WHITE PAPER

GLOBAL USER EVALUATION OF AMBU® aScope™ Gastro

An Analysis based on 532 User Evaluations of Ambu® aScope™ Gastro

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ABSTRACT

Purpose

The aim of this paper is to evaluate the experiences of gastroenterologists and surgeons performing endoscopic procedures with the single-use Ambu aScope Gastro and aBox 2 endoscopy system by collecting their feedback immediately after esophagogastroduodenoscopy (EGD) procedures.

Materials and Methods

Physicians from 16 countries in Europe, United States and the Asia-Pacific region completed a user evaluation after performing an EGD with the new single-use aScope Gastro and aBox 2. A Likert scale was used to measure their perception of the aScope Gastro and aBox 2. Descriptive statistics and standard deviation (SD) were calculated in Microsoft Excel version 2108, and regression analyses were performed in R version 4.2.2.

Results

532 user evaluations were completed. The completion rate of the EGD with the aScope Gastro was 95% (n=507). Of those not completed with aScope Gastro, 1% (n=5) were also unable to be completed with a reusable gastroscope. In 97% (n=516) of the procedures, the single-use gastroscope was found to be clinically acceptable, and 97.2% (n=517) met the physicians' expectations. 97.2% of the evaluations (n=517) rated their overall satisfaction between neutral (26%), satisfied (58%) and very satisfied (13%), with overall satisfaction scoring 3.81/5. The 210° retroflexion was found to exceed expectations in 98% (n=489) of the evaluations for those applicable. Weight, ease of insertion, tip control, suction and water jet function were rated "good" or "very good" in ≥91%. No complications, perforations or other adverse events were reported.

Conclusions

The aScope Gastro met or exceeded the users' expectations in almost all cases. All its individual attributes met or exceeded expectations. The results indicate that the single-use aScope Gastro meets the clinical requirements and demands of gastroenterologists and surgeons, and therefore represents an alternative to reusable gastroscopes.

INTRODUCTION

Endoscopes are categorized as semi-critical devices, and reusable endoscopes require high-level disinfection by trained personnel after each use [4,5], which together with frequent time-consuming repairs bears the risk of endoscope unavailability.

Single-use gastroscopes are developed to improve workflow and availability, and to avoid endoscope-related contamination and infection. The single-use gastroscope aScope Gastro, along with the aBox 2, offers a modern intuitive design and plug-and-play connectivity, and represents an alternative to the reusable gastroscope. It also comes with the advantages of being sterile from the package (which is especially relevant when a gastroscope is needed during a surgical procedure in sterile environments), being always available and not requiring reprocessing and repairs (Figures 1 & 2).

Image quality and field of view of gastroscopes are fundamental for navigation, localization and visualizing key anatomical structures and luminal pathology. However, the mechanical properties of a gastroscope, such as retroflexion and distal tip control, are equally important and required for a range of diagnostic and therapeutic procedures (Figure 3, Table 1).

Retroflexion is used in the stomach [1] in order to assess the lesser curvature and the angulus , a hiatus hernia, the fundus, the area just below the cardia. Sometimes to explore also the narrowing of the lower part of the esophagus from below. Additionally, the retroflexion view is also reportedly preferred in terms of safety and effectiveness for multiple treatments, and manoeuvrability is advantageous during resection of gastric tumours involving the pyloric channel [1,2,3].

Ambu aScope Gastro

The aScope Gastro is a single-use flexible endoscope that is intended to ensure a sterile endoscope for a variety of diagnostic and therapeutic procedures in the upper GI tract. The aScope Gastro is always available and provides the endoscopist with an endoscope with a CMOS camera with dual LEDs and 140° field-of-view for clear visualization of luminal structures and mucosal surface. It comes with a 2.8 mm working channel as well as a dedicated Auxiliary Water Jet channel and 210° retroflexion. The four endoscope buttons can easily program up to eight functions, and the lightweight connector is compatible with standard ancillary devices and tube sets.

