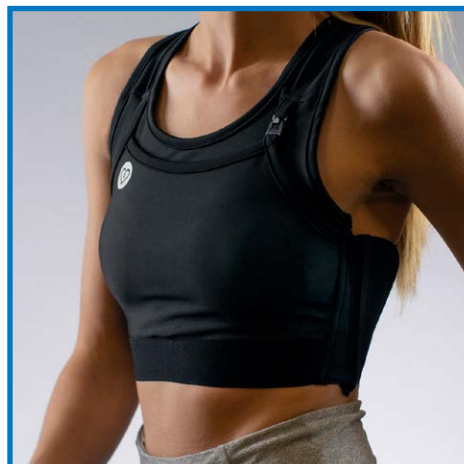


IMPROVING WOMEN'S CARDIOVASCULAR QUALITY OF CARE WITH **CARDIOBRA AND CLARAVUE®**

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ABSTRACT

Advancement in twenty-first century cardiac care for women must prioritize patient experience through innovation and personalization to achieve best practice for accuracy, comfort, safety, and inclusivity. Heart disease remains the number one cause of death in American women: Combatting female Cardiovascular Disease (CVD) requires focused care delivery models designed to meet women's needs with sensitivity to age, weight, ethnicity, religion, cultural background, and socio-economic status. The coordinated use of CLARAVUE (a hygienic, disposable line of electrodes and cables) with CardioBra (a garment designed for comfort, accurate ECG lead placement, and cardiovascular imaging) supports high quality cardiovascular services for all women. CLARAVUE fosters and improves the quality of relevant cardiovascular services through improved scans and traces, superior ergonomics, and enhanced patient comfort in a hygienic, disposable line of electrodes and cables. CLARAVUE's clear view for exemplary patient monitoring features full radiolucency and minimal noise artifact, due to lightweight, direct connect carbon lead wires and ECG sensors. Developed by a female cardiologist for clinical practice in a Women's Heart Center, CardioBra compresses and elevates the breast to improve the accuracy of ECG lead placement and reduce motion artifact. CardioBra increases women's ability to comfortably (and modestly) exercise to full capacity without noise artifact caused by sweat and lead or electrode shifting.

GLOSSARY OF KEY WORDS & PHRASES

Accuracy	Improved Comfort
Accurate Lead Placement	Ischemic Heart Disease
Breast Compression	Minimize Artifact
Breast Elevation	Modesty Dressing Myocardial Profusion Imaging
Breast Motion	Precordial ECG Leads
Breast Support	Radiolucent Nuclear Imaging
Cardiac Testing	Running Bra
Cardiovascular Disease (CVD)	Sonography/Sonographer
Culturally Sensitive Care	Stress Test
Echocardiographic Imaging	Value-Based Care
Exercise Echo	Women's Heart Centers
False Readings	

OVERVIEW

STRESS (EXERCISE ECG) TEST

For patients, the American Heart Association (AHA) explains the purpose of a stress test (also called an exercise test or treadmill test) as a diagnostic tool to “find out how well the heart handles work.”¹ For clinicians, the AHA defines the stress test, (a longstanding staple of cardiac clinical practice which significantly contributes to patient management), as “the continuous monitoring of an ECG (generally a 3-lead or a 12-lead system) with frequent recordings of 12-lead tracings,” including “frequent blood pressure determinations before, during, and after exercise of progressively increasing intensity (usually with a treadmill or cycle ergometer) to any of a number of test end points.”² Exercise stress testing in cardiac care assists in diagnosing coronary artery disease, identifying heart-related causes of symptoms such as chest pain, shortness of breath or lightheadedness, and determining a safe levels of exercise.

