Wet Time for a Foam Hand Sanitizer with 70% ethyl alcohol
Protocol Number MED-2022-DIV60-002

18-NOV-2022
Version 4.0

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INVESTIGATOR ACKNOWLEDGMENT SIGNATURE

- I agree to conduct the study in accordance with the relevant, current protocol and will make any changes in the protocol necessary to protect the safety, rights, or welfare of participants.
- I agree to personally conduct and supervise the investigation as described within.
- I agree to inform all participants that the device is being used for the purposes of an investigational study.
- I will ensure that requirements relating to obtaining informed consent in the guidelines for Good Clinical Practices (GCP), and 21 Code of Federal Regulations (CFR) Part 50 and Institutional Review Board (IRB) review and approval in 21 CFR Part 56 are met.
- I agree to report to the IRB and/or Ethics Committee, according to the protocol, adverse experiences that occur during the course of the investigation in accordance with guidelines for GCP and 21 CFR 812.
- I have read and understood the information in the protocol, including the potential risks.
- I agree to maintain adequate and accurate records in accordance with guidelines for GCP and 21 CFR 812.140 and to make those records available for inspection.
- I will ensure that an IRB compliant with the requirements of guidelines for GCP and 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human participants or others.
- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in the guidelines for GCP and the CFR.

I have received and reviewed this investigational plan. I will conduct the study as described.

Principal Investigator (Print name):
Principal Investigator (Signature):
Date (DD-MMM-YYYY):

DOCUMENT HISTORY

VERSION	DATE	DESCRIPTION
Version 1.0	29-SEP-2022	Initial Release
Version 2.0	09-NOV-2022	Revision to include the waiving of informed consent for this study.
Version 3.0	11-NOV-2022	Update to Section 1.1 Schedule of Activities.
Version 4.0	18-NOV-2022	Update to obtain participant informed consent per request from IRB review.

1. PROTOCOL SUMMARY

1.1. Synopsis

Title:	Wet Time for a Foam Hand Sanitizer with 70% ethyl alcohol
Study Description:	Hand sanitizers are a standard of hygiene requirements. They must be effective at reducing germ count on the hands while ideally providing emollients to moisturize the skin after use. Spectrum™ Advanced Hand Sanitizer Foam (70%) (hereby referred to as Spectrum Advanced Foam) kills over 99.99% of germs within 15 seconds while boasting double digit increases in hand moisture after two weeks of use. In 2002 and 2009 the Center for Disease Control and Prevention (CDC) and World Health Organization (WHO) published guidance that hands should remain wet for at least 15 seconds while being rubbed together after application of an alcohol-based hand rub, though the recommendations do not specify the volume of product to be apply. [1, 2] This study will evaluate the "wet time" of Spectrum Advanced Foam, which will be defined as the length of time in which the sanitizer foam stays wet on the hands while the participant rubs their hands with the foam sanitizer. The participant will first be asked to wash and dry their hands. Participants will review the appropriate hand sanitizer application steps, as detailed by the WHO guidance. Then, a 1.0 mL or 1.4 mL* aliquot of Spectrum Advanced Foam will be dispensed from an automated dispenser[3] to the participant's hands. [1] The participant will be asked to rub their hands together following the WHO method for hand sanitizer application until they declare the product has dried sufficiently for the donning of medical gloves. Study personnel will measure the wet time of Spectrum Advanced foam using a stopwatch.
Phase:	Post-market.

* *The study is to include an interim analysis of the data after 46 participants have completed the study on the medium dispenser setting (1.0 mL). If the results demonstrate a satisfactory 15 second wet time using the medium setting, the study will end and no further recruitment will take place. If at this point, the results demonstrate that the amount of hand sanitizer dispensed under the medium setting (1.0 mL) does not sufficiently stay wet for at least 15 seconds, a second data collection will take place with another 46 participants who will undergo the study using the high dispenser setting (1.4 mL).*

