EHRA Position Documents on new technology or standards of care

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Disclosures

Laurent Fauchier:

• **Lecture fees:** Bayer, BMS Pfizer, Daiichi Sankyo, Boehringer Ingelheim, Medtronic

• **Travel grants:** Bayer, BMS/Pfizer, Boehringer Ingelheim, Livanova, Medtronic, Novartis.

• **Consultant:** Bayer, BMS/Pfizer, Boehringer Ingelheim, Medtronic, Novartis
EHRA scientific documents

• EHRA has published a number of scientific documents over the past years. Some of these have been produced in collaboration with main players in the field of Arrhythmias and systematically published in EP Europace Journal. Today EHRA continues to cover new areas of interest in the field and produce scientific statements, recommendations and position papers.

• Since 2008, EHRA has also produced Scientific Documents in collaboration with different organisations (HRS, ACC, AHA, ESC, APHRS, SOLAECE...), and is continuously launching new Task Forces that tackle new and challenging scientific topics.

www.escardio.org/EHRA
The goal of the committee work is to provide sound advice, based on scientific data and generated by experts in the field, in emerging areas relevant to the management of arrhythmias in Europe.
<table>
<thead>
<tr>
<th>Name</th>
<th>Nationality</th>
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<tbody>
<tr>
<td>Prof. Gregory YH Lip (Chairperson)</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Prof. Bulent Gorenkek (Co-Chairperson)</td>
<td>Turkey</td>
</tr>
<tr>
<td>Prof. Carina Blomstrom Lundqvist</td>
<td>Sweden</td>
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<tr>
<td>Prof. Giuseppe Boriani</td>
<td>Italy</td>
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<td>Dr. Michele Brignole</td>
<td>Italy</td>
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<tr>
<td>Prof. Gheorghe-Andrei Dan</td>
<td>Romania</td>
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<td>Prof. Laurent Fauchier</td>
<td>France</td>
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<tr>
<td>Prof. Werner Jung</td>
<td>Germany</td>
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<tr>
<td>Prof. Andreas Goette</td>
<td>Germany</td>
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<tr>
<td>Dr. Deirdre Lane</td>
<td>United Kingdom</td>
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<tr>
<td>Dr. Francisco Marin</td>
<td>Spain</td>
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<tr>
<td>Dr. Irina Savelieva</td>
<td>United Kingdom</td>
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<tr>
<td>Prof. Christian Sticherling</td>
<td>Switzerland</td>
</tr>
<tr>
<td>Prof. Marc A Vos</td>
<td>Netherlands</td>
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</table>
CLINICAL PRACTICE GUIDELINES

- Atrial Fibrillation 2016 (Management of) 2015
- Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death 2014
- Hypertrophic Cardiomyopathy 2013
- Cardiac Pacing and Cardiac Resynchronization Therapy 2010
- Device Therapy in Heart Failure (Focused Update) 2010

www.escardio.org/EHRA  L. Fauchier
Management of supraventricular arrhythmias: A consensus document by the EHRA endorsed by the HRS,APHRS, and SOLAECCE
Pre-participation cardiovascular evaluation for athletic participants to prevent sudden death: A position paper by the EHRA and the EACPR, branches of the ESC. Endorsed by APHRS, HRS and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrostilofisiologia (SOLACE)

How to Prevent Atrial Fibrillation: A position paper by the European Heart Rhythm Association (EHRA) and European Association of Cardiovascular Prevention and Rehabilitation (EACPR) endorsed by the Heart Rhythm Society (HRS) and Asia Pacific Heart Rhythm Society (APHRS)

Left univentricular pacing for cardiac resynchronization therapy. Thanks to an unrestricted grant from Medtronic
The wearable cardioverter-defibrillator: current technology and evolving indications
Thanks to an unrestricted grant from Zoll
The scientific content has not been influenced in any way by its sponsor.

The scientific content has not been influenced in any way by its sponsor.

