

Development of an Algorithm for Assessment of Ultrasound Quality Control Imaging

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Abstract: The study objective is to evaluation of the image quality on ultrasound images is comprehensive task due to the relatively low image quality compared to other imaging techniques. It's desirable to objectively determine the quality of ultrasound images since quantification of the quality removes the subjective evaluation which can lead to varying results. The scanner will also be more user friendly if the user is given feedback on the quality of the current image.

This paper has investigated in the objective evaluation of image quality in phantom images. It has been emphasized on the parameter spatial variance which is incorporated in the image analysis system developed during the project assignment. The special variance was tested for a variety of settings as far instance different beam densities and number of MLAs. In addition, different power spectra have been evaluated related to the Probe Contact algorithm developed. The algorithm has also been incorporated in the image analysis system. The results show that the developed algorithm gives a good indication of the spatial variance. An image gets more and more spatially variant as the beam density decreases. This study as others in this branch is starting point in the process of obtaining objective evaluation of the image quality in clinical images since others may use it as basis for their work.

Key words: Ultra sound , image quality , Multi Length Adjustable (MLAs), phantom image

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I. Introduction

It is sometimes argued that there is no need for ultrasound quality control testing because (1) the new machines are very reliable and rarely break down, and (2) the sonographer will detect image quality defects during normal scanning. Although both of these statements may be true, they do not necessarily negate the utility of US QC tests. A primary reason is that a set of periodic definitive measurements for each transducer and US unit can identify degradation in image quality before it affects patient scans. Another is that when equipment malfunction is suspected, QC tests can be employed to determine the source of the malfunction. Even equipment that is under warranty or service contract should be checked periodically. QC tests can verify that equipment is operating correctly and repairs are done properly.

1.1 Definition of quality assurance program

All procedures necessary to maintain proper and consistent equipment operation.

The goal is to keep the diagnostic quality of the ultrasound image at a consistently high level.

Good quality assurance will:

- ensure proper equipment operation
- detect gradual changes in performance
- minimize equipment down time
- reduce the number of repeat scans
- optimize operator and patient safety

1.2 Definition of responsibility

Individuals whose input is necessary for good quality assurance include:

1. the physician: (to assess image quality, to direct protocol).
2. the technologist: (to assess image quality, to perform some routine testing and record keeping, to perform routine basic maintenance).
3. Biomedical engineers: (to assess image quality, to perform diagnostic testing, to perform maintenance, to repair malfunctioning equipment, to maintain service records).

1.3 Ingredients of a Quality Assurance Program

- routine preventative maintenance
- routine performance tests
- acceptance testing

Routine Preventative Maintenance

- can be performed by the sonographer
- clean equipment surfaces
- dust monitor and camera surfaces - if accessible
- monitor and adjust VCR tracking if necessary
- assess film quality and adjust multiformat camera controls if necessary
- clean scanner exhaust fan filters
- assess the visual integrity of all transducers and cables
- film processor QC - densitometry, chemicals, etc.

1.3.1 Routine Performance Testing

- may be performed by the sonographer and/or service engineer
- routine testing at fixed time intervals
- Qualitatively assesses that the equipment is performing consistently
- done using test objects and/or phantoms and standardized system

Parameters

- qualitative testing may involve quantitative measurements, but the relative change in those values over time is the parameter that is assessed on a regular basis
- requires regular and accurate record keeping

1.3.2 Acceptance Testing

- performed by a qualified service engineer
- quantitatively measures equipment parameters to ensure that accepted government and regulatory standards are met
- uses test objects, phantoms and other testing equipment such as hydrophones and force balances
- performed on new equipment or when there is suspicion of substandard performance

When should quality assurance be performed? It depends on the specific aspect of the quality assurance program.

For example, assessing the integrity of the transducer scanheads and cables is a component of routine preventative maintenance which can be performed by the sonographer on a daily or weekly basis.

Assessing transducer axial and lateral resolution using a tissue-equivalent phantom regularly every 6 months is part of routine performance testing.

Acceptance testing is usually performed when new equipment arrives and is installed.

Devices Used in Ultrasound Quality Assurance

There are many devices that are used as part of a quality assurance program.

