



Improving Department Results with Single Exposure Dual-Energy Subtraction X-Ray: Clinical, Operational and Financial Benefits

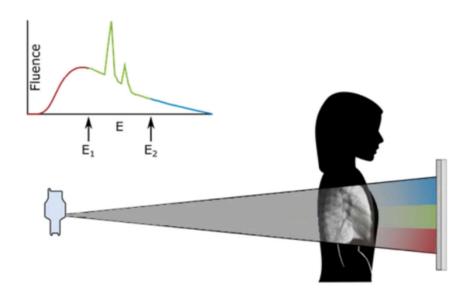
KA Imaging July 27, 2021

> Karim S Karim PhD PEng MBA FEIC Founder and Chief Technology Officer

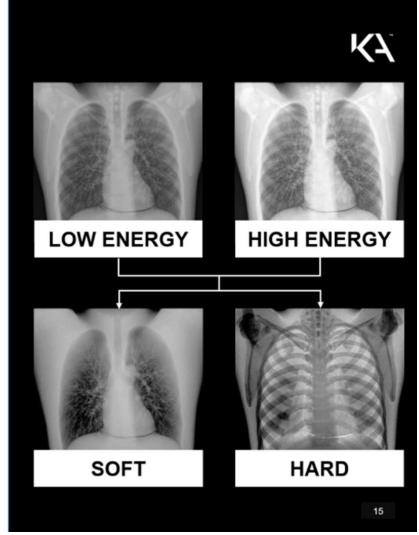
Jay Potipcoe, MRT(R), BA Applications Specialist



Dual-Energy (DE) X-Ray Subtraction (1970s)



Studies have shown that DE enables accurate diagnosis by removing bones/soft tissue from X-ray image.





Problems with Dual Energy

Access

- Higher radiation per scan → Limited use cases
- Not portable
- Cannot substitute standard chest X-ray

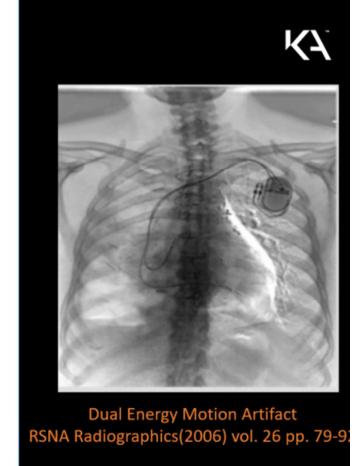
Quality

 DE images unreadable up to 20% of the time due to misregistration errors (motion artifact)

Cost

- · Fixed system available from very few manufacturers
- Large upfront costs (acquisition, installation and maintenance)

DE solutions to date have seen slow adoption because of motion artifacts, higher radiation, change in workflow and expensive X-ray systems





Dual-Energy Solutions: Dual-layer Detector Technology (1990's)



X-RAY Source





DOSE

EFFICIENCY

DQE(u, v)



Energy Separation performed in the detector

X-RAY Detector



Significant loss of photons in mid-

filter

Top Layer Copper mid-filter Bottom Layer

POOR

QUALITY

 Tradeoff between mid-filter thickness, dose efficiency and spectral separation



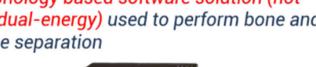
Dual-Energy Solutions: Bone Suppression Software (2010's)



X-RAY SOURCE



Morphology based software solution (not true dual-energy) used to perform bone and tissue separation





Same as chest X-ray



POOR

- · Limited use cases (i.e. nodules)
- · Limited views (i.e. PA/AP only)
- · Cannot effectively distinguish between soft tissue and bone

X-RAY **DETECTOR**





Dual-Energy Solutions: Triple-layer Detector Technology (2020's)

X-RAY SOURCE



Energy Separation performed in the detector

X-RAY **DETECTOR**







- · Three sensor layers capture more photons
- · Better DQE than most chest X-rays







DUAL-ENERGY IMAGE QUALITY

EXCELLENT

- · Layers optimized for high spectral separation
- · Zero motion artifact

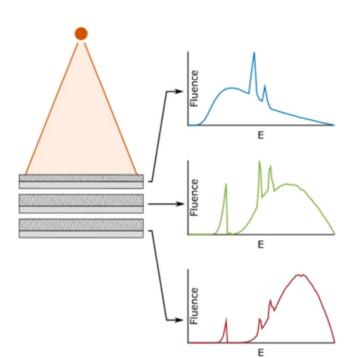


Top Layer Middle Layer (no mid-filter) Single X-ray Exposure **Bottom Layer**



How Do Three Layers Work?





