DISINFECTION OF MOBILE DEVICES FOR USE IN A HEALTHCARE SETTING

OtterBox protective case study conducted by SGS Consumer Testing Services, May 2013.

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Overview

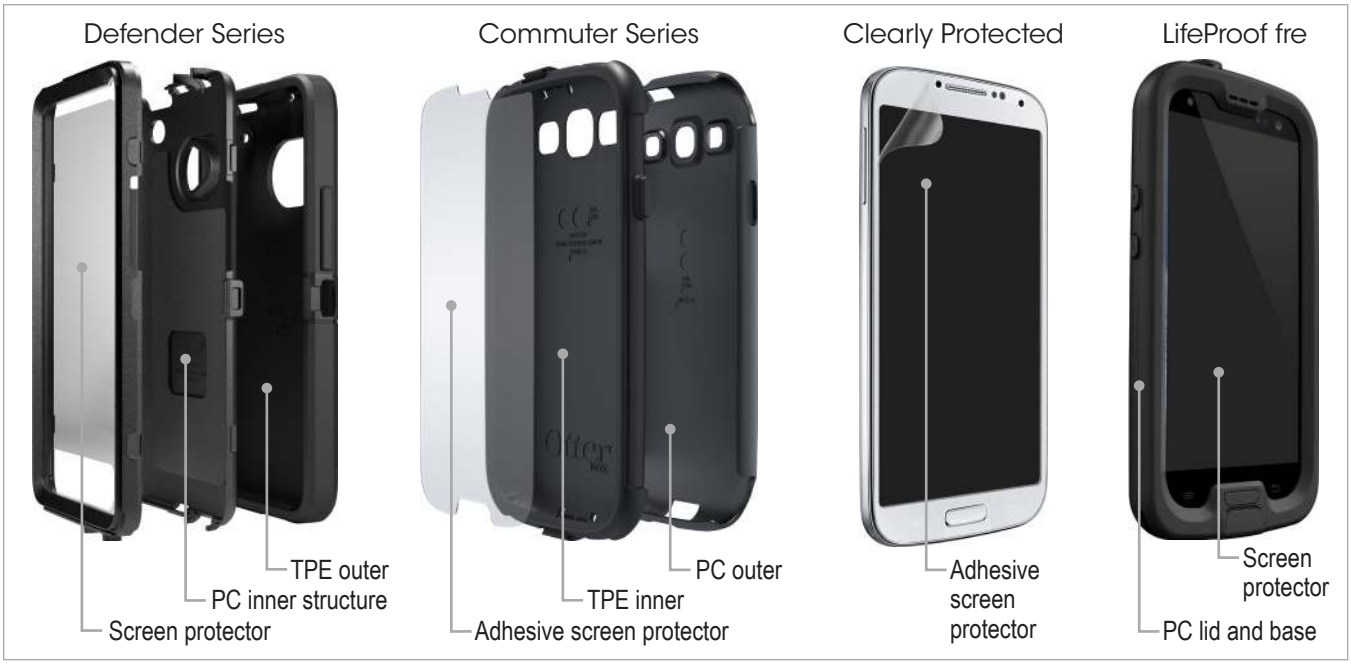
Use of mobile phones in the healthcare setting is rapidly expanding and is contributing to improved healthcare and reduced costs around the globe. This introduction of new technology into clinically sensitive areas creates the risk of passing along microorganisms throughout a hospital. Hospital-acquired infections affect more than 25 percent of admitted patients in developing countries. In the U.S., hospital-acquired infections account for 1.7 million infections per year, one third of which could be prevented by adhering to standard infection control guidelines.[i] Infection control practitioners are creating protocols to address these concerns, which include disinfecting mobile devices with commonly used hospital disinfectants. It is not known whether or not exposing smartphones and tablets to bleach, hydrogen peroxide and quaternary ammonium will damage the devices. This study has been done to encase those devices in a protective cover and evaluate the impact of the disinfectants on the cover. OtterBox cases were exposed to hospital disinfectants over time and evaluated for durability.

