From the Field

Wipe disinfection – further investigation of variable wiping forces in a modified version of the EN 16615 surface test method

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Conflict of interest:
The authors are employees of Tristel Solutions Ltd. whose products were used for the investigations.

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Abstract

Background: Wiping is an effective and established method for decontaminating surfaces, it involves applying liquid while simultaneously removing soils. Chlorine dioxide is a high-level disinfectant that can be applied to surfaces, including those of medical devices, with the aid of mechanical action or wiping. The European Standard (EN) 16615 evaluates the microbiocidal efficacy of a chemical disinfectant when it is applied with mechanical action, i.e., when applied by wiping. It has been suggested that manual methods employing human intervention can lead to variations in a validated process. One such assumption is that variable wiping force that exists between users may influence the effectiveness of the process.

Keywords
- disinfection
- chlorine dioxide
- mechanical action
- wiping
- force
- EN 16615

Method: The average wiping force of individuals with varying physical characteristics was investigated. A bespoke testing apparatus was employed in a series of EN 16615 four-field tests, with the aim to investigate if variable wiping force between individuals impacts the microbiocidal efficacy of a chlorine dioxide-based wipe disinfectant if tested as applied as in practice.

Results: Individuals applied variable forces when wiping. Physical attributes such as hand dominance and body build were shown to influence the force applied. The average wiping force calculated from this pool of participants was found to be lower than the stated range given by the EN 16615. The pre-impregnated chlorine dioxide-based wipe achieved biocidal efficacy in the series of EN 16615 tests. No trend relating to the efficacy of the product and the different forces applied could be drawn.

Conclusion: The data demonstrates that individuals apply different forces to a surface when wiping. However, the variability expressed when wiping has no impact on the microbiocidal efficacy of a manually applied chlorine dioxide-based disinfectant.

Introduction

Effective methods for disinfecting reusable heat-sensitive devices can feature established chemical methods [1, 2]. Typical methods of manually applying a chemical disinfectant to the target surface of these devices can include a process without mechanical action e.g., immersion, or with mechanical action e.g., wiping. It is also accepted that the cleaning stage, prior to disinfection, can be effectively performed using a wipe [3, 4, 5]. "Mechanical action" can be defined as a combination of movements used to remove soils from a surface using a wipe, brush, or mop. Wiping is an application method by which a liquid can be applied to a surface, whilst simultaneously aiding in the removal of soils [6].

Wiping requires human intervention, which may lead to variations in the process making it challenging to validate [7]. For example, the force applied during wiping may differ depending on a multitude of factors [8].

Chlorine dioxide is a well-documented biocide that can be effectively applied using a wipe [1, 9]. When generated in situ, it can provide high-level disinfection of non-porous surfaces including those of invasive, and non-invasive medical devices [10].