EXERCISE VERSUS CHEMICAL STRESS TEST

A stress test examines the heart muscle’s ability to receive sufficient blood during increased heart rate and workload. An exercise cardiac stress test requires walking on a treadmill or riding a stationary bike to examine the heart during a period of rest as compared to a period of increased activity. Routine **exercise stress tests** include the following procedures:

- Clinician places several electrodes on a patient’s arms, legs, and chest. (Note: excess hair removed first with shaving).
- Electrodes connect by wires to an electrocardiogram (EKG) machine, which records the heart’s electrical activity.
- Patient walks on a treadmill or rides a stationary bicycle, starting slowly.
- Walking or pedaling faster, with increasing incline and/or resistance, the patient exercises up to a physician-determined, target heart rate
- The test will conclude before patient reaches the target heart rate in the event of chest pain, shortness of breath, dizziness, fatigue, or an EKG showing heart problems
- After the test, monitoring continues for 10–15 minutes or until patient heart rate returns to normal.³ With exercise stress tests combined with imaging, imaging is acquired immediately after exercise stress to determine if the patient has changes in the contractility of the heart (exercise stress echocardiogram) or blood flow in the heart (exercise stress myocardial perfusion study).

For patients, with chronic back pain, arthritis, or stroke, an exercise stress test may prove infeasible. In such cases, physicians will order a **chemical stress test** which uses intravenously- injected chemical agents to make the heart function as if under stress. Chemical stress agents work by increasing blood flow in the arteries of the heart either by increasing heart rate or by dilating the heart arteries.

The Duke Activity Status Index (DASI), a 12-item self-reported questionnaire about usual physical activities, assists clinicians in screening for patients better suited to pharmacological stress versus exercise stress testing.⁴

¹American Heart Association (2020). *Exercise Stress Test*. <https://www.heart.org/en/health-topics/heart-attack/diagnosing-a-heart-attack/exercise-stress-test>.

² Rodgers, George, et. al. (2000). American College of Cardiology/American Heart Association Clinical Competence Statement on Stress Testing. *Circulation*,102:1726–1738.

³US National Library of Medicine (2020). Stress Tests. Medline Plus, <https://medlineplus.gov/lab-tests/stress-tests/>.

⁴Wijeyesundera, D. & Beattie, W. (2020). Integration of the Duke Activity Status Index into preoperative risk evaluation: a multicenter prospective cohort study. *British Journal of Anaesthesia*, 124,(3

Adverse side effects of chemical stress testing can include cardiac arrest, MI, loss of consciousness, respiratory arrest, electrocardiogram ST segment depression, pulmonary edema, and ventricular fibrillation, dyspnea, and ventricular tachycardia.⁵

EXERCISE STRESS ELECTROCARDIOGRAM TEST PREFERRED FOR WOMEN

The American Heart Association, the American College of Cardiology, and the American Society of Nuclear Cardiology recommend the physical ECG as the initial stress test of choice in patients who can exercise, including women.

Exercise stress testing proves the most commonly used method of diagnosing ischemic heart disease (IHD) in women and the initial noninvasive study of choice. According to the American College of Cardiology/American Heart Association guidelines, non-imaging treadmill exercise stress testing provides an appropriate first line testing of symptomatic women who are deemed intermediate risk for IHD, have a normal resting 12-lead ECG, and are capable of maximal exercise.⁶ The AHA, the ACC, and the American Society of Nuclear Cardiology recommend the standard exercise stress test for most patients who can exercise, including women.

In women, exercise capacity, percentage of age-predicted exercise capacity, chronotropic response, heart rate reserve, blood pressure response, and the Duke Treadmill score can all enhance the diagnostic and prognostic value of exercise ECG.

Until recently, underrepresentation of women, as well as a bias in selection of women when included, led to misconceptions regarding the value of exercise stress testing in women. In the past decade, research on exercise stress testing in women has increased, improving clinical understanding of the diagnostic and prognostic value of physical exercise stress testing in women.

Given the strong diagnostic and prognostic information determined with exercise variables, any woman able to exercise should preferentially undergo exercise stress testing over pharmacological testing.⁷ For a female patient with an abnormal resting ECG, clinicians recommend imaging with exercise stress testing. Imaging can be combined with echocardiograms or nuclear stress testing.

