

SOFTA-MAN®

CLINICAL PAPER SUMMARY

	Study	Summary
COST	T. Koburger (2009), Gutachterliche Stellungnahme / Experts Report - Softa-Man® independant tests verifying EN 12791	The financial and environmental cost to achieve surgical disinfection status in terms of both resources used, and time taken, is important to note. The efficacy of Softa-Man® as a hand antiseptic was evaluated by the testing laboratory Hygiene Nord GmbH, Germany. The following tests were conducted on Softa-Man® against the European Standard EN 12791. Softa-Man® achieved this standard within 90 seconds.
	T. Koburger (2009), Gutachterliche Stellungnahme / Experts Report - Softa-Man® independant tests verifying EN 1500	Softa-Man® achieves European Standard EN 1500 within 15 seconds (both liquid and gel form). The efficacy of Softa-Man® as a hand antiseptic was evaluated by the testing laboratory Hygiene Nord GmbH, Germany. The following tests were conducted on Softa-Man® against the European Standard EN 1500.
	M.P. Tivolacci et. al. (2006), Surgical hand rubbing compared with surgical hand scrubbing: comparison of efficacy and costs	The aim of this study was to compare the efficacy of surgical hand rubbing (SHR) with the efficacy of surgical hand scrubbing (SHS). The costs of SHR and SHS were estimated based on standard hospitals costs. The literature showed that SHR had immediate efficacy that was similar to that of SHS, but SHR had a more lasting effect. SHR reduced costs by 67%. In summary, SHR is a cost-effective alternative to SHS.
	Hand Hygiene presentation referenced directly from Center for Disease Control and Prevention, "Edition 2 Hospital Epidemiology and Infection Control"	Refer to page 14 which highlights a 67% time saving for one nurse over an 8 hour nurse shift comparing between soap/water (7 x 60 sec wash episodes = 56 mins total) and Alcohol based hand rub (7 x 20 sec wash episodes = 18 mins total).
	"MedInsight (2014), Clinical and economic report on the use of alcoholic solutions for surgical hands preparation in Brazilian hospital settings"	This study pointed out several advantages in the use of alcoholic solutions in hand antiseptis in pre-surgical preparation, amongst them are the significant reduction in microbial count, in addition to higher compliance due to ease of use, lower time spent in preparation (SHR vs. SHS >3 mins) and lower irritant effect on hands/skin. Of particular note were clear resource savings indicated when using in particular Soft-lind® Pure (Softa-Man®), when compared to existing SHS technique, up to double the recommended dose by the manufacturer. There were secondary resource savings identified through water savings since alcoholic solutions do not require the use of this antiseptis procedure. Note following comment: "...the reduction in cost between the technologies reaches 47%, not counting the savings in water resource itself".
RESIDUAL GROWTH AND BACTERIAL EFFICACY	"C. Ostermeyer et al. (2005), Efficacy of two distinct ethanol-based hand rubs for surgical hand disinfection – a controlled trial according to EN 12791"	"Aim of the study was to determine the efficacy of two distinct ethanol-based hand rubs for surgical hand disinfection in a controlled cross-over trial according to EN 12791. 20 subjects were included. Avagard, based on 61% ethanol and 1% CHX). Findings: The ABHR with 80% alcohol was found to be effective for surgical hand disinfection, but Avagard (61% alcohol) was not. The addition of 1% Chlorhexidine gluconate to 61% ethanol (w/w) did not outweigh an ethanol concentration of 80% (w/w). Additional comments in reference to this paper: 1. Softa-Man® has 79.5% alcohol, a mixture of ethanol (secondary chain alcohol) and N-Propanol (primary chain alcohol, providing greater skin flora access). 2. Common misunderstanding = The addition of 1% Chlorhexidine gluconate to 61% ethanol did not provide a substantial improvement of the bactericidal efficacy after 3 hours."
	Who Guidelines on Hand Hygiene in Healthcare (2009)	"11.13 Relative efficacy of plain soap, antiseptic soaps and detergents, and alcohols. This shows the different tests for surgical hand antiseptis. Many studies have pointed out with testing on alcohol usage at the immediate effect, and after 1-3 hours effect, ABHR have a better result compared to the others. Comparison of five surgical hand antiseptis products—two alcohol-based hand rubs and three hand washes (active ingredient triclosan, CHG or povidone-iodine) by EN 12791, in an in vivo laboratory test, showed that preparations containing povidone-iodine and triclosan failed the test. Importantly, when testing the same concentration, the results clearly demonstrated that the efficacy range was: N-propanol is the most active, followed by ethanol, then isopropanol."