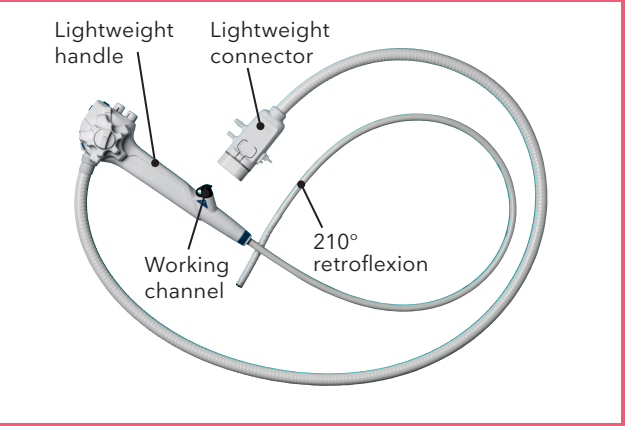


Figure 1: aScope Gastro

Figure 2: aBox 2

Figure 3: aScope Gastro 210° Retroflexion and Distal Tip

Specifications of aScope Gastro	
Optical System	
Field of view	140°
Depth of field	3-100 mm
Illumination method	Dual LEDs
Image enhancement	Yes (Advanced Red Contrast)
Insertion Tube	
Distal tip outer diameter	9.9 mm
Working channel inner diameter	2.8 mm
Working length	1030 mm
Bending Section	
Angulation (Up/Down/Left/Right)	210°/90°/100°/100°
Endoscope Channels	
Working channel inner diameter	2.8 mm
Auxiliary Water Jet Channel	Yes
Weight	
Weight	561 g

Table 1: aScope Gastro Specifications

This white paper is the first study to report and evaluate user experience by collecting doctors' feedback on the perceived performance after EGD with the single-use aScope Gastro and aBox 2 endoscopy system.

METHODS

Evaluation design: The aim of the user evaluation was to systematically collect subjective quality assessments of aScope Gastro to ensure it met the expectations of the physicians. Data was collected from May 2022 to October 2022. Doctors from 16 countries (Australia, Belgium, Denmark, England, Finland, France, Germany, Ireland, Italy, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United States) completed the user evaluation form after an EGD was performed with an aScope Gastro. As no data from patients were obtained, informed consent was not required.

Data Collection: Recruitment of respondents was done by representatives. The data were collected by an online survey tool (Microsoft Forms) directly after the procedure was finished. The physicians received no payment or other compensation for completing the evaluation form. The evaluation forms were collected centrally, and all data were exported to Microsoft Excel.

Five-point Likert scales were used for physicians to express their negative-to-positive strength of agreement with the evaluation questions. The physicians were asked about their subjective experience on 10 attributes of the aScope Gastro (1: weight of aScope Gastro; 2: insertion/intubation; 3: tip control 1:1 response & precision; 4: angulation/210° retroflexion; 5: suction/aspiration; 6: lens cleaning; 7: forward water jet; 8: image resolution; 9: colour reproduction; 10: Advanced Red Contrast (ARC™) image enhancement function) and on five attributes of the aBox 2 (1: connecting the aScope Gastro to the aBox; 2: navigating using the aBox 2 screen; 3: experience of the user interface; 4: obtaining images by using the aBox 2 camera button; 5: recording videos by using the aBox 2 recording button). The physicians were asked to rate the attributes on the 5-point scale ("very poor" (1), "poor" (2), "fair" (3), "good" (4), "very good" (5)). Additionally, the physicians were asked if they found the aScope Gastro clinically acceptable (yes/no) and asked about their overall satisfaction with the single-use gastroscope during the procedure on a 5-point scale ("very dissatisfied" (1), "dissatisfied (2), "neutral" (3), "satisfied" (4), "very satisfied" (5)).

Statistical Methods: Descriptive statistics were calculated for sub-group analyses such as the specialty of the endoscopist and the country where the endoscopist was located. Means and SD were calculated individually and jointly for the 10 performance attributes of the aScope Gastro and for the five attributes of the aBox 2, together with the overall satisfaction. The findings were stated as means ± SD. In addition, regression analyses were performed, examining the mean differences between surgeons and gastroenterologists on user expectations, overall satisfaction and the 10 performance attributes. All statistical analyses were performed in Microsoft Excel version 2108. The Kruskal-Wallis non-parametric one-way analysis of variance was performed in R version 4.2.2.

