

1 **A clinical study to evaluate the safe and effective use of**
2 **Stethoglove, a single use stethoscope cover to reduce**
3 **pathogen transmission during auscultation**

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1 **ABSTRACT**

2 **Objectives:** Stethoscopes carry a significant risk for pathogen transmission. Here, the safe
3 use and performance of Stethoglove[®], a non-sterile, single-use cover for stethoscopes, that is
4 impermeable for pathogens, was investigated by different healthcare professionals (HCPs) in
5 the postoperative care setting of an intensive care unit (ICU).

6 **Methods:** Fifty-four patients underwent routine auscultations with the use of Stethoglove[®]. The
7 participating HCPs (n=34) rated each auscultation with Stethoglove[®] on a 5-point Likert scale.
8 The mean ratings of acoustic quality and Stethoglove[®] handling were defined as primary and
9 secondary performance endpoint.

10 **Results:** 534 auscultations with Stethoglove[®] were performed (average 15.7/user) on the
11 lungs (36.1%), the abdomen (33.2%), the heart (28.8%) or other body-sites (1.9%). No adverse
12 device-effects occurred. The acoustic quality was rated at 4.2±0.7 (mean) with a total of 86.1%
13 of all auscultations being rated at least as 4/5, and with no rating as below 2. The Stethoglove[®]
14 handling was rated at 3.7±0.8 (mean) with a total of 96.4% of all auscultations being rated at
15 least 3/5.

16 **Conclusions:** Using a real-world setting, this study demonstrates that Stethoglove[®] can be
17 safely and effectively used as cover for stethoscopes during auscultation. Stethoglove[®] may
18 therefore represent a useful and easy-to-implement tool for preventing stethoscope-mediated
19 infections.

20

21 **Keywords:** stethoscope, nosocomial infections, auscultation, transmission, polymer

1 ABBREVIATIONS

BMI	Body-Mass-Index
HCI	Healthcare-associated infection
HCP	Healthcare professional
ICU	Intensive care unit
TPU	Thermoplastic urethane

2

1 INTRODUCTION

2 Healthcare-associated infections (HAIs) represent a significant risk for patients ¹. In the United
3 States, the Center for Disease Control (CDC) reports that about 1.7 million patients are
4 estimated to be affected by HAIs every year while they are undergoing in-hospital treatment
5 for other health problems, and about 100,000 patients (approx. 6%) are dying from such HAIs
6 ². Widely regarded as the “physician’s third hand” the stethoscope plays a critical role in the
7 transmission of pathogens ³⁻⁸, and importantly, they harbor similar contamination levels as the
8 HCP’s hand ^{2,6,9}. Notably, with more than 5 billion auscultations per year in the US alone, it
9 represents the most often used medical device in daily clinical practice ².

10 Stethoscopes are crucial for both, in hospital and outpatient environments. They are not
11 only used for standard physical assessments, but also for the examination of special
12 medical conditions such as the diagnosis of abdominal or heart diseases or during routine
13 postoperative care, e.g., in intensive care units (ICU).

14 Disinfection of stethoscopes with isopropyl alcohol is recommended and may be effective at
15 eliminating many pathogens ^{3,5,10}. However, even though stethoscope cleaning guidelines and
16 recommendations from the CDC are available (i.e. continuous wiping with isopropyl alcohol for
17 at least 60 seconds), the overall compliance of health care professionals (HCPs) in the daily
18 clinical routine is reported to be extremely low ^{4,11,12}.

19 A recent study from Boulee and colleagues found that stethoscopes are most often not
20 cleaned between patient auscultations. Moreover, in cases where cleaning was performed
21 it only complied in 4% of the cases with the current CDC guidelines ^{11,13}. The reasons for
22 this non-compliance are multifactorial (e.g. lack of time, material and reminders) ¹². To
23 date, many initiatives to improve stethoscope hygiene have widely failed, and commonly
24 accepted “best practices” are yet to be developed. In addition, even if current stethoscope
25 cleaning guidelines would be practiced, highly virulent pathogens such as methicillin-resistant
26 *S. aureus* (MRSA) or *C. difficile* spores are likely to persist on the stethoscope diaphragm
27 thereby posing a significant risk to the next patient ¹⁴.

1 Alternative strategies to enhance stethoscope hygiene have been limited so far ¹⁵.
2 However, driven by the ongoing COVID-19 pandemic, the search for new stethoscope
3 protection technologies and concepts has recently regained reasonable attention ⁹. One
4 promising approach are microbiological barriers (e.g. single-use, disposable covers) shielding
5 the stethoscope diaphragm direct patient contact ^{15,16}. However, while such concepts may
6 indeed have the potential to improve stethoscope hygiene, they should not alter auscultation
7 accuracy by impairing the acoustic quality of auscultation sounds. Available data is scarce in
8 this regard ¹⁶. Another important requirement for such a device is its ease of use as to enable
9 simple and rapid implementation into the clinical routine workflow ².

