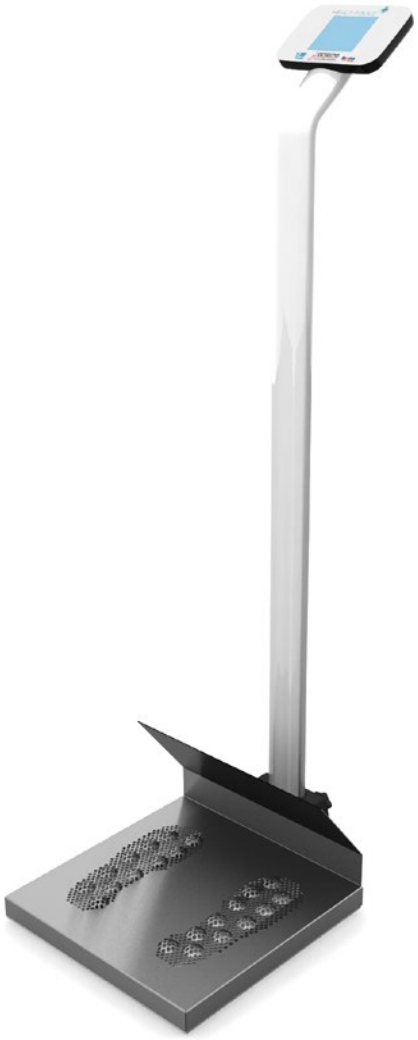
HEALTHYSOLE®

PRODUCT INFORMATION PACKET



DETECTO®

www.Detecto.com

Bulletin No. C272

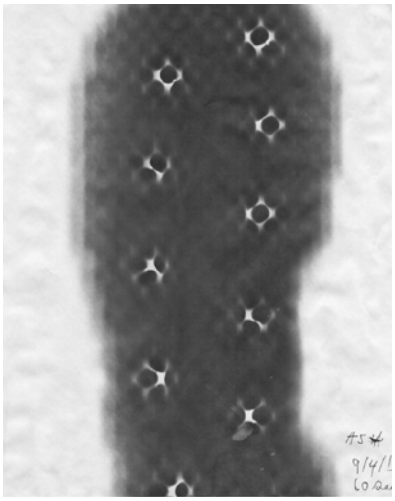
INTRODUCTION

The patented and patent pending HEALTHYSOLE® PLUS System by Detecto is the first clinically proven No-Touch, Hands Free UVC Germicidal, chemical free and Active Disinfection Technology™ to significantly manage the spread of infectious microorganisms traveling on the bottom of shoes.

HEALTHYSOLE® PLUS is a new, effective and groundbreaking use of UVC technology that effectively reduces the dangerous organisms that cause Healthcare Associated Infections (HAIs). By introducing HEALTHYSOLE® PLUS into an existing infection control and prevention program, a healthcare facility adds a significant active layer of defense, that once implemented, reduces the rate of cross contamination and doesn't incur additional labor costs.

Lowering the overall microbial burden in a healthcare facility, leads to a decrease of HAIs. Facilities who have positive performance standards by lowering HAI's, will reduce the additional treatment cost that is otherwise passed to them, shorten extended length of stay for patients, and save more lives.

Until now, infection control and prevention programs have been implemented with systems that can't provide a full and effective line of defense against HAI's. HEALTHYSOLE® PLUS is the first and only chemical free, hands free infection control product available today that actively works (24/7) and effectively kills up to 99% of exposed deadly organisms on the bottom of shoes in just 5-8 seconds resulting in lower overall microbial loads in key areas of hospitals that can lead to the spread of HAIs.



A pixel by pixel analysis was performed on a greyscale image. The irrelevant portions of the image were masked out and the remaining pixels were tallied by their greyscale values. In a greyscale image each pixel uses a single byte to describe its color from white to black. This allows the color to take on a value between 0 and 255. To determine an exposure percentage, a threshold must be chosen. Values below the threshold are labeled "exposed" and values above the threshold are not. This report used a threshold of 120, 97%.

UP TO
97%
EXPOSURE RATE

THE PROBLEM: HAI'S

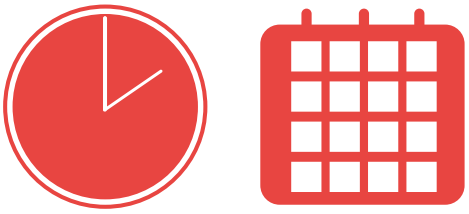
HAI
Hospital Acquired Infection

Healthcare Associated infections also known as Hospital Acquired Infections or HAI's (HAC: Hospital Acquired Conditions) are caused by life threatening microorganisms that have plagued the industry for decades but have gotten out of control and considered an epidemic in more recent years.