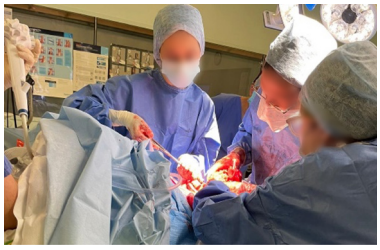
RESULTS

532 user evaluations were completed by physicians from 16 countries. 17% (n=88) were from Northern Europe; 57% (n=304) were from Western Europe; 15% (n=81) were from Southern Europe; 4% (n=22) were from Australasia; and 7% (n=37) were from North America (Table 2). No complications, perforations or other adverse events were reported.

Country	Number (%) of endoscopist evaluations
Northern Europe	**88 (17%)**
Denmark	36 (7%)
Finland	23 (4%)
Norway	24 (5%)
Sweden	5 (1%)
Western Europe	**304 (57%)**
Belgium	36 (7%)
France	53 (10%)
Germany	142 (27%)
Ireland	3 (1%)
Netherlands	33 (6%)
Northern Ireland	1 (0%)
Switzerland	13 (2%)
England	42 (8%)
Southern Europe	**81 (15%)**
Italy	10 (2%)
Spain	71 (13%)
Australasia	**22 (4%)**
Australia	21 (4%)
New Zealand	1 (0%)
North America	**37 (7%)**
United States	37 (7%)

Table 2: Location and number of user evaluations

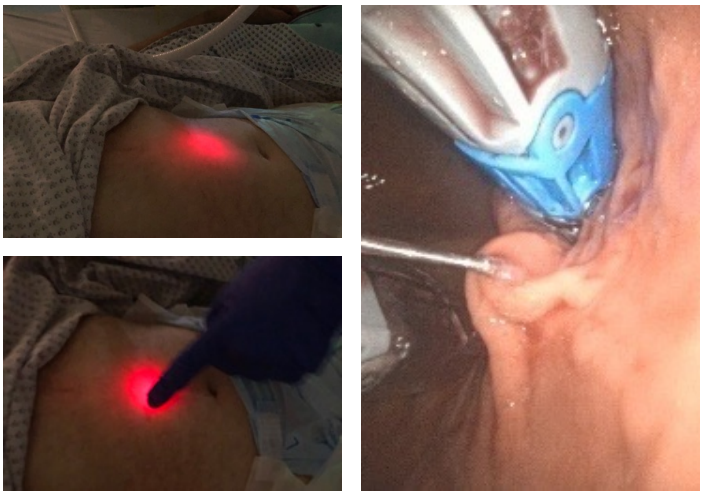
74% (n=392) of the user evaluations were completed by gastroenterologists, 25% (n=135) by surgeons, and 1% (n=5) by other non-specified health care personnel. In 86% (n=456) of the evaluations, the aScope Gastro was used in an endoscopy unit, 12% (n=62) in an operating room/theatre (OR), 1% (n=5) in an intensive care unit (ICU), 0.2% (n=1) in an emergency department (ED), while 2% (n=8) reported that the procedure was performed in another non-specified setting (Images 1-3).



Images 1 and 2: aScope Gastro used during surgical procedures in the OR
Image 3: aScope Gastro used for EGD in the endoscopy unit

Most evaluations performed in the endoscopy unit had diagnostic gastroscopy as the clinical indication (n=417), but the aScope Gastro was also used for therapeutic procedures including percutaneous endoscopic gastrostomy (PEG) placement or removal (n=17), dilation (n=20), foreign body removal (n=10), gastrointestinal (GI) bleeding (n=16), peroral endoscopic myotomy (POEM) (n=1), endoscopic mucosal resection (EMR)/endoscopic submucosal dissection (ESD) (n=15), as well as other therapeutic indications (n=45) such as stent placements, radiofrequency ablation (RFA) and intraoperative EGD (n=11) (Images 4,5).

This study has not collected details on the type of procedures performed in the OR; however, it is known that aScope Gastro has been used when assisting intraoperative GI surgeries and when performing endoscopic sleeve gastrostomies (ESG) and transoral incisionless fundoplication (TIF) procedures (Image 6).



