

# **Digital Allergy Testing**

Nexkin helps physicians better understand, diagnose, treat and follow-up allergies.

Nexkin DSPT is the first medical device and data platform for digitalization of the main allergy test: the skin prick test



# Product



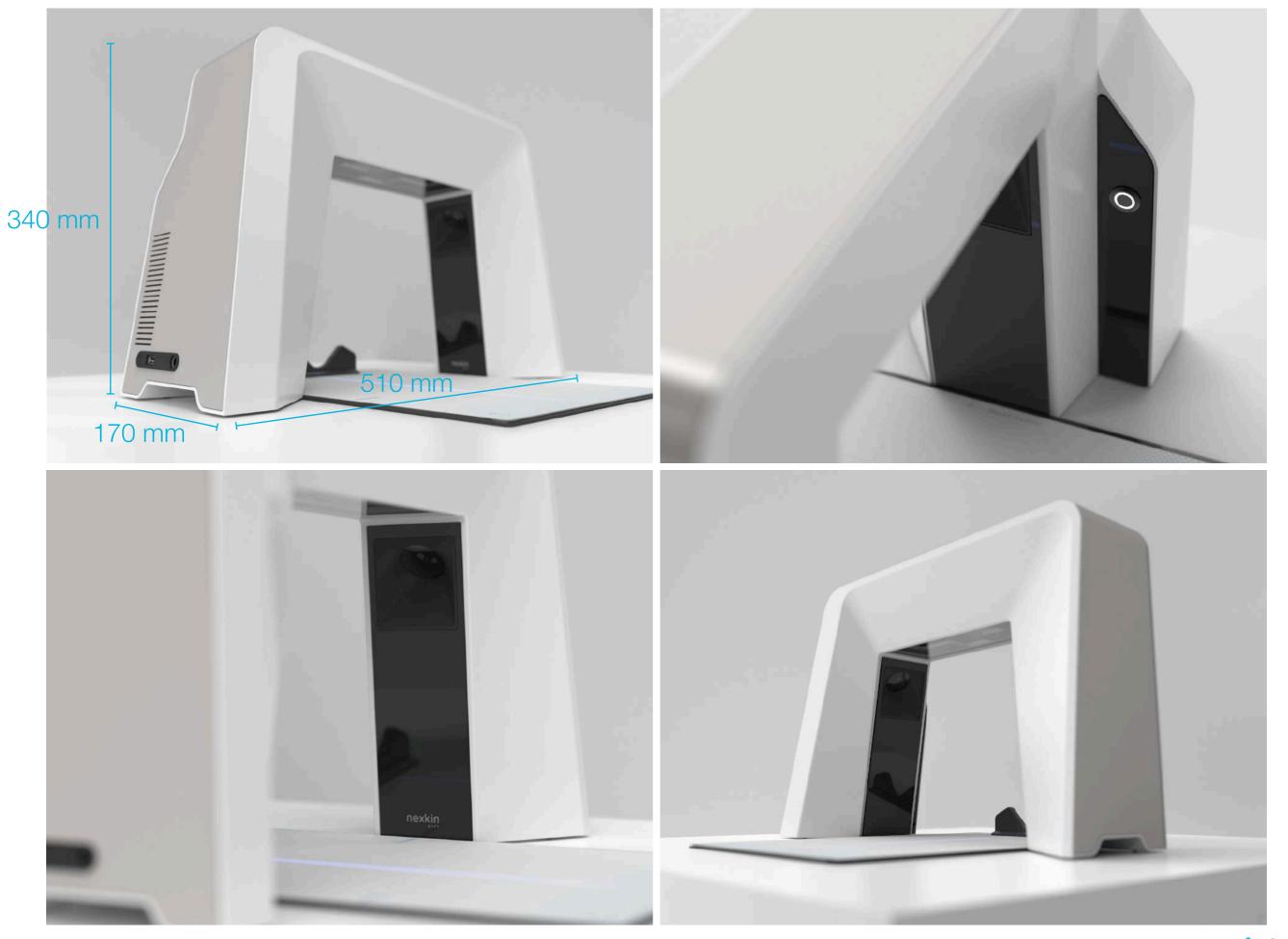




