wfhss
World Federation for Hospital Sterilisation Sciences

ENDOSCOPE REPROCESSING: RETROSPECTIVE ANALYSIS OF 90311 SAMPLES

PINEAU Lionel

EUROFINS HYGIENE HOSPITALIERE

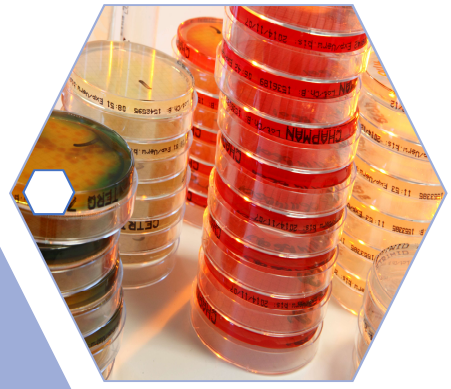
INTRODUCTION

Since 30 years a lot of progresses have been made regarding endoscope reprocessing thanks, among other things to :

- the publication of recommendations/ guidelines,
- the use of automatic endoscope reprocessors compliant to ISO 15883-4,
- the use of non-fixative disinfectants,
- the change in endoscope design,
- the implementation of microbiological surveillance program including endoscope sampling,
- …

which may have contributed directly or indirectly, to improve the overall quality of endoscopes.

INTRODUCTION



Infectious risk?

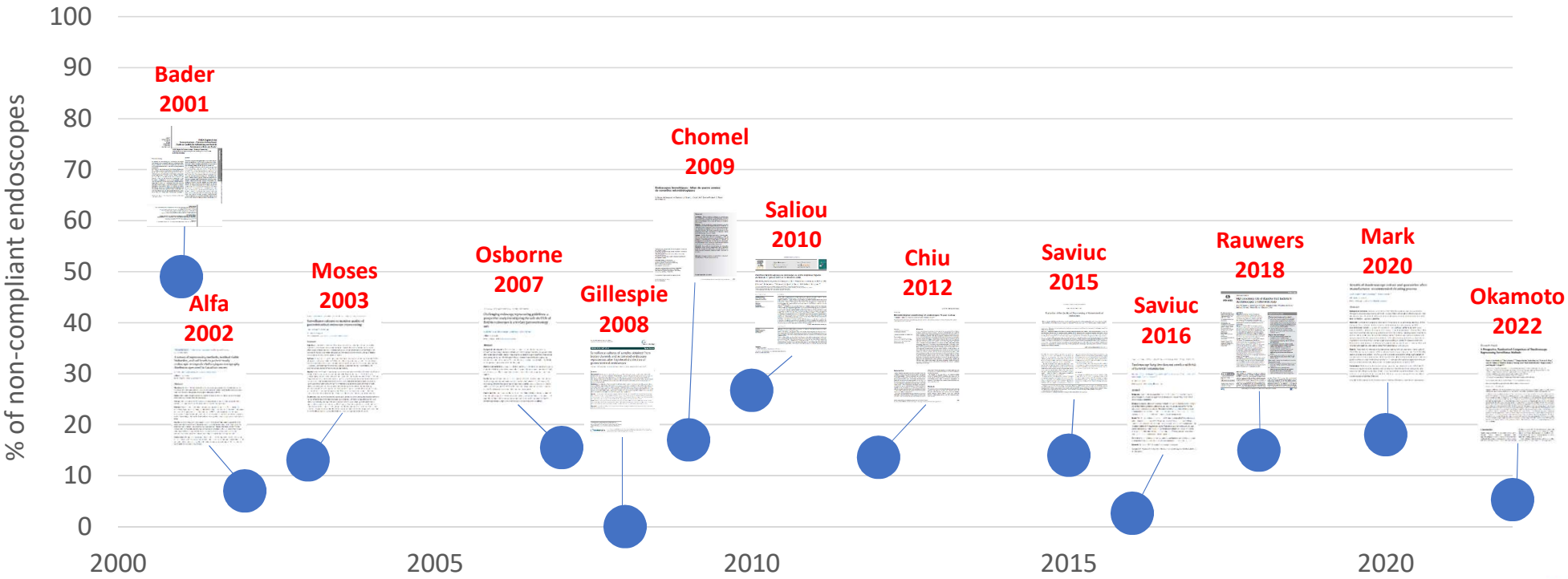
Microbial contamination

Endoscope contamination rate

What is the microbiological quality of your endoscopes?

INTRODUCTION

Studies published in the literature indicate that the contamination level (or non-compliance rate) of ready to use endoscopes varies from 0.4% to 49.0 %



INTRODUCTION

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

In total, from January 2013 through December 2014, the FDA received 75 MDRs encompassing approximately 135 patients in the United States relating to possible microbial transmission from reprocessed duodenoscopes.

"Although routine culturing of endoscopes is not part of current U.S. guidelines, recent outbreaks associated with duodenoscopes have led some facilities to consider regular monitoring to asses the adequacy of duodenoscope reprocessing".

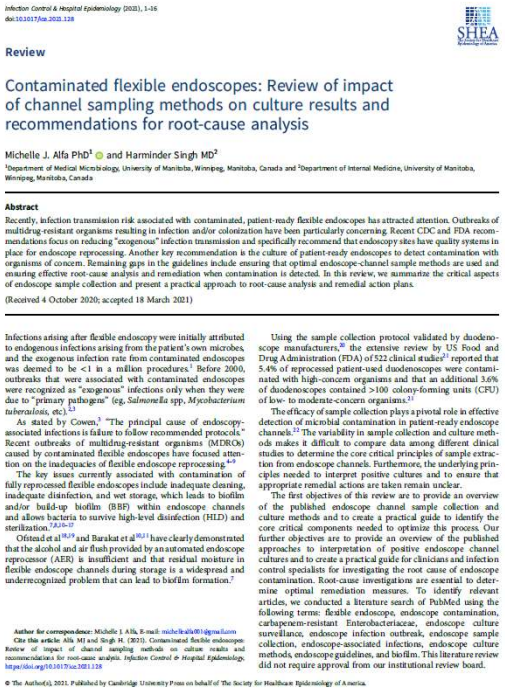
http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html

INFLUENCE OF SAMPLING METHOD

"One of the recent CDC and FDA recommendation is the culture of patient-ready endoscopes to detect contamination with organisms of concern."

"Remaining gaps in the guidelines include ensuring that optimal endoscope-channel sample methods are used and ensuring effective root-cause analysis and remediation when contamination is detected."

In this review, the critical aspects of endoscope sample collection are presented.



Infection Control & Hospital Epidemiology (2021), 1–16
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SHEA

Review

Contaminated flexible endoscopes: Review of impact of channel sampling methods on culture results and recommendations for root-cause analysis

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Abstract

Recently, infection transmission risk associated with contaminated, patient-ready flexible endoscopes has attracted attention. Outbreaks of multidrug-resistant organisms resulting in infection and/or colonization have been particularly concerning. Recent CDC and FDA recommendations focus on reducing "exogenous" infection transmission and specifically recommend that endoscopy sites have quality systems in place for endoscope reprocessing. Another key recommendation is the culture of patient-ready endoscopes to detect contamination with organisms of concern. Remaining gaps in the guidelines include ensuring that optimal endoscope-channel sample methods are used and ensuring effective root-cause analysis and remediation when contamination is detected. In this review, we summarize the critical aspects of endoscope sample collection and present a practical approach to root-cause analysis and remedial action plans.

(Received 4 October 2020; accepted 18 March 2021)

Infections arising after flexible endoscopy were initially attributed to endogenous infections arising from the patient's own microbes, and the exogenous infection rate from contaminated endoscopes was deemed to be <1 in a million procedures.[1] Before 2000, outbreaks that were associated with contaminated endoscopes were recognized as "exogenous" infections only when they were due to "primary pathogens" (eg, *Salmonella* spp, *Mycobacterium tuberculosis*, etc).[2,3]

As stated by Cowen,[2] "The principal cause of endoscopy-associated infections is failure to follow recommended protocols." Recent outbreaks of multidrug-resistant organisms (MDROs) caused by contaminated flexible endoscopes have focused attention on the inadequacies of flexible endoscope reprocessing.[4–9]

The key issues currently associated with contamination of fully reprocessed flexible endoscopes include inadequate cleaning, inadequate disinfection, and wet storage, which leads to biofilm and/or build-up biofilm (BBF) within endoscope channels and allows bacteria to survive high-level disinfection (HLD) and sterilization.[7,8,10–17]

Ofstead et al[18,19] and Barakat et al[20,21] have clearly demonstrated that the alcohol and air flush provided by an automated endoscope reprocessor (AER) is insufficient and that residual moisture in flexible endoscope channels during storage is a widespread and underrecognized problem that can lead to biofilm formation.[7]

Using the sample collection protocol validated by duodenoscope manufacturers,[20] the extensive review by US Food and Drug Administration (FDA) of 522 clinical studies[21] reported that 5.4% of reprocessed patient-used duodenoscopes were contaminated with high-concern organisms and that an additional 3.6% of duodenoscopes contained >100 colony-forming units (CFU) of low- to moderate-concern organisms.[21]

The efficacy of sample collection plays a pivotal role in effective detection of microbial contamination in patient-ready endoscope channels.[22] The variability in sample collection and culture methods makes it difficult to compare data among different clinical studies to determine the core critical principles of sample extraction from endoscope channels. Furthermore, the underlying principles needed to interpret positive cultures and to ensure that appropriate remedial actions are taken remain unclear.