Introduction

The quantity of mobile devices being used in healthcare environments is expanding significantly from year to year. There are currently a total of 5,745 U.S. registered hospitals that include 941,995 staffed beds.[ii] In addition, there are 2,909,357 licensed registered nurses in the United States.[iii,iv,v] Using assumptions for the number of physicians, respiratory therapists, administrative staff, etc., there are a potential 4M+ mobile devices in use throughout the U.S. alone.[vi] In addition, visitors to U.S. hospitals generally carry mobile devices which impose an even greater risk of transmitting infection both in the hospital and out in the community.

The use of mobile technology is expected to have a profound impact on how care is delivered, the quality of patient experience and the cost of healthcare in general. For example, remote patient monitoring allows both the patient and caregiver to closely watch important parameters such as continuous blood glucose or to perform an ECG outside of the hospital or physician's office. Physicians can possibly receive "advanced notice" and intervene much earlier in the progression of a health event. A Brookings Institution analysis undertaken by economist Robert Litan found that remote monitoring technologies could save as much as $197 billion over the next 25 years in the United States.[vii]

Along with improvements to patient care there are also some challenges that come with introducing mobile technology to healthcare environments. In one study participants were asked to disinfect their hands and then make a short call from their cell phone. After using the mobile phone the participant hands had a 93.7% contamination rate.[viii] Microbiologists say that the combination of constant handling and the heat generated by the phones creates a prime breeding ground for all sorts of microorganisms that are normally found on our skin. Using mobile devices in clinically sensitive areas may bring along the risk of transmitting microorganisms to immunocompromised patients, but simple measures like hand washing and wiping down devices can help to minimize this risk.[ix]



Methods

Chemical resistance testing will expose the Defender Series case (screen, TPE outer layer and PC inner structure), Commuter Series (inner TPE, PET adhesive screen and outer PC), LifeProof fre (PC lid with screen protector and PC base), and the Clearly Protected films with widely used medical sanitation wipes (Table 1). In addition to simulating the daily cleaning cycle, each test sample will be exposed to a variety of performance tests to determine if the exposure would impact the durability of the OtterBox case (Table 2).

Table 1

DISINFECTANT NAME	DISINFECTANT COMPONENTS	% BY WEIGHT
Clorox Healthcare Bleach Wipes	Sodium hypochlorite	0.1–1%
	Sodium metasilicate	0.1–1%
	Sodium hydroxide	0.1–1%
Clorox Healthcare Hydrogen Peroxide Wipes	Hydrogen peroxide	1–5%
	Benzyl alcohol	1–5%
PDI Super Sani-Cloth	n-Alkyl dimethyl ethylbenzyl ammonium chloride	0.25%
	n-Alkyl dimethyl benzyl ammonium chloride	0.25%
	Other ingredients	99.50%
	Each cloth saturated with 5,000 ppm of active quaternary ammonium chlorides	
CaviWipes — Metrex Research Corp.	Isopropanol	15%
	Ethanol	7.50%
	Ethylene glycol monobutyl ether (2-butoxyethanol)	1–5%
	Didecyldimethylammonium chloride 7	0.76%
	Water	70–80%

The products were wiped with the various disinfectants to simulate how the cases would be wiped down by a clinician after interacting with a patient. This was repeated 320 times prior to the performance evaluation.

Table 2

Chemical resistance (various disinfectants)

ASTM	PARAMETER
Optical Properties	
D-1003	Haze
VIS Lab Scan AATCC	Color change
Physical Properties	
D-1004	Tear resistance (plastic film & sheeting)
D-624	Tear resistance (rubber & thermoplastic)
D-1708	Tensile strength & elongation
F-1306	Slow rate penetration
MIL STD 810	Drop test
D-1894	Coefficient of friction
D-1790	Brittleness (Commuter Series case only)

ASTM D1003: "Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics." Haze is the scattering of light by a specimen responsible for the reduction in contrast of objects viewed through it. This test method covers the evaluation of specific light-transmitting and wide-angle-light-scattering properties of transparent plastic materials. This test is useful because light that is scattered upon passing through a film or sheet of a material can produce a hazy or smoky field when objects are viewed through the material. For example, an increase in the haze after the wiping of the material could be an indication that the material scatters more light and could result in difficulty viewing through it.

