



Multimodal highly-sensitive PhotonICs endoscope for improved in-vivo COLOn Cancer diagnosis and clinical decision support

Report on training sessions and clinical workshops v2	Deliverable ID:	D8.18
	Due date:	30-09-2020
	Submission date:	30-09-2020
	Editor/Lead beneficiary (name/partner):	M ^a Resurrección López Lozano/CCMIJU Juan Francisco Ortega Morán/CCMIJU
	Internally reviewed by (name/partner):	Antje Haap-Hoff/STORZ Brendan Roycroft/TYNDALL

Abstract:

This document represents the Deliverable 8.18 in the framework of the PICCOLO project. The document describes the second version of the report on training sessions and clinical workshops planned from April 2019 to September 2020, despite the schedule included until June 2020.

Of all the planned training sessions and clinical workshops for such dates, only few activities have been performed, partly due to the unavailability of the device and partly due to the coronavirus outbreak and the following lockdown. Several partners could not perform these activities in hospitals and could not attend the meetings because of safety measures to protect health.

Dissemination level

PU	Public	
CO	Confidential, only for members of the consortium and the Commission Services	X



This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 732111

PICCOLO consortium



Fundación Tecnalia Research & Innovation. (TECNALIA, Spain)

Project coordinator:
Cristina López
Cristina.Lopez@tecnalia.com



Karl Storz GmbH. & Co. (STORZ, Germany)

Contact:
Peter Solleder
Peter.Solleder@karlstorz.com



Light4Tech (L4TNW, Italy)

Contact:
Lorenzo Targetti
l.targetti@l4t.it



University College Cork – Tyndall National Institute (TYN, Ireland)

Contact:
Brendan Roycroft
brendan.roycroft@tyndall.ie



M Squared Lasers Ltd (M2, UK)

Contact:
James Bain
James.Bain@m2lasers.com



European Laboratory for Non Linear Spectroscopy (LENS, Italy)

Contact:
Riccardo Cicchi
rcicchi@lens.unifi.it



Centro de Cirugía de Mínima Invasión Jesús Usón (CCMIJU, Spain)

Contact:
Francisco Miguel Sanchez-Margallo
msanchez@ccmijesususon.com

Imperial College
London

Imperial College of Science, Technology and Medicine (IC,UK)

Contact:
Julian Teare
j.teare@imperial.ac.uk

bioef

basque foundation for health innovation and research

Fundación Vasca de Innovación e Investigación Sanitarias (BIOEF, Spain)

Contact:
Roberto Bilbao
bilbao@bioef.org

Document Info

Contributors

Author	Company	E-mail
María Resurrección López Lozano	CCMIJU	rlopez@ccmijesususon.com
Juan Francisco Ortega Morán	CCMIJU	jfortega@ccmijesususon.com
Riccardo Cicchi	LENS	rcicchi@lens.unifi.it
Julia PopKo	STORZ	Julia.popko@karlstorz.com ,
Cristina López	Tecnalia	Cristina.Lopez@tecnalia.com
Ben Glover	Imperial College	Ben.glover@nhs.net
Nagore Andraca	BIOEF	gestionidi.biobancovasco@bioef.eus

Documents history

Document Version #	Date	Change
V0.1	10/09/2020	Starting version, template
V0.2	11/09/2020	Coordinator's revision
V0.3	18/09/2020	Partners contributions
V0.4	21/09/2020	Integrated version (send to WP members and reviewers)
V0.5	22/09/2020	Updated version (send to Quality Manager)
V0.6	23/09/2020	Updated version (QM sends to project internal reviewers)
Sign off	28/09/2020	Signed off version (for approval to EB members)
V1.0	30/09/2020	Approved Version to be submitted to H2020 office

Table of contents

Document Info.....	3
List of tables	5
Executive summary	6
1. Introduction.....	7
1.1 Objective of this document.....	7
1.2 Structure of this document.....	7
1.3 Acronyms and abbreviations	7
1.4 Relationships with other deliverables	7
2. Training sessions and clinical workshops planned from April 2019 to June 2020	8
3. Report on the training sessions and clinical workshops planned.	10
4. Conclusion/Further work	15
Annex A	16