Primary Objective:	To determine the duration of time during which a 1.0 mL or 1.4 mL* aliquot of Spectrum Advanced Hand Sanitizer Foam remains wet under conventional use conditions.
Primary Endpoint:	The time during which 1.0 mL or 1.4 mL* of Spectrum Advanced Hand Sanitizer Foam remains wet under conventional use conditions.
Study Population:	Number of participants, N = 46. Inclusion criteria Individuals who meet the following criteria will participate in this study: ➢ Individual ≥ 18 years of age. Exclusion criteria Individuals who meet any of the following criteria will not be allowed to participate in this study: ➢ Individual has a self reported skin condition that might result in irritation from the hand sanitizer. ➢ Individual has a known allergy to the ingredients in the test product.
Power Analysis Methods:	The sample size of 46 was estimated for 95% confidence interval based on a standard deviation of 5 seconds and target distance from mean to limits of 1.5 seconds (PASS-Confidence Intervals for One Mean). Results from a previous study conducted by Ecolab (summarized in the Appendix) was utilized as a starting point for sample size estimation for the current protocol, using PASS 2021 Power Analysis and Sample Size Software (2021). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.
Description of Sites/Facilities Enrolling Participants:	The study will be conducted at private rooms within the Northfield location of Medline Industries, LP. Address: Three Lakes Drive

* *The study is to include an interim analysis of the data after 46 participants have completed the study on the medium dispenser setting (1.0 mL). If the results demonstrate a satisfactory 15 second wet time using the medium setting, the study will end and no further recruitment will take place. If at this point, the results demonstrate that the amount of hand sanitizer dispensed under the medium setting (1.0 mL) does not sufficiently stay wet for at least 15 seconds, a second data collection will take place with another 46 participants who will undergo the study using the high dispenser setting (1.4 mL).*

	Northfield, IL, 60093
Description of Study Design:	Informed consent will be obtained from participants in-person or remotely. Participants will then undergo in-person or remote screening, after which participants who meet inclusion criteria will be enrolled in this prospective study. The participant will first be asked to wash and dry their hands, and wait an additional two minutes after drying their hands. Participants will review the steps for applying hand sanitizer, adapted from the WHO guidance. [4] The participant will then be asked to apply an aliquot of Spectrum Advanced Foam, dispensed from an automatic dispenser (X10 Dispenser, Medline Industries, LP), to their hands. The participant will be instructed to rub their hands together with the sanitizer until their hands are dry. Study staff will measure and record the wet time of Spectrum Advanced Foam.
Participant Duration:	Approximately 30 minutes.

1.1. Schedule of Activities (SOA)

Required Study Activities and Assessments	Visit 1
Verification of Eligibility	X
Participant Washes and Dries Hands	X
Participant Waits 2 Minutes	X
Participant Reviews Hand Sanitizer Application Steps (Adapted from WHO)	X
1.0 mL or 1.4 mL * Aliquot of Spectrum Advanced Foam Applied to Palm	X
Study Staff Starts Timer	X
Participant Rubs Hands and Fingers Until Participant Declares to Study Staff that Hands and Fingers are Dry for Donning of Gloves	X
Study Staff Stops Timer	X
Wet Time Measurement	X
Participant Dismissal	X
Adverse Events	X

* *The study is to include an interim analysis of the data after 46 participants have completed the study on the medium dispenser setting (1.0 mL). If the results demonstrate a satisfactory 15 second wet time using the medium setting, the study will end and no further recruitment will take place. If at this point, the results demonstrate that the amount of hand sanitizer dispensed under the medium setting (1.0 mL) does not sufficiently stay wet for at least 15 seconds, a*

second data collection will take place with another 46 participants who will undergo the study using the high dispenser setting (1.4 mL).

2. INTRODUCTION

2.1. Background & Rationale

Hand sanitizers are a standard of hygiene requirements. They must be effective at reducing germ count on the hands while ideally providing emollients to moisturize the skin after use. In 2002 and 2009 the CDC and WHO published guidances that hands should remain wet for at least 15 seconds while being rubbed together after application of an alcohol-based hand rub, though the recommendations do not specify the volume of product to be apply. [1, 2]
The CDC specifically recommends applying alcohol-based hand sanitizers by applying the manufacturer-recommended amount of sanitizer directly to the palm of one hand and then rubbing the hands together. The sanitizer must entirely cover the surfaces of both hands and all fingers while rubbing the hands together until the product has dried.[1]

The goal of this study is to evaluate the "wet time" of Spectrum Advanced Foam, which will be defined in this study as the length of time in which the foam sanitizer stays wet on the hands while the participant rubs their hands with the foam sanitizer.