The first objectives of this review are to provide an overview of the published endoscope channel sample collection and culture methods and to create a practical guide to identify the core critical components needed to optimize this process. Our further objectives are to provide an overview of the published approaches to interpretation of positive endoscope channel cultures and to create a practical guide for clinicians and infection control specialists for investigating the root cause of endoscope contamination. Root-cause investigations are essential to determine optimal remediation measures. To identify relevant articles, we conducted a literature search of PubMed using the following terms: flexible endoscope, endoscope contamination, carbapenem-resistant Enterobacteriaceae, endoscope culture surveillance, endoscope infection outbreak, endoscope sample collection, endoscope-associated infections, endoscope culture methods, endoscope guidelines, and biofilm. This literature review did not require approval from our institutional review board.

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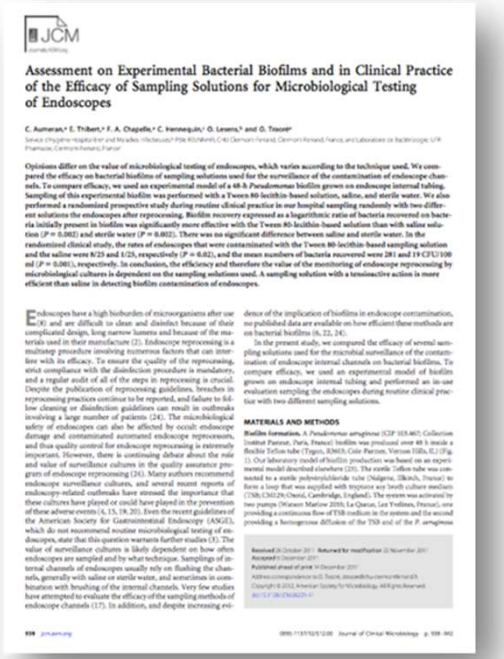
Alfa MJ, Singh H. Contaminated flexible endoscopes: Review of impact of channel sampling methods on culture results and recommendations for root-cause analysis. Infect Control Hosp Epidemiol. 2021 May 7:1-16. doi: 10.1017/ice.2021.128.

INFLUENCE OF THE EXTRACTION FLUID



JCM

Assessment on Experimental Bacterial Biofilms and in Clinical Practice of the Efficacy of Sampling Solutions for Microbiological Testing of Endoscopes

C. Aumeran,[a] E. Thibert,[a] F. A. Chapelle,[a] C. Hennequin,[a] O. Lesens,[b] and O. Traoré[a]

Opinions differ on the value of microbiological testing of endoscopes, which varies according to the technique used. We compared the efficacy on bacterial biofilms of sampling solutions used for the surveillance of the contamination of endoscope channels. To compare efficacy, we used an experimental model of a 48-h *Pseudomonas* biofilm grown on endoscope internal tubing. Sampling of this experimental biofilm was performed with a Tween 80-lecithin-based solution, saline, and sterile water. We also performed a randomized prospective study during routine clinical practice in our hospital sampling randomly with two different solutions the endoscopes after reprocessing. Biofilm recovery expressed as a logarithmic ratio of bacteria recovered on bacteria initially present in biofilm was significantly more effective with the Tween 80-lecithin-based solution than with saline solution ($P = 0.002$) and sterile water ($P = 0.002$). There was no significant difference between saline and sterile water. In the randomized clinical study, the rates of endoscopes that were contaminated with the Tween 80-lecithin-based sampling solution and the saline were 8/25 and 1/25, respectively ($P = 0.02$), and the mean numbers of bacteria recovered were 281 and 19 CFU/100 ml ($P = 0.001$), respectively. In conclusion, the efficiency and therefore the value of the monitoring of endoscope reprocessing by microbiological cultures is dependent on the sampling solutions used. A sampling solution with a tensioactive action is more efficient than saline in detecting biofilm contamination of endoscopes.

Endoscopes have a high bioburden of microorganisms after use (8) and are difficult to clean and disinfect because of their complicated design, long narrow lumens and because of the materials used in their manufacture (2). Endoscope reprocessing is a multistep procedure involving numerous factors that can interfere with its efficacy. To ensure the quality of the reprocessing, strict compliance with the disinfection procedure is mandatory, and a regular audit of all of the steps in reprocessing is crucial. Despite the publication of reprocessing guidelines, breaches in reprocessing practices continue to be reported, and failure to follow cleaning or disinfection guidelines can result in outbreaks involving a large number of patients (24). The microbiological safety of endoscopes can also be affected by occult endoscope damage and contaminated automated endoscope reprocessors, and thus quality control for endoscope reprocessing is extremely important. However, there is continuing debate about the role and value of surveillance cultures in the quality assurance program of endoscope reprocessing (24). Many authors recommend endoscope surveillance cultures, and several recent reports of endoscopy-related outbreaks have stressed the importance that these cultures have played or could have played in the prevention of these adverse events (4, 15, 19, 20). Even the recent guidelines of the American Society for Gastrointestinal Endoscopy (ASGE), which do not recommend routine microbiological testing of endoscopes, state that this question warrants further studies (3). The value of surveillance cultures is likely dependent on how often endoscopes are sampled and by what technique. Samplings of internal channels of endoscopes usually rely on flushing the channels, generally with saline or sterile water, and sometimes in combination with brushing of the internal channels. Very few studies have attempted to evaluate the efficacy of the sampling methods of endoscope channels (17). In addition, and despite increasing evidence of the implication of biofilms in endoscope contamination, no published data are available on how efficient these methods are on bacterial biofilms (6, 22, 24).

In the present study, we compared the efficacy of several sampling solutions used for the microbial surveillance of the contamination of endoscope internal channels on bacterial biofilms. To compare efficacy, we used an experimental model of biofilm grown on endoscope internal tubing and performed an in-use evaluation sampling the endoscopes during routine clinical practice with two different sampling solutions.

MATERIALS AND METHODS

Biofilm formation. A *Pseudomonas aeruginosa* (CIP 103.467; Collection Institut Pasteur, Paris, France) biofilm was produced over 48 h inside a flexible Tefton tube (Tygon, 3/16ID; Cole Parmer, Vernon Hills, IL) (Fig. 1). Our laboratory model of biofilm production was based on an experimental model described elsewhere (23). The sterile Tefton tube was connected to a sterile polyvinylchloride tube (Vidgrip, Ilkirch, France) to form a loop that was supplied with tryptone soy broth culture medium (TSB; CM129; Oxoid, Cambridge, England). The system was activated by two pumps (Watson Marlow 205S; Le Queux, Les Ymlines, France), one providing a continuous flow of TSB medium in the system and the second providing a homogenous diffusion of the TSB and of the *P. aeruginosa*

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0095-1137/12/$12.00

The Tween 80-lecithin-based solution is more efficient than saline solution (NaCl)

- in detecting the presence of biofilm,
- In detecting contaminated endoscopes (8/25 vs. 1/25 for NaCl),
- In increasing the mean number of bacteria recovered (281 CFU vs. 19 UFC/100 ml for NaCl)".

There was no significant difference between saline (NaCl 0,9%) and sterile water.

C. Aumeran, E. Thibert, F. A. Chapelle, C. Hennequin, O. Lesens and O. Traoréa. Assessment on experimental Bacterial Biofilms and in Clinical Practice of the Efficacy of Sampling Solutions for Microbiological Testing of Endoscopes. Journal of Clinical Microbiology. March 2012. Volume 50. Number 3. 938–942

TO SUMMARIZE

Since the recent outbreaks associated with duodenoscopes, the **interest of endoscope sampling** to asses regularly the adequacy of endoscope reprocessing, is well accepted.

Studies published in the literature indicate that the **contamination level** (or non-compliance rate) of ready to use endoscopes varies **from 0.4% to 49.0 %** .

Differences observed between these studies regarding, the sampling method (flush vs flush-brush-flush, one channel vs all channels, …), the nature of the sampling solution (water, 0.9% NaCl, neutralizer,…), the sample culturing protocols (filtration vs centrifugation,…), the interpretation criteria and the limited number of samples analysed, **make difficult the comparison and the interpretation of these values**.

8

OBJECTIVE OF THE STUDY

Perform a retrospective analysis of endoscope sampling realized in France between 2004 and 2021, to determine the mean contamination rate of ready to use endoscopes, evaluate the global trend and identified if differences exist between endoscope families/models.

- 90 311 endoscopes samples collected in 490 private or public hospitals in France,
- The sampling method was based upon the method described in the French guidelines [1, 2].
- All samples were performed by trained technicians.