However, to simplify things I will separate these devices into two broad categories:

- 1) devices used by sonographers
- 2) 2. devices used by service personnel

Let's first look at commercially available devices that are used by sonographers to test imaging performance based on established criteria (AIUM '94, '95, '96).

1.3.3 Tissue-Equivalent Phantom

The most commonly used testing device today is the Tissue-Equivalent (T-E) Phantom.

A T-E phantom is essentially a plastic box containing a material that simulates the acoustic properties of soft tissue. This material usually consists of a mixture of gelatin and graphite powder. Within this tissue equivalent material, the manufacturer usually places a pattern of wires and/or cystic and solid regions that are used generate echoes. Many different patterns are available. Several of these patterns are very similar to the pattern used in the AIUM 100 mm test object.

A T-E phantom attempts to mimic the human body, to mimic soft tissue, with respect to beam transmission. It provides several characteristics of soft tissue such as propagation speed, scattering and attenuation. A typical unit costs around a thousand dollars.

A Tissue-Equivalent phantom will:

- propagate sound at a speed of 1540 m/s
- have an attenuation coefficient close to 0.5 dB/cm per MHz
- have scattering properties that closely mimic soft tissue. On a display, the image from a T-E phantom resembles the scattered echo pattern from liver.

All T-E phantoms are able to assess axial and lateral resolution, system sensitivity, TGC characteristics, and dynamic range. Some phantoms are specifically designed to assess section (elevational) resolution, contrast resolution, and lesion detection. See atlas figure(xxxxx) .

AIUM 100 mm Test Object

The AIUM 100 mm test object was developed earlier than the T-E phantom. Its use has now been superseded by T-E phantoms. However, it played a prominent role in the early development of ultrasound quality assurance and deserves a historical note.

The AIUM 100 mm test object was a plastic box that was filled with water. The water was mixed with an algicide and 9% alcohol to bring its propagation speed up to 1540 m/s. Within the test object a 100 mm x 100 mm pattern of wires was arranged in order to provide a series of reflecting interfaces. (This pattern continues to be used today in several T-E phantoms.)

The test object could be used to measure several imaging parameters, but did not provide either the attenuation or scattering properties of soft tissue. A TGC curve was not used, and obviously, no grayscale information could be provided.

1.4 T-E Phantom System Performance Tests

This section lists several of the most common system performance tests that can be performed using either a T-E phantom and/or the AIUM 100 test object that have a similar pin arrangement.

1.5 Axial Resolution

Axial resolution can be estimated by imaging rod group "a" from face "A". The pins in this group are arranged with decreasing distances between the pins (5, 4, 3, 2, and 1 mm). On the display the distance between the closest two pins that can still be individually identified is an estimate of the axial resolution of the system setup. Note that the pins in group "a" are also staggered to the left in order to prevent shadowing or comet-tail artifacts from obscuring the separation between the pins.

1.6 Lateral Resolution

Rod group "b" can be used to determine lateral resolution. The spacing of the rods in this group from top to bottom is 20, 15, 10, 5, and 3 mm. The lateral resolution is estimated by determining the distance between the two closest pins that can be individually identified. This rod group can be imaged from both face "B" and face "C" to estimate the lateral resolution at two different depths. Remember that lateral resolution is a function of beam width and does vary along the beam.

A better way of assessing beam width and lateral resolution is to scan pin group "c" from face A and obtain a beam profile. The width of each echo displayed from each pin represents the beam width and lateral resolution at each depth as depicted in the adjacent schematic diagram.

1.7 Dead Zone

Rod group "d" is used to estimate the dead zone of the system setup when imaged from face "A". The pins are arranged at different depths from the surface of the test object (2, 4, 6, 8, and 10 mm). The distance from the surface to the first visible pin on the display is an estimate of the dead zone.