List of tables

Table 1. Schedule of training events at CCMIJU from April 2019 to June 2020.....	9
Table 2. Schedule of training events at BIOEF/Osakidetza from April 2019 to June 2020	8
Table 3. Schedule of training events at Imperial College from April 2019 to June 2020.....	8
Table 4. Schedule of clinical workshops until June 2020	9

Executive summary

This document represents the deliverable D8.18 in the framework of the PICCOLO project. The document describes the report on training sessions and clinical workshops carried out from April 2019 to September 2020.

Of all the planned training sessions and clinical workshops for such dates, only few activities have been performed, partly due to the availability of the device and partly due to the coronavirus outbreak and the following lockdown. Several partners could not perform these activities in hospitals and could not attend the meetings because of safety measures to protect health.

1. Introduction

1.1 Objective of this document

In order to maximize impact and user acceptance of the PICCOLO system, several training sessions and clinical workshops have been planned and performed. In these events, end users (gastroenterologists, pathologists and other clinicians) have had the opportunity of testing and using the system in a setting as close as possible to the actual clinical practice and provide feedback. But also, these dissemination events could be targeted to a broader audience, such as scientific community, industry, policy-makers or health system, showing them the benefits of the PICCOLO system, if the setback with the device and the coronavirus outbreak had allowed it. This document is responsible for reporting about training sessions and clinical workshops carried out from April 2019 to 30th September 2020.

1.2 Structure of this document

This document consists of three sections. The first section is the introduction of the document, describing the objective of the document, its structure and the relationship with other deliverables of the PICCOLO project. The second section includes the summary of the clinical and training sessions planned from April 2019 to June 2020 (although this report continues up to September 2020 because of the extension of the project for three months). The last one includes the description of the performed activities in the PICCOLO project during this period, particularly for the training sessions and clinical workshops.

1.3 Acronyms and abbreviations

OCT	Optical Coherence Tomography
MPT	Multiphoton Tomography

1.4 Relationships with other deliverables

The Deliverable D8.18 presented in this document relates to the following deliverables:

- D8.7 Plan on training sessions and clinical workshops v1
- D8.9 Report on training sessions and clinical workshops v1
- D8.15 Plan on training sessions and clinical workshops v2

2. Training sessions and clinical workshops planned from April 2019 to June 2020

The objective of this deliverable is to report the training sessions and/or clinical workshops performed from April 2019 until September 30th 2020, despite the schedule was planned until June 2020. According to the deliverable D8.15 “Plan for the training sessions and clinical workshops v2”, the following tables show the activities proposed for this period by some consortium partners.

Table 1. Schedule of training events at CCMIJU from April 2019 to June 2020

Training events	Date	Location	Target participants
Hands-on Course on Digestive endoscopy	June, 2019	CCMIJU. Experimental Operating rooms	Gastroenterologists
National and International workshop on endoscopy	September, 2019	CCMIJU. Experimental Operating rooms	Gastroenterologists
Workshop on endoscopic retrograde cholangiopancreatography	September, 2019	CCMIJU. Experimental Operating rooms	Gastroenterologists
Hands-on course on digestive echography	October, 2019	CCMIJU. Experimental Operating rooms	Gastroenterologists
Hands-on Course on endoscopic submucosal dissection	October, 2019	CCMIJU. Experimental Operating rooms	Gastroenterologists
Hands-on Course on Digestive endoscopy	June, 2020	CCMIJU. Experimental Operating rooms	Gastroenterologists

Table 1. Schedule of training events at BIOEF/Osakidetza from April 2019 to June 2020