1. Eléments d'assurance qualité en hygiène relatifs au contrôle microbiologique des endoscopes et à la traçabilité en endoscopie. Conseil supérieur d'hygiène publique de France. March 2007 Available at: http://nosobase.chu-lyon.fr/recommandations/ctinils/2007_dispositifs-médicaux_CTINILS.pdf Accessed 16/11/12.
2. DGOS/PF2/DGS/VVS1/PP3/2018/195 du 2 août 2018 relative à l'actualisation du traitement des endoscopes souples thermosensibles à canaux de type duodénoscope au sein des structures de soins

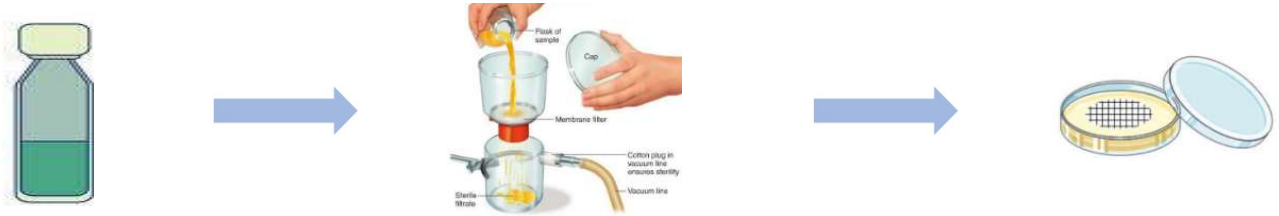
ENDOSCOPE SAMPLING METHOD

- Endoscopes were sampled at least 6 hours after the last reprocessing procedure.
- All endoscope channels were flushed with the recovering solution (20 to 50 ml per channel) using the “flush-suction-flush” method.
- For duodenoscope, the sampling method included a brushing of the distal end as described in several guidelines [1, 2].

1. Centers for Disease Control and Prevention. Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing. Available at http://medbox.iiab.me/modules/en-cdc/www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html. Last accessed 09 April 2022.
2. DGOS/PF2/DGS/VVS1/PP3/2018/195 du 2 août 2018 relative à l’actualisation du traitement des endoscopes souples thermosensibles à canaux de type duodénoscope au sein des structures de soins

SAMPLE ANALYSIS METHOD

- The sampling solution collected at the distal end of the endoscope was analyzed by membrane filtration. All the volume collected was filtered.
- Membranes were incubated 5 days at 30°C on PCA agar (+ 7H10 for 21 days if mycobacteria need to be detected). Microorganisms recovered were identified using standard laboratory method (API, Maldi-Tof,..).
- Results were expressed as the total number of CFU/endoscope.



INTERPRETATION CRITERIA

ENDOSCOPES	TARGET LEVEL	ALERT LEVEL	ACTION LEVEL
Introduced into sterile cavities (e.g. High risk endoscopes: choledoscopes, hysteroscopes and cystoscopes,)	Total aerobic flora <1 CFU		Total aerobic flora >1 CFU or presence of indicator microorganisms (2)
In contact with mucous membranes (e.g. gastroscope, colonoscopes, bronchoscopes, duodenoscopes,..)	Total aerobic flora <5 CFU and no indicator microorganisms	Total aerobic flora between 5 and 25 CFU and no indicator microorganisms	Total aerobic flora >25 CFU or presence of indicator microorganisms

(1) Eléments d'assurance qualité en hygiène relatifs au contrôle microbiologique des endoscopes et à la traçabilité en endoscopie. Conseil supérieur d'hygiène publique de France. March 2007 Available at: http://nosobase.chu-lyon.fr/recommandations/ctinils/2007_dispositifs-médicaux_CTINILS.pdf Accessed 16/11/12.

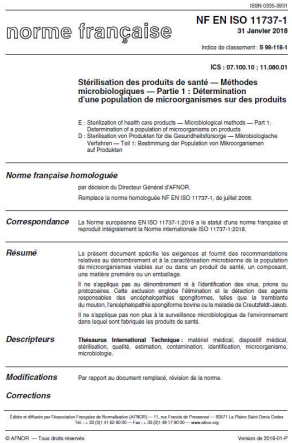
(2) Indicator microorganisms: *Staphylococcus aureus*, Enterobacteriaceae, *Pseudomonas aeruginosa* and other *Pseudomonas*, *Stenotrophomonas maltophilia, Acinetobacter sp*, *Candida sp.*

(3) < 10 CFU/100 ml at 22°C and no *Pseudomonas aeruginosa* for 100 ml

(4) <100 CFU/ml at 22°C and <10 CFU/ml at 37°C, no *Pseudomonas aeruginosa* for 100 ml and no Coliforms for 100 ml

VALIDATION OF THE SAMPLING METHOD

Validation of the sampling method by repeated sampling according to ISO 11737-1.



norme française

NF EN ISO 11737-1
31 Janvier 2018

ICS : 07.100.10 ; 11.080.01

Stérilisation des produits de santé — Méthodes microbiologiques — Partie 1 : Détermination d'une population de microorganismes sur des produits

E : Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
D : Sterilisation von Produkten für die Gesundheitsfürsorge — Mikrobiologische Verfahren — Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten

Norme française homologuée
par décision du Directeur Général d'AFNOR.
Remplace la norme homologuée NF EN ISO 11737-1, de juillet 2006.

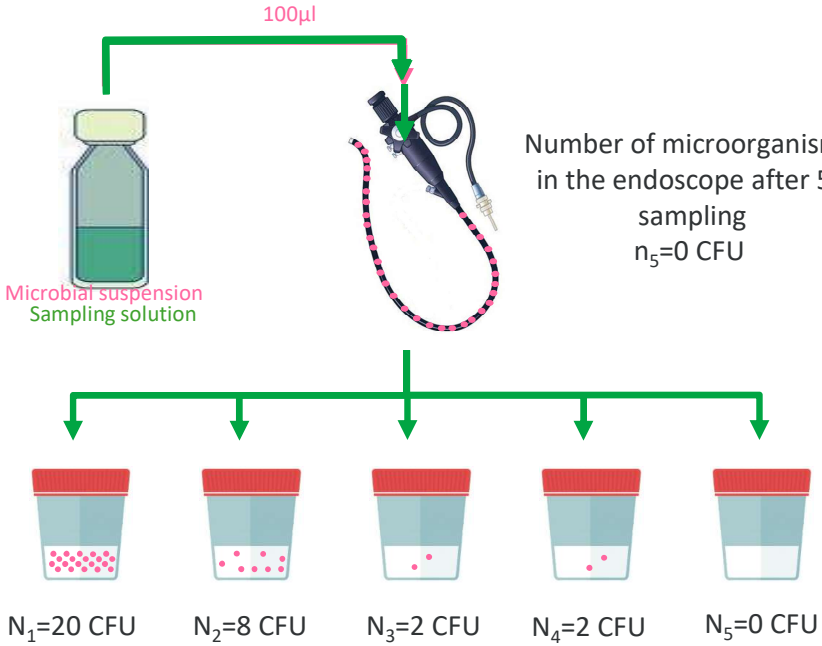
Correspondance La Norme européenne EN ISO 11737-1:2018 a le statut d'une norme française et reproduit intégralement la Norme internationale ISO 11737-1:2018.

Résumé Le présent document spécifie les exigences et fournit des recommandations relatives au dénombrement et à la caractérisation microbienne de la population de microorganismes viables sur ou dans un produit de santé, un composant, une matière première ou un emballage.
Il ne s'applique pas au dénombrement ni à l'identification des virus, prions ou protozoaires. Cette exclusion englobe l'élimination et la détection des agents responsables des encéphalopathies spongiformes, telles que la tremblante du mouton, l'encéphalopathie spongiforme bovine ou la maladie de Creutzfeldt-Jakob.
Il ne s'applique pas non plus à la surveillance microbiologique de l'environnement dans lequel sont fabriqués les produits de santé.

Descripteurs **Thésaurus International Technique :** matériel médical, dispositif médical, stérilisation, qualité, estimation, contamination, identification, microorganisme, microbiologie.

Modifications Par rapport au document remplacé, révision de la norme.