2.2. Study Products

2.2.1. Medline Spectrum™ Advanced Hand Sanitizer Foam (70%)

Spectrum Advanced Hand Sanitizer Foam kills over 99.99% of germs within 15 seconds. The formula includes added moisturizers to help reduce dry skin. The SKU number for Medline Spectrum Advanced Hand Sanitizer Foam is HH70F1000H.

2.3. Risk/Benefit Profile

2.3.1. Potential Study Risks

This study entails minimal risk to the participants. Spectrum Advanced Foam is commercially available and widely used in clinical settings. There is the possibility of minor skin irritation with the application of Spectrum Advanced Foam, however the magnitude of this should be no greater than what occurs through the normal use of the hand sanitizers. In addition, the study is designed such that the test product will be applied on the non-compromised skin of participants with no self-reported known skin conditions, which should impose less risk for study participants.

2.3.2. Potential Study Benefits

Direct benefit to the study participants is unlikely. However, the results from this study will provide the wet time for Spectrum Advanced Foam, which may better inform product efficacy and infection prevention for individuals applying Spectrum Advanced Foam to the hands.

2.3.3. Assessment of Potential Risk/Benefit Profile

As this study entails minimal risk to the study participants and the results may further inform the wet time of Spectrum Advanced Foam, the risk/benefit profile of this study is acceptable.

3. OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINT(S)
Primary		
1. To determine the duration of time during which a 1.0 mL or 1.4 mL* aliquot of Spectrum Advanced Hand Sanitizer Foam remains wet under conventional use conditions.	1. The time during which 1.0 mL or 1.4 mL* of Spectrum Advanced Hand Sanitizer Foam remains wet under conventional use conditions.	1. To evaluate if the wet time of the Spectrum Advanced Hand Sanitizer Foam meets CDC guidance of a minimum 15 seconds wet time.
* *The study is to include an interim analysis of the data after 46 participants have completed the study on the medium dispenser setting (1.0 mL). If at this point, the results demonstrate that the amount of hand sanitizer dispensed under the medium setting (1.0 mL) does not sufficiently stay wet for at least 15 seconds, a second data collection whereby another 46 participants will undergo the study using the high dispenser setting (1.4 mL) will take place. If the results demonstrate a satisfactory 15 second wet time using the medium setting (1.0 mL) with 46 participants, the study will end and no further recruitment will take place.*		

4. STUDY DESIGN

4.1. Overall Design

This will be a prospective study that will be conducted over the course of one study visit. This study will measure the "wet time" of Spectrum Advanced Foam to evaluate if Spectrum Advanced Foam meets the CDC and WHO guidance that hands should remain wet for at least 15 seconds while being rubbed together after application of an alcohol-based hand rub. "Wet time" will be defined as the length of time in which the sanitizer foam stays wet on the hands while the participant rubs their hands with the foam sanitizer.

Informed consent will be obtained either in-person or remotely. Following in-person or remote remote participant screening, the participant will be asked to wash and dry their hands and wait an additional two minutes. The participants will review the steps for hand sanitizer application, adapted from a WHO poster on application of handrubs. The participants will be instructed to apply a 1.0 mL or 1.4 mL* aliquot of Spectrum Advanced Foam to their hands. The Spectrum Advanced foam will be dispensed from an automated dispenser. The participant will then be asked to rub their hands together with the foam sanitizer until their hands are dry, following the WHO recommended method for hand sanitizer application. Study staff will use a stopwatch to measure the wet time: the application of the product to the palm of the participant will indicate the "start time", and the participant stating that their hands have dried will indicate the "stop time".

After the participant has indicated that their hands have dried sufficiently for the donning of gloves, study staff will record the wet time of Spectrum Advanced Foam. The participant will then be dismissed from the study.

4.2. End of Study Definition

A participant will have completed their study participation when all study activities are completed at the end of Visit 1.

This study will be considered complete upon issuance of a Clinical Study Report that has been approved by the Clinical Affairs Director.

5. STUDY POPULATION

5.1. Inclusion Criteria

Individuals who meet the following criteria will participate in this study:

- Individual ≥ 18 years of age.

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* *The study is to include an interim analysis of the data after 46 participants have completed the study on the medium dispenser setting (1.0 mL). If the results demonstrate a satisfactory 15 second wet time using the medium setting, the study will end and no further recruitment will take place. If at this point, the results demonstrate that the amount of hand sanitizer dispensed under the medium setting (1.0 mL) does not sufficiently stay wet for at least 15 seconds, a*

second data collection will take place with another 46 participants who will undergo the study using the high dispenser setting (1.4 mL).