Images 4 and 5: Transillumination with aScope Gastro during a PEG placement
Image 6: A transoral incisionless fundoplication (TIF) procedure with aScope Gastro

Of the 532 gastroscopies, 95% (n=507) of the procedures were successfully completed with the aScope Gastro. 4% (n=20) could not be completed with the aScope Gastro but were completed after the endoscopist converted to a reusable gastroscope. 1% (n=5) could not be completed with either the aScope Gastro or a reusable gastroscope. In 97% (n=516) of evaluations, the aScope Gastro was found to be clinically acceptable.

517 evaluations (97%) were stated to be “very satisfied”, “satisfied” or “neutral” (very satisfied n=70 (13%); satisfied n=309 (58%); neutral n=138 (26%) (Figure 4)). The average satisfaction score was 3.8±0.69.

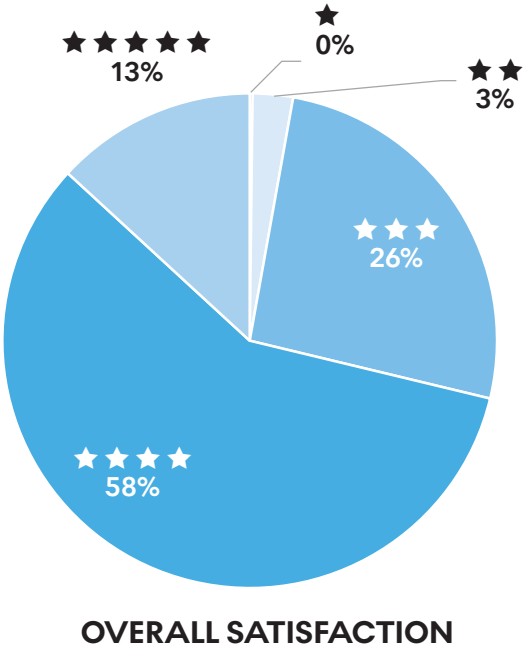


Figure 4: Satisfaction with aScope Gastro
(* very dissatisfied, ** dissatisfied, * neutral, **** satisfied, ***** very satisfied)**

The physicians in the OR (n=62) had a statistically significant higher average overall satisfaction score (4.13±0.61) compared to the physicians performing the EGD in the endoscopy unit (n=456, 3.78±0.68, p<0.05)), while the satisfaction score when the EGD was performed in other settings did not differ (Figure 5).

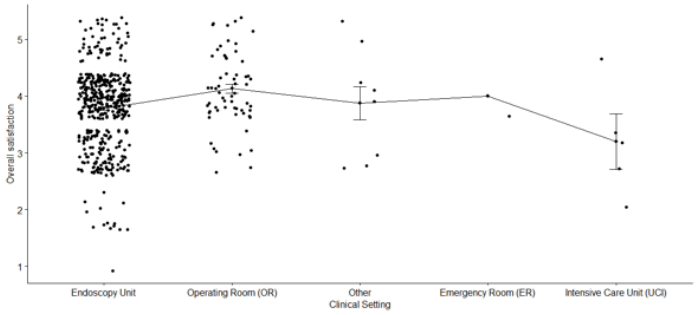


Figure 5: Average overall satisfaction for different settings

The overall satisfaction of all included physicians was 3.81 on a 5-point scale, with 5 as the best rate, with an SD of 0.69. There was no significant difference between gastroenterologists and surgeons, scoring 3.79±0.69 and 3.90±0.69, respectively.

In 97% of the evaluations, the physicians reported that the level of satisfaction for the aScope Gastro was “fair”, “good” or “very good” across all 10 attributes (Figure 6).

For those applicable, all assessed attributes had average ratings of the level of satisfaction ranging from 3.54±0.81 to 4.69±0.52. For those applicable, the attribute Angulation/210° Retroflexion had the highest proportion (99.8%) of positive satisfaction levels (“fair” n=11 (2%); “good” n=126 (25%); “very good” n=363 (72%)).