Between 75,000-99,000 of the nearly 2 million infected patients die annually. **1 in 9 infections lead to death.**

HAI's kill more people in the US annually than AIDS, Breast Cancer, and Auto Accidents combined. **They are the 6th leading killer in the US today!**

HAI's are contracted in a healthcare facility when a patient was admitted for reasons other than the infection they contracted. HAI's can be diagnosed within 48 hours post admission, 3 days after discharge and much as 30 days after an operation.



LAWS, COSTS, DEATHS, CMS/PAY OR NON-REIMBURSEMENT

Federal and state governments, along with private payers, are now restricting payments for healthcare associated infection costs to hospitals. **Hospitals are now responsible to treat HAI's at their own expense.**

According to the CDC the average additional cost to a hospital to treat a patient infected with an HAI is $15,275. On a per-case basis, HAIs can exceed $100,000 to treat the infection.

The healthcare industry reports an additional annual cost to treat HAI's between 28-45 billion dollars, 13.6 million extra patient days (8 days per patient) spent in a hospital and nearly **300 deaths per day**. Not to mention the suffering to mankind that takes place with loss of work, family distress, pain, suffering and long-term effects due to infections.

"Along with leadership of patient safety professionals, an important driver of progress is the move by payers to deny reimbursement for health care related to preventable harm.By placing the costs of HAIs with hospitals, this shift has accentuated the fiscal case for prevention." (Health Care-Associated Infections, A meta-analysis of Cost and Financial Impact on the US Health Care System JAMA 2013)

ECRI Institutes 2015 Top 10 C-Suite Watch List address area decontamination as its No 1 technology-related issue and notes that "Battles may be lost or won on the hospital-acquired infection (HAI) front, but the war wages on as pathogens mutate to resist the latest antibiotics and disinfectants."

HEALTHYSOLE® PLUS'S UVC Germicidal light doesn't allow pathogens to grow or reproduce and has never caused a superbug or antibiotic resistant organism!

NET CHANGE IN HOSPITALS OPERATING DRG REIMBURSMENT AMOUNT

Medicare (CMS) cut payments to the 721 Hospitals in 2015 with the highest rates of infections and other patient injuries. The health law mandates the reductions for the quarter of hospitals that Medicare assessed as having the highest rates of "hospital-acquired conditions," or HACs. (KaiserHealthNews)

Net Change in Base Operating DRG Payment Amount	Number of Hospitals Receiving this Range
$0 to $0	0
$-30,000 to $-20,001	143
$-40,000 to $-30,001	113
$-50,000 to $-40,001	87
$-60,000 to $-50,001	77
$-70,000 to $-60,001	50
$-80,000 to $70,001	53
$-90,000 to $-80,001	38
$-100,000 to $-90,001	35
$-110,000 to $-100,001	34
$-120,000 to $-110,001	19
$-130,000 to $-120,001	19
$-140,000 to $-130,001	23
$-150,000 to $-140,001	17
$-150,000	113

PENALTIES FOR HOSPITAL ACQUIRED CONDITIONS

Medicare is penalizing hospitals with high rates of potentially avoidable mistakes that can harm patients, known as "hospital-acquired conditions." Penalized hospitals will have their Medicare payments reduced by 1 percent over the fiscal year that runs from October 2014 through September 2015. To determine penalties, Medicare ranked hospitals on a score of 1 to 10, with 10 being the worst, for three types of HACs. One is central-line associated bloodstream infections, or CLABSIs. The second is catheter- associated urinary tract infections, or CAUTIs. The final one, Serious Complications, is based on eight types of injuries. Hospitals with a Total HAC Score above 7 will be penalized.