5.2. Exclusion Criteria

Individuals who meet any of the following criteria will not be allowed to participate in this study:

- Individual has a self reported skin condition that might result in irritation from the hand sanitizer.
- Individual has a known allergy to the ingredients in the test product.

5.3. Strategies for Recruitment and Retention

Participants will be recruited from an internal database of Medline employees. Participants will have previously participated in studies conducted by Medline, and/or have agreed to be contacted for future studies, as well as possibly via IRB-approved advertisement(s). Potential participants will be screened and enrolled until a total of 46 participants with complete data are obtained. Participants that do not complete study activities will be withdrawn from the study and replaced to meet the desired N = 46.

6. STUDY PROCEDURES AND ASSESSMENTS

6.1. Visit 1

6.1.1. Informed consent and screening

6.1.1.1. Informed Consent

The study staff will obtain written informed consent from the participant in-person or over a video conference call with the participant. Written consent must be obtained from all participants and documented on an Informed Consent form (ICF) that has received approval by an IRB/Ethics Committee. The ICF will be written in adherence to Good Clinical Practice (GCP) and must comply with all elements required by United States (U.S.) Food and Drug Administration (FDA) 21 CFR 50.25 and International Conference on Harmonization (ICH) 4.8, state and local regulations, and additional elements relevant to specific study situations (including a statement that Medline Industries, LP and relevant authorities have access to participant records). A copy of the signed consent will be provided for each participant.

6.1.1.2. Verification and Eligibility

The PI or delegated study staff will verify the eligibility of the individual for the study, based on the inclusion and exclusion criteria that will be evaluated in the Participant Screening Form. Participant demographics (age and sex), as well as hand size, will be documented. Study staff will verify participant eligibility in the study in-person or over a video conference call with the

participant. The participant will receive a unique screening number that will be recorded in the Participant Screening Form. The participant responses will be included in the Participant Screening Form.

Successfully enrolled participants will be assigned a unique participant identification number based on the order in which they enroll. If the individual is considered eligible to participate in the study, the participant will proceed to the study activities detailed in section 6.1.2.

6.1.2. Hand Sanitizer Application

Participants will first be asked to wash and dry their hands and wait an additional two minutes after their hands have dried before application of the hand sanitizer products. Study staff will record that the participant has washed their hands and waited an additional two minutes in the Case Report Form (CRF). The participants will then review the hand sanitizer application steps detailed in Figure 1, which are adapted from the WHO *"How to Handrub?"* poster. [4]

Figure 1. Hand Sanitizer Application Steps (Adapted from the WHO *"How to Handrub?"* Poster)

The participants will then be instructed by study staff to apply a 1.0 mL or 1.4 mL* aliquot of Spectrum Advanced Foam to their hands, which will be provided from an automated dispenser, following the hand sanitizer application steps. Study staff will begin to measure the wet time using a calibrated stopwatch: the application of the product to the palm of the participant will indicate the “start time”, and the participant stating that their hands have dried will indicate the “stop time”.

Once the participant has indicated that their hands are dry enough to don medical gloves, study staff will stop the stopwatch and record the Spectrum Advanced Foam wet time in the CRF.

6.1.3. Participant Dismissal

After the study staff has recorded the wet time of Spectrum Advanced Foam in the CRF, the participant will be dismissed from the study.

7. ADVERSE EVENTS (AEs)

7.1. Definition of AE

The FDA definition for an AE is: An AE is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure.

However, a narrower definition of AE will be used for this study. In this study, an AE is any untoward medical occurrence related to the topical use of the hand sanitizers during this study, including skin itching, erythema, edema, or any other skin irritation that occurs.

7.2. Definition of Serious Adverse Event (SAE)

The FDA definition of a SAE will be used in this study: An AE or suspected adverse reaction is considered "serious" if, in the view of the PI it results in any of the following outcomes:

- Death,
- A life-threatening adverse event,
- Inpatient hospitalization or prolongation of existing hospitalization,
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or

[*] *The study is to include an interim analysis of the data after 46 participants have completed the study on the medium dispenser setting (1.0 mL). If the results demonstrate a satisfactory 15 second wet time using the medium setting, the study will end and no further recruitment will take place. If at this point, the results demonstrate that the amount of hand sanitizer dispensed under the medium setting (1.0 mL) does not sufficiently stay wet for at least 15 seconds, a second data collection will take place with another 46 participants who will undergo the study using the high dispenser setting (1.4 mL).*

- A congenital anomaly/birth defect.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. All SAEs will be reported to Medline, regardless of potential relationship to the study product(s). SAEs will be reported to the reviewing IRB as necessary according to their reporting requirements.