Training events	Date	Location	Target participants
Internal course- PICCOLO device: operation and use	September 2019 – March 2020	Basurto University Hospital. Gastroenterology Service (OSI Bilbao-Basurto)	Gastroenterologists & Pathologists
Internal course- Images of the PICCOLO device. Possible applications	September 2019 – March 2020	Basurto University Hospital. Gastroenterology Service (OSI Bilbao-Basurto)	Clinicians & Pathologists

Table 2. Schedule of training events at Imperial College from April 2019 to June 2020

Training events	Date	Location	Target participants
Internal course- Familiarisation with the PICCOLO device	July 2019	St Mary’s Hospital, Paddington, London	Gastroenterologists & Endoscopy Nurses
Internal course – Review of the clinicians experience with the PICCOLO device	September 2019	St Mary’s Hospital, Paddington, London	Gastroenterologists and Pathologists
Regional course – Familiarising clinicians with the PICCOLO device	October- November 2019	St Mary’s Hospital, Paddington, London	Senior and Trainee Gastroenterologists

Moreover, the planning of clinical workshops to be carried out by the PICCOLO partners from April 2019 to June 30th, 2020 is shown in Table 4.

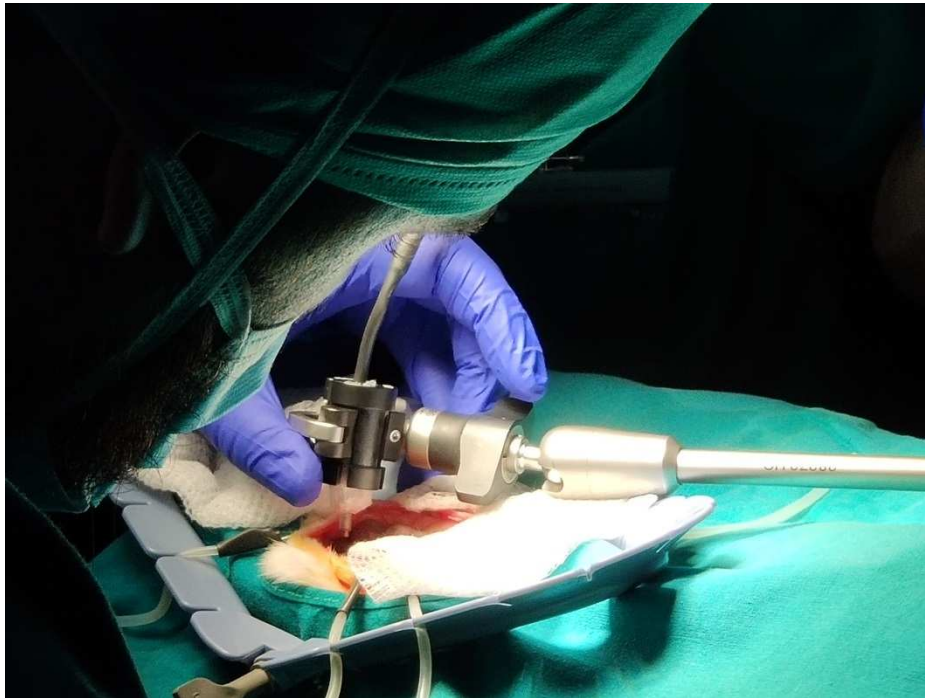
Table 3. Schedule of clinical workshops until June 2020