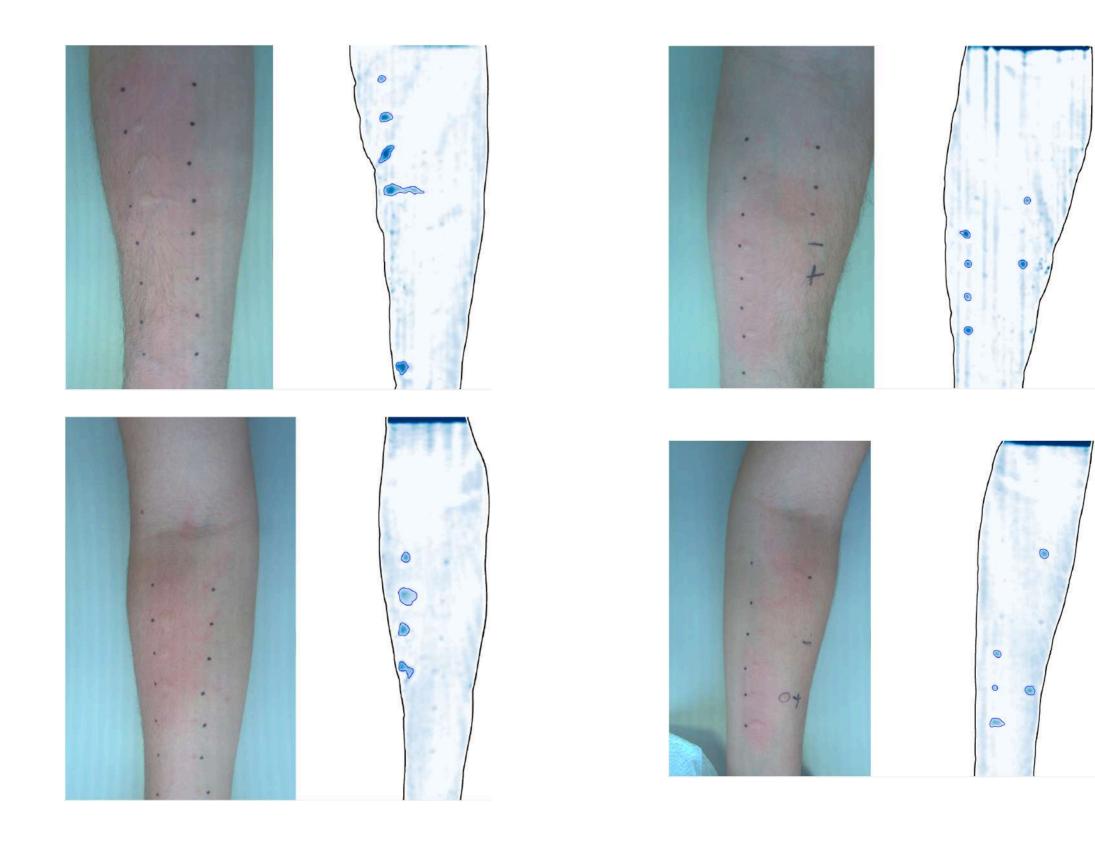
# Nexkin DSPT

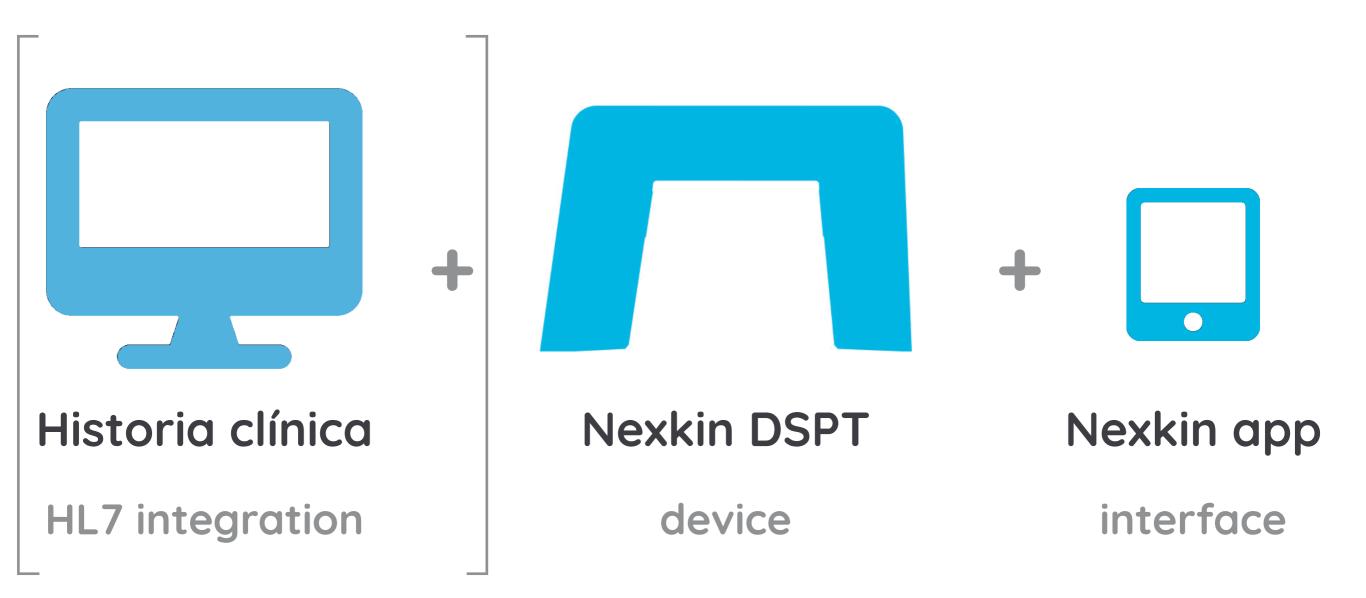
### Nexkin DSPT is an

electromedical Class I device to digitalize the skin prick allergy test. It helps locate wheals in patient's arms during the skin test reading and provides objective wheal measurement.