10 Recently, the medical device Stethoglove[®], a non-sterile, single-use hygienic cover for
11 stethoscopes has been developed. It is impermeable for microorganisms thereby preventing
12 stethoscope-mediated patient-to-patient transmission of pathogens and preserves the
13 acoustic quality of auscultations. Stethoglove[®] can be easily pulled over the stethoscope's bell,
14 part of the tube(s), while being held in the hand of the user to also shield the operating hand
15 during auscultation.

16 In the present clinical study, the safe use and performance of Stethoglove[®] was investigated
17 by different HCPs under real-life conditions in the daily routine setting of an ICU for cardiac
18 surgery patients.

19

20 **PATIENTS AND METHODS**

21 **Study design and objectives**

22 The aim of this single-arm, open-label clinical study was to investigate the safe use and
23 performance of Stethoglove[®] by HCPs under real-life conditions in an ICU for cardiovascular
24 surgery patients. The objectives of the study were to assess 1.) the acoustic quality of
25 auscultations with Stethoglove[®] (primary performance endpoint); and 2.) the overall usability
26 of Stethoglove[®] (secondary performance endpoint) in the daily clinical routine by different
27 HCPs (user groups) including physicians and nurses which were further characterized by their

1 level of clinical experience. The study was approved by the local ethics committee (21-702-
2 MP Mono -IVE17) and the federal authority (94.1-03-5660-13526).

3

4 **Patients and study course**

5 Upon hospital admission on the day prior to their elective cardiovascular surgery adult patients
6 (≥ 18 years) were asked for informed consent to participate in the study. Patients who provided
7 informed consent were screened for inclusion and exclusion criteria (see definitions in
8 supplementary file). In included patients, the participating users performed auscultations as
9 part of their standard postoperative care with Stethoglove[®].

10 After each auscultation the users entered the following information and rating on a study-
11 specific and access-restricted page embedded into the patients' electronic medical record:

12 1. Auscultated organ or body site

13 1) Heart

14 2) Lung

15 3) Abdomen

16 4) Other

17 2. Rating of the acoustic quality of the auscultation with Stethoglove[®] (on a 5-point Likert
18 scale)

1	2	3	4	5
Poor	Moderate	Reasonable	Good	Very good

19

20 3. Rating of the Stethoglove[®] handling as part of the routine working practice (on a 5-point
21 Likert scale)

1	2	3	4	5
Poor	Moderate	Reasonable	Good	Very good

1 **Users**

2 A total of 34 physicians and nurses with different levels of professional experience participated
3 in this study and were assigned to one of the following groups:

4 User group 1: Fully trained physicians (e.g., senior physician, board-certified physician,
5 medical specialist, physicians with at least 8 years of working experience) (n=8)

6 User group 2: Physicians in specialty training (e.g., residents) (n=7)

7 User group 3: Fully trained nurses with at least 10 years of working experience (n=10)

8 User group 4: Fully trained nurses with less than 10 years of working experience (n=9)

9

10 **Device Description**

11 Stethoglove® (Stethoglove GmbH, Hamburg, Germany) is a hygienic stethoscope cover and a
12 safe and effective solution to minimize the risk of patient-to-patient infections caused by
13 contaminated stethoscopes in a health care environment (Figure 1, product images).



1

2

Figure 1: *Product image of single use glove*

3 The non-sterile, single-use glove is pulled over the stethoscope's bell and part of the tube(s),

4 while held in the hand of the user (Figure 2, product handling images).



1

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Figure 2: *Product handling images*

3 Stethoglove® is made of thermoplastic urethane (TPU) and is latex- and powder-free. The TPU

4 material is impermeable for microorganisms such as bacteria, fungi and viruses. Such

5 impermeability was demonstrated with decontaminated stethoscope bells wrapped in a

6 Stethoglove® cover, which were exposed for 30 minutes to confluent bacterial (*S.*

7 *aureus*, *B. diminuta*) and fungal (*A. niger*, *C. albicans*) cultures on agar plates. Swabbing of

8 the unwrapped stethoscope diaphragm post exposure revealed no contaminations

9 [unpublished data]. Viral impermeability was tested in accordance with Method C of ISO Norm

10 16604 (2004) using the blood-borne pathogen Bacteriophage Phi-X1274. Cut-outs from four

11 different areas of a Stethoglove® cover were exposed to the virus-containing suspension in a

1 penetration cell and a sequence of pressures ranging from 0 to 20 kpa was applied each for 5
2 minutes. No virus penetration was detected [unpublished data].