EHRA/APHRS/SOLAECCE expert consensus on Atrial cardiomyopathies definition, characterization, and clinical implication
EACVI/EHRA Expert Consensus on the role of Multi-Modality Imaging for the evaluation of patients with Atrial Fibrillation

Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with non-valvular atrial fibrillation
2015 HRS/EHRA/APHRS/SOLAECCE Expert Consensus Statement on Optimal Implantable Cardioverter-Defibrillator (ICD) Programming and Testing
European Heart Rhythm Association/Heart Failure Association joint consensus document on arrhythmias in heart failure, endorsed by the Heart Rhythm Society and the Asia Pacific Heart Rhythm Society
A roadmap to improve the quality of atrial fibrillation management: proceedings from the fifth Atrial Fibrillation Network/European Heart Rhythm Association consensus conference
AFNET/EHRA Press Release
Antithrombotic management in patients undergoing electrophysiological procedures: an European Heart Rhythm Association (EHRA) position paper endorsed by the ESC Working Group Thrombosis, Heart Rhythm Society (HRS), and Asia Pacific Heart Rhythm Society (APHRS)

Chronic kidney disease in patients with cardiac rhythm disturbances or implantable electrical devices: clinical significance and implications for decision making a position paper of the European Heart Rhythm Association endorsed by the Heart Rhythm Society and the Asia Pacific Heart Rhythm Society
Syncope Unit: rationale and requirement – the European Heart Rhythm Association position statement endorsed by the Heart Rhythm Society
Cardiac tachyarrhythmias and patient values and preferences for their management: the European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (SOLACE)
EHRA Review article on state of the art of leadless pacing. Thanks to an unrestricted grant from St Jude Medical
The scientific content has not been influenced in any way by its sponsor.
### Scientific rationale of recommendations

<table>
<thead>
<tr>
<th>Definitions where related to a treatment or procedure</th>
<th>Consensus statement instruction</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific evidence that a treatment or procedure is beneficial and effective. Requires at least one randomized trial, or is supported by strong observational evidence and authors’ consensus (as indicated by an asterisk).</td>
<td>‘Should do this’</td>
<td>🌟</td>
</tr>
<tr>
<td>General agreement and/or scientific evidence favour the usefulness / efficacy of a treatment or procedure. May be supported by randomized trials based on small number of patients or not widely applicable.</td>
<td>‘May do this’</td>
<td>💛</td>
</tr>
<tr>
<td>Scientific evidence or general agreement not to use or recommend a treatment or procedure.</td>
<td>‘Do not do this’</td>
<td>🚫</td>
</tr>
</tbody>
</table>

- This categorisation for a consensus document should not be considered as being directly similar to that used for official society guideline recommendations which apply a classification (I-III) and level of evidence (A, B and C) to recommendations.
New devices in heart failure: an EHRA report

Review of new devices for the treatment of HF patients introduced in clinical practice or under clinical evaluation:

- cardiac contractility modulation
- spinal cord stimulation
- carotid sinus nerve stimulation,
- cervical vagal stimulation,
- intracardiac atrioventricular nodal vagal stimulation
- implantable haemodynamic monitoring devices.

Kuck KH et al. Europace 2014
The main indication for LAA occlusion today is a relative or absolute contraindication to (N)OACs in patients with AF and a CHA2-DS2-VASc score ≥2.

This recommendation is based on observational studies and registries only.

To be a candidate for LAA occlusion, patients should be able to receive at least several weeks of dual AT followed in most cases by lifelong single antiplatelet drug therapy.