Corrections



$$R = N1/\sum_{k=0}^{n} N_k$$
$$= 20/\ (20+8+2+2+0)$$
$$= 20/32 = 62{,}5\%$$

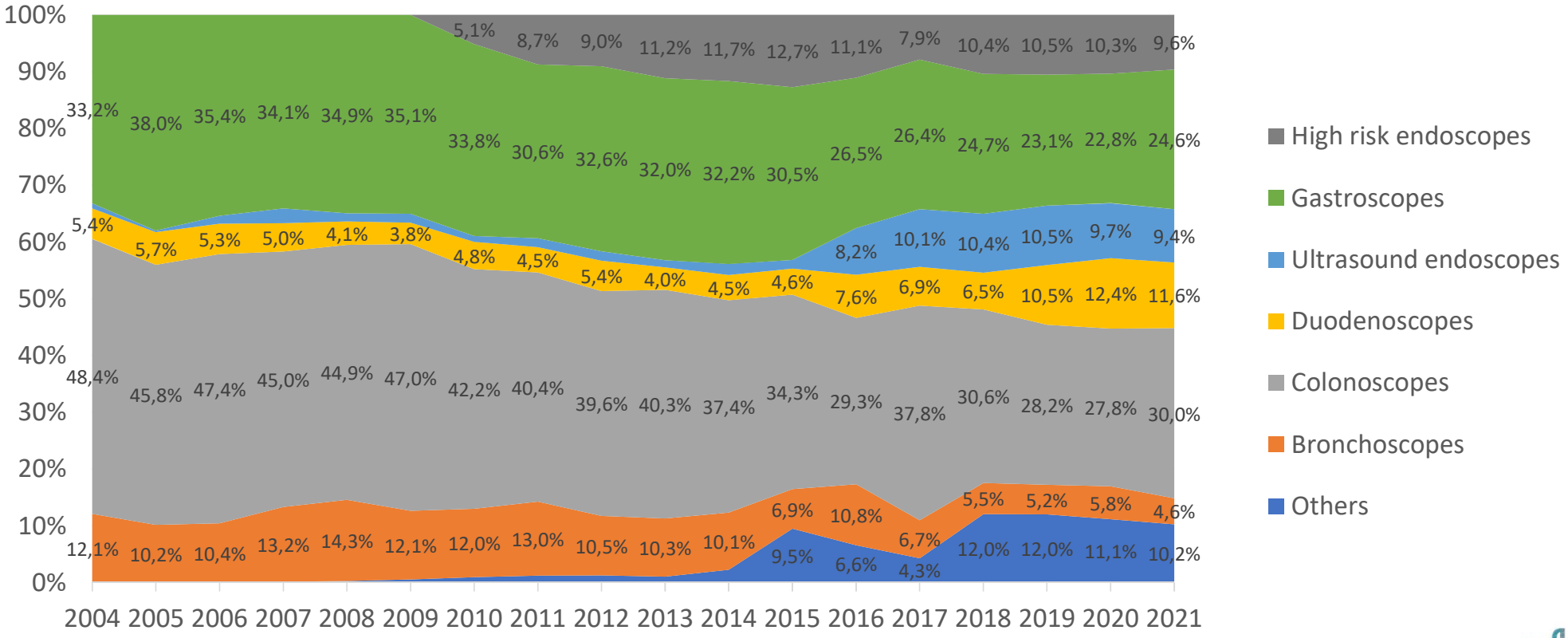
$$\sum_{k=0}^{N} N_k = n_0$$

$$\boldsymbol{R(2) = 76{,}5\%}$$

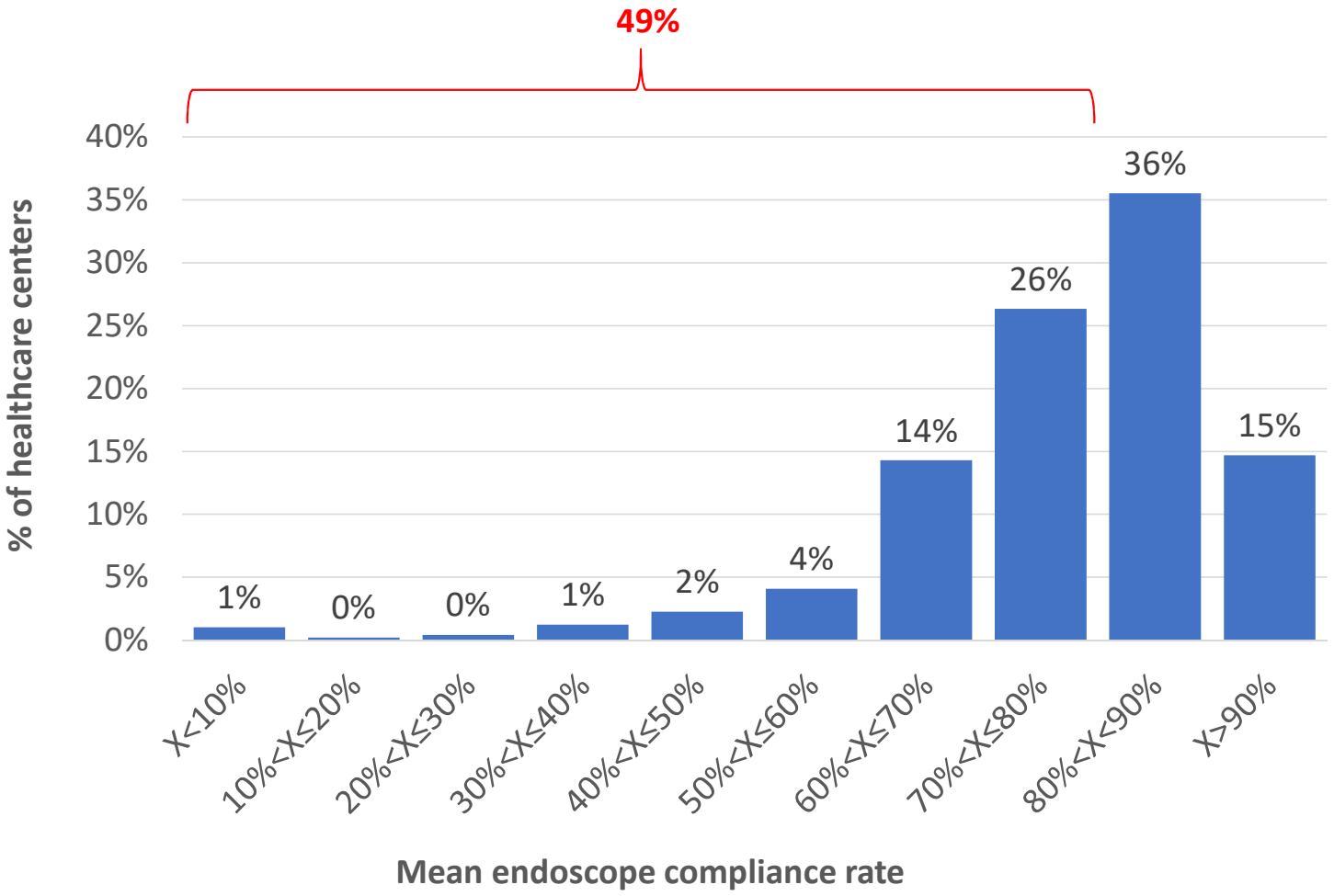
(1) (3) ISO 11737-1 annex C1 Guideline. Available at: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46116. Accessed 10/15/12.
(2) RICHARD M, LUU DUC D, PINEAU L. Efficacy of recovery solutions for endoscopes sampling : a comparative study. SHEA 19th Annual Scientific Meeting, San Diego, March 21st 2009

RESULTS

Nature of the endoscopes sampled



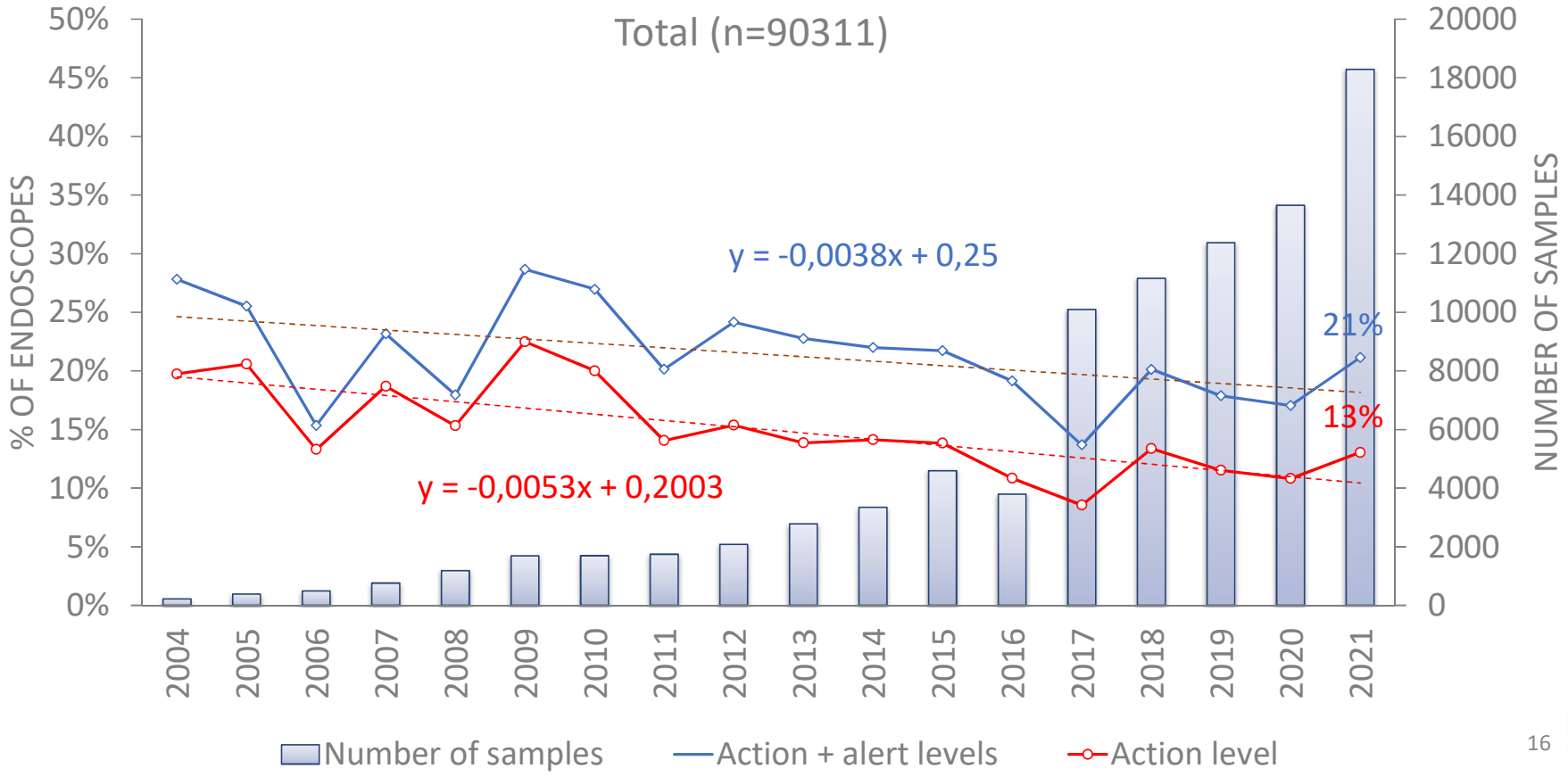
RESULTS



Distribution of the 490 private or public health facilities according to the mean compliance rate of their endoscopes.

