European Heart Journal Supplements (2020) **22** (Supplement G), G211–G216
The Heart of the Matter
doi:10.1093/eurheartj/suaa109

ESC
European Society
of Cardiology

ANMCO POSITION PAPER: The management of suspect or confirmed COVID-19 patients needing urgent electrophysiology and/or electrostimulation procedures

Michele Massimo Gulizia[1,2]*, Massimo Zecchin[3], Furio Colivicchi[4], Giuseppina Maura Francese[1], Adriano Murrone[5], Pasquale Caldarola[6], Andrea Di Lenarda[7], Serafina Valente[8], Loris Roncon[9], Enzo Amodeo[10], Nadia Aspromonte[11], Manlio Gianni Cipriani[12], Stefano Domenicucci[13], Massimo Imazio[14], Fortunato Scotto di Uccio[15], Stefano Urbinati[16], and Domenico Gabrielli[17,18]

[1]*Cardiology Department, Ospedale Garibaldi-Nesima, Azienda di Rilievo Nazionale e Alta Specializzazione "Garibaldi", Catania, Italy*
[2]*Fondazione per il Tuo cuore, Firenze – Heart Care Foundation Onlus, Italy*
[3]*Cardiology Department, A.S.U.G.I, Trieste, Italy*
[4]*Clinical and Rehabilitation Cardiology Department, Presidio Ospedaliero San Filippo Neri, ASL Roma 1, Rome, Italy*
[5]*Cardiology-ICU Department, Ospedali di Città di Castello e Gubbio - Gualdo Tadino Azienda USL Umbria 1, Perugia, Perugia*
[6]*Cardiology-ICU Department, Ospedale San Paolo, Bari, Italy*
[7]*Cardiovascular and Sports Medicine Department, A.S.U. Integrata di Trieste, Italy*
[8]*Clinical-Surgical Cardiology and ICU Department, A.O.U. Senese Ospedale Santa Maria alle Scotte, Siena, Italy*
[9]*Cardiology Department, Ospedale Santa Maria della Misericordia, Rovigo, Italy*
[10]*Cardiology-ICU Department, Ospedale Santa Maria degli Ungheresi, Polistena, RC, Italy*
[11]*Heart Failure Unit, Department of Cardiovascular and Thoracic Sciences, Fondazione Policlinico Universitario A. Gemelli IRCCS, Rome, Italy*
[12]*Cardiology 2-Cardiac Failure and Transplantation Unit, Cardiotoracovascular Department "A. De Gasperis", ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy*
[13]*Cardiology Unit, Ospedale Padre A. Micone, Genova, Italy*
[14]*Cardiology Department, Presidio Molinette, A.O.U. Città della Salute e della Scienza in Turin, Italy*
[15]*Cardiology-ICU Department- Cath Lab, Ospedale del Mare, Naples, Italy*
[16]*Cardiology Department, Ospedale Bellaria, AUSL di Bologna, Bologna, Italy*
[17]*Cardiology Department, Ospedale Civile Augusto Murri, Fermo, Italy; and*
[18]*Italian Association of Hospital Cardiologists, Florence, Italy*

KEYWORDS
COVID-19;
Arrhythmic storm;
Urgent electrophysiology;
Electrostimulation procedures

The aim of this document is the management and organization of patients in need of urgent access to electrophysiology (EP) and pacing procedures during the COVID-19 emergency. Specifically, non-deferrable procedures or irreplaceable with a drug therapy prior to the resolution of the COVID-19 virus emergency [pacemaker (PM)

*Corresponding author. Prof Michele M. Gulizia, Chief of Cardiology, Garibaldi-Nesima Hospital, Catania, Italy. Tel: +39 3384856286;
Email: michele.gulizia60@gmail.com; segreteria@periltuocuore.it

implant/replacement/urgent defibrillator (implantable cardioverter-defibrillator, ICD) or arrhythmic storm or other indication of non-deferrable ablation]. The pacing and electrophysiological procedures urgent as they may be, less and less frequently represent situations of emergency, therefore for almost all cases, it is possible to perform a swab test to determine the positivity to COVID-19 of the patient. In cases where this is not possible, due to situations of emergency, the recommendations and procedures we have indicated are advisable, if not mandatory, in order to avoid the spreading of the virus to healthcare personnel and other patients.