3 Regarding acoustic quality Stethoglove[®] has demonstrated excellent transmission of
4 auscultation sounds in both lab tests and a usability test with HCPs [unpublished data]. By
5 combining this impermeability for microorganism with the preserved acoustic quality of
6 auscultation sounds Stethoglove[®] ensures proper and safe patient-to-patient use of
7 stethoscopes by HCPs in their day-to-day practice and thus improves patient protection from
8 HAIs.

9

10 **Study endpoints**

11 In this study the following performance and safety endpoints were defined:

- 12 • The primary performance endpoint was the rating of the acoustic quality of
13 auscultations with Stethoglove[®] by all users
- 14 • The secondary performance endpoint was the rating of the handling of
15 Stethoglove[®] as part of the routine working practice by all users
- 16 • The safety endpoint was the frequency of observed adverse device effects or
17 serious adverse device effects

18 In addition, the influence of gender, BMI and auscultated organ/body site on the primary and
19 secondary performance endpoints were evaluated

20

21 **Sample size calculation and statistical analysis**

22 The continuous parameter “rating of the acoustic quality during auscultation measured on a 5-
23 point Likert scale (poor, moderate, reasonable, good, very good)” was used as primary
24 performance endpoint. No verification of a pre-defined hypotheses was planned. Instead, a
25 total of 508 recorded auscultations with Stethoglove[®] was calculated to be required based on
26 the following assumptions: a sampling error of 5% (precision), a prognostic accuracy of 95%

1 (reliability), an expected mean of 4 (assessment of acoustic quality, “good”) and a variance of
2 2.3 points (homogeneity).

3 Both the primary and secondary performance endpoints were first evaluated descriptively and
4 then stratified by the following influencing factors: patient gender, BMI and auscultated
5 organ/body site. All analyses were performed within all users, and within each user group.
6 Missing values were not replaced.

7 All measured differences between groups were investigated for numeric variables by means
8 of a two-sided t-Test for independent samples (comparison of 2 groups) and a one-factorial
9 ANOVA (Welch-Test, comparison of more than 2 groups) with a type I error of 0.05. Since no
10 formal hypothesis testing was done, all p-values were interpreted in a descriptive manner.

11

12 **RESULTS**

13 **Baseline characteristics, demographics and safety**

14 A total of 54 patients were enrolled in this study and 534 auscultations with Stethoglove[®] were
15 performed with an average of 9.9 auscultations per patient. Patient characteristics are shown
16 in Table 1.

17 **Table 1 Patient demographics**

Variable		Total Patients (N=54)	Percentage (%)	Statistics
Gender	Female	15	27.8	
	Male	39	72.2	
Body Mass Index	N			54
	Mean ±SD			27.8 ± 5.2
	Median			27.4

	Range (Min – Max)			19.8 - 43.8
	Normal weight (18.5 - 24.9)	19	35.2	
	Overweight (25.0 - 29.9)	19	35.2	
	Class I obesity (overweight) (30.0 - 34.9)	13	24.1	
	Class II obesity (obesity) (35.0 - 39.9)	0	0.0	
	Class III obesity (extreme obesity) (≥ 40.0)	3	5.6	

1 *SD= Standard Deviation

1 More males (n=39) than females (n=15) participated in this investigation which represents the
 2 typical gender distribution in cardiovascular patients. The mean BMI in the patient cohort was
 3 27.8 ± 5.2 kg/cm². The majority of patients (n=35) were overweight, 13 patients suffered from
 4 class I and 3 patients from class III obesity.

5 The rate of auscultations per organ and body site, were evenly distributed between lung
 6 (36.1%), abdomen (33.2%) and heart (28.8%), while only 1.9% of the auscultations were
 7 performed at other body sites (e.g., carotid artery) (Table 2). No adverse device effects (ADEs)
 8 were reported during the study.

9

10 **Table 2: Distribution of auscultations with Stethoglove[®] by body site and user group**

Variable		Total auscultations (N=534)	Percentage (%)	
Organ/Body site	Abdomen	177	33.2	
	Heart	154	28.8	
	Lung	193	36.1	
	Other	10	1.9	
				Average no. per user
User Group	No. 1: Fully trained physicians (N=8)	137	25.7	17.1
	No. 2: Physicians in speciality training (N=7)	114	21.4	16.3