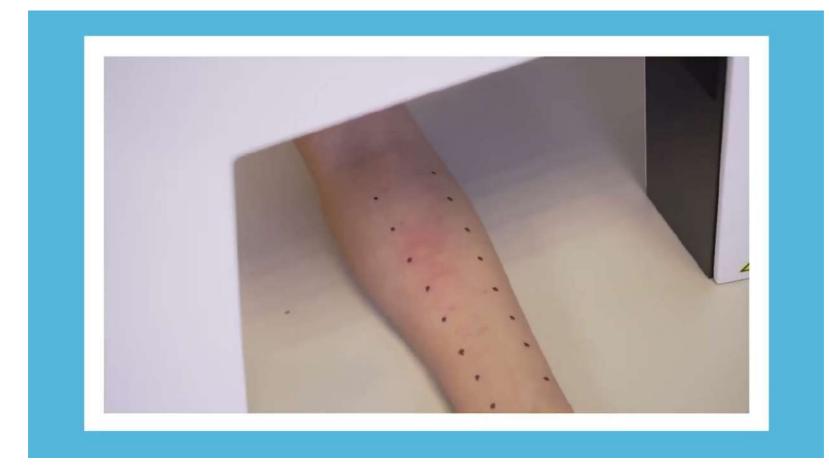


## Wheal detection & Characterization





## Integration with Electronic Health Records



Integration with Electronic Health Records allows for a seamless digital workflow from the test request to its reading and the test results delivery to the allergy specialist.