ASTM D1004: "Standard Test Method for Tear Resistance of Plastic Film and Sheeting." This test method is designed to measure the force to initiate tearing across a specific geometry of a film or sheeting specimen is measured using a constant rate-of-grip separation machine. The force necessary to initiate the tear was determined. Tear resistance testing is significant to test for the reliability of a material. This tear resistance test method was used to test the plastic screen covers. Similar tear resistance results before and after wiping could be an indication that the material still holds its original strength.

ASTM D624: "Standard Test Method for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers." Rubber materials often fail in service due to the generation and propagation of a special type of rupture called a tear. This test method measures the resistance to tearing action. It measures the force per unit thickness required to rupture, initiate, or propagate a tear through a sheet of rubber in the form of the sample die as pictured above. Similar tear strength results before and after wiping could be an indication that the material still holds its original strength. This method was used to test the rubber slip covers.

The actual test method that was used for tensile strength and elongation was **ASTM D1708,** "Standard Test Method for Tensile Properties of Plastics by use of Microtensile specimens." This test method covers the determination of the comparative tensile strength and elongation properties in the form of standard microtensile test specimens. This test method is used generally for thin films such as the screen covers. However, due to the limited size of material, the slip covers were also tested according to this method. Test data used by this method are relevant and appropriate for use in engineering design and quality control. Similar tensile strength results before and after wiping could be an indication that the material holds its original strength.

ASTM D1894: "Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting." This test method covers determination of the coefficients of starting and sliding friction of plastic film when sliding over a stainless steel plate at specified test conditions. The coefficients of friction are related to the slip properties of plastic films that are of wide interest in packaging applications. The static coefficient of friction is the ratio of the force required to move one surface over another to the total force applied normally to those surfaces, at the instant motion starts. The kinetic coefficient of friction — the ratio of the force required to move one surface over another to the total force applied normally to those surfaces, once that motion is in progress. An increase in COFs could be an indication that the material's surface is stickier and more resistive to sliding.

ASTM F1306, "Standard Test Method for Slow Rate Penetration Resistance of Flexible Barrier Films and Laminates." This test method determines the force required to penetrate a flexible barrier film by a slow rate driven probe. The test is performed at room temperature, by applying a biaxial stress at a single test velocity on the material until perforation occurs. The force, to perforation is then determined. Penetration resistance is an important end-use performance of thin flexible materials where a sharp-edged product can destroy the integrity of a barrier wrap. A decrease in the penetration force of a material after wiping could be an indication that the material lost some of its original strength.

The **VIS Lab Scan AATCC** is not an actual method, but is more of an equipment name. The equipment used is a Lab Scan XE and it measures the color change of any material according to the AATCC Gray Scale for evaluation change in color. This scale is according to the specifications of ISO 105/A02. This method describes the gray scale for determining changes in the color of materials. A precise colorimetric specification of the scale is given as a permanent record against which newly prepared working standards and standards that may have changed can be compared. According to the scale a rating of "5" is considered to have no color change and "1" being much significant color change.

Key to Color Change Rating:

5	Negligible or not color staining
4	Slight or negligible color staining
3	Noticeable color staining
2	Considerable color staining
1	Much color staining

The drop test was performed according to OtterBox instructions. It was a 3 foot drop onto a hard floor. Afterwards, the sample was inspected for damage or failure. The drop test of Mil Standard 810 in Table 516.5-IV is intended to ensure the functionality of material after it has been inadvertently dropped before, during, or after a packaging process. It requires that a manually handled package less than 20 lbs. should be tested at a drop height of 30 inches. The samples were tested at 36 inches.