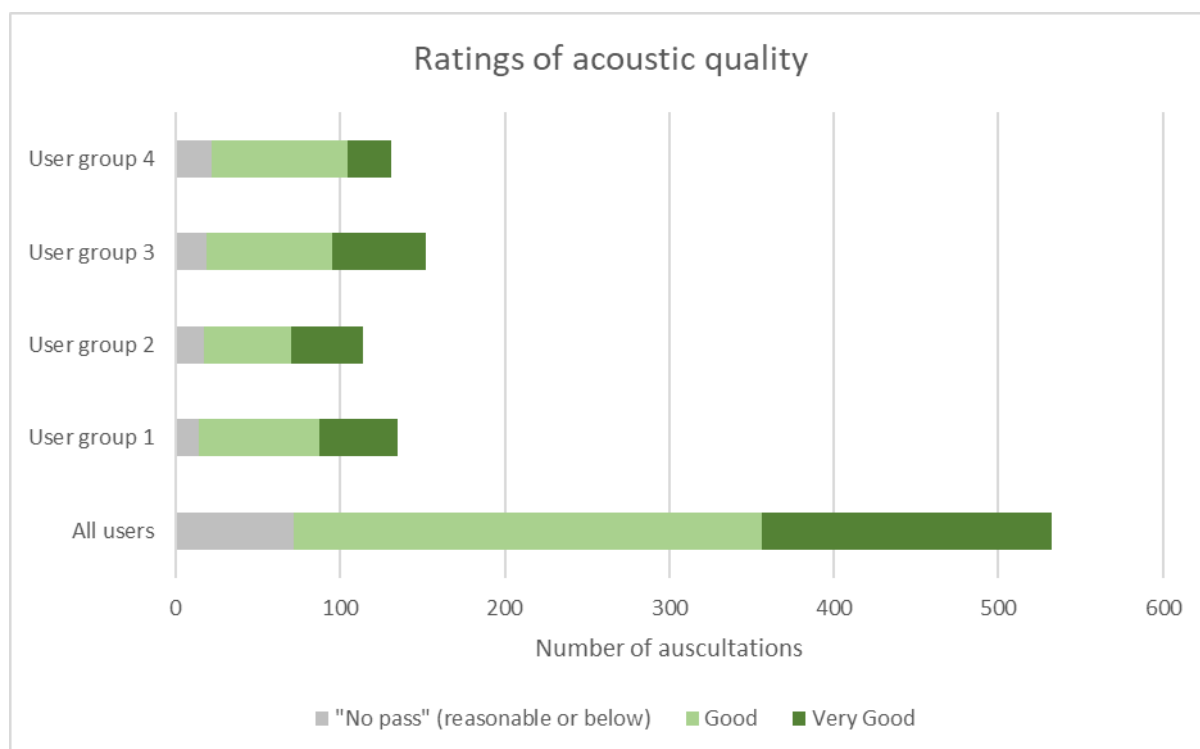
	No. 3: Fully trained nurses with ≥ 10 years of experience (N=10)	152	28.5	13.8
	No. 4: Fully trained nurses with < 10 years of experience (N=9)	131	24.5	16.4
	All (N=34)	534	100	15.7

1

2 **Acoustic quality of auscultations with Stethoglove[®]**

3 Primary Performance Endpoint

4 The mean rating of the acoustic quality of auscultations with Stethoglove[®] by all users was
5 4.2 ± 0.7 (Median 4.0; range 2-5) on a 5-point Likert scale (Table 3). A total of 86.1% of all
6 auscultations with Stethoglove[®] were rated at least "good" (score of 4 or higher) with
7 comparable results across user groups ranging from 88.3% for fully trained physicians (group
8 1), 85.1% for physicians in speciality training (group 2), 87.5% for nurses with 10 or more
9 years of professional experience (group 3), and 83.1% for nurses with less than of
10 professional experience (group 4), respectively (Table 3, Figure 3). No auscultation was
11 rated as "poor" (score of 1). For two out of 534 auscultations no rating was recorded.



1
2 **Figure 3:** Distribution of ratings of auscultation quality among the four user groups. User group
3 4: Fully trained nurses with <10 years of experience, user group 3: nurses with >10 years of
4 experience, user group 3: Physicians in specialty training (e.g., residents), user group 1: Fully
5 trained physicians (e.g., senior physician, board-certified physician, medical specialist,
6 physicians with at least 8 years of working experience)

7
8 *Acoustic quality of auscultations with Stethoglove[®] stratified by gender, BMI and auscultated*
9 *organ/body site*

10 The influence of the independent variables gender, BMI, and auscultated organ/body site on
11 the rating of the acoustic quality of auscultations with Stethoglove[®] by all users was evaluated
12 separately. The rating of the acoustic quality in male and female patients was comparable with
13 a mean score of 4.2 ± 0.7 in males and 4.0 ± 0.7 in females (Median 4.0; range 2-5 for both)
14 (Suppl. Table S1).

