



DIAPATH

Constant Innovation in Anatomic Pathology



Donatello® Series 3

Advanced innovation and technology
in tissue processing

AUTOMATIC TISSUE PROCESSOR FOR HISTOLOGICAL SAMPLES
SDSDT9000



IVD CE

MADE IN ITALY

Donatello® Series 3 Redefining Tissue Processing

Advanced innovation and technology in tissue processing



WATCH THE FILM
"EVERY BREATH
IS A GIFT"

Your unique and unrepeatable sample deserves best-in-class safety

Tissue processing is a one-way process where a number of chemical steps and physical conditions will irreversibly determine the suitable processing of the specimen for the morphological (H&E), IHC and molecular analysis. Diagnostic-therapeutic algorithms for the selection of patients for targeted cancer treatment include immunohistochemical and molecular analysis of histological specimens. **That's why the quality of FFPE (Formalin Fixed Paraffin Embedded) specimens processed is mandatory.** The Donatello® Series 3 is especially designed to preserve the integrity of proteins and nucleic acids in biological tissue samples suitable for diagnosis and evaluation of biomarkers predictive of therapy response.



Evolving Diagnostic and Therapeutic Scenario



Clinical care and
Patient management



Pathology Diagnosis



Nucleic Acid (DNA, RNA)
and protein expression



Target therapies
to slow down or inhibit
tumor' growth

Why 3

Discover how Donatello Series 3 cutting-edge technology redefines tissue processing



1

IMMUNOTHERAPY

Validated tissue processor for the preservation of immunohistochemical expression of PD-L1. The scientific publication demonstrates, in a comparative study, the interference of tissue processing in the evaluation of biomarkers useful in selecting patients who are candidates for immunotherapy.



2

VALIDATED BIOMARKERS PROTOCOLS

The integrated protocols are validated by Diapath in collaboration with reference Hospitals, Laboratories and Research Institutes. These procedures are used daily for diagnostic purposes, immunohistochemistry, *in-situ* hybridisation and molecular biology investigations in order to identify predictive biomarkers of target therapy response.



3

SAFE DIAGNOSIS

Donatello® Series 3 is equipped with E.V.A.† (Emergency eVolved Algorithm) designed for advanced safety. In the event of a mechanical blockage, especially during unmanned processing phases such as overnight processing, in case of critical situations and in the absence of an operator, is able to perform fully automatic troubleshooting operations, choosing the most appropriate corrective recovery action to save the samples.