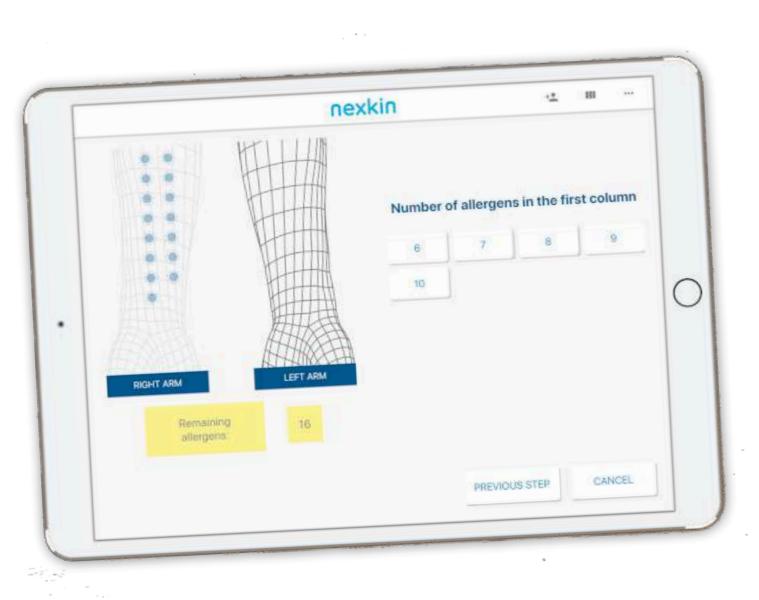
# Device

## Main features

- Automated and digital skin prick test reading
- Locates and measures wheals
- Test results in digital format
- Traceability
- Option for integration in Hospital/Clinic Information System



# App



### Main features

- User friendly interface
- Flexible test configuration: preconfigured custom panels, individual extracts or a combination
- Management of allergen distribution in patient's arms

## Benefits



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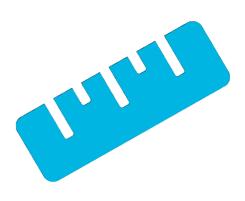
### **Digital data**

Test procedure digitalization, from allergen selection to test reading and results archiving. It allows IT integration, traceability & data exploitation



### Efficiency

Reduces manual tasks allowing health professionals to focus on value added clinical procedures and activities



### Rigour

Brings test reading to a whole new level providing quantitative instead of qualitative results and avoiding potential human errors



### Consistency

Brings consistency to test reading by overcoming the variability currently caused by subjective reading



### Integration

Facilitates team work and integration in clinical procedures and research involving multiple participants



Hygiene

Increases hygiene reducing risks since it eliminates paper use in the procedure workflow

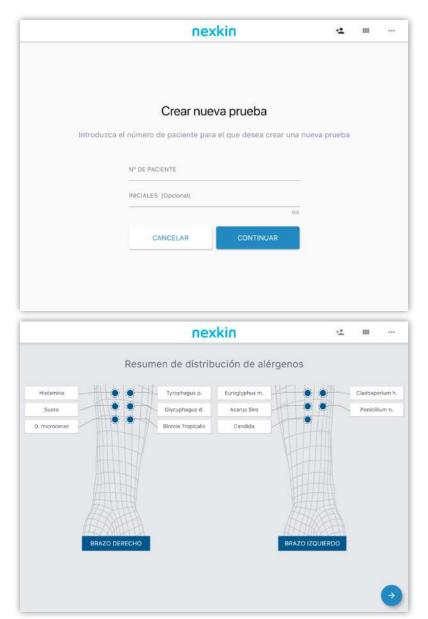


Safety

Ensures distancing and reduces contact between health professionals and patients



# Digitally integrated procedure



Q Buscar X	Prick Estándar	Prick Ácaros y Hongos	Prick Estándar Redu	cido
Alimentos 🔷	Prick Ácaros y Hongos			
eche y A	1 Histamina		2 Suero	
Leche de cabra	3 D. microceras		4 Tyrophagus p.	
Leche de oveja	6 Glycyphagus d.		8 Blomla Tropicalis	
Leche de vaca	7 Euroglyphus m.		8 Acarus Siro	
Leche de vaca (proteínas séricas)	9 Candida		10 Cladosporium h.	
Leche de vaca (caseína)	11 Penicillium n.			
Verduras y v				
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N° de paciente: 12345
Alérgeno
Resultado
Anotaciones

Image: Strain Strai

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## Publications



## Publications

Received: 24 May 2022	Revised: 8 July 2022	Accepted: 23 July 2022
DOI: 10.1111/all.15474		