If antiplatelet therapy is not an option, percutaneous endocardial/epicardial or minimally invasive surgical epicardial LAA occlusion may be alternatives.
Tips and tricks for LAA device implantation

1. Using a PFO for transseptal access may lead to suboptimal delivery sheath alignment with the LAA. Sometimes this problem can be solved by custom shaping the sheath with or without hot air gun.
2. Minimize device sheath time in the LA especially in large LA with LAA sludge and/or pronounced smoke (longer indwelling gear time increases device-associated thrombus risk).
3. Minimize the risk of air embolism:
   a. Generously backbleed the transseptal and access sheath allowing air to exit the sheath prior to inserting any equipment or devices (keep the haemostatic valve and device arm below the midline of the chest). Keeping the haemostatic valve, proximal sheath end, and side arm under water may prevent air entering the system during backbleeding.
   b. Remove dilators, catheters, and transseptal puncture needles slowly.
   c. Flush the device and delivery catheter generously prior to insertion.
4. Choosing a device:
   a. Avoid implanting a Watchman device if the LAA length is less than the device diameter.
   b. Avoid implanting a Watchman device if the LAA diameter is <17 or >30 mm.
   c. Avoid implanting an ACP if the landing zone diameter is >29 mm (31 for Amulet).
   d. Avoid implanting an ACP if the LAA length is <10 mm (7.5 for Amulet).
   e. If the LAA is too large for either the Watchman or ACP (but the maximal diameter <40 mm), suture occlusion with the Lariat technique could be considered.
   f. Avoid Lariat suture ligation in patients with a superiorly oriented LAA or in LAA's that course behind the pulmonary artery (removal of the Lariat loop may be challenging or impossible). Use of the Lariat is contraindicated in patients with prior heart surgery (due to pericardial adhesions) and may be exceedingly difficult or impossible in patients with pectus excavatum.
5. Confirm adequate position:
   a. The shoulder should not protrude beyond the LAA ostium by >20% of its diameter (<4.2 mm for a 21 mm device, <4.8 mm for a 24 mm device, <5.4 mm for a 27 mm device, <6.6 mm for a 30 mm device, and <6.6 mm for a 33 mm device).
   b. Assure optimal compression (10–20%) by both TOE and fluoroscopy.
   c. Do not accept residual leaks of >3 mm.
   d. Look in all standard TOE views (see above).
ACP
   a. Assure slightly concave disc shape.
   b. Optimal: the lobe should be slightly compressed (tyre-shaped). No compression or deformity suggests a too small size or too proximal position, whereas too much compression with significant alteration of the shape suggests too large size or too distal positioning.
   c. The lobe should not protrude more than one-third beyond the left circumflex coronary artery.
   d. Optimally, the disc and lobe should be separated slightly.
   e. Look in all standard TOE views (0°, 30°, 45°, 90°, and 135° for adequate seal and coverage of all lobes).

ACP, Amplatzer Cardiac Plug; LA, left atrium; LAA, left atrial appendage; TOE, transoesophageal echocardiography.
## Parameters for registries of LAA occluders

