Autorizzazione a contrarre e contestuale affidamento, ai sensi dell'art. 50, comma 1, lett. b), del D.Lgs. n. 36/2023, della fornitura in noleggio full risk, della durata di 60 mesi, di n. 1 dispositivo per la disinfezione ad alto livello degli endoscopi flessibili, da destinare alla S.C. di Otorinolaringoiatria del Presidio Ospedaliero di Alghero – ASL n. 1.
CIG: BD10617DF1

Offerta Economica relativa a

Descrizione Autorizzazione a contrarre e contestuale affidamento, ai sensi dell'art. 50, comma 1, lett. b), del D.Lgs. n. 36/2023, della fornitura in noleggio full risk, della durata di 60 mesi, di n. 1 armadio per la disinfezione di endoscopi flessibili da destinare alla S.C. di Otorinolaringoiatria dell'Ospedale Civile di Alghero, ASL n. 1

RdO nr. 6585072

Numero lotto 0

Amministrazione titolare del procedimento

Ente acquirente	AZIENDA SOCIO SANITARIA LOCALE - 1 - DI SASSARI		
Ufficio	S.C. FLUSSI INFORMATIVI E TECNOLOGIE SANITARIE		
Codice fiscale	02884000908	**Codice univoco ufficio**	Non presente
Indirizzo sede	Via enrico costa 57		
Città	Sassari		
Recapito telefonico	+390792005055		
Email	GIUSEPPINA.DURGALI@ASLSASSARI.IT		
Punto ordinante	Giuseppina Durgali		

Concorrente

Forma di partecipazione

Singolo operatore economico

Ragione sociale/Denominazione

PENTAX ITALIA S.R.L.

Partita IVA

11159150157

Tipologia societaria

Società a responsabilità limitata (SRL)

Oggetto dell'Offerta

SISTEMI DI E-PROCUREMENT

Formulazione dell'Offerta Economica = Valore economico (Euro)

Nome	Valore
Valore offerto	109200,00

Il Concorrente, nell'accettare tutte le condizioni specificate nella documentazione del procedimento, altresì dichiara:

- che la presente offerta è irrevocabile ed impegnativa sino al termine di conclusione del procedimento, così come previsto nella lex specialis;
- che la presente offerta non vincolerà in alcun modo la Stazione Appaltante/Ente Committente;
- di aver preso visione ed incondizionata accettazione delle clausole e condizioni riportate nel Capitolato Tecnico e nella documentazione di Gara, nonché di quanto contenuto nel Capitolato d'oneri/Disciplinare di gara e, comunque, di aver preso cognizione di tutte le circostanze generali e speciali che possono interessare l'esecuzione di tutte le prestazioni oggetto del Contratto e che di tali circostanze ha tenuto conto nella determinazione dei prezzi richiesti e offerti, ritenuti remunerativi;
- di non eccepire, durante l'esecuzione del Contratto, la mancata conoscenza di condizioni o la sopravvenienza di elementi non valutati o non considerati, salvo che tali elementi si configurino come cause di forza maggiore contemplate dal codice civile e non escluse da altre norme di legge e/o dalla documentazione di gara;
- che i prezzi/sconti offerti sono omnicomprensivi di quanto previsto negli atti di gara;
- che i termini stabiliti nel Contratto e/o nel Capitolato Tecnico relativi ai tempi di esecuzione delle prestazioni sono da considerarsi a tutti gli effetti termini essenziali ai sensi e per gli effetti dell'articolo 1457 cod. civ.;
- che il Capitolato Tecnico, così come gli altri atti di gara, ivi compreso quanto stabilito relativamente alle modalità di esecuzione contrattuali, costituiranno parte integrante e sostanziale del contratto che verrà stipulato con la stazione appaltante/ente committente.

ATTENZIONE: QUESTO DOCUMENTO NON HA VALORE SE PRIVO DELLA SOTTOSCRIZIONE A MEZZO FIRMA DIGITALE

PENTAX Italia s.r.l. con Unico Socio
Via Clemente Prudenzio n.16
20138 Milano – Italy
Tel. 02.50.99.58.1
www.pentaxmedical.com

11200051

Spett.le
AZIENDA PER LA TUTELA DELLA SALUTE
VIA ENRICO COSTA 57(PIAZZA FIUME)
07100 SASSARI (SS)

Milano 19/09/2026

Ns. rif. 1000005049/522/TD
Vs. rif. RDO 6585072 del 18/09/2026

Oggetto: Procedura Mepa - Trattativa Diretta per la fornitura in noleggio full risk, della durata di 60 mesi, di n.1 armadio per la disinfezione di Endoscopi flessibili da destinare alla S.C. di Otorinolaringoiatria dell'Ospedale Civile di Alghero - ASL N. 1 di Sassari

CONDIZIONI DI ASSISTENZA TECNICA E MANUTENZIONE FULL-RISK

Con il presente contratto PENTAX Italia Srl con Unico Socio si impegna a fornire, alle condizioni e termini che seguono, i servizi di manutenzione come di seguito specificati, volti ad assicurare il regolare funzionamento delle apparecchiature offerte.
Il contratto di manutenzione Full-Risk, per la durata 5 anni su UV SMART D60 , comprende:

Manutenzione preventiva

N. 1 visita annuale, così come richiesto dal produttore, programmata nei giorni ed orari che saranno concordati tra le parti, per il controllo e la manutenzione preventiva delle Apparecchiature al fine di verificarne il regolare funzionamento, effettuando, se del caso secondo la valutazione tecnica di PENTAX Italia Srl con Unico Socio, interventi di "Periodical Service" e prove di funzionamento delle Apparecchiature.

La manutenzione preventiva annuale comprende:
- Prestazione delle ore di manodopera necessarie alla manutenzione;
- Spese di viaggio e trasferta;
- Diritto di chiamata;
- Sostituzione parti critiche (lampade, slider) con verifiche previste secondo guida UV SMART.
- Pulizia del dispositivo
- Test funzionali
- Test di sicurezza elettrica
- Reportistica del servizio

Manutenzione correttiva
Un numero illimitato di interventi non pianificati ed eseguiti dietro richiesta scritta per la riparazione dei guasti occorsi alle Apparecchiature.

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La manutenzione correttiva comprende:

- Prestazione delle ore di manodopera necessarie alla riparazione;
- Ricambi originali delle parti di cui dovesse risultare necessaria la sostituzione, secondo la valutazione tecnica di PENTAX Italia Srl con Unico Socio
- Le parti rimosse o sostituite saranno ritirate da PENTAX Italia Srl con Unico Socio;
- Spese di viaggio e trasferta;
- Diritto di chiamata.

Il contratto di manutenzione Full-Risk ESCLUDE:

- Esecuzione di interventi per la riparazione di guasti causati da: o Uso improprio (utilizzo diverso da quello per cui è stata realizzata l'Apparecchiatura ovvero utilizzo o gestione dell'Apparecchiatura difforme dalle istruzioni riportate nel Manuale d'Uso);
- Negligenza, imprudenza, imperizia;
- Atti dolosi;
- Catastrofi, eventi naturali (alluvioni, terremoti, fulmini, incendi) e, in genere, casi di forza maggiore;
- Danneggiamenti alle Apparecchiature, anche se fortuiti, causati da guasti agli impianti esterni;
- Riparazioni ed interventi eseguiti non a regola d'arte o tentati da soggetti non autorizzati da PENTAX Italia Srl con Unico Socio;
- Modifiche tecniche non eseguite dal servizio tecnico di PENTAX Italia Srl con Unico Socio
- utilizzo di materiali di consumo o di dispositivi accessori o ausiliari non autorizzati;
- Collocazione delle Apparecchiature in ambienti non adatti in quanto privi delle caratteristiche indicate nel Manuale d'Uso (es. eccessivamente umidi o polverosi o con atmosfera corrosiva), ovvero trasferimento delle Apparecchiature in luoghi diversi da quelli di installazione che non siano conformi all'utilizzo delle stesse secondo quanto specificato sul manuale d'uso;
- Collegamenti con strumenti o impianti non compatibili. Sono altresì esclusi dal contratto:
- La manutenzione degli impianti esterni (es. impianti elettrici,), di qualsiasi altro strumento diverso dalle Apparecchiature.

Le forniture ed i servizi esclusi dal presente contratto saranno concordati ed addebitati a parte, previa autorizzazione su apposito preventivo presentato da PENTAX Italia S.r.l.

Copertura del Servizio

PENTAX Italia S.r.l. con Unico Socio *Italia*
Sede Operativa di Milano
Via Clemente Prudenzio, 16
20138 MILANO MI
Tel. 02 50995822 – 841 - 869
e-mail: riparazioni.it@pentaxmedical.com

PENTAX Italia s.r.l. con Unico Socio
Via Clemente Prudenzio n.16
20138 Milano – Italy
Tel. 02.50.99.58.1
www.pentaxmedical.com

Centro di assistenza autorizzato relativo alla Regione Sardegna

TECNO ME DICAL di Alessandro Mura - Sardegna
Statale 131 KM.18.750 SNC
09023 MONASTIR (SU)
tecnomedicalsnc@tiscali.it
Tel/Fax: 070/9178491
Ref. Alessandro Mura Cell. +39 348 7918610

Modalità: La comunicazione del guasto dovrà essere inviata tempestivamente rispetto al verificarsi dell'evento ai seguenti recapiti:

Mail: riparazioni.it@pentaxmedical.com
Tel.: 02 50905822-841-869-836

Il servizio di manutenzione sarà disponibile per la ricezione delle comunicazioni nei seguenti orari:
- dal lunedì al venerdì dalle ore 8.00 alle ore 17.00;

Termini di esecuzione
PENTAX Italia S.r.l. si impegna ad eseguire le prestazioni di manutenzione nei seguenti termini:

Tempo massimo di intervento dalla chiamata in vigenza contrattuale:
PENTAX Italia garantisce un contatto telefonico con un tecnico entro 2 ore lavorative dalla chiamata.

Tempo di intervento garantito:
PENTAX Italia garantisce un tempo di intervento garantito di 8 ore lavorative dalla chiamata per guasto bloccante.

Tempo di risoluzione del guasto:
PENTAX Italia garantisce un tempo di risoluzione del guasto di 3 giorni lavorativi.

Formazione permanente
A garanzia della integrità dei prodotti e della qualità delle lavorazioni, sia i tecnici di Sede che quelli dei Centri di Assistenza Tecnica Autorizzati, seguono corsi specifici e vengono costantemente aggiornati per eseguire le operazioni a cui sono abilitati utilizzando esclusivamente ricambi originali. I corsi vengono tenuti presso la sede PENTAX Italia.

Il SERVICE, attraverso il Customer Service, svolge anche dei programmi di formazione per gli operatori ospedalieri sia post-vendita, inclusa nell'offerta di fornitura, sia a richiesta.
L'attività di formazione post-vendita consiste nell'assistere il cliente nell'installazione e collaudo dell'apparecchiatura, fornire tutte le informazioni per il corretto utilizzo e per la sua corretta gestione, e nel seguire il cliente durante le prime prove pratiche.
La formazione post-vendita consente di accelerare l'operatività, ridurre i problemi di gestione dell'attrezzatura e di conseguenza la necessità di manutenzione.

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La sottoscritta PENTAX Italia S.r.l., con sede a Milano, in base alle stringenti di capitolato, alle apparecchiature proposte ed alla esperienza maturata negli anni per servizi analoghi prestati presso le numerose strutture sanitarie in Italia, PROPONE un servizio di manutenzione ed assistenza tecnica allo scopo di porre le Unità Operative delle strutture Ospedaliere nella condizione di poter contare quotidianamente su un numero di strumenti adeguato per coprire al meglio le loro esigenze nonché su strumenti qualitativamente idonei allo svolgimento sia delle attività programmate che delle eventuali emergenze.

Comunicazione e Rendicontazione

Pentax Italia al termine di ogni intervento si impegna a fornire un rapporto tecnico dettagliato sulle attività eseguite ed il certificato di conformità delle attività svolte secondo le linee guida previste da casa madre. Pentax Italia consegna immediatamente ad ogni intervento tecnico copia cartacea della bolla di lavoro dell'intervento eseguito e si impegna a fornire tramite e-mail una rendicontazione delle bolle di lavoro eseguite. Pentax Italia si impegna a fornire annualmente un certificato di regolare esecuzione delle attività previste dal contratto, includendo inoltre analisi completa e statistiche sui danni riscontrati.
Eventualmente ci rendiamo disponibili per un incontro per l'analisi dettagliata dei dati.

RingraziandoVi per l'attenzione prestataci, è gradita l'occasione per porgerVi distinti saluti.

Documento firmato digitalmente
PENTAX Italia s.r.l. con Unico Socio
Massimo Albertoni
(Nato a Sesto San Giovanni (MI) il 26/09/1973)
Presidente

SCHEDA TECNICA PE203

UVSMART D60

Data: 03/11/2023

Modello	UVSMART D60
Produttore	UV SMART TECHNOLOGIES B.V.
Distributore	PENTAX Italia
Anno di immissione	2023
Grado di sicurezza specificato dalla norma relativa	Classe di protezione I (secondo la IEC/EN 60601-1)
Normative	MDR 2017/745
Classe	IIa

Tabella delle revisioni		
Data	**Revisione**	**Causa della modifica**
03/11/2023	Rev. 00	Prima emissione

C.F. / P. IVA / N. Reg. Imp. di Milano: IT 11159150157 - Capitale Sociale E 6.500.000 i.v. - R.E.A. 1440458 Società soggetta all'attività di direzione e coordinamento della PENTAX Europe Gmbh
La società PENTAX ITALIA S.r.l. ha adottato il Decreto Legislativo n. 231/2001.

1. INTRODUZIONE

1.1. Destinazione d'uso

L'UV Smart D60 è destinato alla disinfezione di dispositivi medici invasivi senza canali fisicamente in grado di adattarsi all'interno dell'area di disinfezione designata.

2. DESCRIZIONE PRODOTTO

Codice	Modello	Descrizione	CND	RDM
UVSD60	UVSD60	Dispositivo di disinfezione D60	Z12011301	2469953

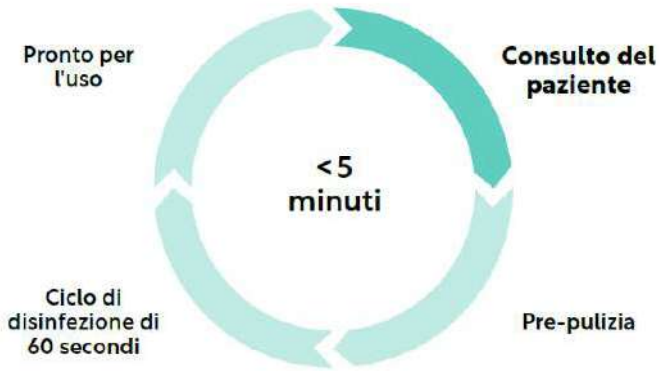
Tabella 1: caratteristiche principali

L'UV Smart D60 è un dispositivo di disinfezione ad alto livello di endoscopi senza canale e sonde TEE in 60 secondi, che necessita una semplice prepulizia manuale utilizzando un panno umido con acqua per rimuovere lo sporco.

Vantaggi:

- Aumenta il turnover dei pazienti
- Completamente tracciabile
- Riduce il numero endoscopi necessari al reparto e la possibilità di danneggiarli durante il trasporto
- Tecnologia brevettata Impelux™ → Disinfezione costante e affidabile dell'intero spettro di microrganismi
- Sostenibile per l'ambiente → Basso consumo energetico e nessuna necessità di prodotti chimici, ricariche o ingombranti materiali monouso
- Completamente adattabile all'ambiente sanitario e porta benefici sia se posizionato in reparto sia se integrato nel CSSD (reparto centrale dei servizi sterili)

Flusso di lavoro veloce e innovativo:



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Modalità di utilizzo:

3. INFORMAZIONI PRODOTTO

3.1. Specifiche tecniche

GENERALI	
Protezione ingresso	IP 20
Tensione nominale	110-220 V
Frequenza	50/60 Hz
Amperaggio nominale	5 A
Max potenza nominale	650 W
Lunghezza d'onda	253.7 nm
Valore fusibile accessibile	230 V: fusibile a tempo 5 A (ø5x20 mm)
Durata prodotto	10 anni
CONDIZIONI OPERATIVE	
Umidità relativa	5% - 90% (senza condensa)
Temperatura	0°C - +40°C
Pressione atmosferica	700hPa – 1060hPa
CONDIZIONI DI TRASPORTO E STOCCAGGIO	
Umidità relativa	5% - 90% (senza condensa)
Temperatura	-20°C - +45°C
Pressione atmosferica	700hPa – 1060hPa
Peso	circa 100kg
Dimensioni (LxHxP)	861 mm x 2033 mm x 473 mm (chiuso)
Tipo di connessione IT	Cavo Ethernet
Tracciabilità	Recuperabile tramite UV Soft e memoria interna D60
Ispezione tecnica (servizio/manutenzione)	Ogni 12 mesi

Tabella 2: Specifiche tecniche

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4. STUDI CLINICI

L'efficacia della disinfezione di UV Smart D60 è stata dimostrata da ricerche e studi clinici condotti presso rinomati centri medici accademici e laboratori di tutto il mondo. UV Smart svolge una costante ricerca per migliorare il prodotto e la sua documentazione clinica.
Di seguito alcuni esempi:

Eurofins Scientific Laboratories ha testato il D60 secondo le norme europee per la disinfezione dei dispositivi medici. Il D60 ha raggiunto la disinfezione ad alto livello secondo la norma EN-14885:2022 per l'intero spettro dei microrganismi.

Lo Spaarne Gasthuis (Paesi Bassi) ha confrontato il D60 con i termodisinfettori standard e ha concluso che la riduzione richiesta è stata soddisfatta. Il D60 ha mostrato un tangibile miglioramento rispetto all'attuale stato dell'arte.

La Marburg University (Germania) ha concluso che la tecnologia Impelux™ del D60 riduce efficacemente la contaminazione batterica sugli endoscopi flessibili.

- **Uno studio multicentrico condotto dal Radboud UMC (Paesi Bassi)** con tre ospedali olandesi ha dimostrato che la pre-pulizia manuale degli endoscopi otorinolaringoiatrici, combinata con la disinfezione del D60, è superiore a quella dei termodisinfettori.
- **L'ospedale UZ Gent (Belgio)** ha riscontrato una netta diminuzione del numero di UFC sulle sonde TEE dopo la disinfezione con il D60. Dopo la disinfezione con il D60, l'impugnatura contiene una quantità sensibilmente inferiore di germi rispetto al termodisinfettore Soluscope.
- **Il NYU Langone (USA)** ha dimostrato che il D60 è in grado di eguagliare l'efficacia del Cidex OPA in un tempo sostanzialmente inferiore.

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UV Smart

D60

Disinfezione ad alto livello di endoscopi
senza canale e sonde TEE in 60 secondi

UVsmart

Cos'è il green standard?

Più pulito. Più green. Più facile.

Una guida per integrare i dispositivi UV-C negli ospedali.

thegreenstandard.nl

Integrazione facilitata

Facilita l'integrazione dei dispositivi UV-C nei flussi di lavoro dell'ospedale.

Efficienza potenziata

Garantisce flussi di lavoro di disinfezione efficienti a costi ridotti.

Conformità green

Favorisce una disinfezione conforme e sostenibile.

Conformità, sostenibilità ed eccellenza

nella disinfezione di alto livello

Disinfezione certificata
Dispositivi medici di classe IIa secondo il MDR.

Conformità agli standard di disinfezione
Soddisfa i rigorosi standard internazionali (EN-15883-4, EN-14885:2018).

Sicurezza ed efficacia clinicamente provate
Completamente approvato e convalidato per la disinfezione di alto livello.

Disinfezione medica specializzata
Ideale per endoscopi ORL flessibili e rigidi senza canale e sonde TEE.

Tracciabilità
Funzionalità di monitoraggio avanzate per garantire che sia sempre tutto pronto in caso di verifica.

Sfide del presente

Processi lenti

Fino a **76** minuti

per riprocessare un endoscopio ORL con lavatrici disinfettanti[1].

Elevate esigenze di inventario

Fino al **+37%**

di inventario richiesto con gli attuali metodi di disinfezione[2].

Metodi costosi

Fino a **280€**

per l'utilizzo di lavatrici disinfettanti finalizzate al ricondizionamento degli endoscopi ORL[1].

Danni agli endoscopi

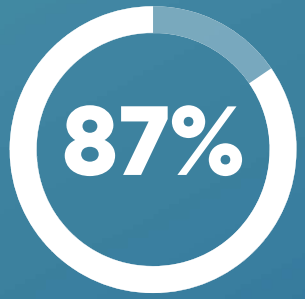
Fino a **x3**

degli endoscopi può essere esposto alla forza di gravità durante il trasporto, causando danni significativi[3].

1- Ofstead, C. L., Quick, M. R., Eiland, J. E., & Adams, S. J. (2017). Uno sguardo al vero costo del ricondizionatamento degli endoscopi. International Association of Healthcare Central Service Material Management.
2- Dati ospedalieri ETZ
3- Dati UMC Utrecht

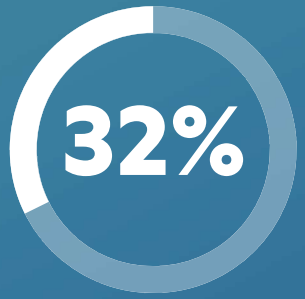
Sostenibilità ed efficienza

a ogni ciclo di disinfezione



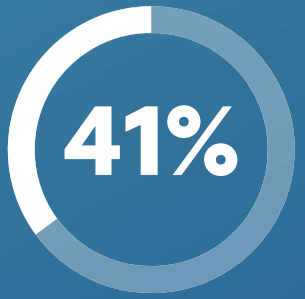
Disinfezione che fa risparmiare tempo[1]

Disinfezione di alto livello automatizzata, coerente e tracciabile in **60 secondi**.



Riduzione dell'inventario degli endoscopi[2]

Tempi di riprocessamento rapidi che garantiscono la **disponibilità continua** dell'endoscopio.



Più conveniente rispetto ad altri metodi[3]

Nessun utilizzo di acqua o materiali monouso durante il processo di disinfezione.

1- Ospedale Reinier de Graaf e Università Tecnica di Delft. (2023). La strada verso un'assistenza sanitaria sostenibile: riduzione delle emissioni di CO2 e dei tempi di risposta grazie a metodi di disinfezione innovativi.
2- Ospedale Elisabeth-TweeSteden (2024). Case Study di una pagina. "D60 Ottimizzazione dell'efficienza e del rapporto costi-efficacia dell'assistenza sanitaria". Disponibile su richiesta.
3- Biadsee, A., Zohar, Y., & Assi, S. (2023). "Analisi della minimizzazione dei costi del ricondizionamento del nasofaringoscopio nella pratica comunitaria".

J. van Kampen

Assistente medico ORL
Langeland Hospital, Paesi Bassi

“Siamo stati in grado di ridurre il nostro ciclo di ricondizionamento da 2–3 ore a pochi minuti. Il tempo riprocessione ora è dedicato ai pazienti, ovvero le persone che alla fine contano di più.”

Ascolta i colleghi

Il nuovo flusso di lavoro

- Tracciabilità completa con codice a barre e/o RFID per il controllo della conformità
- Prestazioni superiori a quelle delle lavatrici disinfettanti; testato e provato in ambito clinico
- Compatibile con i principali produttori di endoscopi e sonde

PENTAX MEDICAL · PHILIPS · XION medical · STORZ KARL STORZ – ENDOSKOPE · SIEMENS

Il D60 si adatta al tuo ambiente sanitario

Facile da usare, il D60 ha un'interfaccia intuitiva e fornisce un chiaro feedback all'utente.

Posiziona il D60

- In reparto
- In clinica
- Nel reparto centrale dei servizi sterili

Come usare il dispositivo D60

Inizio del processo

Performare una pre-pulizia dell'apparecchiatura ed eseguire un test di tenuta.

Scansione

Eseguire la scansione dell'ID e dell'apparecchiatura per la tracciabilità.

Posizionamento

Posizionare l'apparecchiatura nel D60 e chiudere lo sportello.

Disinfezione

Attendere 60 secondi che il dispositivo D60 termini il ciclo.

Scansione

Eseguire la scansione dell'ID per sbloccare lo sportello.

Disinfezione delle mani

Disinfettare le mani.