15 When stratified by BMI the mean rating of the acoustic quality was 4.3 ± 0.6 (for normal weight
16 patients), 4.2 ± 0.8 (for overweight patients), 4.0 ± 0.6 (for class I obesity patients) and $3.8 \pm$
17 0.8 (for class III obesity patients) (Median 4.0; range 2-5 for all BMI groups) (Suppl. Table S2).

1 When stratified by auscultated organ/body site the mean rating of the acoustic quality was 4.3
2 ± 0.7 for lungs, 4.2 ± 0.7 for abdomen, and 4.1 ± 0.6 for the heart (Median 4.0; range 2-5 for
3 all three). For “other” body sites including the carotid artery, femoral artery and stomach, a
4 lower mean rating was assigned (3.3 ± 0.7 ; Median 3.0; range 2-4), however, the underlying
5 number of auscultations was substantially lower than for the lung, abdomen and heart (Suppl.
6 Table S3).

7

8 Acoustic quality of auscultations with Stethoglove[®] by user groups

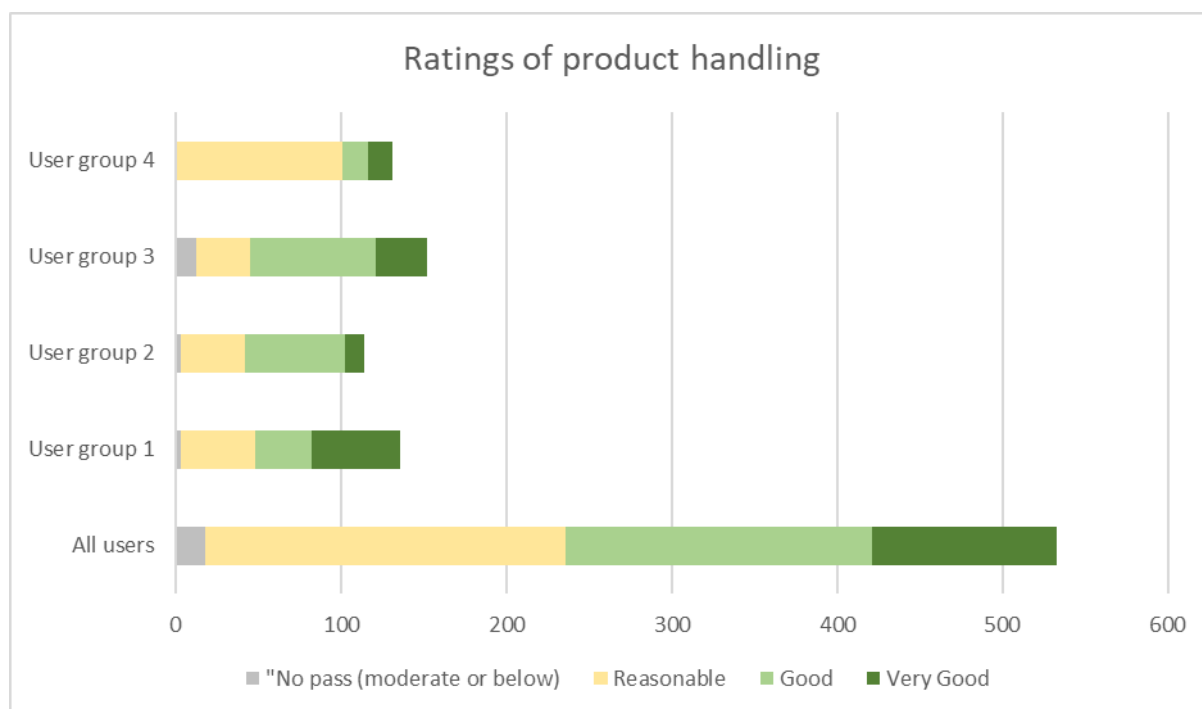
9 The ratings were consistent across all user groups, i.e., 4.2 ± 0.7 for user groups 1-3, and 4.0
10 ± 0.7 for user group 4.

11

12 **Evaluation of Stethoglove[®] usability (handling)**

13 Secondary performance endpoint

14 The mean rating of the handling of Stethoglove[®] in the daily clinical routine by all users was
15 3.7 ± 0.8 (Median 4.0; range 2-5) (Table 4 . A total of 96.4% of all auscultations was rated to
16 be at least “reasonable” by all users, while no auscultation was rated as “poor” (score of 1)
17 (Table 4, Figure 4). This suggests a high level of acceptability to use Stethoglove[®] throughout
18 all user groups. No handling was rated as “poor” (score of 1). For one out of 534 auscultations
19 no rating of the handling was recorded.