PROPOSAL OF CLINICAL WORKSHOPS UNTIL JUNE 2020					
Institution	Webinar	Meeting	Trade Fair	Description	Possible date
Lens/Tyndall	MPT/OCT imaging of colon with PICCOLO device			MPT/OCT imaging of colon tissue using the PICCOLO device will be explained, with particular attention to the features that are relevant from the diagnostic point of view.	Spring 2019
BIOEF/ Osakidetza		European Society of Gastrointestinal Endoscopy (ESGE DAYS)		Round table/Discussion presenting images acquired with the PICCOLO device Title- PICCOLO device: Image acquisition and processing	4 th -6 th April, 2019 (Prague) 2020
		Sociedad Española de Patología Digestiva (SEPD)		Round table/Discussion presenting images acquired with the PICCOLO device Title- PICCOLO device: Image acquisition and processing	13 th -15 th June 2019 (Santander) 2020
		41 Congreso de la Sociedad Española de Endoscopia Digestiva (SEED) (http://www.wseed.org)		Round table/Discussion presenting images acquired with the PICCOLO device Title- PICCOLO device: Image acquisition and validation plan	November 2019
		United European Gastroenterology meeting (UEG)		Round table/Discussion presenting images acquired with the PICCOLO device Title- PICCOLO device: Image acquisition and validation plan	October 2019 (Barcelona)
Storz		Live Surgery/Symposium: "Applications of Fluorescence Imaging using Indocyanine Green"	Naples, Italy	Near Infrared Fluorescence imaging training courses on animals or clinical live surgery demonstrations	April 2019
		Animal Workshop: "Sentinel Lymph Node detection in gynaecological cancers"	Training center IRCAD, Strasbourg, France		July 2019
Imperial College		London Regional Gastroenterology Meeting		Presentation and discussion of the PICCOLO system, the images obtained and the clinical use of the system. Group discussion regarding the imaging system.	September 2019
		North-West Thames IBD and Research meeting		Presentation of the capabilities of the PICCOLO system, and the changes that can be made in endoscopic practice.	November 2019

3. Report on the planned training sessions and clinical workshops

Regarding the training sessions, CCMIJU has performed the following:

- In December 2019, an MPT prototype presentation was carried out at CCMIJU's facilities where clinicians from CCMIJU learned how to use the MPT prototype during the training session.



- In December 2019, a Thorlabs OCT demo was carried out at CCMIJU's facilities. TECNALIA staff performed the training session for CCMIJU clinicians to learn how to use the Thorlabs OCT system.



- An MPT/OCT prototype presentation and Thorlabs OCT demo addressed to the PICCOLO consortium members met in Cáceres to hold the 7th face-to-face meeting on January 2020.

Project partners had the chance to visit the operating room and participate in a training session with the prototype demo. A murine specimen was analysed ex-vivo with the probe and the clinicians had the opportunity to evaluate the features present in a neoplastic polyp.





Regarding the clinical workshops, CCMIJU has performed the following:

- Hands-on Course on Digestive Endoscopy.

In a Hands-on Course on Digestive Endoscopy, held on June 27th and 28th 2019, addressed to gastroenterologists, CCMIJU carried out a clinical workshop at its facilities in order to present the PICCOLO prototype via video (it lasts 6 minutes). After watching it, attendants were asked to fill in a survey (see Annex A), prepared to get relevant info from clinicians about functions, usability and other features of the PICCOLO system.

21 gastroenterologists attended this clinical workshop and filled in the survey.





According to gastroenterologists' opinion, PICCOLO system would meet the current medical needs of colorectal cancer diagnosis. Although participants had no previous experience with OCT and MPT technologies, they think that it would improve results obtained with the imaging techniques they currently use (NBI). The new endoscope would contribute with in-situ diagnosis decision based on visual aids and marks, as gastroenterologists prefer. The PICCOLO system would not replace any clinical staff, but would serve as support and assistance for the detection and decision making in the diagnosis of colorectal cancer, avoiding thus the distrust shown by participants to a diagnosis provided by software without the supervision of a human expert. Usual handling and short acquisition time provided by the PICCOLO system would meet preferences of participants to use it in their service.

- Course of Endoscopic Retrograde Cholangiopancreatography. September 19-20th, 2019

CCMIJU carried out a clinical workshop at its facilities in order to present the PICCOLO prototype via video, afterwards attendants (10) were asked to fill in the same survey as before.

- Course on Endoscopic Submucosal Dissection in Animal Model. October 4-5th, 2019

This activity was performed with 15 attendants, and in the same way as before, with the same results.

- The National and International workshop on endoscopy was addressed to vets and the PICCOLO project was not presented. The Hands-on Course on Digestive endoscopy, planned for June 2020, could not be performed because of the lockdown established by the Spanish Government due to coronavirus.