⁵ US Food & Drug Administration (2016). FDA warns of rare but serious risk of heart attack and death with cardiac nuclear stress test drugs Lexiscan (regadenoson) and Adenoscan (adenosine). <https://www.fda.gov/drugs/drug-safety-and-availability>

⁶ Vavas, E., Hong, S. N., Henry, S., Rosen, S. E., & Mieres, J. H. (2012). Imaging Tests, Provocative Tests, Including Exercise Testing in Women with Suspected Coronary Artery Disease. *Current cardiovascular risk reports*, 6(5), 469–478. <https://doi.org/10.1007/s12170-012-0251-3>.

⁷ Kohli, P. & Guhlali, M. (2010) Exercise Stress Testing in Women. *Circulation*, 122 (24): 2570–2580.

THE PROBLEM

The Center for Disease Control and Prevention (CDC) reports “heart disease is the leading cause of death for women in the United States, killing 299,578 women in 2017—or about 1 in every 5 female deaths,” warning that “despite increases in awareness over the past decades, only about half (56%) of women recognize that heart disease is their number 1 killer.”⁸

Despite gains in awareness of heart disease in women, significant gaps persist in sex-specific research. Currently, the NIH and Food and Drug Administration recommend the inclusion of minorities, elderly women, and pregnant women in clinical trials.⁹ Advancements in the care of CVD in women require sex-and gender-specific clinical training and cultural and diversity training. Medical education programs and journal publications should stress the importance of increased sex- and gender-specific studies on CVD in women to enhance knowledge and quality of care.

Radiation-free, portable, cost-effective, and diagnostically accurate, exercise stress echocardiography provides a highly recommended, preferred, and safe test for premenopausal women with chest pain and heart irregularities. **However, exercise stress testing performed without breast covering and support causes substantial embarrassment and discomfort in female patients.** Traditional exercise stress testing fails to address the need for sensitivity to sex, gender, and cultural differences in CVD care. Specifically, clinicians who administer exercise stress testing in female patients encounter the following impediments to quality care:

PATIENT DISCOMFORT

- Women (especially with hormone-related breast sensitivity or undergoing breast cancer chemotherapies) experience exercise-induced breast pain
- Major discomfort (emotional and physical) as 96% of women report wearing breast support during regular exercise from the time of adolescence¹⁰
- Back and chest pain due to lack of support (which worsens with increased breast size)
- Excessive breast movement during exercise

ACCURACY

- Breast motion causes ECG artifact
- Can limit ability to exercise at full capacity due to discomfort or embarrassment

MODESTY/PRIVACY

- Modesty issues – some women refuse bare-chested testing
- Testing involves stripping to the waist and wearing a paper or thin cloth gown. However, in the case of a stress exercise test, patients must rigorously move with the gown opening at the front to allow for attachment of multiple EKG leads to a bare chest and torso.
- Cultural and religious preferences (see Quality of Care for Patients of Muslim Faith)

⁸ Centers for Disease Control and Prevention (2020). Women and Heart Disease. <https://www.cdc.gov/heartdisease/women.htm>.

⁹ Lundberg, G. & Mehta, L. (2018). Heart Centers for Women: Historical Perspective on Formation and Future Strategies to Reduce Cardiovascular Disease. *Circulation*, 138(11): 1155–1165.

¹⁰ Schurr, J. & Brown, N. (2016). The Influence of the Breast on Sport and Exercise Participation in School Girls in the United Kingdom. *Journal of Adolescent Health*. 58:167-173.