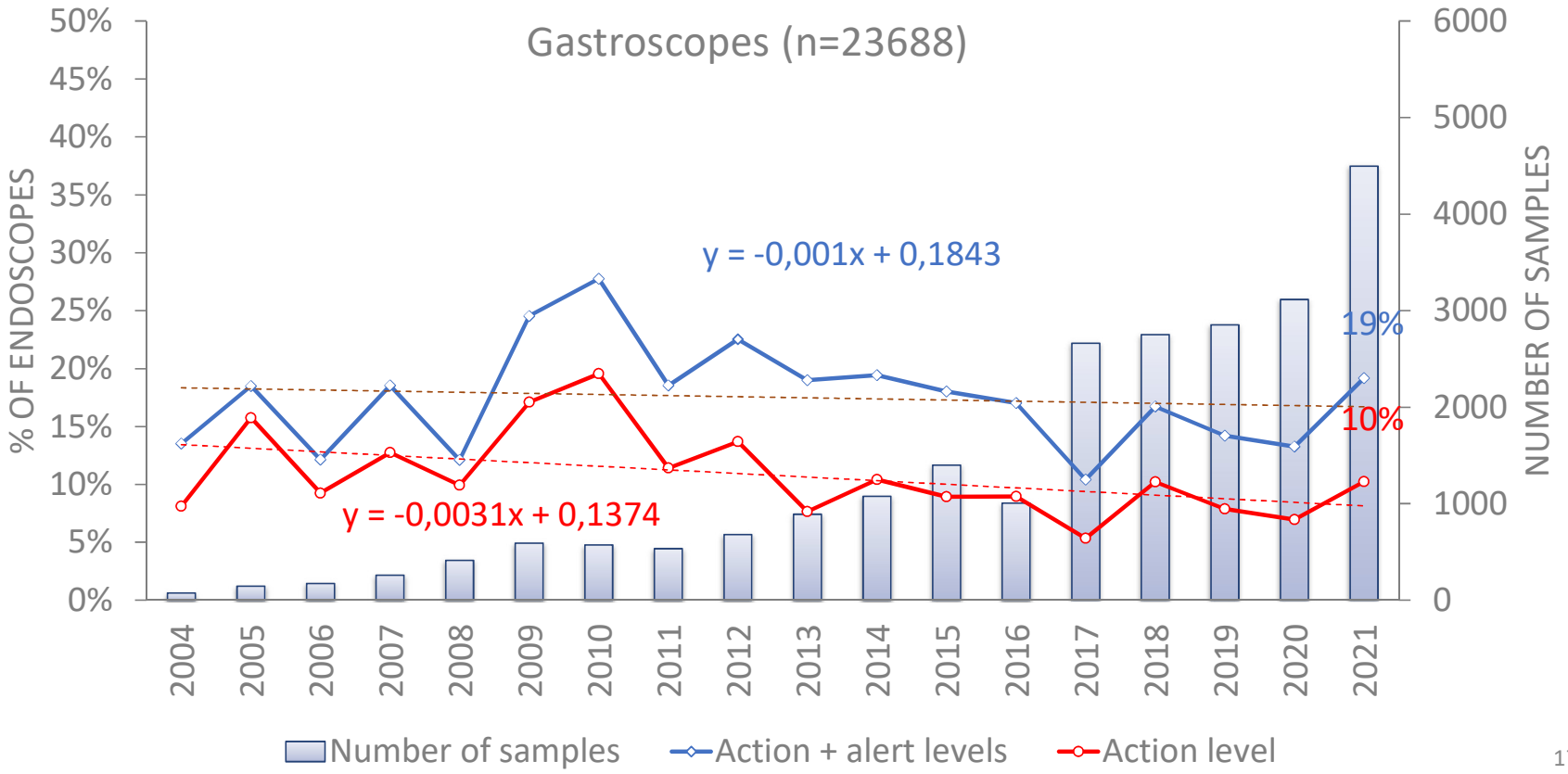
RESULTS

Evolution of the percentage of non-compliant endoscopes.



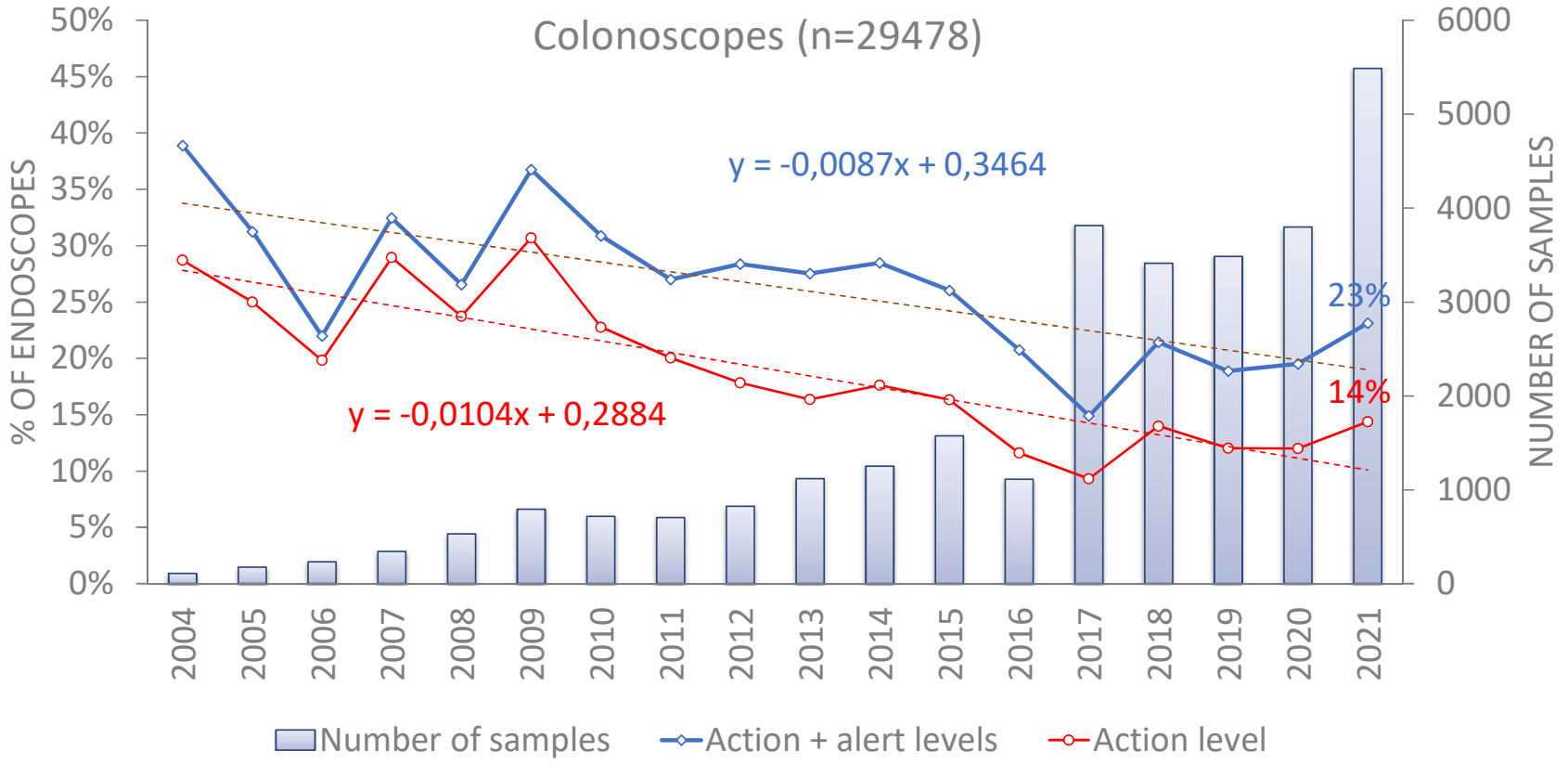
RESULTS

Evolution of the percentage of non-compliant gastroscopes.