- Single 120 kVp exposure generates three distinct spectral X-ray images
- Thickness for each layer can be optimized for best spectral separation without losing X-ray dose efficiency
- X-ray signals from all three layers are added to get the best-in-class dose efficiency X-ray image
- Signals from Layer 1 and Layer 3 are subtracted to yield dual energy images
- Simultaneous acquisition of three images results in zero motion artifact



Single Exposure Dual Energy Solution



Single exposure dual energy digital X-ray detector



DR room

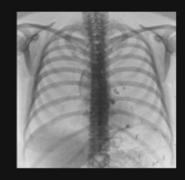
Mobile X-ray

Accessibility and Affordability

Three images from one chest X-ray exposure maintains same clinical technique and dose as digital chest X-ray



Standard X-Ray



High Energy Bone X-Ray



Low Energy Soft Tissue X-Ray





Comparison Between Different Solutions



N/A

Clinical **Use Cases**

Number of X-rays (Radiation)

> Use of Grid

Better Sensitivity than Chest X-ray

Distinguish Calcium from Soft Tissue

AP, PA, Lateral and Oblique Views

Portable and Mobile Applications

Motion Artifacts

Single Exposure Dual-Energy	X-ray + Bone Suppression Software	Dual Exposure Dual Energy	Digital Chest X-ray
More than Chest X-ray	Limited to nodules	Less than Chest X-ray	Standard
Single	Single	Double	Single
As per clinical technique	· · · · · · · · · · · · · · · · · · ·		As per clinical technique
Yes	Marginal	Yes	No
Yes (physics solution)	Marginal (software solution)	Yes (physics solution)	No
Yes	No	No	Yes
Yes	Yes	No	Yes



Absent



Absent



Present





Motion Artifact Comparison



Single exposure DE produces DE images free of motion artifacts

Solution 1: Dual exposure DE

Solution 2: Dual exposure DE

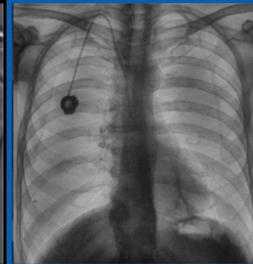
Solution 3: Dual exposure DE

Solution 4: Single exposure DE













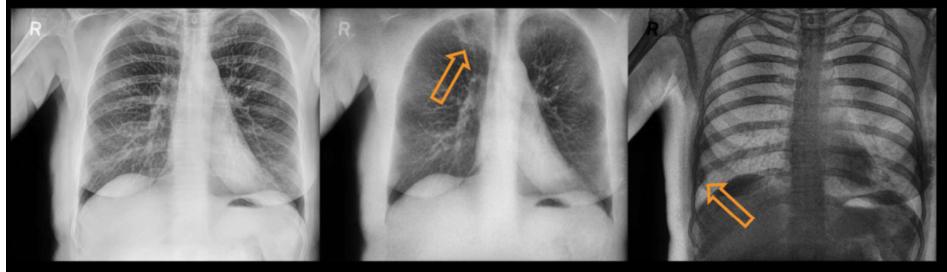
CASE A: Hidden Apical Lesion in RUL



Conventional DR X-Ray

Soft Tissue Image

Bone Image



-This DR image was read as normal by the radiologist, but the patient actually has an apical lung lesion that was missed, due to overlapping bone. When shown the DE images, pathology was seen by the radiologist. Without DE, this would have gone unnoticed, losing valuable proactive treatment time.