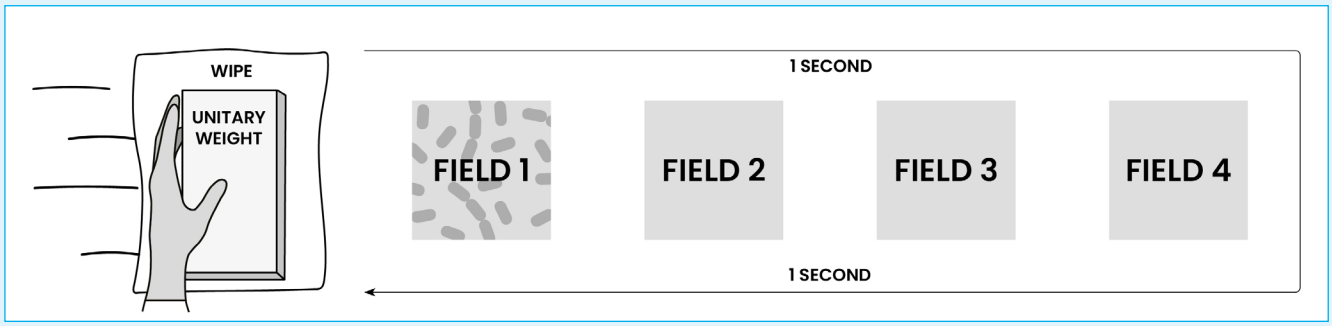

Fig. 1: Employment of mechanical action in the EN 16615 test method

The European Standard (EN) 14885 stipulates a framework for chemical disinfectant tests [11]. Disinfectants must be tested to the required standards before being considered acceptable for use in a real-world application. The tests are designed to best simulate how the disinfectant is intended to be used in practice [8]. One such standard is the EN 16615; this standard is used to evaluate a chemical disinfectant when applied to a surface using mechanical action (within the medical area). The four-field method encompasses attaching a wipe soaked with the disinfectant to a unitary weight of 2.3 kg to 2.5 kg, and wiping through four individually marked test fields, as shown in Figure 1. The recovery of organisms from these test fields are evaluated [12].

The wiping procedure is standardised by a unitary weight, implying the average force an individual may apply to a surface. When applied to the test this assumes that all individuals will wipe with the same force, removing any influence varying user forces may have on the test method. Ultimately, it is expected that user force will vary when performing a wiping procedure, and this may influence the transfer of disinfectant solution to a surface, possibly impacting the efficacy of the product.

A study from 2018 showed concordance with the range of efficacy achieved when the unitary weight was used compared to no weight [13]. Another published study has evaluated the impact of variable user forces when wiping [14]. The wiping force of participants was recorded, and the average force applied was found to be 1.6 kg. This is significantly lower than the parameters of the EN 16615 standard of 2.3–2.5 kg. The study evaluated the impact of different wiping forces on the efficacy of a chlorine dioxide foam disinfectant. The outcome supported the existence of user variability; however, the microbiological effectiveness of the tested disinfectant was not affected. In this study, the product solution was prepared and applied as per the parameters of the standard. Parameters include the employment of the prescribed standard low-lint cleaning cloth saturated with 16ml of disinfectant. Whilst this test parameter may be adequate for disinfectants which are spread by any wipe, this volume of solution is not representative of how pre-impregnated wipes are used in practice. It was therefore considered beneficial to conduct further microbiological evaluations with test parameters adapted to pre-impregnated wipes.

An expanded investigation using the basis of this original study design was implemented. The aim was to identify factors from an individual, such as physical attributes, that my affect wiping force. This included recording the individuals body build, height, weight, and hand dominance. Also, a larger number of participants was included to achieve a more representative finding and calculate more extensive summary statistics.

Further microbiological evaluation was conducted using the methodology of the modified unitary weight on a pre-impregnated wipe product that utilises chlorine dioxide working solution. The volume of solution applied in practice differs to the test standard of 16 ml. The product is also intended to be used with a pre-impregnated wipe substrate which has a different composition and size to the standard wipe used within the EN 16615. As a result, the preparation and application of the disinfectant in this study is equivalent to how it is used in practice. The objective was to analyse the effects on microbiological efficacy at variable wiping forces when a disinfectant is employed according to manufacturer's instructions for use.

Material/Method(s)

Identification of an individual's wiping force

Materials: Weighing scales, dry wipes (100% polypropylene), timer.

Methods: 50 participants were randomly selected to take part in the study and kept unaware of the aim throughout. Participants completed a questionnaire prior to participation in the study which included questions on body build, height, weight, and their dominant hand.

The participants were instructed to wet a dry wipe with a small volume of water and open the wipe flat in the palm of the hand. They were subsequently asked to wipe the surface of the baseplate of the scale in a circular motion for 5 seconds and repeat with the other hand.

The highest and lowest weight achieved on the weighing scale was recorded for each hand separately. Summary statistics including averages were calculated from the results.

Microbiological testing of a pre-impregnated wipe-based disinfectant using different wiping forces

Materials:

Disinfectant: The disinfectant product (Tristel Sporicidal Wipe, part of the Tristel Trio Wipes System) chosen for the test contains the biocidal active ingredient chlorine dioxide (ClO_2). The chemical is activated in situ by combining citric acid and sodium chlorite. Once the working solution is generated a high-level disinfectant wipe is produced with a contact time of 30 seconds.

Wiping cloth: The pre-impregnated wipe substrate of the product was used composing of 46% cellulose and 54% polyester.