Disinfezione riuscita

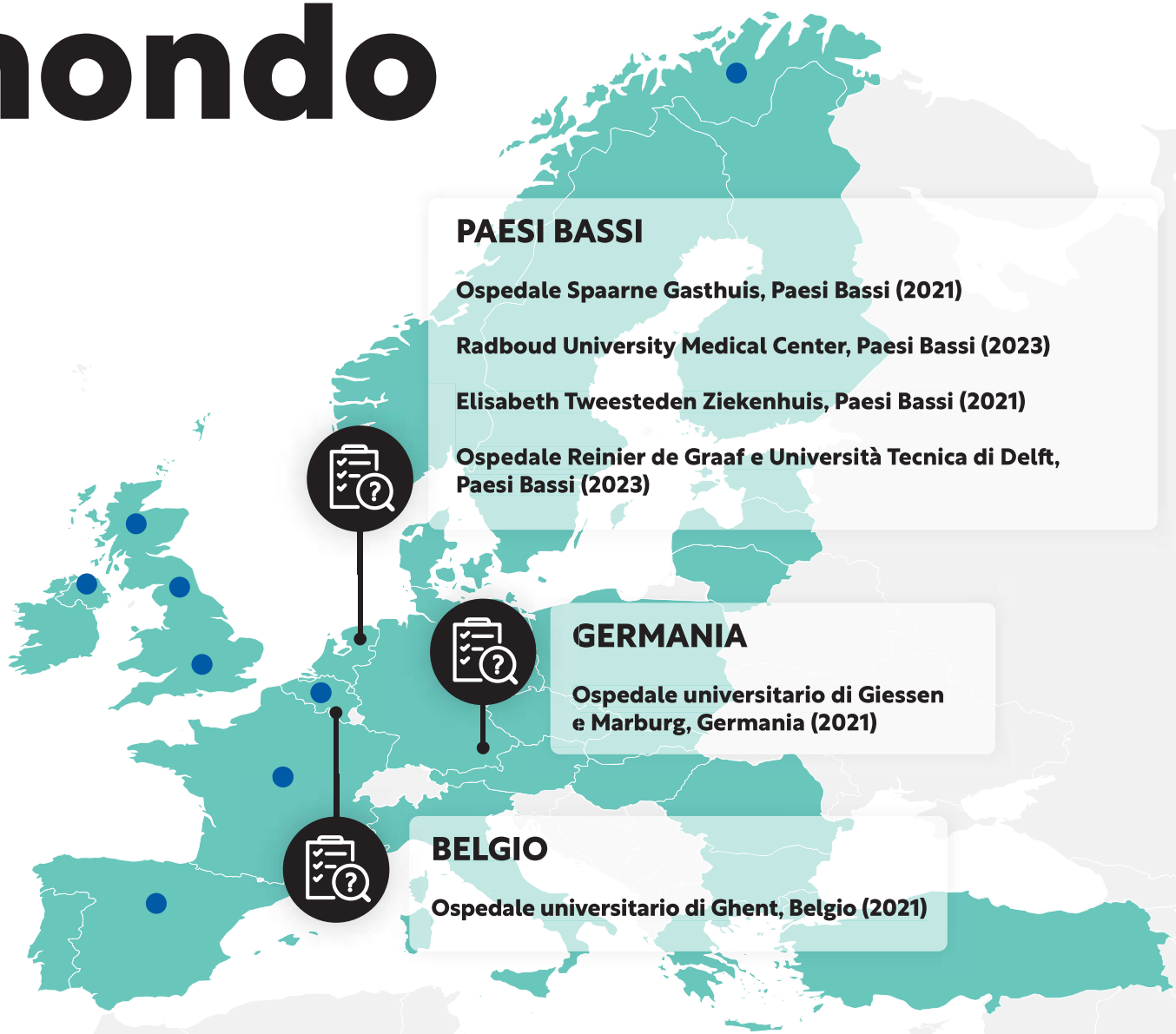
Estrarre l'attrezzatura pronta all'uso.

Supportato da professionisti sanitari

Studi clinici
Disponibile su richiesta

Centri di riferimento
Disponibile su richiesta

nel mondo



PAESI BASSI

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BELGIO

Ospedale universitario di Ghent, Belgio (2021)

La via verso la sostenibilità inizia ora

UV Smart ha sottoscritto il Green Deal europeo, impegnandosi a ridurre le emissioni nette di gas serra di almeno il 55% entro il 2030.

UV Smart progetta tutti i prodotti tenendo conto della sostenibilità. Lunga durata del prodotto, materiali durevoli, approvvigionamento e produzione in loco, basso consumo energetico e drastica riduzione dei materiali monouso sono alla base di tutti i prodotti.

La vittoria più grande inizia quando si utilizza il dispositivo **D60**. All'anno:

- Utilizzo di prodotti chimici ridotto fino a **1547 litri**[1]
- Il consumo di acqua è diminuito fino a **7875 litri**[1]
- Emissioni di CO_2 ridotte di circa **8703,65 chili**[1]

1- Ospedale Reinier de Graaf e Università Tecnica di Delft. (2023). La strada verso un'assistenza sanitaria sostenibile: riduzione delle emissioni di CO2 e dei tempi di risposta grazie a metodi di disinfezione innovativi.

Premio per la sostenibilità

Il modello **UV Smart D60** è stato premiato ai National HealthTech Innovation Awards 2023, ricevendo il premio come "**Best in Sustainability**"

Questo riconoscimento sottolinea il ruolo del dispositivo a favore delle pratiche sanitarie sostenibili. UV Smart D60 è progettato per fornire una disinfezione efficiente, con particolare attenzione alla riduzione dell'impatto ambientale. Questo riconoscimento attesta che il dispositivo soddisfa gli attuali standard di sicurezza ambientale e sanitaria.

"Con ***UV Smart D60***, puoi risparmiare fino a ***8703,65 chilogrammi*** di emissioni di CO2 all'anno, sufficienti per illuminare la Torre Eiffel per ***119 giorni.***[1] "

UV Smart D60

gli add-ons per la disinfezione

1. Gli essenziali per la pre-pulizia

2. Trasporto e conservazione sicuri

3. Conformità e preparazione per verifiche

4. Maneggevolezza sicura ed ergonomia

5. Cura e manutenzione costanti

Scansiona qui
per visualizzare l'elenco dettagliato degli add-ons

thegreenstandard.nl

Connettività

Quando il dispositivo D60 è collegato alla rete intranet della struttura, le informazioni sul riprocessamento possono essere visualizzate su una licenza di UV Soft installata sul desktop o inviate al Sistema Informativo Ospedaliero (SIO).
In questo modo, il personale sarà sempre pronto per eventuali verifiche.

UV Soft

SIO

	D60 senza UV Soft	D60 con UV Soft
Manutenzione annuale: Garantisce un'efficienza operativa costante.	✓	✓
Sostituzioni di parti: Aggiornamenti delle lampade e dei componenti critici.	✓	✓
Validazione delle apparecchiature: Mantiene accurati i livelli di disinfezione.	✓	✓
Supporto tecnico: Assistenza immediata per problemi operativi.	✓	✓
Affidabilità: Mantiene il dispositivo in condizioni ottimali tramite la manutenzione programmata.	✓	✓
Conformità: Garantisce il rispetto continuo degli standard sanitari, fondamentale per i dispositivi autonomi.	✓	✓
Accessibilità: Facilita l'accesso a informazioni aggiornate sul riprocessamento, migliorando la trasparenza operativa.	✗	✓
Sempre pronto per gli audit Conserva automaticamente i registri essenziali per gli audit e verifiche, riducendo significativamente l'onere amministrativo e migliorando l'efficienza.	✗	✓

Durata e manutenzione

D60 ha una durata utile di 10 anni.
Dopo ogni 12 mesi di utilizzo, il dispositivo necessita di manutenzione e viene visualizzato un avviso sul display. Tutte le parti di ricambio e le attività di manutenzione sono incluse nel contratto di assistenza offerto dal distributore locale.

La garanzia di 2 anni non comprende le parti soggette a usura sostituite durante la manutenzione

Il contratto di assistenza prescritto comprende:

Assistenza e manutenzione annuale con garanzia di tempi di inattività minimi (l'attuale parco installato ha un uptime superiore al 99%)

Sostituzione delle parti critiche soggette a usura durante la manutenzione

Controllo del funzionamento del sensore e calibrazione

Formazione (tecnica) per un uso sicuro ed efficace

Specifiche tecniche D60

Nome del prodotto (marchio)	D60 (UV Smart)
Tipo di unità	Dispositivo di disinfezione medica D60 UV-C
Classificazione (secondo la norma IEC/EN 61010-1)	Dispositivo di disinfezione medica
Classe (secondo il MDR)	IIa
Protezione ingresso	IP 20
Tensione nominale, categoria di sovratensione	110-120VAC/220-240VAC (+/- 10%), OVC II
Frequenza	50/60 Hz
Amperaggio nominale	10A/5A
Max. potenza nominale	650 W
Lunghezza d'onda	253,7 nm
Valore fusibile accessibile	Fusibile a tempo 4A (ø5x20mm) x 2 220-240V: fusibile a tempo 5A (ø5x20mm) x 2 110-120V: fusibile a tempo 10A (ø5x20mm) x 2
EMC*	IEC/EN 61326-1/61000-3/4 (A1, CISPR 11)
Durata del prodotto	10 anni

Condizioni operative

Umidità relativa	5% - 90% (senza condensa)
Temperatura	0 °C - +40 °C
Pressione atmosferica	800hPa - 1060hPa

Condizioni di trasporto e conservazione

Umidità relativa	5% - 90% (senza condensa)
Temperatura	-20 °C - +45 °C
Pressione atmosferica	700hPa - 1060hPa
Peso	Approssimativamente 100 kg
Dimensioni (LxHxP)	861 mm x 2033 mm x 473 mm (chiuso)
Tipo di connessione IT	Cavo Ethernet
Tracciabilità	Recuperabile tramite UV Soft e memoria interna D60
Ispezione tecnica (servizio/manutenzione)	Ogni 12 mesi

*Attualmente UV Smart D60 risulta in transizione dalla norma IEC/EN 60601, controllare sempre nella documentazione fornita con il dispositivo a quale norma è conforme il prodotto. Per qualsiasi domanda relativa alla transizione, contattare UV Smart.

Domande frequenti

Il nostro team di Customer Success sarà lieto di rispondere a tutte le tue domande.

D: Posso disinfettare gli endoscopi gastrointestinali con il D60?

R: Poiché gli endoscopi gastrointestinali hanno canali operativi, non possono essere disinfettati nel D60. Il D60 è destinato solo agli endoscopi e alle sonde senza canale operativo, poiché il D60 disinfetta solo le superfici esterne.

D: Il D60 richiede installazioni o collegamenti speciali?

R: No, il D60 richiede solo una presa di corrente da 110 V/220 V per essere utilizzato. Nel caso in cui il D60 sia collegato alla rete intranet della struttura per una maggiore tracciabilità, è necessario un cavo ethernet.

D: È possibile inserire più di un endoscopio nel D60 durante la disinfezione?

D: No, per assicurarsi che gli endoscopi siano disinfettati correttamente, può essere disinfettato solo 1 endoscopio alla volta. Grazie al ciclo di disinfezione di 60 secondi, questa necessità ha un impatto minimo sui tempi di esecuzione ed è ideale per la pre-pulizia dell'endoscopio successivo.

D: Il D60 influisce sull'endoscopio/sonda?

R: Sono stati eseguiti studi approfonditi sui materiali di un'ampia gamma di endoscopi e sonde, che non hanno mostrato alcun deterioramento con la disinfezione del D60. La qualità delle lenti è risultata addirittura migliore rispetto ai disinfettanti chimici e alle lavatrici disinfettanti. L'unico effetto collaterale evidente è una leggera decolorazione delle plastiche bianche/di colore chiaro, che non influisce sulle altre proprietà strutturali del materiale.

D: Posso disinfettare gli endoscopi rigidi nel D60?

R: Sì, gli endoscopi rigidi senza canale possono essere disinfettati nel D60.

D: È necessario pre-pulire l'endoscopio?

D: Sì, la pre-pulizia deve essere effettuata prima di disinfettare l'endoscopio nel D60.
È sufficiente un panno umido con acqua per rimuovere lo sporco dall'endoscopio.

Contattaci per maggiori informazioni

UVsmart

info@uvsmart.nl

uvsmart

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APPROVATO DA:
Classe MDR IIa

ESONERO DI RESPONSABILITÀ
Le informazioni qui contenute hanno lo scopo di descrivere l'uso dei prodotti e non sono destinate a fornire consigli sulle procedure mediche. UV Smart Technologies B.V. non rilascia alcuna dichiarazione o garanzia in merito all'accuratezza, alla completezza o all'idoneità allo scopo delle informazioni/formazioni. I prodotti e le indicazioni specifiche potrebbero non essere disponibili in alcuni mercati, dato che la disponibilità dei prodotti è soggetta all'approvazione normativa (e/o delle pratiche mediche nei singoli mercati). L'operatore sanitario è responsabile dell'implementazione clinica dei prodotti UV Smart. Le istruzioni per l'uso e le linee guida mediche accettate devono essere sempre controllate prima dell'applicazione dei prodotti UV Smart.

CE ISO 13485

UVsmart

UV Smart D60

Verification and Validation Overview

Disinfection of channel-less ENT endoscopes, rigid ENT endoscopes, and TEE probes in 60 seconds

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2 INTRODUCTION

In the field of infection prevention, professionals are tasked with the dual responsibility of staying updated on emerging techniques and ensuring the safety of both patients and healthcare staff. This involves not only understanding new methodologies but also evaluating the potential risks associated with new devices and procedures, formulating clear guidelines, and monitoring adherence.

The UV Smart D60 emerges as a notable device in this context, utilizing UV-C light for the disinfection of channel-less flexible ENT endoscopes, rigid ENT endoscopes, and TEE probes. The UV Smart D60 aligns with the EN-15883-4 and EN-14885:2018 standards, similar to the traditional methods like the washer-disinfector (WD) and chemical wipes (such as Tristel Wipes). This document provides a comprehensive overview of the UV Smart D60, exploring its safety measures, disinfection efficacy, and compatibility in healthcare settings. It also presents real-world validation data, including hospital and laboratory tests, and concludes with feedback from end users.

Additionally, the Annex of this document provides further information and guidance for medical professionals who are considering the implementation of the UV Smart D60 in their facilities. It serves as a resource for those needing to conduct risk assessments and seeking a more comprehensive understanding of the device's functions and potential applications.

This document, including its Annex, can thus be utilized as a reference by experts in the medical field to inform their decision-making process regarding the adoption of the UV Smart D60.

About UV Smart: UV Smart is a leading provider of UV-C light disinfection medical devices for healthcare, dedicated to preventing healthcare-associated infections. Its medical devices, which are CE marked as class IIa, ensure patient and end user safety by quickly and consistently disinfecting a variety of medical equipment. Clinically supported and enhancing sustainability with no use of chemicals and reduced use of disposables, UV Smart devices also save time and costs, enabling more treatments in shorter intervals.

Additionally, UV Smart is certified according to the Quality Management System ISO 13485, under the control of the notified body UDEM Adriatic Croatia, ensuring adherence to high standards of quality and safety.

3 OVERVIEW OF UV-C LIGHT AND HOW IT WORKS

3.1 DEFINITION OF UV-C LIGHT

UV-C light, a specific segment of the ultraviolet (UV) spectrum, is characterized by wavelengths ranging from 200 to 280 nanometers (nm). Often referred to as "germicidal UV" due to its potent disinfecting properties, UV-C light has been extensively studied for its effectiveness in inactivating a wide range of pathogens[1].

Naturally, UV-C radiation is emitted by the sun. However, the Earth's atmosphere, especially the ozone layer, absorbs nearly all UV-C rays, preventing them from reaching the surface. The absorption of UV-C rays by the Earth's atmosphere and its biological implications have been documented in various studies[2].

3.2 HOW IT WORKS

3.2.1 Effect on organisms

The disinfecting capability of UV-C light is attributed to its potential to damage the DNA and RNA of microorganisms. Specifically:

- DNA Damage: UV-C light induces the formation of pyrimidine dimers, particularly thymine dimers, in the DNA of microorganisms. This alteration prevents the DNA from replicating correctly, rendering the microorganism unable to reproduce and thus dying[3].
- RNA Damage: For RNA-based microorganisms, like certain viruses, UV-C exposure can lead to mutations that inhibit the virus from reproducing or functioning properly, thus becoming inactive[4].

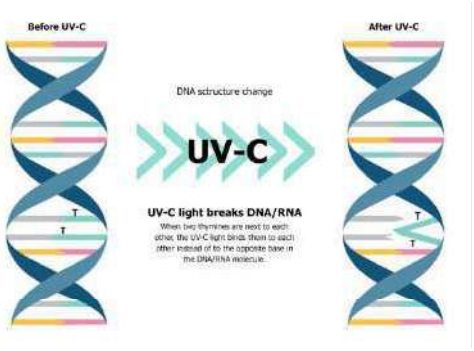

Figure 1. How UV-C works

[1] Kowalski, W. (2009). Ultraviolet Germicidal Irradiation Handbook

[2] Coohill, T. P., & Sagripanti, J. L. (2008). Overview of the inactivation by 254 nm ultraviolet radiation of bacteria with particular relevance to biologically active DNA.

[3] Cadet, J., Sage, E., & Douki, T. (2005). Ultraviolet radiation-mediated damage to cellular DNA.

[4] Ploydaeng, Monthanat, Natta Rajatanavin, and Ploysyne Rattanakaemakorn. "UV - C light: A powerful technique for inactivating microorganisms and the related side effects to the skin." Photodermatology, photoimmunology & photomedicine 37.1 (2021): 12-19. https://onlinelibrary.wiley.com/doi/full/10.1111/phpp.12605#:~:text=UV%2DC%20radiation%20(100%2D,then%20becomes%20non%2Dpairing%20bases.

3.2.2 Efficiency depending on wavelength

The UV Smart D60 employs low-pressure mercury lamps, renowned for their robust disinfection capabilities. A significant factor contributing to their effectiveness is the specific wavelength at which they operate: 254nm. This wavelength is not only widely recognized as optimal for disinfection purposes but also has the added benefit of minimizing material damage. Established scientific literature has consistently shown that 254nm is particularly effective in disrupting the DNA and RNA of microorganisms, rendering them non-functional and preventing their replication[5]. Consequently, this ensures a high-level of disinfection with reduced risks to materials, making it a preferred choice for many applications.

Importantly, the UV Smart D60 uses lamps with only a minimal amount of mercury (less than 15 micrograms) which is allowed under international standards[6], and its rapid disinfection process ensures both effectiveness and safety. Moreover, compared to emerging UVC LEDs, mercury lamps deliver a higher UV-C dose output in shorter durations, making them more efficient for rapid disinfection. This combination offers a robust disinfection solution while maintaining a safe environment for healthcare settings. Mercury lamps will be forbidden for consumer products and retail essential applications in 2027, this will not be the case for the medical application. Simply due to the fact that the amount of mercury is extremely low and that UVC LEDs are not yet powerful enough to reach High-Level Disinfection[7].

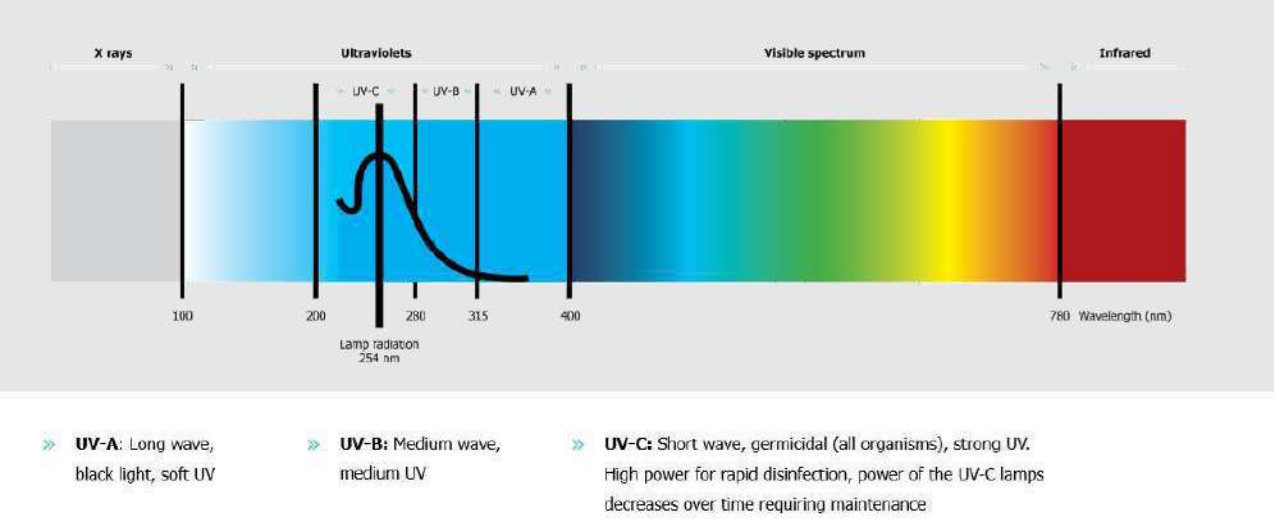

Figure 2. Different types of UV-C light

[5] https://www.mdpi.com/2673-947X/2/3/10
[6] https://www.tuvsud.com/en/e-ssentials-newsletter/consumer-products-and-retail-essentials/e-ssentials-4-2022/eu-ec-ends-certain-rohs-mercury-exemptions-in-lamps
[7] https://www.tuvsud.com/en/e-ssentials-newsletter/consumer-products-and-retail-essentials/e-ssentials-4-2022/eu-ec-ends-certain-rohs-mercury-exemptions-in-lamps

3.3 EFFICACY AND SAFETY

UV-C light has demonstrated for years its effectiveness against a broad spectrum of pathogens, including bacteria, viruses, fungi, yeast, mycobacteria, and spores. Its efficacy, as evidenced by studies like the inactivation of the SARS-CoV virus, showcases its potential in various disinfection applications[8]. In chapter 4, further elaboration is given about the specific efficacy of the UV Smart D60.

However, the power of UV-C light comes with its own set of precautions. Direct exposure to UV-C light can be harmful to humans, leading to risks such as skin burns and eye injuries, particularly to the cornea. To address these safety concerns, the UV Smart D60 is designed in accordance with international safety standards. It is certified according to the IEC 61010 standard, ensuring electrical safety in laboratory equipment. Additionally, the UV Smart D60 is certified following the IEC 62471 standard for the photobiological safety of lamps and lamp systems, and it also complies with ISO 15858:2016, which provides guidelines on 'UV-C Devices — Safety information — Permissible human exposure' detailing safety measures and exposure limits for UV radiation.

These standards collectively ensure the safe operation of UV-C devices like the UV Smart D60, emphasizing the importance of protective measures during the disinfection process, which is conducted in a closed chamber to prevent accidental exposure.

Additionally, a significant advantage of using UV-C light for disinfection is that it leaves no residue in the chamber, unlike some chemical disinfection methods. This ensures a residue-free environment post-disinfection, safe for hospitals staff, patients and the environment.

[8] Darnell, M. E., et al. (2004). Inactivation of the coronavirus that induces severe acute respiratory syndrome, SARS-CoV

4 EFFICACY IN CLINICAL CONDITIONS

4.1 CONTROLLED EFFICACY TESTS (LABORATORY)

Validation is based on EN 14885:2018 and the ISO 15883-4 (adapted to UV), which are all carried out by independent 3rd party laboratories. All reports below are available upon request.

4.1.1 Test methodologies

The UV Smart D60's disinfection capabilities have been thoroughly tested in line with the test methods and standard described in EN 14885:2018, applicable for instrument disinfection. These tests were conducted according to the applicable standards and GLP (Good Laboratory Practice) methods by the laboratory Eurofins Biolab, an independent, reputable, and accredited medical microbiological laboratory certified for both the MDR and FDA.

Two types of carriers have been used for the tests according to EN 14885:2018 and other American standards such as ASTM 2197 & 1837.

- Normal frosted glass was selected as a reference for hard non-porous surfaces like plastic, aluminium, and stainless steel.
- TPE 13 material was used as carrier as a reference for the insertion tube of endoscopes and TEE probes. All TEE-probes and endoscopes are made of this material.

For both carrier types the tests were conducted behind the glass holder in the D60 (see figure 4), which is made from quartz glass. The choice to test carriers behind the quartz glass holder in the D60 is significant as quartz glass inherently blocks UV light slightly, making it the worst-case position in the D60 for UV-C light to reach sufficient levels of disinfection. By testing behind the quartz glass holder, it was aimed to simulate the worst-case scenario. If the UV Smart D60 can effectively disinfect through the glass holder, it underscores its efficacy on other surfaces where the surface is directly illuminated by the UV-C light; such as the insertion tube of TEE-probes and channel-less flexible ENT endoscopes. (See Figure 3. Laboratory test UV Smart D60 - Carriers behind glass).

Real life ENT endoscopes and TEE probes were additionally tested for simulating in-use tests. Meaning real ENT endoscope and TEE probes were contaminated under worst-case scenarios to test the disinfection properties of the UV Smart D60. The probes were inoculated on the tip of the probes, which corresponds to the area being the most in contact for the patient and having complex structure and material. This represents the worst case in terms of material surface and risk for the patient. (See Figure 4. Dried inoculum on the tip of a TEE probe).

The laboratory tests affirmatively demonstrate that Bactericidal, Yeasticidal, Fungicidal, Mycobactericidal, Tuberculocidal, Sporicidal and Virucidal claims as defined in the UV Smart D60 Intended Use are met. Summary of the results are in the Table 1 to Table 7.

Figure 3. Laboratory test UV Smart D60 - Carriers behind glass

Figure 4. Dried inoculum on the tip of a TEE probe

4.1.2 Results and findings

The results confirm that the UV Smart D60 effectively eliminates the full spectrum of pathogens, having successfully achieved the required log reduction measurements according to European test methods to reach High-Level Disinfection (HLD). It has proven under the EN-14885:2018 to be Bactericidal (P. Aeruginosa, S. Aureus, E. coli and E. Hirae), Yeasticidal (C. Auris, C. Albicans), Fungicidal (C. Albicans, A. Brasiliensis), Mycobactericidal (M. Terrae, M. Avium), Tuberculocidal (M. Terrae), Sporicidal (B. Subtilis), and Virucidal (Adenovirus, Poliovirus, Norovirus and Polyomavirus Simian), aligning with the claims stated in the UV Smart D60 Intended Use. A summarized view of these results can be found below. For those interested in a detailed analysis, complete reports are available on demand.

CONCLUSIONS	On the basis of the results obtained in compliance with the assay validity criteria of EN 14561:2006 / UNI EN 14561:2006 and Sponsor requirements, the cycle performed by *UV SMART D60* **IS EFFECTIVE** against *S. aureus, P. aeruginosa, E. coli* and *E. hirae* after the treatment of inoculated glass and TPE carriers after a standard cycle set on the device, using bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions).

Table 1. Summary of Eurofins test results – S. Aureus, P. Aeruginosa, E. Coli and E. Hirae (bactericidal activity)

CONCLUSIONS	On the basis of the results obtained in compliance with the assay validity criteria of EN 14562:2006 / UNI EN 14562:2006 and Sponsor requirements, the cycle performed by *UV SMART D60* **IS EFFECTIVE** against *Candida auris* DSM210920 after the treatment of inoculated glass and TPE carriers after a standard cycle set on the device, using bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions).