1.9 Doppler Testing Devices

Several types of Doppler instrument testing devices are commercially available including test objects, tissue- and blood-mimicking phantoms. Doppler flow phantoms use a flowing blood-mimicking liquid (there are several different types on the market). Phantoms have some disadvantages, such as the presence of bubbles and non uniform flow, but can be arranged to easily simulate clinical conditions, such as tissue attenuation. They can also be calibrated. Doppler test objects use a moving, solid object (belt or string) to create a moving target that produces a Doppler shift. This type of Doppler test object is relatively inexpensive and simple to operate but is not as clinically realistic as the T-E Doppler phantom since it does not simulate tissue attenuation and clinical conditions. They can be calibrated easily and can produce pulsatile and reverse motions. Doppler testing devices are useful for assessing the following Doppler equipment characteristics and to illustrate Doppler concepts:

- maximum or effective penetration (sensitivity) of the Doppler beam (T-E phantoms only) with pulsed wave and colour flow Doppler
- ability to distinguish between different flow directions
- accuracy of the pulsed wave Doppler sample volume alignment (gate position accuracy)
- measurement of flow velocity accuracy
- accuracy of Doppler angle correction
- as a teaching tool - useful to illustrate effect of Doppler angle on Doppler shift, aliasing, Nyquist limit, baseline shifting, and wall filter operation

1.10 Quality Assurance Tests

1.10.1 Sensitivity

- a measurement of the minimum gain setting (with a standard output intensity) required to produce echoes on the display from a specific interface
- a change of 6 dB or greater over time indicates a need for service
- can be measured with an AIUM 100 test object and T-E phantoms

1.10.2 Uniformity

- typically measured for linear arrays
 - a uniform interface should produce a uniform linear echo display
- degradation of this uniformity may indicate an inconsistency between array elements

II. Material And Method

- can be measured with AIUM 100 test object and T-E phantoms

Dead zone

- synonym: ring-down zone, ring-down space
- measures the distance in the extreme near field in which no useful information can be obtained as a result of the ringing of the transducer following electrical stimulation to generate an ultrasound pulse. Typically the dead zone is very small (-1 mm) and not a significant factor even for imaging superficial structures. Some authors have referred to the inability of imaging structures in the dead zone as ring-down time artifact. Most authors do not discuss this topic under artifacts although technically it is. Ring-down artifact caused by resonance is completely different than ring-down time artifact).
- can be measured with AIUM 100 test object and some T-E phantoms.
- AIUM 100 mm test object
- T-E phantom with appropriate rod group
- reflection amplitude beam profiler
- hydrophone
- Schlieren photography
- beam profile phantom

The test object and the phantom incorporate vertical rows of rods which when scanned produce a rough approximation of beam width due to point spreading. The reflection profiler provides an approximation of the beam profile from reflector amplitudes plotted as a function of distance. A miniature hydrophone attached to a plotter can provide a true beam profile by plotting the measured pressure and intensity distribution across the beam. Schlieren photography uses a system of light and mirrors to optically display the sound energy emanating from a source. Beam profiles can be photographed in real-time.

Lesion Detection

- synonym: detail resolution
- The ability of a system to detect small cystic or solid lesions can be examined using a T-E phantom which incorporates a range of small cystic and solid lesions.

Slice Thickness

- The dimension of the beam perpendicular to the plane of section is the slice thickness.
- Slice thickness can be measured using a slice thickness phantom which incorporates a 45o angled scattering plane. Slice thickness for various depths can be measured.

Equipment Cleaning, Disinfecting, and Sterilization

- Cleaning is the removal of soil, and hence the reduction in numbers of microorganisms from the surface. Cleaning can be achieved by washing with soap and water or wiping with 70% alcohol. It is an essential first step prior to sterilization or disinfection. Cleaning is appropriate for low risk or non critical procedures, e.g. transducers used for normal trans abdominal scanning.
- Disinfecting is the inactivation of vegetative bacteria, viruses, and fungi but not necessarily of bacterial spores. Disinfection is required for medium risk or semi-critical medical instruments including those used in contact with intact mucous membranes, e.g. vaginal transducer. Before disinfection, instruments should be cleaned and dried.
- Sterilization is the complete destruction of microorganisms, including bacterial spores. Sterilization is generally achieved by autoclaving (steam under pressure), a process which must never be used with ultrasound transducers since the heat may damage them permanently. Ethylene oxide (gas) sterilization is an alternative for instruments that cannot be autoclaved, including ultrasound transducers. Sterilization is required for high-risk or critical medical procedures involving penetration of skin, membranes or other tissues, e.g. oocyte harvesting or chorion villous sampling. There is no special transducer preparation prior to performing standard transcutaneous scans (abdominal, pelvic, or small parts). However, the transducer should be clean and electrically safe to

operate, e.g. tight fitting connections, intact cable. Scanning gel should be mechanically wiped off the transducer at the end of every study. It is also advisable to clean the transducer with soap and water (cleansing solution in a spray bottle such as Hydrox) or 70% alcohol wipe between patients to reduce the risk of cross-infection from skin flora.