QUALITY OF CARE FOR PATIENTS OF MUSLIM FAITH

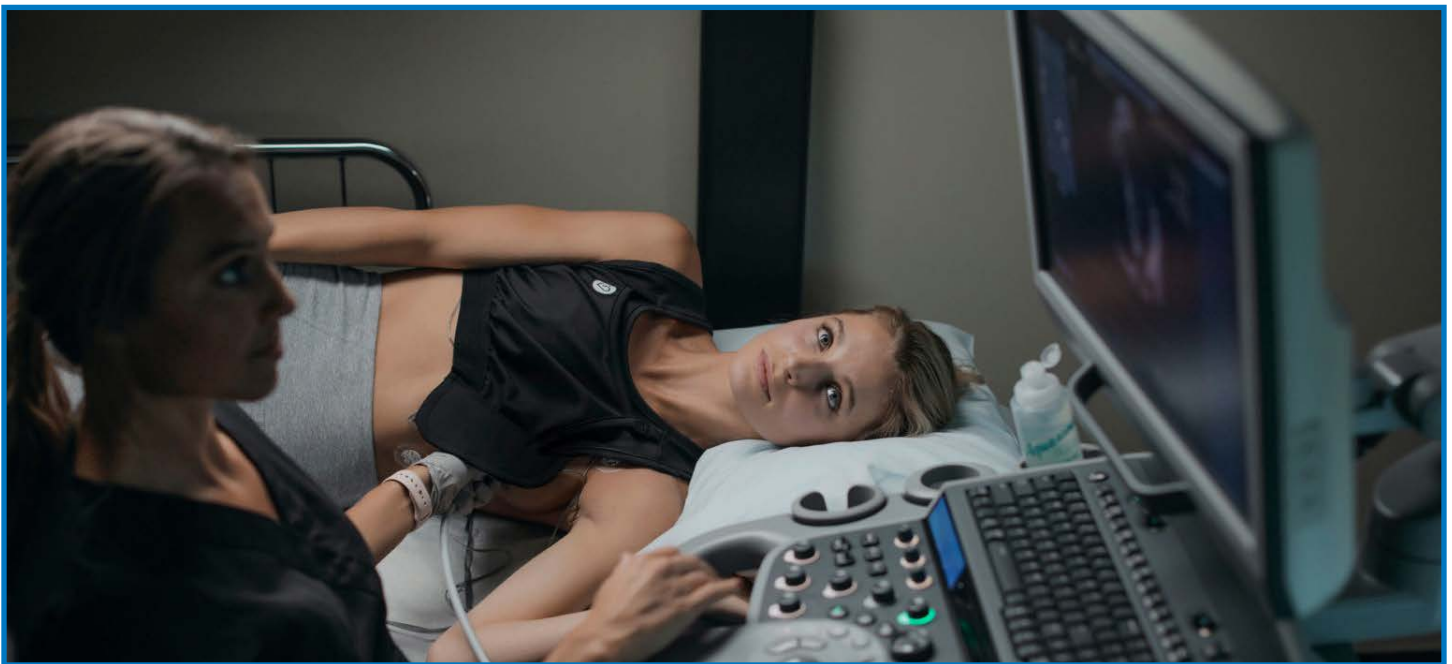
Globally, Islam remains the fastest-growing religion in the world. The number of Muslims in the United States is estimated at 6 million (47% women) and growing. The increasing Muslim population makes it relevant and timely to understand and address barriers to quality care for patients.^{11,12} The Joint Commission, an independent, nonprofit organization, holds hospitals accountable for addressing and maintaining patient rights, including policy, research, patient advocacy, and cultural competence. Healthcare professionals must deliver appropriate health care in a culturally sensitive manner.

For Muslim women, factors which delay the seeking of healthcare include religion-related motivations such as a preference for female clinicians and concerns about preserving modesty.¹³ High-quality care for female patients of the Muslim faith requires a clinician's understanding of differences in ideas of modesty, privacy, dress, and touch restriction.¹⁴

Typically, male technicians may administer or remain present for tests. Ideally, Muslim CVD patients receive care by clinicians of the same gender. If gender-specific care is impossible, a female staff member or patient relative should remain present during examinations.

Most stress tests – performed without a bra in place – disregard Muslim patients' concerns for privacy and modesty. Doctors prioritize efficacy with (1) rapid access to the chest wall during and after the test for imaging and (2) reduced artifact due to clothing movement and electrode shifting.

Ideally, the clinical staff should explain the steps of the physical exam to the female patient, including the need for removal of clothing. If required, clothing removal must occur for as little time as possible.¹⁵



¹¹Attum B & Hafiz S. Cultural Competence in the Care of Muslim Patients and Their Families. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; June 28, 2020.