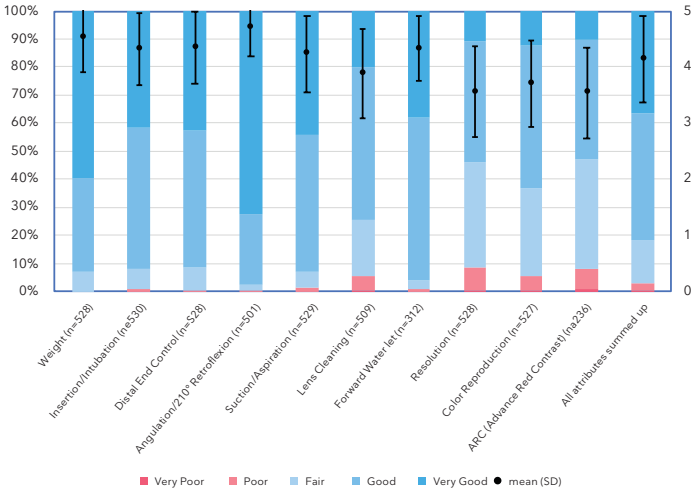


Figure 6: aScope Gastro average results of level of satisfaction of each attribute, and all attributes summed up

In general, the physicians found the aBox 2 endoscopy system easy and intuitive to use (Figure 7). The simplicity of the connection of the aBox 2 to the aScope Gastro had the highest score of 4.59±0.52, followed by the attribute of navigating using the aBox 2 touch screen. 99% of the evaluations found the attribute experience of the user interface superior in terms of ease of use, and similarly 96% found the attribute recording a video by using the aBox 2 recording button superior.

94% found the attribute taking an image by using the aBox 2 camera button superior; 2% found it adequate; and 4% found it inferior.

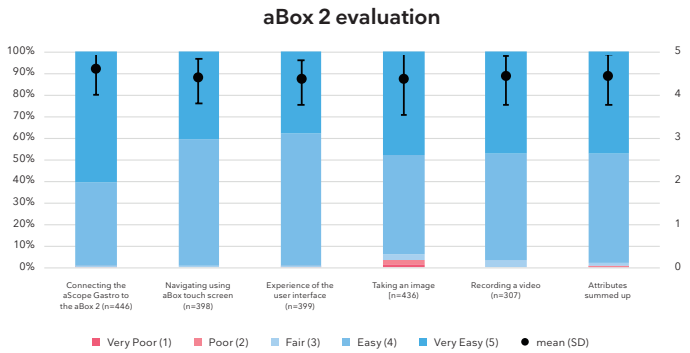


Figure 7: aBox 2 average results of each attribute, and all attributes summed up

DISCUSSION

To offer clinicians the best possible endoscope and to increase patient safety, medical device companies continue to innovate in the healthcare field. Improvements are incorporated in a variety of aspects, including clinical performance, visualization, ergonomics, organizational impact, safety and price. This user evaluation of the aScope Gastro shows that the attributes of the single-use aScope Gastro and of the aBox 2 are valued by physicians, and they are satisfied with all attributes asked about, including manoeuvrability and visualization.

This study showed that the aScope Gastro, with a clinical acceptability of 97% and a 95% completion rate, represents a good alternative to reusable gastroscopes.

Single-use endoscopes come with the advantage of being sterile, thus eliminating the risk of patient infection caused by endoscope cross-contamination. They might also provide a safer alternative for patients and staff after an EGD examination in infectious patients, e.g. patients with COVID, multidrug-resistant organisms (MDROs), tuberculosis, hepatitis and HIV. Some tools needed for endoscopic therapy, such as glues and needles, can damage the endoscope working channel, which can lead to risks of cross-infection. Single-use endoscopes also provide a backup solution when endoscopes are not available in situations where the reprocessing units are not working in that specific moment (e.g. outside working hours); when the reprocessing machines are missing water supply, having power problems or are in service; and in cases of staff shortage. Reusable endoscopes require special storage (drying cabinets) and high-level disinfection right after each use. This has to be performed by trained staff and requires recurrent training [4,5]. An accurate endoscope-reprocessing procedure is crucial, and involves multiple steps requiring skills and awareness of the guidelines associated with the procedure [5]. Reprocessing serves to eliminate microorganisms left on the inner and outer surfaces of the endoscope. The reprocessing guidelines can be challenging to adhere to, and they might not always be sufficient. A recent meta-analysis by Goyal et al. (2022) showed that up to 20% of the reprocessed gastrointestinal reusable endoscopes might be contaminated when used in patients [8–10].
While eliminating concerns about cross-contamination by being sterile straight from the pack, single-use endoscopes have no need for reprocessing or repair, which are two time-consuming and costly processes that might also reduce endoscope availability in the individual departments.