1
2 **Figure 4:** Distribution of ratings of product handling among the four user groups. User group
3 4: Fully trained nurses with <10 years of experience, user group 3: nurses with >10 years of
4 experience, user group 3: Physicians in specialty training (e.g., residents), user group 1: Fully
5 trained physicians (e.g., senior physician, board-certified physician, medical specialist,
6 physicians with at least 8 years of working experience)
7

8 **Table 3: Percentage of Stethoglove® handling rated as “reasonable”, “good” and “very**
9 **good”**

User group	Ratings of handling (% and n)				
	Mean \pm SD	“Reasonable” (score of 3)	“Good” (score of 4)	“Very good” (score of 5)	Combined
All users	3.7 \pm 0.8 (n=533*)	40.8% (n=218)	34.6% (n=185)	21.0% (n=112)	96.4% (n=515)
User group 1	4.0 \pm 0.9 (n=136)	32.9% (n=45)	24.8% (n=34)	39.4% (n=54)	97.1% (n=133)
User group 2	3.7 \pm 0.7 (n=114)	34.2% (n=39)	52.6% (n=60)	10.5% (n=12)	97.3% (n=111)

User group 3	3.8 ±0.8 (n=152)	21.7% (n=33)	50.0% (n=76)	20.4% (n=31)	92.1% (n=140)
User group 4	3.3 ±0.7 (n=131)	77.1% (n=101)	11.5% (n=15)	11.5% (n=15)	100% (n=131)

1 * For one out of 534 auscultations (0.2%) no rating was recorded

2

3 Stethoglove® handling stratified by gender, BMI and auscultated body site of auscultation

4 The influence of the independent variables gender, BMI, and auscultated organ/body site on
5 the rating of the Stethoglove® handling was evaluated separately. The mean rating of
6 Stethoglove® handling by all users was 3.8 ± 0.9 for males and 3.5 ± 0.7 for females (Median
7 4.0; range 2-5 for both).

8 When stratified for BMI, the mean rating of Stethoglove® handling was 3.8 ± 0.8 (for normal
9 weight patients), 3.8 ± 0.9 (for overweight patients), 3.6 ± 0.7 (for class I obesity patients) and
10 3.2 ± 0.5 (for class III obesity patients).

11 When stratified for auscultated organ/body site, the mean rating of Stethoglove® handling was
12 3.7 ± 0.8 for lungs, 3.8 ± 0.8 for hearts, and 3.7 ± 0.8 for the abdomen (Median 4.0; range 2-5
13 for all). For “other” body sites including the carotid artery, femoral artery and stomach, a lower
14 mean rating was assigned (3.6 ± 0.5), however, the underlying number of auscultations was
15 substantially lower than for the lung, abdomen and heart.

16

17 Stethoglove® handling by user group

18 The Stethoglove® handling was rated “reasonable to good” by each of the four user groups
19 (means ranging from 3.3 ± 0.7 to 4.0 ± 0.9).

20

21 **DISCUSSION**

22 In this study, the performance and safe use of Stethoglove®, a new, non-sterile, single-use
23 hygienic cover for stethoscopes, was demonstrated under real-life conditions in the routine

1 setting of an ICU for postoperative care of cardiac surgery patients. In total, 534 auscultations
 2 of different body regions including lungs, heart and abdomen were performed with
 3 Stethoglove[®] and rated for acoustic quality and product handling.

4

5 **Stethoglove[®] offers good acoustic quality of auscultations and an reasonable handling**
 6 **profile**

7 The overall acoustic quality of auscultations with Stethoglove[®] was “good” as rated by all users
 8 with a mean of 4.2 on a 5-point Likert scale (primary performance endpoint). To further explore
 9 this result, we evaluated only those auscultations, that were rated “good” (score of 4) or “very
 10 good” (score of 5), as these ratings were considered most meaningful in terms of acoustic
 11 quality.

12 A total of 86.1% of all auscultations was rated “good” or “very good” across all users, and this
 13 value is in good agreement with the values of each user group (Table 3).