	Who Guidelines on Hand Hygiene in Healthcare (2009)	"13.6 Surgical hand scrub (SHS with medical soap) or Surgical hand rub (SHR) with alcohol-based formulations? Medical soaps are still being used around the world but higher alcohol concentration based hand rubs are considered a better option in reducing bacterial activity for pre-surgical hand preparation. Alcohol is rapid action, time-saving (Softa-Man® only requires 90 sec), less side-effects and no risk of recontamination by rinsing hands with water."

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"Gunter Kampf (2008) What is left to justify the use of Chlorhexidine in hand hygiene?"	"The CDC guideline for hand hygiene describes Chlorhexidine gluconate as an agent with "substantial residual activity". But not all studies support this claim. A review of eight studies which are cited to support "substantial residual activity" show that none of them were performed with validated neutralization. In fact, seven of those eight did not demonstrate any residual activity for Chlorhexidine gluconate. The benefits of using an active agent must outweigh any risks in order to justify its use. If no real benefits are left for Chlorhexidine gluconate in hand hygiene, all the risks count even more such as skin irritation, allergic reactions including anaphylactic shock, and acquired bacterial resistance. Unless there is new and valid evidence to clearly support a benefit of using Chlorhexidine gluconate in hand hygiene, healthcare workers should prefer formulations without this agent."
"G. Kampf / A. Kramer (2004), Epidemiologic Background of Hand Hygiene and Evaluation of the Most Important Agents for Scrubs and Rubs "	This clinical paper demonstrates an important point on each of "ethanol" and "N-Propanol" ingredients (both found in Softa-Man®). It notes that Ethanol is best when it comes to virucidal efficacy and n-Propanol is best when it comes to bactericidal efficacy. With Softa-Man® having a combination of both Ethanol (virucidal) and N-Propanol (bactericidal), it is formulated to be most efficient in hand disinfection hand rub options.
"G. Kampf and C. Ostermeyer (2013) Efficacy of hand rubs with a low alcohol concentration listed as effective by a national hospital hygiene society in Europe"	This clinical paper demonstrates that a formulation (Anios Gel 85 NPC) with a formulation of 70% Ethanol which "claimed to meet EN 1500 standard", actually failed to do so in their investigative lab test. This validates that Ethanol needs at least 77% to achieve optimum working concentration for bactericidal efficacy. Conclusion, if there are alcohol based hand rubs that are below 77% v/v alcohol concentration, and it is claimed that EN 1500 standard is met, then there are serious doubts about the accuracy of testing results that were used to make this claim. Please note, Softa-Man® has 79.5% v/v twin Alcohol concentration, and meets EN 12791 within 90 seconds, and EN 1500 within 15 seconds.
"MedInsight (2014), Clinical and economic report on the use of alcoholic solutions for surgical hands preparation in Brazilian hospital settings"	This study pointed out several advantages in the use of ABHR vs. PVP, in hand antiseptis in pre-surgical preparation. Amongst them are the significant reduction in microbial count, in addition to higher compliance due to ease of use, lower time spent in preparation (SHR vs. SHS >3 mins) and lower irritant effect on hands/skin. Of particular note were clear resource savings indicated when using in particular Soft-lind® Pure (Softa-Man®), when compared to existing SHS technique, up to double the recommended dose by the manufacturer. There were secondary resource savings identified through water savings since alcoholic solutions do not require the use of this antiseptis procedure. Note following comment: "...the reduction in cost between the technologies reaches 47%, not counting the savings in water resource itself".
Gunter Kampf (2013) Efficacy of surgical hand scrub products based on Chlorhexidine is largely overestimated without neutralising agents in sampling fluid	"Surgical hand antiseptics often contain Chlorhexidine gluconate (CHG). There are doubts that the full effect measured for these products might only be achieved after sampling because of a lack of valid neutralizing agents (NAs) in the sampling fluid. Efficacy studies carried out without NAs in the sampling fluid for products with CHG should be critically assessed. Please note: Softa-Man® efficacy studies are all based on using Neutralising Agents, which are accurately demonstrating efficacy."