Table 2. Summary of Eurofins test results – C. Auris (Yeasticidal activity)

CONCLUSIONS	On the basis of the results obtained in compliance with the assay validity criteria of EN 14562:2006 / UNI EN 14562:2006 and Sponsor requirements, the cycle performed by *UV SMART D60* **IS EFFECTIVE** against *Candida albicans* ATCC 10231 after the treatment of inoculated glass and TPE carriers after a standard cycle set on the device, using bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions).

Table 3. Summary of Eurofins test results – C. Auris (Yeasticidal and Fungicidal activity)

CONCLUSIONS	On the basis of the results obtained in compliance with the assay validity criteria of EN 14562:2006 / UNI EN 14562:2006 and Sponsor requirements, the cycle performed by *UV SMART D60* can be considered **EFFECTIVE** against *Aspergillus brasiliensis* ATCC 16404 after the treatment of inoculated glass and TPE carriers with the standard cycle set on the device (60 seconds of contact time), in the adopted test conditions, using bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions).

Table 4. Summary of Eurofins test results – A. Brasiliensis (Fungicidal activity)

CONCLUSIONS	On the basis of the results obtained in compliance with the assay validity criteria of EN 14563:2008 / UNI EN 14563:2009 and Sponsor requirements, the cycle performed by *UV SMART D60* **IS EFFECTIVE** against *Mycobacterium terrae* and *Mycobacterium avium* after the treatment of inoculated glass and TPE carriers after a standard cycle set on the device, using bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions).

Table 5. Summary of Eurofins test results – Myco. Terrae and Myco. Avium (Mycobactericidal and Tuberculocidal activity

CONCLUSIONS	On the basis of the results obtained in compliance with the assay validity criteria of EN 17126:2018 / UNI EN 17126:2019 and Sponsor requirements, the cycle performed by *UV SMART D60* **RESULTS EFFECTIVE** against *Bacillus subtilis* ATCC6633 after the treatment of inoculated glass carriers after a standard cycle set on the device, using bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions).

Table 6. Summary of Eurofins test results – B. Subtilis (Sporicidal activity)

CONCLUSIONS	On the basis of the results obtained in compliance with the assay validity criteria of EN 17111:2018 / UNI EN 17111:2019 and Sponsor requirements, the cycle performed by *UV SMART D60* **RESULTS EFFECTIVE** in completely inactivating *Adenovirus Type 5, Poliovirus Type 1 LSc-2ab, Murine norovirus (MNV, strain S99)* and *Simian virus (strain 777)* after the treatment of inoculated glass carriers after a standard cycle set on the device, using bovine serum albumin (BSA) with a final concentration of 0.3 g/L (0.03% - simulating clean conditions).

Table 7. Summary of Eurofins test results – Adenovirus, Poliovirus, Norovirus, Simian/Polyoma Virus (Virucidal activity)

List of relevant documents	Content
DOC-914	UV Smart D60 - Clinical Evaluation Plan*
DOC-1587	UV Smart D60 - Bactericidal efficacy (Eurofins)
DOC-1588	UV Smart D60 - Fungicidal efficacy (Eurofins)
DOC-1589	UV Smart D60 - Fungicidal and yeasticidal efficacy (Eurofins)
DOC-1591	UV Smart D60 - Mycobactericidal and Tuberculocidal efficacy (Eurofins)
DOC-1592	UV Smart D60 - Sporicidal efficacy (Eurofins)
DOC-1593	UV Smart D60 - Virucidal efficacy (Eurofins)

The above mentioned documents may be shared on request

**This is a confidential document, and the clinical tests and reports contained within it have been reviewed and approved by clinical specialists from the certification body*

4.2 TESTING IN CLINICAL SETTING (HOSPITALS)

4.2.1 Methodologies in a real-world setting

The UV Smart D60 was tested in actual clinical hospital settings to assess its ability to disinfect the outer surfaces of channel-less flexible ENT endoscopes and TEE probes using UV-C light. The testing involved:

- **Measurement before and after:** Levels of contamination of the endoscopes were measured both before and after the application of the UV Smart D60 within the standard reprocessing procedure.
- **Bedside cleaning and pre-cleaning:** all endoscopes underwent bedside cleaning and pre-cleaning according to the validated and verified protocols of UV Smart. These protocols were tested in various clinical studies and hospitals tests to verify the outcomes and validate the results. All the protocols and reports are available and may be shared on request (DOC–2819 UV Smart D60 Workflow Standardization Protocol)
- **Safety Protocols:** When the 'before and after' measurements of the D60 where conducted an additional disinfection procedure with the standard protocol (either a WD or Chemical disinfection) was performed. This to ensure that patient safety was never compromised.
- **Ethical Commission Approval:** All testing procedures were reviewed and approved by the Ethical Commissions of the corresponding hospitals. This step was taken to ensure that the testing was conducted in an ethical manner and in line with established safety standards.

The results from these tests provided data on the UV Smart D60's effectiveness in real-world settings and its potential benefits for hospital disinfection protocols.

4.2.2 Results and implications

The tests have been performed in the following hospitals:

- Spaarne Gasthuis Hospital, The Netherlands (2021) [9]

Results: The first part of the study, conducted in laboratory settings, demonstrated that the UV Smart D60's disinfection process for channel-less flexible endoscopes met the criteria for precision, repeatability, reproducibility, as well as positive and negative controls, achieving the required reduction of microorganisms both with and without a pre-cleaning procedure.

In the second part, carried out in clinical hospital settings, the study revealed that the entire disinfection process with the UV Smart D60, including pre-cleaning, showed a visible improvement in disinfecting channel-less flexible endoscopes compared to the current method using a Washer Disinfector.

- The University Hospital of Giessen and Marburg, Germany (2021) [10]

Results: The flexible endoscopes (FE) were contaminated with a high average value of 916.7 CFU (± 1057 CFU) after clinical usage. After reprocessing, an average contamination of 2.8 CFU (± 1.6) on 14% (n = 7) of the FEs was detected consisting of non-pathogenic species, the remaining FE were sterile. After reprocessing, all FEs were protein-free (< 1 µg). The artificially contaminated test bodies showed no remaining bacterial contamination after disinfection, resulting in an average absolute germ reduction of about 10^7 CFU.

Conclusions: It was concluded that the entire process (including pre-cleaning) with the UV Smart D60 efficiently reduces bacterial contamination of ENT endoscopes without a working channel, as specified in the study publication.

- Ghent University Hospital, Belgium (2021) [11]

Results: The conclusion is that the entire process (including pre-cleaning) with the UV Smart D60 has the same performance as the current method (Washer Disinfector) on the Distel end tip of TEE-probes. In addition, the UV Smart D60 outperforms the Washer Disinfector on the handle of TEE probes.

[9] Report available upon request
[10] Rudhart et al. (2021) - https://pubmed.ncbi.nlm.nih.gov/33713189/
[11] Report available upon request

- **Radboud University Medical Center, The Netherlands (2023) [12]**

Results: A total of 200 FEs without a working channel were divided equally between the two disinfection groups. After clinical use and manual pre-cleaning but before disinfection, 84 of the 100 (84.0%) (UV-C light group) and 79 of the 100 (79.0%) (EWD) FEs were contaminated with at least 1 CFU. FEs that showed no contamination after use were excluded from further analysis. After disinfection with UV-C light, 72 (85.7%) FEs showed no contamination (i.e., 0 CFUs) versus 66 (83.5%) FEs after reprocessing with the EWD.

Conclusion: There is no difference in CFU reduction on contaminated FEs without a working channel between UV-C light disinfection and the current gold standard, the EWD. Thus the entire process (including pre-cleaning) with the UV Smart D60 has the same performance as an EWD.

- **Elisabeth Tweesteden Ziekenhuis, Netherlands (2021) [13]**

Results: The conclusion is that the disinfection method with the UV Smart D60, if combined with manual pre-cleaning according to the provided instructions for use of the ENT endoscopes, can be safely used in patient care.

- **NYU Langone Health, United States (2023) [14]**

Results: The conclusion of the study shows that the decontamination protocols with UV Smart D60 (including pre-cleaning) were as effective in removing contamination from ENT endoscopes as the traditional method of using Cidex OPA. UV Disinfection was found to be faster, simpler, less toxic, and more resource-efficient, which will increase compliance with ENT endoscope disinfection in patient care settings and enhance healthcare workers and patient safety.

Full publication and reports are also available on demand for review.

Conclusion:

Laboratory and hospital tests have shown that the entire process (including pre-cleaning) with the UV Smart D60 effectively disinfects the outer surfaces of medical devices without channels, meeting the standards set by EN 14885:2018 and EN 15883-4. These findings align with existing research on UV-C light disinfection in healthcare settings.

[12] Halmans et al. (2023) - https://pubmed.ncbi.nlm.nih.gov/37882501/
[13] Report available upon request
[14] Ezeh at al. (2023) - https://pubmed.ncbi.nlm.nih.gov/37485725/

4.3 CLINICAL DATA FROM LITERATURE

To validate the efficacy of the UV Smart D60 in comparison with leading disinfection methods, a comprehensive review of clinical data from established literature was conducted in the Clinical Evaluation Report (CER). This methodical approach facilitates a comparison of the UV Smart D60's performance with current state-of-the-art methods under strict MDR & FDA guidelines. The literature search and review protocol, detailed in the UV Smart D60 Clinical Evaluation Report (CER), ensures conclusions are drawn from credible and relevant sources.

Conclusion:

Results from laboratory- and hospital tests confirm that disinfection with the UV Smart D60 is an effective method for disinfection of outer surfaces of channel-less invasive medical devices based on requirements specified in the EN 14885:2018 standard. These results were in concordance with the available literature on disinfection with UV-C light in healthcare environments. From the data presented in this clinical evaluation, it can be concluded that the UV Smart D60 meets the claimed performance as specified in the intended use and that the investigations and clinical data include adequate observations to infer scientific validity of the claims.

List of relevant documents	Content
DOC - 1594	UV Smart D60 - Hospital tests at The Spaarne Hospital
DOC - 1595	UV Smart D60 - Hospital tests at The University Hospital of Giessen and Marburg
DOC - 1596	UV Smart D60 - Hospital tests at Ghent University Hospital
DOC - 2681	UV Smart D60 - Hospital tests at Elizabeth TweeSteden Ziekenhuis (ETZ)
DOC - 2682	UV Smart D60 - Hospital Tests Multi-Center Study
DOC - 2795	UV Smart D60 - NYU Langone Health study
DOC - 1583	UV Smart D60 - Clinical Evaluation Report*

The above mentioned documents may be shared on request

* *Confidential document (cannot be shared). The clinical tests and reports it contains have been reviewed and approved by clinical specialists from the certification body*

5 COMPLETE PROTOCOL FOR IMPLEMENTATION

5.1 CURRENT REPROCESSING WORKFLOW VS. UV SMART D60 WORKFLOW

The traditional reprocessing cycle for channel-less flexible ENT endoscopes & TEE probes is a lengthy and complex process [Figure 6]. Starting from the moment it has been used on the patient, the channel-less flexible ENT endoscopes or TEE probes undergo pre-cleaning in the patient's room, transportation to the reprocessing area, leak testing, manual cleaning, disinfection (typically in a washer disinfector), careful drying, and finally, transportation back to the designated department. This entire process can take 2-3 hours, with the device often waiting in staging areas for various steps. Such a prolonged process not only consumes more resources but can also lead to delays in patient care.

In contrast, the UV Smart D60 introduces a more efficient and sustainable disinfection workflow [Figure 7]. After using the endoscope, the initial step involves removing any visible debris during pre-cleaning in the patient room. The channel-less flexible ENT endoscope or TEE probe is then leak tested and manually cleaned for the second time making a two cleaning steps in the protocol. Upon completing the pre-cleaning the endoscope undergoes disinfection using the UV Smart D60. With the UV Smart D60 ideally positioned adjacent to the department, there's a significant reduction in the need for transporting the endoscopes or probes to different locations. This point-of-care reprocessing not only conserves resources but also eliminates the need for drying or extended transport times. As a result, the endoscope is immediately ready for reuse, promoting a more sustainable approach and facilitating a smoother patient flow. This streamlined process underscores the UV Smart D60's commitment to enhancing operational efficiency while prioritizing patient care and reducing the overall inventory burden.

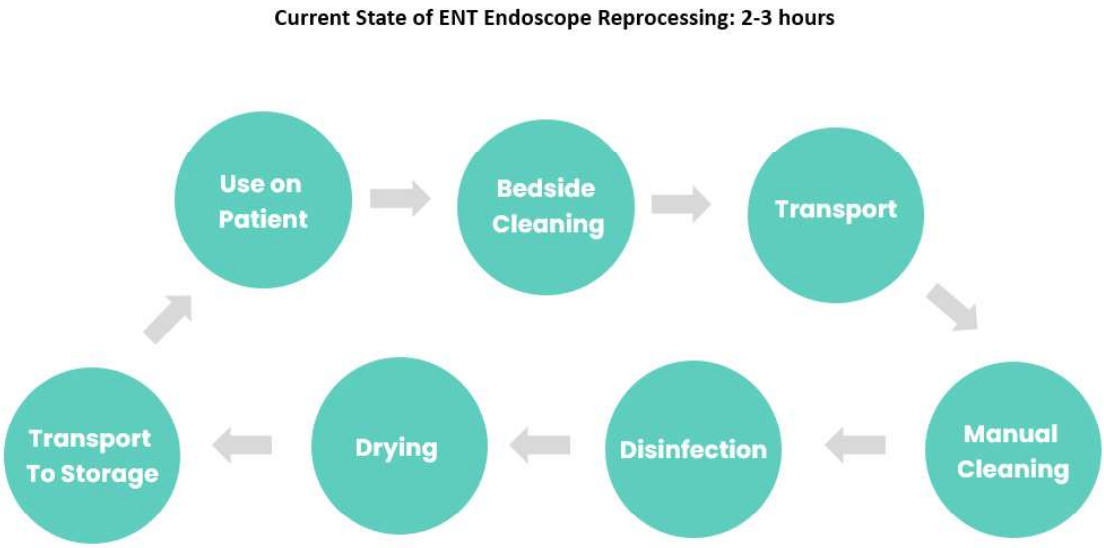

Figure 6. Current state of channel-less flexible ENT endoscopes reprocessing

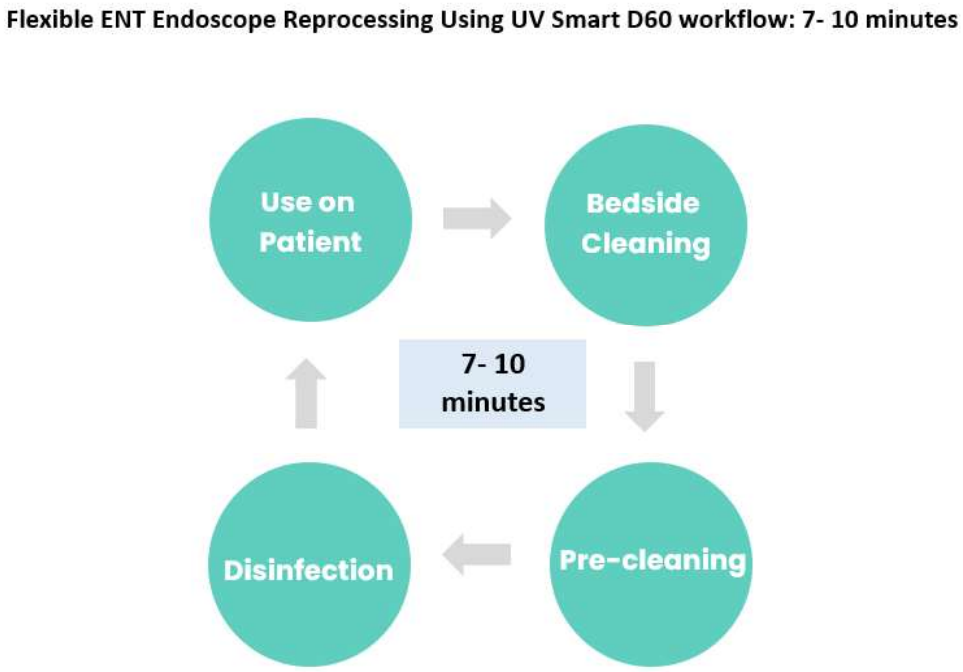

Figure 7. Channel-less flexible ENT endoscope reprocessing with UV Smart D60

5.2 How to ensure the removal of visible debris and efficient pre-cleaning

The efficacy of the high-level disinfection process using the UV Smart D60 is dependent on the thorough removal of visible debris and the execution of a comprehensive pre-cleaning procedure in the patient room and on the cleaning process before disinfection. The manual (pre-)cleaning processes will remove more than 90% of all endoscope contaminants[15] from the endoscope.

5.2.1 Removal of visible debris

Immediate post-examination attention to the endoscope is imperative to prevent the drying and attachment of debris. Following these steps is essential:

1. Initiate the bed-side cleaning process promptly post-use in examination room:
2. Use a clean, microfiber wipe with water to methodically eliminate contamination from the endoscope, strictly following the protocol.

List of relevant documents	Content
DOC – 2819	UV Smart D60 – Workflow Standardization Protocol

The above mentioned document may be shared on request

[15] Rutala et al. 1995; Rutala & Weber, 2004

5.2.2 Cleaning as per UV Smart D60 Protocol

Manual (pre-)cleaning of channel-less flexible ENT endoscope and TEE probes is essential, especially when using disinfection methods like UV Smart D60. While the (pre-)cleaning process is inherently non-reproducible, it can achieve safety and effectiveness when conducted by trained individuals adhering to the protocol. On top of that, with the pre-cleaning and cleaning process; the endoscope is cleaned twice, leaving a very small window for error.

This entails immediate bedside cleaning post-endoscopic examination, using a clean, microfiber wipe with water to eliminate contaminants from the channel-less flexible ENT endoscope's input section and distal end. In the reprocessing room another cleaning step is performed for extra safety, as required by reprocessing standards. By conducting the two cleaning steps, plus confirmation in the track & trace software on the D60 about the (pre-)cleaning, and disinfection in the D60, will lead to a safe reprocessed medical device.

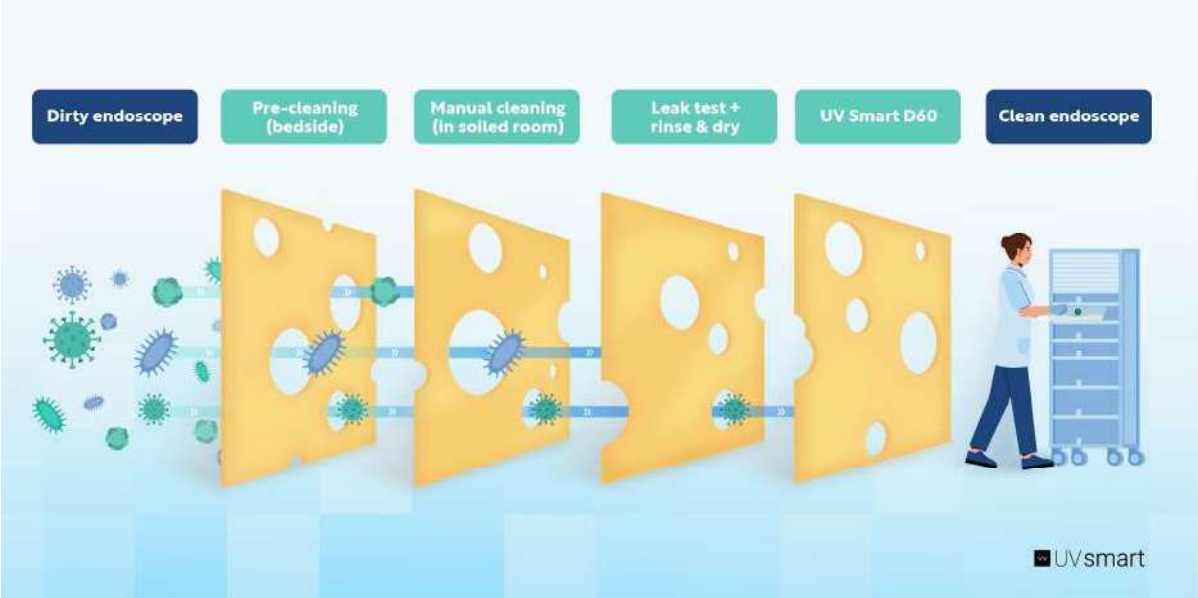

Figure 8. Channel-less Flexible ENT endoscope reprocessing with UV Smart D60

For both steps using a microfiber wipe is recommended because of its unique structure and properties. Microfiber is much finer than regular fibers, allowing it to penetrate microscopic nooks and crannies where contaminants reside. The increased surface area of the cloth, due to its fine fibers, enables it to absorb more dirt, grease, and moisture (to read more, refer to section 5.3 pre-cleaning efficacy – a case study).

Additionally, when rubbed against a surface, microfibers produce a static charge that attracts and traps dust and other particles. The spaces between these fine fibers also draw in and trap contaminants through capillary action. The high-quality microfiber wipe UV Smart recommends has split fibers, which further enhance their cleaning capability by creating more edges to pick up and hold onto contaminants. This ensures a thorough cleaning without leaving lint or residue behind.

For optimal results, follow the full UV Smart D60 protocol. Below is a short summary:

- Thoroughly clean the control body and all associated components using a microfiber wipe with water. This step should be executed for a minimum duration of 20 seconds.
- Then, focus on the lens, ensuring it is meticulously cleaned with a damp microfiber wipe for a minimum set period of 20 seconds.

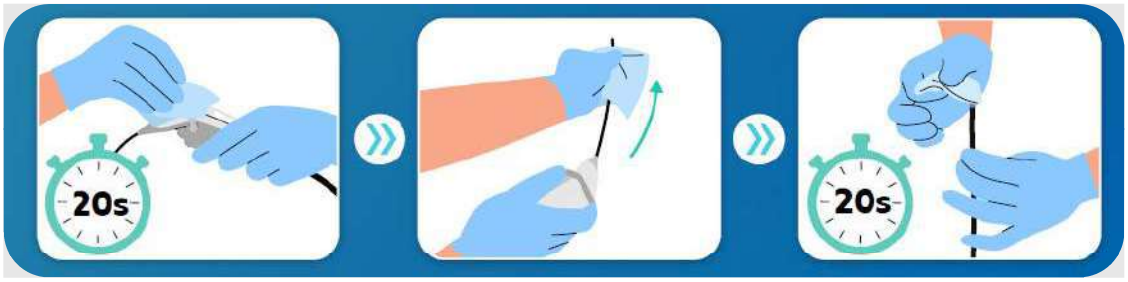

Figure 9. UV Smart D60 pre-cleaning protocol illustration

By meticulously following the steps mentioned in the UV Smart D60 protocol, the ENT scope is optimally prepared for the High-Level disinfection phase, ensuring the highest standards of infection control. We provide a detailed protocol guide for the process.

To further support team training, educational materials such as infographics, leaflets, and posters are available on demand.

Figure 10. Educational content explaining the UV Smart D60 workflow

5.3 PRE-CLEANING EFFICACY – A CASE STUDY

5.3.1 Test methodology

1. Scope of the Test: The primary focus was on the manual (pre-)cleaning process of channel-less flexible ENT endoscopes when using UV Smart's D60, and to compare 3 different (pre-)cleaning processes against each other:
    1. Microfiber wipe with water
    2. Enzymatic pre-cleaning
    3. Nonsterile wipe with water

2. Bedside or Point-of-Care pre-cleaning: Immediately after the endoscopic examination, samples were taken from the insertion tube to determine how 'dirty' the ENT endoscope was. Following this, the channel-less flexible ENT endoscope underwent the first step of cleaning, which is part of the hospital's standard procedures, to remove all visible debris. This cleaning was performed either with a microfiber wipe or a normal nonsterile wipe, depending on the hospital's protocol, solely to eliminate visible debris.
3. Initial Leakage Test: Before the commencement of the manual pre-cleaning, a leakage test was performed. An employee, specifically trained and educated, connected the channel-less flexible ENT endoscope to a (automated) leak tester. Only endoscopes found to be free of leaks proceeded to the next step.
4. Secondary Manual Cleaning: After potential transport and a post-leakage test, the channel-less flexible ENT endoscopes were divided into three different groups, each undergoing a distinct manual cleaning process. One group was cleaned with a microfiber wipe, the second group with an enzymatic cleaner, and the third group with a nonsterile wipe. These methods were employed to remove debris from the insertion tube and distal end of the endoscopes, including the lens, as per the respective protocols for each group. After each cleaning method, another sample was taken to assess the cleanliness of the ENT endoscopes in each group following their respective pre-cleaning steps.
5. Data collection: Clinical trials from Germany, the Netherlands, the United States, and Belgium indicate that the UV Smart D60 process with the microfiber wipe is the most effect method as a cleaning step and is as effective as a cleaning step with enzymatic. is By combining manual cleaning with the UV Smart D60's disinfection capabilities, the channel-less flexible ENT endoscopes and TEE probes undergo a thorough cleaning and disinfection process, ensuring they are adequately disinfected for subsequent use.

5.3.2 Results and findings

- The manual pre-cleaning process remains a human operation, making it crucial to ensure that it is performed by skilled and trained personnel. The immediate bedside cleaning significantly reduces the risk of contaminants remaining on the inserted section of the endoscope, and ensures that two different persons conduct the cleaning: one during the bed-side pre-cleaning and one during the manual cleaning.
- To prevent or exclude human errors as much as possible during the cleaning process, it is important that employees are competent and qualified in this respect. Training, instruction, testing and (re) certification by the supplier of the channel-less flexible ENT endoscope, as well as the cleaning and disinfection equipment, is not only essential, but it should also be mandatory.
- Clinical trials in various countries, such as Germany (Rudhart et al. 2021) [16], the Netherlands (ETZ, 2021) [17] , Netherlands (Radboud, 2023) [18] Belgium (Ghent University Hospital, 2021) [19] and the United States (NYU,2023) [20] have proven and demonstrated the effectiveness of the pre-cleaning and cleaning method with the UV Smart D60 protocol.