Regarding the training sessions at BIOEF/Osakidetza, none of the planned activities related to internal courses were carried out due to the unavailability of the device.

Imperial College planned two internal courses and a regional course as training sessions for familiarisation with the PICCOLO device that have not been performed, partly as it has not been ready and partly due to the Covid-19 crisis stopping routine work.

Finally, according to the clinical workshops planned in Table 4:

- LENS proposed to organise a webinar on MPT/OCT imaging of colon with the PICCOLO device, but the MPT/OCT probe was not able to acquire colon images with sufficient signal-to-noise ratio.
- BIOEF proposed to carry out clinical workshops in several congresses (by the European Society of Gastrointestinal Endoscopy (ESGE DAYS), by Sociedad Española de Patología Digestiva (SEPD), by Sociedad Española de Endoscopia Digestiva (SEED) and the United European Gastroenterology Meeting (UEG)), but finally they were not performed.
- STORZ planned two clinical fluorescence imaging workshops: Live Surgery/Symposium: "Applications of Fluorescence Imaging using Indocyanine Green", and the Animal Workshop: "Sentinel Lymph Node detection in gynaecological cancers". The activity focused on the CE-certified fluorescence imaging product which has been used in the Piccolo project.
- Imperial College planned to present the PICCOLO system at the London Regional Gastroenterology Meeting and the North-West Thames IBD and Research meeting, but finally they were not performed.

4. Conclusion/Further work

This document, produced in September 2020, includes the report of training sessions and clinical workshops performed from April 1st 2019 to September 30th 2020.

Unfortunately, the completion of the planned clinical workshops and training session for 2020 has been interrupted by the coronavirus breakdown and the following lockdown established by the Government of the countries involved in this project.

Annex A

The survey consisted on the following questions (8):

1. Please, indicate your job status

- Resident
- Gastroenterologist/endoscopist

2. Please, indicate the number of colonoscopies your perform per year: _____

3. Do you think the PICCOLO device would meet the current medical needs related to colonoscopy procedure and colorectal cancer diagnosis? If yes, order by importance the medical needs to be met (1 - most important, 4 - least important)

- No
- Yes
 - Reduce time and costs of diagnosis
 - Ensure safe resection margins
 - Determine the depth of invasion of the polyp
 - Reduce missing polyps rate

4. Do you have previous knowledge or experience with photonic technologies?

- Optical Coherence Tomography (OCT)
- Multiphoton Tomography (MPT)
- Fluorescence spectroscopy
- Narrow Band Imaging (NBI)
- Other (Indicate, please): _____
- None

5. Do you think PICCOLO (OCT, MPT and fluorescence) would improve results obtained with advanced imaging techniques currently used (NBI, chromoendoscopy, etc.) for colorectal cancer diagnosis?

- Yes
- No

6. Do you think it is important that a system such as PICCOLO could provide additional information (for example, polyp warning!) for supporting the decision-making in the assessment of polyps or colorectal cancer? If yes, how would you like the associated software to provide you with such additional information?

- No
- Yes

- Highlight it over the endoscopic image
 - Show it outside the endoscopic image
 - Inform by acoustic warning
7. Current diagnostic patterns (Paris, Kudo, etc.) have a high intra- and inter-observer variability. Would you trust the diagnosis obtained by a software automatically?
- Yes, absolutely
 - Yes, under the supervision of a human expert
 - No, but it would be good support for my decision
 - Not at all
8. Would you use this system in your service? If yes, what characteristics would you give more importance to? Multiple choice (max. 3)
- No
 - Yes
 - The endoscope to have good handling characteristics that do not necessitate deviation from normal endoscopic technique
 - The acquisition and processing time from the optical biopsy system (OCT/MPT) to be short
 - The price of the system to be reasonable when compared to competing technologies
 - The overall size of the system to be comparable to standard, currently used endoscope stacks
 - The output of the system is compatible with existing image and data-handling processes