Test surface: The test surface was made from 2.0 mm Polyurethane (PUR)

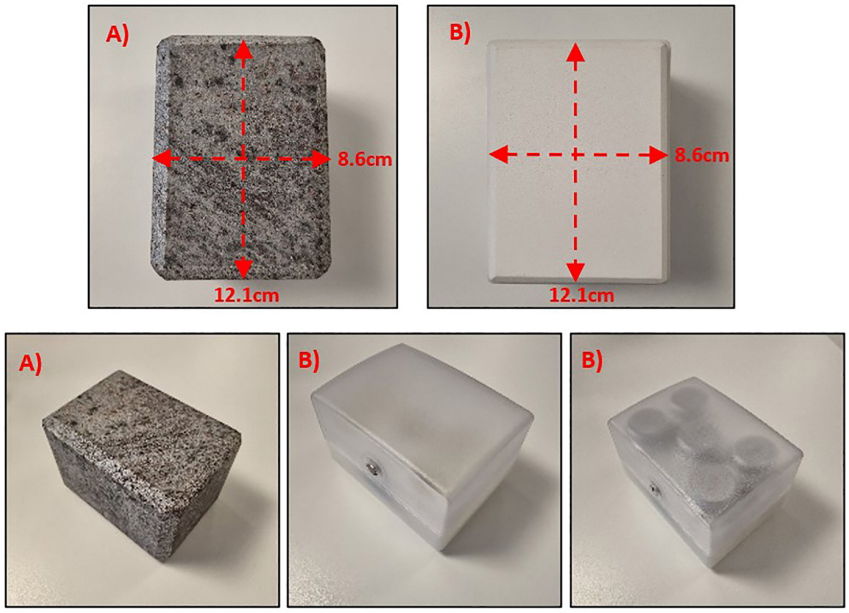

Fig. 2: Comparison of the standard EN 16615 unitary weight (A) to the modified unitary weight (B)