14 **Table 4: Percentage of auscultations with Stethoglove[®] where the acoustic quality was**
 15 **rated as “good” and “very good”**

User group	Ratings of acoustic quality (% and n)			
	Mean \pm SD	“Good” (score of 4)	“Very good” (score of 5)	Combined
All users	4.2 \pm 0.7 (n=532*)	53.2% (n=284)	33.0% (n=176)	86.1% (n=460)
User group 1	4.2 \pm 0.7 (n=135)	53.3% (n=73)	35.0% (n=48)	88.3% (n=121)
User group 2	4.2 \pm 0.7 (n=114)	46.5% (n=53)	38.6% (n=44)	85.1% (n=97)
User group 3	4.2 \pm 0.7 (n=152)	50.0% (n=76)	37.5% (n=57)	87.5% (n=133)

User group 4	4.0 ±0.7 (n=131)	62.6% (n=82)	20.6% (n=27)	83.2% (n=109)
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1 * For two out of 534 auscultations (0.3%) no rating was recorded

2 These results are important for different reasons. First, they indicate a high level of satisfaction
3 among all users with regard to the overall quality of auscultation sound transmission through
4 the specific Stethoglove[®] material. Second, these findings indicate that Stethoglove[®] is
5 capable of ensuring a high degree of auscultation accuracy in different body regions. This
6 finding is of utmost clinical relevance as data on acoustic quality of commercially available
7 stethoscope covers are scarce. Moreover, other technologies such as fully disposable single-
8 use stethoscopes have been reported to come with substantial impairment of auscultation
9 accuracy which may potentially lead to misdiagnoses and may therefore ultimately even impact
10 patients' safety^{16,17}.

11 When stratified for BMI, the ratings 'good' or "very good" were recorded for 91.9% of
12 auscultations in normal weight patients. As expected, the rating of the acoustic quality
13 decreased with increasing BMI (85.1% in overweight patients, 85.3% in class I obese patients,
14 and 62.5% in class III obese patients). This observation is not surprising, as with increasing
15 body fat mass in thoracic or abdominal body areas, heart, lung or gastrointestinal tones would
16 appear muted during normal auscultations. This observation is thus not attributable to the
17 medical device.

18 When stratified for gender, the percentage of all auscultations rated as "good" and "very good"
19 was 81.6% in females and 87.7% in males. Both values are in good agreement with the overall
20 rating by all users (Table 3). The slight difference between males and females might be rather
21 due to their anatomical differences in the upper thoracic area, rather than device-related.

22 When stratified for auscultated body site the rating of the acoustic quality was stated as "good"
23 and "very good" for 87.6%, 89.2%, and 84.2% of all auscultations of the heart, lung, and
24 abdomen. These results are in good agreement with the overall rating by all users (Table 3).

25 Very few auscultations (N=10) were performed on "Other" body sites including carotid and

1 femoral arteries and stomach. The percentage of auscultations rated as “good” or better was
2 lower (40.0%) than for heart, lung, or abdomen. However, this finding is not unexpected and
3 not considered to be attributable to Stethoglove[®] given the general challenge in auscultating
4 these “Other” body sites and their generally low sound profile, especially if no pathological
5 alterations have occurred.

6 In regard to the secondary performance endpoint, this study showed that Stethoglove[®] is easy
7 to handle and may thus enable quick implementation into the clinical routine of HCPs. Handling
8 of the product was rated for 96.4% of all auscultations to be “reasonable”, “good” or “very
9 good” (score of 3, 4 or 5 on the 5-point Likert scale), highlighting the high degree of acceptance
10 by the users and their general willingness to use Stethoglove[®] in their daily work.

11 The stratification analysis showed that despite some expected differences between males and
12 females, body sites as well as among BMI classes, which do all apply to auscultations in
13 general, Stethoglove[®] presented with an overall good performance profile throughout the study
14 and for all patients independent from gender, BMI or auscultated body site. Even in highly
15 obese patients, for which it is well known that auscultations can be truly challenging, the device
16 performed in a satisfying manner based on the user ratings.

17

18 **Stethoglove[®] can be quickly adopted into clinical routine**

19 The high level of acceptance for the product observed in the present study is encouraging
20 when considering the generally extremely low compliance of HCPs towards sufficient
21 stethoscope hygiene or the general reluctance to adopt new technologies or procedures to
22 improve it. Even though stethoscope cleanliness guidelines exist¹³, and despite tremendous
23 educational efforts, this problem remains a key challenge. In fact, most of the approaches
24 taken to enhance stethoscope hygiene have been ineffective and ultimately failed^{2,11,12}. In a
25 recent observational investigation, Boulee et al. evaluated physicians’ frequency and methods
26 of stethoscope and hand hygiene practices. In only 18% of the 400 observed interactions,
27 stethoscopes were cleaned at all, and when done, less than 4% complied with the CDC
28 guidelines¹³. The authors concluded that stethoscope hygiene is largely neglected in daily

1 clinical routine and they strongly urged that the compliance towards stethoscope cleanliness
2 needs to be rapidly addressed ¹¹. To this end, Muniz and colleagues assessed the reasons for
3 poor stethoscope hygiene compliance and anonymously surveyed nurses, nurse practitioners,
4 and physicians at a large academic pediatric hospital. They found that perceived barriers for
5 low stethoscope hygiene included lack of materials on hand, lack of time, and most importantly,
6 lack of visual reminders¹². Hence, the high level of acceptance of Stethoglove[®] seen in this
7 study provides encouraging evidence that the Stethoglove[®] product may be quickly and
8 efficiently adopted by HCPs to become part of their clinical routine in order to help improving
9 patient protection from stethoscope-mediated infections.