The aim of this document is the management and organization of patients in need of urgent access to electrophysiology (EP) and pacing procedures during the COVID-19 emergency. Specifically, non-deferrable procedures or irreplaceable with a drug therapy prior to the resolution of the COVID-19 virus emergency [pacemaker (PM) implant/replacement/urgent defibrillator (implantable cardioverter-defibrillator, ICD) or arrhythmic storm or other indication of non-deferrable ablation].

The arrhythmic storm may concern COVID-19 patients who develop hypo- or hyperkinetic arrhythmias due to the side effects of pharmacological treatment with drugs that could predispone patients to develop severe bradycardia and/or QT prolongation causing sudden cardiac death.

The pacing and electrophysiological procedures urgent as they may be, less and less frequently represent situations of emergency, therefore for almost all cases, it is always possible to perform a nasopharyngeal swab.

The emergency department and/or the referring unit in charge of the patient ascertains the SARS-CoV-2 risk infection through the questions proposed by the COVID-19 pre-triage (*Table 1*). A nasopharyngeal swab is performed, to be processed immediately, to identify the 'confirmed' COVID-19 patients, and by assisting the patient as further described below, allowing in this way, the ordinary management of the negative COVID-19 patients.

Patients in need of urgent pacemaker (PM) implantation should be attended to in a specific area for suspect COVID-19 patients until the swab result has been determined, where they will be subjected to isoprenaline treatment and surveillance with disposable plaques through external transthoracic pacing.

In case of negative swab result, the patient is transferred to a No-COVID Cardiology Unit whereas in case of a positive swab result, is transferred to a COVID Centre provided with an operating room (OR) with adequate equipment and devices for temporary and/or permanent PM implantation.

If the isoprenaline treatment and/or the external transthoracic pacing should not be satisfactory, the patient awaiting the results or with an 'uncertain' result, is urgently transferred to a COVID Cardiology Unit. Should this not be available, the procedure will need to take place in a No-COVID EP lab—in this case, all safety precautions must be taken, both in the lab and along the patient's route. After the procedure, the patient will be transferred to an observation area until the swab result is available.

It is important to note that the variation of the COVID patient pathways is related to the need of a better diagnostic definition (infectious and/or cardiologic) and of a contextual specific preparation of the EP lab (as subsequently indicated).

Concerning the individual protective equipment (IPE) that the Healthcare professionals, involved in Pacing and/or EP lab, must use, depends on one of the following five identified categories of subjects that refer to the hospital:

(1) Patients with absence of suggestive COVID symptoms and no established epidemiological contacts: all the personnel must use the standard protection in accordance with the current protocols which include the use of surgical facemasks, disposable gloves, and isolation gowns;
(2) Patients with suspect COVID-19 symptoms and/or with established epidemiological contacts: the healthcare professionals must be provided with total individual protective equipment (IPE) and FFP2 or FFP3 facemasks in accordance with the current protocols, in case of both intubated or spontaneously breathing non-intubated patients;
(3) Patients with COVID-19 infection in home treatment: the healthcare professionals must be provided with total IPE with FFP3 facemask, in accordance with the current protocols—both in case of intubated or spontaneously breathing non-intubated patients;
(4) COVID-19 hospitalized patients: the healthcare professionals must be provided with total IPE and FFP3 facemasks, in accordance with the current protocols—both in the case of intubated or spontaneously breathing non-intubated patients;
(5) Out-of-hospital resuscitated patients: the healthcare professionals must be provided with total IPE and FFP3 facemasks in accordance with the current

Table 1. Questions provided by the COVID-19 pre-triage

Does the patient have fever or has had fever?
Does the patient have a cough?
Is the patient experiencing changes in taste or sense of smell?
Has the patient been in close contact with suspect or confirmed SARS-CoV-2 infection cases?
Has the patient still been diagnosed with SARS-CoV-2 infection?

protocols—both in the case of intubated patients or spontaneously breathing non-intubated patients.

Negative swab patients who have not been hospitalized in a Cardiology Unit, in accordance with the protocols defined by the single hospital guidelines, may be directly transferred to the EP-lab for the procedure and then returned to the referring unit.