"Gunter Kampf (2008) What is left to justify the use of Chlorhexidine in hand hygiene?"	"The CDC guideline for hand hygiene describes Chlorhexidine gluconate as an agent with "substantial residual activity". But not all studies support this claim. A review of eight studies which are cited to support "substantial residual activity" show that none of them were performed with validated neutralization. In fact, seven of those eight did not demonstrate any residual activity for Chlorhexidine gluconate. The benefits of using an active agent must outweigh any risks in order to justify its use. If no real benefits are left for Chlorhexidine gluconate in hand hygiene, all the risks count even more such as skin irritation, allergic reactions including anaphylactic shock, and acquired bacterial resistance. Unless there is new and valid evidence to clearly support a benefit of using Chlorhexidine gluconate in hand hygiene, healthcare workers should prefer formulations without this agent."
Who Guidelines on Hand Hygiene in Healthcare (2009)	WHO Guideline states in 13.4.2 "Use of brushes - Almost all studies discourage the use of brushes. Early in the 1980s, Mitchell and colleagues suggested a brushless surgical hand scrub. Scrubbing with a disposable sponge or combination sponge-brush has been shown to reduce bacterial counts on the hands as effectively as scrubbing with a brush. Recently, even a randomized, controlled clinical trial failed to demonstrate an additional antimicrobial effect by using a brush. It is conceivable that a brush may be beneficial on visibly dirty hands before entering the operating room. Members of the surgical team who have contaminated their hands before entering the hospital may wish to use a sponge or brush to render their hands visibly clean before entering the operating room area." Studies have proven that use of brushes do not give an additional antimicrobial effect.

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Hand Hygiene presentation referenced directly from Center for Disease Control and Prevention, "Edition 2 Hospital Epidemiology and Infection Control"	Refer to page 11, and 12 which demonstrate clearly that ABHR outperforms CHX and Plain soap/water at up to 3 hours of time.
Who Guidelines on Hand Hygiene in Healthcare (2009)	"WHO Guideline states in 13.4. Surgical hand antiseptics using medicated soap, 'the most active agents (in order of decreasing activity) are Chlorhexidine gluconate, iodophors (PVP), triclosan, and plain soap. Triclosan-containing products have also been tested for surgical hand antiseptics, but triclosan is mainly bacteriostatic, inactive against P. aeruginosa, and has been associated with water pollution in lakes. Rapid regrowth occurs after application of povidone-iodine, but not after use of Chlorhexidine. Note: Povidone-iodine (PVP) remains one of the widely-used products for surgical hand antiseptics, induces more allergic reactions, and does not show similar residual effects."
"P. Goroncy-Bermes (2001) Hand disinfection according to the European Standard EN 1500 (hygienic hand rub): a study with Gram-negative and Gram-positive test organisms"	It was the aim of this study to compare the efficacy of alcohol-based hand disinfectants according to European Standard EN 1500. The results of the in-vitro tests show that the propanol-containing preparation (product B) was significantly more effective against all test organisms than the ethanol-based product A. Please note: Softa-Man® has N-Propanol as one of the two active ingredients.
J. Parienti Et. Al. (2002) Hand-Rubbing with a Aqueous Alcoholic solution vs. traditional Surgical Hand-Scrubbing and 30-day Surgical Site Infection rates, A randomised Equivalence Study	This clinical paper, cited in WHO guidelines, highlights that there is no difference in SSI rates when comparing scrubbing and rubbing. Method: Surgical services used 2 x hand-cleansing methods alternately every other month: a hand-rubbing protocol with 75% aqueous alcoholic solution containing Propanol-1, Propanol-2, and metcetroneum etilsulfate; and a hand-scrubbing protocol with antiseptic preparation containing 4% povidone iodine or 4% Chlorhexidine Gluconate. Conclusions: Hand-rubbing with aqueous alcoholic solution, preceded by a 1-minute non-antiseptic hand wash before each surgeon's first procedure of the day and before any other procedure if the hands were soiled, was as effective as traditional hand-scrubbing with antiseptic soap in preventing surgical site infections. The hand-rubbing protocol was better tolerated by the surgical teams and improved compliance with hygiene guidelines. Hand rubbing with liquid aqueous alcoholic solution can thus be safely used as an alternative to traditional surgical hand-scrubbing.