List of relevant documents	Content
DOC - 2819	UV Smart D60 – Workflow Standardization Protocol
DOC - 2929	UV Smart D60 – Workflow Standardization Catalogue

[16] Rudhart et al. (2021) - https://pubmed.ncbi.nlm.nih.gov/33713189/
[17] Report available up on request
[18] Halmans et al. (2023) - https://pubmed.ncbi.nlm.nih.gov/37882501/
[19] Report available up on request
[20] Ezeh at al. (2023) - https://pubmed.ncbi.nlm.nih.gov/37485725/

6 COMPATIBILITY

6.1 COMPATIBLE WITH LEADING ENDOSCOPE MANUFACTURERS

A potential concern with UV-C disinfection is the effect of UV light on materials. To address this, material compatibility tests are continuously conducted in collaboration with the R&D departments of leading endoscope manufacturers. UV Smart tested multiple ENT endoscopes and TEE probes. Here is a non-exhaustive list of the devices that UV Smart guarantees compatible:

ENT Endoscope manufacturers	TEE probes manufacturers
▪ Atmos ▪ Karl Storz ▪ Laborie ▪ Machida ▪ Olympus ▪ Optim ▪ ORL vision ▪ PatCom ▪ Pentax ▪ Rescope ▪ Xion	▪ Canon ▪ Esaote ▪ Fujifilm ▪ GE Healthcare ▪ Mindray ▪ Oldelft ▪ Philips ▪ Samsung ▪ Siemens Healthineers

Through these tests it is confirmed that even after >3,000 disinfection cycles, there was no significant deterioration of the endoscopes. This confirms that the UV-C light used by the UV Smart D60 is not only effective for disinfection but also safe for the materials of major brand equipment.

A summary of compatibility statements is available upon request.

UV Smart is also continuously leading UV-C compatibility tests with endoscope manufacturers and as soon as the results are available, it is updated online on the compatibility check tool [https://en.uvsmart.nl/compatibiliteit-check].

In figure 11, an overview of the process with all the ENT endoscope and TEE probe manufacturers is provided.

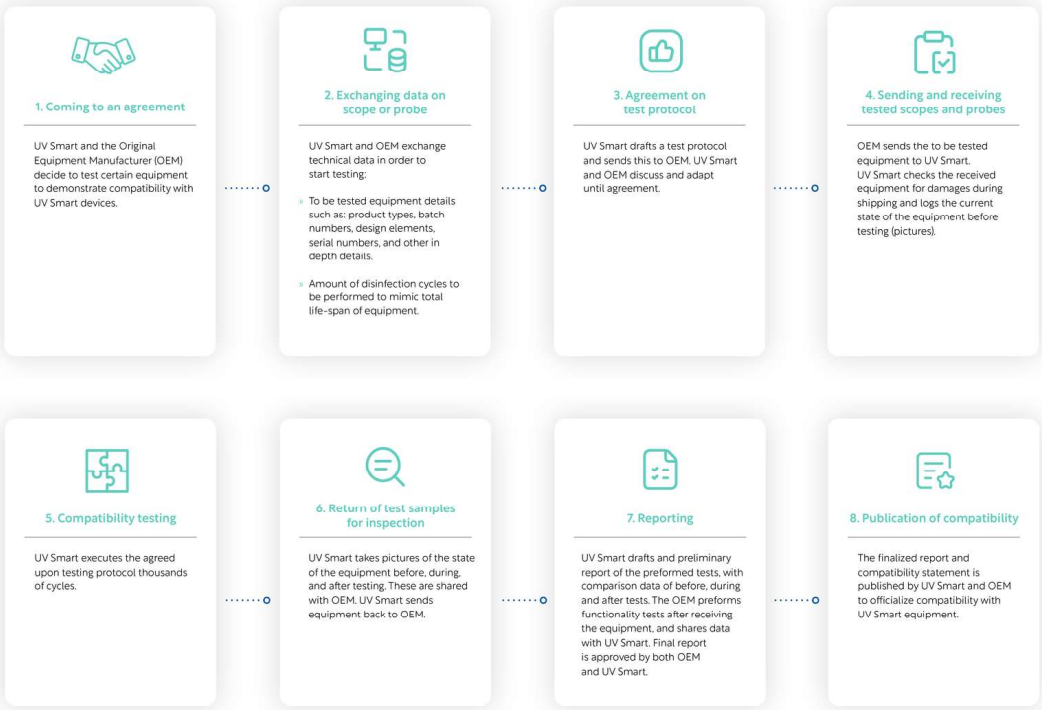

Figure 11. Compatibility process between UV Smart and the original equipment manufacturer

List of relevant documents	Content
DOC - 1536	UV Smart D60 - Material Compatibility Verification Report
DOC - 2412	UV Smart D60 - Masterlist Compatibility
DOC - 2667	UV Smart D60 - Atmos compatibility verification report (flexible endoscopes)
DOC - 1717	UV Smart D60 - Memorandum scope/probe compatibility
DOC - 2258	UV Smart D60 - Oldelft compatibility verification report
DOC - 2416	UV Smart D60 - PatCom Compatibility Verification Report
DOC - 1536	UV Smart D60 - Material Compatibility Verification Report
DOC - 2304	UV Smart D60 - Siemens Compatibility Verification Report
DOC - 1700	UV Smart D60 – Olympus Compatibility Verification Report

The above mentioned documents may be shared on request

6.2 ENDOSCOPE PROTECTION

This section outlines the protective measures the UV Smart D60 employs during its disinfection cycles. The used medical equipment is securely placed inside the UV Smart D60 using a special holding system made of quartz glass letting UV-C light go through and detecting the presence of the equipment. Once positioned with a closed door, UV-C lamps illuminate the equipment. The device is equipped with two sensors that monitor the UV-C dose and electrical current to ensure optimal performance (Independent Monitoring System). All disinfection data is then saved within the UV Smart D60 system. After the cycle, the door automatically unlocks, signalling that the equipment is ready for use.

Figure 12. Endoscope protection and disinfection in the UV Smart D60

Conclusion:

The UV Smart D60 not only ensures effective disinfection through UV-C light but also prioritizes the protection and longevity of ENT endoscopes and TEE probes. Its design and functionality, validated by tests with leading endoscope manufacturers, make it a reliable choice for safeguarding medical equipment without compromising on disinfection efficacy.

7 MONITORING AND TRACEABILITY OF DISINFECTION PROCESS

Effective monitoring ensures that disinfection procedures are consistently performed to the required standards, while traceability offers a clear record of each disinfection cycle. This section outlines the tools, and protocols essential for maintaining these standards and ensuring process reliability.

7.1 VALIDATION AND MONITORING

The UV Smart D60 represents an advancement in disinfection of channel-less flexible ENT endoscopes & TEE probes, integrating meticulous validation, monitoring, and operational guidelines to ensure a safe reprocessed ENT endoscope or TEE probe for the patient. As healthcare settings demand rigorous standards for patient safety, understanding the complexities of this device is essential.

- Independent Monitoring Systems (IMS): IMS are built into the UV Smart D60 to monitor the internal parameters during disinfection. These sensors ensure that conditions inside the device are optimal for each cycle. The IMS in the UV Smart both consists of sensors that measure the UV-C dosage in terms of Joules (J/cm^2), and measure the amperage on the lamps making sure the lamps have consumed enough power to emit the required UV-C dose. If one of the sensors, either UV-C dosage or Amperage, does not meet the threshold the disinfection will not be released as successful and will indicate a failure. This data is captured in the track&trace information linked with each disinfection cycle.
- UV Indicators: UV indicators are simple yet effective tools that change colour or appearance when exposed to UV-C light. Their primary function is to provide users with visual confirmation that the UV-C light has effectively reached the intended surfaces. For the UV Smart D60, these indicators can be strategically placed on surfaces or items intended for disinfection. As the UV-C light operates, any change in the indicator's appearance serves as a tangible sign of the light's coverage. This becomes especially useful as an additional validation step, ensuring that no areas are missed during the disinfection process.

  The significance of these indicators extends to facilitating external validation of the disinfection process. When used with the UV Smart D60, the change in the indicators can be documented and included in the UV Smart traceability booklet. This documentation process is crucial for external validation, as it provides a recorded, tangible proof of the disinfection efficacy. External validation is particularly important in clinical settings where maintaining high standards of disinfection is critical. It allows for an independent verification of the disinfection process, ensuring that it meets the required safety and efficacy standards. By incorporating these indicators into the traceability system, the UV Smart D60

offers a more comprehensive approach to validating and ensuring the quality of the disinfection process, thereby enhancing trust and reliability in its use.

- **UV Smart D60 Protocol:** to ensure proper handling of the entire process surrounding the D60, including the bedside- and pre-cleaning methods, UV Smart developed a full protocol, which has been validated and verified by various hospitals (see chapter 4). Details about this protocol are shared in chapter 5.
- **External Sensors for Validation:** The use of external sensors is a key aspect of the UV Smart D60's validation process. Hospitals are required to perform annual validations of all their disinfection equipment to confirm their continued effectiveness and readiness for use. These external sensors are essential in ensuring the UV-C light emitted by the UV Smart D60 maintains the necessary intensity and coverage. By detecting and measuring the UV-C light, the sensors verify that the UV Smart D60 is delivering the correct dosage needed to effectively disinfect ENT endoscopes and TEE probes. This annual validation process is an important step in ensuring the UV Smart D60 provides reliable and comprehensive disinfection [figure 13a].

- **Lamp Validation:** Lamp validation is a critical component of the UV Smart D60's annual maintenance. To ensure that the UV-C lamps within the device are functioning at their optimal capacity, yearly checks and validations are conducted after the lamps have been replaced with the UV Smart Maintenance Kit. These procedures verify that the lamps emit the correct wavelength and intensity of UV-C light, which is vital for effective disinfection. This is included as part of the annual service fees.
  These validations are typically carried out by trained technicians or specialists from the manufacturer or authorized reseller.

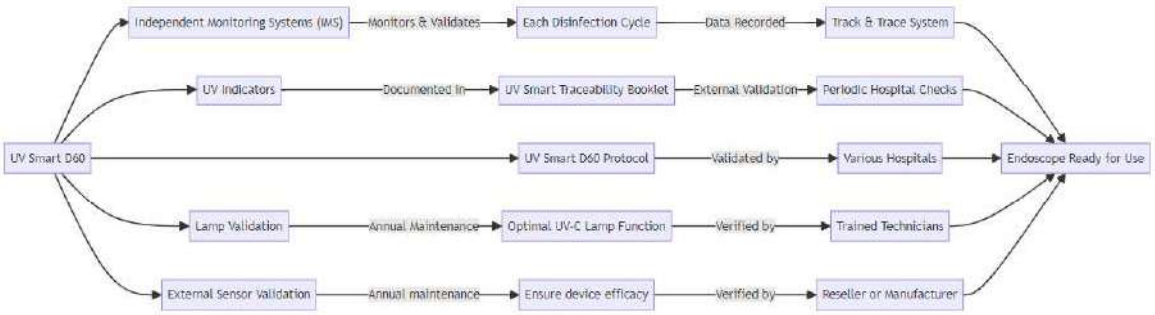

Figure 13a. UV Smart D60 process monitoring

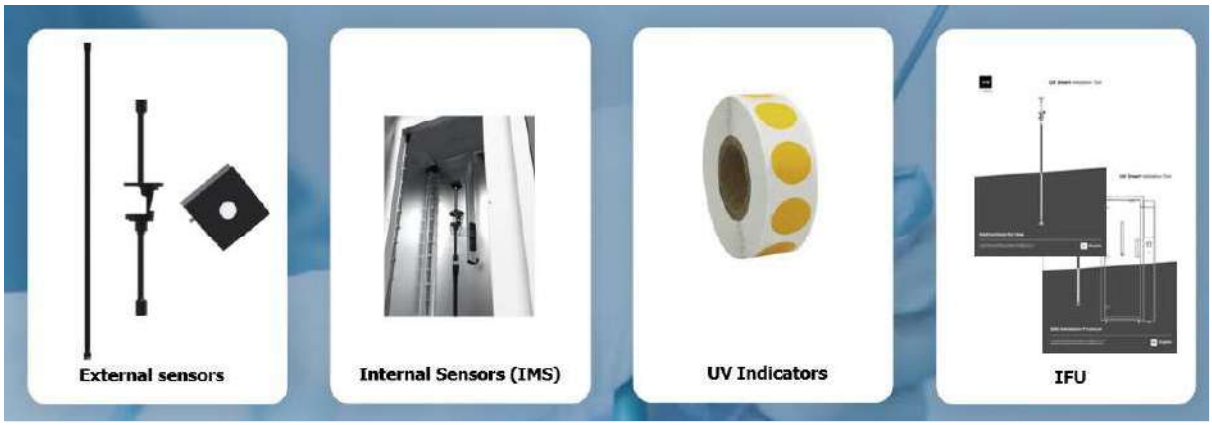

Figure 13b. UV Smart D60 process monitoring

Hospitals play an essential role in the day-to-day operation of the UV Smart D60. While they may not conduct the technical validations themselves, their feedback and observations are indispensable. If hospital staff notice any irregularities or potential malfunctions with the device, they are encouraged to promptly communicate with the manufacturer or the authorized reseller. This ensures that any issues are addressed quickly, maintaining the UV Smart D60's commitment to delivering consistent and effective disinfection.

Figure 14. UV Smart D60 - Internal sensor (upper circle) and validation sensor (lower circle)

The Instruction for Use (IFU) provides detailed guidelines on how to operate the UV Smart D60, including preparation, operation, and post-disinfection procedures. Adhering to the IFU ensures the device's optimal performance and safety, as mentioned in the above points.

List of relevant documents	Content
DOC - 908	UV Smart D60 - Instructions for Use (English)

The above mentioned documents may be shared on request

7.2 TRACEABILITY OF DISINFECTION

Tracking the reprocessing of medical devices is crucial for patient safety and regulatory compliance. By maintaining a detailed log of each disinfection cycle, the UV Smart D60 can ensure that every device used on patients has undergone thorough and effective disinfection. This not only reduces the risk of infections but also provides a clear audit trail for regulatory bodies.

- **Ensuring Data Integrity with UV Smart D60:** Data Integrity ensures that all recorded data is accurate, consistent, and unaltered. The UV Smart D60 employs encryption and secure storage methods to protect data from unauthorized access or tampering.
- **Documentation and Record-Keeping:** Documentation and record-keeping are essential practices to ensure transparency and traceability during reprocessing, providing a verifiable record of each procedure. In the context of the defined intended use, the UV Smart D60's commitment to thorough documentation ensures that users can easily demonstrate compliance, verify procedures, trace the reprocessing of their device, and maintain the highest standards of disinfection during the UV Smart D60's lifetime and beyond. The following data is kept in the records and documented in the UV Smart D60 system (please see figure 9 for the details) :
    - **Date and Time of Disinfection:** The UV Smart D60's logs the exact date and time of each disinfection cycle and provides a precise temporal record of its operations. This timestamped record offers a clear and organized way to assess the frequency and consistency of disinfection activities carried out by the UV Smart D60.
    - **Operator Accountability:** The UV Smart D60's feature of logging the operator details serves as a mechanism for accountability within the disinfection process. The operator has to sign off digitally is she/he conducted the pre-cleaning according to protocol, conducted the leak test, and confirm the option step for rinsing and drying, for full compliance. Additionally, the D60 tracks the user who put an ENT endoscope or TEE probe in the D60 and it tracks which user has taken out the disinfected equipment.
    - **Equipment tracking (Endoscope or TEE Probe ID):** The UV Smart D60 logs the unique ID for each endoscope or probe. By capturing these IDs during each disinfection cycle, the UV Smart D60 provides a clear record of which specific equipment has been disinfected and when.
    - **UV Smart D60 System ID:** For facilities using more than one UV Smart D60 device, this feature ensures that each unit's performance and maintenance history can be individually tracked and reviewed. In the event of any discrepancies or specific maintenance needs, the unique system ID allows for swift identification of the particular UV Smart D60 unit in question.
    - **Cycle Information (Exposure Time, Cycle Number):** The UV Smart D60 logs the following cycle specific information: exposure time and cycle number.

- **IMS information:** the IMS data is captured in the D60, it will show for each cycle the obtained Joules (J/cm^2) and Amperage (A). If both are above the set threshold, then the device will pass the cycle.
- **Final Result of Disinfection (Pass/Fail):** The UV Smart D60s logs the final result of each disinfection cycle, whether it's a pass or fail [Figure 15b].

Conclusion:

The UV Smart D60 is designed with a strong emphasis on traceability. Through its various features, it systematically logs essential details of each disinfection cycle, from the operator involved to the specific equipment ID and the outcome of the disinfection. By capturing and storing the data described above, the UV Smart D60 offers users a clear and organized overview of disinfection activities, ensuring that standards are met, and any potential issues can be promptly addressed.

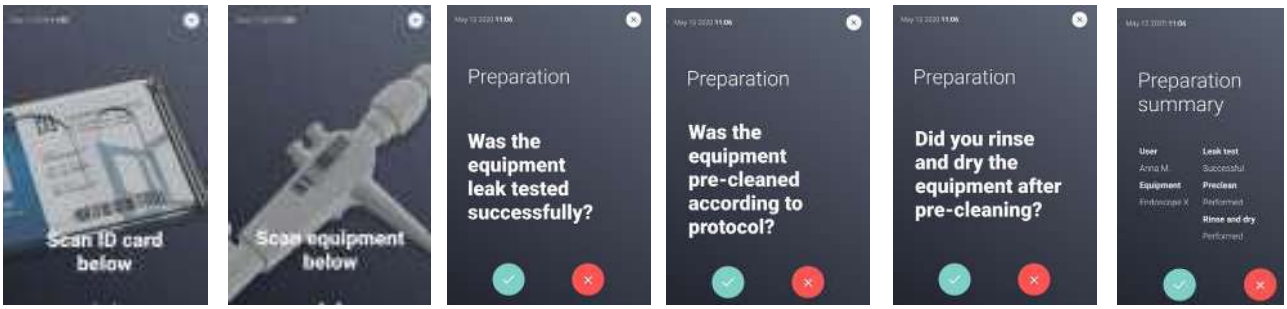

Figure 15a. UV Smart D60 – Track and Trace screen

Figure 15b. UV Smart D60 – Track and Trace screen

8 SAFETY CONSIDERATIONS

In the design, development, and manufacturing of the UV Smart D60, the required standards were followed for medical device design, including ISO 13485:2016, ISO 14971 (Application of risk management to medical devices), and ISO 15883-4 (requirements and tests for washer-disinfectors, which is adapted to UV application). The UV Smart D60 is a certified medical device according to the Medical Device Regulation (MDR) EC 2017/745 (Class IIa), after scrutiny by an independent Notified Body. In addition to these standards, the device has been evaluated and controlled according to the safety-related standards (Electrical Safety and EMC tests & UV-C exposure safety) .

The UV Smart D60 has been subjected to various evaluations and assessments concerning product and electrical safety. Each document focuses on specific safety aspects of the product, from risk management to electromagnetic compatibility. Below is a list of the safety evaluations, tests, and standards with which the UV Smart D60 complies.

8.1 ELECTRICAL SAFETY AND EMC TESTS

Testing has been performed by independent laboratories and test facilities according to:

- IEC 61326-1 (EMC)
- CISPR 11
- IEC 60601-1-2
- IEC 61000-3-2
- IEC 61000-3-3
- IEC 61000-3-12
- IEC 61000-4-2
- IEC 61000-4-3
- IEC 61000-4-4
- IEC 61000-4-5
- IEC 61000-4-6
- IEC 61000-4-8
- IEC 61000-4-11 (EMC)
- 47CFR15.225 (Radio)
- ANSI C63.10-2013 (Radio)
- IEC 61010-1 & -2 (Product safety testing (electrical))
- IEC 61326-1

UL Solutions (Underwriters Laboratories) has performed testing according to IEC 61010, which is the most current safety standard applicable for the UV Smart D60.

The UV Smart D60's adherence to these standards guarantees it is designed to operate reliably in a healthcare environment. Its consistent performance during testing ensures

that disinfection processes are not compromised by electromagnetic interferences, contributing to patient safety and overall infection prevention.

CISPR 11			
Clause	**Requirement – Test case**	**Basic standard**	**Verdict**
7.2	Disturbance voltages	CISPR 11:2015 + AMD1:2016 + AMD2:2019	P
7.2	Electromagnetic radiation disturbance	CISPR 11:2015 + AMD1:2016 + AMD2:2019	P
IEC 61000-3-2			
Clause	**Requirement – Test case**	**Basic standard**	**Verdict**
7.2	Harmonic current emission	IEC 61000-3-2:2018	P (1)
IEC 61000-3-12			
Clause	**Requirement – Test case**	**Basic standard**	**Verdict**
7.2	Harmonic current produced by equipment with input current >16 A and ≤ 75 A per phase	IEC 61000-3-12:2011	N/A (2)
IEC 61000-3-3			
Clause	**Requirement – Test case**	**Basic standard**	**Verdict**
7.2	Voltage changes, voltage fluctuations and flicker	IEC 61000-3-3:2013 + AMD1:2017	P (1)
IEC 61000-3-11			
Clause	**Requirement – Test case**	**Basic standard**	**Verdict**
7.2	Voltage changes, voltage fluctuations and flicker – Equipment with rated current ≤ 75 A and subject to conditional connection	IEC 61000-3-11:2017	N/A (2)
IMMUNITY TEST			
Clause	**Requirement – Test case**	**Basic standard**	**Verdict**
T.2	Electrostatic discharges	IEC 61000-4-2:2008	P
T.2	Radiated, radio - frequency, electromagnetic field	IEC 61000-4-3:2006 + AMD1:2007 + AMD2:2017	P
T.2	Power frequency magnetic fields	IEC 61000-4-8:2009	P
T.2	Electrical fast transient/burst	IEC 61000-4-4:2012	P
T.2	Injected currents (radio frequency common mode)	IEC 61000-4-6:2013	P
T.2	Surge	IEC 61000-4-5:2014 + AMD1:2017	P
T.2	Voltage dips, short interruptions	IEC 61000-4-11:2020	P
Supplementary information: 1. Test performed even if the E.U.T is classified as Class A equipment. 2. Input current <16 A.			

Figure 16. UV Smart D60 electrical safety and EMC tests overview

Figure 16 explanation:

Emission EN 61000-3-2 (2014) & EN 61000-3-3 (2013): These standards relate to the device's impact on the power supply. The UV Smart D60 will not cause unexpected power fluctuations, ensuring stable operation.

IEC 61010-1 UL reports and certificates demonstrate the compliance of the UV Smart product according to the standard IEC 61010-1 on electrical safety for laboratory equipment and according to the standard IEC 61326-1 on EMC. Since the D60 is not patient-contacting, this is the most relevant and current safety standard for reprocessing devices.

List of relevant documents	Content
DOC-2428	UV Smart D60 - CB test certificate of IEC 61010-1 Product Safety test
DOC-2533	UV Smart D60 - CB test certificate IEC 61326-1
DOC-793	UV Smart D60 - Risk Management Results*

The above mentioned documents may be shared on request

**Confidential document. The risk management results file have been reviewed and approved by the notified (certification) body*

8.2 UV-C EXPOSURE SAFETY

The UV Smart D60 has been meticulously designed with patient and operator safety in mind, adhering to several internationally recognized standards, including standard previously mentioned and additional:

- IEC 62471 - Photobiological safety of lamps and lamp systems
- ISO 14971 – Application of risk management to medical devices
- ISO 62366 – Application of usability engineering to medical devices
- ISO 15858 – UV-C Devices Safety information: Permissible human exposure

One of the UV Smart D60 standout features is to monitor use of UV-C light for disinfection and ensure safety levels. To ensure that neither patients nor operators are exposed, the UV-C light is only activated when the UV Smart D60's doors are securely closed. This closure is verified by 4 independent sources: 3x on the door and 1x in the software. This containment ensures that the UV-C light remains within the device at all times. The device's design not only guarantees effective disinfection but also upholds the highest standards of safety by ensuring no direct UV-C light exposure to individuals.

Conclusion: The UV Smart D60 is safe as confirmed by the product safety tests according to the EN IEC 61010 Medical Electrical Equipment and System. All identified risks are mitigated as far as possible, as stated in the UV Smart D60 Risk Management Report (reviewed and approved by Certification body). All risks and side effects are acceptable when weighed against the benefits to the patients and/or users in accordance with all the mentioned standards.

List of relevant documents	Content
DOC-614	UV Smart D60 - Risk Management Plan*
Online	UV Smart D60 - Risk Matrix (GG)*
DOC-793	UV Smart D60 - Risk Management Results*
DOC-2332	UV Smart D60 - CB Test Certificate EN 62471 Photobiological

The above mentioned documents may be shared on request

**Confidential document (cannot be shared). The risk management results file have been reviewed and approved by the notified (certification) body*

9 ECONOMICAL AND SUSTAINABLE IMPACT

9.1 SUSTAINABLE IMPACT AND OPERATIONAL EFFICIENCY

A recent quantitative study, conducted by Reiner de Graaf hospital and Technical University Delft evaluated the sustainability, operational and economic impact of the UV Smart D60 in disinfecting channel-less flexible ENT endoscopes[21]. The findings indicate several potential benefits associated with the UV Smart D60 when compared to traditional methods.

Furthermore the University of London in Ontario, Canada, conducted a cost-analysis of various disinfection methods for ENT endoscopes. Conclusion was that in clinics with more than >2500 procedures per year, the UV Smart D60 was the most cost-effective method.

9.1.1 Environmental impact

The UV Smart D60's approach to disinfection, which emphasizes decentralized disinfection, has shown potential in reducing transportation needs, thereby possibly decreasing the risk of endoscope damage and associated repair costs.

Moreover, the UV Smart D60, when compared to the Medivators Advantage Plus pass-thru washer disinfection by Cantel, demonstrated potential savings in resource consumption. The data suggests potential annual reductions of:

- 1547 liters of chemicals, 7875 liters of water;
- 3686.8 KWh of energy;
- and a decrease in transportation of 2772 kilometers.