Vaginal transducers should be appropriately handled and cleaned between patients. Gel should be thoroughly wiped off the probe, preferably using running water and dried with a soft cloth or paper towel. Next, the transducer should be disinfected with the use of a liquid chemical germicide according to label directions or instructions by infectious diseases control personnel. Ninety-nine percent of the microbial load reduction results from adequate washing with soap and water, and chemical disinfection provides an additional margin of safety. Practitioners should consult with probe manufacturers regarding compatibility of disinfectants. Commonly used disinfectants include glutaraldehyde products such as Metricide, Cidex, and Procide. Glutaraldehyde disinfectants are classified as irritants and are potentially toxic to health care workers and patients. Glutaraldehydes are not known to be carcinogenic or teratogenic agents. Care should be taken to rinse the probe with water or alcohol to remove all traces of the disinfectant prior to use. A special transducer holding station is now commercially available to hold probes between studies (PCI Medical Inc., Deep River, CT). This station features a fume venting and filtering system that eliminates glutaraldehyde fumes and any related breathing risks.

III. Statistical Indices

Clinical data collected during research studies and organized for presentation at scientific meetings or published in medical journals can be described using many different statistical tools and definitions. Common indicators of the performance of diagnostic tests include sensitivity, specificity, negative and positive predictive value, and accuracy. For the registry exam, you should know the following statistical definitions. Unless I am informed otherwise, you should not have to know how to calculate these parameters (therefore formulas are not given) or how these parameters relate to each other (calculations and relationships are relatively complex). Statistics is the science of collecting and arranging information. This information, called data, is normally numerical, and is arranged to depict certain findings. The following statistical terms are commonly used to compare the performance of ultrasound as a diagnostic test against other diagnostic tests. The "Gold Standard" is the currently employed test that provides the best overall results (it is unrounded), e.g. the current gold standard for the diagnosis of ureteral stones is intravenous pyelography.

When a test is compared to the gold standard the results will fall into one or more of four categories. These are:

- 1. A "true positive" This is a result that was positive on the test and positive on the gold standard. This is a good result.
- 2. A "false positive" This is a result that was positive on the test, but negative on the gold standard. This is not a good result. It is an "overcall". Disease was detected where none existed.
- 3. A "true negative" This is a result that was negative on the test and negative on the gold standard. This is a good result.
- 4. A "false negative" This is a result that was negative on the test, but positive on the gold standard. This is not a good result. It is a "miss". Disease was not found where disease actually occurred.

Sensitivity is the ability of a test to find disease when disease is present. A test is sensitive when it does not miss disease. It has a high true positive rate and a low false negative rate.

Specificity is the ability of a test to indicate no disease when there is no disease present (i.e. to exclude disease when a patient is normal). A test is specific when it does not overcall disease in patients who do not have the disease. It has a high true negative rate and a low false positive rate.

Positive Predictive Value (PPV) The PPV is a measure of how likely it is that disease is actually present when the test result is positive. It has a high true positive rate and a low false positive rate.

Negative Predictive Value (NPV) The NPV is a measure of how likely it is that disease is actually absent when the test result is negative. It has a high true negative rate and a low false negative rate.

Accuracy is the ability of a test to give the correct answer. The most accurate test would have a high Sensitivity, a high Specificity, a high PPV, and a high NPV.

BIOEFFECTS AND SAFETY

Every sonographer working with diagnostic ultrasound equipment should know something of the underlying physics and the terminology related to ultrasonic bio effects. Of special importance is the understanding of ultrasound exposures and how they relate to possible hazardous bio effects.

How can high frequency ultrasound waves cause biological effects?

Sound is mechanical vibration of the particles of a medium. When a transducer is coupled to biological tissues, there is cyclic displacement of the particles of the medium, i.e. the particles vibrate in a back and forth motion. As well, the propagation of the sound wave involves localized forces and stresses in the tissues, which

produces temporary changes in the pressure and density of the medium. If the sound energy is sufficiently high, there may also be a localized change in the temperature of the tissues.