DEMONSTRATING THE INTERFERENCE OF TISSUE PROCESSING IN THE EVALUATION OF TISSUE BIOMARKERS: THE CASE OF PD-L1

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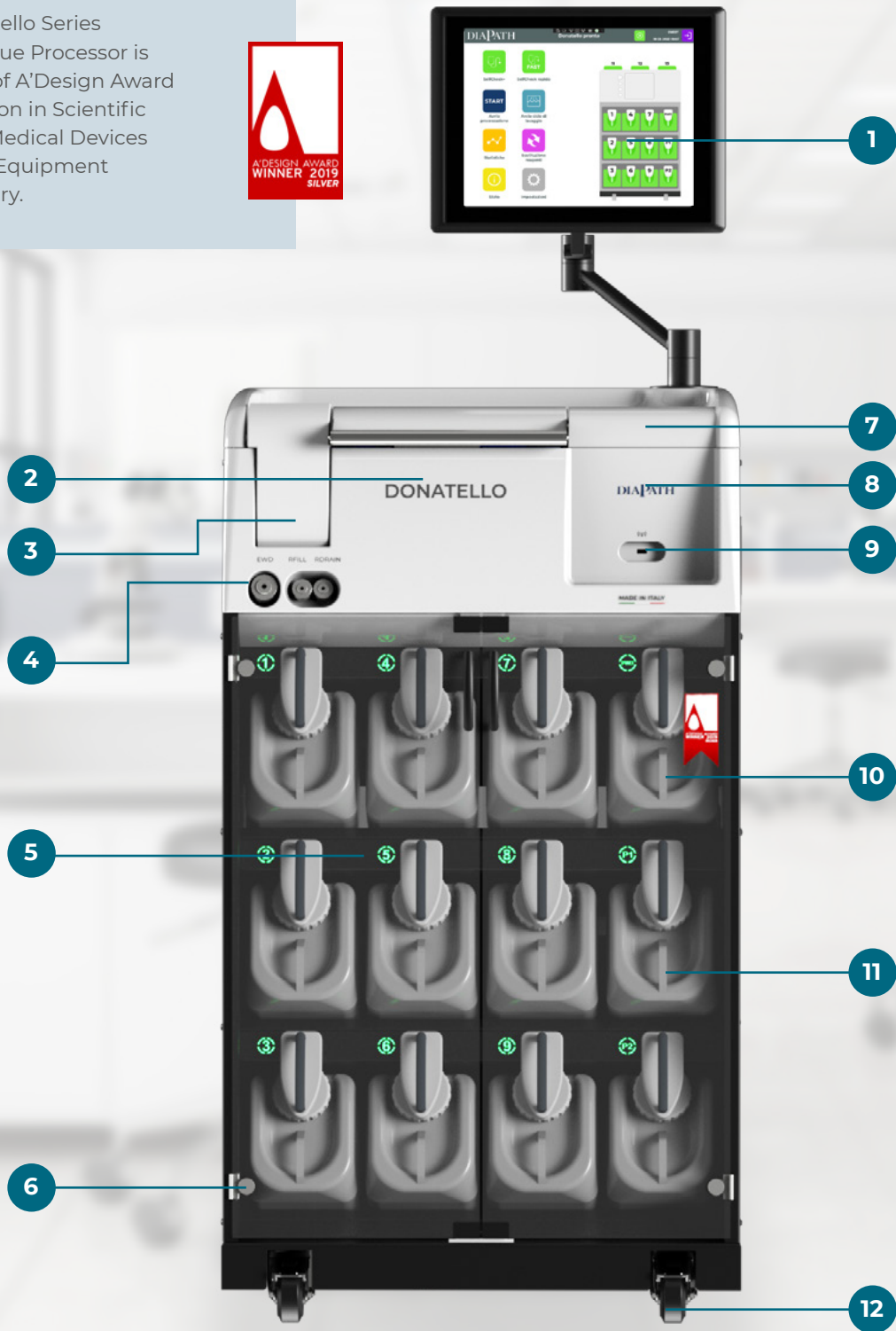
<https://doi.org/10.1016/j.prp.2023.154605>

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Diapath Italian Iconic Design

Diapath Donatello Series Automatic Tissue Processor is Silver Winner of A'Design Award and Competition in Scientific Instruments, Medical Devices and Research Equipment Design Category.



Remote Assistance Plus

Our solution for overall business continuity. Communicate with Diapath experts. A simple web connection is enough.

- Speed in solving problems
- Specialized and tailor-made assistance for you
- Guaranteed competence

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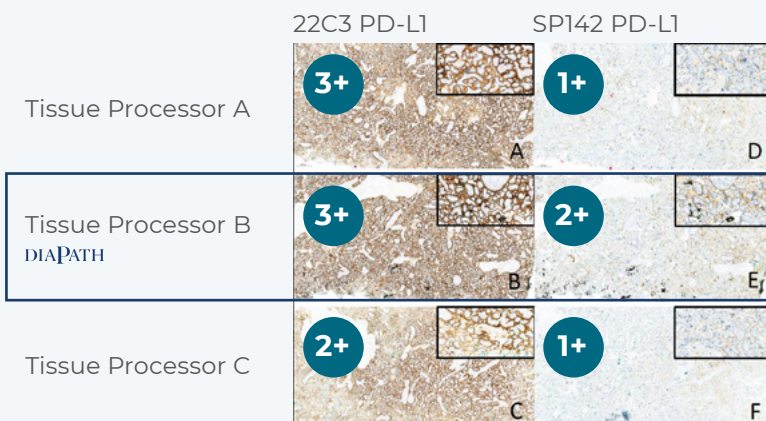
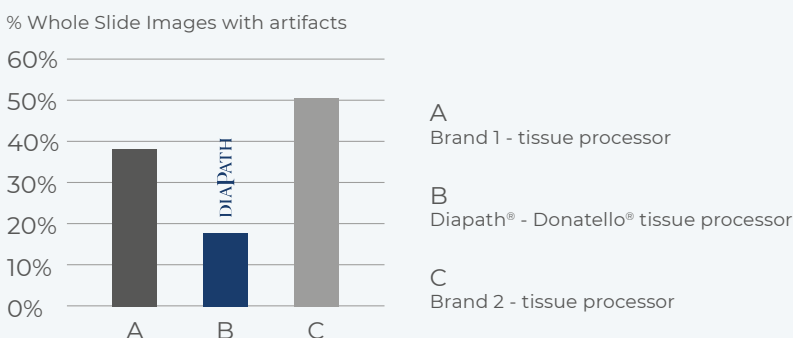
SCAN HERE