Allergy ----- WILEY

Reliability of a novel electro-medical device for wheal size measurement in allergy skin testing: An exploratory clinical trial

#### To the Editor,

LETTER

Skin prick testing (SPT) is the cornerstone of IgE-mediated allergy diagnosis,<sup>1</sup> due to its high sensitivity and specificity.<sup>2</sup> However, a uniform method for wheal measurement does not exist. Ansotegui et al.<sup>2</sup> recommends to measure wheals in millimeters with a ruler, in many centers they are outlined with a pen and transfer by tape to a paper and then measured. Subsequently, the specialist is able to manually measure the maximum (MD) and orthogonal diameter (OD)

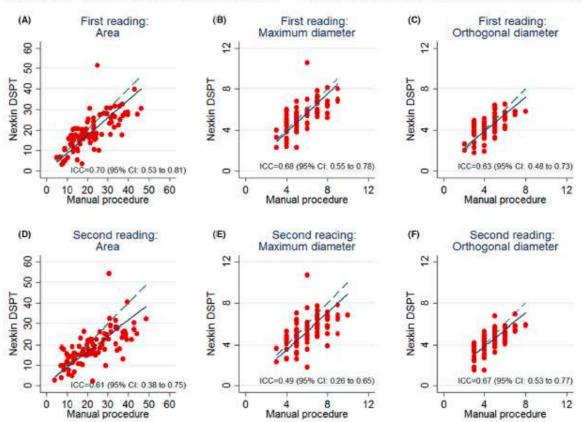


FIGURE 1 Agreement in wheal size between manual measurement procedure and Nexkin DSPT® for first and second readings. 95% CI, 95% confidence interval; ICC, Intraclass correlation coefficient. Dashed lines represent perfect agreement and solid lines indicate reduced major axis (RMA) linear regression

Maria de la Paz Morales-Palacios and Jorge M. Núñez-Córdoba contributed equally.

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Allergy. 2022;00:1-3.

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## Publications

EAACI

#### Allergy EUFOPEAN JOURNAL OF ALLERGY AND CLINICAL MMUNOLOGY

#### **REVIEW ARTICLE**

#### Prick test: evolution towards automated reading

X. Justo<sup>1</sup>, I. Díaz<sup>1</sup>, J. J. Gil<sup>1</sup> & G. Gastaminza<sup>2</sup>

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#### Keywords

allergic reaction; prick test; wheal; automatic measurement.

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Edited by: Werner Aberer

In vivo tests in allergy date back to 1867 when Dr. Charles Blackley applied a porridge of pollen in water on his scratched skin, causing redness, swelling and itching. Later, Schick and Cooke introduced the intracutaneous test. However, it was not until 1950 that Sir Thomas Lewis proposed administering the allergen via the puncture technique (1).

From the onset of using skin tests in the field of allergy, scientists have tried to standardize the reactions obtained so that they are comparable regardless of where and how they have been generated. In general, the objective of standardization covers three parts: the puncture device, the allergens and the process (test and diagnosis).

Regarding the process, the most commonly used method for detecting allergies is known as the prick test. This method is relatively simple and fast. However, prick test, as it is performed newadays, has some limitations in its diagnostics accuracy, especially for food allergy diagnosis (2–4). Besides, the analysis and measurement of the size of the wheals that correspond to a positive reaction are performed in a manual and laborious manner, or by means of a qualitative judgement made by the allergist. While some allergists just visually inspect the reaction, or compare it with the histamine wheal, others try to quantitatively measure the geometry of the wheal.

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Abstract

The prick test is one of the most common medical methods for diagnosing allergies, and it has been carried out in a similar and laborious manner over many decades. In an attempt to standardize the reading of the test, many researchers have tried to automate the process of measuring the allergic reactions found by developing systems and algorithms based on multiple technologies. This work reviews the techniques for automatic wheal measurement with the aim of pointing out their advantages and disadvantages and the progress in the field. Furthermore, it provides a classification scheme for the different technologies applied. The works discussed herein provide evidence that significant challenges still exist for the development of an automatic wheal measurement system that not only helps allergists in their medical practice but also allows for the standardization of the reading and data exchange. As such, the aim of the work was to serve as guideline for the development of a proper and feasible system.