The Cardiologist shall evaluate the possibility of admitting the patient to a Cardiology Unit prior to and/or after the procedure, but only if considered essential.

Positive COVID-19 patients, regardless of the referring unit, will be hospitalized after the procedure in a COVID-19 area, based on the necessary clinical level of intensity of care.

Recommendations

Procedures

- It is advisable to privilege cephalic venous access to reduce the pneumothorax risk when inserting permanent electrodes. In the case of subclavian venous access, perform a fluoroscopic control of the pleural at the end of the procedure. Avoid non-essential post-implantation diagnostic exams (i.e. chest X-ray, if not in the presence of clinical pneumothorax signs), which however must be performed in an adequately protected environment or at the patient's bedside with portable devices in accordance with the hospital guidelines and with the patient's clinical issues.
- The placing of a temporary PM should be avoided when possible, preferring pharmacological management, external transthoracic pacing in sedated patients, and implantation of a permanent device in case of little chance of a spontaneous prompt rhythm recovery. Balloon electrodes should be preferred, in case of temporary transvenous stimulation, as they do not necessitate the use of a fluoroscopy-guided procedure and can be positioned at the patient's bedside. Any eventual placing or removal of electrodes for temporary pacing in the EP-lab will be performed using the same protocol proposed for the other electrophysiological procedures.
- It is preferable to use intradermal sutures with completely absorbable stitches to reduce the number of post-operative wound check-ups. The removal of the sutures or the metallic stitches (when used), for COVID-19 patients, will take place not before 15 days after the reception of a negative swab result.
- For the same reason, as few post-implant check-ups as possible will be scheduled in the hospital for the entire duration of the coronavirus pandemic.
- The procedures for suspect or confirmed COVID-19 patients will be performed in a dedicated OR or EP-lab, where all the necessary equipment will have been positioned and preventively emptied of non-essential equipment to ensure the safe execution of the pacing/electrophysiological procedures.
- The presence of an observer, during the donning/removal of IPE, is advisable to ensure the correct protocol procedure, and to avoid any possible contamination through visual monitoring. To this end, it is appropriate to encourage a team briefing, with all the personnel involved, in order to reduce as much as possible the number of any peri-procedural mistakes during the removal/decontamination operations.

Setting up the OR for positive and/or suspect COVID-19 patients

Equipment to be located inside the OR

- All the unnecessary supply trolleys and electromedical instruments must be removed
- The equipment***** that will, or may be used, during the procedure is to be left in the OR/EP-lab: pacing analyzer, bovie electrosurgery, an external defibrillator for pacing procedures, radiofrequency-ablator, mapping system, external defibrillator, echocardiography, and eventually device programmers.
- The following should also be present***** in the OR: the first aid trolley, the medication trolley and the trolley for exclusive COVID-19 emergency anaesthesiological use.
- The equipment (leads, introducers, surgical supplies, etc.) for each procedure shall be prepared beforehand and nothing must be brought into the OR/EP-lab during the procedure.
- The personnel (technicians, doctors/nurses) not strictly involved in the procedure will remain outside the OR/EP-lab (in the control room if available and possibly connected via interphone).
- The programming of the device (still in the package) must be carried out before the implantation. In the case of a patient with an implanted device, the interrogation/reprogramming must be performed in the OR/EP-lab by placing the head of the programmer (adequately isolated) on the patient for as little time as possible (using wireless programming if available).
- At least four containers for the disposal of special waste (yellow bag) must be available, where all the waste will be kept except for the personnel's disposable garments.

N.B. All the aforementioned OR and electromedical equipment marked with ***** will be covered with a transparent film or disposable nylon to be removed after the disrobing of the personnel at the end of the intervention—for each intervention.

Equipment to be placed outside the OR

- At least two containers for the disposal of contaminated waste (yellow bag).
- At least one container for any uniforms to be sterilized.
- Uniforms, disposable overshoes, and adequately IPE.

How to prepare the OR for the procedure

- Switch on power in the OR
- Check off the OR equipment checklist

- IPE integrity check
- Activate the OR-control room interphone
- Prepare the required equipment for the implantation
- Prepare multiple pairs of sterile gloves (size + size and a half) for the personnel involved.
- Predispose sterile table and containers with surgical set kits.