- 1 **ALL-IN-ONE PC**
With 15" color touchscreen.
- 2 **SAMPLE PROCESSING CHAMBER (SPC)**
In stainless steel, resistant to solvents and heat. 4 capacitive and adaptive level sensors that can detect the presence of the reagent and the correct filling level.
- 3 **SPC LOCK SYSTEM**
Totally controlled by software. Equipped with a system that can detect incorrect process chamber closure and alert the operator in 4 seconds.
- 4 **EWD/RFILL/RDRAIN CONNECTORS**
For external paraffin unloading and for remote loading/unloading of reagents.
- 5 **ACTIVE LED SYSTEM**
Dynamic LED for each reagent station to guide the operator during the replacement of the tanks and view the status of the instrument and the reagents.
- 6 **SECURITY SENSOR**
Able to track possible removal of reagent tanks via sensor.
- 7 **3 CYLINDERS FOR PARAFFINS**
With a capacity of 4.7 (max) and 4.4 (min) liters each.
- 8 **RFID TECHNOLOGY**
Housing for pre-filled tank for a quick and safe identification of reagents and rapid user login.
- 9 **USB PORT**
Easily accessible for exporting the data contained in the instrument database.
- 10 **PWD TANK**
For the internal discharge of the exhausted paraffin in a dedicated tank.
- 11 **12 TANKS FOR REAGENTS**
9 dedicated to processing reagents, 2 dedicated to washing reagents and 1 PWD tank (5 liters each).
- 12 **WHEELS FOR EASY MOVING**
With locking lever.

DEMONSTRATING THE INTERFERENCE OF TISSUE PROCESSING IN THE EVALUATION OF TISSUE BIOMARKERS: THE CASE OF PD-L1

PRESENCE OF ARTIFACTS IN THE WHOLE SLIDE IMAGES (WSI)



“The results of this study suggest that, **analytic conditions** less often motive of consideration such as tissue processing, may be **major culprits in the lack of consistent results of biomarkers evaluation**, such as PD-L1. [...]”

These observations support others reported in the literature that support the **urgent need to standardize tissue processing** and to review the **basic chemistry associated with the biomarkers evaluation**, since it has been proved to fail as a solid quantitative method. [...]”

This study demonstrates the need to review and standardize the tissue processing in pathology laboratories to cope with the **growing needs of precision medicine** inherent quantifications and the production of high quality material necessary for computational pathology usage.



Donatello® Series 3, technology features

SELF-CHECK⁺

The Self-diagnostic system prevents unexpected stops during overnight processing. The procedure is performed automatically before each processing, via automatic check on the sensitive mechanical parts of the processor.

MAXIMUM PRODUCTIVITY

Thanks to its large processing chamber and its reagent mixing technology, Donatello® is able to process up to 420 standard biocassettes, up to 112 Slim Mega Cassettes and up to 56 Super Mega Cassettes (with dedicated basket) with a single run.



E.V.A.⁺ EMERGENCY EVOLVED ALGORITHM

The intelligent virtual algorithm is able, in case of a mechanical blockage, to perform operations in a totally automatic way aimed at solving problems without interrupting the processing. E.V.A.⁺ is also equipped with a voice-user interface making spoken human interaction easy.

ABS (ANTI BLOCK SYSTEM)

The ABS system makes the instrument less susceptible to impurities, such as the incidental presence of organic (release of tissue components during processing), inorganic substances and foreign bodies (dirt, dye powder residues that may accidentally circulate inside the instrument). Insoluble fragments circulating within any hydraulic system may cause blockage phenomena of an embolic-like nature. ABS also contributes to the reduction of cross-contamination between reagents by extending the shelf-life of process reagents.