Provider ID	Hospital	City	State	County	Serious Complications Score	CLABSI Score	CAUTI Score	Total HAC Score	Penalty
123456	Hospital 1	City 1	CA	Los Angeles	6	4	8	6	No Penalty
123456	Hospital 2	City 2	CA	San Mateo	8	8	10	8.65	Penalty
123456	Hospital 3	City 3	CA	Placer	5	3	5	4.35	No Penalty
123456	Hospital 4	City 4	CA	Sacramento	2	3	9	4.6	No Penalty
123456	Hospital 5	City 5	CA	San Diego	4	1	4	3.025	No Penalty
123456	Hospital 6	City 6	CA	San Francisco	8	4	7	6.375	No Penalty
123456	Hospital 7	City 7	CA	Marin	8	8	4	6.7	No Penalty
123456	Hospital 8	City 8	CA	Los Angeles	6	6	3	5.025	No Penalty
123456	Hospital 9	City 9	CA	San Mateo	6	1	5	4.05	No Penalty
123456	Hospital 10	City 10	CA	Solano	9	5	8	7.375	Penalty
123456	Hospital 11	City 11	CA	Contra Costa	3	5	4	3.975	No Penalty
123456	Hospital 12	City 12	CA	Los Angeles	2	5	6	4.275	No Penalty
123456	Hospital 13	City 13	CA	Los Angeles	7	1	10	6.025	No Penalty
123456	Hospital 14	City 14	CA	Solan	8	10	10	9.3	Penalty
123456	Hospital 15	City 15	CA	San Bernardino	9	2	5	5.425	No Penalty
123456	Hospital 16	City 16	CA	Alameda	10	3	8	7.075	Penalty
123456	Hospital 17	City 17	CA	San Joaquin	5	4	3	4.025	No Penalty
123456	Hospital 18	City 18	CA	Alameda	8	7	8	7.675	Penalty
123456	Hospital 19	City 19	CA	Orange	3	4	6	4.3	No Penalty
123456	Hospital 20	City 20	CA	Riverside	3	3	4	3.325	No Penalty
123456	Hospital 21	City 21	CA	Riverside	7	1	5	4.4	No Penalty
123456	Hospital 22	City 22	CA	Santa Clara	9	3	9	7.05	Penalty
123456	Hospital 23	City 23	CA	Santa Clara	8	3	4	5.075	No Penalty
123456	Hospital 24	City 24	CA	Sonoma	4	1	8	4.325	No Penalty
123456	Hospital 25	City 25	CA	Tulare	9	3	3	5.1	No Penalty
123456	Hospital 26	City 26	CA	Los Angeles	10	8	10	9.35	Penalty
123456	Hospital 27	City 27	CA	Kern	8	3	9	6.7	No Penalty
123456	Hospital 28	City 28	CA	Orange	1	6	3	3.275	No Penalty
123456	Hospital 29	City 29	CA	Los Angeles	10	7	9	8.7	Penalty
123456	Hospital 30	City 30	CA	Los Angeles	5	7	8	6.625	No Penalty
123456	Hospital 31	City 31	CA	Orange	7	9	6	7.325	Penalty
123456	Hospital 32	City 32	CA	Los Angeles	10	4	7	7.075	Penalty
123456	Hospital 33	City 33	CA	San Francisco	7	NA	NA	7	No Penalty
123456	Hospital 10	Lakewood	CA	Los Angeles	4	3	2	3.025	Penalty

Provider ID	Hospital	City	State	County	Serious Complications Score	CLABSI Score	CAUTI Score	Total HAC Score	Penalty
123456	Hospital 1	City 1	TX	Nueces	1	6	5	3.925	No Penalty
123456	Hospital 2	City 2	TX	Denton	7	NA	NA	7	No Penalty
123456	Hospital 3	City 3	TX	Collin	10	NA	NA	10	Penalty
123456	Hospital 4	City 4	TX	Travis	3	NA	NA	3	No Penalty
123456	Hospital 5	City 5	TX	Jefferson	1	8	3	3.925	No Penalty
123456	Hospital 6	City 6	TX	Smith	4	NA	1	2.05	No Penalty
123456	Hospital 7	City 7	TX	Titus	6	NA	1	2.75	No Penalty
123456	Hospital 8	City 8	TX	Harris	5	8	7	6.625	No Penalty
123456	Hospital 9	City 9	TX	Harris	4	NA	NA	4	No Penalty
123456	Hospital 10	City 10	TX	Lubbock	7	NA	NA	7	No Penalty
123456	Hospital 11	City 11	TX	Tyler	6	NA	NA	6	No Penalty
123456	Hospital 12	City 12	TX	Tarrant	1	NA	1	1	No Penalty
123456	Hospital 13	City 13	TX	Dallas	9	6	8	7.7	Penalty
123456	Hospital 14	City 14	TX	Dallas	2	4	6	3.95	No Penalty
123456	Hospital 15	City 15	TX	Wichita	3	5	2	3.325	No Penalty
123456	Hospital 16	City 16	TX	Harris	1	8	3	3.925	No Penalty
123456	Hospital 17	City 17	TX	Bexar	10	6	8	8.05	Penalty
123456	Hospital 18	City 18	TX	Lubbock	4	9	4	5.625	No Penalty
123456	Hospital 19	City 19	TX	Travis	7	9	10	8.625	Penalty
123456	Hospital 20	City 20	TX	El Paso	10	10	10	10	Penalty
123456	Hospital 21	City 21	TX	Galveston	10	8	5	7.725	Penalty
123456	Hospital 22	City 22	TX	Tarrant	4	NA	NA	4	No Penalty
123456	Hospital 23	City 23	TX	Uvalde	3	NA	1	1.7	No Penalty
123456	Hospital 24	City 24	TX	Val Verde	1	NA	7	4.9	No Penalty
123456	Hospital 25	City 25	TX	Cameron	9	0	5	6.65	No Penalty
123456	Hospital 26	City 26	TX	Cameron	4	6	7	6.2	No Penalty
123456	Hospital 27	City 27	TX	Cameron	4	6	7	5.625	No Penalty
123456	Hospital 28	City 28	TX	Bowie	6	5	5	5.35	No Penalty
123456	Hospital 29	City 29	TX	Parker	2	10	2	4.6	No Penalty
123456	Hospital 30	City 30	TX	Harris	4	7	7	5.95	No Penalty
123456	Hospital 31	City 31	TX	Harris	7	10	10	8.95	Penalty
123456	Hospital 32	City 32	TX	Wilbarger	7	NA	NA	7	No Penalty
123456	Hospital 33	City 33	TX	Wise	4	5	4	4.325	No Penalty
123456	Hospital 34	City 34	TX	Harris	9	3	NA	5.1	No Penalty