¹²Memoona H. & Connell K. (2011). Patient-Centered Care for Muslim Women: Provider and Patient Perspectives. *Journal of Women's Health*, 20 (1): 73-83.

¹³Milkie Vu, A. & Radejko T., (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health*. 26(6): 586-593.

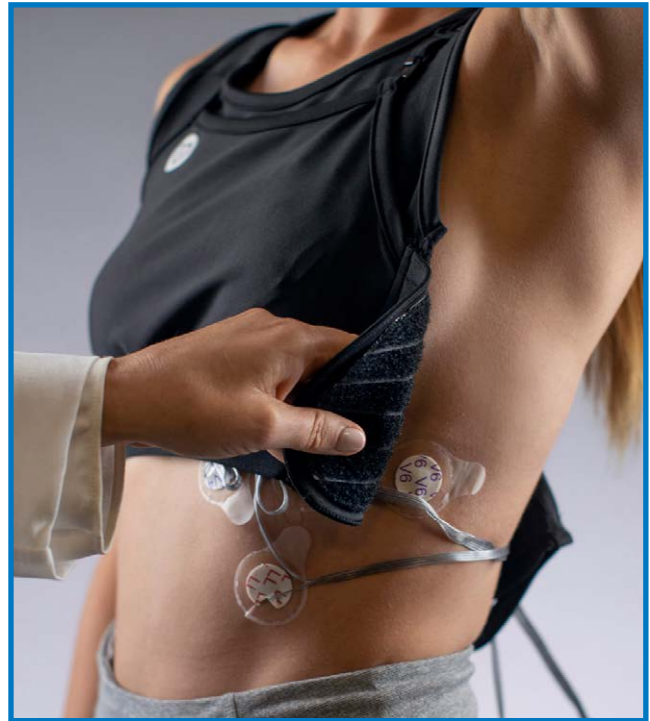
¹⁴Attum B & Hafiz S. Cultural Competence in the Care of Muslim Patients and Their Families. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; June 28, 2020.

¹⁵Blankinship LA. (2018). Providing Culturally Sensitive Care for Islamic Patients and Families. *Journal of Christian Nursing*. 35(2):94-99.

THE SOLUTION: CARDIOBRA (WITH INTEGRATION OF CLARAVUE ELECTRODES)

CARDIOBRA

Dr. Ashley Simmons, a clinical cardiologist and the medical director of The University of Kansas Hospital's Adelaide C. Ward Women's Heart Health Center, founded the CardioBra after identifying a need for better stress testing in women. Patients complained about exercising without a bra in place; sonographers confirmed that women were embarrassed and uncomfortable when told to undress and exercise with a flimsy hospital gown for coverage (frequently with male clinicians).



CardioBra uses elevation and compression for breast support. The electrodes' unique integration with the bra reinforces electrode adherence and promotes ECG lead placement under the breast with added support. CLARAVUE'S low-profile design with the elimination of pinch clips allows for a comfortable fit.

Developed by a female physician and director of a Heart Center for Women (HCW), the CardioBra offers an inclusive approach to CVD care. The CardioBra allows for a clinical practice inclusive of cultural and social issues, culturally tailored health beliefs, and health equity. By customizing healthcare services to a woman's specific exercise stress testing needs, clinicians improve positive health outcomes in diverse populations. Created by a woman for women, the CardioBra provides a technological innovation in CVD care models for female patients.

Wearing the CardioBra, a female patient performs the same exercise protocol; however, with reduced breast motion and increased comfort, the patient can exercise longer and more intensely with a reduction in ECG lead artifact. CLARAVUE's innovatively designed, prewired electrodes provide superior imaging to traditional reusable lead wires and electrodes; specifically, the lightweight, low impedance carbon lead wires, low profile, direct ECG sensor lead wire connection of CLARAVUE improves ECG trace clarity.