Results

Screen Protectors

The screen protectors were tested against a variety of conditions with the main focus being on three areas: visual changes, tackiness and material strength.

Changes in haze or luminous transmission are not recognizable to the human eye below a 5% difference. In all but one situation the difference was under 5%, with the exception being the Clearly Protected Vibrant product being cleaned with Clorox Bleach. This particular disinfectant left a light cloudy film on the screen protector that was able to be wiped off, but took an additional step. On all products, any haze that was noticeable was very easily wiped clean with a damp cloth. This is also noted on the Clorox Healthcare web site as a potential necessary step when their bleach disinfectant is used.

The most significant impact that the cleaning products had on the screen protectors was with regard to coefficient of friction (COF). Static friction is the friction caused when moving your finger from a complete stop across the screen. Kinetic friction refers to the friction during the movement across the screen. Both the Clorox Hydrogen Peroxide and PDI Super Sani-Cloth caused the tackiness of the Clearly Protected Clean screen protector to increase at a level that may impact user satisfaction. In addition, the PDI also increased the COF of the Clearly Protected Vibrant screen protector.

Material strength was tested looking at reduction in tear strength and penetration force. None of the disinfectants changed these parameters in a way that would impact the product use. It is not recommended that users remove and reapply the screen protectors as this will invalidate the warranty on these products, but if the products are used that way exposure to hydrogen peroxide may reduce their tear strength.

Material: Clean Dry Screen Cover (Clearly Protected Clean)

AVERAGE TEST RESULT	CLOROX BLEACH GERMICIDAL	CLOROX HYDROGEN PEROXIDE	PDI SUPER SANI-CLOTH	CAVIWIPES — METREX RESEARCH CORP.
Haze Variation (%)	<5%	<5%	<5%	<5%
Luminous Trans. Variation (%)	<1%	<1%	<1%	<1%
Static Coefficient of Friction % Difference	47%	89%*	82%*	65%
Kinetic Coefficient of Friction % Difference	38%	62%*	60%*	46%
Reduction of Tear Strength	<10%	<20%	<5%	<5%
Penetration Force (lbf) % Difference	<10%	<10%	<10%	<10%
Color Change Rating	5	5	5	5
Color Change Rating	Negligible or no color change			

*Tackiness of material may be noticeable enough to impact performance

Material: Xtreme Dry Screen Cover (Clearly Protected Vibrant)

AVERAGE TEST RESULT	CLOROX BLEACH GERMICIDAL	CLOROX HYDROGEN PEROXIDE	PDI SUPER SANI-CLOTH	CAVIWIPES — METREX RESEARCH CORP.
Haze Variation (%)	<7%	<5%	<5%	<5%
Luminous Trans. Variation (%)	<1%	<1%	<1%	<1%
Static Coefficient of Friction % Difference	18%	27%	58%*	54%
Kinetic Coefficient of Friction % Difference	20%	5%	11%	46%
Reduction of Tear Strength	No reduction	<10%	<5%	<10%
Penetration Force (lbf) % Difference	<10%	<10%	<10%	<10%
Color Change Rating	5	5	5	5
Color Change Rating	Negligible or no color change			

*Tackiness of material may be noticeable enough to impact performance

Case Products

The OtterBox cases were broken down into their components in order to conduct this testing. While most components were tested for all conditions this report highlights the component/condition outcome that is most likely to impact product performance. The Clorox Bleach Germicidal disinfectant had the most significant impact on haze, but as with the screen protection products this haze was easily removed with a damp cloth. None of the products increased the coefficient of friction in a way that would impact usability.

There was negligible or no color change to the components of the Defender Series case that are most visible (the TPE outer slipcover). The inner plastic base did see significant color change with the bleach and hydrogen peroxide based disinfectants. This material is not likely to be seen or cleaned with the wipes as it is nearly completely covered by the outer TPE. Therefore OtterBox recommends that this product is suitable to be cleaned with all products tested.