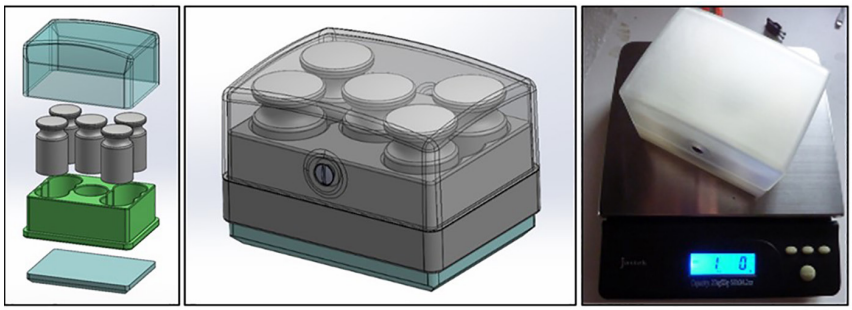

Fig. 3: Design of the modified unitary weight

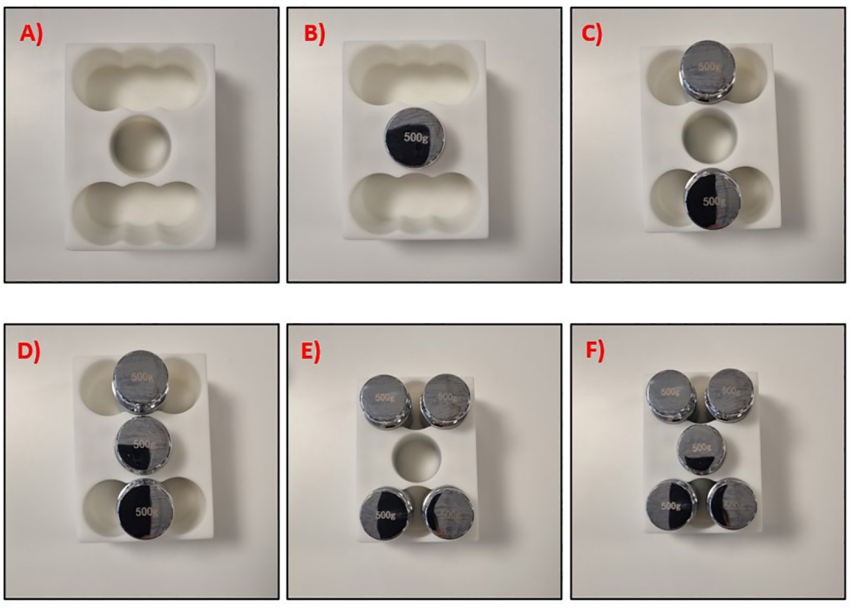

Fig. 4: The arrangement of weights in the modified unitary weight: 1 kg (A), 1.5 kg (B), 2 kg (C), 2.5 kg (D), 3 kg (E), 3.5k g (F)

manufactured by Armstrong DLW GmbH (Bietigheim, Germany).

Bacterial strain medium and growth conditions: *Staphylococcus aureus* ATCC 6538 is a gram-positive bacterium which can be a source of infection if not removed from healthcare surfaces and devices [15, 16]. This strain is also a mandatory test organism in the EN 16615 to claim bactericidal efficacy. For a bactericidal claim to be made efficacy against *Pseudomonas aeruginosa* and *Enterococcus hirae* must also be shown to this standard.

Organic load: 0.3 g/l bovine albumin is recognised as an interfering substance in the EN tests for a disinfectant that is intended to be used on a clean surface in the medical area.

Methods and Modifications

The four-field test was performed following the EN 16615 methodology. The pre-impregnated wipe substrate was used in place of the standard recommended wipe. In addition to this, the standard volume of solution (16 ml) in the EN 16615 was not applied, instead the manufacturer's instructions for use were followed. As a result, the volume of disinfectant solution was significantly less (no more than 6 ml). A contact time of 30 seconds was observed. A modification was made to the unitary weight to allow a range of weights to be applied in the test as per the methodology outlined in the precursor study [14]. The modified weight was provided by Tristel Solutions Ltd. as a substitute for the standard unitary weight.

The width and length of the standard unitary weight specified in the EN 16615 is 8.6 cm x 12.1 cm, the dimensions of the modified weight were identical as shown in Figure 2. The base plate was made from quartz, a material with similar physical properties to the material used for the standard unitary weight (granite).

Figure 3 shows the schematics of the modified unitary weight. The base unit weighed 1 kg, and the weight could be increased using 500 g weights, allowing a test range of 1 kg to 3.5 kg.

The 500 g weights could be arranged to evenly distribute the weight throughout the base plate; Figure 4 shows each possible weight arrangement.

Two test runs of the four-field test were performed to the modified parameters of the EN 16615 at each weight arrangement. The microbiological tests

were performed at an independent laboratory with ISO 17025 accreditation for EN 16615:2015. These investigations were performed as preliminary practice tests to provide information on important factors to be considered when wiping and are not intended to be used to specify a claim according to the relevant EN standard.

Results

Identification of an individual's wiping force

The study included a total of 100 wiping events, from 50 individuals, of which 26 were male and 24 were female. Since the highest and lowest weight of each wiping event were recorded this generated 200 data points. The average force applied to the surface of the scale by each hand of the participants is shown in Figure 5.

In this pool of subjects, the total average of all data points – and hence the average force applied by individuals when wiping a surface – was calculated to be 1,022 g. The median force throughout all 200 data points was 834 g. In comparison to the standard unitary weight as prescribed in EN 16615, 185 data points were below the 2.3 kg mark, four within the range of 2.3 kg to 2.5 kg, and 11 above. 42% of data points appeared within the weight range of 500 g to 999 g.

The range of force applied spanned from the lowest being 98 g, to the highest being 4,017 g. When the average for both hands of each participant is calculated, the lowest force was found to be 185g and the highest 3,370 g. This range was used as a basis for the maximum weight chosen in the microbiological tests.

The mean summary statistics from the data derived from the questionnaire are extrapolated in Table 1. Most of the participants were right-handed (43) compared to left-handed (6), and ambidextrous (1). There was a significant difference in force applied between right and left hands for right-handed and ambidextrous individuals. There was no difference observed for those who were left-handed.