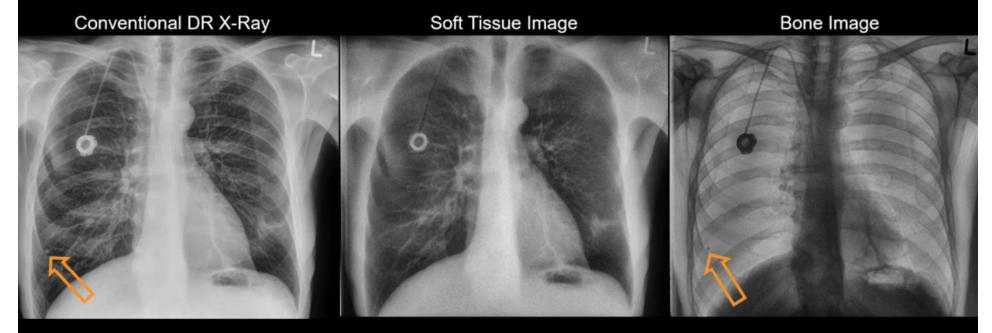
-Incidentally, an older rib fracture also became visible on right side.





CASE B: Hidden Mass in RLL Obscured by Degenerative Bone Disease (PA)





- -This granuloma in the DR image can be classified as being calcified, due to its appearance in the Bone Image.

 -The PortoCath line is very easy to see on the Bone Image
- -There is, however, a mass behind the heart <u>not seen in this PA image</u>. Because KA Imaging's Single Exposure DE detector can perform lateral chest imaging, the mass will be seen in that view.





CASE B: Hidden Mass in RLL Obscured by Degenerative Bone Disease (Lat)



Conventional DR X-Ray

Soft Tissue Image

Bone Image



-The mass seen behind the heart is superimposed over a calcified joint in the conventional DR image. However, the Soft Tissue image clearly displays the mass to the radiologist, by removing the overlapping bone.

-The PortoCath line and sternum are also nicely differentiated in the Bone Image.

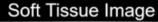




CASE C: Focal Opacity in RUL

ΚĄ

Conventional DR X-Ray









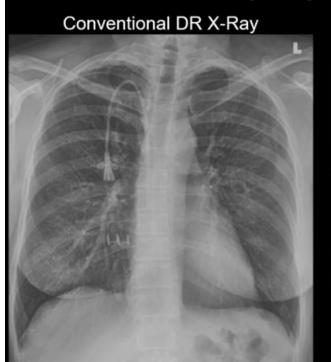
-This case involved a 51-year-old female leukemia patient. The Conventional DR X-Ray was given to the radiologist and read as normal. However, upon subsequently being shown the DE Soft Tissue image, the radiologist noticed a highlighted focal opacity indicating pneumonia (confirmed on CT). This patient would not have received prompt treatment for the pneumonia, if not for the DE image.

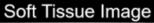


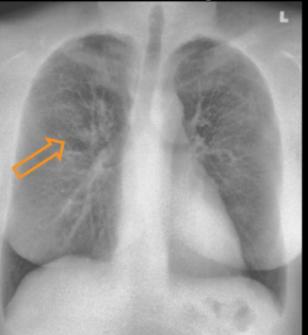


CASE C: Focal Opacity in RUL







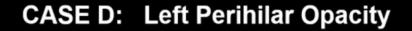


CT Image

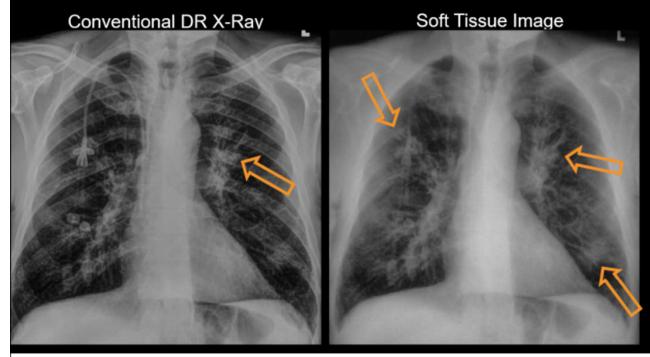


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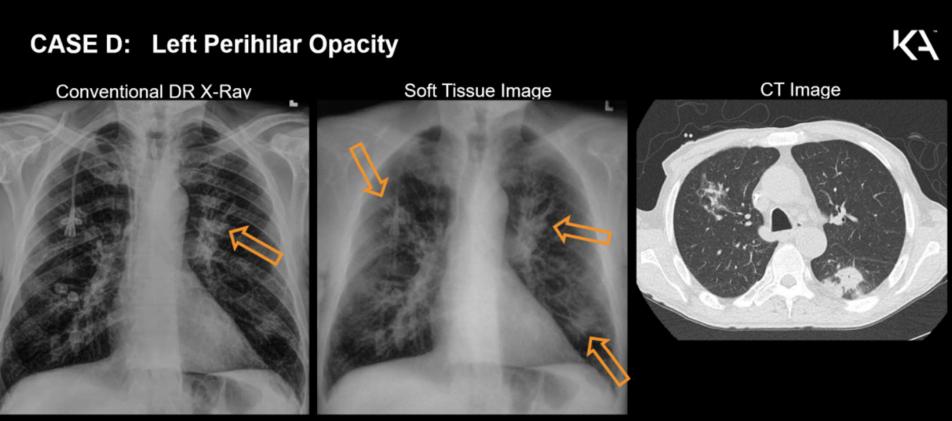