7.3. Severity of AE

The severity of all AEs will be graded on a scale of one through five according to the Common Terminology Criteria for AE guideline, where each grade represents a unique clinical description based on this general guideline:

- **Grade 1:** Mild; asymptomatic or mild symptoms; clinical or diagnostic observation only; intervention not indicated.
- **Grade 2:** Moderate; minimal, local or noninvasive intervention indicated; limited age-appropriate instrumental activities of daily living.
- **Grade 3:** Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting activities of daily living involving self-care.
- **Grade 4:** Life threatening consequences; urgent intervention indicated
- **Grade 5:** Death related to AE

7.4. Relatedness of AE and SAE

- **Unrelated:** This category applies to those AEs which, after careful consideration, are clearly and incontrovertibly due to extraneous causes (disease, environment, etc.)
- **Possible:** This category applies to those AEs for which, after careful medical consideration at the time they are evaluated, a connection with the Investigational Product administration appears unlikely but cannot be ruled out with certainty.
- **Probable:** This category applies to those AEs which, after careful medical consideration at the time they are evaluated, are felt with a high degree of certainty to be related to the study product(s).
- **Definite:** This category applies to those AEs which, after careful consideration, are clearly and incontrovertibly due to the study product(s).

7.5. Expectedness

The PI will be responsible for determining whether an AE or SAE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

7.6. AE Reporting

The AEs will be recorded on the AE form (provided by Medline Industries, LP) by the study staff and reviewed by the PI. Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity. Changes in severity will necessitate a new CRF to document the new level of severity. AEs characterized as intermittent require documentation of onset and duration of each episode.

Non-serious AEs will be reported to the IRB per IRB reporting requirements.

7.7. SAE Reporting

The PI shall complete an SAE Form (provided by Medline Industries, LP) and will be responsible for reporting the event to the IRB, if applicable, per the IRB's reporting requirements. The PI is responsible for conducting an evaluation of the SAE and shall report the results of such evaluation to the FDA and to all reviewing IRBs, if applicable, within 10 working days after the PI first receives notice of the effect. Thereafter, the PI shall submit such additional reports concerning the effect as FDA requests.

For questions regarding this process or the event, you may contact your Medline clinical designee or the Medline Director of Clinical Operations:

Name: Greg Gomez, RN, Clinical Affairs Director
Phone: 224-931-1541
E-mail: clinicaloperations@medline.com

8. INTERIM ANALYSES

The study is to include an interim analysis of the data after 46 participants have completed the study on the medium dispenser setting (1.0 mL). If at this point, the results demonstrate that the amount of hand sanitizer dispensed under the medium setting (1.0 mL) does not sufficiently stay wet for at an average of at least 15 seconds, a second data collection whereby another 46 participants will undergo the study using the high dispenser setting (1.4 mL) will take place. If the results demonstrate a satisfactory average 15 second wet time using the medium setting (1.0 mL) with 46 participants, the study results will be analyzed and it will be decided if an additional study using the 1.4 ml setting is warranted.

9. STATISTICAL CONSIDERATIONS

9.1. Sample Size Determination

The sample size of 46 was estimated for 95% confidence interval based on a standard deviation of 5 seconds and target distance from mean to limits of 1.5 seconds (PASS-Confidence Intervals for One Mean). Results from a previous study conducted by Ecolab (summarized in the Appendix) was utilized as a starting point sample size estimation for the current protocol, using PASS 2021 Power Analysis and Sample Size Software (2021). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass. In the event that a participant withdraws from the study, additional participants will be enrolled to achieve a final number of 46 participants with complete data and until adequate power for analysis has been reached.

9.2. Randomization

No randomization is planned at this time.

9.3. Populations for Analyses

The analyses will be performed on the intent to treat (ITT) population which consists of all subjects who participated in the study, meaning they have full data on all covariates as well as the hand sanitizer dry time.

No per protocol, safety, or other analyses groups are planned.

9.4 Protocol Deviations

The list of protocol deviations will be compiled prior to database lock. All deviations will be reviewed and decisions for handling each of the deviations will be made prior to the start of data analysis.