On average, females exerted a greater wiping force than males, although this difference is slight. No trend could be deduced in relation to the force applied and the height or weight of subjects. The body build type showed those who rated their build as small generally wiped lighter (782 g) than those who rated themselves as medium (1,054 g), this trend continues for those who were classed as large (1,137 g). It can then be determined that an individual's body build type may influence the force applied whilst wiping a surface.

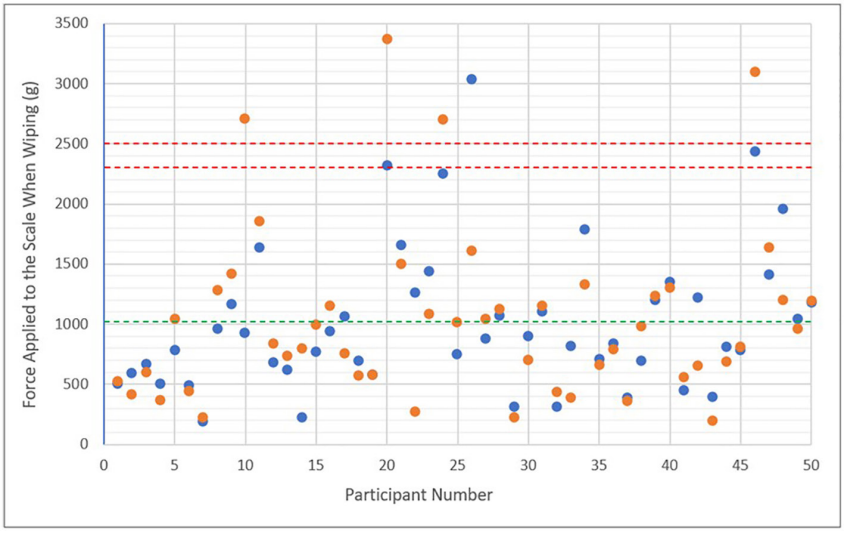

Fig. 5: The average force applied by participants Left hand (Orange) and Right hand (Blue). Total average force applied (green dashed line). EN 16615 unitary weight range (red dashed lines).

Table 1: Results of the participant questionnaire

		Number of participants	Total average wiping force (g)
Gender	Males	26	987
	Females	24	1059
Height (cm)	≤154	3	740
	155 to 177	30	1112
	≥178	17	912
Weight (kg)	0-55	8	841
	56-99	38	1051
	≥100	4	943
Body build	small	9	782
	medium	31	1054
	large	10	1137
Dominant hand	right	43	976
	left	6	1023
	both	1	880

Microbiological testing of a pre-impregnated wipe-based disinfectant using different wiping forces

The modified block weighed 1 kg when no weights were loaded into the base as shown in Figure 3. This was the lowest achievable test weight to allow the dimensions and materials of construction to remain identical to the standard. 500 g weights were found to be an adequate incrementation to reach 3.5 kg which was an acceptable upper limit given the average range of the wiping study.

The results of the four-field test at each weight set, from 1 kg to 3.5 kg, are displayed in Table 2, where each test run

was performed in duplicate, with identical test conditions and instructions.

The disinfectant wipe was shown to possess sufficient biocidal activity in a 30 second contact time at each weight set. No trend could be drawn from the results relating to the increased weight and efficacy of the wipe. The acceptance criteria of ≥5 log reduction on test field 1 was achieved at each weight. The spread of organisms from test fields 2 to 4 were below the acceptance criterion of 50 cfu/25 cm². This was confirmed in the second test run where results were comparable.

Table 2: Results of the four-field test with the modified unitary weight. Acceptance criteria - Test field 1: ≥5 log reduction, Test field 2 to 4: ≤50 cfu/cm²

	Test run 1		Test run 2	
Weight (kg)	Test field 1 (LogR)	Test field 2-4 (cfu/cm²)	Test field 1 (LogR)	Test field 2-4 (cfu/cm²)
1.0	>5.57	15.83	>5.57	<5
1.5	>5.57	<5	>5.57	<5
2.0	>5.57	<5	>5.57	<5
2.5	>5.50	<5	5.30	<5
3.0	>5.50	<5	>5.50	<5
3.5	>5.50	<5	>5.50	<5

Discussion

The study data demonstrates that a high variability of wiping force exists between individuals. Comparable conclusions were made in a previous study [14]. There are variability trends regarding the dominant hand, gender, and body build, but none relating to height and weight.