CT Image

-The Conventional DR image of this 74-year-old male with leukemia was read as showing a possible fungal pneumonia in the left hilar region. The radiologist placed confidence in diagnosis at a mere 1/5. Given the DE Soft Tissue image, the radiologist placed confidence as 5/5 for left hilar fungal pneumonia. Two other bilateral opacities were also noted in the Soft Tissue image (RUL and LLL), that were not shown in the Conventional DR image. Diagnosis was confirmed by CT.





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CASE E: Coronary Stents





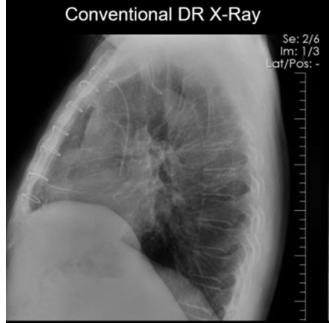


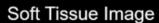




CASE F: Coronary Calcium









Bone Image



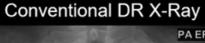
-Calcified Coronary vessels clearly seen in lateral image
-Clearly seen PortoCath line, sternum, and sternal wire ties in Bone Image





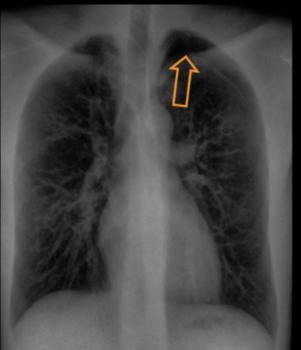
CASE G: Pneumothorax







Soft Tissue Image



Bone Image



-This 26-year-old male presented to the ER with difficulty breathing and chest pain. A single exposure dual energy X-ray detector was used to generate all 3 images, and clearly displays the left apical pneumothorax, best seen in the Soft Tissue Image.





Benefits of Dual Energy Subtraction - Pneumonia



Diagnosis: history, exam, clinical signs, chest X-ray



Pneumonia Misdiagnosed in 33% of patients



Low sensitivity for chest X-ray

		Ser	sitivity	Specificity	
		Chest X-ray	Dual Energy	Chest X-ray	Dual Energy
Interstitial disease	Lung emphysema	45%	75%	84%	83%
	Scarring	77%	96%	76%	70%
	Reticular lung changes	81%	92%	87%	87%
Infective consolidation		41%	61%	98%	97%
Lung atelectasis		22%	67%	99%	99%

Martini, Katharina, Marco Baessler, Stephan Baumueller, and Thomas Frauenfelder. "Diagnostic accuracy and added value of dual-energy subtraction radiography compared to standard conventional radiography using computed tomography as standard of reference." PloS one 12, no. 3 (2017): e0174285.

Dual energy increases sensitivity up to 50%



Early diagnosis and monitoring



Can replace Chest X-ray in Emergency Department



Case Study #2: Indeterminate Nodules

Solitary Pulmonary Nodules (SPN) are prevalent in **0.15%** of the general population

150 million chest X-Rays performed in the US in 2018

Lung cancer is #1 killer out of all cancers worldwide



Late-stage detection leads to high mortality rates



Small nodules are missed on chest X-rays in younger, asymptomatic patients

At 0.15% prevalence, and 150 million chest X-Rays, this indicates up to 225,000 cases of SPN could have been found



1.66 per 1000 cases of missed SPN result in suits. At 225,000 missed cases, this implies 374 patients filed suit



Annual payouts in US for missed nodule lawsuits total ~ \$100 million. This indicates an average of \$294,000 per claim

DE X-Ray has a 33% higher sensitivity for pulmonary nodules, compared to regular X-Ray