CMS ADDITIONAL PENALTIES FOR HAI'S FOLLOWING 2015

For FY 2016 a third CDC NHSN-developed healthcare associated infection measure, SURGICAL SITE INFECTIONS(SSI), will be added to the program.

CMS will also adopt two new outcome measures for the new safety domain that will add to fines assessed to net DRG: hospital-onset METHICILIN-RESISTANT STAPHYLOCOCCUS AUREAS (MRSA) BACTERIA and CLOSTRIDIUM DIFFICILE (C-DIFF) INFECTION. MRSA and C-Diff are two of the deadliest and most common HAIs in the US today!

Penalties will continue to increase year after year for participating hospitals that do not improve standard measures in regards to HAIs rates assessed by CMS for the VBP Program.

Healthcare-Associated Infections (HAI) Measures

- National Healthcare Safety Network (NHSN) Central line- associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons - Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
    - SSI following Colon Surgery
    - SSI following Abdominal Hysterectomy
- National Healthcare Safety Network (NHSN) Catheter-associated Urinary tract Infection (CAUTI) Outcome Measure (NQF #0138)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)
- National Healthcare Safety Network (NHSN) Facility=wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #2717)
- Influenza vaccination coverage among healthcare personnel (HCP) (NQF #0431)

The impact of HAIs outside of the hospital (e.g., in the community and urban environment) is also becoming a focus. In the U.S. there are approximately 26,000 non-hospital healthcare settings-ambulatory surgical centers, dialysis and long-term care facilities-where complex and invasive procedures are increasingly being performed on fragile patients. The corresponding cost for HAIs in this population ranges from $28.4 billion to $33.1 billion/year (based on 2007 CPT). (http://healthcare-executive-insight.advanceweb.com/Archives/Article-Archives/The-Cost-of-Hospital-Associated-Infections.aspx)

5 MOST COMMON INFECTIOUS ORGANISMS

C-Difficile
or deadly diarrhea (C-Diff)

Staphylococcus Aureus
that includes the drug resistant type known and MRSA

Enterobacteriaceae
includes CRE, which is known as the nightmare bacteria

Enterococcus
resistant to certain antibiotics

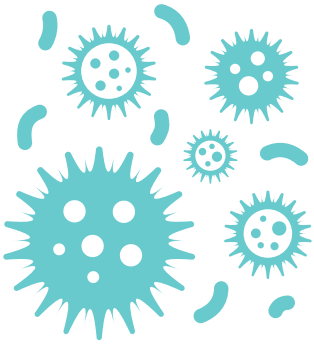
Pseudomonas
cause infections of the lungs and bloodstream

Results from JAMA Study: On an annual basis, Surgery Site Infections (SSI) and Clostridium Difficile (CDI) were estimated to be the most frequent HAIs nationwide (36.0% and 30.3%, respectively).

Both Central Line Associated Bloodstream Infections (CLABSI) and SSI cases caused by MRSA resulted in the highest attributable excess Length of Stay (LOS) (15.7 and 23.0 days, respectively).