Donning individual protective equipment (prior to the arrival of the patient)

Refer to the provided hospital procedures.

Removing IPE (after the patient has left the OR)

Refer to the provided hospital procedures.

Support team (consider only the minimum number)

- IPE donning same as the personnel
- Place the patient on the operating table with the help of the nurse (complete IPE except for the sterile isolation gown)
- Before the procedure and in case of contact replace the external glove before touching any object on the shelves or in the drawers
- Does not perform or transport blood samples [which will be processed in the Cardiac Care Unit (CCU)]
- Must limit contact with the surfaces in the OR.

Anaesthetiological team

The anaesthesiologist provides the support based on the requested procedures and/or the clinical conditions and must be provided with the related IPE which will be disposed of in the OR at the end of the procedure and only after the patient's exit.

Electromedical Company Specialists

Notwithstanding the aforementioned recommendations advising to minimize the presence of members of the operating equipment in the OR/EP-lab, the certified specialist of the referring electromedical company of the device to be implanted or of the ablation system to be used, can be authorized to observe the procedure in accordance with the hospital rules of the individual centre. The specialist must undergo the same COVID-19 pre-triage and body temperature measurement when entering the hospital, self-certify to not being under quarantine or having been in contact with positive COVID-19 subjects. The specialist, however, must always remain in the control room, or in the antechamber, and under no circumstances enter in contact with the patient.

Furthermore, should the OR/EP-lab be equipped with an adequate web connection, the interaction could take place remotely using digital displays or tablets.

The patient

- Must always wear a surgical facemask, even over the oxygen dispensing device (face mask/safety goggles).
- Provides a verbal informed consent or dissent to the procedure, for the state of need, in the presence of the doctor and the nurse. The doctor will indicate the consent in the patient's medical record, undersigned by the nurse as witness of the correct consent or dissent.

End of procedure

- At the end of the procedure, the OR/EP-lab Nurse and/or the Nursing Coordinator alerts the sanitization staff (OR + route).
- The OR/EP-lab door must be kept closed for 1 h before proceeding with the sanitization.
- In the OR/EP-lab, all the reusable medical equipment on the operating table and on the trolley (lead aprons, safety goggles, and face shields) must be sanitized.
- All the medical supplies on the trolley must be disposed of in accordance with the hospital procedure.
- The re-preparation of the OR/EP-lab must take place as soon as possible, by checking off the dedicated checklist.

Check-ups for PM/defibrillator paced out-hospital patients

The same rule applies to carriers of implantable devices (PM, ICD, and loop recorder) concerning the possibility of deferring outpatient check-ups to reduce the number of unnecessary contacts in order to avoid the spreading of the virus among the general population.

The mutual agreement among the major National and International Scientific Societies is to privilege remote control devices and to assist the distribution of 'delivery/transmitters' even for those patients who are not equipped with remote control devices.

In fact, many electromedical companies are having control of remote devices delivered to the homes of the patients who are requesting them.

Patients not equipped with telemonitoring devices are instead to be divided into three distinct categories: low-risk, intermediate-risk, and high-risk subjects.

Patients with an adequate battery longevity, not-pacemaker dependent, and ICD paced for primary prevention, with no symptoms of heart failure or complex arrhythmias, are included among the *low-risk* patients.

Intermediate-risk patients (i.e. not-pacemaker dependent patients, close to the discharge period of the generator) and/or ICD paced patients, pauci-symptomatic for arrhythmias, must be followed with an individual approach and a careful evaluation of the risk/benefit ratio.