9.5. Endpoints

9.5.1. Primary Endpoint

The time during which 1.0 mL of Spectrum Advanced Hand Sanitizer Gel with Aloe Vera and Vitamin E remains wet under conventional use conditions.

9.5.2. Secondary Endpoint

None.

9.6. Demographics, Variables and Covariates

Age will be collected as a continuous measure, with all participants being >=18 years of age. Age strata will be defined as stratum 1: 18-25 years old, stratum 2: 26-41 years old, stratum 3: 42-57 years old, stratum 4: 58-67 years old, stratum 5: 68-76 years old, stratum 6: 77-94 years old, 95+ years old. Age will be considered for secondary analysis.

Sex will be collected as a categorical equal to 0=male, 1=female, or 2=other. Sex will be considered for secondary analysis.

Hand size will be calculated using the formula 2.48 x hand length x hand breadth as described by (Wilkinson et al. (2017), Bellissimo-Rodrigues et al. (2015) and Hsu and Yu (2010)).

9.7. Handling of Missing Values

All missing data will be quantified in the final report and possible biases for any missing data will be reported.

9.8. Statistical Analysis

Statistical analyses will be conducted in SAS® software, Version 9.4 or higher of the SAS System for Windows (Copyright © 2013 SAS Institute Inc.) or other appropriate statistical software. $P<0.05$ will be considered statistically significant.

All continuous variables will be summarized using the following descriptive statistics: (non-missing sample size), mean, standard deviation, median, maximum and minimum. The frequency and percentages (based on the non-missing sample size) of observed levels will be reported for all categorical measures. 95% confidence intervals will be calculated for all means.

A box-and-whisker plot will be employed to display the mean, interquartile range, range, and any possible outliers for wet-to-dry time.

Spearman correlation analysis will be used to examine possible associations between the key variable of dry time with age, sex, and hand size. Additional t-tests or non-parametric tests will be employed to further examine any significant associations found in the correlational analyses between key and covariate measures.

If the results of the interim analysis of 46 participants on the medium dispenser setting (1.0 mL) does not demonstrate that hands stay sufficiently stay wet for at an average of at least 15 seconds, a second data collection whereby another 46 participants will undergo the study using the high dispenser setting (1.4 mL) will take place. All analyses presented above would then be repeated for the data from an additional 46 participants at the high dispenser setting (1.4 mL).

10. SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

a. Regulatory and Ethical Considerations

i. Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the PI and the staff. Therefore, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the PI. All study data and study records will be managed and stored in accordance with the site's policies on data storage and security. All electronic transmission of data will adhere to Health Insurance Portability and Accountability Act (HIPAA) and any local regulations.

Representatives of the IRB, and regulatory agencies may inspect all documents and records required to be maintained by the PI, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

A master list linking participant numbers to patient name and medical record number will be maintained in a secure database by the PI or paper files in secure cabinet(s). The study participant's contact information will be securely stored at each clinical site for internal use during the study. The PI will agree to notify the IRB of any intent to move or destroy these documents.

ii. Study Discontinuation

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the PI and IRB. If the study is prematurely terminated or suspended, the PI will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstance(s) that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants as determined by AE review

The study may resume once concerns about safety, protocol compliance, and data quality are addressed, and the IRB is satisfied.

iii. Data Handling and Record Keeping

Data collection is the responsibility of the study staff at the site under the supervision of the PI. The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported in the CRFs or any other study activity documentation as

part of this study. All the documents should be completed in accordance with Good Documentation Practices (GDP) to ensure accurate interpretation of data.

Final storage of Medline data will be per ICH/GCP guidelines and kept stored in a protected access area for the length of the time required.

iv. Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed.

b. Protocol Deviations

It is the responsibility of the PI and study staff to use continuous vigilance to identify and report deviations on a routine basis. All deviations must be addressed in the study source documents, and reported to Medline Industries, LP. Protocol deviations must be sent to the reviewing IRB per reporting requirements in a timely manner. The PI is responsible for knowing and adhering to the reviewing IRB requirements.

c. Abbreviations

AE	Adverse Event
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GDP	Good Documentation Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Conference on Harmonization
IRB	Institutional Review Board
PI	Principal Investigator

SAE	Serious Adverse Events
SOA	Schedule of Activities
U.S.	United States
WHO	World Health Organization

11. REFERENCES

1. Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR- 16): 11, 13.