The "vigour" with which the particles of a medium vibrate is determined by the amplitude of the wave and depends on the power and intensity of the ultrasonic field (sound beam). The rate with which particles vibrate is determined primarily by the frequency of the transducer.

When ultrasound waves of sufficient energy are transmitted in biological tissues, the possibility of hazardous biological effects (no matter how remote) is of concern. It is well known that ultrasound beams of sufficient intensity can adversely affect and damage biological tissues. This knowledge has been obtained in experimental studies on cells in cultures (in vitro testing) and on living plants and animals (in vivo testing).

What is much less clear is whether exposure to low intensity diagnostic ultrasound during clinical studies causes harmful effects. It is very difficult to apply data derived from in-vitro studies to the clinical situation. Numerous epidemiologic studies (clinical research studies on exposed populations) have been published over the years and none have yielded any conclusive evidence of adverse effects from the clinical use of diagnostic ultrasound.

Let's look at some definitions before we proceed.

Acoustic Output Quantities

Pressure is the amount of force applied over a given area. The units of pressure include newtons/meter², pascals, mmHg, and atmospheres.

The greater the force applied and the smaller the area it is applied to, the greater the pressure exerted. Remember that sound is a pressure wave associated with regions of molecular compression and rarefaction in the medium. When a transducer emits ultrasound waves, the waves propagate in tissues by virtue of molecules undergoing compression and rarefaction. The pressure in the insonated tissues increases and decreases rhythmically as the transducer crystal expands and contracts. Positive pressure peaks are associated with compressions and negative pressure peaks are associated with rarefactions. Pressure can be measured as wave amplitude. Recall that pressure was one of the two acoustic variables that are commonly measured. Pressure is proportional to the magnitude of the transducer excitation voltage. An increase in the size of the excitation voltage at the transducer increases the acoustic pressure. This also increases the output power and beam intensity. Conversely, pressure is decreased by decreasing the size of the excitation voltage.

The size of the excitation voltage is controlled by the output power control. Pressure and intensity are inversely proportional to area, so that beam width also affects pressure. The smaller the beam width, the greater the pressure and intensity. All the factors which influence beam width will therefore affect pressure and intensity. Scientists may use a miniature hydrophone to measure acoustic pressure.

Power and intensity are both proportional to amplitude squared. For example, to produce an increase in acoustic pressure by a factor of 2 (eg. from 10 N/m² to 20N/m²), the power must increase by a factor of four (2²= 4).

$$\text{Power} \propto \text{Amplitude}^2$$

Power

Power is the rate at which ultrasound energy is emitted from the transducer. The unit of power is watts (W) or milliwatts(mW). The acoustic power emitted by diagnostic ultrasound transducers is typically in the low milliwatt range- 20 to 100 mW.

In pulsed wave Doppler mode, a system uses more power than it does in an imaging mode. This is done to generate the longer Doppler pulses. A pulsed wave Doppler system can generate output powers in the 2,000 mW range. This is considerably higher than a conventional imaging system. Scientists may use a radiation force balance or a miniature hydrophone to measure acoustic power.

Intensity is power divided by beam area.

$$\text{Intensity} = \frac{\text{Power}}{\text{Beam Area}}$$

The unit of intensity is watts per centimeter squared (W/cm²) or milliwatts per centimeter squared (mW/cm²).

Beam intensity depends on the output power level and the beam profile of a transducer. Intensity is proportional to power and inversely proportional to beam area. The highest beam intensities exist in the focal zone. A higher beam intensity generates stronger echoes. This improves the system's sensitivity.

The intensity of diagnostic ultrasound beams is difficult to quantify and to measure. Beam intensities vary considerably both within the beam, and in the case of pulsed transducers, within time. In other words, ultrasound beams can be described in terms of both a spatial intensity and a temporal intensity. We'll take a look at both.

Spatial intensity refers to the measurement of ultrasound intensity at a specific place or location within the beam.

There are two spatial factors for beam intensity:

- spatial peak (SP)
- spatial average (SA)

These values apply to both pulsed and continuous wave transducers.