The total average force applied across all wiping events (1,022 g) was significantly below the standard 2.3 kg to 2.5 kg unitary weight used in the EN 16615 methodology which "simulates the average pressure when wiping is performed in practice" [12]. Hence this study confirmed the findings by other studies that the average wiping force is lower than the standard unitary weight [14, 17].

The increase in data points compared to the precursor study allowed a more representative average wiping force to be attained: from 1.6 kg to 1.0 kg, with an even lower median force (0.8 kg). The majority of data points acquired in Figure 5 are below 2 kg (91%) and nearly two thirds are below 1 kg (65%). Only 2% of data points fell into the weight range associated with the EN 16615 standard unitary weight.

In the microbiological tests, a value below 1 kg could not be attained due to the inherent weight of the materials of construction for the base unit of the modified unitary weight. The average wiping force of individuals was found to be below 3.5 kg in this study, making the range of 1kg–3.5kg appropriate. This allowed sufficient scope to identify a trend amongst data points if present.

S. aureus was the only tested organism in this study. As a gram-positive bacterium, this organism is recognized for its elevated resistance to chemical disinfectants when present on a surface, in contrast to gram-negative bacteria. Further investigations would be necessary for a full test series according to EN 16615. This study, however, focused on the impact of variable wiping force applied by the user.

The microbiological results for the four-field test demonstrate that variable weight, i.e., force applied by the user, does not impact the overall efficacy in the EN 16615 method for the chlorine dioxide-based pre-impregnated wipe product.

The efficacy did not increase or decrease when the weight applied was altered. Therefore, there is no evidence in this study to support any relationship between the wiping force and the microbiocidal activity of the disinfectant.

The results confirm an adequate volume of solution is released onto the surface to achieve a sufficient microbiological kill, even when little or great force is applied. Wiping force is therefore not a limiting factor connected to the efficacy of the tested disinfectant wipe. From this it can be drawn that human intervention – in terms of variable wiping force – does not impact the effectiveness of disinfection by wiping.

The European Standard EN 16615 was designed to closely simulate real-world conditions, which comes with limitations. As more variables are introduced, greater variance in results is expected to occur. However, this was not shown in this study.

Force applied when wiping has previously been investigated, however, this is the first study to directly record different wiping forces, their influencing factors, and the impact this has on the biocidal performance of a chemical disinfectant when applied according to the manufacturer's instructions for use. This study did not evaluate the cleaning effectiveness of the wipe. Further research could evaluate how variable forces applied affect the removal of organic debris from a surface. Subsequent studies can include repeating the modified EN 16615 with lighter unitary weights, regardless of the standard materials of construction or dimensions, different wipe substrates, and different actives. Furthermore, factors such as the size of the area to be wiped and the height of the surface to be wiped could influence the wiping force applied. Including an even larger pool of participants could further sharpen the results and provide an even more representative average wiping force result.

Conclusion

The average wiping force assumed in the EN 16615 is greater than what is observed in practice. The data demonstrates that physical properties may influence wiping force, but variability when wiping has no impact on the microbiocidal efficacy of a chlorine dioxide disinfectant wipe. The tested pre-impregnated wipe was shown to possess microbiocidal efficacy despite variable forces being applied. In this scenario, the concern that manual wiping presents a margin of error due to variability exhibited by individuals, ultimately affecting the effectiveness of the disinfectant when used on a surface is allayed. A reproducible outcome across a wide range of different people can be

ascertained when the disinfectant is applied according to user instructions.

These investigations were performed in addition to the relevant European standards which allow for disinfectant claims to be made. They serve as practical tests to confirm officially obtained efficacy data under more varied practical conditions. The results indicate that further investigation would be useful to ascertain more comprehensive data.

Acknowledgements

The independent laboratory that ran the microbiological testing was Eurofins MGS Laboratories Ltd. who hold UKAS accreditation to ISO 17025 for the EN 16615:2015.

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