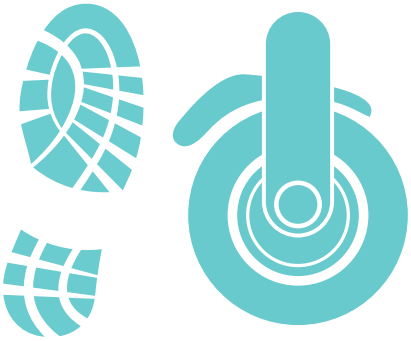
ORGANISMS TO INFECTION

Infections occur when a person is exposed to another infected person, or through one of three environmental routes; **surface, air or water.**



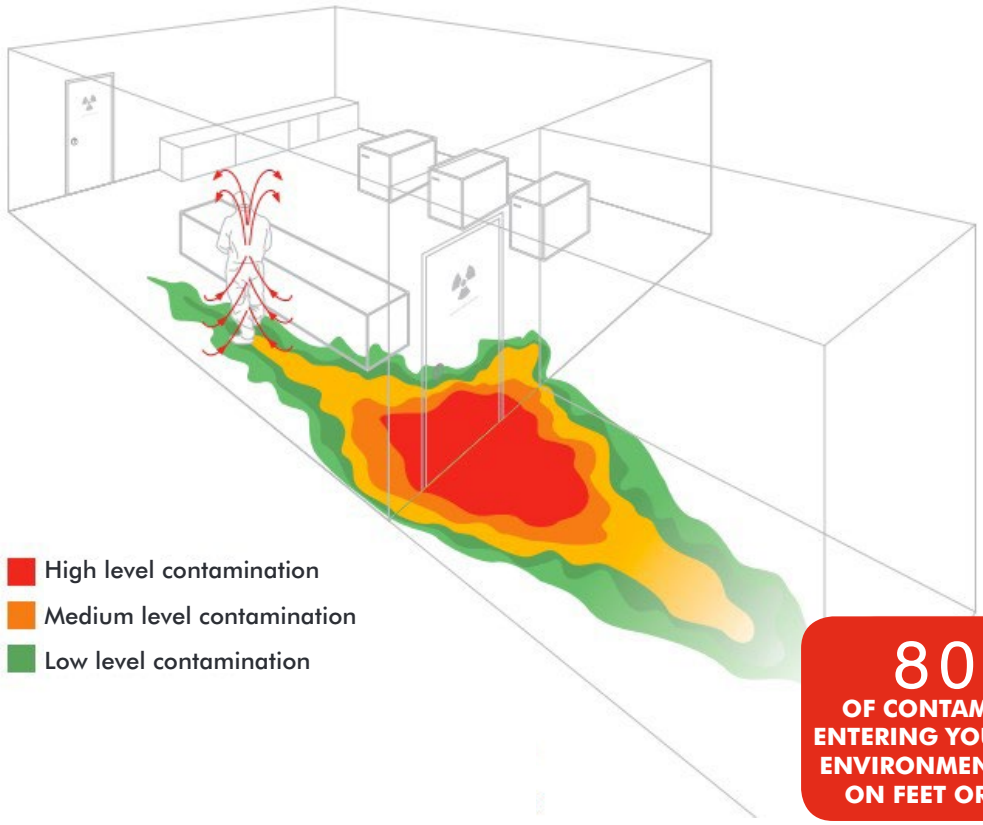
The focus of HEALTHYSOLE® PLUS is to kill microorganisms such as bacterial and viral pathogens and also is effective on fungi and bacterial spores that travel on shoe soles that lead to the spread of infection from both surface and air contamination.

Organisms carried on the bottom of shoes or booties are brought into a healthcare facility from the outside environment. There are also preexisting organisms that transfer from one area of a healthcare facility to another due to shoe sole contamination.



According to a 3M study, **80% of contamination entering a critical environment does so on feet or wheels!**

According to the CDC, "hospital floors become contaminated with microorganisms from settling airborne bacteria by contact with shoes, wheels and other objects. Even with chemical disinfectant applied to a floor being 94-99% effective in the reduction of organisms, the same surface, after testing, has been shown to have bacterial counts back to the pretreatment levels in just a few hours." (CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008)