Where are these spatial intensities measured in a sound beam? Spatial Peak intensity is the maximum intensity in the sound beam and is measured in the centre of the beam in the focal zone. SP intensities for focused transducers are higher than for unfocused transducers because focused transducers have smaller beam areas.

Spatial Average intensity is the spatial intensity averaged over the entire beam area. For a focused transducer, the SA intensity is always lower than the SP intensity

Temporal intensity

Because a pulsed transducer alternates between being ON (transmitting) and OFF (receiving), pulsed ultrasound beam intensity also varies in time. There are three parameters for describing temporal variations in beam intensity:

- pulse average (PA)
- temporal peak (TP)
- temporal average (TA)

PA intensity is the average intensity value during the pulse duration. It is the average intensity while the system is transmitting. This value is lower than TP but higher than TA. It increases most significantly with pulse duration and pulse amplitude. PA intensity is not as commonly used as TP or TA intensity.

TP intensity is the instantaneous peak temporal intensity during the "on time". TP is the highest temporal intensity. TP intensity values are typically 1000 times greater than TA intensity.

TA intensity is the temporal intensity averaged over both the "on time" and the "off time". Since the system is off for a much longer time than it is on during each pulse cycle, TA intensity has a relatively low value. TA intensity is related to the TP intensity by the duty factor (DF) as follows,

determined to meet specifications, the manufacturer may then market it for that application.

Part of the FDA evaluation involves measuring the equipment's output and comparing the values against maximum values determined for pre-1976 instruments which are documented in the 510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices. The current Maximum SPTA values are given in the following table.

510(k) Guide to Maximum SPTA In Situ Ultrasound Intensity Level	
Application	SPTA - mW/cm ²
Adult echocardiography	430
Peripheral vascular	720
Ophthalmic	17
Fetal imaging, and other (abdominal, intraoperative, pediatric, small parts (breast, thyroid, testes), neonatal head, adult head	94

National Electrical Manufacturers Association (NEMA) Webpage: <http://www.nema.org>

What is NEMA? NEMA stands for National Electrical Manufacturers Association. It is a recognized national organization with membership from companies involved in the manufacture and marketing of electrical products including diagnostic medical imaging equipment such as ultrasound scanners. Membership is voluntary. This is not a governmental agency.

NEMA is located in Rosslyn, Virginia and has nearly 500 member companies. The organization is divided into eight divisions: Industrial Automation, Lighting Equipment, Electronics, Building Equipment, Insulating Materials, Wire and Cable, Power Equipment, and Diagnostic Imaging and Therapy Systems. Within the eight divisions are approximately 70 product-specific sections, which hold primary responsibility for development and maintenance of up-to-date product standards.

NEMA has been developing standards for the electrical manufacturing industry for over 70 years, and is today one of the leading standards development organizations in the world. As such, it contributes to an orderly marketplace and helps ensure the public safety. NEMA attempts to promote the competitiveness of its member companies by providing a forum for:

- the development of technical standards that are in the best interests of the industry and the users of its products
- the establishment and advocacy of industry policies on legislative and regulatory matters that might affect the industry and those it serves
- the collection, analysis, and dissemination of industry data

“Conclusion Regarding Bioeffects and Safety”

In more than three decades of use, there has been no report of injury to patients or to operators from medical ultrasound equipment. We in the ultrasound community want to keep that level of safety.

In the past, application-specific output limits and the user's knowledge of equipment controls and patient body characteristics have been the means of minimizing exposure. Now, more information is available. The Mechanical and Thermal Indices provide users with information that can be specifically applied to ALARA. Mechanical and Thermal Indices values eliminate some of the guesswork and provide both an indication of what may actually be happening within the patient and what occurs when control settings are changed. These make it possible for the user to get the best image possible while following the ALARA principle and, thus, to maximize the benefits/risk ratio *.

*from the AIUM Booklet on Medical Ultrasound and Safety 1994

IV. Summary

- US QC is a worthwhile endeavor
- Learning how to do it and doing it develops experience and expertise for the physicist
- Greater communication with technical staff in the Radiology department as well as other departments
- Not difficult nor expensive (relatively speaking) nor time consuming
- Increased interaction with biomedical/clinical engineers
- Accreditation push is on! General scrutiny of imaging QC from radiation “incidents” and US is getting swept in with other modalities

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