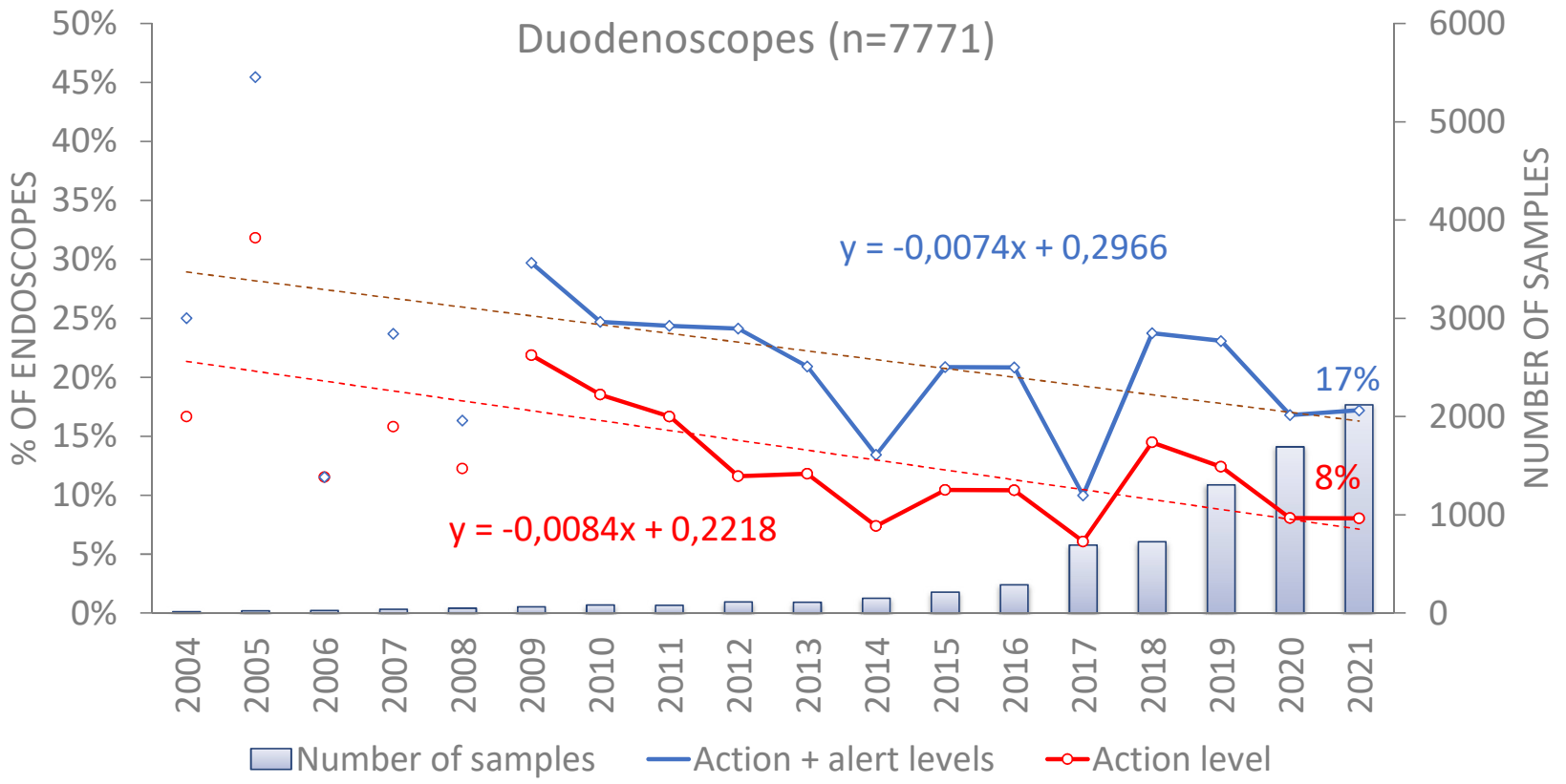
RESULTS

Evolution of the percentage of non-compliant colonoscopes.



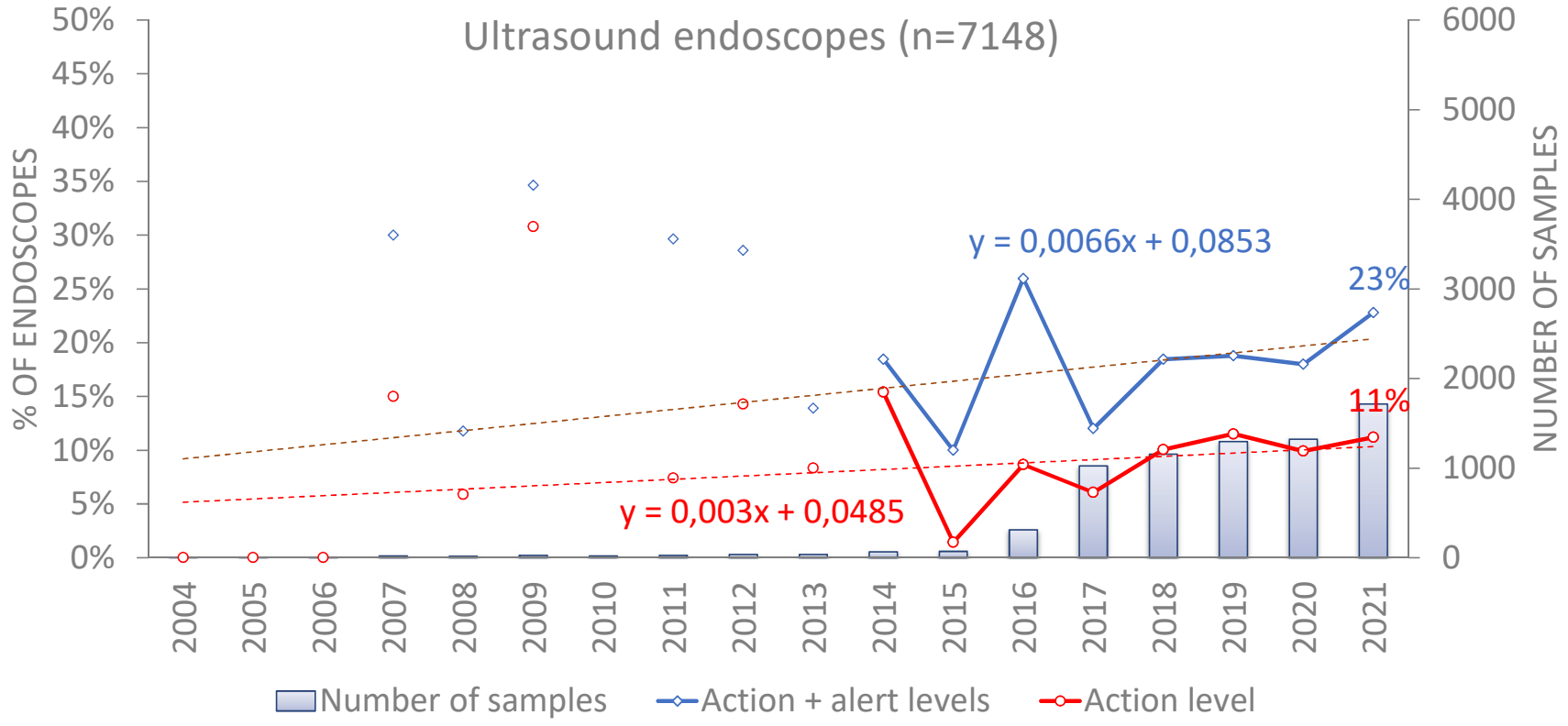
RESULTS

Evolution of the percentage of non-compliant duodenoscopes.