Exercise capacity, also known as functional capacity or cardiorespiratory fitness, provides one of the most important

diagnostic and prognostic markers assessed through exercise stress testing. If exercise induced ECG changes cannot be clearly identified, due to substantial artifact and baseline instability, the validity of the procedure is negatively impacted. CLARAVUE demonstrated in "The Spaghetti Study" less signal noise, reduced baseline instability, significantly more recordings were artifact free using prewired electrodes.

CardioBra's sensitive and innovative design features allow for best practice in exercise stress testing of female patients:

LIMITED BREAST MOVEMENT

CardioBra's supportive design adds breast compression and elevation, improving patient comfort while minimizing motion during exercise.

INCREASED EXERCISE CAPACITY

Exercise capacity, also known as functional capacity or cardiorespiratory fitness, provides one of the most important diagnostic and prognostic markers assessed through exercise stress testing.

ACCURATE ECG LEAD PLACEMENT

CardioBra's design supports accurate placement of ECG leads, in combination with CLARAVUE'S unique labeled leads avoiding incorrect placement (low on abdomen) of precordial ECG leads causes false readings.

REDUCED ARTIFACT

CardioBra eliminates artifact noise due to breast movement and shifting electrodes.

ENHANCED LEAD ADHERENCE

CardioBra provides ECG reinforcement and discourages electrode shifting during exercise.

SUPPORT OF RAPID IMAGING

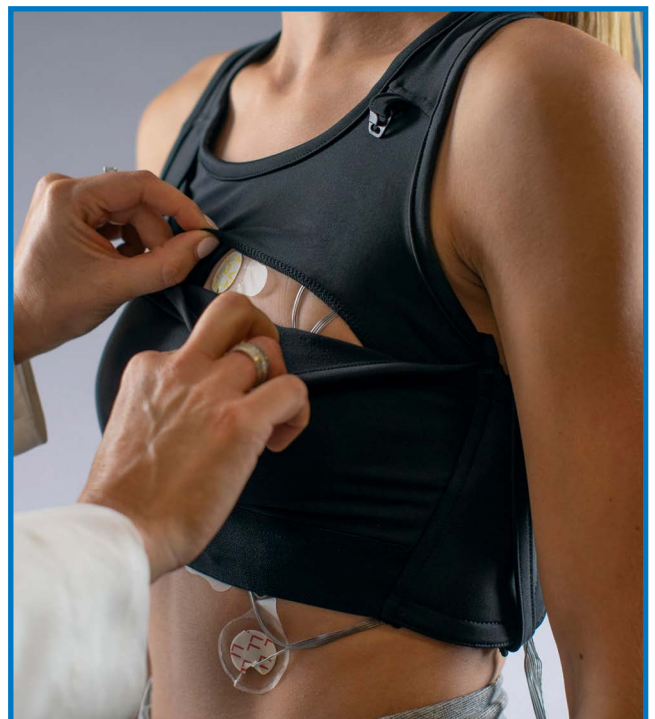
Velcro-latch in CardioBra design provides easy and rapid access to chest wall at the end of exercise stress to allow echocardiographic image acquisition.

RADIOLUCENCY

CardioBra's radiolucent design minimizes artifact in myocardial perfusion imaging.

COMFORTABLE AND MODEST DESIGN

CardioBra improves female cardiac patient experience in exercise stress testing, exposing only the area of the chest wall needed for image acquisition.



CLARAVUE

The CLARAVUE system combines pre-wired, single use, radiolucent ECG electrodes with patented, unique Bioactive trunk cables from Nissha Medical Technologies, SAS – consolidating lead wire sets into two combined connections with the ability to connect with any ECG monitor. Traditional, reusable lead wires can cause ECG artifact, mask abnormal ECG changes, and cause a stoppage of the test to be resolved.

Typically, a complicated array of cables and lead wires placed around the patient during cardiac diagnostic, catheterization and emergency procedures impedes speed and accuracy in care; with CLARAVUE's innovative design proper attachment of electrodes and reduction in tangling of the lead wires contribute to shorter preparation times for testing and surgery, better patient experience, and alleviation of stress in clinical staff. Lead wire management poses a cumbersome task to clinicians; CLARAVUE alleviates the time-consuming duty.