[21] Report available upon request

This could lead to a potential reduction in CO2 emissions by approximately 8703.65 kilograms annually (enough to power the Eiffel Tower for 119 days!). Please see figure 16 for more information.

9.1.2 Operational efficiency

In terms of operational efficiency, the UV Smart D60 protocol has a reported turnaround time of 12 minutes, which is notably shorter than the 60-96 minutes associated with some traditional disinfection methods. This efficiency could lead to time savings, with preliminary data suggesting a potential reduction equivalent to 2.5 Full-Time Equivalent (FTE) employees annually at primary healthcare locations. Additionally, the device's design aims to ensure that endoscopes remain readily available for medical procedures. Please see figure 16 for more information.

WD	Per 2 endoscopes	1596 endoscopes ambulatory clinic	3654 endoscopies main location
Chemicals 2,8 kg CO_2 / liter	600 ml 1,68 kg CO_2 per 600 ml	478.8L 1340 kg CO_2	1096 liter 3069 kg CO_2
Water 0.3 kg CO_2 / liter	3 liter 0.9 kg CO_2	2394L 718 kg CO_2	5481L 2466.4 kg CO_2
Energy consumption	1800 watt 1.8 kwh 0.82 kg CO_2	1.436.400 Watt 1436 KwH 654,82 kg CO_2	3.288.600 Watt 3288 KwH 1499.3 kg CO_2
Kilometers driven 0.185 kg CO_2	11 kilometer 2,035 kg CO_2 per 11 km	2772 kilometers 512 kg CO_2	0 kilometers 0 kg CO_2
Total Co_2	**4.43 kg CO_2**	**3224,82 kg CO_2**	**7034,7 kg CO_2**

D60	Per 2 endoscopes	1596 endoscopes total	3654 endoscopies main location
Chemicals 2,8 kg CO_2 / liter	0 0 kg CO_2	0L 0 kg CO_2	0L 0 kg CO_2
Water 0.3 kg CO_2 / liter	0 0 kg CO_2	0L 0 gram CO_2	0L 0 kg CO_2
Energy consumption	1300 watt 0.59 CO_2	1.037.400 watt 1.037,2 Kwh 472,87 kg CO_2	2375100 2.375,1 KwH 1083 kg CO_2
Kilometers driven 0.185 kg CO_2	0 kilometer 0 kg CO_2	0 kilometer 0 kg CO_2	0 kilometer 0 kg CO_2
Total CO_2	**0,59 kg CO_2**	**472,87 kg CO_2**	**1083 kg CO_2**

Figure 16. Usage Water, Chemicals, Energy and CO2 – The way to sustainable healthcare: Reduction of CO2 emissions and turnaround time through innovative disinfection methods

9.2 ECONOMIC IMPACT

The University of London in Ontario, Canada, conducted a cost-analysis of various disinfection methods for ENT endoscopes. Conclusion was that in clinics with more than >2500 procedures per year, the UV Smart D60 was the most cost-effective method.

9.2.1 Case Study – Cost minimization analysis of ENT endoscopes reprocessing in community practice – Canada

- Background: Reprocessing of ENT endoscope represents a large financial burden to community physicians. The aim of this study was to perform a cost analysis of ENT endoscope reprocessing methods at the community level.
- Methods: Electronic surveys were distributed by email to community otolaryngologists. Surveys were comprised of 14 questions assessing clinic size, ENT endoscope volume, endoscope reprocessing method and maintenance. Four manual techniques were evaluated: (1) soak with ortho-phthalaldehyde solution (Cidex-OPA; Advanced Sterilization Products, Johnson and Johnson Inc., Markham, Canada), (2) soak with accelerated hydrogen peroxide solution (Revital-Ox; Steris Canada Inc., Mississauga, Canada), (3) disinfection with chlorine dioxide wipe (Tristel Trio Wipes System; Tristel plc., Cambridgeshire, UK), (4) UV-C light system (UV Smart, Delft, The Netherlands). All costs are reported in CAD, and consumable and capital costs for reprocessing methods were obtained from reported vendor prices. Time costs were derived from manufacturer recommendations, the Ontario Medical Association Physician's Guide to Uninsured Services, and the Ontario Nurses Association Collective Agreement. Cost analyses determined the most cost-effective reprocessing method in the community setting. Sensitivity analyses assessed the impact of reprocessing volume and labor costs.
- Results: Thirty-six (86%) otolaryngologists responded and answered the survey. The cost per reprocessing event for Cidex-OPA, Revital-Ox, Tristel and UV system were $38.59, $26.47, $30.53, and $22.74 respectively when physicians reprocessed their endoscopes themselves. Sensitivity analyses demonstrated that Revital-Ox was the least costly option in a low volume, however, the UV system remained the most cost effective in higher volumes. The cost per reprocessing event when done by clinic staff was $5.51, $4.42, $11.23, and $6.21 for Cidex-OPA, Revital-Ox, Tristel and the UV system. [Figure 17]

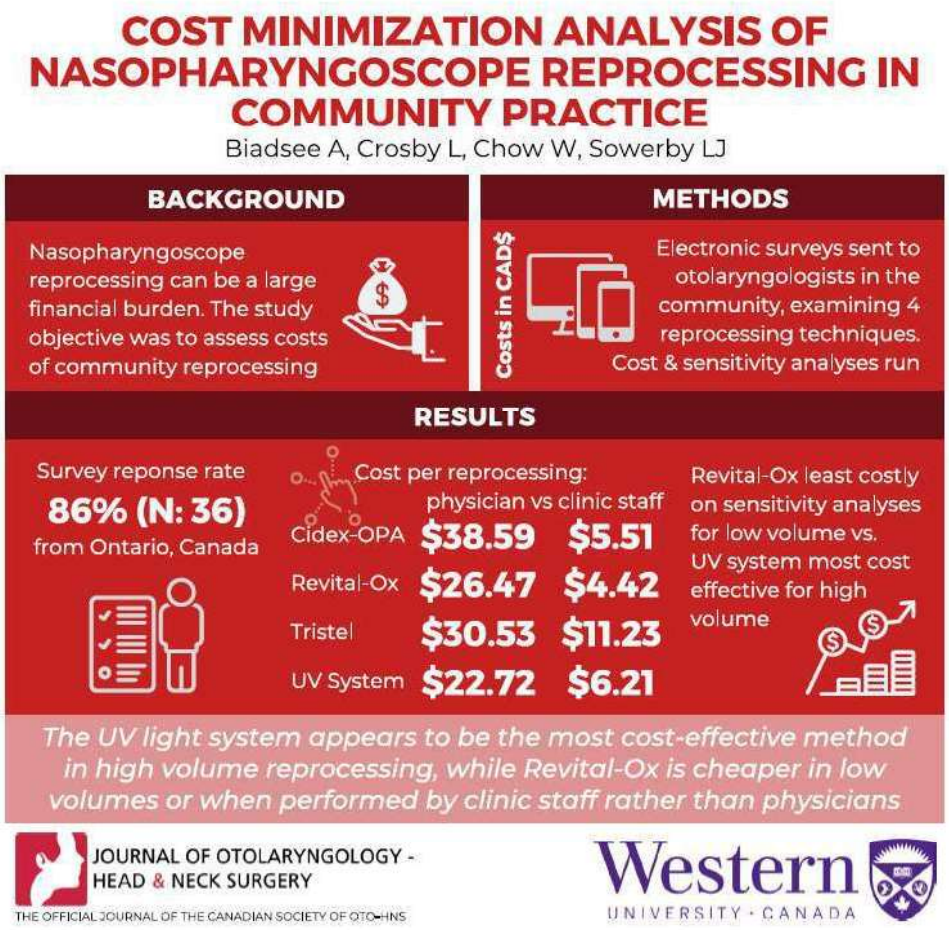

Figure 17. Cost minimization analysis of Nasopharyngoscopy reprocessing in community

9.2.2 Comparative ROI Analysis: UV Smart D60 vs. Traditional Disinfection Methods

To assist healthcare institutions in evaluating the potential advantages of the UV Smart D60, UV Smart has introduced a specialized ROI calculator. This tool allows users to select their current disinfection method—whether it's using a Disposable endoscope, Washer disinfector, or Soaking Chemical Solution—and compare it directly with the UV Smart D60. By inputting specific operational data, institutions can gain tailored insights into potential cost savings, sustainability benefits, and time efficiencies associated with transitioning to the UV Smart D60. This comparative approach not only highlights the economic benefits but also underscores the environmental and operational improvements, positioning the UV Smart D60 as a comprehensive solution for contemporary healthcare disinfection challenges.

The ROI calculator is available on: https://calculatord60.uvsmart.nl

9.2.3 Conclusion

- Reduced Cycle Costs: The UV Smart D60's disinfection method eliminates the dependency on consumables, leading to a decrease in recurring expenses associated with chemicals. Furthermore, the UV Smart D60's process doesn't rely on water, and results in additional utility savings.
- Optimized Device Inventory: The UV Smart D60's efficient disinfection process significantly reduces the time required for reprocessing, minimizing the need for device transportation. This rapid turnaround time ensures that devices are consistently ready for reuse, which directly leads to a reduced need for a large inventory of endoscopes. Healthcare facilities can therefore maintain a smaller number of devices while still meeting their operational needs effectively, thanks to the UV Smart D60's ability to quickly and reliably prepare equipment for next use.
- Labor/Staff Efficiency: By streamlining the disinfection process, the UV Smart D60 reduces both transportation and reprocessing durations. This efficiency can translate to fewer staff hours dedicated to these tasks, potentially leading to notable labor cost savings for healthcare facilities.
- Decreased endoscope Repairs: The UV Smart D60's efficient disinfection process minimizes the handling of endoscopes, thereby reducing the likelihood of device damage. Additionally, since the UV Smart D60 employs UV disinfection instead of chemicals, it may contribute to a longer lifespan for the endoscopes. This can lead to fewer instances of repairs or replacements, resulting in cost savings for healthcare facilities.
- Sustainability: The UV Smart D60's efficient disinfection process leads to a much more sustainable disinfection process; saving tonnes of CO_2 emissions: very low energy consumption, no usage of chemicals and reduce transport costs to zero.

10 Testimonials, Reference Sites and UV Academy

10.1 End users testimonials

10.1.1 Elisabeth-TweeSteden Hospital (ETZ), Tilburg

- Point of contact: Monique Rijpert (Team Leader outpatient ENT, ETZ)
- Background: In 2022, the ENT outpatient clinic at ETZ in Tilburg underwent a significant change by installing two UV Smart D60s for disinfecting all ENT endoscopes. The transition has been smooth, and the first few months have yielded positive outcomes.
- Previous Disinfection Method: Before the UV Smart D60, endoscopes were sent to the Central Sterilization Department (CSD) for overnight disinfection. During the day, due to a lack of immediate disinfection capacity, Endo sheaths were used between patients. Post-use, the endoscope was cleaned with alcohol for reuse. This method was time-consuming, especially for endoscopes used in the ETZ

Waalwijk ambulatory location, which had to be transported to Tilburg for disinfection.

- **Challenges with the Old Method:** Endo sheaths, though functional, obstructed the doctor's view and were a recurring expense. Additionally, careless removal could damage the endoscope tip. Transport bins also occasionally caused damage to the endoscope tips. Plus the costs of a sheath is roughly 10-13eur per sheath, increasing the costs dramatically per cycle.
- **Why UV Smart D60?** The primary motivation was time efficiency. Alternatives like washing machines, even the faster ones, took 20-25 minutes per cycle. The UV Smart D60, with its 60-second disinfection time post-manual cleaning, was the clear choice.
- **Current Process with the UV Smart D60**: ETZ Elizabeth has dedicated a room for pre-cleaning and disinfection, housing two UV Smart D60 units. Two staff members manage the disinfection process. An alert system indicates when a used endoscope is ready for cleaning. After the leak test and manual pre-cleaning, the endoscope is disinfected in the UV Smart D60 and is ready for reuse. On busy days, even with over 50 endoscopes to be reprocessed, the UV Smart D60 ensures efficient disinfection.
- **Testimonial Quote**: *"Some days we need over 50 endoscopes. On such a busy day, disinfecting with the [UV Smart] D60 is still a piece of cake!"*

10.1.2 Reinier de Graaf Hospital and Technical University Delft

- **Background:** The Reinier de Graaf Hospital, in collaboration with TU Delft, embarked on a transformative journey to enhance their disinfection methods. The primary objective was to reduce CO2 emissions and optimize turnaround time for endoscope disinfection.
- **Previous Method:** Endoscopes underwent an 8-step disinfection process, which involved transporting them to the Central Sterilization Department (CSD) for overnight disinfection. This method was time-consuming and depended heavily on the CSD's capacity.
- **Transition to UV Smart D60:** The hospital integrated the UV Smart D60 into their disinfection process, reducing the steps to just 6. This new method eliminated the need for transportation to the CSD, and endoscopes could be disinfected in just 60 seconds after manual pre-cleaning.
- **Benefits Realized:**
    - **Efficiency:** The UV Smart D60's rapid disinfection cycle has streamlined the process, making it possible to disinfect over 50 endoscopes even on the busiest days.
    - **Sustainability:** The new method has significantly reduced the hospital's carbon footprint. With implementing the D60 on an annual basis a total of 8703.65kg of CO2 was saved.
    - **Cost Savings:** The UV Smart D60 method has reduced the consumption of chemicals, water, and energy, leading to substantial savings.
    - **Improved Turnaround Time:** The term 'endoscope turnaround time' now refers to a much shorter duration, indicating how quickly an endoscope is available again for use on the next patient.

- **Testimonial Quote:** *"If a UV Smart D60 is used for disinfection of channel-less flexible ENT endoscopes at the main location, 2.5 FTE (Full time equivalent) employees per year can be saved."*

10.2 Reference sites and training centers

Reference sites and training centers are integral in sharing knowledge and practical application of emerging disinfection technologies, such as the UV Smart D60. These centers provide infection prevention professionals with the opportunity to observe the operational use and outcomes of the UV Smart D60.

UV Smart is in the process of establishing more reference sites across various countries to facilitate localized training and hands-on experience. Today, UV Smart has reference centers in the Netherlands, Belgium, United Kingdom, Germany, USA, Spain, Italy, Switzerland, Norway, Canada, and more countries are following. Detailed information about existing reference sites or training centers is available upon request. To have a meeting with one of the reference sites is also possible.

10.3 UV academy

The UV Academy is a dedicated platform centred on UV-C disinfection in healthcare. It encompasses a diverse range of resources, from detailed studies and articles to foundational information about UV-C light. By accessing the UV Academy, individuals can deepen their understanding of both the scientific principles and practical applications of UV-C, keeping them updated on the latest research and best practices in this evolving disinfection method.

Link UV Academy: https://www.uvsmart.nl/uv-academy

10.4 Recognition in Sustainability

The UV Smart D60 was recognized at the National HealthTech Innovation Awards 2023, receiving the award for 'Best in Sustainability.' This award highlights the device's role in sustainable healthcare practices. The UV Smart D60 is designed for efficient disinfection with a focus on reducing environmental impact. This recognition confirms that the device meets current environmental and health safety standards."

Figure 18. The UV Smart D60 – Best in Sustainability Award – National HealthTech Innovation Awards 2023

11 General Conclusions

In the continuously evolving domain of infection prevention, the introduction of new technologies necessitates thorough evaluation and validation. The UV Smart D60 protocol, utilizing UV-C light for disinfection and (pre-)cleaning with a microfiber wipe, is one such technology that has been assessed in this document. While traditional disinfection methods maintain their established roles, the UV Smart D60 has been shown to align with standards such as EN-15883-4 and EN-14885:2018.

This document has provided a detailed examination of the UV Smart D60, covering its safety parameters, disinfection efficacy, and compatibility in clinical environments. Validation data from both laboratory and hospital settings have been presented to offer a comprehensive view of its performance. Additionally, case studies from end users have been included to provide insights into its practical application.

In summary, the UV Smart D60 represents a potential option for those considering alternative disinfection methods. This document aims to furnish healthcare professionals with the necessary information to make informed decisions regarding its implementation.

12 Annex A – External references

The following documents may be shared on request.

4.1.2. Results and findings

List of relevant documents	Content
DOC-914	UV Smart D60 - Clinical Evaluation Plan
DOC-1587	UV Smart D60 - Bactericidal efficacy (Eurofins)
DOC-1588	UV Smart D60 - Fungicidal efficacy (Eurofins)
DOC-1589	UV Smart D60 - Fungicidal and yeasticidal efficacy (Eurofins)
DOC-1591	UV Smart D60 - Mycobactericidal and Tuberculocidal efficacy (Eurofins)
DOC-1592	UV Smart D60 - Sporicidal efficacy (Eurofins)
DOC-1593	UV Smart D60 - Virucidal efficacy (Eurofins)

4.2.2 Results and implications

List of relevant documents	Content
DOC - 1594	UV Smart D60 - Hospital tests at The Spaarne Hospital
DOC - 1595	UV Smart D60 - Hospital tests at The University Hospital of Giessen and Marburg
DOC - 1596	UV Smart D60 - Hospital tests at Ghent University Hospital
DOC - 2681	UV Smart D60 - Hospital tests at Elizabeth TweeSteden Ziekenhuis (ETZ)
DOC - 2682	UV Smart D60 - Hospital Tests Multi-Center Study
DOC - 2795	UV Smart D60 - NYU Langone Health study
DOC - 1583	UV Smart D60 - Clinical Evaluation Report*

6.2. Endoscope protection

List of relevant documents	Content
DOC - 1536	UV Smart D60 - Material Compatibility Verification Report
DOC - 2412	UV Smart D60 - Masterlist Compatibility
DOC - 2667	UV Smart D60 - Atmos compatibility verification report (flexible endoscopes)
DOC - 1717	UV Smart D60 - Memorandum scope/probe compatibility
DOC - 2258	UV Smart D60 - Oldelft compatibility verification report
DOC - 2416	UV Smart D60 - PatCom Compatibility Verification Report
DOC - 1536	UV Smart D60 - Material Compatibility Verification Report
DOC - 2304	UV Smart D60 - Siemens Compatibility Verification Report
DOC - 1700	UV Smart D60 – Olympus Compatibility Verification Report

The above mentioned documents may be shared on request

Endoscope protection

8.1. Electrical Safety and EMC tests

List of relevant documents	Content
DOC-2428	UV Smart D60 - CB test certificate of IEC 61010-1 Product Safety test
DOC-2533	UV Smart D60 - CB test certificate IEC 61326-1
DOC-793	UV Smart D60 - Risk Management Results*

List of relevant documents	Content
DOC - 908	D60 - Instructions for Use (English)

The above mentioned documents may be shared on request

8.2. UV-C exposure safety

List of relevant documents	Content
DOC-614	UV Smart D60 - Risk Management Plan
Online	UV Smart D60 - Risk Matrix (GG)
DOC-793	UV Smart D60 - Risk Management Results*
DOC-2332	UV Smart D60 - CB Test Certificate EN 62471 Photobiological

9.2.2. Comparative ROI Analysis: UV Smart D60 vs. Traditional Disinfection Methods

List of relevant documents	Content
DOC - 2683	Cost minimization analysis of nasopharyngoscope reprocessing in community practice
DOC - 2945	A quantitative study with Reinier de Graaf Hospital and TU Delft

13 Annex B – Example of rationale for implementation

Subject: Rationale for Deviation from Guidelines in Implementing UV Smart D60 Protocol

Date: [Insert Date]

To: [Hospital Administration/Infection Control Committee]

Dear [Recipient's Name],

I am writing to present a rationale for deviating from the existing guidelines in favor of implementing the UV Smart D60 Protocol within our hospital. The UV Smart D60, backed by extensive research and testing, offers a revolutionary approach to disinfection that can significantly enhance the safety, efficiency, and cost-effectiveness of our healthcare environment.

1. Literature Review on UV-C Light:

Extensive literature on UV-C light has consistently demonstrated its efficacy in eradicating a wide range of pathogens, including bacteria, viruses, and fungi. UV-C light, as utilized in the UV Smart D60, has been proven to be a powerful and reliable method for disinfection, providing a thorough and consistent approach to eliminating infectious agents.

2. Laboratory and Clinical Tests on UV Smart D60:

Rigorous laboratory tests and clinical trials conducted on the UV Smart D60 have consistently shown its effectiveness in reducing microbial contamination. The device has undergone comprehensive assessments, ensuring its ability to meet the highest standards for disinfection in healthcare settings. These tests have demonstrated a significant reduction in microbial load, emphasizing the device's reliability and suitability for our hospital environment.

3. Pre-Cleaning Protocol:

The UV Smart D60 incorporates a pre-cleaning protocol that enhances its efficiency by removing organic material and debris before the UV-C disinfection process. This ensures that the UV light can effectively target and neutralize pathogens, providing an additional layer of safety and reliability in the disinfection process.

4. Compatibility Statements & Tests:

The UV Smart D60 has been subjected to compatibility tests with various medical equipment surfaces and materials commonly found in healthcare settings. These tests have confirmed the device's compatibility with a wide range of materials, assuring us that its implementation will not compromise the integrity of our facility's infrastructure.

5. Advantages of Implementing UV Smart D60:

a) Chemical-Free Disinfection: The UV Smart D60 eliminates the need for chemical disinfectants, promoting a safer work environment for both patients and healthcare professionals while minimizing exposure to potentially harmful substances.
b) Faster Turn-Around Times: The automated and rapid disinfection process of the UV Smart D60 allows for faster turn-around times in patient rooms and other critical areas, reducing the risk of cross-contamination and improving overall operational efficiency.
c) Cost Savings: The long-term cost savings associated with decreased reliance on chemical disinfectants reduced inventory needs, and fewer incidents of endoscope damage, all complemented by enhanced operational efficiency, make the UV Smart D60 a financially prudent investment for our hospital.

In conclusion, based on the robust scientific evidence, thorough testing, and the numerous advantages offered by the UV Smart D60 Protocol, deviating from existing guidelines to implement this innovative technology will undoubtedly contribute to creating a safer, more efficient, and cost-effective healthcare environment.

Sincerely,

[Your Name]

[Your Title/Position]

[Hospital Name]

Please contact us for more information:

UVsmart

info@uvsmart.nl

UV Smart - EMEA

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DOCUMENT REVIEW AND UPDATES:

This document was last reviewed on January 2024. It is essential to ensure that the information contained herein remains current and relevant to the evolving practices and standards in the field of infection prevention and disinfection. As such, this document will undergo periodic reviews and updates. The next scheduled review is set for September 2024. Feedback and insights from professionals in the field are always welcome to enhance the document's accuracy and relevance.

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(DOC-2930) Ver. 0

Radboudumc

A revolutionary way of disinfecting flexible endoscopes without a working channel: UV-C light

A more efficient, cheaper and sustainable way of disinfection – Y. Halmans[1], D.J. Wellenstein[1], M. Romijn[1], A.J.M. van Bemmel[2], H. van den Berge[3], R.A. Scheeren[4], R.P. Takes[1], G.B. van den Broek[1]
1. Radboud University Medical Center, Nijmegen, The Netherlands 2. Medical Spectrum Twente, Enschede, The Netherlands 3. Medical Center Leeuwarden, Leeuwarden, The Netherlands 4. Spaarne Gasthuis, Haarlem, The Netherlands

1. Background

- Flexible endoscopes (FEs) without a working channel can be significantly contaminated after use[1].
- International consensus about FE reprocessing is missing.
- The current disinfection process is *time-consuming* (figure 1).
- Ultraviolet light group C (UV-C) causes destruction of microorganisms and can be used as a disinfection method[2].

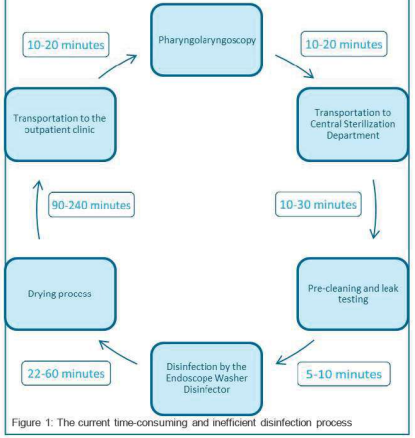

Figure 1: The current time-consuming and inefficient disinfection process

2. Aim

Investigate Colony-Forming Unit (CFU) reduction on FEs without a working channel after UV-C disinfection compared to the Endoscope Washer Disinfector (EWD).

3. Methods

- Performed at three different otorhinolaryngology departments in The Netherlands.
- After pharyngolaryngoscopy and manual pre-cleaning, a culture was collected by rolling the distal end over a Plate Count Agar plate.
- Then, the FE was disinfected by the D60 (60-seconds disinfection process using UV-C light) (figure 2 and video 1) or the EWD (standard disinfection process using water and chemicals).
- After disinfection, a new culture was taken.
- After incubation, a CFU count was performed.

Figure 2: The D60 UV-C light disinfector

4a Results before disinfection

- Total of 600 FEs without a working channel.
- After clinical use, a variable number of CFU was found (figure 3).
- FEs that showed 0 CFU after clinical use were excluded from further analyses.

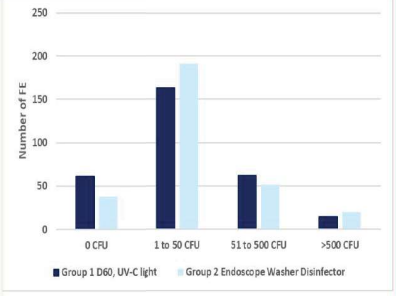

Figure 3: Number of FEs depending on CFU contamination after clinical use by disinfection group

4b Results after disinfection

- In total, 195 of the 239 **(81,6%)** FEs showed 0 CFUs after UV-C light disinfection (figure 4).
- 187 of the 262 **(71,4%)** FEs showed 0 CFUs after disinfection with the EWD (figure 4).