The LifeProof fre product performed very well when exposed to these chemicals. There was no noticeable color change, with the exception again of the residue from the bleach that was easily wiped off. The most significant impact that the disinfectants had on materials was the elongation variation. The change in material property was greater than 100% of a reduction in the pressure required to pull the product apart. Although, this pressure would go well beyond the force that a user could put on the product when used as expected.

The Commuter Series case did experience a noticeable color change when exposed to all products. Those changes are specifically called out in the relevant chart below. While color change does not impact the protection performance of the case it may impact user satisfaction.

The screen protectors provided with the Commuter Series cases are made of polyethylene terephthalate (PET) material. Hospital disinfectants had a negative impact on this material and degradation of the material was seen. For that reason it is not recommended that these screen protectors be cleaned with hospital disinfectants. OtterBox recommends that the Clearly Protected brand screen protector be used instead.

In addition to the testing that was performed on the adhesive screen protectors these cases were tested for brittleness and standard OtterBox and LifeProof drop testing. All three products passed the brittleness and drop testing. This is the testing that has been perceived as the most relevant to understand. The main purpose of a mobile device case is to make sure that case protects the devices inside. Haze and CoF may impact user satisfaction and ultimately guide product preference though all cases tested meet OtterBox protection standards after exposure to these hospital disinfectants.

Material: OtterBox Defender Series

AVERAGE TEST RESULT	CLOROX BLEACH GERMICIDAL	CLOROX HYDROGEN PEROXIDE	PDI SUPER SANI-CLOTH	CAVIWIPES — METREX RESEARCH CORP.
Screen Haze Variation (%)	0.10	<5%	<5%	<5%
Screen Luminous Trans. Variation (%)	<1%	<1%	<1%	<1%
Screen Static Coefficient of Friction % Difference	2%	20%	-3%	11%
Screen Kinetic Coefficient of Friction % Difference	-8%	16%	-22%	3%
TPE Cover Reduction of Tear Strength	<10%	No reduction	No reduction	No reduction
Screen Penetration Force (lbf) % Difference	<10%	<2%	<2%	<5%
Color Change Rating	Negligible or no color change			
Brittleness	Pass	Pass	Pass	Pass
Drop Test	Pass	Pass	Pass	Pass

Material: Lifeproof fre

AVERAGE TEST RESULT	CLOROX BLEACH GERMICIDAL	CLOROX HYDROGEN PEROXIDE	PDI SUPER SANI-CLOTH	CAVICIDE
Screen Haze Variation (%)	<15%	0.10%	<5%	<5%
Screen Luminous Trans. Variation (%)	<1%	<1%	<1%	<1%
Screen Static Coefficient of Friction % Difference	30%	7%	3%	26%
Screen Kinetic Coefficient of Friction % Difference	29%	13%	11%	23%
Tensile Strength % Difference	28%	-42%	42%	20%
Elongation variation %	-92.00	-55.00	> -100.00	> -100.00
Color Change Rating	Negligible or no color change**			
Brittleness	Pass	Pass	Pass	Pass
Drop Test	Pass	Pass	Pass	Pass

Material: OtterBox Commuter Series

AVERAGE TEST RESULT	CLOROX BLEACH GERMICIDAL	CLOROX HYDROGEN PEROXIDE	PDI SUPER SANI-CLOTH	CAVIWIPES — METREX RESEARCH CORP.
Screen Haze Variation (%)	<15%	<5%	<5%	<5%
Screen Luminous Trans. Variation (%)	<2%	<1%	<1%	<1%
Screen Static Coefficient of Friction % Difference	-22%	-125%	-120%	-45%
Screen Kinetic Coefficient of Friction % Difference	61%	32%	35%	59%
TPE Cover Reduction of Tear Strength	No reduction	No reduction	No reduction	No reduction
Screen Penetration Force (lbf) % Difference	<5%	<5%	<5%	<5%
TPE Color Change Rating	4.0	4.0	3.5	4.5
Plastic Outer Color Change Rating	4.0	2.0	3.5	2.0
Brittleness	Pass	Pass	Pass	Pass
Drop Test	Pass	Pass	Pass	Pass

Discussion and Recommendations

Studies have suggested that mobile devices pose a threat of transmitting microorganisms throughout a healthcare facility and back and forth between the communities. Following simple hand washing and disinfection protocols have worked to reduce the amount of hospital acquired infections. In some instances, hospitals have recommended that a similar strategy be taken with mobile devices, and that they be cleaned on a daily basis. The testing that SGS North America Inc. conducted was designed to determine the impact that disinfectants will have on the performance of the protective solutions.