Retroflexion performance

A distinct difference between reusable gastroscopes and the single-use aScope Gastro is retroflexion performance. The physicians in this study were positive about retroflexion, with 98% commenting positively on it and 2% finding it neutral. Retroflexion is essential for the visualization of key anatomical and luminal structures and, although comparable to reusable gastroscopes on a specifications level, the aScope Gastro is single-use and does not degrade over time like conventional reusable gastroscopes do (Image 7).

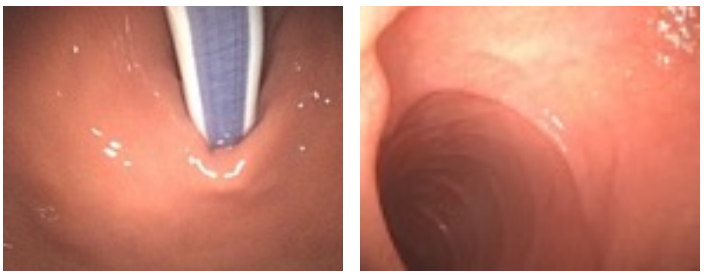


Image 7: Full 210° retroflexion showing the cardia from below during an EGD examination.
Image 8: Endoscopic image of the duodenum during an EGD examination.

Visualization

The physicians were positive regarding the field of view of the aScope Gastro, which fulfilled their needs in 99% of the evaluations (“fair” 17% (n=90); “good” 54.4% (n=287); “very good” 27.3% (n=144)). 1% (n=7) found the field of view “poor”, while none found it “very poor”, despite the image resolution with a single-use setup possibly being lower compared to a reusable setup (Image 8).

Out of 236 answers on Advanced Red Contrast (ARC™), 92% (n=217) were found to be positive, stating it to be “fair”, “good” or “very good”. ARC improves visibility using red colour tones to enhance mucosal surface variations. One endoscopist commented on their evaluation form: *“ARC was very useful when identifying the Z line and helped to identify the presence of villi in D2”*.

Strengths and limitations

The findings of this study provide new knowledge, as no study has yet been published examining the user experience of aScope Gastro. The study's global multicentre design, including physicians from 16 different countries, is a strength that allows for generalizability of the findings. Selection bias was addressed by targeting physicians from several countries. Non-response bias was limited by evaluation directly after finalizing the EGD procedure, and response bias was aimed to be avoided by clear and short questions and by providing scale-based answers to avoid leading questions.

A limitation of the survey is that it was conducted without any prior power calculation to estimate the desired sample size. The 532 evaluations may not represent all global user experience opinions. No pilot testing was performed, which could have raised the risk of misunderstanding the question and thereby having less accurate answers. The availability of the respondents after each case was sometimes challenging, due to the departmental workload and frequent staff shortages.

Sustainability

Sustainability is a critical consideration, not only for the users and societies but also for the industry. Although there are no reliable data to compare the environmental impact of single-use vs. reusable endoscopes regarding their manufacturing, repairs and reprocessing processes, Ambu is fully committed to bringing innovative products to the patients, also in this important aspect, and therefore has introduced initiatives to reduce or compensate for the current environmental effects. In 2023 Ambu launches aScope Gastro Large, the world's first endoscope manufactured with bioplastics, setting new standards for single-use sustainability. By 2025, Ambu will introduce bioplastics in all endoscopes handles and in some parts of the packaging material and will offer a recycling program in all major markets.

CONCLUSION

To our knowledge, this is the first study to collect global user experiences with the single-use gastroscope aScope Gastro from Ambu from a large number of procedures in many countries. The results show that physicians are satisfied overall, with a score of 3.8/5 and a clinical acceptance rate of 97%. In 99% of the physicians' evaluations, they found that the field of view with 140° of the aScope Gastro met or exceeded their expectations. The attributes of Angulation/210° Retroflexion, Weight of the gastroscope and Suction/Aspiration were rated as "very good", showing the remarkably good performance of the single-use gastroscope. In the 532 global evaluation forms, no complications or perforations were reported. The single-use gastroscope allows portability and constant availability, and it eliminates the risk of contamination and avoids time-consuming reprocessing steps, freeing valuable staff working hours when time is scarce[11]. These results indicate that aScope Gastro is a valuable alternative to reusable endoscopes for EGD practice.

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