The *high-risk* group includes, non-exhaustively and in any case based on the patient cardiologist's judgement:

- Dependent pacemaker patients close to the discharge of the battery of the generator
- ICD patients who have recently suffered from syncope or have been subject to electric-shock treatment
- Patients whose ICD emits audible alerts
- Patients with a suspect malfunction of the device
- Patients with a suspect or confirmed device infection

Table 2. Risk factors that predispose to medication arrhythmias

Female gender	Hypokalemia	Frequent cardiac extrasystolia
Age >65	Hypomagnesaemia	Atrial fibrillation
Uncontrolled diabetes	Hypercalcaemia	Basal QT-interval prolongation
Recurrent diarrhea	Cerebral oedema	Long QT-syndrome
Malabsorption	Cerebral haemorrhage	J-wave pattern
Malnutrition	Heart failure and diuretics	Basal bradyarrhythmia
Decompensated cirrhosis	Structural cardiopathy	Hypothermia
Severe chronic renal impairment	Active ischaemic heart disease	Drugs lengthening QT-interval

Table 3. Potentially deferrable main tests and procedures

Clinical area	Potentially deferrable main tests and procedures (in- and out-of-hospital patients)
Pacing and Electrophysiology	
	Election control of PM/ICD (in presence) in the absence of new cardiovascular symptoms
	ECV in stable asymptomatic patients
	Electrophysiological test in stable patients
	Tilting test
	ILR implant in the absence of cryptogenic stroke
	PM implant due to sinus node dysfunction or non-advanced II grade AV Block, without syncope
	Primary prevention ICD implant in low-risk stable patients (limited to outpatients); evaluate the possibility of temporary protection through wearable defibrillator
	CRT upgrade in stable patients
	Closure/occlusion of the left atrial appendage with mechanical device
	Atrial Fibrillation and/or flutter ablation in stable patients
	Supraventricular tachycardia ablation in stable patients
	Ventricular extrasystolia ablation in stable patients
	Extraction/removal of leads/device non associated with infection and/or a pacing system malfunction

AV block, atrio ventricular block; CRT, cardiac resynchronization therapy; ECV, electrical cardioversion; ICD, implantable cardioverter-defibrillator; ILR, implantable loop recorder; PM, pacemaker.

- Carriers of devices in proximity of the warranty expiration declared by the manufacturer.

This group of patients should be traditionally evaluated by following the current protocols and the aforementioned recommendations for negative, suspect, or positive COVID swab patients.

Cardiac arrhythmias and COVID-19

Cardiac arrhythmias are common events in COVID-19 patients. Some drug combinations used for the advanced treatment of these patients [hydroxychloroquine + azithromycin + lopinavir (or ritonavir)] may determine pathological QTc prolongation (correct QT) and determine severe Brady- and tachyrrhythmias that require a close electrocardiographic monitoring, better if telemetric (where possible).

Some risk factors predispose patients to medication arrhythmias; in *Table 2* are listed some of the main ones involved.

In consideration of this, an exceeding QTc interval >550 ms must guide the physician to reconsider the administered combination of the associated anti-COVID therapy, to avoid the onset of malignant ventricular arrhythmias.

Test and potentially deferrable procedures

Table 3 lists the main tests and potential deferrable procedures during the COVID pandemic emergency. However, the choice to defer procedures and/or electrophysiological/pacing/clinical arrhythmological tests must always be performed after a thorough evaluation of the patient's clinical information and only after a careful assessment of the risk/benefit ratio between the diagnostic-therapeutic objective to be achieved and the danger of spreading the COVID-19 virus—both for the patient and healthcare team.

Data availability

The data that support the findings of this study are available from the corresponding author, MMG upon reasonable request.

Disclaimers

This Position Paper was originally published in the Italian language in "Giornale Italiano di Cardiologia", official journal of Italian Federation of Cardiology (IFC), published by Il Pensiero Scientifico Editore [Gulizia MM et al. G Ital Cardiol 2020;21:336–340]. Translated by a representative of the Italian Association of Hospital Cardiologists (ANMCO) and reprinted by permission of IFC and Il Pensiero Scientifico Editore.

Conflict of interest: none declared.

