmonic current distortion' (Ithd) to near 5% regardless of whether the VFD is equipped with a reactor or not.

CTC Marine Projects installed 2 x 750kW Lineators™, one for each of two groups of 5 x 30kW thrusters and 2 x 300kW pump drives in a self contained deck module. During the following sea trials, ships staff monitored both the operation of the two shaft generators and the VTHD on the main switchboards. The ship's electrical engineer reported that the generators operated flawlessly and at no time did the VTHD ever rise above 1.4% and 1.6% on their respective switchboards. The installation of the two 750kW Lineators™ allowed the vessel to meet the 5% voltage distortion limit of the DnV without the need for the rented generators and the additional deck space they required.

(Extracted from "Homing in on Harmonics", an article in Offshore Engineer magazine, February 2006 Issue, pages 55-57, sent in by John Symonds of REO (UK) Ltd, on 27 Jan 06.)

355 Piezo gas lighter controls tape player

In the kitchen we have a radio/tape/cd and recently the tapes have been playing with very poor sound quality. No amount of head cleaning has improved the sound. By chance we found that operating the piezo gun to light the gas hob fixes the problem. Must be switching some 'hiss' correction circuit for which there is no external control, button switch etc.

I think that the transient switches on something that the play button ought to switch on but doesn't. Or rather something it used to switch on but doesn't. However when you buy a radio/CD/tape including a remote all for £42 I guess you get what you pay for - it worked OK until the guarantee was over!

Sometimes when the play button is pressed the sound is OK, but frequently it isn't. When the sound is poor the piezo lighter always seems to fix it. If it is repeatable (and it seems to be so) then it is a good demonstration that external EM threats can change the performance of an electronic circuit - in this case it is beneficial, but it might have been the other way round.

(Sent in by Dave Imeson of Compliance Europe Ltd, on 31 Jan 06.)

356 Radar dome suspected of interfering with car immobilisers and lights

Reports that a radar dome in Norfolk is causing electrical problems with cars are being investigated by the Ministry of Defence (MoD). Motorists say their engines and lights have cut out, and their speedometer dials swing up to 150mph as they drive past the Trimingham radar unit.

Neil Crayford, who runs a garage near the dome, said in the past two months, 30 car owners had reported problems. On Monday, an MoD spokeswoman said the claims were being investigated. Mr Crayford said one night his own car's headlights and dashboard cut out for a few seconds as he drove past the dome in convoy with a colleague - who suffered the same fate.

The former RAF radar operator said: "Something must have changed - either the frequency or output - for this to happen. "I lodged an official complaint with the MoD two weeks ago, but incidents are still happening. We get about five a week, and had three more on Friday."

An MoD spokeswoman said: "We are aware of claims that the remote radar head may be interfering with car immobilisers and we are investigating. "There are other users outside the military that operate on the same frequency as the radar, but there is a possibility we could be causing some problems with cars."

(BBC News / England / Norfolk / "Fears radar dome affecting cars.". *Posted to the IEEE's emc-pstc newsgroup on 24 February 2006, by Iain Summers.)*

357 Cellphones can interfere more strongly with aircraft navigation than previously believed

A study by Carnegie Mellon University researchers in the Department of Engineering and Public Policy (EPP) has found that cell phones and other portable electronic devices, like laptops and game-playing devices, can pose dangers to the normal operation of critical electronics on airplanes. The study will be featured in an article appearing in the March issue of IEEE Spectrum.

"We found that the risk posed by these portable devices is higher than previously believed," said Bill Strauss, who recently completed his Ph.D. in EPP at Carnegie Mellon. "These devices can disrupt normal operation of key cockpit instruments, especially Global Positioning System (GPS) receivers, which are increasingly vital for safe landings." Strauss is an expert in aircraft electromagnetic compatibility at the Naval Air Warfare Center in Patuxent River, Md.

With support from the Federal Aviation Administration, three major airlines and the Transportation Security Agency, EPP researchers crisscrossed the northeast United States on commercial flights, monitoring radio emissions from passenger use of cell phones and other electronic devices. They tracked these radio emissions via a broadband antenna attached to a compact portable spectrum analyzer that fit into an innocuous carry-on bag.

"A laptop computer controlled the system and logged the data," said Granger Morgan, head of the EPP Department. "While we looked primarily at wireless phones, we also discovered that emissions from other portable electronic devices were problematic."

The researchers found that on average one to four cell phone calls are typically made from every commercial flight in the northeast United States. Some of these calls are made during critical flight stages such as climb-out, or on final approach. This could cause accidents, the investigators report.

Both Strauss and Morgan, along with Carnegie Mellon researchers Jay Apt and Dan Stancil, recommend that the Federal Communications Commission (FCC) and the FAA begin to coordinate electronic emission standards. At the moment, there is no formal coordination between the two federal agencies. The researchers also recommend routine monitoring of on-board radio emissions by flight data recorders and deploying specially designed tools for flight crews to monitor passenger use of electronic devices during final approach.

While the FCC recently suggested that it might be appropriate to allow passengers to use cell phones and other electronic devices on airplanes, Morgan disagrees.

"We feel that passenger use of portable electronic devices on aircraft should continue to be limited for the safety of all concerned," Morgan said.

(Carnegie Mellon University Press Release, Feb 28, 2006.)

The regular "Banana Skins" column was published in the EMC Journal, starting in January 1998. Alan E. Hutley, a prominent member of the electronics community, distinguished publisher of the EMC Journal, founder of the EMCIA EMC Industry Association and the EMCUK Exhibition & Conference, has graciously given his permission for In Compliance to republish this reader-favorite column. The Banana Skin columns were compiled by Keith Armstrong, of Cherry Clough Consultants Ltd, from items he found in various publications, and anecdotes and links sent in by the many fans of the column. All of the EMC Journal columns are available at: https://www.emcstandards.co.uk/emi-stories, indexed both by application and type of EM disturbance, and new ones have recently begun being added. Keith has also given his permission for these stories to be shared through In Compliance as a service to the worldwide EMC community. We are proud to carry on the tradition of sharing Banana Skins for the purpose of promoting education for EMI/EMC engineers.

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