SAFE REAGENT

Donatello® Series 3 offers the possibility to set a custom safety reagent for each step of the processing. In the event of a power failure, a Safe Reagent will be loaded into the processing chamber to keep the samples safe until Laboratory staff arrives (only with UPS connection). The Safe Reagent will also intervene downstream of the various attempts of the emergency procedure carried out by E.V.A.⁺

FPS - FAST PROCESSING SYSTEM

Ideal for preheating of the reagent in a safe and homogeneous way before its actual use inside the processing chamber. This technology allows for the processing of small biopsies (up to 1 mm thickness) in less than an hour. The FPS is activated only when the reagent passes through preventing power consumption.

SENSOR LEVEL

For real time fluidodynamic monitoring and detect the presence of the reagent and the correct fill level to prevent samples from drying out.

SECURITY SENSOR

Able to track incidental removal of reagent tanks via sensor (Date, Time, and Operator).

BUBBLING

Innovative reagent mixing technology.

ENERGY MONITORING SYSTEM

Donatello® Series 3 is equipped with a system that can perform real-time monitoring of the instrument's energy consumption, maximizing the energy efficiency of the instrument and increasing overall performance.

RFID TECHNOLOGY

Quick and safe identification of dedicated pre-filled containers. The software and LEDs guide the reagent replacement procedure, thus preventing any reagent refill errors.

ID CARD

RFID-technology-based ID card, makes user login, reagent' and lot expiry' traceability easy and intuitive.





Donatello is safety, for your health.



GREEN SOLUTION - OTTIX

Ottix is Diapath's **patented solution** consisting of two reagents replacing the complete alcohol scale and xylene. Through the application of **protocols validated** and used all over the World for more than ten years, Ottix guarantees **better results** than traditional reagents, especially **when used for processing breast, skin and fatty tissue samples**.

ACTIVATED CARBON FILTERS

Donatello® Series 3 has two high performance activated carbon filters for the **removal of compound hydrocarbons**. The instrument has a suction point, with a dedicated filter, above the processing chamber.

Optional accessories FOR THE COMPLETE LIST, CHECK THE TECHNICAL SHEET

SDSPA9066	Basket for Super Mega Cassettes
CRDEA903-IIIPRO	UPS
SDSBR0001	Barcode reader cordless for Donatello® Series
CRD-RT01N	Router for Remote Assistance
SDSAD0001	Auto dialer 115-230 V
SDSPA9069	Support for pipes
SDXCE9005	ID card USER, RFID-technology-based, 5 pcs
SDSPA9060	Tray for basket

Technical data

	DONATELLO® SERIES 3
MAXIMUM CASSETTE CAPACITY	420 standard, 112 slim mega, 56 super mega
REAGENT TANKS	12 tanks of 5 l each
WAX CYLINDERS	3 cylinders, 4.4-4.7 l each
MAXIMUM PROCESSING CHAMBER VOLUME (SPC)	8 l
REAGENT MANAGEMENT SYSTEM (RMS)	Complete control of reagents and activated carbons filter
SPECIFIC STEAM TREATMENT	Dedicated activated carbon filter with forced ventilation, also in the processing chamber
SIZE (W - D - H)	700x750x1550 mm
WEIGHT	240 kg
POWER	115-230V ±10%, 50-60Hz
REGULATORY STANDARDS	CE-IVD - Compliance with Regulation 746/17



Meet
the expert

Find out more and request
a **virtual demo experience**
with our product specialists

SCAN HERE



Diapath range of solutions for Anatomic Pathology



Galileo SERIES 2

Rotary
microtome



Giotto

Automatic
stainer



Dante

Embedding module +
Cold plate



Cristallo®

Liquid Coverslipping
Technology

Discover the full range on www.diapath.com/products

Acknowledgements DIAPATH



Co-funded by the EU
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Donatello® Series wins
A'Design Award Competition
2019 in the "Scientific
Instruments" category



34th World ranking Design
Award 2021
in the "Medical
Appliances" category



Provider of training
credits recognised by
NSH - National Society
for Histotechnology

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