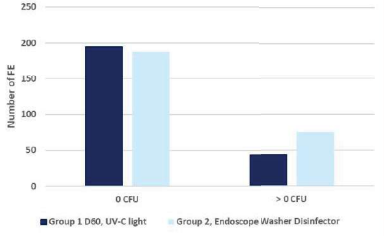

Figure 4: Number of FEs depending on CFU contamination after disinfection by disinfection group

5. Conclusions

- Disinfection with UV-C light might be more effective in CFU reduction on FEs without a working channel compared to the EWD.
- Additional, UV-C light *reduces the duration* of the disinfection process.

1. Kenters N, Huijskens EG, Meier C, Voss A. Infectious diseases linked to cross-contamination of flexible endoscopes. Endosc Int Open. 2015;3(4):E259-65.
2. Owens MU, Deal DR, Shoemaker MO, Knudson GB, Meszaros JE, Deal JL. High-dose ultraviolet C light inactivates spores of Bacillus atrophaeus and Bacillus anthracis sterne on nonreflective surfaces. Applied Biosafety. 2005;10(4):240-7.

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The Effectiveness of UV Smart D60 In Reducing Contamination of Flexible Fiberoptic Laryngoscopes

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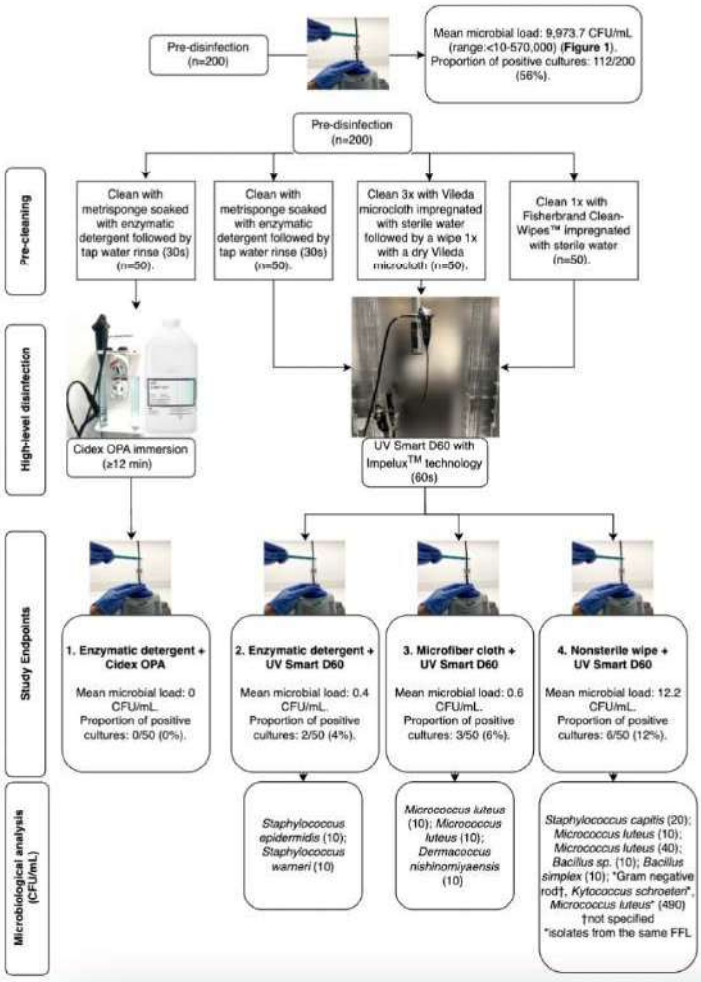
Introduction

- Flexible laryngoscopes (FFLs) are routinely exposed to the mucus membranes of the nasal cavity and pharynx.
- They are semi-critical instruments that require high-level disinfection (HLD)[1].
- Traditional disinfection methods include chemical immersion and automated endoscope reprocessors (AER).
  - Both processes use chemical liquid agents, which are toxic, require lengthy disinfection/processing times, and are incompatible with endoscope material[2-4].
  - These methods may be less suitable for large ENT settings that require rapid FFL turnover[5].
- **The aim of our study was to compare the bactericidal efficacy of various cleaning methods utilizing UV Smart D60 to a standard reprocessing method using Cidex OPA.**

Methods and Materials

- 200 FFLs were sampled after clinical use and another 200 after cleaning with 1 of 4 disinfection methods (**Figure 1**).
- Sample were vortexed (~ 2 minutes) and cultured on blood agar plates.
- If growth was detected, the number of colonies were counted and reported as colony forming units per mL (CFU/mL).
  - Positive post-sample cultures were gram-stained and bacterial identification was performed.
- We utilized a proprietary UV Smart D60 light machine with Impelux™ technology for UV disinfection protocols.
- Effective disinfection was defined as a bacterial count of <10 CFU/mL.

Figure 1. An outline of each decontamination workflow.



Results

- 112 of 200 FFLs had positive bacterial growth (56%).
- Mean microbial load pre-disinfection: 9,973.7 CFU/mL ± 70,136.3 (range: <10 to 570,000 CFU/mL (**Figure 2**).
- Bioburden levels significantly decreased after each disinfection technique ($p<0.001$).
- There was no statistically significant difference between each disinfection group by proportion of positive cultures (**Table 1**) or mean microbial load (**Table 2**) ($p>0.05$).
- 13 bacterium were recovered on 11 FFLs (most common organism isolated was *Micrococcus* sp. (53.8%) (**Table 3**). None of the isolates had high-pathogenicity[6].

Figure 2. Distribution of microbial burden after clinical use and after HLD.

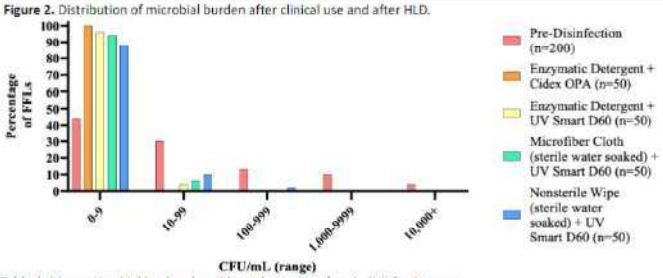


Table 1. Mean microbial load and positive culture rate of each disinfection arm.

Disinfection Protocol	Mean microbial load (CFU/mL)	Positive culture (%)*
Pre-disinfection	9,973.7	112/200[a] (56)
1. Enzymatic detergent + Cidex OPA	0	0/50[b] (0)
2. Enzymatic detergent + UV Smart D60	0.40	2/50[b] (4)
3. Microfiber cloth + UV Smart D60	0.60	3/50[b] (6)
4. Nonsterile wipe + UV Smart D60	12.2	6/50[b] (12)

*Pearson $\chi 2$ test
[a]proportions did significantly differ from each other at p=0.05
[b]proportions did not significantly differ from each other at p=0.05

Table 2. Pairwise comparisons of the mean log CFU of each disinfection arm (Dunn's test).

Disinfection Protocol	Test-statistic*	p-value
Arm 1 vs. 2	-0.326	0.744
Arm 1 vs. 3	-0.489	0.625
Arm 1 vs. 4	-1.152	0.249
Arm 2 vs. 3	-0.163	0.870
Arm 2 vs. 4	-0.826	0.409
Arm 3 vs. 4	-0.663	0.507

*Kruskal-Wallis test with Dunn's correction for pairwise comparisons.

Table 3. Frequency of bacterial organisms (n=13).

Bacterial Species	Source	Frequency (%)
Micrococcus sp.	environmental, skin	7 (53.8)
Coagulase-negative *Staphylococci* sp.	skin	3 (23.1)
Bacillus sp.	environmental	2 (15.4)
Gram-negative rod, not specified	--	1 (7.7)

Conclusion

- Decontamination protocols with UV Smart D60 were as effective in removing contamination from FFLs as our traditional method of using Cidex OPA.
- We found UV disinfection to be faster, simpler, less toxic, and more resource-efficient, which will increase compliance with FFL disinfection in patient care settings and enhance healthcare worker and patient safety.

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References

1. Spaulding EH. The role of chemical disinfection in the prevention of nosocomial infections. In Proceedings of the International Conference on Nosocomial Infections. American Hospital Association Chicago. 1970;1971:254-274
2. Sokol WN. Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA (ortho-phthalaldehyde) high-level disinfectant in 4 patients after cystoscopy. Journal of Allergy and Clinical Immunology. 2004;114(2):392-397. doi:10.1016/j.jaci.2004.04.031
3. Takagawa T, Endo Y. Effects of Glutaraldehyde Exposure on Human Health. Jrnl of Occup Health. 2006;48(2):75-87. doi:10.1539/joh.48.75
4. Cowan RE, Manning AP, Ayliffe GA, et al. Aldehyde disinfectants and health in endoscopy units. British Society of Gastroenterology Endoscopy Committee. Gut. 1993;34(11):1641-1645. doi:10.1136/gut.34.11.1641
5. Biebsee A, Crosby L, Chow W, Sowerby LJ. Cost minimization analysis of nasopharyngoscope reprocessing in community practice. J of Otolaryngol - Head & Neck Surg. 2023;52(1):8. doi:10.1186/s40463-022-00610-9
6. Duodenoscope-Surveillance-Sampling-and-Culturing-Protocols US Food and Drug Administration website. Published online February 2018. Accessed November 1, 2022. https://www.fda.gov/media/111081/download

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MISCELLANEOUS

UV light-based reprocessing of flexible endoscopes without working channel in Oto-Rhino-Laryngology: an effective method?

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Abstract

Background Reprocessing of flexible endoscopes (FEs) is often expensive, time consuming, and becomes increasingly complex, due to rising demands of hygiene. After beneficial results in reprocessing of rigid endoscopes using Impelux™ UV-C light technology, we tested the same method for reprocessing of FEs without working channel.

Materials and methods Testing was performed on FEs without working channel after routine clinical use (transnasal flexible endoscopy). Disinfection consisted of mechanical precleaning and 60 s exposure to Impelux™ UV-C light technology. Bacterial contamination was tested on 50 FEs before and after disinfection. Further 50 FEs regarding protein residuals. The absolute effectiveness of the D60 was tested on 50 test bodies (RAMS) with a standardized contamination of 10^7 colony-forming units (CFU) of Enterococcus faecium.

Results The FEs were contaminated with a high average value of 916.7 CFU (± 1057 CFU) after clinical usage. After reprocessing, an average contamination of 2.8 CFU (± 1.6) on 14% ($n = 7$) of the FEs was detected consisting of non-pathogenic species, the remaining FE were sterile. After reprocessing, all FEs were protein-free (< 1 µg). The artificially contaminated test bodies showed no remaining bacterial contamination after disinfection, resulting in an average absolute germ reduction of about 10^7 CFU.

Conclusion Impelux™ UV-C light technology efficiently reduces bacterial contamination of FEs and might be useful in daily practice.

Keywords Hygiene · Sterilization · Disinfection · Microbiology

Introduction

Flexible endoscopes (FEs) without working channel are an integral part of all endoscopic examinations in various medical disciplines. Within the field of otorhinolaryngology (ORL), they are often used for the clinical examination of the upper aero-digestive tract in terms of transnasal flexible endoscopy. In this context, FEs are especially suitable for patients which are difficult to examine due to an enhanced pharyngeal reflex. In the clinical routine of an ORL-outpatient department, FEs are often used and reprocessed multiple times a day, which is time consuming and associated with a risk of loss or damage of the endoscopes during processing and transportation. According to the results of a previous study on rigid endoscopes, extensive contamination, including pathogenic bacteria, can be assumed after clinical use of the endoscopes in ORL [1]. Hence, the reprocessing of FEs is highly important to prevent transmission of pathogens between the patients. Therefore, the prevention of transmission events is mostly related to an insufficient reprocessing between the patients examinations [2]. In the last years, several outbreaks with highly resistant pathogens revealed the relevance of a reliable reprocessing of the endoscopes [3]. According to the Spaulding`s classification,

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system of medical equipment at least a high-level disinfection is required for endoscopes without working channel due to their classification as semi-critical patient care devices [4–7]. Hence, a large number of high-level disinfection methods are applied for reprocessing of endoscopes in ORL and, up to now, no standard has been implemented. However, reprocessing of FEs on high-level standards gets increasingly complex due to the increasing number of multi-resistant bacteria and the resulting demands of hygiene. Up to now, established methods for reprocessing of FEs are often costly and time consuming and sometimes lacking standardizability. Therefore, new, cheaper and faster methods are required for daily use in an ORL with a high volume of patients, without compromising the safety and quality of reprocessing.

Previous studies have revealed satisfactory results regarding surface disinfection by UV light. In this context, its effectiveness against problematic hospital-acquired-germs or biofilm-building bacteria has to be highlighted [8, 9]. Surface disinfection by UV light is known for more than 120 years. Nils Ryberg Finsen, a Danish physician, was one of the first who successfully treated bacterial infections in patients by UV light. He even was awarded with the Noble Prize for Medicine in 1903 for successfully treating tuberculosis of the skin by UV light [10, 11]. Several years later, in the 1930′s, UV lamps became commercially available and were widely used in medicine after the Second World War. After 1945, disinfection agents were not commonly available in the medical sector, therefore, UV lights were used in permanent operation for prevention of bacterial outbreaks in medical facilities [12]. Due to continuous improvements in technology, UV light has now a wide application range, e.g. it is used worldwide for disinfection of natural drinking water, where it is preferred, as it does not influence its natural taste or smell characteristics [13]. We have previously tested a UV light system for the reprocessing of rigid endoscopes with promising results. In this study, an absolute bacterial reduction on standardized test bodies of about 10^6 CFU was observed. Furthermore, in clinical practice, nearly all endoscopes were sterile and practically protein-free after reprocessing [1]. To our knowledge, UV light systems have not been analyzed for the reprocessing of FEs in ORL to date. In contrast to the D25, the D60 is specially developed for bigger sized endoscopes as FEs in ORL. Thus, in this trial, we analyzed the efficiency of UV-C light in the disinfection of FEs without working channel using the D60 UV light system.

Materials and methods

Reprocessing of endoscopes

The present study was performed at a tertiary care unit. We included the whole spectrum of patients with different ORL diseases, including infectious and non-infectious patients to analyze a representative cross-section of used endoscopes. The tested UV light system was analyzed in an everyday clinical use scenario. In this study, we tested the D60 UV light system (UV Smart, Delft, Netherlands) for reprocessing of non-channel FEs 2.5 × 270 mm, (KARL STORZ SE and Co. KG, Tuttlingen, Germany) with a plastic surface and a steerable tip used within the field of ORL.

The examined FEs were reprocessed by mechanically precleaning for 20 s with a water-soaked tissue. To create these precleaning wipes, we used a box with 100 polyester dry wipes (Schülke Wipes Safe and Easy, Schülke GmbH, Norderstedt, Germany) and filled the box with 2 L of distilled and sterilized water (Ampuwa, Fresenius Kabi Germany GmbH, Bad Homburg, Germany). After precleaning, the air-dried endoscopes were hung in the D60 and got exposed to UV light for further 60 s. Each endoscope was disinfected separately after usage. After UV light exposure, the residual contamination on the endoscopes was evaluated. Finally, in order not to compromise patient safety, each endoscope was reprocessed with a washer-disinfector (WD425E, Belimed, Zug, Switzerland) in accordance with a standardized protocol.

Microbiological examination/protein testing of endoscopes

First, 50 FEs were tested on trypticase soy agar-based surface contact samples (Merck Millipore, Darmstadt, Germany) directly after clinical use (posterior rhinoscopy/laryngoscopy) to evaluate the bacterial contamination on the endoscopes. Then, 50 further FEs were tested by contact sampling after endoscopic examination and reprocessing by water-based precleaning and UV light exposure in the D60. Microbiological tests were taken from the first 12.5 cm of the shaft, due to the length of the contact samples, adjusting the tip of the endoscope a neutral 0 degrees position. The tip and shaft of the examined endoscope were fixed on the ager plate by a sterile tweezer to avoid partial lifting of the endoscope from the test plate. The test plates were incubated at 37 °C for 1 week. Afterwards, matrix-assisted laser desorption ionization time-of-flight mass spectrometry (Bruker Daltonik, Bremen, Germany) was used for microbiological identification. Third, protein residues were tested on 50 endoscopes after clinical use and reprocessing by precleaning and UV exposure using the Medi-Check™ (Hygiena Medisafe GmbH, Wentorf, Germany) test-kit. These tests for protein contamination were used as tracer for prion- and viral load on the endoscopes after usage on the patient. Results were reported by change of color, according to the detected amount of protein contamination on the endoscope. After incubation at 55 °C for 15 min, the range of the test-kit

represented a contamination from 0 (light green) to 50 µg (dark grey/black).

Testing of bactericidal reduction on standardized RAMS test bodies

The effectiveness of disinfection by the D60 was evaluated under standardized conditions with 10 cm stainless-steel test bodies, contaminated with bacterial load of approximately 8×10^7 CFU of *Enterococcus faecium*. 52 test bodies were used: 50 were reprocessed with the D60 and 2 were used to prove the initial bacterial contamination on the test bodies (control samples). The so-called "RAMS" contamination on the surface of the test bodies consists of *Enterococcus faecium*, corn starch, bovine albumin and mucein to simulate an organic contamination on the endoscope. RAMS test bodies are commonly used in testing of reprocessing devices for instruments of the highest category in Spaulding's classification system [5]. Hence, the testing conditions using RAMS test bodies are equal with the highest reprocessing standards in medicine. Methodically, the test body was hung inside the D60 with a metal wire, in the same position as the endoscope is usually placed for reprocessing. The metal wire had no contact with the microbiologically examined parts of the test body and furthermore, the test body did not touch the surface of the D60. The RAMS test bodies were reprocessed in the same way as the tested endoscopes (water-based precleaning and UV-C exposure by the D60). To avoid interference by shadowing, each test body was cleaned separately.

The D60 UV light system

The UV Smart D60 UV light system uses UV-C light for the disinfection of medical endoscopes within 1 min. Except the water-based precleaning, no further detergents or liquids are needed for reprocessing endoscopes by the D60. The endoscopes should not exceed a maximum length of 120 cm to fit into the disinfection chamber (Fig. 1a). The holder for the endoscopes in the D60 is made of transparent glass which allows the UV light to reach the endoscope surface (Fig. 2). For prevention of the carcinogenic UV radiation, the device is sealed while reprocessing. Hence, while applying UV light, the radiation is not able to escape the D60 (Fig. 1b). In accordance to UV Smart's trials, the D60 light system reaches a log-5 bacterial reduction within 1 min. Therefore, the D60 was preset for a disinfection time of 1 min.

The UV technology used in the D60 light system (UV Smart Impelux™ technology) works at a wavelength of 253.7 nm. An application dose of 1962 J/m^2 is delivered in each cycle. According to internal investigations of the manufacturer, the applied UV-C dose does not affect the surface of the endoscope. Nevertheless, it causes DNA and RNA destruction in irradiated microorganisms on the endoscope.

Fig. 1 **a** Arrangement of a FE in the D60. **b** Sealed D60 while reprocessing a FE

Fig. 2 Close-up of the endoscope holder with a FE

Dirt, debris and grime are not penetrable for the germicidal effect of the UV-C light. Hence, all endoscopes must be optically clean before using the UV light system.

Statistics and ethical approval

Excel 2019 (Microsoft Corporation, Redmond, Washington, USA) was used for statistical descriptive analysis. According to the statement of the ethics committee, a formal approval was not needed, as neither patients nor personal data were included. However, this study was notified to the ethics committee of the Medical Faculty of the Philipps-Universität Marburg.

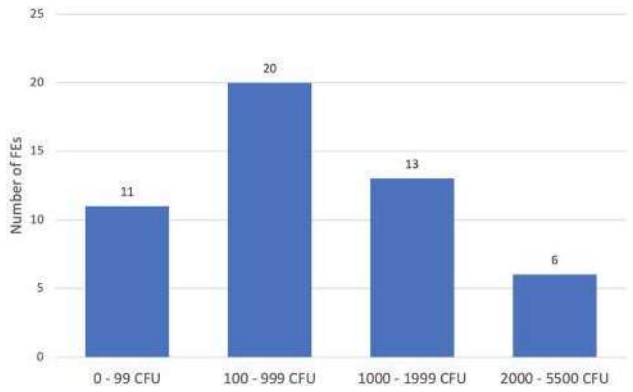

Fig. 3 Number of FEs depending on the contamination on their surface after clinical usage in the patient without disinfection

Table 1 Identified bacteria and number on the FEs after clinical use before UV exposure

Identified bacteria	Number (%)
Coagulase negative *Staphylococcus*	45 (90%)
Micrococcus luteus	16 (32%)
Staphylococcus aureus	13 (26%)
Neisseria species	8 (16%)
Klebsiella aerogenes	7 (14%)
Bacillus species	6 (12%)
Corynebacterium species	5 (10%)
Viridans streptococci	2 (4%)
Klebsiella oxytoca	1 (2%)

Results

Directly after clinical use without any kind of reprocessing a high contamination was found on the FEs. The mean value on all 50 endoscopes was 916.7 CFU (± 1057; 10–5500 CFU) (Fig. 3). A highly variable bacterial flora was found on the FEs, including germs of the permanent mucosal flora (e.g. *Coagulase Negative Staphylococci*) as well as potentially pathogenic bacteria (e.g. *Klebsiella spp.*). The bacterial cultures identified on the microbiological samples and the frequency of detection are shown in Table 1.

The FEs reprocessed by the D60 showed an average contamination of 0.28 CFU. A bacterial contamination was found on seven (14%) FEs (1 CFU in six cases and 8 CFU in one case; ø 2 CFU). The bacteria found on the FEs after reprocessing can all be attributed to the mucosal microflora (*Coagulase Negative Staphylococci*, *Micrococcus luteus*, *Bacillus spp.* and *Corynebacterium spp.*). The remaining 43 (86%) endoscopes were sterile after reprocessing (0 CFU).

After water-based precleaning and UV-C disinfection, all of the 50 tested FEs were nearly protein-free (< 1 µg). Only 2 FEs showed a minimal contamination (< 1 µg), while the other 48 FEs were protein-free (0 µg).

No further bacterial contamination (0 CFU) was found on the 50 standardized RAMS test bodies after reprocessing. The two control samples still were contaminated with 8×10^7 CFU, which results in a germ reduction of about 10^7 for the reprocessed test bodies.

Discussion

In the context of cross-contamination caused by used endoscopes and several healthcare-associated infections with multi-resistant pathogens, new and especially safe ways of surface disinfection might by highly relevant in the future [3]. As shown in a recent study regarding the D25 UV light system, the Impelux™ technology for UV-C disinfection could be a suitable method for handling these problems [1]. However, a device reprocessing FEs by UV light has not been investigated to date. Therefore, we tested the D60 UV light system for reprocessing of FEs, showing results similar to the study on the D25 UV light system and fulfilling the requirements for a successful reprocessing between different patients. However, the results for the D60 (ø 0.28 CFU) were nearly as good as the results for the D25 (ø 0.12 CFU). It is noticeable that only one endoscope was contaminated with more than 1 CFU, which may be explained by an artificial contamination of this FE after reprocessing. In this context, the present study was performed in an outpatient department under clinical conditions. Therefore, handling with the FEs under unsterile conditions after reprocessing may further have influenced the results. Another explanation for the slightly higher contamination found in this study might be the differences in the surface texture between rigid and flexible endoscopes. In contrast to FEs, the surface of rigid endoscopes is made of stainless steel and consists of fewer components. Thus, design-specific characteristics of the FEs such as microscopic gaps between different components might prevent sufficient precleaning and disinfection by UV light. Furthermore, FEs are more difficult to preclean, due to their surface properties and missing mechanical resistance.

Generally, UV radiation destroys the cell's DNA and RNA, by forming thymine dimers. As a result, gene expression and replication is prevented and the irradiated cells die by apoptosis [14]. It is even efficient against otherwise problematic- and multi-resistant pathogens [6, 7, 12], Gram-positive and -negative bacteria, fungal and bacterial spores [15]. This can be explained by the fact that resistance mechanisms or biofilm-building abilities have no influence on the effectiveness of UV light. However, it is generally known that UV light also has a carcinogenic effect in irradiated organisms due to its physical mode of action on the DNA and RNA. Especially, skin cancer due to UV radiation by the sun is a

commonly problem for humans [16]. Hence, the operator requires a sufficient shielding when the device is applying UV light for disinfection reasons. In the device examined here, the shielding against UV radiation is achieved by a box-shaped design as well as a sealing of the device while applying UV light. However, due to its physical properties, UV light does not penetrate solids or not transparent liquids. In the context of ORL, these substances or fluids are represented by secretions of the upper airways, solid mucus or blood. Therefore, it is important to remove this gross contamination by a type of precleaning from the FE before using a UV-based disinfection method. Otherwise, reprocessing of the FE could be insufficient. However, due to its influence on the overall result, the importance of precleaning must be given special weight when examining a new reprocessing method. Therefore, a water-based wipe without any microcide, disinfectant or enzymatic components was used, in order not to interfere with the results by any precleaning agents. Furthermore, we chose a precleaning method that is also cost-effective, practicable and nearly everywhere available.

To date, there are no data in the literature regarding the expectable contamination on FEs after clinical usage within the field of ORL. Only one study analyzed the bacterial contamination on rigid 30° and 70° ORL endoscopes. A high bacterial load, with an average value of 66,908 CFU on the endoscopes was found in this study [1]. In the present study, we also found a high bacterial contamination (ø 916.7 CFU) on the tested FEs after clinical use with a high variety of contamination between the different FEs. However, several factors caused by the patient himself and the examination might influence the amount of contamination on the endoscopes. In this context, mainly the extent of mucosa-contact, the bacterial colonization on the mucosa and the varying infectivity between the patients have to be considered. The germs found correspond mostly to the typical mucosal flora of the upper airways [17]. Nevertheless, it has to be considered, that besides bacteria of the normal mucosal flora also facultative pathogenic bacteria have been found on the FEs after clinical use without disinfection. These pathogenic bacteria are able to cause severe, even life-threatening complications in some patients [4, 18].