- **14 sections with 1 to 13 items**

### Meier B et al.  
*Europace 2014*

### Table 1: Parameters for registries of LAA occluders

<table>
<thead>
<tr>
<th>Section</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic data</td>
<td>Name or registry code, Gender, Age</td>
</tr>
<tr>
<td>Type of device implanted</td>
<td>WATCHMAN, ACP, Other</td>
</tr>
<tr>
<td>Previous failure of LAA occlusion device</td>
<td>(type, date, reason)</td>
</tr>
<tr>
<td>Type of atrial fibrillation</td>
<td>Paroxysmal, Persistent, Long-standing persistent (permanent)</td>
</tr>
<tr>
<td>Cardiovascular history</td>
<td>Ischaemic heart disease, Congestive heart failure, Valvular heart disease, Cardiomyopathy, Arrhythmia, history other than AF</td>
</tr>
<tr>
<td>CHADS2 score</td>
<td></td>
</tr>
<tr>
<td>CHA2DS2-VASc score</td>
<td></td>
</tr>
<tr>
<td>HAS-BLED score</td>
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</tr>
<tr>
<td>Antithrombotic therapy given prior to the implant</td>
<td>ASA, Clopidogrel, Warfarin, Apixaban, Dalteparin, Edoxaban, Prasugrel, Ticagrelor, Low-molecular-weight heparin, Fondaparinux, Other, None</td>
</tr>
<tr>
<td>Indication for implant</td>
<td>Low compliance, History of intracranial bleeding (intracerebral and subdural), History of urinary tract bleeding, History of spontaneous bleeding other than intracranial or urinary tract bleeding (i.e. retroperitoneal haematomas), Recurrent falls, Cognitive impairment, Use of non-steroidal anti-inflammatory drugs, steroids, Personal preference</td>
</tr>
<tr>
<td>Technical data of implant</td>
<td>Success failure, Size of the device implanted, Measure LAA opening, landing zone, and depth, LAA morphology (unilobar, multilobar, ‘cauliflower type’, chicken wing, endocardial, etc.)</td>
</tr>
<tr>
<td>Need for device replacement during the procedure (type and size)</td>
<td></td>
</tr>
<tr>
<td>Procedural complications</td>
<td>Death, Ischaemic stroke, Transient ischaemic attack, Haemorrhagic stroke, Pericardial effusion with tamponade, Valvular complication (i.e. mitral valve damage)</td>
</tr>
<tr>
<td>Device embolization</td>
<td>Bleeding</td>
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<tr>
<td>Major</td>
<td></td>
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<tr>
<td>Minor</td>
<td></td>
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<tr>
<td>Peripheral vascular complication</td>
<td></td>
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<tr>
<td>Pulmonary oedema, Myocardial infarction, Arrhythmia (type)</td>
<td></td>
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<tr>
<td>Pulmonary embolism</td>
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<tr>
<td>Antithrombotic therapy at discharge and length of therapy</td>
<td>ASA, Clopidogrel, Warfarin, Apixaban, Dalteparin, Edoxaban, Prasugrel, Ticagrelor, Low-molecular-weight heparin, Fondaparinux, Other, None</td>
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<tr>
<td>TOE follow-up at 6 weeks, 6 months, and 1 year</td>
<td>Device position (as at implant), Device-related thrombi, Pans-device leak (site), Device embolization</td>
</tr>
<tr>
<td>Clinical follow-up at 6 weeks, 12 months, and yearly thereafter</td>
<td>Death, Ischaemic stroke, Transient ischaemic attack, Haemorrhagic stroke, Device embolization, Major bleed, Minor bleed, Peripheral vascular complication, Pulmonary oedema, Myocardial infarction, Arrhythmia (type), Pulmonary embolism</td>
</tr>
<tr>
<td>Type of antithrombotic therapy</td>
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[www.escardio.org/EHRA](http://www.escardio.org/EHRA)
How to establish a syncope unit: rationale and requirement

• This position paper offers a pragmatic approach to the rationale and requirement for a syncope unit, based on specialist consensus, existing practice, and scientific evidence.

• This document is addressed to physicians and others in administration, who are interested in establishing a syncope unit in their hospital, so that they can meet the standards proposed by ESC-EHRA-HRS.

Kenny RA et al. Europace 2015
### Syncope unit: Quality indicators

#### Quality indicator | Process indicator | Desirable outcome target
--- | --- | ---
1. SU To reduce the rate of unexplained T-LOC | At least 70% of patients receive a definite diagnosis (according to ESC guidelines definitions) | Absolute rate of unexplained T-LOC ≤ 20%
To reduce the rate of hospitalization (in patients at intermediate–high risk from ED) | At least 20% of patients with unexplained syncope after initial ED evaluation have fast-track access to SU for early assessment | < 20% of patients with unexplained T-LOC admitted after ED initial evaluation (according to ESC guidelines definition)
To reduce costs per patient | At least 20% reduction in costs relative to usual local practice | Less than 20% of paced patients have recurrence of syncope at 1 year
To improve the outcome | Less than 5% re-admissions for syncope recurrence in patients with an established and successfully treated diagnosis (according to ESC guidelines definitions) | Less than 20% of paced patients have recurrence of syncope at 1 year