10 Another interesting observation from this study was the rapid learning curve of the
11 Stethoglove[®] application which substantially differs from other stethoscope single-cover
12 concepts that usually target the sole coverage of the stethoscope diaphragm. Stethoglove[®],
13 however, covers the stethoscope bell including the users auscultating hand. After its use, it is
14 easily pulled off the hand (which is still holding the stethoscope) and discarded. In fact, the
15 Stethoglove[®] concept is based on the same principles as other single-use protective
16 equipment that is used in clinical routine (e.g., medical gloves). Notably, this may represent a
17 conceptual advantage when compared to other commercially available standard
18 microbiological stethoscope barriers as these require manual placement of the clean cover on
19 a potentially contaminated stethoscope. These maneuvers carry a considerable risk for
20 iatrogenic contamination of either the clean disc, the user's hand, or both. To the contrary, this
21 risk could be minimized or even fully eliminated with the Stethoglove[®] approach.

22

23 **LIMITATIONS**

24 This study has several limitations: Firstly, this was a single-center study in an ICU setting and
25 user experiences with the product in other healthcare settings are not available yet.

26 However, this study was carried out in a high-demand ICU environment on early postoperative
27 cardiac patients, i.e., a critical patient population. Therefore, although results cannot be
28 generalized to other healthcare settings and patient populations, expansion of observations

1 from this study to other health care areas is anticipated. Secondly, the evaluation of prevention
2 of pathogen transmission was not assessed, and was beyond the scope of this study. Thirdly,
3 to enable a real-life setting, no control group or randomization was added to the study protocol.
4 In addition, auscultating the same patient with and without Stethoglove[®] even in a randomized
5 manner would have caused a bias as the user would have known what to hear after the first
6 auscultation event (whether with or without the Stethoglove[®] cover).
7 Finally, it should also be recognized that the study was carried out on postoperative cardiac
8 patients in a high demand ICU environment. For such freshly operated patients, it is well
9 established that the proper auscultation can be challenging. They are often lying flat in their
10 ICU beds, and usually still carry loads of fluids in their body (e.g., in the pleura or pericardium
11 or abdominally) early after surgery, thus representing a “worst case scenario” population for
12 auscultation.

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16 **CONCLUSION**

17 This study using a real-world healthcare environment of a cardiovascular ICU demonstrated
18 that Stethoglove[®] can be safely and effectively used as a hygienic cover for stethoscopes
19 during auscultations. Device acceptance was high across various HCP user groups indicating
20 the device’s potential of being quickly adopted into daily clinical routine. The rating levels for
21 the acoustic quality of auscultations performed with Stethoglove[®] were high across all user
22 groups. Effects of gender, auscultation site and BMI on the acoustic quality of auscultations
23 Stethoglove[®] were comparable to the effects on auscultations in general, but not attributable
24 to the use or design of the product. Therefore, Stethoglove[®] may represent a safe, simple and
25 useful tool to improve patient safety and to reduce the risk of stethoscope-mediated infections
26 in the clinical routine workflow without impairing the acoustic quality of auscultations.

27

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7 **AUTHOR CONTRIBUTION STATEMENT**

8 TNS and MYE designed and oversaw the clinical study and prepared the first draft of this
9 manuscript. HM, VE, MS, FS, AF and TNS were responsible for patient recruitment and data
10 management. All authors contributed and approved the final draft of this manuscript. Data
11 analysis was performed by Heidi Kulas from the IGES Institute GmbH in Berlin.

12

13 **DATA AVAILABILITY STATEMENT**

14 Data are made available upon reasonable request.

15

16 **FUNDING STATEMENT**

17 This work was supported by Stethoglove GmbH, Hamburg Germany

18

19 **CONFLICT ON INTEREST STATEMENT**

20 MYE is the principal investigator of the study and a scientific advisor to Stethoglove GmbH.

21 Outside the submitted work: 617 V.F. has relevant (institutional) financial activities with

22 following commercial entities: Medtronic 618 GmbH, Biotronik SE & Co., Abbott GmbH & Co.

23 KG, Boston Scientific, Edwards Lifesciences, 619 Berlin Heart, Novartis Pharma GmbH,

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25 support), fees for lectures and speeches, fees for professional consultation 621 and research

26 and study funds.

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