2. World Health Organization (WHO). WHO Guidelines on Hand Hygiene in Health Care. Geneva: WHO, 2009.

3. PRODISPAB, Soap: HHSP1000FM, either table top (HHTABLESTAND) or floor stand (HHSTANDWH).

4. *How to Handrub?* World Health Organization; 2009. https://cdn.who.int/media/docs/default-source/integrated-health-services-(ihs)/infection-prevention-and-control/how-to-handrub-poster.pdf?sfvrsn=f5e8bfb1_6

12. APPENDIX

a. Hand Sanitizer Product Ingredients

i. Spectrum™ Advanced Hand Sanitizer Foam

Ingredients (Active): 70% v/v Ethyl Alcohol
Ingredients (Inactive): (Alphabetical) denatonium benzoate, Glycerin, Glyceryl caprylate, Isopropyl myristate, PEG-12 dimethicone, t-butyl alcohol, Water

b. Ecolab Foam Hand Sanitizer Study Design Bulletin

ECOLAB

Ecolab Foam Hand Sanitizers

PRODUCT USAGE RECOMMENDATIONS FOR ALCOHOL BASED HAND RUBS

In light of pending changes to the 1994 FDA Tentative Final Monograph (TFM) and requirements for Health Care Personnel Hand Wash/Rub, Ecolab has sought alternative guidelines for determining proper dosing of alcohol based hand sanitizers in health care environments. The Center for Disease Control and Prevention[1] (CDC) and World Health Organization[2] (WHO) indicate hands should remain wet for at least 15 seconds while being rubbed together after application of an alcohol-based hand rub. CDC and WHO guidelines further indicate the ideal volume of product to apply to the hands is not known, and may vary for different formulations. Ecolab testing has demonstrated on average 0.7 ml of *Quik-Care Foam Hand Sanitizer* (our fastest drying foam) is sufficient to keep hands wet for at least 15 seconds while being rubbed.

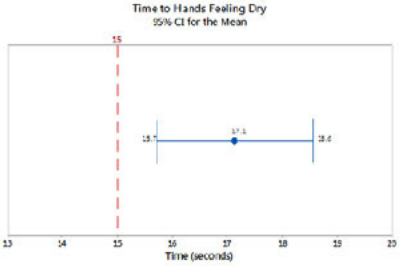
TEST METHOD

0.7ml of *Quik-Care Foam Hand Sanitizer* was dispensed onto one palm of the test subject. The test subject then rubbed his/her hands until dry. An observer using a stopwatch measured the time elapsed from when application began until the test subject indicated his/her hands felt dry. 42 test subjects participated in the study.

STUDY CONCLUSION

Under the conditions of this testing, 0.7 ml of *Quik-Care Foam Hand Sanitizer* was found to remain wet on the hands of a subject for an average of 17.1 seconds.

STUDY DISCUSSION



As indicated, CDC and WHO guidelines state the ideal volume of product to apply to the hands is not known, and may vary for different formulations. This study shows a minimum of 0.7ml of *Quik-Care Foam Hand Sanitizer* can be used to meet the CDC and WHO guidelines indicating hands should remain wet for at least 15 seconds during application of an alcohol-based hand sanitizer. Depending on configuration options, Ecolab Nexa foam dispensers output 0.7ml or 1.0ml of product; therefore, for most people, 1 pump from an Ecolab Nexa foam dispenser delivers enough product to meet the CDC and WHO guidelines on product volume usage.

Ecolab continues to partner with industry and regulatory bodies to navigate the changing landscape for soap and sanitizer use in health care environments.

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[1] Centers for Disease Control and Prevention. Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(No. RR- 16): 11, 13.
[2] World Health Organization (WHO). *WHO Guidelines on Hand Hygiene in Health Care*. Geneva: WHO, 2009

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Hand Sanitizer Wet Time Protocol_MED-2022-DIV60-002_V4.0

Final Audit Report 2022-11-18

Created:	2022-11-18
By:	[redacted]
Status:	Signed
Transaction ID:	CBJCHBCAABAACnDmsY4RQ3-A_mLHmhB6BYdUkrWcxhTo

"Hand Sanitizer Wet Time Protocol_MED-2022-DIV60-002_V4.0 " History

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Agreement completed.
2022-11-18 - 8:37:48 PM GMT