> In general, two main parameters are used: the mean diameter of the wheal and the area, which shows less variability (5). These results have to be interpreted by the allergist, which can introduce additional variability. It has been shown that experts examining the same contours can arrive at different conclusions (6-8). An automated device would potentially reduce the uncertainties introduced by the reading process, minimizing the variability after the puncture is carried out. As Poulsen et al. (9) stated, the two main sources of uncertainties during the reading process are (i) the drawing of the wheal and (ii) the determination of the area. The variability produced by these factors can be significantly reduced by applying new technologies. Even other sources of error not usually taken into account, such as a test misplacement or an incorrect allergen assignation, could be eradicated by using a proper reading method.

This review aimed to describe and analyse the different technologies in the literature that have attempted to automate and standardize the process of measuring the outcomes of an allergy test, pointing out their advantages and disadvantages and discussing what is actually needed in order to develop a reliable wheal measuring system. The focus of the paper is on the reading and measuring part of the outcomes of the prick test, but not on the process or the puncture.

#### EMB COMSoc \_\_\_\_\_

### Medical Device for Automated Prick Test Reading

Xabier Justo<sup>10</sup>, Iñaki Díaz, Jorge Juan Gil, and Gabriel Gastaminza

Abstract—Allergy tests are routinely performed in most hospitals everyday. However, measuring the outcomes of these tests is still a very laborious manual task. Current methods and systems lack of precision and repeatability. This paper presents a novel mechatronic system that is able to scan a pationt's ontire arm and provide allergists with precise measures of wheals for diagnosis. The device is based on 3-D laser technology and specific algorithms have been developed to process the information gathered. This system aims to automate the reading of skin prick tests and make gains in speed, accuracy, and reliability. Several experiments have been performed to evaluate the performance of the system.

Index Terms-Automatic measurement, prick test, wheal.

#### I. INTRODUCTION

A LLERGIES are common diseases for all age groups worldwide. In the developed world, about 20% of people are affected by allergic rhinitis [1] and about 6% of people have at least one food allergy [2].

At present, the most commonly used method for detecting allergies is known as a prick test [3]. The test consists of applying a small amount of allergen to the skin of a patient, usually on the inner forearm (Fig. 1(a)), then making a micro-incision in the skin with a small lancet, thereby bringing the allergen in contact with the body (Fig. 1(b)). As a consequence, a small allergic reaction may arise in the form of a wheal or papule (Fig. 1(c)), whose size and shape determine the degree of sensitivity. In a next step, between 15 to 20 minutes after puncture, a doctor or nurse marks the contour of the wheal with a pen so it can be measured (Fig. 1(d)). This method is often applied simultaneously with different allergens, thereby making it possible to test multiple allergies.

The prick test method is relatively simple and fast. However, the analysis and measurement of the size of the wheals that correspond to a positive reaction are performed in a completely manual manner. No standardized automated system exists for recording and interpreting skin prick tests. Moreover, the

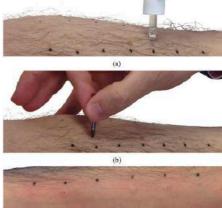
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Justo X, Diaz I, Gil JJ, Gastaminza G. Prick test: evolution towards automated reading. Allergy 2016; DOI: <u>10.1111/all.12921</u>

Justo X, Diaz I, Gil JJ, Gastaminza G. Medical device for automated prick test reading. IEEE Journal of Biomedical and Health Informatics; Vol. 22, NO.3, May 2018; DOI: 10.1109/JBHI.2017.2680840



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Fig. 1. Prick test usual procedure: (a) altergen deposition, (b) puncture with an ALK lancet through the drop of altergen, (c) altergis reaction after 15 min., (d) wheal contour marked with a pen to measure the area and/or diameter.

measures obtained from the test show great variability due to the difficulty of marking and precisely measuring the contour of the wheal [4], [5]. Besides the reading, there are other sources of variability in the prick test.

Knowing what to measure is as important as the measurement itself [6]. In general, two main parameters are used [7]: the

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