OtterBox did not test the impact of the disinfectants on mobile phones or tablets. OtterBox followed the cleaning instructions provided by the disinfectant manufacturers on how to effectively clean plastic products as the test process for each of the case parts. The LifeProof fre case is a dust proof and waterproof design that provides complete coverage for the mobile device as such the entire case can be wiped down without any concern for the device inside. The Defender Series, Commuter Series and Clearly Protected products are not waterproof, making it important to ensure that moisture from the wiping process does not enter the mobile device. For that reason OtterBox is not able to advise users about any exposed areas of the devices that come in to contact with the disinfectants.

The evaluation of the adhesive screen protectors was somewhat subjective. Quantitative analysis was conducted to determine how significant the impact of the disinfectants is, but there is no official standard for haze or coefficient of friction when it comes to these products. An internal team reviewed the samples and determined if the products that were most significantly affected would impact the user's experience. The bleach-based disinfectant seemed to leave a noticeable film behind and may be seen as the least useable disinfectant. The ability to use bleach-based disinfectant is extremely important in the case of C. difficile bacteria and therefore the extra step of wiping the device would be of secondary concern. The bleach film was easily wiped off of the device with a damp cloth and had no noticeable impact on the performance after being wiped off.

DISINFECTANT NAME	DISINFECTANT COMPONENTS	% BY WEIGHT	CLEARLY PROTECTED CLEAN	CLEARLY PROTECTED VIBRANT	DEFENDER SERIES CASE	LIFEPROOF FRE CASE	COMMUTER SERIES CASE
Bleach Wipes	Sodium hypochlorite	0.1–1%	✓*	✓*	✓*	✓*	O*†
	Sodium metasilicate	0.1–1%					
	Sodium hydroxide	0.1–1%					
Hydrogen Peroxide Wipes	Hydrogen peroxide	1–5%	O	✓	✓	✓	O†
	Benzyl alcohol	1–5%					
Quaternary High Alcohol Wipes	Benzyl-C12-18-alkyldimethyl ammonium chlorides	0.1–1%	O	✓	✓	✓	O†
	C12-18-alkyl [(ethylphenyl) methyl] dimethyl, chlorides	0.1–1%					
	Isopropanol	30–60%					
Quaternary Low Alcohol Wipes	Isopropanol	15%	✓	✓	✓	✓	O†
	Ethanol	7.50%					
	Ethylene glycol monobutyl ether (2-butoxyethanol)	1–5%					
	Didecyldimethylammonium chloride 7	0.76%					
	Water	70–80%					

✓ Disinfectant had no noticeable impact on product use or durability

O Disinfectant had no impact on durability but may impact product use as described in results

* This particular disinfectant left a light cloudy film on the screen protector that was able to be wiped off, but took an additional step. On all products, any haze that was noticeable was very easily wiped clean with a damp cloth. This is also noted on the Clorox Healthcare web site as a potential necessary step when their bleach disinfectant is used.

† The screen protector provided with the Commuter Series case is made of polyethylene terephthalate (PET) and is not recommended for use with hospital disinfectants. OtterBox recommends a Clearly Protected screen cover be used instead.

If a hospital or healthcare organization feels that it is appropriate to disinfect their mobile devices they can do so by using an OtterBox or LifeProof case around the device. This will help to protect the device from being damaged by the disinfectant and allow the case to be cleaned following the recommendations provided by the disinfectant manufacturers.

Please direct all inquiries to John Burns, product development department at OtterBox.
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