80%
OF CONTAMINATION ENTERING YOUR CRITICAL ENVIRONMENT DOES SO ON FEET OR WHEELS

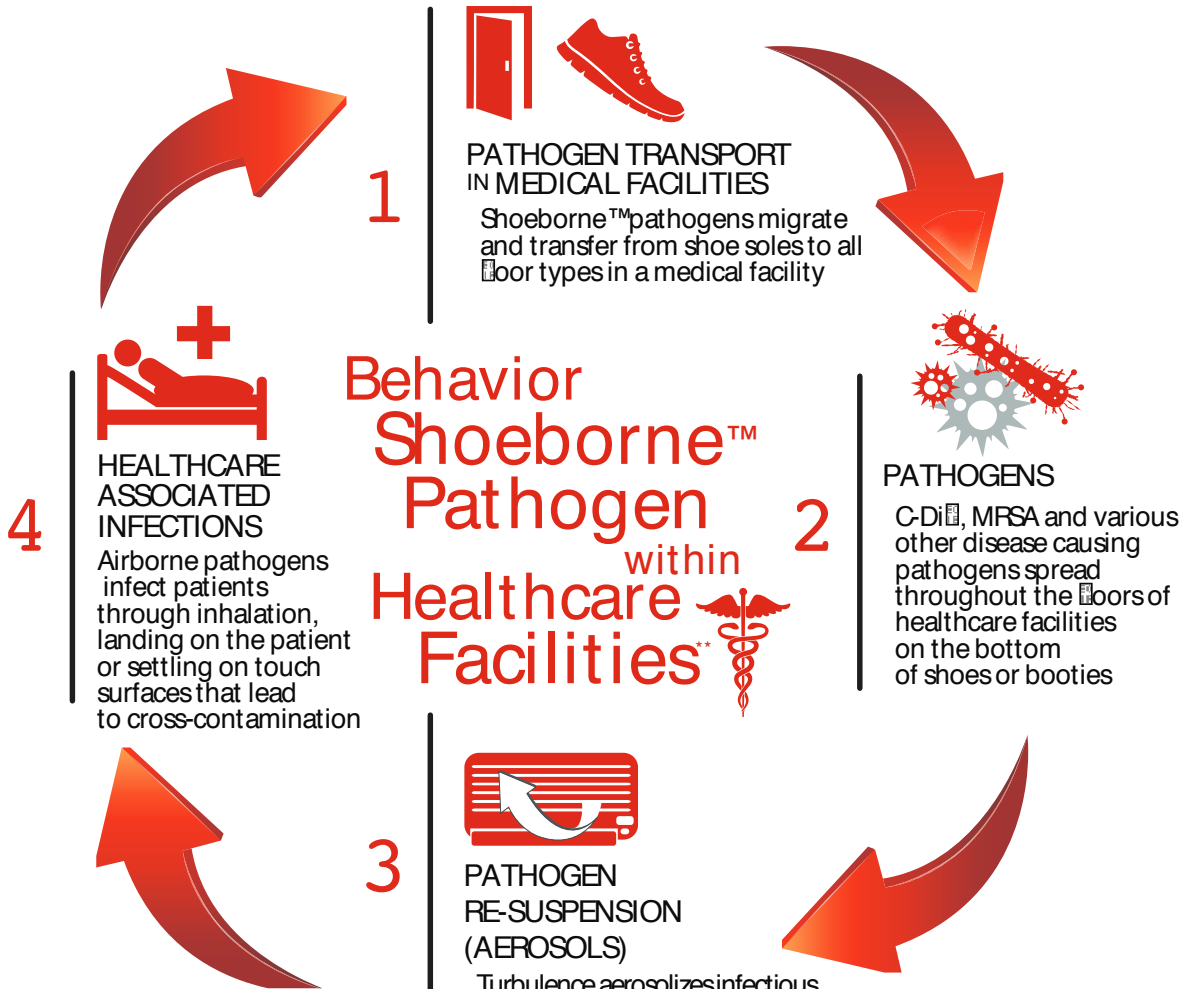
"The floor is a primary source of contaminants since dust, airborne fungal spores, and bacteria tend to gravitate to the floor, and are easily stirred up by activity." (Lidwell and Lowbury 1950)

"Airborne concentrations of pathogens are typically higher near the floor."
(Hospital Airborne Infection-Kowalski 2008)

"It is clinically proven that the bottoms of shoes carry millions of microorganisms on them at any given time, once these pathogens are carried into or within a healthcare facility, there is a 90-99% transfer rate of organisms from the bottom of shoes to the floor."
(Shoe Study-Dr Charles Gerba Sheri Maxwell 2008)

"Organisms on the floor can be re-suspended and become airborne."
(CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008)

"Once airborne an organism can travel and spread far and wide throughout the course of a day and "present an inhalation hazard or they may settle on wounds, catheters, and other equipment and result in infections."
(Hospital Airborne Infection-Kowalski 2008)



Human occupancy directly influences Shoeborne™ organisms that transfer to floors and becoming re-suspended into the air creating serious health hazards that cause HAIs. Human movement that leads to organism migration on the soles of shoes, along with air turbulence influenced by equipment movement and HVAC systems, significantly elevates pathogenic aerosol counts that cause infections.

A Study published April of 2012 titled Human Occupancy as a Source of Indoor Airborne Bacteria proves that "the integration of aerosol science with modern microbial ecology has revealed new insights into the sources and origins of airborne bacteria in indoor environments. Quantitative monitoring of indoor and outdoor air revealed that human occupancy is a dominant factor that contributes to the concentration of indoor airborne bacterial genomes. An important public health consequence of these results is that, through direct inhalation of re-suspended or shed organisms, there is potential for current or previous occupants of a room to contribute substantially to inhalation exposure to bioaerosols."