#### Operations
- **Number of patients**: At least 100 new cases per year per SU
- **Tests**: >95% of patients have a documented ECG; >90% of patients have documented orthostatic tests; >90% have carotid sinus massage, tilt table test, external loop recorder and implantable loop recorder performed according to ESC guidelines indications
- **Waiting list (first visit and follow-up)**: 70% of low-risk patients seen within 3 months; 90% of intermediate-risk patients seen within 2 weeks; No waiting list for high-risk patients

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Kenny RA et al. Europace 2015
Cardiac tachyarrhythmias and patient values and preferences for their management

Critical elements of patient-healthcare professional discussions regarding OAC

- Explain link between AF and stroke and why OAC is usually recommended lifelong
- Patient’s individual risk of stroke by CHA$_2$DS$_2$-VASc
- OAC treatment options
- Patient’s risk of bleeding on OAC and risk/benefit profile
- Drug-specific education
- Emphasise importance of medication adherence
- Bleeding side effects and how to manage these
- In patients taking VKA, importance of anticoagulation control (TTR≥70%)

Lane DA et al. Europace 2015

OAC, oral anticoagulation; TTR, time in therapeutic range; VKA, vitamin K antagonist
Cardiac tachyarrhythmias and patient values and preferences for their management

Key topics for initial discussions with AF patients

- Basic anatomy/physiology of AF
- Explanation of possible symptoms; emphasise that asymptomatic AF is common
- Factors increasing risk of AF development; focus on factors related to patient
- Trajectory of AF – what can the patient expect?
- Discuss consequences of AF
- Discuss treatment options (including OAC)
- Treatment education (pharmacological, non-pharmacological, lifestyle)
- Agree an action plan and follow-up care (who and when)

Lane DA et al. Europace 2015
<table>
<thead>
<tr>
<th>NAME</th>
<th>CHAIRS</th>
<th>STATUS / ACTION</th>
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<tbody>
<tr>
<td>EHRA Position Paper on Device Detected Subclinical Atrial Tachyarrhythmias: Definition, Implications and Management</td>
<td>Bulent Gorenek</td>
<td>Ongoing – reviewers to be appointed</td>
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<tr>
<td></td>
<td>Giovanni Luca Botto</td>
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<td>Screening for Atrial Fibrillation: the European Heart Rhythm Association (EHRA) consensus document endorsed by the Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS), and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (SOLAECE)</td>
<td>Georges H. Mairesse Guiseppe Boriani</td>
<td>Ongoing – reviewers to be appointed</td>
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<td>EHRA/Council on Hypertension joint position document on Arrhythmias in Hypertension, endorsed by HRS, APHRS and SOLEACE</td>
<td>Gregory Lip</td>
<td>Ongoing – reviewers to be appointed</td>
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<td>Antonio Coca</td>
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<td>Consensus document on occupational radiation exposure in the electrophysiology laboratory to personnel with childbearing potential and during pregnancy</td>
<td>Andrea Sarkozy</td>
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<td>Tom De Potter</td>
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<td>Antithrombotic therapy in valvular AF</td>
<td>Gregory Lip</td>
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<td>Steen Husted</td>
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<td>Arrhythmias in Grown up Congenital Heart Disease</td>
<td>Juha-Matti Happonen</td>
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<td>Antonio Hernandez Madrid</td>
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Conclusion

• The scientific documents committee of EHRA is highly active, promoting new scientific documents as position statements, many of which are in collaboration with other Associations, Working Groups and scientific societies.

• A comprehensive coverage of arrhythmias is intended, with the aim to provide ‘state of the art’ consensus on current topics, controversial areas, and offer management options.
Best place where to stay when you are not in Palma

Definitions where related to a treatment or procedure

Scientific evidence that a treatment or procedure is beneficial and effective. Requires at least one randomized trial, or is supported by strong observational evidence and authors’ consensus (as indicated by an asterisk).

‘Should do this’

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