With 33% increase in detection with DE, and the 0.15% prevalence, a hospital taking an average 120 chest X-Rays/day will find 12 extra cases of SPN each year, compared to regular X-Ray



Estimating \$10,000 treatment costs per patient, this allows for an extra \$120,000 in hospital income annually

Earlier and Easier Detection = Better Patient Outcomes, More Downstream Revenue, and Enhanced Risk Avoidance



Benefits of Dual Energy Subtraction - Nodules



	Sensitivity (%)		Specificity		Accuracy		PPV		NPV	
	Chest X-ray	Dual Energy	Chest X-ray	Dual Energy	Chest X-ray	Dual Energy	Chest X-ray	Dual Energy	Chest X-ray	Dual Energy
Small lung nodules < 20 mm, Solid, Part-solid, Non-solid	47.6	63	72.5	72.5	56.7	66.5	75.6	80.1	44.4	53.7

Oda, Seitaro, Kazuo Awai, Kenji Suzuki, Yumi Yanaga, Yoshinori Funama, Heber MacMahon, and Yasuyuki Yamashita. "Performance of radiologists in detection of small pulmonary nodules on chest radiographs: effect of rib suppression with a massive-training artificial neural network." American Journal of Roentgenology 193, no. 5 (2009): W397-W402.

Dual energy increases sensitivity by 33% relative to X-ray



Early detection for proactively finding cases



Replacement for Chest X-ray in Outpatient Settings





Case Study #3: Small-Volume Pneumothorax

Affects up to 35 out of every 100,000 people

Cost of treatment is ~
\$25,000/case.
Cost goes up if case worsens, due to
misdiagnosis



Over 50,000 errorinduced pneumothoraces in USA annually

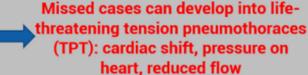


Can cause death quickly if not detected early



Missed often on portable chest X-ray, mistakes not reimbursed

Missed pneumothoraces can progress without diagnosis and treatment





Vented patients at higher risk of TPT when smaller pneumothoraces missed. TPT has mortality rate of up to 91% in ICU patients

DE X-Ray boosts detection sensitivity by 12% and specificity by 8%

Thousands of pneumothorax cases detected and treated earlier



Enhanced patient outcomes. Greater avoidance of malpractice liability

Pneumothorax-related malpractice suits have an average cost of ~ \$143,250/case in the US



DE X-Ray can identify challenging small-volume pneumothoraces in up to 30% of cases where it was missed in regular X-Ray



DE X-Ray can help prevent deaths, painful surgical interventions, and money lost through malpractice suits, by improving early identification of pneumothoraces





Benefits of Dual Energy Subtraction - Pneumothorax



	Chest X-ray	Dual Energy
	# of cases found in study	# of cases found in study
Interns	6.2	8.8
Residents	9.1	11
Senior Physicians	9.5	10.9
Non-radiologists	9.2	10.6
Radiologists	9.5	10.6

Urbaneja, Ayla, Gauthier Dodin, Gabriela Hossu, Omar Bakour, Rachid Kechidi, Pedro Gondim Teixeira, and Alain Blum. "Added value of bone subtraction in dual-energy digital radiography in the detection of pneumothorax: impact of reader expertise and medical specialty." Academic radiology 25, no. 1 (2018): 82-87.

Dual energy detected up to 30% more small volume pneumothoraces



Early detection leads to cost savings and better patient outcomes



Replaces Portable X-ray in Critical Care Units





Clinical Use Cases with High Economic Impact

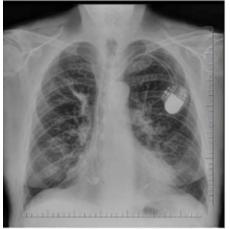


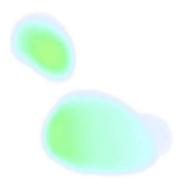
Use Case	Issue	Extra Cases Found Relative to Chest X-ray over 5 years	Improved by DE
Solitary Pulmonary Nodule	Lung is #1 Killer cancer worldwide	60 (US data)	Increase in sensitivity by 33% for nodules < 20mm
Coronary Calcium	Cardiac disease is the #1 Killer in developed countries	205 (US data)	Presence of calcium in DE bone image is strongly correlated with calcium in CT
Pneumonia	33 % of patients misdiagnosed, CXR not sensitive	90 (US data)	Sensitivity increases for infectious consolidation by 50% and atelectasis by 3X
Pneumothorax	>50,000 due to errors in the USA, 20% die	15 (US data)	Up to 30% more small volume pneumothoraces found even by residents and interns
Tuberculosis	1.5 million die annually in LMICs	> 300 (in a high TB prevalence setting in Asia)	Up to 30% increase in sensitivity and NPV for consolidation and cavitation