First and foremost, the Cath Lab care-delivery team must consider "factors essential in selecting the ideal electrode configuration for patient monitoring."¹⁶ Most significantly, highest quality electrocardiogram analysis requires the following considerations in selecting ECG monitoring equipment:

"The action of laying out ECG electrodes, a very common one in medical practice, can cause variations in quality due to the situation or the person in charge. To answer this age-old problem, Claravue has been designed using a revolutionary concept, and would appear to be potentially the future global standard. This was why we evaluated it so highly."

-Executive committee of the Japan Institute of Design Promotion, on awarding CLARAVUE the Good Design Award in the Category of Medical Equipment

BENEFITS TO TEST PROCESS

- Clearer ECG Traces
- Better interpretations
- More accurate test results
- Infection Control – Disposable Lead wires and Bioactive Cables

BENEFITS TO CLINICIAN

- Faster application
- Prewired benefits
- Ease of application
- Reduced workload

BENEFITS TO PATIENT

- Patient Comfort
- Fewer alarms
- Comfortable materials
- Infection Control – Disposable Lead wires and Bioactive Cables

¹⁶Frédéric,L. & Petrovic, T.,(2011). Comparison of the Use of Conventional and Prewired Electrodes for Electrocardiography in an Emergency Setting: The Spaghetti Study *Annals of Emergency Medicine* 57(4): 357-61.

CARDIOBRA & CLARAVUE

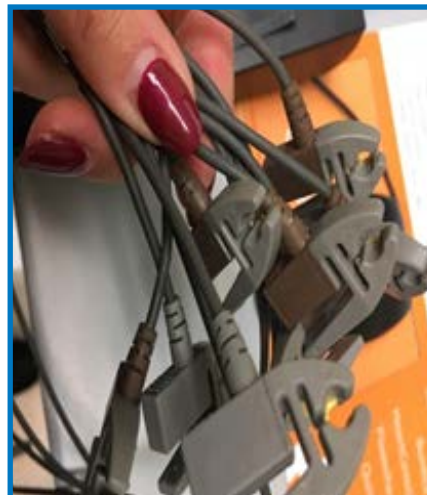
Used with CardioBra, CLARAVUE adheres to the skin with a thin, pain-free, and easily reinforced covering (unlike the butterfly or clamp attachment on other leads).

CLARAVUE'S prewired, disposable electrodes can provide a faster and better-quality ECG recording than conventional electrodes. The "Comparison of the Use of Conventional and Prewired Electrodes for Electrocardiography in an Emergency Setting: The Spaghetti Study"(2007), found significant benefits to the use of pre-wired electrodes in an emergency setting, including the following: (1) recordings with prewired electrodes took significantly less time; (2) signal noise and baseline instability were significantly reduced; and (3) the time saved was not at the expense of the quality of the recording. Notably, the median time saved (25 seconds; 20% faster) was in addition to the time saved disentangling and disinfecting electrodes—a common problem with conventional electrodes. With no specific training in the use of the new electrodes, nurses who had routinely used conventional electrodes, saved valuable time in treating patients.¹⁶

STANDARD ELECTRODES AND LEAD WIRES VERSUS CLARAVUE'S BEST-IN-CLASS DESIGN

Standard Electrodes & Lead Wires

- Reduction of artifact by removing motion at all levels.
- Prewired Electrodes fit comfortably under CardioBra
- Increased Comfort – Lightweight electrodes and lead wires, decreased breast movement
- More accurate and more comfortable testing
- Simple, accurate and fully radiolucent patient monitoring
- Hygienic, Disposable Design



CLARAVUE System



¹⁶ Frédéric, L. & Petrovic, T., (2011). Comparison of the Use of Conventional and Prewired Electrodes for Electrocardiography in an Emergency Setting: The Spaghetti Study *Annals of Emergency Medicine* 57(4): 357-61.