For the standardized RAMS test bodies, an absolute bacterial log reduction factor (LRF) of 7 (from 8×10^7 CFU to 0 CFU) was found in the present study. By reaching an average reduction of LRF 7, the D60 fulfilled the requirements for semi-critical devices defined by the Commission on Hospital Hygiene and Infection Protection at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) in Germany [19]. In the present study, carrier substances as bovine albumin, mucein and corn starch were used which are normally used for testing of reprocessing methods for critical devices. Hence, the results suggest the potential of the tested device in reprocessing of even more difficult contaminations. The results for the standardized test body tests did not fluctuate during the test series. Therefore, it seems that the tested UV system delivers consistent reprocessing quality. In addition, the electronically controlled disinfection process ensures standardized and documented reprocessing cycles.

In addition, the quality of precleaning might have influenced the results. While several studies have investigated the importance of precleaning in UV-based disinfection methods, this issue remains controversial. Nevertheless, there is a tendency in the literature, that precleaning has a rather small effect on the final reprocessing result [20–23]. Furthermore, due to the physical properties of UV radiation, it must be assumed that protein residues are mainly reduced by the mechanical precleaning, but not by the UV light itself.

Some studies found the distance of the UV lamp to the object and further shadowing as one key factor for its performance [15, 24]. In the D60, this distance is relatively short and the light distribution seems to be efficient and prevents shadowing. Nevertheless, it cannot be ruled out that shadowing could have occurred in microscopically small gaps between the components of the FE. In contrast, the RAMS test bodies had a completely flat stainless-steel surface which prevents shadowing effects.

In case of endoscope reprocessing, besides efficiency, economic aspects are of importance. The time required for reprocessing and the associated personnel costs must be taken into account. In comparison to other reprocessing methods for FEs, a reprocessing cycle with the D60 is associated with minimal costs. In addition, the possibility for point-of-care disinfection offers additional advantages. The D60 works with a reprocessing cycle of about 2 min including precleaning, drying and disinfection.

Conclusion

Reprocessing of endoscopes is a complex and time consuming as well as cost-intensive process. In this context, the D60 UV light system showed good disinfection results in a routine clinical setting. In light of its potential for fast and simple point-of-care disinfection, it offers substantial advantages to standard disinfection methods for FE without a working channel.

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Data availability Available, if requested.

Declarations

Conflict of interest S. Rudhart received personal fees from UV Smart as a research assistant, outside the submitted work.

Ethics approval This study does not contain any studies with human participants or animals. All procedures performed in this study were in accordance with the ethical standards of the institution or practice at which the study was conducted. File number: ek_mr_6_12_19_stuck.

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References

1. Rudhart SA, Günther F, Dapper L, Thangavelu K, Gehrt F, Stankovic P, Wilhelm T, Guenzel T, Stuck BA, Hoch S (2020) UV light-based decontamination: an effective and fast way for disinfection of endoscopes in otorhinolaryngology? Eur Arch Otorhinolaryngol 277(8):2363–2369. https://doi.org/10.1007/s00405-020-05978-w
2. Seoane-Vazquez E, Rodriguez-Monguio R (2008) Endoscopy-related infection: relic of the past? CurrOpin Infect Dis 21(4):362–366. https://doi.org/10.1097/QCO.0b013e328301396b
3. Kenters N, Huijskens EG, Meier C, Voss A (2015) Infectious diseases linked to cross-contamination of flexible endoscopes. Endosc Int Open 3(4):E259-265. https://doi.org/10.1055/s-0034-1392099
4. Spaulding EH (1968) Chemical disinfection of medical and surgical materials. In: Lawrence CBS (ed) Disinfection, Sterilization, and Preservation. Lea & Febiger, Philadelphia, pp 517–531
5. Lerner J (2007) Ensuring the effective reprocessing of flexible endoscopes. Health Dev 36(11):352–361
6. Simmons BP (1983) CDC guidelines for the prevention and control of nosocomial infections. Guideline for hospital environmental control. Am J Infect Control 11(3):97–120. https://doi.org/10.1016/0196-6553(83)90122-0
7. Muscarella LF (1996) High-level disinfection or "sterilization" of endoscopes? Infect Control HospEpidemiol 17(3):183–187. https://doi.org/10.1086/647272
8. Marra AR, Schweizer ML, Edmond MB (2018) No-Touch disinfection methods to decrease multidrug-resistant organism infections: a systematic review and meta-analysis. Infect Control HospEpidemiol 39(1):20–31. https://doi.org/10.1017/ice.2017.226
9. Chen LH, Li Y, Qi Y, Wang SN, Gao CQ, Wu Y (2019) Evaluation of a pulsed xenon ultraviolet light device for reduction of pathogens with biofilm-forming ability and impact on environmental bioburden in clinical laboratories. PhotodiagnosisPhotodynTher. https://doi.org/10.1016/j.pdpdt.2019.08.026
10. Finsen NR (1896) Om anvendelse i medicinen af koncentrerede kemiske lysstraaler. Gyldendal, Copenhagen, pp 1–64
11. Nobel Lectures (1967) Physiology or medicine 1901–1921. Elsevier, Amsterdam, pp 121–128
12. Fenton L, Moseley H (2014) UV emissions from low energy artificial light sources. PhotodermPhotoimmunPhotomed 30(2–3):153–159. https://doi.org/10.1111/phpp.12094
13. Lyon BA, Milsk RY, DeAngelo AB, Simmons JE, Moyer MP, Weinberg HS (2014) Integrated chemical and toxicological investigation of UV-chlorine/chloramine drinking water treatment. Environ Sci Technol 48(12):6743–6753. https://doi.org/10.1021/es501412n
14. Wacker ADH, Weinblum D (1960) StrahlenchemischeVeränderung der Bakterien-Desoxyribonucleinsäure in vivo. Naturwissenschaften 47(20):477–477
15. Katara G, Hemvani N, Chitnis S, Chitnis V, Chitnis DS (2008) Surface disinfection by exposure to germicidal UV light. Indian J Med Microbiol 26(3):241–242. https://doi.org/10.4103/0255-0857.42034
16. Deshmukh J, Pofahl R, Haase I (2017) Epidermal Rac1 regulates the DNA damage response and protects from UV-light-induced keratinocyte apoptosis and skin carcinogenesis. Cell Death Dis 8(3):e2664. https://doi.org/10.1038/cddis.2017.63
17. Todar K (2006) Todar's online textbook of bacteriology. University of Wisconsin-Madison Department of Bacteriology Madison, Wis, USA
18. El Zowalaty ME, Gyetvai B (2016) Effectiveness of antipseudomonal antibiotics and mechanisms of multidrug resistance in Pseudomonas Aeruginosa. Pol J Microbiol 65(1):23–32
19. (KRINKO) CfHHaIP (2012) Hygiene requirements for the reprocessing of medical devices. Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM). Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 55(10):1244–1310. https://doi.org/10.1007/s00103-012-1548-6
20. Green C, Pamplin JC, Chafin KN, Murray CK, Yun HC (2017) Pulsed-xenon ultraviolet light disinfection in a burn unit: Impact on environmental bioburden, multidrug-resistant organism acquisition and healthcare associated infections. Burns 43(2):388–396. https://doi.org/10.1016/j.burns.2016.08.027
21. Vianna PG, Dale CR Jr, Simmons S, Stibich M, Licitra CM (2016) Impact of pulsed xenon ultraviolet light on hospital-acquired infection rates in a community hospital. Am J Infect Control 44(3):299–303. https://doi.org/10.1016/j.ajic.2015.10.009
22. Jinadatha C, Villamaria FC, Restrepo MI, Ganachari-Mallappa N, Liao IC, Stock EM, Copeland LA, Zeber JE (2015) Is the pulsed xenon ultraviolet light no-touch disinfection system effective on methicillin-resistant Staphylococcus aureus in the absence of manual cleaning? Am J Infect Control 43(8):878–881. https://doi.org/10.1016/j.ajic.2015.04.005
23. Jinadatha C, Villamaria FC, Ganachari-Mallappa N, Brown DS, Liao IC, Stock EM, Copeland LA, Zeber JE (2015) Can pulsed xenon ultraviolet light systems disinfect aerobic bacteria in the absence of manual disinfection? Am J Infect Control 43(4):415–417. https://doi.org/10.1016/j.ajic.2014.12.012
24. Boyce JM, Havill NL, Moore BA (2011) Terminal decontamination of patient rooms using an automated mobile UV light unit. Infect Control HospEpidemiol 32(8):737–742. https://doi.org/10.1086/661222

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The Effectiveness of Ultraviolet Smart D60 in Reducing Contamination of Flexible Fiberoptic Laryngoscopes

Uche C. Ezeh, MS; Efstratios Achlatis, MD; Tyler Crosby, MD; Paul E. Kwak, MD; Michael S. Phillips, MD; Milan R. Amin, MD

Objective: To compare the effectiveness of disinfection protocols utilizing a ultraviolet (UV) Smart D60 light system with Impelux™ technology with a standard Cidex *ortho*-phthalaldehyde (OPA) disinfection protocol for cleaning flexible fiberoptic laryngoscopes (FFLs).

Methods: Two hundred FFLs were tested for bacterial contamination after routine use, and another 200 FFLs were tested after disinfection with one of four methods: enzymatic detergent plus Cidex OPA (standard), enzymatic detergent plus UV Smart D60, microfiber cloth plus UV Smart D60, and nonsterile wipe plus UV Smart D60. Pre- and post-disinfection microbial burden levels and positive culture rates were compared using Kruskal-Wallis ANOVA and Fisher's two-sided exact, respectively.

Results: After routine use, approximately 56% (112/200) of FFLs were contaminated, with an average contamination level of 9,973.7 ± 70,136.3 CFU/mL. The standard reprocessing method showed no positive cultures. The enzymatic plus UV, microfiber plus UV, and nonsterile wipe plus UV methods yielded contamination rates of 4% (2/50), 6% (3/50), and 12% (6/50), respectively, with no significant differences among the treatment groups ($p > 0.05$). The pre-disinfection microbial burden levels decreased significantly after each disinfection technique ($p < 0.001$). The average microbial burden recovered after enzymatic plus UV, microfiber plus UV, and nonsterile wipe plus UV were 0.40 CFU/mL ± 2, 0.60 CFU/mL ± 2.4, and 12.2 CFU/mL ± 69.5, respectively, with no significant difference among the treatment groups ($p > 0.05$). *Micrococcus* species (53.8%) were most frequently isolated, and no high-concern organisms were recovered.

Conclusion: Disinfection protocols utilizing UV Smart D60 were as effective as the standard chemical disinfection protocol using Cidex OPA.

Key Words: UV disinfection, flexible fiberoptic laryngoscope, semi-critical device.

Level of Evidence: N/A

***Laryngoscope*, 00:1–8, 2023**

INTRODUCTION

Flexible laryngoscopy is a common procedure performed in otolaryngology ("ENT"). Flexible fiberoptic laryngoscopes (FFLs) are routinely exposed to the mucus membranes of the nasal cavity and pharynx potentially resulting in contamination by normal flora and pathogens. In a busy clinical practice, the same FFL may be used and reprocessed several times per day. Currently, there are no available national and international reprocessing guidelines specific to FFLs,[1] and there are gaps and variations in decontamination practices across ENT settings.[2–4] This may ultimately create a risk for iatrogenic infection.

Most published medical device-related outbreaks are linked to contaminated channeled devices[5]; there are few reports linking FFLs to infection.[1] Considering their site of use and simpler design, they retain lower microbial loads than channeled devices do after routine use.[6,7] However, a study published in 2019 revealed a gradual increase in the number of reports relating to contaminated ENT endoscopes.[8]

According to Spaulding's classification,[9] FFLs are semi-critical instruments, defined as those that contact mucous membranes and nonintact skin, which require high-level disinfection (HLD). Unlike sterilization, this process is not generally sporicidal.[7]

HLD is an important step in the prevention of transmission of infection. FFL reprocessing consists of other basic steps such as leak testing, manual pre-cleaning, rinsing, drying, and storage.[10] Endoscope reprocessing has become more complicated and less effective due to sophisticated endoscope design and advancement of knowledge regarding infection control.[11] Transmission of infection via endoscopy is rare, but when it occurs, it is typically related to inadequate reprocessing, noncompliance with recommended guidelines, and use of defective equipment.[5]

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Currently, there are two conventional methods for disinfecting non-channeled ENT endoscopes: chemical immersion and automated endoscope reprocessors (AER).[12,13] Both processes utilize Food & Drug Administration (FDA)-cleared liquid chemical HLDs, including glutaraldehyde, *ortho*-phthalaldehyde (OPA), and peracetic acid. Several studies have shown that these agents are efficacious in disinfecting FFLs.[6,14–16] Unfortunately, liquid disinfectants have toxic side effect profiles, require lengthy immersion times, and may be incompatible with endoscope material.[17–19]

To address these challenges, new emerging methods (disposable sheaths and the Tristel Trio Wipe system (TTWS)) have begun to replace the traditional methods.[13] Recently, investigators had even begun exploring the utility of ultraviolet (UV) light as an HLD for FFLs. UV light technology is not new, but Rudhart et al. found a UV reprocessing machine (UV Smart D60) to be effective in reducing contamination of clinically used rigid laryngoscopes and FFLs.[20,21] The objective of our study was to compare the bactericidal efficacy of various cleaning methods utilizing UV Smart D60 to our clinic's standard reprocessing method using Cidex OPA. We hypothesized that UV light would be as effective as chemical methods for disinfecting FFLs, with the added benefits of being faster, safer, and more time- and resource-efficient.

MATERIAL AND METHODS

This study was performed at a single tertiary academic ENT outpatient clinic. Six non-channeled FFLs (Olympus ENF-VH; Olympus ENF-V3) were used during this study. All endoscopic procedures were performed by a fellow and two laryngologists. This study was exempt from review by the New York University (NYU) Langone Health Institutional Review Board (IRB) as it involved only microbiological sampling and did not involve the collection of any human data or harm to any patients.

Sample Processing and Bacterial Culturing

During the sampling, cleaning, and disinfection processes, gloves were worn by researchers and reprocessing personnel. The investigators employed several sterile techniques to avoid contamination.

For the microbiological investigation, samples were collected immediately after clinical use and following HLD with Cidex OPA or UV Smart D60 (Fig. 1). The distal tip of each FFL was immersed in a 9 mL Butterfield's Phosphate Buffer (pH: 7.2) tube. The tubes were vortexed at medium speed for 2 min (Fig. 2).

Samples were sent for quantitative aerobic plate culture at EMSL Analytical, Inc. (New Jersey), a laboratory certified by the New York State Department of Health, to perform microbiological studies on environmental specimens. The pre- and post-disinfection samples were cultured on blood agar plates. If growth was detected, the number of colonies was counted and reported as colony-forming units per mL (CFU/mL). Effective disinfection was defined as a bacterial count of <10 CFU/mL, considering that this was the lowest detection threshold of

Fig. 1. Arrangement of a flexible fiberoptic laryngoscope (FFL) inside the ultraviolet (UV) Smart D60 light unit. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

EMSL Analytical, Inc. (New Jersey) assays. For the post-samples, positive cultures were gram-stained using standard protocols, and bacterial identification was performed.

The chemical disinfection and UV reprocessing protocols are outlined in Table I. Chemical disinfection was performed by one healthcare worker throughout the study period.

Following experimental decontamination, all UV reprocessed FFLs were decontaminated according to our clinic's reprocessing method using enzymatic detergent for pre-cleaning and Cidex OPA for HLD.

Statistical Analysis

Descriptive analysis was reported as mean ± standard deviation (SD). For statistical analysis, CFUs were log-transformed (mean log $(x+1)_{10}$) to

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TABLE I.
An Outline of Each Decontamination Workflow.

Disinfection Arm	Methods
1. Enzymatic detergent + Cidex OPA (standard method)	FFLs were placed in MaxiZyme Dual Enzymatic Detergent solution (Hardy Diagnostics) and cleaned with a Metrex MetriSponge (30 s). Instruments were then rinsed with tap water (30 s) and subsequently immersed in CIDEX™ OPA Solution (ASP) (12 min) at room temperature (20°C). After completing chemical immersion, the instruments were rinsed with tap water (30 s) and wiped with a 70% isopropyl alcohol-soaked gauze. **Approximate total time**: 13.5 min
2. Enzymatic detergent + UV Smart D60	FFLs were placed in MaxiZyme Dual Enzymatic Detergent solution (Hardy Diagnostics) and cleaned with a Metrex MetriSponge (30 s). Instruments were rinsed with tap water (30 s) and were placed in the UV Smart D60 machine for HLD (60 s). **Approximate total time**: 2 min
3. Microfiber cloth + UV Smart D60	FFLs were wiped 3 times with a Vileda MicroOne Microfiber cloth impregnated with sterile water followed by a wipe 1 time with a dry Vileda microcloth (30 s). Instruments were placed in the UV Smart D60 machine for HLD (60 s). **Approximate total time**: 1.5 min
4. Nonsterile wipe + UV Smart D60	FFLs were wiped once with Fisherbrand Clean-Wipes™ impregnated with sterile water (30 s). Instruments were placed in the UV Smart D60 machine for HLD (60 s). **Approximate total time**: 1.5 min

OPA = *ortho*-phthalaldehyde; UV = ultraviolet.

stabilize the variance. Differences in the amount of microbial burden found before and after disinfection were compared using the Kruskal–Wallis analysis of variance (ANOVA); Dunn's test was performed to delineate significant pairwise comparisons. Data was also categorized as positive (≥10 CFU) and negative cultures (<10 CFU) and

Fig. 2. Sample collection from the flexible fiberoptic laryngoscope (FFL) distal tip surface using vortex and collection tube. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

compared using a two-sided Fisher's exact test with Bonferroni correction. SPSS IBM v28 was used for analysis and $p < 0.05$ was statistically significant.

A post-hoc power analysis was conducted to determine the study's statistical power. The Kruskal-Wallis test's post-hoc power analysis, with an effect size of 0.25, an alpha level of 0.05, and a total sample size of 200 FFLs (with 50 in each treatment group), indicated power of

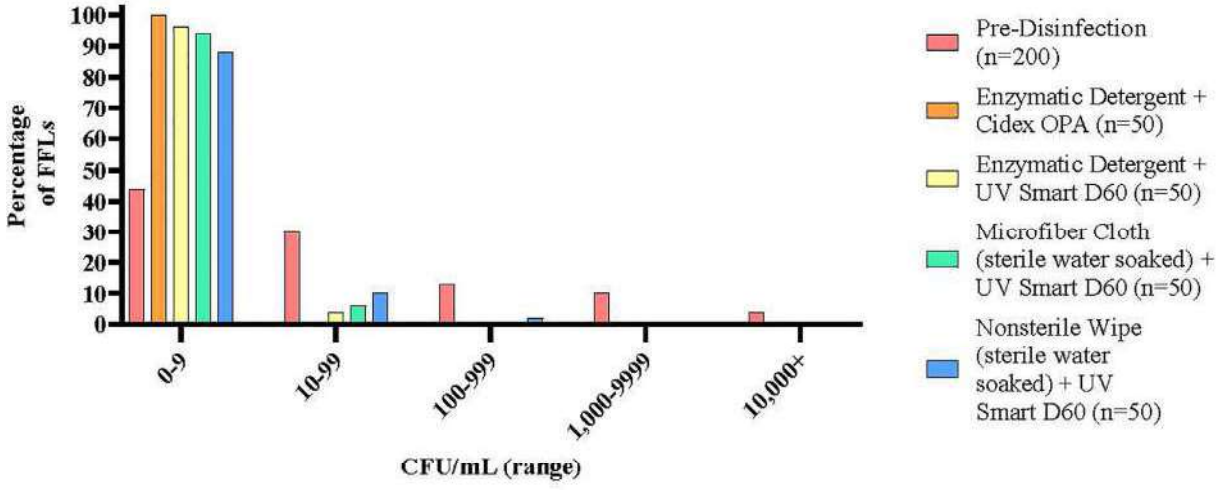

Fig. 3. Distribution of microbial burden after clinical use and after high-level disinfection (HLD). [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

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90%. Similarly, the post-hoc analysis for the fisher's exact test revealed a power exceeding 90%. These tests confirmed that the study possessed sufficient statistical power to detect significant differences in proportions (Fisher's exact test) and mean values (Kruskal–Wallis ANOVA).

RESULTS

Bacterial Contamination of Flexible Fiberoptic Laryngoscope After Routine Use

A total of 200 FFLs were sampled after clinical use, of which 112 of them had bacterial growth (56%). The mean microbial load recovered from the distal tips of FFLs after clinical use was 9,973.7 CFU/mL ± 70,136.3 (range: <10 to 570,000 CFU/mL). Figure 3 shows that 30% of FFLs were contaminated with 10–99 CFU/mL, 13% between 100 and 999, 10% between 1000 and 9999, and 4% greater than 10,000.

Bacterial Contamination Recovered After Disinfection

There was no microbial burden found on FFLs after standard reprocessing (enzymatic + Cidex OPA). There was a mean of 0.40 CFU/mL ± 2 (range: 10 CFU) recovered after enzymatic + UV Smart D60, 0.60 CFU/mL ± 2.4 (range: 10) recovered after microfiber cloth + UV Smart D60, and 12.2 CFU/mL ± 69.5 (range: 10–490) after nonsterile wipe + UV Smart D60. Kruskal-Wallis ANOVA was conducted, and the results showed that there was a statistically significant reduction in the amount of contamination found after each disinfection protocol compared to before reprocessing ($p < 0.001$), but that there was no significant difference in the amount of microbial burden recovered between each method ($p > 0.05$) (Table II).

Our findings showed the following bacterial rates: enzymatic + UV Smart D60 (4%), microfiber cloth + UV Smart D60 (6%), and nonsterile wipe + UV Smart D60 (12%) (Table III). The results of Fisher's exact test revealed a significant difference in contamination rates before disinfection compared to those after each disinfection method ($p < 0.001$). However, no significant differences were observed when the contamination rates between each disinfection method were compared ($p > 0.05$). The pairwise comparison of bacterial culture rates are presented in Supplementary Table 1.

TABLE III.
Positive Bacterial Culture Rates Pre- and Post-Disinfection.

Disinfection Protocol	Proportion of Positive Cultures	Contamination Rates (%)
Pre-disinfection	112/200	56*
1. Enzymatic detergent + Cidex OPA	0/50	0†
2. Enzymatic detergent + UV Smart D60	2/50	4†
3. Microfiber cloth + UV Smart D60	3/50	6†
4. Nonsterile wipe + UV Smart D60	6/50	12†

*Proportions did significantly differ from each other ($p < 0.001$).
†Proportions did not significantly differ from each other ($p > 0.05$).
OPA = *ortho*-phthalaldehyde.

Microorganisms Cultured

The microorganisms isolated are summarized in Table IV. A total of thirteen bacteria were recovered on eleven FFLs, none of which were of high concern (i.e., *Escherichia coli, Klebsiella pneumoniae, Staphylococcus aureus*),[22] and most were found at low amounts (Table V). The most frequent organism isolated was *Micrococcus* sp. (53.8%), a non-pathogenic spore-forming bacteria found in the environment and on the skin. One FFL in the nonsterile wipe plus UV disinfection treatment arm grew more than one bacterial strain (gram-negative rod, *Kytococcus schroeteri*, *Micrococcus luteus*).

TABLE II.
Pairwise Comparison of the Mean Log Colony-Forming Unit (CFU) of Each Disinfection Arm (Dunn's Test).

Bacterial Organisms	Test Statistic	Standard. Test Statistic	Standard. Error	*p*-Value
Pre-disinfection versus Arm 1	−113.707	−7.614	14.934	<0.001
Pre-disinfection versus Arm 2	−107.547	−7.201	14.934	<0.001
Pre-disinfection versus Arm 3	−104.467	−6.995	14.034	<0.001
Pre-disinfection versus Arm 4	−91.937	−6.156	14.934	<0.001
Arm 1 versus2	−6.160	−0.326	18.890	0.744
Arm 1 versus 3	−9.240	−0.489	18.890	0.625
Arm 1 versus 4	−21.770	−1.152	18.890	0.249
Arm 2 versus 3	−3.080	−0.163	18.890	0.870
Arm 2 versus 4	−15.610	−0.826	18.890	0.409
Arm 3 versus 4	−12.530	−0.663	18.890	0.507

1 = Enzymatic detergent + Cidex OPA (ortho-phthalaldehyde); 2 = Enzymatic detergent + UV Smart D60; 3 = Microfiber cloth + UV Smart D60; 4 = Nonsterile wipe + UV Smart D60.

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TABLE IV.
Profile of Bacterial Isolates Recovered After Each Disinfection Process.

Disinfection Processes	Positive Cultures (n = 50 FFL)	Microorganism Isolated (CFU/mL)
1. Enzymatic detergent + Cidex OPA	0	–
2. Enzymatic detergent + UV Smart D60	2	*Staphylococcus epidermidis* (10); *Staphylococcus warneri* (10)
3. Microfiber cloth + UV Smart D60	3	*Micrococcus luteus* (10); *Micrococcus luteus* (10); *Dermacoccus nishinomiyaensis* (10)
4. Nonsterile wipes + UV Smart D60	6	*Staphylococcus capitis* (20); *Micrococcus luteus* (10); *Micrococcus luteus* (40); *Bacillus sp*. (10); *Bacillus simplex* (10); *Gram-negative rod†, *Kytococcus schroeteri**, *Micrococcus luteus** (490)

*Isolates found on the same FFL.
†Not specified.
OPA = *ortho*-phthalaldehyde; UV = ultraviolet.

DISCUSSION

FFLs are indispensable instruments used in ENT practice, and their potential role in infection transmission has been a growing concern. They must be rigorously cleaned and disinfected between each patient encounter, but the fast-pace and demanding nature of ENT clinical practice makes adequate reprocessing particularly challenging.[13] The ideal disinfection system for FFLs should be standardized, fast, and less hazardous, with a minimal risk of endoscope contamination and damage.[13]

We report the results of the first prospective study to evaluate and compare the bactericidal efficacy of UV light disinfection protocols with one using Cidex OPA solution. We found no significant difference between these methods in terms of the amount of residual microbial burden recovered or proportion of positive cultures. In addition, microbiological analysis showed no high-concern pathogens (i.e., *E. coli, Pseudomonas, S. aureus*) in any of the positive cultures post-decontamination. Overall, our study shows that disinfection processes utilizing UV light systems are non-inferior to one using Cidex OPA.