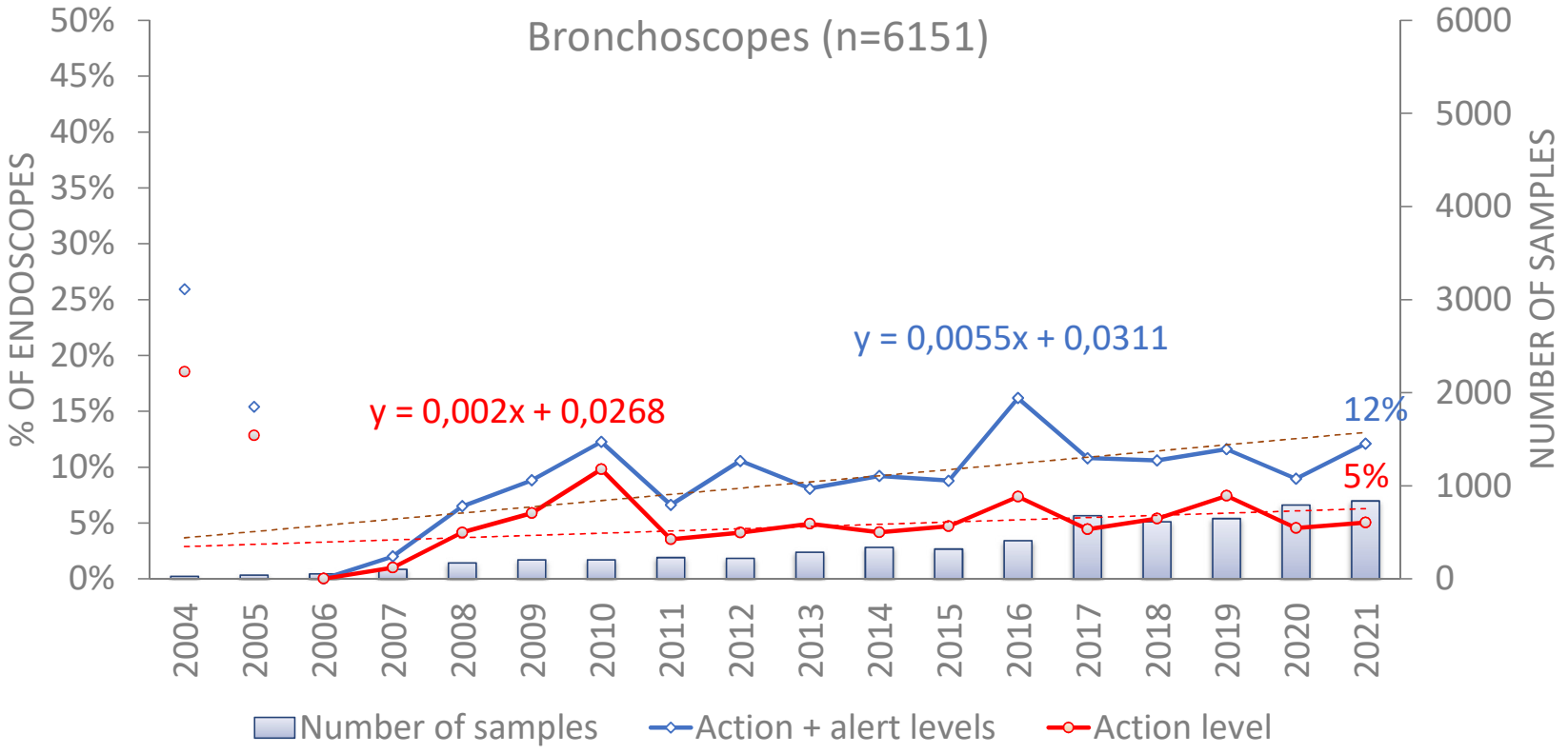
RESULTS

Evolution of the percentage of non-compliant ultrasound endoscopes.



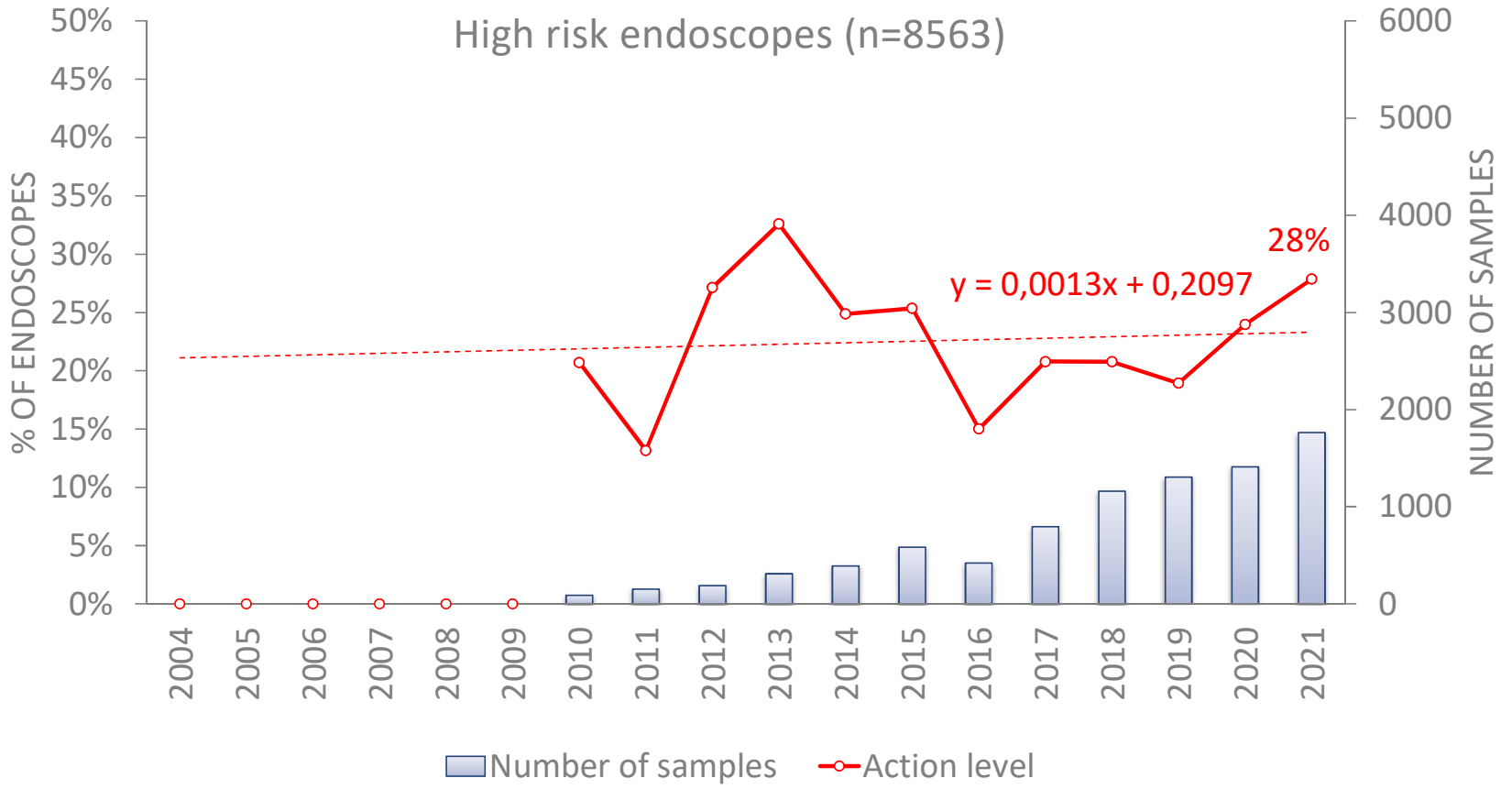
RESULTS

Evolution of the percentage of non-compliant bronchoscopes.



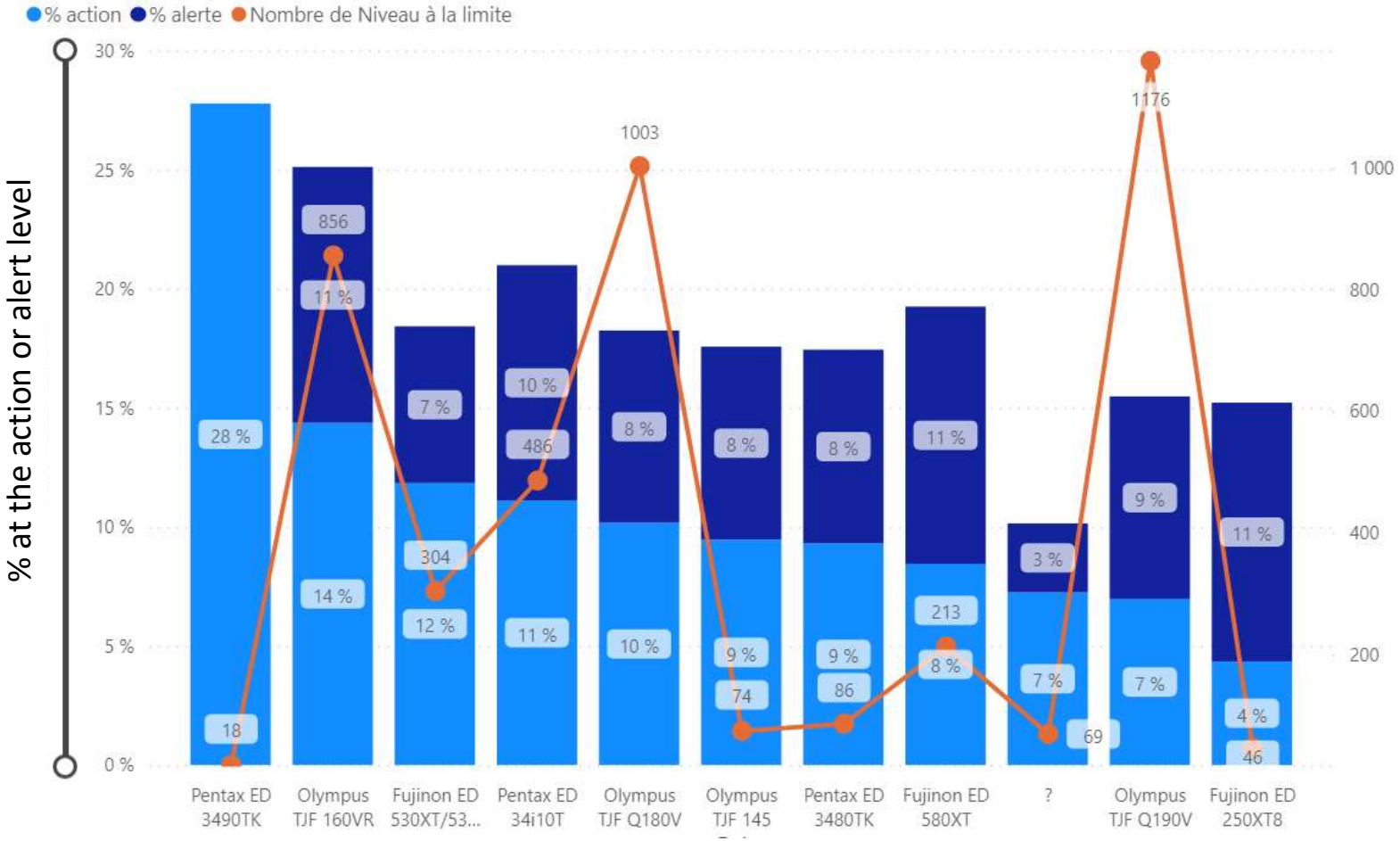
RESULTS

Evolution of the percentage of non-compliant High risk endoscopes.