HEALTHYSOLE PLUS® SPECIFICS

Exposure tests have proven HEALTHYSOLE® PLUS has up to a 99.99% UVC germicidal light exposure rate to the soles of shoes (Exposure rates will vary depending on shoe style, material, dirt and other debris). Kill rate test results (Antimicrobial Testing Lab).

Active disinfection technology and No-Touch Hands Free
Our exclusive active disinfection technology, allows occupants of an environment to consistently (24/7) lower the microbial burden throughout the day with no additional workload. No-Touch and Hands Free technology systems are a method of disinfection that does not incur additional labor cost and is less likely to cause cross contamination than alternative disinfectants.

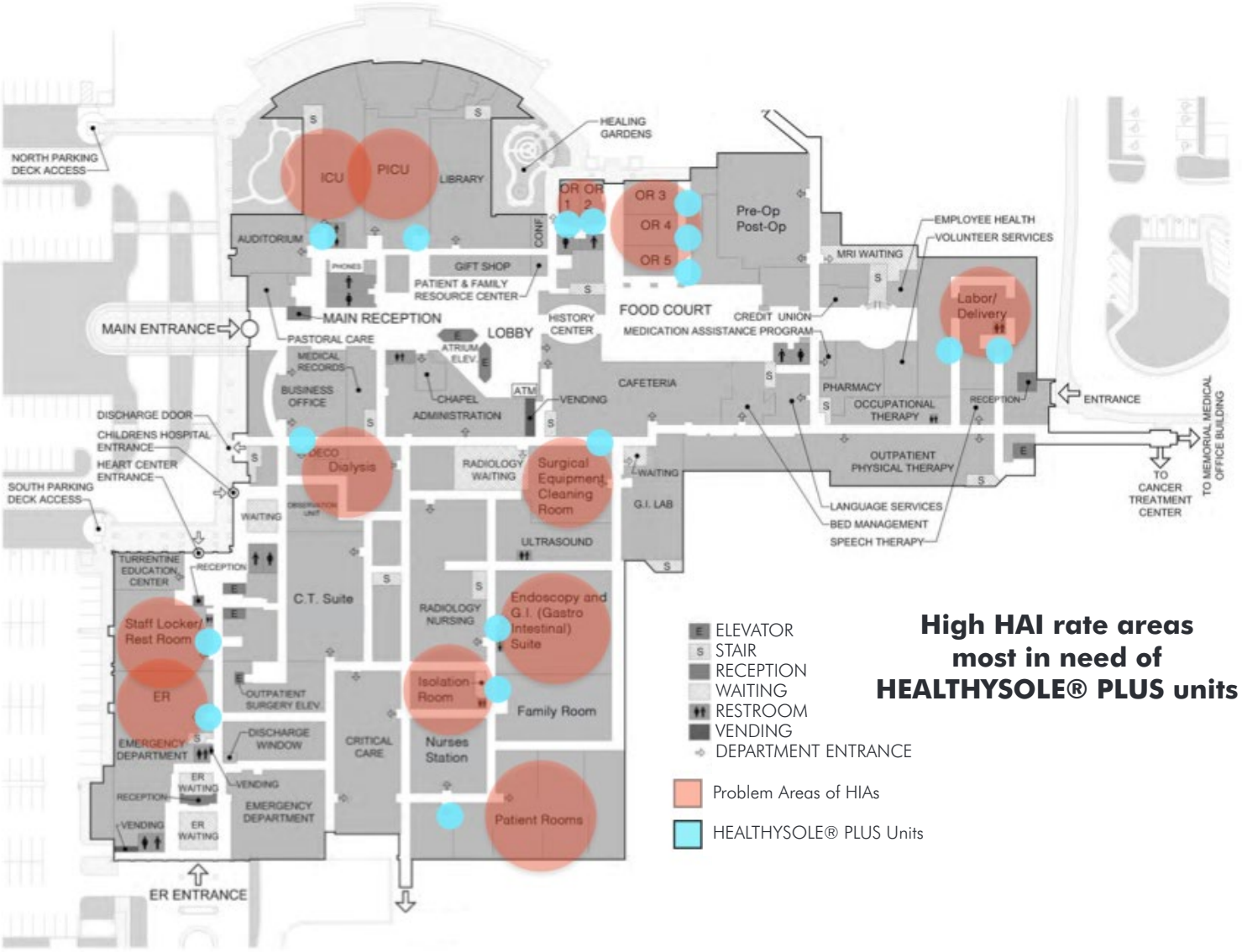
Features and Benefits:

- HealthySole Plus™ UVC lamps utilize our Patented Plasma Stable and Plastic Encapsulation Technology™, making them shatter resistant, self-cleaning and ETL listed
- Kills up to 99% of UVC exposed germs and pathogens in one step
- Disinfects without and harmful gels or chemicals
- 5-8 second (adjustable) disinfection time
- Hands free usage
- 304 hospital grade stainless steel construction
- LCD color computer screen read out
- Countdown disinfection timer with compliance usage counter
- Lamp life gauge
- UL listed components
- HEALTHYSOLE® PLUS is patented and patent pending (US and worldwide)
- WIFI capable reporting
- 1 year lamp life
- Exclusive Smart Ballast Technology™
- Adjustable control viewing angle screen
- UV View™ top plate technology, elevates, reflects and refracts UV rays for best possible exposure and kill rates

UVC Germicidal Light (energy, time, distance)
Kills organism at DNA level – Primarily by inactivating the DNA (nucleic acids) in microorganisms. By separating the molecular bond in the DNA, the microorganism is rendered incapable of replicating, multiplying, and can no longer cause disease (ICT Understanding the Essentials of Germicidal UV Light 2015). Our Exclusive Patented Plastic Encapsulation Technology™ UVC lamps used inside the HealthySole® Plus are broad spectrum UVC light, shatter proof and self-cleaning. UVC Germicidal light is not visible to the human eye. The visible blue light is just an indication that the UVC Germicidal light is on.

Protocol recommendations:
Placing units in locations within the hospital most vulnerable to contract an HAI is imperative! (ICU/PICU, ORs, Surgical Equipment Cleaning Rooms, ER, Labor and Delivery, Dialysis, GI Suite, Mutli-Bed patient rooms)

The most important step to successful staff compliance in a Hospital is to provide a sufficient amount of HEALTHYSOLE® PLUS Units throughout the entire building, and making them visible and convenient to access. Recommended protocol is to use HEALTHYSOLE® PLUS as often as possible, most importantly when traveling into the most vulnerable areas within any healthcare facility. Keeping strict HEALTHYSOLE® PLUS usage protocols, and compliance records, is directly related to the effectiveness of lowering the overall microbial burden that leads to high rates of HAIs within a hospital. It is recommended to closely monitor medical staff that is non-compliant of following protocols specified by Patient Care Staff and Infection Control Depts.



STUDIES USED: ORGANISMS ON SHOES, TRANSFER TO FLOORS, REAEROSOLIZATION

Health Care-Associated Infections, A meta-analysis of Cost and Financial Impact on the US Health Care System JAMA 2013
"We believe that better evaluation of the costs of HAIs could help providers and payers justify investing in this area. In addition, for policymakers, sound estimates of the potential system wide cost savings could mobilize the resources needed to catalyze progress in the cause of improving care and restraining rising health care costs. The purpose of this study was to generate estimates of the costs associated with the most significant and targetable HAIs. To do this, we compiled examinations of the costs of HAIs into robust, precise, broadly applicable estimates of each HAI and also estimated the aggregate annual costs of infections in adults acquired in the inpatient setting.
In summary, our study provides updated, robust, and applicable estimates for resources attributable to the major HAIs that continue to plague modern health care systems and create considerable harm to patients. While widespread quality improvement initiatives have resulted in a decrease in HAIs incidence, much more remains to be done. These estimates may be used for business case development to support investment in HAI reduction efforts. Investment in leadership, practices, and technologies will continue to drive patient safety and allow hospitals to realize cost savings attributed to prevention of HAIs. Ongoing payment reforms such as value-based purchasing coupled with incentives to reduce the frequency of these events should drive local, state, and federal efforts and bring about substantial reduction in patient harm."

Dr Waladyslaw J. Kowalski, Hospital Airborne Infection handbook
Floor is a primary source of contaminants…
Organisms present hazards…

Generation and Behavior of Airborne Particles (aerosols) CDC NIOSH
Particles Removal from Surfaces by Air Flow and Movement
Aerosol Transport Based on Air Flow
Particle Transport from Sources and Resuspension
(Use pg 39 "Overall Scenario Diagram)

SHOE STUDY Dr Charles Gerba Sheri Maxwell 2008
CFUs of Bacteria
Shoe transfer rates

CDC Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008
Floors become recontaminated a few hours after chemical cleaners…

(Plos One) Human occupancy as a Source of Indoor Airborne Bacteria, 2012
Much higher airborne bacteria when human and their normal movement are present

ICT Understanding the Essentials of Germicidal UV Light 2015 Kelly Pyrek
UVC germicidal information

Keizer Health News list of hospitals score sheet
Table 2-5

Net change in base operating DRG payment amount (Medicare)