UV-C technology has been frequently used in healthcare settings for decontamination purposes.[23,24] It has recently emerged as a new technique for disinfecting semi-critical devices, with the literature primarily discussing its use in endocavitary probes.[25–27] Only one previous study evaluated the microbiological efficacy of UV light in disinfecting FFLs. Rudhart et al.[21] conducted a study in 2021 in which 50 FFLs were cleaned with nonsterile wipes impregnated with sterile water and irradiated with UV Smart D60. Their results showed positive cultures in 11 of the 50 instruments (14%). A similar rate was achieved in our study using a similar process (12%). However, we found a lower contamination rate when using enzymatic detergent (4%) or microfiber cloth (6%) in conjunction with UV Smart D60. Although there was no statistically significant difference between these rates, these findings suggest that non-sterile wipes impregnated with sterile water may not be able to adequately disinfect FFLs before irradiation.

In our study, instruments assigned to the Cidex OPA reprocessing arm showed no positive bacterial growth, which is in accordance with previous studies that used chemical disinfectants. Abramson et al.[6] reported a 1.7% positive culture rate after immersing 60 rigid laryngoscopes and FFLs in Cidex OPA for 5 min; no organisms were recovered after a 10-minute exposure. Bhattacharyya and Kepnes[14] reported a 2.1% positive culture rate (1/48) after cleaning FFLs with enzymatic detergent for 5 min and soaking in Cidex OPA solution for 20 min. There was one positive fungal culture, but no bacterial growth. Chang et al.[15] contaminated FFLs in vitro with *S. aureus* and *C. albicans* and compared the efficacy of various disinfection techniques, with some involving immersion in Cidex OPA. Their study did not recover any bacterial isolates from the FFLs after chemical disinfection. An in vivo study by Liming et al.[16] compared several disinfection techniques and they achieved similar results.

TABLE V.
Frequency of Bacterial Organisms (n = 13).

Bacterial Organisms	Species	Source	Frequency, n (%)
Micrococcus luteus	*Micrococcus*	Environmental, skin	7 (53.8)
Kytococccus schroeteri (*Micrococcus* sp.)			
Dermacoccus nishinomiyaensis (also known as *Micrococcus nishinomiyaensis*)			
Staphylococcus epidermidis	Coagulase-negative Staphylococci	Skin	3 (23.1)
Staphylococcus warneri			
Staphylococcus capitis			
Bacillus sp., not specified	*Bacillus*	Environmental	2 (15.4)
Bacillus simplex			
Gram-negative rod, not specified	–	–	1 (7.7)

sp = Species.

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Although chemical disinfectant protocols have been proven to be very effective in decontaminating FFLs, they are hazardous, require extensive monitoring to ensure compliance with manufacturer and regulatory requirements, have lengthy processing times, and may be potentially incompatible with endoscope material.[19,28,29] The advent of AERs has helped reduce the exposure of patients and healthcare workers to these hazardous chemicals and has automated a process that is prone to operator error. Liming et al. demonstrated that the Medivator AER was as effective as Cidex OPA at disinfecting FFLs.[16] However, chemical disinfectants are commonly used in conjunction with AERs, which have long processing cycles and have been previously linked to infection outbreaks.[5]

In the field of ENT, there have been other emerging techniques, including disposable sheaths and TTWS.[12,13] Disposable sheaths can easily be applied and removed from FFLs. Alvarado et al. found no bacterial growth on 100 nasopharyngoscopes after enzymatic cleaning and disinfection with 70% ethanol.[30] Although the use of endoscope sheaths allows for a quicker turnover of instruments, a drawback of this approach is their susceptibility to perforation. The Centers for Disease Control and Prevention (CDC) still recommends instruments with mucosal contact undergo HLD between every use despite being covered with a sheath.[7] TTWS has also become a popular choice in ENT clinics.[31] Hitchcock et al.[32] compared the efficacy of TTWS and Cidex OPA solution in conjunction with AER and PeraSafe chemical immersion in decontaminating flexible nasoendoscopes. The results of their study revealed no bacterial growth after TTWS, one positive culture after PeraSafe immersion, and 3 after Cidex OPA with AER. Furthermore, they demonstrated that disinfection with TTWS had the fastest turnaround time compared with the other two methods and was more user-friendly and cost-efficient.[32] The primary drawback of this approach is its reliance on mechanical action; consequently, the efficacy of disinfection is highly operator-dependent and more susceptible to human error than the synergistic action of manual cleaning and automated HLD.

FFLs typically retain a lower amount of contamination, with estimates being around 3000–5000 CFU.[6] Before disinfection, we recovered a mean bacterial load of 9,973.7 CFU/mL (range: <10 to 570,000), with 44% (88/200) of FFLs found to be sterile (<10 CFU) after procedural use. This is in accordance with a study conducted by Nystrom et al., in which 62% of the surgical devices, including ENT instruments, had <10 organisms after use.[33] Compared to devices used in gastroenterology and pulmonary, FFLs are briefly passed into the upper aerodigestive tract via the nares or oral cavity and may not be exposed to the same amount of microbial burden found in the colon or lower respiratory tract. Additionally, FFLs are non-channeled devices and have fewer accessories and compartments for microorganisms to hide. Our results confirm the notion that FFLs, by virtue of their design and site of use, carry less microbial burden than channeled endoscopes but may still pose a risk for infection transmission if they are inadequately decontaminated.

Micrococcus spp., coagulase-negative staphylococci, and *Bacillus* spp. were the most common strains isolated after disinfection. These microorganisms rarely cause significant infections and were found in low amounts, most likely from skin or environmental sources. These results may be explained by improper hand hygiene, inadequate maintenance of aseptic conditions, use of non-sterile gloves, or mishandling of instruments during sample collection. HLD is effective in killing all forms of microorganisms, except for a large number of bacterial spores. The absence of bacterial spores after pre-cleaning with enzymatic detergent and HLD with either Cidex OPA or UV Smart D60 suggests that these two methods may be more sporicidal than those involving sterile-water pre-cleaning.

Our results also showed no recovery of any high-concern organisms, which is clinically relevant considering that these pathogens have been linked to outbreaks of endoscopy-related infections and are susceptible to developing multidrug resistance.[34] Although the isolates we recovered had low pathogenicity, vulnerable populations (ie. elderly, immunocompromised) may still be at risk of serious infection. Further refinement of our UV disinfection protocols and stricter adherence to aseptic techniques would help minimize contamination.

By minimizing the resources required for disinfection, UV Smart D60 may help eliminate the need to purchase additional endoscope equipment, which is often necessary due to long processing times and rapid instrument turnover. Although our study did not assess cost-efficacy, a recent group performed a cost analysis of four disinfection methods (UV-Smart D60 vs. Cidex OPA vs. TTWS vs. Revital-Ox (hydrogen peroxide solution)) and found UV-Smart D60 to have the shortest amount of labor time and to be the most cost-effective disinfection method for large-volume ENT clinics.[35] Our study team found the device easy to use and safe, which will increase compliance with FFL disinfection in patient care settings and enhance patient safety.

Our study has some limitations. One of the shortcomings of our study is the lack of investigation into the efficacy of UV Smart D60 in eliminating fungal, mycobacterial, and viral growth from FFLs. Previous investigators have demonstrated the efficacy of UV light against HPV on endocavitary probes.[36] Future investigations should consider studying UV Smart D60's efficacy in eliminating other microorganisms. Culturing bacteria before disinfection and comparing them with post-disinfection organisms would have provided valuable insights into our study. However, due to cost limitations, we only cultured bacteria after the disinfection process. In a previous study by Rudhart et al., they cultured organisms before disinfection with UV Smart D60 and commonly isolated non-pathogenic organisms (such as coagulase-negative Staphylococci); few isolates were pathogenic bacteria.[12] This again underscores the significance of effective disinfection practices. Our study was conducted in a non-hospital setting. We recognize that hospitals and hospital-based clinics may be subject to different standards set by the Joint Commission, which could impede the widespread adoption of UV light as an HLD in ENT settings. Additionally, it is important to note that our study specifically compared the efficacy of UV

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disinfection protocols to a Cidex OPA protocol. Different ENT clinics may utilize alternative chemical disinfectants, which would restrict the generalizability of our findings. In the United States, there is only one validated sampling and culturing surveillance protocol, which is proposed by the CDC,[22] and it only applies to channeled instruments. Without a consensus guideline for non-channeled endoscopes, we do not know what the acceptable microbial burden threshold should be for organisms of low-to-moderate concern. We understand that the presence of any contamination following UV protocols, as opposed to none after following the standard reprocessing guidelines for endoscope disinfection, may raise concerns, particularly for vulnerable populations. Although we found no statistically significant differences between our treatment methods, repeat studies may help reinforce our conclusions.

CONCLUSION

Chemical disinfection of FFLs results in substantial workload demands, purchasing expenses, and health and safety risks. Our results showed that our decontamination protocols with UV Smart D60 were as effective in removing contamination from FFLs as our traditional method of using Cidex OPA. Although chemical agents may continue to be used, the use of UV-light systems can ultimately help make FFL decontamination simpler, safer, and less time- and resource-intensive.

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Role of sponsors: The sponsors had no role in the design and conduct of the study, in the collection, analysis, and interpretation.

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BIBLIOGRAPHY

1. Muscarella LF. Prevention of disease transmission during flexible laryngoscopy. *Am J Infect Control*. 2007;35(8):536-544. https://doi.org/10.1016/j.ajic.2006.09.010.
2. Banfield GK, Hinton AE. A national survey of disinfection techniques for flexible nasendoscopes in UK ENT out-patient departments. *J Laryngol Otol*. 2000;114(3):202-204. https://doi.org/10.1258/0022215001905337.
3. Lubbe DE, Fagan JJ. South African survey on disinfection techniques for the flexible nasopharyngoscope. *J Laryngol Otol*. 2003;117(10):811-814. https://doi.org/10.1258/002221503770716269.
4. Chandran D, Lomas J, Anderson J, Green M, McKenzie JL, Grigg R. A state-wide survey of disinfection techniques for nasendoscopies in Queensland ENT out-patient departments. *Aust J Otolaryngol*. 2018;1:28. https://doi.org/10.21037/ajo.2018.10.02.
5. Kenters N, Huijskens E, Meier C, Voss A. Infectious diseases linked to cross-contamination of flexible endoscopes. *Endosc Int Open*. 2015;03(04):E259-E265. https://doi.org/10.1055/s-0034-1392099.
6. Abramson AL, Gilberto E, Mullooly V, France K, Alperstein P, Isenberg HD. Microbial adherence to and disinfection of laryngoscopes used in office practice. *Laryngoscope*. 1993;103(5):503-508. https://doi.org/10.1288/00005537-199305000-00004.
7. Rutala WA. *Guideline for Disinfection and Sterilization in Healthcare Facilities*. Centers for Disease Control and Prevention (CDC); 2008:163.
8. Jiang R, Kasle DA, Alzahrani F, Kohli N, Lerner MZ. A manufacturer and user facility device experience analysis of upper aerodigestive endoscopy contamination: is flexible laryngoscopy different? *Laryngoscope*. 2021;131(3):598-605. https://doi.org/10.1002/lary.28826.
9. Spaulding EH. The role of chemical disinfection in the prevention of nosocomial infections. *Proceedings of the International Conference on Nosocomial Infections, vol. 1970. American Hospital Association Chicago*; 1971:254-274.
10. Rutala WA, Weber DJ. Reprocessing endoscopes: United States perspective. *J Hosp Infect*. 2004;56:27-39. https://doi.org/10.1016/j.jhin.2003.12.035.
11. Omidbakhsh N, Manohar S, Vu R, Nowruzi K. Flexible gastrointestinal endoscope processing challenges, current issues and future perspectives. *J Hosp Infect*. 2021;110:133-138. https://doi.org/10.1016/j.jhin.2021.01.021.
12. Collins WO. A review of reprocessing techniques of flexible nasopharyngoscopes. *Otolaryngol Head Neck Surg*. 2009;141(3):307-310. https://doi.org/10.1016/j.otohns.2009.05.027.
13. Cavaliere M, Iemma M. Guidelines for reprocessing non-lumened, heat-sensitive ENT endoscopes. In: Amornyotin S, ed. *Endoscopy—Innovative Uses and Emerging Technologies*. InTech; 2015. https://doi.org/10.5772/61219.
14. Bhattacharyya N, Kepnes LJ. The effectiveness of immersion disinfection for flexible fiberoptic laryngoscopes. *Otolaryngol Head Neck Surg*. 2004;130(6):681-685. https://doi.org/10.1016/j.otohns.2003.11.004.
15. Chang D. Disinfection of flexible fiberoptic laryngoscopes after In vitro contamination with *Staphylococcus aureus* and *Candida albicans*. *Arch Otolaryngol Head Neck Surg*. 2012;138(2):119-121. https://doi.org/10.1001/archoto.2011.1204.
16. Liming B, Funnell I, Jones A, Demons S, Marshall K, Harsha W. An evaluation of varying protocols for high-level disinfection of flexible fiberoptic laryngoscopes: high-level disinfection of FFLs. *Laryngoscope*. 2014;124(11):2498-2501. https://doi.org/10.1002/lary.24665.
17. Sokol WN. Nine episodes of anaphylaxis following cystoscopy caused by Cidex OPA (ortho-phthalaldehyde) high-level disinfectant in 4 patients after cytoscopy. *J Allergy Clin Immunol*. 2004;114(2):392-397. https://doi.org/10.1016/j.jaci.2004.04.031.
18. Takigawa T, Endo Y. Effects of glutaraldehyde exposure on human health. *J Occup Health*. 2006;48(2):75-87. https://doi.org/10.1539/joh.48.75.
19. Atiyeh K, Chitkara A, Achlatis S, Branski RC, Amin MR. Allergic reaction to ortho-phthalaldehyde following flexible laryngoscopy. *Laryngoscope*. 2015;125(10):2349-2352. https://doi.org/10.1002/lary.25421.
20. Rudhart SA, Günther F, Dapper L, et al. UV light-based decontamination: an effective and fast way for disinfection of endoscopes in otorhinolaryngology? *Eur Arch Otorhinolaryngol*. 2020;277(8):2363-2369. https://doi.org/10.1007/s00405-020-05978-w.
21. Rudhart SA, Günther F, Dapper L, et al. UV light-based reprocessing of flexible endoscopes without working channel in oto-rhino-laryngology: an effective method? *Eur Arch Otorhinolaryngol*. 2021;278(10):4075-4080. https://doi.org/10.1007/s00405-021-06737-1.
22. Duodenoscope-Surveillance-Sampling-and-Culturing-Protocols US Food and Drug Administration website. 2018 Accessed November 1, 2022. https://www.fda.gov/media/111081/download.
23. Nerandzic MM, Cadnum JL, Pultz MJ, Donskey CJ. Evaluation of an automated ultraviolet radiation device for decontamination of Clostridium difficile and other healthcare-associated pathogens in hospital rooms. *BMC Infect Dis*. 2010;10(1):197. https://doi.org/10.1186/1471-2334-10-197.
24. Rutala WA, Gergen MF, Weber DJ. Room decontamination with UV radiation. *Infect Control Hosp Epidemiol*. 2010;31(10):1025-1029. https://doi.org/10.1086/656244.
25. Kac G, Guenneret M, Rodi A, et al. Evaluation of a new disinfection procedure for ultrasound probes using ultraviolet light. *J Hosp Infect*. 2007;65(2):163-168. https://doi.org/10.1016/j.jhin.2006.10.008.
26. Kac G, Podglajen I, Si-Mohamed A, Rodi A, Grataloup C, Meyer G. Evaluation of ultraviolet C for disinfection of endocavitary ultrasound transducers persistently contaminated despite probe covers. *Infect Control Hosp Epidemiol*. 2010;31(2):165-170. https://doi.org/10.1086/649794.
27. Bloc S, Mercadal L, Garnier T, et al. Evaluation of a new disinfection method for ultrasound probes used for regional anesthesia: ultraviolet C light. *J Ultrasound Med*. 2011;30(6):785-788. https://doi.org/10.7863/jum.2011.30.6.785.
28. Cowan RE, Manning AP, Ayliffe GA, et al. Aldehyde disinfectants and health in endoscopy units. *Gut* British Society of Gastroenterology Endoscopy Committee. 1993;34(11):1641-1645. https://doi.org/10.1136/gut.34.11.1641.
29. Fujita H, Sawada Y, Ogawa M, Endo Y. Health hazards from exposure to ortho-phthalaldehyde, a disinfectant for endoscopes, and preventative measures for health care workers. *SanEiShi*. 2007;49(1):1-8. https://doi.org/10.1539/sangyoeisei.49.1.
30. Alvarado CJ, Anderson AG, Maki DG. Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing:

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a prospective clinical trial with nasopharygoscopes. *Am J Infect Control*. 2009;37(5):408-413. https://doi.org/10.1016/j.ajic.2009.04.276.
31. Swift AC. *Guidance on the Decontamination and Sterilization of Rigid and Flexible Endoscopes*. 2010.
32. Hitchcock B, Moynan S, Frampton C, Reuther R, Gilling P, Rowe F. A randomised, single-blind comparison of high-level disinfectants for flexible nasendoscopes. *J Laryngol Otol*. 2016;130(11):983-989. https://doi.org/10.1017/S0022215116008860.
33. Nystrom B. Disinfection of surgical instruments. *J Hosp Infect*. 1981;2:363-368. https://doi.org/10.1016/0195-6701(81)90069-4.
34. Gaynes R, Edwards JR. National Nosocomial Infections Surveillance System. Overview of nosocomial infections caused by gram-negative bacilli. *Clin Infect Dis*. 2005;41(6):848-854. https://doi.org/10.1086/432803.
35. Biadsee A, Crosby L, Chow W, Sowerby LJ. Cost minimization analysis of nasopharyngoscope reprocessing in community practice. *J Otolaryngol Head Neck Surg*. 2023;52(1):8. https://doi.org/10.1186/s40463-022-00610-9.
36. Meyers C, Milici J, Robison R. UVC radiation as an effective disinfectant method to inactivate human papillomaviruses. Liu X, ed. *PLoS One*. 2017; 12(10):e0187377. https://doi.org/10.1371/journal.pone.0187377.

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CERTIFICATE

8002

This certificate was given to the below stated company by UDEM Adriatic d.o.o.
Reference standard is ISO 13485:2016

UV Smart Technologies B.V.

Head Office: Patrijsweg 74, 2289EX Rijswijk, The Netherlands

ISO 13485:2016

Scope: Design, Development, Production, Sales, Installation and Service Activities of Active UV Disinfection Devices.

Certification Audit Date	: 30.03.2023
Decision Date	: 25.05.2026
Reissue Date	: 12.05.2026
Expiry Date	: 11.05.2029

Signature
General Manager

UDEM Adriatic d.o.o.

MD QMS

Hereby, UDEM Adriatic d.o.o certifies that the above stated company has the appropriate management system according to the requirements of the above standard. This certificate is valid from the decision date to the expiry date as long as the system is effectively maintained and surveillance audits are carried out. The validity of the certificate can be checked through www.udemadriatic.com. The certificate is the property of UDEM Adriatic d.o.o and shall be returned if requested.

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EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX Chapter I and III

Certificate Number: M.2022.MDR.1001

Manufacturer Name	:	UV Smart Technologies B.V.
Manufacturer Address	:	Patrijsweg 74 2289 EX Rijswijk The Netherlands
Single Registration Number-SRN	:	NL-MF-000017126
Authorised Representative Name		
(If applicable)	:	NA
Authorised Representative Address	:	NA
Device Scope	:	See the device list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality management system in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III, UDEM Adriatic d.o.o. hereby declares that the requirements of Annex IX (Chapter I and Chapter III) of the Regulation (EU) 2017/745 have been met for the listed devices in this certificate.

The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according to Annex IX Chapter I Section 3 of the aforementioned Regulation.

The report referenced below summarizes the results of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.

For Class I devices covered by this certificate, the involvement of UDEM Adriatic d.o.o. in the conformity assessment procedures is limited: in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions; in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

For Class III and Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of Regulation (EU) 2017/745, covered by this certificate, an EU Technical Documentation Assessment Certificate is required before placing them on the market.

Report Number	: MDR.1021
Date of First Issue	: 04.04.2022
Recertification Date	: -
Revision Date/No	: 18.05.2026/01
Date of Expiry	: 03.04.2027

UDEM Adriatic d.o.o.
General Manager

If any, Previous Certificate(s) No : -

Conditions for or limitations to the validity of this certificate : none

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

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EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX Chapter I and III

Certificate Number: M.2022.MDR.1001

DEVICE LIST COVERED BY THE CERTIFICATE

Class IIa Devices:

Device Name	Active Non-Implantable Devices for Disinfection
Risk Class	Class IIa
Basic UDI-DI	87193266342D603Q
EMDN Code	Z12011301
Models/Types	UV Smart D60
Intended Purpose	Device for disinfection of channel-less invasive medical devices. The medical devices that can be disinfected: • Flexible and rigid Channels-less endoscopes • Invasive transducers. • TEE-probes

Device Name	Active Non-Implantable Devices for Disinfection
Risk Class	Class IIa
Basic UDI-DI	87193266342D253N
EMDN Code	Z12011301
Models/Types	UV Smart D25
Intended Purpose	The UV Smart D25 V2 is intended to reduce micro-organism count by at least log-4 on non-porous outer surfaces (glass, plastic, metal) of (non)invasive medical devices without working channels and other medical equipment. The non-invasive medical devices that could be disinfected with the D25; Infusion pumps, Thermometers, Surveillance monitoring equipment, Stethoscopes, Communication systems, Enteral feeding pumps, Blood pressure monitors, Reflex hammers, Wireless Ultrasound Transducers. The invasive medical devices that could be disinfected with the D25; Rigid otorhinolaryngology scopes without working channels, Wireless endocavitary Ultrasound probes.

Device Name	Active Non-Implantable Devices for Disinfection
Risk Class	Class IIa
Basic UDI-DI	87193266342D453U
EMDN Code	Z12011301

EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX Chapter I and III

Certificate Number: M.2022.MDR.1001

Models/Types	UV Smart D45
Intended Purpose	The UV Smart D45 is intended to high-Level disinfect Ultrasonic Transducers by using UV-C light. The medical devices that can be disinfected with D45: Non-invasive transducers and Invasive transducers

EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX Chapter I and III

Certificate Number: M.2022.MDR.1001

CERTIFICATE HISTORY		
Revision No	**Revision Date**	**Description of Revision**
00	04.04.2022	Initial Certification
01	18.05.2026	-The certificate template has been changed due to the form revision. -All information has been moved to the new certificate template. - "M.2023.MDR.1024" and "M.2023.MDR.1030" numbered certificates are cancelled. All information has been moved to the new certificate template, and device information has been moved to this new revision.

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

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EU Declaration of conformity

UVsmart

Document ID: DOC-1572 **Revision: 5**

Manufacturer:	UV Smart Technologies B.V.
Manufacturer address:	Patrijsweg 74 2289 EX Rijswijk The Netherlands
Single Registration Number:	NL-MF-000017126
Authorized Representative:	Not applicable
Product and trade name:	Active non-implantable devices for disinfection UV Smart D60 Disinfection of channel-less invasive medical devices
Intended Purpose:	Device for disinfection of channel-less invasive medical devices The medical devices that can be disinfected: - Flexible and rigid channel-less endoscopes - Invasive transducers - TEE-probes
Risk class:	IIa, Rule 16 of the Medical Device Regulation
Common Specifications:	
Basic UDI-DI:	87193266342D603Q
EMDN/CND Code:	Z12011301 CLEANING AND DESINFECTION INSTRUMENTS
Notified Body name:	UDEM Adriatic D.O.O.
Notified Body address:	Radnička cesta 54/R3 Zagreb Croatia
Notified Body number:	2696
Conformity assessment procedure:	Annex IX chapter I, III and section 4 of the Medical Device Regulation
Certificate Number and start date:	M.2022.MDR.1001, 4 April 2022
Conditions for or limits to the validity:	- None -

This declaration of conformity is issued under the sole responsibility of UV Smart Technologies B.V..

We hereby declare that the medical device specified in this declaration is in conformance with the Medical Device Regulation EU 2017/745. This declaration is supported by the Quality Management System approval to EN ISO 13485:2016 issued by UDEM Adriatic D.O.O.

This declaration shall be continuously updated and UV Smart Technologies B.V. shall assume responsibility for compliance with the requirements and Common Specifications (Annex I, II, III, XIV and XV) of the Regulation and all other Union legislation applicable to the device.

All supporting documentation is retained at the premises of the manufacturer.

Thijs Kea
Director, on behalf of UV Smart Technologies B.V.

13-Sep-2024
Place & Date (dd-mmm-yyyy)
Location: Rijswijk

D60 - Declaration of conformity (DOC-1572) Ver. 5

Approved By:

(CO-417) QMS documentation update and clean-up

Description

Refer to CR-417

Justification

Refer to CR-417

Assigned To:	Initiated By:	Priority:	Impact:
Deniz Duman	Deniz Duman	Medium	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Deniz Duman	September 19, 2024 8:45 AM CEST	CO-417	5	Published
Marc Jacobse	March 16, 2023 8:11 AM CET	CO-345	4	Superseded
Koen van der Kouwe	February 7, 2023 2:12 PM CET	Not Available	3	Superseded
Koen van der Kouwe	April 6, 2022 3:41 PM CEST	CO-282	2	Superseded
Koen van der Kouwe	March 31, 2022 11:47 AM CEST	Not Available	1	Superseded
Thijs Kea	February 23, 2022 11:02 AM CET	Not Available	0	Superseded