Who Guidelines on Hand Hygiene in Healthcare (2009), 13.4.4 Side-effects of Surgical Hand Scrub	WHO Guideline 13.4.4 Side-effects of surgical hand scrub states: "Skin irritation and dermatitis are more frequently observed after surgical hand scrub with CHX than after use of surgical hand antiseptics with an ABHR. Overall, skin dermatitis is more frequently associated with hand antiseptics using a medicated soap than with an ABHR'. Softa-Man® (ABHR) is unique in the fact that there are 3 emollients contained (Bisabolol; anti-inflammatory and skin reparation properties, Allantoin; anti-irritant and aids the healing of damaged skin, ProVitamen B5; stimulates cellular proliferation), each helping to assist skin care, ultimately increasing tolerability and compliance to hand hygiene; compliance with hand hygiene is a key factor for reducing nosocomial infection rates. Factors influencing compliance include dermal tolerance and skin care properties (Pittet D. Improving adherence to hand hygiene practice: a multidisciplinary approach. Emerging Infectious Diseases 2001; 7(2): 234-240).
D. Voss (2005), Independent laboratory test and results on Tolerability of Softa-Man® over an 8 week period.	Assessment of test results: A total of 20 test persons tolerated the mentioned products very well over an eight-week test under dermatological and clinical conditions. There were no undesired or pathological skin changes in the hands area. Patch testing in accordance with international guidelines before and after the 8 week application period established that none of the 20 adult test persons was sensitised by the product during the application test. None of the test persons showed any skin changes in the patch tests after 24, 48 and 72 hours. It can, therefore, be concluded that use of the product in practise does not lead to undesired skin reactions due to skin irritant or sensitising characteristics.
Technical paper on Bisabolol, Emollient Ingredient in Softa-Man®	Taken from the Technical data sheet: Bisabolol is the main active ingredients of the medical plant chamomile (Matricaria chamomilla) which has been used in traditional medicine for hundreds of years. Bisabolol protects and heals the skin from the effects of daily stress. It is a naturally occurring active ingredient that accelerates the healing process of skin. Bisabolol can be used with confidence in personal care formulations, especially in products for sensitive skin, baby care, after-shave, and after-sun applications. Its added antiinflammatory properties make it a truly versatile active ingredient for skin care products.

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"C. Ostermeyer et. al. (Journal of Hospital Infection 78 (2011)), World Health Organization-recommended hand-rub formulations do not meet European efficacy requirements for surgical hand disinfection in five minutes"	Both WHO-recommended hand-rub formulations failed to meet the EN 12791 efficacy requirements for surgical hand disinfection within 5 min. Please note, Softa-Man® has met the EN 12791 standard. Importantly, It is the unique combination of Ethanol and n-Propanol which has a synergetic effect = boosting efficacy.
ACORN Revised standard 2016, Surgical scrub guidelines	Surgical Hand Scrub (3.1) to be 5 minutes in duration, Subsequent hand scrubs to be 3 minutes in duration. *As a comparison, please note Alcohol based hand rub "Softa-Man®" takes 90 seconds to reach EN 12791 surgical disinfection standard. Alcohol based hand rubs 3.12 "... If hands are visibly soiled and dirty, they must be washed with a non-antimicrobial soap before surgical hand preparation..." however, it also states in the NOTES: "The WHO guidelines state that hand washing prior to application of an ABHR is <u>only necessary when hands are visibly dirty.</u> "
Pittet D. Boyce J. Hand hygiene and patient care: pursuing the Semmelweis legacy. The Lancet Infectious Diseases 2001 April: 9- 20	Graph presented in the Lancet Infectious Diseases 2001 journal shows ABHR activity versus other HH Antiseptic Agents. Conclusions: This clearly demonstrates that Alcohol based hand rubs are most effective category when compared to other more traditional options (PVP, Chlorhexidine etc.). ABHR Speed of Action is fast, and shows highest efficacy against bacteria classes, highlighting that the most optimum range of Alcohol concentration is between: 60 - 90%. Please note: Softa-Man® has 79.5% v/v alcohol content.