References

- American College of Cardiology. General guidance on deferring non-urgent CV testing and procedures during the COVID-19 pandemic. 2020. https://www.acc.org/latest-in-car-diology/articles/2020/03/24/09/42/general-guidance-on-deferring-non-urgent-cv-testing-and-procedures-during-the-COVID-19-pandemic **(6 April 2020)**.
- Associazione Italiana di Aritmologia e Cardiostimolazione (AIAC). Procedure di elettrofisiologia ed elettrostimolazione in epoca COVID-19: le raccomandazioni AIAC. 2020. https://aiac.it/aggiornamento/notizie-e-commenti/co-municazioni/procedure-di-elettrofisiolo-gia-ed-elettrostimolazione-in-epoca-co-vid-19-le-raccomandazioni-aiac **(6 April 2020)**.
- Ayebare RR, Flick R, Okware S, Bodo B, Lamorde M. Adoption of COVID-19 triage strategies for low-income settings. *Lancet Respir Med* 2020;**8**:e22.
- Canadian Heart Rhythm Society. COVID-19 and cardiac device patients. 2020. http://www.ccs.ca/images/Images_2020/CHRS_COVID-19_Update_EN.pdf **(6 April 2020)**.
- Grasselli G, Pesenti A, Cecconi M. Critical care utilization for the COVID-19 outbreak in Lombardy, Italy: early experience and forecast during an emergency response. *JAMA* 2020;**323**:1545.
- Istituto Superiore di Sanità. Indicazioni ad interim per l'effettuazione dell'isolamento e dell'assisenza sanitaria domiciliare nell'attuale contesto COVID-19. Rapporto ISS COVID-19, n. 1/2020. https://www.iss. it/documents/20126/0/Rapporto+ISS+-COVID-19+1_2020+ISOLAMENTO +DOMICILIARE.pdf/47e9ffab-61ba-78 fb-bab7-cc600d660ee7? t=1583831 542224 (6 April 2020).
- Lakkireddy DR, Chung MK, Gopina-Thannair R, Patton KK, Gluckman TJ, Turagam M, Cheung J, Patel P, Sotomonte J, Lampert R, Han JK, Rajagopalan B, Eckhardt L, Joglar J, Sandau K, Olshansky B, Wan E, Noseworthy PA, Leal M, Kaufman E, Gutierrez A, Marine JM, Wang PJ, Russo AM.. Guidance for cardiac electrophysiology during the corona-virus (COVID-19) pandemic from the Heart Rhythm Society COVID-19 Task Force; Electrophysiology Section of the American College of Cardiology; and the Electrocardiography and Arrhythmias Committee of the Council on Clinical Cardiology, American Heart Association. *Circulation* 2020; doi: 10.1161/CIRCULATIONAHA.120.047063.
- Scotto di Uccio F, Valente S, Colivic-Chi F, Murrone A, Caldarola P, Lenarda AD, Roncon L, Amodeo E, Aspromonte N, Cipriani MG, Domenicucci S, Francese GM, Imazio M, Urbinati S, Gulizia MM, Gabrielli D.. Position paper ANMCO: organizzazione della Rete per il trattamento dei pazienti con sindrome coronarica acuta durante emergenza pandemica COVID-19. *G Ital Cardiol* 2020;**21**:332–335.
- Società Italiana di Cardiologia Interventistica (GISE). Gestione emergenza COVID-19 nei reparti di terapia intensiva cardiologica, P.O. Emodinamica e Cardiologia Interventistica, cardiolo-gia degenze e cardiologia ambulatori. https://gise.it/Uploads/EasyCms/Protocollo%20COVID%2019_54321.pdf **(6 April 2020)**.
- Società Italiana di Cardiologia Interventistica (GISE). Gestione sale di emo-dinamica e cardiologia interventistica per emergenza COVID-19. https://gise.it/Uploads/EasyCms/GM%20 CF%20per%20PD%20gestione%20 COVID-19%20_14892.pdf (6 April 2020).
- World Health Organization. Advice on the use of masks in the community, during home care and in healthcare settings in the context of the novel coronavirus (COVID-19) outbreak. 2020. https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-corona-virus-(2019-ncov)-outbreak (6 April 2020).
- World Health Organization. Clinical management of severe acute respiratory infection when COVID-19 is suspected. Interim guidance. 2020. https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-in-fection-when-novel-coronavirus-(n-cov)-infection-is-suspected (6 April 2020).
- World Health Organization. Corona-virus disease (COVID-19) outbreak: rights, roles and responsibilities of health workers, including key considerations for occupational safety and health. https://www.who.int/docs/default-source/coronaviruse/who-rights-roles-respon-hw-COVID-19.pd-f? sfvrsn=bcabd401_0 (6 April 2020).