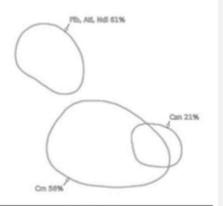


Al vs. Dual Energy









		CASE REPORT	,	
		Abnormality Score		
Att	Atelectasis	485	right upper	
Cels				
Cm	Cardiomegaly	56%	present	
Can	Consolidation	2%	left lower	
Fib	Fibrosis	61%	right upper	
MW				
Ndf	Nodule	18%	right upper	
PER				
Ppm				
Ptx				



This is an example of a commercial AI chest product.

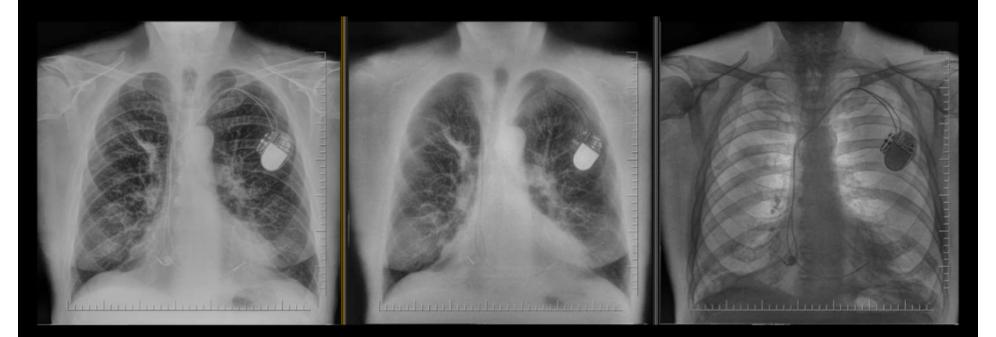
The image on the left is a DR image and the two images on the right are the outputs of the AI algorithms.





Compared with Single Exposure Dual Energy





Al missed nodules in the lower part of the image that are near the mediastinum

There is also pneumonia seen in the soft tissue image that was not identified by the AI



Looking to the Future: Coronary Calcium Scoring (New Use Case for X-ray)



- -Data shows dual energy X-ray is adept at displaying coronary calcifications. There is exciting potential for using DE X-ray for calcium scoring[1]
- -With proper processing applied to DE images, calcified coronary arteries can be visualized, and data shows these images can be used in Agatston calcium scoring
- -Calcium scoring done on proper-quality DE chest X-rays was considerably accurate, as confirmed by subsequent CT calcium scoring[1]
- -Using DE chest X-rays to engage in calcium scoring can expand coronary disease screening programs, keep dose low, and enhance patient care



Yingnan Song, Hao Wu, Di Wen, Bo Zhu, Philipp Graner, Leslie Ciancibello, Haran Rajeswaran, Karma Salem, Mehrdad Hajmomenian, Robert C. Gilkeson and David L. Wilson, "Detection of coronary calcifications with dual energy chest X-rays: clinical evaluation," Int J Cardiovasc Imaging (2020).





Single Exposure Dual Energy Enables New Opportunities For X-ray Imaging





More confident, accurate image interpretation



Save time and benefit patients in Radiology, Emergency and Critical Care departments



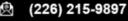
No additional procedure or dose – same as chest X-ray



Leverage existing X-ray equipment and clinical techniques











NGUYEN VAN CONG

Has Attended the Following Webinar

Improving Department Results with Single Exposure Dual-Energy Subtraction X-Ray: Clinical, Operational and Financial Benefits

on

7/27/2021

Sponsored by KA Imaging. Presented by Dr. Karim Karim, Ph.D., PEng, MBA and Jay Potipcoe, BA, MRT. Approved for 1 ARRT Category A CE credit by AHRA (Ref. LEC11337). Approved for 1