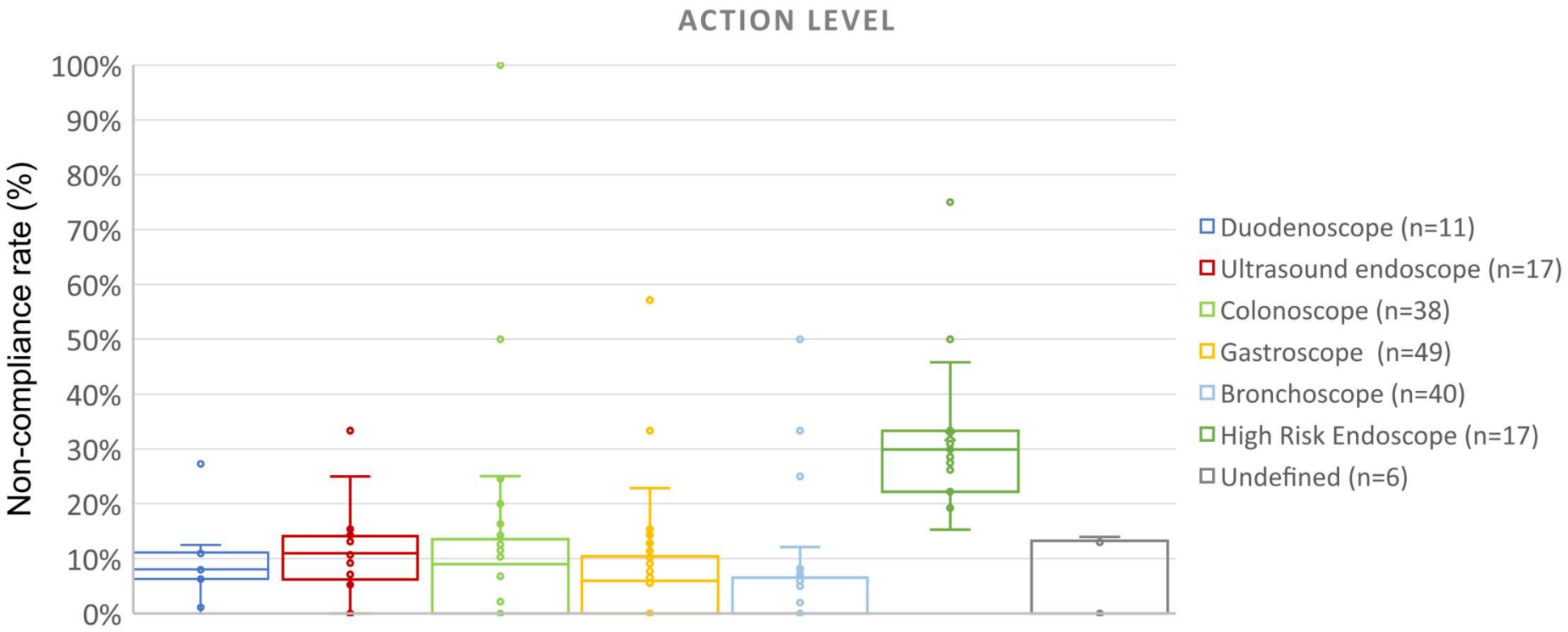
23RD WORLD STERILIZATION CONGRESS

DUODENOSCOPE CONTAMINATION RATE



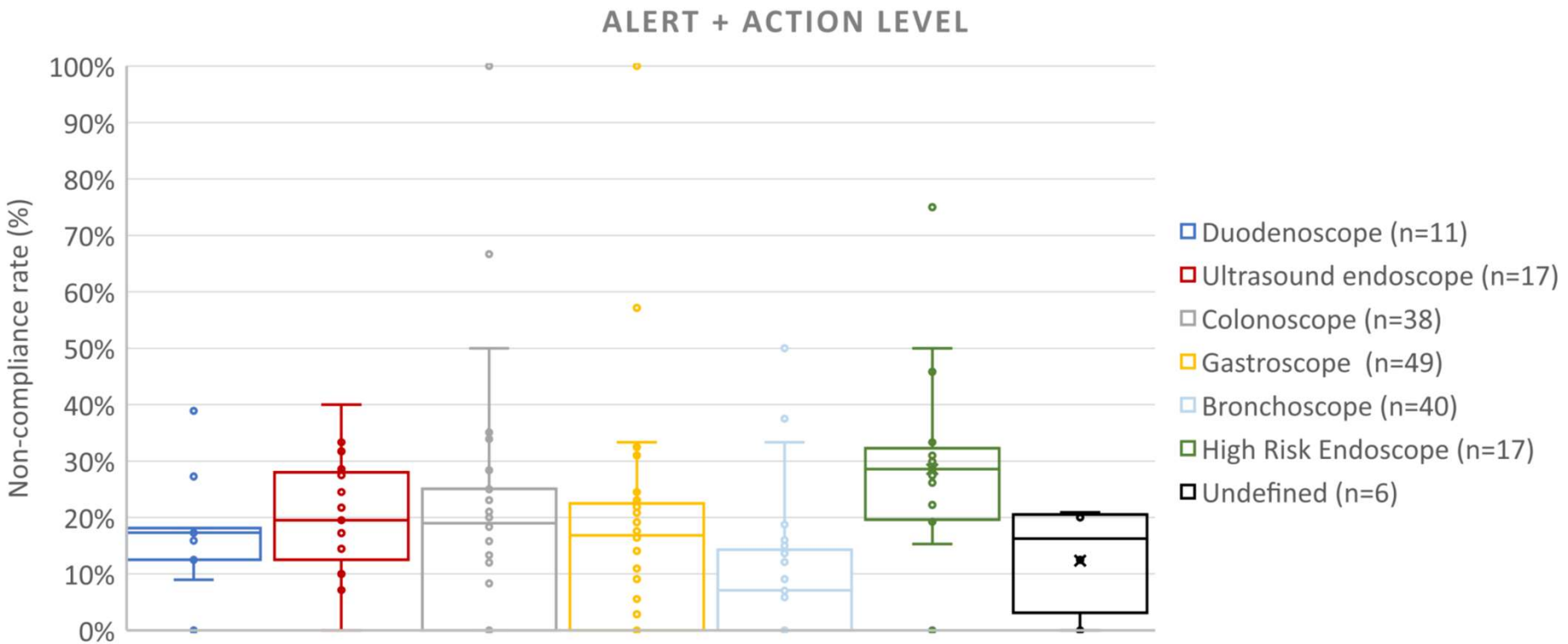
RESULTS

Distribution of endoscopes models according to their mean non-compliance rate



SLIDE TITLE

Distribution of endoscopes models according to their mean non-compliance rate



RESULTS

Nature of the microorganisms recovered from endoscope channels. Occurrence of each microorganism in endoscope samples when a growth was observed (n=16959)

MICROORGANIMS	% (1)	Contamination source
Fungi	11	Environment
Bacillus sp.	35	Environment
Coagulase-negative staphylococcus, *Micrococcus sp.*	35	Human
Other Gram-positif cocci (*Staphylococcus aureus*, *Strpetococcus sp.*,..)	1	Human
Corynebacterium sp.	2	Human
Yeast (*Candida sp.*, *Cryptococcus sp.*, *Rhodotorula sp.*,..)	3	Human
Neisseria sp.	3	Human
Enterobacteriaceae (*Enterobacter sp.*, *Escherichia coli*, *Klebsiella sp.*, *Proteus sp.*, *Serratia sp.*....)	13	Human
Pseudomonas aeruginosa	13	Water
Pseudomonas sp.	6	Water
Other Gram-negative rod (*Burkholderia sp.*, *Stenotrophomonas sp.*, *Sphinghomonas sp.*, *Aeromonas sp.*, *Brevundimonas sp.*,...)	18	Water

(1) The same sample may contain several microorganisms

23RD WORLD STERILIZATION CONGRESS

TO SUMMARIZE

Endoscope familiy	% at the action level in 2021	Trend (%/year)	% at the action and alert levels in 2021	Trend (%/year)
Bronchoscope (n=6151)	5%	↗ (+0,2%)	12%	↗ (+0,6%)
Gastroscope (n=23688)	10%	↘ (-0,3%)	19 %	↘ (-0,1%)
Colonoscope (n=29478)	14%	↘ (-1,0%)	23%	↘ (-0,9%)
Duodenoscope (n=7771)	8%	↘ (-0,8%)	17%	↘ (-0,7%)
Ultrasound endoscope (n=7148)	11%	↗ (+0,3%)	23%	↗ (+0,7%)
High risk endoscope (n=8563)	28%	↗ (+1,3%)	NA	NA
Total (n=90311)	**13%**	**↘ (-0,5%)**	**21%**	**↘ (-0,4%)**

CONCLUSIONS

In 2021 following French guidelines:

- **13.0% of the endoscopes should be quarantine (i.e. at the action level)**
- **8.1% present a contamination rate away from what is considered to be safe use conditions.**

Some improvements are observed but the current microbiological quality of endoscopes remains unacceptable and the safety margin provided by the current reprocessing procedures is not high enough.

Additional efforts must be made to improve the overall microbiological quality of our endoscopes and reduce the risk associated with their use.

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QUESTIONS?